FLexor repAir and REhabilitation (FLARE) trial

Summary of Trial Results

Why did we do this trial?

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

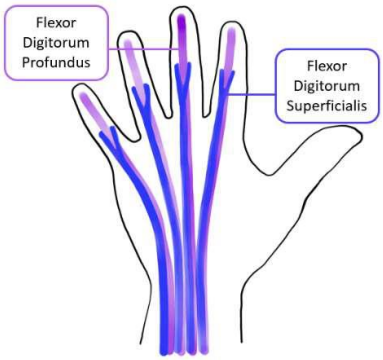

Figure 1: Flexor Digitorum Profundus and Flexor Digitorum Superficialis.

If both flexor tendons are completely cut, surgeons and patients are unsure whether the flexor tendon to the tip of the finger should be repaired alone, or along with the other flexor tendon. Repairing both flexor tendons might give more strength, but has a higher chance of the flexor tendons getting stuck, giving worse movement. Whereas repairing just the flexor tendon to the fingertip alone, might give better movement but less power.

The FLexor repAir and REhabilitation (FLARE) trial aimed to assess whether the repair of one flexor tendon is as beneficial to the patient, as the repair of both flexor tendons.

Who carried out the research?

The FLARE trial was funded by the National Institute for Health and Care Research, sponsored by South Tees Hospitals NHS Foundation Trust, and managed by the York Trials Unit. The co-Chief Investigators were based at Frimley Health NHS Foundation Trust and South Tees Hospitals NHS Foundation Trust. The trial also had oversight committees comprising of clinicians, patients, statisticians, and trial methodologists to advise on the trial.

The trial's Patient and Public Involvement (PPI) group included 4 patients who had previously experienced a flexor tendon injury requiring surgical treatment, along with a patient's carer. The PPI members were involved in the trial from an early stage to advise on whether the patient activities were appropriate (for example, could a patient complete a trial questionnaire during their recovery?), along with advising on whether the written or animated patient information provided about the trial, could be easily understood. The group reviewed the progress of the trial and have had input into this summary of trial results.

What did we do?

We planned to recruit 310 adult patients who had cut both flexor tendons within one finger. The patients were split into one of two treatment groups: the repair of one flexor tendon, or the repair of both flexor tendons. This was a randomised trial and neither the patient nor the surgeon could choose which treatment the patient would receive. The patients were not told which surgical treatment they had received, until their involvement in the trial had ended 6 months after their

surgery. During this time, the patients provided information, either on-line or via post about their hand function, quality of life, treatment satisfaction and other health outcomes, such as whether they required any further medical attention for their flexor tendon injury. Information was also collected from the hospitals about the initial surgical procedure and any further surgery required, the rehabilitation regimen, and whether the patient had experienced any complications. Patients, surgeons and hand therapists were also given the opportunity to take part in a trial interview.

Recruitment took place in 22 hospitals throughout England, Wales and Scotland between August 2023 and April 2025. The trial faced significant challenges and only managed to recruit 43 out of 310 patients needed for the trial. This was due to the number of patients who met the entry criteria for the trial, being much lower than anticipated. Because of this, we had to end the trial early and could not answer our research question.

To add, 73% of the 126 patients who were approached to take part in the trial agreed and were consented. Those who declined to take part, explained that they did not want their surgical treatment to be randomised (17 patients), or that they did not want to take part in the study (5 patients). A further 15 patients declined trial participation for unknown reasons.

How has this trial helped researchers, surgeons and hand therapists?
Despite not completing the trial as planned, the lessons learned, will be crucial for designing and carrying out similar studies in the future. For example, there is support for future work regarding injury prevention, shared decision making among clinicians and patients, along with greater development of anaesthetic and hand therapy-related patient information.

In addition, the FLARE trial will also be a useful resource to other researchers in terms of how to conduct and manage a hand surgery trial, similar to the FLARE trial.

How has this trial helped patients?
We listened to the feedback from the patient trial interviews and the PPI group, that sometimes patients underestimated the impact of the flexor tendon surgery, and were not sure of what to expect during their long term recovery. The PPI group provided ideas for an information resource to advise future patients of what to expect following their flexor tendon injury, and the trial team developed three animated resources. These animations inform the viewer of what flexor tendons are, how patients, interviewed for the FLARE trial, experienced this injury, and suggest what to expect in terms of surgical treatment and recovery. The patients interviewed for the trial, remain anonymous within the animations. If you are interested in viewing this resource, please click on the following link: https://www.youtube.com/@FlexorTendonResource.

What were the findings from the trial interviews?
From examining the 15 patient interviews we found that, for most people, the impact of their flexor tendon injury and surgery is widespread, effecting important and enjoyable activities, as well as their mood. When we interviewed patients after surgery, most appeared reasonably well informed by health care professionals about their injury, operation, hand exercises and splint. But around the time of their surgery, many had underestimated the effect of the operation, due to being unaware of the size of the cast/splint applied after surgery, and length of rehabilitation required. Some also expressed uncertainty and concern about their longer term recovery.

Hand therapists and surgeons agreed in their interviews that patients were often unprepared for the impact of surgery and could have unrealistic expectations of their recovery. These themes were discussed with the PPI group and led to the development of the animated patient flexor tendon

resource (as described above), which aims to help patients understand the impact of their surgery and what to expect during recovery.

Where can I learn more about the FLARE trial?
For further information about the FLARE trial, please click on the following links:

- NIHR Health Technology Assessment webpage:

  https://fundingawards.nihr.ac.uk/award/NIHR133784

- York Trials Unit FLARE trial webpage:

  https://www.york.ac.uk/healthsciences/research/trials/ytutrialsandstudies/trials/flare/

- FLARE trial International Standard Randomised Controlled Trial Number (ISRCTN) webpage:

  https://www.isrctn.com/ISRCTN10918157?q=FLARE%20flexor%20tendon&filters=&sort=&offset=1&totalResults=1&page=1&pageSize=10

The scientific paper from the FLARE trial will be published in due course on the Journal of Hand Surgery's (European Volume) website.