**Participant Information Statement**

*Orthopaedic Research Institute of Queensland*

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| **Title** | Influence of Prosthesis Alignment: Does Kinematic Alignment result in a more balanced Total Knee Arthroplasty? |
| **Short Title** | Verasense TKA: K vs M |
| **Protocol Number** | Version 1.0 |
| **Project Sponsor** | Orthopaedic Research Institute of Queensland (ORIQL) |
| **Coordinating Principal Investigators/**  **Principal Investigators** | Dr Peter McEwen |
| **Associate Investigators** | Dr Ben Parkinson  Dr Mike Reid  Dr Matthew Wilkinson  Andrea Grant  Dr Ryan Faruque |
| **Location** | (Insert Site Location Name) |

**Part 1 What does my participation involve?**

**1 Introduction**

This Participant Information Statement tells you about the research study, explaining the tests and treatments involved as well as the storage and use of the research data captured, so you can make an informed decision about whether or not you want to take part in the research.

Participation in this research is voluntary. You will receive the best possible care whether or not you are involved in the study.

If you decide you do want to take part in the research study, you will be asked to sign the consent section attached. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to have the tests and treatments that are described

• Consent to the use of your personal and health information as described.

**2 Background and aim of the research study**

If you have been invited to be a part of this study you are planning to have a total knee replacement. The study will be investigating the effect of two commonly used surgical alignment techniques for total knee arthroplasty (TKA) and their effects on the balance of the soft tissue ligaments around the knee by looking at pressures in the knee.

Once the components of the knee replacement are inserted, the balance of the knee is judged by how tight the soft tissue ligaments around the knee are. This has traditionally done by feel. If the knee is too tight, these soft tissue ligaments are loosened or released. A new device has been invented to measure the real-time pressures and tightness of the knee during surgery. Our aim is to see which alignment technique produces the best balanced knee and fewer soft tissue ligament alterations.

**3 What does participation in this research involve?**

Consent

Your surgeon will take a medical history from you and determine if you are eligible for the study. If you are, then he will explain the study to you and ask if you wish to participate

We will ask for your consent verbally and electronically to participate in the study. Consent will be obtained prior to any study assessments and procedures. We will ask you to provide consent to participate in research and agree to the Terms and Conditions of accessing FORCE THERAPEUTICS.

What is FORCE THERAPEUTICS?

FORCE THERAPEUTICS is a web-based database where your information will be confidentially stored. You will become familiar with accessing this database to keep in touch with your surgical care team, but also to complete patient assessment questionnaires following your surgery. Please ensure you complete these either in clinic as part of your routine assessment or online through your FORCE THERAPEUTICS profile.

Visits to your doctor after before and after surgery

At time-points after surgery we will ask you to come visit us for routine follow up of how you have been progressing after your knee replacement. If you have any concerns after your surgery, please do not hesitate to contact the care team via the FORCE THERAPEUTICS application or by phone call to your surgeon’s office.

Please see the table below which gives details on each study visit.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Study Visits** | | | | |  |
|  | Pre-Surgery | Surgery | 6 weeks later | 6 months later | 12 months later | 24 months  later |
| Informed Consent  MRI for PSI | x | Surgery |  |  |  |  |
| Clinical exam | x | x | x | x | x |
| Questionnaires | x | x | x | x | x |
| X-ray | x | x | x | x | x |

Pre-surgery:

To make the resulting knee joint as close to your natural anatomy as possible, we will use what is known as patient specific cutting guides. These are cutting blocks that will guide your surgeon to accurately make the appropriate bony cuts to place the knee replacement. We will need an MRI to make these guides. Before surgery we will also randomly allocate you to one of the two surgical alignment techniques. Randomization is done to make the study scientifically powerful. We will ask you to answer some questionnaires regarding the function of your knee before the surgery. We will use this information and compare it to questionnaires done after surgery to assess your progress.

During Surgery:

The surgery to your knees will be done according to your alignment group. During the surgery the pressure-measuring device will be temporarily placed between the thigh and shin bones to assess the pressures they produce. Any appropriate soft tissue ligament alterations will be performed, and the device will be removed. Modern anaesthetic, surgical and pain relief techniques will be used to ensure you have minimal pain after surgery.

Post-Surgery:

You will stay in hospital for several days after the surgery for pain-relief and until you are safe to walk with crutches. After you leave the hospital you will need to attend your study doctor’s clinic for follow up appointments, please refer to the study visits log below.

As explained there will be several assessments performed on you. These are done before your surgery and will be compared with assessments performed after surgery to assess the effect of the TKA.

Assessments:

Physical Assessment:

Assessment of the knee range of motion

Radiological Assessment:

HKA obtained from X-ray

Patient Reported Outcome Measures (PROMs):

ED-5Q

KOOS (includes WOMAC)

Oxford Knee Society Knee Score (pain and function)

Costs:

There are no additional costs associated with participating in this research project.

**4 Other information about the research study**

This study will involve 160 patients across multiple surgical sites.

**5 Do I have to take part in this research study?**

Participation in any research study is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage. Your decision on whether or not to take part, or to take part and then withdraw, will not affect your routine treatment or your relationship with those treating you. You may wish to continue to use FORCE THERAPEUTICS as part of your continuation of care if you decide to not continue in a research project.

**6 What are the possible benefits of taking part?**

Potential benefits of this trial include improved long term outcomes following TKA due to greater accuracy in balancing of the soft tissue surrounding the knee joint. Theoretically this should improve post-operative patient function and satisfaction.

**7 What are the possible risks and disadvantages of taking part?**

This study does not put you at any higher risk than the surgical and anaesthetic risks you would expect to have if not being part of the study and having a TKA. These risks would have been explained to you by your surgeon prior to consenting for the surgery.

**8 Possible side effects from X-rays and imaging**

This research study involves exposure to a small amount of radiation. This exposure however is no greater than the standard post-operative management according to surgical protocol, thus does not put you at an increased risk of side effects.

**9 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

**10 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

**11 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

* Unacceptable side effects
* Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities.

**Part 2 Frequently asked questions**

**1 What will happen to information about me?**

By providing consent to the study doctor and relevant research staff, you consent to collection and use of personal health information for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will be used for the purpose of this research project.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records for the purpose of verifying the procedures and the data relevant to this Participant Information Sheet.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Information about your participation in this research project may be recorded in your health records.

You have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected.

**2 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment.

**3 Who is organising and funding the research?**

This research project is being funded by ORIQL. ORIQL researchers do not receive a personal financial benefit from your involvement in this research project.

**4 Who has reviewed the research project?**

The ethical aspects of this research project have been approved by the Townsville Hospital and Health Services HREC.

**5 Further information and who to contact**

Project related or medical problems that may be related to your involvement in the project you can contact the principal study doctor or your care team through FORCE THERAPEUTICS.

**Clinical contact person**

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| Name | *Andrea Grant* |
| Position | *Research Coordinator* |
| Telephone | *0413 685 331* |
| Email | *Research\_coordinator@oriql.com.au* |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

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| Name | *Townsville Hospital & Health Services* |
| Position | *HREC Coordinator* |
| Telephone | *07 4433 1440* |
| Email | *TSV-Ethics-Committee@health.qld.gov.au* |

For more information on participating in clinical trials you can consult the Australian Clinical Trials website: [www.australianclinicaltrials.gov.au](http://www.australianclinicaltrials.gov.au) The website was developed by the National Health and Medical Research Council (NHMRC) and the Department of Industry and Science which provides general information about clinical trials for consumers, health care providers, researchers and industry.