Intramedullary screw versus Kirschner wire fixation of extraarticular proximal and middle phalanx fractures: a multicenter randomized controlled trial

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Introduction

Hand fractures are one of the most common skeletal injuries and affect a wide range of the population. Commonly affected groups include children and young adults with sports-related injuries, manual labourers with work-related injuries, and the elderly.[1] Although the majority of phalanx fractures may be managed conservatively with good outcomes, operative fixation is indicated for significantly displaced or unstable fracture patterns, and those causing malrotation and scissoring.[2]

There are a variety of options for operative fixation of proximal and middle phalanx fractures, which include closed versus open reduction (CR vs OR) with percutaneous pinning (PP) or internal fixation (IF) techniques. Kirschner wires (K-wire) and plates/screws are the most common CRPP and ORIF techniques, respectively.[3] K-wires allow for fracture fixation with minimal soft tissue injury and preserved blood supply. However, patients can require prolonged postoperative immobilization and are at risk of malunion and pin tract infection.[4] Conversely, ORIF with plates/screws provide rigid fixation allowing for early mobilization, but require opening of fracture site and often periosteal stripping. Complications with ORIF include adhesions and stiffness.[4]

There is emerging evidence for the effectiveness of intramedullary (IM) screw fixation as an alternative technique, providing for IF without the drawbacks of K-wires or plates/screws.[5] IM screw fixation is a minimally invasive technique requiring limited soft tissue dissection that provides rigid fixation of fractures, acting as an internal splint.[6,7] Its biomechanical properties have been well-described in the lower extremity orthopedic literature.[6] IM screw fixation allows for early mobilization because it provides rigid fixation without the operative site morbidity of open reduction technique and its associated complications such as pain, tendon irritation, soft tissue adhesions, stiffness, decreased range of motion and need for hardware removal.[5]

Primary research on IM screws for hand fractures is limited, and existing studies assess both metacarpals and phalanges or only metacarpals. Small observational cohort studies have shown favourable outcomes in return to activity, range of motion, time to radiological healing, and grip strength.[8,9] In 2023, a cost comparison of IM screw vs K-wire fixation of 62 metacarpal and phalangeal fractures was published.[10] The findings showed significantly lower healthcare costs for the uncomplicated IM screw group compared to the uncomplicated K-wire group.[10]

Most recently, a meta-analysis was conducted in 2024 that compared the use of IM screws, K-wires, and plates/screws in metacarpal fractures. Across 1,261 patients in 26 observational studies, IM screws were found to have significantly improved DASH scores, better grip strength, and lower reoperation rates compared to both K-wires and plates/screws. This is highly encouraging evidence for the use of IM screws in metacarpals but again highlights the gap in evidence for phalangeal fractures.[11]

The primary objective of this study is to compare two CR techniques, i.e. IM screw fixation to K-wire fixation, in adult patients with extraarticular proximal or middle phalanx fractures.

Methods

This is a 1:1 parallel randomized controlled trial that is being conducted at our tertiary academic hospital, St. Joseph's Healthcare Hamilton, in Hamilton, Canada. Additional sites awaiting ethical approval are the University of Calgary, Western University, University Health Network, and University of Ottawa. This trial will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement.[12] Main site ethical approval will be obtained by the Hamilton Integrated Research Ethics Board. The trial will be registered with ClinicalTrials.gov.

Eligibility criteria:

Patients will be eligible for inclusion if they are: 1) adult patients ≥18 years old, 2) scheduled for operative management of extraarticular proximal or middle closed phalanx fracture(s) at our tertiary hospital, 3) feasible to perform closed reduction, 4) able to provide informed consent and complete health-related quality of life (HRQoL) questionnaires in English. Patients will be excluded if there are other fractures that cannot be managed with IM screws or K-wires, fractures affecting both hands, other significant injury to the contralateral upper extremity, other intraarticular fractures, significant concomitant hand trauma, or if they cannot commit to 3 month follow up at our institution.

Study recruitment:

Patients will be enrolled from both clinic and emergency department settings of hand-trained academic surgeons across the four tertiary hospital sites. Once eligible patients have been identified for surgery (either in the clinic or emergency department), the research team will be made aware, and the patient will be approached by a study research assistant to review eligibility criteria for potential recruitment. If the patient agrees to participate and meets eligibility criteria, they will be enrolled in the study. The following baseline patient information will be collected from the patient at the time of enrollment: age, sex, gender, handedness, occupation, comorbidities, smoking status, previous hand injury, mechanism of injury, date of injury, affected finger(s), and management preceding surgery.

Interventions:

The treatment arms for this study will be operative fixation of proximal or middle phalanx fractures using IM screws versus K-wires.

For IM screw fixation, the fracture will first be reduced by the surgeon using a closed technique. A small incision will then be made at the head or base of the proximal or middle phalanx. Skin and extensor mechanism will be retracted to expose the planned screw entry side. One or two IM screws of appropriate width and length based on the patient's bony morphology and fracture pattern will then be placed in the phalanx to hold the reduction. Fluoroscopy will be used during the process. The patient will be placed in a plaster splint.

For K-wire fixation, the fracture will first be reduced by the surgeon using a closed technique. One or multiple K-wires will be placed to hold the fracture reduction. Fluoroscopy will be used during the process. K-wires will be cut outside the skin and a plaster splint will be applied. The

K-wires will be removed at the 4-week visit unless a post-operative infection necessitates earlier removal or clinical signs of delayed fracture healing necessitates later removal.[14]

For both groups, protected early range of motion will be initiated by a licensed hand therapist 1 week post-operatively and patients will be offered a thermoplastic splint during their 1-week hand therapy visit. Hand therapy and splinting will be progressed as per the hand therapists' and the surgeons' discretions based on clinical examination. Patient will be seen at 2 weeks, 4 weeks, 8 weeks, 12 weeks, 6 months, and 1 year post-surgery by the surgical team and hand therapy. X-rays will be performed preoperatively and at 4 weeks and 12 weeks post-surgery as per standard of care. Surgical details will also be recorded.

All aspects of care provided to participants as described above is the current standard of practice except for randomization to intervention.

Outcomes:

The primary outcome of this trial will be the DASH score at 12 weeks postoperatively. The secondary outcome will be the following clinical outcomes: DASH, EQ-5D-5L, pain (VAS), total active motion, grip strength, time to return to work, time to discontinuation of full-time splinting/any splinting, complications/adverse events. Outcomes will be gathered at any or all of baseline (pre-operatively), 2 weeks, 4 weeks, 8 weeks, 12 weeks, 6 months, and 1 year.

DASH

The DASH questionnaire will be used as the primary clinical outcome. A core outcome set was determined for hand fractures and joint injuries in adults via international Delphi study in 2023: fine hand use/dexterity, pain/discomfort during activity, pain/discomfort during rest, return to usual work/job, self-hygiene/personal care, range of motion, patient satisfaction with outcome/result.[14] Although the study did not designate a specific patient-reported outcome measure (PROM) to be used, the DASH questionnaire items address many of the aforementioned core outcomes.

The DASH is a region-specific PROM that has been shown to be valid, reliable, and responsive to change in measuring patient-important domains pertaining to the upper extremity.[14,15] In trauma populations, the DASH has been shown to have excellent internal consistency (0.98) and test-retest probability (intraclass correlation coefficient [ICC] = 0.98).[15] The DASH has also been reported to have good criterion validity, construct validity and responsiveness in hand trauma patients.[16] The minimum detectable change (MDC) of the DASH has been estimated to be 9.04 points and the minimally important difference (MID) has been shown to be 12-14 points.[17]

EQ-5D-5L

The EQ-5D-5L questionnaire is a generic PROM with excellent psychometric properties which measures an individual's overall rating of their current health. The questionnaire asks individuals to rate their current mobility, ability to perform self-care/usual activities, pain/discomfort, and anxiety/depression.[18] It can provide a single index value for an individual's "health status" which can be used in future economic evaluations.[19]

Other

Other clinical outcomes gathered will include pain measured using visual analogue scale (VAS), total active motion (as measured by hand therapist, using a goniometer, compared to same finger on contralateral hand), grip strength (as measured by hand therapist, 3 repetitions using a dynamometer, compared to contralateral hand), return to work (patient-reported), timing of splint discontinuation (clinician-reported) and complications/adverse events (clinician-reported). Complications/adverse events may include but are not limited to complex regional pain syndrome, stiffness, delayed union, non-union, malunion, infection, hardware removal, need for reoperation.

Data collection:

Baseline data will be collected by a research assistant at the time of recruitment over the phone. Patients will have the option to complete the DASH/EQ-5D-5L/VAS questionnaires online via REDCap, a secure web platform for online surveys, or via phone interview. Clinical outcomes such as range of motion, return to work, and complications/adverse events will be gathered via electronic medical record chart review. To analyze x-ray data, a judication committee consisting of the principal investigator and two additional hand fellowship-trained surgeons will review images to characterize fractures and the quality of fracture reductions.

Sample size calculation:

We anticipate a minimum sample size of 84 (42 per group), assuming an absolute mean difference of 5 scores with a standard deviation of 7 scores in the DASH score at last follow-up from a recent meta-analysis comparing these interventions in metacarpals[20] with an alpha of 0.05 and a beta of 0.1 (90% power). We intend to finalise the sample size from the data collected directly on phalanx fractures.

Randomization:

Patients will be randomized to undergo IM screw versus K-wire fixation of their fracture in a 1:1 ratio using randomization in blocks of 4. Randomization will be performed using Research Randomizer (Version 4.0)[21] and the sequence will be uploaded to the REDCap randomization module. The allocation sequence will be generated by a research member who is not involved with patient recruitment or clinical patient care, and allocation will occur after initial patient consultation and recruitment preoperatively. By nature of the interventions in this study, blinding will not be possible for the surgeon, hand therapist, or the patient post-operatively.

Statistical methods:

Patient demographics will be presented as descriptive statistics. Dichotomous outcomes will be analyzed using the Chi-Square test for categorical variables. Continuous outcomes will be analyzed using the two-sided t-test. Patients will be analyzed within the group they were allocated to follow the intention-to-treat principle.

Steering committee:

A trial steering committee will meet twice yearly to supervise the progress of the trial. The committee will consist of the lead investigator, the principal investigator, and two other senior academic surgeons who have experience in randomized controlled trials.

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