PATIENT INFORMATION SHEET

You are being invited to take part in a research study called HIPSTER (**H**IP **S**urgical **T**echniques to **E**nhance **R**ehabilitation). It is important that you understand why we are doing this research and what being involved in it means for you. This leaflet provides you with information on the study. Please take some time to read this and to ask us any questions before deciding if you would like to take part. You do not have to decide now and are welcome to discuss the research with your family, friends or GP before you decide. We will contact you again at a later date to ask if you would like to be involved.

Contents

Glossary of abbreviations

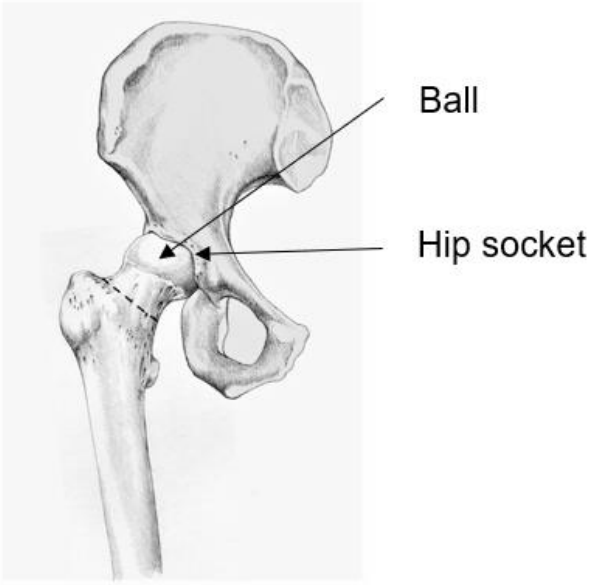
CT	Computerised Tomography
HIPSTER	HIP Surgical Techniques to Enhance Rehabilitation
NIHR	National Institute Health Research
PA	Posterior Approach
PALS	Patient Advise and Liaison Service
PSPA	Piriformis Sparing Posterior Approach
REC	Research Ethics Committee
SPAIRE	Spare Piriformis And Internus Repair Externus
THR	Total Hip Replacement

Why are we doing this research?

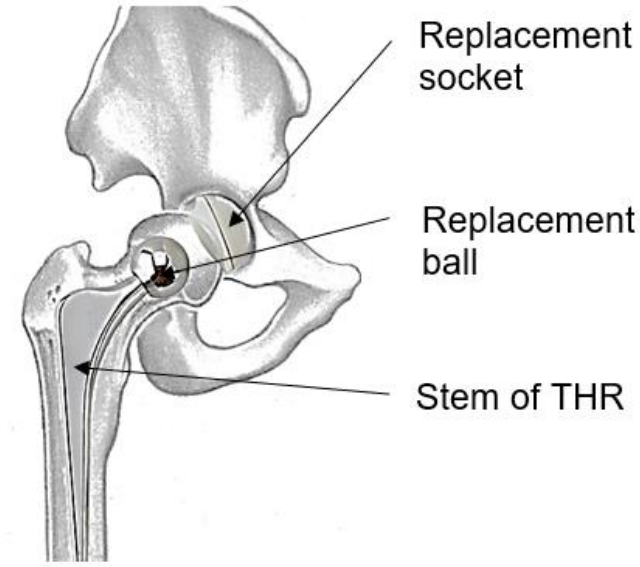
Total hip replacement (THR) surgery is very successful for the majority of people and they report being highly satisfied with the results of their operation. However, a minority of patients continue to have problems after their surgery. More than 10% of patients still have pain in the operated hip one year after surgery, and approximately 6% are dissatisfied with their surgery. Many of these people will require further tests or treatment, and as over 100,000 THRs are completed every year in the UK, even a small improvement in the way the surgery is completed will have a positive impact on thousands of patients and could save millions of pounds for the NHS, along with having wider benefits for society.

Figure 1: Ball and socket hip joint

a) Front view of hip joint



b) Front view of a THR



During THR surgery, in order to reach the hip joint shown in Figure 1a, surgeons cut through tendons, which attach muscles to bone. Tendons provide stability and strength during daily activities. The surgeon can then reach the hip joint to carry out the THR shown in Figure 1b.

There are several ways of carrying out hip replacement surgery through the muscles at the back of the hip (Figure 2). The study will investigate three of these, which are shown in Figure 3:

A. The Posterior Approach (PA): This is the most frequently used method. It involves cutting **three** tendons at the back of the hip joint, which are then repaired once the artificial hip is in place (Figure 3a). It allows a clear view of the hip joint so the artificial ball and socket can be correctly positioned.

B. The Piriformis Sparing Posterior Approach (PSPA): This is a modified version of the PA, which cuts **two** tendons (Figure 3b). This approach preserves one tendon so potentially improving hip strength and post-operative outcomes.
C. The Spare Piriformis And Internus, Repair Externus (SPAIRE) approach: This is also a modification of the PA where **one** tendon is cut (Figure 3c). This preserves two tendons so potentially improving hip strength and post-operative outcomes.

The PSPA and SPAIRE approaches that cut fewer tendons aim to reduce recovery time, improve rehabilitation, and improve patient satisfaction. However, cutting fewer tendons can limit the visibility and access to the hip joint, which can make positioning the socket of the artificial hip more challenging.

Figure 2: The muscles at the back of the hip

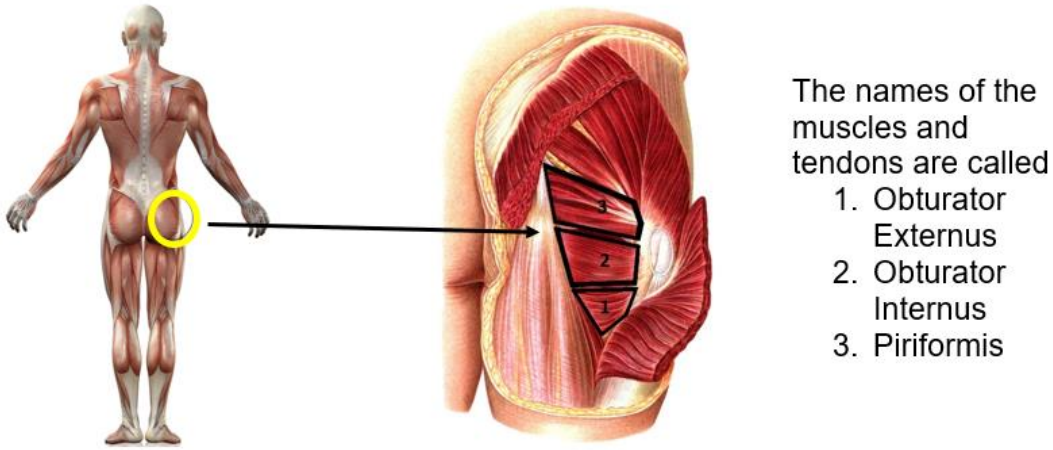


Figure 3: The three approaches to surgery

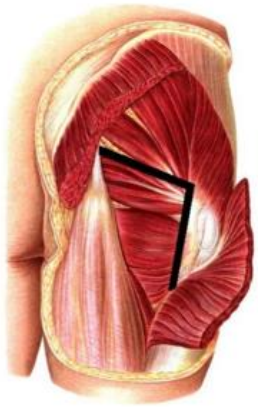


FIGURE 3a:

POSTERIOR APPROACH (PA):
The tendons of three muscles are cut to allow access to the hip joint. After the new ball and socket are implanted, the tendons are repaired.

FIGURE 3b:

PIRIFORMIS SPARING POSTERIOR APPROACH (PSPA):
The tendons of two muscles are cut to allow access to the hip joint. After the new ball and socket are implanted, the tendons are repaired.

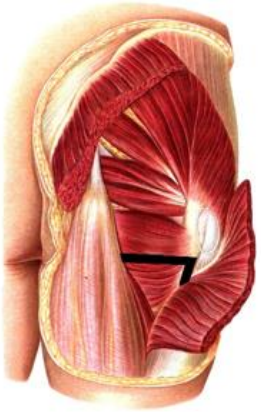


FIGURE 3c:

SPARE PIRIFORMIS AND INTERNUS, REPAIR EXTURNUS (SPAIRE) APPROACH:
The tendon of one muscle is cut to allow access to the hip joint. After the new ball and socket are implanted, the tendon is repaired.

The surgery will be assisted by the MAKO robotic guidance system, which allows surgeons to position the artificial hip components very accurately during the operation; this may also help with the reduced visibility of the joint when fewer tendons are cut. The surgeon retains control of the robot at all times.

The Royal Devon University Healthcare NHS Foundation Trust (Royal Devon) is using the latest robotic system for THRs, and this provides the

opportunity to investigate whether cutting fewer tendons during total hip replacement can improve rehabilitation.

The HIPSTER research study will compare the outcome of THRs completed using the standard posterior approach (PA) where three tendons are cut, with the modified versions where either two tendons, or only one tendon is cut. All surgery will use robotic assistance, so the only difference between groups in the study will be the number of tendons that are cut.

Why have I been invited to take part in this study?

You have been invited to take part in the HIPSTER study because you have osteoarthritis of your hip requiring replacement and would be suitable for surgery through a PA, PSPA or SPAIRE approach with robotic assistance.

Do I have to take part?

No, your participation is entirely voluntary, and you have the right to withdraw at any time, without needing to provide a reason. If you decide not to take part this will not affect your care and treatment will continue as normal.

What will happen to me if I take part?

If you decide you would like to take part in the study, a member of the Research Team will contact you by telephone or email and give you the opportunity to ask any questions. If you still wish to take part, you will be given this information to keep, and arrangements will be made to meet you in clinic where you will be asked to sign a consent form to confirm that you understand what is involved when taking part in the study.

Randomisation

309 patients will take part in the HIPSTER research study. One third of participants will have their operation through a PA approach, one third through the PSPA and one third through the SPAIRE. You have an equal chance of being allocated to one of the three treatments. Neither you, the clinical team, or the Research Team can choose which group you go into. This is so we can make a fair and unbiased assessment about which treatment option is best for patients with your condition. It is important to only take part in this study if you are happy to be allocated to either one of the groups.

Consent clinic

As part of your routine care, you will meet one of the hip surgeons in the Orthopaedic outpatient clinic 6 to 10 weeks before your operation so you can ask questions and provide your consent for surgery.

A member of the Research Team will meet you either at this appointment or at your routine Pre-op Assessment appointment to discuss the HIPSTER study and for you to provide your written consent if you would like to take part. As part of the research:

- You will be asked to complete three questionnaires which measure how much trouble your hip is giving you including how pain and stiffness affect your sleep and daily activities.
- With your permission, a member of the Research Team will collect two blood samples from you to measure for inflammation. The bio-markers that are checked are called creatine kinase and C-reactive protein. The additional blood samples that we will collect from you during the study will be destroyed once analysed at each collection time point, in accordance with the Human Tissue Authority's Code of Practice.
- You will be issued with an activity monitor to wear day and night for two consecutive weeks. This device will measure how much activity you perform, and we will be able to monitor the amount of walking, sitting, lying down and sleeping that you do over a set period of time. It needs to be worn for 24 hours per day, and does not need to be removed for washing. You will be provided with a prepaid envelope to return the monitor to the Research Team at the end of the two weeks. The activity data will be collected, stored and analysed so that you cannot be personally identified by anyone outside the Research Team.

After the consent appointment and before your operation you will receive an appointment for an X-ray and CT scan in the Radiology Department as part of routine planning for your operation.

Inpatient stay

Your stay in hospital will continue as normal. All medical, nursing and therapy care will be unchanged from normal, standard care. This will include regular painkillers to allow you to move comfortably and start walking with crutches or a walking frame, and the help of the Physiotherapists and Nurses. You will also have a post-operative X-ray. We aim to discharge you safely as quickly as possible after your operation. For many people this can be on the same day as their operation. You will be given a separate booklet which fully explains the normal clinical care you will receive.

The only difference will be the type of approach used by the surgeon during your hip replacement operation and an additional blood test to check for inflammation after your operation either on the same day or the day after your surgery.

6 weeks post-operative

6 weeks after your operation, you will attend your routine follow-up appointment in clinic, where you will also be seen by a member of the Research Team.

- You will be asked to complete six questionnaires, and with your consent a member of the Research Team will collect two blood samples from you to measure for muscle damage and inflammation.

You will be provided with the activity monitor again to wear day and night for two consecutive weeks and provided with a prepaid envelope to return the monitor to the Research Team after use.

6 months and 12 months post-operative

You will then have remote follow-up appointments at 6 months and at 12 months after your operation. You will be asked to complete four questionnaires that will be sent to you via email (or post if you prefer). A member of the Research Team will also contact you by telephone to check your progress. You will receive the activity monitor again in the post at these time points to wear day and night for two consecutive weeks and provided with a prepaid envelope to return the monitor to the Research Team after use.

If you agree to take part in this study, we will send a letter to your GP to inform them that you are taking part in the HIPSTER study. At the end of your participation in the study, you and your GP will be sent a notification letter of the treatment allocation you received.

What alternatives are there to taking part in the study?

If you decide that you do not want to take part in the study, you will receive the usual medical care provided in your hospital. Your care will not be affected in any way and your hip replacement surgery will go ahead as planned. All three approaches are routinely used by the surgical team in Exeter. Most commonly patients receive the PSPA approach but when

required surgeons will also perform the PA or SPAIRE approach if these are felt to be of benefit or felt necessary for the patient.

What are the possible benefits of taking part?

There are no direct benefits from taking part, but participation in research like this can help to improve the treatment, care and overall experience of patients who will need this surgery in the future. The additional reviews with a member of the Research Team may also be a reassurance to you during your recovery.

What are the possible disadvantages and risks of taking part?

All three approaches (PA, PSPA, SPAIRE) are routinely used by surgeons all over the UK and the robotic assistance is standard procedure at the Royal Devon. We do not anticipate any additional complications as a result of being involved in the study other than those that can occur for any patient having hip replacement surgery. The risks of THR surgery will be explained to you by your surgeon when you are listed for surgery and at the surgical consent clinic.

Tendon sparing approaches can sometimes be technically more challenging, especially if the tendons and muscles are very strong or stiff. During the operation, if the surgeon considers that the SPAIRE or the PSPA approaches are not technically possible, for any of these reasons,

then he/she will make a decision to use the standard PA approach if necessary.

The study requires exposures to ionising radiation from X-rays and a CT scan which would take place as part of routine clinical care. Therefore, taking part in this study does not expose you to any additional radiation.

Taking part in the study is entirely voluntary and you can withdraw from all or part of the study at any time without giving a reason. However, it is always helpful if you are able to provide a reason so that we can improve things for future studies. Your treatment will continue as normal irrespective of your decision, and your standard of care will not be affected.

You can withdraw from the study by contacting the Study Manager, the study Chief Investigator or Co-Chief Investigator, using the contact details below:

Study Manager:

Holly Whitmore, Research Co-ordinator, HIPSTER study
holly.whitmore@nhs.net

Chief Investigator:

Mr Al-Amin Kassam, Consultant Trauma and Orthopaedic Surgeon
al-amin.kassam@nhs.net

Co-Chief Investigator:

Dr Timothy Holsgrove, Senior Lecturer in Biomechanics and Bioengineering

t.holsgrove@exeter.ac.uk

What will happen to the results of the study?

The research is due to finish in December 2026. The results of the study will be written up after this and published in medical journals and presented at conferences and on social media. Your identity will never be disclosed. On the study consent form we will ask you if you would like to receive a summary of the results once the research is complete.

What if relevant new information becomes available?

Sometimes during a study new information about the treatment being investigated becomes available. If this happens, one of the medical team will discuss this new information with you and any necessary further action.

Expenses

There are no expenses available for taking part in this study. You will be seen by the Research Team at your routine pre-operative assessment appointment and 6 week follow-up appointment so there is no additional

burden of visits. Your follow-up appointments at 6 months and 12 months will both be completed remotely.

What if there is a problem?

If you have any questions or concerns about the study please do not hesitate to contact the Research Team using the contact details below:

Research Team: 01392 406956

Study Manager:

Holly Whitmore, Research Coordinator, HIPSTER study
holly.whitmore@nhs.net

Chief Investigator:

Mr Al-Amin Kassam, Consultant Trauma and Orthopaedic Surgeon
al-amin.kassam@nhs.net

Co-Chief Investigator:

Dr Timothy Holsgrove, Senior Lecturer in Biomechanics and Bioengineering
t.holsgrove@exeter.ac.uk

If you have concerns about the way you have been treated during the course of the study, you can contact the Patient Advice and Liaison Service (PALS): 01392 402093 or email rduh.pals-eastern@nhs.net. If you wish to make a complaint you can contact the Complaints Team: rduh.complaints-eastern@nhs.net.

We do not anticipate that you will be placed at any greater risk by taking part in this study. If something goes wrong due to your participation in this study as a consequence of negligence, normal NHS indemnity applies and the NHS Trust responsible will compensate you. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action, but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

Who is organising and reviewing this study?

The Royal Devon University Healthcare NHS Foundation Trust is the Sponsor for this study, with the British Orthopaedic Associate affiliated Exeter Clinical Trials Unit acting as the co-ordinating centre, along with the Department of Engineering based at the University of Exeter. The study itself will be run at the Royal Devon and Exeter Hospital (Eastern services), which is a centre of excellence for hip arthroplasty. The study is funded by the National Institute for Health and Care Research – Efficacy and Evaluation Programme (NIHR150537).

Any research conducted in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. The HIPSTER study has been reviewed and approved by the Seasonal Research Ethics Committee.

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your

- Name
- Initials
- NHS number
- Hospital number
- Contact details: address, telephone numbers and e-mail address
- Date of Birth
- Sex
- The medical details, blood tests, X-ray and CT results, and operation information collected as part of your normal care.
- Specific information for the research such as questionnaire and activity monitor results.

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.

Some of your information will be sent to the United States of America. As part of the normal use of the MAKO robotic system, the CT images are sent to two companies in the United States – LifeIMAGE and Stryker US (the robotic system manufacturer). LifeIMAGE receive the scans of your hip and pass them to Stryker US to make your unique surgical plan. These images will contain at least two identifiers (e.g. name, hospital number and date of birth) and will only be seen by employees of Stryker and not shared with any other party. Personal identifiable information/data will be shared with these companies to ensure the correct surgical plan is attributed to the correct patient; the surgical plan will then be sent to the Royal Devon and uploaded onto the MAKO robotic system ready for your surgery. They must follow our rules about keeping your information safe. The information used for your surgical planning will not be shared with the Exeter Clinical Trials Unit, or University of Exeter.

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.

The Royal Devon, LifeIMAGE and Stryker US will use appropriate safeguards to ensure that your personal information is treated confidentially and securely. In the unlikely event of a breach of this information the organisation involved will promptly inform the others of any unauthorised access to, or disclosure of personal data. This includes the timing and nature of the security breach and take all reasonable measures to rectify the security breach.

Should you wish to contact any external companies regarding the use of your data, you can direct your enquiry in the first instance to the Research Team:

Research Team: 01392 406956

Study Manager:

Holly Whitmore, Research Coordinator, HIPSTER study

holly.whitmore@nhs.net

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this 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
- by sending an email to the Data Protection Officer at the Royal Devon. Email: rduh.dpo@nhs.net
- by ringing us on 01392 406956

The Royal Devon will keep research data in a secure location during the study and for 10 years after the study has finished; this includes all details of your surgical plan used for the MAKO robotic system sent to the Royal Devon from Stryker US. 10 years after the end of the study the Royal Devon will destroy all study information that identifies you. We will keep all anonymised data indefinitely on secure servers at the University of Exeter for future ethically approved research in this area.

Further information

We encourage you to ask as many questions as you wish, before, during and after your participation. If you have any questions about the study please speak to the Research Team or a member of the direct care team.

Thank you for taking the time to read this leaflet and considering taking part in the HIPSTER study.