

SAGITTAL PLANE BIOMECHANICAL COMPARISON OF TOTAL KNEE
ARTHROPLASTY PATIENTS AND HEALTHY CONTROLS DURING
STAIR DESCENT

A THESIS SUBMITTED TO THE GRADUATE DIVISION OF THE
UNIVERSITY OF HAWAI'I AT MĀNOA IN PARTIAL FULFILLMENT
OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF SCIENCE

IN

ATHLETIC TRAINING

MAY 2017

By

Brandon S. Jentink

Thesis Committee:

Christopher Stickley, Chairperson
Kaori Tamura
Bret Freemyer

ACKNOWLEDGEMENTS

To start, I want to thank my Heavenly Father for blessing me with the opportunity of pursuing a master's degree at the University of Hawai'i at Mānoa. The opportunity to learn and grow in Hawai'i has been a true blessing. Proverbs 3:5-6.

I would like to acknowledge my committee members, Dr. Christopher Stickley, Dr. Kaori Tamura, and Dr. Bret Freemyer. Thank you for your willingness to serve on my committee, and your help and guidance in completing this thesis.

A special thank you goes to Liz Parke for being an outstanding PhD mentor. Thank you for your patience, thoughtfulness, and caring attitude, while helping me complete this thesis. I am so thankful for all of your help during my time in Hawai'i.

Thank you, classmates. I have enjoyed getting to know each one of you over these past two years. Thank you for all the memories and great times that were shared. I look forward to seeing all of the great things you will accomplish.

Thank you, family, and friends for your support. Being far from home was difficult, but your love and support made the hard times easier. I have been richly blessed with so many caring people in my life.

Of course, thank you, Sarah. These past two years were filled with many challenges. Your love and support made this thesis possible. I can't wait to start this next chapter in life with you! I love you, and I'll be home soon.

TABLE OF CONTENTS

ACKNOWLEDGEMENTS	ii
LIST OF TABLES	iv
LIST OF ABBREVIATIONS.....	v
INTRODUCTION	1
METHODOLOGY	3
Participants.....	3
Instrumentation	3
Procedures.....	4
Statistical Analysis.....	6
RESULTS	7
DISCUSSION	15
CONCLUSION.....	19
REVIEW OF LITERATURE	20
Knee Osteoarthritis	20
Implant Designs in Total Knee Arthroplasty	26
Stair Ambulation and Total Knee Arthroplasty Patients	30
Lower Extremity Strength After Total Knee Arthroplasty	34
Knee Joint Kinematics and Total Knee Arthroplasty	39
Clinical Outcomes and Total Knee Arthroplasty.....	43
APPENDIX A: RESEARCH SUBJECT INFORMATION AND CONSENT FORM	47
APPENDIX B: ACTIVITY ASSESSMENT SURVEY	50
APPENDIX C: DATA COLLECTION FORMS	51
Anthropometric Data	51
Data Collection Form.....	52
Manual Muscle Testing Data Collection	53
REFERENCES	54

LIST OF TABLES

<u>Table</u>	<u>Page</u>
Table 1. Demographics of Controls and Pre-TKA Patients.....	7
Table 2. UCLA Scores Overtime Between Controls and TKA Patients	8
Table 3. Six-Month Biomechanical Comparison Between Controls and TKA Patients During Stair Descent	9
Table 4. One-Year Biomechanical Comparison Between Controls and TKA Patients During Stair Descent	11
Table 5. Six-Month Biomechanical Comparison Between Controls and Implant Groups During Stair Descent	13
Table 6. One-Year Biomechanical Comparison Between Controls and Implant Groups During Stair Descent	14

LIST OF ABBREVIATIONS

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

INTRODUCTION

Total knee arthroplasty (TKA) is a surgical procedure commonly used to treat knee osteoarthritis (OA), with approximately 450,000 TKAs performed every year in the United States alone, and this number is expected to increase annually [18]. Previous research has established that knee OA causes considerable pain and physical limitation, producing compensatory motions during functional activities [14, 19, 24]. As osteoarthritic degeneration progresses, there becomes a greater need for TKA to replace damaged bone and cartilage within the knee joint, eliminating the pain caused by the disease and improving functional capabilities [11, 13, 35].

Though TKA patients show marked improvements following surgery in pain reduction and normal walking gait [9, 11], functional capacity in more difficult tasks, such as stair descent, may still be limited [3, 4, 26, 30, 31]. Previous research has provided evidence suggesting that stair descent is more challenging for TKA patients to negotiate than stair ascent due to pain, decreased knee flexion moment (KFM), and knee extensor weakness [3, 4, 26]. However, it is unclear the extent to which patients recover functional capabilities during stair descent following surgery, particularly in regards to improvements in KFM, knee extensor strength, ground reaction force (GRF) and in compensatory motions, such as trunk flexion.

Common TKA femoral implant designs include multi-radius (MR) and single-radius (SR) designs. Multi-radius implant designs use multiple axes of rotation throughout knee range of motion, which are driven by the changing radius of curvature of the femoral component [20], in an attempt to replicate natural movements [12]. In contrast, SR implants incorporate one fixed sagittal axis of rotation positioned more posteriorly to that of MR implants [7, 20], theoretically

reducing anterior knee pain and improving knee extensor function due to a longer extensor lever arm [25, 37, 38]. Significant disagreement remains as to which implant design is most appropriate for producing optimal patient outcomes following TKA [7, 10, 15, 33].

The purpose of this research study was to compare KFM, GRF, peak knee flexion angle (KFA), trunk motion, and time duration during stair descent, as well as isometric knee extensor strength in post-TKA patients at six-months and one-year, to a healthy age-matched control sample. In addition to the evaluation of TKA patient function to healthy controls, function between TKA implant designs was also assessed. It was hypothesized that TKA patients would demonstrate significantly decreased KFM, KFA and isometric knee extensor strength, similar GRF values, and increased trunk flexion when compared to controls. It was also hypothesized that significant differences would exist between implant design types, with the SR implant design allowing for a higher level of function, more comparable to healthy controls.

METHODOLOGY

Participants

Fourteen TKA patients participated in this randomized, longitudinal study. The MR group consisted of nine patients (8 males; 11 knees) and the SR group consisted of five patients (4 males; 8 knees). All TKAs were performed by the same board certified orthopedic surgeon. Inclusion criteria for all participating individuals consisted of the following: under 75 years of age, no previous history of lower extremity fracture, osteotomy or joint replacement, undergoing a unilateral or bilateral TKA for the treatment of knee OA, and physically able to walk without an aid. Total knee arthroplasty patients that were screened for inclusion within this study and completed the first data collection prior to TKA were randomly assigned to receive either a MR implant (Balanced Knee® System, Ortho Development Corporation, Draper, UT), or a SR implant (GetAroundKnee™, Stryker Orthopedics, Mahwah, NJ). Additionally, data were collected on 30 healthy controls (15 males) at a one-time data collection. Inclusionary criteria for the controls included: no history of lower extremity joint surgery, no history of arthritis diagnosis, no diagnosed neurological disorders, no history of Parkinson's disease, and under no physical activity restrictions from their physician. Prior to enrollment in the study, all TKA patients and healthy controls signed informed consent forms approved by the Institution's Committee on Human Studies.

Instrumentation

Participants completed the University of California, Los Angeles (UCLA) Activity Scale at the beginning of every data collection, indicating the number that best described their current perceived activity level [28]. A rating of 1 signified they were “wholly inactive, dependent on others, and could not leave residence”, and 10 signified “regularly participated in impact sports.”

Body mass was determined using a Detecto certifier scale (Webb City Mo, USA), and height was measured using a wall-mounted stadiometer (Model 67032, Seca Telescopic Stadiometer, Country Technology, Inc., Gays Mills, WI, USA).

Stair descent biomechanics data were collected using a three-dimensional motion capture system (Vicon, Inc. Centennial, CO) and two force plates (Advanced Mechanical Technology Incorporated Boston, MA). Retroreflective markers were placed bilaterally on the following bony landmarks: first metatarsophalangeal joints, second metatarsophalangeal joints, fifth metatarsophalangeal joints, bases of fifth metatarsals, medial and lateral malleoli, posterior calcanei, medial and lateral epicondyles of the femur, posterior superior iliac spines, anterior superior iliac spines, and acromioclavicular joints. Unilateral markers were placed on the jugular notch, xiphoid process, spinous process of the seventh cervical vertebrae, spinous process of the tenth thoracic vertebrae, and on the inferior portion of the right scapula. Four arrays consisting of four markers (Vicon, Inc. Centennial, CO) were secured laterally on the shaft of each femur and shank.

A three-step staircase, with dimensions of an 18 cm step rise, a 46 cm step width, and a 28 cm step tread, were used for the stair descent trials [36]. A force plate was embedded on the first step of the staircase and another was embedded flush with the floor at the bottom of the staircase. Kinetic data of the involved limb were analyzed using only the force plate embedded on the first step of the staircase. Following stair descent trials, strength tests were conducted using a Microfet 2 hand-held dynamometer (Hoggan Health Industries, West Jordan, UT).

Procedures

All participants completed the Institutional Review Board consent form during their first visit. Total knee arthroplasty patients completed a total of five testing sessions at one-week pre-

TKA, and post-TKA at six-weeks, three-months, six-months, and one year, as this research study was a part of an overarching study. The analyses of this study focused on post-TKA at six-months and one-year. Control participants completed only one testing session, but followed the same protocol as the TKA patients. Patient age was documented at the beginning of every testing session, as well as anthropometrics, which included height and weight. Shank lengths were determined, and 80% of shank lengths were calculated and marked. These markings served as location points for the hand-held dynamometer during knee extensor strength testing. This allowed for consistent placement of the handheld dynamometer, relative to each participant.

Stair descent consisted of stepping with one foot on each stair, in a reciprocal foot-fall pattern, while progressing down the staircase and contacting the force plate with the involved limb. Patients completed five successful stair descent trials. Kinematic data were collected at 240 Hz, and time synchronized with kinetic data collected at 960 Hz. A low-pass Butterworth Filter was used to filter kinematic data and external joint moments at a 10 Hz cut-off frequency, and ground reaction force data were filtered using a 50 Hz cut-off frequency [17]. Joint moments were calculated using inverse dynamics based on filtered marker trajectories and kinetic data [17]. Patients were prohibited from using the handrail during trials unless they felt their safety was compromised. Trials in which the patient utilized the handrail for assistance were excluded from analysis. A member of the research team was positioned at the bottom of the stairs to assist, if needed. All successful stair descent trials were averaged for data analyses. All knee joint moments were reported as external moments, and knee and trunk flexion values were reported as a positive number.

Following stair descent trials, bilateral knee extensor muscle strength tests were conducted. Knee extensor strength was determined 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. Two trials of a three-second maximal isometric knee extension contraction were completed against the hand-held dynamometer, which was secured by a strap to ensure constant resistance. 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 the Shapiro-Wilk test. Normality of variance between standard deviations was assessed using Levene's test. Differences in anthropometric variables between groups were assessed using a General Linear Model analysis of variance (ANOVA). Multiple General Linear Model tests were utilized to assess differences in dependent variables between 1) controls versus TKA and 2) pairwise between all three testing groups (control, MR, and SR). Post-hoc Tukey tests determined where significant differences existed among groups for each dependent variable. All data were analyzed using SPSS Version 22.0, and an alpha level of $p < 0.05$ was used to determine statistical significance.

RESULTS

Participant demographics were not significantly different between groups, and are listed in Table 1. A total of 14 patients under-going TKA, nine patients (8 males; 11 knees) received the MR implant and five patients (4 males; 8 knees) received the SR implant, and were compared to 30 healthy controls (CON) (15 males). All TKA patients were present for the six-month data collection time period. However, two MR patients (2 males; 3 knees) dropped out of the study, and were not included in the one-year analysis. Therefore, the one-year data analysis included seven MR patients (6 males; 8 knees).

Table 1. Demographics of Controls and Pre-TKA Patients

	CON (n = 30) (30 knees)			MR (n = 9) (11 knees)			P value	SR (n = 5) (8 knees)			P value
	Mean	±	SD	Mean	±	SD		Mean	±	SD	
Age (years)	67.30	±	5.30	64.80	±	6.30	0.289	64.60	±	3.50	0.374
Height (m)	1.64	±	0.11	1.63	±	0.74	0.891	1.67	±	0.82	0.818
Body Mass (kg)	71.20	±	16.10	72.10	±	13.40	0.863	78.80	±	12.30	0.294

TKA = total knee arthroplasty; CON = controls; MR = multi-radius; SR = single-radius; n = number of participants; SD = standard deviation; m = meters; kg = kilograms.

Total knee arthroplasty patients reported lower UCLA Activity Scores compared to controls preoperatively (CON = 7.23, TKA = 4.15, $p = 0.000$), and at six-months post-operatively (CON = 7.23, TKA = 5.38, $p = 0.001$) (Table 2). At six-months post-operatively, TKA patients displayed significantly smaller KFM values at 25% of stance (CON = 1.35 Nm/kg, TKA = 0.81 Nm/kg, $p = 0.000$) and at 50% of stance (CON = 1.41 Nm/kg, TKA = 0.91 Nm/kg, $p = 0.000$), compared to controls. Larger peak trunk flexion values were present in TKA patients during stair descent (CON = 10.51 degrees, TKA = 14.73 degrees, $p = 0.046$). Total knee

arthroplasty patients also demonstrated increased time on the force plate (CON = 0.73 s, TKA = 1.11 s, $p = 0.002$), time to maximum GRF (CON = 0.12 s, TKA = 0.20 s, $p = 0.016$), and time on stairs (CON = 1.16 s, TKA = 1.61 s, $p = 0.002$). Knee extensor strength was also found to be decreased in TKA patients (CON = 79.41 lbs., TKA = 62.84 lbs., $p = 0.028$), compared to controls. Descriptive information for six-month post-TKA variables can be found in Table 3.

Table 2. UCLA Scores Overtime Between Controls and TKA Patients

	CON			TKA			P value
	Mean	±	SD	Mean	±	SD	
Pre-TKA	7.23	±	1.74	4.15	±	1.34*	0.000*
Six-Months Post-TKA	7.23	±	1.74	5.38	±	1.26*	0.001*
One-Year Post-TKA	7.23	±	1.74	6.23	±	1.64	0.085

UCLA = University of California, Los Angeles; TKA = total knee arthroplasty; CON = controls; SD = standard deviation.

* = significant difference between controls and TKA group; ($p \leq 0.01$).

Table 3. Six-Month Biomechanical Comparison Between Controls and TKA Patients During Stair Descent

	CON (n = 30, 30 knees)			TKA (n =14, 19 knees)			P value
	Mean	±	SD	Mean	±	SD	
Max GRF (N/kg)	15.48	±	2.50	14.22	±	2.37	0.091
KFA at 25% of Stance (°)	29.04	±	6.51	25.86	±	6.93	0.121
KFM at 25% of Stance (Nm/kg)	1.35	±	0.29	0.81	±	0.30**	0.000
KFA at 50% of Stance (°)	33.47	±	5.65	31.74	±	6.49	0.338
KFM at 50% of Stance (Nm/kg)	1.41	±	0.28	0.91	±	0.27**	0.000
Peak Trunk Flexion (°)	10.51	±	5.75	14.73	±	8.49*	0.046
Time on Plate (s)	0.73	±	0.10	1.11	±	0.62**	0.002
Time to Max GRF (s)	0.12	±	0.03	0.20	±	0.18*	0.016
Time on Stairs (s)	1.16	±	0.15	1.61	±	0.70**	0.002
Knee Extensor Strength (lbs.)	79.41	±	26.08	62.84	±	25.04*	0.028

TKA = total knee arthroplasty; CON = controls; n = number of participants; SD = standard deviation;
 Max = maximum; GRF = ground reaction force; N/kg = Newtons per kilogram;
 KFA = knee flexion angle; (°) = degrees; KFM = knee flexion moment;
 Nm/kg = Newton-meters per kilogram; s = seconds, lbs. = pounds.

* = significant difference between controls and TKA implant ($p \leq 0.05$).

** = significant difference between controls and TKA implant ($p \leq 0.01$).

At one-year, post-surgery, TKA patients demonstrated a decreased maximum GRF (CON = 15.48 N/kg, TKA = 13.78 N/kg, $p = 0.028$). Total knee arthroplasty patients also displayed a decreased KFM at 25% of stance (CON = 1.35 Nm/kg, TKA = 0.86 Nm/kg, $p = 0.000$) and at 50% of stance (CON = 1.41 Nm/kg, TKA = 0.94 Nm/kg, $p = 0.000$). Larger peak trunk flexion values were found for TKA patients during stair descent (CON = 10.51 degrees, TKA = 16.56 degrees, $p = 0.003$). Significantly increased times for TKA patients were registered on the force plate (CON = 0.73 s, TKA = 1.09 s, $p = 0.001$) and stair descent time (CON = 1.16 s, TKA = 1.60 s, $p = 0.000$). Knee extensor strength was also decreased for TKA patients compared to controls (CON = 79.41 lbs., TKA = 63.46 lbs., $p = 0.038$). These one-year post-TKA variables can be found in Table 4.

Table 4. One-Year Biomechanical Comparison Between Controls and TKA Patients During Stair Descent

	CON (n = 30, 30 knees)			TKA (n = 12, 16 knees)			P value
	Mean	±	SD	Mean	±	SD	
Max GRF (N/kg)	15.48	±	2.50	13.78	±	1.76*	0.028
KFA at 25% of Stance (°)	29.04	±	6.51	27.09	±	5.27	0.343
KFM at 25% of Stance (Nm/kg)	1.35	±	0.29	0.86	±	0.24**	0.000
KFA at 50% of Stance (°)	33.47	±	5.65	32.17	±	6.22	0.497
KFM at 50% of Stance (Nm/kg)	1.41	±	0.28	0.94	±	0.20**	0.000
Peak Trunk Flexion (°)	10.51	±	5.75	16.56	±	6.10**	0.003
Time on Plate (s)	0.73	±	0.10	1.09	±	0.52**	0.001
Time to Max GRF (s)	0.12	±	0.03	0.19	±	0.24	0.137
Time on Stairs (s)	1.16	±	0.15	1.60	±	0.60**	0.000
Knee Extensor Strength (lbs.)	79.41	±	26.09	63.46	±	21.82*	0.038

TKA = total knee arthroplasty; CON = controls; n = number of participants; SD = standard deviation;

Max = maximum; GRF = ground reaction force; N/kg = Newtons per kilogram;

KFA = knee flexion angle; (°) = degrees; KFM = knee flexion moment;

Nm/kg = Newton-meters per kilogram; s = seconds, lbs. = pounds.

* = significant difference between controls and TKA implant ($p \leq 0.05$).

** = significant difference between controls and TKA implant ($p \leq 0.01$).

A further comparison of MR patients, SR patients, and controls was conducted at six-months (Table 5), and one-year post-TKA (Table 6). At six-months post-TKA, KFM at 25% stance was decreased for both the MR patients (CON = 1.35 Nm/kg, MR = 0.70 Nm/kg, $p = 0.000$) and SR patients (CON = 1.35 Nm/kg, SR = 0.95 Nm/kg, $p = 0.003$). Furthermore, KFM at 50% of stance was decreased for both the MR patients (CON = 1.41 Nm/kg, MR = 0.84 Nm/kg, $p = 0.000$) and SR patients (1.41 Nm/kg, SR = 0.99 Nm/kg, $p = 0.001$). The MR patients displayed increased time on the force plate (CON = 0.73 s, MR = 1.29 s, $p = 0.000$), time to maximum GRF (CON = 0.12 s, MR = 0.26 s, $p = 0.001$), and stair descent time (CON = 1.16 s, MR = 1.81 s, $p = 0.000$). Single-radius patients generated less knee extensor strength (CON = 79.41 lbs., SR = 54.95 lbs., $p = 0.035$), compared to controls. Compared to MR patients, SR patients demonstrated decreased time to maximum GRF (SR = 0.12 s, MR = 0.26 s, $p = 0.018$) at six-months post-TKA.

At one-year, KFM values at 25% of stance were decreased for MR patients (CON = 1.35 Nm/kg, MR = 0.73 Nm/kg, $p = 0.000$) and SR patients (CON = 1.35 Nm/kg, SR = 0.95 Nm/kg, $p = 0.001$). The KFM values at 50% of stance remained decreased for MR patients (CON = 1.41 Nm/kg, MR = 0.86 Nm/kg, $p = 0.000$) and SR patients (CON = 1.41 Nm/kg, SR = 0.99 Nm/kg, $p = 0.000$). Peak trunk flexion remained increased for the MR group during stair descent (CON = 10.51 degrees, MR = 20.52 degrees, $p = 0.001$) compared to controls. Increased time deficits remained for MR patients compared to controls for time on force plate (CON = 0.73 s, MR = 1.46 s, $p = 0.000$), time to maximum GRF (CON = 0.12 s, MR = 0.27 s, $p = 0.028$), and time on stairs (CON = 1.16 s, MR = 2.01 s, $p = 0.000$), and to SR patients (MR = 1.46 s, SR = 0.82 s, $p = 0.000$), time to maximum GRF (MR = 0.27 s, SR = 0.12 s, $p = 0.033$), and time on stairs (MR = 2.01 s, SR = 1.29 s, $p = 0.000$).

Table 5. Six-Month Biomechanical Comparison Between Controls and Implant Groups During Stair Descent

	CON			MR			MR to CON	SR			SR to CON	SR to MR
	(n = 30, 30 knees)			(n = 9, 11 knees)			P value	(n = 5, 8 knees)			P value	P value
	Mean	±	SD	Mean	±	SD		Mean	±	SD		
Max GRF (N/kg)	15.48	±	2.50	13.67	±	2.58	0.117	14.91	±	2.04	0.827	0.539
KFA at 25% of stance (°)	29.04	±	6.51	23.56	±	7.23	0.072	28.73	±	5.69	0.992	0.239
KFM at 25% of stance (Nm/kg)	1.35	±	0.29	0.70	±	0.33**	0.000	0.95	±	0.18**	0.003	0.185
KFA at 50% of stance (°)	33.47	±	5.65	30.04	±	7.07	0.262	33.87	±	5.36	0.984	0.387
KFM at 50% of stance (Nm/kg)	1.41	±	0.28	0.84	±	0.30**	0.000	0.99	±	0.20**	0.001	0.477
Peak Trunk Flexion (°)	10.51	±	5.75	13.93	±	10.81	0.377	15.73	±	4.76	0.154	0.849
Time on Force Plate (s)	0.73	±	0.10	1.29	±	0.80**	0.000	0.88	±	0.13	0.570	0.061
Time to Max GRF (s)	0.12	±	0.03	0.26	±	0.22**	0.001	0.12	±	0.03^	0.991	0.018^
Total Time on Stairs (s)	1.16	±	0.15	1.81	±	0.91**	0.000	1.36	±	0.15	0.485	0.078
Knee Extensor Strength (lbs.)	79.41	±	26.09	69.84	±	24.16	0.545	54.95	±	8.70*	0.035	0.410

CON = controls; MR = multi-radius; SR = single-radius; n = number of participants; SD = standard deviation;
 Max = maximum; GRF = ground reaction force; N/kg = Newtons per kilogram; KFA = knee flexion angle; (°) = degrees;
 KFM = knee flexion moment; Nm/kg = Newton-meters per kilogram; s = seconds; lbs. = pounds.
 * = significant difference between controls and MR or SR ($p \leq 0.05$).
 ** = significant difference between controls and MR or SR ($p \leq 0.01$).
 ^ = significant difference between implant designs ($p \leq 0.05$).
 ^^ = significant difference between implant designs ($p \leq 0.01$).

Table 6. One-Year Biomechanical Comparison Between Controls and Implant Groups During Stair Descent

	CON			MR			MR to CON	SR			SR to CON	SR to MR
	(n = 30, 30 knees)			(n = 9, 11 knees)			P value	(n = 5, 8 knees)			P value	P value
	Mean	±	SD	Mean	±	SD		Mean	±	SD		
Max GRF (N/kg)	15.48	±	2.50	13.59	±	2.55	0.117	13.99	±	1.05	0.226	0.961
KFA at 25% of stance (°)	29.04	±	6.51	27.13	±	6.32	0.072	27.07	±	4.80	0.716	0.990
KFM at 25% of stance (Nm/kg)	1.35	±	0.29	0.73	±	0.23**	0.000	0.95	±	0.20**	0.001	0.285
KFA at 50% of stance (°)	33.47	±	5.65	32.45	±	7.12	0.262	31.96	±	5.90	0.799	0.987
KFM at 50% of stance (Nm/kg)	1.41	±	0.28	0.86	±	0.18**	0.000	0.99	±	0.20**	0.000	0.612
Peak Trunk Flexion (°)	10.51	±	5.75	20.52	±	5.68**	0.001	13.59	±	4.76	0.358	0.068
Time on Force Plate (s)	0.73	±	0.10	1.46	±	0.63**	0.000	0.82	±	0.13^^	0.603	0.000^^
Time to Max GRF (s)	0.12	±	0.03	0.27	±	0.36*	0.028	0.12	±	0.02^	0.991	0.033^
Total Time on Stairs (s)	1.16	±	0.15	2.01	±	0.75**	0.000	1.29	±	0.16^^	0.515	0.000^^
Knee Extensor Strength (lbs.)	79.41	±	26.09	61.53	±	26.54	0.545	65.63	±	16.53	0.354	0.939

CON = controls; MR = multi-radius; SR = single-radius; n = number of participants; SD = standard deviation;
 Max = maximum; GRF = ground reaction force; N/kg = Newtons per kilogram; KFA = knee flexion angle; (°) = degrees;
 KFM = knee flexion moment; Nm/kg = Newton-meters per kilogram; s = seconds; lbs. = pounds.

* = significant difference between controls and MR or SR ($p \leq 0.05$).

** = significant difference between controls and MR or SR ($p \leq 0.01$).

^ = significant difference between implant designs ($p \leq 0.05$).

^^ = significant difference between implant designs ($p \leq 0.01$).

DISCUSSION

Results of this study illustrate that post-operative deficits remain during stair descent at six-months and one-year for TKA patients, when compared to healthy controls. Deficits were found in KFM, GRF, peak trunk flexion, stair descent times and knee extensor strength post-TKA. Stair descent values reported in this study are similar to findings of previous research examining TKA patients and healthy controls [26, 29]. Fewer differences in biomechanical variables were observed from six-months to one-year post-TKA, but persistent limitations remained for TKA patients during stair descent.

Knee flexion moment was a key variable of interest for this research study, as it provided understanding to the forces acting at the knee joint. Patients who demonstrate larger KFMs are able to load their knee with increased joint loading forces, indicating higher functioning ability [6]. The biomechanical variables of GRF and KFA are closely associated with KFM. In the present study, similar GRF and KFA values were found between TKA patients and healthy controls over both testing time periods, suggesting that factors other than GRF or KFA were contributing to the significant differences found in KFM values. Research has demonstrated that increased trunk flexion is a compensatory motion for knee extensor weakness, as it is used to transfer the body's center of mass in a more anterior direction, resulting in decreased KFMs and is indicative of lower patient functioning levels [23, 34, 39]. These findings are supported in the present study, as TKA patients demonstrated decreased KFM, increased anterior trunk flexion during stair descent, and decreased knee extensor strength compared to healthy controls at both six-months and one-year following surgery. These findings indicate that compensatory motions contributed to decreased KFMs during stair descent following TKA.

It has previously been reported that stair descent remains more challenging for TKA patients than stair ascent [3, 26, 30, 31]. In this study, TKA patients experienced greater difficulty descending stairs as indicated by the significantly slower descent times compared to controls at both six-months and one-year post-TKA. A factor influencing the challenge of stair descent for TKA patients is knee extensor strength. Research has suggested that increased knee extensor strength allows for improved knee function post-TKA [39]. In the current study, knee extensor strength for TKA patients was decreased compared to healthy controls at six-months and one-year post-TKA, and were similar to findings reported in previous research [1, 29]. Patients with decreased knee extensor strength can be greatly limited in their movements and activity level, thus hindering their overall level of function [32]. Knee extensor strength should be of priority for patient recovery, as findings of this study, as well as previous research, support the importance of adequate knee extensor strength in completing everyday tasks of daily living, such as stair descent.

An interesting finding of the study found that TKA patients reported lower UCLA activity scores at six-months post-TKA compared to controls, but at one-year post-TKA scores were not significantly different. Though TKA patient function was decreased in multiple measures, they perceived to be as physically active as controls, at one-year post-TKA, suggesting that the perception of physical activity level improves between six-months and one-year post-TKA. Previous findings have supported the gradual increase in perceived activity level out to one-year post-TKA [27]. These positive outcome measures may give TKA patients confidence in knowing that the vast majority of patients experience improved activity levels post-TKA.

Though the primary objective of this study was to compare TKA patients to healthy controls, a further analysis was performed to determine which implant design produced

improved biomechanical performance compared to healthy individuals. Findings of previous studies suggest that the SR implant design allows for superior patient function, compared to the MR implant design [20, 25, 37, 38]. However, studies also suggest patient function is equivalent between both implant designs, implying either are proficient for adequate function post-TKA [10, 15]. In the current study, differences between implant designs were present. At six-months post-TKA, MR patients displayed increases for time on the force plate, time to maximum GRF, and overall stair descent time, compared to SR patients and controls. At one-year post-TKA, MR patients demonstrated increases in trunk flexion, time on the force plate, time to maximum GRF, and overall stair descent time, compared to SR patients and controls. Strength output analyzed between implant designs suggested knee extensor strength increased for SR patients between six-months and one-year, whereas strength decreased for MR patients during this same time period. Though previous research suggests strength capabilities are similar between implant designs, biomechanical advantages of the SR implant design may have contributed to the findings of this study [7]. While these results may suggest that the SR implant design is preferable to the MR implant design for patient function and performance, KFM remained decreased at all post-TKA time periods regardless of implant design type, making it difficult to characterize one implant design as being superior.

Several limitations were present in this study. The small sample size of TKA patients as a group limited the power of significant results. The TKA sample sizes were unequal in terms of male and female patients, which may have affected overall averages of the TKA patient group. Additionally, the SR group was made up of more patients undergoing bilateral TKA, which may have potentially affected their recovery and performance during stair descent. Another factor to address are the differences in rehabilitation programs completed by the TKA patients.

Rehabilitation programs were not universal among patients, due to patients completing rehabilitation at different clinics, and these differences may have impacted patient recovery and function during stair descent. Future studies should involve a larger sample size of TKA patients, while controlling for equal sample sizes regarding gender, implant design type, unilateral or bilateral TKA procedure, as well as rehabilitation programs. Controlling these factors will help produce more accurate comparison of TKA patients to healthy controls, as well as comparison between implant design types. Overall, further research is warranted for comparison of function between TKA patients and healthy individuals during stair descent, as well as direct comparison of TKA implant design during stair descent.

CONCLUSION

The results of the present study provide a better understanding of the deficits that remain in TKA patient function after surgery during stair descent. Significant differences in GRF, KFM, trunk flexion, stair descent times and knee extensor strength in TKA patients were still evident out to one-year post-TKA. Total knee arthroplasty patients with knee extensor strength deficits have difficulty overcoming this weakness during the challenging task of stair descent and rely on compensatory motions and more time to complete the task. In addition, results of this study support the notion that SR patients may have slight advantages during stair descent. However, regardless of implant design, deficits remain in both implant designs during stair descent compared to controls.

REVIEW OF LITERATURE

Knee Osteoarthritis

Knee osteoarthritis is a debilitating disease, prevalent in nature [8, 18], and it greatly limits patients from completing common everyday tasks [14, 21, 22, 34]. Studies support the understanding that knee OA causes pain, alters gait, decreases muscle strength, and forces patients to use compensatory movements while walking, when compared to a healthy population [2, 19, 24]. Current research provides insight on how knee OA affects individuals in everyday tasks, such as stair ambulation and rising from a chair, and this can help better understand what proactive measures need to be taken prevent or treat this disease.

Deshpande et al. [8] considered the prevalence of symptomatic knee OA in the United States. Calculations were based on the prevalence of clinically diagnosed knee OA from the National Health Review Survey from 2007-2008. Severity of the cases was determined with Kellgren-Lawrence scores and by using the Osteoarthritis Policy Model. A logistic regression analysis was used to control for age and sex-stratified BMI. Results suggested that there are roughly fourteen million people with symptomatic knee OA, and advanced OA comprises over half of those cases. It was also reported that the majority of individuals diagnosed with knee OA were between the ages of 45 and 65 years of age. Results of this study suggest that knee OA is very prevalent in the United States and that the number of cases are only expected to grow. This supports the importance of understanding how OA progresses and what treatment options are the best for this disease.

Statistical projections were made by Kurtz et al. [18] to estimate the number of total knee arthroplasties (TKA) that will be conducted between the years of 2005 and 2030, for the treatment of knee OA. Projections were based on surveys of hospital discharge records in the

United States from 1990 to 2003. The use of a Poisson regression and a scaled Pearson chi square test were used to determine TKA prevalence. Results found that between 1990 and 2003, the number of TKA procedures increased substantially. It was determined that if the number of TKA procedures performed at the current rate, the demand for primary TKA is projected to grow by 673% between 2005 and 2030. Suggestions made by this study infer that TKA procedures are only expected to grow in prevalence, emphasizing the need for better understanding of knee OA and improvements in treatment strategies.

Leyland et al. [22] used bilateral radiographs to assess long-term prevalence, incidence, and progression of mild and moderate knee OA in 1,003 middle-aged women, between the ages of 44 and 67 years of age, to evaluate the progression of unilateral disease over the course of 15 years. Data was analyzed using Mann-Whitney U tests, Pearson's chi-square tests and Fishers exact test. Results of this study suggested that the annual rates of disease incidence, progression, and worsening between baseline and year 15 were 2.3%, 2.8%, and 3.0%, respectively. An interesting reported finding was that more than half of the subjects remained free of radiographic knee OA over 14 years. Another importing finding was that knees with a baseline K/L grade of 1 had a 4.5-fold greater risk of developing incident ROA compared with knees with a baseline K/L grade of 0; and that the majority of knees that had undergone total replacement by the time of the follow-up visit did not have ROA at baseline. Having been the first long-term study of its kind to look at osteoarthritis formation through the use of radiographs, these important findings can be very beneficial to improving the recognition of osteoarthritis.

Biomechanics of level walking and stair walking were assessed in 54 men with knee OA at different pre-determined gait speeds and compared with healthy control subjects, by Liikavainio et al. [24]. Accelerometers were attached to the symptomatic knee joint, and EMG

data was collected while gait analysis was performed. Patients were instructed to walk up and down stairs as natural as possible at a self-selected speed. Data was analyzed using Student t-tests, one-way ANOVAs, Kruskal-Wallis, Mann-Whitney and Wilcoxon tests. Results of this study suggested knee OA patients demonstrated different muscle activations in the vastus medialis and biceps femoris muscles, suggesting different strategies were used to execute the same walking tasks due to weakness and pain. It was concluded that differences in measured skin mounted accelerometers and ground reaction forces parameters between the knee OA patients and the controls were minor at constant gait speeds, but were significant during stair descent as demonstrated by higher initial peak and maximal horizontal acceleration, attributed to neuromuscular fatigue. Interestingly, it was found that healthy people may load their lower extremities too heavily during normal everyday activities, leading to joint degeneration.

Landry et al. [19] identified biomechanical features, using three-dimensional motion analysis, to characterize the gait patterns of 41 patients with mild to moderate knee OA, waiting to undergo knee arthroplasty. They investigated if the biomechanical differences became more pronounced as the locomotor system is stressed by walking and compared them to healthy controls. Infrared markers were placed on specific locations on the surface of the patients' body and were captured during motion, and data was processed using MATLAB. Each subject completed five walking trials at a self-selected walking speed, and then five walking at a fast speed (roughly 150% faster than self-selected speed). Student t-tests, repeated measures of variance and Tukey tests were used for data analysis. Results of this study recommended that the OA group had larger adduction moment magnitudes during stance and this higher magnitude was sustained for a longer portion of the gait cycle, suggesting compensatory motions are used by OA patients. It was also found that the OA group had a reduced flexion moment and a

reduced external rotation moment during the early stance phase. Walking speed did not seem to elicit any biomechanical differences between the OA and control groups, different than those found at self-selected walking speeds. Differences in gait due to compensatory motions were attributed to the OA process, resulting in pain and weakness. Results of this research study identify differences in knee joint kinetics, and this information can be used to develop interventions for slowing the progression of OA.

Kaufman et al. [14] analyzed gait characteristics in 139 patients with knee OA compared to a control group of 20 healthy adults. Kinematic data was collected while patients walked along a 12-meter walkway for level walking, and ascended and descended a four-step stair case for the stair trials. A repeated measures ANOVA was used to test for significant differences in velocity, joint angles, and gait cycle between the healthy and knee OA patients. A repeated measures ANCOVA was used to control for differences in gait velocity when making comparisons for the knee moments. Results of this study suggested that subjects with knee OA walked slower than the normal subjects, and had a reduced knee peak extension moment compared to normal subjects. Knee OA patients' knee varus moments were also significantly increased compared to the healthy population. It was reported that the highest extension moment occurred while descending stairs, implying stair descent was more stressful than stair ascent and level walking. These findings were attributed to knee OA patients using compensatory motions to control for pain caused by their OA. Findings of this study suggest how painful OA is for patients and the biomechanical adjustments patients make to cope with the disease.

Quadriceps weakness due to OA was studied by Lewek et al [21]. This study included 12 patients with symptomatic, medial compartment knee OA, to determine the extent of quadriceps muscle strength deficits and activation failure in middle aged patients with symptomatic medial

knee osteoarthritis. The control group was considered healthy and underwent the same testing as the treatment group. Isometric quadriceps strength found during a maximal effort volitional contraction of the quadriceps muscle. Strong verbal encouragement was given to help elicit maximal muscle contractions. Isometric quadriceps strength tests were repeated up to three times with a five-minute rest between sessions. Data analysis consisted of one-way analysis of variance for quadriceps strength and activation deficits, Fisher's exact test, and regression analysis. Results suggested knee OA patients had significantly less quadriceps strength relative to body mass index, compared to the control participants. Reasoning for less quadriceps strength was due to disuse of the quadriceps, attributed to lack of motivation, pain, and fear of moving the knee joint. These findings support the idea that quadriceps weakness is prevalent in OA patients, and the potential correlation between quadriceps weakness and knee OA.

Knee OA has been found to alter proprioception, affecting the ability to balance. The purpose of the study, conducted by Bascuas et al.[2], was to assess changes in balance among 44 patients with knee osteoarthritis at one-year after TKA, and its relationship with clinical variables. The modified Clinical Test for Sensory Interaction and Balance (mCTSIB) and the sit-to-stand test were used to assess the participants. Descriptive analysis was based on calculation of averages, standard deviations, medians, and top and bottom quartiles.

Additionally, the Kolmogorov-Smirnov test, a Q-Q plot, chi-square tests, and the Spearman test, were used to analyze data. Results of this study suggested significant changes occurred between pre- and postoperatively for the following variables: increased gait velocity, decreased pain, increased strength of the extensors in both knees, decreased flexion in both knees, and slight improvement in extension of the operated knee. Significant differences were found in mCTSIB scores for the foam surface test, with a moderate to high effect size reported. A significant

correlation was found between the sit-to-stand rising index and muscle strength in the operated leg in both the quadriceps and hamstrings. Likewise, a positive correlation was found between the preoperative rising index and gait velocity. These post-TKA improvements were thought to result from improved response of mechanoreceptors in the capsuloligamentous and musculotendinous structures, improving proprioception, as a result of rehabilitation.

The biomechanics of TKA patients rising from a chair were studied by Su et al. [34]. Twelve TKA patients, 14 patients with knee OA, and 12 healthy controls participated in this research study. Patients were seated on a height-adjustable chair, corresponding to their leg measurements, and were asked to rise from the chair at a natural speed without the use of the arm rests of the chair. Motion analysis was collected using the ExpertVision motion analysis system, with data collected at 60 Hz. Repeated measures ANOVA was conducted to evaluate differences between groups and chair heights. Both the TKA and OA groups required more time to rise from a chair as the height of the chair increased, compared to the control group. Compared to healthy controls, TKA patients demonstrated increased horizontal COM velocity, increased vertical hip joint forces, and decreased vertical COM velocity. Results of this study suggested that knee OA and TKA patients experienced greater difficulty rising from a chair than healthy controls, based on biomechanical variables and compensatory motions that were present.

Studies have shown how prevalent knee OA is [8, 18], and how severely limited knee OA patients are compared to healthy individuals [2, 14, 19, 21, 22, 24, 34]. OA effects are evident in patients through radiographs, gait analysis, walking tests, and strength tests. Research states how stair descent poses greater difficulty than stair ascent and level walking for OA patients [14]. Further studies are necessary to determine why stair descent poses greater challenges than stair

ascent and level walking. Future research will result in additional advances in treatment, whether that is through TKA design or rehabilitation strategies.

Implant Designs in Total Knee Arthroplasty

Currently, there are multiple TKA implant designs. As life expectancy increases, so will the occurrence of TKA procedures. Implants are designed to eliminate pain experienced by OA and meet the functional demands of the patient. Many research studies have compared single (SR) and multi-radius (MR) implant design types, with research supporting SR implant designs are superior during certain movements [20, 25, 37, 38], but discrepancy exists for what implant design is superior [10, 15].

Knee society scores and the chair-rise test were used to compare the knee extensor mechanism function after TKA between 83 MR and 101 SR implant designs in TKA patients by Mahoney et al. [25]. Patients were evaluated by the operating surgeon preoperatively and at six-weeks, three-months, six-months, one-year, and two-years postoperatively. Statistical analysis was performed using unconditional logistic regression. Results suggested that patients in the SR group gained flexion more rapidly, rose from a chair more efficiently and experienced significantly less anterior knee pain when rising from a seated position to a standing position. It was observed that improved extensor mechanism function after TKA was seen in association with design features that increase the length of the extensor mechanism moment arms, which are features of the SR design. After this study concluded, the SR implant design appeared to be superior to the MR implant design when considering the extensor mechanism while rising from a chair.

Wang et al. [37] studied both SR and MR design types to investigate the effect of different arthroplasty designs on knee kinematics and lower limb muscular activation during the

sit-to-stand (STS) movement. Sixteen unilateral, posterior-stabilized knee arthroplasty participants, with excellent Knee Society scores performed 4 trials of the STS test. Three-dimensional video analysis of whole body and joint kinematics and electromyography analysis of quadriceps and hamstring were conducted. One way ANOVAs were used for statistical analyses. Results suggested MR patients demonstrated some functional adaptations while sitting down, such as greater trunk flexion angle and velocity. It was surmised that increased trunk lean serves to reduce the extension moment acting across the hip joint, in turn, reducing knee extension moment required and decreasing the needed knee extensor muscle force. The SR group exhibited less quadriceps electromyography and hamstring co-activation electromyography than the MR group, suggesting SR patients required less eccentric knee extensor muscle activation to rise from a chair. Findings of this study favor the SR implant in knee extension when compared to the MR implant design during the STS movement.

Single-radius and multi-radius design types were compared by Hall et al. [10] to identify potential advantages between implant designs in 100 prospectively randomized individuals who received one of the two TKA prosthetic designs. Postoperatively, the surgical knees were splinted in full extension overnight, followed by physical therapy protocols the first day after surgery, consisting of quadriceps strengthening, passive and active range-of-motion exercises, and weight bearing to tolerance. Active knee range of motion, Knee Society scores, and the ability to rise from a chair were assessed by a physician who was blinded to the implant design type. The Student t-test and Pearson χ^2 test were used to determine significant differences between groups. Results of this study suggested that there were no statistically significant differences between groups at any point in time. These findings are important because they

support the rationale that patients can be confident in knowing that either design type is proficient and will improve their function once they undergo TKA to treat knee OA.

Wang et al. [38] specifically considered biomechanical differences between two implant designs during the STS movement in 16 well-functioning patients who underwent a unilateral TKA. Patients were asked to stand up as quick as possible and then remain standing for five seconds to successfully complete the movement. Statistical analysis included one-way ANOVAs used for all data analysis. Results suggested that there were significant differences for kinematics and electromyography between the SR and MR groups. The SR group completed the STS movement faster than the MR group, and exhibited less arthroplasty limb quadriceps and hamstring co-activation electromyography. Both advantages were accredited to the larger extensor moment in the SR implant design. The MR group demonstrated larger maximum trunk flexion, and greater trunk flexion velocity than that of the SR group, occurring in order to reduce the extension moment acting across the hip joint, in turn, reducing knee extension moment required and decreasing the needed knee extensor muscle force. Based on performance in this study, the SR implant design demonstrated better performance during the STS test, when compared to the MR implant design.

Single-radius and MR implant designs were compared by Kim et al. [15] to determine which was superior for quadriceps recovery after TKA. A total of 164 knees of female patients undergoing primary TKA were randomly assigned to either implant design. Quadriceps recovery was assessed using a dynamometer at the same time points until the first postoperative year. The Baltimore Therapeutic Equipment Primus was used pre- and post-operatively to quantify the extent of quadriceps strength. Statistical analyses were performed using groups independent sample t-tests, chi-square test, and a repeated measures ANOVA. Overall, the SR

implant design was not superior to the MR femoral design in terms of quadriceps recovery during the one-year follow-up after TKA, based on postoperative clinical score and range of motion testing. Results of this study suggest neither implant design is superior, but both influence quadriceps recovery after TKA, similarly.

Single-Radius and MR TKA implant designs were quantitatively compared by Larsen et al [20] during level ground walking, one-year post-TKA. Two groups of subjects diagnosed with advanced knee received either a SR implant or a MR implant. All implant procedures were performed by three different fellowship-trained arthroplasty surgeons from one orthopedic practice. Data collection involved subjects walking at a self-selected speed down an eight-meter walkway, containing four embedded force plates, while position and force data were collected using a digital analysis system. Subjects completed a Lower Extremity Activity Scale and a Knee Society Function and Knee Score with each gait assessment. Between groups comparison was completed using a one-way ANOVA with a Tukey HSD or Dunnett's post hoc test, performed as appropriate, and clinical scores were compared using a two-tailed t-test. Results suggested MR knees remained more extended and had decreased power absorption during weight acceptance, compared to SR knees. Biomechanical differences were likely influenced by patella-femoral moment arm, with SR characterized by a longer extensor moment, and changing ligament laxity throughout the active range of motion, attributed to the MR implant design. Biomechanically the SR implant design seemed to perform more proficiently during level walking at one-year post-TKA when compared to the MR implant design.

Though the results of these studies seem to favor a SR femoral implant design [20, 25, 37, 38], controversy remains when comparing performance of SR and MR implant designs. SR designs are potentially more efficient in aiding extensor function and providing stability of the

knee, but both implant designs have been found to have equal clinical outcome function [10, 15]. Further research studying the performance of these implant designs may help clarify what implant design is best for TKA patients during functional movements, such as stair descent.

Stair Ambulation and Total Knee Arthroplasty Patients

Stair ambulation has proven to cause instability in lower extremities, even in healthy patients [36]. Following TKA, instability is even more prevailing during stair ambulation, especially during stair descent. Comparing stair descent to level walking and stair ascent, studies have suggested that stair descent is the most challenging [3, 26, 30, 31]. Different design types have been noted to improve stair descent efficiency, as well as the importance of anatomical structures [4]. Considering the motions and compensations that occur in TKA patients during stair descent will allow for improvements in rehabilitation protocols, improving their stair ambulation efficiency.

Peak knee flexion during stair descent was investigated in 23 TKA patients and compared to healthy age matched controls by Bjerke et al. [3]. Patients were required to descend a custom-made free standing stair case, without the use of a handrail, using a step-over-step pattern at a comfortable pace, for a total of six trials. The first three trials included a right foot lead and the last three trials included a left foot lead. An eight-camera system captured the movements, and were compiled into three dimensional animations. Paired sample t-tests and a one-way ANOVA were used to determine statistical significance. Results suggested there was a significantly smaller peak knee flexion angle in subjects' prosthetic knee compared to the contralateral healthy knee and controls. Quadriceps peak torque was also lower in the TKA-side compared to the contralateral side and controls it was suggested that reduced quadriceps peak torque may have also contributed to lower peak knee flexion during stair descent. This supports the

importance of strengthening the quadriceps muscles in TKA patients, allowing for improved function.

Borque et al. [4] looked at six fresh-frozen human cadaveric knees, harvested from male and female donors with an average age of 61 years. External forces were applied to each harvested knee to simulate multiple phases of the gait cycle during the loading conditions of a stair descent maneuver. An infrared multi-camera high resolution motion analysis system, allowed for a three-dimensional model to be created of the knee in a specific position. The stair descent experiment was then repeated after implementation with four different designs. Statistical significance was determined using ANOVA with repeated measures between implantation designs, and Fisher PLSD (protected least significant difference) was used when associations were detected. Results supported the notion that healthy quadriceps strength, along with a healthy posterior collateral ligament, are necessary to increase congruity of tibio-femoral interface, allowing for greater stability to occur. With the posterior cruciate ligament intact, the femur translated 2.3 ± 0.8 mm with application of the quadriceps load, and 2.5 ± 1.4 mm from toe-touch to mid-stance. After division of the posterior cruciate ligament, these values increased dramatically to 8.2 ± 3.2 mm (+253%) and 3.1 ± 1.2 mm (+25%), respectively. In the absence of the posterior cruciate ligament, the cruciate substituting designs did not provide proficient stability during stair descent, further emphasizing the importance of the posterior cruciate ligament's function to provide knee stability.

McClelland et al. [26] studied the prevalence of abnormal knee biomechanical patterns in 40 patients with a TKA, in comparison to healthy individuals. Patients were asked to ascend and descend the staircase until a minimum of three, or maximum of five trials of data were collected for each leg. The use of a motion capture analysis system allowed for analyzation of kinematic

data to occur. During stair ascent subjects were instructed to take two steps, at a self-selected speed, on the level walkway before ascending the stair case in a reciprocal footfall pattern. During stair descent, the process was reversed so the participants began on the top step, descended onto the first step, which included a force plate, and descended again on to the walkway, finishing with two steps on the walkway. Hierarchical cluster analysis and independent samples t-tests were used for statistical analysis. The majority of the TKA participants were able to navigate the stairs, but data suggested that participants developed abnormal strategies to ascend or descend the stairs, specifically by avoiding to produce a knee flexion moment. Avoidance to produce a knee flexion moment was attributed to patients preferring not to use their quadriceps, possibly due to fear and muscle weakness, in the operated knee. The findings of this study suggest that recovery of normal stair ambulation may be more difficult than believed. The importance of patients with TKA to complete rehabilitation exercises is stressed in order for improvements to occur, and to allow for more natural knee flexion movements to be produced.

Stacoff et al. [30] looked to provide comparisons of vertical GRF of stair ambulation and how it differed between stair inclination, age, and test-to-test variability during two consecutive steps. Twenty healthy adults were divided into three different age categories. Patients wore shoes during walking trials, in which they walked over a 25-meter walkway or ascended and descended the stairs. Data of two consecutive steps were collected during level walking and stair ambulation, totaling seven test conditions, with participants completing each test condition 8-10 times at a comfortable speed. Statistical analysis consisted of using a one-way ANOVA, a post hoc Bonferroni test, a Kruskal-Wallis test, and a two-tailed t-test. Results suggested that during stair ascent the vertical GRF force pattern was found to change slightly when compared to level

gait, but changed significantly when changed to stair descent. During the steep stair descent condition the average vertical loading increased, as well as variability, and asymmetry. The steep stair descent condition was found to be the most demanding test showing the largest variability and asymmetry, producing the least stable gait pattern. Age was found to be a factor, as the younger group walked faster and produced larger GRF. This study provided evidence that GRF changes between different walking conditions, and further supports the understanding that stair descent provides greater challenges to individuals compared to level walking and stair ascent.

Biomechanical differences were examined between patients who underwent TKA and healthy individuals by Stacoff et al. [31]. Forty patients walked over a 25-meter walkway and climbed a set of stairs, while kinetic and electromyography data were simultaneously collected. Each subject was asked to walk or climb the stair at a comfortable self-selected speed, and completed this 8-10 times. All parameters were tested using the Kruskal-Wallis test. Differences between the test groups were tested using a post- hoc test (ANOVA, Bonferroni). Results of this study suggested that loading patterns of vertical ground reaction forces looked similar between TKA patients and healthy individuals, however there were a few distinct differences. During level gait, a significant reduction in vertical loading on the operated side was found during toe-off and at weight acceptance, indicating TKA patients had a greater difficulty producing the same amount of push-off force, attributed to muscle weakness. During stair descent, patients did not reduce load on the operated side, but increased load variation and side-to-side asymmetry, increasing the mechanical loads on the implant, an indication that compensatory motions were made. Findings of this study suggest muscle weakness affects walking biomechanics of TKA patients, resulting in the use of compensatory motions.

Frontal joint dynamics of 10 participants were assessed by Vallabhajosula et al [36], and were compared between initiating stair ascent from a walk versus standing. Motion data was collected while participants completed five randomized trials of both stair ascents initiated from a self-selected walking pace and initiated from standing. A repeated two-way ANOVA was performed to identify differences between the two conditions. Participants demonstrated greater peak abductor moments at the knee when initiating stair ascent from a walk and at the next ipsilateral step. These results were thought to occur due to enhanced momentum when initiating stair ascent from a walk, initiating greater velocity, resulting in greater peak joint moments at the knee and hip. These findings could be specifically important for individuals with weaker hip abductors, often seen in patients with knee and hip OA. Rehabilitation specialists could provide strengthening exercises to target these weaknesses, improving patients' ability to ascend stairs.

Lower extremity instabilities are evident during stair ambulation [36], resulting in a significant amount of focus placed on the knee in TKA patients during stair ambulation. Implant designs may affect a patient's ability to descend stairs [3, 4, 26, 30, 31], along with deficits at joints, such as the ankle and hip. There is a need for research to examine forces placed on the knee during stair descent in order to provide better reasoning for the difficulty of stair descent for TKA patients. Comparison of different implant designs through the analysis of knee flexion moments, ground reaction forces, and quadriceps strength may provide reasoning as to why TKA patients have greater difficulty with stair descent compared to stair ascent and level walking.

Lower Extremity Strength After Total Knee Arthroplasty

Quadriceps weakness is a common finding in post-TKA patients [7, 29, 32, 35]. This weakness has previously been attributed to failure of voluntary activation of the quadriceps muscle [23]. Though there is a large emphasis placed on quadriceps strengthening during post-

surgery rehabilitation, hamstring strength must be addressed as well. Muscle weakness or imbalances can lead to tendinopathy, causing pain, weakness, and deficiencies for TKA patients [32, 39].

The effects of muscle strength loss after TKA surgery in 30 patients undergoing TKA were studied by Stevens-Lapsley et al. [32]. Patients performed a maximal isometric of the quadriceps and hamstrings against a stationary electromechanical dynamometer, and EMG electrodes were used to quantify hamstrings co-activation during the isometric contraction. A two-way ANOVA, multivariate ANOVA, and a Tukey's post hoc test were used to determine statistical significance. Results of this study suggested quadriceps and hamstrings muscle strength decreased one month post-TKA, and were still weaker than the non-operative leg at six months post-TKA. Overall, observations of this study suggest that although quadriceps dysfunction after TKA is typically recognized and addressed in postoperative therapy protocols, hamstring dysfunction must also be addressed. Failure to properly strengthen the hamstrings along with the quadriceps can result in hamstring weakness and tendinopathy, causing post-TKA dysfunction and pain.

Thomas et al. [35] researched bilateral quadriceps and hamstrings strength and muscle activity during walking in 10 patients pre-TKA, one-month after, and six-months post-TKA, and compared them to a healthy control group. Patients underwent bilateral quadriceps and hamstrings strength testing and assessment of quadriceps/hamstrings co-activation and on/off timing using surface electromyography during the Six-Minute Walk Test. Participants also performed an isometric quadriceps and hamstrings strength assessment using an electromechanical dynamometer. Independent samples t-tests, paired sample t-tests were used to make comparisons and determine statistical significance. Results suggested that TKA patients

reported greater pain, weaker quadriceps and hamstring strength, and couldn't walk as far as controls during a Six-Minute Walk Test, which were attributed to pain and muscle atrophy. These findings suggest the need for clinicians to emphasize bilateral strength and muscle activation retraining during early, post-operative rehabilitation in order for the patient to regain proper function sooner.

Knee strength of 19 TKA patients and 25 healthy individuals were compared by Silva et al.[29]. After completing a moderate intensity warmup, participants' isometric knee flexion and extension strength was found using a dynamometer, in which strength was found at seven specified positions throughout range of motion. Thirty seconds of rest was allowed between each testing, at each position. From each testing position, hamstring to quadriceps ratios were determined, and Knee Society Scores were obtained from each patient. Differences between groups were compared using a two-sample Student's t-test, and a step-wise multivariate regression analysis was used to adjust for patient characteristics. Correlations between patient characteristics were obtained using univariate and multivariate regression analysis. Results suggested that TKA patients displayed a lower average isometric extension peak torque value and a lower isometric flexion peak torque value, when compared to healthy individuals. Less torque produced by TKA patients during isometric strength testing was thought to occur from atrophy, due to decreased use of muscles acting on the knee prior to surgery. Knee Society Scores were positively correlated to the average isometric extension peak torque, and negatively correlated with average isometric hamstring to quadriceps ratios, suggesting greater quadriceps strength was associated with a better functional score. Though there is great variability in knee strength due to characteristics such as age and gender, there was a positive correlation between

extension strength and functional outcome, indicating a need for aggressive strengthening rehabilitation pre- and post-TKA.

D'Lima et al. [7] studied how knee prosthetic designs affect the quadriceps moment and its relationship to quadriceps force, using six fresh-frozen knees from human cadavers. Each knee was prepared with a SR or MR implant and fixated to an Oxford knee rig. Once secured, three-dimensional motion analysis was completed. Femoral and tibial translations and rotations were captured between 0° and 90° degrees. Repeated measures ANOVA was used to test for differences in movements of the knee, between implant designs. Significant differences were seen between normal and implanted knee kinematics, but not between the kinematics of the two implanted conditions. Patellofemoral forces were also lower in the SR design compared to the normal and control knee conditions. The results of this study suggest that a longer lever arm reduces the tension on the quadriceps muscle during knee extension, especially at flexion angles that typically generate high knee moment. Though there were significant differences between the SR and MR knee implants during closed chain knee extension, there were very small differences between these implant designs during open kinetic chain knee extensions when tested at the same angles and load forces, suggesting either is proficient during activities such as walking.

Yoshida et al. [39] investigated whether gait asymmetry persisted over time for patients who underwent TKA and whether knee function was restored as measured by quadriceps strength, knee motion and moments during walking. Twelve knee OA patients underwent unilateral TKA, and their function level was assessed at three and 12-months post-surgery and then compared to the function level of twelve healthy age and body mass matched individuals. All participants performed three performance based functional tests: The Timed Up and Go test,

the Stair Climbing Test, and the Six-Minute Walk Test. Motion analysis was captured using the Vicon motion analysis system, collecting data at 120 Hz and 1080 Hz, respectively, and data analysis was completed using custom written software and Visual 3D. Nonparametric tests, Wilcoxon Signed-Ranks tests, Mann-Whitney U-tests, Spearman Correlation Coefficients, and Spearman's rank correlation coefficients were used for statistical analyses. All clinical measures except for quadriceps strength significantly improved from three to 12 months. At 12 months, gait speed remained significantly slower than controls. It was found that greater hip and lower knee moments were evident in the operated limb, compared to the non-operated limb and controls. Quadriceps strength was found to be positively correlated with faster times on the Time Up and Go test and stair Climbing Tests, and greater distance was covered by the patient during the Six-Minute Walk Test. Outcomes of this study further support the deficiencies that exist for patients post-TKA. Greater quadriceps strength seems to be a driving factor for improved patient function, which should be of primary focus for patients when recovering from TKA.

Li et al. [23] set out to identify what muscles contribute most significantly to vertical support and forward progression when inadequate quadriceps strength is present. Gait data from fourteen TKA patients who underwent bilateral TKA and age-matched healthy controls were used for analysis. Three-dimensional gait analysis and subject-specific musculoskeletal modeling were used to determine lower-limb and trunk muscle forces and muscle contributions to center of mass accelerations during the stance phase of gait. A two-way ANOVA and a one-way ANOVA were for statistical analyses. Results indicated that TKA patients exhibited a 'quadriceps avoidance' gait pattern, with the vasti and rectus femoris contributing less to the knee extension moment during early stance compared to controls. Significant decreases were

found in contribution of the vasti to the vertical acceleration and forward deceleration of the center of mass in TKA patients. The TKA patients compensated for this deficiency by leaning their trunks forward, resulting in significantly increased contributions of the contralateral back extensor muscles to support, and that of the contralateral back rotators to braking. Findings of this study provide further insight into the biomechanical causes of post-operative gait adaptations such as ‘quadriceps avoidance’ observed in TKA patients.

Quadriceps weakness is evident in TKA patients post-surgery [7]. This weakness leads to neuromuscular deficiencies, altered gait, and knee pain [23, 32, 39]. Though the quadriceps are of main focus during post-TKA rehabilitation, the hamstrings play a crucial role in the agonist and antagonist function [29, 35]. Further research examining quadriceps strength and measured variables during stair descent will provide further insight as to why TKA patients have increased difficulty descending stairs, and may reform implant design choice or current rehabilitation techniques in order to improve quadriceps strength post-TKA.

Knee Joint Kinematics and Total Knee Arthroplasty

Total knee arthroplasty implant designs have continually advanced since first being used for treatment of OA. Studies have determined the natural movements of the knee [12], and TKA designs have been engineered based on these findings. Though designs have improved greatly over time, further improvement can be made to enhance clinical outcomes post-TKA [5]. Current research studies have suggested that TKA improves knee kinematics and overall function in patients [11, 16, 33], but further understanding and improvements of TKA implants will allow for even better function, relative to healthy individuals.

Magnetic resonance imaging (MRI) was used to determine the shapes of articular surfaces and their relative movements in six unloaded male cadaver knees by Iwaki et al. [12].

Knees were prepared and moved throughout the range of motion while examined with the use of an MRI, and radii and angular arcs of the femoral circles were then determined and measured. Results of this study suggested specific articulations that occur within the knee joint throughout the ROM. This study could lead to further research using the MRI technique while observing live knees, allowing for better understanding of the location of the axes of rotation, the function of ligaments, the location of the contact areas in normal and early OA joints, and may even demonstrate abnormalities of movement after injury to ligaments. This can provide critical information that can be applied to current TKA implant designs, further enhancing their function and efficiency.

Hatfield et al. [11] examined the effect of TKA on knee joint kinematics and kinetics in 60 patients during gait, to understand if TKA surgery changed the dynamic loading environment and knee motion of those with medial joint OA involvement during gait at one-year post surgery. Three-dimensional motion data of the lower limb and external ground reaction forces were recorded with a synchronized motion capture system and a force platform, while patients walked at a self-selected walking velocity along a 6-meter walkway. Five walking trials were averaged for each patient for their knee flexion joint angle and the three dimensions of net external knee joint moment waveforms. Regression analysis was used to determine the proportion of the postoperative knee adduction moment variance. Results of this study demonstrated that mid-stance knee adduction moment magnitude decreased, and knee flexion angle magnitude increased due to an increase during swing, suggesting the knee implant improved mechanics of TKA patients. Overall, significant changes in the knee flexion angle pattern and the patterns of all three knee joint moment patterns were found postoperatively, and all but the external rotation change moved toward the typical patterns previously reported for healthy individuals. This

occurrence was attributed to the implant design used, as nine patients received medial pivot implants, allowing for more external rotation to occur.

Mid-range instability is a dissatisfaction of TKA patients, which has been attributed to MR implant designs [33], and this was analyzed by Stoddard et al. Eight adult fresh-frozen left-sided lower limbs were disarticulated through the hip, in which all were obtained from a tissue bank. Single-radius implants were implanted in the knees, tested, and removed. Multi-radius designs were then implanted and tested. Loading conditions were then imposed across the range of active knee extension, with conditions including anterior-posterior drawer forces, internal-external rotation torques, and varus-valgus moments. Repeated-measures two-way ANOVAs and post hoc paired t-tests were used to find significant differences. Results suggested TKA implants reproduced comparable kinematics and limits of laxity to that of the natural knee. Differences between the implant designs were not significant, supporting the rationale that both implant designs are proficient during mid-range motion of the knee.

Kinematics of OA and post-TKA knees were examined by Collins et al. [5], with respect to the screw home mechanism, to compare the impact of different prostheses and levels of prosthetic constraint. Participants of this study included two TKA implant design groups of 15 patients, with each group receiving either a SR or MR implant design. Once completed, tibial rotation was recorded at 0°, 15°, 30°, 60°, and 90° flexion. Tibial rotation at 90° flexion served as the baseline for internal-external rotation measurements, and was considered to be 0° external rotation in all cases. Paired two-tailed sample t-tests were used to make comparisons between groups. Results suggested that on average, patients lost 5.3° of external rotation, when compared to pre-operative arthritic knees, thought to be caused by the resection of the ACL and implant design. There were no significant differences between the prostheses or different prosthetic

constraints. Results of this study demonstrated that TKA patients experienced a significant loss of the screw home mechanism. Regardless of either of these designs, patients still experienced a decrease in tibial external rotation during the screw home mechanism of the knee. This research provides further evidence on how implant designs compare and how natural movements of the knee may be hindered due to TKA implant design.

Konno et al. [16] conducted a research study evaluating knee kinematics and patellofemoral contact pressure in 39 TKA patients. Real time assessment of femoral rotation, medial shift, and lateral patellar tilt from knee extension to flexion was measured using a navigation system in kinetic mode. Intraoperative kinematics were measured from 0° to 90° at 10° intervals. Patients with an average medial center of rotation between 0° and 90° knee flexion were defined as belonging to the medial pivot group, and the others were placed in the non-medial pivot group, this included a lateral pivot, parallel motion and paradoxical pivot. Statistical comparison of the maximum value of femoral rotation, medial patellar shift, lateral patellar tilt and contact stress was made using an unpaired t-test. Results suggested there was significantly lower patellofemoral stress in the medial-pivot group when compared to the non-medial pivot group. This suggests that restoring normal tibiofemoral kinematics could result in a decreased risk of patellofemoral problems, such as anterior knee pain. This research emphasizes the importance of precision of intraoperative kinematic measurement, and how they contribute to pain experienced in the anterior knee.

Creaby et. al [6] analyzed the association between knee flexion kinematics and indicators of joint loading during walking in individuals with medial tibiofemoral OA. Eighty-nine participants with medial compartment knee OA were recruited from the local community to participate in this randomized controlled study. Participants completed barefoot walking trials at

a self-selected, normal walking speed, which was monitored using timing gates to ensure consistency between trials. Synchronized three-dimensional kinematic data were collected at 120 Hz using a Vicon motion analysis system with eight cameras. Each participant performed five successful walking trials for each limb and mean data were used for analyses. Pearson correlation coefficients were used to determine the degree of correlation between knee flexion variables and indicators of loading. Additional forward step-wise regression models were used to determine the influence of all knee flexion variables on knee loading indicators. Results demonstrated that peak flexion and flexion excursion were positively correlated with peak vertical ground GRF, but flexion at foot strike was not. Knee flexion at foot strike, peak flexion and flexion excursion were all positively correlated with the peak knee flexion moment. Data obtained from this study provide further understanding of the forces acting upon the knee and their affect upon sagittal plane loading variables on the symptomatic OA knee during walking.

Total knee arthroplasty has been reported to improve knee functions for OA patients [11]. Though femoral implants can't replicate natural movements entirely [16, 33], such as during the screw home mechanism [5], they provide similar actions to enhance function compared to pre-TKA. Future research can help improve the understanding of knee kinematics [6, 12], as well as other variables, such ground reaction force and knee flexion moment. This can help determine what characteristics are advantageous in knee implant designs, helping determine what implant will provide the best functional outcome for OA patients.

Clinical Outcomes and Total Knee Arthroplasty

Total knee arthroplasty is an effective surgical intervention for alleviating pain caused by OA. Studies have demonstrated that TKA procedures are highly successful, decreasing pain and improving a patient's ability to complete everyday tasks [9, 13, 27], but strength deficits are still

a concern for patients, post-TKA [1]. Current literature compares different implant designs, TKA patients and healthy individuals, and self-perceived outcomes.

Single-radius and multi-radius implant designs were compared by Jo et al. [13] in order to determine which design offered better intra-operative stability and clinical outcome. Participants were divided among two groups, with 58 patients receiving a SR implant design and another 58 patients receiving a MR implant design, and all surgeries were completed by one single senior surgeon. After surgery was completed, identical rehabilitation occurred for patients in both groups. Clinical outcome was assessed through passive range of motion, Hospital for Special Surgery (HSS) score, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and the visual analogue scale (VAS) of anterior knee joint pain during stair climbing. Variables were analyzed using an unpaired t-test. Results suggested that TKA patients with the SR femoral design showed better intra-operative stability due to the fixed axis of rotation, offering better ligamentous stability. When considering post-operative clinical outcomes, there were no significant differences between implant designs, suggesting either is an appropriate implant designs that can be used to achieve identical functioning results post-surgery.

Bade et al. [1] investigated how impairment and limitation changes pre- and post-TKA in 24 patients undergoing a primary unilateral TKA, compared to healthy adults, following a standardized rehabilitation program post-surgery. Testing sessions at two weeks preoperatively and at one, three, and six-months postoperatively involved isometric contractions performed against the dynamometer's force transducer, while verbal encouragement was given during each maximum attempt. Range of motion was measured both actively and passively. Functional tests were executed using the stair-climbing test, timed up-and-go test, Six-Minute Walk Test, and

single-limb stance time. Statistical analysis of differences between groups was carried out using an independent samples unequal variance t-test, and a one-way repeated measures ANOVA was used for comparison between testing sessions. Results suggested that compared to healthy older adults, patients performed significantly worse at all times, for all measures, except for single-limb stance time at six-months. Patients needed six months to recover back to preoperative levels on all measures, except knee flexion range of motion, but still exhibited the same extent of limitation they did prior to surgery. These findings suggest patients experience a significant decrease in strength following TKA surgery, evident when compared to a healthy population. Data from this study can show where further emphasis is needed in rehabilitation protocols to help patients gain strength of lower extremity muscles faster and more efficiently, allowing them to regain normal function of their knee.

Finch et al. [9] compared the function of 29 TKA subjects with that of healthy control subjects, as reflected by their perception of pain, stiffness, difficulty, and satisfaction with physical activity as well as to compare their perception with their performance in walking and managing stairs. The Lower Extremity Activity Profile (LEAP) and the Western Ontario McMaster osteoarthritis Index (WOMAC) were used for assessing the implant. Comparisons were made between questionnaires to determine validity of the measures. The General Linear Models procedure was used to compare groups and genders with unequal group sizes. Patients reported more pain and less satisfaction, when compared to the healthy population. At one-year, self-reported measures of perceived functional ability indicated that one year following TKA patients regained 80% of normal function. Despite significant improvement compared with preoperative status, pain and stiffness remained a problem for patients. Though there is improvement in knee function between pre- and post-TKA, this results suggest that when

compared to a healthy population, TKA patients are not as satisfied with their knee function when compared to a healthy population.

Naal et al. [27] looked to determine the short-term improvements, satisfaction rates, and the patient acceptable symptom state after total joint replacement for different patient-reported outcome measures (PROM). This prospective cohort study included 426 consecutive patients with end-stage OA undergoing total hip arthroplasty or TKA. Patients completed the specified PROMs at three, six, and twelve-months post-surgery. Satisfaction rates and patient acceptable symptom state were also assessed at these times. Changes in PROMs from baseline were analyzed using an analysis of covariance, with joint as the between-subjects factor and time as the within-subject factor. Post hoc analysis was performed using unpaired t test with Bonferroni adjustment. Results showed more than 90% of total joint arthroplasty patients improving significantly during the first 12-months after surgery. Improvements were seen all considered measures. These findings support patient satisfaction with total joint arthroplasty, and can serve as reference for future studies and patient-oriented follow-ups.

Overall, TKA has a history of being a successful surgery, greatly benefiting the patient [27]. Though post-TKA function levels are improvements when compared to pre-TKA functionality, further improvements can be made to improve clinical outcomes [1, 9]. Many research studies have examined clinical outcomes of implant designs, but fewer have compared a specific design to another through a longitudinal study [13]. Further research will provide detailed information about the functionality of implants, allowing for revisions to be made, resulting in improved function and patient satisfaction with their TKA implant.

APPENDIX A: RESEARCH SUBJECT INFORMATION AND CONSENT FORM

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

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

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

SPONSOR: Cris Stickle, PhD, ATC

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

SITE(S): University of Hawai‘i at Mānoa
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 Stickle 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.

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

APPENDIX C: DATA COLLECTION FORMS

Anthropometric Data

Subject ID#: _____ Date _____

Age _____ Gender: F / M

Data Collection Period 0 1 2 3 4 5

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-lbf)	Pain Score (HHD/Jt)	Trail 2 Score (ft-lbf)	Pain Score (HHD/Jt)	Trial 3 Score (ft-lbf)	Pain Score (HHD/Jt)	Trial 1 Score (ft-lbf)	Pain Score (HHD/Jt)	Trial 2 Score (ft- lbf)	Pain Score (HHD/Jt)	Trial 3 Score (ft-lbf)	Pain Score (HHD/Jt)
Hip abduction		/		/		/		/		/		/
Knee extension		/		/		/		/		/		/

REFERENCES

1. Bade MJ, Kohrt WM, Stevens-Lapsley JE. Outcomes before and after total knee arthroplasty compared to healthy adults. *The Journal of orthopaedic and sports physical therapy*. 2010;40:559-567.
2. Bascuas I, Tejero M, Monleon S, Boza R, Muniesa JM, Belmonte R. Balance 1 year after TKA: correlation with clinical variables. *Orthopedics*. 2013;36:e6-12.
3. Bjerke J, Ohberg F, Nilsson KG, Foss OA, Stensdotter AK. Peak knee flexion angles during stair descent in TKA patients. *The Journal of arthroplasty*. 2014;29:707-711.
4. Borque KA, Gold JE, Incavo SJ, Patel RM, Ismaily SE, Noble PC. Anteroposterior Knee Stability During Stair Descent. *The Journal of arthroplasty*. 2015;30:1068-1072.
5. Collins DJ, Khatib YH, Parker DA, Jenkin DE, Molnar RB. Tibial rotation kinematics subsequent to knee arthroplasty. *Journal of orthopaedics*. 2015;12:7-10.
6. Creaby MW. It's not all about the knee adduction moment: the role of the knee flexion moment in medial knee joint loading. *Osteoarthritis and cartilage / OARS, Osteoarthritis Research Society*. 2015;23:1038-1040.
7. D'Lima DD, Poole C, Chadha H, Hermida JC, Mahar A, Colwell CW, Jr. Quadriceps moment arm and quadriceps forces after total knee arthroplasty. *Clinical orthopaedics and related research*. 2001:213-220.
8. Deshpande BR, Katz JN, Solomon DH, Yelin EH, Hunter DJ, Messier SP, Suter LG, Losina E. The number of persons with symptomatic knee osteoarthritis in the United States: Impact of race/ethnicity, age, sex, and obesity. *Arthritis care & research*. 2016.
9. Finch E, Walsh M, Thomas SG, Woodhouse LJ. Functional ability perceived by individuals following total knee arthroplasty compared to age-matched individuals without knee disability. *The Journal of orthopaedic and sports physical therapy*. 1998;27:255-263.
10. Hall J, Copp SN, Adelson WS, D'Lima DD, Colwell CW, Jr. Extensor mechanism function in single-radius vs multiradius femoral components for total knee arthroplasty. *The Journal of arthroplasty*. 2008;23:216-219.
11. Hatfield GL, Hubley-Kozey CL, Astephen Wilson JL, Dunbar MJ. The effect of total knee arthroplasty on knee joint kinematics and kinetics during gait. *The Journal of arthroplasty*. 2011;26:309-318.
12. Iwaki H, Pinskerova V, Freeman MA. Tibiofemoral movement 1: the shapes and relative movements of the femur and tibia in the unloaded cadaver knee. *The Journal of bone and joint surgery. British volume*. 2000;82:1189-1195.
13. Jo AR, Song EK, Lee KB, Seo HY, Kim SK, Seon JK. A comparison of stability and clinical outcomes in single-radius versus multi-radius femoral design for total knee arthroplasty. *The Journal of arthroplasty*. 2014;29:2402-2406.
14. Kaufman KR, Hughes C, Morrey BF, Morrey M, An KN. Gait characteristics of patients with knee osteoarthritis. *Journal of biomechanics*. 2001;34:907-915.
15. Kim DH, Kim DK, Lee SH, Kim KI, Bae DK. Is Single-Radius Design Better for Quadriceps Recovery in Total Knee Arthroplasty? *Knee surgery & related research*. 2015;27:240-246.

16. Konno T, Onodera T, Nishio Y, Kasahara Y, Iwasaki N, Majima T. Correlation between knee kinematics and patellofemoral contact pressure in total knee arthroplasty. *The Journal of arthroplasty*. 2014;29:2305-2308.
17. Kristianslund E, Krosshaug T, van den Bogert AJ. Effect of low pass filtering on joint moments from inverse dynamics: implications for injury prevention. *Journal of biomechanics*. 2012;45:666-671.
18. Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *The Journal of bone and joint surgery. American volume*. 2007;89:780-785.
19. Landry SC, McKean KA, Hubley-Kozey CL, Stanish WD, Deluzio KJ. Knee biomechanics of moderate OA patients measured during gait at a self-selected and fast walking speed. *Journal of biomechanics*. 2007;40:1754-1761.
20. Larsen B, Jacofsky MC, Jacofsky DJ. Quantitative, Comparative Assessment of Gait Between Single-Radius and Multi-Radius Total Knee Arthroplasty Designs. *The Journal of arthroplasty*. 2015;30:1062-1067.
21. Lewek MD, Rudolph KS, Snyder-Mackler L. Quadriceps femoris muscle weakness and activation failure in patients with symptomatic knee osteoarthritis. *Journal of orthopaedic research : official publication of the Orthopaedic Research Society*. 2004;22:110-115.
22. Leyland KM, Hart DJ, Javaid MK, Judge A, Kiran A, Soni A, Goulston LM, Cooper C, Spector TD, Arden NK. The natural history of radiographic knee osteoarthritis: a fourteen-year population-based cohort study. *Arthritis and rheumatism*. 2012;64:2243-2251.
23. Li K, Ackland DC, McClelland JA, Webster KE, Feller JA, de Steiger R, Pandy MG. Trunk muscle action compensates for reduced quadriceps force during walking after total knee arthroplasty. *Gait & posture*. 2013;38:79-85.
24. Liikavainio T, Bragge T, Hakkarainen M, Karjalainen PA, Arokoski JP. Gait and muscle activation changes in men with knee osteoarthritis. *The Knee*. 2010;17:69-76.
25. Mahoney OM, McClung CD, dela Rosa MA, Schmalzried TP. The effect of total knee arthroplasty design on extensor mechanism function. *The Journal of arthroplasty*. 2002;17:416-421.
26. McClelland JA, Feller JA, Menz HB, Webster KE. Patterns in the knee flexion-extension moment profile during stair ascent and descent in patients with total knee arthroplasty. *Journal of biomechanics*. 2014;47:1816-1821.
27. Naal FD, Impellizzeri FM, Lenze U, Wellauer V, von Eisenhart-Rothe R, Leunig M. Clinical improvement and satisfaction after total joint replacement: a prospective 12-month evaluation on the patients' perspective. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*. 2015;24:2917-2925.
28. Naal FD, Impellizzeri FM, Leunig M. Which is the best activity rating scale for patients undergoing total joint arthroplasty? *Clinical orthopaedics and related research*. 2009;467:958-965.
29. Silva M, Shepherd EF, Jackson WO, Pratt JA, McClung CD, Schmalzried TP. Knee strength after total knee arthroplasty. *The Journal of arthroplasty*. 2003;18:605-611.
30. Stacoff A, Diezi C, Luder G, Stussi E, Kramers-de Quervain IA. Ground reaction forces on stairs: effects of stair inclination and age. *Gait & posture*. 2005;21:24-38.

31. Stacoff A, Kramers-de Quervain IA, Luder G, List R, Stussi E. Ground reaction forces on stairs. Part II: knee implant patients versus normals. *Gait & posture*. 2007;26:48-58.
32. Stevens-Lapsley JE, Balter JE, Kohrt WM, Eckhoff DG. Quadriceps and hamstrings muscle dysfunction after total knee arthroplasty. *Clinical orthopaedics and related research*. 2010;468:2460-2468.
33. Stoddard JE, Deehan DJ, Bull AM, McCaskie AW, Amis AA. The kinematics and stability of single-radius versus multi-radius femoral components related to mid-range instability after TKA. *Journal of orthopaedic research : official publication of the Orthopaedic Research Society*. 2013;31:53-58.
34. Su FC, Lai KA, Hong WH. Rising from chair after total knee arthroplasty. *Clinical biomechanics (Bristol, Avon)*. 1998;13:176-181.
35. Thomas AC, Judd DL, Davidson BS, Eckhoff DG, Stevens-Lapsley JE. Quadriceps/hamstrings co-activation increases early after total knee arthroplasty. *The Knee*. 2014;21:1115-1119.
36. Vallabhajosula S, Yentes JM, Stergiou N. Frontal joint dynamics when initiating stair ascent from a walk versus a stand. *Journal of biomechanics*. 2012;45:609-613.
37. Wang H, Simpson KJ, Chamnongkich S, Kinsey T, Mahoney OM. A biomechanical comparison between the single-axis and multi-axis total knee arthroplasty systems for the stand-to-sit movement. *Clinical biomechanics (Bristol, Avon)*. 2005;20:428-433.
38. Wang H, Simpson KJ, Ferrara MS, Chamnongkich S, Kinsey T, Mahoney OM. Biomechanical differences exhibited during sit-to-stand between total knee arthroplasty designs of varying radii. *The Journal of arthroplasty*. 2006;21:1193-1199.
39. Yoshida Y, Mizner RL, Ramsey DK, Snyder-Mackler L. Examining outcomes from total knee arthroplasty and the relationship between quadriceps strength and knee function over time. *Clinical biomechanics (Bristol, Avon)*. 2008;23:320-328.