Department of Biomedical Engineering
University of Strathclyde

Evaluating the Accuracy of IMU Devices in Detecting Clinically Significant Changes in Knee Flexion and Extension Angles

Alexandra Grace Ligeti (MSc, BEng (Hons))

This thesis is submitted in fulfilment of the requirements for the degree of PhD in Biomedical Engineering

Department of Bioengineering
University of Strathclyde
Wolfson Building
106, Rottenrow
Glasgow
G4 0NW

Copyright Statement

Signed:

Date:

Acknowledgements

My whole life, I've felt as though my opportunities landed on me because I was in the right place at the right time—not necessarily because I was the right person for the task. This PhD project felt much the same. I often felt out of my depth, unqualified for the challenge, and like an imposter among other PhD students, constantly waiting for someone to discover I didn't belong, and it was all a mistake.

But over time—3.5 years to be precise—I realised this wasn't the case. Professor Phil Rowe saw potential in me long before I saw it in myself. He recognised my stubborn determination and believed I was capable. Together with Dr. Philip Riches, whose support and mentorship helped my confidence and abilities grow, I found my footing.

This PhD offered me more than just the chance to expand my academic knowledge and tackle clinical challenges. It allowed me to grow in character, build resilience, and test my determination. Most importantly, it taught me to believe in myself. I belong here, just as much as anyone else, and I am just as capable. This journey of self-discovery was as challenging as the PhD itself, but it's one I'm deeply grateful to have undertaken.

Thank you to everyone who helped me along the way. While a PhD can be a lonely journey, the people I encountered made it far less so. To the participants who patiently endured my lab sessions and countless stories, to the clinical researchers who recruited these 'active story listeners, also known as patients' and to the surgeons who indulged my "niggles" in recruitment clinics—thank you for making this process feel less solitary.

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When I think back to the girl who attended a farm school in South Africa with no shoes, it feels surreal to be where I am today. I owe so much to my parents, who gave me the opportunities to find myself in those “right places” at the “right times.” Thank you for believing in me and for supporting me every step of the way.

I would also like to give one final special thanks to Philippe Martin, to whom this project was in collaboration with. The MATLAB code used to implement the Seel algorithm was predominantly written by Philippe and was an integral component of this research. So once again, Thank you.

List of Publications and Conference Proceedings

Publications

Forsyth, L, **Ligeti, A**, Blyth, M, Clarke, JV & Riches, PE 2024, 'Validity of wearable sensors for total knee arthroplasty (TKA) rehabilitation: a study in younger and older healthy participants', *The Knee*, vol. 51, pp. 292-302. https://doi.org/10.1016/j.knee.2024.10.006

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Conference Proceedings

Fleming, G, **Ligeti, AG**, Forsyth, LE, Hickey, M, Mulder, K & Riches, P 2023, 'A chaos-inspired biomechanical biomarker of ankle instability', BioMedEng23, Swansea, United Kingdom, 14/09/23 - 15/09/23.

Ligeti, AG, Forsyth, L, Blyth, M & Riches, PE 2023, 'Validation of an IMU wearable during treadmill walking', BioMedEng23, Swansea, United Kingdom, 14/09/23 - 15/09/23.

Ligeti, AG, Forsyth, LE, Blyth, M & Riches, P 2023, 'Assessing knee range of motion using the MotionSense™ wearable device in total knee arthroplasty patients during treadmill and stair walking: a case study', ISTA 2023: The 34th International Congress New York City, United States, 27/09/23 - 30/09/23.

Ligeti, AG, Forsyth, LE, Blyth, M & Riches, P 2023, 'Validation of an IMU wearable measuring knee flexion', ISTA 2023: The 34th International Congress New York City, United States, 27/09/23 - 30/09/23.

Ligeti, AG, Forsyth, L, Blyth, M & Riches, PE 2023, 'Validation of an IMU wearable for treadmill walking', BioMedEng23, Swansea, United Kingdom, 14/09/23 - 15/09/23.

Ligeti, AG, Forsyth, L & Riches, PE 2024, 'Validation of a wearable device for measuring knee angle during level treadmill walking', 39th Congress of the European Society of Biomechanics, Edinburgh, United Kingdom, 30/06/24 - 3/07/24.

Ligeti, AG, Forsyth, LE, Blyth, M & Riches, P 2024, 'Validation of an IMU wearable sensor for treadmill walking and stair ascent/descent', Glasgow Orthopaedic Research Initiative GLORI, Glasgow, United Kingdom, 9/05/24 - 9/05/24.

Penev, V, Giardini, ME, **Ligeti, AG** & Riches, P 2024, 'Markerless motion analysis: evaluation of OpenPose software for clinical gait analysis', BioMedEng24, London, United Kingdom, 5/09/24 - 6/09/24.

Disclosures and Collaboration

This research project was conducted with the financial support of Stryker USA, who provided funding under the terms of a collaborative agreement. As part of this agreement, the technology (MotionSense™), tools, and/or methodologies employed in this study were selected in alignment with the sponsors commercial products and development standards. The use of these technologies reflects the conditions of the funding arrangement and may not necessarily represent a comprehensive comparison with alternative solutions. While every effort was made to maintain scientific rigor and objectivity, the influence of industry sponsorship is acknowledged. The findings and interpretations presented herein are those of the author and do not necessarily reflect the views of the sponsoring organisation.

Further research collaboration was undertaken with Philippe Martin (MINES, Paris), who generously provided a working MATLAB (MathWorks, 2024) implementation of the Seel algorithm (Seel, Raisch and Schauer, 2014), which required rigorous validation testing. Though many other algorithms exist, there was an opportunity to collaborate with Philippe Martin (MINES, Paris), and therefore this algorithm was used to convert IMU data into knee angle measures. His contribution of the code facilitated the validation phase of this study through conversion of raw IMU data into usable sagittal knee angles enabling the practical assessment of the algorithm's performance within the context of the project.

In addition to the collaboration with Philippe Martin, the terms of the contractual agreement with Stryker prohibited direct comparisons between Stryker's technology and other IMU-based systems. As a result, separate analyses were conducted for each IMU technology (MotionSense™ and the wired research IMU device). Differences in analysis methodologies and reporting are therefore intentional and reflect adherence to the contractual requirement to avoid direct comparisons between these technologies. These differences in analytical approaches will be detailed in subsequent sections of the thesis.

Contributions

Though Philippe Martin (MINES, Paris) contributed solely to the implementation of the Seel algorithm (Seel, Raisch and Schauer, 2014) by translating it into usable MATLAB (MathWorks, 2024) code. He was not involved in any other aspect of the project. The remainder of the project was carried out by Alexandra Ligeti, including:

Ethics and Compliance: Preparation and submission of ethics documentation and applications for institutional review.

Participant Management: Recruitment, screening, and obtaining informed consent from study participants.

Data Collection: Design and execution of data acquisition protocols, including setup, calibration, monitoring and data collection.

Data Processing and Analysis: Pre-processing of raw data, adjustment of the Seel algorithm MATLAB scrips to accommodate collected data formats, application of analytical methods, access validity of data and statistical evaluation of results.

Visualisation and Interpretation: Generation of plots, graphs, and figures to represent findings and interpretation of analytical outcomes.

Documentation and Reporting: Drafting, editing, and compiling the research report and supplementary documentation.

Dissemination: Preparation of materials for and delivery of project presentations to stakeholders and academic audiences.

All project planning, coordination, execution and interpretation beyond the MATLAB implementation of the Seel algorithm (Seel, Raisch and Schauer, 2014) were conducted exclusively by Alexandra Ligeti.

Abstract

Total knee arthroplasty (TKA) is a widely successful surgical intervention for managing end-stage knee osteoarthritis (KOA), yet patient outcomes are highly dependent on postoperative rehabilitation. Despite this, adherence to rehabilitation programs remains suboptimal, potentially hindering recovery.

Wearable inertial measurement units (IMUs) have emerged as promising tools to support rehabilitation and enable early diagnostics of unfavourable recovery through remote monitoring, potentially improving patients' compliance to rehabilitation protocols and thus improving functional outcomes. However, the clinical utility of these devices depends on their ability to provide accurate measurements of knee joint kinematics, particularly knee flexion angles.

This study aimed to evaluate the accuracy of two different wearable IMU devices (a Stryker (USA) commercially available technology, MotionSense™ and a wired IMU research device implementing the Seel Algorithm (Seel, Raisch and Schauer, 2014), in measuring knee flexion angles within clinically significant thresholds. Measurements were evaluated across a diverse healthy adult population of varying ages (20 healthy younger participants, ages ranging between 20 - 36 years old and 14 healthy older participants, ages ranging between 60 - 84 years old) and within a TKA clinical population (10 TKA participants, ages ranging between 53 - 71 years old) both preoperatively and postoperatively (1 week postoperatively and at 6 weeks postoperatively), across a broad range of activities of daily living (ADL's).

The commercially available MotionSense™ technology determines sagittal plane knee angle using a mobile-based app with proprietary software that implements a Madgwick filter (Madgwick, 2010), while the wired research IMU device calculates sagittal plane knee angle using the Seel algorithm (Seel, Raisch and Schauer, 2014). Both technologies' measurements were compared against the gold standard opto-electronic motion capture system, Vicon, which tracked 16 retro-reflective markers that were attached to the lower body as per the PlugInGait™ (PIG) model.

The methodology used to evaluate the accuracy of each of the IMU devices differed in protocol. Analysis of the MotionSense™ device incorporated a bespoke graphical user interface (GUI) which was used to manually isolated different movement cycles. Following up-sampling to 100Hz using the MATLAB (MathWorks, 2024) interp1 function, cross-correlation was used to time synchronise the movement cycle windows identified from peak flexion to peak flexion using the xcorr MATLAB (MathWorks, 2024) function for each technology. The population mean movement cycle was then analysed for each population group and for each activity, with the pooled mean population range of motion (ROM) assessed.

Whereas, following conversion of the raw IMU data into sagittal knee angle measurements using the Seel algorithm (Seel, Raisch and Schauer, 2014), the wired IMU research device data was time synchronised to Vicon data using similar methods, by manually selecting peak knee flexion of each technology. As the sampling frequencies differed between the opto-electronic Vicon motion capture system and the wired IMU research device, Vicon was up-sampled to 200Hz, again by means of interpolation (interp1 function). These measures were then analysed by evaluating each populations mean pooled movement cycle window.

For both IMU technologies the zero point for knee flexion depends on marker placement, therefore, the mean knee flexion was subtracted from each data set before calculating a root mean square error (RMSE) between the technologies, determined in each movement cycle window.

Results presented RMSE of less than 5° across both devices, across both healthy and clinical populations and across all activities, including those involving larger ROM and higher joint velocities. RMSE values ranged between 0.86° - 4.70° for the MotionSense™ device, while RMSE values ranged between 2.92° - 4.78° for the wired IMU device. No statistically significant differences between the population groups for each technology was evidenced ($p > 0.05$). Notably, greater discrepancies between the measurement systems were observed during activities involving larger degrees of flexion, for example during the flexion/extension activity performed by the younger healthy population a ROM of 116.5° and RMSE of 3.65° was reported between MotionSense™ and Vicon opto-electronic motion capture system, whereas a RMSE of 1.48° and a ROM of 31.6° was reported for the 1 week postoperative session for the walking activity. Furthermore larger differences were also evidenced during periods associated with faster motion (swing phase displayed larger differences compared to the stance phase for the walking activity). The wearable IMU technologies revealed strong coefficients of correlation and were able to accurately track knee flexion patterns across all population groups.

The findings from the TKA cohort underscore the highly patient-specific nature of recovery and postoperative outcomes, further emphasising the need for personalised rehabilitation approaches and the requirement for innovative technologies to deliver this level of personalised care.

The use of wearable IMUs within clinical and healthcare settings offers substantial benefits within the recovery period, including remote monitoring capabilities and enhanced compliance with rehabilitation protocols.

This study concludes that wearable IMU devices can accurately measure sagittal knee angle supporting their integration into clinical settings. Their ability to provide accurate, objective data validates their use as a practical alternative to traditional in-clinic assessments, particularly in enabling remote and continuous tracking of patient progress. As such, IMUs may represent a valuable asset in modern rehabilitation strategies, facilitating more efficient, patient-centred care.

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List of Abbreviations

ADL	Activities of daily living
ANOVA	Analysis of variance
BMI	Body Mass Index
F/E	Flexion/Extension
FJS	Forgotten Joint Score
GCP	Good Clinical Practice
GUI	Graphical User Interface
HS	Heel strike
IMU	Inertial measurement units
KOA	Knee osteoarthritis
KOOS JR	Knee Injury and Osteoarthritis outcome score for Joint Replacement
NHS	National Health Service
OA	Osteoarthritis
OKS	Oxford knee score
PIG	Plug-in Gait
Post-op	Postoperative

Post-TKA	Following total knee replacement surgery (Postoperative)
Pre-op	Preoperative
Pre-TKA	Before total knee replacement surgery (Preoperative)
PROM	Patient reported outcome measure
r	Correlation of Coefficient
RMSE	Root mean square error
ROM	Range of Motion
SD	Standard deviation
SE	Standard error
TKA	Total Knee Arthroplasty
2D	Two Dimensions
3D	Three Dimensions

Anatomical Planes

Coronal/Frontal	Divides the body into its anterior and posterior portions.
Sagittal/Median	Runs superior to inferior through the body, dividing the body into left and right portions.
Transverse/Horizontal	Divides the body into superior and inferior parts, running horizontally.

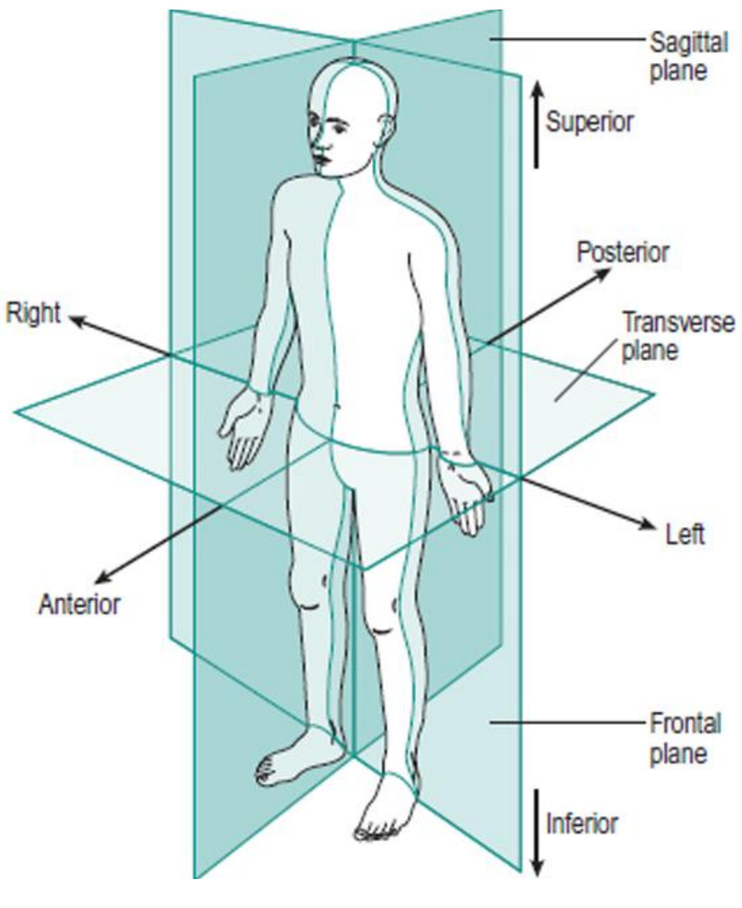
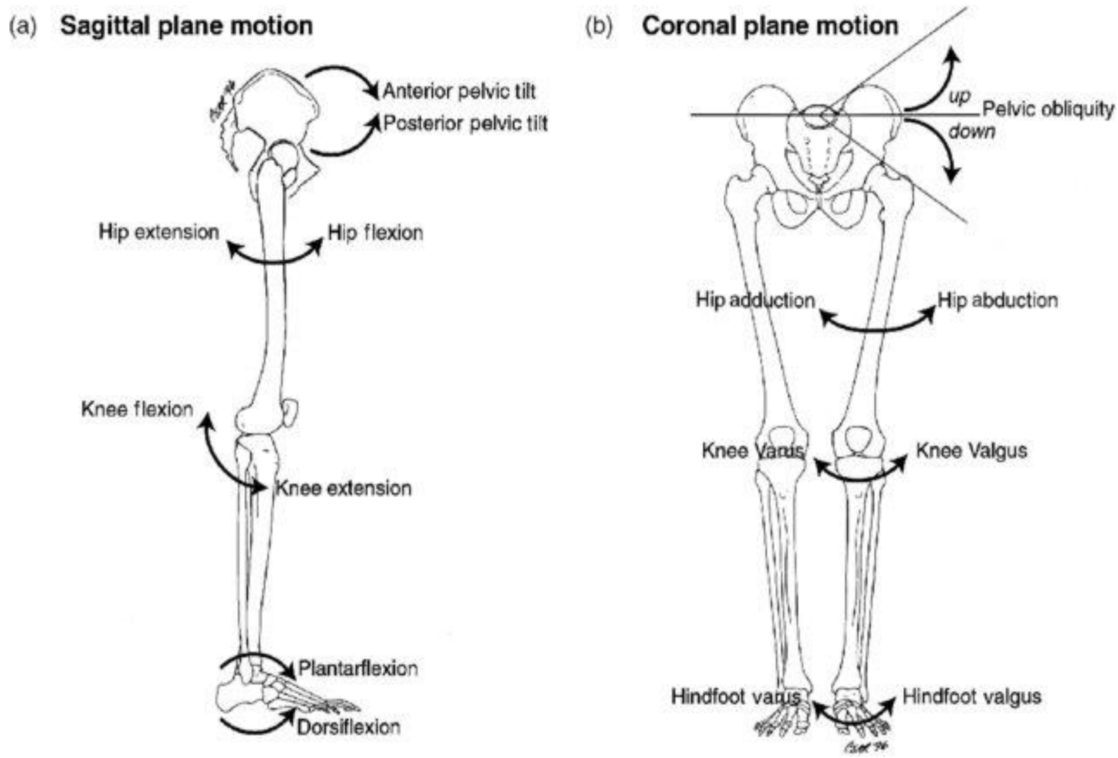


Figure 1.0-1. Human anatomical planes (Levine, 2012).

Knee Joint Range of Motion

Flexion and Extension	Primary movement of the knee joint and occurs in the sagittal plane and about the transverse axis
Internal and External Rotation	Occurs primarily when the knee is flexed and is observed in the transverse plane and about the longitudinal axis
Abduction and Adduction	Adduction of the knee also referred to as Varus (bow-legged), and abduction of the knee also referred to as Valgus (knock-kneed) occurring in the frontal plane and about the sagittal axis.



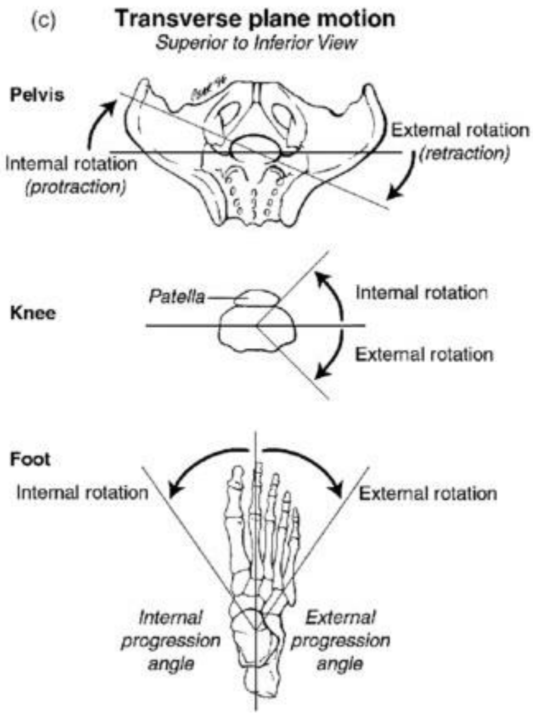


Figure 1.2. Types of motion that occur in the three anatomical planes a) Flexion and Extension in the sagittal plane, b) Valgus and Varus in the frontal plane, c) Internal and external rotation occurring in the transverse plane (Abu-Faraj, Harris and Smith, 2015).

Nomenclature

Accelerometer	A sensor that measures linear acceleration (the rate of change of velocity, represented by α, measured in m/s^2).
Anthropometry	Measurement of size, weight, and proportions of the body.
Calibration	The process of adjusting and verifying the accuracy of a device or system, ensuring its measurements or outputs align with a standard or known reference, used to effectively zero the system.
Compliance	The extent to which a patient follows prescribed medical advice, treatments, or rehabilitation protocols.
Gyroscope	A sensor that measures angular velocity (how fast an object rotates around its axes, represented by ω, measured in rad/s).
IMU	Inertial measurement unit is a device that integrates sensors, such as accelerometers, gyroscopes, and sometimes magnetometers, used to measure linear acceleration, angular velocity, and orientation, allowing for the determination of orientation, velocity and position in space.
Intraoperative	Refers to the period during the surgical procedure itself.
Kinematics	Study of joint motion and angles.
Kinetics	Study of forces and moments exerted on to rigid bodies.
Magnetometer	A sensor that measures magnetic field strength and direction (β, measured in Tesla or Gauss).

Perioperative	Refers to the time period encompassing preoperative, intraoperative, and early postoperative phases.
Physiotherapy	Concentrates on restoring and improving physical movement and function through techniques such as exercise, manual therapy, and patient education. It primarily addresses musculoskeletal limitations post-surgery.
Postoperative	Refers to the period after a surgical procedure.
Preoperative	Refers to the period before a surgical procedure.
Rehabilitation	The broad, multidisciplinary process of restoring function, mobility, or strength after an injury, surgery, or medical condition, typically through therapy and prescribed exercises. Aimed at helping individuals recover and regain independence. It encompasses not only physiotherapy but also other services like occupational therapy.
Spatial	Changing in relation to space.
Temporal	Changing in relation to time.

Conventions

Reporting p-values

$p < 0.001$	$p < 0.001$
$0.001 < p < 0.01$	$p < 0.01$
$0.01 < p < 0.05$	$p < 0.05$
$0.05 < p < 0.1$	Exact value given
$p > 0.1$	$p > 0.05$

Thresholds

The following thresholds were used to evaluate the technologies outcomes:

Correlations were adapted from bandings as defined by Cohen, 1988.

0	No correlation
0.01 - 0.2	Weak correlation
0.21 - 0.40	Moderate correlation
0.41 - 1.00	Strong correlation

While a RMSE < 5.0° was considered clinically acceptable (Chapman, Moschetti, and Van Citters, 2021; Prajapati et al., 2021; Whittle, 1996) and a RMSE < 3.0° was deemed highly accurate (Berner et al., 2020; Rekant et al., 2022).

Chapter 1

1.1 Introduction

Total knee arthroplasty (TKA) is an effective surgery for improving knee functionality, alleviating pain, enhancing quality of life, and decreasing morbidity in those with knee osteoarthritis (KOA) (Hamilton *et al.*, 2015). The demand for TKA procedures is steadily increasing, with over 170, 000 operations performed in the United Kingdom (UK) annually (Knee Replacement - The National Joint Registry, 2023) and over 700, 000 procedures conducted in the United States of America (USA) (Hamilton et al., 2020). It is expected that surgical volumes will increase as the population ages, life expectancy increases and as the prevalence of obesity rises (Inacio et al., 2017).

TKA success is commonly reported through postoperative evaluations, which often include clinical assessments of knee joint function and range of motion (ROM), patient reported outcome measures (PROM's) and occasionally imaging (Cornish et al., 2024). While TKA is generally successful, it is widely reported that approximately 15 – 20% of all TKA patients are dissatisfied with their surgical outcomes (Beswick et al., 2012; Jones et al., 2023). This dissatisfaction is usually characterised by ongoing pain and functional deficits (Bullens et al., 2001; Kahlenberg et al., 2018).

Such dissatisfaction poses significant challenges. Whilst ongoing symptoms can greatly burden the individuals, the impact spreads beyond, also affecting society in several ways. Societal impact comprises of increased healthcare costs, including additional clinic follow-ups, further hospital investigations, prolonged rehabilitation protocols and large expenses associated with complicated revision procedures. While socio-economic factors such as difficulty returning to work and reduced independence further amplify the impact (Hamilton *et al.*, 2015).

Though TKA is commonly performed, rehabilitation plays a crucial role in patient recovery. Rehabilitation has proven to be effective in improving patients' functional abilities, leading to more successful postoperative outcomes (Prill et al., 2022).

Although improvements in knee function can continue up to one year (Bade and Stevens-Lapsley, 2011; Zhou et al., 2015), and beyond (Peng et al., 2023), a large proportion of ROM improvements for both flexion and extension occur in the early postoperative period, which can be as early as 4 weeks following TKA (Van Onsem et al., 2018).

However, achieving these outcomes rely heavily on patient adherence to rehabilitation protocols, with most rehabilitation programmes now being home-based. Unfortunately, adherence remains a persistent challenge, with patients often struggling to perform exercises correctly and consistently at the required intensity. Previous research (Bakaa et al., 2021; Bassett, 2012; Bini and Mahajan, 2017; Bullens et al., 2001; Campbell et al., 2001; Castrodad et al., 2019; Chakrabarti, 2014; Frost et al., 2017; Han et al., 2015; López-Liria et al., 2015; Mistry et al., 2016; Shukla et al., 2016; Vermeire et al., 2001) has reported that poor rehabilitation adherence is common and ultimately leads to unsuccessful recovery outcomes and as a result rehabilitative approaches being altered unnecessarily (Argent, Daly and Caulfield, 2018).

Although home-based rehabilitation has reported superior patient satisfaction (Crawford et al., 2015), several factors contribute to poor compliance, including a lack of standardisation in programme design, minimal clinician-patient interaction, and insufficient guidance on exercise progression (Bandholm, Wainwright, and Kehlet, 2018; Buus et al., 2021). Without clear indicators of functional progress, patients may lose motivation, further reducing adherence and ultimately compromising recovery outcomes (Argent, Daly and Caulfield, 2018). These challenges highlight the need for innovative solutions to increase patient engagement in rehabilitation and to monitor progress effectively (Bandholm, Wainwright, and Kehlet, 2018; Chen et al., 2022; Ibrahim et al., 2015; Parrington et al., 2021).

Wearable technologies may offer a solution in enhancing home-based rehabilitation by providing continuous recovery tracking and enabling remote monitoring by healthcare professionals through the accurate measurement of knee joint angles. Furthermore, these devices may offer frequent quantitative assessment of knee function with greater resolution than subjective survey-based outcome measures (Atallah et al., 2011).

Additionally, when paired with an App they may provide instructional information and motivate patients through real-time feedback of their recovery progress leading to better rehabilitation adherence and greater functional outcomes.

Stryker, USA have recently developed a commercial wearable device called MotionSense™ which remotely supports postoperative TKA rehabilitation, providing personalised rehabilitation regimes, tracking of home exercises, and enabling healthcare professionals to continuously monitor rehabilitative progress and compliance remotely. The MotionSense™ wearable device utilises two inertial measurement units (IMUs), above and below the knee, with knee angle provided using a Madgwick filter (Madgwick, 2010). The Madgwick filter is a type of sensor fusion algorithm commonly used in wearable IMU systems to estimate orientation by combining data from accelerometers, gyroscopes, and magnetometers to produce accurate and drift-reduced orientation estimates. When IMUs are placed on the thigh and shank, the Madgwick filter processes the sensor data to determine the relative orientation between these segments, allowing for precise measurement of sagittal knee angles. This is particularly important in rehabilitation contexts, where consistent tracking of knee motion is needed to assess patient progress.

As with any new commercial product, it is essential that these wearable technologies undergo rigorous validation testing to ensure their accuracy in providing clinically meaningful motion data throughout the postoperative recovery period. This validation is of utmost importance before confident integration of such technologies into rehabilitative settings or clinical practice. Furthermore, it is valuable to ensure accurate clinical interpretation, both to confirm that patients are progressing as expected and to identify cases where recovery may be delayed or deviating from the expected postoperative outcomes.

There is limited literature establishing the validity of wearable sensors to assess knee function shortly following TKA. Particularly literature that focusses on evaluating the accuracy of such devices over many different types of functional activities, that vary in speed, impact and across a broad ROM, that incorporate a relatively large healthy control group of both younger and older participants which presents an opportunity to age-match to a TKA clinical population.

Of the available literature, only a handful (Antunes et al., 2021; Chen et al., 2022; Cornish et al., 2024; Fain et al., 2024; Hafer et al., 2020; Parrington et al., 2021; Wang et al., 2025; Versteyhe et al., 2020) evaluate the accuracy of such devices within a clinical population. However, these studies generally include a restricted population pool, record data at a single time point or only include a simple flexion/extension movement or walking. Typically, investigations have recruited younger healthy cohorts with a maximum 3 - 12 individuals, all assessing different IMU technologies and algorithms against different 3D motion capture systems and models (Poitras et al., 2019).

Although previous research (Ajdaroski et al., 2020; Allseits et al., 2017; Beravs et al., 2011; Cho et al., 2018; El Fezazi et al., 2023; Ghattas and Jarvis, 2021; Jebeli et al., 2017; Jordan et al., 2021; Zhang et al., 2013; Kayaalp et al., 2019; Kobsar et al., 2020; Papi et al., 2015; Poitras et al., 2019; Robert-Lachaine et al., 2017; Shuai et al., 2022; Taylor, Miller and Kaufman, 2017; Zhou et al., 2020) has shown that IMUs can accurately estimate knee joint angles, much of this work has been limited in scope and lacks the breadth necessary to support clinical application in diverse and real-world rehabilitation settings.

Many studies focus exclusively on either healthy younger adults or patients at a single stage of recovery (Antunes et al., 2021; Cornish et al., 2024; Fain et al., 2024; Parrington et al., 2021; Versteyhe et al., 2020), often omitting older adults or those in the early postoperative period. To our knowledge, no previous studies have simultaneously evaluated healthy younger adults, healthy older adults, and a TKA clinical population within a single framework across a diverse set of activities using two different IMU technologies and their associated algorithms. While Wang et al. (2025) assessed the accuracy of wearable IMU devices in both healthy individuals and patients with knee and hip pathologies, their evaluation was limited to walking only. Similarly, Hafer et al. (2020) examined IMU accuracy in healthy younger and older adults as well as individuals with osteoarthritis (OA), but again, only during walking. There remains a clear gap in the literature.

This narrow focus limits the generalisability and undermines the reliability of measures for a TKA population, which typically comprises of older individuals who may present with distinct or atypical movement patterns, functional limitations, and variable recovery trajectories.

Younger adults typically display consistent and well-coordinated gait, while older adults often show altered kinematics due to age-related musculoskeletal changes (Prince et al,. 1997). Despite their importance as a control group for distinguishing normal aging effects from pathological movement patterns, older adults remain underrepresented in IMU validation studies (Kosbar et al., 2020). Furthermore, individuals awaiting TKA frequently demonstrate compensatory strategies, such as irregular gait, reduced joint range, and muscle weakness, resulting in atypical knee mechanics (Farquhar et al., 2009; Wilson et al., 2012). These biomechanical variations could impact IMU data interpretation and the accuracy of derived joint angle estimates (Mundt et al., 2019).

The lack of a substantial, age-diverse healthy control group further constrains the ability to interpret deviations in joint kinematics as pathological or within normal variability. Hence, without validation in these distinct groups, there is a risk of algorithmic error, especially in TKA patients, potentially leading to inaccurate clinical assessments or misguided treatment decisions. Therefore, including younger adults, healthy older adults, and TKA patients is critical for developing robust, generalisable IMU-based motion analysis tools.

Moreover, prior research often evaluates IMU accuracy during a restricted set of functional tasks, mainly focussing on level walking (Cho et al., 2018; McGrath and Stirling, 2022; Patel et al., 2022). However, everyday movements in rehabilitation encompass a broad range of functional activities that challenge the knee joint differently in terms of speed, impact forces, and ROM. These variations can affect sensor performance, yet few studies have systematically tested IMUs across such a comprehensive range of tasks.

In addition, sample sizes seen in earlier works (Chen et al., 2018; El Fezazi et al., 2023; Henkel., 2016; Zhou et al., 2020) are frequently small, limiting the robustness and statistical power of the findings. Though this study has a smaller clinical population, evaluations within this clinical group have been carried out across three separate data collection sessions providing a clearer indication of the performance of such devices both preoperatively and postoperatively.

Finally, previous studies often focus on evaluating a single IMU technology. In contrast, this study incorporates both a commercial IMU device (Stryker's MotionSense™) and a raw, wired IMU sensor processed using the Seel algorithm (Seel, Raisch and Schauer, 2014) in collaboration with Philippe Martin (MINES Paris Tech), allowing for a more rigorous assessment of sensor accuracy under clinically relevant conditions. By validating this bespoke IMU knee flexion algorithm in MATLAB (MathWorks, 2024), it becomes possible to use any IMU device to measure a patient's knee ROM throughout recovery, offering a cost-effective, adaptable and practical alternative to conventional methods such as motion capture systems. Though many algorithms exist, the Seel algorithm (Seel, Raisch and Schauer, 2014) was specifically evaluated as part of an opportunistic collaborative research effort with Philippe Martin (MINES, Paris), whereby existing MATLAB (MathWorks, 2024) code written by the collaborator required extensive validation testing.

This study is designed to address each of these limitations directly. By including a larger healthy cohort of 34 individuals across a wide age range (20 – 84 years old), which enables similar age group comparisons to the TKA population, enhancing the clinical relevance of the findings, however, also taking into consideration the natural variations within gait kinematics of healthy individuals as they age. Furthermore, the inclusion of both preoperative and postoperative TKA patients enables the assessment of IMU performance across different stages of the recovery process. This study further incorporates a diverse set of functional tasks that vary in complexity, speed, and ROM demands, offering a more realistic evaluation of sensor accuracy in conditions that mimic real-world rehabilitation, while including evaluations on two different sensor technologies.

This thesis focussed on evaluating whether both the commercially available MotionSense™ wearable device (Stryker, USA) and the wired IMU research device using the Seel algorithm (Seel, Raisch and Schauer, 2014) in collaboration with Philippe Martin (MINES, Paris) can be implemented to accurately monitor postoperative recovery following TKA surgery and whether these measures are accurate enough to detect clinically significant changes in knee flexion angle.

The scope to successfully implement such a device holds immense value in both a gait analysis laboratory environment and with further adaptations in rehabilitation settings for remote monitoring of patient recovery and personalised treatment plans, specifically for cases where patients cannot easily access healthcare facilities regularly (as a result of restricted movement / lack of independence, isolated location or limited in person appointments available).

1.2 Clinical Problem

Many factors contribute to successful outcomes after TKA, with rehabilitation playing a crucial role in promoting recovery and improving postoperative results (Bandholm, Wainwright, and Kehlet, 2018; Lisi et al., 2017; Mistry et al., 2016; Prill et al., 2022). However, the effectiveness of rehabilitation is contingent on patient adherence to prescribed protocols, which is often suboptimal (Campbell et al., 2001). Poor patient compliance to rehabilitation regimens frequently results in poor postoperative outcomes and increases the likelihood for technically demanding and costly revision surgeries (Sharkey et al., 2002; Suarez et al., 2008).

Assessing the success of TKA involves both subjective measures, such as PROMs, and objective measures like ROM which are recorded before and after surgery. In busy clinical settings with limited resources, knee scores are typically recorded, although they are less sensitive to detecting subtle changes in joint function and kinematics (van Schie et al., 2024), while functional measures are often omitted.

Ideally, instrumented opto-electronic motion capture systems such as Vicon motion capture would be used, as this method is often considered the gold standard for measuring detailed 3D kinematic and kinetic data with high accuracy (Richards, 1999). However, these systems are costly and time-consuming to implement, making them impractical for routine clinical use. They are also limited by the number of visits a patient' attends, often not providing a true reflection of patient recovery as data is only captured at discrete time points rather than providing a continuous outline of recovery progress.

As a more feasible alternative, wearable sensors, such as IMUs have been introduced due to their low cost and ease of use (Versteyhe et al., 2020). Nevertheless, concerns remain regarding the accuracy and ease of use of these devices.

In order for wearable sensors to be integrated into clinical and rehabilitation settings, it is essential that the data they provide accurately reflects patient recovery. Only after establishing the accuracy of such devices can, they be confidently incorporated into clinical practice for broader use.

The implementation of wearables has the potential to act as a powerful tool not only for personalised rehabilitation protocols based off patient requirements and individual recovery progress, but also to enable the continuous monitoring of patient recovery, flagging potential surgery failures or those patients with poor rehabilitation compliance. This continuous window into patient recovery may reduce the risk of suboptimal outcomes and costly revision surgeries through early clinical intervention.

Moreover, by collecting both objective and subjective data at various time points: preoperative, intraoperative, and postoperative, a broader and more detailed understanding can be gained from the different factors that contribute to more favourable postoperative outcomes.

1.3 Research Question and Aims

Are IMU devices accurate enough to measure clinically significant changes in knee flexion angle following TKA?

The primary aim of this thesis was to assess whether IMU devices and their associated algorithms are accurate enough to be confidently used within clinical environments. Specifically, this thesis investigates their capability to detect and measure clinically significant changes in knee flexion and extension angles. Evaluating the technology across a wide range of activities and ROM, at various stages of recovery, ensuring their accuracy and validity in measuring knee flexion angles to be used in supporting clinical rehabilitation and recovery monitoring.

1.4 Thesis Structure

This thesis has been organised as follows:

Chapter 2. Literature Review: provides the reader with an extensive review on the literature currently available on the main topics covered by this research. The chapter begins with a description of the anatomy and physiology of a healthy knee joint. This is followed by a narrative explaining the degradation of the knee joint as a result of KOA, emphasising the common mechanisms of KOA and the symptoms associated with the disease. The treatment options for KOA are then discussed with a focus on TKA. The prevalence and effectiveness of surgical methods for treating KOA are evaluated, highlighting the factors that contribute to successful postoperative outcomes.

The literature review then goes on to describe the pathway of recovery following TKA, describing conventional methods of rehabilitation and the systems traditionally used to measure recovery progress. The limitations of current recovery approaches are explored, introducing a potential solution to these shortcomings through the implementation of wearable devices. The different types of available wearable modalities are highlighted, emphasising the advantages and disadvantages associated with each, comparing these wearable devices with traditional forms of rehabilitation.

A high-level explanation is provided, detailing the current methods available to convert measures captured from wearable devices into understandable and interpretable knee angle data that can be used to track recovery. The literature review reasons the need to validate such devices against clinically acceptable gold standards before they can be safely and confidently employed in healthcare settings. An overview into validation methodologies is provided, with an emphasis on clinically significant thresholds.

The purpose of this literature review is to inform the reader of the limitations in current rehabilitation modals and the effect that suboptimal rehabilitation delivery has on patient outcomes. Highlighting the potential for wearable technologies as an effective alternative for personalised rehabilitation, recovery tracking and early intervention of suboptimal recovery cases.

Chapter 3. Aims and Objectives: this chapter outlines the primary aim of this thesis, and details the objectives designed to address the research question and achieve the aim.

Chapter 4. Methods: the methods section describes the techniques employed to validate the accuracy of novel wearable devices used to determine knee angle measures in clinical and rehabilitative settings. The methods chapter is divided into three main sections.

The first section outlines the complete study design, briefly describing the protocols performed during each stage of this research through the use of a flowchart. The common methodologies used throughout this research thesis are expanded upon, discussing participant recruitment and data collection techniques, laboratory and equipment set ups and finally a description of the statistical analyses used to validate the technologies against opto-electronic system, Vicon motion capture, is detailed.

The remaining two sections focus on either the commercially available MotionSense™ wearable technology or the wired IMU device associated with the Seel algorithm. Providing specific details about where the common methodologies differ between the two sensor technologies and highlighting the different techniques used to analyse the data and the reasons for this.

Notably the practical implementation of the Seel algorithm is described, detailing the process taken to determine knee angles from raw IMU data used for validation. The theory behind the algorithm is also briefly explained.

Chapter 5. Results: this chapter is divided into three sections and presents the data recorded from each of the methods described in Chapter 4.

The first section presents the results from the MotionSense™ validation study, comparing the commercially available device against the opto-electronic system, Vicon motion capture in a healthy population of older and younger adults and in a TKA clinical population across a broad range of activities.

The second section reports the findings from the implementation and validation of the Seel algorithm against the opto-electronic system, Vicon motion capture. This section includes results from both a healthy control population and a TKA clinical population, establishing the accuracy of this algorithm across a range of activities.

The final section goes on to present the findings from a TKA population, describing the clinically relevant changes following TKA surgery, comparing subjective and objective measures. Results of a single TKA patient is also presented in this section, highlighting differences in outcome measures when considering population averages versus an individual's outcomes, emphasising the highly individual nature of recovery. This section provides a practical example of the usability of such wearable devices within healthcare settings and the opportunity to deliver personalised care through such devices.

Chapter 6. Discussion: this chapter discusses the results reported in Chapter 5. The data is compared to previously published TKA research and data from healthy adults. The accuracy of both wearable devices is compared against related validation studies and clinical thresholds, highlighting the feasibility of such technologies in movement analysis laboratories and within clinical settings. Postsurgical success is described through objective and subjective metrics, highlighting the correlations between these measures while emphasising the limitations of only considering one type of metric to assess postoperative outcomes.

The importance of personalised care and individual tailored treatment packages is underscored, as recovery pathways are found to be highly patient specific. Comments are made regarding the most efficient methods for implementing a highly individualised level of care, the feasibility of integrating wearable devices into rehabilitation settings, and the potential of such technologies in revolutionising postoperative recovery. Finally, suggestions into further project advancements are discussed, with recommendations into areas of improvements and expansion.

Chapter 7. Conclusions: the thesis concludes by returning to the research questions, aims, and objectives. A summary of the main findings of the study are provided.

Chapter 2. Background Research

This thesis presents the validation and usability of a commercially available wearable device designed to monitor postoperative joint function and rehabilitation compliance following TKA. The validation results were subsequently used to implement and evaluate the accuracy of the Seel (Seel, Raisch and Schauer, 2014) algorithm for tracking knee joint ROM using raw IMU data.

The primary aim of this thesis was to assess whether these devices are suitable for monitoring postoperative recovery and to evaluate their potential implementation in clinical settings. A key goal of TKA is to enhance knee function and alleviate pain.

Evaluating TKA outcomes requires a comprehensive understanding of the anatomy and physiology of a healthy knee joint. Therefore, this literature review begins by introducing the typical form and function of a healthy adult knee joint.

2.1 Overview of a Healthy Knee Joint

The knee is a weight-bearing hinge-like joint that works harmoniously with the hip and ankle joints, predominantly facilitating flexion and extension of the lower leg (Gupton et al., 2018). The knee is the largest synovial joint in the body, comprising of the femur, patella, and tibia, and includes two interfaces: the tibiofemoral and patellofemoral joints as seen in Figure 2-1.

Various structures, such as ligaments, cartilage, synovial tissues, muscles, and tendons, work together to maintain knee stability and correct joint mechanics (Wilson, 2023).

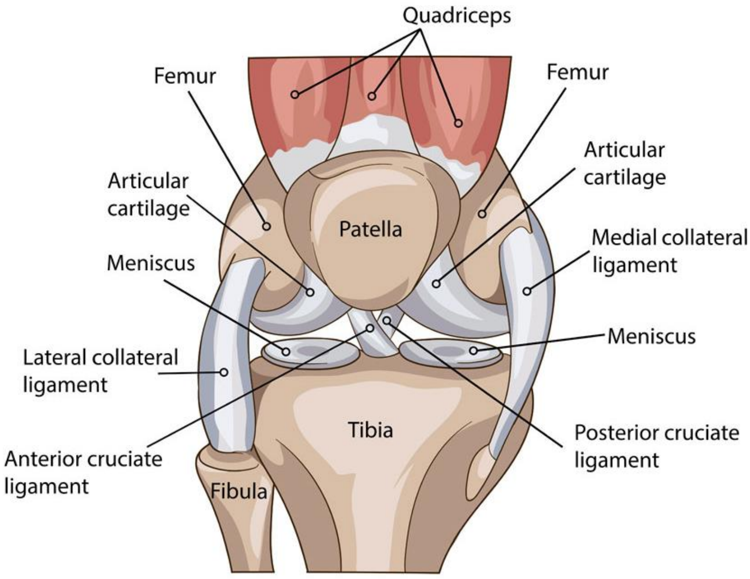


Figure 2-1. Anatomy of a healthy knee joint (Wilson, 2024).

2.1.1 Knee Anatomy

The different structures each have their dedicated role yet complement one another by working in coordination to maintain proper joint function, by contributing to the overall stability and movement of the knee joint. The main structures that make up the knee joint are detailed below.

Bones: The femur and tibia are long bones that form the primary structure of the knee joint. The patella, a triangular sesamoid bone, moves between the femoral condyles, and is stabilised by the patellar ligament and quadriceps tendon (Wilson, 2023).

Menisci: Each bone in the knee joint is lined with a layer of cartilage called the meniscus, primarily composed of collagen. The menisci serve as shock absorbers, reduce friction between bones, and enhance knee stability by improving joint congruence.

Muscles: The quadriceps muscle group (rectus femoris, vastus lateralis, vastus medialis, and vastus intermedius) facilitates knee extension while the hamstring muscles (semitendinosus, semimembranosus, and biceps femoris) enable knee flexion. Muscle strength, particularly in the quadriceps, is crucial for knee stability and movement. A reduction in muscle strength is associated with OA progression and other comorbidities (Yoshida et al., 2008).

Ligaments: The knee is stabilised by four primary ligaments: the anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), and the medial (MCL) and lateral (LCL) collateral ligaments. The ACL and PCL prevent excessive forward and backward translation of the tibia, while the MCL and LCL control lateral movement. The PCL, located behind the ACL, is larger and stronger, providing greater resistance to posterior movement (Fekete et al., 2013; Scuderi and Tria, 2010), these structures provide the knee with most of its stability, restricting majority of its motion to a single plane.

The knee joint relies on the complex interplay of bones, ligaments, muscles, and cartilage to provide stability, movement, and weight-bearing functionality. Understanding these structures is essential for diagnosing and treating knee-related conditions. If one component degrades or does not function as it is intended, increased strain is found in the other parts of the knee, leading to further damage and impaired function.

2.1.2 Biomechanics of a Healthy Knee Joint

2.1.2.1 Kinematics

For the knee to function as expected it must exhibit proper kinematics. Although commonly considered a hinge joint, the knee's centre of rotation is dynamic, moving along a crescent-shaped path during flexion and extension. While the knee allows for movement across multiple planes, Figure 2-2, the primary motion occurs in the sagittal plane (flexion/extension), with limited varus/valgus motion in the frontal plane and some internal/external rotation in the transverse plane (Fekete et al., 2013).

This small degree of medial rotation in full flexion and slight lateral rotation in full extension is known as the "screw-home" mechanism and contributes to knee stability by ensuring correct alignment of the joint (Scuderi and Tria, 2010).

Knee flexion involves a combination of rolling and sliding of the femur on the tibial plateau, which prevents excessive rotation and potential dislocation (Fekete et al., 2013). Rolling prevents tissue impingement during flexion, while sliding ensures stability and proper function. This dual movement allows for a wide ROM while preventing injury (Affatato, 2015).

The knee joint's mobility is balanced by its robust stabilisers, which enable it to withstand significant external stresses. Ligaments and menisci provide static stability, while muscles and tendons offer dynamic stability (Fekete et al., 2013). This balance between movement and control is essential to prevent injury. Additionally, the knee endures substantial compressive and tensile forces across its articular surfaces, ligaments, and muscles, where improper alignment or loading can lead to degenerative conditions such as OA, as mentioned previously (Affatato, 2015).

Healthy knee flexion ranges from 0° to 140°, though requirements vary depending on the activity performed. For example, approximately 60° is required for walking, 90° when climbing stairs, and 110° during running (Stambough, 2019).

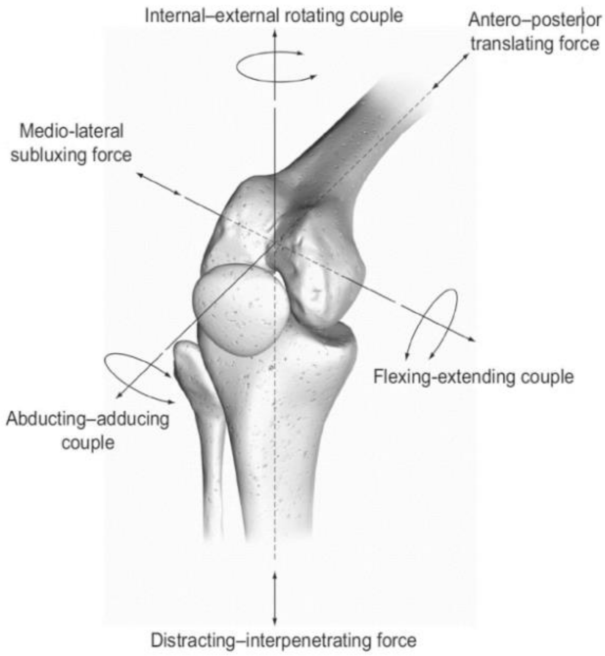


Figure 2-2. Range of motion of the knee joint (Knee - Physiopedia, 2021).

These structures and their associated roles are all responsible for correct kinematics required for healthy joint motion, illustrating shock absorbing, propulsion and stabilising qualities. If knee joint motion is compromised, it is likely affected by and/or affecting the aforementioned stabilisers and could be signs of damage which may lead to further impaired joint performance.

2.1.2.2 Kinetics

Forces and moments act on the knee joint during dynamic movements, placing different stresses across the joint. During normal walking, the tibiofemoral joint experiences forces between 2.8 to 3.4 times body weight, while the patellofemoral joint undergoes forces ranging from 0.8 to 2.6 times body weight (Mesfar and Shirazi-Adl, 2005). These forces increase significantly depending on the type of activity; for example, when walking downhill, compressive forces on the tibiofemoral joint can reach up to 8 times body weight, compared to 5 times when walking uphill.

Knee flexion reduces the contact area between the tibia and femur due to femoral rollback, increasing stress distribution across the joint. Activities such as stair climbing and incline walking, which require greater knee flexion, are considered high-impact activities because they subject the knee to higher forces and stresses, potentially accelerating joint wear.

Although these forces are absorbed by muscles and soft tissues, the ability for these structures to fully absorb and distribute these applied forces optimally are compromised as one ages. This is due to associated decline in muscle mass and strength, altering force distribution across the joint. This may contribute to increased wear and damage to the bone-cartilage interface, causing the cartilage to deteriorate over time. This wear and tear can result in further deterioration of the knee joint, ultimately resulting in pain and impaired joint function.

2.1.3 Conclusions

Thus far the anatomy of a healthy knee joint and the role each structure plays to ensure correct joint function has been described. The complex interplay of each of these structures ensures optimal joint functionality. When these structures do not function as intended, increased wear and joint deterioration may occur resulting in reduced joint function, altered biomechanics and pain.

2.2 Degradation of the Knee

2.2.1 OA Development

Zhang and colleague (Zhang and Jordan, 2010) stated that knee ROM is closely linked to the conditions of the stabilising structures and muscles surrounding the knee joint. It is when the balance between strength, stability and mobility is altered, normal joint biomechanics are compromised, potentially leading to pain and diminished joint function.

Understanding the differences between a normal healthy knee and an affected joint is important for delivering correct treatment to restore function to a diseased knee joint. There are many reasons that may cause a knee joint to function incorrectly, however for the purposes of this thesis, only OA will be considered.

OA arises from severe joint deterioration (Osteoarthritis - Symptoms & Causes - Mayo Clinic, 2019), often triggered by shifts in knee alignment and abnormal forces within the joint. As touched upon previously, under normal conditions, there is a balance between the breakdown and regeneration of articular surfaces, maintained by the formation of cartilaginous matrix in response to natural wear.

However, when the rate of joint degradation exceeds the body's capacity to repair the cartilage, this balance is disrupted, leading to irreversible damage to the cartilaginous matrix (Michael, Schluter-Brust and Eysel, 2010). This damage marks the onset of OA, initiating a cycle of further joint degeneration, including the loss of joint congruency and increased misalignment of the lower limb (Vad, Adin and Solomon, 2023). Over time, this cycle leads to progressive deterioration, resulting in reduced ROM, pain and impaired function.

OA is the most prevalent form of arthritis, affecting approximately 528 million people worldwide (Long et al., 2022). The disease disproportionately affects older individuals, with 73% of cases occurring in people over the age of 55. Women are more commonly affected than men, accounting for 60% of OA cases (Zhang and Jordan, 2010).

KOA is the most common form of OA and is considered a whole joint disease (Vad, Adin and Solomon, 2023). KOA is associated with a range of symptoms, including moderate to severe pain, stiffness, and swelling. The pain, thought to originate from various sources such as the subchondral bone, synovium, menisci, ligaments, or calcium deposits, is often the earliest sign of the disease and can occur during both active and passive movements (Loeser et al., 2012; Vad, Adin and Solomon, 2023).

KOA is a complex, progressive disease that leads to irreversible damage. As KOA progresses, symptoms worsen, leading to severely reduced joint function, decreased mobility, muscle atrophy, and a diminished quality of life (Zhang and Jordan, 2010). Several risk factors contribute to the development of OA as described by Table 2-1.

Table 2-1. Risk factors associated with the development of knee osteoarthritis.

Risk Factors	**Explanation**
Sociodemographic	- Older people are more prone to developing OA, as one becomes older the breakdown of cartilage becomes faster than reformation. - OA is more prevalent in females than in males.
Contact sports and trauma	- Repetitive stresses placed on the joint when playing contact sports or previous injuries may alter lower limb alignment and pose risk to the development of OA.
Genetics	- There is a 40-60% heritability factor of OA development, suggesting OA is likely to be genetic.
Weight	- Carrying excess body weight increases the amount of stress applied to the joints which increases their wear. - Furthermore, fat tissue produces proteins which can result in inflammation around the joints.

2.2.2 The Affected Knee Joint

Given that KOA significantly alters the anatomy of the knee, the function of the joint is also directly affected. Knee ROM is commonly restricted as a result of KOA, with maximum knee flexion angles typically ranging between 80° to 125° (Heidari, 2011; Loeser et al., 2012; Man and Mologhianu, 2014; Zhang and Jordan, 2010), depending on the severity of the condition.

As described previously, a minimum knee flexion angle of 60° is necessary for walking, but a greater ROM is required for activities like stair climbing (Rowe et al., 2000). A more recent study by Collins and colleagues (Collins et al., 2014) supports this claim, reporting that people who are unable to flex their knee above 90° and cannot reach full extension are likely to find it impossible to carry out daily tasks.

As a result of this reduction in ROM and loss of joint function, individuals with KOA deal with daily challenges, including limited independence, difficulty performing common ADL and often rely on others for help.

In addition to reduced function, kinematic studies have consistently demonstrated that individuals with KOA walk at slower speeds, exhibit reduced cadence, and spend more time in the stance phase compared to healthy control subjects (Kaufman et al., 2001; Levinger et al., 2013; McClelland et al., 2017; Yoshida et al., 2008).

These changes in kinematics suggest that altered gait is a means for adults struggling with KOA to mitigate knee pain and maintain functionality through compensatory mechanisms.

2.2.3 Diagnosing OA

Accurate diagnosis of KOA is crucial for providing effective treatment. Symptoms such as knee pain and swelling can result from various causes unrelated to KOA. Therefore, imaging is often necessary alongside pain assessments to correctly diagnose the patient.

Radiographic imaging is commonly used to reveal changes in joint surfaces or bony projections. While KOA-related pain can stem from various sources such as mechanical, inflammatory, neuropathic, or psychosomatic factors (Thirumaran et al., 2023), correctly locating the root cause of the pain enables appropriate treatment to be administered.

Treatment approaches vary based on the severity of the condition and can include non-pharmacologic methods such as patient education, rehabilitation programmes aimed at strengthening muscles, and weight reduction through exercise (Rannou and Poiraudeau, 2010). While medical treatments focus on pain relief with analgesics and anti-inflammatory drugs. Surgical interventions, such as tissue repair, arthroscopic lavage, unilateral knee arthroplasty, and TKA, are considered when all other treatment options fail, with TKA being the most common surgical option (Affatato, 2015; Rannou and Poiraudeau, 2010; Tong et al., 2022; Zeni, Axe and Snyder-Mackler, 2010).

While TKA is not always necessary for KOA, 95% of primary TKA surgeries are performed due to KOA (Long et al., 2022). The procedure is typically reserved for cases where patients experience persistent pain and limited knee ROM, although many individuals with OA do not undergo TKA.

2.2.4 Conclusions

Knee function relies heavily on maintaining its normal anatomy and biomechanics (Scuderi and Tria, 2010). Optimal function is most likely when the joint is correctly aligned and anatomically sound. When a knee joint is not functioning as expected and a person experiences pain and displays altered biomechanics this may signify issues within the joint.

In order for appropriate treatments to be provided, correct diagnosis needs to be made. Patients presenting KOA are eligible for treatments aimed at relieving pain and improving joint function depending on the severity of the disease. Given the complexity of the disease and the intricacies of the knee joint, tailored treatment plans and regular follow-up assessments are essential for effective management.

2.3 TKA as a Treatment Option

As described, there are a wide variety of treatment options available to patients suffering from KOA, with treatment types depending on the severity of the disease (Loeser et al., 2012). KOA management often requires a multidisciplinary healthcare team to control disease progression and prevent further joint degradation. In cases where KOA is not too severe or in the early stages of KOA development conservative treatments are often prescribed to sufferers (Petursdottir, Arnadottir and Halldorsdottir, 2010; Rannou and Poiraudeau, 2010; Roddy et al., 2005; Van Gool et al., 2005; Michael, Schluter-Brust and Eysel, 2010; Zhang and Jordan, 2010).

This typically includes rehabilitation protocols, weight loss programs, and strength training to preserve joint function. Early diagnosis and rehabilitative interventions are the most effective strategies to slow KOA progression and maintain joint function (Loeser et al., 2012; Petursdottir, Arnadottir and Halldorsdottir, 2010; Vad, Adin and Solomon, 2023). However, when KOA becomes too advanced, with severe joint degradation, joint replacement becomes necessary.

This thesis will focus on end stage KOA with the primary treatment option being TKA. TKA aims to restore joint function, reduce pain, improve mobility and ROM, and realign the knee (Michael, Schluter-Brust and Eysel, 2010). The procedure involves removing the damaged articular surfaces of the knee and replacing them with artificial implants. The goal is to restore movement and optimise joint function, either through modification of existing structures or, in severe cases, a combination of modification and reconstruction.

2.3.1 Prevalence of TKA

TKA is a common surgical procedure and its prevalence is increasing. According to LSI’s Global Procedure Volumes Database approximately 3.6 million people undergo TKA worldwide each year, with over 170,000 procedures occurring in the UK (Long et al., 2022; Matharu et al., 2022; Patel et al., 2019).

In the UK, primary TKA constitute around 87% of all knee surgeries (Capelas et al., 2022). TKA primarily targets individuals over the age of 65 with a history of OA. As OA affects women more commonly than men, women undergo TKA more frequently (Hamilton et al., 2015).

In England and Wales, approximately 160,000 knee replacements are performed annually, with an additional 8,000 in Scotland (Matharu et al., 2022). These procedures occur in around 400 hospitals, two-thirds of which are managed by the NHS (Matharu et al., 2022).

The number of TKA surgeries are expected to rise due to an aging population associated with higher life expectancies, higher rates of OA, younger patients requiring surgery and increasing rates of obesity (Hamilton et al., 2015). The growing volume of TKA surgeries has in turn resulted in a corresponding increase in revision surgeries (Atallah et al., 2011; Hamilton. et al., 2015; Lavernia et al., 2008).

Studies predict that the demand for TKA will continue to grow by over 10% annually in the coming years (Kurtz et al., 2009). When considering that about 50% of all joint related surgeries performed in the UK are on the knee, it is important to ensure effective and successful treatment plans and high quality after care (National Joint Registry 15th Annual Report 2018 – HQIP, 2018).

To meet the growing demand and evolving patient demographics, future treatment options and rehabilitation plans must be tailored to address individual patients' functional requirements, aiming to prevent dissatisfaction, poor surgical outcomes and reduce the risk of preventable revision surgeries (Hamilton et al., 2015; Pesteh et al., 2015; Postler et al., 2018).

2.3.2 How Effective is TKA?

TKA is highly effective in reducing morbidity associated with KOA (Bade and Stevens-Lapsley, 2012; Knee Replacement Surgery | NRAS | All the Details on Knee Surgery, 2019). Data from the Swedish Arthroplasty Registry (Price et al., 2018) shows that 96% of all TKA procedures last at least 10 years, while the Australian registry (Postler et al., 2018) reports a 94% 10-year survival rate. Due to the success of TKA, the demand is steadily increasing, with predictive models forecasting continued growth (Kurtz et al., 2009; Matharu et al., 2022).

Primary TKA outcomes are generally excellent, and revision surgeries are only performed when necessary. However, revision surgery is more technically challenging and carries a higher risk of complications compared to primary TKA (Graichen, 2014; Postler et al., 2018; Suarez et al., 2008). Although the revision rates remain low, the large number of initial TKAs performed means that the burden of revision surgeries is growing (Pesteh et al., 2015). TKA complications, such as infection, component wear, and mechanical failure, can all lead to revision surgeries.

To minimise the risk of revision surgery, high-quality aftercare and rehabilitation are crucial for optimising knee function and improving long-term outcomes (Hamilton. et al., 2015).

2.3.3 Conclusions

TKA is considered the standard treatment option for people with end stage KOA. As a result of increasing demands and changing patient demographics more TKA procedures are being performed than ever before, with models predicting a steady increase in the number of future operations.

Despite the overall success of the procedure in restoring function and alleviating pain of an arthritic joint, TKA surgeries sometimes result in unwanted revisions. To prevent unnecessary revision surgeries, it is important that patient aftercare is optimised and that suboptimal surgery outcomes are detected promptly.

2.4 Recovery Pathway Following TKA

2.4.1 What Happens After TKA Surgery?

The goal of all surgery is to discharge the patient as soon as it is safe to do so. In the UK, patients are discharged from hospital approximately 3 - 5 days after surgery, therefore inpatient rehabilitation is extremely short.

Early-stage rehabilitation that occurs during this brief period aims to mobilise the joint and facilitates a safe discharge with guidance from both a physiotherapist and occupational therapist. Healthcare workers ensure that the patient can safely complete basic tasks, such as getting up off a chair and that they can walk short distances in order to ensure that patients can safely return and stay at home independently (Hamilton et al., 2020).

2.4.2 Overview of Conventional Postoperative Rehabilitation

Physical rehabilitation plays a critical component of recovery after TKA, significantly improving functional outcomes and supporting patients' safe return to daily activities (Prill et al., 2022). However, rehabilitation approaches vary globally and even among hospitals (Ibrahim et al., 2015). Variations exist across each stage of care, including the intensity and duration of rehabilitation provided to patients.

Though differences exist, the general structure, importance and recommendations around prehabilitation and post-surgery rehabilitation remain. Prehabilitation typically begins around 4 – 8 weeks prior to surgery and includes strength training focussing on building the major muscles groups through quadriceps sets and straight leg raises. ROM exercises such as heel slides and passive knee extension are performed to aid in mobility, while aerobic conditioning is normally performed on a stationary bicycle to improve cardiovascular fitness. Proprioceptive training helps to improve joint stability, balance and awareness, often including single-leg stance, sit to stand movements heel-to-toe walking and resistance band exercises (Monticone et al., 2010). The primary goal is to enhance muscle strength, joint mobility, and fitness in preparation for surgery (Wallis and Taylor, 2011).

However, there is no universally accepted rehabilitation protocol or physiotherapy regime aimed at optimal TKA recovery, and international recommendations remain unreported (Noble et al., 2006). In the UK, there is uncertainty regarding the availability and standardisation of postoperative physiotherapy resources (Smith et al., 2020), with considerable variation in the delivery and content of rehabilitation programs between hospitals.

Despite this, rehabilitation is strongly linked to improved patient-reported outcomes following TKA (Den Hertog et al., 2012). Evidence suggests that early mobilisation of the joint, within a few hours post-surgery, leads to better outcomes, (Lisi et al., 2017) including shorter hospital stays, with patients discharged on average, 69 hours earlier than those who begin rehabilitation later. Furthermore, the duration of outpatient rehabilitation varies in length and can range between 1 - 6 months depending on the facility and patient (Artz et al., 2015). Westby and colleagues (Westby et al., 2018) recommends a minimum of 6 weeks of rehabilitation post-surgery for good functional outcomes, though length and intensity of programmes are debated.

Pre- and post-TKA exercise-based interventions have also been linked to enhanced recovery, with higher preoperative exercise volumes associated with better postoperative outcomes (Han et al., 2015) and high-intensity, progressive resistance exercises targeting major muscle groups showing better long-term strength and functional outcomes compared to lower-intensity programmes (Bade and Stevens-Lapsley, 2011). It has also been shown that patients with better overall health and fitness tend to have shortened hospital stays and improved early postoperative function (Moyer et al., 2017; Topp et al., 2009).

However, other studies (Alrawashdeh et al., 2021; Bakaa et al., 2021; Konnyu, et al., 2023) comparing different rehabilitation programmes, durations and intensities have found no significant differences between functional outcomes and the type of rehabilitation protocol performed. Though there are conflicting opinions regarding the manner in which rehabilitation is delivered, evidence shows rehabilitation is necessary to consistently improve joint function compared to minimal or no therapy (Hamilton et al., 2020).

2.4.2.1 Postoperative Rehabilitation Pathways

It is clear from the preceding sections that post-TKA rehabilitation protocols are not standardised; however, they all follow similar principles and is structured in progressive phases. Pain management and ice therapy are initiated immediately post-surgery, with physiotherapy starting within the first 24 - 48 hours to mobilise the joint. Exercises carried out in the early phase focus on pain and swelling reduction, muscle activation such as quadricep and glute sets, circulatory support like ankle pumps and early mobility which may take the form of assisted ambulation.

In the first 2 weeks, therapy focuses on improving knee mobility and strengthening surrounding muscles, with gradual weight-bearing and resistance band exercises. Patients typically continue using walking aids during this period. Exercises such as gentle stretches, heel slides, and leg raises aim to restore ROM while managing pain and swelling. These exercises aim to achieve greater degrees of flexion and gait training is prescribed to normalise walking patterns (Mistry et al., 2016). Exercises are typically performed "little and often" to promote better mobility of the joint.

Between 3 - 6 weeks post-surgery, rehabilitation intensifies, focusing on building strength, balance, gait retraining and endurance. Functional activities like stair climbing, chair exercises (sit to stand and stand to sit), and resistance training (such as straight leg raises and quadriceps sets) are incorporated, along with more dynamic ROM exercises like seated knee bends and passive towel knee extensions to optimise outcomes (Mistry et al., 2016) and increase patient independence. Treadmill walking with a focus on heel to toe walking is carried out aiming to improve endurance and gait symmetry. While proprioception exercises often include single-leg weight shifts, balancing on foam pads or eyes-closed balance exercises, all aiming to improve joint stability and joint confidence (Zhang and Xiao, 2020).

By 3 months postoperatively, the patient's proprioception, agility, and balance should all have improved, with patients gradually returning to low-impact activities such as swimming and cycling to improve cardiovascular endurance (Bade and Stevens-Lapsley, 2012). These exercises are typically tailored to individual patient factors and abilities, including preoperative fitness, comorbidities, and rehabilitation goals (Bade and Stevens-Lapsley, 2011; Minns Lowe et al., 2007). Overall, a well-structured, adaptable and personalised rehabilitation protocol is critical to the successful recovery and long-term mobility of individual TKA patients. By this later stage of recovery, typically, only one follow-up appointment with a healthcare provider occurs, unless complications arise.

Throughout the entire recovery period, the primary goals of rehabilitation protocols are to restore quadriceps strength, improve ROM, and enhance functional ability to ensure patients safely perform daily activities independently. Consistency in performing these rehabilitation exercises is crucial, as rehabilitation compliance is strongly correlated with positive outcomes (Forster and Frost, 1982).

2.4.3 Conclusions

Recovery is a major component contributing to the overall success of TKA surgery. Following the TKA procedure, the joint is mobilised to help reduce pain and stiffness and to decrease the length of time the patient stays in hospital. Once the patient is discharged, recovery and functional outcomes are dependent on patient rehabilitation compliance, with limited in person contact between patients and healthcare professionals.

Rehabilitation programmes may vary depending on the facility, with the intensity, duration and type of rehabilitation prescribed varying depending on location (Konnyu, et al., 2023; Lisi et al., 2017; Prill et al., 2022; Sattler et al., 2020).

Though differences in rehabilitation exist, functional outcomes following TKA rely on patient adherence to their rehabilitation protocols. It is therefore important for patients to strictly follow surgery aftercare and carry out their rehabilitation protocols correctly to ensure optimal postoperative success.

2.5 Measuring TKA Success

TKA is clearly effective in alleviating pain and enhancing joint function. While joint function is a good indication of TKA success, patient satisfaction is also a key metric commonly used to evaluate postoperative outcomes. Following TKA, functional improvements are commonly observed early postoperatively, yet patient satisfaction outcomes vary.

According to the Institutes of Health Consensus panel, only 85% of patients are satisfied with their outcomes following TKA (Noble et al., 2006), while other research has shown a broader range with postoperative satisfaction rates between 68% - 93% (Kahlenberg et al., 2018). Understanding the mechanisms that lead to greater satisfaction rates and managing patient postoperative expectations accordingly is important.

Therefore, the ability to accurately monitor and track patient recovery lends itself to timely intervention in cases where patients are not progressing as expected or for early detection of postoperative complications. This proactive approach may help reduce the risk of revision surgeries by addressing issues before they escalate and ultimately improve patient postoperative function and increase satisfaction.

2.5.1 How is TKA Success Measured?

The success of TKA is typically evaluated using a range of outcome measures that assess patient function, pain relief, and overall satisfaction. These measures are generally divided into two categories: objective and subjective measures.

Objective measures are based on quantifiable data gathered through clinical assessments or physical examinations, while subjective measures rely on self-reported patient feedback, reflecting individual experiences, perceptions, and satisfaction with the procedure.

The success of a surgery should therefore be established by evaluating both subjective and objective measures in equal weighting. To improve TKA success, it is therefore important to find a balance between patient satisfaction and good functional outcomes and establish which factors contribute to greater postoperative scores.

2.5.1.1 Objective Measures for Quantifying TKA Success

To determine whether an implant has been successful, objective outcomes are commonly recorded perioperatively. These measures are quantifiable and reproducible, providing critical data used to track improvement or deterioration of a patient and to assess recovery (Hamilton et al., 2020).

Preoperative measures are reported to establish a baseline from which recovery can be compared against and commonly include knee ROM, strength testing, functional performance tests, gait analysis and joint alignment. Each measure is evaluated differently, for example, joint alignment is determined from imaging techniques such as radiographs or MRIs, while functional performance testing has traditionally been evaluated using timed tests like the Timed Up and Go (TUG) test, the 6-minute walk test, and stair climbing assessments (Small et al., 2019).

Moreover, objective measures recorded intraoperatively might include soft tissue balancing, bone resection measures, implant position and alignment, and blood loss. Postoperative measures include the same preoperative measures, though, may include pain and swelling assessments.

Functional tests performed postoperatively are normally compared against preoperative scores. However, these tests do not perfectly reflect ADLs as they do not fully capture real-world movement patterns which may lead to poor postoperative functional scores. Recent research (Small et al., 2019) suggests that incorporating ADL-based assessments together with patient-reported subjective outcome measures (PROMs) may offer a more comprehensive evaluation of TKA success (Small et al., 2019).

Objective measures are useful for providing consistent comparisons across patients at various stages of recovery. These objective outcomes provide clinicians with quantifiable information that can be used in future decision-making by identifying aspects of recovery that need to be addressed, while providing information that may be used to link preoperative measures with favourable postoperative outcomes. Assessing patient outcomes is therefore crucial following treatments or interventions like TKA, to ensure patients are progressing as expected (Padua et al., 2007) and that poor surgical outcomes may be detected promptly.

This thesis incorporates a number of common functional activities used in clinical settings to assess patient function and recovery. To comprehensively evaluate recovery, data should be collected at multiple time points (Kornuijt et al., 2019). Preoperative assessments establish a baseline from which comparison may be drawn against postoperative measures, while regular data collection at set intervals ensures ongoing monitoring of recovery progress.

These data could contribute to developing predictive tools that forecast postoperative functional outcomes based on preoperative functional scores and patient satisfaction (Givens et al., 2018; Zeni and Snyder-Mackler, 2010). Such tools could offer valuable insights to improve postoperative outcomes and enhance surgical planning.

Flexion/Extension as a Common Objective Measure of TKA Success

Knee ROM, particularly flexion and extension, is a critical indicator of joint functionality following TKA (Oka et al., 2020). As previously established, a flexion angle of 90° - 100° is required for most ADLs such as stair navigation, sitting and getting in and out of a car or bathtub (Baliunas et al., 2002; Collins et al., 2014; Kaufman et al., 2001; Rowe et al., 2000). However, many patients struggle to reach this degree of flexion postoperatively (Bauer et al., 2010), reducing their ability to perform basic tasks.

Many factors influence ROM recovery following TKA, of which include preoperative ROM, age, BMI, surgical methods, and rehabilitation adherence (Moghtadaei et al., 2012). Patients with limited ROM pre-surgery often experience significant improvement when compared to baseline measures, while those with normal ROM may temporarily display reduced postoperative ROM due to swelling (Zhou et al., 2015).

Limited postoperative ROM is a common issue reported by patients (Khatri et al., 2009), often leading to patient dissatisfaction (Hamilton et al., 2020). Studies show a strong correlation between early knee flexion (at hospital discharge) and long-term ROM recovery, highlighting the importance of early mobilisation for better functional outcomes (Hamilton et al., 2020; Moghtadaei et al., 2012; Naylor et al., 2012).

Conventionally ROM is a common metric used to measure TKA success, recovery progress and functional improvements during rehabilitation (Collins et al., 2014; Patel, 2019; Khatri et al., 2009). Therefore, this thesis focuses on measuring and quantifying knee flexion and extension across a wide range of activities and at early stages of recovery.

Common Functional Objective Metrics

Though ROM is a common quantifiable metric used to gauge TKA recovery, functional objective measures are essential tools in evaluating the recovery trajectory of individuals following TKA. These measures provide quantifiable insights into mobility, strength, and overall physical performance of the patient (Wright et al., 2011). Commonly used assessments include the Timed Up and Go (TUG) test, the 6-Minute Walk Test (6MWT), Stair Climb Test (SCT) and Sit to Stand test (Dobson et al., 2012). These measures serve not only as indicators of functional ability but also reflect underlying biomechanical adaptations that occur post-surgery.

For instance, the TUG test assesses dynamic balance, lower limb strength, and transitional movement control, all of which are affected by quadriceps weakness and altered proprioception following TKA. Biomechanically, patients often compensate during this task by increasing trunk sway or relying more heavily on the non-operated limb, which can delay symmetrical gait recovery and contribute to long-term movement inefficiencies (Mizner et al., 2005).

The 6MWT, commonly used to evaluate walking endurance and cardiovascular fitness, also highlights the functional limitations imposed by postoperative joint stiffness or pain. Shorter walking distances are often associated with compensatory gait patterns such as reduced knee flexion during swing phase or increased reliance on hip musculature to advance the limb, indicating ongoing biomechanical dysfunction (Bade and Stevens-Lapsley, 2011).

Similarly, the Sit to stand test captures lower extremity power and neuromuscular control. Following TKA, many patients exhibit delayed muscle activation and decreased force generation, particularly in the quadriceps. This results in an increased use of arm support and altered momentum transfer from sit to stand which further emphasises the residual deficits in knee extensor strength and joint stability. From a biomechanical perspective, such compensations can elevate joint loading in adjacent joints such as the hips or the spine, potentially predisposing patients to secondary musculoskeletal issues (Petterson et al., 2009).

The SCT provides critical insight into the eccentric control of knee flexors and the concentric strength of extensors, both of which are often compromised postoperatively. Difficulty with stair descent, in particular, may indicate persistent quadriceps inhibition and limited joint proprioception, which are not always captured in self-reported outcome measures.

Thus, these functional assessments are not merely clinical tools but provide a window into the mechanical efficiency, motor control strategies, and compensatory patterns that develop post-TKA. Understanding their biomechanical implications enables clinicians to target rehabilitation more precisely, promoting symmetrical loading, restoring proper movement mechanics, ultimately enhancing surgical outcomes and improving a patient's independence and functional abilities.

Altered Gait Biomechanics

Persistent pain following TKA can hinder gait biomechanics and functional recovery (Atallah et al., 2011; Kaufman et al., 2001; Lavernia et al., 2008). Studies have shown that approximately 30% of patients continue to experience pain up to two years post-surgery (Dowsey et al., 2012), which can impede the restoration of normal knee function and gait patterns. Altered weight distribution between the operated and non-operated leg often results in muscle weakness and decreased functionality (Levinger et al., 2013; Dowsey et al., 2012), all leading to suboptimal postoperative results.

Early identification of patients struggling with ROM recovery and abnormal gait characteristics is essential. Previously mentioned, there is a strong correlation between knee flexion at the time of hospital discharge and ROM outcomes 12 months post-surgery (Chiang et al., 2017). However, if knee ROM can be continuously tracked throughout recovery, timely intervention in patients with delayed ROM recovery may lead to better functional results and enhanced quality of life. Preventing further gait abnormalities, poor function, dissatisfied patients and potential revision surgeries. The characteristics of gait abnormalities of an affected knee joint will be discussed in section 2.6.

2.5.1.2 Subjective Measures for Quantifying TKA Success

Subjective measures provide an alternative approach used to determine TKA success by considering patients' perspectives. Patient recovery is highly individual and is typically subjectively assessed using PROM questionnaires (Van Onsem et al., 2018), which evaluate key postoperative aspects such as satisfaction, pain, and perceived mobility.

While PROMs provide valuable insights into patient perceptions, discrepancies can arise when compared to objective, performance-based functional measures (Van Onsem et al., 2018). To reiterate, it is therefore important to use both objective and subjective measures in unison when evaluating the overall success of the procedure.

There are several PROMs commonly used; however, this thesis focusses on three questionnaires which are outlined below.

The Oxford Knee Score (OKS) (Fitzpatrick et al., 1998), is commonly used to evaluate pain and function through 12 questions, generating a score between 0 - 48, where a higher score indicates greater satisfaction. ***The Forgotten Joint Score - 12 (FJS)*** (Robinson et al., 2021) assesses a patient's awareness of their artificial joint during daily activities, also scoring between 0 - 48, with higher scores indicating greater awareness and therefore poorer outcomes. ***The Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS JR)***, is a comprehensive questionnaire used to assess joint condition by evaluating 5 subscales. This questionnaire combines pain, stiffness, symptoms and functional ability into a single score, with higher values indicating worse knee health.

PROMs are widely adopted clinically due to their ease of use, low cost, and ability to capture patient-centric outcomes (Dowsey and Choong, 2013). However, they have limitations, including their subjectivity and bias (different patients place value on different aspects of recovery and have varying expectations), lack of sensitivity and specificity to detect functional changes, variability across different questionnaires, inconsistencies in timing of data capture following surgery, and difficulties interpreting the final scores (no clear threshold defining ''good'' and ''bad'' scores) making direct comparisons difficult (Dowsey and Choong, 2013).

More extensive questionnaires may offer deeper insights into aspects of recovery that patients place greater value on but at the cost of reduced completion rates. Despite these limitations, PROMs provide critical information on patient satisfaction beyond what clinical measures alone can provide (Small et al., 2019).

To gain a complete evaluation of TKA outcomes and success, subjective PROMs should be complemented by objective measures such as physical function, ROM, and other clinical assessments (Tew et al., 2020; Vogel et al., 2020). While PROMs provide valuable patient perspectives, their limitations necessitate a balanced approach that integrates both subjective and objective assessments.

Therefore, evaluating TKA success by using both PROMs and functional outcome measures enhances the ability to evaluate the overall success of TKA by incorporating the patient's experience alongside clinical measures of joint functionality, ensuring a more comprehensive, patient-centred assessment of postoperative outcomes is established.

2.5.1.3 Clinically Significant Improvement in Knee ROM

Clinically significant improvements in knee ROM following TKA is typically defined as an increase in ROM that meaningfully enhances functional performance and patient-reported outcomes. A common threshold for clinical significance is an improvement of at least 10° to 15° in knee flexion or extension compared to baseline measurements (Kittelson et al., 2020). This degree of change is generally associated with improved mobility, reduced pain, and enhanced ability to perform daily activities (Chapman, Moschetti and Van Citters, 2021).

Current clinical practice evaluates knee ROM through goniometer measurements or visual assessments (Antunes et al., 2021). However, these conventional measurement techniques are prone to errors and the accuracy is variable depending on which technique is used and who performs the measurement. For example, Edwards and colleagues (Edwards et al., 2004) found that 45% of patients who had their ROM assessments carried out visually, were reported incorrectly by more than 5°. Whereas 22% of patients had ROM measures off by more than 5° using a goniometer (McGrath, Fineman and Stirling, 2018).

Therefore, there is a requirement for accurate and sensitive measurements of ROM improvement following TKA. Particularly if recovery progress is to be tracked accurately and suboptimal outcomes are to be detected correctly.

Timeline for Achieving Clinically Significant ROM Improvements

Length of time is commonly used to access suboptimal recovery. The time required for patients to regain functional ROM post-TKA varies (Chapman, Moschetti, and Van Citters, 2021), and is influenced by factors such as preoperative ROM, surgical technique, rehabilitation adherence, and individual patient characteristics.

Generally, patients can expect to see initial gains in ROM within the first 6 - 12 weeks post-surgery, with the most substantial improvements occurring during this period (Edwards et al., 2004; Kittelson et al., 2020). Therefore, careful monitoring of patient recovery progress is required particularly within this early postoperative phase as vast improvements should be evident.

Full or near-full recovery of ROM often continues over 6 - 12 months (Kittelson et al., 2020), with incremental gains in flexibility and function observed at later stages. Significant long-term recovery may take up to 24 months, particularly in cases with preoperative stiffness or complications.

It is therefore vital that patients are carefully monitored and that their functionality is accurately tracked in order for their recovery progress to be properly monitored if suboptimal recovery is to be detected. Clinicians can only intervene in a timely manner if suboptimal function is detected early.

2.5.2 Patient Follow ups and TKA Failures

According to the British Orthopaedic Association (Swinkels et al., 2009), patient outcomes are typically assessed at 6-, 24-, and 52-weeks following surgery. However, follow-ups beyond 52 weeks are limited due to constraints in funding and limitations in staffing resources (Atallah et al., 2011). Current methods for monitoring outpatients after TKA are insufficient, as early and late causes of knee replacement failures are often not documented adequately.

Early implant infections usually occur within 1 - 6 weeks post-surgery, yet patients are not consistently contacted for follow-up appointments during this period (Atallah et al., 2011). The lack of regular outpatient check-ups can delay the identification and treatment of infections, potentially leading to revision surgery and its associated costs. Prescribing antibiotics and scheduling regular check-ups to monitor postoperative progress could also limit these complications (Atallah et al., 2011).

Although uncommon, implants can fail years following TKA. Later implant failures typically develop 5 - 10 years post-surgery and often go undetected in a home setting. Clinical or radiological assessments are required to confirm these failures, which are not performed as frequently as required (Ramkumar et al., 2019). Continual monitoring of patients following surgery, even in the later stages of recovery may allow for such failures to be detected earlier and prevent further deterioration within the joint.

2.5.3 Conclusions

In order to optimise outcomes following TKA, a detailed assessment of knee function is required. The success of TKA is commonly evaluated using both quantifiable objective measures and patient perceived subjective measures. A successful surgery is one in which meets both criteria. It is therefore important to consider both objective and subjective outcomes in equal weighting when evaluating the success of a surgery. These two measures closely relate, with strong correlations between patient satisfaction and good functional outcomes.

Accurate and granular documentation of a patient's preoperative function and postoperative recovery is required to improve surgery outcomes and may allow for timely intervention in cases where patients are not recovering as expected. This may enable the prevention of timely and costly revision surgeries and improve patient satisfaction following TKA.

2.6 Motion Analysis as a Clinical Evaluation Tool

It has been established that there is a need to accurately measure and quantify knee joint motion. The ability to analyse and track human motion, particularly in the context of rehabilitation post-TKA provides an accurate indication of the improvements in joint function following surgery and rehabilitation and thus is useful for determining the success of the procedure.

There are two types of measuring systems conventionally used to assess biomechanics, analyse gait and accurately monitor recovery (Richards, 1999), both of which are sensitive enough to detect small changes in joint function.

The first type uses visual recordings of body segment positions (image-based optical motion capture), while the second employs magnetic sensors that track segment position and orientation in space (sensor-based). Image-based devices are further divided into passive and active systems: passive systems use light-reflecting markers, while active systems use markers with built-in light sources (Richards, 1999).

Image-based optical motion analysis involves capturing a sequence of images, typically using high-speed cameras, to generate kinematic data based on the observed motion. In most setups, the cameras are positioned around a defined capture volume, allowing the system to track the movement of an object within that space.

Optical motion analysis is becoming increasingly accepted as the ‘gold standard’ outcome measure for assessing human movement (Komnik et al., 2015; McClelland, Webster and Feller, 2007). It is frequently used to evaluate individuals’ functional ability to perform tasks of daily living, especially walking (Levinger et al., 2013).

According to recent research, optical motion analysis is the most effective outcome measure for detecting changes in the function of the knee joint pre- and postoperatively, as other objective tools are often unable to provide accurate and sensitive enough results (Andriacchi and Alexander, 2000; Yunus et al., 2021).

Manual methods of assessing knee function have been criticised for not accurately reflecting the knee’s dynamic motion (Myles et al., 2001; Yang et al., 2016). In contrast, gait analysis through motion capture technologies is specifically designed to evaluate and interpret movement patterns during daily activities, giving gait analysis a distinct advantage over outcome measures that only assess static conditions, providing greater content validity as a result.

Typically, real-time marker locations placed on known anatomical landmarks are captured through motion capture systems (Cappozzo et al., 2005). Force plates determine the forces acting on the body, while muscle activity is assessed through electromyography. Anthropometric data are collected using measuring tapes or callipers which are then used to accurately process the data, using software models.

Joint kinematics are determined using the positions of retro-reflective markers, which are detected in 3D space by infrared cameras in the laboratory (Cappozzo et al., 2005; Davis et al., 1991). Initially, the marker coordinates are expressed relative to the global (or laboratory) reference frame (Davis et al., 1991). Since these markers correspond to anatomical landmarks, their coordinates can be translated into an anatomical reference frame. This allows for the description of the instantaneous position and orientation of the underlying bones and joint centres to be described (Andersen et al., 2012; Cappozzo et al., 2005; Cappozzo et al., 2005; Davis et al., 1991).

Transformation matrices are used to convert marker coordinates from the global 3D reference frame into an anatomical reference frame. Once translated, rigid body mechanic principles are applied to these coordinates to calculate kinematic outputs within the body's reference frame. As a result, knee ROM can be determined by tracking the relative movements of markers placed on the proximal and distal segments of the joint and calculating the angles between their corresponding anatomical axes (Andersen et al., 2012; Brennan, Deluzio and Li, 2011; Davis et al., 1991; Page et al., 2014). Typically, a marker set consisting of around 10 to 50 markers is required to create a full biomechanical model to accurately track human movement.

Biomechanical models found within motion analysis software are commonly implemented to analyse specific gait events that are not directly acquired through camera tracking. In these models, body segments are represented as a kinematic chain of links, comprising of bones and soft tissues. Bones within each segment are treated as non-deformable rigid bodies, and the segments are connected by joints, with up to six degrees of freedom (DOF). The total DOF of the model determines its ability to accurately represent human movement (Andersen et al., 2012; Page et al., 2014).

Motion capture systems enhance movement analysis, by providing a visual means to interpret motion from different perspectives in space (Figure 2-3). This approach allows for a comprehensive description of the movement in all planes of motion and allows for easy comparison of recovery progress. While both kinematic and kinetic data are either directly measured or estimated using mathematical models (Cappozzo et al., 2005), further enhancing movement analysis.

Similarly, the body segment can be viewed from any perspective, enabling a 3D representation. This approach allows for a comprehensive description of the segment's movement in all planes of motion.

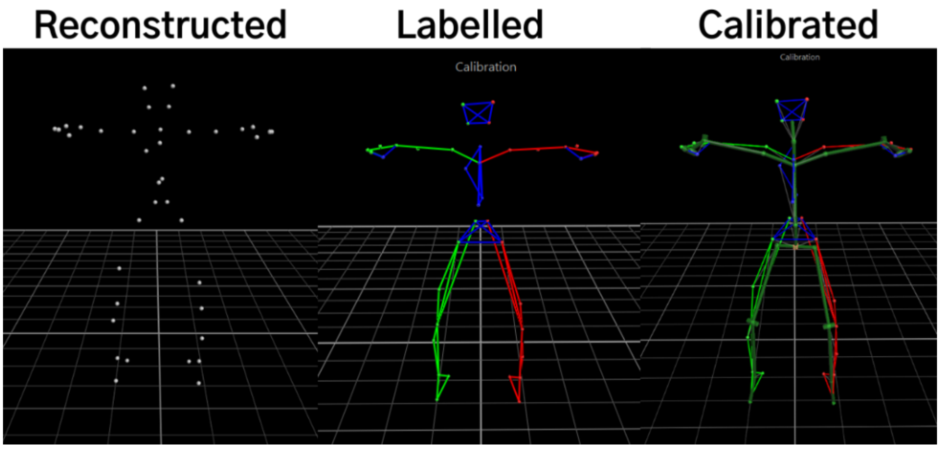


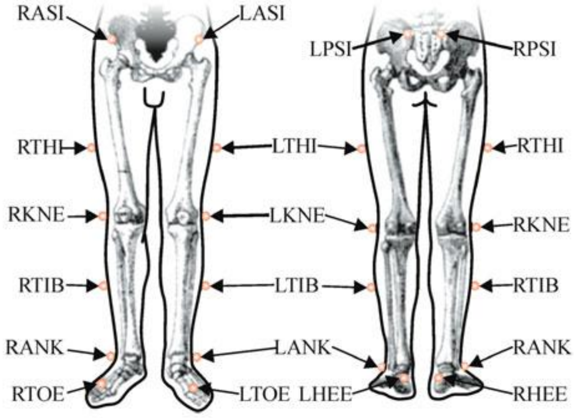
Figure 2-3. Vicon motion capture data processing pipeline.

2.6.1 The Plug-in Gait Model

The Plug-in gait (PIG) model is a widely accepted model (Molina-Rueda et al., 2021; Nair et al., 2010; Paterson et al., 2017) used in motion capture for gait analysis. It relies on data collected from motion capture systems, to estimate joint angles and other kinematic parameters of the lower limbs (Vaughan, Davis and O'Connor, 1992).

The PIG model is Vicon's (Vicon, Oxford, UK) implementation of the broader Conventional Gait Model (Baker et al., 2017; Leboeuf et al., 2023). The origins of which can be traced to the work of John Hagy in the laboratory established by David Sutherland (Sutherland and Hagy, 1972). Vicon developed their own version of the Conventional Gait Model developed as the PIG model for Workstation software. This resulted in the wide adoption of the model within clinical and academic gait analysis (Baker et al., 2017; Leboeuf et al., 2023).

The PIG model uses reflective markers placed on specific anatomical landmarks to track movement (Vaughan, Davis and O'Connor, 1992). Figure 2-4 describes the anatomical locations used for marker placement.



segment	marker	position
pelvis	LASI / RASI LPSI / RPSI	anterior superior iliac spine posterior superior iliac spine
femoral	LTHI / RTHI LKNE / RKNE	over the lower lateral 1/3 surface of the thigh lateral epicondyle
tibial	LTIB / RTIB LANK / RANK	over the lower lateral 1/3 surface of the shank lateral malleolus
foot	LTOE / RTOE LHEE / RHEE	second metatarsal head calcaneus

Figure 2-4. Plug-in Gait Lower Limb model marker placement (Behrens et al., 2012).

Sixteen retro-reflective markers are positioned in specific locations and define the segments of the lower limb (pelvis, thigh, shank, and foot) which are necessary for calculating the motion of joints during activities such as walking.

Beyond joint angles, the PIG model is used to calculate important gait parameters, such as stride length, step length, cadence, and walking velocity (Vaughan, Davis and O’Connor, 1992). Additionally, the model provides insights into the ROM of joints during the gait cycle. This model is a valuable tool for assessing gait performance, diagnosing abnormalities, and monitoring the effects of therapeutic interventions.

2.6.2 Movement Analysis Laboratories and their Limitations

Though motion analysis is increasingly being used by researchers due to its superior accuracy compared to traditional video analysis systems and manual techniques (Cuesta-Vargas, Galan-Mercant and Williams, 2010; Luinge and Veltink, 2005; Picerno, Cereatti and Cappozzo, 2008). They are not commonly implemented as a clinical evaluation tool due to various restraints and limitations.

Although individual retro-reflective markers are crucial for most 3D biomechanical motion capture gait assessments, they have been criticised for being prone to imprecise placement (Cappozzo et al., 2005), inconsistent position (Windolf et al., 2008), and being time-consuming to apply (Akbarshahi et al., 2010; Andriacchi and Alexander, 2000; Fantozzi et al., 2003).

With further sources of error which cannot be controlled for by the use of individual markers known as ‘soft tissue artefact’ (Akbarshahi et al., 2010; Cappozzo et al., 2005; Page et al., 2014; Solav et al., 2014). Neglecting the presence of soft tissue deformation can introduce errors, reducing the accuracy of the results (Peters et al., 2010). The effects of soft tissue artefacts can impact movement dynamics, specifically during activities involving high acceleration and high degrees of flexion (Hatze, 2002). This source of error is caused by the movement of markers in relation to the bone, because of the underlying soft tissue. The markers are attached to the skin, yet movement of the limb causes the tissue surrounding the bone to move relative to the joint, which might cause the markers to move to a position where it no longer represents the precise location of the bony anatomical landmark it was positioned on before.

It is therefore important to ensure precise marker placement when carrying out biomechanical assessments and consider these sources of error. As placement errors directly translate to errors in both kinematic and kinetic data (Andriacchi and Alexander, 2000).

Moreover, using individual markers comes with its own set of challenges. There is a risk that markers may fall off or be occluded during data capture which results in missing or gaps within the data. Occluded data which is caused by markers being blocked out of the cameras field of view, prevents data reconstruction which is necessary to process the data for gait analysis. In these cases, where the number of frames affected by marker occlusions is small, gap filling techniques may be used. However, they should be implemented with caution as they are not always successful or accurate.

Trials where markers are missing are often unusable as the software used to determine the kinematics and kinetics cannot always compensate for this missing information. This loss of data can severely impact the quality of studies.

As described previously, a number of limitations exist in the implementation of motion capture systems, both practically and technically. Motion capture systems are technically complex to operate, which results in skilled operators required to work the systems. Due to their associated complexities these systems are therefore time consuming to use (Jebeli et al., 2017; Yunus et al., 2021) and have high cost associated with their utilisation. Most motion capture systems are also large in size and are not easily portable which all prevent the easy uptake of this technology into clinical environments (Bartlett, 2014).

Before data collection can begin, cameras need to be calibrated, and markers need to be placed accurately on the individual. After data collection, the data then needs to be processed using specialised software, a task that can take several hours, before interpreting the resulting complex graphs (Yunus et al., 2021). These factors create a high barrier for clinical researchers who are not previously trained in motion capture, deterring many from using it.

Therefore, as a result of the aforementioned limitations and challenges with implementing such systems into clinical settings, it is not surprising that movement analysis laboratories are not commonly found within healthcare environments. This technology is not easily accessible to those who could benefit the most from it, therefore, alternatives are required.

2.6.3 Gait Analysis to Assess Biomechanics

Motion analysis has the power to be an effective tool to monitor rehabilitation progress in patients following TKA, examining biomechanics during activities that mimic daily living (McClelland et al., 2017; Smith et al., 2006; Yoshida et al., 2008), and for tracking functional improvements.

In clinical practice, analysing gait provides insights into the extent at which a patient's walking pattern is influenced by an underlying condition (Chambers, Henry and Sutherland, 2002), serving as an assessment rather than a diagnostic tool. By carrying out functional assessments in a movement analysis laboratory a variety of factors can be identified, the most routine assessments involve identifying gait abnormalities by reviewing the walking patterns of an individual.

The clinician specifically looks for asymmetries, such as limping or uneven weight distributions. This provides information regarding dysfunctions in locomotion or other pathologies such as KOA and allows for correct treatment options to be prescribed (Chambers, Henry and Sutherland, 2002) or further tailored.

Gait analysis is useful in providing functional assessments of patients going into the operating theatre and can be used to assess patient improvements by evaluating their recovery against their own preoperative benchmarks.

However, pathological gait can only be identified if the clinician has an understanding into a non-pathological walking pattern (Akbarshahi et al., 2010; Benedetti et al., 2003; Fantozzi et al., 2003; Schiefer et al., 2011; Whittle, 1996). The following section will discuss a normal gait cycle, discussing both healthy and affected knee joint motion and which parameters of gait analysis are commonly used to assess individuals with abnormalities.

2.6.3.1 The Healthy Gait Cycle

Gait refers to any movement involving alternating periods of weight-bearing and non-weight-bearing on the limbs (Mayich et al., 2014) but commonly refers to walking. The complex coordinated efforts of the musculoskeletal system, central nervous system, and peripheral nerves ensure correct motion of the body (Kharb et al., 2011; Whittle, 1996). A healthy gait, which is essential for daily life, occurs when these systems work together in harmony (Mayich et al., 2014).

The normal gait cycle can be divided into two phases known as 'stance' and 'swing'. The stance phase makes up approximately 60% - 62% of the gait cycle and equates to the duration of time that the foot is in contact with the ground. While the swing phase, constitutes the remaining 38% - 40% (Kharb et al., 2011).

During the swing phase the limb is propelled forwards, in front of the stance limb to allow forward progression. The stance phase, being the weight-bearing section of the cycle, often reveals the most inefficiencies (Bercovy, 1991). To further understand the gait cycle, the stance and swing phases can be broken down into distinct periods (Figure 2-5).

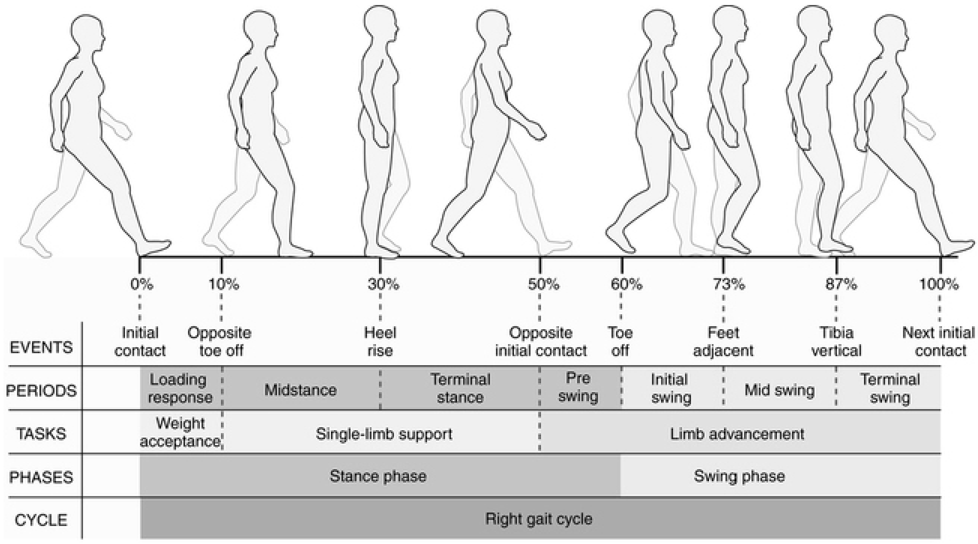


Figure 2-5. Phases of the gait cycle (Neumann, 2010).

After initial contact, the stance phase is typically divided into three or four sub-phases: loading response, mid-stance, terminal stance, and, less commonly, pre-swing. The swing phase, which is the non-weight-bearing phase, is divided into three sub-phases: initial swing, mid-swing, and terminal swing.

In individuals with a normal gait, both limbs go through the same events, periods, and phases, but the movements occur 180° out of phase. Typically, during foot strike, the heel is the first part of the foot to touch the ground, and during foot-off, the toe is the last part to lift off. However, in cases of abnormal gait, this pattern can change, and the first and last points of contact with the ground are called "first contact" and "final contact."

In addition to the phases of gait, a variety of spaciotemporal parameters may be used to describe healthy gait patterns (Robinson and Smidt, 1981). These may include cadence (Slaght et al., 2017; Tudor-Locke et al., 2020), walking speed (Murtagh et al., 2021), stride length (Levine, 2012) and step length and time. These indicators may all be used to provide an overall description of health.

Although the gait cycle remains relatively consistent in normal walking, a number of variables including age, sex, and height can affect gait parameters. It is important to recognise that even among healthy individuals with normal gait patterns, spaciotemporal, kinematic, and kinetic measurements can vary, as gait is naturally a variable and individual specific activity.

However, the values observed in people with normal gait typically fall within a range considered non-pathological. This range accounts for natural differences between individuals, allowing for variation while still classifying the gait as normal. Furthermore, this normal range is also commonly used as a benchmark to evaluate abnormal gait patterns against.

2.6.3.2 Healthy Knee Joint Motion

Lower limb angles, specifically the knee is of particular interest when analysing gait and joint health. Knee angle is defined as the angle between the femur and the tibia, enabling flexion and extension of the lower leg in the sagittal plane, and limited motion in the other planes.

Through the progression of a single gait cycle each joint goes through specific trends (Fukuchi et al., 2018). The knee characteristically displays two flexion and extension peaks during walking, Figure 2-6, with the first flexion peak occurring at around 18% of the gait cycle at the beginning of mid-stance, then the knee tends towards full extension at the start of late stance, and flexes again to a peak of about 50° - 60° during initial swing (Fukuchi et al., 2018). Similar trends are observed during stair navigation; however, the events occur at different stages of the gait cycle, Figure 2-7. Understanding healthy gait patterns and ranges in measures is essential for appropriately diagnosing pathological gait.

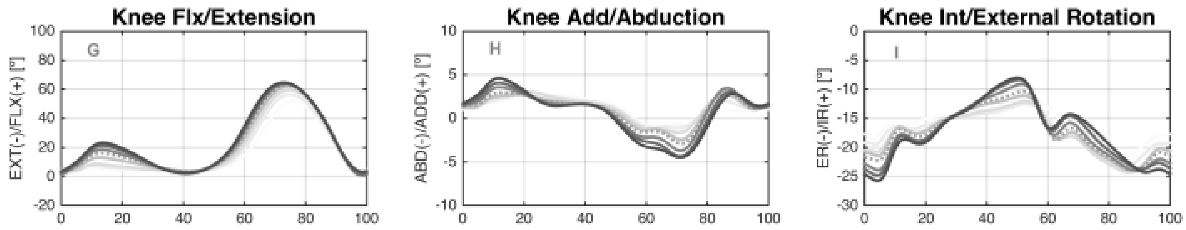


Figure 2-6. Knee joint angles during a complete gait cycle of a healthy adult (Fukuchi et al., 2018).

As established previously, motion in both the frontal and transverse planes function to aid in stability and maintain gait efficiency. The lower limb can be conceptualised as an interlinked multi-segmental system, where a change in one area causes a change in the joints above and below, ultimately affecting the lower limb biomechanics.

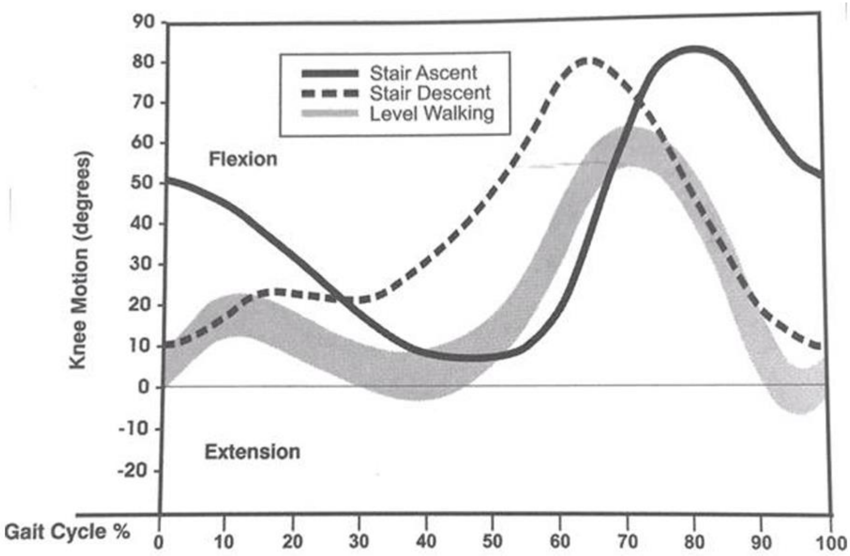


Figure 2-7 Healthy Knee flexion angles during stair navigation and walking (Perry and Burnfield, 2010).

This literature review has emphasised the variability in ROM of a healthy knee joint depending on the type of activity or movement performed (Figure 2-7). Though a greater ROM of 90° - 100° has been suggested as necessary to complete everyday tasks such as stair navigation, getting in and out of a bathtub or car and for sitting (Rowe et al., 2000), individuals with disease and associated comorbidities often experience restricted ranges and these are further reflected in their gait patterns.

2.6.3.3 Affected Joint Motion

Diseases such as KOA affect not only the joint itself, but also many gait parameters. The greater the severity of the disease, the more parameters are affected. Symptoms linked to KOA, such as knee pain, stiffness of the joint and reduced ROM can all result in significant compensations which cause adaptations within the gait cycle (Mayich et al., 2014). When a patient who is affected by OA and requires a TKA is compared against a healthy control, OA patients typically demonstrate altered knee kinematics, often exhibiting reduced knee ROM, Figure 2-8, reduced peak knee flexion angles during swing phase, which limits adequate toe clearance and compromises walking efficiency. Normal peak flexion is around 60°, yet TKA patients often achieve only 45 – 55° of knee flexion (Mizner et al., 2005; McClelland et al., 2007), with a flatter peak flexion displayed in the stance phase compared to healthy adult populations. This limitation is often compounded by quadriceps weakness and joint stiffness.

Kinetic studies reveal a reduction in external knee flexion moments during stance, reflecting impaired extensor control (Benedetti et al., 2003). Spatiotemporal abnormalities are also prevalent, with TKA patients showing slower walking speeds, reduced cadence, shorter stride lengths, longer double-limb support times, and increased step width compared to age-matched healthy adults (Heiden et al., 2009; McClelland et al., 2007). These findings suggest not only reduced physical capacity, but also compensatory mechanisms aimed at improving balance and stability.

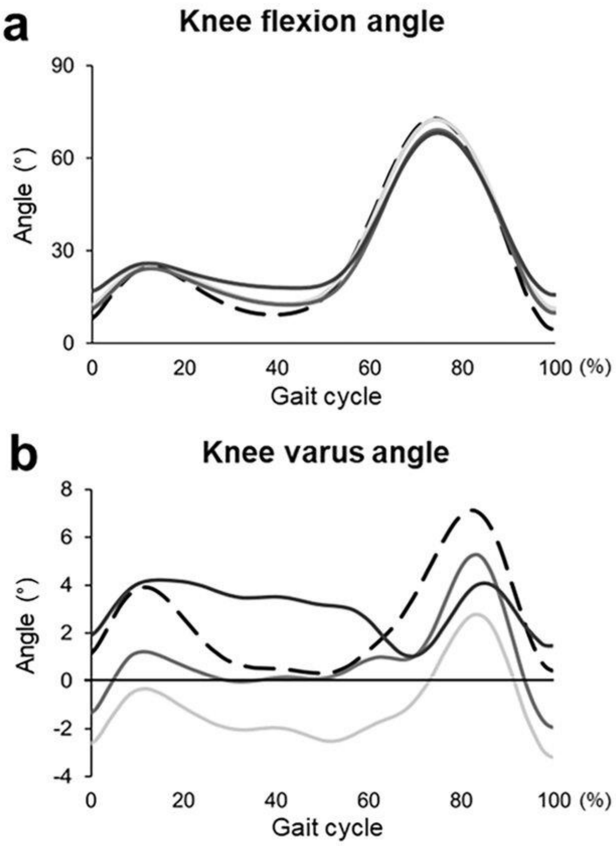


Figure 2-8. Gait cycle of an affected OA knee joint (solid line) and healthy joint (dashed line) during walking (Suzuki et al., 2023).

While other activities such as stair navigation places significantly higher demands on the knee joint, often revealing functional limitations that are not apparent during level walking. Research shows that patients post-TKA frequently adopt a "step-to" strategy, particularly during stair descent, rather than a normal "step-over-step" pattern (McClelland et al., 2011). This modification is often due to restricted knee flexion, which in healthy adults typically exceeds 80 – 90° during stair descent but may remain below 75° post-TKA (Mills et al., 2013).

Kinetic analysis reveals that TKA patients exhibit reduced knee extensor moments, particularly during the eccentric phase of stair descent, suggesting ongoing quadriceps inhibition and reduced neuromuscular control. Proprioceptive deficits following joint replacement may further impair stair performance, increasing reliance on handrails and the contralateral limb for support (McClelland et al., 2011; Mills et al., 2013).

Whereas the sit to stand activity, which is critical for maintaining independence is particularly sensitive to post-TKA neuromuscular deficits. Studies using motion capture and force platforms have shown that individuals post-TKA exhibit reduced peak ground reaction forces on the operated limb and longer transition times during the sit to stand movement (Yoshida et al., 2012; Ganea et al., 2010). To compensate for impaired knee extensor strength, patients often increase trunk flexion to generate momentum or shift weight toward the non-operated limb.

Furthermore, angular velocity during knee extension in the rising phase is significantly reduced in TKA patients, indicative of slowed neuromuscular responses and impaired power generation. These compensations may persist even after initial recovery and have been linked to long-term functional limitations and asymmetrical joint loading (Yoshida et al., 2013).

Understanding the thresholds of healthy gait measures and patterns is essential not only for diagnosing abnormal gait but also for designing effective, individualised treatment plans. Monitoring gait over time allows clinicians to benchmark improvements against normative healthy population values, providing a clear and objective framework for assessing rehabilitation progress.

In the context of TKA patients and affected joint motion, the persistence of movement abnormalities highlights the limitations of traditional rehabilitation in addressing the specific biomechanical and neuromuscular deficits associated with functional tasks such as walking, stair climbing, and sit to stand transitions. As a result, there is a growing consensus in the literature advocating for the integration of advanced, targeted and patient specific rehabilitation approaches (Bade and Stevens-Lapsley, 2011). These include progressive resistance training, neuromuscular electrical stimulation, and gait retraining strategies aimed at restoring more natural and symmetrical movement patterns (Petterson et al., 2008; Petterson et al., 2009; Bade and Stevens-Lapsley, 2011). Furthermore, the use of objective movement analysis tools such as wearable technologies may enhance the detection and monitoring of subtle gait deviations that may not be captured through self-reported measures or visual observation, thereby supporting more data-driven and responsive rehabilitation interventions.

2.6.4 Motion Analysis Through New Technologies

Due to the inherent limitations and associated costs linked with traditional motion capture laboratories other solutions to carry out gait assessments accurately, cost effectively, user friendly and more portably are required.

The employment of wearable devices has been brought forward (Beyond Optical Measurement | Vicon, n.d.). Wearable sensors offer benefits such as continuous motion data collection, which helps draw a clearer picture of patient recovery and may be used to flag cases where patients are not recovering optimally.

Moreover, through the active use of wearable technology, rehabilitation compliance may be improved by prompting patients to complete protocols through remote monitoring mechanisms, which may aid patient motivation.

Therefore, wearable technologies may offer the potential to perform gait analysis more accessibly, with the same accuracy as motion capture. However, has the ability to capture data across the entire recovery period at a higher granularity than previously available.

2.6.5 Conclusions

Currently, 3D gait analysis is the most effective method for collecting kinematic and kinetic data to assess patient functional outcomes. Gait analysis in a clinical environment has the potential to accurately diagnose gait pathologies and track recovery progress following surgery such as TKA. Although gait analysis offers significant advantages, such as being non-invasive, accurate, and reliable, its high cost and complexity have limited its routine use in clinical settings (Prajapati et al., 2021; Sutherland, 2002). Hence wearable technologies have emerged as a promising solution in both research and clinical settings (Carse et al., 2013; Prajapati et al., 2021; Robinson and Smidt, 1981).

2.7 Why Conventions Need to Change

This thesis has outlined the importance of rehabilitation programs in achieving optimal postoperative outcomes and avoiding revision surgery; however, their effectiveness and delivery varies widely (Alrawashdeh et al., 2021; Artz et al., 2015; Bade and Stevens-Lapsley, 2011; Bandholm, Wainwright, and Kehlet, 2018; Konnyu, et al., 2023; Sattler et al., 2020).

As hospital stays shorten and both inpatient and outpatient rehabilitation options become increasingly constrained by high costs and limited resources (Hamilton et al., 2020; Smith et al., 2020), there is a growing need for alternative rehabilitation approaches (Vermeire et al., 2001).

Current rehabilitation models face limitations such as restricted session frequency, delayed rehabilitation progression, and a lack of personalisation as a result of generalised protocols, largely as a direct result of these constraints. Outpatient physiotherapy for TKA costs the NHS approximately £2,182 per patient annually (Capelas et al., 2022). The healthcare system's stressed resources, compounded by reduced hospital stays highlights the need for alternative, more efficient postoperative care and rehabilitation strategies (Mahomed et al., 2008).

A significant concern to healthcare practitioners is the low patient compliance with prescribed rehabilitation. Research reports that up to 76% of patients do not adhere to their rehabilitation regimens, which results in reduced postoperative outcomes (Bahadori et al., 2018).

Monitoring progress is essential, as the effectiveness of rehabilitation is contingent upon patient adherence to prescribed protocols. Non-compliance can lead to increased costs due to avoidable morbidity, hospital admissions, prolonged stays, and potentially unnecessary revision surgeries (Campbell et al., 2001). Patients may also experience poor functional outcomes and persistent pain due to inadequate adherence (Bakaa et al., 2021). Given that 5 - 20% of patients report chronic pain postoperatively (Gan, 2017; Wylde et al., 2017) improving rehabilitation uptake remains a significant challenge.

Currently, rehabilitation after TKA primarily depends on outpatient therapy and self-motivated exercise routines (Chen, Li and Lin, 2016), rather than extended hospital stays and increased clinician contact.

Home-based, self-directed rehabilitation has emerged as a cost-effective alternative, aimed at improving functional outcomes and early detection of joint abnormalities. However, the success of home-based rehabilitation is highly dependent on patient compliance (Chen, Li and Lin, 2016) and motivation. Literature suggests that adherence to unsupervised home rehabilitation can be enhanced by making exercise programs more engaging and interactive, and by providing feedback (Campbell et al., 2001).

Patients generally comply more closely to prescribed rehabilitation programmes when they feel supported by healthcare providers or peers (Chughtai et al., 2019; Li et al., 2017). Additionally, visual and dynamic feedback of patient improvement contributes to a more enjoyable rehabilitation experience, helping to motivate patients to complete their necessary rehabilitation exercises.

2.7.1 Limitations of Current Rehabilitation Modes

Rehabilitation following TKA presents several challenges due to both patient-related and systemic factors. Patient-related limitations include non-compliance, health issues such as pain, and insufficient education (Dorr et al., 2007). Systemic constraints involve high costs associated with ongoing care and difficulties monitoring post-discharge progress, labour demands, resource shortages, and gaps in knowledge (Buhagiar et al., 2019; Kornuijt et al., 2019).

One significant challenge that has been highlighted throughout literature is the variability in rehabilitation techniques and protocols across different healthcare practices. The optimal rehabilitation strategy for post-TKA recovery is not yet well-defined and may vary for each patient (Hamilton et al., 2020). The absence of standardised guidelines leads to inconsistent exercise intensities, durations, and techniques, complicating the determination of effective protocols and potentially affecting patient outcomes (Bakaa et al., 2021).

In addition to the variability in rehabilitation methods, there has been no correlations between the length of hospital stay and functional outcome scores (Dorr et al., 2007), although minimally invasive surgeries are linked to shorter hospital stays, while more traditional methods are associated with longer hospital stays (Dorr et al., 2007; Ogonda et al., 2005).

In the USA, postoperative rehabilitation programs typically involve extended inpatient care, whereas as described previously, in the UK, inpatient rehabilitation is brief, often lasting only 3 - 5 days, with some patients being discharged on the same day as their procedure.

A meta-analysis conducted by Hamilton et al. (2020) consisting of a multicentre, parallel-group randomised controlled trial across 13 secondary and tertiary care centres in the UK, with a total of 334 participants. Their study aimed to evaluate whether a structured course of outpatient physiotherapy offered superior outcomes compared to a single physiotherapy review followed by at home exercise regimens in patients identified as at risk of poor outcomes following TKA (defined as an Oxford knee joint score of ≤ 26). The physiotherapy led participants received 18 sessions of rehabilitation over six weeks which incorporated progressive, goal-oriented, and functional rehabilitation, with weekly modifications based on individual progress. Each session involved one-on-one contact with a physiotherapist, focusing on exercises to improve strength, ROM and functional mobility. While the home-based rehabilitation group were provided with a structured home exercise program, including written instructions and guidance on exercises to perform independently. No further supervised physiotherapy sessions were scheduled, following their initial review session.

No significant differences were observed between the two groups in terms of pain, function, satisfaction, or performance-based functional tests at any time point. The study concluded that, among patients identified as at risk of poor outcomes after TKA, a structured course of outpatient physiotherapy did not result in clinically meaningful improvements compared to a single physiotherapy review followed by a home exercise program. These findings suggest that intensive supervised rehabilitation may not be necessary for all patients, and resources could be better allocated by targeting interventions to those who would benefit most (Hamilton et al., 2020).

Similarly, a study comparing home-based and outpatient rehabilitation found no significant differences in patient outcomes, depending on the location of where rehabilitation takes place (Han et al., 2015).

Another study (Rajan et al., 2004) sought to evaluate traditional outpatient rehabilitation with unmonitored home-based rehabilitation exercise programs. The study compared 120 patients that were divided into two groups, one receiving standard postoperative care with a home-based rehabilitation exercise program and another receiving additional outpatient physiotherapy sessions. All participants were provided with a home exercise program upon discharge. The intervention group received additional outpatient physiotherapy sessions, typically ranging from 4 to 6 sessions, focusing on functional exercises and mobility training. Whereas the control group did not receive any organised outpatient physiotherapy beyond the initial home-based rehabilitation exercise instructions. This study (Rajan et al., 2004) found no significant differences in knee ROM measured 3, 6 and 12 months postoperatively between the two rehabilitation approaches. Further supporting the notion that a well-structured inpatient physiotherapy programme, coupled with clear home exercise instructions, may suffice for many patients recovering from TKA. Emphasising the importance of individualised patient assessment to determine the need for additional outpatient physiotherapy, potentially leading to more efficient use of healthcare resources without compromising patient outcomes.

While a randomised trial (Mahomed et al., 2008) aiming to compare the effectiveness and cost-efficiency of inpatient rehabilitation versus home-based rehabilitation following primary TKA also reported no significant differences in pain levels, physical function and patient satisfaction at 3 months after surgery when comparing inpatient rehabilitation and those completing home-based rehabilitation. Moreover, similar numbers of postoperative complications up to twelve months postoperatively in both groups were reported (Mahomed et al., 2008). A total of 234 patients were randomised into two groups: one receiving inpatient rehabilitation and the other receiving home-based rehabilitation. All participants followed standardised care pathways and were evaluated using validated outcome measures, including patient satisfaction surveys. Assessments were conducted preoperatively and at three and twelve months postoperatively. Mahomed et al. (2008) recommend home-based rehabilitation following joint replacement, highlighting it as a more cost-effective approach compared to inpatient rehabilitation, especially in healthcare systems aiming to optimise resource utilisation without compromising patient outcomes.

Despite these findings, it remains common practice for patients to undergo 6 to 8 weeks of hospital-based rehabilitation following TKA (Han et al., 2015), with the specific exercises prescribed varying depending on healthcare therapist, location and patient. However, this approach to rehabilitation is under scrutiny and whether this length of treatment can feasibly be provided is debated.

2.7.1.1 Improving Postoperative Outcomes Through Rehabilitation Delivery

Rehabilitation faces several challenges. Yet it is well-established that adherence to prescribed rehabilitation programs significantly enhances patient recovery (Glitsch et al., 2022), leading to improved outcomes, including faster recovery, reduced overall operational costs (Papalia et al., 2013) and higher patient satisfaction scores (Bakaa et al., 2021; Campbell et al., 2001; Chakrabarti, 2014; Frost et al., 2017; Petursdottir, Arnadottir and Halldorsdottir, 2010; Van Gool et al., 2005).

Remaining on top of patient improvements and recovery is highly laborious and cost intensive and thus developing a remote method to maintain patient assessment, surveillance and rehabilitation is of benefit to all stakeholders (Buhagiar et al., 2017; Cooper, Bhuskute and Walsh, 2022; Hamilton, 2015).

A highly involved knee rehabilitation program allows patients to re-establish normal functionality of the knee joint, enabling full ROM and better recovery outcomes (Naylor et al., 2012). This is predominantly achieved by continuous surveillance and data collection of the postoperative knee. The necessity for constant data collection enables the therapist to control and adapt the recovery conditions as required by the individual patient, allowing for positive, progressive rehabilitation outcomes in line with patient improvements.

2.7.2 Conclusions

Emerging technologies are increasingly playing a crucial role in supporting remote rehabilitation, enhancing patient rehabilitation compliance and outcomes. Innovations such as wearable devices, mobile apps, and telehealth platforms enable continuous monitoring, real-time feedback, and offer personalised guidance, making it easier for patients to follow rehabilitation programmes at home. By improving accessibility and engagement, these technologies aim to increase adherence rates and enhance overall rehabilitation outcomes, contributing to the success of TKA.

2.8 Wearable Technologies Offering a Solution

Implementing remote monitoring for home-based therapy offers significant benefits to the public healthcare sector. This approach aims to assess patients' physical functionality and mobility after TKA, both objectively and qualitatively (Kayaalp et al., 2019) by reducing the reliance on in-person resources and facilitating the early detection of abnormalities during recovery.

Wearable devices, used as a tool in telerehabilitation, may offer continuous patient monitoring and regular progress reviews, including exercise intensity, frequency, and overall satisfaction. This dynamic feedback allows rehabilitation protocols to be updated in line with recovery improvements, enhancing the effectiveness of the rehabilitation process (Kayaalp et al., 2019).

Moreover, such devices have the potential to replace bulky and expensive motion capture laboratories traditionally used for gait analysis and assessment. These technologies offer dual functionality by enabling rehabilitation monitoring and tracking patient compliance, while also providing continuous data for gait and movement analysis throughout the patient's recovery journey.

2.8.1 Wearable Technologies: An Introduction to IMUs

Inertial Measurement Units (IMUs) are commonly used wearable devices for assessing human biomechanics (Fong and Chan, 2010; Parrington et al., 2021). These systems typically consist of three components: a gyroscope, an accelerometer, and a magnetometer (Beravs et al., 2011). IMUs are valued for their affordability, lightweight design, versatility, and ease of use. They also facilitate motion analysis out with a movement analysis laboratory enabling more natural and realistic movement patterns to be analysed.

2.8.1.1 How Do IMUs Work?

To capture motion in three dimensions, accelerometers and gyroscopes are typically configured in triads and mounted perpendicularly to one another on a segment. Adding magnetometers can enhance the accuracy of dynamic orientation calculations, particularly for determining heading or yaw (Seel, Raisch and Schauer, 2014).

Gyroscopes measure angular velocity, which allows the calculation of changes in orientation through integration over time. However, gyroscopes are prone to drift errors due to cumulative integration inaccuracies. Accelerometers measure linear acceleration, including the effects of gravity, which can be used to estimate pitch and roll orientation but are unable to measure rotational movements directly. Magnetometers detect the Earth's magnetic field, aiding in determining the orientation relative to magnetic north and correcting gyroscope drift. Together, these sensors combine data using sensor fusion algorithms, such as Kalman filters or complementary filters, to provide accurate and reliable measurements of orientation.

Studies have demonstrated good accuracy of IMU-based systems when compared to gold standard motion capture systems, though reliability varies depending on the task and the precise positioning of the devices (Al-Amri et al., 2018; Beravs et al., 2011; Fong and Chan, 2010).

Various algorithms can be employed to determining joint angles using IMUs (Seel, Raisch and Schauer, 2014). Quaternion-based orientation estimation algorithms, such as the Madgwick filter (Madgwick, 2010), have proven effective, with numerous studies confirming their utility (Madgwick, 2010, 2019; Narváez, Árbito and Proaño, 2018; Tadano, Takeda and Miyagawa, 2013). Additionally, Euclidean methods have demonstrated high accuracy in similar applications (Nwaizu et al., 2016).

More robust algorithms utilising advanced sensor fusion techniques can further improve accuracy in IMU kinematic measurement. For example, an algorithm proposed by Seel and colleagues (Seel, Raisch and Schauer, 2014) reduces the dependence on precise device positioning, minimising the human component of error (Laidig, Schauer and Seel, 2017; Seel, Raisch and Schauer, 2014).

2.8.1.2 Challenges of Using IMUs in Biomechanical Settings

Employing IMUs to monitor gait presents various technical and implementation challenges (Antunes et al., 2021; Tunca et al., 2017). These challenges include hardware and software limitations, as well as broader issues related to integration within healthcare networks and data sharing protocols.

2.8.1.3 Technical Concerns and Mitigation Measures

Despite their advantages, several practical concerns hinder the uptake of IMU devices as summarised in Table 2-2. The most prominent issue relates to the calibration or leg registration of these sensors, which is critical for accurate and reliable collection of joint kinematic data (Antunes et al., 2021).

Leg registration ensures that the sensors are properly aligned with a patient's leg (Ajdaroski et al., 2020; McGrath, Fineman and Stirling, 2018). Misalignment with the leg's anatomical axis introduces bias into joint angle measurements, compromising data accuracy (Ajdaroski et al., 2020; McGrath, Fineman and Stirling, 2018). Therefore, incorporating robust calibration processes is essential to ensure a true representation of patient motion.

IMUs are also susceptible to errors, particularly drift in accelerometers and gyroscopes (Pasquet et al., 2016; Tao et al., 2012; Tunca et al., 2017). Over time, small measurement inaccuracies accumulate, resulting in significant deviations from the actual movement. This issue is especially problematic in long-duration gait analyses. To mitigate drift, filtering and calibration algorithms are commonly employed (Chiang et al., 2017).

Another common challenge is noise during dynamic movements, which necessitates the use of low-pass filters to eliminate high-frequency components from the data (Tunca et al., 2017). However, distinguishing between noise and meaningful data, particularly in individuals with mobility disorders, remains a significant challenge. Selecting appropriate filtering techniques is therefore critical for accurate data interpretation (Zhou et al., 2020).

Table 2-2. Challenges associated with IMU devices (Mohd et al., 2018; Sabatini, 2006; Silva, Paiva and Carvalho, 2021; Tunca et al., 2017, Wittmann, Lambercy, and Gassert, 2019).

Component	**Challenge**	**Description**
Magnetometer	Magnetic distortion	Magnetometers are highly sensitive to magnetic interference from nearby objects, electronic devices, or environmental factors. This can lead to inaccurate readings.
	Drift	Over time, magnetometers can experience drift, where the reference magnetic north shifts, affecting long-term accuracy.
	Dependency on Earth's magnetic field	They rely on the Earth's magnetic field, which can be inconsistent indoors or in environments with significant magnetic interference.
Accelerometer	Sensitivity to external accelerations	Accelerometers measure both gravitational and linear accelerations. External forces (e.g., sudden movements, vibrations) can cause noisy data, making it difficult to isolate the gravitational component needed for accurate angle calculations.
	Rapid changes in acceleration	They are excellent at detecting orientation when the system is stationary but less accurate during dynamic conditions due to the influence of linear accelerations.
	Noise	High-frequency noise can affect the precision of the measurements, requiring filtering techniques to smooth out the data.

Gyroscope	Drifting over time	Gyroscopes are prone to integration drift, where small errors accumulate over time, leading to significant inaccuracies in angle measurements if used alone.
	Bias instability	Changes in temperature and other environmental factors can affect the bias of the gyroscope, leading to further inaccuracies.
	Noise	Gyroscopes also suffer from noise, which can complicate accurate angle measurements.

Although IMU devices face several challenges, solutions exist to address these difficulties. For instance, combining gyroscopes and accelerometers leverages the short-term precision of gyroscopes and the long-term stability of accelerometers. This integration mitigates the individual shortcomings of each sensor, providing a more accurate, stable and reliable representation of joint angles in motion tracking (Seel, Raisch and Schauer, 2014).

2.8.1.4 Implementation Barriers within the Healthcare System

The use of wearable technologies presents several technical challenges, as well as additional difficulties related to their implementation within healthcare facilities. These issues arise from both the structure of the healthcare system and the limitations of current solutions (Lewy, 2014).

The current model of care is fragmented, with different providers (hospitals, GPs, physiotherapists, etc.) accessing isolated data sets. This lack of data integration prevents a comprehensive view of patient health and complicates the use of wearable devices, which generate large volumes of data that cannot be easily shared across different systems and to various stakeholders (Lewy, 2014).

Currently, wearable technologies remain largely in the pilot phase, and there is still uncertainty about how best to incorporate them into healthcare workflows (Raghupathi and Raghupathi, 2014). Successful adoption requires the validation of data generated by these devices, along with the development of tools that are user-friendly and that seamlessly integrate into existing systems. Furthermore, managing the significant volumes of data produced by wearables, while maintaining security and privacy, is critical.

For wearable technologies to be fully incorporated into healthcare, changes in care delivery models, data-sharing processes, and collaboration between providers and patients are necessary. Addressing challenges related to data standardisation, privacy, security, and workflow integration is essential to ensure that wearables enhance patient care and achieve widespread adoption.

2.8.1.5 *Wired versus Wireless IMU Systems*

As IMU devices are emerging within healthcare and research settings, debates regarding the accuracy, validity and reliability of their measurements are prevalent (Cho et al., 2018). While wireless technologies offer a number of advantages such as unrestricted mobility compared to wired technologies, wired IMU systems are often considered more accurate and reliable for biomechanical assessments (Franček et al., 2023). This is particularly relevant in controlled environments where data accuracy, reliability, and synchronisation are paramount (Boutaayamou et al., 2025; Cutti et al., 2008; Franček et al., 2023; Hester et al., 2018; Lebel et al., 2017).

Wireless IMU systems are commonly associated with wireless data transmission, which can result in challenges such as latency, packet loss, synchronisation difficulties and signal interference (Calvo et al., 2020; Franček et al., 2023; Hester et al., 2018).

Previous research (Boutaayamou et al., 2025; Cutti et al., 2008; Lebel et al., 2017) comparing the accuracy of wired systems have found measurements captured from wired devices to demonstrate considerable accuracy, highly correlated angle data and absolute magnitude revealing likeness to the opto-electronic gold standard, Vicon motion capture system (Cutti et al., 2008). While other researchers (Lebel et al., 2017) revealed that wired IMU devices present accurate angle measurements, however, the accuracy varies depending on the activity performed.

The inclusion of wired devices over wireless sensors is further emphasised due to their ability to ensure continuous data flow to acquisition systems, minimise transmission delays and loss, and provide high repeatability, as well as stable power and signal transmission (Calvo et al., 2020). This direct connection ensures high-fidelity data capture (Boutaayamou et al., 2025; Cutti et al., 2008; Franček et al., 2023; Hester et al., 2018; Lebel et al., 2017). Moreover, in multi-sensor setups, time synchronisation is a critical factor. Wired connections enable precise timing between devices, ensuring coherent and synchronised data streams.

While wireless IMU systems offer greater freedom of movement and ease of setup, wired IMUs provide superior accuracy and reliability in measuring joint angles, making them preferable in controlled environments where data precision is important.

2.8.2 MotionSense™ a Commercial Sensor to Monitor TKA Recovery

EnMovi Ltd, a subsidiary of Stryker Ltd is an enterprise which focuses on wearable sensor technology and patient data capture through an application, MotionSense™. MotionSense™ is a downloadable mobile application which invites patients to engage with their rehabilitation programs and monitor their recovery progress.

Following TKA surgery, two wearable IMU sensors are attached to the lower limb. One sensor is positioned above, and one sensor is positioned below the knee joint, toward the lateral side of the leg. These sensors continuously communicate with the mobile application via Bluetooth, collecting data throughout the duration the patient wears the devices.

These sensors sample data at 50Hz, which is processed through a Madgwick filter to calculate knee angle. This calculation is based on measuring the angle between the femur and the tibia, as illustrated in Figure 2-9. The collected data can be transmitted to healthcare providers, enabling them to maintain high-quality treatments and improved clinical outcomes.

This technology supports the perioperative patient journey, as the sensors can capture data both preoperatively and postoperatively, allowing clinicians to observe noticeable improvements over time. During the rehabilitation phase, the application provides additional support through daily pain journals, personalised home exercise routines, and notifications. These features ensure that both the patient and their healthcare team remain informed about recovery progress and rehabilitation milestones.

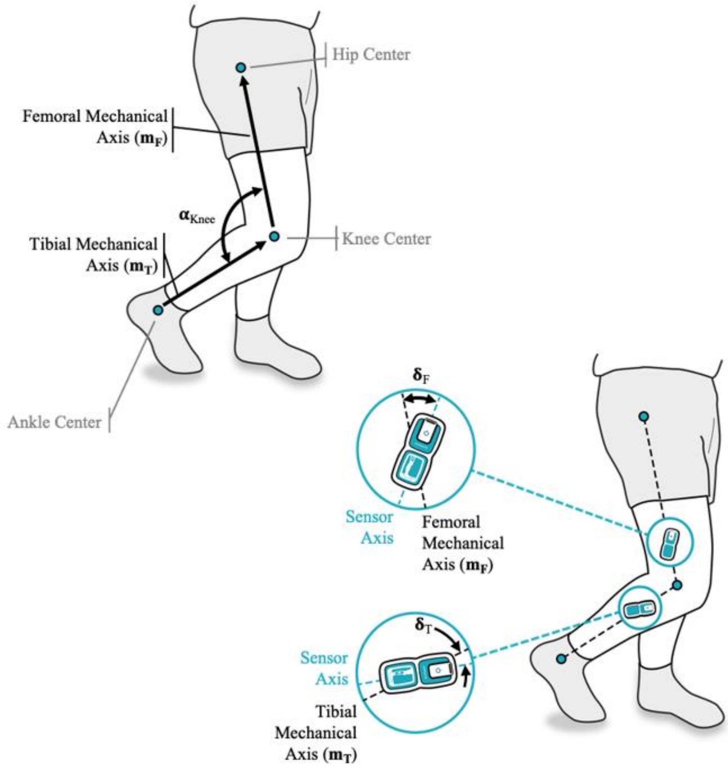


Figure 2-9. MotionSense™ wearable technology attached to the thigh and shank.

2.8.3 Conclusions

Wearable devices, such as IMU sensors, hold significant potential as tools for monitoring rehabilitation compliance in home environments and tracking patient recovery. While these technologies face technical and implementation challenges, their potential benefits, including improved patient engagement and data-driven care, outweigh their limitations.

Although many commercially available devices exist, their suitability for clinical use remains a topic of debate. However, these technologies could play a pivotal role in enhancing healthcare delivery by supporting home-based rehabilitation, improving compliance, and achieving better functional outcomes. To ensure successful implementation, it is essential to evaluate the advantages and disadvantages of different rehabilitation models and address the challenges associated with integrating new technologies into clinical workflows.

2.9 Comparison of Different Rehabilitation Modalities

The previous sections have highlighted the critical role of rehabilitation in improving patient outcomes following surgery. However, there is clear lack of standardisation in rehabilitation practices and limited understanding of which rehabilitation modalities yield the best outcomes, reduce the risk of complications and joint failures (Konnyu et al., 2023; Wylde et al., 2018).

It is therefore essential to evaluate the effectiveness of various rehabilitation methods, understand the components of each approach, and consider their associated costs without compromising patient outcomes (Bandholm, Wainwright, and Kehlet 2018; Han et al., 2015; Konnyu et al., 2023; Moffet et al., 2015; Omari et al., 2021; Wylde et al., 2018).

Rehabilitation can be delivered through several approaches, Table 2-3 below summarises the most common methods and provides a comparison of these modalities.

Table 2-3. Descriptions of common rehabilitation modalities.

Rehabilitation Method	Setting	Supervision	Personalisation	Accessibility	Costs	Support and Motivation	Compliance
Hospital based	Rehabilitation takes place in outpatient or inpatient settings within a hospital or clinic.	Close supervision by healthcare professionals with immediate access to medical assistance if needed.	No universally adopted rehabilitation protocol, thus treatment plans may differ depending on clinician and location.	Accessibility depends on the proximity to healthcare facilities and transportation.	Costs may vary depending on insurance coverage and length of stay. High costs for healthcare system.	Limited social interaction during individual sessions, but potential for peer support in group settings.	Higher likelihood of adherence due to regular monitoring and supervision from clinicians.
Group based	Rehabilitation occurs in a group setting with multiple patients and a therapist.	Supervision shared among therapists for multiple patients simultaneously.	Exercises and activities may be less tailored to individual needs due to group dynamics.	Accessibility depends on the availability and location of group sessions.	Cost-effective by maximising therapist time and resources among multiple patients.	Provides social support, motivation, and peer learning opportunities. A support network is developed.	Peer support and social dynamics may enhance adherence.

Face-to- face	Patients interact directly with therapists in a clinic or hospital setting.	Direct supervision and immediate feedback provided by therapists.	Highly personalised interventions based on direct assessment and ongoing evaluation.	Accessibility may be hindered by travel time and scheduling conflicts.	Costs may include transportation and potential time off from work. Higher costs involved due to increased time and resources.	Direct interaction with therapists enhances motivation, potential for peer support in group settings.	Supervision enhances adherence, but external factors such as scheduling may impact compliance.
Home based	Rehabilitation is conducted in the patient's home environment.	Limited supervision, usually periodic visits by a therapist or remote monitoring.	Potential for personalised care and exercises tailored to individual needs, but often a stock rehabilitation protocol is prescribed.	Convenient for patients, eliminates travel time and transportation issues. Easy for therapists as travel and contact time is eliminated.	May reduce healthcare costs by eliminating the need for hospital visits.	Limited social interaction, potentially impacting motivation.	Adherence may be variable due to limited supervision.

Movement Analysis Laboratory	Patients interact directly with therapists in a clinic or hospital setting, and the session is evaluated through motion capture.	Direct supervision and delayed feedback regarding kinematics are provided by computer software.	Progress is monitored accurately and quantifiably. Rehabilitation can be altered depending on progress measured.	Not accessible, highly time consuming and expensive to run. Limited to one patient per session and often limited sessions available.	Huge expense associated with labour, equipment and time.	Limited social interaction,	Higher likelihood of adherence due to accurate monitoring and supervision from clinicians.
Remote tele-rehabilitation through wearable devices	Rehabilitation is delivered remotely, typically through telehealth platforms or mobile applications.	Supervision provided through video conferencing or remote monitoring tools.	Tailored rehabilitation programs adjusted based on remote assessment and feedback.	Offers accessibility to patients in remote areas, eliminates the need for travel.	Can be cost-effective by reducing the need for hospital visits and transportation.	Limited social interaction, although family members can provide support, and group sessions may be programmed/ interactions with therapist via a mobile application.	Adherence may be influenced by technological barriers and patient motivation; however, reduced rehabilitation may be flagged through remote monitoring and this information can be fed back to the healthcare team to then step in.

Many studies have compared different rehabilitative techniques to identify the most effective methods for delivering patient care and achieving optimal functional outcomes (Argent, Daly and Caulfield, 2018; Bakaa et al., 2021; Bandholm, Wainwright, and Kehlet, 2018; Castrodad et al., 2019; Hamilton et al., 2020; Han et al., 2015; Konnyu et al., 2023; Li et al., 2017; López-Liria et al., 2015; Mahomed et al., 2008; Mistry et al., 2016; Moffet et al., 2015; Proffitt and Lange, 2015; Rajan et al., 2004; Wylde et al., 2018). These studies have examined various approaches to rehabilitation such as traditional physiotherapy, tele-rehabilitation, and home-based rehabilitation, assessing their impact on functional outcomes, biomechanics, completion of ADLs, PROM's, and healthcare utilisation.

A recent review (Konnyu et al., 2023) evaluated the effectiveness of various rehabilitative approaches, including standard physiotherapy, tele-rehabilitation, and home-based rehabilitation. These findings indicated that all approaches yielded improvements during the acute recovery phase and contributed to pain reduction. However, no single method consistently emerged as superior compared to the others. Importantly, the review suggested that while rehabilitation interventions are crucial after TKA, the specific modality may not significantly influence overall patient outcomes.

These findings align with other studies. For instance, Wylde and colleagues (Wylde et al., 2018) explored the relationship between rehabilitation techniques and chronic pain management following TKA, finding no evidence that one method was more effective than another in reducing pain severity after surgery.

Tele-rehabilitation has garnered increasing attention as a potential alternative to conventional methods. Moffet and associates (Moffet et al., 2015) compared tele-rehabilitation, home-based, and face-to-face therapy, with all groups receiving identical interventions of the same duration and assessed at consistent post-surgical time points. Their study demonstrated that tele-rehabilitation was as effective as traditional in-home therapy, yielding comparable recovery outcomes.

Supporting the viability of alternative rehabilitation approaches, a different study (Chughtai et al., 2019) examined outcomes such as patient compliance, time spent completing rehabilitation, clinical scores, and system usability for a tele-rehabilitation system (VERA) in 18 TKA patients. This study reported significant improvements in all outcomes, reinforcing the potential of tele-rehabilitation to complement traditional methods within clinical settings.

While various rehabilitation approaches, including tele-rehabilitation, show similar outcomes, further research is needed to determine whether any method consistently offers superior long-term benefits to patients recovering after TKA. Nonetheless, the growing body of evidence supports the use of tele-rehabilitation as a flexible and effective alternative in post-TKA recovery (Alizadeh et al., 2023; Argent, Daly and Caulfield, 2018; Bullens et al., 2001; Chughtai et al., 2019; Kwasnicki et al., 2015; Lewy, 2014; Li et al., 2017; Proffitt and Lange, 2015; Rajan et al., 2004; Rowe et al., 2000; Salchow-Hömmen et al., 2022; Shukla et al., 2016; Torner et al., 2019; Van Gool et al., 2005; Wylde et al., 2018).

2.9.1 Conclusions

Rehabilitation is a critical phase in recovery, yet the method of delivery—whether in-person or remote—does not appear to significantly influence post-surgical outcomes (Han et al., 2015; Konnyu et al., 2023; Moffet et al., 2015; Sattler et al., 2020). However, evidence suggests that remote rehabilitation offers distinct advantages over traditional face-to-face methods, specifically in monitoring patient recovery after TKA. Among the various tele-rehabilitation approaches, wearable sensors are emerging as a leading option. While these devices show significant potential, further evaluation is required to ensure their successful implementation and widespread acceptance in clinical settings.

2.10 How to determine Knee Joint Angle

2.10.1 Angle Calculation Using Motion Capture

The previous sections discussed the application of models in motion capture systems to support kinematic calculations and facilitate gait analysis.

As outlined in section 2.6.1, the PIG model uses reflective markers placed on specific anatomical landmarks to calculate knee flexion and extension angles through Euler angle decomposition (Figure 2-10). These angles are easily interpreted and can be used to monitor knee joint ROM and track changes during recovery. A common method to determine joint centres is the Vaughan and Davis technique (Vaughan, Davis and O'Connor, 1992) which uses external anatomical landmarks and anthropometric regression equations.

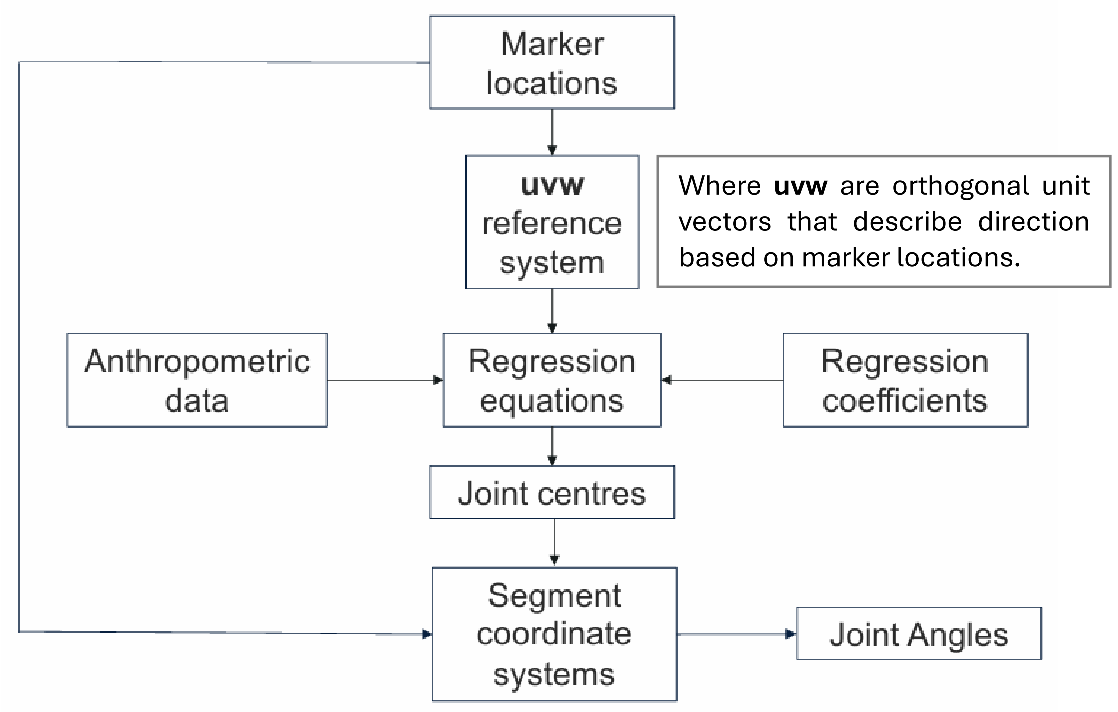


Figure 2-10. Flowchart describing process of determining joint angles from marker positions.

The markers are grouped in such a way as to define body segments and joint centres (Vaughan, Davis and O'Connor, 1992). The hip joint is not directly measured with markers but rather is estimated based on the locations of the Anterior Superior Iliac Spines (ASIS) and Posterior Superior Iliac Spines (PSIS). To determine the hip joint centre the following equation is used:

Equation 1

$$X_{HJC} = X_{ASIS} + \lambda . pelvis\ width$$

$$Y_{HJC} = Y_{ASIS} + \mu . leg\ length$$

$$Z_{HJC} = Z_{ASIS} + \nu . leg\ length$$

Where pelvis width is the distance between the ASIS markers, leg length is the distance from ASIS to lateral malleolus and λ, μ, ν are subject specific regression coefficients.

The knee joint centre is found by determining the midpoint between the medial and lateral epicondyles:

Equation 2

$$KJC = \frac{Lateral\ Epicondyle + Medial\ Epicondyle}{2}$$

Since medial knee markers are often omitted in practical gait analysis, an estimate can be made using the lateral epicondyle and tibial width.

The ankle joint centre is determined as the midpoint between the medial and lateral malleoli and is described by the equation below.

Equation 3

$$AJC = \frac{Lateral\ Malleolus + Medial\ Malleolus}{2}$$

The thigh segment is defined by the hip and knee marker, the shank segment consists of the knee and ankle marker, while the knee joint centre is calculated by considering the position of the marker on the femoral epicondyle and the calibration pose captured during data collection. Any marker malpositioning can have a significant effect on accuracy, as highlighted in previous sections.

Once the body segments have been defined, the coordinate systems are established. Local coordinate systems are defined for each segment respectively by Equation 7. These coordinate systems are based on the anatomical markers and are used to define the orientation of each segment; therefore, the thigh coordinate system will differ to that of the shank (Vaughan, Davis and O'Connor, 1992).

The pelvis coordinate system is defined using both the ASIS and PSIS markers, where:

Equation 4

$$i_{pelvis} = \frac{ASIS_{right} - ASIS_{left}}{|ASIS_{right} - ASIS_{left}|}$$

$$k_{pelvis} = \frac{Midpoint(PSIS) - Midpoint(ASIS)}{|Midpoint(PSIS) - Midpoint(ASIS)|}$$

Where $midpoint\ P/ASIS = \frac{P/ASIS_{right} - P/ASIS_{left}}{2}$

$$j_{\ pelvis} = k_{pelvis} \times i_{pelvis}$$

The thigh coordinate system is defined using the hip joint centre, the knee joint centre and the lateral epicondyle.

Equation 5

$$k_{thigh} = \frac{HJC - KJC}{|HJC - KJC|}$$

$$i_{thigh} = \frac{Lateral\ Epicondyle - KJC}{|Lateral\ Epicondyle - KJC|}$$

$$j_{\ thigh} = k_{thigh} \times i_{thigh}$$

Finally, the shank coordinate system is defined using the knee joint centre, the ankle joint centre and the lateral malleolus.

Equation 6

$$k_{shank} = \frac{KJC - AJC}{|KJC - AJC|}$$

$$i_{shank} = \frac{Lateral\ Malleolus - AJC}{|Lateral\ Malleolus - AJC|}$$

$$j_{\ shank} = k_{shank} \times i_{shank}$$

Once these coordinate systems have been defined, unit vectors are determined to yield Equation 8. The relative orientation of each segment is then calculated to determine the knee joint angle. This requires the calculation of a rotation matrix, R, which considers the rotation of the distal (shank) segment with respect to the proximal (thigh) segment, Equation 9

R is the rotation matrix equating the same position in a rotated set of axes, however, the inverse of the rotation matrix $[R]^{-1}$ is applied in order to rotate the unit vectors within a single global set of axes (Equation 10 and Equation 11).

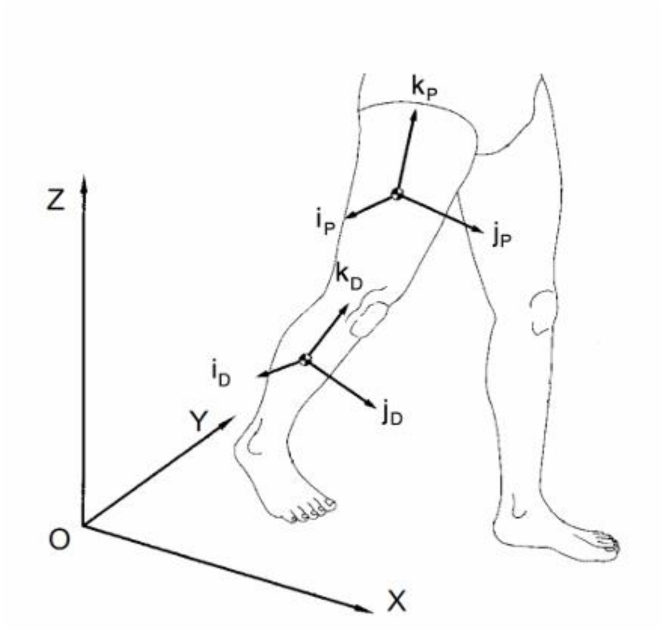


Figure 2-11. Coordinate systems, showing both anatomical segment and global coordinate systems.

Equation 7

$$i_p = \begin{pmatrix} i_{xP} \\ i_{yP} \\ i_{zP} \end{pmatrix} \quad j_p = \begin{pmatrix} j_{xP} \\ j_{yP} \\ j_{zP} \end{pmatrix} \quad k_p = \begin{pmatrix} k_{xP} \\ k_{yP} \\ k_{zP} \end{pmatrix}$$

Equation 8

$$[P] = \begin{bmatrix} i_{xP} & j_{xP} & k_{xP} \\ i_{yP} & j_{yP} & k_{yP} \\ i_{zP} & j_{zP} & k_{zP} \end{bmatrix}, [D] = \begin{bmatrix} i_{xD} & j_{xD} & k_{xD} \\ i_{yD} & j_{yD} & k_{yD} \\ i_{zD} & j_{zD} & k_{zD} \end{bmatrix}$$

Where,

Equation 9

$$[D] = [R]^{-1}[P]$$

$$[D][P]^{-1} = [R]^{-1}[P][P]^{-1}$$

$$[D][P]^{-1} = [R]^{-1}$$

$$[R] = [D]^{-1}[P]$$

And because [D] is constructed of three orthogonal unit vectors [R] can be defined as:

Equation 10

$$[D]^{-1} = [D]^{T}$$

$$[R] = [D]^{T}[P]$$

Where [R] can be expanding to;

Equation 11

$$[R] = \begin{bmatrix} i_{xD} & j_{yD} & k_{zD} \\ i_{xD} & j_{yD} & k_{zD} \\ i_{xD} & j_{yD} & k_{zD} \end{bmatrix} \begin{bmatrix} i_{xP} & j_{xP} & k_{xP} \\ i_{yP} & j_{yP} & k_{yP} \\ i_{zP} & j_{zP} & k_{zP} \end{bmatrix},$$

Equation 12

$$\text{Therefore, } [R] = \begin{bmatrix} i_D \cdot i_P & i_D \cdot j_P & i_D \cdot k_P \\ j_D \cdot i_P & j_D \cdot j_P & j_D \cdot k_P \\ k_D \cdot i_P & k_D \cdot k_P & k_D \cdot k_P \end{bmatrix}$$

However, it is also established that the rotation matrix, [R] can be decomposed into three angles α, β, γ (Equation 13), which correspond to the rotations about the $i_{P,}$ $j_{P,}$ and $k_{P,}$ axes respectively, Figure 2-11.

Equation 13

$$[R] = \begin{bmatrix} cos\gamma cos\beta & sin\alpha sin\beta + cos\alpha sin\gamma & sin\alpha sin\gamma - cos\alpha sin\beta cos\gamma \\ -sin\gamma cos\beta & cos\alpha cos\gamma - sin\alpha sin\beta sin\gamma & sin\alpha cos\gamma + cos\alpha sin\beta sin\gamma \\ sin\beta & -sin\alpha cos\beta & cos\alpha cos\beta \end{bmatrix}$$

$$\alpha = rotation\ about\ i_{P,}\ Flexion/extenstion\ axis$$

$$\beta = rotation\ about\ j_{P,}\ Abduction/adduction\ axis$$

$$\gamma = rotation\ about\ k_{P,}\ internal/external\ rotation\ axis$$

By considering that:

Equation 14

$$sin\beta = k_D \cdot \ i_P$$

Therefore

$$\beta = sin^{-1}(k_D \cdot \ i_P)$$

And considering the trigonometric identities, angles may be determined through:

$$-\frac{sin\alpha cos\beta}{cos\alpha cos\beta} = -tan\alpha = \frac{k_D \cdot \ j_P}{k_D \cdot \ k_P}$$

$$-\frac{sin\gamma cos\beta}{cos\gamma cos\beta} = -tan\gamma = \frac{j_D \cdot \ i_P}{i_D \cdot \ i_P}$$

Thus yielding:

Equation 15

$$\alpha = tan^{-1}\left(\frac{-sin\alpha}{cos\alpha}\right) = -tan^{-1}\left(\frac{k_D \cdot \ j_P}{k_D \cdot \ k_P}\right)$$

Equation 16

$$\gamma = tan^{-1}\left(\frac{-sin\gamma}{cos\gamma}\right) = -tan^{-1}\left(\frac{j_D \cdot \ i_P}{i_D \cdot \ i_P}\right)$$

Although the PIG model automatically calculates joint angles using proprietary Nexus software, it is important to have a basic understanding of the methods used to determine these measurements. This knowledge becomes especially valuable in situations where models are not available, and manual calculation of joint angles are required.

2.10.2 Using IMUs to Monitor Knee Joint Biomechanics

As previously highlighted, IMU devices are increasingly being used to record and measure joint kinematics (Cooper et al., 2009; Mcgrath, 2021; Nüesch et al., 2017; Seel, Schauer and Raisch, 2012; Seel, Raisch and Schauer, 2014; Torino, 2021; Yi et al., 2021). However, since they only capture raw data such as angular velocity and linear acceleration, algorithms are required to process this data and derive meaningful outputs like joint angles (Seel, Raisch and Schauer, 2014).

Many commercial sensors incorporate built-in algorithms to determine the orientation of each sensor with respect to the global fixed coordinate system and to subsequently determine joint angles. The orientations can be represented in different mathematical forms, such as quaternions (which describe both rotation and orientation in 3D space), rotation matrices, or Euler angles (Brennan, et al., 2011). Regardless of the methods used, IMUs demonstrate good ability in measuring joint angles.

2.10.2.1 Research Methods for Determining Knee Angle from IMU Measures

Previous studies have used IMUs to measure joint angles across different activities, such as walking (Beravs et al., 2011; Ortigas Vásquez et al., 2023; Seel, Raisch and Schauer, 2014; Wang et al., 2022), both walking and running (Cooper et al., 2009; Gholami et al., 2020; Jakob et al., 2013), squats (Hindle et al., 2020; Jakob et al., 2013), lunges (Versteyhe et al., 2020) and a variety of common rehabilitation exercises (Lin and Kulić, 2012).

Though IMU's are commonly found in research, the combinations of sensor data may vary. Previous studies have used all three sensor components to determine joint angles (Beravs et al., 2011; Hindle et al., 2020), however, accelerometer and gyroscope data are more frequently used (Cooper et al., 2009; Jakob et al., 2013; Lin and Kulić, 2012; Mcgrath, 2021; Ortigas Vásquez et al., 2023; Seel, Raisch and Schauer, 2012; Versteyhe et al., 2020; Wang et al., 2022). Magnetometer readings are often disregarded because they can be significantly influenced by local magnetic fields (Laidig, Schauer and Seel, 2017; Ortigas Vásquez et al., 2023; Tognetti et al., 2015; Versteyhe et al., 2020), leading to drift and associated inaccuracies.

Although IMUs are widely used in various activities and across different studies, the methods of implementation can vary. Though, the core principles remain consistent, to measure knee flexion angles using IMUs, sensor information (accelerometer, gyroscope and magnetometer data) is combined through a process called sensor fusion. This process involves blending sensor data using various filtering techniques to produce accurate joint angle measurements. Several filtering techniques are commonly used to process data from IMUs, each with its own strengths and application:

Complementary filter (Seel, Schauer and Raisch, 2014): this filter fuses data from two sensors, an accelerometer and a gyroscope, by leveraging their complementary strengths. The accelerometer provides accurate low-frequency (long-term) data, while the gyroscope excels in high-frequency (short-term) data. By applying a low-pass filter to the accelerometer data and a high-pass filter to the gyroscope data, the complementary filter combines the information improving accuracy.

Madgwick filter (Madgwick, 2010): is an efficient orientation filter for IMUs. The Madgwick filter estimates device orientation using accelerometer, gyroscope, and magnetometer data. It is computationally lightweight, making it ideal for embedded systems with limited power. The filter uses a gradient descent method to minimise error between estimated and measured data, providing robust and accurate 3D orientation estimates.

Kalman filter (Cooper et al., 2009): is a recursive algorithm used to estimate the state of a dynamic system from noisy measurements. It combines predictions from the system's dynamics with sensor data to generate optimal estimates. This filter assumes a linear system model and is widely used in various applications requiring real-time state estimation.

The extended Kalman filter (EKF) (Sabatini, 2011): extends the standard Kalman filter to handle non-linear systems. It linearises the system and measurement models at each time step using the Jacobian matrix (partial derivatives), making it suitable for applications like robotics and navigation where non-linear dynamics are common.

The unscented Kalman filter (UKF) (Beravs et al., 2011; Hindle et al., 2020): is another extension of the Kalman filter (Cooper et al., 2009), designed for non-linear systems without the need for linearisation. It uses the unscented transform to generate "sigma points" that represent the distribution of possible states. These points are propagated through the system, and their weighted mean and covariance are used to update the state estimate. The UKF is often more accurate than the EKF, especially for systems with highly non-linear dynamics.

Rauch-Tung-Striebel smoother (RTS) *(Versteyhe et al., 2020)*: is a backward-pass algorithm that improves the state estimates produced by a Kalman filter (Cooper et al., 2009). While the Kalman filter provides real-time (forward) estimates, the RTS processes the data afterward to generate more accurate state estimates by considering the entire dataset.

Each of these filters and smoothers plays a crucial role in improving the accuracy and reliability of IMU data for various applications, especially in dynamic environments. In addition to sensor fusion techniques some studies use large datasets to implement machine learning techniques for joint angle estimation (Lim, Kim and Park, 2020; Renani et al., 2021). However, these data-driven approaches have their own limitations (Gholami et al., 2020). They require extensive and diverse datasets for training models and are susceptible to overfitting, which can hinder their ability to generalise effectively to new, unseen data.

Nazarahari and Rouhani, 2021 conducted an experimental comparative study of 36 sensor fusion algorithms, classifying them into two primary categories: deterministic-based methods, which included the Linear Complementary Filter and Nonlinear Complementary Filter and stochastic-based methods, including the Linear Kalman Filter, Extended Kalman Filter (EKF), Complementary Kalman Filter, Square-root

Unscented Kalman Filter, and Square-root Cubature Kalman Filter. Their findings indicated that, in scenarios where execution time is not a critical factor, the EKF developed by (Sabatini, 2011) delivered the most accurate results. However, when computational efficiency is prioritised, the Linear Complementary Filter proposed by Justa et al., 2020 provided the best performance, striking an effective balance between accuracy and processing speed.

While numerous algorithms are available for estimating knee joint angles from IMU data, this project employed the Seel algorithm (Seel, Schauer and Raisch, 2014) as part of an opportunistic collaboration rather than through an independent selection process. Notably, the Seel algorithm closely aligns with the method used by the MotionSense™ commercial IMU device, making it a practical and sensible choice for this study.

Sensor Fusion Techniques

- Sensor fusion involves combining data from multiple IMU sensors to improve the accuracy of orientation estimation. Common sensor fusion algorithms include:
- **Complementary Filter**: This combines high-frequency gyroscope data with low-frequency accelerometer data to estimate orientation.
- **Kalman Filter**: A more sophisticated method that models the system's dynamics and updates the state estimates using both the process model and measurement updates.
- **Madgwick Filter**: An efficient orientation filter algorithm that uses a gradient descent method to minimise the error between measured and estimated orientation.

Segment Orientation and Joint calculation

- Once the orientations of the thigh and shank segments are estimated using sensor fusion, the knee joint angle can be calculated as the relative orientation between these segments.
- **Quaternion-Based Method**: Quaternions are used to represent the orientation of each segment. The relative orientation is computed using quaternion algebra.
- $q\text{relative}=q\text{thigh}-1\otimes q\text{shank}$
- Here, $q$relative represents the relative orientation between the thigh and shank.
- **Rotation Matrix Method**: Rotation matrices derived from sensor fusion data can be used to compute the relative orientation. The relative rotation matrix is given by:
- $R\text{relative}=R\text{thigh}^{-1}\cdot R\text{shank}$
- Joint angles can then be extracted using Euler angle decomposition.

Euler angle calculation

- Euler angles are extracted from the relative orientation (quaternion or rotation matrix [R]) to determine knee flexion/extension angles. For instance, using the XYZ sequence.
- The flexion angle can be calculated as expanded upon previously or through quaternion to Euler angle conversion.

Kinematic constraints and biomechanical models

- In some methods, kinematic constraints and biomechanical models of the knee are used to improve angle estimation:
- **Two-Link Model**: The thigh and shank are modeled as rigid bodies linked at the knee joint, with constraints applied to limit the possible joint angles based on human anatomy.
- **Inverse Kinematics**: Using joint kinematics to solve for angles that satisfy both the segment orientations and biomechanical constraints.

Figure 2-12. Flowchart outlining the common methods used to determine joint angle

2.10.2.2 Challenges Associated with Using IMUs for Joint Calculation

Although there are many methods used to determine joint angles from IMUs, previous research (Favre et al., 2006; Liu et al., 2009) has reported that accuracy often varies due to the complexity and non-uniformity of the human body and not from the type of model implemented.

The knee has six DOF, while it primarily exhibits flexion and extension, the joint also allows for abduction/adduction and internal/external rotation (Stagni et al., 2005). However, to simplify analysis, the knee is often modelled as a perfect hinge joint, reducing the problem to just a single degree of freedom (Cordillet et al., 2019; Favre et al., 2006; Hu et al., 2021; Laidig, Schauer and Seel, 2017; Martori, 2013; Pacher et al., 2020; Schiefer et al., 2011; Seel, Schauer and Raisch, 2012; Yen and Radwin, 2000). However, this assumption can lead to reduced accuracy in the measurements.

While simplifying the joint model can make the analysis easier, additional challenges exist when using IMU devices. These challenges include difficulties with sensor orientation, misalignment between the IMU's local coordinate system and the body's anatomical axes, and other factors that can affect the accuracy and precision of the measurements. These issues must be carefully considered to ensure reliable results.

2.10.2.3 Solving Variability in IMUs Position on the Body

The most common challenge associated with using IMUs to analyse human motion is ensuring precise alignment between the IMUs' local coordinate axes and the body's anatomical axes. Researchers use various strategies to solve this issue, each with its own strengths and limitations.

Some research (Liu et al., 2009) assumes that the IMUs are mounted precisely along the joint line. This approach presumes perfect alignment between the sensors and the anatomical segments, with the sensor’s local coordinate frames collinear to the anatomical axes. While this method is simple, it often leads to reduced accuracy due to imperfect alignment. More realistic approaches account for the likelihood of misalignment between the sensors local coordinate system and the joint axis, incorporating adjustments to improve accuracy.

The positioning of the sensor relative to the joint axis and body segment can be determined manually (Picerno, Cereatti and Cappozzo, 2008). However, this approach tends to be time consuming and prone to inaccuracies. To address these challenges, alternative methods have been proposed, utilising various calibration poses and movements (Bonfiglio et al., 2024; Cereatti, Trojaniello and Croce, 2015; Cooper et al., 2009; El Fezazi et al., 2023; Favre et al., 2006; Fry et al., 2021; Gholami et al., 2020; Jakob et al., 2013; Laidig, Schauer and Seel, 2017; Laidig, Weygers and Seel, 2022; Lim, Kim and Park, 2020; Liu et al., 2009; Mcgrath, 2021; O'Donovan et al., 2007; Oliveira, Park and Barrance, 2023; Pacher et al., 2020; Rhudy et al., 2024; Savage, 1998; Takeda et al., 2009; Versteyhe et al., 2020).

A common approach is the use of static calibration poses, where participants stand still in a predefined posture for a short duration (Beravs et al., 2011; Cooper et al., 2009; Jakob et al., 2013; Wang et al., 2022). This allows the accelerometer to detect only the gravity vector, aiding in sensor alignment. Some studies also incorporate filtering algorithms to estimate the orientation of IMUs for static alignment (Beravs et al., 2011; Hindle et al., 2020).

Another widely adopted method is functional calibration, where participants perform specific movements prior to data collection (Cutti et al., 2010). These movements are designed to clearly identify the direction of motion within anatomical planes. However, the accuracy of this method depends on how closely the participant performs the movements. Precise identification of joint axes and close alignment of the IMU significantly enhances measurement quality.

In some cases, straps or boxes are used to secure the IMU to the body in predefined orientations (Niswander et al., 2020). More commonly, however, the IMU is placed in an arbitrary orientation on the leg, introducing additional computational challenges.

To overcome the limitations of predefined static or dynamic calibration protocols, alternative methods have been proposed that do not rely on standard poses. For example, Seel and colleagues (Seel, Schauer and Raisch, 2012; Seel, Raisch and Schauer, 2014) developed an innovative calibration approach, which was further refined in subsequent research (Laidig, Schauer and Seel, 2017; Laidig, Weygers and Seel, 2022; Ortigas Vásquez et al., 2023).

This method (Seel, Schauer, and Raisch 2014) eliminates the need for precise sensor-to-segment alignment, manual measurement of body segment lengths, and calibration poses. Additionally, it avoids reliance on magnetometers, which can be inaccurate in non-uniform magnetic fields. A related technique, principal component analysis, has also been employed in some studies (Carcreff et al., 2022) to accurately determine the direction of the sagittal plane.

Seel's dynamic calibration method (Seel, Schauer, and Raisch 2012; Seel, Raisch and Schauer, 2014) has been successfully applied in various studies to measure joint angles during activities such as level walking (Ortigas Vásquez et al., 2023; Seel, Raisch and Schauer, 2014), stair navigation (Ortigas Vásquez et al., 2023), sit to stand (Ortigas Vásquez et al., 2023) and lunges (Versteyhe et al., 2020).

Despite the challenges associated with IMU devices, numerous methods have been developed to enhance measurement accuracy. Among these, techniques that avoid complex calibration protocols are often preferred, with the Seel algorithm (Seel, Raisch and Schauer, 2012) commonly implemented.

2.10.3 Conclusions

Gait analysis plays a crucial role in both research and clinical settings, with knee angle serving as a key metric for evaluating functional outcomes following TKA. To perform effective gait analysis, meaningful data is essential. While various methods are available for collecting motion data, IMU devices have gained popularity due to their numerous advantages.

When using IMUs for gait analysis—particularly for monitoring knee angles—it is crucial to process and present the data in a meaningful way. Several techniques exist for calculating knee angles from IMU data, each with distinct strengths and limitations. Among these, the method proposed by Seel et al. (Seel, Raisch and Schauer, 2012), has drawn attention for its accuracy and ease of use. However, to ensure its reliability for clinical applications, such as monitoring activity and tracking recovery, this algorithm must be validated across a wide range of movements and diverse populations.

2.11 Validating Wearable Technologies

With the growing interest in IMU devices for monitoring biomechanics, assessing joint function, and supporting diagnostic processes, their implementation into healthcare has garnered significant attention. These devices have the potential to address some of the current challenges faced by healthcare systems and alleviate the strain on overburdened facilities.

Recent studies indicate that wearable sensing technology can enhance patient care (Chiang et al., 2017; Cooper, Bhuskute and Walsh, 2022; Kayaalp et al., 2019; Kobsar et al., 2020; Papi et al., 2015). For instance, IMUs can assist physiotherapists and orthopaedic surgeons in detecting movement pattern abnormalities, such as asymmetrical limb loading after anterior cruciate ligament reconstruction (ACLR) or measuring varus thrust in patients with KOA.

Despite their promise, there is limited research on the capabilities and limitations of IMUs, particularly in clinical settings (Taylor, Miller and Kaufman, 2017). To confidently deploy these devices in practice, it is crucial to establish their validity and reliability across various applications by comparing them against trusted and established gold standard measurement systems (Chapman, Moschetti, and Van Citters, 2021; Lavernia et al., 2008).

2.11.1 Previous Studies Validating Wearable Technologies

Previous studies have compared the accuracy of IMU measurements against motion capture systems (Ajdaroski et al., 2020; Al-Amri et al., 2018; Allseits et al., 2017; Beravs et al., 2011; Cho et al., 2018; El Fezazi et al., 2023; Ghattas and Jarvis, 2021; Jebeli et al., 2017; Jordan et al., 2021; Zhang et al., 2013; Kayaalp et al., 2019; Kobsar et al., 2020; Papi et al., 2015; Poitras et al., 2019; Robert-Lachaine et al., 2017; Shuai et al., 2022; Taylor, Miller and Kaufman, 2017; Zhou et al., 2020). These studies focused on evaluating the accuracy of lower leg joint kinematics, finding that IMU wearables could achieve an acceptable level of agreement (RMSE < 5°) for sagittal knee joint angles during various ADLs. However, lower levels of agreement were observed when measuring abduction/adduction angles (Poitras et al., 2019). Despite this limitation, the high accuracy in sagittal plane measurements highlights the potential of IMUs for use in both clinical and home-based rehabilitation settings.

Each study identified specific strengths and limitations of IMU devices. Poitras and associates (Poitras et al., 2019) conducted a systematic review to assess the validity of wearables for joint angle measurement, concluding that accuracy depends significantly on the measurement plane, with flexion/extension angles demonstrating the highest accuracy. Additionally, other research has found the type of activity or movement being analysed strongly influences accuracy, with more complex movements generally yielding lower validity and higher RMSE values, (Cuesta-Vargas, Galan-Mercant and Williams, 2010; Robert-Lachaine et al., 2017).

A common finding across numerous studies (Cornish et al., 2024; Cuesta-Vargas, Galan-Mercant and Williams, 2010; Cutti et al., 2010; Henkel, 2016; Hullfish et al., 2019; Kobsar et al., 2020; Lavernia et al., 2008; Papi et al., 2015; Poitras et al., 2019; Taylor, Miller and Kaufman, 2017; Wong, Wong and Lo, 2007; Zhou et al., 2020) is the importance of proper calibration. Ensuring that the IMU axes align with the body's anatomical axes is crucial for reporting accurate measurements, as different calibration protocols can produce varying outcomes. Since the initial calibration serves as the reference for calculating joint angles during movement, poor alignment of the sensors during placement can significantly degrade data quality.

Furthermore, the length of data collection has been shown to affect accuracy. Studies recording data over shorter periods reported higher accuracy (Dejnabadi et al., 2006), likely due to reduced sensor drift. However, several filtering techniques are available to mitigate the effects of drift during longer recordings.

The overall accuracy of IMU's depends on several factors: the precision of sensor placement, the complexity of the movement being analysed, the algorithm used for data processing, the measurement plane, and the applied biomechanical model. As biomechanical models and calibration techniques continue to improve, IMUs are poised to become a standard tool in clinical and rehabilitation settings.

2.11.2 How Accurate is Accurate Enough?

Before adopting new technologies for clinical use, their accuracy must be evaluated against established clinical standards. Knee flexion is traditionally measured using various methods such as electrogoniometers, short-arm goniometers, digital goniometers, laser projection, and inclinometers. Goniometers are most commonly used (Kiatkulanusorn et al., 2023).

However, research (Hancock et al., 2018; Kiatkulanusorn et al., 2023) has shown that traditional methods can produce highly variable results, with accuracy depending on the measurement technique and the person conducting the measurement. Discrepancies between tools and users can result in measurement differences of between 6° – 14°.

The required level of accuracy in a clinical setting depends on the specific task, the environment in which the device is used, and the precision needed to effectively evaluate patient functionality (Chapman, Moschetti, and Van Citters, 2021 et al., 2021; Lavernia et al., 2008; Milanese et al., 2014; Prill et al., 2021). For a device to be considered clinically acceptable, it should have a correlation reliability coefficient above 0.90 and a standard error (SE) of measurement below 2° is recommended.

Furthermore, devices must be sensitive enough to detect clinically significant changes in knee ROM typically ranging between 5° - 10° following TKA (Rajan et al., 2004; Ramkumar et al., 2019; Smith et al., 2006). Previous research (Cornish et al., 2024; Cuesta-Vargas, Galan-Mercant and Williams, 2010; Hullfish et al., 2019; Kayaalp et al., 2019; Kobsar et al., 2020; Luinge and Veltink, 2005; Mayagoitia, Nene and Veltink, 2002; Mundt et al., 2019; Nüesch et al., 2017; Obradović and Stančin, 2023; Ortigas Vásquez et al., 2023; Patel et al., 2012; Picerno, 2017; Picerno, Cereatti and Cappozzo, 2008; Rhudy et al., 2024; Schall et al., 2016; Taylor, Miller and Kaufman, 2017; Versteyhe et al., 2020; Wong, Wong and Lo, 2007; Yi et al., 2021; Zhou et al., 2020) has demonstrated that IMUs can measure ROM with error rates of 2° - 5° in certain movements and applications.

This level of accuracy suggests that IMU devices are capable of detecting clinically significant changes and monitoring improvements in knee ROM following TKA, particularly for moderate to large changes. However, their precision may not be sufficient for identifying very subtle changes in knee angles. Accurate sensor placement and calibration remain critical to ensuring reliable measurements.

IMUs are useful tools for continuous, long-term monitoring outside of clinical environments. However, for highly precise evaluations, they may still need to be supplemented with traditional motion capture methods.

2.11.3 Conclusions

Numerous studies have evaluated the accuracy of IMU technology across various activities and populations. While the accuracy depends on factors such as methodology, monitored activities, and sensor placement precision, IMUs consistently demonstrate the capability to measure knee angles with a high level of accuracy. When compared to existing clinical standards, these devices show great potential to enhance patient care, offering a valuable tool for both clinical and home-based monitoring

2.12 Summary

This literature review highlights the critical role of rehabilitation compliance in achieving optimal functional outcomes following TKA. The requirement for the continuous assessment of knee function, particularly ROM, throughout the recovery process is emphasised. Regular monitoring is essential for preventing postoperative complications and enabling timely interventions when suboptimal outcomes are identified. However, due to resource constraints, many patients do not receive such detailed care, often resulting in lower satisfaction and suboptimal recovery outcomes.

IMU technology has emerged as a promising solution, enabling remote monitoring of patient progress with greater precision and resolution than traditional methods. While these devices show significant potential, their accuracy can vary depending on factors such as calibration methods, sensor placement, and the complexity of monitored activities. Despite these challenges, IMUs have demonstrated the ability to measure knee angles with clinically acceptable accuracy under certain conditions.

Chapter 3. Aims and Objectives

This thesis aims to determine whether IMU devices are accurate enough to measure clinically significant changes in knee flexion angles during the early postoperative rehabilitation period following elective TKA surgery, and whether these devices may be confidently used to promote rehabilitation compliance and monitor recovery.

To meet this general aim the objectives of this study were as follows:

1. To evaluate the accuracy of IMU devices for measuring sagittal knee joint angles by comparing data to those obtained using the gold standard opto-electronic system, Vicon motion capture (Vicon, Oxford, UK) across a variety of ADLs in a healthy population of different age groups and across a TKA clinical population preoperatively and postoperatively.
2. To validate the Seel algorithm (Seel, Raisch and Schauer, 2014; Seel and Schauer, 2016) for calculating two-dimensional knee flexion joint angles from raw IMU data in both a healthy younger adult population and in a TKA clinical population both preoperatively and postoperatively across various activities.
3. To investigate recovery following TKA surgery by examining changes in knee joint flexion and functional outcomes from pre- to early postoperative phases, integrating objective measurements with patient-reported data, comparing cohort trends with individual case profiles, and demonstrating the clinical utility of wearable sensors in rehabilitation settings.

To quantify the accuracy of both technologies the root mean square error (RMSE), signed differences and Pearson's correlation of coefficient (r) was determined between the sensor measurements and that of the opto-electronic system, Vicon motion capture.

One-way ANOVA tests were performed across the technologies to establish whether differences between these devices were significant ($p = 0.05$).

Agreement between the wearable devices and the opto-electronic system, Vicon motion capture were visually displayed using mean signed error plots and Bland-Altman plots.

While variation within the measures were presented by plotting the standard deviations (SD), standard errors (SE) and 95% confidence intervals.

The following parameters were analysed:

- Joint kinematics: Knee ROM, minimum knee flexion angle, maximum knee flexion angle
- Statistical analysis: RMSE, correlations (Spearman's and Pearson's), Bland-Altman plots, ANOVA ($p = 0.05$), SD, SE, absolute signed differences.
- TKA group reported: PROMs, BMI, treadmill speed, cadence, stride length and knee angle measures.

Chapter 4. Methods

This chapter describes the different methodologies implemented in this thesis. While the studies all share common methodologies, participant groups and similar data analysis techniques, there are differences between the studies. These variations will be highlighted and detailed where appropriate. Firstly, a broad overview of the complete study design is presented with further detail provided for each aspect of the study design elaborated upon in the subsequent sections. Three different population pools were recruited for this study. Two groups of healthy able-bodied participants (who were categorised depending on age) and a single group of TKA patients were recruited. The clinical aspects of this study were carried out in partnership with the Golden Jubilee National Hospital, Clydebank and the Glasgow Royal Infirmary, Glasgow.

4.1 Study Design

This section provides a brief overview of the study design and the various elements involved in the successful completion of this research, further details regarding the specific aspects of the study design will be detailed in subsequent sections. The study design includes participant recruitment, laboratory setup and calibration, data collection and finally data analysis. Firstly, participants were recruited to the project, upon which a date and time for data collection was agreed. Following recruitment, the movement analysis laboratory was set up, which included calibration (which is detailed in subsequent sections, see Section 4.5).

Once the movement analysis laboratory was fully calibrated the participant then had their anthropometric data recorded and both the sensors and markers fitted to their body. The participant was then invited to move into the centre of the room for a static calibration to be taken. The participant was asked to stand stationary in the anatomical position and a static capture was recorded on all devices (Vicon opto-electronic motion capture system, MotionSense™ wearable sensor technology and the IMU wired sensors).

When the static calibration is combined with the participants anthropometric data the position of the joint centres can be calculated, and this is then used to calculate kinematic and kinetic measurements in Vicon Nexus software.

4.1.1 Functional Activities

Following the static calibration the participants were then asked to perform various ADLs in a random order. The researcher provided instruction and a demonstration for each ADL to ensure that each activity was performed correctly by the participant. These activities are briefly described in Table 4-1 below.

Participants were allowed to take breaks between activities and were allowed to stop the session at any point should they not feel well enough to complete the full session or all tasks. During all activities video recordings were captured to provide a reference to kinematic data captured by both sensors and the motion capture system. Once all activities were completed the sensors and retro-reflective markers were removed and the participant was free to change into their casual clothes and leave the laboratory.

Table 4-1. Overview of the activities of daily living performed by the participants.

Task	Brief Description
Get Up and Go	The participant sits on a stool, they then stand up and walk to a 3-metre mark, turn around and walk back to the stool where they then sit back down.
Flexion/Extension	The participant performs a maximum flexion and extension movement while standing up right using a vertical structure for support.
Stationary Cycle	The participant cycles on a stationary bicycle for 2 minutes at a comfortable pace.
Stair Navigation	The participant walks up and down a set of stairs.
Treadmill Walking	The participant walks on a level treadmill at a self-selected comfortable walking speed for up to 5 minutes.

4.1.1.1 Detailed Explanation of Each Activity

4.1.1.1.1 Treadmill Walking

Participants were assisted onto the stationary level treadmill. Participants at the University of Strathclyde were strapped into the safety harness as no handrails were available for this treadmill. Participants at the Glasgow Royal Infirmary and Golden Jubilee National Hospital were encouraged to use the treadmill handrails if they felt unstable, and TKA participants were encouraged to use their assistive walking devices if they preferred to do so, particularly at the earlier postoperative sessions.

Once the participant was positioned on the treadmill and felt comfortable standing on the belt by themselves, the treadmill was then switched on. There was an acclimation period that lasted approximately one minute and was used to determine the natural walking speed of the participant. This was achieved by setting the walking speed to a pace that the participant deemed ''normal and comfortable'', the speed was then gradually increased, if the participant voiced that the speed was too fast, the speed was then returned to a speed at which the participant felt comfortable at.

However, if the participant was comfortable walking at the faster speed, the treadmill speed was further increased until the participant stated that the speed was too quick. The median speed was then determined, and this was the speed set for the 5-minute walk or for as long as they could manage to walk for. The treadmill was then slowed down gradually and eventually brought to a controlled stop. The participant was helped off the treadmill and offered a rest and some water.

4.1.1.1.2 Stair Navigation

Different stairs were used depending on which movement analysis laboratory was used for data capture. If the participant had a session at the Glasgow Royal Infirmary portable stairs were used for the stair navigation activity. This set of stairs comprised of five stairs up and the same five stairs down, with a rail on either side.

However, if the participant attended a laboratory session at the University of Strathclyde a set of ''L-shaped'' stairs that had three stairs on one side and four stairs on the other side were used.

Due to the height restrictions at the Golden Jubilee National Hospital, the stair activity could not take place within this movement analysis laboratory.

Each participant started the trial a few steps away from the first step to ensure that the stairs were climbed in a natural manner. No instruction was given to the participants as to how the stairs should be navigated, and so variations existed. Differences as to which foot strikes the first step varied between participants, while further differences were presented in the stair navigation approach used (step-by-step or step-over-step), some participants used the handrails or their walking device which would further result in variation within the data. These factors should be taken into consideration when interpreting the results.

4.1.1.1.3 Get up and Go Test

Each participant was asked to sit on a stool in a relaxed position with their knees bent, when instructed to get up and walk by the researcher, the participant then stood up from the stool and walked at a comfortable walking pace to a 3-metre line which was marked on the laboratories floor with black tape. Once the participant had reached this line, they were then asked to turn around and walk back towards the stool and return to the seated position. This action was repeated three times.

4.1.1.1.4 Active Flexion and Extension

Each participant was asked to perform a standing active full ROM knee flexion and extension movement. The participant was asked to stand in the centre of the laboratory, a support structure was placed in front of them to aid in their balance.

When the researcher instructed the participant to do so, they were asked to flex their sensored leg as much as possible and then return it to the fully extended position, ensuring their foot was flat on the ground. This movement was repeated three times.

TKA participants were required to flex their operated leg as much as they were able to do before they felt stiffness and pain. These participants struggled to do this movement 1-week postoperatively due to pain and swelling. Furthermore, limited ROM was presented within this population, with many participants displaying difficulty straightening their leg.

4.1.1.1.5 Cycling

The cycling activity was only completed by the healthy able-bodied participants. TKA participants were not required to complete this activity.

Before the participated mounted the stationary bicycle the saddle height was adjusted to each participants normal riding height. The saddle height was determined by adjusting the saddle to what the participant considered to be their normal comfortable saddle height. The height of the saddle varied from participant to participant, some participants preferred a higher saddle that resulted in smaller degrees of knee flexion, while others preferred a lower saddle height, causing an increase in knee flexion angle.

The handlebars of the bicycle were raised in order to minimise marker obstruction, this resulted in all participants cycling in a more upright position. The resistance was set to an easy effort to prevent fatigue and to ensure a constant cadence was maintained. Once the bicycle was setup, the participant was then asked to start pedalling at a leisurely speed that they could maintain for two minutes.

4.1.2 PROM Questionnaires

In addition to the functional activities, each TKA participant completed three PROM questionnaires, namely the Forgotten Joint Score - 12 (FJS), the Oxford Knee Score (OKS) and the Knee Injury and Osteoarthritis Outcome Score for Joint Replacement

(KOOS JR) (Appendix 1, Section 9.5). Each questionnaire was completed before the start of each session and then transcribed into excel following the completion of the session for analysis.

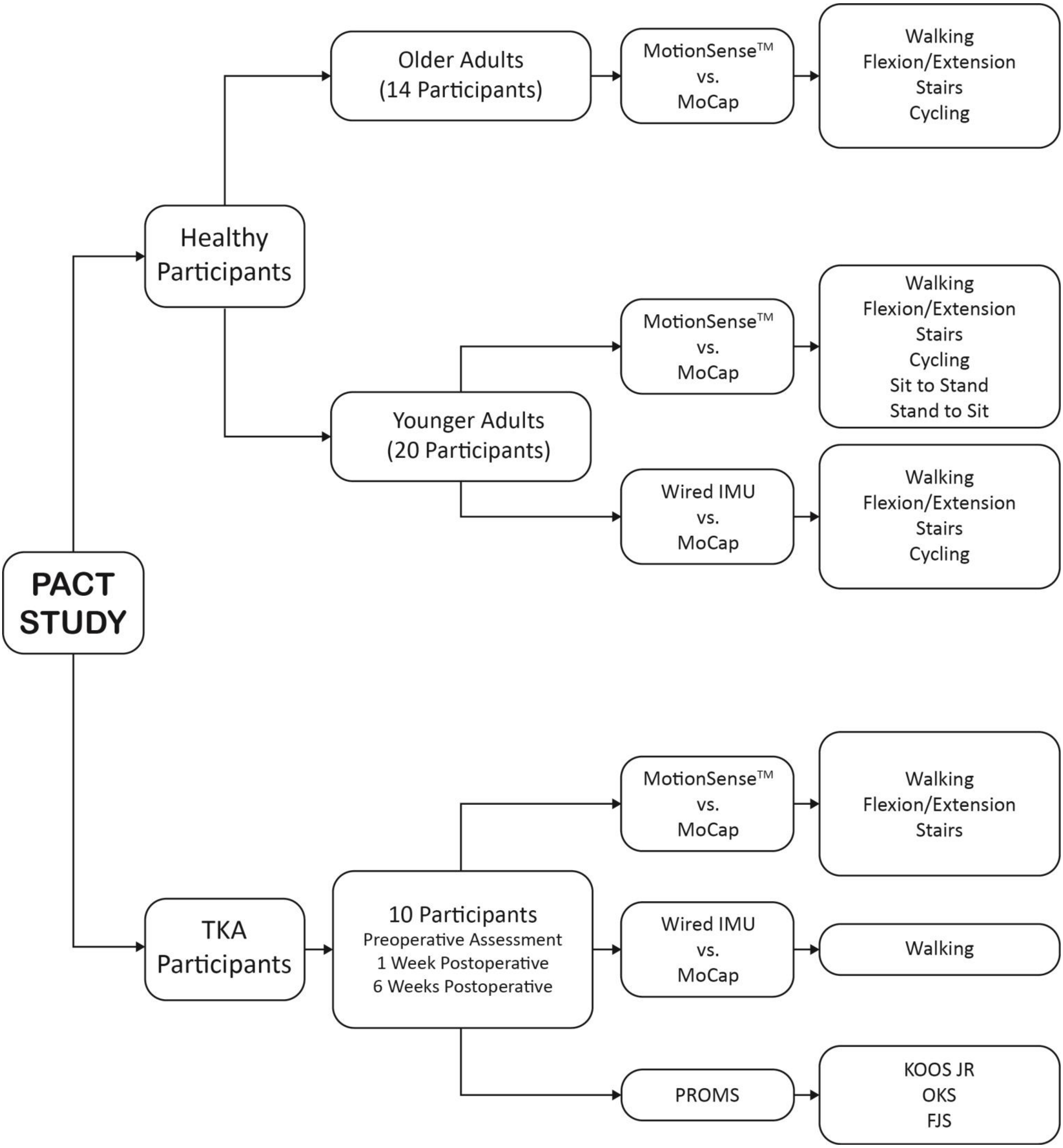
All questionnaires have been converted to a scale out of 100 and ranked so that higher scores can be interpreted as more favourable outcomes to ensure that each questionnaire can be compared against one another.

KOOS JR was used to assess patient-reported pain, symptoms, ability to complete ADLs independently, sports and recreation function, and knee-related quality of life (Beynnon, Roos and Roos, 1998). It produces a final score for each subscale, ranging from 0 - 100, with 0 indicating “severe difficulties” and 100 signifying “no problems at all.” This questionnaire is extensively used and is both valid and sensitive to changes in patients with knee osteoarthritis undergoing conservative or surgical treatment. This score is commonly used to evaluate both immediate and long-term outcomes post TKA, with higher scores representing perfect knee health. For this study, this scoring system was left unchanged.

The FJS is a 12-question questionnaire, with scores ranging from 0 - 4. FJS is used to assess the patient’s ability to forget about their operated artificial joint during different ADLs. Higher scores indicate that patients are less aware of their joint, suggesting a better outcome (Porter et al., 2023). For this study, the FJS was converted to a raw score scale of 100 to allow for comparisons between PROM questionnaires.

The OKS evaluates joint limitations and pain after surgery and consists of 12 questions scored between 0 - 4 with greater scores indicating better functional outcomes post TKA (Sajjadi et al., 2019). The OKS was converted to a raw score scale of 100 to allow for comparisons between PROM questionnaires.

4.2 Study Protocol Summary



4.3 Ethics

Before the study could take place, ethical approval was required. The study was carried out in accordance with the standards of Good Clinical Practice (GCP). All members of the research team had an up-to-date research passport and GCP training (Appendix 2, Section 10.4.1). Ethical approval of the study protocol was granted by the departmental ethics committee at the Department of Biomedical Engineering, University of Strathclyde for younger healthy participants and the NHS Ethics committee, West of Scotland REC 4 for the older healthy and TKA populations (See Appendix 1 Section 9.4.1 for Departmental Ethics and Appendix 1 Section 9.4.2 for NHS Research Ethics IRAS project ID 314702).

The University of Strathclyde Ethics was required for data collection to take place on the university campus and NHS ethics was required for patient recruitment and data collection to take place on NHS grounds. Upon receiving ethical approval 20 younger healthy adults aged between 20 - 36 years old, 14 older healthy adults aged between 60 - 84 years old and 10 TKA patients aged between 53 - 71 years old consented and participated in this study.

4.4 Participants

The healthy cohort consisted of younger participants who were recruited through the University of Strathclyde's biomedical engineering email list, and a group of older participants who were recruited through the University of Strathclyde' ageing network.

Post hoc stratification of age cohorts was performed in the absence of pre-specified recruitment criteria for participant age. Accordingly, participants were retrospectively classified into two groups: younger participants, defined as those under 40 years of age, and older participants, defined as those over 55 years of age. This delineation was applied solely for subsequent subgroup analyses and was not a condition of initial study enrolment.

The TKA participants were recruited through the NHS mailing list and at orthopaedic clinics at the Golden Jubilee National Hospital, Clydebank with the help of Dr. Alistair Ewen or at the Glasgow Royal Infirmary, Glasgow with the help of Dr. James Doonan.

4.4.1 Recruitment Criteria

The inclusion criteria used for participant recruitment for both the healthy and clinical populations is described in Table 4-2.

Table 4-2 Inclusion and exclusion criteria used for participant recruitment.

Healthy Control Group	
Inclusion Criteria	***Exclusion Criteria***
- Able bodied - Normal lower limb function - Free from lower limb musculoskeletal injuries and no prior lower limb surgeries - Able to perform specific activities of daily living - Willing to take part in study	- Any known underlying musculoskeletal, neurological or cognitive condition that may affect motor control and/or movement - Weight >135 kg /300 lbs/21 stones 3.62 lbs - Pregnancy or thought to be pregnant - Unable to give written consent
TKA Clinical Group	
Inclusion Criteria	***Exclusion Criteria***
- Received TKA surgery on one knee only (at the time of study) - Indicated for primary TKA with a primary indication of osteoarthritis will be identified by a consultant orthopaedic surgeon - Able to perform specific activities of daily living - Over 18 years old - Willing to take part - Able to return for follow up sessions	- Contralateral knee pain - Contralateral knee arthroplasty - Any other lower limb impairments (apart from the affected knee) which inhibit normal functional movement - BMI > 35 - Participation in any other clinical trial or study - Pregnancy or thought to be pregnant - Unable to give written consent

4.4.2 Recruitment Strategy

Different recruitment strategies existed between the different population pools. These strategies are described in the flowcharts below. Figure 4-1 and Figure 4-2 outline the processes taken from initial point of contact to the point at which data capture occurred.

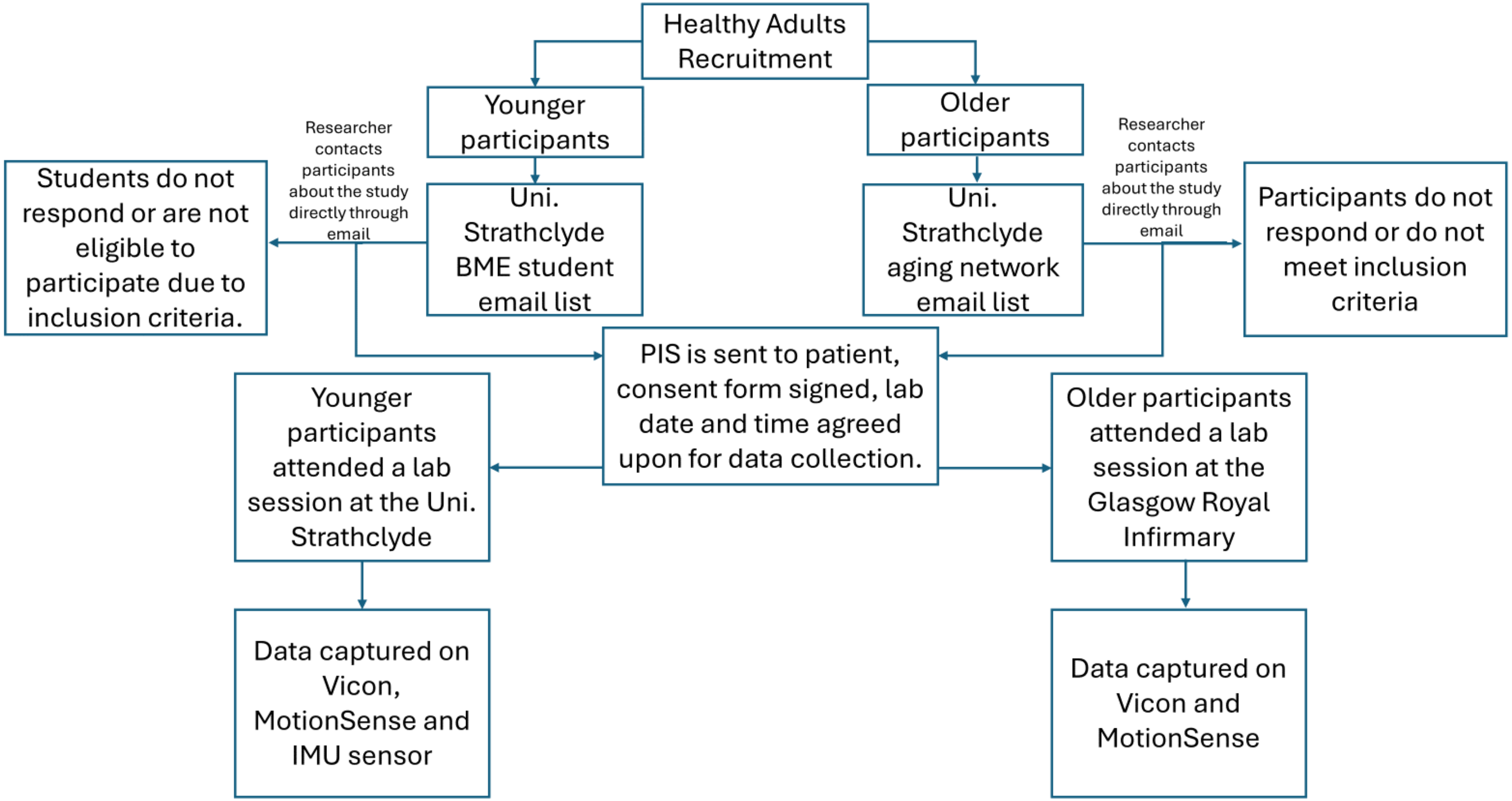


Figure 4-1. Flowchart describing the recruitment strategy and data collection methods used for the healthy older and younger adults.

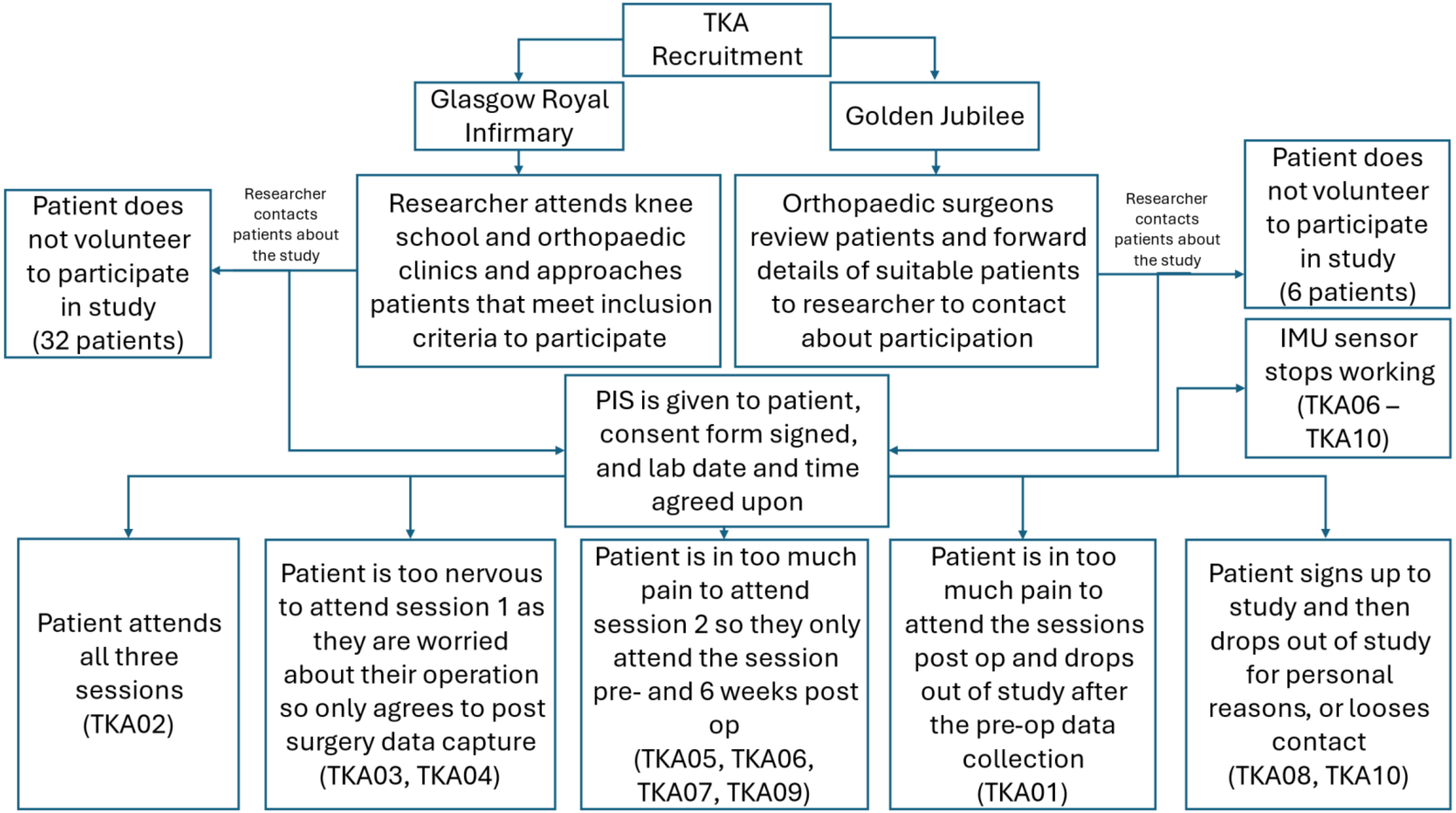


Figure 4-2. Flowchart describing the recruitment strategy and data collection methods used for TKA patients.

4.4.3 Recruited Participants

Following recruitment and obtaining informed consent from participants (Appendix 1, Section 9.3), a date and time for data collection was agreed and scheduled. The descriptive characteristics of the patients who participated in the data collection are summarised in Table 4-3 below.

Table 4-3. Descriptive statistics for all recruited participants, including healthy older and younger adults and the TKA population. Results are presented as a mean (SD) for continuous data and a number for dichotomous data.

	Younger Adults	**Older Adults**	**All Healthy Participants**	**TKA Adults**
Number of participants	20	14	34	10
Age (years)[ab]	24.05 (3.85)	70.57 (5.42)	43.21 (23.67)	62.4 (6.67)
Age Range (years)	20 - 36	60 - 84	20 - 84	53 - 71
Weight (kg)[cd]	69.09 (12.96)	72.39 (12.60)	70.43 (12.73)	88.02 (15.61)
Height (m)[de]	1.76 (0.11)	1.68 (0.09)	1.73 (0.11)	1.73 (0.12)
Body Mass Index (kg/m^2) [cde]	22.28 (2.87)	25.48 (3.22)	23.60 (3.37)	30.09 (3.22)
Sex (F/M)	8 / 12	10 / 4	18 / 16	4 / 6
Physical activity level (H/M/L)	11 / 9 / 0	12 / 2 / 0	23 / 11 / 0	2 / 7 / 1
Dominant Limb (R/L)	18 / 2	12 / 2	30 / 4	7 / 3
Lower Limb sensor worn (R/L)	9 / 11	14 / 0	23 / 11	7 / 3

F: Female; M: Male; R: Right; L: Left; H: High; M: Medium; L: Low
[a]$p<0.001$ between younger vs older adults
[b]$p<0.001$ between younger vs TKA adults
[c]$p<0.05$ between younger vs TKA adults
[d]$p<0.05$ between older vs TKA adults
[e]$p<0.05$ between younger vs older adults

4.5 Motion Analysis

Each healthy participant attended a single testing session either at the biomechanics laboratory at the University of Strathclyde or at the Human Performance Laboratory in the Clinical Research Facility of the Glasgow Royal Infirmary.

While the TKA patients attended three testing sessions: one session preoperatively, one session 1-week postoperatively and a final session 6 weeks postoperatively at either the Human Performance Laboratory in the Clinical Research Facility of the Glasgow Royal Infirmary, or the Movement Analysis Laboratory of the Golden Jubilee National Hospital.

During the laboratory session, the participant read through the participant information sheet (Appendix 1 Section 9.2) and was invited to ask any questions before signing the consent form (Appendix 1 Section 9.3). The participant then changed into appropriate clothing.

The participants were asked to wear tight-fitting sports clothes and comfortable walking shoes. If the participant did not have tight clothes, Lycra bike shorts were provided.

Once appropriately clothed the participants anthropometric data was collected in accordance with the lower body PIG protocol (Vicon Motion Systems, Oxford, UK) which included the participants body mass, height, leg length, knee width and ankle width. These measures were required for data processing.

The participant was then palpated, and 16 retro-reflective markers were placed on specific anatomical bony landmarks as according to the PIG lower limb body model marker set (Vicon Motion Systems, Oxford, UK) using double sided tape (Figure 2-4 and Figure 4-3). Following marker placement two MotionSense™ sensors were placed on the lateral thigh and lower leg on one side only (Figure 4-4).

The younger participants and certain TKA participants (TKA01 – TKA05) had a second wired IMU sensor attached to their lower leg on the lateral thigh and shank on the same side as the MotionSense™ sensors which captured accelerometer and gyroscope data (Figure 4-5). The wired IMU sensor was not worn by the older healthy population and only a select number of TKA patients as it had stopped working.

For the younger adults the MotionSense™ sensor was randomly worn on the left or right side, however for the older adults the sensors were worn on the right side only to aid video capture in the Clinical Research Facility at the Glasgow Royal Infirmary. The sensors were worn on the side of the operated leg for the TKA cohort.

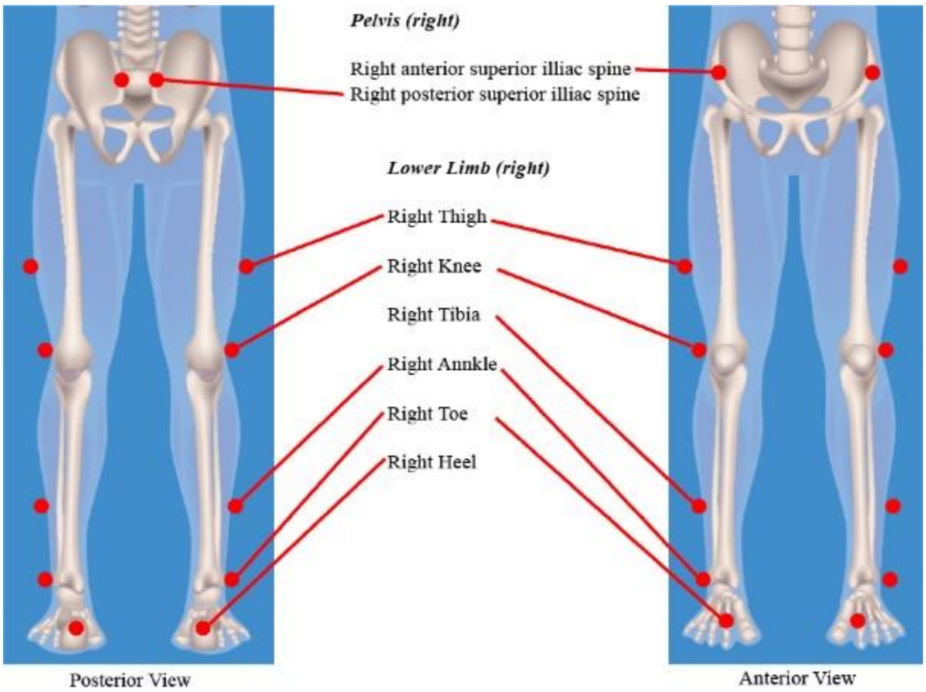


Figure 4-3. Plug-in Gait lower limb model marker locations.

Figure 4-4. Participant with lower body Plug-in-Gait marker model, and left and right sagittal view of participant with MotionSense™ sensors attached to their thigh and shank.

Figure 4-5 Participant with lower body Plug-in-Gait marker model and wired IMU device.

The retro-reflective markers were tracked by a 12-camera Vicon T-series system at the University of Strathclyde and at the Golden Jubilee National Hospital, while a 15-camera Vicon Bonita system was used at the Glasgow Royal Infirmary (Vicon Motion Systems, Oxford, UK).

The MotionSense™ sensors each consisted of a triaxial IMU, including a gyroscope, accelerometer, and magnetometer. The data was received and collected at ~50Hz via Bluetooth to an App on a mobile device in real-time and converted to knee angle using a combination of Madgwick filters (Madgwick, 2010; Madgwick Orientation Filter — AHRS 0.3.1 Documentation, 2019.) to estimate knee orientation while the transformation matrix between the two sensors was calculated to estimate knee angle.

Though knee angle determined by the MotionSense™ sensor was calculated by a propriety algorithm within a mobile phone App, these knee angle measurements were later downloaded onto a computer as .csv files for data analysis. The MotionSense™

sensors outputs different measures such as knee flexion, number of steps, ROM, and time spent weightbearing all calculated through the propriety sensor software.

The wired sensors differ to the MotionSense™ device, the wired sensors measure raw accelerometer, magnetometer and gyroscopic data which is collected at 200Hz and is stored within the data logger. These measures were later downloaded onto a computer using an unpacking software and were saved as .mat files. Once the data had been transferred from the logger to a university computer a bespoke algorithm written in collaboration with Philippe Martin (MINES Paris Tech) based off the Seel algorithm (Seel, Raisch and Schauer, 2014) was then implemented into MATLAB (MathWorks, 2024). Using the Seel algorithm (Seel, Raisch and Schauer, 2014) enabled knee flexion angle to be determined using the raw IMU measures while using a very similar filtering method to that of the MotionSense™ commercial device, while offering the opportunity to validate this approach. This methodology will be detailed in section 4.11 below and will from here on out be referred to as the Seel Algorithm.

As different locations were used for data capture, to ensure all laboratories capture motion accurately to ensure fair comparisons, each Vicon opto-electronic motion capture system was calibrated using the same calibration procedure. The calibration protocol was performed at the beginning of every data capture session as follows; upon arrival the Vicon opto-electronic system was switched on, to allow the cameras to warm up for at least 30 minutes. All reflective objects and camera obstructions were removed from the capture volume, for larger objects that caused reflection but that could not be removed the mask tool was used.

The researcher then carried out a dynamic calibration which involved moving a calibration wand that has retro-reflective markers of a known, set distance within the camera capture volume in view of all cameras. This ensures that the cameras position is set relative to the capture volume using a direct linear transform. This is achieved by calculating the calibration wands marker positions in each of the camera's two-dimensional image and converts this information into a three-dimensional co-ordinate system. This process allows for any markers placed inside the capture volume to be accurately tracked.

The volume origin of the movement analysis laboratory was then set by performing a static calibration, by placing the calibration wand on the floor in the centre of the laboratory in a fixed location, Figure 4-6. Vicon Nexus computer software calculates the relationship between the retro-reflective markers on the wand in three-dimensions against the two-dimensional positions of the calibration wands markers that are captured in each of the camera's field of view. This allows the cameras to be calibrated with respect to the laboratories global orientation system.

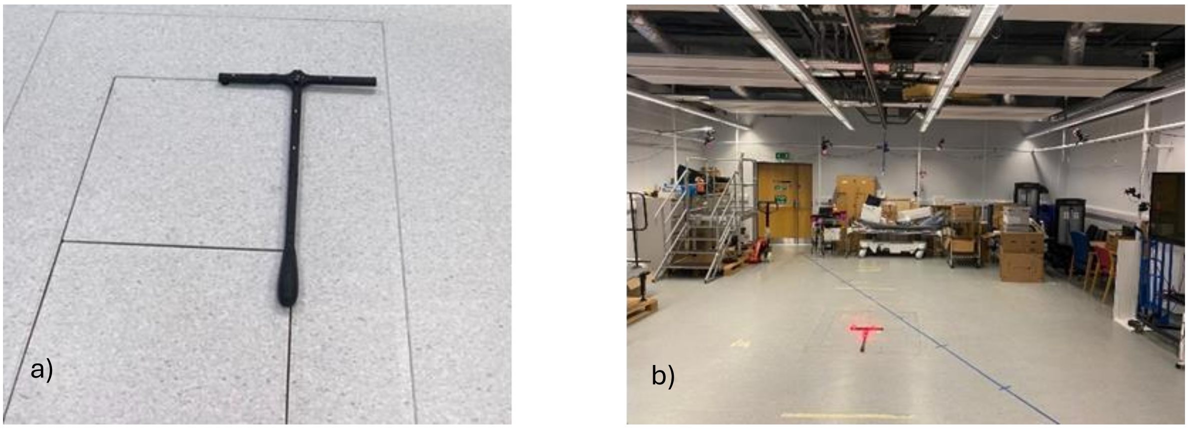


Figure 4-6. a) Calibration wand used for the calibration protocol. b) Setting the volume origin of the laboratory as part of the calibration procedure, to determine the global coordinate frame.

A world error below 0.6 was considered acceptable, if the error was higher in any one of the cameras the calibration protocol was carried out from the beginning until an acceptable world error was achieved. Once calibration was complete the video cameras were switched on and ready to record the full session if the participant had consented to this.

4.6 Equipment

Though much of the experimental methodology and study protocols are consistent between the three population groups, three different movement analysis laboratories (Glasgow Royal Infirmary, Golden Jubilee National Hospital and University of Strathclyde) were used for data capture.

Motion capture systems were consistent between all locations as each movement analysis laboratory made use of Vicon cameras which capture data at a frequency of 100Hz. Vicon Nexus software version 2.13 was used at each location to calibrate the laboratories and to record data. Though the motion capture equipment and software used was the same across all locations, the equipment differed depending on the site.

4.6.1 Treadmill

Treadmill walking data captured at the University of Strathclyde was captured on the CAREN Motek system (Motek Medical, Amsterdam, NL). While treadmill walking data collected at the Glasgow Royal Infirmary's movement analysis laboratory and at the Golden Jubilee National Hospital, was captured on a basic gym treadmill within the laboratory, Figure 4-7.

The Motek CAREN system is an advanced treadmill with a double belt system and safety harness. The speed of the treadmill can be controlled by the operator by shifting the speed on the console, or it may be determined by the participant if set to self-paced mode. However, for this study, it was treated as a standard gym treadmill with the speed dictated by the participant and set by the operator, and the incline kept level.

The standard gym treadmill had handrails on either side of the belt to provide support for the participant. The speed and incline of the treadmill can be manually adjusted through the console, however, for this study the incline was kept level, while the speed was dictated by the participant and set by the operator.

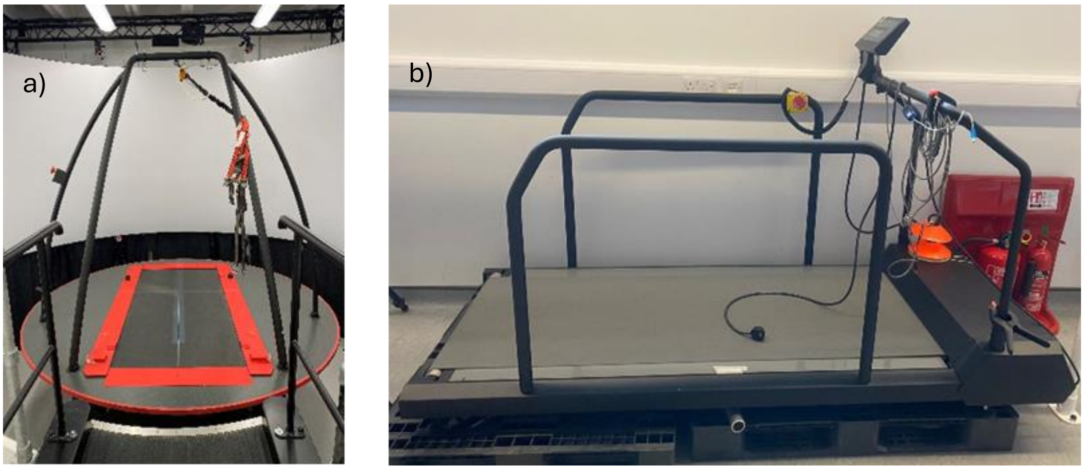


Figure 4-7. Treadmill set up at a) Strathclyde university and b) the Glasgow Royal Infirmary and Golden Jubilee National Hospital.

4.6.2 Stairs

There were no stairs available at the Golden Jubilee National Hospital as the ceiling was too low to allow stairs to be safely navigated by the participants. However, the stairs at the University of Strathclyde differed to those at the Glasgow Royal Infirmary, Figure 4-8.

The stairs used at the University of Strathclyde consisted of three stairs on one side, and four steps on the other. While the stairs used at Glasow Royal Infirmary's movement analysis laboratory consisted of five stairs up and down. Both stairs had railings on either side, which the participants were free to use if they felt they needed to do so. As different sets of stairs were used, the height and depth of the steps also differed.

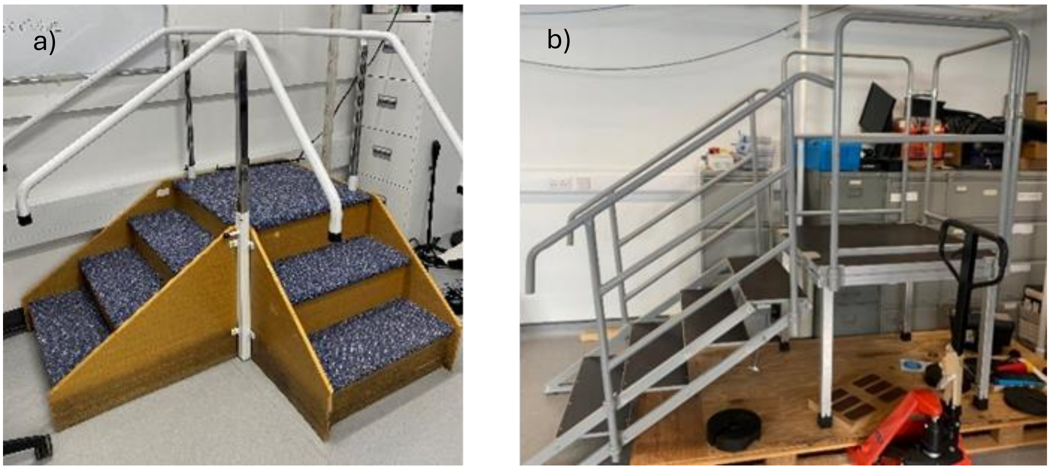


Figure 4-8. Laboratory set up for stair navigation at a) Strathclyde University and b) Glasgow Royal Infirmary.

4.6.3 Stationary Bicycle

The cycling data was captured using a stationary bicycle. The stationary bicycle used at each location was the same, the Monark Ergomedic 828E, Figure 4-9. This stationary bicycle is fully adjustable. The saddle can be positioned forwards and backwards, the seat raised up or down and the handlebars can also be increased or decreased in height depending on the height of the participant. The resistance of the bicycle can be adjusted using the dial at the front of the bicycle.

Figure 4-9.Monark Ergomedic stationary bicycle.

4.6.4 ROM Stability Platform

To complete the full range of motion flexion/extension exercise a vertical platform (Figure 4-10) was designed and then used to maintain the participant's balance. The platform was positioned in the centre of the room, with a 20kg weight placed on the base to ensure its stability.

The participant could then, hold onto the platform to keep their balance when performing full flexion and extension. The platform was 1 metre tall and made from light weight wood to ensure it was both sturdy enough to support the participant, yet light enough to ensure it was portable. The same platform was used at each location.

Figure 4-10. Full range of motion flexion/extension stability platform, used to maintain balance during the Flexion/Extension activity.

4.6.5 Stool

The sit-to-stand and stand-to-sit activity was isolated from the Get Up and Go Test. The stool used for this activity, was a foam stool with no back rest or arm rests (Figure 4-11), this was to ensure minimal marker obstruction occurred. The stool was set to a height of 480mm, the seat had a foam seat covering that measured 45mm thick and had a stiffness of 10.1kg/mm. The height of the stool was kept constant.

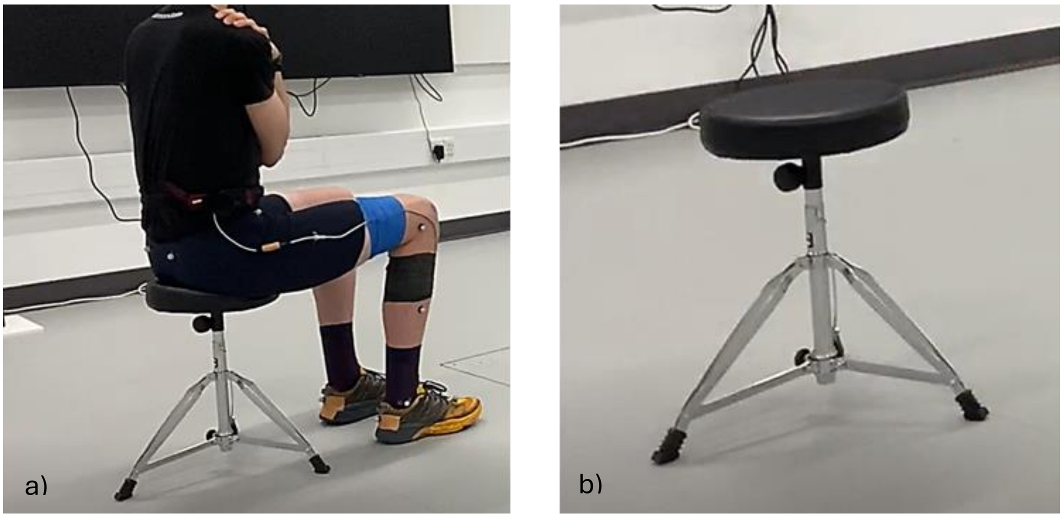


Figure 4-11.a) Participant seated on stool, and b) the stool used to perform the Get up and Go activity.

4.7 Consent Forms and Data Storage

Consent forms were kept confidential, stored indefinitely (with consent) in a locked cabinet in the Department of Biomedical Engineering at the University of Strathclyde. If a participant granted consent, video recordings were taken within the laboratory.

Additionally, all personal information recorded during the laboratory sessions were saved as a backup in a password protected folder on a password protected University of Strathclyde computer and on a password protected external hard drive. An ID key code links the collected data to each participant. The coded list is stored in a locked cabinet at the University of Strathclyde in the Department of Biomedical Engineering.

Any identifying material such as the coded key list, consent forms and kinematic data are only accessible to the named researchers within the departmental and NHS ethics application. All data, for both healthy and TKA participants was pseudonymised, however after 5 years after the completion of this study the coded key will be destroyed, and the data will become anonymous. Participants who volunteered for this study were all assigned a unique study ID number.

All hard copies of the data are kept in locked cabinets at the University of Strathclyde and are only accessible to members of the research team. All kinematic data collected during laboratory sessions were stored on a password protected computer and saved on a password protected external hard drive as a backup. All other related electronic data linked to this study were stored on university computers and were only accessible to members of the research team using their usernames and passwords. No personal data were or will be published of any participant.

4.8 Data Processing

4.8.1 Vicon Kinematic Data

Each trial was cropped in Vicon Nexus to include only the relevant data and if any major gaps were identified during the start or the end of the trials these sections could be excluded from the data. Each activity was cropped to include as much of the trials as possible.

Anatomical markers were then labelled using the Vicon Nexus software and each individual trial was manually checked for any maker gaps or mislabels within the data. If any mislabelling did occur, these maker trajectories were then manually corrected and if there were any gaps in the data due to marker obstructions, these too were corrected by filling these gaps with built in mathematic algorithms within the Nexus software.

The Woltring quantic spline fill was used for gaps of less than five frames. This method of gap filling makes use of interpolation to calculate the position of the marker within the gap, by using the position of the last and the next known marker position and interpolating the markers within the gap from that information. Pattern fill was used for larger gaps which fill markers within the gap by selecting ‘’source’’ markers that are present within the gap and filling the gap based upon the relationship between the markers present in the gap with the markers absent in the gap.

For any gaps present within the treadmill walking and cycling data, the cyclic fill was used. This type of gap filling uses patterns from the gait cycles earlier or later in the data to fill missing markers. As treadmill walking and cycling are both cyclic in nature, this method of gap filling is most appropriate.

Once the gaps had been filled, the Vicon opto-electronic data was exported as .c3d files ready for data analysis.

4.8.2 IMU Sensor Data

The data recorded by the MotionSense™ commercial sensors were manually copied over from an android mobile phone onto a computer after each data collection session. Each activity recorded by the MotionSense™ device were saved in separate files to aid analysis. These files were labelled with the same activity code as the corresponding Vicon file.

For data to be extracted from the wired IMU device and saved onto a computer, the data needed to be 'unpacked'. Unzipping software read in the compressed IMU data and decompressed, extracted and saved the data in separate .mat activity files. These files were then relabelled to match the corresponding activity codes of Vicon. This was carried out after each laboratory data capture session to prevent overriding of data. No data was collected from the older healthy population, as the wired IMU device had stopped functioning which prevented data from being captured on this device.

All data for each participant was saved in separate coded folders according to their participant ID. All activity data collected from the different technologies were labelled using the same activity code to ensure corresponding files were appropriately linked to one another.

4.9 Data Analysis

The data analysis between Vicon and MotionSense™ differed to that of Vicon and the wired IMU sensors, as the functionality of each sensor was slightly different. MotionSense™ outputs knee flexion angles directly, while the wired sensor outputs raw IMU measures. Therefore, different MATLAB (MathWorks, 2024) scripts were used to carry out the analysis of these two devices. The approaches used to compare the commercial MotionSense™ wearable device against Vicon opto-electronic motion capture will be described independently to the methods used to compare the knee flexion angle calculated from the wired IMU device against Vicon opto-electronic motion capture.

4.9.1 Motion Data Captured from the MotionSense™ Device

To effectively compare the MotionSense™ commercial IMU sensor measures to that of Vicon opto-electronic motion capture, a custom semi-automated process was created in MATLAB (MathWorks, 2024). An outline of the process is detailed in flowcharts (Appendix 2 Section 10.2.1).

For each activity, the same procedure was carried out on both Vicon and MotionSense™ data. Firstly, to reduce noise and smooth trajectories, the data was filtered by applying a fourth order zero lag Butterworth filter with a cut off frequency of 8Hz.

A Butterworth filter was chosen as it is a commonly used filter in gait analysis because of its smoothing frequency response and minimal distortion (Roithner and Schwameder, 2000; Yu, 1999). As the MotionSense™ data was already filtered by the proprietary internal algorithm, to avoid over filtering and further attenuation of the signal components, a higher cut off frequency of 8Hz was chosen to preserve as much data as possible while still smoothing any remaining high-frequency noise (Bartlett, 2014; Schreven, Beek and Smeets, 2015).

The sampling frequency differed between Vicon (100Hz) and MotionSense™ (~50Hz). Therefore, MotionSense™ data was up sampled to a frequency of 100Hz using the MATLAB (MathWorks, 2024) interp1 function, to match the sampling frequency of the Vicon data.

Though the researcher made an attempt to simultaneously begin data collection from both of the devices, the systems were not linked nor communicated with one another.

Therefore, the starting times were marginally different between the two technologies. To ensure accurate analysis between the two systems the two signals were time-synchronised over the entire activity period. Time synchronisation was achieved by maximising the cross-correlation of the signals before any comparisons were made.

Manual application of the retro-reflective markers and MotionSense™ sensors on the leg can result in a different zero angle for the knee for each technology. These differences arise due to differences in calibration methods between the technologies and differences in the accuracy of sensor and marker placement on the body. This offset difference was reduced by adjusting the sensor angle so that its mean value equalled that of the mean Vicon angle across the entire activity.

This difference was typically small and resulted in a more meaningful comparison of the technologies by minimising any manual experimental errors resulting from marker and sensor placement.

4.9.1.1 Functional Activity Analysis

Once the data had been processed and was in a usable format, ready for analysis, gait events were then manually determined using a bespoke graphical user interface (GUI), Figure 4-12. The GUI displayed the lower limbs of the participant, which provided a visual aid linking the measures to specific stages of a movement.

To ensure that the analysis focussed on the most relevant and meaningful sections of data, the GUI was used to effectively segment the data into meaningful isolated portions depending on the activity being analysed. The indices of these isolated data portions were stored to ensure that the same section of data was analysed across all devices. Each activities segmented data portion consisted of 100 interval points to represent 100% of the gait cycle.

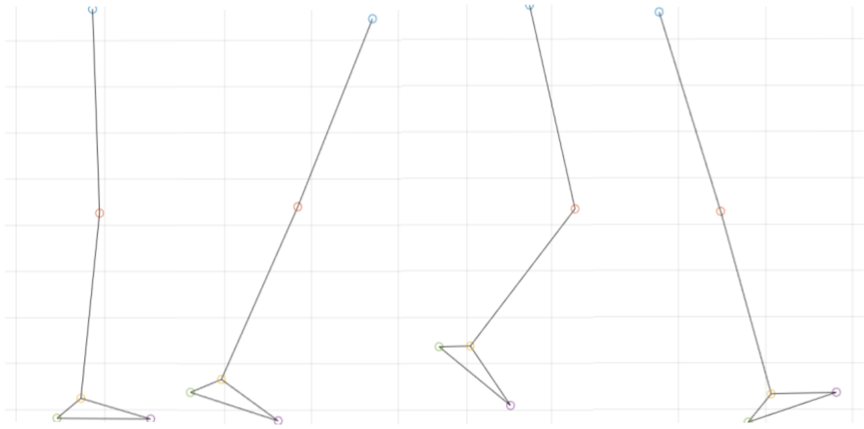


Figure 4-12. Example of a lower limb display using the bespoke GUI for identification of gait events.

Ten gait cycles were manually identified from heel strike to heel strike by visually identifying and selecting individual heel strikes during the walking activity, these heel strikes were determined from foot marker trajectories using the GUI, Figure 4-12.

For the stair navigation activity, foot marker trajectories were used to determine one complete step for both the stair ascent and stair descent, by tracking the heel marker of the sensored leg. The stair navigation activity was isolated from initial contact to initial contact.

Despite participants performing at least a 3-step ascent and descent, only one full gait cycle per trial could be analysed from initial contact to initial contact. As not all participants completed a full stair with their sensored leg, because of the stair arrangement.

Again, using the GUI ten individual pedal strokes were isolated for the cycling activity. The individual pedal strokes were selected starting and ending at the 6 o'clock position (Figure 4-13) where the knee joint is at maximum extension during the pedal stroke. The heel marker was tracked together with the knee flexion angle to determine a complete pedal stroke.

Despite the participants cycling for 2 minutes, the first ~1 minute was used as a habitation period, to ensure a natural pedal stroke and comfortable cadence was reached, thereafter the first ten complete pedal strokes were manually identified and selected where no marker obstructions and dropouts occurred.

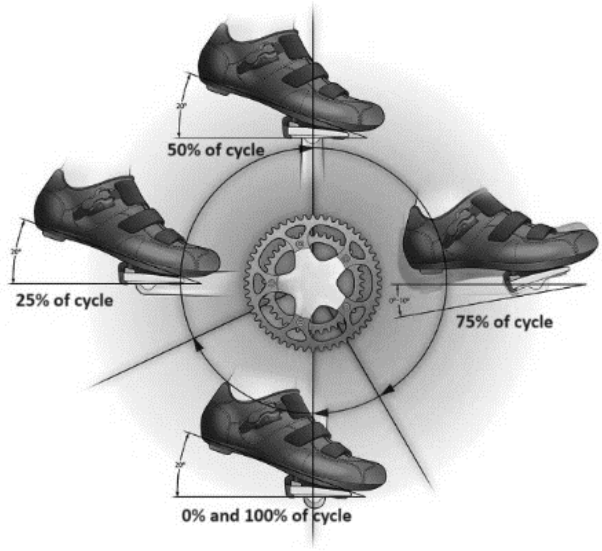


Figure 4-13. Percentage cycle of the pedal stroke for the cycling activity, 0% represents maximum knee extension, while 50% represents maximum knee flexion.

To isolate a complete flexion and extension movement the GUI was used to determine individual flexion and extension repetitions (three in total). The start and end points were defined from the point where the knee is in full extension and ended once the knee angle had returned to full extension after a maximum flexion had been completed, Figure 4-14.

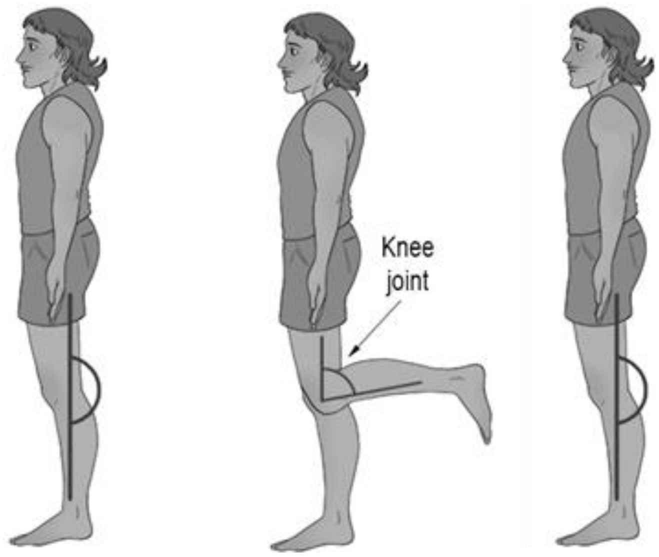


Figure 4-14. Full range of motion flexion/extension activity in the standing position (Patel, 2013).

Due to marker obstructions and participants walking in and out of the motion capture volume during the Get Up and Go activity, this activity was divided into two separate sub movements to aid analysis. These movements were separated into the sit-to-stand movement and the stand-to-sit movement, Figure 4-15.

The sit-to-stand movement was characterised from the point where the participant was seated comfortably on the stool, with their legs bent at ~ 90 degrees, to the point where they were standing fully upright and ready to start walking, just before they took their first step. The stand-to-sit movement was identified from the point when the participant was standing just in front of the stool, once they had returned from the 3-metre mark to the point where they were seated at rest with their legs bent at ~ 90 degrees. These activities were isolated by implementing the same GUI as before.

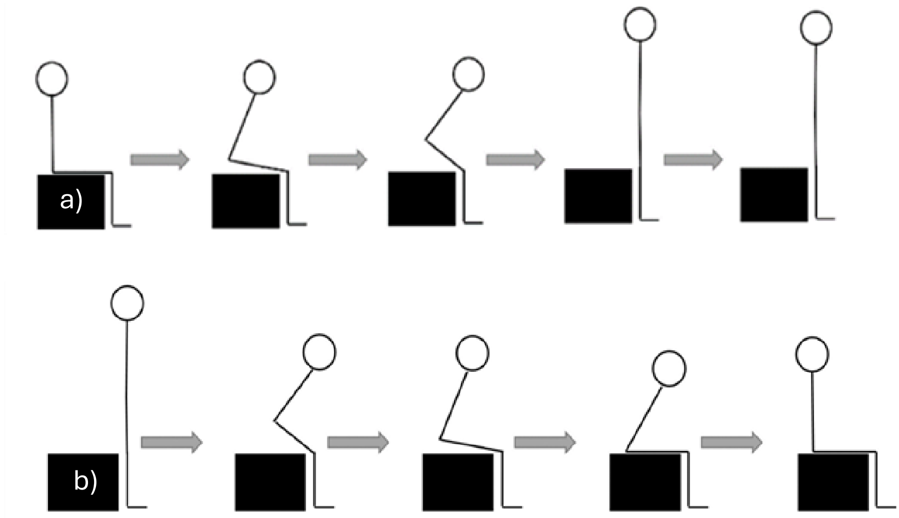


Figure 4-15. a) Sit to stand movement isolated from the Get Up and Go activity. b) Stand to sit movement isolated from the Get Up and Go activity.

As this movement was not specifically a sit to stand and a stand to sit exercise some differences may exist when reviewing the movement patterns.

Once all the relevant activity data was isolated into meaningful sections, including the accurate identification of the start and end points depending on the activity carried out. The isolated data sections consisted of 101 bins that represented the entire data set from 0% to 100% of the gait cycle. This enabled a final opportunity to perform a more precise time-synchronisation on the individual segmented data series using the same cross-correlation methods as before. This final time synchronisation accounted for any minor variation between the time signatures of the MotionSense™ device and the Vicon index.

4.9.1.1.1 Description of Analysed MotionSense™ and Vicon Data

Table 4-4 below describes the full data set considered when comparing MotionSense™ to Vicon. The table outlines the activities evaluated, the population type and size and the portion of data considered. The results presented in this thesis only consider this portion of data.

Differences in the amount of data analysed existed as varying number of participants attended the sessions, occluded markers resulted in gaps in motion capture data and corrupted sensor data prevented certain files from opening. These difficulties prevented complete data setsfrom being analysed, as both technologies data needed to be complete in order for comparisons to be drawn.

Table 4-4. Description of the data sets used to evaluate the accuracy of the MotionSense™ wearable device against Vicon.

Participant Pool		**ADL**	**Num of Participants**	**Num of Cycles per Participant**
Healthy Adults	Younger Adults	Walking	20	10
		Stair Ascent	19	1
		Stair Descent	19	1
		Cycling	18	10
		FE	17	3
		Sit to stand	18	1
		Stand to sit	18	1
	Older Adults	Walking	14	10
		Stair Ascent	14	1
		Stair Descent	14	1
		Cycling	8	10
		FE	14	3
TKA Clinical Population	Preoperative assessment	Walking	6	10
		Stair Ascent	4	1
		Stair Descent	4	1
		FE	5	3
	1 Week postoperative	Walking	2	10
		Stair Ascent	2	1
		Stair Descent	2	1
		FE	0	3
	6 Weeks postoperative	Walking	4	10
		Stair Ascent	4	1
		Stair Descent	4	1
		FE	5	3

FE: Flexion/Extension, Num: Number, ADL: Activities of Daily Living

4.9.2 Motion Data Captured from Wired IMU

The wired IMU sensor which operated using the Seel Algorithm functioned differently to MotionSense™. Therefore, independent MATLAB (MathWorks, 2024) scripts were coded to determine the accuracy of the wired IMU device compared to Vicon data.

The wired IMU device outputs raw unprocessed data (three dimensional gyroscopic, accelerometer and magnetometer measurements) of both the thigh and shank. To effectively compare the accuracy of the wired IMU sensor to that of Vicon motion capture, the IMU data was first put through the Seel algorithm (Seel, Raisch and Schauer, 2014) to calculate knee flexion angle. The working theory of this is detailed in section 4.11.

Following the calculation of knee flexion angle from the raw IMU data, gaps in data were filled and the data was then filtered. Filtering the data reduced the noise and smoothed the data. The IMU data was filtered in the same manner as described previously, however, for this IMU device a cut off frequency of 3Hz was chosen. A cut off frequency of 3 Hz is commonly chosen for gait analysis as primary movement frequencies in human gait normally fall within this range and because no internal filtering occurred pre-analysis, a lower cut off frequency was chosen compared to that of the MotionSense™ device (Bartlett, 2014; Schreven, Beek and Smeets, 2015).

The sampling frequency differed between Vicon (100Hz) and the IMU wired sensor (200Hz), in order to effectively compare the two signals, the Vicon data was interpolated using the MATLAB (MathWorks, 2024) interp1 function to match the sampling frequency of the IMU device.

These two devices did not communicate between one another, therefore, the two signals were time-synchronised over the entire activity period. Time synchronisation was achieved by maximising the cross-correlation of the two signals by manually selecting the starting positions for each signal and aligning the signals from peak to peak (Figure 4-16), using the xcorr function in MATLAB (MathWorks, 2024).

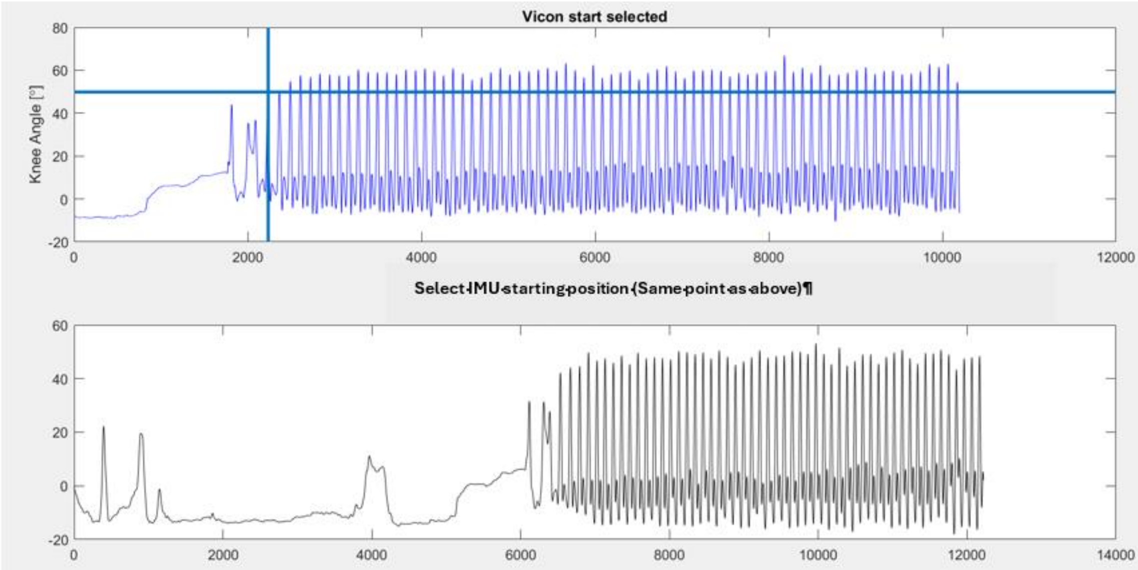


Figure 4-16 Manual selection of starting points, by visually determining the same peak values on both technologies to ensure time synchronisation of the signals.

The offset difference was removed by adjusting the IMU sensor angle so that its mean value equalled that of Vicon across the entire activity.

4.9.2.1 Functional Activity Analysis

Once the data had been processed it was now in a usable format for analysis. Different activities were analysed individually for accurate comparisons; however, the same routine was carried out across each activity.

Meaningful gait events were detected using a semi-automated routine in MATLAB (MathWorks, 2024). This included the manual selection of starting points of each activity. The starting points were determined by identifying the same peak knee flexion angle for both Vicon and the wired IMU sensor. Once the starting point had been identified on both signals, the number of cycles to be analysed per activity was manually inputted.

Flowcharts in Appendix 2 section 10.2.2 outline the procedure carried out to compare the two technologies.

To ensure that the analysis focussed on the most relevant and meaningful sections of data, the data was segmented into meaningful portions depending on the activity being analysed and the number of cycles considered. For the walking activity, each participant had fifty gait cycles analysed, identified from heel strike to heel strike. Gait cycles were determined by manually selecting the peak knee flexion from both measurement systems. The cycling activity included fifty complete pedal strokes per participant, identified from the 3 o'clock position to the 3 o'clock position, Figure 4-17. The flexion/extension activity was analysed from full flexion to full flexion (peak to peak), with three complete repetitions isolated per participant. The stair navigation activity was segmented by manually selecting the start and end points by determining initial contact to initial contact of the sensored leg for both stair ascent and stair descent. One complete step was considered for analysis per participant.

Once the data was segmented appropriately depending on the activity, the series were time-synchronised once again in each gait cycle to account for any minor variation between the technologies and to ensure absolute time synchronisation of signals.

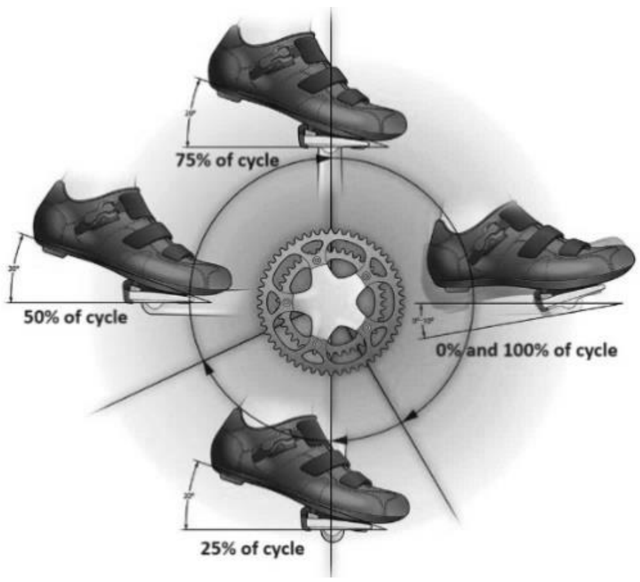


Figure 4-17. Phases of the pedal stroke cycle for the cycling activity 25% represents maximum knee extension and 75% represents maximum flexion of the knee.

4.9.2.1.1 Description of Analysed IMU Sensor Data

The amount of data analysed varied depending on the population group and the type of activity. Differences in data quantity were due to issues such as corrupted data files, faulty sensors, or large gaps in motion capture data due to marker obstructions. These difficulties prevented data from being analysed, as both technologies data needed to be complete in order for comparisons to be drawn. For example, no IMU data was collected from the healthy older adults because the wired IMU sensor malfunctioned and there was no available replacement device.

Table 4-5 outlines the different activities evaluated, the population groups, the size and the portion of data considered. The results presented in this thesis only consider these portions of data.

Table 4-5. Description of the data sets used to evaluate the accuracy of the IMU device against Vicon.

<table>
<tr><th colspan="2">Participant Pool</th><th>ADL</th><th>Num of Participants</th><th>Num of Cycles per Participant</th></tr>
<tr><td rowspan="5">Healthy Adults</td><td rowspan="5">Younger Adults</td><td>Walking</td><td>15</td><td>50</td></tr>
<tr><td>Stair Ascent</td><td>9</td><td>1</td></tr>
<tr><td>Stair Descent</td><td>9</td><td>1</td></tr>
<tr><td>Cycling</td><td>18</td><td>50</td></tr>
<tr><td>F/E</td><td>10</td><td>3</td></tr>
<tr><td rowspan="3">TKA Clinical Population</td><td>Preoperative assessment</td><td>Walking</td><td>3</td><td>50</td></tr>
<tr><td>1 Week postoperative</td><td>Walking</td><td>2</td><td>50</td></tr>
<tr><td>6 Weeks postoperative</td><td>Walking</td><td>4</td><td>50</td></tr>
</table>

F/E: Flexion/Extension, Num: Number, ADL: Activities of Daily Living

4.10 Statistical Analysis

The accuracy of both wearable sensors (MotionSense™ and the wired IMU device) was evaluated using the mean signed error and RMSE between Vicon and the sensor data across the entire activity and where possible individual repetitions were analysed. Pearson's correlations of coefficient (r) were determined between the sensor data and Vicon. While Spearman correlations of coefficients (ρ) were determined between objective and subjective outcome metrics for the clinical TKA population to detect general trends in recovery, without assuming relationship directions.

A clinically significant difference between measures was taken if the difference exceeded ±5°, where a RMSE < 5° was considered to be clinically acceptable. Maximum and minimum knee angles in addition to the ROM, for both the processed Vicon and sensor data were determined from each gait cycle and averaged across all gait cycles (mean ± SD) for each activity and every participant.

One-way ANOVA tests compared participant demographics and all outcome measures.

In this research SE provided information on the accuracy of the wearable device throughout the movement cycle. SE highlighted the mean error between Vicon and the IMU technologies at each time point during the movement cycle. It was calculated as the standard deviation of the error values (variability in the differences between the two technologies) divided by the square root of the number of samples (participants). This provides an estimate of how much the sample mean error deviates from the true mean error for the entire population (Nevill, 1998).

All statistical analysis was performed using Minitab Statistical Software (Minitab, LLC v. 22, USA) using a 0.05 level of significance.

A widely used conventional visual method to assess whether two measurement systems are in agreement with one another is the Bland-Altman plot (Riffenburgh and Gillen, 2020). This plot displays the difference between the two systems across the full measurement range, highlighting areas where larger differences exist, if any systematic differences (bias) are evident and whether errors are random. They are essential when comparing the same measurements from two different methods, and are a good representation of precision, and accuracy within a device.

In order to interpret the Bland-Altman plot it is important to understand the characteristics of the plot and what both axes represent. The x-axis represents the average of the two measurement systems at each data point while the y-axis depicts the difference between the two measurement systems. If the two systems are identical all data points would cluster around the zero line, and the differences would be small.

The mean difference, or bias line, is a horizontal line that displays the mean difference between the systems. If this line is close to zero, the two methods are very similar, however, if the line strays further away from zero, it indicates systematic bias, where one method consistently overestimates or underestimates compared to the other.

The final feature of this plot are the limits of agreement which are two lines, placed 2 standard deviations from the mean difference line, and represent the interval in which 95% of the differences between the two methods are expected to lie. Narrower limits indicate a better agreement. The shape of the data should show random scatter with no trends, and differences should ideally follow a normal distribution across the range of measurements.

For the purposes of this thesis, directional arrows have been added to the Bland-Altman plots to indicate the progression through the gait cycle. These arrows, along with the designated start and stop points, provide a visual reference for identifying specific stages within the gait cycle, aiding in its interpretation.

Bland-Altman plots in conjunction with mean signed error plots were used to visually display differences between the measurement systems, highlighting, areas of closer and lesser agreement.

Furthermore it is important to highlight that in this study, only one movement cycle per participant was analysed for certain activities (stair ascent and stair descent activities). This was due to the physical limitations of the available laboratory setup for the stair navigation activity, which allowed for the capture of only a single complete cycle per trial due to the stair arrangement. Whereas marker dropout and corrupted sensor data limited the sample size of the get up and go activity that was then analysed as two separate sit to stand and stand to sit movements. However, wherever possible more movement cycles were included for a more robust analysis.

It is recognised that in populations such as individuals post-TKA, gait patterns can exhibit increased variability due to compensatory strategies, residual pain, muscle weakness, or limited joint ROM. In such cases, analysing multiple gait cycles is critical to account for this variability and to ensure that the data reflect consistent movement patterns rather than isolated anomalies.

To address this, for activities not constrained by the experimental setup, such as level walking, multiple gait cycles were analysed. This approach ensures a more robust representation of movement in the TKA population where variability is a known factor. For stair negotiation, although only one cycle could be captured, care was taken to ensure it was representative and free from external disturbances or compensatory deviations. When interpreting findings from single-cycle data, these limitations are acknowledged, and results are considered within the context of the broader dataset.

4.11 Implementation of the Seel Algorithm

In order to compare the wired IMU sensor against Vicon opto-electronic motion capture, knee angle measurements are determined from the raw IMU data. The methodology is adapted from methods described in (Seel, Raisch and Schauer, 2014; Seel and Schauer, 2016) and implemented into MATLAB (MathWorks, 2024). The Seel algorithm utilises a similar approach to the Madgwick filter (Madgwick., 2010), which is used in the proprietary algorithm adopted by the MotionSense™ wearable technology. The Seel algorithm was compiled into MATLAB (MathWorks, 2024) scripts by Philippe Martin for collaborative validation, making it the preferred choice.

The theory and technical implementation behind this methodology is described below, together with a brief explanation of its practical applications. This method has been implemented in MATLAB (MathWorks, 2024) scripts, which are detailed and fully commented in Appendix 2.

As described in (Seel, Raisch and Schauer, 2014; Seel and Schauer, 2016), and for the purpose of this study we only consider the accelerometer (a) and gyroscopic (g) measures, while the magnetometer data is ignored. Each participant had two IMU sensors mounted on their lower leg, one on their thigh (IMU_1) and the other on their shank (IMU_2), Figure 4-18.

Each IMU has an associated coordinate system (local coordinate system). It is important to note that these local coordinate systems are different to the anatomical coordinate systems of the thigh and shank on which these devices are mounted on, and that these local coordinate systems may differ between IMU devices depending on their mounting orientations, Figure 4-18 and Figure 4-19.

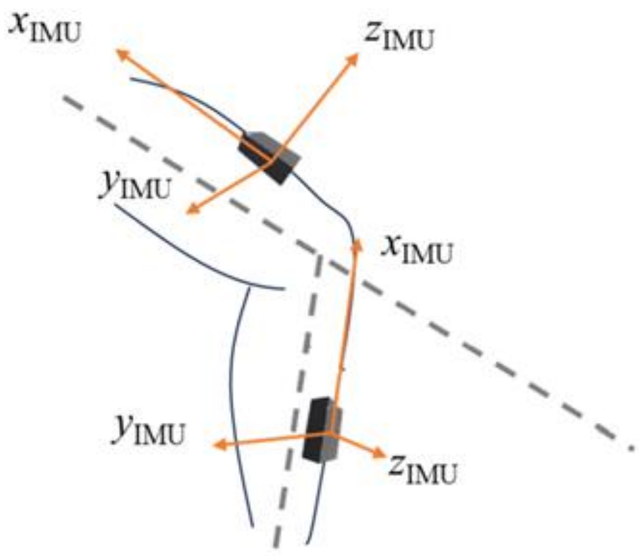


Figure 4-18. IMU devices attached to the lower leg, one on the thigh and the other on the shank, displaying the local coordinate system of each device and the grey dashed line representing the longitudinal axis of each body segment (Rhudy et al., 2024).

To accurately describe the knee angle from IMU data, it is important that the local coordinate system of each sensor is accurately aligned with the anatomical coordinate system of their associated body segment (thigh or shank). However, this is often not achieved by the original placement of these devices on the body segments but rather is initially estimated.

Firstly, the longitudinal axis of each IMU is estimated by considering the accelerometer data in the static calibration trial. During the static calibration, the participant stands upright, with their legs fully extended (flexion angle of zero) in the anatomical position and remains stationary.

As gravity dominates the accelerometer in this situation, the longitudinal axis of each IMU can be estimated by determining the normalised contribution of each axis in the local coordinate system of each sensor. These local longitudinal axes of each sensor are not perfectly collinear with the longitudinal axes of the anatomical coordinate system of each segment due to misalignments. Therefore, a sensor-to-segment calibration is required through the implementation of a transformation matrix to align the local coordinate axes of each sensor to the anatomical axes of the body segments.

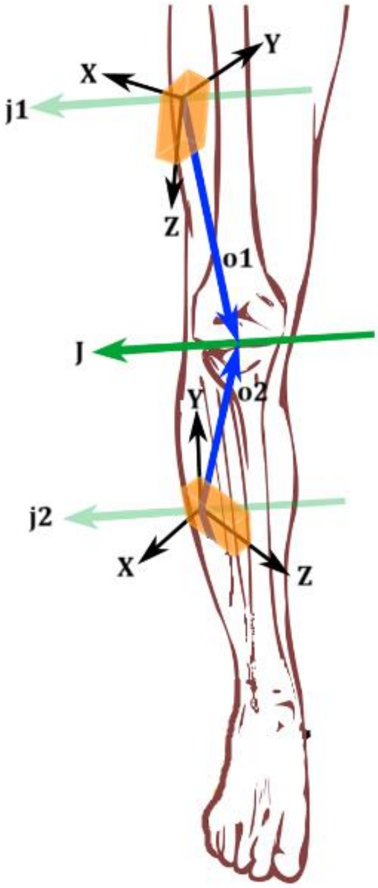


Figure 4-19. Lower leg with IMU sensors, displaying local coordinate system of each IMU device, joint centre vectors (j1/j2) and joint origin vectors (o1/o2) (Seel, Raisch and Schauer, 2014).

To simplify the remaining calculations, the knee joint is assumed to act as a perfect hinge joint (Laidig, Schauer and Seel, 2017) and primarily rotates about the sagittal plane. Therefore, the angular velocity along the knee axis is considered to be minimal but rather occurs predominately in the sagittal plane.

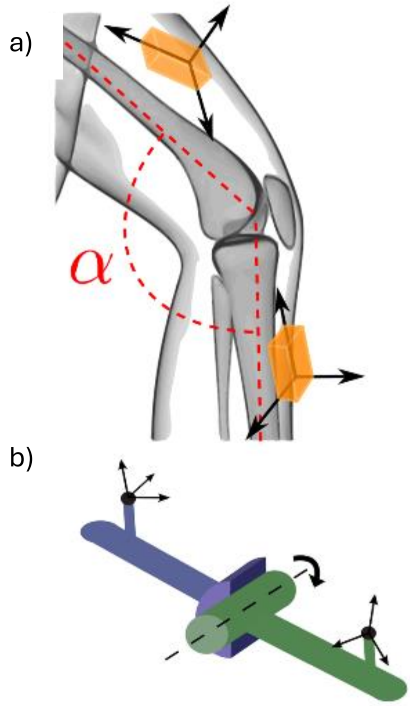


Figure 4-20. a) Two IMU devices attached to the thigh and to the shank, with the local coordinate systems not aligned with the anatomical coordinate system of either segment. b) The knee is acting as a hinge joint connecting each IMU device attached to the respective body segment.

Both IMUs shown in Figure 4-20 measure triaxial accelerations, $a_1(t)$, $a_2(t) \in \mathbb{R}^3$ which can be used to determine distance and position and triaxial angular rates, $g_1(t)$, $g_2(t) \in \mathbb{R}^3$ that provide information about the orientation, over some sampling period Δt, where the subscripts 1 and 2 represent the thigh and shank respectively.

The angular accelerations of each IMU can be calculated using a third order central differencing approximation (Seel, Raisch and Schauer, 2014). Where g represents the gyroscopic angular velocities, Δt represents the sampling period, and the subscripts 1 and 2 indicate the shank and the thigh respectively.

Additionally, the time derivatives, $\dot{g}_1(t)$, $\dot{g}_2(t) \in \mathbb{R}^3$ of each gyroscope can be calculated by determining the third order approximation yielding the angular acceleration:

Equation 17

$$\dot{g}_{1/2}(t) \approx \frac{g_{1/2}(t-2\Delta t) - 8g_{1/2}(t-\Delta t) + 8g_{1/2}(t+\Delta t) - g_{1/2}(t+2\Delta t)}{12\Delta t}$$

Because mounting of the IMU sensors is arbitrary, the location and orientation of the sensors with respect to the leg segments are completely unknown and because of this the coordinate axis of the IMU sensors will not be aligned to that of the anatomic coordinate system or the longitudinal axis of the limb segment or bone. It is therefore necessary to determine the direction and position of the flexion/extension axis by exploiting kinematic constraints (Seel, Schauer and Raisch, 2012).

To simplify the remaining calculations, the knee joint is assumed to act as a perfect hinge joint (Laidig, Schauer and Seel, 2017) and primarily rotates about the sagittal plane. Therefore, the angular velocity about the centre of the knee joint is considered to equal zero.

A cost function is carried out as a means of determining the best alignment of the two sensors to minimise angular velocity along the knee axis (Laidig, Schauer and Seel, 2017; Seel, Raisch and Schauer, 2014) abiding by the knee's kinematic constraints.

The treadmill walking file is used to determine the direction of the knee joint axis (mediolateral axis), as movement will occur primarily in the sagittal plane during this activity.

The result of the optimisation is 3D unit vectors, j_1 and j_2 which correspond to the knee flexion axis (mediolateral axis) in the local coordinates of IMU_1 and IMU_2 respectively.

An optimisation procedure is used to determine the 3D unit vectors, $j_1, j_2 \epsilon\ \mathbb{R}^3$ of the knee joints, which correspond to the knee flexion axis in the local coordinates of the shank and thigh sensors, respectively.

j1 and j2 are constants and depend only on the orientation in which the sensors are mounted with respect to the joint. The angular rates, $g_1(t)$, $g_2(t)$, measured on a hinge joint differ only by the joint angle velocity vector and a (time-variant) rotation matrix.

Hence, their projections into the joint plane have equal lengths for each time instant, described by:

Equation 18

$$\|g_1(t) \times j_1\|_2 - \|g_2(t) \times j_2\|_2 = 0 \forall t$$

Where $\| \ \|_2$ denotes the Euclidean norm (length of the vector). This constraint holds regardless of where and in which orientation the sensors are mounted on the segments.

A comprehensive derivation of Equation 18 is presented below.

As the knee is considered to be a hinge joint and consists of two connected segments (1,2), each segment has an IMU positioned on it, consisting of a gyroscope (g) that measures an angular velocity (ω_1, ω_2) in the local coordinate system of that IMU placed on that segment. These two local coordinate systems are not necessarily aligned with one another.

Each segment's angular velocity can be considered to be composed of the addition of two angular velocities, one being around the hinge joint axis, (ω_{j1}, ω_{j2}), described by unit vectors in the '1' and '2' coordinate systems, j_1 and j_2, and another angular velocity which represents the angular velocity of both segments as if they are rigidly connected (ω_{h1}, ω_{h2}). It is easy to visualise that this angular velocity could be, for example, the angular velocity of the whole leg about the hip. Whilst the magnitudes of ω_{j1} and ω_{j2} may differ, the magnitude of ω_{h1} will be equal to the magnitude of ω_{h2} (magnitudes need to be considered in their local coordinate systems as each IMU may not necessarily be aligned).

Therefore,

$$\|\omega_{h1}\|_2 = \|\omega_{h2}\|_2$$

Further, as vectors ω_{j1} and ω_{j2} are parallel with j_1 and j_2 respectively, their cross product equals zero:

$$\omega_{ji} \times j_i = 0 \qquad\qquad i = 1,2$$

The dot and cross products are defined as

$$a.b = \|a\|\|b\|cos\theta$$

$$a \times b = \|a\|\|b\|n \sin\theta$$

Where n is a unit vector perpendicular to both a and b. It follows that the magnitude of $a \times b$ is

$$\|a \times b\| = \|a\|\|b\||\sin\theta|$$

Thus

$$\|a \times b\|^2 = \|a\|^2\|b\|^2 sin^2\theta$$

$$\|a \times b\|^2 = \|a\|^2\|b\|^2(1 - cos^2\theta)$$

$$\|a \times b\|^2 = \|a\|^2\|b\|^2 - \|a\|^2\|b\|^2 cos^2\theta$$

$$\|a \times b\|^2 = \|a\|^2\|b\|^2 - (a.b)^2$$

Thus

$$\|\omega \times j\|^2 = \|\omega\|^2\|j\|^2 - (\omega.j)^2$$

$$\|\omega \times j\|^2 = \|\omega\|^2 - (\omega.j)^2$$

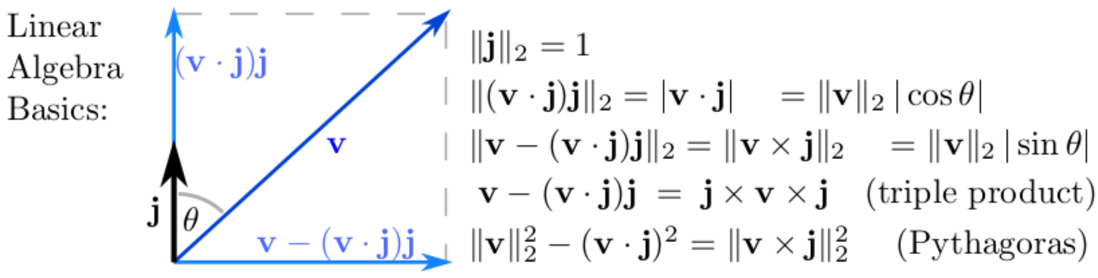


Figure 4-21. Explanation of Seel Algorithm, vector decomposition

Thus when we consider the above diagram shown in Figure 4-21 (where v has been replaced with ω for the purpose of this explanation). Consider vector ω. Its component in the direction of j is

$$(\omega.j)j$$

It will also have a component perpendicular to j and since j is the joint axis, any vector perpendicular to j is in the joint plane. Now, ω and $(\omega.j)j$ form two sides of a triangle in which ω is the hypotenuse. Thus, the magnitude of the side perpendicular to j may be found from Pythagorean trigonometry:

$$\|\omega\|^2 - \left((\omega.j)j\right)^2$$

$$\|\omega\|^2 - (\omega.j)^2 j^2$$

And as $j^2 = 1$

$$\|\omega\|^2 - (\omega.j)^2$$

And we remember that

$$\|\omega \times j\|^2 = \|\omega\|^2 - (\omega.j)^2$$

So, the magnitude of the component of vector ω in the joint plane is

$$\|\omega \times j\|$$

Returning to our two angular velocity vectors of segments 1 and 2, it has been shown that the projection of ω_1 and ω_2 in the joint plane is given by

$$\|\omega_1 \times j_1\|_2 \text{ and } \|\omega_2 \times j_2\|_2$$

These can be written as

$$\left\|(\omega_{h1} + \omega_{j1}) \times j_1\right\|_2 \text{ and } \left\|(\omega_{h2} + \omega_{j2}) \times j_2\right\|_2$$

And since the cross product is distributive over addition, $a \times (b + c) = a \times b + a \times c$

$$\left\|(\omega_{h1} \times j_1) + (\omega_{j1} \times j_1)\right\|_2 \text{ and } \left\|(\omega_{h2} \times j_2) + (\omega_{j2} \times j_2)\right\|_2$$

Since,

$$\omega_{j1} \times j_1 = 0 \text{ and } \omega_{j2} \times j_2 = 0$$

This results in;

$$\|\omega_1 \times j_1\|_2 = \|\omega_{h1} \times j_1\|_2$$

$$\|\omega_2 \times j_2\|_2 = \|\omega_{h2} \times j_2\|_2$$

Since it has been argued that $\|\omega_{h1}\|_2 = \|\omega_{h2}\|_2$ it follows that the magnitudes of the projections of ω_{h1} and ω_{h2} into the joint plane are also equal, such that;

$$\|\omega_{h1} \times j_1\|_2 = \|\omega_{h2} \times j_2\|_2$$

Which gives us the kinematic constraint that

$$\|\omega_1 \times j_1\|_2 = \|\omega_2 \times j_2\|_2$$

The hinge joint axis, j_1 is a constant in the '1' coordinate system, and likewise j_2 is a constant in the '2' coordinate system. However, ω_1 and ω_2 vary with time.

So,

$$\|\omega_1(t) \times j_1\|_2 = \|\omega_2(t) \times j_2\|_2 \qquad \forall t$$

Subsequently, j_1 and j_2 can be identified by minimising the cost function:

Equation 19

$$\Psi(\phi_1, \phi_2, \theta_1, \theta_2) := \sum_{i=1}^{N} e_i^2, \qquad e_i = \|g_1(ti) \times j_1\|_2 - \|g_2(ti) \times j_2\|_2$$

More precisely, j_1 and j_2 are written in spherical coordinates where $\phi_{1/2} and\ \theta_{1,2}$ represents the spherical coordinates for the coordinate transformation from local IMU frames to knee joint frames, required for sensor to segment alignment:

Equation 20

$$j_{1/2} = (cos(\phi_{1/2})cos(\theta_{1/2}), cos(\phi_{1/2})sin(\theta_{1/2}), sin(\phi_{1/2}))^{\,T}$$

Where the pitch angle is described by $\phi_{1/2,} \in [0, \pi]$ and the yaw angle $\theta_{1/2}, \in [0, 2\pi]$.

By minimising $\psi(\phi_1, \phi_2, \theta_1, \theta_2)$, the cost function, the best alignment of the two sensor frames is established.

Once this sensor to segment alignment is achieved through the optimisation of the cost function, the knee flexion angle can be determined by considering the gyroscopic readings.

This equation is based off the assumption that the knee joint functions as a perfect hinge joint. By assuming the knee to be a perfect hinge, angular velocity is limited about the knee axis, while most of the angular velocity occurs in the sagittal plane. With this alignment, the knee flexion angle can be calculated using gyroscope data through the process of integration, as shown Equation 21 below:

Equation 21

$$\alpha_{gyr}(t) = \int_0^t (g_1(\tau) \cdot j_1 - g_2(\tau) \cdot j_2) d\tau$$

After the joint axes have been determined, the coordinates of the joint centres in the local sensor coordinates, o_1 and o_2, are determined from an additional optimisation procedure (Seel, Schauer and Raisch, 2012) shown in Equation 22 as follows:

Equation 22

$$\widetilde{\Psi}(o_1, o_2) := \sum_{i=1}^{N} e_1^2 , \qquad ei = \|a1(t) - \Gamma g_{1(t)}(o_1)\|_2 - \|a2(t) - \Gamma g_{2(t)}(o_2)\|_2$$

Where,

Equation 23

$$\Gamma g_{i(t)}(o_i) := gi(t) \times (gi(t) \ \times o_i) + \dot{g}_i(t) \times o_i, \qquad i = 1,2$$

Equation 24

$$o_1 = \widehat{o_1} - j1 \, \frac{\widehat{o_1} \cdot j_1 + \widehat{o_2} \cdot j_2}{2}, \qquad o_2 = \hat{o}2 - j_2 \frac{\widehat{o_1} \cdot j_1 + \widehat{o_2} \cdot j_2}{2}$$

$\widetilde{\psi}$ (o_1, o_2) is minimised over its arguments. The result refers to an arbitrary point along the joint axis and is defined by $\hat{o}_1$, $\hat{o}_2$, Equation 23. A shift is then applied to move the optimised result as close to the sensors as possible by applying Equation 24.

This optimisation algorithm corrects the acceleration signals for the normal and tangential acceleration components due to the position of the sensors relative to the joint (Seel, Raisch and Schauer, 2014).

This type of correction is sometimes referred to as a lever arm correction. These joint centres are then used to correct the accelerometer measurements as follows:

Equation 25

$$\tilde{a}_1(t) = a_1(t) - \Gamma_{g1(t)}(o_1), \qquad \tilde{a}_2(t) = a_2(t) - \Gamma_{g2(t)}(o_2)$$

$\tilde{a}_1(t)$ and $\tilde{a}_2(t)$ are defined in two different local coordinate systems rotating with respect to one another around a single axis but equal in quantity.

Therefore, by calculating the angle between the projections of $\tilde{a}_1(t)$ and $\tilde{a}_2(t)$ into the joint plane, the flexion/extension angle can be calculated.

Consequently, a pair of joint plane axes $x_{1/2}$, $y_{1/2} \in \mathbb{R}^3$ for each local frame are defined by Equation 26.

Equation 26

$$x_1 = j_1 \times c, \quad y_1 = j_1 \times x_1, \quad x_2 = j_2 \times c, \quad y_2 = j_2 \times x_2, \quad c \nparallel j_1, c \nparallel j_2$$

The accelerometer-based joint angle can then be determined by:

Equation 27

$$\alpha_{\mathrm{acc}}(\mathrm{t}) = \sphericalangle_{2d}\left(\begin{bmatrix}\tilde{a}_1(t)\cdot x_1\\ \tilde{a}_1(t)\cdot y_1\end{bmatrix}, \begin{bmatrix}\tilde{a}_2(t)\cdot x_2\\ \tilde{a}_2(t)\cdot y_2\end{bmatrix}\right)$$

Where $\sphericalangle_{2d}()$ denotes the (signed) angle between two vectors in $\mathbb{R}^2$ and c is any vector not parallel to j_1 or j_2.

For this study we use c = $[1\ 1\ 1]^T$. While the coordinates (x1, y1) and (x2 and y2) represent arbitrary 2D coordinates in the knee joint plane.

As $\alpha_{\mathrm{acc}}(\mathrm{t})$ is not calculated through integration, it is unaffected by drift, however errors may be introduced if $\tilde{a}_{1/2}(t)$, (the shifted accelerations) are collinear, or approximately collinear with the joint axes $j_{1/2}$.

However, practically this is overcome as gravitational acceleration dominates the acceleration signals $a_1(t)$, $a_2(t)$ and $\tilde{a}_1(t)$, $\tilde{a}_2(t)$.

Therefore, the only situation whereby these errors may cause an effect are cases where the knee axis is close to the vertical or in situations where there is a high acceleration in the medial/lateral direction (Seel, Raisch and Schauer, 2014). These cases are very unlikely during walking and other ADLs. Furthermore, o_1, and o_2 are not susceptible to errors as $\Gamma_{g1/2}(t)(o_{1/2})$ in Equation 25 is normally very small in relation to gravitational acceleration.

The joint angle has been calculated by both gyroscopic and accelerometer measures ($\alpha_{gyr}(t)$ and $\alpha_{acc}(t)$), with the gyroscope-based angle resulting in a very accurate angle over short time periods, but susceptible to drift. While the accelerometer-based angle is affected by noise and is less accurate in motions of rapid acceleration changes, however, is unaffected by drift.

Therefore, a resulting angle of good accuracy and minimal drift is achieved by combining both measures using a sensor fusion technique. A complementary filter is used, and the resulting angle is represented by $\alpha_{acc+gyr}(t)$, Equation 28.

A simple implementation example is given by:

Equation 28

$$\alpha_{acc+gyr}(t) = \lambda\alpha_{acc}(t) + (1-\lambda)\left(\alpha_{acc+gyr}(t-\Delta t) + \alpha_{gyr}(t) - \alpha_{gyr}(t-\Delta t)\right), \qquad \lambda \in [0,1]$$

The joint angle calculations described above are limited to rotations around the identified joint axis, in this case the flexion/extension axis. Although this algorithm (Seel, Raisch and Schauer, 2014) could be adapted for measuring abduction/adduction and inversion/eversion angles this thesis focusses on a single plane only.

4.11.1 Summary of the Implementation of the Seel algorithm

A summary of the two main steps taken to determine knee flexion angle from raw IMU measures is briefly outlined below, highlighting the main stages.

Step 1: Initial estimations of IMU orientation and position for both segments

1. Using the static file, the acceleration is used to determine the longitudinal axis of both IMUs as gravity dominates this axis.
2. The sagittal axis of each IMU is determined using the walking file as acceleration is prominent in this direction.
3. The mediolateral axis is estimated by taking the cross product of the sagittal axis and the longitudinal axis to yield a perpendicular vector.
4. A second cross product between the mediolateral axis and the longitudinal axis is carried out, resulting in three orthogonal vectors.

These vectors are all in the local coordinate frame of each IMU sensor and are used to build rotation matrices to determine the segment alignments relative to the joint.

Step 2: Sensor to segment alignment, local coordinates to anatomical coordinates.

1. o_1, o_2 and j_1, j_2 are calculated (Seel, Raisch and Schauer, 2014).
   o_1 and o_2 are the vectors that connect the knee joint centre to the IMU centre.
   j_1 and j_2 are the local joint vectors relative to each IMU.
2. o_1 and o_2, j_1 and j_2 are all calculated using the treadmill walking file, and assuming the knee to behave as a perfect hinge joint.
3. Rotation matrices are determined for each IMU and the relative rotation of the thigh and the shank are calculated using the acceleration and gyroscopic data.
4. The IMU data is transformed into the anatomical coordinate system using these rotation matrices.
5. The knee angle (alpha) is determined via 2D projection using both acceleration data and integration of the gyroscopic data, by considering the relative rotation of the sensor and thigh segments.
6. Using a complementary filter (sensor fusion) the alpha angle is combined to yield a final estimate of the Flexion/Extension angle.

4.11.2 Seel Algorithm Pseudocode

For the full implementation of the Seel Algorithm in MATLAB (MathWorks, 2024) please see Appendix 2, Section 9.3.

1. *Load Vicon and IMU data*

```
CALL get_btk_angles(c3d_file_path)
    → Returns Vicon joint angles and frame count

LOAD IMU accelerometer and gyroscope signals:
    - g_S, g_F: Accelerations from shank (S) and femur (F) IMUs
    - n_S, n_F: Angular velocity (gyro) from shank and femur
    - fs: Sampling frequency
    - j1, j2: Joint axes (unit vectors) for shank and femur,
equation 18 and equation 19
```

2. *Preprocess IMU signals*

```
CALL AngleReconstructionCompare(fc, fs, λ, j1, j2, g_S, g_F, n_S, n_F)
    → Filter IMU data with Butterworth low-pass filter
    → Derive angular velocity derivative using third-order
approximation

    Compute:
        g1, g2       = filtered gyroscope signals (femur and tibia)
        a1, a2       = filtered accelerometer signals
        g1Dot, g2Dot = angular acceleration, Equation 17

    CALL estimateo1o2(g1, g2, g1Dot, g2Dot, a1, a2)
        → Solve optimization problem (nonlinear least-squares)
%Equation 22 and 23
        → Estimates orientation offsets o1, o2 that minimize projection
error %Equation 24

    Compute α̇(angular velocity projection on joint axis), From
Equation 21:
        alphaDotGyr = dot(g2, j2) - dot(g1, j1)

    Integrate alphaDotGyr over time to obtain α_gyr
    CALL projectAngle(...) to compute α_acc using accelerometer-based
projection %Equation 27

    Apply complementary filter, Equation 28:
        α_combined[i] = λ * α_acc[i] + (1 - λ) * (α_combined[i-1] +
Δα_gyr)

    RETURN α_combined as alphaAccGyr (final IMU knee flexion estimate)
```

3. *Synchronise IMU and Vicon data Streams*

```
CALL alignDataStreams_2D(pStream, alphaVicon, alphaAccGyr)

    → Display Vicon and IMU angle plots
    → User manually selects matching gait cycle start points
    → Cross-correlation used to fine-tune alignment

    RETURN RD_lag and vicon_start (alignment indices)
```

4. *Synchronise IMU and Vicon data Streams*

```
CALL CalcMetrics2D(alphaVicon, alphaAccGyr, actn, nCycles, offset)

    → Detect gait cycles using peak detection in flexion angle
signals
    → Align and interpolate both Vicon and IMU signals to 0–100%
gait cycle
    → For each cycle:
        - Compute RMSE between Vicon and IMU
        - Compute ROM (range of motion) for Vicon and IMU
        - Store resampled gait cycle data

    RETURN:
        - RangeVI: ROM data (Vicon and IMU per cycle)
        - RMSE: RMSE per gait cycle
        - cyclealphaVq: Vicon gait cycle curves
        - cyclealpha1Daq: IMU gait cycle curves
        - gc: gait cycle time vector
```

5. *Aggregate, Analyse and Plot the data*

```
FOR all subjects:
    - Extract IMU/Vicon angles and metrics from CalcMetrics2D
    - Concatenate angle curves for all subjects
    - Compute mean angle curves and ROM
    - Compute RMSE and correlation per subject

    Store:
        - alphaVicon_GC, alpha_IMU: all gait cycles (Vicon, IMU)
        - Vicon_GC, IMU_GC: subject mean gait cycles
        - ROMIMU_diff: ROM error
        - RMSE_IMU, CORR_IMU

Compute:
    - Overall RMSE across all points
    - Mean ± SD of angle difference (Vicon - IMU)

Plot:
    - Mean knee flexion with shaded ±1.96*SD bands
    - Overlay Vicon and IMU mean traces
    - Error plots (signed & absolute)
```

4.12 Spaciotemporal Parameter Calculations

Spatiotemporal gait parameters were derived from kinematic data collected during the treadmill walking activity. Stride length, stride time, and cadence were computed based on heel strike events and known treadmill speed.

Stride Time and Stride Length:

Stride time was determined by using the heel strike indices manually selected from the bespoke GUI as described in Section 4.9. Specifically, the time interval between two successive heel strikes were used as the stride time:

Equation 29

$$t_{stride} = t_{HeelStrike_{i+1}} - t_{HeelStrike_{i}} \quad i = 1:10$$

Where:

$t_{HeelStrike_{i+1}}$ is the timestamp of the i^{th} heel strike for a given leg.

With the stride time calculated and the treadmill speed ($v_{treadmill}$) known and is measured in meters per second, stride length (L_{stride}) was then computed using the relationship and given in meters:

Equation 30

$$\mathrm{L_{stride}} = \mathrm{v_{treadmill}} \times t_{stride}$$

Cadence Calculation:

Cadence was calculated using the derived stride length and treadmill speed. Since one stride consists of two steps, cadence was given as steps per minute and determined by:

Equation 31

$$c = \frac{2 \times \mathrm{v_{treadmill}} \times 60}{\mathrm{L_{stride}}} = \frac{2 \times 60}{\mathrm{t_{stride}}}$$

Where the factor 60 converts seconds to minutes.

Each parameter was averaged across 10 consecutive gait cycles for each participant to ensure consistency and reduce variability. Subsequently, a pooled population average was calculated by averaging each parameter across the entire population

Chapter 5. Results

This chapter presents the findings from three distinct studies, each detailed in its own section.

Section 5.1 assesses the accuracy of the commercially available MotionSense™ wearable device against Vicon opto-electronic motion capture across a broad range of activities in a healthy population, of both older and younger adults and in a TKA clinical population, both preoperatively and postoperatively.

Section 5.2 presents the accuracy of the Seel algorithm used to calculate knee flexion angles from raw IMU data in both a healthy population across a broad range of activities and a TKA clinical population during level treadmill walking both preoperatively and postoperatively.

Section 5.3 explores key biomechanical changes following TKA surgery. This section highlights postoperative improvements in knee angle during the acute recovery phase, aiming to assess whether IMU devices are sensitive enough to detect improvements during rehabilitation. Additionally, the MotionSense™ data of an individual TKA patient is presented, providing both qualitative and quantitative data to support these findings. By exploring a patient's unique recovery journey through the evaluation of their data, the potential need for personalised care approaches is highlighted, evidencing the opportunity of wearable devices within the rehabilitation journey.

5.1 Validation of MotionSense™

The accuracy of the MotionSense™ device is discussed separately for each activity, while comparisons between different populations are made within the same activity. Comparisons between the sensor accuracy are determined through RMSE, Bland-Altman plots and correlation coefficients.

The population demographics and anthropometrics varied between trials and are detailed in section 4.4.3.

Comparisons are primarily conducted between the healthy populations and the TKA population; however, where data is unavailable for the TKA population, comparisons are limited to healthy populations only.

5.1.1 Walking Results

During level treadmill walking, ten gait cycles per participant were isolated for comparisons of sensor accuracy. For comparisons between population groups, an average gait cycle was calculated by pooling the data from each group.

In addition to age, height and weight also differed significantly among the younger, older, and TKA adults (Table 4-3, $p < 0.05$). The older healthy adults walked significantly slower compared to the younger healthy group (0.94 ± 0.12 ms-1 vs 1.17 ± 0.07 ms-1, mean ± SD, $p < 0.001$, respectively). The TKA cohort walked significantly slower than both healthy older and younger adults across all three assessment points: preoperative assessment (0.56±0.14 ms-1), 1-week postoperative assessment (0.52 ± 0.14 ms-1), and 6 weeks postoperative assessment (0.60±0.28 ms-1 mean ± SD, $p < 0.001$). However, no significant differences in walking speed were observed within the TKA cohort between the sessions ($p > 0.05$).

Knee flexion patterns for treadmill walking were similar between all populations, however the healthy adults displayed the highest similarities in knee flexion patterns between Vicon and MotionSense™ when comparing both the groups pooled SD and SE in Figure 5-1 and Figure 5-2 respectively. Visually, the TKA population resembled the closest similarities to the healthy adult population at 6 weeks post-surgery where the swing phase apex is beginning to emerge, compared to their preoperative and 1-week postoperative knee flexion patterns.

The TKA population displayed limited knee extension across all three visits compared to both the younger and older healthy adults as well as reduced knee flexion during the stance phase compared to the healthy control groups (Figure 5-1 and Figure 5-2). The TKA population displayed 20° knee flexion at heel strike compared to the 10° knee flexion the healthy population exhibited. However, both Vicon and MotionSense™ were able to accurately trace the movement patterns for all populations and at each stage of recovery for the clinical population.

The greatest difference between the two measurement systems as shown by the grey shaded regions indicating one standard error occurred predominantly during periods of higher knee flexion, with larger differences evidenced in the TKA population compared to both healthy adult cohorts, Figure 5-1 and Table 5-1. Variation within measurements is displayed by the grey shaded regions displaying the standard deviations (Figure 5-2), occurring during the swing phase and at maximum knee flexion for both healthy groups, while larger variation was evident in the TKA cohort during the stance phase and during periods of larger knee flexion.

MotionSense™ more commonly over estimated peak flexion compared to Vicon, while more often underestimated minimum flexion, this is particularly distinct for the TKA population. The greatest difference between Vicon and MotionSense™ was during minimum flexion, recording a maximum difference of -1.18° for the TKA population ($p > 0.05$), while the maximum difference observed for maximum flexion was 1.00° for the older adults ($p > 0.05$). As expected, ROM measures were smaller for the TKA population, however the differences between MotionSense™ and Vicon were greatest in the TKA population compared to the healthy cohort (Table 5-1).

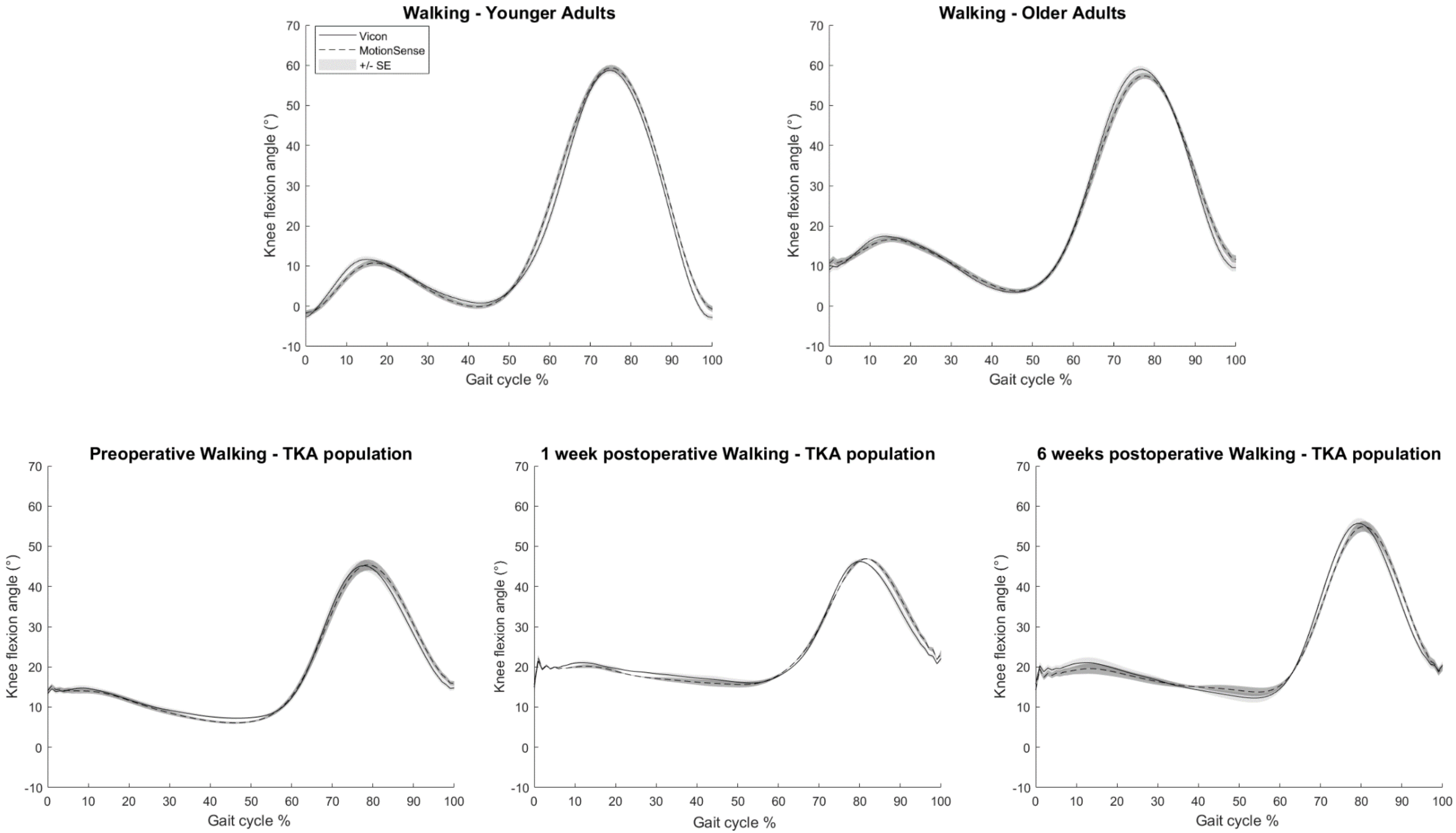


Figure 5-1. Mean knee flexion (SE) from initial contact including the stance and swing phase of the gait cycle.

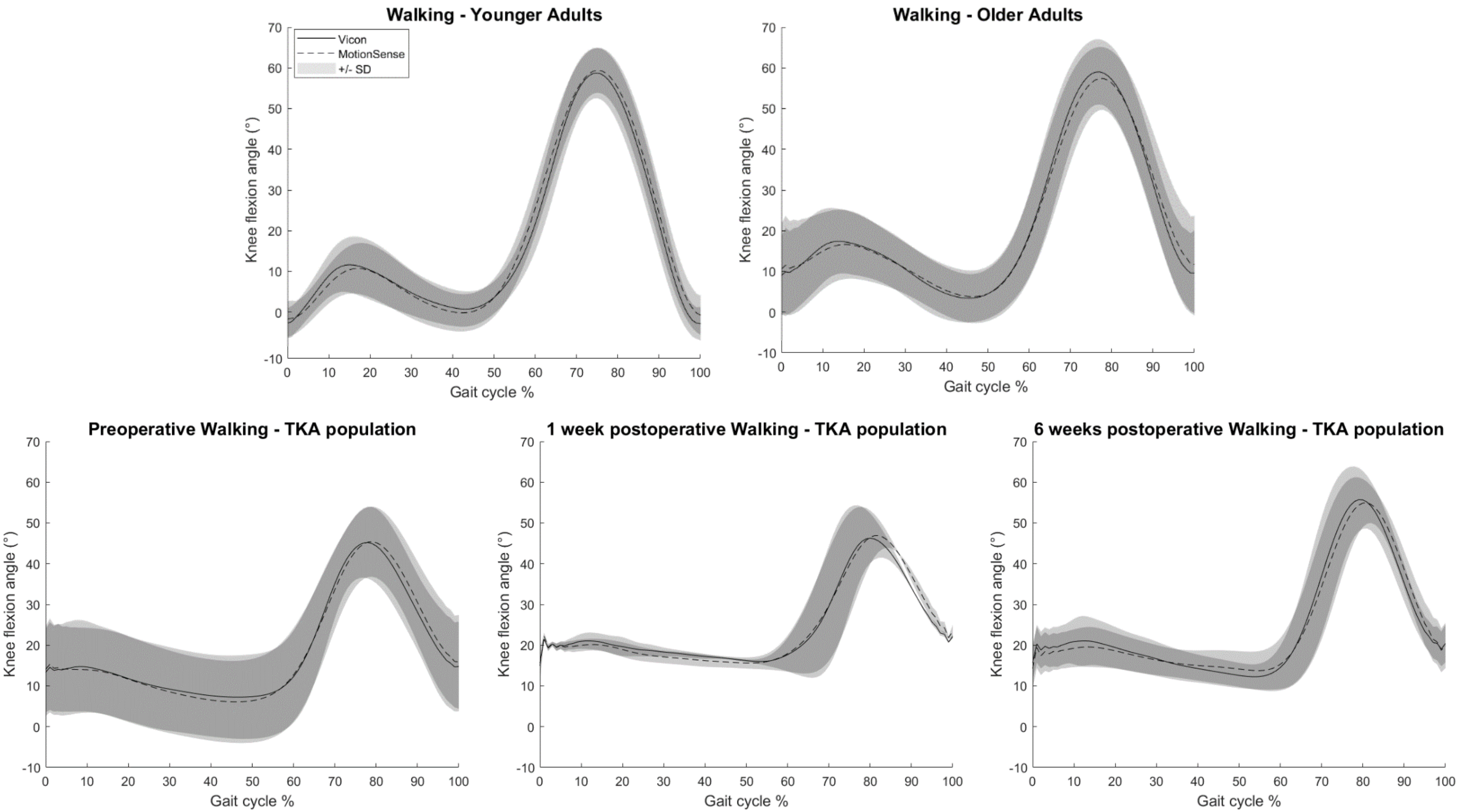


Figure 5-2. Mean knee flexion (SD) from initial contact including the stance and swing phase of the gait cycle.

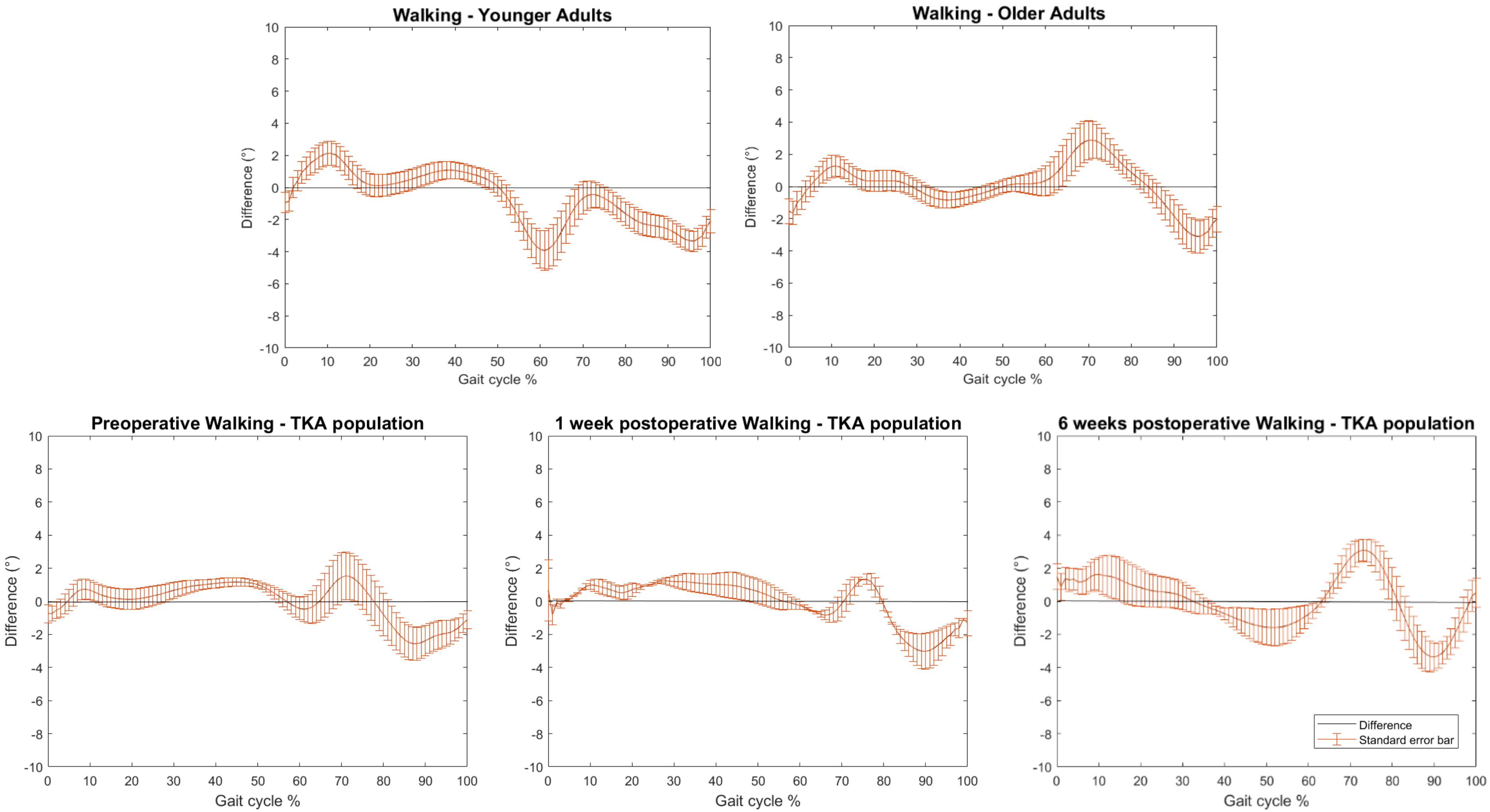


Figure 5-3. Mean signed error between the measurement technologies over whole gait cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by MotionSense™, and a positive difference an underestimation, walking showed a statistically significant difference ($p < 0.05$). between the older and younger adults and between the younger adults and 1-week postoperative session for the TKA group.

Figure 5-3 describes the same signed difference as a function of the gait cycle percentage, with error bars representing one standard error. Similar patterns were observed between the TKA population and the healthy older population, with errors peaking during initial swing at around 70% of the gait cycle.

The largest difference between Vicon and MotionSense™ (-3.93° difference) was observed for the healthy younger adults at 60% of the gait cycle, during pre-swing, just as the limb begins to accelerate. While the older healthy adults reported a maximum difference during the swing phase, reaching a difference of 2.97°. The TKA population reported a maximum difference (-3.72°) at 6 weeks postoperatively, which occurred at around 90% of the gait cycle. The difference between the two technologies never exceeded 4.00° for all population groups.

Table 5-1. Mean knee angle (SD) results for walking for healthy adults and TKA clinical population.

Walking		Knee Angle (°)								
		Max Flexion			Min Flexion			ROM		
		Vicon	***MS***	***Δ***	***Vicon***	***MS***	***Δ***	***Vicon***	***MS***	***Δ***
Healthy Population	Younger Adults	59.4 (6.1)	59.8 (5.5)	-0.4 (8.2)	-3.4 (3.9)	-2.7 (4.4)	-0.7 (6.1)	62.7 (4.7)	62.5 (4.4)	0.3 (2.9)
	Older Adults	59.9 (8.4)	58.8 (7.9)	1.0 (2.9)	2.1 (6.2)	2.1 (7.2)	0.4 (2.3)	57.4 (6.1)	56.7 (5.5)	0.7 (4.3)
	All Healthy Adults	59.6 (7.0)	59.4 (6.7)	0.2 (3.1)	-1.0 (5.8)	-0.7 (6.2)	-0.3 (2.4)	60.6 (5.9)	60.1 (5.6)	0.4 (3.6)
TKA Population	Preoperative	45.5 (8.8)	45.9 (8.3)	-0.5 (3.1)	7.0 (10.3)	5.8 (10.2)	1.2 (0.5)	38.5 (9.7)	40.2 (8.0)	-1.6 (3.6)
	1 Week postop	47.1 (6.2)	47.9 (4.8)	-0.9 (1.4)	15.5 (1.3)	14.3 (3.2)	1.2 (1.9)	31.6 (5.0)	33.6 (1.7)	-2.0 (3.3)
	6 Weeks postop	56.4 (7.1)	55.5 (5.3)	1.0 (2.6)	11.9 (3.3)	13.1 (4.5)	-1.2 (1.6)	44.6 (3.9)	42.4 (0.8)	2.2 (3.3)

Postop: Postoperative, Min: Minimum, Max: Maximum; ROM: Range of Motion; MS: MotionSense™; Δ: difference between Vicon and MotionSense™ (and pooled SD).

The RMSE for walking ranged between 1.48° to 2.57° (Table 5-2) for all population groups. The lowest RMSE value was found in the TKA population at 1-week post-surgery, while the greatest RMSE was evidenced during the preoperative assessment for the TKA population. The RMSE was similar between both the healthy younger adults and the healthy older adults. There was no statistically significant difference in the RMSE values between both the healthy adult groups and the TKA group ($p > 0.05$).

A strong correlation was found between Vicon and MotionSense™ for the healthy cohorts and the TKA population ($p << 0.01$).

Table 5-2. Mean RMSE (SD) results for walking for healthy adults and TKA clinical population.

Walking			
		RMSE (°)	***r***
Healthy Population	*Younger Adults*	2.41 (0.85)	0.98
	Older Adults	2.39 (0.68)	0.99
	All Healthy Adults	2.40 (0.77)	0.99
TKA Population	*Preoperative*	2.57 (1.03)	0.99
	1 Week postop	1.48 (0.47)	0.99
	6 Weeks postop	2.26 (0.95)	0.99

Postop: Postoperative
RMSE: Root Mean Square Error (and SD)
r: Pearson Coefficient of Correlation

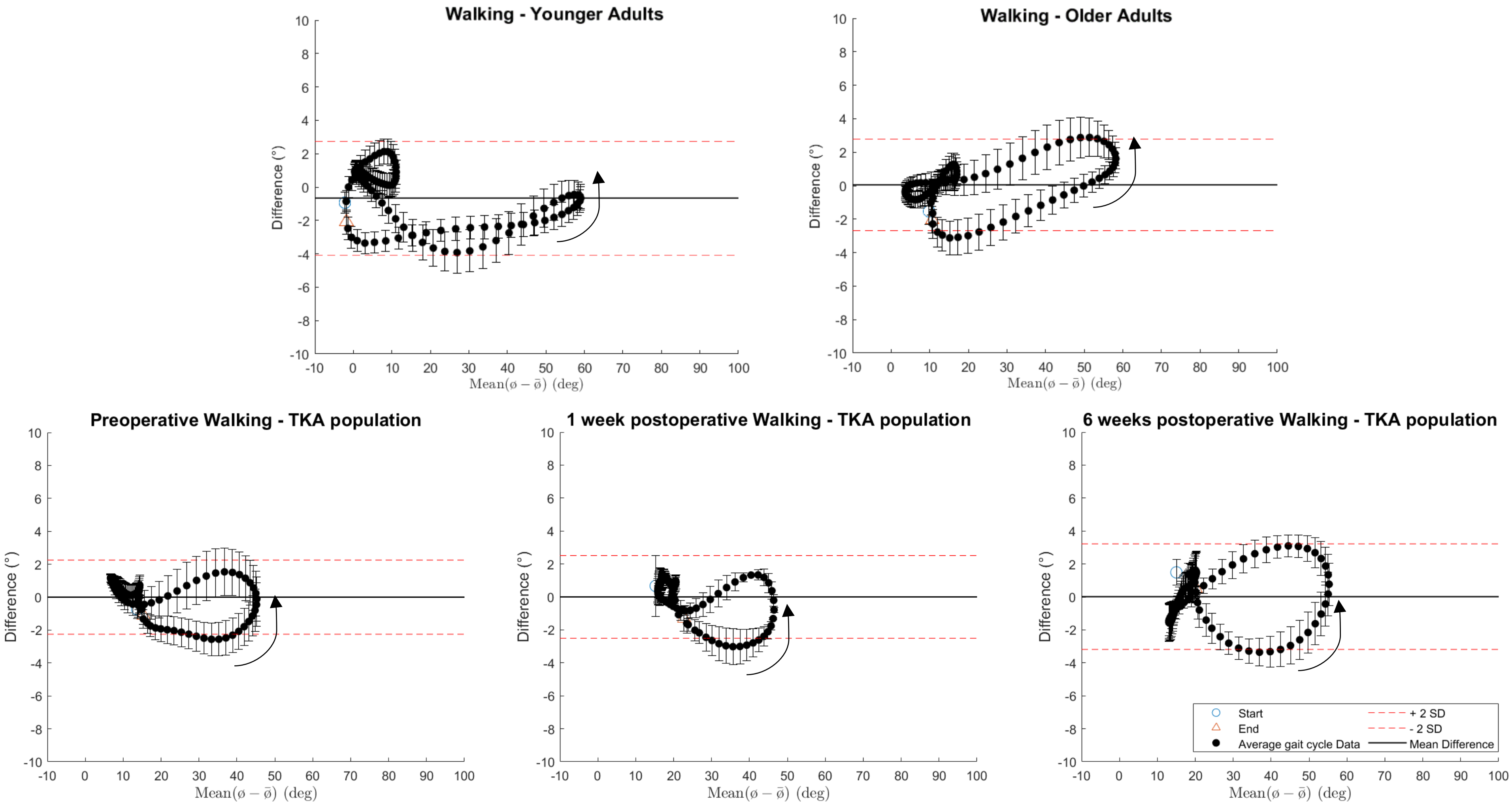


Figure 5-4. Bland-Altman plots of the mean error between the measurement technologies over whole gait cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by MotionSense™, and a positive difference an underestimation.

Figure 5-4 depicts a Bland-Altman plot to assess whether the signed difference between the technologies varied with the mean knee flexion. Larger differences were evidenced when data points exceeded the limits of agreement (red dashed line representing ± 2 standard deviations), however, naturally 5% of the data is expected to be found outside of these limits of agreement, and so these findings are not unexpected. The limits of agreements are narrow in width across all populations, suggesting little variation between the measurement systems. For the healthy adults and TKA cohort the mean difference equals zero or lies very close to zero, indicating no systematic differences between the two technologies. For smaller knee angle measures the differences between the two technologies cluster close to zero. MotionSense™ presents a closer level of agreement in smaller degrees of flexion compared to larger flexion angles, this is evidenced in both the healthy groups and the TKA clinical population.

5.1.2 Stair Navigation Results

To ensure a clear comparison of stair navigation activities, it is essential to consider variations in stair height between the populations, as each group used different sets of stairs depending on which movement analysis laboratory they attended. Additionally, natural variations within each population and differences in individual performance should not be discounted. These factors may contribute to further differences in knee angle measures and patterns and should be taken into account when interpreting the results.

Participants received no specific instructions on stair climbing technique, which led to notable kinematic differences in the manner in which participants navigated the stairs, particularly between the healthy individuals and the TKA population. The TKA group typically used a step-by-step approach to ascend and descend the stairs, often relying on handrails or walking aids, while both healthy populations generally adopted a step-over-step method. There was also no guidance on which foot should lead when initiating the climb.

Knee flexion patterns for stair navigation were similar between the older and the younger healthy adult population, however, differences were observed when comparing both the older and younger healthy populations to the TKA clinical cohort.

The TKA population resembled similarities in knee flexion angle to both healthy populations by 6 weeks postoperatively, for both the stair ascent and descent. However, preoperatively and 1 week postoperatively the TKA population revealed a reduced ROM and peak flexion angle compared to both healthy populations, as well decreased flexion in the stance phase during stair navigation (Figure 5-5 , Figure 5-6, Figure 5-8 and Figure 5-9). Vicon and MotionSense™ were able to accurately trace the movement patterns for both healthy and TKA populations at each period for both stair ascent and descent.

The greatest variation between the two measurement systems as shown by the grey shaded regions indicating the standard errors (Figure 5-5 and Figure 5-8) which are more evident in the TKA clinical population, specifically at 6 weeks following surgery for both stair ascent and stair descent compared to both healthy groups. These differences are especially apparent during periods of higher knee flexion and during periods that involve a dynamic change of velocity, notably during pre-swing.

Variation within measurements is displayed by the grey shaded regions displaying one standard deviation (Figure 5-6 and Figure 5-9). For the stair ascent activity, the TKA population evidenced the greatest variability within measures, particularly during the preoperative assessment. For the stair descent activity, the largest variations were seen in the TKA population at 6 weeks postoperatively. These variations are prominent during stages of deep knee flexion for both the stair ascent and stair decent.

The maximum and minimum flexion angles are detailed in Table 5-3. MotionSense™ more commonly underestimated peak flexion angles and overestimated minimum flexion angles compared to Vicon, for both the older and younger healthy adults and for the TKA population at 6 weeks post-TKA. However, the opposite was observed for the TKA population during their preoperative assessment and at 1-week postoperatively, where MotionSense™ appeared to underestimate minimum flexion angle, and overestimate peak flexion angle.

The difference between Vicon and MotionSense™ was largest in flexion compared to extension, recording a maximum difference of 5.81° for the older healthy adults during the stair descent activity ($p < 0.05$) and of -3.42° between minimum flexion for older adults during stair ascent ($p > 0.05$).

MotionSense™ recorded a smaller ROM compared to Vicon, with larger differences in ROM measures observed in the healthy populations and in the TKA population at 6 weeks postoperatively.

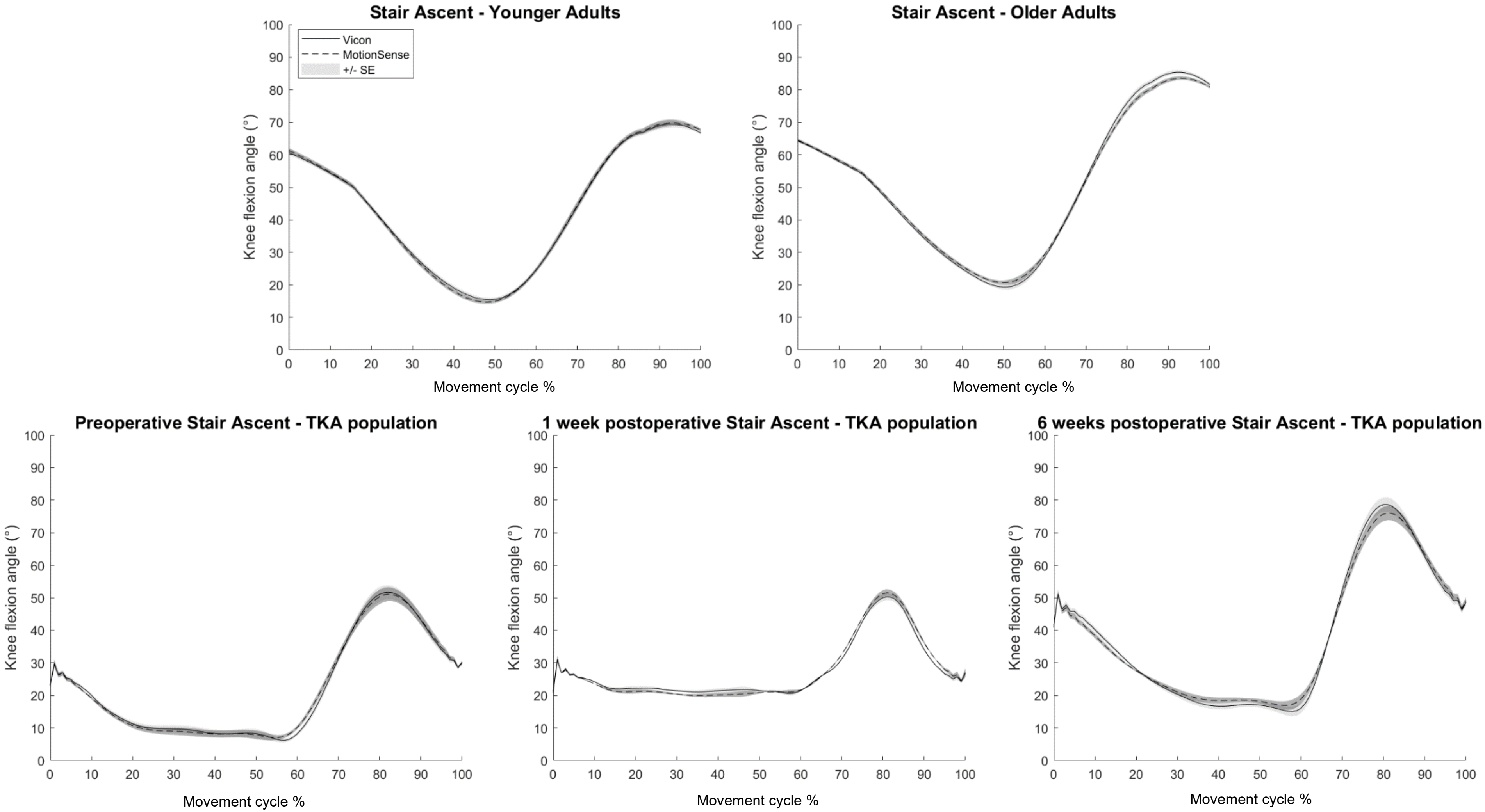


Figure 5-5. Mean knee flexion (SE) from initial contact including the stance and swing phase of the movement cycle.

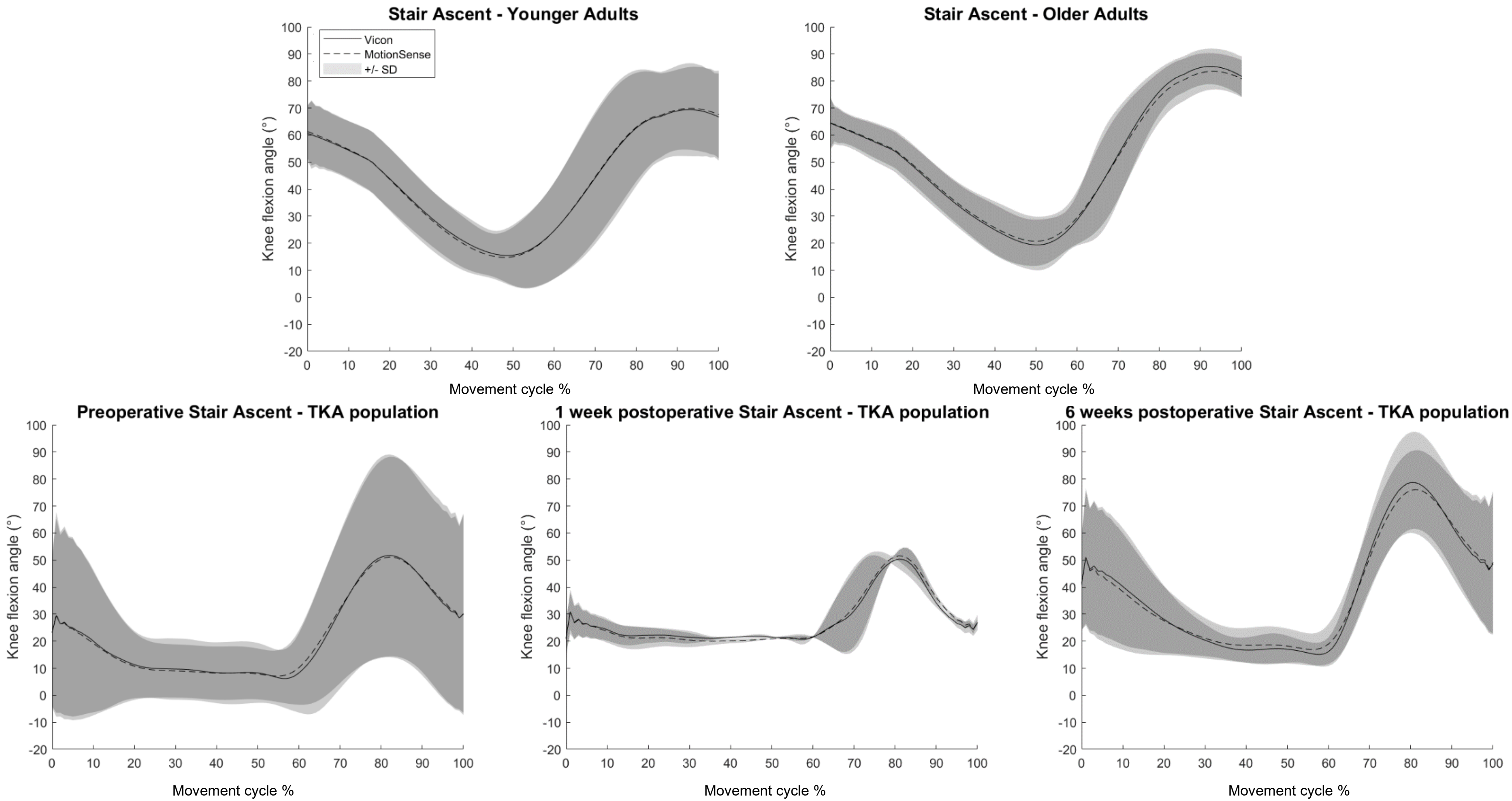


Figure 5-6. Mean knee flexion (SD) from initial contact including the stance and swing phase of the movement cycle.

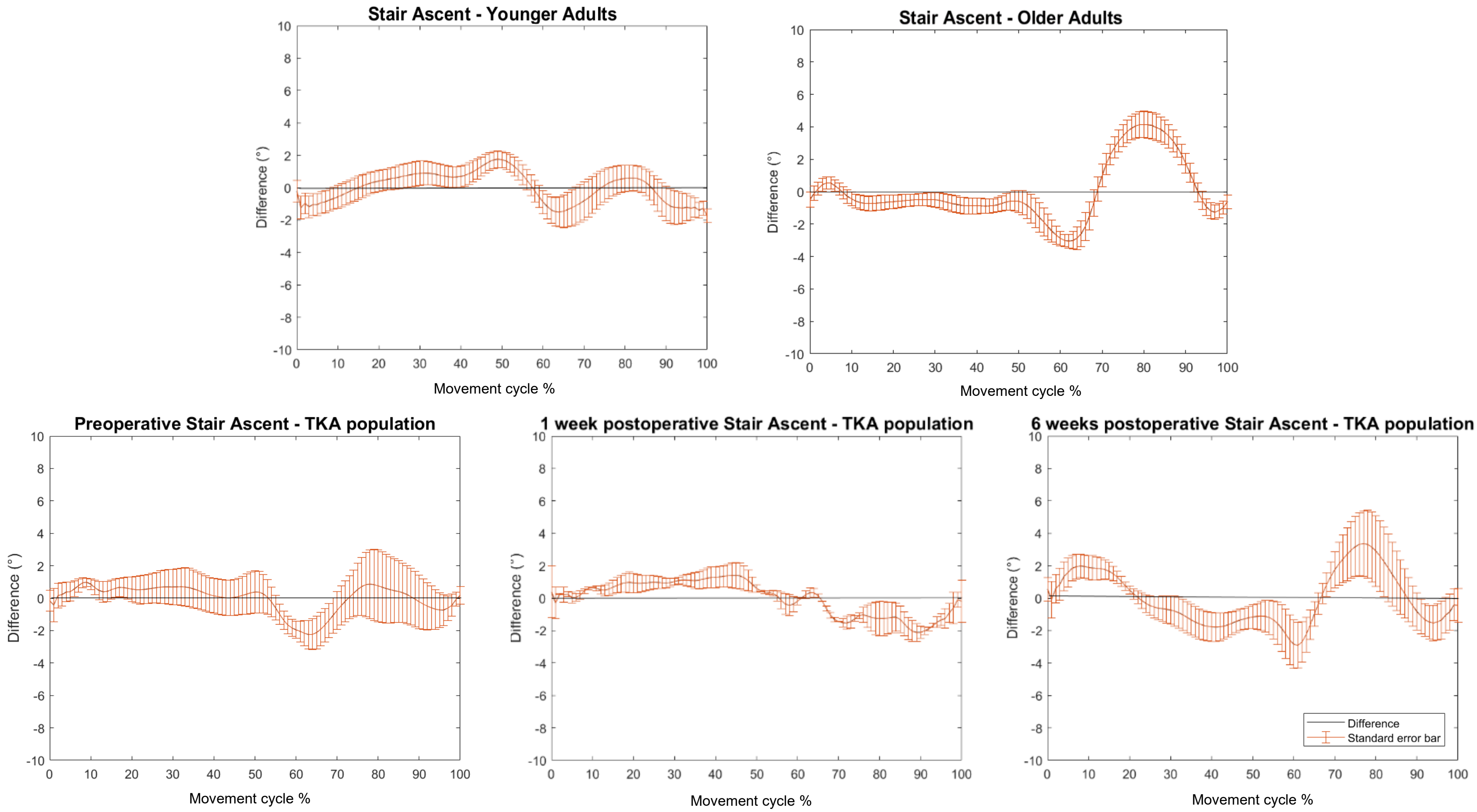


Figure 5-7. Signed error between the measurement technologies over whole movement cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by MotionSense™, and a positive difference an underestimation.

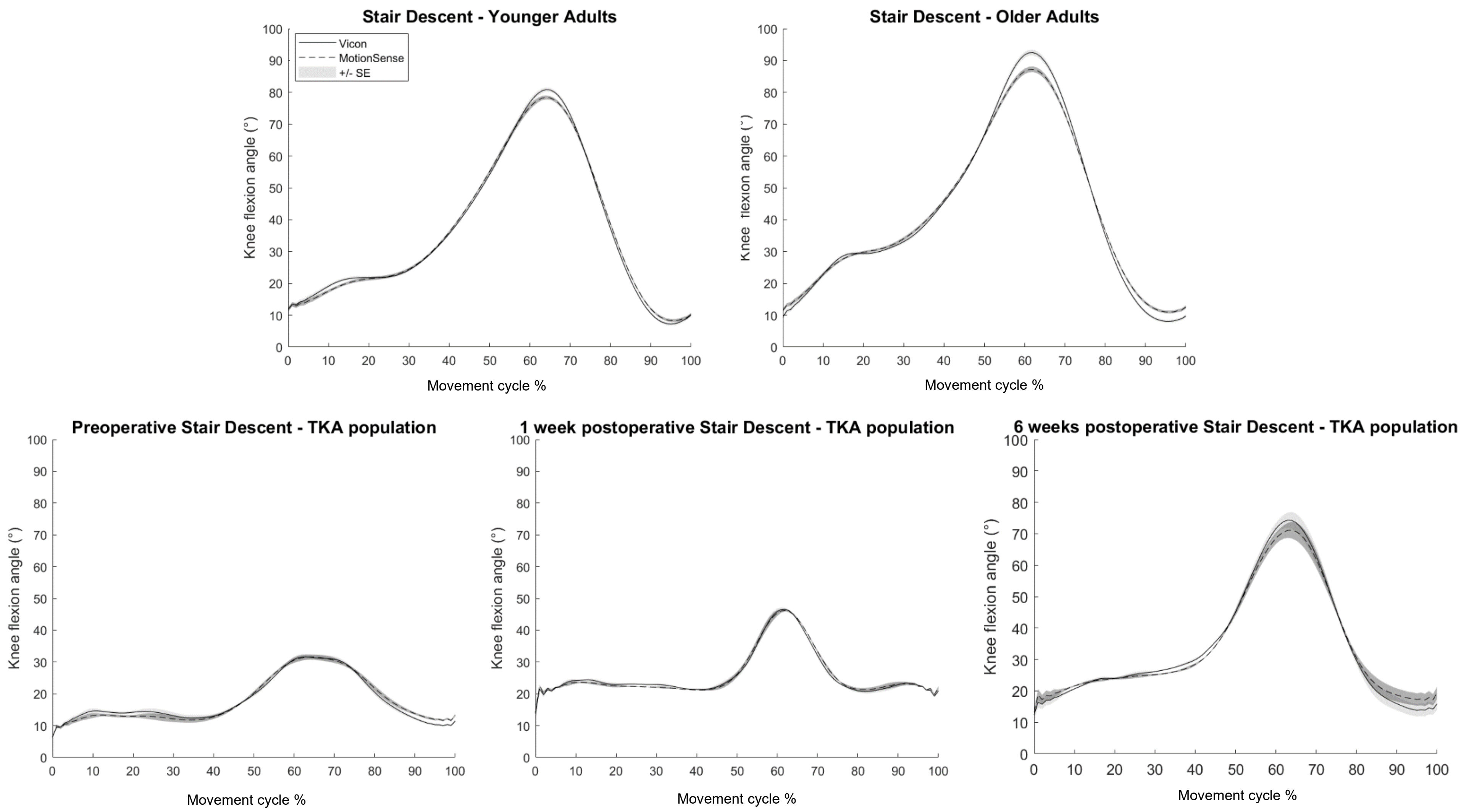


Figure 5-8. Mean knee flexion (SE) from initial contact including the stance and swing phase of the movement cycle.

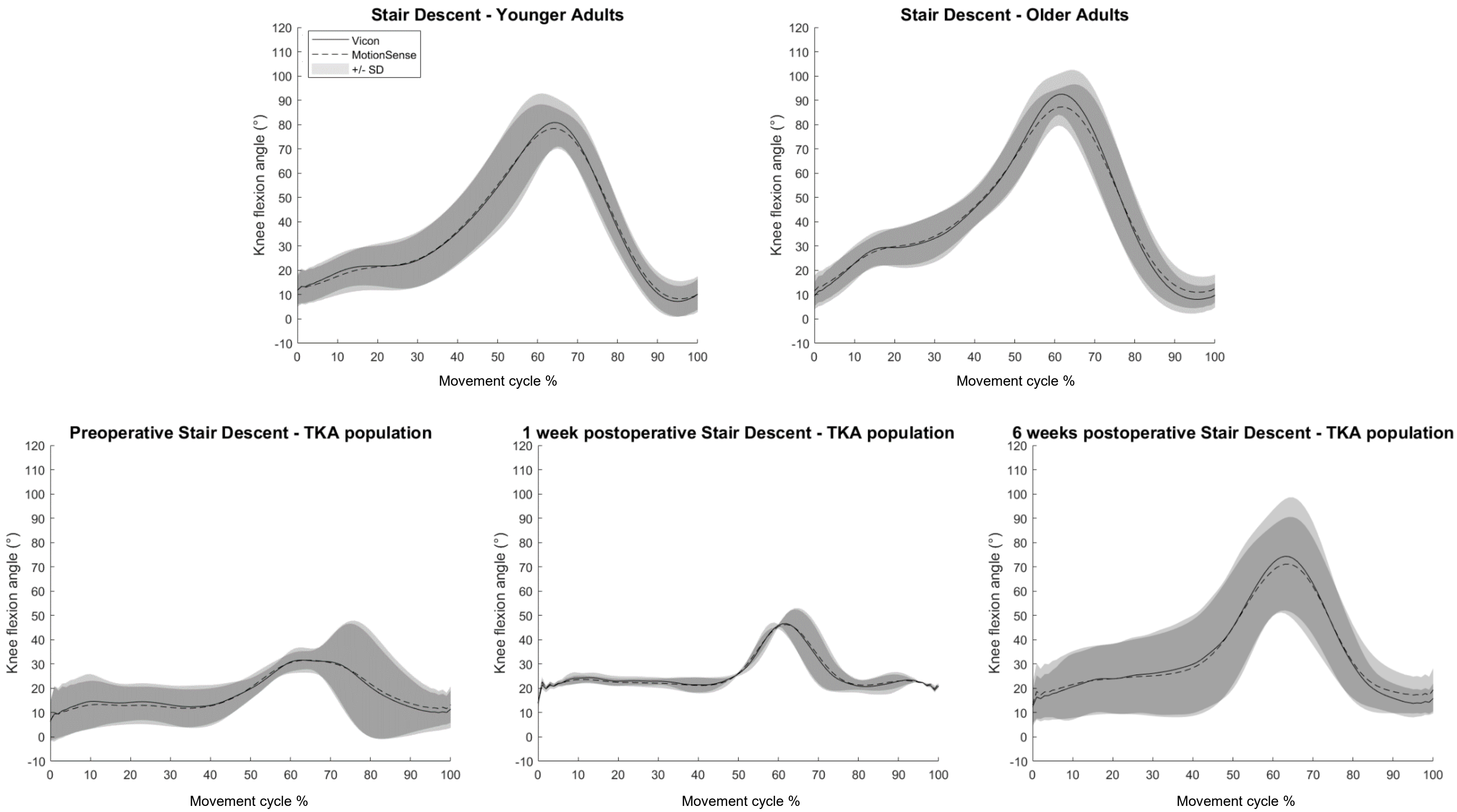


Figure 5-9. Mean knee flexion (SD) from initial contact including the stance and swing phase of the movement cycle.

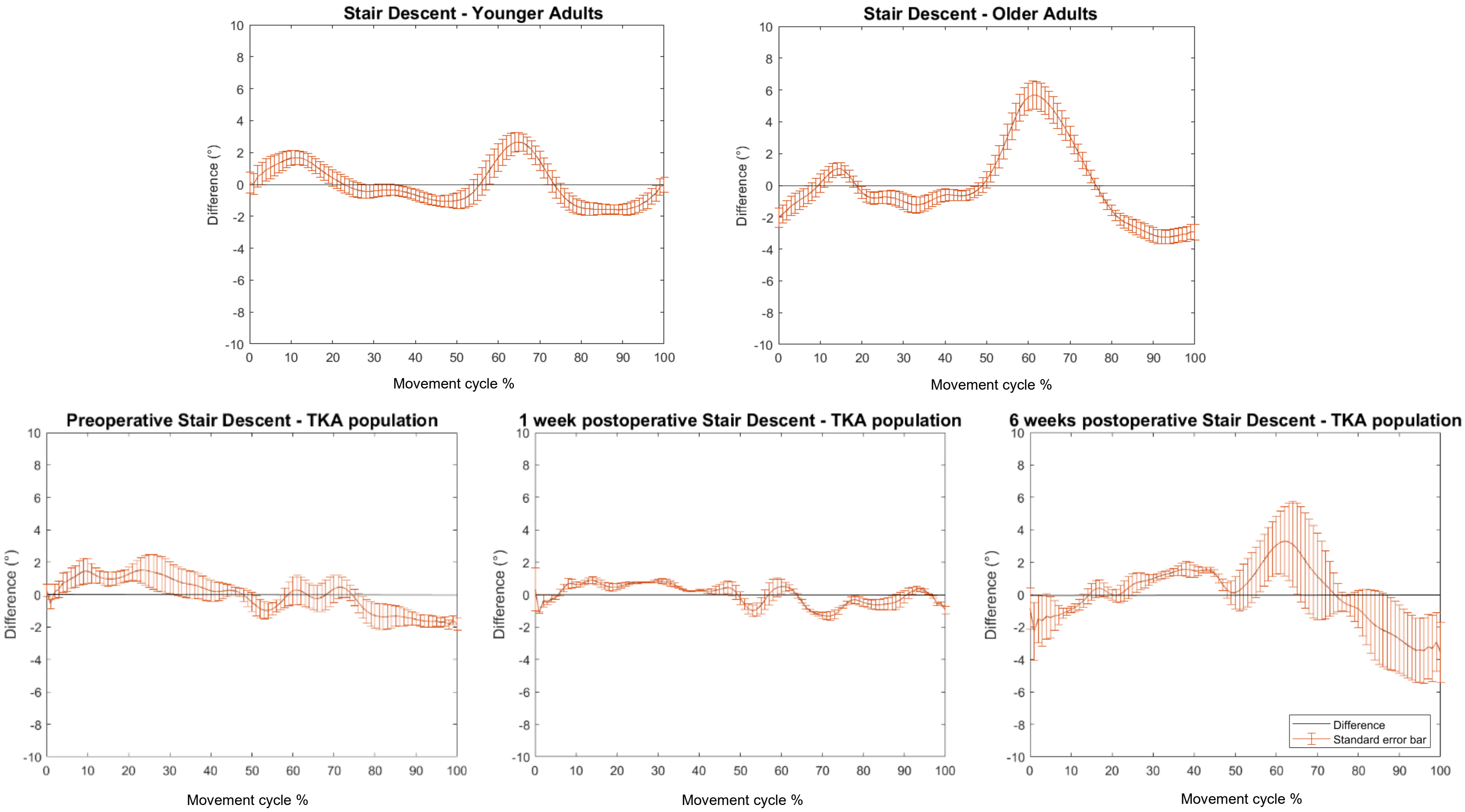


Figure 5-10. Signed error between the measurement technologies over whole movement cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by MotionSense™, and a positive difference an underestimation.

Figure 5-7 and Figure 5-10 describes the same signed difference as a function of the gait cycle percentage. The older healthy adults and the TKA population at 6 weeks post-surgery displayed similar patterns in differences for both the stair ascent and stair descent activity. For the stair ascent activity error peaked during the swing phase, nearing heel strike for both the older healthy population (+4.16° difference) and the TKA population at 6 weeks postoperative (+3.40° difference).

For the stair descent the error peaked around toe off for all populations. The healthy younger adults reported an error of +2.66° while the healthy older adults reported a difference of +5.68°. The TKA population reported a maximum error of 3.80° at 6 weeks postoperative. For both stair ascent and stair descent the maximum error coincides with peak flexion angle for all population groups.

Table 5-3. Mean knee angle (SD) results for all participants for stair navigation.

		Knee Angle (°)								
		Max Flexion			Min Flexion			ROM		
		Vicon	***MS***	***Δ***	***Vicon***	***MS***	***Δ***	***Vicon***	***MS***	***Δ***
Younger Adults	Stair Ascent	87.1 (12.7)	85.8 (11.9)	1.3 (3.6)	6.5 (5.9)	7.1 (6.5)	-0.3 (2.1)	80.3 (13.5)	78.7 (11.9)	1.7 (4.9)
	Stair Descent	85.7 (10.8)	82.1 (9.5)	3.6 (2.5)	6.0 (5.5)	6.6 (5.9)	-0.6 (1.9)	79.7 (11.2)	75.5 (9.0)	4.2 (4.1)
Older Adults	Stair Ascent [a]	97.2 (7.1)	93.4 (8.3)	3.8 (2.2)	10.6 (5.7)	14.0 (6.8)	-3.4 (2.9)	86.6 (4.8)	79.4 (5.6)	7.2 (3.8)
	Stair Descent [a]	97.5 (6.5)	91.5 (7.7)	5.8 (3.1)	6.1 (4.8)	9.7 (6.1)	-2.9 (2.1)	91.0 (4.7)	82.4 (5.8)	8.6 (4.1)
All Healthy Adults	Stair Ascent [a]	91.0 (11.9)	88.3 (11.3)	2.7 (3.4)	8.0 (5.9)	9.7 (7.6)	-1.7 (2.7)	83.0 (11.1)	78.6 (9.9)	4.4 (5.3)
	Stair Descent [ab]	90.7 (10.9)	86.1 (9.9)	4.6 (5.4)	6.3 (5.2)	7.8 (6.1)	-1.6 (2.4)	84.4 (10.5)	78.3 (8.4)	6.1 (4.8)
TKA Preoperative	Stair Ascent	53.6 (34.9)	53.2 (34.7)	-1.3(4.1)	5.3 (10.6)	6.6 (9.4)	0.4(1.33)	48.4 (28.1)	46.6 (27.3)	1.8(5.2)
	Stair Descent	39.5 (8.8)	39.7 (9.6)	-0.2 (1.6)	6.6 (8.2)	6.3 (7.6)	0.3(0.65)	32.9 (2.2)	33.4 (4.1)	-0.5(1.9)
TKA 1 Week postop	Stair Ascent	51.5 (2.7)	52.5 (1.5)	-1.0 (1.1)	18.4 (0.9)	17.6 (2.7)	0.7 (1.8)	33.1 (1.7)	34.9 (1.2)	-1.8 (2.9)
	Stair Descent	48.3 (2.8)	47.7 (4.1)	0.6 (1.3)	14.2 (0.8)	13.9 (2.9)	0.3 (3.7)	34.1 (2.0)	33.8 (7.1)	0.3 (5.1)
TKA 6 Weeks postop	Stair Ascent	78.9 (18.7)	76.3 (5.4)	2.6 (4.3)	13.6 (3.1)	15.9 (14.5)	-2.3 (2.8)	65.3 (17.4)	60.4 (10.7)	4.9 (6.9)
	Stair Descent	74.9 (23.7)	71.5 (19.0)	3.4 (4.9)	12.1 (6.3)	13.2 (8.7)	-1.1 (3.1)	62.8 (22.4)	58.3 (17.4)	4.5 (7.3)

Postop: Postoperative, Min: Minimum, Max: Maximum; ROM: Range of Motion; MS: MotionSense™; Δ: difference between Vicon and MotionSense™ (and pooled SD).
[a]$p<0.05$ between Vicon and MS for range of motion
[b]$p<0.05$ between Vicon and MS for maximum flexion

The RMSE for the stair navigation activity ranged between 0.86° to 2.83° (Table 5-4). For stair ascent RMSE values ranged between 1.13° to 2.77°, while the stair descent activity reported RMSE values between 0.86° to 2.83°.

Smaller RMSE values were reported in the TKA population compared to the healthy population, with the lowest RMSE values reported during the 1-week postoperative assessment for both stair ascent and stair descent. The greatest RMSE was reported during stair descent in the older healthy population.

There were no significant differences between RMSE for the healthy younger and healthy older participants, nor between both healthy populations and the TKA population for the stair navigation activity ($p > 0.05$).

Table 5-4. Mean RMSE (SD) results for all populations for stair navigation.

Stair Navigation Activity				
			RMSE (°)	***r***
Stair Ascent	Healthy Population	Younger Adults	2.77 (0.83)	0.99
		Older Adults	2.60 (0.96)	0.99
		All healthy Adults	2.70 (0.88)	0.99
	TKA Population	Preoperative	2.08 (0.76)	0.99
		1 Week postoperative	1.13 (0.52)	0.99
		6 Weeks postoperative	2.45 (0.89)	0.99
Stair Descent	Healthy Population	Younger Adults	2.41 (0.77)	0.99
		Older Adults	2.83 (0.99)	0.99
		All healthy Adults	2.59 (0.88)	0.99
	TKA Population	Preoperative	1.33 (0.38)	0.99
		1 Week postop	0.86 (0.07)	0.99
		6 Weeks postop	2.62 (1.88)	0.99

Postop: Postoperative, RMSE: Root Mean Square Error (and SD), r: Pearson Coefficient of Correlation.

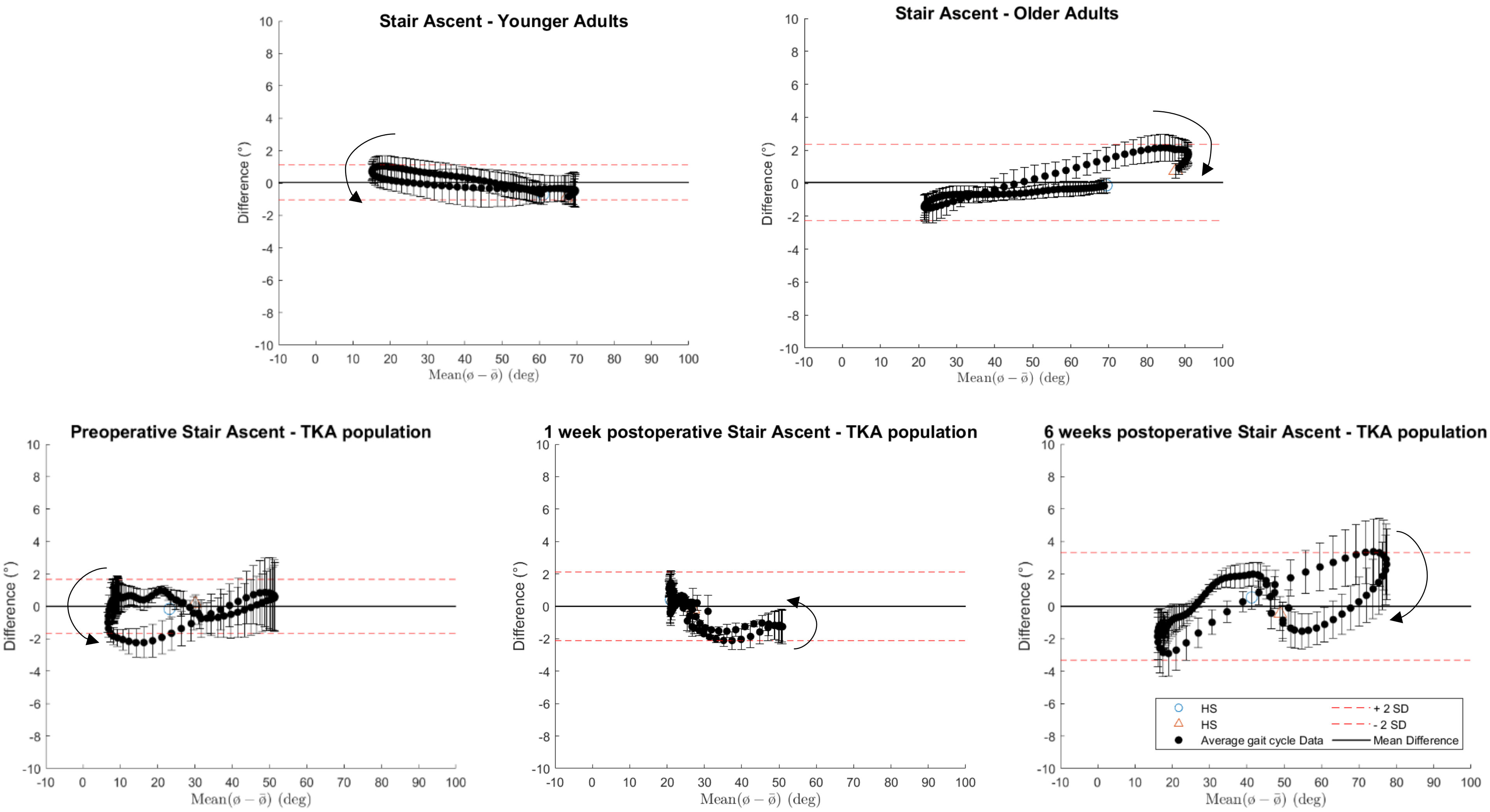


Figure 5-11. Bland-Altman plots of the mean error between the measurement technologies over whole movement cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by MotionSense™, and a positive difference an underestimation.

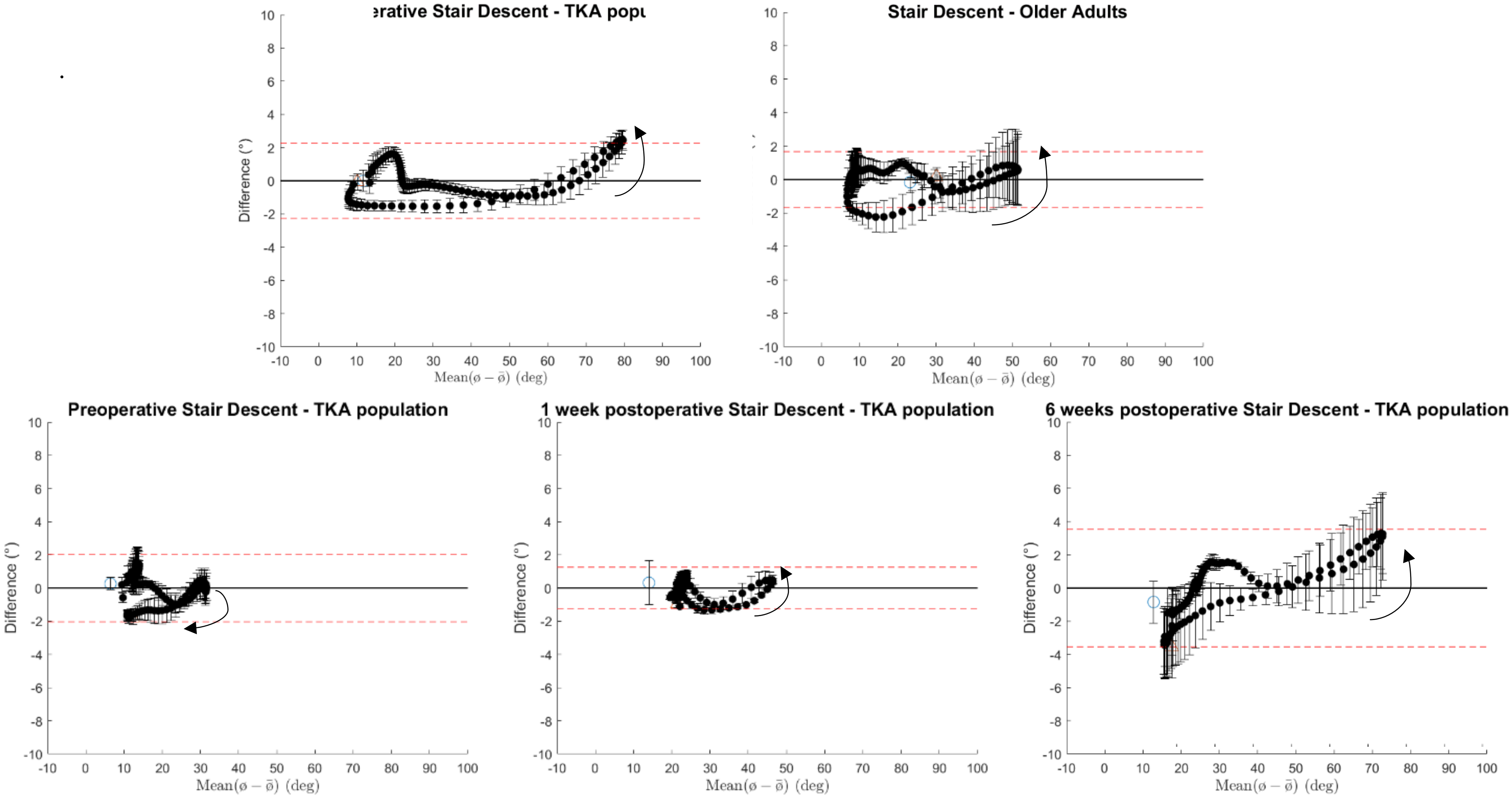


Figure 5-12. Bland-Altman plots of the mean error between the measurement technologies over whole movement cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by MotionSense™, and a positive difference an underestimation.

Figure 5-11 and Figure 5-12 depicts a Bland-Altman plot to assess whether the signed difference between the technologies varied with the mean knee flexion. Differences only surpassed the limits of agreement at higher degrees of flexion (as knee flexion approached 90°) in the older healthy population during the stair descent activity.

Wider limits of agreement and a greater spread of data points were observed for the TKA population at 6 weeks postoperatively, for both the stair ascent and stair descent activity. Whereas data is closely clustered about the mean-difference line for both stair ascent and stair descent for the TKA population 1-week post-surgery. The younger healthy population had narrower limits of agreement for both stair ascent and stair descent compared to the older healthy population. For both stair ascent and stair descent the mean difference line is zero for all populations, indicating no system bias.

5.1.3 Flexion/Extension Results

Each participant completed three flexion/extension repetitions. Comparisons were made between the pooled average of each population. However, no data was available for analysis for the TKA population 1 week postoperatively.

For the TKA population preoperative ROM often depends on the severity of the OA or other issues leading to the surgery, however, many patients experience a reduction in ROM (often less than 100°) and restricted extension due to stiffness, pain and joint degradation (Chiu et al., 2002). Moreover, patients often experience a temporary reduction in ROM following TKA as a result of pain, swelling and stiffness. However, as the patient recovers and postoperative symptoms subside, joint ROM should improve. This is highlighted in Figure 5-13 and Figure 5-14, where preoperative peak flexion is restricted for the TKA population compared to the healthy populations, while postoperative peak flexion and extension is limited compared to preoperative baseline measures. Apart from the reduction in joint ROM, knee flexion patterns were similar between the healthy populations and TKA group (Figure 5-13 and Figure 5-14). Additionally, knee flexion patterns were similar between both technologies.

Differences between measurement systems, as shown by the grey shaded regions indicating one standard error (Figure 5-13), occurred mainly during stages of greater knee flexion or during instances of rapid motion, with the TKA population reporting larger differences compared to the healthy population.

While variation within each population is highlighted by the grey shaded region representing one standard deviation (Figure 5-14). Larger variations within the populations were reported at maximum flexion, with the TKA population displaying greater deviations within data compared to both healthy groups.

The maximum and minimum flexion angles are detailed in Table 5-5. The largest difference between Vicon and MotionSense™ was reported during maximum flexion by the older healthy adults, with a difference of 6.98°, ($p < 0.05$). Older healthy adults reported the largest difference between the measurement systems for minimum flexion angle, reporting a difference of -2.70°, ($p > 0.05$). MotionSense™ was more accurate when reporting smaller angles compared to larger angles of flexion. Furthermore, MotionSense™ tended to underestimated knee angle measures for larger degrees of flexion, while overestimated angles during minimum flexion.

Notably, there is a significant discrepancy in minimum flexion angle between the groups. Six weeks post-surgery, the TKA population exhibited a much higher minimum flexion angle compared to both their baseline measurements and the healthy control populations Figure 5-13 and Table 5-5.

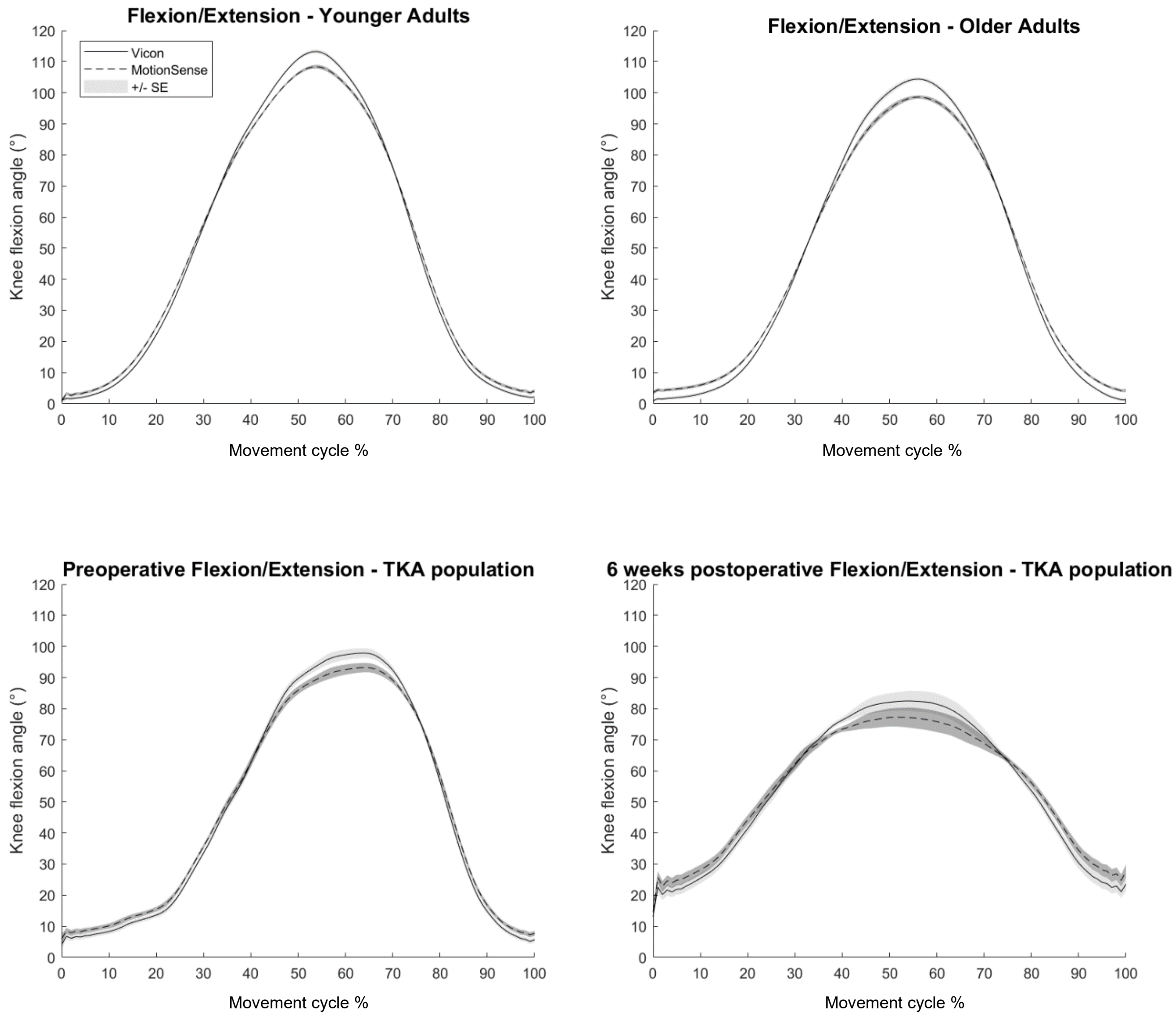


Figure 5-13. Mean knee flexion (SE) from initial contact including maximum flexion and full extension.

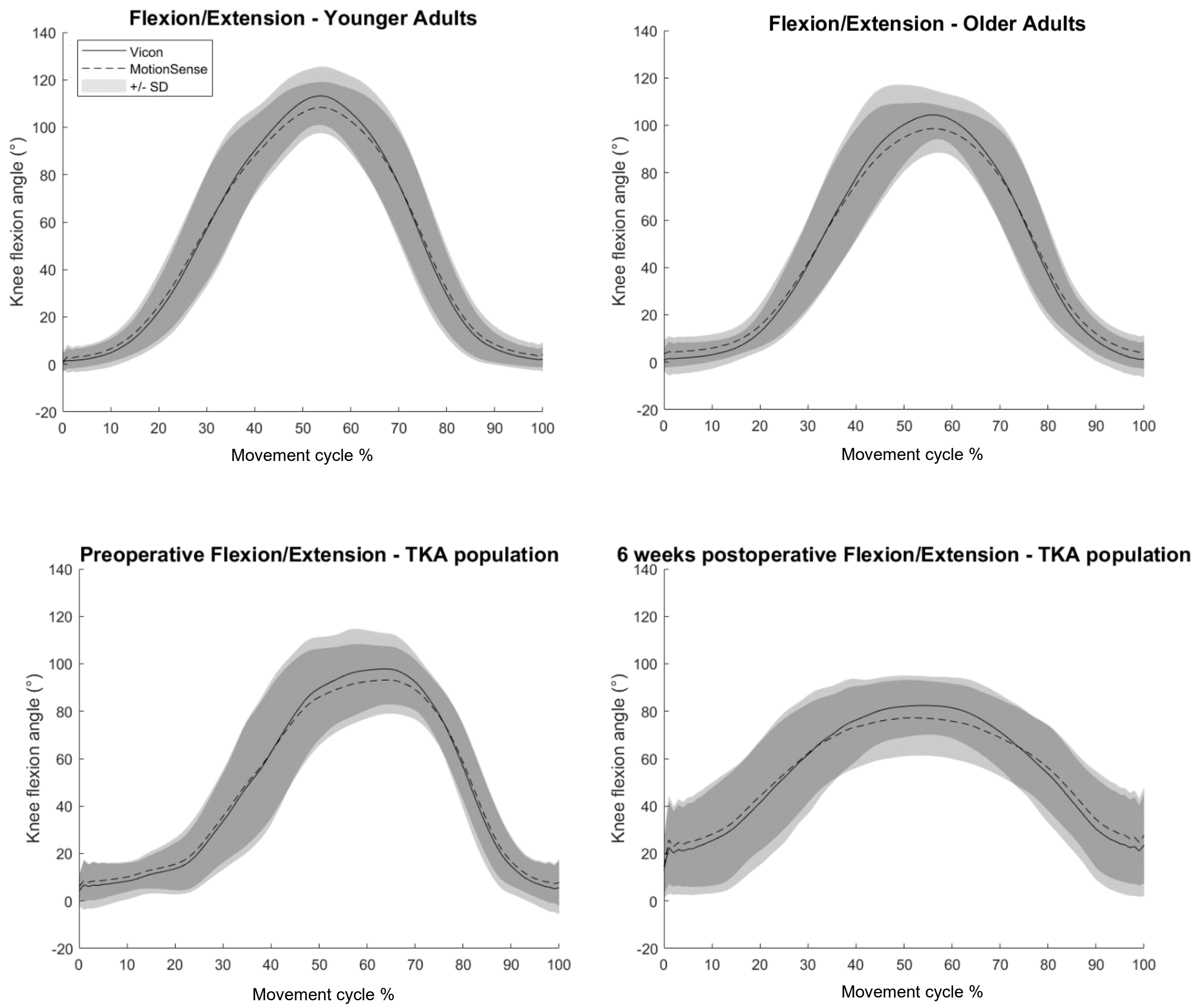


Figure 5-14. Mean knee flexion (SD) from initial contact including maximum flexion and full extension.

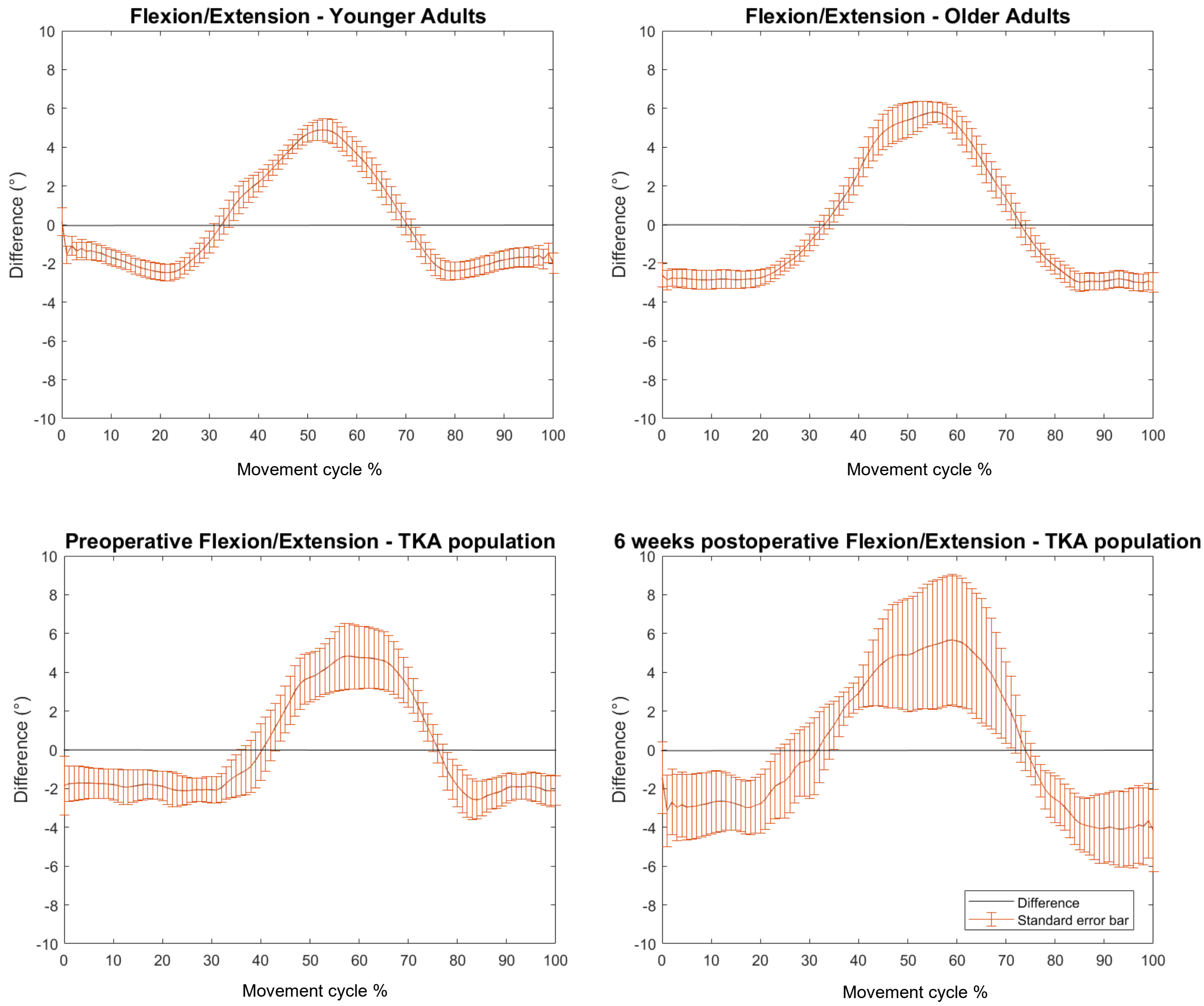


Figure 5-15. Signed error between the measurement technologies over whole movement cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by MotionSense™, and a positive difference an underestimation.

Figure 5-15 displays the mean signed error across the complete activity cycle. The same trend was displayed within both healthy groups and the TKA population, revealing greater differences around ~50% of the gait cycle during peak flexion.

For the healthy population the error peaked at maximum flexion (~50% of the gait cycle), reaching a maximum difference at 53% of the gait cycle in the younger population (+4.89° difference) and 56% of the gait cycle for the older adults (+5.08° difference), respectively. While the TKA population displayed the largest difference, during peak flexion (50 - 70% of the cycle) reaching a maximum error of (+5.61° difference) reported at 6 weeks postoperatively.

The largest differences are reported at maximum knee flexion, with a positive difference reported for all populations, highlighting that MotionSense™ underestimates peak flexion angles compared to Vicon (Table 5-5).

Table 5-5. Mean knee angle (SD) results for healthy and TKA populations for the flexion/extension activity.

		Knee Angle (°)								
		Max Flexion			**Min Flexion**			**ROM**		
		Vicon	***MS***	***Δ***	***Vicon***	***MS***	***Δ***	***Vicon***	***MS***	***Δ***
Younger Adults	Flexion/ Extension	116.6 (11.4)	110.9 (10.2)	5.8 (2.2)	0.1 (4.2)	0.1 (4.2)	0.0 (2.6)	116.5 (13.1)	110.8 (10.4)	5.7 (4.5)
Older Adults	Flexion/ Extension[ab]	108.8 (7.9)	101.8 (7.8)	7.0 (2.8)	-0.1 (5.8)	2.6 (5.9)	-2.7 (1.9)	108.9 (9.8)	99.3 (9.2)	9.5 (4.0)
All Adults	Flexion/ Extension	113.1 (10.6)	106.0 (10.1)	6.3 (2.4)	0.0 (4.9)	1.2 (5.1)	0.2 (3.1)	113.1 (12.2)	105.6 (11.3)	2.0 (8.1)
TKA Preoperative	Flexion/ Extension	99.7 (15.9)	94.5 (14.6)	5.2 (3.7)	2.7 (8.4)	4.32 (6.1)	-1.6 (3.1)	97.0 (19.8)	90.2 (17.7)	6.8 (6.2)
TKA 6 Weeks postop	Flexion/ Extension[a]	83.2 (12.0)	77.6 (15.8)	5.6 (7.5)	12.9 (12.2)	14.6 (11.7)	-1.7 (4.6)	70.4 (15.2)	63.0 (16.8)	7.4 (11.7)

Postop: Postoperative, Min: Minimum, Max: Maximum; ROM: Range of Motion; MS: MotionSense™; Δ: difference between Vicon and MotionSense™ (and pooled SD)
[a]$p<0.05$ between Vicon and MS for range of motion
[b]$p<0.05$ between Vicon and MS for maximum flexion

The RMSE ranged between 3.21° to 4.70° (Table 5-6), with the largest RMSE reported for the TKA population 6 weeks postoperatively, while the smallest RMSE value was reported preoperatively. A maximum difference of 1.49° was reported between the RMSE values preoperatively vs 6 weeks postoperatively for the TKA population.

There were no significant differences in RMSE values between the younger and older healthy participants or the TKA population ($p > 0.05$).

A positive strong correlation is displayed for all populations for flexion/extension activity, Table 5-6.

Table 5-6. Mean RMSE (SD) results for flexion/extension for healthy adults and the TKA population.

			RMSE (°)	**r**
Flexion/ Extension	*Healthy Population*	Younger Adults	3.65 (1.24)	0.99
		Older Adults	4.09 (1.62)	0.99
		All Adults	3.85 (1.42)	0.99
	TKA Population	Preoperative Assessment	3.21 (1.75)	0.99
		6 Weeks postop	4.70 (3.41)	0.99

Postop: Postoperative
RMSE: Root Mean Square Error (and SD)
r: Pearson Coefficient of Correlation

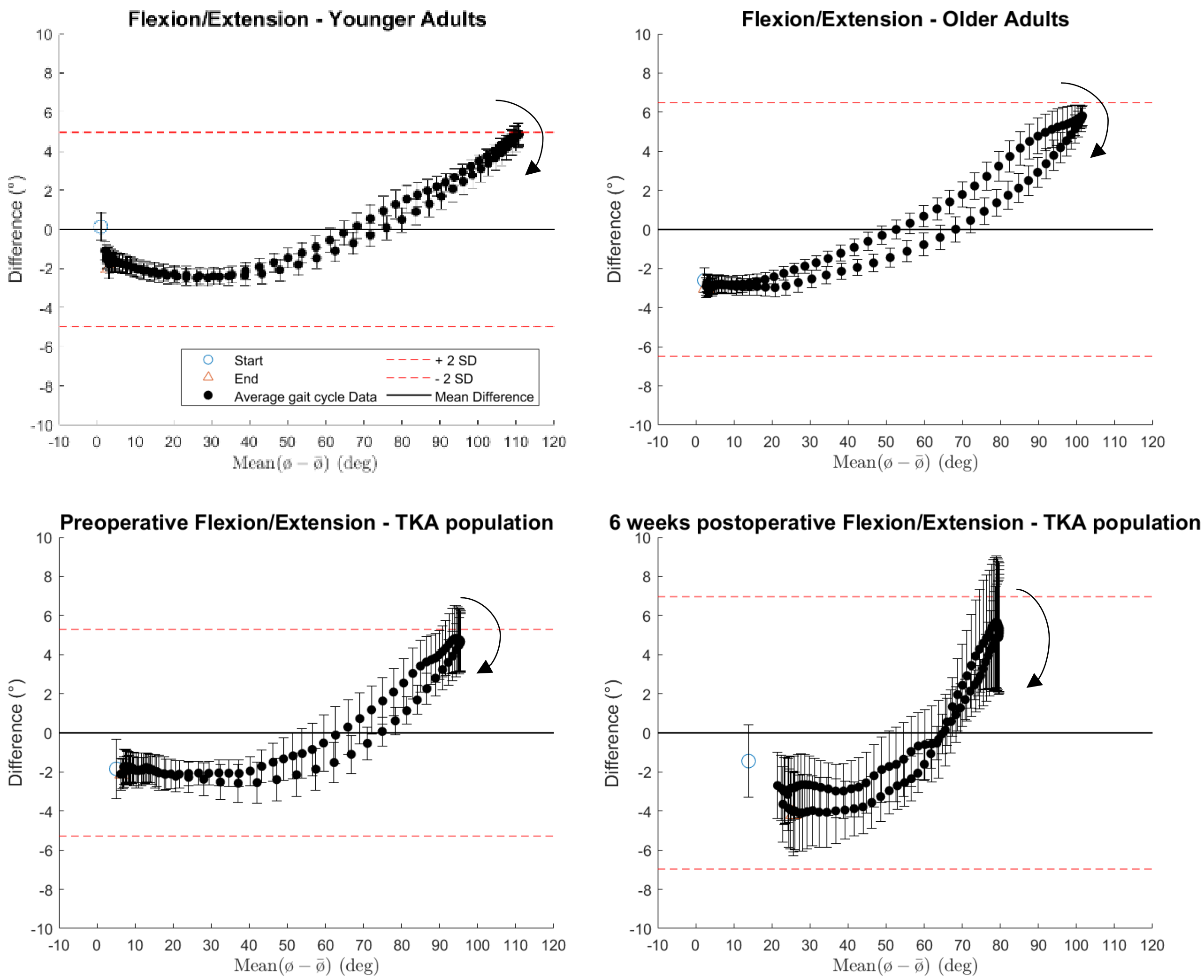


Figure 5-16. Bland-Altman plots of the mean error between the measurement technologies over whole movement cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by MotionSense™, and a positive difference an underestimation.

Figure 5-16 depicts a Bland-Altman plot to assess whether the signed difference between the technologies varied with the mean knee flexion. Wider limits of agreement were observed, suggesting a lower degree of agreement between the measurement systems as there is a greater spread between measurement. The mean difference line is zero for all populations for the flexion/extension activity, indicating no bias between Vicon and MotionSense™.

Good agreement was found between Vicon and MotionSense™ for both the healthy and TKA populations. All data points were found within the acceptable limit bounds, though these bounds were wide. The healthy populations showed a tighter clustering of data points compared to the TKA population. Additionally, a consistent trend was observed across all groups: at higher degrees of flexion, MotionSense™ underestimate knee angle measures, while at smaller knee flexion angles, MotionSense™ overestimated the values, as indicated by positive and negative differences, respectively.

5.1.4 Cycling Results

The TKA population did not participate in the cycling activity and so no clinical data will be presented for this activity. However, both groups of healthy adults completed two minutes of comfortable cycling. For each participant, ten pedal strokes were analysed, and pooled averages were calculated for both younger and older healthy adults. These averages were then compared between the groups.

Knee flexion patterns between the two technologies were similar across both the younger and older adults (Figure 5-17 and Figure 5-18). The greatest disparity within the groups, as shown by the grey shaded region indicating the SE between the measurement systems, occurred during stages of higher knee flexion or during instances of faster joint accelerations (Figure 5-17). While variation within the populations is shown by the grey shaded region representing one standard deviation (Figure 5-18).

For both the healthy younger and older adults, MotionSense™ recorded smaller ROM and lower maximum flexion values compared to Vicon. Furthermore, larger differences were observed for the older population compared to the younger adults ($p > 0.05$). The difference between Vicon and MotionSense™ was greatest in flexion compared to extension (Table 5-7), recording a maximum difference of 5.72° between maximum flexion ($p > 0.05$) and -3.10° between minimum flexion for older adults ($p > 0.05$). Older participants pedalled at a significantly slower cadence than younger participants (67.99 ± 9.01 rpm vs. 60.25 ± 9.98 rpm, mean ± SD, $p < 0.05$, younger vs older adults respectively).

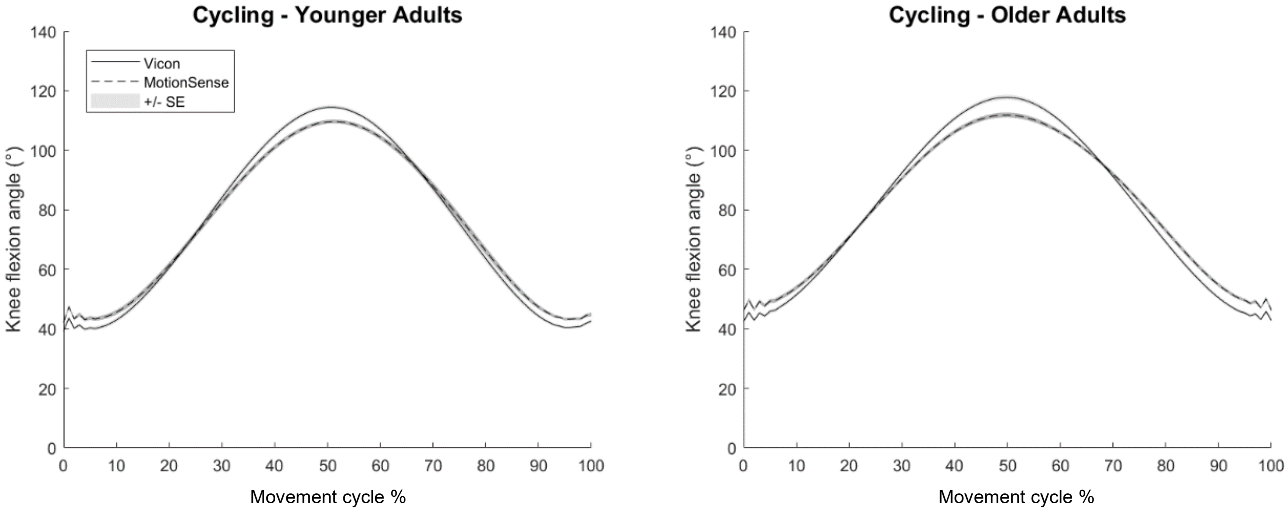


Figure 5-17. Mean knee flexion (SE) from full extension to full extension cycle for a pedal stroke.

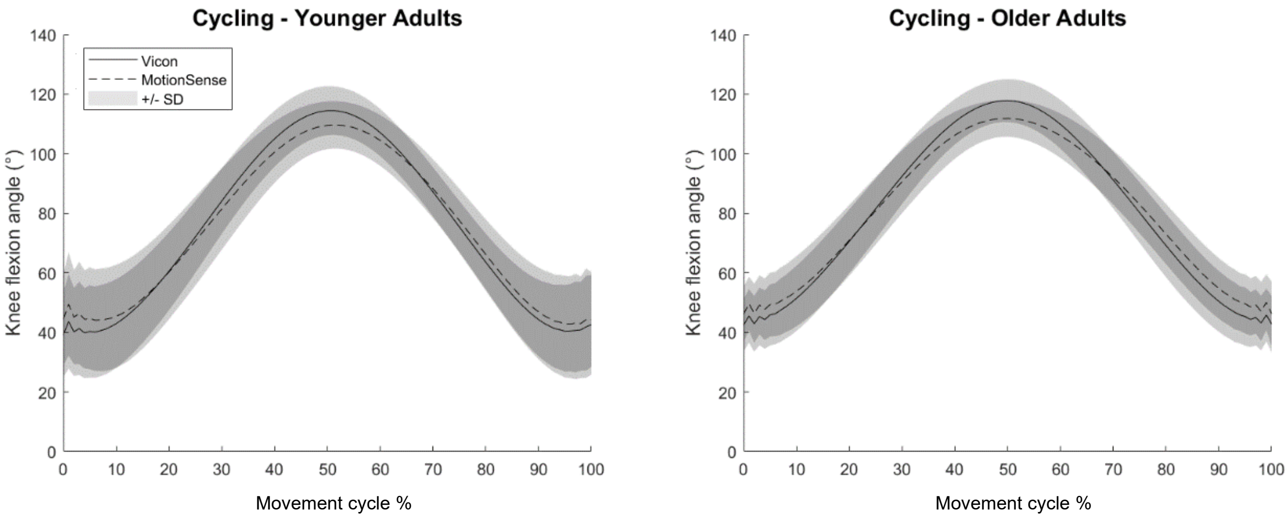


Figure 5-18. Mean knee flexion (SD) from full extension to full extension cycle for a pedal stroke.

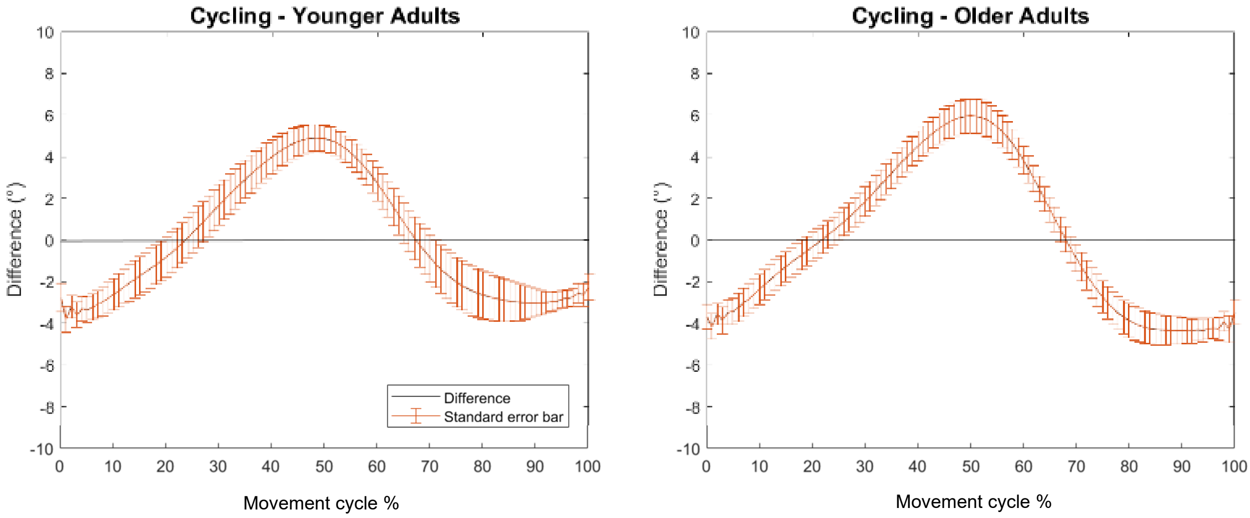


Figure 5-19. Signed error between the measurement technologies over whole pedal cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by MotionSense™, and a positive difference an underestimation.

Figure 5-19 describes the signed difference as a function of the gait cycle percentage. During cycling the error peaked at maximum flexion, when the pedal was at the 12 o' clock position (50% gait cycle) for older adults (+5.96° difference), and at 49% of the gait cycle for younger adults (4.90° difference). For both healthy groups maximum error coincides with peak flexion or at points where movements are associated with higher accelerations.

Table 5-7. Mean knee angle (SD) results for healthy adults for cycling.

		Knee Angle (°)								
		Max Flexion			**Min Flexion**			**ROM**		
		Vicon	***MS***	***Δ***	***Vicon***	***MS***	***Δ***	***Vicon***	***MS***	***Δ***
Cycling	Younger Adults	114.6 (8.2)	110.0 (7.8)	4.6 (2.6)	37.6 (14.4)	39.6 (14.9)	-2.0 (1.9)	77.0 (7.8)	70.5 (9.5)	6.5 (3.8)
	Older Adults	118.1 (7.0)	112.4 (6.2)	5.7 (2.4)	40.7 (9.1)	43.9 (10.5)	-3.1 (1.7)	77.3 (4.8)	68.5 (5.6)	8.8 (3.5)
	All Adults	115.7 (7.9)	110.7 (13.6)	4.9 (2.5)	38.6 (12.9)	40.9 (13.3)	-1.2 (2.6)	77.1 (7.0)	69.9 (8.4)	7.5 (4.3)

Min: Minimum, Max: Maximum; ROM: Range of Motion; MS: MotionSense™; Δ: difference between Vicon and MotionSense™ (and pooled SD)

Table 5-8. Mean RMSE (SD) results for cycling for younger and older adults.

	Cycling	
	RMSE (°)	***r***
Younger Adults	4.05 (2.49)	0.99
Older Adults	4.57 (1.46)	0.99
All Adults	4.22 (2.21)	0.99

RMSE: Root Mean Square Error (and SD)
r: Pearson Coefficient of Correlation

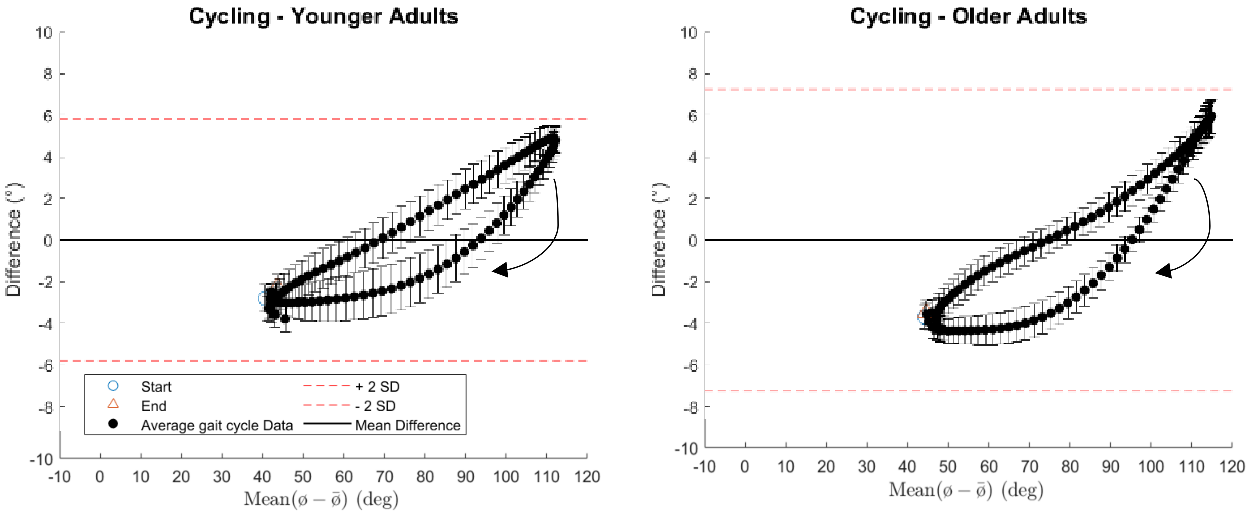


Figure 5-20. Bland-Altman plots of the mean error between the measurement technologies over whole movement cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by MotionSense™, and a positive difference an underestimation.

The RMSE for both healthy age groups ranged between 4.05° to 4.57° (Table 5-8). The RMSE was smaller for younger adults, with a maximum discrepancy of 0.52° between the younger and older adults. There were no significant differences between RMSE for the healthy participants ($p > 0.05$). Both healthy populations displayed a strong positive coefficient of correlation.

Figure 5-20 depicts a Bland-Altman plot to assess whether the signed difference between the technologies varied with the mean knee flexion. Differences between the measurement systems never exceeded the limits of agreement represented by ± 2 standard deviations. However, larger differences between MotionSense™ and Vicon were evident at higher degrees of knee flexion. Furthermore, positive differences were observed during periods of greater flexion, while negative differences were presented at lower flexion angles. This indicates that MotionSense™ underestimates peak flexion angles, while overestimates smaller angles during the cycling activity.

5.1.5 Get up and Go Results

This section details the accuracy of the MotionSense™ device compared to Vicon during the "Get Up and Go" activity for younger healthy adults. To facilitate analysis, the activity was divided into two key movements: sit-to-stand and stand-to-sit. For each participant, one sit-to-stand and one stand-to-sit movement were analysed, and the average results across the entire group were compared.

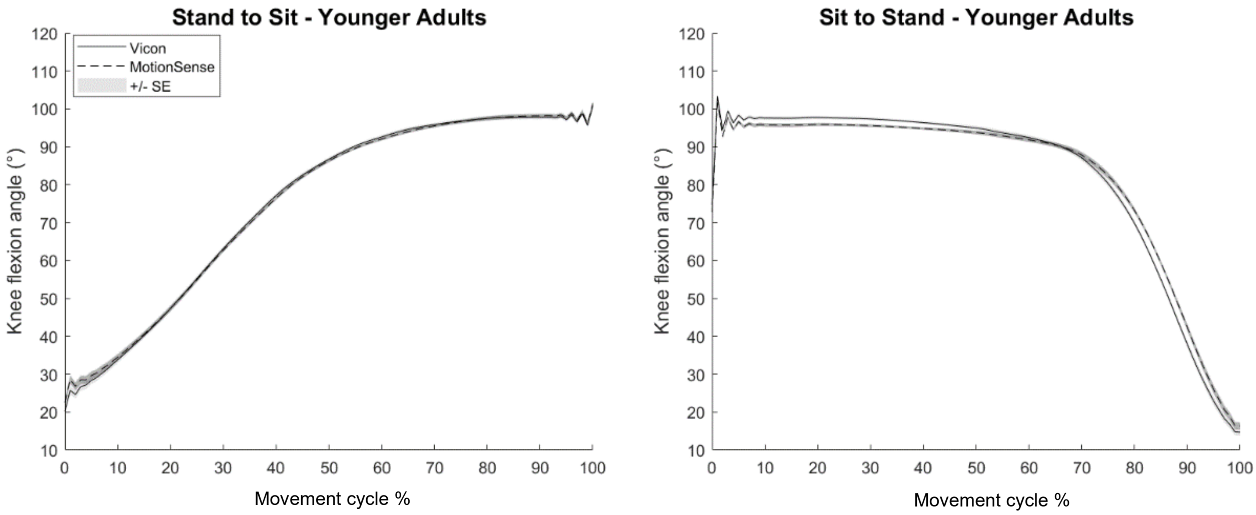


Figure 5-21. Mean knee flexion (SE) for complete sit to stand and stand to sit activity.

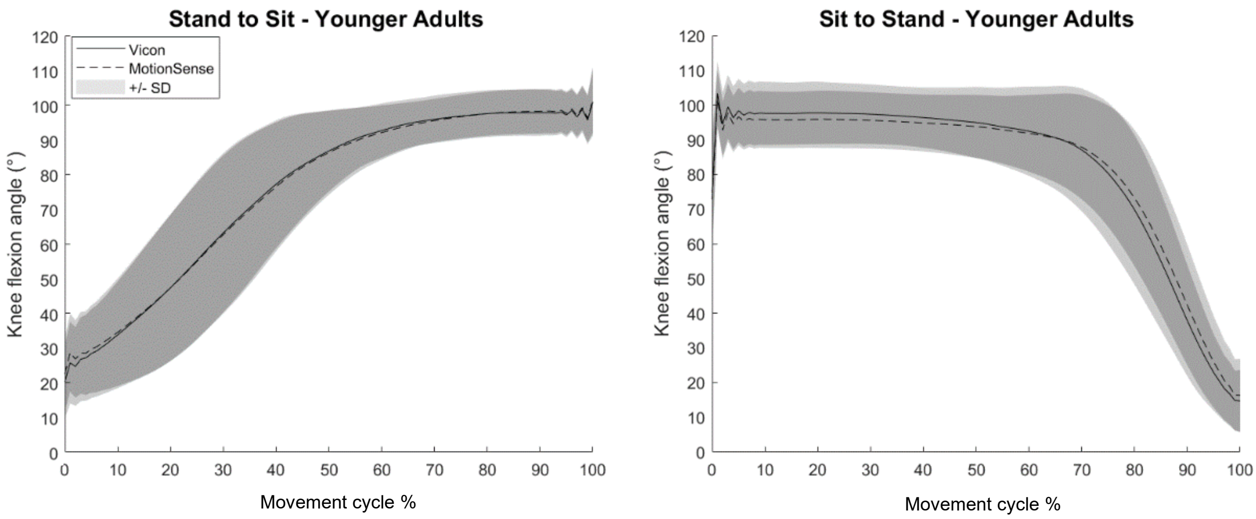


Figure 5-22. Mean knee flexion (SD) for complete sit to stand and stand to sit activity.

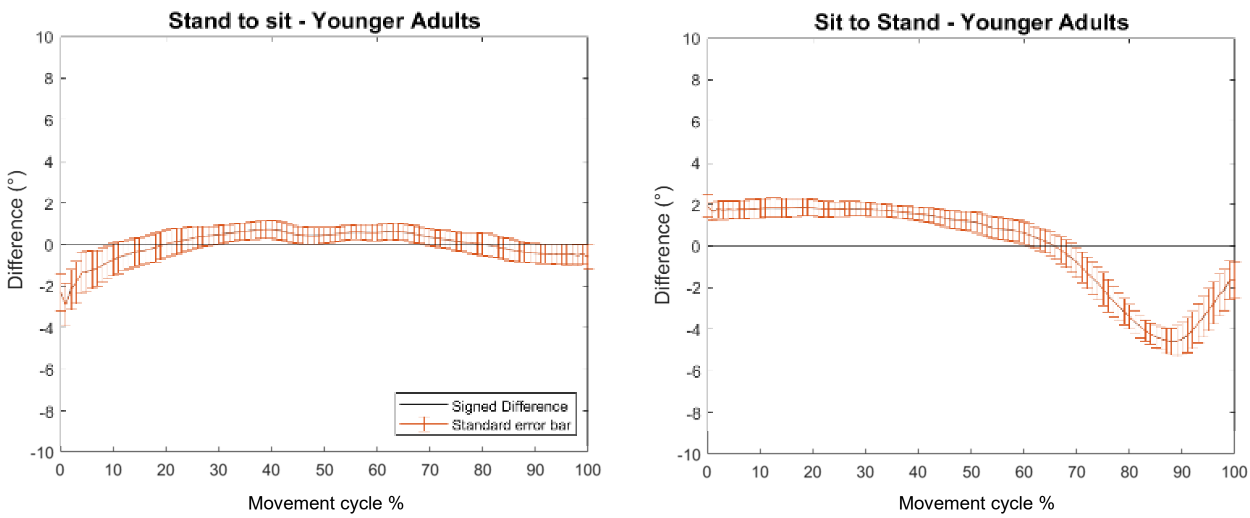


Figure 5-23. Signed error between the measurement technologies over whole movement cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by MotionSense™, and a positive difference an underestimation.

Both technologies displayed similar knee flexion patters for both the sit-to-stand and stand-to-sit activity (Figure 5-21 and Figure 5-22). Differences between the technologies are highlighted by the grey shaded region indicating one standard error (Figure 5-21), while variation within the participant measures are indicated by the grey shaded regions displaying one standard deviation (Figure 5-22). Variations were larger during periods of faster movement, as shown in Figure 5-22. The maximum and minimum knee flexion angles are detailed in Table 5-9. MotionSense™ measured smaller ROM measures compared to Vicon. However, ROM measures were not significantly different between the two systems ($p > 0.05$).

Both the sit-to-stand and stand-to-sit activities reported very similar RMSE values ($p > 0.05$), with the stand to sit activity reaching a maximum RMSE of 2.89°. Correlation values indicated a very strong positive correlation between Vicon and MotionSense™ (Table 5-10). Figure 5-23 describes the signed difference as a function of the gait cycle percentage. Stand-to-sit reported the smallest differences across the gait cycle with a maximum error as the participants begins to sit from the standing position (-2.93° difference). While the stand-to-sit activity had the largest error just as the participant left the stool and moved to the standing position about to take their first step (-4.24° difference). These errors coincide with periods of faster movements and quicker changes of knee joint angle.

Table 5-9. Mean knee angle (SD) results for get up and go for younger adults.

		Knee Angle (°)								
		Max Flexion			**Min Flexion**			**ROM**		
		Vicon	***MS***	***Δ***	***Vicon***	***MS***	***Δ***	***Vicon***	***MS***	***Δ***
Younger Adults	Sit to Stand	104.3 (8.6)	102.1 (8.2)	2.1 (2.1)	14.1 (8.3)	15.8 (9.9)	-1.7 (3.7)	90.2 (10.5)	86.4 (10.6)	3.8 (4.7)
	Stand to sit	103.3 (6.2)	103.9 (6.2)	-0.5 (2.5)	20.0 (10.5)	22.1 (10.7)	-2.1 (3.9)	83.3 (12.3)	81.7 (13.7)	1.6 (5.6)

Min: Minimum, Max: Maximum; ROM: Range of Motion; MS: MotionSense™; Δ: difference between Vicon and MotionSense™ (and pooled SD)

Table 5-10. Mean RMSE (SD) results for younger adults.

Younger Adults		
	RMSE (°)	***r***
Sit to stand	2.89 (1.62)	0.99
Stand to sit	2.31 (0.93)	0.99

RMSE: Root Mean Square Error (and SD)
r: Pearson Coefficient of Correlation

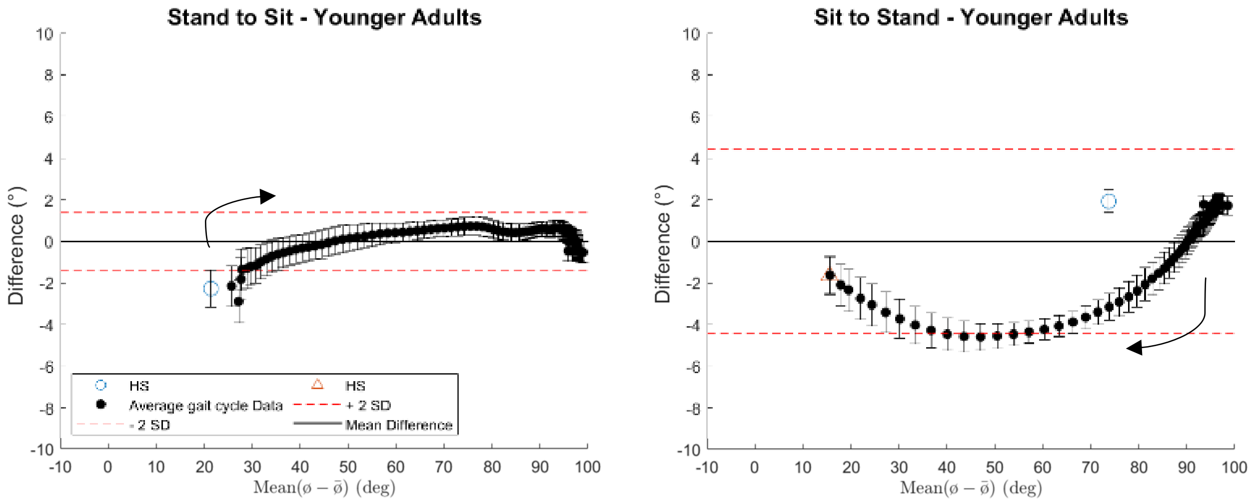


Figure 5-24. Bland-Altman plots of the mean error between the measurement technologies over whole gait cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by MotionSense™, and a positive difference an underestimation.

Figure 5-24 depicts a Bland-Altman plots to assess whether the signed difference between the technologies varied with the mean knee flexion. Differences became particularly evident when measurements exceeded the limits of agreement. The stand-to-sit activity displayed narrower limits of agreement suggesting closer agreement between Vicon and MotionSense™, while the sit-to-stand activity had wider limits.

5.2 Validation of the Seel Algorithm

The results presented in this section compare the accuracy of the Seel IMU algorithm used for determining knee joint angles from raw IMU data against the opto-electronic Vicon motion capture system. The accuracy of the system is first evaluated across a healthy younger adult population over a diverse range of activities, evaluating its ability to accurately track sagittal knee joint angle. The accuracy of this algorithm is then assessed across a clinical TKA population during level treadmill walking, validating the systems accuracy both preoperatively and postoperatively.

5.2.1 Healthy Younger Adult Population

Knee flexion patterns were similar for both the IMU sensor and Vicon for all ADLs within the younger healthy adult population (Figure 5-25 and Figure 5-26). Larger differences between the two measurement systems occurred during stages of greater knee flexion (Figure 5-25), represented by the grey shaded regions indicating one standard error.

The greatest variation within the data sets can be seen by the grey shaded region displaying the 95% confidence interval (Figure 5-26), occurring during instances of larger flexion angles and during movements that are associated with greater angular velocities. Stair navigation had the greatest variation within the data compared to the other activities. While the biggest differences between the IMU sensor and Vicon were evidenced for the flexion/extension activity ($p < 0.05$), displayed from peak flexion to peak flexion. For all activities, the largest difference between Vicon and the IMU sensor occurred in deep flexion compared to extension (Table 5-11), recording a maximum difference of 8.14° between maximum flexion during flexion/extension activity ($p < 0.05$), while cycling showed the greatest difference of -3.68° between minimum flexion ($p > 0.05$). The IMU more commonly underestimated maximum flexion angles leading to positive differences between the systems, while overestimating minimum flexion angles resulting in negative differences.

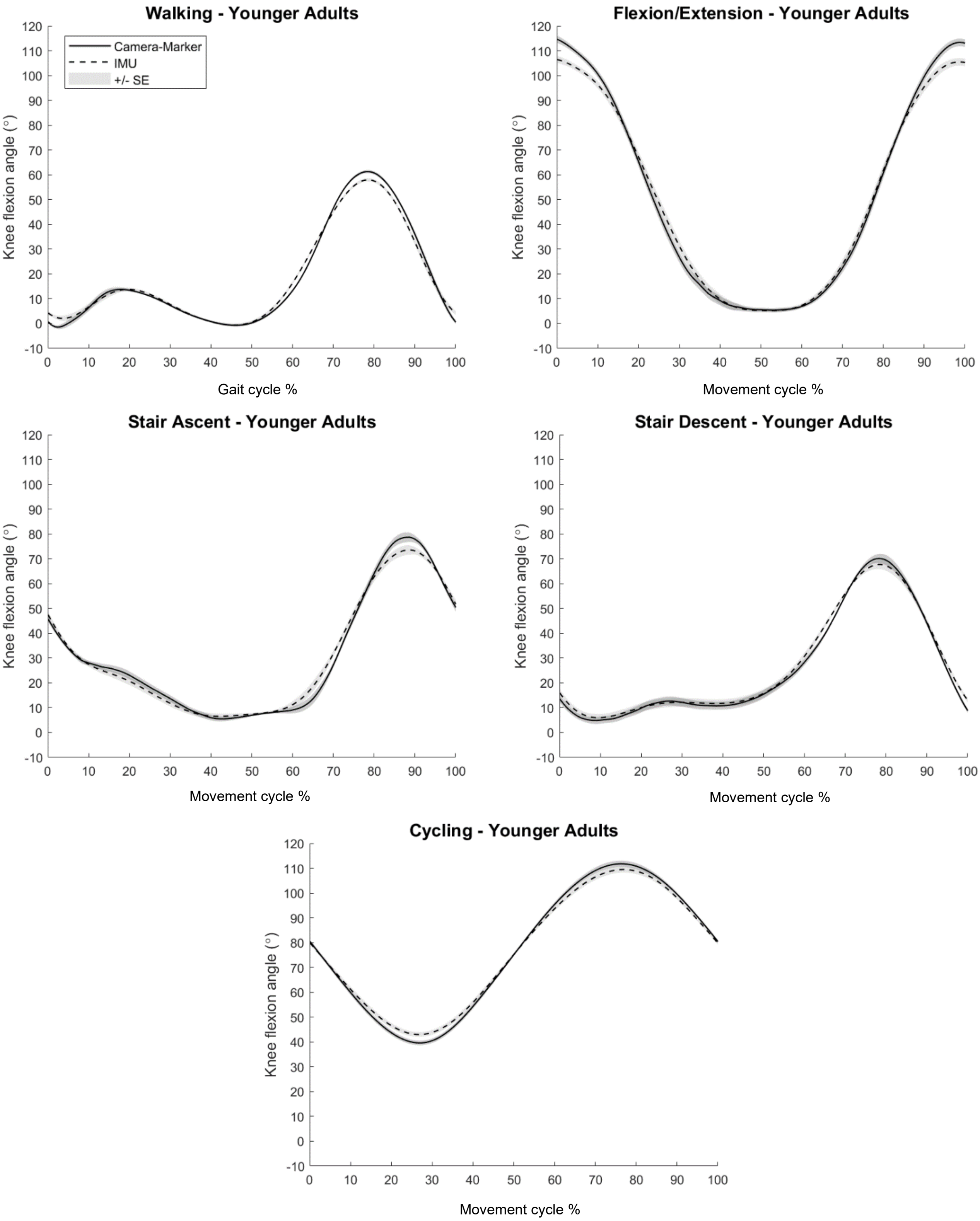


Figure 5-25. Mean knee flexion (SE) from initial contact to initial contact for differ ADLs for healthy young adults.

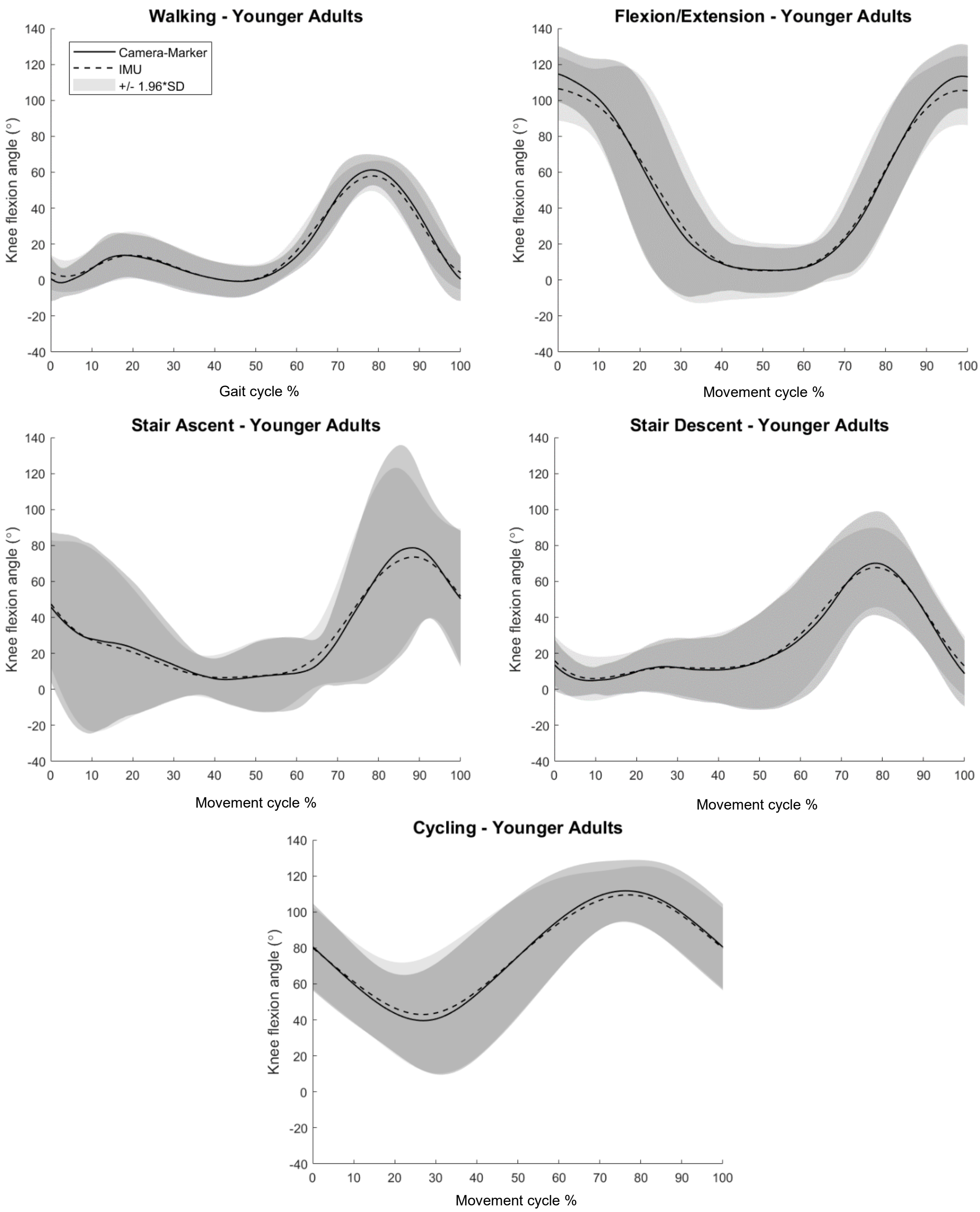


Figure 5-26. Mean knee flexion (and 95% confidence interval) from initial contact to initial contact for different ADLs for healthy young adults.

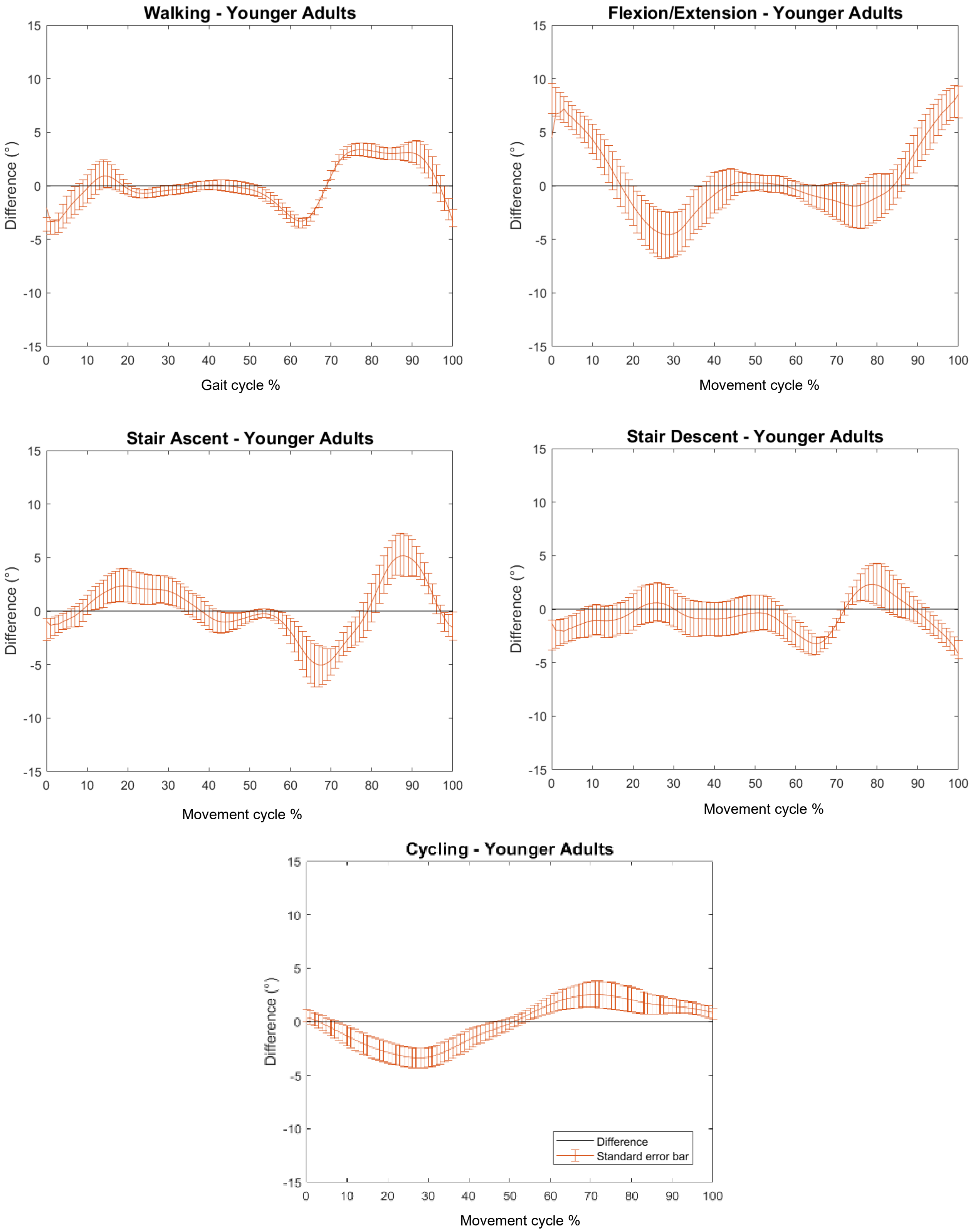


Figure 5-27. Signed error between the measurement technologies over whole gait cycle for each ADL for healthy young adults. Error bars display one standard error. A negative difference reports an overestimation of knee angle by the IMU, and a positive difference an underestimation.

Figure 5-27 describes the signed difference as a function of the movement cycle percentage, where the error bars represent one standard error. The flexion/extension activity had the greatest difference during maximum flexion, occurring at 0% and at 100% of the cycle (7.12° difference), and with larger errors observed during periods of faster movements or sudden changes in direction. Periods associated with faster movements occur from around 10% - 30% of the movement cycle (-4.55 ° difference) as the shank moves away from the thigh to carry out a full extension and then from around 80% - 100% of the gait cycle, where the shank is raised towards the thigh returning to maximum flexion.

During walking, the maximum error was observed around initial contact, with a difference of -3.84°. Other notable differences occurred at approximately 60% of the gait cycle during toe-off (-3.49° difference), from 74% - 90% of the gait cycle during mid-swing to terminal swing (~3.00° throughout this period), and just before heel strike (-3.01° difference). These differences were observed when the knee reached higher degrees of flexion or during faster movements, particularly in the swing phase.

In the cycling activity, the largest errors occurred around 28% of the pedal stroke cycle, with a difference of -3.39°. The knee reaches minimum flexion at 25% of the cycle, and by 28% of the gait cycle the limb has reached the bottom of the pedal stroke and begins changing direction, pulling the leg up towards maximum knee flexion (75% of the cycle). Larger errors were further observed at 72% - 75% of the cycle, during peak knee angle flexion, with a difference of 2.57°.

For stair ascent, the greatest differences between measurement systems were seen at 67% and at 88% of the gait cycle during the swing phase, with errors reaching -5.18° and 5.23°, respectively.

For stair descent, smaller differences were noted compared to those reported during stair ascent. With stair descent reporting maximum errors during late stance and approaching early swing at 65% of the cycle (-3.41° difference) and at 79% of the cycle when the knee reached maximum flexion (2.40° difference). Additional key differences were observed during the foot placement phase at the end of the cycle (100% of the gait cycle), with a difference of -3.80°.

In all activities, the maximum error aligns with peak knee flexion. Additionally, in cycling, stair navigation, and the flexion/extension activity, larger differences are observed during phases of rapid movement or sudden direction changes that are associated with larger deviations in angular velocities. For example, in cycling, these differences appear at the bottom of the pedal stroke, just before the pull-up phase. In the flexion/extension activity, greater errors occur when the limb rapidly changes direction from maximum to minimum flexion and the reverse also being true, with a change from minimum to maximum flexion. In stair navigation, larger differences are noted during the swing phase, where faster movements are required to reposition the leg for clearing the step.

Table 5-11. Mean knee angle (SD) results for activities of daily living for younger adults.

		Knee Angle (°)								
		Max Flexion			**Min Flexion**			**ROM**		
		Vicon	**IMU**	**Δ**	**Vicon**	**IMU**	**Δ**	**Vicon**	**IMU**	**Δ**
Younger Adults	Walking	61.7 (3.0)	58.3 (3.6)	3.4 (1.9)	-3.1 (3.8)	-0.9 (4.4)	-2.2 (3.4)	64.8 (3.0)	59.2 (3.8)	5.6 (4.4)
	Cycling	113.5 (8.1)	110.9 (6.7)	2.6 (4.0)	37.2 (14.7)	40.9 (16.1)	-3.7 (2.8)	76.3 (7.6)	70.0 (11.5)	6.3 (6.7)
	Flexion/ Extension[ab]	114.6 (8.5)	106.5 (9.7)	8.1 (2.9)	5.0 (6.7)	4.7 (8.2)	0.4 (1.7)	109.6 (11.7)	101.9 (14.0)	7.7 (3.5)
	Stair Ascent	83.7 (21.5)	78.2 (17.7)	5.5 (4.2)	2.3 (2.3)	2.6 (2.3)	-0.3 (1.2)	81.4 (21.6)	75.6 (17.1)	5.8 (4.8)
	Stair Descent	69.9 (5.5)	68.8 (4.0)	1.1 (2.7)	3.0 (3.7)	4.6 (4.9)	-1.6 (3.3)	66.9 (5.9)	64.2 (2.6)	2.7 (4.7)

Min: Minimum, Max: Maximum; ROM: Range of Motion; MS: MotionSense™; Δ: difference between Vicon and MotionSense™ (and pooled SD)
[a] $p < 0.05$ between Vicon and IMU for maximum flexion
[b] $p < 0.05$ between Vicon and MS for range of motion

The pooled RMSE ranged between 1.20° to 6.07° during walking for all 50 gait cycles, between 0.56° to 5.57° during cycling for all 50 pedal strokes, between 2.52° to 5.31° for stair ascent, 2.47° to 6.16° for stair descent and between 3.36° to 5.51° for the flexion/extension activity for all participants (Table 5-12) .

Cycling had the lowest RMSE, while the greatest RMSE was measured during the flexion/extension activity.

There were no statistically significant differences observed between the RMSE values for stair descent, stair ascent, and flexion/extension activities ($p > 0.05$). However, RMSE values for walking and cycling were found to be statistically significant ($p < 0.05$).

The correlation between Vicon and the IMU sensor for all activities indicates a strong positive correlation between the two technologies, suggesting that the measurements from the IMU device are in strong agreement to that of the opto-electronic Vicon motion capture system.

Table 5-12. Mean RMSE (SD) and correlation coefficient (r) results for all activities for younger adults.

Activity	**RMSE**	**r**
Walking	3.28 (0.81)	0.99
Cycling	2.92 (1.95)	0.99
Flexion/Extension	4.60 (0.73)	0.99
Stair Ascent	4.21 (0.87)	0.99
Stair Descent	4.42 (0.74)	0.98

RMSE: Root Mean Square Error (and SD)
r: Pearson Coefficient of Correlation

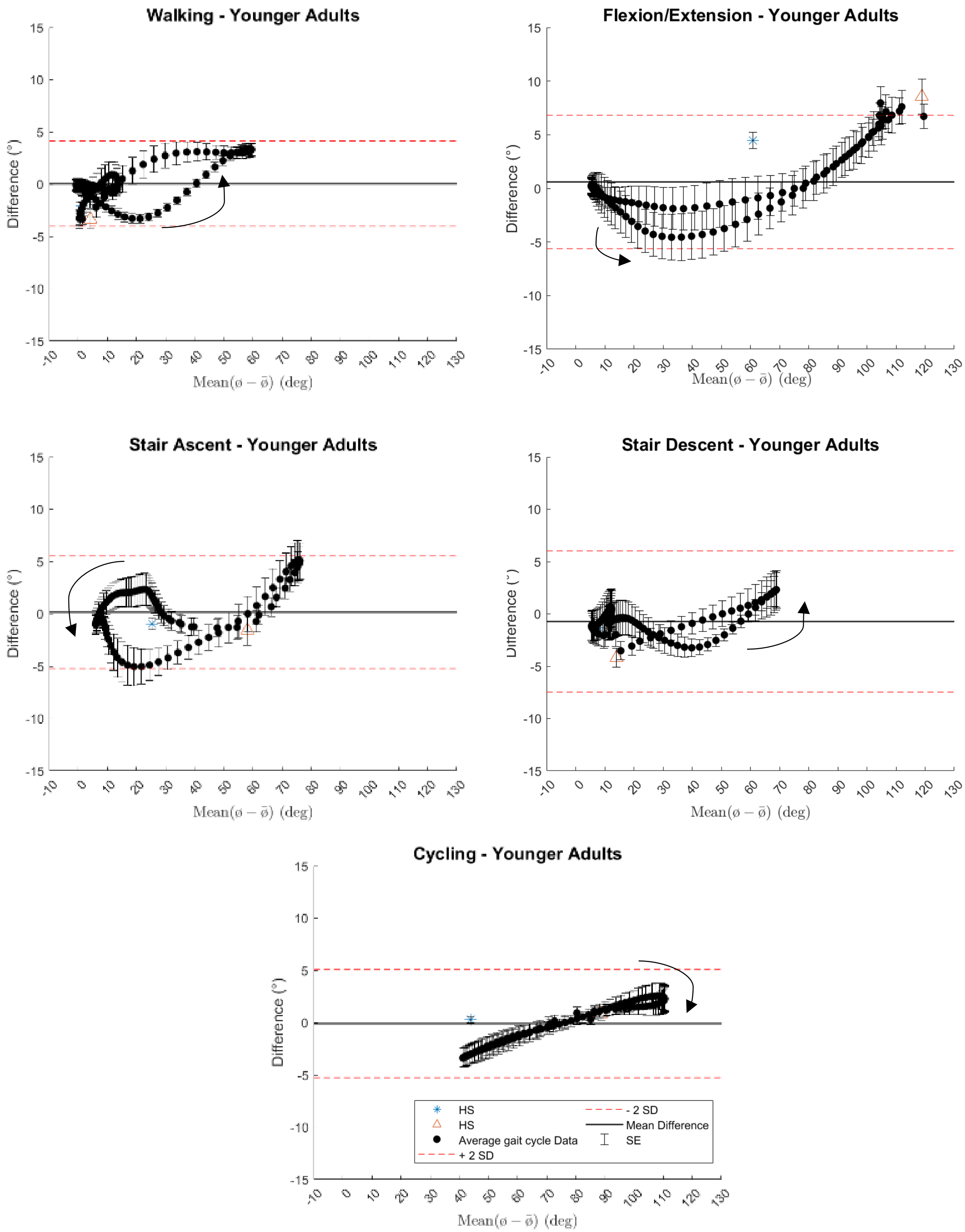


Figure 5-28. Bland-Altman plots of the mean error between the measurement technologies over whole movement cycle for each ADL for the healthy younger adults. Error bars display one standard error. A negative difference reports an overestimation of knee angle by the IMU, and a positive difference an underestimation.

Figure 5-28 depicts Bland-Altman plots used to evaluate whether the signed difference between Vicon and the IMU device changes with mean knee flexion. All activities showed an acceptable level of accuracy, with data for cycling, stair navigation, and walking falling within the limit bounds. However, the flexion/extension activity exceeded the limit bounds, especially at higher degrees of knee flexion where larger differences occurred. The flexion/extension activity displayed a particularly notable error of 8° difference between the measurement systems at 100° knee flexion. Whereas, walking displayed the narrowest limits of agreement, while flexion/extension showed the widest range in limit bounds among all activities.

Each activity displayed a mean difference line of zero or near to zero, notably with the flexion/extension activity and the stair descent activities mean difference line equalling 0.65° and -0.72°, respectively. Moreover, across all activities consistent trends were observed between the two technologies. During larger degrees of knee flexion positive differences between the technologies were observed due to the underestimation of knee angle measures by the IMU device compared to that of the opto-electronic Vicon motion capture system. While for smaller knee flexion angles the differences between the two systems was negative indicating an overestimation in knee joint angle by the IMU device.

5.2.2 TKA Population

It is important to note that out of the 10 TKA participants that consented to this study only 5 participants had their data recorded on the wired IMU sensor, therefore, the results presented in this section only consider those 5 TKA participants.

Knee flexion patterns were similar for both measurement systems for walking (Figure 5-29 and Figure 5-30). Larger differences between the two measurement systems occurred during periods of greater knee flexion (Figure 5-29), represented by the grey shaded regions indicating one standard error. Preoperatively and 6 weeks postoperatively the IMU device underestimated peak flexion, however, 1-week postoperatively the system overestimated peak flexion angles. Though at 1-week postoperatively the TKA population displayed a reduction in ROM, decreased minimum and maximum flexion in the stance phase and limited peak flexion, the system accurately traced knee angles throughout the cycle.

The greatest variation within the data sets can be seen by the grey shaded region displaying the 95% confidence interval (Figure 5-30), highlighting the spread between the participant measures. Larger variations between measures were presented during the preoperative assessment compared to both postoperative sessions, with greater deviations observed in the swing phase compared to the stance phase.

The largest difference between Vicon and the IMU sensor occurred in maximum flexion compared to minimum flexion (Table 5-13). A maximum difference of 9.81° was observed at maximum flexion during the preoperative assessment, while the 1-week postoperative assessment revealed the largest differences at minimum flexion (-2.46° difference). There were no statistically significant differences between the two measurement systems at any time point for the walking activity ($p > 0.05$). The IMU generally underestimated maximum flexion angles, leading to positive differences between the systems, while underestimating minimum flexion angles, resulting in negative differences. Consequently, the IMU device under reported ROM for each time point for walking.

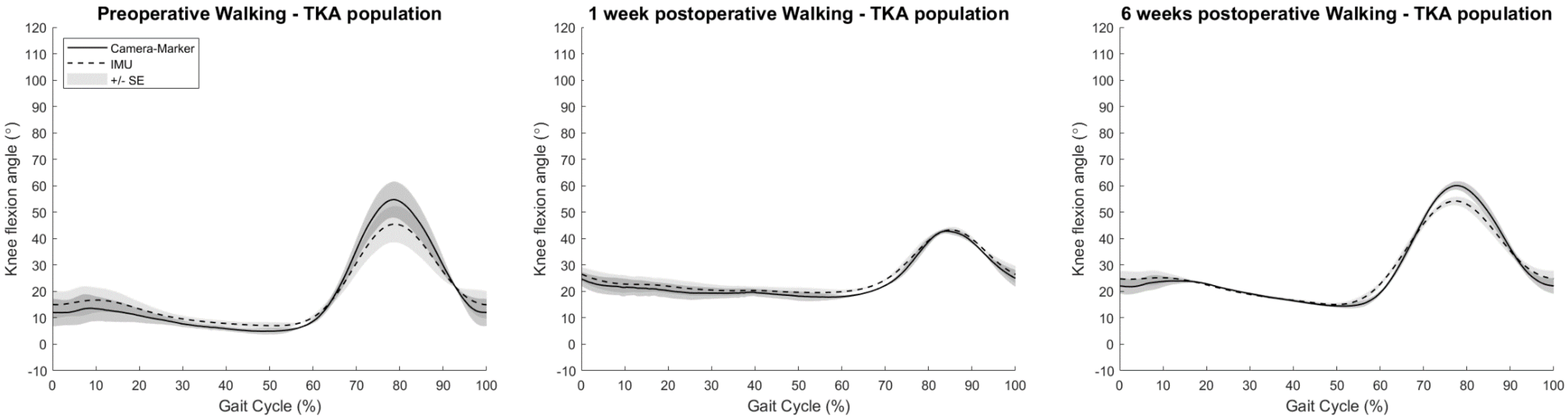


Figure 5-29. Mean knee flexion (SE) from initial contact including the stance and swing phase of the gait cycle for each time point for the TKA population.

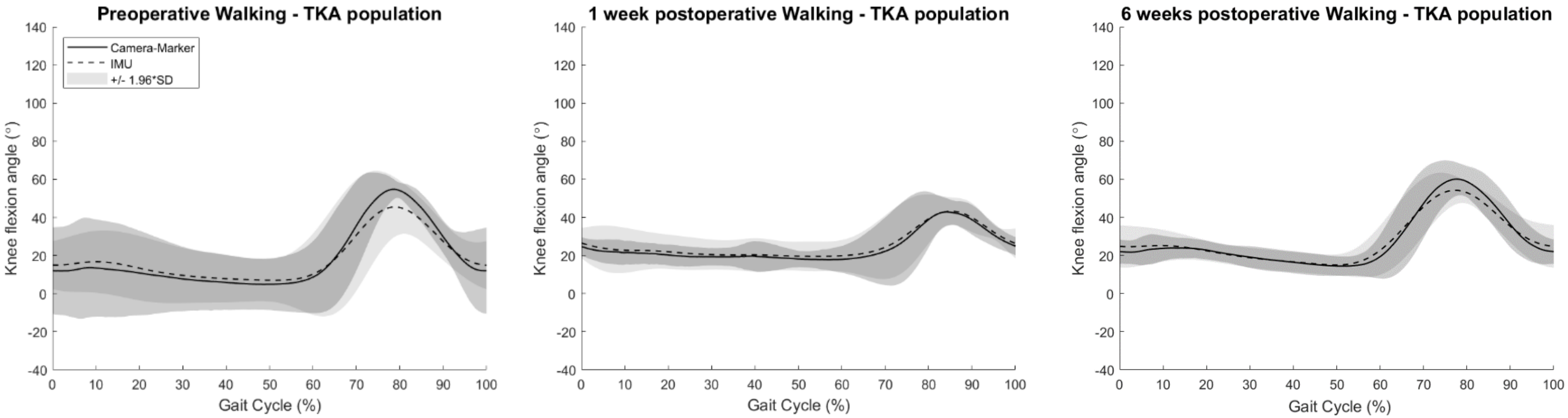


Figure 5-30. Mean knee flexion (and 95% confidence interval) from initial contact including the stance and swing phase of the gait cycle for each time point for the TKA population.

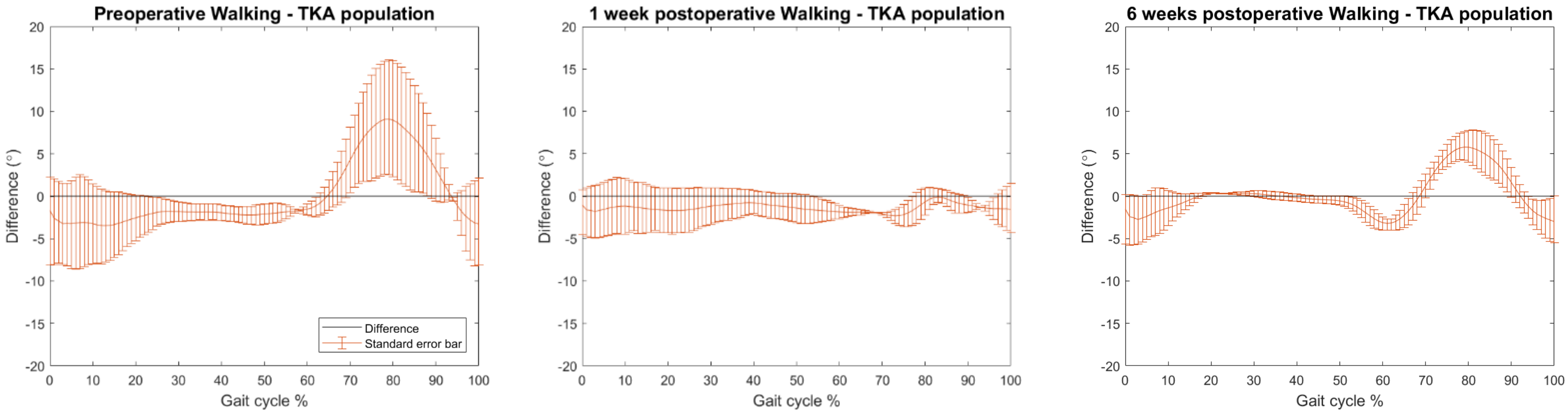


Figure 5-31. Signed error between the measurement technologies over whole gait cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by the IMU, and a positive difference an underestimation.

Figure 5-31 describes the signed difference as a function of the gait cycle percentage. Preoperative walking reported the largest difference compared to both postoperative sessions. The largest error between Vicon and the IMU device occurred at 80% of the gait cycle, during mid-swing at maximum flexion (9.30° difference). However, notable differences were observed at 8% of the gait cycle during loading response (-2.97° difference) and at 100% of the gait cycle at heel strike (-3.18° difference).

Six weeks post-TKA revealed the greatest differences between the two systems at approximately 79% of the gait cycle at peak knee flexion during the swing phase (difference of 5.90°). Notable differences were also observed during toe off at around 62% of the gait cycle (-3.32° difference).

One week postoperatively the differences between the two systems were consistent throughout the gait cycle, with a maximum difference of -1.93° reported at 68% of the gait cycle during the swing phase. During this session, the IMU device was in close agreement to the measures reported by Vicon.

Larger differences were observed when the knee reached larger degrees of maximum flexion or during faster periods of movement (swing phase), this was evidenced during the preoperative assessment and at 6 weeks postoperative session particularly.

Table 5-13. Mean knee angle (SD) results for walking for TKA patients.

	Knee Angle (°)								
	Max Flexion			**Min Flexion**			**ROM**		
	Vicon	***IMU***	***Δ***	***Vicon***	***IMU***	***Δ***	***Vicon***	***IMU***	***Δ***
Preoperative	55.2 (1.4)	46.0 (10.7)	9.2 (9.3)	4.8 (9.7)	6.3 (8.9)	-1.5 (0.7)	50.4 (8.3)	39.7 (1.8)	10.7 (10.1)
1 Week postop	43.6 (0.5)	44.1 (1.6)	-0.5 (2.1)	17.1 (3.7)	19.6 (4.8)	-2.5 (1.1)	26.5 (3.1)	24.6 (6.3)	2.0 (3.2)
6 Weeks postop	60.4 (4.2)	54.3 (3.3)	6.1 (3.0)	14.1 (2.4)	14.7 (2.6)	-0.7 (0.5)	46.3 (1.9)	39.5 (2.1)	6.8 (2.9)

Postop: Postoperative, Min: Minimum, Max: Maximum; ROM: Range of Motion; IMU: Inertial measurement unit; Δ: difference between Vicon and IMU (and pooled SD)

The pooled RMSE ranged from between 3.36° to 4.78° for all three sessions for the walking activity (Table 5-14). The 1-week postoperative assessment revealed the highest level of accuracy between the IMU device and Vicon, while the preoperative assessment demonstrated the lowest level of agreement between the two technologies. There were no statistically significant differences between the RMSE of each session (p > 0.05).

The correlation of coefficient indicated a very strong positive relationship between Vicon and the IMU sensor measurements for each time point.

Table 5-14. Mean RMSE (SD) results for walking TKA population.

Walking			
		RMSE (°)	***r***
Session	Preoperative	4.78 (4.59)	0.97
	1 Week postop	3.36 (0.05)	0.95
	6 Weeks postop	3.68 (2.16)	0.96

Postop: Postoperative
RMSE: Root Mean Square Error (and SD)
r: Pearson Coefficient of Correlation

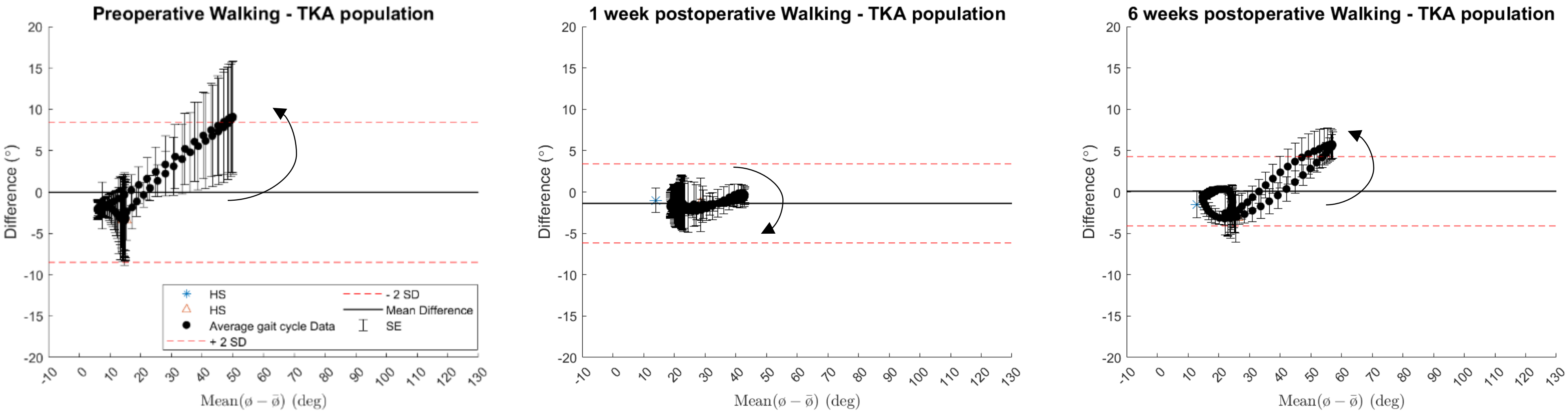


Figure 5-32. Bland-Altman plots of the mean error between the measurement technologies over whole gait cycle. Error bars display one standard error. A negative difference reports an overestimation of knee angle by the IMU, and a positive difference an underestimation.

Figure 5-32 depicts Bland-Altman plots to assess whether the signed difference between Vicon and the IMU device varied with the mean knee flexion. Differences only became unacceptable at larger angles of knee flexion, highlighted both preoperatively and at 6 weeks postoperatively, with data points extending beyond the limits of agreement at greater degrees of flexion.

For larger degrees of flexion, the difference between the systems is positive, suggesting an underestimation of knee angle by the IMU. However, at smaller degrees of flexion, the differences between the IMU and Vicon is negative, indicating that the IMU is overestimating knee angles.

The mean difference line equals zero for both preoperative and 6 weeks postoperative, revealing no systematic bias. However, a mean difference of just below zero (-1.37°) for 1-week postoperatively was reported, suggesting that on average the IMU overestimated knee angles compared to Vicon.

Despite the observed system bias (mean difference line just below zero), the data presented 1-week postoperatively displayed the closest agreement between the two measurement systems, with all data points found within narrow limit bounds and closely clustered around zero. This implies that there is a high level of accuracy between the opto-electronic Vicon motion capture system and the wired IMU sensor.

5.3 Biomechanical Assessment of Rehabilitation Post TKA

5.3.1 Overview of TKA Recovery

Optimal knee ROM required to achieve a satisfactory level of function post TKA has been defined to be as low as 95º (Miner et al., 2003) to as high as 130º (Devers et al., 2011) depending on the movement performed. However, following TKA over 20% of patients do not report clinically relevant pain relief or functional improvements (Kahlenberg et al., 2018; Sajjadi et al., 2019).

This chapter evaluates key biomechanical measures and subjective PROM data for a TKA population both pre- and post TKA, evaluating the degree of subjective and functional improvements in the short period following TKA, and whether links between the two measures can be established. This chapter further expands on the practical applications of the aforementioned wearable IMU technologies and the benefits these technologies may pose to postoperative recovery. This is presented through functional outcomes within the clinical population's recovery period.

Table 5-15 presents the participants who attended each session, as complete data sets were not achieved for all participants, as a result of marker occlusion or due to faulty sensors. The measurement data presented only considers Vicon opto-electronic measurements as these data are considered to be ground truths upon which the clinical efficacy of both wearable technologies were scored and evaluated against. This should be considered when interpreting the results.

While 48 patients were screened for the study, only 10 provided consent to participate. The remaining patients declined for a variety of reasons, including stress related to their upcoming surgery, reluctance to impose on others for transportation to the laboratory, concerns about potential pain, a lack of understanding about the importance of research volunteers, absence of perceived personal benefit, disinterest, or fear. Of these 10 patients that did consent to the study, 8 of these patients attended their preoperative testing session, 4 patients attended 1 week postoperatively, while 7 patients attended 6 weeks postoperatively. This small sample size should be kept in mind when interpreting these results.

It is important to highlight, of the patients who attended the preoperative assessment, the same 5 patients attended the 6 week follow up session (Table 5-15 and Table 5-16). The data presented is Vicon data and PROM group averages. Where only operated leg data is discussed in Table 5-17.

Table 5-15. TKA participant descriptive information and which sessions they attended.

				Data Presented		
Patient ID	***Sex (F/M)***	***Age (years)***	***Side of TKA (L/R)***	***Preoperative session***	***1 Week postop***	***6 Weeks postop***
TKA01	m	56	R	Y	N	N
TKA02	f	71	R	Y*	Y	Y
TKA03	m	57	L	N	Y*	Y
TKA04	f	65	R	N	Y	Y
TKA05	f	68	R	Y	N	Y
TKA06	f	65	R	Y	N	Y*
TKA07	m	68	L	Y	N	Y*
TKA08	m	67	R	Y	Y*	N
TKA09	m	54	R	Y	N	Y*
TKA10	m	53	L	Y*	Y*	N

Postop: Postoperative, F: Female, M: Male, L: Left, R: Right,
Sessions attended: Y: Yes, N: No
* Vicon data not included in analysis due to occlusions.

Table 5-16. Mean weight and BMI (SD) results for all time points for the TKA population.

		Sex (F/M)	Age (years)	Side (L/R)	Weight (kg)	BMI (kg/m^2)
TKA Population	*Preoperative*	3 / 5	62.8 (7.2)	2 / 6	88.0 (15.6)	29.6 (3.4)
	1 Week postop	2 / 3	64.4 (7.0)	3 / 2	87.3 (1.0)	28.9 (2.3)
	6 Weeks postop	4 / 3	64.0 (6.2)	2 / 5	84.4 (11.6)	29.1 (3.6)

Postop: Postoperative, BMI: Body Mass Index, F: Female, M: Male, L: Left, R: Right

The average mass of the group 6 weeks postoperatively was not significantly different from the groups baseline mass recorded at their preoperative assessment ($p > 0.05$). A mean weight loss of 3.66kg was reached by the TKA population by 6 weeks postoperatively.

5.3.1.1 Peak ROM Measures

The mean ROM at each time point for all the activities are summarised in

Table 5-17. For all three activities the TKA population showed improvements in both maximum flexion and ROM by 6 weeks post-TKA compared to the groups preoperative baseline measures.

Table 5-17. Mean Knee angle (SD) results for all activities for the TKA population.

		Knee Angle (°)		
		Max Flexion	***Min Flexion***	***ROM***
Walking	Preoperative	45.5 (8.8)	7.0 (10.3)	38.5 (9.7)
	1 Week postop	47.1 (6.2)	15.5 (1.3)	31.6 (5.0)
	6 Weeks postop	56.4 (7.1)	11.9 (3.3)	44.6 (3.9)
Stair Ascent	Preoperative	53.6 (34.9)	5.3 (10.6)	48.4 (28.1)
	1 Week postop	51.5 (2.7)	18.4 (0.9)	33.1 (1.7)
	6 Weeks postop	78.9 (18.7)	13.6 (3.1)	65.3 (17.4)
Stair Descent	Preoperative	39.5 (8.8)	6.6 (8.2)	32.9 (2.2)
	1 Week postop	48.3 (2.8)	14.2 (0.8)	34.1 (2.0)
	6 Weeks postop	74.9 (23.7)	12.1 (6.3)	62.8 (22.4)

Postop: Postoperative, Max: Maximum; Min: Minimum, ROM: Range of Motion (and pooled SD).

No significant differences in knee angles (minimum flexion, maximum flexion and ROM) were observed across different time points for the same activity, suggesting no significance change in knee angles preoperatively to 6 weeks postoperatively. Similarly, when comparing knee angles across the different activities at the same time point, no significant differences were observed, ($p > 0.05$). These findings should be considered with caution as they may be as a result of the smaller sample size, and absolute changes should be considered instead.

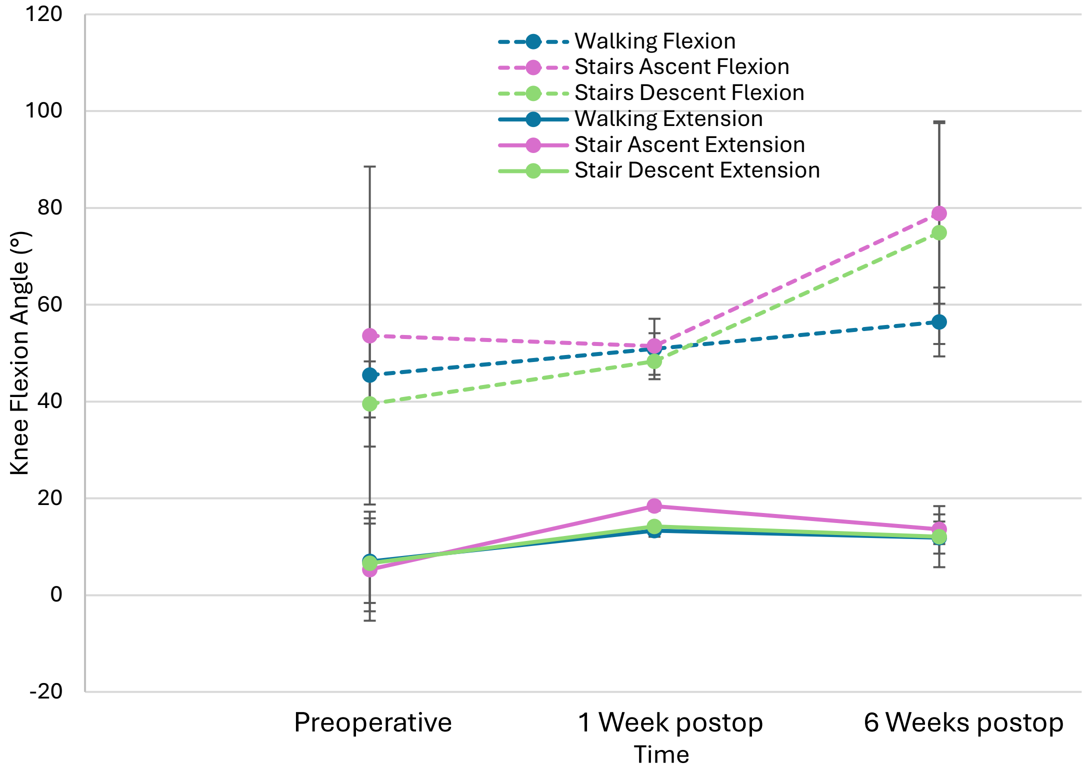


Figure 5-33. Mean minimum knee extension and mean maximum flexion angle for the pooled TKA population, preoperatively and postoperatively for stair navigation and walking. Each error bar represents one standard deviation, with the colours representing individual activities, dashed line indicating maximum flexion and the solid line minimum flexion.

Figure 5-33 displays the TKA populations pooled average maximum flexion and minimum flexion values, with error bars indicating one standard deviation for the TKA participants at each time point for each activity. No significant differences were noted between preoperative baseline measures and 6 weeks post-TKA data for each activity. Maximum flexion values increased from base line measures for each activity by 6 weeks, while minimum flexion angles had almost restored to preoperative baseline measures for each activity by 6 weeks postoperatively.

It is important to take note of the standard deviation of the minimum flexion at 6 weeks postoperatively compared to the preoperative baseline measures. At 6 weeks postoperative the minimum flexion standard deviations did not reach the same full extension range as preoperative standard deviations.

No significant differences were found in ROM between the preoperative assessment and the two postoperative examinations, again possibly as a result of the limited sample size. However, ROM increased for all activities by 6 weeks post-TKA. Walking reported a 6.0° improvement in ROM (~17% increase) at 6 weeks post-TKA compared to preoperative baseline measures, stair ascent improved by 16.9° (~35% increase) by 6 weeks postoperative and stair descent recorded the highest improvement of 29.9° (~91% increase) compared to baseline measures. Overall, across all activities, the TKA group increased their average ROM by 16.6°, from 39.9° preoperatively to 56.5° at 6 weeks postoperatively (~42% increase).

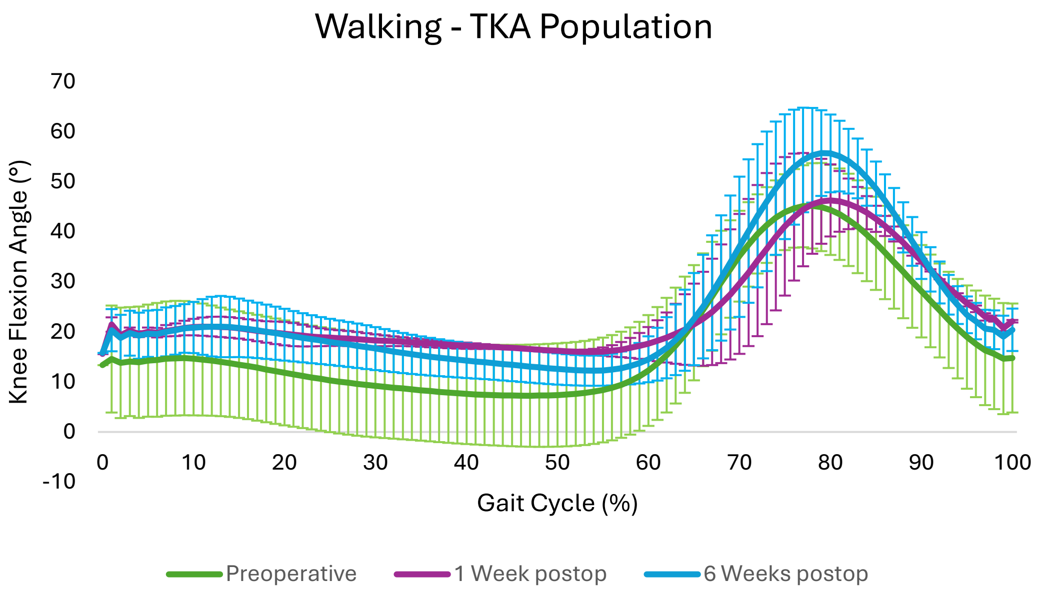


Figure 5-34. Average gait cycle from heel strike to heel strike for the pooled TKA clinical population, showing the average knee flexion angle for level walking at each data collection session, error bars represent one standard deviation.

Maximum flexion angles were greatest 6 weeks following surgery, however minimum flexion was limited postoperatively (Figure 5-34), this is evidenced particularly in the stance phase at 1-week postoperatively.

5.3.1.2 Walking Speed and Cadence

Walking speed, cadence and stride length is summarised in Table 5-18. No significant differences were observed between each time point for both walking speed and cadence ($p > 0.05$).

Table 5-18. Mean treadmill walking speed and cadence (SD) results for the TKA population at each time point.

	Mean (± SD)		
	Walking Speed (m/s)	***Cadence (steps/min)***	***Stride length (m)***
Preoperative	0.56 (0.15)	88.3 (18.0)	0.81 (0.31)
1 Week postoperative	0.42 (0.18)	79.5 (21.2)	0.69 (0.37)
6 Weeks postoperative	0.60 (0.27)	90.8 (19.8)	0.85 (0.42)

Spearman's correlation coefficients were calculated between preoperative measures of BMI, ROM and walking speeds and cadence against 6 weeks postoperative ROM. Results of the analysis highlighted that preoperative BMI ($r = -0.60$), preoperative ROM ($r = 0.51$), preoperative cadence ($r = 0.72$), and preoperative walking speed ($r = 0.50$) had strong correlations with 6 weeks postoperative ROM, Table 5-19.

Table 5-19. Spearman's correlation coefficients for the TKA populations baseline measures and their 6 week postoperative ROM

Correlation Coefficient (ρ)	
	6 Weeks postoperative ROM
*Preoperative BMI****	-0.60
*Preoperative ROM****	0.51
*Preoperative Walking Speed****	0.50
*Preoperative Cadence****	0.72

*Weak correlation
**Moderate correlation
***Strong correlation

The PROM scores are presented in Table 5-20. The PROM scores have all been scaled to a score out of 100, with 100 representing perfect knee health or total satisfaction, the best possible outcome. For all PROM questionnaires 6 weeks post-surgery reported the highest values, and therefore better patient satisfaction compared to the baseline measure and 1 week after surgery.

Table 5-20. Mean PROM score (SD) results for the TKA population at each time point.

	FJS	OKS	KOOS JR
Preoperative	15.1 (13.3)	37.8 (15.0)	41.3 (9.7)
1 Week postop	12.5 (15.3)	38.5 (19.0)	46.4 (12.0)
6 Weeks postop	36.3 (38.3)	55.7 (13.3)	57.3 (7.7)

Postop: Postoperative, FJS: Forgotten Joint Score, OKS: Oxford Knee Score, KOOS JR: Knee injury and Osteoarthritis Outcomes Score for Joint Replacement.

No significant differences were observed between the different time intervals and the same PROM questionnaire measure ($p > 0.05$), though this may be as a result of the limited sample size 1 week postoperatively. However, during the preoperative session the FJS revealed significant differences to both the OKS and the KOOS JR ($p < 0.01$). Furthermore, postoperatively, the FJS reported significantly different values compared to KOOS JR ($p <0.05$) 1-week postoperatively.

When considering all three PROMs at each time point, significant differences ($p < 0.05$) were only observed between the preoperative measures and the 6 weeks postoperative results for the KOOS JR score. However, no other significant differences were reported. Notably, the FJS consistently scores lower at each time point compared to the other PROM measures.

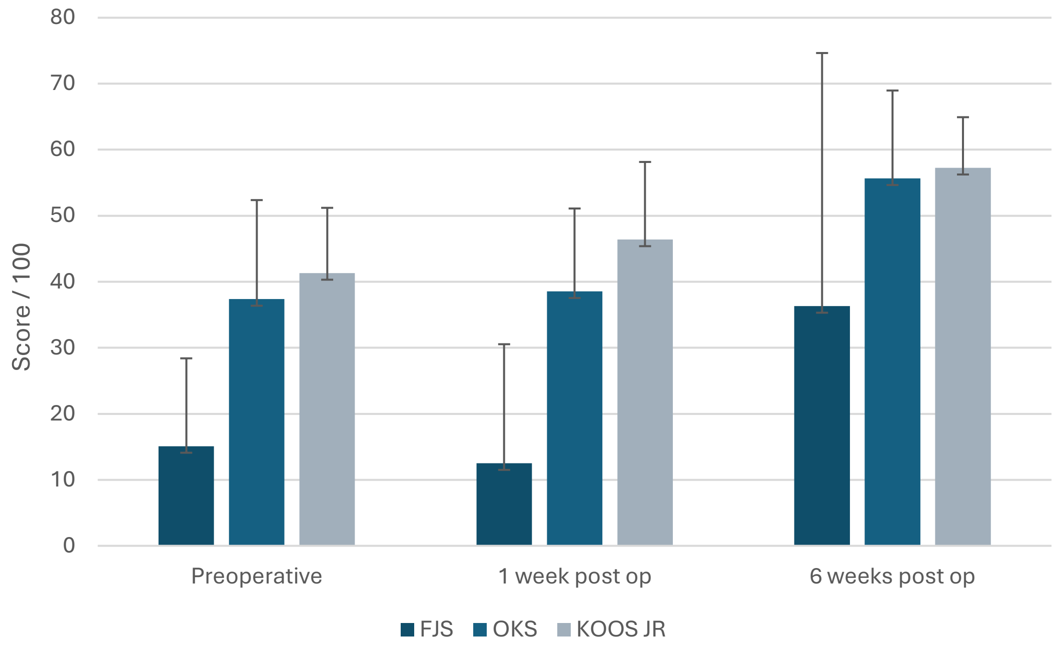


Figure 5-35. Mean TKA population PROM scores (and SD) for each questionnaire for the TKA population collected at each laboratory session.

Figure 5-35 presents the mean population PROM scores for each questionnaire at each time point. For FJS and OKS, 1-week post TKA presents lower results compared to the TKA groups baseline preoperative measures. However, by week 6 postoperatively, an increase in all PROM scores is observed compared to both baseline and 1-week postoperative measures.

Spearman's coefficients of correlation were determined between the different PROM scores and ROM during walking both preoperatively and at 6 weeks post TKA. Moderate to strong coefficients of correlation were found (FJS: -0.34, OKS: 0.49, KOOS JR: 0.46) between the PROM scores and walking ROM at week 6, moreover, weak correlations were presented preoperatively (FJS: 0.16, OKS: 0.17, KOOS JR: -0.10) between PROM scores and ROM. This trend suggests that better functional outcome measures relate to better patient reported outcomes, and ultimately greater patient satisfaction, consequently, lower PROM scores may represent reduced ROM, Table 5-21.

Table 5-21. Spearman's correlation displaying the relationships between preoperative and postoperative PROM scores to ROM

Correlation Coefficient (ρ)			
	PROM Questionnaire	*Preoperative ROM*	*6 weeks Postoperative ROM*
Preoperative Assessment	*FJS*	0.16*	-0.36**
	KOOS JR	-0.10*	0.60***
	OKS	0.17*	0.53***
6 Weeks Postoperative Assessment	*FJS*	0.01*	-0.34**
	KOOS JR	0.60***	0.46***
	OKS	0.33**	0.49***

*Weak correlation
**Moderate correlation
***Strong correlation

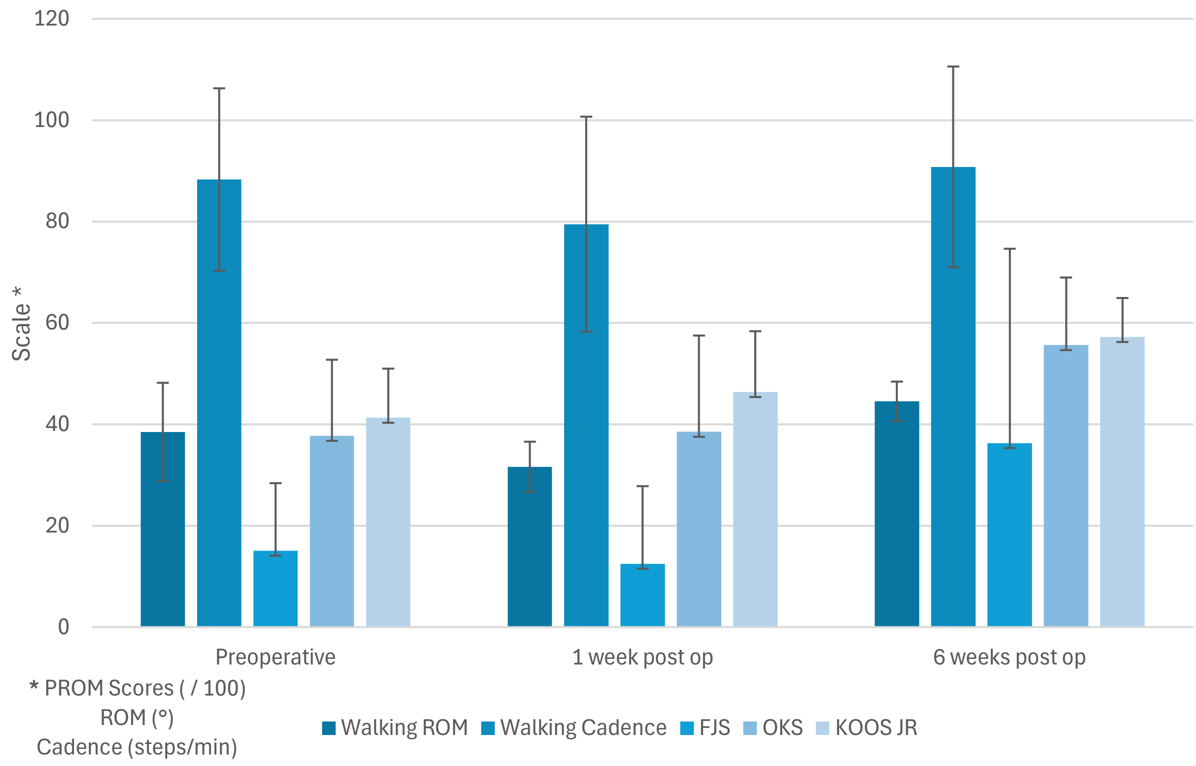


Figure 5-36. Mean subjective (PROM scores and +SD) and objective walking measures (± SD) for the pooled TKA population at each time point, the error bars represent one standard deviation.

Figure 5-36 displays both subjective and objective measures at each time point. By 6 weeks post-surgery ROM had improved compared to 1-week postoperative measures, with mean PROM measures reflecting those functional improvements. Conversely, 1-week following surgery the TKA population displayed a reduction in both ROM and cadence, with mean PROM measures following the same trend. PROM measures reveal agreement to the reduction in joint function.

5.3.2 Recovery on an Individual Patient Level

In this subsection the data of an individual patient is presented. Data is of a 71-year-old female who volunteered and consented to the study, she attended all three testing sessions. The data presented demonstrates the usability of the MotionSense™ wearable device, all data presented has been recorded from the commercial device. The participant had a TKA performed on her right knee. Walking and stair navigation data was collected preoperatively, 1-week and 6 weeks postoperatively. All data presented is of her operated leg, ten gait cycles were analysed for walking, while only one step was analysed for the stair navigation exercise.

Table 5-22. Descriptive statistics of the TKA participant at each time point.

	Weight (kg)	**BMI (kg/m^2)**
Preoperative	90.5	31.1
1 Week postop	88.2	30.3
6 Weeks postop	85.0	29.2

Postop: Postoperatively, BMI: Body Mass Index.

5.3.2.1 Peak ROM Measures

Table 5-23 presents the operated knee angle data both pre- and postoperatively for stair navigation and treadmill walking, displaying both the minimum and maximum knee angles for all activities at each time point.

Table 5-23. Mean Knee angle (SD) results for each activity for the TKA participant.

Activity	Time point	Max Flexion (°)	Min Flexion (°)	ROM (°)
Walking	Preoperative	42.2 (1.9)	11.7 (0.5)	30.5 (1.8)
	1 Week Postop	52.7 (1.5)	15.7 (0.8)	37.0 (2.0)
	6 Weeks Postop	56.6 (0.7)	11.1 (0.5)	45.5 (0.8)
Stair Ascent	Preoperative	48.3	6.8	41.5
	1 Week Postop	53.3	19.0	34.3
	6 Weeks Postop	91.6	12.3	79.4
Stair Descent	Preoperative	37.4	7.0	30.4
	1 Week Postop	46.4	13.7	32.7
	6 Weeks Postop	90.7	8.3	82.4

Postop: Postoperative Max: Maximum; Min: Minimum, ROM: Range of Motion (and pooled SD).

The participant's ROM considered across all activities at 6 weeks post TKA showed a significant difference compared to ROM measures preoperatively and one week postoperatively ($p < 0.05$). Furthermore, the participant's maximum flexion angle considered across all activities at 6 weeks post TKA showed a significant difference compared to maximum flexion preoperatively ($p < 0.05$).

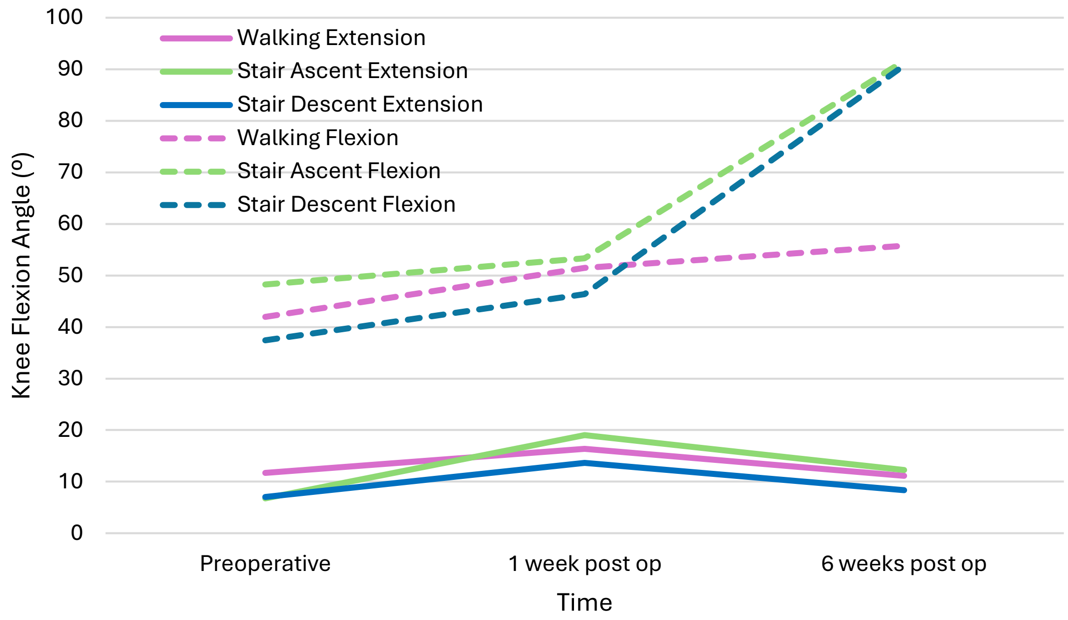


Figure 5-37. Maximum and minimum knee flexion angles for each activity for the TKA participant at each time point.

The participant's maximum flexion angle increased for all activities at both 1week postoperatively and at 6 weeks postoperatively compared to her baseline measures. While her ROM increased at 6 weeks postoperatively compared to her baseline measures for all activities. Minimum flexion improved by 6 weeks post-surgery compared to her 1-week postoperative measures, however, by 6 weeks postoperative, her minimum flexion angle had not yet been restored or improved compared to her baseline measurements (Figure 5-37).

5.3.2.2 Walking Speed and Cadence

This participant walked with a walking aid both pre- and postoperatively (Figure 5-38). Preoperatively and 6 weeks postoperatively she used a walking frame, however, at the 1-week postoperative stage she used crutches.

Walking speed and cadence is presented in Table 5-24. Both walking speed and cadence showed the same trend, 1-week post TKA, speed and cadence reduced from her preoperative baseline. However, by 6 weeks postoperatively both cadence and walking speed was higher than both the preoperative baseline and 1-week post TKA measures.

Table 5-24. Gait parameters for the TKA participant at each time point.

	Walking speed (m/s)	**Cadence (steps/min)**	**Stride length (m)**
Preoperatively	0.64	84.40	0.91
1 Week postop	0.56	73.04	0.92
6 Weeks postop	0.69	90.00	0.92

Postop: Postoperative.

Figure 5-38. Walking aids used by participant preoperatively and postoperatively.

5.3.2.3 Biomechanical Alignment

Preoperatively the patient displayed excessive bilateral valgus deformity (Figure 5-39), with a valgus angle ranging between 6° - 10° throughout the gait cycle. Her affected knee displayed a greater degree of valgus when her leg was weighted in the stance phase compared to the swing phase.

Figure 5-39. Walking during the preoperative session.

Figure 5-40. Walking at 1 week post-TKA.

Figure 5-41. Walking at 6 weeks post-TKA.

Postoperatively the patient showed a reduction in valgus angle, with her non operated leg revealing a larger degree of valgus compared to her operated leg (Figure 5-40 and Figure 5-41). This observation reveals an improvement in valgus deformity following surgery.

5.3.2.4 PROMS

All three PROM scores are displayed in Table 5-25 and Figure 5-42 at each time period.

Table 5-25. Patient reported outcome measures (PROMs) for each time point for the TKA participant.

	FJS	OKS	KOOS JR
Preoperatively	8	31	28
1 Week postop	31	44	42
6 Weeks postop	48	56	64

Postop: Postoperative

All three PROM scores showed an improvement from the patients' preoperative baseline score, with 6 weeks postoperatively exhibiting significantly different PROM values compared to the patients' preoperative baseline ($p < 0.05$), Figure 5-42.

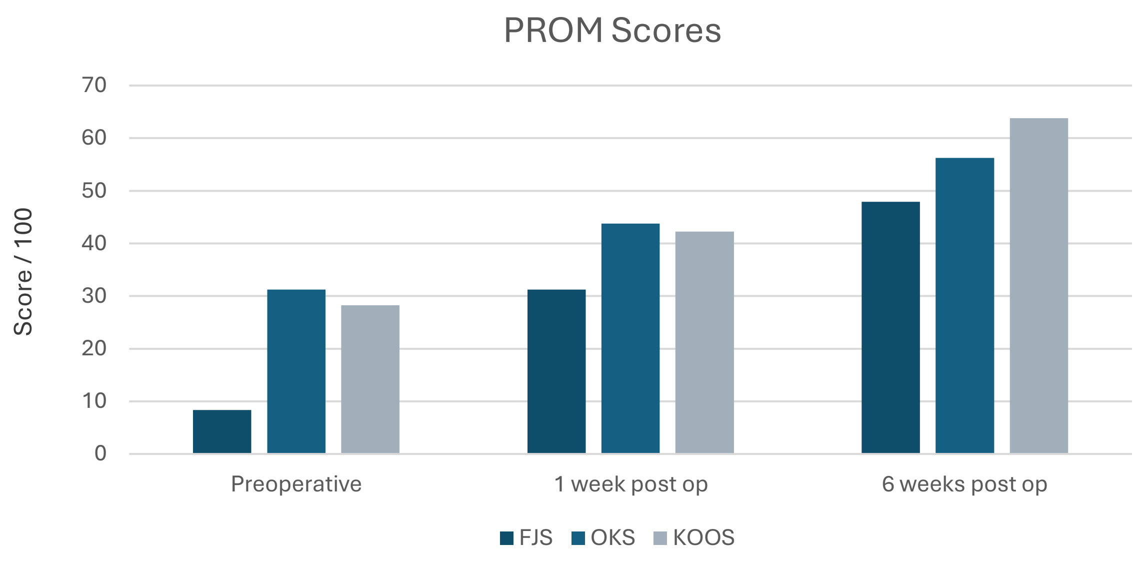


Figure 5-42. Patient reported outcome measures at each session for the TKA participant (Post op: Postoperatively).

Figure 5- 43 compares functional measures against the patient's subjective measures. The patient's outcome measures and ROM improved from baseline, however, a small decrease in cadence was observed 1-week postoperatively, yet this improved from baseline by 6 weeks postoperatively. The same general trend is observed between all variables, postoperative function is greater compared to 1-week postoperatively and preoperative scores.

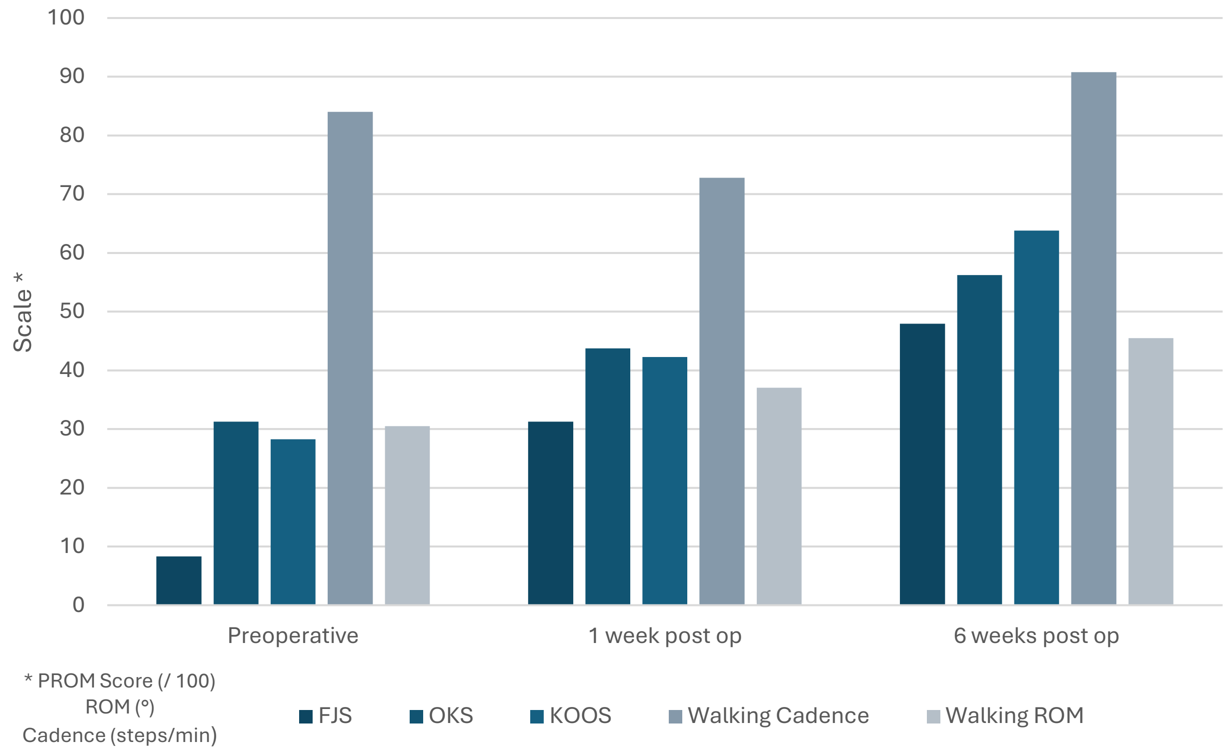


Figure 5-43. Objective and subjective outcomes for the TKA patient, PROM scored out of 100, Cadence measured in steps/min and ROM measured in degrees.

Spearman's correlations were calculated between PROM scores and ROM measures at each time point respectively, preoperatively ROM and average PROM scores resulted in a strong correlation of r = 0.61, 1-week post-surgery resulted in a strong negative correlation, r= -0.69 and 6 weeks post-TKA resulted in a strong positive correlation of 0.91. Higher PROM scores are generally observed to correlate with better functional outcome measures, Table 5-26.

Table 5-26. Correlation of Coefficients between subjective and objective measures throughout the recovery period, from preoperative base measures to the 6 week postoperative time point.

Correlation Coefficient (ρ)							
		Preoperative PROM Scores	*1 Week Postoperative PROM Scores*	*6 Weeks Postoperative PROM Scores*	*Preoperative ROM*	*1 Week Postoperative ROM*
Preoperative	ROM	0.61***	0.60***	0.04*	1.00***	0.17*
1 Week Postoperative		-0.68***	-0.69***	-0.98***	0.17*	1.00***
6 Weeks Postoperative		0.98***	0.98***	0.91***	0.45***	-0.81***

*Weak correlation
**Moderate correlation
***Strong correlation

Chapter 6. Discussion

6.1 Validation of MotionSense™

Following TKA patients often experience an initial decline in passive knee ROM due to postoperative pain and swelling caused by surgical trauma (Kort et al., n.d.). This reduction in ROM is accompanied by decreased performance in functional tasks such as walking and stair climbing speed (Bade, Kohrt and Stevens-Lapsley, 2010). Failure to regain walking speed postoperatively, even when pain is resolved, has been linked to both poor functional outcomes and the onset of new comorbidities (White et al., 2011).

Improved ROM facilitates more effective muscular contractions during exercise, enhancing strength and contributing to recovery (Alrawashdeh et al., 2021). Notably, the most significant improvements in flexion and extension occur within the first four weeks following surgery (Kornuijt et al., 2019), with greater ROM and mobility correlating with higher patient satisfaction (Van Onsem et al., 2018). To safely resume ambulation and other ADL's, restoring functional ROM is crucial and typically achieved through structured rehabilitation programs.

Wearable technologies offer promising support in early stages of recovery by enabling continuous, remote monitoring of patient progress. These tools can enhance home-based rehabilitation and alert clinicians to potential concerns (Vrints et al., 2011). However, their clinical utility depends on the accuracy of motion tracking. Evidence suggests that devices evaluated under realistic conditions produce more reliable data (Cutti et al., 2010; Fernandez et al., 2018; Kavanagh and Menz, 2008; Mannini and Sabatini, 2010; Mayagoitia, Nene and Veltink, 2002; Wang et al., 2023).

This study compared the MotionSense™ IMU to the gold-standard opto-electronic Vicon motion capture system in both healthy individuals and TKA patients across various ADL's. The MotionSense™ IMU maintained accuracy within a 5° clinical threshold, demonstrating agreement with Vicon opto-electronic motion capture and supporting its potential use in clinical rehabilitation.

6.1.1 Walking activity

Walking revealed a strong agreement between the two technologies, with a RMSE < 3° in both older and younger healthy adults and in the TKA clinical population. This represented a closer agreement compared to other similar gait studies, all reporting results within a larger threshold of < 5° (Cho et al., 2018; McGrath and Stirling, 2022; Patel et al., 2022).

Most recently in healthy populations, McGrath and colleague (McGrath and Stirling, 2022), Berner and colleagues (Berner et al., 2020), and Rekant and colleagues (Rekant et al., 2022) conducted validation analyses between motion capture and IMU sensors reporting knee flexion RMSE values between 3.30 to 3.77° and strong coefficients of multiple correlation values of 0.84 to 0.99, respectively. Of the previous research all was conducted in a smaller group of young healthy adults over 6 - 15 gait cycles of treadmill walking (Cho et al., 2018; McGrath and Stirling, 2022; Patel et al., 2022).

Similarly to the study reported in this thesis, Cornish et al (Cornish et al., 2024) evaluated the accuracy of IMU devices within a TKA clinical population at the 1-year post robotically assisted TKA time point. Cornish et al, compared two approaches (a proprietary kinematic model sensor algorithm and a quaternion-based approach) of determining knee angle from an IMU device against optical motion capture technology, however, used ground reaction forces to determine precise gait events. Their study made use of three IMU sensors, one placed on top of the foot, one anteriorly positioned on the thigh and the final placed anteriorly on the shank. The study included multiple activities, though, only analysed a single gait cycle per participant. As in agreement with this thesis, reported knee angles presented by Cornish and colleagues included the relative knee joint angle, which were determined by subtracting the average knee angle from the complete data set to mitigate any calibration or offset bias.

Cornish and colleagues, reported RMSE values between 3.14° to 13.28° for both approaches, which is significantly greater than RMSE values reported in this study ($p < 0.05$), with the walking activity reporting closer agreement compared to stair navigation, in line with the findings presented by the healthy population of this study, however, for our TKA population stair navigation (ascent and descent) reported the lowest RMSE, followed by walking. Furthermore, Cornish et al revealed neither sensor algorithm superior to the other. Correlation coefficients reported by Cornish et al, agreed with values reported by this study, evidencing strong correlations across all population groups. Additionally, in agreement with findings reported by Cornish et al, IMU devices tended to over-estimate knee angle during the swing phase and under-estimated knee angle during the stance phase, which is particularly evident in the healthy younger population of this study.

Despite the different age groups, and significantly slower gait speeds of the older adults compared to the healthy younger adults, there were no statistical differences recorded between both healthy groups RMSE in our study, possibly due to gait speed being within the range required for accurate IMU angle measurements (Lützner et al., 2014).

Previous literature has reported gait speeds of 1.0 – 2.2 m/s have the highest accuracy for IMU sensors (Cho et al., 2018), with lower accuracy reported above and below this range (Cooper et al., 2009). Although the older healthy adults and TKA population presented in this research study walked, on average, below this threshold it was not enough to affect the RMSE of the IMU device.

During walking the results of this study did not exceed a RMSE of 2.57° across the entire population of healthy and clinical participants (44 participants) for level walking. The lowest RMSE was reported by the TKA population at 1-week postoperatively (1.48°), while the largest RMSE was recorded in the TKA population, during their preoperative assessment (2.57°). These results are partially consistent with the findings of Wang et al. (2025), who evaluated IMU technology against motion capture during walking in both healthy and clinical populations. In their study, the healthy control group demonstrated an RMSE of less than 5°, aligning with our findings. However, their large clinical cohort of 240 patients with either hip or knee pathology exhibited higher RMSE values, ranging from 2.5° to 8°. Similarly, a study by Hafer et al. (2020) found that IMUs can accurately measure knee joint angles during walking when compared to motion capture. Like our study, they assessed three distinct populations: 10 healthy younger adults, 10 healthy older adults, and 10 individuals with osteoarthritis. Their results showed high accuracy across all groups, with a maximum RMSE of just 0.8°. This higher level of accuracy may be attributed to differences in experimental methodologies, particularly in sensor-to-segment alignment protocols.

Our results are, however, within clinically acceptable thresholds (Bonnefoy-Mazure et al., 2020; Deckey et al., 2023; Hullfish et al., 2019), suggesting that these sensors could be utilised within healthcare settings, though are greater than those reported by (Hefer et al., 2020).

No statistically significant differences existed between RMSE values of the healthy populations and the TKA group. The higher level of accuracy found within the clinical population at 1-week postoperatively may be due to the TKA population walking with more limited and controlled ROM early in the postoperative period, where movements are slower and more constrained, due to pain and swelling/stiffness which allows the IMUs to capture knee angles with greater precision (Cornish et al., 2024).

The accuracy of the IMU sensors in comparison to the opto-electronic motion capture system varied across the gait cycle. The difference between the measurements was greater during the swing phase. During the stance phase, the foot is in contact with the ground, and the body's weight is supported by the instrumented leg. This phase typically involves less rapid movement and fewer dynamic changes compared to the swing phase. Consequently, there is less noise and fewer artifacts in the sensor data during this phase given less associated movement of the muscle and underlying tissues, leading to more accurate measures (Jordan et al., 2021; Mcgrath, 2021; Taylor, Miller and Kaufman, 2017). This explanation may also account for the lower errors associated with the 1-week postoperative data. This high level of control and consideration exhibited during this stage of recovery when walking may reduce the errors caused due to noise within the measurements.

At the 1-week postoperative session, the standard deviation for the clinical population was notably greater during the swing phase compared to the stance phase, particularly between 60% and 80% of the gait cycle. This discrepancy can be attributed to the small sample size at this session (two individuals), which amplifies the variability in individual gait patterns. Since gait cycles are highly personal and the data analysis considered the segmented portion of data from heel strike to heel strike, gait events (such as the transition from stance to swing) may occur at slightly different points for each participant. In this case, one participant's slightly longer stance phase relative to another's contributes to the observed increase in standard deviation. However, though the gait cycles differ between the participants, these unique variations are accurately captured by both measurement system, with both technologies reflecting the same patterns in standard deviations.

These findings presented in our research are in line with results from previous studies reporting greater differences between angle measures in swing phase compared to stance phase (Cornish et al., 2024; Jordan et al., 2021; Mcgrath, 2021; Taylor, Miller and Kaufman, 2017). Overall findings reported in this study align with previous studies (Cho et al., 2018; Cornish et al., 2024; Jakob et al., 2013; Kobsar et al., 2020; Mcgrath, 2021; Mundt et al., 2019; Nüesch et al., 2017; Papi et al., 2015; Patel et al., 2012; Rhudy et al., 2024; Taylor, Miller and Kaufman, 2017) results.

6.1.2 Stair Navigation

Few studies (Zhang et al., 2013; Mundt et al., 2019) have evaluated the accuracy of IMUs when measuring sagittal knee angles in a healthy adult population for stair navigation. With only one study comparing the accuracy of an IMU device across stair navigation in a TKA population (Cornish et al., 2024), however this study did not evaluate the accuracy within a clinical population at various time points throughout recovery, but rather measured knee flexion at 1-year postoperatively robotic assisted surgery.

Stair navigation revealed an agreement of < 3° across all populations and at all time points for the clinical population. RMSE values ranged from 0.86° to 2.83°, with lower RMSE values reported in the TKA population for both stair ascent and stair descent compared to the healthy adults.

The techniques used by the TKA population to navigate the stairs was different to the healthy populations and should be noted when interpreting the results. These differences in stair navigation approach may lead to discrepancies. The healthy population adopted a step over step method, with each leg alternatively climbing a different step, resulting in faster movements but requiring more muscular control and balance. However, the TKA population navigated the stairs using the step-by-step technique, that requires more time and more control to safely navigate the stairs. This method ensures maximum stability as both feet are on the same step before moving onto the next step. The lower RMSE values presented by the TKA population may be due to these slower movement patterns associated with this step-by-step approach. This reduction in speed results in more stable and less noisy signals improving the sensor accuracy.

The results reported for the healthy population partially support those of Zhang and colleagues (Zhang et al., 2013), who conducted a comparison between IMU and 3D motion capture technologies across 10 young healthy individuals, evaluating the absolute difference between the technologies across a single gait cycle. For the sagittal plane Zhang et al, (Zhang al., 2013) reported the greatest difference between the technologies was found during stair descent followed by walking and then stair ascent ($p > 0.05$). In contrast, the results from this study found that walking had the greatest agreement, followed by stair descent, and then stair ascent with the poorest performance evidenced in the healthy population compared to the clinical group. However, like Zhang and colleagues (Zhang et al., 2013) this did not reach statistical significance. Furthermore, the results presented in this study for both stair ascent and stair descent in the healthy population are significantly smaller than RMSE values reported in (Mundt et al., 2019) that reported errors of between 9.9° to 11.9° for stair navigation across a population of 12 individuals, evaluating a single movement cycle. Mundt et al (Mundt et al., 2019), reported similar findings, with stair descent revealing the highest level of accuracy followed by stair ascent and with the largest errors associated with level walking, but too did not reach statistical significance.

Whereas in a similar clinical study evaluating IMU accuracy against motion capture 1-year postoperatively within a TKA population, Cornish and associates (Cornish et al.,

2024) reported walking to have the highest accuracy, with stair ascent and descent performing significantly worse ($p < 0.05$). Though, findings reported in our study evaluates both preoperative and postoperative measures, with the preoperative measures recorded in the acute recovery phase following surgery. These sensors performed accurately in both stair ascent and stair descent across all three visits, reporting a maximum RMSE of 2.62° during stair descent at 6 weeks postoperatively. Cornish and colleagues (Cornish et al., 2024) reported errors of between 6.78° to 12.06° for stair navigation. The MotionSense™ sensor used in this study performed significantly better ($p < 0.05$) for both stair ascent and stair descent at all three time points compared to (Cornish et al., 2024) which used the same approach as our research to account for offset differences between the IMU technology and motion capture. The differences in study results may be attributed to variations in the participants' mobility levels and the timing of data collection. Our study captured data very shortly after surgery, when patients are likely to be moving more slowly and cautiously. In contrast, Cornish (2024) assessed participants at a later stage of recovery, where participants would be moving at quicker rates and more confidently, potentially explaining the lower error observed in our findings.

When comparing the accuracy between the healthy and the clinical TKA population no statistically significant differences existed between RMSE values ($p > 0.05$). The TKA population showed lower RMSE values 1-week post operatively which may be due to the slower more controlled approach this population adopted to carefully navigate the stairs.

Moreover, during the stair navigation exercise at the 1-week postoperative session, the standard deviation for the clinical population was greater during the swing phase compared to the stance phase. This trend is similar to the findings observed during treadmill walking and can be explained by the same factors. The small sample size at this session highlights individual variability in stair navigation patterns.

Stair navigation introduces additional biomechanical challenges, such as the need for greater joint control and stability, which can further emphasise individual differences (Gallagher, VandenBussche and Callaghan, 2013; Igawa and Katsuhira, 2014).

Movement cycles were segmented from heel strike to heel strike, however, during stair navigation, the timing and coordination of gait events may vary more significantly between participants. For instance, one individual may take slightly longer in the stance phase to stabilise before initiating the swing phase, while another may transition more quickly. These differences in movement strategies contribute to the larger standard deviation observed during the swing phase.

Larger differences were observed during greater degrees of flexion for the stair navigation activity which is further supported by similar findings reported in (Mundt et al., 2019). As the TKA population displayed a reduced ROM and limited peak flexion this may have resulted in the clinical population having lower errors compared to the healthy population. All populations reported excellent coefficients of correlations for both stair ascent and stair descent, reporting higher levels of agreement compared to previous research (Cornish et al., 2024; Mundt et al., 2019).

6.1.3 Flexion/Extension

Maximum flexion and extension movements are commonly performed to evaluate TKA recovery progress, however, is often evaluated either visually or measured using a goniometer as part of clinical assessments. Previous studies (Edwards et al., 2004; Mcgrath, 2021) have reported that visual methods can be off by up to 5° in 45% of cases, while goniometer readings can be off by up to 5° in 22% of cases (McGrath, Fineman and Stirling, 2018).

In this study the commercial IMU MotionSense™ sensor was evaluated across both healthy and clinical TKA groups, with RMSE values reported between 3.21° to 4.70°. The largest RMSE was reported in the TKA population 6 weeks post operatively, however, RMSE values are consistent with similar studies evaluating flexion/extension using IMU devices across a TKA population of 8 individuals, with data captured within three months postoperatively (Antunes et al., 2021) and within a healthy population consisting of 5 individuals (Mitternacht et al., 2022).

Larger differences in measurements were reported in peak flexion across both healthy groups and within the TKA population, with the commercial MotionSense™ device more commonly under reporting peak flexion values. IMU algorithms tend to struggle to accurately determine larger flexion angles due to the knee joint's non-linear nature. Rotations and translations are more pronounced at higher flexion angles and this higher degree of freedom present during maximum flexion may amplify these differences (Schall et al., 2016). Furthermore, these differences may be further compounded by soft tissue artifacts, sensor drift, and gravitational influences, making it harder for the algorithms to accurately model the knee's movement during maximum ROM activities (Ferrari et al., 2008; Garling et al., 2007; Mitternacht et al., 2022; Peters et al., 2010). These discrepancies are not unexpected and frequently occur in movements that reach the sensors end of range, limited by sensor calibration and resolution, resulting in larger errors occurring in extreme measurements (Antunes et al., 2021; Torino, 2021).

Minimum flexion differences should also be noted, the TKA population displayed much larger minimum flexion angles postoperatively compared to their preoperative baseline measures and to the healthy adults'. This reduction in minimum flexion of the TKA cohort may as a result of pain and swelling following surgery (Hewitt and Shakespeare, 2001; McClelland et al., 2017; Yoshida et al., 2008). This reduced ability for the leg to move into extension may cause difficulties in leg registration and possible challenges when calibrating the zero angle of the sensor. These associated calibration limitations may have resulted in the differences between the measurement systems as the commercial IMU wearable device would be reporting angles with an associated offset bias.

Moreover, greater variability within the data for all population groups was observed during the flexion/extension exercise, where the broader limits of agreement in Bland-Altman plots (Figure 5-16) may reflect differences in participant strength, mobility, and muscular control (Pavol, Michael and Grabiner, 2000). Full flexion/extension exercises test the limits of motion, so individual physiological differences may contribute to variability in ROM measures, particularly in the TKA population, accounting for this variability.

Though this activity tested the extreme measurement boundaries resulting in a high degree of variability within measurements across each population group, the IMU device measured knee flexion angle within a clinically acceptable agreement of < 5°, resulting in measures in line with available literature (Antunes et al., 2021; Mitternacht et al., 2022)

6.1.4 Cycling

The cycling activity was only performed by the healthy population of older and younger adults. These results did not exceed a RMSE of 4.57°. Despite age differences, no significant differences in RMSE were recorded between the age groups. However, older participants pedalled at a significantly slower cadence than younger participants (67.99 ± 9.01 rpm vs. 60.25 ± 9.98 rpm, mean ± SD, $p < 0.05$, younger vs older adults respectively), with all participants cycling at a lower cadence compared to a previous similar study (Obradović and Stančin, 2023), though pedalled within the same range as (Marin-Perianu et al., 2013).

Cycling had the highest RMSE compared to all the activities performed by the healthy population, (4.05 ± 2.49 vs 4.57 ± 1.46, mean ± SD, younger vs older participants), likely due to the high degree of flexion required and the dynamic changes in velocity throughout the pedal stroke. Though larger RMSE values were found within the cycling activity, these results are in line with results reported by previous research (Cordillet et al., 2019; Marin-Perianu et al., 2013; Obradović and Stančin, 2023) all reporting RMSE between 3.74° to 8.49°. With larger errors similarly reported during faster pedalling compared to slower pedalling (Marin-Perianu et al., 2013).

Of the previous research available, RMSE values of 4.81 ± 8.23° (mean ± SD) for 10 pedal strokes across 8 healthy participants were reported by (Obradović and Stančin, 2023), while larger RMSE of 6.73° and 8.49° were reported by (Cordillet et al., 2019) and (Marin-Perianu et al., 2013) respectively. This study reported smaller RMSE values across both younger and older healthy adults, compared to the previous research.

The variability of knee angle within the cycling measures may be attributed to differences in participant saddle height. Since the participants were not experienced cyclists and chose saddle heights based on comfort, maximum knee flexion angles may have varied. This variability is largely linked to the differences in saddle height rather than sensor accuracy. A limitation of the cycling activity is the difficulties in marker occlusion, particularly with those markers associated with the ASIS. This limitation further highlights the advantage of using IMU devices compared to traditional motion capture technologies.

MotionSense™ accuracy varied throughout the pedal stroke, with the greatest error observed at 50% of the cycle, at maximum flexion, and at the beginning of the next pedal stroke. Larger errors presented at the beginning of the pedal stroke, may be due to the force exerted through the pedal, when pulling the leg upwards, causing rapid changes in leg direction. This force and direction change may result in perturbations through the leg's soft tissue, contributing to measurement system discrepancies (Akbarshahi et al., 2010; Garling et al., 2007), the same situation would occur in the power phase of the pedal stroke as the leg exerts force downwards onto the pedal.

The larger errors in cycling may further be explained due to the rapid cyclic nature of the movement, which can push the limits of the sensors' dynamic range and filtering algorithms. Dynamic and repetitive movements measured by IMUs often suffer from drift, as noted in literature (Cordillet et al., 2019), though techniques like the Kalman filter can mitigate drift, they may not completely eliminate errors. This drift might contribute to the higher RMSE when comparing the sensors to Vicon (Cordillet et al., 2019; Obradović and Stančin, 2023), though these findings were not observed for the walking activity.

When evaluating maximum flexion angle and cadence during cycling, the results reported in this study reported lower cadence and smaller flexion angles than those found in literature (Cordillet et al., 2019; Obradović and Stančin, 2023), though within similar cadence to that reported by (Marin-Perianu et al., 2013). These differences in flexion angle and cadence may be due to differences in saddle height. The participants in this study, were not regular cyclists and used a stationary bicycle, while the participants in (Obradović and Stančin, 2023) and (Marin-Perianu et al., 2013) were experienced cyclists using their own bicycles specifically set up to the riders' specifications. Higher saddle heights are associated with reduced knee flexion and increased knee extension, likely resulting in lower cadences (Chang et al., 2016). Therefore, our participants are likely cycling with saddle heights slightly too high compared to the other research (Chang et al., 2016; Cordillet et al., 2019; Marin-Perianu et al., 2013; Obradović and Stančin, 2023).

A further shortcoming of the cycling activity was the difficulty in capturing full datasets on the motion capture system as ASIS marker obstruction was a common limitation (Boddy *et al.*, 2019). Though this resulted in the researcher asking the participants to adjust their cycling posture, this common challenge associated with marker occlusion further builds the case for the opportunity IMUs pose in the field of motion analysis.

Our study, which included a larger and more age-diverse population, reported cycling RMSE values consistent with or lower than those in similar studies (Cordillet et al., 2019; Marin-Perianu et al., 2013; Obradović and Stančin, 2023) with a strong correlation between the measurement systems.

6.1.5 Sit to Stand and Stand to Sit Activities

The MotionSense™ IMU accurately measured knee flexion angle in both the sit-to-stand and stand-to-sit activity for the healthy population, with RMSE values < 3°. The results in our study outperformed similar studies (Cornish et al., 2024; El Fezazi et al., 2023; Lebel et al., 2017), including those studies isolating these movements from a get-up-and-go protocol across 7 participants and evaluating the technology against the PIG optoelectronic motion capture kinematic model (El Fezazi et al., 2023).

As with previous activities, errors were greatest during periods of higher joint accelerations and larger flexion angles. In the stand to sit activity, this was observed as the participant began moving toward the stool, with errors stabilising once seated. During the sit to stand activity, errors remained consistent while seated but increased as the participant raised themselves from the stool, particularly during the momentum transfer phase, where joint angle accelerations are at their highest.

Our study aligns with similar research (El Fezazi et al., 2023), also reporting smaller RMSE values in the stand-to-sit movement compared to sit-to-stand when isolating these movements from a get-up and go movement. Biomechanically, sit to stand movements require more coordination and muscle engagement to generate enough force to stand, leading to higher acceleration and rapid joint angle changes. These dynamic changes increase the potential for IMU measurement errors due to drift and alignment issues. In contrast, the stand-to-sit movement is slower, more controlled, and smoother, leading to more accurate measurements with fewer sudden changes in acceleration and orientation.

Consistent with previous research (El Fezazi et al., 2023; Uhlenberg and Amft, 2024), stand-to-sit movements generally exhibit smaller RMSE due to their more predictable and controlled nature, which minimises sensor drift and alignment issues. This is further supported by the smaller limits of agreement in Bland-Altman plots for stand-to-sit movements compared to sit-to-stand movements

6.1.6 Summary of Findings

The accuracy of the MotionSense™ commercial IMU device varied within populations and between activities. However, RMSE of < 5 ° for all activities and across all populations, with strong coefficients of correlation were reported.

A strength of this study is the large population size (44 participants), comprising of two healthy control groups (34 participants) of varying ages (20 - 84 years old) and abilities, and a TKA clinical population (10 patients), with data collected both pre- and postoperatively. Furthermore, a wide range of activities across this varied population was evaluated.

It is important to highlight that in studies evaluating the accuracy of IMU devices for measuring knee angle, the reliability and generalisability of findings are highly dependent on sample size and demographic diversity. A larger sample provides greater statistical power and reduces the influence of individual variability, which is particularly important when assessing biomechanical measurements, this is particularly relevant for the clinical population. Furthermore, achieving a balanced distribution across age and gender is crucial, as factors such as joint flexibility, muscle mass, and movement patterns can vary significantly across different demographic groups. Without such representation, results may not accurately reflect the performance of IMU devices across the broader population, limiting the clinical and practical applicability of the findings. Including a diverse and sufficiently large participant pool enhances confidence in the accuracy and usability of IMU technology in real-world settings.

The accuracy of the commercial IMU sensor in comparison to the motion capture system varied depending on the activity, stage of movement cycle, ROM and speed of movement. For example, when considering the accuracy of the device during the gait cycle the difference between the measurements was greater during the swing (60 - 100%) versus the stance phase (0 - 60%) for all activities. The stance phase involves less rapid movement and fewer dynamic changes compared to the swing phase, as the limb is in contact with the ground. Consequently, there is less noise and fewer artifacts in the sensor data during this phase given less associated movement of the muscle and underlying tissues.

The stance phase is thought to lead to more accurate measurements of joint angles of the IMUs as the orientation between the IMU and anatomical coordinate frames is reduced (Taylor, Miller and Kaufman, 2017). Furthermore, during stance phase there is minimal movement in the frontal and transverse planes increasing accuracy of MotionSense™ and limiting the inaccuracies of the PIG hinge model of the knee joint (Ferrari et al., 2008).

Moreover, across all activities and populations MotionSense™ more commonly underestimated peak flexion angle, resulting in positive differences between the measurement system, while overestimated minimum flexion angles resulting in negative differences, this is in agreement with findings reported by (Ferrari et al., 2008). These differences may further be accounted due to difficulties in leg registration when calibrating the sensor resulting in mechanical misalignments causing measurement bias.

Soft tissue artefacts influence motion analysis differently across body segments and technologies. Research indicates that the thigh experiences greater translational and rotational errors than the shank (Garling et al., 2007; Peters et al., 2010). These artefacts also affect measurement technologies differently; for instance, IMU devices tend to overestimate sagittal plane knee angles during stance and underestimate them during swing, due to soft tissue interference (Ferrari et al., 2008). Similarly, limitations in motion capture systems such as Vicon, including assumptions about anthropometrics, kinematic joint definitions, and marker placement variability, contribute to inaccuracies (McGrath and Stirling, 2022).

The Cardan angles used to describe knee joint motion; flexion/extension, abduction/adduction, and internal/external rotation, which are not orthogonal (Wu et al., 2002), meaning significant motion in one plane, especially during high knee flexion, can affect measurements in another due to angular crosstalk (Leardini et al., 2014). Misalignment in the flexion/extension axis during calibration further exacerbates this issue by introducing errors in the transverse and frontal planes, particularly at greater flexion angles.

The physical differences between MotionSense™ IMUs and opto-electronic Vicon motion capture reflective markers, such as size, shape, and placement also contribute to variation in recorded motion (Ferrari et al., 2008; Leardini et al., 2005; Peters et al., 2010; Stagni et al., 2005; Torino, 2021). Additionally, participant heterogeneity, including differences in body composition, sensor placement, and gait technique, likely amplifies these discrepancies. These effects are especially pronounced in activities involving sustained knee flexion, such as stair navigation and flexion/extension tasks, which show higher RMSE compared to walking. Nevertheless, all activities across all population groups showed a strong correlation and clinically acceptable RMSE < 5°. These findings support the use of IMUs for measurement of sagittal plane knee measures for various ADLs.

The methodology adopted within this research should be taken into consideration when interpreting results and comparisons made between previous findings in available literature. Though similar approaches have been used in prior research (Hafer et al., 2020; Mcgrath, 2021; Jiang et al., 2022; McGrath and Stirling, 2022; Cornish et al., 2024) it is important to re-emphasise the method used to eliminate the offsets between the wearable technology and the motion capture system. Due to manual application of both devices onto the leg this can result in different zero angle for the knee. These differences are associated with differences between the calibration methods of each system and differences in marker and sensor placement on the body. Therefore, to account for this offset the difference was reduced by adjusting the sensor angle so that its mean value equalled that of the mean Vicon angle across the entire activity. The challenge associated with accurate sensor placement and its associated offset error may impact clinical usability and the resulting clinical data. However, such offsets may be overcome through the implementation of calibration protocols or minimising the offset through methods as described above.

This study presented findings from a larger cohort of healthy individuals than previously reported on (Ajdaroski et al., 2020 – 8 healthy participants; El Fezazi et al., 2023 – 7 healthy participants; Henkel, 2016 – 1 healthy participant; Hafer et al., 2020 – 20 healthy participants; Leardini et al., 2014 – 5 healthy participants; Papi et al., 2015 – 14 healthy participants; Patel et al., 2022 – 15 healthy participants; Robert-Lachaine et al., 2017 – 12 healthy participants; Zhou et al., 2020 – 5 healthy participants), including both younger and older adults, as well as a smaller cohort of TKA patients both preoperatively and postoperatively.

Results from a wide range of activities is presented, for all population groups, enabling comparisons between activities but also between clinical and healthy population groups which is a strength of the research. Furthermore, TKA postoperative data is presented in the acute recovery stages (1-week following surgery) which is not commonly documented (Al-Amri et al., 2018; Antunes et al., 2021; Cutti et al., 2010; Ferrari et al., 2010; Hullfish et al., 2019; Prill et al., 2021) and across a larger population than results presented by (Antunes et al., 2021 – 8 TKA participants; Chen et al., 2018 – 5 TKA patients).

Although the IMU MotionSense™ wearable sensor is intended for a TKA population, performing a validation across a healthy population of both older and younger adults is an asset of this research. This is due to the largest errors being reported in deep flexion at end of ROM and during periods of rapid movement. Given that the TKA population displayed reduced ROM and slower movement patterns the accuracy of the IMU device is more greatly tested in a healthy population compared to the TKA clinical, suggesting that the device is more appropriately used in a clinical population.

An additional advantage of the findings presented in this research is the wide range of activities and ROM presented for the TKA population at various time points. By evaluating sensor accuracy both pre- and postoperatively it becomes possible to determine whether IMU sensors are sensitive enough for recovery monitoring in the acute recovery period.

6.2 Validation of the Seel Algorithm

Clinically, the recovery of patients following TKA is commonly assessed through gait analysis and PROMs (Abu-Faraj et al., 2015; Davis, 1997; Hulleck et al., 2022). These assessments are typically conducted at specific follow-up intervals, resulting in sporadic snapshots of patient progress. The accuracy of these evaluations varies significantly depending on the resources available. Advanced facilities may use motion capture laboratories to obtain accurate joint biomechanics, whereas resource-limited settings often rely on visual and manual measurements of knee flexion angle (Hulleck et al., 2022).

However, these conventional methods lack the ability to continuously monitor ROM, particularly after hospital discharge when patients continue recovery at home. Currently, no standardised clinical system exists for ongoing knee angle monitoring outside clinical settings (Davis, 1997; Hulleck et al., 2022). In response, IMUs have garnered attention due to their capacity for continuous data collection throughout the postoperative period (Al-Amri et al., 2018; Chapman, Moschetti, and Van Citters, 2021; Ois Routhierid et al., 2020).

IMUs offer dual advantages: they can enhance rehabilitation compliance by remotely monitoring functional improvements and delivering real-time feedback via mobile applications (Bolam et al., 2021; Parrington et al., 2021). Additionally, the high-resolution data these devices generate can facilitate early detection of atypical recovery trajectories, allowing timely interventions that may prevent the need for revision surgery (Atallah et al., 2011; Kornuijt et al., 2019).

Although various commercial IMU systems are available (Jebeli, Bilesan, and Arshi, 2017), they often entail substantial costs, including upfront device expenses, licensing fees, software maintenance, and data access charges. Furthermore, these systems are frequently constrained by proprietary algorithms and limited access to raw data, hindering customisation and scalability across different clinical environments.

A potentially more flexible and cost-effective alternative is the use of off-the-shelf IMU devices combined with open-source processing methods, such as the Seel algorithm, to compute knee angle measurements. This approach could offer a customisable and scalable solution capable of matching the accuracy of commercial systems, while remaining adaptable to various clinical needs.

For this to be viable in practice, however, the Seel algorithm must demonstrate sufficient accuracy to ensure that the resulting data is clinically meaningful and accurately reflects patients' functional outcomes. Therefore, this study aimed to validate the algorithm, based on the method developed by Seel and colleagues (2014), for determining knee angle measurements in both healthy individuals and patients who have undergone TKA.

6.2.1 Healthy Control Group

The algorithm demonstrated accurate performance across all activities when compared to the gold-standard opto-electronic motion capture system. The maximum RMSE was 4.60° during the flexion/extension activity, while the lowest RMSE recorded was 2.92° during cycling, averaged over 50 pedal strokes. The Seel algorithm consistently underestimated peak knee flexion and overestimated minimum flexion compared to Vicon, with the largest signed difference of 8.14° during peak flexion in the flexion/extension task and -3.68° during minimum flexion in cycling.

Previous validation studies focused primarily on slower, controlled movements such as walking (Boonstra et al., 2006; Huddleston et al., 2006; Tong and Granat, 1999), or used less accurate reference systems (Dejnabadi et al., 2006). For instance, Favre et al. (2009) examined IMU accuracy during walking but required a standing calibration protocol for accurate sensor-to-segment alignment to.

Compared to similar studies (Boonstra et al., 2006; Cooper et al., 2009; Cuesta-Vargas, Galan-Mercant and Williams, 2010; Ghattas and Jarvis, 2021; Hu et al., 2021; Huddleston et al., 2006; Jiang et al., 2022; Kavanagh and Menz, 2008; Kobsar et al., 2020; Lim, Kim and Park, 2020; Luinge and Veltink, 2005; Mayagoitia, Nene and Veltink, 2002; McGrath and Stirling, 2022; Mundt et al., 2019; Narváez, Árbito and Proaño, 2018; Nüesch et al., 2017; Obradović and Stančin, 2023; Ortigas Vásquez et al., 2023; Papi et al., 2015; Picerno, Cereatti and Cappozzo, 2008; Poitras et al., 2019; Rhudy et al., 2024; Seel, Raisch and Schauer, 2014; Taylor, Miller and Kaufman, 2017; Tong and Granat, 1999; Uhlenberg and Amft, 2024; Versteyhe et al., 2020; Zhang et al., 2013; Zhou et al., 2020), this study reports lower or comparable RMSE values, achieved over more repetitions, a broader range of activities, or within a larger sample size. Commonly, earlier studies include 3 to 12 healthy participants and assessed 4 to 30 gait cycles, while this study involved 20 participants and evaluated 50 cycles for both walking and cycling.

Errors within 5° are generally accepted as clinically acceptable (Robertson et al., 2014), as they do not significantly impact rehabilitation outcomes. This study remained within this threshold across all activities. A strong correlation ($r = 0.99$) between IMU and Vicon measurements was observed across all tasks, which is greater than those reported in Al-Amri et al. (2018), Chapman et al. (2019), and Deckey et al. (2023), and aligning with Zhang et al. (2013).

Methodological differences likely explain discrepancies across these studies. For example, Al-Amri et al. (2014) studied 26 adults across three functional tasks, while this study assessed five tasks in 20 participants aged 20 to 36. Only the walking task was common to both and could be compared directly. Al-Amri et al. also focused on within- and between-rater reliability using opto-electronic motion capture and IMUs across different sessions, in addition to validity. However this study only emphasised validity between the technologies. Differences in data collection and processing also existed between the two studies. Al-Amri et al. used a trigger to ensure simultaneous data collection as well as MATLAB functions for accurate synchronisation and resampling and identified heel strike using methods as described by Zeni et al. (2008). Despite differences, both studies corrected offset bias to improve comparability. Collectively, these variations in experimental design and analytical approaches likely contributed to the differences in outcomes observed between the studies. Nonetheless, findings from previous research remain valuable in contextualising the current results and contribute meaningfully to the broader understanding of IMU system performance in clinical movement analysis.

Observed discrepancies in measurements during faster movements or larger flexion angles are consistent with prior research (Hullfish et al., 2019). These deviations are attributed to soft tissue artifacts, where tissue movement relative to the bone during full flexion or rapid motion affects IMU accuracy (Akbarshahi et al., 2010; McGrath and Stirling, 2022; Taylor, Miller and Kaufman, 2017). Such artifacts are particularly evident during high-speed motions or abrupt direction changes, introducing sensor vibration and data noise (Akbarshahi et al., 2010; McGrath and Stirling, 2022; Taylor, Miller and Kaufman, 2017). Additional errors may stem from sensor drift or limitations in filter optimisation, especially in tasks involving variable speeds (Guignard et al., 2021; Ludwig, 2018; Madgwick, 2010; Schreven, Beek and Smeets, 2015). Filters tailored for specific movements may not generalise well, affecting measurement accuracy.

In walking, the swing phase (60%-100% of the gait cycle) exhibited higher errors than the stance phase due to greater dynamic motion. Stair navigation showed RMSE values comparable to previous studies (Lebleu et al., 2020; Mundt et al., 2019; Zhang et al., 2013), though this study found greater accuracy during ascent than descent, contrary to Zhang et al. (2013). Similar to walking, larger discrepancies occurred at higher flexion angles and during swing phases.

Cycling produced the lowest RMSE (2.92°), lower than reported by Cordillet et al. (2019). Errors were greatest during pedal stroke transitions, particularly at 20%-35% (recovery phase) and 70%-80% (start of power phase), when joint acceleration changes direction. These phases involve significant shifts in angular velocity and soft tissue deformation, affecting sensor alignment (Akbarshahi et al., 2010; Garling et al., 2007; Page et al., 2014; Peters et al., 2010; Solav et al., 2014).

Greater errors were noted at extremes of flexion and extension, as in the flexion/extension task, due to complex rotations and translations that challenge accurate joint tracking. IMUs were powered on and off between trials, introducing potential calibration variation and drift. Collecting continuous data could mitigate these inconsistencies by reducing startup variability.

The accuracy of IMU-based measurements is influenced by calibration protocols (Cutti et al., 2010; de Vries et al., 2010; Fradet et al., 2017). Misalignment between sensor and segment axes is a major error source (Cordillet et al., 2019; Fradet et al., 2017; Pacher et al., 2020), with studies showing a linear relationship between alignment precision and measurement accuracy (Brennan, Deluzio and Li, 2011). Calibration could thus enhance measurement accuracy, but improper implementation may compromise results.

Although no formal calibration was used in this study, offset correction ensured mean knee angles from IMU matched those from Vicon, a method supported in prior research (Mcgrath, 2021; Jiang et al., 2022; McGrath and Stirling, 2022; Cornish et al., 2024). The measurements align with existing literature (Ajdaroski et al., 2020; Cooper et al., 2009; Favre et al., 2009; Jakob et al., 2013; Jiang et al., 2022; Narváez, Árbito and Proaño, 2018; Obradović and Stančin, 2023; Oliveira, Park and Barrance, 2023; Rhudy et al., 2024; Tadano, Takeda and Miyagawa, 2013; Takeda et al., 2009; Tognetti et al., 2015; Tong and Granat, 1999; Watanabe and Saito, 2011; Zhou et al., 2020) and fall within clinically acceptable thresholds (Cooper et al., 2009; Favre et al., 2006; Lebleu et al., 2020; Liu et al., 2009; Mcgrath, 2021; Poitras et al., 2019; Seel, Raisch and Schauer, 2014; Versteyhe et al., 2020).

The IMU system reliably measured knee joint angles across 50 trials for each activity. The findings suggest IMUs are a viable alternative to traditional motion capture systems for assessing knee flexion, with potential applications in rehabilitation monitoring and post-TKA recovery. A notable strength of the method is its lack of need for calibration or predefined poses, simplifying usage (Duong et al., 2019; Hu et al., 2021; Pacher et al., 2020; Tognetti et al., 2015; Versteyhe et al., 2020). Yet, this may be a limitation in clinical settings, where leg alignment is harder to assess without calibration, particularly post-surgery (Antunes et al., 2021; Mayagoitia, Nene and Veltink, 2002; Picerno, Cereatti and Cappozzo, 2008). Introducing a calibration protocol could enhance accuracy in these contexts.

6.2.2 TKA Clinical Population

Although patients often report satisfaction with their outcomes following TKA, the function of the knee post-surgery frequently differs from its state prior to the onset of disease and surgery. While TKA typically improves mobility, gait and joint biomechanics often remain altered compared to pre-disease and pre-surgical patterns. Common deviations include a prolonged stance phase on the operated limb, reduced knee flexion during swing, and altered load distribution. Additional changes such as slower walking speeds, shorter stride lengths, and decreased limb symmetry can persist due to lasting impacts on muscle function and joint mechanics.

Despite the procedure's success in restoring much of the knee's function and alleviating pain, it often results in a knee that moves and feels different from a natural healthy joint, particularly in motion patterns and proprioceptive feedback. These changes are shaped by surgical techniques, prosthetic design, and preoperative patient-specific factors like muscle strength and joint alignment, all of which may contribute to altered knee kinematics, muscle function, ligament stability, and joint loading.

Given the significant differences in kinematics, movement patterns, and gait parameters observed after surgery compared to a healthy knee joint, it is essential to assess the accuracy of wearable devices in measuring knee flexion angles in these clinical populations. As these devices are intended to support rehabilitation and monitor recovery, reliable data is critical for clinical decision-making.

The Seel algorithm (Seel, Raisch and Schauer, 2014) demonstrated accurate measurement within a TKA clinical population during preoperative and postoperative walking. A maximum RMSE of 4.78° was recorded preoperatively, with a minimum RMSE of 3.36° reported 1-week postoperatively, no significant differences were observed between each time point for walking ($p > 0.05$).

While prior validation studies (Antunes et al., 2021; Cornish et al., 2024) have assessed wearable devices in clinical populations, most focus on healthy individuals. Among the clinical studies, many evaluate fewer gait cycles or later postoperative stages. In contrast, this study included 5 TKA patients assessed both preoperatively and one week postoperatively, analysing 50 gait cycles per participant. The RMSE values (3.36° to 4.78°) reported here outperform those in similar studies, such as Allseits et al. (2018), which reported an RMSE of 6.50° across 40 gait cycles in healthy participants, and Cornish et al. (2024), who observed RMSE values of 5.76° to 7.00° in 14 TKA patients assessed one-year post-surgery.

Consistent with prior findings (Allseits et al., 2018; Antunes et al., 2021), this study found that IMU devices tend to underestimate peak knee flexion angles compared to gold-standard motion capture systems. This discrepancy was more pronounced in the preoperative data, where patients demonstrated greater ROM and maximum flexion than at one week postoperatively. Specifically, the Seel algorithm underestimated maximum flexion by up to 9.18° preoperatively, while the maximum discrepancy in minimum flexion reached -2.46° at one week post-TKA.

Larger errors tended to occur during phases of greater flexion, particularly during the swing phase, as also noted by Cornish et al. (2024) and Ferrari et al. (2008). Contributing factors include post-surgical challenges with leg registration and soft tissue movement, which can distort sensor and marker placement (Johnson et al., 2020). These soft tissue artifacts increase with greater knee angles due to enhanced displacement of the skin and underlying tissue (Akbarshahi et al., 2010; McGrath and Stirling, 2022). Thus, larger discrepancies observed preoperatively and at six weeks may be linked to greater achievable flexion during these periods compared to one week postoperatively, when swelling and pain are at their peak.

Strong correlations were observed between the IMU and Vicon systems across all three data collection points (r = 0.95 to 0.97), aligning with results from Huang et al. (2020), who evaluated the accuracy of IMU technology against professional rehabilitation technology across 11 TKA patients.

The IMU showed agreement in measuring knee flexion during treadmill walking both before and after surgery. Bland-Altman–like plots confirmed this, showing narrow limits of agreement (within 15° across percentiles), with previous results (Guignard et al. 2021) supporting these findings and a small systematic bias of -1.37° at one week postoperatively. Despite this, the close clustering around the mean difference line suggests the systems can effectively be considered equivalent.

The Seel algorithm consistently measured knee flexion with RMSE values below 5° across all time points, demonstrating its ability to accurately measure subtle improvements in ROM from one to six weeks post-TKA. These values fall within clinically acceptable thresholds (Bonnefoy-Mazure et al., 2020; Hullfish et al., 2019), supporting the potential of IMU devices for clinical application in monitoring early-stage rehabilitation and tailoring patient-specific care.

However, limitations exist. This study included only five participants, one of whom had a severe valgus deformity, and focused solely on level treadmill walking. Future work should expand to larger samples and a broader range of movements, speeds, and flexion angles to validate the algorithm's robustness. Although prior work (Appendix 3, Chapter 11) demonstrated high accuracy under sensor placement offsets, further research is needed for broader clinical adoption.

Additionally, incorporating a standardised calibration protocol may improve accuracy. Swelling in the acute postoperative phase often limits full extension, complicating zero-point calibration. Including a bent-knee calibration step could reduce offset errors and improve alignment. Finally, continuous accuracy throughout recovery should be further explored to ensure these devices can reliably monitor patient progress at a granular level across all stages of rehabilitation.

6.2.3 Summary of Findings

Comparisons between the Seel algorithm and Vicon opto-electronic motion capture underscore the potential of IMUs to transform motion analysis in clinical and rehabilitation contexts. While the Seel algorithm demonstrated higher accuracy in the healthy population compared to the TKA group, all results remained within clinically acceptable thresholds (Deckey et al., 2023; Hullfish et al., 2019). No significant differences in RMSE were observed for walking between the two populations ($p > 0.05$), and results aligned with findings from similar validation studies (Cornish et al., 2024; Jiang et al., 2022; Kobsar et al., 2020; McGrath and Stirling, 2022; Nüesch et al., 2017).

Among the activities tested, cycling in the healthy younger adult group demonstrated the highest agreement (RMSE = 2.92°), while preoperative walking in the TKA group showed the lowest (RMSE = 4.78°). Despite the TKA cohort exhibiting limited ROM and restricted peak flexion, especially during stance at 1-week post-op, the Seel algorithm effectively characterised knee flexion across both populations, with strong correlation coefficients across all activities.

The IMU algorithm consistently underestimated peak flexion, particularly during high-speed movements or those involving abrupt directional changes. However, these variations did not significantly impair overall accuracy, as all measurements remained within clinically acceptable thresholds (Al-Amri et al., 2018; Chapman, Moschetti and Van Citters, 2021; Deckey et al., 2023). These findings are consistent with previous research validating IMU performance in both clinical and healthy populations (Antunes et al., 2021; Cornish et al., 2024; Cutti et al., 2010; McGrath and Stirling, 2022; Versteyhe et al., 2020; Zhang et al., 2013; Zhou et al., 2020).

However, limitations inherent to the PIG model must be acknowledged. At higher degrees of knee flexion, errors related to crosstalk and coordinate system misalignment become more pronounced. Discrepancies between the IMU and PIG coordinate systems can also lead to systematic bias, particularly as Vicon opto-electronic motion capture uses a calibration routine based on joint centres, while the IMU system relies on kinematic assumptions for orientation estimation (Seel, Schauer and Raisch, 2012; Guignard et al., 2021).

Measurement inaccuracies can arise in both systems. In Vicon opto-electronic motion capture system, these may stem from manual misplacement of retroreflective markers, leading to incorrect segment alignment. In IMUs, they may result from simplifications within the algorithm or soft tissue artifacts affecting sensor stability, challenges shared by both systems (Johnson et al., 2020; Akbarshahi et al., 2010).

Attaching reflective markers directly to IMU sensors could reduce alignment errors, enabling more precise technical comparisons between systems. Nonetheless, analysing IMU outputs independently remains valuable, as it reflects the practical, real-world application of these devices outside of controlled lab environments.

A key strength of this study lies in its inclusion of both healthy younger adults and post-TKA patients, as well as the diversity of activities performed by the healthy cohort. Notably, this study evaluated a greater number of gait cycles (50 per participant) and included earlier postoperative time points than many prior investigations.

The strong agreement observed across both populations, and a range of ROMs highlights the accuracy and adaptability of the algorithm. Yet, for successful clinical integration, further attention must be paid to sensor calibration, data interpretation, system integration, and user training. With these considerations addressed, IMUs hold significant promise in enhancing the accessibility and effectiveness of rehabilitation and diagnostics.

6.3 Recovery Biomechanics of a TKA Population

Knee joint biomechanics play a vital role in shaping both objective and subjective outcomes following TKA. Quantitatively, greater knee ROM is often interpreted as an indicator of improved joint function postoperatively (Moghtadaei et al., 2012), and is a key metric for evaluating surgical success. However, PROM questionnaires are equally as important (Churruca et al., 2021; Tew et al., 2020; Vogel et al., 2020), offering insights into patient satisfaction and perceived recovery by capturing elements such as pain, mobility, and quality of life.

While PROMs provide valuable subjective data, their interpretation requires caution. Woolhead et al. (2005) noted that patients often feel a strong desire to report positive perceptions of surgical outcomes despite ongoing pain or mobility limitations. This phenomenon underscores the complex relationship between clinical indicators and personal expectations. Yet Kahlenberg et al. (2018) highlighted that unmet expectations can lead to dissatisfaction, even when objective outcomes are favourable, emphasising the importance of managing expectations throughout the surgical journey.

Thus, evaluating TKA success demands a balance between biomechanical metrics and patient-reported experiences. Improvements in knee ROM, while useful, may not align with a patient's subjective sense of recovery. A more comprehensive assessment is achieved by examining both biomechanical and PROM data pre- and postoperatively. This dual approach allows for a fuller understanding of recovery and supports more individualised care.

Incorporating preoperative assessments to predict recovery trajectories can further enhance clinical care. By managing expectations and personalising rehabilitation plans, clinicians can improve outcomes and promote patient-centred care. This holistic strategy ensures that success is not defined solely by surgical or mechanical improvements but also by how recovery is experienced by the patient.

Additionally, interpreting TKA recovery requires consideration of both population-level trends and individual patient variability (Cushner et al., 2024; Kittelson et al., 2020; Kornuijt et al., 2019; Woolhead et al., 2005). While population averages offer benchmarks for clinical outcomes and help standardise care, they cannot capture the nuances of each patient's goals, needs, and definitions of success. Personalised care plans that reflect individual recovery patterns enable clinicians to respond proactively to atypical progress, potentially preventing complications.

Ultimately, combining population-level benchmarks with tailored, patient-specific interventions forms the foundation of effective, holistic TKA management (Castellarin et al., 2023; Churruca et al., 2021). This dual perspective ensures outcomes are both clinically sound and personally meaningful.

6.3.1 Group Results

6.3.1.1 Objective Metrics

The results of this study highlight that recovery following TKA is highly individualised and influenced by several factors, including preoperative physical and mental health, surgical complexity, and patient activity levels, findings that align with previous research (Dash et al., 2017; Kahn et al., 2013; Lingard et al., 2004; Sharma et al., 1996). By six weeks postoperatively, significant improvements were observed, particularly in knee ROM, which increased across all activities. Notably, for walking, improvements were also seen in stride length, cadence, and speed, consistent with the data reported by Cushner et al. (2024).

Cushner et al. (2024) also documented substantial interpatient variability during the early postoperative period, influenced by sex, age, and preoperative health status, patterns similarly observed in this study. These findings underscore the wide range of recovery trajectories seen following TKA.

Although postoperative ROM improved overall, the improvements were not uniform across all parameters. Maximum knee flexion increased from baseline by six weeks, but knee extension did not return to preoperative levels during the same period. These findings are consistent with previous studies reporting persistent deficits in extension post-TKA (Mutsuzaki et al., 2017). Possible causes include pain, swelling, stiffness, and anxiety, which can restrict full leg extension in the early recovery phase.

Additionally, surgical trauma to the extensor mechanism and preexisting quadriceps weakness may contribute to limited extension (Mizner and Petterson, 2005). Quadriceps weakness can persist for several years postoperatively and has been linked to long-term functional impairments (Rowe et al., 2000). While surgeons often observe full ROM intraoperatively (Kornuijt et al., 2019), this does not always translate to functional performance in the early postoperative phase.

In the initial weeks after surgery, pain and stiffness tend to improve rapidly, while gains in ROM and function occur more gradually. Despite variability in timelines, most patients experience meaningful improvement within the early recovery phase (Bade et al., 2010; Hatfield et al., 2011; Levinger et al., 2013; Liebensteiner et al., 2008; Mizner and Petterson, 2005; Pua et al., 2015; Ro et al., 2020; Tibesku et al., 2011; van den Boom et al., 2014).

This study supports the findings of Kornuijt et al. (2019), showing that knee flexion and extension recovery follows a nonlinear trajectory, with flexion improving more consistently than extension. For most daily activities, including stair navigation, a knee ROM of 0° – 100° is required (Rowe et al., 2000). However, in this study, patients had not achieved this threshold by six weeks; for instance, stair descent showed a maximum ROM of only 82.42°.

Despite this, the results align with comparable studies that have reported similar early postoperative ROM measures (Cushner et al., 2024; Kittelson et al., 2020; Mizner et al., 2011; Pua et al., 2015). However, the literature also highlights inconsistencies, with some studies reporting significant flexion improvements (Hatfield et al., 2011; Tibesku et al., 2011), while others found minimal or no change (Levinger et al., 2013; Liebensteiner et al., 2008; van den Boom et al., 2014), often depending on the activity measured, sample size, and follow-up period.

In line with Cushner et al. (2024) and Liebensteiner et al. (2008), this study also observed improved gait speed within six weeks postoperatively. However, previous research has noted that gait parameters do not consistently return to preoperative norms (Bączkowicz et al., 2018; Benedetti et al., 2003; Fantozzi et al., 2003; Liebensteiner et al., 2008), with improvements occurring at different stages for different individuals.

Strong correlations were found in this study between preoperative BMI, ROM, and walking speed and postoperative ROM at six weeks, echoing findings by Cushner et al. (2024), Liebensteiner et al. (2008), and Ro et al. (2020). However, Pua et al. (2015) reported no strong link between BMI and postoperative ROM, indicating continued debate on the role of BMI in recovery outcomes.

Further support comes from Chiang et al. (2017), who used IMU sensors to assess knee joint angles in TKA patients and found that ROM at six weeks had returned to preoperative levels. While they did not observe strong predictive relationships between preoperative or perioperative factors and outcomes, they emphasised the highly individualised nature of recovery, a theme consistent with our findings.

While this study observed statistically significant improvements in knee ROM and flexion by six weeks postoperatively, its small sample size and variable participant numbers at each time point warrant caution when generalising the results. Additionally, as the study focused exclusively on early postoperative outcomes, long-term functional conclusions cannot be drawn. Existing literature suggests that functional recovery may continue for up to a year post-surgery (Zeni and Snyder-Mackler, 2010). Nonetheless, capturing early ROM measures may be valuable in identifying atypical recovery patterns and informing patient-specific rehabilitation strategies.

6.3.1.2 Subjective Metrics

Despite the clinical success of TKA, little information can be found in the literature about the relationship between PROMs and functional joint outcomes, particularly whether links can be made between functional ROM, preoperative health and PROM scores. Evidence suggests (Sharma et al., 1996; Lingard et al., 2004; Woolhead, Donovan and Dieppe, 2005; Kahn, Soheili and Schwarzkopf, 2013; Spiering et al., 2024) that mental and emotional health as well as patient expectation influences postoperative PROM scores. Specifically, patients who exhibit worse preoperative emotional and mental states tend to have reduced functional scores postoperatively, and in turn lower postoperative PROM scores. Moreover, in those patients that have good functional scores preoperatively, yet have high postoperative expectations, PROM scores associated with these patients reveal lower outcome scores, than perhaps their functional ability suggests.

Directly following TKA there is a reduction in ROM, which may impair function and, therefore, could deteriorate quality of life, stall rehabilitation progress and patient recovery motivation which may have a knock-on effect to reduced patient satisfaction (Bullens et al., 2001; Liebensteiner et al., 2008). However, this may work in the reverse, where functional outcomes may be limited, yet patients are satisfied with their outcomes, which results in a positive response to rehabilitation compliance, improved joint function and increased postoperative ROM. Therefore, it is important to consider the recovery process through both subjective and objective measures, determining the relationship between these two factors and what they mean in terms of improved patient recovery.

PROM scores revealed higher satisfaction scores across all three questionnaires by 6 weeks post TKA compared to both preoperative and 1-week post-surgery scores. These scores are not unexpected, 1-week postoperatively the patient will still be experiencing pain and reduced joint functionality as a result of stiffness and pain. Therefore, the apparent reduction in PROM scores is reflective of this (Bullens et al., 2001; Liebensteiner et al., 2008).

KOOS JR consistently scored higher results at all three visits compared to the other questionnaires, with the FJS consistently scoring the lowest. The OKS and FJS revealed lower results at 1-week post-surgery compared to their preoperative scores, indicating a reduction in function, and an increase in joint pain and joint awareness post-TKA compared to baseline measures. Though these questionnaires score different outcomes, comparing them together provides a clearer indication of what aspects of recovery patients value most.

Though all PROMS attempt to measure the success of TKA from the patient's perspective, few specifically address patient satisfaction, but rather focus on pain, function and quality of life (Bullens et al., 2001; Sajjadi et al., 2019; Spiering et al., 2024). By highlighting aspects that patients deem as important, postoperative outcomes may be better managed and planned for.

Moderate but statistically significant correlations were reported between PROM scores and ROM at 6 weeks post-surgery (Table 5-21), suggesting that patient perceived outcomes are indeed related to functional outcomes. These finding are similar to results reported in previous studies (Padua et al., 2007; Liebensteiner et al., 2008; Devers et al., 2011), though (Devers et al., 2011) reports a correlation between knee ROM and patient satisfaction their findings were not statistically significant. However, findings showed that patients that experienced an increase in knee flexion had a significant positive association with achievement expectation and functional improvement. These findings allude to the complex nature of recovery and patient perceived outcomes, as although (Devers et al., 2011) reports that the degree to which a patient's function restores does not directly affect their satisfaction, it does indeed influence fulfilment of expectations, functional ability and knee perception.

6.3.1.3 Summary

The findings of this study should be interpreted in light of several limitations. Most notably, the small sample size of TKA patients, combined with inconsistent attendance across assessment sessions, limits the generalisability of the results. In such a small cohort, individual patient data can disproportionately influence group averages, making the dataset more susceptible to outliers. Consequently, the large standard deviations observed are likely due to the impact of individual variability rather than a true representation of the broader TKA population. Additionally, the study population was drawn from a single catchment area in Scotland, and all participants were white, generally overweight, and demonstrated low preoperative health. This homogeneity restricts the applicability of the findings to more diverse populations.

Several dynamic factors can influence knee function before and after TKA, including changes in pain, stiffness, joint alignment, and soft tissue balance. These variables complicate the task of isolating the key drivers behind observed improvements. Emotional well-being and patient expectations also play a substantial role in both functional outcomes and PROM scores. A larger, more diverse cohort and multivariate statistical modelling would be required to accurately determine which specific factors most strongly influence recovery.

Despite these limitations, the study reinforces that TKA recovery is highly individualised. Patients with better preoperative health metrics; such as lower BMI, greater joint function, and higher activity levels; tended to demonstrate superior objective and subjective outcomes by six weeks postoperatively. However, when these patients held unrealistic expectations, they often reported lower PROM scores, despite improved functional performance.

Conversely, patients with poorer baseline function or higher pain levels often reported the greatest relative improvement in PROM scores, even if their absolute postoperative function remained below that of their healthier peers. These findings underscore the complex relationship between subjective satisfaction and objective recovery metrics.

Predicting postoperative ROM remains inherently difficult due to the range of influencing factors, including age, sex, diagnosis, baseline ROM, surgical technique, implant design, mental health, and the quality of rehabilitation (Bullens et al., 2001; Cushner et al., 2024; Liebensteiner et al., 2008; Woolhead et al., 2005). Nevertheless, improving the accuracy of ROM predictions could benefit clinical practice by fostering more informed preoperative discussions and managing patient expectations around functional recovery.

A significant implication of this study is the value of integrating objective measures (such as ROM and gait metrics) with subjective PROM data into a composite score of overall postoperative health. Such a measure could better represent surgical success by equally weighting functional capacity and patient perception. However, interpreting these composite outcomes must still be done on an individual basis, given the personal nature of recovery trajectories. Although trends in the data indicated that patients with higher PROM scores also demonstrated improved ROM, walking speed, and cadence, these associations were not uniform across all participants (see Table 5.19). This variability further reinforces the need for individualised assessment when evaluating recovery progress.

These findings are consistent with prior literature (Bączkowicz et al., 2018; Devers et al., 2011; Liebensteiner et al., 2008; Padua et al., 2007), which also report positive correlations between functional improvements and increased patient satisfaction. The results highlight the importance of involving patients in preoperative discussions to determine which aspects of recovery are most important to them. This approach can guide both surgical planning and rehabilitation strategies, enabling better alignment between clinical goals and patient expectations.

In summary, while this study observed functional improvements across all activities compared to baseline, the degree of improvement varied significantly between individuals. These findings underscore the importance of personalised rehabilitation programs tailored to each patient’s preoperative condition, recovery goals, and functional requirements, thereby enhancing both clinical outcomes and patient satisfaction.

6.3.2 An Individual TKA Patient

This study presented detailed recovery data from a single patient to examine how objective measures (representing surgical goals) and subjective experiences (reflecting patient-perceived outcomes) evolve over time. By comparing these individual-level insights with broader population trends, the study aimed to explore the added value of personalised assessment in understanding functional recovery and patient satisfaction. Furthermore, it demonstrated the potential of IMU-based wearable technologies to capture nuanced movement patterns that support tailored rehabilitation approaches.

Ultimately, integrating objective and subjective measures at the individual level may improve how success is defined and achieved in TKA, ensuring that both clinical and patient goals are meaningfully addressed in postoperative care.

6.3.2.1 Objective Metrics

The results of this study revealed that recovery is individualised and non-linear. While the patient assessed in this study exhibited improvements in ROM across all activities by six weeks post-surgery, these improvements were not uniform across flexion and extension angles. Notably, maximum flexion increased as early as one week postoperatively, although the change was not statistically significant at that stage. By six weeks, however, this improvement reached statistical significance ($p < 0.05$).

In contrast, minimum flexion initially declined one week after surgery compared to preoperative values but showed improvement by six weeks, though it had not yet returned to baseline. These findings align with previous literature (Hewitt & Shakespeare, 2001; Kornuijt et al., 2019; Mizner et al., 2011), which similarly reported non-linear patterns of recovery in knee flexion and extension. Kornuijt et al. (2019) specifically noted that postoperative extension may be limited due to pain, swelling, soft tissue healing, and patient anxiety.

At six weeks postoperatively, the patient achieved a maximum flexion angle of 92° and an overall ROM of 82°. While this indicates functional improvement, further progress is needed, as a flexion range of 0° to 110° is generally required for safe performance of most activities of daily living (Mizner et al., 2011). Other studies report ROMs within this range are typically achieved by 7–8 weeks post-surgery (Mizner et al., 2011; Pua et al., 2015; Kornuijt et al., 2019). Since the current data extend only to the six-week mark, no conclusions can be drawn regarding later-stage recovery.

Relative to the group averages reported in this thesis, this patient began with a lower baseline ROM across all tasks but achieved six-week postoperative values comparable to the cohort ($p > 0.05$), with superior ROM during stair navigation. Temporal gait parameters followed a similar trend, with walking speed and cadence improving by six weeks compared to both baseline and one-week postoperative values. These results support findings by Saari et al. (2005), and are consistent with evidence suggesting that increased walking speed can influence knee angles during gait (Andriacchi and Alexander, 2000). By six weeks, the patient's gait parameters exceeded the population average, further indicating positive functional recovery.

Moreover, the high degree of valgus deformity exhibited by this patient preoperatively should be taken into consideration as this may have had an impact on the patients postoperative outcomes, and influenced her preoperative function. Literature suggests that TKA in valgus knees significantly improves joint function and patient quality of life by reducing pain, correcting deformity and increasing mobility (Rajgopal et al., 2018). The success of a TKA on a valgus knee depends on a well-positioned implant with a stable construct that correctly restores the normal mechanical axis of the limb and joint line to a neutral alignment of approximately 3° (Rossi et al., 2014). Valgus knee deformities are not uncommon with 10% of patients who undergo TKA exhibiting a greater degree of valgus (Alesi et al., 2022). It is well established that excessive preoperative malalignment of the knee joint predisposes the patient to a greater level of risk of surgical failure compared to well-aligned knees (Rossi et al., 2014). For this reason, it is important to correct the deformity during surgery even if it does not completely eliminate the increased risk of failure.

Preoperative assessment also revealed a significant valgus deformity, which likely affected both baseline function and postoperative outcomes. Valgus alignment, observed in roughly 10% of TKA cases (Alesi et al., 2022), is known to increase surgical complexity but can result in marked functional improvement when successfully corrected (Rajgopal et al., 2018). Effective outcomes depend on achieving proper implant positioning and restoring neutral limb alignment (Rossi et al., 2014). Although excessive malalignment is associated with increased risk of surgical failure, correcting deformity remains essential, even if risk cannot be entirely eliminated.

Though this section examined absolute MotionSense™ angles, this patient's valgus deformity did not compromise the accuracy of knee angle measurements obtained using these IMU sensors. Validation data presented in Appendix 3 (Chapter 11) confirmed that IMU systems maintain measurement reliability even in the presence of known angular offsets. Thus, the application of wearable technology in complex cases remains viable for accurate monitoring and rehabilitation guidance.

Improvement in valgus alignment was observed as early as one week postoperatively, and by six weeks, the patient demonstrated significant improvements in ROM ($p < 0.05$), walking speed, and cadence compared to baseline. Although valgus knees are considered more complex, studies suggest no consistent association between the degree of preoperative deformity and postoperative functional outcomes (Alesi et al., 2022; Liu et al., 2024; Rossi et al., 2014), which is reflected in this case.

Throughout the recovery timeline, the patient used assistive devices, initially relying on treadmill handrails preoperatively and transitioning to crutches postoperatively. The use of such devices is known to influence gait, particularly cadence and walking speed (Joo et al., 2024; Liu et al., 2009). At one week post-surgery, discomfort, pain, and unfamiliarity with the crutches likely contributed to the reduced gait metrics.

When comparing this patient's functional measures to group averages, no statistically significant differences were found ($p > 0.05$). This may reflect the limited sample size used for comparison. Nevertheless, the patient's outcomes; ROM, gait speed, and cadence, fall within ranges previously reported in the literature (Cushner et al., 2024; Dash et al., 2017; Mizner et al., 2011; Wang et al., 2019; Zeni & Snyder-Mackler, 2010), suggesting a positive early recovery trajectory despite her preoperative valgus alignment and baseline functional limitations.

6.3.2.2 Subjective Metrics

The PROMs assessed in this study revealed early and sustained postoperative improvements. Notably, improvements were evident as early as one week post-surgery, with substantial increases across all PROMs by six weeks following TKA. Among the three PROMs used, the FJS consistently yielded the lowest results across all time points.

Although the patient initially reported lower preoperative PROM scores compared to the study's TKA population averages, her scores surpassed the population means by one week postoperatively and continued to improve through the six-week mark. These results underscore both individual progress and the variability in recovery experiences relative to group norms.

It is critical to acknowledge that the choice of PROM tool can significantly shape how recovery is interpreted. Each questionnaire targets specific dimensions of recovery; such as pain, function, or joint awareness; and uses unique scoring systems that can lead to divergent conclusions about patient outcomes. To facilitate cross-comparison, all PROMs in this study were scaled to a standardised 0–100 range, where 100 represents the best possible outcome. While this method enhances comparability, it does not eliminate the intrinsic variability in scope, sensitivity, and focus across PROMs.

The disparity in results between PROMs was particularly evident in the patient's FJS scores, which indicated a high level of joint awareness both before and after surgery. Despite this, the patient did not report dissatisfaction with the surgical outcome. In contrast, PROMs assessing pain and functional ability (e.g., KOOS JR and OKS) showed marked improvements postoperatively, suggesting meaningful clinical progress.

This highlights a critical point: if interpreted in isolation, the FJS could suggest a suboptimal recovery due to persistent joint awareness. However, when considered alongside PROMs that capture pain reduction and improved physical function, a more accurate narrative of recovery emerges. This reinforces the need for a multidimensional approach to PROMs rather than reliance on a single metric, especially when aiming to understand the full scope of a patient's postoperative experience.

An aggregated approach, incorporating multiple PROMs that assess various aspects of recovery, such as function, pain, awareness, and psychological adaptation, offers a more comprehensive and nuanced perspective. This also reflects the diverse values that patients place on different elements of recovery, further emphasising the importance of tailoring rehabilitation and outcome evaluation to the individual.

This variation in subjective outcomes supports findings from recent literature (Deckey et al., 2023; Spiering et al., 2024; Sutton et al., 2023; van Schie et al., 2024), which have shown that PROM results can vary depending on the specific tool used and the patient's own recovery priorities. These studies reinforce the value of setting realistic expectations preoperatively and ensuring patients have a clear understanding of the TKA procedure and anticipated outcomes.

By analysing average PROM scores across all tools used, this study presented a more holistic view of patient satisfaction over time. At six weeks post-TKA, the patient's PROM scores were comparable to or exceeded those reported in previous studies (Carlson et al., 2018; Churruca et al., 2021; Spiering et al., 2024; Yap et al., 2021). Her OKS at one week was higher than values reported by Yap et al. (2021), who evaluated satisfaction across 536 patients up to one year post-TKA. While her baseline KOOS JR was initially lower than the cohort in Spiering et al. (2024), by six weeks, her scores aligned with that study's three-month outcomes—suggesting a strong recovery trajectory, especially in pain reduction and functional improvement.

It is important to note that recovery continues well beyond the six-week mark. Carlson et al. (2018) report that many patients "forget" about their artificial joint between six and twelve months post-surgery. Given this, the improvements observed in this study, though encouraging, should be interpreted with caution, as they likely represent only an early stage in the full recovery process, where residual pain and inflammation may still be present.

In conclusion, the key insight from this study is that subjective recovery outcomes are strongly influenced by the choice of PROM and the weight patients assign to different recovery domains. Evaluating recovery through an aggregated, multidimensional PROM framework provides a more accurate and balanced representation of the patient's postoperative experience. This approach supports more effective personalisation of care and enhances alignment between clinical goals and patient expectations.

6.3.2.3 Summary

This study examined the postoperative trajectory of a single patient presenting with severe bilateral valgus deformity, a factor that introduces surgical complexity and may impact recovery outcomes. Given this patient's atypical preoperative condition, interpretation of the findings requires context and caution. However, the outcomes reported are consistent with previous literature, such as Van Onsem et al. (2018), who found that improvements in ROM and functional ability were strongly associated with increased patient satisfaction following TKA.

While it is essential to define what constitutes meaningful improvement in patients with complex presentations, generalising these results to broader populations should be approached carefully. The presence of valgus deformity and the patient's reduced preoperative function increased the procedural challenge, yet the early postoperative outcomes, both functional and subjective, were comparable to group averages and consistent with established recovery patterns reported in the literature.

These findings reinforce the importance of evaluating TKA success not only through surgical metrics but by considering the patient's baseline status, their perceived improvements, and their specific recovery goals. Despite TKA's well-documented success in managing knee osteoarthritis (Graichen, 2014; Kahn et al., 2013; Sajjadi et al., 2019), patient outcomes are not uniform. Expectations, baseline function, and comorbidities all contribute to the variability in postoperative trajectories, often leading to discrepancies between objective scores and perceived recovery.

Importantly, this study also highlights the potential role of IMU technologies in capturing detailed, continuous, and individual-specific functional data throughout recovery. The granular insights provided by wearable IMUs offer a promising avenue for more responsive and personalised rehabilitation monitoring, particularly valuable in complex cases where standard measures may fall short of fully capturing recovery nuances.

In conclusion, while this single-patient case cannot be generalised, it illustrates how individual characteristics, especially preoperative functional status and structural deformities, can influence recovery. The alignment of this patient's outcomes with broader population trends supports the utility of wearable technologies like IMUs in enhancing recovery assessment and promoting personalised care in TKA rehabilitation.

6.4 Holistic Discussion

Defining successful outcomes following TKA remains a multifaceted challenge, owing to the intricate interplay between objective biomechanical function, subjective patient experiences, and the diverse expectations of different healthcare stakeholders (Bullens et al., 2001; Padua et al., 2007; Tew et al., 2020; van Schie et al., 2024). While clinicians often assess surgical success based on functional gains, such as ROM, stability, and gait restoration, patients may evaluate their recovery based on pain reduction, return to valued activities, or psychosocial well-being. Thus, success must be redefined as a convergence of quantifiable biomechanical outcomes and qualitative PROMs. Such a paradigm requires rehabilitation strategies that are not only functionally effective but also responsive to individual patient profiles and their own recovery trajectories.

One of the key findings of this study based on the evaluation of functional movements pre- and post-operatively in a cohort of 10 TKA patients, was the significant variability observed in recovery dynamics. For instance, improvements in maximum knee flexion ranged from 1.61° for the walking activity to 35.40° for stair navigation within six weeks post-surgery, with notable standard deviations presented for each activity postoperatively. Importantly, despite this range, minimum flexion lag persisted in several patients until the sixth postoperative week. These results underscore the non-linear and heterogeneous nature of functional recovery post-TKA, as previously established in the literature (Mizner et al., 2011; Kornuijt et al., 2019; Yoshida et al., 2008).

By focusing solely on population averages, clinicians risk overlooking individual outliers whose recovery deviates substantially from the norm. This has important clinical implications. Patients failing to meet averaged recovery benchmarks may either be over-treated or under-supported if their unique profiles are not accounted for. The correlations identified in this study between preoperative function (e.g., ROM, BMI, and walking speed) and postoperative outcomes (ROM and PROMs) reinforce the predictive value of preoperative baselines (Hamilton et al., 2020; Bade, Kohrt, and Stevens-Lapsley, 2010). These findings argue persuasively for personalised rehabilitation protocols that adapt to individual physiological and functional baselines rather than conform to aggregated normative curves.

PROMs such as the OKS, KOOS JR, and the FJS add critical subjective dimensions to outcome evaluation. In this study, PROM improvements correlated with objective gains in ROM and gait performance. However, when outcomes were reviewed at the individual patient level, variability was observed. This reinforces the notion that subjective satisfaction is not solely dictated by biomechanical restoration but also by the extent to which functional recovery aligns with a patient's preoperative expectations and lifestyle demands (Dash et al., 2017; Woolhead et al., 2005; Vogel et al., 2020). Such variation between patients further supports the call for recovery pathways tailored not only to biomechanical deficits but also to patient-defined goals and satisfaction metrics.

In light of these findings the potential of wearable IMU devices to support personalised rehabilitation strategies is contingent upon their ability to deliver clinically accurate data. In this study, both the commercial MotionSense™ system and an IMU implementation using the Seel algorithm (Seel, Raisch, and Schauer, 2014) were validated against gold-standard Vicon opto-electronic motion capture, across both healthy and clinical populations.

IMU accuracy fell within a clinically acceptable RMSE range of 0.86°–4.78°, with strong correlation coefficients (0.95–0.99). These results are consistent with previously reported benchmarks for IMU performance in dynamic tasks (Cutti et al., 2010; Mundt et al., 2019; Cornish et al., 2024). However, several biomechanical and algorithmic challenges were observed. For example, zero-angle registration difficulties were common among TKA participants due to post-surgical swelling and limited extension at rest. This compromised the device's ability to accurately calculate the 'zero' value of the system. Additionally, intermittent signal desynchronisation (49–51 Hz) and sensor reinitialisation caused minor phase offsets, occasionally impacting ROM measurements. These challenges were reduced by accounting for the differences in 'zero' angles by applying an offset bias to the IMU measures to ensure the mean value equalled that of Vicon opto-electronic motion capture, while the fluctuations in phase were minimised by segmenting the measurement data into movement cycles and then time synchronising these movement cycles by maximining the correlation between the technologies. Despite these difficulties, the knee angle data reported from the IMUs were visually and temporally consistent with those from the opto-electronic Vicon system, with reported differences below clinically meaningful thresholds (Bonnefoy-Mazure et al., 2020; Deckey et al., 2023).

These findings confirm that IMU devices possess the technical fidelity required for accurate tracking of sagittal knee motion during key ADLs, directly addressing the research question. When used appropriately, they provide a feasible method for continuous, remote monitoring of joint kinematics in real-world settings. The strength of IMU technology lies not only in its biomechanical accuracy but also in its potential to close the feedback loop between patient performance and rehabilitation planning. IMUs, when integrated into cloud-based systems, enable real-time data capture and remote clinician oversight (Papi et al., 2015; Atallah et al., 2011; Parrington et al., 2021). This facilitates early intervention in cases of poor recovery progression, preventing avoidable long-term deficits and reducing the burden of costly revision surgeries. Furthermore, the real-time tracking of metrics such as ROM, with the potential inclusion of cadence, stride length, etc, provides actionable information for dynamically adjusting rehabilitation protocols to meet individual patient needs.

Moreover by incorporating PROM data into remote rehabilitation platforms, these systems can also track subjective progress in parallel with objective measures, providing a more comprehensive view of recovery. This holistic feedback structure enhances clinical decision-making and supports patient engagement and adherence, both of which are known to be low in post-surgical rehabilitation (Campbell et al., 2001; Chakrabarti, 2014).

Personalised, remote rehabilitation presents a scalable solution to the increasing demand for joint replacement surgeries, especially in health systems facing resource constraints. For rural, housebound, or mobility-limited patients, wearable IMUs offer accessible, cost-effective alternatives to frequent in-person assessments. As this study demonstrates, wearable technology can accurately track early postoperative recovery, a phase often underrepresented in current research yet critical for identifying complications and modulating interventions.

This study extends the current literature in several ways. While prior research (Boonstra et al., 2006; Cooper et al., 2009; Cuesta-Vargas, Galan-Mercant and Williams, 2010; Ghattas and Jarvis, 2021; Hu et al., 2021; Huddleston et al., 2006; Jiang et al., 2022; Kavanagh and Menz, 2008; Kobsar et al., 2020; Lim, Kim and Park, 2020; Luinge and Veltink, 2005; Mayagoitia, Nene and Veltink, 2002; McGrath and Stirling, 2022; Mundt et al., 2019; Narváez, Árbito and Proaño, 2018; Nüesch et al., 2017; Obradović and Stančin, 2023; Ortigas Vásquez et al., 2023; Papi et al., 2015; Picerno, Cereatti and Cappozzo, 2008; Poitras et al., 2019; Rhudy et al., 2024; Seel, Raisch and Schauer, 2014; Taylor, Miller and Kaufman, 2017; Tong and Granat, 1999; Uhlenberg and Amft, 2024; Versteyhe et al., 2020; Zhang et al., 2013; Zhou et al., 2020), has validated IMU technology in controlled settings, this work confirms its viability in a clinical postoperative context, including early-stage TKA recovery, which remains underexplored (Antunes et al., 2021; Chapman et al., 2019; Cornish et al., 2024; Hafer et al., 2020; Wang et al., 2025) and is a period marked by altered gait patterns and high variability in movement. The strong agreement with opto-electronic motion capture supports the technical robustness of IMUs under realistic functional tasks, such as walking and sit-to-stand transitions for example.

Furthermore, by simultaneously evaluating functional outcomes and patient-reported metrics and directly comparing IMU-derived data to gold-standard motion capture systems this study bridges the gap between technical validation and clinical translation.

Moreover, the findings advance the conversation around personalisation in orthopaedic recovery. Findings indicate that PROM improvements do not always correspond with biomechanical recovery, suggesting that subjective measures alone may not capture the full scope of post-operative function. With postoperative function further describing the heterogeneity of TKA recovery, supported by (Moffet et al., 2004). Where many rehabilitation programs remain protocol-driven and group-based, our results argue for a patient-specific model of care, informed by real-time data sensitive to individual trajectories.

In sum, personalised, remote rehabilitation leveraging wearable IMU technology offers a viable path toward optimising TKA recovery. The multifactorial nature of surgical success demands integration of biomechanical precision, patient-reported outcomes, and adaptable care delivery. By establishing the validity of IMU-derived metrics and their alignment with clinical outcomes, this work lays the groundwork for translating sensor-based monitoring into remote rehabilitation platforms. IMUs enable this integration by accurately measuring quantitative knee joint ankle and have scope to record qualitative recovery metrics, supporting early, individualised intervention, and enhancing patient compliance. As healthcare shifts toward data-driven and patient-centric models, these tools provide the technological infrastructure to deliver high-quality, equitable postoperative care, tailored not to the population average, but rather to each individual patient.

6.5 Limitations and Future Work

Several limitations should be acknowledged when interpreting these findings.

The sample size, particularly within the TKA cohort, was limited. While this is consistent with precedent in similar sensor validation studies involving clinical populations (Chen et al., 2015; Chapman et al., 2019; Antunes et al., 2021; Cornish et al., 2024), it restricts the generalisability of inter-subject comparisons and statistical correlations.

Future studies should aim for larger, stratified samples to better assess population-wide applicability. Limited sample sizes were due to challenges in participant recruitment and patient dropouts during the study period. Although recruitment rates did improve following the introduction of participant incentives, the available timeframe for data collection had elapsed, preventing further enrolment.

Moreover the study was confined to only the early postoperative phase (~6 weeks post-TKA). Consequently, it does not capture the full continuum of recovery, including long-term kinematic adaptations or sustained improvements in PROMs. Longitudinal studies are needed to establish whether IMUs can detect clinically meaningful changes across the entire recovery trajectory, with patient usability and adherence accessed throughout this timeframe.

The current implementation of the Seel algorithm focuses on sagittal plane motion only. While knee flexion/extension is a critical component of TKA recovery, important insights may be missed without tracking frontal and transverse plane motions. The current 2D Seel algorithm should be refined to improve calibration accuracy and reduce drift in clinical populations. Once optimised, it should be extended to 3D tracking to capture more comprehensive joint mechanics, potentially improving clinical insight and functional evaluation.

Although validated in clinical settings, the IMU systems were not tested in unsupervised, home-based environments. This limits our understanding of their real-world feasibility, especially when sensors are self-applied by patients. Future validation in home environments is crucial for assessing usability, data quality, and compliance under remote care conditions.

Finally, future research should explore whether integrating IMU-derived kinematic data with PROMs collected both preoperatively and postoperatively, alongside intraoperative metrics and baseline patient information, can improve the prediction of recovery trajectories following TKA. Investigating this combination of data sources may support the development of robust predictive models capable of identifying patients at risk of poor outcomes. Such models could facilitate more personalised rehabilitation strategies and enhance clinical decision-making. These future studies would be critical for transitioning toward fully autonomous remote rehabilitation platforms.

Chapter 7. Conclusions

This thesis sought to establish whether IMU devices are accurate enough to detect clinically significant changes in knee flexion angle following TKA surgery. Sensor accuracy was evaluated across a broad range of ADLs in both a diverse healthy population of varying age groups and within a clinical population of TKA patients. Sensor measures were evaluated against the gold standard motion capture system, Vicon.

This thesis comprised of three studies, each with its own objectives.

Firstly, the accuracy of a commercial wearable device, MotionSense™ was established within a population of both healthy and TKA participants across a broad range of activities. The results presented in this study demonstrated that the commercial wearable device accurately measured knee ROM within a 5° margin of error in both population groups and across all ADL's. These findings align with previous research, confirming the device's potential utility in clinical and rehabilitation settings. However, the device exhibited less accuracy during deep flexion and activities involving rapid or multidirectional movements, highlighting areas for potential improvement in wearable technology for dynamic motion tracking. These findings provide good confidence in the inclusion of such technologies into healthcare systems, and the impact they can have on improving rehabilitation compliance and enhancing functional outcomes.

The subsequent study went on to evaluate the feasibility of using any IMU device with the Seel algorithm (Seel, Raisch and Schauer, 2014) to track knee ROM across different ADLs in a healthy younger population and during preoperative and postoperative walking within a TKA population. The algorithm functioned in a similar manner to that of the commercially available MotionSense™ device and accurately captured knee ROM, with RMSE reported < 5 ° for all population groups and across all activities. As found within the commercial wearable devices, larger discrepancies were also found in angles of deep flexion or during faster movements. However, as the TKA population exhibited reduced ROM and was found to have characteristically slower movements these errors do not largely affect this population.

These findings align with previously reported values and the measures presented by the MotionSense™ commercial wearable device, both falling within clinically acceptable thresholds. These results suggest that IMU-based devices, coupled with the Seel algorithm, could be effectively integrated into clinical settings to support rehabilitation monitoring and feedback in TKA recovery. Additionally, the algorithm's customisability and adaptability enhance its utility for various applications.

However, for wearable devices to be effectively implemented within treatment plans an insight into TKA recovery needed to be understood to ensure recovery and rehabilitation may be appropriately managed and accurately captured by these technologies. Therefore, the final study mapped the general recovery pathways following TKA surgery, discussing both objective and subjective improvements and how these measures were interlinked. This study provided a practical clinical example into the usability of such wearable technologies. TKA patients' recovery was evaluated by tracking their ROM preoperatively and postoperatively across multiple activities, alongside PROM scores. Results indicated that patients with better preoperative function tended to have improved postoperative outcomes, with strong correlations between functional outcomes and PROM scores. Though there are nuances within this statement, with results from the group study and the individual patient study highlighting that population averages do not always reveal individual outcomes and that an ideal treatment plan is one which considers patients individually.

Functionally, patients that exhibit good health before surgery, often display more successful postoperative function and improved mobility, yet PROM scores may not truly capture these improvements. This is because patients that are healthier going into the surgery often have higher surgical expectations, and these expectations often result in reduced satisfaction. However, for the most part, subjective and objective scores do show positive correlations, whereby improvements in one more often than not reveal improvements in the other. This variability within patient health, expectation, postoperative recovery, etc highlights the importance of individualised patient care and the necessity for personalised recovery management.

By monitoring early improvements in ROM after TKA, we identified a threshold to assess the wearable device's sensitivity in detecting subtle changes, reinforcing the device's value in tracking progress during early rehabilitation. Though we do acknowledge the limitations within the small sample size and range of activities evaluated, these results were found to be in agreement with previous research. Furthermore, the results presented in this thesis provides strong evidence and highlight the clinical these devices hold within clinical settings.

Overall, this thesis underscores the potential of wearable devices to accurately quantify sagittal plane knee motion across different ADLs in both healthy and TKA populations. Both commercial and wired IMU sensors demonstrated strong agreement with Vicon opto-electronic motion capture, with all results falling within clinically acceptable thresholds < 5°. Wearable technologies show significant promise for clinical applications, serving as valuable tools for postoperative care by providing real-time data to guide rehabilitation and improve patient outcomes.

Chapter 8. References

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Chapter 9. Appendix 1- Practical Information

9.1 Study Protocol

Study title: Performance and Activity Classification post Total knee arthroplasty (PACT)

Summary of study: Total knee arthroplasty is becoming more prevalent with more than 100,000 procedures taking place in the United Kingdom each year. Relative to biomechanical issues, post-operative knee stiffness and reduced knee movement are common difficulties and factors associated with patient dissatisfaction following surgery.

Greater knee movement postoperatively indicates a better long-term knee mobility recovery. Therefore it is vital that patients receive adequate rehabilitative care and those who experience reduced knee range of motion are detected as soon as possible and assisted promptly.

Postoperative rehabilitation is predominately now home-based. However, home-based rehabilitation has been associated with poor compliance. There is therefore an increased demand for guidance and surveillance of patients on rehabilitation programs once in their home environment.

Wearable technologies present a solution to remotely monitor patients and enabling assessments of patient progress to be reviewed and performed at home.
EnMovi Ltd (a Scottish subsidiary of Stryker) have developed MotionSense™ including two IMU wearable sensors and an app to remotely support post-operative knee replacement rehabilitation (Figure 1).

This provides personalised rehabilitation, tracking of home exercises and daily activity, and enables healthcare professionals to continuously monitor rehabilitative progress remotely. IMU technology is ubiquitous nowadays, such as in your mobile phone to determine whether the orientation is landscape or portrait, and MotionSense™ has been through FDA approval.

Figure 1. MotionSense box (left), IMU wearables in box (middle) and attached to leg (right).

The objective of this study is the collection of data using the EnMovi Ltd wearable sensors to enable the development and training of algorithms to classify function of the knee and monitor knee movement. The data should also be accurate and reliable, and include a broad level of functionality, for performance of all abilities to be monitored accurately during rehabilitation. Only once this is achieved can healthcare professionals make informed decisions regarding patients.

Study objectives: The primary objective of this study is to develop algorithms to classify whole body movement based on knee movement in a TKA population. This requires a large database to be generated using the EnMovi Ltd wearables, and needs to be conducted across a broad level of functionality and tasks to enable performance monitoring during rehabilitation and daily activity using artificial intelligence.

The secondary objective is to assess the accuracy and reliability of knee movement using the wearable sensors to validate the data collected from the IMU wearables. Outcomes will be compared to gold-standard motion analysis when completing various activities of daily living.

Study population: The study will recruit a TKA population and an age-matched control group (healthy group). Each group is important given that the TKA population is the intended population for the MotionSense™, and the control group can provide normative data which can be used to identify how close to normal knee function is. This will aid the monitoring process when developing the algorithms.

Study protocol: TKA patients will visit the laboratory three times to complete an assessment before surgery, 1-week after surgery, and 6-weeks after surgery. Healthy participants will visit the laboratory once only.

Participants will be asked to bring a signed consent form with them to their laboratory appointment. Participants will already have been sent a participant information sheet prior to booking a time to come to the laboratory and signing the consent form, however a participant information sheet will also be available to review on entering the laboratory. All questions about the upcoming experiment will be answered. Additional copies of the consent form will be available if required.

Participants will need to wear appropriate clothing so that accurate motion of the body can be recorded. Participants will be required to wear tight cycling type shorts (eg. Lycra) and a sports t-shirt.
Participant's should wear their own shoes – flat trainers that do not cover or rise higher than the ankle. It is the participant's choice to wear socks or not with their shoes. Appropriate clothing will be provided to participants if it is not an option to supply their own clothes. Shoes and socks will not be provided. Between uses all clothing will be quarantined for 72 hours and then washed.

Once appropriately clothed, retroreflective markers will be attached to the lower limb for lower body kinematic data to be collected. Bony landmarks will be palpated and identified by the researcher for marker placement.

Concurrently, the EnMovi Ltd sensors will be attached to the lower limb.
There are 2 types of EnMovi Ltd sensors to be attached to the body:
• Commercial sensor (works via Bluetooth)
• Research sensor (works using wires and a data logger)

Both devices use the same hardware, however the research sensor is connected to a data logger with wires, and the commercial sensor connects to the App via Bluetooth. The commercial sensor uses algorithms and outputs predetermined outcomes (eg. knee flexion, number of steps, range of motion, and time spent weightbearing). The research sensor enables raw acceleration and gyroscope data to be extracted from the experiment.

Similar to other wearable devices, the sensors for both will attach to the thigh and leg (see Figure 1 above).

The following tasks will be performed to make up the biomechanical assessment (see below). The order of the assessment will be randomly assigned using an online random number generator.

Before any information and data is collected from the participant the consent form will be signed and dated, any questions the participant may have will be answered and the researcher will explain the protocol and activities before proceeding.

PROMs questionnaires will be completed by the TKA group. Three different surveys (promis 10, koos jr and the oxford knee score) will be read and completed before the ADL protocol begins.

Time up and go test - Participant is instructed to stand up from a chair, walk 3m, turn, walk 3m back to chair, and sit back down again. This should be completed at a comfortable and normal pace for the participant.

Active and passive range of motion - Participant will be asked to perform a knee flexion/extension movement by themselves. The tester will then repeat this movement with the participant by moving their leg for them as the participant remains passive

Wearable sensor calibration movements - Participant will stand with one foot on a small box for knee flexion angle to be calibrated. Participant will lie on floor with leg extended for leg extension angle to be calibrated. Participant will sit on chair with knee flexed and foot flat on floor. Foot will slide forward to extend the knee. Participant will sit on chair with knee flexed and foot flat. In this position foot will be slide up and down wall keeping toe in contact with the wall.

5 minutes of level, treadmill walking - Participant will walk at a comfortable pace
Stair ascent and stair descent Participant will be instructed to climb up a flight of stairs to the top (4 steps) and then descend the stairs (4 steps) on portable stairs in the biomechanics laboratory.

Healthy participants only will also conduct the following additional tasks:

5 minutes of Cycling - Participant will cycle on stationary bike in the biomechanics laboratory at a steady and comfortable pace.
Vertical Jumps/Hops - Participant will be asked to perform countermovement jumps and hops in the biomechanics laboratory.

For all the above activities, a 12 camera Vicon Nexus motion analysis system, including sagittal plane optical video (only utilised if participant consents), will track the retroreflective markers. Individual trials (except level walking) shall be performed three times with the devices removed between trials to assess attachment-re-attachment intra-subject variability. Participants will also be given rest breaks between each condition tested to minimise the physical endurance required during the data collection session.

Following laboratory testing, and only for those who have consented to video being taken, a short outdoor circuit will be completed. This has been included as a real-world environment, including pavement walking, and stair ascent and descent. In the Golden Jubilee National Hospital this circuit will take place inside the hospital opposed to outdoors so that stair ascent and descent can be included. This circuit will only be undertaken if the participant feels confident, competent, and comfortable to do so. They will also determine the pace of the walk. Volunteers will be constantly videoed using a GoPro in addition to the wearable collecting data, enabling synchronisation of data and activity. They have been provided by the University of Strathclyde. Prior to walking outside all markers will be removed and participants will be changed into their own clothes. The wearable sensors will remain attached. Water will be available after completion.

Videos are optional for participants in the laboratory as they are useful in the laboratory as a visual check to refer back to in case the wearable kinematics have uncertain output and the proprietary algorithms do not classify the movement appropriately. In such situations a review of the movement is necessary. Videos are required out with the laboratory as this is the only way movements can be classified accurately (to the nearest second).

The participants will then be thanked for their time and participation. After the final visit to the laboratory participants will be eligible to receive a £50 Love2Shop voucher to thank them for their participation. This will be emailed or handed to the participant at the final laboratory visit. Participants must complete all specified visits to be eligible to receive the voucher. Data analysis will be carried out by the above named researchers.

<u>Inclusion criteria:</u>
TKA patients:
1. On wait list for TKA surgery on one knee only (at the time of study). The implant, surgeon, or surgical protocol does not effect eligibility to be part of this study.
2. Indicated for primary TKA with a primary indication of osteoarthritis will be identified by a consultant orthopaedic surgeon
3. Able to perform specific activities of daily living (detailed in 2 Participant Information Sheet.docx)
4. over 18 years old
5. BMI < 35

Healthy Participants:
1. Able bodied
2. normal lower limb function
3. Free from lower limb musculoskeletal injuries and no prior lower limb surgeries
4. Able to perform specific activities of daily living (detailed in 2 Participant Information Sheet.docx)
5. Over 18 years old
6. BMI < 35

Exclusion criteria:
TKA patients:
1. Contralateral knee pain
2. Contralateral knee arthroplasty
3. Any other lower limb impairments (apart from the affected knee) or neurological conditions which inhibit normal functional movement
4. BMI > 35
5. Participation in any other clinical trial or study
6. Pregnancy or thought to be pregnant
7. Symptoms of Covid-19 (temperature, loss of taste/smell, or cough)
8. Are self-isolating due to Covid-19
9. Not having negative results from 2 lateral flow tests performed in the week prior to testing These criteria are included within the participant information and consent forms (attached), which must be completed by all participants.

Healthy participants:
1. Any known underlying musculoskeletal, neurological or cognitive condition that may affect motor control and/or
movement
2. BMI > 35
3. Pregnancy or thought to be pregnant
4. Symptoms of Covid-19 (temperature, loss of taste/smell, or cough)
5. Are self-isolating due to Covid-19
6. Not having negative results from 2 lateral flow tests performed in the week prior to testing These criteria are included within the participant information and consent forms (attached), which must be completed by all participants.

Study location:
Human Performance Laboratory
Clinical Research Facility
New Lister Building
Glasgow Royal Infirmary
G31 2ER

Motion Analysis Laboratory,
Clinical Research Facility,
Golden Jubilee National Hospital,
Beardmore Street,
Glasgow,
G81 4HX

The University of Strathclyde,
Department of Biomedical Engineering,
Biomechanics laboratory,
WC106,
Woflson Centre,
106 Rottenrow East,
G4 0NW.

Study recruitment:
TKA patients

Glasgow Royal Infirmary:
TKA patients on the waiting list for TKA surgery at either GRI or Stobhill hospital will be contacted by the NHS Trauma and orthopaedics research team at the GRI with information about the study. This will be a letter sent in the post (Participant Recruitment Letter.docx).

Potential participants will be identified by Mr Blyth, Miss Ligeti, and Dr Forsyth on the NHS computers in the GRI from the waiting list for TKA. To complete this we will request Miss Ligeti and Dr Forsyth are permitted access to the facility and this information under supervision of Mr Blyth and Dr Doonan.
This will enable patients to be identified for the recruitment letter to be sent out to from the NHS and the letters to be updated with names and addresses. The information used will be accessed on an NHS computer, will not leave the NHS facility, and will be under NHS supervision of Mr Blyth.

Only once the patient has directly contacted the researchers when interested in the study will the researchers be able to contact the patient.

Patients who are interested will contact the researchers directly for more information about taking part in the study. Patients will then be sent the full participant information sheet (PIS) and consent form by Miss Ligeti, one of the researchers, and encouraged to ask any questions they might have. At least 48 hours after receipt of the PIS Miss Ligeti will contact the potential volunteer to arrange the test time in the lab should they wish to participate. The patient will have the option for this to be at the pre-operative appointment or at another time more suitable to the patient prior to surgery (but within 3 weeks of the surgery).

Before commencement of the trial the PIS and consent form will be reviewed with the researcher and the participants shall be required to sign the consent form if they still wish to participate in the study.

Golden Jubilee National Hospital:
For the following process the term “GJNH orthopaedic research team” refers to Dr Alistair Ewen (orthopaedic research coordinator), Hollie Leonard (research physiotherapist), Swati Chopra (research physiotherapist), and research nurse (Elaine Matthews) who are NHS staff employed in the GJNH orthopaedic research centre. The

University of Strathclyde research team include Alexandra Ligeti, Dr Lauren Forsyth, and Dr Philip Riches.

The clinical team is the consultants, their fellow or physicians associate at the GJNH.

All potential TKA patients on the clinic lists of the participating consultant orthopaedic surgeons at the Golden Jubilee National Hospital (GJNH) will be screened (1-2 days before clinic) in relation to the inclusion/exclusion criteria for the study. On the morning of clinic, the GJNH orthopaedic research team inform the direct clinical team of potential study patients and discuss together who could be suitable. The consultant will let the patient know of the research study and if the patient is happy to speak to a member of the GJNH orthopaedic research team, the consultant will transfer the patient to a GJNH orthopaedic research team member.

This GJNH orthopaedic research team member will discuss the study further and provide the patient with a Patient Information Sheet (PIS). Patients will be given at least one day from receiving the PIS before they are contacted by phone for verbal consent by Alexandra Ligeti, if the patient has not already made contact using the contact details on the PIS. The intention is to contact all potential participants who have been given a copy of the PIS by telephone a few days after receipt to ask for verbal consent, answer any further questions, and organise the first laboratory visit.

This is for practical reasons to allow time to provide Alexandra Ligeti with the necessary telephone numbers, check laboratory and researcher availability between the GJNH orthopaedic and Strathclyde research teams, and to organise the biomechanical testing. The patient will attend research study visit and have time to discuss any queries before going through the informed consent process with Alexandra Ligeti. For the further two follow up testing sessions the patient will either communicate with Alexandra Ligeti to arrange a suitable time for these either on day of previous testing or Alexandra Ligeti will phone the patient to arrange this.

A screening log is kept to record the clinics, documenting why patients were not suitable, who declined, who is interested and the dates they were seen etc. This provides evidence of the dates patients were approached, consented etc and that due process was followed (ie. regarding patient selection).

For all participants (GRI and GJNH) there The participant will havewill be the option for testing to be at the pre-operative appointment or at another time more suitable to the participant prior to surgery (but within 3 weeks of the surgery). Participants will also have the option to complete testing at the hospital from which they were recruited or the Wolfson Centre at the University of Strathclyde.

For TKA patients the experiment offers a £50 Love2Shop voucher and travel costs of up to £40 will be reimbursed. Participants must complete all specified visits to be eligible to receive the voucher.

Healthy Participants
Healthy participants will be recruited by an email sent to all Biomedical Engineering staff and students at the University of Strathclyde (3 Participant Recruitment Email.docx) via the departmental office to inform of the project and provide contact details of the researcher (Alexandra Ligeti) so those interested can request a participant information sheet.

Miss Ligeti will provide the full PIS and consent form (attached), and encourage potential volunteers to ask any questions they might have. At least 48 hours after receipt of the Participant Information Sheet Miss Ligeti will contact the potential volunteer to arrange a test time in the lab should they wish to participate. Before commencement of the trial the PIS and consent form will be reviewed with the researcher and the participants shall be required to sign the consent form if they still wish to participate in the study.

The experiment offers no incentives nor reimbursements to any potential participants.

9.2 Participant Information Sheets

9.2.1 Healthy Population Information Sheet

Participant Information Sheet

Name of department: Biomedical Engineering
Title of the study: Accuracy and repeatability assessment of the EnMovi Ltd wearable devices

Introduction

The objective of this study is to assess the accuracy and repeatability of knee kinematics using EnMovi Ltd wearable sensors, used in conjunction with the app. These will be compared to gold-standard motion analysis using healthy participants when completing various activities of daily living. This data will be provided to EnMovi Ltd for further product development.

The study is part of a collaboration between University of Strathclyde and EnMovi Ltd. The study will be conducted as part of Miss Ligeti's PhD, supervised by Dr Riches and supported by Dr Forsyth.

What is the purpose of this investigation?

The MotionSense™ app has been developed to remotely support post-operative knee replacement rehabilitation. This provides personalized rehabilitation, tracking of home exercises and daily activity, and enables healthcare professionals to continuously monitor rehabilitative progress remotely.

It is important that the data collected is accurate and reliable. Therefore the purpose of this study is to validate the accuracy and reliability of the wearable sensors in a healthy population, used in conjunction with the app.

Do you have to take part?

No. It is your decision to take part in this investigation and you can refuse to participate before or during the investigation itself without giving any reason whatsoever. Up until your data is anonymised, you can ask for it to be removed from the study. Not taking part in this study or withdrawal will not affect your standing or your relationship with the University or the external company in any way.

What will you do in the project?

You will be asked to attend a session (location given below) for 1.5-2 hours at an agreed time between January 2022 and May 2022.

You will need to wear appropriate clothing so that accurate motion of the body during the biomechanical assessment can be recorded. You will be required to wear tight cycling type shorts and a sport t-shirt. Furthermore, you will be asked to bring sport-type shoes (flat trainers that do not cover or rise higher than the ankle). It is your choice to wear socks. Appropriate clothing (not socks/shoes) can be provided if necessary, although you may prefer to wear your own clothes. To track your movement individual reflective markers will be stuck externally onto your body using medical grade non-allergic tape (figure 3).

Be aware that placing markers requires physical contact. Alongside the markers, EnMovi Ltd sensors will be attached to the lower limb.

There are 2 types of EnMovi Ltd sensors:

- Commercial sensor
- Research sensor

Both devices will be attached to the body. The commercial sensor is controlled using an app, and the research sensor enables raw acceleration data to be extracted from the experiment. The sensors for both will attach to the thigh and leg, and also on the lower back for the research sensor.

Videos may be taken if you agree to this beforehand on the consent form. This is optional for the biomechanical assessment but essential for the campus walk. Videos will be not anonymised. If you wish to take part but do consent to being video you can complete the biomechanical assessment only.

The experiment offers neither incentives nor reimbursement. The laboratory session will take place in the following location:

The University of Strathclyde,
Department of Biomedical Engineering,
Biomechanics laboratory,
WC106,
Woflson Centre,
106 Rottenrow East,
G4 0NW.

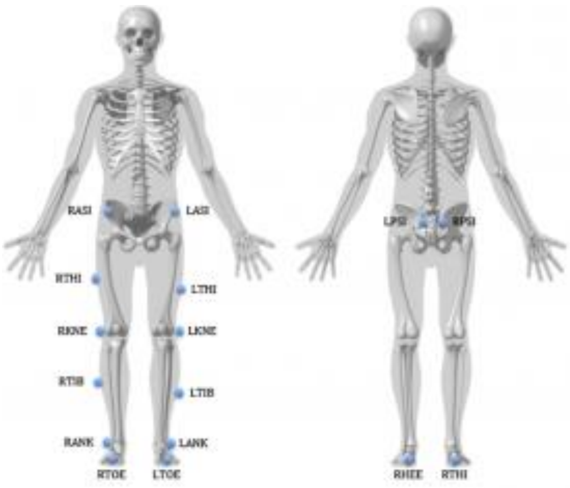


Figure 1). Locations for Plug-in-Gait markers (image: c-motion.com)

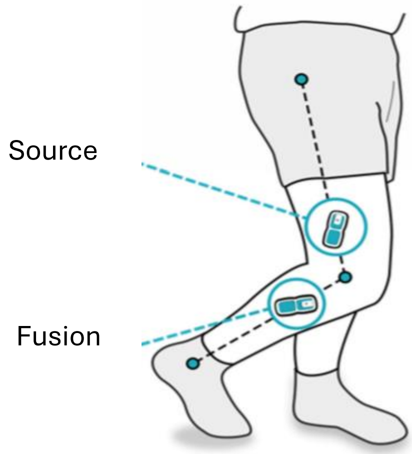


Figure 2. Commercial sensors attached to right limb. Research sensor (not pictured) will be attached next to source and fusion, plus an additional sensor attached to the lower back.

Once prepared you will carry out a series of tasks as part of the biomechanical assessment (table 1). Individual trials (except level walking) shall be performed three times. The order for completing these tasks will be randomly generated. Participants will also be given rest breaks between each condition tested to minimise the physical endurance required during the data collection session.

Table 1). Biomechanical assessment

Task	Description
Time up and go test	Participant is instructed to stand up from a chair, walk 3m, turn, walk 3m back to chair, and sit back down again. This should be completed at a comfortable and normal pace for the participant.
Active and passive range of motion	Participant will be asked to perform a knee flexion/extension movement by themselves. The tester will then repeat this movement with the participant by moving their leg for them as the participant remains passive
Wearable sensor calibration movements	Participant will stand with one foot on a small box for knee flexion angle to be calibrated. Participant will lie on floor with leg extended for leg extension angle to be calibrated. Participant will complete a selection of toe and heel slides.
5 minutes of level, treadmill walking	Participant will walk at a comfortable pace and harness will be worn for safety
Bicycle spin	Participant will spin at a comfortable pace for two minutes at various seat heights.
Jumps and hops	Participant will be required to do a selection of jumps and hops.
Stair ascent and stair descent	Participant will be instructed to climb up a flight of stairs to the top (4 steps) and then descend the stairs (4 steps) on portable stairs in the biomechanics laboratory.

Following the tasks in table 1, only if you have consented to video and the weather is suitable, you will complete a campus-based circuit (figure 4). This includes rough-ground walking and stair ascent and descent.

Volunteers will be constantly videoed using a smart phone in addition to the wearable collecting data, enabling synchronisation of data and activity. Videos give a visual check to refer back to when a review of the movement is necessary. Videos are required outdoors as this is the only way we can accurately (to the nearest second) classify movements. Prior to walking outside all markers will be removed and you will be changed into your own clothes. The wearable sensors will remain attached. Water will be available after completion.

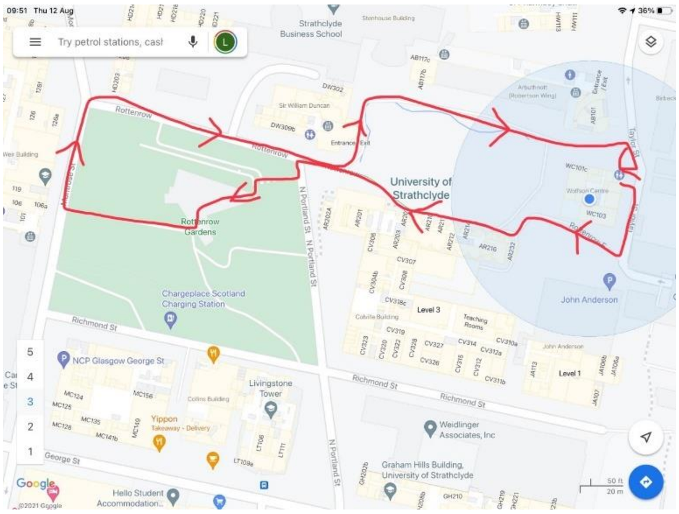


Figure 3). Route for campus walk

Why have you been invited to take part?

The chosen participants will be over 18 years of age and self-report to meeting the following criteria:

Inclusion criteria

- Able bodied
- normal lower limb function
- Free from lower limb musculoskeletal injuries and no prior lower limb surgeries
- Able to perform specific activities of daily living (see table 1)

Exclusion criteria

- Any known underlying musculoskeletal, neurological or cognitive condition that may affect motor control and/or movement
- Weight >135 kg /300 lbs/21 stones 3.62 lbs
- Pregnancy or thought to be pregnant
- Symptoms of Covid-19 (temperature, loss of taste/smell, or cough)
- Are self-isolating due to Covid-19
- Not having performed 2 lateral flow tests in the week prior to testing session

What are the potential risks to you in taking part?
You might observe some skin irritation from the tape which will last no more than one day. The biomechanical assessment requires performance of activities of daily living. These should be carried out routinely by all participants, however there is a risk of tripping or falling.
There is a risk for transmission of COVID-19. Face masks will be worn by everyone (participant/staff/students) during testing and government/university guidelines will be followed at all times.

What happens to the information in the project?
You will be asked to consider whether you wish to provide consent for the following:
- Consent to being videoed as part of the project.

Any identifiable information
The consent form will be kept confidential, stored in a locked cabinet in the Department of Biomedical Engineering. These forms will be available to Strathclyde University staff and the Strathclyde University members of the research team only.

An ID code will link the experimental data to the participant. The code list will be stored in a locked cabinet in the Department of Biomedical Engineering. The coded list will only be available to Strathclyde University staff and the Strathclyde University members of the research team.

EnMovi Ltd will not have access to this data and it will be destroyed 2 years after completion of the study. At this point data will become completely anonymous. Data will be securely stored and its access and destruction will be in accordance with the University of Strathclyde Data Protection Policy. All computing systems holding electronic data, and all hard data will be stored within lock & key, and/or, magnetic swipe card security access enabled offices and laboratories within the Department of Biomedical Engineering of the University of Strathclyde.

All pseudo-anonymous experimental data will be stored on Microsoft Teams with secure access only by the research team from Strathclyde University and EnMovi Ltd. Video data will only be shared with EnMovi Ltd if you give explicit consent since this data is not anonymised.

In addition, anonymised data will be made publicly available for further study. All the information will be saved as a backup on password protected University of Strathclyde computers and on a password protected folder on external hard drives.

The University of Strathclyde is registered with the Information Commissioner's Office who implements the Data Protection Act 1998. All personal data on participants will be processed in accordance with the provisions of the Data Protection Act 1998.

What happens next?
Once you understand the information given above and would like to take part in this research study, you can contact Alexandra Ligeti (see details below) to schedule your appointment. Please bring your signed consent form with you to your appointment.
In the case that you do not wish to be involved in the project, then the investigators of this study would like to take the opportunity to thank you for taking interest in this study.

If you would like to receive feedback about the progress of the study post-analysis you can contact any of the investigators on the contact details given below.

Researcher contact details:
Researcher: Alexandra Ligeti
Department of Biomedical Engineering
Wolfson Centre
Glasgow G4 0NW
E-mail: alexandra.ligeti.2016@strath.ac.uk

Researcher: Lauren Forsyth
Department of Biomedical Engineering
Wolfson Centre
Glasgow G4 0NW
E-mail: lauren.forsyth@strath.ac.uk

This investigation was granted ethical approval by the Department Ethics Committee. If you have any further questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Linda Gilmour
Secretary to the Departmental Ethics Committee
Department of Biomedical Engineering
Wolfson Centre,
106 Rottenrow East
Glasgow G4 0NW
Tel: 0141 548 3298
E-mail: linda.gilmour@strath.ac.uk

9.2.2 TKA Population Information Sheet

Participant Information Sheet

Name of department: Biomedical Engineering

Title of the study: Performance and activity classification post total knee arthroplasty

Introduction

The University of Strathclyde is working with a company, Enmovi Ltd, to develop an App that can improve the rehabilitation of people who have had a knee replacement. The App will take data from sensors placed above and below the knee and determine what activity they are doing, for example whether someone is walking, standing up, sitting down, going up stairs etc.

The App will also be able to determine how much the knee bends, which is a good indicator of how well someone is recovering from their operation. To achieve this, we require a large database of movement data to be collected across a broad range of people with different levels of knee function and across a large number of typical activities of daily living. These data will be collected in either the clinical research laboratory of the Glasgow Royal Infirmary or Golden Jubilee National Hospital, or the Wolfson Centre at the University of Strathclyde, and also outside the laboratory around and about the hospital or university.

All research data collected, including video data of your movement, during the sessions be anonymised and then shared with EnMovi Ltd for App development. Personal data, such as your name and contact details, will not be shared.

The study will be conducted as part of a PhD thesis for Miss Alexandra Ligeti, who will be supervised by Dr Philip Riches and additionally supported by Dr Lauren Forsyth.

What is the purpose of this investigation?

Total knee arthroplasty is becoming more prevalent with more than 100,000 procedures taking place in the United Kingdom each year. Post-operative knee stiffness and reduced knee movement are the most common difficulties and factors associated with patient dissatisfaction following surgery. Greater knee movement postoperatively indicates a better long-term knee mobility recovery.

Postoperative rehabilitation is predominately home-based. However, home-based rehabilitation has been associated with poor compliance. There is therefore an increased demand for guidance and surveillance of patients on rehabilitation programs once in their home environment. Wearable technologies present a solution to remotely monitor patients, enabling assessment of patient progress to be reviewed and performed at home. However, the wearable technologies need to work across a wide range of activities if the resulting data is to be trusted.

The app has been developed to remotely support post-operative knee replacement rehabilitation and monitor recovery progress. This study will provide this data to enable further development of this system to allow for the functionalities of this system may be improved.

Do you have to take part?

No. It is your decision to take part in this investigation and you can refuse to participate before or during the investigation itself without giving any reason whatsoever. Up until your data is anonymised, you can ask for it to be removed from the study, however once the data has been deleted after a period of three years removing your data from this project will not be possible.

On completion of the study you will receive a £50 Love2Shop voucher. This will be emailed or handed to you after your final visit. You must attend all required sessions to be eligible for the voucher.

Please also note that travel expenses up to £40 per visit will be covered, therefore you are required to keep a receipt of all travel relating to this study.

What will you do in the project?

You will be asked to attend a session (location given below) for 1.5- 2 hours at an agreed time between August 2022 and August 2024. You will need to wear appropriate clothing so that accurate motion of the body during the biomechanical assessment can be recorded. You will be required to wear tight cycling type shorts and a sport t-shirt. Furthermore, you will be asked to bring sport-type shoes (flat trainers that do not cover or rise higher than the ankle). It is your choice to wear socks.

Appropriate clothing (not socks/shoes) can be provided if necessary, although you may prefer to wear your own clothes. To track your movement individual reflective markers will be stuck externally onto your body using medical grade non-allergic tape (figure 3). Be aware that placing markers requires physical contact. Alongside the markers, EnMovi Ltd sensors will be attached to the lower limb.

There are 2 types of EnMovi Ltd sensors:

- two sensors that communicate via Bluetooth, and
- two sensors that work using wires and a data logger.

Both devices will be attached to the body. The bluetooth sensor uses an existing development algorithm and outputs measurements to a phone. The wired sensor enables raw acceleration data to be extracted from the movement and this shall be used to determine knee flexion from literature models.

Videos may be taken if you agree to this beforehand on the consent form. This is optional for the biomechanical assessment but essential for the outdoor walk. Videos will be not anonymised. If you wish to take part but do not consent to being videod you can complete the biomechanical assessment only.

The laboratory session will take place in one of the following locations:

Human Performance Laboratory,
Clinical Research Facility,
New Lister Building,
Glasgow Royal Infirmary
8-16 Alexandra Parade,
Glasgow,
G31 2ER

Motion Analysis Laboratory,
Clinical Research Facility,
Golden Jubilee National
Hospital,
Beardmore Street,
Glasgow,
G81 4HX

The University of Strathclyde,
Department of Biomedical
Engineering,
Biomechanics laboratory,
WC106,
Woflson Centre,
106 Rottenrow East,
G4 0NW

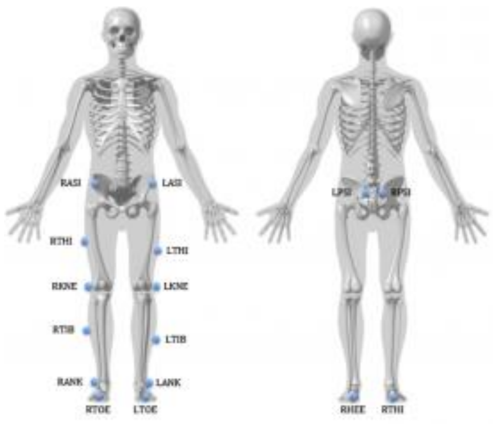


Figure 1). Locations for Plug-in-Gait markers

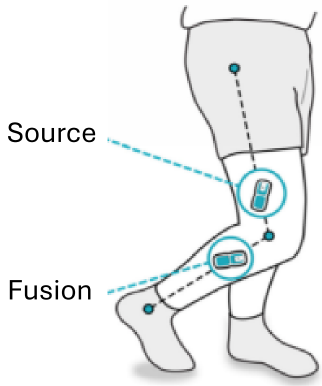


Figure 2. Commercial sensors attached to right limb. Research sensor (not pictured) will be attached next to source and fusion, plus an additional sensor attached to the lower back.

Table 1). Biomechanical assessment

Task	Description
Questionnaire	You will be asked to complete three short surveys about your knee function.
Time up and go test	You will be asked to stand up from a chair, walk 3m, turn, walk 3m back to chair, and sit back down again. This should be completed at a comfortable and normal pace for you.
Active and passive range of motion	You will be asked to perform a knee flexion/extension movement by yourself. The researcher will then repeat this movement by physically moving your leg for you as you remain passive
Wearable sensor calibration movements	You will be asked to stand with one foot on a small box (20cm in height) while resting their other foot on the floor directly next to the box for knee flexion angle to be calibrated. You will be asked to slide your toe up and down a vertical wall while maintaining your foot parallel to the ground. You will be required to slide your foot forwards and backwards along the floor in seated position.
5 minutes of level, treadmill walking	You will be asked to walk at a comfortable pace and harness will be worn for safety. Do not worry if you are unable to walk for 5 minutes, this is an upper limit. You may use a walking aid if you normally use one.
Stair ascent and stair descent	You will be asked to climb up a short flight of stairs to the top (4 steps) and then descend the stairs (4 steps) at a comfortable pace. There are handrails should you need them. This activity is not completed if you are visiting the laboratory at the Golden Jubilee National Hospital.

Upon entry you will be required to read and sign a consent form, any questions will be answered. Following this, the markers and sensors will be placed on your body as explained above. Once prepared you will carry out a series of tasks as part of the biomechanical assessment (table 1). Individual trials (except level walking) shall be performed three times. The order for completing these tasks will be randomly generated. You will be given rest breaks between each condition tested to minimise the physical endurance required during the data collection session.

Following the tasks in table 1, and only if you have consented to video and the weather is suitable, you will complete a circuit outside the laboratory. At the Glasgow Royal Infirmary or University of Strathclyde this be outdoors (figure 3) and includes rough-ground walking and stair ascent and descent. At the Golden Jubilee National Hospital this walk will take place inside the hospital. It will include stair ascent and descent.

Prior to walking outside all markers will be removed and you will be changed into your own clothes. The wearable sensors will remain attached. You will be videoed using a smart phone. These videos give us a visual check of the movement and are required outdoors as this is the only way we can accurately (to the nearest second) classify movements. Water will be available after completion.

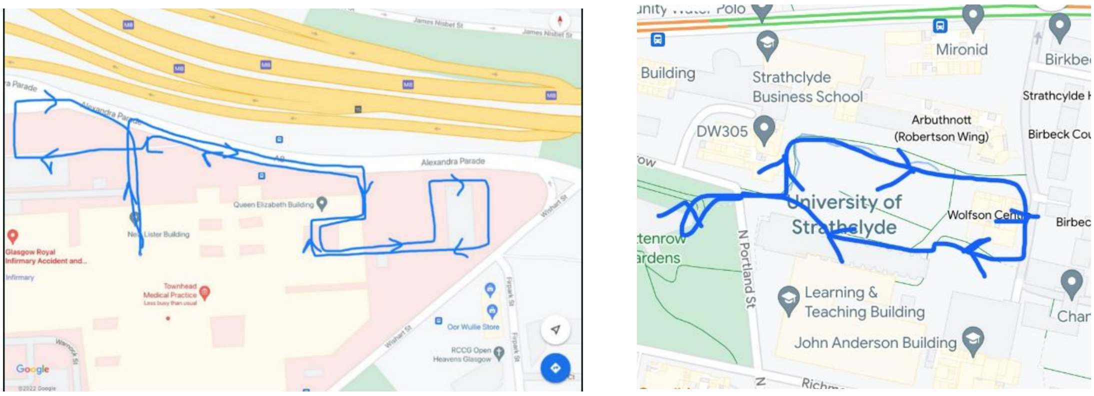


Figure 3). Route for outdoor walk for Glasgow Royal Infirmary (left) and University of Strathclyde (right)

Why have you been invited to take part?
The chosen participants will be over 18 years of age and self-report to meeting the following criteria:

Inclusion criteria

- Received total knee replacement surgery on one knee only (at the time of study)
- Indicated for primary total knee replacement surgery with a primary indication of osteoarthritis as identified by a consultant orthopaedic surgeon
- Able to perform specific activities of daily living (see table 1)

Exclusion criteria

- Contralateral knee pain
- Contralateral knee arthroplasty
- Any other lower limb impairments (apart from the affected knee) which inhibit normal functional movement
- BMI > 35
- Participation in any other clinical trial or study
- Pregnancy or thought to be pregnant

What are the potential risks to you in taking part?

You might observe some skin irritation from the tape which will last no more than one day. The biomechanical assessment requires performance of activities of daily living. These should be carried out routinely by all participants, however there is a risk of tripping or falling. There is a risk for transmission of COVID-19. If you prefer, face masks will be worn by everyone (participant/staff/students) during testing and government/university guidelines will be followed at all times.

What happens to the information in the project?

You will be asked to consider whether you wish to provide consent for the following:

- Consent to being videoed as part of the project.

Any identifiable information

The consent form will be kept confidential, stored in a locked cabinet in the Department of Biomedical Engineering. These forms will be available to Strathclyde University staff and the Strathclyde University members of the research team only.

An ID code will link your experimental data to you. The code list will be stored in a locked cabinet in the Department of Biomedical Engineering. The coded list will only be available to Strathclyde University staff and the Strathclyde University members of the research team. EnMovi Ltd will not have access to this data and it will be destroyed 2 years after completion of the study. At this point data will become completely anonymous. Data will be securely stored and its access and destruction will be in accordance with the University of Strathclyde Data Protection Policy. All computing systems holding electronic data, and all hard data will be stored within lock & key, and/or, magnetic swipe card security access enabled offices and laboratories within the Department of Biomedical Engineering of the University of Strathclyde.

All experimental data will be stored pseudo-anonymously, and coded with an ID-number. All the research data will be saved as a backup on password protected University of Strathclyde computers in the biomechanics laboratory.

Research data will be shared with EnMovi Ltd as external collaborators under the auspices of a data sharing agreement which adheres to UK law and ensures GDPR compliance. Pseudo-anonymous experimental data will be transferred via the network and stored upon Microsoft Teams, as well as video data if explicit consent given, thereby providing access to all members of the research team including EnMovi Ltd as external collaborators.

The phones on which the videos are recorded on are research phones and do not have SIMS. The phones are stored at the University and will only be used for this project for the duration of the project. Once the videos are extracted from the phone, they shall be deleted from the phone. The phones will be wiped of all videos before being re-used.

Anonymised data will be made publicly available for further study. All the information will be saved as a backup on password protected University of Strathclyde computers and on a password protected folder on external hard drives.

The University of Strathclyde is registered with the Information Commissioner's Office who implements the Data Protection Act 1998. All personal data on participants will be processed in accordance with the provisions of the Data Protection Act 1998.

What happens next?

Once you understand the information given above and would like to take part in this research study, you can contact Alexandra Ligeti (see details below) to schedule your appointment. In the case that you do not wish to be involved in the project, then the investigators of this study would like to take the opportunity to thank you for taking interest in this study.

If you would like to receive feedback about the progress of the study post-analysis you can contact any of the investigators on the contact details given below. A lay summary of your results will be made available to you upon completion of this study.

Researcher contact details:
Researcher: Alexandra Ligeti
Department of Biomedical Engineering
Wolfson Centre
Glasgow G4 0NW
E-mail: alexandra.ligeti@strath.ac.uk

Researcher: Lauren Forsyth
Department of Biomedical Engineering
Wolfson Centre
Glasgow G4 0NW
E-mail: lauren.forsyth@strath.ac.uk

9.3 Consent Forms

9.3.1 Healthy Population Consent Form

Consent Form for Participants

Name of department: Biomedical Engineering
Title of the study: Accuracy and repeatability assessment of the EnMovi Ltd wearable devices

- I confirm that I have read and understood the Participant Information Sheet for the above project and the researcher has answered any queries to my satisfaction.
- I confirm that I have read and understood the Privacy Notice for Participants in Research Projects and understand how my personal information will be used and what will happen to it (i.e. how it will be stored and for how long).
- I understand that my participation is voluntary and that I am free to withdraw from the project at any time, up to the point of completion, without having to give a reason and without any consequences.
- I understand that I can request the withdrawal from the study of some personal information and that whenever possible researchers will comply with my request. This includes the following personal data:
    - video recordings of physical tests that identify me;
- I understand that anonymised data (i.e. data that do not identify me personally) cannot be withdrawn once they have been included in the study.
- I understand that any information recorded in the research will remain confidential and no information that identifies me will be made publicly available.
- I consent to being a participant in the project.

Optional:

- I consent to the use of videography as part of the project. Yes/ No

Full Name of Participant:	
Signature of Participant:	Date:

9.3.2 TKA Population Consent Form

Consent Form for Participants

IRAS ID: 314702

Centre Number: CRF Glasgow Royal Infirmary

Golden Jubilee National Hospital

Wolfson Centre University of Strathclyde

Study Number: 1

Participant Identification Number for this trial:

Name of department: Biomedical Engineering
Title of the study: Performance and Activity Classification post Total knee arthroplasty

1. I confirm that I have read and understood the Participant Information Sheet for the above project dated .... and the researcher has answered any queries to my satisfaction.
2. I confirm that I have read and understood the Privacy Notice for Participants in Research Projects and understand how my personal information will be used and what will happen to it (i.e. how it will be stored and for how long).
3. I understand that relevant sections of my medical notes/records will be accessed by the researcher and that data collected during the study, may be looked at by individuals from the University of Strathclyde and Enmovi Ltd where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
4. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.
5. I understand that my participation is voluntary and that I am free to withdraw from the project at any time, up to the point of completion, without having to give a reason and without any consequences.
6. I understand that I can request the withdrawal from the study of some personal information and that whenever possible researchers will comply with my request, and that I understand this is not possible after a period of 3 years has passed once data has been destroyed

    This includes the following personal data:

    Video recordings of physical tests that identify me.

7. I understand that anonymised data (i.e. data that do not identify me personally) cannot be withdrawn once they have been included in the study.
8. I understand that any information recorded in the research will remain confidential and no information that identifies me will be made publicly available.
9. I understand anonymised data will be shared with Enmovi Ltd to help improve the functionality of the MotionSense™ wearable device.
10. I consent to being a participant in the project.

Optional:

11. I consent to the use of videography as part of the project. Yes/ No

12. I consent to the videos taken being shared with EnMovi Ltd Yes/ No

Full Name of Participant:	
Signature of Participant:	Date:
Full Name of Researcher seeking consent:	
Signature of Researcher seeking consent:	Date:

Privacy Notice for Participants in Research Projects

Introduction	
This privacy notice relates to individuals participating in research projects led by the University of Strathclyde. It explains how the University of Strathclyde will use your personal information and your rights under data protection legislation. It is important that you read this notice prior to providing your information. Please note that this standard information should be considered alongside information provided by the researcher for each project, which is usually in the form of a Participant Information Sheet (PIS). The PIS will include further details about how personal information is processed in the particular project, including: what data is being processed; how it is being stored; how long it will be retained for, and any other recipients of the personal information. It is usually given to participants before they decide whether or not they want to participate in the research.	
Data controller and the data protection officer	
The University of Strathclyde is the data controller under data protection legislation. This means that the University is responsible for how your personal data is used and for responding to any requests from you in relation to your personal data. Any enquiries regarding data protection should be made to the University's Data Protection Officer at dataprotection@strath.ac.uk.	
Legal basis for processing your personal information	
If you are participating in a research project, we may collect your personal information. The type of information that we collect will vary depending on the project. Our basis for collecting this information is outlined below:	
Type of information	Basis for processing
Personal information and associated research data collected for the purposes of conducting research.	It is necessary for the performance of a task carried out in the public interest.
Certain types of personal information such as information about an individual's race, ethnic origin, politics, religion, trade union membership, genetics, biometrics (where used for ID purposes), health, sex life, or sexual orientation are defined as 'Special Category' data under the legislation.	It is necessary for the performance of a task carried out in the public interest and It is necessary for scientific or historical research purposes in accordance with the relevant legislation (Data Protection Act 2018, Schedule 1, Part 1, Para 4).
Criminal conviction / offence data	It is necessary for the performance of a task carried out in the public interest and is processed in accordance with Article 10 of the General Data Protection Regulation and the Data Protection Act 2018, Schedule 1, Part 1, Para 4.
Details of transfers to third countries and safeguards	
For some projects, personal information may be transferred outside the UK. This will normally only be done when research is taking place in locations outside the UK. If this happens, the University will ensure that appropriate safeguards are in place. You will be fully informed about any transferring of data outside the UK and associated safeguards, usually in the Participant Information Sheet.	
Sharing data	

If data will be shared with other individuals or organisations, you will be advised of this in the PIS.
Retention of consent forms
If you participate in a research project, you may be asked to sign a participant consent form. Consent forms will typically be retained by the University for at least as long as the identifiable research data are retained. In most cases they will be retained for longer, the exact time frame will be determined by the need for access to this information in the unfortunate case of an unanticipated problem or a complaint. 5 years after the research is completed will be suitable for many projects, but beyond 20 years will be considered for any longitudinal or 'high risk' studies involving children, adults without capacity or a contentious research outcome.
Data subject rights
You have the right to: be informed about the collection and use of your personal data; request access to the personal data we hold about you; request to have personal data rectified if it is inaccurate or incomplete; object to your data being processed; request to restrict the processing of your personal information; and rights related to automated decision-making and profiling. To exercise these rights please contact dataprotection@strath.ac.uk. Please note, many of these rights **do not** apply when the data is being used for research purposes. However, we will always try to comply where it does not prevent or seriously impair the achievement of the research purpose.
Right to complain to supervisory authority
If you have any concerns/issues with the way the University has processed your personal data, you can contact the Data Protection Officer at dataprotection@strath.ac.uk. You also have the right to lodge a complaint against the University regarding data protection issues with the Information Commissioner's Office (https://ico.org.uk/concerns/).

9.4 Ethics Approval

9.4.1 Departmental Ethics Approval

To:	Dr Phil Riches	Date:	01 August 2025
From:	Departmental Ethics Committee	Ref:	KR/LG

Paper DEC/BioMed/2021/305 – Accuracy and repeatability assessment of the EnMovi Ltd wearable devices

The above paper was discussed by the DEC at the meeting held on 7 September 2021. The decision of the Committee was that the application could be approved by Convener's Action, subject to the following points/recommendations being undertaken:

Application Form

Section 4 – Non-Strathclyde collaborating investigator(s)

While it is clear data will be shared with non-Strathclyde investigators it is not clear whether they are going to contribute to the investigation?

It is stated later on in the application there will be a data sharing agreement in place; this must be approved by RKES and needs to be in place before the research commences. A copy of the data sharing agreement should be provided to Linda Gilmour to be kept with the application.

We have been communicating with RDMS and EnMovi and the data sharing plan is nearing completion. It will be finalised and approved before commencement of the project.

Section 6 – Location of the investigation

This should also include details of the proposed outdoors circuit.

Sentence & route map added:

‘Proposed outdoor circuit route around campus starting from the above address. See route below.’

<u>Section 10 – Ethical issues</u>

It is unclear why video and photographs are required. This should be clarified in Section 16 and also in the PIS. It would appear given that these aspects are optional they may not be essential for the research. If indeed they are required, researchers should consider whether participants with identifiable features which could not easily be pixilated should actually be excluded from participating (add to exclusion criteria).

The option for photographs has been removed, however video remains an option/is required for outside part of study. The consent form, PIS, and application have been amended. Video information has been clarified in section 10 paragraph 4 and last paragraph, section 16 second last paragraph, and PIS in paragraph before table in section **What will you do in the project?**

‘Video is optional in the lab as it is useful as a visual checker to review if movement is not classified correctly by the sensors. However, video outside of the lab is required as this is the only way movements can be classified accurately (to the nearest second). Video will be not be anonymised, but will only shared with EnMovi if explicit consent given.’

In the PIS page 2 second paragraph reads to highlight that the videos are not anonymous but can still take part:

Videos may be taken if you agree to this beforehand on the consent form. This is optional for the biomechanical assessment but essential for the campus walk. Videos will be not anonymised. If you wish to take part but do consent to being video you can complete the biomechanical assessment only.

Please provide further clarification on storage of photographs and video. If full anonymisation has not been possible is it still the intention to share this with collaborators EnMovi?

Video data will be extracted from the phones and stored alongside the pseudo-anonymous experimental data. Only if explicit consent given will video data be shared with EnMovi. This is clarified in the final paragraph where it now reads:

‘All pseudo-anonymous experimental data shall be securely saved as a backup on password protected University of Strathclyde computers in the biomechanics laboratory and then transferred and stored upon Microsoft Teams, thereby providing access to all members of the research team including EnMovi Ltd as external collaborators. Video data will only be extracted from the phones to password protected University of Strathclyde computers in the biomechanics laboratory and only transferred to Microsoft Teams if explicit consent is given.’

Add a paragraph regarding ethical issues associated with close proximity e.g. intimate palpation for marker placement and in relation to Covid; also include the issue pertaining to tightly fitting clothing for the indoor testing. New paragraph 3 has been added and reads:

‘On the day of testing the participant will be required to wear tight fit clothing in the lab to accurately track body movement during testing. This will also require palpation of bony landmarks where tester will be in close proximity to the participant. The researcher will wash their hands beforehand and only be in close proximity for the minimum time required. Once the need for close contact has ended the researcher will wash their hands and markers, as written in RA2658.’

Section 12 – Participants

Inclusion criteria

No. 3 – “no prior surgeries” – clarification that this would only relate to those impacting mobility or balance etc. Have clarified lower limb surgeries.

Exclusion criteria

Include aspects pertaining to covid19 in line with government and university guidelines; e.g. exclude those with covid symptoms, those isolating etc; for research and teaching with physical contact, new risk assessments identify that parties are required to provide 2 negative lateral flow tests..

Suggest excluding participants with tattoos or other physical body markings that could not be easily pixelated. Added. Exclusion criteria now has the below added:

- Symptoms of Covid-19 (temperature, loss of taste/smell, or cough)
- Are self-isolating due to Covid-19
- Not having performed 2 lateral flow tests in the week prior to testing session

Section 14 – Method of recruitment

1st Para – 1st sentence – please remove “as well as other students attending Biomedical Engineering classes”. Removed.

2nd Para – 4th line – Remove “only if they have not already contacted Miss Ligeti within this 48 hour time period”, as this maybe unnecessary and limit potential participants. Researchers could propose a date by which any interested parties may respond. Removed.

Section 16 – Methodology

Page 5 - Test Session: Change 1.5 hours – suggest maximum time limit for the session. Have stated will last from 1.5-2 hours.

Page 6 3rd Para – All clothing will be washed between users – this needs to be quarantined for 72 hours before washing in line with current risk assessments. Added.

4th Para – Clarification with regards to what sensors/markers will be attached to each participant, an image indicating the number of sensors and locations of sensors and included in the PIS would be helpful. Image of marker locations/sensor locations added to application and PIS.

Table

Harness – There needs to be in place Covid infection protocol for the harness – there is a risk assessment in place for this – see Dr A Kerr – which must be referred to in the application and must be read and signed by all researchers. On reflection a harness will not be worn on the treadmill, and this has been deleted from the table. Participants are healthy and will be given time to become comfortable walking on the treadmill before any trials are recorded.

Stair ascent and stair descent – please clarify these are stairs within the biomechanics lab? Have clarified. The stairs are portable and assessment will be carried out within biomechanics laboratory.

Last Para – It appears that the video footage will be taken by a smart phone which is not a piece of research equipment assigned specifically to this project. If this data is going to be captured on a personal phone there needs to be full consideration of data protection.

Clarification has been added to the paragraph stating:

‘These are research phones and do not have SIMS. They have been provided by EnMovi and are the only phones to have the EnMovi MotionSense™ App running. The phones are stored at the University and will only be used for this project for the duration of the project. Once the videos are extracted from the phone, they shall be deleted from the phone. The phones will be wiped of all videos before being returned to EnMovi.'

Car ingress/egress – lack of information provided here with regards to whom this car belongs, there needs to be full consideration of infection control on all touch surfaces within the vehicle in relation to Covid. This was still included in error and has been removed as is not part of this study.

<u>Section 18 – Data collection, storage and security</u>

2nd last sentence – insert "fully anonymised" data. Done.

<u>Section 19 – Potential risks or hazards</u>

See previous points regarding risk assessments. There are multiple risk assessments already in place e.g. ER2658 which covers some aspects of this proposed research. The researchers must contact the department safety committee to identify which risk assessments and protocols are already in place, referring to these in this application and ensure all parties read and sign these risk assessments.

Have added:

'Researchers have also read and signed risk assessments RA2658 which identify protocols in place regarding work in biomechanics labs during COVID-19.'

<u>Section 20 – What method will you use to communicate the outcomes</u>

Please add "as approved by EnMovi Ltd". Done.

<u>Section 21 – How will the outcomes of the study be disseminated</u>

Please add PhD thesis if appropriate. Done.

<u>Consent Form</u>

Please use the newest/updated version of the consent form on the website and add additional bullet points as necessary.

Last bullet point – this conflicts with what was previously stated in the application regards data sharing.

Form updated to newest version.

Last bullet point amended to support application

<u>Participant Information Sheet</u>

All previous recommendations made in relation to the application form should be addressed in the PIS. Done.

<u>Introduction</u>

Add details about the research team. Done.

<u>What is the purpose of this investigation</u>?

This has clearly been written for a patient group e.g. "This provides your personalised……remotely". This section must be rewritten for the target audience.

Now reads:

'The MotionSense™ app has been developed to remotely support post-operative knee replacement rehabilitation. This provides personalized rehabilitation, tracking of home exercises and daily activity, and enables healthcare professionals to continuously monitor rehabilitative progress remotely.

It is important that the data collected is accurate and reliable when using the sensors and App. Therefore the purpose of this study is to validate the accuracy and reliability of the wearable sensors in a healthy population, used in conjunction with the app.'

Please carry out a sense check on the PIS. Done.

Campus based circuit – make a statement this will only be carried out if weather is suitable. Done.

In relation to Covid: Please include information in line with government guidelines in relation to Covid and the need for isolation which must be considered before deciding to attend a test session. Additional criteria have been added to inclusion/exclusion criteria and clarification has been added to section **What are the potential risks to you in taking part?**

<u>Recruitment E-mail</u>

Include inclusion/exclusion criteria. Done

3rd Para – amend in line with previous comments. Done

Expand to include optional outdoor session which will be videoed. Added.

Include timelines e.g. the duration of the study. Added.

Risk Assessment

Student researchers – please sign off risk assessment. All have now signed.

Please note that investigators MUST have all relevant ethical approval, insurance cover, and sponsorship/management approval in place BEFORE the study can begin.

I would be grateful if you could email the required amendments to the Secretary to the Departmental Ethics Committee, Linda Gilmour. When emailing the amended application, please summarise in your email your response to each of the points raised above (preferably beside each point) and also mark clearly in the amended application the changes that you have made e.g. track changes.

Please contact me if you have any questions.

Kind Regards

Karyn Ross

Convener

Departmental Ethics Committee

9.4.2 NHS Ethics Approval

WoSRES

West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Dr Philip Riches
Reader
University of Strathclyde
Wolfson center
106 Rottenrow East
Glasgow
G4 0NW

West of Scotland REC 4
Research Ethics
Ward 11, Dykebar Hospital
Grahamston Road
Paisley
PA2 7DE

Date 29 August 2022
Direct line 0141 314 0213
E-mail WoSREC4@ggc.scot.nhs.uk

Dear Dr Riches

Study title:	**Functional performance and classification of activities of daily living post total knee arthroplasty.**
REC reference:	**22/WS/0084**
Protocol number:	**1**
IRAS project ID:	**314702**

Thank you for your letter of 03 August 2022, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC. A list of the Sub-Committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Contract/Study Agreement template [Student contract]		
Covering letter on headed paper [Revision answers to application]		03 August 2022
IRAS Application Form [IRAS_Form_27052022]		27 May 2022
Letter from funder [Studentship_Ligeti]		11 March 2021
Letters of invitation to participant [Healthy control recruitment email clear]	V2	22 June 2022
Letters of invitation to participant [Healthy control recruitment email tracked changes]	V2	22 June 2022
Letters of invitation to participant [TKA recruitment email clear]	V2	01 July 2022
Non-NHS/HSC Site Assessment Form [Risk Assessment]	V1	03 August 2022
Participant consent form [Consent form clear]	V2	21 June 2022
Participant consent form [Consent form tracked changes]	V2	21 June 2022
Participant information sheet (PIS) [PI for TKA clear]	V4	21 June 2022
Participant information sheet (PIS) [PI TKA tracked]	V4	21 June 2022
Participant information sheet (PIS) [PI For healthy control clear]	V4	21 June 2022
Participant information sheet (PIS) [PI For healthy control tracked changes]	V4	21 June 2022
Research protocol or project proposal [Protocol tracked]	V2	22 June 2022
Sample diary card/patient card [Data log TKA]	V1	18 May 2022
Sample diary card/patient card [Data log Healthy clear]	V2	07 July 2022
Sample diary card/patient card [Data log Healthy tracked changes]	V2	07 July 2022
Schedule of Events or SoECAT [Programme of work clear]	V2	23 June 2022
Schedule of Events or SoECAT [Programme of work tracked changes]	V2	23 June 2022
Summary CV for Chief Investigator (CI) [CI CV]		
Summary CV for student [CV_Ligeti]		
Summary CV for supervisor (student research) [CV_Riches (CI and Supervisor)]		
Validated questionnaire [Oxford knee score]		
Validated questionnaire [Koos JR]		
Validated questionnaire [Promis 10]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 314702	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Abibat Adewumi

On behalf of
Dr Michael Fail
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

After ethical review guidance for sponsors and investigators – Non CTIMP Standard Conditions of Approval]

Copy to: Miss Angelique Laverty

Lead Nation Scotland: gram.nrspcc@nhs.scot

Administrator: **Ms Elaine O'Neill**
E-Mail: elaine.o'neill2@ggc.scot.nhs.uk
Website: [West of Scotland Innovation Hub | Innovation Hub (woshealthinnovation.scot)]

Clinical Research & Innovation
Wos Innovation Hub
ICE Building
QEUH
Glasgow G51 4TF

23 December 2022

Mr Mark Blyth
Consultant Orthopaedic Surgeon
Glasgow Royal Infirmary
84 Castle Street
Glasgow G4 0SF

NHS GG&C Board Approval

Dear Mr M Blyth,

Study Title:	Functional performance and classification of activities of daily living post total knee arthroplasty.
Principal Investigator:	Mr Mark Blyth
GG&C HB site	Glasgow Royal Infirmary
Sponsor	Strathclyde University
R&I reference:	INGN22OR204
REC reference:	22/WS/0084
Protocol no: (including version and date)	V2; 22/06/2022

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004

   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

2. **For all studies** the following information is required during their lifespan.
   a. First study participant should be recruited within 30 days of approval date.

b. Recruitment Numbers on a monthly basis
c. Any change to local research team staff should be notified to R&D team
d. Any amendments – Substantial or Non Substantial
e. Notification of Trial/study end including final recruitment figures
f. Final Report & Copies of Publications/Abstracts
g. You must work in accordance with the current NHS GG&C COVID19 guidelines and principles.

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

E O'Neill

Ms Elaine O'Neill
Industry Collaboration Project Manager

Cc: Mrs Louise McKean (Strathclyde University)
Ms Angelique Laverty (Strathclyde University)
Dr Jamie Doonan (Strathclyde University/NHS GG&C)

9.5 PROM Questionnaires

9.5.1 Oxford knee score

PROBLEMS WITH YOUR KNEE

During the past 4 weeks..

✓tick one box for every question

1 *During the past 4 weeks........*

How would you describe the pain you usually have from your knee?

None	Very mild	Mild	Moderate	Severe
❑	❑	❑	❑	❑

2 *During the past 4 weeks........*

Have you had any trouble with washing and drying yourself (all over) because of your knee?

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
❑	❑	❑	❑	❑

3 *During the past 4 weeks........*

Have you had any trouble getting in and out of a car or using public transport because of your knee? (whichever you would tend to use)

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
❑	❑	❑	❑	❑

4 *During the past 4 weeks........*

For how long have you been able to walk before pain from your knee becomes **severe**? (*with or without a stick)*

No pain/ More than 30 minutes	16 to 30 minutes	5 to 15 minutes	Around the house only	Not at all - pain severe when walking
❑	❑	❑	❑	❑

5 *During the past 4 weeks........*

After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?

Not at all painful	Slightly painful	Moderately painful	Very painful	Unbearable
❑	❑	❑	❑	❑

6 *During the past 4 weeks......*

Have you been limping when walking, because of your knee?

Rarely/ never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
❑	❑	❑	❑	❑

During the past 4 weeks...

✓**tick one box for every question**

7	***During the past 4 weeks***........ **Could** you kneel down and get up again afterwards? Yes, Easily ❑ With little difficulty ❑ With moderate difficulty ❑ With extreme difficulty ❑ No, Impossible ❑
8	***During the past 4 weeks***........ Have you been troubled by pain from your knee in bed at night? No nights ❑ Only 1 or 2 nights ❑ Some nights ❑ Most nights ❑ Every night ❑
9	***During the past 4 weeks***........ How much has pain from your knee interfered with your usual work *(including housework)*? Not at all ❑ A little bit ❑ Moderately ❑ Greatly ❑ Totally ❑
10	***During the past 4 weeks***........ Have you felt that your knee might suddenly 'give way' or let you down? Rarely/ never ❑ Sometimes, or just at first ❑ Often, not just at first ❑ Most of the time ❑ All of the time ❑
11	***During the past 4 weeks***........ **Could** you do the household shopping on your own? Yes, Easily ❑ With little difficulty ❑ With moderate difficulty ❑ With extreme difficulty ❑ No, Impossible ❑
12	***During the past 4 weeks***........ **Could** you walk down one flight of stairs? Yes, Easily ❑ With little difficulty ❑ With moderate difficulty ❑ With extreme difficulty ❑ No, Impossible ❑

9.5.2 Knee Injury and Osteoarthritis Outcome Score

orthotoolkit

<u>Knee injury and Osteoarthritis Outcomes Score for Joint Replacement (KOOS JR) Survey</u>

Patient Name: ______________________________ Patient MRN: ______________________________

Date: _______________________________________ Affected Knee: R L (Circle One)

Instructions:

This survey asks for your opinion about your knee and helps us understand how well you are able to complete your usual activities. Answer each question by ticking the appropriate box (only <u>one</u> box for each question). If you are uncertain about how to answer a question, please give the best answer you can.

I. Stiffness

Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint. What amount of knee stiffness have you experienced the <u>last week</u> during the following activities?

S1. How severe is your knee stiffness after first wakening in the morning?

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4)

II. Pain

What amount of knee pain have you experienced the <u>last week</u> during the following activities?

P1. Twisting/pivoting on your knee

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4)

P2. Straightening knee fully

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4)

P3. Going up or down stairs

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4)

P4. Standing upright

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4)

III. Function, daily living

This section describes your ability to move around and to look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the <u>last week</u> due to your knee.

A1. Rising from sitting

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4)

A2. Bending to the floor/pick up an object

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4) orthotoolkit

III. Scoring:

The KOOS JR is scored by summing the raw response (range 0-28) and then converting it to an interval score using the table provided below. The interval score ranges from 0 to 100 where 0 represents total knee disability and 100 represents perfect knee health.

Raw Summed Score (0-28)	Interval Score (0-100)	Raw Summed Score (0-28)	Interval Score (0-100)	Raw Summed Score (0-28)	Interval Score (0-100)	Raw Summed Score (0-28)	Interval Score (0-100)	Raw Summed Score (0-28)	Interval Score (0-100)
0	100.000	6	70.704	12	57.140	18	42.281	24	24.875
1	91.975	7	68.284	13	54.840	19	39.625	25	20.941
2	84.600	8	65.994	14	52.465	20	36.931	26	15.939
3	79.914	9	63.776	15	50.012	21	34.174	27	8.291
4	76.332	10	61.583	16	47.487	22	31.307	28	0.000
5	73.342	11	59.381	17	44.905	23	28.251		

_________ Interval Score (100 points)

KURMIS ORTHOPAEDICS

Forgotten Joint Score (FJS-12)

PATIENT NAME: ________________________________ **Today's date:** / /

Please answer the following 12 questions in relation to your joint replacement.

Place a tick ✓ next to the words that best describes **your answer**.

Are you aware of your artificial joint ...

1. ... in bed at night ? ☐ Never ☐ Almost never ☐ Seldom ☐ Sometimes ☐ Mostly	**2.** ... when you are sitting on a chair for more than one hour ? ☐ Never ☐ Almost never ☐ Seldom ☐ Sometimes ☐ Mostly
3. ... when you are walking for more than 15 minutes ? ☐ Never ☐ Almost never ☐ Seldom ☐ Sometimes ☐ Mostly	**4.** ... when you are taking a shower or bath ? ☐ Never ☐ Almost never ☐ Seldom ☐ Sometimes ☐ Mostly
5. ... when you are traveling in a car ? ☐ Never ☐ Almost never ☐ Seldom ☐ Sometimes ☐ Mostly	**6.** ... when you are climbing stairs ? ☐ Never ☐ Almost never ☐ Seldom ☐ Sometimes ☐ Mostly

Office use only:

DOS: / /

Location:

Joint:

Side:

Implant combination:

Forgotten Joint Score (continued)

Are you aware of your artificial joint ...

7. ... when you are walking on uneven ground ? ☐ Never ☐ Almost never ☐ Seldom ☐ Sometimes ☐ Mostly	**8.** ... when you are standing up from a low-sitting position ? ☐ Never ☐ Almost never ☐ Seldom ☐ Sometimes ☐ Mostly
9. ... when you are standing for long periods of time ? ☐ Never ☐ Almost never ☐ Seldom ☐ Sometimes ☐ Mostly	**10.** ... when you are doing housework or gardening ? ☐ Never ☐ Almost never ☐ Seldom ☐ Sometimes ☐ Mostly
11. ... when you are taking a walk or hiking ? ☐ Never ☐ Almost never ☐ Seldom ☐ Sometimes ☐ Mostly	**12.** ... when you are doing your favourite sport ? ☐ Never ☐ Almost never ☐ Seldom ☐ Sometimes ☐ Mostly

Thank you.

Chapter 10. Appendix 2- Technical Information

10.1 MotionSense™ Wearable commercial device

Information for **healthcare professionals**

MotionSense with OrthoLogIQ. Where innovation meets recovery.

MotionSense | Patient interaction

MotionSense is a wearable remote therapeutic monitoring device that helps guide and empower patients through their knee replacement recovery.

This device sends patient recovery information directly to the surgeon and care team, allowing them to personalize a patient's recovery by customizing physical therapy exercises and capturing key metrics such as:

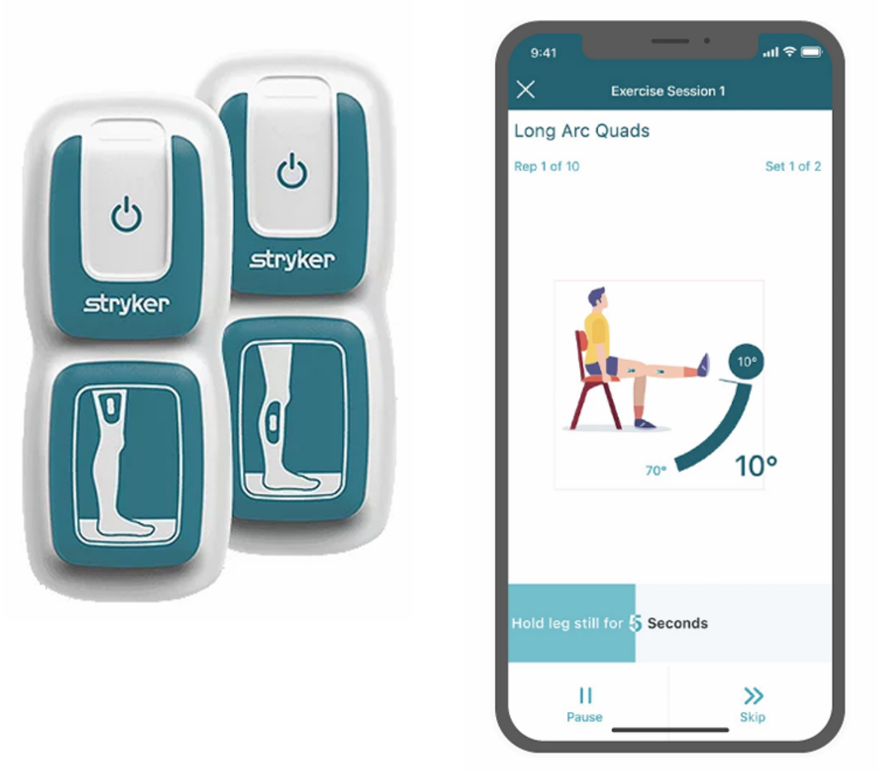
Pain scores

Range of motion

Wound images

Daily steps

PROM collection



OrthoLogIQ | Surgeon and Care Team interaction

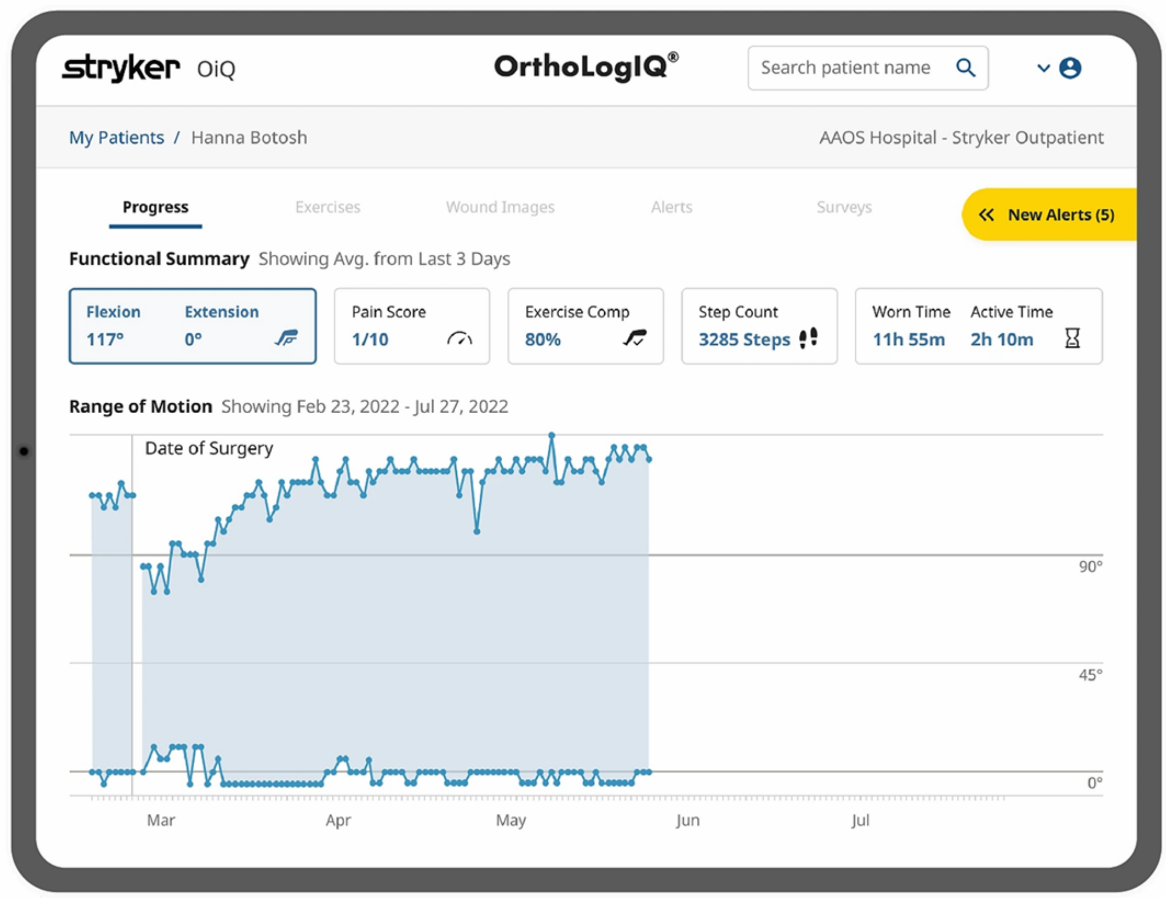
OrthoLogIQ is a cloud-based platform that allows surgeons and care teams to view the patient recovery data captured by MotionSense. It quantifies orthopedics and patient recovery, enabling healthcare providers to remotely monitor and personalize pre-operative and post-operative care, with the goal of improving patient outcomes at a lower cost.

Patient list

- Create patient profiles
- Link individual patients with data from their MotionSense app
- Remotely access patient data from anywhere with a secure, HIPAA-compliant platform
- Review knee recovery metrics (range of motion, weight-bearing time, activity, steps, etc.)

Dashboard

- Review and analyze patient data
- Utilize actionable data to determine if interventional care is needed
- Receive notifications to quickly identify patients who need attention



Key features

Remote monitoring and engagement

Engage patients outside of the clinic through real-time capture of prescribed exercise completion. Encourage a positive recovery by monitoring home exercise plans, range of motion progress, wound images, and much more.

Patient-Reported Outcome Measures

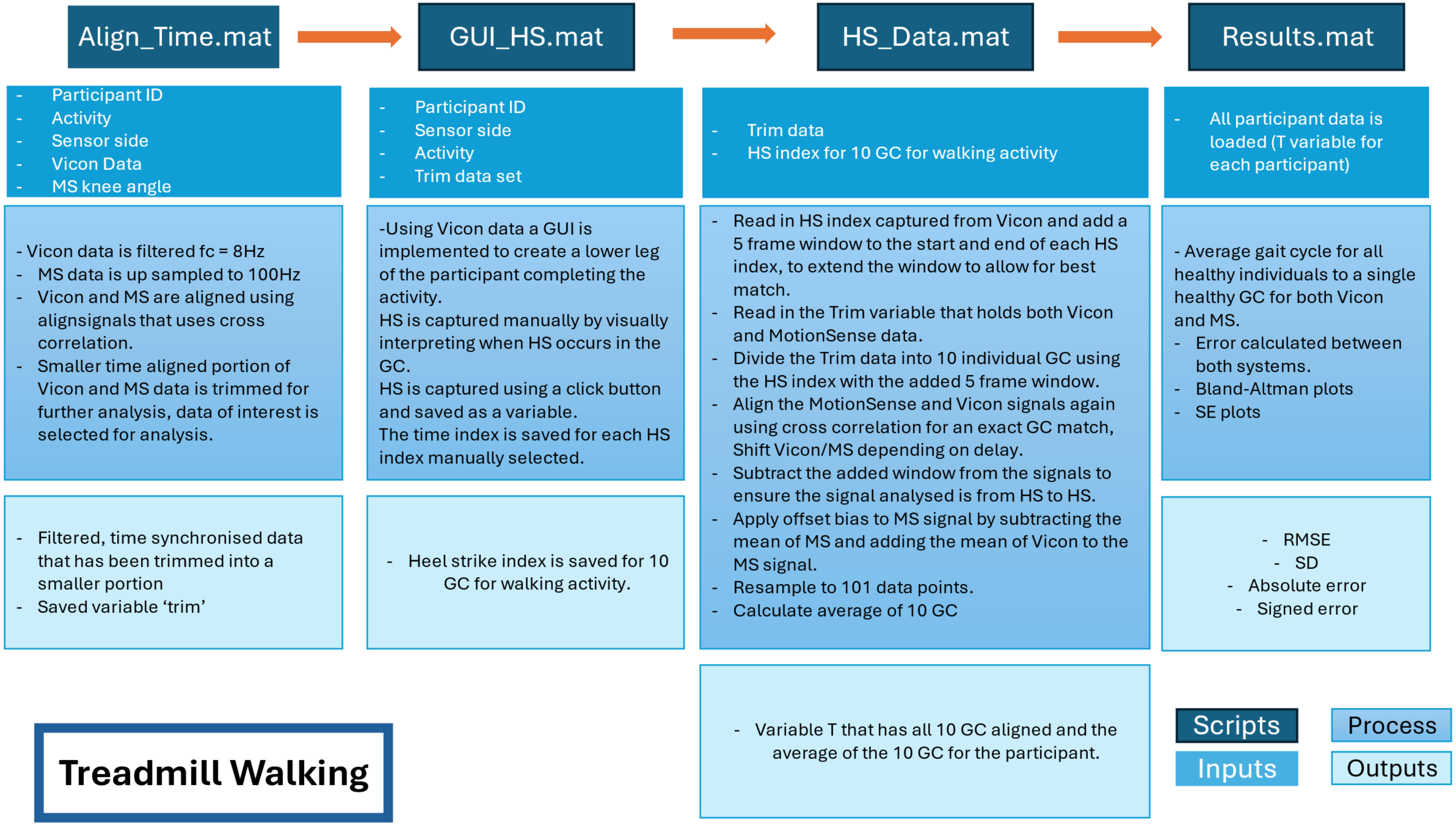
Efficiently collect PROM surveys (KOOS, KOOS-Jr, PROMIS-10, VR-12) and daily pain scores.

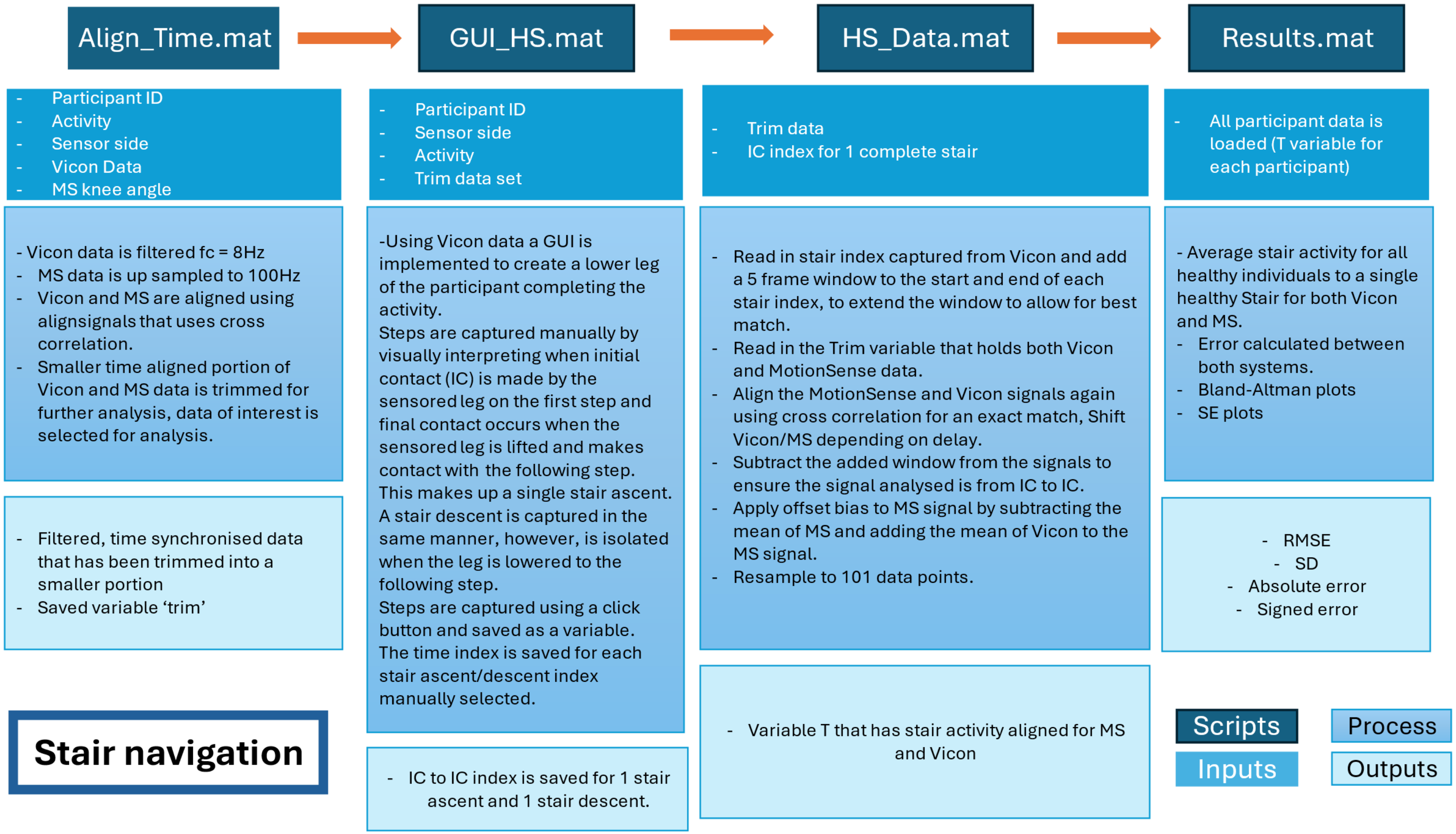
Dashboard and analytics

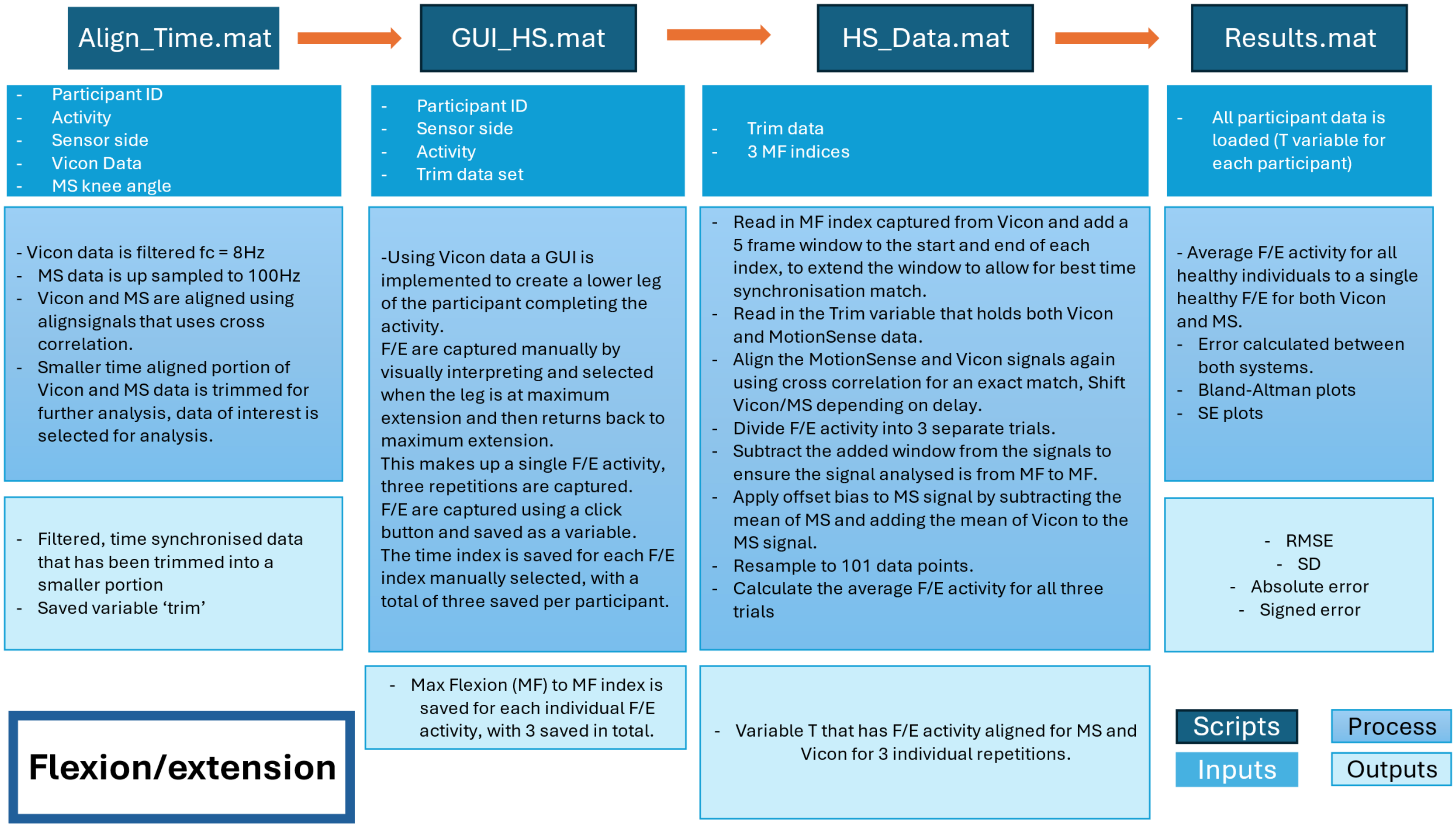
Quickly identify, evaluate, and intervene with high-risk patients using the daily reporting in the OrthoLogIQ dashboard.

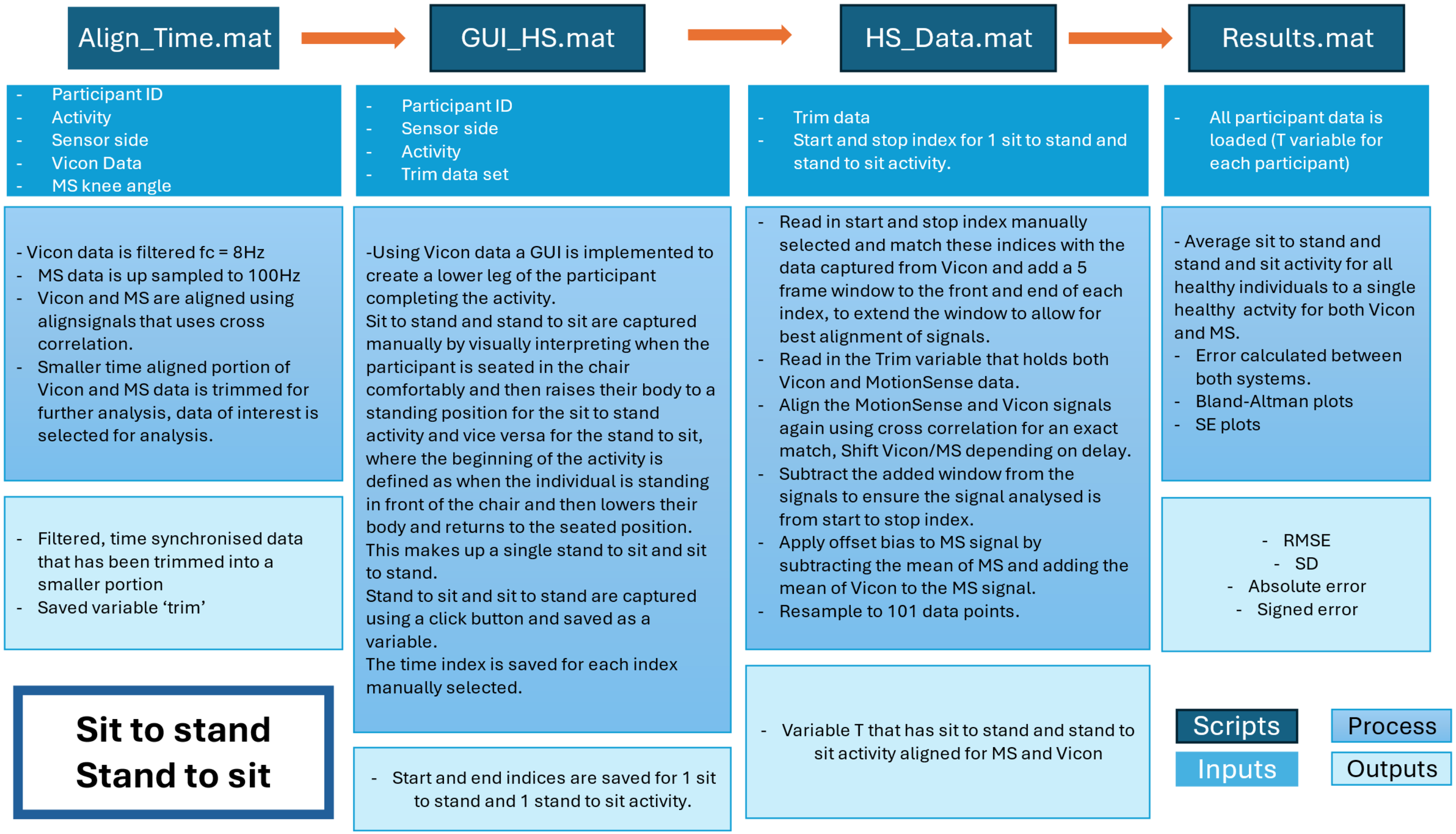
10.2 Flowcharts of Data Analysis Process

10.2.1 Validation of MotionSense™ Code Flowchart




Align_Time.mat
GUI_HS.mat
HS_Data.mat
Results.mat
- Participant ID
- Activity
- Sensor side
- Vicon Data
- MS knee angle
- Vicon data is filtered fc = 8Hz
- MS data is up sampled to 100Hz
- Vicon and MS are aligned using alignsignals that uses cross correlation.
- Smaller time aligned portion of Vicon and MS data is trimmed for further analysis, data of interest is selected for analysis.
- Filtered, time synchronised data that has been trimmed into a smaller portion
- Saved variable 'trim'
- Participant ID
- Sensor side
- Activity
- Trim data set
-Using Vicon data a GUI is implemented to create a lower leg of the participant completing the activity.
Steps are captured manually by visually interpreting when initial contact (IC) is made by the sensored leg on the first step and final contact occurs when the sensored leg is lifted and makes contact with the following step.
This makes up a single stair ascent.
A stair descent is captured in the same manner, however, is isolated when the leg is lowered to the following step.
Steps are captured using a click button and saved as a variable.
The time index is saved for each stair ascent/descent index manually selected.
- IC to IC index is saved for 1 stair ascent and 1 stair descent.
- Trim data
- IC index for 1 complete stair
- Read in stair index captured from Vicon and add a 5 frame window to the start and end of each stair index, to extend the window to allow for best match.
- Read in the Trim variable that holds both Vicon and MotionSense data.
- Align the MotionSense and Vicon signals again using cross correlation for an exact match, Shift Vicon/MS depending on delay.
- Subtract the added window from the signals to ensure the signal analysed is from IC to IC.
- Apply offset bias to MS signal by subtracting the mean of MS and adding the mean of Vicon to the MS signal.
- Resample to 101 data points.
- Variable T that has stair activity aligned for MS and Vicon
- All participant data is loaded (T variable for each participant)
- Average stair activity for all healthy individuals to a single healthy Stair for both Vicon and MS.
- Error calculated between both systems.
- Bland-Altman plots
- SE plots
- RMSE
- SD
- Absolute error
- Signed error
Stair navigation
Scripts
Process
Inputs
Outputs


Align_Time.mat
GUI_HS.mat
HS_Data.mat
Results.mat
- Participant ID
- Activity
- Sensor side
- Vicon Data
- MS knee angle
- Participant ID
- Sensor side
- Activity
- Trim data set
- Trim data
- 3 MF indices
- All participant data is loaded (T variable for each participant)
- Vicon data is filtered fc = 8Hz
- MS data is up sampled to 100Hz
- Vicon and MS are aligned using alignsignals that uses cross correlation.
- Smaller time aligned portion of Vicon and MS data is trimmed for further analysis, data of interest is selected for analysis.
-Using Vicon data a GUI is implemented to create a lower leg of the participant completing the activity.
F/E are captured manually by visually interpreting and selected when the leg is at maximum extension and then returns back to maximum extension.
This makes up a single F/E activity, three repetitions are captured.
F/E are captured using a click button and saved as a variable.
The time index is saved for each F/E index manually selected, with a total of three saved per participant.
- Read in MF index captured from Vicon and add a 5 frame window to the start and end of each index, to extend the window to allow for best time synchronisation match.
- Read in the Trim variable that holds both Vicon and MotionSense data.
- Align the MotionSense and Vicon signals again using cross correlation for an exact match, Shift Vicon/MS depending on delay.
- Divide F/E activity into 3 separate trials.
- Subtract the added window from the signals to ensure the signal analysed is from MF to MF.
- Apply offset bias to MS signal by subtracting the mean of MS and adding the mean of Vicon to the MS signal.
- Resample to 101 data points.
- Calculate the average F/E activity for all three trials
- Average F/E activity for all healthy individuals to a single healthy F/E for both Vicon and MS.
- Error calculated between both systems.
- Bland-Altman plots
- SE plots
- Filtered, time synchronised data that has been trimmed into a smaller portion
- Saved variable 'trim'
- RMSE
- SD
- Absolute error
- Signed error
- Max Flexion (MF) to MF index is saved for each individual F/E activity, with 3 saved in total.
- Variable T that has F/E activity aligned for MS and Vicon for 3 individual repetitions.
Flexion/extension
Scripts
Process
Inputs
Outputs



Align_Time.mat
GUI_HS.mat
HS_Data.mat
Results.mat
- Participant ID
- Activity
- Sensor side
- Vicon Data
- MS knee angle
- Vicon data is filtered fc = 8Hz
- MS data is up sampled to 100Hz
- Vicon and MS are aligned using alignsignals that uses cross correlation.
- Smaller time aligned portion of Vicon and MS data is trimmed for further analysis, data of interest is selected for analysis.
- Filtered, time synchronised data that has been trimmed into a smaller portion
- Saved variable 'trim'
Sit to stand
Stand to sit
- Participant ID
- Sensor side
- Activity
- Trim data set
-Using Vicon data a GUI is implemented to create a lower leg of the participant completing the activity.
Sit to stand and stand to sit are captured manually by visually interpreting when the participant is seated in the chair comfortably and then raises their body to a standing position for the sit to stand activity and vice versa for the stand to sit, where the beginning of the activity is defined as when the individual is standing in front of the chair and then lowers their body and returns to the seated position. This makes up a single stand to sit and sit to stand.
Stand to sit and sit to stand are captured using a click button and saved as a variable.
The time index is saved for each index manually selected.
- Start and end indices are saved for 1 sit to stand and 1 stand to sit activity.
- Trim data
- Start and stop index for 1 sit to stand and stand to sit activity.
- Read in start and stop index manually selected and match these indices with the data captured from Vicon and add a 5 frame window to the front and end of each index, to extend the window to allow for best alignment of signals.
- Read in the Trim variable that holds both Vicon and MotionSense data.
- Align the MotionSense and Vicon signals again using cross correlation for an exact match, Shift Vicon/MS depending on delay.
- Subtract the added window from the signals to ensure the signal analysed is from start to stop index.
- Apply offset bias to MS signal by subtracting the mean of MS and adding the mean of Vicon to the MS signal.
- Resample to 101 data points.
- Variable T that has sit to stand and stand to sit activity aligned for MS and Vicon
- All participant data is loaded (T variable for each participant)
- Average sit to stand and stand and sit activity for all healthy individuals to a single healthy actvity for both Vicon and MS.
- Error calculated between both systems.
- Bland-Altman plots
- SE plots
- RMSE
- SD
- Absolute error
- Signed error
Scripts
Process
Inputs
Outputs

Align_Time.mat

- Participant ID
- Actvity
- Sensor side
- Vicon Data
- MS knee angle

- Vicon data is filtered fc = 8Hz
- MS data is up sampled to 100Hz
- Vicon and MS are aligned using alignsignals that uses cross correlation.
- Smaller time aligned portion of Vicon and MS data is trimmed for further analysis, data of interest is selected for analysis.

- Filtered, time synchronised data that has been trimmed into a smaller portion
- Saved variable 'trim'

GUI_HS.mat

- Participant ID
- Sensor side
- Actvity
- Trim data set

-Using Vicon data a GUI is implemented to create a lower leg of the participant completing the activity.
Pedal stroke (PS) is captured manually by visually interpreting when each pedal stoke occurs in the cycle, knee at max extension to knee back to max extension (bottom of pedal stroke – 6 o'clock position full 180 degree cycle).
Pedal stroke is captured using a click button and saved as a variable.
The time index is saved for each Pedal Stroke index manually selected.

- Pedal stroke index is saved for 10 full pedal strokes for cycling activity.

HS_Data.mat

- Trim data
- PS index for 10 Cycles for cycling activity

- Read in PS index captured from Vicon and add a 5 frame window to the start and end of each PS index, to extend the window to allow for best match.
- Read in the Trim variable that holds both Vicon and MotionSense data.
- Divide the Trim data into 10 individual cycles using the PS index with the added 5 frame window.
- Align the MotionSense and Vicon signals again using cross correlation for an exact cycle match, Shift Vicon/MS depending on delay.
- Subtract the added window from the signals to ensure the signal analysed is from PS to PS.
- Apply offset bias to MS signal by subtracting the mean of MS and adding the mean of Vicon to the MS signal.
- Resample to 101 data points.
- Calculate average of 10 PS

- Variable T that has all 10 GC aligned and the average of the 10 GC for the participant.

Results.mat

- All participant data is loaded (T variable for each participant)

- Average cycle for all healthy individuals to a single healthy GC for both Vicon and MS.
- Error calculated between both systems.
- Bland-Altman plots
- SE plots

- RMSE
- SD
- Absolute error
- Signed error

Cycling

Scripts | Process
Inputs | Outputs

10.2.2 Validation of IMU Algorithm Flowchart

Two_compare.m

Required before running code:
- Folder to store data outputs
- Vicon Data processed and contained within a single folder

Functions required:
- Get_btk_angles
- Sensor_to_segment_dir
- Standing_calibration
- AngleReconstructionCompare
- alignDataStreams_2D
- CalcMetric2D

Manual inputs:
- Change actn code depending on what activity is being analysed
- Adjust TimeEnd according to activity, if T06 is selected change to 20, if anything else, change to 70. (Adjusts the length of time depending on the activity).
- Change valid to the number of participants to include in the analysis. Number correlated to the coded ID.

Operation of code:

1. Using BTK angles are read in from Vicon
2. Side of body sensor is attached is selected(L/R)
3. Gaps in data filled
4. Load in calibration files
5. Standing calibration is performed-> IMU coordinate frame is adjusted to anatomic frame. ML axis is defined using the treadmill walking.
6. AngleReconstructionCompare is used to calculate alpha angled from the research device (Seel code).
7. Interpolate Vicon & IMU so all vectors are the same size
8. alignDataStreams function to time synchronise signals based on Xcross
9. Analysis window created to line up signals
10. Apply bias to IMU to account for different calibrations aixs
11. Analyse per gait stats
12. Save data in the folder previously created

Outputs
- Dat_store which is a structure of num of individuals X 5
- Where each row represents a person
- And each column:
  1. The gait cycle time
  2. angle Vicon for each gc separated, each row is a separate gc
  3. angle IMU for each gc separated, each row is a separate gc
  4. ROM- min, max, ROM in each column respectively (order is Vicon, IMU).
  5. RMSE, Calculated for each GC.

ResultsPlot.m

Required before running code:
- File created after running Two_compare

Functions required:
- None

Manual inputs:
- None

Operation of code:

1. Reads in the activity file to be plotted.
2. Calculates average ROM for each sensor
3. Tabulates RMSE for IMU +/- 1 std
4. Calculates correlation Coefficient for IMU and MS respectively +/- 1 std
5. Plots GC for IMU and Vicon with 95% confidence interval shaded region

Outputs
1. Table of coefficient of correlation values for IMU +/- 1std
2. RMSE for IMU +/- 1std
3. ROM, min, max values for Vic, IMU
4. GC plot with shaded 95% confidence interval

FUNCTIONS

AlignDataStreams.m

Inputs
- Vicon knee angle, IMU knee angle and pstream
- Pstream is the amount of data to show in the figures, range from 0.25-0.5

Operation of code:
1. Plot signals (Vicon, IMU)
2. Select start point for analysis on Vicon curve
3. Select start point for analysis on IMU curve that corresponds to Vicon start point
4. Cross-correlation is used to best match the peaks of the signal and lag of the signal is stored.
5. All signals are time synchronised with one another

Outputs
- Delay of IMU to Vicon signal
- Start time of Vicon signal

Sensor_to_Segment_dir.m

Inputs
- Acceleration and gyroscope from IMU
- Side of body L/R

Operation of code:
1. Adjusting gyroscopic data and accelerometer data depending on whether the IMU is on the L/R side of body

Outputs
- Accelerometer data for L/R body segment
- Gyroscope data for L/R body segment

Standing_calibration.m

Inputs
- Gyroscope for segment (fusion and source, 'n')
- Accelerometer data (fusion and source 'g')

Operation of code:
The IMUs are placed on the thigh and shank in an arbitrary position .
The coordinate axis of the IMUs arent aligned to the anatomic coordinate system.
The Flexion-Extension axis is defined by applying the Seel algorithm to the treadmill walking activity.
The Internal-external rotation axis (or mechanical axis) is defined using the static calibration pose (the down arrow).
The IMU data are taken while the participant is static - this defines this axis.
A cross product is taken between the F/E axis and the I/E axis to define the M/L axis followed by on last cross product between the I/E axis and M/L axis to achieve three orthogonal vectors which define the anatomical coordinate system.
This is done for each IMU to define a rotation matrix to transform the raw IMU data to an anatomic coordinate frame.
1. Treadmil file is loaded.
2. Medial lateral axis is estimated as according to seel code (j1 and j2).
3. Cross product to define orthogal axis
4. Build and apply rotational matrices

Outputs
- Calibrated gyroscope and accelerometer data for fusion and shank

Angle Reconstruct.m

Inputs
- Imu data (,g_S,g_F,n_S,n_F)
- fc,fs,lamda,j1,j2

Operation of code:
1. Filter IMU data with low pass butterworth files
2. Apply third order derivative function
3. Calculate IMU knee flexion angle
4. Using a complementary filter, the gyroscope data and accelerometer data is combined to estimate alpha (seel code)

Outputs
- IMU alpha angle

FUNCTIONS

Estimatej1j2.m

Inputs
- G1 and g2

Operation of code: Uses kinematic constraint and least squares to determine the orientation of the joint axis (j1 would be a vector which defines the joint axis relative to IMU1, j2 of imu2) relative to each IMU.

See: PMID: 24743160

Outputs
- J1 and j2

Estimateo1o2.m

Inputs
- G1 and g2, g1dot, g2dot, a1 and a2

Operation of code: Uses kinematic constraint and least squares to determine the position of the joint centre (o1 o2) relative to each IMU.

See: PMID: 24743160

Outputs
- O1 and o2

Thirdorderapprox.m

Inputs
- G and dt

Operation of code: calculate the derivate of the inputs using a third order numerical approximation

Outputs
- gdot

ProjectAngle.m

Inputs
- Imu data (,g_S,g_F,n_S,n_F)
- fc,fs,lamda,j1,j2

Operation of code: implements the alpha angle calculation via sensor fusion (complementary filter) by combining acc and gyro to reduce drift caused by gyro.
See: PMID: 24743160

Outputs
- IMU alpha acceleration

CalcMetrics.m

Inputs
- alphaVicon, alphaMS, alphaIMU, activity, num of cyles and bia(offset)

Operation of code:
- Calculates location of peaks in the three signals and adjusts signals by applying the offset bias.
- Aligns signals for analysis of individual GC
- - Calculates RMSE values and ROM

Outputs
- ROM, RMSE, individual GC for the measures

10.3 MATLAB Scripts

10.3.1 Seel Algorithm MATLAB Scripts

10.3.1.1 Two_compare.mat

```
clear all
%% Main code

% Add path where activity files are stored
%addpath 'C:\...'
addpath('C:\Users\lexil\Documents\PhD\Patient_Study\Healthy Participants\Participant_data\Experimental_Data')%Young

% Display instructions for selecting data directories and formatting
disp('Select Data File Location')
disp('***Make sure file sin in the following format***')
disp('myDir/H01/Vicon/...')
disp('myDir/H01/ResearchDevice/...')

myDir = uigetdir; %Gets directory for vicon data

% Folder where activity files are stored
disp('Select File Location to store Results')
ResultsDir = uigetdir; %Directory to store Results

% setting of constraints
fs = 200; % IMU sampling frequency
fVicon = 100; % Vicon Sampling Frequency
t_vicon = 1/fVicon; % Timestamp Vicon


%% Options
lamda = 0.01; % To be used for Complementary Filter, value as per Seel paper.
```

```matlab
fc = 3; % Lowpass Filter Cutoff Frequency

%activity: {'walking','stairs','cycling','F/E'};
act_coded = {'T05','T06','T07', 'T03'};

% Choose activity to analyse: {'walking (1)','stairs (2)','cycling (3)','F/E (4)'};
actn = 1;

%Number of gait cycles to analyze:
%{'walking (1)','stairs (2)','cycling (3)', F/E (4)};
nCycles = [50 1 50 3];

%Time after XCORR to analyze- analysis window
TimeStart = 0;
TimeEnd = 70; % Adjust depending on length of files, for shorter files change to ~30

% Side placment of IMUs for each sequential subject
side = ['R' 'L' 'L' 'L' 'R' 'L' 'L' 'R' 'R' 'L' 'R' 'L' 'R' 'L' 'R' 'L' 'R' 'L' 'R' 'L'];

% Choose which subjects to include in analysis (P1-P20)
valid = [1:20];

%% Main

act_code = act_coded{actn};

for c = 1:length(valid)

    % Build strings to access files
    pt = valid;
    if pt(c)<10
        pts = string(['H0',num2str(pt(c))]);
    else
        pts = string(['H',num2str(pt(c))]);
    end
```

```
%counter
disp(c)

%% Vicon

%% Strings to capture vicon Calibration and Activity Files
vicon_calib = [myDir,'\',char(pts),'\Vicon\T00_R.c3d'];
vicon_file = [myDir,'\',char(pts),'\Vicon\',act_code,'.c3d'];

% Load Vicon Angles from BTK software
[~, viconCalibs] = get_btk_angles(vicon_calib);
[~, viconAngles] = get_btk_angles(vicon_file);


% Change Vicon readings for Left or Right side IMU mounting
if side(pt(c)) == 'R'
    viconAngle = viconAngles.RKneeAngles; %Right knee angle
end
if side(pt(c)) == 'L'
    viconAngle = viconAngles.LKneeAngles; %Left knee angle
end

alphaVicon_raw = viconAngle(:,1); %Vicon knee angle

% Algorithm to fill missing or gaps in Vicon data through interpolation
t_hold = 1:length(viconAngle);
ind = find(viconAngle(:,1) ~= 0);
alphaVicon_rem = viconAngle(ind,1);
t_rem = t_hold(ind);
alphaVicon=interp1(t_rem,alphaVicon_rem,t_hold)';


%% Research IMU Wired Device
%String to load calibration files- static pose capture
calibfile_name = [myDir,'\',char(pts),'\ResearchDevice\T00_C.mat'];
load(calibfile_name)
```

```
    % Change IMU readings based on L or R mounting (Vectors will point in
    % different directions depending on mounting
    [aSegF, gSegF] = sensor_to_segment_dir(g_F,n_F,side(pt(c)));
    [aSegS, gSegS] = sensor_to_segment_dir(g_S,n_S,side(pt(c)));


%     Performs automatic calibration from IMU coordinate frame to anatomic
%     frame. ML axis is defined using treadmill walking. Superior/Inferior axis (transverse plane) is defined
%     using a static calibration - down vector
    [a1c, a2c, g1c, g2c, j1p, j2p] = standing_calibration(aSegF, gSegF,aSegS, gSegS,side(pt(c)),myDir, pts, act_code);


    %Use Seel Code to generate alpha angles from Research wired IMU Device
    alphaAccGyr_cal = AngleReconstructionCompare(fc,fs,lamda,j1p,j2p,a1c,a2c,g1c,g2c);


    %% Analysis

    % Interpolate data so that all vectors are the same size by upsampling
    % data
     alphaAccGyr_fs = AngleReconstructionCompare(fc,fs,lamda,j1p,j2p,a1c,a2c,g1c,g2c);
     alphaAccGyr = interp1((1/fs):1/fs:(1/fs)*(length(alphaAccGyr_fs)),alphaAccGyr_fs,t_vicon:t_vicon:1/fs*(length(alphaAccGyr_fs)));

    pStream = 0.25; % Amount of data to show in the figures to initiate to XCorr. 0.25 - 0.5 is appropriate

    % Function to align data streams based on XCorr
    [RD_start, vicon_start] = alignDataStreams_2D(pStream, alphaVicon,alphaAccGyr);
    close all

    SampleStart = TimeStart*fVicon; % Starting point
    SampleEnd = TimeEnd*fVicon + SampleStart;  % Ending point


    % Apply analysis window (Time Start to Time End)
    alphaVicon_align = alphaVicon(vicon_start+SampleStart:vicon_start+SampleEnd);
    alpha1D_align = alphaAccGyr(RD_start+SampleStart:RD_start+SampleEnd) ;
```

```
    %Align the mean values to remove offset bias (RD will reflect the same mean value and Vicon)
    alpha1D_align = alpha1D_align +(mean(alphaVicon_align)-mean(alpha1D_align ));

    t_align = t_vicon:t_vicon:length(alpha1D_align)*t_vicon;


    % Calculate per Gait Cycle Statistics to be used in ResultsPlot.mat
    [ROM,RMSE,alphaVicon_GC, alpha1D_GC, gc]  = CalcMetrics2D(alphaVicon_align, alpha1D_align, actn, nCycles(actn),26);

    dat_store{c,1} = gc;
    dat_store{c,2} = alphaVicon_GC;
    dat_store{c,3} = alpha1D_GC;
    dat_store{c,4} = ROM;
    dat_store{c,5} = RMSE;

   % Quick visual Plots of the two technologies
    figure

    patch([gc,flip(gc)],[mean(alphaVicon_GC)-1.96*std(alphaVicon_GC) flip(mean(alphaVicon_GC)+1.96*std(alphaVicon_GC)) ],[1 0
0],'facealpha',0.2,'edgealpha',0)
    hold on
    patch([gc,flip(gc)],[mean(alpha1D_GC)-1.96*std(alpha1D_GC) flip(mean(alpha1D_GC)+1.96*std(alpha1D_GC)) ],[0 0
0],'facealpha',0.1,'edgealpha',0)
    plot(gc ,mean(alpha1D_GC),'k')
    plot(gc, mean(alphaVicon_GC),'k--')

    grid on
    ylabel('F/E [\circ]')
    xlabel('Gait Cycle %')

    xticks([20 40 60 80 100])
    xticklabels([{'20%'},{'40%'},{'60%'},{'80%'},{'100%'}])
    g(1) = patch(NaN,NaN,[1 0 0],'facealpha',0.2);
    g(2) = patch(NaN,NaN,[0 0 0],'facealpha',0.2);
    g(3) = patch(NaN,NaN,[0 0 1],'facealpha',0.2);
    legend(g,'Vicon Camera-Marker','IMU','location','northwest')
```

```
    pause

    close all

end

filename = [ResultsDir,'/',act_coded{actn},'.mat'];

filenameA = filename;
plu = 2;

% So not to overwrite files
while isfile(filename)

    filename = [filenameA,num2str(plu)];
    plu = plu+1;
end


save(filename, 'dat_store')
```

10.3.1.2 Sensor_to_segment_dir.mat

```
%Determine the direction of gravity through static file and side of leg
%Directional vector changes depending on leg mounting (L or R), and so two the coordinate system

function [as,gs] = sensor_to_segment_dir(a,g,side)

%Acceleration data, invert z axis
as = a;
as(:,3) = -a(:,3);

%Gyroscope, invert z axis
gs = g;
gs(:,3) = -g(:,3);

%Adjust the direction of the accelerometer and gyroscope data to account for the mounting orientation of the IMU sensor on the body
segment. The axes are flipped accordingly based on whether the IMU is mounted on the left or right leg to standardize the coordinate
frame for downstream analysis.
if side == 'R'
    as(:,1) = -a(:,1);
    gs(:,1) = -g(:,1);
end

if side == 'L'
    as(:,2) = -a(:,2);
    gs(:,2) = -g(:,2);
end


end
```

10.3.1.3 standing_calibration.mat

```
function [a1cal, a2cal, g1cal, g2cal, j1p, j2p] = standing_calibration(g_F,n_F,g_S,n_S,side, myDir, pts, act_code)

% Load treadmill file
jointAxis_file = [myDir,'\',char(pts),'\ResearchDevice\T05.mat'];
load(jointAxis_file)

%Adjust sensor reading, g is accelerometer and n is gyroscope, and apply sensor orientations
[~, g1c] = sensor_to_segment_dir(g_F,n_F,side);
[~, g2c] = sensor_to_segment_dir(g_S,n_S,side);

% Define (SI Axis) Superior/Inferior axis (transverse plane) to determine down vector, compute median accelerometer values
stand_a1 = median(g_F);
stand_a2 = median(g_S);

 %Joint vectors relative to each imu
[j1p,j2p] = estimatej1j2(g1c',g2c');

%Estimate ML axis
% Cross products to define orthogonal coordinate system
% NORMALIZE the median acceleration to get resting Z-axis (rest_z)
rest_z1 = stand_a1/norm(stand_a1);
% COMPUTE approximate forward (progression) vector
prog_v1 = cross(j1p,rest_z1); %forward vector
prog_v1 = prog_v1/norm(prog_v1);

% COMPUTE adjusted z axis
adj_z1 = cross(prog_v1,j1p);

rest_z2 = stand_a2/norm(stand_a2);
prog_v2 = cross(j2p,rest_z2);
prog_v2 = prog_v2/norm(prog_v2);
adj_z2 = cross(prog_v2,j2p);
```

```
% Build rotation matrices
 R1 = [prog_v1', j1p, adj_z1'];
 R2 = [prog_v2', j2p, adj_z2'];


%String to load activity files
activity_file = [myDir,'\',char(pts),'\ResearchDevice\',act_code,'.mat'];
load(activity_file)

%Apply sensor to segment transformations to get femur and shank a and g.
[a1, g1] = sensor_to_segment_dir(g_F,n_F,side);
[a2, g2] = sensor_to_segment_dir(g_S,n_S,side);

% Initialise vectors
 a1cal = zeros(size(a1));
 a2cal = zeros(size(a1));
 g1cal = zeros(size(a1));
 g2cal = zeros(size(a1));

 %Apply Rotation to find relative orientation of thigh and shank relating
 %imu to anatomical coordinate system, Transform all sensor data to anatomical coordinate systems
for i = 1:length(a1cal)

    a1cal(i,:) = transpose(R1*transpose(a1(i,:)));
    a2cal(i,:) = transpose(R2*transpose(a2(i,:)));

    g1cal(i,:) = transpose(R1*transpose(g1(i,:)));
    g2cal(i,:) = transpose(R2*transpose(g2(i,:)));

end


end
```

10.3.1.4 thirdOrderApproxDerivitive

```
% COMPUTE numerical derivative at index i using 5-point central difference
% Equation 17
function g_dot = thirdOrderApproxDerivitive(g, dt)

for i = 3:length(g)-2

    g_dot(1,i) = (g(1,i-2)-8*g(1,i-1)+8*g(1,i+1)-g(1,i+2))/(12*dt);
    g_dot(2,i) = (g(2,i-2)-8*g(2,i-1)+8*g(2,i+1)-g(2,i+2))/(12*dt);
    g_dot(3,i) = (g(3,i-2)-8*g(3,i-1)+8*g(3,i+1)-g(3,i+2))/(12*dt);


end
```

10.3.1.5 Estimatej1j2.mat

```
function [j1,j2] = fun(g1,g2)
 % INITIALIZE optimization variables
x0 = [0; 1; 0; 1];
opts1=  optimset('display','off');

% Run non linear least squares optimisation
[x,~] = lsqnonlin(@(x)error1(x,g1,g2),x0,[],[],opts1);

% Convert optimised angles to joint axis unit vectors
% joint axis- Equation 20
j1 = [cos(x(1))*cos(x(2));cos(x(1))*sin(x(2)); sin(x(1))];
j2 = [cos(x(3))*cos(x(4));cos(x(3))*sin(x(4)); sin(x(3))];

% reorient j1,j2 assuming R1to1p,R2to2p close to identity
j1 = sign(j1(2))*j1;
j2 = sign(j2(2))*j2;


%% Utility functions
    function r = error1(x,g1,g2)
        j1 = [cos(x(1))*cos(x(2)); cos(x(1))*sin(x(2)); sin(x(1))];
        j2 = [cos(x(3))*cos(x(4)); cos(x(3))*sin(x(4)); sin(x(3))];

        %equation 18, determine cross products
        c1 = cross( g1 , repmat(j1,[1 length(g1)]) );
        c2 = cross( g2 , repmat(j2,[1 length(g2)]) );

        %equation 19, difference in vector norms
        r = vecnorm(c1) - vecnorm(c2);

    end
end
```

10.3.1.6 Estimateo1o2.mat

```
function [o1,o2] = estimateo1o2(g1,g2,g1Dot,g2Dot,a1,a2)

opts1=  optimset('display','off');

% INITIALIZE estimate of joint center offset vectors
o_initial= [ones(3,1) ones(3,1)];

% RUN nonlinear least squares optimization to minimize error2, Optimise o1 and o2
such that predicted accelerations match measured accelerations
[o,~] = lsqnonlin(@(o)error2(o,g1,g2,g1Dot,g2Dot,a1,a2),o_initial,[],[],opts1);

% Extract optimised vectors
o1 = o(:,1);
o2 = o(:,2);

%% Utility functions

    function r = error2(o,g1,g2,g1Dot,g2Dot,a1,a2)
        % SPLIT input matrix o into two 3D vectors
        o1 = o(:,1);
        o2 = o(:,2);

        % COMPUTE rotational acceleration component
        c1 = cross( g1 , cross( g1 , repmat(o1,[1 length(g1)]) ) );
        c2 = cross( g2 , cross( g2 , repmat(o2,[1 length(g2)]) ) );

        % ADD tangential acceleration
        Gamma_o1 = c1 + cross( g1Dot , repmat(o1,[1 length(g1)]) );
        Gamma_o2 = c2 + cross( g2Dot , repmat(o2,[1 length(g2)]) );

        % ESTIMATE linear accelerations at joint centers
        p1 = a1 - Gamma_o1;
        p2 = a2 - Gamma_o2;

        %equation 22
        r = vecnorm(p1) - vecnorm(p2);

    end

end
```

10.3.1.7 projectAngle.mat

```
%The projection of the shank IMU's orientation and the thigh IMU's orientation onto
knee joint coordinate system.
function alphaAcc = projectAngle(g1, g2, a1, a2, g1Dot, g2Dot, o1 ,o2, j1, j2)

% Calculate the cross products for orientation vectors
c1 = cross( g1 , cross( g1 , repmat(o1,[1 length(g1)]) ) ); %cross g1 with o1 and
then with g1
c2 = cross( g2 , cross( g2 , repmat(o2,[1 length(g2)]) ) );

% Add tangential acceleration to get total rotational acceleration (Gamma)
% equation 23
Gamma_o1 = c1 + cross( g1Dot , repmat(o1,[1 length(g1)]) );
Gamma_o2 = c2 + cross( g2Dot , repmat(o2,[1 length(g2)]) );


%Adjust accelerations for joint coordinates

a1_joint = a1 - Gamma_o1; %equation 25
a2_joint = a2 - Gamma_o2; %equation 25

%Define constant reference vector for projection (typically [1;1;1] is used to
ensure a valid cross product)
c = [1;1;1];

%equation 26: local coordinate systems orthogonal to joint axis
x1 = cross(j1,c);     % x1 perpendicular to joint axis j1
x2 = cross(j2,c);

y1 = cross(j1,x1);    % y1 perpendicular to j1 and x1
y2 = cross(j2,x2);

% Determine dot products for joint accelerations
% Project joint-centered accelerations onto local coordinate systems
v1 = [dot(a1_joint,x1.*ones(3,length(a1_joint)));
dot(a1_joint,y1.*ones(3,length(a1_joint)))];
v2 = [dot(a2_joint,x2.*ones(3,length(a2_joint)));
dot(a2_joint,y2.*ones(3,length(a2_joint)))];

%Normalise to unit vectors
v1 = v1./vecnorm(v1);
v2 = v2./vecnorm(v2);

%relative rotation matrices between projected vectors
Calpha = v1(1,:).*v2(1,:) + v1(2,:).*v2(2,:); %cos alpha
Salpha = -v1(1,:).*v2(2,:) + v1(2,:).*v2(1,:); %sin alpha

%Calculate angle of rotation
alphaAcc = atan2(Salpha,Calpha); %equation 27

end

%% https://www.mdpi.com/1424-8220/18/9/2759
```

10.3.1.8 AngleReconstructionCompare.mat

```
function alphaAccGyr =
AngleReconstructionCompare(fc,fs,lamda,j1,j2,g_S,g_F,n_S,n_F)

%% Get IMU measurements

%% filter parameters

[b,a] = butter(4,fc/(fs/2), 'low');

%1 is Femur and 2 is tibia
% Transpose all filtered signals
g1 = transpose(filtfilt(b, a,n_S));
g2 = transpose(filtfilt(b, a, n_F));
a1 = transpose(filtfilt(b, a, g_S));
a2 = transpose(filtfilt(b, a, g_F));


% Third order approximation of first derivative- used to estimate angular velocity
derivitives
%equation 17
g1Dot = thirdOrderApproxDerivitive(g1,1/fs);
g2Dot = thirdOrderApproxDerivitive(g2,1/fs);

g1 = g1(:,2:length(g1)-1);
g2 = g2(:,2:length(g2)-1);
a1 = a1(:,2:length(a1)-1);
a2 = a2(:,2:length(a2)-1);

% estimate o1 and o2
[o1,o2] = estimateo1o2(g1,g2,g1Dot,g2Dot,a1,a2);

% alphaDot from gyros, Equation 21
alphaDotGyr = dot( g2 , repmat(j2,[1 length(g2)]) ) - dot( g1 , repmat(j1,[1
length(g1)]) );

for i = 1 :length(alphaDotGyr)

    %Integration of gyro signal over time using cumulative trapezoidal rule.
    %Equation 21
    alphaGyr(i) = 180/pi*trapz(alphaDotGyr(1:i))/fs;

end

% compute alphaAcc via 2D projection
alphaAcc = 180/pi*projectAngle(g1, g2, a1, a2, g1Dot, g2Dot, o1, o2, j1, j2);
alphaAccGyr = zeros(length(alphaAcc),1);

% Implement Complementary filter to combine gyro and accelerometer estimates of
% alpha
for i = 2:length(alphaAcc)

    alphaAccGyr(i) = lamda*alphaAcc(i)+(1-lamda)*(alphaAccGyr(i-1)+alphaGyr(i)-
alphaGyr(i-1)); % equation 28


end
```

10.3.1.9 alignDataStreams_2D.mat

```
function [RD_lag, vicon_start] = alignDataStreams_2D(pStream, aVicon, aRD)

%Time synchronise Vicon and the IMU device by manually selecting starting
%points.

figure()
%Select point that matches Vicon from the wired IMU
subplot(2,1,2)
plot(aRD(1:round(pStream*length(aRD))),'k')

%Select point, analysis starting point
subplot(2,1,1)
plot(aVicon(1:round(pStream*length(aVicon))),'b')

xlabel('Sample')
ylabel('Knee Angle [\circ]')
title('Select Vicon Starting Cycle (blue)')

vicon_roi = drawcrosshair;
vicon_start = round(vicon_roi.Position(1));

figure()
subplot(2,1,1)
plot(aVicon(1:round(pStream*length(aVicon))),'b')
xlabel('Sample')
ylabel('Knee Angle [\circ]')
title('Vicon start selected')
drawcrosshair('Position',vicon_roi.Position);

subplot(2,1,2)
plot(aRD(1:round(pStream*length(aRD))),'k')
title('Select IMU Starting Cycle [same point as above] (red)')

clc

RD_roi = drawcrosshair;
RD_start = round(RD_roi.Position(1));

%Apply cross correlation to synchronise the two measurement signals.
[r,lags] = xcorr(aRD(RD_start:end),aVicon(vicon_start:end),100);
[~,ind_maxCORR] = max(r);

lagAmount = -lags(ind_maxCORR);

RD_lag = round(RD_start-lagAmount);
clc


end
```

10.3.1.10 CalcMetrics2D.mat

```
function [RangeVI,RMSE, cyclealphaVq,cyclealpha1Daq,gc]  =
CalcMetrics2D(alphaVicon,alpha1D,actn,nCycles, offset)

% Find peaks in Vicon and IMU signals
[pV,locsVf] = findpeaks(smooth(alphaVicon,10),'MinPeakDistance',30);
[p1,locs1] = findpeaks(smooth(alpha1D,10),'MinPeakDistance',30);

% Apply peak height threshold (activity-dependent)
thresh = [0.7 0.3 0.3 0.3];

% Filter peaks above threshold, then apply offset to locate full stride cycles
locsV = locsVf(pV>max(pV)*thresh(actn))+offset;
locsf1 = locs1(p1>max(p1)*thresh(actn))+offset;

% Define gait cycle vector
gc = 0.1:0.1:100;

for i = 1:nCycles

%Interpolate IMU knee angle over gait cycle
cyclealpha1 = alpha1D(locsf1(i):locsf1(i+1));
cycle_length_IMU1D = 0:100/(length(cyclealpha1)-1):100;
cyclealpha1Daq(i,:)  = interp1(cycle_length_IMU1D,cyclealpha1,gc);

% Interpolate Vicon knee angle over gait cycle
cyclealphaV= alphaVicon(locsV(i):locsV(i+1));
cycle_length_V = 0:100/(length(cyclealphaV)-1):100;
cyclealphaVq(i,:) = interp1(cycle_length_V,cyclealphaV,gc);


% Compute RMSE between Vicon and IMU for the cycle
RMSE(1,i)= sqrt(mean((cyclealpha1Daq(i,:)-cyclealphaVq(i,:) ).^2));

% Compute range of motion (ROM) for Vicon and IMU
RangeVI(i,:) = [min(cyclealphaVq(i,:)) max(cyclealphaVq(i,:))
max(cyclealphaVq(i,:))- min(cyclealphaVq(i,:))  min(cyclealpha1Daq(i,:))
max(cyclealpha1Daq(i,:)) max(cyclealpha1Daq(i,:))- min(cyclealpha1Daq(i,:))];


end

end
```

10.3.1.11 get_btk_angles.mat

```
% This function is highly tailored for gait analysis and expects certain standard
marker labels from vicon, furthermore assumes that BTK library is available and
configured correctly.
%Reads in vicon C3D files
function [frame_number_read, angles] = get_btk_angles(filenameincludinglocation)

 [acq, byteOrder, storageFormat] = btkReadAcquisition([filenameincludinglocation]);

    % markers is a structure containing the 3D trajectory of the markers.
    markers     = btkGetMarkers(acq);

%     % if a model has been run in Vicon, the following variables may be available
     angles      = btkGetAngles(acq);
     forces      = btkGetForces(acq);
     moments     = btkGetMoments(acq);
     powers      = btkGetPowers(acq);

    % any analogue data including force plate recordings
    analogs     = btkGetAnalogs(acq);
    ratio       = btkGetAnalogSampleNumberPerFrame(acq);
    analogsDownsampled = [];
    labels      = fieldnames(analogs);
    frame_number_read = btkGetAnalogFrameNumber(acq);

    btkCloseAcquisition(acq)
```

10.3.1.12 ResultsPlot.mat

```
load ('C:\Users\lexil\Documents\PhD\Patient_Study\Healthy Participants\Participant_data \2D_IMU_Results\20062024\T05.mat')

%If subjects need to be excluded post hoc, you can list the participant number here
omits = [];

% Initialise variables
alphaVicon_GC=[];
alpha_IMU=[];
plot_imu = zeros(1000,4);
plot_vic = zeros(1000,4);

Vicon_GC=[];
IMU_GC=[];

% dat_store{c,1} = gc; %Gait cycle 0-100
% dat_store{c,2} = alphaVicon_GC; %Vicon
% dat_store{c,3} = alpha1D_GC; %RD
% dat_store{c,4} = ROM;
% dat_store{c,5} = RMSE;

j=0;
sz = size(dat_store);

for i = 1:sz(1)-length(omits) %

if i == omits

else
```

```
% ROM data for Vicon and IMU
ROM_all = dat_store{i,4};

ROMIMU_diff(i,:) =  mean(ROM_all(:,1:3))-mean(ROM_all(:,4:6));
ROMIMU(i,:)      =  mean(ROM_all(:,4:6));
ROMVic(i,:)      =  mean(ROM_all(:,1:3));

% Average gc for each individual
alphaVicon_GC = [alphaVicon_GC;(dat_store{i,2})];
alpha_IMU = [alpha_IMU;dat_store{i,3}];

% Average gc for each individual
Vicon_GC = [Vicon_GC;mean(dat_store{i,2})];
IMU_GC = [IMU_GC;mean(dat_store{i,3})];
RMSE = dat_store{i,5};

% Extract RMSE
RMSE_IMU = [RMSE_IMU ;RMSE(1,:)];

% Extract correlation between vicon and IMU
CORR_IMU(i) = corr(reshape(dat_store{i,2},[],1),reshape(dat_store{i,3},[],1));

end
end

% Convert to column vectors
Vicon_GC = Vicon_GC'; % Same as alphaVicon_GC but column vector
IMU_GC = IMU_GC';     % Same as alphaIMU but column vector
diff = Vicon_GC - IMU_GC;
ave_diff = mean(Vicon_GC') - mean(IMU_GC'); %population average
std_diff = std(diff,0,2);
SE = std_diff/sqrt(i);
```

```
% Results table
var = ["alphaIMU"];
RMSEtable = [mean(mean(RMSE_IMU,2)) std(mean(RMSE_IMU,2))];
table(var,RMSEtable)
var2 = ["alpha"];
CORR = [mean(CORR_IMU) std(CORR_IMU)];
table(var2,CORR)

GC_all_IMU = reshape(alphaVicon_GC,[],1)-reshape(alpha_IMU,[],1);
GC_all_IMU(abs(GC_all_IMU)<30);

RMSE_IMUa = sqrt(mean(GC_all_IMU.^2));


gc = dat_store{1,1};

sig = 1.96; %95% Confidence intervals


%% Plots
% PLOT 1: Mean ± 1.96 SD of Knee Flexion Across Gait Cycle
figure
set(gcf,'Color','w');
patch([gc,flip(gc)],[mean(alphaVicon_GC)-sig*std(alphaVicon_GC) flip(mean(alphaVicon_GC)+sig*std(alphaVicon_GC)) ],[0 0
0],'facealpha',0.2,'edgealpha',0)
hold on
patch([gc,flip(gc)],[mean(alpha_IMU)-sig*std(alpha_IMU) flip(mean(alpha_IMU)+sig*std(alpha_IMU)) ],[0 0
0],'facealpha',0.1,'edgealpha',0)
plot(gc ,mean(alpha_IMU),'k--','LineWidth',1)
plot(gc, mean(alphaVicon_GC),'k-','LineWidth',1)
xlim([0 100])
ylim([-40 140])
```

```
ylabel('Knee flexion angle (\circ)')
xlabel('Gait Cycle (%)')
g(1) = plot(NaN,NaN,'k-','LineWidth',1);
g(2) = plot(NaN,NaN,'k--','LineWidth',1);
rgb = [0 0 0];
FaceAlpha = (0.1);
g(3) = patch([NaN],[NaN],rgb,'EdgeAlpha', 0, 'FaceAlpha',FaceAlpha);
legend(g,'Camera-Marker','IMU','+/- 1.96*SD','location','northwest')

%PLOT 2: Error Analysis Across Gait Cycle
% Subplot 1: Plot mean IMU and Vicon knee angle
figure()
subplot(3,1,1)
plot(gc ,mean(alpha_IMU),'k--','LineWidth',1)
hold on
plot(gc, mean(alphaVicon_GC),'k-','LineWidth',1)
legend('IMU','Vicon')
xlabel('Gait cycle %')
ylabel('Knee Angle (deg)')
ylim([-40 100]);
grid on

% Subplot 2: Plot signed error
subplot(3,1,2)
plot(gc, (mean(alphaVicon_GC)-mean(alpha_IMU)),'k-','LineWidth',1)
legend('Signed difference')
xlabel('Gait cycle %')
ylabel('Difference (deg)')
ylim([-10 10]);
grid on

% Subplot 3:Plot absolute error
```

```
subplot(3,1,3)
plot(gc, abs(mean(alphaVicon_GC)-mean(alpha_IMU)),'k-','LineWidth',1)
legend('Absolute difference')
xlabel('Gait cycle %')
ylabel('Difference (°)')
ylim([-10 10]);
```

10.4 Certificates and Forms

10.4.1 Good Clinical Practice

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Coordinating Centre

CERTIFICATE OF ACHIEVEMENT

Alexandra Ligeti

has completed the course:

Introduction to Good Clinical Practice (GCP) eLearning

December 1, 2021

Modules Completed

- Introduction to Health and Social Care Research
- Good Clinical Practice
- Informed Consent
- Data Collection and Documentation
- Safety Reporting
- Summary

This course is worth 4 CPD points.

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Chapter 11. Appendix 3- Preceding Validation Study

Prior to carrying out this research detailed within this thesis a preceding study was conducted to assess the accuracy and reliability of these IMU devices in both static and dynamic conditions. This involved testing the IMUs using a combination of double and single pendulum systems to simulate both predictable cyclic and chaotic motion. To further evaluate sensor performance, IMUs were strategically placed on the pendulums at known, preset offset angles, allowing for a systematic investigation into the impact of sensor misalignment. These tests were performed across a range of predefined speeds and offset angles to assess how well the devices could maintain accuracy under varying conditions. The results demonstrated promising reliability and accuracy, reinforcing the need for further validation in both healthy and clinical populations to determine their effectiveness in real-world rehabilitation scenarios.

To open and view the preceding validation study please double click on the image below and the study will be available to view, alternatively, please access it via this link:

Validation of sensors_Thesis.pdf

Validation of a commercially available wearable sensor

Master Thesis

Alexandra Ligeti

Institution: University of Strathclyde, Department of Biomedical Engineering

Master Program: Biomedical Engineering

Student No: 202065668

Supervisor: Dr Philip Riches