OPerative versus non-opERAtive management of isolated ULNAr diaphyseal fractures (OPERA-Ulna): protocol for a randomized controlled trial

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Aims

Isolated fractures of the ulnar diaphysis are uncommon, occurring at a rate of 0.02 to 0.04 per 1,000 cases. Despite their infrequency, these fractures commonly give rise to complications, such as nonunion, limited forearm pronation and supination, restricted elbow range of motion, radioulnar synostosis, and prolonged pain. Treatment options for this injury remain a topic of debate, with limited research available and no consensus on the optimal approach. Therefore, this trial aims to compare clinical, radiological, and functional outcomes of two treatment methods: open reduction and internal fixation (ORIF) versus nonoperative treatment in patients with isolated ulnar diaphyseal fractures.

Methods

This will be a multicentre, open-label, parallel randomized clinical trial (under National Clinical Trial number NCT01123447), accompanied by a parallel prospective cohort group for patients who meet the inclusion criteria, but decline randomization. Eligible patients will be randomized to one of the two treatment groups: 1) nonoperative treatment with closed reduction and below-elbow casting; or 2) surgical treatment with ORIF utilizing a limited contact dynamic compression plate and screw construct. The primary outcome measured will be the Disabilities of the Arm, Shoulder and Hand questionnaire score at 12 months post-injury. Additionally, functional outcomes will be assessed using the 36-Item Short Form Health Survey and pain visual analogue scale, allowing for a comparison of outcomes between groups. Secondary outcome measures will encompass clinical outcomes such as range of motion and grip strength, radiological parameters including time to union, as well as economic outcomes assessed from enrolment to 12 months post-injury.

Ethics and dissemination

This trial has been approved by the lead site Conjoint Health Research Ethics Board (CHREB; REB14-2004) and local ethics boards at each participating site. Findings from the trial will be disseminated through presentations at regional, national, and international scientific conferences and public forums. The primary results and secondary findings will be submitted for peer-reviewed publication.

Take home message

- Isolated fractures of the ulnar diaphysis are infrequent, yet present significant challenges due to potential complications such as nonunion, limited forearm motion, and radioulnar synostosis.
- Despite their clinical importance, the optimal treatment approach remains uncertain.
- Our study addresses this critical gap in the literature by comparing the clinical, radiological, and functional outcomes of two treatment methods: open reduction and internal fixation versus non-operative treatment.

Bone & Joint Open

Introduction

Isolated ulnar diaphyseal fractures, commonly known as "nightstick" fractures, are often sustained during physical altercations, and are frequently observed in young males involved in violent activities.[1,2] McQueen et al[2] reported that approximately 38% of ulnar diaphyseal fractures result from direct trauma, where the patient instinctively raises an arm for protection, while 31% are caused by simple falls, and 14% are associated with pedestrian road traffic accidents. The incidence of ulnar diaphyseal fractures varies between 0.02 per 1,000 and 0.04 per 1,000 individuals.[2–5] Although these fractures are relatively uncommon, they are often accompanied by complications that significantly impact patient outcomes. Nonunion rates range from 12% to 14%, while 18% to 32% of patients experience reduced range of motion (ROM) in forearm rotation.[6,7] Furthermore, patients commonly exhibit marked limitations in elbow flexion and extension ROM, along with the development of radioulnar synostosis.[6,8] Pain is another prevalent complication.[9] Consequently, despite the rarity of isolated ulnar diaphyseal fractures, the associated complications can lead to severe impairment, hindering patients from returning to work or achieving pre-injury functional status.[10]

The optimal treatment approach for isolated ulnar diaphyseal fractures remains uncertain due to the lack of consensus.[9,11] Currently, there is limited prospective research available, with only three randomized controlled trials (RCTs) investigating different treatment options, as summarized in Table I.[10,12,13] However, these studies suffer from several limitations, including inadequate descriptions of randomization methods (or the use of quasi-randomization methods), small sample sizes ranging from 29 to 46 patients, inconsistent and limited follow-up periods, high rates of loss-to-follow-up reaching up to 48%, absence of sample size calculations, and a lack of validated outcome measures. Furthermore, there is a significant paucity of prospective research comparing surgical and non-surgical management approaches.

Studies have reported similar time to fracture union for nonoperative treatment strategies when comparing pre-fabricated functional short-arm bracing to above-elbow plaster casting, as well as when comparing short-arm plaster cast, long-arm plaster cast, or Ace Wrap bandage (3M, USA) were compared.[10,12] However, it is worth noting that in the latter study, 70% of patients in the Ace Wrap elastic bandage group experienced treatment failure due to pain and/or increased fracture angulation, leading them to switch to one of the plaster cast groups. The short-arm brace group demonstrated improved wrist flexion and extension ($p < 0.004$), and the functional brace group[12] exhibited enhanced patient satisfaction and earlier return to work, as reported with a limited 20-week follow-up period.[10,12] In terms of surgical management, a comparison between open reduction and internal fixation (ORIF) using two different types of plates, the point contact fixator (Pc-Fix) and the limited contact dynamic compression plate (LC-DCP), showed no significant differences in ROM, pain, time to union, or complication rates at the 12-month follow-up.[13]

In a larger retrospective case-control study involving a sample size of 70 patients, various plate and screw surgical fixation strategies (ranging from 2.0 mm plates to 3.5 mm plates) were compared to different nonoperative treatment strategies (including brace, short-arm cast, long-arm cast, or sling).[9] The study revealed significantly higher rates of nonunion (36.4%; $p = 0.001$) and malunion (45.5%; $p < 0.001$) in the nonoperative treatment group. However, it is important to note that the operatively treated group exhibited a relatively high rate of secondary surgeries (40.5%). This study's findings should be interpreted within the context of its limitations. The study encompassed a range of treatment options, had a high loss-to-follow-up rate, was conducted in a single-centre setting, and included patients with multiple injuries. Such factors may introduce potential biases and limit the generalizability of the results. A second retrospective study, which included 95 patients, revealed that the healing outcomes of isolated ulnar shaft fractures did not significantly differ between surgical and non-surgical treatment.[14] However, around 20% of patients treated non-surgically eventually required surgical fixation. Furthermore, distal-third fractures had a higher chance of converting to surgical fixation, while middle-third fractures had an increased risk of nonunion. Like the first retrospective study, this second study had limitations, including being underpowered.

In summary, there is a lack of RCTs directly comparing surgical treatment using standard ORIF to standard nonoperative treatment for isolated ulnar diaphyseal fractures. As a result, there is currently no consensus on the optimal approach for treating this type of fracture, leading to clinical equipoise in the field. Despite the relative rarity of this injury, it is associated with notable complications. Therefore, it is crucial to establish the most effective treatment method to minimize the subjective nature of surgical decision-making, which currently exists due to a lack of robust evidence. The aim of this study is to provide robust evidence for the optimal treatment method for isolated fractures of the ulnar shaft in adults.

Methods

Trial design and clinical setting

This trial will be a multicentre, open-label, parallel RCT registered under National Clinical Trial number NCT01123447, with an additional parallel prospective cohort arm for eligible patients who choose not to undergo randomization. A pre-trial consort diagram for this trial is exhibited in Figure 1. The objective of the trial will be to evaluate and compare clinical, radiological, and functional outcomes of operative treatment versus nonoperative treatment for patients diagnosed with isolated ulnar diaphyseal fractures. Patient recruitment will take place at multiple trauma centres across Canada, which are part of the Canadian Orthopaedic Trauma Society. The lead site for this trial will be Foothills Medical Centre (Calgary, Canada), along with the multiple participating sites detailed in Supplementary Table i.

Patient and public involvement

This trial has been designed to address the existing clinical knowledge gap, considering the input from patients and the absence of clinical practice guidelines for the management of ulnar diaphyseal fractures. The trial hopes to generate valuable insights that will guide future orthopaedic trauma practices in addressing this significant clinical issue. The findings of this trial will be of utmost importance to various stakeholders, including patients and their families, surgeons, primary

Table I. Summary of prospective trials evaluating management of ulnar diaphyseal fractures.

Reference	Treatment 1	Treatment 2	Treatment 3	Main outcomes	Limitations
Gebuhr et al[12]	Pre-fabricated functional short-arm bracing (n = 20)	Above-elbow plaster casting (n = 19)		No significant difference between fracture union time	13% loss-to-follow-up rate
				Improved return to work in functional braced group	15% protocol violation rate
					Limited 20-week follow-up
Atkin et al[10]	Short-arm plaster cast (n = 14)	Long-arm plaster cast (n = 9)	Ace wrap bandage (n = 8)	No significant difference between fracture union time	Quasi-randomization by time of presentation to hospital
				70% of patients in the Ace wrap bandage group experienced treatment failure due to pain and/or increased fracture angulation	70% of Ace wrap group crossed over to another treatment group
				Short-arm brace group demonstrated improved wrist flexion and extension ($p < 0.004$)	Average follow-up of 20 weeks
					48% loss-to-follow-up rate
Leung and Chow[13]	ORIF with point contact fixator (n = 45)	ORIF with LC-DCP (n = 47)		No significant difference in range of motion, pain, time to union, or complication rates	Change of randomization strategy
				No significant reduction in operating time in the Pc-Fix group (78 minutes) compared to the LC-DCP group (92 minutes ($p = 0.06$))	Included open fractures and the majority were combined radius and ulna fractures

LC-DCP, limited contact dynamic compression plate; ORIF, open reduction and internal fixation; Pc-Fix, point contact fixator.

care physicians, emergency room physicians, and hospital administrators. By providing vital information, this trial has the potential to enhance decision-making processes and improve patient care within the field of orthopaedic trauma, and specifically isolated ulnar diaphyseal fractures.

Patient selection

This trial aims to recruit participants who meet both the patient and fracture criteria outlined in Table II. To ensure consistency and avoid potential biases, a maximum of two closed reductions will be attempted before patients are included in this trial. By implementing this protocol, the trial aims to maintain standardized inclusion criteria and provide reliable and comparable data for analysis.

Experimental intervention

Eligible patients participating in this trial will be randomized to one of two treatments. The first being nonoperative treatment, which includes closed reduction (if required to meet fracture inclusion criteria) followed by short-arm casting. The second will be surgical treatment, specifically ORIF, using a LC-DC plate and screw construct. Randomization will ensure that patients are assigned to their treatment group in a fair and unbiased manner, allowing for a comprehensive comparison of the outcomes between the two treatment groups.

Randomization

Patients will be randomized in a 1:1 ratio using variable block sizes and stratification by recruiting site. The randomization process will be conducted through an automated structure integrated into the Research Electronic Data Capture (REDCap) system, starting from 2016.[18] Prior to this date, randomization will be performed using StudyTRAX (Sciencetrax, USA). Research coordinators at each participating site will initiate the randomization process. Blinding of both the patient and the surgeons to the treatment allocation is not feasible due to the visible differences between cast and surgical incision. Additionally, treatment allocation will not be concealed during the patients' follow-up assessments.

Prospective cohort at the lead site

Patients who choose not to undergo randomization, but are willing to provide informed consent to participate in the prospective cohort at the lead site, will receive the standard care determined by a discussion between the patient and their attending surgeon. Participants in the non-randomized prospective cohort will undergo the same questionnaires and clinical assessments as those in the randomized treatment groups. Their fracture will be treated according to the treatment discussed and agreed upon with their surgeon. The follow-up for these participants will be conducted with the same frequency and approach as in the randomized treatment groups.

Primary outcome measure: functional outcomes

To assess functional outcomes and quantify differences between treatment groups, this trial will utilize validated functional outcome tools with the primary focus on the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire at the 12-month post-injury follow-up.[19] The following

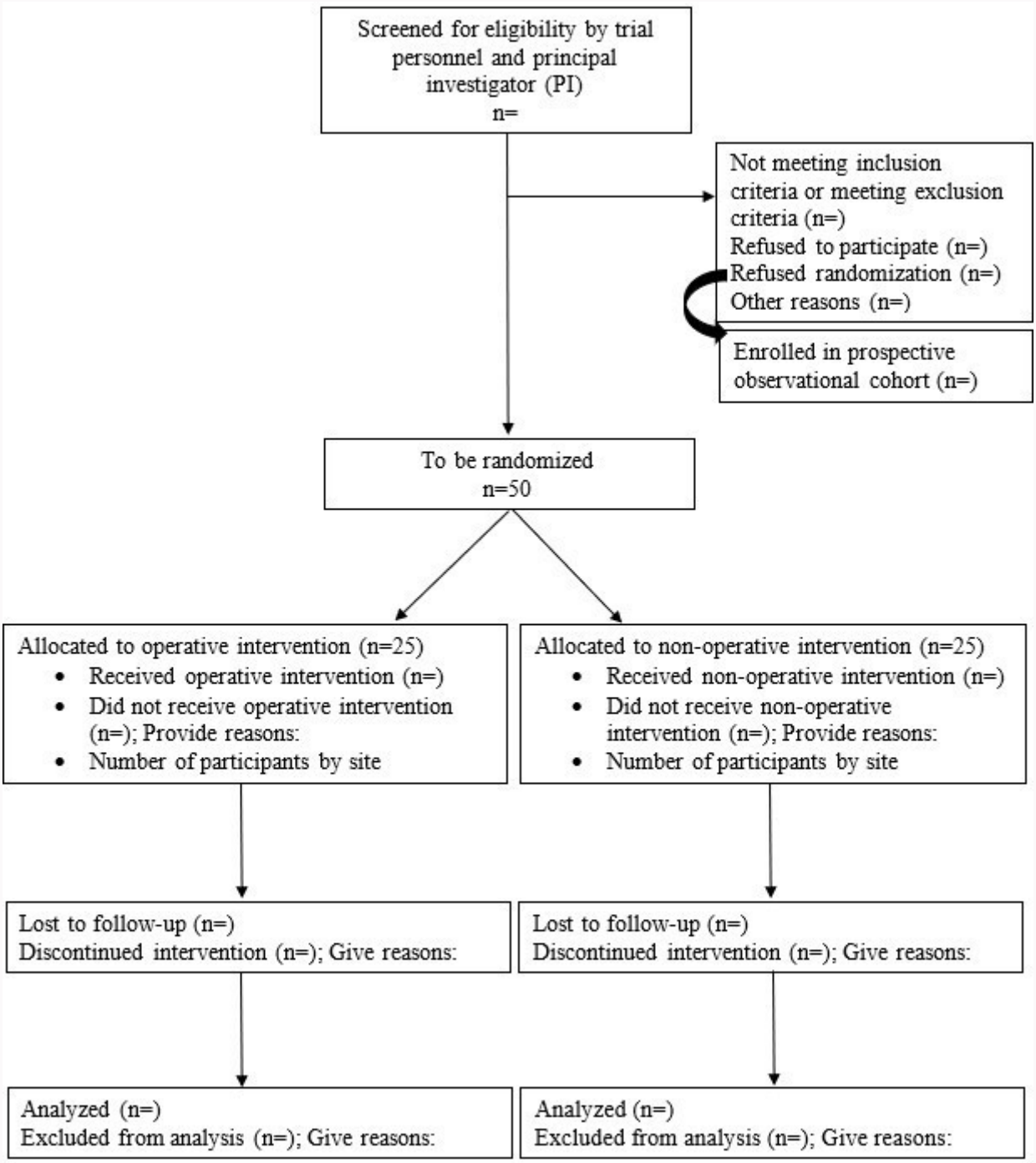

Fig. 1
Pre-trial CONSORT diagram.

validated instruments will be employed at each follow-up assessment:

1. **DASH questionnaire**: This validated self-administered questionnaire consists of 30 items and evaluates the functional capacity of the affected upper limb. It provides insights into the impact of the forearm injury on the overall limb function.[19–21]
2. **Short Form 36 (SF-36) questionnaire**: This self-administered questionnaire comprises 36 items and assesses the patient's reported overall health status and ease of performing daily activities. It offers a comprehensive evaluation of the individual's health-related quality of life.[21,22]
3. **Pain visual analogue scale (VAS)**: The standardized pain VAS is used to measure the intensity of pain experienced by the patients. This scale allows participants to rate their pain levels on a scale ranging from 0 to 10, providing valuable insights into pain management and perception.[23]

All three questionnaires will be administered to the participants during designated follow-up visits. Each questionnaire captures different aspects of the patient's health outcome, enabling a comprehensive assessment of the injury

Table II. Inclusion and exclusion criteria based on patient and fracture pattern criteria.

Inclusion criteria	
Patient inclusion criteria	**Fracture inclusion criteria**
• Aged 16 years or older and skeletally mature. • Has an isolated extra-articular ulnar diaphyseal fracture. • Presents and is enrolled within 14 days of the initial injury. • Is medically fit for a general anaesthetic. • Is willing and able to provide written informed consent for trial participation. • Is willing and able to comply with the trial protocol including follow-up evaluations.	• Subject has an isolated ulnar diaphyseal fracture (AO/OTA type 22-A1.1, 22-A1.2, 23-A1.2, 23-A1.3, or 22-B1.1, 22-B1.2) without extension to the articular surface.[15] • Fracture is displaced, but displacement is < 50% after closed reduction, if closed reduction is required. • Fracture less than 30° of angulation following closed reduction, if closed reduction is required.
Exclusion criteria	
Patient exclusion criteria	**Fracture exclusion criteria**
• Patient has pre-existing ipsilateral wrist injury, degenerative condition, or congenital anomaly. • Patient has a delay in treatment greater than 14 days from time of injury and presentation. • Patient has an active infection in the area of the potential surgical approach. • Patient has concomitant injury which, in the opinion of the attending surgeon, is likely to impair rehabilitation or prolong ulnar fracture healing time (another long bone fracture, ipsilateral limb injury). • Patient has a history of rheumatoid arthritis, fibrous dysplasia, chronic renal failure, Paget's disease, or osteopetrosis. • Patient has a high risk of death from surgery (i.e. American Society of Anesthesiologists (ASA) grade V).[16] • Patient is likely unable to maintain follow-up (i.e. no fixed address, plans to move out of town in the next year, states they are unable to comply with protocol, etc). • Patient has cognitive impairment or language difficulties that would impede the valid completion of questionnaires in English. • Participant is currently pregnant or planning on pregnancy within the trial follow-up period. • Patient is a prisoner, currently detained.	• Patient has an articular fracture (AO/OTA Type 23-A1.1, 23-B, or 23 C).[15] • Open fracture (any Gustilo-Anderson Type).[17] • Segmental ulna fracture. • Fractures within 2 cm of the distal radioulnar joint (AO 23-A1.1). • Fracture of the proximal 1/3 of the ulnar shaft (i.e. Monteggia fracture pattern, AO Type 21 A, 22-A1.3, 22-B1.3). • Pathological fracture.

and its impact. The total administration time for all three questionnaires will be approximately 15 minutes. Additionally, this trial will consider the time taken for participants to return to their pre-injury level of work as an important outcome. This parameter provides an objective measure of the participants' ability to resume their regular work activities following their injury.

Secondary outcome measures: clinical, radiological, and economic outcomes

Clinical outcome measures in this trial will include the assessment of ROM and grip strength. Trained physical therapists or research coordinators at each participating site perform these evaluations. ROM follows the guidelines set by the American Society of Hand Therapists.[24] It encompasses various movements, including wrist flexion and extension, pronation, supination, ulnar/radial deviation, and elbow flexion and extension, pronation, supination, ulnar and radial deviation, and elbow flexion and extension. ROM will be quantified in degrees, and measurements of the contralateral, uninjured arm will be taken as a baseline reference. The results will be expressed as a percentage relative to the ROM of the contralateral arm, providing a comparative measure. Grip strength will be assessed using a handgrip dynamometer (Sammons Preston Rolyan JAMAR model, USA). The measurement will be conducted with the elbow positioned at 90° and the wrist in a neutral pro-supination alignment. Three readings are to be taken, and the average recorded. Grip strength will be expressed as a percentage relative to the contralateral side, allowing for a standardized assessment of hand strength.[19]

Radiological outcomes in this trial will involve the measurement of displacement and angulation through radiograph imaging. Two orthogonal views of the affected forearm, namely the posterior-anterior (PA) and lateral views, will be used for evaluation. Displacement expressed in millimetres, and angulation, measured in degrees, will be assessed based on these radiological images. The evaluation will be conducted at each participating site, and all

Table III. Data collection and follow-up timepoints.

Variable	Baseline	2 weeks	6 weeks	12 weeks	6 months	12 months
DASH	X	X	X	X	X	X
SF-36	X	X	X	X	X	X
VAS	X	X	X	X	X	X
Clinical evaluation	X	X	X	X	X	X
Radiograph	X	X	X	X	X	X
Grip strength			X	X	X	X
ROM						
Cast			X	X	X	X
ORIF		X	X	X	X	X

DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; ORIF, open reduction and internal fixation; ROM, range of motion; SF-36, 36-Item Short-Form Health Survey questionnaire; VAS, visual analogue scale.

radiographs will be anonymized and sent to the lead site for central adjudication and assessment of time to union. Displacement will be measured by quantifying the number of cortical widths involved. Angulation will be determined by analyzing the degree of deviation from the normal alignment in the PA and lateral forearm radiographs. Time to union, an important radiological outcome, will be defined as the presence of bridging callus observed on both orthogonal views. Data collection for defining union commences at the six-week follow-up visit. During data collection, the visibility of the fracture line on the orthogonal views, as well as the presence of callus formation, will be documented.

Data collection for the cost-effectiveness analysis encompasses various factors related to healthcare use and costs, including the length of hospital stay and any expenses associated with complications that may arise during the one-year follow-up period. For patients in the surgical ORIF group, additional data will be collected, such as the duration of surgery, length of plate used, and the number and type of screws employed. By gathering this information, the economic analysis aims to compare the costs associated with each treatment group. It seeks to identify potential differences in the expenses incurred for each treatment group, as well as the cost related to managing and addressing any complications that may arise in both the surgical and nonoperative population.

Data collection and follow-up

Standardized postoperative care and instructions will be provided to all participants in the trial to optimize their recovery. Prior to hospital discharge, patients will receive detailed guidance on postoperative exercises from a qualified physical or occupational therapist. These instructions aim to facilitate the restoration of ROM and functional abilities. Following treatment, all patients will initiate ROM exercises for the fingers, elbow, and shoulder immediately post-treatment. These exercises promote joint mobility and prevent stiffness or contractures. For the surgical ORIF group, specific attention will be given to the wrist during the recovery process. ROM exercises for the wrist will be introduced within a timeframe of seven to 14 days postoperatively, allowing sufficient healing of the skin incisions. After surgery, the surgical ORIF group will receive appropriate postoperative care, including the application of a soft dressing. The usage of a splint or cast, if necessary, will be carefully documented to monitor the specific management approach in this group.

In the nonoperative treatment group, the initiation of wrist ROM exercises will be delayed until the cast is removed, which will typically occur at a minimum of six weeks post-injury. This delay is necessary to ensure proper healing of the fracture and avoid any potential complications associated with premature mobilization. Once the cast is removed and fracture healing is confirmed clinically and radiologically, both treatment groups will begin a similar timeline for initiating strengthening exercises. This typically occurs between six to eight weeks post-injury. The specific timing may vary depending on individual patient factors and the guidance of the healthcare team.

Table III provides a comprehensive overview of the follow-up schedule and data collection summary this trial will employ. To ensure accurate and efficient data entry, each recruiting site will utilize the data collection case report forms, which can be accessed through REDCap for direct input. The lead site will take charge of monitoring data queries monthly, and data query reports will be promptly sent to each participating site for resolution.

Sample size calculation

The primary outcome measure in this trial will be the DASH score assessed at the 12-month post-injury mark. Based on previous research, the minimal clinically important difference (MCID) for the DASH score has been established as 15 and its standard deviation (SD) is identified as 15.[20,25] In order to achieve a statistical power of 80% to detect a difference of 5% with an α of 0.05 and β of 0.2, the calculated sample size will be 25 patients per group, considering a potential loss-to-follow-up rate of 50%. This power calculation was performed using R statistical software v. 4.2.0 (R Foundation for Statistical Computing, Austria).

Considering the higher rate of loss-to-follow-up observed in previous studies involving this patient population, the multicentre design of this trial, and the inclusion of

multiple secondary outcomes, a sample size of 25 patients per group will be used for this trial. Consequently, the total sample size required is 50 participants.[10]

Data analysis plan

The study population will be characterized using descriptive statistics, presenting mean and SD for continuous variables, and frequencies and percentages for categorical data. The intention-to-treat analysis will be employed, utilizing independent-samples *t*-tests to compare the mean scores of the DASH, SF-36, and VAS questionnaires, as well as the time to return to work. For the secondary analysis, analysis of variance (ANOVA) will be conducted, followed by pairwise comparisons, to evaluate the DASH, SF-36, and ROM data at each follow-up interval. Independent-samples *t*-test will be used to assess the time to union data. Furthermore, exploratory subgroup analyses are planned to examine treatment effects in relation to covariates such as age, sex, site, handedness, and injury classification.

An interim analysis will be scheduled to be conducted when 50% of the study is completed. An independent data safety and monitoring committee will be granted access to the interim results to assess whether there are any statistically or clinically significant factors that necessitate discontinuing the study for patient safety purposes. Predefined criteria have been established to guide the decision-making process for early trial discontinuation. These criteria include observing a two-fold increase in fatal or life-threatening serious adverse events (SAEs), a three-fold or greater difference in DASH scores, or a three-fold or greater non-functional ROM between the groups. These predetermined thresholds will be used as a basis for determining if any immediate action is required to ensure patient safety and the integrity of the study.

The prospective cohort group data will be analyzed using the statistical analysis outlined above, using within-group statistical analyses.

Ethics and dissemination

This trial will be approved by the lead site research and ethics board (REB14-2004) and by the respective local ethics board at each participating site. All patient data will be de-identified and stored on the secure, web-based REDCap database developed in accordance with institutional regulations; thus, no patient data will be stored on the local hard drives of data entry computers. The clinical research unit (CRU) at the Cumming School of Medicine at the University of Calgary will provide oversight of data acquisition, management, and data quality assessment auditing. At the CRU, the data collection platforms operate in a validated state. Validation is part of a multi-stage data life cycle that includes planning, design, programming, testing, commissioning, documentation, operation, monitoring, and modification. A combination of role-based access and strict password management processes ensure secure access to research data management. Following the completion of the study, research data will be kept securely in accordance with the policy for long-term storage from the University of Calgary and the Conjoint Health Research Ethics Board (CHREB). When the mandated period expires, all research data will be destroyed.

We will disseminate the findings of the trial through presentations at regional, national, and international scientific conferences and public forums. The primary results and secondary findings will be submitted for peer-reviewed publication. In addition, we will seek widespread dissemination to the general public in collaboration with our study partners, such as the Canadian Orthopaedic Trauma Society. Patients or the general public were not involved in the design, conduct, reporting, or dissemination plans of our research.

The optimal treatment for patients with ulnar diaphyseal fractures remains controversial.[9,11] This study has been designed to inform future orthopaedic trauma practice regarding this important clinical issue that will provide vital information for stakeholders, including patients and their families, surgeons, primary care physicians, emergency room physicians, and hospital administrators.

Supplementary material

A summary of the proposed trial sites across Canada.

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S. Bajammal: Conceptualization, Methodology, Writing – review & editing.
R. Leighton: Conceptualization, Methodology, Investigation, Project administration, Writing – review & editing.
K. Witges: Conceptualization, Methodology, Project administration, Writing – original draft, Writing – review & editing.
K. Rondeau: Conceptualization, Data curation, Formal analysis, Methodology, Validation, Visualization, Writing – review & editing.
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Data sharing

The datasets generated and analyzed in the current study are not publicly available due to data protection regulations. Access to data is limited to the researchers who have obtained permission for data processing. Further inquiries can be made to the corresponding author.

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Ethical review statement

This study has received institutional research ethics board (REB) approval (REB14-2004).

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