AN EVALUATION OF KNEE ADDUCTION MOMENT, VARUS THRUST, AND GROUND REACTION FORCE BEFORE AND AFTER TOTAL KNEE ARTHROPLASTY IN OSTEOARTHRITIC KNEE PATIENTS

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Abstract and Key Word

Frontal plane gait deviations have been identified as important factors for the progression of knee osteoarthritis (OA), especially in the medial compartment. External knee adduction moment (KAM), varus thrust, and ground reaction forces (GRF) within the osteoarthritic population were examined before and after total knee arthroplasty (TKA). Ten adult volunteers preparing to undergo TKA were recruited and a control group consisting of 11 volunteers from the community. A longitudinal repeated measures design was conducted prior to TKA and three weeks, six weeks, three months and six months post-surgery. External KAM in OA patients reduced after surgery, however, progressively increased over time, approaching baseline numbers at six months. Varus thrust increased overtime reaching numbers double baseline values in OA patients. The GRF was lower in the knee OA patients compared to controls and remained decreased throughout study. While walking velocity may be a factor in GRF and thereby KAM, the increase cannot fully explain the increase in KAM after surgery. Weak knee stabilizers and altered gait mechanics could potentially explain the continued increase in varus thrust. Also, static alignment and joint instability may be an integral part to the increases of KAM and varus thrust that needs to be studied more thoroughly. Further research on strengthening and gait retraining protocols following TKA, may help to better understand these biomechanical factors and their effect on the progression of knee OA.

Key Words: Osteoarthritis, knee, frontal gait biomechanics, total knee arthroplasty, external knee adduction moment, varus thrust, ground reaction forces.

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Introduction

Osteoarthritis (OA) is the most common synovial joint disorder affecting the elderly and one of the main causes of chronic disability in this population [16]. The cause of OA is idiopathic and research in regard to the causes of this disability is deficient [34]. The pathology of OA includes loss of hyaline cartilage, degeneration of articular cartilage, and is diagnosed at the point in which underlying bone is exposed [23]. Cartilage breakdown limits the ability to transmit loads evenly leading to further bone injury, severe pain, and malalignment causing gait changes [23].

Frontal plane gait deviations have been identified as factors in the development of knee OA, especially in the medial compartment [2]. Increases in external knee adduction moment (KAM) and varus velocity, also known as varus thrust, create an increase in dynamic varus alignment within the knee during weight bearing resulting in uneven distribution of forces, specifically increasing the load in the medial compartment [2,5]. This load increase has been shown to be a strong predictor for the presence, severity, dynamic instability, and progression of knee OA [2,15].

When the severity of OA increases and end stage knee OA is reached, total knee arthroplasty (TKA) is the most common surgery performed to restore function [12]. During TKA, the proper mechanical axis of the lower limb is reestablished allowing proper distribution of loads across the knee, leading to decreased pain and improved mobility at the knee joint[9]. Appropriate anatomical alignment also decreases the KAM, possibly removing the increased joint load within the medial compartment [26]. However, these joint loads are still higher in individuals who have undergone TKA than in a healthy adult population. While the cause

remains unclear, researchers hypothesize that static alignment alone does not adequately account for the dynamic loads at the knee joint during gait [27,33].

The KAM is calculated as the product of ground reaction forces (GRF) in the frontal plane and the perpendicular distance from the GRF to the center of the knee joint. The magnitude and loading pattern of GRF observed in individuals with knee OA is influenced by body mass, frontal alignment of the knee joint, and walking velocity [7,36]. Characteristically, the GRF runs from the center of pressure, near the body's center of mass, and its changes are due to lower limb alignment and joint center position [13]. Patients with knee OA have decreased GRF magnitude compared to healthy controls which is associated with decreased stride length, longer stride interval, and decreased gait velocity [6].

Increases in KAM within the symptomatic OA population within previous literature have been identified as potentially damaging dynamic knee joint loading patterns [12,15,27]. However, studies involving KAM pre- and post-TKA have been limited [13,19,26] and inconsistent while varus thrust has only been considered preoperatively [4,5,20]. Ground reaction forces in patients with knee OA compared to healthy controls have been reported yet are inconsistent; both higher and lower GRF have been reported in the knee OA population compared to controls [7,13]. Therefore, the purpose of this study is to examine external KAM, varus thrust, and GRF within the OA population before TKA and at three and six weeks and at three and six months post-operatively compared to healthy age-matched controls. The following research hypotheses were examined: 1. External KAM and varus thrust will decrease postoperatively in OA patients but remain higher than controls, and 2. Vertical GRF will

be lower than controls in OA patients preoperatively and initially during postoperative examination but will reach levels similar to controls by the end of six months.

Methods

Research Design

A longitudinal repeated measures design was conducted consisting of TKA patients with trials held pre- and post-surgery. Participants were assessed within three weeks prior to surgery, and post-operatively at three weeks, six weeks, three months and six months and compared to a group of healthy age-matched controls. The independent variables were time and the TKA procedure. The dependent variables were peak KAM, peak varus thrust, peak GRF, and peak walking velocity.

Participants

Ten adult volunteers [age = 18-85] were recruited from a pool of knee OA patients undergoing TKA by the same Board Certified orthopedic surgeon at Straub Clinic and Hospital. Inclusion criteria were: under 85 years of age, undergoing unilateral TKA, no previous surgery to the lower extremity and able to walk without the use of an aide. A control group of healthy volunteers from the local community were matched by age, weight, and body mass index (BMI) to the knee OA participants. Inclusion criteria for the control group were: no previous surgery to lower extremity, ability to walk without a walking aid, and absence of rheumatoid or inflammatory arthritis. Patients for the TKA group were screened and cleared for study participation by the same surgeon during their routine visit. Participants in the control group were asked to fill out a medical history questionnaire prior to the study participation, volunteers with possible contraindications were excluded from study participation. The study was approved

by the University Human Studies Program (HSP) and the Western Institutional Review Board (WIRB) prior to data collection. Signed informed consent forms approved by the University of Hawaii HSP and WIRB were obtained prior to study participation.

Procedure

Anthropometrics and walking gait data were collected bilaterally on the TKA and control participants in the University of Hawai‘i at Manoa Human Performance and Gait Laboratory. Anthropometric data including height, weight, leg length, knee and ankle joint width, age, and gender were recorded. Height was measured using a standiometer (Model 67032, Seca Telescopic Stadiometer, Country Technology, Inc., Gays Mills, WI, USA), and weight was assessed using a Befour PS6600-ST scale (Befour, Inc., Saukville, Wisconsin, USA). Following the anthropometric measurements, walking gait biomechanics were collected using a three-dimensional (3D) motion capture system (Vicon MX, Vicon, Inc., Centennial, CO) consisting of six or 13 Vicon MX cameras, Vicon software (Nexus, Vicon, Inc., Centennial, CO), and two force plates (Advanced Mechanical Technology Incorporated, Boston, MA). Walking speed was recorded using two infrared timers placed four meters apart (Speed Trap II, Brower Timing Systems, Draper, UT, USA). A total of 27 reflective markers were placed on the following landmarks prior to the walking trials: anterior superior iliac spine, posterior superior iliac spine, lateral thigh, lateral and medial knee joint lines, lateral shank, lateral and medial malleoli, head of second metatarsal, posterior calcaneus, and acromioclavicular joint bilaterally, clavicle, sternum, spinous processes of C7 and T10, and inferior border of right scapula. Reflective markers on medial knees and malleoli were removed following a static trial. Participants were asked to walk barefoot across the 10-meter data collection

walkway at a self-selected velocity. A successful walking trial included the entire foot contacting the force plate without the patient attempting to target the force plate through a visible change in gait. Three successful trials were collected on each leg.

Statistical Analysis

Descriptive statistics including means, standard deviations, and ranges were generated for all demographic characteristics and variables of interest. Comparisons of demographic variables between OA and controls were completed using t-tests. All moments were calculated using external moments. Changes in KAM, varus thrust, GRF, and walking velocity over time for OA patients and controls were examined using multiple one-way repeated measures ANOVA's. A mixed-method, repeated measure ANOVA was run to determine potential interactions between OA and controls over time. Independent *t*-tests were run to determine the difference between controls and OA patients at each time period. All statistical analyses were conducted using SPSS version 21.0 (IBM, Armonk, NY, USA) with an alpha level of $p \leq 0.05$.

Results

Ten TKA patients (males = 4; females = 6) and eleven control participants (males = 7; females = 4) completed this study. Demographic information by groups is presented in table 1. There were no significant differences by group or by gender within each group for age, height, weight or BMI.

Table 1. Demographic variables (±SD) by group at baseline

	n	Age (yrs)	Height (m)	Weight (kg)	BMI
OA	10	66.9 (± 6.7)	1.627 (±.089)	73.27 (±15.11)	27.47 (± 4.23)
Controls	11	62.2 (±3.8)	1.652 (±.084)	71.91 (±8.20)	26.33 (± 2.12)
OA= osteoarthritic patients; SD=Standard deviation; BMI= Body mass index					

External KAM was significantly lower in the OA group three weeks post-TKA (p=.002) and neared significance at six weeks (p=.056) post-TKA when compared to pre-TKA values (F(2.895, 26.054)=4.947; p=.008) (Table 2). There were no significant changes over time for control patients. There was a significant interaction (p=.009) for KAM between groups (F(2.745,52.159)=4.494). Significantly lower KAM differences occurred for OA patients compared to controls at three weeks (p=.0005), six weeks (p=.0005), three months (p=.011) and six months (p=.03) (Table 2).

Table 2 KAM (± SD) by group

KAM	Pre-TKA			3 Weeks			6 Weeks			3 Months			6 Months		
	Mean	SD	Sig.	Mean	SD	Sig.	Mean	SD	Sig.	Mean	SD	Sig.	Mean	SD	Sig
OA	0.66	±0.18	p=0.39	0.42*	±0.08	**p=0.005**	0.49	±0.12	**p=0.005**	0.54	±0.16	**p=0.011**	0.58	±0.12	**p=0.03**
Control	0.64	±0.12		0.64	±0.15		0.71	±0.14		0.71	±0.16		0.70	±0.15	

Pvalue indicates the result of independent t-tests between groups, significance marked in bold
* = Significant difference compared to pre-TKA within OA group indicated by one way repeated ANOVA
p≤.05
OA= osteoarthritic patients; KAM=Knee adduction moment; TKA=Total Knee Arthroplasty SD=Standard deviation;

Table 3 Varus thrust (±SD) by group

Thrust	Pre-TKA			3 Weeks			6 Weeks			3 Months			6 Months		
	Mean	SD	Sig.	Mean	SD	Sig.	Mean	SD	Sig.	Mean	SD	Sig.	Mean	SD	Sig
OA	99.85	±55.4	.234	138.16	±61.62	**0.05**	128.75	±69.49	0.136	191.8*	±101.94	**0.012**	167.78*	±77.35	**0.009**
Control	84.42	±39.2		96.79	±46.87		95.19	±66.48		107.67	±49.29		93.7	±40.82	

P value indicates the result of independent t-tests between groups, significance marked in bold
* = Significant difference compared to pre-TKA within OA group indicated by one way repeated ANOVA
p≤.05
OA= osteoarthritic patients; TKA=Total Knee Arthroplasty SD=Standard deviation;

Varus thrust was significantly higher compared to baseline at three months (p=.034) and six months (p=.004) in OA patients (Table 3). Varus thrust did not change significantly over time for control patients (F(3.281,32.809)=.56; p=.66). Osteoarthritic patients compared to controls had significantly higher varus thrust at three weeks (p=.05), three months (p=.012), and at six months (p=.009) (Table 3).

In OA patients, GRF initially decreased significantly at three weeks compared to baseline (p=.026) then slowly increased until reaching a significantly higher value than baseline by six months (p=.026) (Table 4). The GRF did not change significantly over time for control subjects. The GRF of OA patients was significantly lower than controls at each time period (Table 4).

Table 4 GRF (±SD) by group

GRF	Pre-TKA			3 Weeks			6 Weeks			3 Months			6 Months		
	Mean	SD	Sig.	Mean	SD	Sig.	Mean	SD	Sig.	Mean	SD	Sig.	Mean	SD	Sig
OA	9.9	±0.42	**.00**	9.61*	±0.29	**0.00**	9.78	±0.32	**0.00**	10.1	±0.46	**0.001**	10.43*	±0.37	**0.006**
Control	10.97	±0.61		10.92	±0.68		11.17	±0.71		11.22	±0.89		11.16	±0.75	

P value indicates the result of independent t-tests between groups, significance marked in bold
*= Significant difference compared to pre-TKA within OA group indicated by one way repeated ANOVA
p≤.05
OA= osteoarthritic patients; GRF=Ground Reaction Force; TKA=Total Knee Arthroplasty SD=Standard deviation;

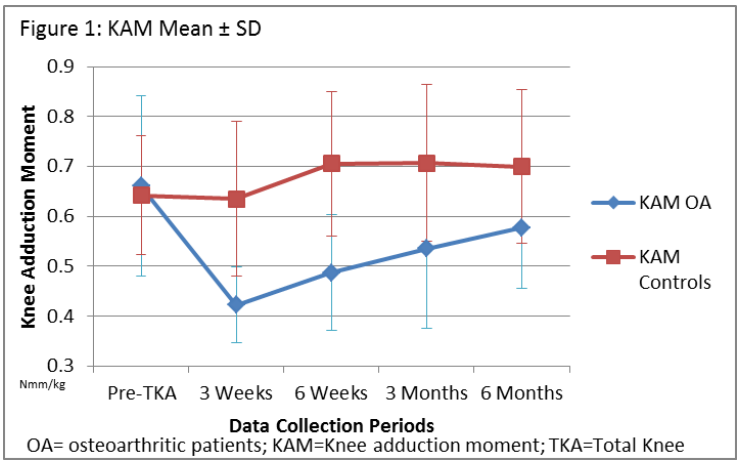
There were no significant changes in walking velocity over time in the OA patients compared to baseline (F(1.735,15.612)=4.475; p=.033). However, walking velocities were significantly lower at three weeks (p=.001), six weeks (p=.001) and three months (p=.028) when compared to the six month values (F(1.735, 15.612)=4.475; p=.033). Walking velocity was significantly higher in controls at three months (p=.045) and six months (p=.009) when compared to baseline (F(2.061, 20.613)=4.553; p=.022). There was a significant main effect for walking velocity between groups (F(1.979,37.593)=3.352; p=.046). The OA patients compared to controls had significantly lower walking velocities at three weeks (p=.001), six weeks (p=.002), and three months (p=.044) (Table 5).

Table 5 Walking velocity (±SD) by group

Velocity	Pre-TKA			3 Weeks			6 Weeks			3 Months			6 Months		
	Mean	SD	Sig.	Mean	SD	Sig.	Mean	SD	Sig.	Mean	SD	Sig.	Mean	SD	Sig
OA	1.1	±0.28	0.092	0.87	±0.30	**0.001**	0.97	±0.32	**0.002**	1.14	±0.36	**0.044**	1.21	±0.43	0.085
Control	1.25	±0.23		1.3	±0.19		1.4	±0.25		1.37	±0.19		1.42	±0.21	

Independent t-tests, significance marked in bold
p≤.05
OA= osteoarthritic patients; KAM=Knee adduction moment; TKA=Total Knee Arthroplasty SD=Standard deviation

Discussion



The most important finding of the present study was that despite a reduction in KAM immediately following TKA, KAM increased rapidly in the subsequent weeks, reaching pre-TKA levels by six weeks, presumably without a change in static alignment (Figure 1). Knee adduction moment, defined as the product of a resultant ground reaction force (GRF) and the perpendicular distance from the GRF to the knee joint center of rotation [13] has been linked to the severity and progression of knee OA [1,18,20]. Total knee arthroplasty, in addition to replacing the damaged joint surfaces, addresses the predominant varus malalignment of the knee and establishes a more neutral alignment. Previous research has reported a decrease in KAM after TKA, citing the cause as a decrease in the distance between the center of the knee joint and the vector of GRF [12,26,27]. In the current study, KAM decreases significantly by three weeks post-TKA in the OA patients when compared to pre-TKA and fall significantly lower than controls, which is consistent with this previous research [12,26,27]. The longevity of this decrease was first evaluated by Orishimo et al. [26], who reported an increase in KAM between six months and one year. The present study demonstrated that KAM may return to pre-surgery levels sooner than previously thought.

Previous research has shown a high correlation between static alignment and KAM prior to surgery, leading to the progression of OA within the medial compartment [14]. Therefore, decreases in KAM are viewed as an important indicator of success following surgery. However,

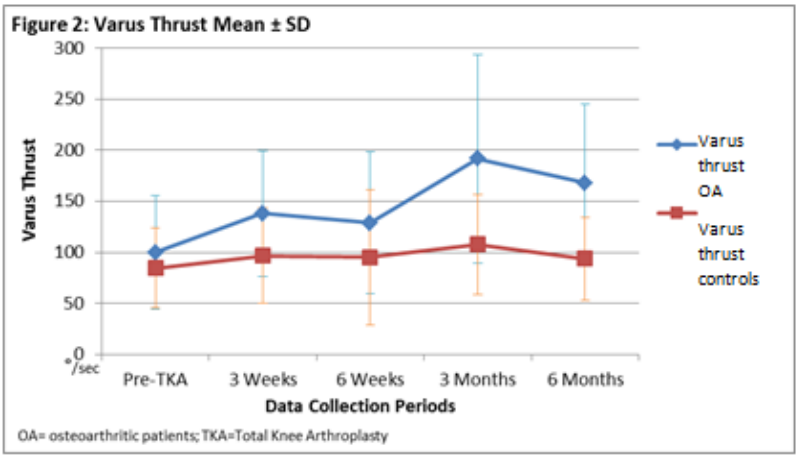
Orishimo et al. [26] and Prodromos et al. [27] both found no correlation between static alignment and KAM following surgery. This suggests that improvements in static alignment from TKA are not solely responsible for decreases in KAM immediately following surgery and return of KAM to pre-surgery levels in the subsequent week or months.

Increases in walking velocity have been previously reported as a contributing variable to the increase in KAM [25,26,29] although several conflicting results have been reported. Some researchers have reported similar walking speeds between OA patients and controls, however, OA patients still presented with greater KAM [19,24,25]. These finding are similar to the current study and could indicate that walking velocity may only be a small contributor to the KAM. Robbins and Maly [29] reported a 15% increase in walking velocity would result in a 7% increase in knee adduction moment. From three weeks to six months in the current study, walking velocity and KAM increased 28%, over doubling the 13% increase in KAM compared to walking velocity, previously determined by Robbins and Maly [29]. These findings indicate there is still uncertainty about the effect of walking velocity on KAM but it is clear that walking velocity is not the only factor contributing to an increase in KAM.

Similar to walking velocity, GRF is also commonly cited as a contributing variable to the increase in KAM post-TKA [7,22,28]. In the current study, GRF had similar changes to KAM, with a significant decrease three weeks post-TKA when compared to pre-TKA values but increased above baseline in the subsequent weeks, reaching significance at six months. Hunt et al. [13] supports these results, reporting a positive correlation between KAM and GRF but also noted that peak KAM and peak GRF occurred at different percentages of stance, therefore, GRF may not be a significant contributor to increases in KAM. A stronger positive correlation was found between KAM and the lever arm distance in the same study done by Hunt et al. [13], suggesting that alignment may be a greater contributor to KAM than GRF. However, static

alignment appears not to change within one year after surgery, and therefore, justification exists to consider dynamic lower extremity alignment during walking gait and how consequent movements contribute to the increased KAM seen post-TKA.

Varus thrust, or varus velocity, is the dynamic movement of the knee into greater varus alignment previously described in literature within the symptomatic OA population and is positively correlated with static alignment and KAM [4,5,17,18,20,32]. Incongruent joint surfaces apparent in OA patients cause an increase in shear and compression forces within the medial compartment of the knee, which, along with progressive increases in static varus alignment, could cause capsule-ligamentous instability and subsequent muscle weakness [18]. These changes may serve to increase varus thrust and further the progression of OA. In contrast to previous research which quantified varus thrust [18], varus thrust in the current study was not significantly different in the OA group when compared to controls prior to TKA. Although severity of OA was not collected in the current study, this lack of difference could be explained due to the increased static varus alignment in OA patients, which has been previously shown to decrease varus velocities [4,5,17,18,20]. Following TKA in the present study, varus thrust increased to levels significantly greater than pre-TKA by three months. Previous research has demonstrated that decreases in varus alignment, which are the goal TKA, may result in increased in varus thrust [4].



Previous researchers have reported both varus thrust and KAM are significant predictors in the presence and severity of OA. One proposed theory suggested the presences of high varus thrusts could be caused by the lacked of appropriate lateral soft tissue stability or muscle activation to provide sufficient stability to the joint, therefore resulting in greater KAM [32]. However, the changes and relationship between varus thrust and KAM after TKA have not been previously studied. In the current study, a significant decreased in KAM, most likely due to changes in static alignment, and a slight increase in varus thrust were present immediately following TKA. The lack of decrease in varus thrust after TKA, similar to the decrease in KAM, and the continued increases during the following weeks, could indicate that despite the return to a more neutral static alignment, instability within the knee still exists. If lateral ligaments and capsular laxity are not properly balanced during TKA and medial musculature is not properly maintained and strengthen, a dynamic instability could be created, indicated by an increase in varus thrust. There is, however, a decrease in varus thrust between three and six months, without a decrease in KAM. Muscular strengthening during this time could provide stability to the knee, decreasing the varus thrust, but destructive gait patterns may have already been established in response to the high varus velocities, resulting in the continued increase in KAM. Therefore, establishing a ligamentous-balanced knee during TKA, as well as addressing medial knee strength prior to and after TKA is paramount.

Conclusion

In conclusion, despite a decrease in KAM immediately following surgery, KAM increased back to pre-TKA levels by six weeks post-TKA. Although GRF and walking velocity increases after TKA, this increase may not be great enough to completely explain the increase in KAM. The immediate and continual increase in varus thrust could indicate the inability to stabilize the knee during walking, leading to altered gait mechanics, increased KAM, and

ultimately implant wear and failure. Further research is need to determine if strengthening and gait retraining protocols help to reduce varus thrust and KAM in conservative OA treatments and post-TKA rehabilitation programs.

Limitations

Walking velocity was not controlled during the current study which may cause variability within our dependent variables. Initial investigation used only six Vicon 3D motion analysis cameras, improving to 13 mid-study. Errors in data collecting early on have led to a few patients' averages only using two trials to determine the mean, and in one instance, making only one output available for analysis. Finally, the current study has been completed in the state of Hawai'i and heavily based on an Asian population and could alter subject demographics and gait.

Literature Review

Frontal alignment of the knee relates to the severity and rate of progression of knee osteoarthritis (OA). Deviations from neutral alignment cause increased loads and degeneration of the cartilage in the compartments of the knee. Varus alignment is most commonly seen causing a medial shift within the knee and a change in the ground reaction force (GRF). A higher degree of knee OA severity before TKA has been connected to higher rates of KAM. After TKA, KAM data has been inconsistent and seldom studied. The resulting varus thrust is associated with external knee adduction moment (KAM). Limited data on KAM, varus thrust, and GRF following TKA therefore require more thorough analysis.

Epidemiology

Osteoarthritis (OA) is the most common joint disorder in the world affecting elderly people and is one of the main causes of chronic disability [16]. Knee pain affects 10% of all adults over the age of 55 and 25% of those affected are disabled because of it [2,34]. One in every three individuals over the age of 63 have exhibited evidence of knee OA [35]. The pathology of OA includes loss of hyaline cartilage and degeneration of articular cartilage. As the cartilage breaks down, load transmission is disrupted leading to further bone injury [23]. As OA progresses, changes occur in the bone underneath the cartilage such as osteophytes, outgrowths, or bony sclerosis [10].

Risk factors for OA include multiple variables. OA is estimated to be inherited in 40-60% of all adults who have this disorder. Factors such as obesity, older age, or being female increase the risk of OA progression [15,34]. Individuals with an increased BMI have an increased risk of developing knee OA than a healthy adult [15]. Joint stiffness and pain are the two most common signs and symptoms related to this disease. OA has been associated with functional limitations

due to structural damage or malalignment of the knee. Knee OA has been found to impair balance, strength and proprioception in the involved adult.

Kaupilla et al. (2009) studied characteristics of end-stage knee OA disability in 88 adults preparing to undergo TKA [16]. The individuals completed self-administered questionnaires, Western Ontario and McMaster Universities OA Index (WOMAC) and the RAND 36-item Health Survey, active flexion range of motion, anterior-posterior radiographs, 15 meter walk test, stair ascent and descent, and isometric muscle strength testing. The researchers objectively studied physical performance and compared these results to subjective questionnaires and self-reported disability. A linear regression was used to compare WOMAC to knee laxity, BMI, and age. Bivariate analyses were used to compare the WOMAC function score to the 15m walk, stairs, and relative peak torque of flexion and extension. The results of this study concluded that pain, BMI, and laxity of the knee were key features of self-reported disability [16]. The physical performance tests, and muscle testing correlated with disability however statistically was not significant [16]. No association between radiographic severity, restricted range of motion and reported disability was found [16].

A longitudinal cohort study by Thompson et al. (2010) identified different patterns of knee pain and related them to risk factors for knee OA [34]. This study by the osteoarthritis initiative was completed with 2,677 participants identifying knee pain or aching on a knee pain map. The map was an image of the knee where individuals marked where the location of the pain was and the level of severity (no pain, localized pain, regional pain). A multinominal logistic regression to relate the location of the knee pain, to nine risk factors (age, sex, race, BMI, history of knee injury, history of knee surgery, hand OA, and family history of knee replacement) was used for statistical analysis.

Results of this study specified risk factors and knee pain patterns that helped describe the subset of knee OA [34].

Forestier et al. (2011) studied the prevalence of generalized OA in patients already diagnosed with knee OA [10]. Residing in France, 302 patients were included in the study all having clinical signs and symptoms of OA. Three criteria sets were then used to determine generalized OA: Kellgren-Moore criteria, ACR criteria, and Dougados criteria [10]. A Chi square test and Mann-Whitney U test were used in Statistica version 5 for data analysis (P value <.05). Bonferroni's correction for multiple comparisons (n=27) was performed and P values were set at <.0018 (.05/27) [10] . Kellegren-Moore criteria for interphalangeal OA, was met in 42 patients, ACR criteria diagnosis of generalized OA was met by 124 patients, Dougados criteria met 127 patients. There were 156 patients who met at least one definition of generalized OA indicating more than half of the patients with knee OA had generalized OA [10].

OA knee progression was further studied by Lynn et al. (2007) and the effect KAM and gait shear forces has upon it [21]. Twenty-eight individuals with no clinical symptoms of OA had gait analysis performed and returned for a follow-up five to 11 years later (average=7.5 years). Radiographs, anthropometric measurements and the self-reported WOMAC questionnaire were all completed. Paired student t-tests were performed to determine differences between visits in gait velocity and frontal plane knee alignment. Wilcoxen signed rank test was used to determine difference in radiographic scores and Pearson correlation coefficients were calculated for adduction moment magnitude and shear force. In 15 patients, knees became more osteoarthritic and radiographic score increased [21]. Only two patients developed symptoms as well as radiographic evidence of knee OA. One had the largest adduction moment and developed signs of medial OA while the other had the smallest adduction moment but a high lateral-medial shear force and developed signs of lateral OA [21]. Limitations of this study included limited data

from the initial visit and participants. At the time of initial data collecting, this study was not planned and therefore minimal information on each participant's health status was collected. Also, no comparative group with knee OA was used to compare changes over the years in OA progression.

In conclusion, knee loading is related to body mass, therefore overweight individuals increase the mechanical stresses. Faulty muscle or joint biomechanics can also be a predisposing factor for OA. Malalignment of the lower extremity negatively influences gait mechanics and encourages progression of OA [3]. Thereby, causing more pain and limiting a person's functional ability to perform normal daily activities. These changes become problematic to the patient, causing further degeneration of the joint.

Frontal Gait Biomechanics

Mechanical influences, particularly in the frontal plane, have been associated with knee OA. The most common gait outcome measured is external knee adduction moment (KAM) [13,30]. During the adduction moment an increased load will occur at the articulation of the medial femoral condyle and the medial aspect of the tibial plateau [13]. Knee adduction moment is the result of ground reaction forces in the frontal plane and the perpendicular distance to the center of the knee joint rotation[13]. Knee OA is 10 times more common in the medial compartment due to a higher load in the medial compartment cartilage [3,15]. Often a varus deformity occurs and a medial shift of the standing load-bearing axis transpires [14,33] called varus thrust. Multiple studies have hypothesized knee OA patients walk with increased peak KAM [8] and a higher varus thrust. Other studies have implied the importance of dynamic knee joint loads using the KAM [15].

Alignment of the knee and its relationship to kinematic and kinetic measures during gait were studied by Teixeira et al. (1996) [33]. Dynamic factors were identified in 11 patients (six men and five women) all whom had a diagnosis of knee OA and no previous history of surgery on either knee [33]. Questor Precision Radiograph (QPR) was used to assess the static lower limb alignment. A 3D WATSMART camera system and AMTI force platform collecting kinematic and kinetic data. Four markers were placed on the lateral aspect of the leg (greater trochanter, lateral femoral epicondyle, fibular head, and lateral malleoli). Participants walked at their natural gait velocity past two 3D cameras. Correlation coefficients statistics were determined using Systat software between QPR and biomechanical data. Results of this study showed no relationship between lower limb alignment and force during gait [33]. However, static lower limb alignment and dynamic joint angles proved a relationship between alignment and kinetic and kinematic measures. Osteoarthritic patients have a slower gait pace and higher stance phase ratios. These are gait-characteristics associated with pain-avoidance. Dynamic gait analysis should be used in evaluation of alignment to help develop treatment for knee OA [33].

Most research commonly seen in knee OA is focused on medial compartment involvement. Medial compartment is nine times more common than lateral compartment and therefore, gait mechanics of lateral compartment is less studied. Butler et al. (2011) compared frontal-plane kinematics and kinetics in a cross-sectional study [3]. Three groups, lateral knee OA, medial knee OA, and a healthy control group, each consisting of 15 participants were used in this study. Individuals were asked to walk a 25-m walkway in a 6-camera motion analysis laboratory across a force platform with markers placed anatomically on lower extremity bony landmarks. Statistics included a one-way ANOVA, pos hoc Tukey test, and Chi-square analysis ($P<.02$). Results indicated that peak knee abduction moment was significantly lower in lateral knee OA group than controls [3]. However, control group knee abduction moments were

significantly lower than in medial knee OA group. This same pattern was observed during peak knee adduction angle. The conclusion of the study stated that patients with medial compartment OA drastically differed than patients with lateral compartment OA [3]. Frontal plane gait biomechanics vary at the knee, hip and ankle between groups and should be considered during interventions and treatment.

Mild to moderate OA patients had their gait characteristics assessed in a study by Landry et al.(2007) [19]. Forty-one symptomatic patients were compared to 43 controls with no history of arthritis or surgery to their lower extremity. Patients were required to walk a runway for five trials at a self-selected velocity, with an additional five trials then taken at a 150% of the self-selected walking velocity. Three-dimensional motion analysis was used to assess gait characteristics while principal component analysis was used to test differences in waveforms. Student t-tests were used to determine statistical differences in age, height, weight, and body mass between knee OA patients and controls. A two-factor repeated measures ANOVA was used for stride characteristics while post-hoc Tukey test compared pairwise comparisons. No differences were found between the OA patients and controls patients in stride length, stride time, or walking speed, for either self-selected or fast gait [19]. Osteoarthritic patients during self-selected and fast walks had a larger adduction moment overall during stance than the control patients. The OA patients at both speeds had higher overall adduction moment magnitudes. However, the magnitude was not affected by speed. This study used principal components analysis (PCA) to detect changes in gait waveforms to help improve analysis technique[19].

Kaufman et al.(2001) studied kinematic and kinetic data of 139 patients (47 males and 92 females) with knee OA versus 20 control patients [15]. The participants were analyzed during level walking, ascending stairs, and descending stairs. Participants

walked a 12m walkway as well as climbing up and down four 18cm stairs without using a railing. Computerized ADTECH motion analysis system using six video cameras and a 21 reflective marker set prominent on significant lower extremity bony landmarks. Ground Reaction Loads (GRL) were collected using force plates along the runway as well as the first two steps of the stairway. Statistical analysis software (SAS) was used to record repeated measures ANOVA to test differences in velocity, joint angles, and gait cycle between knee OA patients and controls. While comparing knee moments, differences in gait velocity were determined via repeated measures ANCOVA. Kaufman stated that OA patients walked at significantly slower velocities than controls ($p<0.01$) [15]. Patients with knee OA had a significantly increased varus moment at the knee ($p=.02$). Knee valgus moment between controls and patients had no significant difference [15].

Foroughi et al. (2011) studied muscle strength and its effect on frontal plane moments [11]. This study was completed using 54 females in a 6-month resistance training program. Participants were divided into two different groups, a high intensity resistance training group which trained at 80% of their peak muscle strength, and a sham exercise group with minimal resistance and no progression. A 38-marker set was used on standard bony landmarks found in the lower extremity and recorded with 10 video cameras, 3D motion analysis software, and two force plates. Participants walked a 10-m walkway for five trials at their own self-selected velocity. Strength tests involved a one repetition maximum set performed on knee extension, hip abduction and adduction, knee flexion, leg press, and plantar flexion. Results after six months of resistance training found no changes occurred in peak knee or hip adduction moment compared to the sham group [11]. Hip adduction moment decreased amongst the whole population studied, however no significance was found between samples studied. Resistance training did aid in

reducing pain. Researchers believe that joint loading may have other contributions than muscle strength involved [11].

Adduction moment, ground reaction forces and frontal plane lever arm during gait were studied by Hunt et al. (2006) [13]. This study included 100 knee OA patients (18 women, 82 men) and 100 controls. Participants completed the WOMAC self-report questionnaire then walked barefoot for ten trials at a self-selected walking velocity while gait analysis via an eight camera motion capturing system time synchronized with a single floor platform occurred. Paired t-tests were used to compare peak and midstance magnitudes of KAM, frontal plane GRF, and frontal plane lever arm. A two-factor repeated measures ANOVA was used to evaluate differences between variables and limbs (involved verse uninvolved limb) then variables were examined using Fisher's Z transformation [13]. Results from Hunt indicated peak KAM and frontal plane lever arm magnitude were significantly greater ($p<0.001$) in limbs with knee OA. Ground reaction forces were significantly less ($p<.001$) in OA patients than controls [13]. In knees with OA, Pearson product moment correlations had a greater association between peak KAM and frontal plane lever arm than with GRF.

A cross-sectional study completed by Baliunas et al.(2002) determined peak KAM was higher in patients with knee OA when compared to controls [2]. External knee adduction is associated to the force distribution between the medial and lateral compartments of the knee and the torque that adducts the knee during gait [2]. Thirty-one participants (18 females, 13 males) with medial OA receiving conservative treatment were compared to 31 asymptomatic controls. Patients with signs of medial compartment joint space narrowing and no signs in the lateral compartment were included as the knee OA patients. The control patients required no history of knee trauma or diagnosis of OA

or rheumatoid arthritis. Reflective markers were placed on the lower extremity of each participate and camera system and force plate were used to collect data. Patients walked at self-selected velocities of 'slow', 'normal', and fast. The peak external knee adduction moment was significantly greater than in controls ($p=0.003$) [2]. There was no significant correlation with sagittal knee angles or knee range of motion. One major limitation of this study involves the possibility of undiagnosed knee OA in the control patients. No knee radiographs were taken for the asymptomatic patients therefore OA could have been present even if no symptoms were present. No follow up data were recorded to determine whether or not conservative treatment was reducing the knee loads or if the subject's OA was progressing. The authors suggest a follow up longitudinal study to track the loading patterns during the progression of knee OA [2].

Varus deformity in knee OA patients and the interaction between knee stabilizers was analyzed by Schipplein and Andriacchi (2005) [30]. Fifteen patients (6 male) with moderate medial knee OA were evaluated during walking and the effect a varus deformity had on flexion-extension moments. A second control group with no history of knee injury consisting of 20 patients (11 male) was also studied. Light emiting diodes we placed on bony landmarks of the lower extremity and captured via an optoelectric system. Each participant walked a 10-m walkway and over a force plate. The OA group had an average varus deformity of 9 degrees and a high adducting moment. The adducting moment was higher compared to controls during mid-stance phase, causing the OA group to adopt a gait demanding higher muscle force and greater flexion-extension moments.

Varus thrust was observed during gait in the osteoarthritis initiative, a prospective observational cohort study by Chang et al. (2010) [5]. Presence of varus thrust was observed in 3592 individuals through gait observation, followed by multiple logistic regressions with generalized estimating equations identifying factors associated with thrust presence. Chang

found an increase in varus thrust was found in individuals who had more severe knee OA [5]. While originally comparing valgus to varus alignment in African Americans to Caucasians in this study, the resultant factors associated with varus thrust are important. Weaker knee muscles, varus laxity, and decreased extensor strength were found in the presence of varus thrust and increased knee OA severity [5].

Chang et al.(2004) examined varus thrust, physical function outcome, and OA progression in a second article [4]. Two hundred thirty-seven patients underwent full-limb radiographs and gait analysis to asses for varus thrust. Sixty four of the patients returned within one month to determine the maximum knee adduction moment. Six passive markers attached to the lower extremity were used with four Qualisys optoelectronic cameras and a single Bertec multicomponent force plate. The WOMAC questionnaire and radiographs were taken 18 months later [4]. Logistic regression statistical analysis was used to estimate odds ratios for medial compartment OA progression. Knee results with a varus thrust present was associated with a 4-fold increase in progression of medial knee OA. Knees with varus thrust also had a greater peak adduction moment during gait and a poorer physical function outcome [4].

A cross-sectional study by Lo et al. (2012) examined static alignment with pain in patients with knee OA versus varus thrust [20]. Two groups of participants were created. One with definite varus thrust consisted of 25 individuals, the second group was without varus thrust and had 57 participants. Patients were recording walking a 20-m walkway at a self-selected speed towards a stationary standard digital camera (60 Hz). Posteroanterior radiographs were also taken the same day, and pain assessment was concluded through WOMAC pain questionnaire. Patients with symptomatic knee OA and varus thrust are highly associated with greater overall knee pain. This is especially seen during weight-bearing activities.

Currently, only one study has looked at varus thrust after surgery. Three dimensional knee motion before and after high tibial osteotomy (HTO) was performed on 20 knee OA patients by Takemae et al. (2006) [32]. The two variables focused on in this study were lateral thrust and screw home movement and the relationship between them to clinical results. Nineteen patients, two men 17 women, were used with one patient having bilateral medial knee OA. Radiographic evaluation was performed by all particpants. An electrogoniometer was used to assess 3D knee motion during gait. Patients walked a 5m walkway at a natural pace. Significant differences among the patients were determined via Wilcoxon signed-rank test, paired t-test ad student's t-test ($p<.05$). Results for this study include lateral thrust was observed in 18 of the 20 knees before HTO and only seven afterwards [32].

Total Knee Arthroplasty

Total Knee Arthroplasty (TKA) is an orthopedic procedure that is performed to increase functionality of the knee and treatment for end-stage arthritis [8,12]. Each year in the United States more than 500,000 TKA surgeries are performed [31]. Before TKA is implemented, conservative treatment is first prescribed. Rehabilitation and anti-inflammatory medications are recommended to treat the signs and symptoms of OA such as pain and swelling. Conservative treatment for OA includes weight loss for heavier patients, and exercises to strengthen the musculature in the surrounding area [16]. Patients display abnormal knee function due to kinematic alterations after TKA. As pain decreases post-operatively, TKA patients have been shown to change dynamic loading and knee motion. TKA reduces pain, yet the recovery of muscle strength to normal levels compared to a healthy adult the same age is rare. Also, functionality in TKA patients improves from pre-surgery numbers. However these numbers still typically remains deeply diminished compared to controls.

Biomechanics of the knee joint are important in understanding the tibiofemoral load, leading to cartilage degeneration. D'Lima et al. (2007) studied in vivo measurements of shear forces as well as moments in the knee following TKA, testing the durability of the component [8]. One 83 year old male subject had a custom tibial component implanted that measured orthogonal forces as well as moments. Three months following surgery, knee kinematics, GRF, tibial forces and moments were calculated in a motion analysis lab using six Vicon cameras, three force plates and reflective skin markers [8]. The patient was instructed to walk at a comfortable place, rising and siting in a chair, stair climbing, and squatting. External moments were measured using GRF and inverse dynamics. A significant limitation to this study is that only one patient is used, and variables could change on multiple people. Also, kinetmatics and data acquired were only compared to mathematical models. Extneral knee flexion and external KAM recorded from the computer output were greater than flexion and adduction moments in vivo recorded on the tibial tray [8]. Shear forces and moments were found low compared to total knee forces.

Altered knee motion and gait patterns were studied by Hatfield et al. (2011) one week prior to TKA and one year postoperatively [12]. Forty-two patients with severe medial compartment knee OA completed five trials of walking a 6-m walkway at a self-selected pace. Participants also completed the WOMAC questionnaire at both data collections. Three-dimensional motion analysis capture system and a single force plate were used, and the gait waveforms were analyzed using principal component analysis (PCA) to statistically determine variability. Results of this study included improved walking speed, stride length, and WOMAC scores ($P<.05$)[12]. Knee adduction moment and mid-stance values were decreased post-TKA indicating improved dynamic loading.

Researchers found the changes in knee joint motion and loading more typical of asymptomatic gait patterns and should be viewed as an improvement in function.

In contrast to Hatfield's research on improved knee adduction moment one year post-TKA, Orishimo et al. (2012) found that while TKA improved knee adduction moment six months after surgery, the results were lost at one year [26]. Radiographs and gait analysis was performed on 15 patients (7 men 8 women) pre-surgery, 6-months and 1-year postoperatively. Weight bearing radiographs were also taken to assess frontal plane knee alignment. Reflective markers were placed over the lower extremity at prominent bony landmarks and data were collected by five infrared cameras in congruence with a multicomponent force plate and calculated using Visual 3D software. Patients walked at a self-selected pace across a 6-m walkway for five gait trials. Single-factor repeated measures ANOVA was used to compare function scores, gait velocity, knee ROM during gait and peak knee adduction angle. Separate repeated-measures ANOVA compared peak knee adduction moment and impulse between the 3 time periods. Orishimo determined peak knee adduction angle initially reduced after surgery (37%) however increased again at the one year follow-up compared to pre-surgical levels (53%). This same increase occurred for knee adduction moment as well. Six months postoperative knee adduction moment was reduced (85%), before increasing at one year (94%). Improvement in static alignment from pre-surgery to post did not correlate with changes in peak adduction moment[26]. One important limitation of this study was no control group was used to compare. Researchers suggest that lack of pain and higher gait velocity contributed to a less cautious gait and therefore a higher moment.

Prodromos et al. (1985) studied the relationship between dynamic loading during gait with TKA clinical outcomes [27]. Twenty-one patients (12 men, 9 women) with knee OA and a control group of fifteen adults (6 men, 9 women) were tested. All participants had radiographs

and gait analysis analyzed preoperatively and one year postoperatively. A second follow up occurred later than 3 years after surgery in 19 OA patients. Standard radiographs were analyzed for changes in alignment and arthritis severity. Six light-emitting diodes were used as markers and placed on bony landmarks of the lower extremity, collected via an optical electronic system and used along with a piezoelectric force plate. Statistical analysis included student test as well as significance of Person correlation coefficients using the t statistic [27]. Adduction moment at the knee during preoperative walking was predictive of postoperative results. Patients with lower initial adduction moment had better clinical outcomes than patients with larger moments. A reoccurrence of varus deformity was found in patients with a higher adduction moment [27]. Knee joint alignment however did not predict loading during gait. No significance occurred based on knee score, initial varus deformity, age or weight.

Appendix A. Relevant Forms

A.1. Institutional Review Board Form

UNIVERSITY OF HAWAI'I

Committee on Human Studies

MEMORANDUM

December 1, 2010

TO: Iris Kimura, Ph.D.
Principal Investigator
Kinesiology & Rehabilitation Science

FROM: Nancy R. King
Director

SUBJECT: CHS # 17860, "Risk Factors for Total Knee Arthroplasty Failure: Prospective Investigation"

This is to acknowledge receipt of your response dated October 1, 2010, to the stipulations issued by the Committee on Human Studies (CHS) during its review of the project identified above at its meeting on May 19, 2010. The information you provided satisfactorily addressed CHS stipulations, and the project, including the Medical History Form and revised consent form, is approved for one year effective November 19, 2010.

This memorandum is your record of CHS approval of this study. Please maintain it with your study records.

CHS approval for this project will expire on November 18, 2011. If you expect your project to continue beyond this date, you must submit an application for renewal of this CHS approval. CHS approval must be maintained for the entire term of your project.

If, during the course of your project, you intend to make changes, you must obtain CHS approval prior to implementing them. Unanticipated problems that are likely to affect study participants must be promptly reported to the CHS.

You are required to maintain complete records pertaining to the use of humans as participants in your research. This includes all information or materials conveyed to and received from participants as well as signed consent forms, data, analyses, and results. These records must be maintained for at least three years following project completion or termination, and they are subject to inspection and review by CHS and other authorized agencies.

Please notify this office when your project is completed. Upon notification, we will close our files pertaining to your project. Reactivation of CHS approval will require a new CHS application.

Please contact this office if you have any questions or require assistance. We appreciate your cooperation, and wish you success with your research.

1960 East-West Road, Biomedical B104, Honolulu, Hawaii 96822-2303
Telephone: (808) 956-5007, Facsimile: (808) 956-8683, Website: www.hawaii.edu/irb

A.2. Informed Consent Form TKA Participant

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

Principal Investigators: Iris F. Kimura, PhD, ATC, PT; Kaori Tamura, MS, ATC; Cass K. Nakasone MD MSME;

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 the 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: (1) walk for 6 m at a comfortable speed 6-10 times (Gait Analysis), (2) stand on single leg and balance 1-3 times on each leg (Trendelenburg), (3) rise from a sitting position, walk 3m, then return to the chair, 1-3 times (Up and Go Test), (4) Push into stationary objects (either researcher's hand or fixed dynamometer) with your leg for 3 sec for 8 different leg movements (Isometric Strength). The entire procedure will take approximately 45 minutes. You will be asked to return to the Gait Lab seven more data collection sessions (you will receive $20 for the parking fee and transportation each data collection session) over the next three years to repeat this procedure (please see Table 1 below). In addition, you will be asked to fill and sign the Health Insurance Portability and Accountability Act (HIPAA) Release Form if you authorize the release of your X-ray information to the researchers. X-ray will be used to obtain your knee alignment angle, and you will not be asked to take any additional X-ray as a result of this study.

Table 1. Data Collection Time Line

		Pre Op	3 Weeks Post Op	6 Weeks Post Op	3 Months Post Op	6 Months Post Op	1 Year Post Op	2 Years Post Op	3 Years Post Op
Knee Patients (n=100)	Gait Analysis	X	X	X	X	X	X	X	X
	Trendelenburg	X	X	X	X	X	X	X	X
	Up and Go Test	X	X	X	X	X	X	X	X
	Isometirc Strength	X	X	X	X	X	X	X	X
	Paper/Pencil Tests	X	X	X	X	X	X	X	X
Control Subjects (n=50)	Gait Analysis	X	X	X	X	X	X	X	X
	Trendelenburg	X	X	X	X	X	X	X	X
	Up and Go Test	X	X	X	X	X	X	X	X
	Isometirc Strength	X	X	X	X	X	X	X	X

	Paper/Pencil Tests	X	X	X	X	X	X	X	X	*Risk*

Factors for Total Knee Arthroplasty Failure: Prospective Investigation

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. These risks are similar your routine rehabilitation and daily activities, and will not affect your recovery from the surgery.

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 or Iris F. Kimura PhD, ATC, PT, at 956-3797. 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, Iris F. Kimura PhD, ATC, PT, at 956-3797 at any time.

_____
Participant's Printed Name

_____ _____
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, 1960 East-West Rd., Biomed Bldg. Ste. B-104, Honolulu, Hawaii 96822, Phone (808) 956-5007.

A.3. Informed Consent Form Control Participant

INFORMED CONSENT
To Participate in a Research Study
"CONTROL PARTICIPANT"

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

IX. INVESTIGATORS

Principal Investigators: Iris F. Kimura, PhD, ATC, PT; Cass K. Nakasone, MD, MSME

Investigators: Rachele E. Vogelpohl, MS, ATC; Kaori Tamura, MS, ATC;
Ryan Molzon, BS, ATC; Sienna Handegard, ATC; Bryant Hoer, ATC;
Catherine Rose, ATC;

X. TITLES

Functional Recovery and Gait Biomechanics following Total Hip Arthroplasty: a Longitudinal Study
Risk Factors for Total Knee Arthroplasty Failure: Prospective Investigation

XI. 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 purpose of this study is to look at the biomechanical and functional gait (walking) characteristics of patients who have received either total hip or knee replacement surgeries, and compare them to "normal" gait of individuals (control participants) who do not have hip or knee replacement surgery.

XII. DESCRIPTION OF PROCEDURES

You will be asked to fill out a Medical History Questionnaire and four other questionnaires regarding your physical and mental health relative to your ability to participate in this arthritis (osteoarthritis) study as a "control" participant prior to the first day of data collection. Your responses to the above questionnaires will be screened (reviewed) by a medical doctor. If you are cleared for participation and you choose to participate in this study 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 sessions. When you arrive at the Gait Lab, you will be asked to perform the following four tasks: (1) walk for 6 m (20 feet) at a comfortable speed 6-10 times (Gait Analysis); (2) balance on one leg at a time, 1-3 times each (Trendelenburg); (3) stand up from a seated position in a chair, walk 3m (10 feet), then return to the chair, 1-3 times (Up and Go Test); (4) push your leg into the researcher's hand and/or muscle testing device (dynamometer) for 3 sec for 8 different leg movements (Isometric Strength). The entire procedure will take approximately 60 minutes. You will be asked to return to the Gait Lab for seven more data collection sessions over the next three years to repeat this procedure (please see Table 1 below).

Table 1. Data Collection Time Line

		Initial Visit	3 Weeks	6 Weeks	3 Months	6 Months	1 Year	2 Years	3 Years
Control Subjects (n=50)	Gait Analysis	X	X	X	X	X	X	X	X
	Trendelenburg	X	X	X	X	X	X	X	X
	Up and Go Test	X	X	X	X	X	X	X	X
	Isometirc Strength	X	X	X	X	X	X	X	X

	Paper/Pencil Tests	X	X	X	X	X	X	X	X

XIII. RISKS

Due to the level of physical activity involved, there is a "slight" 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 National Athletic Trainers' Association, Board Of Certification 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 principal investigators: Iris F. Kimura, PhD, ATC, PT at 956-3797, Rachele E. Vogelpohl, MS, ATC, or Kaori Tamura, MS, ATC at 956-3801. 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.

XIV. 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 (results) following total hip or knee replacement surgery.

XV. COMPENSATION

You will receive 20 dollars for your trouble and transportation (parking etc.) to and from the University of Hawaii Gait Laboratory each time you come to a data collection session.

XVI. 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.

IX. 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 principal investigator or institution or any employee or agent thereof from liability for negligence.

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 principal investigators: Iris F. Kimura, PhD, ATC, PT at 956-3797 or Rachele E. Vogelpohl, MS, ATC at 956-3801 at any time.

_____

Participant Name (print)

_____ _____

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, 1960 East-West Rd., Biomed Bldg. Ste. B-104, Honolulu, Hawaii 96822, Phone (808) 956-5007.

Appendix B: Data collection form

B.1. 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)	

B.2. Walking Trials Data 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 C. Raw Data

Subject	Gender (F=0 M=1)	KAM One	KAM Two	KAM Three	KAM Four	KAM Five
002	1	0.6390	0.3362	0.4542	0.9108	0.7915
005	1	0.2966	0.3683	0.7293	0.4810	0.5410
006	0	0.5977	0.4002	0.3341	0.4212	0.4234
011	0	0.8100	0.3895	0.4403	0.4885	6.1451
018	1	0.8947	0.3578	0.3713	0.3570	0.3955
019	0	0.6914	0.4776	0.4860	0.6696	0.7273
020	0	0.7248	0.3439	0.4096	0.4629	0.5967
021	0	0.6420	0.4028	0.4680	0.4451	0.5073
024	0	0.7507	0.5395	0.5825	0.5989	0.5628
027	1	0.8974	0.5241	0.5807	0.5054	0.6244
028	0	0.4761	0.4737	0.4592	0.4990	0.6047
C-001	1	0.6512	0.6545	0.7072	0.7583	0.6537
C-002	1	0.4776	0.3221	0.5766	0.5939	0.4623
C-003	1	0.7409	0.7601	0.0305	0.9871	0.8638
C-004	1	0.7291	0.7708	0.9046	0.8674	0.9715
C-005	0	0.6894	0.5365	0.5255	0.6975	0.6218
C-006	1	0.5980	0.5200	0.5726	0.7837	0.5803
C-007	1	0.7664	0.8086	0.7953	0.8323	0.7400
C-009	0	0.8438	0.7636	0.7518	0.7837	0.8477
C-010	1	0.5735	0.7766	0.6912	0.7392	0.8016
C-015	0	0.6067	0.6023	0.8216	0.6859	0.7268
C-019	0	0.6814	0.7391	0.9030	0.7427	0.7931
C-020	1	0.4465	0.4912	0.5097	0.2889	0.4994

Subject	Gender (F=0 M=1)	Varus One	Varus Two	Varus Three	Varus Four	Varus Five
002	1	223.221	151.332	110.464	149.089	270.774
005	1	163.977	174.445	34.664	101.669	190.435
006	0	63.679	105.351	99.225	146.113	171.413
011	0	84.872	81.246	218.088	255.892	1306.646
018	1	104.496	246.904	192.838	365.195	297.332
019	0	76.982	193.898	68.431	182.104	91.762
020	0	107.222	75.728	204.495	368.514	218.386
021	0	49.025	131.496	232.282	231.507	108.849
024	0	62.534	31.021	39.817	115.483	71.138
027	1	51.033	160.614	144.187	79.911	99.349
028	0	96.300	110.851	161.137	178.366	158.370
C-001	1	42.736	69.050	22.217	51.479	26.647
C-002	1	51.573	54.691	203.474	143.994	97.508
C-003	1	43.175	24.785	51.365	44.901	125.733
C-004	1	119.144	113.626	137.934	123.057	130.623
C-005	0	118.806	95.545	80.565	118.433	110.430
C-006	1	55.822	83.628	8.339	129.811	58.507
C-007	1	60.563	87.861	144.495	65.365	131.509
C-009	0	151.057	169.425	94.705	129.811	171.790
C-010	1	64.564	63.563	44.189	120.356	67.911
C-015	0	107.691	130.773	185.372	199.893	94.383
C-019	0	119.065	173.595	96.887	79.562	73.506
C-020	1	37.549	22.904	28.893	22.609	67.863

Subject	Gender (F=0 M=1)	GRF One	GRF Two	GRF Three	GRF Four	GRF Five
002	1	9.7365	9.3310	9.3169	9.2802	10.5543
005	1	9.6310	9.5675	9.8170	9.9312	10.4458
006	0	9.7416	9.7816	9.6196	9.7522	9.6230
011	0	10.5987	9.7019	10.1961	10.7596	10.9083
018	1	10.0719	9.5724	9.7999	9.8631	10.2647
019	0	9.2279	9.2468	9.2903	10.0741	11.0117
020	0	10.1602	9.2439	9.9354	10.3031	10.4296
021	0	10.2740	10.1365	9.8399	9.8972	10.1373
024	0	10.5747	9.9355	9.9736	10.3595	10.5610
027	1	10.1838	9.6534	9.8450	10.7294	10.6259
028	0	9.4227	9.5907	10.3955	10.7800	10.6516
C-001	1	9.8974	9.8215	10.2853	10.6265	10.3753
C-002	1	11.2182	10.6947	10.8708	10.6452	11.1373
C-003	1	10.8849	11.0736	0.4578	11.2587	10.9132
C-004	1	11.2884	11.1131	12.1694	12.8548	12.6326
C-005	0	11.5815	11.4133	10.8727	12.2223	11.7116
C-006	1	10.4034	10.3160	10.2764	10.6890	10.3691
C-007	1	12.0163	11.0504	12.4821	12.4599	12.0716
C-009	0	11.3458	11.3123	11.2595	10.6890	10.7762
C-010	1	11.0850	12.4448	11.3050	10.9548	11.0636
C-015	0	10.7907	10.8136	11.2172	11.0050	11.3772
C-019	0	10.4772	10.7077	11.5341	11.2669	10.9982
C-020	1	10.5469	10.4506	10.5900	10.0416	10.2556

Subject	Gender (F=0 M=1)	Walking Velocity One	Walking Velocity Two	Walking Velocity Three	Walking Velocity Four	Walking Velocity Five
002	1	1.2749	1.4784	1.7029	2.0619	2.3097
005	1	0.7355	0.7582	0.9635	1.0817	1.1156
006	0	1.2245	0.5718	0.5861	0.7075	0.7445
018	1	0.6695	0.9947	0.904	0.9727	1.0702
019	0	1.1384	0.9812	0.9616	1.2356	1.2934
020	0	1.6643	1.1379	0.7982	1.1368	1.2086
021	0	1.1874	0.5332	0.7625	0.937	0.8417
024	0	0.953	0.5936	0.7369	0.9537	1.007
027	1	1.0426	0.7331	0.9924	1.06	1.1374
028	0	1.1034	0.9283	1.2992	1.2848	1.4073
C-001	1	1.0067	1.0583	1.2572	1.3058	1.24
C-002	1	1.1616	1.2529	1.9179	1.5404	1.6147
C-004	1	1.293	1.2779	1.4793	1.5452	1.6077
C-005	0	1.4044	1.3919	1.4767	1.4701	1.5022
C-006	1	0.9081	1.0237	1.014	0.9978	1.0832
C-007	1	1.5094	1.4725	1.4968	1.5367	1.541
C-009	0	1.7002	1.6077	1.5059	1.4764	1.5902
C-010	1	1.2368	1.4196	1.3732	1.3771	1.6418
C-015	0	1.251	1.2763	1.3593	1.367	1.3219
C-019	0	1.2188	1.3954	1.5321	1.3905	1.4307
C-020	1	1.0872	1.0798	1.0297	1.0376	1.0737

Appendix D. References

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