

# Closing wedge high tibial osteotomy for unicompartmental knee osteoarthritis: staples and cast fixation versus TomoFix plate fixation - a randomised trial

<b>Submission date</b> 27/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/06/2014	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr T M van Raaij

### Contact details

Erasmus University Medical Centre  
Department of Orthopaedic Surgery  
P.O. Box 2040  
Rotterdam  
Netherlands  
3000 CB

## Additional identifiers

### Protocol serial number

2; NTR483

## Study information

Scientific Title

**Acronym**

Closing HTO

**Study objectives**

Closing wedge osteotomy with plate fixation only will result in earlier mobilisation and better 1-year results considering pain and function then staple and cast fixation.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Received from the local medical ethics committee

**Study design**

Randomised active controlled parallel group trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Arthritis, osteoarthritis

**Interventions**

Closing wedge high tibial osteotomy: staples and cast fixation versus TomoFix plate fixation.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Is the accuracy of achieved correction of the mechanical limb axis post-operatively compared to the pre-operatively planned correction superior for closing wedge HTO with plate fixation?

Measurement:

Conservation of corrected angular limb deformity 1 year after surgery (success rate [%]).  
(Surgery is successful when the femoral-tibial axis 1 year after osteotomy is corrected accurately two degrees or less compared to the preoperative planned mechanical axis correction.)

**Key secondary outcome(s))**

1. Does the functional outcome differ between the two bone defect implants? Measurement:

1.1. Knee range of motion (ROM)

1.2. Pain score (Visual Analogue Scale)

1.3. Hospital for Special Surgery (HHS) Knee Service Rating System

1.4. Western Ontario and McMaster University Osteoarthritis Index (WOMAC)

- 1.5. Health-related quality-of-life score (EuroQol)
- 1.6. Complication
2. Which surgical technique is most efficient? Measurement: cost efficiency

**Completion date**

31/12/2007

## Eligibility

**Key inclusion criteria**

1. Patients (male and female) with symptomatic medial osteoarthritis of the knee who are not indicated for a knee arthroplasty
2. Above 18 years of age
3. Patient is knowledgeable and able to understand the treatment consequences
4. Informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Mechanical axis not through the medial compartment (HipKneeAnkle angle greater than 180 degrees)
2. Rheumatoid arthritis
3. HipKneeAnkle angle less than 169 degrees
4. Range of motion (ROM) less than 100 degrees
5. Extension deficit 15 degrees
6. Collateral ligament insufficiency (instability grade 3)
7. Indication for a supracondylar femur osteotomy
8. Not able to speak or understand Dutch

**Date of first enrolment**

01/08/2004

**Date of final enrolment**

31/12/2007

## Locations

## Countries of recruitment

Netherlands

## Study participating centre

Erasmus University Medical Centre

Rotterdam

Netherlands

3000 CB

## Sponsor information

### Organisation

Erasmus Medical Centre (The Netherlands)

### ROR

<https://ror.org/018906e22>

## Funder(s)

### Funder type

Not defined

### Funder Name

Not provided at time of registration

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes