North Cumbria Integrated Care NHS Foundation Trust

Patient Information Sheet

CASK trial; Compression After Surgery of the Knee

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Who is carrying out the study and why?

The Chief Investigator for this study is Mr Matt Dawson, consultant Orthopaedic surgeon, working in collaboration with fellow surgeons and specialist nurses in the Orthopaedics Department of North Cumbria Integrated Care NHS Foundation Trust. This study has been developed by NHS staff and is carried out in the Cumberland Infirmary and West Cumberland Hospital. The study will take place in a hospital setting with support and oversight from the study team, nursing staff and research staff. Where appropriate, research delivery staff will be delegated to provide support with data collection and processing.

The aim of this study is to determine the level of pain experienced by patients after osteotomy surgery and if there is a difference between two types of bandaging; non-compression bandaging and Andoflex TLC Calamine Lite dual-layer-compression bandaging.

Why have I been invited?

You are being asked to participate in this research study because your clinical team have identified you as someone who is due to have surgery on your knee (knee replacement or osteotomy) and that your leg will be bandaged after this surgery.

Do I have to take part?

You do not have to take part; it is entirely up to you to decide whether you would like to be involved in our study. Take your time, discuss things with others and ask us about anything that is not clear or if you would like more information. Regardless of whether you decide to take part or not, your clinical treatment will not be affected by your decision. You are free to withdraw at any time without explanation and this will not affect the standard of care you receive in any way. If you withdraw at any stage of the study, then we will retain any study information collated up to that point.

What will happen to me if I take part?

If you decide that you may want to take part in the study, one of the research staff, which may be the chief investigator or a trained and delegated member of the study team, will take

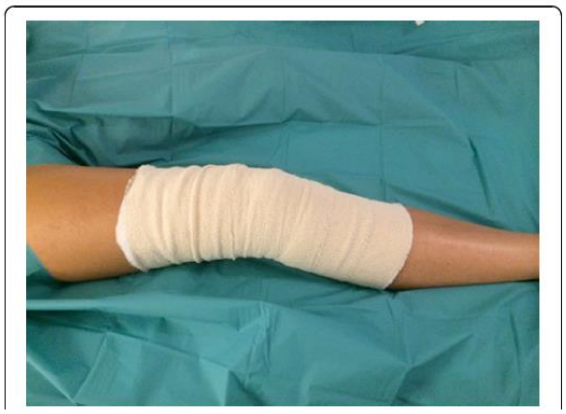
written consent from you. We ask permission to access your medical records to record data related to your knee osteotomy. We also ask permission to inform your GP of your participation in the study.

On the day of your surgery you will be allocated to either the '**Control' group** or the '**Andoflex' group**.

- **Control group**: you will receive current standard care non-compression bandaging (cotton wool and crepe bandaging over the wound site) for up to 48 consecutive hours. This bandage covers your leg from calf to thigh.
- **Andoflex group**: you will receive Andoflex TLC Calamine Lite dual layer compression bandaging straight after surgery for five consecutive days. This bandage covers your leg from toe to groin.

Other than the type of bandaging, other care will be as per usual clinical practice. You will be in the study for a period of 12 weeks, of which only the first five days are classed as the 'intervention phase'. Thereafter, for the remainder of the 12 week period you will be followed up as you normally would in normal clinical practice.

Figures 1 & 2. Standard wool and crepe bandaging (left) vs Andoflex dual layer compression bandaging device (right)



Per research visit you will be asked to complete up to two short questionnaires related to your knee osteotomy at five time points (see table 1). These questionnaires cover topics such as knee function, pain experience, and satisfaction regarding the bandaging. Some questionnaires are part of the regular management of knee patients (such as KOOS, Knee injury and Osteoarthritis Outcome Score). The questionnaires will be done together with a member of the research team during your clinic appointments and will take approximately 5 to 10 minutes. Some additional questionnaires will be completed over the phone or via post or e-mail (whichever of the three you prefer).

Table 1, Timeline and overview of different study visits

Type of visit	Point of contact	What will happen?
Pre-surgery (<0 weeks)	Orthopaedics department (standard clinic appointment)	• Written Informed Consent • Collection of baseline information • Standard care questionnaire about knee function
Day of surgery (day 0)	Orthopaedics department (standard clinic appointment)	• No research activity apart from application of bandaging
Day 5	Telephone/email/post	• Study related questionnaire *(topic: pain)*
Day 12	Telephone/email/post	• Study related questionnaires *(topics: pain, bandage satisfaction)*
Week 6	Orthopaedics department (standard clinic appointment)	• Study related questionnaires *(topic: pain, knee function)*
Week 12	Telephone/email/post	• Standard care questionnaire about knee function

What are the possible benefits of taking part?

For participants in the control group there is no direct benefit for taking part in this study. You will be cared for in exactly the same manner as you normally would, bar the introduction of a few questionnaires. However, by taking part you will contribute to comparison of the effectiveness of aftercare for knee surgery, to optimise management of knee osteoarthritis in the future. You will also help for us to compare pain associated with different types of knee surgery, which may help patients make an informed choice about surgery in the future. For participants in the Andoflex group there may be benefits in terms of pain after the procedure. However, this has not yet been proven and established, and this study is aimed to assess this. You cannot claim payments, reimbursement of expenses or any other benefits or incentives for taking part in this research.

What are the possible disadvantages and risks of taking part?

There are no major personal safety risks anticipated regarding taking part in this study. Bandaging itself can lead to some skin irritation and discomfort, and compression bandaging may affect blood flow if not applied correctly. Like with any invasive procedure, knee surgery

carries (post-operative) risks such as bleeding, blood clots and infection. However, the surgery procedure itself is not classed as being part of this post-surgery CASK bandaging study and you will be asked to give separate written consent for the surgery itself. If you do decide to take part in the CASK study, and your surgeon, nurse or the research team learns of important new information that might affect your desire to remain in the study, they will tell you as soon as possible. Appropriate precautions are in place to ensure your medical and personal information is kept safe (see next sections).

What will happen to the information that I give?

All data will be held in secure environments in NHS Trusts. The requirements of the Data Protection Act and NHS Code of Confidentiality will be followed at all times. All researchers will be fully trained in NHS Confidentiality. Data released (e.g. by publication) will be anonymous; it will not contain any information that could lead to the identification of an individual participant. As part of providing a research grant for this study, we will share *anonymised* research data with Milliken Healthcare (the manufacturer of the Andoflex two layer compression system), for which we will ask your written consent.

Will my participation in the study be kept confidential?

A member of your direct care team has screened your details to ensure you are eligible to take part in the study; these details will not be shared with anyone else in the research team. All information that you give us will be kept strictly confidential. You will be asked to give your name and contact details because we wish to match this with your medical information (for your specific UTI episode).

All your personal details will be treated as STRICTLY CONFIDENTIAL, in line with the Data Protection Act and General Data Protection Regulation for health and care research. Your data collected during your participation in the CASK study will be entered into a password-protected database and analysed – using only NHS computers and servers. For the data analyses, your study data will <u>not</u> be identified by your name – only by study number. Appropriate measures will be enforced to protect your identity in all presentations and publications, as required by United Kingdom regulations. The Sponsor's clinical research staff, consultants, one or more nominated research organisation(s) working on behalf of Sponsor, Sponsor's auditors or their representatives, the NHS representatives and regulatory authorities may have direct access to the study files, but your medical records will not be accessed.

We will need to use information from you and from your hospital medical records for this research project. This information will include your name. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or

contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What if something goes wrong?

If you have any concerns at any stage of your involvement in this research project, please feel free to discuss these with the research team. We will do our best to resolve any problems quickly. If you are still unhappy and wish to complain about any aspect of the way you have been approached, the normal National Health Service (NHS) complaints mechanisms are available to you (Patient Experience Team contact details below). The study is covered by NHS insurance in relation to the design, management and conduct of the research, but not for no fault compensation.

What will happen if I don't want to carry on with the study?

Your participation in the study is voluntary. You can refuse to take part, or you can withdraw at any time. If you choose to withdraw, your clinician will continue treating you as he or she normally would and you do not have to give a reason as to why you wish to withdraw from the study. If you withdraw after signing the study consent form, you will not be able to re-enter the study. Any data collected up to the point where you withdraw will be retained for analysis as part of the study. The latter also applies if you were to lose capacity to take part during the study.

Where can you find out more about how your information is used?

You can find out more about how we use your information
•at www.hra.nhs.uk/information-about-patients/
•our leaflet available from www.hra.nhs.uk/patientdataandresearch
•by asking one of the research team, further down this leaflet at 'Contact for further information'
•Within the sponsor NHS Trust for this study via the Data Protection Officer pals@ncic.nhs.uk

Who is organising and funding the study?

The study is organised by Orthopaedic Surgeon Mr Matt Dawson in collaboration with the Orthopaedics and Research Departments of North Cumbria Integrated Care NHS Foundation Trust. This NHS Trust is also the study sponsor for indemnity purposes. The study has been reviewed and approved by the National Ethics Research Service, Wales REC 7 committee, REC ref 21/WA/0252, the Health Research Authority and the NHS Trust (North Cumbria Integrated

Care NHS Foundation Trust) where the study is conducted. Milliken Healthcare is funding this study by means of an academic research grant.

The research team acts as a contact point and coordinator for patients requiring information and support. If concerns are raised, referral of patients/families on to other professional agencies will be done as appropriate and according to the Trust guideline.

Contact for further information

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from the ROBOT research team:

- Name: Ms Lucy Bell (orthopaedic specialist nurse), and Mr Matt Dawson (orthopaedic surgeon)
- Phone number: 01228 814751 or 01768 245975
- Email: Research@ncic.nhs.uk

Generic information on taking part in clinical research can be obtained from the Patient Experience Team, tel 0800 633 5547 or PET@ncic.nhs.uk , or from websites such as the NHS Choices website, http://www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Thank you for taking the time to read this information sheet