

Annex #1: CT scan protocol for patient-specific bone strength prediction

Calibration

At the outset of the study, European spine phantom (ESP) needs to be scanned on each CT scanner that will be used during the study. If such phantom is not available at the requester's hospital, one of our experts can do a calibration session on site with our own phantom. A calibration protocol must be performed for each scanner and for each Current/Voltage setting to be used in the study.

We assume that modern CT scanners x-ray tubes are stable for at least 12 months. If the study last longer than 12 months, then ESP scan should be repeated every 12 months.

Please notice that this calibration is different from those performed by standard Quality Assurance protocols in place in most hospitals and is an essential requirement for model development.

Imaging Protocol

All subjects should receive a bilateral full femoral CT scan, which should extend from 2cm above the femoral head to 2cm below the knee. In order to have an optimal calibration with an acceptable radiation dose the CT scans should be performed at 100 kV, and a constant tube current; any automatic algorithm that adjust current/voltage dynamically during the scan should be excluded.

We recommend using a standardised current of 120 mA, which is ok for female patients of average body weight. If the cohort includes patients with lower or higher than average body weight, we can process also data collected at 80, 100, 120, 140 mA, as far as the current remains constant during the whole scan. If this second approach is to be used, we will need a full calibration scan of ESP at each current value to be used in the cohort.

For GE CT scanners, we recommend using **Standard** reconstruction algorithm.

For other CT scanners (Siemens, Toshiba etc) please contact us to discuss the appropriate reconstruction algorithm for the study.

Old CT Scanners

Voltage: 100kV

Current: 120mA

CT scan protocol should be organised in three blocks with different settings in the femoral diaphysis and the two epiphyses (Figure 1). For spiral CT systems the Pitch P and the longitudinal dimension of the detector collimation D should be set for each block as indicated in Figure 1.

New CT Scanners

Voltage: 100kV

Current: 120mA

CT scan should be performed with uniform slice thickness of 0.625mm and a pitch of 1 over the whole femur.

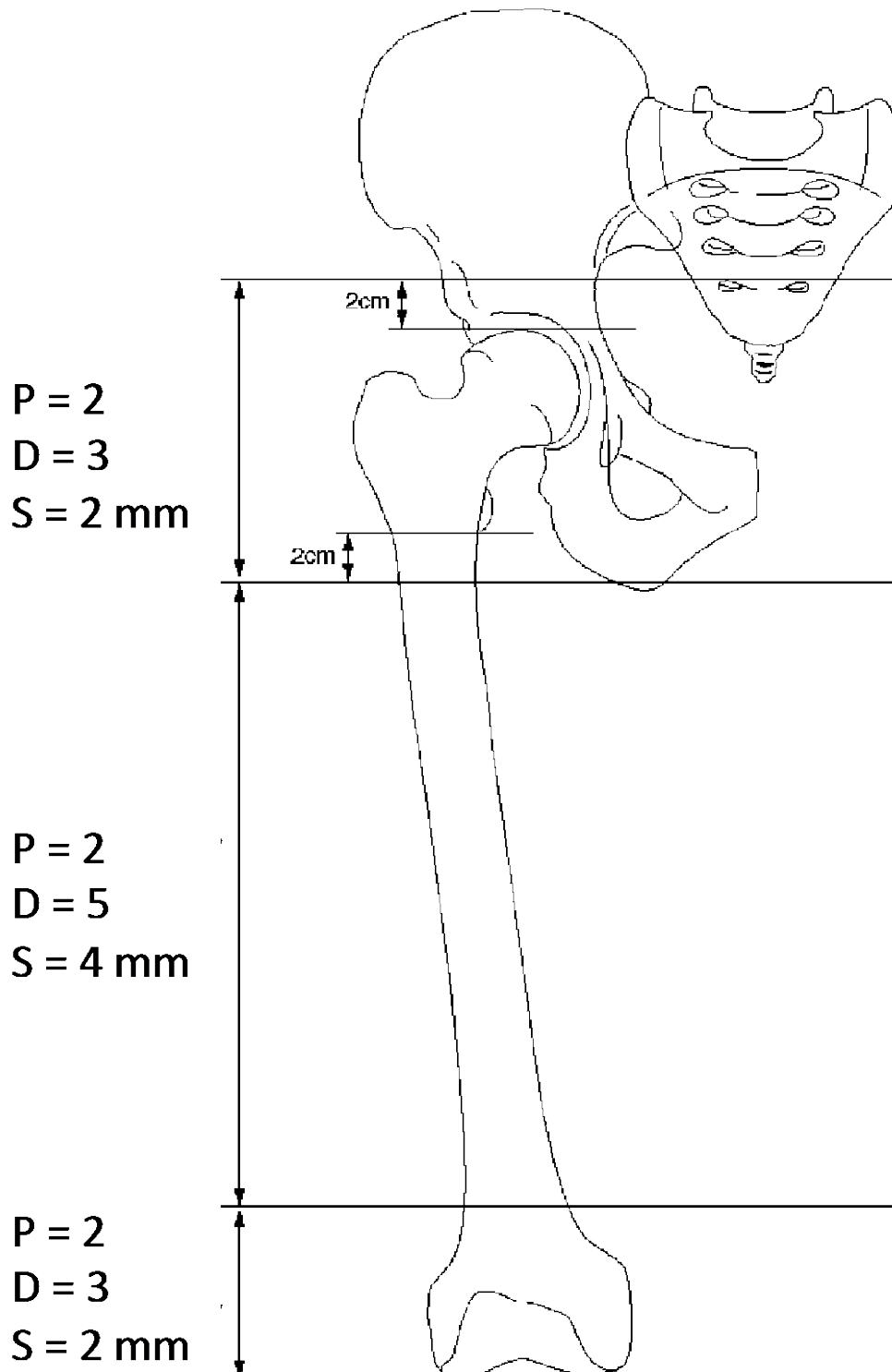


Figure 1: Whole femur should be scanned with a slice thickness of 2mm in the distal and proximal epiphysis and 4mm in the diaphysis.

Radiation Dose

The ImPACT CT Patient Dosimetry Calculator was used to compute effective radiation dose. It makes use of the “Normalised organ doses for x-ray computed tomography calculated using Monte Carlo techniques” NRPB-SR250 released by Public Health England on 11/2014, and based on the organ weighting scheme ICRP-103. It calculates the effective dose in mSv for each organ present within the scan length. Mathematical phantom used with ImPACT software extends from head through proximal femur only. CT dose calculations were done for GE LightSpeed CT scanner. Effective dose was calculated for a proximal femur scan in males and females.

Currently the proximal femur scan is performed at 120 kV and the tube current is modulated between 80 mA and 200 mA with a slice thickness of 0.625mm. This corresponds to effective dose in the range of **2.5 – 6.2 mSv** for males and **1.5 – 3.8 mSv** for females.

When we analyse the distribution of dose in different organs, we find that majority of the dose is contributed by gonads, colon and bladder for both females and males. For example, the total effective dose for males at 120kV/200mA is 6.2 mSv. Its distribution among different organs in mSv is as follows:

Gonads:	3	Bone marrow:	0.47
Colon:	1	Bone surface:	0.09
Bladder:	1.2	Skin:	0.06

Thus, more than 80% of the dose is contributed by the above-mentioned three organs. If we extend the scan length to include whole femur up to below the knee, the additional dose contribution would come from bone marrow, bone surface and skin. In order to estimate the effective dose for full femur scan, we assumed the additional dose to be double the value of total dose contributed by bone marrow, bone surface and skin in the proximal femur scan. For the current clinical protocol settings, it will be an additional 1.24 mSv.

By reducing the tube voltage from 120 kV to 100 kV while keeping the remaining scan settings the same, the whole femur scan would result in an effective radiation dose in the range of **1.9 – 4.8 mSv** for males and **1.3 – 3.2 mSv** for females.