**A multi-centre, parallel group, two arm, non-inferiority randomised controlled trial to compare clinical and cost-effectiveness of suture fixation versus tension band wiring for simple olecranon fracture fixation in adults. Simple Olecranon Fracture Fixation Trial (SOFFT) PROTOCOL**

**Abstract**

*Aims:* Olecranon fractures are usually caused by falling directly on to the olecranon or following a fall on to an outstretched arm. Displaced fractures of the olecranon with a stable ulnohumeral joint are commonly managed by open reduction and internal fixation. The current predominant method of management of simple displaced fractures with ulnohumeral stability (Mayo IIA) in the UK and internationally is a low-cost technique using tension band wiring. Suture or suture anchor techniques have been described with the aim of reducing the hardware related complications and re-operation. An all-suture technique has been developed to fix the fracture using strong synthetic sutures alone. The aim of this trial is to investigate the clinical and cost-effectiveness of tension suture repair versus traditional tension band wiring for the surgical fixation of Mayo Grade IIA fractures of the olecranon.

*Methods:* SOFFT is a multi-centre, pragmatic, two-arm parallel-group, non-inferiority, randomised controlled trial. Participants will be assigned 1:1 to receive either tension suture fixation or tension band wiring. 280 adult participants will be recruited. The ~~with the~~ primary outcome ~~being~~ will be the Disabilities of the Arm Shoulder and Hand (DASH) score at 4-months post randomisation. Secondary outcome measures include DASH (at 12, 18, and 24 months), pain, Net Promotor Score (Patient Satisfaction), EuroQol 5 Dimensions (5L) Score (EQ5D-5L), radiological union, complications, elbow range of movement and re-operations related to the injury or to remove metalwork. An economic evaluation will assess the cost-effectiveness of treatments.

*Discussion:* There is currently no high-quality evidence comparing the clinical and cost effectiveness of the tension suture repair to the traditional tension band wiring currently offered for the internal fixation of displaced fractures of the olecranon. The Simple Olecranon Fracture Fixation Trial (SOFFT) is a RCT with sufficient power and design rigour to provide this evidence for the subtype of Mayo Grade IIA fractures.

## Introduction

**Background**

Olecranon fractures are usually caused by falling directly on to the olecranon or following a fall on to an outstretched arm.(1) The estimated UK incidence of olecranon fractures is 12 per 100,000 population, with reports that approximately three quarters of all olecranon fractures are displaced, simple fractures with a stable ulnohumeral joint (classified as Mayo Type IIA), which require surgery in most cases.(2)

Displaced fractures of the olecranon with a stable ulnohumeral joint are commonly managed by open reduction and internal fixation. The current predominant method of management in the UK and internationally is a low-cost technique using tension band wiring with two parallel/ longitudinal Kirschner wires (k-wires) and a cerclage wire in a ‘figure of 8 loop’. (3) Whilst the surgical outcome of this technique is good with high rates of satisfaction and fracture union (4, 5) there are risks of improper wire placement, joint penetration with metalwork, nerve or blood vessel injury, restriction of movement, wire migration that can threaten the skin, and non-union of the bone. Furthermore, due to the prominence of the metalwork under the skin, a common complication is that the metalwork causes pain, or can break through the skin. Thus, patients may require a second surgery to remove the wires, with the associated surgical risks and delayed recovery for patients, along with costs for the healthcare system. The mean rate of metalwork removal in the UK National Health Service (NHS) is estimated at 36%. (6)

Suture or suture anchor techniques have been described with the aim of reducing the hardware related complications and re-operation. (3, 7-9) From the suture anchor technique described by Ravenscroft, (10) an all suture technique has been developed by Watts et al. to fix the fracture using strong synthetic sutures alone. (7) Tension suture repair is considered less likely to require a second surgery to remove the fixation material. An intervention that is not inferior to the current method in terms of patient function, but that reduces the need for a second surgical procedure would have substantial patient benefit. In addition to reducing patient discomfort and the need for re-operation, this also has the potential to provide cost savings to the healthcare system.

**Rationale**

There is currently no high-quality evidence from a RCT comparing the clinical and cost effectiveness of the surgical interventions available for fractures of the olecranon,(11) including the tension suture repair compared to the traditional tension band wiring currently offered in the NHS.

# Aim and objectives

The aim of this study is to investigate the clinical and cost-effectiveness of tension suture repair versus traditional tension band wiring for the surgical fixation of Mayo Grade IIA fractures of the olecranon. A full list of objectives is provided in Table 1.

**Table 1: SOFFT objectives**

|  |
| --- |
| **PRIMARY OBJECTIVE** |
| To undertake a multi-centre parallel group RCT to determine whether tension suture repair is not inferior to traditional tension band wiring for the internal surgical fixation of simple displaced Mayo Grade IIA fractures of the olecranon in adult patients aged 16 years or older, based on functional outcome as measured by the DASH score at 4 months. |
| **SECONDARY OBJECTIVE** |
| Undertake a 9-month internal pilot to obtain robust estimates of recruitment and confirm trial feasibility. |
| To undertake an analysis of the rate of re-operation. |
| To investigate the cost-effectiveness of the two interventions from the NHS perspective in order to identify the most efficient provision of future NHS care and to describe the resource impact on the NHS for the two treatment options. |

# Methods

# Trial Design

SOFFT is a pragmatic multi-centre, participant-blinded, non-inferiority randomised controlled trial with parallel groups, allocated on a 1:1 ratio. An economic evaluation is also included. A 9-month internal pilot phase will assess assumptions about recruitment and fidelity of implementation of the tension suture technique.  The trial is registered with International Standard Randomised Controlled Trial Number (ISRCTN) as ISRCTN87904264.

## Study Participants

Adults ≥16yrs of age who have sustained a Mayo Grade IIA fracture of the olecranon requiring surgical fixation.

## Study Setting

Patients will be recruited from Trauma and Orthopaedic Departments of NHS Major Trauma Centres and Trauma Units within the UK that routinely manage patients with a fracture of the olecranon. A minimum of 24 sites will be required.

## Eligibility Criteria

Included patients must fulfil all of the eligibility criteria, which are presented in Table 2. Eligibility will be confirmed by an appropriately delegated surgeon prior to the patient being invited to join the study.

**Table 2 – SOFFT Eligibility criteria**

|  |
| --- |
| **PARTICIPANT INCLUSION CRITERIA** |
| * Patients aged ≥ 16years * Mayo Grade IIA acute fracture within 3 weeks of injury * Closed or Gustil~~l~~o and Anderson grade 1 open injury\* * The surgeon believes the patient will benefit from surgical intervention * Ability to give informed consent |
| **PARTICIPANT EXCLUSION CRITERIA** |
| * Surgery contra-indicated * Gustil~~l~~o and Anderson grade 2 or 3 open injury * Associated upper limb injuries or prior upper limb pathology adversely affecting function * Evidence of fracture comminution (Mayo Grade IIB) or instability around the elbow and/or forearm (Mayo Grade III) * Evidence that the patient would be unable to adhere to trial procedures or complete questionnaires * Previous entry into SOFFT * Concurrent olecranon fracture in the opposite limb |

\*Gustilo and Anderson grade 1 open injury, that is a wound measuring less than 1cm with no evidence of contamination, will be eligible for inclusion.

## Interventions

Participants will undergo treatment as soon as practical and within three weeks of the injury according to ~~as per~~ the randomisation allocation under the care of one of the participating surgeons.

### **Standard Tension Band Wiring (TBW)**

TBW will be undertaken according to standard AO technique and the ten criteria established by Schneider for optimal technique (12) using two longitudinal K-wires and one or two steel cerclage wires in a figure of eight configuration to provide compression.

### **Tension Suture Repair (TSR)**

TSR approach involves neutralizing the deforming forces of triceps by passing strong synthetic sutures through the tendon to the bone distal to the fracture site, thereby transmitting this deforming force to the other side of the fracture and neutralizing the effect. TSR involves:

- Accurate fracture reduction.

- Compression with a clamp.

- A transverse 2.5mm drill hole placed in the ulna distal to the fracture site (no less than 2mm, no more than 3.5mm).

- Repair with ~~two lengths of Number 2 synthetic~~ braided suture passed through the drill hole and the insertion of triceps to the olecranon (no less than 2 sutures, more than two sutures can be use up to a maximum of 4.

- Suture material should be Orthocord, Fibrewire or Fibretape; (Vicryl, Ticron or Ethibond should not be used).

- Suture size not less than No.2 and not greater than No.5.

- A minimum of two sutures should be configured according to technique of Das, Jariwala and Watts (7).

- Sutures must be passed through the triceps tendon at the insertion to the olecranon, suture knots should be buried under the anconeus muscle.

- No supplementary k-wires should be used.

## Surgeon Training

To standardise delivery of interventions across all sites, Principal Investigators will be required to attend a training course to learn the correct tension suture technique. The standard AO technique of tension band wiring of the olecranon will also be revised and the ten criteria established by Schneider (12) for optimal technique. Assessments of understanding will be undertaken using a structured questionnaire.

Training will be cascaded by the PI to other participating surgeons on the delegation log at a site to ensure all those providing the surgery are adequately trained in the technique. A record of training undertaken will be maintained.

Fidelity of the techniques will be monitored by the CI using intraoperative photographs and for the TSR intervention a checklist completed by the operating surgeon. Any departures from the techniques are reviewed by each oversight committee.

## Rehabilitation/Physiotherapy

All participants will receive standardised, written physiotherapy information detailing the exercises they may perform for rehabilitation following their injury. All post-surgery rehabilitation will be left to the discretion of the clinical team.

Data on rehabilitation received by participants will be collected at the 4, 12, 18 and 24 month follow-up by participant self-report and from hospital records.

## Outcomes

### **Primary outcome**

The primary outcome measure is the Disabilities of the Arm Shoulder and Hand (DASH) score at 4-months post randomisation. The DASH was chosen as the primary outcome measure because it captures the range of ways in which patients are likely to be affected by the fracture including activities of daily living, pain, social activities and sleep (http://www.dash.iwh.on.ca/). The 30-item PROM is designed for use in people with musculoskeletal disorders of the upper limb and is a reliable and valid instrument (13).

### **Secondary outcomes**

Secondary outcomes will be collected at 4, 12 and 18-months post-randomisation for the whole population. There will be an additional endpoint of 24-month follow-up for all patients recruited in the first 18 months of the recruitment period (approximately two-thirds of the total sample) to help reduce costs and length of the trial (Table 3).

**Table 3 – SOFFT secondary outcomes**

|  |
| --- |
| * DASH (at 12, 18, and 24 months). |
| * Visual Analog Scale (VAS): a unidimensional measure of pain intensity which has been widely used in adults (14). The VAS consists of a 100-millimetre line representing a continuous scale. The line is anchored at both ends with the verbal descriptors ‘No pain’ and ‘Worst imaginable pain’(15). |
| * Net Promotor Score (Patient Satisfaction): an overarching measure of patient satisfaction. The score assesses the likelihood of the patient recommending the healthcare received to friends or relatives using an 11-point numeric scale with 0 representing ‘not at all likely’ and 10 representing ‘extremely likely’. (16, 17) Responses scoring 9-10 are classed as “Promoters”, those scoring 7-8 “Passives” and those scoring 0-6 “Detractors”. The percentage of Detractors is subtracted from the percentage of Promoters to yield the Net Promotor Score with a range from -100 (all Detractors) to 100 (all Promoters). |
| * EuroQol 5 Dimensions (5L) Score (EQ5D-5L): measures health-related quality of life in terms of 5 dimensions: mobility, ability to self-care, ability to undertake usual activities, pain and discomfort, anxiety and depression. The EQ-5D-5L will be scored according to the User Guide (18). EQ-5D-5L data will be collected twice at baseline: i.e. once to assess patient health related quality of life on the day (after the injury) and once with regard to the week before injury. |
| * Radiological union: union will be defined as the presence of bridging trabeculae seen on anterior-posterior and lateral x-rays of the elbow at 4 months. The assessment of union will be undertaken by two assessors independent of the trial. The 4-month x-ray is part of routine practice. |
| * Complications: Information on all complications will be collected. Expected complications that will be recorded will include (but not be limited to) deep wound infection, (using Centres for Disease Control (CDC) and Prevention definition (19) superficial infection (using CDC definition), rehospitalisation, nerve and skin problems. |
| * Elbow Range of Movement: Elbow range of flexion, extension, pronation and supination will be assessed at 4 months by a suitably trained independent observer using a hand-held goniometer following trial specific instructions. |
| * Re-operations related to the injury or to remove metalwork; reason for reoperation will be recorded. The decision to have further surgery will be made by the patient and their treating clinician. There are no protocols restricting the decision to re-operate but data will be collected on the reasons for re-operation e.g. discomfort, stiffness, prominent fixation device, infection, patient choice, surgeon choice. |
| * Resource use and work impact: An accurate record of procedures at hospital level will be put in place in order to record the cost of each type of surgery and related complications via a surgical form specifically designed for this trial. Patient-reported questionnaires and hospital forms will be designed to collect information on hospital stay (initial and subsequent inpatient episodes, outpatient hospital visits and A&E admissions); primary care consultations (e.g. GP, nurse and physiotherapy); work impact of both interventions; and return to work and return to normal activities. |

**Participant timeline**

Participants will be followed up at 4, 12, 18 months post randomisation, and at 24 months for participants who reach this point within the trial window.

Table 4 indicates the overall trial assessment schedule and flow of trial participants through the study, based on the recommended figure in the Standard Protocol Items: recommendations for Interventional Trials (SPIRIT) (20)

**Table 4 - SOFFT Study Assessment Schedule**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Assessment**  (M=month) | **Baseline#**  **(Clinic)** | **Randomisation** | **Intervention** | **M4”**  **(Clinic / remote)** |  | **M12**  **(Remote Questionnaire)** | **M18**  **(Remote Questionnaire)** | **M24\***  **(Remote Questionnaire)** |
| **Allowed variation in days** |  |  |  | +/- 14 |  |  |  |  |
| Eligibility screen | x |  |  |  |  |  |  |  |
| Informed consent | x |  |  |  |  |  |  |  |
| Demographics | x |  |  |  |  |  |  |  |
| Randomisation |  | x |  |  |  |  |  |  |
| **Assessments** |  |  |  |  |  |  |  |  |
| DASH | X^ |  |  | x |  | x | x | x |
| VAS (pain) | x |  |  | x |  | x | x | x |
| Net Promotor Score |  |  |  | x |  | x | x | x |
| Euroqol EQ-5D-5L | X^ |  |  | x |  | x | x | x |
| X-ray | x |  |  | x |  |  |  |  |
| Perioperative data |  |  | X~ | x |  |  |  |  |
| Elbow range of Movement+ |  |  |  | x |  |  |  |  |
| Fracture union using radiographic assessment |  |  |  | x |  |  |  |  |
| Patient & Surgeon preferences | x |  |  |  |  |  |  |  |
| Treatment Information |  |  |  | x |  |  |  |  |
| Reoperation |  |  |  | x |  | x | x | x |
| Complications |  |  |  | x |  | x | x | x |
| Resource Use |  |  |  | x |  | x | x | x |
| Return to work and normal activities |  |  |  | x |  | x | x | x |

#Baseline measures will be collected prior to randomisation

\*For those participants who reach this timepoint by the end of the planned follow-up period

^Collected pre- and post-injury

~Intra-operative fluoroscopy images will be obtained

“Visit may be conducted remotely in the event of local restrictions arising from COVID-19. Window for radiology assessments only is -14 days to +2months +Objective ROM measurements will be performed at the clinic visit with an additional participants self-reported assessment based on photographs of their elbow in maximum extension and flexion using a standardised protocol.

**Sample Size**

Minimal clinical important differences for the DASH are around 10 points from individual studies using anchor-based methods (13, 21). We estimate that a 10 point difference on the DASH at 4 months represents the threshold at which differences become important and which would represent an appropriate non-inferiority margin. For 90% power, assuming standard deviation of 23 (7, 21-25) and 20% attrition, 280 participants are required to establish non-inferiority of tension suture fixation compared with tension band wiring technique within a margin of 10 points of the DASH, based on an upper limit of a 95% confidence interval.

## Participant Recruitment

Potential participants will be identified from Emergency Departments, fracture clinics and /or orthopaedic trauma meetings of participating hospital sites. All patients presenting with olecranon fractures will be screened, with eligibility confirmed by a delegated clinician and recorded on the Study Eligibility case report form.

Eligible patients will be approached and provided with a detailed participant information sheet, outlining the study and clearly explaining the risks and benefits of trial participation.

Patients will have the opportunity to ask questions before written informed consent for the study is obtained by appropriately delegated staff. A video is also available online for additional information about the study for patients.

All participating sites will keep screening logs to capture numbers of ineligible or non-consenting patients at each site and to determine the reasons for exclusion and non-consent.

**Internal Pilot**

An internal 9-month pilot study will test assumptions about the number of sites open, number of eligible participants, number recruited, number randomised, number of crossovers and the fidelity of the intervention. The progression criteria will be to have 24 sites open to recruitment, to have a 50-70 % acceptance rate (proportion of eligible patients recruited) to participate in the trial and 80% follow-up of recruited patients for the primary outcome at the 4 months.

## Treatment Allocation

After completion of informed consent and completion of baseline data collection, participants will be randomly allocated in a 1:1 ratio to tension suture fixation or tension band wiring, using computer generated permuted blocks of random sizes, stratified by centre. Randomisation will be performed independently using a secure, online randomisation service (https://ytu.york.ac.uk/YorkRand/) hosted by YTU to ensure allocation concealment.

### **Blinding**

Participants will blinded to the treatment they have received. Outcome assessments will be performed wherever possible by assessors blind to treatment allocation. It is not feasible to blind the surgeon to the allocation.

**Data management**

## Data collection

Data will be collected at baseline, 4, 12 and 18-months post-randomisation via participant questionnaires or investigator Case Report Forms (CRF). Baseline data and 4-month data will be collected at recruiting sites by clinical and/or research staff. Postal copies of the patient questionnaires will be sent to the participant at 4, 12, 18 and 24 months and supplemented by information collected from patients’ medical records by research staff.

**Participant retention**

To minimise attrition, we will use multiple methods to keep in touch with patients. A pre-notification letter will be sent to the participant two weeks before the follow-up questionnaire is due and a text message reminder will also be sent on the day patients are expected to receive the postal questionnaire. This has been shown to significantly reduce time to questionnaire response.(26) Two and 4-week postal reminders will also be sent where required and where these methods fail there will be a final attempt to obtain data via telephone, prioritising the primary outcome measure.

The SOFFT trial will act as a host trial for an embedded study within a trial (SWAT) which aims to evaluate an intervention to improve retention. The protocol can be found at https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/FileStore/Filetoupload,1098876,en.pdf.

We will also write newsletters during the trial to keep the participants informed and engaged with the trial, which can enhance response rates.(27)

**Data management**

Paper CRFs and questionnaires will be designed using TeleForm software(28)and used to record all the information required from the protocol. Data completed by trial participants will be collected via questionnaires and data collected from the hospital will be recorded on paper CRFs by hospital staff. Each trial participant will have a unique six-digit identification number that will be recorded on all CRFs.

The data collected will be posted to YTU and scanned into a secure web-based interface developed for this study. A secure electronic management system will be used to track participant recruitment and study data, including CRF returns. Data from scanned CRFs will be verified through cross checking of the data against the hard copy. A validation plan for the CRFs will be written to identify key variables and the plan will include detailed coding for the CRFs. Any data queries generated followed this validation will be raised with the site research team. Quality Control will be applied at each stage of data handling to ensure that all data are reliable and have been processed correctly.

Free-text responses in questionnaires will be checked for anything that indicates that the participant could be at risk of harm. Where this occurs, the Principal Investigator and Research team will be notified via email.

All data will be completely anonymised for the analysis and any reports or publications generated. For the purposes of ongoing data management, once randomised, individual patients will only be identified by participant identification numbers.

### **Statistical Analysis Plan**

Full analyses will be detailed in a statistical analysis plan (SAP), which will be finalised prior to the end of data collection. This trial will be reported according to the CONSORT guidelines for clinical trials. (29)

**Pilot Phase Analysis**

The recruitment rate and 95% confidence interval (CI) will be estimated from the data collected. A CONSORT diagram will be produced to show the flow of participants through the study and the following outcomes calculated: number of eligible patients; proportion of eligible patients approached for consent; proportion of eligible patients not approached and reasons why; proportion of patients approached who provide consent; proportion of patients approached who do not provide consent; proportion of patients providing consent who are randomised; proportion of patients randomised who do not receive the randomly allocated treatment; proportion of patients dropping out between randomisation and follow-up.

Data will be summarised on the reasons why eligible patients were not approached, reasons for patients declining to participate in the study; reasons why randomised patients did not receive their allocated treatment and reasons for drop-out, if available.

Results will be compared against the study’s recruitment assumptions and progression targets, and continuation of the trial or relevant modifications will be decided by the funding body.

**Main trial**

Statistical analyses will be on intention to treat (ITT) basis with patients being analysed in the groups to which they were randomised. Statistical significance will be at the 5% level (unless otherwise stated in the SAP), and analyses will be conducted in the latest available version of Stata or similar statistical software.

Baseline characteristics will be presented by trial arm. All trial outcomes will be reported descriptively by group (as randomised and as analysed) at all time points at which they were collected. Continuous data will be summarised as means, standard deviations, medians and ranges, whereas data on further procedures and complications will be summarised as frequencies and percentages. Outcomes will be illustrated graphically over time where appropriate, including confidence intervals.

The primary analysis model will be a mixed effects regression analysis, with DASH scores at 4, 12 and 18 months follow-up as the dependent variable, adjusting for baseline DASH, randomised group and other pertinent baseline characteristics as fixed effects and including treating centre as random effects. The model will account for similarities of scores by the same person by means of an appropriate covariance structure. The estimated treatment group differences at 4 months will be reported as the primary endpoint. Non-inferiority will be accepted if the upper bound of the two-sided 95% CI (equivalent to a one sided 97.5% CI) for the treatment difference at 4 months lies within the non-inferiority margin of 10 points. Secondary analyses will include an estimate of treatment group differences at 12 and 18 months from the same model. A secondary analysis model will include the 24 month time point in the primary model for those participants who would have reached that time point. In non-inferiority comparisons in the presence of treatment switching the ITT analysis could bias towards the null, which may lead to false claims of non-inferiority, hence we will undertake both ITT and Complier average causal effect (CACE) analyses. The amount of missing data will be mitigated by including all data in the primary analysis model, which allows the inclusion of any patient with complete baseline data and valid outcome data at one or more follow-up points. The nature of missingness for outcome data will be explored and multiple imputation considered if appropriate. Secondary continuous outcomes will be analysed by similar mixed effects regression analyses.

### **Health Economic Analysis**

The economic evaluation will assess the impact of available treatments for the treatment of Mayo Grade IIA fractures of the olecranon on the health of the patient and the costs to the NHS and personal social services (PSS), both in the short and the long term. The short-term cost-effectiveness of tension suture repair compared to tension band wiring for surgical fixation will be estimated using direct results of the trial up to 18 months of follow-up (and 24 months where data are available). As non-union of the fracture has potentially life long implications, we will consider an extrapolation analysis to estimate the health and cost implications beyond the duration of the SOFFT trial. Individual patient data from the trial will be used to evaluate resource use, costs and health outcomes associated with the surgical procedures and will be collected over the follow-up period of the trial.

The primary economic outcome will be the additional cost per quality-adjusted life year (QALY) gained by undergoing tension suture repair using an intention-to-treat approach. Costs and health outcome data for the economic analysis will be collected prospectively during the trial at baseline, 4, 12 and 18 months (and 24 months for those participants that reach this timepoint during the trial).

Health care resource use will be presented for both arms in terms of mean value, standard deviation and mean difference (with 95% CI) between the groups. The cost of each type of surgery and related complications will be essential for the analysis. Hence, an accurate record of procedures at hospital level (e.g. centres in the trial) will be put in place in order to record per patient information (e.g. surgical procedures, complications related to the procedures, other medical complications). Costs relating to surgical procedures will be micro-estimated based on time in theatre, staff time, consumables and devices, and nights in hospital after the procedure. Unit costs will be derived from established national costing sources such as NHS Reference Costs and PSSRU Unit costs of health and social care. Unit costs will be multiplied by resource use to obtain a total cost for each patient. QALYs will be estimated by means of the EQ-5D as recommended by the NICE appraisal guidance.(30) Patients will complete the EQ-5D-5L (https://www.nice.org.uk/about/what-we-do/our-programmes/nice guidance/technology-appraisal-guidance/eq-5d-5l) and descriptive statistics will be summarised by trial arm for each time point. (31)

Regression methods will be used for the incremental analysis as this allows differences in prognostic variables. Patterns of missing data will be summarised and the impact of missingness assessed using multiple imputation techniques if necessary. A range of sensitivity analysis will be conducted to test the robustness of the results under different scenarios, including probabilistic sensitivity analysis. (31) An extrapolated model will be used to estimate cost-effectiveness over a lifetime.

A literature review will be conducted to explore whether previous economic evaluations have assessed the cost-effectiveness of tension suture repair versus tension band wiring for the SOFFT population, in case previous models exist these could be adapted to estimate the long-term cost-effectiveness. If no previous models are retrieved a de novo model will be developed. The extrapolation analysis will be conducted in accordance with the NICE Guide to the Methods of Technological Appraisal (30) and Decision Modelling for Health Economic Evaluation. (32)

## Monitoring

## Data Monitoring

Data monitoring will be undertaken regularly by the Trial Management Group (TMG), Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) comprised of independent clinicians and health service researchers with appropriate expertise. The DMC will review accumulating trial data and advise the sponsor (directly or indirectly) on the future management of the trial. The DMC will review all serious adverse events which are thought to be treatment related and unexpected. The independent members of the DMC committee will be allowed to see unblinded data. The DMC will adopt a DAMOCLES charter (33) which will define its terms of reference and responsibilities in relation to oversight of the trial.

Data from the internal pilot phase will be used by the DMC and TSC to check the assumptions about the feasibility of the trial and its continuation, particularly concerning recruitment assumptions. These data will also contribute to the final analyses.

Continuation of the trial will be decided by the funding body.

**Adverse Event management**

Adverse events are defined as any untoward medical occurrence in a trial participant to whom a research treatment or procedure has been administered and which does not necessarily have a causal relationship with the treatment. Adverse events may be a non-serious adverse event (AE) or a serious adverse event (SAE). For the purposes of SOFFT, we will only collect AE data for events that are related to the original elbow injury, unexpected and reported up to 12 months following trial treatment.

Complications expected with this condition and treatments are detailed in Table 5 and will not be reported as AEs, these complications will be recorded in the SOFFT follow up CRFs.

An appropriate member of the site research team will record observed AEs on an Adverse event report form and send to York Trials Unit within an agreed timescale (five days). SAEs should be notified to the Principal Investigator and to York Trials Unit within 24 hours of the research staff or clinical team becoming aware of the event.

The PI or delegated clinician will record an assessment of causality (to trial treatment). Once received, causality and expectedness will be confirmed by the Chief Investigator. SAEs that are deemed to be unexpected and related to the trial will be notified to the Research Ethics Committee (REC) and sponsor within 15 days. Follow-up reports a month later will be reviewed by the CI to ensure that adequate action has been taken and progress made.

All such events will be reported to the TSC and DMC at their next meetings. All participants experiencing SAEs will be followed up as per protocol until the end of the trial. Where repeated AEs of similar type are observed, these will be discussed with the DMC and will be onward reported to Sponsor and REC should concerns be raised in relation to the type of event and/or frequency observed.

**Table 5 - Expected complications associated with olecranon fracture fixation surgery.**

|  |  |
| --- | --- |
| **General surgical complications** | |
| Infection at surgical site | Complex regional pain syndrome (CRPS) |
| Bleeding/haematoma | Wound healing problems |
| Stiffness | Seroma |
| Heterotopic ossification | Neurological complications |
| Rehospitalisation | Skin problems |
| Granuloma / suture abscess | Sinus |
| Cutaneous nerve injury / neuroma / numbness / altered sensation | Unexplained pain |
| **Anaesthetic related complications** | |
| Myocardial infarction (MI) | Cerebrovascular accident (CVA) |
| Venous thromboembolism (VTE) | Block related nerve lesion |
| **Complications specific to olecranon fracture surgery** | |
| Non-union | Delayed union |
| Mal-union | Fracture displacement |
| Hardware prominence | Hardware migration |
| Hardware failure | Fixation failure |
| Ulna nerve lesion | Median nerve lesion |
| Radial nerve lesion | Radioulnar synostosis |
| Vascular injury | Ulnohumeral instability |

**Auditing**

Data monitoring will be undertaken by the Trial Management Group (TMG), who will meet initially monthly and then on a three-monthly basis following the pilot phase. The independent members of the TSC and DMC will also monitor the data. This will be reported to the sponsor (Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust) and regular progress reports will be submitted to the funding body. The study will be conducted in line with the standards set out in the Research Governance Framework for Health and Social Care and the guidelines for Good Clinical Practice. (34)

# Ethics and Dissemination

The study will be conducted to protect the human rights and dignity of the patient as reflected in the Declaration of Helsinki. (35)

Formal NHS Research Ethics Committee (REC) approval was granted on 16th June 2020 (North West - Greater Manchester Central Research Ethics Committee) Health Research Authority (HRA) approval was also granted on 16th June 2020. Local R&D approvals (confirmation of capacity and capability) will be obtained for participating sites.

**Protocol amendments**

Any further amendments to the trial protocol will be agreed with the funding body, Sponsor, TSC, DMEC, and the TMG as required and submitted for approval by the HRA and REC where required.

## Patient Confidentiality

The researchers and clinical care teams must ensure that patients’ anonymity will be maintained and that their identities are protected from unauthorised parties. Patients will be assigned a unique participant identification number and this will be used on CRFs; patients will not be identified by their name. Sites will keep securely and maintain the patient Enrolment Log showing participant identification numbers and names of the patients. This unique participant number will identify all CRFs and other records and no names will be used, in order to maintain confidentiality.

All records will be kept in locked locations. All consent forms will be secured safely in a separate compartment of a locked cabinet. Clinical information will not be released without written permission, except as necessary for monitoring by the trial monitors.

At the end of the study, data will be securely archived by participating sites and the University of York for a minimum of ten years.

**Declarations of interest**

Independent members of the DMEC and TSC will be required to provide written confirmation that they have no competing interests to declare.

## Access to Data

Access to source data/documents to conduct trial-related monitoring, audits and regulatory inspection is sought from participants during the informed consent discussion. Participants will consent to provide access to their medical notes.

**Ancillary and post-trial care**

Due to the pragmatic nature of this trial, participants should attend any routine clinical appointments that may be scheduled outside of trial visits, in line with the routine care pathway at the participating site.

If there is negligent harm during the trial, when the NHS Trust owes a duty of care to the person harmed, NHS Indemnity covers NHS staff and medical academic staff with honorary contracts only when the trial has been approved by the R&D department.

# Patient and Public Involvement

Patient and Public Involvement (PPI) group involvement began in the study design stage with the CI meeting with the Sponsor Trust Musculoskeletal PPI group.

The PPI group contributed to study design and to patient facing study material such as patient information sheets, consent forms, patient rehabilitation leaflet and patient questionnaires. Other key time points for consultation are identified as when the study is being set up, at the end of the pilot and when the study is being written up and disseminated.

A PPI member is a lay co-applicant and will be the link between the research team and the PPI group. They will represent the views of the PPI group at meetings of the TMG and will facilitate input from the PPI group.

# Dissemination

A dissemination and publication policy developed with an agreement between partners including ownership and exploitation of intellectual property, and publication rights, will ensure that any intellectual property generated during the project is protected and that the publication process is organised in a fair, balanced and transparent manner.

Targets for dissemination will include NICE, Clinical Commissioning Groups, the Department of Health and the Speciality Advisory Committees (SAC) for the curriculum for clinicians who will undertake treatment of olecranon fractures. The study protocol and results will be presented orally and will be made publicly available in appropriate publications and a summary of the study will be made available in plain English for patient-focused outlets.

The executive summary and copy of the trial report will be sent to NICE and other relevant bodies, including Clinical Commissioning Groups, so that the study findings can inform their deliberations and be translated into clinical practice nationally. We will also work with the relevant National Clinical Director in the Department of Health to help ensure the findings of the trial are considered when implementing policy and will work with the Speciality Advisory Committees (SAC) to incorporate the findings into the training curriculum for clinicians who will undertake treatment of olecranon fractures. The British Elbow and Shoulder Society have adopted the trial for inclusion in their research portfolio which will facilitate dissemination of findings to relevant stakeholders. A number of dissemination channels will be used to inform clinicians, patients and the public about the results of the study.

An HTA monograph will be produced and on completion of the study, the findings of the HTA report will be presented at national and international meetings of organisations. The study report will be published in peer reviewed high impact general medical and orthopaedic journals.

An updated video of the surgical technique and including study outcomes will be submitted to Bone and Joint Essential Surgical Techniques for peer-review publication.

The study results will be shared with relevant evidence synthesis teams (including within the Cochrane Collaboration) in order to ensure that results are incorporated in future systematic reviews.

A summary of the study report, written in lay language will be produced and made available to participants, members of our user group and relevant patient-focused websites.

**Twitter: @SOFFTrial**

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Table 6 details key items from the trial registration data set in line with World Health Organization recommendations as noted in SPIRIT recommendations for clinical trial protocols. (20)

**Table 6 - Details of trial registration for SOFFT as per the recommended World Health Organization Trial Registration Data Set**

|  |  |
| --- | --- |
| Trial registration | ISRCTN87904264 |
| Date of registration | 19th May 2020 |
| Funder information | The National Institute for Health Research Health Technology Assessment programme (HTA Project: NIHR127739) |
| Sponsor | Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust |
| Scientific title | Simple Olecranon Fracture Fixation Trial (SOFFT) Suture fixation versus tension band wiring for simple olecranon fracture fixation: a multi-centre randomised controlled trial |
| Countries of recruitment | England, Wales, Scotland |
| Health condition(s) or problem(s) studied | Clinical diagnosis of a Mayo Grade IIA acute Olecranon fracture. |
| Intervention(s) | Tension Band Wiring technique vs Tension Suture Repair technique |
| Key inclusion and exclusion criteria | *Inclusion criteria:*  • Patients aged ≥ 16years  • Mayo Grade IIA acute fracture within 3 weeks of injury  • Closed or Gustil~~l~~o and Anderson grade 1 open injury  • The surgeon believes the patient will benefit from surgical intervention  • Ability to give informed consent  *Exclusion Criteria:*  • Surgery contra-indicated  • Gustil~~l~~o and Anderson grade 2 or 3 open injury  • Associated upper limb injuries or prior upper limb pathology adversely affecting function  • Evidence of fracture comminution (Mayo Grade IIB) or instability around the elbow and/or forearm (Mayo Grade III)  • Evidence that the patient would be unable to adhere to trial procedures or complete questionnaires  • Previous entry into SOFFT  • Concurrent olecranon fracture in the opposite limb |
| Study type | Interventional  Allocation: randomized controlled trial with 1:1 allocation  Primary purpose: non-inferiority study comparing clinical and cost-effectiveness of intervention |
| Date of first enrolment | 19th October 2020 |
| Target sample size | 280 |
| Recruitment status | Recruiting |
| Primary outcome | DASH at 4 months post randomisation |
| Key secondary outcomes | DASH (at 12, 18, and 24 months), pain,  net Promotor Score (Patient Satisfaction,  EuroQol 5 Dimensions (5L) Score (EQ5D-5L, radiological union, complications, elbow range of movement, re-operations related to the injury or to remove metalwork and resource use and work impact. |

*DASH - Disabilities of the Arm Shoulder and Hand*

**References:**

1. Powell AJ, Farhan-Alanie OM, Bryceland JK, Nunn T. The treatment of olecranon fractures in adults. MUSCULOSKELETAL SURGERY. 2017;101(1):1-9.

2. Duckworth AD, Clement ND, Aitken SA, Court-Brown CM, McQueen MM. The epidemiology of fractures of the proximal ulna. Injury. 2012;43(3):343-6.

3. Henseler JF, van der Zwaal P, Dijkstra PD. Use of sutures as Kirschner wire and tension-band wire for olecranon fractures: a technical note. J Orthop Surg (Hong Kong). 2014;22(3):440-2.

4. Karlsson MK, Hasserius R, Besjakov J, Karlsson C, Josefsson PO. Comparison of tension-band and figure-of-eight wiring techniques for treatment of olecranon fractures. J Shoulder Elbow Surg. 2002;11(4):377-82.

5. Chalidis BE, Sachinis NC, Samoladas EP, Dimitriou CG, Pournaras JD. Is tension band wiring technique the "gold standard" for the treatment of olecranon fractures? A long term functional outcome study. Journal of Orthopaedic Surgery and Research. 2008;3(1):9.

6. Duckworth AD, Clement ND, White TO, Court-Brown CM, McQueen MM. Plate Versus Tension-Band Wire Fixation for Olecranon Fractures: A Prospective Randomized Trial. J Bone Joint Surg Am. 2017;99(15):1261-73.

7. Das AK, Jariwala A, Watts AC. Suture Repair of Simple Transverse Olecranon Fractures and Chevron Olecranon Osteotomy. Tech Hand Up Extrem Surg. 2016;20(1):1-5.

8. Bateman DK, Barlow JD, VanBeek C, Abboud JA. Suture anchor fixation of displaced olecranon fractures in the elderly: a case series and surgical technique. J Shoulder Elbow Surg. 2015;24(7):1090-7.

9. Cha SM, Shin HD, Lee JW. Application of the suture bridge method to olecranon fractures with a poor soft-tissue envelope around the elbow: Modification of the Cha-Bateman methods for elderly populations. J Shoulder Elbow Surg. 2016;25(8):1243-50.

10. Ravenscroft MJ, Phillips N, Mulgrew E, Yasin MN. Suture Anchor Fixation of Olecranon Fractures: A Case Series. Shoulder & Elbow. 2013;5(2):116-9.

11. Matar HE, Ali AA, Buckley S, Garlick NI, Atkinson HD. Surgical interventions for treating fractures of the olecranon in adults. Cochrane Database Syst Rev. 2014(11):Cd010144.

12. Schneider MM, Nowak TE, Bastian L, Katthagen JC, Isenberg J, Rommens PM, et al. Tension band wiring in olecranon fractures: the myth of technical simplicity and osteosynthetical perfection. Int Orthop. 2014;38(4):847-55.

13. Angst F, Schwyzer HK, Aeschlimann A, Simmen BR, Goldhahn J. Measures of adult shoulder function: Disabilities of the Arm, Shoulder, and Hand Questionnaire (DASH) and its short version (QuickDASH), Shoulder Pain and Disability Index (SPADI), American Shoulder and Elbow Surgeons (ASES) Society standardized shoulder assessment form, Constant (Murley) Score (CS), Simple Shoulder Test (SST), Oxford Shoulder Score (OSS), Shoulder Disability Questionnaire (SDQ), and Western Ontario Shoulder Instability Index (WOSI). Arthritis Care Res (Hoboken). 2011;63 Suppl 11:S174-88.

14. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). Arthritis Care Res (Hoboken). 2011;63 Suppl 11:S240-52.

15. McCormack HM, Horne DJ, Sheather S. Clinical applications of visual analogue scales: a critical review. Psychol Med. 1988;18(4):1007-19.

16. Reichheld FF. The one number you need to grow. Harvard business review. 2003;81(12):46-55.

17. Hamilton D. F LJV, Gaston P., Patton J. T., MacDonald D. J., Simpson A. H. R. W. and Howie C. R. Assessing treatment outcomes using a single question. The Bone & Joint Journal. 2014;96-B(5):622-8.

18. van Reenen MaJ, B. EQ-5D-5L User Guide: Basic information on how to use theEQ-5D-5L instrument. The Netherlands: EuroQol Research Foundation

2015((Version 2.1)).

19. Horan TC, Andrus M, Dudeck MA. CDC/NHSN surveillance definition of health care-associated infection and criteria for specific types of infections in the acute care setting. Am J Infect Control. 2008;36(5):309-32.

20. Chan AW, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-7.

21. Franchignoni F, Vercelli S, Giordano A, Sartorio F, Bravini E, Ferriero G. Minimal clinically important difference of the disabilities of the arm, shoulder and hand outcome measure (DASH) and its shortened version (QuickDASH). J Orthop Sports Phys Ther. 2014;44(1):30-9.

22. Chiari-Grisar C, Koller U, Stamm TA, Wanivenhaus A, Trieb K. Performance of the disabilities of the arm, shoulder and hand outcome questionnaire and the Moberg picking up test in patients with finger joint arthroplasty. Arch Phys Med Rehabil. 2006;87(2):203-6.

23. Costa ML, Achten J, Plant C, Parsons NR, Rangan A, Tubeuf S, et al. UK DRAFFT: a randomised controlled trial of percutaneous fixation with Kirschner wires versus volar locking-plate fixation in the treatment of adult patients with a dorsally displaced fracture of the distal radius. Health Technol Assess. 2015;19(17):1-124, v-vi.

24. Angst F, John M, Goldhahn J, Herren DB, Pap G, Aeschlimann A, et al. Comprehensive assessment of clinical outcome and quality of life after resection interposition arthroplasty of the thumb saddle joint. Arthritis Rheum. 2005;53(2):205-13.

25. MacDermid JC, Wessel J, Humphrey R, Ross D, Roth JH. Validity of self-report measures of pain and disability for persons who have undergone arthroplasty for osteoarthritis of the carpometacarpal joint of the hand. Osteoarthritis Cartilage. 2007;15(5):524-30.

26. Keding A, Brabyn S, MacPherson H, Richmond S, Torgerson D. Text message reminders to improve questionnaire response rates in RCTs: findings from three randomised sub-studies. Trials. 2015;16(S2):P103.

27. Mitchell N, Hewitt CE, Lenaghan E, Platt E, Shepstone L, Torgerson DJ, et al. Prior notification of trial participants by newsletter increased response rates: a randomized controlled trial. Journal of clinical epidemiology. 2012;65(12):1348-52.

28. software. OSaST. <https://ocrsolution>. com/teleform- software/.

29. Schulz KF, Altman DG, Moher D, the CG. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Medicine. 2010;8(1):18.

30. NICE. Methods guides. Guide to the Methods of Technology Appraisal. London: National Institute for Health and Care Excellence; 2013.

31. Faria R, Gomes M, Epstein D, White IR. A guide to handling missing data in cost-effectiveness analysis conducted within randomised controlled trials. Pharmacoeconomics. 2014;32(12):1157-70.

32. Briggs A, Sculpher M, Claxton K. Decision modelling for health economic evaluation: Oup Oxford; 2006.

33. A proposed charter for clinical trial data monitoring committees: helping them to do their job well. The Lancet. 2005;365(9460):711-22.

34. guidelines MRCGrpPa. [Available from: <https://www.mrc.ac.uk/publications/browse/good-research-practice-principles-and-guidelines/>. 2012 [

35. subjects WMAWDoHepfmrih. [Available from: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>. 2013 [