

THE ANALYSIS OF SAGITTAL PLANE KNEE BIOMECHANICS IN
OSTEOARTHRITIC PATIENTS UNDERGOING A TOTAL COMPARTMENTAL OR
UNICOMPARTMENTAL KNEE ARTHROPLASTY COMPARED TO HEALTHY
CONTROLS DURING STAIR DESCENT

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LIST OF ABBREVIATIONS

Osteoarthritis.....	OA
Total knee arthroplasty.....	TKA
Unicompartmental knee arthroplasty.....	UKA
Multi-radius.....	MR
Single-radius.....	SR
University of California, Los Angeles.....	UCLA
Knee flexion angle.....	KFA
Knee flexion moment.....	KFM

INTRODUCTION

Osteoarthritis (OA) is the most prevalent form of arthritis, affecting 24 million people¹, with the knee being the most affected joint². Osteoarthritis causes decreased range of motion (ROM) and cartilage degeneration of the affected joint¹. This results in abnormal walking gait and associated difficulty with activities of daily living, such as stair descent¹. Osteoarthritic patients have a longer period of double-support and increased ground reaction force during mid stance, indicating there is abnormal knee joint loading during gait and OA patients need longer periods of support to ambulate². Stair descent is a physically demanding task due to increased knee joint loading³. This increased knee joint loading results in knee extensor weakness, and can lead to a decreased velocity, as well as an increased stride width, compared to healthy controls⁴.

Total Knee Arthroplasty (TKA) is a surgical intervention that replaces the medial and lateral diseased compartments of the knee and is the most widely used intervention for restoring knee function to OA patients⁵. It has been estimated that approximately four million adults in the US over the age of 50 have undergone a TKA procedure⁶. At four weeks postoperatively, TKA patients reported difficulty rising from a chair and descended stairs at a slower pace than those with no difficulty rising from a chair⁷. Previous research shows that 70% of TKA patients demonstrate abnormal moment patterns and anterior knee pain, indicating that TKA patients do not all return to full knee function by 12 months⁸. At 12-months post-operative deficits remained in TKA patients for decreased knee flexion angles, and knee extension moments during stance phase contributing to a quad avoidance gait compared to controls⁵. Similar results for decreased knee flexion angles and knee extension moments were found during stair descent^{9,10}.

Unicompartmental Knee Arthroplasty (UKA) is a surgical intervention that replaces the medial compartment of the knee while a majority of the knee joint anatomical structures remain untouched during the surgical procedure, including retention of the ACL and PCL¹¹. Unicompartmental Knee Arthroplasty survivorship is comparable to TKA, with both at 88%- 92% ten-years post-operatively¹²⁻¹⁴. Using self-reported questionnaires, previous research suggests UKA patients reported improved patient satisfaction on pain and function compared to TKA patients¹⁵. During level walking, UKA patients demonstrate similar walking velocities to healthy controls^{16,17}. Additionally, when performing downhill walking, UKA patients walked at an increased velocity of 15% compared to TKA patients and with similar gait parameters to healthy controls¹⁷.

Based on self-reported assessment questionnaires, 86% of UKA patients were satisfied following surgical intervention, compared to only 71% of TKA patients¹⁸. No differences during stair descent in peak knee flexion angle (PKFA), peak knee flexion moment (PKFM), and vertical ground reaction force (vGRF) were reported in patients undergoing a TKA in one limb and a UKA on the contralateral limb¹⁹. However, TKA patients experience a decreased knee extensor strength compared to UKA patients following surgery²⁰.

The majority of support for UKA comes from patient reported outcomes, rather than gait analysis during stair negotiation^{11,15,18,21}. There is a lack of research evaluating sagittal plane knee biomechanics during stair descent in patient's under-going a TKA or UKA for the treatment of OA, compared to age-matched healthy controls. Therefore, the purpose of this study is to compare sagittal plane knee biomechanics in TKA and UKA

patients compared to healthy controls. It is hypothesized that UKA patients will have improved knee flexion angle and knee flexion moment compared to TKA patients. Additionally, it is hypothesized that UKA patients will exhibit sagittal plane biomechanical values more similar to healthy controls.

METHODOLOGY

Research Design

A longitudinal design was utilized to investigate the effectiveness of Unicompartamental knee arthroplasty (UKA) implant design when compared to total knee arthroplasty (TKA) implants and healthy controls. Biomechanical assessment of osteoarthritic (OA) patients during stair negotiation occurred within one-week prior to surgery and post-surgery at six-weeks, three-months, six-months and one-year. Healthy control participants completed a single biomechanical assessment and used for comparison of biomechanical variables of interest to knee arthroplasty patients.

Participants

Fifty-eight participants were included in this study. The UKA group consisted of seven patients (9 knees) compared to nine healthy control knees, and the TKA group consisted of 18 patients (24 knees) compared to 24 healthy control knees. Inclusion criteria for all arthroplasty patients consisted of: under 75 years of age, no previous history of lower extremity fracture, osteotomy, or joint replacement, undergoing an unilateral or bilateral UKA or TKA for the treatment of osteoarthritis, and physically able to walk without an aid. Total knee arthroplasty patients were screened for inclusion for this study and randomly assigned to receive either a single radius (SR) (GetAroundKnee™, Stryker Orthopedics, Mahwah,NJ) or a multi-radius (MR) implant (Balanced Knee® System, Ortho Development Corporation, Draper, UT) design. All UKA patients screened for inclusion received an Oxford→ Partial Knee Implant (Zimmer Biomet Orthopedics, Warsaw, IN). All TKA and UKA surgeries were performed by the same board certified orthopedic surgeon. Biomechanical assessment of enrolled

arthroplasty patients occurred within one week prior to surgery and post-surgery at six-weeks, three-months, six-months and one-year. Data was collected on healthy control participants in the same manner on the right limb only at a one-time data collection.

Inclusionary criteria for the controls included: between 55-75 years of age with no previous history of heart condition, balance or fainting disorders, Parkinson's Disease, diagnosed neurological disorders, diabetes mellitus, rheumatoid arthritis, osteoarthritis, surgery to the hip, knee or ankle or injury or severe knee pain in the last six months.

Prior to enrollment in the study, all participants signed informed consent forms approved by the Institution's Human Studies Program. Once consent was gained, participants received an ID number that was used for all data collection sessions and paperwork. All participant data was kept in a filing cabinet in a locked office within the Biomechanics Human Performance Lab at the University of Hawai'i at Mānoa. All adverse events, such as injury during testing sessions, were monitored and reported to the Institutional Review Board in accordance to the reporting criteria.

Procedures

All biomechanical analyses was conducted at the University of Hawai'i Gait Laboratory. Upon arrival at each visit, participants completed The University of California at Los Angeles (UCLA) activity questionnaire that asked the participant "to circle a number from 1-10 that best described their current activity level" (1-being wholly inactive, dependent on others, and cannot leave residence, 10-regularly participates in impact sports). Supplemental questions to be answered by participants consisted of: 1) "how does your knee affect your ability to rise from a chair?" (1-"because of my knee I cannot rise from a chair" to 4-"my knee does not affect my ability to rise from a chair")

and 2) “are you satisfied with your replacement?” (“yes” or “no”). Control participants, in addition to completing the UCLA activity questionnaire, completed a health questionnaire to determine eligibility to participate as a control subject in this study. Following completion of the surveys, participant’s height was collected using a wall-mounted stadiometer (Model 67032, Seca Telescopic Stadiometer, Country Technology, Inc., Gays Mills, WI, USA) and body mass was collected using a Detecto certifier scale (Webb City Mo, USA). Shank lengths were recorded as the distance measured from the lateral knee joint line to the distal lateral malleolus; 80% of shank length was calculated and marked. These markings served as location points for placement of the hand-held dynamometer during knee extensor strength testing, to allow for consistent placement of the dynamometer relative to each patient.

Twenty-nine reflective markers were placed bilaterally over: anterior superior iliac spines, posterior superior iliac spines, medial and lateral femoral condyles, medial and lateral malleoli, calcanei, base and head of the fifth metatarsals, head of the first and second metatarsals and acromioclavicular joints. Rigid marker arrays were placed bilaterally on lateral thighs and shanks. Single reflective markers were placed over: xiphoid process, superior aspect of manubrium at the jugular notch, vertebral spinous process of cervical seven, thoracic vertebral spinous process of thoracic ten and the inferior angle of the right scapula. Markers on the medial femoral epicondyle, medial malleolus and head of the first metatarsal were used for calibration purposes during a static trial only and were removed for stair trials.

A three-step staircase, with dimensions of an 18 cm step rise, 46 cm step width and 28 cm step tread was used for stair negotiation assessment. Each participant began

descending the stairs with a reciprocal foot-fall pattern with the surgical limb contacting the ground and second-step. A handrail was provided for safety but patients were instructed not to use it unless balance was compromised. If the handrail was used, the trial was discarded. A member of the research team was positioned at the bottom of the stairs at all times to provide further assistance if needed. During stair negotiation trials, marker positions were collected using a Vicon Nexus motion capture system (Vicon, Inc., Centennial, CO). Two force plates (Advanced Mechanical Technology Incorporated, Boston, MA), one embedded flush with the floor and one instrumented within the second step of the stairs, were used to collect kinetic data. Kinematic data was collected at 240 Hz and time synchronized with kinematic data collected at 960 Hz. A low-pass Butterworth filter was used to filter kinematic data and kinetic data used for calculation of external joint moments at a 10 Hz cut-off frequency and ground reaction force data was filtered using a 50 Hz cut-off frequency. Knee flexion angle and knee extension moments were reported at 25% and 50% to account for the biphasic pattern that occurred during stair descent. Twenty-five percent represented after heel contact on the force plate, and 50% represented the time before toe-off. Joint moments were calculated using inverse dynamics based on filtered marker trajectories and kinetic data. All joint moments were reported as external moments and knee flexion angle values were reported as a positive number. All data was processed with Visual 3D (C-Motion, Inc., Germantown, MD). Due to high intra-subject variability previously reported during stair climbing in the OA population, five successful trials were averaged²².

Following stair descent trials, bilateral knee extensor muscle strength tests was performed using a handheld dynamometer (Hoggan Health Industries, West Jordan, UT).

Placement of the dynamometer was at the marked 80% length of the shank and secured in place by a strap to ensure constant resistance. Knee extensor strength was performed with the patient seated in a recumbent position with their knee flexed to 65° and their trunk extended 130° from the surface of the treatment table with their hands placed on the table behind them supporting their trunk in this position. Participants were instructed to build a force over three seconds, holding the maximal force contraction for two seconds. Two trials of a three-second maximal effort isometric knee extension contraction was completed. A third trial was completed if the second trial did not measure within 10% force output of the first trial. Verbal encouragement was given to help elicit maximal force production by the participant during strength testing.

Statistical Analysis

Data normality was assessed using Shapiro-Wilk Test and Levene's Test to assess homogeneity of variance between groups for biomechanical variables of interest.

Analysis of variance (ANOVA) was performed to identify significant differences in dependent variables between controls, TKA, and UKA groups (p value, F-ratio). When assumptions of ANOVA were violated, e.g. significant Shapiro-Wilk or Levene's, the Mann Whitney U test was utilized for non-parametric analysis (MW p value).

Frequencies reported for questions: "how does your knee affect your ability to rise from a chair?", and patient satisfaction were reported. All data was analyzed using SPSS Version 22.0 and an alpha level of $p < 0.05$ was used to determine statistical significance.

RESULTS

Patient demographics were not significantly different between groups and are listed in table 1. Fifty-eight patients were included in this study (n=7 UKA, n=18 TKA, n=33 healthy controls).

Table 1. Participant Demographics.

	UKA (N=7)	CON (N=9)	UKA vs. CON	TKA (N=18)	CON (N=24)	TKA vs. CON	UKA vs. TKA
	Mean (SD)	Mean (SD)	<i>P</i> Value	Mean (SD)	Mean (SD)	<i>P</i> Value	<i>P</i> Value
Age	68.0 (3.7)	68.1 (4.5)	0.948	65.0 (5.0)	63.8 (6.9)	0.564	0.159
Height (m)	1.7 (.09)	1.7 (.08)	0.192	1.7 (.09)	1.7 (.09)	0.462	0.716
Weight (kg)	85.2 (16.4)	86.9 (19.5)	0.851	81.7 (16.0)	80.6 (15.8)	0.82	0.633

UKA, unicompartmental knee arthroplasty; TKA, total compartmental knee arthroplasty.

CON, controls; SD, standard deviation; $P \leq 0.05$ significance.

m, meters; kg, kilograms.

Unicompartmental Knee Arthroplasty v. Total Knee Arthroplasty

Seven UKA (2 bilateral, aged 67.9 ± 3.7) patients were compared to 18 TKA (6 bilateral, aged 64.9 ± 5.0) patients. Biomechanical variable means and standard deviations can be seen in table 2.

No spatiotemporal variables or knee extensor strength were significantly different between the UKA and TKA patients. The UKA group produced 6.4° greater knee flexion angle (KFA) at 25% of stance six-months post-operatively compared to the TKA group (MW $p=0.015$) and 8.7° more at one-year ($p=0.001$, F-ratio=14.422). Knee flexion angle at 50% of stance six-months post-operatively was 5.5° greater in the UKA patients ($p=0.05$, F-ratio=4.184) and 8.9° greater one-year ($p=0.002$, F-ratio=11.693). At six-months, the UKA generated $0.3 \text{ Nm}\cdot\text{kg}^{-1}$ more knee flexion moment (KFM) at 25% of stance than the TKA ($p=0.012$, F-ratio=7.077) and at one-year $0.4 \text{ Nm}\cdot\text{kg}^{-1}$ more ($p=0.004$, F-ratio=10.16). The UKA also demonstrated $0.3 \text{ Nm}\cdot\text{kg}^{-1}$ more KFM at 50% of stance six-months post-operatively, and $0.4 \text{ Nm}\cdot\text{kg}^{-1}$ more at one-year ($p=0.003$, F-

ratio=11.234). Knee extension power was 108.6 W greater in the UKA group one-year post-operatively compared to the TKA group ($p=0.038$, F-ratio=4.794).

There was no significant difference between UKA and TKA patients and their “how does your knee affect your ability to rise from a chair?” question, and patient satisfaction question. All UKA and TKA patients were satisfied with their implants, and at one year were able to rise from their chair. Percent frequencies for patient group answers can be seen in table 3.

Unicompartmental Knee Arthroplasty v. Healthy Controls

Seven UKA (2 bilateral, aged 68.0 ± 3.7) patients were compared to nine healthy controls (aged 68.1 ± 4.5). Biomechanics variables means and standard deviations can be seen in table 4.

The controls were 1.4 seconds faster to descend the stairs pre-operatively (MW $p \leq 0.001$), 2.4 seconds faster at six-weeks (MW $p \leq 0.001$), 0.4 seconds faster at three-months (MW $p=0.003$), and 0.3 seconds faster at six-months ($p \leq 0.001$, F-ratio=16.974) than the UKA group. Knee extensor strength was not statistically significantly at any time point. Unicompartmental knee arthroplasty (UKA) patients produced 9.6° greater KFA at 25% of stance one-year post-operatively ($p=0.002$, F-ratio=13.323) than the controls. Knee flexion angle at 50% of stance at one-year was 10.3° greater in the UKA patients ($p=0.003$, F-ratio=13.369) than the controls.

Pre-operatively, the controls produced $3.6 \text{ N} \cdot \text{kg}^{-1}$ more of ground reaction force on the first force plate during stair descent than the UKA (MW $p=0.031$). The controls also produced $0.5 \text{ Nm} \cdot \text{kg}^{-1}$ greater KFM at 25% of stance pre-operatively ($p=0.025$, F-ratio=6.254) and at six-weeks post-operatively ($p=0.012$, F-ratio=8.075) than the UKA.

The controls generated $0.3 \text{ Nm}\cdot\text{kg}^{-1}$ greater KFM at 50% of stance than the UKA at six-weeks post-operatively ($p=0.025$, F-ratio=6.12). Knee extension power was 202.0 W greater in the controls pre-operatively ($p=0.007$, F-ratio=9.887), 203.5 W greater six-weeks post-operatively ($p=0.006$, F-ratio =9.962), and 152.1 W greater three-months post-operatively ($p=0.038$, F-ratio =5.139) than the UKA group.

Total Knee Arthroplasty v. Healthy Controls

Eighteen TKA (6 bilateral, aged 64.9 ± 5.0) patients were compared to 24 healthy controls (aged 63.8 ± 6.9). Biomechanics variables means and standard deviations can be seen in table 5.

The controls were more quickly to descend the stairs than the TKA pre-operatively by 1.5 seconds (MW $p\leq 0.001$), 1.7 seconds faster at six-weeks (MW $p\leq 0.001$), 1.5 seconds faster at three-months (MW $p\leq 0.001$), 1.8 seconds faster at six months (MW $p\leq 0.001$), and 1.1 seconds faster at one-year (MW $p\leq 0.001$). Controls demonstrated 4.0° greater KFA at 25% of stance post-operatively at six-weeks ($p=0.016$, F-ratio =6.419), three-months ($p=0.009$, F-ratio =7.437), and six-months (MW $p=0.041$) than the TKA.

The controls produced $2.1 \text{ N}\cdot\text{kg}^{-1}$ more ground reaction force on the first force plate of stair descent pre-operatively (MW $p=0.007$), $2.6 \text{ N}\cdot\text{kg}^{-1}$ more six-weeks post-operatively ($p\leq 0.001$, F-ratio=16.922), and $1.8 \text{ N}\cdot\text{kg}^{-1}$ more three-months post-operatively (MW $p=0.012$). The controls on the second force plate of stair decent produced $2.0 \text{ N}\cdot\text{kg}^{-1}$ more pre-operatively ($p=0.003$, F-ratio=9.9), $2.8 \text{ N}\cdot\text{kg}^{-1}$ more at six weeks ($p\leq 0.001$, F-ratio=18.313), and $1.8 \text{ N}\cdot\text{kg}^{-1}$ more at three-months ($p=0.017$, F-ratio=6.222). Knee flexion moment at 25% of stance was $0.6 \text{ Nm}\cdot\text{kg}^{-1}$ greater in controls

pre-operatively ($p \leq .001$, F-ratio =46.053), 0.7 $\text{Nm} \cdot \text{kg}^{-1}$ greater at six-weeks ($p \leq .001$, F-ratio =63.626), 0.6 $\text{Nm} \cdot \text{kg}^{-1}$ greater at six-months ($p \leq .001$, F-ratio =40.931), and 0.5 $\text{Nm} \cdot \text{kg}^{-1}$ more at one-year ($p \leq .001$, F-ratio=32.112) than the TKA. Controls also generated 0.6 $\text{Nm} \cdot \text{kg}^{-1}$ greater KFM at 50% of stance pre-operatively (MW $p \leq 0.001$), 0.5 $\text{Nm} \cdot \text{kg}^{-1}$ greater at six-weeks (MW $p \leq 0.001$), 0.5 $\text{Nm} \cdot \text{kg}^{-1}$ more at six-months ($p \leq 0.001$, F-ratio=38.199), and 0.4 $\text{Nm} \cdot \text{kg}^{-1}$ more at one-year ($p \leq 0.001$, F-ratio=24.547) than TKA. Knee extension power was 185.1 W more in controls pre-operatively (MW $p \leq 0.001$), 215.0 W at six-weeks post-operatively (MW $p \leq 0.001$), 204.7 W at three-months (MW $p \leq 0.001$), and 182.4 W at six-months (MW $p < 0.001$), and 147.71 W greater at one-year ($p \leq 0.001$, F-ratio=17.317) than TKA patients.

The controls were stronger by 19.7 pounds of force (lbs.) in knee extensor strength than the TKA patients pre-operatively ($p = 0.015$, F-ratio=6.416) and 35.2 lbs. at six-weeks ($p \leq 0.001$, F-ratio=22.171), 27.3 lbs. at three-months ($p \leq 0.001$, F-ratio=17.642), 23.7 lbs. at six-months ($p = 0.003$, F-ratio=9.813), and 17.5 lbs. at one-year ($p = 0.027$, F-ratio=5.225) post-operatively.

Table 2. Descriptive Measures of Biomechanical Variables Over Time for UKA and TKA Groups.

Spatiotemporal	Pre-Operative					6-Weeks			
	Group	N	Mean (SD)	95% CI	P Value	N	Mean (SD)	95% CI	P Value
Total Time on Stairs (s)	UKA	7	2.5 (1.2)	1.4-3.7	0.199 ^d	9	3.5 (3.9)	0.5-6.5	0.754 ^d
	TKA	22	2.6 (3.1)	1.2-4.0		12	2.9 (3.8)	0.5-5.3	
Kinematics									
KFA at 25% of stance (°)	UKA	7	24.0 (8.1)	16.5-31.5	0.761 ^c	9	26.6 (3.8)	23.7-29.6	0.194 ^c
	TKA	22	25.2 (9.4)	21.1-29.4		12	24.4 (3.7)	22.0-26.8	
KFA at 50% of stance (°)	UKA	7	33.5 (13.9)	20.6-46.4	0.354 ^c	9	30.7 (3.0)	28.4-33.0	0.583 ^c
	TKA	22	29.1 (9.9)	24.7-33.4		12	31.9 (5.8)	28.2-35.6	
Kinetics									
KFM at 25% of stance (Nm/kg)	UKA	7	0.9 (0.4)	1.3-0.5	0.296 ^c	9	0.9 (0.4)	1.2-0.6	0.693 ^d
	TKA	22	0.7 (0.4)	0.9-0.5		12	0.7 (0.2)	0.8-0.6	
KFM at 50% of stance (Nm/kg)	UKA	7	1.0 (0.4)	1.4-0.7	0.122 ^d	9	1.0 (0.3)	1.2-0.8	0.095 ^c
	TKA	22	0.8 (0.4)	1.0-0.7		12	0.9 (0.2)	1.0-0.8	
GRF 1 (N/kg)	UKA	7	12.2 (3.4)	9.1-15.4	0.438 ^d	9	13.5 (4.1)	10.4-16.6	0.808 ^d
	TKA	22	13.1 (2.8)	11.9-14.4		12	12.7 (2.0)	11.4-13.9	
GRF 2 (N/kg)	UKA	7	14.1 (2.8)	11.5-16.6	0.598 ^c	9	15.7 (4.1)	12.6-18.9	0.262 ^d
	TKA	22	14.7 (2.6)	13.5-15.8		13	13.9 (2.2)	12.6-15.2	
Knee Power Extension (W)	UKA	7	274.4 (86.5)	354.4-194.4	0.409 ^d	9	272.9 (120.8)	365.7-180.1	0.345 ^d
	TKA	22	255.8 (118.8)	308.4-203.1		12	225.9 (88.0)	281.8-170.0	
Strength									
Knee Extensor Strength (lbs.)	UKA	9	81.9 (37.8)	52.9-110.9	0.237 ^c	9	70.9 (26.9)	50.2-91.5	0.068 ^c
	TKA	24	67.1 (28.9)	54.9-79.3		20	51.5 (24.7)	40.0-63.1	
Spatiotemporal									
Total Time on Stairs (s)	3-Months					6-Months			
	UKA	9	1.5 (0.3)	1.3-1.7	0.263 ^d	9	1.4 (0.2)	1.3-1.5	0.773 ^d
TKA	21	2.7 (3.4)	1.1-4.2	23		3.0 (4.2)	1.2-4.8		
Kinematics									
KFA at 25% of stance (°)	UKA	9	27.6 (5.8)	23.2-32.1	0.139 ^c	9	30.6 (6.2) ^a	25.9-35.4	0.015 ^d
	TKA	21	24.0 (6.1)	21.2-26.8		23	24.2 (6.8)	21.3-27.2	
KFA at 50% of stance (°)	UKA	9	32.5 (5.8)	28.0-36.9	0.395 ^c	9	35.8 (7.3) ^a	30.2-41.4	0.050 ^c
	TKA	21	29.8 (8.4)	26.0-33.6		23	30.3 (6.7)	27.4-33.2	
Kinetics									
KFM at 25% of stance (Nm/kg)	UKA	9	1.1 (0.4)	1.3-0.8	0.819 ^c	9	1.1 (0.2) ^a	1.3-0.9	0.012 ^c
	TKA	22	1.0 (0.9)	1.4-0.6		23	0.8 (0.3)	0.9-0.7	
KFM at 50% of stance (Nm/kg)	UKA	9	1.1 (0.3)	1.4-0.9	0.924 ^c	9	1.2 (0.2) ^a	1.3-1.0	0.020 ^c
	TKA	21	1.1 (1.0)	1.6-0.6		23	0.9 (0.3)	1.0-0.8	
GRF 1 (N/kg)	UKA	9	14.3 (4.0)	11.2-17.4	0.982 ^d	9	14.6 (3.7)	11.8-17.4	0.509 ^d
	TKA	20	13.4 (2.6)	12.2-14.6		23	14.3 (2.6)	13.2-15.4	
GRF 2 (N/kg)	UKA	9	17.0 (3.3)	14.5-19.5	0.150 ^d	8	16.9 (2.9)	14.5-19.4	0.368 ^d
	TKA	21	14.8 (3.1)	13.4-16.2		22	16.1 (2.5)	15.0-17.2	
Knee Power Extension (W)	UKA	9	324.3 (133.0)	426.5-222.0	0.077 ^d	9	356.4 (142.9)	466.2-246.5	0.078 ^d
	TKA	20	236.2 (127.1)	295.7-176.7		23	258.5 (84.1)	294.8-222.1	
Strength									
Knee Extensor Strength (lbs.)	UKA	9	67.7 (35.6)	40.4-95.1	0.480 ^d	9	86.8 (38.0)	57.6-116.0	0.112 ^d
	TKA	22	59.4 (18.6)	51.2-67.7		23	63.1 (27.1)	51.3-74.8	

Table 2. Descriptive Measures of Biomechanical Variables Over Time for UKA and TKA Groups.

Spatiotemporal	1-Year				
	Group	N	Mean (SD)	95% CI	P Value
Total Time on Stairs (s)	UKA	7	1.3 (0.2)	1.1-1.4	0.120 ^d
	TKA	19	2.3 (3.3)	0.7-3.9	
Kinematics					
KFA at 25% of stance (°)	UKA	8	35.8 (5.8) ^b	30.9-40.6	0.001 ^c
	TKA	18	27.1 (5.2)	24.5-29.7	
KFA at 50% of stance (°)	UKA	7	41.7 (5.7) ^a	36.4-47.0	0.002 ^c
	TKA	19	32.7 (6.0)	29.9-35.6	
Kinetics					
KFM at 25% of stance (Nm/kg)	UKA	8	1.3 (0.4) ^a	1.6-1.0	0.004 ^c
	TKA	19	0.9 (0.3)	1.0-0.8	
KFM at 50% of stance (Nm/kg)	UKA	7	1.4 (0.3) ^a	1.7-1.1	0.003 ^c
	TKA	19	1.0 (0.2)	1.1-0.9	
GRF 1 (N/kg)	UKA	7	15.7 (3.5)	12.4-18.9	0.427 ^d
	TKA	19	14.3 (2.2)	13.2-15.4	
GRF 2 (N/kg)	UKA	7	18.5 (3.0)	15.7-21.2	0.096 ^c
	TKA	19	16.6 (2.3)	15.5-17.7	
Knee Power Extension (W)	UKA	8	401.8 (154.0) ^a	530.5-273.0	0.038 ^c
	TKA	19	293.1 (100.1)	341.4-244.9	
Strength					
Knee Extensor Strength (lbs.)	UKA	9	90.0 (37.8)	60.9-119.0	0.096 ^c
	TKA	21	69.3 (26.5)	57.2-81.3	

UKA, unicompartmental knee arthroplasty; TKA, total knee arthroplasty.

SD, standard deviation; CI, confidence interval.

KFA, knee flexion angle; (°), degrees; KFM, knee flexion moment.

Nm/kg, newton-meters per kilogram; (N/kg), newtons per kilogram.

GRF 1, force plate in stairs; GRF 2, force plate in ground; (W), watts; (s), second; (lbs.), pounds.

^a, significant difference ($P \leq 0.05$).

^b, significant difference ($P \leq 0.001$).

^c, ANOVA.

^d, Mann Whitney U-test.

Table 3. Percentages of UKA and TKA Patients' Satisfied, and "Chair Rise" Ability.

	Pre-Operative		6-Weeks		3-Months		6-Months		1-Year	
	UKA (N=7)	TKA (N=18)	UKA (N=7)	TKA (N=14)	UKA (N=7)	TKA (N=16)	UKA (N=7)	TKA (N=17)	UKA (N=7)	TKA (N=14)
Satisfied Patient	100%	n/a	100%	n/a	100%	n/a	100%	83.30%	100%	77.8%
Chair Rise Question										
"2"	42.9%	44.4%	14.3%	5.6%	14.3%	5.6%	14.3%	11.1%	14.3%	5.6%
"3"	14.3%	44.4%	57.1%	44.4%	0%	44.4%	0%	22.2%	14.3%	0.0%
"4"	14.3%	11.1%	28.6%	27.8%	85.7%	38.9%	85.7%	61.1%	71.4%	72.2%
Missed				22.20%		11.10%		5.50%		22.20%

UKA, unicompartmental knee arthroplasty; TKA, total knee arthroplasty.

"2", Because of my knee, I can only rise from a chair if I use my hands and arms to assist.

"3", I have pain when rising from the seated position, but it does not affect my ability to rise from the seated position.

"4", My knee does not affect my ability to rise from a chair.

Table 4. Descriptive Measures of Biomechanical Variables Over Time in UKA and Control Groups.

Spatiotemporal	Pre-Operative					6-Weeks			
	Group	N	Mean (SD)	95% CI	P Value	N	Mean (SD)	95% CI	P Value
Total Time on Stairs (s)	UKA	7	2.5 (1.2) ^b	1.4-3.7	0.000 ^d	9	3.5 (3.9) ^b	0.5-6.5	0.000 ^d
	CON	9	1.1 (0.1)	1.0-1.2		9	1.1 (0.1)	1.0-1.2	
Kinematics									
KFA at 25% of stance (°)	UKA	7	24.0 (8.1)	16.5-31.5	0.523 ^c	9	26.6 (3.8)	23.7-29.6	0.829 ^c
	CON	9	26.2 (5.1)	22.2-30.1		9	26.2 (5.1)	22.2-30.1	
KFA at 50% of stance (°)	UKA	7	33.5 (13.9)	20.6-46.4	0.674 ^c	9	30.7 (3.0)	28.4-33.0	0.760 ^c
	CON	9	31.3 (5.6)	27.1-35.6		9	31.3 (5.6)	27.1-35.6	
Kinetics									
KFM at 25% of stance (Nm/kg)	UKA	7	0.9 (0.4) ^a	1.3-0.5	0.025 ^c	9	0.9 (0.4) ^a	1.2-0.6	0.012 ^c
	CON	9	1.3 (0.3)	1.6-1.1		9	1.3 (0.3)	1.6-1.1	
KFM at 50% of stance (Nm/kg)	UKA	7	1.0 (0.4)	1.4-0.7	0.142 ^d	9	1.0 (0.3) ^a	1.2-0.8	0.025 ^c
	CON	9	1.4 (0.3)	1.6-1.1		9	1.4 (0.3)	1.6-1.1	
GRF 1 (N/kg)	UKA	7	12.2 (3.4) ^a	9.1-15.4	0.031 ^d	9	13.5 (4.1)	10.4-16.6	0.063 ^d
	CON	9	15.8 (1.9)	14.3-17.3		9	15.8 (1.9)	14.3-17.3	
GRF 2 (N/kg)	UKA	7	14.1 (2.8)	11.5-16.6	0.068 ^c	9	15.7 (4.1)	12.6-18.9	0.546 ^d
	CON	9	16.6 (2.4)	14.8-18.5		9	16.6 (2.4)	14.8-18.5	
Knee Power Extension (W)	UKA	7	274.4 (86.5) ^a	354.4-194.4	0.007 ^c	9	272.9 (120.8) ^a	365.7-180.1	0.006 ^c
	CON	9	476.4 (151.1)	592.5-360.3		9	476.4 (151.1)	592.5-360.3	
Strength									
Knee Extensor Strength (lbs.)	UKA	9	81.9 (37.8)	52.9-110.9	0.984 ^c	9	70.9 (26.9)	50.2-91.5	0.363 ^c
	CON	9	82.2 (24.4)	63.5-100.9		9	82.2 (24.4)	63.5-100.9	
Spatiotemporal									
Total Time on Stairs (s)	3-Months					6-Months			
	UKA	9	1.5 (0.3) ^a	1.3-1.7	0.003 ^d	9	1.4 (0.2) ^b	1.3-1.5	0.001 ^c
CON	9	1.1 (0.1)	1.0-1.2		9	1.1 (0.1)	1.0-1.2		
Kinematics									
KFA at 25% of stance (°)	UKA	9	27.6 (5.8)	23.2-32.1	0.581 ^c	9	30.6 (6.2)	25.9-35.4	0.114 ^c
	CON	9	26.2 (5.1)	22.2-30.1		9	26.2 (5.1)	22.2-30.1	
KFA at 50% of stance (°)	UKA	9	32.5 (5.8)	28.0-36.9	0.683 ^c	9	35.8 (7.3)	30.2-41.4	0.162 ^c
	CON	9	31.3 (5.6)	27.1-35.6		9	31.3 (5.6)	27.1-35.6	
Kinetics									
KFM at 25% of stance (Nm/kg)	UKA	9	1.1 (0.4)	1.3-0.8	0.095 ^c	9	1.1 (0.2)	1.3-0.9	0.120 ^c
	CON	9	1.3 (0.3)	1.6-1.1		9	1.3 (0.3)	1.6-1.1	
KFM at 50% of stance (Nm/kg)	UKA	9	1.1 (0.3)	1.4-0.9	0.112 ^c	9	1.2 (0.2)	1.3-1.0	0.133 ^c
	CON	9	1.4 (0.3)	1.6-1.1		9	1.4 (0.3)	1.6-1.1	
GRF 1 (N/kg)	UKA	9	14.3 (4.0)	11.2-17.4	0.332 ^c	9	14.6 (3.7)	11.8-17.4	0.222 ^d
	CON	9	15.8 (1.9)	14.3-17.3		9	15.8 (1.9)	14.3-17.3	
GRF 2 (N/kg)	UKA	9	17.0 (3.3)	14.5-19.5	0.666 ^d	8	16.9 (2.9)	14.5-19.4	0.963 ^d
	CON	9	16.6 (2.4)	14.8-18.5		9	16.6 (2.4)	14.8-18.5	
Knee Power Extension (W)	UKA	9	324.3 (133.0) ^a	426.5-222.0	0.038 ^c	9	356.4 (142.9)	466.2-246.5	0.103 ^c
	CON	9	476.4 (151.1)	592.5-360.3		9	476.4 (151.1)	592.5-360.3	
Strength									
Knee Extensor Strength (lbs.)	UKA	9	67.7 (35.6)	40.4-95.1	0.330 ^c	9	86.8 (38.0)	57.6-116.0	0.730 ^d
	CON	9	82.2 (24.4)	63.5-100.9		9	82.2 (24.4)	63.5-100.9	

Table 4. Descriptive Measures of Biomechanical Variables Over Time in UKA and Control Groups.

Spatiotemporal	1-Year				
	Group	N	Mean (SD)	95% CI	P Value
Total Time on Stairs (s)	UKA	7	1.3 (0.2)	1.1-1.4	0.114 ^d
	CON	9	1.1 (0.1)	1.0-1.2	
Kinematics					
KFA at 25% of stance (°)	UKA	8	35.8 (5.8) ^a	31.0-40.6	0.002 ^c
	CON	9	26.2 (5.1)	22.2-30.1	
KFA at 50% of stance (°)	UKA	7	41.7 (5.7) ^a	36.4-46.9	0.003 ^c
	CON	9	31.3 (5.6)	27.1-35.6	
Kinetics					
KFM at 25% of stance (Nm/kg)	UKA	8	1.3 (0.4)	1.6-1.0	0.861 ^c
	CON	9	1.3 (0.3)	1.6-1.1	
KFM at 50% of stance (Nm/kg)	UKA	7	1.4 (0.3)	1.7-1.1	0.767 ^c
	CON	9	1.4 (0.3)	1.6-1.1	
GRF 1 (N/kg)	UKA	7	15.7 (3.5)	12.4-18.9	0.837 ^d
	CON	9	15.8 (2.0)	14.3-17.3	
GRF 2 (N/kg)	UKA	7	18.5 (3.0)	15.7-21.2	0.193 ^c
	CON	9	16.6 (2.4)	14.8-18.5	
Knee Power Extension (W)	UKA	8	401.8 (154.0)	530.5-273.0	0.330 ^c
	CON	9	476.4 (151.1)	592.5-360.3	
Strength					
Knee Extensor Strength (lbs.)	UKA	9	90.0 (37.8)	60.9-119.0	0.612 ^c
	CON	9	82.2 (24.4)	63.5-100.9	

UKA, unicompartmental knee arthroplasty; CON, controls.

SD, standard deviation; CI, confidence interval.

KFA, knee flexion angle; (°), degrees; KFM, knee flexion moment.

Nm/kg, newton-meters per kilogram; (N/kg), newtons per kilogram.

GRF 1, force plate in stairs; GRF 2, force plate in ground; (W), watts; (s), second; (lbs.), pounds.

^a, significant difference ($P \leq 0.05$).

^b, significant difference ($P \leq 0.001$).

^c, ANOVA.

^d, Mann Whitney U-test.

Table 5. Descriptive Measures of Biomechanical Variables Over Time in TKA and Control Groups.

Spatiotemporal	Pre-Operative					6-Weeks			
	Group	N	Mean (SD)	95% CI	P Value	N	Mean (SD)	95% CI	P Value
Total Time on Stairs (s)	TKA	22	2.6 (3.1) ^b	1.2-4.0	0.000 ^d	12	2.9 (3.8) ^b	0.4-5.3	0.000 ^d
	CON	24	1.2 (0.1)	1.1-1.2		24	1.2 (0.1)	1.1-1.2	
Kinematics									
KFA at 25% of stance (°)	TKA	22	25.2 (9.4)	21.1-29.4	0.344 ^d	12	24.4 (3.7) ^a	22.0-26.8	0.016 ^c
	CON	24	28.4 (4.8)	26.4-30.4		24	28.4 (4.8)	26.4-30.4	
KFA at 50% of stance (°)	TKA	22	29.1 (9.9)	24.7-33.4	0.113 ^d	12	31.9 (5.8)	28.2-35.6	0.497 ^d
	CON	24	33.2 (4.2)	31.4-34.9		24	33.2 (4.2)	31.4-34.9	
Kinetics									
KFM at 25% of stance (Nm/kg)	TKA	22	0.7 (0.4) ^b	0.9-0.5	0.000 ^c	12	0.7 (0.2) ^b	0.8-0.6	0.000 ^c
	CON	24	1.4 (0.3)	1.5-1.2		24	1.4 (0.3)	1.5-1.2	
KFM at 50% of stance (Nm/kg)	TKA	22	0.8 (0.4) ^b	1.0-0.7	0.000 ^d	12	0.9 (0.2) ^b	1.0-0.7	0.000 ^d
	CON	24	1.4 (0.3)	1.5-1.3		24	1.4 (0.3)	1.5-1.3	
GRF 1 (N/kg)	TKA	22	13.1 (2.8) ^a	11.9-14.4	0.007 ^d	12	12.7 (2.0) ^b	11.4-13.9	0.000 ^c
	CON	24	15.2 (1.7)	14.5-15.9		24	15.2 (1.7)	14.5-15.9	
GRF 2 (N/kg)	TKA	22	14.7 (2.6) ^a	13.5-15.8	0.003 ^c	13	13.9 (2.2) ^b	12.6-15.2	0.000 ^c
	CON	24	16.7 (1.7)	15.9-17.4		24	16.7 (1.7)	15.9-17.4	
Knee Power Extension (W)	TKA	22	255.8 (118.8) ^b	308.4-203.1	0.000 ^d	12	225.9 (88.0) ^b	281.8-170.0	0.000 ^d
	CON	24	440.8 (126.4)	494.2-387.5		24	440.8 (126.4)	494.2-387.5	
Strength									
Knee Extensor Strength (lbs.)	TKA	24	67.1 (28.9) ^a	54.9-79.3	0.015 ^c	20	51.5 (24.7) ^b	40.0-63.1	0.000 ^d
	CON	24	86.8 (24.8)	76.3-97.2		24	86.8 (24.8)	76.3-97.2	
Spatiotemporal									
Total Time on Stairs (s)	3-Months					6-Months			
	TKA	21	2.7 (3.4) ^b	1.1-4.2	0.000 ^d	23	3.0 (4.2) ^b	1.2-4.8	0.000 ^d
CON	24	1.2 (0.1)	1.1-1.2		24	1.2 (0.1)	1.1-1.2		
Kinematics									
KFA at 25% of stance (°)	TKA	21	24.0 (6.1) ^a	21.2-26.8	0.009 ^c	23	24.2 (6.8) ^a	21.3-27.2	0.041 ^d
	CON	24	28.4 (4.8)	26.4-30.4		24	28.4 (4.8)	26.4-30.4	
KFA at 50% of stance (°)	TKA	21	29.8 (8.4)	26.0-33.6	0.152 ^d	23	30.3 (6.7)	27.4-33.2	0.209 ^d
	CON	24	33.2 (4.2)	31.4-34.9		24	33.2 (4.2)	31.4-34.9	
Kinetics									
KFM at 25% of stance (Nm/kg)	TKA	22	1.0 (0.9)	1.4-0.6	0.061 ^c	23	0.8 (0.3) ^b	0.9-0.7	0.000 ^c
	CON	24	1.4 (0.3)	1.5-1.2		24	1.4 (0.3)	1.5-1.2	
KFM at 50% of stance (Nm/kg)	TKA	21	1.1 (1.0)	1.6-0.6	0.160 ^c	23	0.9 (0.3) ^b	1.0-0.8	0.000 ^c
	CON	24	1.4 (0.3)	1.5-1.3		24	1.4 (0.3)	1.5-1.3	
GRF 1 (N/kg)	TKA	20	13.4 (2.6) ^a	12.2-14.6	0.012 ^d	23	14.3 (2.6)	13.2-15.4	0.142 ^c
	CON	24	15.2 (1.7)	14.5-15.9		24	15.2 (1.7)	14.5-15.9	
GRF 2 (N/kg)	TKA	21	14.8 (3.1) ^a	13.4-16.3	0.017 ^c	22	16.1 (2.5)	15.0-17.2	0.218 ^d
	CON	24	16.7 (1.7)	15.9-17.4		24	16.7 (1.7)	15.9-17.4	
Knee Power Extension (W)	TKA	20	236.2 (127.1) ^b	295.7-176.7	0.000 ^d	23	258.5 (84.1) ^b	294.8-222.1	0.000 ^d
	CON	24	440.8 (126.4)	494.2-387.5		24	440.8 (126.4)	494.2-387.5	
Strength									
Knee Extensor Strength (lbs.)	TKA	22	59.4 (18.6) ^b	51.2-67.7	0.000 ^c	23	63.1 (27.1) ^a	51.3-74.8	0.003 ^c
	CON	24	86.8 (24.8)	76.3-97.2		24	86.8 (24.8)	76.3-97.2	

Table 5. Descriptive Measures of Biomechanical Variables Over Time in TKA and Control Groups.

Spatiotemporal	1-Year				
	Group	N	Mean (SD)	95% CI	P Value
Total Time on Stairs (s)	TKA	19	2.3 (3.3) ^b	0.7-3.9	0.000 ^d
	CON	24	1.2 (0.1)	1.1-1.2	
Kinematics					
KFA at 25% of stance (°)	TKA	18	27.1 (5.2)	24.5-29.7	0.415 ^c
	CON	24	28.4 (4.8)	26.4-30.4	
KFA at 50% of stance (°)	TKA	19	32.7 (6.0)	29.8-35.6	0.660 ^d
	CON	24	33.2 (4.2)	31.4-34.9	
Kinetics					
KFM at 25% of stance (Nm/kg)	TKA	19	0.9 (0.3) ^b	1.0-0.8	0.000 ^c
	CON	24	1.4(0.3)	1.5-1.2	
KFM at 50% of stance (Nm/kg)	TKA	19	1.0 (0.2) ^b	1.1-0.9	0.000 ^c
	CON	24	1.4 (0.3)	1.5-1.3	
GRF 1 (N/kg)	TKA	19	14.3 (2.2)	13.2-15.4	0.096 ^d
	CON	24	15.2 (1.7)	14.5-15.9	
GRF 2 (N/kg)	TKA	19	16.6 (2.3)	15.5-17.7	0.887 ^c
	CON	24	16.7 (1.7)	15.9-17.4	
Knee Power Extension (W)	TKA	19	293.1 (100.1) ^b	341.4-244.9	0.000 ^c
	CON	24	440.8 (126.4)	494.2-387.5	
Strength					
Knee Extensor Strength (lbs.)	TKA	21	69.3 (26.5) ^a	57.2-81.3	0.027 ^c
	CON	24	86.8 (24.8)	76.3-97.2	

TKA, total knee arthroplasty; CON, controls.

SD, standard deviation; CI, confidence interval.

KFA, knee flexion angle; (°), degrees; KFM, knee flexion moment.

Nm/kg, newton-meters per kilogram; (N/kg), newtons per kilogram.

GRF 1, force plate in stairs; GRF 2, force plate in ground; (W), watts; (s), second; (lbs.), pounds.

^a, significant difference ($P \leq 0.05$).

^b, significant difference ($P \leq 0.001$).

^c, ANOVA.

^d, Mann Whitney U-test.

DISCUSSION

The main finding of this study was that the UKA patients demonstrated more favorable biomechanics, loaded their knees more, and were faster at descending stairs compared to the TKA patients, and when compared to their respective control groups. Stair descent values between the UKA and TKA patients are similar to previous research showing no significant difference at eight-weeks post-operatively for biomechanical variables during gait²⁰. Patients undergoing UKA demonstrated significantly better outcomes starting at six-months and continuing to one-year post-operatively with greater knee angles and moments at 25% and 50% of stance when compared to TKA patients. Similar to previous research showing UKA patients walked 15% faster than TKA patients during downhill walking, UKA patients in this study were able to descend stairs more quickly than the TKA patients¹⁷. At six-months and one-year post-operatively both UKA and TKA patients were satisfied with their implants, and were able to rise from a chair. Some patients still reported pain or needing arms for assistance with rising from a chair, but those frequencies were lower than pain free and assistance free rising from a chair.

The UKA patients demonstrated similar biomechanical variables at all time points. At one-year post-operatively the UKA patients exceeded knee angles at both 25% and 50% of stance when compared to healthy controls. Knee moments were similar between groups as early as three-months post-operatively, and this is supported with previous literature finding that 70% of UKA patients had normal biphasic flexion/extension moment patterns²⁸. Ground reaction force, knee extension power and knee extensor strength were also similar between the UKA patients and healthy controls at all time points. The UKA were less quick to descend stairs than controls up to six-

months post-operatively, and returned to similar values at one-year post-operatively; this is similar to research concluding UKA had improved spatiotemporal values than TKA¹⁶. Previous research concluding superior outcomes in UKA has been limited to gait analysis or patient reported questionnaires, not stair descent, specifically.

Deficits during stair descent were present in the TKA patients when compared to their healthy controls at all time points for several biomechanical variables of interest. The TKA patients demonstrated decreased knee angles at six-weeks, three-months and six-months post-operatively than the healthy controls, which is similar to findings in literature⁵. Smaller knee moments were produced by the TKA patients pre-operatively, six-weeks, six-months and one-year post-operatively than the healthy controls, and this is similar to previous research concluding that only 23% of TKA had normal extension moment patterns during gait³. There were decreased ground reaction forces six-weeks, three-months and six-months post-operatively when compared to controls. The TKA patients at all time points produced less knee extension power and knee extensor strength when compared to their controls. Only knee angles and ground reaction force returned to values similar to controls one-year post-operatively.

Several limitations were present in this study. There were unequal sample sizes in the UKA and the TKA groups, and only two of the seven UKA patients received bilateral implants compared to six of the 18 TKA. Some patients were not present at every data collection, making unequal sample sizes between the data collections. This could be due to the convenience of getting to the biomechanics gait laboratory for the patients. The small sample size in the UKA patients could have attributed to the non-parametric analysis that were analyzed. The non-parametric Mann-Whitney U test found additional

significant variables than the ANOVA analyses. Another factor were the differences in rehabilitation programs between the UKA and TKA patients. Rehabilitation programs were not standardized between patients due to them being completed at different clinics, and this may have impacted the post-surgical biomechanical variables during stair descent. Patella resurfacing was performed on all TKA patients, and the UKA patients did not have patella resurfacing. The difference in resurfacing could have affected the proprioception of the TKA patients and their ability in returning to similar control values. Future studies should involve equal sample sizes between UKA and TKA groups, as well as equal comparisons for patients with bilateral operations. Controlling these factors would allow for more accurate results for post-surgical outcomes. Overall, further analysis should be done with a larger UKA sample size to allow for more accurate comparison during stair descent.

CONCLUSION

UKA patients demonstrated more optimal stair descent biomechanics than TKA patients at both six-months and one-year post-surgery. Additionally, UKA patients were more similar to their control group than the TKA patients were to their control group at one-year post-surgery. The UKA patients were not significantly different than their controls at the six-months and one-year time points, whereas the TKA showed deficits up to one-year post-operatively. Both UKA and TKA patient groups were satisfied with their implants, in spite of biomechanical differences suggesting improved outcomes in UKA patients. Results of this study support the UKA implant as the preferred surgical intervention for OA patients, when indicated, over the TKA implant.

REVIEW OF LITERATURE

Osteoarthritis

Osteoarthritis is the most prevalent form of arthritis, and most commonly affecting the knee joint². There are approximately 24 million people living with osteoarthritis (OA)¹, and four million adults living that underwent a total knee arthroplasty (TKA) procedure⁶. As people get older there is a decrease in knee extensor strength⁴, and decreased knee range of motion (ROM)¹, which is important for descending stairs.

Weinstein et al. ⁶ identified that there is an increase in total knee arthroplasty (TKA) in younger adults and an increased life expectancy, resulting in more individuals living with TKA longer than before. The Osteoarthritis Policy (OAPol) Model was used to take into account data on TKA incidence, and estimate the prevalence of primary and revision TKA among adults in the United States (US). The 2009 US census data was used. In adults over 50 years of age, there was 4.2% with TKA, and 11.5% were diagnosed with symptomatic knee osteoarthritis (OA). Approximately four million adults in the US over the age of 50 were estimated to be living with TKA, and 536,100 living with revised TKA.

Chen et al.² used 3D Vicon optoelectronic motion analysis, six infrared cameras, and reflective markers to analyze sagittal plane knee mechanics during gait in elderly (n=15, aged 63.5±11.3), OA (n=20, aged 65.5±9.3), and healthy controls (n=20, aged 21.7±4.5). Walking is an important task for independent living in the elderly population. The OA patients had longer double-limb support than the elderly and healthy control groups, and the elderly had longer double-limb support

than the controls. There was decreased ground reaction force (GRF) during heel strike and toe off, and increased GRF during midstance in the OA group. The OA patients had abnormal knee joint loading during gait, and gait characteristics when compared to elderly and healthy controls.

A study by Ko et al.⁴ performed 3D gait analysis patterns and knee strength in 190 participants that were placed in three groups based on age: Middle age (32-57, N=27), old age (58-78, N=125), and oldest age (79-93, N=38). Participants were asked to walk at preferred speed and fastest speed without running. Knee extensor strength was measured using Kinetic Communicator isokinetic dynamometer. The Spline Regression Model and Generalized Linear Regression models were used for statistical analysis. Maximum isokinetic knee concentric strength was significantly lower for the oldest age group compared to middle age. The old age group had slower gait speed and wider stride width, and decreased concentric knee strength. So, there is a steady decline in gait speed and increased stride width with age, which can be a result of decreased isokinetic knee extensor strength.

There are approximately 24 million knee osteoarthritis (OA) patients in Japan⁶. Igawa et al.,¹ investigated lower extremity joint kinematics and kinetics during stair descent in 12 individuals; four patients with early stage unilateral knee OA (n=1 male, aged 76 ± 7), and eight healthy (aged 69 ± 6) controls were used. The patients' severity of OA was determined with Kellgren-Lawrence grading system. Kinematic and kinetic data was collected with 3D motion analysis. Patients were asked to descend a five-step staircase, at a self-selected speed without assistive devices. Data was collected on the dominant limb on the healthy controls, and the

involved limb on the OA patients. The Mann-Whitney-U test was used for data analysis. Knee joint angle of knee OA patients was less than the healthy controls during 12-23% of the gait cycle. Knee ROM was less than that of healthy controls during stair descent, and there was decreased eccentric quadriceps contraction. There was a significant difference in knee flexion moments in favor of healthy controls. The ratio of contribution of knee joint power of OA was less than healthy controls. Results of this study indicate that the decreased knee joint angle, ROM and moment could be causes of difficult stair descent in OA patients.

In conclusion, there are 24 million people living with OA^{1,4}, and this can get treated with a knee arthroplasty procedure to improve patient function. As people get older there is decreased knee extensor strength and decreased stride length during gait²; as well as decreased knee ROM and eccentric quadriceps contraction during stair descent¹.

Total Knee Arthroplasty and Patient Satisfaction

Total Knee Arthroplasty (TKA) is a surgical intervention for the treatment of knee osteoarthritis (OA). Self reported patient questionnaires like the Total Knee Function Questionnaire (TKFQ), the Short Form-12 (SF-12), Oxford Knee Score (OKS), Scottish Index of Multiple Deprivation (SIMD), and Knee Society Score (KSS) collect patient reported satisfaction on knee function postoperatively^{8,24,25}. Patients are generally satisfied with their implant, and some were dissatisfied with their implant because of increased knee stiffness, swelling of the knee, decreased activity, and problems with activity's of daily living (ADL's)²⁴.

Noble et al.²⁴ determined which factors contributed to patient satisfaction with TKA. Two-hundred-fifty-three patients (n=148 women, average age 68.1 years), at least one year post operation completed a self-survey of Total Knee Function Questionnaire (TKFQ). An analysis of variance (ANOVA), univariate logistic model, and multivariate logistic model were used. Seventy five percent of patients were satisfied, 11% were neutral, and 14% were dissatisfied. Factors of decreased satisfaction were aged 60 to 75 years, knee stiffness once per week, swelling of the knee once per week, use of analgesics at least once per day for pain. Fourteen percent of satisfied patients said they were less active post operative, and 32% of dissatisfied said they were less active post operative. Forty five percent of satisfied patients had problems with activities of daily living (ADL's), and 71% of dissatisfied patients had problems with ADL's. The dissatisfied patients were significantly different than the satisfied patients for function for stretching, leg strengthening exercises, turning/pivoting, moving laterally, dancing, gardening and squatting.

Scott et al.²⁵ identified predictors of dissatisfaction in 177 TKA in 157 patients less than 50 years of age (n=177 women, average age 50). Three cruciate retaining TKA implants were used. Patient outcomes were collected preoperative and 12 month postoperative at preoperative and 12-months postoperative. The results of the 177 TKA were compared to 2831 TKA's in patients greater than 55 years of age. The Short Form-12 (SF-12), Oxford Knee Score (OKS), Scottish Index of Multiple Deprivation (SIMD), Knee Society Score (KSS), ROM, and radiographs were collected. Univariate analysis was completed with the student's *t* test, Mann-

Whitney U test, One way-analysis of variance (ANOVA), Chi-squared test, Fisher's exact test, Pearson's correlation, and Multivariate Binary Logistic Regression were used. Seventy two percent (133/177) patients were satisfied, and 25% (44/177) were dissatisfied with their TKA. The mean SF-12 decreased in both satisfied and dissatisfied groups. The OKS increased in both TKA groups. Post-operative predictors of dissatisfaction were the SF-12, OKS, and knee flexion less than 90°.

In conclusion self reported patient questionnaires are used to determine TKA satisfaction. Patients dissatisfaction was the result of knee stiffness, knee swelling, decreased function, and problems with ADL's²⁴. Despite these dissatisfied factors, patients were overall satisfied with their implant. Noble et al. concluded that out of 253 TKA patients, 75% were satisfied and 14% were dissatisfied. Scott et al. concluded that out of 177 patients that underwent a TKA procedure, 72% were satisfied and 25% were dissatisfied with their implant²⁵.

Total Knee Arthroplasty and Gait Analysis

The evaluation of a TKA implant can be done with three dimensional gait analysis, timed 30-second chair rise tests, and isokinetic strength tests^{5,7,8}. Three dimensional gait analysis provides variables to determine the success of the implant. There is a decrease in knee flexion angles and knee flexion moments one year post-operative, compared to participants pre-operative values⁵. When evaluating the ability to rise from a chair, TKA patients that needed their hands and arms to assist them when rising from a chair descended stairs slower than patients that did not need their hands and arms for assistance⁷. The evaluation of descending stairs is also used^{9,10}. Research shows decreased peak knee flexion

angle when descending stairs⁹, and there was an abnormal knee moment pattern in correlation with the decreased knee flexion angles¹⁰.

Smith et al.⁸ studied if abnormal external flexion and extension moment patterns are present after TKA and if there are pre-operative identifiable factors. Thirty four patients (41 TKA knees, aged 69 ± 7 years), and 20 healthy controls (67 ± 7 years) were included in this study. Data was collected pre-operative and at 12 to 18 months post-operative. The Knee Society Clinical Rating System, Knee pain scale, and knee pain diagram were used at each clinical evaluation. Gait analysis was completed with a six camera Vicon 370 motion analysis, and a walk way embedded with two force plates. Patients were fitted with reflective markers, and walked five to eight trials at a self-selected pace. The Mann-Whitney U-test, paired *t*-test, Levene's test, Bonferroni correction for non-parametric statistics, two factor repeated measures ANOVA, and multiple linear and regression models were used. The Knee society score and Knee Society Function score increased significantly pre-operative to post-operative. The Knee pain scale significantly decreased pre-operative to post-operative. At follow up 41.5% of TKA patients had anterior knee pain, and increased their self-selected walking pace. The healthy controls had greater single limb support, less double limb support, and smaller stance phase times than TKA patients. Thirty percent of TKA patients had a biphasic external knee flexion and extension moment pattern, 40% had a flexor moment pattern, and 30% had an extensor moment pattern. The indicators for post-operative anterior knee pain were peak external flexor moment during early midstance, and knee flexion angle at heel strike. There was a significant interaction between change in

peak terminal stance knee extension moment and presence of post-operative anterior knee pain.

Li et al.⁵ quantified differences in muscle function during walking between 14 bilateral TKA patients (aged 67 ± 7 yrs.) to 40 age matched healthy controls. Data was collected 12 months postoperative, with an eight camera three dimensional gait analysis. The patients were fitted with 15 reflective markers, and the walkway was embedded with two force platforms. A two-way and one-way analysis of variance (ANOVA) were used. TKA patients had decreased knee flexion angles, and knee extension moments during early stance compared to controls. There was decreased knee extension moment produced by the vasti muscles and rectus femoris during early stance. The peak knee flexion angles during stance was 9.7° for TKA patients, compared to 16.2° in healthy controls. The peak knee extension moment was 0.25 N m/kg in TKA patients, compared to 0.42 N m/kg in healthy controls. The decreased knee flexion during gait caused a decreased knee extension moment created by GRF at the knee, which decreased the demand on the vastus muscles to generate a resistive knee extension moment.

A study by Nyland et al.⁷ did a retrospective, posttest design that evaluated the self-reported chair-rise ability ratings for indicating patient readiness to begin safe stair climbing. Thirty one patients ($n=22$ females, aged 63 ± 6.4) scheduled for TKA for the treatment of unilateral knee OA were included in the study. Patients completed at three to four weeks post-operation the Knee Outcome Survey-Activity of Daily Living Scale (KOS-ADLS), a 30-second chair-rise test, a timed stair ascent and descent test, and knee extensor and flexor torque strength with an isokinetic

dynamometer. The multivariate general linear model analysis of variance, Pearson product moment correlations, and Post hoc Tukey tests were used for statistical analysis. Participants were placed into three groups based on their response to their ability to rise from a chair. Twelve responded, "Because of my knee, I can only rise from a chair if I use my hands and arms to assist" (group one); 12 responded, "Because of my knee, I can only rise from a chair if I use my hands and arms to assist" (group two); seven responded, "my knee does not affect my ability to rise from a chair" (group three). Group three had greater knee flexion torque, performed more sit-to-stand repetitions, greater peak knee extensor torque, and scored higher KOS-ADLS than groups one and two. Groups three and two descended stairs quicker than group one. Indicating that the ability to rise from a chair correlates to the ability to descend stairs.

Bjerke et al.⁹ compared peak knee flexion during stair descent in 23 patients with TKA on one knee to their contralateral knee, and to 23 healthy age matched controls. TKA patients were post-operative from one to three years. All subjects performed six stair trials at a self-selected pace. Peak passive knee flexion, joint position sense were collected, and isokinetic quad strength were collected. An eight camera system and three dimensional analysis were used for whole body kinematics. The Kolmogorov-Smirnov, paired sample *t*-test, one way ANOVA, Pearson Correlation, and Multiple Regression Analysis were used for statistical analysis. Quad peak isokinetic torque was lower in the TKA side compared to the contralateral side and the healthy controls. There was decreased peak knee flexion during stair descent in the TKA leg compared to their contralateral leg.

McLelland et al.¹⁰ investigated knee flexion and extension patterns during stair ascent and descent in 40 TKA patients (n=13 bilateral TKA) to a healthy population (N=33). TKA patients were postoperative 12 to 18 months. The American Knee Society Score (KSS) was collected at 12 months postoperative, and Total Knee Function Questionnaire (TKFQ) was collected during motion analysis. Motion analysis was collected with an eight camera Vicon MX3. Patients walked a 10-meter walk way embedded with two force plates, to a two step stair case embedded with one force plate on the first step. The patients were fitted with 14-reflective markers, and five trials were collected on each limb. Euler's angles were used for joint kinematics, and knee flexion angles and moments in the sagittal plane were analyzed. Hierarchical analysis, step wise discriminant function analysis, and independent sample *t*-test were used for statistical analysis. Of the 40 TKA patients, 21 completed stair descent and 26 completed stair ascent. Stair descent is more difficult than stair ascent. Patients with an abnormal knee moment pattern descended the stairs with less knee flexion and lower peak knee flexion than healthy controls. Peak knee flexion angles and moments were not significantly different between patients with bilateral TKA and unilateral TKA.

In conclusion three dimensional analysis of gait and stair descent provide kinetic and kinematic variables to be used to evaluate a TKA implant. When evaluating gait and stair descent there is a decrease in peak knee flexion angles, and a decrease in isokinetic quad strength^{5,9}. Meaning TKA post-operative patients have decreased knee function when compared to healthy controls^{9,10}.

Unicompartmental Knee Arthroplasty and Patient Satisfaction and Survivorship

An alternative to Total Knee Arthroplasty (TKA) is Unicompartmental Knee Arthroplasty (UKA). Unicompartmental Knee Arthroplasty is indicated for those with anteromedial knee osteoarthritis, intact cruciate ligaments, and full lateral cartilage thickness¹². The Knee Injury Osteoarthritis Outcome score, American Knee Society Score, Oxford Knee Score, University of California Los Angeles (UCLA) activity score, Forgotten Joint Score, and clinical radiographs were used to assess the survivorship and satisfaction of a UKA implant^{12-14,18,21,26}. In longitudinal and retrospective studies the UKA survivorship 10 years post-operatively was 88% to 91.2%^{12,14}, and in patients greater than 60 years of age a survivorship of 96%¹³. Indicating it produces favorable functional and durable outcomes in OA patients greater than or less than 60 years of age¹³.

Emerson et al.¹² conducted a longitudinal follow up in 213 medial UKA patients (173 knees, n=95 men, average aged 67), to evaluate the survivorship of the implant and patient reported outcomes. The American Knee Society Score (AKSS), and anteroposterior and lateral radiographs were collected at six weeks, six months, one year, and every two years after that. Survival Analysis was completed with a life table method and Microsoft Excel Macros. The average follow up was at 10 years, and survivorship of UKA was 88%. The mean preoperative AKSS Knee Score was 50, and increased to 93 postoperative. Twenty patients (n=20 knees) were revised at an average of 6.2 years for lateral compartmental osteoarthritis (LCOA).

Medial UKA implants are generally used on those greater than 60 years of age. Price et al.¹³ compared the 10 year survivorship and clinical outcomes of the

Oxford UKA in patients greater than or equal to 60 years of age (n=512), and less than 60 years of age (n=52)(average age 70). A life table using revision as the end point was used for survivorship, and the Hospital for Special Surgery (HSS) Knee Score was used for clinical outcomes. Statistics were completed with the log Rank test, and Student's *t*-test. Twenty four knees were revised (n=20, ≥60 yrs of age, n=4 <60 yrs of age). The 10-year survivorship for ≥ 60 age group was 96%, compared to 91% for <60 age group. The 10-year postoperative HSS knee score was 52 in <60 age group, and 86 in ≥60 age group. The 10-year ROM was 116° in <60 age group, and 111° in ≥60 age group. The UKA implant produces functional and durable outcomes in those greater than or less than 60 years of age.

Clement et al.¹⁴ did a retrospective study on 28 women (average age 71), and 21 men (average age 68) that underwent Oxford Phase-3 UKA. Data was collected post-operatively at six weeks, six months, and every year after. The Oxford Knee Score (OKS), Visual Analog Scale for pain and satisfaction, and radiographs were collected. The Kaplan-Meir Survival Analysis and Multiple Logistic Regression were used. The average follow up was seven years (7.2). At nine years the survival rate was 91.2%, and only four knees underwent revision.

Streit et al.²⁶ evaluated clinical and radiological findings preoperative and postoperatively at three and 12 months, three years, and every five years after in 107 knees (average aged 57, 25-60 yrs). The Functional and objective American Knee Society Score (AKSS-F, AKSS-O) and Oxford Knee Score (OKS), and anteroposterior radiographs were collected. The University of California Los Angeles (UCLA) activity score was collected at final follow up. The Kaplan-Meir

survival analysis determined at five years postoperative there was 97% UKA survival. Five knees were revised, and 66 patients were very pleased with their UKA. Ninety-two knees were viewed radiographs, and five developed OA in the lateral compartment. The OKS, AKSS-O, UCLA score, and knee flexion angle and ROM all improved significantly at final follow up. Streit et al.²⁶ concluded that at five years (5 ± 1.6 yrs) follow up UKA implant had high survival and patient satisfaction.

In conclusion UKA is a favorable alternative to TKA as it has approximately 90% survivorship at 10 years follow up^{12-14,26}. Also, 66 UKA patients out of 107 knees were very satisfied with their implant based on the KSS, OKS, and UCLA questionnaires²⁶.

Unicompartmental Knee Arthroplasty V. Total Knee Arthroplasty Patient Reported Outcomes

Patient reported outcomes are used to compare UKA and TKA implants. Surveys used are the Knee Injury Osteoarthritis Outcome Score (KOOS), Knee Society Scoring System, Forgotten Joint Score, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), High Flexion Knee Score (HFKS), and EuroQol-5D (EQ-5D) were used^{11,15,18,21}. At two years post-operatively UKA patients had higher function scores than TKA for rising from a chair and descending stairs, and 86% were satisfied with their UKA compared to 71% satisfaction for their TKA¹⁸.

The study by Fabre-Aubrespy et al.²¹ did a retrospective study to analyze UKA in 101 patients (aged 75 to 90) undergoing fixed-bearing UKA and were matched to 101 patients receiving primary mobile bearing UKA. Clinical outcomes

were collected with the Knee Injury Osteoarthritis Outcome Score (KOOS), Knee Society Scoring System, and Forgotten Joint Score; and radiographs were collected pre-operatively, post-operatively and at follow up²¹. Chi-square tests, and a paired *t* test were used for data analysis. At an average follow up of eight years, the UKA group had higher KOOS scores for symptoms, pain, activities of daily living, and activity and quality of life when compared to TKA group. At an average follow up of 16 years, there was no significant difference between UKA and TKA group for the number of revision surgeries. UKA can be an alternative to TKA patients based on having higher functional and forgotten joint scores than TKA. However, previous research states that UKA has more revision surgeries than TKA.

Kim et al.¹⁸ compared 100 UKA patients and 416 TKA patients satisfaction and reported outcomes using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) to assess pain, stiffness and function, the propensity score matching (PSM) questionnaire, the Forgotten Joint Score (FJS), and high flexion knee score (HFKS). Patient outcomes were assessed at one and two years post-operatively. All TKA patients had four implants used, and UKA had three implants used. The Chi-square test, and the Wilcoxon signed-rank test was used for data analysis. There was a significant difference in the FJS score and HFKS score at two years post-operation with UKA having a higher score than TKA. The UKA had higher function scores on the HFKS for UKA than TKA for questions going over descending stairs, or rising from a chair. The patient satisfaction had 86% satisfaction for UKA, when compared to 71% for TKA.

Lombardi et al.¹¹ questioned if UKA compared to TKA for durability, incidence of complications and manipulations, recovery, postoperative clinical function, patient perceived outcomes, and return to sport and return to work. Previous research shows UKA has survivorship of 10 years like that of TKA, when the mobile-bearing UKA became available in 2004²⁷. There were 115 medial UKAs compared to 115 TKAs. Clinical outcomes were collected at six weeks postoperatively, using the Knee Society (KS) clinical rating system and Lower Extremity Activity Scale. A non-paired, two-tailed Student *t* test, and Pearson's Chi-square test were used. Seven UKA and three TKA patients had revision surgeries. Seven TKAs underwent manipulation, compared to zero UKA. Hemoglobin concentration was higher, hospital stays were shorter and had greater ROM, and could walk further distances on discharge for UKA compared to TKA. At six weeks UKA had more ROM than TKA, and although both groups had similar KS scores, the UKA group had higher functional scores. At final follow up the UKA had higher ROM, but improvement in both groups was similar. UKA is a favorable surgical device for function and the treatment of anteromedial osteoarthritis of the knee.

Lygre et al.¹⁵ compared pain and function at least two years post-operation for TKA or UKA in 1344 participants (n=972, TKA). The Knee Injury and Osteoarthritis Outcome Score (KOOS), and EuroQol-5D (EQ-5D) were used. The independent-samples Student *t* test, Pearson chi-square test, multiple logistic regression, multiple linear regression, and the Bonferroni correction method were used. When comparing UKA to TKA there was significant differences on the KOOS for function in daily living, function in sport and recreation in favor of UKA. There

was no significant difference for improved quality of life between UKA and TKA. The UKA and TKA patients experienced pain and function differently, with ROM being more favorable for UKA. UKA patients may have better function with bending the knee and stability due to the intact cruciate ligaments.

In conclusion patient reported outcomes are in favor of UKA when compared to TKA. There is increased knee range of motion, function when descending stairs and rising from a chair, and greater satisfaction in UKA patients^{11,15,18,21}.

Unicompartmental Knee Arthroplasty V. Total Knee Arthroplasty Gait Analysis

Unicompartmental knee arthroplasty (UKA) patients and TKA patients are analyzed with gait assessment, treadmills embedded with force plates, fresh frozen cadavers, or a two camera optoelectronic digitizer system^{16,17,19,20,23,28}. When patients undergo the UKA procedure on one limb and the TKA implant on the contralateral limb, there is no significant difference between knee extension strength and sagittal knee moments²⁰. However, when treadmills embedded with force plates were used 92% of healthy controls were classified as UKA patients¹⁶, and that 70% of UKA patients had a normal biphasic flexion/extension moment patterns at the knee²⁸.

A study by Jung et al.¹⁹ compared knee kinematics of six patients (n=4 females, aged 65.0 ± 7.5) during stair negotiation in patients with TKA on one limb and UKA on their contralateral limb. Each patient performed five continuous stair negotiation trials at a comfortable pace (average follow up 34.3 ± 11.7 months). The Nonparametric Friedman test was used to test for significance. There was significantly greater knee flexion angle, vertical GRF, and knee joint moments during

descent than ascent which indicates stair descent requires more knee function than stair ascent. In this study, no differences were reported between the TKA and UKA limb for knee flexion, knee flexion moments or GRF during stair descent.

Braitto et al.²⁰ used a prospective comparative design to analyze gait in 15 UKA and 17 TKA patients post-operatively. Outcomes were collected preoperatively and eight weeks postoperatively using three-dimensional (3D) gait analysis and knee extensor torque. Statistical analysis was completed with a multivariate analysis of variance, and the Hotelling-Spur test. At eight weeks postoperatively, they reported TKA patients had a greater decrease in knee extensor torque than UKA, however both exhibited a decrease in strength compared to preoperative. Both UKA and TKA groups had decreased knee extension when walking, and the sagittal knee moments (extension/flexion) had no significant differences between surgical groups. They concluded that at eight weeks postoperatively there was no significant difference in gait analysis between TKA and UKA groups.

Unicompartmental knee arthroplasty can be a more favorable surgery for young or middle aged patients that are more athletic and expect more function. Patil et al.²³ tested if UKA returned the knee to normal knee function in simulated stair climbing in cadavers. Six, fresh frozen cadaver, left knees, were included in this study (aged 73 to 89). There was significant difference for tibial rotation between the tricompartmental replacement and the intact knee. The current-generation fixed-bearing unicompartmental design with low conformity was used, and knee kinematics during flexion after the unicompartmental implant were similar to the intact knee. Meaning, the unicompartmental implant can return patients close to

normal knee function. The anterior cruciate ligament being removed did not affect the integrity of the unicompartmental design.

Wiik et al.¹⁷ analyzed downhill walking on a treadmill embedded with force plates in TKA (n=14), UKA (n=19) and healthy controls (n=19). Patient reported outcomes (Oxford Knee Score, UCLA, EuroQol5, EuroQol) and temporospatial gait parameters were collected. The one way ANOVA, post hoc Tukey test, independent t test, and Chi squared test were used for statistical analysis. The UKA and TKA patients both had increased stride width when compared to healthy controls. The UKA patients walked 15% faster than TKA patients, and TKA patients had decreased stride length than the UKA group. Overall, UKA patients had more similar gait parameters to the healthy controls than TKA group.

Jones et al.¹⁶ tested if a decision tree would classify the gait of healthy controls (n=121) more similar to UKA (n=12) or TKA (n=12) patients. A decision tree differentiated between the gait of UKA and TKA patients, using gait parameters, and multiple walking velocities up to their maximum walking speed, to determine which group was more classified as healthy controls. Gait analysis was performed with a treadmill embedded with force plates. All participants walked on the treadmill for six minutes, and then speed was increased at 0.5 km/h until a maximum walking speed was reached. Temporospatial gait parameters and vertical ground reaction force were collected at 10s speed and 100 Hz. Oxford knee scores were collected during gait analysis. A program written in Matlab designed eight trees to be used. The output of the tree was a binary prediction for if the patient was more similar to UKA or TKA. One-hundred-eleven healthy controls were

classified as UKA (92%), six were classified as TKA (5%), and four were inconclusive (3%)¹⁶. The maximum walking speed of UKA matched that of healthy controls (2.2 m/s), whereas TKA had a significantly decreased maximum walking speed (1.6 m/s). Since there was 92% classified as UKA this supports the theory that intact cruciate ligaments, and unaffected lateral tibiofemoral and patellofemoral compartments result in improved physiological gait.

Chassin et al.²⁸ evaluated if the retention of the ACL in UKA patients avoid gait adaptations that have been documented in TKA. Ten patients (n=7 males, aged 60 to 80), at an average follow up of 19 months post operation completed this study. Limb alignment was determined with standing radiographs, and motion measurements were collected with a two-camera optoelectronic digitizer system. Limb motion was collected based on six points, and a force plate was embedded in the middle of a 10-meter walkway. The external moments of flexion/extension, adduction/abduction, and internal/external rotation of the hip, knee and ankle were used²⁸. The Fisher's exact test was used for significance. Seven UKA patients (70%) maintained normal biphasic pattern of flexion/extension moments about the knee. The stance phase moments changed from external flexion, to extension, and back to flexion. Two UKA patients had an extension pattern, in which the extension moment was consistent through the stance phase. This is favorable to research by Andriacchi et al.³ that found 23% of TKA patients that had normal flexion/extension moment patterns.

In conclusion gait analysis with treadmills revealed similar gait patterns to healthy controls in UKA patients compared to TKA patients^{16,17}. This study determined if biomechanical analysis of stair descent show similar results.

APPENDIX A: RESEARCH SUBJECT INFORMATION AND 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

Principal Investigators: Cris Stickley, PhD, ATC

Investigators: Elizabeth Parke, MS, ATC

II. TITLE

**Biomechanical Analysis of Level Walking and Stair Climbing Tasks
Across a Lifespan.**

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 purpose of this study is to evaluate biomechanical variables during level walking and stair climbing tasks in a healthy control population.

IV. DESCRIPTION OF PROCEDURES

You will be asked to report to the University of Hawaii at Manoa Gait Lab (Sherriff 100) for a one-time data collection. The entire visit will take approximately 60 minutes.

When you arrive at the Gait Lab measurements about your body will be taken and you will be asked to perform the following tasks:

- (1) Complete a health history questionnaire as well as a physical activity questionnaire
- (2) Walk for 6 meters at a various speed multiple times,
- (3) Walk up and down stairs at a comfortable speed 5 times, and
- (4) push into stationary objects (fixed dynamometer) with your leg for three seconds for two different leg movements to measure lower leg strength.

V. RISKS

Due to the physical activity involved, there is a slight risk of injury. You may also have some discomfort, muscle cramping or soreness during or after test sessions. Although we have people to assist you and handrails in place during the stair climbing task, there is a slight chance of falling during the test. There is a very

remote chance of cardiac arrest and/or death. These risks are comparable to your routine activities of daily living.

The investigators of this study 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 principal investigator, Cris Stickley, PhD, ATC, at 513-259-4666 or Elizabeth Parke, MS, ATC at 336-402-3816. 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.

You cannot participate in this study if you are pregnant because the information collected during the walking test 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 think you might be pregnant during the course of this data collection, you must inform the researchers, and you will be excluded from study participation.

VI. BENEFITS

You may not receive direct/immediate benefits. However, you will obtain information regarding your walking and running gait upon requests.

VII. COMPENSATION

No compensation will be given to patients throughout this study, however, a parking fee of five dollars will be reimbursed when the patients arrives at data collection with a receipt. Reimbursement will only be given to for data collections the patient is present.

VIII. 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 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.

If you have any questions related to this study, please contact any of the principal investigators: Cris Stickley at 513-259-4666 or Elizabeth Parke, MS, ATC, at 336-402-3816 at any time.

Participant's Printed Name

Signature of Participant

Date

Witness Signature

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.

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Biomechanical Analysis of the Oxford®
Unicompartmental Knee Implant Design During Level
Walking and Stair Negotiation

PROTOCOL NO.: 2016-007

SPONSOR: Cris Stickley, PhD, ATC
Honolulu, Hawaii
United States

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

**STUDY-RELATED
PHONE NUMBER(S):** Cass Nakasone, M.D.
808-522-4000

Cris Stickley PhD, ATC
808-956-3798

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 a participant 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 (investigational) 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 study is to compare the function of patients with the Oxford partial knee implant design during level walking and stair negotiation tasks.

Approximately 20 people will participate in this study.

PROCEDURES

If you decide to participate in this study you will be receiving per the physician’s protocol the Oxford partial knee implant which is approved by the FDA for the type of surgery you are having and will be used according to their approved indication.

You will be asked to report to the University of Hawaii at Manoa, Kinesiology and Rehabilitation Science Laboratory (Gait Lab) (Sherriff 100) for all testing before and after your knee surgery.

Upon arrival to the Gait Lab, you will be asked to fill out one survey in reference to your current pain and activity level.

When you arrive at the Gait Lab measurements about your body will be taken and you will be asked to perform the following tasks:

- (1) walk for 6 meters at a comfortable speed 6-10 times (Gait Analysis),
- (2) walking up and down stairs at a comfortable speed 3-4 times, and
- (3) push into stationary objects (fixed dynamometer) with your leg for three seconds for two different leg movements (Isometric Strength).

You will also be asked some questions about your daily activities. The entire visit will take approximately 60 minutes.

You will be asked to go to the Gait Lab for your first study visit before your surgery. Each visit to the Gait lab will take approximately 60 minutes. You will be asked to return to the Gait Lab four more times over the next one year to repeat the procedures listed above (please see Table 1 below for visit schedule).

Table 1. Visit Time Line

	Before Surgery	6 Weeks After Surgery	3 Months After Surgery	6 Months After Surgery	1 Year After Surgery
Gait Analysis (test)	X	X	X	X	X
Isometric Strength	X	X	X	X	X
Survey	X	X	X	X	X

RISKS AND DISCOMFORTS

There are risks associated with your knee replacement surgery. These include:

- Blood clots that can, in rare cases, be life threatening
- Complications after a blood transfusion
- Allergic reaction to the medications or materials used

- Injury to arteries in your leg
- Surgery may not reduce your pain and stiffness, possibly requiring more treatment
- Surgery may cause more pain

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 people to assist you and handrails in place, there is a chance of falling during the 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 information collected during the walking test 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 excluded from study participation.

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 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 knee replacement.

PAYMENT FOR PARTICIPATION

You will be given \$5 that can be applied towards parking and/or transportation to the University of Hawaii Gait Laboratory each time you come for a visit. The money will be given to you after you arrive to the facility so it is a reimbursement. If you do not finish the study, you will be paid only for the visits you have completed.

COSTS

There are no additional costs related to the procedures and visits that may result from your participation in this research study.

Any costs associated with parking/transportation over and above the \$5 provided will be your responsibility. The fee for parking at the University of Hawaii parking structure is \$5 during the week and \$6 on the weekends.

ALTERNATIVE TREATMENT

Your alternative is not to participate in this study.

USE AND DISCLOSURE OF YOUR HEALTH INFORMATION:

By signing this form, you are authorizing the use and disclosure of individually identifiable information. Your information will only be used/disclosed as described in this consent form and as permitted by state and federal laws. If you refuse to give permission, you will not be able to be in this research.

This consent covers all information about you that is used or collected for this study. It includes

- Past and present medical records
- Research records
- Records about your study visits.
- Information gathered for this research about:
 - Physical exams
 - Laboratory, x-ray, and other test results
 - Questionnaires
- Records about the implanted medical device.

Your authorization to use your identifiable health information will not expire even if you terminate your participation in this study or you are removed from this study by the study doctor. However, you may revoke your authorization to use your identifiable information at anytime by submitting a written notification to the principal investigator, Cass Nakasone, MD at 888 S. King Street, Honolulu, HI 96813. If you decide to revoke (withdraw or “take back”) your authorization, your identifiable health information collected or created for this study shall not be used or disclosed by the study doctor after the date of receipt of the written revocation except to the extent that the law allows us to continue using your information. The investigators in this study are not required to destroy or retrieve any of your health information that was created, used or disclosed for this study prior to receiving your written revocation.

By signing this consent form you authorize the following parties to use and or disclose your identifiable health information collected or created for this study:

- Cass Nakasone, MD and his research staff for the purposes of conducting this research study.

- Straub Medical Center and Hawai'i Pacific Health
- The University of Hawai'i

Your medical records may contain information about AIDS or HIV infection, venereal disease, treatment for alcohol and/or drug abuse, or mental health or psychiatric services. By signing this consent form, you authorize access to this information if it is in the records used by members of the research team.

The individuals named above may disclose your medical records, this consent form and the information about you created by this study to:

- The sponsor of this study and their designees (if applicable)
- Federal, state and local agencies having oversight over this research, such as the Office for Human Research Protections in the U.S. Department of Health and Human Services, Food and Drug Administration, the National Institutes of Health, etc.
- The University of Hawai'i
- Hawaii Pacific Health (HPH) Officials, the Western Institutional Review Board, and the HPH Office of Compliance for purposes of overseeing the research study and making sure that your ethical rights are being protected.

Some of the persons or groups that receive your study information may not be required to comply with federal privacy regulations, and your information may lose its federal privacy protection and your information may be disclosed without your permission.

COMPENSATION FOR INJURY

In the event of any physical injury from the research, only immediate and essential medical treatment is available. 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 study coordinator: Cris Stickle Ph.D., ATC, at 808-956-3798. You should understand that if you are injured in the course of this research process that you or your medical insurance 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;
- you become pregnant;
- 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 Hawai'i at Manoa.

QUESTIONS

Contact Cris Stickley Ph.D., ATC at 808-956-3798 or 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®)
1019 39th Avenue SE Suite 120
Puyallup, WA 98374-2115
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

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Biomechanical Comparison of Multi- and Single Radius Implant Designs During Level Walking and Stair Climbing Tasks

OL NO.: 2014-018
WIRB® Protocol #20141194

SPONSOR: Cris Stickley, PhD, ATC

INVESTIGATOR: Cass Nakasone, MD
888 South King Street
Honolulu, Hawaii 96813
United States

SITE(S): University of Hawaii at Manoa
PE/A Complex Room 231, Lower Campus Road
Honolulu, Hawaii 96822
United States

Straub Clinic & Hospital
888 S. King Street
Honolulu, Hawaii 96813
United States

STUDY-RELATED

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

Cris Stickley PhD, ATC
808-956-3798

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 (investigational) 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 study is to compare the function of patients, implanted with either a multi-radii or a single radius total knee arthroplasty design, during level walking and stair climbing tasks. You are being asked to participate in this study because you are undergoing total knee arthroplasty. About 100 subjects are expected to participate.

PROCEDURES

If you decide to participate in this study, you will be randomly assigned (by chance) to one of four possible groups and receive either a single radius knee implant or one of three multiple radii knee implants. You have an equal chance of being assigned to any one of the four implant groups. The implants that will be used in this study are:

- GetAroundKnee™, Stryker Orthopedics (single radius)
- Balanced Knee® System, Ortho Development (multiple radii),
- Persona™ Total Knee, Zimmer (multiple radii)
- NexGen®, Zimmer (multiple radii)

These types of implants are approved by the FDA for the type of surgery you are having and will be used according to their approved indication.

You will be asked to report to the University of Hawaii at Manoa, Kinesiology and Rehabilitation Science Laboratory (Gait Lab) (Sherriff 100) for all testing visits before and after your knee surgery.

Upon arrival to the Gait Lab, you will be asked to fill out one survey in reference to your current pain and activity level. Measurements about your body will be taken and you will be asked to perform the following tasks:

- (1) walk for 6 meters at a comfortable speed 6-10 times (Gait Analysis),
- (2) walking up and down stairs at a comfortable speed 3-4 times, and
- (3) push into stationary objects (fixed dynamometer) with your leg for three seconds for two different leg movements (Isometric Strength).

You will also be asked some questions about your daily activities. The entire visit will take approximately 60 minutes.

You will be asked to go to the Gait Lab for your first study visit before your surgery. You will be asked to return to the Gait Lab 5 more times over the next two years to repeat the procedures listed above (please see Table 1 below for visit schedule). Each visit to the Gait lab will take approximately 60 minutes.

Table 1. Visit Time Line

	Before Surgery	6 Weeks After Surgery	3 Months After Surgery	6 Months After Surgery	1 Year After Surgery	2 Years After Surgery
Gait Analysis (test)	X	X	X	X	X	X
Isometric Strength	X	X	X	X	X	X
Paper/Pencil Survey	X	X	X	X	X	X

RISKS AND DISCOMFORTS

Being randomized to one type of knee implant instead of the others, may lead to greater or lesser stability of the knee post-surgery.

There are risks associated with your knee replacement surgery, whether or not you participate in this study. These include:

- Blood clots that can, in rare cases, be life threatening
- Complications after a blood transfusion

- Allergic reaction to the medications or materials used
- Infection
- Injury to arteries or nerves in your leg
- Surgery may not reduce your pain and stiffness, possibly requiring more treatment
- Surgery may cause more pain
- Risks of anesthesia

You will be asked to review and sign a separate consent form for your knee surgery, and your surgeon will explain the risks of the procedure in more detail.

Gait analysis risks

Due to the level of physical activity involved during the testing procedures, 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 people to assist you and handrails in place, there is a chance of falling during the 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 information collected during the walking test 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 removed from study participation.

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 may not receive direct/immediate benefits from study participation. 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 total knee replacement.

PAYMENT FOR PARTICIPATION

You will not be paid for your participation in the study.

You will be given \$5 that can be applied towards parking and/or transportation to the University of Hawaii Gait Laboratory each time you come for a visit. The money will be given to you after you arrive at the facility with a receipt, so it is a reimbursement. You will be reimbursed only for the visits that you attend.

COSTS

You are not expected to have additional costs related to the procedures and visits that may result from your participation in this research study.

Any additional costs associated with parking/transportation over and above the \$5 provided will be your responsibility. The fee for parking at the University of Hawaii parking structure is \$5 during the week and \$6 on the weekends.

ALTERNATIVE TREATMENT

If you decide not to participate in this study, you will receive your knee replacement surgery with the type of implant that your doctor feels is best for you. Your follow-up care will be the same whether or not you are in this study.

USE AND DISCLOSURE OF YOUR HEALTH INFORMATION:

By signing this form you are authorizing the use and disclosure of individually identifiable information. Your information will only be used/disclosed as described in this consent form and as permitted by state and federal laws. If you refuse to give permission, you will not be able to be in this research.

This consent covers all information about you that is used or collected for this study. It includes

- Past and present medical records
- Research records
- Records about your study visits.
- Information gathered for this research about:
 - Physical exams
 - Laboratory, x-ray, and other test results
 - Questionnaires
- Records about the implanted medical device.

Your authorization to use your identifiable health information will not expire even if you terminate your participation in this study or you are removed from this study by the study doctor. However, you may revoke your authorization to use your identifiable information at any time by submitting a written notification to the principal investigator, Cass Nakasone, MD at 888 S. King Street, Honolulu, HI 96813. If you decide to revoke (withdraw or “take back”) your authorization, your identifiable health information collected or created for this study shall not be used or disclosed by the study doctor after the date of receipt of the written revocation except to the extent that the law allows us to continue using your information. The investigators in this study are not required to destroy or retrieve any of your health information that was created, used or disclosed for this study prior to receiving your written revocation.

By signing this consent form you authorize the following parties to use and or disclose your identifiable health information collected or created for this study:

- Cass Nakasone, MD and his research staff for the purposes of conducting this research study.
- Straub Clinic & Hospital and Hawai'i Pacific Health

Your medical records may contain information about AIDS or HIV infection, venereal disease, treatment for alcohol and/or drug abuse, or mental health or psychiatric services. By signing this consent form, you authorize access to this information if it is in the records used by members of the research team.

The individuals named above may disclose your medical records, this consent form and the information about you created by this study to:

- The sponsor of this study and their designees (if applicable)
- Federal, state and local agencies having oversight over this research, such as the Office for Human Research Protections in the U.S. Department of Health and Human Services, Food and Drug Administration, the National Institutes of Health, etc.
- The University of Hawai'i
- Hawaii Pacific Health (HPH) Officials, the Western Institutional Review Board, and the HPH Office of Compliance for purposes of overseeing the research study and making sure that your ethical rights are being protected.

Some of the persons or groups that receive your study information may not be required to comply with federal privacy regulations, and your information may lose its federal privacy protection and your information may be disclosed without your permission.

COMPENSATION FOR INJURY

In the event of any physical injury from the research, only immediate and essential medical treatment is available. 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 regular medical doctor and inform the study coordinator: Cris Stickley Ph.D., ATC, at 808-956-3798. You should understand that, if you are injured in the course of this research process, you or your medical insurance 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;
- you become pregnant;
- 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 Cris Stickley Ph.D., ATC at 808-956-3798 or 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, input, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
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 B: ACTIVITY ASSESSMENT SURVEY

UCLA ACTIVITY SCALE

Subject ID#: _____ Data Collection Period 0 1 2 3 4 5 6 7

Please circle the number that best describes current activity level.

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

Please circle the number that best answers the following question. "How does your knee affect your ability to rise form a chair?":

1. "Because of my knee I cannot rise from a chair."
2. "Because of my knee, I can only rise from a chair if I use my hands and arms to assist."
3. "I have pain when rising from the seated position, but it does not affect my ability to rise from the seated position."
4. "My knee does not affect my ability to rise from a chair."

Are you satisfied with your implant? YES NO

APPENDIX C: DATA COLLECTION FORMS

Anthropometric Data

Subject ID#: _____

Date _____

Age _____

Gender: F / M ^[SEP]

Data Collection Period 0 1 2 3 4 5 ^[SEP]

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

Patient's Operated leg: L / R

Dominant leg: L / R

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	

Stair Ascent		
Trial	Which foot hit the plate	Walking Pace (s)
1	R / L	
2	R / L	
3	R / L	

Stair Decent		
Trial	Which foot hit the plate	Walking Pace (s)
1	R / L	
2	R / L	
3	R / L	

Manual Muscle Testing Data Collection

Subject ID#: _____ Data Collection Period 0 1 2 3 4 5 6 7

Patient's Operated leg: L / R

Dominant Leg: L / R

Tester: _____

	Left Leg						Right Leg					
	Trial 1 Score (ft-lb _f)	Pain Score (HHD/Jt)	Trail 2 Score (ft-lb _f)	Pain Score (HHD/Jt)	Trial 3 Score (ft-lb _f)	Pain Score (HHD/Jt)	Trial 1 Score (ft-lb _f)	Pain Score (HHD/Jt)	Trial 2 Score (ft-lb _f)	Pain Score (HHD/Jt)	Trial 3 Score (ft-lb _f)	Pain Score (HHD/Jt)
Hip abduction		/		/		/		/		/		/
Knee extension		/		/		/		/		/		/

REFERENCES

1. Igawa T, Katsuhira J. Biomechanical analysis of stair descent in patients with knee osteoarthritis. *J Phys Ther Sci.* 2014;26(5):629-631.
2. Chen CP, Chen MJ, Pei YC, Lew HL, Wong PY, Tang SF. Sagittal plane loading response during gait in different age groups and in people with knee osteoarthritis. *Am J Phys Med Rehabil.* 2003;82(4):307-312.
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