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Protocol Article

Suture fixation versus tension band wiring in simple displaced olecranon fractures – a study protocol

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ABSTRACT

INTRODUCTION. Olecranon fractures, particularly the Mayo Type 2A two-part fracture, are typically treated with Kirschner wires (K-wires) and tension band wiring. While effective, this method is associated with a high complication risk, leading to reoperations. Recently, new suture fixation techniques have been described that do not involve the insertion of metal. This new technique may mitigate risks associated with K-wires and tension band wiring without impacting healing or function. This study compares the reoperation rate and outcome of suture fixation with traditional tension band wiring.

METHODS. This is a prospective, randomised, double-blinded, multicentre study. The allocation ratio is 1:1, and the groups are parallel. A total of 88 adult participants will be recruited. Participants will be assigned to receive either suture fixation or traditional tension band wiring. Follow-up is one year. The primary outcome is the reoperation rate. Secondary outcome measures include the Disabilities of the Arm, Shoulder and Hand (DASH), the EuroQol-5 Dimensions (EQ-5D) score, radiological outcomes and complications.

CONCLUSIONS. There is room for improvement in treating Mayo Type 2A fractures, and this study will allow us to investigate a new treatment method. The new suture fixation technique for treating olecranon fractures can potentially offer a similar or improved functional outcome compared to tension band wiring while lowering the reoperation rate significantly.

FUNDING. The study is initiated and conducted by the participating physicians within the financial framework of the participating departments.

TRIAL REGISTRATION. The trial is registered with www.clinicaltrials.gov, ID number: NCT04189185.

Olecranon fractures are common, with an estimated population incidence of 11.5 per 100,000 persons [1]. The most frequent type is the simple Mayo Type 2A two-part fracture, comprising as much as 74% of all olecranon fractures [1]. The typical treatment for this type involves osteosynthesis with Kirschner wires (K-wires) and tension band wiring [2], which has been shown to produce satisfactory healing and good functional outcomes [2]. However, the method carries a high risk of complications such as wound healing problems, joint penetration with metalwork, osteosynthesis material discomfort and nerve injury, often leading to reoperation rates of up to 70% [2-7]. Recently, a new technique has been described that does not involve the insertion of metal. This technique relies solely on strong suture fixation [8-10]. In small series, this technique demonstrated a potential to reduce the high risk of wound problems and discomfort from osteosynthesis material without adversely affecting fracture healing or functional outcomes [8-10].

We hypothesise that suture fixation of Mayo Type 2A two-part olecranon fractures may yield a lower reoperation rate than tension band wiring.

Methods

Trial design

This is a prospective, randomised, double-blinded, multicentre study. The allocation ratio is 1:1 and the groups are parallel.

Study setting

The patients will be recruited from the trauma units and orthopaedic departments of the following centres:

- Aalborg University Hospital, Clinic Farsø

- Regional Hospital, Viborg

- Regional Hospital, Horsens

- Kolding Hospital

- Aarhus University Hospital.

The patient base for the study is approximately 800,000 individuals. A total of 88 patients will be included based on the following criteria.

Inclusion criteria

- Adult patients (aged ≥ 18 and ≤ 75 years) with an olecranon fracture of Mayo Type 2A.

Exclusion criteria

- Bilateral upper extremity fracture

- Open fracture

- Associated neurovascular impairment

- Additional fracture on the same upper extremity

- Pathological fracture

- Patients reporting unilateral or bilateral elbow problems before their fracture

- Cases in which surgery cannot be conducted within 14 days of the occurrence of the fracture

- Conditions that preclude the execution of one of the two regimes, e.g., mental illness and substance abuse

- Medical contraindication against surgery

- Previous elbow-near fracture on the same side.

Treatment

All surgeons participating in the study are trained in both procedures on cadaver elbows. The procedure is performed within 14 days of the trauma. Prophylactic antibiotics in the form of 1.5 g of cefuroxime IV are administered.

After the skin incision, skin and subcutaneous tissue are raised as a flap. Subperiosteal dissection around the

fracture ends is performed, and the fracture is reduced using bone forceps.

For surgery with K-wires and tension band wiring, the following technique is used:

Two parallel 1.6 mm K-wires are inserted longitudinally from the proximal olecranon fragment into the ulna distally. A 1.0 mm cerclage wire is passed through a 2 mm transverse drill tunnel and bent in a figure-eight configuration. The cerclage is threaded through the triceps tendon behind the olecranon over the K-wires and tensioned. Finally, the K-wires are countersunk into the olecranon.

For suture fixation, the technique described by Das et al. [9] is used:

A transverse 2.5 mm tunnel is drilled at least 15 mm distal to the fracture to a depth of at least 10 mm from the dorsal cortex. Two No. 2 Orthocord (DePuy-Synthes) sutures are used for suturing. The sutures are passed through the drill hole and the insertion of the triceps to the olecranon. A minimum of two sutures are used. The suture technique is described by Das et al. [9].

After osteosynthesis by either technique, the elbow is moved throughout its range to ensure stability. After wound closure, a rigid 90-degree splint (or similar) is applied for two weeks.

After two weeks, the patient is seen for removal of bandage and staples, and for X-rays. Free active movement of the elbow is allowed, but heavy lifting or pushing must be avoided until six weeks after surgery.

Follow-up

Participants are followed up at two weeks, six weeks, three months, six months and 12 months after randomisation.

X-rays of the elbow are taken when the patient is seen in the emergency department, after surgery and after two and six weeks and six months. An independent physician assesses X-ray images. X-rays of the elbow are taken in the anterior-posterior and lateral planes.

Complications

The treatment of any complications is discussed with a blinded colleague, and the patient is treated according to department guidelines. In the event of complications, the patient participates in the study according to the intention-to-treat principle.

Blinding of observers and participants

Study participants will be blinded to the treatment until the end of the study.

Observers measuring functional outcomes and patient-reported outcomes will be blinded.

Registered variables

All variables are entered into a corresponding database. Information from the patient's medical record is not used.

Primary outcome measures:

- Total reoperation rate after one year.

Secondary outcome measures:

- The Disabilities of the Arm, Shoulder, and Hand (DASH) score [11] after one year

- The EuroQol-5 Dimensions (EQ-5D) questionnaire [12]

- Date of return to usual activity/job

- Number of sick days following the primary operation

Number of sick days following possible removal of osteosynthesis material

- Non-union, defined as a lack of healing after six months

- Range of motion in the elbow and forearm measured in degrees

- Complications related to treatment: infection, nerve damage, vascular injury, etc.

- Reason for reoperation

- Measurement of elbow load in the patient's occupation (patients are asked whether they believe their occupation is elbow-straining, yes/no).

An overview of the registered variables is provided in **Table 1.**

TABLE 1 Overview of registered variables.

	Inclusion	2 weeks	6 weeks	3 months	6 months	12 months
Patient ID number	√					
Fracture side R/L	√					
Date of fracture DD/MM/YYYY	√					
Age at inclusion, years	√					
Sex M/F	√					
Smoking status? Y/N	√					
Working? Y/N	√					
Type of occupation?	√					
Shoulder straining work? Y/N	√					
Fracture of dominant side? Y/N	√					
DASH score	√	√	√	√	√	√
EQ-5D	√	√	√	√	√	√
Elbow flexion, degrees		√	√	√	√	√
Forearm rotation, degrees		√	√	√	√	√
Sick leave, days		√	√	√	√	√
X-rays		√	√		√	
X-rays evaluating PA? Y/N					√	
Is surgery for PA planned? Y/N					√	
Does the patient want surgery for PA? Y/N					√	
Complications?[a] Y/N		√	√	√	√	√
Has the patient been reoperated? Y/N		√	√	√	√	√

DASH = Disabilities of the Arm, Shoulder, and Hand; DD = date; EQ-5D = EuroQol-5 Dimensions; F = female; ID = identification; L = left; M = male; MM = month; N = no; PA = pseudoarthrosis; R = right; Y = yes; YYYY = year.
a) Includes notes.

Disabilities of the Arm, Shoulder, and Hand and EuroQol-5 dimensions at inclusion

At inclusion, patients complete the DASH and EQ-5D questionnaires based on a recall of their elbow function in the week prior to the trauma. From two weeks onwards, the questionnaires are filled out based on the current

function of the elbow.

Trial registration: The trial is registered with www.clinicaltrials.gov, ID number NCT04189185.

DISCUSSION

Sample size calculation

The required number of patients is determined based on the study's primary endpoint, which is the overall reoperation rate after one year. The assumptions are as follows:

Significance level: $\alpha = 5\%$

Power: $1 - \beta = 80\%$

Estimated reoperation rate after tension band wiring (TBW): 60%

Estimated reoperation rate after suture fixation (SF): 10%

Superiority margin: 20%.

The estimated reoperation rates are based on the literature. A conservative estimate of the reoperation rate after TBW is 60% [2-7]. Most reoperations following TBW are due to the removal of osteosynthesis material [2-7]. Reoperations after SF are expected to be due to infection, non-union and fracture displacement. No reoperations involving the removal of osteosynthesis material are expected after SF. Based on these assumptions, the estimated reoperation rate after SF is 10%. Given these parameters, the required number of patients in each treatment group was calculated to be 35. Considering an estimated dropout rate of up to approximately 20%, 88 patients must be randomised for the study.

Randomisation

Randomisation is 1:1, stratified by centre, with block sizes of two, four, six or eight in random order. The operator is blinded to the order of the blocks. Each centre will have 20 sequentially numbered opaque envelopes. The trial concludes when 88 patients have been included.

Informed consent

Patients are discharged from the emergency department with an angular plaster cast and pain medication according to the guidelines of the participating departments. Patients with olecranon fractures are seen for follow-up in the outpatient clinic within a week. Written information is provided in the outpatient clinic, and the doctor responsible for participating departments provides oral information. In the outpatient clinic, patients may decline participation.

If patients agree to participate in the study, the operation is planned within 14 days after the injury date. Patients who do not wish to participate are treated according to the department's guidelines.

Risks and side effects

Treatment with TBW is considered the gold standard for Mayo Type 2A olecranon fractures.

A high reoperation rate of around 60-70% after osteosynthesis with TBW is reported in the literature, primarily due to discomfort from the osteosynthesis material. The risk of vascular/nerve damage or infections following osteosynthesis with TBW is low [2-7].

Since the only difference between the two treatments is the choice of osteosynthesis material, no increased risk of vascular/nerve damage or infections is anticipated.

Theoretically, a possibility exists of osteosynthesis suture failure and, thus, fracture displacement, but this phenomenon has not been described in the literature [8, 9].

In the study, two additional sets of X-ray images are taken beyond the standard treatment procedure. The extra maximum additional radiation exposure is thus 0.12 mSv. In comparison, a round-trip flight across the Atlantic exposes one to 0.10 mSv. The average annual background radiation in Denmark is 3.0 mSv. The extra radiation exposure from participation in the study is thus minimal.

Formalities

The project was approved by:

- The department managements of the involved departments

- The Regional Scientific Ethical Committee for North Denmark.

The project was registered with:

- www.clinicaltrials.gov, ID number: NCT04189185.

Economics

The study is initiated and conducted by the participating physicians and is within the financial framework of the participating departments. There are no conflicts of interest among the participating physicians.

Ethical considerations

The risk of vascular/nerve damage and infection is estimated to be the same in both groups. Even though previous studies have shown a similar functional outcome, an inherent risk exists of suture fixation, resulting in an inferior outcome. The only known risk of participating in the study is exposure to a maximum of 0.12 mSv of radiation. Therefore, the overall risks associated with participating in the study are considered ethically justifiable.

If suture osteosynthesis is found to be superior, this will lead to fewer wound problems and reoperations, justifying the trial.

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