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Bone and Soft Tissue Informed Preoperative Planning in Total Knee Arthroplasty

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Abstract

Total knee arthroplasty (TKA) is a widely performed and highly effective procedure for managing end-stage knee osteoarthritis, yet up to 20% of patients report dissatisfaction with their outcomes. This dissatisfaction has sparked a shift toward personalised solutions, focusing on tailoring alignment strategies to individual patient anatomy and biomechanics. Knee classification systems, such as the Coronal Plane Alignment of the Knee (CPAK), offer a framework for categorising knees based on their alignment and have been used to guide intraoperative decision-making and alignment selection. However, these tools predominantly focus on coronal plane alignment, overlooking the critical influence of soft tissue dynamics and the multi-dimensional variability of knee morphology. This limitation underscores the need for more comprehensive tools that incorporate both bony and soft tissue considerations to optimise alignment and improve patient outcomes.

This dissertation aimed to evaluate the predictive utility of CPAK for three-dimensional (3D) knee morphology and joint gaps. It also compared functional laxity assessments to intraoperative surgical laxity evaluations and how they may relate to patient-reported outcome measures (PROMs). To address the challenges identified, the thesis developed novel tools for TKA planning, including a joint distraction radiology protocol for assessing soft tissue behaviour and a 3D-to-two-dimensional (2D) registration method for integrating functional data into preoperative workflows. These tools were combined to create the Distracted Alignment protocol, a planning framework designed to balance alignment in both extension and flexion by incorporating bony anatomy and soft tissue gaps.

The findings revealed the limitations of CPAK in capturing the complexity of 3D knee morphology and joint gap variability, underscoring the need for multi-dimensional analysis tools. Functional laxity assessments better predicted postoperative PROMs than intraoperative surgical laxity, providing valuable insights for preoperative planning.

Specifically, preoperative functional laxity displayed weak correlations with 12-month postoperative Knee Osteoarthritis and injury Outcome Score Symptoms ($r = 0.33$, $p = 0.02$) and Quality of Life outcomes ($r = 0.38$, $p = 0.01$). The joint distraction radiology protocol and 3D-to-2D registration demonstrated high intra-observer and inter-observer reliability, supporting their use in evaluating knee alignment and soft tissue balance. This was particularly true in the coronal plane with mean absolute differences below 1° for tibiofemoral alignment and below 1 mm for joint gaps observed across all three functional positions. The Distracted Alignment protocol delivered patient-specific alignments that closely mirrored healthy knee morphology, maintaining a coronal hip-knee-ankle angle within 1° of the constitutional alignment of a healthy population. By integrating both hard and soft tissue characteristics, the Distracted Alignment protocol offers a holistic approach to TKA planning and lays a strong foundation for advancing personalised alignment strategies.

Achievements

Publications

- Preoperative Joint Distraction Imaging and Planning Protocol for Total Knee Arthroplasty. The Journal of Arthroplasty (2023).
  Ishaan Jagota, Joshua Twiggs, Brad Miles, David Liu

- Large multiplanar changes to native alignment have no apparent impact on clinical outcomes following total knee arthroplasty. Knee Surgery, Sports Traumatology, Arthroscopy (2023).
  Payam Tarassoli, Jonathan M. Warnock, Yoong Ping Lim, Ishaan Jagota, David Parker

- Functional preoperative assessment of coronal knee laxity better predicts postoperative patient outcomes than intraoperative surgeon-defined laxity in total knee arthroplasty. Knee Surgery, Sports Traumatology, Arthroscopy (2024).
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- Robotic-Assisted Total Knee Arthroplasty Results in Shorter Navigation Working Time With Similar Clinical Outcomes Compared to Computer-Navigated Total Knee Arthroplasty. The Journal of Arthroplasty (2024).
  Jade P Y Ho, Ishaan Jagota, Joshua G Twiggs, David W H Liu

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  Aida Orce Rodríguez, Ishaan Jagota, Jonathan V Bare, Andrew Shimmin

- Coronal plane alignment of the knee classification system does not effectively predict tibiofemoral joint gaps in arthritic knees undergoing total knee arthroplasty. Knee Surgery, Sports Traumatology, Arthroscopy (2025).
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- Cementless tibial fixation results in slower recovery but equivalent outcome at 12 months in primary total knee arthroplasty. Arthroplasty Today (2025).
  Khairul A. Ayob, Joshua G. Twiggs, Ishaan Jagota, David Liu

Conference Presentations

2024

Australian Orthopaedic Association Annual Scientific Meeting, October 2024

- Assessment of Coronal Joint Laxity and the Coronal Alignment of the Knee (CPAK) Classification System
  David Liu, Ishaan Jagota, Alex Shen, Estelle Wigmore, Joshua Twiggs, Brad Miles
- *Anatomical Tibial Rotational References and Outcomes in Total Knee Arthroplasty*
  Jonathan Bare, Andrew Shimmin, Ishaan Jagota, Estelle Wigmore, Alex Shen, Joshua Twiggs, Brad Miles
- *Does Lateral Femoral Condyle Hypoplasia in Valgus knees truly exist?*
  Brett Fritsch, Ishaan Jagota, Estelle Wigmore, Alex Shen, Joshua Twigs, Brad Miles
- Accuracy Testing of a Mixed Reality Headset for Femoral Cut Block Alignment During Total Knee Arthroplasty
  Justin Roe, Lachlan Mizon, Joshua Twiggs, Ishaan Jagota, Brad Miles

Australian Knee Society Annual Scientific Meeting, October 2024

- *Does Lateral Femoral Condyle Hypoplasia in Valgus knees truly exist?*
  Brett Fritsch, Ishaan Jagota, Estelle Wigmore, Alex Shen, Joshua Twigs, Brad Miles

2023

- Australian Orthopaedic Association Annual Scientific Meeting, November 2023
- *AI Detection of Pain from Facial Expression - The New PROMS?*
  Justin Roe, Frances Yu, Ishaan Jagota, Joshua Twiggs, Brad Miles
- *Does Change in CPAK Phenotype with TKA Intervention Impact Patient Outcome?*

Andrew Shimmin, Jonathan Bare, Aida Orce, Ishaan Jagota, Joshua Twiggs, Brad Miles

- *Detection of Knee Range of Motion from Images Using Artificial Intelligence*
  Andrew Shimmin, Justin Roe, David Liu, Jonathan Bare, Chloe Franken, Ishaan Jagota, Joshua Twiggs, Brad Miles
- *Laxity of the Knee During TKA: Awake versus Anaesthetised*
  David Liu, Willy Theodore, Andy Li, Ishaan Jagota, Joshua Twiggs, Brad Miles
- *Anatomical Phenotyping of the Knee for TKA Planning: Beyond the Coronal Plane*
  Jonathan Bare, Andrew Shimmin, Justin Roe, Brett Fritsch, Ishaan Jagota, Joshua Twiggs, Brad Miles
- *Functional Preoperative Tibial Rotational References and Outcome in TKA*
  Jonathan Bare, Andrew Shimmin, Ishaan Jagota, Joshua Twiggs, Brad Miles

International Society for Technology in Arthroplasty Annual Congress, September 2023

- *AI Detection of Pain from Facial Expression – The New PROMS?*
  Justin Roe, Frances Yu, Ishaan Jagota, Joshua Twiggs, Brad Miles
- *Detection of Knee Range of Motion from Images Using Artificial Intelligence*
  Qipeng (Alex) Shen, Chloe Franken, Ishaan Jagota, Joshua Twiggs, Brad Miles, Justin Roe, Andrew Shimmin, Jonathan Bare

Computer Assisted Orthopaedic Surgery Annual Meeting, June 2023

- *Functional References for Tibial Axial Rotation in Total Knee Arthroplasty*
  Ishaan Jagota, Andrew Shimmin, David Liu, David Parker, Brett Fritsch, Joshua Twiggs, Brad Miles
- *Novel Methodology for Measuring the Medial Proximal Tibial Angle in TKA*
  Ishaan Jagota, William Walter, Evan Jenkins, Mathew Lim, Joshua Twiggs, Brad Miles

- *Novel Patellofemoral Ligament Modelling & Anterior Knee Pain After TKA*
  Ishaan Jagota, David Parker, Brett Fritsch, Jobe Shatrov, Joshua Twiggs, Brad Miles

Orthopaedic Research Society Annual Meeting, February 2023

- Novel Methodology for Measuring the Medial Proximal Tibial Angle in Total Knee Arthroplasty (Poster)
  Ishaan Jagota, William Walter, Evan Jenkins, Matthew Lim, Joshua Twiggs, Brad Miles
- Novel Patellofemoral Ligament Modelling & Anterior Knee Pain After Total Knee Arthroplasty (Poster)
  Ishaan Jagota, David Parker, Brett Fritsch, Jobe Shatrov, Joshua Twiggs, Brad Miles
- *Functional References for Tibial Axial Rotation in Total Knee Arthroplasty (Poster)*
  Ishaan Jagota, Andrew Shimmin, David Liu, Brett Fritsch, David Parker, Joshua Twiggs, Brad Miles

2022

Australian Orthopaedic Association / New Zealand Orthopaedic Association Combined Combined Scientific Meeting, October 2022

- *Functional References for Tibial Axial Rotation in Total Knee Arthroplasty*
  Ishaan Jagota, Andrew Shimmin, David Liu, David Parker, Brett Fritsch, Joshua Twiggs, Brad Miles
- *Novel Methodology for Measuring the Medial Proximal Tibial Angle in TKA*
  Ishaan Jagota, William Walter, Even Jenkins, Mathew Lim, Joshua Twiggs, Brad Miles
- *Novel Patellofemoral Ligament Modelling & Anterior Knee Pain After TKA*
  Ishaan Jagota, David Parker, Brett Fritsch, Jobe Shatrov, Joshua Twiggs, Brad Miles

London Knee Meeting, October 2022

- Population Level Validation of a Novel Joint Distraction Radiology Protocol in TKA Planning
  Jonathan Bare, David Liu, Ishaan Jagota, Joshua Twiggs, Brad Miles
- *Preoperative planning in TKA*
  Jonathan Bare, Ishaan Jagota, Joshua Twiggs, Brad Miles

Australian Knee & Sports Surgery / New Zealand Knee & Sports Surgery Combined Society Meeting, October 2022

- *Novel Patellofemoral Ligament Modelling & Anterior Knee Pain After TKA*
  David Parker, Brett Fritsch, Ishaan Jagota, Joshua Twiggs, Brad Miles

International Society for Technology in Arthroplasty Annual Congress, September 2022

- Population Level Validation of a Novel Joint Distraction Radiology Protocol in TKA Planning
  Joshua Twiggs, Ishaan Jagota, David Liu, Max Hardwick-Morris, Brad Miles
- *Novel Methodology for Measuring the Medial Proximal Tibial Angle in TKA*
  Willy Theodore, William Walter, Matthew Lim, Ishaan Jagota, Joshua Twiggs, Brad Miles
- Validation of a Patient Outcome Prediction Tool Relative to Surgeon Predictions of Patient Outcome in Total Knee Replacement
  Matthew Baker, Joshua Twiggs, David Liu, Ishaan Jagota, David Parker, Brett Fritsch, Justin Roe, Brad Miles

Computer Assisted Orthopaedic Surgery Annual Meeting, June 2022

- Population Level Validation of a Novel Joint Distraction Radiology Protocol in TKA Planning
  Ishaan Jagota, David Liu, Joshua Twiggs, Brad Miles
- Comparison of a Novel Joint Distraction Radiology Protocol in TKA Planning with Navigated Joint Gaps
  Ishaan Jagota, David Liu, Joshua Twiggs, Brad Miles

European Federation of National Associations of Orthopaedics and Traumatology, June 2022

- Is trochlear recreation related to patient outcomes following total knee arthroplasty? A CT analysis of a single-radius femoral component with minimum 2-year follow-up
  Jobe Shatrov, Ishaan Jagota, Joshua Twiggs, Brett Fritsch, Bill Walter, David Parker

Orthopaedic Research Society Annual Meeting, February 2022

- Failure to Recreate the Native Tibial Medial Centre of Rotation Following TKA Surgery leads to Reduced Patient Outcomes
  Ishaan Jagota, Jonathan Bare, Andrew Shimmin, Joshua Twiggs
- Comparison of a Novel Joint Distraction Radiology Protocol in TKA Planning with Navigated Joint Gaps (Poster)
  David Liu, Ishaan Jagota, Joshua Twiggs
- Population Level Validation of a Novel Joint Distraction Radiology Protocol in TKA Planning (Poster)
  David Liu, Ishaan Jagota, Joshua Twiggs

2021

Australian Orthopaedic Association Annual Scientific Meeting, November 2021

- Population Level Validation of a Novel Joint Distraction Radiology Protocol in TKA Planning
  David Liu, Ishaan Jagota, Joshua Twiggs
- Comparison of a Novel Joint Distraction Radiology Protocol in TKA Planning with Navigated Joint Gaps
  David Liu, Ishaan Jagota, Joshua Twiggs
- Remote pre- and rehabilitation as an in-patient rehabilitation alternative in patients undergoing total knee replacement
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List of Abbreviations

2D	Two-dimensional
3D	Three-dimensional
AA	Anatomic alignment
ACL	Anterior cruciate ligament
ADL	Activities of daily living
aHKA	Arithmetic hip-knee-ankle angle
aMA	Adjusted mechanical alignment
ANOVA	Analysis of variance
AOANJRR	Australian orthopaedic association national joint replacement registry
AP	Anteroposterior
AURORA	Australian universal resection, orientation, and rotation analysis
BMI	Body mass index
CI	Confidence interval
CPAK	Coronal plane alignment of the knee
CR	Cruciate retaining
CT	Computer tomography
DA	Distracted alignment
DFF	Distal femur flexion
DOF	Degrees of freedom
ED	Extension distracted
EQ-5D	EuroQol – five-dimension questionnaire
FA	Functional alignment
FD	Flexion distracted
FJS	Forgotten Joint score
FL	Functional laxity
FMA	Femoral mechanical angle
HA	Hyaluronic acid
HKA	Hip-knee-ankle
HXLPE	Highly cross-linked polyethylene
ICC	Intraclass correlation coefficient
iKA	Inverse kinematic alignment
IQR	Interquartile range
JLO	Joint line obliquity
KA	Kinematic alignment
KL	Kellgren-Lawrence
KOOS	Knee osteoarthritis and injury outcome score

KOOS-JR	Knee osteoarthritis and injury outcome score joint replacement short form
KSS	Knee society score
LCL	Lateral collateral ligament
LDFA	Lateral distal femoral angle
LOS	Length of stay
LPFL	Lateral patellofemoral ligament
LPTL	Lateral patellotibial ligament
MA	Mechanical alignment
MCID	Minimally clinically important difference
MCL	Medial collateral ligament
MP	Medial pivot
MPFL	Medial patellofemoral ligament
MPTA	Medial proximal tibial angle
MPTL	Medial patellotibial ligament
MRI	Magnetic resonance imaging
NEU	Neutral
NSAIDs	Non-steroidal anti-inflammatory drugs
OA	Osteoarthritis
OKS	Oxford knee score
PCA	Posterior condylar axis
PCL	Posterior cruciate ligament
PFL	Patellofemoral ligament
Post-FL	Postoperative functional laxity
Post-SL	Post-implantation surgical laxity
Pre-FL	Preoperative functional laxity
Pre-SL	Pre-implantation surgical laxity
PROM	Patient reported outcome measure
PS	Posterior stabilised
PSI	Patient specific instrument
QoL	Quality of live
RCT	Randomised controlled trial
rKA	Restricted kinematic alignment
ROM	Range of motion
SD	Standard deviation
SF-12	Rand 12-item short form survey instrument
SL	Surgical laxity
TEA	Transepicondylar axis
TKA	Total knee arthroplasty

TMA	Tibial mechanical angle
UCLA	University of California, Los Angeles
UHMWPE	Ultra-high molecular weight polyethylene
UK	United Kingdom
UKA	Unicompartmental knee arthroplasty
USA	United States of America
VAL	Valgus
VAR	Varus
VAS	Visual analogue scale
WB	Weightbearing
WOMAC	Western Ontario and McMaster Universities osteoarthritis index
WSL	Whiteside's line
xBW	Multiple of body weight

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Chapter 1:

Introduction

1.1. Research Motivation

Osteoarthritis (OA) is a leading cause of joint pain and disability, and its incidence is increasing both in Australia and globally [1], [2], [3]. Total knee arthroplasty (TKA) is a highly effective treatment for end-stage OA, offering significant pain relief and improved mobility [4], [5]. However, despite its success, studies report that an average of 10%, and up to 20%, of TKA patients report dissatisfaction following the procedure [6], [7], [8]. This persistent dissatisfaction drives ongoing research into how surgical techniques, implant design, and planning can enhance patient outcomes and satisfaction.

Historically, mechanical alignment was the predominant strategy for TKA, aiming to position prosthetic components neutral to the mechanical axis to balance load distribution and maximise implant survivorship [9]. While effective in many cases, this approach does not account for the natural anatomical variability between patients. As a result, it frequently requires soft tissue releases to achieve a balanced TKA [10]. With advancements in prosthetic design enabling non-neutral alignments, newer strategies like kinematic alignment, anatomic alignment, and functional alignment have emerged. These approaches strive to better recreate the patient's native anatomy and kinematics [11]. Despite these advancements, dissatisfaction rates remain high, emphasising the need to look beyond bony alignment alone and consider the role of the soft tissue envelope in achieving joint balance and stability [6], [7].

Orthopedic surgeons frequently emphasise the importance of joint balance and stability in TKA. A balanced soft tissue envelope is critical for ensuring a stable and functional knee postoperatively [12]. Surgeons also recognise the value of preoperative planning in reducing uncertainties during surgery [13], [14]. Yet, despite the increasing focus on personalised alignment strategies, current preoperative planning methods rarely integrate detailed soft tissue information. This disconnect limits the ability to create truly balanced TKA plans in both extension and flexion.

The overarching goal of this dissertation is to explore how preoperative TKA planning can incorporate soft tissue characteristics to enable more balanced, patient-specific surgical plans. By addressing this gap, the research aims to contribute to the development of holistic preoperative planning approaches that consider the three-dimensional knee morphology and soft tissue behavior, paving the way for improved patient outcomes and satisfaction in TKA.

1.2. Thesis Structure

This dissertation explores the critical role of soft tissue behavior in total knee arthroplasty (TKA) and aims to advance preoperative planning by integrating comprehensive soft tissue information. By addressing the limitations of existing alignment strategies and classification systems, this research seeks to develop innovative approaches to optimise surgical planning enhance patient outcomes. The structure of the thesis is outlined below:

Chapter 1: Introduction

This is the current chapter. This chapter introduces the research motivation, highlighting the challenges and limitations of current TKA planning and alignment strategies, particularly in achieving balanced and patient-specific outcomes. It sets the stage for the dissertation by framing the importance of integrating soft tissue information into preoperative planning and outlining the key research questions. Additionally, the structure of the thesis is presented to provide an overview of the chapters and their contributions to addressing these challenges.

Chapter 2: Literature review

The literature review provides a brief background of the knee, total knee arthroplasty and key technologies and developments that have shaped the industry. The chapter discusses how the definition of successful total knee arthroplasty has been defined over time and discusses surgical and non-surgical factors which may impact patient outcomes. Finally, the chapter highlights some key gaps in literature and outlines the aims of this thesis.

Chapter 3: Variability of three-dimensional knee morphology cannot be effectively assessed using a coronal plane knee alignment classification in total knee arthroplasty patients

This chapter lays the foundation for the entire thesis by identifying a critical gap in the literature: conventional classification systems, like the coronal plane alignment of the knee (CPAK), focus solely on coronal plane alignment and therefore may not fully capture the three-dimensional (3D) complexity of knee morphology. This leads to challenges for TKA planning, as factors like tibial and femoral rotation, tibial slope, and femoral flexion are not adequately addressed despite their importance for successful surgical outcomes. The key takeaway is that a more comprehensive, three-dimensional classification system is needed for effective TKA planning. This chapter sets up the need for a multi-dimensional approach and paves the way for the exploration of other critical factors in knee alignment, particularly joint laxity and functional assessments.

Chapter 4: Functional preoperative assessment of coronal knee laxity better predicts postoperative patient outcomes than intraoperative surgeon-defined laxity in total knee arthroplasty

Building on the limitations of coronal plane assessments, this chapter introduces the concept of functional laxity as a key factor in TKA planning. Here, the focus shifts from anatomical measurements to the functional behavior of the knee joint. The study demonstrates that preoperative functional laxity (measured when the patient is awake) is a better predictor of postoperative outcomes than intraoperative assessments done while the patient is under anesthesia. This chapter highlights the variability in soft-tissue behavior and the importance of assessing knee laxity in a functional state, further challenging the current reliance on intraoperative assessments. The key takeaway is that soft-tissue profiles should be integrated into preoperative planning to better guide surgeons, linking directly to the idea that more comprehensive, patient-specific strategies are required. This naturally leads to the question of how we can better assess the knee in functional positions, setting the stage for the next chapter.

Chapter 5: Intra-observer and Inter-observer validation of a three-dimensional to two-dimensional registration technique for anatomical assessment of knees undergoing total knee arthroplasty

After establishing the need for better functional assessments in the previous chapter, this chapter validates a technical approach that allows for accurate anatomical assessments in various functional positions. The 3D-to-two-dimensional (2D) registration technique is introduced as a reliable method for translating 3D knee morphology into functionally meaningful assessments, with high reproducibility in the coronal plane. This chapter's key takeaway is the technical validation of a method that supports functional assessments of the knee, providing a robust tool for preoperative planning and analysis. This links directly to the findings from Chapter 4 by offering a validated method to better understand and plan for the functional behavior of the knee, and sets up the next discussion on the challenges faced by current classification systems despite technical advancements.

Chapter 6: Coronal plane alignment of the knee classification system appears inadequate to effectively assess coronal joint laxity in osteoarthritic knees

This chapter revisits the discussion of CPAK (introduced in Chapter 3) by specifically addressing its limitations in accounting for coronal joint laxity. Building on the findings from Chapter 4, which demonstrated that functional laxity better predicts postoperative outcomes, this chapter argues that current classification systems are insufficient for TKA planning because they do not account for joint gap variability. The takeaway is that CPAK and other coronal-only approaches remain limited in their ability to serve as comprehensive guides for surgical planning. This connects directly to the following chapter, where a new approach – integrating both soft tissue and bony anatomy – will be explored.

Chapter 7: Preoperative Joint Distraction Imaging and Planning Protocol for Total Knee Arthroplasty

This chapter presents a new imaging and planning protocol that integrates both the hard tissue (bony anatomy) and soft tissue (joint gaps) into a single preoperative planning approach. The use of joint distraction radiographs allows for a more holistic assessment of the knee, balancing both extension and flexion spaces. This approach, which the study shows leads to alignments comparable with healthy knee morphology, ties together the entire narrative: it addresses the need for multi-dimensional, patient-specific planning that considers both bone and soft-tissue information. The key takeaway is that combining anatomical and functional data provides a more holistic and personalised approach to TKA planning, equipping surgeons to better plan for joint balance, potentially improving patient outcomes.

Chapter 8: Discussion and Conclusion

This chapter synthesizes the key findings of the thesis, contextualizing them within the broader challenges and advancements in TKA planning. It begins by revisiting the overarching aims and key findings from Chapters 3 to 7. The chapter then explores the clinical implications of these findings, with a focus on bridging the gap between research and clinical practice. It also addresses the limitations of the methodologies and offers suggestions for further research. Finally, the chapter provides the conclusions from the work presented in this dissertation.

Chapter 2:

Literature Review

2.1. Knee Anatomy, Osteoarthritis and Treatment Options

2.1.1. Anatomy of the Knee

The knee joint is a complex synovial joint which consists of three key osseus structures, the femur, tibia and patella. These bones result in the medial and lateral tibiofemoral and patellofemoral articulations, which combined enable the flexion-extension mechanism of the knee.

The tibiofemoral joint can be divided into the medial and lateral tibiofemoral compartments which enable the articulation of the femoral condyles over the tibial plateau. The articulation involves the femur rolling and gliding over the tibial surface during the extension and flexion of the knee [15].

The patellofemoral joint, comprising the posterior surface of the patella and distal femur, functions as a mechanical pulley during the extension of the tibiofemoral joint. During knee motion, the patellar contact point on the femur changes with flexion angle, shifting from the trochlear groove in early flexion to the intercondylar region at higher flexion angles. Compressive patellofemoral joint reaction forces result from the muscle tension and are dissipated throughout the joint through the contact area between articular tissue of the patellar surface and femur [16].

The ligaments of the knee play a key role in the stabilisation of the joint. The primary tibiofemoral ligamentous stabilisers include the posterior cruciate ligament (PCL), anterior cruciate ligament (ACL), medial collateral ligament (MCL) and the lateral collateral ligament (LCL). The key patellofemoral ligaments are the medial patellofemoral ligament (MPFL), lateral patellofemoral ligament (LPFL), medial patellotibial ligament (MPTL) and the lateral patellotibial ligament (LPTL). These ligaments are visualised in **Figure 2.1** and **Figure 2.2** and the origin, insertion and function of these ligaments are outlined in **Table 2.1**. The patella is further stabilised by the fibrous connective tissue of the medial and lateral retinacula.

The knee joint also employs numerous secondary stabilisers including ligaments, tendons, and muscles. The details of these have been excluded for the purpose of this literature review and will be outlined in later sections as required.

Hyaline articular cartilage covers the articular surfaces of the tibiofemoral and patellofemoral joints. This cartilaginous tissue is highly effective at absorbing shock and transmitting forces throughout the joint during the motion, thus enabling relatively high load bearing activities [17]. The meniscus is a fibrocartilaginous tissue located between the distal femur and proximal tibia. It acts as a cushion for the medial and lateral condyles of the femur, providing stability and load distribution through the joint [18]. Synovial fluid is contained within the synovium membrane and provides nutrients to the avascular cartilage and lubrication for joint articulation, thus reducing friction and the resulting wear for articulating cartilage surface [19].

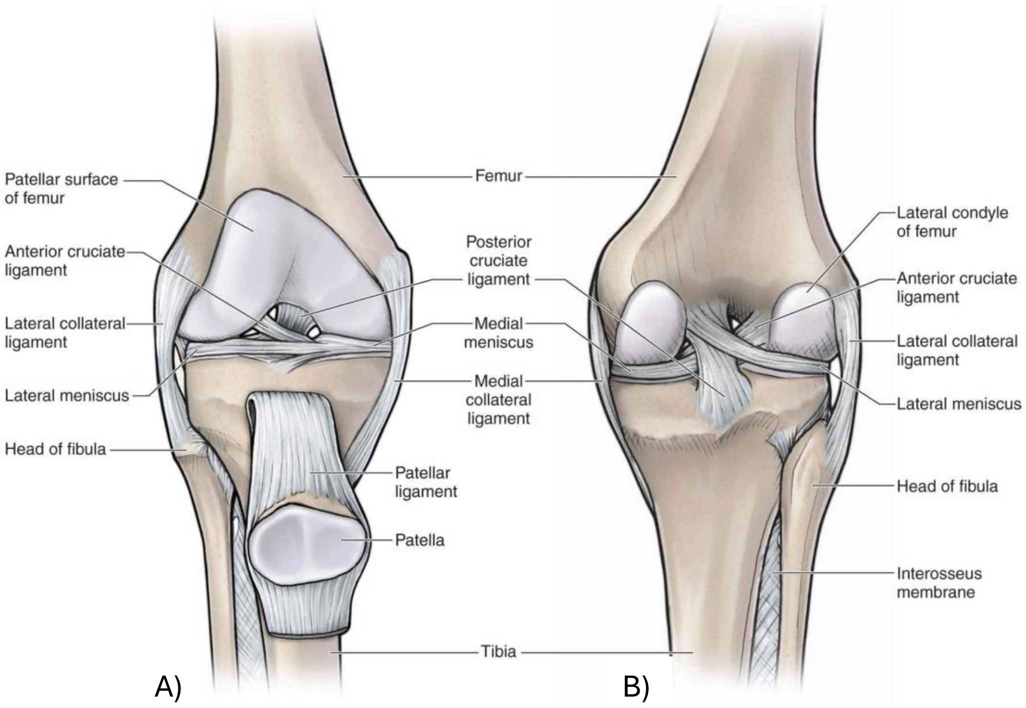

Figure 2.1. *Representation of the anatomy of the knee joint, including bones and soft tissues including the key cruciate ligaments. A) Anterior view. B) Posterior view [20].*

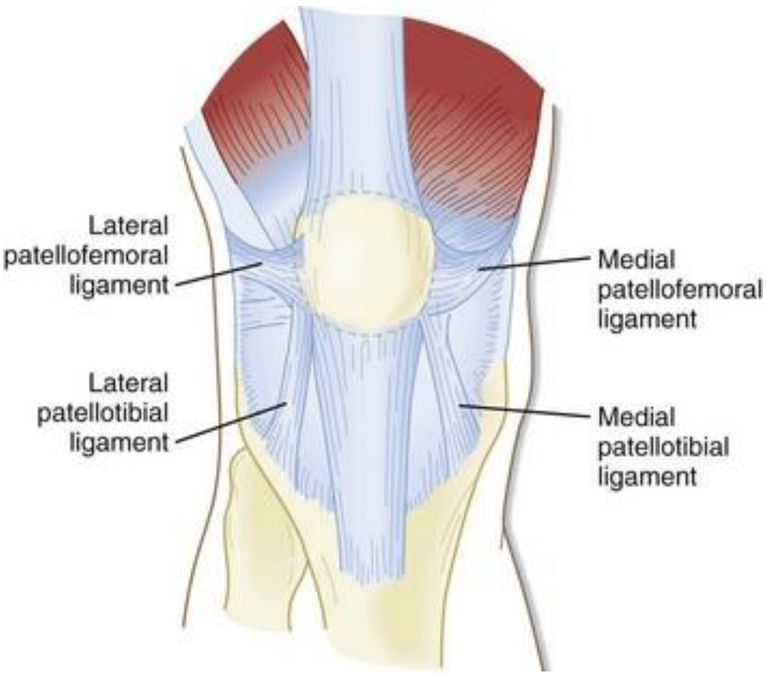

Figure 2.2. *Representation of the knee joint and the patellofemoral and patellotibial ligaments [21].*

Table 2.1. Details of the key stabilising ligaments of the tibiofemoral and patellofemoral joint.

Ligament	Origin	Insertion	Function
ACL	Posterior-medial aspect of the lateral femoral condyle	Anterior aspect of the proximal tibial plateau	Stabilise against anterior-to-posterior translation of the tibia relative to the femur and prevents excessive anterolateral rotation of the tibia [22]
PCL	Anterior-lateral aspect of the medial femoral condyle	Posterior edge of the proximal tibial plateau	Stabilise the joint by restricting posterior-to-anterior translation of the tibia relative to the femur as well as prevent excess external rotation of the tibia [23]
MCL	Medial femoral epicondyle	Periosteum of the proximal tibia	Restrict valgus stress on the joint and tibial anterior-medial rotation [24]
LCL	Lateral femoral epicondyle	Posterior to the anterior point of the fibular head	Restrict the varus stress on the joint as well as tibial posterior-medial rotation [25]
MPFL	Bony groove between the adductor tubercle and the medial epicondyle [26]	Superior two-thirds of the medial patellar edge [26]	Guide patellar tracking and prevent lateral patellar subluxation. The MPFL is the primary stabiliser against lateral patellar instability [27], [28]
LPFL	Distal and anterior to the lateral epicondyle [29]	Middle-third of the lateral aspect of the patella[29]	Prevent medial instability of the patella
MPTL	Distal one-third of the medial aspect of the patella [30]	Medial to the patellar tendon inserting and 5-22mm distal to the joint line [30]	Secondary stabiliser against lateral instability of the patella [28]
LPTL	Alongside the lateral border of the patellar tendon [31]	Lateral tibial condyle between the anterior tibial tuberosity and Gerdy's tubercle [31]	Despite limited research on the LPTL but it is hypothesised to be the secondary stabiliser against medial instability of the patella

2.1.2. Kinematics and kinetics of the tibiofemoral joint

The knee functions as a complex system where the kinematics and kinetics of the patellofemoral and tibiofemoral joints are biomechanically interdependent. However, to maintain a clear focus on the primary subject of this investigation, the following analysis is centred on the tibiofemoral articulation. A detailed examination of patellofemoral biomechanics, while clinically important, is therefore considered beyond the scope of this thesis.

Kinematics

The tibiofemoral joint has six degrees of freedom (DOF), with three rotational and three translational movements – all of which are measured relative to the three perpendicular anatomical axes. Of the six DOF, flexion/extension, internal/external rotation and anteroposterior (AP) translation are considered primary motions, with varus/valgus rotation, mediolateral translation and superior-inferior translation being secondary motions. While the extent of these motions can vary between subjects depending on anatomy, age, training and activity, below are some guidelines.

Flexion/extension is the most prominent DOF of the tibiofemoral joint, with movement ranging from full-extension (i.e. 0° flexion) to 150° for active flexion and up to 160° for passive flexion [32], [33], [34]. The LCL becomes loose with tibiofemoral flexion, allowing axial rotation and varus/valgus motion of the tibiofemoral joint [35]. The axial rotation does not occur uniformly throughout knee flexion [36], with a sharper internal rotation of the tibia relative to the femur (of 5°–10°) from 0° to 30° flexion [34], [37], attributed to the screw-home mechanism [38], [39]. This is followed by a more continuous rate or even a slight reversal of axial rotation from 30° to 120° flexion [34], [37]. Varus alignment gradually increases with tibiofemoral flexion. From full extension to 30° flexion, a small varus rotation of approximately 2° occurs [34], increasing by an additional 3-4° as the knee approaches 120° [34], [37] after which no change in coronal alignment is observed [34].

During knee flexion, both femoral condyles glide posteriorly along the tibia, with the lateral femoral condyle exhibiting greater posterior translation than the medial femoral condyle, creating a medial pivot kinematic pattern [33], [35], [40]. This posterior movement of the femoral condyles, known as femoral rollback, is more pronounced during weightbearing deep knee bends (e.g. squats) than during lesser flexion activities such as gait [36]. Johal et al. noted that during passive flexion, the lateral femoral condyle moves posteriorly while the medial femoral condyle displays minimal posterior translation until 120° flexion, after which both condyles move posteriorly to a similar extent [32]. In contrast, a cadaveric study by Victor et al. highlights that muscle loading can reduce this femoral rotation and translation during flexion [41]. Mediolaterally, the femur initially shifts 1.7 mm laterally from full extension to 30° flexion, remains largely stable (0.1 mm lateral movement) from 30° to 120° flexion, before shifting 3.8 mm medially in deep flexion [34]. Superior-inferior translation of the tibiofemoral joint is negligible through knee ROM [42].

Kinetics

Tibiofemoral flexion is primarily driven by the hamstring muscle group, including the bicep femoris (short and long head), semitendinosus, and semimembranosus, and are also supported by the gastrocnemius and plantaris muscles [43], [44], [45]. The popliteus muscle assists the tibiofemoral flexion by providing the torque required to “unlock” the knee as it moves out of full extension [43]. The gracilis and sartorius muscles support the axial tibiofemoral rotation [43], [46]. Tibiofemoral extension is driven by the quadriceps femoris muscle group, comprised of the rectus femoris, vastus lateralis, vastus medialis, and vastus intermedius [47]. The tensor fasciae latae assists with extension, especially during weightbearing activities [48].

Internal loads from muscle contractions, such as those of the quadriceps and hamstrings, combine with external loads from body weight, gravity, and ground reaction forces to determine the net contact forces on the tibiofemoral joint [49]. These contact forces vary by activity and are reported to be up to 2.0–3.1 times body weight (xBW) during gait, while stair ascent and descent impose higher loads of 2.3–4.4 xBW and 3.0–4.4 xBW, respectively [49], [50], [51], [52]. Squatting generates contact forces between 2.5–4.0 xBW, whereas transitioning from sitting to standing produces 2.5–3.0 xBW, and standing to sitting results in 2.3–2.9 xBW [49], [50], [52]. Notably, while total tibiofemoral contact forces appear similar across healthy, osteoarthritic, and TKA subjects, osteoarthritic individuals exhibit greater medial compartment loading compared to healthy counterparts [53].

It is important to acknowledge that these tibiofemoral movements are intricately coupled with the kinematics of the patellofemoral joint. The patella acts as a crucial pulley for the extensor mechanism, tracking along the femoral groove and intercondylar region during flexion and extension. However, as the central focus of this thesis is the tibiofemoral joint, a detailed analysis of patellofemoral kinematics is considered beyond the scope of this review.

2.1.3. Pathophysiology and Osteoarthritis

Arthritis is one of the leading causes of chronic knee pain and disability [1]. Although there are many forms knee arthritis, osteoarthritis (OA) is the most common. Osteoarthritis is a multifaceted disease caused by several factors including trauma, mechanical forces, inflammation, genetic and environmental factors [1]. In the early stages of OA, cartilage is more affected than surrounding tissues and, as an avascular tissue, has a limited capacity to heal [54]. Individuals often experience pain with further progression of the OA, once non-cartilaginous tissues begin to undergo changes such as subchondral bone remodelling and osteophyte formation, laxity of ligaments, synovial effusion as well as the weakening of per-articular muscles [54]. When OA is severe, these changes may cause debilitating pain, poor joint function and inferior quality of life [54].

Osteoarthritis can by classified as primary or secondary. Primary OA is idiopathic, whereas secondary OA is caused by trauma and/or mechanical misalignment. The severity of an individual’s OA is typically graded using either the Kellgren-Lawrence (KL) or Ahlback classification systems, which involve radiographic assessment of the knee joint [55], [56], [57]. The assessment involves considering typical changes due to the disease such as the presence of osteophytes, narrowing joint space, osseous deformities, and sclerosis. The grading of these classification systems is outlined in **Table 2.2**.

Knee OA impacts over 2.2 million (approximately 9%) of Australians [2] and over 250 million individuals globally [3]. The disease is more prevalent in aged and female populations. A meta-analysis by Cui et al. evaluated 88 studies with over 10 million participants [58]. The authors found the global prevalence of knee OA to approximately 23% for individuals over 40 years of age and 35% for individual aged between 70 and 79. Additionally, the prevalence ratio of women to men was found to be 1.69 for the global population.

Table 2.2. *Summary of the Kellgren-Lawrence and Ahlback OA classification systems.*

Grade	Classification System	
	Kellgren-Lawrence [55]	**Ahlbäck** [56], [57]
0	Definite absence of radiographic changes of OA	No joint space narrowing
1	Possible osteophyte presence but doubtful of joint space narrowing	Narrowing of the articular space
2	Definite but minimal presence of changes due to OA	Obliteration or almost obliteration of the articular space
3	Definite joint space narrowing, sclerosis, and presence of moderately sized osteophytes	Bone attrition less than 5 mm
4	Presence of large osteophytes, severe sclerosis, joint space narrowing as well as osseus deformities	Bone attrition between 5 and 15 mm
5	Not applicable (only 4 grades defined)	Bone attrition greater than 15mm

2.1.4. Treatment Options

Osteoarthritis is largely irreversible and most available treatment options aim to manage symptoms such as pain and stiffness as well as enhance functionality, range of motion (ROM) and quality of life. Numerous non-surgical treatments are available during earlier stages of knee OA including non-pharmacological, pharmacological and injectable options, whereas surgical intervention is a common treatment option for patients with severe knee OA.

Non-Pharmacological Management

Physical inactivity can have adverse impacts on an individual's knee joint as well as their general wellbeing. The absence of mechanical loading of the knee joint can increase the rate of cartilage degeneration within the joint, decrease levels of glycosaminoglycan as well as impair flexibility and joint mechanics [54]. Additionally, inactivity can also increase the risk of the development of comorbidities such as obesity [59]. Therefore, light-to-moderate physical activity can enhance an individual's general wellbeing and knee joint health by preventing or reducing the risks of the aforementioned issues. The impact profile of a given exercise has the potential to aggravate an osteoarthritic joint and so exercise routines should be personalised to an individual's physical condition and requirements [59].

Physical exercise can also aid with weight loss which can be beneficial for overweight and obese OA patients. The knee joint bears 2 to 3.1 times one's total body weight during walking [49]. As a result, any reduction in weight has a magnifying reduction in the forces acting on the joint. Further, Messier et al. outlined that there is a 10% decrease in the risk of developing knee OA for each kilogram decrease in bodyweight for overweight and obese older adults [60]. Inversely, weight gain increases the risk of developing the disease.

Pharmacological Management

Non-steroidal anti-inflammatory drugs (NSAIDs) are one of the most common pharmacological treatment options for knee OA symptoms. NSAIDs are cyclooxygenase inhibitors, which reduce the production of prostaglandins, ultimately reducing inflammation and the associated pain [54]. A meta-analysis by Lin et al. highlighted that although the use of NSAIDs has exhibited superior pain management properties relative to placebos for short-term use its benefits are not sustained over longer durations [61].

Intra-articular corticosteroids elicit immunosuppressive and anti-inflammatory effects and may provide short-term pain relief [62]. Several studies have investigated the use of corticosteroids but results regarding its efficacy, duration of use, adverse effects are highly variable[54]. As a result, some clinicians and health boards consider the evidence to be inconclusive and so do not recommend it as a treatment option [54], [63]. Intra-articular hyaluronic acid (HA) is a natural glycosaminoglycan which provides lubrication and has shock absorbing properties. HA concentration significantly decreases for OA patients and so it is hypothesised that intra-articular HA can be used to restore the HA levels and associated benefits within an OA joint [64]. Literature regarding the efficacy of HA for the treatment of knee OA is conflicting and so further research is required [54], [64], [65].

Platelet rich plasma (aim to regenerate the OA affected joint by limiting inflammatory reactions mediated by cytokines and release a range of growth factors which ultimately promote the healing of bone and soft tissue [66]. This is a relatively new treatment and results reported thus far indicate that the treatment is promising and safe [66], [67]. Further research is required to obtain a better understanding of the optimal production parameters for these.

Surgical Intervention

Patients with end-stage OA who have been unsuccessful in relieving symptoms via non-surgical treatment options may be deemed to be appropriate to receive surgical intervention [54]. Surgical intervention for knee OA often comes in the form of either unicompartmental knee arthroplasty (UKA) or TKA. The fundamental aim of the two are the same, wherein the diseased tissue from the knee joint is removed and replaced with synthetic implants [68]. In a UKA this involves distal femur and proximal tibia of either the medial or lateral compartment (depending on the progression of the OA), whereas for TKA this involves replacing both tibial and femoral compartments as well as the posterior patella surface where deemed appropriate [68].

2.2. Total Knee Arthroplasty

2.2.1. TKA and Goals

The primary aims of a TKA involve the relief of symptoms such as pain, restoration of physical function and mobility. TKAs are widely considered one of the most successful and cost-effective orthopaedic procedures [4], [5]. It is especially effective for elderly patients with debilitating OA but is becoming increasingly common amongst younger populations with OA. The incidence of TKA has been approximated to rise between 2- and 3- fold between 2019 and 2030, at which point it is projected to cost the Australian healthcare system at least $3.4 billion, annually [69].

2.2.2. Components

Most primary TKA constructs consist of four components: the femoral component, tibial baseplate, tibial insert, and patella button. The tibial baseplate and femoral component are typically manufactured from cobalt-chromium or titanium alloys, while the tibial insert and patella button are typically made of polyethylene variants. The most common polyethylene variants used in TKA are Ultra High Molecular Weight Polyethylene (UHMWPE) and Highly Cross-Linked Polyethylene (HXLPE). The latter has become more prominent after displaying superior wear properties in total hip arthroplasties [70]. However, there remains limited evidence of this translating across to TKAs. Vitamin-E infused HXLPE has recently been introduced due to its potential to further reduce polyethylene wear in-vitro but requires further in-vivo analysis [71]. An example of a complete TKA construct is displayed in **Figure 2.3**.

When selecting components for TKA, surgeons must consider various design options. For instance, cemented or cementless fixation options are available for TKA. Cemented designs rely on bone cement mixtures for fixation whereas cementless components use press fit components to enable osseointegration. While cementless components are often recommended for younger, more active, and obese patients due to higher stresses at the bone-implant interfaces [72], [73], studies show similar long-term revision rates and clinical outcomes between the two fixation types [72], [74]. The three most common femoral component designs are Cruciate Retaining (CR), Posterior Stabilised (PS), and Medial Pivot (MP) (**Figure 2.4**). While MP TKAs better emulate healthy knee kinematics [75], a network meta-analysis by Phillips et al. found no significant differences in revision rates, complication rates, short-term function or long-term function between the three implant variants [76]. A key differentiating factor between tibial baseplate designs is whether they are fixed or mobile bearing. Fixed bearing prostheses lock in the axial alignment of the tibia, whereas mobile bearing allows the articulating polyethylene tibial insert to rotate freely during the ROM (**Figure 2.5**) [73]. However, a meta-analysis by Hantouly et al. reported no significant clinical or functional differences between fixed and mobile bearing designs across short-, mid- and long-term follow-ups [77]. These findings suggest that modern TKA implant designs have reached maturity, and further improvements in patient outcomes may rely more on factors like alignment strategies than on implant design alone [78].

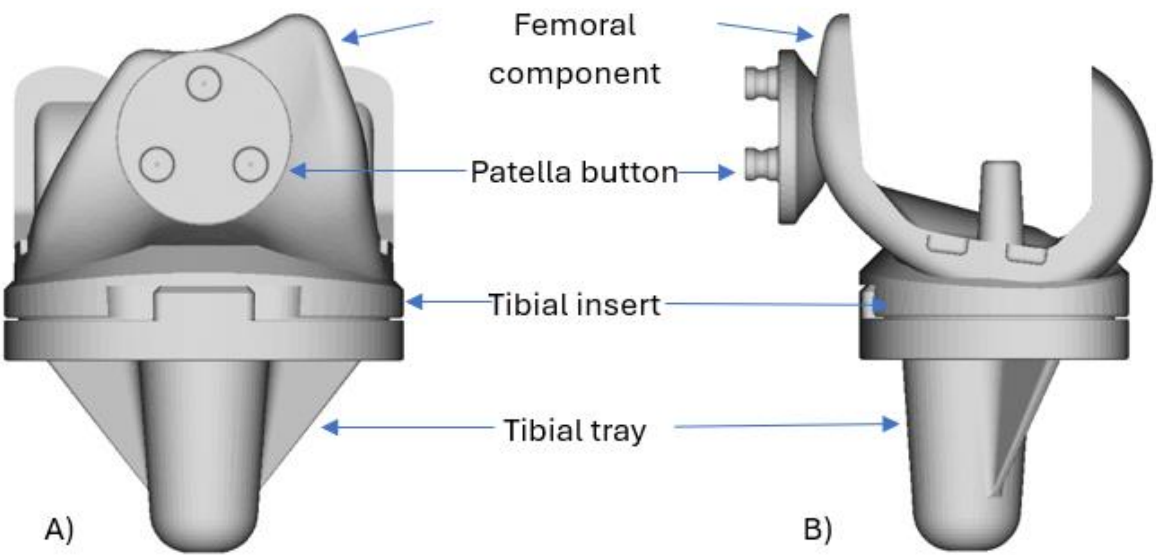

Figure 2.3. *Typical construct for a primary TKA. A) Anterior view and B) posterior view.*

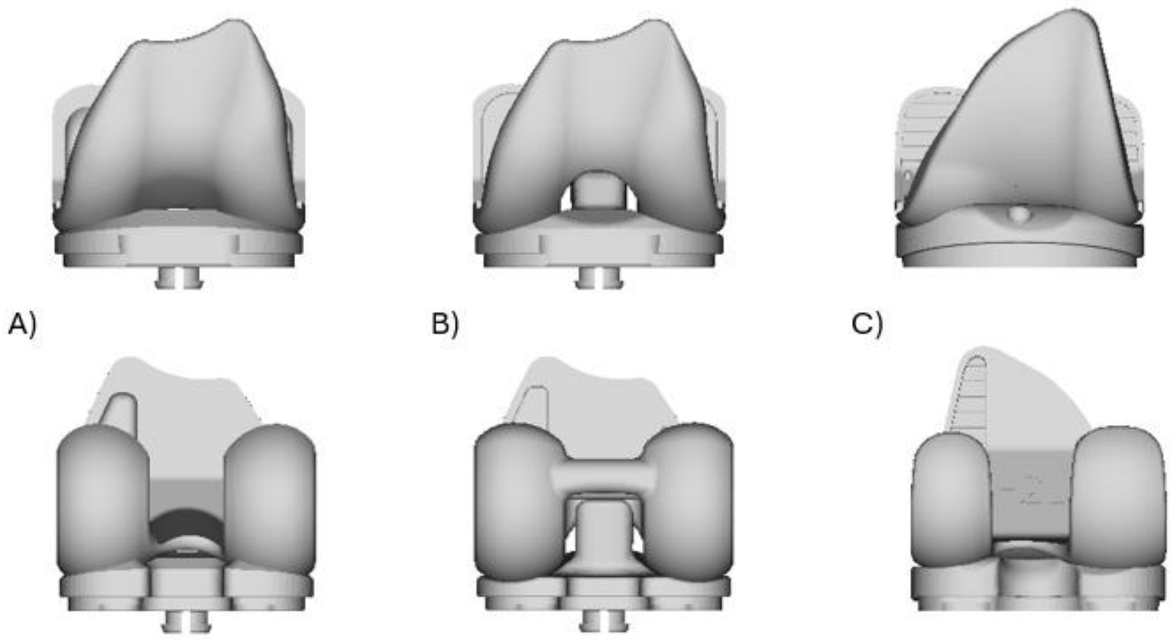

Figure 2.4. *Example of some common variants of femoral component and tibial insert combinations. The top image provides an anterior view and the bottom the posterior view of A) cruciate retaining, B) posterior stabilising and C) medial pivot designs.*

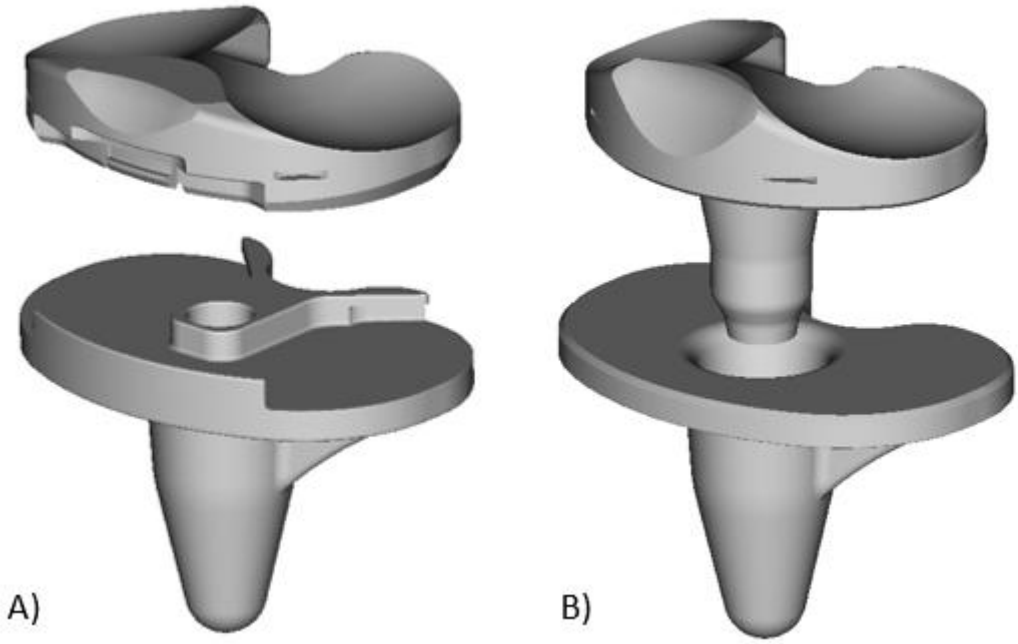

Figure 2.5. *A) Fixed bearing and B) rotating platform tibial tray and insert constructs. The fixed bearing design axially locks in the tibial insert position relative to the tibial tray whereas the rotating platform design accommodates axial rotation of the tibial insert relative to the tray and as a result the tibiofemoral joint during range of motion.*

2.2.3. Component Alignment

Component alignment in TKA refers to the rotational and translational positioning of the prostheses relative to the native anatomy of the knee [79]. Alignment targets can vary based on multiple factors including patient specific anatomy and deformity, alignment philosophy (detailed in Section 2.6), surgical technique, intraoperative delivery tools (detailed in Section 2.7.2), implant constraints, targets in literature and surgeon preference [80], [81]. Accurately achieving a given TKA alignment refers to precise recreation of a target alignment, and various delivery technologies (detailed in Section 2.7.2) can be used to help achieve this. Some of these delivery tools such as computer navigation or robotics can also be used to measure the achieved alignment intraoperatively, whereas radiographic (X-ray or computed tomography (CT)) or magnetic resonance imaging (MRI) assessments can be used for postoperative analysis of achieved alignment.

2.3. Measuring Success and Drivers of TKA Outcome

Traditionally, orthopaedic surgeons judged whether a TKA was successful with consideration to factors such as implant survival and functional or physiological complications. However, literature has evidenced that patients consider additional aspects such as the ability to perform specific activities which may impact their quality of life, and so patients and surgeons ultimately have different definitions of success [82].

2.3.1. Survivorship

Traditionally, survivorship was a key objective measure for success in TKA. The rate of survivorship of a TKA is defined as the inverse of the revision rate. According to the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) 2024 annual report, the TKA revision rate for knees with a primary diagnosis of OA is 6.1% after 15 years, equating to a survivorship rate of 93.9% [83]. The primary causes for these revisions were infection (27.9%), loosening (21.3%), instability (10.4%), joint pain (7.5%) and patellofemoral pain (6.6%), with component loosening becoming increasingly prevalent over time [83]. The overall survivorship rate in Australia is consistent with recent findings from other national registries published between 2020 and 2021 [84], [85], [86]. Ultimately, long-term TKA survival has been shown to be correlated to a number of factors including, but not limited to, component design [87], delivery tools [88], patient variables [89] as well as surgeon and hospital factors [90].

Patient satisfaction, which accounts for self-reported domains like pain and function, offers a more patient-centric measure of TKA success than implant survivorship alone. While reported satisfaction rates are moderately high, typically ranging from 75% to 90% [91], [92], this metric provides a more nuanced picture of success than revision rates do. A study by Price et al. exemplifies this point [93]. In their analysis, 18% of the patient cohort required a revision at 12-years, indicating a survival rate of 82%. However, with additional consideration to moderate or severe pain or below satisfactory functional outcomes, the survival rate was just 59%. This disparity demonstrates that a comprehensive definition of TKA success must integrate both implant survivorship and patient-reported outcomes.

2.3.2. Patient-Reported Outcome Measures

Healthcare organisations such as private health-insurance companies are shifting from volume-based to value-based reimbursement systems, which focus on outcome driven results [94]. This is one reason why there has been an increasing shift towards the use of patient-reported outcome measures (PROMs) as a key measure for success following a TKA. PROMs refer to instruments (such as surveys) which allow for the quantitative measurements of a given patient's perception of outcome. The patient's responses to the PROMs questionnaires are typically quantified to enable the calculation of a score, which is then used as an objective measure of the patient's outcome before and/or after a procedure.

The most common TKA-specific PROMs instruments include the Oxford Knee Score (OKS), Western Ontario and McMaster Osteoarthritis Index (WOMAC), Knee Osteoarthritis and Injury Outcome Score (KOOS), and the new Knee Society Score (KSS). The OKS is comprised of 12 questions, which focus on outcomes relating to pain and activities of daily living (ADL) [95]**.** The WOMAC osteoarthritis index consists of a total of 24 questions which are divided into 3 subscales: pain, stiffness and physical function [96]. The KOOS was developed as an extension of WOMAC and contains a total of 42 questions across 5 subscales: pain, symptoms, functionality during ADL, functionality during sports and recreation, and quality of life (QoL) [97]. The additional subscales provide a better understanding of the impact on additional aspects of the patient's life. However, the increased number of questions within the questionnaire comes as a cost as it leaves it more prone to be left incomplete [98]. The Forgotten Joint Score (FJS) was developed in 2012 making it a relatively modern PROMs questionnaire [99]. It was developed for use after joint arthroplasties with the objective to determine the patient's ability to forget the artificial joint in daily life.

Despite the increasing push to measure PROMs, it is important to consider the limitations associated with these metrics. The scoring mechanism of some PROMs instruments may make them vulnerable to the ceiling effect. This occurs when the results begin to cluster around the higher scores, making it increasingly difficult to differentiate between patients who are performing well or even for a single patient at different time-points. In the study published by Eckhard et al., patients were asked to complete preoperative and postoperative KOOS, WOMAC and OKS as well as postoperative FJS [100]. The authors assessed the results of the 380 and 193 patients who completed the surveys at their 1-year and 2-year follow-up, respectively. They defined the ceiling effect as over 15% of the patients achieving the highest obtainable score for a specific survey and observed the occurrence of a ceiling effect for the KOOS Pain and ADL subscales at the 1-year follow-up, and WOMAC and KOOS Pain, Symptoms, ADL and QoL subscales at the 2-year follow-up. Similar results have been reported by additional studies [98], [101], highlighting the limitations of certain PROMs instruments for evaluating patients with 'high' or 'good' scores. However, it should be noted that the FJS has been observed to result in a low ceiling effect, enabling it to differentiate between otherwise well-performing cohorts [102], [103], [104]. Additionally, PROMs questionnaires are subjective by nature and so have the potential to be influenced by psychological factors. These may be more apparent in specific domains, such as function, where self-reported function provides information about an individual's perceived function as opposed to reflecting their actual function [105].

2.3.3. Non-Surgical Drivers of Patient Outcome

As outlined below, numerous studies have highlighted the importance of investigating non-surgical variables due to their potential to influence postoperative patient outcomes. These risk factors may even be considered by surgeons when evaluating patient appropriateness for TKA.

Surgeon and Hospital Factors

Establishing robust patient selection criteria is crucial to ensure TKA is performed only on those likely to benefit. Most orthopaedic surgeons would agree that severe OA impacting the quality of life is a primary indicator for TKA, typically after non-surgical treatments have failed and imaging confirms knee pathology [106], [107]. Organisations like the United Kingdom's (UK's) National Institute for Health and Care Excellence recommend "prolonged and established" symptoms to avoid premature TKA [108]. While criteria often include clinical findings and PROMs, patient selection remains partly intuitive with no universal consensus among surgeons. Riddle et al. proposed a surgical appropriateness criterion incorporating factors such as age, radiological assessment, joint mobility and stability, disease localisation and patient reported symptoms [109]. The authors reported that only 48% of TKA recipients met these criteria, while 21% and 31% were deemed inconclusive or inappropriate to receive a TKA, respectively. Their analysis revealed that inappropriate candidates realised no clinical improvement in the short-term, although long-term outcomes aligned with the other groups. This underscores the critical need for a clearly defined patient selection criteria to avoid suboptimal outcomes.

Various patient outcome prediction tools have been developed to assist in the selection process. Sanchez-Santos et al. [110] and Onsem et al. [111] proposed models with limited clinical adoption. Lungu et al. developed a more practical model using a flowchart to guide clinicians through the selection process, though this model has yet to be externally validated [112]. The patient expectation management AI tool by Twiggs et al. considers a broad range of 110 preoperative factors including joint pain, functional impairment, medication use, lifestyle choices, comorbidities, and social and employment status [113]. This tool is promising for clinical use but requires further validation to determine how surgeons can effectively integrate it into their decision-making process.

High surgical and hospital volumes are associated with improved TKA outcomes. Kazarian et al. reported that high-volume surgeons more accurately achieved accurate alignment targets than both low-volume surgeons and trainees [114]. While alignment accuracy does not directly translate to better outcomes, Lau et al. highlighted a general trend of improved patient outcomes with higher surgeon volumes, albeit with some variability across studies [115]. Judge et al. reported significantly lower 5-year revision rates in high-volume hospitals [90], with additional studies showing increased revision rates, morbidity, and length of stay (LOS) in low volume settings [116], [117], [118], [119]. This evidence supports the potential benefits of centralising TKA care to enhance outcomes [120].

Patient Factors

Patient satisfaction is a critical metric for TKA outcomes [121]. Despite advancements in component design and surgical techniques, around 1 in 5 patients remain dissatisfied with their TKA [6], [7], [122]. Misaligned expectations significantly impact satisfaction, with over 36% of patients having higher expectations than their surgeons [123], particularly among men who often opt for surgery earlier and expect better outcomes than women [123], [124], [125], [126]. Surgeons also tend to overestimate patient outcomes outcome [127], highlighting the need for effective expectation management through educational interventions and prediction tools [113], [123], [128], [129], [130].

Patient age and OA progression at the time of TKA can also influence outcomes. The AOANJRR indicates higher revision rates for younger patients, partly due to their increased functional demands and prosthesis longevity requirements [83]. Additionally, TKA recipients with less severe OA often experience inferior outcomes and higher dissatisfaction compared to those with advanced deformities [131], [132]. However, delaying TKA too long can lead to severe deformities, increasing procedural complexity and risks [133], [134], [135]. Public and private healthcare structures also impact TKA timing, with public patients in countries like Australia and the UK facing much longer wait times than private patients [136], [137].

Demographic and lifestyle factors have been studied in relation to TKA outcomes. For instance, Ritter et al. observed that while women reported lower pain scores preoperatively and in the medium term postoperatively compared to men, the degree of improvement from TKA was similar in both groups [138]. However, longer wait times for women before surgery may contribute to poorer outcomes due to advanced OA progression [139]. Socioeconomic factors such as lower income and education have also been linked to decreased satisfaction and functional outcomes [140], [141]. While Ayers et al. found no direct association between preoperative comorbidities and short-term functional outcomes [142], other studies suggest that conditions like back pain may independently predict worse pain, function, and satisfaction following TKA [113], [143].

Psychological factors, including depression and anxiety, are associated with inferior TKA outcomes. Kazarian et al. observed that patients with greater symptoms of depression were associated with inferior preoperative and postoperative PROMs [144]. Additionally, depressed patients are 6 times more likely to be dissatisfied with their TKA [145]. Anxiety has also been linked to worse short-term postoperative stiffness [146] and 1-year postoperative OKS outcomes [105]. Other factors, such as pain catastrophising and central sensitisation may also influence postoperative pain and function [144].

Rehabilitation and Prehabilitation

Rehabilitation programs play a critical role in enhancing postoperative pain, function and QoL [147]. Traditionally, patients received inpatient rehabilitation with 32% and 20% of Australian and American TKA patients, respectively, admitted to such facilities [148]. LOS varies with surgical complexity, age, socioeconomic status, and race [149], [150], [151], [152]. The shift towards Ambulatory Surgery Centres in USA highlights the viability of alternative rehabilitation models, including home-based programs that show comparable outcomes to inpatient and clinic-based care [153], [154].

Prehabilitation aims to improve postoperative outcomes and decrease costs by reducing the need or length of hospital LOS [155], [156]. Sharma et al. reported that prehabilitation significantly shortened LOS, although it did not significantly affect short-term postoperative pain, function, or stiffness outcomes [157]. Conversely, Jahic et al. reported short-term (3- and 6-month postoperative) benefits of prehabilitation, but these results were not sustained at 12 months after TKA [158]. Technological advancements have made remote, digital prehabilitation and rehabilitation programs more accessible, offering similar benefits to traditional methods while accommodating the growing demand for TKA [69], [159], [160], [161], [162], [163].

2.3.4. Implant systems

Revision rate for most modern TKA prostheses is within 2-5% at 5-years postoperative and 5-10% at 15 years, with a higher failure rate observed for PS designs [83]. Medial pivot designs have displayed similar survivorship to minimally stabilised prostheses at the 10-year interval [83], whilst also providing superior FJS scores relative to PS prostheses [164]. This suggests that the MP design may provide a more ‘normal’ postoperative feel for patients.

As previously outlined, the incidence of patella resurfacing during TKA varies greatly around the world. The AOANJRR reports the 15-year cumulative revision rate for when patellar resurfacing was performed and not performed during TKA to be 5.4% and 7.1%, respectively [83]. This larger revision rate may be partially due to the increased risk of anterior knee pain that is associated with leaving the patella unsurfaced during TKA [165].

Results from the AOANJRR 2024 Annual Report also indicate that the component survivorship may vary depending on fixation [83]. However, the superior fixation technique is design dependent and varied for CR, PS and MP constructs. This is further highlighted by the lack of evidence in literature to support to use of one specific fixation method over another [166].

2.3.5. Additional surgical drivers

With advancements in prosthesis design aimed at more closely replicating native knee anatomy and kinematics, recent TKA research has increasingly focused on optimising joint balance, alignment strategies, and delivery technologies. These topics are explored in detail in Chapters 2.5, 2.6, and 2.7, respectively. Apart from these, some additional surgical drivers of patient outcomes are discussed below.

The intraoperative use of a tourniquet reduces quadriceps muscle volume and strength [167], [168]. Multiples studies have highlighted the short-term benefits of not using a tourniquet, although these advantages diminished over the long term [168], [169]. Macfarlane et al.'s meta-analysis has also highlighted that the use of regional anaesthesia over general anaesthesia may also reduce short-term patient pain outcomes [170]. Although there is no clear impact of operating times on patient reported outcomes [171], prolonged surgical durations can increase the risk of complications such as infections following a TKA [172], [173].

2.3.6. Implications of TKA Failure

If a TKA procedure fails and the patient is fit for surgery, the patient is typically treated with a revision TKA. However, it should be noted that TKA failure and the potential resulting revision TKA can have substantial health and economic implications. Baker et al. reported that the rate of medical complications within 90 days of the procedure was 6.5% and 14% for primary and revision TKAs, respectively [174]. The authors also investigated the 90-day mortality rate after a primary and revision TKA, which were found to be 0.7% and 4.8% respectively. Mortality rates after revision TKA have been found to be further elevated for failure due to infection and fracture [175].

Revision TKA is also substantially more costly relative to primary TKAs [69], [176]. This is due to a combination of factors including greater operating times, cost of prostheses, greater likelihood for need of longer in-patient length of stay (LOS) and greater likelihood of intraoperative and postoperative complications [177]. Furthermore, periprosthetic joint infections can be severe and have extreme impacts on a patient's quality of life as well as apply a large financial and resource burden on hospitals and the healthcare system [178], [179].

The absolute number of TKAs is expected to increase in the coming years due to the increasing prevalence of OA. Despite advancements in prosthesis design, surgical technique and execution tools the absolute number of failed TKAs is also expected to rise significantly [180]. This is further influenced by factors such as the decreasing mean age of TKA recipients with the 45–55-year-old subpopulation of recipients growing most rapidly [181]. Younger TKA patients are typically more active and will have a longer remaining lifespan, thus increasing the likelihood of TKA component failure and the potential need for a revision TKA [182]. Therefore, it is imperative to obtain a better understanding of the various drivers of TKA outcome.

2.4 Patient Specific Anatomy of the Knee

2.4.1. Patient Specific Anatomy of the Native Knee

Variability in patient anatomy exists and it is known that patient specific anatomy can play a role in general knee alignment as well as TKA. In the knee joint, anatomic variability can occur in all three planes, which can have implications for pre- and postoperative biomechanics as well as component alignment during TKA.

Coronal Alignment of the Knee

Although the coronal alignment of the tibia, femur and overall knee joint can vary, it was previously estimated that the mean coronal hip-knee-ankle (HKA) angle across the population was 0° or neutral to the mechanical axis. However, Bellemans' et al. study observed that the healthy knee joints of young adults had a constitutional coronal HKA angle of 1.3° varus with a standard deviation of 2.3° [183] (**Figure 2.6**). They noted that the male subpopulation exhibited a more varus coronal alignment (1.9° varus) relative to the female subpopulation (0.8° varus), with considerable inter-patient variability within both groups. Further, 32% male knees and 17% female knees had a constitutional varus alignment of greater than 3°, highlighting that the assumption of a mechanically neutral knee is not appropriate. This inherent variability in coronal knee alignment is further supported by numerous studies examining both healthy and OA populations [10], [183], [184], [185], [186], [187], [188], [189], [190], [191]. These studies reinforce the wide distribution of coronal HKA, emphasising the need for personalised analysis and targets during TKA. These results are summarised below in **Table 2.3**.

Sagittal Alignment of the Knee

The sagittal alignment of the knee has also been reported to be highly variable. An analysis by Panguad et al. reported a mean posterior tibial slope of 6.3° with a range of -5.5° to 14.7° for healthy knees [187]. Such variability has also been observed in the osteoarthritic population with Meier et al. reporting a posterior tibial slope of 7.4° ± 3.5°

in a study population of greater than 15,000 [192]. In addition to inter-patient variability in sagittal tibial alignment, studies have also reported intra-patient discrepancies between the sagittal alignment of the medial and lateral compartments of the tibia, in both healthy [193] and OA knees [194].

Although there is less literature available on the sagittal femoral alignment, the existing literature highlights variation between patients as well as ethnicities. Hood et al. analysed the sagittal femoral alignment of 1,235 subjects with no evidence of prior fracture, deformities, or surgical implants [195]. The authors assessed the angle between the mechanical axis and the distal femur flexion (DFF) axis (the centroid line through the distal third of the femur) on the sagittal plane (**Figure 2.7**). The mean DFF angle was observed to be 2.90° ± 1.52°. Although this result in itself does not seem highly variable, 8.1% of sample population had a DFF greater than 5°. Differences in the DFF between ethnicities was also observed between different ethnicities (**Figure 2.8**).

The variability in native sagittal tibial and femoral alignment, both between and within patients, underscores the importance to setting personalised alignment targets during TKA to optimise postoperative outcomes

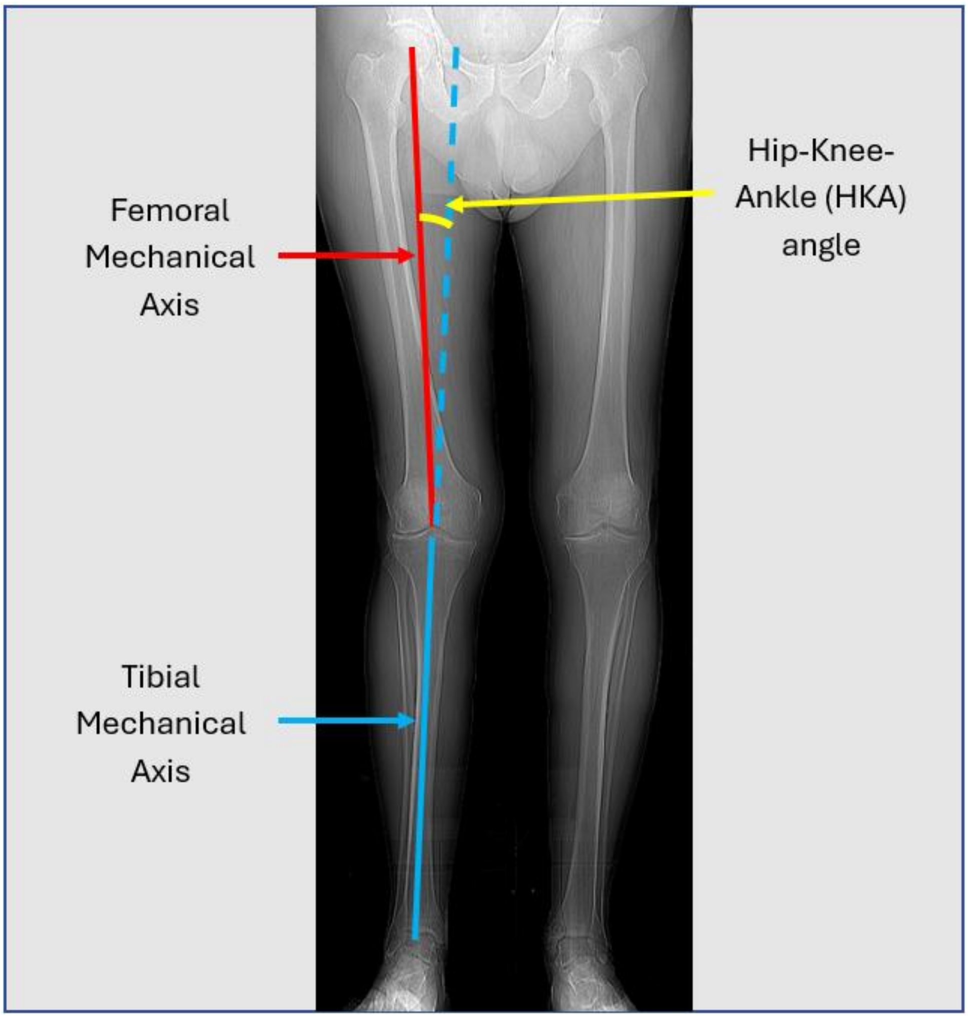

Figure 2.6. *The solid red line joins the femoral head to the centre of the knee and defines the femoral mechanical axis. The solid blue line represents tibial mechanical axis which is defined as the line from the centre of the knee to the centre of the ankle. The dotted blue line is an extension of the tibial mechanical axis. The angle between the femoral and tibial mechanical axes (displayed in yellow) is the long leg hip-knee-ankle (HKA) angle, which is synonymous with the long leg coronal angle. This was believed to be an average of neutral (0°) across the population but Bellemans et al. observed a mean HKA of 1.3° varus in a young healthy population [183].*

***Table 2.3**. Summary of literature reporting the native HKA angles of healthy and osteoarthritic knees. CT, computer tomography*

Study	Year Published	Imaging Modality	Sample Size	Mean (°, Varus)	Standard Deviation (°)
Healthy Knees					
Bellemans et al. [183]	2012	Long leg radiograph	500 knees (250 patients)	1.3	2.3
Deep [184]	2014	Long leg radiograph	267 knees (135 patients)	1.2	4
Lin et al. [185]	2018	Long leg radiograph	214 knees (214 patients)	1.2	3.1
Hirschmann et al. [186]	2019	Long leg radiograph	308 knees (160 patients)	0.3	2.9
Pangaud et al. [187]	2020	Long leg radiograph	756 knees (378 patients)	0.4	Not reported
Osteoarthritic Knees					
Luyckx et al. [189]	2013	CT	231 knees (231 patients)	2.9	6.4
Thienpont et al. [190]	2014	CT	2,637 knees (2,505 patients)	3.5	5.5
Bao et al. [191]	2017	Long leg radiograph	50 knees (50 patients)	5.7	5.0
MacDessi et al. [10]	2021	Long leg radiograph	138 knees (125 patients)	2.9	7.4

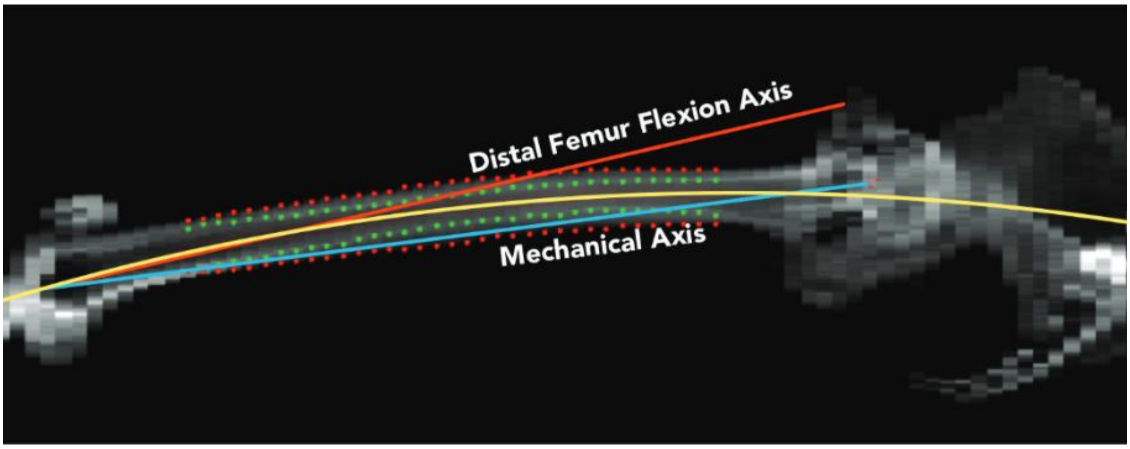

Figure 2.7. *The distal femoral flexion axis (red), the femoral mechanical axis (blue) and the centre of the femoral shaft (yellow) displayed on the sagittal plane. The angle between the distal femoral flexion axis and mechanical axis was defined as the distal femoral flexion angle [195].*

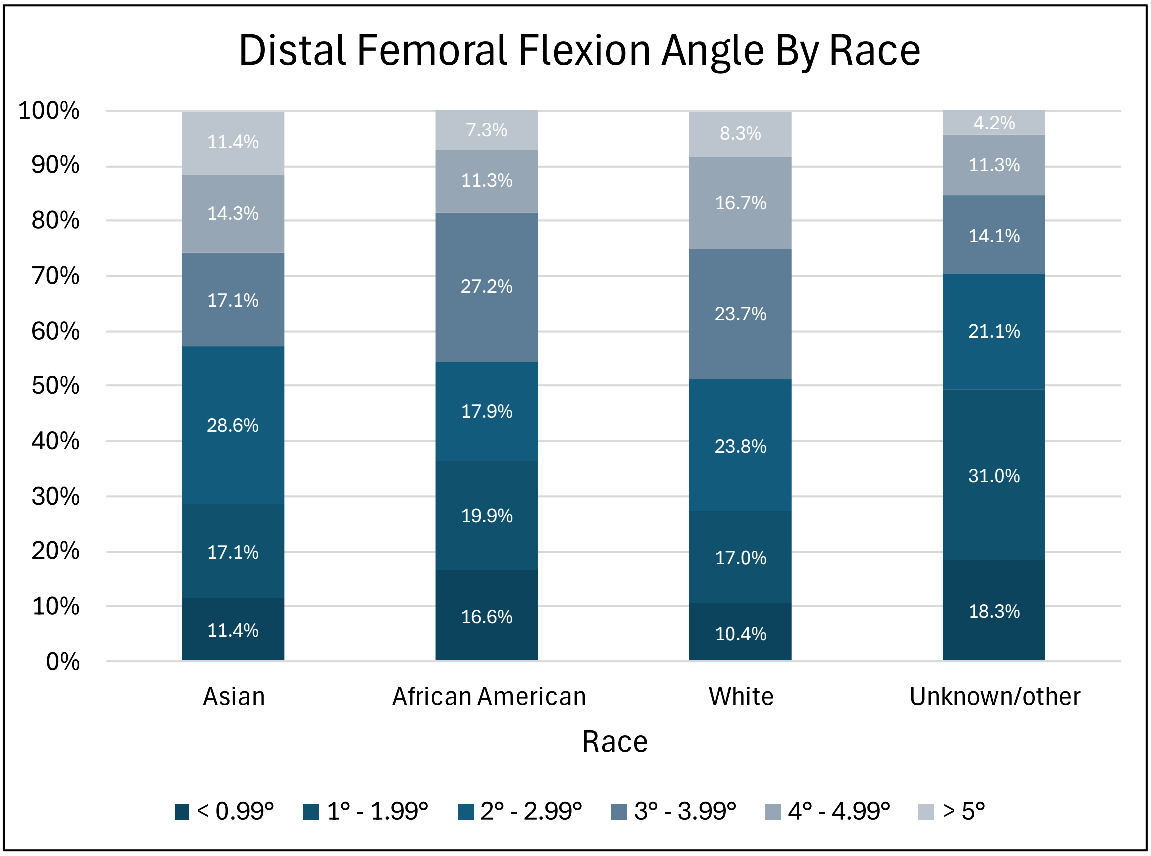

Figure 2.8. *Distal Femoral Flexion angle by race as observed by Hood et al. [195].*

Axial Alignment of the Knee

The primary references axes used to define femoral component rotation in TKA include the posterior condylar axis (PCA), surgical transepicondylar axis (TEA) [196] and Whiteside's Line (WSL) [197], [198]. In 2009, Victor performed a literature review on the rotational alignment of the distal femur containing 16 studies [199]. He concluded that the surgical TEA was on average 3° externally rotated from the PCA and that the WSL was perpendicular to the TEA and so 93° externally rotated from the PCA. Victor also noted that the studies reviewed generally reported large ranges and high standard deviations, thus indicating high inter-patient variability. This has been further highlighted by large scale studies in recent years [200], [201].

Saffarini et al. performed a systematic review to investigate a range of tibial rotation reference axes in TKA [202]. The authors only considered studies which reported the angle between the reference tibial axis and the surgical TEA. After a final consideration of 22 studies, the authors found that the angles between most tibial axial axes and the TEA had a large range and variability, with only 6 studies reporting a standard deviation of below 5°. Furthermore, the tibial tubercle is often used to determine the tibial axial reference axis and has exhibited large variability between patients [203].

Inter-patient variability for the knee anatomy is evident and can also be influenced by a range of factors including gender [183], [184], [187], [204] and ethnicity[205]. In addition to those outlined above, a range of additional anatomical variations may impact the biomechanics of the knee joint, including but not limited to the morphology of the trochlear groove [206], [207], [208], tibial torsion [209], [210] and femoral anteversion [211]. As highlighted above, the alignment of the knee can vary between patients in the coronal, sagittal and axial axes. As a result, it is important to consider patient specific solutions for patient specific anatomies during TKA. This should influence TKA alignment strategies which is discussed later, in Section 2.5.2 Alignment Strategies.

2.4.2 Knee Alignment Classification Systems

Knee classification systems can provide insight into native and post-TKA knee alignment. By accounting for patient-specific anatomy, such tools can guide alignment strategies, providing a more personalised approach to TKA planning. However, these systems primarily focus on the coronal plane, often overlooking 3D knee morphology and soft tissue, which can also display high inter-patient variability.

Neutral, Varus, and Valgus

The conventional classifications of neutral, varus or valgus has long been the foundation for understanding the coronal alignment of both native, arthritic and post-TKA knees. These categories are determined based on the calculation of the coronal HKA angle, generally measured on a coronal plane radiograph or 3D imaging modality such as CT or MRI. The HKA angle is defined by the angle formed between the mechanical axis of the femur and the mechanical axis of the tibia. While the window for neutral can vary, it typically refers to a range of 0° ± 3°.

While this system has been widely used in both clinical practice and research, it oversimplifies knee alignment since it does not consider joint line obliquity or convergence angle and is influenced by the position in which the coronal alignment assessment is performed [80], [212]. For example, HKA assessment of an osteoarthritic knee in a weightbearing position (e.g. AP radiograph) will generally result in a greater HKA deformity than when measured in a supine position (e.g. CT scan) due to differences in tibiofemoral loading [213]. Additionally, HKA measurements may be influenced by the disease progression of osteoarthritis. This has led to a growing recognition of the need for more sophisticated classification systems.

Five types of lower extremities by Lin et al.

Lin et al. proposed a new classification system for lower limb alignment by assessing the mechanical alignment of the femur and tibia to address limitations in the traditional varus-neutral-valgus approach [185]. Using radiographs from 214 healthy individuals, they defined five alignment categories based on the HKA angle, lateral distal femoral angle (LDFA), and medial proximal tibial angle (MPTA). Although more alignments than the five common categories identified in their study are theoretically possible, these were not clearly defined [214]. Furthermore, the classification did not consider joint line obliquity and requires validation to observe its distribution across an osteoarthritic population undergoing TKA.

Functional Knee Phenotypes

In 2019, Hirschmann et al. introduced the concept of the functional knee phenotypes, which considered five phenotypes each for the HKA, LDFA and MPTA. This provided a total of 125 theoretical coronal knee phenotypes, of which they observed 43 in a healthy population [214]. However, due to more extreme HKA, femoral and tibial angles observed in osteoarthritic knees, more phenotypes for each component have been suggested, further increasing the number of theoretical functional knee phenotypes [215]. While it may provide some insight and support coronal alignment research, the vast number of phenotypes result in a complex system. Furthermore, it is limited by the fact that HKA assessment may be affected by assessment position and osteoarthritis related deformity [215].

Coronal Plane Alignment of the Knee (CPAK)

MacDessi et al.'s coronal plane alignment of the knee (CPAK) classification system seeks to overcome the limitations of the earlier knee phenotyping solutions by incorporating the constitutional coronal alignment, which remains constant despite joint space narrowing [10]. The classification system categorises knee alignment based on two key parameters, the arithmetic HKA (aHKA) and joint line obliquity (JLO). The aHKA is calculated as the difference between the MPTA and LDFA (i.e. aHKA = MPTA – LDFA) and categorises the coronal limb alignment into three categories: varus (aHKA < -2°), neutral (-2° ≤ aHKA ≤ +2°), and valgus (aHKA > +2°). JLO is defined as the sum of the MPTA and LDFA (i.e. JLO = MPTA + LDFA) and describes the orientation of the joint line as either apex distal (JLO < 177°), neutral (177° ≤ JLO ≤ 183°), or apex proximal (JLO > 183°). Together, these parameters define nine distinct phenotypes to describe coronal alignment (**Figure 2.9**).

MacDessi et al. reported similar distributions of CPAK phenotypes in healthy and osteoarthritic populations, supporting its utility in representing constitutional alignment [10]. The system assumes that reproducing a patient's CPAK phenotype during TKA should restore their native alignment, and therefore may guide selection of alignment strategy [10]. However, a recent study by Orce Rodriguez et al. assessed the impact of recreating native CPAK phenotypes on a range of PROMs (OKS, KOOS, FJS, University of California, Los Angeles Activity Scale (UCLA) and visual analogue scale (VAS)) in bilateral TKA with SAIPH implants [216]. Among 140 knees, postoperative CPAK phenotype recreation was achieved in only 27.9% of cases, but no significant differences in PROMs were observed between joints where the phenotype was recreated and those where it was not. These findings suggest that recreating native coronal alignment phenotypes may not significantly influence patient satisfaction or functional outcomes, highlighting the multifactorial nature of post-TKA recovery

Despite this, many studies have investigated variations in CPAK phenotype distributions between gender and patient ethnicity [217], [218], [219], [220], [221] and, the tool has also been used to guide balanced coronal joint gaps during TKA [10], [222]. However, as with the other knee alignment classification systems discussed, CPAK focuses on the coronal plane. This is partially due to the tool being designed using two-dimensional radiographic assessments [10]. For CPAK to effectively support the selection of patient-specific alignment strategies in TKA planning, further research is required to understand the relationship between CPAK and 3D knee morphology as well as joint gaps.

In summary, the knee alignment classification systems have progressed from a simple varus-valgus model to more personalised, multi-parameter solutions. Despite this evolution, common limitations persist. These classification tools are predominantly confined to the 2D coronal plane, overlooking 3D knee morphology and soft tissues. Furthermore, many were developed using young and/or healthy patient cohorts but are clinically applied to older, osteoarthritic knees, where cartilage can confound the assessment of constitutional alignment. The clinical impact of this is highlighted by a systematic review from Giurazza et al., which reported that CPAK phenotype distributions vary significantly with disease status [223]. This underscores the need for further validation to confirm the clinical generalisability of any classification system across diverse patient populations.

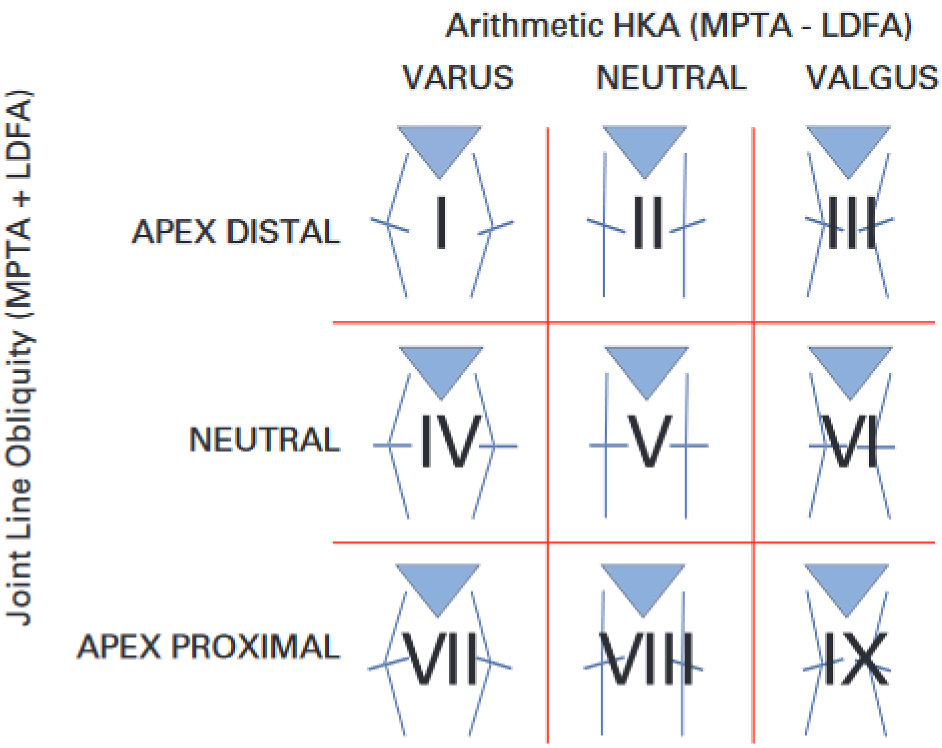

Figure 2.9. *The nine phenotypes as per the coronal pane alignment of the knee (CPAK) classification system [10].*

2.5. Coronal Knee Laxity and Balance in TKA

In the context of TKA, coronal knee laxity refers to the concept of joint looseness or instability in the coronal plane, encompassing how much the medial or lateral compartments can open under stress. Laxity is typically assessed with the application of varus/valgus stress or an axial distraction force and measured as a resultant angle or angular deviation. Coronal joint gaps refer to the linear distance between the femoral condyles and tibia in the coronal plane, measured in millimetres. Coronal joint gaps can be measured with or without the application of varus/valgus stress or an axial distraction force. In all cases, but especially when measured with a stressed or distracted joint, joint gap measurements provide an indication of joint laxity. Large joint gaps or laxity angles may suggest that a compartment or the overall joint is loose with potential instability, while small joint gaps or laxity angles may suggest potential tightness. Because these concepts are closely intertwined, the literature often uses "joint gaps" and "laxity" interchangeably; however, for consistency in this literature review, the specific terminology from each discussed study has been preserved.

2.5.1. Importance of Mediolateral Joint Balance and Ligament Laxities in TKA

Knee joint balance has been established as a key goal of TKA [224] and balancing the knee was even an integral part of the surgical techniques of TKA pioneers John Insall and Michael Freeman in the 1970's [225], [226]. Further, soft tissue imbalance within the knee may result in greater polyethylene wear, component failure [227] and potential ligament damage or pain [228]. Therefore, it is important to consider the state of functional stability, in which the joint is stable without being over-tensioned.

Despite the importance of achieving tibiofemoral balance during TKA, there has been increasing discussion about what constitutes appropriate balance. Orthopaedic surgeons have traditionally aimed for equal medial and lateral compartment joint gaps both in extension and flexion [229]. Separately, many clinicians also sought to match the overall extension and flexion gaps intraoperatively [229], [230]. This was largely driven by the dominance of the mechanical alignment (MA) approach and the goal to balance loading across the medial and lateral compartments of the prosthesis throughout the ROM [227]. With a gradual shift away from mechanical alignment as a default alignment for all patients, this target has been increasingly questioned in literature [231], [232], [233], [234].

2.5.2. Coronal Laxity of the Healthy Knee

Mediolateral knee joint laxities are generally determined with the application of varus or valgus stress on the joint. Okazaki et al. performed an in-vivo study assessing the ligament laxities of 50 healthy knees in extension and flexion [235]. The authors applied 15 kg of varus and valgus stresses on the joint using a Telos device (Weiterstadt, Germany) and obtained radiographs of the joints in the stressed positions. In extension, they observed a mean varus angle of 4.9° in varus stress and -2.4° in valgus stress, whereas in flexion they found mean varus angles of 4.8° in varus stress and -1.7° in valgus stress. The core finding of the study was that lateral laxity was prevalent within the healthy knee and the authors hypothesised that this may be necessary to allow the medial pivot mechanisms of the healthy knee. Despite some variation in methodologies and population demographics, similar findings have been published in numerous studies, highlighting the prevalence of lateral knee laxity in the healthy population in extension [184], [236] and flexion [237]. These studies assessed laxity in awake individuals, where subconscious muscle contractions may have influenced measurements, potentially underestimating passive laxity.

Knee laxity is also influenced by gender with females displaying greater knee laxity than males [184], [237], [238], [239], [240]. Shultz et al. have highlighted that this also varied based on the female menstrual cycle [238]. However, since OA primarily effects the elderly population, most female OA patients would have undergone menopause and so this is less of a factor for TKA recipients.

Nowakowski et al. applied a distraction force to assess the extension and flexion gaps of male cadaveric knee joints with no history of surgery or deformity [230]. The distraction force ensured the ligaments were tense. Regardless of the load applied, the authors noted that the mean extension gaps were smaller than the mean flexion gaps in the medial and lateral compartments, respectively. Further, the lateral joint gaps were on average larger than the medial gaps in extension and flexion, respectively. The authors also examined the impact of ACL and PCL resection on these joint gaps. Resection of the ACL predominantly increased both extension gaps with just minor impacts to the flexion gaps. Resection of the PCL had an opposite effect, primarily increasing the flexion gaps with a small impact on the extension gaps. Although this study was performed on physiologic cadaver knees, it is hypothesised that these results would translate to osteoarthritic knees intraoperatively.

2.5.3. Coronal Laxity of the Osteoarthritic Knee

The progression of OA often leads to the degeneration of the meniscus and articular cartilage of the tibiofemoral joint and formation of osteophytes. As the severity of the OA increases, so does the degree of degeneration. As a result, the tibiofemoral joint gap of the affected compartment narrows, ultimately increasing the joint laxity and instability [241], [242], [243]. However, the results published by Sharma et al. suggest that some of this increased joint laxity may predate the OA and may instead be due to changes in the joint and surrounding ligaments with age [244].

The study by Fishkin et al. compared the stiffness of the knees of OA patients undergoing TKA to OA cadavers and non-OA cadavers [245]. The authors noted that the OA joints of the patients and cadavers were stiffer than the non-osteoarthritic cadaveric knees, suggesting that MCL stiffness and contracture may occur with varus OA deformities. This aligned with additional literature before and around the time [246], [247]. However, in 2013 Okamoto et al. assessed the medial and lateral extension joint gaps for a series of OA knees with varying degrees of varus deformities [248]. The authors did not observe any contraction of the medial laxity with greater varus deformation of the joint. Instead, they noted statistically significant increases in the lateral joint gap between knees with a severe varus deformity (>20°) relative to mild (<10°) or moderate (10° to 20°) varus deformities, indicating that the lateral ligament laxity increases with an increasing varus deformity. Results from Sekiya et al. suggest that this lateral laxity in varus knees may diminish within 3 months after a TKA, and so should be considered when targeting specific joint gap laxities intraoperatively [249]. Due to a vast majority of OA knees comprising of varus deformities, there is limited research on the behaviour of joint laxity in valgus joints.

2.5.4. Evaluating Coronal Joint laxity in TKA

Intraoperative assessment of laxity and balance

Historically, achieving balance in TKA has largely depended on the surgeon's subjective tactile assessment, or based on 'feel'. While there is no consensus on technique, this approach generally involves the manual application of varus and valgus forces on the knee joint and is performed either at specific angles such as full extension or 90° flexion, or throughout the ROM. Due to the lack of standardised technique, application of a manually applied force and inherent subjectivity due to a tactile assessment, such an assessment of balance is highly variable.

Heesterbeek et al. reported that a surgeon's perception of balance may be influenced by numerous patient-related factors including patient body mass index (BMI), gender and degree of joint contracture [250]. Additionally, a recent multi-centre prospective study by MacDessi et al. observed that surgeon defined assessment of balance is highly variable between surgeons [251]. The authors also compared the surgeon defined assessment of balance to what was measured using the VERASENSE sensor (Stryker, USA) and observed that the extent of surgical experience (in this case a comparison of high-volume surgeon with a trainee) had no effect on the ability to accurately determine balance. While this technique allows for intraoperative assessment of native laxity, the approach is subjective, highly variable and may not be accurate.

Technological advancements have produced assistive tools to reduce the subjectivity of laxity and balance assessment during TKA. Spacer blocks are commonly used during TKA to provide an estimation of the initial tibiofemoral extension and flexion gaps following bone resection. They simulate the thickness of the final implant and so provide insight into the expected joint gaps after implantation, guiding any further balancing that may be required before implantation [252].

Ligament tensioning devices apply a controlled, measurable distraction force to the joint in attempt to simulate soft tissue tension during weight-bearing. As a result, it provides more objective and consistent comparison of intercompartmental and extension-flexion soft-tissue laxity. However, there is no consensus regarding the optimal tension force during the use of these tools [228]. As with spacer blocks, conventional tensioning devices are limited to soft-tissue assessment at full extension 0° and 90° flexion [253].

Pressure sensors, such as VERASENSE, enable surgeons to obtain quantitative intraoperative data on tibiofemoral balance across the ROM. By measuring and reporting medial and lateral compartmental forces and mediolateral intercompartmental load differences, these devices provide real-time feedback to guide decisions on component selection, alignment, and soft tissue release [254]. An early study by Gustke et al. reported that achieving a mediolateral force difference ≤ 15 lbs using VERASENSE was associated with superior clinical outcomes 6-months after the TKA, including better KSS Pain and Function scores and WOMAC scores [255]. However, numerous, more recent studies report comparable PROMs between patients with balanced and unbalanced TKAs as measured by VERASENSE [256], [257] and that results are comparable to those obtained with manual balancing techniques [258]. Despite this, these studies claim that such tools can improve intraoperative balance and reduce potential complications such as manipulation under anaesthesia [254], [257], [258], [259]. Further research is required to establish whether senor-defined balance thresholds result to meaningful improvements in long-term clinical outcomes.

A key limitation of spacer blocks, tensioning devices and pressure sensors is that they all require the tibial cut before use. As a result, they do not assess preoperative laxity but instead are used to estimate post-implantation laxity during the use of trial prosthesis, guiding any final intraoperative adjustments required to achieve a predetermined balance target.

The use of computer navigation or robotics systems during TKA can also increase the objectivity of surgeon laxity assessment. While this still requires manually applied varus and valgus forces by the surgeon as they manipulate the joint through the ROM, these devices can record the resultant coronal angles, providing a laxity range, or window. This can be used prior to any bony resections to estimate the patient's preoperative, arthritic laxity. In such cases, it is sometimes used to provide insight into the whether the knee is 'correctable' with TKA (i.e. correctability of the knee in TKA refers to whether the prosthesis can be coronally aligned within fixed boundary (usually 3°) of the mechanical axis, without the need for soft-tissue release) [260]. The use of navigation or robotics also enable post-implantation assessment to verify the achieved joint laxity, and whether the joint is coronally balanced. Although the soft-tissue assessments from navigation and robotics can often be performed prior to any bone cuts, they necessitate some soft-tissue incision for joint exposure. Additionally, the accessibility to these technologies varies globally with 57% of TKAs in Australia being performed with the use of navigation or robotics [83] compared to just 7, 4, and 1% in the United States, United Kingdom, and Sweden, respectively [261]. The costs associated with navigation and robotics systems may hinder their global uptake. Since most systems continue to rely on surgeons to manually stress the joint, the resultant laxity assessments remain subjective and variable.

All the common intraoperative laxity and balance assessment solutions discussed above either require bone resections, soft-tissue incision or manual load application and so may not reflect an accurate measure of joint laxity of the knee either pre- or post-implantation.

Non-invasive laxity assessment in TKA

While intraoperative tools provide real-time assessment of joint balance, non-invasive solutions such as those involving the use of arthrometers and/or radiographs can provide a more consistent technique for preoperative and postoperative assessment of coronal laxity.

The Telos stress device (Wölfersheim, Germany) is one of the most commonly reported arthrometers in the literature for assessing coronal knee alignment in TKA patients. It provides a controlled mechanism to apply varus or valgus stress to the knee, with applied loads typically ranging between 75 and 150 N, depending on the specific protocol [262]. The device is frequently used in radiology protocols to capture the alignment of the joint under stress, offering a static assessment of coronal joint gaps and laxity. By applying stress at multiple flexion angles, the Telos arthrometer allows for a more comprehensive understanding of joint behaviour. This method displays high intra-rater and inter-rater reliability for preoperative assessment of osteoarthritic knees [263] as well as post-TKA evaluations of coronal laxity [264]. In a retrospective analysis, Lee et al. reported that preoperative ligamentous laxity, as determined using a Telos stress radiology protocol, was predictive of the extent of soft-tissue release required to achieve a mechanical alignment during TKA [265]. Building on this, Tsukeoka et al. used a Telos protocol to evaluate coronal knee laxity both preoperatively and postoperatively in awake and anaesthetised patients. They observed that anaesthetised patients exhibited higher mean varus and valgus stress angles, suggesting that the absence of muscular contribution in these patients led to greater measured ligamentous laxity compared to awake patients [266]. Together, these studies underscore the importance of non-invasive laxity assessment techniques, such as the Telos arthrometer, for standardised evaluations of coronal laxity. Conducting these assessments with patients awake may better reflect their functional or comfortable laxity thresholds, providing valuable insights for surgical planning and postoperative evaluation. Despite its value in joint laxity research, there is limited literature to suggest the use of such an arthrometer in practice, resulting in a gap between research and clinical practice [260].

2.5.5 Impact of Laxity and Balance on Postoperative TKA Outcomes

Research into the relationship between coronal joint gaps, laxity, and postoperative outcomes in TKA is expanding. Sappey-Marinier et al. observed that preoperative varus and valgus laxities, as well as varus-valgus laxity differences measured using the Telos device, did not significantly correlate with 2-year postoperative FJS, OKS and KOOS [267]. While these findings suggest that preoperative laxity alone may not be predictive of long-term patient satisfaction or functional improvement, there is limited literature evaluating the relationship between preoperative coronal laxity and postoperative outcomes in TKA.

Intraoperatively, the relationship between joint laxity and outcomes becomes more defined. McEwen et al. postoperatively assessed 192 TKA with kinematically aligned TKAs with a mean follow-up of 3.5 years [268]. Through their investigations, the authors observed mean postoperative medial and lateral extension joint gap laxities of 0.7mm and 0.8mm, respectively and mean medial and lateral flexion joint gap laxities of 2.2mm and 4.5mm, respectively. Their results also highlighted that a lateral flexion gap laxity of greater than 2mm was statistically significantly associated with superior postoperative OKS and KOOS Pain, ADL, Sports and QoL sub scores, although not all of these were above the minimally clinically important difference (MCID). While this suggest that some residual lateral gap laxity may enhance patient outcomes, excessive lateral gap laxity should be avoided. Inokuchi et al. reported that excessive intraoperative lateral laxity (>4°) in extension is associated with significantly inferior functional improvement after TKA, including lower KSS functional scores and worse performance on timed-up-and-go tests at one-year postoperatively [269]. Similarly, Okamoto et al. reported that excessive lateral laxity in flexion of > 5 mm resulted in inferior KSS symptoms score one-year postoperatively [270]. Literature also notes that post-implantation medial laxity or tightness can also result in significantly inferior 1- and 2-year postoperative KOOS Pain [232], [233], [271], and 1-year postoperative KOOS ADL outcomes [271].

Despite these findings, clear intraoperative laxity targets remain undefined. In 2022, Wakelin et al. proposed mediolateral joint balance targets for extension, mid-flexion, and flexion based on a prospective analysis of 135 knees, showing that achieving these targets resulted in superior KOOS Pain outcomes by 8.3, 5.6, and 2.8 points, respectively ($p < 0.05$ for all) [232]. They also reported a compounding benefit, with achieving any two targets improving outcomes by 8-10 points and achieving all three enhancing outcomes by 11.2 points. However, subsequent study, found that only the flexion target remained significantly associated with improved two-year postoperative KOOS Pain outcomes, while the extension and mid-flexion targets did not [233]. These findings underscore the need for further research to refine intraoperative laxity targets for enhanced long-term TKA outcomes.

Postoperatively, the relationship between residual laxity and patient outcomes remains complex and multifaceted. Hamilton et al. assessed postoperative knee laxity in asymptomatic patients using manual medial/lateral stress testing, with a mean follow-up of 46.2 months. They found no significant association between postoperative laxity and either OKS scores or functional clinical outcomes [272]. However, Mizu-uchi et al. reported that greater postoperative valgus laxity was linked to improved satisfaction and symptom scores, potentially due to its alignment with natural knee kinematics [273]. In contrast, Tsukiyama et al. observed minimal impact of postoperative medial extension or lateral flexion gaps on patient outcomes but highlighted that medial flexion laxity was associated with significantly worse PROMs [274]. Interestingly, they also identified a moderate correlation between lateral extension laxity and improved satisfaction, symptom relief, and functional outcomes. These findings underscore the variability in how different types of laxity influence outcomes and suggest that patient-specific factors, such as kinematics and preoperative alignment, play a critical role in modulating these effects.

While research has highlighted the importance of joint gaps and laxity in influencing postoperative outcomes, the relationships remain variable and complex. This variability likely reflects the patient-specific nature of knee anatomy and biomechanics, underscoring the need for personalised approaches to gap assessment and surgical planning in TKA.

2.6. Alignment Strategies in TKA

Prior to commencing a TKA, a clinician must decide as to which alignment philosophy they want to implement. Some may choose to employ a single alignment philosophy for most or all their patients whereas others may strategically vary the alignment technique based on a specific patient's anatomy.

2.6.1. Mechanical Alignment and Variations

Mechanical Alignment

The mechanical alignment (MA) has remained the dominant component alignment technique in TKA for decades. The technique involves aligning the femoral component to the femur mechanical axis, which is the line that extends from the centre of the femoral head to the intercondylar notch of the distal femur. Likewise, the tibial prosthesis is aligned neutral to the tibial mechanical axis, which results from the line between the centre of the proximal tibial plateau and the ankle centre [275] (**Figure 2.10A**). It was historically believed that aligning the implants neutral to the mechanical axes, would result in a more even tibial load distribution through the prosthesis [9] and a range of literature has outlined the strong survivorship of MA TKAs [9], [276], [277], [278], [279]. As a result, many surgeons have adopted and retained the MA alignment philosophy as a systemic approach for TKA component positioning. It should be noted that aligning the prostheses coronally neutral may result in inter-compartmental gap imbalances, thus requiring ligament releases to achieve joint balance [10].

Adjusted Mechanical Alignment

The adjusted mechanical alignment (aMA) approach was developed to overcome some of the limitations of the strict MA approach. The femoral component is aligned up to a maximum of 3° varus or valgus from the mechanical axis, preserving any moderate coronal deformities and preventing the over-correction of larger coronal deformities, which may otherwise occur when using the traditional MA technique. The tibial component generally maintains a mechanically neutral coronal alignment for even tibial load distribution [280], [281]. Although there are some results indicating strong functional outcomes when employing an aMA approach [282], further research is required.

2.6.2. Anatomic Alignment

The anatomic alignment (AA) approach was established by Hungerford and Krackow in the 1980's and like MA, it is considered a systematic approach [283]. The AA technique aims to restore the anatomic alignment of the joint by aligning to femoral and tibial components to the femoral and tibial anatomic axes. Although there are multiple methods through which the anatomic axis of the femur can be measured, one common technique is to form a line that extends through the centre of the femoral shaft down to the centre of the knee [284], for which the intercondylar notch of the distal femur may be used as a proxy (**Figure 2.10A**). The femoral anatomic axis is on average 5-7° valgus relative to the femoral mechanical axis.

Such component position of the AA approach arguably promotes an even tibial load distribution [285] whilst allowing for enhanced patello-femoral biomechanics [286]. Despite published mid-to-long term clinical outcomes that were comparable to MA results[287], there has been limited uptake of this alignment philosophy [81].

2.6.3. Kinematic Alignment and Variations

Kinematic Alignment

The kinematic alignment (KA) technique is a patient-specific alignment philosophy which aims to restore the native and pre-arthritic anatomy of the joint [11]. The KA approach utilises landmarks to align the femoral and tibial components to the coronal, sagittal and axial kinematic axes [11]. Additionally, the strategy aims to restore the native pre-arthritic anatomy by replacing any resected bone and cartilage with implanted material, whilst also accounting for cartilage and/or bone wear due to arthritis [288], [289]. The traditional KA approach is ligament sparing [290], with a vast majority of joint gap balancing occurring using tibial recuts. Howell et al. developed a decision tree to guide clinicians on how to correct common imbalances during KA TKAs via tibial recuts [11]. A tabulated version of this is presented in **Table 2.4.**

Numerous studies have investigated the resulting coronal alignment when employing a KA approach as well as postoperative patient outcome. Dosset et al. observed that there was no significant difference between the postoperative coronal alignment between the KA TKA and MA TKA populations. Further, the authors noted that patients with a KA TKA procedure displayed faster postoperative recovery with significantly superior patient outcome and ROM at the 6-month follow up [291]. This is consistent with much of the existing literature, which also highlight the superior functional outcomes of the KA whilst displaying similar or better patient reported outcomes than MA [289], [292]. These superiors functional and patient outcomes have contributed to an increased uptake in KA TKAs as surgeons aim to better restore the native anatomy of the patient.

Nonetheless, the KA alignment has some inherent challenges. Firstly, performing tibial recuts can be challenging and time-consuming and literature suggests that many surgeons may be opting for soft tissue release unless extensive balancing is required [10], [293], [294]. Further, it can be difficult to infer the pre-arthritic anatomy of the knee [295]. Although some studies highlight that the femoral anatomy may be predictable, such evidence does not exist for the tibia [296]. Surgeons may also be cautious in recreating more ‘extreme’ coronal alignments as these have the potential to be biomechanically inferior and may result in prosthetic complications if recreated.

Restricted Kinematic Alignment

The restricted kinematic alignment (rKA) technique was developed to combat limitations associated with recreating joints which have substantial coronal limb deformities [295], [297]. This approach follows the principles of the KA technique but adjusts the tibial and femoral resections to apply limits to the lateral distal femoral angle, medial proximal tibial angles achieved as well as the resulting tibiofemoral coronal angle [295]. Almaawi et al. performed a large-scale study and observed that for 51% preoperative knees, the rKA approach did not require any correction, thus providing identical alignments to the KA technique. Minimal corrections were required for 32% of patients and more significant corrections necessary for the remaining 17% of joints[295].

Inverse Kinematic Alignment

The inverse kinematic alignment (iKA) philosophy has been introduced in recent years [298] and has gained popularity with the use of robotic systems in TKA [299]. The alignment philosophy is quite similar to the traditional KA approach with one key difference. The KA approach involves performing the femoral cut to align the femoral component to the kinematic axes first and then orienting the tibial resection to achieve joint balance. As the name suggests, the iKA technique involves the inverse; The tibial cut is aligned to the kinematic axes and then the orientations of the femoral cuts are adjusted to ensure joint balance. Coronal angle restriction may also be put in place bounding the MPTA to 84-92°, LDFA to 84-93° and the overall coronal angle to lie between 6° varus and 3° valgus [298].There is limited literature on the outcome of iKA since it is still a relatively new alignment strategy. Nonetheless, Winnock de Grave et al. have published a study which suggest that iKA may result in superior short-term patient satisfaction relative to aMA [298].

2.6.4. Functional Alignment

Functional Alignment (FA) is a relatively new alignment strategy in TKA that aims to restore a patient's native pre-arthritic knee kinematics by tailoring bone resections and implant positioning to their specific anatomy [300]. During FA, a foundational preoperative plan (typically MA or KA) is used, which is then refined intraoperatively using robotic or computer-assisted systems [301], [302]. These technologies combine techniques such as measured resection, gap balancing, predictive modelling to virtually position the prostheses and minimise the need for soft tissue releases [12]. FA leverages 3D bony anatomy along with predicted (pre-resection) and verified (post-resection) intraoperative soft-tissue laxity measurements to 'fine-tune' the 3D alignment of the implants, achieving balanced joint alignment mediolaterally and in extension and flexion.

Currently, there are limited studies comparing patient outcomes with FA to other alignment strategies. Hazratwala et al. report promising short-term outcomes with FA [303], and Choi et al. observed superior two-year postoperative outcomes with FA compared to MA [304]. However, Parratte et al. found similar clinical outcomes between FA and MA, suggesting the need for larger-scale studies to fully evaluate patient outcomes [305]. Despite these mixed results, FA has demonstrated advantages in several areas, including better gap balancing than MA and KA [306], [307], [308], less bone resection and a reduced need for recuts compared to KA [303], [307], [308], [309], and faster postoperative recovery than MA [305].

As an emerging alignment philosophy, FA is still under development. While some preliminary guidelines on boundary alignment parameters exist, further research is essential to refine these parameters and establish evidence-based protocols for its widespread adoption [310], [311].

Despite extensive research on various alignment strategies in TKA, there is no clear consensus on which approach yields superior patient outcomes. While this highlights the need for further investigation into patient outcomes across alignment strategies, it also suggests the need for individualised approach to TKA planning and execution [312], [313].

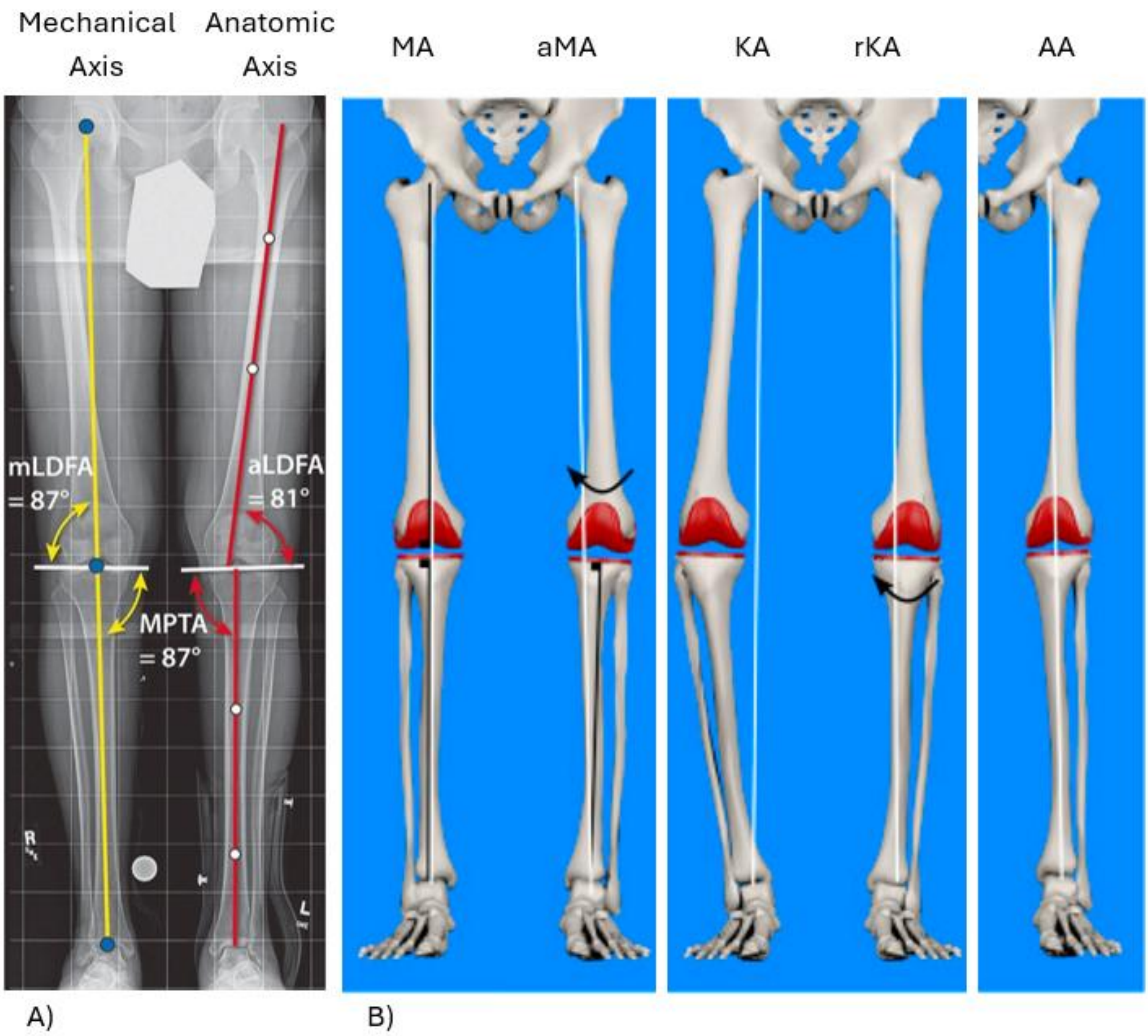

Figure 2.10. *A) Representation of the femoral and tibial mechanical axes (yellow) and anatomic axes (red) [279]. B) Key TKA component alignment techniques including Mechanical Alignment (MA), adjusted MA (aMA), Kinematic Alignment (KA), restricted KA (rKA) and Anatomic Alignment (AA). Adapted from [81].*

Table 2.4. *Tabulated version of the decision tree produced by Howell et al. [11] showing how to manoeuvre residual coronal imbalances during a kinematically aligned total knee arthroplasty (TKA).*

Coronal imbalance	Balancing action for a kinematically aligned TKA
Tight in extension and flexion	Remove more tibia.
Tight in extension, stable in flexion	Remove posterior osteophytes. Strip posterior capsule. Decrease posterior tibial slope.
Tight in flexion, stable in extension	Increase posterior tibial slope until tibial offset from femur is restored to normal at 90° flexion.
If in extension, tight medial and loose lateral	Remove medial osteophytes. Recut tibia in 2° more varus. Use a thicker liner.
If in extension, tight lateral and loose medial	Remove lateral osteophytes. Recut tibia in 2° more valgus. Use a thicker liner.
Fixed valgus	Release arcuate complex and popliteus tendon. Recut tibia in 2° more varus.

2.7. Preoperative Planning and Intraoperative Execution

2.7.1. Preoperative Planning Tools and Protocols

Surgical planning is an important aspect of a TKA for most orthopaedic surgeons. Although inter-operative delivery tools such as navigation and robotics systems have enabled a degree of inter-operative templating, preoperative planning remains more common. Preoperative surgical planning for TKA can be performed in two or three dimensions. Weightbearing antero-posterior radiographs of the knee or lower limb are typically used for 2D templating whereas 3D planning requires 3D imaging modalities such as CT or MRI scans.

Both 2D and 3D planning provide valuable insights into component sizing and alignment prior to TKA, with consideration to a given surgeon's preferred surgical technique and alignment philosophy [314]. Although 2D templating achieves high accuracy in implant size approximation, 3D planning offers superior precision in predicting the exact component size [315], [316]. This is due to the higher anatomical fidelity provided by 3D imaging, which can also influence alignment decisions. Additionally, 3D planning achieves high intra-observer and inter-observer reliability for component alignment [316]. Despite these advantages, 2D templating remains more widely accessible and is often regarded as sufficiently accurate for estimating component sizes [315].

Preoperative planning not only enhances accuracy and efficiency in component sizing and positioning but is also associated with reduced operative time, shorter length of stay and fewer complications after TKA [317]. Moreover, it enables surgeons to identify potential concerns such as anatomical deformities, in advance, thereby simplifying the surgical procedure and reducing the risk of intraoperative complications [13], [14]. However, literature on preoperative planning with consideration of soft tissue laxity is scarce, limiting its role in guiding soft tissue management or balancing joint gaps during surgery.

2.7.2. Intraoperative Delivery Tools

Historically, surgeons utilised manual instruments intraoperatively to aid them with achieving their target alignment. Additional surgical delivery solutions have become available with technological advancements. These execution tools include patient specific guides, computer navigation and robotics.

Conventional Instruments

Despite the availabilities of newer TKA execution technologies, conventional instruments remains a commonly utilised delivery technology in Australia [83] and abroad [84], [318]. The use of conventional instruments for TKA involve the use of intra- or extra-medullary rods, which align the distal femoral and proximal tibial cuts. To perform the femoral cuts, an extra-medullary rod is first inserted into the distal femur and a coronal angle is chosen at which the distal femoral resection is performed. An antero-posterior sizer is then utilised to determine the femoral component size and the axial rotation relative to the posterior condyles. Finally, a 4-in-1 cutting block is set on the resected distal femur and is used to perform the anterior, posterior, anterior chamfer and posterior chamfer cuts. An intra- or extra-medullary rod can be used to align the tibial cut, thus defining the coronal and sagittal alignment of the tibial component. Once this is performed, the axial rotation and translational position of the tibial component is determined using the trial tibial implants [319].

The order of tibial and femoral cuts may vary depending on the surgical technique employed. Additional conventional instruments such as spacer blocks may also be used to assess intraoperative joint balance and guide potential bone re-cuts or soft tissue release [320].

Patient Specific Instrumentation

Patient Specific Instrumentation (PSI) is an alternative to conventional instrumentation. PSIs require 3D imaging modalities such as CT or MRI to obtain the geometry of the patient. The technology also requires a preoperative surgical plan, which may also be prepared using the patient specific anatomical information from the imaging. The planned alignment and patient specific geometry are used to reverse engineer tibial, femoral and/or patellar PSIs. Intraoperatively, the PSIs can be utilised in one of two ways. First, the PSI can be fitted onto the bone and used to perform the resections to execute the ultimate plan. However, since most PSIs are 3D printed using materials such as plastic or nylon [321], some surgeons find that the cut slot may flex and reduce the accuracy of the resection(s). As a result, many use the PSI to affix reference pinholes through which a cutting block can be inserted.

PSIs were initially promising as a delivery tool but meta-analyses have shown the technology may not enhance accuracy in achieving alignment [322], [323], [324], [325]. Furthermore, many PSIs are CT-informed and do not consider soft tissue. As a result, if gaps are not balanced, surgeons may need to perform recuts or soft tissue releases. The need for recuts has been reported in up to 27% of TKAs performed with PSIs, though this may vary based on PSI design and imaging modality used [326]. Nonetheless, some publications have reported that the use of PSIs can reduce operating times and so it is still an actively available delivery tool [327], [328].

Computer Navigation

Computer navigation has become increasingly popular with almost one-fifth of the TKAs performed in Australia in 2023 being with the aid of computer navigation [83]. Two forms of navigation systems exist; image based and imageless.

Imageless computer navigation systems display a virtual model with landmarks that are obtained intraoperatively using a pointer and tracker with fixed reference points. In some cases, the virtual model displayed may be a morphed statistical shape model of a bone but is not the patient's actual anatomy. Image-based computer navigation is overall quite similar with the key difference being that the virtual model displayed is of the patient's bones and is generally obtained from a preoperative CT scan. These systems also enable surgeons and technicians to intraoperatively plan the alignment prior to making any cuts as well as verify the resections once they have been performed.

Meta-analyses have highlighted that the use of computer navigation can improve accuracy and the ability to reduce the malalignment in comparison to both conventional instruments and PSIs [322], [329]. Despite this, studies have not been able to prove superior patient outcome with the use of computer navigation [330], [331]. Widespread use of surgical navigation in TKA is limited by the associated costs as well as increased operating time [332], [333].

Robotics

Robotic delivery systems are built on top of image-based or imageless navigation systems and so provide some additional functionality to computer navigation. These systems can be classified as open or closed platform and either active, semi-active or passive systems. A closed platform system restricts use to the robot manufacturer's own implants, whereas an open-platform systems allow for a wider range prostheses [334]. While open platforms provide surgeons with greater freedom of choice in prostheses selection, closed platform systems allow for greater specificity, precision and functionality [335], [336]. Robotics systems provide greater surgical autonomy than navigation systems. Passive systems automatically position the cutting slot for the planned resection, which is then manually performed by the surgeon [334]. Semi-active systems also provide haptic feedback during resection to prevent soft tissue damage or additional resection [337]. Active systems perform the bone resection autonomously based on a pre-approved surgical plan, with minimal surgeon intervention during the resection itself [334]. The protection of soft tissue is perhaps why better patient pain outcomes have been observed in the early postoperative phase [338], [339]. Robotics systems have also proven to improve alignment accuracy relative to conventional instruments [340], [341] but are also known to increase costs as well as operating times which may increase the chance of complications such as infection [342]. Overall, the use of robotics has shown minimal impact on patient outcome and longer-term studies are required [343], [344].

As outlined in section 2.5.4, both computer navigation and robotics systems enable the assessment of joint laxity or medial and lateral joint gaps before and after bone resections. This facilitates intraoperative planning of component alignment and the verification of joint balance with trial components. If joint balance is unsatisfactory during trialling, surgeons can make bone recuts or perform soft tissue releases to achieve the desired alignment. Joint laxity and tibiofemoral gaps can also be reassessed after prosthesis implantation to confirm balance.

Utilisation Rates of Delivery and Execution Technologies

There has been an increase in utilisation of TKA delivery technologies. For instance, the rates of PSIs, computer navigation, robotics and non-technologically assisted TKAs in Australia in 2023 were 11.4%, 21.4%, 35.7% and 31.5%, respectively [83]. The rate of technologically assisted TKA delivery has increased dramatically in the last from under 25% in 2010 to 68.5% in 2023 [83]. However, it should be noted that the use of delivery technologies varies across different regions and was estimated to be much lower in USA (<7% in 2014), UK (<4% in 2018) and Sweden (<1% in 2017) [261], [318].

2.8. Summary

TKA is a widely used surgical intervention that provides significant relief to patients with severe arthritis, improving pain, function, and quality of life. However, despite being considered one of the most successful orthopaedic procedures, up to 20% of patients report dissatisfaction with their outcomes. This highlights the need for better understanding and refinement of surgical approaches to optimise patient satisfaction and functional outcomes.

Several alignment strategies are available for TKA, ranging from traditional mechanical alignment to more modern approaches such as kinematic and functional alignment. Recent trends have shifted toward strategies that aim to optimise joint balance while minimising the need for soft tissue release, with a broader focus on personalised alignments tailored to the patient's native anatomy and kinematics. However, when incorporating laxity assessments, these personalised alignments primarily rely on intraoperative evaluations rather than preoperative. However, further research is required into which of the two laxity assessments provide greater insight into postoperative PROMs, as optimising patient outcomes remains a key goal.

Alignment classification systems, such as the Coronal Plane Alignment of the Knee (CPAK), have gained traction as tools to guide decision-making in alignment strategy selection and soft tissue management. CPAK, in particular, has shown promise in research and clinical settings for informing alignment strategies and minimising soft tissue releases. While these systems provide valuable insights into coronal alignment, their ability to predict 3D knee morphology and soft tissue behaviour remains unclear.

Preoperative planning plays a vital role in achieving a balanced TKA in extension and flexion. If classification systems like CPAK can accurately predict 3D knee morphology and soft tissue characteristics, they could lay comprehensive foundations for holistic 3D preoperative planning. If not, there is a pressing need to develop alternative methods for preoperative TKA planning that account for soft tissue behaviour alongside bony anatomy, addressing the growing demand for personalised, patient-specific alignment strategies.

Chapter 3:

Variability of three-dimensional knee morphology cannot be effectively assessed using a coronal plane knee alignment classification in total knee arthroplasty patients

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3.1. Abstract

Purpose

Optimal reproduction of the native three-dimensional (3D) alignment in total knee arthroplasty (TKA) influences outcomes; however, much of the modern TKA alignment research, such as the coronal plane alignment of the knee (CPAK), focuses only on coronal alignment. Tibial, femoral and tibiofemoral measurements on the axial and sagittal planes were evaluated for their relationship to the arithmetic hip-knee-ankle angle (aHKA) and joint line obliquity (JLO). These 3D anatomical measurements are also evaluated across CPAK groups.

Methods

A retrospective analysis of the 360 Med Care computed tomography (CT) database was performed. Patient CT scans were segmented and landmarked. Linear regression analysis compared 12 axial and sagittal plane measurements (representing tibial, femoral and tibiofemoral rotation, tibial slope and femoral flexion) with both aHKA and JLO. Non-parametric tests assessed these anatomical measurements across the different CPAK groups, while Cohen's delta (*d*) determined the effect size.

Results

With a sample size of 7,450 osteoarthritic knees, significant but weak relationships ($r < 0.30$) were observed between all 12 anatomical measurements and both aHKA and JLO. Tibiofemoral rotations between Insall's axis and both the posterior condylar and the surgical transepicondylar axes demonstrated large effect sizes ($d > 0.80$). However, trivial to small effect sizes ($d < 0.50$) were broadly observed across the 12 axial and sagittal measurements, underscoring their limited clinical significance.

Conclusions

While useful for describing coronal knee anatomy, CPAK phenotypes fail to differentiate tibial, femoral and tibiofemoral rotation, tibial slope or femoral flexion – crucial aspects of 3D surgical planning. Therefore, more comprehensive knee phenotyping solutions are required to guide individualised TKA alignment strategies.

Level of Evidence: Level II

3.2. Introduction

Knee phenotyping classification systems guide alignment strategy by considering patient-specific anatomy, but they predominantly focus on the coronal plane. Conventional classifications of neutral, varus or valgus, oversimplify knee alignment by not considering joint line obliquity and are influenced by the assessment position (e.g. weightbearing or supine) [80], [212]. Moreover, measurements may be influenced by the disease progression of an arthritic knee. In 2019, Hirschmann et al introduced functional knee phenotypes, which considered the hip-knee-ankle (HKA), tibial and femoral coronal angles, identifying 43 phenotypes in a healthy population [214]. While useful for alignment strategy, this system is complex and limited by HKA assessment, which is influenced by assessment position and osteoarthritis-related deformity [215]. MacDessi et al's coronal plane alignment of the knee (CPAK) classification system addresses these limitations by considering constitutional coronal limb alignment [10], which remains constant despite joint space narrowing. CPAK classifies knees into nine phenotype groups using arithmetic HKA (aHKA) and joint line obliquity (JLO) [212]. Although CPAK phenotype distribution varies with gender and patient ethnicity [217], [218], [219], [220], [221], it is used as an operative alignment strategy to guide joint balance optimisation [10], [222]. As a simple and pragmatic tool, CPAK was developed using two-dimensional (2D) antero-posterior radiographs, thus restricting knee phenotyping to the coronal plane.

However, TKA outcomes are influenced by three-dimensional (3D) anatomical variability. For instance, distal femoral rotation variability [345] complicates the use of a standard 3° rule for external rotation of the transepicondylar axis (TEA) relative to the posterior condylar axis (PCA) [200]. While tibial tubercle referencing rotations display high variability [203], excessive tibiofemoral internal rotation or rotational mismatch can result in inferior postoperative pain and functional outcomes [346], [347], [348], [349]. Inter-patient [192] and intra-patient [193], [194], [350] tibial slope variability also complicate TKA planning. Due to such anatomical variabilities, standardised rotational and sagittal alignment strategies may not be suitable for all patients [295]. Therefore, it is important to understand the relationship between CPAK parameters and axial and sagittal plane variables.

Corbett et al. investigated the relationship between rotational and sagittal measurements and aHKA and JLO and evaluated these variables across CPAK groups [351]. However, their analysis was limited to five anatomical variables and a moderate TKA population size. This study expands on their work by examining a broader range of axial and sagittal characteristics in a considerably larger patient cohort.

Our primary aim is to investigate the linear relationship between 12 common axial and sagittal measurements and aHKA and JLO, in a large TKA patient cohort. We also evaluate how these anatomical measurements vary across CPAK groups. We hypothesise limited relationships between the axial and sagittal measurements and both aHKA and JLO, with few clinically applicable differences across CPAK groups.

3.3. Methods

A retrospective analysis of the 360 Med Care computed tomography (CT) database was performed, comprised of patients from 107 different orthopaedic surgeons who were undergoing TKA between 17 August 2015 and 8 January 2024. Joints undergoing revision or complex primary surgery, where revision protheses were required were excluded from the study.

All patients received a bilateral lower-limb preoperative CT scan with a maximum slice thickness of 1.25mm. The CT scans were segmented and landmarked by engineers using Simpleware ScanIP (Synopsys, Inc., Mountain View, USA), to produce 3D reconstructed bone models. Each set of 3D bone models and landmarks were quality checked by a second, senior engineer to ensure accuracy. The bone models and landmarks were reproduced if any discrepancies were observed between the two engineers. Representations of the landmarks are displayed in **Figure 3.1**.

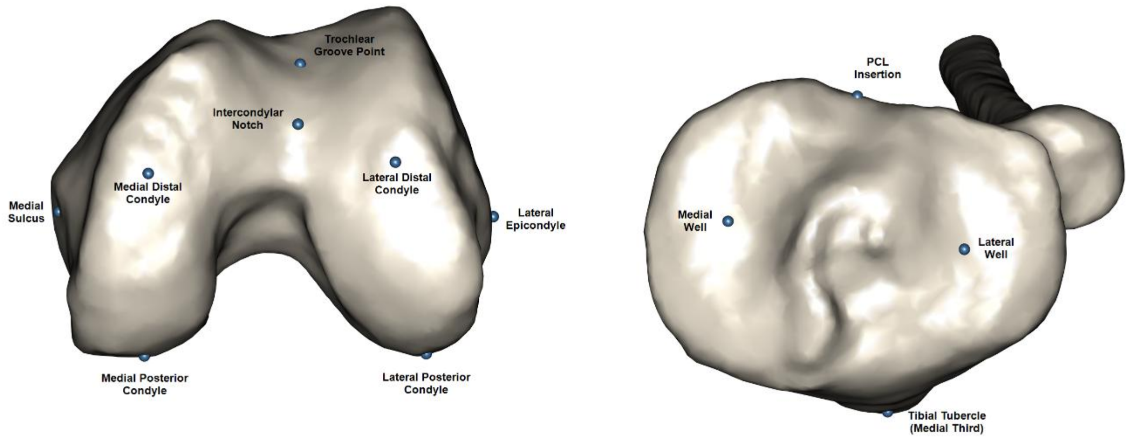

Figure 3.1. *Representation of the key landmarks on the distal femur and proximal tibia. PCL, posterior cruciate ligament.*

The final bone models and landmarks were used to calculate a range of measurements with a focus on coronal, axial and sagittal measurements as outlined and defined in **Table 3.1**. An internal analysis on unpublished data demonstrated these measurements to be repeatable to ±1°. On the coronal plane the medial proximal tibial angle (MPTA) and lateral distal femoral angle (LDFA) were calculated and used to determine the aHKA (MPTA – LDFA) and JLO (MPTA + LDFA). The aHKA and JLO measurements were used to define the knee as varus, neutral or valgus and apex distal, apex neutral or apex proximal, respectively. By combining the aHKA and JLO definitions for a knee, it was categorised in accordance with CPAK [10].

Consistent with literature, CPAK types VII, VIII and IX were excluded from all statistical analysis as they comprised a small portion of the population [10]. Descriptive statistics, including mean and standard deviation and interquartile range (IQR), were used to characterise all anatomical measurements described in **Table 3.1** across the full study population as well as each CPAK type. Pearson's correlation coefficients were used to investigate the linear relationship between the aHKA and JLO with each of the axial and sagittal anatomical measurements, with $p < 0.05$ denoting statistical significance. The normality of the data across the cohort and each CPAK group was tested subjectively using histograms and Q-Q plots as well as objectively with measures of skewness and kurtosis. Due to non-parametric distributions, Kruskal-Wallis tests were performed to compare the mean values of the axial and sagittal measurements across the different phenotypes. Where statistical significance was observed, post hoc Mann-Whitney U was used to identify which pairs of phenotypes displayed significantly different distributions for the measurement. The *p*-values obtained from the post hoc analysis were adjusted using the Bonferroni method, with an adjusted significance of $p < 0.0033$. For each axial and sagittal measurement, Cohen's delta (d) was used to measure the absolute standardised mean difference between each pair of phenotypes, where a larger value would denote a greater effect size. Values of <0.2, 0.2 to 0.5, 0.5 to 0.8 and > 0.8 were deemed trivial, small, moderate, and large, respectively. All statistical analyses were performed in Posit R Studio (Boston, United States).

Table 3.1. *Details of the anatomical measurements used for the analyses, including plane of measurement, reference bone(s) and description of the measurement. Apart from the CPAK constituents, these specific measurements were used as they were routinely available from the 3D analyses performed during TKA planning for each patient within the study cohort.*

MPTA, medial proximal tibial angle; LDFA, lateral distal femoral angle; aHKA, arithmetic hip-knee-ankle angle; JLO, joint line obliquity; PCL, posterior collateral ligament; sTEA, surgical transepicondylar axis; PCA, posterior condylar axis; AP, anteroposterior; CT, computed-tomography.

Measurement	Plane	Bone Reference	Description
Medial Proximal Tibial Angle (MPTA)	Coronal	Tibia	The medial angle between the mechanical axis of the tibia and the line joining the medial and lateral tibial wells.
Lateral Distal Femoral Angle (LDFA)	Coronal	Femur	The lateral angle between the mechanical axis of the femur and the line joining the medial and lateral distal condyles.
Arithmetic Hip-Knee-Ankle Angle (aHKA)	Coronal	Tibiofemoral	aHKA = MPTA – LDFA The aHKA can be categorised as varus (aHKA < -2°), neutral (-2° ≤ aHKA ≤ 2°) or valgus (aHKA > 2°).
Joint Line Obliquity (JLO)	Coronal	Tibiofemoral	JLO = MPTA + LDFA The JLO can be categorised as apex distal (JLO < 177°), apex neutral (177° ≤ JLO ≤ 183°) or apex proximal (JLO > 183°).
Tibial Torsion	Axial	Tibial	Angle between the line joining the medial and lateral wells and the line joining the medial and lateral malleoli. Positive angle denotes external rotation.
Insall's Axis to Cobb's Axis	Axial	Tibial	The degree of external rotation of Insall's axis from Cobb's axis. Insall's axis was defined as the line joining the posterior collateral ligament (PCL) insertion point and the medial third of the tibial tuberosity[352].

			Cobb's axis was defined as the line joining the medial and lateral condylar centres[353].
sTEA to PCA	Axial	Femoral	The degree of external rotation of the surgical transepicondylar axis (sTEA) from the posterior condylar axis (PCA). sTEA was defined as the line joining the medial sulcus and lateral epicondyle landmarks. PCA was defined as the line joining the medial and lateral posterior condyle landmarks.
Femoral AP Axis to sTEA	Axial	Femoral	The degree of external rotation of the femoral anteroposterior (AP) axis from the sTEA. The AP axis was the same as Whiteside's Line, was defined as the line joining the deepest part of the trochlear groove and centre of the intercondylar femoral notch [198].
Femoral AP Axis to PCA	Axial	Femoral	The degree of external rotation of the femoral AP axis from the PCA.
Insall's Axis to sTEA	Axial	Tibiofemoral	The degree of external rotation of Insall's axis from the sTEA with consideration to tibiofemoral position during the CT scan.
Insall's Axis to PCA	Axial	Tibiofemoral	The degree of external rotation of Insall's axis from the PCA with consideration to tibiofemoral position during the CT scan.
Cobb's Axis to sTEA	Axial	Tibiofemoral	The degree of external rotation of Cobb's axis from the sTEA with consideration to tibiofemoral position during the CT scan.
Cobb's Axis to PCA	Axial	Tibiofemoral	The degree of external rotation of the Cobb's axis from the PCA with consideration to tibiofemoral position during the CT scan.
Medial Tibial Slope	Sagittal	Tibial	The degree of posterior tibial slope (flexion) of the medial plateau relative to the tibial mechanical axis. The tibial mechanical axis was defined as the line joining the centre of the medial and lateral malleoli

			to the centre of the PCL insertion and the medial third of the tibial tubercle.
Lateral Tibial Slope	Sagittal	Tibial	The degree of posterior tibial slope (flexion) of the lateral plateau relative to the tibial mechanical axis.
Femoral Bow Flexion	Sagittal	Femoral	The angle between the femoral mechanical axis and the line joining the distal femur centre to the mid-femur centre. This was used as a proxy for femoral bow flexion. Positive angle denotes flexion. The femoral mechanical axis was defined as the line joining the femoral head centre to the distal femur centre. The mid-femur centre was the point at the centre of femur at the cross-section halfway between the distal femur centre and femoral head centre landmarks.

3.4. Results

Demographic characteristics and CPAK distributions for the 7,450 knees from 6,235 patients are outlined in **Table 3.2**. The most common group was type II (apex distal JLO with a neutral aHKA), representing 34.6% of the study cohort. Types I (31.8%) and III (21.0%) were the next most frequent groups. In descending order, types I (38.3%), II (33.1%) and III (13.8%) were most prevalent amongst men and types II (35.%), III (27.0%) and I (26.5%) were most common amongst women.

Weak linear correlations were observed between the axial and sagittal measurements assessed and the aHKA and JLO (**Table 3.3**). Axially, the femoral antero-posterior (AP) axis to surgical TEA (sTEA) angle displayed the strongest relationship to aHKA ($r = -0.14$, $p < 0.001$) and the Insall's axis to PCA measurement had the strongest correlation to JLO ($r = -0.28$, $p < 0.001$). Of the sagittal measurements, medial tibial slope displayed the strongest relationship to both aHKA ($r = -0.19$, $p < 0.001$) and JLO ($r = -0.21$, $p < 0.001$).

The mean values and distributions for the axial and sagittal measurements across the different CPAK phenotypes are displayed in **Table 3.4** and **Figure 3.2** respectively. **Table 3.5** outlines the *d* values for each axial and sagittal measurement across each CPAK group pairing, whilst **Figure 3.3** summarises the post hoc pairwise comparisons between the CPAK measurements for each phenotype. The largest *d* values were observed between CPAK phenotypes I and VI for the rotation of Insall's axis relative to both the sTEA (0.83) and PCA (0.85). Femoral AP axis to sTEA angle displayed a moderate *d* of 0.68 between CPAK groups III and IV. Sagittally, the medial tibial slope exhibited a moderate *d* (0.66) between CPAK phenotypes I and V, whereas the lateral tibial slope exhibited the lowest maximum *d* (0.23, between groups IV and V) across all anatomical measurements assessed.

Table 3.2. *Patient demographics for the full study cohort and for the men and women subpopulations.*

CT, computed-tomography; HKA, hip-knee-ankle angle; MPTA, medial proximal tibial angle; LDFA, lateral distal femoral angle; aHKA, arithmetic hip-knee-ankle angle; JLO, joint line obliquity; CPAK, coronal plane alignment of the knee; IQR, inter-quartile range.

Measurement	**All (n = 7,450)**	**Men (n = 3,336)**	**Women (n = 4,114)**
Left/Right	3,475/3,975	1,572/1,764	1,903/2,211
Age (Years)	69.7 (IQR 11.6)	68.8 (IQR 11.7)	70.4 (IQR 11.4)
CT HKA (° Varus)	4.0 (IQR 7.2)	5.2 (IQR 5.77)	2.9 (IQR 8.2)
MPTA (°)	86.3 (IQR 3.7)	86.0 (IQR 3.64)	86.5 (IQR 3.6)
LDFA (°)	86.8 (IQR 3.3)	87.3 (IQR 3.16)	86.4 (IQR 3.3)
aHKA (°)	-0.5 (IQR 5.2)	-1.3 (IQR 4.83)	0.2 (IQR 5.2)
JLO (°)	173.1 (IQR 4.6)	173.3 (IQR 4.7)	172.9 (IQR 4.5)
CPAK Type			
I	2,370 (31.8%)	1,279 (38.3%)	1,091 (26.5%)
II	2,577 (34.6%)	1,104 (33.1%)	1,473 (35.8%)
III	1,567 (21.0%)	459 (13.8%)	1,108 (27.0%)
IV	261 (3.5%)	158 (4.7%)	103 (2.5%)
V	324 (4.3%)	171 (5.1%)	153 (3.7%)
VI	282 (3.8%)	115 (3.4%)	167 (4.1%)
VII	20 (0.3%)	13 (0.4%)	7 (0.2%)
VIII	11 (0.1%)	9 (0.3%)	2 (0.0%)
IX	38 (0.5%)	28 (0.8%)	10 (0.2%)

***Table 3.3**. Correlations of the axial and sagittal anatomical measurements to the arithmetic Hip-Knee-Ankle angle (aHKA) and joint line obliquity (JLO).*

sTEA, surgical trans-epicondylar axis; PCA, posterior condylar axis; AP, antero-posterior.

Anatomical Measurement	Bone Reference	Plane	aHKA			JLO		
			r	*p*	Slope	*r*	*p*	Slope
Tibial Torsion	Tibial	Axial	0.05	<.001	0.03	-0.06	<.001	-0.03
Insall's Axis to Cobb's Axis	Tibial	Axial	-0.05	<.001	-0.06	-0.23	<.001	-0.22
sTEA to PCA	Femoral	Axial	0.03	.008	0.07	-0.13	<.001	-0.25
Femoral AP Axis to sTEA	Femoral	Axial	-0.14	<.001	-0.12	0.14	<.001	0.10
Femoral AP Axis to PCA	Femoral	Axial	-0.13	<.001	-0.11	0.09	<.001	0.07
Insall's Axis to sTEA	Tibiofemoral	Axial	-0.13	<.001	-0.10	-0.24	<.001	-0.17
Insall's Axis to PCA	Tibiofemoral	Axial	-0.12	<.001	-0.09	-0.28	<.001	-0.19
Cobb's Axis to sTEA	Tibiofemoral	Axial	0.10	<.001	0.09	0.09	<.001	0.07
Cobb's Axis to PCA	Tibiofemoral	Axial	0.09	<.001	0.08	0.14	<.001	0.11
Medial Tibial Slope	Tibial	Sagittal	-0.19	<.001	-0.15	-0.21	<.001	-0.15
Lateral Tibial Slope	Tibial	Sagittal	0.03	.004	0.03	-0.04	<.001	-0.03
Femoral Bow Flexion	Femoral	Sagittal	0.02	.077	0.06	0.07	<.001	0.19

Table 3.4. *Mean and standard deviation of the axial and sagittal measurements of the full study cohort and each CPAK group from I to VI.*

CPAK, coronal plane alignment of the knee; sTEA, surgical trans-epicondylar axis; PCA, posterior condylar axis; AP, antero-posterior.

Measurement	**Full Study Cohort (n = 7450)**	**CPAK Group**					
		I (n = 2,370)	II (n = 2,577)	III (n = 1,567)	IV (n = 261)	V (n = 324)	VI (n = 282)
Tibial Torsion (°)	17.71 ± 7.99	17.48 ± 8.24	17.75 ± 7.66	18.39 ± 7.90	15.97 ± 8.53	16.30 ± 7.69	18.50 ± 8.31
Insall's Axis to Cobb's Axis (°)	5.30 ± 3.66	5.75 ± 3.61	5.40 ± 3.53	5.34 ± 3.58	4.08 ± 3.81	3.90 ± 3.37	3.85 ± 4.25
sTEA to PCA (°)	1.60 ± 1.81	1.63 ± 1.79	1.59 ± 1.76	1.80 ± 1.84	1.13 ± 1.86	1.18 ± 1.76	1.44 ± 1.93
Femoral AP Axis to sTEA (°)	90.90 ± 4.79	91.41 ± 4.57	90.62 ± 4.80	89.85 ± 4.87	92.99 ± 4.36	92.03 ± 4.67	91.36 ± 4.49
Femoral AP Axis to PCA (°)	92.51 ± 4.83	93.03 ± 4.61	92.22 ± 4.85	91.65 ± 4.96	94.12 ± 4.30	93.20 ± 4.63	92.80 ± 4.76
Insall's Axis to sTEA (°)	9.94 ± 5.07	10.86 ± 4.70	10.25 ± 4.95	9.56 ± 5.26	8.53 ± 4.86	7.63 ± 4.87	6.72 ± 5.21
Insall's Axis to PCA (°)	11.69 ± 5.25	12.65 ± 4.84	11.98 ± 5.11	11.45 ± 5.46	9.87 ± 4.91	9.00 ± 4.98	8.30 ± 5.36
Cobb's Axis to sTEA (°)	-4.64 ± 4.50	-5.11 ± 4.34	-4.85 ± 4.40	-4.22 ± 4.55	-4.45 ± 4.58	-3.74 ± 4.73	-2.87 ± 4.85
Cobb's Axis to PCA (°)	-6.39 ± 4.55	-6.90 ± 4.39	-6.59 ± 4.42	-6.11 ± 4.66	-5.79 ± 4.44	-5.11 ± 4.78	-4.45 ± 4.68
Medial Tibial Slope (°)	12.24 ± 5.01	13.51 ± 5.01	12.17 ± 4.50	11.47 ± 4.75	11.98 ± 5.15	9.97 ± 5.71	10.01 ± 6.05
Lateral Tibial Slope (°)	8.24 ± 4.93	8.13 ± 4.29	8.13 ± 4.41	8.65 ± 5.24	8.60 ± 4.70	7.22 ± 6.98	8.77 ± 7.93
Femoral Bow Flexion (°)	2.37 ± 1.31	2.31 ± 1.33	2.38 ± 1.29	2.35 ± 1.28	2.35 ± 1.48	2.64 ± 1.36	2.42 ± 1.25

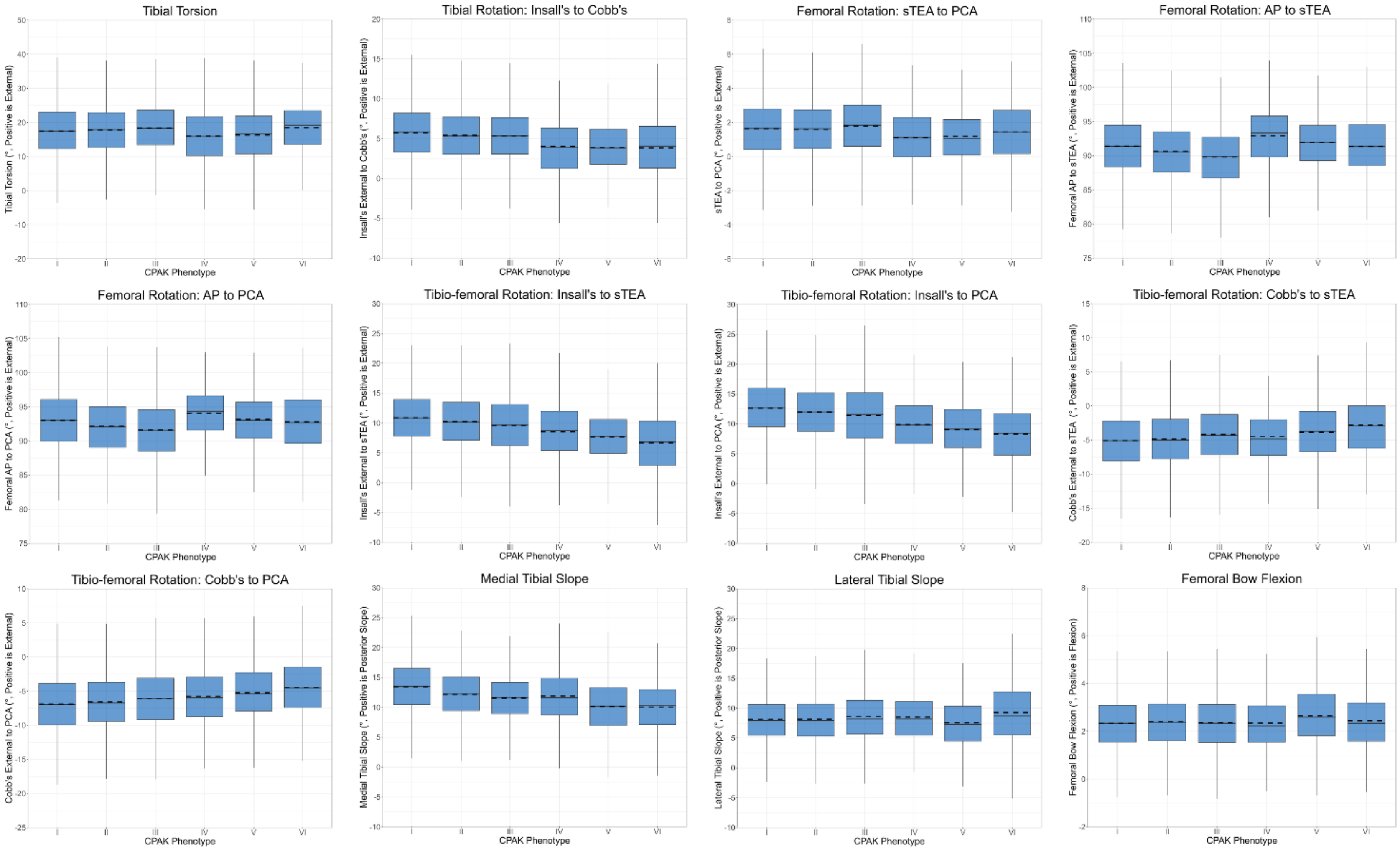

Figure 3.2. *Boxplots displaying the spread of values for the twelve axial and sagittal anatomical measurements across the six CPAK phenotypes assessed.*

Femoral AP, femoral anteroposterior axis; PCA, posterior condylar axis; sTEA, surgical transepicondylar axis.

Table 3.5. *Cohen's delta (d) values for each axial and sagittal measurement between Coronal Plane Alignment of the Knee (CPAK) groups. The rows and columns correspond to different CPAK groups (I to VI), with d values reported at the intersections to indicate the effect size for differences between the respective CPAK group pairings. Effect sizes were categorised as trivial (<0.2), small (0.2-0.5), moderate (0.5-0.8), or large (>0.8). For most pairwise comparisons, d values indicated a trivial or small effect size, suggesting minimal differences between CPAK groups that are unlikely to be clinically significant.*

sTEA, surgical trans-epicondylar axis; PCA, posterior condylar axis; AP, antero-posterior.

A. Tibial Torsion

	II	III	IV	V	VI
I	0.03	0.11	0.18	0.15	0.12
II		0.08	0.22	0.19	0.09
III			0.29	0.27	0.01
IV				0.04	0.30
V					0.27

B. Insall's Axis to Cobb's Axis

	II	III	IV	V	VI
I	0.10	0.11	0.45	0.53	0.48
II		0.02	0.36	0.44	0.40
III			0.34	0.42	0.38
IV				0.05	0.06
V					0.01

C. sTEA to PCA

	II	III	IV	V	VI
I	0.02	0.10	0.27	0.25	0.10
II		0.12	0.25	0.24	0.08
III			0.36	0.35	0.19
IV				0.02	0.16
V					0.14

D. Femoral AP Axis to sTEA

	II	III	IV	V	VI
I	0.17	0.33	0.35	0.13	0.01
II		0.16	0.52	0.30	0.16
III			0.68	0.46	0.32
IV				0.21	0.37
V					0.15

E. Femoral AP Axis to PCA

	II	III	IV	V	VI
I	0.17	0.29	0.24	0.04	0.05
II		0.11	0.42	0.21	0.12
III			0.53	0.32	0.24
IV				0.21	0.29
V					0.09

F. Insall's Axis to sTEA

	II	III	IV	V	VI
I	0.13	0.26	0.49	0.67	0.83
II		0.13	0.35	0.53	0.69
III			0.20	0.38	0.54
IV				0.18	0.36
V					0.18

G. Insall's Axis to PCA

	II	III	IV	V	VI
I	0.13	0.23	0.57	0.74	0.85
II		0.10	0.42	0.59	0.70
III			0.31	0.47	0.58
IV				0.18	0.31
V					0.14

H. Cobb's Axis to sTEA

	II	III	IV	V	VI
I	0.06	0.20	0.15	0.30	0.49
II		0.14	0.09	0.24	0.43
III			0.05	0.10	0.29
IV				0.15	0.34
V					0.18

I. Cobb's Axis to PCA

	II	III	IV	V	VI
I	0.07	0.17	0.25	0.39	0.54
II		0.10	0.18	0.32	0.47
III			0.07	0.21	0.36
IV				0.15	0.29
V					0.14

J. Medial Tibial Slope

	II	III	IV	V	VI
I	0.28	0.42	0.3	0.66	0.63
II		0.15	0.04	0.43	0.40
III			0.1	0.29	0.27
IV				0.37	0.35
V					0.01

K. Lateral Tibial Slope

	II	III	IV	V	VI
I	0.00	0.11	0.1	0.16	0.10
II		0.11	0.1	0.16	0.10
III			0.01	0.23	0.02
IV				0.23	0.03
V					0.21

L. Femoral Bow Flexion

	II	III	IV	V	VI
I	0.05	0.03	0.03	0.24	0.08
II		0.02	0.02	0.20	0.03
III			0.00	0.22	0.06
IV				0.2	0.05
V					0.17

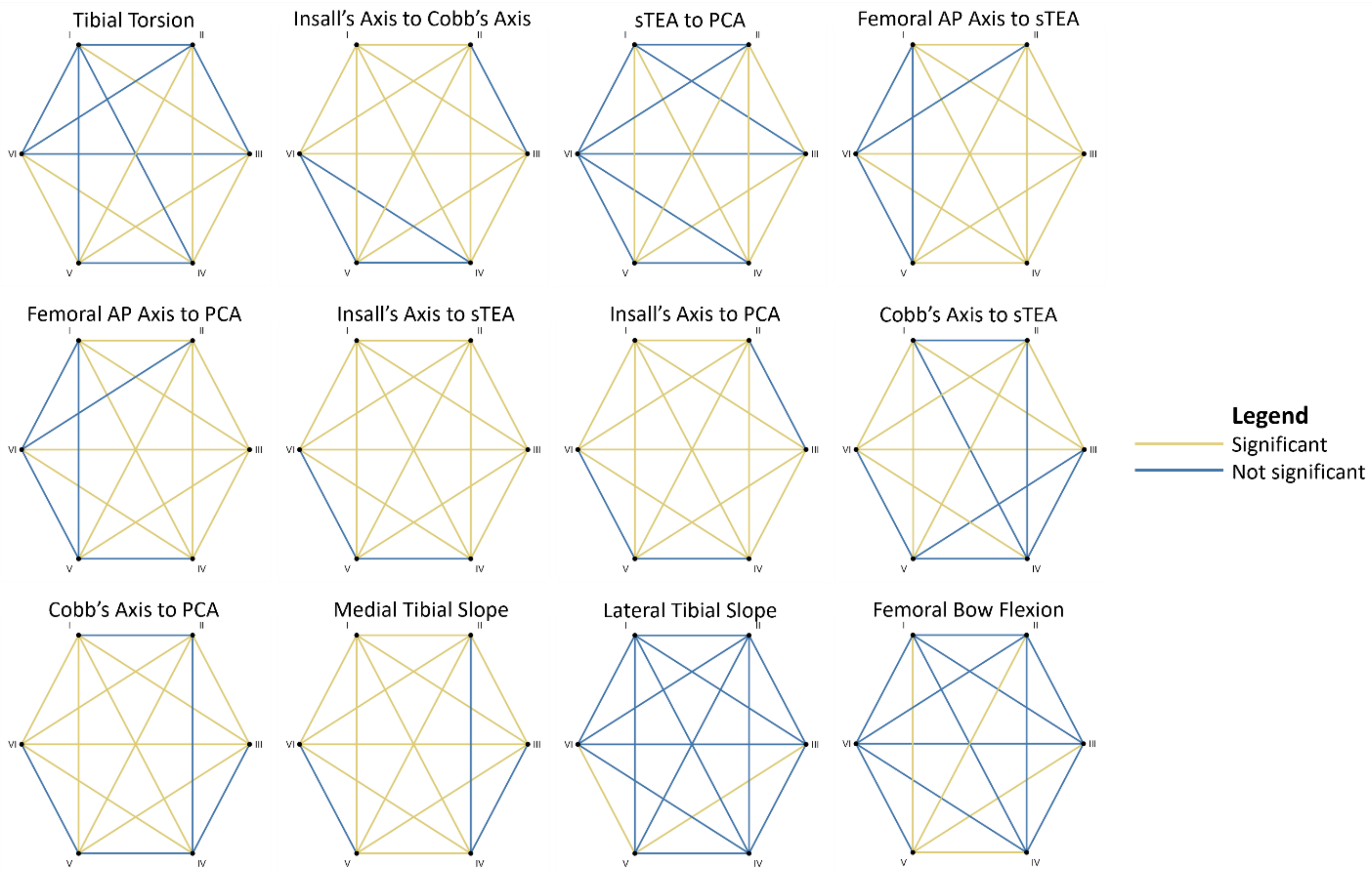

Figure 3.3. *Network plots displaying the post hoc Mann-Whitney U test results. After adjusting the p-values using the Bonferroni method, significant results are highlighted in gold and non-significant results in blue.*

Femoral AP, femoral anteroposterior axis; PCA, posterior condylar axis; sTEA, surgical transepicondylar axis.

3.5. Discussion

In this study, most anatomical rotational and sagittal measurements displayed weak linear relationships to both aHKA and JLO. These significantly different findings were attributed to the large sample size, which enhances the statistical power [354]. Further, our analysis highlighted significant differences in axial and sagittal measurements between different CPAK groups. However, the impact of these differences was generally small, as indicated by the *d* values. Notably, large effect sizes were observed only in the tibiofemoral rotations, specifically for the angles between Insall's axis and the sTEA, and Insall's axis and the PCA. This suggests that while CPAK grouping may be associated with variabilities in axial and sagittal planes, it does not effectively distinguish between axial and sagittal characteristics of the knee and is therefore insufficient to describe 3D alignment of the knee during analysis and TKA planning.

Axially, internal rotation of the femoral AP axis relative to sTEA was observed with increased constitutional valgus alignment. This reflects the findings of Luyckx et al who assessed femoral AP to sTEA rotation relative to HKA [189]. However, clinical implications in TKA require careful consideration. When comparing CPAK group 1 with 3 and 4 with 6, we observe greater femoral external rotation (sTEA to PCA angle) with increasing aHKA. Such an increase in coronal alignment due to either greater tibial or femoral valgus increases the lateral extension joint gap. Meanwhile, greater femoral external rotation decreases the lateral flexion gap and lateralises the femoral trochlea. As a result, the weak statistical finding of internal rotation of femoral AP to sTEA should be treated with caution during TKA as any planned femoral internal rotation can cause extension/flexion gap mismatch. It may therefore be safer to assume no clinical relationship exists, as supported by the lack of a strong effect size (maximum $d = 0.68$) and the findings of Corbett et al, who observed no significant linear relationships between rotational alignment and aHKA or JLO [351].

The external rotation of Insall's axis to both sTEA and PCA displayed weak correlations to aHKA ($r = -0.14$, $p < 0.001$ and $r = -0.13$, $p < 0.001$, respectively) and JLO ($r = -0.24$, $p <$

0.001 and $r = -0.28$, $p < 0.001$, respectively). The latter may be driven by internal tibial rotation (Insall's to Cobb's angle) with an increase in JLO. However, during their assessment of Akagi's line [29] relative to the sTEA in 100 patients, Aglietti et al observed no significant relationship to coronal long leg deformity [28]. Corbett et al also employed Akagi's line, measuring its rotation to the PCA [25]. Whilst finding no relationship to aHKA, they observed a significant correlation between tibiofemoral rotation and JLO. This suggests that aligning the tibial component with a fixed reference (e.g. neutral) to Insall's axis may increase the risk of tibial internal rotation or tibiofemoral rotational mismatch as the JLO increases. Nonetheless, the large effect sizes observed for tibiofemoral rotation between CPAK groups I and VI were not mirrored across the other groups. This highlights that the classification system is unable to distinguish tibiofemoral rotational alignment, which is required to support 3D TKA planning.

In the sagittal plane, a weak correlation was observed between medial tibial slope and both aHKA ($r = -0.19$, $p < 0.001$) and JLO ($r = -0.21$, $p < 0.001$), suggesting a decrease in medial posterior tibial slope as either the aHKA becomes more valgus or JLO apex becomes more proximal. Similarly, Panguad et al observed a significant decrease in medial posterior slope as the coronal alignment categorisation shifted from varus to neutral and neutral to valgus [187]. Their multivariate analysis highlighted that the medial tibial slope was correlated to the HKA ($R^2 = -0.368$, $p < 0.001$), while no such relationship was apparent for the lateral tibial slope. Perhaps this is due to the intra-patient variability in medial and lateral tibial slope, reported to be 2.6° on average [350] but greater than 3° for over 45% of osteoarthritic patients [194]. Although intra-patient difference in medial and lateral tibial slope was not assessed in the study, the mean medial and lateral posterior slope values of 12.24° and 8.24°, respectively, provide some insight into the variability between the two compartments. This is emphasised by the lower effect size observed for lateral tibial slope than medial across most CPAK group pairings. The trivial or weak effect sizes observed for both slope measurements suggests that the CPAK classification system cannot guide tibial slope alignment, which is a key component of TKA planning.

The CPAK distribution of this study population varied from the CPAK distribution of an arthritic population as originally reported by MacDessi et al [19]. Most notably a greater proportion of patients in our study were classified as apex distal than neutral, with a CPAK category of I, II or III. This trend is supported by similar distributions observed in published 3D analyses [351], [355]. Further, Sasaki et al observed that 2D JLO assessments may be influenced by tibial rotation and knee flexion and demonstrated that 3D joint surface orientation does not correlate to such 2D measurements [356]. Therefore, the difference in CPAK distribution is likely attributable to different imaging modality. We believe that preoperative TKA planning should be performed using 3D joint assessment rather than plain 2D radiographic assessment.

This study had some limitations. The 12 axial and sagittal plane measurements used are non-exhaustive. However, given the lack of consensus on the most suitable references for these tibial, femoral and tibiofemoral measurements they do provide an acceptable basis to be used for 3D analysis. They are reflective of commonly used anatomical references; however, we do acknowledge that alternate measurements may yield stronger relationships to aHKA and JLO, and/or better differentiate between CPAK phenotypes. Although CPAK types VII, VIII and IX were excluded from statistical analysis, these accounted just 0.9% of the study cohort. This low proportion reflects distributions observed in regions across the globe [10], [219], [220], [221], [351], [355], [357], [358]. Additionally, the patient population was predominantly Caucasian and so caution must be exercised in generalising these results to other ethnicities.

3.6. Conclusion

While the CPAK classification system holds value for describing the knee anatomy in the coronal plane, it displays limited scope in addressing the knee's 3D complexity, thus suggesting the need for more comprehensive classification systems. Future classification systems should be capable of reflecting diverse anatomical variation in all anatomical planes, thereby aiding surgeons' selection of an appropriate alignment strategy for an individualised TKA. Such classification systems would also add value as a research tool to assess outcomes of TKA relative to 3D alignment. Future research should be directed towards developing and validating such 3D classification systems.

Chapter 4:

Functional preoperative assessment of coronal knee laxity better predicts postoperative patient outcomes than intraoperative surgeon-defined laxity in total knee arthroplasty

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4.1. Abstract

Purpose

Intraoperative laxity assessments in total knee arthroplasty (TKA) are subjective, with few studies comparing against standardised preoperative and postoperative assessments. This study compares coronal knee laxity in TKA patients awake and anaesthetised, pre- and post-prosthesis implantation, evaluating relationships to patient-reported outcome measures (PROMs).

Methods

A retrospective analysis of 49 TKA joints included preoperative and postoperative computer tomography scans, stress radiographs, and Knee injury and Osteoarthritis Outcome Score (KOOS) questionnaire results preoperatively and 12-month postoperatively. The imaging was used to assess functional laxity (FL) in awake patients, while computer navigation measured intraoperative surgical laxity (SL) pre-implantation and post-implantation, with patients anaesthetised. Varus and valgus stress states and their difference, joint laxity, were measured.

Results

SL was greater than FL both pre-implantation (8.1° (interquartile range [IQR] 2.0°) and 3.8° (IQR 2.9°), respectively) and post-implantation (3.5° (IQR 2.3°) and 2.5° (IQR 2.7°), respectively). Pre-implantation, SL was more likely than FL to categorise knees as correctable to ±3° of the mechanical axis. Preoperative FL correlated with KOOS Symptoms ($r = 0.33$, $p = 0.02$) and Quality of Life (QoL) ($r = 0.38$, $p = 0.01$), while reducing medial laxity with TKA enhanced postoperative QoL outcomes ($p = 0.02$).

Conclusions

Functional coronal knee laxity assessment of awake patients is generally lower than intraoperative surgical assessments of anaesthetised patients. Preoperative SL may result in over-correction of coronal TKA alignment, while preoperative FL better predicts postoperative patient outcomes and reflects the patients' native and tolerable knee laxity. Preoperative FL assessment can be used to guide surgical planning.

Level of Evidence: Level II

4.2. Introduction

In the pursuit of improved satisfaction rates in total knee arthroplasty (TKA), surgical technique and protheses designs have evolved to better emulate the native knee anatomy and kinematics [359], [360], [361]. Recent advances in the understanding of knee phenotypes, such as the functional knee phenotypes [214] and the coronal plane alignment of the knee [10], allow estimation of the native coronal bony anatomy of osteoarthritic knees [362]. While such phenotypes display some relationships to coronal knee laxity, there remains high variability in ligamentous knee morphology [363], [364], [365]. An appropriate assessment of the native coronal knee laxity is required for TKA planning to optimise ligament balance with minimal disruption to the soft-tissue envelope during TKA [12], [360]. However, the current surgical standard for native coronal knee laxity assessment involves intraoperative assessment prior to bone resections by applying manual varus and valgus forces with the patient anaesthetised. This method for native knee laxity assessment lacks standardisation and remains subjective due to non-uniform manual force application. Further, surgeon assessment of balance have been reported to be inconsistent and influenced by surgeon experience [366], [367], [368], thus raising concerns about its suitability to represent the native or constitutional knee laxity.

Alternate non-invasive methods to preoperatively assess patient-specific coronal knee laxity using X-rays under varus and valgus loading have been proposed [266], [369]. These techniques offer objective laxity assessment, are predictive of the extent of tissue release [265], and importantly, profile native coronal knee laxity with the patient awake. This approach aids soft tissue informed preoperative TKA planning and enables systematic comparisons of coronal laxity before and after surgery, enhancing understanding of its impact on patient outcomes. Prior research has examined the difference in joint laxity between timepoints, with patients awake and anaesthetised [266], [369], [370] and analysed the relationship between joint laxity at a single timepoint, such as postoperatively, and patient-reported outcomes measures (PROMs)

[262], [270], [272]. However, the relationship between changes in coronal laxity across operative states and PROMs remains underexplored.

The primary aim of this study is the compare coronal knee laxity of a TKA cohort preoperatively and postoperatively when awake, using a standardised protocol, and intraoperatively pre- and post-prosthesis implantation using the surgical standard approach with the patient anaesthetised. Secondary aims include investigating the relationship between both knee laxity and the difference in laxity between operative states and PROMs. We hypothesise that pre- and post-prosthesis implantation laxity are lower in patients when awake compared to anaesthetised, and the difference between awake and anaesthetised laxity will be lower post-implantation than pre-implantation. Further, we hypothesise that awake laxity assessments will have stronger relationships to PROMs than anaesthetised intraoperative assessments.

4.3. Methods

A retrospective analysis was performed on 49 joints from 46 patients undergoing primary TKA for knee osteoarthritis (OA), recruited by one surgeon between February 29, 2016, and March 29, 2017. Patients with inflammatory arthritis, extra-articular deformity, undergoing complex primary or unicompartmental to total knee arthroplasty, or those unable to complete imaging due to contraindications, refusal, or lack of access, were excluded from the study. A preoperative analysis of functional knee phenotypes [214] was used to describe the coronal knee anatomy of the study population (**Figure 4.1**). A power analysis with 80% power, a 5% two-tailed significance level, a medium effect size (calculated using early data) and an assumption of no attrition determined a minimum sample size of 30 subjects. Ethics approval was granted by Bellberry Human Research Ethics Committee (Sydney, Australia), application number 2012-03-710.

Patient-Reported Outcome Measures

Patients completed the Knee injury and Osteoarthritis Outcome Score (KOOS) questionnaire preoperatively and 12-months postoperatively. The five KOOS subscales of pain, symptoms, activities of daily living (ADL), quality of life (QoL) and sports, and improvement in score from preoperative to postoperative were calculated.

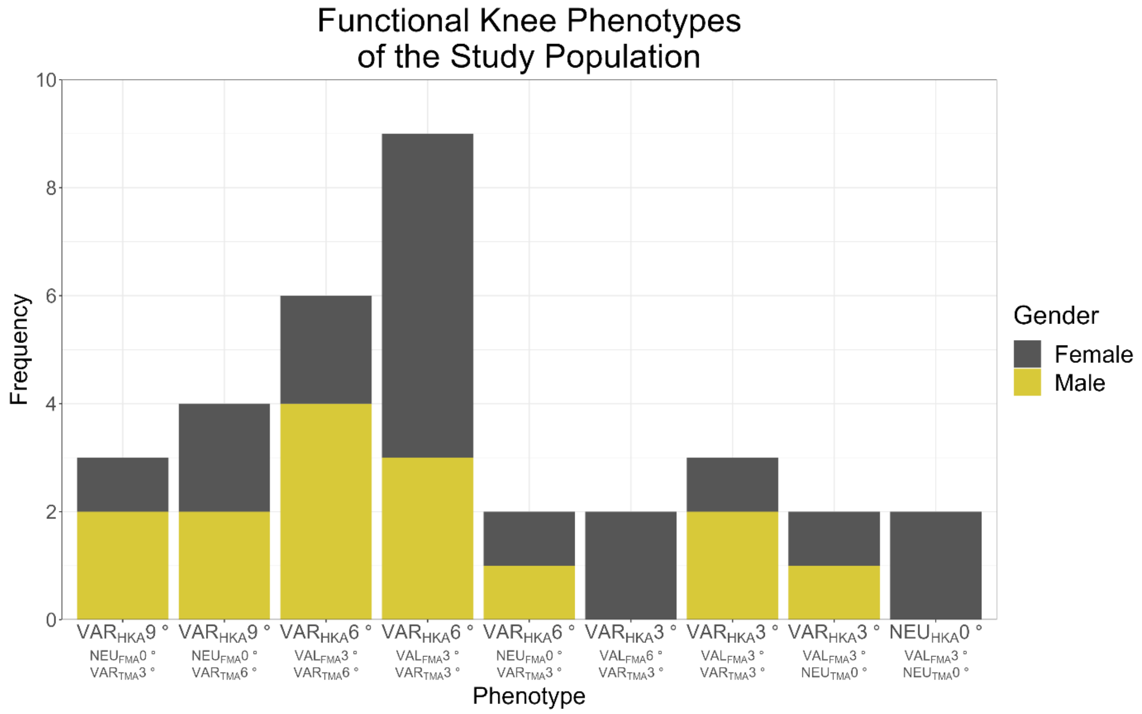


Figure 4.1. *Common functional knee phenotypes observed within the study population. These 9 phenotypes contain over 67% (33) of the study population, with the remaining 16 knees all spread across different phenotypes.*

VAR, varus; NEU, neutral; VAL, valgus; HKA, hip-knee-ankle angle; FMA, femoral mechanical angle; TMA, tibial mechanical angle.

Surgical Technique and Intraoperative Laxity Assessment

All TKAs were performed by the investigating surgeon using a Corin Omni Apex (Raynham, Massachusetts) cruciate-retaining prosthesis. Intraoperatively, with the patient anaesthetised, ligament laxity was measured using the Corin OMNINav computer navigation system at two timepoints; pre-implantation, prior to bone preparation, osteophyte removal and soft-tissue release except for medial arthrotomy for joint exposure and landmarking using the navigation tool; and after prosthesis implantation, before joint closure. Varus and valgus stresses were manually applied throughout the range of motion (ROM) and the OMNINav system recorded the resulting Hip-Knee-Ankle (HKA) angles. The stressed HKA angle measurements at 10° flexion were extracted. OMNINav was also used for the delivery of tibial and femoral resections and gap balancing. The surgeon targeted a mechanically aligned TKA within ±3° of neutral to the mechanical axis. No routine medial release was performed initially except to access and remove significant osteophytes. The tibia cut was performed first neutral to mechanical axis. The extension and flexion (90°) gaps were then re-tensioned using a laminar spreader to plan final femoral component alignment, aiming for equal medial and lateral gaps and 1-millimetre greater flexion than extension gap. The deep medial collateral ligament was released if necessary to remove medial tibial osteophytes. A medial capsular release was performed along the tibial cut rim if the overall HKA was greater than 3° varus but was not required in any cases in the study cohort. Any residual fixed flexion beyond 5° was corrected with posterior capsular release from the femur.

Preoperative and Postoperative Radiology Capture and Image Processing

Within two months preoperatively, patients underwent a long-leg supine computer tomography (CT) scan as per the Australian Universal Resection, Orientation, and Rotation Analysis (AURORA) protocol [371] and two radiographs under varus and valgus stress using a Telos SD-900 (Wölfersheim, Germany) device. The device features two counter-supports on one side of the leg and a centrally-positioned force pad on the other. During varus and valgus stress, the force pad was placed medially and laterally to the knee, respectively, aligning with the tibial tuberosity. Counter-supports were positioned at the proximal femur and distal tibia and with the knee flexed between 0-20° [260], [372], [373]. The operator gradually increased the applied force to a maximum of 150N [260], [372], [373], stopping if the patient indicated significant discomfort. Radiographs were then taken. A subset of 37 patients also received 6-month postoperative imaging, following the same protocol. All imaging was performed at a single radiology centre by specifically trained technicians.

Preoperative CT scans were segmented and landmarked using Simpleware ScanIP (Version M-2017.06; Synopsys, Inc., Mountain View, USA), producing 3-dimensional (3D) bone models. These models were registered to the 2-dimensional (2D) stress radiographs using Mimics (Materialise, Belgium) R19 Research software following Li et al's method [260], allowing HKA angle measurements at varus and valgus extents. Postoperatively, prostheses and preoperative bone models were registered to the postoperative CT scan via 3D-to-2D registration using Simpleware ScanIP, yielding postoperative 3D bone models and landmarks. These were then registered to the postoperative stress radiographs using the established preoperative process. The imaging workflow is summarised in **Figure 4.2**. Both preoperatively and postoperative segmentation, landmarking and registrations were performed by an engineer and were quality checked by a senior engineer. All radiographic measurements were calculated using a custom script in Posit R Studio v1.2.5019 (Boston, USA) , using the anatomical landmarks in the CT and stressed positions. These processes have reported sub-millimetre and sub-degree intra-observer and inter-observer variability and high reliability [371], [374].

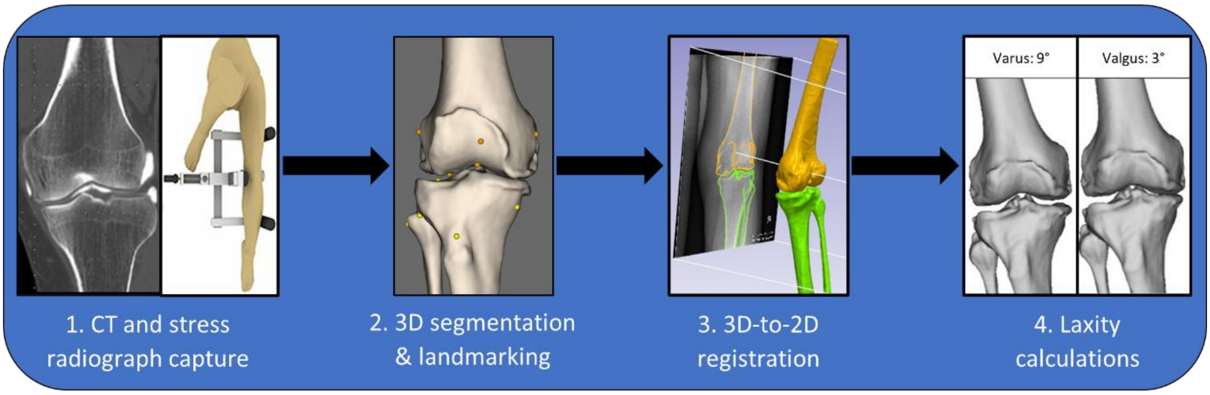


Figure 4.2. *Summary of the preoperative and postoperative laxity assessment workflow, which involves computed-tomography (CT) and stress radiograph capture, 3-dimensional (3D) segmentation and landmarking, 3D-to-2-dimensional registration and the calculation of laxity measurements.*

Laxity Measurements

Table 4.1 outlines the anatomical measurements employed in our study. HKA angles under varus and valgus stress in the preoperative and postoperative and pre-implantation and post-implantation (intraoperative) settings were used to calculate knee laxity. Larger laxity values indicated looser knees; smaller values indicated tighter knees. The OMNINav system's HKA angles under stress determined the Surgical laxity (SL) both pre-implantation (Pre-SL) and post-implantation (Post-SL), with patients anaesthetised. Functional laxity (FL) described knee laxity in conscious patients with the standardised force application both preoperatively (Pre-FL) and postoperatively (Post-FL). Differences in stress HKA angles and joint laxity across operative states were also calculated.

The use of the Telos stress device for quantifying joint laxity and associated measurements has been demonstrated to be reliable. Previous studies show high intra-rater reliability for measuring pre-operative joint space width (ICC = 0.80 to 0.98) in osteoarthritic knees [263], as well as excellent test-retest reliability for measuring post-operative coronal angles in extension (ICC = 0.96) after TKA [264].

Statistical Analysis

Patient demographics were assessed for mean and standard deviation. Data normality was evaluated subjectively using histograms and Q-Q plots, and objectively by analysing skewness and kurtosis, and was determined to follow a normal distribution. Pearson's linear correlations assessed relationships between each pair of laxity measurements and between anatomical measurements (joint laxity, and varus and valgus stress HKA angles) and patient outcomes (preoperative, postoperative, and improvement of the five KOOS subdomain scores). Patients were also categorised by whether they displayed greater joint laxity and stress HKA angles, either preoperatively or pre-implantation and subsequently PROMs were evaluated using the Mann-Whitney

U test. Similar analyses were performed comparing PROMs between the postoperative and post-implantation, preoperative and postoperative, and pre-implantation and post-implantation settings. A *P*-value of .05 indicated statistical significance and all statistical analyses were performed using Posit R Studio v1.2.5019 (Boston, USA).

__Table 4.1.__ Description and formulae of key anatomical measurements performed.

Term	Description	Formula
Hip-Knee-Ankle (HKA) Angle	Angle subtended by the femoral and tibial mechanical axes. A positive angle denotes a varus HKA angle. Measured for the pre- and postoperative supine CT positions. Measured for the varus and valgus stress positions preoperatively and postoperatively as well as intraoperatively, both pre-implantation and post-implantation.	
Laxity	The absolute difference between the varus and valgus stress angles. Measured preoperatively and postoperatively as well as intraoperatively, both pre-implantation and post-implantation.	$\text{Laxity} = \lvert HKA_{Varus} - HKA_{Valgus} \rvert$
Surgical Laxity (SL)	Knee laxity as measured intraoperatively with the patient anaesthetised. Measured pre-implantation (Pre-SL) and post-implantation (Post-SL).	
Functional Laxity (FL)	Knee laxity as measured with the patient in a conscious state. Measured preoperatively (Pre-FL) and postoperatively (Post-FL).	
Joint Laxity Difference	Difference in laxity between two operative states. Determined between the surgical measurements, functional measurements, before implantation and after implantation.	Pre-implantation: Pre-SL – Pre-FL Post-implantation: Post-SL – Post-FL Surgical: Pre-SL - Post-SL Functional: Pre-FL – Post-FL
Correctability	Indicates whether the laxity range falls within ±3° of neutral to the mechanical axis.	

4.4. Results

Table 4.2 summarises patient demographics. Post-implantation and postoperative data were available for 44 and 37 of the 49 joints, respectively. There was a significant difference between the mean preoperative (5.1°, interquartile range [IQR] 3.9°) and postoperative (2.2°, IQR 2.2°) supine CT HKA angles ($p < 0.001$).

Table 4.2. *Patient demographics. CT, computer-tomography; HKA, hip-knee-ankle angle; IQR, interquartile range*

Variable	Total	Men	Women
Joints	49	23	26
Left/Right	19/30	10/13	9/17
Age (years)	67.3 (IQR 9.9)	69.4 (IQR 8.9)	65.3 (IQR 12.0)
Preoperative CT HKA (°, Varus)	5.1 (IQR 3.9)	5.9 (IQR 3.6)	4.3 (IQR 3.7)
Postoperative CT HKA (°, Varus)	2.2 (IQR 1.8)	2.3 (IQR 2.0)	2.1 (IQR 1.6)

On average, Pre-SL (8.1°, IQR 2.0°) was considerably greater than Pre-FL (3.8°, IQR 2.9°), while Post-SL (3.5°, IQR 2.3°) slightly exceeded Post-FL (2.5°, IQR 2.7°) (**Figure 4.3**). Pearson's correlation indicated a moderate relationship between Post-SL and both Pre-SL and Post-FL ($r=0.46$, $p=.002$ and $r=0.40$, $p=.02$, respectively). Pre-SL was greater than Pre-FL for 92%, Post-SL exceeded Post-FL for 100% and Pre-FL was greater than Post-FL for 73% of joints with respective data available, resulting in positive mean differences in pre-implantation, post-implantation, surgical and functional joint laxities (**Table 4.3**). Correctability was observed in 45 and 100% of knees preoperatively and intraoperatively (pre-implantation), respectively. Varus stress yielded larger mean HKA angles preoperatively (6.7°, IQR 3.9°) and pre-implantation (6.6°, IQR 4.0°) than postoperatively (3.6°, IQR 1.6°) and post-implantation (2.0°, IQR 3.3°). Mean valgus stress HKA angles were 2.9° (IQR 4.2°), -1.5° (IQR 4.0°), 1.1° (IQR 2.7°) and -1.5 (IQR 2.3°) varus for the preoperative, pre-implantation, postoperative and post-implantation measurements, respectively. **Figures 4.4 and 4.5** illustrate the distribution of these varus and valgus stress HKA angles, respectively.

The study cohort displayed significant improvements in all five KOOS subscales from the preoperative to 12-month postoperative state (**Table 4.4**).

Significant correlations were observed between both Pre-FL and preoperative valgus stress HKA angle and postoperative KOOS Symptoms (r=0.33, p=.02 and r=-0.28, p=.05, respectively) and QoL (r=0.38, p=.01 and r=-0.31, p=.03, respectively) scores. Post-FL correlated with improvements in KOOS ADL (r=0.35, p=.04) scores. Although there were no significant relationships between pre-implantation surgical laxity measurements and PROMs, Post-SL displayed moderate negative correlation with postoperative KOOS Symptoms (r=-0.37, p=.01), which was driven by the varus stress HKA angle (r=0.35, p=.02). Additionally, differences in FL and functional valgus stress HKA angles significantly correlated with postoperative KOOS QoL outcomes (r=0.35, p=.03 and r=-0.41, p=.01, respectively). **Table 4.5** displays these correlations with the five KOOS subscales.

Patients with a more varus HKA angle during functional valgus stress postoperatively than preoperatively displayed superior KOOS QoL outcomes (**Figure 4.6**). No significant relationships were observed between greater preoperative or postoperative surgical measures and PROMs, nor between greater functional or surgical laxity or stress HKA angle measurements in the pre-implantation or post-implantation settings.

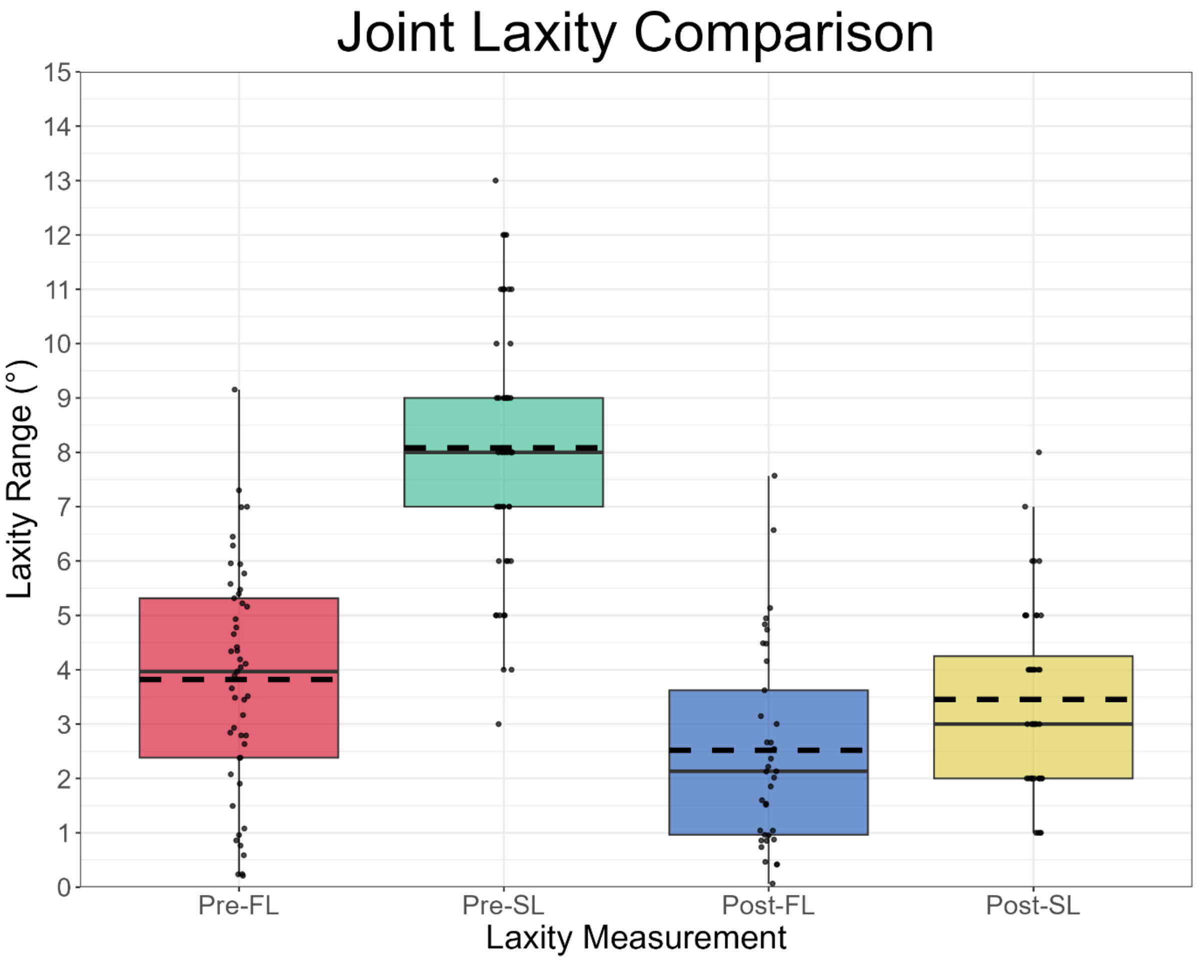


Figure 4.3. *Boxplot of the laxity measurements across the preoperative, intraoperative and postoperative settings. Each pair of measurements (except preoperative functional laxity (Pre-FL) and post-implantation surgical laxity (Post-SL)) was statistically significantly different to each other ($p < 0.05$). Pre-SL, pre-implantation surgical laxity; Post-FL, postoperative functional laxity.*

Table 4.3. *The mean (and interquartile range [IQR]) varus and valgus stress hip-knee-ankle (HKA) angles and joint laxity at the different time points and difference in these measurements between time points. Note: A positive stress HKA value denotes a varus HKA angle.*

	Pre			**Post**			**Pre-to-Post**	
	Functional (n = 49)	**Surgical (n = 49)**	**Difference (Absolute) (n = 49)**	**Functional (n = 37)**	**Surgical (n = 44)**	**Difference (Absolute) (n = 34)**	**Functional Measurement Difference (Absolute) (n = 37)**	**Surgical Measurement Difference (Absolute) (n = 44)**
Varus Stress HKA (°, Varus)	6.7 (IQR 5.2 - 9.1)	6.6 (IQR 4.0 – 9.0)	0.1 (IQR -1.1 – 1.7) (1.6, IQR 0.5 – 2.3)	3.6 (IQR 2.5 – 4.2)	2.0 (IQR 0.0 – 3.3)	1.8 (IQR 0.8 – 3.2) (2.4, IQR 1.1 – 3.2)	2.9 (IQR 1.4 – 4.8) (3.6, IQR 1.6 – 5.6)	4.6 (IQR 2.0 – 6.3) (4.7, IQR 2.0 – 6.3)
Valgus Stress HKA (°, Varus)	2.9 (IQR 1.4 - 5.6)	-1.5 (IQR - 3.0 – 1.0)	4.4 (IQR 2.8 – 6.0) (4.4, IQR 2.8 – 6.0)	1.1 (IQR 0.0 – 2.8)	-1.5 (IQR - 3.0 – -0.8)	2.4 (IQR 1.2 – 3.5) (2.7, IQR 1.7 – 3.6)	1.5 (IQR -0.8 – 4.0) (3.6, IQR 1.6 – 4.7)	0.0 (IQR -1.0 – 2.0) (2.0, IQR 1.0 – 3.0)
Laxity Range (°)	3.8 (IQR 2.4 - 5.3)	8.1 (IQR 7.0 – 9.0)	4.3 (IQR 2.3 – 7.0) (4.5, IQR 2.3 – 7.0)	2.5 (IQR 1.0 - 3.6)	3.5 (IQR 2.0 – 4.3)	0.7 (IQR -0.3 – 2.0) (1.5, IQR 0.5 – 2.1)	1.5 (IQR -0.5 – 3.6) (2.4, IQR 1.3 – 3.8)	4.6 (IQR 3.0 – 6.0) (4.6, IQR 3.0 – 6.0)

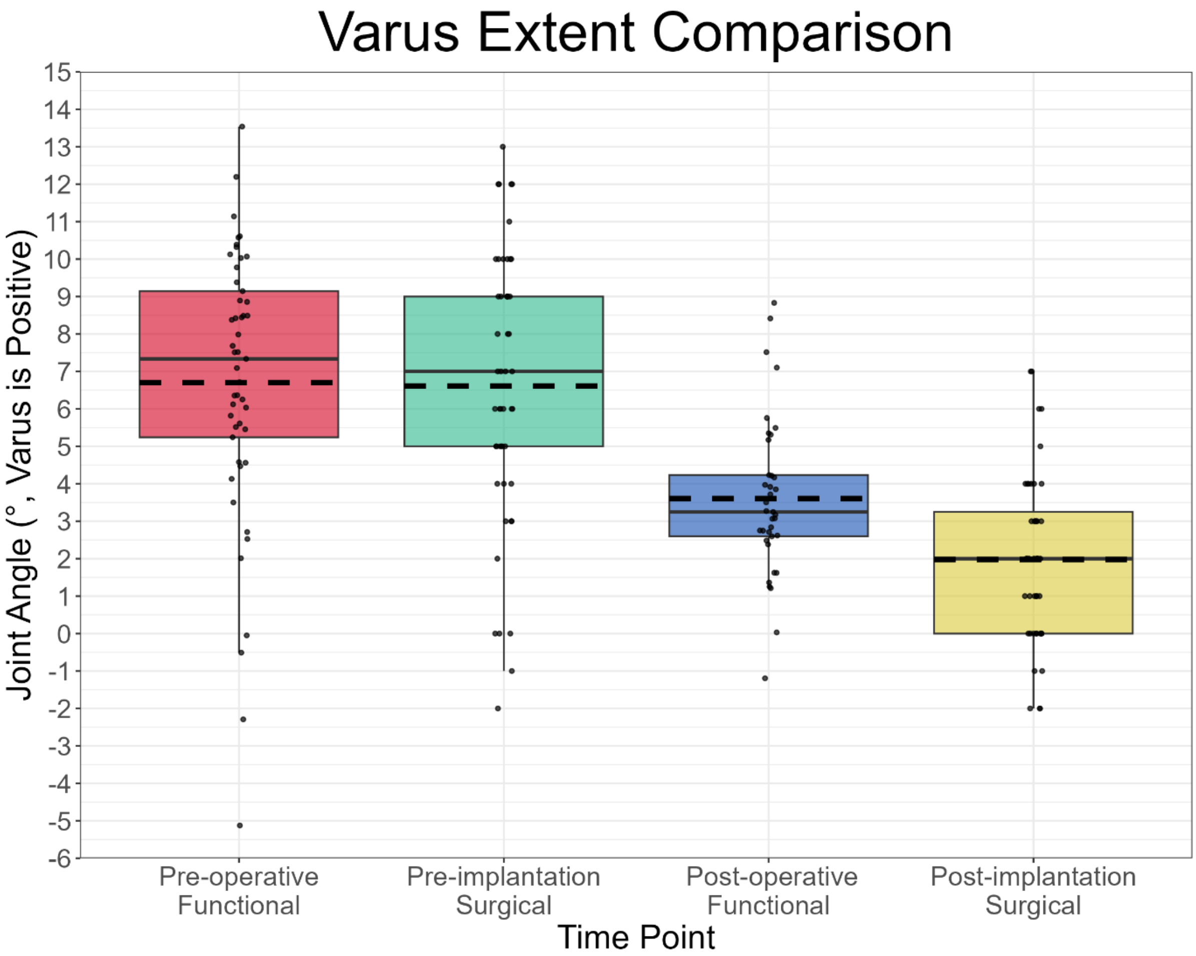


Figure 4.4. *Boxplot of the resulting hip-knee-ankle (HKA) angle in the varus stress state across the preoperative, intraoperative and postoperative settings. Each pair of measurements (except preoperative functional and pre-implantation Surgical) was statistically significantly different to each other ($p < 0.05$).*

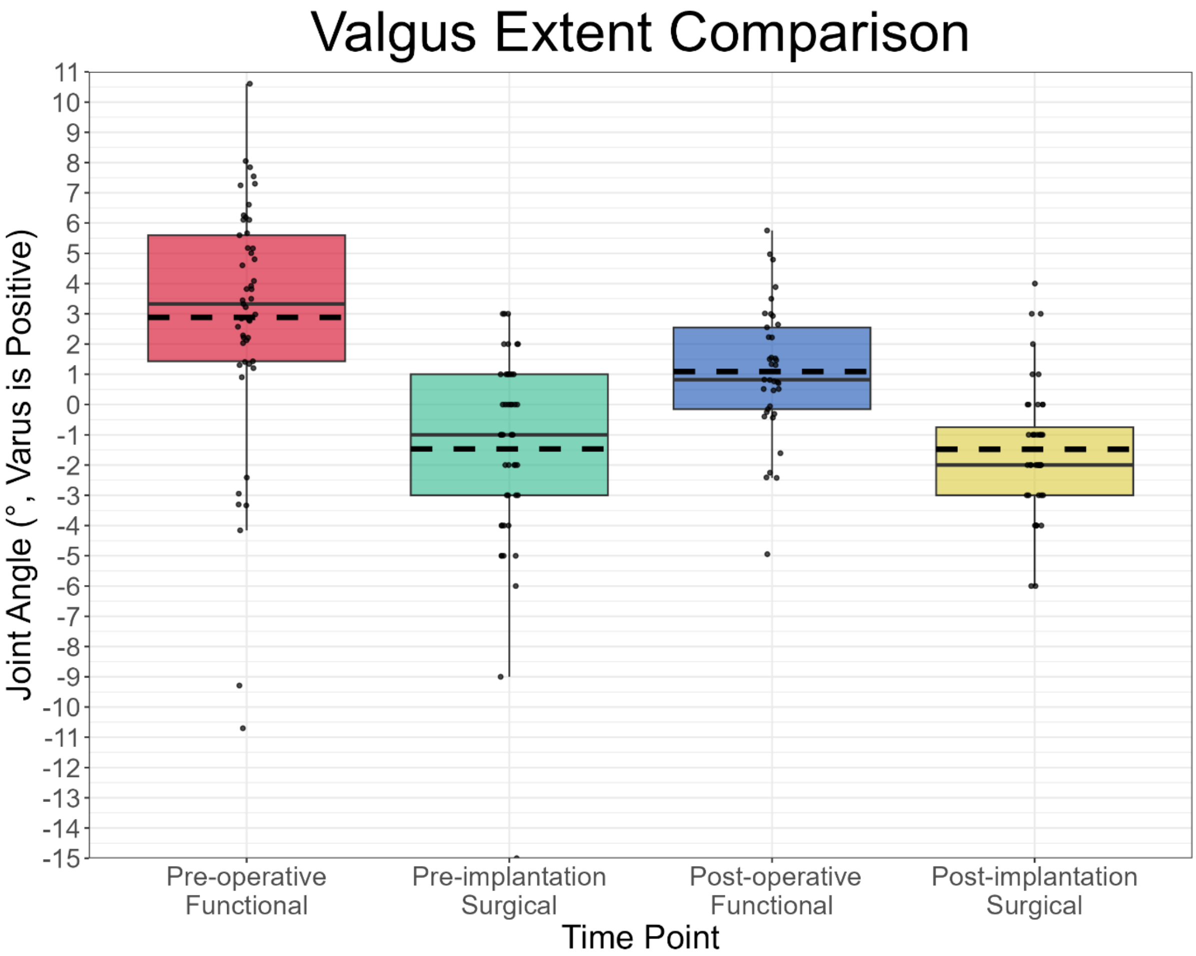


Figure 4.5. *Boxplot of the resulting hip-knee-ankle (HKA) angle in the valgus stress state across the preoperative, intraoperative and postoperative settings. Each pair of measurements (except preoperative surgical and post-implantation surgical) was statistically significantly different to each other (p < 0.05).*

Table 4.4. *Mean preoperative and 12-month postoperative Knee injury and Osteoarthritis Outcome Score (KOOS) subdomain scores and the difference in scores between the two time points. ADL, activities of daily living; QoL, quality of life; IQR, interquartile range*

KOOS Subdomain	Preoperative	Postoperative (12-Month)	*P* value	Difference
Pain	42.9 (IQR 19.4)	88.4 (IQR 11.1)	< 0.001	45.5 (IQR 27.8)
Symptoms	43.9 (IQR 32.1)	84.0 (IQR 14.3)	< 0.001	40.1 (IQR 39.3)
ADL	46.5 (IQR 25.5)	88.6 (IQR 14.1)	< 0.001	42.1 (IQR 36.8)
QoL	25.3 (IQR 31.3)	77.6 (IQR 31.3)	< 0.001	52.3 (IQR 50.0)
Sports	19.8 (IQR 31.7)	77.8 (IQR 28.3)	< 0.001	59.4 (IQR 50.0)

Table 4.5. *Correlation of stress HKA angles and laxity data to the five Knee injury and Osteoarthritis Outcome Score (KOOS) subdomains preoperatively and postoperatively, and to the change in the scores from pre-to-postoperative state for these subdomains. The stress hip-knee-angle (HKA) angles data was measured in the preoperative, intraoperative and postoperative settings and the differences were calculated between pre-to-intraoperative states and pre-to-postoperative states. ADL, activities of daily living; QoL, quality of life. Pre-FL, preoperative functional laxity; Pre-SL, preoperative surgical laxity; Post-FL, postoperative functional laxity; Post-SL, postoperative surgical laxity. * Indicates P value < 0.05.*

	Postoperative (12 months)					Improvement				
	Pain	Symptoms	ADL	QOL	Sports	Pain	Symptoms	ADL	QOL	Sports
Preoperative										
Varus stress HKA	0.05	−0.07	0.04	−0.07	0.15	−0.11	−0.14	−0.05	0.00	0.10
Valgus stress HKA	−0.01	−0.28*	−0.05	−0.31*	−0.01	−0.11	−0.18	−0.12	−0.14	0.04
Joint laxity (Pre-FL)	0.11	0.33*	0.15	0.38*	0.23	0.03	0.08	0.09	0.19	0.05
Preimplantation (intraoperative)										
Varus stress HKA	0.12	0.00	0.17	−0.16	0.28	−0.12	−0.07	0.01	−0.09	0.22
Valgus stress HKA	0.04	−0.15	−0.05	−0.23	0.01	−0.08	−0.13	0.01	−0.02	0.17
Joint laxity (Pre-SL)	0.13	0.22	0.27	0.06	0.39*	−0.12	0.00	−0.02	−0.13	0.06
Postimplantation (intraoperative)										
Varus stress HKA	0.20	0.35*	0.15	0.15	0.16	−0.05	0.06	−0.10	−0.08	−0.27
Valgus stress HKA	−0.02	−0.23	−0.18	−0.32*	−0.14	0.22	0.24	0.20	0.25	0.13
Joint laxity (Post-SL)	−0.18	−0.37*	−0.20	−0.25	−0.21	0.15	0.10	0.15	0.22	0.34
Postoperative										
Varus stress HKA	0.09	0.01	−0.06	−0.10	−0.15	−0.11	−0.27	−0.03	−0.18	−0.05
Valgus stress HKA	0.00	−0.05	−0.12	−0.11	−0.02	−0.27	−0.30	−0.29	−0.25	−0.13
Joint laxity (Post-FL)	0.15	0.09	0.13	0.02	−0.20	0.24	0.15	0.35*	0.19	0.28
Difference (preimplantation)										
Varus stress HKA	−0.12	−0.13	−0.22	0.13	−0.23	0.11	0.00	−0.03	0.15	−0.04
Valgus stress HKA	−0.07	−0.22	−0.08	−0.16	0.02	−0.04	−0.10	−0.13	−0.14	−0.06
Joint laxity	0.02	−0.05	0.09	−0.17	0.14	−0.11	−0.08	−0.07	−0.20	0.01
Difference (postimplantation)										
Varus stress HKA	−0.05	0.04	0.02	0.03	−0.16	0.05	0.09	0.12	−0.05	−0.06
Valgus stress HKA	−0.15	0.04	−0.11	0.10	−0.09	0.01	0.10	−0.07	−0.02	−0.04
Joint laxity	0.00	−0.03	−0.07	0.13	0.13	−0.01	−0.08	−0.15	0.03	0.04
Difference (functional)										
Varus stress HKA	−0.19	−0.13	−0.21	−0.20	0.05	−0.08	0.02	−0.16	−0.02	0.13
Valgus stress HKA	−0.19	−0.30	−0.22	−0.41*	−0.17	−0.04	−0.05	−0.10	−0.15	0.10
Joint laxity	0.06	0.23	0.13	0.35*	0.37	−0.07	0.03	−0.04	0.15	−0.04
Difference (surgical)										
Varus stress HKA	0.07	0.00	0.20	−0.18	0.37*	−0.10	0.07	0.00	−0.11	−0.11
Valgus stress HKA	0.09	0.03	0.08	−0.04	0.13	0.06	0.13	0.07	0.18	0.39*
Joint laxity	0.07	0.05	0.21	−0.10	0.36*	−0.20	−0.06	−0.09	−0.15	−0.26

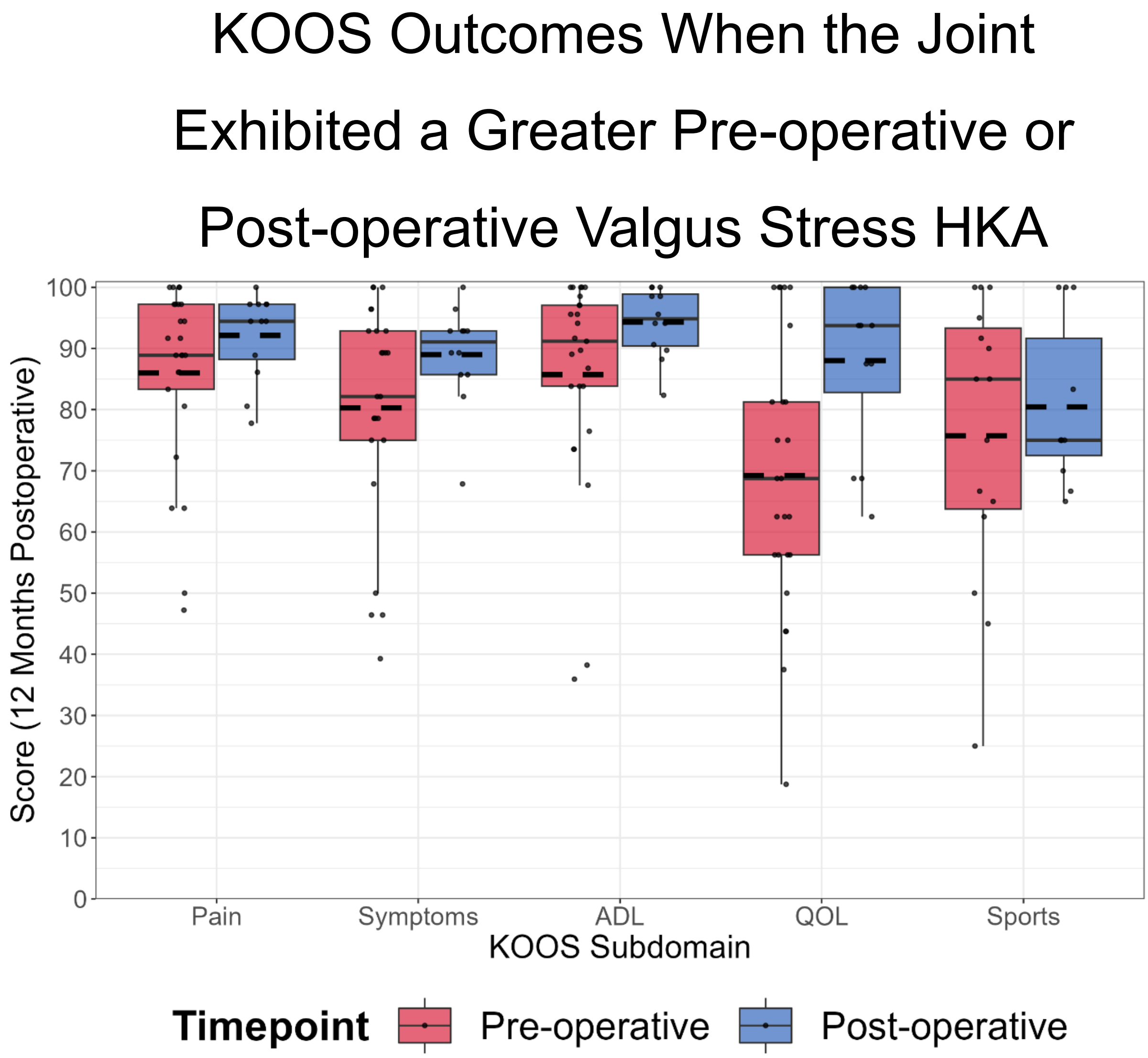


Figure 4.6. *Boxplot of patient Knee injury and Osteoarthritis Outcome Score (KOOS) subdomain scores at 12-months post-TKA based on whether patients had greater functional valgus stress hip-knee-ankle (HKA) angle preoperatively (red) or postoperatively (blue).*

** Denotes a statistically significance. Patients with greater functional valgus stress preoperatively than postoperatively had a mean postoperative quality of life (QoL) score of 69.2, whereas patients with a greater postoperative measurement exhibited a mean QoL score of 88.0 (p = 0.02). ADL, activities of daily living.*

4.5. Discussion

The primary finding was that Pre-SL (8.1°, IQR 2.0°) was significantly greater than Pre-FL (3.8°, IQR 2.9°), on average, with 92% of knees displaying greater Pre-SL than Pre-FL. Further, Pre-SL deemed all knees in anaesthetised patients correctable to ±3° from neutral to the mechanical axis, while the preoperative Pre-FL analysis in awake patients indicated only 45% as correctable. This has implications for TKA target alignment and planning as the intraoperative measurement may be excessive and overestimate the correctability of coronal deformities and knee laxity. While literature acknowledges predictive capabilities of surgeon-assessed intraoperative laxity for determining the magnitude of required soft-tissue release [375], [376], [377], questions remain about whether it measures functional knee laxity [370]. Post-SL (3.5°, IQR 2.3°) was greater than Post-FL (2.5°, IQR 2.7°) in all joints, highlighting that the discrepancy stems from the differing laxity assessment techniques. The functional laxity measurements involve applying controlled varus and valgus stresses to conscious patients, proven reliable for evaluation of knee laxity and joint gaps due to the measurable and standardised force application [263], [264]. However, potential subconscious muscle contractions in awake patients, patient discomfort, and tolerance to loading may limit the laxity range. Intraoperatively, SL assessment involved manual stress application to anaesthetised patients. These clinician-applied stresses are subjective, exhibit intra- and inter-surgeon variability and may be influenced by experience [367], [378].

The significantly greater mean SL difference than FL difference was driven by the pre-implantation SL and FL differences. While preoperative and pre-implantation varus stress HKA angles were comparable, the substantial 4.4° difference in valgus stress HKA reflects Clarke et al's findings of significantly greater angular displacement during intraoperative valgus stress [370]. The post-implantation laxity difference was also similar to the 0.6° implied by Clarke et al, despite their use of manual forces for the clinical laxity assessment. These findings may reflect subconscious muscle activations with valgus stress [379], potentially explaining the similar varus but different valgus stress HKA angles we observed between the preoperative and pre-implantation settings.

Pre-FL displayed significant relationships to PROMs, with correlations between Pre-FL and postoperative KOOS QoL (r=0.38) and Symptoms (r=0.33), suggesting that patients with greater preoperative knee laxity experienced enhanced quality of life and fewer knee OA symptoms postoperatively. Conversely, negative relationships between preoperative functional valgus stress HKA angle and KOOS QoL (r=-0.31) and Symptoms (r=-0.28) indicate that these superior outcomes are more prominent for joints with greater preoperative medial compartment laxity. Further research is required to understand this phenomenon, but possible explanations include greater preoperative laxity enabling easier joint correction during TKA without soft tissue releases, correction of preoperative laxity with balanced TKA improving joint stability and confidence and/or patients with greater laxity having more compliant tissues, achieving greater range of motion.

Post-FL was the only significant predictor of patient outcome improvement, specifically KOOS ADL (r=0.35). Our study, like Hamilton et al [272], found no relationship between postoperative laxity in awake patients and postoperative outcomes. In contrast, Mizu-uchi et al reported that greater postoperative valgus laxity correlated with higher postoperative symptoms and satisfaction scores [273]. These conflicting findings may stem from the use of varying PROMs questionnaires. Correlations of Post-SL and post-implantation surgical varus stress HKA measurements with KOOS Symptoms (r=-0.37 and r=0.35, respectively) indicate that maintaining lower post-implantation laxity with some residual lateral compartment laxity enhances outcomes. This complements literature noting that residual post-implantation medial laxity or tightness negatively impacts 1- and 2-year postoperative KOOS Pain [232], [233], [271], and 1-year postoperative KOOS ADL outcomes [271]. The absence of a relationship between Pre-SL and outcomes in our study may stem from the variability or inability to accurately quantify applied force during Pre-SL measurement. VERASENSE and robotic systems enable force and displacement measurement during gap balancing and their use displays comparable short-term outcomes to manually-balanced TKAs [258], [380]. However, the application of force to anaesthetised patients may still exceed individual ligament pain tolerances. Constitutional ligament tension is likely patient specific, highlighting the importance of preoperative standardised assessments, such as Pre-FL in awake patients, which provide greater control and are more indicative of patient outcomes post-TKA. Though not always practical in common practice, they can serve as valuable research tools to better understand patient-specific ligament properties and make TKA balancing more scientific and objective.

No significant relationships were found between pre-implantation or surgical joint laxity differences and PROMs. However, a moderate correlation was observed between FL difference and postoperative KOOS QoL (r=0.35), driven by the difference between preoperative and postoperative valgus stress HKA angle (r=-0.41). Patients with greater postoperative varus HKA angles during valgus stress, than preoperative, experienced superior postoperative KOOS QoL outcomes, implying that decreasing medial compartment laxity with TKA may enhance outcomes. These findings highlight the importance of medial compartment stability throughout knee ROM [232], given the comparative tolerance of lateral laxity [274], [381]. This might be attributed to greater native lateral laxity [235], [382] and diminishing lateral collateral ligamentous laxity post-TKA [249], suggesting that medial tibiofemoral joint stability should be prioritised during surgical planning and technique.

Limitations

Our study has several limitations. The stress radiology protocol requires applying a controlled force of up to 150N or the patient's maximum threshold, potentially affecting reliability if the ideal patient specific force is not used. While the final applied load was not recorded, studies applying 150N for coronal laxity assessment in osteoarthritic knees report no significant discomfort [260], [273], [372], [373]. The Telos SD-900, effective for knee laxity research [369], [372], [260], [264], [383], [274], [384], is labour-intensive and not commonly available in clinical practice. More scalable imaging protocols like those by Jagota et al [385] and Tokuhara et al [386], involving knee distraction with ankle weights, are needed for broader clinical application. The limited sample sizes of 44 and 37 out of 49 joints with post-implantation measurements and postoperative stress radiographs, respectively, were also a constraint, partly due to the time-consuming protocol and retrospective analysis, which may impact results [387]. The surgeon's intraoperative laxity assessment technique is subjective and may vary between surgeons. However, the surgeon has 15 years of experience with a high TKA volume. Pre-implantation intraoperative laxity assessments were performed after medial arthrotomy but before anterior cruciate ligament or osteophyte removal, and ligament release, which may have contributed to the variations between preoperative and intraoperative laxities due to soft tissue release during exposure. Additionally, specific anaesthesia protocol data was not collected. As a result, the potential influence of variations in anaesthetic agents on neuromuscular relaxation, and thus on intraoperative laxity, is unknown. The effect of different anaesthetic agents on coronal knee laxity is not well-established in literature, warranting further investigation to clarify this relationship. Lastly, Pre-FL measurements may not accurately reflect the patient's constitutional laxity due to the diseased state of the knee. Nevertheless, we observed greater correlations between PROMs and awake Pre-FL than anaesthetised Pre-SL.

4.6. Conclusion

Preoperative assessment of coronal knee laxity in an awake patient is considerably different from intraoperative laxity measurements with patients under anaesthesia. While preoperative laxity assessment better predicts postoperative patient outcome and is arguably a more suitable measurement for the native and functional coronal knee laxity, further research is required to understand the factors contributing to this relationship. The stress radiology protocol used for preoperative and postoperative laxity assessment enables a consistent comparison of laxity before and after TKA and allows for soft tissue informed preoperative planning.

Chapter 5:

Intra-observer and Inter-observer validation of a three-dimensional to two-dimensional registration technique for anatomical assessment of knees undergoing total knee arthroplasty

Ishaan Jagota, Rami Al-Dirini, Mark Taylor

5.1. Abstract

Purpose

Accurate assessment of knee alignment and joint gaps is crucial for TKA research, planning and analysis. This study aimed to evaluate the intra-observer reproducibility and inter-observer reliability of a feature-based 3D-to-2D registration technique for evaluating tibiofemoral alignment and joint gaps in functional positions.

Methods

Thirteen patients undergoing TKA received preoperative CT scans and three functional X-rays (weight bearing, extension distracted, flexion distracted). Three-dimensional bone models were generated from the CT scans, and 3D-to-2D registration was performed to translate the bones to the functional positions. Intra-observer analysis was performed on a subset of seven knees, for which three engineers registered each knee twice with a three-week interval between registrations. Inter-observer reliability was assessed on all thirteen knees with initial registrations by two engineers that were reviewed and refined by two senior engineers. Tibiofemoral angular alignment (coronal, axial and sagittal) and medial and lateral joint gaps were measured and compared across registrations.

Results

Coronal plane measurements exhibited high reproducibility and reliability across all positions, with mean absolute differences below 1° for tibiofemoral alignment and below 1 mm for joint gaps. Coronal alignment also displayed excellent inter-observer intraclass correlation coefficient (ICC) values across all positions (ICC > 0.98). Axial and sagittal measurements displayed moderate variability (mean absolute differences of 2.7°-4.7°; ICCs ≥ 0.74) in most positions except sagittal flexion in the flexion distracted position (ICC = 0.19).

Conclusions

The validated 3D-to-2D registration technique demonstrates robust reproducibility and reliability for coronal plane alignment and joint gaps in functional positions, supporting its use in TKA planning and analysis. While axial and sagittal measurements exhibited greater variability, they remained clinically acceptable. This technique offers a scalable and accessible solution for integrating functional 3D assessments into preoperative workflows.

Level of Evidence: Level II

5.2. Introduction

With limitations of two-dimensional (2D) radiographs in describing three-dimensional (3D) knee anatomy, 3D imaging, such as computed tomography (CT) and magnetic resonance imaging (MRI) are becoming increasingly widespread in total knee arthroplasty (TKA) [388], [389]. While such imaging modalities provide valuable anatomical information and enable preoperative and postoperative 3D analyses, they typically capture the patient in a supine position, thus lacking the functional context of the weight bearing knee. Increasing efforts are being made to assess the knee in functional or stressed positions to better understand native preoperative alignment, kinematics, and soft tissue behaviour [260], [390], [391]. Additionally, research has shown that reproducing native knee anatomy can influence patient outcomes [305], [392], which underscores the importance of assessing these factors preoperatively. While such 3D functional analyses may guide alignment strategies and provide insight into postoperative patient outcomes, much of this research is still evolving, and there is a need to integrate these insights into clinical practice to optimise preoperative planning.

In clinical workflows, CT imaging is often captured alongside functional X-rays to provide a comprehensive view of knee morphology. Image processing techniques can be employed to register the 3D morphology derived from the CT to the 2D X-rays, enabling a more detailed understanding of knee alignment and behaviour. Three-dimensional-to-2D registration is a key technique for translating 3D anatomical information into various functional positions. This process can be either feature-based or intensity-based. Feature-based registration aligns key anatomical landmarks or contours between the 3D model and 2D radiographs [390], while intensity-based registration typically employs algorithms to match image pixel intensities of the digitally reconstructed radiographs (from the CT or MRI) to the 2D radiograph through an iterative process [393]. While feature-based is labour intensive, it displays greater reliability and requires fewer computational resources than intensity-based registration, thus making it more accessible [393]. Although accuracy can be improved by registering 3D models to radiographs across multiple views of a given position, single-plane registration is compatible with conventional radiography machines [394], [395].

Single-plane, feature-based 3D-to-2D registration techniques offer an accessible approach to assess 3D knee morphology in functional positions, presenting a relatively low-resource solution. Despite their potential to provide a detailed understanding of knee behaviour and to guide preoperative analysis and planning, there is limited literature evaluating the use and validation of such techniques when applied to arthritic knees undergoing TKA. Intra-observer and inter-observer validation of this process could enhance both research and clinical practice, supporting more personalised and precise preoperative TKA planning.

The aim of this study was to investigate the intra- and inter-observer reliability of tibiofemoral angular measurements and joint gaps obtained during feature-based 3D-to-2D registration using CT and coronal radiographs for osteoarthritic knees undergoing TKA. Measurements were assessed in three functional positions; weightbearing, extension distracted, and flexion distracted. It is hypothesised that coronal plane measurements will exhibit high reproducibility and reliability, while moderate but clinically acceptable results will be observed in the axial and sagittal planes.

5.3. Methods

A series of 13 patients undergoing TKA for knee osteoarthritis who received preoperative CT and X-ray imaging for surgical planning were included in this study. Patients were excluded if they were unable to complete imaging due to contraindications, refusal or limited access and also if they displayed signs of inflammatory arthritis or extra-articular deformities. Patients undergoing a complex primary TKA or unicompartmental to TKA were also excluded. Of the 13 patients, 7 were evaluated for intra-observer reproducibility, and all 13 were assessed for inter-observer reliability. These sample sizes were based on published intra-observer and inter-observer reliability assessments [371]. The ethics for data collection and analysis was approved by the Bellberry Human Research Ethics Committee (application number 2012-03-710, Sydney, Australia).

Radiology capture and image processing

All patients received a bilateral long-leg CT scan with a maximum slice thickness of 1.25mm in the transverse plane and 1mm in the coronal and sagittal planes. Patients also received three functional antero-posterior radiographs; one in a weightbearing position and two stressed radiographs in extension and flexion. In extension, the patient stood on a platform with their non-operative leg and the operative leg free hanging in full extension. They were provided a balance bar for additional support while standing on their non-operative leg. In flexion, the patient sat on a tall stool to ensure their feet were unable to reach the ground. The knee joint was passively flexed to 90° and both legs were relaxed and free hanging (**Figure 5.1**). A standardised axial joint distraction force was applied to the operative leg using a 2.5 kg ankle weight during both distracted radiographs. The applied mass was 1 kg greater than outlined in Tokuhara et al's protocol, accounting for the different study populations. Tokuhara et al investigated healthy knees [386], whereas our protocol was applied to patients who had end-stage osteoarthritis of the knee undergoing TKA, who are typically either overweight or obese (body mass index [BMI] ≥ 25) [396].

Simpleware ScanIP (*version M-2017.06, Synopsys, Inc.,* Mountain View, USA) was used to segment and landmark the CT scans, producing 3D reconstructed bone models. The tibial and femoral bone models and landmarks were quality checked by a second engineer to ensure accuracy. The key landmarks are displayed in **Figure 5.2**. The 3D-to-2D registration process was also performed using Simpleware ScanIP and involved contour matching of the 3D tibial and femoral bone models to the respective bones in each functional X-ray (**Figure 5.3**).

The patients' native medial and lateral joint gaps were calculated in both extension and flexion distracted positions and were defined as the distance between the most inferior point on the respective femoral condyle and a plane along the proximal tibial plateau. These were determined with a custom script developed using Posit RStudio (Boston, United States). The tibial plane was defined using reference landmarks for the medial and lateral edges of the proximal tibial surface as well as an anterior and posterior landmark on the lateral compartment of the proximal tibial surface. The lateral compartment was used to obtain a reference slope as it was the unaffected side for the majority of joints. These landmarks are displayed in **Figure 5.4**.

The presence of osteophytes may result in ligament tenting, which can reduce the medial and lateral tibiofemoral joint gaps and final alignment. A geometric osteophyte correction algorithm was developed and implemented using Posit RStudio to model the post-osteophyte removal joint gaps and alignment in extension and flexion. This algorithm measured the direct and wrapped ligament paths. The length of the pseudo, direct path was defined as the straight-line distance from the origin to the insertion point of the medial collateral ligament (MCL) and the lateral collateral ligament (LCL). The wrapped path was defined as the shortest possible path from the origin to the insertion points of the MCL and LCL, whilst wrapping around any bony tissue. The increase in medial and lateral joint gaps due to osteophyte removal were defined as the difference in the lengths of the direct and wrapped paths for the MCL and LCL. The native joint gaps along with osteophyte correction provided the final medial and lateral joint gaps in both extension and flexion. The corrected positions were also used to calculate tibiofemoral coronal, axial and sagittal alignment.

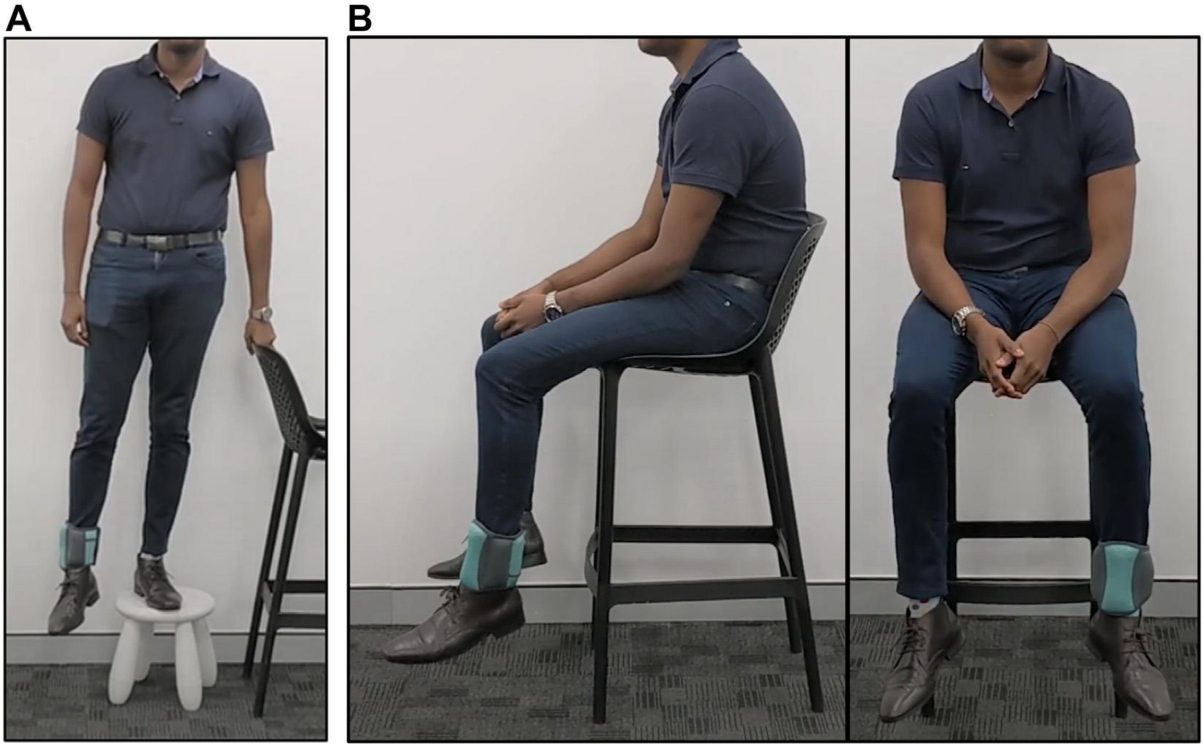


Figure 5.1. *A) Extension distracted position and B) Flexion distracted position.*

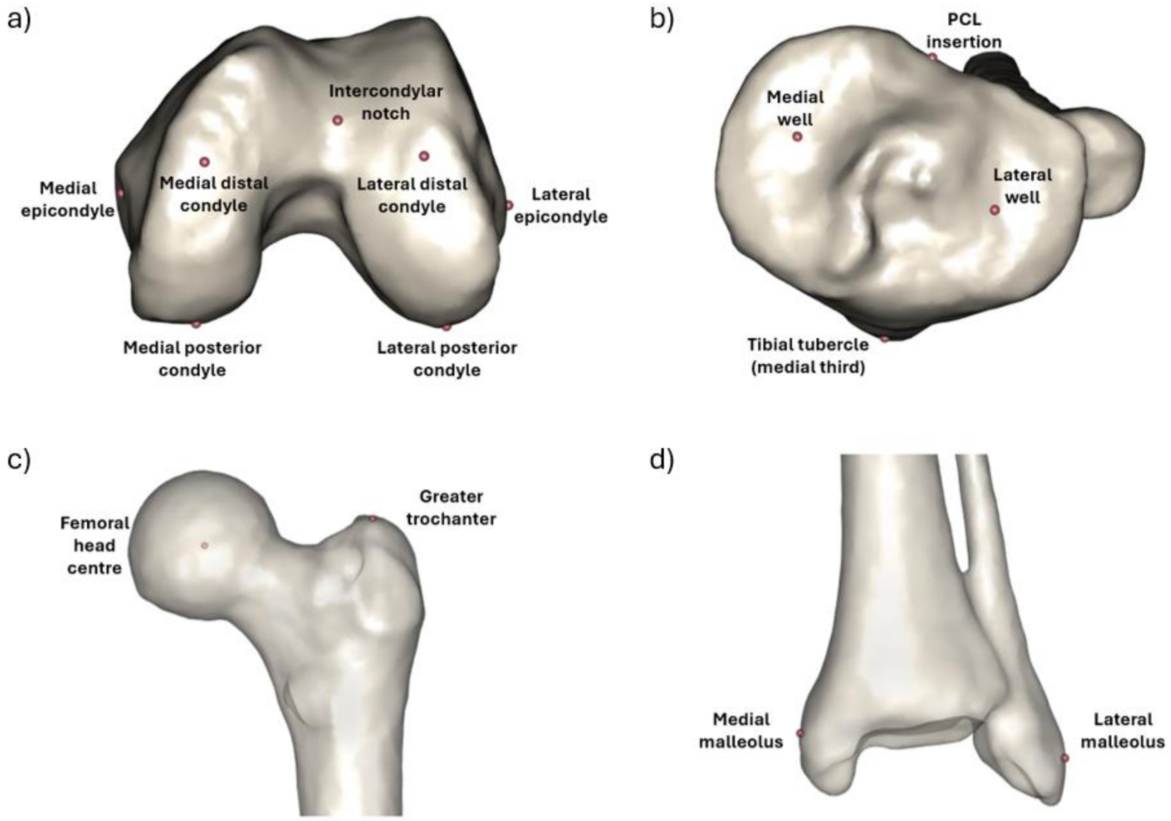


Figure 5.2. *Representation of the key landmarks on the a) distal femur, b) proximal tibia, c) proximal femur and d) distal tibia.*

PCL, posterior cruciate ligament.

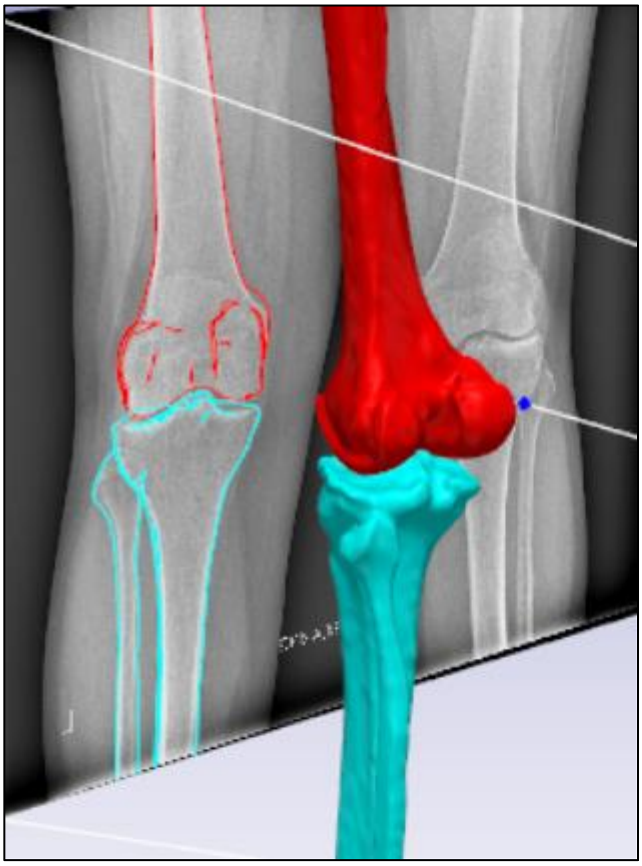


Figure 5.3. *Representation of the feature-based 3D-to-2D registration process as performed using Synopsis ScanIP. The contours of the femur (red) and tibia (blue) bone reconstructions are projected on the 2D coronal radiograph. The positions of these bone models are then adjusted by engineers until the contours of the models match the features of the corresponding bones in the radiograph, ultimately providing the 3D tibiofemoral anatomy in the functional position.*

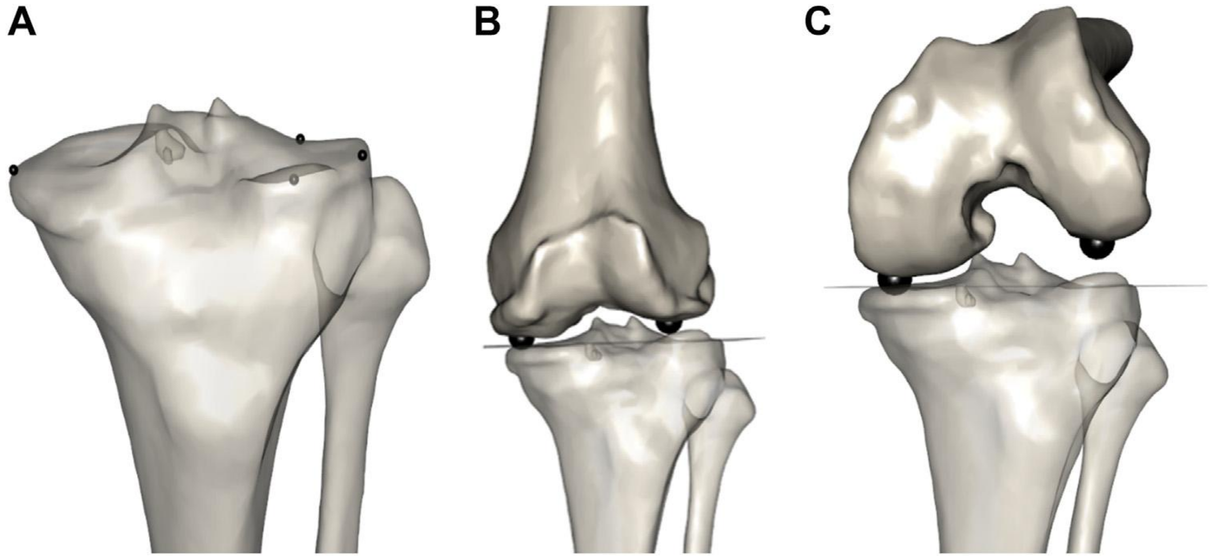


Figure 5.4. *A) Representation of the 4 points utilised to define the proximal tibial plane B) Extension distracted reconstruction. The two black spheres on the distal femur represent the most inferior points on the medial and lateral femoral condyles with the knee in extension C) Flexion distracted reconstruction. The two black spheres on the posterior femur represent the most inferior points on the medial and lateral femoral condyles with the knee in flexion.*

Intra-observer reproducibility

Each knee was assessed by three independent observers, all of whom were trained engineers with experience with 3D-to-2D image registration. For each knee, the observers registered the tibial and femoral bone models to the three functional X-ray positions (weightbearing, stressed extension, and stressed flexion) twice. Recall bias was minimised by maintaining a minimum interval of three weeks between the two registration attempts for each observer. Five key measurements were calculated on each knee: tibiofemoral alignment in the coronal, sagittal, and axial planes, as well as the medial and lateral intercompartmental joint gaps (**Table 5.1**). The absolute differences in these measurements between the two registration attempts were calculated for each functional position, and the mean absolute difference and standard deviation were determined across all knees to quantify reproducibility.

Inter-observer reliability

First, two observers registered the bone models to the functional X-ray positions. These registrations were then reviewed by a third and fourth observer, who refined the position where necessary. The five tibiofemoral alignment and joint gap measurements (**Table 5.1**) were then calculated for each functional position, and the absolute differences between the measurements across registrations of the two pairs of observers were determined. The mean absolute difference and standard deviation were calculated for each functional position across the series. Additionally, the inter-observer intraclass correlation coefficient (ICC) was determined as a measure of reliability. With consideration to guidelines published by Koo and Li [397] and Walter et al [398], ICC values of <0.5 were defined as poor, 0.5 to 0.7 as moderate, 0.7 to 0.9 as very good and 0.9 to 1 as excellent.

All statistical analyses were performed using Posit R Studio (Boston, United States) v1.2.5019. The demographics of the intra-observer and inter-observer patient groups are displayed in **Table 5.2**.

Table 5.1. *Definitions of the tibiofemoral angular measurements and joint gaps determined during both intra-observer and inter-observer analyses.*

Measurement	Description
Coronal Hip-Knee Ankle	The angle subtended by the femoral mechanical axis and tibial mechanical axis on the coronal plane. The femoral mechanical axis was defined as the line joining the centre of the femoral head to the centre of the intercondylar notch. The tibial mechanical axis was defined as the line joining the tibial eminence and the midpoint of the medial and lateral malleoli
Sagittal Long Leg Flexion	The angle subtended by the femoral mechanical axis and tibial mechanical axis on the sagittal plane.
Axial Tibiofemoral Rotation	The angle subtended by Insall's axis and the surgical transepicondylar axis (sTEA). Insall's axis was defined as the line joining the posterior collateral ligament (PCL) insertion point and the medial third of the tibial tuberosity [352]. sTEA was defined as the line joining the medial sulcus and lateral epicondyle landmarks.
Medial Joint Gap	The distance between the most inferior point on the medial femoral condyle and the plane along the proximal tibial plateau.
Lateral Joint gap	The distance between the most inferior point on the lateral femoral condyle and the plane along the proximal tibial plateau.

Table 5.2. *Demographics of the study population for the intra-observer and inter-observer analyses. CT, computed tomography; HKA, hip-knee-angle; MPTA, medial proximal tibial angle; LDFA, lateral femoral distal angle; SD, standard deviation; IQR, interquartile range.*

Measurement	Intra-observer Assessment	Inter-observer Assessment
Joints	7	13
Left/Right	2/5	7/6
Age (Years)	66.0 (SD 8.4, IQR 5.3)	68.5 (SD 7.7, IQR 4.7)
CT HKA (° Varus)	3.6 (SD 4.9, IQR 5.2)	4.1 (SD 4.0, IQR 4.2)
MPTA (°)	86.5 (SD 1.2, IQR 0.8)	86.7 (SD 1.4, IQR 1.3)
LDFA (°)	86.5 (SD 2.1, IQR 2.6)	86.1 (SD 1.9, IQR 2.6)

5.4. Results

Intra-observer analysis

Table 5.3 summarises the mean errors between repeated observations for each of the three observers and across all observers combined, displaying high reproducibility. The coronal HKA angle exhibited particularly low intra-observer variability with combined mean differences of 0.8° ± 0.6°, 0.6° ± 0.5° and 0.9° ± 0.6° for the weightbearing, extension distracted, and flexion distracted positions, respectively. The largest mean difference for HKA across all observers was in the flexion distracted position (1.1° ± 0.5°). Similarly, the medial and lateral joint gap displayed high reproducibility across all three positions with combined mean absolute differences of 0.6 mm ± 0.6 mm and 0.8 mm ± 0.7 mm , 0.7 mm ± 0.5 mm and 0.8 mm ± 0.5 mm, and 0.9 mm ± 1.0 mm and 0.9 mm ± 1.4 mm for weightbearing, extension distracted, and flexion distracted positions, respectively. Greater variability was observed in the long leg flexion and axial rotation measurements, with combined mean differences ranging between 2.7° to 4.7° and 2.7° to 3.6°, respectively.

Inter-observer analysis

The inter-observer reliability results of the tibiofemoral measurements between the two observer groups across the different positions are displayed in **Table 5.4**. In the coronal plane, sub-degree and sub-millimetre mean errors were observed in all positions. The HKA angle and lateral joint gap displayed excellent inter-observer reliability, while the medial joint gap exhibited very good reliability in extension distracted and flexion distracted positions and moderate reliability in weightbearing. Axial rotation displayed very good reliability (ICC ≥ 0.74 across all three positions), whereas sagittal long leg flexion was less reliable, especially in the flexion distracted position (ICC = 0.19). The observations of the two groups across the 13 joints are displayed in **Figure 5.4**.

Table 5.3. *Intra-observer reproducibility results, displaying the mean absolute differences (± standard deviation) in tibiofemoral alignment and joint gap measurements across three functional positions (weightbearing, extension distracted, and flexion distracted) for 7 knees. The results are shown for each of the three observers (A, B, and C) individually, as well as for all three observers combined (n = 21).*

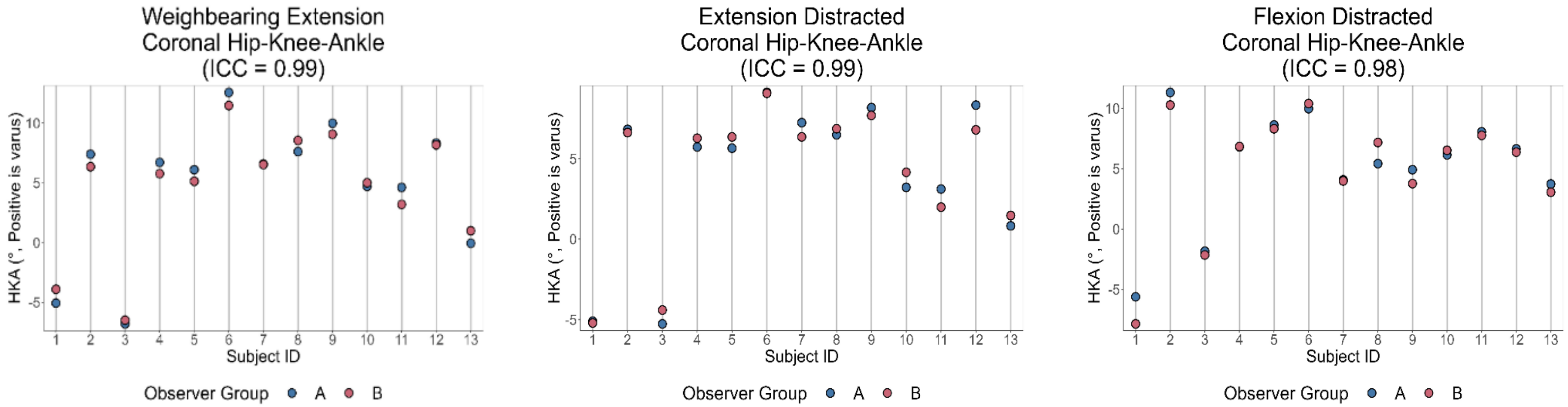
Measurement	**Position**	**Observer**			
		Combined (n = 21)	A (n = 7)	B (n = 7)	C (n = 7)
Coronal Hip-Knee Ankle (°)	Weightbearing	0.8 (± 0.6)	0.7 (± 0.5)	0.7 (± 0.5)	1.0 (± 0.7)
	Extension Distracted	0.6 (± 0.5)	0.8 (± 0.6)	0.5 (± 0.3)	0.5 (± 0.5)
	Flexion Distracted	0.9 (± 0.6)	1.1 (± 0.5)	1.0 (± 0.7)	0.6 (± 0.4)
Sagittal Long Leg Flexion (°)	Weightbearing	2.7 (± 3.0)	2.0 (± 1.4)	3.5 (± 4.5)	2.7 (± 2.5)
	Extension Distracted	3.1 (± 2.1)	3.6 (± 2.1)	3.7 (± 2.2)	2.1 (± 1.9)
	Flexion Distracted	4.7 (± 3.9)	3.7 (± 3.9)	4.4 (± 3.4)	6.0 (± 4.4)
Axial Tibiofemoral Rotation (°)	Weightbearing	3.6 (± 3.8)	4.8 (± 5.0)	2.4 (± 1.4)	3.8 (± 4.3)
	Extension Distracted	3.5 (± 2.5)	3.8 (± 3.4)	3.2 (± 1.9)	3.4 (± 2.1)
	Flexion Distracted	2.7 (± 1.7)	1.9 (± 0.9)	3.4 (± 2.0)	2.7 (± 2.0)
Medial Joint Gap (mm)	Weightbearing	0.6 (± 0.6)	0.6 (± 0.7)	0.8 (± 0.6)	0.4 (± 0.3)
	Extension Distracted	0.7 (± 0.5)	0.7 (± 0.6)	0.6 (± 0.4)	0.7 (± 0.5)
	Flexion Distracted	0.9 (± 1.0)	1.3 (± 1.1)	1.0 (± 1.3)	0.4 (± 0.3)
Lateral Joint Gap (mm)	Weightbearing	0.8 (± 0.7)	0.7 (± 0.9)	0.9 (± 0.7)	0.8 (± 0.5)
	Extension Distracted	0.8 (± 0.5)	0.8 (± 0.5)	0.8 (± 0.3)	0.6 (± 0.5)
	Flexion Distracted	0.9 (± 1.4)	0.7 (± 1.1)	1.3 (± 2.0)	0.8 (± 0.9)

Table 5.4. *Inter-observer reliability results, displaying the mean absolute differences (± standard deviation) in tibiofemoral alignment and joint gap measurements across three functional positions (weightbearing, extension distracted, and flexion distracted) for 13 knees. The intraclass correlation coefficient (ICC) and 95% confidence interval (CI) are also reported for each measurement.*

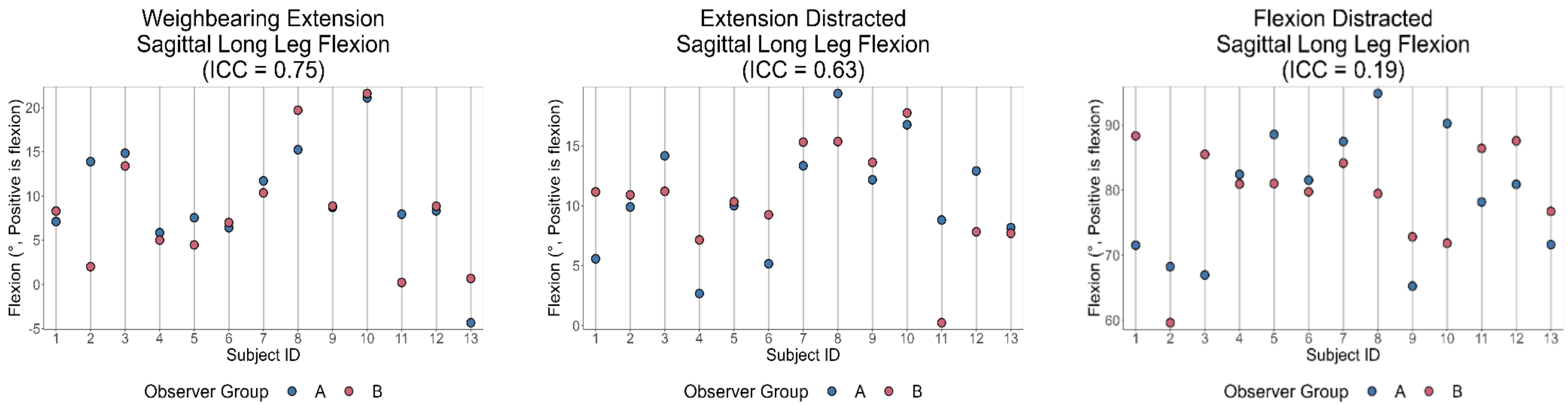
Measurement	Position	Mean (± SD)	ICC	95% CI
Coronal Hip-Knee Ankle	Weightbearing	0.8° (± 0.4°)	0.99	0.96 to 1
	Extension Distracted	0.6° (± 0.4°)	0.99	0.96 to 1
	Flexion Distracted	0.7° (± 0.7°)	0.98	0.94 to 0.99
Sagittal Long Leg Flexion	Weightbearing	3.0° (± 3.5°)	0.75	0.37 to 0.92
	Extension Distracted	3.1° (± 2.4°)	0.63	0.12 to 0.87
	Flexion Distracted	9.2° (± 6.1°)	0.19	-0.43 to 0.67
Axial Tibiofemoral Rotation	Weightbearing	2.8° (± 3.0°)	0.74	0.35 to 0.91
	Extension Distracted	2.9° (± 2.4°)	0.79	0.45 to 0.93
	Flexion Distracted	3.4° (± 2.0°)	0.81	0.49 to 0.94
Medial Joint Gap	Weightbearing	0.9mm (± 0.4 mm)	0.59	0.07 to 0.86
	Extension Distracted	0.8mm (± 0.4 mm)	0.80	0.46 to 0.93
	Flexion Distracted	0.8mm (± 0.5 mm)	0.75	0.37 to 0.91
Lateral Joint Gap	Weightbearing	0.8mm (± 0.4 mm)	0.96	0.87 to 0.99
	Extension Distracted	0.9mm (± 0.6 mm)	0.90	0.7 to 0.97
	Flexion Distracted	0.6mm (± 0.6 mm)	0.97	0.91 to 0.99

Figure 5.5. *Intra-class coefficient (ICC) dot plots of all observations of the two observer groups during inter-observer reliability testing of the tibiofemoral alignment and joint gaps for each functional position (weightbearing, extension distracted, and flexion distracted) across 13 joints. HKA, hip-knee-ankle.*

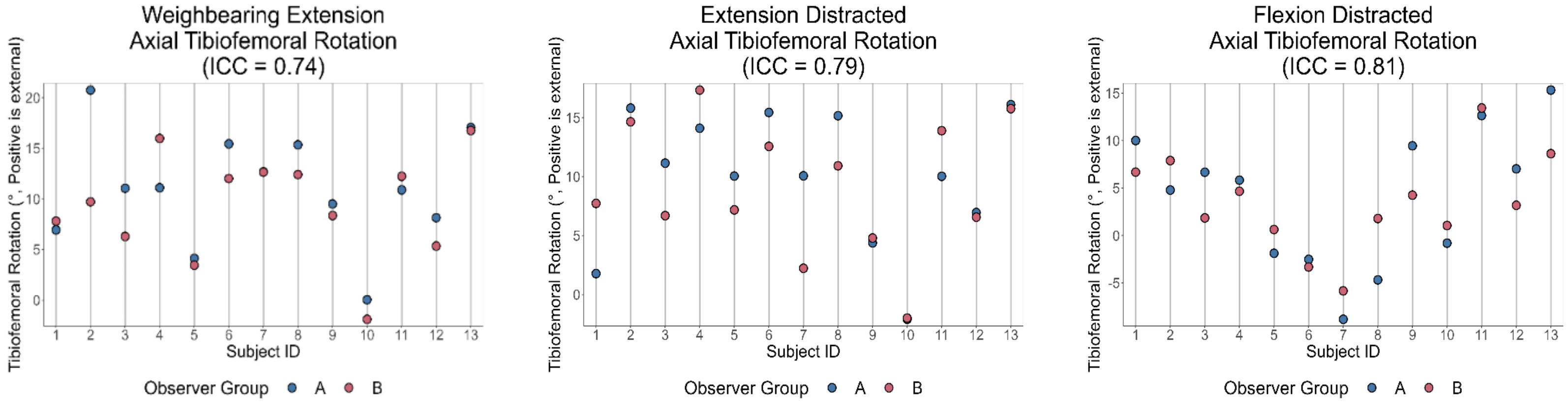
A) Coronal Hip-Knee-Ankle



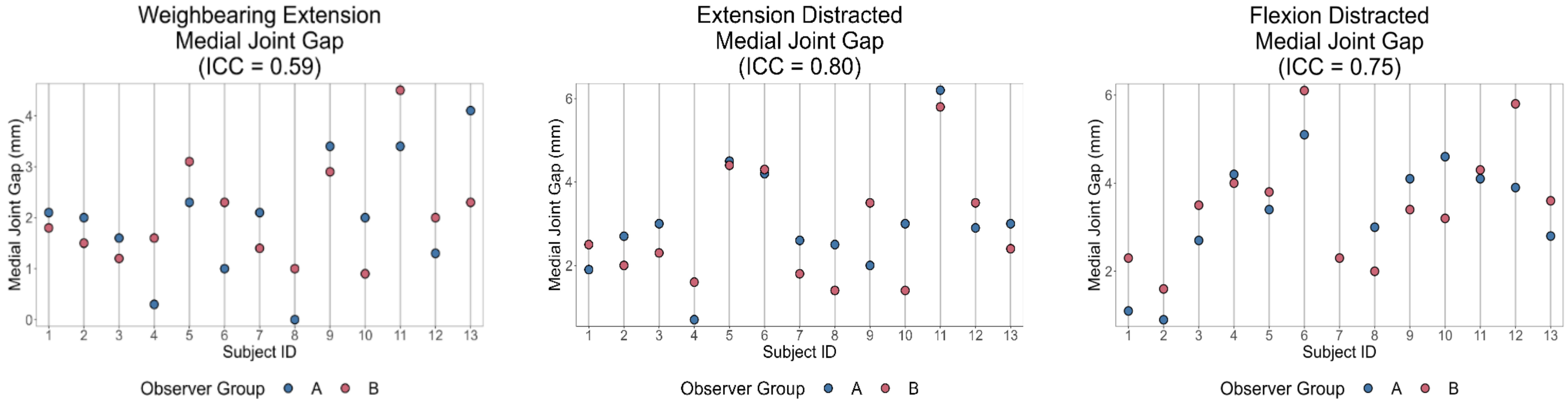
B) Sagittal Long Leg Flexion



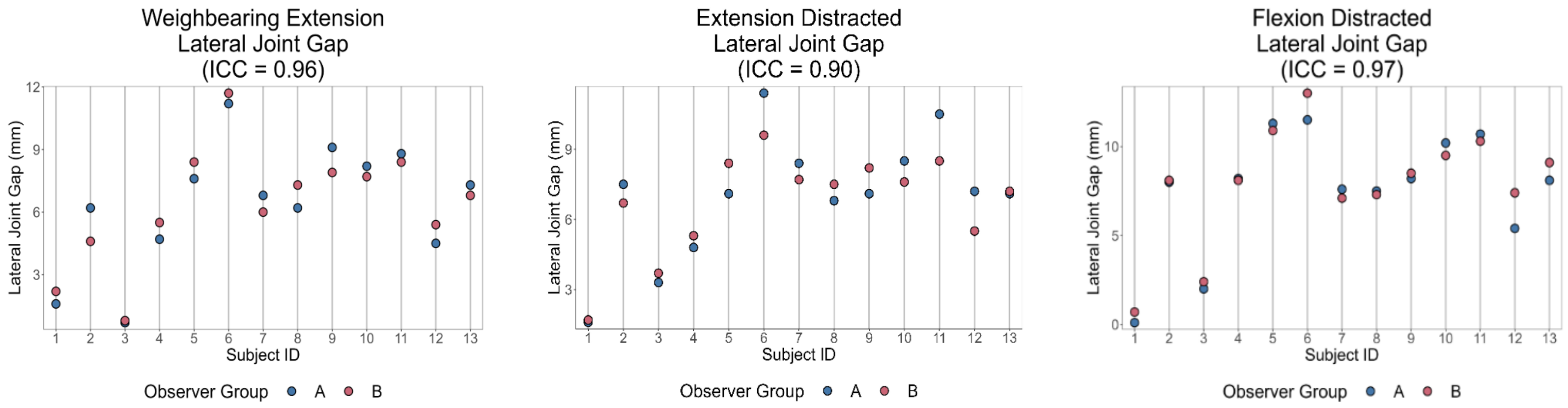
C) Tibiofemoral axial rotation



D) Medial Joint gap



E) Lateral joint gap



5.5. Discussion

The 3D-to-2D registration technique presented in this study demonstrates high intra-observer reproducibility and inter-observer reliability for tibiofemoral alignment, especially in the coronal plane, across all three functional positions. This suggests that the registration technique is consistent and reliable for evaluating coronal knee alignment and joint gaps in various functional states. While limited literature is available for direct comparisons of intra-observer reproducibility in 3D-to-2D knee joint registration, the inter-observer ICC values for tibiofemoral HKA and intercompartmental joint gaps in this study were comparable to the inter-rater ICC values for coronal plane measurements reported by Roth et al. (ICC = 0.96) using bi-planar EOS 3D-to-2D registration in weightbearing [390]. The exception was the moderate inter-observer ICC (0.59) for medial joint gap measurements in weightbearing. This is perhaps due to the less distinct medial compartment features in weightbearing radiographs for varus osteoarthritic knees, in which the medial compartment cartilage is worn. Such challenges have not been reported during the assessment of intercompartmental gaps using stress radiographs, such as the extension and flexion distracted positions used in this study [385], [386]. The robustness of coronal plane measurements underscores the strength of the registration technique for accurate preoperative analysis and planning in total knee arthroplasty.

While single-plane coronal X-rays for 3D-to-2D registration yield strong reproducibility and reliability for in-plane measurements such as coronal alignment and joint gaps, they are inherently less accurate for out-of-plane measurements. For axial rotation, mean absolute differences ranged between 2.7° and 3.6°, with very good inter-observer reliability across all positions. Despite similar intra-observer results, sagittal flexion showed more variability, with poor, moderate and very good inter-observer reliability in flexion distracted, extension distracted and weightbearing, respectively. This variability partially stems from the increased difficulty in identifying distinct distal femoral contours on coronal X-rays with the knee flexed, as well as the inherent limitations of single-plane 3D-to-2D registration techniques which exhibit lower accuracy for measurements impacted by out of plane translations [399], [400], [401], [402], [403], [404], [405]. While further research is required to optimise out-of-plane registration accuracy, the axial and sagittal tibiofemoral measurements are not currently routinely considered during TKA alignment planning. Encouragingly, the mean absolute differences align with accuracy thresholds of ±3° commonly used for surgical delivery technologies [406], [407]. Therefore, the method outlined in this study provides a viable foundation for the potential use of functional axial and sagittal tibiofemoral measurements in preoperative planning and analysis.

Alternative imaging techniques can improve the accuracy of 3D to 2D registration, while some may make it obsolete. Orthogonal biplanar radiographs or fluoroscopy have shown to reduce out-of-plane error during 3D-to-2D registration [408]. However, studies report that this can be achieved with imaging across two planes with an angular separation of just 15-30 degrees [394], [395]. EOS imaging technology (ATEC, Paris, France), with its orthogonal X-ray beams, enables biplanar 3D-2D registration [390] and, through statistical modelling, can render 3D anatomical reconstructions without the need for CT or registration [409]. However, both types of systems are limited in the functional positions they can assess due to hardware constraints [410], and they are less accessible and cost-effective than conventional radiographs [409]. CT and magnetic resonance imaging (MRI) captured in functional positions, such as sitting or standing, can bypass registration altogether. However, these systems are typically limited to a single position, requiring more radiation (for CT) and resources to evaluate multiple positions [412], [413], [414]. They are also less widely available and have a higher risk of movement during weightbearing scans [414]. Therefore, 3D-to-2D single-plane registration remains a practical and scalable solution for functional 3D assessment of knee anatomy in TKA planning.

Limitations

This study has some potential limitations. The 3D-to-2D registration was performed with coronal radiographs in weightbearing, extension distracted, and flexion distracted positions. Therefore, caution is needed when extrapolating these results to other functional positions or to radiographs taken in different planes. Additionally, this study focused on native osteoarthritic knees before TKA, and further research is needed to assess the reproducibility and reliability of the method in postoperative knees with implanted prostheses. This could be achieved by applying the same registration protocol to postoperative 3D models produced by the AURORA protocol [371]. Further, the segmentation and registration were performed by trained engineers. While this may limit the generalisability of the results to routine clinical settings, the authors believe that it should be the required standard for clinical use. Future research is required to investigate whether the experience of and background (e.g. engineer vs surgeon) of the observer impacts the reproducibility of the results presented in this study. The changes in joint gaps due to the osteophyte correction algorithm are a best estimate and require further validation through comparison of the algorithm's outputs to intraoperatively observed measurements.

5.6. Conclusion

The feature-based 3D-to-2D registration process outlined in this study demonstrated high intra-observer reproducibility and inter-observer reliability for tibiofemoral alignment and joint gap measurements, particularly in the coronal plane. Although axial and sagittal angular measurements displayed greater variability, they remained clinically acceptable. Therefore, this technique is suitable for guiding TKA research, analysis and surgical planning. While validated in weightbearing, extension distracted, and flexion distracted positions for pre-TKA osteoarthritic knees, further validation is required for other functional positions and post-TKA knees.

Chapter 6:

Coronal plane alignment of the knee classification system appears inadequate to effectively assess coronal joint laxity in osteoarthritic knees

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6.1. Abstract

Purpose

Achieving optimal mediolateral balance in extension and flexion is critical for improving outcomes in total knee arthroplasty (TKA). However, many knee classification tools, such as coronal plane alignment of the knee (CPAK), do not directly consider the soft tissue profile of the joint. This study evaluated the variation in tibiofemoral gap measurements across CPAK phenotypes and examined the relationships between preoperative tibiofemoral joint gaps and the arithmetic hip-knee-ankle angle (aHKA) and joint line obliquity (JLO), important for TKA planning and execution.

Methods

A retrospective analysis of 433 knees from the 360 Med Care CT database was performed. Patients received preoperative long-leg CT scans and extension and flexion stress radiographs. The CT scans were segmented and landmarked to produce three-dimensional bone models and derive anatomical measurements, including aHKA and JLO. The models were registered to the two distracted radiographs, and an osteophyte correction algorithm was applied to calculate the medial and lateral joint gaps in extension and flexion. Composite gap measurements (mean and difference) were also determined. Pearson's correlation and multivariate regression assessed the relationships between joint gaps and aHKA and JLO. Analysis of variance (ANOVA) compared joint gaps across CPAK groups.

Results

Small but statistically significant differences in joint gap measurements were observed between CPAK groups I and III, and II and III. Weak univariates correlations were observed between aHKA and joint gaps ($r \leq |0.32|$), with fewer significant relationships for JLO ($r \leq |0.15|$). Multivariate regression explained only 10.22% and 1.42% of aHKA and JLO variance, respectively.

Conclusions

While useful for describing coronal alignment, CPAK displayed limited predictive capability for preoperative tibiofemoral joint gaps in TKA patients. Direct assessment of joint gaps remains crucial for surgical planning. Future research should focus on integrating joint gap measurements with bony morphology in preoperative planning workflows to improve TKA personalisation.

Level of Evidence: Level II

6.2. Introduction

Recent philosophies in total knee arthroplasty (TKA) have marked a shift from traditional, fixed alignment methods toward more personalised, patient-specific approaches [80]. These individualised techniques aim to achieve better joint balance while minimising soft tissue release [294], [415]. Key to this balance is an understanding of the soft tissue tension of the knee through tibiofemoral joint gaps and/or knee laxity and its relationship to alignment and bony morphology, which play a critical role in postoperative TKA stability [232], [416]. However, determining the optimal alignment strategy for each patient remains challenging due to high inter-patient variability in both bony anatomy [192], [194], [200], [203], [350], [417] and soft tissue characteristics [363], [364], [418].

Knee classification systems are integral in characterising anatomical variations among TKA patients, providing a framework for alignment strategies. Traditionally, these systems categorised the coronal knee alignment into broad groups – neutral, varus or valgus – which, while helpful, lack consideration of joint line obliquity (JLO) and may be influenced by assessment position (e.g. supine or weightbearing) or potential soft tissue degeneration, particularly the anterior cruciate ligament, that commonly occurs in arthritic knees [80], [212]. The coronal plane alignment of the knee (CPAK) classification system, introduced by MacDessi et al., addresses these limitations by categorising the knees using both the arithmetic hip-knee-ankle (aHKA) angle and JLO to create a more nuanced understanding of coronal knee alignment [10]. While studies indicate that CPAK does not fully capture the three-dimensional (3D) complexity of knee morphology [417] and that its phenotype distributions vary across gender and ethnicity [217], [218], [219], [220], [221], CPAK has been employed as a tool to guide alignment strategy and joint balance optimisation [10], [222].

Despite CPAK's clinical utility, limited research has examined whether its coronal alignment parameters, aHKA and JLO, or phenotypes offer insight into the knee's soft tissue behaviour. This gap in the literature raises questions about whether CPAK alone can provide a comprehensive framework for TKA planning without consideration to soft tissue factors. This is important to explore because preoperatively assessed joint laxity has been shown to predict postoperative outcomes [391] and such joint gap and laxity data can contribute additional information to facilitate patient-specific TKA planning to balance medial and lateral tibiofemoral gaps in extension and flexion [385]. Moreover, achieving joint gap and laxity balance targets can enhance postoperative patient outcomes [232], [233].

The primary aim of this study was to evaluate how preoperative medial, lateral and composite joint gap measurements in extension and 90° flexion vary across CPAK groups in a patient cohort undergoing primary TKA for osteoarthritis. The secondary aim was to assess the relationship between the joint gap measurements and aHKA and JLO. The study hypothesis was that statistically significant differences in joint gap measurements will be present between CPAK phenotypes and that the relationships between the joint gap measurements and aHKA and JLO are linear.

6.3. Methods

A total of 433 knees from 407 patients (26 bilateral) were retrospectively analysed. All patients were recruited for TKA between 29 April 2021 and 6 October 2023, with the procedure performed by 1 of 10 orthopaedic surgeons across 12 different orthopaedic centres. The inclusion criteria required patients to be a part of the 360 Med Care computed tomography (CT) database and have preoperative extension distracted and flexion distracted radiographs. Joints undergoing revision or complex primary surgery, where revision prostheses (e.g. hinged implants, constrained condylar knees, stems, etc.) were required were excluded from the study. Patient demographics including joint side, age at the time of surgery and coronal alignment parameters are outlined for the study cohort as well as the male and female subpopulations in **Table 6.1**. While the male and female subpopulations displayed similar mean JLO values, differences in aHKA were observed. Ethics was approved by Bellberry Human Research Ethics Committee (Sydney, Australia, application number 2012-03-710).

Table 6.1. *Patient demographics for the full study cohort and for the male and female subpopulations. Demographics are reported as amount or mean (interquartile range).*

CT, computed-tomography; HKA, hip-knee-ankle angle; MPTA, medial proximal tibial angle; LDFA, lateral distal femoral angle; aHKA, arithmetic hip-knee-ankle angle; JLO, joint line obliquity; IQR, inter-quartile range.

Measurement	All	Male	Female
Total joints	433	202	231
Left/Right	210/223	98/104	112/119
Age (Years)	70.3 (IQR 13.0)	69.7 (IQR 11.9)	70.8 (IQR 13.2)
CT HKA (° Varus)	4.0 (IQR 6.7)	5.3 (IQR 5.5)	3.4 (IQR 6.7)
MPTA (°)	86.4 (IQR 3.3)	86.1 (IQR 3.7)	86.7 (IQR 3.0)
LDFA (°)	86.7 (IQR 3.2)	87.0 (IQR 2.7)	86.4 (IQR 3.3)
aHKA (°)	-0.3 (IQR 4.6)	-0.9 (IQR 4.4)	0.3 (IQR 4.4)
JLO (°)	173.1 (IQR 4.4)	173.1 (IQR 4.4)	173.0 (IQR 4.5)

Radiology capture, and image processing

Preoperatively, each patient received a bilateral long-leg CT scan and two stressed antero-posterior radiographs: one each in extension and flexion. The maximum CT slice thickness was 1.25 mm in the transverse plane and 1 mm in the coronal and sagittal planes. For the two stress radiographs, the knee was axially distracted using 2.5kg ankle weights as described by Jagota et al. [385] and described in Chapter 5 of this dissertation. The series of two-dimensional (2D) CT slices were segmented semi-automatically and landmarked by trained engineers using Simpleware ScanIP (version M-2017.06, Synopsys, Inc., Mountain View, USA) to create 3D bone models. ScanIP was also utilised for feature-based 3D-to-2D registration of the bone reconstructions to each of the two stress radiographs. This registration process, detailed in Chapter 5 , displays low intra-observer and inter-observer variability, with a mean absolute error ≤ 0.9 mm and inter-observer intraclass coefficient values between 0.75 and 0.97 for measuring medial and lateral joint gaps in extension and flexion. During processing, the segmentations, landmarks and registrations were all quality checked by a senior engineer to ensure accuracy. The landmarks enabled anatomical measurements of the knee and limb in the CT and stressed radiograph positions.

CPAK measurements

The 3D bone reconstructions and corresponding landmarks were used to determine key coronal plane measurements required to calculate CPAK types. This included the medial proximal tibial angle (MPTA) and lateral distal femoral angle (LDFA), which were required to calculate the aHKA (MPTA – LDFA) and JLO (MPTA + LDFA). As established by Macdessi et al., the aHKA was used to categorise the knee as neutral, varus or valgus and the JLO was used to categorise the knee as apex distal, apex neutral or apex proximal [10]. Together, the aHKA and JLO groupings defined the CPAK phenotype of each knee.

Joint gap calculations and osteophyte correction

The native medial and lateral intercompartmental joint gaps were determined for each knee in the extension distracted and flexion distracted positions. These gaps were defined as the distance between the most inferior point on the respective femoral condyle and a plane across the proximal tibial plateau. The proximal tibial plane was defined using four reference landmarks: the medial and lateral edge landmarks of the proximal tibial surface, and the most anterior and posterior landmarks along the lateral proximal tibial surface. The lateral compartment was selected due to being less affected in the greater proportion of osteoarthritic joints [419]. These joint gap measurements were determined automatically using a custom developed script in RStudio (Posit, USA).

Ligament tenting due to the presence of osteophytes can result in the tightening of the medial and lateral tibiofemoral joint gaps. Intraoperatively, such osteophytes are usually removed before gap or laxity assessment of the knee. To account for this and better emulate post-osteophyte removal joint gaps, a geometric algorithm was developed and applied in both extension and flexion. The algorithm calculated the length of two ligament path types: direct and wrapped. The pseudo, direct path was defined as the straight-line distance between the origin and insertion points of the medial collateral ligament (MCL) and lateral collateral ligament (LCL). The wrapped path was defined as the shortest possible path from the origin to the insertion points of the MCL and LCL, whilst accounting for, or ‘wrapping around’ any intervening bony structures, such as osteophytes. It was assumed that after osteophyte removal, the medial and lateral tibiofemoral joint gaps would increase by the difference in the ligament paths for the MCL and LCL, respectively. As a result, the difference between the lengths of the direct and wrapped paths of the MCL and LCL were calculated in both extension and flexion These were added to the original medial and lateral joint gaps to provide the final joint gap calculations, in both extension and flexion. These four intercompartmental joint gap measurements were also used to determine the average extension gap, average flexion gap, extension gap difference and flexion gap difference for each patient. These composite gap measurements are defined in **Table 6.2**.

Table 6.2. *Definitions for the four composite gap measurements.*

Measurement	Definition
Average extension gap	$\frac{(Medial\ extension\ gap\ +\ lateral\ extension\ gap)}{2}$
Average flexion gap	$\frac{(Medial\ flexion\ gap\ +\ Lateral\ flexion\ gap)}{2}$
Extension gap difference	$Lateral\ extension\ gap - Medial\ extension\ gap$ Positive number denotes a larger lateral gap than medial gap.
Flexion gap difference	$Lateral\ flexion\ gap - Medial\ flexion\ gap$ Positive number denotes a larger lateral gap than medial gap.

Statistical analysis

Descriptive statistics, including mean and standard deviation, were employed to summarise the medial and lateral joint gaps in both extension and flexion as well as the composite joint gap measurements. These were described for the study cohort as well as for each CPAK phenotype. Data normality was evaluated subjectively using histograms and Q-Q plots, and objectively by analysing skewness and kurtosis, and was determined to follow a normal distribution. The linear relationship between the each of the eight joint gap measurements and aHKA and JLO were analysed using Pearson's correlation coefficients, with p-values below 0.05 indicating statistical significance. Separate multivariate linear regression analyses were performed to evaluate the ability of the four intercompartmental joint gaps (medial and lateral gaps in extension and flexion) to predict aHKA and JLO independently. Correlation coefficients of < 0.4, 0.4 to 0.7 and > 0.7 were considered weak, moderate and strong, respectively. One-way analysis of variance was conducted to compare the mean values of the four joint gap measurements across the CPAK phenotypes. Where statistical significance ($p < 0.05$) was observed, post hoc Tukey's Honest Significance Difference tests were used to identify which pair(s) of phenotypes displayed significantly different means for the given measurement.

6.4. Results

CPAK distribution

The CPAK distribution of the study patient population are displayed in **Figure 6.1**. As in previous studies, CPAK types VII, VIII and IX represented less than 1% of the study population and so were excluded from all statistical analyses [351], [365], [417]. CPAK type II (apex distal JLO and neutral aHKA) was most frequent across the study cohort (41.6%) as well as the male (40.6%) and female (42.4%) subpopulations. CPAK types I (25.2%) and III (21.9%) were the next most common across the study cohort.

Joint gaps across CPAK Phenotypes

The mean values and the distribution of the intercompartmental joint gaps in both extension and flexion across the different CPAK groups are presented in **Table 6.6** and **Figure 6.2**, respectively. A general trend was observed in which medial gaps increased, and lateral gaps decreased from CPAK types I to III and IV to VI, with some statistically significant differences observed. Notably, CPAK types I and III differed significantly in all four intercompartmental gap measurements (medial and lateral, in both extension and flexion) as well as in extension and flexion gap differences. CPAK types II and III also exhibited statistically significant differences in medial extension and flexion gaps, lateral flexion gap, and both extension and flexion gap differences. While additional differences were noted involving types IV and V, the small sample sizes in CPAK groups IV, V, and VI limited the strength of statistical inferences for these phenotypes.

Univariate regression analysis

Weak yet statistically significant linear relationships were observed between all four intercompartmental joint gap measurements and aHKA. Specifically, aHKA correlated with the medial extension gap (r = 0.21, p < 0.001), lateral extension gap (r = -0.15, p = 0.002), medial flexion gap (r = 0.20, p < 0.001) and lateral flexion gap (r = -0.21, p < 0.001). These correlations suggest a weak trend towards medial extension and flexion gaps increasing, and lateral extension and flexion gaps decreasing as aHKA increases. Only the medial flexion gap displayed a significant correlation with JLO (r = 0.15, p = 0.002).

Of the composite gap measurements, the extension gap difference and flexion gap difference were weakly correlated to aHKA (r = -0.31, p < 0.001 and r = -0.32, p < 0.001). This suggests that as aHKA increases, the medial joint gap increases relative to the lateral compartment, to a similar effect in extension and flexion. The average flexion gap measurement also displayed a weak yet significant relationship with JLO (r = 0.15, p = 0.003).

The Pearson's correlation coefficients between all joint gap measurements and aHKA and JLO are summarised in **Table 6.3**.

Multivariate regression analysis

The multivariate linear regression revealed that all four intercompartmental joint gaps significantly influenced aHKA (**Table 6.4**). However, the model demonstrated limited explanatory power, with a residual standard error of 3.75° and an adjusted R2 of 10.22%. For JLO, the multivariate regression results were weaker, explaining only 1.42% of the variance, with a residual standard error of 3.43° (**Table 6.5**). Notably, the medial flexion gap was the only statistically significant predictor of JLO.

Figure 6.1. *Preoperative CPAK distribution for the cohort of 433 knees, categorised by male (red) and female (blue). The proportion of knees categorised within each of the nine phenotypes is displayed for the overall cohort (T) as well as for the male (M) and female (F) subpopulations.*

aHKA, arithmetic hip-knee-ankle angle; CPAK, coronal plane alignment of the knee; JLO, joint line obliquity.

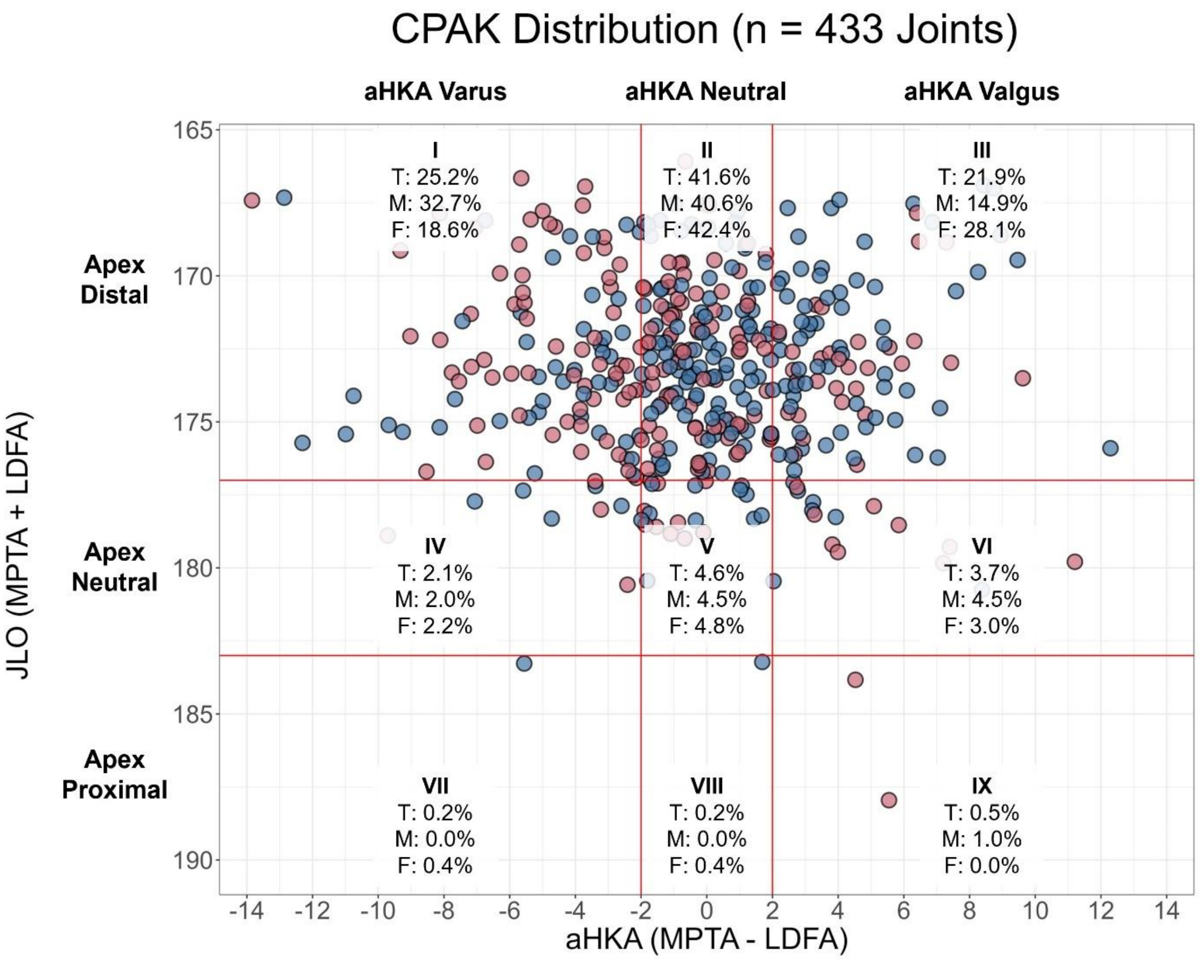


Table 6.3. *Pearson correlation coefficients of the joint gap measurements to both the arithmetic hip-knee-ankle angle (aHKA) and the joint line obliquity (JLO).*

Variable	**Correlation coefficient (*r*)**	
	aHKA	**JLO**
Medial extension gap	0.22**	0.07
Lateral extension gap	-0.15*	0.01
Medial flexion gap	0.21**	0.15*
Lateral flexion gap	-0.21**	0.06
Average extension gap	0.03	0.06
Average flexion gap	-0.03	0.15*
Extension gap difference	-0.31**	-0.03
Flexion gap difference	-0.32**	-0.08

** indicates $p < 0.05$, ** indicates $p < 0.001$.*

Table 6.4. *Results for the multivariate linear regression model evaluating the predictive relationship between the medial and lateral joint gaps in extension and flexion and arithmetic hip-knee-ankle angle (aHKA). The model explains 11.05% of the variance in aHKA (adjusted R^2 = 10.22%), with a residual standard error of 3.75° and F statistic of 13.3 ($p < 0.001$). With statistical significance at $p < 0.05$, all four intercompartmental joint gap measurements were significant predictors.*

Variable	Coefficient	Standard Error	t Value	*p* Value
(Intercept)	0.82	0.63	1.31	0.19
Medial extension gap	0.30	0.11	2.81	0.005
Lateral extension gap	-0.22	0.11	-2.12	0.03
Medial flexion gap	0.24	0.09	2.65	0.008
Lateral flexion gap	-0.25	0.09	-2.90	0.004

Table 6.5. *Results for the multivariate linear regression model evaluating the predictive relationship between the medial and lateral joint gaps in extension and flexion and joint line obliquity (JLO). The model explains just 2.33% of variance in JLO (adjusted R^2 = 1.42%), with a residual standard error of 3.43° and F statistic of 2.56 ($p = 0.04$). With statistical significance at $p < 0.05$, the medial flexion gap was the only significant predictor of JLO.*

Variable	Coefficient	Standard Error	t Value	*p* Value
(Intercept)	171.84	0.57	300.25	< 0.001
Medial extension gap	-0.08	0.10	-0.81	0.42
Lateral extension gap	-0.02	0.10	-0.22	0.82
Medial flexion gap	0.18	0.08	2.18	0.03
Lateral flexion gap	0.13	0.08	1.60	0.11

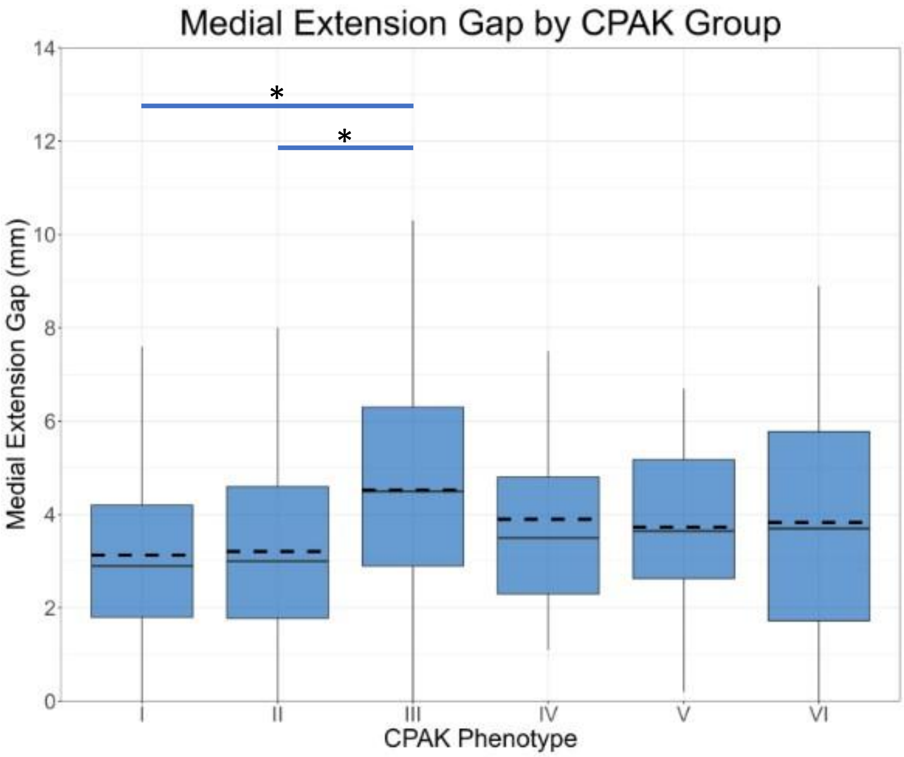
Table 6.6. *Mean and standard deviation of the axial and sagittal measurements of the full study cohort and each CPAK group from I to VI.*

CPAK, coronal plane alignment of the knee.

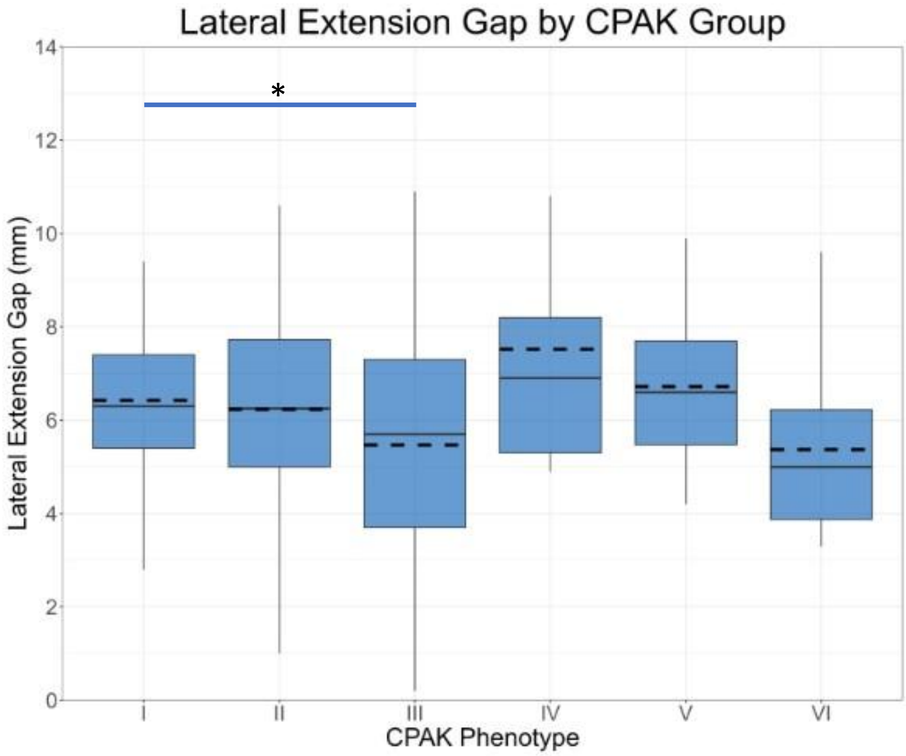
Measurement	All Groups (n = 433)	CPAK Group					
		I (n = 109)	II (n = 180)	III (n = 95)	IV (n = 9)	V (n = 20)	VI (n = 16)
Medial Extension Gap (mm)	3.54 ± 2.12	3.13 ± 2.07	3.21 ± 1.98	4.52 ± 2.07	3.90 ± 2.04	3.73 ± 1.83	3.83 ± 2.72
Lateral Extension Gap (mm)	6.14 ± 2.17	6.43 ± 2.06	6.23 ± 2.12	5.47 ± 2.35	7.52 ± 2.82	6.72 ± 1.56	5.37 ± 1.77
Medial Flexion Gap (mm)	4.24 ± 2.51	3.86 ± 2.73	3.77 ± 2.12	5.15 ± 2.44	4.74 ± 3.60	5.93 ± 3.13	4.46 ± 1.79
Lateral Flexion Gap (mm)	7.10 ± 2.63	7.70 ± 2.27	7.10 ± 2.38	6.12 ± 3.10	8.90 ± 3.14	8.17 ± 2.39	6.17 ± 1.80
Average Extension Gap (mm)	4.84 ± 1.68	4.78 ± 1.62	4.72 ± 1.66	5.00 ± 1.73	5.71 ± 2.22	5.22 ± 1.37	4.60 ± 1.98
Average Flexion Gap (mm)	5.67 ± 1.99	5.78 ± 2.02	5.44 ± 1.77	5.63 ± 2.16	6.82 ± 3.01	7.05 ± 2.39	5.31 ± 1.27
Extension Gap Difference (mm)	2.60 ± 2.67	3.30 ± 2.56	3.02 ± 2.41	0.95 ± 2.77	3.62 ± 2.10	2.99 ± 2.02	1.54 ± 2.33
Flexion Gap Difference (mm)	2.86 ± 3.26	3.83 ± 2.98	3.33 ± 2.81	0.97 ± 3.53	4.16 ± 3.05	2.24 ± 2.86	1.71 ± 2.54

Figure 6.2. *Distributions of the joint gap measurements by CPAK type. For each box, the horizontal solid line represents the median, while the horizontal dotted line indicates the mean. The lower edge of the box corresponds to the 25th percentile (Q1), and the upper edge corresponds to the 75th percentile (Q3), illustrating the interquartile range (IQR) (Q3 – Q1). The whiskers (vertical solid lines) extend from the lower and upper boundaries of the box to the smallest and largest values within 1.5 times the IQR from these boundaries, respectively. * indicates statistically significant (p < 0.05) differences between the two groups at either end of the blue line. CPAK, coronal plane alignment of the knee.*

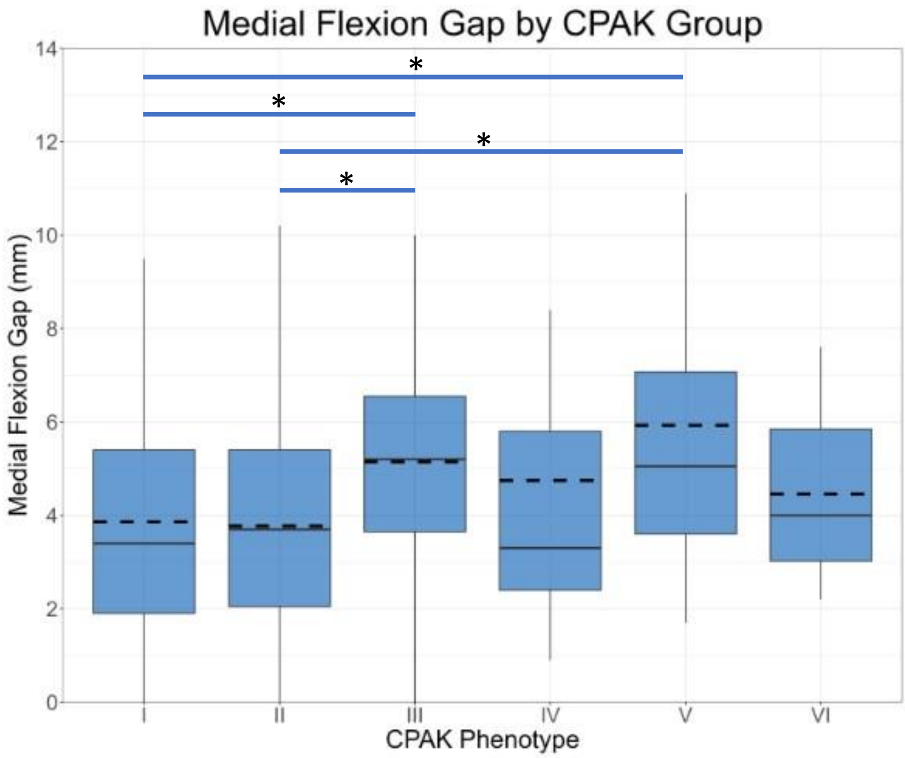
A) Medial extension gap measurements across CPAK phenotypes, with significant differences between phenotypes I and III, and II and III.



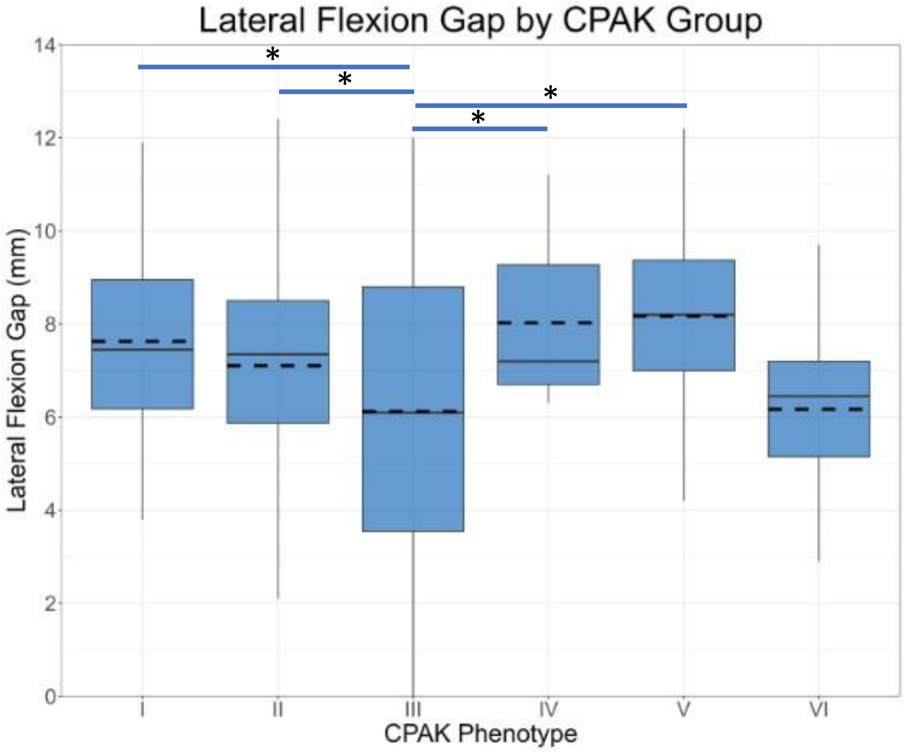
B) Lateral extension gap measurements across CPAK phenotypes, with significant differences between phenotypes I and III.



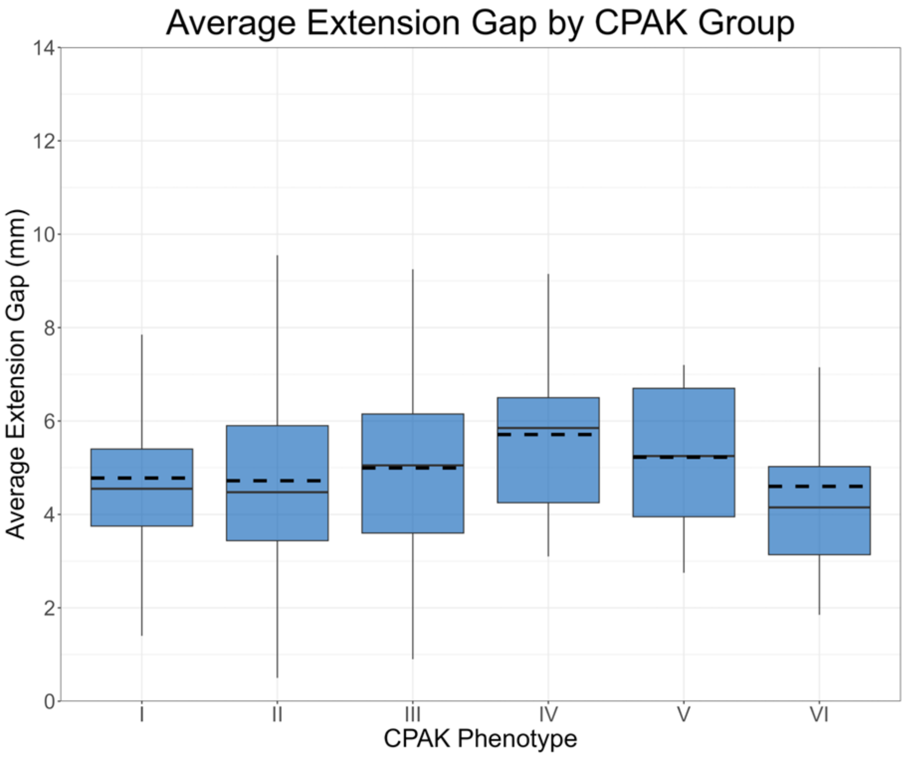
C) Medial flexion gap measurements across CPAK phenotypes, with significant differences between phenotypes I and III, I and IV, II and III, and II and V.



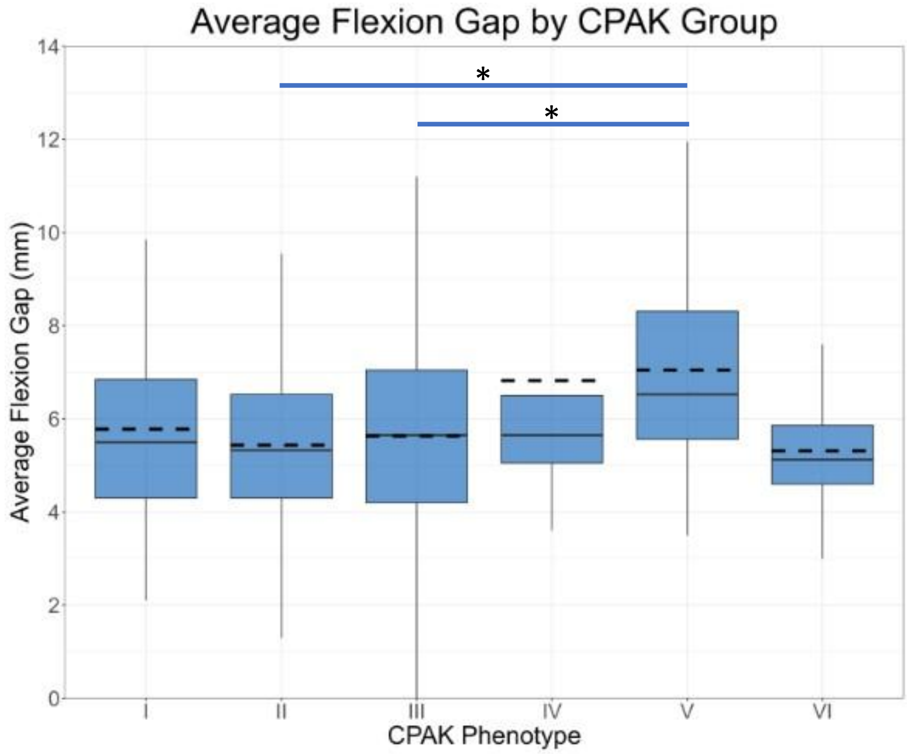
D) Lateral flexion gap measurements across CPAK phenotypes, with significant differences between phenotypes I and III, II and III, III and IV, and III and V.



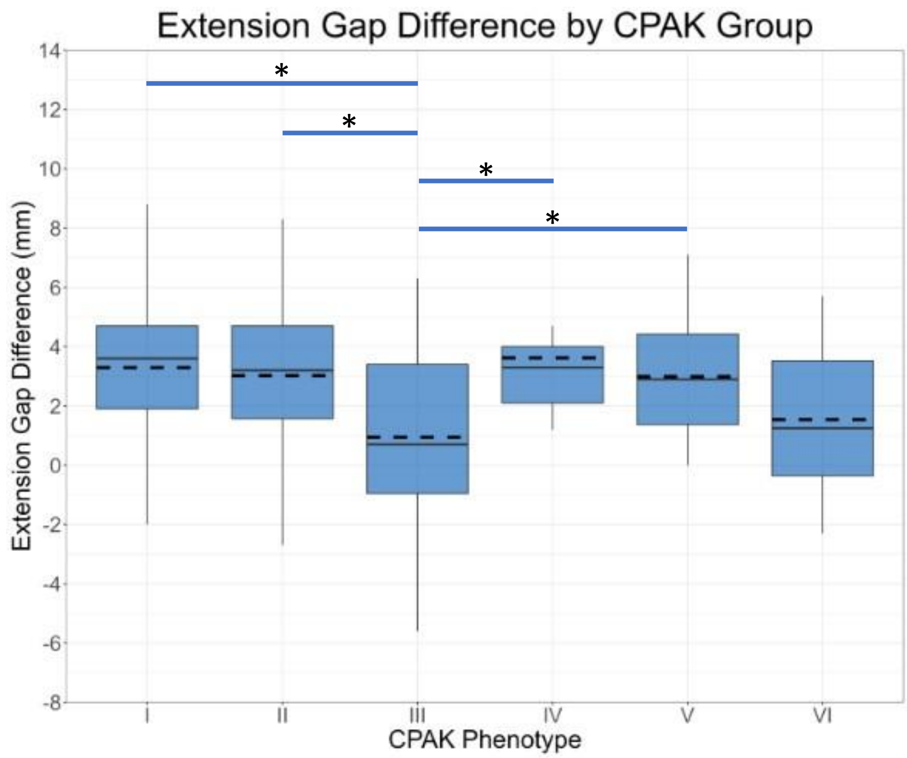
E) Average extension gap measurements across CPAK phenotypes. No significant differences were observed between phenotype pairs.



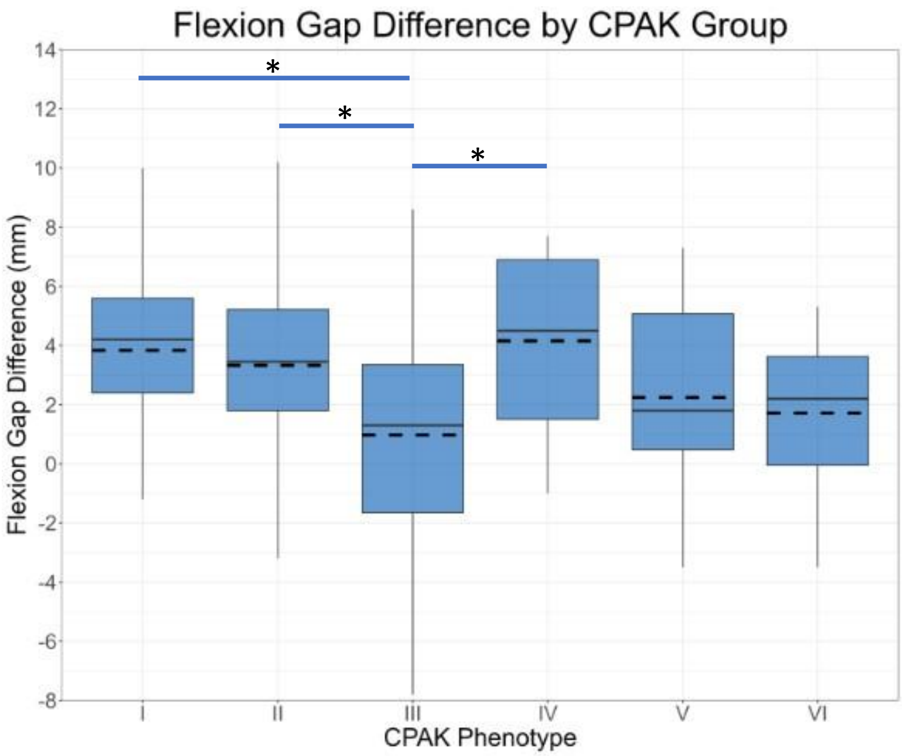
F) Average flexion gap measurements across CPAK phenotypes, with significant differences between phenotypes II and V and III and V.



G) Extension gap difference measurements across CPAK phenotypes, with significant differences between phenotypes I and III, II and III, III and IV and III and V.



H) Flexion gap difference measurements across CPAK phenotypes, with significant differences between phenotypes I and III, II and III and III and IV.



6.5. Discussion

This study found that CPAK phenotypes, and aHKA and JLO exhibited low predictability for medial, lateral and composite joint gaps in both extension and flexion. Although some statistically significant differences in joint gap measurements were observed between CPAK groups, the phenotypes did not demonstrate distinct joint gap profiles in extension and 90° flexion. Notably, significant differences in multiple joint gap measurements were found between CPAK types I and III and II and III, suggesting that these may be driven by differences in aHKA. While statistically significant linear correlations were observed between aHKA and medial gaps, lateral gaps, and gap differences, they were weak, with the highest Pearson's correlation coefficient magnitude of 0.32. Fewer statistically significant correlations were noted between JLO and joint gaps, with the medial and average flexion gaps displaying the largest coefficients ($r = 0.15$ for both). Multivariate regression analyses further underscored the limited relationship between joint gaps and aHKA and JLO, with joint gaps explaining a very small proportion of the variance in aHKA (10.2%) and JLO (1.4%). Overall, these findings suggest that CPAK groupings, aHKA and JLO provide limited insight into soft tissue behaviour and cannot reliably predict patient-specific tibiofemoral joint gaps in extension and 90° flexion. Clinically therefore, following the CPAK principles will not always result in a balanced TKA. Surgeons still need to consider patient specific soft tissue characteristics as well as their balance target preferences in their approach to alignment.

While statistically significant differences were observed between CPAK types I and III and II and III for many of the joint gap measurements, the magnitude of these differences was generally small – often less than 2 mm – raising questions about their clinical relevance. Although there is currently no established minimum clinically important difference (MCID) for preoperatively measured joint gaps in TKA, intraoperative studies offer a useful reference point. Wakelin et al. demonstrated that patients with medial and lateral gaps, or mediolateral gap differences, within defined intraoperative balance windows experienced significantly better KOOS pain scores and were more likely to achieve the Patient Acceptable Symptom State (PASS) [233]. Importantly, their data shows that that a change of more than 2 mm in gap size would shift over 50% of patients who initially met these balance targets outside of the optimal range. Based on this reference threshold, the small differences in mean intercompartmental and composite gap measurements observed between CPAK phenotypes in the current study are unlikely to be clinically meaningful. Grosso et al. observed that MPTA significantly influenced medial, but not lateral, extension and flexion distractibility in varus knees, while LDFA showed no statistically significant impact [364]. Since the MPTA and LDFA are used to determine the aHKA and JLO, which in turn define the CPAK groups, this may explain why the phenotypes did not display distinct joint gap profiles. However, Holland et al. analysed 1,112 robotic TKAs and identified unique joint gap curve morphologies for CPAK groups I to VI from 0° to 110° flexion [365]. While they reported mean joint gaps at 10° intervals, no statistical testing validated the differences between groups. Unlike this study's preoperative stress radiographs on conscious patients, Holland et al. measured gaps intraoperatively after medial release and anterior and posterior crucial ligament removal [365], factors which can impact the intercompartmental extension and flexion gaps [420], [421] . Therefore, further research is required to establish whether the joint gap morphologies for CPAK groups are truly distinct. Until this can be established, alternative approaches are required to preoperatively profile and plan for joint gaps during TKA.

While studies investigating the relationship between intercompartmental and composite joint gaps with aHKA and JLO are limited, our findings reflect weak but variable relationships between coronal alignment and joint gap behaviour. In varus knees, Graichen et al observed that greater varus deformity was associated with statistically significant decreases in medial extension and flexion gaps and an increase in lateral extension gap, resulting in a reduced medial-to-lateral gap difference [363]. The extension gap difference was more strongly correlated to HKA ($r = 0.79$) compared the flexion ($r = 0.40$). In valgus knees, Eller et al. observed an increase in medial gaps and decrease in lateral gaps with increased valgus deformity [418]. They also observed stronger correlations between the extension gap difference and HKA ($r = 0.82$) relative to flexion (*r* = 0.21). These trends align with our study, where weak correlations were observed between aHKA and medial, lateral, and composite gaps, with coefficients ranging from -0.32 to 0.22, reflecting the limited predictive value of coronal alignment parameters. Furthermore, Grosso et al. observed increased medial distractibility in both extension and flexion as varus deformity increased [364]. While this contrasts the directionality of the results observed in the current study and by Graichen et al. [363], their result may be influenced by their definition of distractibility, which was the difference between the post-tibial resection, distracted joint gap less the resected bone thickness. Despite these results, all these studies emphasise the high inter-patient variability in intercompartmental and composite joint gap measurements in extension and flexion with standard deviations of greater than 2 mm for each [363], [364], [418].

The weak results between coronal alignment parameters and joint gaps during both univariate and multivariate regression analyses suggest that other factors influence joint gaps apart from bone morphology and degree of deformity. One potential explanation is the dynamic behaviour of knee deformity during flexion, with as few as 14% of patients maintaining their coronal deformity throughout flexion range of motion [422]. High variability is observed for the remainder of patients with their coronal deformity either increasing (17%), increasing before decreasing (22%), decreasing (29%) or decreasing past neutral to the opposite direction (e.g. from varus in extension to valgus in flexion) (13%) as the knee moves from extension to flexion [422]. Patient factors may also influence joint gap behaviour. In a cohort of neutral and varus knees, Graichen et al. observed that female patients had larger mean extension and flexion gaps than men (by 0.5mm), while body mass index and age had minimal impact [363]. However, these variables did not influence gaps in valgus knees [418]. While further research is required to understand the variables that influence native joint gaps, we can conclude that joint gap behaviour is complex and cannot be effectively predicted by coronal alignment parameters such as aHKA and JLO.

Limitations

This study has some potential limitations. While CPAK types VII, VIII and IX were excluded from most of the statistical analyses, they accounted for just 0.9% (4) patients. This reflects published statistical analyses [351], [365], [417] and proportions of diverse populations across the world [10], [219], [220], [221], [351], [355], [357], [358]. Additionally, the CPAK distribution in this study varied from the arthritic population assessed by MacDessi et al. [10]. This is likely due to the different imaging modalities used to assess bone morphology. The current study performs 3D anatomical analysis from CT scans to measure LDFA, MPTA, aHKA and JLO whereas the original method described by MacDessi et al. obtained measurements directly from 2D antero-posterior radiographs [10]. We believe that 3D anatomical analysis is the gold standard for TKAs and the CPAK distribution in the current study aligns with other published 3D analyses [351], [355]. The change in joint gaps with the osteophyte correction algorithm and the final calculated joint gaps are a best estimate and require further validation. Due to the imaging protocol, the joint gaps were measured at 0° and 90° of flexion. Expanding this to additional flexion angles is possible but requires precise apparatus set up to ensure that passive knee flexion is achieved at the desired angle(s). Furthermore, the patient cohort was predominantly Caucasian, and the results cannot be extrapolated to other ethnic groups or patient populations. We are also not advocating or able to define joint gap targets but rather highlighting the population variability in soft tissue behaviour and its independence from distal femoral and proximal tibial anatomy. Surgeons need to be cognizant of the fact that blindly following bony morphology alone will not result in the same TKA gaps in all patients. Thus, restoring a patient's CPAK category, aHKA and JLO may not deliver the tibiofemoral balance that the surgeon has aimed for. Our findings further emphasise the need for methods to objectively measure soft tissue gaps and laxity and correlate these with patient outcomes. This will permit soft tissue parameters as well as alignment targets to be defined for individual patients, with the aim of improving TKA function and longevity.

6.6. Conclusion

This study demonstrated that while the CPAK classification system and phenotypes are useful for describing bone-referenced coronal knee anatomy, they do not effectively predict preoperative medial, lateral or composite joint gaps in extension and flexion within a TKA patient cohort. To achieve optimal joint balance in TKA, a thorough understanding of the soft tissue profile is essential. Given the lack of a reliable predictor for preoperative tibiofemoral joint gaps, direct assessment of these gaps is currently necessary to inform surgical planning. Further research is needed to develop a preoperative planning workflow that incorporates joint gap measurements as well as bone anatomy, aiming to enhance both joint balance and patient outcomes.

Chapter 7:

Preoperative Joint Distraction Imaging and Planning Protocol for Total Knee Arthroplasty

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7.1. Abstract

Purpose

Current preoperative Total Knee Arthroplasty (TKA) planning strategies are bone-referencing and do not consider the ligamentous profile of the knee. This study assessed the mean Hip-Knee-Ankle (HKA) angle of the planned Distracted Alignment (DA), an alignment output using a joint distraction radiology and planning protocol, which incorporates preoperative evaluation of ligament laxity.

Methods

A retrospective study of 144 knees undergoing TKA was performed. Each patient received a preoperative computer tomography (CT) scan, a weightbearing antero-posterior knee radiograph, and distracted knee radiographs in extension and flexion. The imaging was used to develop a preoperative DA plan aiming for medio-lateral and extension-flexion space balance. The mean DA, weightbearing and arithmetic HKA angles were compared to each other, and to the HKA of a healthy non-arthritic population.

Results

The mean weightbearing, arithmetic and planned DA HKA angles were 4.8° (inter-quartile range [IQR] 6.5°) varus, 0.4° (IQR 4.5°) varus, and 2.2° (IQR 4.0°) varus, respectively. This compares to a healthy adult HKA angle of 1.3° varus. The difference between the planned DA and arithmetic HKA angles was greater than 3° for 36% of the patients in the study population.

Conclusions

The planned DA HKA angle was fundamentally different from the arithmetic HKA angle, but comparable to a healthy population. Considering both hard and soft tissue

information of the knee, we believe the planned DA resulting from the joint distraction radiology protocol allows for optimised preoperative surgical planning in TKA.

Level of Evidence: Level II

7.2. Introduction

Achieving joint balance during total knee arthroplasty (TKA) can result in superior postoperative patient satisfaction [423], proprioception [424] and range of motion (ROM) [425]. Tibiofemoral balance and stability are key drivers of new alignment philosophies. However, different alignment strategies may aim to achieve this in varying techniques.

Mechanical alignment (MA) is the historical gold standard, prioritising even load distribution through the medial and lateral compartments of the prostheses [279]. Any residual joint gap imbalances are corrected by releasing the surrounding soft tissue. However, ligament releases in TKA have been correlated to inferior patient-reported outcomes at 2 years postoperatively [426] and may have negative implications for postoperative proprioceptive recovery [424]. The degree of soft-tissue release required to balance a joint can be difficult to quantify, introducing the risk of excessive release which may result in joint instability [427] or unfavourable soft-tissue tension. This may contribute to postoperative patient dissatisfaction rates of up to 20% in MA TKAs [6], [7]. Therefore, minimizing ligament releases is often preferred in an attempt to reduce soft-tissue trauma and enhance postoperative patient outcomes.

Kinematic alignment (KA) and most other non-neutral alignment approaches are driven by bony anatomy and consider bone-referencing measurements such as arithmetic hip-knee-ankle (aHKA). These strategies are guided by bone-referencing classification systems such as the coronal plane alignment of the knee (CPAK), which considers the aHKA and joint line obliquity (JLO) to prescribe a patient-specific surgical alignment based on observed deformity [10]. These alignment strategies aim to be ligament-sparing by better emulating a patient's pre-arthritic bony anatomy and constitutional alignment. These approaches assume the coronal plane laxity of the knee is the same for every patient with similar aHKA and JLO. However, Li et al (2022) observed that varus-valgus laxity of the knee is variable even in patients who have similar coronal alignment [260], so imbalances may still occur when performing KA. Traditionally, these techniques overcome residual imbalances via tibial bone recuts [11]. However, recuts can be challenging, time-consuming, and recent studies have highlighted that these alternative alignment strategies continue to utilize soft-tissue release as the most common rebalancing solution [10], [294]. Previous studies have determined that knowledge of soft-tissue profile can assist with balancing the joint during TKA [260], [428], highlighting the need for preoperative analysis of both the soft tissue and bony anatomy to optimize surgical plans.

In 2005, Kanekasu et al published a radiology protocol that enabled the assessment of the flexion joint gap whereby a patient sits with their knee passively flexed at 90° [429]. Tokuhara et al modified this protocol by applying a 1.5 kilogram (kg) weight to the ankle and observed that the distraction force enabled reproducible visualization of the flexion gap [386]. We further adapted this protocol to allow for evaluation of the extension and flexion soft-tissue tibiofemoral joint gaps. Information obtained from this imaging protocol was input into a preoperative planning protocol to generate a functional alignment known as the Distracted Alignment (DA). The planned DA approach differs from MA and KA techniques by preoperative consideration of the soft-tissue characteristics and bony anatomy during surgical planning in TKA.

This study aimed to compare the coronal Hip-Knee-Ankle (HKA) angle achieved by the planned DA to the weightbearing HKA and aHKA angles for a TKA patient population, and to the HKA angle of a healthy non-arthritic population published by Bellemans et al (2012) [183]. We hypothesized that the HKA angle and individual component alignment when considering both bony anatomy and patient-specific soft-tissue characteristics will differ from that achieved when using the aHKA method, but still comparable to a healthy population.

7.3. Methods

We analysed a retrospective series of 144 patients who underwent primary TKA by 4 experienced orthopaedic surgeons between March 4, 2020 and May 26, 2021. A single surgeon recruited 88% (130) of patients. The patient demographic characteristics including age at time of surgery, sex, side, and CT-based HKA are outlined in **Table 7.1**. Any patients who did not complete imaging, for reasons such as contraindications, refusal, or lack of access, were implicitly excluded from the study. Ethics was approved by Bellberry Human Research Ethics Committee, application number 2012-03-710.

Table 7.1. *Demographics of study population. CT, computed tomography; HKA, Hip-Knee-Ankle angle; IQR, inter-quartile range.*

Characteristic	All (n = 144)	Men (n = 68)	Women (n = 76)
Left/Right	60/84	29/39	31/45
Age (Years)	70.9 (IQR 9.8)	71.4 (IQR 8.5)	70.6 (IQR 10.6)
Supine CT HKA Varus (°)	4.2 (IQR 5.7)	5.5 (IQR 6.2)	3.2 (IQR 6.8)

Radiology Capture and Image Processing

All patients were preoperatively imaged at 1 of 6 radiology centres. The imaging protocol comprised of a bilateral lower-limb computed tomography (CT) scan, a weightbearing antero-posterior knee radiograph, and distracted radiographs in extension and flexion. The distracted radiographs were taken in line with the imaging protocol in Chapter 5. To summarise for the reader - In extension, the patient stood on a platform with their non-operative leg and the operative leg free hanging in full extension. They were provided a balance bar for additional support while standing on their non-operative leg. In flexion, the patient sat on a tall stool to ensure their feet were unable to reach the ground. The knee joint was passively flexed to 90° and both legs were relaxed and free hanging. An ankle weight of 2.5 kg was applied during both distracted radiographs to axially distract the joint.

The CT scan was segmented and landmarked by engineers using Synopsys Simpleware ScanIP (Exeter, United Kingdom) to produce 3-dimensional (3D) reconstructed bone models. The same software was used for 3D-to-2D registration of the bone models to the weightbearing and distracted radiographs using the protocol outlined in Chapter 5. Next, a custom osteophyte correction algorithm was applied using Posit RStudio (Boston, USA) to model the post-osteophyte removal joint gaps in extension and flexion. The details of this algorithm are outlined in Chapter 5. To summarise, the algorithm measured the difference between direct (straight-line) and wrapped (shortest bony wrapped) ligament paths for the MCL and LCL. The difference in path lengths quantified the increase in medial and lateral joint gaps to account for expected osteophyte removal, which were added to the native gaps to determine the final medial and lateral joint gaps in extension and flexion.

Preoperative Planning

For each patient, a mechanical alignment was initially planned. The preoperatively determined joint gaps were analysed and the component positioning in extension and flexion was adjusted by an engineer to achieve joint balance. Joint balance was defined as equal flexion and extension gaps and equal medial and lateral tibiofemoral gaps. The final planned alignment was also reviewed by the surgeon. A summary of the complete preoperative analysis protocol is outlined in **Figure 7.1** and a detailed example of the osteophyte correction process, and DA plan are displayed in **Figure 7.2**. Contraindications of DA planning include patients with limited extension or flexion ROM, preventing the knee joint from passively reaching less than or equal to 10° fixed flexion or up to 90° of flexion. For instance, the presence of a fixed flexion contracture of greater than 10° after the application of the joint distraction weights may reduce the reliability of the preoperative joint gap assessment and resulting DA plan.

Calculations and Data Analyses

The mean and inter-quartile range (IQR) of the weightbearing, arithmetic and planned DA HKA angles of the study population were determined and compared to the mean HKA angle of a healthy population. The weightbearing HKA of our study population and the HKA of the healthy population assessed by Bellemans et al were defined as the angle subtended by the femoral mechanical axis and the tibial mechanical axis[183]. The aHKA was defined as the difference between the medial proximal tibial angle and lateral distal femoral angle[430]. The HKA for the planned DA was defined as the difference between the planned tibial varus and femoral valgus. As per the definitions above, a positive HKA angle indicated varus.

Two-tailed paired *T*-Tests were utilised to investigate any statistically significant differences between the weightbearing, arithmetic and planned DA HKA angles. The statistical significance of the differences between these three angles relative to the HKA of the healthy population was investigated using one-tailed unpaired *T*-Tests. A *P*-value of 0.05 was set for significance and all statistical analysis was performed using Posit RStudio (Boston, United States). A patient-level analysis also investigated the difference between the aHKA and planned DA HKA angles for each patient.

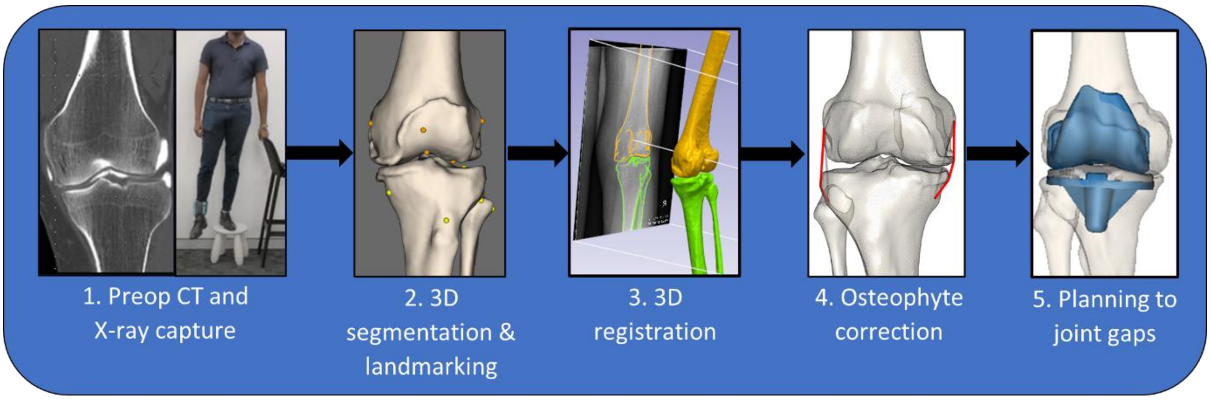
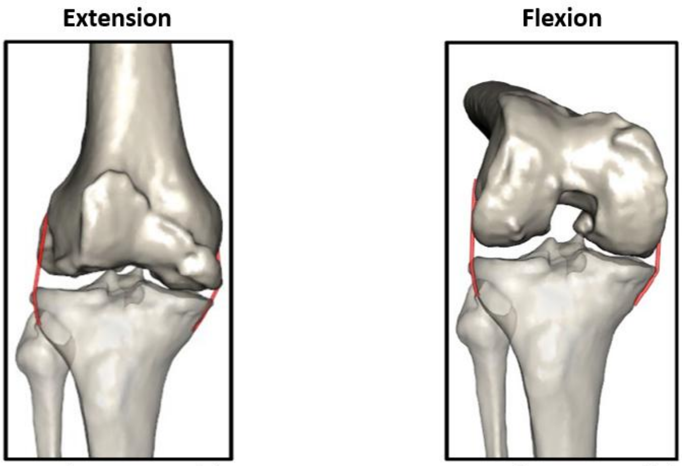


Figure 7.1. *Flowchart of the preoperative analysis protocol, which involves preoperative CT (Computed Tomography) and X-ray capture, 3D (Three Dimensional) segmentation and landmarking, 3D registration, osteophyte correction as well as surgical planning.*

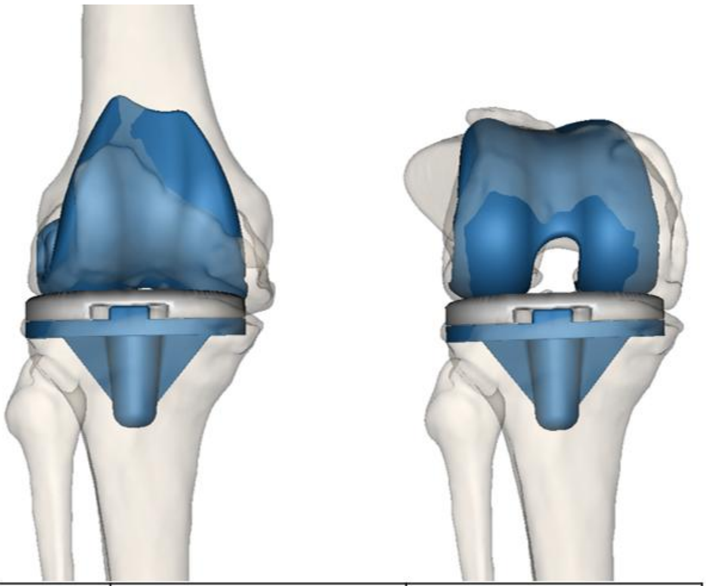
Figure 7.2. *A detailed example of the osteophyte correction and DA (Distracted Alignment) planning process.*



Lateral	Medial		Lateral	Medial
6.8mm	3.5mm	Native joint gaps	6.8mm	2.8mm
1.0mm	2.1mm	Osteophyte correction	0.0mm	2.3mm
7.8mm	5.6mm	Final Joint gaps	6.8mm	5.1mm

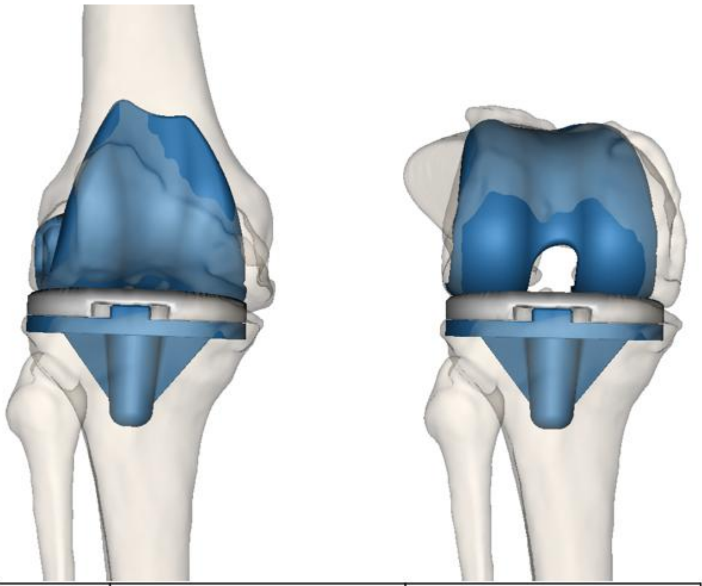
DA HKA: 3° Varus

A) The native joint gaps are first determined and are adjusted by the amounts determined by the osteophyte correction algorithm. In this example, the medial and lateral gaps in extension and medial gap in flexion are predicted to increase with osteophyte removal. The native gaps and correction amounts are summed to obtain the final joint gaps.



MA Plan	Femur			Tibia		
Coronal	0° (Neutral) to MA			0° (Neutral) to MA		
Sagittal	2° Flexion			3° Posterior Slope		
Axial	0° (Neutral) to TEA (2° External to PCA)			0° (Neutral) to Insall's Axis		
Resections		Medial	Lateral		Medial	Lateral
	Distal	9mm	6mm	Proximal	6mm	8mm
	Posterior	9mm	7mm			

B) As a default, a mechanical alignment is initially planned as a starting point. Although subtle, it can be observed that the planned alignment is medially tight and laterally loose in extension and generally loose in flexion.



DA Plan	Femur			Tibia		
Coronal	0° (Neutral) to MA			3° Varus		
Sagittal	5° Flexion			3° Posterior Slope		
Axial	2° Internal to TEA (0° (Neutral) to PCA)			0° (Neutral) to Insall's Axis		
Resections		Medial	Lateral		Medial	Lateral
	Distal	9mm	6mm	Proximal	8mm	7mm
	Posterior	5mm	5mm			

C) By planning, with consideration to the determined joint gaps and DA HKA (Hip-Knee-Ankle) angle, the implant positioning is updated and can be seen to be balanced both medially and laterally in both extension and flexion. The key changes in alignment parameters and associated reasons in this specific are as follows:

i. Tibial component rotated to 3° varus to achieve the DA HKA and balance the extension gaps.

ii. Femoral component moved posterior, reducing the posterior femoral resections and the medial and lateral flexion gaps.

iii. Femoral component internally rotated by 2° to reduce the medial flexion gap.

iv. Femoral component was placed in 5° flexion to reduce excessive anterior femoral notching.

7.4. Results

The mean HKA angle of the patient population in the standing weightbearing position was 4.8° (IQR 6.5°). The mean planned DA HKA (2.2°, IQR 4.0°) and aHKA (0.4°, IQR 4.5°) angles were both comparable to the constitutional HKA angle of a healthy population (1.3°). The distribution of these measurements is displayed in **Figure 7.3**. The mean of each HKA measurement differed significantly from the others ($P < 0.01$). **Table 7.2** highlights that the DA plan results in less 'extreme' coronal resection angles on the femur and tibia relative to the KA.

The difference between the planned DA HKA and aHKA angles displayed a discrepancy of less than or equal to 3° between the two coronal angles in 64% of patients and greater than 3° in the remaining 36% of the study cohort (**Figure 7.4**).

Table 7.2. *Comparison of the mean coronal component positioning for the planned distracted, kinematic, and mechanical alignments. Note: aHKA is the coronal alignment of a kinematic alignment plan. aHKA, arithmetic Hip-Knee-Ankle angle; IQR, inter-quartile range.*

Planned Alignment	Femoral Component Coronal Valgus (°)	Tibial Component Coronal Varus (°)
Mechanical Alignment	0 (IQR 0)	0 (IQR 0)
Kinematic Alignment (aHKA as the coronal alignment)	3.3 (IQR 3.2)	3.6 (IQR 4.6)
Distracted Alignment	0.1 (IQR 0)	2.2 (IQR 4.0)

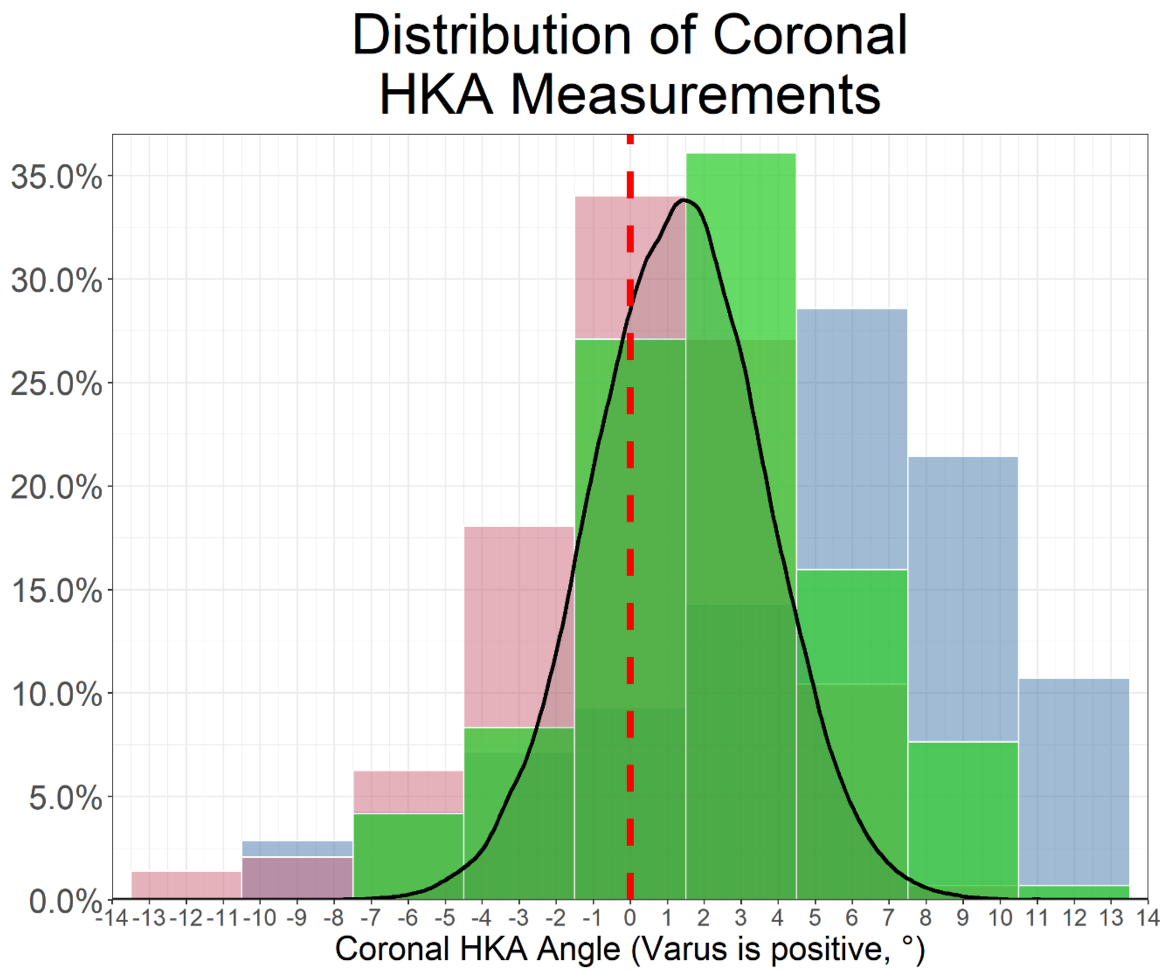


Figure 7.3. *Comparison of the weight-bearing (blue), arithmetic (red), and planned DA (Distracted Alignment) (green) HKA (Hip-Knee-Ankle) angles for the patient population of this study. The distribution of the HKA angles of a healthy population as per Bellemans et al (2012) is represented by the black line. For reference, the vertical red dashed line at the HKA of 0 ° (neutral) represents the target HKA of the MA (Mechanical Alignment) technique.*

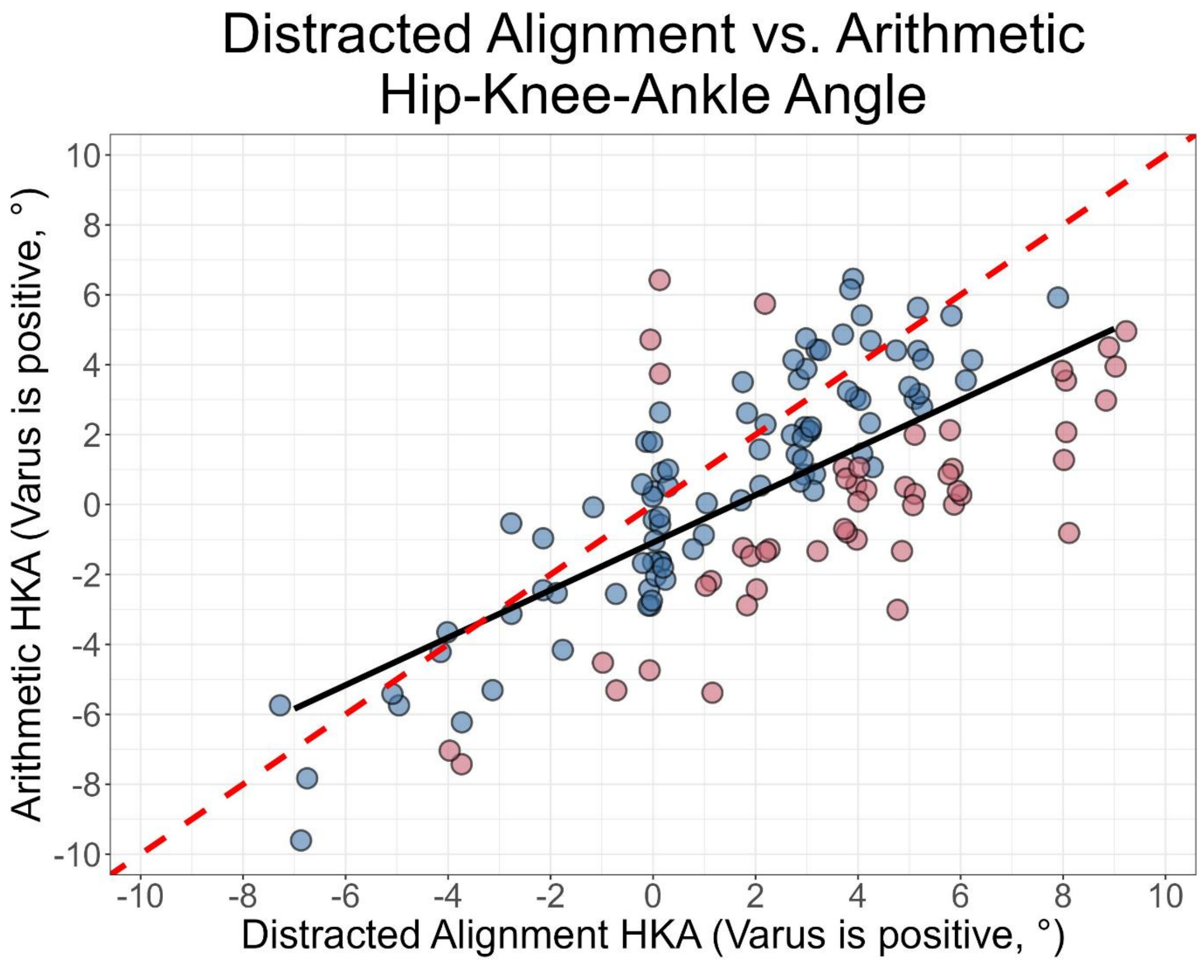


Figure 7.4. *Dot plot of the difference between the planned DA (Distracted Alignment) HKA (Hip-Knee-Ankle) and aHKA (arithmetic HKA) angles. The blue dots highlight the joints with a discrepancy of less than or equal to 3° between the two HKA angles whereas the red dots represent those with a difference of greater 3°. The black line is the linear regression, and the red dashed line indicates perfect agreement (y = x).*

7.5. Discussion

The primary finding of our study was that although the mean planned DA and arithmetic HKA angles were both within 1° of the healthy population, they had a discrepancy of greater than 3° for 36% of patients. The planned DA accounts for both the bony anatomy of the knee and patient-specific characteristics of the soft-tissue envelope. The aHKA angle – a key driver of the KA philosophy – is bone-referencing only, without consideration to the supporting ligaments. We believe that static bone-referencing measurements are insufficient for TKA planning and that the input of both patient-specific bony anatomy and soft-tissue laxity are required to achieve coronal balance in TKA with bone cuts alone.

In 2012, Bellemans et al analysed a young, asymptomatic cohort of knees and reported that the healthy population had a mean residual varus alignment of 1.3° [183]. The planned DA presented in our study had a mean alignment of 2.2°, which is relatively more varus but still comparable to the native constitutional alignment of the healthy population. This may be due to the more varus coronal femoral alignment of osteoarthritic knees compared to young non-arthritic knees [431]. Although relatively more neutral, the mean aHKA angle of the study population of 0.4° was also within 1° of the mean HKA of the healthy population. As expected, the mean weightbearing HKA angle of the patient population of 4.8° was moderately varus due to loss of articular cartilage and the compressive forces acting on the joint in the load-bearing position.

Literature has established that joint balance in TKA is driven by both soft tissue and bony anatomy, not solely the latter. Li et al (2022) published that the bony anatomy alone was insufficient to determine the correctability of the knee to the mechanical axis without the need for soft-tissue release [260]. However, they observed that this was possible with knowledge of the soft-tissue laxities of the joint. Therefore, using bone-referencing strategies for TKA provides a hard-tissue solution for a soft-tissue procedure, which may result in imbalances. This was observed by Shatrov et al (2022), who published that KA TKAs do not achieve soft-tissue balance in extension and flexion in 34 and 50% of cases, respectively [307]. The planned DA preoperatively considers the knee's bony anatomy and ligamentous profile, guiding implant positioning to coronally align to the planned DA HKA, while also balancing the medial and lateral tibiofemoral joint gaps in extension and flexion. Although a similar result may be achieved through intraoperative assessment, intraoperative gap balancing has limitations.

Currently, surgeons can intraoperatively assess soft-tissue laxities and compartmental gaps using several technologies. The most basic of these options is the use of spacer blocks after bone cuts. Tensioning devices and pressure sensors also enable surgeons to intraoperatively obtain information on tibiofemoral balance. However, all three of these tools necessitate one or more bony cuts to be completed prior to evaluation of the soft-tissue profile. More recently, navigation systems and robotics can be utilised to acquire intraoperative soft-tissue laxities and compartmental gaps. The precision of these technologies, especially robotics, has increased the popularity of functional alignment strategies in TKA [415], [432], which aim to balance the extension and flexion joint gaps and soft-tissue tension whilst maintaining a patient's native alignment [432]. Early literature on functional alignment in TKA presents promising short-term patient outcomes [306], further emphasising the importance of considering soft tissue during TKA. Although the soft-tissue assessments from navigation and robotics can often be performed prior to any bone cuts, they necessitate some soft-tissue incision for joint exposure. Most systems also rely on surgeons to manually stress the joint, which can reduce the reliability and reproducibility of the assessment. Additionally, the accessibility to these technologies varies globally with 57% of TKAs in Australia being performed with the use of navigation or robotics [83] compared to just 7, 4, and 1% in the United States, United Kingdom, and Sweden, respectively [261]. The costs associated with navigation and robotics systems may hinder their global uptake.

The preoperative assessment of joint gaps and soft-tissue laxities can enable a more holistic approach to preoperative surgical planning in TKA, providing orthopaedic surgeons with a planned functional alignment prior to any bone resections. This can assist surgeons by minimising the need for soft-tissue release, bone recuts, or compromised alignments which may otherwise occur. Stress radiology protocols with Telos (Wölfersheim, Germany) arthrometers have been previously used to preoperatively evaluate the soft tissue of the knee [260], [369]. However, such protocols have proven to be time-consuming and the frequently recommended applied force of 150 Newtons [260], [373] may cause patients a large degree of discomfort [260]. These factors limit the clinical applicability and scalability of the arthrometer technique. To the best of our knowledge, our joint distraction radiology protocol did not encounter these challenges. Instead, limited physical resources and time were required to setup and execute the protocol and it was also clinically implemented within the publishing surgeon's routine practice, thus highlighting its potential for wide-scale adoption.

The process of adjusting the initial MA plan to the final Distracted Alignment (DA) is guided by a systematic framework rather than a prescriptive algorithm. The primary objective is to use the distracted joint gap measurements to preoperatively plan balanced joint gaps. This framework allows for specific, quantifiable adjustments to the implant position to meet this goal. Starting from the baseline plan (e.g. MA), the coronal, axial and sagittal angular and positional alignment of the protheses can be adjusted to balance the medial and lateral joint gaps in both extension and flexion. The reason this process is not a single, locked-down algorithm is to accommodate the variability in implant manufacturer constraints, surgical philosophies and patient-specific needs. The definition of a balanced knee is not universally agreed upon and can depend on the surgeon's preference or the chosen implant design. For example, while one surgeon may target symmetrical 0 mm residual gaps, another using a medial-pivot prostheses may intentionally plan for 1-2 mm of residual lateral laxity in flexion. Ultimately, the DA framework provides the quantitative data (the joint gaps) and the tools (adjustable component parameters) to achieve a desired outcome. It empowers the surgeon to implement their preferred alignment strategy based on objective, patient-specific soft-tissue data, rather than imposing a single definition of correct alignment.

Limitations

There were potential limitations associated with our study. The TKA patients in our study had a median age of 70 years, whereas the healthy population assessed by Bellemans et al were aged between 20 and 27 years [183]. The ideal comparison would comprise of the same subjects before and after any indications for TKA. Also, radiology was captured across 6 centres, potentially reducing reliability. This was minimized by providing each centre with a clearly defined protocol. Moreover, the number of radiology centres involved reduces any bias in technique and highlights the potential for wide-scale implementation of the protocol. We applied a standardized mass of 2.5 kg for all patients. However, further research is required to determine the most appropriate mass or whether it should be varied according to patient demographics. The imaging protocol uses a CT scan for 3D analysis, and although CT access may be limited and pose radiation concerns, its availability is expected to grow with the rise of robotics [261], [396]. There is also a fundamental level of error associated with the 3D-to-2D registration process outlined in the methods. The reliability of this approach has previously been illustrated [403]. Furthermore, the osteophyte correction algorithm implemented is a best estimate, and along with the magnitude of the compartmental gaps before and after its implementation, it requires additional validation. Due to its geometric nature, the algorithm does not account for biomechanical properties or identify potential structural changes in the integrity of the ligaments. The implant alignments were planned by an engineer with the goal of equal medial and lateral balance and reviewed by the surgeons, which may not reflect all surgeon preferences in gap balancing. Additionally, the preoperative balancing may not accurately reflect intraoperative information due to gap changes with knee exposure. We believe however, it provides the surgeon a good starting point and additional information to successfully perform a gap balanced TKA with minimal soft tissue release over and above bone referencing systems such as CPAK.

Future work will investigate creating appropriate boundaries for the planned DA as it can result in ‘extreme’ coronal alignments for patients with severe coronal deformities. We also plan to research the ideal distraction weight according to patient demographic group. Additionally, the magnitude of the joint gaps before and after the implementation of the osteophyte correction algorithm and the resulting difference require further validation. The authors aim to perform this by comparing to intraoperatively observed measurements. The imaging protocol and planned DA are a part of the publishing surgeon's preoperative surgical planning process, and we look forward to performing further work investigating clinical and patient-reported outcomes linked to this approach relative to alternate TKA alignment strategies.

7.6. Conclusion

The joint distraction radiology protocol described in this study allows for preoperative analysis of the soft tissue and bony anatomy of the knee. This can be used to produce a functional planned DA, which has a mean HKA angle that is comparable to that of a healthy population. Since the planned DA accounts for both soft-tissue gaps and the bony anatomy, whereas aHKA referencing alignments are determined by the bony anatomy alone, the two are fundamentally different. As a result, we believe the planned DA provides a more holistic approach to preoperative planning in TKA. Although further research and validation of the processes involved in developing the planned DA is required, this technique provides a standardized approach to obtain intra-compartmental joint gap information, whilst remaining clinically practical and scalable.

Chapter 8:

Discussion and Conclusion

8.1. Overview

This dissertation aimed to examine whether functional preoperative joint gap data and 3D knee morphology could be accurately predicted by current knee classification systems, specifically the coronal plane alignment of the knee (CPAK). Recognising the limitations of such systems, the thesis also introduced and evaluated a novel TKA planning protocol that accounts for knee laxity through distracted joint gap measurements in extension and flexion alongside bony anatomy considerations. These aims were systematically addressed across Chapters 3 to 7 through a series of retrospective analyses and methodological developments.

Chapter 3 investigated the relationship between 3D knee morphology and the CPAK coronal parameters (aHKA and JLO) and phenotypes in a retrospective analysis of 7,450 arthritic knees. The findings revealed weak correlations between CPAK parameters and tibial, femoral and tibiofemoral measurements in the axial and sagittal planes. While statistically significant differences were observed across CPAK groups, effect sizes were generally small, indicating that 3D knee morphology is highly variable and not strongly predicted by coronal alignment alone. While this study did not assess joint laxity, these findings underscore the need for a multi-dimensional analysis tool to enhance TKA planning.

Chapter 4 examined functional laxity (FL) both preoperatively and postoperatively using Telos stress radiographs, an established method in literature, and compared these to surgical laxity (SL) assessed intraoperatively at pre-implantation and post-implantation timepoints. The study also explored the relationship between these measurements and 12-month postoperative KOOS sub-scores. Key findings showed that SL evaluations consistently produced greater coronal knee laxity measurements than FL evaluations, while FL better predicted postoperative KOOS QoL and Symptoms sub-scores. These results suggest that FL provides more accurate insights for TKA planning by reflecting a patient’s true laxity in an awake state.

Chapter 5 introduced a joint distraction radiography protocol to evaluate tibiofemoral joint gaps in extension and flexion. This study validated the registration of pre-landmarked 3D bone models to distracted radiographs through intra-observer and inter-observer reliability analyses. The protocol demonstrated high reliability for coronal plane angular and joint gap measurements, while axial rotation and sagittal flexion measurements were moderately reliable but still appropriate for research purposes. These results confirmed the protocol's utility in generating reliable data for coronal HKA and intercompartmental joint gaps.

Chapter 6 revisited aHKA, JLO and the CPAK groups using a subset of 433 patients from Chapter 3 to investigate their relationship with intercompartmental and composite joint gap measurements. This study found that CPAK parameters and phenotypes were insufficient predictors of joint gap behaviour, further emphasising the system's limitations in guiding soft-tissue-informed alignment strategies.

Chapter 7 introduced and evaluated the Distracted Alignment (DA) protocol by integrating the joint gap data from the radiology protocol established in Chapter 5 into a preoperative TKA planning pipeline. The study compared the planned DA alignment with mechanical alignment (MA), kinematic alignment (KA), and the constitutional alignment of a healthy population. DA produced a coronal alignment comparable to healthy knees, with less extreme tibial and femoral resections than KA. Moreover, the planned DA HKA differed from aHKA in over one-third of patients, reflecting its consideration of both bony and soft-tissue data. These findings highlight DA as a viable, soft-tissue-informed approach to preoperative TKA planning.

8.2. General Discussion

8.2.1. Need for multi-dimensional analysis tools

Historically, knee alignment classification systems have predominantly focused on the coronal plane. The conventional framework of neutral, varus and valgus, has provided a foundational understanding of alignment by categorising the HKA angle. While effective in describing coronal alignment, these classifications are oversimplified. Subsequent advancements, such as the five alignment categories proposed by Lin et al., and the many potential functional knee phenotypes proposed by Hirschmann et al., incorporated the MPTA and LDFA in addition to the HKA, offering a more nuanced understanding of coronal alignment [185], [214]. These systems provide a deeper understanding of the high variability of the native coronal alignment, and for example, how two knees with a similar HKA can be fundamentally different because of their femoral and tibial alignments. However, their complexity has limited widespread clinical adoption. Most recently, the CPAK, introduced a classification system integrating the constitutional coronal alignment and JLO [10]. With just nine potential phenotypes that can be visualised using a 3x3 grid, the system provides a digestible approach for considering preoperative and postoperative knee alignment. Furthermore, it is unaffected by potential changes in tibiofemoral joint space and so may be more reflective of a patient's pre-arthritic alignment. However, these tools remain fundamentally focused on the coronal plane and are limited in addressing the multi-dimensional variability of the knee as well as soft tissue laxity.

The focus on the coronal plane, while valuable, addresses only part of the problem. For instance, Orce Rodriguez et al. examined CPAK phenotype recreation in TKA in a single-centre study using a single implant system [216]. Their results demonstrated no significant difference in KOOS, OKS, FJS, UCLA, VAS pain or VAS patient satisfaction scores between knees where CPAK phenotypes were recreated and those where they were not. Similar results have been observed by Bertugli et al. [433] and Agarwal et al. [434], suggesting that recreating coronal alignment alone is insufficient for achieving superior postoperative outcomes. This highlighting the need for a more comprehensive understanding of knee morphology and function, and that coronal alignment is just one part of the puzzle.

The limitations of current knee classification systems stem from the inherent 3D variability of knee morphology, which cannot be fully captured by coronal alignment alone. As demonstrated in Chapters 3 and 6 of this dissertation, the arthritic knee displays significant inter-patient variability in anatomical characteristics, including tibiofemoral angular alignment and joint gaps. These anatomical measurements showed only weak correlations with CPAK's coronal parameters (aHKA and JLO) and did not exhibit distinct measurements across different CPAK groups. These findings align with those of Corbett et al., who also reported substantial variability in 3D knee alignment and limited relationships between CPAK classifications and key axial and sagittal anatomical parameters [351]. Additionally, several studies have highlighted the high variability of joint laxity and intercompartmental gap measurements in knee undergoing TKA [363], [364], [418]. Furthermore, stability of the knee throughout the ROM can result in superior patient outcomes. Studies have outlined the importance of maintaining soft tissue balance not only in extension but also in flexion, where imbalances can lead to inferior PROMs [232], [233], [269], [270]. This underscores the need for classification tools that consider multi-dimensional knee morphology and function.

Given the high variability of 3D knee anatomy and soft tissue gaps – and their influence on patient outcomes – it is essential to expand preoperative TKA analysis to encompass bony anatomy and soft tissue characteristics beyond just the coronal pane in extension.

While not covered in the scope of this thesis, biomechanical factors can also influence patient outcomes. For instance, component malalignment can increase joint loading and may impact fixation and long-term implant survivorship, while bone quality can also influence postoperative TKA outcomes [435], [436], [437]. Therefore, a more comprehensive approach must integrate multi-planar alignment characteristics, soft tissue behaviour throughout the ROM as well as biomechanical considerations to provide a more robust foundation for surgical decision-making. However, developing such a system presents a complex challenge that requires extensive research and multidisciplinary collaboration.

One potential approach could involve identifying a key set of parameters across these different categories, that drive TKA planning or are known to influence TKA outcomes. This could include:

- Coronal plane anatomy: HKA and JLO, which provide insights into overall limb alignment and joint angle.
- Axial plane anatomy: Tibiofemoral rotation, which plays a crucial role in rotational stability and patellofemoral kinematics.
- Sagittal plane anatomy: medial and lateral posterior tibial slope, which can affect postoperative flexion and stability.
- Soft tissue characteristics: Coronal laxity and/or intercompartmental joint gaps measured throughout the ROM, which can impact functional outcomes. Notably, Chapter 6 demonstrated that coronal alignment parameters showed only weak correlations with intercompartmental joint gaps, highlighting the need to also consider soft tissue during TKA planning.
- Biomechanical considerations: joint loading and bone stress, which can influence long-term implant survivorship and postoperative patient outcomes.

These parameters could then be analysed using statistical and computational modelling tools, such as machine learning or principal component analysis, to identify underlying patterns and group knees into distinct clusters. It is hypothesised that this approach would reveal multi-dimensional knee alignment phenotypes that better capture anatomical and functional diversity than current coronal classification methods. However, the high inter-patient variability of these parameters necessitates a large sample size (in the hundreds or thousands) to ensure the robustness and generalisability of findings. Ensuring that the clusters are clinically meaningful and actionable requires additional efforts. The identified clusters must be intuitive and easy to use in clinical settings. A possible solution is visualising knee morphology within a structured classification framework, as effectively achieved by CPAK [10]. Alternatively, decision trees could be developed to allow easy categorisation of a knee into an appropriate phenotype. Further, the clusters must be validated against functional and non-functional outcomes including clinical assessments and PROMs to determine their predictive value. Subgroup analysis could determine whether certain phenotypes correspond to specific surgical techniques, alignment strategies or prosthesis types. The initial validation would involve retrospective data to leverage large existing datasets, before the prospective validation to determine whether the phenotypes are suitable to guide TKA planning and intraoperative decision-making with the goal of enhanced patient outcomes. Successfully developing such a multi-dimensional framework has the potential to transform TKA analysis and planning toward a more data-driven, patient-specific approach that accounts for both anatomical structure and functional knee behaviour.

8.2.2. Functional vs surgical assessment of the knee in TKA

The evaluation of joint gaps and laxity is critical for achieving alignment and balance in TKA. Broadly, these assessments can be categorised into surgical and functional approaches. Surgical assessments, as noted in Chapter 4, are performed intraoperatively with the patient under anaesthesia, using manually applied stress or intraoperative tools to evaluate soft tissue tension and compartmental gaps. In contrast, functional assessments, such as those in Chapters 4-7, are conducted with the patient awake, often in load bearing, stressed or distracted positions. While surgical assessments are widely integrated into traditional workflows, they are inherently subjective and may not reflect the patient’s true laxity. Functional assessments, on the other hand, provide a more standardised and comprehensive evaluation, though they remain largely confined to research settings.

To the best of my knowledge, intraoperative coronal knee laxity assessment remains the most widely used method for evaluating joint laxity and balance during TKA. This is primarily due to its practicality in real-time decision-making. This approach provides valuable information for alignment planning, such as assessing the correctability of the knee to a reference (e.g. the mechanical axis), as well as evaluating balance during gap balancing techniques. However, these assessments typically rely on manually applied stress and/or visual estimation, making them inherently subjective and prone to variability. MacDessi et al. compared the accuracy of surgeon-defined assessment of knee balance to that determined by the VERASENSE sensor in 322 manual TKAs [366]. Balance was assessed at 10°, 45° and 90° after placing trial components and prior to any ligament releases. During surgeon assessment of balance, the surgeon manually applied varus and valgus stress to the knee, relying on tactile feedback and visual estimation of joint tension, while the sensor provided objective data on compartmental pressures and balance. The accuracy of the surgeon-defined assessment of balance was 63%, 57.5%, and 63.8% at 10°, 45°, and 90° of flexion, respectively, when compared to sensor data. Additionally, the surgeon balance assessment demonstrated low specificity and poor agreement with sensor data, especially at higher flexion angles. Notably, the study also found no improvement in accuracy of surgeon-defined assessment with continued sensor use, indicating a lack of a learning effect. MacDessi et al. investigated this further through a prospective, multicentre study of 285 TKAs across eight surgeons [251]. In this study, the authors also observed low accuracy of surgeon-defined assessment of balance relative to VERASENSE. The mean accuracy was across the surgeons 58.3%, 61.2% and 66.5% at 10°, 45° and 90° respectively. Further, surgeon experience displayed no influence on test accuracy and significant inter-surgeon variability was observed. These findings highlight the limitations of subjective surgeon assessments in determining soft tissue balance and suggest.

Sensor technology provides more reliable and consistent measurements, assisting in identifying imbalances. While definitions may vary between different sensors, literature frequently notes knees with mediolateral intercompartmental load differences of ≤ 15 lbs to be balanced [255], [256], [257], [428]. Multiple studies have investigated the outcomes of patients with balanced and unbalanced TKAs as defined with sensor measurements. These studies found comparable postoperative patient outcomes for both cohorts, specifically for KSS, EuroQol five-dimension questionnaire (EQ-5D), UCLA and KOOS [256], [257]. Furthermore, a systematic review by Sava et al. reported comparable postoperative outcomes for patients who received sensor-balanced and manually-balanced TKAs [258]. While this posits whether these technologies justify their cost, it appears that their value lies in reducing potential postoperative complications [254], [258]. It should be noted that sensors do not allow for laxity assessment prior to bone resection, instead only providing insight into estimated postoperative balance.

Robotics and navigation devices can be used in conjunction with manually applied stress to evaluate knee laxity throughout the knee ROM and prior to bone resections. While literature on pre-resection joint gaps and laxity assessment using navigation systems remains limited, there is a growing body of evidence supporting the use of robotic systems for this purpose. In a sample of 12 cadaveric human knees, Scholl et al. observed high reliability of ligamentous laxity assessment using the MAKO system (Stryker, USA) [438], while Yee et al. high inter- and intra-rater reliability for pre-resection ligament tension evaluations in 24 knees with the CORI system (Smith & Nephew, UK) (ICC > 0.90), though they noted lower intra-rater reliability for the lateral flexion gap (ICC = 0.89) [439]. Additionally, Woelfle et al. found that surgeon-applied stress using the ROSA system (Zimmer Biomet, USA) provided comparable flexion gap measurements to a ligament tensor [440]. However, in a study of 40 knees using the NAVIO system (Smith & Nephew, UK), Sohmiya et al. highlighted that joint distraction forces during robotic-assisted TKA may be influenced by the surgeon's experience, with experienced surgeons producing greater gaps [367]. These findings suggest that while robotic systems offer significant potential for consistent assessments, variability between systems and the influence of surgeon technique remain critical areas for further investigation. Furthermore, the intraoperative capture of laxity measures introduces additional time pressure for surgical planning, as any necessary adjustments must be made in real time.

The functional assessments introduced in Chapter 4 and Chapter 5, provide significant advantages over traditional surgical (intraoperative) coronal laxity and gap evaluation. These methods offer two key benefits that can improve the reliability and applicability of joint gap and laxity measurements. First, functional assessments are performed with patients awake, allowing evaluation of the knee within the patient's comfort threshold. As highlighted in Chapter 4, both pre-implantation and post-implantation laxities were higher during intraoperative surgical assessments compared to the respective functional assessments. This suggests that intraoperative measurements may overestimate the laxity experienced by patients in their awake state. This is further emphasised by Tsukeoka and Tsuneizumi, who used a Telos stress radiology protocol to assess postoperative coronal laxity both under anaesthesia and while awake [266]. Their findings showed significantly greater varus and valgus laxities under anaesthesia, with 23% of patients displaying a difference of ≥3° compared to awake assessments. These results emphasise the importance of evaluating laxity within an awake, functional context for a more accurate representation of patient-specific joint behaviour. Secondly, the use of standardised protocols and objective evaluation can overcome potential variability otherwise observed through subjective and variable intraoperative laxity assessments. This standardisation can improve the reliability of assessments and enable direct comparison of data across different timepoints, such as preoperative to postoperative or even at multiple timepoints after the procedure, offering valuable insights.

Despite its potential, functional laxity assessments face four key challenges. First, they require additional resources, including specialised imaging such as stress radiographs (Chapter 4) and distracted radiographs (Chapter 5-7). These additional scans not only increase patient exposure to radiation but also place a greater burden on radiology centres. The resource demands can vary significantly depending on the protocol. For example, the stress radiology protocol in Chapter 4 was more technically demanding than the distracted radiology protocol in Chapters 5-7, requiring additional technician training and time to acquire the images — an observation based on anecdotal experience rather than formal testing. This resource disparity was one of the driving factors behind the development of the joint distraction radiology protocol. Beyond imaging, greater engineering resources are also necessary for the associated image processing and analysis. However, with the increasing adoption of 3D preoperative planning as a gold standard in TKA, these challenges may become more manageable as infrastructure and expertise continue to evolve. Second, functional laxity assessments are currently primarily used for research, and their potential to inform intraoperative decisions is yet to be realised. As achieved with the DA planning protocol in Chapter 7, such laxity data needs to be integrated into surgical workflows. Third, the applied stress during the functional laxity protocol used in Chapters 4-7 may have been limited by patient discomfort, potentially stopping at a lower load than the maximum possible. While this reduces the standardisation of the protocol, continuing to apply force beyond the patient's tolerance would be unethical. Furthermore, since patients are unlikely to function beyond their discomfort threshold, functional laxity assessments still provide a clinically relevant representation of knee laxity in a conscious individual. Fourth, cadaveric studies are frequently used in preclinical trials and implant design to evaluate joint behaviour under controlled conditions. While functional laxity assessment protocols can also be performed on cadaveric specimens, the absence of dynamic muscle activation in these models limits their applicability to conscious patients. As a result, findings from in-vitro studies may not fully reflect the true joint behaviour observed in living subjects. Instead, functional laxity assessments, as discussed in this thesis, offer valuable insights into patient-specific laxities and facilitate research on their impact on clinical outcomes.

Both surgical and functional laxity assessments share a common limitation: they are designed to prioritise clinical feasibility over precision, often at the expense of accurately capturing the mechanical properties of individual ligaments. For example, functional assessments typically rely on external stress or joint positioning to infer ligament tension, without directly accounting for the complex, patient-specific variability in ligament behaviour. Similarly, surgical assessments rely on tactile feedback and visually estimated balance, which lack the granularity required to truly understand ligament mechanics. As highlighted by Andersen and Pedersen, optimising laxity tests through computational modelling could provide more tailored and precise evaluations by simulating how specific forces affect ligaments [441]. Andersen and Theodorakos further emphasise that ligament properties, such as stiffness and elasticity, vary significantly between patients, underscoring the need for more advanced methods to accurately account for these differences [442]. However, these approaches are currently impractical for routine clinical use, leaving a gap between what is measurable in research and what can be applied in practice.

8.2.3. Bridging the gap between functional laxity research and clinical practice through TKA planning

Functional laxity assessments, and functional evaluations of the knee more broadly, have largely remained confined to research settings. These assessments have provided valuable insights into the biomechanics of both healthy and osteoarthritic knees, advancing our understanding of joint balance, soft tissue behaviour and the impacts of TKA. Despite their significant contributions to the field, functional assessments have not yet seen widespread adoption in clinical practice. This could be for several reasons, including the need for additional time, resources, and expertise required to perform such evaluations. Furthermore, it can be difficult translating the findings into practical, actionable surgical strategies.

Another key challenge in bridging the gap between research and clinical practice lies in the limitations of cadaveric studies, which are frequently used to study knee laxity and balance [360], [438], [443]. While these studies provide valuable insights into biomechanics, they inherently lack muscle activation, making their results more reflective of an anaesthetised state. As observed in Chapter 4, laxity assessments under anaesthesia often overestimate the “true” laxity experienced by awake patients. This discrepancy underscores the need for further validation of cadaveric findings through functional assessments performed on awake patients. Future research could also explore the development of mathematical or statistical models to transform anaesthetised laxity measurements to estimate functional laxity based on existing datasets, including those presented in this thesis. Bridging this gap is essential for defining clinically relevant targets that align with patient-specific functional thresholds and improving the applicability of research findings to surgical decision-making.

While preoperative functional assessments remain underutilised in clinical settings, intraoperative knee laxity and gap data have significantly shaped modern TKA alignment strategies, particularly through the development of FA. Unlike MA, which targets neutral limb alignment, or KA, which focuses on recreating constitutional alignment, FA leverages intraoperative laxity evaluations via robotics or computer navigation systems to dynamically refine component alignment plans. By integrating real-time data on joint gaps and soft tissue tension, FA customises implant positioning to restore a patient's native knee kinematics, achieving mediolateral and extension-flexion joint balance. Although still a relatively new technique, early evidence indicates that FA offers superior gap balancing compared to MA and KA, reduces bone resections and recuts compared to KA, and enables faster postoperative recovery than MA [303], [305], [306], [307], [308], [309]. FA represents a pivotal shift in TKA alignment strategies, as it is the first major approach to prioritise soft tissue balance in both extension and flexion while minimising soft tissue releases, truly acknowledging TKA as a procedure that fundamentally addresses the soft tissue behaviour of the knee.

The DA approach introduced in Chapter 7 of this dissertation presents a form of a preoperatively planned FA. Like FA, DA requires an initial planned alignment, such as MA or KA. Then, using soft tissue data in the form of intercompartmental joint gaps measured in extension and flexion, the planned component alignment is adjusted to achieve mediolateral and extension-flexion joint balance. This process enables a more personalised alignment strategy that considers both bony anatomy and soft tissue behaviour. The goal of DA is to provide surgeons with a preoperative plan that incorporates tibiofemoral balance in both extension and flexion, enhancing the surgeon's understanding of the knee prior to surgery. This additional insight into component sizing, alignment, and soft tissue-related deformities reduces intraoperative uncertainties and potential complications. DA has the potential to be executed using manual instruments or PSIs, making it a viable alternative to FA for surgeons without access to costly computer-navigation or robotics systems. While over 57% of TKAs in Australia are performed using either robotics or navigations systems, this number is as low as 7% in USA, 4% in UK and 1% in Sweden [261], [318]. As such, DA planning offers a more accessible solution for many surgeons, particularly as the adoption of 3D imaging in arthroplasty continues to grow [444], [445]. For surgeons equipped with robotics or computer-navigation technologies, DA can serve as a preoperative alignment strategy tailored for FA, effectively replacing the traditional MA or KA base plan. The shared goals of DA and FA – achieving joint balance while minimising soft tissue releases – may reduce the extent of intraoperative fine-tuning required, streamlining the surgical workflow and potentially improving outcomes.

During this thesis, a prototype software was developed at 360MedCare to support preoperative DA planning. The software provides a detailed visualisation of bone positioning and the resulting joint gaps in both extension and flexion distracted positions. By incorporating component alignment and thickness, it estimates post-implantation joint gaps, enabling gap-informed TKA planning. For instance, in **Figure 8.1**, the software displays medial and lateral extension gaps of 2.4 mm and 6.5 mm, respectively, and medial and lateral flexion gaps of 3.9 mm and 5.3 mm, respectively, suggesting mediolateral imbalances and general laxity in both extension and flexion while using a default plan. Conversely, **Figure 8.2** demonstrates how updated component alignment through DA achieves balanced medial and lateral gaps in both extension and flexion, all within a range of 0 mm to 1 mm. The integration of this prototype into preoperative planning offers significant advantages by facilitating gap-informed alignment strategies such as DA, potentially improving TKA balance without soft tissue release. Moreover, the software has potential to be incorporated into computer navigation or robotics systems, further enhancing its utility in a clinical setting. Further work is required to build out the software capabilities and to validate the DA imaging and planning protocol as outlined later in Chapter 8.4. Nonetheless, incorporating DA planning into software platforms highlights its potential to bridge the gap between research and clinical practice.

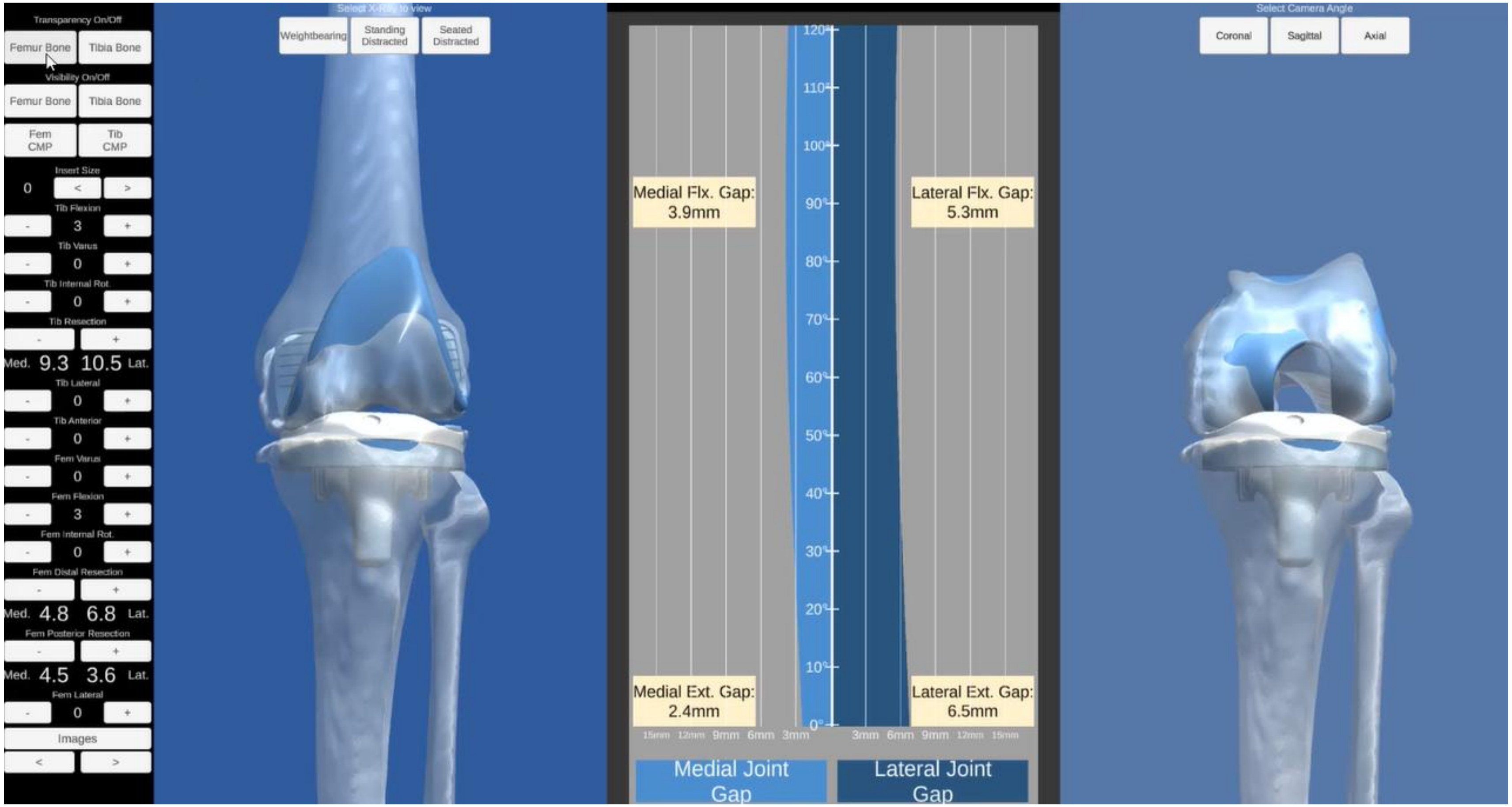


Figure 8.1. *Prototype software output displaying the medial and lateral joint gaps for a default alignment plan. The left panel visualises the bones in the extension distracted position, while the right panel shows the bones in the flexion distracted position. The centre panel illustrates joint gaps at extension (0°) and flexion (90°), with the estimated joint gap curve for the full range of motion. The displayed gaps are 2.4 mm and 6.5 mm for medial and lateral extension, and 3.9 mm and 5.3 mm for medial and lateral flexion, respectively, indicating mediolateral imbalances and general laxity.*

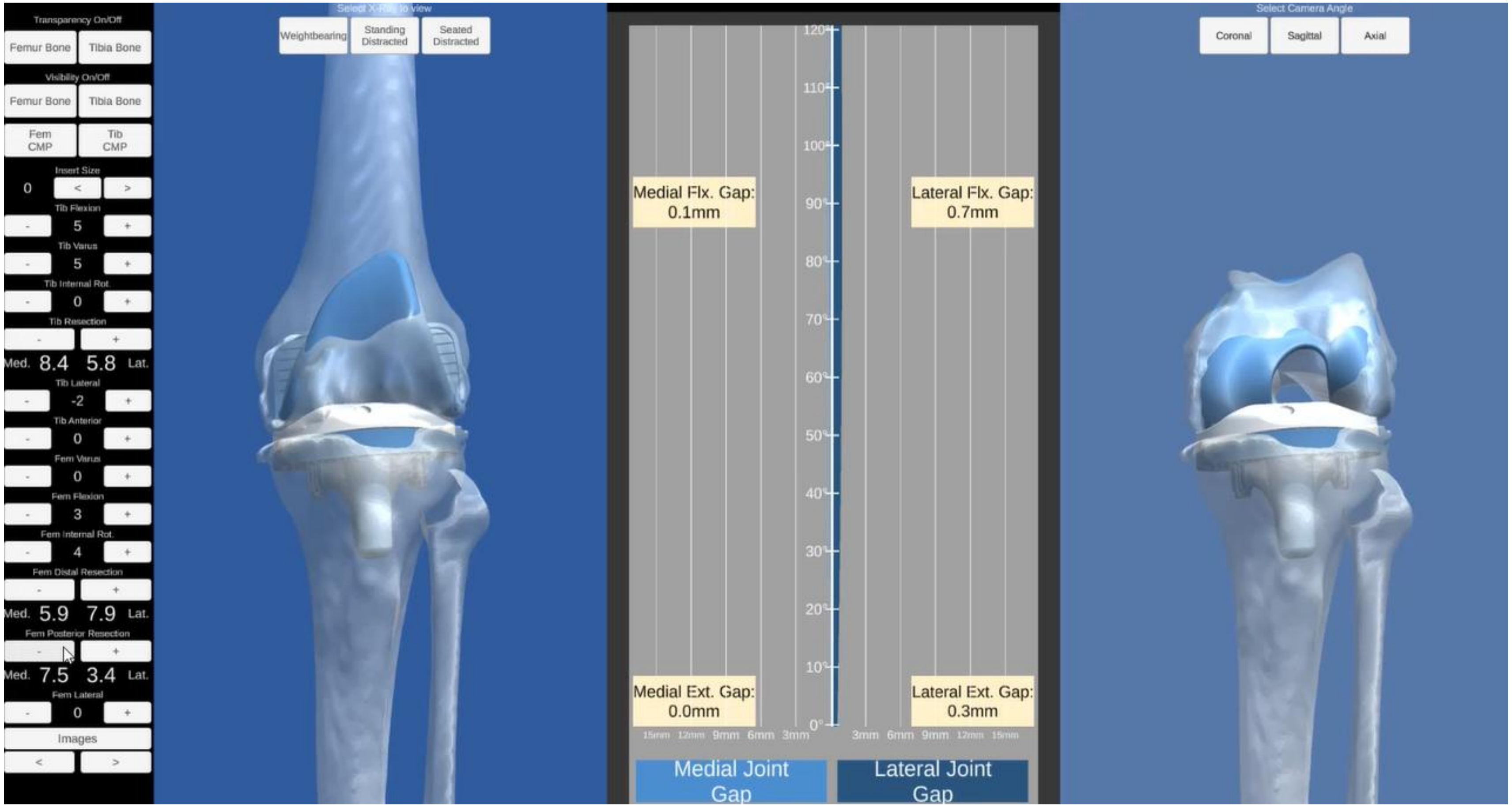


Figure 8.2. *Prototype software output after adjusting the component alignment through DA planning. The left panel visualises the bones in the extension distracted position, while the right panel shows the bones in the flexion distracted position. The centre panel illustrates joint gaps at extension (0°) and flexion (90°), with the estimated joint gap curve for the full range of motion. The planned distracted alignment achieves balanced medial and lateral joint gaps, in both extension and flexion, with all values falling within a range of 0 mm to 1 mm, indicating improved mediolateral balance and joint stability.*

8.3 Limitations

The findings and methodologies presented in this dissertation are subject to several potential limitations that should be acknowledged to provide context for the interpretation of the results and their applicability to clinical practice.

8.3.1. Distracted radiology protocol

In addition to a CT scan, the radiology protocol introduced in Chapter 5 involves three radiographs, two of which incorporate joint distraction – one in extension and the other in flexion. These radiographs axially distract the knee joint to eliminate excess slack in the knee ligaments, particularly the MCL and LCL, insight into the patient's native, pre-arthritic knee alignment. For this protocol, 2.5 kg ankle weights were used for joint distraction, an adjustment from the 1.5 kg weights used in the original flexion distracted imaging protocol by Tokuhara et al. [386]. This increase accounts for differences in study populations. Tokuhara et al. examined healthy Japanese knees [386], whereas this thesis focused on patients with end-stage osteoarthritis undergoing TKA in Australia, who are typically overweight or obese [83]. Although this adjustment represents a reasoned estimate, further research is required to determine the optimal mass for successful joint distraction, which may vary between patients. The protocol combines CT imaging, functional and distracted radiographs, and a registration process to enable preoperative functional assessments of knee alignment and laxity. While this approach addresses many limitations of intraoperative alignment and laxity assessments, it remains a static evaluation, providing information only at full extension (i.e. 0° flexion) and at 90° flexion. This data supports coronally balanced TKA plans at these specific angles. However is does not account for mid-flexion stability, which literature highlights as crucial for achieving successful postoperative outcomes [232], [233]. This is a key limitation in the current protocol that warrants further exploration. Additionally, implementing the joint distraction imaging protocol incurs certain costs. While relatively straightforward, it requires (1) a tall chair or stool with back support, (2) a short platform, and (3) ankle weights. This could increase the burden on healthcare systems and radiology centres. Nevertheless, with appropriate training and in cases where CT scans and standard X-rays are already part of routine preoperative workflows, integrating this protocol should be feasible. Moreover, while not explicitly tested, the time and costs associated with this protocol appear to be lower than those required for stress radiograph protocols using the Telos device (as in Chapter 4), which necessitates specialised equipment and technical expertise. Further research is required to determine whether the joint distracted radiographs can be acquired using an EOS scanner, which could simplify the workflow by eliminating the need for a CT scan and 3D-to-2D registration. This could streamline the process, further reducing resource demands on both healthcare systems and engineering teams.

8.3.2. Ligament modelling and osteophyte correction assumptions

The ligament model and associated osteophyte correction protocol introduced in Chapter 5, and subsequently applied in Chapters 6 and 7, relies on a geometric ligament model with several key assumptions. First, the origin and insertion points of the LCL and MCL were estimated using bony landmarks, as this information cannot be accurately determined using CT scans or radiographs. Second, the ligaments were each modelled as a single bundle, simplifying the complex multi-fascicle structures of the LCL and MCL. However, Montgomery et al. reported that in comparison to multi-bundle simulations, single-bundle models can sufficiently capture key kinematic behaviours of the knee [446]. Third, ligament tenting was defined as the difference between the straight-line path of a ligament (from origin to insertion) and the wrapped path that ‘stretched’ around bony structures. Bones were not explicitly classified as osteophytes. Instead, the model assumed that any ‘stretch’ exceeding 1 mm was due to osteophytes. When greater than 1 mm, the ‘stretch’ amount was then used to adjust the joint gap, simulating the expected effect of intraoperative osteophyte removal. These assumptions mean the modelled ligaments may not fully reflect a patient’s true anatomy as observed intraoperatively. Additionally, the measured stretch could vary depending on the anteroposterior position of the ligaments relative to the osteophytes, introducing variability in the estimated corrections. Despite these limitations, the ligament modelling and osteophyte correction protocol strikes a practical balance between patient-specificity, computational efficiency, and clinical applicability. Future advancements, such as integrating machine-learning algorithms, statistical shape modelling, or soft tissue imaging modalities like MRI, could enable more precise and clinically relevant simulations of ligament behaviour and osteophyte correction.

8.3.3. Retrospective data

The use of retrospective data across all studies in this thesis introduces several limitations that must be acknowledged. Retrospective datasets, not originally collected with the specific aims of this research, can lead to potential inconsistencies in data quality, standardisation, completeness or limited sample sizes. Additionally, the lack of randomisation and control over confounding variables, such as variations in surgical techniques or patient demographics, limits the ability to establish causality and generalise findings across broader populations.

Two examples illustrate the impact of these limitations on the analysis. First, the Telos stress radiology protocol used in Chapter 4 was no longer used in clinical practice when the study specific was conducted. As a result, the sample size of the study could not be increased further. Second, generalisability to diverse populations is limited by the demographic composition of the dataset. Although ethnicity was not explicitly recorded in the retrospective dataset, the contributing surgeons all practiced in Australia, where the patient cohort is assumed to be predominantly Caucasian. As anatomical and biomechanical differences may exist between ethnic groups, caution is required when extrapolating these findings to other populations.

While robust protocols, statistical methods, and, where possible, large sample sizes were employed to mitigate these challenges, the inherent biases and constraints of retrospective data necessitate cautious interpretation of the results. Nonetheless, leveraging retrospective data enabled the inclusion of larger patient samples than would have been feasible in a prospective study, especially in Chapters 3, 6 and 7. This approach facilitated the investigation of clinically relevant questions in a shorter timeframe and with fewer resources. The findings of this dissertation lay a strong foundation for further prospective analyses to validate and expand upon the insights gained.

8.3.4. KOOS Subscales

In Chapter 4, we observed that FL better predicted postoperative patient outcomes compared to SL, with the KOOS subscales used as the primary measure of patient outcomes. However, a notable limitation of using KOOS subscales is the ceiling effect, where patients with strong outcomes tend to score at the upper limit, making it challenging to distinguish between "good" and "exceptional" results. This limitation can obscure subtle variations in postoperative outcomes, particularly in high-functioning patients undergoing TKA. Although not available in the retrospective datasets used in this thesis, alternative PROMs like the Forgotten Joint Score (FJS) have been developed to address this issue. The FJS offers greater sensitivity for detecting subtle differences in outcomes by assessing how often patients “forget” the presence of their artificial joint in daily activities [99]. To provide a more nuanced evaluation of patient outcomes, future studies should consider incorporating complementary PROMs like the FJS.

8.4. Further Research

8.4.1. Determining laxity targets using functional assessments

Using functional assessments to determine knee laxity and alignment targets represents a promising avenue for future research in preoperative TKA planning. In their prospective analysis of 135 knees, Wakelin et al. evaluated the relationship between intraoperatively measured mediolateral joint gaps in extension, mid-flexion and flexion, and one-year postoperative PROMs [232]. The authors identified distinct mediolateral joint balance targets for each flexion category. Achieving these targets resulted in superior KOOS Pain outcomes by 8.3, 5.6 and 2.8 points, respectively ($p < 0.05$ for all). Interestingly, the benefits of achieving the targets were compounding. Achieving any two of the three targets improved postoperative KOOS Pain outcome by an average of 8-10 points ($p < 0.05$), while achieving all three targets enhanced KOOS Pain outcome by 11.2 points ($p < 0.05$).

In a separate prospective study, Wakelin et al. explored the relationship between medial, lateral and medio-lateral joint gaps in extension, mid-flexion and flexion, and two-year postoperative KOOS scores [233]. Here, only achieving the flexion target significantly improved KOOS Pain outcomes at the two-year follow-up, while satisfying the extension, mid-flexion or all three targets simultaneously did not yield significant improvements. This suggests that their previously suggested targets are more applicable to short-term outcomes. The study also proposed nine joint balance targets, encompassing medial laxity, lateral laxity, and mediolateral balance across extension, mid-flexion, and flexion. Again, they observed a compounding effect, with greater adherence to these targets associated with superior patient outcomes. These findings demonstrate the potential of defining optimal laxity targets at various flexion angles to guide surgical alignment and enhance patient outcomes, particularly when targets are satisfied throughout the range of motion.

Building on these insights, the joint distraction radiology protocol introduced in Chapter 5 offers a means to preoperatively evaluate and define laxity targets using functional laxity assessments, with patients in an awake state. Future research could focus on validating this protocol for standardised preoperative and postoperative knee assessments, enabling more consistent evaluations of alignment and joint gaps. Additionally, studies comparing preoperative and postoperative joint balance would provide insights into their relationship with patient outcomes, helping refine joint balance targets for TKA planning. Investigating the correlation between preoperatively determined joint gaps and intraoperatively observed gaps could also help ensure a seamless transfer of preoperative planning data to intraoperative execution.

Beyond achieving balanced joint gaps, the registration protocol presented in Chapter 5 supports the registration of 3D bone models to radiographs in functional positions, enabling research into alternative alignment strategies to further optimise patient outcomes. For instance, while coronal alignment has traditionally been prioritised, tibiofemoral axial alignment has received less attention despite evidence linking excessive internal rotation of the tibia or tibiofemoral joint to inferior patient outcomes. Excessive tibial internal rotation (>5.8° to >9.0°), combined tibiofemoral internal rotation (>4.7° to >8.7°), and rotational mismatches between the tibial and femoral components (>5.8° to >10.0°) have been associated with increased pain and reduced function [41], [42], [43], [44], [45].

Given the significant impact of tibiofemoral rotational alignment on patient outcomes, defining rotational targets is important. However, variability in these rotational targets underscores two key needs. First, tibial axial alignment should be assessed relative to the femur, as evaluating it in isolation may lead to malrotation and patellofemoral complications [347]. Second, more consistent methods are required to determine rotational alignment targets. Previous studies, such as those by Aglietti et al. and Nam et al., used 2D and 3D CT analyses to project the femoral TEA onto the tibia [447], [448]. While these studies enabled evaluation of tibial axial alignment relative to the femur, both were conducted in supine CT positions. The CT, joint distraction imaging and image processing protocols used in Chapters 5-7 of this dissertation provide the opportunity to preoperatively assess tibiofemoral alignment in functional positions. Pilot studies using these imaging and image processing pipelines have been performed (Appendix 1 and Appendix 2). With further research, these methods could help establish general or patient-specific targets for tibiofemoral rotational alignment in TKA.

Such research has the potential to refine alignment targets for TKA planning and execution, bridging the gap between research and clinical practice, and ultimately optimising patient outcomes.

8.4.2. Postoperative outcomes of Distracted Alignment

Chapter 7 of this dissertation introduces the concept of preoperatively planned DA in TKA. While the methodology for DA planning has been established, further research is required to validate its clinical benefits and assess its impact on patient outcomes. Two streams of studies are proposed: First, investigating DA as the achieved alignment and second, evaluating DA as the base planned alignment for FA.

Stream 1: Investigating DA as the achieved alignment

The first stream of research should assess DA as the achieved alignment in TKA. As an initial step, a retrospective analysis could compare achieved alignments for DA with other common alignment strategies such as MA and KA. In this analysis, achieved TKA alignments would be compared to their respective preoperative plans and categorised based on which alignment they most closely resemble. Once all TKAs have been appropriately categorised, outcomes such as patient-reported outcome measures (PROMs), patient satisfaction, clinical results, functional outcomes, and postoperative complications could be compared across the alignment groups. Joint stability and balance in both extension and flexion would also be key metrics for evaluation. Although retrospective studies offer valuable insights, they are inherently limited by the availability and quality of existing data. If these studies reveal that achieving DA leads to comparable or improved outcomes compared to other alignment strategies, a prospective study would be the logical next step.

A multi-centre, prospective, randomised controlled trial (RCT) could then evaluate the intraoperative and postoperative effects of performing a DA TKA relative to MA or KA. Intraoperative variables to investigate would include the extent of soft tissue release or rebalancing required and the length of surgery. Postoperative outcomes would focus on PROMs, patient satisfaction, functional outcomes (including joint stability in extension and flexion), length of hospital stay, and postoperative complications such as revisions or manipulation under anaesthesia. These outcomes should be assessed at both short-term intervals (e.g., 6 months and 1 year) and longer-term follow-ups (e.g., 2 years and 5 years) to capture both immediate and sustained impacts of DA.

Stream 2: Investigating DA as the base planned alignment for FA

The second stream of research should explore the potential of planned DA as a base alignment for intraoperative FA. A simulation study could serve as a starting point, comparing preoperatively planned DA, MA, and KA to determine the extent of intraoperative fine-tuning required to achieve joint balance in a cohort of patients undergoing FA. For this study to be feasible, preoperative DA, MA and KA plans would be required in addition to the intraoperative robotics data that would provide details of the patient's native anatomy and soft tissue laxity. This study would provide insight into how well each alignment strategy serves as a foundation for FA and inform refinements to DA protocols. Building on this, a prospective RCT could be conducted, in which all patients receive a FA TKA using a robotic system. The preoperative base alignment plan for each TKA would be randomly assigned to DA, MA, or KA. This study would compare intraoperative factors such as the amount of fine-tuning required, and the extent of soft tissue release or rebalancing performed. Postoperative outcomes would include PROMs, patient satisfaction, functional outcomes, joint stability, length of stay, and rates of complications such as revision surgery or manipulation under anaesthesia.

These two streams of research would provide a comprehensive understanding of DA's clinical utility, both as an independent alignment strategy and as a foundational plan for FA. The findings could help establish evidence-based guidelines for implementing DA in TKA, ultimately improving patient outcomes and advancing alignment strategies in clinical practice.

8.4.3 Alternate applications of geometric ligament modelling

The ligament modelling technique used in this thesis presents opportunities for applications beyond its current scope, both within TKA research and in broader orthopaedic contexts. Within TKA, ligament modelling could be expanded estimate additional soft tissue structures of the tibiofemoral joint. It could also be expanded to investigate the patellofemoral joint, particularly to address issues such as potential overstuffing or understuffing of the anterior compartment of the knee. Patellofemoral overstuffing has been associated with inferior patient pain and functional outcomes ($p < 0.05$) [449]. Additionally, both overstuffing and understuffing of the patellofemoral joint can alter knee biomechanics, potentially leading to complications [450]. Future research could utilise similar geometric ligament modelling techniques to simulate the patellofemoral ligaments (PFLs) and evaluate changes to the joint resulting from the planned or achieved TKA.

To conduct such an investigation, a ligament model would need to compare the medial and lateral PFL lengths in the native, preoperative state to those in the postoperative state. Measurements should be taken across a range of flexion angles, as the risk of overstuffing varies throughout the range of motion [451]. This could be achieved using an imaging and processing pipeline similar to that used in Chapters 5-7, adapted to focus on the patellofemoral joint. The relationship between PFL lengths, or changes in these lengths due to TKA, and patient outcomes—such as anterior knee pain—should then be evaluated. This would provide valuable insights into whether the model can effectively detect anterior knee pain and how it could inform alignment targets to optimise TKA outcomes.

During this thesis, a pilot study (Appendix 3) assessed the relationship between postoperative Kujala score – a validated questionnaire designed to detect anterior knee pain – and PFL lengths in TKA patients. The study sampled ten knees with low Kujala scores (indicating anterior knee pain) and ten with high scores (indicating minimal or no pain). The results revealed a significant moderate inverse correlation between postoperative PFL lengths and Kujala scores, suggesting that patellofemoral overstuffing increases the risk of anterior knee pain after TKA. These findings establish a foundation for further research into how ligament modelling can address patellofemoral alignment and complications in TKA.

Beyond TKA, similar modelling approaches has been employed in other orthopaedic contexts, such as simulating the interaction between the iliopsoas tendon and acetabular cup in total hip arthroplasty and hip resurfacing procedures [452], [453]. In one study, Hardwick-Morris et al. modelled iliopsoas ligaments with and without the acetabular cup, identifying ligament “stretch” as a marker of impingement – a key risk factor for postoperative groin pain. Since validation, this model has been applied in preoperative planning to investigate risk factors for iliopsoas tendonitis. Such applications highlight the versatility of geometric ligament modelling for analysing soft tissue dynamics relative to bony anatomy and component alignment, with potential for expansion to other joints and orthopaedic procedures.

8.5 Conclusion

This dissertation highlights limitations of existing coronal knee classification systems, such as CPAK, in accounting for the complex 3D knee morphology and soft tissue variability – both crucial factors during TKA component alignment. To address these limitations, this thesis introduces a scalable joint distraction radiology protocol, coupled with a reliable 3D-to-2D registration method, enabling functional preoperative assessments. Using these protocols, a novel, soft-tissue-informed TKA planning approach – Distracted Alignment – was developed, integrating bony anatomy and soft-tissue gaps to provide surgeons with a balanced preoperative plan in both extension and flexion. The Distracted Alignment provides a holistic and personalised TKA planning approach. Further research that evaluates achieved alignment and postoperative outcomes using Distracted Alignment are required.

Chapter 9:

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Chapter 10:

Appendix

Appendix 1. Abstract: Functional Preoperative Tibial Rotational References and Outcome in Total Knee Arthroplasty

The abstract below was submitted to, and presented at, the Australian Orthopaedic Association Annual Scientific Meeting 2023

Authors: Ishaan Jagota, Jonathan Bare, Andrew Shimmin, Joshua Twiggs, Brad Miles

Title: Functional Preoperative Tibial Rotational References and Outcome in TKA

Introduction: Tibial rotational alignment is an important consideration in Total Knee Arthroplasty (TKA) procedures, with known negative patient impacts of tibial malrotation. However, there are many competing tibial rotational references for use during TKA, covering tibial only and tibiofemoral referencing measurements. This study aimed to determine the relationship between different tibial and tibiofemoral rotational reference axes, including Insall's axis, Cobb's axis, and alignment to the projection of the surgical transepicondylar axis (TEA) on the proximal tibial plateau in the supine Computed Tomography (CT), Weightbearing (WB), Extension Distracted (ED) and Flexion Distracted (FD) positions. This study also sought to determine whether achieved tibial rotational component alignment relative to these reference axes influenced patient reported outcome measures.

Methods: A retrospective study comprised of 498 knee joints was performed. All patients obtained a preoperative long-leg supine CT scan, WB antero-posterior radiograph, and 2 stress radiographs, (1 in extension and the other in flexion) whereby a 2.5kg weight was attached to the freely hanging ankle of the operative limb to distract the joint. Each CT scan was segmented and landmarked, and the resulting 3D bone

models were registered to each radiograph. The angle of Insall's axis was determined relative to Cobb's axis as well as the projection of the surgical TEA on the proximal tibia in the CT, WB, ED and FD positions. KOOS and Rand 12-item short form survey (SF-12) PROMs questionnaires were completed by patients preoperatively and postoperatively at 3-, 6- and 12-month timepoints.

Results: The mean external rotation of Insall's axis relative to Cobb's axis was 4.84° (± 3.37°). The mean external rotation of Insall's axis relative to the projection of the TEA in the CT, WB and ED positions was 9.67° (± 4.71°), 9.65° (± 6.59°) and 8.31° (± 6.44°), respectively. Multiple weak correlations were observed between PROMs and the magnitude of external rotation of Insall's axis relative to the TEA projection on the tibial plateau in a WB position. Improvements were observed in KOOS Pain ($r = 0.24$, $p = 0.03$), Symptoms ($r = 0.21$, $p = 0.05$), QoL ($r = 0.22$, $p = 0.04$) subdomains, and KOOS joint replacement short-form (KOOS-JR) ($r = 0.29$, $p < 0.01$) from preoperative to 3 months postoperative. Similar improvement in KOOS Pain ($r = 0.21$, $p = 0.04$) was observed from preoperative to 12 months postoperative.

Conclusions: The key results of the study suggest that tibiofemoral rotational references, especially WB TEA projection, have a degree of predictive power for assessing improvements in PROMs likely to be achieved. This suggests that the WB TEA projection might be a reliable reference for tibial component alignment. Research is ongoing to assess whether these results are reflected in analysis of postoperative tibial alignment.

Appendix 2. Abstract: Anatomical Tibial Rotational References and Outcomes in Total Knee Arthroplasty

The abstract below was submitted to, and presented at, the Australian Orthopaedic Association Annual Scientific Meeting 2024

Authors: Ishaan Jagota**,** Jonathan Bare, Andrew Shimmin, Estelle Wigmore, Alex Shen, Joshua Twiggs, Brad Miles

Title: Anatomical Tibial Rotational References and Outcomes in TKA

Introduction: Tibial component rotation alignment is an important consideration in Total Knee Arthroplasty (TKA) procedures. Although tibial and tibiofemoral malrotation are known to negatively impact patient outcomes, there is limited literature outlining how best to rotational align the tibial component. This is in part due to the large number of anatomical references for tibial rotation, including tibial only and tibiofemoral anatomical axes. This study investigates achieved tibial rotational alignment relative to different tibial and tibiofemoral reference axes and its relationship to patient reported outcomes measures (PROMs). The reference axes included the tibial referencing Insall's axis and Cobb's axis as well as the projection of the surgical transepicondylar axis (TEA) on the proximal tibial plateau in the CT, Weightbearing (WB), extension distracted (ED) and flexion distracted (FD) positions.

Methods: A retrospective series of 76 TKAs was assessed. All patients obtained a preoperative long-leg supine CT scan, WB antero-posterior radiograph and stressed ED and FD radiographs whereby a 2.5kg weight was attached to the freely hanging ankle of the operative limb to distract the joint in extension and flexion, respectively. Each CT

scan was segmented and landmarked, and the resulting 3D bone models were registered to the two radiographs. The position of Insall's axis, Cobb's axis and to the preoperative projection of the TEA in the CT, WB, ED and FD on the proximal tibial plateau were all determined. Postoperatively, patients received a CT scan. The preoperative bone models and landmarks and the component model and landmarks were registered to postoperative CT scan, enabling the calculation of the achieved tibial component rotational alignment relative to the various reference axes. Patients also completed KOOS questionnaire both preoperatively and at least 12 months postoperatively.

Results: On average, the achieved alignment of the tibial component was rotated 2.45° (±5.1°) internal to Insall's axis and 2.92° (±5.09°) external to Cobb's axis. The rotation relative to the projections of the TEA in the preoperative CT, WB, ED and FD TEA positions was 7.81° (±6.26°), 7.26° (±7.29°), 6.79° (±7.38°) and 1.72° (±6.6°) external, respectively.

When comparing to PROMs, a weak relationship was observed between external rotation of the tibial component relative to Insall's axis and an improvement pre-to-postop KOOS Pain score ($r = 0.25$, $p = 0.03$). Additionally, greater mean postop KOOS Pain outcomes were observed when the tibial component rotation was either external or neutral to the WB TEA projection as opposed to internal (85.9°, 85.8° and 82.5°, respectively).

Discussion and Conclusion: The results emphasise the need for caution during rotational alignment of the tibial component during TKA. While some internal rotation relative to Insall's axis may be acceptable, the WB TEA projection can provide additional guidance to define a patient-specific range for axial alignment of the tibial component. This can help reduce the risk of component malalignment and enhance patient outcomes in TKA.

Appendix 3. Abstract: Novel Patellofemoral Ligament Modelling & Anterior Knee Pain After Total Knee Arthroplasty

The abstract below was submitted to, and presented at, the Computer-Assisted Orthopaedic Surgery Annual Meeting 2023

Authors: Ishaan Jagota, Brett Fritsch, David Parker, Jobe Shatrov, Joshua Twiggs and Brad Miles

Title: Novel Patellofemoral Ligament Modelling & Anterior Knee Pain After Total Knee Arthroplasty

Introduction: Postoperative tibial and tibiofemoral malrotation can result in pain [1], stiffness [2], patellar instability [3] and excessive poly component wear [4]. Malrotation directly accounts for 2.3% of revision surgery in Australia, but this number may be as high as 30% when we consider the aforementioned factors in aggregate [5]. Furthermore, studies have outlined that excessive tibial internal rotation and tibiofemoral rotational mismatch can result in inferior patient pain and functional outcomes [1, 6-8]. This highlights the importance of accounting for the femoral axial alignment whilst axially aligning the tibial component. Some studies have even suggested using the projection of the transepicondylar axis (TEA) on the proximal tibial plateau as a reference for tibial rotation [9-10]. However, this analysis is generally performed using a supine CT scan and therefore does not represent a functional position. This study investigates different tibial rotational references by comparing Insall's axis to Cobb's axis, as well as the projection of the TEA on the proximal tibial plateau in the CT, weightbearing and extension distracted reference frames.

Methods: A retrospective study comprised of 325 knee joints was performed. All patients obtained a preoperative long-leg supine CT scan, weightbearing antero-posterior radiograph and an extension distracted radiograph. Each CT scan was segmented and landmarked, and the resulting 3D bone models were registered to the two radiographs. The position of Insall's axis was determined relative to Cobb's axis as well as the projection of the surgical TEA on the proximal tibia in the CT, weightbearing and extension distracted positions. A summary of the process is displayed in Figure 1.

Results: A total of 325 joints were analysed and the mean external rotation of Insall's axis relative to Cobb's axis was 4.84° (± 3.37°). The mean external rotation of Insall's axis relative to the projection of the TEA in the CT, weightbearing and extension distracted positions was 9.67° (± 4.71°), 9.65° (± 6.59°) and 8.31° (± 6.44°), respectively (Figure 2).

Discussion: Although numerous tibial rotational reference axes exist, there is a lack of consensus amongst surgeons on which is most appropriate during TKA. It has also been noted in literature that tibial and femoral axial rotation mismatch is associated with postoperative knee pain. Therefore, it is important to consider references for axial rotation which can be used to align both femoral and tibial components. There have been prior efforts to establish femoral references for tibial rotation, which also involved the projection of the TEA onto the tibial plateau using either 2D CT slices [9] or 3D CT reconstructions [10]. However, these prior protocols analyse the knee joint in a supine CT position and fail to consider functional tibiofemoral alignment. The study weightbearing and extension distracted TEA projections provide a more functional position in which to assess the tibiofemoral axial alignment. The variability of these functional TEA projections were consistent with published results [9, 10].

It is important to highlight the variation between different tibial rotational reference axes as these ultimately influence component alignment is targeted and/or reported. A better understanding of the different tibial rotational reference axes including functional axes may assist the industry in reaching a consensus on a single or few reference axes for reporting purposes.

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