Point-of-Care Tomosynthesis Imaging of the Wrist

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ABSTRACT

Introduction:

Musculoskeletal injury to extremities is a common issue for both stateside and deployed military personnel, as well as the general public. Superposition of anatomy can make diagnosis difficult using standard clinical techniques. There is a need for increased diagnostic accuracy at the point-of-care for military personnel in both training and operational environments, as well as assessment during follow-up treatment to optimize care and expedite return to service. Orthopedic tomosynthesis is rapidly emerging as an alternative to digital radiography (DR), exhibiting an increase in sensitivity for some clinical tasks, including diagnosis and follow-up of fracture and arthritis. Commercially available digital tomosynthesis systems are large complex devices. A compact device for extremity tomosynthesis (TomoE) was previously demonstrated using carbon nanotube X-ray source array technology. The purpose of this study was to prepare and evaluate the prototype device for an Institutional Review Board-approved patient wrist imaging study and provide initial patient imaging results.

Materials and Methods:

A benchtop device was constructed using a carbon nanotube X-ray source array and a flat panel digital detector. Twenty-one X-ray projection images of cadaveric specimens and human subjects were acquired at incident angles from −20 to +20 degrees in various clinical orientations, with entrance dose calibrated to commercial digital tomosynthesis wrist scans. The projection images were processed with an iterative reconstruction algorithm in 1 mm slices. Reconstruction slice images were evaluated by a radiologist for feature conspicuity and diagnostic accuracy.

Results:

The TomoE image quality was found to provide more diagnostic information than DR, with reconstruction slices exhibiting delineation of joint space, visual conspicuity of trabecular bone, bone erosions, fractures, and clear depiction of normal anatomical features. The scan time was 15 seconds and the skin entrance dose was verified to be 0.2 mGy.

Conclusions:

The TomoE device image quality has been evaluated using cadaveric specimens. Dose was calibrated for a patient imaging study. Initial patient images depict a high level of anatomical detail and an increase in diagnostic value compared to DR.

INTRODUCTION

Musculoskeletal injury (MSKI) is an enormous burden to the U.S. Armed Forces, responsible for more than half of the medically nondeployable military population, resulting in 2 million health care visits annually.[1] Musculoskeletal injury is the chief medical issue undermining military readiness.[2] Though combat-related MSKI can be life-threatening, noncombat-related MSKI occurs six times more frequently.[1] In a study of recent conflicts in Iraq and Afghanistan (2003–2014), 47% of all 19,755 non-battle injuries involved the extremities.[3] Extremity injury is generally assessed with conventional two-dimensional digital radiography (DR), but complex anatomy of the wrist can make diagnosis difficult or impossible with standard DR.[4] The scaphoid is particularly concerning, as an undiagnosed fracture can result in avascular necrosis requiring subsequent surgical stabilization and chronic pain. Unfortunately, up to 30% of scaphoid fractures are missed in initial imaging with DR and are often recommended for escalation to computed tomography (CT), if available.[5,6] Computed tomography scanners are sensitive to temperature, humidity, vibration, particulates, and chemicals, so are not well-suited for deployment to austere environments.

Digital tomosynthesis (DTS) is rapidly emerging as a valuable tool in orthopedic imaging, providing an increase in diagnostic accuracy over standard DR.[5] Digital tomosynthesis

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has been shown to detect scaphoid fractures as effectively as CT but with much lower patient radiation dose and monetary cost.[7] Commercially available DTS systems employ a single X-ray source and complex mechanical translation to acquire projection images of the patient at various incident angles for reconstruction into quasi three-dimensional reconstruction slice images. The images are presented in a stack, allowing the reader to scroll through the anatomy and effectively remove superimposed features. Digital tomosynthesis systems typically require a large room to accommodate the hardware. Our team previously demonstrated the feasibility of constructing a compact tomosynthesis system for imaging of extremities.[8] A carbon nanotube X-ray source array was incorporated in lieu of a conventional single-beam X-ray tube. The purpose of this study was to evaluate the prototype device in preparation for an Institutional Review Board-approved patient imaging study to investigate clinical utility for detection of fractures within the scaphoid and/or distal radius.

METHODS

Compact Extremity Tomosynthesis (TomoE) Device

The experimental imaging system is a benchtop device composed of an X-ray source array (XinVivo, Inc., Morrisville, NC), containing seven individually addressable carbon nanotube-enabled focal spots, and a digital flat panel detector (Teledyne Dalsa, Waterloo, ON, Canada) (Fig. 1). The array is operated in three positions to mimic a long source array, to achieve a larger angular span. Projections are acquired over a linear distance of 29 cm, generating a 40 degree angular span at the source-to-detector distance of 40 cm. The detector is a 30 × 30 cm panel with 99 μm pixel size. Fig. 1a depicts the shielded system and Fig. 1b depicts the system hardware, including the source array, translation stage, and flat panel detector.

Image Acquisition

The scan sequence is performed by operating the source array in three positions (Fig. 1b). Seven projections are acquired at 7 frames per second in each position, with 2 translations, for a total of 21 projections and total scan time of 15 seconds. The tube is operated at a voltage of 55 kVp, tube current of 2 mA,and various exposure levels. Projection images were reconstructed with an iterative reconstruction technique.

Dosimetry

Skin entrance dose was evaluated at multiple exposure levels with a dosimeter and ion chamber (Accu Pro, RadCal Corp., Monrovia, CA). Literature values for commercial DTS wrist scans range from 0.185 to 0.25 mGy.[9–11] Peak anode voltage was also verified with the dosimeter and kilovoltage accessory.

Phantom, Specimen, and Patient Imaging

A line pair test phantom was imaged to assess system resolution. Plot profiles were acquired in various regions of interest (ROI) in the reconstruction slice image in the plane of focus of the bar pattern to determine the ultimate in-plane spatial resolution.

Four cadaver wrist specimens were imaged in multiple orientations to assess image quality and validate system hardware configurations. Four ankle specimens were imaged to evaluate potential clinical utility of the device for future imaging studies.

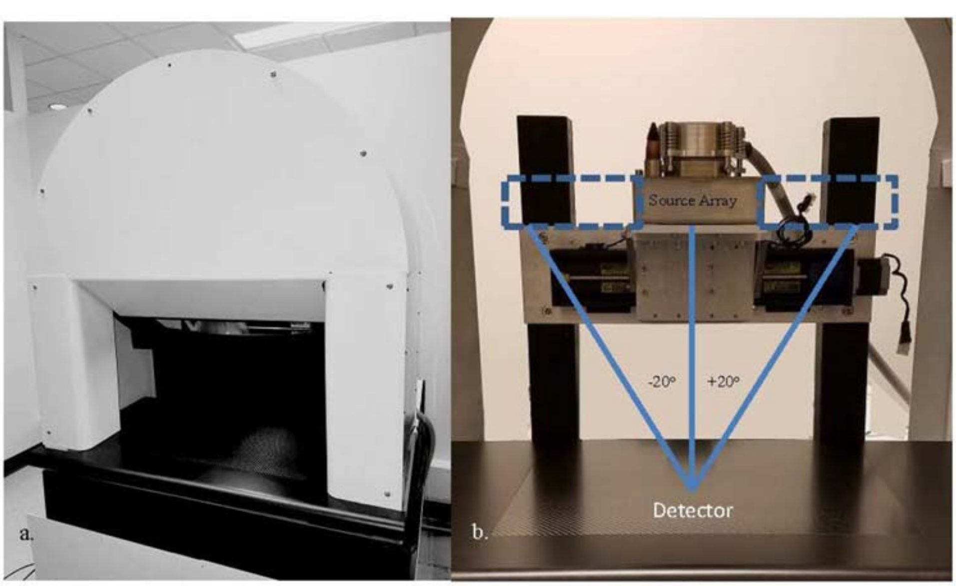

FIGURE 1. Compact extremity tomosynthesis system (a) with and (b) without shielding panels; the source array is shown at the central imaging position. Dashed lines represent the other 2 positions used to achieve 40 degrees of angular coverage.

A patient imaging study was approved by the campus Institutional Review Board and registered at ClinicalTrials.gov.[12] The patient study was initiated with exposure calibrated to generate an entrance skin dose of 0.2 mGy. At the time of writing, two patients with suspected fracture had been imaged with DR (Siemens FLUOROSPOT Compact, Siemens Healthineers, Munich, Germany) and subsequently with the TomoE device.

Specimen and patient images were reviewed by a radiologist for diagnostic accuracy and feature conspicuity.

RESULTS

Dosimetry

The system was operated at multiple exposure levels and a dose relationship established. Total exposure was adjusted to 0.076 mAs to produce a skin entrance dose of 0.20 ± 0.01 mGy, measured with the dosimeter. Peak anode voltage was assessed three times with a computed average of 54.9 $\pm$ 1.2 kVp.

Scan Time

The total active scan time, including imaging and 2 linear translations, was 15 seconds. This is clinically acceptable and should not result in substantial patient motion.

Image Quality

A reconstruction slice image in the plane of focus of the line pair phantom is shown in Fig. 2. The magnified image (Fig. 2b) indicates the ROI assessed by the plot profile (Fig. 2c). The bars are clearly delineated up to approximately three line pairs per millimeter, after which they are indistinguishable.

Eight cadaver specimens, four wrists and four ankles, were successfully imaged at multiple exposure settings with the TomoE device. Reconstructions were performed at 1 mm slice thickness, similar to literature values.[9–11]

Sample reconstruction slice images are shown in Fig. 3. Fig. 3a and b are slice images of a wrist, acquired in a posterior-anterior (PA) orientation. Fig. 3a is in the plane of focus of the triquetrum, lunate, scaphoid, and capitate. Fig. 3b, a slice 6 mm anterior, depicts the trapezium, hook of the hamate, and pisiform. Reconstruction slice images of an ankle, acquired in an oblique orientation, are shown in Fig. 3c and d. Fig. 3c is in the plane of focus of Lisfranc's joint and the distal mediotarsal joint, talus, navicular, cuneiform, cuboid, and distal metatarsal bones. Fig. 3d is a slice image 15 mm anterior and depicts the medial cuneiform, calcaneus, and first and second metatarsals. A radiologist reviewed the images in comparison to the corresponding conventional

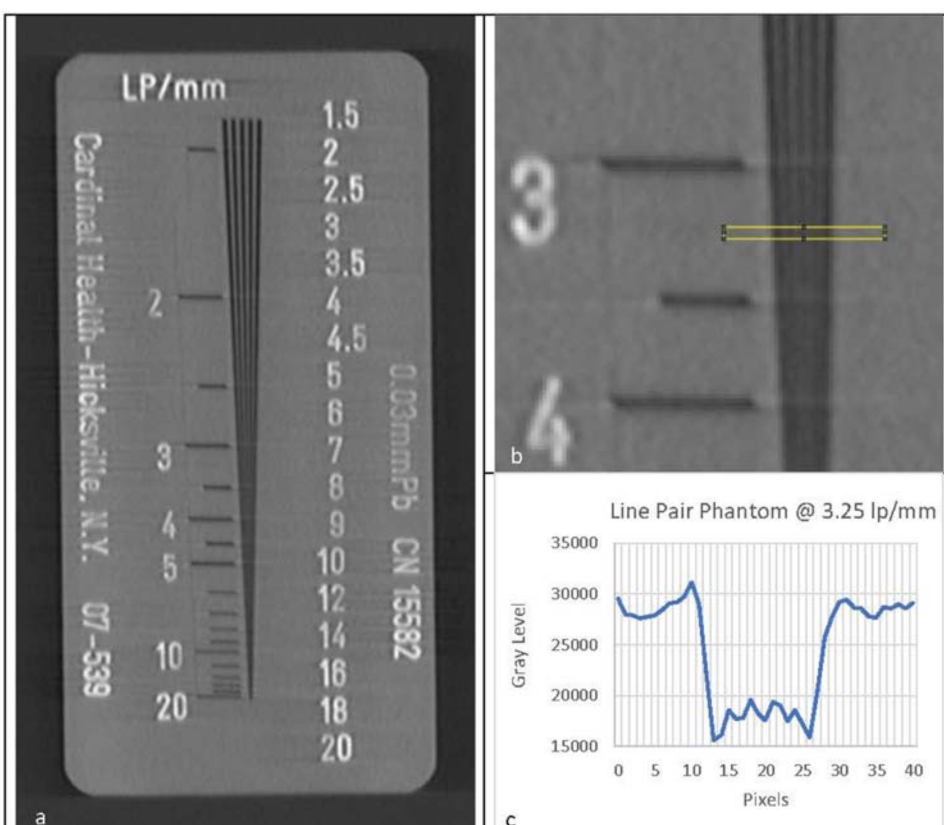

FIGURE 2. Reconstruction slice image (a) and inset (b) of line pair phantom with corresponding plot profile (rectangular ROI) indicating system resolution of >3 lp/mm.

FIGURE 3. Reconstruction slice images of cadaveric specimens: PA view of wrist (a), (b) and OBL view of an ankle (c), (d).

radiographs. Joint space and articulating surfaces were easily visualized in both wrist and ankle images and exposure level was deemed adequate for the wrist. Higher exposure protocols will be investigated for future studies including the foot and ankle.

Two patients had been imaged at the time of writing and sample images are shown in Fig. 4. Fig. 4a is a conventional PA radiograph of a suspected wrist fracture. Fig. 4b is the corresponding tomosynthesis reconstruction slice image in the plane of focus of the posterior aspect of the distal radius. The four-view DR wrist series and PA tomosynthesis reconstruction images were reviewed by a radiologist. The reconstruction slice images of this patient were found to have equivalent visualization of articulating surfaces, with improved conspicuity of joint space and subchondral bone over the DR images. The presence of fracture in the distal radius was obvious in both modalities, though the reconstruction slice images provided additional detail as a comminuted fracture with intra-articular extension.

DISCUSSION

Dose

The system was calibrated to match reported dose for commercial DTS wrist scans. Though DTS results in slightly higher dose than DR, it is substantially less than CT.[9–11] Ankle images in this study were acquired using the wrist protocol, though commercial DTS ankle/foot scans typically employ an increased exposure.[13] The source array is capable of much higher exposures and future studies involving lower extremities would require an additional dose-matching calibration.

FIGURE 4. Sample patient images: (a) radiograph; (b) corresponding reconstruction slice image clearly depicting fractures in the distal radius.

Scan Time

Though a scan time of 15 seconds is clinically acceptable, a shorter time is desirable to reduce patient discomfort and reduce the likelihood of patient motion. This benchtop system was constructed using an existing short X-ray source array in three positions to mimic a longer array. Translation of the source array accounts for approximately 10 seconds. A clinical system would incorporate a purpose-built, longer source array with 21 focal spots, providing the 40-degree angular span with no mechanical motion. This would result in a substantial decrease of scan time.

Image Quality

The system resolution was found to be ~3 line pairs per millimeter. Though adequate for thin objects, such as the wrist in the PA orientation, this value will decrease with increasing object thickness in which features are further from the detector. A purpose-built system for fracture detection in larger extremities will require a smaller X-ray focal spot to achieve the needed system resolution.

A radiologist reviewed the tomosynthesis reconstruction slice PA specimen wrist images and found them to provide additional clinical utility over standard radiographs, with superior depiction of anatomy, including joint space, subchondral bone, and articulating surfaces. It was the opinion of the radiologist that the PA wrist scans incorporating higher exposure than 0.076 mAs did not substantially improve diagnostic accuracy and additional patient radiation dose is not warranted. Lateral wrist images (not shown) also displayed additional diagnostic information over DR, but lower image quality than PA reconstruction slice images because of increased object thickness, resulting in decreased penetration/contrast, and decreased source-detector distance, which exacerbates the effects of the finite focal spot size. An increase in exposure for lateral images may be beneficial. An X-ray source array with decreased focal spot size would also provide higher resolution images of thick anatomy and would be preferable in a purpose-built clinical system.

Ankle reconstruction slice images also provided additional diagnostic information in comparison to DR, although acquired at the low-dose wrist protocol. Image quality was somewhat lower in the ankle images than the wrist. Future studies involving the ankle would require an increase in exposure, comparable to commercial DTS systems, and would also benefit from a source array with smaller focal spot size.

Preliminary patient images are presented in this study in Fig. 4. The DR image appears to have higher resolution than the reconstruction slice image but contains substantial feature superposition (Fig. 4a). The tomosynthesis reconstruction image stack is composed of 60 images, each representing 1 mm of object thickness. Each image contains some focused features, with blurring of out-of-plane structures. The slice image presented is through the plane-of-focus of the posterior aspect of the distal radius, in which an intra-articular comminuted fracture is clearly visible (Fig. 4b). In adjacent slices (not shown), the depth and direction of the fracture are apparent to the reader. The fracture is much more subtle in the corresponding DR image, obscured by overlapping anatomy.

CONCLUSIONS

The TomoE device has been used to image cadaveric specimens to validate imaging protocols and skin entrance dose before an upcoming patient imaging study. Reconstruction slice images allow individualization of bones in the carpal and tarsal joints. Dose has been matched to literature values for commercial DTS systems and a patient imaging study has been initiated. Though the current sample size for both specimen and in vivo imaging is too low for meaningful statistical analysis, preliminary images indicate an increase in diagnostic information over conventional radiography. Full evaluation of the sensitivity, specificity, and receiver operating characteristics will be performed at the culmination of the patient imaging study.

Orthopedic tomosynthesis has been demonstrated to provide additional clinical utility over radiography and can replace CT for some tasks. The TomoE device accomplishes these tasks with a much smaller footprint and reduced complexity in comparison to commercially available DTS systems. A compact extremity imaging device such as this has military and civilian applications in trauma centers, orthopedic/rheumatology clinics, and could be fabricated for portable/ambulatory use. There is a need for increased diagnostic accuracy of extremity injuries at the point-of-care in military training and theater environments. A compact, robust imaging system would be valuable for initial diagnosis as well as for follow-up care to optimize outcomes and facilitate the return to active duty.

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CONFLICT OF INTEREST

Some of the authors are inventors on a pending patent application for stationary orthopedic tomosynthesis. Otto Zhou has equity ownership and serves on the board of directors of Xintek, Inc., to which the technologies used or evaluated in this project have been or will be licensed. Jianping Lu has equity ownership in Xintek, Inc. All activities have been approved by institutional COI committees.

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