EVALUATION OF PATIENT-REPORTED OUTCOME MEASURES AND LEVEL WALKING BIOMECHANICS IN TOTAL KNEE ARTHROPLASTY PATIENTS

by

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A thesis submitted to the faculty of
The University of North Carolina at Charlotte
in partial fulfillment of the requirements
for the degree of Master of Science in
Mechanical Engineering

Charlotte

2020

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ABSTRACT

CHRISTINA AVERY CALLAHAN. An Evaluation of Patient-Reported Outcome Measures and Level Walking Biomechanics in Total Knee Arthroplasty Patients. (Under the direction of DR. NIGEL ZHENG)

Total Knee Arthroplasty (TKA) is frequently used to treat individuals who are in the end stages of knee osteoarthritis (OA). While level-walking may seem to be a simple activity of daily living for most, it can be challenging for those who experience severe OA. A complete understanding of both patient-perceived function and their actual biomechanical function is critical for establishing standardization in pre- and post-operative TKA procedures. The primary goal of TKA is to alleviate pain, increase range of motion, restore functional ability and improve the overall quality of life to those who have OA. While majority of patients report to have improved pain and function, there are a good amount that still remain unsatisfied and have gait abnormalities.

The purpose of this study was to investigate both patient-reported outcome measures (PROMs) and biomechanical measures of function as well as analyze the correlations between the two. Evaluation of improvement in these variables as well as comparing TKA data to healthy controls was important for gaining a complete understanding of functional improvement. Multiple types of PROMs were used and the vertical ground reaction force (vGRF) was the variable of interest collected from gait analysis assessment.

The results from this study reconfirmed findings from previous TKA research regarding the improvement of subjective measures of function following surgery. TKA subjects demonstrated significant improvement in PROMs over the course of the study

and there were also significant correlations between the different types of PROMs used. Majority of the improvement in PROMs occurred from pre-op to 6-months and 6-months to 12-months. Based on these findings, it may be more time and cost-efficient to eliminate the 1-week and 1-month follow-ups. There was also improvement of vGRF variables of TKA subject from pre-op to 6-months post-op. TKA subjects demonstrated bilateral differences between the implant and non-implant at the pre-op assessment but improved to values similar to the healthy controls at the post-op assessment.

TKA subjects demonstrate significant improvement in PROMs and improvement of vGRF. However, there were only few correlations found between the improvement of PROMs and the improvement of vGRF variables from pre-op to 6-months post-op. This study confirms that there is a gap between subjective and objective measures of function and more research and consistent findings will be necessary to close that gap.

DEDICATION

I would like to first and foremost dedicate this to my parents and family, who are responsible for all that I have achieved this far. I would not be here today without them and their constant love and support. I would also like to dedicate this to my advisor Dr. Nigel Zheng. He has always pushed me to do my best and his guidance and wisdom has led me through majority of my academic journey. Lastly, I would like to dedicate this to all my team members Hannah Stokes, Chang Shu, and Fangjian Chen for all their help and advice throughout my research.

ACKNOWLEDGEMENTS

Firstly, I would like to thank God for giving me the strength and patience to carry out this research. I would like to acknowledge my advisor Dr. Nigel Zheng of the Department of Mechanical Engineering and Engineering Science at the University of North Carolina, Charlotte for the constant guidance, preparation and motivation he has given me throughout this journey of completing a master's thesis. I will forever be indebted to him for all that he has done for me and taught me the last four years. I would also like to express my sincere gratitude to my committee members Dr. Youxing Chen and Dr. Russell Keanini also of the Department of Mechanical Engineering and Engineering Science at the University of North Carolina, Charlotte for their very valuable comments and guidance throughout my thesis journey. Finally, I express my utmost gratitude to my parents Charles and Donna Callahan for providing me with constant support and encouragement throughout my years of study and through the process of researching and writing this thesis. This accomplishment would not have been possible without them. The study is funded by Smith and Nephew through an investigator-initiated study (IIS) award to Dr. Zheng. Assistance in subject recruitment from the OrthoCarolina Research Institute is much appreciated.

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LIST OF ABBREVIATIONS

ANOVA	Analysis of Variance
ASA	American Society of Anesthesiologists
BMI	Body Mass Index
CDC	Center of Disease and Control
FJS-12	Forgotten Joint Score
IRB	Institutional Review Board
KSS	Knee Society Score
KSS EXP & SAT	Knee Society Score—Expectation and Satisfaction Score
KSS FUNC	Knee Society Score—Functional Score
KSS OBJ	Knee Society Score—Objective Score
OA	Osteoarthritis
PAR-Q	Physical Activity Readiness Questionnaire
PROMs	Patient-Reported Outcome Measures
SF-12	Short-Form Survey
TKA	Total Knee Arthroplasty
vGRF	Vertical Ground Reaction Force

CHAPTER 1: INTRODUCTION

1.1 Background

According to the Center of Disease and Control (CDC), osteoarthritis (OA) affects over 32.5 million US adults (CDC, 2020). OA, described as the "wear and tear" arthritis, occurs when the cartilage that protects the ends of bones in the joint slowly deteriorates, most commonly affecting the hands, hips and knees. In the end stages of OA, the cartilage wears down completely resulting in bone to bone contact and extreme pain and stiffness. A common treatment option for patients that are symptomatic of severe OA in the knee is total knee arthroplasty (TKA). TKA, better known as total knee replacement, is one of the most cost-effective and consistently successful orthopedic surgeries performed to date, being practiced for more than 50 years (Varacallo, Luo, & Johanson, 2020). Discussed in a study by Sloan, the National Inpatient Sample reports there were 680,150 total knee replacements in 2014 (Sloan, 2020). Based on linear regression models this number is expected to increase 189% by 2030 for a projected 1.28 million procedures. Because the number of TKA procedures continues to increase drastically, improving the standardization of pre- and post-operative procedures is a critical component for restoring function in the replaced knee joint.

The primary goals of TKA are to deliver pain relief, restore mobility and function and improve the overall quality of life to those who suffer from severe OA. TKA, as well as other lower extremity joint replacements, originated as a procedure that was frequent in elderly patients (> 65 years) of low activity levels (Losina & Katz, 2012). Although, in recent years, there has been a dramatic increase in the utilization of TKA to treat younger patients (< 65 years) and more importantly those with greater functional expectations

(Biggs, Whatling, Wilson, & Holt, 2019). Traditionally, success of TKA was dependent on the surgeon's point of view based on factors such as survival rate of the implant and complications. However, further research has demonstrated that the success of TKA is also very associated with patient-reported outcome measures (PROMs) (Canfield, Savoy, Cote, & Halawi, 2020). PROMs are commonly used as subjective tool for monitoring a patient's quality of life and changes in physical function prior to and following surgery (Yorkston, 2019). While PROMs do provide a comprehensive understanding of a patient's perspective and surgical outcome expectations, they fail to capture changes in objective or performance-based measures of function relative to TKA. Because self-reported measures have been found to be predominantly influenced by pain, it is possible that patients with severe OA have a difficult time distinguishing between pain and functional restraints when self-evaluating their ability to perform activities of daily living (Biggs et al., 2019).

For decades lab-based gait analysis has been used as an objective tool for measuring patients' functional progression from pre- to post-TKA surgery, evaluating discrepancies between performance-based and patient-perceived functional changes (J. A. McClelland, Webster, & Feller, 2007). Gait analysis is a clinical tool generally used to gain a better understanding of a person's underlying biomechanics while walking. Traditional biomechanics such as evaluating ground reaction forces on the knee during level-walking are utilized to provide a better understanding of how well TKA actually restores a healthy gait in patients who are in the end-stages of OA. There have been consistent findings that TKA patients demonstrate abnormal forces on their arthritic/implant leg before surgery compared to their healthy leg as well as compared to healthy subjects (David R. Burnett,

2015). Other studies have found that TKA patients demonstrate improvement following TKA surgery by presenting no bilateral (between two limbs) differences and only slight differences compared to healthy subjects (Naili et al., 2017). A thorough understanding of joint loading and mechanics of the knee is important for improving pre and post TKA procedure protocols.

Current researchers continue to shift their focus towards improving the standardization in the way both subjective patient-perceived outcomes and objective gait biomechanics are measured before and after TKA. The reason for this is because solely using PROMs or biomechanical gait analysis each have limitations. Studies have shown that analyzing PROMs only tends to result in an overestimation of a patient's short and long-term restored physical function due to high expectations and instant pain relief post TKA. On the other hand, the use of only gait analysis provides little to no insight on the patients' perspective of pain, physical function, expectations or satisfaction (Bolink, Grimm, & Heyligers, 2015). The abundance of PROMs and biomechanical variables that can be analyzed has led to inconsistent findings in TKA research.

1.2 Objectives

Because of the disadvantages in solely using PROMs or biomechanical analysis, the goal of this project is to analyze both patient-reported outcome measures of function and objective biomechanical measures of function individually, as well as assess the relationship between the two. This goal will be achieved through the completion of three research objectives. The first objective of this research is to statistically analyze the change in PROMs over time as well as determine any correlations among the different types of PROMs used. The second objective is to evaluate level-walking biomechanics of TKA

patients by analyzing between limb differences, investigating any changes in variables from pre-op to 6-months post-op and comparing variables to those of healthy controls. The third and final objective is to investigate correlations between changes in level-walking gait variables and changes in PROMs scores.

1.3 Research Hypothesis

It was hypothesized that TKA subjects would demonstrate improvement of PROMs scores and there would also be correlations between the different types of PROMs used. In addition, TKA subjects would also demonstrate improvement of vGRF variables and there would be differences in vGRF variables between TKA subjects and healthy controls. Lastly, it was hypothesized that there would be correlations between the improvement in PROMs scores and the improvement of vGRF variables for TKA subjects.

1.4 Limitations

This study has some important limitations to take into consideration.

- All gait analysis testing was conducted in a laboratory setting.
- Due to practical life reasons, there are slight discrepancies in the times for 1-week, 1-month, 6-months and 12-months follow-up.
- There is an unequal balance of male and female subjects. There is a greater number of males in this study.
- Sample-sizes are smaller than ideal for statistical analysis.
- Due to COVID-19 in-person testing for 6-month follow-ups has been at a standstill since March 2020.

1.5 Organization of Content

Chapter 1 provides an overview of the purpose and goals of this research study. Chapter 2 is a literature review that provides relevant information on the prevalence of TKA, types of PROMs and how they apply to TKA, gait analysis, ground reaction forces, and the benefits of using PROMs and gait analysis together. Chapter 3 details the methods used to complete this research including the study participants, gait analysis, data organization and statistical analysis procedures. Chapter 4 discusses the results of the research. Finally, Chapter 5 presents conclusions of the study and future recommendations.

CHAPTER 2: LITERATURE REVIEW

The purpose of this study is to individually evaluate patient-reported outcome measures of function (PROMs) and biomechanical objective measures of function as well as assess any relationships between the two. This chapter highlights the review of previous literature on the prevalence and purpose of total knee arthroplasty (TKA) and methods of evaluating function including PROMs, biomechanical gait analysis and the utilization of ground reaction force variables.

2.1 Prevalence of Total Knee Arthroplasty

TKA is the most frequently performed inpatient surgical procedure in the United States and is commonly used to treat patients who are in the end stages of OA (Feng, Novikov, Anoushiravani, & Schwarzkopf, 2018). OA is the most common form of arthritis and one of the most prominent causes of disability in adults over the age of 65 years (Neogi, 2013). However, current research has shown that TKA is becoming more utilized in younger patients as well as those with greater functional expectations. Patients with OA typically experience a significant amount of pain and often struggle with carrying out normal activities of daily living. The primary goal of TKA is to help patients with OA by reducing pain, improving mobility and range of motion and restoring functional ability to perform activities of daily living (de Achaval et al., 2016). Several studies have shown that overall patients are about 60%-80% satisfied following TKA and have considerable improvements in terms of pain reduction and functional improvements (Clement et al., 2018; Turcot et al., 2013). However, other studies have shown that even though patients have demonstrated these improvements, about 20-40% of patients still report having limited function, disability, and overall reduced quality of life (Naili et al., 2017).

A thorough understanding of patient perceptions and their actual biomechanical function during level-walking is critical for improving the standardization of pre- and post-op TKA procedures. A complete understanding of the biomechanics of level-walking not only includes TKA patients, but also evaluating healthy individuals as a baseline in order to determine whether or not the surgery and recovery were successful. Ideally, any discrepancies found between TKA and healthy subjects would be identified. A successful TKA surgery would include alleviating pain, restoring mobility and function and improving the overall quality of life to those who suffer from severe OA. As the medical industry continues to shift from value-based care to patient-centered care it is important to take into consideration the surgical outcomes that matter to patients (Tseng & Hicks, 2016). These outcomes include bodily pain, expectations and satisfaction, physical function and their overall general health perceptions. Several studies have attempted to provide insight on the correlations between patient-perceived outcomes and biomechanical outcome measures using gait analysis (Biggs et al., 2019; Y. Jiang, Sanchez-Santos, Judge, Murray, & Arden, 2017; J. McClelland, Zeni, Haley, & Snyder-Mackler, 2012; Mizner et al., 2011; Naili et al., 2017).

2.2 Patient-Reported Outcome Measures

Changes in physical function following TKA surgery are commonly observed using patient-reported outcome measures (PROMs). Majority of the improvement in PROMs scores will occur in the first 6-months following surgery (Canfield et al., 2020). The implementation of PROMs continues to become more popular because they are used as a method to improve the lacking connection between patients and surgeons regarding the outcome of the procedure (Ramkumar, Harris, & Noble, 2015). PROMs exist in the

form of a survey and contain information that comes directly from the patient without interpretation from anyone else. PROMs are commonly used as a subjective measure to monitor a patient's quality of life and changes in physical function prior to and following surgery (Yorkston, 2019). The utilization of PROMs in TKA and general clinical research has become highly favored because they provide important information regarding outcomes that matter to patients. These outcomes include, but are not limited to, bodily pain, expectations and satisfaction, physical function and overall general health perceptions mentally and physically. Currently, there are numerous validated PROMs used in clinical and research settings to asses a wide variety of health-relevant concepts corresponding to the outcome of TKA (Cella, 2014). PROMs are typically divided into two categories: generic and disease-specific PROMs.

2.2.1 Short-Form Survey (SF-12)

The SF-12 is the most frequently used generic PROM used in clinical and research settings. It a multipurpose short form (SF) that measures the generic health status of a patient and is also a validated quality of life assessment tool (Clement, Weir, Holland, Gerrand, & Deehan, 2019). It was developed to be a shorter, more consolidated version of the SF-36 which is used in larger surveys. One of the biggest advantages of the SF-12 is the shortness and conciseness of it making it less burdensome for patients to fill out. Concepts covered in the SF-12 include physical functioning, role-physical, bodily pain, general health, energy/fatigue, social functioning, role-emotional, mental health and change in overall health. Studies have shown that SF-12 scores are directly correlated to overall satisfaction of TKA subjects (Clement et al., 2018; Clement & Burnett, 2013; Clement et al., 2019).

2.2.2 Knee Society Score (KSS)

One of the more common disease-specific PROMs associated with TKA is the 2011 Knee Society Scoring System. The KSS PROM is an updated version of the 1989 Knee Society Clinical Rating System and is a validated system that evaluates pain relief, functional abilities, satisfaction and fulfillment of expectations. KSS is composed of five components including Patient Demographics, Objective Knee Score, Patient Expectations, Patient Satisfaction and Functional Knee Score. Research has shown that while TKA subjects present significant improvement in all categories following surgery they demonstrated the most improvement of the Functional Score (Giesinger, Hamilton, Jost, Behrend, & Giesinger, 2015; Jacofsky & Allen, 2016; Kuroda et al., 2016).

2.2.3 Forgotten Joint Score (FJS-12)

Another common disease specific PROM used for TKA is the (FJS-12). It is a 12-question survey that assesses a patient's ability to forget about an artificial joint as a result of a successful treatment. Consistent findings in the research of this PROM could give more insight as to if or when the prosthetic feels normal to the patient. The FJS-12 has been used in research to evaluate TKA patients at numerous follow-up times, however, it was found that most patients will demonstrate the most improvement within the first year following surgery (Carlson et al., 2018; Hamilton et al., 2017; Rosinsky et al., 2020).

2.2.4 Limitations of PROMs

While PROMs do provide a comprehensive understanding of a patient's perspective and surgical outcome expectations, they fail to capture changes in objective or performance-based measures of function relative to TKA (Biggs et al., 2019). It is also

possible that patients with severe OA have a difficult time distinguishing between pain and functional restraints when self-evaluating their abilities to carry out simple activities of daily living. Therefore, when assessing a patient's functional improvement following TKA surgery, it is important to analyze both subjective and biomechanical objective measures of function, including gait analysis.

2.3 Level Walking Gait Analysis

The continuous progression of TKA has been significantly influenced by knowledge obtained from gait analysis research (Michael, Golshani, Gargac, & Goswami, 2008). Evaluating level walking gait is an important component in TKA assessment because it facilitates the identification of abnormal gait characteristics. Results generated from gait assessments of TKA subjects has proven to sufficiently provide objective criteria for evaluating functional improvement following the procedure.

To quantify variables of a person's gait, it is important to focus on the events that occur during one complete gait cycle. One gait cycle is measured from heel-strike to heel-strike and consists of two phases, the stance phase and swing phase (Figure 1). On average, about 60% of the gait cycle is the stance phase which is the time period of when the foot is in contact with the ground. The other 40% of the gait cycle is the swing phase which is when the foot is not in contact with the ground.

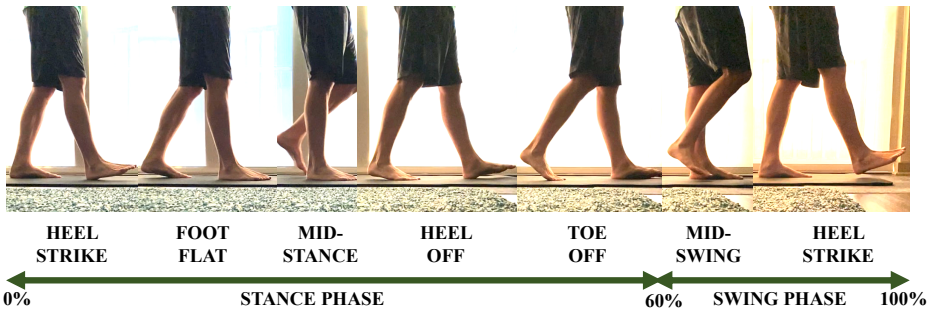

FIGURE 1 Human walking gait cycle (0-100%), stance and swing phase of the right leg.

Although gait analysis has been used quite frequently as a research tool for TKA protocols, only few studies demonstrate objective gait assessment being utilized a routine procedure for functional assessment (Rahman, Tang, Monda, Miles, & McCarthy, 2015). Gait analysis assessments typically take place in a laboratory setting using a three-dimensional motion capture system and two force plates (Henriksen, Graven-Nielsen, Aaboe, Andriacchi, & Bliddal, 2010). This type of assessment can be expensive and time consuming making it an unrealistic clinical procedure for the number of patients undergoing TKA. However, with the utilization of clinical force plates is becoming more versatile, the collection of ground reaction forces may be more feasible with portable force of pressure sensors.

2.3.1 Vertical Ground Reaction Forces

Ground reaction forces measured by the force plates are one of the most frequently analyzed biomechanical measures because they help characterize human movement. The ground reaction force is used to measure characteristics of movement and is a 3-component vector representing forces in the vertical anterior-posterior and medial-lateral planes. The vertical ground reaction force (vGRF) has the highest magnitude of the three resulting in force greater than 100% body weight and sparks a significant interest in TKA researchers (X. Jiang, Napier, Hannigan, Eng, & Menon, 2020). Figure 2 displays a vGRF curve generated during one step or one gait cycle.

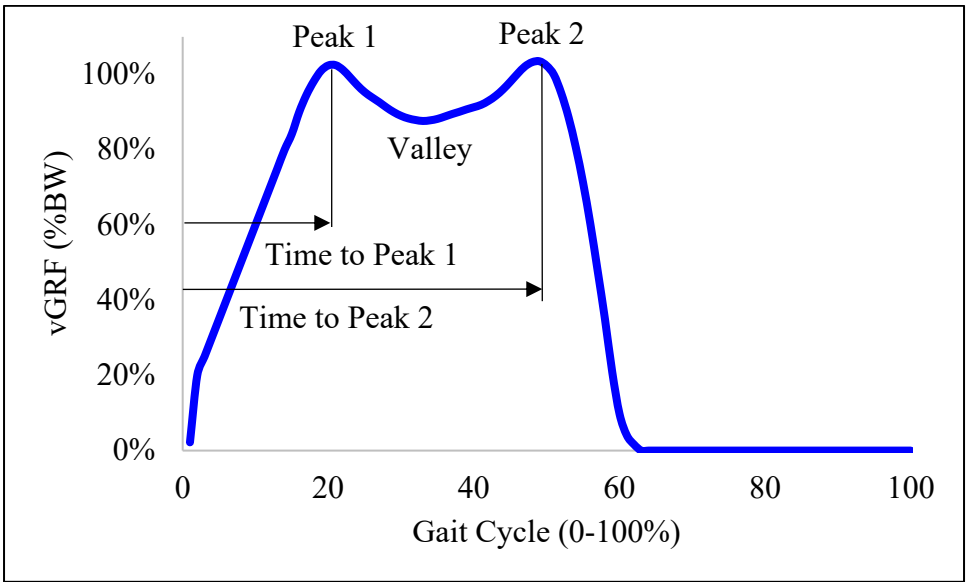

FIGURE 2 Vertical ground reaction force curve generated during one step.

The first peak force (Peak 1) is known as the passive peak which occurs on account of weight acceptance and an increase in muscular forces. This peak force is achieved during the very beginning of the mid-stance phase as one transitions from double-leg to single-leg support. Through the mid-stance phase, the knee extends while the COM transitions upward. During this time there is a reduction in force (Valley) due to the deceleration of the COM as it reaches its maximum. Following the Valley, the vGRF increases until a second peak is achieved during push-off phase before the toe-off. The second peak force (Peak 2) is known as the active peak and is the force applied by the foot into the ground as it pushes off. (X. Jiang et al., 2020; Kramers-de Quervain, Kampfen, Munzinger, & Mannion, 2012). The magnitude and timing of peak forces directly influences the amount of load experienced by the joints and muscles of the lower limb (X. Jiang et al., 2020). For someone who has "normal gait" the vGRF curve during one step will have an M-shape consisting of two peaks of approximately the same magnitude and a distinct valley between peaks. Those who have abnormal gait will

typically present peaks of unequal magnitudes and have a vGRF curve that is flatter between peaks.

Current research not only focuses on differences in vGRFs between TKA and healthy subjects but also bilateral differences between the affected and non-affected limbs of TKA subjects. Pre-operatively have shown that TKA patients exert significantly less force and spend significantly less time on their affected limb compared to their healthy limb as well as compared to healthy controls (Burnett, Campbell-Kyureghyan, Topp, & Quesada, 2015; Pozzi, Snyder-Mackler, & Zeni, 2015). Post-operatively, research has also shown that TKA subjects demonstrated significant improvement in vGRF variables of the affected limb, yet still present differences compared to the non-affected limb and healthy controls (Kramers-de Quervain et al., 2012; Yoshida, Zeni, & Snyder-Mackler, 2012). However, some studies found that there were no significant differences between peak vGRFs and time to peaks between affected and non-affected limbs as well as compared to healthy controls (Jafarnezhadgero, Fatollahi, Amirzadeh, Siahkouhian, & Granacher, 2019; Milner, 2008)

CHAPTER 3 RESEARCH METHODOLOGY

3.1 Study Participants

39 subjects with confirmed tibiofemoral OA who were scheduled for primary TKA surgery at OrthoCarolina were recruited into the study. Potential subjects were initially informed by a recruitment letter sent from OrthoCarolina via mail and email. Then, a follow-up phone call was made to all potential subjects from the UNC Charlotte Biomechanics and Motion Lab to confirm eligibility and answer any questions they may have about the study. The study protocol was approved by UNC Charlotte's Institutional Review Board (IRB) and all participants gave written informed consent.

The inclusion and exclusion criteria for OA patients consider age, body mass index (BMI), health history, American Society of Anesthesiologists (ASA) score and Physical Activity Readiness Questionnaire (PAR-Q) test (Table 1). At the time of analysis, 39 patients had completed pre-op assessment, 36 subjects had completed the one-week follow-up, 35 subjects had completed the 1-month follow-up, 29 subjects had completed the 6-month re-assessment and 20 subjects had completed the 12-month follow-up. Due to practical life reasons, there was variability in the timing for follow up visits.

TABLE 1 Inclusion and exclusion criteria for OA study participants.

Inclusion criteria	Exclusion criteria
▪ Age 50-75 years old ▪ BMI less than 33 ▪ to be operated on by Dr. Ronald Singer or Dr. Michael Bates ▪ Walk with or without aid ▪ ASA score 1 and 2 ▪ No additional joint replacements of lower extremity joints	▪ Unable to walk ▪ Past major head, neck, and trunk injuries/pathologies ▪ Systemic inflammatory diseases ▪ Neurologic diseases ▪ Unable to read and provide informed consent ▪ ASA score 3 and 4 ▪ Answered "YES" to any of the questions on the PAR-Q ▪ Additional joint replacements of hip or ankle joints

10 subjects who were between the ages of 50 and 75 with no lower limb surgeries, no diagnosis of arthritis issues in the legs and were able to ascend/descend stairs without help were recruited into the study. These subjects were recruited from local senior centers and social media advertisements.

3.2 Patient-Reported Outcome Measures

Three validated PROMs were used to assess perceived pain and function. Table 2 displays the types of PROMs collected at each test time. The SF-12 and the KSS were collected pre-op and 1-month, 6-months, and 12-months post-op. The SF-12 was also collected 1-week post-op and the FJS-12 was collected for 1-month, 6-months and 12-months follow-ups. The SF-12 used in this study is a shortened version of the SF-36, which is one of the most generic PROMs used by clinicians, covering a variety of categories including vitality, physical functioning, bodily pain, generic health perceptions, physical role functioning, emotional role functioning, social role functioning and mental health. Lastly, the KSS and FJS-12 PROMs focus more on the artificial joint directly. The KSS focuses on multiple categories which are symptoms, patient

satisfaction, patient expectations, functional activities, standard activities, advanced activities, and discretionary knee activities. The FJS-12 is a simple, concise 12-item PROM that evaluates patients' ability to forget their artificial joint in everyday life. Using all three PROMs in the study allows a more accurate representation of patient perceived pain and function.

TABLE 2 Each patient-reported outcome measure collected at the respective test time.

Pre-op	**1-Week Post-op**	**1-Mon Post-op**	**6-Mon Post-op**	**12-Mon Post-op**
KSS SF-12	SF-12	KSS SF-12 FJS	KSS SF-12 FJS	KSS SF-12 FJS

3.3 Biomechanical Gait Analysis

Three-dimensional gait analysis was performed during level-walking on 39 patients with OA who were scheduled to have TKA surgery and 10 healthy control subjects. 29 TKA subjects have returned to complete a 6-month follow-up assessment. All gait analysis testing was performed at the UNC Charlotte Biomechanics and Motion Analysis Lab. Motion analysis data was collected using a 10-camera motion capture system (VICON) that tracked reflective markers attached to subjects in specific anatomical positions (Figure 3). Marker trajectories were collected using the cameras capturing at 120 Hz and ground reaction forces were collected from two force platforms embedded into a 3.7 m walkway, also capturing at 120 Hz. For data analysis, only the ground reaction force data was used. Five trials were performed with the subjects walking at a self-paced speed across the walkway. The three best trials were used for data analysis.

FIGURE 3 Anterior and posterior views of TKA subject with motion capture markers attached to the body.

3.4 Data Organization

3.4.1 Patient-Reported Outcome Variables

All PROMs scores were collected from patients on paper copies and transferred to an Excel template for analysis. A specific algorithm was used to calculate SF-12 scores. The SF-12 has a total of three scores: Mental Health Score (27 points), Physical Heath Score (20 points) and Total Score (47 points). The KSS was also divided into three scores: Objective Score (2 questions, 0-20 points), Expectation and Satisfaction Score (8 questions, 0-55 points) and Functional Score (16 questions, 0-100 points). KSS scores were calculated by summing values of all the questions in each section. Lastly, when

calculating the score for FJS-12, all of the responses were summed. The sum is divided by the number of responses that were completed and then multiplied by 25 to get a value that ranges from 0-100. The score is then is subtracted from 100 to change the direction of the final score so that higher scores indicate a high degree of "forgetting" the artificial joint and also representing a lower degree of awareness If the patient failed to respond to more than 4 of the questions, then the total score should be discarded. This goes for missing values as well as questions that were "not relevant" to the patient.

3.4.2 Vertical Ground Reaction Force Variables

All C3D files from the VICON software were loaded into a custom MATLAB program. Vertical ground reaction force variables (vGRF) Peak 1, Peak 2, Valley, Time to Peak 1 and Time to Peak 2 were extracted from the data set for both left and right legs of TKA and healthy subjects. Changes in peak vGRF variables Peak 1 – Peak 2, Peak 1 – Valley and Peak 2 – Valley were calculated by finding the difference in magnitude between each peak and all vGRF variables were normalized by converting the force in Newtons to % bodyweight. For each participant at each test time, averages across the three trials of all variables were used for statistical analysis.

3.4.3 Statistical Analysis

All statistical analysis was performed using IBM Statistical Package for the Social Science (SPSS, Chicago, IL). PROMs and vGRF data for Objectives 1, 2 and 3 were summarized with means and standard deviations. For Objective 1, changes in PROMs over time were analyzed using Paired Samples *t*-Test and One-way Analysis of Variance (ANOVA). Correlations between the different types of PROMs used at each test time were assessed using the Pearson's correlation coefficient. For Objective 2, between limb

and between group comparisons and changes in vGRFs over time were evaluated using Paired Samples *t*-Test and One-way ANOVA. Lastly, for Objective 3, Pearson's correlation coefficients were used to analyze the correlations between changes in vGRF variables and the changes in KSS and SF-12 PROMs variables from pre-op to 6-months post-op. FJS-12 was not included in Objective 3 because it was not collected at the pre-op test time.

CHAPTER 4: RESULTS DISCUSSION

The detailed analysis and findings of results from applying the methodology is presented in this section. To begin, the analysis to assess the trends and relationships between PROMs scores is presented, followed by the analysis of vGRF variables and how each of them correlate with the PROMs scores.

4.1 Objective 1—Analysis of PROMs

The purpose of the first objective was to investigate any improvement in PROMs over the course of the study as well as evaluate any correlations between the three different types of PROMs used. A total of 15 patients who had completed pre-op assessment and all of the respective follow-ups were included in the analysis.

4.1.1 Changes in PROMs Over Time

SF-12 scores were summarized using means and standard deviations (Table 3). Higher scores for the SF-12 indicate better physical function, better mental health and better overall health for the physical, mental and total scores respectively. The SF-12 scores significantly improved by a total 4% for the SF-12 Physical Score ($p=.034$ from pre-op to 12-months post-op. Subjects also demonstrated significant improvement for the physical score from pre-op to 6-months ($p=.035$), 1-month to 6-months ($p=.005$) and 1-month to 12-months ($p=.001$). There were no significant changes in the SF-12 Physical Score from pre-op to 1-week, pre-op to 1-month and 1-week to 1-month. Also, no significant changes were observed for SF-12 Mental Score and SF-12 Total Score.

TABLE 3 Results (Mean±SD) for SF-12 Scores.

SF-12 Score	Pre-op	1-week	1-mon	6-mon	12-mon
Physical Health Subscore	59±7%	58±7%	58±5%	63±5%	63±6%
Mental Health Subscore	70±7%	68±8%	68±7%	69±5%	68±5%
Total Score	65±6%	64±5%	64±5%	66±5%	66±5%

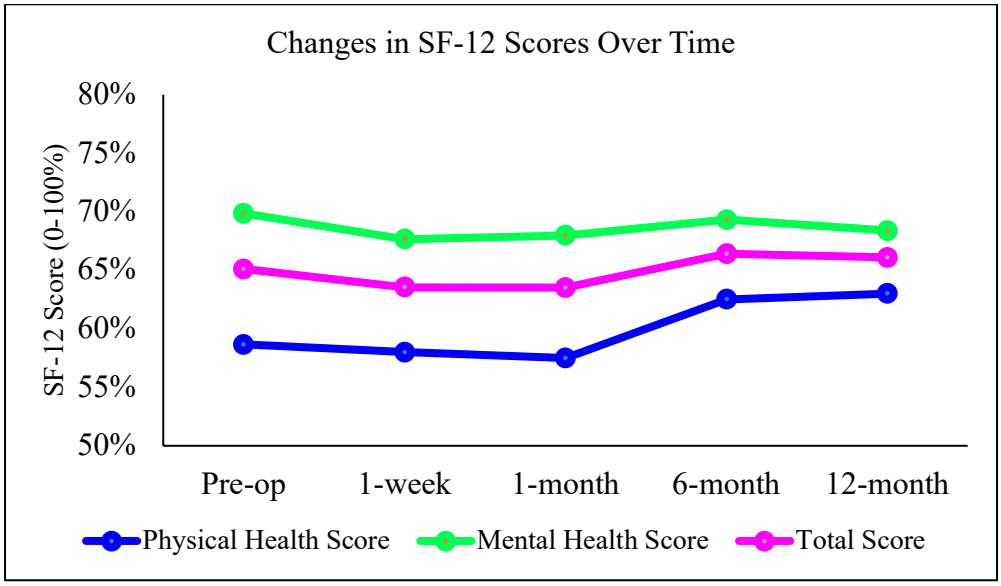

FIGURE 4 Changes in Physical, Mental and Total SF-12 Scores over time.

The FJS-12 Scores were summarized with means and standard deviations (Table 4). Subjects with higher FJS-12 scores have a higher degree of "forgetting" and lower degree of awareness of their artificial joint. The FJS-12 Scores significantly improved from 1-month to 12-months by a total of 35 points (p=.005). No significant improvement was demonstrated in the intermediate follow-ups from 1-month to 6-months and 6-months to 12-months.

TABLE 4 Results (Mean±SD) for FJS-12 Scores.

	Pre-Op	1-mon	6-mon
FJS-12 Score	30±22	47±26	65±28

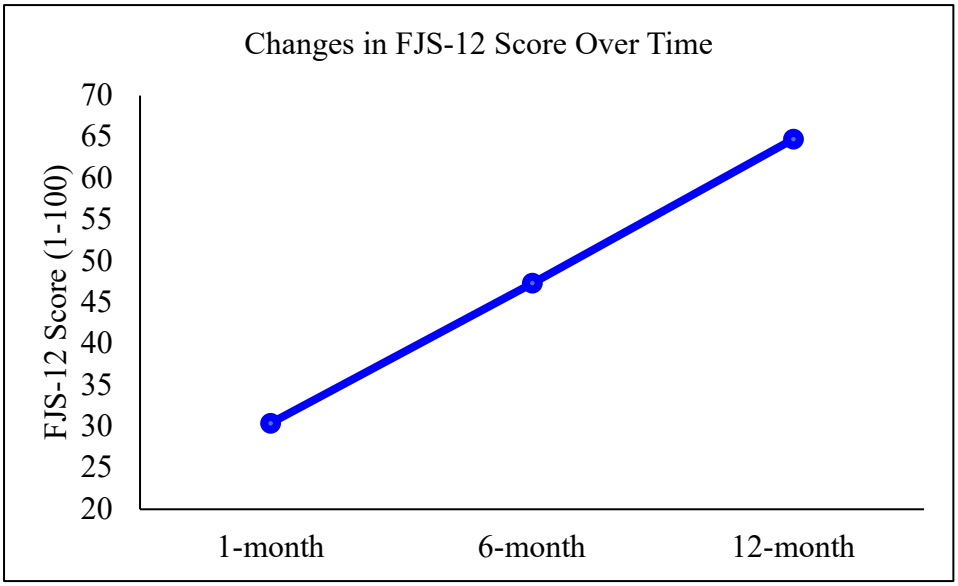

FIGURE 5 Changes in the FJS-12 Score over time.

Knee Society Scores were summarized using means and standard deviations (Table 5). A lower KSS Objective score indicates the subject has a lower pain level. Subjects showed significant improvement by a total of 4 points from pre-op to 12-months (p=.015). There was also significant improvement pre-op to 1-month (p=.023) and pre-op to 6-months (p=.015). No significant improvement was demonstrated in the intermediate follow-ups from 1-month to 6-months and 6-months to 12-months.

TABLE 5 Results (Mean±SD) for KSS Scores.

KSS Score	Pre-op	1-mon	6-mon	12-mon
Objective Score	11±6	6±6	6±6	4±5
Expectation and Satisfaction Score	28±8	38±9	41±11	45±10
Functional Score	49±17	56±24	72±19	71±22

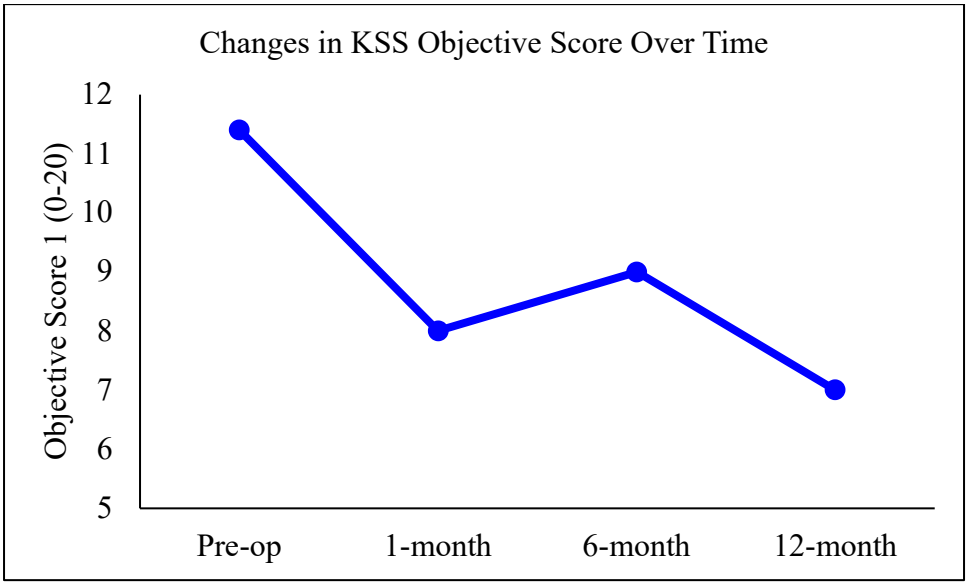

FIGURE 6 Changes in the KSS Objective Score over time.

For the KSS Expectation and Satisfaction Score, a higher score indicates the subject has high post-surgery expectations and satisfaction. Subjects showed significant improvement from pre-op to 12-months by a total of 17 points ($p<.001$). There was also significant improvement from pre-op to 1-month ($p=.004$), pre-op to 6-months ($p=.001$), 1-month to 12-months ($p<.001$). No significant changes discovered from 1-month to 6-months or 6-months to 12-months.

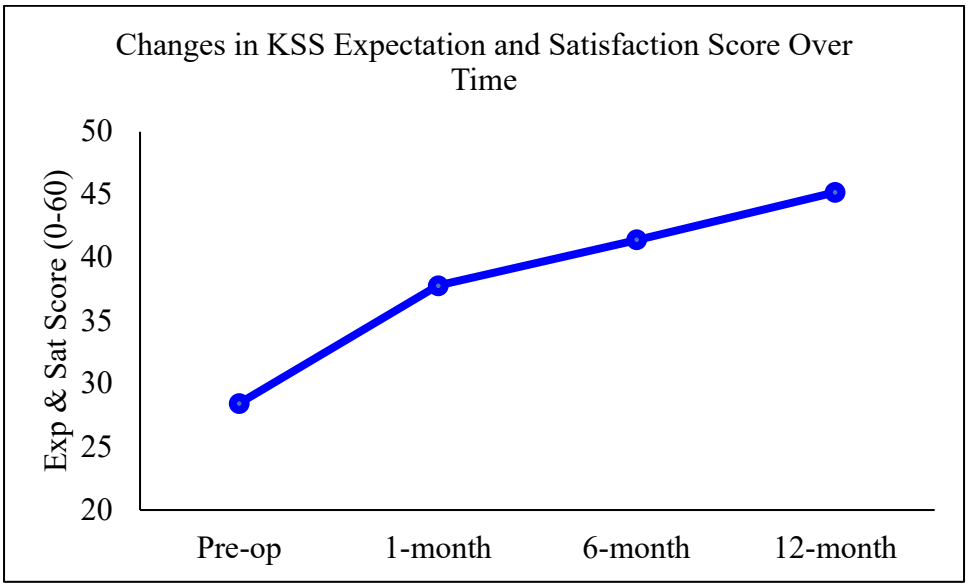

FIGURE 7 Changes in the KSS Expectation and Satisfaction Score over time.

Lastly, for the KSS Functional Score, a higher score indicates greater functional ability when performing activities of daily living. Subjects demonstrated significant improvement from pre-op to 12-months by a total of 22 points (p=.002). There was also significant improvement pre-op to 6-months (p<.001), 1-month to 6-months (p=.020) and 1-month to 12-months (p=.037). No significant changes observed pre-op to 1-month and 6-months to 12 months.

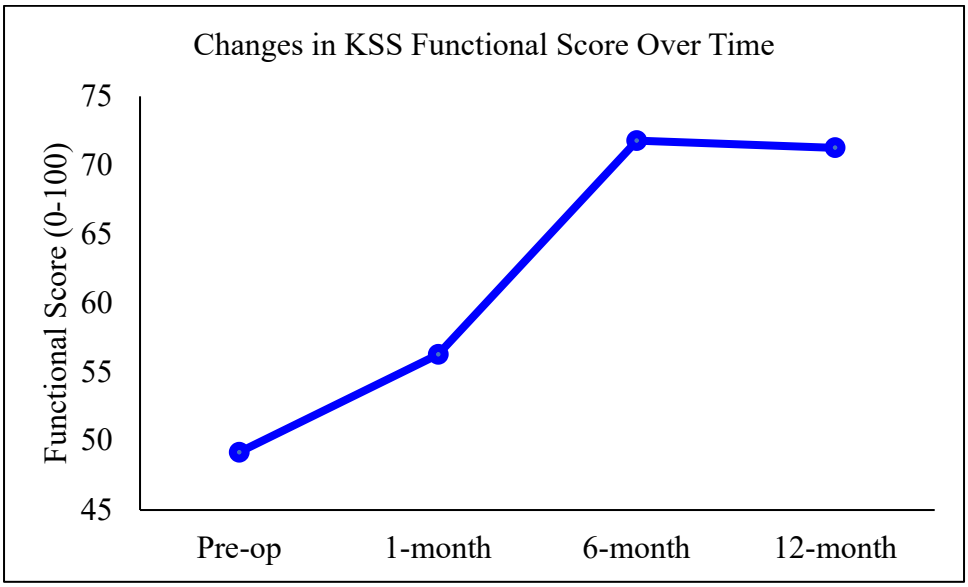

FIGURE 8 Changes in the KSS Functional Score over time.

4.1.2 Correlations Between PROMs

During pre-op assessment subjects reported 6 different scores: KSS Objective Score, KSS Expectation and Satisfaction Score, KSS Functional Score, SF-12 Mental Score, SF-12 Physical Score and SF-12 Total Score. The KSS Objective Score was observed to be significantly correlated to the KSS Expectation and Satisfaction Score ($p=.025$). Subjects who reported to have a lower pain level also reported to have higher expectations and satisfaction. The KSS Functional Score was significantly correlated to the SF-12 Physical Score ($p=.014$) and SF-12 Total Score ($p=.037$). The SF-12 Total Score also showed significant correlations between SF-12 Mental Score ($p=.033$) and SF-12 Physical Score ($p=.001$).

The only scores collected at the time of the 1-week follow-up were from the SF-12 PROM: the SF-12 Physical Score, SF-12 Mental Score and SF-12 Total Score.

Significant correlation was present between SF-12 Mental Score and SF-12 Total Score ($p<.001$).

For the 1-month follow-up the same 6 scores from pre-op assessment were reported as well as the FJS-12 Score. The KSS Objective Score 1 was significantly correlated to the KSS Functional Score ($p=.023$). Subjects who reported a lower pain level also reported having a higher functional ability to perform activities of daily living. Similar to the pre-op assessment, the SF-12 Total Score showed significant correlations between the SF-12 Mental Score ($p<.001$) and SF-12 Physical Score ($p=.031$). There were no significant correlations between the FJS-12 Score and any of the other PROMs scores.

The same 7 scores collected at the time of the 1-month follow-up were also reported at the 6-months and 12-months follow-ups. Strong correlations were observed between PROMs for the 6-months reassessment. The KSS Objective Score 1 was shown to be significantly correlated all other PROMs scores; KSS Expectation and Satisfaction Score ($p=.028$), KSS Functional Score ($p<.001$), FJS-12 Score ($p=.001$), SF-12 Physical Score ($p=.046$), SF-12 Mental Score ($p=.030$) and SF-12 Total Score ($p=.024$). The KSS Expectation and Satisfaction score was also observed to be significantly correlated to the KSS Functional Score ($p=.003$), FJS-12 Score ($p<.001$), SF-12 Physical Score ($p=.017$) and SF-12 Total Score ($p=.027$). The KSS Functional Score showed significant correlations between FJS-12 Score ($p=.001$) and SF-12 Mental Score ($p=.045$). Lastly, there were significant correlations between the SF-12 Physical Score and SF-12 Mental ($p=.003$) as well as significant correlations between SF-12 Total Score and SF-12 Physical Score ($p<.001$) and SF-12 Mental Score ($p<.001$).

There were fewer correlations between PROMs for the scores reported at 12-months than there were at 6-months. The KSS Objective Score was significantly correlated to the KSS Expectation and Satisfaction Score ($p=.003$) and KSS Functional Score ($p=.006$). The KSS Expectation and Satisfaction Score and KSS Functional Score were significantly correlated to one another ($p<.001$) and also correlated to the FJS-12 Score ($p=.009$, $p=.006$). Lastly, similar to 1-month and 6-months follow-ups, the SF-12 Total Score was significantly correlated to the SF-12 Physical Score ($p<.001$) and SF-12 Mental Score ($p<.001$).

4.2 Objective 2—Analysis of vGRF Variables

The purpose of the second objective was to investigate any bilateral differences in vertical ground reaction force variables as well as investigate any significant improvement in these variables from pre-op to 6-months post-op. Vertical ground reaction force variables of TKA subjects were also compared to healthy controls. Data from 17 TKA subjects who had completed both pre-op and 6-months post-op assessments and 10 healthy subjects were included in the analysis.

4.2.1 Between Limb and Between Group Comparisons

4.2.1.1 Left vs. Right Leg

Table 6 details the between limb bilateral differences of vGRF variables between left and right legs for pre-op, post-op and Healthy subjects. Healthy subjects as well TKA subjects at 6 months post-op presented no significant bilateral differences between the left and right legs. That means for each of the vGRF variables these subjects demonstrated similar values for both left and right legs with the differences between the two being approximately zero. However, TKA subjects demonstrated significant between

limb differences of Valley (p=.046) and Time to Peak 1 (p=.014) variables at the pre-op assessment.

TABLE 6 Results of bilateral gait analysis parameters between left and right legs for TKA subjects at pre-op and post-op and healthy subjects. * Indicates significance ($p<0.05$).

	Pre-op	**Post-op**	**Healthy**
Peak 1 (%BW)	1.6±.5.5	1.9±6.0	5.0±3.2
Peak 2 (%BW)	7.1±5.9	.94±3.6	-1.8±5.6
Valley (%BW)	-1.5±2.9*	-.82±2.2	-.60±1.7
Time to Peak 1 (%GC)	-2.8±.4.1*	-.24±4.2	.40±3.3
Time to Peak 2 (% GC)	-.29±5.9	.29±.4.8	-.80±3.2
Peak 1-Peak 2 (%BW)	.18±5.0	-1.8±4.6	-1.7±5.9
Peak 1-Valley (%BW)	2.8±7.0	2.6±7.4	.80±4.0
Peak 2-Valley (%BW)	2.0±7.5	1.6±4.4	-1.5±7.2

The right leg presented a significantly higher value for the Valley while also demonstrating a significantly longer Time to Peak 1. As stated in the literature review section, the Valley represents the reduction in the vGRF that occurs as the knee bends slightly through midstance, the COM displaces in a downward. When subjects demonstrate a higher Valley or lower %BW vGRF during this time, their COM shifts downward while the knee bends approximately 20 degrees. Because majority (76%) of subjects were scheduled to have TKA surgery on the right leg at the time of pre-op assessment, this indicates that subjects were increasing walking speed in order to reduce the amount of weight bearing on the impaired leg. Similarly, the right leg demonstrated having a significantly longer Time to Peak 1 than the left leg. The time it takes to reach a

maximum peak in the vGRF is inversely proportional to the loading rate or the rate that the force increases as the foot contacts the ground when walking. Therefore, these findings suggest that subjects altered their gait biomechanics in order to decrease the loading rate on the impaired leg.

Figure 9 displays curves of bilateral differences of vGRF variables between left and right legs for **(A)** TKA pre-op, **(B)** TKA post-op and **(C)** Healthy subjects. The TKA pre-op curve presents very distinct differences between the left and right legs compared to the TKA post-op and healthy plots where the lines are almost the same. Statistically, the bilateral differences between the left and right leg were similar between TKA subjects at post-op and healthy subjects. However, TKA subjects demonstrated significantly greater bilateral differences between the left and right leg for Time to Peak 1 ($p=.049$) at pre-op compared to healthy subjects. This suggests TKA subjects altered their gait in order to a achieve a longer time to reach Peak 1 and a reduced loading rate of the right leg compared to the left leg while healthy subjects did not.

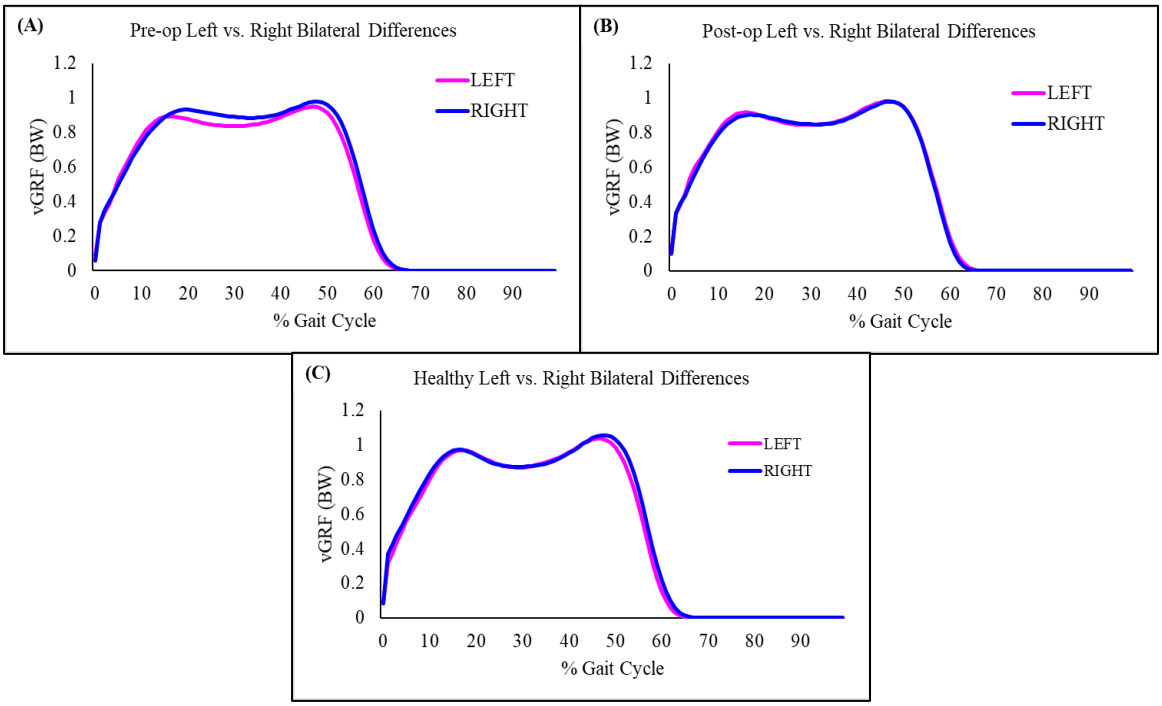

FIGURE 9 Results of bilateral gait analysis parameters between left and right legs for **(A)** TKA pre-op, **(B)** TKA post-op and **(C)** Healthy subjects.

4.2.1.2 Implant vs. Non-Implant Leg

Table 7 details the between limb bilateral differences of vGRF variables between the implant and non-implant legs for pre-op and 6 months post-op. Because the healthy subjects do not have an implant and non-implant leg, the bilateral differences between the left and right legs were used. TKA subjects demonstrated significant between limb bilateral differences between the implant and non-implant legs at the pre-op test time for Peak 2 (p=.006) and Peak 2-Valley (p=.009). There were no significant between limb bilateral differences of vGRF variables at 6-months post-op.

TABLE 7 Results of bilateral gait analysis parameters between implant and non-implant legs for TKA subjects at pre-op and post-op and healthy subjects. * Indicates significance ($p<0.05$).

	Pre-op	**Post-op**
Peak 1 (%BW)	-1.5±5.5	-1.8±6.0
Peak 2 (%BW)	-3.5±4.7*	-1.6±3.3
Valley (%BW)	.94±3.2	.47±.23
Time to Peak 1 (%GC)	1.5±4.8	.71±4.1
Time to Peak 2 (% GC)	.65±5.9	.06±.4.8
Peak 1-Peak 2 (%BW)	-1.2±4.8	.88±4.9
Peak 1-Valley (%BW)	-2.4±7.2	-1.9±7.6
Peak 2-Valley (%BW)	-4.5±6.2*	-1.9±4.3

Unlike the results of the bilateral differences between the left and right legs, there were no significant differences between the implant leg and non-implant at pre-op for Valley and Time to Peak 1. However, both Peak 2 and Peak 2-Valley variables were significantly lower on the implant leg compared to the non-implant leg. During the toe-off phase, an increase in knee extension is required to transfer muscular power. Because TKA patients have demonstrated a lower Peak 2 in the implant leg compared to the non-implant leg, it is likely that they were not able to achieve full extension of the knee due to pain, range of motion or other issues regarding the impaired leg. With that being said, because the implant leg demonstrated a lower Peak 2, there was also less of a difference in magnitude between Peak 2 and Valley.

Figure 10 also displays curves of between limb bilateral differences of vGRF variables between the implant and non-implant leg or **(A)** TKA pre-op and **(B)** TKA post-op groups. There were no significant differences between bilateral differences of the implant and non-implant between pre-op and post-op groups.

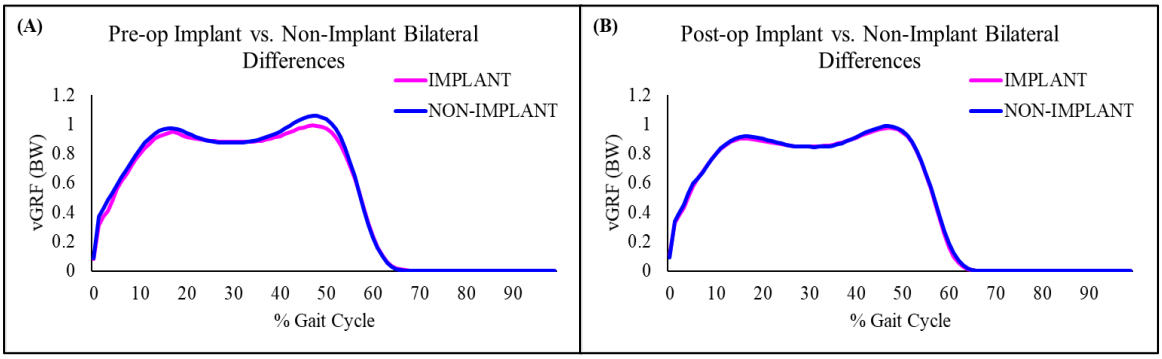

FIGURE 10 Results of between limb bilateral differences between implant and non-implant legs for **(A)** TKA pre-op and **(B)** TKA post-op groups between limb bilateral differences between left and right legs for the Healthy group.

4.2.2 Changes in Vertical Ground Reaction Forces Over Time

Changes were evaluated from pre-op to 6-months for both implant and non-implant legs. Table 8 presents vGRF details of the implant leg for pre-op and 6-months post-op. Pre-post represents the difference in pre-op and post-op values for each vGRF variable. For the implant leg only, Valley was significantly higher ($p<.001$) at pre-op than at 6-months post-op, while Peak 2-Valley was significantly lower ($p=.011$) which suggests significant improvement of both variables.

TABLE 8 Changes Vertical Ground Reaction Force Variables over time for the implant leg. * Indicates significance ($p<0.05$).

	Pre-op	Post-op	Post-Pre	Healthy
Peak 1 (%BW)	100±7	97.1±8	-2.9±4	99.9±6
Peak 2 (%BW)	101±5	102±7	.2±5	106±6
Valley (%BW)	88.1±4*	83.7±6	-4.5±4	84.7±4
Time to Peak 1 (%GC)	20±5	18±3	-2±5	18±3
Time to Peak 2 (% GC)	47±3	47±3	.176±2	47±2
Peak 1-Peak 2 (%BW)	4.7±3	6.1±4	1.4±4	6.1±5
Peak 1-Valley (%BW)	11.9±7	13.5±8	-1.6±5	14.9±6
Peak 2-Valley (%BW)	13.4±6*	17.9±9	-4.6±7	20.1±9

Similar to the results from the Between Limb and Between Group Comparisons section, the Valley was significantly higher ($p<.001$) for the implant leg while the difference between Peak 2 and Valley (Peak 2-Valley) ($p=.011$) was significantly lower from pre-op to post-op as well as compared to healthy controls. Based on these findings, the values of Valley decreased significantly from 88.1±4 %BW at pre-op to 83.7±6 %BW at 6-month post-op. This significant decrease in %BW suggests that subjects subconsciously increased their walking speed in order to avoid greater weight bearing on the implant leg possibly due to pain or other issues. Although at 6-months post-op, subjects demonstrated similar values of Valley compared to the healthy subjects. TKA subjects also demonstrated a significant increase in Peak 2-Valley from 13.4±6 %BW at pre-op to 17.9±9 %BW at 6-months post-op. This suggests that before surgery subjects were not able to achieve required increase in knee extension between the mid-stance and toe-off phase potentially due to pain, limited range of motion or other reasons. That

increase in knee extension is necessary in order to present a distinct weight transition between the Valley and Peak 2. However, the results show that patients had improvement from pre-op to 6-months post-op by having Peak 2-Valley values at post-op similar to those of healthy subjects.

Table 9 presents vGRF details of the non-implant leg for pre-op and 6-months post-op. Pre-post represents the difference in pre-op and post-op values for each vGRF variable. There were no significant differences in the non-implant leg from pre-op to 6-months post-op as well as no significant differences between the non-implant leg compared to the healthy subjects.

TABLE 9 Changes Vertical Ground Reaction Force Variables over time for the non-implant leg. ***** Indicates significance ($p<0.05$).

	Pre-op	**Post-op**	**Pre-Post**	**Healthy**
Peak 1 (%BW)	101±5	103±7	2.6±5	99.9±6
Peak 2 (%BW)	105±8	103±9	1.6±5	106±6
Valley (%BW)	85.2±5	83.2±8	4.0±4	84.7±4
Time to Peak 1 (%GC)	19±5	18±3	1±5	18±3
Time to Peak 2 (% GC)	47±4	47±3	-.80±5	47±2
Peak 1-Peak 2 (%BW)	5.9±4	5.2±4	-.70±4	6.1±5
Peak 1-Valley (%BW)	4.2±8	5.4±11	-1.2±7	14.9±6
Peak 2-Valley (%BW)	17.8±9	19.9±12	-2.1±8	20.1±9

4.2 Objective 3—Changes in vGRFs and Changes in PROMs Over Time

The third objective was to investigate any relationships between the improvement of vertical ground reaction force variables and the improvement of TKA PROMs. Because there were no significant changes in the non-implant leg from pre-op to 6-

months post-op discovered in Objective 2, only the improvement of the implant leg was included. PROMs and vGRF data from the same 17 subjects used in Objective 2 were included in the analysis.

4.2.1 Changes in vGRF Variables vs. Changes in SF-12 Scores

Based on the findings of Objectives 1 and 2, subjects demonstrated significant improvement from pre-op to 6-months post-op for the SF-12 Physical Score ($p=.035$), Valley ($p<.001$) and Peak 2-Valley ($p=.011$). There was no significant improvement of the SF-12 Mental and Total Scores as well as the rest of the vGRF variables.

Figure 11 displays a scatter plot with trendlines between the changes in Peak 1 and changes in SF-12 Physical, SF-12 Mental and SF-12 Total Scores. Positive change in Peak 1 and positive change in SF-12 Scores represents patients having improvement in these variables. There were significant correlations between Peak 1 and the SF-12 Physical Score ($p=-.556$), SF-12 Mental Score ($p=-.625$) and SF-12 Total Score ($p=-.694$). This indicates that having a negative change in Peak 1 or a reduced weight acceptance on the implant leg correlates to positive improvement of the SF-12 Scores.

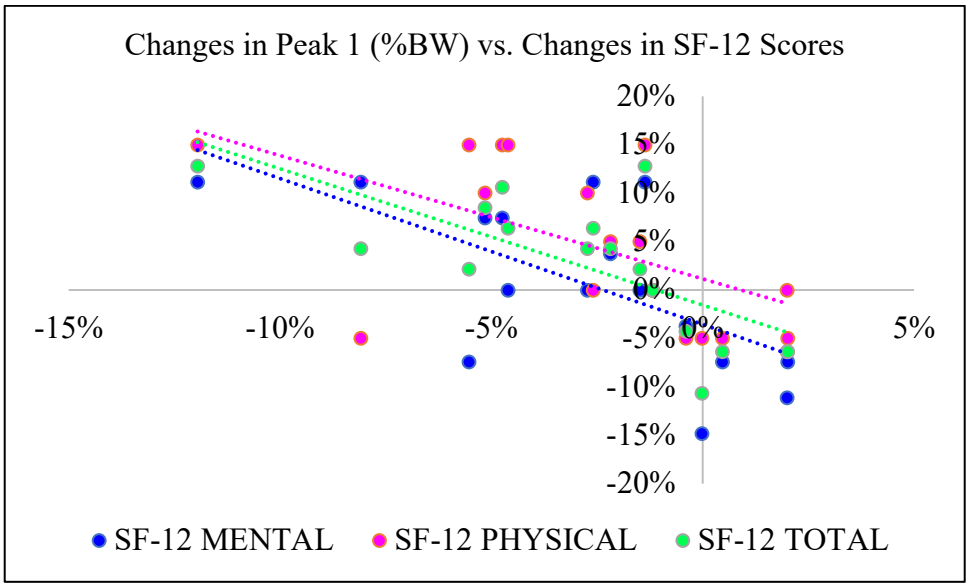

FIGURE 11 Changes in Peak 1 vs. Changes in SF-12 Physical, Mental and Total Scores.

Figure 12 displays a scatter plot with trendlines between the changes in Peak 2 and changes in SF-12 Physical, SF-12 Mental and SF-12 Total Scores. Positive change in Peak 2 and positive change in SF-12 Scores represents patients having improvement in these variables. There were significant correlations between Peak 2 and the SF-12 Physical Score (p=-.485) and SF-12 Total Score (p=-.550). This indicates that having a negative change in Peak 2 or a reduced push-off force on the implant leg correlates to positive improvement of the SF-12 Physical and SF-12 Total Scores.

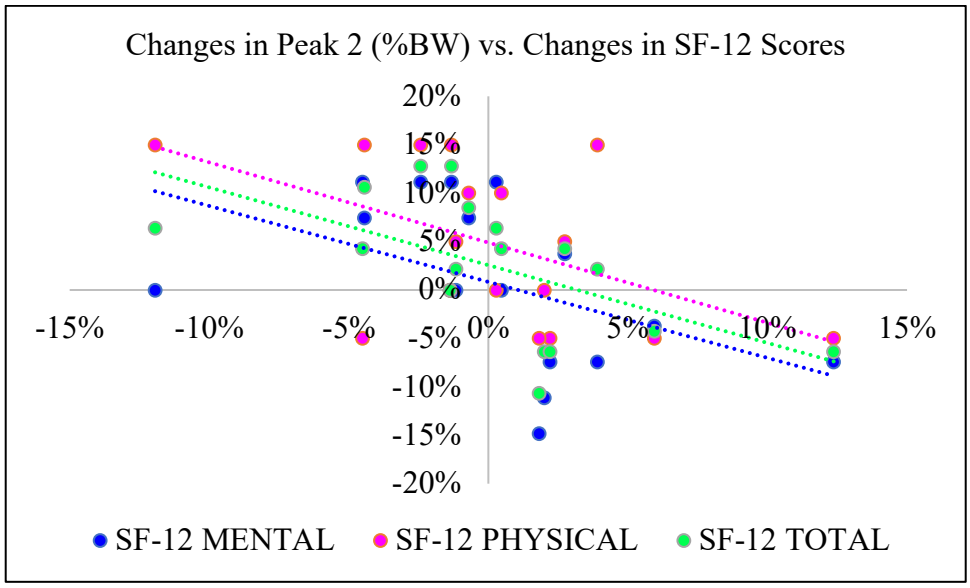

FIGURE 12 Changes in Peak 2 vs. Changes in SF-12 Physical, Mental and Total Scores.

Figure 13 displays a scatter plot with trendlines between the changes in Valley and changes in SF-12 Physical, SF-12 Mental and SF-12 Total Scores. Negative change in Valley and positive change in SF-12 Scores represents patients having improvement in these variables. There were no significant correlations between the changes in Valley and changes in SF-12 Scores. Based on Figure 13, improvement of the Valley correlates to improvement of SF-12 Mental and Total Scores, but not the SF-12 Physical Score.

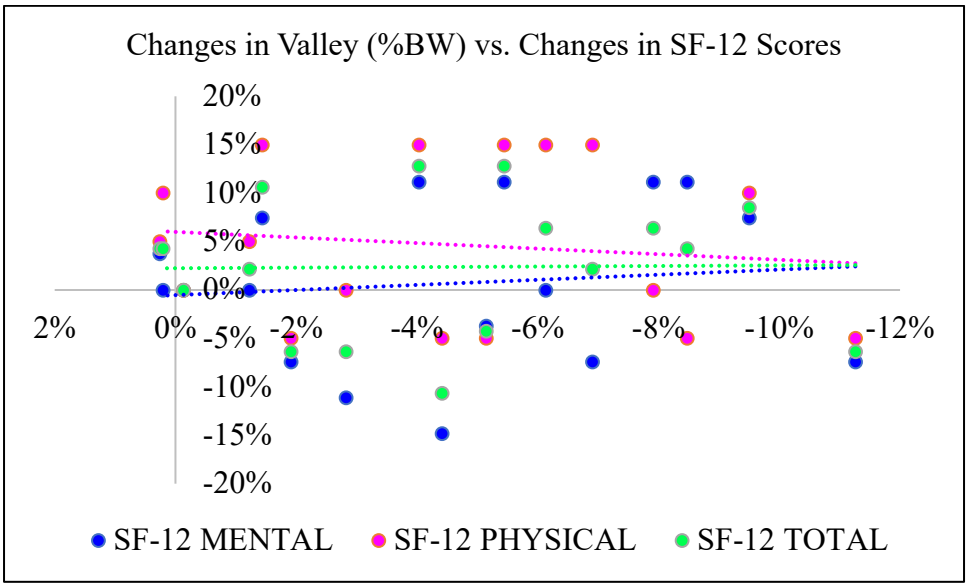

FIGURE 13 Changes in Valley vs. Changes in SF-12 Physical, Mental and Total Scores.

Figure 14 displays a scatter plot with trendlines between the changes in Time to Peak 1 and changes in SF-12 Physical, SF-12 Mental and SF-12 Total Scores. Negative change in Time to Peak 1 and positive change in SF-12 Scores represents patients having improvement in these variables. There were no significant correlations between the changes in Time to Peak 1 and changes in SF-12 Scores. Based on Figure 14, improvement in Time to Peak 1 correlates to improvement in the SF-12 Mental Score, but not the SF-12 Physical and SF-12 Total Scores.

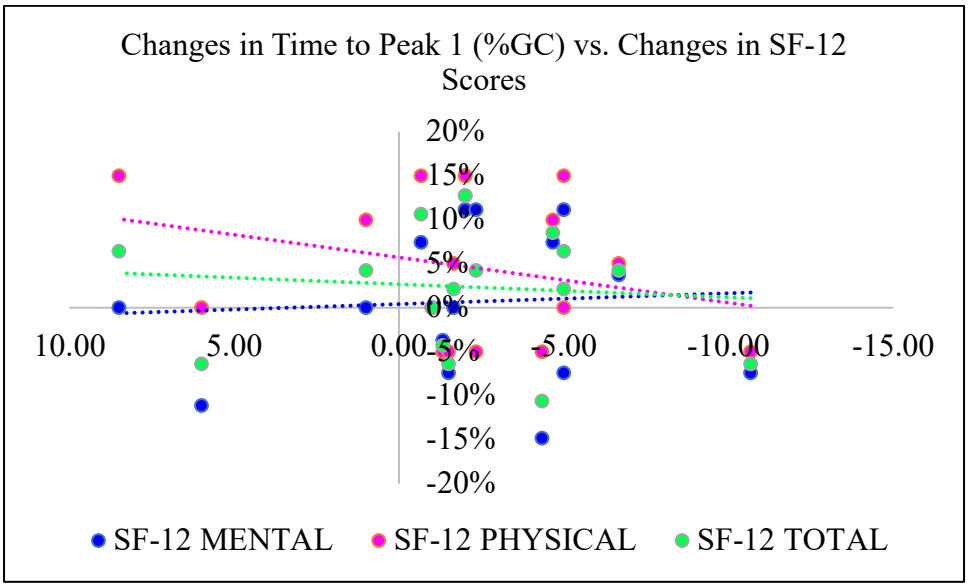

FIGURE 14 Changes in Time to Peak 1 vs. Changes in SF-12 Physical, Mental and Total Scores.

Figure 15 displays a scatter plot with trendlines between the changes in Time to Peak 2 and changes in SF-12 Physical, SF-12 Mental and SF-12 Total Scores. Negative change in Time to Peak 1 and positive change in SF-12 Scores represents patients having improvement in these variables. There were no significant correlations between the changes in Time to Peak 2 and changes in SF-12 Scores. Based on Figure 15, improvement in Time to Peak 2 correlates to improvement in the SF-12 Mental Score and SF-12 Total Score but not the SF-12 Physical Score.

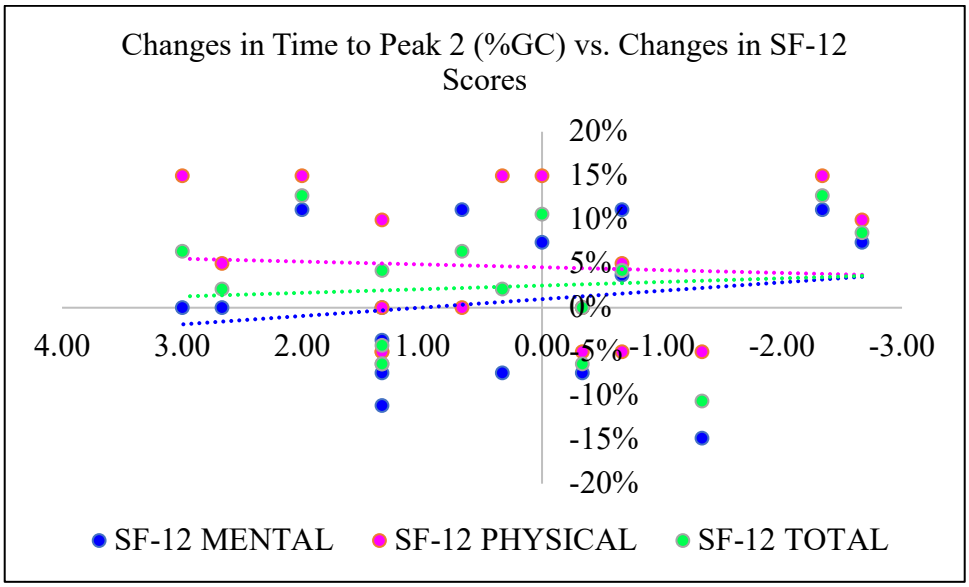

FIGURE 15 Changes in Time to Peak 2 vs. Changes in SF-12 Physical, Mental and Total Scores.

Figure 16 displays a scatter plot with trendlines between the changes in Peak 1-Peak 2 and changes in SF-12 Physical, SF-12 Mental and SF-12 Total Scores. Negative change in Peak 1-Peak 2 and positive change in SF-12 Scores represents patients having improvement in these variables. There were no significant correlations between the changes in Peak 1-Peak 2 and changes in SF-12 Scores. Based on Figure 16, improvement in Peak 1-Peak 2 correlates to improvement in the SF-12 Mental Score and SF-12 Total Score but not the SF-12 Physical Score.

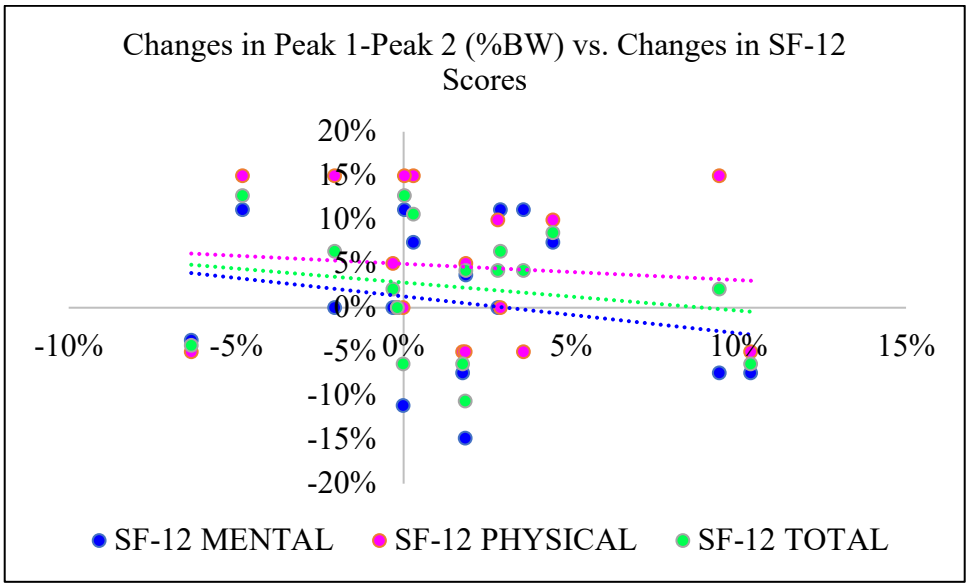

FIGURE 16 Changes in Peak 1-Peak 2 vs. Changes in SF-12 Physical, Mental and Total Scores.

Figure 17 displays a scatter plot with trendlines between the changes in Peak 1-Valley and changes in SF-12 Physical, SF-12 Mental and SF-12 Total Scores. Negative change in Peak 1-Valley and positive change in SF-12 Scores represents patients having improvement in these variables. There were significant correlations between the changes in Peak 1-Valley and changes in the SF-12 Physical Score (p=-.503) and the SF-12 Total Score (p=-.524). There were no significant correlations between the changes in Peak 1-Valley and the changes in the SF-12 Mental Score.

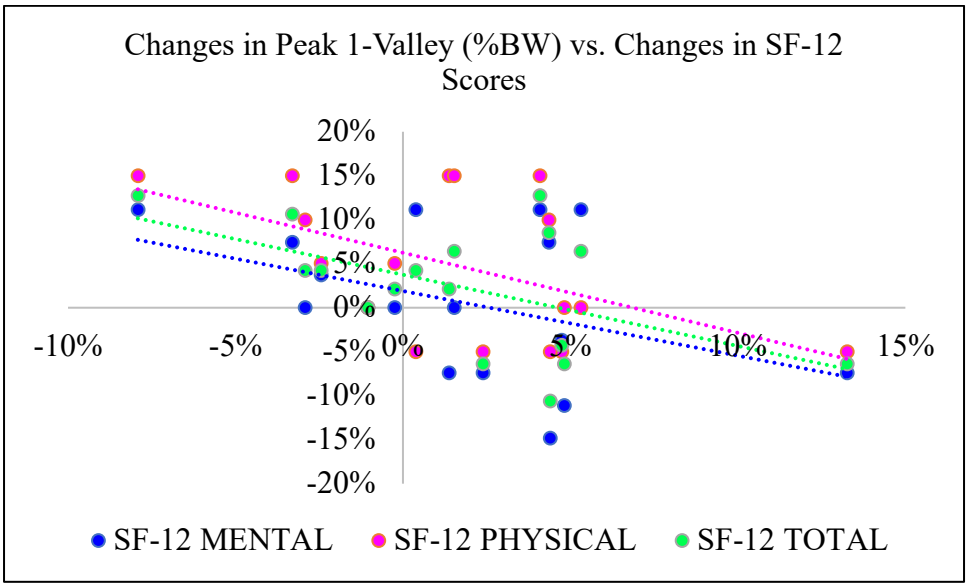

FIGURE 17 Changes in Peak 1-Valley vs. Changes in SF-12 Physical, Mental and Total Scores.

Figure 18 displays a scatter plot with trendlines between the changes in Peak 2-Valley and changes in SF-12 Physical, SF-12 Mental and SF-12 Total Scores. Negative change in Peak 2-Valley and positive change in SF-12 Scores represents patients having improvement in these variables. There were significant no significant correlations between the changes in Peak 2-Valley and the changes in SF-12 Scores.

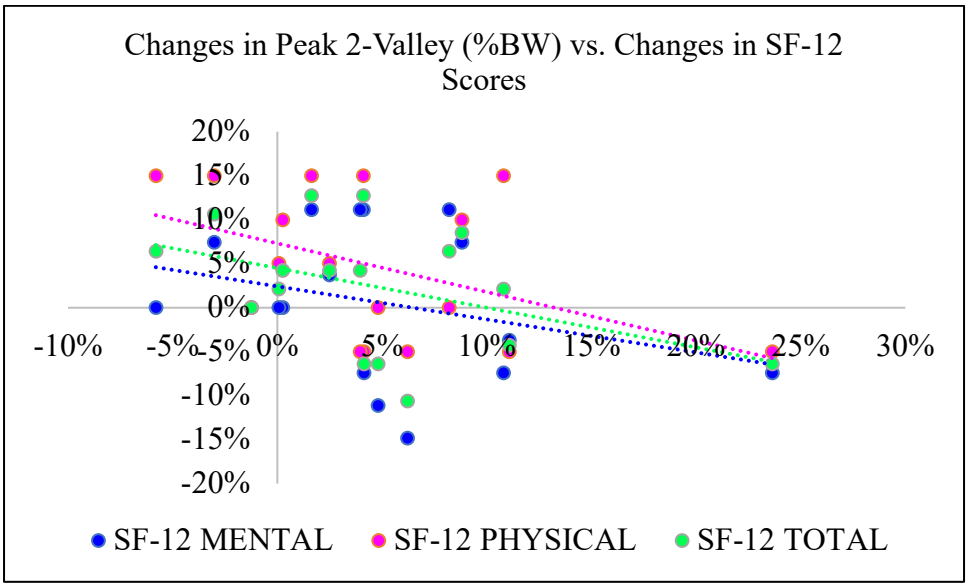

FIGURE 18 Changes in Peak 2-Valley vs. Changes in SF-12 Physical, Mental and Total Scores.

4.2.2 Changes in vGRF Variables vs. Changes in KSS Scores

Based on the findings of Objectives 1 and 2, subjects demonstrated significant improvement from pre-op to 6-months post-op for the KSS Objective Score ($p=.015$), the KSS Expectation and Satisfaction Score ($p=.001$), the KSS Functional Score ($p<.001$) and Peak 2-Valley ($p=.011$). There was no significant improvement of the SF-12 Mental and Total Scores as well as the rest of the vGRF variables. While there were no significant correlations between changes in vGRF variables and changes in KSS scores, there were interesting trends discovered.

Figure 19 displays a scatter plot with trendlines between the changes in Peak 2 and changes in KSS Objective, KSS Expectation and Satisfaction and KSS Functional Scores. Positive change in Peak 1, KSS Expectation and Satisfaction and KSS Functional Scores and negative change in KSS Objective Score represents patients having improvement in these variables. Improvement of Peak 1 correlated positively with the

improvement of the KSS Objective Score and negatively with the KSS Expectations and Satisfaction and KSS Functional Scores.

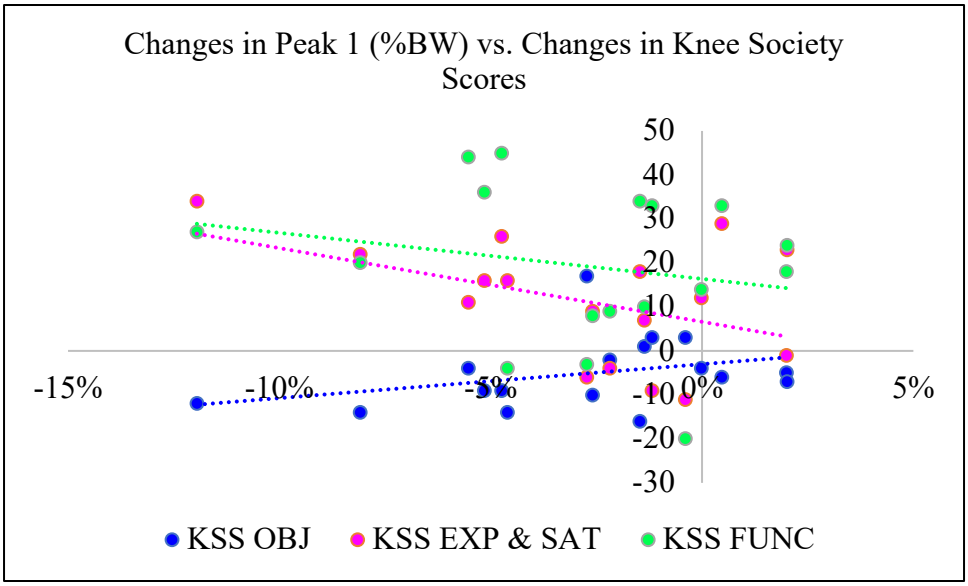

FIGURE 19 Changes in Peak 1 vs. Changes in KSS Objective, Expectation and Satisfaction and Functional Scores.

Figure 20 displays a scatter plot with trendlines between the changes in Peak 2 and changes in KSS Objective, KSS Expectation and Satisfaction and KSS Functional Scores. Positive change in Peak 2, KSS Expectation and Satisfaction and KSS Functional Scores and negative change in KSS Objective Score represents patients having improvement in these variables. Improvement of Peak 2 correlated positively with the improvement of the KSS Objective and KSS Functional scores and negatively with the KSS Expectation and Satisfaction Score.

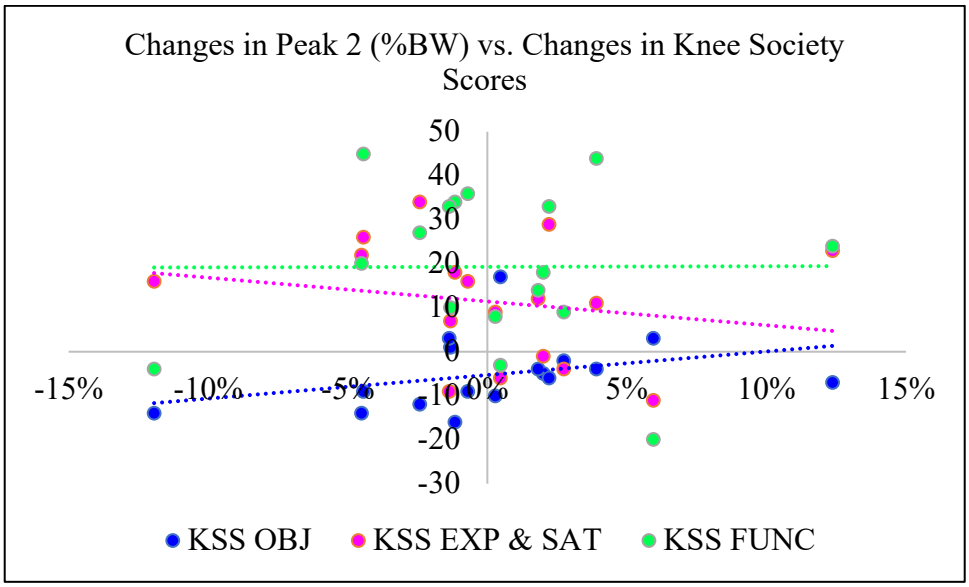

FIGURE 20 Changes in Peak 2 vs. Changes in KSS Objective, Expectation and Satisfaction and Functional Scores.

Figure 21 displays a scatter plot with trendlines between the changes in Valley and changes in KSS Objective, KSS Expectation and Satisfaction and KSS Functional Scores. Negative change in Valley and KSS Objective Score and positive change in KSS Expectation and Satisfaction and KSS Functional Scores represents patients having improvement in these variables. Improvement of the Valley correlated positively with the improvement of the KSS Expectation and Satisfaction and KSS Functional Scores and negative with the KSS Objective Score.

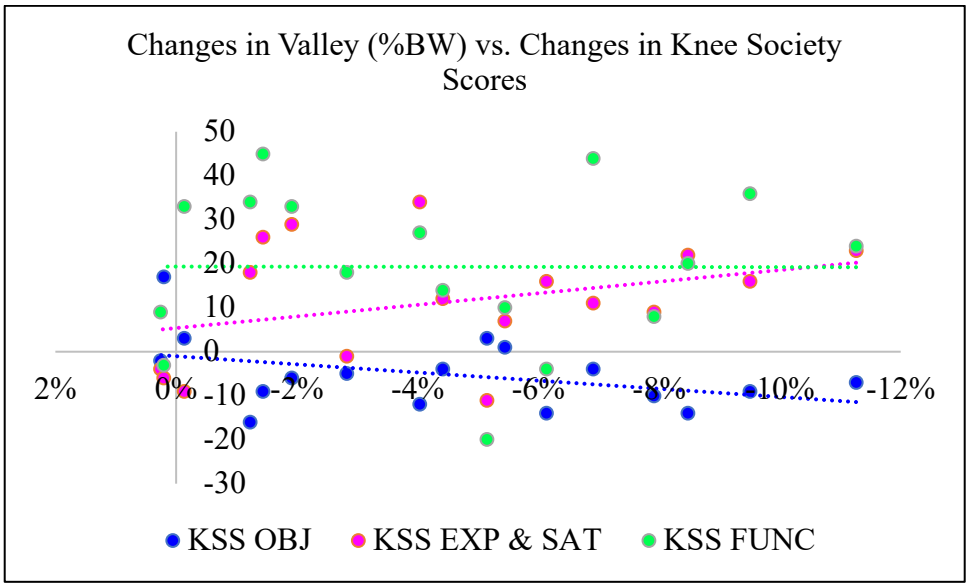

FIGURE 21 Changes in Valley vs. Changes in KSS Objective, Expectation and Satisfaction and Functional Scores.

Figure 22 displays a scatter plot with trendlines between the changes in Time to Peak 1 and changes in KSS Objective, KSS Expectation and Satisfaction and KSS Functional Scores. Negative change in Time to Peak 1 and KSS Objective Score and positive change in KSS Expectation and Satisfaction and KSS Functional Scores represents patients having improvement in these variables. Improvement in Time to Peak 1 correlated positively with all KSS Scores.

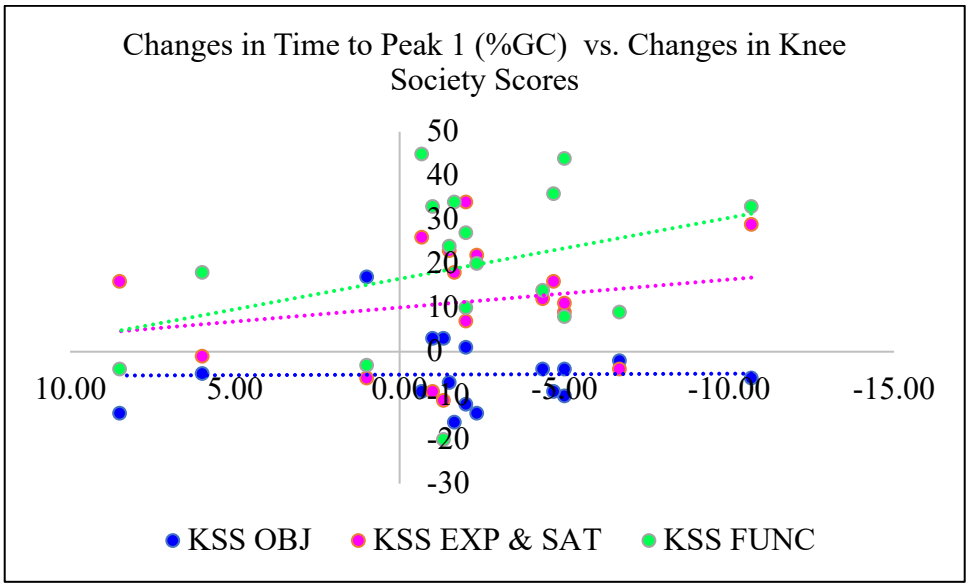

FIGURE 22 Changes in Time to Peak 1 vs. Changes in KSS Objective, Expectation and Satisfaction and Functional Scores.

Figure 23 displays a scatter plot with trendlines between the changes in Time to Peak 1 and changes in KSS Objective, KSS Expectation and Satisfaction and KSS Functional Scores. Negative change in Time to Peak 2 and KSS Objective Score and positive change in KSS Expectation and Satisfaction and KSS Functional Scores represents patients having improvement in these variables. Improvement in Time to Peak 2 correlated positively with the KSS Objective and KSS Functional Scores and negatively with the KSS Expectation and Satisfaction Score.

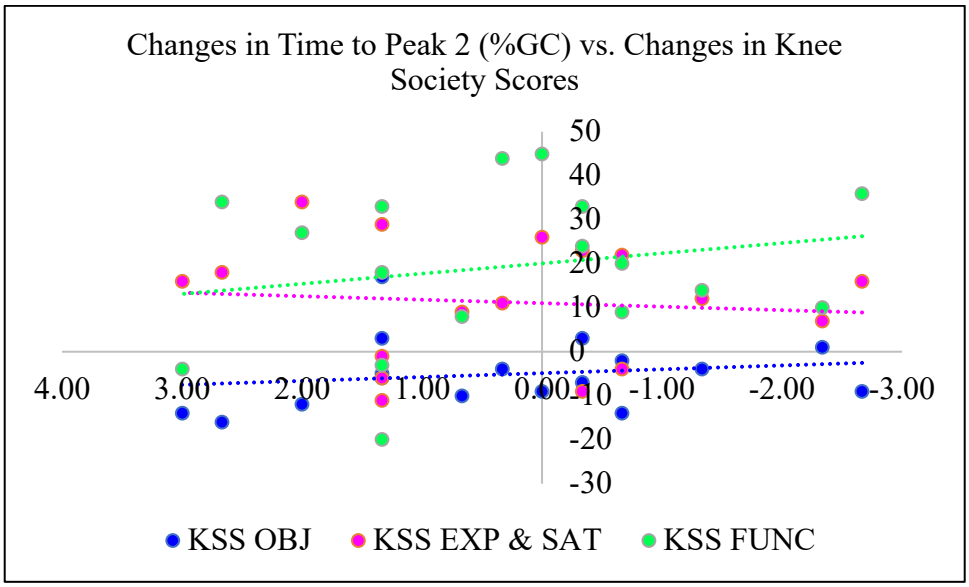

FIGURE 23 Changes in Time to Peak 2 vs. Changes in KSS Objective, Expectation and Satisfaction and Functional Scores.

Figure 24 displays a scatter plot with trendlines between the changes in Peak 1-Peak 2 and changes in KSS Objective, KSS Expectation and Satisfaction and KSS Functional Scores. Positive change in Peak 1-Peak 2, KSS Expectation and Satisfaction and KSS Functional Scores and negative change in KSS Objective Score represents patients having improvement in these variables. Improvement in Peak 1-Peak 2 positively correlates with all KSS Scores.

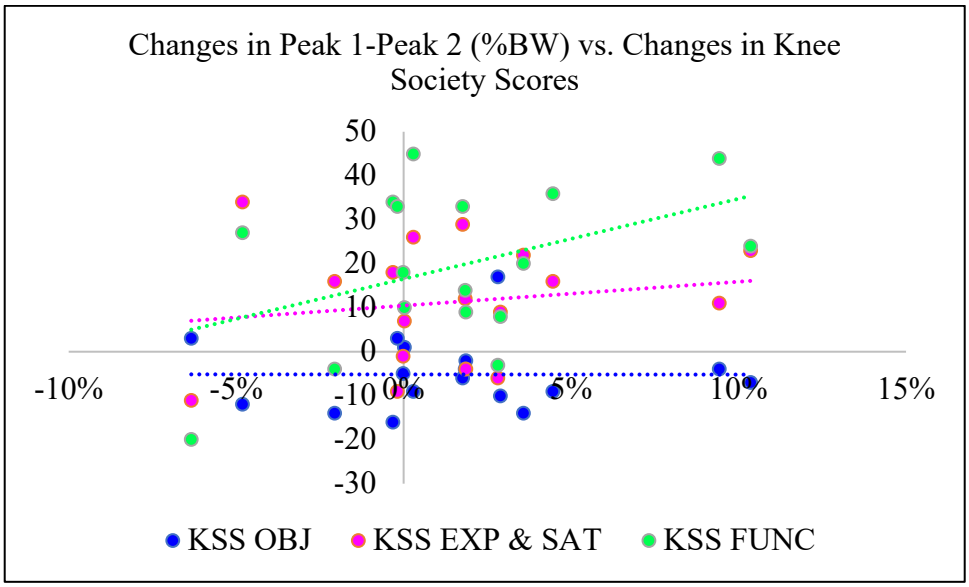

FIGURE 24 Changes in Peak 1-Peak 2 vs. Changes in KSS Objective, Expectation and Satisfaction and Functional Scores.

Figure 25 displays a scatter plot with trendlines between the changes in Peak 1-Valley and changes in KSS Objective, KSS Expectation and Satisfaction and KSS Functional Scores. Positive change in Peak 1-Valley, KSS Expectation and Satisfaction and KSS Functional Scores and negative change in KSS Objective Score represents patients having improvement in these variables. Improvement of Peak 1-Valley negatively correlates with all KSS Scores.

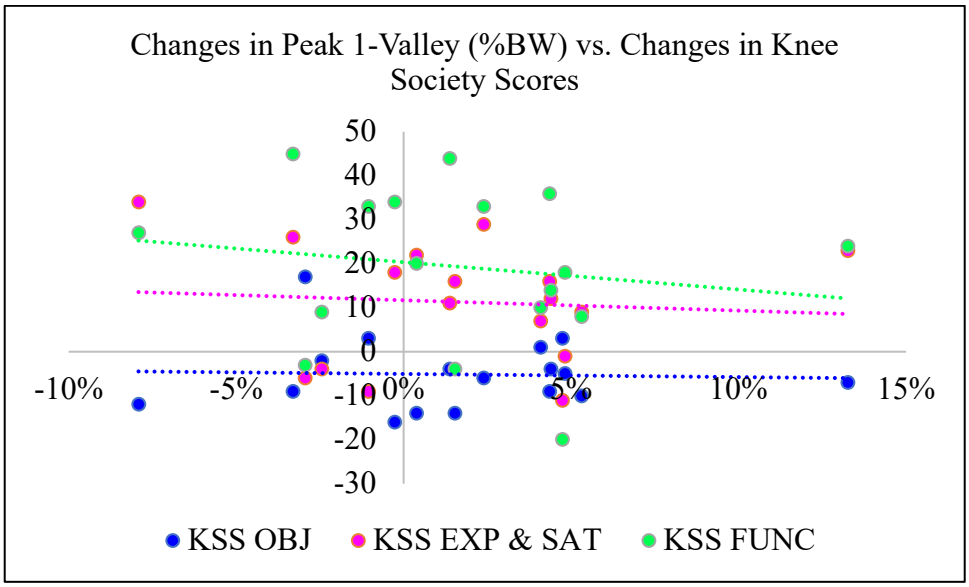

FIGURE 25 Changes in Peak 1-Valley vs. Changes in KSS Objective, Expectation and Satisfaction and Functional Scores.

Figure 26 displays a scatter plot with trendlines between the changes in Peak 2-Valley and changes in KSS Objective, KSS Expectation and Satisfaction and KSS Functional Scores. Positive change in Peak 2-Valley, KSS Expectation and Satisfaction and KSS Functional Scores and negative change in KSS Objective Score represents patients having improvement in these variables. Improvement in Peak 2-Valley positively correlates with all KSS Scores.

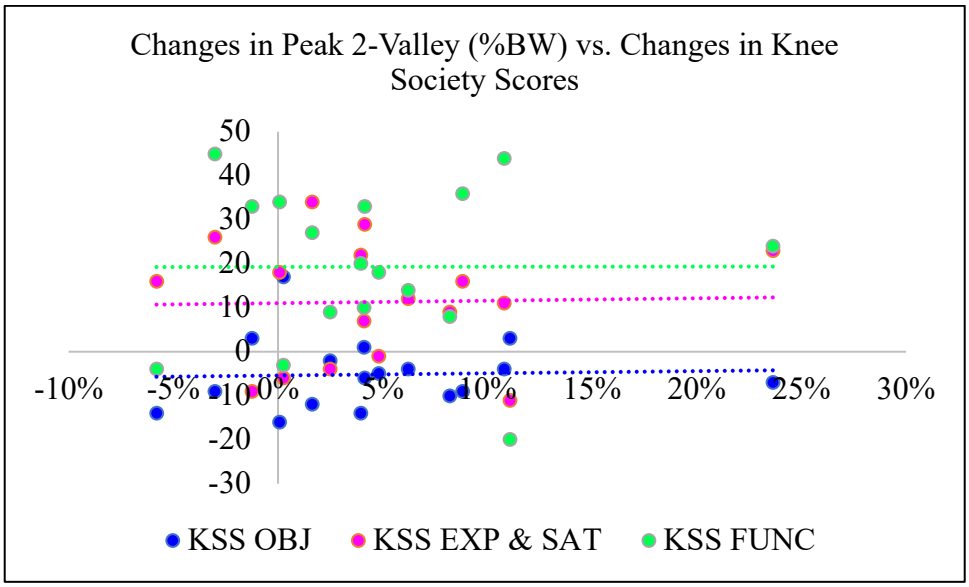

FIGURE 26 Changes in Peak 2-Valley vs. Changes in KSS Objective, Expectation and Satisfaction and Functional Scores.

CHAPTER 5: CONCLUSIONS AND RECOMMENDATIONS

Total Knee Arthroplasty is one of the most frequently performed and consistently successful orthopedic procedures performed to data. However, there is a lack in standardization of pre- and post-op protocols. Once of the reasons for this is the gap between results of subjective and objective measures of function. The study consisted of three primary objectives in order investigate both subjective and objective measures of function and evaluate the relationship between the two; (1) investigate changes in PROMs over time as well as any correlations between the different PROMs used (2) evaluate bilateral differences and improvement of vGRF variables and compare TKA subjects to healthy controls and (3) analyze any correlations between the improvement PROMs and vGRF variables.

5.1 Objective 1—Analysis of PROMs

Two of the biggest concerns in TKA research regarding PROMs is the optimal collection window and which PROMs are most effective. This study adds support to both of these research questions by evaluating PROMs at both pre-op and multiple follow-up times and investigating correlations between different types of PROMs both generic and disease specific.

Overall, findings of this study match well with previous studies of TKA subjects demonstrating significant improvement post TKA operation. There were also significant correlations between all PROMs at pre-op and 6-months post-op. Because majority of the improvement and correlations between PROMs occurred from pre-op to 6-months and 6-months to 12-months, it may be more time and cost-efficient to eliminate 1-week and 1-month intermediate follow-ups. Also, with more consistent findings in the correlations

between different types of PROMs used, they could be combined into one single PROM for TKA research and clinical procedures.

5.2 Objective 2—Analysis of vGRF

This study has reconfirmed some of the gait abnormalities that are seen with TKA subjects as well as the improvement from pre- to post-op that has been investigated previously. TKA subjects presented significant bilateral differences in few vGRF at pre-op for both the evaluation of left and right legs and implant and non-implant legs. However, these differences were not present at 6-months post-op. When evaluating changes in vGRF over time, majority of vGRF variables for TKA subjects presented no significant differences between pre-op and post-op and also presented similar values to the healthy controls. The bilateral differences and improvement discovered in this study suggest that subjects may have altered their gait as a result of pain, limited range of motion or any other functional limitations.

5.3 Changes in vGRFs and Changes in PROMs Over Time

Surprisingly, there were few correlations between the improvement of PROMs and improvement of vGRF variables. The improvement of SF-12 Scores, which is the generic PROM, had significant correlations with the improvement vGRF while the KSS Scores, the disease-specific PROM, did not. Because this study contributes to previous findings of limited correlations between subjective patient-reported outcome measures of function and objective biomechanical measures of function, further investigation needs to be done on whether PROMs adequately reflect changes in functional improvement.

REFERENCES

Biggs, P. R., Whatling, G. M., Wilson, C., & Holt, C. A. (2019). Correlations between patient-perceived outcome and objectively-measured biomechanical change following Total Knee Replacement. *Gait Posture, 70*, 65-70. doi:10.1016/j.gaitpost.2019.02.028

Bolink, S. A., Grimm, B., & Heyligers, I. C. (2015). Patient-reported outcome measures versus inertial performance-based outcome measures: A prospective study in patients undergoing primary total knee arthroplasty. *Knee, 22*(6), 618-623. doi:10.1016/j.knee.2015.04.002

Burnett, D. R., Campbell-Kyureghyan, N. H., Topp, R. V., & Quesada, P. M. (2015). Biomechanics of Lower Limbs during Walking among Candidates for Total Knee Arthroplasty with and without Low Back Pain. *Biomed Res Int, 2015*, 142562. doi:10.1155/2015/142562

Canfield, M., Savoy, L., Cote, M. P., & Halawi, M. J. (2020). Patient-reported outcome measures in total joint arthroplasty: defining the optimal collection window. *Arthroplast Today, 6*(1), 62-67. doi:10.1016/j.artd.2019.10.003

Carlson, V. R., Post, Z. D., Orozco, F. R., Davis, D. M., Lutz, R. W., & Ong, A. C. (2018). When Does the Knee Feel Normal Again: A Cross-Sectional Study Assessing the Forgotten Joint Score in Patients After Total Knee Arthroplasty. *J Arthroplasty, 33*(3), 700-703. doi:10.1016/j.arth.2017.09.063

CDC. (2020). Osteoarthritis. Retrieved from https://www.cdc.gov/arthritis/basics/osteoarthritis.htm#:~:text=OA%20affects%20over%2032.5%20million%20US%20adults

Cella, D. (2014). Progression-free survival, patient-reported outcomes and the Holy Grail. *J Community Support Oncol, 12*(8), 265-266. doi:10.12788/jcso.0061

Clement, N. D., Bardgett, M., Weir, D., Holland, J., Gerrand, C., & Deehan, D. J. (2018). The rate and predictors of patient satisfaction after total knee arthroplasty are influenced by the focus of the question: a standard satisfaction question is required. *Bone Joint J, 100-B*(6), 740-748. doi:10.1302/0301-620X.100B6.BJJ-2017-1292.R1

Clement, N. D., & Burnett, R. (2013). Patient satisfaction after total knee arthroplasty is affected by their general physical well-being. *Knee Surg Sports Traumatol Arthrosc, 21*(11), 2638-2646. doi:10.1007/s00167-013-2523-y

Clement, N. D., Weir, D., Holland, J., Gerrand, C., & Deehan, D. J. (2019). Meaningful changes in the Short Form 12 physical and mental summary scores after total knee arthroplasty. *Knee, 26*(4), 861-868. doi:10.1016/j.knee.2019.04.018

David R. Burnett, N. H. C.-H., Robert V. Topp, and Peter M. Quesada. (2015). Biomechanics of Lower Limbs during Walking among Candidates for Total Knee

Arthroplasty with and without Low Back Pain. *BioMed Research International, 2015*, 8. doi:https://doi.org/10.1155/2015/142562

de Achaval, S., Kallen, M. A., Amick, B., Landon, G., Siff, S., Edelstein, D., . . . Suarez-Almazor, M. E. (2016). Patients' expectations about total knee arthroplasty outcomes. *Health Expect, 19*(2), 299-308. doi:10.1111/hex.12350

Feng, J. E., Novikov, D., Anoushiravani, A. A., & Schwarzkopf, R. (2018). Total knee arthroplasty: improving outcomes with a multidisciplinary approach. *J Multidiscip Healthc, 11*, 63-73. doi:10.2147/JMDH.S140550

Giesinger, J. M., Hamilton, D. F., Jost, B., Behrend, H., & Giesinger, K. (2015). WOMAC, EQ-5D and Knee Society Score Thresholds for Treatment Success After Total Knee Arthroplasty. *J Arthroplasty, 30*(12), 2154-2158. doi:10.1016/j.arth.2015.06.012

Hamilton, D. F., Loth, F. L., Giesinger, J. M., Giesinger, K., MacDonald, D. J., Patton, J. T., . . . Howie, C. R. (2017). Validation of the English language Forgotten Joint Score-12 as an outcome measure for total hip and knee arthroplasty in a British population. *Bone Joint J, 99-B*(2), 218-224. doi:10.1302/0301-620X.99B2.BJJ-2016-0606.R1

Henriksen, M., Graven-Nielsen, T., Aaboe, J., Andriacchi, T. P., & Bliddal, H. (2010). Gait changes in patients with knee osteoarthritis are replicated by experimental knee pain. *Arthritis Care Res (Hoboken), 62*(4), 501-509. doi:10.1002/acr.20033

Jacofsky, D. J., & Allen, M. (2016). Robotics in Arthroplasty: A Comprehensive Review. *J Arthroplasty, 31*(10), 2353-2363. doi:10.1016/j.arth.2016.05.026

Jafarnezhadgero, A., Fatollahi, A., Amirzadeh, N., Siahkouhian, M., & Granacher, U. (2019). Ground reaction forces and muscle activity while walking on sand versus stable ground in individuals with pronated feet compared with healthy controls. *PLoS One, 14*(9), e0223219. doi:10.1371/journal.pone.0223219

Jiang, X., Napier, C., Hannigan, B., Eng, J. J., & Menon, C. (2020). Estimating Vertical Ground Reaction Force during Walking Using a Single Inertial Sensor. *Sensors (Basel), 20*(15). doi:10.3390/s20154345

Jiang, Y., Sanchez-Santos, M. T., Judge, A. D., Murray, D. W., & Arden, N. K. (2017). Predictors of Patient-Reported Pain and Functional Outcomes Over 10 Years After Primary Total Knee Arthroplasty: A Prospective Cohort Study. *J Arthroplasty, 32*(1), 92-100 e102. doi:10.1016/j.arth.2016.06.009

Kramers-de Quervain, I. A., Kampfen, S., Munzinger, U., & Mannion, A. F. (2012). Prospective study of gait function before and 2 years after total knee arthroplasty. *Knee, 19*(5), 622-627. doi:10.1016/j.knee.2011.12.009

Kuroda, Y., Matsumoto, T., Takayama, K., Ishida, K., Kuroda, R., & Kurosaka, M. (2016). Subjective evaluation before and after total knee arthroplasty using the 2011 Knee Society Score. *Knee, 23*(6), 964-967. doi:10.1016/j.knee.2016.06.008

Losina, E., & Katz, J. N. (2012). Total knee arthroplasty on the rise in younger patients: are we sure that past performance will guarantee future success? *Arthritis Rheum, 64*(2), 339-341. doi:10.1002/art.33371

McClelland, J., Zeni, J., Haley, R. M., & Snyder-Mackler, L. (2012). Functional and biomechanical outcomes after using biofeedback for retraining symmetrical movement patterns after total knee arthroplasty: a case report. *J Orthop Sports Phys Ther, 42*(2), 135-144. doi:10.2519/jospt.2012.3773

McClelland, J. A., Webster, K. E., & Feller, J. A. (2007). Gait analysis of patients following total knee replacement: a systematic review. *Knee, 14*(4), 253-263. doi:10.1016/j.knee.2007.04.003

Michael, J. M., Golshani, A., Gargac, S., & Goswami, T. (2008). Biomechanics of the ankle joint and clinical outcomes of total ankle replacement. *J Mech Behav Biomed Mater, 1*(4), 276-294. doi:10.1016/j.jmbbm.2008.01.005

Milner, C. E. (2008). Interlimb asymmetry during walking following unilateral total knee arthroplasty. *Gait Posture, 28*(1), 69-73. doi:10.1016/j.gaitpost.2007.10.002

Mizner, R. L., Petterson, S. C., Clements, K. E., Zeni, J. A., Jr., Irrgang, J. J., & Snyder-Mackler, L. (2011). Measuring functional improvement after total knee arthroplasty requires both performance-based and patient-report assessments: a longitudinal analysis of outcomes. *J Arthroplasty, 26*(5), 728-737. doi:10.1016/j.arth.2010.06.004

Naili, J. E., Iversen, M. D., Esbjornsson, A. C., Hedstrom, M., Schwartz, M. H., Hager, C. K., & Brostrom, E. W. (2017). Deficits in functional performance and gait one year after total knee arthroplasty despite improved self-reported function. *Knee Surg Sports Traumatol Arthrosc, 25*(11), 3378-3386. doi:10.1007/s00167-016-4234-7

Neogi, T. (2013). The epidemiology and impact of pain in osteoarthritis. *Osteoarthritis Cartilage, 21*(9), 1145-1153. doi:10.1016/j.joca.2013.03.018

Pozzi, F., Snyder-Mackler, L., & Zeni, J., Jr. (2015). Relationship between biomechanical asymmetries during a step up and over task and stair climbing after total knee arthroplasty. *Clin Biomech (Bristol, Avon), 30*(1), 78-85. doi:10.1016/j.clinbiomech.2014.11.001

Rahman, J., Tang, Q., Monda, M., Miles, J., & McCarthy, I. (2015). Gait assessment as a functional outcome measure in total knee arthroplasty: a cross-sectional study. *BMC Musculoskelet Disord, 16*, 66. doi:10.1186/s12891-015-0525-2

Ramkumar, P. N., Harris, J. D., & Noble, P. C. (2015). Patient-reported outcome measures after total knee arthroplasty: a systematic review. *Bone Joint Res, 4*(7), 120-127. doi:10.1302/2046-3758.47.2000380

Rosinsky, P. J., Chen, J. W., Lall, A. C., Shapira, J., Maldonado, D. R., & Domb, B. G. (2020). Can We Help Patients Forget Their Joint? Determining a Threshold for Successful Outcome for the Forgotten Joint Score. *J Arthroplasty, 35*(1), 153-159. doi:10.1016/j.arth.2019.08.014

Sloan, M. a. S., Neil P. (2020). Projected Volume of Primary and Revision Total Joint Arthroplasty in the United States, 2030-2060 Retrieved from http://submissions.mirasmart.com/Verify/AAOS2018/Submission/out/AAOS2018-002064.PDF

Tseng, E. K., & Hicks, L. K. (2016). Value Based Care and Patient-Centered Care: Divergent or Complementary? *Curr Hematol Malig Rep, 11*(4), 303-310. doi:10.1007/s11899-016-0333-2

Turcot, K., Sagawa, Y., Jr., Fritschy, D., Hoffmeyer, P., Suva, D., & Armand, S. (2013). How gait and clinical outcomes contribute to patients' satisfaction three months following a total knee arthroplasty. *J Arthroplasty, 28*(8), 1297-1300. doi:10.1016/j.arth.2013.01.031

Varacallo, M., Luo, T. D., & Johanson, N. A. (2020). Total Knee Arthroplasty (TKA) Techniques. In *StatPearls*. Treasure Island (FL).

Yorkston, K., Baylor, Carolyn. (2019). Patient-Reported Outcomes Measures: An Introduction for Clinicians. *ASHAWire, 10*, 8-15. Retrieved from https://doi.org/10.1044/2018_PERS-ST-2018-0001

Yoshida, Y., Zeni, J., & Snyder-Mackler, L. (2012). Do patients achieve normal gait patterns 3 years after total knee arthroplasty? *J Orthop Sports Phys Ther, 42*(12), 1039-1049. doi:10.2519/jospt.2012.3763

APPENDIX A: 2011 KNEE SOCIETY SCORE (PRE-OP)

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KNEE SOCIETY SCORE: PRE-OP

DEMOGRAPHIC INFORMATION (To be completed by patient)

1- Today's date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

2- Date of birth ☐☐ / ☐☐ / ☐☐☐☐

3- Height (ft' in") ☐ ☐☐

4- Weight (lbs.) ☐☐☐

5- Sex ○ Male ○ Female

6- Side of this (symptomatic) knee ○ Left ○ Right
If both knees will be operated on, please use a different form for each knee

7- Ethnicity
○ Native Hawaiian or other Pacific Islander ○ American Indian or Alaska Native ○ Hispanic or Latino
○ Arab or Middle Eastern ○ African American or Black ○ Asian ○ White

8- Please indicate the expected date and surgeon for your knee replacement operation

Date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

Name of Surgeon ☐

9- Will this be a primary or revision knee replacement?
○ Primary ○ Revision

To be completed by surgeon

10- Charnley Functional Classification (Use Code Below) ☐

A Unilateral Knee Arthritis	C1 TKR, but remote arthritis affecting ambulation
B1 Unilateral TKA, opposite knee arthritic	C2 TKR, but medical condition affecting ambulation
B2 Bilateral TKA	C3 Unilateral or Bilateral TKA with Unilateral or Bilateral THR

OBJECTIVE KNEE INDICATORS (To be completed by surgeon)

ALIGNMENT

1- Alignment: measured on AP standing Xray (Anatomic Alignment) — **25 point max**

Neutral: 2-10 degrees valgus	(25 pts)
Varus: < 2 degrees valgus	(-10 pts)
Valgus: > 10 degrees valgus	(-10 pts)

INSTABILITY

2- Medial / Lateral Instability: measured in full extension — **15 point max**

None	(15 pts)
Little or < 5 mm	(10 pts)
Moderate or 5 mm	(5 pts)
Severe or > 5 mm	(0 pts)

3- Anterior / Posterior Instability: measured at 90 degrees — **10 point max**

None	(10 pts)
Moderate < 5 mm	(5 pts)
Severe > 5 mm	(0 pts)

JOINT MOTION

4- Range of motion (1 point for each 5 degrees)

Deductions

Flexion Contracture — **Minus Points**

1-5 degrees	(-2 pts)
6-10 degrees	(-5 pts)
11-15 degrees	(-10 pts)
> 15 degrees	(-15 pts)

Extensor Lag — **Minus Points**

<10 degrees	(-5 pts)
10-20 degrees	(-10 pts)
> 20 degrees	(-15 pts)

SYMPTOMS (To be completed by patient)

1- Pain with level walking (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

2- Pain with stairs or inclines (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

3- Does this knee feel "normal" to you? (5 points)

○ Always (5 pts) ○ Sometimes (3 pts) ○ Never (0 pts)

Maximum total points (25 points)

PATIENT SATISFACTION

1- Currently, how satisfied are you with the pain level of your knee while sitting? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

2- Currently, how satisfied are you with the pain level of your knee while lying in bed? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

3- Currently, how satisfied are you with your knee function while getting out of bed? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

4- Currently, how satisfied are you with your knee function while performing light household duties? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

5- Currently, how satisfied are you with your knee function while performing leisure recreational activities? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

Maximum total points (40 points)

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)**

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

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

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

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

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

Maximum total points (15 points) ☐

FUNCTIONAL ACTIVITIES (To be completed by patient)

WALKING AND STANDING (30 points)

1 - Can you walk without any aids (such as a cane, crutches or wheelchair)? **(0 points)**

O Yes O No

2 - If no, which of the following aid(s) do you use? **(-10 points)**

O wheelchair (-10 pts) O walker (-8 pts) O crutches (-8 pts) O two canes (-6 pts)

O one crutch (-4 pts) O one cane (-4 pts) O knee sleeve / brace (-2 pts)

O other

3 - Do you use these aid(s) because of your knees? **(0 points)**

O Yes O No

4 - For how long can you stand (with or without aid) before sitting due to knee discomfort? **(15 points)**

O cannot stand (0 pts) O 0-5 minutes (3 pts) O 6-15 minutes (6 pts)

O 16-30 minutes (9 pts) O 31-60 minutes (12 pts) O more than an hour (15 pts)

5 - For how long can you walk (with or without aid) before stopping due to knee discomfort? **(15 points)**

O cannot walk (0 pts) O 0-5 minutes (3 pts) O 6-15 minutes (6 pts)

O 16-30 minutes (9 pts) O 31-60 minutes (12 pts) O more than an hour (15 pts)

Maximum points (30 points)

STANDARD ACTIVITIES (30 points)

How much does your knee bother you during each of the following activities?	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	I never do this	
1 - Walking on an uneven surface	○	○	○	○	○	○	○	
2 - Turning or pivoting on your leg	○	○	○	○	○	○	○	
3 - Climbing up or down a flight of stairs	○	○	○	○	○	○	○	
4 - Getting up from a low couch or a chair without arms	○	○	○	○	○	○	○	
5 - Getting into or out of a car	○	○	○	○	○	○	○	
6 - Moving laterally (stepping to the side)	○	○	○	○	○	○	○	

Maximum points (30 points)

ADVANCED ACTIVITIES (25 points)

1 - Climbing a ladder or step stool	○	○	○	○	○	○	○	
2 - Carrying a shopping bag for a block	○	○	○	○	○	○	○	
3 - Squatting	○	○	○	○	○	○	○	
4 - Kneeling	○	○	○	○	○	○	○	
5 - Running	○	○	○	○	○	○	○	

Maximum points (25 points)

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

- ☐ Swimming
- ☐ Golfing (18 holes)
- ☐ Road Cycling (>30mins)
- ☐ Gardening
- ☐ Bowling
- ☐ Racquet Sports (Tennis, Racquetball, etc.)
- ☐ Distance Walking
- ☐ Dancing / Ballet
- ☐ Stretching Exercises (stretching out your muscles)

Workout and Gym Activities

- ☐ Weight-lifting
- ☐ Leg Extensions
- ☐ Stair-Climber
- ☐ Stationary Biking / Spinning
- ☐ Leg Press
- ☐ Jogging
- ☐ Elliptical Trainer
- ☐ Aerobic Exercises

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 activites from list above)	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	
1.	○	○	○	○	○	○	
2.	○	○	○	○	○	○	
3.	○	○	○	○	○	○	

Maximum points (15 points)

Maximum total points (100 points)

APPENDIX B: 2011 KNEE SOCIETY SCORE (POST-OP)

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KNEE SOCIETY SCORE: POST-OP

DEMOGRAPHIC INFORMATION (To be completed by patient)

1- Today's date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

2- Date of birth ☐☐ / ☐☐ / ☐☐☐☐

3- Height (ft' in") ☐ ☐☐

4- Weight (lbs.) ☐☐☐

5- Sex
○ Male ○ Female

6- Side of this (surgically treated) knee
○ Left ○ Right
If both knees have been operated on, please use a different form for each knee

7- Ethnicity
○ Native Hawaiian or other Pacific Islander ○ American Indian or Alaska Native ○ Hispanic or Latino
○ Arab or Middle Eastern ○ African American or Black ○ Asian ○ White

8- Please indicate date and surgeon for your knee replacement operation

Date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

Name of Surgeon ☐

9- Was this a primary or revision knee replacement?
○ Primary ○ Revision

To be completed by surgeon

10- Charnley Functional Classification (Use Code Below) ☐

A Unilateral Knee Arthritis	C1 TKR, but remote arthritis affecting ambulation
B1 Unilateral TKA, opposite knee arthritic	C2 TKR, but medical condition affecting ambulation
B2 Bilateral TKA	C3 Unilateral or Bilateral TKA with Unilateral or Bilateral THR

OBJECTIVE KNEE INDICATORS (To be completed by surgeon)

ALIGNMENT

1- Alignment: measured on AP standing Xray (Anatomic Alignment) — **25 point max**

Neutral: 2-10 degrees valgus	(25 pts)
Varus: < 2 degrees valgus	(-10 pts)
Valgus: > 10 degrees valgus	(-10 pts)

INSTABILITY

2- Medial / Lateral Instability: measured in full extension — **15 point max**

None	(15 pts)
Little or < 5 mm	(10 pts)
Moderate or 5 mm	(5 pts)
Severe or > 5 mm	(0 pts)

3- Anterior / Posterior Instability: measured at 90 degrees — **10 point max**

None	(10 pts)
Moderate < 5 mm	(5 pts)
Severe > 5 mm	(0 pts)

JOINT MOTION

4- Range of motion (1 point for each 5 degrees)

Deductions

Flexion Contracture — **Minus Points**

1-5 degrees	(-2 pts)
6-10 degrees	(-5 pts)
11-15 degrees	(-10 pts)
> 15 degrees	(-15 pts)

Extensor Lag — **Minus Points**

<10 degrees	(-5 pts)
10-20 degrees	(-10 pts)
> 20 degrees	(-15 pts)

SYMPTOMS

(To be completed by patient)

1- Pain with level walking (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

2- Pain with stairs or inclines (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

3- Does this knee feel "normal" to you? (5 points)

O Always (5 pts) O Sometimes (3 pts) O Never (0 pts)

Maximum total points (25 points)

PATIENT SATISFACTION

1- Currently, how satisfied are you with the pain level of your knee while sitting? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

2- Currently, how satisfied are you with the pain level of your knee while lying in bed? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

3- Currently, how satisfied are you with your knee function while getting out of bed? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

4- Currently, how satisfied are you with your knee function while performing light household duties? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

5- Currently, how satisfied are you with your knee function while performing leisure recreational activities? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

Maximum total points (40 points)

PATIENT EXPECTATION (To be completed by patient)

Compared to what you expected before your knee replacement:

1- My expectations for pain relief were... **(5 points)**

- O Too High- "I'm a lot worse than I thought" (1 pt)
- O Too High- "I'm somewhat worse than I thought" (2 pts)
- O Just Right- "My expectations were met" (3 pts)
- O Too Low- "I'm somewhat better than I thought" (4 pts)
- O Too Low- "I'm a lot better than I thought" (5 pts)

2- My expectations for being able to do my normal activities of daily living were... **(5 points)**

- O Too High- "I'm a lot worse than I thought" (1 pt)
- O Too High- "I'm somewhat worse than I thought" (2 pts)
- O Just Right- "My expectations were met" (3 pts)
- O Too Low- "I'm somewhat better than I thought" (4 pts)
- O Too Low- "I'm a lot better than I thought" (5 pts)

3- My expectations for being able to do my leisure, recreational or sports activities were... **(5 points)**

- O Too High- "I'm a lot worse than I thought" (1 pt)
- O Too High- "I'm somewhat worse than I thought" (2 pts)
- O Just Right- "My expectations were met" (3 pts)
- O Too Low- "I'm somewhat better than I thought" (4 pts)
- O Too Low- "I'm a lot better than I thought" (5 pts)

Maximum total points (15 points) ☐

FUNCTIONAL ACTIVITIES (To be completed by patient)

WALKING AND STANDING (30 points)

1 - Can you walk without any aids (such as a cane, crutches or wheelchair)? (0 points)

○ Yes ○ No

2 - If no, which of the following aid(s) do you use? (-10 points)

○ wheelchair (-10 pts) ○ walker (-8 pts) ○ crutches (-8 pts) ○ two canes (-6 pts)

○ one crutch (-4 pts) ○ one cane (-4 pts) ○ knee sleeve / brace (-2 pts)

○ other

3 - Do you use these aid(s) because of your knees? (0 points)

○ Yes ○ No

4 - For how long can you stand (with or without aid) before sitting due to knee discomfort? (15 points)

○ cannot stand (0 pts) ○ 0-5 minutes (3 pts) ○ 6-15 minutes (6 pts)

○ 16-30 minutes (9 pts) ○ 31-60 minutes (12 pts) ○ more than an hour (15 pts)

5 - For how long can you walk (with or without aid) before stopping due to knee discomfort? (15 points)

○ cannot walk (0 pts) ○ 0-5 minutes (3 pts) ○ 6-15 minutes (6 pts)

○ 16-30 minutes (9 pts) ○ 31-60 minutes (12 pts) ○ more than an hour (15 pts)

Maximum points (30 points)

STANDARD ACTIVITIES (30 points)

How much does your knee bother you during each of the following activities?	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	I never do this	
1 - Walking on an uneven surface	○	○	○	○	○	○	○	
2 - Turning or pivoting on your leg	○	○	○	○	○	○	○	
3 - Climbing up or down a flight of stairs	○	○	○	○	○	○	○	
4 - Getting up from a low couch or a chair without arms	○	○	○	○	○	○	○	
5 - Getting into or out of a car	○	○	○	○	○	○	○	
6 - Moving laterally (stepping to the side)	○	○	○	○	○	○	○	

Maximum points (30 points)

ADVANCED ACTIVITIES (25 points)

1 - Climbing a ladder or step stool	○	○	○	○	○	○	○	
2 - Carrying a shopping bag for a block	○	○	○	○	○	○	○	
3 - Squatting	○	○	○	○	○	○	○	
4 - Kneeling	○	○	○	○	○	○	○	
5 - Running	○	○	○	○	○	○	○	

Maximum points (25 points)

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

- ☐ Swimming
- ☐ Golfing (18 holes)
- ☐ Road Cycling (>30mins)
- ☐ Gardening
- ☐ Bowling
- ☐ Racquet Sports (Tennis, Racquetball, etc.)
- ☐ Distance Walking
- ☐ Dancing / Ballet
- ☐ Stretching Exercises (stretching out your muscles)

Workout and Gym Activities

- ☐ Weight-lifting
- ☐ Leg Extensions
- ☐ Stair-Climber
- ☐ Stationary Biking / Spinning
- ☐ Leg Press
- ☐ Jogging
- ☐ Elliptical Trainer
- ☐ Aerobic Exercises

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 activites from list above)	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	
1.	○	○	○	○	○	○	
2.	○	○	○	○	○	○	
3.	○	○	○	○	○	○	

Maximum points (15 points)

Maximum total points (100 points)

APPENDIX C: FORGOTTEN JOINT SCORE

FJS-12 score

The following 12 questions refer to how aware you are of your artificial hip/knee joint in everyday life.

Please tick one answer from each question.

Are you aware of your artificial joint…

1. … in bed at night?

○ never ○ almost never ○ seldom ○ sometimes ○ mostly

2. … when you are sitting on a chair for more than 1 hour?

○ never ○ almost never ○ seldom ○ sometimes ○ mostly

3. … when you are walking for more than 15 minutes?

○ never ○ almost never ○ seldom ○ sometimes ○ mostly

4. … when you are taking a bath/shower?

○ never ○ almost never ○ seldom ○ sometimes ○ mostly

5. … when you are traveling in a car?

○ never ○ almost never ○ seldom ○ sometimes ○ mostly

6. … when you are climbing stairs?

○ never ○ almost never ○ seldom ○ sometimes ○ mostly

7. … when you are walking on uneven ground?

○ never ○ almost never ○ seldom ○ sometimes ○ mostly

8. … when you are standing up from a low-sitting position?

○ never ○ almost never ○ seldom ○ sometimes ○ mostly

9. … when you are standing for long periods of time?

○ never ○ almost never ○ seldom ○ sometimes ○ mostly

10. … when you are doing housework or gardening?

○ never ○ almost never ○ seldom ○ sometimes ○ mostly

11. … when you are taking a walk/hiking?

○ never ○ almost never ○ seldom ○ sometimes ○ mostly

12. … when you are doing your favorite sport?

○ never ○ almost never ○ seldom ○ sometimes ○ mostly

APPENDIX D: SHORT-FORM SURVEY

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**:

☐₁ Excellent ☐₂ Very good ☐₃ Good ☐₄ Fair ☐₅ 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. **Moderate activities** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	☐₁	☐₂	☐₃
3. Climbing **several** flights of stairs.	☐₁	☐₂	☐₃

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. **Accomplished less** than you would like.	☐₁	☐₂
5. Were limited in the **kind** of work or other activities.	☐₁	☐₂

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. **Accomplished less** than you would like.	☐₁	☐₂
7. Did work or activities **less carefully than usual**.	☐₁	☐₂

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

☐₁ Not at all ☐₂ A little bit ☐₃ Moderately ☐₄ Quite a bit ☐₅ 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?	☐₁	☐₂	☐₃	☐₄	☐₅	☐₆
10. Did you have a lot of energy?	☐₁	☐₂	☐₃	☐₄	☐₅	☐₆
11. Have you felt down-hearted and blue?	☐₁	☐₂	☐₃	☐₄	☐₅	☐₆

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.)?**

☐₁ All of the time ☐₂ Most of the time ☐₃ Some of the time ☐₄ A little of the time ☐₅ None of the time

Patient name: Date: PCS: MCS:

Visit type (circle one)
Preop 6 week 3 month 6 month 12 month 24 month Other:_____

APPENDIX E: INFORMED CONSENTS

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The University of North Carolina at Charlotte
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Charlotte, NC 28223-001

THE WILLIAM STATES LEE
COLLEGE OF ENGINEERING

Department of Mechanical Engineering
and Engineering Science
704/687-8253
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Informed Consent for Biomechanics Motion Analysis Laboratory Data Bank

If you are a parent, as you read the information in this Consent Form, you should put yourself in your child's place to decide whether or not to allow your child to take part in this study. Therefore, for the rest of the form, the word "you" refers to your child.

If you are a child or adolescent reading this form, the word "you" refers to you.

We (Nigel Zheng, Ph.D. and assistants) are asking permission from you,

_____
Printed name of study participant ("study subject")

to store some of your medical information which you provide to us. The Principal Investigator (the person in charge of this research) or a representative of the Principal Investigator will also describe this data bank to you and answer all of your questions. Your participation is entirely voluntary. Before you decide whether or not to take part, read the information below and ask questions about anything you do not understand. If you choose not to participate in this study you will not be penalized or lose any benefits that you would otherwise be entitled to.

The choice to let Nigel Zheng, Ph.D. keep your data for doing research is entirely up to you. If you decide that your data can be kept for research but you later change your mind, tell Nigel Zheng, Ph.D. at (704) 687-7301 who will remove and destroy any of your data that he still has. Otherwise, the data may be kept until Nigel Zheng, Ph.D. decides to destroy them. You have the right to see and copy the information that is collected from you and stored in the data bank. There will be no cost to you for any data collected and stored.

If you agree, the following data will be collected and stored in the data bank:

- Records of physical exams and physical measurements of your body segments
- Results from the Motion Analysis
- Results from Biomechanical evaluations
- Diaries and questionnaires
- Videotape records from the Motion Analysis
- Ultrasound and/or MRI results, if requested by us.

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Your participation will include completing questionnaires about your health and medical history. We will measure you height, weight, body fat, and take measurements of your body. If you have experienced any type of joint injury, we will discuss this with you and ask you to describe the injury and the treatment you received or are still receiving. Then we'll ask you to warm up as you would normally do before performing exercise or a sports activity. We'll attach reflective sphere beads to your body and have you to walk, run, or perform the normal motions of your sport activity. While you do this we will be video and audio recording your movements. We will also be collection data from each of the reflective sphere beads we placed on your body. All of this information will be stored in our data bank so that we can use it later. For example, we may want to look at all the motion data we collected from individuals with knee injuries.

Your data will be kept in a secure location in a data bank called the University of North Carolina at Charlotte Biomechanics/Motion Analysis Laboratory Data Bank so that it may be used in future research to learn more about your medical condition and other medical problems. Once collected, you may be called from time to time to update information on your health that is necessary to keep the data bank current.

Although every effort will be made to keep your information confidential, there is a small risk that an unauthorized person may obtain your information. Therefore, there is a very slight risk that a test result could be linked to your identity and inadvertently disclosed to a third party. In addition, you might have to decide whether or not to discuss the findings with members of your family. If a third party (like your employer or insurer) learned the results, there is a risk of discrimination that could affect your employability or insurability, of stigma, and of the unpredicted disclosure of this information to others.

Nigel Zheng, Ph.D. and associates will be allowed to collect, use and/or give out your data. They may give your data to other researchers whose research is approved by an Institutional Review Board (IRB) (An IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). They may also give your data to a study sponsor, the Food and Drug Administration, the Department of Health and Human Services, the Office of Human Research Protections, or other Government agencies. There is a risk that information received by these authorized persons or agencies could then be passed on to others beyond your authorization and not covered by the law.

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator may benefit if the results of this study are presented at scientific meetings or in scientific journals. Although your data will never be sold, it is possible that new treatments, medicines, therapies or products could be created from studies that use your data. If that happens, the Principal Investigator and the University of North Carolina at Charlotte could receive significant financial benefits. You will not be offered any payment or any other financial benefit.

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Signatures

As a representative of this study, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how the participant's protected health information will be collected used and shared:

_____ _____
Signature of Person Obtaining Consent & Authorization Date

Consenting Adults. You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared. You will get a copy of this Form. You have been given the opportunity to ask questions before signing this form, and you have been told that you can ask other questions at any time.

Adult Consenting for Self. By signing this form, you voluntarily agree to participate in this study and hereby authorize the collection, use and sharing of your protected health information as described in sections 17-26 above. By signing this form, you are not waiving any of your legal rights.

_____ _____
Signature of Adult Consenting & Authorizing for Self Date

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study and hereby authorize the collection, use and sharing of protected health information for the person named below as described in sections 17-26 above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

_____ _____
Consent & Authorization Signature Date
of Parent/Legal Representative

_____
Print: Name of Legal Representative of and Relationship to Participant:

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Participants Who Cannot Consent But Can Read and/or Understand about the Study. Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

_____ _____

Assent Signature of Participant Date

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Consent to be Videotaped and to Different Uses of the Videotape(s)

With your permission, you will be videotaped during this research. Your name or personal information will not be recorded on the videotape, and confidentiality will be strictly maintained. When these videotapes are shown, however, others may be able to recognize you.

The Principal Investigator of this study, Nigel Zheng, Ph.D., will keep the videotape(s) in a locked cabinet. These videotapes will be shown under his direction to students, researchers, doctors, or other professionals and persons.

Please sign ***one*** of the following statements that indicates under what conditions Dr. Zheng has your permission to use the videotape.

I give my permission to be videotaped solely for this research project under the conditions described.

_____Signature _____Date

I give my permission to be videotaped for this research project, as described in the Informed Consent Form, and for the purposes of education at the University of North Carolina at Charlotte.

_____Signature _____Date

I give my permission to be videotaped for this research project, as described in the Informed Consent Form; for the purposes of education at the University of North Carolina at Charlotte; and for presentations at scientific meetings outside the University.

_____Signature _____Date

Department of Mechanical Engineering and Engineering Science
9201 University City Boulevard, Charlotte, NC 28223-0001
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Informed Consent for

Prospective Evaluations of Patients with Journey II BCS in Gait Biomechanics, Proprioception, Balance and Functional Capacities

Project Purpose

You are invited to participate in a research study because you had a total knee replacement (TKR) or you are a healthy subject for our study. The primary purpose of this study is to learn the differences in how the knee works during level, incline and stair walking, balance and proprioception in people with one of two total knee replacement (TKR) designs (bi-cruciate posterior stabilizing and posterior stabilizing) and those whose knees are healthy. Please ask the study staff to explain any words or information that you do not clearly understand. Before agreeing to be in this study, it is important that you read and understand the following explanation of the procedures, risks, and benefits.

Investigator(s)

Nigel Zheng, Ph.D., Professor and his research assistants at UNC Charlotte.

Eligibility

You are invited to participate in this study if you are going to have total knee replacement with either bi-cruciate posterior stabilizing or posterior stabilizing implants, or you are healthy to serve as one of our healthy controls.

Overall Description of Participation

If you agree to participate in the study as a TKA subject, you will be asked to attend these sessions, 1) a pre-surgery biomechanical test session within two weeks of your TKR surgery, 2) a phone interview session at one week, 3) two biomechanical test sessions at one month (optional) and six months after your TKR surgery, and 4) one session to fill out responses to survey forms at 12th month after your TKR

surgery. Each of the three biomechanics laboratory testing session which will take about 2 hours to complete at the Biomechanics/Sports Medicine Lab on the UNC Charlotte campus. If you agree to participate in the study as a healthy control subject, you will be asked to attend one session.

You will need to wear shorts and t-shirt for the study procedures. Your shorts should be close-fitting so we can see how your body moves during the study procedures. The phone interview session will last no more than 20 - 30 minutes and the final survey session will not last more than 30 minutes.
At the start of each biomechanical test session, you will complete the patient satisfaction score, and a few survey forms [EQ-5D, SF-12, Knee Society Scoring system score, current pain medication, and Physical Activity Readiness Survey (PAR-Q)]. Following completion of the surveys, you will change into appropriate testing attire and footwear. Height and weight will be recorded. You may walk for a few minutes in the lab to get ready. You will then be asked to perform these daily activities:

- get out of a chair, walk about 9 feet, and walk back to the chair,

After these daily activities, we will also perform some tests. You will perform:

- balance test
- proprioception test (that measures a subject's ability to reposition a joint to a predetermined position)
- knee range of motion test

After completion of the aforementioned tests, you will be asked to complete level, ramp and stair walking tests. An EMG electrode will be placed on several lower limb muscles on you. You will be asked to perform several movements to test the electrode attachment for the muscles. The electrodes are used to record the electrical signals of the muscles and will not discharge any electrical shock or hurt to you. Reflective markers will be placed on your body using double-sided tapes. You will then perform 3-5 successful tests for each of five walking test movement conditions: level walking, uphill walking at 5°, downhill walking 5°, stair ascent, and stair descent. Tests need to be completed at your own speed. You will be asked to rate your knee pain before and after each of the five walking conditions.
None of the instruments will interfere with your ability to do the test. We have 4 home security cameras installed in the lab. If you do not wish us to record the tests, please let us know now so we will turn off these cameras.

If you have any further questions, interests or concerns about any equipment to be used in this test, please feel free to ask the investigators or other research personnel.

Length of Participation

Your participation will take approximately 2.5 hours for each session in the lab.

Risks and Benefits of Participation

The possible risk of injury in this study is highly unlikely, not higher than the risks you are facing in your daily living. Additionally, research assistants will be present to spot you during the test to ensure you are protected from losing your balance at any time during the study. Our 3D motion capture system and 3D whole body scanner work like regular cameras and do NOT have any radiation. You should not experience pain or discomfort with the testing procedure. However, if you do you should inform the investigators and testing will be stopped immediately.

You may not benefit from your participation in this study directly. If you want, you can receive your individual study information to share with your personal physician in case it might be helpful to your future health care. The information gained from your case may benefit others with your condition. Identifying the gait abnormalities following TKR with different TKR designs may be also beneficial in improving future TKR designs, and surgical and rehabilitation methods in order to achieve higher levels of patients' functions after their knee joint replacements.

Compensation/Payment/Incentives

If you are one of healthy controls, you will receive a $30 Walmart gift card at the completion of participation. If you are one of TKA subjects, you will receive a $150 Walmart gift card at the completion of participation.

Possible Injury Statement

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. UNC Charlotte has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

Volunteer Statement

You are a volunteer. The decision to participate in this study is completely up to you. If you decide to be in the study, you may stop at any time. You will not be treated any differently if you decide not to participate in the study or if you stop once you have started. Unfortunately, you will not receive a Walmart gift card.

Confidentiality Statement

Any identifiable information collected as part of this study will remain confidential to the extent possible and will only be disclosed with your permission or as required by law.

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by Carolinas HealthCare System, UNC Charlotte, OrthoCarolina, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

Statement of Fair Treatment and Respect

UNC Charlotte wants to make sure that you are treated in a fair and respectful manner. Contact the Office of Research Compliance at 704-687-1871 or uncc-irb@uncc.edu if you have questions about how you are treated as a study participant. If you have any questions about the actual project or study, please contact Dr. Nigel Zheng (704-687-7301, nzheng@uncc.edu).

Approval Date

This form was approved for use on *Month, Day, Year* for use for one year.

Participant Consent

I have read the information in this consent form. I have had the chance to ask questions about this study, and those questions have been answered to my satisfaction. I am at least 18 years of age, and I agree to participate in this research project. I understand that I will receive a copy of this form after it has been signed by me and the principal investigator of this research study.

_____ _____

Participant Name (PRINT) DATE

_____

Participant Signature

_____ _____

Investigator Signature DATE