

GAIT MECHANICS IN THE EARLY POST-SURGERY PERIOD FOLLOWING
TOTAL KNEE ARTHROPLASTY

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Keywords: Total knee arthroplasty; kinetics; kinematics

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ABSTRACT

Purpose

Total knee arthroplasty (TKA) surgeries in the United States are estimated to increase to 3.48 million by 2030. The majority of previous TKA gait research involves post-surgery outcomes at two months to eight years after surgery. To date, no previous TKA investigations have involved three dimensional gait analyses as early as three weeks post-surgery. It is important to understand the effect of TKA on kinetic and kinematic variables to reduce the risk of further damage and deterioration of lower extremity joints. Therefore, the purpose of this study was to evaluate changes in kinetic and kinematic gait characteristics in TKA subjects during the early post-surgery period, in comparison to a control group.

Methods

A 2x2 repeated measures analysis of variance (ANOVA) design was used to compare seven TKA subjects and seven healthy, age-matched controls. Gait data including walking velocity, kinetic, and kinematic variables were collected at pre-surgery (PRE) and post-surgery (POST) test periods.

Results

The repeated measures ANOVA revealed significant differences ($p < 0.05$) between the groups and across test periods for maximum vertical ground reaction force (MVGRF) and maximum knee adduction moment (MKADM). Significant group differences were found regardless of test period for walking velocity and maximum knee varus angle (MKVA).

Conclusion

Within the limitations of this study relative to the small sample size, gait differences between the TKA and control groups were detected in the early post-surgery period.

Keywords: Total knee arthroplasty; kinetics; kinematics

CONTENTS

ACKNOWLEDGEMENTS	II
ABSTRACT	III
LIST OF TABLES	5
LIST OF FIGURES.....	6
PART I	7
Introduction	7
Method	8
Results	12
Discussion	13
PART II.....	21
Literature Review.....	21
APPENDIX A	35
APPENDIX B	36
APPENDIX C	38
APPENDIX D	40
APPENDIX E.....	44
APPENDIX F	52
APPENDIX G	55
APPENDIX H	57

LIST OF TABLES

<u>Table</u>	<u>Page</u>
1. Demographic data for TKA and control groups at PRE and POST test periods.....	14
2. Walking velocity, kinetic, and kinematic variables for TKA and control groups at PRE and POST test periods	15

LIST OF FIGURES

<u>Figure</u>	<u>Page</u>
1. Interaction effect for MVGRF for TKA and control groups at PRE and POST test periods.....	16
2. Interaction effect for MKADM for TKA and control groups at PRE and POST test periods.....	17
3. Group main effect for MKVA for TKA and control groups.....	18
4. Group main effect for walking velocity for TKA and control groups.....	19

PART I

Introduction

Total knee replacement (arthroplasty) surgeries in the United States almost quadrupled from 129,000 in 1990 to 402,100 in 2003 [1, 2] and are estimated to increase by 673% to 3.48 million by 2030 [1]. These increases are primarily due to the expected rise in the prevalence of osteoarthritis (OA) [3], which causes degeneration or complete loss of the articular cartilage, leaving the bony surface unprotected [4] and producing debilitating pain [5]. The most effective treatment for knee OA is total knee arthroplasty (TKA) [6, 7], involving replacement of the bony joint surfaces of the distal femur and proximal tibia with artificial joint components. The goal of TKA is to realign the knee with the hip and ankle joints to evenly distribute load across the articular surfaces [8]. Component alignment is essential for long-term stability of the replaced joint, as malalignment can lead to premature component loosening, one of the leading causes of early revision surgery and mechanical TKA failure [9, 10]. Altered gait mechanics have also been associated with subsequent component loosening [11]. Therefore, the study of gait in post-surgery TKA is of particular importance.

The majority of previous TKA gait research involves post-surgery outcomes at three months to eight years [12-19]. Results from these studies revealed increased walking ability with improvements in temporal-spatial parameters (velocity, cadence, stride length, step length, and stride time) increased knee range of motion (ROM), and decreased knee moments post-surgery. Conversely, one study indicated that at two months post-surgery, TKA subjects demonstrated slower walking speeds, decreased knee flexion ROM, reduced knee flexion moments, and an increased percentage of double

limb support while walking compared to pre-surgery values [20]. To our knowledge only one study involved investigation of TKA gait as early as 11.1 days post-surgery and found significant increases at day 15 in both walking speed and step length [21]. However, subjects performed walking trials in water to use buoyancy to reduce stresses on the operated joint, which may not provide an accurate representation of post-surgery gait.

To date, no previous TKA investigations have involved three dimensional gait analyses as early as three weeks post-surgery. It is important to understand the effect of TKA on kinetic and kinematic variables to reduce the risk of further damage and deterioration of lower extremity joints [22]. Therefore, the purpose of this study was to evaluate changes in kinetic and kinematic gait characteristics in TKA subjects during the early post-surgery period, in comparison to a control group.

Method

Research Design

A prospective longitudinal design using ten 2x2 Analysis of Variance (ANOVA) with Repeated Measures (RM) were used to compare the TKA and control groups, at pre-surgery (PRE), and at three to eight weeks (POST) post-surgery. Dependent variables included: walking velocity; kinetic data via: maximum vertical ground reaction force (MVGRF), maximum knee flexion moment (MKFM), maximum knee extension moment (MKEM), maximum knee abduction moment (MKABM), maximum knee adduction moment (MKADM); and kinematic data via: knee flexion angle at heel strike (KFAHS),

maximum knee flexion angle (MKFA), maximum knee varus angle (MKVA), and knee flexion excursion (KFE).

Subjects

Subjects were seven knee OA patients electing to undergo unilateral (n=6) or bilateral (n=1) TKA. All joint replacement surgeries were performed by the same Board Certified orthopedic surgeon fellowship trained in TKA who also prescribed the rehabilitation protocol. Signed Health Insurance Portability and Accountability Act (HIPAA) Release Forms (Appendix A) were obtained for the release of clinical information. Control subjects were a group of seven healthy controls recruited from the local community (Appendix B) who underwent medical screening prior to study participation. The control group also completed a medical history questionnaire (Appendix C) confirming that they were free of OA or any neuromuscular disease that could affect walking. Descriptive data for TKA and control groups is presented in Table 1. Prior to study enrollment, all subjects signed informed consent forms (Appendix D), which were approved by the University's Committee on Human Studies. Additionally, the TKA group also signed informed consent forms approved by the Western Institutional Review Board (Appendix E). Both TKA subjects and controls were excluded from the study if they had a history of previous lower extremity joint replacement, a neurological or orthopedic condition that affected walking, or if they required the use of an assistive device while walking [23, 24].

Surgical Approach

The standard medial parapatellar approach to TKA involves a midline skin incision of 12- to 18-cm in length [25] followed by medial retraction of the underlying tissues to expose the quadriceps muscles [25]. The quadriceps tendon is split approximately eight centimeters in length above the patella, extended distally over the patella and through the patellar ligament to the tibial tubercle [25]. The fibers of the quadriceps muscles are separated from the medial border of the patella. The patella is then dislocated laterally and the medial half of the quadriceps tendon is retracted over the medial femoral condyle [25]. After the joint is exposed, femoral and tibial bone cuts are made and resected. The components are typically aligned using intramedullary guides and the joint is checked for ROM, patellar tracking, and collateral ligament balance before components are cemented in place.

Data Collection

Subjects underwent pre- and post-surgery testing at the University's Human Performance Gait Laboratory. Pre-surgery (PRE) gait analysis took place within two weeks prior to surgery [15, 26, 27] and post-surgery (POST) gait analysis occurred within three to eight weeks post-surgery for the TKA group. The post-surgery evaluation for TKA subjects was completed at an average of 4.57 ± 1.71 weeks after surgery. Control subjects were tested at an initial collection period (PRE) and again three weeks later (POST). Subjects were instructed to wear comfortable clothing including loose fitting shorts during each data collection period. All data were collected by a Board of

Certification Certified Athletic Trainer (BOC-ATC). Height was measured using a wall-mounted stadiometer (Seca corp., Hanover, MD, USA) and body mass determined using a digital scale (Befour, Inc., Saukville, WI, USA). Subjects were then fitted with the Knee Alignment Device Alike set of 27 infrared retro reflective markers (1.4 cm in diameter) attached to the following anatomical locations: clavicle, C7 spinous process, T10 spinous process, right scapula, sternum, and bilaterally at the AC joints, ASIS, PSIS, thigh, medial and lateral knee, tibia, medial and lateral ankle, heel, and toe according to the Vicon manual (Vicon, Inc., Centennial, Colorado, USA) [28]. During testing, subjects walked barefoot at a comfortable, self-selected pace through a four meter data collection field, where walking velocity was determined using infrared timers (Speed Trap II, Brower Timing Systems, Draper, UT, USA) [26, 29-31]. Walking data included three “successful” trials on each lower extremity where the foot of the evaluated limb was placed completely on the force plate without altering gait (targeting) [23, 24]. Data included in the statistical analysis was limited to a single surgical limb for both unilateral and bilateral TKA subjects (left=5, right=2). The evaluated limb of control subjects was matched to that of the TKA group.

A three-dimensional (3D) motion capture system (Vicon MX, Vicon, Inc., Centennial, Colorado, USA), including six Vicon MX13 motion capture cameras (Vicon, Inc., Centennial, Colorado, USA) and Vicon software (Nexus and Polygon, Vicon, Inc., Centennial, Colorado, USA), was used to capture, reduce, and analyze kinematic data. Two force plates (Advanced Mechanical Technology Incorporated, Boston, Massachusetts, USA) embedded flush with the floor surface were used to collect kinetic data during walking trials. Kinematic data were collected at 240Hz and time

synchronized with kinetic data collected at 480Hz then smoothed using a Woltring filter (MSE 10) [32].

Statistical Analyses

Descriptive statistics were generated for all subject demographic data and t-tests were performed to compare the TKA and control groups. A 2x2 ANOVA with repeated measures was performed on the ten dependent variables. Tukey Post-Hoc tests were used when significant interactions were revealed to determine where the differences occurred. All statistical analyses were conducted using SAS v9.1 (SAS Institute Inc., Cary, NC) with an alpha level of $p \leq 0.05$.

Results

Age was found to be significantly different ($p=0.0428$) between the TKA and control groups at the PRE and POST test periods. Demographic characteristics for the TKA and control groups are presented in Table 1. Significant interactions were revealed between TKA and control groups and PRE and POST surgery data collection periods for MVGRF ($p=0.0398$) and MKADM ($p=0.0053$). Tukey post-hoc tests for the aforementioned dependent variables revealed divergent results between groups during the POST test periods. The TKA group MVGRF measures decreased by 0.13 Nm/kg, while conversely the control group MVGRF measures increased by 0.43 Nm/kg during the POST test period. The TKA group MKADM measures decreased by 0.35 Nm/kg, and conversely the control group MKADM measures increased by 0.03 Nm/kg during the POST test period.

Table 1. Demographic data (mean±SD) for TKA (n=7) and control (n=7) groups at PRE and POST test periods.

Group	Age (years) *	Height (m)	Weight (kg)	BMI
TKA PRE	67.28±7.04	1.63±0.11	76.15±18.0	28.10±4.51
Control PRE	60.28±4.15	1.67±0.07	69.97±5.08	24.85±1.64
TKA POST	67.28±7.04	1.64±0.11	73.95±16.41	26.05±4.09
Control POST	60.57±3.86	1.68±0.07	69.67±5.26	24.68±1.42

TKA: total knee arthroplasty; PRE: pre-surgery; POST: post-surgery

*Indicates a statistically significant difference (p=0.0428) between the TKA and control groups at the PRE and POST test periods

Significant TKA and control group differences were revealed regardless of test period for walking velocity (p=0.0253) and MKVA (p=0.0206). Tukey post-hoc test results indicated that the TKA group (0.84 m/s²) walking velocity was slower than that of the control group (1.16 m/s²). Similarly, the TKA group (4.41 degrees) MKVA was smaller than that of the control group (13.97 degrees). Results from the 2x2 ANOVA are presented in Table 2.

Discussion

Early (4.57±1.71 weeks) post-surgery TKA 3D gait analysis results were similar to previously reported findings assessed at two months to three years. The majority of previous research has been limited to TKA gait assessment three months to several years post-surgery. Results of these studies indicate improvements in temporal-spatial parameters, and knee kinetics and kinematics following TKA. [12-19] To our knowledge Ouellet et al. [20] was the only study that investigated gait as early as two months after TKA and reported post-surgical gait findings converse to those previously reported [12-19] and to the present study findings. These opposing findings signify the importance of early post-surgery TKA gait assessment.

Table 2. Walking velocity, kinetic, and kinematic variables (mean±SD) for TKA (n=7) and control (n=7) groups at PRE and POST test periods (all knee moments are external).

	PRE		POST	
	TKA	Control	TKA	Control
Walking velocity (m/s) [†]	0.87 ± 0.22	1.12 ± 0.22	0.81 ± 0.35	1.21 ± 0.17
MVGRF (N/kg)*	9.82 ± 0.48	10.45 ± 0.56	9.69 ± 0.34	10.88 ± 0.68
MKFM (Nm/kg)	0.17 ± 0.15	0.19 ± 0.09	0.15 ± 0.11	0.30 ± 0.20
MKEM (Nm/kg)	-0.44 ± 0.24	-0.52 ± 0.23	-0.37 ± 0.22	-0.63 ± 0.18
MKABM (Nm/kg)	-0.08 ± 0.04	-0.03 ± 0.04	-0.08 ± 0.03	-0.05 ± 0.05
MKADM (Nm/kg) [§]	0.57 ± 0.16	0.68 ± 0.14	0.36 ± 0.07	0.71 ± 0.13
KFAHS (°)	10.27 ± 11.49	10.26 ± 2.73	11.40 ± 10.28	9.77 ± 2.03
MKFA (°)	39.85 ± 14.08	41.92 ± 3.23	34.23 ± 17.08	41.41 ± 7.22
KFE (°)	29.58 ± 6.21	31.66 ± 4.72	22.83 ± 10.10	31.63 ± 7.06
MKVA (°) [#]	6.20 ± 8.18	13.64 ± 5.96	2.62 ± 9.40	14.30 ± 6.79

TKA: total knee arthroplasty; PRE: pre-surgery; POST: post-surgery; MVGRF: maximum vertical ground reaction force; MKFM: maximum knee flexion moment; MKEM: maximum knee extension moment; MKABM: maximum knee abduction moment; MKADM: maximum knee adduction moment; KFAHS: knee flexion angle at heel strike; MKFA: maximum knee flexion angle; KFE: knee flexion excursion; MKVA: maximum knee varus angle

† Indicates a significant group effect for walking velocity (p=0.0253) for TKA and control subjects

* Indicates a significant interaction effect for MVGRF (p=0.0398) for TKA and control groups at PRE and POST test periods

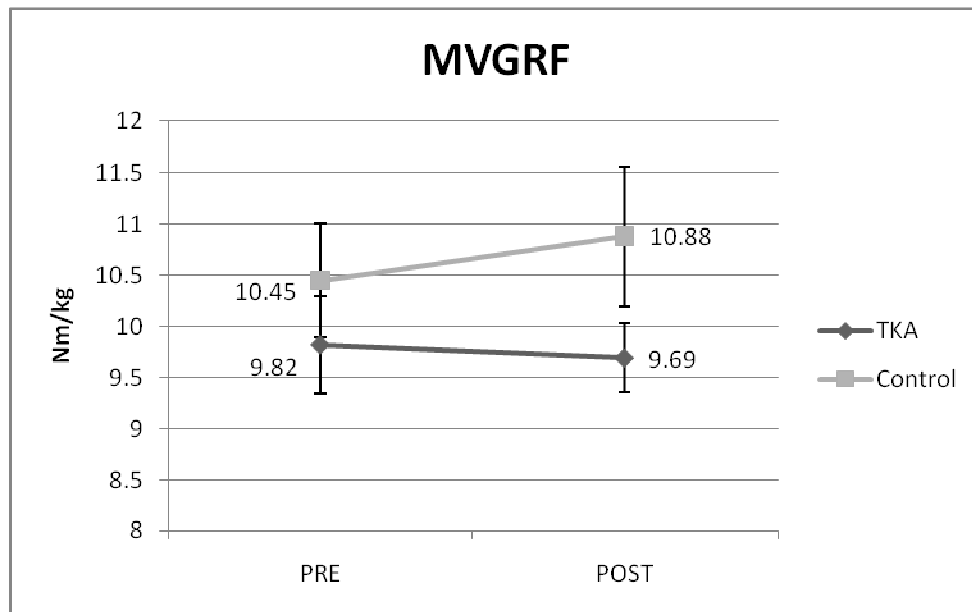
§ Indicates a significant interaction effect for MKADM (p=0.0053) for TKA and control groups at PRE and POST test periods

Indicates a significant group effect for MKVA (p=0.0206) for TKA and control subjects

Interaction Effects

The TKA group in the present study revealed smaller MVGRF than the control group post-surgery (Figure 1), which is consistent with Otsuki et al. [13] and McClelland et al. [19] who assessed TKA gait pre- and post-surgery, respectively. Results of both aforementioned studies revealed decreased vertical GRF of TKA compared to control groups. Otsuki et al. reported the pre-surgery vertical GRF decrease as an attempt to reduce forces at the knee in response to pain. The decrease in MVGRF seen in the present study post-surgery suggests that TKA subjects may retain pre-operative abnormal walking patterns or that they also attempted to reduce joint stress and subsequent pain via compensatory gait patterns.

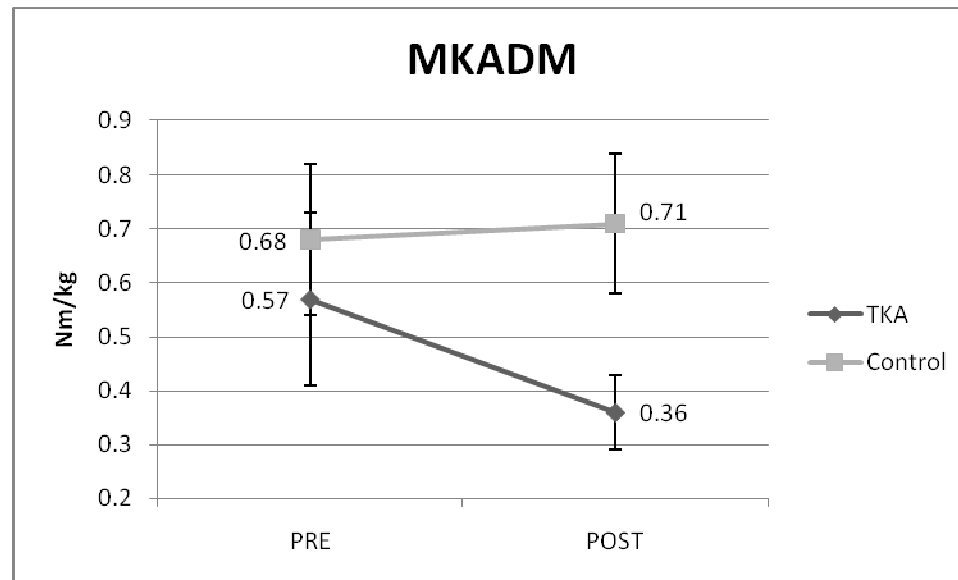
Figure 1. Interaction effect ($p=0.0398$) for MVGRF for TKA and control groups at PRE and POST test periods (error bars represent standard deviation).



The TKA group revealed a decreased MKADM while the control group revealed an increased MKADM POST (Figure 2). The results of the present study are consistent with the findings of Benedetti et al. [17] and McClelland et al. [19] who also reported decreased MKADM in TKA subjects compared to controls at six and 12 months post-surgery, respectively. The decrease in MKADM in the TKA group POST as compared to the control group POST may be attributed to a compensatory mechanism used to reduce the MKADM in order to lessen medial knee joint compartment loading [17]. Additionally, Mandeville et al. [12] reported decreased mean knee adduction moments ($p < 0.0125$) within TKA subjects following surgery. The post-surgery decrease in knee adduction moment has been attributed to frontal plane realignment of the knee joint due to surgery [12]. Mandeville et al. also found a strong positive correlation between frontal

knee angle and frontal knee moment in TKA subjects during walking both pre- ($r=0.92$) and post-surgery ($r=0.73$). [12]

Figure 2. Interaction effect ($p=0.0053$) for MKADM for TKA and control groups at PRE and POST test periods (error bars represent standard deviation).

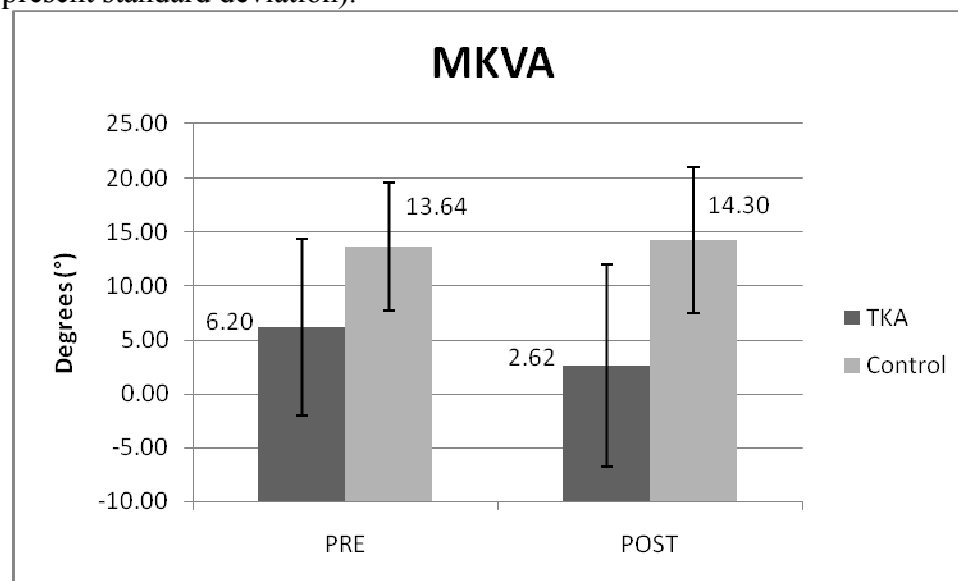


Main Effects

The TKA groups demonstrated reduced MKVA during both test periods compared to the control group (Figure 3). Increased knee varus angle has been identified as a risk factor for the progression of OA, as it places increased stress on the medial compartment of the knee joint [33]. Typically, knee varus angle is higher in pre-surgery TKA subjects compared to controls, which contradicts the results of the present study. The knee varus angle normally refers to a static measure such as a radiograph, whereas the MKVA measured in the present study represents a dynamic 3D measure. Hunt et al. [34] reported a strong correlation between full-length standing radiographs and lower limb alignment obtained from dynamic 3D gait analysis. However, Hunt reported a high percentage of variance (29%) via the 3D measures of lower limb alignment that could not

be explained by the static radiographs. These results suggest that dynamic changes in MKVA occurring during walking may not represent the static varus angle at the knee. The dynamic changes in MKVA may be due to increased laxity in the knee joint which has been seen in TKA subjects [33]. Therefore, TKA subjects often attempt to reduce the laxity in the knee by using a compensatory mechanism known as a “stiff knee” which involves co-contractions of agonist and antagonist muscles to stabilize the knee joint during walking [17]. This may explain the reduced MKVA seen in the TKA group, which suggests that a reduction in MKVA may contribute to a smaller post-surgery MKADM. The increased MKVA seen in the control group in the present study supports the need for further investigation of the relationship between static and dynamic MKVA assessment which may further explain the atypical results of the present study.

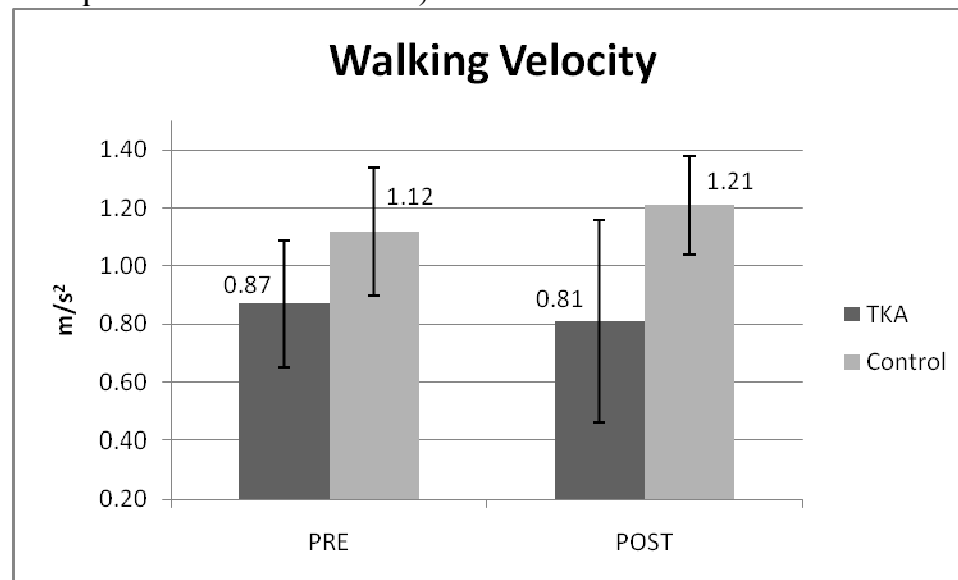
Figure 3. Group main effect ($p=0.0206$) for MKVA for TKA and control groups (error bars represent standard deviation).



The TKA group in the present study walked slower than the control group regardless of test period (Figure 4). This result is supported by Kaufman et al. [35], who

reported that pre-surgery TKA subjects walked slower than controls in an attempt to reduce knee pain during gait. Post TKA subjects also continue to demonstrate slower walking velocities at six months to one year post-surgery compared to controls [15, 16]. The literature suggests that TKA subjects may have slower walking velocities due to post-surgical pain and inadequate time for recovery. This may also explain the decrease in MVGRF seen in TKA subjects compared to the control group, as both decreased walking velocity and MVGRF are outcomes of the compensatory strategy used by TKA subjects to reduce knee joint loading and pain.

Figure 4. Group main effect ($p=0.0253$) for walking velocity for TKA and control groups (error bars represent standard deviation).



Limitations

A possible limitation of the present study was that walking velocity was not controlled, as subjects were allowed to walk at a comfortable, self-selected velocity. This delimitation was chosen to evaluate the subjects' natural gait, since asking them to walk at a standardized pace may have elicited altered gait mechanics.

Summary

Although the TKA subjects in the present study were able to complete several gait trials without aid at three to eight weeks after surgery, the results of this study suggest that TKA subjects are not able to obtain normal biomechanics in the early post-surgery period. These results support previous research by Ouellet et al. [20] in which the gait of TKA subjects was assessed two months post-surgery and revealed significantly ($p < 0.05$) decreased walking speed and knee flexion moments compared to healthy subjects. Ouellet's findings, combined with the results of this study, illustrate that in the early-to-mid post-surgery period, TKA subjects are not able to recover biomechanically to reach values demonstrated by healthy control subjects. However, a favorable surgical outcome was found for TKA subjects, which was a reduced MKADM post-surgery. This outcome may be attributed to frontal plane realignment of the knee joint at surgery, which is one of the major goals of TKA. Therefore, this study provides evidence that early post-surgery biomechanical changes are detectable in TKA subjects.

Recommendations

A small number of subjects were used in the evaluation as the analysis was limited to those subjects for whom we had both pre- and early post-surgery data. A larger number of subjects is recommended to provide more variability within the data and thereby result in an increased number of significant findings. However, even with a small sample size several variables in the present study were found to be statistically significant between the TKA and control groups. An additional recommendation is to decrease the range and variability in the POST TKA data collection time period to more

closely match the control group. This may have provided increased consistency in the data and therefore a more reliable interpretation of the results.

Conclusion

Within the limitations of this study relative to the small sample size, gait differences between the TKA and control groups were detected in the early post-surgery period.

PART II

Literature Review

Osteoarthritis

Osteoarthritis (OA) is a degenerative articular disease occurring most frequently in the elderly population [36], and most commonly affects the knee joint [37, 38], especially in persons over the age of 50 [39]. The estimated lifetime risk of developing symptomatic knee OA is approximately 45%, rising to 66% in obese persons [40]. The age- and sex-standardized incidence rates of symptomatic hip, knee, and hand OA were 88, 240, and 100 per 100,000 person-years, in subjects in a Massachusetts health maintenance organization [41]. The third National Health and Nutrition Examination Survey (NHANES III) revealed approximately 37% of subjects over 60 years of age had radiographic knee osteoarthritis [36]. The prevalence of OA is expected to rise due to the increased life expectancy of the population [42].

Osteoarthritis is defined symptomatically, radiographically, and clinically [36]. Symptomatic OA is generally defined by the presence of symptoms of pain, aching, or stiffness in a joint along with radiographic OA [36]. Radiographs have been considered the reference standard to determine the severity of OA through the presence of osteophytes, sclerosis, cysts, and deformity along with measurement of joint-space narrowing (inter-bone distance) [36]. As a result of the loss of protective articular cartilage in the joint, the bony surfaces become uncovered and individuals with knee OA often experience debilitating pain [4, 5]. With the elderly population now expecting to live more active lifestyles, resolution of the symptoms experienced with knee

osteoarthritis is commonly sought after [5]. Pain and disability are reported as the primary factors motivating individuals to undergo joint replacement surgery [5].

Total Knee Arthroplasty (TKA)

The most effective treatment for patients with severe OA of the knee is TKA [6, 7], involving replacement of the bony joint surfaces of the distal femur and proximal tibia with an artificial joint component. Throughout the past decade the number and rate of TKA surgeries in the United States have increased from 129,000 in 1990 to 402,100 in 2003 [1, 2], and are estimated to grow by 673% to 3.48 million procedures nationally by the year 2030 [1]. This growth can be attributed to increased recognition of the effectiveness of the procedure in treating degenerative disease of the knee [2], the strong relationship between obesity and the risk of osteoarthritis [2], and the expected increase in patient demand for the procedure [1].

TKA Surgical Technique. Several different surgical approaches have been developed since the inception of TKA in the 1970's, with the most common being the medial parapatellar approach [43]. This technique involves a midline skin incision of 12- to 18-cm or a lateral parapatellar skin incision [25]. After the incision is made, the skin and underlying tissues are retracted medially to expose the quadriceps muscles [25]. The quadriceps tendon is split approximately eight centimeters in length above the patella, extended distally over the patella and through the patellar ligament to the tibial tubercle [25]. The fibers of the quadriceps muscles are then separated from the medial border of the patella. The patella is then dislocated laterally and the medial half of the quadriceps tendon is retracted over the medial femoral condyle [25].

Clinical Outcomes Following TKA. Excellent outcomes have been reported in subjects who undergo TKA [7, 44-47], and long-term success of components has been reported with survival rates of 90% or greater at 10 years post-surgery [48, 49]. Pavone et al. [44] conducted a retrospective review of post-surgery clinical outcomes in 25 subjects (mean(range): age 78(53-94) years) using a modified Knee Society rating system following TKA at an average of 19 years follow-up. The modified Knee Society system uses a 10-point scale (1=poor function, 10=excellent function) that assesses pain (presence, severity, frequency, and location), walking distance, the need for walking assistance, the presence of a limp, grinding or clicking in the anterior knee, difficulty with ADL, and the influence of TKA on social activities. Subjects were asked to rate the function of the knee before surgery and at the time of follow-up, and overall satisfaction of the surgery was evaluated. Results were presented as means and ranges for modified Knee Society scores, and the percentage of subjects reporting specific outcomes. Overall, subjects reported improvement in function of the knee and 72% reported excellent satisfaction with the operation. The authors concluded that although TKA has undergone many changes in recent years, long-term success of components lead to excellent knee function several years post-surgery.

In addition to long-term success, many subjects experience decreased pain and increased physical function immediately following the TKA procedure [45]. Karachalios et al. [45] reported beginning on the first post-surgery day, 50 subjects (mean(range): age 70.8(54-77) years; BMI 31.5(28-35)) who underwent TKA demonstrated improvements in mean Knee Society Scores (KSS)—knee score, function score, and total score—and Oxford knee scores, and decreased pain as measured by the Visual Analog Scale (VAS).

The KSS was developed by Insall [50] and is a clinical rating system divided into separate knee and function scores. The knee score includes point values for the components of pain, ROM, and stability, with deductions for flexion contracture, extensor lag, and alignment. The function component rates walking ability on level ground and climbing stairs, and includes deductions for the use of assistive devices. The Oxford knee score is a 12-item questionnaire which assesses knee pain and function, and the impact on ADL [51]. Student's *t*-test indicated significant ($p=0.01$) differences between pre-surgery and final follow-up (3 years post-surgery) scores for each component of the Knee Society Score (KSS) and the Oxford knee score. Mean KSS and Oxford knee scores continued to improve until one year post-surgery and remained constant until the final follow-up, the only exception being the KSS mean function score which decreased by one point [45]. Results of this study indicate improvements in pain, knee function, and ADL functioning for TKA subjects immediately after surgery and lasting up to three years post-surgery.

Further studies have reported subjects with TKA achieve decreased stiffness, improved walking ability, and greater range of motion (ROM) within three months post-surgery [7, 44, 46]. Bachmeier et al. [7] prospectively studied 108 knee OA subjects (mean \pm SD: age 72 \pm 7.0 years) who underwent TKA. Clinical, functional, and behavioral outcomes were assessed pre-surgery and by mail every three months post-surgery for one year using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Medical Outcomes Study SF-36 Health Survey (MOS SF-36) questionnaires. The WOMAC is a multidimensional, self-administered outcome measure developed by Bellamy [52] for clinical trials in subjects with hip or knee osteoarthritis. It

investigates the dimensions of pain (5 items), stiffness (2 items) and physical function (17 items). The MOS SF-36 is a self-administered, generic health-related quality of life instrument that assesses 36 items across eight dimensions: physical functioning, role/physical functioning, bodily pain, general health, vitality, social functioning, role/emotional functioning, and mental health [53]. The WOMAC scores on a 1–5 best to worst scale, which was transformed to the MOS SF-36 0–100 worst to best scale. The Student's *t*-test and Mann–Whitney U-Wilcoxon sum W test indicated significantly ($p < 0.05$) improved WOMAC scores for pain, stiffness, and physical function, and improved all areas of the MOS SF-36 over time except general health which was not influenced by the surgery. Improvements in physical functioning and pain on the MOS SF-36 were statistically significant ($p < 0.05$) at every follow-up, whereas the improvements in physical role functioning, vitality, and social functioning were significant from 6 months on. The authors concluded that subjects who underwent TKA showed improvements in virtually all domains as determined by the WOMAC and MOS SF-36 questionnaires.

Similar outcomes were investigated by Nilsson et al. [46] who studied 102 OA subjects (mean \pm SD: age 71 \pm 8.0 years; BMI 28.4 \pm 3.6) scheduled for TKA. Subjects completed the Knee injury and Osteoarthritis Outcome Score (KOOS) and MOS SF-26 questionnaires pre-surgery and at six months, one year, and five years post-surgery. The KOOS is an extension of the WOMAC, and is a 42-item self-administered questionnaire that covers 5 dimensions: pain, other disease-specific symptoms, ADL function, sports and recreation function, and knee-related quality of life. Continuous outcomes were given as mean (SD) and range, and ordinal outcomes were given as percentages.

Subjects reported improved walking ability at each follow-up and a 93% satisfaction rating at five years post-surgery. The authors concluded that the outcomes experienced by TKA subjects fulfilled pre-surgery expectations to a considerable extent.

Additional clinical measures were investigated by Yoshida et al. [47], who studied 12 TKA subjects (mean±SD: age 61.33±6.88 years; height 1.73±0.10 m; weight 86.02±11.23 kg; BMI 28.94±3.60) and 12 healthy controls (mean±SD: age 61.85±6.23 years; height 1.76±0.11 m; weight 84.34±9.94 kg; BMI 27.35±3.97) at three and 12 months post-surgery. Measurements of physical function were determined by Knee Outcome Survey – Activities of Daily Living Scale (KOS-ADLS) and the MOS SF-36. The KOS-ADLS is a knee specific, self-reported measure of knee function and is used to assess knee function over time. Subjects also performed three functional tests: the Timed up-and-go (TUG test), the Stair Climbing Test (SCT), and the 6 minute walk (6MW) test. The TUG is a measure of mobility and requires subjects to stand from a chair, walk 3 meters, turn around, return to the chair, and sit down [54]. The SCT measures the time it takes a subject to go up and down a flight of stairs as quickly as they feel safe and comfortable [55, 56]. In the 6MW test, subjects are asked to cover as much distance as possible during the six minute time period [57]. Investigators also measured knee flexion and extension ROM using a standard long arm goniometer, and quadriceps strength was assessed with an isokinetic dynamometer (Kin-Com 500H). Wilcoxon Signed-Ranks tests demonstrated significant ($p < 0.05$) improvements in the questionnaire scores for the TKA group between three and 12 months post-surgery. Spearman Correlation Coefficients indicated significant ($p < 0.05$) associations between quadriceps strength and performance in the functional tests for the TKA group. Wilcoxon Signed-Ranks tests

indicated significant improvements in knee flexion ($p=0.005$) and extension ($p=0.014$) ROM between the two testing periods. The authors concluded that subjects who have undergone TKA demonstrate improvements in quadriceps strength and in function, as measured by questionnaires and functional testing, with values approaching those of the control subjects.

Results of the preceding studies demonstrate excellent post-surgery clinical outcomes in subjects undergoing TKA. In contrast, subjects who have undergone TKA have also reported recoveries that can take up to 1 year for full functional improvement [58]. Subjects experience prolonged rehabilitations characterized by pain and more difficulty completing ADL compared to controls [59]. Rossi et al. [59] compared mobility, perceived pain, stiffness, and physical function, between 11 TKA subjects (mean \pm SEM: age 70.71 ± 2.11 years; weight 86.30 ± 5.45 kg; height 172.49 ± 1.79 cm; BMI 29.00 ± 1.13) and an age- and sex-matched control group using the timed up-and-go test (TUG) and the WOMAC. A 1-tailed paired t-test indicated at an average of 17 months post-surgery, the TKA group demonstrated significantly ($p < 0.05$) slower TUG scores. Descriptive statistics and frequencies indicated the majority of subjects in this study reported more difficulty with ADL, and also had moderate pain and difficulty climbing stairs.

The goal of TKA is to realign the knee with the hip and ankle joints to evenly distribute load across the articular surfaces [8]. Component alignment is essential for long-term stability of the replaced joint, as malalignment can lead to premature component loosening and early revision surgery [10]. Subjects with component

loosening have demonstrated altered gait mechanics compared to TKA subjects who do not experience loosening [11].

Knee Kinetics and Kinematics During Gait

Subjects with OA of the knee have shown altered gait mechanics as a form of compensation to minimize joint loading and pain [35]. Decreased walking speeds, knee excursion, and vertical ground reaction forces (GRF) have been reported for subjects with knee OA compared to controls [13, 35]. It is important to know whether gait is normal after TKA to reduce the risk of further damage and deterioration of lower extremity joints [22]. Numerous studies have evaluated gait characteristics in TKA subjects both pre- and post-surgery [14-16, 18, 23, 24, 26, 27]. Pre-surgery, gait patterns of knee OA subjects have been characterized by slower velocities, shorter stride lengths, increased stance times, neutral knee extensor moments, and limited knee flexion at single limb support when compared to control values [13, 14, 27, 35]. Kaufman et al. [35] investigated gait characteristics of 139 OA subjects (mean±SD: age 57±12.5 years; weight 85±17 kg; height 167±9.7 cm) and 20 controls mean±SD: age 30±8 years; weight 75±17 kg; height 173±11 cm). Gait was analyzed during level walking and stair climbing using a computerized motion analysis system (Expertvision-Motion Analysis Corp.) and two force plates (Kistler Instrument Corp.). Level walking trials were completed along a 12 meter walkway. Repeated measures of ANOVA and ANCOVA indicated the OA subjects had significantly ($p < 0.01$) slower walking velocities, less peak knee motion ($p < 0.01$), reduced peak knee extension moments ($p = 0.02$), and increased knee varus moments ($p = 0.02$) compared to the controls. It was concluded by the authors that the

reduction of knee extensor moments by OA subjects was an attempt to minimize their pain during walking. Additionally, the authors reported that knee moment values found in this study were similar to those reported in previous investigations.

Smith et al. [14] investigated kinetic and kinematic gait variables in 34 OA subjects (mean±SD: age 69±7 years; height 169±8 cm; weight 86.9±17.6 kg; BMI 30.5±5.8) scheduled for TKA and 20 controls (mean±SD: age 67±7 years; height 170±6 cm; weight 72.2±10.5 kg; BMI 24.9±2.9). Gait analysis was performed with a VICON 370 motion analysis system and two AMTI force platforms while OA subjects walked at their naturally selected speed in comfortable footwear with a low heel for a minimum of five trials. The control group walked at a slow, medium, and fast pace, and the data from the speed closest to the OA group was used for comparisons. Pre-surgery, OA subjects demonstrated poorer temporal-spatial parameters (velocity, cadence, stride length, step length, stride time, etc.), and mean knee flexion angles and moments compared to controls. Multiple linear and logistic regression models indicated that higher pre-surgery peak knee flexion moments were predictors of post-surgery anterior knee pain. The results of this study indicate that subjects with knee OA demonstrate abnormal gait patterns pre-surgery.

In a similar study, Mandeville et al. [27] investigated walking trials of 21 pre-surgery OA subjects (mean±SE: age 62.60±1.60 years; height 1.66±0.02 m; weight 884.90±38.20 Newton's; BMI 32.6±1.08) and 21 age-matched controls (mean±SE: age 62.70±0.90 years; height 1.70±0.02 m; weight 753.40±26.70 Newton's; BMI 26.60±0.73) using a motion analysis system (Motion Analysis Corp.) and two AMTI force plates. For gait analysis, subjects walked down a 10 meter walkway at their preferred walking speeds

while barefoot. A mixed-model analysis of co-variance (ANCOVA) indicated significantly ($p < 0.0125$) slower pre-surgery walking velocities and shorter stride lengths in the OA group compared to the controls. In the same investigation, the authors reported OA subjects demonstrated reduced knee extensor moments and knee flexion during single-limb support. The authors concluded that these variables demonstrate the subjects' compensation to protect the knee by stiffening the joint during the stance phase of gait.

Unconventional methods were used by Otsuki et al. [13] to examine the gait of 53 knee OA subjects (mean(range): age 68.2(50-85) years) and 14 healthy, age-matched controls (mean(range): age 68(61-78) years). Gait analysis was performed using a pressure measuring system (MP-4800; Anima, Tokyo, Japan) on a 6 meter long walkway, and subjects walked at a free speed in bare feet. Unpaired t-tests indicated the mean stance time for the OA group was significantly ($p=0.0006$) longer than the control group. Additionally, the average vertical force of the OA group was significantly ($p=0.01$) lower than the control group. Results of the preceding investigations are consistent with the antalgic gait pattern previously reported in which knee OA subjects attempt to reduce the forces at the knee during stance phase in response to pain [35]. Furthermore, pre-surgery knee flexion angles of OA groups have been shown to be less than controls [14, 27], suggesting an added mechanism of unloading a painful knee via a stiff-legged gait [27].

A number of gait variables have been shown to improve for TKA subjects post-surgery, including temporal-spatial parameters, knee moment values, and total knee ROM [14, 15, 26]. In a separate investigation, Mandeville et al. [15] conducted gait analysis during level walking and obstacle crossing in 21 TKA subjects (mean \pm SD: age 63.7 \pm 7.56 years; height 1.66 \pm 0.09 m; weight 91.52 \pm 17.83 kg; BMI 32.9 \pm 4.95) and 22

healthy, age-matched controls (mean±SD: age 62.7±4.26 years; height 1.70±0.09 m; weight 76.79±14.46 kg; BMI 26.6±3.35). Gait was analyzed using a motion analysis system (Eagle Digital System, EVaRT 4.4, Motion Analysis Corp.) and two AMTI force plates as subjects walked along a 10 meter walkway at preferred speeds while barefoot. Two-way mixed ANOVAs indicated all temporal-spatial parameters significantly ($p < 0.0125$) improved following TKA. Comparable results were discovered by Liebensteiner et al. [26], who performed pre- and post-surgery gait analysis of 20 TKA subjects (mean: age 72 years; height 1.65 m; weight 75 kg). A VICON 370 motion analysis system was used to collect kinematic data one day prior to surgery and three months post-surgery while subjects walked 8 meters at their own speed for 10 trials. Wilcoxon tests indicated improvements in stride length, gait velocity, maximal hip extension, and double support (% gait cycle) following TKA surgery, although not statistically significant. Similarly, in the aforementioned study by Smith et al. [14], TKA subjects improved knee flexion moment values and knee flexion angles post-surgery, although values were not statistically significant. The results of the preceding studies indicate that as gait measures improve following TKA and approach those of control subjects, walking ability and therefore quality of life are enhanced for post-surgery TKA subjects.

Despite successful outcomes demonstrated by subjects following TKA, compared to healthy, age-matched control groups, subjects continue to have decreased walking velocity, less knee excursion, lower vertical GRF, reduced knee moments, and abnormal walking patterns during gait [14-16, 18, 19]. Although it was found by Mandeville et al. [15] that all temporal-spatial parameters improved post-surgery, TKA subjects continued

to demonstrate significantly slower walking velocities ($p=0.001$) and shorter stride lengths ($p=0.0005$) than controls. Similarly, Wilson et al. [18] performed gait analysis on 16 TKA subjects (mean(range): age 69(36-84) years; weight 82(55-114) kg) and 16 controls (mean(range): age 68(56-75); weight 72(52-109) kg). Data was collected using a VICON motion analysis system and two AMT force platforms while subjects walked at a comfortable speed. Two-tailed t-tests indicated the TKA group had significantly less mean knee ROM ($p>0.001$) and lower maximal knee flexion moments ($p>0.01$) during level walking than the control group. The authors concluded that the decreased ROM demonstrated by the TKA group may have been caused by compromised proprioception or retained patterns of abnormal gait used pre-surgery. Equivalent results were found by Andriacchi et al. [16], who studied 26 TKA subjects (mean \pm SD: age 60.7 \pm 12.8 years) and 14 healthy controls (mean \pm SD: age 62.4 \pm 6.3 years). Motion was analyzed by observing the spatial position of six light-emitting diodes using an optoelectronic system and GRF acquired using a piezoelectric force platform. Subjects walked comfortably at slow, normal, and fast speeds along a 10 meter walkway. Student's t-tests indicated slower walking speeds, shorter stride lengths, abnormal patterns of flexion-extension moments during stance phase, and less change in the angle of knee flexion during stance in the TKA group.

McClelland et al. [19] evaluated the gait of 40 TKA subjects (mean \pm SD: age 69.1 \pm 8.0 years; height 165.5 \pm 11.5 cm; mass 86.4 \pm 17.5 kg) and 40 age- and sex-matched controls (mean \pm SD: age 69.6 \pm 8.3 years; height 165.0 \pm 9.0 cm; mass 76.2 \pm 14.9 kg). An eight camera Vicon MX3 motion analysis system and two Kistler force plates were used to collect gait data at 12 months post-surgery. Subjects performed six walking trials on a

10 meter walkway at a comfortable speed. Results revealed that TKA subjects had significantly lower maximum vertical GRF ($p < 0.001$), maximum knee flexor moments ($p < 0.001$), maximum knee extensor moments ($p < 0.004$), and maximum knee adductor moments ($p < 0.001$) than the control group. The authors concluded that although reduced knee moments may help survival of the artificial joint components, they also represent abnormal knee kinetics.

The majority of previous TKA gait research has involved post-surgery outcomes at three months to eight years [12-19]. Conversely, one study conducted by Ouellet et al. [20] investigated TKA gait outcomes at two months post-surgery. Included in the study were 16 TKA subjects (mean \pm SD: age 66.8 \pm 10.2 years; height 163.0 \pm 5.5 cm; mass 77.3 \pm 11.4 kg) and 18 healthy control subjects (mean \pm SD: age 60.0 \pm 7.9 years; height 166.8 \pm 7.2 cm; mass 72.8 \pm 12.0 kg). Gait data was collected using a video camera and 2-dimensional motion analysis system including an AMTI force platform while subjects walked at a natural cadence along a 10 meter walkway. Results indicated that TKA subjects demonstrated slower walking speeds ($p < 0.0001$), decreased knee flexion ROM ($p < 0.0001$), reduced knee flexion and extension moments ($p < 0.0001$, and $p < 0.008$), and compared to the control group [20]. To our knowledge, only Giaquinto et al. [21] has investigated TKA gait as early as 11.1 \pm 1.7 days post-surgery. The analysis included 20 TKA subjects and 20 healthy, age-matched controls. Subjects performed walking trials in water to use buoyancy to reduce stresses on the operated joint, and walked two meters at a self-selected speed. Results indicated significant increases at post-surgery day 15 in both walking speed and step length. However, allowing subjects to perform walking trials in water may not provide an accurate representation of post-surgery gait. The

previous research suggests that TKA subjects rarely achieve fully normative values for gait variables post-surgery. Altered gait mechanics have been associated with subsequent component loosening [11], one of the leading causes of mechanical TKA failure along with polyethylene wear [9, 10]. Researchers are interested in finding ways to prevent TKA subjects from experiencing altered gait mechanics post-surgery in order to reduce the risk of revision surgery.

Successful clinical outcomes [7, 44-47] and a number of gait variables have been shown to improve for subjects following TKA [14-17, 26]. Although improvements in gait have been demonstrated in TKA subjects in the mid- to long-term post-surgery period, to our knowledge no previous TKA investigations have involved three dimensional gait analyses as early as three weeks post-surgery. It is important to know whether gait is normal after TKA to reduce the risk of further damage and deterioration of lower extremity joints [22]. Therefore, the study of gait in the early post-surgery period is a promising area of research.

APPENDIX A

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

APPENDIX B

RECRUITMENT FLYER FOR CONTROLS

**Do you have healthy knees and hips?
Are you interested in assessing your walking gait, functionality,
and muscle strength?**

The Department of Kinesiology and Rehabilitation Science at the University of Hawai'i Manoa is seeking volunteers to participate in a research study: *Risk Factors for Total Knee Arthroplasty Failure: A Longitudinal Investigation*

Background Information

The number of total knee arthroplasty (TKA) surgeries has been increasing dramatically. While TKA is a very successful surgical procedure for severe knee arthritis, the risk factors for failure are unknown. The purpose of this research is to investigate the possible risk factors for TKA failure in order to reduce such incidences in the future.

What are the benefits for participants?

You may not receive direct/immediate benefits. However, you will obtain information regarding your walking gait, functional activity capacity, hip muscular strength, and behavioral characteristics. The results of this study will help to maintain and optimize the beneficial effect of TKA.

What is involved in the study?

3 years follow up after initial session:

- Total of 8 data collection sessions over 3 years
- 45 min for each data collection session

Data to be collected:

- Walking gait
- Functional capacity
- Muscle strength
- Questionnaires

Inclusionary criteria:

- Free from knee and hip osteoarthritis
- No previous TKA
- No other injuries
- Adult under 85 years of age

For more information contact:

Rachele Vogelpohl, MS, ATC - rachelev@hawaii.edu (808) 956-3801

Kaori Tamura, MS, ATC - ktamura@hawaii.edu (808) 956-3801

Department of Kinesiology and Rehabilitation Science
1337 Lower Campus Road, Room 231, Honolulu, HI



**UNIVERSITY
of HAWAII®
MĀNOA**

APPENDIX C

MEDICAL HISTORY QUESTIONNAIRE

Date _____

Participant # _____

**UNIVERSITY OF HAWAII AT MANOA
DEPARTMENT OF KINESIOLOGY AND REHABILITATION SCIENCE
MEDICAL HISTORY FORM**

Instructions: Please complete each question to the best of your knowledge/ability. If you have any questions, please ask the investigators.

Part 1. Participant Information

Participant's Name: _____

Date of Birth: _____ Age (years) _____ Sex: M / F

Home Address: _____

City/State/Zip: _____ Email: _____

Home/Cell Phone () _____ Emergency Phone () _____

Emergency Contact Person/Relationship: _____

Hospital Preference _____

Doctor Preference _____ Phone _____

Part 2. Medical History

Instruction: Please identify any condition that you have or had that might restrict your participation in physical activity. If you answer yes to any of the following, please describe the proper aid requirements on the next page.

A. General Conditions

- | | | | | |
|--------------------------------------|-----|-----|------|---------|
| 1. Fainting Spells | Yes | No | Past | Present |
| 2. Headaches | Yes | No | Past | Present |
| 3. Convulsions/epilepsy | Yes | No | Past | Present |
| 4. Asthma | Yes | No | Past | Present |
| 5. High Blood Pressure | Yes | No | Past | Present |
| 6. Kidney Problems | Yes | No | Past | Present |
| 7. Intestinal Disorder | Yes | No | Past | Present |
| 8. Hernia | Yes | No | Past | Present |
| 9. Diabetes | Yes | No | Past | Present |
| 10. Heart Disease/Disorder | Yes | No | Past | Present |
| 11. Dental plate | Yes | No | Past | Present |
| 12. Poor Vision | Yes | No | Past | Present |
| 13. Poor Hearing | Yes | No | Past | Present |
| 14. Skin Disorder | Yes | No | Past | Present |
| 15. Allergies | Yes | No | Past | Present |
| Specific _____ | | | Past | Present |
| 16. Joint Dislocation Or separations | Yes | No | | |
| Specify _____ | | | Past | Present |
| _____ | | | Past | Present |
| 17. Allergies | | Yes | No | |
| Specify _____ | | | Past | Present |
| 18. Other _____ | | | | |
| _____ | | | Past | Present |

B. Injuries

- | | | | | |
|------------------|-----|----|------|---------|
| 1. Toes | Yes | No | Past | Present |
| 2. Feet | Yes | No | Past | Present |
| 3. Ankles | Yes | No | Past | Present |
| 4. Lower Legs | Yes | No | Past | Present |
| 5. Knees | Yes | No | Past | Present |
| 6. Thighs | Yes | No | Past | Present |
| 7. Hips | Yes | No | Past | Present |
| 8. Lower Back | Yes | No | Past | Present |
| 9. Upper Back | Yes | No | Past | Present |
| 10. Ribs | Yes | No | Past | Present |
| 11. Abdomen | Yes | No | Past | Present |
| 12. Chest | Yes | No | Past | Present |
| 13. Neck | Yes | No | Past | Present |
| 14. Fingers | Yes | No | Past | Present |
| 15. Hands | Yes | No | Past | Present |
| 16. Wrists | Yes | No | Past | Present |
| 17. Forearms | Yes | No | Past | Present |
| 18. Elbows | Yes | No | Past | Present |
| 19. Upper Arms | Yes | No | Past | Present |
| 20. Shoulders | Yes | No | Past | Present |
| 21. Head | Yes | No | Past | Present |
| Specify _____ | | | | |
| _____ | | | Past | Present |
| 22. Others _____ | | | | |
| _____ | | | Past | Present |

APPENDIX D

CONSENT FORM

INFORMED CONSENT
To Participate in a Research Study

Department of Kinesiology and Rehabilitation Science, University of Hawaii at Manoa
1337 Lower Campus Road, PE/A Complex Rm. 231, Honolulu, HI 96822
Phone: 808-956-7606

I. INVESTIGATORS

Principle Investigators: Kaori Tamura, MS, ATC; Iris F. Kimura, PhD, ATC, PT

II. TITLE

Risk Factors for Total Knee Arthroplasty Failure: Prospective Investigation

III. INTRODUCTION

The following information is being provided to help you decide if you would like to participate in this study. This form may have words that you do not understand. If you have questions, please ask us.

The principle investigators in this study are currently graduate students at the University of Hawaii, completing this research as part of their PhD program requirements. The purpose of this study is to investigate the risk factors for total knee arthroplasty failure.

IV. DESCRIPTION OF PROCEDURES

You will be asked to fill out a Medical History Questionnaire and three other questionnaires regarding your osteoarthritis and state of mind (behavior) prior to the first day of data collection. You will then be asked to report to the University of Hawaii at Manoa, Kinesiology and Rehabilitation Science Laboratory (Gait Lab) (Sherriff 100) for all testing. When you arrive at the Gait Lab, you will be asked to perform the following four tasks that resemble activities of daily living, such as walking, standing balance, sit to stand, and muscle strength assessment. The entire procedure will take approximately 45 minutes. You will be asked to return to the Gait Lab seven more times (approximately when you have your doctor's check-ups) over the next three years to repeat this procedure.

V. RISKS

Due to the level of physical activity involved, there is a risk of injury. You may have pain in your affected joint during testing. You may also have some discomfort, muscle cramping or soreness during or after test sessions. Although we have a fall prevention system, there is a chance of falling during the walking test. There is a very remote chance of cardiac arrest and/or death. The investigators are NATABOC certified athletic trainers and First Aid/CPR/AED trained. In the event of any physical injury from the research, only immediate and essential medical treatment is available including an AED. First Aid/CPR and a referral to a medical emergency room will be provided. In the event of any emergency incidence outside the lab as a result of this research, contact

your medical doctor and inform the principle investigators: Kaori Tamura MS ATC at 956-3801, Dr. Iris F. Kimura at 956-3797, or Dr. Christopher Stickley at 956-3798.

You should understand that if you are injured in the course of this research process that you alone will be responsible for the costs of treating your injuries.

VI. BENEFITS

You may not receive direct/immediate benefits. However, you will obtain information regarding your walking gait, functional activity capacity, hip muscular strength, and behavioral characteristics. Results of this study may assist physicians, physical therapists, and athletic trainers to ensure the optimal clinical outcomes to maintain the beneficial effects of TKA and to reduce the potential risk of TKA failure.

VII. CONFIDENTIALITY

Your research records will be confidential to the extent permitted by law. Agencies with research oversight, such as The University of Hawaii Committee on Human Studies, have the right to review research records.

An identification number will be used to identify you during the study, which will be known only to you and study personnel. In addition, all data and subject (identity) information will be kept under lock and key in the Department of Kinesiology and Rehabilitation Science at the University of Hawaii at Manoa. These materials will be permanently disposed of in a period not longer than 5 years. You will not be personally identified in any publication arising from this study. Personal information about your test results will not be given to anyone without your written permission.

VIII. CERTIFICATION

I certify that I have read and I understand the foregoing, that I have been given satisfactory answers to my inquiries concerning the project procedures and other matters and that I have been advised that I am free to withdraw my consent participation and to discontinue participation in the project or activity at any time without prejudice.

I herewith consent to participate in this project with the understanding that such consent does not waive any of my legal rights, nor does it release the principle investigator or institution or any employee or agent thereof from liability for negligence.

I attest that I am not currently limited from full participation in my chosen sport due to injury.

I attest that I do not believe that I am currently pregnant and that should I become pregnant during participation in this study that I will voluntarily withdraw from further participation.

If you have any questions related to this study, please contact any of the principle investigators: Kaori Tamura MS ATC at 956-3810, Dr. Iris F. Kimura at 956-3797, or Dr. Christopher Stickley at 956-3798 at any time.

Subject ID Number

Signature of Participant

Date

If you cannot obtain satisfactory answers to your questions, or have complaints about your treatment in this study, please contact: Committee on Human Subjects, University of Hawai'i at Manoa, 2540 Maile Way, Honolulu, Hawaii 96822, Phone (808) 956-5007.

APPENDIX E

WESTERN INSTITUTIONAL REVIEW BOARD (WIRB)
INFORMED CONSENT FORM

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: A PROSPECTIVE COMPARISON OF THE BIOMECHANICAL AND FUNCTIONAL GAIT CHARACTERISTICS OF INDIVIDUALS UNDERGOING EITHER A DIRECT ANTERIOR OR MINI-INVASIVE POSTERIOR TOTAL HIP ARTHROPLASTY: A LONGITUDINAL, MULTI CENTERED STUDY.

PROTOCOL NO.: None
WIRB® Protocol #20100778

SPONSOR: University of Hawaii
Honolulu, Hawaii
United States

INVESTIGATOR: Cass Nakasone, M.D.
888 South King Street
Honolulu, Hawaii 96813
United States

SITE(S): Straub Clinic and Hospital Bone and Joint Center
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Honolulu, Hawaii 96813
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University of Hawaii, Manoa
PE/A Complex Room 231
1337 Lower Campus Road
Honolulu, Hawaii 96822
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Queens Medical Center
Suite 608
1380 Lusitana Street
Honolulu, Hawaii 96813
United States

**STUDY-RELATED
PHONE NUMBER(S):** Cass Nakasone, M.D.
808-522-4232

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may

take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this consent form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form
- Having the study doctor or study staff explain the research study to you
- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the research;
- Any possible benefits to you;
- The possible risks to you;
- How problems will be treated during the study and after the study is over.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

The purpose of this research study is to analyze the walking biomechanical and functional characteristics following a total hip replacement to determine when patients return to normal.

PROCEDURES

If you decide to take part in this study:

You will be asked to complete 9 data collection sessions over the next three years: 1.) before surgery, 2.) 2 weeks, 3.) 4 weeks, 4.) 6 weeks, 5.) 3 months, 6.) 6 months, 7.) 1 year, 8.) 2 years, and 9.) 3 years following your total hip replacement.

Data Collection Time Line

		Before surgery	2 Weeks After surgery	4 weeks After surgery	6 Weeks After surgery	3 Months After surgery	6 Months After surgery	1 year After Surgery	2 Years After Surgery	3 Years After Surgery
HIP Patients (n=100)	Gait Analysis	X	X	X	X	X	X	X	X	X
	Trendelenburg	X	X	X	X	X	X	X	X	X
	Up and Go Test	X	X	X	X	X	X	X	X	X
	Isometric Strength	X	X	X	X	X	X	X	X	X
	Functional Scores	X	X	X	X	X	X	X	X	X

At each data collection session you will be asked to:

1. Complete 3 questionnaires about your osteoarthritis and your state of mind. These questionnaires include: the Harris Hip Function Score, the Western Ontario and McMaster Universities Osteoarthritis Index, and the Short Form Health Survey.
2. Push as hard as you can into a non-moving strength measuring device in 8 different leg motions: hip flexion, extension, abduction, adduction, internal rotation, external rotation, knee flexion, and extension. This will be done on both legs.
3. Walk 6 meters (about 20 feet) 6 to 10 times at a self selected (natural) walking speed.
4. Balance on one leg 3 times, and then repeat on the opposite leg.
5. Perform the Timed Up and Go test. This test is a timed test where you will be asked to sit in a chair, then stand, walk 3 meters (about 10 feet), turn around, and return to a seated position in the chair.

One data collection session will take approximately 60 minutes.

Information will also be collected from your medical records and stored on the secured database at Straub Clinic and Hospital. The following items will be reviewed and entered into a data collection spreadsheet:

1. History of total hip replacement surgery and other leg surgeries
2. Age, height, weight, and body mass index at the date of total hip replacement surgery
3. Pre-operative diagnosis

4. Hospital length of stay
5. Discharge disposition
6. Anesthesia physical status and analgesic medications used before and following surgery
7. Arthrotomy component characteristics
8. Tourniquet time
9. Anesthesia type
10. Hip radiographs
11. Pre-discharge blood transfusions, hematocrit and hemoglobin levels
12. Peri-operative physical therapy outcomes
13. Surgical complications
14. Date of discharge from physical therapy

RISKS AND DISCOMFORTS

Due to the level of physical activity involved, there is a risk of injury. You may have pain in your affected joint during testing. You may also have some discomfort, muscle cramping or soreness during or after test sessions. Although we have a fall prevention system, there is a chance of falling during the gait trials, the balancing test, and the Up and Go test. There is a very remote chance of cardiac arrest and/or death. These risks are comparable to your routine rehabilitation and activities of daily living, and will not affect your recovery from the surgery.

You cannot participate in this study if you are pregnant because the walking biomechanics collected may not accurately represent your normal walking characteristics. If you are unaware that you are pregnant, participation in this study will result in no more danger to the mother or fetus than normal activities of daily living. However, if you become pregnant or think you might be pregnant during the course of this study, you must inform the researchers, and you will be taken out of the study.

NEW INFORMATION

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a revised consent form if this occurs.

BENEFITS

You will not receive direct/immediate benefits from participating in this study. However, you will obtain information regarding your walking gait, functional activity capacity, hip and knee muscular strength, and behavioral characteristics. Results of this study may assist physicians, physical therapists, and athletic trainers to ensure the optimal clinical outcomes following total hip replacement surgery.

PAYMENT FOR PARTICIPATION

You will receive \$5 for each data collection session. This money can be applied to your parking and transportation to and from the University of Hawaii Gait Laboratory. You will be paid only for the visits you have completed.

COSTS

You will be responsible for parking and transportation to and from the University of Hawaii, Manoa, Kinesiology and Rehabilitation Science, Human Performance and Gait Laboratory

(Sherriff 100). You will be given \$5 per data collection session that can be applied toward the parking fee or transportation; however, the money will be given after you arrive at the facility, so it is a reimbursement. The fee for parking at the University of Hawaii, Manoa parking structure is \$4 during the week and \$5 on the weekends. Any other cost associated with parking/transportation over and above the \$5 provided will be your responsibility.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

ALTERNATIVE TREATMENT

This is not a treatment study. Your alternative is not to participate in this study. Your follow-up care is the same whether or not you are in this study.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about your study visits.
- Information gathered for this research about:
 - Data collection sessions
 - Questionnaires

Who may use and give out information about you?

- The study doctor and research assistant that will be reviewing your medical records at Straub Clinic and Hospital.

Who might get this information?

- The research team at the University of Hawaii, Manoa, Department of Kinesiology and Rehabilitation Science
- Representatives of outside groups hired by Straub Clinic and Hospital or the Western Institutional Review Board for audits to make sure studies are done as required.

Your information may be given to:

- The University of Hawaii, Committee on Human Studies
- Hawaii Pacific Health
- Western Institutional Review Board[®] (WIRB[®])

Why will this information be used and/or given to others?

- To do the research
- To study the results, and
- To see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

- Then you will not be able to be in this research study.

May I review or copy my information?

- Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

- Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

COMPENSATION FOR INJURY

The study doctors are National Athletic Trainers' Association/Board of Certification certified athletic trainers and First Aid/CPR/Automated External Defibrillator (AED) trained. In the event of any physical injury from the research, only immediate and essential medical treatment will be available including an AED. First Aid/CPR and a referral to a medical emergency room will be provided. In the event of any emergency incidence outside the gait lab as a result of this research, contact your medical doctor and inform the study doctor: Dr. Cass Nakasone at 808-522-4232. You should understand that if you are injured in the course of this research process that you alone will be billed for the costs of treating your injuries.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some of the end of study procedures done.

SOURCE OF FUNDING FOR THE STUDY

This research study is sponsored by the University of Hawaii, Manoa.

QUESTIONS

Contact Dr. Cass Nakasone at 808-522-4232 for any of the following reasons:

- if you have any questions about this study or your part in it
- if you feel you have had a research-related injury or
- if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Subject Name (printed)

CONSENT SIGNATURE:

Signature of Subject

Date

Signature of Person Conducting Informed Consent Discussion

Date

APPENDIX F

DATA COLLECTION FORMS

Anthropometric Data

Subject ID#: _____ Date _____

Age _____ Gender: F / M

Data Collection Period 0 1 2 3 4 5 6 7 8

Center: Control / Straub / Queens

Patient's Operated leg: L / R Dominant Leg: L / R

Date of Surgery _____

Weeks after Surgery _____

Vicon/Nexus Measurements

Weight (kg)	
Height (mm)	
Age (yrs)	
Left leg length (mm)	
Left knee width (mm)	
Left ankle width (mm)	
Right leg length (mm)	
Right knee width (mm)	
Right ankle width (mm)	

Data Collection Form

Subject ID#: _____

Data Collection Period 0 1 2 3 4 5 6 7 8

Patient's Operated leg: L / R Dominant leg: L / R

Center: Control / Straub / Queens

Total Trials: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

Walking Trials		
Trial	Which foot hit the plate	Walking Pace (s)
1	R / L	
2	R / L	
3	R / L	
4	R / L	
5	R / L	
6	R / L	

APPENDIX G
RAW SUBJECT DATA

RAW DATA FOR TKA SUBJECTS

Test Period	Subject ID	Age (years)	Height (m)	Weight (kg)	BMI	Walking velocity (m/s ²)	MVGRF (Nm/kg)	MKFM (Nm/kg)	MKEM (Nm/kg)	MKABM (Nm/kg)	MKADM (Nm/kg)	KFEAHS (°)	MKFA (°)	KFE (°)	MKVA (°)
PRE	TKA002	62	1.837	99.6	29.51488	1.27489	9.736	457.102	-232.377	-32.658	638.963	11.186	42.630	31.444	12.934
	TKA003	62	1.595	62.2	24.449445	0.859972	10.253	138.176	-140.690	-75.280	454.116	-0.062	33.356	33.418	14.285
	TKA005	67	1.700	90	31.141869	0.758212	9.624	492.069	-147.908	-176.229	314.680	7.252	32.249	24.997	-2.253
	TKA006	79	1.535	76.2	32.339866	0.571754	9.74162	567.22	-68.7307	-51.8424	597.7163	27.3006	58.07663	30.7760	-5.15732
	TKA011	61	1.494	46.8	20.967404	0.762661	10.6673	87.6135	-497.587	-61.1718	822.279	-7.07154	19.19415	26.2656	14.4515
POST	TKA013	75	1.669	71.1	25.524481	0.919945	9.52260	649.119	-86.9817	-67.5539	490.7773	15.4726	36.07787	20.6052	1.59785
	TKA019	65	1.630	87.2	32.820204	0.981225	9.22790	710.911	-57.2506	-101.051	691.4177	17.864	57.43157	39.5675	7.555783
	TKA002	62	1.826	90.9	27.26229	1.478391	9.331	244.401	-75.949	-70.6852	336.2155	24.154	37.648	13.494	14.598
	TKA003	62	1.607	60	23.23376	0.482426	10.192	140.125	-275.659	-85.0244	340.9867	-7.493	4.411	11.904	8.013
	TKA005	67	1.714	89.7	30.533094	0.963475	9.568	558.450	-129.501	-146.461	368.2833	12.774	34.991	22.217	-0.513
POST	TKA006	79	1.543	76.7	32.215399	0.586061	9.78162	542.485	-57.3122	-73.2341	400.249	19.10073	52.59983	33.4991	-12.4159
	TKA011	61	1.496	47.1	21.045426	0.505922	9.70191	89.1534	-369.852	-107.997	389.5133	4.576487	20.75753	16.1810	10.77249
	TKA013	75	1.683	68.2	24.077763	0.743311	10.0352	689.965	-78.4441	-73.8566	218.342	13.02123	37.02897	24.0077	-4.86317
	TKA019	65	1.639	85.1	31.679014	0.961644	9.24680	388.944	-122.716	-21.6514	477.5577	13.68487	52.2005	38.5156	2.750185

MVGRF: maximum vertical ground reaction force; MKFM: maximum knee flexion moment; MKEM: maximum knee extension moment; MKABM: maximum knee abduction moment; MKADM: maximum knee adduction moment; KFEAHS: knee flexion/extension angle at heel strike (flexion is positive); MKFA: maximum knee flexion angle; KFE: knee flexion excursion; MKVA: maximum knee varus angle

RAW DATA FOR CONTROL SUBJECTS

Test Period	Subject ID (leg)	Age (years)	Height (m)	Weight (kg)	BMI	Walking velocity (m/s ²)	MVGRF (Nm/kg)	MKFM (Nm/kg)	MKEM (Nm/kg)	MKABM (Nm/kg)	MKADM (Nm/kg)	KFEAHS (°)	MKFA (°)	KFE (°)	MKVA (°)
PRE	C003 (R)	63	1.634	71.8	26.89	0.988067	10.039	367.460	-87.063	-77.830	693.638	10.877	42.072	31.195	11.266
	C003 (L)	63	1.634	71.8	26.89	0.988067	9.930	523.682	-194.129	38.228	822.157	14.055	39.225	25.170	23.917
	C004	55	1.738	76.2	25.23	1.293039	11.028	667.803	-244.045	-37.087	865.065	12.835	46.078	33.243	20.128
	C005	58	1.544	60	25.17	1.404389	11.322	533.395	-199.968	-9.162	624.018	8.300	40.198	31.898	7.980
	C006 (L)	64	1.725	68.7	23.09	0.908115	10.030	323.206	-230.253	-50.598	417.231	8.164	45.187	37.022	11.618
	C006 (R)	64	1.725	68.7	23.09	0.908115	10.097	321.047	-71.867	-79.960	714.349	6.444	43.483	37.039	11.272
POST	C011	55	1.752	72.6	23.65	1.363366	10.727	960.839	-358.762	-61.019	627.762	11.149	37.219	26.070	9.347
	C003 (L)	63	1.647	71.2	26.25	1.164843	10.563	583.157	-370.294	24.314	893.906	10.238	33.646	23.409	27.979
	C003 (R)	63	1.647	71.2	26.25	1.164843	11.074	883.766	-125.209	-42.218	760.093	9.442	39.825	30.383	8.221
	C004	55	1.736	76.4	25.35	1.277929	11.035	655.041	-298.994	-87.802	782.795	13.203	46.155	32.953	16.823
	C005	59	1.546	59.9	25.06	1.391914	12.068	481.775	-218.675	16.343	751.282	6.222	41.155	34.934	13.521
	C006 (L)	64	1.721	67.8	22.89	1.023661	10.491	441.204	-232.379	-91.534	482.966	9.817	51.997	42.180	8.218
C006 (R)	64	1.721	67.8	22.89	1.023661	9.847	522.170	-137.717	-70.730	624.602	10.108	45.604	35.496	11.245	
C011	56	1.744	73.4	24.13	1.460936	11.124	905.511	-731.093	-106.859	702.9943	9.417	31.489	22.071	14.131	

APPENDIX H

STATISTICAL ANALYSIS

```

data preop;
input id group $ trial $ kmaxvar maxgrf maxkaddmom walkvel;
datalines;
1 0 1 11.266 10.039 693.638 0.988066628
2 0 1 23.917 9.930 822.157 0.988066628
3 0 1 20.128 11.028 865.065 1.29303855
4 0 1 7.980 11.322 624.018 1.404388629
5 0 1 11.618 10.030 417.231 0.908115147
6 0 1 11.272 10.097 714.349 0.908115147
7 0 1 9.347 10.727 627.762 1.363366295
8 1 1 12.934 9.736 638.963 1.274890088
9 1 1 14.285 10.253 454.116 0.859971549
10 1 1 -2.253 9.624 314.680 0.758212355
11 1 1 -5.157323333 9.741626667 597.7163333 0.571753627
12 1 1 14.4515 10.66735 822.279 0.762661098
13 1 1 1.59785 9.522603333 490.7773333 0.919945372
14 1 1 7.555783333 9.227903333 691.4176667 0.981225454
1 0 2 27.979 10.563 893.906 1.164842569
2 0 2 8.221 11.074 760.093 1.164842569
3 0 2 16.823 11.035 782.795 1.277929448
4 0 2 13.521 12.068 751.282 1.391913966
5 0 2 8.218 10.491 482.966 1.023661018
6 0 2 11.245 9.847 624.602 1.023661018
7 0 2 14.131 11.124 702.9943333 1.460935859
8 1 2 14.598 9.331 336.2155 1.478390524
9 1 2 8.013 10.192 340.9866667 0.48242593
10 1 2 -0.513 9.568 368.2833333 0.96347549
11 1 2 -12.4159 9.781623333 400.249 0.586060573
12 1 2 10.77249333 9.701913333 389.5133333 0.505921844
13 1 2 -4.863173333 10.03526 218.342 0.743311373
14 1 2 2.750185 9.246806667 477.5576667 0.961644367
;
run;
proc glm data=preop;
class id group trial;
model kmaxvar = group id(group) trial group*trial trial*id(group);
means group | trial;
test h=group e=id(group);
test h=trial e=trial*id(group);
test h=group*trial e=trial*id(group);
lsmeans group/adjust = tukey tdiff pdiff cl e=id(group);
lsmeans trial/adjust = tukey tdiff pdiff cl e=trial*id(group);
lsmeans group*trial/adjust = tukey tdiff pdiff cl e=trial*id(group);
title 'Two-Way Repeated Measures ANOVA';
run;
proc glm data=preop;
class id group trial;
model maxgrf = group id(group) trial group*trial trial*id(group);
means group | trial;
test h=group e=id(group);
test h=trial e=trial*id(group);
test h=group*trial e=trial*id(group);
lsmeans group/adjust = tukey tdiff pdiff cl e=id(group);
lsmeans trial/adjust = tukey tdiff pdiff cl e=trial*id(group);
lsmeans group*trial/adjust = tukey tdiff pdiff cl e=trial*id(group);
title 'Two-Way Repeated Measures ANOVA';
run;

```

```

proc glm data=preop;
class id group trial;
model maxkaddmom = group id(group) trial group*trial trial*id(group);
means group | trial;
test h=group e=id(group);
test h=trial e=trial*id(group);
test h=group*trial e=trial*id(group);
lsmeans group/adjust = tukey tdiff pdiff cl e=id(group);
lsmeans trial/adjust = tukey tdiff pdiff cl e=trial*id(group);
lsmeans group*trial/adjust = tukey tdiff pdiff cl e=trial*id(group);
title 'Two-Way Repeated Measures ANOVA';
run;

proc glm data=preop;
class id group trial;
model walkvel = group id(group) trial group*trial trial*id(group);
means group | trial;
test h=group e=id(group);
test h=trial e=trial*id(group);
test h=group*trial e=trial*id(group);
lsmeans group/adjust = tukey tdiff pdiff cl e=id(group);
lsmeans trial/adjust = tukey tdiff pdiff cl e=trial*id(group);
lsmeans group*trial/adjust = tukey tdiff pdiff cl e=trial*id(group);
title 'Two-Way Repeated Measures ANOVA';
run;

```

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