



**Lento Medical,
Inc.**

**Instructions for Use – Clinical MRI Scanning
Protocol – TKR**



Lento PST[®] System

Instructions for Use – Clinical MRI Scanning

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This is a quick reference guide for the MRI Technologist as an aid in rapidly setting up the listed MRI scanning equipment. There is a full MRI reference guide for use in positioning and patient orientation which is available upon request if it has not already been supplied or is misplaced. There is also an MRI upload reference guide to assist with uploading completed images to the Lento Medical cloud database.



WARNING: It must be noted that the use of MRI scanners in patients with metallic implants in or near the knee joint may adversely affect the quality and accuracy of the images obtained. For this reason it is generally recommended that such MRI scans not be attempted.



WARNING: The use of MRI scans for making custom cutting guides in pediatric patients has not been studied and the results of the use of Lento cutting guides in these patients is unknown. For this reason it is generally recommended that such MRI scans not be attempted. Please verify the MRI request with the ordering physician.



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The following organization is the Authorized Representative for the Lento PST® System:



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A. PATIENT SET-UP

1. Patient should be metal/implant free in the scan volume.
2. Place patient supine, feet first, for lower extremity with affected limb as close to IsoCenter as possible
3. Consider using small foam wedges to stabilize or support the joint.
4. Use tape, sponges and/or Velcro straps on extremity to maintain anatomic “toes up” position.
5. Remind patient to remain motionless during the entire scan.
6. Landmark or Zero table
7. Begin scanning at the Distal Tibia (Ankle) for the Coronal T1 Series, move to the Knee series and complete the study with the Hip series (see Figure 11).
8. Phased array coils (receive only coils) or the “Body Coil” may be used in order to scan the hip and ankle without removing the knee surface coil. New GEM suite GE systems have built in phased array coils in table.

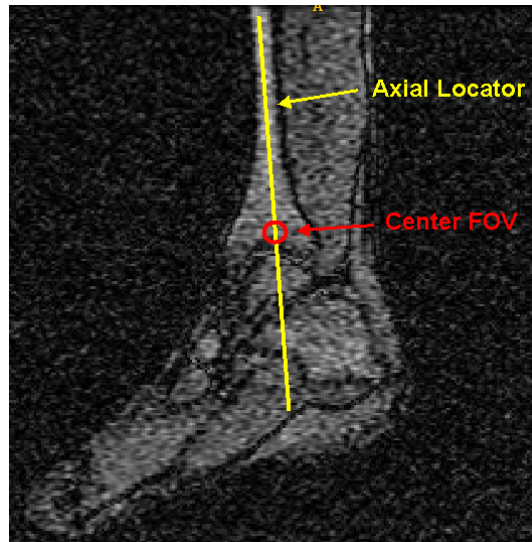
B. SCANNER SET-UP

1. Enter patient name (Last, Middle, First)
2. Enter patient DOB. (dd/mm/yyyy)
3. Enter scan date (dd/mm/yyyy)
4. Enter left or right joint (Right/Left)
5. Enter patient gender (M/F)
6. Enter name of Surgeon (Last, Middle, First)
7. Enter name of imaging center

C. CORONAL T1 DISTAL/ANKLE MRI PROTOCOL

1. Perform one 3 plane (Axial, Coronal, Sagittal) locator scan
2. Perform a Coronal(T1FSE) series using the minimum scan
 - i. parameters:

Slice Plane:	Coronal
Slice thickness (mm):	4
Spacing/Gap (mm):	1
Number of slices:	10
FOV(mm):	240 mm
Matrix:	256 x 160
NEX:	2
NPW/Anti-Aliasing/Fold Over Suppression:	ON
File Series Name:	"Coronal Ankle"



**Figure 1
Coronal Slice Placement**

D. CORONAL T1 DISTAL TIBIA/ANKLE SLICE POSITIONING

View the **Sagittal** locator to place the slice Coronally through the long axis of the Tibia. *The Axial locator slices are not used for alignment.* Center the FOV approximately one inch above the Tibial Talar joint space. See Figure 1 for slice position and FOV centering.

E. CORONAL FSE PD KNEE MRI PROTOCOL

1. Perform one 3 plane (Axial, Sagittal, Coronal) locator series.
2. Refer to "Lento Knee Imaging Reference for 1.5T and 3T Scanners section for the Coronal scan parameters

F. CORONAL FSE PD KNEE SLICE POSITIONING

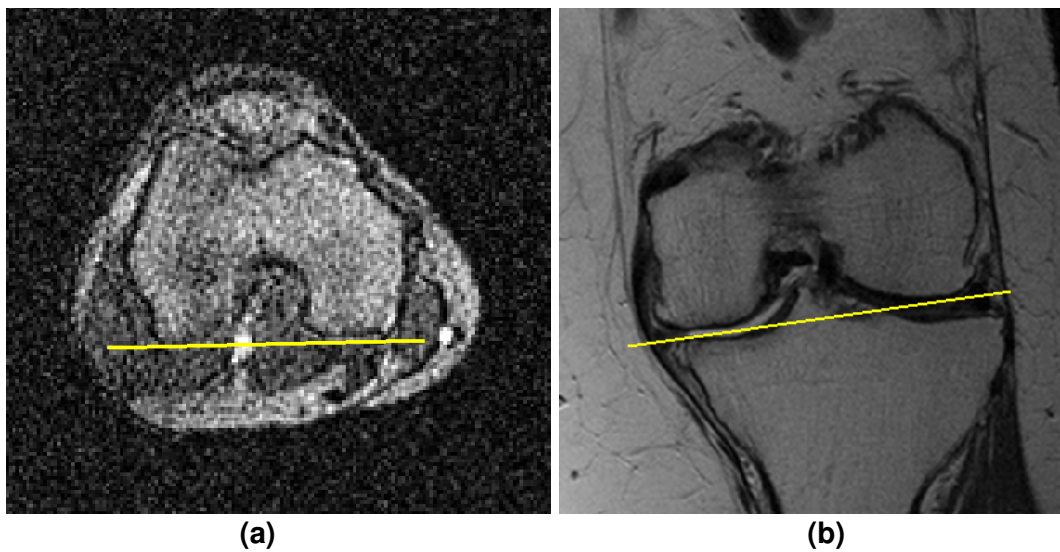
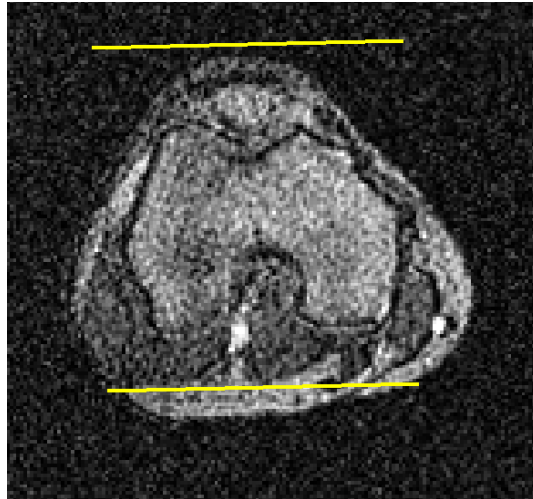


Figure 2

Slice Positioning through Posterior Reference and Distal Reference Lines

1. Using the best axial and coronal locator images that show in Figure 2
 - i. both posterior lateral and medial condyles, place slice parallel through the posterior reference for correct slice angle
 - ii. The both distal lateral and medial condyles, place slice parallel through the distal reference for correct slice angle.



**Figure 3
Slice Coverage**

2. Slice coverage must include all of the Femur including the condyles, Tibia and Patella as shown in Figure 3



**Figure 4
Centering FOV**

- Using the best sagittal locator image that shows the center of knee, adjust the FOV to be centered at the “point” of the femur as shown below in Figure 4.



Figure 5
Axial axis of the Knee joint

- Find the true Axial plane or axis of the knee joint as shown in Figure 5 by the yellow dash line.

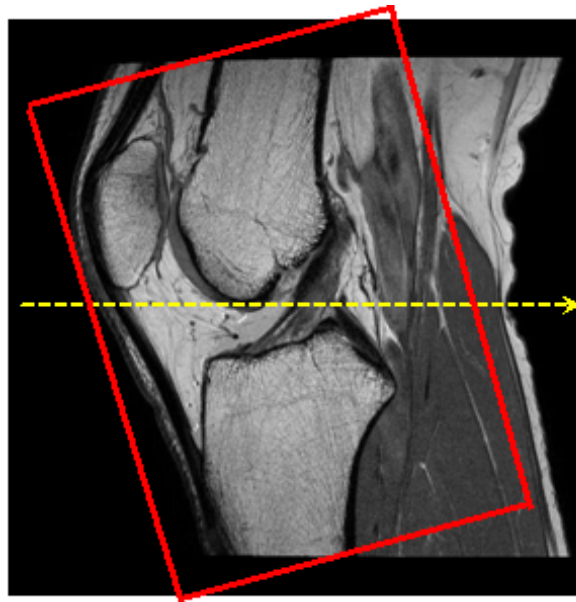


Figure 6
Slice Coverage



5. Enter File Series Name: “Coronal Knee.”

Lento Knee Imaging Reference for 1.5T and 3T MRI Scanners

1. General Electric

3plane Localizer Scan Parameter	GP FLEX (GE Users), 4mm x 1mm Skip 24cm FOV, Matrix 256x192
Coronal Knee: Pulse Sequence	FRFSE-XL CORONAL
Mode	2D
Imaging Option	No Phase Wrap ON, Tailored RF, 3DGR (3D Geometry Correction for software version 23+)
TE (Echo Time)	Min Full
TR (Repetition Time)	Use TR to get series in one acquisition
Flip Angle (deg)	90
Echo Train Length (ETL) Turbo Spin Factor (TSF)	7
FOV(Field of View)	18cm
Slice Thickness(mm)	3mm
Spacing/Skip/Gap/Distance Factor(mm)	0mm
Scan Matrix/Voxel Size (Base Resolution x Phase Resolution)	256 x 256
NEX/NSA/Averages	2
Frequency Direction	S/I

***Higher resolution than 256 x 256 is allowed, using software.**



2. Philips

3plane Localizer Scan Parameter	4mm x 1mm Gap, 240mm FOV, Voxel Size to equal 256 x 192
Coronal Knee: Pulse Sequence	TSE CORONAL
Mode	2D
Imaging Option	Fold Over, Suppression ON, 100% Sampling, "Default" Selected for Distortion Correction
TE (Echo Time)	~24 to 35 (28 nominal)
TR (Repetition Time)	Use TR to get shortest scan time
Flip Angle (deg)	90
Echo Train Length (ETL) Turbo Spin Factor (TSF)	8
FOV(Field of View)	180mm
Slice Thickness(mm)	3mm
Spacing/Skip/Gap/Distance Factor(mm)	0mm
Scan Matrix/Voxel Size (Base Resolution x Phase Resolution)	256 x 256
NEX/NSA/Averages	2
Frequency Direction	S/I

***Higher resolution than 256 x 256 is allowed, using software.**



3. Siemens

3plane Localizer Scan Parameter	4mm x 25% Distance Factor, 240mm FOV, Base Resolution 256 x 80% Phase Resolution
Coronal Knee: Pulse Sequence	TSE CORONAL
Mode	2D
Imaging Option	100% Phase Oversampling 3D Distortion Correction Filter ON
TE (Echo Time)	~24 to 35 (28 nominal)
TR (Repetition Time)	Use TR to get shortest scan time
Flip Angle (deg)	120
Echo Train Length (ETL) Turbo Spin Factor (TSF)	7
FOV(Field of View)	180mm
Slice Thickness(mm)	3mm
Spacing/Skip/Gap/Distance Factor	0%
Scan Matrix/Voxel Size (Base Resolution x Phase Resolution)	256 x 256
NEX/NSA/Averages	2
Frequency Direction	H/F

***Higher resolution than 256 x 256 is allowed, using software.**



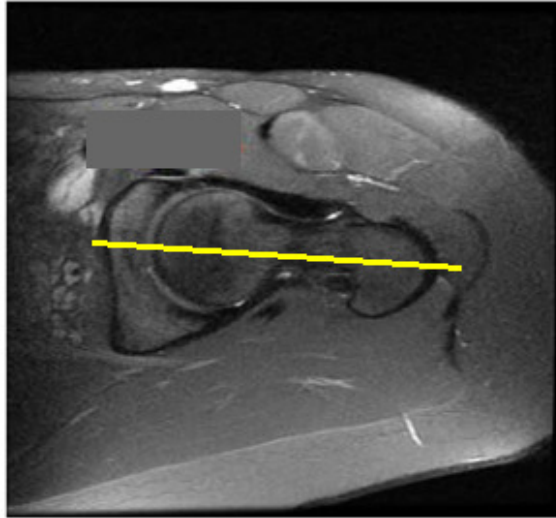
4. Toshiba

3plane Localizer Scan Parameter	4mm x 1mm Spacing, 24cm FOV, Matrix 256 x 192
Coronal Knee: Pulse Sequence	TSE CORONAL
Mode	2D
Imaging Option	Fold Over Suppression ON, IDC(Intelligent Distortion Correction) Selected
TE (Echo Time)	~24 to 35 (28 nominal)
TR (Repetition Time)	Use TR to get shortest scan time
Flip Angle (deg)	90, Flop Angle 160
Echo Train Length (ETL) Turbo Spin Factor (TSF)	7
FOV(Field of View)	18cm
Slice Thickness(mm)	3mm
Spacing/Skip/Gap/Distance Factor(mm)	0mm
Scan Matrix/Voxel Size (Base Resolution x Phase Resolution)	256 x 256
NEX/NSA/Averages	2
Frequency Direction	S/I

***Higher resolution than 256 x 256 is allowed, using software.**

G. CORONAL T1 HIP MRI PROTOCOL AND SLICE POSITIONING

1. Perform one 3 plane (Axial, Sagittal, Coronal) locator scan.
2. Perform a Coronal (T1 FSE) series using the minimum scan parameters total below:
3. Place Coronal slice plane parallel through long axis of the femoral neck when viewing the axial locator as shown in Figure 8. Center the 14 slices to cover the Femoral Head, Neck, and Greater Trochanter as shown in Figure 9.



**Figure 10
Center Hip FOV**

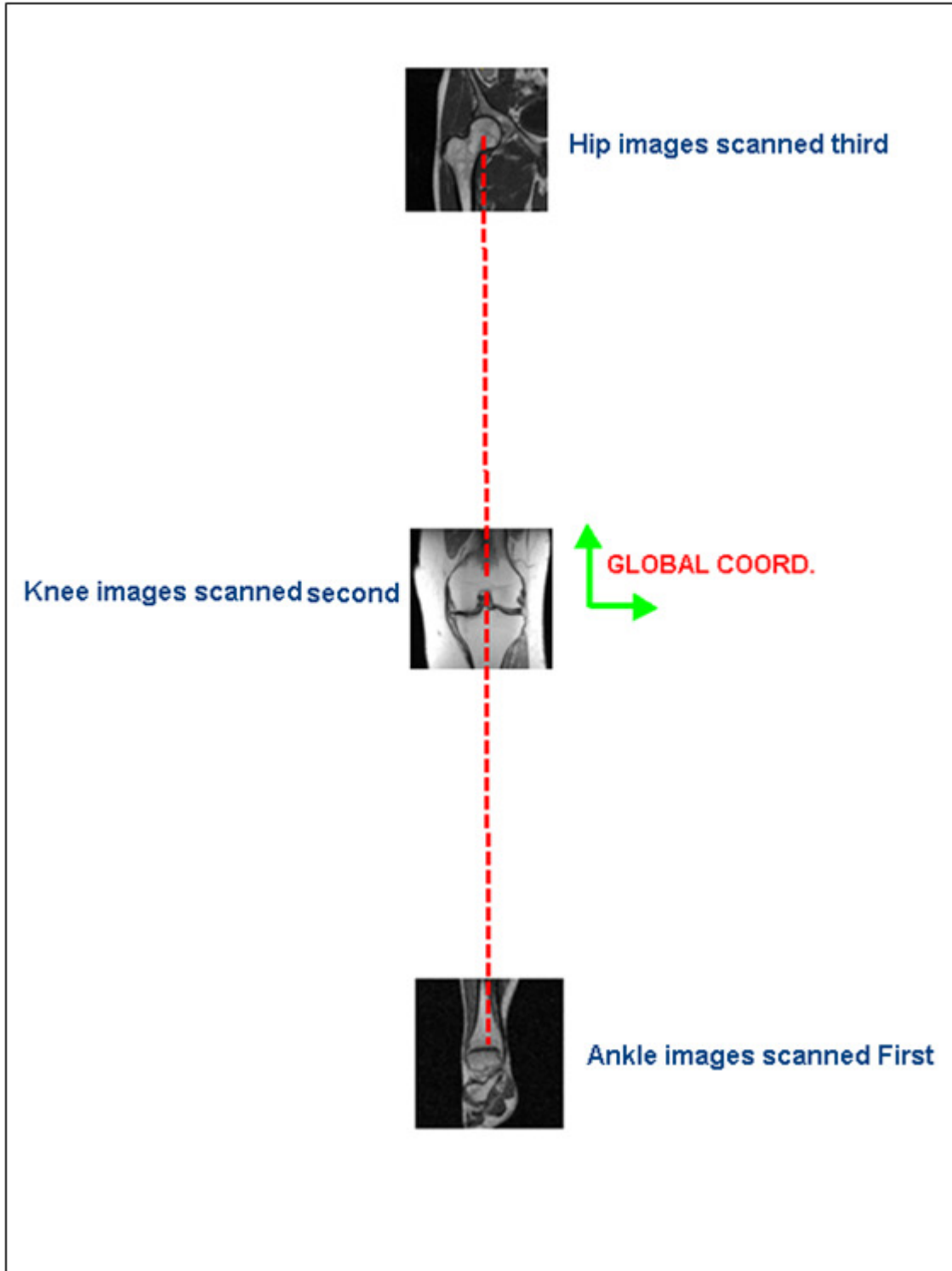
Slice Plane:	Coronal
Slice thickness (mm):	4
Spacing/Gap (mm):	1
Number of slices:	14
FOV(mm):	240 mm
Matrix:	256 x 160
NEX:	2
NPW/Anti-Aliasing/Fold Over Suppression:	ON
File Series Name:	"Coronal Hip"

I. QUALITY CHECK AND METAL ARTIFACT INSTRUCTIONS

- a. Coverage: Include 1 or 2 slices of soft tissue on both medial and lateral side of bony knee anatomy.
- b. Motion: Make sure sequential transition of the bone/cartilage outline does not jump or shift back and forth between slices
- c. If patient presents with metal in the affected lower extremity follow these instructions
 - Metal Hardware Knee – Do **NOT** Scan the patient. Refer them back to the surgeon
 - Metal Hardware Hip and/or Distal Tibia – Use MARS (Metal Artifact Reduction Sequence) series. Keep in mind the FOV, Slice Thickness, and Spacing/Gap/Skip/Distance Factor must be set to our parameters. Do not use FAT SAT at any time.
 - For those facilities that do not use a MARS series, increase the bandwidth and NEX/NAQ/NSA to help increase signal to noise ratio.

II. FILE FORMAT & OUTPUT

- a. Save all image series in DICOM format
- b. Upload the following DICOM files to Lento Medical's database (www.LentoMedical.net)
 - i. Coronal FSE PD Knee Series
 - ii. Coronal FSE PD Hip Series
 - iii. Coronal FSE PD Ankle Series



**Figure 11
Scanning Order**

III. HIP, ANKLE, AND KNEE MRI SAMPLE IMAGES

a. HIP MRI



(a)

(b)

(c)

b. ANKLE MRI

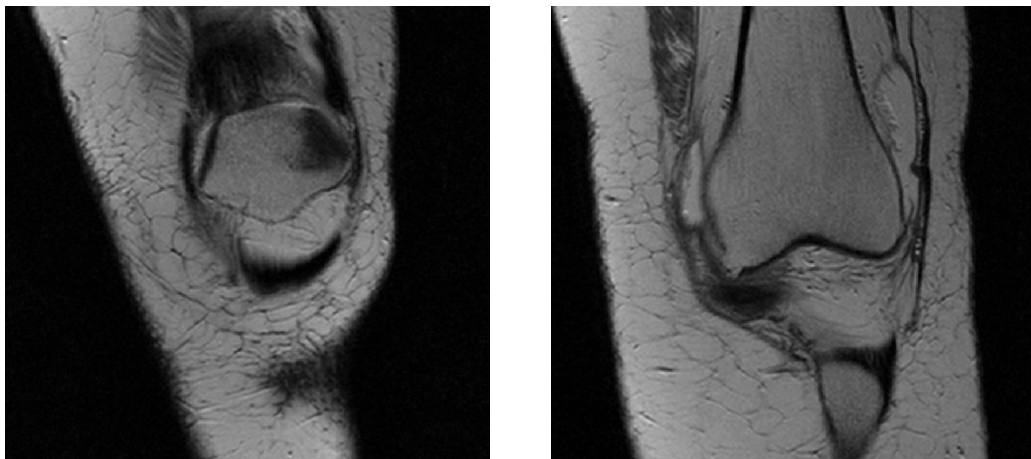


(a)

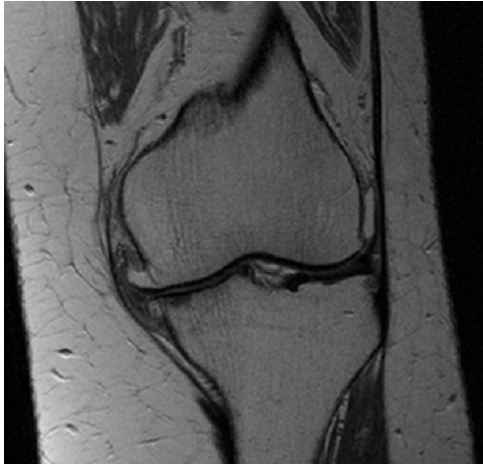
(b)

(c)

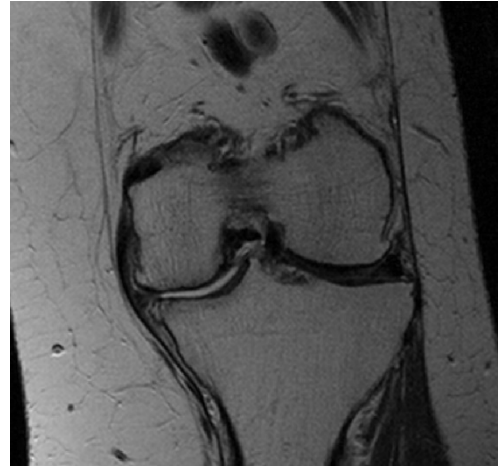
c. KNEE MRI



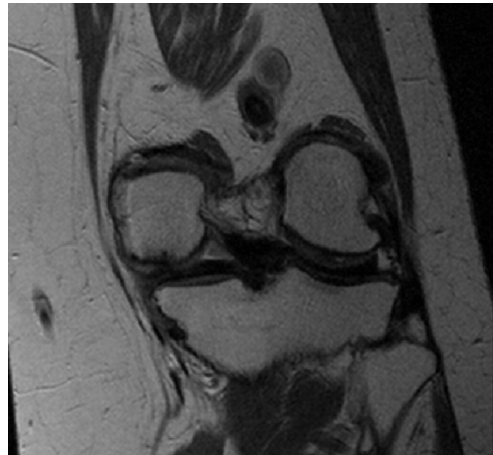
(a)



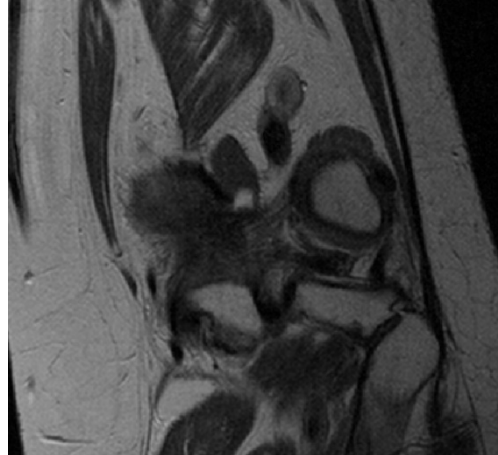
(b)



(c)



(d)



(e)

(f)