Full title:

A Prospective Randomised Control Trial Comparing Functional with Mechanical Axis Alignment in Total Knee Arthroplasty.

Short title:

RCT: FA TKA vs MA TKA

Chief Investigator:

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An Investigator Innitated Study

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STUDY SUMMARY

Identifiers	
ANZCTR Registry Number	ACTRN12621000060842
HREC St. John of God Subiaco Number	
Full (Scientific) title	A prospective randomised controlled trial comparing Functional with Mechanical Axis Alignment in total knee arthroplasty.
Health condition(s) or problem(s) studied	Knee osteoarthritis
Study Type i.e. Cohort etc.	Prospective, randomised, blinded, single-centre study
Target sample size	100
Location	St John of God Subiaco Hospital Salvado Rd Subiaco 6008
Study timelines	
Study Duration/length	4 years
Expected Start Date	01/12/2020
End of Study Date	01/12/2024
Key Study milestones	12/07/2020 - HREC applications 02/2021 - HREC meeting and ethical approval to commence study 03/2021- Commence patient recruitment and record outcomes of interest 12/2021 - Complete patient recruitment 12/2023 - Complete recording 2 yr outcomes of interest on all patients 06/2024 - Collate data and perform statistical analyses 02/2025 - Disseminate findings with publication in peer reviewed journal
Funding	Investigator initiated study
Sponsor	St John of God Healthcare
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KEY WORDS

Functional Alignment
Kinematic Alignment
Mechanical Alignment
Total Knee Arthroplasty
Clinical Outcomes

LIST OF ABBREVIATIONS

AE	Adverse Event
AOANJRR	Australian Orthopaedic Association National joint Registry
AP	Anteroposterior
CI	Chief Investigator
CRF	Case Report Form
EQ5D-5L	European Quality of Life Measurement – 5 Dimension
FA	Functional Alignment
FJS	Forgotten Joint Score
HKA	Hip Knee Angle
HREC	Human Research Ethics Committee
KA	Kinematic Alignment
kFA	Kinematic axis alignment planned Functional Alignment
KOOS JR	Knee osteoarthritis outcome score. Junior version
LAT	Lateral
MA	Mechanical alignment
mFA	Mechanical axis alignment planned Functional Alignment
OA	Osteoarthritis
OKS	Oxford Knee Score
PHK	Perth Hip & Knee Clinic
PICF	Patient Information and Consent Form
PROMS	Patient Reported Outcome Measures
QA	Quality Assurance
RATKA	Robotically Assisted Total Knee Arthroplasty
RCT	Randomised Control Trial
RP	Research Physiotherapist
SAE	Serious Adverse Event
TKA	Total Knee Arthroplasty

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1. Introduction

Total knee arthroplasty (TKA) is the most effective treatment for patients with symptomatic end-stage knee osteoarthritis that has not responded to appropriate non-operative management. The aims of TKA are to provide pain relief and improve function. Accuracy of limb alignment, implant positioning, and soft tissue balance after TKA are important prognostic factors that affect postoperative clinical outcomes and long-term implant survivorship. Published literature has shown between 80% and 90% of patients are satisfied following this procedure. (1,2)

To this end there are two much debated theories of postoperative alignment after TKA. In total knee arthroplasty with mechanical alignment the aim is to achieve neutral limb alignment. This was to optimise longevity of TKA and prevent early failure. Total knee arthroplasty with kinematic alignment aims to restore the patient's own pre-arthritic knee anatomy with more natural alignment and preservation of native function. Enthusiasts debate both theories and it is yet to be established whether one is superior to the other.

An issue with both of these alignment theories is that they are purely related to bony anatomy. Neither considers soft tissue tension or balance before the bony cuts are made. Once the bony cuts are made the soft tissue balance is assessed and ligaments released until the TKA is balanced to the surgeon's satisfaction. In an initial cohort study well over 50% of patients in both groups required soft tissue releases to balance the TKA if these alignment theories were strictly adhered to.

The accuracy of soft tissue balancing is surgeon dependent and there is evidence that even experienced knee surgeons are poor at manually determining if a knee is balanced (3). This becomes particularly important when considering over half of these procedures throughout the world are performed by surgeons who undertake less than 25 TKA per year.

Robotic assisted TKA with the Mako robot (Stryker, Florida, USA) has enabled a pre-resection balancing technique. This enables assessment of soft tissue laxity and adjustment of the initial plan to achieve balanced soft tissue with alteration of component alignment. Once the knee has been virtually balanced on the planning software, robotic arm assisted surgery is undertaken to accurately replicate the plan resulting in a balanced TKA.

Functional alignment depends on the soft tissue tension to determine the TKA alignment and thereby minimizes the need for soft tissue release. As the collateral ligaments due not contract through the disease process of osteoarthritis, re-tensioning these ligaments following the removal of osteophytes should act as a surrogate of individual limb alignment. Although the overall limb alignment in this technique is independent of the initial plan the individual component position and joint line obliquity will vary depending on whether the knee was planned with a mechanical axis(mFA) or a kinematic axis(kFA) alignment. Assessment of the Perth Hip and Knee

Registry data would suggest on average a two degree difference in component position in both joint line obliquity and femoral rotation.

The need for soft tissue release to balance the knee in both MA and KA alignment makes them unsuitable for a computer enabled planning and balancing algorithm. This is due to variation in surgical skill and the difficulty in standardizing soft tissue releases. Functional Alignment is well suited to automated algorithms as the surgical steps to balance the knee (bony cuts) would be robot assisted and therefore have an in-built quality control. The development of computer algorithms to plan and balance the knee arthroplasty could potentially improve the overall quality of TKA performed.

Limits are placed in Functional alignment to prevent the severely arthritic knee with attenuated ligaments being placed in extremes of alignment. Understanding the "safe zone" for functional alignment is important for patient selection, implant choice, extent of intraoperative deformity correction, and long-term follow up. Furthermore, some disease pathology such as bone tumors, previous trauma, and congenital deformities may be present in conjunction with the arthritic knee and will have altered the native alignment of the limb. In such cases, using functional alignment to reproduce the altered anatomical alignment and mechanical function may have a detrimental effect on knee mechanics and wear.

A preliminary series by the principal investigator involved 122 TKR with mFA and over 350 kFA aligned knees since the introduction of RATKA into my practice. In an initial cohort of patients with functional alignment substantial differences were seen in femoral and tibial component position depending on whether a mechanical or kinematic plan was used. The final HKA angle was not changed as the coronal limb alignment is dictated by the collateral ligaments. The femur was 2 degrees valgus and the tibia 4 degrees varus with the kinematic plan compared to a neutral femur and 2 degree varus tibia with a mechanical plan. These small changes in position effect the three-dimensional relationships of the implants with the soft tissues. The initial cohort showed improved outcomes with the KA plan. There were confounding factors in that the groups were sequential, with MA plan group forming part of the surgeon's learning curve. For the planned study a KA plan will be used as superior results have been seen in this group in the initial series..

1.1 Current evidence

There are no prospective studies looking at Functional alignment. Prospective studies comparing functional outcomes between the MA and KA groups have been performed but the main limitation of these studies has been the inability to accurately measure the desired deviation from neutral alignment as well as achieving the implant position to a high degree of accuracy. There is a paucity of studies using standardised techniques for intraoperative alignment and limited data relating these findings to clinical outcomes with long- term follow up.

Matsumoto et al (7) conducted a prospective randomised study on 60 patients with varus osteoarthritis undergoing computer navigated TKA and showed kinematic alignment was associated with improved postoperative angles of flexion, functional activity scores, and more parallel joint line orientation in relation to the floor during single- and double-leg standing compared to patients with TKA using mechanical alignment. The true mechanical axis, which runs from the centre of the femoral head to the inferior aspect of the calcaneus passed through a neutral position in the kinematic group and a slightly lateral position in the mechanical group. The authors suggested that this more natural weight-bearing position in TKA with kinematic alignment may reduce pre-existing concerns of increased polyethylene wear and implant loosening in this patient group. However, patient follow-up was limited to one year following surgery, two separate types of implants were used within each treatment group, patients with severe valgus/varus deformities were excluded, and intraoperative kinematic assessment was not performed despite the use of computer navigation.

Waterson et al (8) conducted a prospective randomised trial on 71 patients undergoing primary TKA and showed that there was no difference between kinematically aligned and mechanically aligned TKA with respect to the Knee injury and osteoarthritis outcome score (KOOS), American knee society score, 36-item short form survey (SF 36), European Quality of Life questionnaire with 5 dimensions for adults (EQ-5D), range of movement, two-minute walk, and timed up and go tests at one year following surgery. In this study, patient-specific cutting blocks were used to achieve kinematic alignment and standard extra- or intramedullary instrumentation was used to achieve mechanical alignment. No intraoperative navigation or robotic systems were used to confirm limb alignment, functional outcomes were only assessed for up to one year, and findings were poorly correlated to radiological outcomes.

Dossett et al (9) conducted a prospective randomised study on 88 patients and showed patients undergoing kinematic knee alignment had improved Oxford knee score (OKS), Western Ontario and Mcmaster Universities Arthritis Index (WOMAC), and improved range of motion compared to mechanically aligned TKA at a minimum of two-years follow-up. The odds ratio for having a pain-free knee was 3.2 with mechanical alignment compared to 4.9 with kinematic alignment in TKA. However, in this study accuracy of the cutting blocks was not assessed, preoperative scores were universally better in the kinematic alignment group compared to the mechanical alignment group, and the study was performed on private patients in the United States, which may have introduced a selection bias.

1.2 Need for a trial

There is a need for high quality evidence on the clinical and radiological benefits of functionally aligned TKA. This study would show if there is any superior outcomes to be obtained from functional alignment. Clinical and functional outcomes should also be correlated to longer-term outcomes to better establish the “safe zone” for functional alignment.

Currently the vast majority of TKA throughout the world is undertaken utilizing MA alignment. Any change to a newer technique from the current 'gold standard' would need to be justified by improved clinical outcomes as there is no long term longevity data for Functional Alignment. Both surgeons and patients are only able to consider the relative risks and benefits of this technique once they are defined by sound scientific evidence. This study will contribute to the body of this evidence.

2. Objectives

The overall aims of this prospective, randomised double-blinded controlled trial are to compare functional, clinical, and radiological outcomes in FA TKA versus MA TKA. Patients undergoing MA TKA will form the control group and those undergoing FA TKA will form the investigation group. A superiority design will be used to evaluate whether FA TKA provides superior outcomes compared to MA TKA. Primary and secondary objectives will be used to quantify and draw inferences on differences in the efficacy of treatment between the two groups. To ensure accuracy of planning and implantation robotic arm assisted surgery will be utilized in both groups (Stryker MAKO, Fort Lauderdale, FL). Standardised post-operative care will be undertaken to ensure the only difference between groups is alignment of implants.

2.1 Primary objective

- The primary objective of this study is to compare clinical outcomes at two years following surgery between FA TKA and MA TKA. The primary outcome measure for this study is the Forgotten Joint Score (FJS) at two years after surgery. The null hypothesis is that there is no difference in functional scores at two years following surgery between patients undergoing MA TKA (control group) versus FA TKA (investigation group). The hypothesis is that outcome measures obtained at two years after surgery in patients undergoing FA TKA are not achievable using MA TKA. Further PROMs will be used to further assess clinical outcomes including Forgotten Joint Score (FJS), Oxford Knee Score (OKS), Knee injury and osteoarthritis outcome Junior score (KOOS Jr), VAS Pain, and Kujala scores preoperatively and postoperatively at 3 months, 1 year and 2 years. Also health-related quality of life will be measured using European Quality of Life questionnaire with 5 dimensions for adults (EQ-5D-5L) preoperatively and postoperatively at 3 months, 1 year and 2 years. Range of movement (degrees) in knee joint during inpatient admission and postoperatively at 6 weeks, 3 months, 1 year and 2 years.

2.2 **Secondary objectives** The secondary objectives of the study are:

- Determine lower limb alignment achieved with both alignment techniques. Lower limb alignment as assessed using standing long leg x-rays performed postoperatively at 3 months. Measurements of the hip-knee-angle (HKA), medial proximal tibial angle (MPTA) and lateral distal femoral angle (LDFA). Also evidence of imbalance with implant lift off will be measured.

- Determine if there are any differences in analgesic requirements based on alignment method used. Analgesia requirements during inpatient admission and postoperatively at 6 weeks, 3 months, 1 year and 2 years will be measured.
- Determine whether alignment method utilized has an effect on the sagittal stability of the TKA. Assessment of sagittal stability at Preop, 3 months, 1 year and 2 years will be undertaken with an arthrometer "Lachmeter".
- Determine whether alignment method utilized has an effect on functional outcomes. This will be assessed by a combination of
    - Maximum voluntary isometric force using a hand-held dynamometer at Preop, 3 months, 1 year and 2 years.
    - Sit to stand values as measure of function at Preop, 3 months, 1 year and 2 years.
- Intra-operative balance achieved with both alignment techniques. Surgeon blinded measurement of intraoperative balance achieved with Verasense sensor (smaller cohort)
- To determine if there is a difference in knee kinematics between the two techniques. Measurement of knee kinematics with Verasense sensor to assess presence or absence of medial pivot (smaller cohort)

3. Study Design

3.1 Study Type

This study is a prospective, single-centre, randomised, double-blinded, controlled study. Patients undergoing MA TKA will form the control group and those undergoing the FA TKA will form the investigation group.

3.2 Study Location

The study base will be Perth Hip and Knee Clinic, 1/1 Wexford St, Subiaco 6008, WA. All Patients will have surgery and their inpatient stay will be at St John of God Subiaco Hospital with recruitment and follow up at either Perth Hip and Knee Clinic, (Subiaco or Murdoch rooms) or Midland Orthopaedics (Suite 11 St John of God Midland Hospital, Clayton Rd. Midland). All confidential study information will be stored on designated-password protected research computers and assigned research offices at Perth Hip and Knee Clinic.

3.3 **Investigation Team** The Chief investigator, Mr Gavin Clark is the Head of Department at St John of God Midland Hospital and Consultant Orthopaedic Surgeon at St John of God Subiaco Hospital. The majority of Mr Clark's research stems from arthroplasty and optimising postoperative clinical and radiological outcomes. Mr Clark is fully trained and experienced in performing Mako robotic arm-assisted TKA.

Mr Dermot Collopy is a senior Orthopaedic Consultant Surgeon at St John of God Subiaco Hospital and co-investigator in this study. Mr Collopy is fully trained and experienced in performing Mako robotic arm-assisted TKA.

All operative procedures will be undertaken by Mr Clark and Mr Collopy.

Mrs Beth Tippett is a Research Physiotherapist that will assist in patient recruitment, data collection and statistical analysis. There is also a clinical fellow, additional physiotherapists in the practice, and two Orthopaedic registrars that can provide further assistance if required.

3.4 Study population and groups

Patients with symptomatic knee osteoarthritis requiring TKA will be recruited from the Mr. Clark's and Mr Collopy's private rooms at Perth Hip & Knee Clinic. All patients will be screened for eligibility based on the predefined inclusion and exclusion criteria (section 5.1). Patients interested in participating in the study will be provided with an information leaflet and contact telephone number for further information (Appendix 19.7). Details of those patients expressing an interest to participate in the study will be recorded and then be forwarded to the Research Physiotherapist.

TheResearch Physiotherapist will telephone or meet with the patient to answer any additional queries and confirm whether or not the patient would like to participate in the study. More complex queries will be escalated to the Chief Investigator who will telephone the patient directly to discuss these issues further. Ideally, the time frame from the orthopaedic consultation to the decision to participate in the study will be approximately one week, which will give the patient sufficient time to perform further research, discuss study participation with family and/or friends, and contact the Research Physiotherapist for any additional information. This time frame may be shortened if a patient is agreeable with the study, due to patient flow and appointment availability at the consulting rooms. Contact details of the Research Physiotherapist and Chief Investigator are provided within the patient information leaflet.

If the patient agrees to participate in the study, the Orthopaedic fellow will randomise the patient into one of the two treatment groups. Patients allocated to mFA TKA will form the 'control group' whilst those allocated to kFA TKA will form the 'investigation group'. The method for randomisation is discussed in section 3.6. Written informed consent for both the operative procedure and inclusion into the study will be signed at the preadmission visit (Appendix 19.7). The procedure for obtaining written informed consent is discussed in more detail in section 5.

3.5 **Sample Size** In total, 100 patients will be enrolled in a 1:1 ratio between the two treatment groups. This will ensure that the minimum of 90 patients required to answer the study question are followed up for the duration of the study. The enrolment goal is to have at least 45 patients in each of the two treatment groups completing the study. Sample size calculation and statistical analysis are more comprehensively detailed in section 6.

3.6 Randomisation procedure

The system for randomisation will be the same throughout the study period and must be strictly adhered to. The following method will be used to allocate a trial patient to either the mFA TKA ('Control group') or to the kFA TKA ('Investigation group').

Randomisation will be carried out using a blocked effect. This method is designed to randomize subjects into two groups that result in equal sample sizes over time. The blocks will be small (n=4), and balanced within the predetermined group assignments, which will keep the number of subjects in each group similar at all times. There will be no stratification factors involved in the randomization as randomization will occur before the trial starts. Using a randomization website (www.random.org), a random number (between 1 and 100000) will be generated. This will form the "seed" number for the blocked randomization process. Using a randomization website (www.sealedenvelope.com) the randomization list will be created. Patients will be allocated in a sequential order of consent, strictly adhering to the allocation of groups. Screen shots of the randomization process and seed number will be taken throughout, and held from the CI to minimize randomization bias. The orthopedic fellow will then privately communicate to the CI the allocated group, to enable alignment and templating planning to be performed using the MAKO software. All patients and clinical staff recording the post operative clinical outcomes of interest will remain blinded to minimize performance and detection bias.

If the patient initially agrees to participate in the study and then changes his/her mind at a later stage, they are free to do so without any compromise to their further care. If this occurs before obtaining informed consent then the patient's decision will be relayed to the operating surgeon who will discuss suitable options directly with the patient, and organise postoperative follow-up care as per all routine (non-study) patients undergoing TKA at Perth Hip and Knee Clinic. There randomisation number will not be reallocated to the next patient, to ensure the blocks remain concealed. Drop in and out details are in section 6. If the patient agrees to participate in the study and then declines further inclusion after surgery has been performed, then the patient's follow-up care will be arranged as per routine TKA follow up at Perth Hip and Knee Clinic. Patients will be notified that once statistical analysis of the study has been performed, and all patient data has been de-identified for analysis, they will not be able to withdraw their clinical data. Statistical analysis of patients that drop out is discussed in section 6. Following randomisation and informed consent at the preadmission visit, baseline information will be recorded and documented in the Perth Hip and Knee Clinic Socrates database. Data handling and management are recorded in more detail in section 9.

3.7 Surgical Intervention: MA vs. FA TKA

All patients undergoing TKA will undergo preoperative CT scan of the leg to establish the extent of the disease process, determine bone resection, and plan implant sizing and positioning. The preoperative CT scan will be used to create individualized plans for achieving mechanical and kinematic alignment and stored within the robotic program that is used during the operative procedure. This will ensure that all implants and equipment for achieving either mechanical alignment or functional alignment are ready and available for use in theatre. These

plans will provide the initial point from which functional alignment will be achieved.

Following informed consent and randomisation into one of the two treatment groups, patients will undergo robotic-arm assisted TKA by one of the participating surgeons. Surgery in both groups will be undertaken through the standard anteromedial arthrotomy with positioning of reference pins in the femur and tibia for registration of the hip centre, ankle position and limb alignment. The femur will be prepared first in all operations. Cruciate retaining technique will be used in both groups. Interoperative requirement for a more constrained implant will result in exclusion from the study.

In MA TKA, tibial and femoral osteotomies in the coronal plane will be planned perpendicular to the tibial and femoral mechanical axes respectively to achieve neutral overall alignment. Soft tissue balance will be assessed and minor adjustments to bony alignment made to balance the knees with a maximal adjustment of two degrees valgus and two degrees varus of coronal alignment from neutral. Femoral rotation will be planned to surgical epicondylar axis and adjustments to rotation made to allow equal flexion and extension balance (to within 1mm). If balance can not be achieved within these boundaries then soft tissue release will be undertaken.
In the sagittal plane, 0-3 degrees of posterior tibial slope and 0-5 degrees of femoral component flexion will be used to optimise implant sizing whilst preventing notching. In the axial plane, the tibial component aligned to Akagi's line, which connects the medial border of the patellar tendon attachment to the middle of the posterior cruciate ligament.

In kFA TKA, femoral and tibial osteotomies will be planned for equal bony resections from the femoral condyles to replicate the patients anatomy. In the coronal plane, the distal femoral resection will be 6.5mm from the subchondral bone of both medial and lateral condyles, with compensation for wear by adjusting the resection by 1-3mm. In the proximal tibia, there will be 7mm of resection from the subchondral bone from both the medial and lateral tibial plateau. In the sagittal plane, resection angle will be determined intraoperatively to closely match the native femoral flexion and tibial slope. In the axial plane, posterior femoral resection will be 6.5mm from the subchondral bone of both medial and lateral posterior condyles. Tibial rotation will be aligned to Akagi's line. Adjustments will be made to bony alignment to balance soft tissues within the boundaries of six degrees varus and three degrees valgus Hip-Knee-Ankle (HKA) alignment. Femoral component alignment will be limited to six degrees of valgus and three degrees of varus in the coronal plane. Tibial alignment will be limited to six degrees of varus and three degrees of valgus in the coronal plane. Combined flexion of the components will be limited to ten degrees of flexion. Only if balance can not be achieved within these boundaries will soft tissue release be undertaken.

In both groups, polyethylene thickness will be selected to maximise range of motion whilst avoiding hyperextension and ligament laxity. Tibial depth will be adjusted to maintain insert thickness between 9 and 14mm. Any TKA requiring a 16 mm or greater polyethylene insert thickness will be excluded from the study.

Patients in both groups will undergo the same inpatient and outpatient postoperative rehabilitation programme. Intra-operative data will be recorded using the surgical data form (Appendix 19.7). The only difference between the two treatment groups is that the control group will undergo MA TKA and the investigation group will undergo FA TKA.

3.8 Description of the device

The Stryker Triathlon (Stryker Navigation, Mahwah, NJ) cruciate retaining knee system with patellar resurfacing will be used in both groups. The femoral component will be un-cemented, patella and tibial components will be cemented. This implant and its surgical instruments are already in routine use for TKA at St John of God Subiaco Hospital. The surgical team are fully trained and experienced with the use of the instruments and surgical equipment for these implants.

All postoperative rehabilitation will follow Perth Hip and Knee Clinic standard practice at St John of God Subiaco Hospital for patients undergoing TKA. This will include a combination of inpatient and outpatient physiotherapy as required. Each patient will have standard radiographic and clinical follow-up. The required outcomes from these clinical and radiological assessments will be recorded in the follow-up investigator form at discharge.

3.9 Post operative follow up

All patients included in this study will undergo orthopaedic review at the PHK Clinic or Midland Orthopeadic Clinic at 2-3 weeks, 6 weeks, 3 months, 1 year and 2 years following surgery. These are the routine follow-up time intervals for non-study patients undergoing TKA at PHK. Clinical and radiological outcomes of interest will be recorded by blinded observers using case report forms during these follow-up times (Appendix 19.1). The RP and fellow will assist in this.

3.10 Clinical and radiological assessment

The FJS, EQ5D-5L, OKS, VAS Pain, Likert scale , KOOS Jr and Kujala Anteior knee pain scores are validated tools for the clinical assessment of patients after knee arthroplasty (10,11,18,19). Each of these scores is completed preoperatively and then at regular intervals during follow-up (Appendix 19.1) This information is routinely discussed at each of these outpatient consultations but patients in this study will have the information recorded within these validates questionnaires to facilitate data analysis.

Routine clinical measures of height, weight, range of movement and pain description will be taken. To test endurance and strength, a 30 sec Sit to stand test will be measured. This test asks the participant to stand up / sit down from a standardised chair height within 30 seconds (Appendix 19.6). To measure the AP stability of the knee (20), a lachmeter reading will also be recorded at the post operative intervals and to measure strength, a hand

held dynamometer test will also be performed.

	Preoperative	Discharge	6 weeks	3 months	1 year	2 years
Patient demographics	X					
Patient medical history	X					
Operation details		X				
Clinical history and PROMS (FJS, EQ5D-5L, OKS, VAS pain, KOOS Jr, Kujala Anterior Knee Pain, Likert scale)	X		X (FJS and VAS only)	X	X	X
Functional Examination (Lachmeter testing, Range of Movement, Hand Held Dynamometer, 30s STS test)	X	X (range only)	X (range only)	X	X	X
Adverse Events	At occurrences through study period					

Table 1. Timelines for clinical data collection in all study patients.

	Preoperative	Discharge	6 weeks	3 months	1 year	2 years
Plain knee joint radiographs	X	X			X	X
Plain long-leg radiographs	X			X		
CT Knee joint	X					

Table 2. Timelines for radiological data collection in all study patients. Assessment windows will be as followed; 6 weeks review (± 1 week), 3 month review ((± 2 weeks), 12 month review ((±2 months), 2 year review ((± 2 months).

4.1 Study Timeline

Patients will be recruited from the private rooms at Perth Hip & Knee clinic. Based on the volume of TKAs performed and recruitment rates from previous studies within clinic, patients are expected to be recruited at a rate of 10 patients per month. The recruitment process will therefore take approximately 10-12 months from the start of the study. From the date of the operation, each patient will be followed-up for 24 months. A further six months will be required for data collection, analysis and dissemination of findings. The total duration of the study will therefore be 40 months.

4.2 Patient withdrawal criteria and procedure

All patients included into this study are free to withdraw from the study at any time without compromise to their future treatment. On withdrawal, patients will revert to the standard follow-up regimen for routine TKAs at the study site. The end of study form will be completed and the reason for withdrawal documented (Appendix 19.2). This form will also be completed if the patient is lost to follow-up or dies during the course of the study.

Enrolled patients will be withdrawn from the study if:

- The patient withdraws consent for participation in the study
- The patient is no longer able to comply with study instructions, attend scheduled appointments or complete questionnaires
- The patient undergoes implant revision

Data to the point of withdrawal will be used for analysis.

5.0 Consent

Patients with symptomatic knee osteoarthritis requiring TKA will be recruited from the private rooms at Perth Hip & Knee Clinic. All patients will be screened for eligibility based on the predefined inclusion and exclusion criteria (section 5.1) by a member of the clinical team. This includes the Orthopaedic Consultant Surgeon, Clinical Fellow, or Research Physio. If the patient meets the all of the inclusion criteria (section 5.1) and none of the exclusion criteria, and expresses an interest to participate in the study they will be provided with a patient information sheet (Appendix 19.7). This provides details about the study, treatment, follow-up and contact details for further information. All members of the clinical team are familiar with the study and will address any preliminary questions about the study. Details of those patients expressing an interest to participate in the study will be recorded in the patient contact sheet , which will be a password protected excel document that only Dr Clark, Dr Collopy and Beth Tippett will have access to.

One week after this outpatient consultation, the Research Physiotherapist will telephone the patient to answer any additional queries and confirm whether or not the patient would like to participate in the study. If the patient agrees to participate in the study, the Research Physiotherapist will randomise the patient into one of the two treatment groups. Patients allocated to mFA TKA will form the ‘control group’ whilst those allocated to kFA TKA will form the ‘investigation group’. The method for randomisation is discussed in Section 3.6. Written informed consent for both the operative procedure and inclusion into the study will be signed at the preadmission appointment.

The ideal length of time between initial consultation and obtaining informed consent for inclusion into the study is at least 1 week. This method provides time for potential participants to consider the trial and ask questions before written consent for participation is requested. This time may be shortened due to patient flow and clinic appointment availability, as long as the patient is agreeable. Consent will be taken by the study coordinator or by

a designated member of the surgical team who is familiar with the study.

If the patient initially agrees to participate in the study and then changes his/her mind at a later stage, they are free to do so without any compromise to their further care. If this occurs before obtaining informed consent then the patient's decision will be relayed to the Operating Surgeon who will discuss suitable options directly with the patient, and organise postoperative follow-up care as per all routine (non-study) patients undergoing TKA at Perth Hip & Knee Clinic. If the patient agrees to participate in the study and then declines further inclusion after surgery has been performed then the patient's follow-up care will be arranged as per routine TKA follow up. Statistical analysis of patients that drop out is discussed in section 6. Following randomisation and informed consent, baseline information will be recorded and documented in the baseline investigator form (Appendix 19.1). Data handling and management are recorded in more detail in section 9.

Being able to provide informed consent to the study is of paramount importance. Therefore, patients who lack the capacity to provide this, for example patients with dementia, will not be considered for the study. It is also important to the data collection scheme that patients are able to follow commands, read and interpret questions via questionnaires. Those who cannot hear, read or understand English, will not be considered for the study.

Participants will not receive any preferential treatment or payment for taking part in the study.

5.1 Eligibility Criteria

The inclusion and exclusion criteria for all patients included in this study is shown below:

Inclusion Criteria

- Patient has symptomatic knee osteoarthritis requiring primary TKA
- Patient and surgeon are in agreement that TKA is the most appropriate treatment
- Patient is fit for surgical intervention following review by surgeon
- Patient is between 45-75 years of age at time of surgery, computer literate, and able to complete patient reported outcome measures independently.
- Patient must be capable of giving informed consent and agree to comply with the postoperative review program
- Patient must be a permanent resident in an area accessible to the study site
- Patient must have sufficient postoperative mobility to attend follow-up clinics and allow for radiographs to be taken
- Patient has tried non-pharmacologic therapy's including ; patient education, self-management programs, aerobic exercise, weight loss, physiotherapy and occupational therapy
- Patient has tried appropriate pharmacologic therapies including ; regular paracetamol and NSAIDS if appropriate

Exclusion Criteria

- Patient is not suitable for routine primary TKA. E.g. patient has ligament deficiency that requires a constrained prosthesis
- Interoperative requirement for a more constrained implant.
- Intraoperative requirement for the PCL to be released. These patients will be still included in the study, but analyzed with an intention to treat principal.
- Patient has bone loss that requires augmentation
- Patient requires revision surgery following previously failed correctional osteotomy or ipsilateral TKA (eg. Post high tibial or distal femoral osteotomy)
- Patient requires a polyethylene inset of 16mm or greater.
- Patient is immobile or has another neurological condition affecting musculoskeletal function
- Patient is less than 44 years of age or greater than 76 years of age
- Patient is a compensable patient. I.e. Worker's compensation claim or motor vehicle accident.
- Patient is already enrolled on another concurrent clinical trial
- Patient is unable or unwilling to sign the informed consent form specific to this study
- Patient is unable to attend the follow-up program
- Patient is non-resident in local area or expected to leave the catchment area postoperatively
- Patients who lacks capacity to provide consent, or the ability to understand the study protocol due to a cognitive condition (eg. Dementia)
- Patient is unable to communicate effectively in English.

6.0 Statistical Methods

6.1 Power / Sample size calculation

Primary Outcome measure: Functional outcome as assessed using the FJS score at two years following Mako-arm assisted TKA.

Using data from our initial cohort recording functional outcomes, the mean FJS score at 1 year in the mFA TKA was 59 (SD 6) and in the kFA TKA was 75 (SD 8). It is assumed that MA results will be no better than mFA results. The study was powered to demonstrate a 12 point difference in the Forgotten Joint score, which is the minimal clinical important change in the score. Using a one tailed analysis (assuming superior results with the kFA), an alpha value of 0.05 and power of 0.80, and accounting for expected drop-out rate of 10%, this study will need 100 patients to answer the study question.

6.2 Endpoint Analysis

6.2.1 Primary Endpoint

The analysis of the per-protocol population will be considered the primary analysis. The differences

between the MA TKA and FA TKA groups will be analysed by calculating the difference from baseline, per patient, and a two-sided confidence interval for the difference between the changes from baseline will be calculated. This confidence interval will cover the true difference in the percentage change from baseline with a probability of 95%.

6.2.2 Secondary Endpoints

Standard statistical methods will be employed to analyse the data. It is anticipated that the following techniques may be used: descriptive statistics, t-test, paired t-test, analysis of variance, Fisher exact test, Chi-square test, and graphical displays. Assumptions of normality will be tested with the Shapiro-Wilk test. Assumptions of homogeneity of variance will be tested with Levene's test. If the distributional assumptions are (severely) violated, non-parametric techniques, such as Mann-Whitney's test will be employed.

All tests will be declared statistically significant if the calculated p-value is less or equal to 0.05. All tests will appear as two-sided p-values. Summary statistics will consist of numbers and percentages of responses in each category for discrete measure, and of means, medians, standard deviation, 95% confidence interval, minimum, maximum for continuous measures, and will be presented per treatment group.

6.3 Intention-to-treat population

The intention-to-treat (ITT) population is defined as all randomised patients assigned to either the mFA TKA or kFA TKA group, regardless of adherence with the entry criteria, regardless of the treatment they actually received, and regardless of subsequent withdrawal from treatment or deviations from the protocol. In the event that MA is converted to FA or vice versa intraoperatively, analysis will be performed using the ITT population and the treatment actually received by the patients. Intra-operative conversion from one method to another will however, be documented and presented/ published as part of the study.

In the event that there are errors in the randomization assignment, the analysis will be performed using the assigned treatment, not the treatment that the patient actually received. Any patient terminated early from the clinical trial will be included in the ITT population. All attempts will be made to collect complete follow-up evaluations for these patients despite study exit. These patients will be included in the analysis using univariate or multivariate-imputation methods.

6.4 Per-protocol population

The per-protocol population is defined as all patients who are randomised to MA TKA or FA TKA and complete the study according to the protocol.

In the event that there are errors in the randomisation assignment, the analysis will be performed using the treatment that the patient actually received, not the assigned treatment. Patients will be considered protocol violators if they do not meet the eligibility criteria as outlined in the protocol. Other reasons to be considered a protocol violator include, but are not limited to, protocol violations, and any actions that compromise the effectiveness of the treatment, such as receiving a secondary treatment. Protocol violators will not be considered as part of the per-protocol population and will be listed separately with the reason for their exclusion from the per-protocol population.

6.5 Baseline Data

Baseline data will be recorded for each patient after completion of the consent form. This data will be recorded on Socrates, as detailed in the Data Management Plan (Section 9).

7.0 Patient and Public Involvement

This study will not actively include any patients or lay members of the public to assist in the study design, management, analysis of results or dissemination of findings. Patients will be provided with a lay summary of the research findings after completion of the study.

8.0 Funding and Supply of Equipment

Stryker Orthopaedics will be supplying the lachmeter and dynamometer for this study. St. John of God Healthcare currently fund a 1 FTE RP who will also assist in this project.

9.0 Data Handling and Management

9.1 Data Quality Assurance and Monitoring

The principle of Good Clinical Practice will be adhered to throughout with the research team responsible for its own regular internal audit for quality, recruitment goals and results targets. This will be in the form of monthly research meetings for those involved in the trial. The Investigator will designate one or more appropriately trained and qualified individuals to monitor the progress of the clinical study. As per section 2.1.1 of the NHMRC Code, all clinical trial research data will be retained for a minimum of 15 years from the date of publication or 5 years following the completion of the research.

9.2 Onsite Monitoring

On-site monitoring visits shall occur throughout the course of the clinical study by the Chief Investigator. The Chief Investigator shall permit and assist the IDSM (should they chose to monitor the study) to carry out verification of completed case report forms (CRFs) against data in the source

documents, which shall occur as per the departmental policy for undertaking such activities.

All personnel involved with the conduct of the study must undertake to maintain the confidentiality of patients in the study. The requirements of the current Good Clinical Practice guidelines will be adhered to for data processing.

10.0 Consent and Case Report Form Storage

All case report forms (CRFs) must be completed and signed by staff that are listed on the site staff delegation log and authorised by the CI/ PI to perform this duty. The CI/PI is responsible for the accuracy of all data reported in the CRF.

Data required according to this protocol are to be recorded on the CRFs as soon as possible. Patients will be identifiable with a unique study number. Only the research physiotherapist will have the key to identify individual patients. All CRFs must be legible and completed in black ink. Any necessary corrections are to be made by drawing a single line through the incorrect entry and writing in the revision, and must be initialed and dated by the investigator or his or her representative. Data are not to be obliterated by blacking out, using correction fluid or by erasing the original entry. Any documents related to the study must be archived directly at the study site. These documents include listings that identify study subjects, research group allocated to each study subject, consent forms, and all completed CRFs. All consent forms and CRFs will be stored by the CI/PI investigator in a locked filing cabinet in a dedicated locked research office. This office has key access with monitored security. Patient data will be logged electronically using each patient's unique identification number with Socrates computer software on an encrypted, password-protected research computer on the Perth Hip and knee clinic network. This computer is located within a dedicated lockable research office within Perth Hip and Knee Clinic Subiaco.

11.0 Assessment and Management of Risks

The trial will be conducted in full conformance with the principles of the Declaration of Helsinki and ICH Good Clinical Practice guidelines. All data will be stored securely and held in accordance with Data Protection Act 1998. The trial will be reported in line with the CONSORT statement.

Written informed consent will be obtained from all patients participating in the study. Patient safety is of paramount importance and all participants will be treated with respect and dignity throughout. Inclusion or exclusion from the study will not impact the quality of the care they receive. Participants will not receive any preferential treatment or payment for taking part in the study, and are free to leave the study at any point without any compromise to their further treatment.

There is no "safe" radiation dose but it is best clinical practice to limit radiation exposure as much as possible. Routine radiological follow-up of patients undergoing TKA at Perth Hip & knee Clinic includes

anteroposterior and lateral knee radiographs at discharge, and anteroposterior skyline and lateral radiographs at 1 year, and 2 years postoperatively. Additional standard long-leg radiographs are performed at 3 months following TKA. In this study, the same protocol will be adhered to with no additional radiation dose.

12.0 Recording and Reporting of adverse events

12.1 Definitions of Adverse Events

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved.
Serious Adverse Event (SAE).	Any adverse event that: □ results in death, □ is life-threatening*, □ requires hospitalisation or prolongation of existing hospitalisation**, □ results in persistent or significant disability or incapacity, or □ consists of a congenital anomaly or birth defect
*A life- threatening event, this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. ** Hospitalisation is defined as an in-patient admission, regardless of length of stay. Hospitalisation for pre-existing Conditions or planned upcoming surgeries (ie. Other knee replaced), including elective procedures do not constitute an SAE.	

Table 3. Definition of adverse events

Category	Definition
Non-severe	The adverse event does not interfere with the participant's daily routine, and does not require further procedure; it causes slight discomfort
Life threatening	The adverse event interferes with some aspects of the participant's routine, or requires further procedure, but is not damaging to health; it causes moderate discomfort
Hospitilsation required / prolonged	The adverse event results in alteration, discomfort or disability which is clearly damaging to health
Permanent of significant disability/ incapacity	Permanent of significant disability/ incapacity

Table 4. Severity of SAE classification

13.3 Causality

Category	Definition
Related	There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out.
Probably related	There is evidence to suggest a causal relationship, and the influence of other factors is unlikely
Possibly related	There is some evidence to suggest a causal relationship (e.g. the event occurred within a reasonable time after administration of the study procedure). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant events).
Not related	There is no evidence of any causal relationship.
Not assessable	Unable to assess on information available

Table 5. Causality of SAE classification

capture events related to the mFA TKA and kFA TKA. The assessment of relationship of an adverse event to these additional safety issue(s) will also be carried out as part of the study.

14.0 Recording of Serious Adverse Events

All serious adverse events will be recorded in the medical records and the CRF, and the sites AE log.
All serious adverse events (SAEs) must be recorded on a serious adverse event form (appendix 19.4). The Principal Investigator will complete the SAE form and the form will be emailed to the SJOG HREC Committee within 5 working days of becoming aware of the event. The Chief Investigator will respond to any SAE queries raised by the primary HREC as soon as possible. Where the event is unexpected and thought to be related to the procedure this must be reported by the Investigator to the Therapeutic Goods Administration via the Incident Reporting and Investigation Scheme within 15 days.

All SAE's will be reported as per the flow diagram below.

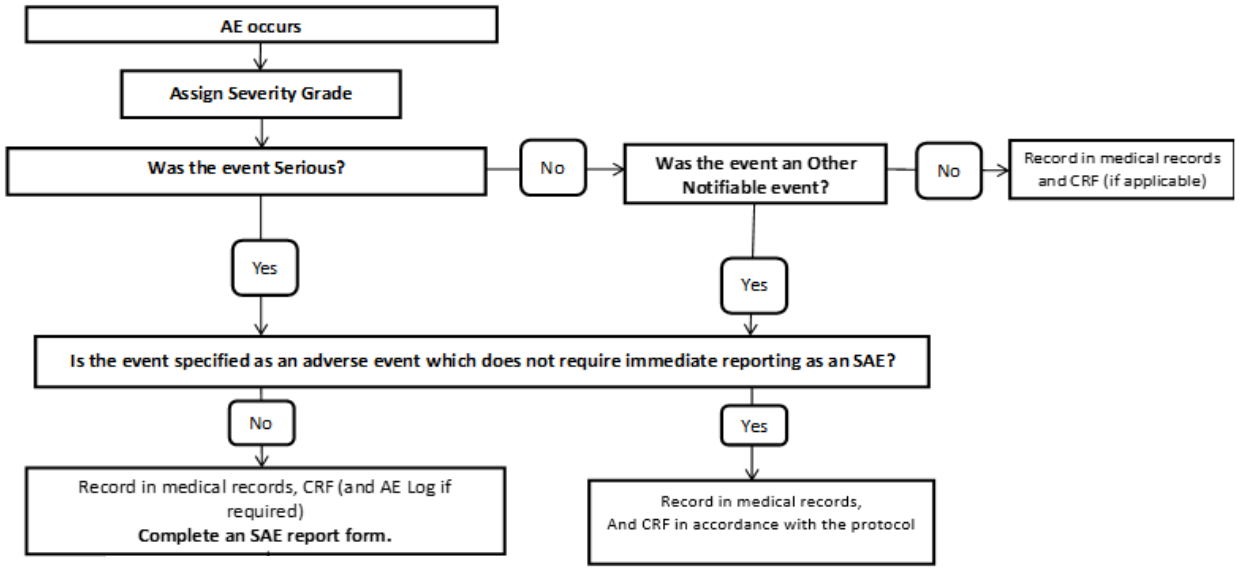

Diagram 1. Flow chart for reporting SAE's.

14.0 Reporting Incidents

14.1 Protocol deviations and notification of protocol violations

A deviation is usually an unintended departure from the expected conduct of the study protocol, which does not need to be reported to the TGA. The principal investigator will monitor protocol deviations.

A protocol violation is a breach which is likely to effect to a significant degree –

a) the safety or physical or mental integrity of the participants of the study; or
b) the scientific value of the study.

The Chief investigator and IDSM will be notified immediately of any case where the above definition applies during the study conduct phase.

14.2 Reporting Incidents involving a medical device

Adverse device effects (complications) are defined as any of the following:

a) Any device component failure (e.g. excessive migration of the implant or failure otherwise).
b) Local complications arising from use of the TKA implants to include osteolysis, inflammation, local tissue reaction, periprosthetic fracture.
c) Bone fracture during implantation
d) Nerve damage arising from implant placement (as evidenced immediate postoperative by motor and/or sensory deficit not present preoperatively).
e) Large vessel damage arising during surgery (with large blood loss, i.e. > 1500 ml).
f) Prosthetic joint infection
g) Surgical site infection
h) Loosening of prosthetic components
i) Other adverse events that are deemed device related and serious.

All serious adverse events, life-threatening problems, or deaths that occur during or following the use of the devices during the study should be fully documented in the research record by the Chief Investigator including the onset date, complete description of the event, severity, duration, action taken, and outcome. The event should be documented at the appropriate interval case report form. The Chief Investigator will be responsible for notifying the reviewing Research Ethics Committee, of any unanticipated adverse events according to local regulations. The Chief Investigator will record all non-serious adverse events on the appropriate case report form.

Some adverse events may lead to subsequent surgical intervention. The surgical intervention should be reported separately from the presentation of the other adverse event. For example, if the adverse event is reported at the 3 months visit and a revision subsequently occurs after the 3 months visit, the revision should be reported in the next follow-up visit.

In the short term, revisions will usually occur due to acute/chronic infection, instability, and/or subject experiencing severe pain due to various causes. This data will be used in combination with clinical assessment, target history / examination and further investigation to determine likelihood of requiring revision.

For all cases where revision was necessary, the investigator must record and forward a description of intraoperative findings including: presence of local reaction to implant, gross subsidence of implant, and any intraoperative findings relating to the device failure. This information will be recorded by the intra-operative

product specialist, and information will be submitted to the TGA via the medical device incident reporting guide. Explant analysis will occur throughout the duration of this study.

15.0 Training

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files. All personnel working on this study will have completed the Guideline for Good Clinical Practice ICH E6(R2) Qualification.

16.0 Archiving

Site files will be stored in the locked research room at Perth Hip and Knee Subiaco. As per the NHMRC code, data will be stored for 15 years. Patient information will be located on Genie Medical Solutions software, and on research database Socrates. Both of this software programs are located on servers within Australia, and are automatically back up. These programs can only be accessed by login and password, and are located on computers at Perth Hip and Knee Clinic.

17.0 Publication and Dissemination Policy

The findings of this study will be published in peer-review journals. There are no terms or conditions to the funding that may impact upon publication and dissemination. Authorship will reflect the amount of time spent designing the study, collating the data and writing the manuscript.

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Date Form Completed		Height	
Date of Operation		Weight	
Study Number		BMI	
Date of Randomisation		Side	
CT date		Sex	F □ M □
Plain film Xray (A/P, lat, Skyline)		Age	

19.0 Appendices

Appendix 19.1 : Patient Case Report Forms

Patient ID :

Preop

1. Relevant Past Medical History

_____
_____
_____
_____
_____

2. Previous Surgery to knee (including dates)

_____
_____
_____
_____
_____

3. Other relevant notes in history

_____
_____
_____
_____
_____

4. Additional future elective surgery planned

_____

_____
_____
_____
_____

5. Current Medication and Analgesia Regime

_____
_____
_____
_____
_____

- PROMS
  - Oxford
  - Forgotten joint
  - Kujala
  - Eq5D-5L
  - Vas Pain
  - Koos JR
- Functional
  - Range
  - Mobilisation Equipment
  - Lachmeter
    - 90*
    - 20*
  - Dynamometer
    - Knee flexion (achillies)
    - Knee extension (Anterior distal shin)
  - 30STS
    - Mods?

Completed by :

6 weeks

1. Current Medication and Analgesia Regime

_____
_____
_____
_____
_____

2. Hospital Admission since last visit - if need be, complete SAE.

_____
_____
_____

3. How satisfied are you with your knee replacement?

0 Extremely satisfied 0 Satisfied 0 Neutral 0 Dissatisfied 0 Extremely Dissatisfied

- PROMS
  - Forgotten joint
  - Vas Pain
- Functional
  - Range
  - Mobilisation Equipment
  - Dynamometer
    - Knee Flexion (Achille's)
    - Knee Extension (Anterior distal shin)

Physio Observations and Treatment plan

_____
_____
_____
_____
_____

3. Protocol Deviation and reason why

_____
_____
_____
_____
_____

Completed by :

3 Months

1. Current Medication and Analgesia Regime

_____
_____
_____
_____
_____

2. Hospital Admission since last visit - if need be, complete SAE.

_____
_____
_____

3. How satisfied are you with your knee replacement?

0 Extremely satisfied 0 Satisfied 0 Neutral 0 Dissatisfied 0 Extremely Dissatisfied

- PROMS
  - Oxford
  - Forgotten joint
  - Kujala
  - Eq5D-5L
  - Vas Pain
  - KOOS Jr.
- Functional
  - Range
  - Mobilisation Equipment
  - Lachmeter
    - 90*
    - 20*
  - Dynamometer
    - Knee Flexion (Achillies)
    - Knee Extension (Distal anterior shin)
  - 30STS
    - Mods?

- XRAY (A/P, lat, skyline and LLWB)

3. Physio Observations and Treatment plan

_____
_____
_____
_____
_____

4. Protocol Deviation and reason why

_____
_____
_____
_____
_____

Completed by :

12 Months

1. Current Medication and Analgesia Regime

_____
_____
_____
_____
_____

2. Hospital Admission since last visit - if need be, complete SAE.

_____
_____
_____

3. How satisfied are you with your knee replacement?

0 Extremely satisfied 0 Satisfied 0 Neutral 0 Dissatisfied 0 Extremely Dissatisfied

- PROMS
  - Oxford
  - Forgotten joint
  - Kujala
  - Eq5D-5L
  - Vas Pain
  - KOOS Jr.
- Functional
  - Range
  - Mobilisation Equipment
  - Lachmeter
    - 90*
    - 20*
  - Dynamometer
    - Knee Flexion (Achillies)
    - Knee Extension (Anterior distal shin)
  - 30STS
    - Mods?

- XRAY (A/P, lat, skyline)

3. Physio Observations and Treatment plan

_____
_____
_____
_____
_____

4. Protocol Deviation and reason why

_____
_____
_____
_____
_____

Completed by :

24Months

1. Current Medication and Analgesia Regime

_____
_____
_____
_____

2. Hospital Admission since last visit - if need be, complete SAE.

_____
_____
_____

3. How satisfied are you with your knee replacement?

0 Extremely satisfied 0 Satisfied 0 Neutral 0 Dissatisfied 0 Extremely Dissatisfied

- PROMS
  - Oxford
  - Forgotten joint
  - Kujala
  - Eq5D-5L
  - Vas Pain
  - KOOS Jr.
- Functional
  - Range
  - Mobilisation Equipment
  - Lachmeter
    - 90*
    - 20*
  - Dynamometer
    - Knee Flexion (Achillies)
    - Knee Extension (Anterior distal shin)
  - 30STS
    - Mods?

- XRAY (A/P, lat, skyline)

3. Physio Observations and Treatment plan

_____
_____
_____
_____
_____

4. Protocol Deviation and reason why

_____
_____
_____
_____
_____

Completed by:
Please complete end of study form.

Appendix 19.2 – End of Study Form

END OF STUDY FORM

RCT: MAKO mFA TKA vs MAKO kFA TKA

Name (Initials only)	**Study Number:**	□ M □ F	**DOB:**
Date of form completion			
Years since operation			
Classification	□ Reached end of follow-up		
	□ Complete withdrawal from study Reason (if given):		
	□ Withdrawal from study apart from survivorship analysis Reason (if given):		
	□ Lost to follow-up		
	□ Death		
	□ Implant removed		

If withdrawn from study, does patient agree to be contacted annually for survivorship analysis?

Comments

Signature of PI:

Date:

Appendix 19.3: Clinical Trial Letter to GP

Dr. Gavin Clark and Dr. Dermot Collopy

St. John of God Hospital Subiaco

Perth Hip and knee Clinic Subiaco

1/1 Wexford Street, Subiaco 6008. (08) 6489 1777

Dear Dr [XXX],

Patient name: **Patient DOB:**
Research Code No: **Enrolment Date:**

I am writing to let you know that the above patient has consented to taking part in our research study at St John of God Subiaco Hospital. This study is a prospective randomised controlled trial comparing clinical and radiological outcomes in patients undergoing functionally aligned Mako robotic-arm assisted total knee arthroplasty comparing those with a mechanical axis aligned knee replacement to those with a functionally aligned knee replacement. This alteration in alignment has a minor effect on overall alignment but changes individual component position in three dimensions.. Both surgical approaches are established techniques with excellent outcomes in patients with knee osteoarthritis. The findings of this study will enable us to determine which of the two surgical treatment options provides better clinical outcomes following TKA.

All patients included in this study will receive the same preoperative treatment and postoperative rehabilitation program. A computer will randomly allocate each patient to one of the two treatment groups. To preserve the double-blinded nature of this study, both patients and observers recording outcomes of interest will be blinded to the treatment group. All participants will complete a series of health- related questionnaires during their follow-up consultations.

Patients will undergo clinical follow up at 2 weeks, 6 weeks, 3 months, 1 year and 2 years after operative intervention. The surgery will be undertaken at St John of God Subiaco Hospital and follow up will be at the Perth Hip and Knee Clinic or Midland Orthopaedics. Each patient will be followed for two years following surgery and the total study duration is three years. After this time, data relating to the clinical and radiological outcomes will be collated, analysed and findings published in peer reviewed journals. Participants will also receive a lay summary of the pertinent research findings. My standard ongoing follow up of joint replacement patients each five years will then resume.

Please let me know if you would like any further information. Thank you.

Yours Sincerely,

Mr Gavin Clark Mr Dermot Collopy

Consultant Orthopaedic Surgeons
St John of God Subiaco Hospital
Perth Hip and Knee Clinic

Appendix 19.4 Local Site SAE / AE Form

ST JOHN OF GOD
Health Care

Local Site SAE/SUSAR/USADE Report

This is a dynamic PDF form. Depending on your answers, certain questions will appear and text boxes will expand.

Full Study Title:

Short Title/Acronym: SJGHC HREC Ref:

Event Type: Study Type: SJGHC Participating Site:

Event Term:

Investigator(s): Report # to SJGHC HREC:

Date of Event: Study ID: Age: Female Male

Event Description and Management:

Event Outcome:

- Fatal
- Life Threatening
- Hospitalisation required/prolonged
- Permanent or significant disability/incapacity
- Other:

Event Relationship to Study

- Related to
- Probably related
- Possibly related
- Not related

Is this event a documented side effect? (i.e. specified in the study protocol) Yes No

How often has this same event occured to date in the present study?

As a researcher conducting this clinical trial, in your opinion, are any amendments required to the Protocol and/or Participant Information and Consent Form(s)? Yes No

As a researcher conducting this clinical trial, in your opinion, are there any implications for the continued conduct of the study? Yes No

Name: Position:

Signature:
(click box to insert image of signature)

Date:

Please ensure any person who has electronically signed this document is copied in on the submission to the Ethics Office.

Please attach any supporting documentation to this form, including reports from the IDMC when they are received.

Appendix 19.5 PROMS (10,11)

EUROQOL EQ-5D 5L

Patient Name_____ **ID** _____ **Side** ☐Right ☐Left

Date of review: _____/_____/_____

Follow up period: **PreOp** OR _____ weeks/months/years (circle one)

By placing a tick in one box in each group below, please indicate which statement best describes your own health state today. *Do not tick more than one box in each group.*

Mobility
1. ☐I have no problems in walking about
2. ☐I have slight problems in walking about
3. ☐I have moderate problems in walking about
4. ☐I have severe problems in walking about
5. ☐I am unable to walk about

Self-care
1. ☐I have no problems washing or dressing myself
2. ☐I have slight problems washing or dressing myself
3. ☐I have moderate problems washing or dressing myself
4. ☐I have severe problems washing or dressing myself
5. ☐I am unable to wash or dress myself

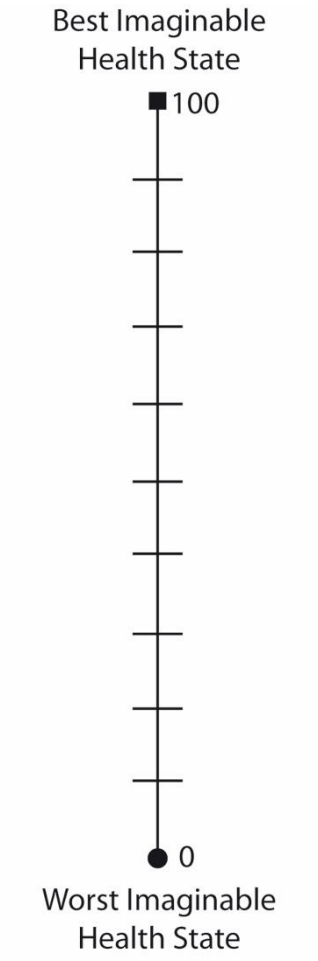
Usual activities (e.g. work, study, housework, family or leisure activities)
1. ☐I have no problems doing my usual activities
2. ☐I have slight problems doing my usual activities
3. ☐I have moderate problems doing my usual activities
4. ☐I have severe problems doing my usual activities
5. ☐I am unable to do my usual activities

Pain/Discomfort
1. ☐I have no pain or discomfort
2. ☐I have slight pain or discomfort
3. ☐I have moderate pain or discomfort
4. ☐I have severe pain or discomfort
5. ☐I have extreme pain or discomfort

Anxiety/Depression
1. ☐I am not anxious or depressed
2. ☐I am slightly anxious or depressed
3. ☐I am moderately anxious or depressed
4. ☐I am severely anxious or depressed
5. ☐I am extremely anxious or depressed
6.

Your Health State Today

To help people say how good or bad a health state is, we have drawn a scale on which the best state you can imagine is marked 100 and the worst state you can imagine is marked by 0. We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line on the scale below to whichever point on the scale indicates how good or bad your health state is.



Forgotten Joint Score FJS12

Patient Name_____ **ID** _____ **Side** ☐Right ☐Left

Date of review: _____/_____/_____ OR **Follow up period: PreOp** OR _____ weeks/months/years (circle one)

Are you aware of your affected or artificial joint…

1. … in bed at night?
   ☐never ☐almost never ☐seldom ☐sometimes ☐mostly

2. … when you are sitting on a chair for more than 1 hour?
   ☐never ☐almost never ☐seldom ☐sometimes ☐mostly

3. … when you are walking for more than 15 minutes?
   ☐never ☐almost never ☐seldom ☐sometimes ☐mostly

4. … when you are taking a bath/shower?
   ☐never ☐almost never ☐seldom ☐sometimes ☐mostly

5. … when you are traveling in a car?
   ☐never ☐almost never ☐seldom ☐sometimes ☐mostly

6. … when you are climbing stairs?
   ☐never ☐almost never ☐seldom ☐sometimes ☐mostly

7. … when you are walking on uneven ground?
   ☐never ☐almost never ☐seldom ☐sometimes ☐mostly

8. … when you are standing up from a low-sitting position?
   ☐never ☐almost never ☐seldom ☐sometimes ☐mostly

9. … when you are standing for long periods of time?
   ☐never ☐almost never ☐seldom ☐sometimes ☐mostly

10. … when you are doing housework or gardening?
    ☐never ☐almost never ☐seldom ☐sometimes ☐mostly

11. … when you are taking a walk/hiking?
    ☐never ☐almost never ☐seldom ☐sometimes ☐mostly

12. … when you are doing your favourite sport?
    ☐never ☐almost never ☐seldom ☐sometimes ☐mostly

Oxford Knee Score

Patient Name_____ **ID** _____ **Side** ☐Right ☐Left

Date of review: _____/_____/_____

Follow up period: **PreOp** OR _____ weeks/months/years (circle one)

Please answer the 12 questions below.

1. During the past 4 weeks… How would you describe the pain you usually have from your knee?

☐None ☐ Very mild ☐Mild ☐Moderate ☐Severe

---

2. During the past 4 weeks… Have you had any trouble washing and drying yourself (all over) because of your knee?

☐No trouble at all ☐Very little trouble ☐ Moderate trouble ☐Extreme difficulty ☐Impossible to do

---

3. During the past 4 weeks…Have you had any trouble getting in and out of a car or using public transport because of your knee (whichever you would tend to use)?

☐No trouble at all ☐Very little trouble ☐ Moderate trouble ☐Extreme difficulty ☐Impossible to do

---

4. During the past 4 weeks… For how long are you able to walk before the pain from your knee becomes **severe** with or without a stick)?

☐No pain – more than 30 minutes ☐16- 30 minutes ☐ 5-15 minutes

☐Around the house only ☐Not at all - pain severe when walking

---

5. During the past 4 weeks… After a meal (sat at a table) how painful has it been for you to stand up from a chair because of your knee?

☐Not at all painful ☐Slightly painful ☐ Moderately painful ☐ Very painful ☐ Unbearable

6. During the past 4 weeks… Have you been limping when walking, because of your knee?

☐Rarely/Never ☐Sometimes or just at first ☐Often, not just at first ☐ Most of the time ☐All of the time

---

7. During the past 4 weeks… Could you kneel down and get up again afterwards

☐Yes, easily ☐With little difficulty ☐ With moderate difficulty ☐ With extreme difficulty ☐No, impossible

---

8. During the past 4 weeks… Have you been troubled by pain from your knee in bed at night?

☐No nights ☐ Only one or two nights ☐ Some nights ☐ Most nights ☐Every night

---

9. During the past 4 weeks… How much has pain from your knee interfered with your usual work? (including housework)

☐Not at all ☐A little bit ☐Moderately ☐ Greatly ☐Totally

---

10. During the past 4 weeks… Have you felt that your knee might suddenly "give way" or let you down?

☐Rarely/Never ☐Sometimes or just at first ☐Often, not just at first ☐ Most of the time ☐All of the time

---

11. During the past 4 weeks… Could you do household shopping on your own?

☐Yes, easily ☐With little difficulty ☐ With moderate difficulty ☐ With extreme difficulty ☐No, Impossible

---

12. During the past 4 weeks… Could you walk down one flight of stairs?

☐Yes, easily ☐With little difficulty ☐ With moderate difficulty ☐ With extreme difficulty ☐No, Impossible

Kuujala Anterior Knee Pain Score

Patient Name_____ **ID** _____ **Side** ☐Right ☐Left

Date of review: _____/_____/_____

Follow up period: **PreOp** OR _____ weeks/months/years (circle one)

Patients - please place an X in one box on each line to indicate your response to that question.

1. Do you have a limp?

None | Slight or periodical | Constant

2. Support

Full support without pain | Painful | Weight bearing impossible

3. How far are you able to walk?

Unlimited | More than 2 km | 1-2 km | Unable

4. Are you able to use stairs?

No difficulty | Slight pain when descending | Pain when both descending and ascending | Unable

5. Are you able to squat?

No difficulty | Repeated squatting painful | Painful each time | Possible with partial weight bearing | Unable

6. Are you able to run?

No difficulty | Painful after more than 2 km | Slight pain from start | Severe pain | Unable

7. Are you able to jump?

No difficulty | Slight difficulty | Constant pain | Unable

Patients - please place an X in one box on each line to indicate your response to that question.

8. Are you able to sit for prolonged periods with knees flexed?

☐ No difficulty	☐ Pain after exercise	☐ Constant pain	☐ Pain forces to extend knees temporarily	☐ Unable

9. Do you suffer from pain?

☐ None	☐ Slight and occasional	☐ Interferes with sleep	☐ Occasionally severe	☐ Constant and severe

10. Do you suffer from swelling?

☐ None	☐ After severe exertion	☐ After daily activities	☐ Every evening	☐ Constant

11. Do you suffer from abnormal painful kneecap (patella) movements (subluxations)?

☐ None	☐ Occasionally in sports activities	☐ Occasionally in daily activities	☐ At least one documented dislocation	☐ More than two dislocations

12. Do you suffer from atrophy of thigh? (wasting of thigh muscles)

☐ None	☐ Slight	☐ Severe

13. Do you suffer from flexion deficiency? (cant bend your knee fully)

☐ None	☐ Slight	☐ Severe

KOOS Jr.

Patient Name_____ **ID** _____ **Side** ☐Right ☐Left

Date of review: _____/_____/_____

Follow up period: **PreOp** OR _____ weeks/months/years (circle one)

Stiffness

The following question concerns the amount of joint stiffness you have experienced during the last week in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.

	None	Mild	Moderate	Severe	Extreme
1. How severe is your knee stiffness after first wakening in the morning ?	☐	☐	☐	☐	☐

Pain

What amount of knee pain have you experienced the last week during the following activities?

	None	Mild	Moderate	Severe	Extreme
2. Twisting/pivoting on your knee	☐	☐	☐	☐	☐
3. Straightening knee fully	☐	☐	☐	☐	☐
4. Going up or down stairs	☐	☐	☐	☐	☐
5. Standing upright	☐	☐	☐	☐	☐

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the last week due to your knee.

	None	Mild	Moderate	Severe	Extreme
6. Rising from sitting	☐	☐	☐	☐	☐
7. Bending to floor/pick up an object	☐	☐	☐	☐	☐

Patient Satisfaction and VAS Pain- Post op

Follow up period: _____ Weeks / Months / Years (add the delay and circle one)

Patients - please place an X in one box on each line to indicate your response to that question.

How well did the surgery or treatment on your joint:

1. Relieve the pain ?

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

2. Increase your ability to perform regular activities ?

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

3. Allow you to perform heavy work or sport activities (if allowed by Dr) ?

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

4. Meet your expectations ?

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

5. Would you have the operation or treatment again if needed, on another joint ?

Definitely yes	Probably yes	Possibly not	Definitely not
☐	☐	☐	☐

For this part of the questionnaire, simply place a vertical line at the position on the line below, that corresponds accurately with your perception of your answer to the question.
Please ensure that your line crosses the horizontal line, inside the shaded area.

6. How satisfied are you with your medical care?

Least satisfied ——————————— Most satisfied

7. How normal does your affected joint feel ?

Least Normal ——————————— Normal

8. How would you rate your pain ?

No Pain ——————————— Worst possible pain

Patient satisfaction and pain - preop

6. How satisfied are you with your medical care?

Least satisfied ——— Most satisfied

7. How normal does your affected joint feel ?

Least Normal ——— Normal

8. How would you rate your pain ?

No Pain ——— Worst possible pain

Appendix 19.6 Functional Testing protocols

30-second Chair Stand Test (13,14)

Participant

- Comfortable walking footwear (e.g. tennis shoes/cross trainers) should be worn.
- The participant sits in the chair in a position that allows them to place their feet flat on the floor, shoulder width apart, with knees flexed slightly more than 90 degrees so that their heels are somewhat closer to the chair than the back of their knees.
- The arms are crossed at the wrists and held close to the chest (across chest).

Tester

- The tester stands close to the side of the chair for safety and so as they can observe the technique, ensure that the participant comes to a full stand and full sit position during the test.

Practice

- A practice trial of one or two slow paced repetitions is recommended before testing to check technique and understanding.

Procedure

- From the sitting position, the participant stands up completely up so hips and knees are fully extended, then completely back down, so that the bottom fully touches the seat. This is repeated for 30 seconds.
- Same chair should be used for re-testing within site.
- If the person cannot stand even once then allow the hands to be placed on their legs or use their regular mobility aid. This is then scored as an adapted test score.

Equipment

- Timer / stopwatch
- Straight back chair with a 17 inch seat height, preferably without arms
    - The same chair should be used for re-testing between sites.

Verbal instructions – to be followed exactly.

"For this test, do the best you can by going as fast as you can but don't push yourself to a point of overexertion or beyond what you think is safe for you.

1. Place your hands on the opposite shoulder so that your arms are crossed at the wrists and held close across your chest. Keep your arms in this position for the test.
2. Keep your feet flat on the floor and at shoulder width apart.
3. On the signal to begin, stand up to a full stand position and then sit back down again so as your bottom fully touches the seat.
4. Keep going for 30 seconds and until I say stop.
5. Get ready and START".

Scoring

- On the signal to begin, start the stop watch. Count the total number of chair stands (up and down equals one stand) completed in 30 seconds. If a full stand has been completed at 30 seconds (i.e. standing fully erect or on the way down to the sitting position), then this final stand is counted in the total.
- The participant can stop and rest if they become tired. The time keeps going.
- If a person cannot stand even once then the score for the test is zero.
- Next, allow the hands to be placed on their legs or use their regular mobility aid. If the person can stand with adaptions, then record the number of stands as an adapted test score (see score sheet). Indicate the adaptations made to the test.

Minimal reporting standards

N.B. The individual should use the assistive device (if any) they would normally use to perform the activity at the time of testing, irrespective of how they performed it previously. However, if an assistive device/rail is used, then it should be recorded for that occasion.

Dynamometer Testing (15-17)

Before testing, subjects to be seated in the exercise chair or plinth with no back support. The patient to be instructed to remain seated in an upright position and place both hands on his or her upper legs to avoid compensation. The "make" method for strength testing to performed rather than the "break" method as it has been shown to have better reliability and provide more accurate measures.

For knee flexion, Dynamometer to be placed on the posterior aspect of the calcaneus. For knee extension, the Dynamometer to be positioned perpendicular to the anterior aspect of the tibia, 5 cm proximal of the medial malleolus. Patient limb to be positioned at 90 degrees of flexion, measured with a goniometer, in an open chain postion. As previous studies have experienced patients being too strong for testers, the dynamometer will be fixated to the base of the plinth via a purpose-built cradle during testing (Figure 1).. The straps to be fixated to standardised attachment in the treatment rooms (figure 2). Patients may have one test attempt prior to the recording attempt. The patient to be instructed to gradually build up strength for two seconds to avoid explosive contraction, then to continue with a three-second maximal contraction as used in previous studies.

Patient to be instructed identically each time, and encouraged to “go go go” during each attempt. There is to be a 30 second rest between each attempt to allow for muscle recovery. Knee extension is be performed first, followed by knee flexion. The initial measurement is to be performed on the unaffected leg, followed by the affected leg, and thereafter alternated in a similar fashion for both flexion and extension. This will be measured three times of each leg.

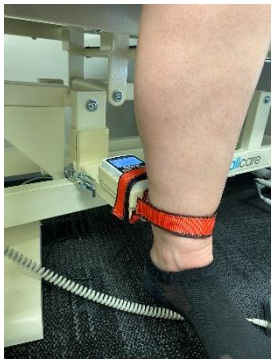


Figure 1 – Note: arms to be placed on upper legs, not on plinth

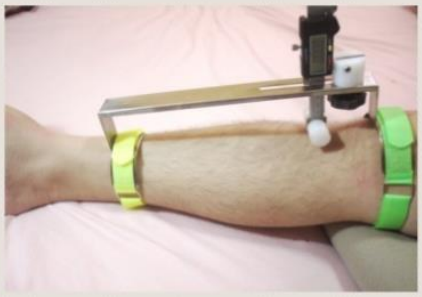
Figure 2

Lachmeter Testing

To be performed at 20* and 90* knee flexion. Plinth to be set up to correct angles. **Appendix 19.7**

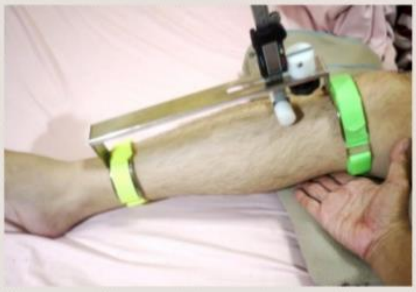
Step 1

Put a cushion behind the Thigh and position the ***Lachmeter*** with the Patella end on the Knee.



Step 2

Secure the ***Lachmeter*** firmly by pulling the Velcro Strap and latch it down. Repeat on the Tibia end.



Observe that the muscle is relax.

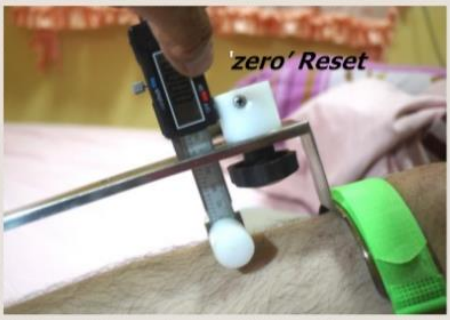
Step 3.

Loosen the adjusting Knob and move the depth gage so that the stylus foot is at the position to be measured.

Tighten the Adjusting Knob in this position.

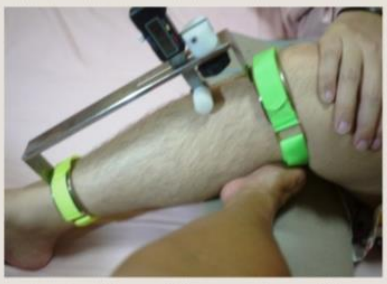
Step 4.

Turn on the Digital Depth Gage and reset to zero by pressing the 'Zero' reset button

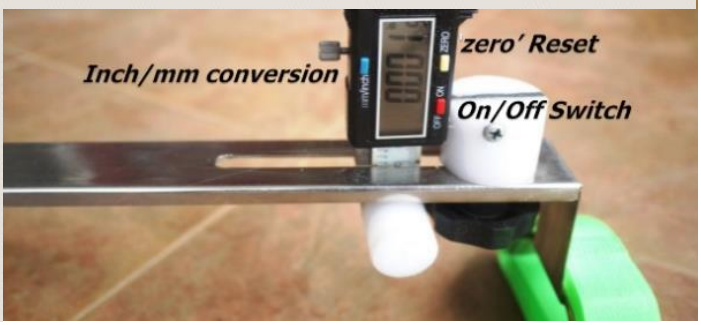


Step 5.

Pull the Leg to the maximum limit and note down the reading on the Digital Readout.



Repeat this process 3 times on the same knee and note down the average of the 3 readings.



Appendix 19.7Patient Information and Consent Form

Participant Informed Consent Form

Prospective Randomized Control Trial Comparing Functionally Aligned Total Knee Arthroplasty Utlising Mechanical Axis aligned planning versus Kinematic Axis Planning

Short Title: RCT: MAKO mFA TKA vs MAKO kFA TKA

This information sheet explains the research project and describes what will be involved should you decide to participate. Please read the information carefully and ask Dr Gavin Clark, Dr Dermot Collopy or Beth Tippett any questions you might have.

1. What is the purpose of the project?

This project is being conducted by Perth Hip and Knee Clinic. The objective of this study is to compare clinical and radiological outcomes in robotic-arm assisted TKA using mechanical alignment (MA TKA) versus robotic-arm assisted TKA with functional alignment (FA TKA). Both FA TKA and MA TKA are performed through similar skin incisions, robotic-guidance, and use identical implants. In MA TKA, bone is prepared and implants positioned to ensure that that the overall alignment of the leg is in neutral. In FA TKA, the bone is prepared and implants positioned to restore the natural alignment of the patient's leg. Both of these surgical techniques provide excellent outcomes in TKA but it is not known which of the two techniques is better for patient recovery. Mako robotic-assisted TKA is an established treatment for arthritis of the knee joint. The positions of the implants and overall alignment of the leg are important as they influence how quickly the implants wear out and need replacing. The aim of this study is to determine if patient recovery is better with functionally aligned Mako robotic-assisted total knee arthroplasty (FA TKA) or mechanically aligned Mako robotic-assisted total knee arthroplasty (MA TKA).

2. Why have I been asked to participate?

You have been asked to take part in this project because you will undergo a robotic-assisted Total Knee Replacement performed by Dr Clark. Patients who received/will receive a Total Knee Replacement implanted with the assistance of Mako at St John of God Hospital Subiaco will be invited to participate in this project.

3. Which type of TKA will I receive?

The surgeon will review your medical records and confirm that it is safe for you to receive either the KA TKA or FA TKA. An online computer programme will then be used to randomly assign you to one of the two treatment groups. Randomly assigning patients to a treatment is a scientific method used in many clinical studies to reduce bias.

4. What is the information being collected?

As per routine protocol all patients undergoing a total knee replacement will undergo preoperative CT scan of the knee joint to establish the extent of the disease process, determine bone resection, and plan implant sizing and positioning. Preoperative clinical data such as your demographics, medical history, and joint range/function will be taken along with 6 standardised questionnaires. Intraoperative data will also be recorded during your surgery, which will be retrieved from the MAKO robot along with your operation record. Postoperative data, including joint range of movement/function, analgesia requirements, hospital length of stay, concurrent medical issues will be recorded, along with 6 standardised questionnaires. Functional testing of joint range, stability (using a Lachmeter: Image 1) and strength (using a hand held dynamometer : Image 2) will occur preoperatively, 3m, 12m and 2 years. Plain film x-rays will be taken preoperatively, on discharge, 3 months, 1 year and 2 years as per standard of care. At 3 months, a plain long leg x-ray will also occur. All data will be de-

identified prior to analysis.

5. Do I have to participate?

Participation in this project is voluntary, and it is up to you to decide if you want to take part. Your surgeon can answer any questions you might have about the project before you decide to participate. If you do not wish to participate in this project and you wish to replace your knee joint with a Mako robotic arm assisted procedure, your surgeon will perform your surgery according to their standard clinical practice. Your surgeon can tell you detailed facts about this treatment and the benefits of other types of treatment you can have. You should feel free to talk with your surgeon about other options and/or inform your surgeon if you do not want to partake in this project.

You have the right to refuse to sign this consent form, but if you do not sign it, you will not be able to participate in this project. Your health care outside of this project, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form.

If you do decide to participate you will be asked to sign a consent form, and will be given a copy of this document for your own records. Your referring GP will also be sent a notice of clinical trial involvement. You are free to withdraw from the project at any time and do not need to provide a reason for doing so. If you choose to withdraw from the project, any of your data that has already been collected prior to the withdrawal of consent will be used and retained. If you decide not to take part, or withdraw from the project, your decision will not affect the relationship or treatment you receive from Dr Clark.

6. What will happen to me if I participate?

Your project participation begins once you sign this consent form. If deemed suitable, the surgeons will discuss the trial with you during your consultation. After your consultation, the research physiotherapist will contact you to discuss your involvement and to answer any questions. You may wish to discuss this trial with your GP, family and friends about your involvement. If you choose to participate, you will sign the consent form at your pre-admission appointment as well as undergo the preoperative testing. The preoperative testing will include function, strength, range as well as 6 standardised questionnaires. Preoperative testing will take roughly 30 minutes to complete. Once you have completed the surgery, you will continue with the standard follow up care provided by your surgeon, as well as the same functional testing at 6 weeks, 3 months, 12 months and 2 years. Please check with the surgeon if you are unsure of what this involves. All patients will not be required to return to the surgeon for any tests or visits beyond what would normally be required for follow-up care of knee replacement patients.

If you choose to participate in this project, a de-identified version of your pre-operative CT , x-rays, intraoperative data, robotic session file, demographics and outcomes will be archived in the Perth Hip and Knee Registry for future research, training and medical education.

7. What do I have to do?

There are no lifestyle or dietary restrictions regarding this project. If you sign the consent form below, you will still follow the normal standard of care as described by Dr Clark and Dr Collopy.

8. What will happen to the information being collected during the project?

If you participate in this project, your medical records and identity will be protected as required by law and as explained in this consent. The research team will use the de-identified version of your pre-operative CT, x-rays, intraoperative data, demographics and outcomes collected as part of standard practice for your surgery to complete this project. The research team will use the information collected during this project for the purposes described in this consent, and for any future anticipated or unanticipated scientific uses as the research team may deem

appropriate. The results will be written up as an educational project in a thesis and published in a recognised medical journal. This will be undertaken by a Dr Clark as part of his PhD studies. A lay report will also be sent to you within one year after completion of the study. You will not be identified in any report or publication released. Confidential information held about you will be stored on a password-encrypted computer file and destroyed at five fifteen years after completion of the study.

9. What are the possible side effects or risks of participating?

There are no side effects related to this project. In general, there are no additional risks for you because of participation in this project, as there will be no changes from standard clinical practice for this procedure. Your surgeon should have already informed you of risks/side-effects associated with knee replacement surgery, but to summarize, you may experience
none, some or all the effects listed below to varying degrees during/ following your surgery, irrespective of whether you are involved in this research study:

- Pain and symptoms of non-inflammatory degenerative joint disease may persist to a lesser or greater degree than before surgery.
- Your ability to use your knee may be worse compared to before surgery.
- Deep vein thrombosis (DVT) – a blood clot in the veins of your legs which can cause pain and swelling (occurs in approximately 26% of patients). Rarely (less than 2% of patients), parts of the clot may break off and go to the lungs which can be fatal.
- Some blood loss occurs during surgery – you may need extra blood given to you if you lose a large volume of blood.
- Infection in the joint or at the wound site which may require antibiotics or further surgery (occurs in approximately 1% of patients). Bone fracture (occurs in less than 1% of patients).
- Redness and scarring at the wound site.
- Damage to nerves and blood vessels (rare).

Other medical complications of surgery can occur, especially if you already have a pre-existing condition. Such complications include heart attack, stroke, kidney failure, pneumonia, bladder infection, or allergic reaction to medication

See Question 14 for more information regarding the possible risks related to your personal information. Talk to your surgeon if you have any questions about the risks of robotic-arm assisted knee replacement surgery, or about any risks associated with participating in this project.

10. What are the possible benefits of participating?

There are no additional risks or benefits to you as a patient as part of this study. Routine Operative techniques and post-operative care are undertaken in both groups. The data collection undertaken as part of this study is also Dr Clark's normal standard of care as part of the Perth Hip and Knee Clinic Registry. You might not receive any benefits from participating in this project but the results might help others that have joint replacement surgery in the future.

11. What are my alternative treatment options?

You have discussed alternative treatments with your surgeon which include but are not limited to: conservative non-surgical treatment, robotic-arm assisted total knee replacement surgery, total knee replacement surgery without the assistance of the arm, or no treatment at all.

12. What are the financial disclosures of this project?

Mr Clark and Mr Collopy are a paid consultants for Stryker Orthopaedics whom manufacture both the Mako robot

and the knee implant used in this study. Neither surgeon is receiving any financial benefits for undertaking this study.

13. What if new information becomes available?

Sometimes during the course of a project, new information becomes available about the technique being studied. If new information does become available, Dr Clark and Dr Collopy will discuss this with you.

14. Will my participation in this project be kept confidential?

If you participate in this Project, your medical records and identity will be kept confidential as required by law and as explained in this consent. In Australia these privacy laws and regulations comprise the Privacy Act 1988 (Cth) and the Australian Privacy Principles.

Once you sign this consent form, you allow your surgeon, their staff (including the study co-ordinator) and the hospital to give information about your health, medical records or the procedure (including CT scan, pre-operative plan, x-rays, intraoperative data, robotic session file, demographics and outcomes) to the research team, and you allow the research team to see and use this Personal Information and other information collected during, or in connection with the project. Other people or groups that may see this Personal Information collected in this Project include:

- The investigator (being the surgeon) who conducts this study and their research staff.
- Government bodies or agencies, such as the United States Food and Drug Administration (FDA) or the Australian Therapeutic Goods Administration (TGA), that may inspect all records relating to the Project.
- People who ensure that medical treatment and research studies are safe, such as the Ethics Committee that reviews the Project.

Some of the persons and groups listed above may not be required by law to protect your health information to the same extent as your surgeon and the hospital. Once your health information has been released, it may be re-disclosed or used for other purposes.

By signing this consent form, you also allow Perth Hip and Knee (or its related entities) to de-identify and/or store or your de-identified Personal Information in a Research and Development database for future research, product development, training and medical education. The data will be labelled with a unique code in place of your name, and will be stored in a password-protected database. Whilst you do not own your Personal Information, you have a right of access to your Personal Information upon your written request.

The trial is registered on Australian New Zealand Clinical Trials Registry under ACTRN12621000060842 and clinicaltrials.org under NCT04748510.

15. What are the costs involved to participate in this project?

The cost of your treatment and surgery is not affected by participation in this product and costs will be determined by your surgeon with your out of pocket expense dependant on your insurer. You will not be paid for participating in this project.

16. What if something goes wrong?

Perth Hip & Knee will not provide compensation, reimbursement, or free medical treatment if you suffer an injury or other medical complications as a result of your medical treatment, including your participation in this project. The principal investigators, Dr Clark and Dr Collopy, should be contacted immediately at **(08) 6489 1777** if such injury or complication occurs. They have informed you of the hospital's policy and their policy on such matters. Your insurer

may or may not cover such injuries or complications, however, by signing this consent form, you are not waiving any legal rights that you would otherwise have.

17. Who has reviewed the project?

The St John of God Human Research and Ethics Committee (HREC) has given ethical approval for the conduct of this project HREC # 1626 . If you have any concerns or complaints, you can contact the Executive Officer of the Committee on **(08) 9382 6940** on a confidential basis.

18. Who should I contact for more information?

This patient information leaflet has been provided in advance of your surgery to give you sufficient time to decide on your participation in the study. Should you require any further information then please do not hesitate to contact us using the details below:

Dr Gavin Clark
Chief Investigator
Consultant Orthopaedic Surgeon
Perth Hip and Knee Clinic
1/1 Wexford St
Subiaco WA 6008
Tel: 08 6489 1777

Dr Dermot Collopy
Chief Investigator
Consultant Orthopaedic Surgeon
Perth Hip and Knee Clinic
1/1 Wexford St
Subiaco WA 6008
Tel: 08 6489 1733

Beth Tippett
Research Physiotherapist
Perth Hip and Knee Clinic
1/1 Wexford St
Subiaco WA 6008
Tel: 08 6489 1777

Image 1: Lachmeter

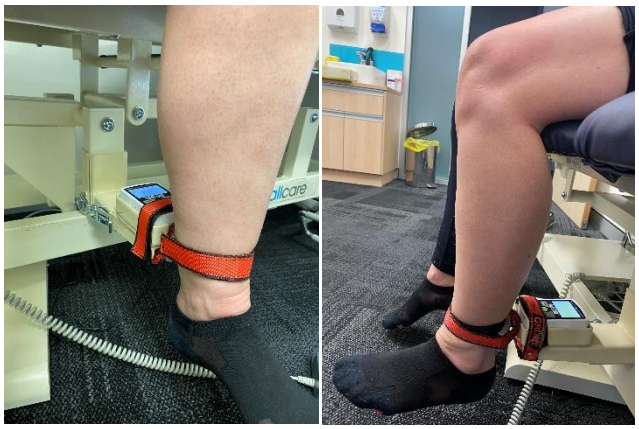


Image 2: Hand Held Dynamometer

Consent

Prospective Randomized Control Trial Comparing Functionally Aligned Total Knee Arthroplasty Utlising Mechanical Axis aligned planning versus Kinematic Axis Planning.

- Being part of this study is your choice. If you decline to participate in the study, it will not prejudice your care.
- By signing this form, you agree that Perth Hip & Knee Clinic) will be the sole owners of any and all intellectual property, including inventions, discoveries, materials, works of authorship and copyrighted materials, that is created, conceived, discovered or reduced to practice during or as a result of this project.
- By signing and dating this form below, you are saying you have carefully read all the sections of this Participant Information Form and Informed Consent Form (Protocol 1.6.1, HREC approval date : 10/11/21) and wish to participate in the project. You are also saying someone has answered all of your questions and that you voluntarily consent to be in this project. If you do not sign this form, you will not be able to take part in this project.

_____

Name of Participant/Legal Representative (Printed)

_____ _____

Signature of Participant/Legal Representative **Date Signed**

I, the undersigned have discussed the nature and purpose of the study and the possible risks and benefits of participation with the participant and/or legally authorised representative. I believe that the participant and/or their representative has been fully informed, using language which is understandable and appropriate, and has understood this explanation.

_____ _____

Signature of Investigator **Date Signed**

Withdrawal of Consent

I hereby **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal will not make any difference to my medical care or my relationship with my surgeon or other clinic staff.

_____

Name of Participant/Legal Representative (Printed)

_____ _____

Signature of Participant/Legal Representative **Date Signed**

This Withdrawal of Consent should be forwarded to:

Dr Gavin Clark and Dr Dermot Collopy
Perth Hip & Knee
Suite 1/1 Wexford Street
Subiaco WA 6008

A signed and dated copy of this entire form must be given to the patient. All parties must sign and date this research consent form in their own handwriting, in black ink.

19.8 Intraop Data Collection Form

Patient Details

RCT Patient ID-☐☐☐☐ Height: ☐☐☐cm Weight: ☐☐☐kg BMI: ☐☐

Gender: ☐ Male ☐ Female **ASA Score** _____ **Total Knee Replacement:** ☐ Left ☐ Right

Pre-Operative

ACL Intact: ☐ Yes **OR** ☐ No

Pre-Operative Plan – Femur *(Preplanning page after surgeon review)* ***Size***:____

Femoral Coronal Alignment: _____˚ ☐ Varus **OR** ☐ Valgus

Femoral Rotation to *TEA:* _____˚ ☐ Internal **OR** ☐ External

Femoral Rotation to *PCA:* _____˚ ☐ Internal **OR** ☐ External

Distal Femoral Resection: Lateral _____mm Medial _____mm

Post Femoral Resection: Lateral _____mm Medial _____mm

Femoral Flexion Angle: _____˚ ☐ Extension **OR** ☐ Flexion

Pre-Operative Plan – Tibia *(Preplanning page after surgeon review)* ***Size***:____

Tibial Alignment: _____˚ ☐ Varus **OR** ☐ Valgus

Tibial Rotation: _____˚ ☐ Internal **OR** ☐ External

Tibial Slope: _____˚ ☐ Anterior **OR** ☐ Posterior

Tibial Resection: Lateral _____mm Medial _____mm

Intra-Operative

Surgical Times *(Please record in 24-hour format)*

Surgery Start: ☐☐:☐☐ Implantation: ☐☐:☐☐ Surgery Finish: ☐☐:☐☐

(Knife-to-skin) (Hour) (Mins) *(Final implant placed) (Hour) (Mins)* *(Wound Closure) (Hour) (Mins)*

Surgical Theory *(Select one)*

☐ Mechanical Alignment **OR** ☐ Mechanical w/ Bony Release **OR** ☐ Functional Alignment

Initial Limb Alignment *(Joint balancing page – ACL and osteophytes removed)*

ROM: _____˚ **TO** _____˚ ***Note:*** *Record hyperextension as a negative value.*

Knee Alignment - Extension Without Stress: _____˚ ☐ Varus **OR** ☐ Valgus

Flexion Without Stress: _____˚ ☐ Varus **OR** ☐ Valgus

Maximum Gap Values: Extension Pose (5-15˚ flexion)

Maximal Varus: _____˚ ☐ Varus **OR** ☐ Valgus Lateral Gap: _____mm

Maximal Valgus: _____˚ ☐ Varus **OR** ☐ Valgus Medial Gap: _____mm

RCT Patient ID-☐☐☐☐

Maximum Gap Values: Flexion Pose (85-95˚ flexion)

Maximal Varus: _____˚ ☐ Varus **OR** ☐ Valgus Lateral Gap: _____mm

Maximal Valgus: _____˚ ☐ Varus **OR** ☐ Valgus Medial Gap: _____mm

Changes to Implant Position and order of changes:

Femoral Coronal: Y/N
Femoral Rotation: Y/N
Femoral Sagittal: Y/N
Femoral AP Position: Y/N
Femoral Depth: Y/N
Tibial Coronal: Y/N
Tibial Rotation: Y/N
Tibial Slope: Y/N
Tibial Depth: Y/N

Total number of changes: ____

Details of changes:

Final Intra-Op Plan

Final Plan – Femur ***Size:*** ____

Femoral Coronal Alignment: _____˚ ☐ Varus **OR** ☐ Valgus

Femoral Rotation to *TEA:* _____˚ ☐ Internal **OR** ☐ External

Femoral Rotation to *PCA:* _____˚ ☐ Internal **OR** ☐ External

Distal Femoral Resection: Lateral _____mm Medial _____mm

Post Femoral Resection: Lateral _____mm Medial _____mm

Femoral Flexion Angle: _____˚ ☐ Extension **OR** ☐ Flexion

Final Plan – Tibia ***Size:*** ____

Tibial Alignment: _____˚ ☐ Varus **OR** ☐ Valgus

Tibial Rotation: _____˚ ☐ Internal **OR** ☐ External

Tibial Slope: _____˚ ☐ Anterior **OR** ☐ Posterior

Tibial Resection: Lateral _____mm Medial _____mm

Final Plan – Alignment & Maximal Gaps

Knee Alignment - Extension Without Stress: _____˚ ☐ Varus **OR** ☐ Valgus

Flexion Without Stress: _____˚ ☐ Varus **OR** ☐ Valgus

Maximum Gap Values: Extension Pose (5-15˚ flexion)

Maximal Varus: _____˚ ☐ Varus **OR** ☐ Valgus Lateral Gap: _____mm

Maximal Valgus: _____˚ ☐ Varus **OR** ☐ Valgus Medial Gap: _____mm

Maximum Gap Values: Flexion Pose (85-95˚ flexion)

Maximal Varus: _____˚ ☐ Varus **OR** ☐ Valgus Lateral Gap: _____mm

Maximal Valgus: _____˚ ☐ Varus **OR** ☐ Valgus Medial Gap: _____

RCT Patient ID-☐☐☐☐

Soft Tissue Releases: ☐ Yes **OR** ☐ No

If Yes: *(Please circle applicable)*

MCL:	None	Microfenestration *(minor)*	Surgical release *(knife)*
LCL:	None	Microfenestration *(minor)*	Surgical release *(knife)*
PCL:	None	Partial	Complete

Other: *(if major surgical release/knife was required, please include detail of what structures were released and in what order)*_____

_____

__

Post-Implantation

Triathlon Type: CS / CR / PS *(Circle one)* Insert Thickness: _____

Final Limb Alignment *(Joint balancing page)*

ROM: _____˚ **TO** _____˚ ***Note:*** *Record hyperextension as a negative value.*

Knee Alignment - Extension Without Stress: _____˚ ☐ Varus **OR** ☐ Valgus
Flexion Without Stress: _____˚ ☐ Varus **OR** ☐ Valgus

Maximum Gap Values: Extension Pose (5-15˚ flexion)

Maximal Varus: _____˚ ☐ Varus **OR** ☐ Valgus Lateral Gap: _____mm

Maximal Valgus: _____˚ ☐ Varus **OR** ☐ Valgus Medial Gap: _____mm

Maximum Gap Values: Flexion Pose (85-95˚ flexion)

Maximal Varus: _____˚ ☐ Varus **OR** ☐ Valgus Lateral Gap: _____mm

Maximal Valgus: _____˚ ☐ Varus **OR** ☐ Valgus Medial Gap: _____mm

Patella Tracking *(Select one)*

☐ Excellent **OR** ☐ Acceptable **OR** ☐ Poor *(Requiring release)*

Femoral Bone Loss : ☐ Yes **OR** ☐ No

Note: *When capturing 'maximum stressed gaps' - if applying a valgus force to the knee and the 'maximal valgus' is still in varus, this should be recorded as varus (vice versa for max varus).*

19.9 Detailed Surgical Planning

All Patients will have pre-operative CT scan for planning as per current standard technique.

Prior to surgery Patient's pre-operative plan will be formulated on the basis of their randomisation.

The **control group** will be planned to mechanical axis alignment.

To do this the tibia will be sized to best match with the tibial plateau size without more than 2mm overhang anterolaterally or posteriorly and no overhanging of cortices medial and laterally. The coronal angulation of the tibia will be 0° of varus/valgus and posterior slope will be 3°. Resection depth will be set to a depth of 7mm maximal resection.

The femur will initially be planned with the same size as the tibia and 8mm resection depths posteriorly and distally. Coronal angulation will be zero degrees varus/valgus and flexion of 3° for males and 5° for females. Size is then adjusted to allow best match to condylar radius of curvature. Femoral rotation will be set to parallel to surgical epicondylar axis. Femoral flexion angle is then altered within the range of 0-7° to optimise the anterior cut exit point. If unable to accommodate size without notching anterior cortex or having the tip of the implant achieving bony contact, size will be altered to achieve this. Medial lateral width of component will not overhang distal femur or will be downsized.

The **investigation group** will be planned with Kinematic Axis alignment. This will be changed to functional alignment intra-operatively once soft tissue balance assessed.

To achieve this the tibia will be sized to best match with the tibial plateau size without more than 2mm overhang anterolaterally or posteriorly and no overhanging of cortices medial and laterally. The resection depths will be set to 7mm medially and laterally. (N.B. This may exceed 6° of varus angulation but this will be adjusted intra-operatively).

The same size femur is then used as starting size. 6.5mm resections are planned medially and laterally from the distal and posterior condyles.(N.B. this may result in excessive valgus but this will be adjusted intra-operatively). Femoral flexion angle is then altered within the range of 0-7° to optimise the anterior cut exit point. If unable to accommodate size without notching anterior cortex or having the tip of the implant achieving bony contact size will be altered to achieve this. Medial lateral width of component will not overhang distal femur or will be downsized.

Tibial slope is then matched to native slope whilst not exceeding combined femoral flexion and tibial slope of more than 10°. If this value exceeds 10° then tibial slope is reduced.

A standard anaesthetic approach involving Spinal anaesthetic involving 2.5mls of heavy bupivacaine and 30-60mcg buprenorphine(dependant on patient size and comorbidities). An Adductor block is then performed with ultrasound guidance using bupivacaine. Sedation or GA is then undertaken as per patient preference for comfort and anxiety. If the anaesthetic is required to be altered for any reason it will be done so at the discretion of the Consultant Anaesthetist in the best interests of the patient and any variation will be recorded.

Surgical approach is consistent for both groups. Following Anaesthetic and IDC insertion a pre-prep is undertaken with alcohol based skin prep. A tourniquet is then applied and inflated to 300mm Hg immediately prior to skin preparation and draping. The surgical area is then protected with an iodine occlusive dressing (Ioban).

The incision is midline with a medial parapatellar approach. Trackers and checkpoints are inserted into the femur and tibia, The ACL is resected if present.

Registration is then undertaken. Osteophytes are then removed from distal femur and medial tibia. A pre-resection

balancing workflow is then undertaken with maximal soft tissue gaps measured at 10 degrees of flexion and 90 degrees of flexion.

This results in the following table which values are the used as per below treatment algorithms to balance TKA

	Medial maximal gap(mm)	Lateral maximal gap(mm)
Extension	**	**
Flexion	**	**

The aim is to balance the knee within the alignment principles of each treatment arm such that extension is balanced from medial to lateral to within 1mm (2mm acceptable) and balanced from extension to flexion on the medial side to within 1mm (2 mm acceptable). The lateral flexion gap is allowed to be lax with the resections described above. The lateral flexion gap should not be tighter than the medial flexion gap.

For the **Control Group** (MA alignment) the following is undertaken to balance the TKA
These steps are undertaken but will always observe limits in below table

Parameter	Limit
HKA	2° varus – 2° valgus
Tibial coronal	2° varus – 2° valgus
Tibial slope	0°-3° posterior slope
Femoral coronal	2° varus – 2° valgus
Femoral rotation	0° IR to 3° ER to SEA
Femoral flexion	0°-7° flexion
Combined flexion (tibial slope + femoral flexion)	Max 10°

STEP 1
Alter tibial resection depth until maximal extension gap is 20mm

STEP 2

Balance the extension gap as per table below

Gap measurements	Action
Lateral ext = 20mm Medial ext <20mm	Increase Tibial varus up to two degrees with COR locked on LTP
Lateral = 20mm Medial = 20mm	Move on to Flexion balance
Lateral < 20mm Medial = 20mm	Increase Femoral valgus up to two degrees with COR locked on MFC

The medial or lateral side may remain tight after these steps. This indicates the need for soft tissue release. These will be undertaken at the trial phase where the soft tissues will be under tension and release is easier to perform.

STEP 3

Balance Medial flexion gap as per table below. N.B. If medial extension gap remains tight aim to match medial flexion gap to equalise medial side

Gap measurements	Action
Medial Flex = Medial Ext Lateral flex >=20mm	Move on to check Femoral flexion
Medial flex < Medial extension Lateral flex >= 20mm	Externally rotate femur by up to 3 degrees with COR locked on posterior lateral femoral condyle
Medial flex < Medial extension Lateral flex < 20mm	Increase posterior resection depth until medial flexion depth equals medial extension gap. (N.B. need to check femoral rotation allows for sufficient bone contact anteriorly)
Medial flex > Medial extension Lateral flex > 20mm	Decrease posterior resection depth until medial flexion depth equals medial extension gap. (N.B. need to check femoral rotation prevents notching anteriorly)
Medial Flex = Medial Ext Lateral flex < 20mm	Requires internal rotation of femur with COR locked on posterior medial femoral condyle (N.B. Surgeon required to check stability of femoral tracker in flexion with the checkpoint as this may cause this rare combination)

STEP 4

Check Anterior cut on plan to ensure enough bone contact without notching. Anterior cut should exit within 1cm of tip of femoral prosthesis. Femoral flexion with COR locked at centre of femoral component radius of curvature should be adjusted within the range 0-7 degrees of flexion to finalise component position.

STEP 5

Execute bone cuts as planned and trial with 9mm insert. Perform soft tissue releases as necessary to balance gaps within 1mm. Utilise ligament balancing page on Mako software to assess soft tissue balance aim for equal gaps and accept differences of up to 2mm if best efforts to balance have been made. Assess sagittal stability clinically and upsize insert if positive drawer test. Partial PCL release can be performed for sagittal balance if tight. This can then be trialled and if adequate sagittal stability a CS insert utilised. IF PCL needs to be completely released for balance then conversion to a PS component will be required.

STEP 6

Insert definitive implants. Tibia and Patella are cemented. The femoral component is uncemented. Reassess balance for final measurements.

STEP 7

Lavage of joint with pulsatile lavage system. LA infiltration with 80-100ml(dependant on patient mass) of 0.2% Bupivicaine, 1g tranexamic acid and 1 ml 1:1000 Adrenaline throughout capsule and soft tissues. Closed in layers with either subcuticular sutures or staples dependant on patient skin quality.

For the **Investigation Group** (Functional alignment) the following is undertaken to balance the TKA. These steps are undertaken but will always observe limits in below table

Parameter	Limit
HKA	6° varus – 3° valgus
Tibial coronal	6° varus – 3° valgus
Tibial slope	0°-7° posterior slope
Femoral coronal	3° varus – 6° valgus
Femoral rotation	6° IR to 6° ER to SEA
Femoral flexion	0°-7° flexion
Combined flexion (tibial slope + femoral flexion)	Max 10°

STEP 1
Alter tibial resection depth until maximal extension gap is 20mm

STEP 2

Balance the extension gap as per table below

Gap measurements	Action
Lateral ext = 20mm Medial ext <20mm	Increase tibial varus up to 6° with COR locked on LTP. If reach Tibial limit of 6° varus then decrease femoral valgus with COR locked on LFC until balanced or reach HKA limit.
Lateral = 20mm Medial = 20mm	Move on to Flexion balance
Lateral < 20mm Medial = 20mm	Decrease tibial varus with COR locked on MFC until reach HKA limit

The medial or lateral side may remain tight after these steps. This indicates the need for soft tissue release. These will be undertaken at the trial phase where the soft tissues will be under tension and release is easier to perform.
STEP 3

Balance Medial flexion gap as per table below. N.B. If medial extension gap remains tight aim to match medial flexion gap to equalise medial side

Gap measurements	Action
Medial Flex = Medial Ext Lateral flex >=20mm	Move on to check Femoral flexion
Medial flex < Medial extension Lateral flex >= 20mm	Externally rotate femur with COR locked on posterior lateral femoral condyle until balance achieved
Medial flex < Medial extension Lateral flex < 20mm	Increase posterior resection depth until medial flexion depth equals medial extension gap. (N.B. need to check femoral flexion allows for sufficient bone contact anteriorly)

Medial flex > Medial extension Lateral flex > 20mm	Decrease posterior resection depth until medial flexion depth equals medial extension gap. (N.B. need to check femoral rotation prevents notching anteriorly)
Medial Flex = Medial Ext Lateral flex < 20mm	Requires internal rotation of femur with COR locked on posterior medial femoral condyle (N.B. Surgeon required to check stability of femoral tracker in flexion with the checkpoint as this may cause this rare combination)

STEP 4

Check Anterior cut on plan to ensure enough bone contact without notching. Anterior cut should exit within 1cm of tip of femoral prosthesis. Femoral flexion with COR locked at centre of femoral component radius of curvature should be adjusted within the range 0-7 degrees of flexion to finalise component position.

STEP 5

Execute bone cuts as planned and trial with 9mm insert. Utilise ligament balancing page on Mako software to assess soft tissue balance aim for equal gaps and accept differences of up to 1mm. For greater differences adjust plan of tibial cut to balance if possible within specified limits. Perform recut and reassess balance. If unable to achieve balance within limits of bony alignment perform soft tissue releases as necessary to balance gaps within 1mm. Utilise ligament balancing page on Mako software to assess soft tissue balance aim for equal gaps and accept differences of up to 2mm if best efforts to balance have been made. Assess sagittal stability clinically and upsize insert if positive drawer test. Partial PCL release can be performed for sagittal balance if tight. This can then be trialled and if adequate sagittal stability a CS insert utilised. IF PCL needs to be completely released for balance then conversion to a PS component will be required.

STEP 6

Insert definitive implants. Tibia and Patella are cemented. The femoral component is uncemented. Reassess balance for final measurements.

STEP 7

Lavage of joint with pulsatile lavage system. LA infiltration with 80-100ml(dependant on patient mass) of 0.2% Bupivicaine, 1g tranexamic acid and 1 ml 1:1000 Adrenaline throughout capsule and soft tissues. Closed in layers with either subcuticular sutures or staples dependant on patient skin quality.

Post-operative Management

All patients will be transferred to recovery. There they will have standard pain protocol guidelines followed. When alert, comfortable and stable the patient will be transferred back to the orthopaedic ward. Intravenous fluids will continue until drinking oral fluids.

Patients will be charted regular slow release narcotic analgesia and immediate release narcotic to be given as required. Oxycodone will be first choice narcotic with Tapentadol, Buprenorphine, and Tramadol as second line agents.

Patients will also be charted regular Paracetamol, Celebrex (if<80 years and good renal function), Pregabalin (dose dependant on age and size). They will have regular aperients.

All patients will have regular cryotherapy.

IDC will be removed prior to 8am morning after surgery. IV cannula will be removed after last dose of IV Abs (24/24 post surgery).

Patients will be stood and have their knee ranged on day of surgery. They will mobilise as able and no limits will be placed on flexion range.

Patients will have daily Physiotherapy and undertake self-directed exercise three times per day consisting of seated flexion exercises and bed based extension exercises.

Discharge criteria will be patient comfortable and safely mobile utilising oral analgesia, with a dry wound and greater than 80 degrees of flexion, having had a bowel motion.