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Original Research Article

A blinded, three-arm randomised trial assessing joint function and measuring three-dimensional knee joint kinematics in individuals six months after a total knee joint replacement; comparing a medially stabilised design, to standard fixed bearing conventional designs – posterior stabilising and cruciate retaining

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ABSTRACT

Background: No randomised trial exists to assess the relative prosthetic performance of three fixed bearing total knee joint replacement construct designs through clinical functional outcomes and biomechanical gait analysis at six months after the index procedure.
Methods: The design of a double blinded, prospective, randomised trial with three parallel patient groups is presented. Patients reviewed in consultant clinic with radiographic and clinical diagnosis of osteoarthritis of the knee, with the condition deemed severe enough to require a total knee joint replacement (TKJR) are eligible. Subjects enrolled in the trial are randomised to one of the three TKJR construct designs approximately ten days prior to scheduled date of surgery. Each subject is then followed up for at least twelve months. Repeated measure of Analysis of Variance (ANOVA), and Analysis of Covariance (ANCOVA) will be utilised to uncover any clinical functional differences in each trial group in each time interval.
Results: Differences in clinical functional scores at each time interval compared to pre-intervention, as well as between group differences in clinical functional scores at each time interval will be examined. At six months after the operation, biomechanical measurements of joint motion, ground reaction forces, and muscle electromyographic (EMG) activity will be recorded simultaneously from each subject for four test conditions: level walking, stair ascent, stair descent, and chair rise.
Conclusions: This randomised trial is designed to better understand the relationships between the clinical functional outcomes and replaced knee kinematics in three fixed bearing total knee replacement construct designs at six months postoperatively.

Keywords: Outcome, Knee prosthetic design, Osteoarthritis, Patient reported outcome measure

INTRODUCTION

Total knee joint replacement (TKJR) is the most common treatment of end stage osteoarthritis providing patients with reliable pain relief and restoration of moderate function of daily activities. The procedure is associated with excellent longevity and survivorship - 93.5% at 12 years.[1] In Australia, the use of primary TKJR continues to increase with 50,623 TKJR procedures performed in 2015.[2] There were 6.1% more procedures than 2014 and 130.4% more than 2003. As a proportion of all knee replacement procedures, primary TKJR increased from 76.7% in 2003 to 87.7% in 2015.[2] In the United States alone, the demand for this procedure is expected to grow as high as 3.48 million procedures per year by 2030.[3]

The availability of different prosthetic designs is broad, reflecting the quest to optimise the performance and longevity of the prosthesis.[4] The various prosthetic designs are based on in vivo studies of knee motion that promote a number of biomechanical rationales, including single radius, multi radii, fixed–bearing, mobile–bearing, posterior stabilised, cruciate retaining, and cruciate sacrificing designs.[5-11]

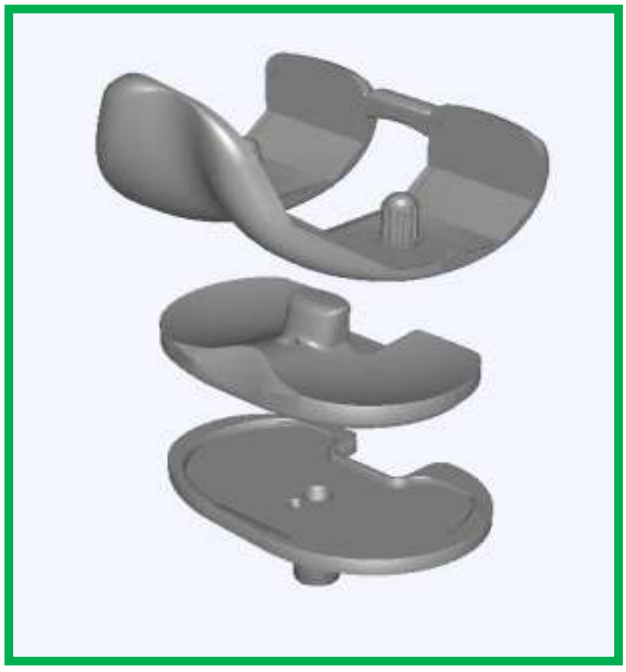

Figure 1: Posterior stabilised (PS) total knee joint replacement construct design.

The total condylar knee prosthesis was first used in 1974, and associated with high functional scores.[12] In 1978, a new 'cam and post' design, the posterior-stabilized (PS) modification, was introduced, where the tibial post articulated with the femoral cam as the knee flexed.[9] This design (Figure 1) was developed to provide a mechanical constraint to anterior translations of the femoral condyles during flexion, which was observed in cruciate sacrificing prostheses.[11,13] The induced posterior displacement will avoid impingement and thereby improve the range of motion of the knee clinically.[13] The intended benefits would translate to improved stair climbing ability, range of motion (ROM) and prevention of posterior subluxation of the tibia.[14,15]

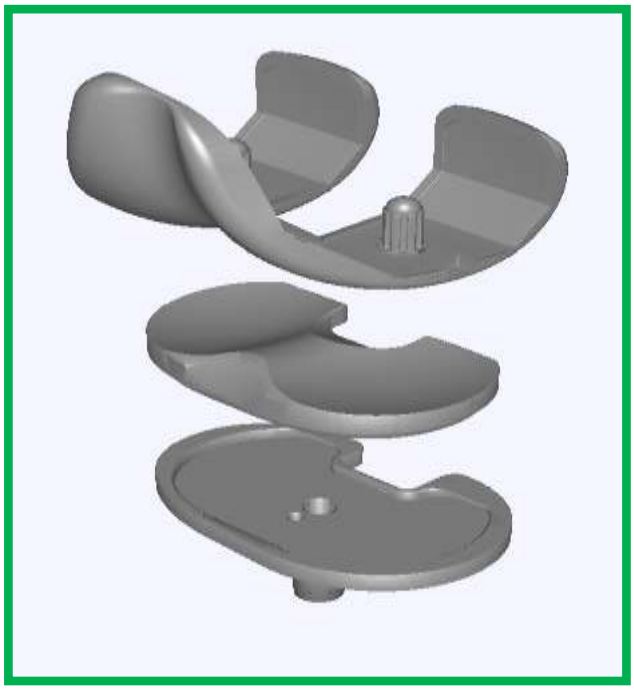

Figure 2: Cruciate retaining (CR) total knee joint replacement construct design.

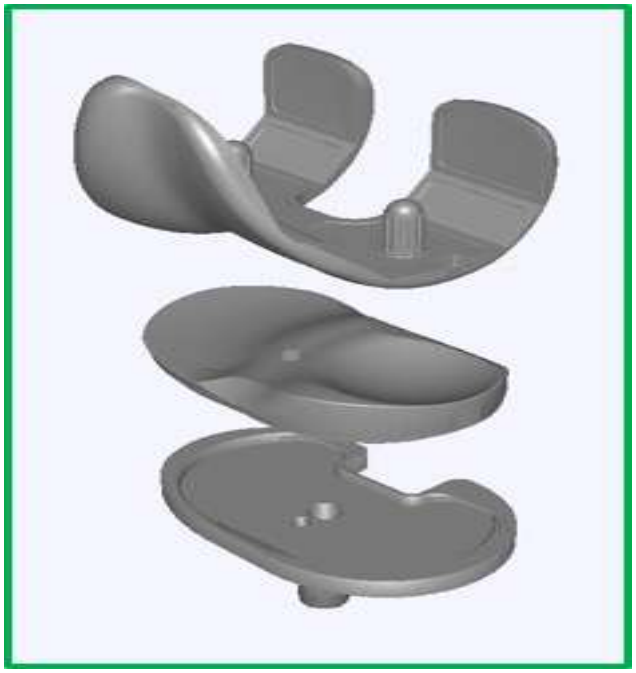

Figure 3: Medial stabilised (MS) total knee joint replacement construct design.

The other prominent knee arthroplasty design centred around the concept of retaining the posterior cruciate

ligament (PCL). PCL retention is based on the assumption that the retained PCL facilitates femoral rollback, and therefore increases range of motion of the knee and moment arm of the quadriceps.[15] This Cruciate Retaining (CR) construct design (Figure 2), is used widely by many surgeons.[16]

The enhanced medial stabilizer was based on the concept of providing stability through the complete arc of knee flexion.[4] The medial stabilised femoral component has a C-curve design with a near constant radius of curvature of the distal and posterior femur. The tibial component is asymmetric with a highly conforming medial aspect (Figure 3). A conforming medial articular spherical surface with a higher anterior lip allows the tibia to internally rotate around a medial axis as the knee construct flexes, and permits posterior rolling and sliding of the lateral femoral condyle around a stable spinning medial femoral condyle during knee flexion.[4,17] The epicondylar axis of the femur serves as the axis of rotation of the medial stabilised implant. In theory, these design features would lower the contact stresses on the tibial surface, providing for enhanced durability of the polyethylene.[17] Some studies have shown that the medial stabilised design provides good anteroposterior stability throughout the range of motion whilst the spherical shape permits tibial-femoral rotation around a medial axis.[4,17,18] This is known as the medially conforming 'ball-and-socket' construct.

While TKJR provides an effective solution to the debilitating effect of end stage knee joint arthritis, its degree of success has been subjected to increased scrutiny because 15 to 30% of patients remain dissatisfied with the outcome of the procedure, and the large perceived difference between patients and their surgeons regarding the success of the procedure.[19-21] Traditionally the outcome of knee surgery has been evaluated using radiographic parameters or surgeon's clinical assessment of joint function such as stability, alignment, and range of motion. The rise of patient reported outcome measures (PROMs) is an additional means to quantify orthopaedic procedure outcomes.[22]

From the biomechanical perspective, the bearing geometry and kinematic pattern of prosthetic designs can strongly influence the clinical functional outcome after a TKJR.[23] Hence understanding the in vivo motions of human joint has become increasingly important. The evolution of TKJR prosthetic design has led engineers to consider normal knee kinematics as a basis of improving prosthetic function.[24] Ongoing research into knee kinematics using in vivo dynamic video fluoroscopy has revolutionized and improved our understanding of how knee replacement constructs function in patients compared to normal knees.[25]

Study goals and objectives

This study aims to characterize, in vivo, the kinematic behaviour of 3 specific TKJR designs and to determine at six months postoperatively whether clinical and PROM correlated with post-operative knee kinematics.

The null hypothesis proposes that clinical, functional and biomechanical outcomes following total knee replacement surgery will not be influenced by variations in the design of fixed-bearing TKJR prosthesis. Furthermore, the authors propose that there will be no difference in clinical functional outcomes six months and twelve months after total knee replacement irrespective of TKJR prosthetic design.

METHODS

Study design

This study is a prospective, double blinded, randomized trial to collect and measure subjective knee joint function using PROM, as well as three-dimensional knee joint kinematics utilizing biplane mobile fluoroscopy and video motion capture technologies as published by Guan et al.[26] in individuals who have undergone a total knee joint replacement. We will compare a medially stabilized construct design to standard fixed bearing conventional designs - posterior stabilized and cruciate retaining designs from a single joint implant manufacturer. As a prospective randomized trial, the study strategy will be constructed and presented according to the recommendations of the Consolidated Standards of Reporting Trials statement (CONSORT).[27] The clinical trial is registered at Australian and New Zealand Clinical Trial Registry (ANZCTR, identifier: ACTRN12613001278729), which may be accessed online at www.anzctr.org.au. Ethics approvals are obtained from both the hospital and the university ethics committees respectively. The general overview of the clinical trial is outlined in Figure 2. Patients who are referred to the orthopaedic consultant clinic with a diagnosis of knee joint osteoarthritis without clinical and radiographic findings of ipsilateral hip joint arthritis, between the age of 45 and 85, and condition deemed severe enough to require a total knee replacement are eligible to participate in this trial.

Inclusion criteria

Inclusion criteria were clinical and radiographic diagnosis of osteoarthritis (OA) in the knee; age 50 to 85 years old; on waiting list for primary total knee joint replacement for osteoarthritis; seen and assessed by one of four arthroplasty consultants.

Exclusion criteria

Exclusion criteria were BMI ≥36.0; unable to ambulate independently preoperatively; severe angular deformities of the lower limb; deleterious to postoperative outcome if randomized; the total knee joint replacement is as a treatment for neoplastic disease; already has a knee replacement in the contralateral knee; inability to provide own consent due to language difficulties.

Screening of participants

All patients who meet the inclusion criteria will be invited to participate in the study. After informed consent is obtained, each trial participant is assigned to a study subject identification number to ensure all data provided by the participant remained anonymous. At the time of enrollment, the surgeons involved are asked to complete the clinical assessment questionnaire which forms part of the Knee Society Score. Once the subject is enrolled in the study, medical and social histories are taken as well as demographic details were recorded.

Duration of the project

The study is expected to run for three years, with the intervals and recruitment process as shown in Figure 4, and Table 1. The recruitment officially commenced in March 2015, and ceased in early October 2016. By March 2017, all 75 subjects have had their respective TKJR surgery. At the time of writing, 73 of 75 participants have had their six months follow-up and gait analysis, and 45 have had their respective twelve months follow- up. Data input has kept pace with the progress of the study without 'unblinding' the lead investigator.

Table 3: SPIRIT trial study.

Activity/Assessment	Enrolment	$-t_1$ (3 months before operation)	Randomisation	Surgery (t_0)	t_1 (6 months postop)	t_2 (12 months postop)
Demographics	X					
Eligibility screen	X					
Informed consent	X					
Patient reported outcome assessment battery[a]		X			X	X
Randomisation			X			
Total knee joint (TKJR) replacement surgery				X		
Clinical function tests[b]		X			X	X
Gait analysis battery[c]					X	
X-ray assessments[d]		X			X	
Computed tomography (CT) scan[e]					X	

[a]Assessment items include Knee Society Score (KSS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and Oxford Knee Score (OKS). [b]Patients will complete the 6 Minutes Walk Test (6MWT) and 'Up and Go' Test (UGT) at each time interval. [c]Gait analysis assessments include video motion capture with surface markers, simultaneous electromyographic activity recordings, and biplane mobile stereo fluoroscopy while performing four everyday activities. [d]Assessments include X rays of the knee concerned, and long leg alignment views. [e]CT scan Hollywood- Perth Protocol.

Ethics

Informed consent

The lead investigator obtains informed consent from all potential participants using approved patient informed consent form (PICF, Appendix 1). The PICF is signed and dated by the patient, a witness, as well as the lead investigator. This form is then scanned into the hospital network system. A copy of the PICF is then given to the patient for their reference.

Clinical and functional outcome measures

Within three months prior to surgery, each enrolled subject will attend a preadmission clinic for medical and functional assessments. Each participant will complete a set of questionnaires containing Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Oxford Knee Score (OKS), as well as Knee Society Score (KSS). Two clinical function tests: Timed Up and Go (TUG) test and Six Minute Walk Test (6MWT) will also be performed during the clinic.[28] Weightbearing AP, lateral, views will be obtained at the time of the clinic as well as long-leg standing x-rays. The long leg standing films will be obtained using a set of three 43cm x 36cm cassettes with a graduated grid. The lower limbs will be fully extended and positioned on a custom-made Perspex footrest that allows the tibial tuberosities to face forward and the lateral malleoli be 30 cm apart.[29] These results will be compared with those obtained at six months postoperatively.

Surgery and randomisation

All subjects will be prepared for surgery as per hospital protocol. Spinal anaesthesia with sedation and femoral nerve block will be administered prior to surgery. An above knee tourniquet to 300-millimeter Mercury will be used to reduce intraoperative blood loss. All three TKJR designs are sourced from a single manufacturer (Medacta International SA, Switzerland). A standard approach will

be used characterized by a midline skin incision, a medial parapatellar approach for exposure, excision of Hoffa's fat pad, and the use of standardised cutting guides provided by the manufacturer to determine relevant axes and for guiding the femoral cuts. Femoral implant sizing will be estimated through the femoral sizing jig as provided by the manufacturer. The tibial cut will be made with the aid of standardised cutting guides provided by the manufacturer. After this, the tibial base plate size will be estimated using a series of trial tibial base plates. Posterior femoral osteophytes will be removed prior to trialing of the components. All patellae will be resurfaced. The knee will be tested for stability through a full range of motion on the operating table with all the trial components in place. The definitive components will be implanted once the surgeon is satisfied with the stability of the knee with the trial implants in place. Two mixes of polymethyl methacrylate based cement permeated with Gentamicin (SMARTSET™ GHV Bone Cement, Depuy Synthes International, Zuchwil, Switzerland) will be used to cement all components. The wound is then lavaged again prior to layered closure with a drain in situ for the first 24 hours postoperatively.

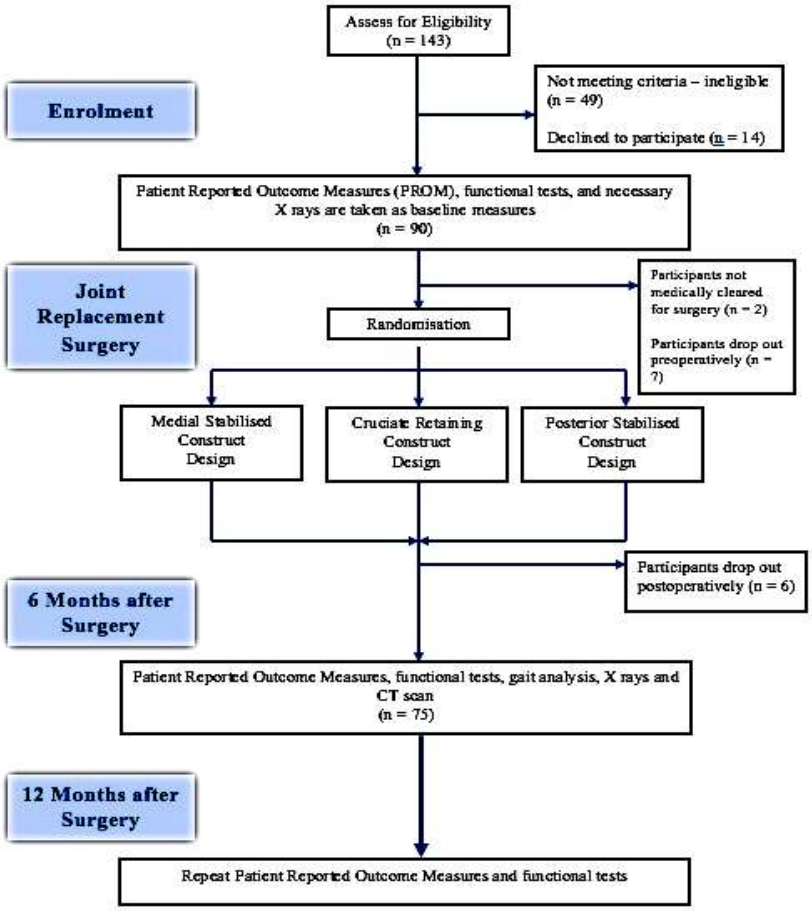

Figure 4: Clinical trial overview flowchart.

A random number generator within Microsoft® Excel will be used to generate the randomization sequence and maintained centrally by one of the investigators, who will not be involved in assessment of participants. The randomisation schedule will be communicated to the surgical operating team approximately ten days prior to the scheduled surgery.

Data management and statistical analysis

Data management

All information and data related to each subject in the clinical trial will be documented and categorised in the specific Excel worksheets in a secure location within the department and only accessible by authorized personnel. All relevant radiology requests for films and scans will be stored in secure area within the department.

Sample size calculation and statistical analysis

To defeat the null-hypothesis and demonstrate a difference of 5.0 (SD 5.0) in these PROMs between the three parallel groups at all time points (alpha value=0.05, and power=90%), this study will require 25 participants in each group. We will aim to recruit 30 subjects per group to account for an approximate drop-out rate of 20%.

Repeated measures of Analysis of Variance (ANOVA) would be used to see if there is a change in the various functional scores and outcomes between the baseline (pre-intervention), six months and twelve months after the TKJR surgery. To investigate the differences in the change in PROM values in each group in each interval, a repeated measure of Analysis of Covariance (ANCOVA) would be used. Categorical variables would be analysed using chi-squared tests (or Fisher's Exact tests for small samples) while continuous variables would be applied to (parametric) t-tests and (non-parametric) Mann-Whitney tests for symmetrically and asymmetrically distributed data, respectively. We anticipate that randomization will ensure that the comparator arms are balanced at baseline for all prognostic correlates and confounder of outcomes – both observed and unobserved.

Role of the investigators

The principle investigators (PC, MP, MD) are responsible for study design, coordination and oversight. Investigator (TY) blinded to clinical treatment is responsible for maintenance of standards of ethics, coordination of activities, recruitment of patients, updating of records, data safety and security, as well as communication between the two departments involved in the study. This investigator is also part of the team performing the gait analysis together with Investigators (HG, SG) and is responsible for using the Image Intensifiers used during the gait analysis in the Biomotion Laboratory. The surgical teams are not blinded to the type of implants used for each patient, however the surgical teams are not involved in the running of the study, data collection, nor analysis.

RESULTS

Clinical and functional outcome assessments

The PROM questionnaires will be obtained within three months prior to surgery, and at six and twelve months postoperatively. The TUG and 6MWT assessments will also be obtained at the preoperative clinic and postoperative follow up intervals.[28] Long-leg, weight-bearing standing anteroposterior (AP) and lateral radiographs will again be taken at six months after the knee replacement. Computed tomography (CT) scan of the operated knee using the Perth CT protocol would be used to assess component rotation with respect to each other in three dimensions at six months postoperatively.[30] This will be analysed independently by certified radiologists.

Biomechanical outcome measures

Biomechanical data will be collected in the Biomotion Laboratory at the Department of Mechanical Engineering, University of Melbourne. Biplane X-ray data, video motion data, ground reaction force data, and muscle electromyographic (EMG) data will be collected simultaneously as the subject performs a series of activities, including walking over level ground, stepping up, stepping down and rising from and sitting down on a chair. Six-degree-of-freedom kinematics of the replaced knee will be measured at a sampling rate of 200 Hz using a mobile biplane x-ray (MoBiX) imaging system capable of measuring TKA rotations and translations to accuracies of 0.65° and 0.33 mm respectively.[26] The three dimensional coordinates of 45 retroreflective markers attached to predetermined bony landmarks of each subject will be recorded with a nine-camera video motion capture system (VICON, Oxford Metrics Ltd., Oxford) sampling at 120 Hz. Ground reaction forces acting on the subject's feet will be measured using two portable force plates (AMTI, Watertown, MA) sampling at 1080 Hz. For 15 randomly selected subjects whose BMI is less than 30, muscle EMG activity will be recorded from the following muscles of the TKR leg using procedures described by Dorn et al gluteus maximus, gluteus medius, medial hamstrings, lateral hamstrings, vastus lateralis, vastus medialis, rectus femoris, medial gastrocnemius, lateral gastrocnemius, soleus and tibialis anterior.[31] A full-body musculoskeletal model comprised of 10 segments and 23 degrees of freedom will be implemented in OpenSim, an open-source biomechanics simulation software package, to calculate the net joint moments developed about the hip, knee and ankle of the TKR limb.[32]

Subsequent surgical interventions and follow- up

Any episodes of return to operating theatre subsequent to the index procedure will be categorized and documented. These patients will remain in the study. All patients will be followed up at six and twelve months postoperatively as part of the clinical trial. Any adverse event or subsequent surgical interventions as outlined above will be followed until the event is resolved.

Trial status

The trial is currently closed for recruitment, and the majority of subjects have completed the six months postoperative gait analysis, 12 month follow-up is underway.

Expected outcomes of the study

The null-hypothesis is that clinical, functional and biomechanical outcomes following TKJR are not influenced by variations in the construct design of fixed-bearing TKJR prosthesis. In this proposed double blinded, randomized trial, each patient is monitored from recruitment phase, and followed up until 12 months after the respective knee replacement surgery. An extensive range of information and data will be obtained from the PROMs, from the x-ray and CT scan results, as well as the gait analysis data from these participants. This will enable an adequate and dependable assessment on the clinical performance of each of the TKJR construct designs, as well as an amalgamation of the differences in biomechanical outcome with the clinical performance of

each of the three parallel groups at six months after TKJR. The data collected in this study will also reliably detect any differences in the clinical functional outcome through PROMs at six months and twelve months after TKJR in any of the three prosthetic design groups. The resulting Level I evidence will further the understanding of the relationship between clinical function and knee kinematics after TKJR. If the null-hypothesis is defeated, and the trial confirms that there is a statistically significant clinical functional difference in one of the TKJR prosthetic design groups, the prosthetic design should be subjected to longer-term studies and comparative large volume registry data interrogated for supporting trends. Similarly, if there is no statistically significant improvement of clinical functional outcomes at twelve months when compared with the PROM data at six months after TKJR, interrogation of national registry data will allow an assessment of generalisability of findings.

DISCUSSION

The objectives of this clinical trial are two- fold, namely, to examine the relative performance of three prosthetic construct designs through the use of PROM as clinical functional outcomes, and to establish any relationship between the clinical functional outcomes and prosthetic knee kinematics at six months after surgery. A secondary outcome is to compare the clinical functional outcomes between six months and twelve months after surgery in all three groups. We are aware of only two randomised control trials comparing prosthetic performances of two different TKJR construct designs in the clinical setting.[33,34] The two trials involved smaller number of participants. This randomised trial is designed to investigate the prosthetic performance of the three fixed bearing construct designs in both clinical and biomechanical settings.

In our clinical trial, the KSS, WOMAC and OKS, were chosen for outcome measures of clinical function. All three outcome measures are condition specific, validated, widely used, as well as being sensitive and responsive to changes. The KSS is unique in that it contains both patient reported, and surgeon reported components.[20] The latest version continues to provide reliability, validity, and is widely accepted and adopted in the orthopaedic community.[20,21] The scoring system took the common-sense approach of using two scales to express and separately define the clinical and subjective status of the knee.[21] Hence the outcome of the total knee joint replacement was derived from severity of pain reported by the patient (50 points), the objective clinical examination finding parameters by the surgeon (50 points), and a functional determination score based on the patient's ability to walk and climb stairs (100 points).[20,35-37]

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a multidimensional, self- administered outcome measure developed and introduced by Bellamy in 1982.[38,39] The index is condition specific, it inspects the characteristics of pain, stiffness and physical function.[40] It is validated, reliable, sensitive to change, and proven to be a responsive instrument.[22,40,41] In their prospective study, Escobar et al. concluded that the minimal change in WOMAC scores to show a clinically significant difference was 15 points.[42] Similarly, designed specifically for measuring outcomes in knee joint replacement, the 12 item Oxford Knee Score is self- administered, and examines 12 activities of daily living, with each item scored from one (normal function) to five (extreme difficulty). The best to worst score in OKS is hence 12 to 60. The Oxford Knee Score has proven to be valid, consistent, reliable and responsive to changes.[16,43]

CONCLUSION

There are different reports of clinical performance of the medial stabilised design when compared to other knee TKJR designs, and there is a lack of data evaluating clinical function and fluoroscopic analysis of the medial stabilised design compared to others in the context of a randomised trial. This single blinded, randomised trial involving three parallel patient cohorts will be able to provide reliable data and analyses to assess the prosthetic performance of each construct design *in vivo*, and to examine possible relationship between the clinical functional outcomes and the replaced knee kinematics at six months postoperatively.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee of St. Vincent's Hospital, Melbourne, and the University of Melbourne, Victoria, Australia

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