Protocol

Outcome Analysis of Distal Third Tibial Fractures Treated With Minimally Invasive Plate Osteosynthesis: Protocol for a Prospective Observational Study

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Abstract

Background: Distal third tibial fractures are difficult to treat owing to the subcutaneous anteromedial border of the tibia, its tenuous periosteal vascularity, and the proximity of the fracture to the ankle joint. Minimally invasive plate osteosynthesis (MIPO) using a locking compression plate (LCP) preserves fracture biology by avoiding direct exposure of the fracture site.

Objective: This study aims to describe the functional and radiological outcomes of closed distal third tibial fractures (Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association [AO/OTA] types A, B, and C1) treated with MIPO-LCP in an Indian tertiary care setting. The study is descriptive and hypothesis generating and is not designed as a comparative effectiveness trial.

Methods: This is a single-center, single-arm, prospective observational cohort study to be conducted at a rural tertiary center in India over 24 months (May 2026 to April 2028). Thirty adults aged 18 to 80 years with closed AO/OTA type A, type B, or type C1 distal third tibial fractures are to be enrolled consecutively. The primary outcomes are the American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot score at 6 months, administered by an independent assessor, and the time to radiological fracture union, assessed using the Radiographic Union Scale for Tibia (RUST). Secondary outcomes include the Olerud-Molander Ankle Score (OMAS), complications, and time to full weight-bearing. Exploratory regression analysis will be performed. Follow-up is scheduled at 6 weeks, 3 months, 6 months, and 12 months.

Results: Ethics approval was obtained on July 8, 2025. Enrollment has been ongoing since May 1, 2026. As of September 2026, five participants have been enrolled. Results are expected between 2028 and 2029.

Conclusions: This protocol will generate prospective, hypothesis-generating data on MIPO outcomes in India. Findings will be descriptive only and, given the sample size limitation (n=30), cannot support definitive claims. Results will inform future comparative trials.

Trial Registration: Clinical Trials Registry–India CTRI/2026/04/108996; https://tinyurl.com/2j9eh8kp

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KEYWORDS

distal tibial fracture; minimally invasive plate osteosynthesis; MIPO; locking compression plate; LCP; American Orthopaedic Foot and Ankle Society score; AOFAS score; Olerud-Molander Ankle Score; OMAS; Radiographic Union Scale for Tibia score; RUST score

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Introduction

Background

Distal third tibial fractures represent a distinct clinical entity within the spectrum of lower-limb long-bone injuries and continue to pose substantial treatment challenges. The distal tibial metaphysis is invested by a thin and relatively avascular soft tissue envelope medially, lacks muscular coverage anteriorly, and is functionally coupled to the ankle joint. Preservation of periosteal integrity is critical for fracture healing, and disruption of the local biological environment may result in delayed union, nonunion, infection, and poor functional recovery [1]. Furthermore, the limited soft tissue coverage surrounding the distal tibia predisposes patients to wound complications, while even minor malalignment can adversely affect ankle biomechanics and lead to chronic pain and disability [2]. In India, distal tibial fractures commonly occur following high-energy mechanisms such as road traffic collisions and falls from height, particularly among economically productive adults, with outcomes often influenced by delayed presentation and restricted access to rehabilitation services.

Conventional open reduction and internal fixation (ORIF) achieves direct visualization and anatomical reduction but requires extensive soft tissue dissection and periosteal stripping, potentially compromising fracture biology and increasing the risk of infection and healing complications [3-5]. Intramedullary nailing preserves the periosteum and minimizes soft tissue disruption; however, fixation in the distal metaphysis remains technically demanding because of the short distal fragment, limited distal fixation options, and increased risk of malalignment, particularly in fractures close to the tibial plafond [6,7]. These limitations have encouraged the development of fixation strategies that aim to provide adequate mechanical stability while preserving the biological environment necessary for fracture healing.

Minimally invasive plate osteosynthesis (MIPO) using a locking compression plate (LCP) combines indirect fracture reduction with biological preservation. Through small remote incisions, a precontoured plate is inserted subcutaneously without directly exposing the fracture site. Locking screw technology provides angular stability independent of bone quality, while preservation of the fracture hematoma and periosteal blood supply facilitates secondary callus-mediated healing. Published studies have reported favorable union rates and functional outcomes following MIPO-LCP, supporting its role as a biologically friendly fixation strategy for distal tibial fractures [8-12].

Despite increasing adoption of MIPO-LCP, important gaps remain within the existing evidence base. Many published studies are retrospective, include heterogeneous fracture patterns, use variable outcome measures, or have limited follow-up durations. The use of validated patient-reported outcome measures (PROMs) and standardized radiological assessment tools has also been inconsistent. Furthermore, prospective evidence from Indian tertiary care centers remains limited, despite differences in injury mechanisms, patient demographics, health care resources, access to rehabilitation, and follow-up patterns compared with those in high-income settings.

Therefore, this prospective observational cohort study aims to describe the clinical, functional, and radiological outcomes of closed distal third tibial fractures (Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association [AO/OTA] types A, B, and C1) treated with MIPO-LCP at a single Indian tertiary care center and to explore potential patient- and fracture-level factors associated with these outcomes. The primary outcomes are functional recovery measured by the American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot score at 6 months and time to radiological union assessed using the Radiographic Union Scale for Tibia (RUST). Secondary outcomes include patient-reported functional recovery assessed using the Olerud-Molander Ankle Score (OMAS), postoperative complications, time to full weight-bearing, and exploratory assessment of factors associated with functional and radiological outcomes. This study is descriptive and hypothesis generating and is not designed as a comparative effectiveness trial.

Review of Literature

The evolution of fixation strategies for distal tibial fractures reflects a progressive recognition that the biological integrity of the fracture environment is at least as important as mechanical stability and that the two need not be in conflict.

Conventional ORIF vs MIPO

Kim et al [10] conducted a prospective randomized study comparing MIPO with minimal ORIF in 58 patients with simple distal tibial fractures (29 per group). Both groups achieved equivalent radiological union rates and functional scores at 1 year; the minimal ORIF group did not demonstrate higher rates of infection or wound dehiscence. The authors concluded that both techniques are effective for simple (AO/OTA types A and B1) fractures. The relevance of this study to the present protocol is that it establishes MIPO as noninferior to ORIF for this fracture subset, providing a historical benchmark against which the present cohort may be contextualized.

MIPO vs Intramedullary Nailing

The debate between MIPO plating and intramedullary nailing for distal tibial fractures has been studied in several prospective and retrospective series. Nath et al [11] randomized 40 patients and found no significant difference in union time (18.45 vs 20 weeks) or mean AOFAS score (92.6 vs 91.2) between intramedullary nailing and MIPO, but reported a higher incidence of implant irritation, ankle stiffness, and wound infection in the MIPO group. Schwarz et al [13] reported that institutional MIPO outcomes and complication rates were consistent with the published literature and comparable to those with nailing in terms of healing success. Similarly, Janssen et al [7] reported comparable healing outcomes between plating and nailing, although concerns regarding malalignment remained more prominent with intramedullary nailing in distal metaphyseal fractures. Helfet and Suk [14] described MIPO as a safe, reliable technique specifically suited to fractures in the distal metaphysis where intramedullary nailing is technically constrained. Cumulatively, these data suggest that MIPO is an

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acceptable, biologically sound alternative to nailing for appropriately selected extra-articular and simple partial-articular distal tibial fractures, while carrying a marginally higher risk of wound-related complications that must be monitored prospectively.

Union Rates and Functional Outcomes Following MIPO

Several prospective and retrospective series have reported favorable outcomes following MIPO. Redfern et al [8] documented 100% fracture union with a mean union time of 23 weeks and no deep infections in patients treated with minimally invasive plating. Vidović et al [9] reported a mean union time of 19.7 weeks and similarly favorable healing outcomes, although implant prominence was identified as a common complication. These findings support the biological rationale of minimally invasive fixation and provide benchmarks for interpretation of the present cohort.

Malalignment and Radiological Assessment

Misalignment is a known issue with MIPO because it relies on indirect reduction and does not allow direct viewing of the joint. According to Zou et al [15], bridge plating may be the preferred technique for complex tibial fractures (AO/OTA type C); however, MIPO is associated with a higher risk of malalignment than ORIF. This protocol defines stringent intraoperative fluoroscopic criteria to mitigate this risk, with malunion prospectively tracked as a secondary outcome. Radiological union is assessed using the RUST scoring system (validated 4-point scale, with scores ranging from 4 to 12), which rates callus and cortical bridging for each cortex independently, reducing assessor subjectivity.

Pilon Fractures and the Relevance of Articular Involvement

Sourougeon et al [12] conducted a thorough review of the use of MIPO for tibial pilon fractures, which are classified as type C, concluding that good functional outcomes with low complication rates are achievable when adequate indirect reduction of the articular surface is feasible. However, evidence for complex multifragmentary (types C2 and C3) fractures is weaker, and MIPO alone cannot address significant articular comminution or step-off [16]. This supports the present protocol's decision to restrict eligibility for complex articular fractures to type C1 only; types C2 and C3 are excluded because MIPO alone cannot address significant articular comminution or step-off [16-18]. Type C1 fractures (simple complete articular) are included, with percutaneous lag screw fixation used to restore articular congruity when needed.

Outcome Measurements

The AOFAS ankle-hindfoot score has been widely used in distal tibial fracture studies but has notable limitations, including a clinician-assessed alignment component, ceiling effects in well-recovered patients, and less robust psychometric validation compared to modern PROMs. The OMAS, a 9-item fully patient-reported measure with established validity and reliability, is included alongside AOFAS to provide a more comprehensive and patient-centered assessment, aligning the study with current outcome measurement standards.

Evidence Gap

Despite this body of evidence, systematic reviews consistently identify methodological weaknesses in existing studies, including retrospective design, heterogeneous fracture populations, short or incomplete follow-up, variable outcome instruments, and inconsistent use of validated PROMs. Although MIPO-LCP has become an accepted treatment option for distal tibial fractures, most available evidence originates from retrospective or comparative studies with limited representation from Indian tertiary care settings. Prospective observational cohorts using validated clinician-reported and PROMs remain limited, particularly in resource-variable settings where injury mechanisms, rehabilitation access, and follow-up patterns may differ substantially from those in high-income populations. The present study aims to address this evidence gap through prospective consecutive enrollment, standardized radiological assessment using the RUST score, incorporation of validated PROMs, and independent outcome assessment.

Methods

Study Design and Level of Evidence

This single-center, single-arm, prospective observational cohort study will be conducted in the Department of Orthopaedic Surgery, Acharya Vinoba Bhave Rural Hospital and Jawaharlal Nehru Medical College, Maharashtra, India. There is no comparator group, randomization, or allocation; all participants will receive MIPO with LCP. The study is descriptive and hypothesis generating. The protocol was prepared in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) reporting guidance for observational studies.

Data collection began in May 2026 and will continue for 24 months. Each participant will be followed for a minimum of 12 months after surgery.

Sample Size

The sample size was calculated using a precision-based approach appropriate for a single-arm descriptive cohort. On the basis of the prospective series by Nath et al [11] (mean AOFAS 91.2, SD 6.81) and Redfern et al [8] (similar functional scores), a conservative pooled estimate of a mean AOFAS score of 85 with an SD of 10 is assumed to account for the Indian tertiary care population, where comorbidity burden and time to surgery may be higher than in published series.

To estimate the population, with a mean AOFAS score with a 95% CI of ±4 points, the required sample size is as follows:

$$n=z^2\times SD^2/d^2=(1.96)^2\times(10)^2/(4)^2\approx 24$$

Rounding upward to 25 and adding 20% for anticipated loss to follow-up yields a sample size of 30. A target enrollment of 30 consecutive eligible patients is therefore being adopted. The study is not powered for subgroup comparisons, multivariable modeling beyond exploratory purposes, or detection of infrequent complications; these analyses are acknowledged as hypothesis generating and will be reported accordingly.

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Participant Selection

Participant eligibility criteria, including the inclusion and exclusion criteria, are provided in Textbox 1.

Textbox 1. Participant eligibility criteria.

Inclusion criteria

- Age 18 to 80 years, of either sex
- A diagnosis of a closed distal third tibial fracture confirmed on anteroposterior and lateral plain radiographs
- A fracture classified as Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association [AO/OTA] type A (extra-articular), type B (partial articular, without complete disruption of the articular surface), or type C1 (simple complete articular) and located within the distal third of the tibial shaft
- Intact neurovascular status of the affected limb at presentation
- Planned operative treatment with minimally invasive plate osteosynthesis with locking compression plate
- Willingness to provide written informed consent and to comply with the scheduled follow-up program

Exclusion criteria

- History of prior surgical intervention involving the ipsilateral tibia (open reduction and internal fixation, intramedullary nailing, or external fixation)
- Polytrauma (Injury Severity Score >16) or associated neurovascular injury of the affected limb
- Open fractures (all grades), pathological fractures, or fractures with severe metaphyseal comminution (AO/OTA type C2 or C3)
- Complete intra-articular fractures classified as AO/OTA type C2 or C3 (complex multifragmentary articular fractures). Type C1 fractures (simple complete articular fractures) are included. Preoperative computed tomography imaging is to be performed in all cases in which plain radiographic classification is ambiguous or for surgical planning of type C1 fractures.
- Age >80 years
- Inability or unwillingness to comply with follow-up for a minimum of 6 months

Preoperative Assessment and Preparation

On admission, all patients will undergo a standardized clinical assessment including documentation of the mechanism of injury, time elapsed since injury, neurovascular status, limb compartment pressures where indicated, and associated injuries (Multimedia Appendix 1). Routine preoperative investigations will be performed according to the institutional anesthetic protocol. Anteroposterior and lateral radiographs of the whole tibia and the ankle will be obtained in all cases; computed tomography (CT) will be performed in all cases of suspected articular involvement (AO/OTA types B and C1) for preoperative planning. For type C1 fractures, CT is mandatory to assess articular step-off and guide the surgical approach. Fractures will be classified by the operating surgeon according to the AO/OTA system; a second independent classification will be performed by the coinvestigator to assess interobserver agreement.

Patients with significant soft tissue swelling will receive standardized antiedema treatment before surgery: strict limb elevation above the level of the heart and localized cryotherapy applied for 20-minute cycles every 2 hours for 5 to 7 days, or until the appearance of cutaneous wrinkling. Pharmacological antiedema agents will not be administered as part of the study protocol unless indicated for a concurrent medical reason. Intravenous first-generation cephalosporin prophylaxis will be administered 30 minutes before skin incision.

Surgical Technique

All procedures will be performed under spinal or general anesthesia with the patient in the supine position on a radiolucent operating table. A pneumatic tourniquet will be used on the thigh. A vertical or curvilinear incision of approximately 3 to 4 cm will be placed, centered approximately 1 cm proximal to the tip of the medial malleolus and extending proximally along the anteromedial border of the distal tibia. Meticulous dissection will be performed to protect the great saphenous vein and saphenous nerve. A subcutaneous tunnel will be made using a blunt periosteal elevator or a dedicated tunneling device; the use of a hemostat alone is to be avoided owing to the risk of creating an irregular tunnel with potential soft tissue injury. The periosteum and fracture hematoma will be preserved throughout. Fracture reduction will be achieved under continuous fluoroscopic guidance using indirect reduction techniques. A 3 mm Kirschner wire used as a joystick or a pointed reduction clamp applied percutaneously may be used to assist reduction. A precontoured distal tibial LCP will be inserted through the subcutaneous tunnel, and its position will be confirmed under fluoroscopy in both anteroposterior and lateral planes. Distal locking screws will be inserted through stab incisions in the standard fashion, followed by proximal cortical screws. Final fluoroscopic images will be obtained and stored; acceptance criteria for alignment will be angulation not exceeding 5° in any plane and shortening not exceeding 10 mm. If a displaced posterior malleolar fragment is identified on preoperative CT, percutaneous anterior-to-posterior lag screw fixation will be performed prior to LCP application. Total fluoroscopy screening time per case will be recorded. For AO/OTA type C1 fractures

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(simple complete articular fractures), percutaneous lag screw fixation of the articular fragment will be performed under fluoroscopic guidance prior to LCP application, if needed to achieve articular congruity.

Postoperative Management

A well-padded below-knee plaster slab will be applied in the immediate postoperative period. Non–weight-bearing mobilization with crutches will commence on the first postoperative day. Sutures will be removed at 2 weeks. Graduated weight-bearing will be permitted once radiological evidence of callus formation is confirmed, typically between 6 and 12 weeks after surgery. Ankle range-of-motion exercises will be prescribed from the second postoperative week. Patients will receive a standardized physiotherapy program at each follow-up visit.

Outcome Measures

Primary Outcomes

The primary outcomes are (1) functional recovery, assessed by the AOFAS ankle-hindfoot score at 6 months after surgery; and (2) time to radiological fracture union, defined as the first follow-up visit at which the RUST score threshold (≥10) is met.

The AOFAS score (Multimedia Appendix 2) is a 100-point composite scale evaluating pain (40 points), function, including gait, range of motion, and stability (50 points), and alignment (10 points). Scores of 90 to 100 are excellent, 75 to 89 are good, 50 to 74 are fair, and <50 are poor. To minimize detection bias, the AOFAS score at all time points will be administered and recorded by an independent research assistant or physiotherapist who is not a member of the surgical team, is blinded to the patient's intraoperative record, and is kept unaware of the patient's postoperative clinical course (including complication status and radiological findings) to the extent feasible. Patients will be instructed not to discuss their surgical or postoperative history with the assessor prior to completing the score. The 12-month AOFAS score constitutes a secondary durability end point.

PROM: OMAS

The OMAS (Multimedia Appendix 3) is a 9-item, fully patient-reported instrument validated for ankle and distal tibial injuries. It evaluates pain, stiffness, swelling, stair climbing, running, jumping, squatting, use of supports, and return to work or preinjury activity, yielding a total score of 0 to 100 points (100=no symptoms). The OMAS will be completed by the patient independently (without clinician assistance) at the 6-month and 12-month visits and will constitute a secondary outcome at both time points. The 6-month OMAS serves as the primary PROM end point.

Radiological Outcomes: RUST Score

At each follow-up, radiological healing will be checked using RUST (Multimedia Appendix 4). This scale evaluates 4 cortices of the bone (anterior, posterior, medial, and lateral), each scored on a scale from 1 to 3, giving a total score of 4 to 12. Union is defined as a RUST score ≥10 with no cortex scoring <2. Two blinded observers will score each radiograph independently. Interobserver agreement will be assessed using the intraclass correlation coefficient (ICC). Time to radiological union is a coprimary outcome. The median time to union, with its 95% CI, will be estimated using the Kaplan-Meier method.

Secondary Outcomes

The secondary outcomes are (1) delayed union, defined as a RUST score of <10 with no increase between consecutive assessments at 20 weeks (approximately 4.5 months), a threshold that allows early detection of potential healing failure (nonunion is not declared until 9 months); (2) malunion, defined as angular malalignment exceeding 5 degrees in any plane or shortening exceeding 10 mm, confirmed radiologically at the time of union; (3) nonunion, defined as failure to achieve a RUST score of 10 or higher by 9 months after surgery or radiological evidence of atrophic nonunion at any time; (4) surgical site infection, classified according to Centers for Disease Control and Prevention (CDC) criteria as superficial (confined to the skin and subcutaneous tissue, managed without surgery) or deep (involving deeper structures, requiring surgical debridement); (5) implant-related complications, including hardware prominence causing cutaneous irritation, implant breakage, or screw loosening; and (6) time to full weight-bearing, defined as independent ambulation on a flat surface without any walking aid.

A summary of outcome measures, definitions, and time points is provided in Table 1.

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Table 1. Summary of outcome measures.

Priorities and domains	Instruments and definitions	Time points
Primary priorities		
Functional	American Orthopaedic Foot and Ankle Society ankle-hindfoot score (0-100); administered by an independent assessor	6 months (primary) and 12 months (durability)
Radiological union	RUST[a] score (4-12); threshold ≥10=union; intraclass correlation coefficient for interobserver agreement	6 weeks, 3 months, 6 months, and 12 months
S econdary priorities		
PROM[b] (functional)	Olerud-Molander Ankle Score (0-100); patient-reported	6 months (primary PROM) and 12 months
Delayed union	RUST <10 with no progression between consecutive assessments at 20 weeks	20 weeks
Malunion	>5° angular malalignment in any plane or>10 mm shortening at the time of union	At the time of union
Nonunion	RUST <10 at 9 months after surgery	9 months
Complications	Surgical site infection (Centers for Disease Control and Prevention criteria), implant-related complications, and other complications	Continuously through 12 months
Weight-bearing	Time to full independent weight-bearing	Each follow-up visit
Predictor priority: multivariable	Univariable linear regression analyses	Exploratory; 12-month data

[a]RUST: Radiographic Union Scale for Tibia.

[b]PROM: patient-reported outcome measure.

Follow-Up Schedule

Following surgery, patients will be evaluated clinically and radiologically at 6 weeks, 3 months, 6 months, and 12 months. Table 2 summarizes the follow-up visit schedule, which includes clinical evaluation, radiological assessment, and outcome measurement time points.

Table 2. Schedule of follow-up visits, assessments, and outcome measures.

Visits	Clinical assessments	Radiological assessments	Outcome instruments
6 weeks	Wound review; ROM[a]; weight-bearing status; complications	Anteroposterior and lateral radiographs of the tibia and ankle; RUST[b] score	—[c]
3 months	ROM; weight-bearing status; complications	Anteroposterior and lateral radiographs; RUST score	—
6 months	ROM; weight-bearing status; complications	Anteroposterior and lateral radiographs; RUST score	AOFAS[d] ankle-hindfoot score (independent assessor); OMAS[e] (patient reported)
12 months	ROM; weight-bearing status; complications; implant review	Anteroposterior and lateral radiographs; RUST score	AOFAS ankle-hindfoot score (independent assessor); OMAS (patient reported; secondary durability end point)

[a]ROM: range of motion.

[b]RUST: Radiographic Union Scale for Tibia.

[c]Not applicable.

[d]AOFAS: American Orthopaedic Foot and Ankle Society.

[e]OMAS: Olerud-Molander Ankle Score.

Statistical Analysis

Data will be entered into a secure database and analyzed using SPSS (version 27.0; IBM Corp). All tests will be 2-tailed, with $P<.05$ considered statistically significant. Given the exploratory, hypothesis-generating nature of this study, P values will be interpreted descriptively, and no adjustment for multiple comparisons will be made.

Continuous variables will be summarized as means (SDs) or medians (IQRs) based on the distribution, which will be assessed using the Shapiro-Wilk test. Categorical variables will be presented as frequencies and percentages with 95% CIs.

The primary outcomes (as defined in the Outcome Measures section) will be analyzed as follows: the mean AOFAS score at 6 months will be reported with a 95% CI, along with the distribution across outcome categories; time to radiological

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union will be analyzed using Kaplan-Meier methods, with median time to union and the 95% CI reported. Patients not achieving union or those lost to follow-up will be censored at their last assessment.

Secondary outcomes will be analyzed descriptively, with continuous variables summarized using appropriate measures of central tendency and categorical variables summarized as proportions with 95% CIs.

Exploratory predictor analysis will be performed to assess potential associations between selected patient- and fracture-level variables and functional or radiological outcomes. AOFAS score at 6 months (continuous outcome) will be analyzed using univariable linear regression. Given the limited sample size (n=30), only univariable linear regression will be performed to explore associations between selected patient- and fracture-level variables and the AOFAS score at 6 months. Multivariable models will not be constructed due to the high risk of overfitting. Logistic regression for union outcomes will not be performed. All findings will be reported as exploratory and hypothesis generating only, rather than as definitive predictors.

Interobserver agreement for RUST scoring will be assessed using a 2-way mixed-effects ICC with absolute agreement; ICC values >0.75 will be interpreted as good agreement.

Ethical Considerations

Ethics approval was obtained from the institutional ethics committee of Datta Meghe Institute of Higher Education and Research (DMIHER [DU]/IEC/2025/308, dated July 8, 2025). The trial is registered with the Clinical Trials Registry–India (CTRI; CTRI/2026/04/108996). Written informed consent (English or Marathi) is being obtained (Multimedia Appendix 5); participation is voluntary, and data are being deidentified and securely stored. Deidentified data will be shared (9-36 months after publication) via institutional email.

Results

As of September 2026, the study had received institutional ethics approval (DMIHER[DU]/IEC/2025/308) and prospective registration with CTRI (CTRI/2026/04/108996) on April 21, 2026. Five participants have been enrolled since May 1, 2026. Results of the study are expected to be available for analysis and publication by 2028 to 2029.

Discussion

Anticipated Principal Findings

This prospective observational cohort study is designed to evaluate clinical, functional, and radiological outcomes following MIPO using LCP in distal third tibial fractures. As this is a study protocol, no outcome data are currently available; however, based on existing literature and the biological rationale of minimally invasive fixation, favorable trends are anticipated.

Functional recovery at 6 months is expected to be satisfactory, with most patients expected to achieve good-to-excellent outcomes, consistent with prior prospective series reporting high AOFAS scores following MIPO [8,9,19-21]. This anticipated finding would reflect the preservation of periosteal blood supply and fracture biology associated with minimally invasive techniques.

Patient-reported outcomes are expected to be broadly consistent with clinician-based assessments, as demonstrated in previous studies using validated ankle outcome measures [20,21]. The combined use of clinician-based and patient-reported measures is intended to provide a more comprehensive evaluation of recovery.

Radiological union is anticipated within a clinically acceptable timeframe, consistent with previously reported union times ranging from approximately 16 to 24 weeks in MIPO cohorts [8,9,22]. The use of a standardized scoring system with independent observers is expected to improve the objectivity and reproducibility of union assessment.

The overall complication profile is expected to be acceptable, with low rates of deep infection and nonunion reported in prior studies [21,22]. However, minor complications, such as superficial infection or implant irritation, may occur more frequently, as noted in previous series [11]. Time to full weight-bearing is expected to align with standard rehabilitation timelines described in similar cohorts.

Exploratory regression analysis may identify potential predictors of outcome; however, given the limited sample size, such findings will be interpreted cautiously and considered hypothesis generating.

Comparison With Prior Work

The anticipated findings are consistent with published studies demonstrating favorable outcomes with MIPO in distal tibial fractures. Prior series have reported high union rates and good functional recovery, supporting the biological advantages of minimally invasive fixation [8,9,21].

Comparative studies suggest similar functional outcomes and union rates between MIPO and intramedullary nailing, although MIPO may be associated with a slightly higher incidence of wound-related complications [11]. Intramedullary nailing, however, is associated with higher rates of malalignment in distal metaphyseal fractures, particularly those with short distal fragments [7,23].

This study builds upon existing evidence by incorporating methodological refinements, including a prospective design, consecutive enrollment, the use of a validated PROM, independent outcome assessment, and standardized radiological evaluation. These features are intended to address limitations of prior studies, including heterogeneity in outcome measurement and potential assessment bias [12].

Dissemination Plan

Findings from this study are intended for dissemination through peer-reviewed publications, conference presentations, and institutional academic forums. Deidentified aggregate data may inform future multicenter studies and comparative trials evaluating fixation strategies for distal tibial fractures.

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Strengths and Limitations

Strengths of the study include its prospective design, validated outcome measures (AOFAS, OMAS, and RUST with interobserver agreement), and independent functional assessment. Limitations include the single-arm design (no comparator), small sample size (n=30, which is underpowered for subgroup analyses), and exclusion of older adults (aged >80 years), open fractures, and type C2-C3 patterns, which may limit generalizability. The single-center design restricts external validity but ensures protocol consistency. Cost-effectiveness will not be evaluated.

Implications

If the anticipated findings are confirmed, this study will provide prospective evidence supporting MIPO-LCP for appropriately selected patients, generate hypotheses for future trials, and inform cost-effectiveness research.

Conclusions

This protocol will generate prospective, hypothesis-generating data on MIPO outcomes for distal tibial fractures (AO/OTA types A, B, and C1) in an Indian setting. Due to the small sample size (n=30) and single-arm design, no definitive comparative claims can be made. Findings will inform future adequately powered trials.

Acknowledgments

Generative AI–assisted language tools (QuillBot [Learneo Inc] and Grammarly [Superhuman Platform Inc]) were used for language refinement and paraphrasing during manuscript preparation. No AI tool was used to draft questions for research surveys. All generated content was reviewed, edited, and approved by the authors, who take full responsibility for the final content.

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Data Availability

Deidentified data will be made available upon reasonable request to the corresponding author following completion of the study.

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Authors' Contributions

VT contributed to the conception and design of the work, definition of the intellectual content, drafting of the manuscript, and literature review, and approved the final version of the manuscript.
BP contributed to the conception and design of the work, literature review, revision of the manuscript for important intellectual content, and approval of the final version of the manuscript. All authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Data collection form.
[DOCX File , 25 KB-Multimedia Appendix 1]

Multimedia Appendix 2

American Orthopaedic Foot and Ankle Society ankle-hindfoot score questionnaire.
[DOCX File , 18 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Olerud-Molander Ankle Score questionnaire.
[DOCX File , 18 KB-Multimedia Appendix 3]

Multimedia Appendix 4

Radiographic Union Scale for Tibia scoring form.

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[DOCX File , 16 KB-Multimedia Appendix 4]

Multimedia Appendix 5

Patient consent form.
[DOCX File , 40 KB-Multimedia Appendix 5]

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Abbreviations

AO/OTA: Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association
AOFAS: American Orthopaedic Foot and Ankle Society
CDC: Centers for Disease Control and Prevention
CT: computed tomography
CTRI: Clinical Trials Registry–India
ICC: intraclass correlation coefficient
LCP: locking compression plate
MIPO: minimally invasive plate osteosynthesis
OMAS: Olerud-Molander Ankle Score
ORIF: open reduction and internal fixation
PROM: patient-reported outcome measure
RUST: Radiographic Union Scale for Tibia
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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