

# **A Novel In-Office Cone Beam Computed Tomography (CBCT) Scanner for Early Diagnosis of Osteomyelitis in a Diabetic Patient**

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## **Abstract**

Osteomyelitis is one of the most feared complications of diabetic foot ulceration, which often leads to lower extremity amputation and disability. Early diagnosis of osteomyelitis increases the likelihood of successful treatment and allows to minimize surgical resection and preserve ambulatory function. Unfortunately, most of the currently available imaging modalities are of limited use in assessing early stages of bone infection due to their low specificity and sensitivity for early osteolytic changes. Magnetic resonance imaging, though sensitive and specific, is very costly, which precludes its use during initial assessment of diabetic foot infection. In this report, we describe the use of a novel portable cone-beam computed tomography (CBCT) device, PedCAT, which may serve as a relatively inexpensive, accurate and readily available tool for early diagnosis of osteomyelitis in a diabetic patient. The success of this imaging modality is illustrated by two case studies, in which the use of PedCAT allowed us to diagnose and treat osteomyelitis in a timely manner, before any signs of bone destruction became apparent on plain radiographs. Though this report focuses on osteomyelitis, we believe that portable CBCT scanners hold unlimited potential in facilitating an accurate diagnosis of many musculoskeletal deformities of lower extremities, and would make a useful addition to an arsenal of imaging modalities currently available to a podiatric surgeon.

## Introduction

Diabetes mellitus affects an estimated 285 million people worldwide, and its prevalence is currently on the rise.<sup>1</sup> Osteomyelitis is one of the most devastating complications of diabetes, affecting 20-66% of people with diabetic foot ulcers<sup>2</sup> and often culminating in amputations. Early diagnosis of osteomyelitis increases the likelihood of successful management and allows to minimize bone resection. However, despite the multitude of diagnostic modalities available, there is currently no single reliable and readily-available test for timely and accurate diagnosis. Though plain radiographs in conjunction with clinical findings continue to be the primary initial imaging modality for diagnosis of osteomyelitis, they may not reveal acute osteolytic changes for up to 20 days from the onset of infection, or until the bony density is reduced by 30-50%.<sup>3</sup> Nuclear imaging scans possess limited specificity and spatial resolution, and are expensive and time-consuming.<sup>4</sup> Though magnetic resonance imaging (MRI) is presently considered the most reliable imaging test for diagnosis of osteomyelitis,<sup>3</sup> its high cost significantly reduces its availability. The latest guidelines published by the Infectious Diseases Society of America (IDSA) suggest that MRI should be used for diagnosis of osteomyelitis in patients with diabetic foot infection only after they have failed a 2 weeks-long course of broad-spectrum antibiotics, and serial plain radiographs were inconclusive.<sup>5</sup> This approach may delay crucial surgical intervention in patients with acute bone infection and lead to unnecessary antibiotics exposure and more extensive bone loss. Therefore, an accurate and readily available modality for imaging of osteomyelitis is essential in order to achieve more timely diagnosis and improve outcomes.

Traditionally, computed tomography (CT) has been of limited use for diagnosis of lower extremity osteomyelitis due to its relatively low sensitivity and specificity compared to MRI, as well as high patient's radiation exposure.<sup>6</sup> While the advent of high-performance multi-detector CT (MDCT) scanners has remarkably improved the safety, quality and resolution of CT imaging,

its role in diagnosis of lower extremity pathology remained minimal due to its high cost and limited availability. Cone-beam computed tomography-based devices, with their compact size, affordable cost and high image quality have successfully bridged the gap between conventional CT and in-office three-dimensional data acquisition and image reconstruction. During the last 10 years, cone-beam computed tomography (CBCT) has become an imaging tool highly regarded in maxillofacial and dental reconstructive surgery.<sup>7-9</sup> Introduction of PedCAT, the first CBCT scanner designed for imaging of lower extremities, made CT more accessible for routine in-office diagnosis and preoperative planning of podiatric problems. This report describes our initial experience with PedCAT in diagnosing of early stages of osteomyelitis in diabetic patients.

## **Technique**

### *Conventional CT vs CBCT*

CBCT is a modified version of traditional computer tomography, which allows for faster image acquisition, reduced scanner size and lower radiation burden. The differences between the two types of imaging modalities are determined by the shape of the X-ray beam. The traditional CT scanners utilize a fan-shaped X-ray beam, which travels in a helical progression around the patient and acquires multiple two-dimensional projections of the field of view (FOV).<sup>10</sup> The acquired data set is then processed by the computer software, which performs an individual two-dimensional reconstruction of each slice and stacks the slices to obtain a three-dimensional image.<sup>10</sup>

In contrast to traditional CT, CBCT utilizes a three-dimensionally divergent cone-shaped X-ray beam, which still acquires two-dimensional image projections, but does so in a single 180 degrees revolution around the subject.<sup>11</sup> CBCT's acquisition of the entire FOV in one rotation eliminates the need for multiple gantry excursions around the area of interest and leads to a more rapid data collection. The shorter scan time results in improved image sharpness due to

reduction in patient's external and internal movement artifacts.<sup>8</sup> In addition, decreased scan time drastically reduces patient's radiation exposure and makes CBCT-based devices a safer alternative to conventional CT (Table 1).

The type of imaging source-detector complex is another principle difference that distinguishes CBCT from CT. Traditional CT machines are composed of a high-photon rotating anode generator and solid-state charge-coupled device detectors.<sup>8</sup> Such configuration is very bulky and expensive, which limits CT's availability to major hospitals that are able to accommodate the large size and afford the high cost of the scanner. In contrast, CBCT devices consist of a low-energy inexpensive anode tube and a flat-panel amorphous silicon image detector.<sup>8</sup> The configuration of these machines is much simpler and materials are less costly, which translates into smaller size and greater affordability, making them suitable for private practices and wound care centers.

#### *PedCAT device*

PedCAT (Curvebeam LLC, Warrington, PA) is a CBCT-based device designed for imaging of musculoskeletal pathology of the foot and ankle. The technical specifications of PedCAT are listed in Table 2. The unique design of this machine makes it suitable for imaging of a single foot or both feet simultaneously in a non-weight bearing or fully weight bearing position. The patient positioning platform is equipped with handle-bars and a seat cushion permitting the patient to either stand or sit comfortably during the scan (Figure 1A).

PedCAT system consists of four components: PedCAT device ("machine"), operator console, external server and viewing console (Figure 1C). PedCAT device acquires a complete set of imaging data as a series of two-dimensional projections using an X-ray source attached to a rotating gantry. While the gantry is making one full revolution around the area of interest, its precise angular position is determined by an optical encoder located on the gantry. When the gantry reaches a predetermined position (every 1 degree for a total of 360 projections), an X-ray beam is pulsed through the area of interest producing a two-dimensional image projection. A

complete 360 degree rotation allows acquisition of projections from all angles, for optimal reconstruction of three-dimensional data.

The acquired data set is sent to the external server (Figure 1C), which performs image reconstruction using the Fieldkamp-Davis-Kress computational algorithm.<sup>12</sup> The reconstruction produces a series of DICOM image slices, used to create a series of images, which are stacked vertically to create a 3D volume.

The viewing console (Figure 1C) is a personal computer dedicated to viewing of CBCT images located in the physician's office. CubVue software allows the user to manipulate the entire 3D volume of image data, which is represented by small three-dimensional cubes or "voxels" (volumetric pixels). Each DICOM slice is a two-dimensional matrix of voxels, either 0.3mm or 0.37mm in size. A three-dimensional matrix of volumetric data is created by stacking the DICOM slices together.

CubVue software (Figure 1B) allows the user to select among several desired modes in order to aid in evaluation of the images. The images can then be viewed on a medical-grade monitor provided with the system, or on any other viewing station located on the doctor's network. The volumetric data set is a collection of all available voxels. In a default mode called multi-planar reconstructions (MPR), the data is presented as secondary reconstructed images in three orthogonal planes, axial, sagittal, and coronal, at a thickness set by its native resolution.<sup>10</sup> The oblique view mode allows the user to set a plane of reference other than the ones included in the standard MPR views. The software can also be utilized to create volume renderings of the objects and to manipulate the available data to focus on the desired tissue layers by removing less dense layers using a process called thresholding. The virtual three-dimensional objects can be rotated and viewed at any desired angle, and can be rendered translucent or opaque. The volume renderings can also be colorized to make them appear more life-like and to facilitate identification of certain structures. Standard imaging tools including the ability to zoom,

pan, adjust contrast and brightness, and make accurate distance and angle measurements are also available.

The operator console (Figure 1) is a personal computer located in the physician's office, which is connected directly to the external server via Ethernet cable. It allows the operator to enter/access patient information and initiate image acquisition.

#### *Application of PedCAT for Early Diagnosis of Osteomyelitis in Diabetic Patients*

Early radiographic signs of osteomyelitis are subtle and often missed. Visualization of early signs of bone destruction, such as focal demineralization, osteolysis, periostitis, osteosclerosis and cortical thickening,<sup>13</sup> is invaluable in facilitating timely diagnosis and early surgical intervention. Due to its poor sensitivity for early osteolytic changes, plain radiography is of limited value in imaging of initial stages of osteomyelitis.<sup>3</sup> Computed tomography offers significant benefits for imaging of early osteolytic changes. It facilitates accurate depiction of bone pathology, such as cortical bone destruction, periostitis and local demineralization.<sup>14</sup> Because of its high spatial resolution and contrast, CT is helpful in visualization of soft tissue abscesses and sinus tracts, allowing to evaluate the extent of infection and assisting in pre-operative planning.<sup>14</sup> Ability to view the anatomical structures in multiple planes eliminates distortion and superimposition artifacts, which are very common in plain film radiography.

Below, we report two case studies of diabetic patients, who presented to our clinic during the past year with infected neuropathic foot ulcers and were evaluated for potential osteomyelitis using plain film radiographs and PedCAT CBCT scanner. In both cases, PedCAT was instrumental in identifying bone infection. The diagnosis of osteomyelitis was later confirmed by positive findings on bone biopsy. The use of CBCT device enabled us to diagnose and treat osteomyelitis in a timely manner, preventing its spread to adjacent bone and soft tissue, and minimizing the amount of required surgical resection.

### *Case 1*

A 49 year old diabetic female presented with an infected neuropathic ulcer at the lateral aspect of her fourth digit. The ulcer demonstrated malodor, cellulitis that extended to fourth metatarsophalangeal joint and positive probe-to-bone test. The plain film radiographs and CBCT were utilized in order to rule out osteomyelitis and assess the extent of soft tissue infection. The weight-bearing X-rays of the affected foot (Figure 2A) revealed subtle lucency at the lateral aspect of the proximal phalanx of the fourth digit, which was contiguous with the ulcer location. However, this finding alone was not sufficient to yield a conclusive diagnosis. The images obtained using PedCAT (Figure 2B) clearly demonstrated the break in the cortex and the area of osteolysis involving the proximal phalanx of the fourth digit. The head of the fourth metatarsal and adjacent digits appeared intact. These findings, in conjunction with the clinical appearance of the affected digit, led to a preliminary diagnosis of osteomyelitis. The patient was treated with an arthroplasty of the fourth proximal interphalangeal joint, and has fully recovered. The bone specimens obtained intraoperatively were sent for biopsy, which confirmed our preliminary diagnosis of osteomyelitis.

### *Case 2*

A 53 year old diabetic male presented with an infected neuropathic ulcer at his fifth metatarsal head, which exhibited malodor, edema and erythema extending through the plantar lateral aspect of fifth metatarsal shaft and probed to joint capsule. The X-rays demonstrated no signs of bone involvement (Figure 3 A, C), while CBCT (Figure 3 B, D) revealed distinct areas of cortical lysis and bony fragmentation of the fifth metatarsal head. The proximal two thirds of the shaft of the fifth metatarsal appeared unaffected, with intact cortex, uniform bony density and lack of osseous fragmentation. The patient was treated with partial resection of the fifth metatarsal. The bone biopsy has confirmed our preliminary diagnosis of osteomyelitis.



## Discussion

Early diagnosis of osteomyelitis in a diabetic patient represents a diagnostic challenge due to the lack of an affordable and high-resolution imaging device. Here, we have reported our initial experience with PedCAT, a CBCT-based scanner designed for imaging of the foot and ankle. We have found that PedCAT produces images with high spatial resolution and great detail, which could be invaluable for diagnosis of osteomyelitis at its initial stages, when plain radiographs are unhelpful. PedCAT is compact and convenient for use at a small outpatient treatment facility. The accompanying software is user-friendly and facilitates quick and easy navigation of the reconstructed image data in all three planes and at different angles. Though in our case studies we have not taken advantage of the option allowing to scan the patient in both, a weight-bearing and a non-weight bearing positions, this option could be highly useful for evaluation of complex fractures and dislocations of the foot and ankle.

While our study is limited by the small patient population size and absence of clearly-defined objective criteria for diagnosis of osteomyelitis on CBCT images, it is the first report of a truly portable, CT scanner specifically designed for the foot and ankle region. Further evaluation of this device in a larger population, and assessment of its use for imaging of other foot and ankle pathologies will provide useful information about its value in podiatric practice.

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## **Table legends**

Table 1. Radiation doses associated with plain X-rays, CT and CBCT.

Table 2. Technical specifications of PedCAT device.

## Figure legends:

**Figure 1:** PedCAT device. (A) PedCAT machine in clinical setting; (B) Screenshot of a PedCAT CubVue software user interface demonstrating the user controls, three-dimensional volume rendering of the image, and three orthogonal image projections; (C) Device sequence diagram demonstrating the four components of the PedCAT system.

**Figure 2:** Comparison of X-ray and CBCT findings for patient presented in Case Study 1. (A) Anteroposterior weight-bearing X-ray view of the foot demonstrating a subtle cortical lucency at the proximal phalanx of the fourth digit; (B) Transverse weight-bearing CBCT view demonstrating the break in the cortex and the area of osteolysis at the proximal phalanx of the fourth digit; (C) Lateral weight-bearing X-ray view of the foot is unhelpful due to cortical overlap of the digits; (D) Saggital weight-bearing CBCT view reveals micro-fragmentation and osteolysis at the proximal phalanx of the fourth digit. The arrow points at the lesion.

**Figure 3:** Comparison of X-ray and CBCT findings for patient presented in Case Study 2. (A) Anteroposterior weight-bearing X-ray view of the foot does not demonstrate any osteolytic changes at the fifth metatarsal head; (B) -Coronal view of the foot demonstrates micro-fragmentation and osteolysis at the level of 5<sup>th</sup> metatarsal head;(C) Lateral weight-bearing X-ray view of the foot is unhelpful due to cortical overlap of the digits; (D) Saggital CBCT view reveals micro-fragmentation and osteolysis at the fifth metatarsal head. The arrows point at a sclerotic bone fragment loosely attached to the fifth metatarsal head.



## Tables

Table 1

<b>Technique</b>	<b>Effective Dose in microseverts (<math>\mu\text{Sv}</math>)</b>
Daily Background	8
Coast to coast round trip airline flight	30
Dental Full Mouth X-ray Series	50
Dental Medium FOV MDCT scan	860
Dental CBCT exam	87
Chest X-ray	100
MDCT of Chest	7000
Extremity X-ray	1
MDCT of a Foot	1000
PedCAT CBCT, medium FOV scan of foot/ankle region	30-40



Table 2

<b>PedCAT Device TECHNICAL SPECIFICATIONS</b>	
3D Imaging Volume	20cm (height) x 35cm (diameter) and smaller
Resolution	0.3 mm, 0.37 mm voxel sizes
Procedure time	19-68 seconds
Maximum exposure time	9 seconds
Tube voltage	100-120 kVp
Tube current	3-5 mA
Image detector	Amorphous silicon flat panel
Gray scale	14 bit
Dimensions	4ft (h) x 4ft (w) x 5ft (d)
Weight	400 lbs
Power Requirements	1500VA