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Compensation of surgical technique rotational alignment variations in total knee arthroplasty

Submission date 25/10/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 17/11/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/11/2025	**Condition category** Surgery	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Total knee replacement surgery (also called total knee arthroplasty) helps people with severe knee arthritis regain mobility and reduce pain. During surgery, the position and rotation of the artificial joint parts can vary depending on the surgical technique used. These small differences in alignment may affect how the knee feels and functions.
This study compares three surgical techniques for total knee replacement to find out how each affects the rotation of the knee components and whether these differences influence recovery and function two years after surgery.

Who can participate?
Adults with painful knee osteoarthritis who need total knee replacement surgery and have not improved with non-surgical treatments can take part. People with previous fractures or bone surgery around the knee are excluded.

What does the study involve?
Participants are randomly assigned to one of three surgical groups:
-Measured Resection (MR) – the standard technique.
-Gap Balancing with Computer-Assisted Surgery (GB-CAS) – uses a computer to guide bone cuts.
-Gap Balancing with Force-Sensor Soft Tissue Balancing (FS-STB) – uses sensors to measure ligament pressure.

All patients receive the same type of cemented knee implant. CT scans and X-rays are taken before and after surgery to measure the implant positions. Patients are followed for two years and complete knee function and pain questionnaires (Knee Society and WOMAC scores).

What are the possible benefits and risks of participating?
There may be no direct personal benefit, but the findings could help improve surgical accuracy and future patient outcomes. Risks are minimal and limited to extra imaging and assessment time. Surgical risks are the same as for any standard knee replacement.

Where is the study run from?
The study is run from Germans Trias I Pujol University Hospital (Spain), Orthopaedic Surgery Department, in collaboration with the Radiology Department.

When is the study starting and how long is it expected to run for?
Recruitment began in 2015 and finished in 2017. Participants are followed for two years after surgery.

Who is funding the study?
This study has no external funding. It is being carried out as part of institutional clinical research.

Who is the main contact?
Name: Jose´A Hernández-Hermoso
Position: Orthopedic Surgeon
Institution: Germans Trias I Pujol University hospital
Email: jahernandezh.germanstrias@gencat.cat

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Jose A Hernández-Hermoso

ORCID ID
https://orcid.org/0000-0002-9167-3782

Contact details
Germans Trias i Pujol University hospital
Badalona. Barcelona
Spain
08916
+34 93497 8880
jahernandezh.germanstrias@gencat.cat

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
AC-14-033

Study information

Scientific Title

Different femoral and tibial rotation alignment among measured resection and gap-balanced total knee arthroplasty is compensated by the soft tissue envelope resulting in similar combined knee rotation and clinical outcomes

Acronym
RATKA study

Study objectives
We hypothesized that the measured resection technique, gap-balanced computer-assisted surgery and gap-balanced technique using a force-sensor soft tissue balancing device for achieving both mechanical and rotational alignment in TKA will result in some variation in native knee rotational alignment. We anticipate that the differences in femoral, tibial, and combined TKA rotations will be insufficient to significantly affect the 2-year clinical outcome scores.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/03/2015, Comitè Ètic Hospital Universitari Germans Trias i Pujol (Carretera Canyet s /n, Badalona. Barcelona, 08916, Spain; +34 93 4978880; ceic.germanstrias@gencat.cat), ref: AC-14-033

Study design
Interventional prospective randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Total Knee Arthroplasty surgical techniques in primary osteoarthritis patients

Interventions
Sixty patients were randomly assigned to one of three groups, with 20 patients in each group. A simple random sampling method was used -sealed envelopes-. All three groups underwent mechanically aligned TKA. The first group (MR group) underwent the measured resection technique, the second group (GB-CAS group) underwent gap balancing with CAS, and the third group (FS-STB group) underwent gap balancing with a force-sensor soft-tissue balance device. Follow up for 6 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Femoral component rotation is measured using Berger’s femoral component rotation angle (BFA) on non-contrast-enhanced helical 2D-CT scans at 1–2 months preoperatively and 6 months postoperatively
2. Tibial component rotation is measured using the Anatomic Tibial Angle (ATA) on non-contrast-enhanced helical 2D-CT scans at 1–2 months preoperatively and 6 months postoperatively

3. Combined femoral and tibial rotation in the native knee is measured using the Transepicondylar Posterior Tibial Angle (TE_PTA) on non-contrast-enhanced helical 2D-CT scans at 1–2 months preoperatively
4. Combined femoral and tibial rotation in the TKA knee is measured using the Transepicondylar Posterior Tibial Component Angle (TE_PTCA) on non-contrast-enhanced helical 2D-CT scans at 6 months postoperatively
5. Axial imaging of the femoral epicondylar axis, proximal tibial plateau, tibial tubercle, and ankle joint is performed using non-contrast-enhanced helical 2D-CT scans at 1–2 months preoperatively and 6 months postoperatively
6. Distances and angles in CT images are measured using the Alma Workstation 4.2.3.0 software at 1–2 months preoperatively and 6 months postoperatively

Key secondary outcome(s))
Clinical assessment using the Knee Society Score (KSS), WOMAC score at 1–2 months preoperatively and 6 months postoperatively

Completion date
31/12/2017

Eligibility

Key inclusion criteria
Patients with painful primary osteoarthritis who were unresponsive to nonoperative treatments and scheduled for TKA.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
55 years

Upper age limit
85 years

Sex
All

Total final enrolment
55

Key exclusion criteria
Patients with a history of femoral or tibial fractures or previous tibial or femoral osteotomy were excluded to avoid potential alterations in rotational alignment.

Date of first enrolment
23/04/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Spain

Study participating centre
Germans Trias i Pujol University Hospital
Carretera Canyet s/n
Badalona. Barcelona
Spain
08916

Sponsor information

Organisation
Hospital Universitari Germans Trias i Pujol

ROR
https://ror.org/04wxdxa47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Germans Trias i Pujol Universtity Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Jose A Hernández-Hermoso, jahernandezh.germanstrias@gencat.cat

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	in Spanish		03/11/2025	No	No