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3D-printed orthosis versus plaster immobilisation for stable distal radius fractures

Submission date
15/09/2026

Recruitment status
No longer recruiting

Registration date
01/10/2026

Overall study status
Completed

Last Edited
30/09/2026

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
A distal radius fracture is a break in one of the bones near the wrist. Stable fractures can often be treated without surgery by keeping the wrist still while the bone heals. A plaster cast is commonly used for this. However, 3D printing can be used to make a lightweight support, called an orthosis, that may offer an alternative to plaster.
The aim of this study was to compare a 3D-printed orthosis with a standard plaster cast for treating adults with stable distal radius fractures. The researchers wanted to find out how the two treatments affected arm and hand function. They also assessed pain, quality of life and participants' experiences of using the 3D-printed orthosis

Who can participate?
Adults aged 18 to 59 years with a stable distal radius fracture that could be treated without surgery could take part
People could not take part if they had a pre-existing bone condition or other important health problem that could affect treatment, had previously fractured the same arm, had an open fracture, had another condition that could affect treatment or assessment of arm function, or had been wearing a plaster cast for more than 10 days before joining the study

What does the study involve?
A total of 10 participants took part. They were randomly placed into one of two groups
Participants in the first group had their plaster cast replaced with a 3D-printed orthosis made from a type of plastic called polylactic acid (PLA). An orthosis was selected based on the size of the participant's hand and wrist and was then shaped using heat to provide an individual fit. It was held in place with tubular mesh and Velcro straps. Participants used the orthosis throughout their treatment as recommended by the clinical team
Participants in the second group continued to use a standard plaster cast according to usual clinical recommendations
Arm and hand function was assessed at the start of the study and at the end of treatment, up to 6 weeks later, using a questionnaire. The researchers also assessed pain and health-related quality of life. Participants who used the 3D-printed orthosis were asked about its safety, comfort, practicality and their satisfaction with it

What are the possible benefits and risks of participating?
The 3D-printed orthosis may provide an alternative way of supporting the wrist while the fracture heals. Taking part may not have provided a direct benefit to individual participants, but the results may help researchers understand whether this type of orthosis could be useful for treating stable wrist fractures in the future
The study record does not provide specific information about possible risks. As with any method of keeping a fractured wrist still, participants could potentially experience discomfort or problems with the fit of the support. Participants were monitored during follow-up, including assessment of the safety and comfort of the 3D-printed orthosis

Where is the study run from?
The study was run at the Hospital de Clínicas, Universidade Estadual de Campinas (UNICAMP), in Campinas, Brazil

When is the study starting and how long is it expected to run for?
March 2023 to December 2023.

Who is funding the study?
The study was funded by the Faculdade de Ciências Médicas, Universidade Estadual de Campinas (School of Medical Sciences, State University of Campinas), Brazil

Who is the main contact?
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Contact information

Type(s)
Scientific, Public, Principal investigator

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Study information

Scientific Title

A randomised controlled comparative study of 3D-printed orthosis versus plaster immobilisation for stable distal radius fractures

Study objectives
To compare the clinical and functional outcomes of 3D-printed orthosis versus conventional plaster immobilisation in adults with stable distal radius fractures treated conservatively.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/02/2023, Research Ethics Committee of the State University of Campinas (Saturnino de Brito, 45, Campinas, 13083-889, Brazil; +55 (19) 3521-8936; cep@unicamp.br), ref: 5.905.856

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Distal radius fractures

Interventions
Participants were initially immobilised with a plaster cast for no more than 10 days prior to study inclusion. Following enrolment and baseline assessment, participants were randomly allocated to either the 3D-Printed Orthosis Group (G3D) or the Plaster Cast Group (PG). Randomisation was performed using the online computer-generated randomisation tool RANDOM.ORG.

Group 1 – 3D-printed orthosis:
Participants allocated to the intervention group had their plaster immobilisation replaced with a customisable 3D-printed orthosis made of polylactic acid (PLA). The orthosis was selected according to hand/wrist size and later thermally moulded to the participant. It was secured using a tubular mesh and Velcro straps and used throughout the conservative treatment period according to clinical recommendations.

Group 2 – Conventional plaster immobilisation:
Participants allocated to the control group continued with conventional plaster immobilisation for the conservative treatment of the stable distal radius fracture, according to standard clinical recommendations.

The intervention and follow-up period lasted up to 6 weeks after study inclusion, with clinical follow-up visits scheduled at approximately 1, 2, 4, and 6 weeks, according to the patient's clinical progress. Pain and functional outcomes were assessed during the follow-up period using the Visual Numerical Pain Scale (VNPS) and the QuickDASH questionnaire.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
3D-printed orthosis

Primary outcome(s)
1. Upper limb function measured using QuickDASH (Disabilities of the Arm, Shoulder and Hand) questionnaire score at baseline and at the end of treatment (up to 6 weeks)

Key secondary outcome(s)

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Stable distal radius fractures treated conservatively

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
59 Years

Sex
All

Total final enrolment

Key exclusion criteria
1. Pre-existing bone disease or significant comorbidities that could interfere with treatment
2. Previous fracture of the same limb
3. Open fracture
4. Other conditions affecting treatment or functional assessment
5. Plaster immobilisation for more than 10 days before enrolment

Date of first enrolment
01/03/2023

Date of final enrolment
30/11/2023

Locations

Countries of recruitment
Brazil

Sponsor information

Organisation
Universidade Estadual de Campinas (UNICAMP)

ROR
https://ror.org/04wffgt70

Funder(s)

Funder type

Funder Name
Faculdade de Ciências Médicas, Universidade Estadual de Campinas

Alternative Name(s)
School of Medical Sciences, State University of Campinas, Faculdade de Ciências Médicas - UNICAMP, Faculdade de Ciências Médicas, FCM, UNICAMP, FCM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Brazil

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available