**Outcomes following randomised patellar resurfacing vs retention in anatomically designed total knee arthroplasty**

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| 1. PROJECT DETAILS
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* 1. Project Details

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| **Protocol/Research Project Title:** | Outcomes following anatomically designed total knee arthroplasty with randomised patellar resurfacing versus retention.  |
| **Protocol Number (Version and Date):** | Version 1, 1 May 2020 |
| **Project Start Date:** | Once approval granted | **Project Finish Date:** | 30 Months after start |
| **Coordinating Principal Investigator Name:** | Prof Piers J. Yates |
| **Coordinating Principal Investigator Contact Details:** | Orthopaedics WA, Wexford Medical Centre, Murdoch, 6150piersyates@hotmail.com |
| **Co-Investigators:** | Dr Heidi WilsonProf Gareth ProsserA/Prof Christopher JonesMr Peter D’AlessandroDr Steve EdmondstonMs Jade Evans |
| **Sponsor Name (if applicable):** | n/a |

* 1. Project Summary

This will be a randomised prospective study aiming to evaluate and compare patient reported outcome measures (PROMs) in patients who have their patella resurfaced during Total Knee Arthroplasty (TKA) and those who don’t. To control for variability between implant design, only patients undergoing TKA using the SAIPHTM knee system (MatOrtho, Surrey, UK) will be recruited. Patients who are unable to participate due to cognitive impairment or language barriers, those with chronic pain in a joint other than the operative site, those with a previous high tibial osteotomy to the site and those with posttraumatic or inflammatory arthritis will be excluded from the study.

Recruitment will occur at time of booking for the procedure, basic patient demographics will be recorded and consenting patients will complete three questionnaires pre-operatively; the Oxford Knee Score (OKS), the Patient Knee Implant Performance (PKIP) score, and the Kujala Anterior Knee Pain Score (AKPS). Clinical assessment will involve documentation of range of movement, radiological assessment with plain radiographs from which Kellgren Lawrence score will be determined and long leg alignment using EOS imaging, both of which are current standard of care. Patients will be randomised by computer generated block randomisation to receive patella resurfacing or not to receive patella resurfacing. The three surgeons performing the arthroplasty procedure are experienced in both interventions. Signs of patellofemoral arthritis will be documented intraoperatively according to Outerbridge score, but findings will not alter intervention. Patients will be blinded to the intervention.

Patients will be asked to repeat the three PROMs, with the addition of the Forgotten Joint Score (FJS) and the Patients Global Impression of Change (PGIC) at 6 weeks and 12 months post-operatively. At these reviews, range of movement will also be recorded, and plain radiographs performed in line with current standard practice. Results will be collected and stored in a de-identified manner. Study protocol will be registered with clinical trials.gov prior to commencement.

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| 1. PROJECT DETAILS TEAM ROLES & RESPONSIBILITIES
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* 1. Coordinating Principal Investigator

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| **Name:** | Piers J. Yates |
| **Affiliation(s):** | Orthopaedics WA, St. John of God Murdoch Hospital |
| **Position(s):** | Consultant Orthopaedic Surgeon, Head of Orthopaedics |
| **Contact Details:** | Address: Orthopaedics WA, Wexford Medical Centre, 15/3 Barry Marshall Parade, Murdoch WA 6150Phone: 0418 594 392Email: piersyates@hotmail.com |
| **Investigator Responsibilities:** | Prof Piers Yates is a consultant orthopaedic surgeon and will:* be involved in the project design and implement the research plan as outlined in this proposal
* provide patients for study recruitment
* completing consent
* provide intellectual and critical assessments on data analysis and results
* provide progress reports as required
* present the results of this study at professional meetings
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* 1. Associate Investigator

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| **Name:** | Dr Heidi Wilson |
| **Affiliation(s):** | Fremantle Hospital  |
| **Position(s):** | Orthopaedic Registrar |
| **Contact Details:** | Phone: 0450 501 290Email: Heidi.wilson1@my.nd.edu.au |
| **Investigator Responsibilities:** | Dr Heidi Wilson will be responsible for:* study coordination and set up
* management of human ethics
* data collection
* filing and collating trial documentation
* analysis and reporting
* present the results of this study at professional meetings
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| **Name:** | Prof Gareth Prosser |
| **Affiliation(s):** | Orthopaedics WA, St. John of God Murdoch Hospital |
| **Position(s):** | Consultant Orthopaedic Surgeon |
| **Contact Details:** | Address: Orthopaedics WA, Wexford Medical Centre, 15/3 Barry Marshall Parade, Murdoch WA 6150Email: ghprosser@yahoo.com |
| **Investigator Responsibilities:** | Prof Gareth Prosser will be responsible for:* providing patients for study recruitment
* completing consent
* providing intellectual and critical assessments on data analysis and results
* present the results of this study at professional meetings
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| **Name:** | A/Prof Christopher Jones |
| **Affiliation(s):** | Orthopaedics WA, St. John of God Murdoch Hospital |
| **Position(s):** | Consultant Orthopaedic Surgeon |
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| **Investigator Responsibilities:** | Mr Chris Jones will be responsible for:* providing patients for study recruitment
* completing consent
* providing intellectual and critical assessments on data analysis and results
* present the results of this study at professional meetings
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| **Name:** | Mr Peter D’Alessandro |
| **Affiliation(s):** | Orthopaedics WA, St. John of God Murdoch Hospital |
| **Position(s):** | Consultant Orthopaedic Surgeon |
| **Contact Details:** | Address: Orthopaedics WA, Wexford Medical Centre, 15/3 Barry Marshall Parade, Murdoch WA 6150Email: dalessandro.peter@gmail.com |
| **Investigator Responsibilities:** | Mr Peter D’Alessandro will be responsible for:* providing patients for study recruitment
* completing consent
* providing intellectual and critical assessments on data analysis and results
* present the results of this study at professional meetings
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| **Name:** | Dr Steve Edmondston |
| **Affiliation(s):** | St John of God Murdoch Hospital  |
| **Position(s):** | Orthopaedic Research Officer |
| **Contact Details:** | Address: St John of God Murdoch Hospital, 100 Murdoch Dr, Murdoch WA 6150Phone: 08 9438 9008Email:  |
| **Investigator Responsibilities:** | Dr Steve Edmondston will be responsible for:* supporting protocol development
* participation in investigator meetings
* data management, analysis and reporting
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| **Name:** | Ms Jade Evans |
| **Affiliation(s):** | St John of God Murdoch Hospital  |
| **Position(s):** | Orthopaedic Research Officer |
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| **Investigator Responsibilities:** | Ms Jade Evans will be responsible for:* study coordination and set up
* management of human ethics
* filing and collating trial documentation
* organising investigator meetings
* analysis and reporting
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| 1. RATIONALE / BACKGROUND
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Patellofemoral complaints are a common reason for revision of Total Knee Arthroplasty (TKA) (1). Resurfacing of the patella during TKA remains contentious (2, 3) without strong clinical evidence to support this practice over non-resurfacing (4). The decision to resurface is generally based on surgeon preference and implant type, with surgeons often grouped as those who routinely resurface, selectively resurface or never resurface (4). Opponents of patella resurfacing site implant complications, such as fracture, as their reasoning (4). The evidence on the topic is mixed. Studies discouraging routine patella resurfacing include meta analyses of prospective studies that found no significant difference in patient reported outcome measures (PROMs), quality of life, mean total healthcare cost or physical performance at follow up between resurfaced and non-resurfaced groups (3, 5, 6). Conversely, the Australian Orthopaedic Association’s National Joint Replacement Registry results demonstrate a higher overall revision rate for TKAs that do not resurface the patella (1), and a systematic review that supports patella resurfacing due to lower reoperation rates and higher PROMs (7).

Few studies take into consideration the variability of the femoral component design, and in particular trochlear design is emerging as an area of interest (8). The SAIPHTM knee system (MatOrtho, Surrey, United Kingdom), is a medial ball and socket design aiming to mimic anatomical asymmetry allowing for physiological kinematics during range of motion. Additionally, the SAIPHTM knee system utilises a lateralised trochlear allowing for patellofemoral tracking closer to that which occurs physiologically, regardless of whether or not the patella is resurfaced (9). The system has demonstrated excellent mid-term patient reported and radiological outcomes at a mean follow up of 5.3 years (10, 11) with a low revision rate that is comparable to other commonly used prosthesis (1).

The Kujala Anterior Knee Pain Score (AKPS) is a PROM questionnaire with scores from 0 (worst) to 100 (best) specifically targeting patellofemoral symptoms, and has been validated in use on TKA patients (10). The Patient Knee Implant Performance (PKIP) score is validated in the assessment of patients post TKA, and correlates function with improved stability, satisfaction, confidence and motion(12). The Oxford Knee Score (OKS) is widely used in the literature since its introduction in 1996, and as a joint specific PROM aims to reduce the influence of comorbidities(13). The OKS produces a score from 0-48, with higher numbers associated with better outcomes, and has demonstrated excellent reliability(14). However, it is not patellofemoral specific. The Forgotten Joint Score (FJS-12) is a validated 20 item, 0-5 point questionnaire assessing the patient’s ability to forget about their prosthetic joint in everyday life. Some items can be considered patellofemoral targeting questions such as symptoms whilst sitting for >1hr and climbing stairs(15). The Patients Global Impression of Change (PGIC) is a single question self-report measure and reflects a patient's belief about the efficacy of treatment (16).

The Outerbridge Classification was described in 1961 and assigns a grade from 0-IV to the cartilage being examined, with 0 representing normal cartilage. The scoring system was initially developed to describe chondromalacia of the patella. It is validated for assessment of patellofemoral disease on direct visualisation (17). The Kellgren-Lawrence classification is a validated system for classifying tibiofemoral osteoarthritis based on radiographical findings (18).

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| 1. PROJECT AIMS / OBJECTIVES / HYPOTHESES
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This study aims to determine if patella resurfacing with SAIPHTM arthroplasty implants impacts postoperative patient reported outcome measures with patellofemoral specific questionnaires. The null hypothesis is that there will be no statistically significant difference between patients who undergo patella resurfacing during a SAIPHTM knee replacement and those who do not undergo resurfacing.

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| 1. PROJECT DESIGN
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* 1. Study Classification (HREA Criteria)

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| [ ]  Action research[ ]  Biospecimen analysis[ ]  Data linkage research[ ]  Ethnographic research | [ ]  Epidemiological research[x]  Interventional / Clinical Trial research[ ]  Observational research[ ]  Survey / Interview / Focus Group research |

* 1. Study Type and Design – This is a prospective longitudinal randomised and single blind study. Patients undergoing a SAIPHTM knee replacement will be randomised to receive patellar resurfacing or retain their native patella. Preoperative and post-operative patient reported outcome measures will be assessed. The OKS, PKIP, and AKPS will be completed pre-operatively and at 6 weeks and 12 months post-operatively. The FJS-12 and the PGIC will be completed at 6 weeks and 12 months post-operatively. (Please see Table 1 below for a summary)

An email will be sent 6 weeks and 12 months post-operatively and will collect data using a standardised survey link developed by our research team, which when completed and sent will automatically upload into the study REDCap database. Results between the two groups will be analysed.

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|  | OKS | PKIP | AKPS | FJS-12 | PGIC |
| Pre-operatively  | ✔ | ✔ | ✔ | - | - |
| 6 Weeks Post-op  | ✔ | ✔ | ✔ | ✔ | ✔ |
| 12 Months Post-op | ✔ | ✔ | ✔ | ✔ | ✔ |

 Table 1. Summary of PROMs and their use during the study

* 1. Participants
		1. Source of participants, datasets or collections - Participants will be recruited through Orthopaedics WA at St John of God Murdoch Hospital if they are undergoing a SAIPHTM TKA with Prof Piers Yates, Prof Gareth Prosser, A/Prof Christopher Jones or Mr Peter D’Alessandro.
		2. Sample size and statistical or power issues –

Treatment outcome will be evaluatedon the primary outcome measure which is the AKPS. The minimal clinically important difference for the AKPS is 10% (19). Sample size calculation is based on a two-way repeated measures ANOVA, and assumes a between person standard deviation of 15% based on Agarwalla et al (20). A sample size of 80 (40 in each group) provides a minimum 80% power (α=0.05) to detect significant between group differences, and allowing for a 12.5% dropout.

* + 1. Participant inclusion criteria
* Adult participants greater than >18 years of age
* Participants undergoing primary knee arthroplasty for osteoarthritis with SAIPHTM knee system by Prof Piers Yates, Prof Gareth Prosser, A/Prof Christopher Jones or Mr Peter D’Alessandro.
	+ 1. Participant exclusion criteria
* Participants with poor English who are unable to complete the questionnaires and understand instructions
* Bilateral TKA
* Posttraumatic OA
* Previous HTO previous TTO +/- MPFL
* Previous patella dislocation
* Rheumatoid/inflammatory arthritis
* Dementia
* Chronic pain not related to operative knee
* Patients with significant patella maltracking as diagnosed by the treating surgeon
	1. Participant Withdrawal Criteria and Procedures - participants may withdraw from the study at any stage without implication to current or future treatment. Upon notification, they will be withdrawn from the study and have no further involvement. In the case of the participant requiring additional surgery on the operative joint during the 12-month observation time, they will be withdrawn from the study without implication to current or future treatment.
	2. Participant Recruitment – all eligible patients who provide consent for a primary TKA, in whom a SAIPHTM knee system is appropriate, under the care of Prof Piers Yates, Prof Gareth Prosser, A/Prof Christopher Jones or Mr Peter D’Alessandro will be invited to participate in person by their treating surgeon at their booking visit. Patients will be given the opportunity to read patient information and ask any questions prior to deciding. This process is estimated to take approximately 30 minutes.
	3. Participant Consent – the participant will be provided with a copy of the Patient Information and Consent Form by their treating surgeon and given adequate time to read through. The study procedure will be explained and consent will be provided by return of the signed consent form.
	4. Research Activities & Data Collection –. Basic information (age, gender, height and weight) will be obtained from the participant. The assessment results for the patient will include their preoperative range of movement, questionnaire results and radiological findings. The grade of patellofemoral osteoarthritis, based on intraoperative findings, will be documented. Post operatively, range of movement and questionnaire results will be collected. All data will be entered into the electronic data platform REDCapTM.
	5. Data Linkages *–­* N/A
	6. Randomisation, Blinding and Bias – After approval from the treating surgeon and voluntary informed consent by the participant, the participant will be randomised by computer generated block randomisation to receive either patella resurfacing or not to receive patella resurfacing. Participants will be blinded to treatment group. All patients who meet the inclusion criteria will be invited to participate in the study.
	7. Project Duration –

It is estimated that a recruitment phase of 12 months will fulfil trial power requirements. Allowing for waitlist time and a small buffer for 12 month follow up, an estimated total project duration of 30 months is predicted.

* 1. Project Termination Criteria –

This project will be terminated when statistically significant results have been demonstrated, or when data for adequate patient numbers have collected according to our sample size calculation of 40 patients in each group.

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| 1. TREATMENT OF PARTICIPANTS
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Participants will provide written informed consent prior to completing any questionnaires or randomisation to treatment group. All patients undergoing elective primary TKA with SAIPHTM knee system will be invited to participate. Participants will be asked to complete the OKS, PKIP score, FJS, AKPS and PGIC during their regular post-operative surgeon reviews at 4-6 weeks and 12 months post-operatively.

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| 1. INVESTIGATIONAL DRUG OR DEVICE DETAILS
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N/A

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| 1. OUTCOME MEASURES
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The primary outcome of this study will be the patella specific PROM, AKPS. Secondary outcomes will be assessed using FJS, OKS, PGIC and PKIP, validated TKA PROM questionnaires that will be used to assess overall satisfaction, including tibiofemoral symptoms and the knee function as a whole. Post-operative range of movement will also form a component of the secondary outcome measures.

All PROM questionnaires have been validated in the assessment of knee symptoms pre- and post-arthroplasty, with the exception of FJS which is validated for use post-arthroplasty only.11-15

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| 1. ASSESSMENT OF SAFETY
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This research is of low risk and designed in accordance with Section 2.1 of the National Statement. Regardless of treatment group, patients will be receiving standard care. There is currently no consensus on whether patella resurfacing is merited regardless of patellofemoral osteoarthritis, nor on whether it causes undue harm, therefore there is no foreseeable risk that patients in either treatment group will come to harm that is not otherwise inherent in TKA. Patients will receive routine pre- and post-operative care, with the completion of the four questionnaires the only additional requirement of the patient. These questionnaires will be completed pre-operatively, at 6 weeks post operatively and 12 months post operatively. Participation will occur at surgeon follow up appointments which routinely occur at these time points regardless of study participation. The data will be collectively analysed and no participant will be identifiable in any results or published work. Results of this study will guide future clinical practice in specific relation to SAIPHTM knee systems.

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| 1. DATA MANAGEMENT, STATISTICAL ANALYSIS AND RECORD KEEPING
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All randomised participants will be included in the data analysis such that an intention-to-treat analysis will be performed, independent of protocol adherence.

Categorical data will be compared with the use of the chi-square test or the McNemar test for the comparisons of preoperative and postoperative data. The unpaired t-tests or the Mann-Whitney U tests will be used to analyze differences in continuous variables between the two treatment groups. Nonparametric statistics will be used for analysis of continuous variables when data were not normally distributed.

Cox proportional hazards regression analysis will be used to assess associations between potential explanatory variables, including patella resurfacing, and the Patient Global Impression of Change. The criteria for statistical significance will be set at p<0.05.

Researchers will ensure the data is used responsibly and respectfully, and that the privacy and confidentiality of participants is safeguarded at all costs. All data will be collected by a research team member onto the case report form (eCRF) directly from the source data. Data will be entered into the electronic data platform REDCapTM (Research Electronic Data Capture, Vanderbuilt <https://redcapmurdoch.sjog.org.au/redcap/> version [9.6.1](https://projectredcap.org/)) The REDCap database is password-protected and all paper records of consent will be kept in a locked filing cabinet in a locked office in the Murdoch Centre for Orthopaedic Research, St John of God Murdoch Hospital or in Orthopaedics WA, St John of God Murdoch Hospital. All computer and paper records will be restricted to Dr Heidi Wilson, Prof Piers Yates, Dr Steve Edmondston and Ms Jade Evans. All records will be kept for a minimum of 7 years after project completion or publication.

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| 1. MONITORING / AUDIT
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Data collected for this project will be permitted to undergo project-related monitoring and auditing, providing direct access to source data/documents, as required.

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| 1. QUALITY CONTROL AND QUALITY ASSURANCE
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This project will be conducted in compliance with the protocol, Good Clinical Practice and application regulatory requirements. Quality control & quality assurance measures will be taken to ensure the quality of data.

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| 1. ETHICS
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This research is of low risk and designed in accordance with Section 2.1 of the National Statement. Participants will be provided with a Participant Information and Consent Form at the time of their Orthopaedic consult. Participants will be required to provide a signed consent form for consent to be confirmed. Participation is voluntary and will not affect participants’ current or future management if they wish to decline participation or withdraw from the study.

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| 1. BUDGET, FINANCING, INDEMNITY AND INSURANCE
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This study will be funded by the Orthopaedic Research Foundation of Western Australia (ORFWA)

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| 1. STUDY RESULTS AND PUBLICATION
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The results of this study will be presented at professional meetings or conferences, and published in a peer-reviewed journal. The data will be collectively analysed and no participant will be identifiable in any published work.

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| 1. REFERENCES
 |

1. Association AO. National Joint Replacement Registry (AOANJRR)- Hip, Knee and Shoulder Arthroplasty: 2019 Annual Report. Adelaide: Australian Orthopaedic Association; 2019.

2. Fu Y, Wang G, Fu Q. Patellar resurfacing in total knee arthroplasty for osteoarthritis: a meta-analysis. Knee Surgery, Sports Traumatology, Arthroscopy. 2011;19(9):1460-6.

3. He J-Y, Jiang L-S, Dai L-Y. Is patellar resurfacing superior than nonresurfacing in total knee arthroplasty? A meta-analysis of randomized trials. The Knee. 2011;18(3):137-44.

4. Coory JA, Tan KG, Whitehouse SL, Hatton A, Graves SE, Crawford RW. The Outcome of Total Knee Arthroplasty With and Without Patellar Resurfacing up to 17 Years: A Report From the Australian Orthopaedic Association National Joint Replacement Registry. The Journal of arthroplasty. 2020;35(1):132-8.

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