The Potential Clinical and Economic Impact of Chest Digital Tomosynthesis using Distributed X- ray Source Arrays

Introduction

Digital tomosynthesis (DT), where a conventional X-ray tube is moved through a range of angles to derive 3D data, has been shown to give better diagnostic information than 2D X-ray. Recently, new, compact X-ray sources have been arranged in stationary arrays for DT with the prospect of providing this improved imaging capability more widely.

Background

The introduction of DT in the diagnostic work-up of chest patients, has demonstrated significant potential to reduce the need for computed tomography (CT) and therefore to reduce patient X-ray exposure as well as imaging costs. As a 3D imaging technique, DT can provide more diagnostic accuracy than a simple 2D - planar X-ray by removing the obscuring effect of overlaying anatomical structures. It may also reduce time to diagnosis in the clinical workflow.

Clinical Challenge

Conventional chest X-ray (CXR) is limited by the superimposition of bony structures onto the soft tissue of the chest making some diagnoses challenging. Some lesions are misinterpreted or not identified when obscured by superimposed structures. Extra-pulmonary or pulmonary vascular structures can simulate a true pulmonary lesion on CXR, which are later found to only be pseudo-lesions using CT. Although CT is more accurate, it involves additional waiting times, delays in patient management, a significantly higher radiation-exposure and higher cost.

Current Solution

DT as Problem Solver

DT represents a valuable alternative imaging method to characterise equivocal findings on CXR. Using DT to reduce referrals for CT scans results in reduced diagnostic delays, as well as reduced radiation-exposure and lower overall healthcare costs. A further advantage of DT over CT is the rapid verification of equivocal findings directly in the X-ray department without having to book the patient in for a CT scan. Several groups (Refs 2-4, 12) have considered the ability of chest DT to better characterise and anatomically locate indeterminate lesions that were detected in a planar CXR (Figure 1).

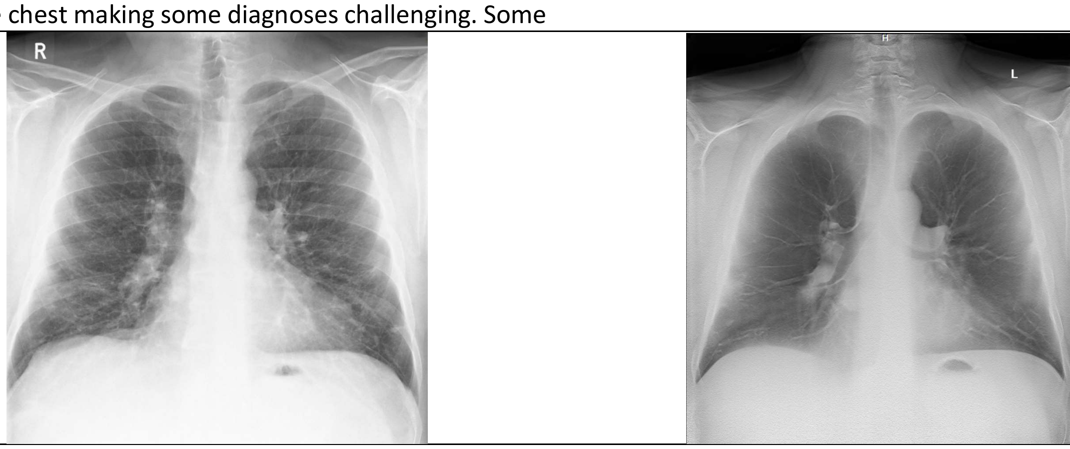

Figure 1: With a normal chest X-ray (left), the 2D nature of the image can mean that details in the lungs are obscured by overlying ribs and collar bones. A slice through a 3D tomosynthesis volume (right) shows internal anatomical details in the chosen plane with much greater clarity

The investigators concluded that DT did indeed improve diagnostic confidence and accuracy, and aided improved evaluation of suspected pulmonary masses, including the identification of intra-pulmonary and extra-pulmonary lesions. In up to 75% of all patients with equivocal CXR findings, the utilisation of DT allowed a definite diagnosis with no additional CT exam required.

These patients benefited from a prompt diagnosis, less radiation-exposure and reduced costs, with associated health economic benefits (Table 1).

Limitations of Current DT Solutions

The limited depth resolution of DT (due to the acquisition covering only a circa 40-degree angle instead of 360 degrees as in a CT exam) may lead to difficulties in localising some structures as well as to artefacts. Given that the acquisition time on commercially available systems ranges from five to twelve seconds, breathing induced motion artefacts, and consequently blurred images are another concern with chest DT. Holding their breath for up to twelve seconds can be very difficult for many patients and the resulting artefacts are often impossible to correct - even with sophisticated reconstruction algorithms. None of the existing DT systems are mobile, therefore cannot be used for point-of-care diagnostics. They are also too large and expensive to be deployed in primary care or out of hospital setting.

Table 1 – Costs, radiation exposure and diagnostic delay for different chest imaging modalities.

	CXR	DT	CT
Total Cost / Euro *	€15	€42	€65 – 114
Mean Effective Dose/mSv*	0.06	0.11	3.00
Delay after CXR		0.5-1hrs	Hours to weeks***

Different countries will have different costs depending on national healthcare models, but it is likely that the use of DT and reduced used of CT would generate savings in all regions.

*Cost evaluation based on: Quaia, E. et al. (2014). Diagnostic imaging costs before and after digital tomosynthesis implementation in patient management after detection of suspected thoracic lesions on chest radiography. Insights Imaging, 5 (1), 147-55.

**Dose estimates based on: Quaia, E. et al. (2011) Analysis of the impact of digital tomosynthesis on the radiological investigation of patients with suspected pulmonary lesions on chest radiography. Eur Radiol, DOI 10.1007/s00330-012-2440-3

*** UK NHS: NHS Diagnostic Waiting Times and Activity Data, March 2017

Cold Cathode Emitters for DT imaging

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 rectangle. By sequentially activating emitters, projection images from different angles can be taken without the need to physically move the source; resulting in a 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 Nanotubes (CNT) that can be seen as a substitute for a moving X-ray source. They were able to demonstrate the potential of linear X-ray source arrays for use in clinical studies in patients with cystic fibrosis (32). Since only one emitter is active per projection image, the beam geometry in this arrangement is the same as for a conventional X-ray source (Fig 2)

Stationary Tomosynthesis using a Flat Panel Source (FPS)

Adaptix's novel FPS uses a rectangular array of emitters instead of a just a line. 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 can produce X-ray energies in a range relevant for medical imaging: 20-120 keV. The array generates a large number of overlapping X-ray conelets, and a raster system allows for each X-ray emitter to be fired individually or in clusters. Control of the emission process is achieved through electromagnets, avoiding the common problem of high-voltage switching.

The use of an FPS for tomosynthesis enables the source to be much closer to the patient than standard CXR stand-off distances (Fig 2).

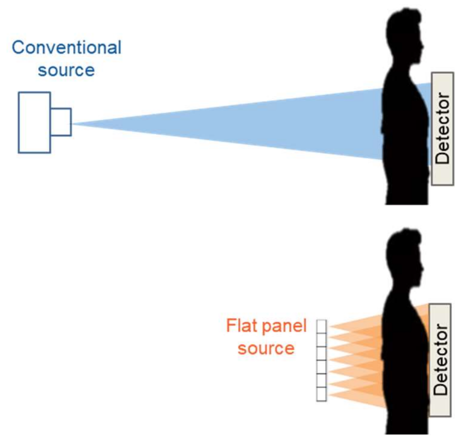

Figure 2; Differences in beam geometry and standoff –distance between a conventional X-ray tube, including linear arrays and a Flat Panel Source

By applying the inverse–square law, a 50 cm standoff distance for the FPS, versus 170 cm or more for a traditional X-ray tube, translates into a 13 times 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. 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 normally associated with X-ray tubes. No rotating anodes or active cooling is required. Thermal and side-scattered radiation problems are also mitigated due to the reduced standoff distance used for the array compared to conventional tube sources. A further benefit of the array is the tight beam spots (Focal Spots) that are just a few hundred µm — well below the typical millimetre range for conventional X-ray tubes.

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, reducing the number of images required and dose to the patient. This reconstruction will include automatic volume voxelization, iterative image reconstruction, noise and artefact reduction as well as computational optimisation.

General Benefits of FPS-based DT

An FPS-based DT system can address many of the limitations of conventional DT and provide additional clinical and economic benefits. Bulky X-ray tube assemblies and motorised gantries would no longer be required, and the new device would be compact, lightweight and, if necessary, mobile. Its lower power demands and small footprint could promote its use in primary care, remote emergency care and polyclinics, which would allow easy access to advanced X-ray imaging. The source and housing will be a similar size to a flat panel X- ray detector and could be deployed within a few minutes. This form-factor could translate into improved clinical workflow, better acceptance by staff and reduced total cost as compared to existing mobile CXR technologies with big, heavy batteries and motors.

By choosing an innovative manufacturing approach where arrays of emitters can be mass-produced, the solution will also be less expensive than existing products. With no risk of blur from mechanical movement, the overall acquisition time will be shorter compared with conventional DT systems, reducing the risk of patient motion artefacts and therefore enhancing image quality and patient compliance.

It is anticipated that an FPS-based DT system will have better spatial resolution than conventional DT and also systems using a linear array (because the emitters are in a two-dimensional array so equivalent to performing a sweep of different projection angles along two orthogonal axes). The increased spatial resolution will be complemented by the new, dynamic reconstruction process, which is based on the variability of X-ray attenuation by different tissue types. Using the principles of image segmentation by delineating tissue boundaries, an FPS-based DT system will be able to optimise the contrast resolution within the different tissue classes (such as air, bone or soft tissue), leading to improved diagnostic image quality.

FPS-based DT and Chest Imaging Workflow

The anticipated advantages of an FPS-based DT system could influence patient management, cost and dose (Table 2):

- The low radiation exposure (in the same range than a standard digital CXR) could potentially allow an FPS-based DT system to replace the current practice of CXR followed by DT. The patient would undergo only a DT exam and no CXR, saving radiation exposure, imaging and diagnostic time and costs.
- It is likely that fewer patients with equivocal findings or suspected nodules on their first examination would need a CT after an FPS-based DT due to the anticipated improvement in image quality compared to CXR.
- The low input power requirement, lower cost and small footprint could improve patient access and decrease time to diagnosis.

Figure 3: An imaging system based on a flat panel source with low input power requirements gives the opportunity for making low-cost 3D imaging available alongside normal 2D equipment.

Table 2 Anticipated Workflow Impact of DT exploiting Adaptix FPS

Workflow Improvements	Rationale	Clinical & Economical Benefit
Fewer patients requiring CT after FPS-based DT	○ Better image quality ○ Better contrast ○ Less scatter ○ Fewer motion artefacts	○ Significantly less radiation ○ Prompter diagnosis ○ Lower cost treatment ○ Decreased patient anxiety
CXR is replaced by FPS-based DT	○ Similar dose ○ Rapid acquisition ○ Easy access ○ Mobility ○ Low cost device	○ One exam ○ Lower risk of equivocal findings ○ Rapid diagnosis and treatment ○ Less cumulative radiation ○ Lower cost
Wider availability of DT	○ Mobility ○ Small footprint ○ Low cost device ○ Ease of use	○ Rapid diagnosis and treatment ○ Less travel ○ Patient acceptability
Reduction in patient radiation exposure per DT exam	○ Adaptive field ○ Innovative reconstruction ○ Less scatter	○ Patient and environmental benefits

Summary

In the last decade, DT has been successfully used as a problem-solving modality in diagnostic chest imaging. Using 3D imaging in the form of DT to increase diagnostic confidence compared to CXR alone can save costs, reduce patient dose, optimise time to diagnosis and reduce the use of CT resources.

As an addressable distributed array of X-ray emitters, Adaptix's innovative FPS can overcome many current limitations of DT that use a conventional X-ray source and increase the overall positive impact of DT on the chest imaging workflow, patient dose and imaging cost. Given the compact design and technical capabilities of the FPS, mobile DT will likely become a reality.

More clinical investigations will be required to better understand and confirm the impact of a mobile, low-dose 3D imaging system on patient management and outcome. Adaptix is convinced that introducing 3D X-ray imaging as a point-of-care technology has the potential to transform healthcare and introduce higher diagnostic accuracy to all those patients.

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Glossary:

DT - Digital Tomosynthesis
CT - Computed Tomography
FPS - Flat Panel Source
mSv - milliSievert
CXR - Conventional Chest X-ray