KNEE BIOMECHANICS AFTER REPLACEMENT SURGERY (KBARS STUDY):
THE EFFECT OF KNEE PROSTHESIS DESIGN ON KNEE BIOMECHANICS DURING LOCOMOTION FOLLOWING KNEE REPLACEMENT SURGERY.

Version: v2

Date: November 23, 2015

Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

Contributor List

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Sponsors:

Sydney Orthopaedic Research Institute

Surgical Specialties

Contributor task matrix

No particular order	Ideas	Work	Writing	Stewardship	Signature
Corey Scholes	Write study protocol;	Design the experiment and analytical plan; supervise method development	co-write and 1st review of manuscript first draft	Provide direct leadership and financial oversight of project; assist securing funding; manage personnel	
Aaron Beach	Assist in writing study protocol	Recruit patients; conduct data collection, design and conduct data analysis and statistical analysis	First author of manuscript first draft		
Richard Verheul	Critical review study protocol;	Facillitate patient recruitment of Evolution group			
Myles Coolican	Review/approve protocol	Approve patient recruitment – control group		Assist with stewardship	
David Parker	Critical review of protocol; contribute to clinical problem definition and methodology	Approve patient recruitment – control group	Critical review of manuscript	Primary stewardship of project; secure funding; attest to integrity of work	
Gianmarco Regazzola		Recruit patients, conduct patient evaluation, collect data			
SORI staff		Assist with patient recruitment (control group)			
NSKC staff		Assist with patient recruitment (control groups)			
Richard Verheul secretarial staff		Assist with patient recruitment (Evolution group)			

Table of Contents

CONTENTS

1. GLOSSARY OF ABBREVIATIONS & TERMS

Abbreviation	Description (using lay language)
CR	Cruciate-retaining prosthesis design
PS	Posterior-stabilized prosthesis design
EMG	Electromyography; measurement of muscle electrical activity during movement
RCT	Randomized controlled trial

2. STUDY SITES

2.1 STUDY LOCATION/S

[List all locations, their address & contact details this study or parts of the study will be conducted]

Site	Address	Contact Person	Phone	Email
Sydney Orthopaedic Research Institute	Level 1, 445 Victoria Avenue, Chatswood	Corey Scholes	02 9904 7182	cscholes@sori.com.au
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3. FUNDING AND RESOURCES

3.1 SOURCE/S OF FUNDING

Financial and in-kind support from Sydney Orthopaedic Research Institute

Financial support sought from Surgical Specialties

In-kind support from Dr Richard Verheul

4. PROTOCOL SYNOPSIS

Title	Functional analysis of the Advance/Evolution total knee replacement in-vivo during functional locomotion
Objectives	To determine if; I. the tibiofemoral motion and muscle activity of the *Advance/Evolution* in-vivo, is more normal compared to CR or PS implants under the same task demands; II. the tibiofemoral motion or muscle activity observed across implant types are associated with patient self-reported function or satisfaction with the arthroplasty procedure
Study Design	Retrospective cross-sectional
Planned Sample Size	66 patients between 3 groups
Selection Criteria	<u>*Inclusion*</u> • *Advance* or *Evolution* unilateral TKRs performed a minimum of 12months prior to testing • *PS unilateral TKRs* performed a minimum 12 months prior testing matched to the *Advanced/Evolution* group • *CR unilateral TKRs* performed a minimum 12 months prior testing matched to the *Advanced/Evolution* group • BMI <35kg/m^2 • Able to walk on a treadmill for 60secs, step down from, and up onto a 20cm step. Able to walk on treadmill for two 60 sec blocks <u>*Exclusion*</u> • People whose primary language is other than English (LOTE) need to understand directions being given • Women who are pregnant and the human foetus this is a contraindication of a TKR • Children and/or young people (i.e. <18 years) This group only receives a TKR under extremely rare circumstances

	• People with an intellectual or mental impairment need to understand directions being given • People highly dependent on medical care Need to be healthy to participate - part of the exclusion criteria • Co-morbidities that may impair gait • Bilateral (staged/simultaneous) TKR • UKR on contralateral knee • Unavailable for return assessment • Extra-articular deformity • Pregnancy due to gait impairment
Study Procedures	Standard clinical measurements, patient-reported outcomes and kinematic testing during stepping and walking using motion capture
Statistical Procedures Sample Size Calculation: Analysis Plan:	Aims I and II: One-way analysis of variance with Dunn-Sidak post-hoc comparisons for internal tibial rotation magnitude Aim III: Correlation analysis (Pearson or Spearman-Rho) between Oxford-12 total score or Forgotten Knee Score and tibial rotation during locomotion Power calculation summary attached
Duration of the study	10 -14 months

5. INTRODUCTION/BACKGROUND INFORMATION

5.1 INTRODUCTION

Research into the mechanical behaviour of the native knee in-vivo during functional movement has prompted some modification to the tibiofemoral articulation of total knee replacement designs. Specifically, some have attempted to replicate the medial pivot motion of the native knee by modifying TKR joint geometry. While the concept of mimicking the human body in prosthetic designs is commendable, without a thorough approach and careful evidence-based progression in design, there is a risk of compromising the function and longevity of the prosthesis.

The first attempt by Wright Medical (*Advance*) in this process has displayed mixed revision rates in the European and Australian TKR registries. The revision rates (all-

causes) range from 3.04% at 7yrs in the UK registry (N = 4308) to 8.8% in the Australian registry at 10yrs (N = 1688). These results do not compare favourably to the GenII in the Australian registry (4.8%; N = 25242) or the UK registry (2.46%; N = 27455). Danish registry data at 10yrs suggest that there may be a difference in revision risk between cemented (3.1%; N = 749) and hybrid components (8.8%; N = 772). The clinical results in the peer-reviewed literature is somewhat mixed, with earlier studies raising concerns about limited post-operative range of motion. One study (Shakespeare, Ledger, & Kinzel, 2006) reported reduced range of motion in *Advance* knees (N = 261), particularly those with high-flexion pre-operatively, in comparison to a posterior-stabilised implant (N = 288). Further, a clinical follow-up at 7yrs (N = 265) (Karachalios et al., 2009) estimated better survival at 9yrs than the registries (2.5%), but reported a reasonably high incidence of complications (17%), such as poor wound healing, pulmonary embolisms and anterior knee pain. However they also reported non-optimal component alignment in 7.5% of implanted knees, as measured by post-operative radiographs. Others reported a high incidence of infection in *Advance* knees (Kim, Yoon, & Kim, 2009), during a staged bilateral randomised controlled trial (N = 184). In addition, they reported significantly less post-operative clinical scores, with significantly increased self-reported pain compared to posterior-stabilised knees. However, the average range of motion was 124° (range 60-150).

A more recent follow-up (Fan, Hsieh, Hsieh, Shih, & Lee, 2010) with a smaller sample (N = 58) reported no failures or mal-alignment and an average range of motion of 115.4±1.8° at average 5yrs post-operatively. The latest clinical follow-up of 162 knees at an average of 7yrs (Vecchini et al., 2012) reported the lowest revision rate (1.4%), with an average range of motion of 112.5°. Interestingly, the authors reported a significant effect of gender on post-operative clinical scores. Other commentary has suggested that the increased thickness of the medial insert could lead to medial tightening which requires slight modification of the surgical technique to compensate and maintain satisfactory flexion (Bae, Song, & Cho, 2011). This retrospective analysis reported no significant differences in clinical change scores for PCL retaining (N = 67) or sacrificing (N = 70) at an average of 4yr follow-up, although the PCL retaining sample displayed

significantly higher post-operative range of motion. An RCT (Pritchett, 2011) of 239 staged bilateral TKRs reported no significant differences in clinical scores or RoM between the *Advance* and PS, PCL-retaining, bicruciate-retaining or mobile-bearing implants. However, patients indicated a significantly higher rate of preference for the *Advance*. The authors speculated that this may be due to enhanced extensor function afforded by the kinematics of the implant.

Despite the clinical outcomes of the medial-pivot knee, there remain a number of fundamental questions regarding the kinematic behaviour of the implant in-vivo. That is, whether knees replaced with the *Advance/Evolution* reliably replicate tibiofemoral kinematics during locomotion that is more normal than existing implants and what relationship any improvement in the kinematic profile has with patient outcome. An earlier in-vivo kinematic study of the *Advance* using fluoroscopy demonstrated comparable internal tibial rotation with weight-bearing knee flexion during locomotion (Schmidt, Komistek, Blaha, Penenberg, & Maloney, 2003). However, the sample size was small (n = 5) and 2 patients displayed no tibial rotation. In contrast, a fluoroscopy study (n = 8) reported initial external tibial rotation followed by internal rotation during a step-up task (Miyazaki et al., 2011). Others have shown differences in kinematics between the original *Advance* insert and a modified design known as the *double-high* insert. A cadaver study (n = 7) reported medial pivot motion in the standard insert when the PCL was resected, but no significant difference in contact mechanics in the *double-high* insert between PCL conditions (Omori et al., 2009). In addition, tibiofemoral kinematics with the *double-high* insert have been reported to be more variable in-vivo during kneeling (n = 9) compared to a standard insert (n = 9) (Barnes, Sharma, Blaha, Nambu, & Carroll, 2011). Importantly, the tibial rotation reported in-vivo may not fully replicate the normal knee. A cadaver study (n = 10) reported a similar rotation pattern between implanted (*Advance*) and intact knees; however the magnitude of tibial rotation during mechanically-driven knee extension was significantly less in the implanted knees (Barnes et al., 2012). More recent in-vivo studies have reported patellofemoral motion in the *Advance* that more closely resembles the normal pattern in comparison to previous reports for PS and CR designs

(Ishida et al., 2012), as well as the "partial restoration" of tibiofemoral kinematics during weightbearing knee bend (n = 7) in females with valgus deformity (Kitagawa, Ishida, Chin, Tsumura, & Iguchi, 2012). While the results to-date are encouraging with respect to promoting more-normal tibiofemoral and patellofemoral kinematics in-vivo, fundamental questions remain to be answered with convincing evidence.

The evidence for the *Advance/Evolution* medial pivot design in terms of improved extensor function over previous designs also remains limited. Firstly, a previous study indicated that the muscle activity in knees replaced with a cruciate-retaining (CR) implant may require up to three times the muscle activity required to perform level walking compared to the non-operated contralateral limb up to 2years post-arthroplasty (Lester, Shantharam, & Zhang, 2013). Secondly, a recent under-powered prospective comparison (N = 5) (Reynolds, Dervin, & Mario, 2012) found no difference in quadriceps activation magnitude between *Advance/Evolution* knees and healthy age-matched controls during level or incline walking 6months after total knee arthroplasty. Theoretically a more stable implant design that more closely replicates the axis of rotation of the native knee would encourage muscle activity that would more closely resemble normal. However, to-date the in-vivo clinical data supporting such a relationship between implant design and knee function remains lacking.

5.2 KNOWLEDGE GAP

The existing literature identifies a potential for the medial-pivot knee, in this case the *Advance/Evolution,* to encourage a normal pattern of tibiofemoral rotation in-vivo. However, these studies are limited by small sample sizes and insufficient statistical analysis and the findings to-date suggest that the implanted knees do not fully replicate normal rotation (Barnes et al., 2012) or tibiofemoral rotation does not appear in every implanted knee in-vivo (Kitagawa et al., 2012; Schmidt et al., 2003). In addition, the theoretical link between improved stability and motion and the efficiency of muscle function during locomotion has yet to be established in-vivo. Furthermore, none of the studies investigating *Advance/Evolution* biomechanics have related their findings to the patient's self-reported function or satisfaction with the procedure.

6. STUDY OBJECTIVES

6.1 RESEARCH QUESTIONS

The logical progression to address the limitations in the current knowledge is to establish whether;

1. the tibiofemoral motion and muscle activity of the *Advance/Evolution* in-vivo is more normal compared to CR or PS implants under the same task demands;
2. the tibiofemoral motion or muscle activity observed across implant types are associated with patient self-reported function or satisfaction with the arthroplasty procedure

6.2 PRIMARY OBJECTIVES

To address aims I and II, a comparative kinematic in-vivo study will be performed between *Evolution* knees compared to case-matched patients.

Expected outcomes

The proposed research study has a number of potential outcomes which will prompt further investigation. The 3 main possible outcomes are that internal tibial rotation and anterior-posterior stability is observed in;

All *Advance/Evolution* knees:

This will validate the functional aspect of the prosthesis design and prompt further questions regarding the relationship between implant function and patient function, and satisfaction.

Some*:*

Based on the literature, it is expected that some patients will exhibit rotation and stability while others will not. This will require further investigation with respect to the factors determining the presence or absence of rotation, such as patient characteristics, surgical factors or aspects of rehabilitation.

None:

The important directions from this outcome are to identify why this sample of patients did not exhibit these characteristics and determine whether knees of patients rotate pre-operatively.

6.3 Outcome Measures

- Internal tibial rotation and anterior-posterior stability during treadmill walking and stepping up and down from a raised step.
- Patient-reported outcome measures (Oxford Knee Score, VR-12)

7. Study Design

7.1 Power Analysis

A power analysis conducted with GPower (v3.1.9) (Faul, Erdfelder, Buchner, & Lang, 2009) suggests that a total sample size of 66 (22 in each group; CR; PS; Evolution) is required to detect a "large" difference in tibial rotation between prosthesis types using a one-way analysis of variance (ANOVA) with power of 80% and alpha set at 5%. To detect a "medium" sized difference, each group requires 53 patients. Considering the number of patients implanted with the Evolution to-date, the smaller group size is a more realistic target.

7.2 Patients and Recruitment

A consecutive series of *Advance* or *Evolution* unilateral TKRs were performed by Dr Richard Verheul. Patients suitable for the study with a minimum 12 months follow up will be contacted by Dr Richard Verheul with a written letter. Once the patient will express their interest to participate to the study, they will be contacted by phone by the SORI research personnel. Following written informed consent, each patient will undergo standard clinical measurements and kinematic testing in the motion capture laboratory in Chatswood. Each *Advance/Evolution* patient would be matched for age, gender, BMI, with a patient at 1-2yr after receiving a standard CR or PS knee using SORI

database. The control group patients will be contacted by phone by SORI research personnel. These patients will also be consented and measured in the same way to form the control groups of the study.

7.3 MEASUREMENTS

Standard clinical measurements will be collected post-operatively at the time of testing. These include height and weight, a general health questionnaire (VR-12) a knee function questionnaire (Oxford Knee Score) and passive range of motion measured with hand-held goniometry. At the completion of the clinical measurements the patient will be prepared for motion capture with the placement of several reflective markers on the body (Figure 1). The patient will then be familiarized with 2 locomotion tasks, walking on a treadmill and stepping down from a step (Figure 2). Once the patient indicates that they are comfortable with the tasks, they will walk on the treadmill for 3 minutes at a self-selected comfortable walking speed, while the motion capture system records the marker positions for 60 seconds . The process will be repeated a second time with the patient walking at a slightly faster speed (+30% of comfortable). The motion capture will also be performed as the patient steps up from, and down onto the floor from a step 20cm high for a total of 10 trials each.

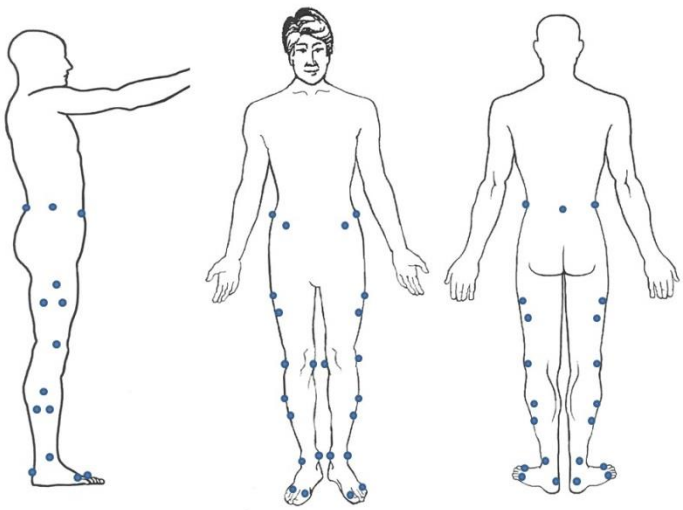

Figure 1: Model illustrating placement of reflective markers (white spheres) for motion capture.

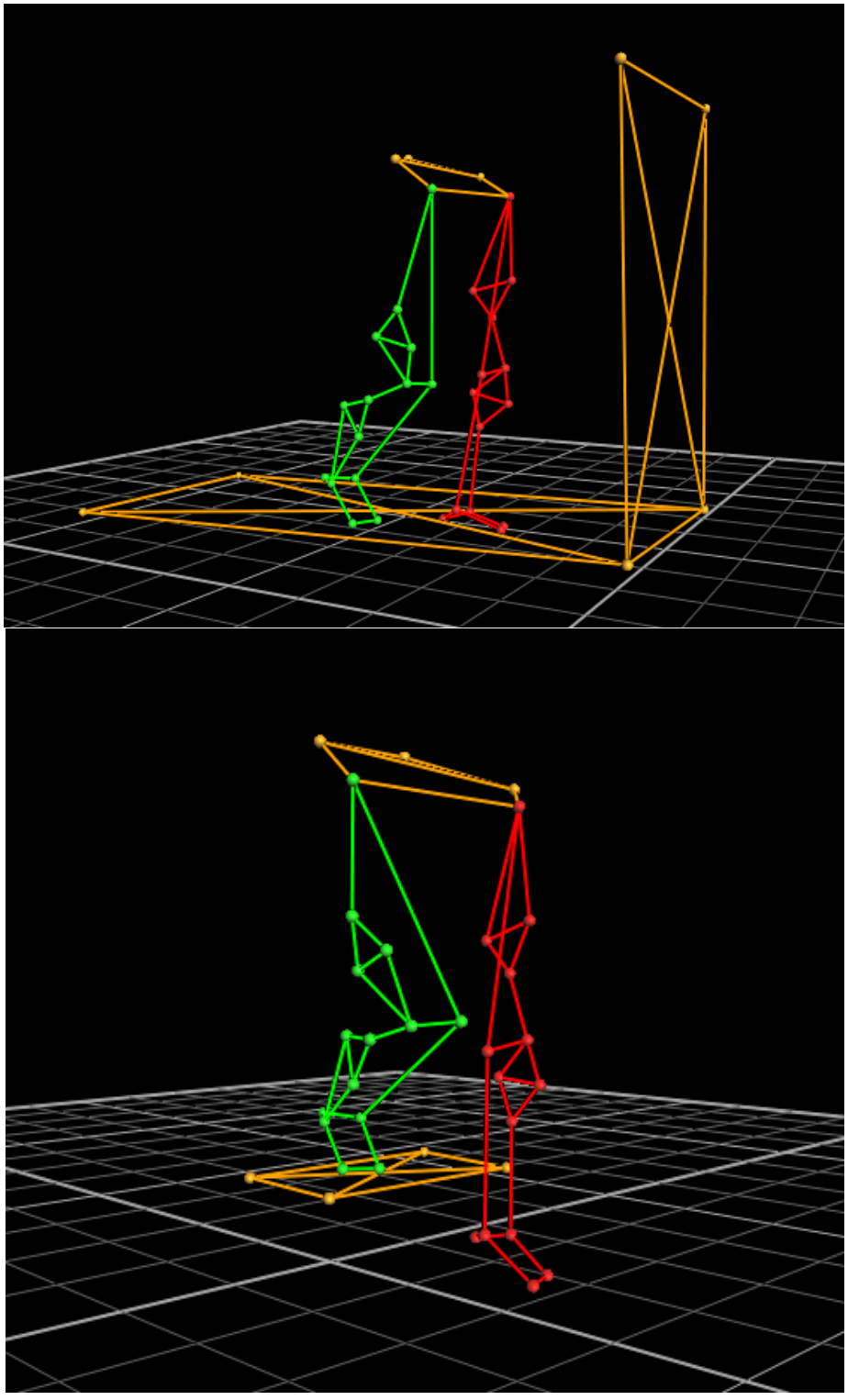

Figure 2: Stick figure representation of body position during walking (top) and stepping down from a step (bottom).

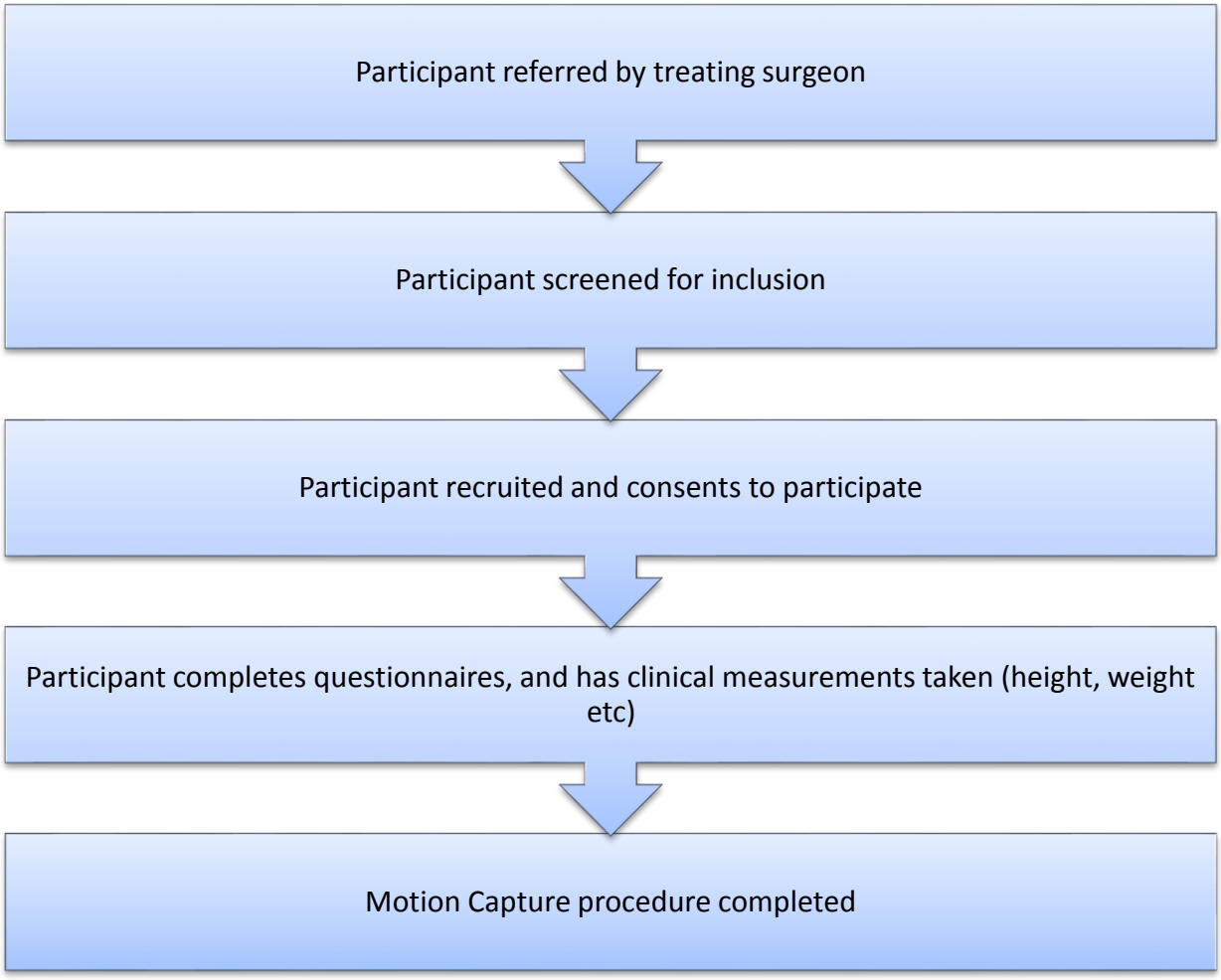

Figure 3. Study design and data collection process

7.4 ASSESSMENT DETAILS

Screening and clinical measurements

Following written informed consent, the participant will fill out self-reported function questionnaires (VR-12, OXF12) and undergo a series of clinical measurements, including height and weight, as well as knee range of motion using short arm goniometry.

Data collection/ Kinematic measurements

A motion capture system with 10 optoelectronic cameras (Bonita, Vicon Ltd, UK) will be used to track markers mounted on the skin that represent the movement of the lower limb segments. Reflective markers will be placed on both of the participant's legs with adhesive tape. When the participant is prepared, the participant will then be asked to perform ten step downs from a standard step 20cm high landing on the ground with their operated leg, then ten step ups onto the step from the ground. Following this, they will then walk on a treadmill for an initial warm up period to acclimatise to the task. The patients will walk two times forn an average time of 3 minutes, each time. The positions of the reflective markers will be recorded as the participant walks for 60 seconds at a comfortable gait speed and a model of the lower-limb motion generated using computer software (Visual 3D v5, C-Motion, Canada) (Figure 4). Finally, a passive test of knee extension and flexion will be performed with the subject lying supine on a massage table.

Electromyography will be used to synchronously record muscle activity from the knee extensors (quadriceps) and knee flexors (hamstrings) from the replaced and non-operated limbs during the locomotion movements. During preparation for motion capture, wireless sensors (Trigno Lab, Delsys Inc, USA) with disposable electrodes (2 per muscle) will be attached with double-sided tape to the skin surface of the belly of each muscle of interest according to SENIAM guidelines. For the quadriceps the muscles of interest will be the vastus medialis (VM), rectus femoris (RF) and vastus lateralis (VL) and for the hamstrings, the biceps femoris (BF) and medial hamstrings (MH) with the semitendinosus and semimembranosus closely co-located. Prior to locomotion, each patient will be asked to perform maximal voluntary contractions (MVC) while they are secured to a chair with the knee at 90˚ for the quadriceps and 60° for the hamstrings

while the EMG system records the muscle activity. Patients will be familiarised with this task at the commencement of the measurement session and provided a rest period prior to recording the MVC trials. The baseline muscle activity will be used to establish normative values against which the participant's muscle activity recorded during locomotion will be compared. Each patient will be asked to perform 3 maximal contractions for each muscle group for 30sec duration, with the middle 15seconds used to calculate the MVC signal baseline for each muscle.

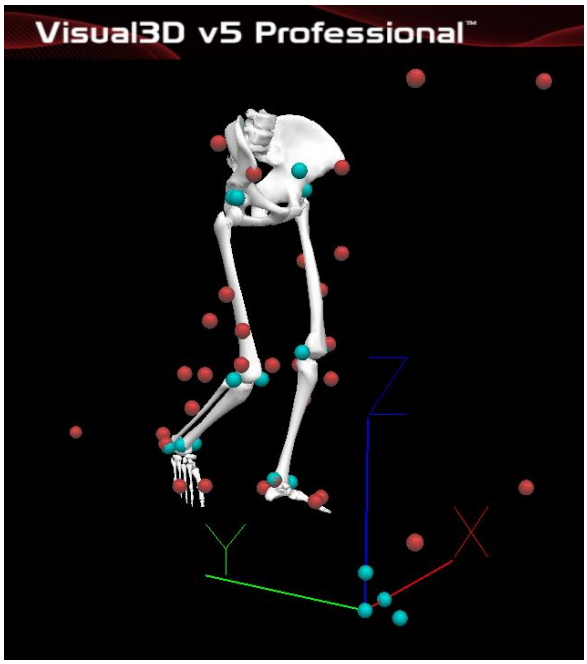

Figure 4: Computer-generated model (Visual3D v5) of the pelvis and lower-limbs during walking at the instant of left foot heel strike.

Figure 5. Order of procedures for motion capture data collection

7.5 *Data Analysis and Statistics*

The recorded marker positions will be processed to describe the angle of the knee in 3-dimensions at each instant of the movement, particularly when the lower limb is loaded in contact with the treadmill or the ground. Of key interest is the rotation of the tibia relative to the femur as the knee is loaded, referred to as tibial rotation. In the normal knee, the tibia rotates internally to the femur and this kinematic pattern reflects the medial pivot motion of the native knee (Figure 6). The presence of this rotation will be assessed in each patient and the magnitude of rotation during the walking and stepping tasks will be compared between groups using appropriate standard statistical tests. Similarly, the *Advance/Evolution* knee is expected to be stable in the sagittal plane during functional movement, therefore translation of the tibia relative to the femur will be quantified and compared. The tibiofemoral rotation will be extracted from each cycle of the locomotor tasks and compiled into a data spreadsheet for further analysis.

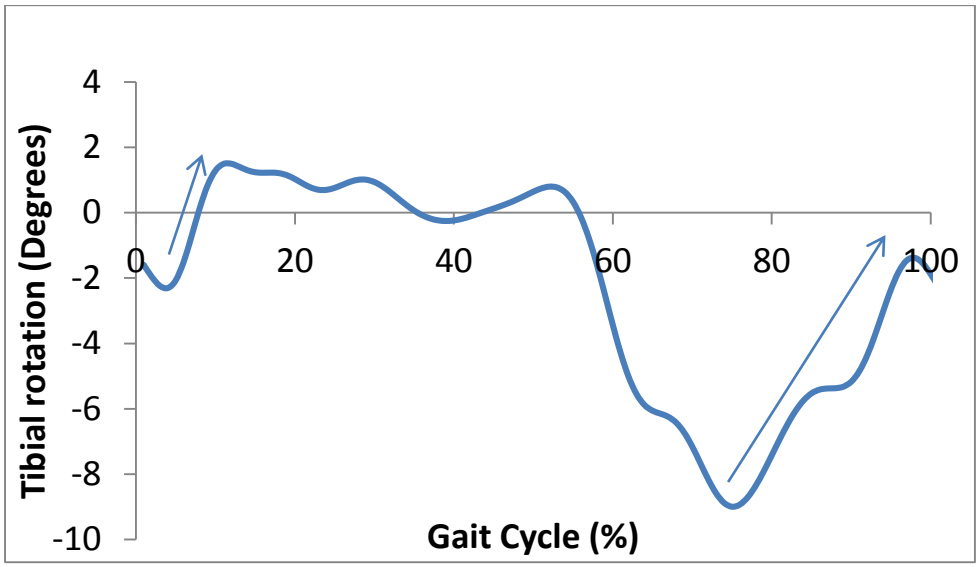

Figure 6: Tibial rotation during walking from heelstrike (0%) to heelstrike (100%) in a healthy adult male, with internal rotation indicated by arrows.

The electromyography signal recorded from each muscle will be synchronised to the motion capture data and segmented based on the gait cycle. The magnitude of the signal recorded during the locomotor activities will be normalised to the MVC signals. A root mean square (RMS) of the signal will be calculated during the period of foot contact and maximum knee flexion (loading response) and from terminal extension to toe-off (propulsion) during both level walking and the step-down movement and described as a % of MVC.

The means/medians of the likely confounders of knee biomechanics (kinematics and muscle activity) for each of the three groups will be compared as per the following table. Should any significant differences be identified, these factors will be included as covariates when comparing tibiofemoral motion and muscle activity between the three groups.

Demographics	Spatiotemporal	Kinetic
Age	Speed	Joint moments
Gender	Step length	Flexion/extension
BMI	Step width	Abd/adduction
Surgery to followup delay	Step frequency	Int/external rotation

	Initial double support time	

Aim 1

The first aim of the study will be addressed by the use of two alternative techniques. The first assumes that each patient has been appropriately matched for age, gender, BMI and surgery to followup delay across each of the implant design groups. Therefore, each of the 25 patients recruited into the medial-pivot group will be compared to a matched control in the PS and CR groups. A one-way ANOVA will be performed comparing tibiofemoral rotation and muscle activation amplitude on each trio of patients (N = 25) and the proportion of significant differences calculated for each dependent variable. The alternative will be to aggregate the data within each group and compare the three groups with a one-way ANOVA. In both techniques, significant confounders identified will be included as a covariate.

Aim 2

A significant relationship between tibiofemoral motion and muscle activity will be assessed using a form of multivariate multilinear regression with self-reported questionnaires (VR-12, OKS) as dependent variables and the kinematic and electromyography measures as independent variables. The average knee biomechanics data from each partipant will be included in the model (N = 66 – 75) and a partial least squares analysis will be used to examine the relationship between the independent and dependent variables.

7.6 RESOURCES AND TIMELINE

The expected total duration of the project from initial funding approval to the provision of results ready for presentation is between 1 and 1.5yrs. The key resources required are a;

- research assistant for the duration of the project
- An engineer to setup processes and code for data analysis
- Software and hardware dedicated to the project

An estimated timeline is listed below;

- Ethics application and approval (4months)
- Recruitment and testing (medial-pivot and control groups) (6months)
- Analysis (2months)

- Write-up and final approval (2months)
- Estimated total (14months)

7.7 Budget and Funding

The proposed research will require the following key resources as outlined below:

Item	Description	Cost/unit	Total Cost (AU)
Scope and Proposal	Preparation, revision and dissemination		$2500
Ethics submission	Application fees, entity agreements, insurance		$4000
Research personnel	Research assistant (PT) Engineer (PT)	$69 891pa x (1.2x0.6)* $63 000pa x 0.2#	$62 000 $12 600
EMG system	System to detect muscle activity		$30 000
Patient Recruitment	Incentives for participation Transport reimbursement for Evolution group		$1000
Software & Hardware	Data and Statistical analysis Desktop PC	3000 1500	$5000
Bench fees and overhead		20% of project cost	$17 220
		TOTAL	$ 103 320

8. Study Population

8.1 Recruitment Procedure

A consecutive series of Advance or Evolution unilateral TKRs were performed by Dr Richard Verheul. Patients suitable for the study with a minimum 12 months follow up will be contacted by Dr Richard Verheul with a written letter. Once the patient will express their interest to participate to the study, they will be contacted by phone by the SORI research personnel. Following written informed consent, each patient will undergo standard clinical measurements and kinematic testing in the motion capture laboratory in Chatswood. Each Advance/Evolution patient would be matched for age, gender, BMI, with a patient at 1-2yr after receiving a standard CR or PS knee using SORI database. The control group patients will be contacted by phone by SORI research personnel. These patients will also be consented and measured in the same way to form the control groups of the study.

8.2 INCLUSION CRITERIA

- Advance or Evolution unilateral TKRs performed a minimum of 12months prior to testing.
- PS unilateral TKRs performed a minimum 12 months prior testing and matched to the Advanced/Evolution group.
- CR unilateral TKRs performed a minimum 12 months prior testing and matched to the Advanced/Evolution group.
- BMI <35kg/m2
- Able to walk on a treadmill for 60secs, step down from, and up onto a 20cm step. Able to walk on treadmill for two 60 sec blocks

8.3 EXCLUSION CRITERIA

- People whose primary language is other than English (LOTE) need to understand directions being given
- Women who are pregnant and the human foetus this is a contraindication of a TKR
- Children and/or young people (i.e. <18 years) This group only receives a TKR under extremely rare circumstances
- People with an intellectual or mental impairment need to understand directions being given
- People highly dependent on medical care Need to be healthy to participate - part of the exclusion criteria
- Co-morbidities that may impair gait
- Bilateral (staged/simultaneous) TKR
- UKR on contralateral knee
- Unavailable for return assessment
- Extra-articular deformity
- Pregnancy due to gait impairment.

8.4 CONSENT

After inclusion in the study is determined and the procedures explained, participants who are willing to take part will be asked to provide written informed consent prior to testing.

9. PARTICIPANT SAFETY AND WITHDRAWAL

9.1 RISK MANAGEMENT AND SAFETY

Risk 1: Patients falling from the treadmill; slip/trip during gait analysis

Mitigation: The treadmill has support rails which participants can use to assist getting on and off the treadmill, as well as when walking. The lab technician will also provide assistance.

Risk 2: Injury when mounting stationary bike

Mitigation: A step will be used, as well as lab technician providing assistance.

Risk 3: Patient anxiety due to data collection close to surgery date

Mitigation: Communicate empathetically with patients; clarify that the data collection is for research purposes and does not have any bearing on the surgical procedure.

9.2 Handling of Withdrawals

Participants have the right to withdraw from the study at any time. If a participant withdraws from the study prior to the post-operative data collection, their initial data will be removed from the system and destroyed. At this point in the study, a replacement cannot be made and the sample size will be reduced by one.

10. Data Management and Security

10.1 Details of where records will be kept & How long will they be stored

Motion capture data will be recorded on the laboratory computer at SORI and backed up to the shared server at the end of a collection session (V Drive/Vicon Database). This server is routinely backed-up hourly and daily. All data is protected by password secure systems. The data will remain on these secure servers for 15 years.

10.2 Managing Data Loss

The above protocol will ensure data loss after collection is minimized. During the data collection, it is crucial data corruption is minimized. This includes retro-reflective markers being kept in an optimal state. If damage occurs, the affected markers are replaced. Recordings must be checked immediately after to ensure there are no problems that would render the files unusable. In the event of any problems, another recording will be taken.

11. References

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