Purpose: To assess the diagnostic performance of a prototype cone-beam CT (CBCT) scanner developed for musculoskeletal extremity imaging. Studies involved controlled observer studies conducted subsequent to rigorous technical assessment as well as patient images from the first clinical trial in imaging the hand and knee.

Methods: Performance assessment included: 1.) rigorous technical assessment; 2.) controlled observer studies using CBCT images of cadaveric specimens; and 3.) first clinical images. Technical assessment included measurement of spatial resolution (MTF), contrast, and noise (SDNR) versus kVp and dose using standard CT phantoms. Diagnostic performance in comparison to multi-detector CT (MDCT) was assessed in controlled observer studies involving 12 cadaveric hands and knees scanned with and without abnormality (fracture). Observer studies involved five radiologists rating pertinent diagnostics tasks in 9-point preference and 10-point diagnostic satisfaction scales. Finally, the first clinical images from an ongoing pilot study were assessed in terms of diagnostic utility in disease assessment and overall workflow in patient setup.

Results: Quantitative assessment demonstrated sub-mm spatial resolution (MTF exceeding 10% out to 15-20 cm-1) and SDNR sufficient for relevant soft-tissue visualization tasks at dose <10 mGy. Observer studies confirmed optimal acquisition techniques and demonstrated superior utility of combined soft-tissue visualization and isotropic spatial resolution in diagnostic tasks. Images from the patient trial demonstrate exquisite contrast and detail and the ability to detect tissue impingement in weight-bearing exams.

Conclusions: The prototype CBCT scanner provides isotropic spatial resolution superior to standard-protocol MDCT with soft-tissue visibility sufficient for a broad range of diagnostic tasks in musculoskeletal radiology. Dosimetry and workflow were advantageous in comparison to whole-body MDCT. Multi-mode and weight-bearing capabilities add valuable functionality. An ongoing clinical study further assesses diagnostic utility and defines the role of such technology in the diagnostic arsenal.

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