



RACER

Robotic Arthroplasty:
A Clinical and cost Effectiveness
Randomised controlled trial

Trial Number

Randomisation & Day of Surgery Pack

If you have any queries please contact the central study team at:

RACER@warwick.ac.uk

Pack Contents:

- ***Patient CRF's:***
 - *Randomisation Form*
 - *Surgery Form*
 - *MAKO Robot Form*
- ***Day of Surgery Blinded Envelope(s)***
- ***Research Guides:***
 - Randomisation & Day of Surgery Instruction Booklet
 - Surgery Manual



Randomisation Form

Keep this form in the Day of Surgery Blinding Envelope

To randomise a participant please follow the link: <https://ctu.warwick.ac.uk/racer>

If you experience problems, use the 24 hour automated telephone system on 024 7526 2666 . The PIN number can be found in the Randomisation and Day of Surgery Pack Instructions . If these two systems fail please use the manned telephone line (9am to 5pm Monday to Friday: 02476 150 402).

1. PARTICIPANT DETAILS:

PARTICIPANT TRIAL NUMBER:

TNO -

a. Participant Initials:

b. Age: c. Sex: Male Female

d. Hospital number:

e. BMI: . OR Height: cm Weight: kg

f. Which knee is being randomised? Left Right

g. Most affected knee compartment: Medial Lateral Patellofemoral

h. Registering site:

i. Has the participant consented to enter the study? No Yes

2. PARTICIPANT CONSENT:

(Please note: your name must be on the trial delegation log)

a. Has consent been verbally re-confirmed today? No Yes

b. Name of person re-confirming consent:

3. PARTICIPANT ELIGIBILITY:

a. Has eligibility been re-confirmed today? No Yes

If no, please explain why:

b. Name of person re-confirming eligibility:

4. SURGEON DETAILS:

a. Name of operating (first) surgeon:

a. Type of implant planned: Posterior stabilised Cruciate sacrificing Cruciate retaining

b. Patella resurfacing planned: No Yes Selective

c. Tourniquet will be used: No Yes

5. ALLOCATION:

Robotic TKR

Standard TKR

Form completed by (print name): _____

(Please note: your name must be on the trial delegation log)

Signature: _____

Date signed:

- -

TNO:

 Initials:

 Site Code:
1a. Pre-op plan:
FEMUR:

 Varus/valgus: . degrees

 Int/ext: . degrees

 Flexion: degrees

 Size:
Distal resection:

 M: . mm

 L: . mm

Post. Resection:

 M: . mm

 L: . mm

Difference between TEA and PCA:
 . degrees

1b. Pre-op plan:
TIBIA:

 Varus/valgus: . degrees

 Int/ext: . degrees

 Slope/Flexion: degrees

 Size:

 Med. Resection: . mm

 Lat. Resection: . mm

2. Work Flow:

 Pre-resection: No Yes

 Measured resection: No Yes

 Gap Balancing: No Yes
Cut First:

 Tibia: No Yes

 Femur: No Yes
3. Deformity:

 Varus/valgus (no stress): . degrees

 Is varus/valgus correctable prior to ligament release: No Yes
ROM:

 Ext: . degrees

 Flexion: degrees

TNO:

 Initials:

 Site Code:
4a. Intra-op: Initial Gaps

 Ex. Med Gap: mm

 Ex. Lat Gap: mm

 Flexion. Med Gap: mm

 Flexion Lat Gap: mm

4b. Intra-op:
FEMUR:

 Varus/valgus: . degrees

 Int/Ext: . degrees

 Flexion: degrees

 Size:
TIBIA:

 Varus/valgus: . degrees

 Int/Ext: . degrees

 Slope/Flexion: degrees

 Size:
4c. Intra-op: Planned Gaps

 Ex. Med Gap: mm

 Ex. Lat Gap: mm

 Flexion Med Gap: mm

 Flexion Lat Gap: mm

5a. Final:
FEMUR:

 Varus/valgus: . degrees

 Int/ext: . degrees

 Flexion: degrees

 Size:
Distal resection:

 M: . mm

 L: . mm

Post. Resection:

 M: . mm

 L: . mm

5b. Final:
TIBIA:

 Varus/valgus: . degrees

 Int/ext: . degrees

 Slope/Flexion: degrees

 Size:

 Med. Resection: . mm

 Lat. Resection: . mm

 Insert thickness: mm

5c. Posterior cruciate ligament excised:

 Yes

 No

TNO:

 Initials:

 Site Code:
6. Trials:

 ROM Ext: degrees

 ROM Flexion: degrees

 Varus/Valgus: . degrees

 Ex. Med. Gap: mm

 Ex. Lat. Gap: mm

 Flx. Med.Gap: mm

 Flx. Lat. Gap: mm

7. Final implant after cementation:

 ROM Ext: degrees

 ROM Flexion: degrees

 Varus/Valgus: . degrees

8. Please detail any specific comments below:**9. Have the surgery session files been exported from the MAKO Robot onto the removable (external) encrypted device?**

 Yes*

 Date of export: - -

 No

 If **not possible at the time of surgery**, please ensure the session files remain on the Robot until an export to a external hard drive is possible.

*Please note: The surgery session files **MUST** be pseudonymised using the standard naming convention of "RACER-K_TNO_SiteCode_Date" prior to being transferred to Warwick.

*(Please note: your name **must** be on the trial delegation log)*

Name of Surgeon who performed the surgery (print name): _____

Date completed: - -



Surgery Form

TNO:

Initials:

Site Code:

SURGERY DETAILS

1. Date of Surgery: --

2. Surgery Start Time (*Knife to Skin*) : Surgery End Time (End of Closure) :

3. Type of anaesthesia: General Regional (spinal)

4. Block used? No Yes

5. Name of operating surgeon:

6. Grade of operating surgeon (please choose one option):

Consultant Non-Consultant Specialist Post-CCT Trainee

7. Was there a senior supervising surgeon present? No Yes

If **YES**, name of senior supervising surgeon:

8. Grade of senior supervising surgeon, if present (please choose one option):

Consultant Non-Consultant Specialist Post CCT Trainee

9. Was the senior supervising surgeon scrubbed? No Yes

10. Tourniquet used? No Yes

If **YES**, tourniquet time: mins

11. Time from incision to closure: mins

12. Was the patella resurfaced? No Yes

13. Type of implant:
Posterior stabilised Cruciate Sacrificing Cruciate retaining

14. Any complications? No Yes (if **YES**, please provide details in box below)



Surgery Form

TNO:

Initials:

Site Code:

SURGERY DETAILS

15. Ligament release (please circle yes or no for all options below):

Superficial MCL release Yes No

Lateral capsule release Yes No
(for lateral compartment OA)

More extensive medial release Yes No

More extensive lateral release Yes No

Lateral retinacular release Yes No
(For PFJ/patellar tracking)

Other (Please specify below) Yes No

PCL release Yes No

16. Detail ligament releases:

17. Changes to planned bony cuts:

18. FEMUR:

Final size:

19. TIBIA:

Final size:

Insert thickness: mm

20. PATELLA:

Final size: mm

Asymmetrical Symmetrical

(Please note: your name **must** be on the trial delegation log)

Surgeon who completed form (print name): _____

Signature: _____

Date signed: - -