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PROTOCOL

A randomized controlled trial to compare clinical and cost-effectiveness of suture fixation versus tension band wiring for simple olecranon fracture fixation in adults: The Simple Olecranon Fracture Fixation Trial (SOFFT) protocol

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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 grade 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 reoperation. 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 multicentre, pragmatic, two-arm parallel-group, non-inferiority, randomized 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 primary outcome will be the Disabilities of the Arm, Shoulder and Hand (DASH) score at four months post-randomization. Secondary outcome measures include DASH (at 12, 18, and 24 months), pain, Net Promotor Score (patient satisfaction), EuroQol five-dimension five-level score (EQ-5D-5L), radiological union, complications, elbow range of motion, 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 randomized controlled trial with sufficient power and design rigour to provide this evidence for the subtype of Mayo grade IIA fractures.

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Introduction

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

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fractures with a stable ulnohumeral joint (classified as Mayo grade 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 (K-)wires and a cerclage wire in a 'figure of eight loop'.[3] While 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 nonunion 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 NHS is estimated at 36%.[6]

Suture or suture anchor techniques have been described with the aim of reducing the hardware related complications and reoperation.[3,7-9] From the suture anchor technique described by Ravenscroft et al,[10] an all suture technique has been developed by Watts et al[7] to fix the fracture using strong synthetic sutures alone. 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 reoperation, this also has the potential to provide cost savings to the healthcare system.

Rationale. There is currently no high-quality evidence from a randomized controlled trial (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.

Aims 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 I.

Methods

Trial design. SOFFT is a pragmatic multicentre, participant-blinded, non-inferiority RCT with parallel groups, allocated on a 1:1 ratio. An economic evaluation is also included. A nine-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 Randomized Controlled Trial Number (ISRCTN) as ISRCTN87904264.

Study participants. Adults aged ≥ 16 years 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 II. Eligibility will be confirmed by an appropriately delegated surgeon prior to the patient being invited to join the study.

Interventions

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

Standard tension band wiring. Tension band wiring (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. Tension suture repiar (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 2.5 mm drill hole placed in the ulna distal to the fracture site (no less than 2 mm, no more than 3.5 mm).
- Repair with braided suture passed through the drill hole and the insertion of triceps to the olecranon (no less than two 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.

Table I. Simple Olecranon Fracture Fixation Trial (SOFFT) objectives.

Primary objective
To undertake a multicentre, 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 over, based on functional outcome as measured by the DASH score at four months.
Secondary objective
Undertake a nine-month internal pilot to obtain robust estimates of recruitment and confirm trial feasibility.
To undertake an analysis of the rate of reoperation.
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.

DASH, Disabilities of Arm, Shoulder and Hand; RCT, randomized controlled trial.

Table II. Simple Olecranon Fracture Fixation Trial (SOFFT) eligibility criteria.

Participant inclusion criteria
■ Patients aged ≥ 16 years
■ Mayo grade IIA acute fracture within three weeks of injury
■ Closed or Gustillo and Anderson grade I open injury*
■ The surgeon believes the patient will benefit from surgical intervention
■ Ability to give informed consent
Participant exclusion criteria
■ Surgery contraindicated
■ Gustillo and Anderson grade II or III 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 I open injury, that is a wound measuring < 1 cm with no evidence of contamination, will be eligible for inclusion.

Surgeon training. To standardize delivery of interventions across all sites, principal investigators (PIs) 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 et al[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 chief investigator 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 standardized, 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 four, 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[13] at four months post-randomization. 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. The 30-item patient-reported outcome measures is designed for use in people with musculoskeletal disorders of the upper limb and is a reliable and valid instrument.[14]

Secondary outcomes. Secondary outcomes will be collected at four, 12, and 18 months post-randomization 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 III).

Participant timeline. Participants will be followed up at four, 12, and 18 months post-randomization, and at 24 months for participants who reach this point within the trial window.

Table IV 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).[21]

Sample size. Minimal clinical important differences for the DASH are around ten points from individual studies using anchor-based methods.[14,22] We estimate that a ten-point difference on the DASH at four 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 and 20% attrition,[7,22–26] 280 participants are required to establish non-inferiority of tension suture fixation compared with tension band wiring technique within a margin of ten points of the DASH, based on an upper limit of a 95% confidence interval (CI).

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

Table III. Simple Olecranon Fracture Fixation Trial (SOFFT) secondary outcomes.

Secondary outcomes
Disabilities of Arm, Shoulder and Hand score at 12, 18, and 24 months.
Visual nalogue acale (VAS): a unidimensional measure of pain intensity which has been widely used in adults.[15] The VAS consists of a 100 mm line representing a continuous scale. The line is anchored at both ends with the verbal descriptors 'no pain' and 'worst imaginable pain'.[16]
Net Promotor Score (NPS; 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'.[17,18] Responses scoring 9 to 10 are classed as "promoters", those scoring 7 to 8 "passives" and those scoring 0 to 6 "detractors". The percentage of detractors is subtracted from the percentage of Promoters to yield the NPS with a range from -100 (all detractors) to 100 (all promoters).
EuroQol five-dimensions five-level score (EQ-5D-5L): measures health-related quality of life (HRQoL) in terms of five dimensions: mobility, ability to self-care, ability to undertake usual activities, pain and discomfort, and anxiety and depression. The EQ-5D-5L will be scored according to the user guide.[19] EQ-5D-5L data will be collected twice at baseline: i.e. once to assess patient HRQoL 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 four months. The assessment of union will be undertaken by two assessors independent of the trial. The four-month radiograph 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,[20] superficial infection (using CDC definition), rehospitalization, nerve, and skin problems.
Elbow range of motion: Elbow range of flexion, extension, pronation and supination will be assessed at four 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 reoperation (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.

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 nine-month pilot study will test assumptions about the number of sites open, number of eligible participants, number recruited, number randomized, 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 to 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 four 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. Randomization will be performed independently using a secure, online randomization service hosted by York Trials Unit to ensure allocation concealment.[27]

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, four, 12, and 18 months post-randomization via participant questionnaires or investigator case report forms (CRFs). Baseline data and four-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 four, 12, 18, and 24 months and supplemented by information collected from patients' medical records by research staff.

Participant retention. To minimize 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.[28] Two- and four-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.[29]

We will also write newsletters during the trial to keep the participants informed and engaged with the trial, which can enhance response rates.[30]

Table IV. Simple Olecranon Fracture Fixation Trial (SOFFT) study assessment schedule.

Assessment	Baseline (clinic)*	Randomization	Intervention	Month 4 (clinic/ remote)†	Month 12 (remote questionnaire)	Month 18 (remote questionnaire)	Month 24 (remote questionnaire)‡
Allowed variation in days				± 14			
Eligibility screen	x						
Informed consent	x						
Demographics	x						
Randomization		x					
Assessments							
DASH	X§			x	x	x	x
VAS (pain)	x			x	x	x	x
Net Promotor Score				x	x	x	x
EQ-5D-5L	X§			x	x	x	x
Radiograph	x			x			
Perioperative data			x¶	x			
Elbow range of motion+				x			
Fracture union using radiological assessment				x			
Patient and 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 randomization.
†Visit may be conducted remotely in the event of local restrictions arising from COVID-19. Window for radiology assessments only is -14 days to + two months+. Objective range of motion 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 standardized protocol.
‡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.
DASH, Disabilities of Arm, Shoulder and Hand; EQ-5D-5L, EuroQol five-dimension five-level; VAS, visual analogue scale.

Data management. Paper CRFs and questionnaires will be designed using TeleForm software,[31] 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 randomized, 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.[32]

Pilot phase analysis. The recruitment rate and 95% 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 randomized; proportion of patients randomized who do not receive the randomly allocated treatment; and

Table V. Expected complications associated with olecranon fracture fixation surgery.

Expected complications	
General surgical	
Infection at surgical site	Complex regional pain syndrome
Bleeding/haematoma	Wound healing problems
Stiffness	Seroma
Heterotopic ossification	Neurological complications
Rehospitalization	Skin problems
Granuloma/suture abscess	Sinus
Cutaneous nerve injury/neuroma/numbness/altered sensation	Unexplained pain
Anaesthetic-related	
Myocardial infarction	Cerebrovascular accident
Venous thromboembolism	Block related nerve lesion
Specific to olecranon fracture surgery	
Nonunion	Delayed union
Malunion	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

proportion of patients dropping out between randomization and follow-up.

Data will be summarized on the reasons why eligible patients were not approached, reasons for patients declining to participate in the study, reasons why randomized 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 analyzed in the groups to which they were randomized. 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 (StataCorp, USA) or similar statistical software.

Baseline characteristics will be presented by trial arm. All trial outcomes will be reported descriptively by group (as randomized and as analyzed) at all time points at which they were collected. Continuous data will be summarized as means, standard deviations, medians and ranges, whereas data on further procedures and complications will be summarized 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 four, 12, and 18 months follow-up as the dependent variable, adjusting for baseline DASH, randomized 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 four 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 four months lies within the non-inferiority margin of ten 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 analyzed 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

Table VI. Details of trial registration for Simple Olecranon Fracture Fixation Trial (SOFFT), as per the recommended World Health Organization trial registration data set.

Variable	Details
Trial registration	ISRCTN87904264
Date of registration	19 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 multicentre, randomized 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 versus tension suture repair technique
Key inclusion and exclusion criteria	**Inclusion criteria:** ■ Patients aged ≥ 16 years ■ Mayo Grade IIA acute fracture within three weeks of injury ■ Closed or Gustillo and Anderson grade 1 open injury ■ The surgeon believes the patient will benefit from surgical intervention ■ Ability to give informed consent **Exclusion criteria:** ■ Surgery contraindicated ■ Gustillo 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	19 October 2020
Target sample size	280
Recruitment status	Recruiting
Primary outcome	Disabilities of Arm, Shoulder and Hand (DASH) at four months post-randomization
Key secondary outcomes	DASH (at 12, 18, and 24 months), pain, Net Promotor Score (patient satisfaction), EuroQol five-dimension five-level score (EQ-5D-5L) radiological union, complications, elbow range of motion, re-operations related to the injury or to remove metalwork, and resource use and work impact.

to 18 months of follow-up (and 24 months where data are available). As nonunion 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, four, 12, and 18 months (and 24 months for those participants that reach this time-point 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.[33] Patients will complete the EQ-5D-5L,[34] and descriptive statistics will be summarized by trial arm for each time point.[35]

Regression methods will be used for the incremental analysis as this allows differences in prognostic variables. Patterns of missing data will be summarized 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.[35] 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,[33] and Decision Modelling for Health Economic Evaluation.[36]

Monitoring

Data monitoring. Data monitoring will be undertaken regularly by the trial management group (TMG), trial steering committee (TSC), and data monitoring committee (DMC) composed 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,[37] 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 V 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 PI 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 chief investigator 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.

Auditing. Data monitoring will be undertaken by the 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.[38]

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.[39]

Formal NHS Research Ethics Committee (REC) approval was granted on 16 June 2020 (North West - Greater Manchester Central Research Ethics Committee) Health Research Authority (HRA) approval was also granted on 16 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 organized in a fair, balanced, and transparent manner.

Targets for dissemination will include NICE, Clinical Commissioning Groups, the Department of Health (DoH), and the Speciality Advisory Committees (SACs) 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 DoH to help ensure the findings of the trial are considered when implementing policy and will work with the SACs 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.

Table VI 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.[21]

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References

1. **Powell AJ**, **Farhan-Alanie OM**, **Bryceland JK**, **Nunn T**. The treatment of olecranon fractures in adults. *Musculoskelet Surg*. 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):343–346.
3. **Henseler JF**, **van der Zwaal P**, **Dijkstra PDS**. Use of sutures as Kirschner wire and tension-band wire for olecranon fractures: a technical note. *J Orthop Surg (Hong Kong)*. 2014;22(3):440–442.

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):377–382.
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. *J Orthop Surg Res*. 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-A(15):1261–1273.
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):1090–1097.
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):1243–1250.
10. **Ravenscroft MJ**, **Phillips N**, **Mulgrew E**, **Yasin MN**. Suture anchor fixation of olecranon fractures: a case series. *Shoulder & Elbow*. 2013;5(2):116–119.
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**, **et al**. Tension band wiring in olecranon fractures: the myth of technical simplicity and osteosynthetical perfection. *Int Orthop*. 2014;38(4):847–855.
13. **No authors listed**. The DASH outome measure. http://dash.iwh.on.ca/ (date last accessed 10 January 2023).
14. **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. *Arthritis Care Res*. 2011;63(S11):S174–S188.
15. **Hawker GA**, **Mian S**, **Kendzerska T**, **French M**. Measures of adult pain: visual analogue 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.
16. **McCormack HM**, **Horne DJ**, **Sheather S**. Clinical applications of visual analogue scales: a critical review. *Psychol Med*. 1988;18(4):1007–1019.
17. **Reichheld FF**. The one number you need to grow. *Harv Bus Rev*. 2003;81(12):46–54.
18. **Hamilton DF**, **Lane JV**, **Gaston P**, **et al**. Assessing treatment outcomes using a single question: the net promoter score. *Bone Joint J*. 2014;96-B(5):622–628.
19. **van Reenen MaJ B**. *EQ-5D-5L User Guide: Basic information on how to use theEQ-5D-5L instrument (Version 2.1)*. The Netherlands: EuroQol Research Foundation, 2015.
20. **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):309–332.
21. **Chan A-W**, **Tetzlaff JM**, **Altman DG**, **et al**. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med*. 2013;158(3):200–207.
22. **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):30–39.
23. **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):203–206.
24. **Costa ML**, **Achten J**, **Plant C**, **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, .
25. **Angst F**, **John M**, **Goldhahn J**, **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):205–213.
26. **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):524–530.
27. **No authors listed**. York Trials Unit. https://ytu.york.ac.uk/YorkRand/ (date last accessed 15 December 2022).
28. **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):S2.
29. **No authors listed**. Queen's University Belfast. https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/FileStore/Filetoupload,1098876,en.pdf (date last accessed 15 December 2022).
30. **Mitchell N**, **Hewitt CE**, **Lenaghan E**, **et al**. Prior notification of trial participants by newsletter increased response rates: a randomized controlled trial. *J Clin Epidemiol*. 2012;65(12):1348–1352.
31. **No authors listed**. Telecom software. https://ocrsolution.com/teleform- software/ (date last accessed 15 December 2022).
32. **Schulz KF**, **Altman DG**, **Moher D**, **CONSORT Group**. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMC Med*. 2010;8:18.
33. **No authors listed**. National Institute for Health and Care Excellence guide to the methods of technology appraisal. https://www.nice.org.uk/process/pmg9/chapter/foreword (date last accessed 15 December 2022).
34. **No authors listed**. NICE position statement on use of the EQ-5D-5L value set for England. https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/technology-appraisal-guidance/eq-5d-5l (date last accessed 10 January 2023).
35. **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):1157–1170.
36. **Briggs A**, **Sculpher M**, **Claxton K**. *Decision modelling for health economic evaluation*. Oup Oxford, 2006.
37. **DAMOCLES Study Group, NHS Health Technology Assessment Programme**. A proposed charter for clinical trial data monitoring committees: helping them to do their job well. *Lancet*. 2005;365(9460):711–722.
38. **No authors listed**. MRC principles and guidelines for good research practice. https://www.mrc.ac.uk/publications/browse/good-research-practice-principles-and-guidelines/ (date last accessed 15 December 2022).
39. **No authors listed**. World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ (date last accessed 15 December 2022).

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