A multicentre, randomized, pragmatic, parallel group, non-inferiority trial to compare the clinical and cost-effectiveness of sling immobilization versus surgery in the management of adults with a displaced fracture of the distal clavicle

Protocol for the DIDACT randomized controlled trial

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Aims

Fractures of the clavicle primarily occur in young males and constitute 2.6% to 5% of all fractures in adults. Distal clavicle fractures, where the outer end of the collarbone breaks, account for 20% to 25% of all clavicle fractures. These fractures can be called displaced if the ligaments connecting the collarbone to the shoulder blade (coracoclavicular complex) rupture. Such displaced fractures (Neer's type II and V) are currently treated with an operation involving fracture fixation or with sling immobilization. This protocol describes a randomized controlled trial that aims to evaluate the clinical and cost-effectiveness of these two types of treatment which are used for displaced distal clavicle fractures.

Methods

The DIsplaced DistAl Clavicle Fracture Trial (DIDACT) is a pragmatic, parallel, two-arm individually randomized non-inferiority trial of 214 adult patients with a radiologically confirmed diagnosis of a displaced distal clavicle fracture. Participants will be randomly allocated on 1:1 basis to surgery with locking plate fixation (with or without coracoclavicular (CC) sling, or CC reconstruction alone) or sling immobilization. In the sling immobilization group, if symptomatic nonunion occurs, participants would be offered surgical fixation (typically at the three-month follow-up). The primary outcome and endpoint will be the self-reported Disabilitities of the Arm, Shoulder and Hand questionnaire (DASH) at 12 months. The DASH will also be collected as a secondary outcome at baseline, six weeks, three, and six months after randomization. Other secondary outcomes include shoulder pain, EuroQol five-dimension five-level questionnaire (EQ-5D-5L), complications (e.g. infections, reoperations), fracture healing, healthcare costs, patient treatment preferences,

satisfaction with appearance of their shoulder, sensitivity or pain to touch, and range of motion.

Conclusion

There is uncertainty around whether a sling immobilization pathway is non-inferior to surgery and which of these two treatments is cost-effective. The DIDACT trial is a sufficiently powered and rigorously designed study to inform clinical decisions for the treatment of adults with this injury.

Take home message

- Despite a lack of evidence from systematic reviews, data suggests a worldwide trend to increasing use of surgical fixation for the treatment of distal clavicle fractures.
- The treatment of distal clavicle fractures with or without surgery has been identified as a high-priority research topic by the James Lind Alliance and UK orthopaedic trauma network.
- The research question of whether sling immobilization is non-inferior to surgical fixation for adults with a radiological diagnosis of a displaced fracture of the distal clavicle that does not involve the acromioclavicular joint will address a key area of contention among surgeons.

Introduction

Background and rationale

Fractures of the clavicle primarily occur in young males, and constitute 2.6% to 5% of all fractures in adults.[1] Distal clavicle fractures account for 20% to 25% of all clavicle fractures.[1,2] The outer part of the collarbone breaks and separates, and these fractures can be displaced, in that the bone fragments do not line up. This ruptures the ligaments connecting the collarbone to the shoulder blade (coracoclavicular complex) and can be classified as Neer's type II and V.[3] These are currently treated with an operation involving fracture fixation or with sling immobilization.[1,2]

Surgery, whereby the bone fragments are realigned and fixed into place, may reduce the risk of the fracture not healing (nonunion).[4] However, patients treated with surgery are at risk of complications, including infection, plate breakage, and refracture after metal removal.[4] A second operation may be required to remove the metalwork due to prominence,[5] leading to a further impact on patients' lives including work activities and caring responsibilities. Nonoperative treatment, using a sling, carries a low risk of complications (15%) and has a relatively low immediate treatment cost.[4,6] Sling treatment requires a period of immobilization, typically between two and four weeks, to restrict activities while providing comfort during the early painful stages of healing. The risk of nonunion with nonoperative treatment is as high as 35% to 40%, but this appears to cause minimal functional deficits in most individuals.[5] If a nonunion occurs following sling treatment, and surgical intervention is indicated, it can prolong the treatment period and increase costs.[7]

Despite the lack of evidence of superiority, more distal clavicle fractures are now treated with surgery than non-surgical treatments, with data suggesting a worldwide trend to increasing use of surgical fixation.[5,6] The James Lind Alliance and UK orthopaedic trauma network have identified the treatment of distal clavicle fractures with or without surgery as a high-priority research topic.[8,9] The importance of this research question has further been confirmed in our national survey of shoulder surgeons from the British Elbow and Shoulder Society (BESS), who agree there is a need for this trial and a lack of consensus on how to manage this patient population.[10]

For the proposed trial, the surgical arm will comprise the locking plate (with or without coracoclavicular (CC) reconstruction or CC reconstruction alone). The hook plate will not be included in either of the trial arms, because the locking plate is considered superior to the hook plate by the clinical community, with practice moving towards locking plate over hook plate in the UK, so there could be a significant lack of surgeon equipoise.[11] A third trial arm would increase the cost of a trial, and including hook plates in the locking plate arm would decrease the statistical power of the trial. Finally, our patient representatives supported the decision not to include hook plates because of the risk of a further operation to remove them, to avoid damage to the rotator cuff muscles.

This randomized controlled trial (RCT) will answer the question of whether a non-surgical pathway is non-inferior to surgery for the treatment of adults with a displaced fracture of the distal end of the clavicle. The concomitant health economic evaluation will identify which is the most cost-effective treatment option for the UK NHS.

For the content of this protocol, we used the standard protocol items: Recommendations for Interventions Trials (SPIRIT)[12] and the CONSORT guidelines.[13]

Aims and objectives

The aim of this study is to provide good-quality evidence of the clinical and cost-effectiveness of sling immobilization compared with surgery in the management of adults with a displaced fracture of the distal clavicle. The specific objectives are listed in Table I.

Trial design

DIDACT is a two-arm, pragmatic, multicentre, individually randomized, non-inferiority trial with parallel groups, allocated on a 1:1 ratio using randomly permuted blocks of varying block sizes and stratified by age (< 65 or ≥ 65 years).[14] There will be a 12-month internal pilot to assess the assumptions about site setup and recruitment. The trial will include a full health economic evaluation. As with many surgical trials, it will not be feasible to blind patients, surgeons, or outcome assessors to the treatment allocation.

Methods

Study setting

We will recruit from a minimum of 23 NHS Major Trauma Centres and Trauma Units within the UK. Patients will be identified in hospital when presenting with their index

Table I. Trial objectives.

1	To determine whether self-reported functional outcome, measured by the Disabilities of the Arm, Shoulder and Hand questionnaire at 12 months, following sling immobilization is non-inferior to surgical fixation in adults with a displaced fracture of the distal clavicle.
2	To confirm the feasibility of the study in a 12-month internal pilot to obtain robust estimates of site setup and recruitment.
3	To determine the effectiveness of sling immobilization versus surgery in adults with a displaced fracture of the distal clavicle at six weeks, three, six, and 12 months post-randomization.
4	To determine the cost-effectiveness of the two treatments to inform the most efficient provision of future care and to describe the resource impact on the UK NHS.

shoulder fracture, either in the Emergency Department (ED) or Fracture Clinic and/or the orthopaedic trauma meeting.

Eligibility criteria

Patients must meet all the eligibility criteria to be included in the trial. The eligibility criteria are presented in Table II. Patient eligibility for the study will be confirmed by an orthopaedic surgeon or delegated clinician prior to their recruitment and recorded on REDCap (Research Electronic Data Capture).

As per routine practice, no specific requirements regarding who can deliver the surgical procedure or apply the sling will be in place. During site setup, it will be confirmed that both treatments can be delivered at participating sites.

Interventions

Eligible and consenting patients will be randomly allocated to either sling immobilization or surgical fixation. The materials (leaflets and videos) referred to below for participants can be found on the DIDACT website.[15]

Sling immobilization (intervention): Upper limb support is provided with a sling that is applied in the ED to relieve pain, allow for swelling, and to provide comfort. A sling is typically worn for between two and four weeks, the preferred length of complete immobilization in the BESS survey (n = 84, 46%),[10] and can be discarded when pain resolves or when there is evidence of fracture union. Overall, however, this can take six to eight weeks.[10] Each recruiting centre will be provided with a standardized protocol for the application and management of sling immobilization. The type of sling used will be the clinician's decision. Trial participants will also be provided with a standardized 'Sling Use and Initial Self-care' leaflet and video to manage their sling care. The type of sling and duration of use will be recorded. Patients' progress and bone healing in the non-operative pathway will be assessed clinically and radiologically when they attend hospital visits as would occur during routine clinical practice. Finally, surgeons will consider the need for surgery for patients who are immobilized in a sling if there is evidence of symptomatic nonunion using established indicators,[16] for example no callus, fracture movement, and patient symptoms.[17] Therefore, the need for surgery, when clinically indicated, and which will typically occur at the three-month visit, is part of an already established pathway of care in the sling immobilization group as a shared decision between the patient and surgeon.

Surgery (comparator): Locking plates are inserted through an incision at the top of the shoulder and applied to the end of the clavicle with screws into the distal end of the fracture. Some surgeons prefer to put a coracoclavicular (CC) sling to the fractured bone to provide additional stability,[18] or perform CC reconstruction alone when the distal fragment is very small.[19] The exact technique of surgical approach and insertion of the type of plate and CC sling will be recorded and will be the surgeon's decision. The principles of fixation with a plate are the same for all types of plate; the choice of plate type, size, and screw positions will be the surgeon's decision. The exact techniques and metalwork used will be recorded.

Postoperatively, the arm will be placed in an appropriately sized sling with guidance provided to participants on how to manage the sling and postoperative care, including axillary (armpit) hygiene and exercises. Movement of the arm will be expected to be encouraged from day one, with sling use initially for comfort, and to be discarded by the participant typically by two weeks after surgery. The type of sling used will be the healthcare professional's decision and will be recorded.

To reflect the pragmatic design, the level of experience of the operating surgeon will not be defined. All surgeons performing surgery on trial participants will be required to be familiar with the techniques and equipment that they are using. We will record the number of operations the surgeon has previously performed on this fracture population and their grade.

All participants will receive physiotherapy, which may be delivered in person or remotely. Each centre will be provided with a 'Physiotherapist Guidance' document about undertaking the physiotherapy. The frequency and timing of the physiotherapy will be a shared decision between the patient and physiotherapist. Participants will be provided with a standardized 'Advice and early exercise' leaflet and video about undertaking home exercises. The use and acceptability of the home exercises, and frequency and setting within which the physiotherapy is performed, will be collected from participants.

Outcomes

The participants in this trial will be followed up at six weeks, and three, six, and 12 months post-randomization.

At baseline, we will record participant demographic characteristics and treatment preferences, the DASH score to assess their functioning a week before their injury and post-injury functioning,[20] shoulder pain in the past 24 hours using an 11-point numeric rating scale (NRS),[21] and the EuroQol five-dimension five-level questionnaire (EQ-5D-5L).[22] Patient satisfaction with appearance of shoulder and sensitivity/pain to touch will also be recorded. The

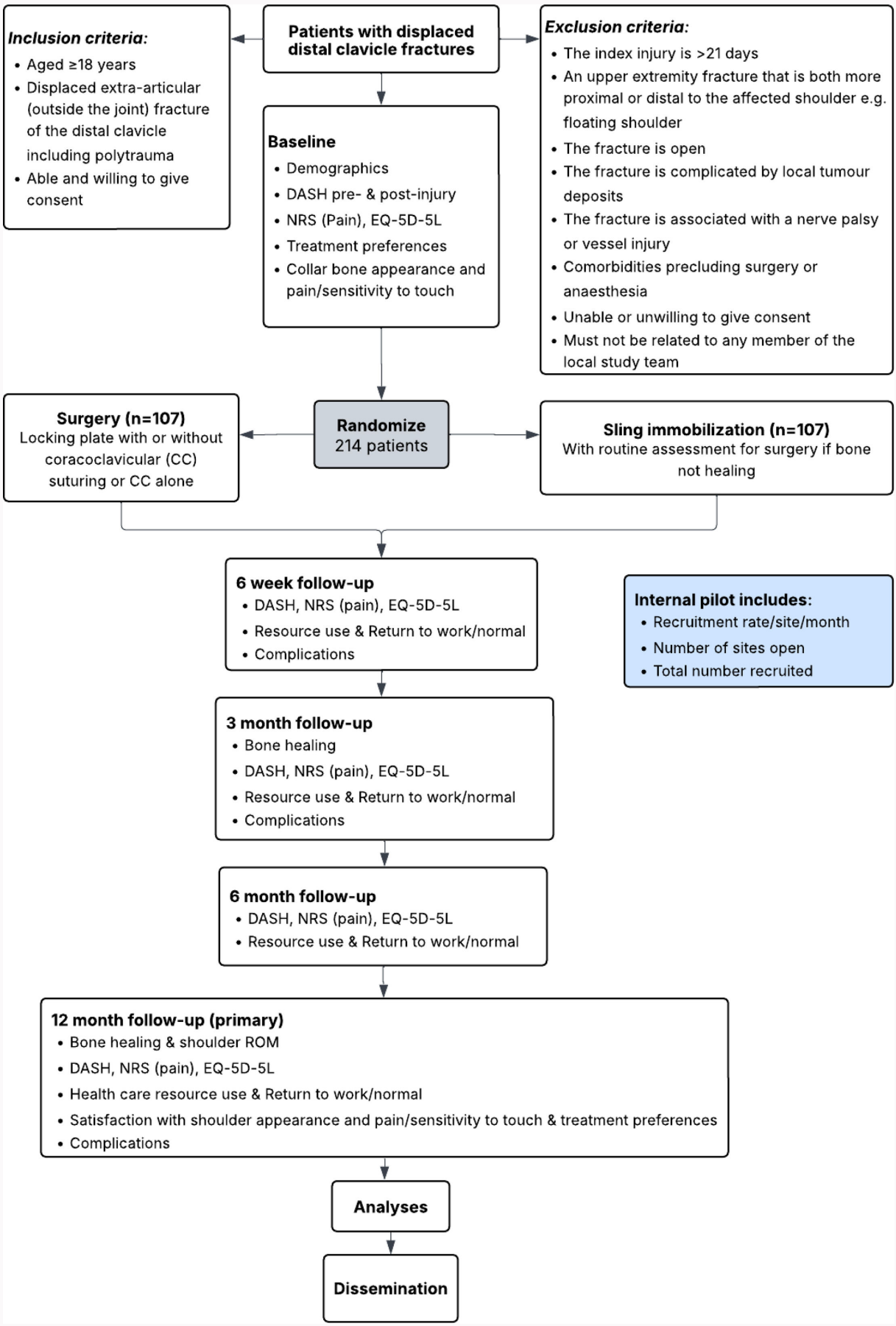

Fig. 1
Overview of trial design and flow of participants through the trial. CC, coracoclavicular; DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; EQ-5D-5L, EuroQol five-dimension five-level questionnaire; NRS, numeric rating scale; ROM, range of motion.

Table II. Patient eligibility criteria.

Inclusion criteria
Patients aged 18 years or older.
Displaced extra-articular (outside the joint) fracture of the distal clavicle based on routine radiological assessment, with or without polytrauma.
Able and willing to give consent.
Exclusion criteria
The index injury is > 21 days.
An upper limb fracture both more proximal or distal to the same affected shoulder, e.g. floating shoulder.
The fracture is open.
The fracture is complicated by local tumour deposits.
The fracture is associated with a nerve palsy or vessel injury.
Comorbidities precluding surgery or anaesthesia.
Unable or unwilling to give consent.
Must not be related to any member of the local study team.

surgeon or authorized staff will confirm the classification of the fracture, where necessary, after randomization.[3,23,24]

The primary outcome measure will be the DASH (a 30-item self-administered outcome measure of upper limb disability and symptoms scored 0 (no disability) to 100 (severe disability)) at 12 months.[20] This is when participants in both trial arms will have completed their treatment pathways.

The following secondary outcomes will be measured at six weeks, and three, six, and 12 months post-randomization unless otherwise stated. Upper limb disability and symptoms will be measured by DASH. Shoulder pain will be measured using an 11-item unidimensional NRS of pain intensity in adults,[21] with 0 representing 'no pain' and 10 representing 'worst imaginable pain' in the past 24 hours.[25]

Health-related quality of life will be measured using the EQ-5D-5L, a validated measure with five dimensions (mobility, ability to self-care, ability to undertake usual activities, pain and discomfort, anxiety and depression), each with five levels of severity.[22] The EQ-5D-5L utility will be converted using the mapping function recommended by the National Institute for Health and Care Excellence (NICE) guidance.[26,27]

Patient-reported questionnaires and hospital records review forms will be designed to collect information on hospital stay (initial and subsequent inpatient episodes, outpatient hospital visits, and ED admissions); primary care consultations (e.g. general practitioner (GP), nurse, and physiotherapy); and return to work and to normal activities.

Data on complications will be collected at six weeks, and three and 12 months, including (but not limited to) deep wound infection (using Centers for Disease Control (CDC) and Prevention definition),[28] superficial infection (using CDC definition), rehospitalization (e.g. repeat surgery to remove metalwork), and nerve and skin problems.

The following data will be collected at 12 months post-randomization only. Participants will be asked to use a five-item unidimensional Likert scale to rate both their satisfaction with the appearance of their shoulder, which ranges from 'very satisfied' to 'very dissatisfied', and to record how sensitive or painful it is to touch the area where the collarbone is broken. Participants will self-assess the range of motion (ROM) of both their shoulders,[29,30] using a diagram-based questionnaire that has evidence of reliability.[31,32] Finally, a single question will ask whether the participant at this time has no treatment preference or prefers surgery or sling.

Bone healing (i.e. union, nonunion, and malunion) will be assessed and recorded using routine radiographs (typically anteroposterior and axial views) by the participating surgeons in clinic at the three- and 12-month post-randomization follow-up. If radiographs are not routinely available at these timepoints, or the participant does not attend, then the most recently available radiographs will be used. At 12 months, however, if a hospital does not routinely take radiographs these will be requested to be done as part of the research. Radiological union will be defined as complete cortical bridging between the medial and lateral fragments on radiographs. Nonunion will be defined as a lack of radiological healing with clinical evidence of pain and motion at the fracture site.[24] Radiological malunion will be defined as loss of the anatomical contour of the clavicle and whether it is symptomatic or not.[31]

Imaging will be performed at participating sites and may be undertaken at a different hospital site (including non-NHS sites) to the recruiting hospital in line with any changes to the routine imaging pathway at the recruiting site. Appropriate approvals under Ionizing Radiation (Medical Exposure) Regulations (2017) will be obtained to ensure risk is minimized. For hospitals that may not take routine radiographs at 12 months to assess bone healing, which will be an additional research exposure, this has been addressed in the Integrated Research Application System (IRAS) application and explained to participants in the information sheet.

Participant timeline

Participants will be followed up at six weeks, and three, six, and 12 months post-randomization, with the primary endpoint being 12 months post-randomization.

Table III. Study assessment schedule.

	Timepoint						
Schedule	**Baseline**	**Randomization**	**Treatment delivery**	**Wk 6**	**Mth 3**	**Mth 6**	**Mth 12**
Enrolment							
Eligibility screen	X						
Informed consent	X						
Baseline participant questionnaire*	X						
Fracture classification	X†						
Randomization		X					
Interventions							
Sling immobilization			X				
Surgery			X				
Assessments							
Operation data‡			X				
Participant follow-up questionnaire*				X	X	X	X
Reoperations§				X			X
Fracture union/nonunion/malunion					X		X
Complications, e.g. infections, reoperations				X	X		X
Adverse events				X	X		X
Patient preferences							X
Patient satisfaction with appearance of shoulder and sensitivity/pain to touch							X
Shoulder range of motion							X

*Participant baseline and follow-up questionnaires include Disabilities of the Arm, Shoulder and Hand questionnaire, numeric rating scale, EuroQol five-dimension five-level questionnaire, health resource use, and return to work and normal activities.
†Fracture classification may be collected after randomization, if necessary, to ease burden on site staff when consenting and performing randomization.
‡Operation data only collected for participants allocated to the surgery arm or for participants in the sling arm if there is evidence of symptomatic nonunion and they undergo surgery.
§A second operation may be required to remove the metalwork due to prominence.

Table III illustrates the overall time schedule of enrolment, interventions, and assessments for trial participants through the study.

Sample size

This was calculated using a SD value of 20 as estimated from a Canadian trial in this patient population, which was acquired via direct communication with the study authors.[4] Minimal clinically important differences for the DASH are around ten points from individual studies using anchor-based methods.[20,32] A ten-point difference on the DASH at 12 months represents the threshold at which treatment differences become important to patients and clinicians that would represent an appropriate non-inferiority margin. This is the approach that has been taken in other surgical National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) funded trials: DISC HTA - 15/102/04;[33] HAND2 NIHR127393; SOFFT NIHR127739. For 90% statistical power, 170 participants are required to demonstrate non-inferiority of sling immobilization compared with surgical fixation within a margin of ten points on the DASH (SD 20), based on the upper limit of a 95% two-sided CI (equivalent to a one-sided 97.5% CI). Assuming 20% attrition at 12 months' follow-up gives the total target sample size of 214. This rate of attrition should be feasible, as was found with the SWIFFT trial (HTA 13/26/01) in a similar patient population that compared similar treatment options and the completion of a patient-reported outcome measure as the primary outcome at 12 months.[34]

Recruitment

The identification of potential participants will be undertaken by the direct care team in the ED, fracture clinics, and/or the orthopaedic trauma meeting of participating NHS hospitals. Study posters will be displayed for patients, generic staff, and staff in the ED. Radiographs taken as part of routine care will be used to assess eligibility (typically anteroposterior and axial views). A surgeon or clinician delegated to perform this task will confirm eligibility and they, or another member of the direct team, will invite the patient to consider joining the study.

After the initial identification of the patient by the direct care team and invitation to take part (either in person or by telephone), it will be a delegated member of the

study team (for example, a Research Nurse) who will explain the study in more detail and seek consent. The patient will be provided with a participant information sheet (PIS) and complementary infographic sheet in an appropriate language either in person or via post or email, and have time to ask questions of the surgeon and authorized staff at the site before deciding on taking part. The PIS will include a link to an animation, something which is commonly used to communicate about a study in a more engaging and accessible way.[35] Potential participants will be given contact details so they can ask questions of hospital staff and discuss the trial with friends/family prior to agreement to take part. When approached, the patient will be asked whether they have had sufficient time to consider participation and whether they agree to consent at that time; if required, they will be given further time to decide on whether to take part. Consent will be sought to enable the sharing of identifiable data with the York Trials Unit (YTU) to facilitate data collection. All members of staff involved in the informed consent process must have training in good clinical practice (GCP).

Patients who are consented on-site will have the option to provide consent electronically using the REDCap study database; otherwise, a paper consent form will be provided. Consent obtained electronically will be held on a General Data Protection Regulation (GDPR)-compliant secure software platform,[36] which will be password-protected with access limited to named members of the study team. Copies of consent forms will be automatically generated following online completion and submission by patients. A copy will be provided to participants and available to the recruiting site in REDCap.

In the event that patients attend virtual fracture clinics, or staff are unavailable to consent a patient in clinic at hospital, consent can also be undertaken remotely with the patient via telephone or videoconference. The same methods will be used to obtain consent and baseline data, i.e. electronically using the REDCap study database, or via a paper consent form posted to the patient along with a paper copy of the baseline Case Record Form (CRF) which will be returned to the hospital. The patient should, where possible, sign the paper consent form, which on receipt will be uploaded by site staff to REDCap, or complete electronically, in the presence of the GCP-trained authorized person taking consent. The authorized staff should record in the patient's case notes and in the 'Comments' electronic CRF (eCRF) in REDCap to explain any discrepancies in dates when the patient and the staff member signed for consent. As above, a copy of consent will be provided to participants and be available to the recruiting site in REDCap, which will also record whether it was on-site or remote consent.

Allocation

Allocation will be on a 1:1 ratio, using randomly permuted blocks of varying block sizes and stratified by age (< 65 or ≥ 65 years) as a surrogate for the fragility of the fracture.[14] The allocation schedule will be generated by trial statisticians (KB, LS) otherwise not involved in the recruitment or randomization of participants. It will be implemented using a secure web-based randomization service managed by YTU, ensuring allocation concealment. The hospital staff at the site will confirm patient eligibility and consent, and access the online service to perform the randomization within 21 days of the index injury.

Blinding (masking)

As with many surgical trials, it will not be feasible to blind patients, surgeons, or outcome assessors to the treatment allocation. The health economists will be blinded until data lock.

Data collection methods

Trial participants will complete eCRFs of participant report forms at baseline and the follow-up timepoints (six weeks, and three, six, and 12 months post-randomization) with supplemental telephone/video follow-up for non-responders from which the data will be entered directly into the study database. Postal completion of paper follow-up CRFs will also be permissible for participants who for any reason cannot complete the data electronically, or when the questionnaires are provided in languages other than English. Paper CRFs returned by participants will be entered into the study database. Contact details will be provided to participants should they need support with completing questionnaires. Delegated staff at participating sites will complete eCRFs of hospital review forms as shown in the study assessment schedule, and will be offered an electronic tablet to do this.

To minimize attrition, we will use multiple methods to keep in contact with participants. We will ask participants for full contact details (including mobile phone number and email address). Participants will also be asked to consent to agree to their GP being contacted for their address and using NHS Digital (the Spine portal) to help stay in contact in England and Wales or the Community Health Index in Scotland. For all follow-up data collection, two reminders (at two weeks and four weeks from when due) will be sent to non-responding participants, with a final attempt to obtain data by a telephone/video call at six weeks. Around a month before the 12-month follow-up is due (primary endpoint), the participant will receive by post/electronically a flyer informing them to expect the questionnaire, as there is evidence that pre-notification can improve response rates.[37] Participants will be informed in the PIS that they will receive a gift voucher for completing questionnaires at six weeks (£5), three months (£5), six months (£20), and 12 months (£20).[37] The increase at six months is because the data collection is not aligned to a routine clinic visit and at 12 months as this is the primary endpoint.

We will text participants to prompt completion as part of the embedded SWAT (Study Within A Trial) and non-responders will be contacted via text, email, or mobile when necessary to arrange a time to complete the questionnaire over the telephone or video.[37] Regular newsletters will be sent to participants during the trial to keep them informed and engaged.[38]

Imaging and reports from peripheral sites to the participating hospitals will be directly accessed by the recruiting site to help with assessment of bone union. Imaging will also be retrieved by the participating hospital from local area/regional hospitals using Picture Archiving Communication Systems (PACS). Furthermore, if a participant moves away from the participating site and is followed up at a hospital not taking part in the trial, follow-up data (e.g. reoperations,

complications, infections) will be requested securely through 'NHSmail'. Both these mechanisms for capturing data are available as would occur in routine clinical practice. A bespoke letter and flyer are also available to hospital staff to encourage participant attendance at the 12-month clinic, which is the primary endpoint for the study.

Data management

The trial data will be managed on REDCap hosted on a secure cloud server in Amazon Web Services, in the UK region. A CRF specification plan will be completed for all the instruments to be included in the database with the respective questions, responses, and validation rules. A project specification form will also be completed, which details the requirements of the project, such as which events are due and who has access to the system and their role. The randomization system will be hosted outside of REDCap; it will take data from and feed back into REDCap.

As a duty of care, participant data will be reviewed to check for anything that indicates that the participant could be at risk of harm. Where this occurs, the hospital team will be notified and so will their GP as necessary.

YTU will develop the study database in REDCap and manage the data collection. All reporting of data collection will be undertaken in line with CONSORT.[13]

Embedded study within a trial (SWAT)

An embedded SWAT will be conducted to evaluate whether including a request to complete the questionnaire within a specified (seven-day) timeframe affects questionnaire return rate.[39] This is SWAT 221 on the Northern Ireland SWAT repository, which includes the protocol.[39] Participants will be individually randomly allocated on a 1:1 ratio to get a prompt at each follow-up that either will or will not ask for the questionnaire to be completed within the next seven days. Block randomization will be used, stratified by the main trial treatment arm using varying block sizes. Our Patient Advisory Group (PAG) has informed the wording of the text message.

Statistical analysis

Statistical analyses will be detailed fully in a statistical analysis plan (SAP) agreed by the Independent Data Monitoring Committee (IDMC) and Trial Steering Committee prior to the end of data collection.

Internal pilot: The recruitment rate will be estimated from the data collected. A CONSORT diagram will be constructed to show the flow of participants through the study, and the following outcomes calculated: number of patients screened; proportion of eligible patients and reasons for ineligibility; 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; proportion of patients dropping out between randomization and follow-up; proportion of patients for whom a primary outcome is recorded. 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.

Main trial: For the analysis of the full trial a CONSORT flow diagram will be provided to display the flow of participants through the study. Baseline characteristics will be presented descriptively by group. All outcomes will be reported descriptively at all collected timepoints. Continuous data will be presented using means and SDs or medians and ranges as appropriate, and categorical data will be presented using frequencies and percentages. The primary analysis will be conducted on an intention-to-treat (ITT) basis, analyzing patients in the groups to which they were randomized. A linear mixed-effects repeated measures model will be used to compare groups, adjusting for stratification factors and relevant baseline covariates as fixed effects and centre as a random effect. Non-inferiority will be demonstrated if the upper bound of the two-sided 95% CI (equivalent to a one-sided 97.5% CI) for the difference in mean DASH scores (sling immobilization minus surgical fixation) is less than 10 at the 12-month timepoint. Sensitivity analyses and analyses or descriptive summaries of secondary outcomes will also be undertaken.

Completeness of data at follow-up will be reported by group. 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. All analyses will be conducted in STATA v18 (StataCorp, USA), or later (to be confirmed in the final report).

The embedded health economic evaluation assesses the relative cost-effectiveness of sling immobilization compared with surgery in the management of adults with a displaced fracture of the distal clavicle, to determine which treatment offers the best value for money for the NHS. The methods will be consistent with the NICE Guide to the Methods of Technology Appraisal.[27]

The costs of providing the treatments will be based on national tariff data. Applying national average costs makes the results more generalizable when cost-effectiveness results are considered for wider adoption by policymakers. We will also include the cost of the operation to remove metalwork implanted in the surgery group and the necessary surgery following nonunion in the sling immobilization group. These costs represent key extra costs of the respective treatment arm and are an important resource implication which is factored into the economic evaluation.

A NHS and personal social services (PSS) costing perspective will be taken in the base case analysis. Relevant costs will include treatment costs, wider NHS resource use, and related social services. Quantities recorded are multiplied by national average unit costs in the appropriate year at the time of analysis to derive a cost profile for each participant in each arm of the trial.[40,41] The time horizon of the analysis will be 12 months.

We will conduct a secondary analysis to explore the impact of productivity costs and extra personal spending on cost-effectiveness results. The trial will assess the impact of both treatments on days of lost employment by participants and their unpaid carers, as well as any paid additional care required. The wider cost data do not form

Table IV. List of 'expected' adverse events for the DIsplaced DistAl Clavicle Fracture Trial (DIDACT) trial.

Surgery arm expected events
Complications of anaesthesia or surgery • e.g. wound complications • infection • damage to a nerve or blood vessel • frozen shoulder • coracoid fracture • metalwork failure • thromboembolic events
Secondary operations for or to prevent infection, malunion, nonunion or for symptoms related to the metalwork
Sling expected events
Swelling
Bruising
Discomfort or stiffness from sling use

part of the base case, but can be submitted as supplementary evidence.

Effectiveness measure of cost-utility analysis will be quality-adjusted life-years (QALYs), derived from EQ-5D-5L utilities at baseline, six weeks, and three, six, and 12 months following the area under the curve approach.[42]

Regression methods, adjusted for key covariates, will be used to estimate incremental costs and QALYs (on an ITT basis) by surgery compared with sling immobilization. Incremental costs are divided by incremental QALYs to construct an incremental cost-effectiveness ratio (ICER) when both are positive.

We will perform the non-parametric bootstrap to produce 5,000 replications to assess uncertainty around the point estimate of the ICER, as its validity does not depend on any specific form of underlying distribution. The bootstrapped iterations will be used to construct the 95% CI of incremental costs and QALYs, respectively. A cost-effectiveness plane and a cost-effectiveness acceptability curve (CEAC) will also be constructed based on the bootstrap iterations,[43] to illustrate the probability that the surgery is more cost-effective than sling immobilization at different acceptable ICER threshold values, and marked specifically at the NICE maximum acceptable ICER threshold range of £20,000 to £30,000/QALY and also £13,000/QALY by empirical studies.[27,44]

A range of sensitivity analyses will be undertaken to assess the impact of missing data. In the main analysis, missing data will be imputed using multiple imputation method and analyzed following Rubin's rule.[45] As part of the sensitivity analysis, we will conduct complete case analysis (CCA), whereby results are analyzed only for those participants who have both the completed cost and outcome data at all timepoints. We will also examine the assumption of missing data pattern using pattern mixture modelling.[46]

We will maintain the integrity and neutrality of the heath economic analysis by presenting a detailed a priori health economics analysis plan. The plan will pre-specify the methods used for the health economic analysis, the data sources, and the outcomes for analyses.

Data monitoring

A Trial Steering Committee (TSC) will monitor progress of the study, provide independent advice, and the independent chair will make recommendations to the funder. An Independent Data Monitoring Committee (IDMC) will monitor the data arising from the trial and recommend to the TSC on whether there are any ethical or safety reasons why the trial should not continue. The TSC and IDMC will meet regularly to provide oversight to the study. The project will also be monitored by the sponsor, and a representative will be invited to attend the TSC meetings. A Trial Management Group (TMG) will monitor the day-to-day management (e.g. protocol and ethics approvals, setup, recruitment, data collection, data management) of the study chaired by the Chief Investigator (HPS).

Harms (adverse event management)

Participants will be allocated to routinely delivered treatments in the NHS, and therefore the risks are not increased through trial participation. Adverse events (AEs) are defined as any untoward medical occurrence in a trial participant, and which do not necessarily have a causal relationship with the treatment. Only medical occurrences specific to the participants' clavicle fracture that are 'unexpected' and up until the 12-month follow-up will be classified as events when non-serious. This is because 'expected' events (Table IV) are well known complications for the two routine treatment options which the specialist clinical care teams will be experienced in managing.

Serious adverse events (SAEs) will be defined as any untoward medical occurrence that results in death; is life-threatening (i.e. it places the participant, in the view of the Investigator, at immediate risk of death); requires hospitalization or prolongation of existing inpatients' hospitalization (unplanned refers to emergency hospitalizations resulting in an inpatient stay, while prolonged hospitalization is deemed to be where a patient's stay is longer than expected); results in persistent or significant disability or incapacity; and any other important medical condition which, although not included in the aforementioned items, may require medical or surgical intervention to prevent one of the outcomes listed.

Medical occurrences specific to the participant's clavicle fracture that are serious and up until the 12-month follow-up will all be reported as SAEs (including deaths for any reason), whether expected or not.

A delegated member of staff at the hospital will record all AEs or SAEs on the appropriate eCRF in REDCap. In addition, sites should follow their own local procedures for the reporting of any adverse events.

AEs and SAEs will be reported to YTU within five days or 24 hours, respectively, of the site investigator becoming aware of them. Once received, causality (or 'relatedness') and expectedness will be confirmed by the Chief Investigator. SAEs that are deemed to be unexpected and related to the trial treatment will be flagged to the Research Ethics Committee (REC) and sponsor within 15 days.

To ensure that adequate action has been taken and progress made, the Chief Investigator may request a follow-up report one month after reporting of any AEs or SAE.

AEs and SAEs will be monitored regularly at TMG meetings and reported to the TSC and IDMC when they meet.

Table V. Details of trial registration for DIsplaced DistAl Clavicle Fracture Trial (DIDACT) as per the recommended World Health Organization Trial Registration Dataset.

Trial Registration	**ISRCTN11981704**
Date of Registration	31 July 2023
Funder Information	The National Institute for Health Research Health Technology Assessment programme (reference number NIHR150159)
Sponsor	University Hospitals of Leicester NHS Trust
Scientific title	Sling immobilization compared to surgery in the management of adults with a displaced fracture of the distal clavicle (DIDACT): a multicentre, pragmatic, parallel group, non-inferiority, randomized controlled trial
Countries of recruitment	UK, England, Scotland, Wales
Health condition(s) or problem(s) studied	Displaced distal clavicle fracture
Intervention	Arm 1: Sling immobilization – upper limb support with a sling, typically for two to four weeks, followed by surgical fixation if symptomatic nonunion of the fracture typically at the three-month follow-up. Arm 2: Surgery – locking plate fixation, with or without CC sling, or CC reconstruction alone when the distal fragment is very small.
Key inclusion and exclusion criteria	Inclusion criteria Patients aged 18 years or older. Displaced extra-articular (outside the joint) fracture of the distal clavicle based on routine radiological assessment, with or without polytrauma. Able and willing to give consent. Exclusion criteria The index injury is > 21 days. An upper limb fracture both more proximal or distal to the same affected shoulder e.g. floating shoulder. The fracture is open. The fracture is complicated by local tumour deposits. The fracture is associated with a nerve palsy or vessel injury. Comorbidities precluding surgery or anaesthesia. Unable or unwilling to give consent. Must not be related to any member of the local study team.
Study type	Interventional Allocation: randomized controlled trial with 1:1 allocation Primary purpose: non-inferiority study comparing clinical and cost-effectiveness of interventions
Date of first enrolment	September 2023
Target sample size	214
Recruitment status	Recruiting
Primary outcome	DASH score at 12 months
Key secondary outcomes	Shoulder pain; health-related quality of life (EQ-5D-5L); complications; fracture healing; patient preferences, satisfaction with appearance of their shoulder/sensitivity or pain to touch, and range of motion.

CC, coracoclavicular; DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; EQ-5D-5L, EuroQol five-dimension five-level questionnaire.

Auditing

As previously detailed, data monitoring will be undertaken by the IDMC, TSC, and TMG; this includes reporting any issues with trial conduct, including protocol deviations and AEs. This will also be reported to the sponsor and funder in regular progress reports.

The trial will comply with the approved protocol and adhere to the Health Research Authority (HRA), the UK Health Department policy framework,[47] and MRC Good Clinical Practice Guidance.[48] An agreement will be in place between the site Principal Investigator and the sponsor, setting out respective roles and responsibilities.

Monitoring of recruiting sites to ensure that the trial is complying with the approved protocol and regulatory requirements will also be undertaken by YTU. The monitoring plan will be kept in the Trial Master File.

Patient and public involvement

We undertook a consultation with our PAG to inform the design and delivery of the study. This included the PAG agreeing to be randomized between sling compared with surgery on the understanding that surgery would be possible later if indicated.

Our PAG discouraged including hook plates, owing to concerns that these need to be removed in a further operation due to the risk of damage to the rotator cuff muscles which, in the long term, could slow the speed of recovery and cause more pain to and a greater burden on patients. The proposed trial design should be more acceptable to patients and is centred around what is important to them. Our PAG also recommended the use of electronic data collection where possible, supported the use of financial incentives for participants, and provided guidance on appropriate amounts.

During the trial, our PAG will contribute to the development of study materials (e.g. patient information sheet, leaflets, and videos about patient care), advise on optimizing the inclusion of patients with regard to our aims for equality, diversity, and inclusion, and we will discuss with them any challenges that arise in the delivery of the study.

We will work closely with our PAG to develop various outputs: a leaflet that summarizes the findings in plain, simple language; an infographic and animation; and a booklet about the condition.

Ethics and dissemination

Research ethics committee approval

Research Ethics Committee approval for this trial protocol (version 3.0) was granted on 3 December 2024 (East of England - Essex Research Ethics Committee). HRA approval for the study was also issued on 3 December 2024.

Protocol amendments

Any substantial amendments to the protocol during the trial will be submitted to REC/HRA for approval, having been agreed with the funding body, Sponsor, TSC, DMEC, and the TMG. Non-substantial amendments covering minor modifications to the protocol will be agreed with the sponsor prior to submission to REC. All amendments will be communicated to participating sites for implementation in accordance with guidance. All amendments will be documented in the final report to the funding body.

Confidentiality

The researchers and clinical care teams must ensure that patient confidentiality will be maintained and that their identities are protected from unauthorized parties. Patients will be assigned a unique participant identification number which will be used on eCRFs. Sites will securely maintain the patient Enrolment Log, which shows participant identification numbers and names of the patients. This unique participant number will identify all eCRFs and other records.

All records will be kept in locked locations. All paper copies of consent forms will be secured safely in a separate compartment of a locked cabinet. Electronic copies will be stored separately to clinical information and access restricted to study personnel. Clinical information will not be released without written permission, except as necessary for monitoring purposes.

Declaration 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

Data will be held securely on the cloud-hosted REDCap server. Access to the study interface will be restricted to named authorized individuals who have been granted user rights by a REDCap administrator at YTU. Authorized users will be required to set passwords in line with the University of York's policy and enable two-factor authentication. Study documents (paper and electronic) held at the University of York will be retained in a secure (kept locked when not in use) location for the duration of the trial. All work will be conducted following the University of York's data protection policy, which is publicly available.[49]

The sponsor, University Hospitals of Leicester NHS Trust, is the data controller for this study, which will be detailed in a collaboration agreement between the sponsor and the University of York. There will also be an agreement between the sponsor and each of the participating sites (within the model Non-Commercial Agreement (mNCA)) that will include data-sharing responsibilities with YTU.

The Investigator(s)/institution(s) will permit authorized representatives of the sponsor and applicable regulatory agencies direct access to source data/documents to conduct trial-related monitoring, audits, and regulatory inspection. Trial participants are informed of this during the informed consent discussion. Participants will consent to provide access to their medical notes.

Ancillary and post-trial care

This is a pragmatic trial, studying treatments which are routinely available in the NHS. As such, any post-trial care following this injury should be accessible to all trial participants in discussion with their clinician.

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 feasibility of the trial has been approved by the R&D department. NHS indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm.

Dissemination

We will develop a dissemination strategy at the outset of the project which will be amended by the TMG as required during the study. This will provide established pathways for the dissemination of the results when they are available. BESS has adopted the trial for inclusion in their research portfolio which will facilitate dissemination of findings to relevant stakeholders. Dissemination channels will be used to inform clinicians, patients, and the public about the project and the results of the study. This will include publishing in peer-reviewed journals, presenting at appropriate national and international conferences, and cascading results to trainee surgeon networks, industry, and Getting It Right First Time (GIRFT). The study results will be shared with NICE, relevant evidence synthesis teams, and other relevant bodies. Findings will be summarized in plain language for the benefit of patients.

Discussion

This trial will improve knowledge about whether a sling immobilization pathway is non-inferior to surgery and which

of these two treatments is cost-effective. Results will be disseminated through peer-reviewed publications, and the evidence will help to inform clinical practice. Table V displays key items from the trial registration data set in line with World Health Organization recommendations.

Social media

Follow the DIDACT Trial on X @didact_trial
Follow the York Trials Unit on X @YorkTrialsUnit

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ICMJE COI statement

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YorQuit, which is funded by Yorkshire Cancer Research, all of which are unrelated to this protocol. M. Barrett is employed as a Trial Support Officer on DIDACT, and is supported by a NIHR pre-doctoral fellowship (NIHR304940). S. Brealey is employed as the Trial Manager on DIDACT, as well as the ACTIVE and RAPSODI trials. K. Glerum-Brooks was a member of the NIHR HTA Commissioning Committee from 2015 to 2022, and was paid as Deputy Chair from 2019 to 2022; her institution received payments for her role as NIHR Senior Investigator, Co-Director of the NIHR RSS, and member and Chair of the NIHR HTA General Committee, and she was an unpaid member of the NIHR CTU SAC from 2020 to 2022. J. Li receives their salary from a NIHR HTA grant (150159). S. Parrott reports awards from other government departments, Yorkshire Cancer Research, and the Higher Education Commission for various trials, unrelated to this protocol. H. Rodrick and F. Rose are employed as Trial Coordinators on DIDACT as well as the RAPSODI trial. L. Strachan is employed as Statistician on DIDACT, as well as AMICABLE, BART II, EPLAYS II, SOFFT, RESTART P and VenUS 6.

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