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RACER

Robotic Arthroplasty:
A Clinical and cost Effectiveness Randomised controlled trial

Surgical Manual

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Contents

CT Scan

Each patient requires a pre-operative CT scan. This scan must follow the Mako Knee CT Scanning Protocol & the RACER trial CT manual.

Femur Axes Definition

1. Femur Mechanical Axis: The Femur Mechanical Axis is defined by a line connecting the 'Hip Centre' to the 'Femur Knee Centre'.

    a. 'Hip Centre' is defined as the centre point of a circle fit to the femoral head in the coronal, sagittal, and transverse planes.

    b. 'Femur Knee Centre' is defined at the most distal point of the trochlear groove in the coronal and sagittal views.

2. Transepicondylar Axis (TEA): The mediolateral TEA is defined by a line connecting the 'Medial Epicondyle' to the 'Lateral Epicondyle'. The Femur Mediolateral (ML) Axis is parallel to the TEA in the transverse plane.

    a. 'Medial Epicondyle' is defined by a point in the bony sulcus, which is called the surgical medial epicondyle. It is not the clinical medial epicondyle, which is the most proud (or prominent) bony protuberance that can be palpated clinically.

    b. 'Lateral Epicondyle' is defined by the most proud (or prominent) point on the lateral bony protuberance.

3. Femur Anteroposterior (AP) Axis: The 'Femur AP Axis' is naturally perpendicular to the 'Femur ML Axis'. The 'Femur AP Axis' is approximately parallel to Whiteside's line, which is the line through the deepest groove of the trochlea.

Tibia Axes Definition

1. Tibia Mechanical Axis: The Tibia Mechanical Axis is defined by a line connecting the 'Tibia Knee Centre' to the 'Ankle Centre'.

    a. 'Tibia Knee Centre' is defined as the proximal exit location of the anatomic tibial shaft in both the coronal and sagittal views.

    b. 'Ankle Centre' is computed from the collection of the medial and lateral malleoli landmarks. The line connecting the two malleoli will appear externally rotated (approximately 20°) from the Tibia Mediolateral (ML) Axis. The malleoli landmarks are located on the outermost bony protuberances, halfway from the most anterior and most posterior edges when viewed by an externally rotated plane. The 'Ankle Centre' is computed as 44% from the medial malleolus and 56% from the lateral malleolus.

2. Tibia Anteroposterior (AP) Axis: The 'Tibia AP Axis' is set using the 'Rotational Landmark' and is defined by a line connecting the 'PCL Centre' to the medial 1/3 of the tibial tubercle.

a. 'PCL centre' is defined as the centre of the PCL insertion region, which is characterized by a bright dense region of bone in the transverse view. Place the centre of the blue rotation bar (ML axis) there. The PCL insertion can be best visualized in the transverse view by setting the crosshair below the lowest compartment in the coronal view be it medial or lateral.

b. Medial 1/3 of the tubercle is defined as the approximate anterior-medial corner of the tubercle as visualized by a transverse cross-section at the level of the tibial tubercle. Rotate the green arrow bar (AP axis) until it intersects the medial 1/3 of the tibial tubercle.

3. Tibia Mediolateral (ML) Axis: The 'Tibia ML Axis' is naturally perpendicular to the 'Tibia AP Axis'. The malleoli landmarks should match the location as palpated during the bone registration process using the 'Patient Landmark' page. Because the malleoli landmarks do not lie in a plane parallel to the coronal plane, they should not be located as the outermost protuberance in the coronal plane.

MAKO TKR SURGICAL TECHNIQUE

Sagittal Femoral Component Rotation

In the sagittal plane, the femur typically exhibits a natural anterior bow. During conventional surgical procedures, the femoral intramedullary rod approximates the distal 1/3 of the femur, which due to the sagittal bow of the femur creates approximately 4° of flexion with respect to the femur mechanical axis in the sagittal plane. The Mako TKA Application displays sagittal rotation values with respect to the femur mechanical axis. To replicate referencing with an IM rod, the femoral component should be rotated ≥0° flexion. The upper limit of flexion should be within 8 degrees unless abnormal anatomy in which case this can be increased at the surgeon's discretion.

Coronal Femoral Component Alignment

For both varus and valgus knees, note the depth of the distal trochlear groove. If desired, distal condyle resection depth can be modified from the default plan to resect to the level of the native depth of the trochlear groove.

The optimal femoral component size is the largest component that does not overhang the anterior femur, does not notch the anterior femur, does not overhang the medial and lateral resected bone edges, and does not overstuff the patellofemoral compartment.

Tibial Component Positioning

The optimal tibial component size is the largest component that does not overhang the perimeter of the tibial plateau.

Anteroposterior (AP) and Mediolateral (ML) position and axial rotation of the tibial component is ultimately determined post-resection by the surgeon with the baseplate trial during manual tibial keel preparation. The Sharp Probe or Blunt Probe can be placed on the medial, lateral, and anterior edges of the trial and compared to the planned placement to help guide final component position.

Tibial component posterior slope (range):

- CR: 3° (0-3) posterior slope.
- CS (PCL retaining): 3° (0-3) posterior slope.
- CS (PCL sacrificing): 0° (0-1) posterior slope.
- PS: 0° (0-1) posterior slope.

Operative Setup

Choice of anaesthetic technique will be at the discretion of the surgical & anaesthetic teams. However, **if the patient maintains awareness through the surgery every effort should be made to blind the patient to the technique used.** This should include the use of a surgical screen, using drapes and audio equipment for the patients use. The presence or absence of robotic equipment in theatre should not inform the patient of the randomisation – if randomised to conventional surgery it is recommended that at least the MAKO console and cameras be left in theatre.

The Robotic Arm is located on the operative side, and the Camera Stand is located opposite the Robotic Arm. Since direct-line-of-sight is required for all tracking arrays, the non-operative side must be free of camera obstruction during steps of the procedure that require real-time tracking (e.g., 'Bone Registration', 'Bone Preparation'). It is recommended to place the camera directly across from the Robotic Arm, or slightly towards the patient's head or feet, to allow a surgical assistant to assist in the procedure without blocking direct-line-of-sight between the camera and the bone arrays or probes. The Surgeon Monitor can be placed in a comfortable viewing location for the surgeon. The Guidance Module should be located where the MPS can maintain direct observation of the surgeon.

Prior to commencing the case the surgeon must confirm with the MPS that the correct Patient Name, Patient ID, Operative Side, and Implant System are selected. It is recommended that this step is included in the required operative timeout at the beginning of the procedure.

The use of a surgical tourniquet should be used as the surgeon's standard practice and recorded prior to randomisation. The surgeon's standard approach should be used for the procedure and the PCL retained or sacrificed in line with the surgeon's standard practice. The Mako leg positioner self-retraction system is optional.

Bone Array Placement

The standard 4mm bone pins or the 3.2mm pins can be used at the surgeon's discretion.

Tibial pins:

The tibial pins can either be inserted through the standard incision or through sperate stab incisions as follows :-

1. Using a scalpel, make one incision through the skin and fascia a minimum of 10 cm (approximately four finger breadths) inferior to the tibial tubercle and 1-1.5 cm medial to the tibial crest.

2. The second incision can be completed by using either of the following methods:

    a. Make the second stab incision approximately 15 mm distal to the previous incision, or

    b. Place the most proximal sleeve of the Array Stabilizer through the first incision and make an incision where the distal sleeve rests on the skin.

3. Fully seat the Array Stabilizer through both incisions so that the barrels are on the bone surface.

4. Drive one of the bone pins through the first cortex and pierce the second cortex.

5. While holding the Array Stabilizer in place, drive the second bone pin through the first cortex and pierce the second cortex.

Surgeons should be consistent in the trial in their use of pins within the incision or through separate incisions. The same incisions need to be used for robotic and conventional surgery.

Femoral pins:

The femoral pins can be inserted through the standard incision into the distal femur. Fully seat the Array Stabilizer through both incisions so that the barrels are on the bone surface then drive one of the bone pins through the first cortex and pierce the second cortex while holding the Array Stabilizer in place, drive the second bone pin through the first cortex and pierce the second cortex

Array Assembly (Femur and Tibia)

1. Loosely assemble the Pelvic Array Adaptor and 2-Pin Clamp.

2. Sliding the clamp over the bone pins seat the clamp against the top of the Array Stabilizer. Orient the assembly such that the clamp's screw points away from the camera and the Pelvic Array Adaptor's screw points away from the incision.

3. Attach the Knee Femoral Array to the Pelvic Array Adaptor.

4. Position the array as desired.

5. Using the Square Driver, sufficiently tighten the screws in this order:

a. Array screw

b. Pelvic Array Adaptor screw

c. Clamp screw.

Camera View

Adjust the camera such that all tracking arrays are visible from full extension to full flexion.

Bone Registration and Check Point Insertion

The femoral and tibial checkpoints should be placed, and bone registration completed. Bone registration points must be collected on bone. When points are collected in regions that are covered in cartilage the Sharp Probe should be used to penetrate the cartilage allowing access the bone surface.

Intra-operative Planning

Depending on the surgeon's normal practice either the measured resection or ligament balancing workflow can be used. If the ligament balancing workflow is used, then pre or post resection balancing can be used in line with the surgeon's normal practice.

Bone Preparation

The order of bone cuts can be changed in line with the surgeon's preference.

The "extended boundary" function can be used for final bone preparation at the surgeon's discretion; however, care should be taken to preserve the soft tissues.

Trial Reduction and Joint Assessment

Joint laxity and ligament tension can be assessed to balance the knee with the surgeons preferred technique.

If the post resection balance is not as desired, the implant plan (position, orientation, and/or size) can be modified after initial bone resections have been made via the 'Implant Planning' or 'Ligament Balancing' pages.

Examples include:

- In the event of tight flexion and extension gaps, the surgeon may opt to increase the resection depth of the tibial component and recut the tibia.
- In the event of a tight flexion gap and a balanced extension gap, the surgeon may opt to increase the posterior slope of the tibial component and recut tibia.
- In the event of a flexion contracture (tight extension gap) and a balanced flexion gap, the surgeon may opt to increase the resection depth of the distal femoral component and recut the femur.

Patellar Preparation

Patella resurfacing should be undertaken at the discretion of the surgeon and in line with their routine practice.

Implant Insertion

The final implants should be cemented using the surgeon's standard practice. Modification of the final alignment can be made while the cement remains malleable guided by the alignment values. Final alignment should be recorded once the cement has fully cured.

STANDARD INSTRUMENT TECHNIQUE

The Pre-operative CT can be reviewed as part of pre-operative planning if you wish, but it is not required, and the surgeon does not have to follow the plan.

The surgical technique should be conducted in line with the technique detailed in the Stryker surgical protocol:

https://www.strykermeded.com/media/1165/triathlon-surgical-protocol.pdf

Extra incisions for blinding

If the surgeons standard robotic technique is to make separate stab incisions for tibial array placement then two similar incisions should be made in the same manner in the standard technique patients to ensure blinding.

Coronal Femoral Component Alignment

For both varus and valgus knees, the Femoral Alignment Guide may be set to 5, 6 or 7º of valgus to resect the correct dept of bone and align the femoral component.

The optimal femoral component size is the largest component that does not overhang the anterior femur, does not notch the anterior femur, does not overhang the medial and lateral resected bone edges, and does not overstuff the patellofemoral compartment.

Tibial Component Positioning

The surgeon may use either the extra or intra medullary tibial jig.

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