Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of surgical outcomes of distal one-third humerus fractures using Philos plate versus a 3.5 distal medial plate: A Randomized controlled Trial

Protocol summary

Study aim

To compare the surgical outcomes of two fixation methods for distal one-third humeral fractures.

Design

Prospective, two-arm, parallel-group randomized controlled trial with 64 participants. Patients will be individually randomized in a 1:1 ratio using a computer-generated simple randomization sequence to receive either two PHILOS plates or a 3.5-mm distal medial locking plate. This is a single-center study.

Settings and conduct

This single-center trial will be conducted in an orthopedic surgery setting. Eligible patients with acute, isolated distal one-third humeral fractures requiring surgical fixation will be enrolled and randomly allocated to one of the two intervention groups. Participants will undergo the assigned surgical fixation method and will be followed clinically and radiographically at 2, 6, and 12 months after surgery. Functional outcomes, pain, elbow range of motion, fracture healing and alignment, fixation stability, and postoperative complications will be assessed during follow-up. No blinding is planned.

Participants/Inclusion and exclusion criteria

Inclusion criteria: * Adults aged ≥18 years. * Acute, isolated, extra-articular distal one-third humeral fracture confirmed radiographically and requiring surgical fixation. * Medically eligible for surgery and able to provide informed consent. Exclusion criteria: * Open, pathological, or intra-articular fractures. * Associated fractures or neurovascular injuries affecting treatment or functional assessment. * Previous surgery or significant trauma involving the affected humerus or elbow. * Conditions preventing surgery, informed consent, or follow-up.

Intervention groups

Group A – PHILOS plates Group B – 3.5-mm distal medial locking plate

Main outcome variables

* DASH score * VAS pain score * Elbow range of motion * Fracture alignment and union * Fixation stability * Postoperative complications * Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260912071019N1**
Registration date: **2026-09-13, 1405/06/22**
Registration timing: **prospective**

Last update: **2026-09-13, 1405/06/22**
Update count: **0**

Registration date

2026-09-13, 1405/06/22

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-09-14, 1405/06/23

Expected recruitment end date

2026-11-14, 1405/08/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of surgical outcomes of distal one-third humerus fractures using Philos plate versus a 3.5 distal medial plate: A Randomized controlled Trial

Public title

Philos plate vs 3.5 distal medial plate in humerus fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults aged 18 years or older. Patients with an acute, isolated fracture of the distal one-third of the humeral shaft confirmed by radiographic evaluation. Extra-articular distal-third humeral fractures requiring operative fixation. Patients who provide written informed consent to participate in the study. Patients who are medically eligible for surgical treatment.

Exclusion criteria:

1. Patients with open fractures or fractures associated with significant soft-tissue injury. 2. Pathological fractures or fractures associated with an underlying bone disease. 3. Intra-articular distal humeral fractures. 4. Associated fractures of the ipsilateral upper limb that may affect functional assessment. 5. Pre-existing neurological or musculoskeletal disorders affecting the function or range of motion of the affected upper limb. 6. Associated neurovascular injuries requiring additional surgical intervention. 7. Patients with a history of previous surgery or significant trauma to the affected humerus or elbow. 8. Patients with severe medical comorbidities or contraindications to surgery or anesthesia. 9. Patients unwilling or unable to provide informed consent or comply with the scheduled follow-up assessments. 10. Patients who withdraw consent or are lost to follow-up during the study.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be individually randomized in a 1:1 ratio into two treatment groups using simple randomization. Group A will receive fixation with two PHILOS plates, while Group B will receive fixation with a 3.5-mm distal medial tibial locking plate adapted for use in distal-third humeral fractures. The randomization sequence will be generated using a computer-generated random sequence, with each eligible participant assigned to either Group A or Group B according to the generated sequence. No stratification or clustering will be used. Allocation concealment will be maintained until the time of treatment allocation. The randomization sequence will not be disclosed to the investigators responsible for patient assessment before allocation.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

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Isfahan, Hezar Jerib Avenue, JM76+5M3 Isfahan University

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Approval date

2025-12-27, 1404/10/06

Ethics committee reference number

IR.MUI.MED.REC.1404.395

Health conditions studied

1

Description of health condition studied

Distal one-third humeral fractures

ICD-10 code

M80.02

ICD-10 code description

Age-related osteoporosis with current pathological fracture, humerus

Primary outcomes

1

Description

The primary outcome variable is the Disabilities of the Arm, Shoulder and Hand (DASH) score, assessed at 12

months after surgery. The DASH score will be used to compare the functional outcome of the affected upper limb between patients treated with two PHILOS plates and those treated with a 3.5-mm distal medial locking plate. Lower DASH scores indicate better upper-limb function.

Timepoint

12 months

Method of measurement

The Disabilities of the Arm, Shoulder and Hand (DASH) score will be measured using the standardized 30-item DASH questionnaire. Participants will complete the questionnaire to assess symptoms and functional limitations of the affected upper limb. The DASH score will be calculated according to the standard scoring method, ranging from 0 to 100, with higher scores indicating greater disability.

2

Description

The Visual Analogue Scale (VAS) pain score will be assessed to compare postoperative pain intensity between the two treatment groups. Pain scores will be evaluated during follow-up and compared between patients treated with two PHILOS plates and those treated with a 3.5-mm distal medial locking plate. Higher VAS scores indicate greater pain intensity.

Timepoint

2, 6, and 12 months after surgery.

Method of measurement

Pain intensity will be measured using a Visual Analogue Scale (VAS), with scores ranging from 0 to 10. A score of 0 indicates no pain and a score of 10 indicates the worst imaginable pain. Higher scores indicate greater pain intensity.

3

Description

Elbow range of motion will be assessed to compare postoperative elbow mobility between the two treatment groups. The range of motion of the affected elbow will be evaluated during follow-up after fixation with either two PHILOS plates or a 3.5-mm distal medial locking plate.

Timepoint

2, 6, and 12 months after surgery.

Method of measurement

Elbow range of motion will be measured using a standard goniometer. Flexion, extension, pronation, and supination of the affected upper limb will be assessed and recorded in degrees.

4

Description

Fracture alignment will be assessed to compare the radiographic quality of fracture reduction and maintenance of alignment between the two treatment groups. Alignment of the distal one-third humeral fracture will be evaluated after fixation with two PHILOS plates or a 3.5-mm distal medial locking plate.

Timepoint

2, 6, and 12 months after surgery.

Method of measurement

Fracture alignment will be assessed using standard postoperative and follow-up radiographs of the humerus. The radiographs will be evaluated for maintenance of reduction, angular deformity, and displacement of the fracture site.

5

Description

Fracture union will be assessed to compare the radiographic healing of distal one-third humeral fractures between the two treatment groups. The occurrence and timing of fracture union, as well as delayed union or nonunion, will be recorded during follow-up.

Timepoint

2, 6, and 12 months after surgery.

Method of measurement

Fracture union will be assessed using serial radiographs of the humerus. Union will be determined based on radiographic evidence of bridging callus and progressive disappearance of the fracture line, together with clinical evidence of fracture healing. The time to union will be recorded in months after surgery.

6

Description

Fixation stability will be assessed to compare the maintenance of implant position and fracture fixation between the two treatment groups. Evidence of loss of fixation, implant displacement, screw loosening, plate failure, or other mechanical complications will be recorded during follow-up.

Timepoint

2, 6, and 12 months after surgery.

Method of measurement

Fixation stability will be assessed by clinical examination and serial radiographs of the affected humerus. Radiographs will be evaluated for implant position, loss of reduction, screw loosening or migration, plate deformation or breakage, and other evidence of mechanical failure.

7

Description

Postoperative complications will be assessed to compare the safety profiles of the two fixation methods. Complications of interest include surgical-site infection, neurovascular injury, hardware failure, delayed union, nonunion, and other clinically relevant postoperative complications occurring during follow-up.

Timepoint

2, 6, and 12 months after surgery, with complications recorded throughout the follow-up period.

Method of measurement

Postoperative complications will be assessed through clinical examination, review of medical records, and radiographic evaluation when indicated. The presence, type, severity, and timing of complications will be recorded throughout the follow-up period.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients will undergo open reduction and internal fixation of acute extra-articular distal one-third humeral fractures using two PHILOS (Proximal Humeral Internal Locking System) plates in an orthogonal 90°–90° configuration. Intervention group 2: Patients will undergo open reduction and internal fixation using a 3.5-mm distal medial tibial locking plate adapted for fixation of the distal one-third of the humerus.Both groups will receive standard postoperative care and will be clinically and radiographically followed at 2, 6, and 12 months after surgery. Outcomes will include functional status, pain, elbow range of motion, fracture alignment and union, fixation stability, and postoperative complications.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra tertiary care center affiliated with Isfahan University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
Mohammad Parhamfar
Position
Associate professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
De-identified Individual Participant Data__Philos vs median distal plate The dataset will include de-identified individual participant data collected during the study, including demographic characteristics, treatment group allocation, pain scores, Disabilities of the Arm, Shoulder and Hand (DASH) scores, elbow range of motion, radiographic fracture healing and alignment, fixation stability, and postoperative complications. Direct personal identifiers will be removed before sharing. The shared dataset will contain data necessary to reproduce or further analyze the study outcomes while protecting participant confidentiality.
When the data will become available and for how long
The de-identified individual participant data will become available 6 months after publication of the study results and will remain available for 5 years thereafter.
To whom data/document is available
The de-identified individual participant data (IPD) and supporting study documents will be available to researchers and investigators from academic institutions, research organizations, healthcare institutions, and other organizations, including non-academic or commercial organizations, upon reasonable request. Access will be provided for scientifically and ethically appropriate purposes, subject to protection of participant confidentiality and applicable ethical and institutional requirements.
Under which criteria data/document could be used
De-identified individual participant data (IPD) and supporting study documents may be shared upon reasonable request for scientifically and ethically appropriate purposes, including secondary analyses, methodological research, replication of the study findings, and systematic reviews or meta-analyses. Requests should include a brief description of the proposed research question, analysis plan, and intended use of the data. Requests will be reviewed by the principal investigator and, when necessary, the relevant institutional ethics authorities. Data will be provided only when the proposed use is consistent with participant consent, applicable ethical requirements, and protection of confidentiality. No attempt to re-identify individual participants will be permitted.
From where data/document is obtainable
The de-identified individual participant data and supporting study documents will be obtainable from the research team at Alzahra Tertiary Care Center, affiliated with Isfahan University of Medical Sciences, Isfahan, Iran. Researchers interested in accessing the data should contact the principal investigator, Dr. Mohammad Parhamfar, through the institutional contact details provided by Isfahan University of Medical Sciences. Requests may also be submitted through the corresponding institutional research or ethics office. Data access will be subject to the criteria specified for data use, protection of participant confidentiality, and applicable institutional and ethical requirements.

What processes are involved for a request to access data/document

Researchers wishing to access the de-identified individual participant data (IPD) or supporting study documents should submit a written request to the principal investigator, Dr. Mohammad Parhamfar, through the institutional contact details provided by Isfahan University of Medical Sciences. The request should briefly describe the research purpose, proposed analyses, and intended use of the requested data. The research team will review the request for scientific appropriateness, ethical considerations, compatibility with participant consent, and protection of confidentiality. If additional institutional or ethical approval is required, the applicant will be informed and asked to provide the relevant documentation. Requests will generally be reviewed within 30 days of receipt of a complete request. Following approval, the de-identified data or requested documents will be prepared and securely provided to the applicant, generally within an additional 15 days. The total process is therefore expected to take approximately 30–45 days, depending on the complexity of the request and any required institutional or ethical review. No directly identifying information will be provided, and data will be shared only in accordance with the approved data-use criteria and applicable ethical and institutional requirements.

Comments