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DIDACT

Surgery compared with sling immobilisation in the management of adults with a **displaced fracture of the distal clavicle - trial (DIDACT)**: a multi-centre, pragmatic, parallel group, non-inferiority, randomised controlled trial

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[@DidactTrial](https://twitter.com/DidactTrial)

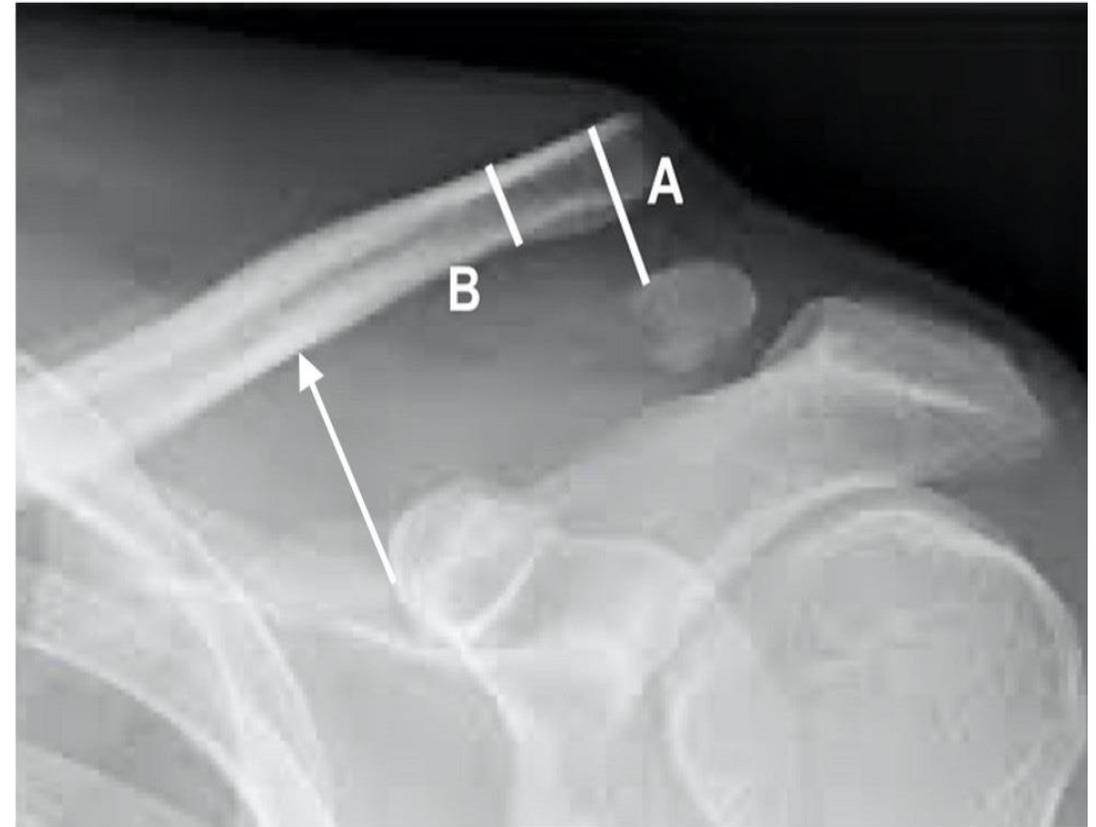
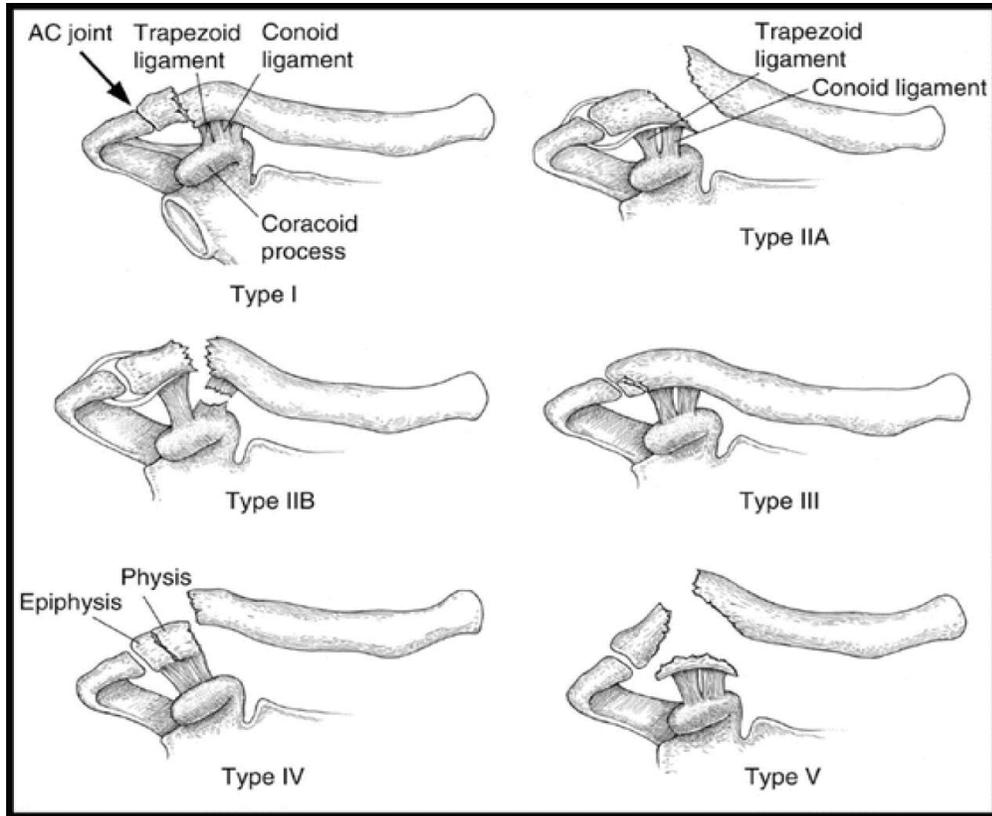
Study Importance

- RCT commissioned by NIHR and endorsed by BESS.
- High research priority topic (1. James Lind Alliance, 2. UK orthopaedic trauma network and 3. BESS survey identified surgery vs sling)
- No high quality evidence. (Small RCT)
- No Health Economic Evaluation: (**cost to the NHS of surgical fixation approximately £6 million p/a**).
- Patient informed decision.

Study Importance

- Fractures of the clavicle: 2.6–5% of all fractures in adults
- **Distal clavicle fractures: 20-25% of all clavicle fractures.**
- Treated with sling: Risk of Nonunion (35-40%)
- Treated with surgery: reduced risk of non-union & possible quicker recovery.
- **Risk of complication;** (estimated at 48%) including infection, plate breakage and refracture after metal removal.

What is Distal?



What is Displaced?

- Vertical displacement: the distance (D) between proximal and distal fragments (mm) as the amount of vertical translation, assessed as a percentage of the clavicle shaft width at the fracture site A=cortex-to-cortex distance, B= Clavicle shaft width
- $D=A/B\%$



What is DIDACT?



Intervention

Surgery – locking plate fixation, with or without coracoclavicular (CC) sling, or CC reconstruction alone when the distal fragment is very small.

Comparator

Sling immobilisation – upper limb support with a sling, typically for 2 to 4 weeks, followed by surgical fixation if symptomatic non-union of the fracture typically at the 3 month follow-up.



How to identify patients for DIDACT? “Every patient counts”

Stephen Brealey (Trial Manager)

Update on progress end of Feb 24

- 16 sites **green lit** to recruit (target is 27 sites).
- **Screened** 130 patients. Mostly not eligible as not the right fracture population i.e. distal/displaced clavicle fracture.
- **Randomised** 15 patients from 10 sites. THANK YOU to all sites for screening and recruiting so far. Have until **30 June 2025**.
- Fractures of the clavicle, constitute around 3-5% of all fractures in adults; distal clavicle account for 20-25% of clavicle fractures.
- **TWO** key issues with identifying patients: (1) Missing patients/ approached too late; (2) biased by treatment expectation before recruitment consultation.

How to identify patients?

- Patients can be identified in (i) emergency department (ii) fracture clinics (iii) orthopaedic trauma meeting.
- Once identified can provide the patient with the Patient Information Sheet **in person** or via **post** or **email**.
- Can **ring** the patient to ask whether they would like to discuss the study further.



Role of Emergency Department (ED)

- Patients can be identified in ED but not approached about the study (unless on delegation log).
- Important that staff not involved in recruitment don't suggest expected treatment choice ahead of recruitment consultation.
- Engage regularly with ED staff.
- AE flyer/poster being prepared & laminated cards for PC stations.

Scantlebury et al. *Trials* (2021) 22:461
<https://doi.org/10.1186/s13063-021-05420-4>

Trials

RESEARCH

Open Access

Embedding qualitative research in randomised controlled trials to improve recruitment: findings from two recruitment optimisation studies of orthopaedic surgical trials



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A&E flyer/poster (draft)



DO YOU HAVE A PATIENT AGED 18+ WITH A
DISPLACED DISTAL
CLAVICLE FRACTURE?



THEY MAY BE ELIGIBLE FOR THE **DIDACT** STUDY!

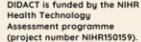


DIDACT is comparing
Surgery with Slings for
distal clavicle fractures

**PLEASE BE MINDFUL OF
DISCUSSING TREATMENT OPTIONS
(I.E. HAVING SURGERY OR WEARING A SLING)**

Please don't mention the study, as DIDACT will be
introduced to the patient by the research team

Further Information about the study:
Local Principal Investigator: [NAME]
[PHONE NUMBER/EMAIL ADDRESS]



DIDACT is funded by the NIHR
Health Technology
Assessment programme
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How to identify patients for DIDACT?

Practical methods to identify patients

Understand difficulties with staff turnover, part-time workers, multiple sites and have some suggestions:

1. Raise awareness across specialities – “Think distal clavicle fracture – Think DIDACT”
2. Use **WhatsApp group** (particularly if over multiple sites) – helps to see if a patient is eligible, then arrange a time when they can be seen by surgeon and research nurse/physiotherapist
3. Ensure staff working “**out of hours**” or **on-call** are aware of the study (again minimise bias with treatment expectations/missing patients) & to know who to contact
4. Appoint eligible staff as **NIHR Associate PIs** and endorsed by Royal Colleges
5. Search **electronic systems** to identify patients e.g. fracture clinic, ED, Radiology
6. At **Registrar/Specialty Trainee induction** update new staff about ongoing trials
7. Posters both for **patient** and **staff** are available to be displayed



**How to obtain patient consent for
DIDACT?
“Think balance”**

Stephen Brealey (Trial Manager)

Communicating research to patients

- **TRUST.** Patients need trust and to feel confident in who is explaining the study. Surgeon and research staff to jointly be positive about the study and its importance to inform best practice.
- **REASSURANCE.** Patients may be unsettled about the lack of certainty. Do reassure them about taking part, like you would a patient about a treatment they need in clinical practice.
- **THINK BALANCE.** Important that staff remain neutral about the treatment options even when asked for their advice i.e. be balanced. See Patient Information Sheet about pro's and con's.
- **CHANGEABLE.** Patients may think 'no' initially but agree having had time to reflect and talk about the study. Patients with apparent preferences can change their minds. Bring the patient into balance too.

Key messages to patients

- BOTH types of treatment are commonly used in the NHS to treat this injury. Neither are new treatments. BOTH work, but surgeons (across the UK) genuinely don't know which is better, or if they are alternatives.
- Taking part in this study is an opportunity to improve the future care of patients (**appeal to ALTRUISM**).
- Your surgeon thinks you are suitable for this study and is happy for you to have either treatment.
- Your best interests are important to us, and if you take part you will have a treatment that is suitable for you. By taking part, you are likely to have more attention/better experience as you will be in a study of national priority.

Explaining randomisation

- Patients need to ‘make sense’ of randomisation, as can feel like a loss of autonomy.
- Patients receptive to randomisation if understand the debate about sling vs surgery is pretty equal across the UK and no agreed treatment.
- Explain that randomisation takes the pressure off the patient deciding on their treatment.
- **Avoid** gambling metaphors / referring to the computer deciding (can evoke fear or mistrust) / “toss of a coin” (flippant and unprofessional).
- Explain that have an **“equal chance”** of receiving either treatment and that is the **“fairest method”** to produce two groups of patients that are **“similar in every respect”**. I (e.g. surgeon/RN) and you (patient) can’t choose your treatment, so there will be no bias in the study outcome.



Managing patient preferences

- Recognise you have your own preferences and be careful not to provide your personal or other team members' preferences.
- Patients may need to balance trade-offs between altruism, treatment preferences and personal circumstances.
- Recognise the patient may have preferences; if so, probe a little to understand why the patient has that preference, explain both treatment options and encourage the patient to keep an open mind.
- Reassure the patient that for either treatment they will be looked after by the NHS and by being part of a national study.
- Choice of words is important. Avoid using the word 'trial' and use 'study' instead.

PPIE feedback

- Reassure patients: both treatments are suitable for them & will help with the pain and movement.
- Emphasise that taking part in the study is for the greater good to benefit future patients.
- Help give back to the NHS and get best value for money.
- Surgeons need the evidence to discuss with patients the most appropriate care that they need.
- **Patient didn't trust himself having a sling** – Tell them will get a lot of support (including leaflet/video) about sling care and the NHS is here to help you with this / different slings are available / explain all patients will have a sling and will initially be uncomfortable with either treatment option at the start.
- **Patient preferred surgery because wife had this for a similar injury** – Explain that what works for one person doesn't work for someone else / everyone heals differently / need to consider whether it was the *same injury* and whether have the *same hobbies or lifestyles*.
- **Patient's father decided for son to have surgery** – Explain that everyone heals differently / what's the evidence of quicker recovery from surgery / there is risk of infection or another break next to the metal work or may need to remove the metalwork i.e. pro's and con's of both options.

Summary – ‘Think balance’ be ‘positive’ and appeal to ‘altruism’

| <i>Conveying clinical equipoise</i> | <i>Describing randomisation</i> | <i>Patient preferences</i> |
|--|--|---|
| <ul style="list-style-type: none"> • Acknowledge uncertainty • Explain the advantages and disadvantages of both treatments • Think ‘balance’..... | <ul style="list-style-type: none"> • Focus on the process and purpose of randomisation • Avoid gambling metaphors • Caution around referring to computers | <ul style="list-style-type: none"> • Ask patient to keep an open mind • Understand their preference(s) • Balance views, tailored to concerns |