

# A study of patient records to assess a new classification system for intertrochanteric fractures

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/04/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
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## Plain English summary of protocol

### Background and study aims

Intertrochanteric fracture refers to a hip fracture that occurs in the region between the main part of the femur and the ball that fits into the hip socket in the pelvis. This type of broken hip is the most common joint injury in the elderly. To improve guidance for doctors on how to best treat these fractures, we wanted to describe the different types of intertrochanteric fractures. Existing classification systems do not describe the shape of the fracture in enough detail. The purpose of this study was to classify intertrochanteric fractures and to assess how practical the new classification is when doctors are treating patients.

### Who can participate?

Adults aged 18 years and older who have fallen indoors or outdoors and had an intertrochanteric fracture.

### What does the study involve?

This is a chart review study. The study involves investigating the patient notes and other records of people who had surgery for certain types of broken hip. Participants who underwent internal fixation using an intramedullary nail are reviewed. Their fractures are classified based on the new classification system. Their post-surgery scans and their final follow up data are used to calculate their mobility and complications.

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

There are no direct benefits or risks with participating.

### Where is the study run from?

Chinese PLA General Hospital (China)

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

September 2009 to May 2017

Who is funding the study?  
The capital health research and development of special (China)

Who is the main contact?  
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## Contact information

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## Additional identifiers

**EudraCT/CTIS number**  
N/A

**IRAS number**

**ClinicalTrials.gov number**  
N/A

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

Radiological parameters, clinical functions and complications associated with different intertrochanteric fractures

## Study objectives

Patients with different types had different clinical outcomes and complication rates.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics Committee of the Chinese PLA General Hospital, 10/05/2009

## Study design

Retrospective chart review

## Primary study design

Observational

## Secondary study design

Case series

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

No participant information sheet available

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

Intertrochanteric fracture

## Interventions

We retrospectively analyzed the data from medical records of patients who underwent closed reduction and intramedullary internal fixation (CRIF) to treat intertrochanteric fractures. All patients were treated using a general or spinal anesthetic and using indirect reduction and percutaneous surgical techniques. All surgeries were performed by senior orthopedic surgeons who were familiar with the surgical procedures. All the patients participated in similar rehabilitation protocols. Postoperative radiographs were also performed to evaluate the reduction and fixation positions of the patients. Time from fracture to surgery, duration of the surgical procedure (assessed by anesthesiology records), and intraoperative bleeding volume were recorded. Five radiographic parameters including femoral head height (FHH), femoral neck-shaft angle (FNSA), the length of medial cephalic nail (Lmcn), tip-cortex distance (TCD), and tip-apex distance (TAD) and four functional parameters including Functional Independence Measure (FIM), Parker-Palmer mobility score, the Timed Up and Go (TUG) test and the 2-minute walk test

(2MWT) were used to evaluate the postoperative functional states and mobilization levels. In addition to this, postoperative complications were also recorded. All the parameters are used to evaluate the clinical outcome.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

Radiographic parameters were measured on the radiographs obtained immediate postoperatively and the final follow-up using the measuring devices on the digital screen. All results were calibrated according to the ratio of the known diameter of the cephalic nail to its diameter on the digital image. Complications like loss of reduction, cut-out, excessive sliding of the cephalic nail, implant breakage, nonunion, infection, periprosthetic fracture and loss of mobility were some of the complications recorded during the follow-up. We defined loss of reduction as the loss of NSA greater than 10°. Excessive sliding was defined as sliding distance  $\geq 10$  mm.

1. Femoral head height (FHH). The FHH relative to the nail was measured, allowing for the subsequent loss of reduction analysis. This measurement was done by drawing two lines, both perpendicular to the shaft nail. One was placed at the top edge of the nail and one was placed at the superior edge of the femoral head. The distance between these two lines was measured and designated as the FHH.
2. Femoral neck-shaft angle (FNSA). FNSA was measured by the angle between the femoral shaft and the femoral neck shaft.
3. The length of medial cephalic nail (Lmcn). Lmcn was the distance between the tip of the cephalic nail and medial edge of the shaft nail. The sliding distance of the cephalic nail was calculated by the Lmcn parameter in two periods.
4. Tip-cortex distance (TCD). TCD was the distance from the tip of cephalic nail to the femoral head cortex.
5. Tip-apex distance (TAD). We calculated TAD as described by Baumgaertner et al. using the anteroposterior and lateral radiographs to evaluate the implant position.

## **Secondary outcome measures**

1. The Functional Independence Measure (FIM) assessment of degree of disability depends on the patient's score in 18 categories, focusing on motor and cognitive function at the final follow-up
2. Functional level was also measured using the Parker-Palmer mobility score at the final follow-up
3. Time taken to rise from a standard arm chair, walk 3 meters at a comfortable pace using their customary walking aid, turn, walk back to the chair, and sit down is measured using timed "Up & Go" (TUG) test at the final follow-up
4. 2-minute walk test (2MWT), which measures the distance walked in 2 minutes

## **Overall study start date**

01/09/2009

## **Completion date**

01/05/2017

## **Eligibility**

### **Key inclusion criteria**

1. Computerised tomography (CT) scan data of the proximal femur obtained before surgical intervention
2. CT image thickness less than 3.0 mm
3. A minimum of 1 year of radiographic follow-up
4. Patients aged 18 years and older
5. Low-energy mechanism of injury
6. Participants underwent internal fixation using a intramedullary nail

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

504

**Key exclusion criteria**

1. Pathological fractures such as carcinomas, metastases of the bone, primary malignant or benign tumors, and metabolic disorders
2. Patient had mental disorder
3. Patient walked with assistive device before the fracture
4. Fractures with associated neurovascular injuries
5. Patient had pre-existing osteoarthritis or previous surgeries to the affected hip joints

**Date of first enrolment**

01/09/2009

**Date of final enrolment**

01/05/2017

**Locations****Countries of recruitment**

China

**Study participating centre**

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# Sponsor information

## Organisation

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## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/04gw3ra78>

# Funder(s)

## Funder type

Not defined

## Funder Name

The capital health research and development of special

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

## Intention to publish date

01/05/2018

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Li (lijiantao618@163.com).

## IPD sharing plan summary

Available on request