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Comparing a new 3D-printed leg brace with standard surgery for treating shin bone fractures

Submission date 21/05/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/05/2026	**Overall study status** Ongoing	
Last Edited 21/05/2026	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
Clinical efficacy of digital intelligence-based 3D-printed reduction braces in the treatment of tibiofibular fractures

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/05/2026, Ethics Committee of Henan Luoyang Orthopedic Hospital (Henan Provincial Orthopedic Hospital) (Luoyang Orthopedic Hospital of Henan Province (Henan Provincial Orthopedic Hospital),No. 82 Qiming South Road, Luoyang, Luoyang, 471000, China; +86 379-63546181; hnslyzgyyllwyh@aliyun.com), ref: 2026YJSKT0022-02

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Tibiofibular fractures (closed tibial shaft fractures)

Interventions
Participants were randomly assigned to either the intervention group or the control group.
The intervention group received treatment utilizing a patient-specific, digital intelligence-based, 3D-printed reduction brace, which was combined with closed reduction and percutaneous fixation. Preoperative CT data were employed for three-dimensional reconstruction, virtual reduction simulation, and the design of individualized braces. During the surgical procedure, the customized 3D-printed brace was applied to guide fracture reduction and facilitate Kirschner wire fixation through pre-designed channels.
The control group underwent conventional suprapatellar intramedullary nail fixation under fluoroscopic guidance.
Both groups received standardized postoperative nursing care, including anticoagulation therapy, infection prophylaxis, and rehabilitation training, according to the same postoperative protocol.
There is no follow up.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Digital intelligence-based 3D-printed reduction brace

Primary outcome(s)
1. Operative time measured using Minutes measured from skin incision to wound closure using operating room record at At the end of surgery

2. Intraoperative fluoroscopy frequency measured using Number of times C-arm fluoroscopy is used during the operation (recorded by operating room staff) at During surgery

3. Intraoperative blood loss measured using Estimated blood loss in milliliters (mL) using suction canister measurement and weighing of surgical gauze/swabs at During surgery

Key secondary outcome(s))

Completion date
01/09/2027

Eligibility

Key inclusion criteria
1. Age between 12 and 65 years, irrespective of gender
2. AO/OTA 42 type tibial shaft fractures, with or without associated fibular fractures (4F2)
3. Absence of other concomitant injuries or congenital diseases that could interfere with fracture healing
4. Signed informed consent and the ability to cooperate fully with the entire treatment process and subsequent follow-up

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 years

Upper age limit
65 years

Sex
All

Total final enrolment
28

Key exclusion criteria

1. Open, neglected, or pathological fractures
2. Bilateral tibiofibular fractures
3. Pregnant or lactating women
4. Patients with severe cardiovascular disease, hepatic or renal dysfunction, severe coagulopathy, or other critical illnesses that preclude surgical tolerance
5. Patients with major psychiatric disorders

Date of first enrolment
01/09/2025

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
China

Sponsor information

Organisation
Luoyang Orthopedic Hospital of Henan Province (Henan Provincial Orthopedic Hospital)

Funder(s)

Funder type

Funder Name
Luoyang Orthopedic Hospital of Henan Province (Henan Provincial Orthopedic Hospital)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available