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Patient Information Sheet
3D and 2D Motion Capture Gait Analysis of Lower Limb Orthopaedic Patients

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Invitation

You are respectfully invited to take part in a scientific research study. Before deciding whether or not to participate, it is important for you to understand why this medical research is being conducted, and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

What is the purpose of the research study?

The main purpose of this study is to assess the use of three-dimensional gait analysis to measure the success (or otherwise) of lower limb surgery i.e. surgery involving the pelvis, hip, knee, foot and ankle.

Why have I been invited?

You are either:

- a patient with a lower limb problem
- a patient who is planned to undergo (or has already undergone) lower limb surgery.

Do I have to take part?

No - it is entirely up to you to decide whether you would like to take part in this study. Your doctor, or a project investigator, will describe the study and go through this information sheet with you, which will then be given to you. If you decide to take part in this study, you will be asked to sign a Consent Form. Even after signing the Consent Form, you are

free to withdraw at any time, without any need to give a reason. Withdrawing from the study will not in any way affect the standard of care you receive.

What will happen to me if I take part?

You will undergo gait analysis, which is non-invasive, and will take part in the Biodynamics Laboratory at Charing Cross Hospital, London, and will last approximately 90 minutes.

N.B. You will need to bring a pair of shorts, short sleeved or sleeveless top, and comfortable walking shoes to wear during the gait analysis assessment.

- You will be asked to complete questionnaires online via JointPro database (you can choose to complete this onsite or at your own convenience). If you have previously completed questionnaires via JointPro independent of your participation in this study, we will like to ask your permission via the study consent form to access this data to be used for the purposes of this study.
- Height, weight and leg length measurements will be recorded.
- You will be asked brief general health questions.
- You will also be asked to walk on a treadmill (modified to contain force measuring plates beneath the belt) and asked to carry out several tasks, including walking on the flat, and walking both uphill and downhill. We will modify the speed and the slope of the treadmill within the limits of your comfort, to assess how you walk and what you feel comfortable with.
- You will also be asked to part in the below additional assessment that are not mandatory for taking part in this research study and you can freely opt out.
    - To analyse your movements, you will be asked to participate in an optional three-dimensional gait analysis involving placement of small, adhesive, reflective markers on your joints and extremities.
    - As part of the three-dimensional gait analysis assessment, you will also be asked if you would like to take part an additional assessment. This assessment will include asking you to step up and down from a step.

This will be repeated 10 times on each leg or less as limited by your comfort level on a stationary treadmill.

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If you are due to undergo lower limb surgery we will ask you to come back for 1 and/or 2 post-op appointment where you will repeat the above steps.

We will also be requesting for your permission to access and retain any previous imaging data you may have taken as part of your standard of care in relation to this study. You will be asked to sign a clause in the consent form agreeing to allow us to access your imaging data and medical notes for the purposes of this research.

What are the possible side-effects and risks of taking part?

Whilst performing the gait assessment you may find that some of the tasks we ask you to perform cause you some discomfort, pain, or a feeling of instability. Should this happen simply inform the researcher and if you need to rest or want to stop, you can do so at any time. We do not want to cause you any pain but do want to understand the limits of comfortable function for you at this particular point in your journey of health advancement. The treadmill is fitted with safety hand-rails, harness, “stop” cord, and an emergency stop button for your safety. We will be attaching the reflective markers to your skin using adhesive tape, which may cause some temporary redness of the skin. If you have allergies or skin conditions (e.g eczema, dermatitis, etc), please inform the researcher and he or she will use an elastic material to protect your skin.

What are the possible benefits of taking part?

Taking part in the study may be of no direct benefit to you, but we hope that the collective results will provide a greater insight into the use of gait analysis as an objective measurement tool in orthopaedics and hopefully inform future implant choice and design.

What happens when the research study stops?

If you take part in the gait assessment before having an operation, we will invite you back for a repeat assessment after you have recovered from your operation. Otherwise you will be followed up according to normal routine by your medical team.

Will my taking part in the study be kept confidential?

Any information you give us will be kept strictly confidential. If the study is published in a book or scientific journal, no individual will be identified in any way. Imperial College Healthcare NHS Trust / Imperial College and the regulatory authorities may review the data to ensure the study is being conducted properly and meets the appropriate regulations.

Further information on Imperial College London's retention periods may be found at https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/records-and-archives/public/RetentionSchedule.pdf. You will also be provided with additional GDPR wording to accompany this patient information leaflet.

What if something goes wrong?

Imperial College London holds insurance policies, which apply to this study. If you experience injury and or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Mr Gareth Jones, Tel 0203 3115216, email: g.g.jones@imperial.ac.uk). The normal National Health Service complaints mechanisms are also available to you such as contacting the local Patient Advice Liaison Services (PALS; pals@imperial.nhs.uk, 020 3313 0088). A member of the team will be able to give you their contact information upon request. If you are still not satisfied with the response, you may contact the Imperial College, Joint Research Compliance Office.

What will happen to the results of this research study?

The overall results of this study will be analysed by the research team before presentation at scientific conferences and publication in scientific journals. No individual subject will be identified in any report or presentation arising from the research. If you would like to receive the results of the completed study, we are happy to send it to you electronically as an email, or by post. Please let us know if you would like this information.

Who is organising and funding the research?

This research is funded by The Wellcome trust & EPRSC and The Michael Uren Foundation Turst. The study is being organised by a research team based at Imperial College, London.

Who has reviewed the study?

This study has been submitted to the (NRES Committees-North of Scotland) REC and reviewed by the Imperial College Joint Research Compliance Office.

Further Information and contact details

If you have any further questions, or require further information, please do not hesitate to contact Dr Amy Maslivec:

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