Image Acquisition Protocol

Agili-C IDE Study (543)

CLN0021

medicalmetrics INC.

MRI Acquisition Protocol

Application: Soft Tissue Knee

The MR protocol must be set up in advance and saved on the scanner console, to be copied and used for each subject at each study visit. The Exam Card should be sent to Medical Metrics (MMI) for review prior to scheduling study subjects. This ensures consistency across subjects throughout the duration of the study.

Protocol Set-Up

- Save the Protocol created during Site Training as “MMI CartiHeal 543” or similar.
- Save each scan exactly as indicated in the table below.
- Avoid running sequences in Research Mode.
- Use the same knee coil for a subject during the course of study to ensure consistent image quality, if possible.
- Avoid generating secondary DICOM files.
- If DICOM de-identification is performed, only protected health information should be removed. The scan and sequence specific details should remain intact.
- Once the protocol has been set up, it should not be changed unless the scanner configuration requires parameter adjustments (e.g., increasing TR to address SAR limitations).

PROTOCOL NAME (Exam Card)	“MMI CartiHeal 543”
Localizer / Reference / Scout	"Localizer"
Coronal Intermediate-Weighted FSE	"Cor IW"
Coronal Proton Density Weighted FSE w/ Fat Saturation	"Cor PD FS"
Sagittal Intermediate-Weighted FSE	"Sag IW"
Sagittal Proton Density Weighted FSE w/ Fat Saturation	"Sag PD FS"
Axial Intermediate-Weighted FSE	"Ax IW"
Axial T2 Weighted FSE w/ Fat Saturation	"Ax T2 FS"
Sagittal T1 Weighted FSE	"Sag T1"
Oblique T2 Proton Density Weighted FSE w/ Fat Saturation	"Obl T2 FS"

Hardware

- An MRI scanner of 1.5T field strength is recommended for this study. Some variation in recommended acquisition parameters is to be expected depending on field strength, scanner manufacturer, software version, software release number and hardware configuration.
- The MRI scanner must be approved for clinical use.
- A dedicated knee coil should be used. An 8-channel coil is recommended.

Subject and Positioning

- Please instruct subjects to remain still during the MRI exam to minimize motion artifacts.

- The knee coil base should be placed on the gantry in alignment with the marks on the table for such a coil.
- A knee pad may be used beneath the knee and should be positioned similarly across multiple study subjects and visit intervals.
- The knee must be positioned within the coil such that the bottom of the patella is in alignment with the center mark of the knee coil.
- The subject should be encouraged to relax the leg being imaged and hold it in a neutral position consistently over the course of the MRI exam. The foot should be in a vertical position during image acquisition.
- A strap may be used to secure the coil and the contralateral knee during the MRI imaging, with padding as necessary to ensure subject comfort.

Imaging Anatomy

- Ensure that the **entire knee** is imaged.
- The imaging slab should remain unchanged across sequences acquired in the same orientation. This means that the slices for all axial series should be collected at the same location, i.e. without repositioning the slab. The same applies for sagittal and coronal acquisitions also.

Image Acquisition

- Please use Auto Shim for all acquisitions, manual shimming is not necessary for this protocol.
- Receiver bandwidth should be set high, such that the chemical shift artifact is minimized.
- Please ensure that the anatomy is centered in the Field of View (FOV).
- For all return visits, please use subjects' **Screening** exams as reference for visual guidance in determining FOV extent, slice positioning, and angulation. This will aid in the accuracy of image analyses and help comparative review of the anatomy.
- Changes to repetition time (TR) may be necessitated by specific absorption rate (SAR) limits imposed by the scanner console. This is acceptable. The technologist or supervising radiologist may chose to utilize phase oversampling and/or modify the number of slices to accommodate an altered scan TR.
- Additional Imaging sequences may be added at the supervising radiologist's discretion or if they are routinely performed as 'standard-of-care' sequences.

Other Notes

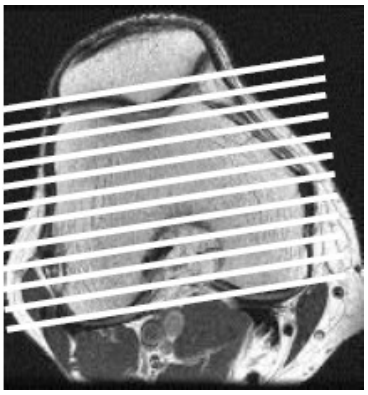
- All MRI Images should be sent to the imaging core lab for the study, in DICOM format. These may be burned to media with an image viewer, where possible.
- No contrast-based sequences are prescribed in this MRI protocol.

1.5 Tesla MRI Acquisition Sequences

1. *3- PLANE LOCALIZER*

Pulse Sequence: Localizer 3-Plane
TR/TE/Flip angle: Default scanner settings
FOV: 20 cm x 20 cm
Number of Slices: 5 / direction
Imaging Mode: 2D/Multi-slice
Averages: 1
Slice Thickness/Gap: 5 mm/1 mm

Notes: This sequence may be run per site protocols, more than once if required. Additional calibration scans (field map, parallel coil reference scans, etc.) should be run after a suitable localizer scan is acquired.



2. *CORONAL IW SEQUENCE*

Purpose: 2D Anatomic Coronal Imaging
Imaging Mode: 2D/Multi-slice
Pulse Sequence: Fast Spin Echo (FSE)
TR/TE/Flip angle: ≥3000 ms / 30-40 ms / NA
FOV: 14 cm x 14 cm
Matrix: 512 x 256 (or larger)
Receiver BW: 80-120 Hz/pixel
Averages: 2
Slice Thickness/Gap: 3.0 to 3.5 mm / 0 mm

Notes: This sequence may be a double-oblique sequence. Correct alignment will result in a scan plane that is tangential to the posterior femoral condyle surfaces in the axial plane and parallel to the femoral-tibial axis in the sagittal plane. Make sure to center the joint in the FOV and that enough slices are used to cover the whole joint.

3. *CORONAL PD-WEIGHTED SEQUENCE w/ FAT SATURATION*

Purpose: 2D Anatomic Coronal Imaging
Imaging Mode: 2D/Multi-slice
Pulse Sequence: Fast Spin Echo (FSE) with Fat Suppression (or Turbo Spin Echo)
TR/TE/Flip angle: ≥3000 ms / 10-20 ms / NA
FOV: 14 cm x 14 cm
Matrix: 512 x 256 (or larger)
Receiver BW: 80-120 Hz/pixel
Averages: 2
Slice Thickness/Gap: 3.0 to 3.5 mm / 0 mm

Notes: This sequence may be a double-oblique sequence. Correct alignment will result in a scan plane that is tangential to the posterior femoral condyle surfaces in the axial plane and parallel to the femoral-tibial axis in the sagittal plane. Make sure to center the joint in the FOV and that enough slices are used to cover the whole joint. Ensure Fat Saturation pulse is turned on.

4. *SAGITTAL IW SEQUENCE*

Purpose: 2D Anatomic Sagittal Imaging
Imaging Mode: 2D/Multi-slice
Pulse Sequence: Fast Spin Echo (FSE)
TR/TE/Flip angle: ≥3000 ms / 30-40 ms / NA
FOV: 14 cm x 14 cm
Matrix: 512 x 256 (or larger)
Receiver BW: 80-120 Hz/pixel
Averages: 2
Slice Thickness/Gap: 3.0 to 3.5 mm / 0 mm

Notes: It is recommended that the frequency encode be set to the superior-inferior direction. Make sure to center the joint in the FOV and that enough slices are used to cover the whole joint. Slices should be perpendicular to the condyles.

5. *SAGITTAL PROTON DENSITY SEQUENCE WITH FAT SATURATION*

Purpose: 2D Anatomic Sagittal Imaging
Imaging Mode: 2D/Multi-slice
Pulse Sequence: Fast Spin Echo (FSE) with Fat Suppression (or Turbo Spin Echo)
TR/TE/Flip angle: ≥3000 ms / 10-20 ms / NA
FOV: 14 cm x 14 cm
Matrix: 512 x 256 (or larger)
Receiver BW: 80-120 Hz/pixel
Averages: 2
Slice Thickness/Gap: 3.0 to 3.5 mm / 0 mm

Notes: It is recommended that the frequency encode be set to the superior-inferior direction. Make sure to center the joint in the FOV and that enough slices are used to cover the whole joint. Slices should be perpendicular to the condyles. Ensure Fat Saturation pulse is turned on.

6. *AXIAL IW SEQUENCE*

Purpose: 2D Anatomic Sagittal Imaging
Imaging Mode: 2D/Multi-slice
Pulse Sequence: Fast Spin Echo (FSE)
TR/TE/Flip angle: ≥3000 ms / 30-40 ms / NA
FOV: 14 cm x 14 cm
Matrix: 512 x 256 (or larger)
Receiver BW: 80-120 Hz/pixel
Averages: 2

Slice Thickness/Gap: 3.0 to 3.5 mm / 0 mm

Notes: The lateral and medial menisci must be completely contained in the imaging volume. Make sure to center the joint in the FOV and that enough slices are used to cover the whole joint.

7. *AXIAL T2 SEQUENCE w/ FAT SATURATION*

Purpose: 2D Anatomic Axial Imaging
Imaging Mode: 2D/Multi-slice
Pulse Sequence: Fast Spin Echo (FSE) with Fat Suppression (or Turbo Spin Echo)
TR/TE/Flip angle: ≥3000 ms / ≥70 ms / NA
FOV: 14 cm x 14 cm
Matrix: 512 x 256 (or larger)
Receiver BW: 80-120 Hz/pixel
Averages: 2
Slice Thickness/Gap: 3.0 to 3.5 mm / 0 mm

Notes: Apply Fat Saturation Pulse. The lateral and medial menisci must be completely contained in the imaging volume. Make sure to center the joint in the FOV and that enough slices are used to cover the whole joint.

8. *SAGITTAL T1*

Purpose: 2D Anatomic Axial Imaging
Imaging Mode: 2D/Multi-slice
Pulse Sequence: Fast Spin Echo (FSE)
TR/TE/Flip angle: 600-800 ms / 10-20 ms / NA
FOV: 14 cm x 14 cm
Matrix: 512 x 256 (or larger)
Receiver BW: 80-120 Hz/pixel
Averages: 2
Slice Thickness/Gap: 3.0 to 3.5 mm / 0 mm

Notes: It is recommended that the frequency encode be set to the superior-inferior direction. Make sure to center the joint in the FOV and that enough slices are used to cover the whole joint. Slices should be perpendicular to the condyles.

9. *OBLIQUE PD WEIGHTED SEQUENCE w/ FAT SATURATION*

Purpose: 2D Anatomic Axial Imaging
Imaging Mode: 2D/Multi-slice
Pulse Sequence: Fast Spin Echo (FSE) with Fat Suppression (or Turbo Spin Echo)
TR/TE/Flip angle: ≥3000 ms / 10-20 ms / NA
FOV: 14 cm x 14 cm
Matrix: 512 x 256 (or larger)
Receiver BW: 80-120 Hz/pixel
Averages: 2
Slice Thickness/Gap: 3.0 to 3.5 mm / 0 mm

Notes: Apply Fat Saturation Pulse. Slices should be oriented orthogonal to the articular surface where the scaffold is placed.