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CT-BIT: Bone Investigational Toolkit

INVESTIGATIONAL USE ONLY

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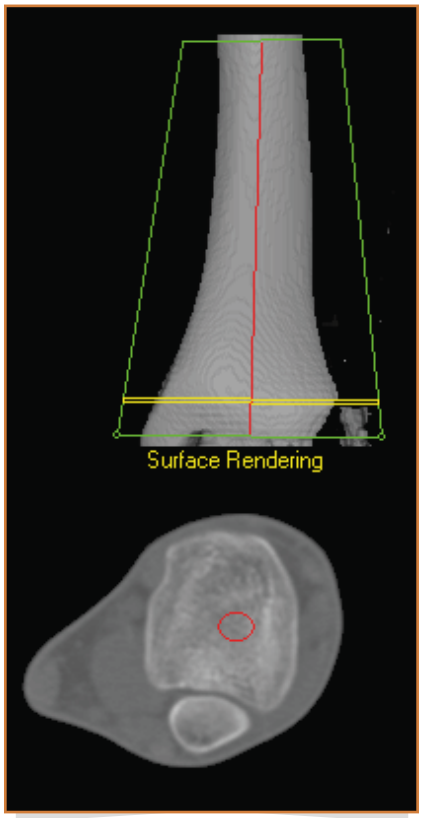
Standard volumetric QCT can provide a detailed 3D representation of bone structure at the spine and hip. The MindwaysCT Bone Investigational Toolkit (CT-BIT) extends our QCT Pro™ and CliniQCT® asynchronous calibration software software to produce accurate BMD analysis beyond these regions. In addition, CT-BIT calculates mineral density distribution and geometry information to allow the characterization of bone status or change in response to therapy, aging or disease processes. Through its script-driven flexibility, the QCT Pro™ CT-BIT extension provides access to a vast array of measures and capabilities for the investigation of bone.

Volumetric pQCT

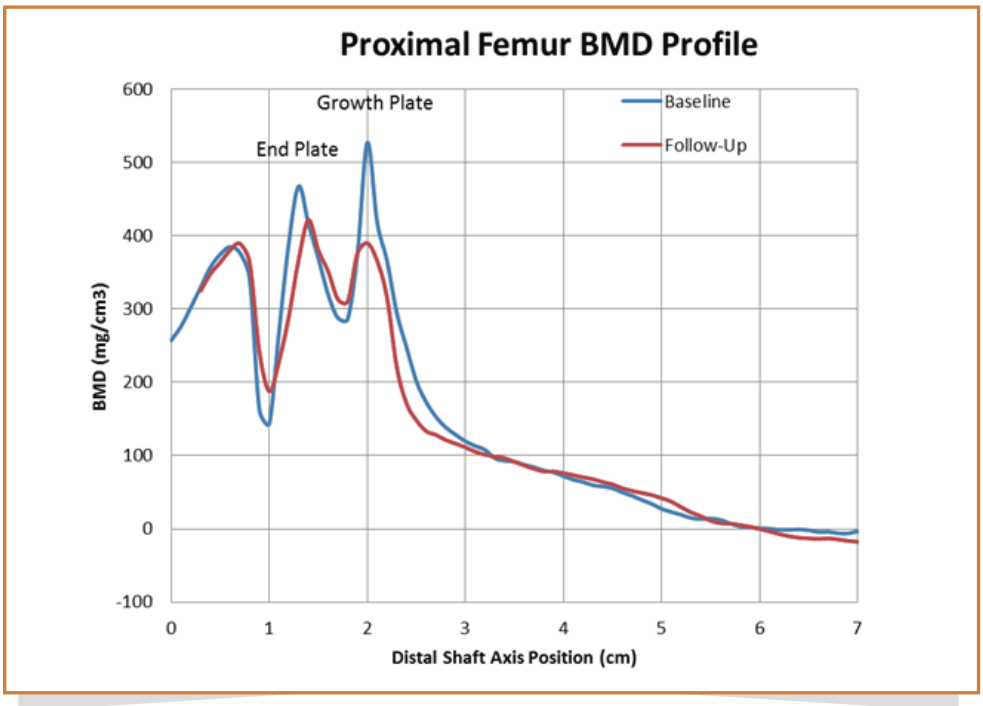
QCT can have a particular advantage in pediatric bone density measurement, where bone size will significantly alter areal BMD as measured by DXA making it almost impossible to differentiate between growth and an actual increase in bone density. Because x-ray dose is usually a factor in the diagnostic evaluation of children, peripheral QCT (pQCT) rather than axial QCT spine or hip measures are often used to provide BMD measurement at the radius or tibia.

Until recently, pQCT has usually been performed on a dedicated machine, but there are significant advantages to performing pQCT bone density assessment on a clinical Whole Body Scanner using QCT Pro™ CT-BIT:

- The cost of adding a QCT system to a standard CT scanner is considerably less than the cost of a dedicated pQCT machine;
- Patient motion artifacts are reduced with scan times of a few seconds instead of the 90 seconds per slice using a dedicated pQCT machine;
- Accurate matching of sections of bone during growth are feasible with a volume compared with scanning a few slices using a dedicated machine.



An entire volume may be analyzed instead of having to identify individual slices.



The growth plates of developing bones may be matched for accurate time-series comparison

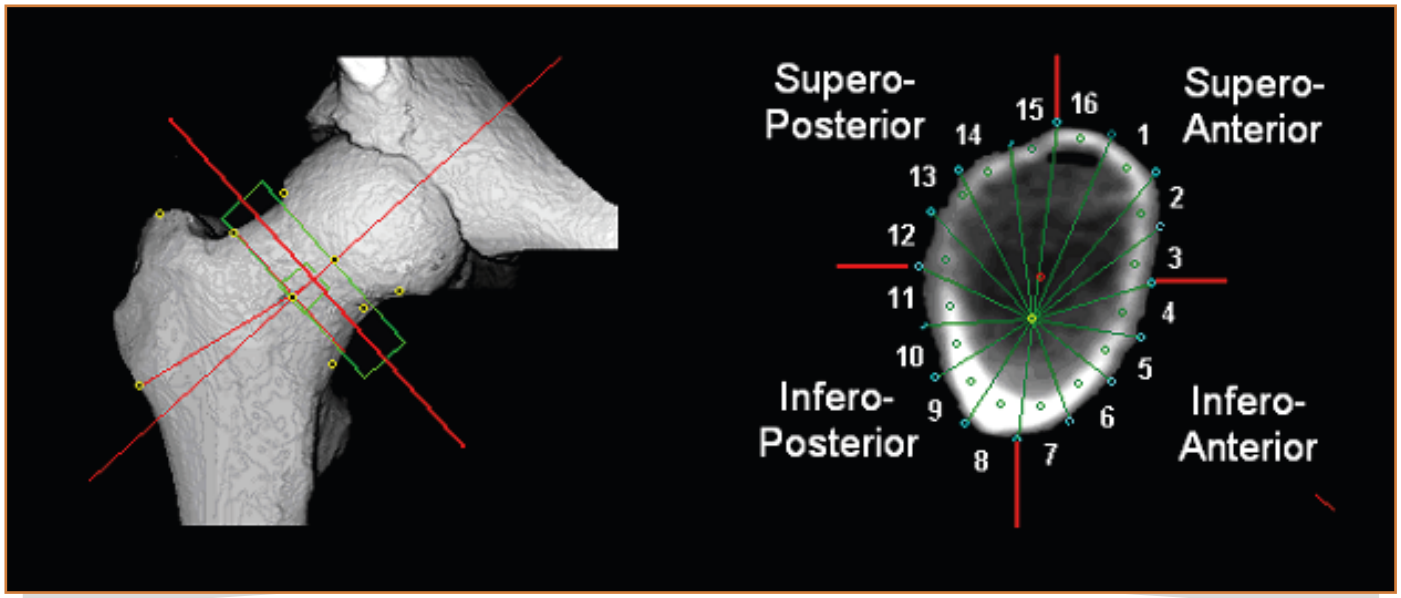
CT- BIT Cross-Sectional Image Measurements

- Cortical Area
- Trabecular Area
- Cortical Thickness
- Principal Axes
- Bending Moments (CSMI)
- Section Moduli
- Buckling Ratio

Cortical Thickness Measures

Focal thinning of cortical bone in the proximal femur may predispose a hip to fracture. Detecting such defects in clinical CT is challenging; cortical bone may be significantly thinner than the imaging system resolution. Accurate cortical thickness estimation requires good estimation of the cortical density which is provided by QCT.

The CT-BIT extension provides a flexible script-driven framework for cortical thickness measurement using QCT data from QCT Pro™. Comparison of measurements may be made using an automated frame of reference based upon anatomical landmarks for accurate registration. In addition, cortical thickness and distribution measurement may be made at anatomical sites other than the hip.

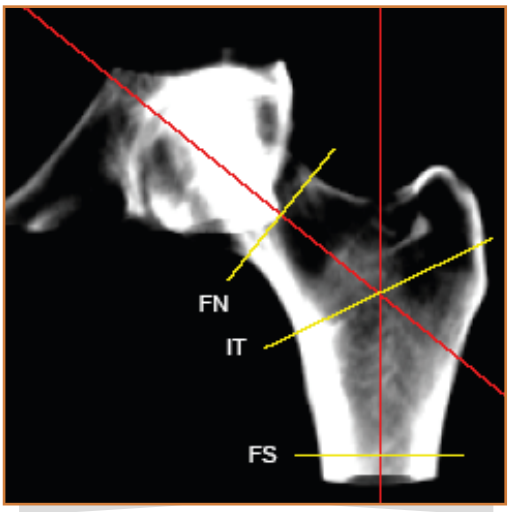


Cortical thickness measurements are made using a radial coordinate system based on anatomical landmarks

HSA and Cross Sectional Analysis

CT-BIT incorporates standard Hip Structural Analysis (HSA) measures using DXA-like area density projections methods to analyze three cross-sectional profiles at the Femoral Neck (FN); Intertrochanteric (IT) and Femoral Shaft (FS) regions. For each region, the distribution of the bone mass across the bone is extracted then parameters related to geometry and mechanical strength are calculated.

Volume density in cortical, trabecular and total bone compartments may also be extracted at the spine or peripheral sites such as the tibia or radius. In addition, CT-BIT includes template analysis scripts to help you customize and automate the complex analysis of your sets of QCT image data.



The standard HSA measures may be calculated at femoral Neck (FN), Intertrochanter (IT) and Femoral Shaft (FS) regions.

Data Export

CT-BIT analysis results are stored in the standard QCT Pro™ database. The database contents can be exported as delimited text files that can be imported into applications such as SPSS® or Excel® or other applications for further data processing and statistical analysis. Additionally, 2D projection images, cross-sectional images and reformatted volumetric data sets can be exported in DICOM format for use in your own or third-party applications.

The QCT Pro™ Bone Investigational Toolkit includes:

- DICOM File Import Tools
- Supplementary Femoral Neck Analysis and Image Export Tools
- Cross-Sectional Image Analysis Module
- QCT Pro™ Header Editor for anonymizing cases
- QCT Pro™ Image Editor
- QCT Pro™ Database Export Utility

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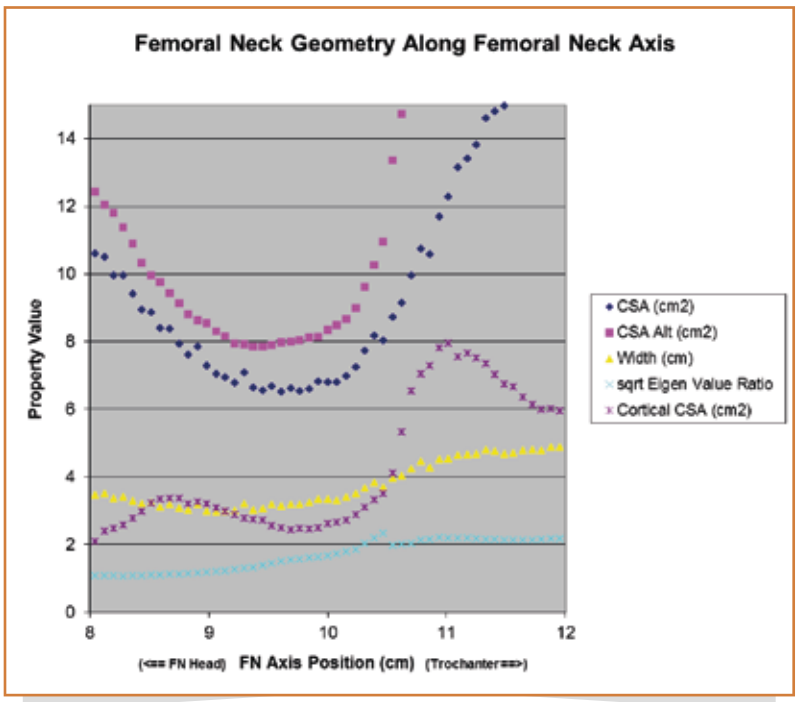
Excel® is a registered trademark of Microsoft Corporation



Exported data can be easily exported for further analysis in third-party applications.

Asynchronous Calibration

CT-BIT™ can also be used with CliniQCT®, our asynchronous calibration technology which means a calibration phantom does not need to be present on the table during the QCT scan. CliniQCT® calibration technology means better workflow and efficient re-use of CT scans acquired for other purposes, including the retrospective analysis of archived CT images.