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Comparing two high tibial osteotomy plates in terms of pain and plate removal

Submission date 03/02/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/03/2020	**Overall study status** Ongoing	
Last Edited 07/10/2025	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims

In osteoarthritis, tissues where two bones make contact in the knee joint become damaged or worn away and walking can become painful or uncomfortable, sometimes with a feeling of grinding or catching in the knee. The whole knee joint can be replaced with artificial components to treat knee osteoarthritis, but this is a serious surgery that can take a long time to recover from. In younger patients (aged 55 to 64 years) it is likely that the knee replacement might need to be redone after about 10 years. High tibial osteotomy (HTO) is a simpler surgery that aims to realign the knee joint of there is wear on one side more than the other. It involves inserting a wedge into the tibia (shin bone) near the knee joint in order to move the force involved when a person is walking onto the healthy side of their knee joint. This surgery can delay the point where a knee replacement is necessary by 8-10 years.

In HTO, a metal plate is used to hold the wedged-open tibia in place while the bone heals, which takes up to a year. This plate can be left in place afterwards, but some patients experience discomfort from the plate and need another operation to remove it. This study aims to compare two HTO plates to see if one results in less pain after surgery or fewer removal operations.

Who can participate?

There will be no open recruitment for this study. Patients scheduled to undergo HTO at the study hospital will be asked if they would like to participate.

What does the study involve?

Participants will be randomly allocated to receive one of the two HTO plates. They will not know which one they have received. The surgery will be carried out as normal, other than which plate is used. After surgery, participants will be asked to rate their pain for the first 5 days. They will come to the outpatient clinic at 2 weeks, 6 weeks and 1 year after surgery for routine assessment. At 2 years after the surgery, they will be sent a questionnaire asking whether they have had the plate removed or are scheduled to have it removed.

What are the possible benefits and risks of participating?

There are no risks involved to the research participants as the treatment they receive will not differ to their standard care. The two plates are both CE-marked, which means they are considered safe, and they are both on the market. There is no potential benefit for the

participant other than the contributing to better healthcare for future patients. Qualified and experienced members of the research team will ensure that participants are carefully managed to maintain safety and comfort for the duration of the study

Where is the study run from?
North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
November 2016 to October 2026

Who is funding the study?
Newclip Technics (France), which produces one of the plates used in this study, and the UK National Institute for Health Research (NIHR)

Who is the main contact?
Corina Negrut, corina.negrut@nbt.nhs.uk

Contact information

Type(s)
Public

Contact name
Mrs Corina Negrut

Contact details
Clinical Research Centre – Bristol Knee Group
North Bristol NHS Trust
Southmead Hospital
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB
+44 (0)117 4148131
corina.negrut@nbt.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
211393

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 34888, IRAS 211393

Study information

Scientific Title
Removal of metalwork following high tibial osteotomy: A randomised controlled trial comparing removal of metalwork rates for the ActivMotion (Newclip) and Tomofix (Synthes) high tibial osteotomy plates

Acronym
REMATCH

Study objectives
This study aims to compare two different plates currently used in high tibial osteotomy (HTO) surgery (knee realignment). The purpose of the metal osteotomy plates is to maintain the correct realignment achieved at surgery whilst the bone heals. The TomoFix and ActivMotion plating systems are both used in current practice and comply safety regulations.

Once the correction has healed (approx. 12 months) the plate can be left in. Some patients may however experience discomfort related to the plate and benefit from plate removal, about a year after their initial operation. The ActivMotion plate design is a smaller than the Tomofix and it is therefore potentially less likely to cause discomfort. It is anticipated that second operations for plate removal will be less frequent than for the Tomofix plate.

A small cohort study (Tomes et al. Unpublished data) suggested that plate removal rates may be much lower – 5%. However there has been no comparative study. In this study we would like to compare the number of plates that need removal following surgery, assess pain levels in patients in the first 2 years following surgery and compare the amount of analgesia used in the immediate post-operative recovery period.

Patients who will be asked to participate are those about to have a high tibial osteotomy. Participants will be asked to complete a questionnaire before they have their operation and 12 months after the operation to assess their pain and function. They will also be asked to record their pain levels before their operation, for 5 days after their operation and at each of their routine follow ups (2 and 6 weeks and 12 months). The amount of analgesia participants use will be recorded in the initial post-operative period. This information will be used to compare the outcome of the plates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/07/2017, London - West London & GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham NG1 6FS; +44 (0)207 104 8007; NRESCommittee.London-WestLondon@nhs.net), ref: 17/LO/0896

Study design
Randomised; Interventional; Design type: Treatment, Surgery

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
High tibial osteotomy (HTO) for knee realignment

Interventions
This is a randomised controlled trial comparing two high tibial osteotomy plates - both currently used in standard practice and both CE marked. The research nurses working on the study will follow a Standard Operating Procedure (SOP) to complete randomisation using block randomisation via sealed numbered envelopes. The randomised treatment will be recorded in the patient's hospital notes plus study notes, and the surgeon will be notified. Patients will be blinded to their allocation treatment.

20 patients will be recruited to each arm at one NHS Trust site. The study duration comprises 2 years recruitment and 2 years follow up.

At the pre-operative visit, a baseline assessment of pain will be recorded and the KOOS score will be used to record baseline pain, quality of life and function.

On the day of surgery, leg circumference and wound measurements will be taken at the end of the operation.

On Days 1-5 post-surgery, pain levels will be recorded by patients at home for 5 days following surgery using a Visual Analogue Score (VAS). The research team will contact participants by telephone on day 1 and day 4 to provide support with this process. Patients will then use pre-paid envelopes to return their VAS scores to the research team.

At the Week 2, Week 6 and Month 12 visits, participants will be seen in the outpatient clinic. VAS pain scores will be recorded at each visit. A KOOS score will be recorded at 12 months.

A postal questionnaire will be sent to patients at 2 years following surgery to establish whether they have had their plate removed or have been listed for plate removal.

The X-rays performed for this study are the same as those performed in standard care and routine treatment for patients with this condition.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
1. TomoFix 2. ActivMotion

Primary outcome measure
Proportion of participants requiring removal of plate or listed for plate removal within 2 years of surgery assessed using a questionnaire posted to participants

Secondary outcome measures
1. Pain assessed using a visual analogue score (VAS) at 1-5 days, 2 weeks, 6 weeks and 1 year post-operatively
2. Pain associated with knee osteoarthritis assessed using the Knee Osteoarthritis Outcome Score (KOOS) score at baseline and 1 year
3. Knee function assessed using the KOOS score at baseline and 1 year
4. Quality of life related to knee problems assessed using the KOOS score at baseline and 1 year
5. Wound size assessed using the measurements of the circumference of the limb and the wound incisions taken at the time of surgery.

Overall study start date
03/11/2016

Completion date
01/10/2026

Eligibility

Key inclusion criteria
1. Standing varus malalignment benefitting from high tibial osteotomy correction
2. Diagnosed with current osteoarthritis of the knee
3. Aged over 18 and under 65 years
4. Candidate to be implanted with a Tomofix or ActivMotion plate
5. Understands and accepts the obligation to comply with the required follow-up visits and is logistically able to meet all study requirements
6. Has signed informed consent for the use of their personal private data

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants

Planned Sample Size: 40; UK Sample Size: 40

Total final enrolment
37

Key exclusion criteria
1. Has declined to sign informed consent for the use of their person /private data
2. Correction greater than 14 mm opening wedge
3. Flexion contracture greater than 15°
4. Knee flexion under 90°
5. Medial/lateral tibial subluxation over 1 cm
6. Medial bone loss of over 3 mm
7. Inflammatory arthritis
8. Arthritis in the lateral compartment
9. Patella baja
10. Weight over 110 kg
11. Severe patellofemoral symptoms
12. Unaddressed ligamentous instability
13. Fixed flexion contracture
14. Known or suspected osteoporosis or osteopenia based on medical history and radiographic images
15. Current use of nicotine products.
16. Requires other surgical procedures at the time of the HTO surgery excluding arthroscopic exploration, chondroplasty, meniscectomy and cartilage preservation procedures
17. Diabetes mellitus

Date of first enrolment
07/09/2017

Date of final enrolment
04/06/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Research and Innovation
Level 3
Learning and Research Building
Southmead Hospital
Westbury-on-Trym
Bristol
England
United Kingdom
BS10 5NB
+44 (0)117 4149336
Researchsponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Industry

Funder Name
Newclip Technics

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/03/2027

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No