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# Does soft tissue balancing using intraoperative pressure sensors improve clinical outcomes in total knee arthroplasty? A protocol of a multicentre randomised controlled trial

Samuel J MacDessi,[1,2,3,4] Aziz Bhimani,[5,6] Alexander W R Burns,[7,8] Darren B Chen,[1,2] Anthony K L Leong,[5,6,9] Robert B Molnar,[1,10] Jonathan S Mulford,[11] Richard M Walker,[12,13] Ian A Harris,[14,15] Ashish Diwan,[1,4] Jil A Wood[3]

**Correspondence to**
Dr. Samuel J MacDessi;
samuelmacdessi@sydneyknee.com.au

## ABSTRACT

**Introduction** Soft tissue imbalance is considered to be a major surgical cause of dissatisfaction following total knee arthroplasty (TKA). Surgeon-determined manual assessment of ligament tension has been shown to be a poor determinant of the true knee balance state. The recent introduction of intraoperative sensors, however, allows surgeons to precisely quantify knee compartment pressures and tibiofemoral kinematics, thereby optimising coronal and sagittal plane soft tissue balance. The primary hypothesis of this study is that achieving knee balance with use of sensors in TKA will improve patient-reported outcomes when compared with manual balancing.

**Methods and analysis** A multicentred, randomised controlled trial will compare patient-reported outcomes in 222 patients undergoing TKA using sensor-guided balancing versus manual balancing. The sensor will be used in both arms for purposes of data collection; however, surgeons will be blinded to the pressure data in patients randomised to manual balancing. The primary outcome will be the change from baseline to 1 year postoperatively in the mean of the four subscales of the Knee Injury and Osteoarthritis Outcome Score (KOOS$_4$) that are most specific to TKA recovery: pain, symptoms, function and knee-related quality of life. Secondary outcomes will include the surgeon's capacity to determine knee balance, radiographic and functional measures and additional patient-reported outcomes. Normality of data will be assessed, and a Student's t-test and equivalent non-parametric tests will be used to compare differences in means among the two groups.

**Ethics and dissemination** Ethics approval was obtained from South Eastern Sydney Local Health District, Approval (HREC/18/POWH/320). Results of the trial will be presented at orthopaedic surgical meetings and submitted for publication in a peer-reviewed journal.

**Trial registration number** ACTRN#12618000817246

### Strengths and limitations of this study

► This will be a large, multicentre, randomised controlled trial that will inform future practice about the benefits of using intraoperative pressure sensors for soft tissue balancing in total knee arthroplasty (TKA) surgery.
► The study will be investigator-initiated, theoretically minimising selection and reporting bias.
► It will be pragmatic, aiming to include all patients who routinely undergo TKA in the general population.
► The secondary outcomes will provide rich multimodal data, including objective radiological and functional information and significant patient-derived evidence.

function for the majority of people with end-stage knee osteoarthritis. However, up to 20% of patients undergoing TKA internationally report some dissatisfaction following their surgery.[1–3] The Australian Clinical Outcomes Registry,[4] and the Swedish Knee Arthroplasty Registry[5] report similar results in terms of patients who rate their knee as either 'fair', 'poor' or 'unknown/no answer' at follow-up.

Dissatisfaction following TKA is a multi-factorial problem. The surgical causes are commonly related to soft tissue imbalance or malalignment. Both of these can result in knee stiffness, instability, asymmetric joint laxity and patellofemoral maltracking. Malalignment may also result in early component failure, implant loosening, polyethylene wear or osteolysis.[3 5–8]

Achieving balance of soft tissues through a range of motion is now considered a primary surgical goal to optimise patient outcomes. The main surgical technique for surgeons

## INTRODUCTION

Total knee arthroplasty (TKA) is a successful operation in alleviating pain and improving

**Figure 1** Pressure sensor trial inserts. (A) Variants of Verasense inserts that are available in both cruciate-retaining and posterior-stabilised designs. (B) Wireless graphical display of compartmental loads and tibiofemoral contact points in real time.

to determine knee balance is subjective intraoperative assessment using varus and valgus stressing of the knee. A recent study at our institution found that surgeon-determined assessment of knee balance was poor, particularly when determining if the knee was unbalanced, with a specificity of 37.7%.[9] Other methods that have been used to optimise balance have included gap balancing (where femoral extension and flexion osteotomies are made based on ligament tension) and computer-assisted navigation, which can assess ligament elongation. However, none of these methods is able to quantify knee compartment pressures and tibiofemoral kinematics.

Intraoperative pressure 'sensors' have recently been introduced for use during TKA to quantify soft tissue balance and tibiofemoral kinematics (figure 1A and B). The Verasense System (OrthoSensor, Dania Beach, Florida, USA) uses microelectronic sensors embedded in a standardised trial spacer to determine pressures at peak contact points in the medial and lateral tibiofemoral compartments during component trialling. Real-time analysis of compartmental loads allows a combination of ligamentous releases and bone readjustments to be performed to optimise coronal and sagittal plane soft tissue balance. The sensor also allows dynamic optimisation of tibiofemoral positioning through a range of motion.[10]

In 2013, Gustke and colleagues evaluated 176 patients using pressure sensors for soft tissue balancing.[11] The cohort was separated into balanced versus unbalanced groups based on recorded intercompartmental pressure differentials. At 6 months, the balanced cohort demonstrated significantly better patient-reported scores compared with the unbalanced group. However, there was no control group in this study (both groups used sensor data), and the number of patients in the unbalanced group (13%) was significantly smaller than those

in the balanced cohort (87%). A 2-year follow-up report found that satisfaction scores were significantly higher in the balanced cohort (96.7% satisfied) versus the unbalanced group (82.1% satisfied).[12]

Elmallah *et al* reported on a series of 22 patients who received either sensor-guided assessment (n=10) or manual gap balancing (n=12).[13] Patients with sensor-guided balancing (SGB) had significantly lower medial compartmental loads at 10°, 45° and 90° of flexion, compared with the manual balancing (MB) cohort. Additionally, the sensor group had a lower mean difference between medial and lateral compartment loads and a greater need for soft tissue releases to balance the knee. This study also found improved tibiofemoral congruence in the sensor group versus the MB group, but it did not include patient-reported outcomes.

Because soft tissue imbalance may lead to patient dissatisfaction and potentially to revision knee surgery, it is important to determine whether improvements in soft tissue balance during TKA significantly improve clinical outcomes. There are no published randomised controlled trials (RCTs) that have quantified knee balance and determined whether surgical balancing using sensors improves patient outcomes compared with manual techniques.

The primary aim of this study is to determine if there is benefit in using sensors to achieve knee balance in TKA surgery. Our primary hypothesis, using an intention-to-treat analysis, is that achieving knee balance with use of sensors will improve $KOOS_4$ outcomes at 12 months when compared with current MB techniques. Secondary hypotheses are that functional and additional patient-reported outcomes will improve using sensors for knee balancing, and that surgeon-determined (manual) assessment of knee balance is a poor predictor of the true state of soft tissue balance.

## METHODS AND ANALYSIS
### Study design
We will conduct a multicentred, investigator-initiated RCT comparing the clinical outcomes of SGB versus MB in patients undergoing TKA. Sensors will be used in both arms for objective analysis of balance; however, in the MB group, the surgeon will be blinded to the data provided by the insert.

Eight surgeons will undertake surgeries at 11 different sites, in both public and private hospitals. All surgeons have a minimum experience of 8 years in specialist practice (range 8–13 years) and an annual TKA surgical volume ranging from 50 to 300 TKA cases per annum. Five of eight surgeons have used the sensor for a minimum of 1 year, while the other three have used the sensor for 15–30 cases. All surgeons will follow the surgical technique as per the manufacturer's product guidelines.[14]

In order to increase pragmatism of this study, we will aim to include all patients who would routinely undergo elective TKA surgery in the general population. As such, we will include both unilateral and bilateral procedures,

patients with extra-articular deformity from prior fracture or osteotomy and those with severe stiffness. These variables will be analysed in regression models.

## Eligibility
### Inclusion criteria
1. All patients suitable for TKA aged 20–85 years.
2. Patients who meet the indications for primary TKA using the Legion or Genesis II cruciate-retaining or posterior-stabilised TKA system (Smith & Nephew, Memphis, Tennessee, USA). These prostheses have identical articular geometric characteristics with posterior condylar design differences being adjusted for through surgical technique.
3. Subjects diagnosed with one or more of the following conditions:
   – Osteoarthritis.
   – Rheumatoid or other inflammatory arthritis.
   – Posttraumatic osteoarthritis.

### Exclusion criteria
1. Requirement of constrained prostheses (constrained condylar or rotating hinge prosthesis) due to significant ligament deficiencies.
2. TKA for acute fracture or tumour.
3. Participants unable to provide consent or complete questionnaires due to cognitive incapacity or English language deficiency.
4. Participants unable to commit to full follow-up schedule over 2 years.

Potential participants received a patient information sheet, with invitation for participation and explanation of the trial. All participants consented before allocation (online supplementary appendix 1: Master Patient Information Sheet and Consent Form).

## Allocation
Randomised allocation (1:1) per patient will occur at the commencement of surgery through the National Health and Medical Research Council Clinical Trial Centre's centralised telephone service. Stratification factors will include patient age, surgeon and gender. The surgeon will be notified of the treatment allocation only after data have been independently recorded on the state of knee balance and immediately prior to any knee balancing being undertaken.

For those patients undergoing bilateral TKA (or sequential unilateral TKA at different time points during the trial), both knees will be allocated to the same arm, as randomisation will be done at the level of the patient, not the knee. This is because the primary outcome instrument partly measures overall function and quality of life, outcomes that patients are unable to attribute to one limb over another.

Although the surgeons will not be blinded to the allocation, the participants, assessors and statisticians will be blinded to enable unbiased collection and analysis of outcomes. Independent data collectors will be employed to undertake randomised allocation and data recording, and to ensure transparency, concealment and integrity of blinding. Sensor data will be concealed from the surgeon while the initial assessment of knee balance is undertaken. Data will then be available to the surgeon for balancing in those patients allocated to the SGB group only. Concealment of sensor data will be maintained in the MB group. Consolidated Standards of Reporting Trials 2010 guidelines will be used to report enrolment, allocation, follow-up and analysis of the study group (figure 2). SPIRIT 2013 checklist and SPIRIT-PRO extensions are also provided in online supplementary table 1 to ensure adherence to study protocol.

Unblinding will occur only when knowledge of the treatment allocation is essential for further clinical management, such as a need for revision knee surgery for instability or malalignment.

## Interventions
### Treatment (SGB) Group
In the SGB group, surgeons will be allowed to use intraoperative sensor data to balance the knee as per surgical protocol. Compartmental pressure loads will be recorded prior to, and then on completion of knee balancing at 10°, 45° and 90° of flexion.

### Control (MB) Group
In MB group, surgeons will use their method of choice to achieve knee balance. This may include manual assessment of soft tissue balance with ligaments stressing, gap balancing methods with spacer blocks, use of computer-assisted stress curves of coronal laxities or use of tensiometers. The technique to achieve knee balance will be recorded. Compartmental pressure loads will be recorded prior to, and on completion of knee balancing with the sensor in situ, but the sensor data will not be viewed during knee balancing.

## Baseline measures
### Baseline data
Baseline data will include age, gender, laterality of surgery, body mass index and primary diagnosis of TKA. In addition, description of extra-articular deformities (degree and location), prior knee ligament surgeries and prior osteotomy surgeries will be recorded.

### Operative data
Operative data to be recorded will include type of prosthesis (cruciate-retaining, posterior-stabilised), and size and fixation method of each implant. The decision to resurface the patella and implant characteristics will be recorded. Other operative details will include operating time (wound incision to skin closure), alignment technique (conventional guides, image-derived guides, computer-assisted, robotic-assisted), surgical approach and intraoperative complications. The American Society of Anaesthesiologists grade[15] will be recorded.
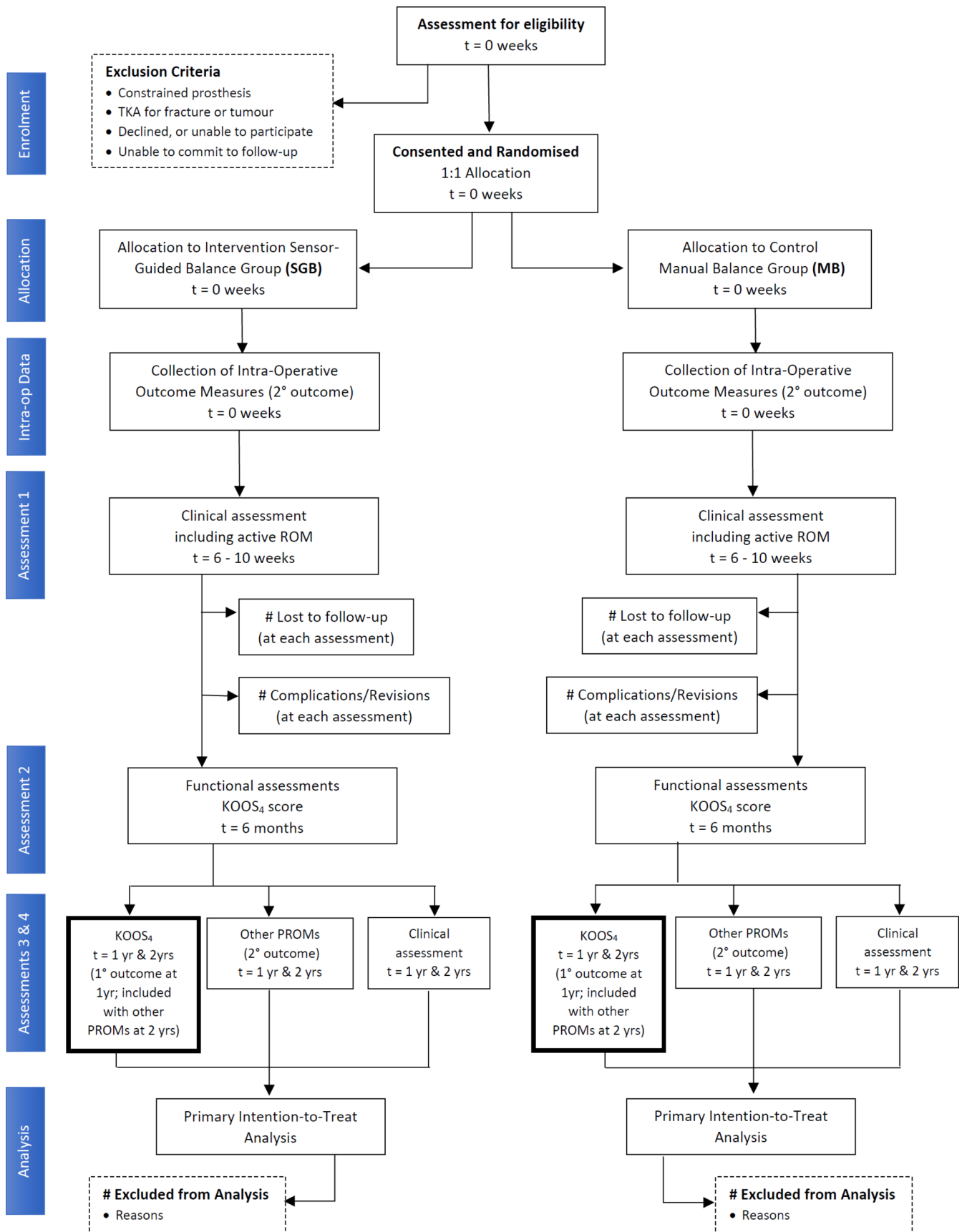
**Figure 2** Sensor-guided balancing in TKA RCT protocol. Patient flow diagram. #, number; KOOS₄, Knee Osteoarthritis Outcome Score, including mean aggregated components of four domains: pain, symptoms, function in daily living and knee-related quality of life; PROMs, patient-reported outcome measures; RCT, randomised controlled trial; t, time point; TKA, total knee arthroplasty.

## Primary outcome measure

The primary outcome measure will be the difference between preoperative and 1 year postoperative mean of the four subscales of the Knee Injury and Osteoarthritis Outcome Score ($KOOS_4$) that are most specific to TKA recovery: pain, symptoms, function in daily living and knee-related quality of life. The fifth subscale, function in sport/recreation, has a significant floor effect in this population and therefore will not be included.[16 17] The $KOOS_4$ is an aggregated mean of the four subscales, each scored 0–100 (worst to best). This method of analysis is based on recommendations by the score designers for use in RCTs.[16] The $KOOS_4$ will be administered 12 months postoperatively.

## Secondary outcome measures

### In-hospital data

In-hospital data to be obtained are as follows:
1. Length of stay (from day of surgery to day of discharge).
2. Discharge destination:
   – Home.
   – In-patient rehabilitation unit.
   – Nursing home facility.

### Patient-reported outcome measures

1. *KOOS*: at 6 months and 2 years to assess longitudinal progress.[16 17]
2. *Knee Society Score (KSS 2011)*: preoperatively and at 1 and 2 years postoperatively. The KSS is both patient-derived and physician-derived, and assesses pain, function and objective clinical and radiographic outcomes.[18]
3. *Forgotten Joint Score:* preoperatively and at 1 and 2 years postoperatively. The FJS-12 focuses on patients' awareness of their knees in everyday life. Low ceiling effects and good relative validity allow monitoring of long-term outcomes, particularly in well-performing groups after TKA.[19]
4. *EQ5D-5L*: preoperatively and at 1 and 2 years postoperatively. EQ5D is a standard measure of overall health status that provides a simple descriptive profile and an index value for health status.[20 21]

Strategies for improving adherence to protocol outcomes will include clear elucidation during consenting of the importance of committing to follow-up visits, patient-reported outcome measures (PROMs) and X-rays. Participants will have the opportunity to ask questions, and key messages about the study will be reinforced at each visit. In order to prevent missing data, administrative systems will be employed to diligently schedule follow-up appointments, provide reminders and monitor retention.

### Intraoperative outcome measures

#### Surgeon determination of knee balance

Without assistance of sensor data, the surgeon will be asked about the status of knee balance at 10°, 45° and 90° of knee flexion with the sensor in situ (Balanced: Yes or No). 'Agreement' is defined as the agreement with the sensor at two out of three knee positions.

#### Tibiofemoral compartmental pressure loads

Initial and final medial and lateral compartmental pressure loads will be compared in both groups at assessment angles of knee flexion. 'Balanced' using the sensor will be defined as a pressure difference of <15 psi between medial and lateral compartments at all flexion angles, with no individual pressure exceeding 40 psi.[10]

#### Tibiofemoral match

The sensor provides tibiofemoral rotational alignment data as a measure of tibiofemoral match between the femoral component and sensor insert. Tibiofemoral match will be compared in both groups at 10°, 45° and 90° of knee flexion and is recorded in degrees. External rotation will be recorded as a positive value and internal rotation as a negative value. Deviation of >5° from neutral will be defined as a mismatch. Optimal rotation will be defined as the rotational coupling of ≤5° at two out of three knee positions.

The surgical assistant will also perform a blinded assessment of knee balance as well as record pressuring loads and tibiofemoral match. The experience of the assistant will be recorded (fellow, senior resident, junior resident). Relationships between level of experience and capacity to determine balance will be explored as well as level of agreement between assessors. Repeatability of quantitative measures will be analysed using intraclass correlation coefficients with two-way mixed-effects models. However, surgeon-recorded data only will be used as the end point for analysis as this is more representative of surgical practice.

### Radiographic measures

Preoperative and postoperative radiographs will include hip-to-ankle alignment films and knee AP erect, 30° lateral and skyline x-rays as per the study assessment timeline. Radiographic data will include hip-knee-ankle angle, lateral distal femoral angle, medial proximal tibial angle and any extra-articular femoral or tibial angular deformities measured in the coronal and sagittal planes.

### Functional outcome measures

#### Knee range of motion

This will be measured at 10 weeks and 6 months postoperatively. Measurements will be performed in supine position based on the photographic method of Naylor *et al.*[22] This method was found to be superior to goniometry alone, and a photographic record allows repeatability and blinding. This will allow the surgeons and their assistants to image active range of motion, but not evaluate it at the time, minimising observer bias. Markers will be placed on the greater trochanter, lateral epicondyle of the femur and lateral malleolus. Knee flexion will be recorded as a positive value and knee hyperextension as a negative value. The following will be recorded: maximal active extension (with hyperextension as negative, full extension as zero and flexion contracture as positive) and

maximal active flexion. From these two values, the arc of knee motion will be calculated.

### Timed up and go test

This will be measured at 6 months postoperatively. Participants will be asked to stand up from a standard chair (seat height 44–47 cm), walk a distance of 3 m (marked on the floor) at a comfortable pace, turn, walk back and sit down. Participants will be permitted to use routine walking aids. No physical assistance will be given. This task will be performed twice. Shorter times indicate better performance.[23]

### Six-minute walk test (6MWT)

This will be measured at 6 months postoperatively. The participant will be instructed to walk as far as possible for 6 min up and down a 25 m path, pivoting to turn at the end of each lap. Timing will commence as the participant steps over the start line. Standardised encouragement will be given to the patient after each minute. If they are unable to complete 6 min, they will be instructed to maintain their position while the assessor measures the final partial lap with a trundle wheel. The use of a walking aid and standing rests will be permitted. This task will be performed once. High repeatability of the 6MWT has been established in patients awaiting TKA.[24]

### Complications

Recorded complications will include serious adverse events related to the operation (eg, stiffness requiring manipulation under anaesthesia [reoperation] or total or partial component exchange [revision]) and adverse events unrelated to the operation (box 1). Intraoperative and postoperative complications will be assessed and recorded at all time points (table 1). Incidents will be reported to Human Research Ethics Committee and RGO offices as per NSW Health policy and procedures.

PROMs will be monitored throughout the study to supplementally inform the clinical care of individual participants.

### Sample size

Roos and colleagues recommend the minimum clinically important change in $KOOS_4$ to be between 8 and 10 with an SD of 15. The four subscales, each a score out of 100, will be aggregated as a mean value.[16 25] An RCT investigating TKA versus non-operative treatment for osteoarthritis by Skou et al used the $KOOS_4$ with subscales of pain, symptoms, function and QoL. They found a 1 year change in $KOOS_4$ of 32.5 points (95% CI 26.6 to 38.3) in the TKA group.[26]

Using a one-to-one allocation, 5% significance, an SD of 15 and a 90% power to detect the minimum 8-point difference in change on the $KOOS_4$, a sample size of 75 patients per group will be required to test the primary hypothesis. Assuming a 10% loss to follow-up, a minimum of 167 patients in total will be required to ensure adequate sample size with an intention-to-treat analysis of SGB versus MB.

### Box 1    Complications

- ► Bleeding
- ► Cardiac event
- ► Cellulitis
- ► Death
- ► Deep venous thrombosis (specify index leg, other leg, both legs)
- ► Delirium
- ► Dislocation or joint instability requiring bracing or surgery
- ► Drug reaction
- ► Fall
- ► Fat embolus
- ► Fracture
- ► Index joint reoperation/revision during study period
- ► Joint or lower limb swelling
- ► Joint stiffness requiring surgery (manipulation or revision)
- ► Leg length discrepancy
- ► Muscle weakness
- ► Nerve injury
- ► Parasthaesia or numbness
- ► Pressure area
- ► Pulmonary embolus
- ► Respiratory infection
- ► SSI requiring intravenous antibiotics
- ► SSI requiring oral antibiotics
- ► SSI requiring surgery with prosthetic removal
- ► SSI requiring surgery without prosthetic removal
- ► Stroke
- ► Unexpected pain
- ► Urinary infection or retention
- ► Wound dehiscence
- ► Other, specify

SSI, surgical site infection.

However, previously published data from the principal investigator noted that use of an intraoperative pressure sensor results in an additional 46.5% of surgical adjustments beyond what the surgeon believed was required on manual assessment to achieve knee balance.[27] Hence, we anticipate that there will be approximately half of TKAs in the MB group that will be balanced, and that all knees in the SGB group will be balanced.

Assuming any difference in clinical outcomes between groups will most likely result from improvement in knee balance as opposed to use of the sensor, a further sample size calculation was undertaken on an as-treated basis comparing balanced versus unbalanced knees. With a three-to-one allocation of balanced to unbalanced knees (three of four knees being balanced once treated), an SD of 15 and a 90% power to detect the minimum 8-point difference in change on the $KOOS_4$ score, we will require 150 patients in the balanced group and 50 in the unbalanced group if the null hypothesis were to be rejected. A total sample size of 200 patients will be required, with a 10% loss to follow-up requiring a total sample size of 222.

### Data collection and monitoring

All PROM data will be obtained from patients at preoperative and postoperative consultations in paper form, and

**Table 1** Schedule of study assessments

| | Preoperative | Intraoperative | Index admission | 6–10 weeks | 6 months | 1 year | 2 years |
|---|---|---|---|---|---|---|---|
| Signed informed consent and Patient Information Sheet | X | | | | | | |
| Demographics | X | | | | | | |
| Intraoperative data | | X | | | | | |
| Clinical assessment | X | | | X | | X | X |
| KOOS score | X | | | | X | X | X |
| KSS score | X | | | | | X | X |
| FJS score | X | | | | X | X | X |
| EQ5D-5L score | X | | | | | X | X |
| In-hospital data | | | X | | | | |
| Functional assessments | | | | | X | | |
| Knee range of motion | X | | | X | X | X | X |
| Radiographs: AP, Lat, Skyline (and 4-ft films preoperatively) | X | | X | | X | X | X |
| Adverse event reporting | | X | X | X | X | X | X |

FJS, Forgotten Joint Score; KOOS, Knee Injury and Osteoarthritis Outcome Score; KSS, Knee Society Score.

then stored centrally in a password-protected database accessed only by the study coordinator. Intraoperative data will be collected by the data collector and forwarded to the study coordinator. Postoperative follow-ups will be completed by the treating surgeons and their assistants. A research physiotherapist who is blinded to patient allocation will be recruited to undertake functional outcome measures at the relevant time points.

No formal data monitoring committee is deemed necessary for this trial because of its minimal risks and because both trial arms will offer standard, accepted surgical interventions. The accumulating data, however, will be monitored continuously by the principal investigator and the study coordinator to determine if the trial should be modified or discontinued.

Auditing of trial conduct will be carried out by South Eastern Sydney Local Health District Human Research Ethics Committee.

### Stopping rules

This trial will not involve a primary safety endpoint, nor activities of high risk to study participants. It will use a device already entered onto the Australian Register of Therapeutic Goods. The risks of participating in the study will be comparable to standard medical care, and the sensor will be used within its approved product indications by experienced clinicians performing an established intervention in line with local, national and international protocols (Type A Risk Category).

In the course of a routine TKA, trial tibial inserts are used to provisionally determine the correct size of the final tibial insert. The sensor takes the place of the usual trial insert, performing the same indicative sizing function, while also providing measurements of pressure within the tibiofemoral compartments.

For these reasons, formally articulated stopping rules for harm will be considered unnecessary for this study. Similarly, because the trial investigates outcomes associated with a device that is approved and already being used routinely, and because recruitment will be finished before the primary outcome measure is collected, it is not anticipated that there will be a need for stopping rules for benefit.

Interim monitoring for a pattern of unexpected serious adverse effects will be conducted weekly by the study coordinator to determine if the trial should be modified or discontinued early.

### Data analysis

Normality of data distribution will be assessed, and Student's t-test will be used to compare differences in means with continuous variables. Chi-squared test and Fisher's exact test will be used for categorical data analysis as appropriate. Intention-to-treat analysis will be performed in the primary analysis. In addition, an as-treated analysis including participants according to treatment received will be added as a secondary analysis. Any differences in baseline patient and operative

characteristics between groups will be adjusted for in regression models.

If >20% of data are missing from the randomised sample, the missing data will be imputed. However, attempts will be made to minimise missing data by contacting patients directly by phone or via mail follow-up.

## Patient and public involvement
Neither patients nor the public were involved in the development of the research question, study design or implementation of this trial.

## ETHICS AND DISSEMINATION
### Safety considerations
As the two groups being analysed will be offered current routine standards of care, we do not anticipate either the intervention or control arm will be associated with any adverse events beyond those that patients are normally exposed to during TKA.

All sites where the trial is conducted will have provisions for liability insurance, and it will be a requirement for each site to maintain their own indemnity insurance. There will be additional information in the Patient Information Sheet and Consent form instructing participants to notify the principal investigator of any adverse events or complications that arise during the course of the trial.

## Data management
Data from local site investigators will be submitted securely to the study coordinator and stored in a password-protected database in the chief-investigator's rooms. All records that contain names or other personal identifiers will be stored separately from study records identified by code numbers. The electronic database will be maintained on a password-protected computer and any papers are locked in a filing cabinet accessible only to the study coordinator. At the end of the study, all paper copies will be scanned and destroyed. During the trial period, only the study coordinator will have access to the full trial data set.

## Dissemination
The aggregate, deidentified results of this research will be presented at national and international orthopaedic surgical meetings and submitted to a high impact journal for publication. Additionally, the authors will publish a deidentified, participant-level data set and statistical code after journal publication to enable verification and replication of the study.

## Author affiliations
[1]Orthopaedic Surgery, St George Private Hospital, Kogarah, New South Wales, Australia
[2]Orthopaedic Surgery, The Canterbury Hospital, Campsie, New South Wales, Australia
[3]Clinical Research, Sydney Knee Specialists, Kogarah, New South Wales, Australia
[4]St George Clinical School, University of New South Wales, Kogarah, NSW, Australia
[5]Orthopaedic Surgery, Wollongong Private Hospital, Wollongong, New South Wales, Australia
[6]Orthopaedic Surgery, Wollongong Public Hospital, Wollongong, New South Wales, Australia
[7]Orthopaedic Surgery, Canberra Private Hospital, Deakin, Australian Capital Territory, Australia
[8]Orthopaedic Surgery, Calvary John James Private Hospital, Deakin, Australian Capital Territory, Australia
[9]Orthopaedic Surgery, Kareena Private Hospital, Caringbah, New South Wales, Australia
[10]Orthopaedic Surgery, The Sutherland Hospital, Caringbah, New South Wales, Australia
[11]Orthopaedic Surgery, Calvary St Luke's Hospital, Launceston, Tasmania, Australia
[12]Orthopaedic Surgery, Sydney Southwest Private Hospital, Liverpool, New South Wales, Australia
[13]Orthopaedic Surgery, The Fairfield Hospital, Prairiewood, New South Wales, Australia
[14]South West Sydney Clinical School, University of New South Wales, Liverpool, New South Wales, Australia
[15]Whitlam Orthopaedic Research Centre, Ingham Institute for Applied Medical Research, Liverpool, New South Wales, Australia

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