3D Distal Extremity Imaging using Mobile Tomosynthesis X-ray Sources

Introduction

Fractures of the hand and feet make up >50% of all fractures[1], but the complex anatomy in those areas often makes the assessment and interpretation by 2D X-ray images difficult[6,9,11,14]. Frequently only advanced imaging methods such as Magnetic Resonance Imaging (MRI), Computed Tomography (CT) or bone scintigraphy allow the detection of an otherwise occult fracture in the wrist or ankle[9, 10]. However these types of imaging tests are expensive, not always easily accessible and, apart from MRI, involve higher radiation exposure.

Digital tomosynthesis (DT), a low-dose and inexpensive imaging technique where X-rays are emitted from a limited range of angles to derive 3D data, has been shown to give better diagnostic information than 2D X-ray in detecting and characterising scaphoid fractures and other bony injuries of the distal extremities. Recently, new, compact X-ray sources have been used in stationary arrays for DT with the prospect of providing this improved imaging capability more widely from small, lightweight devices.

Clinical Challenge

One of the most common fractures is that of the scaphoid bone in the wrist, which is at high risk of injury if a person falls heavily on an outstretched hand. Scaphoid fractures occur most often in young men and represent around 5% of all fractures[2].

Standard 2D X-ray is currently the primary imaging tool for wrist injuries; its diagnostic accuracy is however limited by the superimposition of bony structures. Even though images are often acquired in several positions (anteroposterior, lateral, oblique and occasionally dedicated scaphoid views), initial radiographs do not always detect scaphoid fractures, in particular in non-displaced fractures[11]. It is estimated that up to 40% of scaphoid fractures are missed at initial presentation due to inconclusive clinical signs and 2D X-ray results [7,9].

Although bone scintigraphy, CT or MRI are more accurate in diagnosing fractures, they involve additional waiting times, delays in patient management, higher cost and usually higher radiation exposure. To mitigate against misdiagnosis and potential litigation claims, patients with inconclusive 2D X-ray are often treated with wrist immobilisation and a follow-up X-ray after two weeks[4,11]. The current workflow can have the following negative impacts on patient health, healthcare cost and legal risk:

1. Referrals for a diagnostic CT, MRI or bone scintigraphy after ambiguous X-rays lead to additional charges. Sheffield Children's Hospital, typical of many large hospitals, estimates spending £1m/year (circa $1.3m/year) on this. CT scans, as well as bone scintigrams, expose the patient to additional radiation which is an order of magnitude higher than 2D X-ray [10,12].
2. Timely diagnosis, appropriate immobilisation and potentially surgery are instrumental in the successful management of a scaphoid fracture; a delay in diagnosis and can lead to the delayed or incomplete union of the bone, decreased grip strength, decreased range of motion, and osteoarthritis of the radiocarpal joint [6,11,13].
3. Mismanagement of hand and wrist fractures is one of the most common sources of litigation for EU healthcare systems e.g. from 1995 to 2012, the UK National Health Service Litigation Authority recorded 492 claims relating to fractures of the hand and wrist of which 74% were settled, with the most common reason being incorrect, missed or delayed diagnosis. The average cost was €42,000 (circa $47,600)[8]. The average verdict/settlement for wrist fracture cases in the US ranges between $50,000 – 100,000 based on the information from three states[23].
4. Unnecessary immobilisation causes cost and inconvenience to patients. A paper by Shetty et al. 2012[3] found that 84% of patients with an ambiguous 2D X-ray for a wrist fracture were immobilised for 2 weeks before follow-up imaging, but only 6% had confirmed fractures.

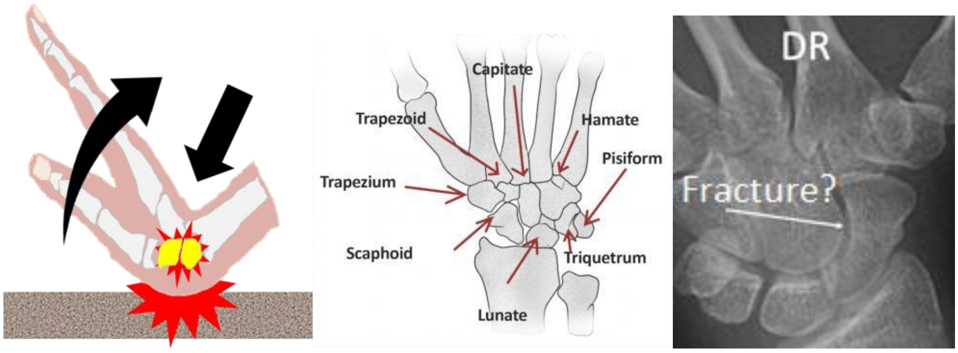

Fig 1: Extremity fractures, for example in the wrist, are common e.g. forceful hyperextension of the wrist when falling onto an outstretched hand (left), but the multiple bones of the wrist (centre image[6]) cause partial overlaps in 2D X-rays (right) that can make the diagnosis of a fracture difficult.

The potential of Tomosynthesis

Evidence from Current DT Solutions

Conventional digital tomosynthesis (DT) systems work by physically moving a traditional X-ray tube through a range of positions to capture multiple ultra-low dose projection images from a variety of different angles. The acquired projection images are used to reconstruct 3D slices through the volume. In contrast to CT, the range of angles used in DT is much less than 360˚, which substantially reduces the radiation exposure of the patient.

In orthopaedic surgery, DT has shown its value in detecting, characterising and monitoring various conditions and bony injuries. Compared to 2D X-ray, DT showed a superior diagnostic accuracy[2,15,16] in detecting and assessing otherwise occult fractures, such as those in the wrist and ankle. Recent publications consider DT as a valid imaging tool to evaluate scaphoid fractures, as it is less expensive and more accessible than CT and other advanced imaging modalities[16]. Promising data also suggest that DT will play an increasing role in monitoring fracture healing and other postsurgical changes, in particular given the current research on metal artefact suppression algorithms [4,17]. As a low radiation exposure exam[12] that can be easily integrated into a clinical workflow, DT can reduce the need for more complex imaging methods.

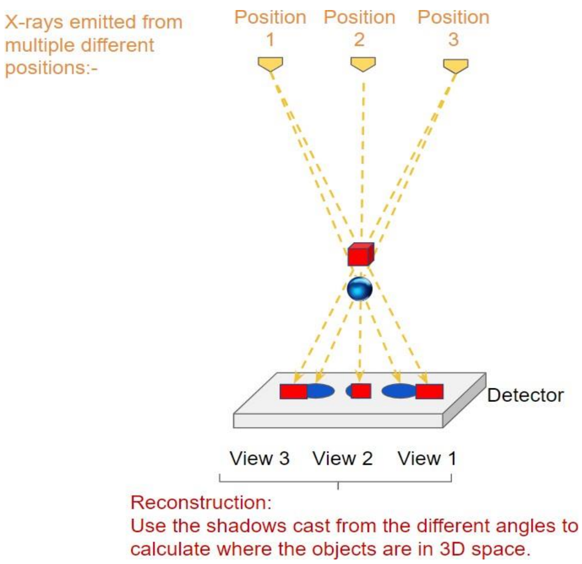

Fig 2: The principle of tomosynthesis

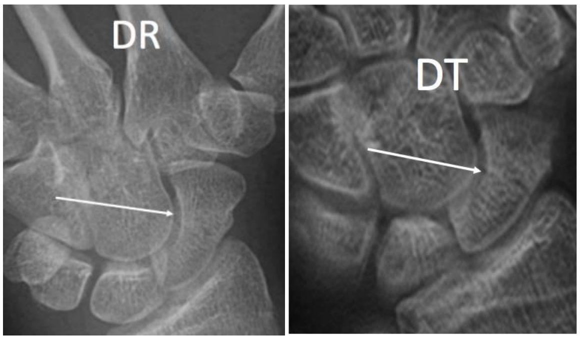

Fig 3: DT (right) allows better visualization of a scaphoid fracture than planar X-ray (DR, left side).
Image courtesy: Dr Sian Phillips, Princess of Wales Hospital, Bridgend, UK.

Benefits of DT relative to CT

DT can be superior to imaging with a conventional CT scanner- despite using a much lower radiation dose:

1. DT offers higher in-plane resolution[18] (even if the resolution between planes is less than CT and does not allow to slice the volume in all directions).
2. The ability of some DT systems to perform weight-bearing imaging would be beneficial for example for detecting subtle Lisfranc injuries of the foot (Fig 4). Those can occur after severe trauma, but also after seemingly trivial stumbling accidents. Lisfranc injuries are often missed on conventional radiographs at the time of initial presentation and a delay in diagnosis of more than six months is associated with a poor outcome, highlighting the importance of prompt diagnosis and treatment [19-22].
3. CT tends to show streak-artefacts when metal is present, which can impact the image quality in postsurgical images. DT (like 2D X-ray) does not show in-plane streak artefacts and potential minor artefacts can be corrected [4].

Note that there are some specialist Cone-beam CT systems dedicated to orthopaedics that also offer weight- bearing imaging.

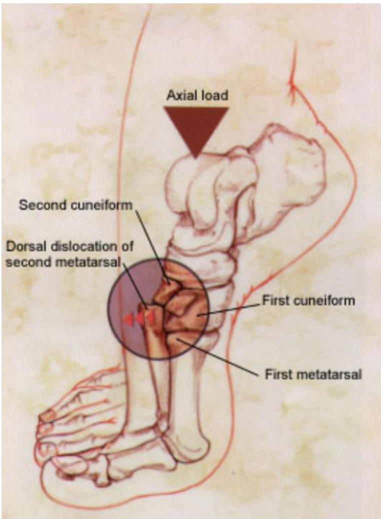

Fig 4. Lisfranc Injury of the foot could benefit from weight-bearing as well as 3D imaging[21].

Fig 5: Weight-bearing imaging can help highlight sources of pain. However, these systems are still rather large and expensive (A Shimadzu DT system (left) and a Carestream CBCT system (right)).

Limitations of Current DT Solutions

Not one of the clinically available DT systems is mobile, and therefore cannot be used for point-of-care diagnostics. They are also too large and expensive to be deployed outside of a hospital setting into primary care and often require a dedicated three-phase power supply and ceiling mounting system, making installation costly and time-consuming. Given that the acquisition time on commercially available systems ranges from at least five to twelve seconds and requires the physical motion of a heavy x-ray tube, blurred images can be a concern associated with DT.

Whereas conventional X-ray tubes used for DT operate with a single thermionic (heated) cathode, recent technical developments have enabled the development of so-called cold cathode emitters. These generate electrons without using heat, are more compact than conventional solutions, and the emitters can be arranged in different geometric forms such as a line or a square. By sequentially activating emitters, projection images from different angles can be taken without the need to physically move the source; resulting in faster acquisition time and less chance of motion blur. This technology has been described as "stationary tomosynthesis". One group used a linear array of Carbon Nanotube (CNT) emitters and was able to demonstrate the potential of linear X-ray source arrays for use in clinical studies in patients with cystic fibrosis[6].

Stationary Tomosynthesis using a Flat Panel Source (FPS)

Adaptix's novel Flat Panel Source (FPS) uses a square array of emitters instead of a just a line [24,25]. It has the potential to enable lower-cost, smaller footprint, higher performance DT devices that are compact enough to be employed at the patient's bedside.

The FPS Technology

The FPS is composed of an array of cold cathode field emitters that are triggered in a raster pattern to generate a large number of overlapping X-ray conelets sequentially. Control of the emission process is achieved through electromagnets, avoiding the common problem of high-voltage switching.
The use of an FPS with a square array of emitters for tomosynthesis enables the source to be much closer to the patient than standard 2D X-ray standoff distances (Fig 6).

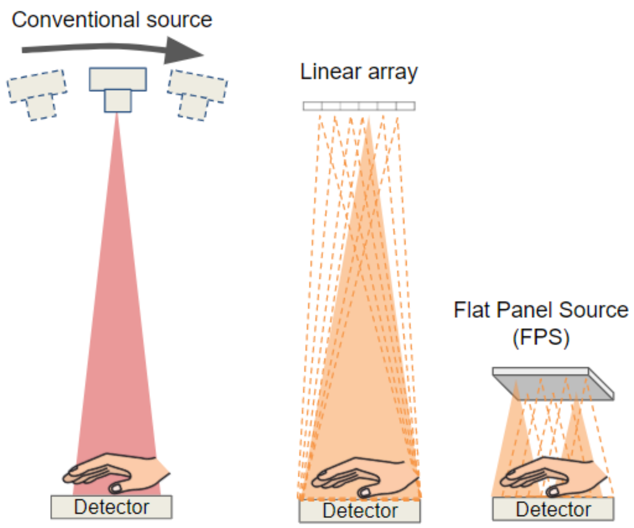

Fig 6: Differences in beam geometry and standoff – distance between performing tomosynthesis with a conventional X-ray tube (left), a linear array of small tubes (middle) and a Flat Panel Source (right).

Halving the standoff distance results in a fourfold decrease in required input power. A further reduction of around 45 times is achieved by using a series of low-power acquisitions over time rather than a single high-power acquisition as in a 2D X-ray. Conversion of the electron beamlets into X-rays is achieved through transmissive Bremsstrahlung targets.

The low input power, the inherently distributed arrangement of the FPS and the nature of the substrates holding the targets all ameliorate the heat generation that is typically associated with X-ray tubes. No rotating anodes or active cooling are required. Side-scattered radiation problems are also mitigated due to the reduced standoff distance used for the array compared to conventional tube sources. The lower input power per emitter also helps reduce the size of the focal spot that is possible to achieve[26].
This innovative approach is complemented by application of an advanced image reconstruction solution, which utilises "sparse data" techniques along with other concepts to optimise image reconstruction.

FPS- based DT in Extremity Imaging

An FPS-based DT system can address many of the limitations of conventional DT and provide additional clinical and economic benefits. Specifically for Orthopaedic applications, Adaptix is developing a source with a square array of 7x7 emitters operating at 60 kV in conjunction with a 15x11cm dynamic detector to acquire a dataset within 5 seconds.
Given the geometry and the size of the source, it would be suitable to be integrated into a point-of-care device that could be used for inpatient and outpatient imaging, for example in orthopaedic offices, fracture clinics, ski resort urgent care centres or during major sports events. Its lower power demands, small footprint and easy deployment, will likely translate into improved clinical workflow, better acceptance by staff and reduced total cost. The device can be used on a desktop for hand imaging or on the floor for weight-bearing foot imaging (Fig 7).

Fig 7: An Adaptix system based on a flat panel source, configured for desktop hand imaging (left), or weight-bearing foot imaging (right), the latter may allow for example point-of-care weight-bearing 3D imaging to immediately assess foot injuries at larger sports events such as Football or Rugby games.

It is anticipated that an FPS-based DT system will have less blur than a conventional DT device and better depth resolution than systems using a linear array (because the emitters are in a two-dimensional square array, so it is the equivalent to performing a sweep of different projection angles along two orthogonal axes).
Lastly, by choosing an innovative manufacturing approach where arrays of emitters can be mass-produced, the solution will be less expensive than existing products.

Benefits of an FPS in the Orthopaedic diagnostic workflow

The potential advantages of an FPS-based DT system could influence patient management, cost and dose in orthopaedic imaging. The ability of point-of-care DT to promptly exclude or confirm fractures such as those of the scaphoid or a Lisfranc injury could lead to the following benefits.

1. Fewer patients requiring immobilisation after an ambiguous 2D X-ray image, reducing healthcare and economic costs and patient inconvenience.
2. Fewer patients needing to undergo advanced diagnostics such as CT, MRI or bone scintigraphy, reducing radiation exposure, time to diagnosis as well as costs.
3. The lower radiation dose compared to CT would be particularly attractive when imaging children e.g. when assessing non-accidental injuries.
4. Enabling primary care providers to provide point-of-care 3D imaging without the need to send the patient to an external imaging centre.
5. More patients being given advance 3D imaging and therefore more accurate, early diagnosis.
6. Lower radiation exposure than CT (comparable to the four standard views typically used for a suspected scaphoid fracture), could potentially allow an FPS-based DT system to replace the current practice of 2D X-ray followed by DT; instead, the patient would undergo only a DT exam, saving radiation exposure, imaging and diagnostic time and costs.
7. Enabling weight-bearing 3D imaging of the lower extremities to be performed more widely, allowing timely diagnosis and treatment of foot injuries during sports events.

Summary

In the last decade, digital tomosynthesis (DT) has demonstrated its clinical value in detecting and monitoring various bony injuries and other orthopaedic conditions. As a low-dose, low-cost and relatively accessible modality, DT has the potential to become an effective imaging tool in the workup of patients with clinical suspicion of scaphoid fractures and other wrist and ankle injuries.
As an addressable distributed array of X-ray emitters, Adaptix's innovative Flat Panel Source can overcome many current limitations of conventional DT and allow the development of small, portable point-of-care DT systems, that would bring this powerful diagnostic tool into orthopaedic and primary care practices as well as into more remote locations like ski resort urgent care clinics.

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Glossary:

DT - Digital Tomosynthesis
CT-ComputedTomography
CBCT – Cone Beam CT
MRI–MagneticResonanceImaging
FPS - Flat Panel Source