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Gait analysis following Total Knee Arthroplasty during Inpatient Rehabilitation: Can findings predict LOS, ambulation device, and discharge disposition?

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Gait analysis following Total Knee Arthroplasty during Inpatient Rehabilitation: Can findings predict LOS, ambulation device, and discharge disposition?

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy

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We hereby certify that this dissertation, submitted by _, conforms to acceptable standards and is fully adequate in scope and quality to fulfill the dissertation requirement for the degree of Doctor of Philosophy in Physical Therapy.

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Abstract

Title: Gait analysis following Total Knee Arthroplasty during Inpatient Rehabilitation: Can findings predict LOS, ambulation device, and discharge disposition?

Background: Total knee arthroplasty (TKA) is the treatment of choice for end-stage knee osteoarthritis. Growth in the number of procedures performed annually in the United States is expected to increase steadily. Post-operative rehabilitation settings vary and include both institutional and community based physical therapy (PT) services. Despite access to PT, deficits in gait often persist for months and even years after surgery. Slow gait speed, asymmetrical walking patterns, and prolonged time in double-limb support following the TKA often lead to the need for an assistive device for walking and prolong the rehabilitation phase. **Purpose:** The purpose of this study is to analyze early gait during inpatient rehabilitation to quantify both the improvements made and deficits that remain in important gait variables. This study identifies predictor variables that contribute to the variance in discharge ambulation device use and IRF length of stay. **Subjects:** A convenience sample of 230 patients discharged to an IRF following a TKA (160 following a single TKA and 70 following a bilateral procedure) was used for this analysis. **Method:** Paired *t*-tests were used to compare temporal and spatial gait variables from the initial gait assessment compared to the discharge gait assessment in patients following single TKA to determine remaining deficits. Right vs left comparisons were made for patients following a bilateral procedure. A binary logistic regression was used to identify predictors associated with the

need for a two-handed ambulation device at discharge. A multiple linear regression developed a model to assess predictors of the inpatient rehabilitation length of stay. Finally, a self-assessment to evaluate patient confidence with walking (mGES scale) was correlated to actual gait speed performed on the gait analysis in a sample of patients from our study population. **Findings:** Deficits in step length, step time and percent of single limb support remained in the involved limb compared to uninvolved limb at discharge from inpatient rehabilitation following single TKA; no limb differences between the right and left side were noted in patients after bilateral TKA. The discharge gait speed of 54.6 cm/sec for single TKA patients and discharge speed of 61.5 cm/sec for bilateral TKA patients is within the classification of limited community ambulators and making them appropriate for a home discharge. But despite improvement from admission to discharge, the gait speed for both groups in our study remain below the gait speed identified by prior studies 3-months following TKA surgery where speed reached 135 cm/sec. The need for a two-handed ambulation device, such as bilateral canes or a walker, was associated with slow walking speed and prior use of a device before surgery. A longer rehabilitation length of stay was associated with slower initial gait speed, lower motor FIM scores and reduced knee extension at admission. The mGES patient self-report conducted at the time of the discharge gait assessment showed a moderate correlation to the discharge gait speed; however, the pairing of the admission mGES with the admission gait speed was not significantly correlated.

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Finally, to my Burke mentor and friend, Dr. Mary Beth Walsh, I dedicate this study. Working with her for the past 22 years has inspired me to seek information about what really impacts the outcome of the patients we serve at Burke. Her brilliant example has been a source of motivation and inspiration. Her dedication and commitment to the field of rehabilitation medicine has ensured it remains available for those patients who need it.

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Chapter 1

Introduction

The purpose of this chapter is to introduce the reader to this dissertation and provide a background into the topic of total knee arthroplasty and the use of post- acute services in an inpatient rehabilitation setting. It contains insight into the problems to be investigated as well as a list of research questions posed by the investigators. The highlight of the proposal is on the ability of gait speed to predict important outcomes such as length of stay and ambulation device needed at discharge. The introduction also includes a list of pertinent terms used throughout the manuscript.

Total knee arthroplasty (TKA) is the treatment of choice for end-stage osteoarthritis, following failed conservative management of pain and functional decline. The number of TKAs performed annually in the United States has more than doubled over the past decade[1, 2] and has now exceeded 700,000 per year.[3] Although TKA are predominantly single limb procedures, the numbers of bilateral total knee arthroplasties performed are rapidly growing. Of TKAs performed between 2004 and 2007, more than 10% were bilateral.[4] It is anticipated that the number of total knee procedures in the United States will reach 3.5 million by 2030.[5] The primary goal of this surgical intervention is to relieve pain and improve function, especially walking. Among those who undergo the procedure there is wide variation in outcomes achieved. Factors, such as age, gender, prior level of function, pain, and body mass index, have been identified as predictors of post-operative function such as range of motion (ROM), walking, and stair climbing.[6, 7] Interestingly when functional outcomes were compared between persons who had a single TKA to a bilateral TKA, no functional differences existed in a cohort of 511 clinically similar patients.[8]

Following TKA, post-surgical deficits in gait result in shorter step length, decreased cadence and speed, and increased double-limb support time which often persist for years.[9, 10] In addition, too much or too little step width is associated with falls in older persons.[11] Deficits, such as these, often result in the need to use an assistive device for walking. Assistive devices, such as canes, crutches and walkers, provide stability, augmentation of muscle action, and reduction of weight bearing load during walking.[12] Despite their importance, the use of assistive devices such as cane or walker, can potentially have a destabilizing biomechanical effect that may result in falls caused by tripping or lack of balance control.[13] Stevens et al[14], highlighted the prevalence of falls associated with ambulation devices. When comparing ambulation devices there were seven times as many injuries associated with the use of walkers compared to canes, and women who used walkers fell 2.6 times more than men.

Problem. Abnormal spatial and temporal gait patterns following TKA persist up to a year or more following surgery. When persons with TKA were compared to age matched controls at six months post-surgery, step length, step duration and velocity increased after surgery while remaining lower than the values demonstrated by the control group.[15] Although visual gait assessments, strength and range of motion measures are a part of the physical therapy program in inpatient rehabilitation following TKA, rarely is a comprehensive gait analysis assessment used to quantify deficits in step time, step length, stride length, percent single and double limb support to predict outcome after TKA. Indoor ambulation with a single straight cane or no device is the goal at discharge from an inpatient rehabilitation setting following TKA and is achieved about 90% of the time.[16] The need for an ambulation device is based on stability, muscle action, weight bearing load and need for one or both upper extremities for balance.[17] Consideration of the potential risks associated with an ambulation device should be weighed against the risk of falls and should help in the selection of the least restrictive device to encourage community ambulation after TKA. Knowledge of gait parameters, such as speed, steps per minute, step length, step time, stride length, step width and percentage of double limb support, may provide additional insight during rehabilitation into key factors that predict the need for a specific ambulation device.

In addition to gait variables that can provide insight into the use of assistive device and discharge disposition; an individual's walking speed might impact their walking confidence. The Modified Gait Efficacy Scale (mGES) has been used to assess older adults' perception of their level of confidence with walking during challenging circumstances such as walking over obstacles, on uneven surfaces and up and down stairs.[18] Using a reliable and valid tool, such as the mGES, may correlate with information found in performance-based measures.

Although the settings for post-operative rehabilitation following TKA vary, those who cannot go directly home after surgery often receive therapy in an inpatient setting such as inpatient rehabilitation facility (IRF) or skilled nursing facilities (SNF). Despite the large number of patients who go directly home following TKA, 11% still receive inpatient rehabilitation in an IRF.[19, 20] The goal of this study is to analyze the gait patterns of patients following single and bilateral TKA who have been admitted to an IRF. Gait assessments were conducted on admission and the day before discharge using the Proto Kinetics Zeno walkway (PKMAS). Gait variables were compared between admission and discharge to better understand which variables improved during this relatively short IRF length of stay (LOS). In addition, using the uninvolved limb of single knee subjects as a control, step length, step time, stride length and stride width, stride speed and single limb support time between the involved vs. uninvolved were compared.

Using predictive modeling, patient characteristic, initial gait parameters, and other clinical finds were evaluated to determine their ability to predict length of stay, discharge disposition and ambulation device at discharge from the IRF setting. In a subset of patients, gait speed was correlated to the mGES. The assessments, taken at admission and discharge, were compared.

Relevance

Knee arthroplasty provides for an effective reduction of pain and adequate restoration of function for those suffering from advanced osteoarthritis. Following surgery, physical therapy is often prescribed to facilitate adequate range of motion, reduce post-operative pain and improve functional activities of daily living, especially walking. Function is assessed as part of a rehabilitation program and consists of the need for assistance with transfers to and from the bed, toilet and bathtub/shower, walking, and stair climbing. In an IRF setting assessment of cognitive and functional items are standardized and assessed on a 7-point scale, the Functional Independence Measure (FIM). [21-23] In addition, the selection of an appropriate assistive walking device and training the patient how to use it is an important part of the rehabilitation process. Considering the benefits of a walking device (to reduce lower limb loading and thereby alleviate joint pain, or compensate for weakness with the risk associated with its use) is an important role of the physical therapist.[13]

Despite the opinion that gait speed is considered the sixth vital sign[24], it is not reported as part of the standardized post-acute Inpatient Rehabilitation Facility Patient Assessment Instrument (IRFPAI) data set which includes the FIM. Prior studies in rehabilitation setting and within the community have used gait speed to predict mortality, poor quality of life, physical and cognitive functional decline, and falls.[25, 26] In rehabilitation settings it has been used in the stroke population as a predictor of length of stay and nursing home placement.[27] Gait speed has also been used to classify household vs. community walkers among the elderly.[28] In older adults gait speed of less than 0.8 m/sec has been identified as pathological and low functioning. [29] Although gait speed as an assessment of the geriatric client has been established[30]; little information is available specifically for those immediately following TKA.

The addition of a self-assessment scale to measure confidence in walking may correlate with gait speed and thus be useful in predicting important outcomes. The mGES is a 10-item measure that assesses older adults' perception of their walking confidence during challenging circumstances. The scale demonstrated test-retest reliability, a SEM of 5.23 points and internal consistency. The mGES was also correlated to measures of confidence and fear, function and disability and performance-based mobility as a measure of concurrent validity in community-dwelling older adults.[18] In addition its use was associated with the Rating of Perceived Exertion (RPE) when used with adults over 65 years of age.[31]

Following TKA gait measurements have been used to evaluate different prosthetic devices and surgical approaches. These measurements include velocity, stride length, and arcs of motion of the hip, knee and ankle. Compared to age-matched controls without knee pathology, patients 3 years after TKA still exhibited deficits in kinematic, kinetic and spatiotemporal variables such as longer double-limb stance and prolonged cycle times.[32] Gait analysis of the involved limb compared to non-operative limb after TKA found a shorter step length and decreased cadence in the involved limb.[10] In a study comparing TKA patient six-month post-surgery to age matched controls the TKA patients walked slower than the controls. The uninvolved side of the TKA demonstrated longer stance time and shorter step length than controls.[33] Using a three-dimensional motion analyses to measure gait parameters, decreased hip adduction and increased toe-out on the side of arthroplasty after TKA surgery were found.[34] In another study post-surgical TKA subjects speed remained significantly slower and stride length significantly shorter at both 2 weeks and 6 months post-surgery compared to age – matched controls.[35] Although walking function improves post-operatively as evident by the increase in speed and stride length; deficits compared to age-matched controls deficits exist for years following TKA.[33] Although no information was available regarding the years of symptoms before undergoing a TKA, Andriacchi et al suggest post-operative gait deficits may be related to a learned preoperative abnormal pattern that gradually develops with the progression of the disease.[36, 37]

To assess gait speed there are several simple methods that provide some basic information. A 50-foot timed walk test can be used to determine gait speed. The commonly used Timed Up and Go (TUG) incorporates walking, turning and sit to stand within one assessment, but cannot be used solely for determining gait speed.[38] Although 50 foot timed test and the TUG have been used to provide evidence of improvement in walking endurance and speed, they have not been used to predict clinical outcomes or length of stay.[29] While these tests are simple to perform and can detect mobility impairment, they lack detailed objective information about gait patterns. That is why this study will utilize the data from the Zeno walkway: speed, along with gender, age, body mass index, FIM scores and range of motion, as predictors of discharge ambulation device, LOS, and discharge disposition.

To date no studies have used gait speed, along with demographic and other clinical variable following TKA to predict important outcomes such as length of stay, discharge ambulation device and discharge disposition. In addition, a subjects' perceived confidence in walking has never been compared to actual gait speed in this patient population.

The purposes of this study are as follows:

(1) Using the non-operated limb as a control after single TKA, compare involved vs. non-involved lower extremity step length, stride length, stride width, step time, stride time, stride speed, single limb support to determine if differences between the operated limb and non-operated limb remain at discharge from an IRF.

(2) Describe the right and left limb on these same variables following bilateral TKAs. Although there is no control group for comparison, it is important to determine if there is a difference between the right and left operated limbs in patients who had a bilateral procedure.

(3) Identify if gait speed, age, gender, body mass index (BMI), and history of assistive device use prior to surgery can predict the need and type of ambulation device at discharge from an IRF.

(4) Determine if length of stay and discharge disposition can be predicted by early gait speed in persons post TKA along with initial motor and cognitive FIM sub-scores, and initial knee flexion and extension ROM.

(5) Determine if there is an association between gait speed and the patient rated mGES score from assessments taken at admission and discharge.

Research Questions

(1) For persons discharged from an IRF following unilateral TKA is there a significant difference in step length, stride length, stride width, step time, stride time, stride speed, single limb support between the involved (operated limb) and the uninvolved limb?

(2) Are there right and left differences in step length, stride length, stride width, step time, stride time, stride speed, single limb support following bilateral TKAs?

(3) Does gait speed, age, gender, body mass index, and use of ambulation device prior to surgery predict the need for a one-handed (cane or no device) compared to a two-handed (bilateral canes or walker) ambulation device at discharge?

(4) Does initial gait speed predict the IRF length of stay and discharge destination? Can additional functional information, such as initial motor and cognitive FIM and initial knee flexion and extension ROM improve the prediction? Can a safe cut-off value be established for safe ambulation with a one-handed ambulation device using the discharge gait speed?

(5) Is there a relationship between gait speed and a patients' self-reported mGES score for ambulation at admission and discharge from the IRF?

Definition of Terms

Inpatient Rehabilitation Facility (IRF) - IRFs are freestanding rehabilitation hospitals and rehabilitation units in acute care hospitals designated for patients who require intensive, interdisciplinary post-acute rehabilitation services.

Functional Independence Measurement (FIM) - a uniform system of measurement for disability based on the *International Classification of Impairment, Disabilities, and Handicap;* measures the level of a person's disability and indicates how much assistance is required for the individual to carry out activities of daily living. The FIM scale assesses physical and cognitive disability and focuses on the level of disability indicating the burden of care. Items are scored on the level of assistance required for an individual to perform activities of daily living. The scale includes 18 items, of which 13 are physical domains and 5 items are cognition items. Possible scores range from 18 to 126, with higher scores indicating more independence. [21-23] The items in the physical domain referred to as the motor score as well as the total FIM score will be used in this paper.

The modified Gait Efficacy Scale (mGES) – is a 10-item measure that addresses older adults' perception of their level of confidence in walking during challenging circumstances. The items are scored individually on a 10-point scale, with 1 denoting no confidence, giving a total score range of 10 to 100, with 100 representing complete confidence in all tasks.[18]

Temporal and Spatial Gait Measurement:

Step Length – is the distance between corresponding successive points on the heel of opposite feet measured parallel to the direction of progression and is expressed in cm.

Stride Length - the distance between two successive placements of the same foot. It consists of two step lengths, left and right, each of which is the distance by which the named foot moves forward in front of the other one.

Stride width – also referred to as base gait, is the side to side distance between the line of the two feet, usually measured at the mid-point of the heel. PKMAS uses the Step Length and Stride length measurement protocols as outline by Huxham in Defining spatial parameters for non-linear walking. Gait and Posture, 159-163.[39]

Step Time – The period taken for one step and is measured from first contact of one foot to the first contact of following other foot, expressed in seconds.

Swing Time – The period when the foot is not in contact with the ground, expressed in seconds.

Double limb support – the phase of gait when both feet are on the ground. Double limb support occurs for two periods; the first period begins at initial contact, and lasts for the first 10 to 12 percent of the cycle. The second period of double limb support occurs in the final 10 to 12 percent of stance phase.

Single limb support – the phase of gait when only one limb is on the ground. Single limb support occurs for two periods of 38% of the normal gait cycle.

Toe In/Out Angle – is the angle between lines bisecting the foot (from 2nd toe to mid heel) and the line of progression (~ 15^0.)

Speed – also referred to as gait velocity in the PT literature, is the distance traveled by the body per unit of time. The Protokinetics system reports speed in centimeters per second (cm/sec). Although the PT literature often uses the terms gait speed and gait velocity synonymously, this paper will use the term speed with the exception when an author of a study used the term velocity.

Cadence – refers to the number of steps taken in a specific period of time, usually per minute. The Protokinetics determines it as the number of footfalls minus one, divided by the ambulation time (steps/min).

Length of Stay (LOS) - The number of days a patient spends in the rehabilitation program. The day of admission is the first day and the discharge day is not counted in the length of stay calculation.

Study Goals

Bindawas et al, recently highlighted the importance of mapping the trajectory in function following unilateral hip and knee replacement after discharge from an inpatient medical rehabilitation stay.[40] Despite this important work there is currently no data on the early gait patterns of patients within a week following TKA. Also, no studies to date have used gait speed immediately following TKA to predict important outcomes such as LOS, discharge ambulation device and discharge disposition. In addition, a subjects' perceived confidence in walking has never been compared to their actual gait speed.

This study utilized gait speed from the Zeno walkway to determine its contribution to the discharge ambulation device, LOS and discharge disposition.

Assessing individual confidence with walking may provide insight into the functional skills of walking outdoors, climbing stairs and walking over objects. Improving one's confidence in walking may be an important target of intervention to reduce the barriers to a community discharge and improve mobility after a TKA.

Summary

This study identified gait measures that can be used to predict the ambulation device needed by patients at discharge, the post-acute LOS and discharge disposition from an IRF. With the goal of discharging all patients back to the community walking with either a cane or no device in the shortest period of time gait speed can provide valuable information that can be used to predict these important outcomes. The establishment of cut off values for gait speed needed to walk with a one-handed ambulation device can lead to safe discharge recommendations by the physical therapist. This study also investigated how well the patients' own perception of their walking ability correlates with their own gait speed.

In addition, comparing step length, stride length, step width, step time, stride time and single limb support time of an involved and uninvolved (control) lower extremity can help clinicians to select interventions and feedback designed to improve walking. Establishing typical improvements in gait variables from admission to discharge provides a baseline for future studies that attempt to improve walking immediately following TKA.

Chapter 2

Introduction

The purpose of this chapter is to conduct a thorough review of the literature and establish a better understanding of early post-operative function following total knee arthroplasty. This chapter review the prevalence of osteoarthritis of the knee and the number of single and bilateral replacements performed each year as the treatment of choice for end-stage symptoms. Outcomes following knee arthroplasty, including the benefits and deficits experienced after surgery, will be described. An analysis of gait patterns is discussed as well as the role and use of assistive devices for this patient population. The chapter identifies and reports outcomes following TKA beginning at two-weeks post-surgery and up to 2 years as reported in prior studies. A gap in the literature is that no prior study analyzed early gait patterns during post-acute rehabilitation in an inpatient rehabilitation facility after total knee arthroplasty to provide information on early recovery. No prior attempts to use gait speed to predict length of stay or assistive ambulation device at discharge from an inpatient rehabilitation hospital were found in the literature. Finally, the chapter highlights a new tool used to measure an individuals' self-confidence while walking. The investigators determined the useful of this tool for understanding a patients' confidence during walking and it potential association with the patients' gait speed.

Historical overview

Prevalence of osteoarthritis leading to total knee arthroplasty

Osteoarthritis (OA) is the most common chronic condition of the joints. This condition occurs when the cartilage or cushion between joints breaks down leading to pain, stiffness and swelling.[41] It is the most common form of arthritis affecting 27 million people in the United States. Among persons with OA 13.9% are adults aged 25 years and older and 33.6% (12.4 million) are older than 65.[42] OA results in pain, stiffness, joint restrictions, and impaired mobility. The knee joint as a primary site for OA results in pain, impaired function, and reduced quality of life.

Increased life expectancy and frequency of obesity in younger individuals has led to an increased prevalence of OA in the knee.[43] Common risk factors include age, obesity, previous joint injury, overuse of the joint, weak thigh muscles, and genes. Longstanding OA can lead to abnormal gait patterns compared to health people of the same age and are linked to slower gait speed. Cadence, step length, walking base, time of double support phase in patients with knee osteoarthritis also worsened compared to health subjects.[44] A slower walking speed contributes to a lower cadence, shorter step length, and shorter duration of double stance phase of the involved leg compared to normal group.

Osteoarthritis is initially managed conservatively with non-steroidal pain medication and physical therapy. Once OA has progressed to the point of daily pain that interferes with performing activities of daily living many choose the route of total knee arthroplasty (TKA). The primary goal of this surgical intervention is to relieve pain and improve function, especially walking. Knee arthroplasty provides for an effective reduction of pain and adequate restoration of function for those suffering from advanced osteoarthritis. Factors predicting the need for TKA include advanced age, decline in activities of daily living, poor performance of the Timed Up and Go (TUG) test, weak quadriceps, and reduced knee extension.[45]

For end stage osteoarthritis of the knee TKA is the treatment of choice to reduce pain and stiffness and improve function; ultimately improving one's quality of life. The number of TKAs performed annually in the United States has more than doubled over the past decade[1] and as of 2015 has reached 715,000 per year[46, 47] making it the most common major surgical procedure performed in the US. Although the procedures are predominantly elective single TKAs; for those with bilateral symptoms more are electing to have a bilateral total knee arthroplasty. Of the TKAs performed between 2004 and 2007, more than 10% were bilateral[4] bringing the number of annual procedures over 65,000 per year.[48] It is anticipated that the number of total knee procedures in the United States will reach 3.48 million annually by 2030.[5] A study reporting current utilization of knee arthroplasty found a marked increase in the volume of primary TKA procedures being performed since 1991. This steady increase in TKA volume over a ten year period was found to be driven not only by the increases in the number of

Americans enrolling in Medicare but also a substantial increase in the per capita utilization of TKA procedures (from 31.2 procedures per 10,000 Medicare enrollees in 1991 to 62.1 procedures per 10,000 in 2010).[49] This trend in utilization was also found in younger individuals due, in part, by the development of newer arthroplasty procedures such as bicompartmental and unicondylar knee replacements. An increase in the number of procedures performed has also led to an increase use of post-acute services following TKA. Skilled nursing facilities (SNF) and inpatient rehabilitation facilities (IRF) are the primary settings for an inpatient post-acute rehabilitation setting following TKA. On average patients who required post-acute care in a SNF added an additional 15 days and those receiving care in an IRF add 9 days to their total LOS following surgery.[50] The resulting cost impact of the procedure and post-acute aftercare to our healthcare system, especially to Medicare, makes it an important topic. Increased use of post-acute services has led to payment reform; in April 2016 the Center for Medicare and Medicaid (CMS) implemented the first mandatory bundled payment system in designated metropolitan areas known as the Comprehensive Care for Joint Replacement Model (CJR). CJR has standardized care and contained costs while encouraging communication and coordination between hospitals and post-acute providers to maintain quality of care and reduce readmissions. This level of focus on joint replacements in the US encourages the tracking of important clinical variable after surgery to ensure a successful outcome.

Post-operative functional outcomes. Among those who undergo a total knee arthroplasty there is wide variation in clinical outcomes achieved. A post-operative survey found that TKA procedures restore a person's ability to do many routine activities like age matched controls who did not have a TKA, but only half reported their knee to be normal after knee replacement. For time/distance components of gait TKA patients show shorter step length, wider step width, and shorter gait cycle compared to the gait of control subjects. The TKA group also has shorter step time, single support time, and swing time, and longer double support time compared to normal subjects.[15] As activities become more demanding fewer post-operative TKA patients report symptom-free function such as when squatting or kneeling compared to age-matched controls performing the same activities.[51] Specific to knee kinematics during walking knee flexion excursion is less in the operated knee after TKA than in healthy controls of a similar age.[52] Reduced knee function may be a consequence of a quadriceps avoidance gait pattern developed prior to surgery to minimize pain in the affected knee or due to joint restrictions following surgery. Even though pain resolves over time this pre-surgery gait pattern often remains up to 18 months after surgery.[51] Investigation of variables associated with poor knee range of motion, continued difficulty with walking and stairs[6, 7] and a longer hospital LOS,[53] point to age, pre-surgical level of function, post-operative pain, the use of an assistive device prior to admission, and BMI as predictors.

With an increased interest and use of bilateral TKA for those with bilateral OA in the knee, it is important to compare those patients as well. In a cohort of 511 clinically similar subjects found no difference in functional outcomes between patients who had a single TKA compared to a bilateral TKA.[8]

Gait analysis. An important area of recovery after TKA is walking and despite rehabilitation efforts deficits often continue long after surgery. In general, a gait assessment can be useful in identifying specific areas of deficits as a focus for physical therapy treatment. An analysis of the gait cycle can be a very useful tool as a precursor for selecting a therapeutic intervention to improve walking. Temporal-spatial gait variables are important predictors of falls[54, 55] and quantification of the effect of interventions.[56] Temporal measures, such as gait speed, can be particularly useful for assessing health status, activity levels, and quality of life and is predictive of morbidity and mortality.[57]

Gait analysis can be conducted by visual assessment or by using sophisticated equipment such as a pressurized walking mat or cameras capturing reflective joint markers while walking. By definition gait analysis refers to the instrumented measurement of the movement patterns that make up walking and the associated interpretation of these.[58] Richard Brand proposes four reasons for performing clinical gait analysis: differential diagnoses, assessment of severity of disease or injury, monitor progress and predict outcome.

Gait analysis can be useful in revealing information that can lead to the selection of clinical interventions.[59] Understanding how a patient's condition is likely to respond to the treatment is another important benefit. The prediction of outcomes provides information for patient management and the effectiveness of intervention.[58] The gait cycle is comprised of two phases, the stance phase and the swing phase. On average the stance phase represents approximately 60% of the gait cycle, while the swing phase comprises 40%.[60] Appendix A illustrates the difference between these phases of gait.

Gait analysis conducted on a force platform provides data about two types of variable; temporal and spatial. Step length, a spatial variable, is the distance between corresponding successive points of heel contact of the opposite feet. Stride length is the distance between successive points of heel contact of the same foot. Stride width is the side by side distance between the lines of the two feet. Degree of toe out represents the angle of foot placement and may be found by measuring the angle formed by each foot's line of progression and the line intersecting the center of the heel and the second toe. Commonly reported spatial (distance) variables include step length, stride length, stride width, and degree of toe out. Appendix B provides a visual representation of important gait variables that are available from the pressurized walkway.

Single limb time is the amount of time that passes during the period when only one foot is on the supporting surface during a gait cycle. Double limb time is the amount of time that a person spends with both feet on the ground during one gait cycle. During a normal gait cycle, double limb support occurs 20% of the time while single limb occurs 80%. The time spent in double support decreases as the speed of walking increases. Cadence is the number of steps per unit of time. Normal cadence is 100-115 steps per minute.[61] Another useful predictive variable of a gait analysis is gait speed.

Gait velocity and gait speed are synonymous and is the distance covered by the body in a unit of time. Average speed equals step length x cadence and the average walking speed is 80 cm/sec. As an important outcome measure, there are several simple methods to measure gait speed. A 50-foot timed walk test can be used to determine gait speed. The test-retest reliability of the 50-foot timed walk was very high at an ICC of 0.98 with a SEM=0.3.[62] Another commonly used test is the Timed Up and Go (TUG) which incorporates walking, turning and sit to stand within one assessment.[38] Although the 50-foot timed test and the TUG have been used to provide evidence of improvement in functional walking and speed, they have not been used for predictive purposes and cannot provide objective gait variables such as step length and stride length.[29] Thus the use of a computer-assisted gait assessment tool can provide more meaningful data.

Two gait analysis systems commercially available are the GaitRite® and PKmas®. When the ZenoWalkway was compared to the original pressure sensored gait mat called the GAITRite the ICCs were all above 0.84. Specific to the variable of interest in this study the ICC for speed, cadence, stride length, step length, stride duration, step duration were 1.00, double limb support duration was 0.99 and base width was 0.84.[63] In addition, strong concurrent validity was established in this trial with the GAITRite®. The reliability of repeated measures was good at preferred and fast gait speed, cadence, stride length, single support, and proportion of time spent in double limb support for this walkway.[63, 64] The strong concurrent and test-retest reliability provide the confidence of the inoperability of the two systems as well as internal consistency of the Zeno Walkway.

Gait speed to predict adverse events. Gait speed is a measure of distance covered in a specific time and is reported in feet or meters or centimeters per second and is considered to be the sixth vital sign.[24] It is a simple, inexpensive and reliable assessment that has been useful in predicting outcomes such as mortality, morbidity, and adverse events such as falls. Gait speed is divided into two different types; comfortable or usual-pace and fast or maximum gait speed.[65] Comfortable gait speed is calculated by dividing the test distance by the test time. Peel, Kuys and Kein[30] systematically reviewed the literature on the importance of gait speed in a comprehensive geriatric assessment. Their meta-analysis highlighted the mobility limitations experienced by older people in clinical setting, such as subacute rehabilitation settings, and emphasizes the need for ongoing rehabilitation for community reintegration. Gait speed can serve as a clinically important predictive marker for early home discharge as well as an identifier of patients at risk for unplanned readmissions following elective ambulatory surgery.[66] These findings corroborate the results of other studies demonstrating the role of gait speed to predict hospital length of stay following surgery and stroke.[67] In community dwelling older people, gait speed at usual pace has been a strong predictor of mortality[68], functional decline and institutionalization.[25] Gait speed slower than 0.4 m/s identifies individuals unable to perform basic activities of daily living; and speed less than 0.8 m/s is associated with reduced capacity for community ambulation.[24] Reference ranges for men and women by age group have been determined. For women in their 70s mean comfortable gait speed is 1.33 m/sec and for men of the same age group is calculated at a mean of 1.27 m/sec.[65] A study conducted in a transitional care facility demonstrated that walking speed can be used for early detection of older patients at risk of poor clinical outcomes. Despite daily rehabilitation, gait speeds of institutional patients remain below cut-off set for community ambulation. For example among 351 older persons admitted to a transitional care program the mean discharge gait speed was 0.54 m/s, below the 0.8 m/s target for community re-integration.[69] In a rehabilitation settings gait speed was used as a predictor of LOS and nursing home placement post stroke.[27] Specific to TKA, Lee found that women who had a TKA walked significantly slower than their age matched controls 1 year following surgery.[15] In a similar study that included males the 1 year post-operative knee pattern was slower and included a stiff knee pattern.[70] It is important to know whether gait patterns return to normal after TKA. A normal gait pattern after surgery can reduce the risk of damage and deterioration of the prosthesis and reduce the risk of a revision in addition to improving the likelihood for community ambulation.

Selection and training of an assistive device. Selecting and training in the use of an appropriate assistive walking device is an important part of the rehabilitation process. Proper selection of an assistive device starts with the understanding of the patient's functional needs as well as the gait pattern that is used with each device. The ability to move one's lower extremities in a reciprocal gait pattern while using a device will dictate the most stable and least stressful pattern. For orthopedic conditions, such as after TKA, the physiological demand of the device and the patient's comorbidities should be taken into consideration when selecting the proper device.[12] Physical therapists play a major role in selecting the most appropriate assistive device for walking. They consider the need for reducing lower limb loading and alleviation of joint pain, as well as providing compensation for limb weakness.[13]

Elderly people commonly use assistive devices. It is estimated that 6.1 million community-dwelling adults use an ambulation device such as canes, walkers and crutches with the majority of those over the age of 65 years.[71] The purpose of an assistive device is to improve mobility, reduce disability, delay functional decline, and reduce the need for a caregiver.[12, 13] In addition to providing stability and balance during walking, assistive devices help to improve confidence and feelings of safety and independence.[17] For those over the age of 65 years, 10 percent use canes and 4.6 percent use walkers. Regarding the safety when using assistive devices, there are mixed reports. Some findings support the use of canes and walkers to improve balance and mobility in older adults and those with other clinical conditions; while other reports highlight the association between device use and risk of falls. Canes and walkers have been prescribed since the 1950 for improvement of balance and mobility during activities of daily living[72] and continue today. Providing assistive devices for walking as part of a fall prevention programs in residential living centers reduced the incidence of falls.[73, 74] In contrast to the benefits of ambulation devices on falls prevention, other studies highlight their contribution to the risk of falls. Stevens and Thomas reported the frequency of injuries and hospital readmissions associated with walkers and canes represented just 2.6% of falls treated in hospital emergency rooms.[14] Of those the majority occurred in the home while walking. Several additional studies report the use of a mobility aide as a predictor of increased falls in older adults.[75, 76]

In addition to the potential risks associated with the use of an assistive device, a high rate of device abandonment may also put people at risk. Reports as high as 30% to 50% of people discontinue the use of mobility aids soon after receiving it and is a notable concern that may contribute to instability.[77, 78] This issue highlights the importance of selecting and training people on the need and use of an assistive device to effectively increase mobility and reduce disability.

Device selection is first based on the goal of its use. A careful analysis of the person's needs and desired gait pattern should precede the selection of a device. The goals of an assistive device include broadening the base of support, improving balance and stability, reducing the load to one of the lower limbs, augmenting muscle action, assisting propulsion, and transmitting sensory cues through the hand.[79] After TKA the primary goal of an assistive device is to help redistribute weight from the weak and painful operated limb, improve stability by increasing the base of support, and provide tactile cues about the ground for balance. Canes help with balance and are used by people who do not need the upper extremity to bear weight. Two canes provide a wider base of support and balance the arm swing and step time but require concentration and coordination. Walkers improve stability in persons with lower extremity weakness or poor balance by increasing the base of support and allow support to be distributed through a person's upper extremity. Disadvantages of a walker over a cane is that walkers require greater attentional demands and cannot be used on stairs.[12] Walkers are more stable but result in a slower and abnormal gait pattern because all four legs of the walker are in contact with the ground prior to each step. Front-wheeled, or two-wheeled walkers are less stable but provide the opportunity for a more fluid gait pattern over a standard walker. The use of a straight cane at discharge is preferred following an IRF stay after a TKR because it provides better means for community living. Variables such as age, body mass index, admission FIM and admission gait speed were assessed to determine their predictive value in the need for an assistive device at discharge.

Selection of an appropriate device depends on the person's strength, endurance, balance, vestibular function, cognitive function, vision and environmental demands.[12] For patients following TKA a front wheeled walker is frequently used immediately following surgery as it facilitates greater and longer step lengths compared to a standard walker.[80] When sufficient balance, stability and confidence are achieved patients transition from a walker to a cane. This transition makes it easier to navigate in the community.

Self-reported measures of confidence. Self-assessment tools have been used in rehabilitation setting to measure progress and outcomes. Examples of frequently used tools to assess knee function in people after TKA include the Western Ontario and McMaster University Osteoarthritis Index (WOMAC)[81]and the Knee Injury and Osteoarthritis Outcome Score (KOOS).[82] The WOMAC is the most commonly used outcome instrument of assessment of patient-related treatment effects of OA and was demonstrated to have good test-retest reliability for each of the three subscores. Test-retest reliability was satisfactory with ICCs of 0.86 for pain, 0.68 for stiffness, and 0.89 for functional status.[83] The intraclass correlation coefficients for the KOOS were over 0.75 for all subscales indicating sufficient test-retest reliability. Comparing the KOOS to the WOMAC construct validity testing provided evidence that demonstrated the KOOS to be at least as responsive as the WOMAC.[84] Since clinicians rely on both patient report and direct observation and examination prior to selecting therapeutic interventions self-report tools can play a role in treatment decisions. With mobility as an essential component of independent living it may be useful to measure a client's confidence and perception of his or her ability to complete a task. Self-assessment tools have been developed to assess older adults' confidence with walking and fear of falling. A questionnaire to measure a person's ability to avoid a fall may be useful in predicting adverse events. As an example, the mFES is a 14-item "balance efficacy" questionnaire provides insight into a person's confidence to avoid falls during non-hazardous activities of daily living has been found to be internally consistent and demonstrates good test-retest reliability. The overall ICC for the mFES was 0.93.[85] Although these self-assessment tools have been found to be reliable and valid they are not sufficient to measure an individual's confidence in walking during everyday activities.

The Gait Efficacy Scale (GES) was developed to specifically capture an individual's confidence during walking. Efficacy expectations are likely to precede performance. Low self-efficacy could influence when and where walking occurs and could impose limitations despite actual performance.[86] Although the GES captures confidence in walking, it does not include frequently encountered community walking obstacles. In response, the modified Gait Efficacy Scale (mGES) was developed which included everyday walking scenarios such as walking on hardwood floors and grass, negotiating curbs, and climbing stairs

(Appendix C). The mGES has been used to assess older adults' perception of their level of confidence with walking during challenging circumstances such as walking over obstacles, on uneven surfaces and up and down stairs. The mGES demonstrated test-retest reliability within the 1-month period with a SEM of the mGES was 5.23 points.[18] Using a reliable and valid tool, such as the mGES, may correlate with information found in performance-based measures of function such as gait speed, but has not previously been tested.

Theory and research literature specific to the topic:

Post-operative care. Knee arthroplasty provides an effective reduction of pain and adequate restoration of function for those suffering from advanced osteoarthritis. The use of rehabilitation following surgery has been found to mitigate post-operative deficits and facilitate returning to routine activities. Physical therapy is often prescribed to facilitate adequate range of motion, reduce post-operative pain, improve functional activities of daily living, and improve balance and walking. The decision regarding the most appropriate discharge destination following TKA has been a frequent debate and is often based on geographic availability, medical insurance, and patient need. The most common discharge destinations after joint replacement include home (70%)[53], followed by SNF (19%), and IRF (11%).[19, 49, 87] Patients receiving inpatient rehabilitation in an IRF following joint replacement surgery usually show substantial improvements in functional performance from admission to discharge[88] especially when compared to other post- acute setting such as home care[89] and skilled nursing facilities.[90, 91] But a bivariate analysis comparing institutional discharge to community discharge following TKA revealed that a discharge to either a SNF or an IRF are independent risk factors for post discharge adverse events and 30-day readmission.[87] This increased risk of adverse events provides insight into the level of complexity of patients that require institutional discharge prior to going home. These patients are more frequently female, have more comorbid conditions, higher body mass index, poorer function immediately post op and limited psychosocial support; thus, requiring an inpatient post-acute discharge after surgery.

A retrospective study reporting the trajectory of recovery of over 12,000 patients following joint replacement surgery reported substantial improvement in motor skills following admission to an IRF. The functional status of this cohort reached above the need for assistance by another person for important activities of daily living including dressing, transfers, and walking. This study reported the functional status of patients at three and six months in the same key functional motor areas.[40]

A functional assessment of the patient receiving care in an IRF is an important part of the service and include an assessment of transfers to and from the bed, toilet and bathtub/shower, and the ability to walk and climb stairs. These items are standardized within a group of functional and cognitive skills represented in the Functional Independence Measure (FIM)[21-23] (Appendix D) FIM scores, as well as demographic and other clinical information are reported on the Inpatient Rehabilitation Function – Patient Assessment Instrument (IRFPAI) (Appendix E) and serves as the basis of reimbursement for the IRF stay. The use of an assistive device is an important component of the functional skills assessed. The use of an ambulation device is reported for bed, chair and wheelchair transfers, toilet transfers and tub/shower transfers, walking and stair negotiation. Selection of the most appropriate device involves an assessment of deficits while in the IRF combined with the anticipated needs based upon the discharge disposition. A more restrictive device will limit function for those returning to a community setting. For example, walkers are large, more difficult to maneuver in a home and community settings and cannot be used on stairs, but are appropriate for reducing weight bearing to alleviate pain post-operatively following TKA.

Use of assistive devices following TKA. Post-operative pain, deficits in range of motion and strength, and a higher than average fall risk, may lead to the need for an assistive device for walking following TKA. Assistive devices, such as canes, crutches and walkers, provide stability, augmentation of muscle action, and reduction of weight bearing load during walking.[12] Two main reasons for prescribing assistive walking device are to decrease weight bearing on the involved limb and reduce the risk of falling while increasing mobility. Despite their importance, the use of assistive devices can potentially have a destabilizing biomechanical effect that may result in falls caused by tripping or lack of balance control.[13] Stevens et al[14] highlighted the prevalence of falls associated with ambulation devices. When comparing ambulation devices there were seven times as many injuries associated with the use of walkers compared to canes, and women who used walkers fell 2.6 times more than men. One should note however that the regular use of a walking aid was not a significant risk factor for surgery-related falls after TKA.[92] This finding was replicated with a nationally representative sample of Medicare beneficiaries after adjusting for demographics, health and physical function. Gell, Wallace and LaCroix found the incidence of falls and recurrent falls was not associated with the use of multiple devices or any particular type of device.[93] Looking at these findings collectively, the goal of providing the least restrictive ambulation device to encourage community re-integration, while minimizing falls risk, should be considered an important part of the physical therapy recommendation for walking aids.

The need for an ambulation device is based on stability, muscle action, weight bearing load and need for one or both upper extremities for balance.[17] Consideration of the potential risks, such as falls, associated with the use of an ambulation device should be weighed against the benefit and should help in the selection of the least restrictive device to encourage community ambulation after TKA. Knowledge of gait parameters, such as speed, steps per minute, step length, stride length, step width and percentage of double limb support, may provide additional insight during rehabilitation into key factors that predict the need for a specific ambulation device.

Gait asymmetry following TKA. The increase prevalence of TKA highlights the need to assess post-operative gait specifically step length, double limb support and gait speed. Gait analysis is a tool that can identify specific areas of asymmetry during walking.

An antalgic gait pattern is likely the reason for slow gait speed and an asymmetrical gait pattern in the early post-operative period following TKA. Antalgic gait is a compensatory pattern adopted to remove or diminish the discomfort caused by pain in the lower limb. This pattern results in a decreased duration of the stance phase of the affected limb to reduce weight bearing due to pain. Weakness in the quadriceps musculature and reduced knee extension ROM on the operated leg can also contribute to this asymmetrical pattern. Reduction in pain and improvement in strength and ROM will help to improve gait symmetry over time.

In addition to gait symmetry, transitioning from a two-handed walking device, such as a walker or bilateral canes, to a one-handed device, such as a cane, during the IRF stay is monitored. Since slower walking speed has been previously observed in persons using an ambulation device [94], gait speed, along with pain, balance and reduced weight bearing after knee replacement surgery, may impact the type of device needed. The goal of transitioning from a walker to a cane or no device is important for community reintegration following a TKA. Gait training in an IRF setting is progressive and often include transitioning from a walker to bilateral canes then to a single cane and, for some patients, no device by discharge. Management of post-operative pain and speed throughout the inpatient acute rehabilitation stay may contribute to the improvement in gait within the first 2 weeks following surgery. As pain is reduced, improvement in gait symmetry is usually observed. Gait symmetry involves a more balanced pattern between the right and left limb during walking, which is achieved by a more equal step length and step time between the left and right limbs. The gait cycle is a single sequence of events between two sequential initial contacts by the same limb. A *cyclogram,* part of the PKmas output, paints a very vivid picture of the gait cycle (Figure 1). In this visual depiction, one can see imbalances between the right and left limb.

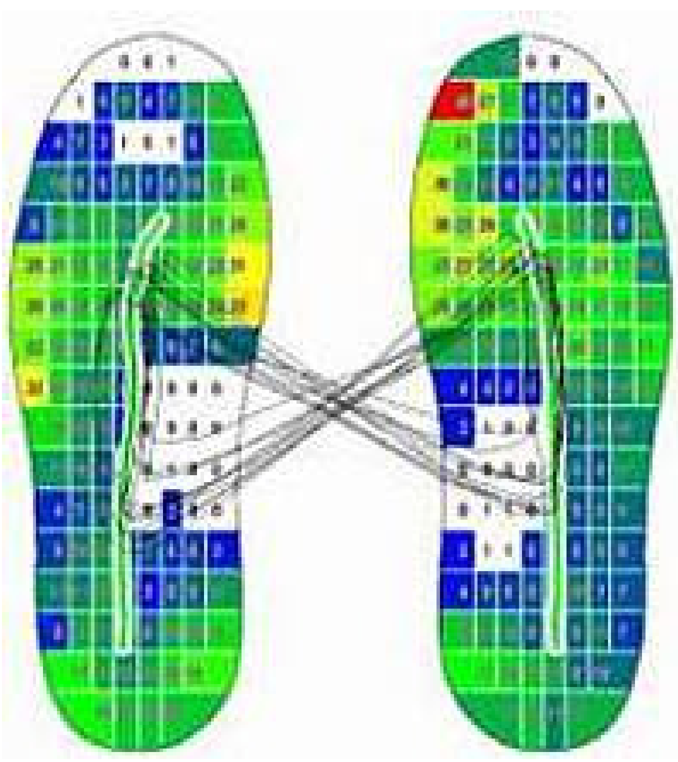


Figure 1: Cyclogram depicting gait symmetry and foot pressure mapping

The cyclogram along with objective information on step length, stride length, stride width, step time, stride time, stride speed, single limb support provides important information about asymmetries between the right and left sides. Thus, to compare the operated limb to the non-operated limb, analysis of these gait variables is required. Duration, which is a time reference, is the interval between two sequential initial floor contacts by the same limb (stride time). An example of an asymmetrical gait pattern noted by differences in the operated and non-operated limb is seen in Figure 2.

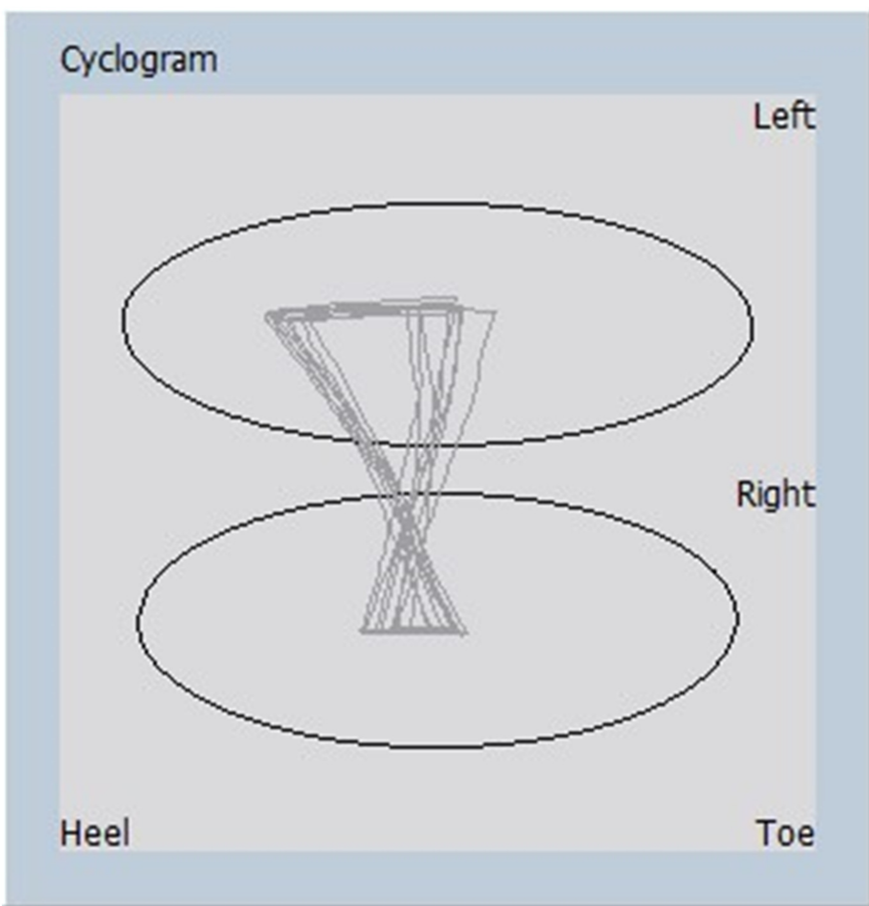


Figure 2: Cyclogram of patient during an early walk following a Right TKA

A resulting shift in the center of gravity away from the operated side, as noted by the 'X' closer to the operated limb in the Cyclogram, can result in balance deficits that may lead to falls or inefficient gait patterns.

Gait Speed following TKA. While improvement in walking during inpatient rehabilitation is important and predictable, understanding the existence of asymmetries between the operated and non-operated leg can lead to improved gait training strategies in physical therapy. Gait normalizes when step length and step time are even. The center of gravity during walking improves when step length is equal (Figure 3).

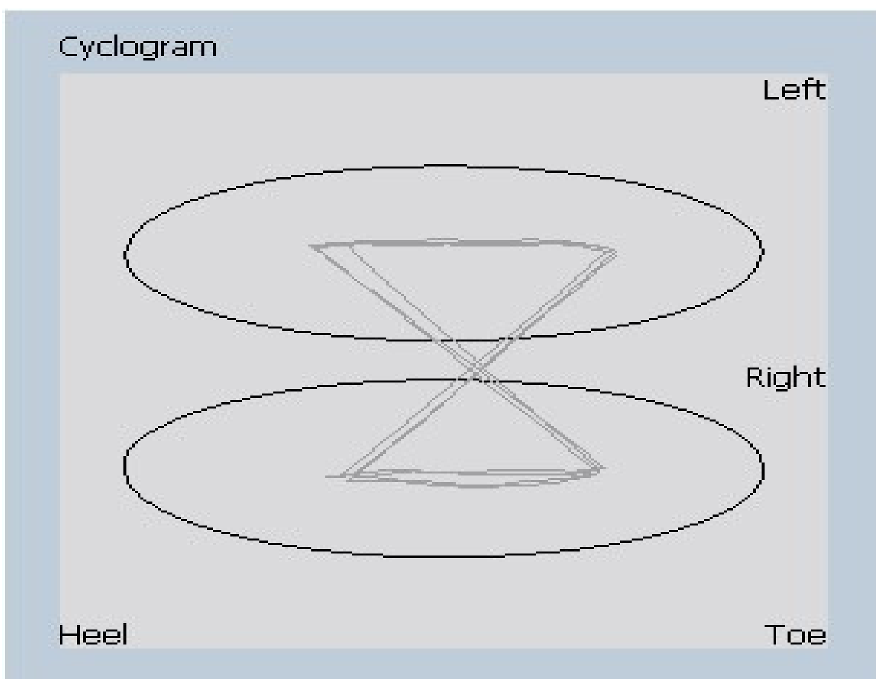


Figure 3: Improvement in Cyclogram with improved gait symmetry

Lee et al[15] reported that after TKA surgery, patients took shorter steps, had a wider base of support, and a shorter gait cycle compared with control persons. Despite post-operative literature that 6 months after surgery most healing is completed, Lee et al provide evidence of persistent gait deficits that could affect function. In a similar study, Casartelli et al[33] obtained gait variables from patients 6 months following TKA and were compared with those of age-matched healthy controls. Casartelli et al used an electronic walkway, called the GAITRite, to assess gait during normal (self-selected) walking speed and fast-paced walking. The results showed that 6 months after a TKA, persons walked slower than controls at both normal and fast-paced walking. The mean normal walking speed 6 months' post-surgery was 123 cm/sec while the mean fast walking speed was 160 cm/sec. Both were slower than the normal pace achieved by control persons who walked an average speed of 140 cm/sec and a fast speed at 185 cm/sec. When comparing the involved side of the TKA patient with the limb of a control person, the TKA patient had shorter single-limb support time than both sides of the control person during normal-paced walking. The post-surgical patients spend on average 37% of the gait cycle in single limb support (SLS) compared to 39% of the gait cycle achieved by the control persons during normal walking. During fast-paced walking, the involved side of the TKA patients showed deficits when compared with either side of the control persons. But the difference between the post-surgical patients and the controls was less. At fast speed the post-surgical patients spent 39% of the gait cycle in SLS compared to the controls who spent

40%. Regarding stance time, Casartelli et al showed that the uninvolved limb of TKA patients had a longer stance time (62%) than either side of the control (60%). The average stance time as a percentage of the gait cycle was 70% on the involved limb at discharge which is longer than the patients 6-months after surgery. Casartelli et al's last finding was that following a TKA, patients walked slower than controls at both normal and fast speeds. Chen et al[10] and McClelland et al[51] found similar results. After knee replacement, patients had a slower velocity, shorter stride length, and less cadence compared with controls that did not have surgery. McClelland et al quantified the stride length for the post-surgical TKA patients who achieved an average stride length of 121 cm. This is shorter than normal controls who achieve a 125-cm stride length. Chen et al also showed that post-surgical TKA patients had shorter swing and longer stance phases in gait. Prior studies compared patients who had a TKA with control persons matched for sex, age, body mass, and height. In addition to differences noted in temporal and spatial gait variables, knee range of motion was also reduced in patients following TKA compared with their age-matched controls.[52] Reduced knee range of motion was previously identified as a risk for post-operative falls in patients following TKA.[95, 96] Despite the depth of work in this area, no prior investigators compared the involved limb with the uninvolved limb in patients following TKA in a post-acute setting. Such a comparison would have identified if imbalances between the two limbs existed in patients following TKA.

Meaningful change in gait speed has been established at 0.10-0.17 m/s for usual walking pace and is modifiable with physical therapy.[97] This MCID was established using patients with orthopedic conditions (hip fracture) and patients with neurological conditions such as multiple sclerosis and after stroke.[97] An improvement of 0.1 m/s in gait speed during post-acute rehabilitation care was associated with twice the likelihood of being discharged to the community, and a 42% increased likelihood of living in the community at 6 months' post discharge.[69] An increase in walking speed is associated with reduced mortality[68] and hospitalization.[57] Despite the opinion that gait speed is considered the sixth vital sign[24], it is not a standardized post-acute measure included on the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRFPAI). Prior studies conducted in rehabilitation and community settings identified gait speed as a predictor of mortality, poor quality of life, physical and cognitive functional decline and falls.[25, 26] Gait speed has also been used to classify household vs. community walkers among the elderly.[28] Compared to the Timed Up and Go, which is commonly used to predict falls in the elderly, gait speed demonstrates improved predictive value for falls and other outcomes when used in an outpatient setting.[98] For older adults' gait speed of 0.8 m/sec or lower was defined as a pathological gait.[29] Although gait speed as an assessment of the geriatric client has been established[30] and reference values have been published,[65] little information is available specifically for those immediately following TKA. If gait speed norms were available for those following TKA clinicians would be able to compare patient progress and determine a slower than normal recovery. This information could lead to more specific gait training interventions to minimize these deficits before they become chronic. Criteria, such as MCID specifically following TKA, would help interpret changes in scores at the individual level. This type of information will help a clinician decide whether the current treatment is effective or whether a new intervention is warranted. Gait speed may also be helpful for establishing norms for the use of assistive devices during the first few weeks of rehabilitation. To date, no study has used gait speed in the evaluation of an assistive ambulation device or the readiness to progress from a walker to a cane. This may be an effective way to reduce gait deficits and minimize falls risk during the early phases of recovery.

Gait deficits and fall risk following TKA. Following TKA gait assessments have been used to evaluate trajectory of recovery and identify deficits that may persist after the surgery. Measures such as gait speed, stride length, time spend in double limb support and arcs of motion of the hip, knee and ankle have frequently been cited in the literature. Compared to age-matched controls without knee pathology, patients 3 years after TKA still exhibited deficits in kinematic, kinetic, and spatiotemporal variables such as longer double-limb stance and prolonged cycle times.[32] Gait analysis of the involved limb compared to non-operative limb after TKA identified a shorter step length and decreased cadence in the involved limb.[10] Casartelli, Item-Glatthorn, Bizzini, Leunig and Maffiuletti comparing TKA patients six month post-surgery to age matched controls and showed that the TKA patients walked slower. The uninvolved side of the TKA demonstrated longer stance time and shorter step length than controls as well.[33] Using a three-dimensional motion analyses to measure gait parameters, decreased hip adduction and increased toe-out on the side of arthroplasty after TKA surgery were found by Tazawa, Sohmiya, Wada, Defi and Shirakura.[34] Mandeville, David-Osternig, Louis, Chou and Li-Shan found that post-surgical TKA patients remain significantly slower with stride length significantly shorter at both 2 weeks and 6 months post-surgery compared to age–matched controls.[35] Although walking function improved post-operatively as evident by the increase in step and stride length; deficits compared to age-matched controls exist for years following TKA.[33] Although no information was available regarding the years of symptoms before undergoing a TKA, Andriacchi et al suggest post-operative gait deficits may be related to a learned preoperative abnormal pattern that gradually develops with the progression of the disease.[36, 37] Despite these useful studies about gait following TKA, none were performed in an inpatient rehabilitation setting during the early rehabilitation phase when gait training and the selection of an assistive device are important for reducing post-operative gait deviation and establishing a stable, symmetrical gait pattern.

Gait deficits after TKA ultimately result in shorter step length, decreased cadence and speed and increased double-limb support which can persist for years.[9, 10] In addition to these gait deficiencies knee flexion excursion is decreased in the operated knee after TKA compared to healthy controls of similar age.[52] The reduction of knee flexion could be a compensatory strategy to minimize pain. These abnormal gait patterns after TKA may accelerate damage and deterioration to the prosthetic device as well as contribute to increased falls and the need for an assistive device following TKA. Specific to falls following TKA; a prospective, observational study by Swinkels, Newman and Allain reported that 46% of patients who fell preoperatively also fell after surgery within the first year.[99] A six month prospective study of elderly subjects who underwent TKA revealed a fall incidence of 32.9%, higher than that in the elderly population in general.[95] Although post-operative falls rate is lower than the preoperative fall rate of 48%, the results reveal a higher risk of falls following TKA compared with healthy elderly people. In addition, too wide or too narrow step width is associated with falls in older persons.[11] Falls tend to occur more frequently soon after discharge from acute care hospitals, with 24.1% occurring within the first week and 51.8% within the first month.[92] In addition patients who fell pre-operatively had an 8-fold increase in risk of a post-operative fall.[99] Post-operative range of motion of the knee and ankle plantar flexion[95] and knee muscle strength[96] were determined to be clinical risk factors for falls; whereas age, living alone and psychiatric disease were demographic findings associated with surgery-related falls.[92] Despite the strong association of gait speed to predict adverse outcomes, such as falls in the elderly,[100] its use has not been reported in early post-operative TKA patients.

Self-assessment to measure confidence in walking. There are many self-assessment tools that have been used to assess quality of life after TKA.

These include the previously discussed WOMAC and KOOS Scales. Although these tools assess a person's ability to perform activities of daily living as well as levels of pain and stiffness, they do not address confidence and the sense of security performing functional activities such as walking. Perceived ability and confidence play an important role in determining functional independence. Persons using an assistive device have reported improved confidence and feelings of safety, resulting in increased activity levels and independence. Assessment tools are available to assess confidence with walking and may be useful in the prescription of a walking aid. The Gait Efficacy Scale (GES) was developed to assess an individual's self-efficacy in walking tasks.[31] Confidence and expectations may precede walking performance and influence when, where and how walking occurs.[101] Recently a modified version of this tool was developed to include items more commonly encountered in everyday walking. The new scale removed less frequently used items, such as escalators, and replaced them with more frequently encountered situations, such as walking outdoors on grass, curbs and climbing stairs. This more useful scale, the Modified Gait Efficacy Scale (mGES), is a 10-item measure that assesses older adults' perception of their walking confidence during challenging circumstances. The mGES demonstrated test-retest reliability and the standard error of the mean (SEM) of the tool was 5.23 points. The mGES was also correlated to measures of confidence and fear, function and disability and performance-based mobility as a measure of concurrent validity in community-dwelling older adults.[18] In addition its use was associated with the Rating of Perceived Exertion (RPE) when used with adults over 65 years of age.[31] The addition of a self-assessment scale, such as the mGES to measure confidence in walking, may correlate with gait speed and, thus, useful in predicting important outcomes such as readiness for a cane or discharge home.

Problem

Abnormal spatial and temporal gait patterns following TKA often persist for years following surgery. Numerous studies highlight post-surgical deficiencies in step length, step duration, time in double limb support and gait speed. These studies were conducted between six months and two years following surgery. Since we were unable to assess gait prior to surgery it is not possible to determine the impact of years of discomfort on early post-operative gait patterns. The antalgic gait pattern observed following surgery is likely due to post-operative pain but may also be impacted by the persistence of a pre-operative abnormal gait. Thus, analyzing gait during early post-operative rehabilitation following TKA may provide some insight into early, potentially modifiable, patterns resulting in an improved outcome.

Although visual gait assessments are a part of the physical therapy assessment in inpatient rehabilitation following TKA, rarely is a comprehensive gait analysis assessment used to quantify deficits in step length, stride length, stride width, step time, stride time, stride speed, single limb support after TKA. During an investigation of the benefit of having a portable gait analysis tool at

Burke Rehabilitation Hospital, all patients following TKA were routinely assessed on the ZenoWalkway. The gait analysis data from the ZenoWalkway provided information on the early recovery process following TKA which is missing from the current literature. Understanding the trajectory of recovery from immediately following surgery will help identify those patient that vary from the norm so that treatment interventions could be altered and outcomes improved.

Physical therapists often change a patient's ambulation device as part of their rehabilitation progression. For example, patients usually start with a more supportive and restrictive device, such as a walker, and transition to a less supportive or restrictive device like a cane. Besides the general guidelines of no more than minimal support for balance to successfully use a cane there is limited criteria for the timing of this transition. It may be possible to use gait speed as a criterion for the safe transition of a patient from one assistive device to another after TKA. Indoor ambulation with a straight cane or no device is the discharge goal from an IRF setting following TKA and is achieved about 90% of the time[16]; but the device used for outdoor community ambulation is not known. Information about gait speed may provide insight during rehabilitation regarding the readiness and safe use of the specific ambulation device.

There are many performance measures used in rehabilitation settings to assess walking. These include the FIM, the TUG, 50-foot timed test and the six-minute walk test. Although clinicians use these measures to assess function and improvement, they often do not assess a patient's confidence or readiness to perform a task such as community walking. Perceived confidence in walking may be a factor in what a person does versus what he or she is able to do. In addition to gait variables that can provide insight into the use of assistive device and discharge disposition, individuals' walking speed might be impacted by their walking confidence. The Modified Gait Efficacy Scale (mGES) has been used to assess older adults' perception of their level of confidence with walking during challenging circumstances such as walking over obstacles, on uneven surfaces and up and down stairs.[18] Using a reliable and valid tool, such as the mGES, may correlate with information found in performance-based measures.

Study goals

The goal of this study is to analyze the gait patterns of patients following single and bilateral TKA who have been admitted to an IRF. Gait assessments were conducted at admission and the day before discharge using the ProtoKinetics Zeno walkway (PKMAS) following the manufacturer's guideline for clinical application facilitated consistent protocol for the gait assessment.[102] Gait variables were compared between admission and discharge to better understand which variables improved during this relatively short LOS. In addition, using the uninvolved limb of single knee subjects as a control, mean differences in step length, stride length, stride width, step time, stride time, stride speed, single limb support between the involved vs. uninvolved limb were compared.

Using predictive modeling, this study evaluated initial gait speed to determine its ability to predict LOS, discharge disposition and ambulation device at discharge. Discharge gait speed was also analyzed to determine differences between those who are discharged with a walker or bilateral canes compared to those discharged using a cane or no device. The additional analysis of gait speed to determine a cut off speed that is associated with the ability to transition to a cane (one-handed device) from a walker (two-handed device) was established. In a subset of patients, gait speed was correlated to the patient reported mGES scale. The assessments taken at admission and discharge was compared to the corresponding mGES scores. Measuring gait speed, along with a patient reported confidence measured by the mGES in a clinical setting provided useful information in helping make evidence-based decisions regarding optimal treatment and selection of an assistive device for patients following total knee replacement surgery. Identifying discrepancies between the operated limb and the non-operated limb during the discharge gait assessment provides information about abnormal gait variable that still exist after inpatient rehabilitation that will require continued focus if further rehabilitation is obtain in an outpatient setting.

Summary

This study identified gait measures and other clinical variables that can be used to predict the ambulation device needed by patients at discharge following TKA, as well as LOS and discharge disposition from an IRF. With the goal of discharging all patients back to the community walking with either a cane or no device, this study provides physical therapists with valuable information to predict these important outcomes. The establishment of cut off values for different ambulation devices should improve the safety of the discharge recommendations. This study also investigates how well the patient's own perception of their walking ability correlates with the objective gait measures of gait speed. In addition, comparing step length, stride length, step width, step and stance time and time in single-limb support of involved and uninvolved (control) lower extremity will help clinicians select interventions and provide concrete feedback designed to improve walking and improving gait symmetry. Establishing a trajectory of improvements in gait variables from admission to discharge provide a baseline for future studies that attempt to improve walking following TKA.

Chapter 3

Methodology

Introduction

The purpose of this chapter is to discuss the method used in this study to understand early post-operative outcomes, such as gait deviations, need for ambulation device and rehabilitation length of stay, for persons after total knee arthroplasty who receive inpatient rehabilitation. Details on the study design, study subjects, data collection, procedures and data analysis are described. A gait analysis was performed at the initiation and conclusion of the inpatient rehabilitation stay for patients following TKA. A comparison of the improvement from admission to discharge is summarized. For those who had a single knee arthroplasty, a comparison of gait findings between the involved (operated) limb and uninvolved limb are made from the discharge gait assessment to determine any residual deficits still present at discharge. For the bilateral TKA subjects' right verses left comparison show improvements made at discharge. This study used both logistic regression and multiple linear regression analysis to evaluate the predictive power of gait speed, initial FIM scores, knee range of motion, age, gender and BMI, and prior need for an ambulation device on LOS, discharge ambulation device and discharge destination. The study also evaluated the relationship between gait speed and the patients' own confidence with walking using a relatively new patient assessment tool called the mGES.

Research Methods

Study Design. Approval from the Burke Rehabilitation Hospital and Nova Southeastern University's Institutional Review Board (IRB) was obtained prior to the start of the study. For subjects completing the modified Gait Efficacy Scale (mGES) informed consent was obtained.

This study utilized a retrospective chart review among a cohort of patients following TKA who were transferred from an acute care hospital, where the TKA procedure was performed, to an inpatient rehabilitation facility (IRF) for post-acute rehabilitation. It was carried out in a 150 bed IRF in White Plains, NY using patients admitted during 2015. The rehabilitation program is designed to transition patients from the acute care hospital immediately following surgery to home. The focus on functional rehabilitation provides a therapeutic environment to practice activities of daily living and community based locomotion preparing patients to return home at their highest functional level. This post-acute service is goal oriented and time limited providing 24-hour medical supervision with intensive physical and occupational therapy complemented by a rehabilitation nursing program. The objective of the IRF stay is to maximize functional recovery and independence prior to returning to the community or to the least restrictive setting. An IRF is commonly used for inpatient rehabilitation following a TKA. For example, in 2014 this facility treated over 300 patients following a single or bilateral TKA. The average age was 71. Ninety-three percent returned home immediately following a 9.3-day average length of stay.

Study Subjects. This study included 230 patients admitted to Burke Rehabilitation Hospital following TKA between January 1, 2015 and December 15, 2015. All patients were transferred within ten days following surgery from an acute care hospital following either a bilateral or single knee replacement. The need for post-acute rehabilitation was determined by the acute facility and was based on the patient's functional progress and medical needs following surgery. To qualify for inclusion in this study the patients meet the following criteria: (1) had undergone a TKA and were admitted to the Burke IRF within 10 days of their surgery; (2) were between the ages of 40 to 85 years of age; and (3) had a gait analysis as part of the admission assessment. Patients were excluded if (1) the TKA was a revision or unicondylar procedure; (2) they had comorbid conditions, such as a stroke or other neurological condition, any major orthopedic abnormality, or a psychological/psychiatric condition that would interfere with the rehabilitation plan, and (3) did not meet the inclusion criteria.

Data Collection. Gait speed was measured using the Zeno Electronic Walkway. This 2 x 16 feet Walkway with 18432 pressures sensing cells (ZenoMetrics LLC, Peekskill, NY), using the ProtoKinetics LLC, Havertown, PA software (PKMAS) to conduct the gait assessment. All other variables, such as FIM score, range of motion values, prior living situation, prior use of an ambulation device, were abstracted from the facility's electronic medical record (EMR) and were collected as part of routine care. This non-experimental, observational cohort utilized a convenience sample of patients who have had a TKA and required an IRF level of care for rehabilitation. Demographic information such as age, gender, race, body mass index and prior ambulation status are summarized.

A comprehensive assessment using the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRFPAI) was completed for each patient as routine procedure (Appendix E). The IRFPAI contains patient demographic information, diagnosis and comorbid medical conditions as well as a comprehensive functional assessment called the Functional Independence Measure (FIM). The medical team used items in the FIM to assess functional activities of daily living as well as cognition and communication status. All therapists and nurses at Burke were educated in the scoring of the FIM items. The training was conducted by the facilities Prospective Payment System (PPS) coordinator. This training is repeated annually. Burdens of care for each item is assessed on a scale from 1 to 7 denoting the amount of help needed for each activity (Appendix D). Higher scores indicate higher level of independence, with a score of 7 indicating complete independence. Lower scores reveal the need for more caregiver assistance. A score of 1 indicating most of the assistance to complete an activity is provided by the caregiver while the subject performs less than 25% of the skill. The FIM portion of the IRFPAI was completed on admission and discharge. The admission assessment may include a score of a “0” for functional items not performed within the initial three-day assessment period. All items contained in the IRFPAI, as well as a complete physical and occupational therapy evaluation, were entered into the facility’s EMR called Medilinks™.

The gait assessment was conducted on the Zeno™ walkway and analyzed using the PKMAS software. Following the analysis key gait parameters, step length, stride length, gait speed and cadence were entered into the Medilinks EMR. All other gait variables, including stride width, step time, stride time, stride speed, single limb support, were maintained in the Zeno Walkway software in a secure laptop.

All patients admitted on or after September 8th completed a Modified Gait Efficiency Scale (mGES). This self-assessment tool quantified each patient confidence during walking. The mGES was completed immediately prior to the patient’s initial and discharge gait assessment.

Procedures

On the day of admission all patients admitted for rehabilitation following a TKA received a physical examination by a member of the medical staff at Burke Rehabilitation Hospital as well as a nursing assessment. One of the orthopedic physical therapy staff conducted an introductory session informing the patient of the therapy schedule and daily program that would commence the following day.

On the second day after admission all patients participated in two therapy sessions in the AM; one with a physical therapist and the other with an occupational therapist. In addition to the physical and occupational therapy session on the second day, each patient had an initial gait assessment on the Zeno Walkway. The PM therapy program included two additional therapy sessions; one PT and the other OT. The total therapy time per day was 3 hours for each participating patient.

During the therapy evaluations patients were assessed in several domains: self-care, sphincter control, transfers, locomotion, communication, and social cognition. Scores in each of these areas were based on the patient's need for assistance and were entered into the facility's EMR as part of the IRFPAI as the FIM scores. All scores were obtained during the first three days of admission and involved staff from physical and occupational therapy and nursing.

During the gait assessment, each patient wore street clothes or sweatpants and soft sole shoes such as sneakers. The assessment included two walks along the 14-foot pressure sensory Zeno walkway. The patients began the walk at the start of the walkway. Once the patient walked the complete length of the walkway that completed the test; a second walk was initiated from the opposite end of the walkway. The two walks were combined and averaged into one assessment. During the assessment patients used the assistive device assigned to them by their primary PT. All of patients used a rolling walker for their first gait assessment.

During the gait assessment on the Zeno Walkway the PT aided and guarded the patient when needed.

In addition to the gait assessment, outcome measures of physical function were also assessed during the initial assessment. This included ROM, pain level, and strength. Knee ROM was measured using a standard 2-arm plastic goniometer, with the axis of the goniometer placed over the lateral epicondyle of the femur, the proximal arm aligned with the greater trochanter of the femur, and the distal arm aligned with the lateral malleolus of the ankle. Active knee flexion and extension were performed and measured in the supine position. The PT asked the patient for a self-assessment of their pain at rest and during activity. A numeric rating scale was used to quantify knee pain. Quadriceps strength was measured from a sitting position. The patient was asked to extend his/her knee. Manual resistance was applied only if the patient achieved full extension with strength documented using a 0/5 to 5/5 scale.

During the weekly team conference, patient status was discussed and the discharge setting and date were determined by the orthopedic team. This meeting was attended by the clinical staff working with each patient and led by the patient's primary physician. Input from nursing, therapy and social work helped determine the appropriate discharge plan and this information was shared with the patient and his/her family by the social work staff.

The day before discharge the patient was re-evaluated to determine their progress and improvement. All eighteen FIM items were reassessed by the appropriate staff member and enter into the EMR. When possible, a final gait assessment was repeated by the PT and the results were shared with the patient and entered into the facility's EMR.

For the last 56 patients who were admitted on or after September 8, 2015, the mGES self-assessment was given immediately prior to the patient's admission and discharge gait analysis and scores were entered the EMR.

Data Analysis. This study used descriptive summaries, differences in means, correlations and regression analysis to study gait findings and outcomes of patients receiving inpatient rehabilitation following single or bilateral TKA. Secondary data analysis of variables collected as part of routine care from patients admitted to an inpatient rehabilitation facility was used.

All data was analyzed using the IBM Statistical Package for the Social Sciences (SPSS) Version 24. All statistical tests were non-directional, and $p < 0.05$. Categorical variables (gender, ambulation device, and discharge disposition) were dummy coded into numeric values for ease of analysis. The discharge ambulation device categories were recoded in SPSS into a dichotomous variable. One group for patients needing a one-handed device such as a cane or no device and the second group included persons who used a two-handed device such as bilateral canes or a walker at discharge. Discharge disposition was also dichotomized into those discharged to home/community verses those discharged to a SNF or other institutional care setting.

Descriptive statistics, including mean and standard deviation, were reported for continuous data, and number and percentage of participants for categorical data for the total sample or by subgroup such as bilateral or unilateral. Depending on distribution and type of variable, parametric or nonparametric statistics were used to examine correlations or compare means. An independent *t*-test or non-parametric equivalent was performed to determine differences in age, BMI, initial motor, cognitive and total FIM scores, initial velocity and cadence between patients who had a single and bilateral procedure. A chi-square for nominal data evaluated gender differences between groups. Since differences did not exist in gender, BMI, initial FIM scores, initial gait velocity or cadence between patients who had a unilateral compared to a bilateral total knee arthroplasty the full sample was used for both the logistic and linear regressions.

To address question 1 and 2 a paired *t*-test was performed to compare admission and discharge gait data on each patient who had a single TKA. Analysis of step length, stride length, stride width, step time, stride time, stride speed, single limb support was compared for side (involved vs. non-involved) and time (admission vs. discharge). For patients who had one knee replaced the analysis compared the operated limb with the non-operated limb. For patients following a bilateral procedure the analysis compared the right knee with the left knee.

Question 3 was addressed using a binary logistic regression. To investigate the impact of initial gait speed, patient age, gender, BMI, and prior use of an ambulation device (independent variables) on the use of an assistive device (dependent variable) at discharge a logistic regression was conducted. At the time of discharge all patients were categorized into one of four ambulation device categories: no device, a single cane, bilateral canes and a rolling walker. To address question 3 using a logistic regression the use of an assistive device at discharge was recoded as a binary variable. When no device or a one-handed device, such as a cane, was used it was coded as a "1"; and a two-handed device such as bilateral canes or a walker was needed it was coded as a "2". These categories were based on the frequently used progression following a total knee arthroplasty and the patients' stability and balance requirements. To avoid multi-collinearity, we ran the collinearity statistic for the main variables and reported the Tolerance and VIF statistic. The Enter method, whereby all the predictors were entered simultaneously, was employed. The Wald statistic assessed whether a predictor variable significantly contributes to the variance in the categorical outcome. The regression co-efficient for each significant predictor variable was reported and the overall model compared the baseline status before the predictor variable was entered. Those variables with significant Exp(B) were used to establish a parsimonious model using the most important variable to predict the outcome of the discharge ambulation device. A Hosmer-Lemeshow assessed how well the model fits the data. An odds ratio (OR) measured the association between an exposure and an outcome. The OR represents the odds that an outcome will occur give an exposure, compared to the odds that the outcome occurring in the absence of that exposure. When a logistic regression is calculated the Exp (B) is the estimated increase in the log odds of the outcome per unit increase in the value of the exposure. An odds ratio (OR) equal to 1 means the exposure does not affect the odds of outcome; when the OR is greater than one the exposure is associated with higher odds of the outcome; and an OR less than one indicates the exposure is associated with a lower odd of the outcome. The 95% confidence interval (CI) was used to estimate the precision of the OR.[103] Nagelkerke's R^2 estimated how much variance in the outcome is explained by the predictor variables.

To determine the usefulness of the gait speed for ambulation device decision making and a potential cutoff score for recommending a cane (one-handed device) over a walker or two-canes (two-handed device) at discharge, we developed a receiver operating characteristic (ROC) curve using discharge gait speed. In an ROC analysis, the sensitivity and 1-specificity were calculated to establish a possible cutoff point on a scale. These values were then plotted with sensitivity on the y-axis and 1-specificity on the x-axis. The ROC analysis allowed us to define the best cutoff score for determining cane or no device for walking at discharge based on the highest sensitivity and specificity associated with gait speed. We also calculated positive and negative predictive values on the total sample. Model calibration for the gait speed value was examined with the Hosmer-Lemeshow goodness-of-fit test.

All continuous data are expressed in terms of mean ± SD and categorical variables are expressed as proportions or percentages to answer question 4. The Kolmogorov Smirnov test was performed to test normality of continuous variables. The correlation tests were conducted between the variables collected (gait speed, initial motor, initial cognitive and total FIM scores, knee flexion and knee extension range of motion) and the IRF length of stay using Spearman Rank Correlation. The variables that had a significant correlation with the IRF length of stay were utilized to perform the multivariate analysis. Once the three variable that were correlated with IRF length of stay were identified a multiple linear regression was used to develop a model for predicting rehabilitation LOS (dependent) from initial gait speed, motor FIM scores and the patient's initial active knee extension ROM. The multivariate analysis was performed by the General Linear Model having the fixed effects of LOS and the covariates as a mixture of the continuous predictor variables. For all tests $p < 0.05$ was considered significant.

Correlations amongst the predictor variables were analyzed for multi-collinearity to ensure there is not a problem before performing with the regression. Since no *a priori* hypothesis had been made to determine the order of entry of the predictor variables, a direct method is used for the multiple linear regression analysis. The lists of predictive variables were entered to determine the contribution of each to the variance in LOS. The independent variables include initial gait speed, motor and cognitive FIM scores and initial active knee flexion and extension ROM. Basic descriptive statistics and regression coefficients were reported using $p < 0.05$ to determine the predictors. The predictors with the lowest non-significant regression coefficients were removed and additional regressions analysis was conducted until a final regression includes only those predictors that contribute to the explained variance in the LOS. An adjusted R-squared was reported in the final model with a confidence interval to account for the percent of variance in LOS explained by the predictor variables. The strength of each predictor is provided in a table.

Prior to performing the linear regression four key assumptions were tested to reduce the chance of creating a Type I or Type II error. These tests included assessing that the variables are normally distributed; a linear relationship between the independent and dependent variables; an assessment of collinearity between the independent variables and a level of autocorrelation in the data. To ensure a sufficient sample size we evaluated the number of cases per independent variable. We used seven predictors so, using the guidance from Tabachnick and Fidell[104], our total sample of 230 patients is sufficient to adequately assess these predictors. The formula used to ensure a large enough sample size is: $N \geq 50 + 8m$ (where m is the number of predictors and N as the sample size.

Since the mGES is an ordinal scale, a Spearman's rank correlation was used to establish the relationship between gait speed and the mGES for both the initial and discharge gait assessment to answer the final question. An r value was reported using $p < 0.05$ as a cut off for significance of the relationship between the two variables. To evaluate whether there is an improvement in the patient's walking confidence between admission and discharge the Wilcoxon signed ranks was used to compare pre-and post mGES scores. The median difference in the scores was reported using $p < 0.05$ as a cut off.

Formats for presenting results

The results of this study are presented in a variety of formats. Subject characteristics are described in the text with a summary of the important demographic and clinical finding provided in a table. A comparison between subjects who had a single TKA compared to a bilateral procedure is presented in a Table highlighting variables such age, gender, BMI, as well as initial clinical outcomes such as gait speed, cadence, and FIM scores.

The results of the paired *t*-test comparing the clinical and demographic variables for subjects who had a single versus bilateral TKA are presented in a Table format. Measures of central tendency for demographic characteristics as well as results of comparison statistics (repeated measures ANOVA or Wilcoxon signed ranks tests) are presented in a Table and described in the narrative. Based on the assessment of normality parametric or non-parametric statistics are used as appropriate. Confidence intervals are included as appropriate.

The results of the multivariate regression are described in the text of the results section. For the multiple linear regressions, the adjusted R squared was reported for the goodness of fit assessment. For the logistic regression related to the dichotomous outcome of use of a cane/no device to walker/bilateral canes are reported as an odds ratio.

The raw data showing the correlation between the initial gait speed and the initial patient reported mGES score and the discharge gait speed and the patient reported mGES is presented in Figures using scatter plot diagrams. The findings from the Wilcoxon signed ranks comparing pre/post mGES scores is described in the text of the results.

Psychometric Properties of the Tests and Measures

Inter-rater and intra-rater reliability was not assessed for the gait assessment tool utilized in this study because the assessment was conducted by only one person, the principle investigator. Currently, sufficient literature exists documenting excellent test-retest, inter-rater, intra-assessment reliability and predictive validity for each functional outcome measure utilized in this study. Table 1 provides a summary of the psychometric properties obtained from the literature for each functional outcome measure.

Table 1. Psychometric Properties of Variables

Outcome Measure	Clinometric Property	Measurement	Population
Gait Speed[65]	Test-retest Reliability	ICC = .93 & .97	Healthy older adults
Comfortable Gait Speed[105]	Test-retest Reliability	ICC = .97	Community ambulators
Comfortable Gait Speed[106]	Inter-walk distance Reliability	r = .933	Noninstitutional adults
Comfortable Gait Speed[107]	Test-retest Reliability	ICC = .92	Parkinson's Disease
Usual Gait Speed[2]	Predictive Validity	RR = 2.20, 95% CI 1.7-2.74	Older persons
Gait Speed[100]	Predictive of hospitalization	RR = 5.9, 95% CI 1.9-8.5	Well-functioning adults >75 yrs
FIM[22]	Inter-rater Reliability	ICC = .96	Clinician in IRF settings
mGES[18]	Test-retest Reliability	ICC = .93	Community dwelling adults
PKmas vs GAITRite[63]	Inter-program reliability	ICC = .99	Health older adults & adults' s/p hip fracture

Gait Speed – is a quick, inexpensive, reliable measure of functional capacity with well-documented predictive value for health-related outcomes, falls, and discharge destination. Bohannon found excellent test- retest reliability for comfortable and fastest gait speeds with interclass correlation coefficients ICC = 0.93 and 0.97. The article also reported healthy adults in the sixth and seventh decade of life walked at comfortable gait speeds of 1.36m/sec and 1.27 m/sec respectively.[65] Test-retest results were replicated reporting ICC = .97 in community ambulators.[105] A study by Egarton examined the level of agreement and inter-program variability between the Zeno Walkway and the GAITRite® using data from older people walking at self-selected and preferred speed. Very high levels of agreement for outcome variables indicated the walkways were interchangeable.[63]

Functional Independence Measure (FIM) - is a well-known standardized measure used to estimate the amount of assistance needed by, and the amount of effort required from the patient to perform 18 functionally related activities. This 18-item scale assesses progress during inpatient rehabilitation along two dimensions: motor (13 items) and cognitive (5 items). The FIM evaluates six areas of function: self-care, sphincter control, mobility, locomotion, communication, and social cognition. It can evaluate change among individuals with any progressive, reversible, or fixed neurological, musculoskeletal, and other disorder.

The FIM is designed to measure the burden of care associated with functional activities. FIM interrater reliability in was established by Hamilton et al. Clinicians from 89 IRF's reported FIM to Uniform Data System for Medical Rehabilitation (UDS) from January 1988-June 1990 evaluated 1018 patients with the FIM. FIM total, domain, and subscale score intraclass correlation coefficients (ICC) were calculated using ANOVA; FIM item score agreement was assessed with unweighted Kappa coefficient. Total FIM ICC was 0.96; motor domain 0.96 and cognitive domain 0.91; subscale score range: 0.89 (social cognition) to 0.94

(self-care). FIM item Kappa range: 0.53 (memory) to 0.66 (stair climbing). A subset of 24 facilities meeting UDSMR data aggregate reliability criteria had Intraclass and Kappa coefficients exceeding those for all facilities. It is concluded that the 7-level FIM is reliable when used by trained/tested inpatient medical rehabilitation clinicians.[22]

Functional outcome measurements were assessed on two occasions during the course of the study. The collection assessments for the outcome measures occurred at the onset of the admission to the IRF and on the day before discharge.

The modified Gait Efficacy Scale (mGES) – is a 10-item measure that addresses older adults' perception of their level of confidence in walking during challenging circumstances.[18] The items are scored individually on a 10-point scale, with 1 denoting no confidence, giving a total score range of 10 to 100, with 100 representing complete confidence in all tasks. In a study by Newell with older adults, the mGES demonstrated test-retest reliability within the 1-month period (ICC=.93, 95% confidence interval=.85, .97). The mGES was internally consistent across the 10 items (Cronbach α=.94). The mGES was related to measures of confidence and fear (r=.54-.88), function and disability (Late-Life Function and Disability Instrument, r=.32-.88), and performance-based mobility (r=.38-.64).[18]

Chapter 4

Results

Introduction

The chapter includes the results of this observation study investigating the gait assessments obtained from patients following total knee arthroplasty surgery who were transferred to an inpatient rehabilitation facility. The study results are presented using a combination of text, tables and figures to illustrate the findings and responds to the research questions. The chapter provides information addressing (1&2) differences in gait variables (step length, stride length, stride width, step time, stride time, stride speed, single limb support) between the operated and non-operated limb at discharge from an IRF for patient after a single TKA, as well as differences between the right and left limbs in a bilateral TKA. (3) Predicting the type of ambulation device required at discharge. (4) Predicting LOS based on initial gait speed, FIM scores and knee (flexion and extension) range of motion. (5) Determining correlation between gait speed and the patient reported mGES taken at admission and discharge in a subset of patients.

Results

Descriptive Characteristics of the Sample. The demographic characteristics of the 230 patients who were transferred to a rehabilitation facility following either a single or bilateral TKA between January 1 and December 1, 2015 are summarized in Table 2. The average age of the sample was 71 ± 8 years old with an age range between 45-89 years. The patients' average BMI was 31± 6 kg/m^2. More than half of the patients did not use an ambulation device prior to their knee replacement (59%). Prior to surgery 41% of the patients used an assistive device for outdoor ambulation. For those needing an assistive device for walking 83% used a cane, 13% used a walker, 3% used crutches and 1 patient (1%) used a quad cane. Fee for service Medicare was the predominant form of insurance.

Table 2. Descriptive Characteristics of 230 patients admitted to the IRF for rehabilitation following a TKA

Characteristics	**Level**	**N (%) or Mean ± SD**
Gender	Men	70 (30%)
	Women	160 (70%)
Race	White	198 (86%)
	Black	21 (9%)
	Hispanic/Latino	6 (3%)
	Asian	5 (2%)
Living Arrangement	Lives alone	90 (39%)
	Lives with family	134 (58%)
	Lives with friend or caregiver	6 (3%)
Prior use of device	No device	135 (59%)
	Cane	79 (34%)
	Walker	12 (5%)
	Crutches	3 (1%)
Insurance type	Medicare (Fee for service)	171 (74%)
	Medicare – Advantage	3 (1%)
	Private or another source	56 (24%)
Age	In years	70.5 ± 8.12
BMI	kg/m^2	31.3 ± 6.51
Acute LOS	In days	4.3 ± 1.52

[a] TKA: total knee arthroplasty; IRF: inpatient rehabilitation facility; BMI: body mass index; kg/m^2: kilograms per meter squared; LOS: length of stay; SD: standard deviation

All patients were transferred directly from an acute care hospital where the surgery was performed following an average acute care hospital stay of 4 days. All 230 patients had an initial gait assessment and an initial physical therapy evaluation the day after admission to the IRF, but 14 did not have a discharge gait assessment. Reasons for this included that 11 were discharged on a weekend when the gait assessment was unavailable and the for non-weekend discharges the gait therapist was not available for the remaining 3 patients.

Gait speed and cadence from the initial gait analysis as well as the motor, cognitive and total FIM scores are provided in Table 3. All data, both clinical and demographic, including was obtain from the hospital EMR from the initial assessments conducted by nursing, social work, PT and OT hospital staff within the first three days of admission.

Table 3. Initial Clinical Information about all patients, both single TKA and bilateral TKA, (N=230) obtained from the initial gait assessment and 3-day assessment period

Initial Clinical Variables	**Mean**	**SD**	**Minimum**	**Maximum**
Speed (cm/sec.) & (ft/min)	29.51 (58.1 ft/min)	13.37	4.96	60.76
Cadence (steps/min)	52.44	15.60	15.5	89.84
FIM_Motor	46.10	3.92	31.0	55.0
FIM_Cognitive	28.66	2.25	20.0	32.0
FIM_Total	74.75	5.26	53.0	87.0

[a] TKA: total knee arthroplasty; FIM: Functional Independent Measure; SD: standard deviation; cm/sec.: centimeter per second; min: minute; ft/min: feet per minute.

Comparison between patient with Unilateral and Bilateral TKA. A comparison of the patients in the single verses bilateral TKA group revealed differences in demographic and clinical variables. Persons with a unilateral TKA were older, $t_{(228)} = 7.064$, $p < .001$ (two-tailed) than those who had a bilateral TKA. The mean age of the single TKA patients was 73 years old compared to the bilateral group whose mean age was 65 years. Despite the younger age the bilateral TKA patients averaged a lower initial motor FIM score of 45, $t_{(228)} = 2.99$, $p = .003$ (two-tailed) compared to the single TKA patients who had an average motor FIM score of 47. The motor FIM scores contributed to a significant difference in lower total initial FIM score, $t_{(228)} = 2.34$, $p = .020$ between the groups. The single TKA patients' average total FIM on admission was 75 while the bilateral patients had an average total FIM score of 73. There was no difference in the cognitive scores between the groups.

Both unilateral and bilateral patients had an average acute care length of stay post-surgery of 4 days. The BMI was also similar between groups with the unilateral patients averaging 31.6 kg/m² and the bilateral at 30.4 kg/m². Initial gait speed and cadence were also similar between unilateral and bilateral patients. The unilateral patients' speed averaged 29 cm/sec and cadence averaged 54 steps/min and the bilateral group speed averaged 30 cm/sec. and cadence averaged 51 steps/min. No differences were noted in initial gait speed, gait cadence, acute length of stay, or BMI between patients who had a single or bilateral TKA. Table 4 provides a comparison between the single TKA and bilateral TKA patients and includes both demographic and initial clinical findings. Levene's test for equality of variance provided support for proceeding with the use of equal variance assumed.

Table 4. Comparison of persons with single TKA (n=170) versus bilateral TKA (n=60) pertaining to admission demographic and clinical information

Variable	Type of surgery	Mean	SD	Std. Error Difference	Mean difference (95% CI)	*p*
Age*(years)	TKA (B) TKA	72.56 64.75	7.07 8.14	1.11	5.63 to 9.99	< .001
BMI (kg/m[a])	TKA (B) TKA	31.62 30.35	6.87 5.28	.976	-.657 to 3.19	.196
Acute LOS (days)	TKA (B) TKA	4.29 4.53	1.49 1.59	.228	-.695 to .345	.285
Initial Speed (cm/sec.) & (ft/min)	TKA (B) TKA	29.28 (57.5 ft/min) 29.93 (59.7 ft/min)	13.45 14.02	2.01	-5.09 to 2.83	.575
Initial Cadence (steps/min)	TKA (B) TKA	53.59 50.92	15.30 16.39	2.34	-1.94 to 7.28	.256
Initial Motor FIM*	TKA (B) TKA	46.55 44.82	3.77 4.09	.579	.579 to 2.87	.003
Initial Cognitive FIM	TKA (B) TKA	28.68 28.58	2.33 2.03	.339	-.569 to .767	.771

[a] *indicates significant difference between groups based on an independent t-test at $p<0.05$.
[b] TKA: total knee arthroplasty; (B): bilateral; BMI – body mass index; LOS: length of stay; FIM: functional independence measure; cm: centimeter; sec: second; SD: standard deviation; CI: confidence interval; kg/m: kilograms per meter

Table 5. Frequency of Gender by Surgical Intervention				
		Impairment		Total
Gender		Single TKA	Bilateral TKA	
	Female	131	29	160
	Male	39	31	70
Total		170	60	230

[a]TKA: total knee arthroplasty

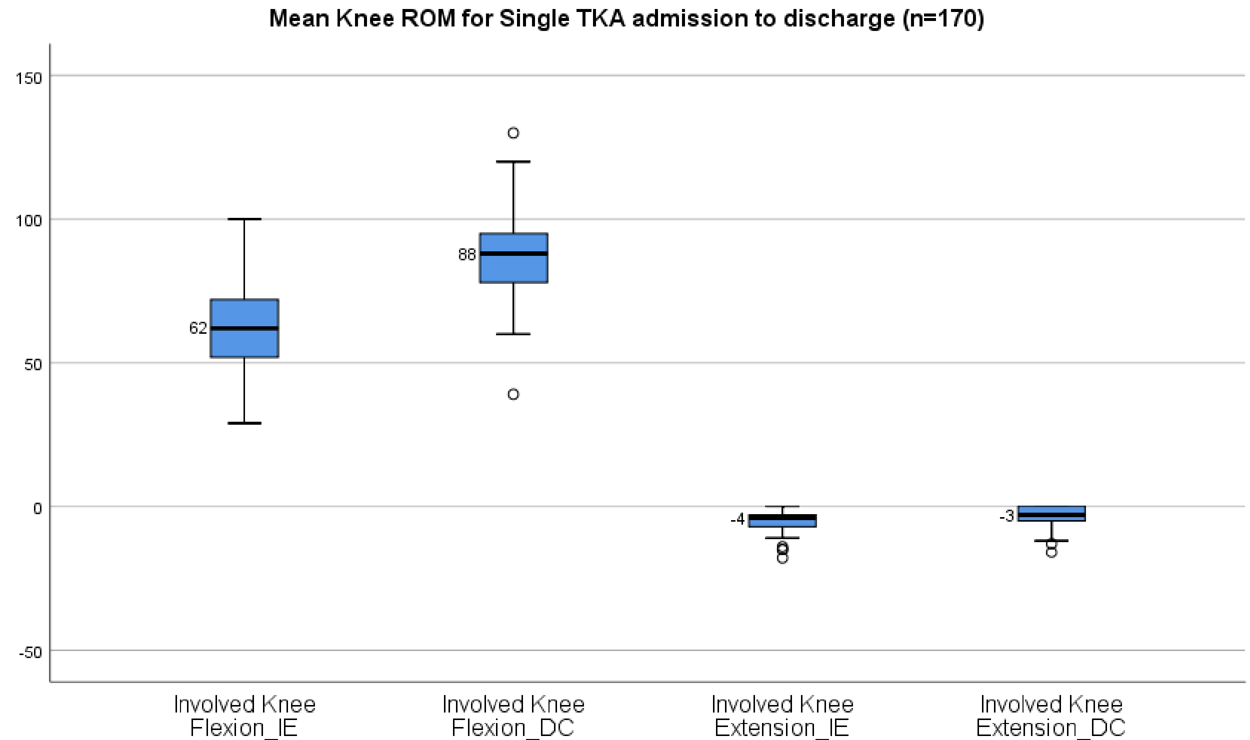
There was a larger proportion of men (52%) in the bilateral group x^2 (1, n=230) = 17.28, $p < .001$ compared to those who had a single TKA (23%). Patients who had bilateral procedures were more likely to have private insurance whereas the unilateral patient were more likely to have traditional Medicare or managed Medicare x^2(2, n=230) = 52.09, $p < .001$. See Tables 5 and 6 for details.

Table 6. Frequency of Insurance Type by Surgical Intervention				
		Impairment		
Insurance Type		Single TKA	Bilateral TKA	Total
	Medicare Fee for Service	148	23	171
	Medicare Advantage	1	2	3
	Private Insurance/Other	21	35	56
Total		170	60	230

[a]TKA: total knee arthroplasty

Change in knee range of motion and gait in patients with Single TKA. Each of the 170 patients in our sample had an initial physical therapy assessment on the day after admission. Based on this initial assessment the group had an average knee flexion range of motion of 62 ± 13 degrees and lacked an average of 4 ± 3 degrees of knee extension. Based on the findings of the discharge assessment performed on the day before discharge, single TKA patients averaged

88 ± 12 degrees of flexion and lacked 3 ± 2 degrees of knee extension. Figure 4 provides the improvement from admission to discharge for knee flexion and extension range of motion in single TKA patients.



[a] TKA – total knee arthroplasty; IE – initial evaluation; DC – discharge evaluation

Figure 4. Mean Active Flexion and extension ROM at admission versus discharge unilateral TKA

This reveals a significant improvement from initial assessment to discharge for knee flexion, $t_{(170)} = 6.84$, $p = <.001$ and knee extension, $t_{(170)} = 7.05$, $p < .001$ range of motion. The mean improvements in flexion and extension ROM for patients following a single TKA are presented in Table 7.

Table 7. Change in knee range of motion from admission to discharge among the surgical knee in persons with a unilateral knee arthroplasty (n=170)				
ROM (degrees)	Mean	SD	Std Error	Mean difference (95% CI)
DC Flexion vs IE Flexion	21.98	13.1	1.0	15.64 – 28.34
DC Extension vs IE Extension	1.7	3.2	.24	1.2 to 2.2

[a] ROM: range of motion; DC: discharge; IE: initial evaluation; SD: Standard Deviation; Std: standard; CI: confidence interval

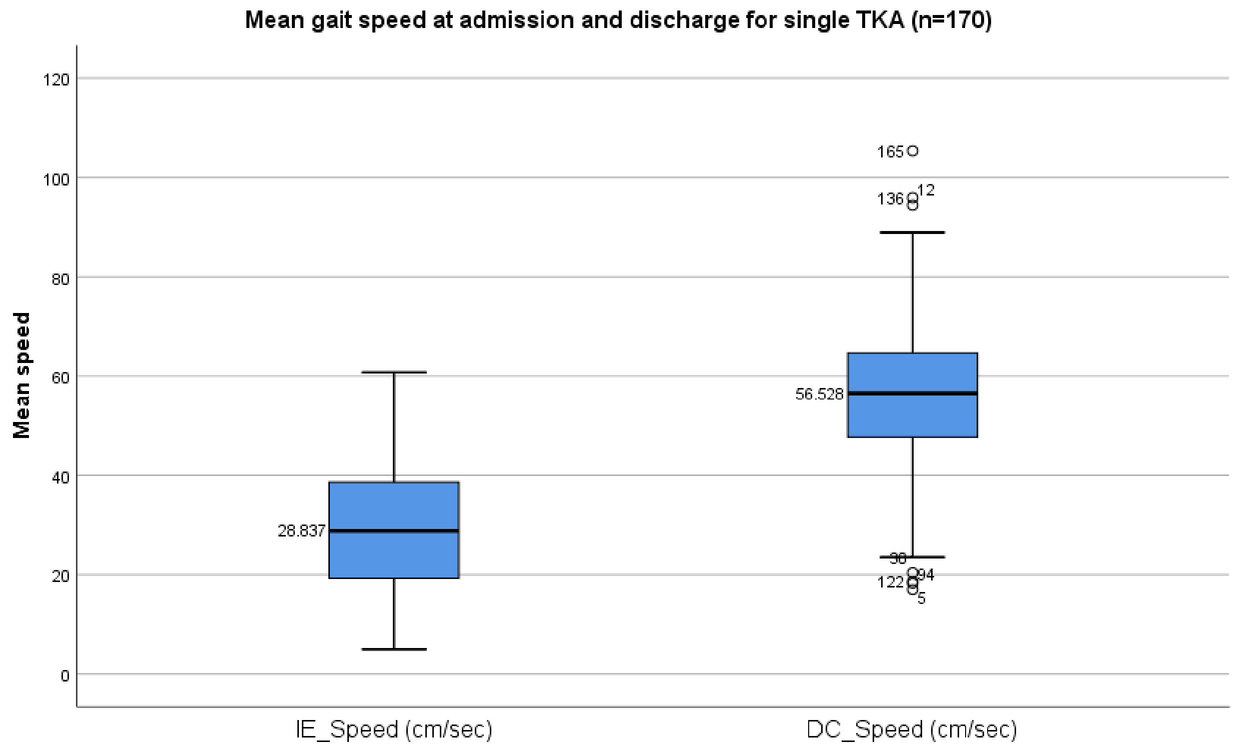
In patients who had a single TKA all gait variables improved from admission to discharge except for stride width. These include speed, $t_{(159)} = 21.74$, $p < .001$; cadence, $t_{(159)} = 19.89$, $p < .001$; step length, $t_{(159)} = 15.32$, $p < .001$; stride length, $t_{(159)} = 17.48$, $p < .001$; stride width, $t_{(159)} = 1.51$, $p = .159$; step time, $t_{(159)} = 11.67$, $p < .001$; stride time, $t_{(159)} = 13.21$, $p < .001$; stride speed $t_{(159)} = 21.72$, $p < .001$; and single limb support $t_{(159)} = 20.06$, $p > .001$. Mean improvement for each variable is provided in Table 8.

Figure 5 provide information on improvement in gait speed from the initial gait assessment to the discharge gait assessment for patients following single TKA.

Table 8. Change in gait variables between admission and discharge for patients after single TKA (N=160)				
Gait Variable	**Mean**	**SD**	**95% CI**	***p***
Speed (cm/sec.) & (ft/min)	**26.63 (52.4 ft/min)**	**14.33**	**24.36 to 25.03**	**< .001**
Cadence (steps/min)	**21.81**	**13.82**	**19.64 to 23.97**	**< .001**
Step Length (cm)	**8.55**	**7.04**	**7.44 to 9.65**	**< .001**
Stride Length (cm.)	**21.59**	**15.57**	**19.16 to 24.03**	**< .001**
Stride Width (cm.)	**.562**	**.372**	**.173 to 1.29**	**= .133**
Step Time (sec)	**1.30**	**.566**	**1.21 to 1.41**	**< .001**
Stride Time (sec)	**1.37**	**.805**	**1.31 to 1.43**	**< .001**
Stride Speed (cm/sec)	**50.79**	**14.59**	**48.27 to 53.31**	**< .001**
Single limb support (%)	**24.35**	**4.44**	**23.69 to 25.03**	**< .001**

[a] TKA: total knee arthroplasty; cm: centimeter; sec: second; min: minutes; %: percent; SD: standard deviation; CI: confidence interval; Std: standard

Question 1 & 2 – Difference between operated and non-operated limb at discharge. To determine if differences between the operated and non-operated limb remain at discharge a comparison of the discharge gait variable between limbs was conducted for the unilateral TKA patients.



[a]TKA – total knee arthroplasty, cm/sec. – centimeters/second; IE – initial evaluation; DC – discharge evaluation.

Figure 5. Mean Gait speed at admission verse discharge for TKA patients

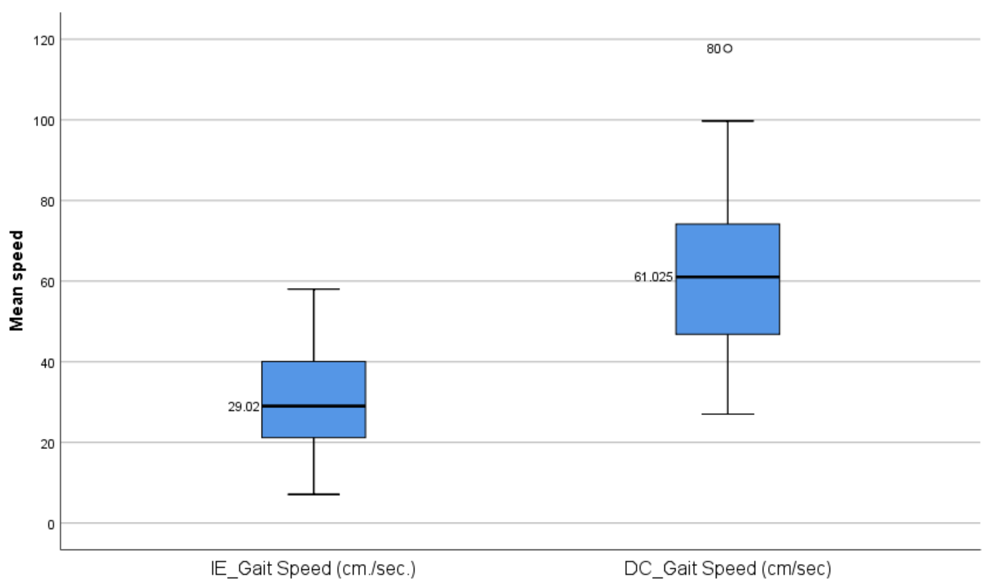
The results of 159 patients for 6 gait values are presented in Table 9 and address question 1. Step length, step time, and single limb support were the only gait variables that differed between the operated and non-operated limbs at discharge. Step length of the involved limb averaged 43.27 cm and was significantly longer that the uninvolved limb at 41.71 cm, $t_{(158)} = 4.22$, $p < .001$. This translated into a significantly longer step time (.824 sec) for the operated limb compared to the .811 sec for the non-operated limb at discharge, $t_{(158)} = 2.07$, $p = .040$. Percent single-limb support in the involved limb was 26.62% and represented more of the gait cycle than the uninvolved limb at 29.88%, $t_{(158)}$ =10.43, p <.001.

Table 9. Differences in gait variables taken during the discharge gait assessment between the involved and uninvolved limb (n=159) in unilateral TKA patients

Gait Variable	Mean	SD	95% CI	*p*
Step Length (cm)*	1.55	4.63	.826 to 2.278	< .001
Stride Length (cm)	.364	3.62	-.930 to .203	= .207
Stride Width (cm)	.017	.616	-.114 to .079	= .726
Step Time (sec)*	.753	.158	.727 to .775	< .001
Stride Time (sec)	.017	.172	-.045 to .009	= .197
Stride Speed (cm/sec)	.104	1.15	-.076 to .284	= .254
Single Limb Support (%)*	3.26	3.94	2.64 t0 3.88	< .001

[a] *-all differences between the involved verses the uninvolved gait variable is significant at p< 0.05
[b] cm: centimeter; sec: second; SD: standard deviation; CI: confidence interval; %: percent.

There were 60 patients who had a bilateral procedure. Upon admission, the average active right knee flexion ROM was 70 ± 14 degrees and average active left knee flexion was 70 ± 15 degrees ($t_{(59)}$ = -.105, p = .917). Active right knee extension lacked 4.5 ± 3.1 degrees and the active left extension was similar at 4.2 ± 2.7 degrees ($t_{(59)}$ = .519, p = .606). A comparison between the right and left limbs for both knee flexion and extension ROM revealed no statistical difference. At discharge, significant improvement in both knee flexion and extension ROM of both knees was noted and resulted in an average discharge ROM of 93 ± 13 degrees of flexion on the right side and an average discharge ROM of 94 ± 12.1 degrees of flexion on the left. Right knee extension improved to –2 ± 2.1 degrees with the left averaging –2 ± 2.4 degrees at discharge. Once again neither the flexion ($t_{(59)} = 1.36$, $p = .179$) nor the extension ($t_{(58)} = -1.25$, $p = .216$) right to left knee comparison revealed a difference. In addition to ROM, gait speed and cadence significantly improved during rehabilitation with an average improvement in speed of 30.41 cm/sec, $t_{(56)} = 13.51$, $p < .001$. Cadence improved an average of 22 steps/min, $t_{(56)} = 9.67$, $p < .001$. Figure 6 provide information on improvement in gait speed from the initial gait assessment to the discharge gait assessment.



[a]TKA – total knee arthroplasty, cm/sec. – centimeters/second; IE – initial evaluation; DC – discharge evaluation

Figure 6. Mean Gait speed at admission verse discharge for bilateral TKA patients (N=60)

A comparison of right vs. left sided limb variables revealed that there was minimal difference between sides in any of the gait variables assessed during the initial gait assessment. When comparing the difference between right and left limbs during the discharge gait assessment, only stride speed showed a significant difference between sides, $t_{(56)} = -2.43$, $p = .018$. The stride speed of the right limb (62 cm/sec.) was faster than the left limb (61 cm/sec). The mean differences between the right and left limb for each of the gait variables are in Table 10. This provides information to address question 2.

Table 10. Mean differences in gait variables taken during the discharge gait assessment between the right and left limb (n=57) in bilateral TKA patients

Gait Variable	**Mean**	**SD**	**95% CI**	***p***
Step Length (cm)	.263	4.82	1.54 to 1.016	= .682
Stride Length (cm)	1.484	8.46	3.729 to .759	= .190
Stride Width (cm)	.091	.671	.087 to .269	= .309
Step Time (sec)	.003	.066	.020 to .014	= .715
Stride Time (sec)	.007	.098	.033 to .019	= .596
Stride Speed (cm/sec) *	.552	1.72	1.01 to .096	= .018
Single limb support (%)	.217	2.74	.512 to .945	= .554

[a] *-all differences between the involved verses the uninvolved gait variable is significant at P< 0.05
[b] cm: centimeter; sec: second; SD: standard deviation; CI: confidence interval.

Question 3 - Prediction of Ambulation Device at Discharge. A binary logistic regression was used to predict the need for a two-handed device, such as bilateral canes or a walker, among 260 patients following TKA. Predictor variables from data collected at the beginning of the inpatient rehabilitation stay, included gait speed, age, gender, BMI, and the use of an ambulation device prior to surgery. Statistically significant variables were entered to create the most appropriate and parsimonious variables in the binary logistic regression. Only gait speed and the use of an ambulation device prior to surgery were significant and included in the final model.

The final model explained 27% of variance. The model was found to fit the data adequately (Hosmer and Lemeshow's $x^2 = 7.92$, $p = .442$), and could predict the need for a two-handed device (Omnibus x^2 (6) = 53.57, $p >.001$). Two variables were included in the model (initial gait speed and prior use of an assistive device) and were added using the Enter method. Both initial gait speed and prior device use were statistically significant and identified as predictors for the need for a two-handed device at discharge. The need for bilateral canes or a walker at discharge was associated with slower initial gait speed (OR = 1.07, 95% CI, 1.04 – 1.09) and the use of any type of assistive device prior to surgery (OR=3.050, 95% CI, 1.58 – 5.88). (Table 11)

The global fit is largely reflective of two predictors; gait speed and prior device use, because age, sex or BMI was not statistically significant. The OR for gait speed was 1.075 which indicated that for every 1.075 cm/sec decrease in gait speed there is an increased likelihood of needing a two-handed device, such as a walker or bilateral canes. The OR for the prior use of a device was 3.050, thus the odds of needing a walker or bilateral canes at discharge is over 3 times higher if the subjects used any type of ambulation device prior to surgery. This model successfully predicted the need for a two-handed device 74.3% of the time.

Table 11. Results from the binary logistic regression identifying variables to predict discharge ambulation device

		B	S.E.	Sig.	Odds Ratio	95% C.I.for EXP(B)	
						Lower	Upper
	Prior device(1)	1.115	.336	.001	3.050	1.580	5.887
	IE_Speed (cm/sec)	.063	.014	.001	1.065	1.036	1.096
	Age	-.016	.022	.472	.985	.944	1.027
	BMI	.005	.028	.865	1.005	.952	1.061
	Gender(1)	-.107	.356	.764	.899	.447	1.805
	Constant	-.329	2.123	.877	.720		

[a] Variables entered on step 1: Speed, Age at Admission; Prior Device; Sex and BMI
[b] B: Beta; Std: standard; CI: confidence interval; p: significance level.

ROC Curve to establish a cut-off score for use of cane at discharge. The present study also demonstrated the accuracy of gait speed for predicting ambulation device needed at discharge from an IRF. Our initial attempt to use the initial gait speed to predict the discharge ambulation device resulted in a low area under the curve (AUC) score of 0.733(95% confidence interval = .664 - .802, p <.001). But given the importance of discharge gait speed at a predictor for the use an ambulation device, the establishment of a cut-off value needed to successfully ambulate with a straight cane or no device was determined. The calculation of sensitivity and specificity of various cut-off values of discharge gait speed for predicting the use of a cane at discharge from an IRF following TKA procedures show that sensitivity and specificity has an inverse relationship. The area under the curve for the discharge gait speed is 0.802 (95% confidence interval = 0.733-.871, p <.001) for the use of a cane or no device. The curve and the corresponding AUC show that a cut-off using discharge gait speed can be used to discriminate patients who can successfully walk with a cane or no device at the end of rehabilitation following a TKA. Carefully balancing sensitivity and specificity the cut off score yielding the most accurate prediction of discharge device of a cane or no device from the sample of patients following TKA that had a discharge gait speed score is 57.78 cm/sec (0.617, sensitivity and 0.79, specificity). This appears to be the gait speed that patients post TKA need in order to successfully use a cane or no device at discharge. A cross-tabulation of actual ambulation device at discharge compared to predicted ambulation device based on the discharge gait speed identified by the ROC analysis indicated that 88% of the patients using a straight cane or no device at discharge were accurately identified by the model. Based on this same analysis the model also correctly identified 81% of those using a walker or bilateral canes at discharge. (Table 12)

To emphasize the importance of gait speed as it relates to the use of an ambulation device, Table 13 compares discharge gait speed and the discharge ratios of step length, step time, stride velocity and single limb support between those using a one-handed vs. two-handed device.

Table 12: Crosstabulation indicating the Actual Ambulation Device Category compared to the Predicted Device Category based on Discharge Gait Speed				
		Ambulation Device Category		
		0=Two-handed device	**1=One-handed device**	**Total**
Success	Predict Success	13	93	106
	Predict Fail	56	68	124
Total		69	161	230

Device Category categories whose column proportions do not differ significantly from each other at the .05 level.

No difference is observed in the ratios between the operated and non-operated limbs when using either a one-handed vs. two-handed device providing evidence of gait symmetry, but significant differences in gait speed are noted between these groups indicates its importance.

Question 4 - Prediction of length of stay. A multiple linear regression was undertaken to examine variance in the inpatient rehabilitation length of stay for patients following TKA using variables from the initial assessment. Prior to conducting the analysis, correlation assessments between all the variables were assessed. Because there was a high correlation between the initial motor FIM score and the initial total FIM score (r = .920) and an unacceptable Tolerance and VIF values it was determined that multicollinearity existed and thus the initial total FIM score was dropped from the analysis.

Table 13 Difference in Gait Speed and Variables between One-handed and Two-handed devices at Discharge

Variable	Type of device	Mean	SD	95% CI	*p*
DC Gait speed*	One-handed	62.39	14.71	12.73 to 21.55	< .001
	Two-handed	45.25	15.27		
IRF LOS*	One-handed	8.68	2.01	-2.25 to -.832	< .001
	Two-handed	10.22	3.38		
Ratio – Step length	One-handed	1.03	.114	-.034 to .035	= .991
	Two-handed	1.03	.121		
Ratio – Step time	One-handed	1.01	.074	-.072 to -.008	= .063
	Two-handed	1.05	.162		
Ratio – Stride Velocity	One-handed	1.00	.025	-.002 to .002	= .179
	Two-handed	.926	.018		
Ratio – Single limb support	One-handed	.925	.119	-.044 to .044	= .999
	Two-handed	.925	.157		

For the remaining variables, acceptable Tolerance and VIF values were noted. Initial gait speed had values of .745 for Tolerance and 1.34 for VIF; admission cognitive FIM is .826 for Tolerance and 1.21 for VIF; total motor FIM is .700 for Tolerance and 1.43 for VIF; initial knee flexion is .820 for Tolerance and 1.22 for VIP; and initial knee extension is .966 for Tolerance and 1.035 for VIP. Table 14 provides evidence that each of the variables is normally distributed as assessed by the skewness and kurtosis values. In addition, Q-Q Plots were also checked for normality.

The Durbin-Watson test was conducted to evaluate the presence of auto-correction in the data. The test revealed a value of 2.093 which showed there was no auto-correlation. Cook's distance was assessed to find influential outliers in a set of predictor variables. No outliers were identified as indicated by a Cooks' D score of .403 which is less than the established cut off of 1.

Table 14. Tests of Normality for initial clinical variables: speed and FIM scores

	N	**Mean**	**Skewness**		**Kurtosis**	
	Statistic	**Statistic**	**Statistic**	**Std. Error**	**Statistic**	**Std. Error**
IE_Gait Speed (cm./sec.)	230	29.51437	.342	.160	-.661	.320
Initial Motor FIM	230	46.10	1.079	.160	1.585	.320
Initial Cognitive FIM	230	28.66	-.908	.160	1.250	.320
Initial Total FIM	230	74.76	-.863	.160	1.172	.320
Initial Knee Flexion	230	64.67	.119	.160	-.333	.320
Initial Knee Extension	230	-4.52	-.652	.160	1.211	.320
Valid N (listwise)	230					

[a] IE: Initial Evaluation; cm/sec: centimeters per second; FIM: Functional Independence Measure: Std: standard.

The last assumption assessed was the presents of homoscedasticity and heteroscedasticity of the dependent variable. This was performed by viewing the scatter plot. The scatter plot provided evidence that the error terms along the regression were equal around the line of best fit and there was no evidence of bow-tie or fan shape data. (Figure 7)

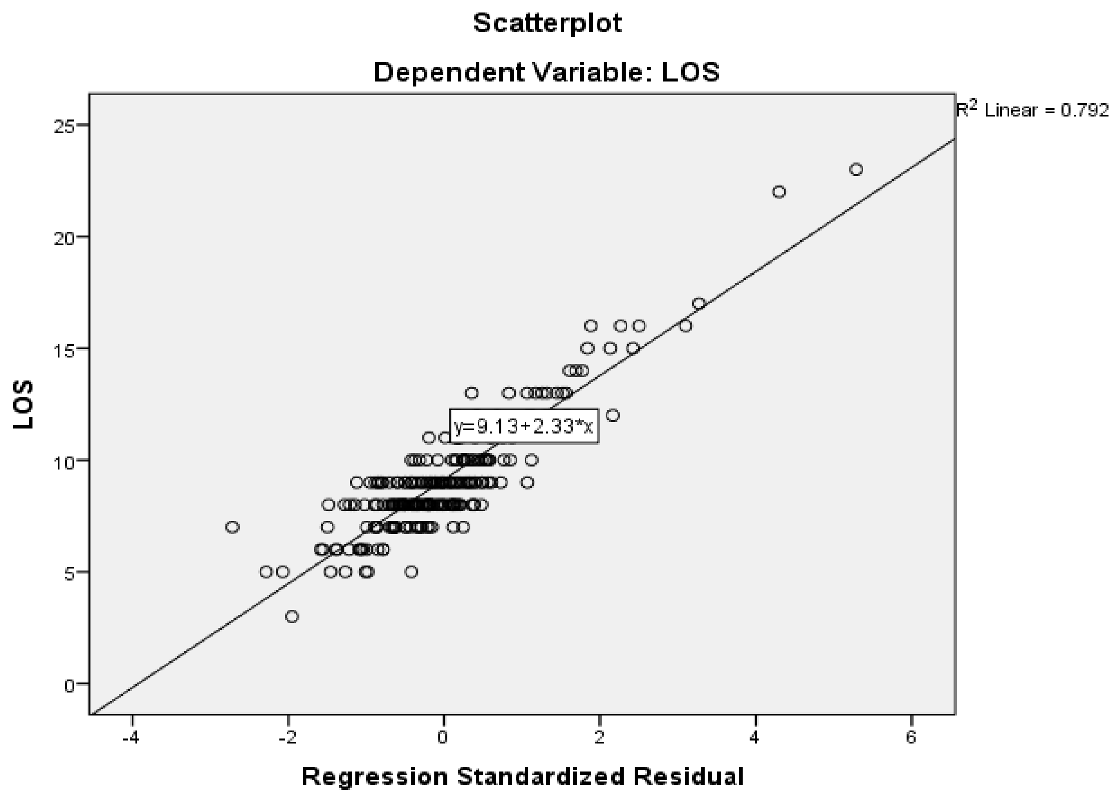


Figure 7: Line of best fit for length of stay of full patient sample (n=230)

With the assumptions of linear regression met and contributing independent variables identified, we proceeded with the regression. The mean IRF length of stay was 9 days (SD ± 2.5) with a range from 3 to 23 days. The univariate analysis of variance identified a potential association between initial gait speed, initial motor FIM, and initial knee extension and the IRF length of stay. Conversely, initial cognitive FIM and knee flexion range of motion did not show a significant correlation with the IRF length of stay. Thus, initial gait speed, initial motor FIM and knee extension range of motion were utilized to perform the multivariate analysis model. A multiple linear regression was undertaken to examine variance in LOS as explained by initial gait speed, motor FIM, and initial knee extension ROM contributing to the post-acute LOS in an IRF setting. These initial variables were assessed by the primary treating physical therapist within the first 2 days of the IRF stay. Gait speed, motor FIM and knee extension were confirmed to be independently associated with the IRF length of stay. A significant model ($F(3,226) = 21.458$, $p < .001$) predicted 24% of the sample outcome variance of LOS (Adj. R^2 .241). All independent variables were loaded into the model using the Enter method. Table 11 shows the mean value for initial speed, initial motor FIM, initial cognitive FIM and initial knee flexion and extension range of motion with evidence of a normal distribution for each variable. The regression model was significantly better at predicting outcome than a random method. All but one of the predictors significantly contributed to the model. Gait speed ($t = -4.019$, $p < .001$), motor FIM ($t = -4.010$, $p < .001$), knee extension ($t = -2.551$, $p = .011$) were found to contribute to the model. A review of the Beta weights in Table 15 identified that gait speed was the more important predictor of the IRF length of stay.

Table 15. Multivariate Analysis (General Linear Model) – Examining factors associated with LOS in patients after TKA

Variable	**B**	**CI 95%**		**Partial eta**	**value**
		Inferior	**Superior**	**squared**	***p***
Gait Speed	-.050	-.074	-.025	-.256	< .001
Initial Motor FIM	-.168	-.251	-.086	-.255	< .001
Initial Knee Extension ROM	-.123	-.217	-.028	-.151	= .011

*$p<.05$ [b]B:Beta; CI: confidence interval

Question 5 - Correlation of gait speed with patient reported mGES scores. The final analysis involved determining whether there was a correlation between gait speed and the patient reported mGES for confidence during challenging walking activities. The initial mGES score was correlated with the initial gait speed and the discharge mGES were correlated with the discharge gait speed. The last 56 patients admitted to the IRF in 2015 completed the two mGES assessments; the first one prior to the patient's initial gait assessment and the second one just prior to their discharge gait assessment. Due to the fact that it was conducted with such a small sample the analysis is considered pilot work for future studies. Prior to performing the correlation, normality assessments for admission and discharge gait speed and the two reports of mGES by patient were determined. Given a sample size over 50 cases the Kolmogorov-Smirnov was used to determine normality of the four variables using pairwise section, Table 16 Because normality was not significant for initial and discharge speed and initial mGES a Spearman's correlation was used for non-parametric variable.

Table 16. Tests of Normality for gait speed and mGES scores

Variable	**Kolmogorov-Smirnova**			**Shapiro-Wilk**		
	Statistic	**df**	**Sig.**	**Statistic**	**df**	***p***
IE_Speed (cm/sec)	.100	52	.200*	.950	52	.029
DC/Speed (cm/sec)	.101	52	.200*	.947	52	.021
IE_Patient mGES Score	.084	52	.200*	.971	52	.222
DC_Patient mGES Score	.715	52	.001	.911	52	.001

[a] * This is a lower bound of the true significance.
[b] Lilliefors Significance Correction, mGES: modified gait efficacy scale; IE: Initial Evaluation; DC: discharge; df: degrees of freedom; Sig: significant

Table 17 provides descriptive information about the variables included in the correlation. The mean initial gait speed was 29.51±13.37 cm/sec. and mean discharge speed was 56.43 ±17.22cm/sec. and the patient reported mGES scores at admission was 49.13 ±18.01 and mean discharge mGES scores was 74.44 ±17.32.

Table 17: Description Statistics for variables included in speed and mGES correlations					
Variable	**N**	**Mean**	**Std. Deviation**	**Minimum**	**Maximum**
IE_Speed (cm/sec)	230	29.51	13.37	4.96	60.76
DC_Speed (cm/sec)	216	56.43	17.22	16.98	117.72
IE_Patient mGES score	56	49.13	18.01	12	79
DC_Patient MGES score	54	74.44	17.32	35	100
Valid N (listwise)	52				

[a] IE: initial evaluation; DC: discharge evaluation; cm: centimeter; sec: second; mGES: Modified Gait Efficacy Scale; Std: standard

There was a weak and non-significant correlation found between initial gait speed and the initial mGES as reported by the patient: x^2 $(_{54})$ = .158, p =.244 but a moderate and significant correlation between discharge gait speed and the discharge mGES reported by the patient prior to the final gait assessment, x^2 $(_{51})$ = .309, p = .024. Figure 8 and 9 are the resulting scatterplots for the two correlations.

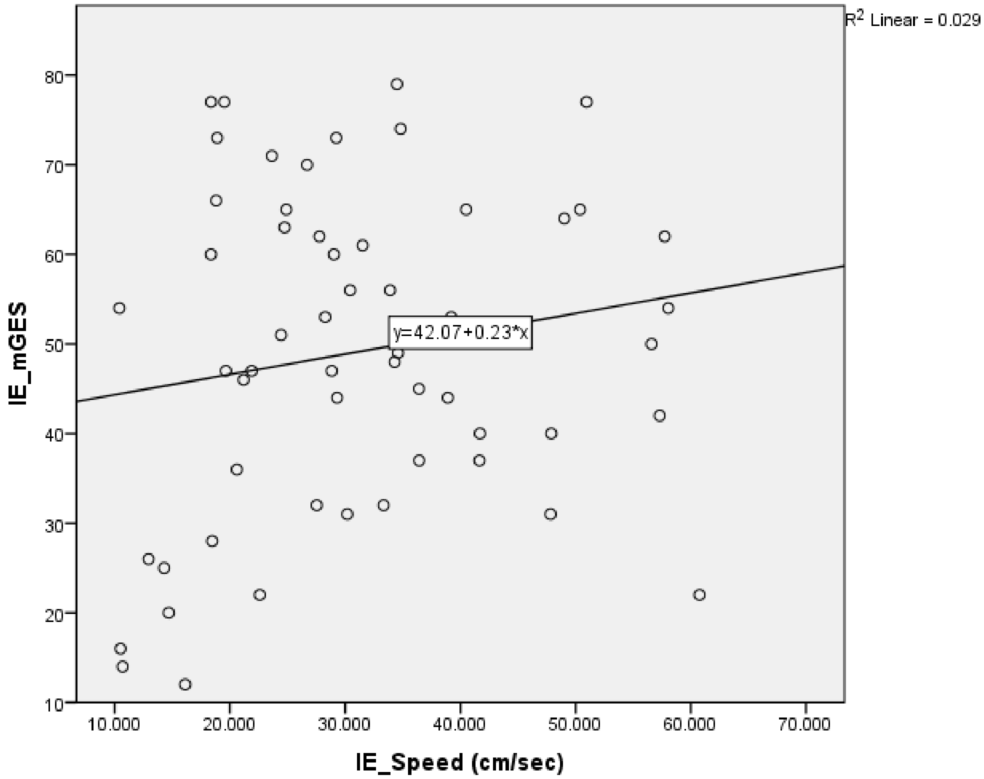


Figure 8. Scatterplot for Initial gait speed and Initial patient reported mGES (n=56)

Summary of results

The purpose of this investigation was to identify the presences of gait deviations that exist at the end of rehabilitation in IRF patients who had unilateral surgery. This comparison was also made for patients who had a bilateral procedure and analyzed any differences between the two limbs at discharge. This study also focused on determining whether gait speed, along with patient demographic information, such as age, gender, BMI, and prior ambulation device use, can be used to predict the type of ambulation device needed at discharge.

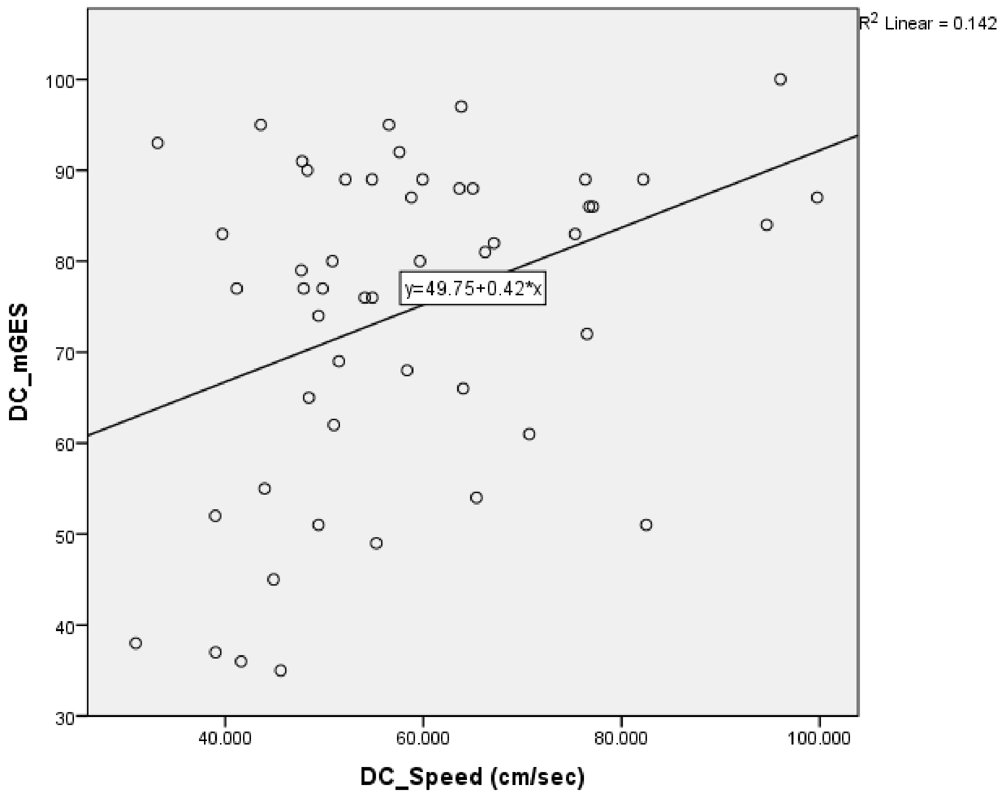


Figure 9. Scatterplot for Discharge gait speed and Discharge patient mGES (n=54)

In addition, the study assessed whether gait speed can be used as a predictor of LOS in an IRF along with motor and cognitive FIM scores, and knee range of motion. Finally, in a small sample of patients this study evaluated a new patient reporting measure called the mGES to determine if it correlated with actual gait speed. The mGES was completed just prior to both the initial and discharge gait analysis and assessed the patients' confidence with walking. This chapter described the results as they relate to the five research questions of this study.

All the gait variables collected as part of the gait assessment improved during inpatient rehabilitation following either a single or bilateral TKA. But when the operated and non-operated limbs were compared on the discharge gait assessment, difference were noted. For patients who had a single TKA, a comparison between the operated limb and the non-operated limb showed that only step length, step time and single limb support differed at discharge. Stride length, stride width, stride time and stride speed showed no difference between the operated and non-operated limb at discharge. Although stride length is equal to the sum of the two steps lengths, Balasubramanian[108] demonstrated that even in chronic stroke patients with hemiparesis stride length will be equal for left and right limbs if the person is walking in a straight line, even in the presence of marked gait asymmetry. Since the gait assessment was performed on a fixed straight walkway then this finding is also to be expected. For the bilateral TKA patients, only stride speed was different between the right and left operated limb.

When investigating the ability of gait speed, patient age, gender, BMI, and prior use of a device before surgery, a two-step analysis was conducted. The univariate analysis showed that only gait speed and prior device use were important enough to be included in the final logistic regression. The results of the binary logistic regression identified that of the five variables included in the analysis, only gait speed and prior use of an assistive device, contributed significantly to the model. Slower gait speed at admission and the use of an ambulation device prior to surgery contributed to the need for a two-handed device (bilateral canes or walker) at discharge.

Gait speed, motor FIM, and knee extension assessed the day after admission were identified as significant predictors of the inpatient rehabilitation LOS. The high correlation between motor FIM and total FIM resulted in multicollinearity, thus total FIM was dropped from the analysis. Although initial knee flexion and cognitive FIM were included in the linear regression, neither were identified as a significant predictor. Thus, slower gait speed, motor FIM scores and a lack of full knee extension contributed to a longer length of stay in the IRF setting.

The use of a subject reported confidence assessment taken just prior to the gait assessment showed a correlation between the discharge mGES and the discharge gait speed. This relationship was not identified with the pairing of gait speed and the self-reported mGES taken during the initial gait assessment.

Finally, a cut-off value for discharge gait speed was used to establish the necessary speed needed to use a one-handed device, such as a cane, or no device at discharge from IRF after a TKA. An ROC curve was used to establish a gait speed cut off value that allowed patients the ability to successfully ambulate in the community following a TKA with a cane or no device.

Chapter 5

Introduction

A discussion of the findings of this study are provided in this chapter. The chapter provides the principle findings related to the research questions. Implications of the results for clinicians working with similar populations are discussed. The strengths and limitations of the study are also identified. Finally, recommendations are provided for future research and concludes with a summary of the investigation and its findings.

Discussion

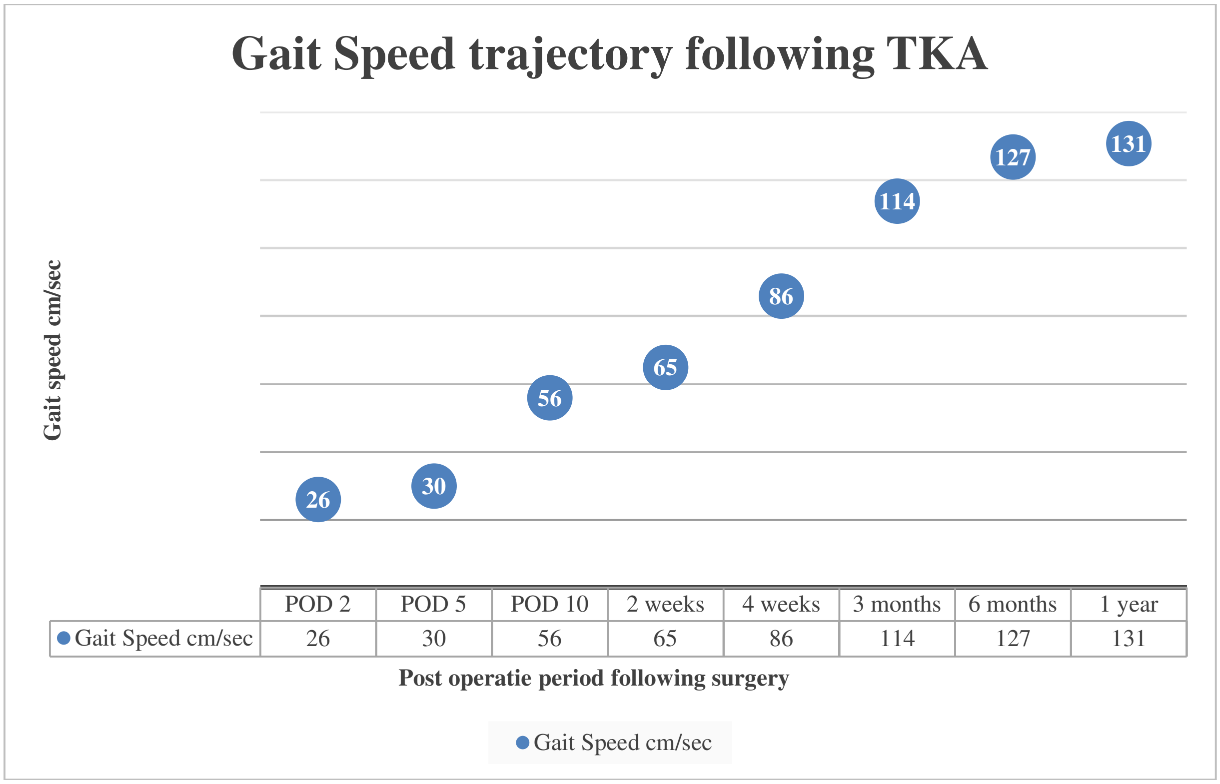
The aim of this study was to measure the level of gait symmetry at discharge using the Zeno Walkway. Temporal and spatial gait variables were compared at admission and discharge to quantify improvement following a TKA. In addition, predictive factors of the inpatient rehabilitation length of stay and need for an assistive device at discharge were identified. By comparing the admission gait assessment with discharge assessment improvements during the IRF stay were quantified and supported this post-acute level of care. The discharge gait assessment identified the presences of asymmetries between the operated and non-operated knee in several gait variables; thus, useful for identifying deficits that continue to remain in patients following TKA at the end of the IRF stay. These deficits helped establish the need for continued physical therapy in an outpatient setting. Comparing the mean differences between the operated limb and the non-operated limb at discharge highlight gait variables that continue to result in an uneven gait pattern. The results of the gait assessment have clinical implications as they provide guidance to clinicians for gait training during the acute rehabilitation phase of recovery, and they provide evidence for the need to continued PT in an outpatient setting or home environment.

An important goal during an IRF stay following a TKA is to return safely home or to the least restrictive environment at the highest level of functional independence. A community discharge often requires reducing the need for an assistive device or transitioning to the least restrictive device while walking safely. Allowing a patient to transition home using the least restrictive ambulation device reduces barriers during outdoor walking and improves the likelihood for community re-entry. The use of a walker or the need for two canes can create obstacles during community walking and is associated with increased falls and reduced community access. Identifying both modifiable and non-modifiable factors which contribute to the need for a two-handed ambulation device may allow for a more focused PT program and improve the likelihood of a patient being discharged using a cane or no device at the end of an IRF stay. Because gait speed has been a powerful predictor of early discharge following ambulatory surgery and a predictor of unplanned readmissions [66], its use can now be used as a predictor of IRF LOS and the need for an ambulation device following TKA.

The final goal of this study was to evaluate whether patients' own perception of their walking abilities matches the objective measure of gait speed. The use of a self-reported questionnaire to assess a patient's readiness for routine and advance walking tasks, such as outdoor terrain, escalators, curbs and ramps, was used for this analysis. Interventions to improve gait and other functional activities that may be influenced by a patient's perception of his or her ability to walk were studied. Thus, if walking is perceived to be effortful, regardless of actual performance and speed, then a post-surgical orthopedic patient may self-limit physical activities, resulting in a less active lifestyle.

The present study showed that after TKA, patients' gait improved from admission to discharge during rehabilitation in an IRF setting. Most notably, gait speed improved from 29.8 cm/sec at the initial gait assessment to 56.4 cm/sec at the discharge re-assessment. This finding provides evidence that TKA patients who received rehabilitation in an IRF have sufficient speed for household and limited community ambulation. Cadence also improved significantly from 53 steps per minutes to 75 steps per minute.

This study provides information on early post-operative gait speed following a TKA. The gait speed evaluated during the IRF stay adds to the existing literature and provides two additional data points for post-operative days (POD) five and ten. This information can be used to create a trajectory of average gait speed from POD 2 up to 1 year following surgery. I created a graph trajectory of improving gait speed following TKA with data from earlier studies starting from the acute care hospital and adding data from inpatient rehabilitation to those studies assessing gait up to 1 year after surgery. This information allows to a physical therapist to determine if a patient's current status is on pace with prior information as a point of reference. Figure 10 was created to provide that trajectory with time post-surgery along the y axis and speed along the x axis.



[a] POD: post-operative day; cm/sec: centimeters per second.
[b] References: [32, 40, 52, 94, 109, 110]

Figure 10: Provides the trajectory of improvement in gait speed after TKA beginning the day after surgery through one-year post TKA

Residual deficit in gait variables at discharge (Question 1 and 2)

While improvement from admission to discharge is important and predictable, understanding the existence of asymmetries between the operated and non-operated leg can lead to improved gait training strategies in physical therapy. After knee arthroplasty, patients had a slower gait speed, shorter step length, and less cadence compared with controls who did not have surgery. Chen et al showed that post-surgical TKA patients had shorter swing and longer stance phases within the gait cycle.[10] Prior studies compared patients who had a TKA with control persons matched for sex, age, body mass, and height. In addition to differences noted in temporal and spatial gait variables, knee range of motion was also reduced in patients following TKA compared with their age-matched controls.[52] Reduced knee range of motion was previously identified as a risk for post-operative falls in patients following TKA.[95, 96] Despite the depth of work in this area, no prior investigators compared the involved limb with the uninvolved limb in patients following TKA during post-acute rehabilitation. Such a comparison would identify if imbalances between the two limbs existed following TKA.

Our study was the first to compare the involved and uninvolved sides of patients following a single TKA at discharge from an inpatient rehabilitation facility. Our results showed that during the discharge gait assessment, a significant difference in mean step length, step time and single limb support existed between the operated and non-operated limbs. However, no difference was noted in stride length, stride width, stride time, and stride speed. This result is anticipated and consistent with prior literature that demonstrated post-operative deficits in TKA patients resulted in slower gait speed and cadence and shorter stride length, percent single limb support in the operated limb after surgery.[51] There are a number of reasons that differences in step length, step time and single limb support between the operated and non-operated limbs continue to exist at the time of discharge from the IRF. The patients may still have post-operative pain in the operated limb resulting in less time weight bearing on that the operated side. This will result in a shorter step length and shorted step time. In our sample range of motion in the operated limb did not achieve full terminal knee extension by discharge. As a result, heel strike on the operated limb occurred with a slight knee bend shortening the step length; reducing step time and stance time.

Despite the differences in these gait measures, several temporal measures were not different between the operated and non-operated limbs. This resulted in an interesting finding in our study; patients made accommodations in their gait pattern, which resulted in an even stride length, stride time, and stride speed as noted by the operated and non-operated limbs comparison; whereas in prior studies these deficits, as compared to age-matched controls, continued two months or more following surgery.

Patients from prior studies were not transferred to an inpatient rehabilitation facility following surgery where patients participated daily physical therapy. Instead, patients from prior studies went directly home from the acute care hospital following surgery and received physical therapy as part of homecare or in an outpatient clinic several times per week. Home-based and community-based services may not have been sufficient to reduce those deficits and normalize the side-by-side temporal and spatial imbalances.

The progress in our patient sample leading to a more symmetrical gait pattern at discharge maybe related to daily, progressive gait training which allowed 70% of patients to be able to use a cane.

Improvement in gait symmetry can also be demonstrated by calculating the ratio of key gait variables, such as step length, step time, and percent in single-limb support between the operated to non-operated knee. A ratio of one indicates complete symmetry between the operated limb and the non-operated limb. In our patient sample, the ratio of step length between the operated verses non-operated ratio at admission was 1.58, indicating a step length of nearly twice the distance between limbs. At discharge, the ratio for step length averaged 1.04, which is much closer to an equal length between limbs. Similarly, step time improved between admission and discharge with ratios from the initial walk at 1.24 changing to 1.02 by discharge. The near perfect 1.0 ratio in step length and step time between the limbs during the discharge gait assessment provides evidence of improved gait symmetry during rehabilitation at the IRF for our study sample of patients following a single TKA. Gait symmetry identified by these discharge ratios was found equally in patients discharged using a two-handed compared to one-handed ambulation device.

The step length, step time, and percent single-limb support findings were consistent with prior work, but the lack of deficits in stride width, stride time, and gait speed provide evidence as to why gait asymmetry often remain for months and even years' post-surgery. Early and aggressive gait training at an IRF may contribute to the improvement in stride speed and other important variables, but early gait speed data shows how significant the deficits are in the early phase of rehabilitation. Deficits in step length of the involved limb in patients after a single TKA may also be a factor of available knee range of motion. Normal knee flexion and extension range of motion was not achieved by our patients at discharge. Because most patients continue to lack terminal knee extension at discharge from the IRF, it may contribute to a reduced step length on the operated side, which would affect step time. This finding supports the need for aggressive therapy to improve knee extension during the PT sessions at the IRF.

The recent implementation of the Comprehensive Care for Joint Replacement (CJR) for Medicare beneficiaries resulted in more discharges directly home or to a skilled nursing facility following a TKA. It will be important to follow future patients to ensure that an unintended consequence of persistent gait deviations is not a byproduct of CJR. Thus, continued studies investigating the outcome of patients following TKA who receive post-surgical physical therapy in different settings is recommended.

Patients who had a bilateral procedure did not have a control limb to compare the involved vs uninvolved sides. Our results showed that at discharge, there were no differences between the right and left operated sides during the discharge gait assessment except for limb velocity. This result was different from the single TKA population where difference in step length, step time and percent of single limb support were noted between the operated and non-operated knees. but the lack of difference between the right and left limbs in the bilateral population was predictable since both limbs were operated on. Although no difference was demonstrated between limbs, speed, cadence, stride length and percentage of time in single limb support were all worse than those of aged matched controls.[51] Health subjects in their 60's walked an average of 1.36 m/sec and those in their 70's walk 1.27 m/sec whereby our bilateral TKA patients walked an average speed of 0.61 m/sec at discharge. Our single TKA group walked a slightly slow pace at discharge averaging 0.57 m/sec.

Predictors of discharge ambulation device (Question 3)

During early post-operative care after a TKA, all patients used an assistive device during ambulation to help maintain stability and reduce pain during weight bearing. However, an important goal throughout post-acute rehabilitation is the transition to the least restrictive ambulation device that provides pain relief and stability during walking. Reintegrating into the community is easier if a patient uses either a one-handed device, such as a cane, or no assistive device.[17] This is because devices requiring the use of both hands, such as bilateral canes or a walker, are more cumbersome and require more coordination when navigating in a community setting. According to a detailed Standard of Care following a TKA from Brigham and Women's Hospital Department of Rehabilitation Services Physical Therapy, most patients are expected to ambulate without assistive devices within 2 to 4 weeks of their surgery (Appendix F). The use of a walker or two canes is a barrier to community ambulation, which is especially true for persons who navigate stairs, escalators, public transportation, and revolving doors to enter and exit buildings. The use of two canes can also be difficult to coordinate and result in motor planning challenges. Despite being a more stable support then a single cane, the sequencing of two canes during walking requires a high degree of concentration and planning. In addition, the use of an assistive device has previously been associated with functional decline. Mahoney, Sager, and Jalaluddin[76] explored predictors of functional decline after controlling for demographic and illness-related characteristics as well as prehospital function. Mahoney et al found that mobility impairment was associated with an ambulation device and was a significant predictor of functional decline.[111] The use of a walker resulted in a 2.8 times greater risk of decline in ADL function following hospital discharge (p = .0002). Three months after discharge, patients who used an assistive device prior to their hospitalization were more likely to have a decline in both activities of daily living ($p = .02$) and instrumental activities of daily living ($p = .003$).[111] Thus, an important rehabilitation goal following TKA is the transition to a cane or no device prior to re-entering the community. Previous investigators reported that 90% of patients discharged from an IRF walked indoors with a cane or no device[90], but no investigators to date provided information on the use of a device for outdoor or community ambulation following TKA. Physical therapy sessions in an IRF attempt to simulate community environments and allow patients to practice negotiating obstacles and walking up curbs, ramps, and stairs. However, community distances and situational activities that require faster gait speed for functional community ambulation are difficult to replicate in an institutional setting. Thus, inpatient therapy may not adequately prepare patients for the functional challenges for a community discharge. To help address community demands physical therapists should consider the community and setting each patient is being discharged to. Establishing unique goals for ambulation distances and speed to ensure patients are adequately prepared for a community reintegration specific to their needs is warranted. Robinett and Vondran[112] identified three community settings and recorded typical distances and speeds needed to safely and independently navigate as a community dweller. For example, the distance needed to navigate a supermarket among urban, suburban, and rural settings ranged from 230 to 342 meters. Gait speed recorded for safe street crossing in these three settings ranged from 30 to 83 m/min (50 to 138 cm/sec). The use of a walker or other two-handed devices during community ambulation will likely slow one down. The present study indicated that 70% of the patients who had a TKA were ambulating outdoors with a cane (66%) or no device (4%) at the time of discharge from the IRF; while 16% used bilateral canes and 15% required a walker. No differences were noted in the use of a device between patients who had single TKA compared to bilateral procedure, but discharge gait speed was slower in patients who were discharged using a two-handed device compared to a one-handed device. Despite the difference in speed, right/left limb ratio of step length, step time, stride velocity and percent single limb support was close to 1 and were not significantly affected by the type of device used. For those patients unable to ambulate outdoors with a cane, it was important to determine if gait speed or other modifiable variables contributed to the need for a two-handed device. Our study assessed patient characteristics of age, sex, BMI, surgical type and prior use of a device along with initial gait speed as contributors to the variability associated with the need for a more restrictive ambulation device, such as a walker or bilateral canes. Because all patients performed their initial gait assessment using a front-wheeled rolling walker the type of device did not contribute to differences in initial gait speed. Our univariate analysis of these predictors found that only gait speed and prior device were potential contributors to the type of device needed at discharge. Because type of surgery, unilateral or bilateral, was not a predictor, it was deemed appropriate to look at the total sample instead of analyzing single TKA and bilateral TKA patients separately.

Assessing the influence of BMI was investigated because prior investigators found that higher BMI was associated with slower recovery[113] and difficulty performing functional mobility tasks, such as walking and stair climbing.[114] In a later study, Stickles observed more difficulty with functional reach and shorter single-leg stance time in patients with higher BMI, although differences in the 10-meter walk and timed get-up-and-go test or chair rise were not found.[115] In addition, BMI was associated with reduced knee ROM and a greater need for a manipulation after TKA.[116] Our study did not identify BMI as a predictor for the need for a walker or bilateral canes at discharge from the IRF.

Age was identified as a risk factor affecting patient outcomes after TKA in prior research.[117] Age was also identified as a predictor for lower functional outcome and identified as a prognostic factor for joint revision surgeries.[105] Despite the increased risk of older age on functional outcomes, age had no effect on ROM or need for post-surgical manipulation.[116] In our final regression our results did not show the contribution of age as a significant predictor of discharge device use. There is wide variability in person's functional status at different ages; whereby some older patients function at a higher level than younger patients. It is likely that chronological age is less likely a factor but rather functional age may be a better predictor for the need of an ambulation device. No prior literature was found to determine the consistency of this finding.

Prior device use and gait speed were the only variables contributing to the need for bilateral canes or walker at discharge in our study. It was determined that the combination of these two variables was associated with 26% of the variance for this outcome. Although this model does not explain all of the variance, it does identify gait speed as a potentially modifiable variable that can be addressed during inpatient therapy. Walking faster proportionally lengthens single-limb stance and shortens the two double-stance intervals. Conceptually, if physical therapists in the IRF setting focus on having the patient walk faster, even while using a walker, it may decrease the need for a two-handed device at discharge. Our facility tries to transition patients from a walker to a cane as early as possible. During early gait training with a cane, patients often experience reduced stability resulting in an unsteady gait pattern requiring the addition of hand-held support or contact guard by a therapist. This pattern could result in slower walking speed compared with when the patient uses a walker. Early training with a cane may not be as beneficial toward the ultimate transition to one-handed device. Early gait training with a cane prior to having sufficient speed and stability may result in a fear of falling or poor balance. Such fear may contribute to a slower gait speed and overall insecurity. It may be more beneficial to simply encourage a faster pace of walking while using a rolling walker and transitioning to a cane once sufficient gait speed is achieved.

This study also provides evidence that discharge gait speed should be assessed to ensure safe ambulation with a cane. Although the selection of an ambulation device is made based on a holistic assessment, a therapist may find the use of gait speed beneficial for contributing to a recommendation of a one-handed device. Our findings demonstrated that discharge gait speed can be a useful objective measure for the accurate selection of ambulation device at discharge. A cut-off gait speed for successfully walking with a cane at discharge was identified. Based on the patients in our study and balancing the specificity and sensitivity of gait speeds, 58 cm/sec was identified as the target speed to transition patients from a walker to a cane. This produced a positive likelihood ratio (+LR) of 3.14 indicating a small but useful test for predicting a true positive using discharge gait speed as the criterion measure. More work in this area is needed to help shape the physical therapy interventions for post-operative rehabilitation following a TKA.

Predictors of IRF Length of Stay (Question 4)

When studying the post-operative rehabilitation course prior studies showed variability in achieving functional independence by the patients following knee arthroplasty. These may be the result of the post-acute care received by these patients and may contribute to inpatient rehabilitation length of stay. Information on acute care hospital LOS following TKA showed that hospital LOS of greater than 4 days was attributed to older age, Hispanic race, lower median household income, weekend admission, and being discharged to another facility for rehabilitation.[118] Baseline lower motor and cognitive FIM scores have been associated with a longer acute LOS in patient following joint replacement.[91, 119] No investigators to date analyzed predictors of post-acute LOS following TKA. We were interested in expanding this knowledge by evaluating if a combination of clinical variables reduces the LOS following a TKA. We evaluated the impact of gait speed, in conjunction with motor and cognitive FIM scores and knee ROM, as a predictor of the LOS in TKA patients treated in an IRF. In our patients, the mean gait speed improved significantly from an average admission speed of 30 cm/sec to an average discharge speed of 56 cm/sec (Table 18). Also provided in Table 18 is the feet per minute conversion, which is more frequently used in US clinics and hospital settings.

Table 18. Mean Gait Speed and Cadence from admission to discharge

Admission vs. Discharge variables	**Variable:**	**Mean**	**Std. Deviation**	**t**	***p***
Gait speed (cm/sec) & (ft/min)	IE_Gait Speed	29.8 (58.7 ft./min)	13.4	25.35	< .001
	DC_Gait Speed	56.4 (111 ft./min)	17.2		
Cadence (steps/min)	IE_Cadence	53.3	15.6	21.82	< .001
	DC_Cadence	75.1	13.4		

[a] IE: initial evaluation; DC: discharge; cm/sec: centimeters per second; min: minute; ft/min: feet per minute

Motor FIM scores also improved significantly from an average admission score of 46 to an average discharge score of 72. Improvement was not noted in the cognitive FIM score in which the average discharge score of 33 was only 4 points higher than the average admission score of 29.

In our linear regression model, faster gait speed, higher motor FIM, and knee extension range of motion were associated with a shorter LOS. The total FIM score was not included in the variables selected due to its strong correlation (.90) to the motor FIM sub-score and its contribution to multicollinearity among the variables. Our model shows that initial gait speed, initial motor FIM, and initial knee extension ROM contributed significantly to LOS and were associated with 24% of the variance observed in the LOS in our population. Once again, gait speed surfaces as a critical and potentially modifiable variable not often assessed during an IRF stay, despite its reputation as the sixth vital sign [24] and a predictor of many adverse events.[57] [100] [29] [61] [69] [120] Thus, post-acute physical therapy services should focus on gait speed and symmetry as a primary goal of care. The emphasis on gait speed could impact both the discharge ambulation device as well as the inpatient rehabilitation LOS.

Our desire to evaluate gait speed as a contributor to an institution discharge was not possible in our study because all but three patients were discharged home. Further analysis into why these three patients were discharged to a SNF include the following: one patient had a history of schizophrenia, which interfered with her therapy progress. The schizophrenia was not identified during the initial patient selection process. Another patient lived alone prior to surgery. This patient's only relatives were from the Philippines and could not offer post-discharge support. Even though the patient could independently walk over 250 feet at discharge, the patient's family felt a SNF discharge would be a safer option at the time. The final patient had a complicated stay, which included two falls and a transfer to an acute hospital due to medical complications. She also lived alone and her family felt that she could benefit from more time in rehabilitation due to her fall history.

Analysis of other patient populations at our facility found that patients following stroke, cardiac and pulmonary conditions, and hip fractures have a greater frequency of a SNF discharge. Thus, gait speed may be identified as a predictor of community discharge in other patient diagnostic groups, which is a potential area of future research important to the field of rehabilitation, but not the TKA patients.

Correlation between mGES with Gait Speed (Question 5)

A relatively new evaluation tool introduced in prior work is the mGES. This self-assessment completed by a patient provides information on a patient's confidence during both indoor and outdoor walking. The mGES assesses a patients' perceived confidence while navigating challenging community situations. Newell found the psychometric properties of the tool in the mGES was associated with performance-based mobility measures. Fast gait speed, simple and complex walking while talking tests (WWT), the narrow base of support walking, and an obstacle test were associated with higher levels of confidence.[18]

Aside from the initial study establishing the psychometric properties of the tool, our study is the first to correlate patients' self-confidence score on the mGES with the objective measure of gait speed during recovery from an orthopedic procedure. Our study included a subset of 56 patients from our convenience sample of 230 admitted to our IRF after September 8th. We compared these patients' initial mGES score with their initial gait speed and their discharge mGES with their final gait assessment gait speed. We did not find a correlation between the initial gait speed and the initial mGES scores, but we did find a moderate and significant correlation between the discharge pair: discharge gait speed and discharge mGES scores. The disparity between the correlations may be due to a larger number of subjects using canes during the discharge gait assessment. The use of a cane during walking may be perceived by patients as a higher skill, thus translated into more confidence during walking. Also since all of the patients used a rolling walker during their initial gait assessment, this may have resulted in a sense of confidence during indoor walking but a lack of awareness of community obstacles. In addition, the sample size may not be sufficient to adequately assess the relationship between these two variables. Nevertheless, the results highlight the importance of assessing patients' own perception of their abilities in combination with a therapist report of objective functional outcomes, especially at discharge. The fact that our patient showed a more streamlined relationship between perception and actual gait speed and had reduced variability in the second mGES assessment demonstrates that they had a better perspective of their functional limitations. Patients' perspective can add insight into patients' confidence level and readiness for discharge. Because this study was considered a pilot project, using only a subset of our total sample, a more thorough look into the role of patient confidence and self-selected walking speed following orthopedic surgery may be useful in future studies.

Study Limitations

There were several limitations and delimitation of this research. The use of only one IRF where patients were included in the analysis is the first study limitation. A single site study limited the sample size and created a potential geographic bias, limiting surgical sites and post-operative protocols. Although prior analysis determined a sufficient sample size for the analysis, there may be regional and institutional difference that could affect patient outcome and thus affect the generalizability of the study. Prior to the start of the study, we reached out to two IRFs that also treat a significant number of patients after TKA, but neither had a GaitRite or ZenoWalkway to conduct a gait assessment; thus, inclusion of additional institutions was not feasible.

The second limitation was that the five-physical therapist working in the orthopedic unit at the time of the study had a range of 1.5 to 11 years of experience. This resulted in different levels of knowledge and experience involved in managing the patients during the study period. This was somewhat mitigated by the fact that all the therapy staff were part of a one-year orthopedic rotation, and all the staff were oriented to a consistent post-TKA therapy protocol.

Because the first gait assessment was conducted post surgically, there was no prior knowledge of gait deficits that the patients might have developed prior to the TKA procedure. Lack of awareness of prior abnormal gait patterns or prior gait speed created the third limitation for this study. A pre-surgical gait assessment would have provided additional information about the effects of long-standing pain and/or altered gait patterns on post-operative gait.

Another limitation is that since the study was conducted with patients admitted during 11 months of 2015 our rapidly changing health care system may have led to changes in post-acute settings of care and length of stay. For example, bundled arrangements for total knee care, as part of CJR, impacted both setting of care and LOS; transitioning more skilled nursing facilities with a reduced length of stay.

The use of secondary data precluded the investigator's ability to explore additional information about the patients. Knowledge of the number of symptomatic years of pain and disability as well as the patient's pain level at the time of the gait assessment would have provided additional information potentially useful to our investigators. Awareness of existing comorbid heath conditions that might have impacted the patients' outcome would also have enhanced this study. Future research conducted in a prospective manner should include important variables, such as pain level, prior gait speed, and comorbid conditions, in the analysis.

The use of a self-reported confidence scale, measured by the mGES, provided insight into each patient's walking confidence at both admission and discharge during the IRF stay. Although the mGES was only assessed in 56 of our study patients, its use in an IRF setting has never been reported in the literature.

This is the first study to analysis early gait findings to evaluate side to side differences following a TKA in patients who received rehabilitation care in an IRF setting. The earliest investigation of gait deficits following discharge from an acute care hospital after TKA patients was complete within 2 weeks of surgery. Although there is new information regarding the trajectory of recovery after TKA, data was limited to the early post-acute phase.

Thus, another limitation was the length of time patients were followed post operatively. This study only represented the inpatient rehabilitation phase following surgery. Because patients continue to improve up to 6 months before they plateau,[11] gait deficits, especially those associated with pain, may have resolved during the subsequent weeks and months post operatively. Continued follow up and further gait assessment would have helped to determine when plateau in gait speed occurred and how well our population compared to patients in prior studies at the same time points.

Contribution the study makes to the field

As reimbursement moves from a fee for service model to a bundled payment model for Medicare beneficiaries, the need to track outcomes and adverse events becomes increasingly important. The introduction of bundled payment for joint replacement commenced on April 1, 2016 resulted in a combined payment mechanism for the acute and post-acute services. This program gives hospitals and clinicians an incentive to work together to ensure that beneficiaries received coordinated care at a reduced cost. Acute and post-acute providers now need to work together to collect and analyze outcomes across the continuum, including 30-days post discharge. Ensuring the best possible outcome for patient following TKA, while minimizing adverse events, makes this study important for this patient population. Information on important variables such as gait speed, discharge disposition, use of assistive device and LOS in a post-acute environment establishes norms and benchmarks. Establishing early post-surgery trajectory of recovery provides information about the development of abnormal gait patterns. Understanding early gait patterns allows for treatment modification and the use of alternative interventions to help minimize potential long term abnormal gait patterns often developed after a TKA.

Summary

The influx of baby-boomers reaching the age of 65 and becoming Medicare beneficiaries has led to an increase in the number of TKA procedures performed in the US over the past decade. This trend is predicted to continue and establishes the need to assess the outcomes of those receiving TKAs. The primary goal of this surgical intervention is to reduce pain and improve gait function.

Thus, it is important to assess pain and function immediately post-surgery as well as long term after the procedure to ensure the most effective treatment is provided. The goal of this study was to analyze the gait patterns of patients, following single and bilateral TKA procedures, who received inpatient rehabilitation following surgery. Gait analysis along with other functional assessments, such as the FIM and range of motion, were analyzed at admission and the day before discharge at the IRF. This study provides information regarding normal recovery of gait speed; and spatial gait variables including step length and stride length. This data can be used to establish recovery norms for these variables as well as determine deficits in the operated limb that did not achieve the non-operated limb level by discharge.

This was the first study using a pressure sensored gait assessment tool to assess walking within a week of a TKA. Although some of the gait variables were not different between the operated and non-operated limb during the discharge gait assessment, step length, step time, and percent of single-limb support persisted as deficits after discharge from the IRF in patients who had a single TKA.

This study also assessed the role of gait speed when determining the need for an assistive device at discharge from an IRF. Gait speed, patient age, BMI, and prior use of a device were evaluated to identify which factors predicted to the need for a two-handed walking device. Only gait speed and prior device use contributed to the variance associated with the need for an assistive device.

A similar analysis was conducted to assess variables contributing to the IRF length of stay. Gait speed, motor FIM scores, and knee extension ROM contributed to 24% of the variation in IRF length of stay.

To answer the final question, gait speed was correlated with the patient's perceived confidence with walking as assessed by the mGES. The pairing of the initial and the final gait assessments with the patient's reported mGES score prior to each gait assessment were evaluated in a 56 patients who received post-acute rehabilitation at this IRF during the study period of 2015. Only a moderately positive correlation was found between gait speeds at discharge and the discharge mGES scores.

This study provided new information to the breath of research assessing the outcomes in patients following TKA surgery. Prior studies were conducted several months and even years following surgery.[10, 33, 35, 52, 121, 122] Our study analyzed gait during the post-acute rehabilitation after a TKA and contributed to establishing baseline outcomes achieved following care during an IRF stay. It is also the first study to use gait speed to determine the need for an ambulation device and to predict IRF LOS following TKA. The study highlights the importance of gait speed during the recovery phase following a TKA and its impact on outcome. It is also the first to assess patients' confidence during walking following TKA surgery. To date the mGES has not been studied in an IRF environment and thus may open the door for future studies using this tool.

Adding variables in the regression model in future studies could help explain more of the variance contributing to the need for an ambulation device and LOS. Expanding the role of patient self-reports of confidence as part of an IRF assessment may help to better understand a patient's readiness for discharge. Assessing patients prior to surgery and following them for 3-month post-surgery through all aspects of post-acute rehabilitation, including outpatient setting, maybe appropriate for future studies, especially in light of the new CJR-bundled reimbursement system. In addition to IRFs, patients also receive care at home through home care services, in outpatient facilities, and in SNF settings. Data collection at each setting as well as across combined settings can improve the knowledge of recovery and add timeframes to functional improvement after knee replacement surgery.

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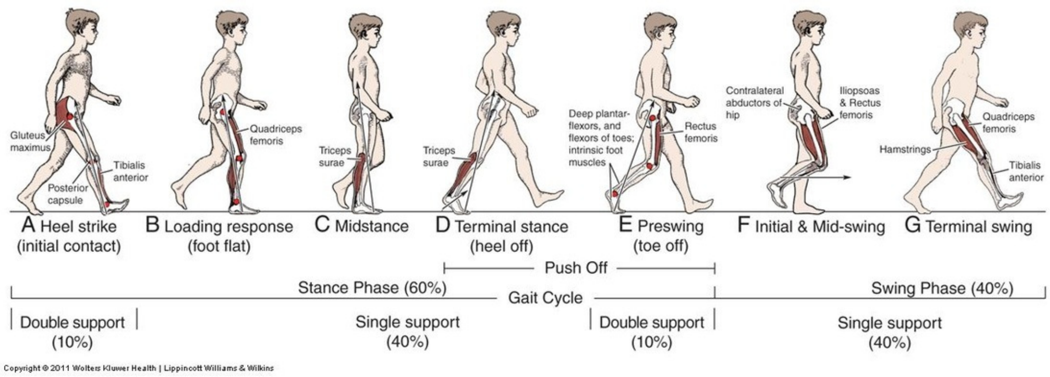
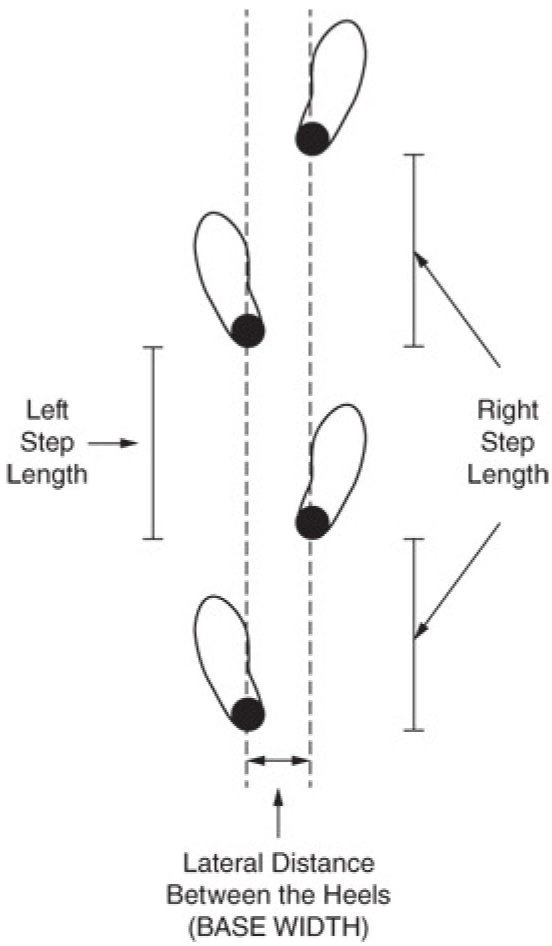
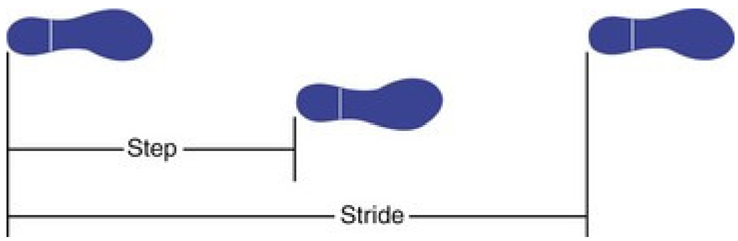
Appendix A: Gait Cycle



Appendix B: Step and stride length (heel to heel)



Appendix B. Step vs. Stride Length



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Appendix C: Modified Gait Efficacy Scale (mGES)

Appendix.
The Modified Gait Efficacy Scale (mGES)

1. How much confidence do you have that you would be able to safely walk on a level surface such as a hardwood floor?

1	2	3	4	5	6	7	8	9	10

No Confidence — Complete Confidence

2. How much confidence do you have that you would be able to safely walk on grass?

1	2	3	4	5	6	7	8	9	10

No Confidence — Complete Confidence

3. How much confidence do you have that you would be able to safely walk over an obstacle in your path?

1	2	3	4	5	6	7	8	9	10

No Confidence — Complete Confidence

4. How much confidence do you have that you would be able to safely step down from a curb?

1	2	3	4	5	6	7	8	9	10

No Confidence — Complete Confidence

5. How much confidence do you have that you would be able to safely step up onto a curb?

1	2	3	4	5	6	7	8	9	10

No Confidence — Complete Confidence

6. How much confidence do you have that you would be able to safely walk up stairs if you are holding on to a railing?

1	2	3	4	5	6	7	8	9	10

No Confidence — Complete Confidence

7. How much confidence do you have that you would be able to safely walk down stairs if you are holding on to a railing?

1	2	3	4	5	6	7	8	9	10

No Confidence — Complete Confidence

8. How much confidence do you have that you would be able to safely walk up stairs if you are NOT holding on to a railing?

1	2	3	4	5	6	7	8	9	10

No Confidence — Complete Confidence

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Appendix D: FIM Scoring tool in the IRFPAI

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTER FOR MEDICARE & MEDICAID SERVICES

OMB No. 0938-0842

Function Modifiers*

Complete the following specific functional items prior to scoring the FIM™ Instrument:

	Admission	Discharge
29. Bladder Level of Assistance (Score using FIM Levels 1 - 7)	☐	☐
30. Bladder Frequency of Accidents (Score as below)	☐	☐

7 - No accidents
6 - No accidents; uses device such as a catheter
5 - One accident in the past 7 days
4 - Two accidents in the past 7 days
3 - Three accidents in the past 7 days
2 - Four accidents in the past 7 days
1 - Five or more accidents in the past 7 days

Enter in Item 39G (Bladder) the lower *(more dependent) score from Items 29 and 30 above*

	Admission	Discharge
31. Bowel Level of Assistance (Score using FIM Levels 1 - 7)	☐	☐
32. Bowel Frequency of Accidents (Score as below)	☐	☐

7 - No accidents
6 - No accidents; uses device such as ostomy
5 - One accident in the past 7 days
4 - Two accidents in the past 7 days
3 - Three accidents in the past 7 days
2 - Four accidents in the past 7 days
1 - Five or more accidents in the past 7 days

Enter in Item 39H (Bowel) the lower (more dependent) score of Items 31and 32 above.

	Admission	Discharge
33. Tub Transfer	☐	☐
34. Shower Transfer	☐	☐

(Score Items 33 and 34 using FIM Levels 1 - 7; use 0 if activity does not occur) *See training manual for scoring of Item 39K (Tub/Shower Transfer)*

	Admission	Discharge
35. Distance Walked	☐	☐
36. Distance Traveled in Wheelchair	☐	☐

(Code items 35 and 36 using: 3 - 150 feet; 2 - 50 to 149 feet; 1 - Less than 50 feet; 0 – activity does not occur)

	Admission	Discharge
37. Walk	☐	☐
38. Wheelchair	☐	☐

(Score Items 37 and 38 using FIM Levels 1 - 7; 0 if activity does not occur) See training manual for scoring of Item 39L (Walk/Wheelchair)

39. FIM™ Instrument*

	Admission	Discharge	Goal
SELF-CARE			
A. Eating	☐	☐	☐
B. Grooming	☐	☐	☐
C. Bathing	☐	☐	☐
D. Dressing - Upper	☐	☐	☐
E. Dressing - Lower	☐	☐	☐
F. Toileting	☐	☐	☐
SPHINCTER CONTROL			
G. Bladder	☐	☐	☐
H. Bowel	☐	☐	☐
TRANSFERS			
I. Bed, Chair, Wheelchair	☐	☐	☐
J. Toilet	☐	☐	☐
K. Tub, Shower	☐	☐	☐
LOCOMOTION (W - Walk, C - Wheelchair, B - Both)			
L. Walk/Wheelchair	☐☐	☐☐	☐
M. Stairs	☐	☐	☐
COMMUNICATION (A - Auditory, V - Visual, B - Both)			
N. Comprehension	☐☐	☐☐	☐
O. Expression (V - Vocal, N - Nonvocal, B - Both)	☐☐	☐☐	☐
SOCIAL COGNITION			
P. Social Interaction	☐	☐	☐
Q. Problem Solving	☐	☐	☐
R. Memory	☐	☐	☐

FIM LEVELS

No Helper
7 Complete Independence (Timely, Safely)
6 Modified Independence (Device)

Helper - Modified Dependence
5 Supervision (Subject = 100%)
4 Minimal Assistance (Subject = 75% or more)
3 Moderate Assistance (Subject = 50% or more)

Helper - Complete Dependence
2 Maximal Assistance (Subject = 25% or more)
1 Total Assistance (Subject less than 25%)

0 Activity does not occur; Use this code only at admission

DRAFT

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Appendix E: Inpatient Rehabilitation Facility – Patient Assessment Instrument

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTER FOR MEDICARE & MEDICAID SERVICES

OMB No. 0938-0842

Identification Information*

1. Facility Information
   A. Facility Name ______
   B. Facility Medicare Provider Number ______
2. Patient Medicare Number ______
3. Patient Medicaid Number ______
4. Patient First Name ______
5A. Patient Last Name ______
5B. Patient Identification Number ______
6. Birth Date __/__/____ MM / DD / YYYY
7. Social Security Number ______
8. Gender (*1 - Male; 2 - Female*) ______
9. Race/Ethnicity (*Check all that apply*)
   - American Indian or Alaska Native A. ____
   - Asian B. ____
   - Black or African American C. ____
   - Hispanic or Latino D. ____
   - Native Hawaiian or Other Pacific Islander E. ____
   - White F. ____
10. Marital Status ______
    (*1 - Never Married; 2 - Married; 3 - Widowed; 4 - Separated; 5 - Divorced*)
11. Zip Code of Patient's Pre-Hospital Residence ______
12. Admission Date __/__/____ MM / DD / YYYY
13. Assessment Reference Date __/__/____ MM / DD / YYYY
14. Admission Class
    (*1 - Initial Rehab; 2 - Evaluation; 3 - Readmission; 4 - Unplanned Discharge; 5 - Continuing Rehabilitation*)
15A. Admit From
    (*01- Home (private home/apt., board/care, assisted living, group home, transitional living); 02- Short-term General Hospital; 03 - Skilled Nursing Facility (SNF); 04 - Intermediate care; 06 - Home under care of organized home health service organization; 50 - Hospice (home); 51 - Hospice (institutional facility); 61 - Swing bed; 62 - Another Inpatient Rehabilitation Facility; 63 - Long-Term Care Hospital (LTCH); 64 - Medicaid Nursing Facility; 65 - Inpatient Psychiatric Facility; 66 - Critical Access Hospital; 99 - Not Listed*)
16A. Pre-hospital Living Setting ______
    Use codes from 15A. Admit From
17. Pre-hospital Living With ______
    (*Code only if item 16A is 01- Home: Code using 01 - Alone; 02 - Family/Relatives; 03 - Friends; 04 - Attendant; 05 - Other*)
18. DELETED
19. DELETED

Payer Information*

20. Payment Source
    (*02 - Medicare Fee For Service; 51- Medicare-Medicare Advantage; 99 - Not Listed*)
    A. Primary Source ______
    B. Secondary Source ______

Medical Information*

21. Impairment Group ______ Admission ______ Discharge
    Condition requiring admission to rehabilitation; code according to Appendix A.
22. Etiologic Diagnosis A. ____ B. ____ C. ____
    (*Use ICD codes to indicate the etiologic problem that led to the condition for which the patient is receiving rehabilitation*)
23. Date of Onset of Impairment __/__/____ MM / DD / YYYY
24. Comorbid Conditions
    Use ICD codes to enter comorbid medical conditions

A. ____	J. ____	S. ____
B. ____	K. ____	T. ____
C. ____	L. ____	U. ____
D. ____	M. ____	V. ____
E. ____	N. ____	W. ____
F. ____	O. ____	X. ____
G. ____	P. ____	Y. ____
H. ____	Q. ____	
I. ____	R. ____	

24A. Are there any arthritis conditions recorded in items #21, #22, or #24 that meet all of the regulatory requirements for IRF classification (in 42 CFR 412.29(b)(2)(x), (xi), and (xii))? ______ *(0 - No; 1 - Yes)*

25. DELETED
26. DELETED

Height and Weight
(While measuring if the number is X.1-X.4 round down, X.5 or greater round up)

25A. Height on admission (in inches) ______
26A. Weight on admission (in pounds) ______
    Measure weight consistently, according to standard facility practice (e.g., in a.m. after voiding, with shoes off, etc.)
27. Swallowing Status ______ Admission ______ Discharge
    3- *Regular Food*: solids and liquids swallowed safely without supervision or modified food consistency
    2- *Modified Food Consistency/Supervision*: subject requires modified food consistency and/or needs supervision for safety
    1- *Tube/Parenteral Feeding*: tube/parenteral feeding used wholly or partially as a means of sustenance
28. DELETED

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Version 1.3
Effective October 1, 2015

Function Modifiers*

Complete the following specific functional items prior to scoring the FIM™ Instrument:

	Admission	Discharge
29. Bladder Level of Assistance (Score using FIM Levels 1 - 7)	☐	☐
30. Bladder Frequency of Accidents (Score as below)	☐	☐

7 - No accidents
6 - No accidents; uses device such as a catheter
5 - One accident in the past 7 days
4 - Two accidents in the past 7 days
3 - Three accidents in the past 7 days
2 - Four accidents in the past 7 days
1 - Five or more accidents in the past 7 days

Enter in Item 39G (Bladder) the lower (more dependent) score from Items 29 and 30 above

	Admission	Discharge
31. Bowel Level of Assistance (Score using FIM Levels 1 - 7)	☐	☐
32. Bowel Frequency of Accidents (Score as below)	☐	☐

7 - No accidents
6 - No accidents; uses device such as a ostomy
5 - One accident in the past 7 days
4 - Two accidents in the past 7 days
3 - Three accidents in the past 7 days
2 - Four accidents in the past 7 days
1 - Five or more accidents in the past 7 days

Enter in Item 39H (Bowel) the lower (more dependent) score of Items 31 and 32 above.

	Admission	Discharge
33. Tub Transfer	☐	☐
34. Shower Transfer	☐	☐

(Score Items 33 and 34 using FIM Levels 1 - 7; use 0 if activity does not occur) *See training manual for scoring of Item 39K (Tub/Shower Transfer)*

	Admission	Discharge
35. Distance Walked	☐	☐
36. Distance Traveled in Wheelchair	☐	☐

(Code items 35 and 36 using: 3 - 150 feet; 2 - 50 to 149 feet; 1 - Less than 50 feet; 0 – activity does not occur)

	Admission	Discharge
37. Walk	☐	☐
38. Wheelchair	☐	☐

(Score Items 37 and 38 using FIM Levels 1 - 7; 0 if activity does not occur) See training manual for scoring of Item 39L (Walk/Wheelchair)

39. FIM™ Instrument*

	Admission	Discharge	Goal
SELF-CARE			
A. Eating	☐	☐	☐
B. Grooming	☐	☐	☐
C. Bathing	☐	☐	☐
D. Dressing - Upper	☐	☐	☐
E. Dressing - Lower	☐	☐	☐
F. Toileting	☐	☐	☐
SPHINCTER CONTROL			
G. Bladder	☐	☐	☐
H. Bowel	☐	☐	☐
TRANSFERS			
I. Bed, Chair, Wheelchair	☐	☐	☐
J. Toilet	☐	☐	☐
K. Tub, Shower	☐	☐	☐
LOCOMOTION (W - Walk, C - Wheelchair, B - Both)			
L. Walk/Wheelchair	☐ ☐	☐ ☐	☐
M. Stairs	☐	☐	☐
COMMUNICATION (A - Auditory, V - Visual, B - Both)			
N. Comprehension	☐ ☐	☐ ☐	☐
O. Expression (V - Vocal, N - Nonvocal, B - Both)	☐ ☐	☐ ☐	☐
SOCIAL COGNITION			
P. Social Interaction	☐	☐	☐
Q. Problem Solving	☐	☐	☐
R. Memory	☐	☐	☐

FIM LEVELS

No Helper
7 Complete Independence (Timely, Safely)
6 Modified Independence (Device)

Helper - Modified Dependence
5 Supervision (Subject = 100%)
4 Minimal Assistance (Subject = 75% or more)
3 Moderate Assistance (Subject = 50% or more)

Helper - Complete Dependence
2 Maximal Assistance (Subject = 25% or more)
1 Total Assistance (Subject less than 25%)

0 Activity does not occur; Use this code only at admission

Discharge Information*

40. Discharge Date ___/___/______ MM / DD / YYYY

41. Patient discharged against medical advice? ______ *(0 - No; 1 - Yes)*

42. Program Interruption(s) ______ *(0 - No; 1 - Yes)*

43. Program Interruption Dates
(Code only if item 42 is 1 - Yes)

A. 1st Interruption Date [ ] MM / DD / YYYY
B. 1st Return Date [ ] MM / DD / YYYY

C. 2nd Interruption Date [ ] MM / DD / YYYY
D. 2nd Return Date [ ] MM / DD / YYYY

E. 3rd Interruption Date [ ] MM / DD / YYYY
F. 3rd Return Date [ ] MM / DD / YYYY

44C. Was the patient discharged alive? ______ *(0 - No; 1 - Yes)*

44D. Patient's discharge destination/living setting, using codes below: (answer only if 44C = 1; if 44C = 0, skip to item 46) ______

(01- Home (private home/apt., board/care, assisted living, group home, transitional living); 02- Short-term General Hospital; 03 - Skilled Nursing Facility (SNF); 04 - Intermediate care; 06 - Home under care of organized home health service organization; 50 - Hospice (home); 51 - Hospice (institutional facility); 61 - Swing bed; 62 - Another Inpatient Rehabilitation Facility; 63 - Long-Term Care Hospital (LTCH); 64 - Medicaid Nursing Facility; 65 - Inpatient Psychiatric Facility; 66 - Critical Access Hospital; 99 - Not Listed)

45. Discharge to Living With ______
(Code only if item 44C is 1 - Yes and 44D is 01 - Home; Code using 1 - Alone; 2 - Family / Relatives; 3 - Friends; 4 - Attendant; 5 - Other)

46. Diagnosis for Interruption or Death ______
(Code using ICD code)

47. Complications during rehabilitation stay
(Use ICD codes to specify up to six conditions that began with this rehabilitation stay)

A. ______ B. ______
C. ______ D. ______
E. ______ F. ______

* The FIM data set, measurement scale and impairment codes incorporated or referenced herein are the property of U B Foundation Activities, Inc. © 1993, 2001 U B Foundation Activities, Inc. The FIM mark is owned by UBFA, Inc.

Therapy Information

O0401. Week 1: Total Number of Minutes Provided

O0401A: Physical Therapy
a. Total minutes of individual therapy ______
b. Total minutes of concurrent therapy ______
c. Total minutes of group therapy ______
d. Total minutes of co-treatment therapy ______

O0401B: Occupational Therapy
a. Total minutes of individual therapy ______
b. Total minutes of concurrent therapy ______
c. Total minutes of group therapy ______
d. Total minutes of co-treatment therapy ______

O0401C: Speech-Language Pathology
a. Total minutes of individual therapy ______
b. Total minutes of concurrent therapy ______
c. Total minutes of group therapy ______
d. Total minutes of co-treatment therapy ______

O0402. Week 2: Total Number of Minutes Provided

O0402A: Physical Therapy
a. Total minutes of individual therapy ______
b. Total minutes of concurrent therapy ______
c. Total minutes of group therapy ______
d. Total minutes of co-treatment therapy ______

O0402B: Occupational Therapy
a. Total minutes of individual therapy ______
b. Total minutes of concurrent therapy ______
c. Total minutes of group therapy ______
d. Total minutes of co-treatment therapy ______

O0402C: Speech-Language Pathology
a. Total minutes of individual therapy ______
b. Total minutes of concurrent therapy ______
c. Total minutes of group therapy ______
d. Total minutes of co-treatment therapy ______

	Quality Indicators- Admission Assessment		Quality Indicators- Discharge Assessment
Enter Code ☐	**Unhealed Pressure Ulcer(s)- Admission** **M0210.** Does this patient have one or more unhealed pressure ulcer(s) at Stage 1 or higher at Admission? **0.** No → skip to question **I0900 on Admission Assessment** **1. Yes** → continue to question **M0300A on Admission Assessment**	Enter Code ☐	**Unhealed Pressure Ulcer(s)- Discharge** **M0210.** Does this patient have one or more unhealed pressure ulcer(s) at Stage 1 or higher on Discharge? **0. No**→ skip to question **M0900A on Discharge Assessment** **1. Yes** → continue to question **M0300A on Discharge Assessment**
	M0300. Current Number of Unhealed Pressure Ulcers at Each Stage- Admission		**M0300. Current Number of Unhealed Pressure Ulcers at Each Stage- Discharge**
Enter Number ☐	**M0300A. Stage 1:** Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have a visible blanching; in dark skin tones it may appear with persistent blue or purple hues. **M0300A1. Number of Stage 1 pressure ulcers:** enter how many were noted at the time of admission	Enter Number ☐ Enter Number ☐ Enter Number ☐	**M0300A. Stage 1:** Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have a visible blanching; in dark skin tones it may appear with persistent blue or purple hues. **M0300A1.** Enter **total** number of pressure ulcers currently at **Stage** 1. **If patient has no Stage 1 pressure ulcers at discharge, skip to Item M0300B1.** **M0300A2.** Of **<u>these</u> Stage 1** pressure ulcers present at discharge, enter number that were: (a) present on admission as a Stage 1 **and** (b) remained at Stage 1 at discharge. **M0300A3.** Of **<u>these</u>** Stage 1 pressure ulcers, enter the number that were **not present on admission.** (i.e. – New stage 1 pressure ulcers that have developed during the IRF stay)
Enter Number ☐	**M0300B. Stage 2:** Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister. **M0300B1. Number of Stage 2 pressure ulcers:** enter how many were noted at the time of admission	Enter Number ☐ Enter Number ☐ Enter Number ☐ Enter Number ☐	**M0300B. Stage 2:** Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister. **M0300B1.** Enter **total** number of pressure ulcers currently at Stage **2. (If patient has no Stage 2 pressure ulcers at discharge, skip to Item M0300C1.)** **M0300B2.** Of **<u>these</u> Stage 2** pressure ulcers present at discharge, enter the number that were: (a) present on admission, **and** (b) remained at Stage 2 at discharge. **M0300B3.** Of **<u>these</u> Stage 2** pressure ulcers present at discharge, enter the number that were: (a) present on admission as an **unstageable pressure ulcer** due to the presence of a **non-removable device and** (b) when it became stageable, the pressure ulcer was staged as a Stage 2, **and** (c) it remained at Stage 2 at the time of discharge. **M0300B4. Of <u>these</u>** Stage 2 pressure ulcers present at discharge, enter the number that were: (a) not present on admission; **or** (b) were at a lesser stage at admission and worsened to a Stage 2 during the IRF stay

	Quality Indicators- Admission Assessment, Continued		Quality Indicators-Discharge Assessment, Continued
	M0300. Current Number of Unhealed Pressure Ulcers at Each Stage- Admission, Continued		**M0300. Current Number of Unhealed Pressure Ulcers at Each Stage-Discharge, Continued**
	M0300C. Stage 3: Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.		**M0300C. Stage 3:** Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.
Enter Number ☐	**M0300C1. Number of Stage 3 pressure ulcers:** enter how many were noted at the time of admission	Enter Number ☐	**M0300C1.** Enter **total** number of pressure ulcers currently at **Stage 3. (If patient has no Stage 3 pressure ulcers at discharge, skip to Item M0300D1.**
		Enter Number ☐	**M0300C2.** Of **these Stage 3** pressure ulcers present at discharge, enter the number that were: (a) present on admission, **and** (b) remained at Stage 3 at discharge.
		Enter Number ☐	**M0300C3.** Of **these Stage 3** pressure ulcers present at discharge, enter the number that were: (a) present on admission as an **unstageable pressure ulcer, and** (b) when it became stageable, it was staged as a **Stage 3; and** (c) it remained at **Stage 3** at the time of discharge.
		Enter Number ☐	**M0300C4.** Of **these Stage 3** pressure ulcers present at discharge, enter the number that were: (a) not present on admission; **or** (b) were at a lesser stage at admission and worsened to a Stage 3 during the IRF stay; **or** (c) were unstageable due to a non-removeable device at admission, initially became stageable at a lesser stage, , but then progressed to a Stage 3 by the time of discharge.
	M0300D. Stage 4: Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.		**M0300D. Stage 4:** Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.
Enter Number ☐	**M0300D1. Number of Stage 4 pressure ulcers:** enter how many were noted at the time of admission	Enter Number ☐	**M0300D1.** Enter **total** number of pressure ulcers currently at **Stage** 4. **(If patient has no Stage 4 pressure ulcers at discharge, skip to Item M0300E1.)**
		Enter Number ☐	**M0300D2. Of these Stage 4** pressure ulcers present at discharge, enter number that were: (a) present on admission at Stage 4 , **and** (b) remained at Stage 4 at discharge.
		Enter Number ☐	**M0300D3. Of these Stage 4** pressure ulcers present at discharge, enter the number that were: (a) present on admission as an **unstageable pressure ulcer, and** (b) when it became stageable, it was staged as a **Stage 4**, and (c) it remained at **Stage 4** at the time of discharge.
		Enter Number ☐	**M0300D4. Of these Stage 4** pressure ulcers present at discharge, enter the number that were: (a) not present on admission); **or** (b) were at a lesser stage at admission and worsened to a Stage 4 by discharge; or (c) were unstageable on admission, initially became stageable at a lesser stage, and then progressed to a Stage 4 by the time of discharge.

	Quality Indicators-Admission Assessment, Continued		Quality Indicators-Discharge Assessment, Continued
Enter Number ☐	**M0300E. Unstageable Pressure Ulcers due to non-removable dressing/device:** Known but not stageable due to the presence of a non-removable dressing/device. **M0300E1. Number of unstageable pressure ulcers due to non-removable dressing/device**: enter how many were noted at the time of admission	Enter Number ☐ Enter Number ☐ Enter Number ☐	**M0300E. Unstageable Pressure Ulcers due to a non-removable dressing or device:** pressure ulcers that are known but not stageable due to the presence of a non-removable dressing or device. **M0300E1.** Enter **total** number of pressure ulcers currently **Unstageable** due to a **Non-removable dressing or device.** **(If patient has no pressure ulcers Unstageable due to Non-Removable Device at discharge, skip to Item M0300F1.)** **M0300E2.** Of **<u>these</u> Unstageable** pressure ulcers due to a **non-removable dressing** or **device** present at discharge, enter number that were:(a) present on admission as an unstageable pressure ulcer due to **non-removable dressing or device**; **and** (b) remained unstageable due to **non-removable dressing or device** until discharge. **M0300E3. Of <u>these</u> Unstageable** pressure ulcers due to **non-removable dressing or device** present at discharge, enter number that were (a) present on admission as a stageable pressure ulcer **and** became **unstageable due to non-removable dressing or device** during the IRF stay; and (b) remained unstageable due to a **non-removable dressing** or **device** until discharge.
Enter Number ☐	**M0300F. Unstageable Pressure Ulcers due to slough and/or eschar:** pressure ulcers that are known but not stageable due to coverage of wound bed by slough and/or eschar. **M0300F1. Number of unstageable pressure ulcers due to slough and/ or eschar**: enter how many were noted at the time of admission	Enter Number ☐ Enter Number ☐ Enter Number ☐	**M0300F. Unstageable Pressure Ulcers due to slough or eschar:** pressure ulcers that are known but not stageable due to coverage of wound bed by slough and/or eschar. **M0300F1.** Enter **total** number of pressure ulcers currently **Unstageable** due to a **Slough and/or Eschar.** **(If patient has no pressure ulcers Unstageable due to Slough and/or Eschar at discharge, skip to Item M0300G1.)** **M0300F2. Of <u>these</u> Unstageable** pressure ulcers due to **slough and/or eschar** present at discharge, enter number that were: (a) present on admission as an unstageable pressure ulcer due to **slough and/or eschar**; **and** (b) remained unstageable due to **slough and/or eschar** until discharge. **M0300F3. Of <u>these</u> Unstageable** pressure ulcers due to **slough or eschar** present at discharge, enter number that were: (a) present on admission as a stageable pressure ulcer **and** became unstageable due to **slough and/or eschar**, during the IRF stay; **and** (b) remained unstageable due to **slough and/or eschar** until discharge.
Enter Number ☐	**M0300G. Unstageable Pressure Ulcers with Suspected Deep Tissue Injury (DTI) in evolution:** suspected deep tissue injury in evolution. **M0300G1. Number of unstageable pressure ulcers with Suspected Deep Tissue Injury in evolution:** enter how many were noted at the time of admission	Enter Number ☐ Enter Number ☐	**M0300G. Unstageable Pressure Ulcers with Suspected Deep Tissue Injury (DTI) in evolution:** suspected deep tissue injury in evolution. **M0300G1.** Enter **total** number of **unstageable pressure ulcers with Suspected Deep Tissue Injury.** **(If patient has no Unstageable pressure ulcers with Suspected Deep Tissue Injury at discharge, skip to Item M0900A.)** **M0300G2. Of <u>these</u> unstageable pressure ulcers with Suspected DTI** present at discharge, enter number that were:(a) present on admission as an unstageable pressure ulcer due to a **suspected deep tissue injury**, **and** (b) remained unstageable due to a **suspected DTI** until discharge.

Quality Indicators- Admission Assessment, Continued		Quality Indicators-Discharge Assessment, Continued	
	I0900. Pressure Ulcer Risk Conditions- Admission		**M0900. Healed Pressure Ulcers- Discharge**
	Indicate below if the patient has any of the following pressure ulcer risk conditions: (**NOTE:** You must also document the appropriate ICD codes for any pressure ulcer risk conditions documented below in Item 24 "Comorbid Conditions" above.)		Indicate the number of pressure ulcers that were: (a) present on **Admission**; **and** (b) have completely closed (resurfaced with epithelium) upon **Discharge.** If there are no healed pressure ulcers noted at a given stage, enter 0.
Enter Number ☐	**I0900A.** Peripheral Vascular Disease (PVD) 0. No 1. Yes	Enter Number ☐	**M0900A.** Stage 1
Enter Number ☐	**I0900B.** Peripheral Arterial Disease(PAD) 0. No 1. Yes	Enter Number ☐	**M0900B.** Stage 2
Enter Number ☐	**I2900A.** Diabetes Mellitus (DM) ***If I2900A = 0, skip I2900B-D*** 0. No 1. Yes	Enter Number ☐	**M0900C.** Stage 3
Enter Number ☐	**I2900B.** Diabetic Retinopathy 0. No 1. Yes	Enter Number ☐	**M0900D.** Stage 4
Enter Number ☐	**I2900C.** Diabetic Nephropathy 0. No 1. Yes		
Enter Number ☐	**I2900D.** Diabetic Neuropathy 0. No 1. Yes		
			O0250. Influenza Vaccine – Discharge - Refer to current version of IRF-PAI Training Manual for current influenza vaccination season and reporting period.
		Enter Code ☐	**O0250A.** Did the **patient receive the influenza vaccine *in this facility*** for this year's influenza *vaccination* season? **0. No →** Skip to O0250C, If influenza vaccine not received, state reason **1. Yes →** Continue to O0250B, Date influenza vaccine received
			O0250B. Date influenza vaccine received → Complete date and skip to Z0400A, Signature of Persons Completing the Assessment ☐☐ ☐☐ ☐☐☐☐ MM DD YYYY
		Enter Code ☐	**O0250C. If influenza vaccine not received, state reason:** **1. Patient not in this facility** during this year's influenza vaccination season **2. Received outside of this facility** **3. Not eligible** - medical contraindication **4. Offered and declined** **5. Not offered** **6. Inability to obtain influenza vaccine** due to a declared shortage. **9. None of the above**

Item Z0400A. Signature of Persons Completing the Assessment[a]

I certify that the accompanying information accurately reflects patient assessment information for this patient and that I collected or coordinated collection of this information on the dates specified. To the best of my knowledge, this information was collected in accordance with applicable Medicare and Medicaid requirements. I understand that this information is used as a basis for ensuring that patients receive appropriate and quality care, and as a basis for payment from federal funds. I further understand that payment of such federal funds and continued participation in the government-funded health care programs is conditioned on the accuracy and truthfulness of this information, and that I may be personally subject to or may subject my organization to substantial criminal, civil, and/or administrative penalties for submitting false information.

Signature	Title	Date Information is Provided	Time
A.			
B.			
C.			
D.			
E.			
F.			
G.			
H.			
I.			
J.			
K.			
L.			

Appendix F:

BRIGHAM AND WOMEN'S HOSPITAL
A Teaching Affiliate of Harvard Medical School
75 Francis St., Boston, Massachusetts 02115

Department of Rehabilitation Services

Total Knee Arthroplasty Protocol:

The intent of this physical therapy protocol is to provide the clinician with a guideline of the post-operative rehabilitation course of a patient who has undergone a total knee arthroplasty (TKA) at Brigham and Women's Hospital (BWH). It is by no means intended to be a substitute for one's clinical decision making regarding the progression of a patient's post-operative course based on their physical exam/findings, individual progress, and/or the presence of post-operative complications. If a clinician requires assistance in the progression of a post-operative patient, the clinician should consult with the referring surgeon.

This physical therapy protocol applies to primary total knee arthroplasty. In a revision total knee arthroplasty, or in cases where there is more connective tissue involvement, Phase I and II should be progressed with more caution to ensure adequate healing.

Progression to the next phase is based on Clinical Criteria and/or Time Frames as appropriate.

Pain Management
Adequate pain control after TKA is important in expediting patient progress with mobility and range of motion after surgery. This in turn may result in a shorter hospital stay and improved patient satisfaction.

Pain management following TKA at Brigham and Women's Hospital (BWH) is multimodal and may include:

- *Pre-operative dose of medications* including Acetaminophen and/or Celebrex.
- *Spinal or epidural analgesia* – Administered as a continuous infusion or as a one-time dose, lasting 6-8 hours. Intrathecal opioids may be added to the anesthetic cocktail. Side effects of epidural injection may include low blood pressure and decreased motor function. If a continuous infusion is used, it is typically stopped at 6am on post-operative day #1.
- *Peripheral nerve blocks* – Femoral and/or sciatic nerveblocks may be administered as a continuous infusion for a period following surgery, or as a one-time dose, lasting 6-8 hours. If a continuous infusion is used, it is typically stopped at 6am on post-operative day #1. Potential side-effects may include nerve damage and a lack of muscle control in the immediate post-operative period.
- *IV or oral analgesics* – This may include use of an opioid Patient-Controlled Analgesia (PCA). Post-operative pain medications may include *opiods* (short-acting and continuous-release Oxycodone, Dilaudid, Morphine), *centrally-acting analgesics* (Acetaminophen), *anti-inflammatory agents* (NSAIDs, COX-2 inhibitors, Ketorolac), *α-agonists* (Gabapentin, Tramadol), and/or *transdermal patches* (typically an opioid such as Fentanyl, used in conjunction with oral pain regiment).
- *Local analgesics* - intra-articular or periarticular injections during TKA surgery may be used for post-operative pain control and to improve range-of-motion (ROM).

Intra-articular injections may include a combination of ropivicaine, epinephrine, Ketorlac, and clonididne.

Due to the use of epidural anesthesia and/or peripheral nerve blocks at BWH, it is important to assess the extent of motor and sensory block the first 48 hours after surgery. Patients' must demonstrate adequate quadriceps and lower extremity motor control to participate safely in out-of-bed (OOB) activities.

Phase I – Immediate Post Surgical Phase (Day 0-3):

The goal of physical therapy intervention during the early post-operative phase is to decrease swelling, increase range of motion, enhance muscle control and strength in the involved lower extremity and maximize patients' mobility with a goal of functional independence. Physical therapy interventions are also directed towards identifying other sensomotor or systemic conditions that may influence a patients' rehabilitation potential.

Goals:

The patient will:

1. Perform bed mobility and transfers with the least amount of assistance while maintaining appropriate weight bearing (WB) precautions.
2. Ambulate with an assistive device for 25-100 feet and ascend/descend stairs to allow for independence with household activities while maintaining appropriate WB.
3. Regain at least 80 degrees of passive and active range of motion in the knee to perform sit to stand transfers with minimal compensatory activity.
4. Gain knee extension less than or equal to -10 degrees.
5. Independently perform operative extremity Straight Leg Raise (SLR) exercise.
6. Verbalize understanding of post-operative activity recommendations/precautions including use of proper positioning of the lower extremity, range of motion and strengthening exercises.
7. Patients will also be educated on superficial massage of the knee joint to minimize hypersensitivity following surgery.

Use of a *Continuous Passive Motion* (CPM) machine is not part of the standard of care for patient's s/p TKR at BWH. Use of a CPM *may* be indicated according to surgeon preference, or in cases where post-operative knee range-of-motion (ROM) is severely restricted due to revision or reconstructive surgery, severe post-operative pain, limb girth and/or edema, or impaired ability to participate in ROM exercises.

Observation and Assessment:

- **Observe for any signs of deep vein thrombosis (DVT): increased swelling, erthymia, calf pain.**

- If a large amount of drainage is present, or there is blistering or frail skin around the knee joint or the lower extremities, discuss with the nurse and decide if notifying the surgical team is indicated.
- Assess patients' pain using the visual analogue scale. Ensure that patients are premedicated with oral/IV pain medication 30-60 minutes prior to treatment. Cryotherapy is recommended following physical therapy treatment to reduce pain, discomfort and swelling in the knee joint.

Therapeutic exercise and functional mobility:

- Active/active assisted/passive (A/AA/PROM) exercises (seated and supine).
- Patella femoral and tibial femoral joint mobilization and soft tissue mobilization as indicated.
- Soft tissue massage.
- Isometric quadriceps, hamstring, and gluteal isometric exercises.
- Straight leg raises (SLR)
- Lower extremity range of motion (ROM) and strengthening as indicated based on evaluation findings.
- Closed chain exercises (if patient demonstrates good pain control, muscle strength and balance). Close-chained exercises should be performed with bilateral upper extremity support while maintaining appropriate WB precautions.
- Gait training on flat surfaces and on stairs.
- Transfer training.

Modalities:

- Continuous Cryotherapy for 72 hours after surgery, or at least 5 times/day.
- Patients are encouraged to use cryotherapy for 20 minutes before and after their independent exercise program.

Precautions:

- Weight bearing as tolerated (WBAT) with assistive device (unless indicated otherwise by the surgeon) to full weight bearing.
- Monitor wound healing and consult with referring MD if signs and symptoms of excessive bleeding and poor incision integrity are present.
- Monitor for signs of DVT, pulmonary embolism (PE), and/or loss of peripheral nerve integrity. In these cases, notify the MD immediately.
- No exercises with weights or resistance.
- Avoid torque or twisting forces across the knee joint especially when WB on involved limb.

Positioning:

- A trochanter roll should be used as needed to maintain neutral hip rotation and promote knee extension.

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- A towel roll should be placed at the ankle to promote knee extension when patients are supine in bed.
- Nothing should be placed behind the operative knee, to promote maximal knee extension and prevent knee flexion contracture.

Criteria for progression to the next phase:

- Ability to demonstrate Quadriceps contraction and/or perform a straight leg raise (SLR)
- Active knee range of motion (AROM) -10°-80°
- Minimal pain and inflammation
- Independent transfers and ambulation at least 100 feet with appropriate assistive device.

Phase II – Motion Phase (Day 3 – Week 6)

Goals:

- Improve knee active range of motion (AROM) to >/= 0-110 degrees
- Muscle strengthening of the entire operative extremity with emphasis on knee extensor and flexor muscle groups.
- Attention should also be directed toward any weakness present in the operative extremity as well as any generalized weakness in the upper extremities, trunk or contralateral lower extremity.
- Proprioceptive training to improve body/spatial awareness of the operative extremity in functional activities.
- Endurance training to increase cardiovascular fitness.
- Functional training to promote independence in activities of daily living and mobility.
- Gait training: Assistive devices are discontinued when the patient demonstrates adequate lower extremity strength and balance during functional activities (usually 1-4 weeks)
- Decrease inflammation/swelling
- Return to functional activities

Therapeutic Exercises:
Weeks 1-4

- AA/A/PROM, stretching for flexion (>90 degrees) and extension
- Stationary Bicycle for ROM, begin with partial revolutions then progress as tolerated to full revolutions (no resistance).
- Patella femoral and tibial femoral joint mobilization as indicated.
- Continue isometric quadriceps, hamstring, and gluteal isometric exercises
- Supine heel slides and seated Long Arc Quad (LAQ)
- SLR in 4 planes (flexion, abduction, adduction, extension)

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- Neuromuscular electrical stimulation (NMES) for quads if poor quad contraction is present. NMES parameters to be set based on goal of exercise/activity. See neuromuscular electrical stimulation procedural standard of care for specific details.)
- Gait training to improve function and quality of involved limb performance during swing through and stance phase. Patients are encouraged to wean off their assistive device at the latest by the end of second week from surgery.
- Postural cues/ reeducation during all functional activities as indicated.

Weeks 4-6

- Continue above exercises
- Continue patella femoral and tibial femoral joint mobilization as indicated.
- Continue NMES of quads if poor muscular performance of quad is present. May progress NMES use from isometric quad activity to isotonic and functional activity
- Front and lateral step up and step down.
- 1/4 front lunge.
- Use sit to stand and chair exercises to increase knee flexion during functional tasks.
- Continue stationary bicycle for ROM
- Begin pool program if incision is completely healed

*Note: Exercises with resistance may be initiated *as tolerated* for operative extremity after goals for the first phase have been met, and the patient has met criteria for progression to the next phase.

Modalities:

- Cryotherapy 1-3x/day for swelling and pain management.
- Other modalities at the discretion of the therapist based on clinical findings (Please see Department of Rehabilitation Services Modality specific procedures).

Precautions:

- WBAT with assistive device as needed to minimize compensatory gait. Patient may be encouraged to use a straight cane within one week of surgery if he/she is WBAT to FWB. Patients may be weaned from assistive device by 2 weeks if they did not use an assistive device preoperatively and post-operative muscle performance is adequate for weight acceptance.
- Monitor wound healing and consult with referring MD if signs and symptoms of infection are present.
- Monitor for increased edema and continue with cryotherapy as needed.

Criteria for progression to the next phase:

- AROM 0-110'
- Good voluntary quadriceps control

- Independent ambulation community distances (>/= 800 feet), without assistive device, deviations or antalgia
- Minimal pain and inflammation

Phase III – Intermediate phase (week 7-12):

Goals:

- Maximize post-operative ROM (0-115 degrees plus)
- Good patella femoral mobility.
- Good strength all lower extremity musculature.
- Return to most functional activities and begin light recreational activities (i.e. walking, pool program)

Therapeutic Exercises:

- Continue exercises listed in Phase II with progression including resistance and repetitions. It is recommended to assess hip/knee and trunk stability at this time and provide patients with open/closed chain activities that are appropriate for each patient's individual needs.
- Continue patella femoral and tibial femoral joint mobilization as indicated.
- Initiate endurance program, walking and/or pool.
- Initiate and progress age-appropriate balance and proprioception exercises.
- Discontinue NMES of quads when appropriate quad activity is present.

Criteria for progression to next phase:

- AROM without pain, or plateaued AROM based on preoperative ROM status.
- 4+/5 muscular performance based on MMT of all lower extremity musculature.
- Minimal to no pain or swelling.

Phase IV – Advanced strengthening and higher level function stage (week 12-16):

Goals:

- Return to appropriate recreational sports / activities as indicated
- Enhance strength, endurance and proprioception as needed for activities of daily living and recreational activities

Therapeutic Exercises:

- Continue previous exercises with progression of resistance and repetitions.
- Increased duration of endurance activities.
- Initiate return to specific recreational activity: golf, doubles tennis, progressive walking or biking program.

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Criteria for Discharge:
(These are general guidelines as patients may progress differently depending on previous level of function and individual goals.)

- Non-antalgic, independent gait
- Independent step over step stair climbing
- Pain-free AROM
- At least 4+/5 muscular performance based on MMT of all lower extremity musculature.
- Normal, age appropriate balance and proprioception.
- Patient is independent with home exercise program.

Permission to reprint the Total Knee Protocol was obtained by the Department of Rehabilitation at the Brigham and Women’s Hospital.