Strength and function After Non-operative treatment of Displaced olecranon fractures in the elderly: implications of standing UP from a seat (***STAND UP Study***)

Study Protocol

Version 1

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Principal Investigator

Farhad Moola, MD FRCSC

Oren Zarnett, MD

Co-Investigator(s)

Bertrand Perey, MD FRCSC

Kelly Apostle, MD FRCSC

Trevor Stone, MD FRCSC

Dory Boyer, MD FRCSC

Darius Viskontas, MD FRCSC

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INTRODUCTION AND BACKGROUND

The standard of care for displaced olecranon fractures is open reduction and internal fixation to facilitate bony opposition and union given the deforming pull of the triceps on the proximal fragment. However, many elderly patients have multiple medical comorbidities and are poor surgical candidates. Further, wound-healing problems in these patients can be a difficult and often devastating problem to treat.

Emerging literature suggests that displaced olecranon fractures in elderly patients can have acceptable outcomes with non-operative management. While these studies are largely retrospective, there has been one prospective cohort and one randomized controlled trial evaluating outcomes. The randomized controlled trial was stopped short due to ethical considerations from increased complications in the operative group (Duckworth et al. 2017).

Among all the published studies, the average Mayo Elbow Performance Index (MEPI) score ranges from 88 to 96 (scored out of 100), and the mean arc of motion ranges from 106 to 129 degrees.

Elbow extension weakness is a big concern in elderly patients because they require this movement to get out of a chair from a seated position. Non-operative treatment frequently results in a non-union with an expected extension strength deficit. While elbow strength is one component of the MEPI, only one study specifically published extension strength after non-operative treatment of displaced olecranon fractures. Gallucci et al. (2014) reported that according to the motor scoring scale, 64% have extension strength of M5 and 35% have M4 strength. However, no study to our knowledge specifically quantifies this deficit beyond the motor scoring scale.

There remains a large gap in the literature as to the expected elbow extension weakness that these patients can expect with non-operative management of displaced olecranon fractures. This study aims to fill this gap of knowledge. If extension weakness proves not to be as profound as previously expected, it may influence more surgeons to consider non-operative management in low demand or medically unwell elderly patients.

PURPOSE AND JUSTIFICATION

PRIMARY QUESTION:

What is the expected extension strength in patients with Mayo type II olecranon fractures who are managed non-operatively?

SECONDARY QUESTION:

What other functional outcomes are expected for patients with Mayo type II olecranon fractures who are managed non-operatively, and does it compare to what has been previously published in the literature?

PRIMARY OBJECTIVE:

Quantify extension strength after both operative and non-operative treatment of olecranon fractures.

SECONDARY OBJECTIVE:

Report the Mayo Elbow Performance Index (MEPI), Disabilities of the arm, shoulder, and hand (DASH) score, range of motion, and participant satisfaction of both operative and non-operative treatment.

RESEARCH HYPOTHESIS:

Patients with non-operative treatment of olecranon fractures will have significantly reduced extension strength compared to operative treatment.

METHODS

STUDY DESIGN:

This will be a prospective cohort study comparing operative to non-operative treatment outcomes of displaced olecranon fractures. This study will not dictate the treatment a patient will receive.

SAMPLING DESIGN AND PARTICIPANT SELECTION:

Patients who present either to the Royal Columbian Hospital (RCH) or the treating surgeon's clinic with a Mayo type II olecranon fractures will be approached for inclusion in this study. They will be approached regarding this study after their treatment plan (operative versus non-operative) has been decided by the treating surgeon based on discussion with the patient. This study will be based out of RCH and will include patients who either present directly to RCH or are referred to one of the treating surgeons at RCH from an outside hospital for definitive management.

INCLUSION CRITERIA:

1. ≥65 years of age
2. Mayo type II olecranon fracture
3. Ambulatory (with or without the use of walking aides)

EXCLUSION CRITERIA:

1. Additional injuries to the affected arm or contralateral arm
2. Associated nerve injury
3. Dementia or cognitive impairment that inhibits the collection of outcome measures
4. Likely problems, in the judgement of the investigator, with maintaining follow-up (i.e. patients with no fixed address, not mentally competent to give consent, intellectually challenged, patients without adequate support, etc.)
5. Injury or previous deficit to the contralateral arm
6. Currently enrolled in any other research study involving drugs or medical devices
7. Open fractures
8. Inability to provide informed consent

METHOD OF RECRUITMENT:

Patients who meet the inclusion criteria, and have elected to undergo non-operative management after discussion with their treating surgeon will be approached for recruitment into the study. Similarly, patients who meet inclusion criteria and elect to have operative fixation of their fracture will also be approached for recruitment into this study. Contact regarding the study will be made either by the

treating surgeon, fellow, or resident. If the patient agrees to discuss possible participation in the study, a member of the research staff will meet with the patient to discuss the study in full and obtain consent if appropriate.

INFORMED CONSENT:

The consent discussion will be delegated to the orthopaedics research staff who will go over the informed consent for the study with the patient including a thorough and complete discussion of the FHREB approved consent form, including risks/benefits, and participant responsibilities. The patient will be given sufficient time to consider the study and ask questions prior to making a decision. Should the patient elect to participate they will be asked to sign and date the consent form and appropriate documentation of the study consent process will be noted. A copy of the consent form will be given to the participant, a copy will be filed to the hospital chart, and the original consent will be filed in the research chart. The patients will be approached either in the hospital or treating surgeon's office regarding the study. Patients have until 6 weeks post-treatment to decide if they want to partake in the study.

STUDY PROCEDURES

RANDOMIZATION: N/A

INTERVENTION: N/A

This study will not dictate which treatment a participant receives. The treating surgeon, irrespective of the study, will decide treatment after discussion with the participant. We will prospectively follow the outcome of both operative and non-operative treatment of displaced olecranon fractures based on the treatment recommendation of the treating surgeon. Currently the standard of care is fixation of displaced olecranon fractures; however, there is growing evidence that non-operative management of elderly patients with olecranon fractures achieve satisfactory outcomes.

TREATMENT PROTOCOL:

We will leave the treatment protocol for both the non-operative and operative arm to the discretion of the treating surgeon. They will be able to fix the fracture with a technique they deem appropriate, and splint the patient as per the attending surgeon's routine practice.

REHABILITATION PROTOCOL:

We will leave the rehabilitation for both non-operative and the operative arm to the discretion of the treating surgeon.

STUDY VISITS:

Participants will be evaluated at 6 weeks (+/- 1 week), 26 weeks (+/- 2 weeks), and 52 weeks (+/- 4 weeks) post treatment.

DEMOGRAPHIC DATA TO BE COLLECTED:

- Age
- Sex
- Clinical Frailty Scale
- Hand dominance
- Additional injuries

DATA TO BE COLLECTED AT EACH VISIT:

- DASH score (upper limb function score)
- SF12 (General health assessment)
- MEPI (Elbow functional impairment score)
- Extension strength (neutral, pronation, and supination) with the shoulder 90 degrees of abduction
- Elbow range of motion
- Complications, Adverse and Serious Adverse Events
- Patient satisfaction score (/10)
- Yes/no: Able to get out of a chair independently from a seated position

CLINICAL VISITS:

We wish to document outcomes early (6 weeks), intermediate (26 weeks), and long-term (52 weeks). We expect that participants will have plateaued in their recovery by 52 weeks post treatment. These time points coincide with standard of care clinical visits and have been used in many studies looking at non-operative treatment of olecranon fractures. We expect that participating in this study will add an additional 15 minutes to each clinical visit.

DATA COLLECTION:

- Site for data collection: Royal Columbian Hospital and/or surgeon's office (Fraser Orthopaedic Institute/Fraser Orthopaedic Trauma Clinic)
- Time frame: December 2020 – March 2024. (24 months for recruitment/12 months for f/u)
- Demographics: age, sex
- Additional injuries
- Clinical Frailty Scale
- Rehab protocol (if splint is used, type and duration)
- Range of motion: A goniometer will be used to measure the arc of elbow motion with the participant seated and shoulder adducted.
- Strength: Elbow extension strength (Newtons) will be measured with the participant seated and the forearm in full pronation and shoulder adducted to mimic getting out of a chair (measured 3 times with the average value recorded). Both the affected arm and contralateral arm will be measured for comparison.
- The DASH, MEPI, and clinical frailty scale are validated scoring tools (Vincent et al.; Cusick et al.; Rockwood et al)

MEASURES:

Response variables (measures of interest)

- Extension strength
    - Primary outcome measure
    - Measured in newtons
    - Continuous variable
    - Measured by examiner
- Arc of motion
    - Secondary outcome measure
    - Continuous variable
    - Measured by examiner
- MEPI (secondary outcome measure)
    - Secondary outcome measure
    - Patient-reported
    - Continuous variable
- DASH (secondary outcome measure)
    - Secondary outcome measure
    - Patient-reported
    - Continuous variable
- Satisfaction score (/10)
    - Secondary outcome measure
    - 1=low, 10=high
    - Patient-reported

The response variables will be used in the final analysis. Non-operative and operative fixation will be compared using a t-test for each variable.

TIME LINE:

Study start up: September 2020- October 2020

Recruitment: December 2020- December 2022

Follow-up: December 2022- December 2023

Study wrap up: December 2023- March 2024

SAFETY ASSESSMENTS

COMPLICATIONS:

Those complications directly associated to the olecranon fracture will be captured on the Complication Form and those that require surgical management will be recorded on the Surgical Intervention Form. Participants will be closely followed during their clinical course and if a complication should arise, appropriate measures, which may include re-operation, will be employed at the surgeon's discretion. All events will be followed from date of onset through to outcome or end of study, whichever comes first.

ADVERSE AND SERIOUS ADVERSE EVENTS:

Events occurring outside the area of the elbow fracture will be captured on the Outside Event(s)/Serious Adverse Event(s) Form.

An Adverse Event (AE) is defined as an untoward change from baseline in the participant's condition. Assessment and identification of all adverse events (AE's), serious adverse events (SAE's) and complications will be reported. All events will be followed from date of onset through to outcome or end of study, whichever comes first. Type, duration, management and/or treatment of events/complications and resolution will be recorded.

A Serious Adverse Event (SAE) is any adverse occurrence or response to the treatment/intervention, whether expected or not, that:

- Requires inpatient hospitalization or prolongation of existing hospitalization - Results in persistent or significant disability/incapacity - Is life-threatening - Results in death
- Based upon appropriate medical judgment, is an important medical event that may jeopardize the patient or may require medical intervention to prevent one of the outcomes listed above.

Information on study-related SAEs occurring during the course of the study will be provided to investigators in a timely manner.

REPORTING PROCEDURES:

All SAEs, regardless of their relationship, will be reported through the appropriate Case Report Forms (CRFs), within 24 hours of becoming aware of the occurrence.

Institutional guidelines with respect to reporting SAEs to the FHREB will be followed.

ANALYTIC PLAN

SAMPLE SIZE

50 participants total (25 participants in the operative and 25 participants in the non-operative arms).

- Accounting for a 20% loss to follow-up, death, withdraw from the study, or crossover of treatment arm we will aim to recruit 60 patients (30 in each arm)

This is based on the power analysis from Duckworth et al. (2017) using the expected difference in DASH score between operative and non-operative score. This would provide 80% power to detect a significant

difference (α=0.05). Given the lack of studies reporting extension deficits following displaced olecranon fractures we used the DASH score as a surrogate. We expect that obtaining these numbers is feasible from our patient population.

STATISTICAL PLAN

Participants who miss a follow-up appointment will be excluded from that specific time point analysis. Patients who cross over from the non-operative to the operative treatment arm will be excluded at all time points after they cross over. At each time point, the mean of each reported variable will be compared using a t-test between the two groups (operative and non-operative). Statistical significance will be defined as $p<0.05$.

ETHICAL CONSIDERATIONS

POTENTIAL BENEFITS:

If non-operative treatment results in satisfactory outcomes, it may influence more surgeons to elect treating displaced olecranon fractures without surgery; thereby, minimizing operative complications to future patients.

POTENTIAL RISKS:

This study poses minimal risk because treatment will be determined independently from this study. It is possible that a participant may experience some pain during testing (range of motion or extension strength), although we do not anticipate that this will be excessive or anything more than they would otherwise experience during regular rehabilitation from this injury. There is a potential that some questions within the questionnaires may make the patient uneasy or upset. They may also spend more time in the office to collect the data then they otherwise would have for a normal office visit.

PARTICIPANT SAFETY PROVISIONS:

We will make note of any complication and serious adverse events that occurs in either treatment arm; however, because this study is not dictating treatment we do not foresee any reason that this study would be stopped early nor is there the need to monitor data before out targets have been reached.

CONFIDENTIALITY:

All CRFs will be identified using a sequential participant number (e.g. 001, 002) and will be the only identifier noted on the headers of the CRFs.

All CRFs will be kept secured in locked cabinets/offices that will be accessible only to study personnel. All electronic data will be password-protected and accessible only to study personnel.

WITHDRAWAL:

Participants may withdraw from the study at any time, without disclosure, and without any affect to their care or treatment.

BLINDING:

As this is a prospective cohort study of consecutive patients, surgeons, participants and research personnel are not blinded.

STUDY MONITORING:

The Principal Investigators will provide overall supervision of the study. Any protocol amendments and decisions about continuation or termination of the study will be discussed and mutually agreed upon by the Principal Investigators.

DATA MANAGEMENT

Data management will be coordinated through the Royal Columbian Hospital/ Fraser Orthopaedic Research Society (FORS).

CRFs will be the primary source of data collection for the study. Completed CRFs will be kept on-site and filed in the participant's study binder. The forms will be monitored for missing, ineligible or illogical responses prior to data entry. Queries will be brought to the attention of the research team and revisions/amendments will be made in an expedited manner.

ETHICS:

The study protocol, case report forms, questionnaires and the participant information and consent form will be submitted and approved by the FH Research Ethics Board prior to study implementation and recruitment. The study will be conducted in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, the International Conference on Harmonization Guidance E6: Good Clinical Practice E6: Consolidated Guidelines, applicable government regulations and institutional research policies and procedures.

PLANS FOR PUBLICATION AND CONFERENCE PRESENTATIONS

We plan to present the findings from this study both at conferences and in a peer-reviewed journal.

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