

# Early versus delayed mobilization after leg fractures with the N-force fixation system

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/09/2018	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/10/2021	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

After having surgery for leg fractures, patients are often advised not to bear weight on this leg for around 6 weeks. This delayed weight bearing allows the fracture time to heal; however, the delay has been associated with other complications, such as osteoporosis and problems with movement. Advances in surgical techniques for fractures, such as one called the N-force fixation system, have been shown to allow patients to bear weight on their limbs sooner, which may avoid these complications. This study aims to look at the differences between the effects of the N-force fixation system on early (after 2 weeks) and late (after 6 weeks) weight bearing after leg fracture surgery.

### Who can participate?

Patients aged 18-80 with a proximal fracture of the leg

### What does the study involve?

Participants will be randomly assigned to 1 of 2 groups. Both groups will receive fixation surgery for their leg fractures; however, one group will be asked to begin weight-bearing on this leg after 2 weeks (early) and the other will be asked to do so after 6 weeks (delayed). Participants will be asked to complete questionnaires, X-rays and CT scans throughout the study.

### What are the possible benefits and risks of participating?

The possible benefit to participants taking part is that early weight-bearing may help to avoid potential complications associated with late weight-bearing. There are no known risks to participants taking part in this study.

### Where is the study run from?

Leeds General Infirmary (UK)

### When is the study starting and how long is it expected to run for?

March 2017 to April 2020

### Who is funding the study?

Zimmer Biomet (USA)

Who is the main contact?  
Professor Peter V Giannoudis  
Professor and Chairman within Academic Department of Trauma and Orthopaedic Surgery/  
Honorary Orthopaedic and Trauma Consultant  
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## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
v0.20

## Study information

**Scientific Title**  
Tibia plateau pure and split depression fractures (AO 41-B2 and B3) stabilised with N-Force/iN3 bone cement +/- plate augmentation: A prospective single centre feasibility randomised controlled trial comparing early (2 weeks) versus delayed (6 weeks) weight bearing

**Acronym**  
TIB-N-Force Study

**Study objectives**  
Is there a difference between early (2 weeks) and delayed (6 weeks) weight bearing for tibial plateau fractures (Schazker II and III)?

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Provisional favourable approval from Yorkshire & The Humber - Leeds East Research Ethics Committee, 15/08/2018, 18/YH/0293

## **Study design**

Interventional randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Tibial plateau fracture

## **Interventions**

Participants will be randomly allocated using unstratified block randomisation with varying block sizes into 2 arms, with 15-20 patients in each arm. Participants in both groups will receive the same treatment with the N-force system. This is an augmented fixation system, integrating fenestrated screws and a Bone Substitute Material (BSM) called N-Force Blue into a single construct to provide improved metaphyseal void fill and increase structural support of the implant. N-Force Blue is injected directly into the fenestrated screw with the use of a sheath assembly, to help minimise BSM leakage into the soft tissues. This fixation system will be used as a means of surgical fixation for participants' tibial plateau fractures.

After 2 weeks, one group will be asked to begin bearing weight on this leg (2 weeks), whereas the other group will be asked to do so after 6 weeks (delayed).

There will be a 52 week follow-up period, where participants will be assessed at 2, 6, 12, 24 and 52 weeks after surgery.

## **Intervention Type**

Other

## **Primary outcome(s)**

1. Quality of life, assessed at the baseline and at week 6, 12, 24 and 52, using:

1.1 12-item Short Form Health Survey (SF-12)

1.2. EuroQol-5D (EQ-5D)

2. Pain whilst weight-bearing, assessed using the Numeric Pain Rating Scale (NPRS) at the baseline and at week 2, 6, 12, 24 and 52

3. Patient mobilisation, assessed using a timed "up-and-go" test (TUG) at weeks 6 and 12

## **Key secondary outcome(s)**

1. Time to bone healing, assessed using:

1.1. Clinical measures:

1.1.1. Painless full weight bearing

1.1.2. Functional Index in Trauma (FIX-IT) score

1.2. Radiological measures - Radiographic Union Scale in Tibial fractures (RUST) scale with a CT scan

2. Proportion of participants healed at 3 and 6 months after surgery

3. Rate of surgical re-intervention at 6 months after surgery

4. Incidence of loss of reduction, secondary collapse or further surgical intervention at the 6 month follow up

**Completion date**

01/04/2020

**Reason abandoned (if study stopped)**

Objectives no longer viable

## Eligibility

**Key inclusion criteria**

1. Aged 18 years or older
2. Skeletally mature
3. Acute unilateral closed tibia plateau fractures as primary injury
4. Willing and able to provide informed consent and participate in all study activities and visit schedule
5. Ambulatory prior to injury

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Open/compound tibial plateau fracture
2. Fracture type 41 C according to Muller AO classification
3. Multi-segmental fracture (more than one fracture site within tibia)
4. Polytrauma (Injury Severity Score of 17 or more)
5. Prior or concomitant illnesses that may affect healing or outcome
6. Exposure to drugs that can affect the bone metabolic state within the past 3 months
7. Receiving chemotherapy, radiation treatment or immunosuppressant drugs
8. Currently enrolled in any other study that may impact on the results of the present study
9. Resident outside of Leeds
10. Pregnant or breastfeeding
11. If female: not currently using and not willing to use an effective form of contraception for 12 months post-surgery
12. Metal allergy

**Date of first enrolment**

01/10/2018

**Date of final enrolment**

01/12/2019

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

**Leeds Teaching Hospital NHS Trust**

Great George St,

Leeds

United Kingdom

LS9 7TF

## Sponsor information

### Organisation

university of Leeds

### ROR

<https://ror.org/024mrx33>

## Funder(s)

### Funder type

Not defined

### Funder Name

Zimmer Biomet

### Alternative Name(s)

Zimmer Biomet Spine, Zimmer Biomet Biologics

### Funding Body Type

Private sector organisation

### Funding Body Subtype

For-profit companies (industry)

### Location

United States of America

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to patient confidentiality.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No