



RACER

Robotic Arthroplasty:

A Clinical and cost Effectiveness
Randomised controlled trial

Imaging Manual

This manual outlines the imaging process required for RACER Trial patients and should be used in conjunction with the MAKO TKR Protocol.

1. Introduction

All participants registered in the RACER study will receive 2 CT scans.

The 1st CT scan is pre-operative and is required for the planning of the surgery, it will be performed for all participants. This CT will follow the Stryker protocol (see attached STRYKER protocol) with minimisation of the radiation dose as per instructions below. The Knee CT for planning includes images of the hip and ankle to produce and a three-dimensional plan suited to the needs of the MAKO system.

The planning CT scan must be done at least 2 weeks prior to surgery, but no more than 12 weeks before the planned date of surgery to ensure bone shape does not change due to disease progression.

If, for unexpected reasons, the surgery is delayed such that the CT scan was performed more than 12 weeks before the actual date of surgery, then the surgeon will make a clinical decision whether to accept the use of the current CT or repeat the scan, according to their normal clinical practice.

At 3 months after surgery the participants will undergo a focused, low-dose CT to assess implant rotation. This is of the knee only; the hip and ankle does not need to be imaged for the second scan.

A long-leg alignment x-ray will also be performed (ideally on the same day to save repeat visits), for the assessment of Hip-Knee-Ankle angle.

The second CT should be booked before the participant is discharged from hospital.

2. Instructions on minimisation of radiation on Mako Manual (see attached Stryker MAKO Manual)


Knee scanning parameters:

- Spiral/helical scanning using a pitch of approximately 1. Note slices should be thinner for the knee (0.5 to 1mm) compared to the hip and ankle (2.5-5mm). Minimise coverage of hip and ankle but insure minimum required features are included – see image.
- 3 regions: hip, knee and ankle
- Continuous scan within regions (using one scout or topogram with three groups)
- Use a bone reconstruction kernel (algorithm) throughout
- 512 x 512 Matrix: Image must be square
- kV: 120
- mA: adjust for a maximum DLP of 450-500mGy.cm through hips (250-300mGy.cm is achievable if iterative reconstruction is available), 200-250mGy.cm through the knee, and 150-200mGy.cm through ankle.
- Record dose used (total DLP as a minimum, DLP and CT DIvol to each area if possible).
- For the post-op CT, use the same principles as above, but image the knee only (to include the whole prosthesis)

3. CT Form

For both imaging appointments, a CT form is required to be completed. This form needs to be returned to the Warwick trial office at racer@warwick.ac.uk.

Please see an example of the form below:

Imaging Form		
TNO: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Initials: <input type="text"/> <input type="text"/> <input type="text"/>
		Site code: <input type="text"/> <input type="text"/> <input type="text"/>
<p>1. Pre-op CT SCAN</p> <p>1a) Initial or Repeat CT Scan? <input type="checkbox"/> Initial <input type="checkbox"/> Repeat <i>If repeat, please specify reason</i></p> <p>1b) Date of CT Scan <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>1c) Please specify the knee which was investigated <input type="checkbox"/> Right Knee <input type="checkbox"/> Left Knee</p> <p>1d) Has this CT scan been performed as per protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If No, please provide detail below:</i></p> <p>1e) Has a serious adverse event occurred associated with this appointment? <input type="checkbox"/> Yes* <input type="checkbox"/> No <i>*If Yes, please report accordingly within RACER Protocol timelines</i></p> <p>Form Completed by (print name):</p> <p>Signature:</p> <p>Date signed: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p>	<p>2. Post-op CT SCAN</p> <p>2a) Initial or Repeat CT Scan? <input type="checkbox"/> Initial <input type="checkbox"/> Repeat <i>If repeat, please specify reason</i></p> <p>2b) Date of CT Scan <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>2c) Please specify the knee which was investigated <input type="checkbox"/> Right Knee <input type="checkbox"/> Left Knee</p> <p>2d) Has this CT scan been performed as per protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If No, please provide detail below:</i></p> <p>Form Completed by (print name):</p> <p>Signature:</p> <p>Date signed: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p>	<p>3. Post-op long leg X-RAY</p> <p>3a) Initial or Repeat X-Ray? <input type="checkbox"/> Initial <input type="checkbox"/> Repeat <i>If repeat, please specify reason</i></p> <p>3b) Date of X-Ray <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>3c) Please specify the knee which was investigated <input type="checkbox"/> Right Knee <input type="checkbox"/> Left Knee</p>

[See the Stryker MAKO CT protocol for additional information]