FLiP Investigators *et al.*
*Pilot and Feasibility Studies* (2026) 12:51
https://doi.org/10.1186/s40814-026-01789-8

Pilot and Feasibility Studies

RESEARCH

Open Access

# Fracture table vs. lateral positioning for intramedullary fixation of femur fractures (The FLiP Trial): the feasibility of a cluster randomized crossover trial

FLiP Investigators, Daniel E. Axelrod[1*], Sheila Sprague[1,2], Ernesto Guerra-Farfan[3], Yaiza Garcia-Sanchez[3], Brad Meulenkamp[4], Melanie Dodd-Moher[5], Sofia Bzovsky[1], Christy Shibu[1], Gina Del Fabbro[1], Jodi L. Gallant[1], Thomas Mammen[6] and Herman Johal[1]

## Abstract

**Background** Femoral shaft fractures are common severe injuries that carry an elevated risk of operative complications, including femoral malrotation, neurologic, and vascular injuries. There is no definitive research comparing two commonly used surgical tables and patient positions in aiding with both reduction and fixation of femoral shaft fractures. The objective of this pilot trial was to test the feasibility of a cluster randomized crossover trial that assesses the comparative effectiveness of supine positioning on a fracture table versus lateral positioning on a radiolucent table for antegrade intramedullary fixation of femoral shaft fractures.

**Methods** Three orthopaedic trauma centres participated in this pilot trial. Each clinical site was randomized to a starting position, crossed over to the other treatment after 2 months, and alternated treatments in this fashion for the length of the trial. During the enrolment phase, we assessed compliance, enrolment rates, participant follow-up, and accurate documentation of the primary clinical outcome. The feasibility success criteria were: (1) 90% enrolment of eligible participants during enrolment phases; (2) 90% compliance with the trial interventions as per the cluster randomization crossover scheme; (3) timely collection of primary outcome data (i.e., within 6 weeks of fracture) in 95% of participants, (4) 90% completion of participant follow-up data; and (5) definition of the primary outcome as a categorical variable with an appropriate threshold value. Feasibility outcomes were summarized using descriptive statistics reported as means (standard deviation) or medians (first quartile, third quartile) for continuous variables depending on their distribution and counts (percentage) for categorical variables.

**Results** All five of the criteria for feasibility were met. Of the 110 eligible patients identified at the three clinical sites, 101 (91.8%) were enroled over a 2.5-year period and 95/101 (94.1%) received the correct cluster-assigned treatment. The primary outcome (malrotation measured on the CT) was accurately documented within 6 weeks of fracture for 98% of participants (99/101) with 93 participants completing the final follow-up (92.0%). Lastly, the trial data informed an appropriate threshold, a malrotation cut off of 15°, for the primary outcome in the definitive trial.

*Correspondence:
Daniel E. Axelrod
daniel.axelrod@medportal.ca
Full list of author information is available at the end of the article

**Conclusions** These results confirm the feasibility of a definitive trial comparing patient positioning during intramedullary fixation of femoral shaft fractures using a cluster randomized crossover trial design. However, due to funding limitations, a slower than anticipated enrolment, and concerns with surgical equipoise, this trial did not proceed to the definitive phase.

**Trial registration** ClincialTrials.gov NCT03868280.

**Keywords** Femoral shaft fracture, Antegrade intramedullary fixation, Supine position, Lateral position, Cluster randomized crossover trial

## Key messages regarding feasibility

1) What uncertainties existed regarding the feasibility?
   - Uncertainties related to patient enrolment, treatment allocation compliance, timely primary outcome collection, completeness of follow-up data collection, participant retention and accuracy of malrotation cut-off set at 15° existed.
2) What are the key feasibility findings?
   - All five of the criteria for feasibility were met, with 91.8% of eligible patients enroled over a 2.5-year period (threshold: 90%), 94.1% receiving the correct cluster-assigned treatment (threshold: 90%), the primary outcome (malrotation measured on the CT) was accurately documented within 6 weeks of fracture for 98% of participants (threshold: 95%), 92.0% of participants completing the final follow-up (threshold: 90%), and trial data informed an appropriate threshold, a malrotation cut off of 15°, for the primary outcome in the definitive trial.
3) What are the implications of the feasibility findings for the design of the main trial?
   - The pilot phase results confirm the feasibility of a definitive trial comparing patient positioning during intramedullary fixation of femoral shaft fractures using a cluster randomized crossover trial design. However, a slower than anticipated enrolment, concerns with surgical equipoise in the orthopaedic community, and due to limited funding opportunities, this trial did not proceed to the definitive phase.

## Introduction

Femoral shaft fractures represent high energy injuries with a high global burden, occurring at a rate between 14 and 42.5/100,000 person years, with approximately 1 in 10 road traffic accidents worldwide resulting in a femoral shaft fracture requiring surgery [1]. Additionally, there are significant disparities in the burden of diaphyseal femur fractures, with 91% occurring in lower middle-class income countries, and the majority affecting younger males [2].

To help mitigate the effects of ongoing pain, blood-loss, and worsening inflammation from unstable fracture ends, femoral shaft fractures require urgent management [3, 4]. Definitive internal fixation using reamed, locked intramedullary nailing (IMN) has become the standard of care as it provides fracture stability while facilitating nursing care and patient mobilization [5, 6]. Multiple femoral IMN techniques exist; however, most femoral shaft fractures can be treated with an antegrade nail using either supine (fracture table) or lateral (free-leg drape) positioning [7].

Despite the adoption of femoral IMN, patient-reported function following femur fracture fixation varies widely [8]. Incorrect positioning of the fracture fragments by more than 15° relative to the native limb rotation (femoral malrotation) is associated with poor functional recovery, low health-related quality of life, gait abnormalities, difficulty with stairs, and delayed return to pre-injury activity [7, 9, 10]. Significant femoral malrotation (>15°) occurs in up to 55% of patients following femoral shaft fracture IMN, as measured by post-operative computer tomography (CT) scans [9, 11]. Numerous intraoperative assessments have been used to judge rotation, including cortical diameter, lesser trochanter profile and others, though none are easily reproducible or reliable [12].

While the orthopaedic surgery community agrees that femoral shaft fractures should be treated with IMN, there is a lack of agreement on whether the patient should be placed in the *supine position on a fracture table (SFT)* or in the *lateral position on a standard radiolucent operating table (LRT)*. Our research team recently conducted a survey among members of the Canadian Orthopaedic Association to assess patient positioning preferences, revealing a clear divide: 56% of respondents preferred the supine position on a fracture table, while 44% favored the lateral position [13]. Moreover, most respondents were supportive of a clinical trial examining this topic and wished to participate if eligible.

The FLiP Investigators developed the protocol for the Fracture Table versus Lateral Positioning for Intramedullary Fixation of Femur Fractures Trial. The trial compares

the effectiveness of two surgical positions and table choices in the management of femur fractures. The primary outcome of the definitive trial will be risk of femoral malrotation as assessed through postoperative CT imaging following a validated protocol [14]. Secondary outcomes will include patient-reported quality of life, mobility, and intraoperative complications. The FLiP trial follows a cluster randomized crossover design, which is unique amongst randomized trials in orthopaedic surgery [15]. This trial design will help reduce contamination (i.e., the incorrect surgical position being used as per cluster randomization) between treatment arms and facilitate patient enrolment, given that patients with this type of injury are often unable to provide consent during the limited hours between injury and definitive emergency surgery [16].

Prior to embarking on a large definitive cluster randomized crossover trial, *a pilot trial was performed* to demonstrate feasibility. The pilot trial assessed areas of uncertainty that may impact the feasibility of performing the definitive trial, including (1) enrolment of participants during enrolment phases; (2) application of the trial interventions as per the cluster randomization crossover scheme; (3) collection of primary outcome data within the appropriate period, 4) completion of participant follow-up; and (5) definition of the primary outcome as a categorical variable with an appropriate threshold value.

## Methods

Three orthopaedic trauma centres participated in this pilot trial, two in Canada and one in Spain. Each clinical site was randomized to a starting surgical position and table. After a run-in period and a 2-month enrolment period, they crossed over to the other surgical position and repeated this pattern of crossing over surgical positions every two months for the duration of participant enrolment. Participants were followed for 6 months post-fracture fixation surgery. Feasibility outcomes were assessed over the duration of the pilot trial. The trial was registered with ClincialTrials.gov (number NCT03868280). The trial was approved by the local research ethics boards, including the Hamilton Integrated Research Ethics Board (#4336), the Clinical Trials Ontario-Qualified Research Ethics Board (2108), and the Vall d'Hebron University Hospital Research Ethics Committee (#PR(TRA)540/2020). The McMaster Surgical Methods Centre provided trial oversight and trial coordination.

### Randomization and the run-in phase

Each clinical site was randomly assigned treatment allocation order by personnel at the Surgical Methods Centre using a computer-generated randomization table. Prior to initiating patient recruitment, each clinical site completed a 1-month run-in phase. During this time, the sites began using their pre-assigned operative position for eligible femur fracture surgeries. This run-in period was implemented to ensure that acceptable compliance was achieved before initiating participant enrolment. Compliance was monitored by the Surgical Methods Centre by reviewing data submitted by research personnel at each clinical site. Research personnel documented compliance with administering the allocated treatment during the run-in phase and submitted this weekly to the Surgical Methods Centre. The weekly reports included the total number of eligible femoral shaft fracture patients operated on, the proportion who received the assigned treatment intervention, and the proportion who did not receive the assigned intervention, along with deviation details (e.g., name of attending surgeon, position used, rationale for not using the assigned positioning).

### Enrolment phase

Following the initial run-in phase, participant recruitment began. Each clinical site continued to use their previously assigned surgical position and operative table for all eligible femur fracture surgeries over an approximate 2-month enrolment period. Participants received the allocated treatment for their initial fracture management surgery, as well as for repeat planned surgeries, even if the repeat surgery fell within the subsequent enrolment period that used the non-allocated position. After the first enrolment period was complete, the sites crossed over to the opposite position and moved directly into the second 2-month enrolment phase. No run-in phase was implemented at the time of crossover to the second position. This pattern of crossing over surgical positions every two months continued for the duration of the enrolment period. The Surgical Methods Centre continued to monitor compliance by reviewing data submitted by research personnel at each clinical site. Surgical Methods Centre personnel verified that each enroled participant in a given cluster received the correct surgical position for that cluster at the clinical site.

### Eligibility criteria

Eligible patients were adults aged 18 years of age or older, with diaphyseal or subtrochanteric femur fractures appropriate for antegrade fixation. Surgery had to be performed by a participating surgeon or delegate. The patient had to provide informed consent and be enroled within 6 weeks of femoral shaft fixation. Specific exclusion criteria included injury factors that would preclude treatment in both operative positions, such as ipsilateral tibia or acetabular fractures, pregnancy, and others.

**Table 1** Feasibility outcomes

| Feasibility outcome | Hypothesis | Criteria for success | Method of analysis |
|---|---|---|---|
| Patient enrolment | Pilot trial will demonstrate feasibility to enrol patients in definitive trial | 90% of eligible patients are enroled. Ineligible is defined as patient not screened within 6 weeks of fracture but was otherwise eligible | Proportion of patients enroled/patients eligible |
| Treatment allocation compliance | Pilot trial will demonstrate feasibility for clinical sites to comply with treatment allocation in definitive trial | 90% compliance with the randomization treatment allocations | Proportion of participants who received the correct treatment allocation for their cluster |
| Primary outcome data collection for enroled patients | Pilot trial will demonstrate feasibility to obtain primary outcome (post-operative imaging) for enroled patients in definitive trial | CT scans obtained within 6 weeks of their fracture in 95% of participants | Proportion of participants who obtained CT scans within 6 weeks |
| Participant retention and follow up data | Pilot trial will demonstrate feasibility to collect follow up data on patients in definitive trial | 95% completed data collection on baseline, surgical, and peri-operative case report forms (CRFs), and 90% complete follow-up data on the CRFs | Proportion of complete data in all case report forms |
| Accuracy of malrotation cut-off at 15° | Pilot trial will demonstrate feasibility to use malrotation as a categorical variable, with a cut-off of 15° in the definitive trial | Sensitivity analysis identifying 15° as the appropriate cut off point for malrotation | Multivariate regression |

### Clinical outcomes and participant follow-up

The secondary objectives of the pilot trial represent the clinical objectives of the definitive trial. The primary objective of the definitive trial is to determine if lateral positioning leads to improved rotational alignment of the operative limb, determined using post-operative CT scans. The secondary objectives of the definitive trial are to determine if lateral positioning affects: 1) health-related quality of life, 2) modified Harris Hip Score, 3) operative time, 4) use of intraoperative fluoroscopy, 5) need for open reduction, 6) use of reduction adjuncts, 7) complications from use of the fracture table or from lateral positioning, 8) length of hospital stay, and 9) days of ventilator support.

### Pilot trial outcomes and success criteria

The primary outcome was feasibility, which was comprised of five equally weighted factors. To consider the trial "feasible," all five factors had to meet or surpass feasibility thresholds determined *a priori*. These five factors include 1) patient enrolment, 2) treatment allocation compliance, 3) primary outcome data collection, 4) participant retention, and 5) determining an appropriate threshold for the primary outcome of femoral malrotation. The criteria for success were determined *a priori* through a review of best standards for reporting and analyzing pilot and feasibility studies, with the methods of analyses described below (Table 1) [17, 18].

### Sample size

Since the feasibility objectives in our pilot trial did not lend themselves to traditional quantitative sample size calculations [19–21], we estimated a sample size of the pilot trial to 2 to 4 clusters with an enrolment period of 6–12 months. An enrolment period of 6 months allowed each site to enrol patients into each treatment group, and we estimated that between 60 and 100 participants would be enroled across 2 clusters. This approach allowed us to assess the feasibility of FLiP as a definitive large trial. The PREP-IT trial, also coordinated through the Surgical Methods Centre, conducted a vanguard phase using 2 clusters to successfully confirm feasibility and refine the case report forms [22]. Additionally, other orthopaedic fracture trials conducted through the Surgical Methods Centre using a traditional randomized controlled trial design have successfully conducted pilot studies using sample sizes ranging from 60 to 100 participants [23].

### Statistical analysis and principles

The analysis and reporting of these results follow the CONSORT guidelines for the reporting of randomized pilot and feasibility trials, as well as the CONSORT extension for cluster trials [24] and crossover trials [25]. The process of participant enrolment and flow throughout the trial was summarized using a flow diagram. Participant demographics, medical history, surgical details, and peri-operative details were summarized by treatment group using descriptive summary measures. Descriptive measures were expressed as means and standard deviations, or medians and interquartile ranges for continuous variables depending on the distribution, and number and percent for categorical variables. All patients enroled in the trial were included in the analysis, regardless of level of adherence to the intervention, or any other deviation from protocol. We did not impute for missing data in this pilot trial.

## Results

### Feasibility criterion 1: patient enrolment

Three orthopaedic trauma centres participated in the FLiP pilot trial: 1) Hamilton Health Sciences General Site (HGH) in Hamilton, Ontario, Canada, 2) Hospital Universitari Vall D'Hebron (HUVH) in Barcelona, Spain, and 3) the Ottawa Hospital, Civic site (OCH) in Ottawa, Ontario, Canada. These pilot sites were randomized to one of two patient positions and operative tables and completed run-in and pilot phases successfully.

Between November 17, 2020, and June 26, 2023, a total of 247 patients were screened within the pilot phase, with 110 patients meeting eligibility criteria. Of these 110 patients, 101 provided informed consent (91.8%) and were enroled into the trial (Fig. 1). The most common reasons for exclusion were patient did not have midshaft femur fracture appropriate for antegrade fixation ($n=34$), inability to obtain informed consent from the patient or proxy ($n=18$), previous external fixation of femoral shaft fracture ($n=16$), and having a pathologic fracture ($n=16$). All reasons for exclusion are listed in Table 2. Of note, it took over 2.5 years to enrol the 101 participants across 3 clinical sites, which equates to 3 participants per month being enroled.

More female ($n=53$) than male ($n=48$) participants were enroled, with an average age of 61.6 (SD 26.7 years). Most fractures were a result of a fall (62.4%), were subtrochanteric (62.3%), and classified as simple (AO 32-A) (53.5%). Further details on participant demographics and fracture and injury characteristics are provided in Table 3.

### Feasibility criterion 2: treatment allocation compliance

During the enrolment phases, contamination rates were closely monitored. Ninety-four percent (95/101, 94.1%) of participants were positioned and treated with the appropriate operating room table during their initial surgery. One clinical site; however, did not meet the 90% feasibility threshold for correct treatment and was

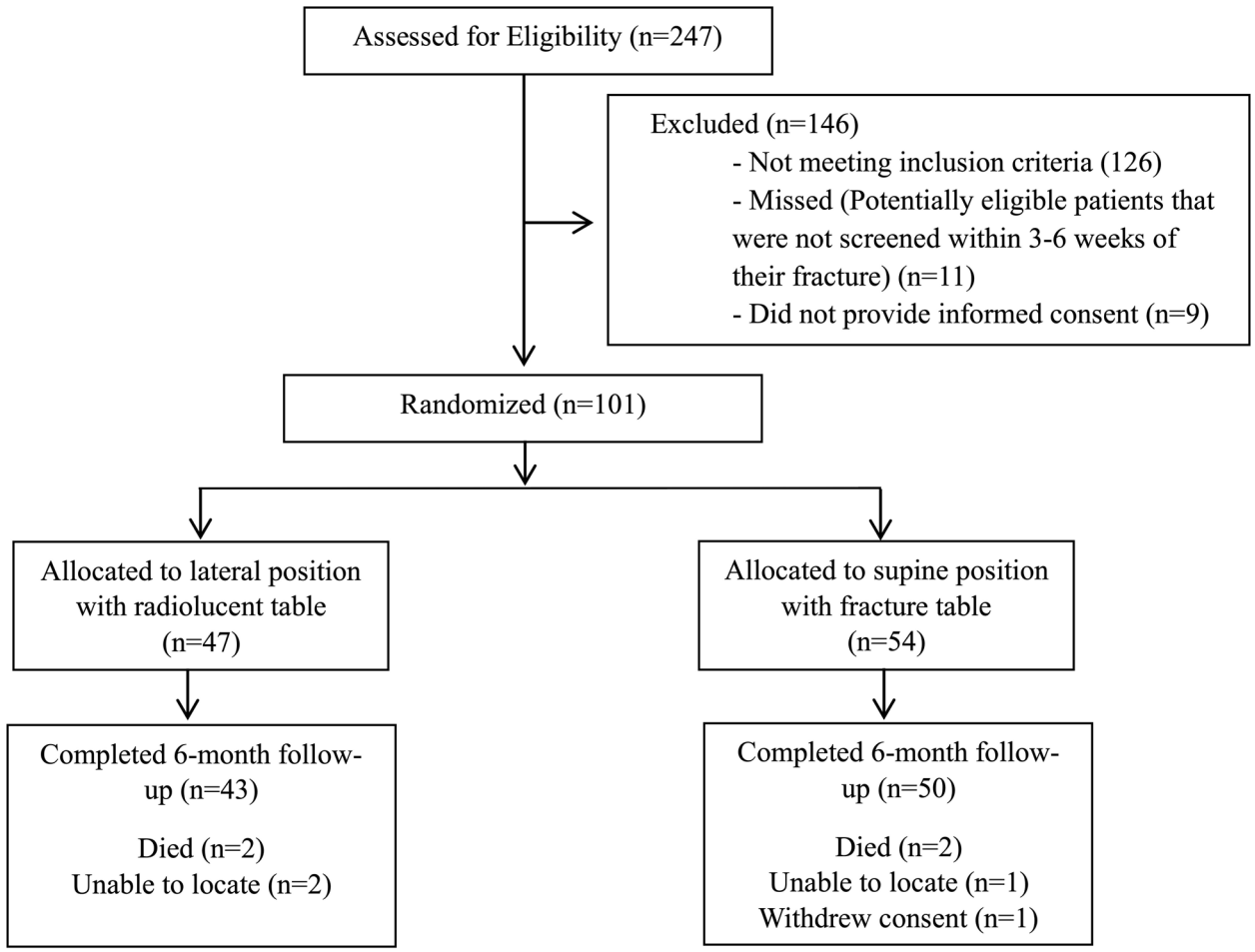


**Fig. 1** Participant flow diagram

responsible for 5 of 6 events of inappropriate treatment allocation (Table 4).

#### Feasibility criterion 3: primary outcome data collection

The primary outcome data (CT scans within 6 weeks of fracture) was collected for 98.0% (99/101) of participants across the three pilot sites. CT scans were taken for every participant as part of the standard of care across academic centres. Throughout the trial, the Surgical Methods Centre conducted remote and on-site monitoring to ensure sites were collecting and reporting the primary outcome. As an error rate of less than 5% in the documentation of the primary outcome data was required, this feasibility criterion was met (Table 4).

#### Feasibility criterion 4: participant retention data

Participant follow-up visits were also completed as per protocol. Research personnel completed all baseline, surgical, and peri-operative case report forms for all participants (101/101, 100.0%). The criteria of at least 90% of follow-up data collected on the case report forms was met for all participants (101/101, 100.0%) across all three sites (Table 4). Ninety-two percent (93/101) of participants completed the final 6-month follow-up visit. The reasons for eight participants not completing the final follow-up visit included death (4 participants), unable to be located (3 participants), and withdrawal of consent (1 participant).

#### Feasibility criterion 5: accuracy of malrotation cut-off at 15°

An unblinded statistician, not involved with either the pilot or definitive trial, reported that a 15° cut-off for malrotation would yield an appropriate and feasible sample size for a definitive trial given preliminary results. With an expected loss to follow up of 10%, a between-cluster intra-cluster correlation coefficient of 0.004 and between-cluster variance of 0 observed in the pilot phase, an expected number of 15 recruiting clusters (sites) and rounding to the nearest multiple of 20 to ensure balance among the clinical sites and two interventions, the

**Table 2** Reasons for exclusion

| Reason for exclusion | Number of patients excluded $n = 146$ patients number (%) |
|---|---|
| Patient did not have a midshaft (diaphyseal) femur fracture appropriate for antegrade fixation | 34 (23.3) |
| Inability to obtain informed consent from the patient or proxy | 18 (12.3) |
| Previous external fixation of femoral shaft fracture | 16 (11.0) |
| Pathologic fracture | 16 (11.0) |
| Likely problems, in the judgment of study personnel, with maintaining follow up with the patient | 11 (7.5) |
| Patient not screened within 6 weeks of their fracture but was otherwise eligible (Missed) | 11 (7.5) |
| Patient did not provide informed consent | 9 (6.2) |
| Ipsilateral acetabular fracture | 6 (4.1) |
| Ipsilateral tibia fracture | 6 (4.1) |
| Ipsilateral femoral neck fracture | 5 (3.4) |
| Bilateral femur fracture | 4 (2.7) |
| Patient under 18 years of age | 4 (2.7) |
| Periprosthetic fracture | 2 (1.4) |
| Terminal illness with expected survival less than 6 months | 2 (1.4) |
| Inability to be positioned in lateral due to other concomitant injury | 1 (0.7) |
| Surgery was not performed by participating surgeon or delegate | 1 (0.7) |

estimated sample size for a definitive trial would be 340. Table S1 outlines the summary of the initial sample size assumptions that yield ≥ 80% power to detect a difference between the treatments (Appendix 1).

## Discussion

Currently, the choice between lateral positioning on a radiolucent table, or supine positioning on a fracture table when operating on a diaphyseal or a subtrochanteric femur fracture is dependent on surgeon preference, with limited evidence to guide decision making. Moreover, complications following treatment of femoral shaft fractures are common, and can lead to substantial disability. It is possible that clinical outcomes could be improved through appropriate patient positioning and treatment choices.

Orthopaedic surgeons who prefer the *LRT* believe it offers improved access to the start point for IMN as well as to the rest of the femur for manipulation, resulting in a better reduction of the fractured limb [26]. Additionally, a recent cohort study, adjusted for associated injuries, found that patients treated using the *LRT* had shorter intensive care unit stays and a reduced number of days on a ventilator, indicating that there may be a protective effect from a respiratory standpoint [27]. Lastly, the standard operating room table used in the *LRT* approach, is readily available, less expensive, and does not require additional setup prior to the procedure. However, there are concerns that lateral positioning may lead to longer operative times as additional positioning aids and reduction maneuvers may be required.

Proponents of positioning femoral shaft fracture patients using *SFT* argue that the fracture table provides a constant traction force to stabilize the fractured limb and allows for better intraoperative imaging. This allows surgeons to reduce operative time and minimize the need for surgical assistants. However, constant and prolonged traction poses known risks to neurovascular structures [28] associated with the central post and may overpower feedback from the natural resting tone of the surrounding thigh musculature, leading to a higher incidence of fixation in a malrotated position.

The FLiP pilot trial, implemented at three orthopaedic trauma centres, was used to evaluate the feasibility of a cluster crossover randomized controlled trial design to better inform clinical decision making within the clinical controversy. All the clinical criteria corresponding to definitive trial feasibility surpassed thresholds for feasibility success, defined a priori, during the pilot of the FLiP trial.

The run-in phase was successful regarding the number of eligible femoral shaft fracture patients appropriately recruited at each centre. Patient recruitment followed a predictable seasonal pattern with more recruitment happening in mid-winter and summer months, with relatively light recruitment in shoulder seasons. This phenomenon of seasonal variation in trauma patients has been well described previously and was addressed through bimonthly cluster crossovers to the opposite intervention [29–31]. Moreover, recruitment volume mirrored trauma centre volume with the busiest trauma centres recruiting the most patients per month.

**Table 3** Participant demographics and fracture characteristics

| Characteristic | Lateral position with radiolucent table *n* = 47 | Supine position with fracture table *n* = 54 |
|---|---|---|
| Age, years, mean (SD) | 62.7 (27.6) | 60.2 (25.8) |
| Sex, n (%) | | |
| Female | 27 (57.4) | 26 (48.1) |
| Male | 20 (42.6) | 28 (51.9) |
| Body mass index, kg/m2, n (%) | | |
| Underweight (BMI < 18.5) | 2 (4.3) | 1 (1.9) |
| Normal weight (18.5–24.9) | 24 (51.1) | 24 (44.4) |
| Overweight (25–29.9) | 12 (25.5) | 18 (33.3) |
| Obese (BMI > 30) | 9 (19.1) | 11 (20.4) |
| Cigarette smoking history, n (%) | 14 (29.8) | 24 (44.4) |
| Functional Comorbidity Index, mean (SD) | 1.9 (1.8) | 1.6 (1.5) |
| Mechanism of injury, n (%) | | |
| Motor vehicle accident | 14 (29.8) | 16 (29.6) |
| Driver/passenger | 8 (57.1) | 7 (43.8) |
| Pedestrian/cyclist | 1 (7.1) | 2 (12.5) |
| Motorcycle | 3 (21.4) | 5 (31.2) |
| Cycling accident | 0 (0.0) | 1 (6.2) |
| Recreational vehicle | 2 (14.3) | 1 (6.2) |
| Fall | 31 (66.0) | 32 (59.3) |
| Standing | 28 (90.3) | 26 (81.2) |
| Height (< 1 m) | 2 (6.5) | 2 (6.2) |
| Height (≥ 1 m) | 1 (3.2) | 4 (12.5) |
| Other | 2 (4.3) | 6 (11.1) |
| Direct trauma (blunt) | 0 (0.0) | 1 (16.7) |
| Crush injury | 1 (50.0) | 2 (33.3) |
| Twist injury | 1 (50.0) | 1 (16.7) |
| Blast injury | 0 (0.0) | 2 (33.3) |
| Work related injury, n (%) | 3 (6.4) | 3 (5.6) |
| Injury Severity Score, mean (SD) | 10.5 (3.7) | 11.6 (5.4) |
| Fracture type, n (%) | | |
| Proximal 1/3 diaphysis | 31 (66.0) | 35 (64.8) |
| Mid-diaphysis | 15 (31.9) | 19 (35.2) |
| Distal 1/3 diaphysis | 1 (2.1) | 0 (0.0) |
| Subtrochanteric fracture, n (%) | 29 (61.7) | 34 (63.0) |
| AO classification, n (%) | | |
| AO 32-A (simple fracture) | 25 (53.2) | 29 (53.7) |
| AO 32-B (wedge fracture) | 14 (29.8) | 11 (20.4) |
| AO 32-C (complex fracture) | 8 (17.0) | 14 (25.9) |

Compliance remained high during the run-in phase and during the enrolment periods. Minimal contamination (i.e., the incorrect surgical position being used as per cluster randomization) occurred during the run-in phase and enrolment periods. Importantly, site crossovers to the other intervention did not lead to a higher-than-expected rate of contamination. This was prevented through clear communication with each site through emails and posters with appropriate treatment allocation for that enrolment period listed in each operating room theatre.

Lastly, acceptable rates of patient follow-up and attainment of post-operative CT scans within six weeks of initial surgery were met. Although the effectiveness of the CRFs used during this pilot trial was not a formal outcome, our feasibility trial allowed for the assessment of data collection. Using experience from previous pilot trials, we did not formalize the CRFs until the first

**Table 4** Feasibility outcomes

| Feasibility outcome | Feasibility criteria | Feasibility outcomes n (%) | Feasibility criteria met |
|---|---|---|---|
| Patient enrolment | At least 90% of eligible patients enroled | Total: 101/110 (91.8%)<br>HGH: 32/36 (88.9%)<br>OCH: 21/25 (84.0%)<br>HUVH: 48/49 (98.0%) | Yes |
| Treatment allocation compliance | At least 90% compliance with the randomization treatment allocations | Total: 95/101 (94.1%)<br>HGH: 27/32 (84.4%)<br>OCH: 21/21 (100.0%)<br>HUVH: 47/48 (97.9%) | Yes |
| Primary outcome data collection for enroled patients | CT scans obtained within 6 weeks of their fracture in at least 95% of participants | Total: 99/101 (98.0%)<br>HGH: 30/32 (93.8%)<br>OCH: 21/21 (100.0%)<br>HUVH: 48/48 (100.0%) | Yes |
| Participant retention and follow up data | 1. At least 95% of data collection on baseline, surgical, and peri-operative case report forms completed<br>2. At least 90% of follow-up data on the case report forms completed | Baseline, surgical, and peri-operative case report forms:<br>Total: 101/101 (100.0%)<br>HGH: 32/32 (100.0%)<br>OCH: 21/21 (100.0%)<br>VHUH: 48/48 (100.0%)<br>Follow-up case report forms:<br>Total: 101/101 (100.0%)<br>HGH: 32/32 (100.0%)<br>OCH: 21/21 (100.0%)<br>HUVH: 48/48 (100.0%) | Yes |
| Accuracy of malrotation cut-off at 15° | Sensitivity analysis identifying 15° as the appropriate cut off point for malrotation | 15° was identified as the appropriate cut off point for malrotation | Yes |

*HGH* Hamilton Health Sciences General Site, *OCH* the Ottawa Hospital, Civic site, *HUVH* Hospital Universitari Vall D'Hebron

participant was enroled in the run-in period. This provided the opportunity for minor changes to the CRFs, including formatting and data input to allow for efficient completion during the remainder of the pilot phase.

This pilot trial is limited by slower than anticipated enrolment. It took over 2.5 years to enrol 101 participants across three clinical sites. This pilot trial is also limited by only including three clinical sites. These clinical sites may not be representative of the orthopaedic surgery community as they were very keen to participate in the pilot phase and demonstrated a high level surgical equipoise between the two treatment groups. When planning for a definitive phase, we faced challenges with both enrolment timelines as well as with selecting clinical sites with a high level of surgical equipoise.

In summary, the success criteria of the FLiP pilot study were met. However, due to slow enrolment, concerns with surgical equipoise at many hospitals, and funding limitations, the FLiP trial did not proceed to the definitive phase.

## Appendix

Table S1. Sample size assumptions for the primary outcome

| | | Proportion of patients experiencing ≥15 degrees of malrotation following lateral position with manual traction on a radiolucent table | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | 0.13 | 0.15 | 0.17 | 0.19 | 0.21 | 0.23 | 0.25 |
| Proportion of patients experiencing ≥15 degrees of malrotation following supine position on a fracture table | 0.41 | 102 | 124 | 151 | 186 | 234 | 298 | 390 |
| | 0.43 | 90 | 108 | 130 | 157 | 194 | 242 | 308 |
| | 0.45 | 79 | 94 | 112 | 135 | 163 | 200 | 249 |
| | 0.47 | 71 | 83 | 98 | 116 | 140 | 168 | 206 |
| | 0.49 | 63 | 74 | 86 | 101 | 120 | 143 | 173 |
| | 0.51 | 57 | 66 | 76 | 89 | 105 | 123 | 147 |
| | 0.53 | 51 | 59 | 68 | 79 | 92 | 107 | 126 |

* Between cluster ICC = 0.004; Between period variance = 0; Number of clusters = 15; Number of periods = 2; Alpha = 0.05

**Abbreviations**

| | |
|---|---|
| CRF | Case Report Form |
| CT | Computer Tomography |
| FLiP | Fracture Table vs. Lateral Positioning for Intramedullary Fixation of Femur Fractures |
| HGH | Hamilton Health Sciences General Site |
| HUVH | Hospital Universitari Vall D'Hebron |
| IMN | Intramedullary Nailing |
| LRT | Lateral Position on a Standard Radiolucent Operating Table |
| OCH | The Ottawa Hospital, Civic Site |
| SD | Standard Deviation |
| SFT | Supine Position on a Fracture Table |

**Acknowledgements**

The FLiP Investigators

Writing Committee: Daniel Axelrod (McMaster University, Hamilton, ON), Sheila Sprague (McMaster University, Hamilton, ON), Ernesto Guerra-Farfan (Vall d'Hebron University Hospital, Barcelona, Spain), Yaiza Garcia-Sanchez (Vall d'Hebron University Hospital, Barcelona, Spain), Brad Meulenkamp (The Ottawa Hospital, Ottawa, ON), Melanie Dodd-Moher (The Ottawa Hospital, Ottawa, ON), Sofia Bzovsky (McMaster University, Hamilton, ON), Christy Shibu (McMaster University, Hamilton, ON), Gina Del Fabbro (McMaster University, Hamilton, ON), Jodi L. Gallant (McMaster University, Hamilton, ON), Thomas Mammen (McMaster University, Hamilton, ON), Herman Johal (McMaster University, Hamilton, ON).

Executive Committee: Daniel Axelrod (Principal Investigator, McMaster University, Hamilton, ON), Herman Johal (Principal Investigator, McMaster University, Hamilton, ON), Sheila Sprague (Principal Investigator, McMaster University, Hamilton, ON), Carlos Prada (Co-Investigator, McMaster University, Hamilton, ON), Lehana Thabane (Co-Investigator, McMaster University, Hamilton, ON).

Adjudication Committee: Thomas Mammen (McMaster University, Hamilton, ON), Dan Tushinski (Hamilton Health Sciences – Juravinski Site, Hamilton, ON).

Co-Investigators: Carlos Prada (McMaster University, Hamilton, ON), Aaron Nauth (St. Michael's Hospital, Toronto, ON), Andrew Furey (Memorial University of Newfoundland, St. John's, NL), Prism Schneider (University of Calgary, Calgary, AB), Janie Wilson (McMaster University, Hamilton, ON), John Morellato (University of Mississippi Medical Centre, Jackson, MS).

Surgical Methods Centre, McMaster University, Hamilton, ON: Paula McKay, Christy Shibu, Gina Del Fabbro, Sofia Bzovsky.

Hamilton Health Sciences – General Site, Hamilton, ON: Herman Johal, Jamal Al-Asiri, Brad Petrisor, Dale Williams, Bill Ristevski, Matthew Denkers, Krishan Rajaratnam, Jodi L. Gallant, Sarah MacRae, Kaitlyn Pusztai, Sara Renaud.

The Ottawa Hospital, Ottawa, ON: Brad Meulenkamp, Allan Liew, Karl-Andre Lalonde, Manisha Mistry, Geoffrey Wilkin, Steven Papp, Stephen Kingwell, Wade Gofton, Braden Gammon, Melanie Dodd-Moher.

Vall d'Hebron University Hospital, Barcelona, Spain: Ernesto Guerra-Farfan, Juan Antonio Porcel-Vazquez, Jose Vicente Andres-Peiro, Jordi Tomas-Hernandez, Jordi Teixidor-Serra, Jordi Selga, Carlos Alberto Piedra-Calle, Diego Soza, Lledo Batalla, Ferran Blasco-Casado, Yuri Lara, Yaiza Garcia-Sanchez.

MútuaTerrassa University Hospital, Barcelona, Spain: Jordi Salvador Carreño, Javier Abarca Vegas, Pablo Castillon Bernal, Saioa Quintas Alvarez, Olga Gomez Ortiz, Laura Rey Fernandez, Judit Lopez Catena.

Hospital Clínic Barcelona, Barcelona, Spain: Anna Carreras-Castañer, Montsant Jornet-Gibert, Pere Torner, Jaime Isern-Kebschull, JC Soler-Perromat, Borja Campuzano-Bitterling, Marina Renau-Cerrillo, Pilar Camacho-Carrasco, Oscar Ares, J. Alonso Zumbado-Dijeres, Marian Vives-Barquiel, Jessica Martinez-de-la-Mata, Ivan Salinas-Casas.

Flinders Medical Centre, Adelaide, Australia: Ruurd Jaarsma, Katharina Denk, Bhavin Jadav, Taran Oberai.

**Authors' contributions**

All authors reviewed the manuscript and provided critical input regarding its intellectual content.

**Funding**

Supported by research grants from the Canadian Institutes of Health Research (169995), the Hamilton Academic Health Sciences Organization (HAHSO), and the Canadian Orthopaedic Trauma Society. The funders had no role in the trial design, collection, management, analysis, and interpretation of data.

**Data availability**

The datasets used and/or analysed during the current trial may be available from the corresponding author on reasonable request.

## Declarations

**Ethics approval and consent to participate**

This protocol, the consent form template, and the case report forms have been reviewed and approved by the Hamilton Integrated Research Ethics Board. The protocol, clinical site-specific informed consent forms, and any participant recruitment material were reviewed and approved by each clinical site's local ethics board. Prior to commencement of the trial each clinical site provided the Surgical Methods Centre with a copy of the ethics board approval.

**Consent for publication**

Not applicable.

**Competing interests**

The authors declare no conflict of interest with regards to this trial.

**Author details**

[1]Division of Orthopaedic Surgery, Department of Surgery, McMaster University, 1280 Main Street West, Hamilton, ON L8S 4L8, Canada. [2]Department of Health Research Methods, Evidence, and Impact, McMaster University, 1280 Main Street West, Hamilton, ON L8S 4L8, Canada. [3]Department of Orthopaedic Surgery and Traumatology, Vall d'Hebron Institut de Recerca (VHIR), Vall d'Hebron Hospital Universitari, Passeig Vall d'Hebron 119-129, Barcelona 08035, Spain. [4]Division of Orthopaedic Surgery, University of Ottawa, 75 Laurier Ave E, Ottawa, ON K1N 6N5, Canada. [5]Ottawa Hospital Research Institute, 1053 Carling Avenue, Ottawa, ON K1Y 4E9, Canada. [6]Department of Medical Imaging, McMaster University, 1280 Main Street West, Hamilton, ON L8S 4L8, Canada.

Received: 11 April 2024 Accepted: 18 February 2026
Published online: 13 March 2026

**References**

1. Mock C, Cherian MN. The global burden of musculoskeletal injuries: challenges and solutions. Clin Orthop Relat Res. 2008;466(10):2306.
2. Agarwal-Harding KJ, Meara JG, Greenberg SLM, Hagander LE, Zurakowski D, Dyer GSM. Estimating the global incidence of femoral fracture from road traffic collisions: a literature review. J Bone Joint Surg. 2015;97(6):e31.
3. O'Toole RV, O'Brien M, Scalea TM, Habashi N, Pollak AN, Turen CH. Resuscitation before stabilization of femoral fractures limits acute respiratory distress syndrome in patients with multiple traumatic injuries despite low use of damage control orthopedics. J Trauma Acute Care Surg. 2009;67(5):1013–21.
4. Pape H. Effects of changing strategies of fracture fixation on immunologic changes and systemic complications after multiple trauma: damage control orthopedic surgery. J Orthop Res. 2008;26(11):1478–84.
5. Morshed S, Miclau IIIT, Bembom O, Cohen M, Knudson MM, Colford JJM. Delayed internal fixation of femoral shaft fracture reduces mortality among patients with multisystem trauma. J Bone Joint Surg Am. 2009;91(1):3.
6. Wolinsky PR, McCarty E, Shyr Y, Johnson K. Reamed intramedullary nailing of the femur: 551 cases. J Trauma. 1999;46(3):392–9.
7. Gausepohl T, Pennig D, Koebke J, Harnoss S. Antegrade femoral nailing: an anatomical determination of the correct entry point. Injury. 2002;33(8):701–5.
8. Stannard JP, Bankston L, Futch LA, McGwin G, Volgas DA. Functional outcome following intramedullary nailing of the femur: a prospective randomized comparison of piriformis fossa and greater trochanteric entry portals. J Bone Joint Surg. 2011;93(15):1385–91.
9. Braten M, Terjesen T, Rossvoll I. Torsional deformity after intramedullary nailing of femoral shaft fractures. Measurement of anteversion angles in 110 patients. J Bone Joint Surg Br. 1993;75(5):799–803.

10. Jaarsma RL, Ongkiehong BF, Gruneberg C, Verdonschot N, Duysens J, van Kampen A. Compensation for rotational malalignment after intramedullary nailing for femoral shaft fractures. An analysis by plantar pressure measurements during gait. Injury. 2004;35(12):1270–8.
11. Zeckey C, Monsell F, Jackson M, Mommsen P, Citak MM, Krettek C, et al. Rotational malalignment after intramedullary nailing of femoral fractures. Injury. 2004;18(3):168–72.
12. Vetter SY, Keil C, von Recum J, Wendl K, Grutzner PA, Franke J. Postoperative malrotation after closed reduction and intramedullary nailing of the femur: a retrospective 5-year analysis. Z Orthop Unfall. 2014;152(5):498–503.
13. Rubinger L, Axelrod D, Bozzo A, Gazendam A, Al-Asiri J, Johal H. (FLiP) fracture-table vs. lateral positioning for femoral intramedullary nailing: a survey of orthopaedic surgeon preferences. Injury. 2020;51(2):429–35.
14. Tornetta P 3rd, Ritz G, Kantor A. Femoral torsion after interlocked nailing of unstable femoral fractures. J Trauma. 1995;38(2):213–9.
15. Arnup SJ, McKenzie JE, Hemming K, Pilcher D, Forbes AB. Understanding the cluster randomised crossover design: A graphical illustraton of the components of variation and a sample size tutorial. Trials. 2017;18(1):1–15. Available from: https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-2113-2. Cited 2022 Oct 3.
16. Rietbergen C, and MMJ of E, 2011 undefined. The design of cluster randomized crossover trials. journals.sagepub.com. 2011;36(4):472–90. Available from: https://journals.sagepub.com/doi/abs/10.3102/1076998610379136?casa_token=_wbmyt5XStsAAAAA:Jthg9ssjVyxD6dp9gCwcFwoaO1VljCAKdsQhkTGCWMHjx4aFZQXkdRzB7_jnrjqPqVSFbYKxB_0Ihxk. Cited 2022 Oct 3.
17. Lancaster GA, Thabane L. Guidelines for reporting non-randomised pilot and feasibility studies. Pilot Feasib Stud. 2019;5(1):114.
18. Sim J. Should treatment effects be estimated in pilot and feasibility studies? Pilot Feasb Stud. 2019;5(1):107.
19. Applied SJPSTJ of, 2005 undefined. Sample size of 12 per group rule of thumb for a pilot study. Wiley Online Library. 2005;4(4):287–91. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/pst.185?casa_token=9RCp7xUR4-cAAAAA:lE4SIxhDhQku3eStIuhyMX4P6Sny0zwRL_Jc_gizEm3MVDmjuQ6C2qBnHBcAwlOfAVSED_2W3giUxqjhig. Cited 2022 Oct 3.
20. Cocks K, epidemiology DTJ of clinical, 2013 undefined. Sample size calculations for pilot randomized trials: a confidence interval approach. Elsevier. Available from: https://www.sciencedirect.com/science/article/pii/S0895435612002740?casa_token=ZLI0dfa1JD0AAAAA:EiIs6KkzDvHGiCu0KoLv7MCJXI5GvCxjkBcROYKjZT83MHtG1SL2xUeEni57Z5AgpkvCW3owLlDy. Cited 2022 Oct 3.
21. Viechtbauer W, Smits L, Kotz D, Budé L, … MSJ of clinical, 2015 undefined. A simple formula for the calculation of sample size in pilot studies. Elsevier. Available from: https://www.sciencedirect.com/science/article/pii/S0895435615003030?casa_token=fOscCKUgdIoAAAAA:8nZw0EgUMrQQinQL3ogiSZ1YR8wmcYMG4KHFULFfuFBAMuEW7Xk3orJzY6jC0BAEuWBDTyw4XtOt. Cited 2022 Oct 3.
22. Slobogean G. Aqueous-PREP: A Pragmatic Randomized Trial Evaluating Pre-operative Aqueous Antiseptic Skin Solutions in Open Fractures [Clinical trial registration] [Internet]. clinicaltrials.gov; 2023 Mar. Report No.: NCT03385304. Available from: https://clinicaltrials.gov/study/NCT03385304.
23. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, et al. A tutorial on pilot studies: the what, why and how. BMC Med Res Methodol. 2010;10(1):1.
24. Hemming K, Taljaard M, McKenzie JE, Hooper R, Copas A, Thompson JA, et al. Reporting of stepped wedge cluster randomised trials: extension of the CONSORT 2010 statement with explanation and elaboration. The BMJ. 2018;363:k1614.
25. Dwan K, Li T, Altman DG, Elbourne D. CONSORT 2010 statement: extension to randomised crossover trials. BMJ. 2019;366:l4378. https://doi.org/10.1136/bmj.l4378. PubMed PMID: 31366597.
26. Stephen DJG, Kreder HJ, Schemitsch EH, Conlan LB, Wild L, McKee MD. Femoral intramedullary nailing: comparison of fracture-table and manual traction. A prospective, randomized study. J Bone Joint Surg. 2002;84(9):1514–21. American Volume.
27. Reahl GB, O'Hara NN, Coale M, O'Hara LM, Castillo R, O'Toole RV, et al. Is lateral femoral nailing associated with increased intensive care unit days? a propensity-matched analysis of 848 cases. J Orthop Trauma. 2018;32(1):39–42.
28. Mei-Dan O, McConkey MO, Young DA. Hip arthroscopy distraction without the use of a perineal post: prospective study. Orthopedics. 2013;36(1):e1-5.
29. Nahmias J, Poola S, Doben A, Garb J, Gross RI. Seasonal variation of trauma in Western Massachusetts: fact or folklore? Trauma Surg Acute Care Open. 2017;2(1):e000120.
30. Rising WR, O'Daniel JA, Roberts CS. Correlating weather and trauma admissions at a level I trauma center. J Trauma - Injury Infect Crit Care. 2006;60(5):1096.
31. Hind J, Lahart IM, Jayakumar N, Athar S, Fazal MA, Ashwood N. Seasonal variation in trauma admissions to a level III trauma unit over 10 years. Injury. 2020;51(10):2209.


## Publisher's Note