FLexor repAir and REhabilitation (FLARE) Trial

Patient Information Sheet

Dear patient,

We invite you to take part in our study.

Your hospital is working with other NHS hospitals and the University of York on a study. The study compares two types of surgical repair for patients who have a cut through the flexor tendons that bend the middle knuckle and the tip of their finger. Both surgeries are already used within the NHS.

We are looking for 310 patients around the country to take part in this study. Will you be one of them?

The decision is yours.

Who: The study involves adult patients with suspected complete division of both flexor tendons in a finger.

What: Comparing surgical repair of both tendons versus single tendon to the end of the finger.

Why: Each finger has two flexor tendons as shown in Figure 1. One runs to the tip of the finger (in purple -flexor digitorum profundus), the other stops halfway down (in blue - flexor digitorum superficialis). Together they bend the finger into the palm.

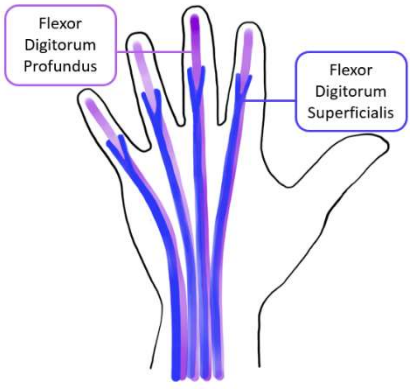

Figure 1: Flexor Digitorum Profundus and Flexor Digitorum Superficialis

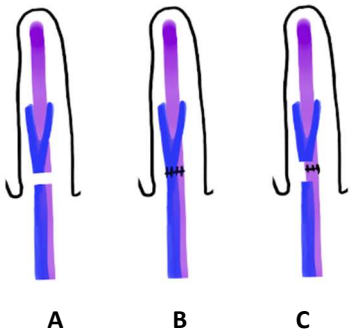

Figure 2: Surgical Repair of Flexor Tendons

A] both tendons injured **B]** both tendons repaired
C] single tendon repaired (flexor digitorum profundus)

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Why have I been invited to take part?
You have an injured finger and might have cut both flexor tendons in your finger.

What do flexor tendons do?
Each finger has two flexor tendons. They are rope like structures connecting the muscles in your forearm to the bones of your fingers. One tendon goes to the fingertip and the other halfway down the finger (see Figure 1). They bend your fingers into the palm.

How are flexor tendon injuries treated?
Surgeons usually offer to repair the tendons with stitches. This gets the finger moving again.

Why is the FLARE trial needed?
If both tendons are completely cut, surgeons and patients are unsure whether the tendon to the tip of the finger should be repaired alone or along with the other tendon.

Why the uncertainty?
Repairing both tendons might give more strength but has a higher chance of the tendons getting stuck, giving worse movement.
Repairing just the tendon to the fingertip alone might give better movement but less power.

What is involved in the FLARE trial?
We are recruiting 310 patients. Half will have just the tendon to the fingertip repaired. Half will have both tendons repaired.
We will then compare the outcome of both groups to see if there is a difference. This will help future patients and surgeons make decisions about their treatment.

Do I have to take part?
You do not have to take part. Involvement in the FLARE Trial is voluntary.

If you choose to take part, you can still stop at any time.

If you choose not to take part, you will still receive the best treatment available in the opinion of your surgeon.

<u>What is the aim of this study?</u>
Flexor tendons are smooth cords in fingers that help them to bend. There are two flexor tendons in each finger, which join the muscles in the forearm to bones in the fingers. One tendon bends the middle knuckle, the other bends the fingertip.
When a deep cut at the base of the fingers has gone completely through these flexor tendons, surgeons may repair both tendons back together, or only one. It is currently

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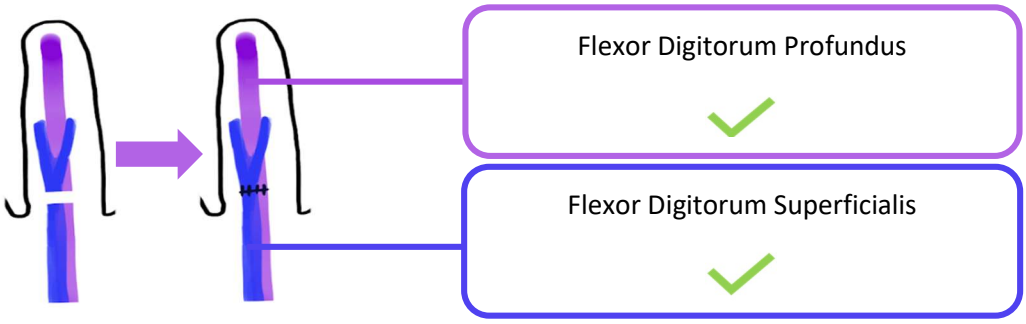
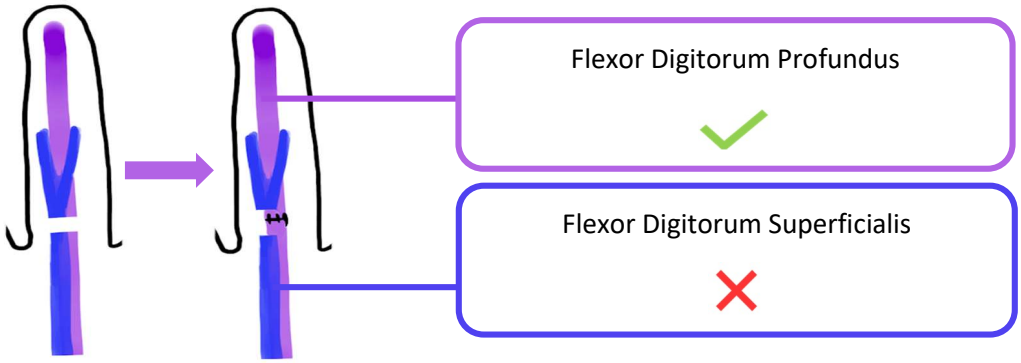
unknown if the repair of one tendon is as beneficial to the patient, as the repair of both tendons. The chances of experiencing problems or complications after surgery, are likely to remain similar whether you have one or both flexor tendons repaired, but the function of the finger can be affected differently.

Repair of both tendons, connected to knuckle and fingertip



- The surgeon sews the ends of each tendon back together
- Commonly done in the NHS
- Strong repair
- More scar tissue which may make it impossible to fully straighten the finger.

Repair of only one tendon, connected to fingertip



- The surgeon sews back together the ends of the tendon that's connected to the fingertip
- Commonly done in the NHS
- Strong repair but possible reduced grip strength
- Less scar tissue, which may make it possible to fully straighten the finger.
- If this treatment is effective for such injuries, it may also save the NHS money.

In this study, we want to find out whether adults who have just had one flexor tendon repaired are at least as happy with the results as adults who have had both flexor tendons repaired.

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What happens if I take part?

1. Consent

If you agree to take part in the FLARE Trial, we will ask you to read and sign a consent form. This states that you are volunteering to take part in the study.
If you are unable to complete the consent form because of your injury, a witness can complete the consent form on your behalf.

2. Information about you

After providing your consent, you will be asked to fill out a questionnaire about your injury and your ability to carry out everyday tasks. Research staff will also collect some other basic details about you from your medical records or by asking you.

3. Hand surgery

You will receive surgery to repair your tendons. During your surgery, your surgeon will look at your injury and make a final decision on whether you can take part in the study.

If your surgeon confirms that you are eligible to take part: your treatment will be determined by a process called randomisation. The surgeon will then carry out the treatment that has been decided.
You will not be told whether one or both tendons have been repaired. However, at the end of the study you will be told how you can find out which of the treatments you did receive should you wish to do so.

If your surgeon confirms that you are not eligible to take part in the study at this point: They will perform the surgery that they deem necessary, and you will be told that you are no longer taking part in the study as soon as it is appropriate.

4. Randomisation

This is a method for producing two groups of patients who are similar in every respect (for example age). One group will have surgery to repair both tendons and one group will have surgery to repair one tendon only. Randomisation is done using a computer programme designed for this purpose and you will be equally as likely to receive either type of surgical repair.
By the end of the study, we can be confident that any differences in the patient outcomes between groups is due to the treatment they received, rather than any other differences between the groups.

5. Discharge

You will be discharged from hospital with a splint to protect the tendon repair just like the patients who do not take part in the study.

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6. Clinic visits and hand therapy

After your surgery, you will be asked to attend clinic visits and will receive hand therapy, the same as the patients who are not taking part in the study. Study information will be collected at your routine appointments completed within one week of your surgery and then at six weeks and three months after your surgery.

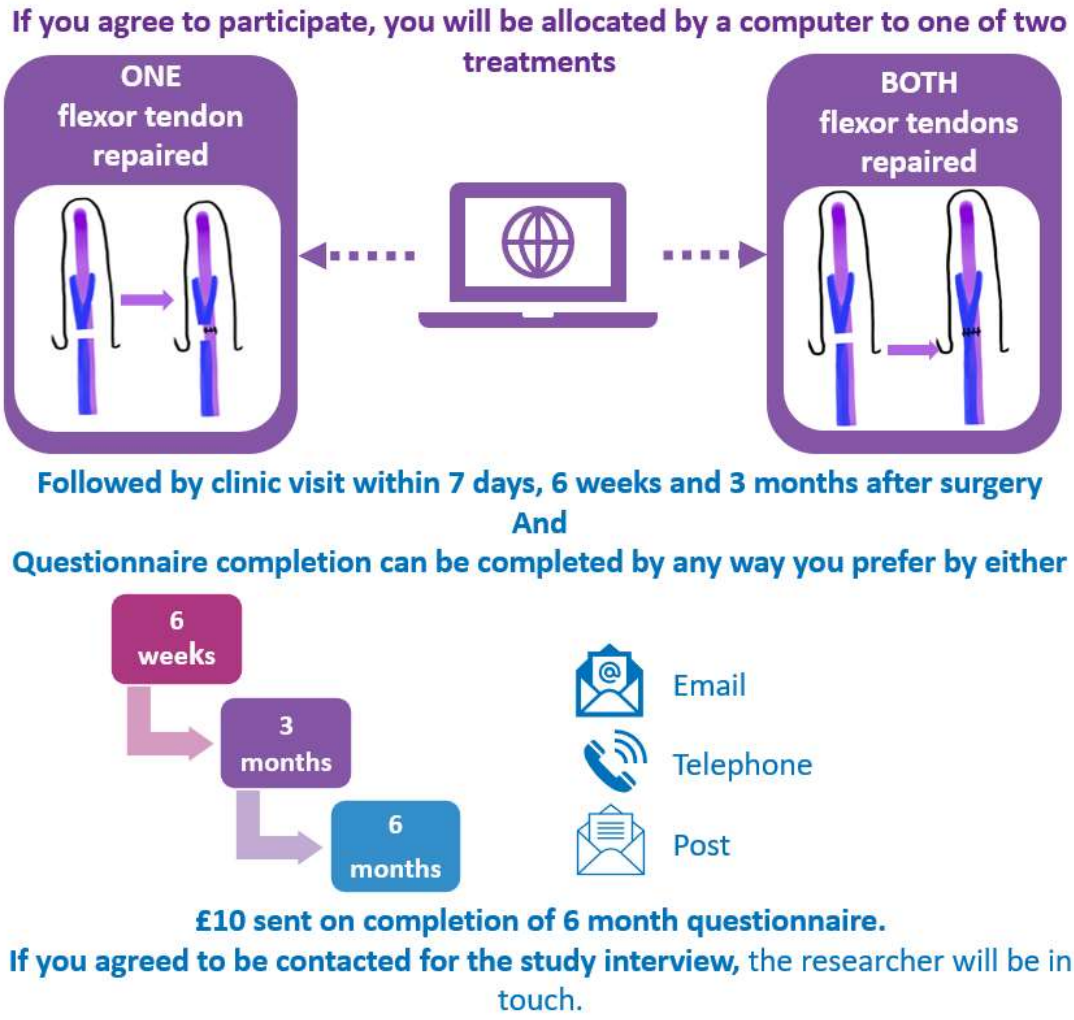
You should attend any other routine clinical appointments that may be scheduled as part of your ongoing care.

7. Questionnaires

We will send you questionnaires to fill out at three points after your surgery (six weeks, three months and then six months after surgery). You can choose to receive and complete this questionnaire online (by email), on paper (by post) or by telephone.

8. Optional interview

Finally, with your permission, the York Trials Unit team will contact you to ask if you want to take part in an interview about your experiences and receiving treatment for this injury, your recovery and taking part in research.



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How will I be contacted?

- Email: We will use your email to send you the questionnaires and update you about the study with a newsletter. We will also email you if we lose contact with you using the other methods.
- Post: We will use your contact details to send you the study questionnaires and newsletters if you are not able to use email.
- Mobile/landline: We will use your mobile number to contact you when a questionnaire is not returned.

With your agreement, we may also contact you in future about this study or other related studies.

Possible Benefits and Disadvantages of Taking Part

The outcome following flexor tendon injuries requiring surgical repair can only be improved with the help of patients. Taking part in this study means that you help improve the care of future patients with a similar injury to yours.

There is no increased risk to you by participating in the study. The NHS has treated patients with both of the surgical techniques that we are comparing in this study for many years. You will face the same anaesthetic and surgical risks as patients with the same injury, who are not participating in the study.

For both types of surgery, the operation will usually take 45 – 60 minutes and the surgical wounds will be the same.

The surgical risks include:

- Wound infection: If this were to occur it is usually treated with antibiotics. There may be wound healing problems.
- Flexor tendon re-rupture: After about 1 in every 20 tendon repair operations, the repair fails and the affected tendon ruptures (breaks or splits). Further surgery may be required to repair the tendon.
- Tendon adhesion: the tendons become stuck to surrounding tissue causing loss of movement which is usually minor.
- In rare cases there can be damage to nerves and blood vessels.

Common anaesthetic risks include:

- feeling or being sick
- dizziness or feeling light-headed
- shivering and feeling cold

The common side effects of anaesthetic usually do not last very long and wear off on their own.

The length of your surgery and hospital stay will not be increased by taking part in the study. The number of hospital visits that you will be required to attend will not be increased.

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You will be asked to complete a total of 4 questionnaires over the next 6 months. Each questionnaire will take up to 15 minutes to complete.

More Information about Taking Part

What if there is a problem or any concerns?

If you are concerned with any aspect of this study, you should speak to your treating clinician or one of the researchers who will do their best to answer your questions (see contact details at the end of this information leaflet).
If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it.
If you wish to complain, or have any concerns about the way you have been approached or treated, the normal NHS complaints mechanisms are available to you. (e.g., by contacting the Patient Advice and Liaison Services (PALS) at the hospital).

Will my taking part in the study cost me anything, and will I be paid?

Participation in this study will not cost you anything. You do not need to make any extra hospital visits for this study, and we will send questionnaires via email or through the post (free-post return envelopes will be provided).
Once your involvement in the study is over, you will receive a £10 reward as a thank you for helping us.
We hope that helping to improve medical care for future patients will be a rewarding experience for you.

Will my GP be involved?

If you agree to take part in the study, we will let your GP know.
If we have any concerns about your health during the study, if you agree, we will talk to your GP.

Who is organising and funding this study?

This study is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (Reference: NIHR133784).
The sponsor is South Tees Hospitals NHS Foundation Trust; they are responsible for ensuring that the study follows all applicable laws and regulations.
York Trials Unit, based at the University of York, will be managing the day to day running of the study.
Your surgeon will not get paid for their involvement in the study. Your hospital gets paid when a patient agrees to take part and for collecting data. This covers the cost to the hospital for helping with the study.

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Who has reviewed this study?
Before any research goes ahead, it is looked at by an independent group of people, called a Research Ethics Committee. They are there to protect your interests. This research has been reviewed and given a favourable opinion by the North West - Greater Manchester Central Research Ethics Committee (Reference: 23/NW/0004).

How have patients and public been involved in this study?
Groups of patients and members of the public who have had experience of this injury, have been involved in all aspects of this study. They have given feedback on the design of the study and helped with developing patient materials, including this information leaflet.
The research team worked closely with a patient representative to get funding for this study. These people continue to be involved to give a patients' perspective on the ongoing running of the study.

How can I find out about the results of the study?
This study is due to finish in the summer of 2025.
Once the study has ended and the results have been analysed, reports will be published in medical journals, presented at conferences, and shared via social media and the study website. You will not be identified in any of these.
You will be asked whether you would like to receive a summary of our findings, in the final study questionnaire that you will receive six months after your surgery. If you choose to receive the study results, we will use the contact details you provide to us to send these to.

What if relevant new study information becomes available?
We will contact you to update you. If we are asking for new information to be collected about you, we will ask you to complete a new consent form so that we have your decision on paper.

I'm not sure about taking part- where can I get more information about the study?
We would be very pleased to answer any questions you may have. Please contact a member of the team using the contact details listed below.

The FLARE Trial has a website at www.flaretrial.com

Contact details
If you want any further information, please contact us. A friend or relative may speak to us on your behalf if you wish.

- If you would like specific information about this study, you may contact: FLARE Trial coordinators at York Trials Unit: ytu-flare-trial@york.ac.uk or Telephone: 01904 321522.

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- If you would like independent advice about whether or not to take part, the Patient Advice and Liaison Service (PALS) or Patient Advice and Support Service (PASS) or Research and Development team (R&D) are available to you. Please contact the FLARE Trial coordinators at York Trials Unit for details of your local site PALS, PASS or R&D contacts.
- Speak to the doctor or research nurse involved within the study at your hospital. Contact details available separately or via ytu-flare-trial@york.ac.uk.

You can find independent information on research in general at the following website: https://www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-learn-about-research/

More Information about Taking Part

How will we use information about you?

If you take part, we will tell your GP and any doctor or nurse who may be treating you.
We will need to use information from you and from your medical records for this research project.
This information will include your:

- Name
- Contact details (address, email and telephone number)
- Date of Birth
- NHS Number [or CHI Number Scotland only]
- Sex
- Ethnicity

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.

How will your information be stored?

Information collected about you during the research and from your health records will be held securely on paper or electronically at the hospital and at York Trials Unit, who are organising the research, or at an alternative secure facility. Information will be kept strictly confidential and will be held in line with the UK General Data Protection Regulations (GDPR) and Data Protection Act 2018.

Your name, address, email and telephone number will be stored securely at the University of York and your hospital to allow us to contact you. The information collected about you

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will be stored on Research Electronic Data Capture (REDCap), which is a secure 'cloud' hosted server designed to collect and store research data.

You will be given a study participant identification (ID) number, which will be used to identify you on all study forms.

The sponsor, as data controller, has to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This provides the legal basis for our use of your data; GDPR Article 6(1)(e) and Article 9(2) (j).

This means that when you agree to take part in a research study, we will use your data (including your health data) in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we must demonstrate that our research serves the interests of society as a whole. Research will be carried out in accordance with the UK Policy Framework for Health and Social Care Research.

At the end of the study, the identifiable data collected from you will be securely archived for a minimum of 5 years. Confidential and secure destruction will then be arranged.
Any identifying information will be kept strictly confidential, and access will be limited to the original study team.
Study results that do not include your name or personal details may be stored indefinitely for other analyses in the future. Researchers analysing the clinical data in the future will be unable to identify you.

Anyone who views the information we collect during the study, and your medical records, will have a duty of confidentiality to you as a research participant.

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.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records/ your hospital. If you do not want this to happen, tell us and we will stop.
- 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.

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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/
- at www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team (contact details in section 6)
- Sending an email to the Sponsor's Data Protection Officer Contact: Steven Orley, Email: stees.dpo@nhs.net, Telephone (Main Switchboard): 01642 850850
- South Tees Hospital NHS Trust (sponsor) Patient Privacy Notice is available at: https://www.southtees.nhs.uk/resources/how-your-personal-information-is-used-by-south-tees-hospitals-nhs-foundation-trust/
- The University of York Data Protection Policy can be accessed here: https://www.york.ac.uk/records-management/dp/

Thank you for reading this information sheet and for considering whether to take part.

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