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## Wearable sensors and total knee arthroplasty: Assessing quantitative function to improve the patient experience

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A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Medical Biophysics

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## Abstract

Osteoarthritis (OA) is a chronic degenerative disease for which the only long-term solution is total knee arthroplasty (TKA), though many patients are not satisfied with their TKA. Satisfaction in TKA patients is not well understood. Subjective questionnaires and objective functional tests have been previously used to assess TKA outcomes, but both have disadvantages. Wearable sensors have facilitated affordable biomechanical measurement in OA and TKA populations. The objective of this work was to use wearable sensors alongside functional tests with TKA patients to identify quantitative function that related to subjective function and satisfaction. A wearable sensor-setup was validated before implementation in a TKA population. Quantitative sensor metrics describing the motion of individual leg segments was found to correlate with subjective function and satisfaction. This study provided strong evidence towards the connection between quantitative function and patient experience and may be able to identify functional deficiencies for targeted therapy to improve satisfaction.

## Keywords

Osteoarthritis, Total Knee Arthroplasty, Orthopedic, Inertial Measurement Units, Wearable Sensors, Biomechanics, Functional Test, Timed-Up-And-Go Test, Patient Reported Outcome Measures, Satisfaction

## Co-Authorship Statement

The following thesis contains one manuscript that has been submitted for publication (Chapter 2) and a manuscript that is in preparation for submission to a scientific journal (Chapter 3). As the first author of these manuscripts, I was a significant contributor to all aspects of the studies as well as the manuscript preparations. Specific involvement included: contributions to study design, collection of all data, statistical analysis, clinical interpretation of data, drafting and final approval of the manuscripts. Dr. Matthew Teeter, as the principle investigator and my supervisor, provided support throughout the experimental process and was responsible for the study conceptions and final approval of study designs, guidance on data interpretation, and editorial insight.

Chapter 2 is an original validation study entitled “Repeatability of measuring knee flexion angles with wearable inertial sensors” and has been submitted to *The Knee* in April 2018 and is currently under review. This manuscript was co-authored by Megan C. Fennema, Riley A. Bloomfield, Dr. Brent A. Lanting, Dr. Trevor B. Birmingham, and Dr. Matthew G. Teeter. As first author I contributed to manuscript preparation, design and execution of the study, analysis and interpretation of data, and manuscript preparation. Riley Bloomfield provided software design of the wearable sensors being validated and assistance with experiment execution. Dr. Brent Lanting provided guidance on study design. Dr. Trevor Birmingham provided access to laboratory equipment and guidance on data analysis.

Chapter 3 is an original research article entitled “Novel sensor-instrumented Timed-Up-and-Go metrics relate to subjective function and satisfaction in TKA patients” and is in preparation for submission to the *Journal of Arthroplasty* in 2018. This manuscript was co-authored by Megan C. Fennema, Riley A. Bloomfield, Dr. Douglas D. Naudie, Dr. James L. Howard, Dr. Brent A. Lanting, and Dr. Matthew G. Teeter. As first author I contributed to study design, collection and interpretation of data, and manuscript preparation. Riley Bloomfield provided software and user interface design of wearable sensors and ongoing technological support. Dr. Douglas Naudie and Dr. Howard provided support through patient referral. Dr. Brent Lanting provided guidance on study design and support through patient referral.

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## List of Abbreviations

3D	Three Dimensional
AAD	Additive Angular Displacement
ACL	Anterior Cruciate Ligament
ANOVA	Analysis of Variance
ASTM	American Society for Testing and Materials
AUC	Area Under Curve
BMI	Body Mass Index
CI	Confidence Interval
CR	Cruciate Retaining
DMOAD	Disease Modifying Osteoarthritis Drug
IMU	Inertial Measurement Unit
ISO	International Standards Organization
KSS	Knee Society Score questionnaire
LCL	Lateral Collateral Ligament
MCL	Medial Collateral Ligament
M:F	Male to Female ratio
CON	Contralateral-limb
OA	Osteoarthritis
OP	Operative-limb
PCL	Posterior Cruciate Ligament
PROM(s)	Patient Reported Outcome Measure(s)
PS	Posterior Stabilized
ROC	Receiver-Operator Characteristic (eg. ROC curve)
SAAD	Average Step Additive Angular Displacement
SC	Step Count
SD	Standard Deviation
SEM	Standard Error of Measurement
SF-12	Short Form 12 questionnaire
TAAD	Total TUG Additive Angular Displacement
TKA	Total Knee Arthroplasty
TUG	Timed-Up-and-Go
UCLA	University of California, Los Angeles (eg. UCLA Activity Score)
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index questionnaire

## Chapter 1

### 1 Introduction

#### 1.1 Osteoarthritis

##### 1.1.1 Osteoarthritis Pathophysiology

Osteoarthritis (OA) is a chronic degenerative disease that targets both weight bearing and non-weight bearing joints of the body.<sup>1</sup> Healthy joint cartilage acts as a lubricated surface for articulation and load transmission, and adapts to loading by increasing regional thickness.<sup>1, 2</sup> Due to being avascular, articular cartilage is sensitive to injury and is especially sensitive to degenerative changes.<sup>2</sup> Once OA has initiated, cartilage degeneration overtakes adaptive processes and articular cartilage deteriorates.<sup>1, 2</sup> In addition to cartilage degeneration, changes to the synovium, meniscus, ligaments, and subchondral bone also occur.<sup>2</sup> Clinical symptoms that comprise a diagnosis of OA include joint space narrowing, malalignment, pain, stiffness, and disability.<sup>1, 3</sup> The pathology of OA is multifaceted, with mechanical, structural, genetic, and environmental factors playing a part in its development.<sup>1-3</sup> The risk for developing OA increases with age, obesity, previous joint injury, and presence of metabolic disease.<sup>1-3</sup> Risk for developing OA can be reduced by maintaining a mobile lifestyle, managing weight, and reducing risk of joint injury.<sup>2</sup> The pathogenesis of this disease is still under review and the complete picture of OA is not yet resolved.<sup>1, 3</sup> The multi-factorial nature of OA contributes to the complexity in deriving disease modifying OA drugs (DMOADs).<sup>1, 3</sup> No DMOADs currently exist, and even if novel DMOADs were derived in the near future it would still take decades before they would be available for public use.<sup>2</sup> The only long-term solution for OA is joint replacement, though the lifetime of this solution is also limited. This lack of effective medicinal treatment for OA contributes to the global burden of OA.

##### 1.1.2 Physical Burden

OA affects millions of people worldwide and is the leading cause of chronic disability in individuals over 70.<sup>2, 4</sup> The number of individuals affected by OA will continue to increase in agreement with the aging population and rise in obesity.<sup>2, 4</sup> In Canada alone, over 4.6

million individuals are affected by OA.<sup>5</sup> The progressive degeneration of joints in this disease causes severe pain, stiffness, loss of function, and swelling, together these result in limited ability to complete normal activities of daily living and decreases in quality of life.<sup>2,4,5</sup> Most commonly, joints affected by OA include hands, hips, knees, feet, and joints of the spine.<sup>5</sup> OA of the hip and knee joints tend to cause the greatest quality of life burden due to the effect on weight-bearing ability.<sup>4</sup> The physical burden to national and global populations is widespread and consequentially there are impacts to the economy.

### 1.1.3 Economic Impact

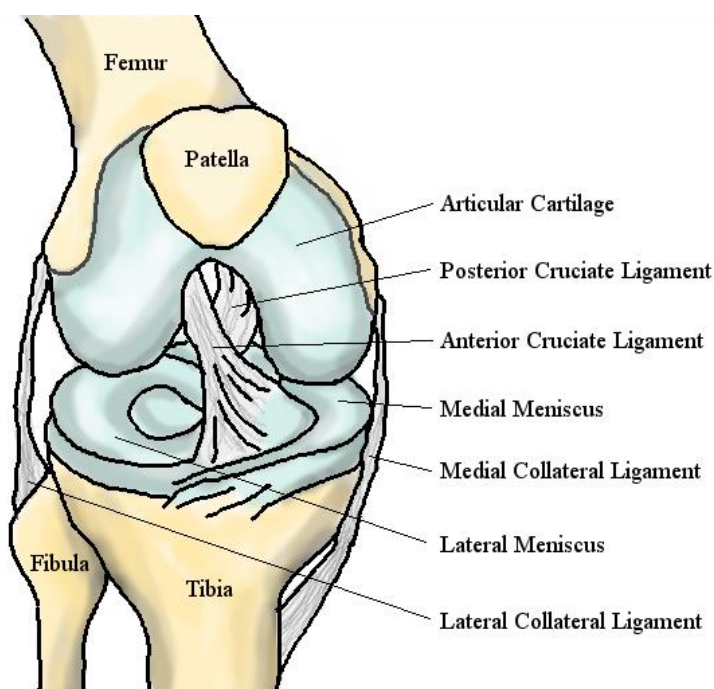
The direct cost of OA is projected to increase to \$7.6 billion in Canada by 2031.<sup>6</sup> The greatest contributor to direct cost is hospitalization, and 95% of this hospitalization cost is due to hip and knee surgeries.<sup>6</sup> \$4.7 billion of the direct cost of OA in 2031 will solely be a result of the hospitalization, physician, and prescription drug costs of hip and knee replacements.<sup>6</sup> While the direct cost of OA is heavy, the indirect costs of OA increase the total cost substantially. The disability associated with OA causes productivity costs due to work loss, and from 2010 to 2031 this cost will increase by almost 50%.<sup>7</sup> The increase in direct and indirect costs due to OA highlight the need for preventative and effective treatment of OA.

## 1.2 Total Knee Arthroplasty

### 1.2.1 Knee Anatomy & Biomechanics

Before describing the total knee arthroplasty (TKA) surgical procedure and its outcomes, it is important to have a background of the knee anatomy and function. While the knee is sometimes thought of as a hinge, there is more complexity involved to facilitate the articulation between the upper and lower leg. Body weight is transmitted from the femur to the tibia, with the patella acting to increase leverage during knee extension (**Figure 1**).<sup>8</sup> Ligaments, muscles, and menisci act to facilitate and stabilize the knee joint at rest and during motion.<sup>9</sup> There are four ligaments worth noting in the context of TKA (**Figure 1**). The anterior cruciate ligament (ACL) resists anterior displacement of the tibia, the posterior cruciate ligament (PCL) resists posterior tibia displacement, and the medial collateral ligament (MCL) and the lateral collateral ligament (LCL) resist valgus and varus rotation

of the knee, respectively.<sup>4</sup> The quadriceps muscle group, located on the front of the thigh, is the primary mechanism for extension of the tibia and the hamstring muscle group, located on the back of the thigh, is the primary knee flexion facilitator.<sup>9</sup> These muscle groups also offer dynamic stability of the knee.<sup>9</sup> The menisci are cartilaginous tissue acting as load bearing surfaces between the femur and tibia that also guide rotation and stabilize translation of the joint (**Figure 1**).<sup>9</sup> During level walking, the medial contact point of the tibia and femur creates a pivot for axial rotation, while the lateral contact of the tibia and femur allows more anterior and posterior translation.<sup>10</sup> Similarly, during greater knee flexion the medial portion of the femur experiences minimal change in contact position on the tibia while axially rotating, and the lateral contact position of the femur rolls posteriorly along the tibia with increased flexion.<sup>10</sup> Together, the quadriceps and hamstring muscle groups enact extension and flexion, the ligaments keep the femur and tibia within normal limits during this motion, and the medial and lateral menisci offer smooth, cushioning surfaces for this motion. The knee joint is a complex system that is consequently difficult to provide with an ideal replacement.



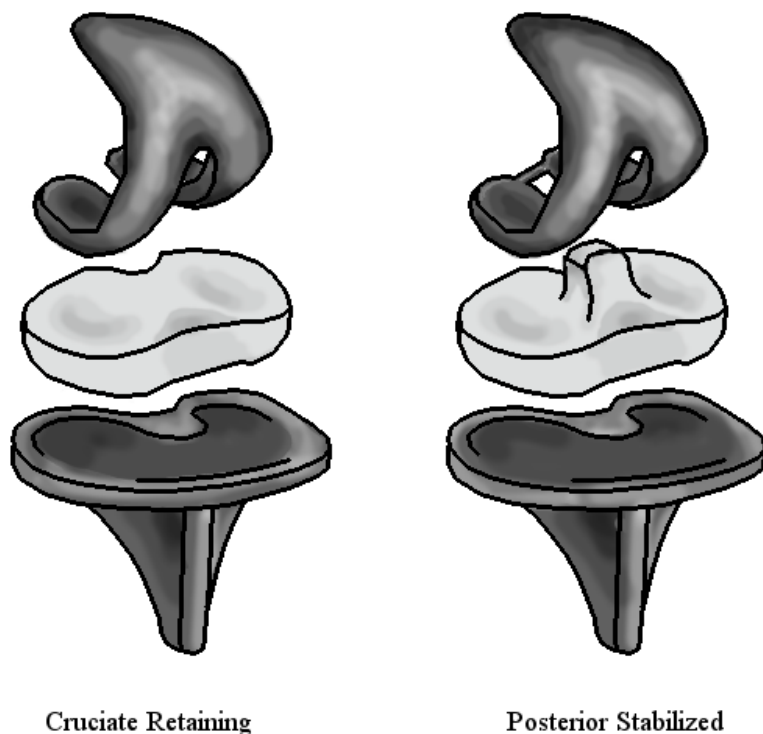
**Figure 1: Ligaments and menisci of the knee.**

## 1.2.2 TKA Procedure

TKA is a surgical solution reserved for individuals with severe knee OA which restores quality of life and ability to participate in normal activities of daily living for its recipients. This procedure replaces the diseased femoral, tibial, and sometimes patellar components of the knee joint with artificial components.<sup>11</sup> The femoral implant is typically composed of metal, the tibial component is a flat metal platform with a polyethylene insert (**Figure 2**), and the patellar implant is a dome-shaped polyethylene cap, though a patellar implant is not always implemented.<sup>4</sup> TKA is the recommended treatment for severe OA and is effective in treating the pain and loss of function associated with this disease.<sup>11</sup>

In general terms, the TKA procedure involves resection of diseased bone from the femur, tibia, and sometimes patella which is then replaced by implants. Bone resection of the femur and tibia and balancing of ligament tensions during the TKA surgery influence the rotation of the femoral component post-TKA.<sup>12</sup> Consequently, a surgical goal of TKA is bone resection and ligament balancing to create a symmetrical gap between the femur and tibia.<sup>12</sup> Techniques vary with surgeon preferences for creating balanced flexion and extension gaps. After resection, the implant type inserted is at the discretion of the surgeon and the implant may or not be cemented in place – depending on bone quality.<sup>4</sup> Implant type may vary depending on a surgeon's choice to retain a healthy PCL or sacrifice a damaged PCL, resulting in cruciate retaining (CR) implant or a posterior-stabilizing (PS) implant that has a post as a feature of the polyethylene tibial insert to prevent posterior displacement of the femur (**Figure 2**).<sup>4</sup> An implant may also have a fixed or mobile polyethylene cushion which may differ depending on the activity level, age, or weight of the patient.<sup>4</sup> There are many opportunities for variation in the TKA procedure, which may result in differences in outcomes of patients undergoing this surgery.<sup>13</sup>





**Figure 2: Cruciate retaining and posterior stabilized knee implants.**

### 1.2.3 TKA Outcomes

TKA has been widely accepted as a successful surgical treatment for knee OA based on implant survival and surgeon-based outcomes.<sup>14</sup> However, greater improvements in functional outcomes are perceived by surgeons than are reported by patients.<sup>15</sup> Many people are dissatisfied and continue to experience pain and functional difficulties after their TKA surgery.<sup>14, 16</sup> Dissatisfaction is multifactorial and more severe dissatisfaction may be associated with instability, stiffness, and lack of social support.<sup>17</sup> It is important to keep patient experiences in mind when assessing treatment to improve patient outcomes and prevent future healthcare burdens.

## 1.3 TKA Assessment Tools

### 1.3.1 Surgeon Assessment

Throughout the TKA process the surgeon is involved with assessing the function and experience of the patient. This evaluation can involve reviewing X-rays of the joint,

physical examination, and obtaining a clinical history from the patient.<sup>18</sup> Though OA is primarily evaluated through a history and physical examination, X-rays may be used to identify alignment of the knee, joint space narrowing, increased bone density, or bony overgrowths.<sup>18</sup> The physical examination can be used to assess and monitor range of motion, alignment deformity, limitation during active and passive movement, joint instability, joint swelling, or pain during motion.<sup>19</sup> A patient's clinical history is also an important tool for a surgeon in evaluating symptoms of pain, stiffness, or function and their progression.<sup>19</sup> Surgeon assessment varies between surgeons as can be expected, but there is also variation between the doctor's assessment and the patient's experience.<sup>20</sup> This is cause for the development of techniques that encompass the patient experience and quantitative outcomes.

### 1.3.2 Patient Reported Outcome Measures

Patient reported outcome measures (PROMs) take the form of surveys in which patients answer questions aimed to quantify qualities such as pain, function, or satisfaction. PROMs are frequently used in clinics to assess outcomes of TKA at pre- and post-surgery time points. The Short Form 12 (SF-12), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and the Knee Society Score (KSS) questionnaires are commonly implemented in clinics to assess general health, lower limb function with respect to OA, and TKA specific functional outcomes, respectively.<sup>21-24</sup> The WOMAC is the most commonly used survey tool to assess TKA outcomes.<sup>21</sup> This questionnaire uses a Likert scale to score 5 questions related to pain, 2 questions related to stiffness, and 17 questions related to function. The SF-12 and KSS assess outcomes in a similar fashion.<sup>22, 24</sup> PROMs offer simple, resource efficient, and validated methods for quantitatively monitoring TKA outcomes.<sup>21</sup> However, there are disadvantages associated with PROMs. Surveys are often prone to floor or ceiling effects, where participants choose the lowest or highest score available.<sup>25</sup> This is common for PROMs assessing TKA patients due to the large improvement often provided by this surgery.<sup>25</sup> This can conceal potentially key distinctions between subjects. As well, due to the ordinal nature of PROMs the outcomes may not fully encapsulate a patient's symptoms, function, or experience.

Therefore, it is important to use surveys that have valid content for the intended purpose to more accurately assess outcomes.

### 1.3.3 Functional Tests

Functional tests are another method used to monitor TKA outcomes that is widely used in the research field. These tests rely on a participant completing a physical task that has the goal of being analogous to normal activities of living. Examples of functional tests include the 6-minute-walk test, the sit-to-stand test, or the timed-up-and-go test.<sup>26</sup> These tests typically quantify function using start to finish variables such as distance traveled or time to complete. Functional tests offer further simple and resource efficient methods of evaluating OA and TKA outcomes.<sup>26, 27</sup> While the typical singular outcomes of functional tests can condense general function into a quantity, these values are not descriptive of differences in strategies or adaptations that a participant may employ to complete the test.

#### 1.3.3.1 The Timed-Up-and-Go Test

The timed-up-and-go (TUG) test has been previously used to evaluate the functional performance of patients with knee pathologies.<sup>28, 29</sup> During this test, the participant stands up from a chair, walks 3 m to a measured goal, turns around at the goal, walks back to the chair, then turns around to sit back down in the chair.<sup>30</sup> This test is less intensive than the 6-minute walk test and stair ascending/descending tests, and it is more likely that post-operative patients are able to complete it at earlier timepoints.<sup>29</sup> The TUG test has excellent same-day test-retest reliability with TKA patients.<sup>28</sup> Changes in TUG test time above 2.27 s can be attributed to a “real” change in function for TKA patients outside of standard errors of the mean (SEM).<sup>28</sup> As well, the TUG test has been demonstrated to be an appropriate tool for assessment of function shortly after TKA with respect to amount of change and relationship to patient-perceived improvement.<sup>31</sup> The feasibility and measurement properties of the TUG test make it an excellent tool for use in both clinical and research evaluations of TKA populations.

### 1.3.4 3D Motion Capture Laboratories

Motion capture cameras are the gold standard for external motion tracking and have previously been applied to functional assessment of TKA patients.<sup>32-35</sup> This type of assessment requires stationary labs with an expensive setup of infrared cameras that track reflective markers, and trained personnel. Often these labs also implement ground force plates to measure loading during gait which can be used to calculate moments of force – commonly referred to as torque – at the knee. Common measures extracted from these methods include knee flexion angles, ranges of motion, moments about the knee, or ground reaction forces during gait.<sup>32, 36</sup> Studies using 3D motion labs have previously shown that there are kinetic and kinematic differences between pre-TKA, post-TKA, and healthy asymptomatic adults, as well as improvements post-TKA that bring patients closer to asymptomatic biomechanics.<sup>32-35</sup> Research using these gait labs have shown that TKA patients walk with less range of motion during the different phases of gait compared to control populations.<sup>36</sup> This is believed to affect patients' ability to perform functional activities.<sup>36</sup> Abnormal moment patterns about the flexion axis have been shown to differentiate between a majority of control and TKA subjects, and increases in moments in the adduction axis have been linked to implant alignment and loosening.<sup>36</sup> While 3D motion capture labs have given insight into the biomechanics of TKA patients, these labs cannot be easily applied to assess or monitor patients outside of research participation.

### 1.3.5 Wearable Motion-Based Sensors

Wearable sensors have become increasingly popular amongst the public in recent years, making it a more affordable opportunity for research. Inertial measurement units (IMUs) are one of these motion-based sensor types that have increased in prevalence. IMUs are composed of three micro-electromechanical systems: a gyroscope, a magnetometer, and an accelerometer. These components work together to retrieve angular data in the form of displacement, velocity, and/or acceleration. Previous work has exploited these characteristics to quantify gait and lower limb motion.<sup>37-39</sup> Spatiotemporal and kinematic parameters derived from individual sensors during functional activities have discriminated between OA patients and healthy subjects,<sup>40</sup> and have shown differences between pre- and post-TKA patients.<sup>41</sup> Common metrics derived from these sensors include ranges of

angular displacement of specific body landmarks, peak angular velocities or accelerations of these landmarks in different planes of motion, cadence, stride velocity, or stride length.<sup>42, 43</sup> A novel application of these sensors is to use information gathered from multiple sensors to calculate angles of joint motion.<sup>44-47</sup> While this technique involves more intensive sensor software development, it allows for the collection of measurements analogous to the kinematic metrics derived in specialty 3D motion capture labs at a fraction of the cost. IMUs have great potential for evaluating and monitoring pathologies affecting motion in research and clinical settings.

## 1.4 Thesis Objectives and Hypotheses

Given the rise in popularity and decreasing price of wearable sensors, this technology offers a feasible opportunity for more personalized medicine in an orthopedic clinic setting. This work aims to set the tone for implementing wearable technology in the clinic for TKA populations while keeping the patient experience at its core. The objectives of this thesis are to: (1) validate an IMU setup in a controlled environment for the measurement of knee joint angles, and (2) implement the IMU setup during trials of the TUG test in a population of post-TKA patients to derive novel metrics relating to PROMs that can be used to assess quantitative function that is patient-important. We hypothesize that the IMU setup will measure knee joint angles with acceptable accuracy and precision at different speeds and after re-positioning. We also hypothesize that when implemented into a group of 1- or 2-year post-TKA patients during TUG tests that new sensor-derived metrics will relate to patient-reported satisfaction and function.

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## Chapter 2

### 2 Repeatability of measuring knee flexion angles with wearable inertial sensors

#### 2.1 Introduction

Assessments of knee joint flexion and extension range of motion is commonly used by surgeons to track patient function following knee arthroplasty.<sup>1</sup> Patients that experience post-arthroplasty improvements in knee biomechanics during gait typically report good outcomes, while those who lack improvements do not.<sup>2</sup> Clinicians often collect rudimentary data using manual, hand-held goniometers, which are known to have poor accuracy. In research settings, this type of kinematic information of knee joints can be gathered through a variety of devices, including most commonly electro-goniometers and 3D motion capture cameras. However, these have multiple factors limiting their potential application in clinics. Electro-goniometers are limited to two planes of motion, and the physical strain gauge that measures angles requires specific placement and could potentially interfere with incisions. 3D motion capture cameras are the gold standard for motion capture, but this modality requires a stationary lab, complex interpretation, substantial patient time commitment, and is very expensive.

Inertial measurement units (IMUs) have become increasingly popular as a method to capture motion data.<sup>3</sup> These sensors commonly measure acceleration, velocity, and orientations in space and cost much less than a traditional 3D motion capture camera system.<sup>4</sup> IMUs can be used to calculate joint angles using the orientations in space collected from two separate sensors.<sup>5</sup> Aside from cost, the small physical nature and wireless capability of IMUs means they can be attached unobtrusively to subjects as wearable sensors and then be implemented during physical activities to evaluate joint characteristics that are supplementary values of joint function.<sup>6,7</sup> These sensors also have great potential for assessment outside of the lab environment by tracking functional tests or daily activities. Wearable sensors can be easily applied to knee joint research to provide important information regarding characteristic functionality of knee joint pathologies,<sup>6</sup> and have the potential for instant clinician interaction and data interpretation.

As the use of IMUs for such assessments is increasing, clinicians and researchers must be aware of their limitations with respect to accuracy and repeatability of their measurements. The purpose of the present study was to determine the strengths, weaknesses, and areas for improvement for a typical set of IMUs. The primary objective of this experiment was to evaluate the measurement repeatability of IMU joint angles in comparison to an electro-goniometer and a 3D motion capture camera setup using a repeatable robot controller and an anthropomorphic leg phantom. The secondary objectives were to determine any effects of joint speed and sensor positioning on the joint angles collected by these sensors. We hypothesize that 1) the IMU's will provide less bias than the electro-goniometer to the 3D motion capture markers due to their lack of mechanical constraints, and 2) the IMUs will have greater repeatability error than the electro-goniometer due to cumulative dual-sensor error but will provide repeatability comparable to a manual goniometer.

## 2.2 Methods

### 2.2.1 Robot & Phantom Setup

A 6-degree-of-freedom robotic controller was used in this experiment to provide repeatable motion paths to determine the bounds of repeatability of wearable sensors for future studies with human subjects. This represents the best-case scenario, therefore if the accuracy limits are not acceptable here, then such sensors would not be appropriate for clinical use where accuracy is likely to be worse. The phantom itself provided anatomical references for positioning of the modalities as well as simulated soft tissue that could introduce motion artifacts that would be typical of a patient. In addition to being a repeatable platform for evaluation, this experimental setup allowed for simulation of human motion that was completely controlled. The anthropomorphic leg phantom (Sawbones Fully Encased Leg, Pacific Research Laboratories, Vashon, WA) was affixed to the robot via a custom fixture to anchor the upper segment of the leg to a stationary platform and to affix the lower segment to the mobile end-effector of the robot arm. The end-effector of the robot arm was programmed to move in an arc to revolve the lower segment of the leg phantom about the knee joint to approximately 120 degrees of flexion from a straight-leg position.

## 2.2.2 Motion Capture Modalities

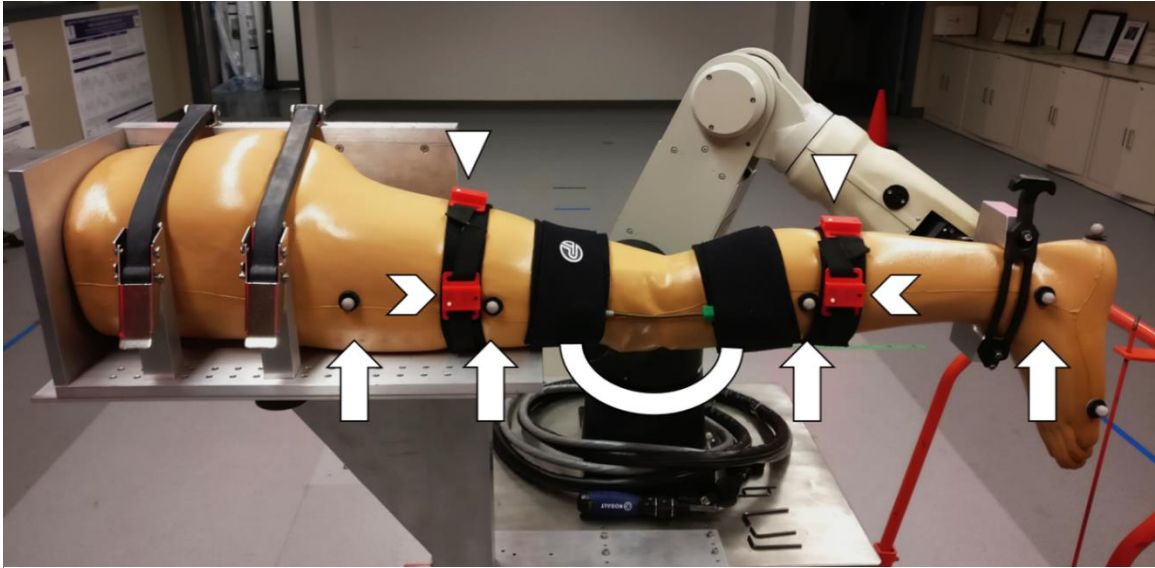
Three motion capture modalities were used in this experiment: 3D motion capture cameras, an electro-goniometer, and two IMU setups. See **Figure 3** for the setup of the motion capture modalities described as follows. An 11-camera, 3D motion capture system (Motion Analysis Corporation, Santa Rosa, CA) with four passive reflective markers was used as a gold standard for non-invasive motion capture technology to compare the wearable sensors against. The four reflective markers for the 3D motion capture cameras were affixed along the lateral side of the leg phantom using double-sided tape, with two of the markers placed on the upper segment of the leg and the other two on the lower segment. For each of the four anatomic markers, 3D Cartesian coordinates were gathered at a sample rate of 60 Hz over the duration of each test. These unprocessed data were then input into a custom MATLAB script (MathWorks, Natick, MA). This script isolated and calculated the flexion-extension angles between the upper leg segment and the lower leg segment for each sample point throughout each test. This was achieved via the following steps: a 3D virtual line or “vector” along the upper leg segment was created by subtracting proximal thigh marker coordinates from the distal thigh marker coordinates, the lower leg segment vector was created in the same manner with distal and proximal tibial marker coordinates, the dot product of the upper and lower leg vectors was calculated, the cross product of the upper and lower leg vectors was calculated and normalized, then the arctangent of the normalized cross product and the dot product was taken to determine the angle of flexion of the leg.

A wireless electro-goniometer (Biometrics Ltd., Newport, UK) was also used as a comparator for the proposed IMU systems. The electro-goniometer was attached laterally on the leg phantom across the approximate center of motion of the knee joint using double-sided tape and adjustable straps. Angular data were collected at 100 Hz and wirelessly transmitted from the goniometric sensor to a computer with Biometrics DataLITE version 10.05 which processed the goniometric data automatically to produce flexion-extension angles.

Lastly, IMUs (mbientlab, San Francisco, CA) were used to measure the angle between the upper and lower segments of the leg phantom at a sample rate of approximately 25 Hz. Two IMU setups were used in the following experiment, each with two IMUs. For the first

setup, the IMUs were positioned on the posterior side of the leg phantom with one on the upper segment and one on the lower segment. This posterior placement was used to approximate an anterior placement on a patient. A true anterior placement was not viable on the leg phantom in this experiment due to the interaction of the custom fixture with the anterior portion of the thigh, as can be seen in **Figure 3**. However, the posterior IMU placement is an appropriate simulation for an anterior IMU placement since the IMUs rotate about the same sensor axes for both anterior and posterior placements. For the second IMU setup the IMUs were positioned on the lateral side of the leg phantom, with one IMU on the upper segment and one on the lower segment again.

For both IMU setups, orientation data were transmitted via Bluetooth from each IMU to an iPhone (Apple Inc., Cupertino, CA). A custom application calculated the angle between the leg segments by determining the difference in sensor orientation of the upper with respect to the lower IMUs. Orientation estimations were expressed in quaternions to prevent Gimbal lock. This phenomenon occurs when one of three axes of rotation aligns with another and causes a degree of freedom to be lost, which results in incorrect rotational movements. Thus, quaternion representations are advantageous in the case of wearable sensor technology. From the quaternion orientation estimations of the upper and lower IMUs the custom software separated the flexion-extension component from the internal-external rotation and varus-valgus components of the joint movement by breaking the quaternion difference into three separate rotations corresponding to clinical joint angles.<sup>8</sup>

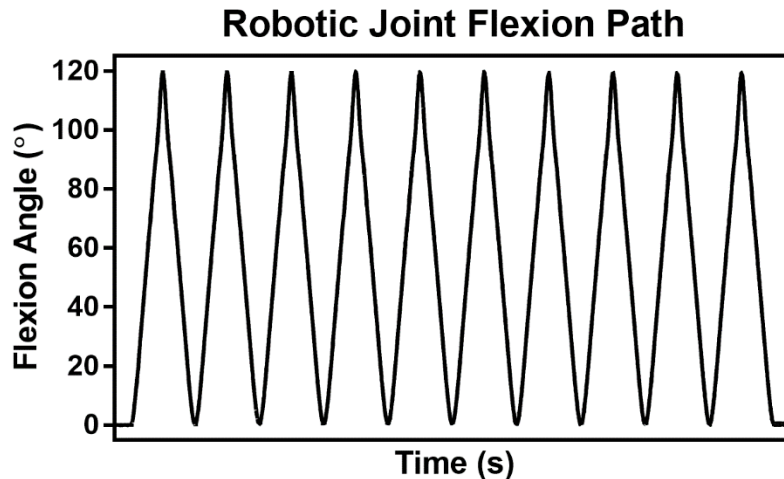


**Figure 3: Experimental setup of the motion capture modalities on the leg phantom. The upward pointing arrows indicate the 3D camera reflective markers used for angle calculation, the upward facing arc encompasses the length of the electrogoniometer, the downward pointing triangles indicate the posterior IMUs, and the right and left pointing chevrons indicate the lateral IMUs. The two unaccounted for reflective markers on the foot of the phantom were used as a means for identifying the lower segment from the upper leg segment in post-processing.**

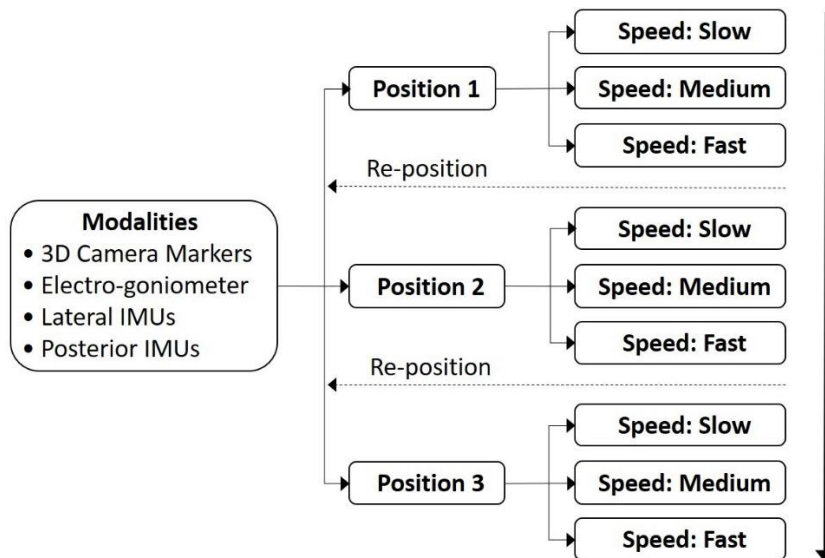
### 2.2.3 Experimental Procedure

All motion capture modalities gathered data concurrently while attached to the robotic leg phantom during the following tests. Each test involved a ten-cycle run of the 120 degree motion arc described above to assess repeatability of each modality within each test. The motion pathway of the robot is depicted by the waveform graph in **Figure 4** of a representative test captured by the 3D motion capture camera markers. **Figure 5** depicts the series of events in the experiment, described as follows. To assess repeatability at different speeds, the ten-cycle test was replicated for three increasing angular speeds of approximately 15, 30, and 50 degrees per second, with the fastest speed being characteristic of activities of daily living.<sup>9</sup> After the initial three tests at different speeds, the electrogoniometer and all four IMUs were removed from the leg phantom, the electrogoniometer was tared against a straight surface, and then both sensor modalities were re-positioned on the leg phantom to assess placement repeatability and to simulate test-retest conditions using the same operator. For each re-position of the sensors, the three increasing speed

tests were repeated. Nine robot tests were completed in total, which comprised positioning the sensors three times and three speed tests per position.



**Figure 4: Motion pathway of the robotic leg phantom during each individual test.**



**Figure 5: This flow chart depicts the experimental flow of the nine robot tests.**

## 2.2.4 Data Processing

The main outputs for all three modalities were flexion angles over time. The initial straight-leg position of the phantom was assigned a value of zero degrees of flexion, and therefore

initial values were subtracted as offsets. From these flexion angles over time, the 10 peaks and 9 troughs of the motion waveform were extracted for each test using a custom MATLAB program. These peaks and troughs were then used to compare the tests for the different modalities, positions, and speeds. To determine the effects of sensor type, re-positioning, and changes in flexion speed, IBM SPSS Statistics 25 (IBM Corporation, Armonk, NY) was used to conduct three-way ANOVA and Bonferroni's post hoc correction. Statistically significant differences between tests were determined as any comparison with  $p \leq 0.05$ . GraphPad Prism 7.00 (GraphPad Software, La Jolla, CA) was used to calculate means, standard deviations, and 95% confidence intervals to show the repeatability of minimum and maximum angles reached during a singular test. Repeatability was assessed using the standard deviation as described by Langlois et al. on current ASTM and ISO recommendations.<sup>10</sup> Bias and standard deviation of bias was also calculated in GraphPad Prism using Bland-Altman's methods.<sup>11</sup>

## 2.3 Results

Mean, standard deviation, and confidence intervals of maximum and minimum flexion are presented in **Table 1** and **Table 2**, respectively, for each 10-cycle test of every modality, position, and speed. The overall average maximum flexion angles across all tests for the 3D camera markers, electro-goniometer, posterior IMUs, and lateral IMUs in respective order were  $119.4 \pm 0.3^\circ$ ,  $112.4 \pm 0.5^\circ$ ,  $116.2 \pm 2.4^\circ$ , and  $118.3 \pm 1.1^\circ$ . The overall average minimum flexion angles across all tests in the same order were  $0.2 \pm 0.1^\circ$ ,  $-0.1 \pm 0.1^\circ$ ,  $0.6 \pm 0.7^\circ$ , and  $-0.3 \pm 2.7^\circ$ . Average maximum and minimum flexion angles for every test and modality are graphically presented in **Figure 6**.

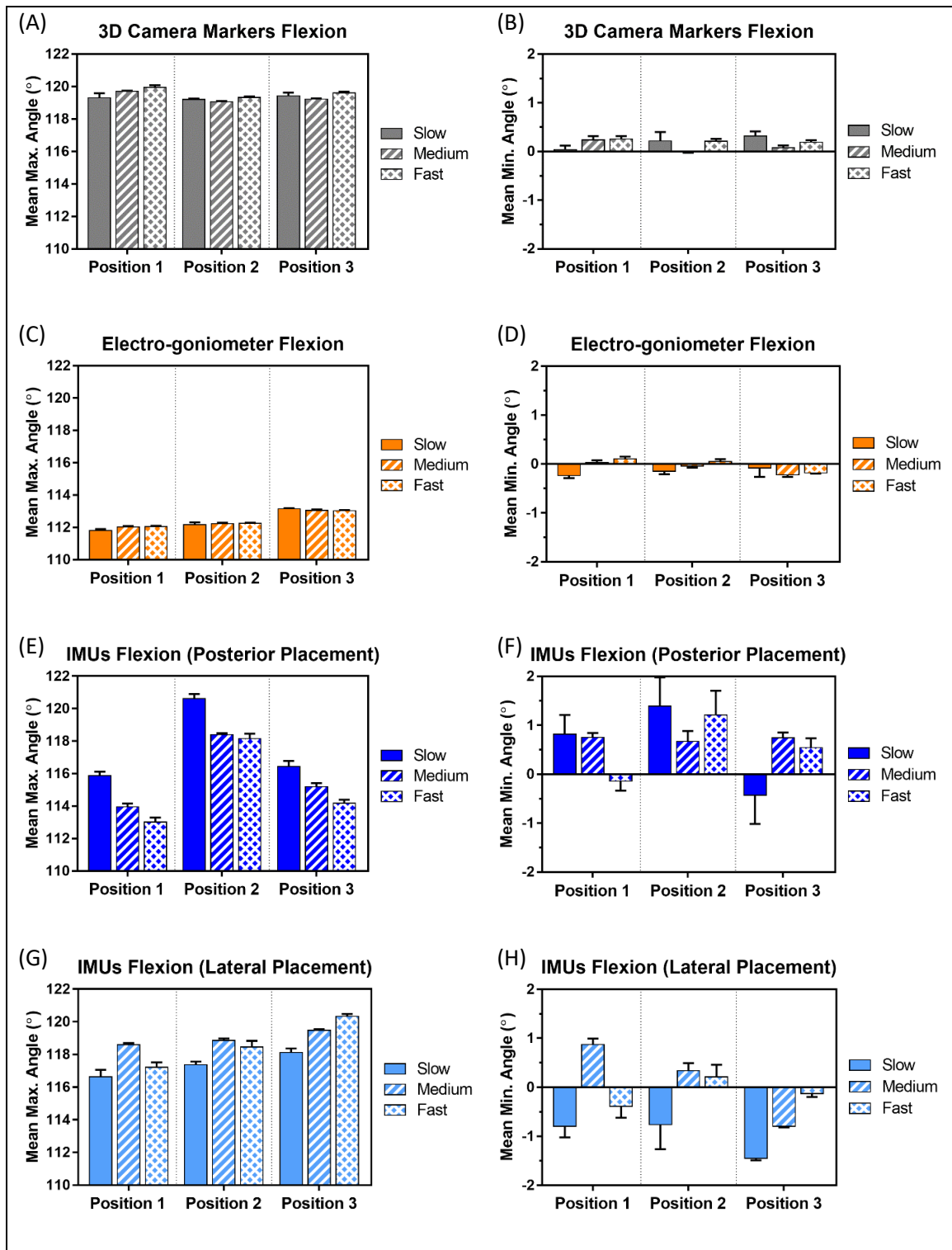
Observation of the bias of the maximum flexion angles for the different sensor setups to the 3D camera markers showed bias  $\pm$  standard deviation (SD) of  $7.0 \pm 0.6^\circ$ ,  $3.2 \pm 2.6^\circ$ , and  $1.1 \pm 1.2^\circ$  for the electro-goniometer, posterior IMUs, and lateral IMUs, respectively (**Figure 7**). For comparisons of minimum flexion for the different wearable sensor setups to the 3D camera markers, differences of less than  $1^\circ$  were observed for all sensor types (**Table 2**). Sensor type, re-positioning, and speed changes – and the interactions between them – caused statistically significant effects to the flexion angles (**Table 3**), with sensor



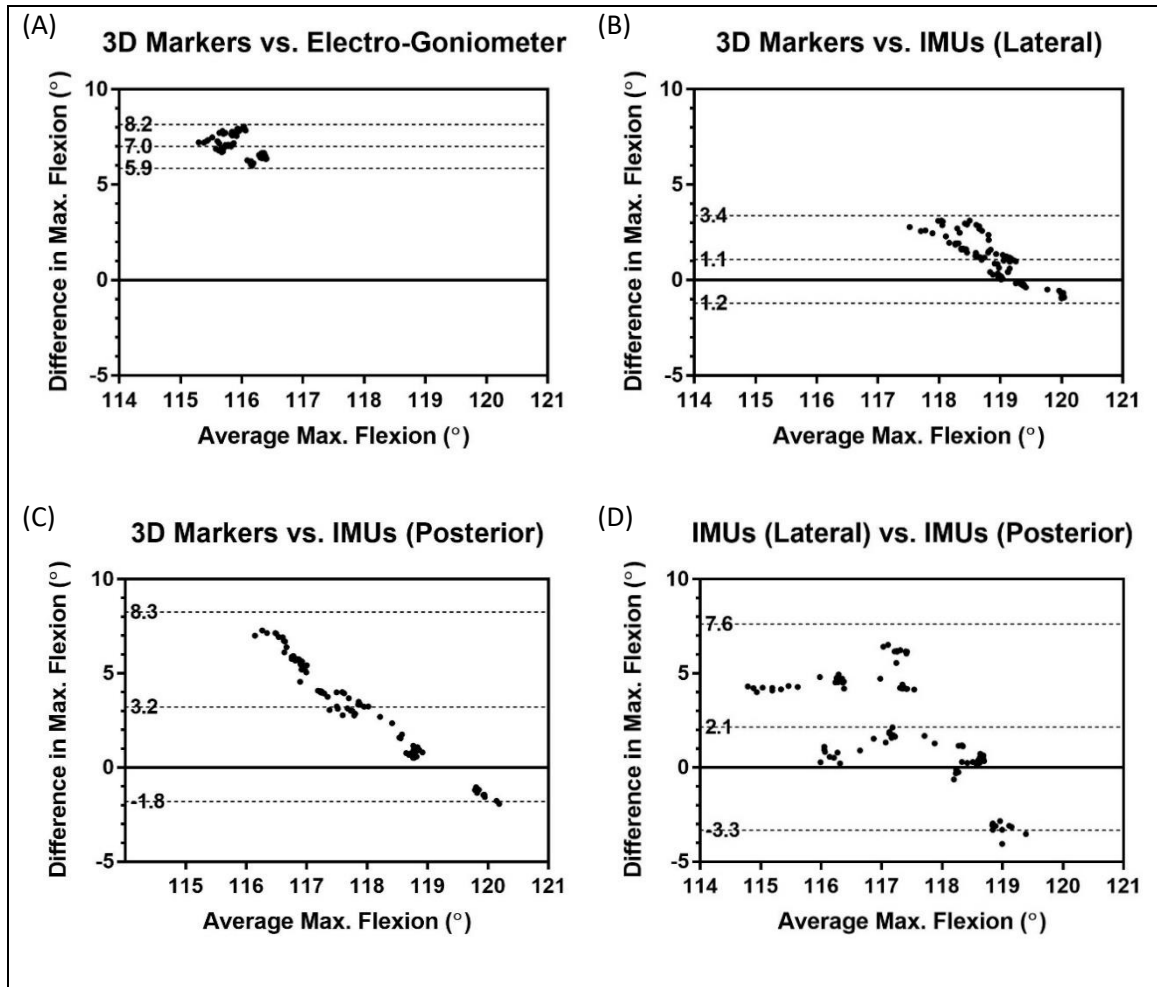
type having a greater effect than re-positioning, and re-positioning having a greater effect than speed.

Sensor re-positioning showed varied degrees of qualitative effects on maximum flexion comparisons for the different modalities (**Figure 6**). Since the 3D camera markers were not re-positioned between tests, they did not show any observable re-positional patterns. Slight re-positioning patterns were observed for the electro-goniometer, with the greatest difference in flexion angles being approximately  $1^\circ$ . The posterior and lateral IMUs had less obvious re-positioning patterns. The greatest difference in maximum flexion angles due to re-positioning was less than  $5^\circ$  for the posterior IMUs and approximately  $3^\circ$  for the lateral IMUs. No obvious patterns were observed on the minimum flexion angles as an effect of re-positioning for the 3D camera markers, electro-goniometer, posterior IMUs, or lateral IMUs. The greatest differences in minimum flexion angles were approximately  $0.3^\circ$ ,  $0.3^\circ$ ,  $1.8^\circ$ , and  $1.7^\circ$  for the 3D markers, electro-goniometer, posterior IMUs, and lateral IMUs, respectively.

Qualitatively, joint flexion speed had varying effects on maximum flexion comparisons for the different modalities (**Figure 6**). No obvious patterns with increasing speeds were observed for the 3D camera markers and the electro-goniometer, and the greatest differences in flexion angles were  $0.6^\circ$  and  $0.2^\circ$ , respectively. The posterior IMUs showed a visually obvious pattern of decreasing maximum flexion angles with increasing speeds. The greatest change in maximum flexion angles was less than  $3^\circ$  for the posterior IMUs and approximately  $2^\circ$  for the lateral IMUs. Effects of robot flexion speed showed no visually obvious patterns with increasing speeds on minimum flexion angles, and the greatest differences in minimum flexion angles due to speed were approximately  $0.2^\circ$ ,  $0.2^\circ$ ,  $1^\circ$ , and  $1.5^\circ$  for the 3D camera markers, electro-goniometer, posterior IMUs, and lateral IMUs, respectively.



**Figure 6:** This composite figure depicts the mean angles measured by each modality during each of the nine tests, where A, C, E, and G are maximum flexion angles, and B, D, F, and H are minimum flexion angles of the 3D motion capture camera markers, electro-goniometer, posterior IMU setup, and lateral IMU setup, respectively.



**Figure 7: Bland-Altman plots of the maximum flexions for the different sensing modalities vs. the 3D camera markers (A-C), and the Lateral IMU setup vs. the Posterior IMU setup (D). Hashed lines denote the lower 95% limit of agreement, bias, and upper 95% limit of agreement.**

**Table 1: Mean  $\pm$  standard deviation (SD) and 95% confidence intervals (CI) of maximum flexion in degrees for each test and each modality.**

	Position 1			Position 2			Position 3		
	Slow	Medium	Fast	Slow	Medium	Fast	Slow	Medium	Fast
<b>3D Camera Markers</b>									
Mean $\pm$ SD	119.3 $\pm$ 0.3	119.7 $\pm$ 0.0	119.9 $\pm$ 0.1	119.2 $\pm$ 0.0	119.1 $\pm$ 0.0	119.3 $\pm$ 0.1	119.4 $\pm$ 0.2	119.2 $\pm$ 0.0	119.6 $\pm$ 0.1
95% CI	119.1, 119.5	119.7, 119.7	119.9, 120.0	119.2, 119.2	119.0, 119.1	119.3, 119.4	119.3, 119.6	119.2, 119.3	119.6, 119.7
<b>Electro-goniometer</b>									
Mean $\pm$ SD	111.8 $\pm$ 0.1	112.0 $\pm$ 0.1	112.0 $\pm$ 0.1	112.2 $\pm$ 0.1	112.2 $\pm$ 0.1	112.3 $\pm$ 0.0	113.1 $\pm$ 0.0	113.1 $\pm$ 0.1	113.0 $\pm$ 0.0
95% CI	111.8, 111.9	112.0, 112.1	112.0, 112.1	112.1, 112.3	112.2, 112.3	112.2, 112.3	113.1, 113.2	113.0, 113.1	113.0, 113.1
<b>IMU (Posterior Position)</b>									
Mean $\pm$ SD	115.9 $\pm$ 0.2	114.0 $\pm$ 0.2	113.0 $\pm$ 0.3	120.6 $\pm$ 0.3	118.4 $\pm$ 0.1	118.2 $\pm$ 0.3	116.4 $\pm$ 0.3	115.2 $\pm$ 0.2	114.2 $\pm$ 0.2
95% CI	115.7, 116.1	113.8, 114.1	112.8, 113.2	120.4, 120.8	118.3, 118.5	117.9, 118.4	116.2, 116.7	115.0, 115.4	114.0, 114.3
<b>IMU (Lateral Position)</b>									
Mean $\pm$ SD	116.6 $\pm$ 0.4	118.6 $\pm$ 0.1	117.2 $\pm$ 0.3	117.4 $\pm$ 0.2	118.9 $\pm$ 0.1	118.5 $\pm$ 0.4	118.1 $\pm$ 0.2	119.5 $\pm$ 0.1	120.3 $\pm$ 0.1
95% CI	116.3, 116.9	118.5, 118.7	117.0, 117.4	117.2, 117.5	118.8, 119.0	118.2, 118.7	117.9, 118.3	119.4, 119.5	120.2, 120.4

**Table 2: Mean  $\pm$  standard deviation (SD) and 95% confidence intervals (CI) of minimum flexion in degrees for each test and each modality.**

	Position 1			Position 2			Position 3		
	Slow	Medium	Fast	Slow	Medium	Fast	Slow	Medium	Fast
<b>3D Camera Markers</b>									
Mean $\pm$ SD	0.0 $\pm$ 0.1	0.2 $\pm$ 0.1	0.3 $\pm$ 0.1	0.2 $\pm$ 0.2	0.0 $\pm$ 0.0	0.2 $\pm$ 0.1	0.3 $\pm$ 0.10	0.1 $\pm$ 0.0	0.2 $\pm$ 0.0
95% CI	0.0, 0.1	0.2, 0.3	0.2, 0.3	0.1, 0.4	0.0, 0.0	0.2, 0.2	0.2, 0.4	0.0, 0.1	0.2, 0.2
<b>Electro-goniometer</b>									
Mean $\pm$ SD	-0.2 $\pm$ 0.1	0.0 $\pm$ 0.0	0.1 $\pm$ 0.1	-0.2 $\pm$ 0.1	-0.0 $\pm$ 0.0	0.1 $\pm$ 0.0	-0.1 $\pm$ 0.2	-0.2 $\pm$ 0.0	-0.2 $\pm$ 0.0
95% CI	-0.3, -0.2	0.0, 0.1	0.1, 0.1	-0.2, -0.1	-0.1, 0.0	0.0, 0.1	-0.2, 0.1	-0.3, -0.2	-0.2, -0.2
<b>IMU (Posterior Position)</b>									
Mean $\pm$ SD	0.8 $\pm$ 0.4	0.8 $\pm$ 0.1	-0.1 $\pm$ 0.2	1.4 $\pm$ 0.6	0.7 $\pm$ 0.2	1.2 $\pm$ 0.5	-0.4 $\pm$ 0.6	0.7 $\pm$ 0.1	0.5 $\pm$ 0.2
95% CI	0.5, 1.1	0.7, 0.8	-0.3, 0.0	0.9, 1.8	0.5, 0.8	0.8, 1.6	-0.9, 0.0	0.7, 0.8	0.4, 0.7
<b>IMU (Lateral Position)</b>									
Mean $\pm$ SD	-0.8 $\pm$ 0.2	0.9 $\pm$ 0.1	-0.4 $\pm$ 0.2	-0.8 $\pm$ 0.5	0.3 $\pm$ 0.2	0.2 $\pm$ 0.2	-1.5 $\pm$ 0.0	-0.8 $\pm$ 0.0	-0.1 $\pm$ 0.1
95% CI	-1.0, -0.6	0.8, 1.0	-0.6, -0.2	-1.1, -0.4	0.2, 0.5	0.0, 0.4	-1.5, -1.4	-0.8, -0.8	-0.2, -0.1

**Table 3: F(df<sub>effect source</sub>, df<sub>error</sub>) and p values for factors affecting maximum and minimum flexion of leg phantom.**

Effect Source	Maximum Flexion		Minimum Flexion	
Sensor Type	F(3,27)= 25395.56	p<0.001	F(3,24)=130.86	p<0.001
Speed	F(2,18)=20.03	p<0.001	F(2,16)=48.42	p<0.001
Reposition Instance	F(2,18)=2040.87	p<0.001	F(2,16)=40.61	p<0.001
Sensor Type * Speed	F(6,54)=513.65	p<0.001	F(6,48)=46.14	p<0.001
Sensor Type* Reposition Instance	F(6,54)=2946.44	p<0.001	F(6,48)=55.85	p<0.001
Speed * Reposition Instance	F(4,326)=35.80	p<0.001	F(4,32)=37.15	p<0.001
Sensor Type * Speed * Reposition Instance	F(12,108)=36.36	p<0.001	F(12,96)=41.49	p<0.001

## 2.4 Discussion

Wearable sensors are becoming more prevalent and represent a potential straightforward and low-cost tool for quantifying patient function before and after joint arthroplasty. Range of motion in pre-operative knee arthroplasty patients has been shown to be of predictive of post-operative range of motion and can be used as a tool to assess patient recovery.<sup>1</sup> We endeavoured to assess a representative IMU-type sensor and its ability to collect joint flexion angles in comparison to an electro-goniometer and a 3D motion capture camera system. This simple quantity was used in this study to assess the performance of an IMU setup in the measurement of knee joint flexion angle. Specifically, we wanted to investigate repeatability of knee joint flexion angles and the effects of speed and placement on the IMUs using the same lab and operator.

Repeatability of each modality within each individual test was evaluated through observation of the standard deviation and 95% confidence intervals of maximum and minimum flexion values. For the maximum flexion values, all sensing modalities demonstrated standard deviations of approximately  $\pm 0.4$  degrees or less and confidence interval widths of 0.6 degrees or less within each 10-cycle test, regardless of speed or position. Similarly, the minimum flexion measured by the 3D camera markers, electro-goniometer, posterior IMUs, and lateral IMUs deviated less than  $\pm 0.6$  degrees and had confidence interval widths of 0.9 degrees or less. These within-test standard deviations and confidence intervals should provide acceptable precision in reporting knee joint angles during short functional tests with knee replacement patients, considering that currently in clinics flexion range of motion in pre-arthroplasty patients is measured using a manual goniometer which has a standard error of measurement (SEM) of 4.1 degrees.<sup>1</sup>

Effects of different sensor types, position, and speed changes were evaluated to simulate test and re-test conditions using the same lab and operator. All sources of change and interactions between sources of change caused statistically significant effects to the maximum and minimum flexion angles. The greatest source of difference by a large margin was change to the sensor type, while the smallest effect was due to changes in speed. While statistically significant differences were observed in these comparisons, the magnitude of these differences needed to be taken into consideration since statistically significant

differences in sensor measurements of repeatable robotic joint flexion measurement may not correspond to detectable differences for patient range of motion. The posterior IMU setup demonstrated a difference in flexion of 4.7 degrees due to re-positioning, which is slightly greater than the SEM for a manual goniometer in pre-operative knee patients.<sup>1</sup> This may result in a slightly greater minimal detectable change for knee patients if using a posterior IMU placement. All changes due to speed were less than 3 degrees which is less than the manual goniometer SEM.

In this experiment, the reliability of the electro-goniometer, posterior IMU setup, and lateral IMU setup measurements were evaluated by comparison to the benchmark 3D camera markers using Bland-Altman tests. Only maximum flexion values were evaluated for this portion of the experiment, as joint angles were initialized to starting offset of each test. The lateral IMU placement had the least bias of the maximum flexion angles in comparison to the 3D marker angles. While the electro-goniometer was observed to have the least standard deviation of bias from the 3D markers, its bias was by far the largest. This may be due to a limitation of the electro-goniometer technology, as they are known to have crosstalk errors that prevent the sensor from accurately measuring greater flexion magnitude.<sup>12</sup> These inherent crosstalk errors are unique to each individual sensor and can range from 2-10 degrees at flexion amplitudes of 100 degrees.<sup>12</sup> This is a major disadvantage of this sensor type and provides further motivation for the use of IMUs which are not limited to constrained placement and mechanical strain gauge sensing.

Two different IMU anatomical placements were considered in this experiment for future patient use, the posterior and lateral IMU placements. The different setups activated different planes of motion of the IMUs during flexion, and the goal of this portion of the experiment aimed to assess any difference in performance. As mentioned earlier, the posteriorly placed IMUs displayed patterns of decreasing flexion angles with increasing flexion speed, though the error due to speed is less than the SEM of a manual goniometer. The bias to the 3D markers of the maximum angles of the laterally placed IMUs was also less than the posterior IMUs. However, the difference in bias may be attributed to the lateral IMUs and the 3D markers both being aligned on the lateral side of the leg phantom. The bias when looking at the two different placements was 2.1 degrees. The differences

between these two placements could be attributed to differences in mechanisms used by the IMUs to determine orientations in certain planes of the sensor's motion.

The lateral and posterior positions of the IMUs in this experiment may be considered analogous to medial and anterior placements, respectively, since flexion occurs about the same respective axes of the IMUs. Medial sensor placements on patients would likely be affected by the contralateral leg and would be undesirable for placement. An anterior IMU setup could benefit from sensor placement along the tibia to reduce soft tissue movement due to muscle bodies. This placement option was not tested in this experiment due to constraints created by the fixture attaching the leg phantom to the robot base, though is likely to be a viable placement option. In a clinical setting, the posterior IMU setup would be impractical to attach to a patient and measurements may also be affected by large muscle bodies along the posterior chain. As well, the position of a posterior sensor setup may also be interfered with if patients are able to flex their knee to the point of contact of the thigh and calf. Either of these IMU setups can avoid any knee surgery incisions since the two units are not connected to each other – an advantage over electro-goniometers, which are connected.

Several limitations are apparent in this study, stemming from the robotically-controlled phantom and modality positioning. A robotically-controlled anthropomorphic leg phantom was used in the present study to provide a repeatable platform for assessment of our novel IMU joint angle estimation system. A limitation of this method was the inability to provide the kinematic nuances of realistic human motion. However, this experimental setup provided an advantageous balance between a highly repeatable but unrealistic mechanical jig study design and a less repeatable but realistic human subject study design. As well, the 3D markers were not re-positioned for the duration of the experiment to ensure differences in flexion angles were not due to changes in position or settling of the leg phantom between tests. This also provided a baseline for repeatability of the phantom motion for which to compare the repeatability of the different sensors. However, this limited an opportunity to show the error due to re-positioning of the 3D markers. The 3D markers were also only placed laterally along the phantom leg, which limited posterior placement comparisons. Lastly, the custom fixture attaching the leg phantom to the robot prevented an anterior

placement of the IMUs. However, the posterior positioning of the IMUs may be considered analogous to an anterior placement, since flexion occurs about the same respective axes of the IMUs.

In summary, the use of IMUs has increased in research as an inexpensive method of motion capture. Due to the extra processing required and increase in areas for potential error to calculate angles using these sensors, this application has not yet been fully taken advantage of.<sup>5</sup> While both posterior and lateral IMU setups demonstrated statistically significant effects due to position and speed changes, both IMU setups assessed in this experiment demonstrated repeatability in measurement of range of motion that is akin to manual goniometer methods used clinically. The IMUs also provided less bias than the electrogoniometer at greater flexion angles. Calculations of SEM and minimal detectable change is required in future studies involving IMUs placed on actual patient knees. An anterior IMU setup analogous to the posterior positions used in this experiment would be advantageous in the clinic for ease of sensor alignment. Since both lateral and posterior IMU setups provided clinically viable repeatability in this experiment, a lateral or anterior IMU setup is recommended for use in dynamic range of motion measurement in future knee patient research.



## 2.5 References

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## Chapter 3

### 3 Novel sensor-instrumented Timed-Up-and-Go metrics relate to subjective function and satisfaction in TKA patients

#### 3.1 Introduction

Total knee arthroplasty (TKA) offers an increase in quality of life and a long-term solution for individuals with severe osteoarthritis (OA) that would otherwise manage their disease to a limited extent with symptom-focussed medications. Unfortunately, 1 in 5 patients report that they are not satisfied with their TKA at 1-year post-surgery,<sup>1</sup> and many continue to experience pain and functional difficulties.<sup>2,3</sup> The problem of dissatisfaction for TKA is complex as many factors can contribute to its cause.<sup>3</sup> To assess the outcomes of TKA in a way that benefits the patient most, it is important to keep the patient experience in mind.

Patient reported outcome measures (PROMs) are important clinical tools for measuring surgery effectiveness and patient outcomes. PROMs take the patient experience into account and report on qualities such as satisfaction, pain, and function. However, PROMs can be prone to indeterminate content validity, floor and ceiling effects, and poor responsiveness to clinical change.<sup>4,5</sup> The categorical outcomes of surveys can also disguise the continuous nature of the patient experience, resulting in patients being grouped together despite differing symptoms, or even reduced responsiveness to individual change.<sup>4</sup> More quantitative measurements of function that relate to PROMs may provide new insight into strategies to improve the TKA process.

Functional tests offer simple, quantitative methods of measuring physical function.<sup>6,7</sup> A big advantage of functional tests is that they require minimal resources, which is beneficial for implementation into a clinical setting. The timed-up-and-go (TUG) test has been previously demonstrated to reliably measure TKA patient function and improvement after their surgery.<sup>8-10</sup> This test only requires a chair, a stopwatch, and a 3 m marked distance on the ground.<sup>11</sup> However, the only output for the TUG test is the length of time a participant takes to complete the test. While this singular measure relates to function of a TKA patient, it fails to describe specific functional areas – other than completing the test quicker – to

improve on a patient's reported function. For example, two patients may complete the TUG test in a similar time, but one may do so with a limp.

The use of wearable sensors for activity tracking has risen in popularity among the public in recent years, making it an increasingly inexpensive opportunity for scientific research. Inertial measurement units (IMUs) are a common type of wearable sensor that can track orientations in space using its gyroscopic, magnetometer, and accelerometer components. Studies have previously implemented IMUs to quantify biomechanical characteristics of gait in healthy, OA, and TKA populations.<sup>12-16</sup> Similarly, research has implemented IMUs during the TUG test to evaluate functional performance of young adults,<sup>17</sup> older adults,<sup>16, 18</sup> and Parkinson's disease patients.<sup>19</sup> IMUs have also been used to calculate kinematic measurements typically collected in 3D motion capture labs.<sup>20-23</sup> The objective of this current study is to implement IMUs alongside the TUG test in a population of TKA patients to identify new, descriptive, functional metrics related to PROMs.

## 3.2 Methods

### 3.2.1 Study Design

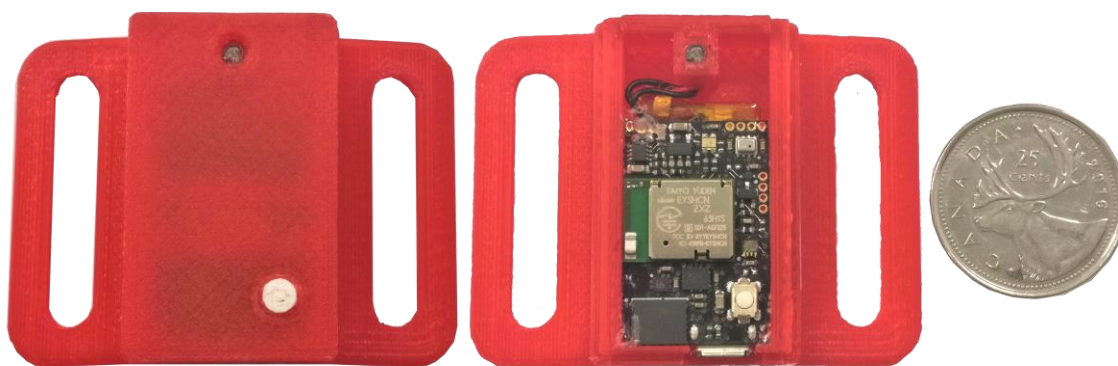
IRB approval was obtained for a case series study investigating patients that received a primary TKA for OA 1- or 2-years previously. Patients were excluded if their surgery was not performed by one of the three participating surgeons in this study. Individuals were also excluded if they had a language and/or cognitive barriers, a revision TKA surgery, a TKA on their contralateral leg less than 1 year prior, or a neuromuscular disorder.

### 3.2.2 Patient Procedure

Patients were recruited on the day of their 1- or 2-year post-operative appointment ( $n = 82$ ; M:F = 31:51; age =  $67 \pm 10$  yrs; BMI =  $32 \pm 7$  kg/m<sup>2</sup>), during which they completed a booklet of questionnaires containing the SF-12, WOMAC, KSS surveys as part of their regular appointment. After providing informed consent, participants answered the UCLA Activity Score survey, and completed three TUG tests instrumented with IMUs. For the TUG test, participants were instructed to stand up from a chair, walk 3 m to a marked line on the floor, turn around, walk back, and turn to sit down at a comfortable pace.

### 3.2.3 Sensor Setup

Four IMUs were implemented during the TUG test and were affixed to the anterior side of the body at proximal and distal positions to the knee joint on both legs. For each wearable sensor unit, an IMU development board (MetaMotionR, MBientLab, San Francisco, CA, USA) and a rechargeable lithium-polymer battery were inserted into a custom 3D-printed case approximately 1.2 x 3.0 x 4.0 cm in size **Figure 8**. The case featured two wings with slots for insertion of straps to affix to the study participants. The sensors transferred data via Bluetooth to an Apple iPod Touch which was configured to temporarily store raw data without a persistent wireless connection. Custom software was developed to identify sensor orientations and calculate knee joint angles at a sampling rate of approximately 25 Hz.<sup>23</sup>



**Figure 8: Wearable sensors (closed and open cases) with quarter for scale.**

### 3.2.4 Sensor Metrics

From the sensor-instrumented TUG test potential metrics of movement and function were proposed. Proposed metrics fit into categories as spatiotemporal, angular, velocity, and acceleration quantities, described in **Table 4**. Spatiotemporal metrics of the TUG test detected by the sensors included: Total TUG, Sit-to-Stand, Walk-to-Goal, Walk-to-Chair, and Turn-to-Sit time segments, as well as step counts for the operative- and contralateral-limbs, and a total step count ( $SC_{OP}$ ,  $SC_{CON}$ ,  $SC_{TOT}$ ). Specific angles and angle ranges were detected for operative- and contralateral-limbs and included: Start-TUG and End-TUG flexion/extension angles, Sitting-to-Loading flexion angle range at the beginning of the TUG, maximum flexion of the average step, and flexion/extension range of the average

step. Velocity and acceleration values were calculated for the average step of the operative- and contralateral-limbs, including flexion and extension velocities and accelerations.

**Table 4: List of sensor metrics and descriptions.**

Sensor Metrics	Description
<b>Spatiotemporal</b>	
Total TUG Test	Total time (s) taken to complete TUG test.
Sit-to-Stand (% Sit-to-Stand)	Time (s) taken to go from a sitting to standing position. (% out of Total TUG test)
Walk-to-Goal (% Walk-to-Goal)	Time (s) taken to walk to 3-meter goal distance after sit-to-stand and before turn-at-goal. (% out of Total TUG test)
Turn-at-Goal (% Turn-at-Goal)	Time (s) taken from start to end of turn at goal distance. (% out of Total TUG test)
Walk-to-Chair (% Walk-to-Chair)	Time (s) taken to walk 3-metres back to chair after turn-at-goal and before turn-to-sit. (% out of Total TUG test)
Turn-to-Sit (% Turn-to-Sit)	Time (s) taken from start of turn at chair to seated position. (% out of Total TUG test)
Step Count ( $SC_{OP}$ , $SC_{CON}$ , $SC_{TOT}$ )	Number of gait cycles (swing and stance phases) of the operative knee, contralateral knee, or in total during the walking segments of the TUG.
<b>Velocity &amp; Acceleration</b>	
Average Step: Flex. Velocity	Average flexion angular velocity ( $^{\circ}/s$ ) of swing phase of gait cycle for the average step of the TUG test walking segments.
Average Step: Ext. Velocity	Average extension angular velocity ( $^{\circ}/s$ ) of swing phase of gait cycle for the average step of the TUG test walking segments.
Average Step: Flex. Acceleration	Average flexion angular acceleration ( $^{\circ}/s^2$ ) of swing phase of gait cycle for the average step of the TUG test walking segments.
Average Step: Ext. Acceleration	Average extension angular acceleration ( $^{\circ}/s^2$ ) of swing phase of gait cycle for the average step of the TUG test walking segments.
<b>Angular</b>	
Start-TUG: Flex./Ext. Angle	Angle ( $^{\circ}$ ) of operative or contralateral knee while sitting just prior to starting the test.
End-TUG: Flex./Ext. Angle	Angle ( $^{\circ}$ ) of operative or contralateral knee while sitting when settled after the test.
Sitting-to-Loading: Flex./Ext. Range	Angle range ( $^{\circ}$ ) of operative or contralateral knee when transitioning from a settled sitting position to a ready-to-load position for standing up.

Average Step: Max. Flex. Angle	Maximum flexion angle ( $^{\circ}$ ) of the operative or contralateral knee for the average step of the TUG test walking segments.
Average Step: Flex. Range	Angle range ( $^{\circ}$ ) from the start of the swing phase of the gait cycle to the maximum step flexion of the operative or contralateral knee for the average step of the TUG test walking segments.
TUG Test: Additive Angular Displacement ( $TAAD_{OP}^{F/E}$ , $TAAD_{CON}^{F/E}$ , $TAAD_{OP}^{I/E}$ , $TAAD_{CON}^{I/E}$ , $TAAD_{OP}^{V/V}$ , $TAAD_{CON}^{V/V}$ )	General motion of knee joint in degrees ( $^{\circ}$ ) over the entire TUG test in <i>single axes of rotation</i> (flexion/extension, internal/external rotation, varus/valgus) for operative- and contralateral -limbs.
TUG Test: Additive Angular Displacement ( $TAAD_{OP}^{Low}$ , $TAAD_{CON}^{Low}$ , $TAAD_{OP}^{Up}$ , $TAAD_{CON}^{Up}$ )	General motion of limb segments (ie. lower sensor = shank, upper sensor = thigh) in degrees ( $^{\circ}$ ) over the entire TUG test in <i>all axes of rotation</i> for operative- and contralateral-limbs.
Average Step: Additive Angular Displacement ( $SAAD_{OP}^{F/E}$ , $SAAD_{CON}^{F/E}$ , $SAAD_{OP}^{I/E}$ , $SAAD_{CON}^{I/E}$ , $SAAD_{OP}^{V/V}$ , $SAAD_{CON}^{V/V}$ )	General motion of knee joint in degrees ( $^{\circ}$ ) over an averaged gait cycle in <i>single axes of rotation</i> (flexion/extension, internal/external rotation, varus/valgus) for operative- and contralateral -limbs.
Average Step: Additive Angular Displacement ( $SAAD_{OP}^{Low}$ , $SAAD_{CON}^{Low}$ , $SAAD_{OP}^{Up}$ , $SAAD_{CON}^{Up}$ )	General motion of limb segments (ie. lower sensor = shank, upper sensor = thigh) in degrees ( $^{\circ}$ ) over an averaged gait cycle in <i>all axes of rotation</i> for operative- and contralateral-limbs.

Novel metrics identified from this experiment were calculated using sensor orientations and were based on values of flexion/extension, internal/external rotation, varus/valgus rotation, and tri-axial movement of operative- and contralateral-limbs and lower and upper sensors (**Table 4**). An Additive Angular Displacement (AAD) was calculated by summing the differences in angles from one sampling point to the next over a given sampling period (such as over a gait cycle). Patients with greater motion during the sampling period will have higher AAD values. The flexion/extension, internal/external rotation, and varus/valgus AADs utilized angular differences between the lower and upper sensors about these single axes of rotations; these were calculated for both the operative- and contralateral-knees ( $AAD_{OP}^{F/E}$ ,  $AAD_{CON}^{F/E}$ ,  $AAD_{OP}^{I/E}$ ,  $AAD_{CON}^{I/E}$ ,  $AAD_{OP}^{V/V}$ ,  $AAD_{CON}^{V/V}$ ). The tri-axial AADs were calculated using each individual sensor's 3D orientation separately, therefore AADs specific to the lower and upper sensors were calculated for the operative- and contralateral-limbs ( $AAD_{OP}^{Low}$ ,  $AAD_{CON}^{Low}$ ,  $AAD_{OP}^{Up}$ ,  $AAD_{CON}^{Up}$ ). The displacements summed in these cases were the angles needed to transform a sensor's orientation at a sampling point to the orientation at the next sampling point using the shortest 3D rotation about as single, unconstrained axis. The sampling periods over

which the AAD metrics were summed were either over the entire TUG test or over an averaged step (TAAD and SAAD, respectively).

### 3.2.5 Statistical Analysis

GraphPad Prism 7 was used to perform statistical operations. Correlations between sensor-derived metrics and PROMs were calculated with the non-parametric Spearman's correlation coefficient ( $\rho$ ).<sup>24</sup> Correlations in this study were qualified as weak (0.20-0.39), moderate (0.40-0.59), strong (0.60-0.79), or very strong (0.80-1.0). Additionally, participants were grouped by sex, body mass index (BMI), implant type, and satisfaction scores. Male and female subjects were identified and grouped. BMI was divided into scores less than 30 and 30 or greater, in which a BMI greater than this score represents obesity. Subject implant types were divided into posterior stabilized (PS) and cruciate retaining (CR) implant groups. KSS satisfaction scores were divided midway, with the satisfied and unsatisfied groups corresponding to approximate questionnaire answers of "Very Satisfied" or "Satisfied," and "Neutral," "Dissatisfied" or "Very Dissatisfied," respectively. Differences in PROMs or sensor metrics between groups were determined using parametric t-tests for normally distributed data and non-parametric t-tests were used for non-normally distributed data. Receiver-operator characteristic (ROC) curves and area under the curve (AUC) were calculated for outcome measures that were significantly different between satisfaction groups.

## 3.3 Results

Comparing PROMs and patient demographics to sensor metrics demonstrated statistically significant correlations between subjective and objective function. A table of means, standard deviations, minimums, and maximums for all metrics are presented in **Appendix A**. Weak and moderate significant correlations were observed between the segmented TUG test times and PROMs (**Table 5**), and more moderate correlations were observed for the total TUG time and walking time segments specifically. Similarly, angular sensor metrics based on the total TUG and the walking segments of the TUG test displayed moderate significant correlations to PROMs (**Table 6**). Sensor metrics shown in **Table 6** were selected due to their more consistent significant correlations with PROMS. A complete

matrix of Spearman correlations between all measures of patient characteristics, PROMs, and sensor metrics can be observed in **Appendix B**.

**Table 5: Spearman ( $\rho$ ) correlation matrix of PROMs versus temporal sensor metrics. Moderate or greater correlations are denoted in bold and insignificant correlations are not shown.**

Spearman ( $\rho$ )	Total TUG	Sit-to-Stand	Walk-to-Goal	Turn-at-Goal	Walk-to-Chair	Turn-to-Sit
UCLA	<b>-0.48</b>	<b>-0.53</b>	-0.36	-0.37	-0.38	-0.29
SF-12 Mental	-0.28	-0.27	-0.22		-0.26	
SF-12 Physical	<b>-0.49</b>	-0.37	<b>-0.47</b>	-0.32	<b>-0.45</b>	-0.32
WOMAC Pain	-0.33		-0.38	-0.24	-0.35	-0.27
WOMAC Stiffness	-0.30	-0.23	-0.39		-0.27	
WOMAC Function	<b>-0.48</b>	-0.36	<b>-0.56</b>	-0.39	<b>-0.47</b>	-0.34
WOMAC Total	<b>-0.43</b>	-0.32	<b>-0.52</b>	-0.31	<b>-0.44</b>	-0.30
KSS Symptoms	-0.38		-0.37	-0.22	-0.38	-0.26
KSS Satisfaction	<b>-0.46</b>	-0.37	<b>-0.46</b>	-0.25	<b>-0.44</b>	-0.34
KSS Expectations	-0.34	-0.32	-0.31		-0.33	-0.30
KSS Function	<b>-0.56</b>	<b>-0.53</b>	<b>-0.43</b>		<b>-0.47</b>	<b>-0.58</b>
KSS Objective Indicators						-0.26
Knee Eval. Function	-0.40	-0.32	-0.39		-0.39	-0.27
Knee Eval. Total Knee	-0.29		-0.33		-0.29	
Knee Eval. Total	<b>-0.43</b>	-0.34	<b>-0.45</b>		<b>-0.42</b>	-0.32



**Table 6: Spearman ( $\rho$ ) correlation matrix of PROMs versus selected sensor metrics. Moderate or greater correlations are denoted in bold and insignificant correlations are not shown.**

Spearman ( $\rho$ )	Step Count (SC)			Total TUG: AAD <sup>F/E</sup>		Total TUG: AAD <sup>Low</sup>		Total TUG: AAD <sup>Up</sup>		Average Step: AAD <sup>F/E</sup>		Average Step: AAD <sup>Low</sup>		Average Step: AAD <sup>Up</sup>	
	OP	CON	TOT	OP	CON	OP	CON	OP	CON	OP	CON	OP	CON	OP	CON
UCLA Activity	-0.35	-0.28	-0.34	-0.32	-0.24	<b>-0.4</b>	<b>-0.43</b>	-0.39	<b>-0.4</b>	0.22	0.32	0.38	0.35	0.37	0.33
SF-12 Mental										0.32	0.24	0.26	0.3	0.34	0.29
SF-12 Physical	<b>-0.54</b>	-0.38	<b>-0.49</b>	<b>-0.49</b>	-0.36	-0.34	-0.33	-0.32	-0.34			<b>0.49</b>	<b>0.48</b>	<b>0.47</b>	<b>0.46</b>
WOMAC Pain	<b>-0.44</b>	-0.25	-0.36	-0.22	-0.23					0.27		0.35	0.36	0.39	0.37
WOMAC Stiffness	<b>-0.42</b>	-0.25	-0.37	-0.22							0.37	0.32	0.32	0.39	0.29
WOMAC Function	<b>-0.6</b>	<b>-0.43</b>	<b>-0.57</b>	-0.36	-0.36	-0.33	-0.26			0.3		<b>0.49</b>	<b>0.5</b>	<b>0.53</b>	<b>0.47</b>
WOMAC Total	<b>-0.57</b>	-0.38	<b>-0.52</b>	-0.31	-0.33	-0.26	-0.24			0.3		<b>0.47</b>	<b>0.47</b>	<b>0.51</b>	<b>0.45</b>
KSS Symptoms	<b>-0.46</b>	-0.33	-0.33	-0.32	-0.24	-0.31					0.24	0.37	0.37	0.31	0.39
KSS Satisfaction	<b>-0.45</b>	-0.29	-0.38	-0.32	-0.31	-0.26	-0.26	-0.24				<b>0.42</b>	<b>0.48</b>	<b>0.44</b>	<b>0.45</b>
KSS Expectations	-0.25	-0.26	-0.27		-0.27							0.29	0.28	0.34	0.3
KSS Function	<b>-0.56</b>		-0.39	-0.33		<b>-0.49</b>	<b>-0.45</b>	-0.37	<b>-0.4</b>	0.36	<b>0.47</b>	<b>0.42</b>	<b>0.45</b>	<b>0.43</b>	<b>0.4</b>
KSS Objective Indicators															
Knee Eval. Function	-0.29	-0.32	-0.31		-0.24					0.29	0.28	0.39	0.35	<b>0.41</b>	0.31
Knee Eval. Total Knee			-0.24			-0.26	-0.33		-0.3						
Knee Eval. Total	-0.32	-0.38	-0.36		-0.25	-0.26	-0.26	-0.24	-0.3	0.3	0.33	<b>0.41</b>	0.39	<b>0.44</b>	0.32

The only significant difference observed between the PROMs of the male (N = 31; age = 69±9 yrs; BMI = 31.7±6.9 kg/m<sup>2</sup>; PS:CR = 12:19) versus female (N = 51; age = 66±10 yrs; BMI = 65.9±10.1 kg/m<sup>2</sup>; PS:CR = 21:30) grouping was a greater number of males reporting a better UCLA Activity Score (6.3±1.5 vs. 5.3±1.7; p = 0.009). No significant differences in sensor metrics between male and female groupings were observed. Trends toward significant differences were observed in the contralateral limbs, where females had slightly greater SAAD<sub>CON</sub><sup>Low</sup> (130.7±23.1 vs. 122.5±17.9; p = 0.09) and SAAD<sub>CON</sub><sup>Up</sup> (93.0±20.6 vs. 84.6±16.8; p = 0.06).

For the BMI <30 group (N = 38; age = 69±10 yrs; M:F = 16:22; BMI = 26.6±2.7 kg/m<sup>2</sup>; PS:CR = 15:23), significantly more favourable PROMs and step counts were observed than the BMI ≥30 group (N = 44; age = 65±10 yrs; M:F = 15:29; BMI = 36.7±6.3 kg/m<sup>2</sup>; PS:CR = 18:26), as shown in **Table 7**.

**Table 7: Mean ± standard deviation values of PROMs and sensor metrics significantly different between BMI groups.**

Mean±SD	BMI < 30	BMI ≥ 30	p-value
UCLA Activity	6.2±1.4	5.3±1.8	p = 0.007
SF-12 Physical	44.5±7.6	37.2±11.9	p = 0.003
WOMAC Function	81.1±13.6	67.8±22.6	p = 0.01
WOMAC Total	79.8±13.3	68.5±21.7	p = 0.02
SC <sub>TOT</sub> (#)	10.4±2.0	12.53.5	p = 0.005
SC <sub>OP</sub> (#)	5.4±1.0	6.4±1.8	p = 0.005
SC <sub>CON</sub> (#)	5.0±1.2	6.1±2.0	p = 0.003

No significant differences were observed between PS (N = 33; age = 65±12 yrs; M:F = 12:21; BMI = 32.7±8.7 kg/m<sup>2</sup>) and CR (N = 49, age = 68±8 yrs, M:F = 19:30; BMI = 31.6±5.8 kg/m<sup>2</sup>) groups for PROMs or sensor metrics.

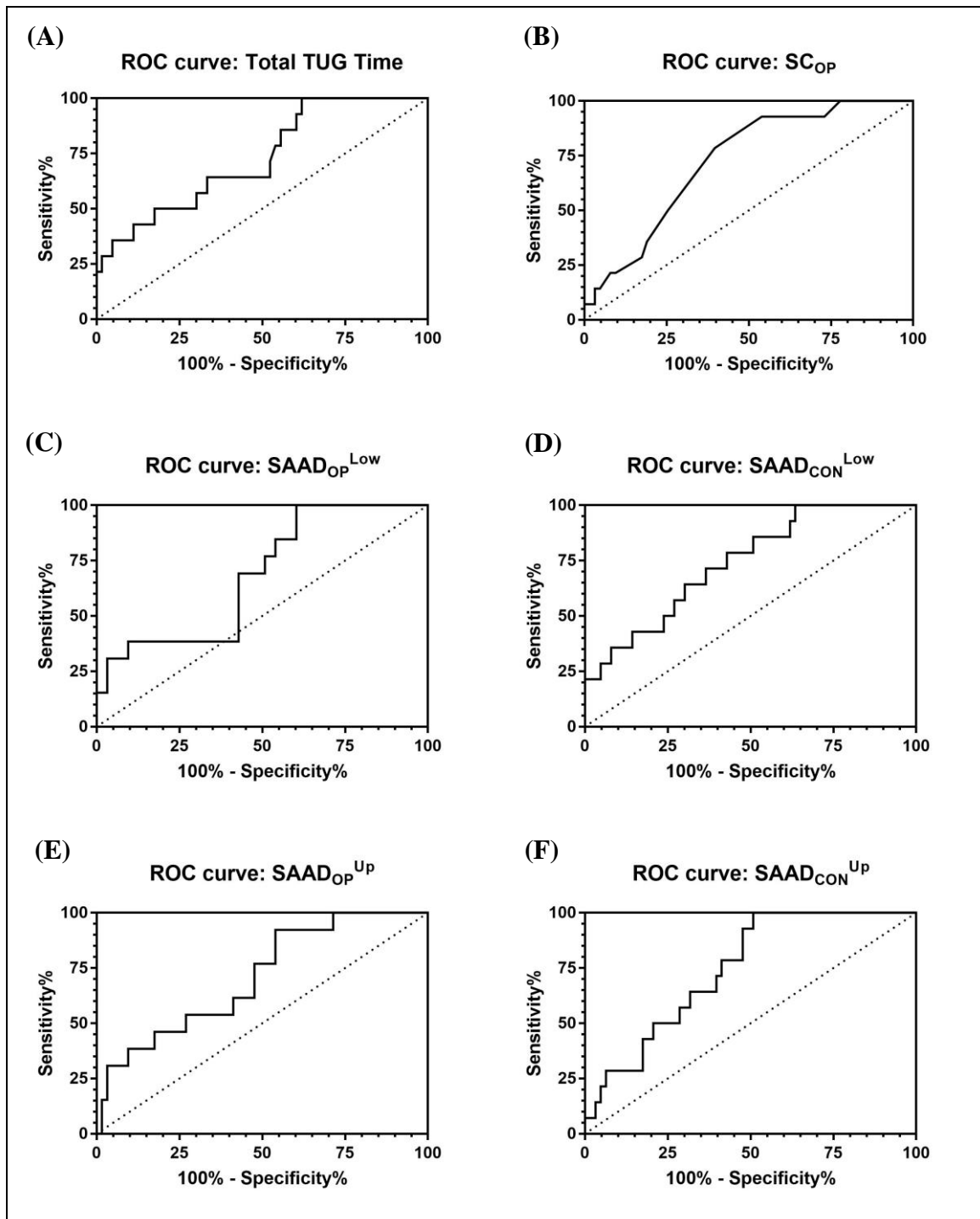
Significant differences between satisfied (N = 63; M:F = 25:38; PS:CR = 23:40) and unsatisfied (N = 14; M:F = 6:13; PS/CR = 8:6) patients were observed for patient characteristics, PROMs, and sensor metrics, with 18% of participants being unsatisfied. Variation in statuses of contralateral knees was observed for unsatisfied patients, ranging from no evidence of OA to indications for severe OA. 18% of patients also reported the highest possible score for satisfaction. Satisfied patients were older (68±9 vs. 58±10 yrs;

$p = 0.0004$ ) and had lower BMIs ( $31.2 \pm 6.0$  vs.  $37.4 \pm 9.8 \text{ kg/m}^2$ ;  $p = 0.02$ ). Satisfied patients demonstrated significantly more favourable PROMs and sensor metrics than their unsatisfied counterparts, as shown in **Table 8**.

**Table 8: Mean  $\pm$  standard deviation values of PROMs and sensor metrics significantly different between satisfied and unsatisfied patients.**

Mean $\pm$ SD	Satisfied	Unsatisfied	p-value
UCLA Activity	6.0 $\pm$ 1.5	4.0 $\pm$ 1.9	$p < 0.0001$
SF-12 Mental	56.1 $\pm$ 7.3	46.6 $\pm$ 12.8	$p = 0.005$
SF-12 Physical	43.1 $\pm$ 9.8	31.4 $\pm$ 8.2	$p < 0.0001$
WOMAC Pain	82.6 $\pm$ 16.1	53.2 $\pm$ 20.9	$p < 0.0001$
WOMAC Stiffness	72.0 $\pm$ 16.4	47.3 $\pm$ 29.5	$p = 0.0003$
WOMAC Function	79.1 $\pm$ 16.2	52.3 $\pm$ 20.0	$p < 0.0001$
WOMAC Total	79.1 $\pm$ 14.7	51.6 $\pm$ 18.3	$p < 0.0001$
KSS Symptoms	22.6 $\pm$ 3.8	17.7 $\pm$ 4.2	$p = 0.0002$
KSS Expectations	10.2 $\pm$ 2.9	5.1 $\pm$ 1.6	$p < 0.0001$
KSS Functional Activities	71.3 $\pm$ 16.3	41.4 $\pm$ 18.5	$p < 0.0001$
Total TUG (s)	12.1 $\pm$ 3.4	17.1 $\pm$ 6.8	$p = 0.007$
SC <sub>OP</sub> (#)	5.7 $\pm$ 1.4	6.9 $\pm$ 2.1	$p = 0.01$
SAAD <sub>OP</sub> <sup>Low</sup> (°)	130.1 $\pm$ 21.3	114.1 $\pm$ 23.2	$p = 0.02$
SAAD <sub>CON</sub> <sup>Low</sup> (°)	132.0 $\pm$ 20.7	112.0 $\pm$ 20.6	$p = 0.002$
SAAD <sub>OP</sub> <sup>Up</sup> (°)	91.9 $\pm$ 18.7	77.4 $\pm$ 17.2	$p = 0.01$
SAAD <sub>CON</sub> <sup>Up</sup> (°)	93.6 $\pm$ 19.8	76.8 $\pm$ 13.4	$p = 0.003$

For the ROC curves of the satisfied versus unsatisfied patients, the AUCs for the Total TUG time and SC<sub>OP</sub> were 0.72 and 0.72. The AUCs of the SAAD<sub>OP</sub><sup>Low</sup>, SAAD<sub>CON</sub><sup>Low</sup>, SAAD<sub>OP</sub><sup>Up</sup>, and SAAD<sub>CON</sub><sup>Up</sup> were 0.68, 0.74, 0.71, and 0.74, respectively. The ROC curves can be observed in **Figure 9**. Total TUG times greater than 11 s were sensitive to 100% of unsatisfied patients and specific to 38%. For 100% sensitivity to unsatisfied patients, values of the SAAD<sub>OP</sub><sup>Low</sup> and SAAD<sub>CON</sub><sup>Up</sup> less than 138° and 94°, respectively, had specificity of 40% and 49%. The other sensor metrics had reduced specificity in comparison.



**Figure 9: Satisfaction ROC curves for (A) Total TUG Time, (B)  $SC_{OP}$ , (C)  $SAAD_{OP}^{Low}$ , (D)  $SAAD_{CON}^{Low}$ , (E)  $SAAD_{OP}^{Up}$ , and (F)  $SAAD_{CON}^{Up}$ .**

### 3.4 Discussion

This study has demonstrated that quantitative metrics derived from the sensor-instrumented TUG test significantly correlate to several PROMs of post-TKA patients. While most significant correlations between PROMs and sensor metrics were weak or moderate correlations, strong correlations were not anticipated due the subjective versus objective nature of the two data collection types. Previously, Bolink et al. described the potential for performance-based measures to objectively capture changes in physical function of TKA patients.<sup>24</sup> The correlations observed in this study further emphasize the natural connection between PROMs and functional movement. However, the predominantly moderate correlations also draw attention to the superficial understanding of function that PROMs are able to reveal.

Timed segments of the TUG test significantly correlated to PROMs. While significant correlations were observed for all time segments of the TUG test with PROMs, the Total TUG time and the Walk-to-Goal and Walk-to-Chair time segments moderately correlated with PROMs more often. Specifically, these three temporal metrics moderately correlated with the SF-12 Physical score, the WOMAC Function and WOMAC Total scores, the KSS Satisfaction and KSS Function scores, and the Objective Knee Evaluation Total score. The greater correlations of the walking components with PROMs suggests the reliance of these subjective outcomes to a patient's walking ability, which has been previously observed.<sup>25</sup> The total time and walk time of the TUG test have also been previously found to have strong test-retest reliability in a study of older adults.<sup>16</sup> In this study these temporal segments were derived from the instrumented sensors with minimal computation and could be easily be implemented with other sensing units to reliably provide objective measures of function.

Step counts significantly correlated with several PROMs and were simple to identify. The SC<sub>OP</sub> and SC<sub>TOT</sub> were more correlated than the Total TUG time to the SF-12 Physical score and all WOMAC scores. The SC<sub>OP</sub> had greater correlations with function-based PROMs than the SC<sub>TOT</sub>. This again highlights the importance of walking to subjective function.<sup>25</sup> The SC<sub>CON</sub> was less correlated to PROMs than the SC<sub>OP</sub> and SC<sub>TOT</sub> scores, which may in part be due to the focus of some questionnaires on the operative-limb as well as the

influence of patients' operative-limbs on their perceived health. Novel sensor metrics were also identified that significantly correlated with PROMs. AADs of the total TUG and the average step represent more general angular motion and the AADs of the lower and upper sensors, specifically, represent motion of the thighs and calves, respectively. The step-based AADs significantly correlated with all PROMs, while sensor metrics related to velocity, acceleration, or AADs about a singular axis or over the total TUG did not significantly correlate as consistently or had weaker correlations with PROMs. The step-based AADs, walking time segments, and operative-limb step counts had the greatest correlations of all the sensor metrics to satisfaction, which emphasizes the influence of walking ability on patient-reported outcomes.

In addition to correlations of parameters, data were also grouped to identify any significant differences. Patients were first grouped by sex, as kinematic differences have been previously described between male and female TKA patients.<sup>26, 27</sup> In this study no significant differences in the sensor metrics were observed between males and females. However, trends towards significance in the  $SAAD_{CON}^{Low}$  and  $SAAD_{CON}^{Up}$  were observed, showing females having greater motion of their contralateral-limbs. This may relate to previously observed differences in quadriceps strength between male and female TKA patients,<sup>27</sup> or perhaps greater knee abduction and hip adduction found in OA females than males.<sup>28</sup> This finding of slight differences in biomechanics between the sexes may influence the satisfaction of males versus females due to this metric's correlations to satisfaction and other PROMs. Further study of this effect may be of benefit for consideration of sex-specific differences to therapeutic intervention.

Grouping patients according to BMI showed anticipated differences in general health and physical function (SF-12 Physical, WOMAC Function, WOMAC Total). This grouping also showed significant differences in step counts, where the larger BMI group took more steps to complete the TUG test. This reinforces the connection of BMI to function, which has been reported on previously.<sup>29</sup> While subjective function has been associated with satisfaction,<sup>1</sup> and step counts in this current study are correlated to reported satisfaction, the connection of BMI to satisfaction is not as clear. Satisfaction is complex and some literature has not found differences in BMI between satisfied and unsatisfied patients.<sup>1</sup> In

patients moderately dissatisfied an elevated BMI has previously been associated, although the same association was not observed with more severe dissatisfaction.<sup>3</sup> The connection of satisfaction to BMI may be composite in nature, where a higher BMI does not necessarily lead directly to dissatisfaction.

When grouping implant types into PS and CR, no discernable differences were observed. This aligns with disagreement in the literature surrounding the benefit of either implant type over the other.<sup>30</sup> Proof of distinct clinical advantage of the PS or CR implant types has yet to be resolved.

When grouping satisfied and unsatisfied patients, significant differences were observed in patient characteristics, PROMs, and sensor metrics. This reinforces the multi-factor nature of patient satisfaction as previously described,<sup>1, 3, 29</sup> and also highlights the potential diversity of patients reporting that they are unsatisfied. The finding that unsatisfied patients were younger in this study is unexpected and worrying since, consequentially, this suggests that younger patients may live longer with a TKA that they are not satisfied with. A weak direct relationship between age and satisfaction was observed in this study, while weak inverse relationships were observed in conflicting studies.<sup>1, 29</sup> Bourne et al. reported mean ages of 68 and 70 for satisfied and unsatisfied patients, while in this study the mean age for satisfied patients was also 68, the mean age for unsatisfied patients was 60. This finding may be due to a difference in population age distributions between studies, or a surgeon-specific difference in proportion of younger patients with more risk factors present.

The satisfied group of patients also had lower BMIs, though the mean was above the threshold for obesity. As mentioned previously, the relationship between satisfaction and BMI may not be explicit, considering a significant correlation between the two factors was not observed despite finding a significant difference between satisfied and unsatisfied patients. Satisfied patients were more active, which aligns with previous research,<sup>31</sup> and indicates that facilitating healthy-active living would improve TKA outcomes. Factors of pain, stiffness, function, and symptoms were also identified as influencing satisfaction in this study, as supported by previous literature.<sup>1, 3</sup> The ceiling effect observed with the satisfaction score should also be mentioned, where a ceiling effect is described as  $\geq 15\%$

scoring the highest possible score.<sup>4</sup> Potential causes of this effect could be ambiguity of the survey questions, inadequate survey answer options, patients seeking to please their surgeon, or perhaps true satisfaction. These effects may have skewed the number of truly unsatisfied patients.

The influence of function on satisfaction was also observed in the significant differences of sensor metrics between satisfied and unsatisfied patients. The sensor metrics observed to differ between satisfied and unsatisfied patients were measures that described motion in more general terms, with walking-based metrics showing greater correlations. The most specific sensor metrics observed to identify unsatisfied patients with maximum sensitivity were the Total TUG time, SAAD<sub>OP</sub><sup>Low</sup>, and SAAD<sub>CON</sub><sup>Up</sup>. The correlation of contralateral-limb metrics to satisfaction suggests the importance of the function of the contralateral knee on patient outcomes. Both the operative- and contralateral-limbs play a part in the satisfaction of patients, and the implementation of sensors with the TUG test may allow detection of specific functional deficiencies that can be targeted as areas for therapeutic intervention. These metrics have the potential to be used in orthopedic clinics to identify patients that are at risk of dissatisfaction due to poor function. The TUG test could be implemented in clinics with a simple stopwatch to screen for at-risk patients with the Total TUG time, while sensor-implemented TUG tests could identify at-risk patients with greater specificity with the step-based AADs.

This study was limited by several modifiable and unmodifiable factors that are worth attention when interpreting results. The population included in this experiment was from a single site and may differ from other populations. It should also be noted that while the booklet of questionnaires given to the patients was standard practice for their appointments, the entirety of the booklet was not always fully completed. This was likely due to the mental and time burdens required to fill out the questionnaires, and this resulted in fewer outcome measures from surveys that were further into the booklet. As well, wearable technology is subject to skin motion artifacts that may add noise that disrupts kinematic measurement signals, which may reduce correlations of metrics detected by the sensors. As well, one participant of this study had an irregular stance phase of the gait cycle for their operative knee and the sensor software was unable to autonomously segment and



correctly identify step-based metrics for that limb. Thus step-based data for the limb of that patient was excluded. This presents an area for improvement in our sensor software that will need to be addressed for future studies. This case series study reported on single patient time points rather than following patients at pre- and post-TKA time points to monitor outcomes over time and their relationship to pre-TKA function. The sensor metrics derived in this experiment are values that were suspected to be of importance by the authors. In the future, a machine learning-based approach to determine identifiers may prove to be advantageous in classifying patient outcomes.

In conclusion, PROMs are an important tool that allows for patient input on their own experiences, though the nature of these tools do not necessarily illuminate areas where intervention may be beneficial. Novel sensor metrics were identified that moderately correlated with PROMs, indicating an overlap of outcomes between subjective and objective measures of function. Walking-based parameters were more consistently correlated with PROMs, suggesting the importance of walking ability to the patient experience. This experiment also identified significant differences in sensor metrics between satisfied and unsatisfied TKA patients. Quantitative measures of function that are descriptive of specific movement may provide added value to the TKA outpatient process through detection of biomechanical deficiencies and identification of patients at risk for dissatisfaction. With the integration of a sensor-implemented functional test that is representative of daily activities into the clinical procedure, outcomes of function and satisfaction may be improved through targeted therapeutic intervention.

### 3.5 References

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## Chapter 4

### 4 Conclusions and Future Directions

#### 4.1 Overview of Objectives

The physical and economic impacts of osteoarthritis (OA) globally and in Canada put a heavy burden on the healthcare system and patient quality of life.<sup>1-3</sup> The projected increase of patients affected by this disease will only serve to exacerbate the consequences of OA.<sup>4</sup> While total knee arthroplasty (TKA) is widely considered a successful solution for end-stage OA, many patients are not satisfied with the outcomes of their surgery.<sup>5-7</sup> Satisfaction and subjective function has been recently associated.<sup>8</sup> However, quantitative function in TKA patients is not fully understood, perhaps due to the multi-factor nature of satisfaction. The overarching goal of this thesis was to introduce wearable technology into a clinical setting with TKA patients to identify quantitative function that relates to the patient experience of outcome. The specific objectives tested included validation of a sensor setup's ability to measure knee joint angles in a controlled environment, followed by implementation of the sensors in a population of post-TKA patients during TUG functional tests to derive novel quantitative and function metrics relating to patient-reported outcome measures (PROMs).

#### 4.2 Summary of Results

In Chapter 2 of this thesis, the ability of an IMU sensor setup to collect joint flexion angles was assessed in comparison to an electro-goniometer and a 3D motion capture camera system. Repeatability of knee joint flexion angles and the effects of speed and placement on the IMUs using the same lab and operator was investigated. Maximum and minimum flexion values were detected, and all sensing modalities demonstrated standard deviations of less than  $\pm 0.6^\circ$  in angles within each individual test, while keeping speed and position constant. This should provide acceptable precision in reporting knee joint angles within short functional tests. Speed and positioning effects were observed between tests when these factors were varied. All changes in flexion angle due to speed were less than  $3^\circ$  and the greatest difference in maximum/minimum IMU flexion angles due to re-positioning was  $4.7^\circ$ . Currently in clinics, flexion/extension range of motion in TKA patients is

measured using a manual goniometer which has a standard error of measurement (SEM) of  $4.1^{\circ}$ .<sup>9</sup> The greatest re-positioning difference of the IMUs is comparable to this value, which may correspond to a slightly greater minimal detectable change in range of motion for TKA patients.

In Chapter 3, IMUs were implemented alongside the TUG test in a population of 1- and 2-year post-TKA patients to identify new, descriptive, functional metrics related to PROMs. This experiment demonstrated many significant moderate correlations of quantitative sensor metrics derived from the TUG test to PROMs. These correlations emphasize the overlap of subjective and objective function, while also revealing the innate differences between patient experience and quantitative function. Novel metrics defined as step-based Additive Angular Displacements (AADs) consistently demonstrated significant moderate correlations with PROMs. These metrics describe general motion that is specific to the lower or upper limbs. Walking-based measures of function – step-based AADs, walking time segments, and operative-limb step counts – were observed to have greater significant correlations to satisfaction, highlighting the importance of walking to patient outcomes. Implementation of sensors with the TUG test may allow detection of specific functional deficiencies in walking that can be targeted as areas for therapeutic intervention to improve the patient experience.

## 4.3 Future Directions

### 4.3.1 Continuation of TKA Studies

For the scope of this master's thesis a single timepoint of post-TKA patients was collected to assess the potential of a sensor-instrumented TUG test as a source for quantitative functional outcome measures. While this provided important insight into the value of new sensor metrics and their potential for improvement of the patient experience, this study did not touch on the capability of this method to monitor patients over time. Bolink et al. has previously assessed TKA patients pre-operatively and 1-year post-operatively using performance-based tests and a single sensor attached to the low back.<sup>10</sup> This study provided insight into the magnitude of change that occurs from pre- to post-TKA and relationships to PROMs, though it did not provide information on early post-TKA changes or specific

functional movements of the limb segments. As part of studies that are currently underway, we have collected sensor-instrumented TUG test data for patients at pre-TKA, and 2-weeks, 6-weeks, 6-months, and 1-year post-TKA timepoints. These studies aim to assess the ability of the novel sensor metrics identified in this thesis to monitor specific quantitative outcomes of function in relation to PROMs. By comparing functional data before and at several points after TKA, we may be able to better understand how TKA affects functional motion and identify specific functional motion that is associated with greater satisfaction over time. This will provide a more complete understanding of the changes to knee function in TKA patients, how this function influences the patient experience, and perhaps identify when early therapeutic intervention may be beneficial.

#### 4.3.2 At-Home Monitoring

The sensor instrumentation outlined in this thesis could be easily implemented into orthopedic clinics to monitor and assess function, but another exciting application is at-home assessment of rehabilitation exercises and function. Similarly, at-home “serious” games are being developed to target musculoskeletal rehabilitation using a Kinect camera system and IMUs.<sup>11, 12</sup> A simple at-home application of the sensor system presented in this thesis could be to assess the quantitative functional outcomes of the TUG test for patients who are unable to make it to appointments. Further in the future this system could be used to assess and monitor common physiotherapy exercises prescribed to TKA patients or other performance-based tests. An at-home system could help to facilitate physiotherapy and identify patients with functional deficiencies who may need further therapeutic intervention. This potential application could improve the outcomes of TKA patients who live in remote areas, do not have access to transportation, or have other barriers to attending appointments.

#### 4.3.3 Classification through Machine Learning

An important component of this thesis was the development of metrics from the data collected by the wearable sensors that related to the function and satisfaction of TKA patients. Creating metrics to classify function and satisfaction in this way is limited by human imagination. Machine learning is a new and expanding field of research which takes

advantage of computer algorithms to learn complicated patterns from data which can be applied to predict diagnosis, outcomes, or risks in medical applications.<sup>13</sup> Machine learning is being applied across a variety of disciplines and has made its way to orthopedics.<sup>13</sup> Machine learning techniques have recently been implemented to classify OA patients from controls using ground reaction force data,<sup>14</sup> and 3D gait analysis.<sup>15</sup> Kinematic classifiers identified by machine learning from 3D gait analysis also correlated to the WOMAC function score.<sup>15</sup> While satisfaction in TKA is much more subjective than a diagnosis of OA, machine learning has the potential to determine relationships between kinematic data and subjective scores. The use of machine learning towards this application could be of great benefit in improving PROMs and the patient experience.

#### 4.4 Conclusions

This thesis endeavoured to ascertain relationships between quantitative function and the patient experience of TKA outcomes using wearable technology. Knee flexion angle was originally targeted as an outcome measure in the validation of the IMUs since it is commonly recorded in orthopedic clinics. However, differences in positioning of the IMUs may influence the angles detected due to motion about other axes of rotation, as observed in Chapter 2. This observation may have contributed to weaker correlations of flexion/extension sensor metrics to PROMs in Chapter 3 compared to the greater correlations observed for sensor metrics describing motion in all axes of rotation. This thesis provided strong evidence towards the connection between quantitative functional motion and the patient experience, and importantly, sensor metrics may be able to determine patients at risk for dissatisfaction due to functional deficiencies. By implementing sensor-instrumented functional tests representative of daily activities into orthopedic clinics, outcomes of function and satisfaction may be improved through targeted therapeutic intervention.



## 4.5 References

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## Appendix

### Appendix A: PROMs and Sensor Metrics Table of Values

		Mean	SD	Min.	Max.
	Age	67.1	10.0	43.0	88.0
<u>Subject Characteristics</u>	Height (cm)	169.1	9.8	152.0	195.0
	Weight (kg)	91.8	23.5	52.2	186.2
	BMI	32.0	7.1	18.3	57.5
<u>UCLA Activity</u>	UCLA Activity	5.7	1.7	2.0	9.0
<u>SF-12</u>	Mental	54.2	9.3	21.7	67.0
	Physical	41.0	10.4	18.6	57.8
	Pain	77.5	20.3	15.0	100.0
<u>WOMAC</u>	Stiffness	67.8	21.6	0.0	100.0
	Function	74.4	19.6	16.2	100.0
	Total	74.3	18.6	12.3	100.0
	Symptoms	21.7	4.3	11.0	29.0
	Satisfaction	30.0	9.2	0.0	40.0
<u>KSS</u>	Expectations	9.3	3.3	3.0	15.0
	Func. Activities	64.8	20.8	17.0	98.0
	Obj. Indicators	60.7	8.4	25.0	74.0
	Function	84.4	18.4	20.0	100.0
<u>Objective Knee Evaluation</u>	Total Knee	92.8	10.0	46.0	100.0
	Total	177.2	25.5	66.0	200.0
	Total TUG	13.1	4.5	7.1	29.8
	Sit-to-Stand	1.5	1.8	0.5	11.7
	Walk-to-Goal	3.6	1.2	1.3	7.9
	Turn-at-Goal	0.6	0.2	0.0	1.7
	Walk-to-Chair	4.8	1.8	2.5	11.8
<u>Temporal TUG Segments</u>	Turn-to-Sit	1.9	0.7	1.0	4.5
	% Sit-to-Stand	10.4	7.8	4.3	51.0
	% Walk-to-Goal	28.3	3.6	8.6	33.8
	% Turn-at-Goal	4.7	1.7	0.0	8.9
	% Walk-to-Chair	36.9	4.1	19.9	46.8
	% Turn-to-Sit	14.8	2.9	7.6	20.9
<u>Start-TUG:</u>	Op.	83.3	13.3	49.3	109.8
<u>Flex./Ext. Angle</u>	Con.	88.0	12.6	59.0	114.4
<u>End-TUG:</u>	Op.	81.3	11.9	52.5	103.5
<u>Flex./Ext. Angle</u>	Con.	86.3	14.1	55.0	136.0
<u>Sitting-to-Loading:</u>	Op.	5.9	5.7	0.0	26.3
<u>Flex./Ext. Range</u>	Con.	6.0	5.7	0.0	30.4

		Mean	SD	Min.	Max.
<u>Walking TUG</u>	Op.	5.9	1.6	3.3	13.0
<u>Segments:</u>	Con.	5.6	1.8	2.3	14.0
<u>Step Count</u>	Total	11.5	3.1	6.3	27.0
<u>Total TUG:</u>	Op.	755.8	127.3	512.7	1128.0
<u>AAD Flex./Ext.</u>	Con.	791.9	142.2	500.1	1291.0
<u>Total TUG: AAD</u>	Op.	427.4	134.0	226.5	857.0
<u>Int./Ext. Rotation</u>	Con.	454.8	133.0	234.0	951.3
<u>Total TUG:</u>	Op.	251.4	75.5	123.3	648.4
<u>AAD Var./Val.</u>	Con.	280.1	148.8	135.2	1348.0
<u>Total TUG: AAD</u>	Op.	1171.0	129.7	823.5	1541.0
<u>(Lower Sensors)</u>	Con.	1185.0	133.5	845.0	1619.0
<u>Total TUG: AAD</u>	Op.	1037.0	102.7	840.0	1356.0
<u>(Upper Sensors)</u>	Con.	1055.0	110.9	801.6	1388.0
<u>Average Step:</u>	Op.	53.8	7.1	35.6	75.6
<u>Max. Flex. Angle</u>	Con.	55.0	9.3	30.6	97.4
<u>Average Step:</u>	Op.	40.9	7.2	26.3	67.9
<u>Flex./Ext. Range</u>	Con.	42.8	8.9	21.2	77.6
<u>Average Step:</u>	Op.	276.2	68.0	154.1	495.2
<u>Flex. Velocity</u>	Con.	288.0	75.7	119.0	479.3
<u>Average Step:</u>	Op.	267.0	70.1	123.3	470.5
<u>Ext. Velocity</u>	Con.	291.2	80.9	119.6	557.9
<u>Average Step:</u>	Op.	4740.0	1800.0	1382.0	9513.0
<u>Flex. Acceleration</u>	Con.	5106.0	1925.0	1144.0	10451.0
<u>Average Step:</u>	Op.	4782.0	1792.0	1744.0	11076.0
<u>Ext. Acceleration</u>	Con.	5175.0	1905.0	1698.0	8720.0
<u>Average Step:</u>	Op.	85.8	15.0	55.7	138.1
<u>AAD Flex./Ext.</u>	Con.	90.0	17.8	45.1	141.1
<u>Average Step: AAD</u>	Op.	41.6	14.3	16.0	80.5
<u>Int./Ext. Rotation</u>	Con.	43.2	14.4	20.2	97.1
<u>Average Step:</u>	Op.	25.3	9.3	9.5	60.4
<u>AAD Var./Val.</u>	Con.	28.2	21.1	11.8	201.3
<u>Average Step: AAD</u>	Op.	126.8	22.1	78.7	176.0
<u>(Lower Sensors)</u>	Con.	127.6	21.6	75.7	177.0
<u>Average Step: AAD</u>	Op.	89.0	18.9	52.9	130.9
<u>(Upper Sensors)</u>	Con.	89.8	19.6	52.8	138.4

## Appendix B: Correlations of PROMs and Sensor Metrics

Spearman's correlations ( $\rho$ ) in the following tables have been colour-coded as very strong, strong, moderate, and weak in black, medium grey, light grey, and white, respectively. Direct and inverse correlations are denoted by positive and negative signs, respectively. Non-significant correlations were left blank (no sign, no colour).

Spearman ( $\rho$ )		Average Step AAD (Upper Sensors)		Average Step AAD (Lower Sensors)		Average Step AAD Var./Val.		Average Step AAD Int./Ext. Rotation		Average Step AAD Flex./Ext.		Average Step Ext. Acceleration		Average Step Flex. Acceleration		Average Step Ext. Velocity		Average Step Flex. Velocity	
		Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.
<u>Subject Characteristics</u>	Age			-	-														
	Height (cm)																		
	Weight (kg)																		
	BMI							-											
<u>UCLA Activity</u>	Activity Score	+	+	+	+		+		+	+	+		+	+	+		+	+	+
<u>SF-12</u>	Mental	+	+	+	+					+	+			+	+		+	+	+
	Physical	+	+	+	+		+	+	+										
<u>WOMAC</u>	Pain	+	+	+	+		+	+											
	Stiffness	+	+	+	+						+								
	Function	+	+	+	+		+	+	+		+								+
	Total	+	+	+	+		+	+	+		+								
<u>KSS</u>	Symptoms	+	+	+	+														
	Satisfaction	+	+	+	+					+									+
	Expectations	+	+	+	+														+
	Func. Activities	+	+	+	+					+	+			+				+	+
	Obj. Indicators																		
<u>Objective Knee Evaluation</u>	Function	+	+	+	+					+	+						+		+
	Total Knee													+					
	Total	+	+	+	+					+	+			+		+		+	+
<u>Temporal TUG Segments</u>	Total TUG	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Sit-to-Stand	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Walk-to-Goal	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Turn-at-Goal	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Walk-to-Chair	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Turn-to-Sit	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	% Sit-to-Stand																		
	% Walk-to-Goal														+				+
	% Turn-at-Goal		+	+	+														
	% Walk-to-Chair	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
% Turn-to-Sit	+	+	+	+															
<u>Start-TUG: Flex./Ext. Angle</u>	Op.									+									
	Contra.						+	+											
<u>End-TUG: Flex./Ext. Angle</u>	Op.									+									+
	Contra.									+	+		+						+
<u>Sitting-to-Loading: Flex./Ext. Range</u>	Op.																		
	Contra.								+										

Spearman (ρ)		Average Step Flex./Ext. Range		Average Step Max. Flex. Angle		Total TUG: AAD (Upper Sensors)		Total TUG: AAD (Lower Sensors)		Total TUG: AAD Var./Val.		Total TUG: AAD Int./Ext. Rotation		Total TUG: AAD Flex./Ext.		Walking TUG Segments Step Count		Sitting-to-Loading Flex./Ext. Range	
		Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Total	Contra.	Op.	Contra.	Op.	
<u>Subject Characteristics</u>	Age																		
	Height (cm)					-	-	-	-										
	Weight (kg)																		-
	BMI			-		+	+	+		+						+	+	+	
<u>UCLA Activity</u>	Activity Score	+				-	-	-	-	-				-	-	-	-	-	
<u>SF-12</u>	Mental		+		+														
	Physical					-	-	-	-					-	-	-	-	-	
<u>WOMAC</u>	Pain		+											-	-	-	-	-	
	Stiffness		+		+									-	-	-	-	-	
	Function		+						-	-				-	-	-	-	-	
	Total		+		+				-	-				-	-	-	-	-	
<u>KSS</u>	Symptoms																		
	Satisfaction						-	-	-					-	-	-	-	-	
	Expectations													-	-	-	-	-	
	Func. Activities	+	+	+		-	-	-	-	-				-	-	-	-	-	
<u>Objective Knee Evaluation</u>	Obj. Indicators																		
	Function	+	+							-		-	-	-	-	-	-	-	
	Total Knee						-	-	-	-				-	-	-	-	-	
	Total	+	+			-	-	-	-	-			-	-	-	-	-	-	
<u>Temporal TUG Segments</u>	Total TUG	-	-	-		+	+	+	+	+				+	+	+	+	+	
	Sit-to-Stand	-	-	-		+	+	+	+			+	+		+	+	+	+	
	Walk-to-Goal	-	-		-	+	+	+	+	+				+	+	+	+	+	
	Turn-at-Goal													+	+	+	+	+	
	Walk-to-Chair	-	-			+	+	+	+	+				+	+	+	+	+	
	Turn-to-Sit	-	-	-		+	+	+	+	+					+	+	+	+	
	% Sit-to-Stand						+	+	+										
	% Walk-to-Goal																		
	% Turn-at-Goal						-	-	-	-									
	% Walk-to-Chair																+	+	+
% Turn-to-Sit																			-
<u>Start-TUG: Flex./Ext. Angle</u>	Op.	+		+		-		-											
	Contra.	+		+				-	-										
<u>End-TUG: Flex./Ext. Angle</u>	Op.	+		+		-		-	-										
	Contra.	+		+				-	-										
<u>Sitting-to-Loading: Flex./Ext. Range</u>	Op.																		+
	Contra.																		

Spearman (ρ)		End-TUG: Flex./Ext. Angle		Start-TUG: Flex./Ext. Angle		Temporal TUG Segments										Objective Knee Evaluation				
		Contra.	Op.	Contra.	Op.	% Turn-to-Sit	% Walk-to-Chair	% Turn-at-Goal	% Walk-to-Goal	% Sit-to-Stand	Turn-to-Sit	Walk-to-Chair	Turn-at-Goal	Walk-to-Goal	Sit-to-Stand	Total TUG	Total	Total Knee	Function	
<u>Subject Characteristics</u>	Age	+				+													+	
	Height (cm)	+	+	+	+	+				-					-					
	Weight (kg)																			
	BMI	-	-	-	-					+					+					
<u>UCLA Activity</u>	Activity Score	+	+	+	+					-	-	-	-	-	-	-	+		+	
<u>SF-12</u>	Mental	+																		
	Physical										-	-	-	-	-	-	+		+	
<u>WOMAC</u>	Pain										-	-	-	-	-	-	+	+	+	
	Stiffness										-	-	-	-	-	-	+	+	+	
	Function										-	-	-	-	-	-	+	+	+	
	Total										-	-	-	-	-	-	+	+	+	
<u>KSS</u>	Symptoms										-	-	-	-	-	-	+	+	+	
	Satisfaction										-	-	-	-	-	-	+	+	+	
	Expectations										-	-	-	-	-	-	+	+	+	
	Func. Activities			+					+	-	-	-	-	-	-	-	+		+	
<u>Objective Knee Evaluation</u>	Obj. Indicators		+		+						-	-	-	-	-	-			+	
	Function										-	-	-	-	-	-	+	+		
	Total Knee	+	+		+			+			-	-	-	-	-	-	+	+		
<u>Temporal TUG Segments</u>	Total TUG		-		-	-	+	-		+	+	+	+	+	+	+				
	Sit-to-Stand	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+				
	Walk-to-Goal					-	+		+	+	+	+	+	+	+	+				
	Turn-at-Goal							+				+								
	Walk-to-Chair					-	+	-		+										
	Turn-to-Sit					+		-	-											
	% Sit-to-Stand	-	-	-	-															
	% Walk-to-Goal		+	+	+	-														
	% Turn-at-Goal																			
	% Walk-to-Chair																			
	% Turn-to-Sit																			
<u>Start-TUG: Flex./Ext. Angle</u>	Op.	+	+	+																
	Contra.	+	+																	
<u>End-TUG: Flex./Ext. Angle</u>	Op.	+																		
	Contra.																			

Spearman (ρ)		Average Step: AAD (Upper Sensors)		Average Step: AAD (Lower Sensors)		Average Step: AAD Var./Val.		Average Step: AAD Int./Ext. Rotation		Average Step: AAD Flex./Ext.		Average Step: Ext. Acceleration		Average Step: Flex. Acceleration		Average Step: Ext. Velocity		Average Step: Flex. Velocity	
		Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.
Walking TUG	Op.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Segments:	Contra.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Step Count	Total	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total TUG:	Op.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
AAD Flex./Ext.	Contra.		-		-						+						+		
Total TUG: AAD	Op.							+	+										
Int./Ext. Rotation	Contra.					+		+	+	-									
Total TUG:	Op.						+											+	
AAD Var./Val.	Contra.					+													
Total TUG: AAD	Op.		-		-														
(Lower Sensors)	Contra.		-		-					-	-								
Total TUG: AAD	Op.																		
(Upper Sensors)	Contra.		-																
Average Step:	Op.										+							+	+
Max. Flex. Angle	Contra.	+		+	+					+	+	+	+	+	+	+	+	+	+
Average Step:	Op.	+	+	+	+		+			+	+	+	+	+	+	+	+	+	+
Flex./Ext. Range	Contra.	+	+	+	+					+	+	+	+	+	+	+	+	+	+
Average Step:	Op.	+	+	+	+	+	+			+	+	+	+	+	+	+	+	+	+
Flex. Velocity	Contra.	+	+	+	+	+	+			+	+	+	+	+	+	+	+	+	+
Average Step:	Op.	+	+	+	+	+	+	+		+	+	+	+	+	+	+	+	+	+
Ext. Velocity	Contra.	+	+	+	+	+	+			+	+	+	+	+	+	+	+	+	+
Average Step:	Op.	+	+	+	+	+	+	+		+	+	+	+	+	+	+	+	+	+
Flex. Acceleration	Contra.	+	+	+	+	+	+	+		+	+	+	+	+	+	+	+	+	+
Average Step:	Op.	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Ext. Acceleration	Contra.	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Average Step:	Op.	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
AAD Flex./Ext.	Contra.	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Average Step: AAD	Op.	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Int./Ext. Rotation	Contra.	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Average Step:	Op.	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
AAD Var./Val.	Contra.	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Average Step: AAD	Op.	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
(Lower Sensors)	Contra.	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Average Step: AAD	Op.	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
(Upper Sensors)	Contra.	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+



Spearman (ρ)		Average Step Flex./Ext. Range		Average Step Max. Flex. Angle		Total TUG: AAD (Upper Sensors)		Total TUG: AAD (Lower Sensors)		Total TUG: AAD Var./Val.		Total TUG: AAD Int./Ext. Rotation		Total TUG: AAD Flex./Ext.		Walking TUG Segments: Step Count		
		Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Contra.	Op.	Total	Contra.	Op.
<u>Walking TUG Segments: Step Count</u>	Op.	-	-	-	-	+	+	+	+					+	+	+	+	+
	Contra.					+	+	+	+	+			+	+	+	+	+	+
<u>Total TUG: AAD Flex./Ext.</u>	Op.		+		+	+	+	+	+		+		+	+	+	+	+	+
	Contra.	+				+	+	+	+	+	+		+	+	+	+	+	+
<u>Total TUG: AAD Int./Ext. Rotation</u>	Op.					+	+	+	+	+	+	+		+	+	+	+	+
	Contra.	-		-		+	+	+	+	+	+	+		+	+	+	+	+
<u>Total TUG: AAD Var./Val.</u>	Op.					+	+	+	+	+	+	+		+	+	+	+	+
	Contra.					+	+	+	+	+	+	+		+	+	+	+	+
<u>Total TUG: AAD (Lower Sensors)</u>	Op.					+	+	+	+	+	+	+		+	+	+	+	+
	Contra.	-				+	+	+	+	+	+	+		+	+	+	+	+
<u>Total TUG: AAD (Upper Sensors)</u>	Op.	-				+												
	Contra.					+												
<u>Average Step: Max. Flex. Angle</u>	Op.		+	+														
	Contra.	+	+															
<u>Average Step: Flex./Ext. Range</u>	Op.	+																
	Contra.																	

Spearman (ρ)		KSS					WOMAC				SF-12		UCLA Activity	Subject Characteristics			
		Obj. Indicators	Func. Activities	Expectations	Satisfaction	Symptoms	Total	Function	Stiffness	Pain	Physical	Mental	Activity Score	BMI	Weight (kg)	Height (cm)	Age
<u>Subject Characteristics</u>	Age	+		+	+		+							-	-		
	Height (cm)														+		
	Weight (kg)						-	-	-	-	-	-	+				
	BMI						-	-	-	-	-	-		+			
<u>UCLA Activity</u>	Activity Score	+	+	+	+	+	+	+	+	+	+						
<u>SF-12</u>	Mental		+		+	+	+	+	+								
	Physical		+	+	+	+	+	+	+	+	+						
<u>WOMAC</u>	Pain	+	+	+	+	+	+	+	+	+	+						
	Stiffness		+	+	+	+	+	+	+	+	+						
	Function		+	+	+	+	+	+	+	+	+						
	Total		+	+	+	+	+	+	+	+	+						
<u>KSS</u>	Symptoms		+	+	+												
	Satisfaction		+	+													
	Expectations		+														
	Func. Activities																
	Obj. Indicators																

## Appendix C: UCLA Activity Score Questionnaire

TUG After TKA

Study ID: \_\_\_\_\_

Date: \_\_\_\_\_

### UCLA Activity Score

Check one box that best describes current activity level.

- 1: Wholly Inactive, dependent on others, and can not leave residence
- 2: Mostly Inactive or restricted to minimum activities of daily living
- 3: Sometimes participates in mild activities, such as walking, limited housework and limited shopping
- 4: Regularly Participates in mild activities
- 5: Sometimes participates in moderate activities such as swimming or could do unlimited housework or shopping
- 6: Regularly participates in moderate activities
- 7: Regularly participates in active events such as bicycling
- 8: Regularly participates in active events, such as golf or bowling
- 9: Sometimes participates in impact sports such as jogging, tennis, skiing, acrobatics, ballet, heavy labor or backpacking
- 10: Regularly participates in impact sports

Version: 29-May-2017

## Appendix D: Short Form-12 (SF-12) Questionnaire

### SF-12 Health Survey

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. **Answer each question by choosing just one answer.** If you are unsure how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

<sub>1</sub> Excellent    <sub>2</sub> Very good    <sub>3</sub> Good    <sub>4</sub> Fair    <sub>5</sub> Poor

The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	YES, limited a lot	YES, limited a little	NO, not limited at all
2. <b>Moderate activities</b> such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>
3. Climbing <b>several</b> flights of stairs.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	YES	NO
4. <b>Accomplished less</b> than you would like.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
5. Were limited in the <b>kind</b> of work or other activities.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	YES	NO
6. <b>Accomplished less</b> than you would like.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
7. Did work or activities <b>less carefully</b> than usual.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>

8. During the **past 4 weeks**, how much **did pain interfere** with your normal work (including work outside the home and housework)?

<sub>1</sub> Not at all    <sub>2</sub> A little bit    <sub>3</sub> Moderately    <sub>4</sub> Quite a bit    <sub>5</sub> Extremely

These questions are about how you have been feeling during the **past 4 weeks**.

For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm & peaceful?	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>6</sub>
10. Did you have a lot of energy?	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>6</sub>
11. Have you felt down-hearted and blue?	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>6</sub>

12. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relatives, etc.)?

<sub>1</sub> All of the time    <sub>2</sub> Most of the time    <sub>3</sub> Some of the time    <sub>4</sub> A little of the time    <sub>5</sub> None of the time

## Appendix E: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Questionnaire

WOMAC Survey Form Name: \_\_\_\_\_

---

Instructions: In Sections A, B, and C, questions will be asked about your hip or knee pain. Please mark each response with an X. If you are unsure about how to answer a question, please give the best answer you can.

---

A. Think about the pain you felt in your hip/knee during the last 48 hours.

Question: How much pain do you have? None    Mild    Moderate    Severe    Extreme

	None	Mild	Moderate	Severe	Extreme
1. Walking on a flat surface	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Going up and down stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. At night while in bed, pain disturbs your sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Sitting or lying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Standing upright	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

---

B. Think about the stiffness (not pain) you have in your hip/knee during the last 48 hours. Stiffness is a sensation of decreased ease in moving your joint.

None    Mild    Moderate    Severe    Extreme

6. How severe is your stiffness after first awakening in the morning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. How severe is your stiffness after sitting, lying, or resting in the day?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

---

C. Think about the difficulty you had in doing the following daily physical activities due to your hip/knee during the last 48 hours. By this we mean your ability to move around and look after yourself.

Question: What degree of difficulty do you have? None    Mild    Moderate    Severe    Extreme

	None	Mild	Moderate	Severe	Extreme
8. Descending stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Ascending stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Rising from sitting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Standing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Bending to the floor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Walking on flat surfaces	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Getting in and out of a car, or on or off a bus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Going shopping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Putting on your socks or stockings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Rising from the bed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Taking off your socks or stockings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Lying in bed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Getting in or out of the bath	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Sitting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Getting on or off the toilet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Performance heavy domestic duties	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Performing light domestic duties	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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## Appendix F: Knee Society Score (KSS) Questionnaire

### OBJECTIVE KNEE INDICATORS (To be completed by surgeon)

ALIGNMENT	
<b>1- Alignment: measured on AP standing Xray (Anatomic Alignment)</b>	<b>25 point max</b>
Neutral: 2-10 degrees valgus (25 pts)	<input type="text"/>
Varus: < 2 degrees valgus (-10 pts)	
Valgus: > 10 degrees valgus (-10 pts)	

INSTABILITY	
<b>2- Medial / Lateral Instability: measured in full extension</b>	<b>15 point max</b>
None (15 pts)	<input type="text"/>
Little or < 5 mm (10 pts)	
Moderate or 5 mm (5 pts)	
Severe or > 5 mm (0 pts)	
<b>3- Anterior / Posterior Instability: measured at 90 degrees</b>	<b>10 point max</b>
None (10 pts)	<input type="text"/>
Moderate < 5 mm (5 pts)	
Severe > 5 mm (0 pts)	

JOINT MOTION	
<b>4- Range of motion (1 point for each 5 degrees)</b>	<input type="text"/>
<b>Deductions</b>	
<b>Flexion Contracture</b>	<b>Minus Points</b>
1-5 degrees (-2 pts)	<input type="text"/>
6-10 degrees (-5 pts)	
11-15 degrees (-10 pts)	
> 15 degrees (-15 pts)	
<b>Extensor Lag</b>	<b>Minus Points</b>
<10 degrees (-5 pts)	<input type="text"/>
10-20 degrees (-10 pts)	
> 20 degrees (-15 pts)	

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**SYMPTOMS****(To be completed by patient)**

<b>1- Pain with level walking</b>											<b>(10 - Score)</b>
0	1	2	3	4	5	6	7	8	9	10	<input style="width: 50px; height: 30px;" type="text"/>
<b>none</b>						<b>severe</b>					
<b>2- Pain with stairs or inclines</b>											<b>(10 - Score)</b>
0	1	2	3	4	5	6	7	8	9	10	<input style="width: 50px; height: 30px;" type="text"/>
<b>none</b>						<b>severe</b>					
<b>3- Does this knee feel "normal" to you?</b>											<b>(5 points)</b>
<input type="radio"/> Always (5 pts) <input type="radio"/> Sometimes (3 pts) <input type="radio"/> Never (0 pts)											<input style="width: 50px; height: 30px;" type="text"/>

**Maximum total points (25 points)**

**PATIENT SATISFACTION**

<b>1- Currently, how satisfied are you with the pain level of your knee while sitting?</b>					<b>(8 points)</b>
<input type="radio"/> Very Satisfied (8 pts)	<input type="radio"/> Satisfied (6 pts)	<input type="radio"/> Neutral (4 pts)	<input type="radio"/> Dissatisfied (2 pts)	<input type="radio"/> Very Dissatisfied (0 pts)	
<b>2- Currently, how satisfied are you with the pain level of your knee while lying in bed?</b>					<b>(8 points)</b>
<input type="radio"/> Very Satisfied (8 pts)	<input type="radio"/> Satisfied (6 pts)	<input type="radio"/> Neutral (4 pts)	<input type="radio"/> Dissatisfied (2 pts)	<input type="radio"/> Very Dissatisfied (0 pts)	
<b>3- Currently, how satisfied are you with your knee function while getting out of bed?</b>					<b>(8 points)</b>
<input type="radio"/> Very Satisfied (8 pts)	<input type="radio"/> Satisfied (6 pts)	<input type="radio"/> Neutral (4 pts)	<input type="radio"/> Dissatisfied (2 pts)	<input type="radio"/> Very Dissatisfied (0 pts)	
<b>4- Currently, how satisfied are you with your knee function while performing light household duties?</b>					<b>(8 points)</b>
<input type="radio"/> Very Satisfied (8 pts)	<input type="radio"/> Satisfied (6 pts)	<input type="radio"/> Neutral (4 pts)	<input type="radio"/> Dissatisfied (2 pts)	<input type="radio"/> Very Dissatisfied (0 pts)	
<b>5- Currently, how satisfied are you with your knee function while performing leisure recreational activities?</b>					<b>(8 points)</b>
<input type="radio"/> Very Satisfied (8 pts)	<input type="radio"/> Satisfied (6 pts)	<input type="radio"/> Neutral (4 pts)	<input type="radio"/> Dissatisfied (2 pts)	<input type="radio"/> Very Dissatisfied (0 pts)	

**Maximum total points (40 points)**


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**PATIENT EXPECTATIONS (To be completed by patient)**

**What do you expect to accomplish with your knee replacement:**

**1- Do you expect your knee joint replacement surgery will relieve your knee pain? (5 points)**

- no, not at all (1 pt)  
 yes, a little bit (2 pts)  
 yes, somewhat (3 pts)  
 yes, a moderate amount (4 pts)  
 yes, a lot (5 pts)

**2- Do you expect your surgery will help you carry out your normal activities of daily living? (5 points)**

- no, not at all (1 pt)  
 yes, a little bit (2 pts)  
 yes, somewhat (3 pts)  
 yes, a moderate amount (4 pts)  
 yes, a lot (5 pts)

**3- Do you expect you surgery will help you perform leisure, recreational or sports activities? (5 points)**

- no, not at all (1 pt)  
 yes, a little bit (2 pts)  
 yes, somewhat (3 pts)  
 yes, a moderate amount (4 pts)  
 yes, a lot (5 pts)

**Maximum total points (15 points)**

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STANDARD ACTIVITIES (30 points)								
How much does your knee bother you during each of the following activities?	no bother	slight	moderate	severe	very severe	cannot do (because of knee)	I never do this	
	5	4	3	2	1	0		
1 - Walking on an uneven surface	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
2 - Turning or pivoting on your leg	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
3 - Climbing up or down a flight of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
4 - Getting up from a low couch or a chair without arms	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
5 - Getting into or out of a car	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
6 - Moving laterally (stepping to the side)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
<b>Maximum points (30 points)</b>								<input type="text"/>
ADVANCED ACTIVITIES (25 points)								
1 - Climbing a ladder or step stool	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
2 - Carrying a shopping bag for a block	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
3 - Squatting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
4 - Kneeling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
5 - Running	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
<b>Maximum points (25 points)</b>								<input type="text"/>

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### DISCRETIONARY KNEE ACTIVITIES (15 points)

Please check 3 of the activities below that you consider *most important* to you.

(Please do not write in additional activities)

Recreational Activities	Workout and Gym Activities
<input type="checkbox"/> Swimming	<input type="checkbox"/> Weight-lifting
<input type="checkbox"/> Golfing (18 holes)	<input type="checkbox"/> Leg Extensions
<input type="checkbox"/> Road Cycling (>30mins)	<input type="checkbox"/> Stair-Climber
<input type="checkbox"/> Gardening	<input type="checkbox"/> Stationary Biking / Spinning
<input type="checkbox"/> Bowling	<input type="checkbox"/> Leg Press
<input type="checkbox"/> Racquet Sports (Tennis, Racquetball, etc.)	<input type="checkbox"/> Jogging
<input type="checkbox"/> Distance Walking	<input type="checkbox"/> Elliptical Trainer
<input type="checkbox"/> Dancing / Ballet	<input type="checkbox"/> Aerobic Exercises
<input type="checkbox"/> Stretching Exercises (stretching out your muscles)	

Please copy all 3 checked activities into the empty boxes below.

How much does your knee bother you during each of these activities?

Activity (Please write the 3 activities from list above)	no bother	slight	moderate	severe	very severe	cannot do (because of knee)	
	5	4	3	2	1	0	
1. <input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
2. <input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
3. <input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
<b>Maximum points (15 points)</b>							<input type="text"/>

**Maximum total points (100 points)**

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## Appendix G: Health Science Research Ethics Board Approval Notice



**Western  
Research**

Research Ethics

### Western University Health Science Research Ethics Board HSREB Delegated Initial Approval Notice

**Principal Investigator:** Dr. Brent Lanting

**Department & Institution:** Schulich School of Medicine and Dentistry/Orthopaedic Surgery, London Health Sciences Centre

**Review Type:** Delegated

**HSREB File Number:** 109398

**Study Title:** The relationship between patient reported outcome measures and variability in wearable sensor-implemented Timed-Up-and-Go tests after total knee arthroplasty

**HSREB Initial Approval Date:** June 29, 2017

**HSREB Expiry Date:** June 29, 2018

**Documents Approved and/or Received for Information:**

Document Name	Comments	Version Date
Revised Western University Protocol	Received June 22, 2017	
Letter of Information & Consent		2017/05/26
Instruments	UCLA Activity Score	2017/05/29
Data Collection Form/Case Report Form	Received May 30, 2017	

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Ethics \_\_\_\_\_  
\_\_\_\_\_ half of Dr. Marcelo Kremenutzky, HSREB Vice Chair

EO: Erika Basile \_\_\_ Grace Kelly \_\_\_ Katelyn Harris \_\_\_ Nicola Morphet \_\_\_ Karen Gopaul \_\_\_ Patricia Sargeant \_\_\_

## Appendix H: Curriculum Vitae

# Megan Fennema

### EDUCATION

- September  
2016 – Present     **Master of Science, Medical Biophysics**  
Department of Medical Biophysics  
The University of Western Ontario, London, Ontario, Canada
- September  
2011 – April  
2016     **Bachelor of Engineering, Biomedical Engineering, Co-op**  
School of Engineering  
The University of Guelph, Guelph, Ontario, Canada

### POSITIONS

- September  
2016 – January  
2018     **London Health Sciences Centre, London, Ontario**  
*Part-time Research Assistantship*  
Department of Orthopaedic Surgery  
*Supervisor:* Dr. Matthew Teeter & Dr. Parham Rasoulinejad  
*Project:* ‘Computer-aided design of a novel spine implant’
- September  
2016 – August  
2018     **Lawson Health Research Institute, London, Ontario**  
*Volunteer Student Representative, Lawson Association of Fellows & Students*  
*Responsibilities:* Organize social events for Lawson affiliates
- September  
2017 – March  
2018     **Inspiring Young Women in STEM Conference, London, Ontario**  
*Graduate Expo Organizational Volunteer*  
*Responsibilities:* Assist in organizing Graduate Expo portion of conference
- May 2016 –  
August 2016     **London Health Sciences Centre, London, Ontario**  
*Summer Research Student*  
*Supervisor:* Dr. Matthew Teeter  
*Project:* ‘Programming of 6-degree-of-freedom robot for articulation of anthropomorphic leg phantom to simulate knee joint motion’
- April 2015 –  
December  
2015     **Robarts Research Institute, London, Ontario**  
*Research Assistant, Undergraduate Co-op Student*  
*Supervisor:* Dr. Grace Parraga  
*Project:* ‘Ventilation MRI during Exercise and Methacholine Challenge’
- January 2014 –  
August 2014     **BlackBerry Ltd., Waterloo, Ontario**  
*Software Test Associate, Undergraduate Co-op Student*
- April 2013 –  
August 2013     **Advanced Design Solutions, Stratford, Ontario**  
*Project Manager Assistant, Undergraduate Co-op Student*

## HONOURS AND AWARDS

- 2017 – **Collaborative Training Program in Musculoskeletal Health Research**  
2018 **Transdisciplinary Award**  
*Awarded to students in CMHR based on candidate's academic achievements, and quality and novelty of the transdisciplinary research project, and its fit within Western's Bone & Joint Institute*  
Institutional  
**\$10,000 per year**
- 2016 – **Western Graduate Research Scholarship**  
2018 *Awarded to graduate students with a minimum admission average of 78% and continued minimum average of 80% throughout their graduate studies.*  
Institutional  
**\$1,500 per semester**
- 2016 **Dean's Honours List, University of Guelph**  
*Awarded to students taking full-time studies who have obtained a minimum semester average of 80.0%.*  
Institutional
- 2014 **Dean's Honours List, University of Guelph**  
*Awarded to students taking full-time studies who have obtained a minimum semester average of 80.0%.*  
Institutional
- 2011 – **Dean's Honours List, University of Guelph**  
2012 *Awarded to students taking full-time studies who have obtained a minimum semester average of 80.0%.*  
Institutional
- 2011 **Entrance Scholarship, University of Guelph**  
*Awarded to students taking full-time studies who have obtained an admission average of 90.0% or greater.*  
Institutional  
**\$3,000**
- 2011 **Queen Elizabeth II Aiming for the Top Scholarship**  
*Recognizes students who have shown academic excellence at the high school level.*  
Provincial  
**\$100**

## PRESENTATIONS & PUBLICATIONS

### A. Journal Articles

#### Accepted (1)

1. Bloomfield RA, **Fennema MC**, McIsaac K, Teeter MG. Proposal and Validation of a Knee Measurement System for Patients with Osteoarthritis. *IEEE Transactions on Biomedical Engineering*. May 2018.

#### Submitted (1)

2. **Fennema MC**, Bloomfield RA, Lanting BA, Birmingham TB, Teeter MG. Repeatability of measuring knee flexion angles with wearable inertial sensors. *The Knee*. Submitted April 2018.

### B. Oral Presentations

#### Presented (6)

1. **Fennema MC**, Bloomfield RA, Naudie DD, Howard JL, Lanting BA, Teeter MG. Improving patient satisfaction post-TKR: New insight via novel wearable sensor metrics. *Canadian Bone and Joint Conference*. London, Ontario, Canada. May 2018.
2. **Fennema MC**, Bloomfield RA, Naudie DD, Howard JL, Lanting BA, Teeter MG. Wearable sensors identify new metrics: One step closer to understanding function in knee replacement patients. *Medical Biophysics Departmental Seminar*. London, Ontario, Canada. February 2018.
3. **Fennema MC**, Bloomfield RA, Birmingham TB, Lanting BA, Teeter MG. Towards Individualized Osteoarthritis Care Using Wearable Sensors. *2017 Annual Alan C. Burton Day, Invited Student Speaker*. London, Ontario, Canada. April 2017.
4. **Fennema MC**, Bloomfield RA, Birmingham TB, Lanting BA, Teeter MG. Stepping into the Future of Individualized Osteoarthritis Care: Wearable Sensors. *Medical Biophysics Departmental Seminar*. London, Ontario, Canada. March 2017.
5. **Fennema MC**, Bloomfield RA, Birmingham TB, Lanting BA, Teeter MG. Evaluation of Wearable Sensors using a Robotic Knee Joint Phantom and 3D Motion Capture. *2017 Imaging Network of Ontario Symposium*. London, Ontario, Canada. March 2017.
6. Bloomfield RA, **Fennema MC**, Lanting BA, McIsaac KA, Teeter MG. Knee joint measurement during the timed up and go test using low-cost wearable sensors. *2017 Imaging Network of Ontario Symposium*. London, Ontario, Canada, March 2017.

### C. Posters

#### Presented (11)

1. **Fennema MC**, Bloomfield RA, Naudie DD, Howard JL, Lanting BA, Teeter MG. Inside the TUG test: Wearable sensors identify new metrics related to function in post-TKR patients. *Imaging Network of Ontario 2018 Symposium*. Toronto, Ontario, Canada. March 2018.

2. **Fennema MC**, Bloomfield RA, Naudie DD, Howard JL, Lanting BA, Teeter MG. Novel wearable sensors identify metrics within TUG test related to function in TKR patients. *Orthopaedic Research Society 2018 Annual Meeting*. New Orleans, Louisiana, United States. March 2018.
3. **Fennema MC**, Bloomfield RA, Birmingham TB, Lanting BA, Teeter MG. Variability of Wearable Sensors for Knee Joint Assessment Tested with a Robotically Driven Leg Phantom. *2017 Canadian Orthopaedic Association Annual Meeting*. Ottawa, Ontario, Canada. June 2017.
4. **Fennema MC**, Svenningsen S, Eddy RL\*, Leary D, Maksym G, Parraga G. Can the Forced Oscillation Technique and a Computational Model of Respiratory System Mechanics Explain Asthma Ventilation Defects? *2016 Annual International Society for Magnetic Resonance in Medicine Meeting*. Singapore. June 2016. (\*presenter)
5. **Fennema MC**, Capaldi DPI\*, Sheikh K, Svenningsen S, McCormack D, Parraga G. The Abnormal Airways that Dominate Asthma Attack: New clues using ventilation MRI during Exercise- and Methacholine-Challenge. *2016 American Thoracic Society Conference*. San Francisco, California, United States. June 2016. (\*presenter)
6. **Fennema MC**, Bloomfield RA, Birmingham TB, Lanting BA, Teeter MG. Wearable Sensor Performance Evaluation Using 3D Motion Capture and a Robotic Phantom. *2017 London Health Research Day*. London, Ontario, Canada. March 2017.
7. Bloomfield RA\*, **Fennema MC**, Lanting BA, McIsaac KA, Teeter MG. Extraction of distinctive knee usage characteristics through instrumented functional testing. *2017 London Health Research Day*. London, Ontario, Canada. March 2017. (\*presenter)
8. **Fennema MC**, Duong P, Hilker R, Silva M. Crop Sensing and Modelling System. *University of Guelph Engineering Design IV Open House*. Guelph, Ontario, Canada. March 2016.
9. **Fennema MC**, Kohut M, McFarlan A, Tong K. Addressing peripheral vascular disease in diabetic patients: A prototype proposal for the Dia-Stim Calf Wrap. *University of Guelph Engineering Design III Exposition 2015*. Guelph, Ontario, Canada. March 2015.
10. **Fennema MC**, Kohut M, Nagy A. Regaining upper limb function after a stroke: A prototype proposal for the TheraTrak portable rehabilitation device. *University of Guelph Biomechanical Engineering Design Showcase 2014*. Guelph, Ontario, Canada. December 2014.
11. **Fennema MC**, Bilyea A, Mejia E. Asthma attack prevention: A prototype presentation for the AirAME device. *University of Guelph Bio-Instrumentation Design Exhibition 2014*. Guelph, Ontario, Canada. December 2014.

## EVENT PARTICIPATION

May 2018	<b>Canadian Bone and Joint Conference</b> <i>Attendee &amp; Selected Speaker</i>
March 2018	<b>Imaging Network of Ontario 2018 Symposium</b> <i>Attendee &amp; Poster Presenter</i>
March 2018	<b>Orthopedic Research Society 2018 Annual Meeting</b> <i>Attendee &amp; Poster Presenter</i>
March 2018	<b>Inspiring Young Women in STEM</b> <i>Graduate Expo Organizational Volunteer</i>
November 2017	<b>Ivey Workshop: Health Systems Structure and Trends</b> <i>Participant</i>
September 2017	<b>Ivey Workshop: Small &amp; Medium Enterprises – Building the Case for Commercialization &amp; Venture Capital Investment</b> <i>Participant</i>
June 2017	<b>Canadian Orthopaedic Association Conference</b> <i>Attendee &amp; Poster Presenter</i>
June 2017	<b>Robarts Research Retreat</b> <i>Attendee</i>
May 2017	<b>Bone &amp; Joint Institute: MSK Research Retreat</b> <i>Attendee</i>
May 2017	<b>Ivey Workshop: Health Economics &amp; Decision Logic</b> <i>Participant</i>
April 2017	<b>AC Burton Day</b> <i>Attendee &amp; Invited Student Speaker</i>
April 2017	<b>Ivey Workshop: Introduction to Pharmaceuticals &amp; Medical Devices</b> <i>Participant</i>
March 2017	<b>Imaging Network of Ontario Conference</b> <i>Attendee &amp; Oral Presentation Speaker</i>
March 2017	<b>London Health Research Day</b> <i>Attendee &amp; Poster Presenter</i>
June 2015	<b>International Society for Magnetic Resonance in Medicine Conference</b> <i>Attendee</i>