

Digital Tomosynthesis Applications and the NANO-X Solution

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Introduction

Digital Tomosynthesis (DTS) is a well-established technique for producing slice images using x-ray systems. It is a refinement of conventional geometric tomography, which was developed in the 1930's by the Italian radiologist Alessandro Vallebona¹. In conventional geometric tomography, the x-ray tube and image receptor move in synchrony on opposite sides of the patient to produce a plane of structures in sharp focus at the plane containing the fulcrum of the motion; all other structures above and below the fulcrum plane are blurred and thus less visible in the resulting image. DTS, on the other hand, allows an arbitrary number of in-focus planes to be generated retrospectively from a sequence of projection radiographs that are acquired during a single motion of the x-ray tube. From these projection radiographs, specific planes are reconstructed to create new images that provide enhanced quality and specificity. The term tomosynthesis originates from two Greek words: "tomos" for a section or a slice and "synthesis" for a process².

DTS overcomes the difficulties of geometric tomography by permitting reconstruction of many slices from multiple low-dose acquisitions of image data. It uses an X-ray source and a digital detector to acquire a set of projection images that are combined to synthesize any coronal plane in the patient³. Unlike conventional tomography, DTS is not limited to reconstruction of a single plane, but rather can generate an arbitrary number of slice images throughout the entire volume of the patient⁴.

In this way, it provides a unique and powerful perspective. It addresses one of the primary weaknesses of conventional single-projection X-ray imaging: the superimposition of tissues and structures on each other, which can obscure abnormal findings⁵. Despite some early successful proofs of concept, DTS has only recently become practical as a clinical imaging modality. This technique was successfully implemented in Digital Breast Tomosynthesis (DBT) and is now in wider use for additional clinical applications⁶.

Current Situation

Several manufacturers of X-ray equipment, now have commercial DTS. As with the various more classical tomographic systems, these vary in their geometric and motion parameters. As a results, there is a growing number of scientific publications, demonstrating the advantages of DTS imaging of chest, abdomen, breast, head, and neck⁷. For example, DTS provides improved visibility of anatomical structures in the chest, such as lungs, airways, sternum and ribs with more accuracy⁸.

Yet, as of today, the positioning of this technology in routine imaging workflow is not common. Various barriers, such as price (in their current form, these machines

Tomosynthesis Applications

Digital breast tomosynthesis (DBT)

In clinical practice, DTS has been extensively researched and developed for breast imaging, where the gold standard is mammography. However, in denser breasts, detectability of routine mammography can be compromised as the breast tissue can mask lesions^{9,10}. DTS provides a method to overcome this limitation, allowing for depth localization without the increased dose from CT.

Digital chest tomosynthesis

DTS of the chest, is a promising technology which overcomes significant limitations associated with plain chest X-ray and brings some advantages by permitting the reconstruction of various image slices from multiple low-dose acquisitions of image data.

Compared to standard radiography, DTS of the chest has several advantages including improved lesion detection due to a reduction in image noise or composite artefact, better depth localization and contrast resolution (Figure 1). Recent reports have shown that the use of DTS, as an alternative to conventional chest radiography, leads to considerable improvement in diagnostic content⁷.

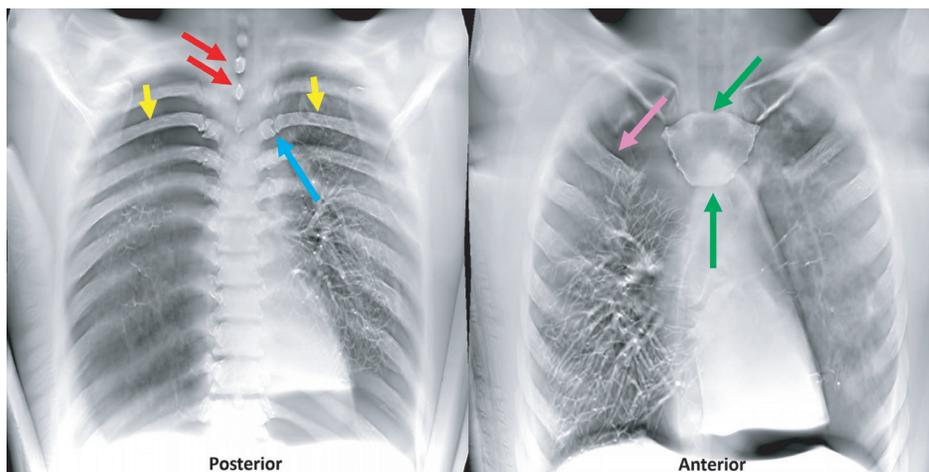


Figure 1. Anthropomorphic chest phantom (Lungman, Kyoto Kagaku, Japan) images by Nanox.ARC DTS system*. On the posterior image the spinous processes of the upper thoracic vertebra (red arrows), the upper posterior ribs (yellow arrows) and the posterior costovertebral junctions (blue arrows) are sharp while the other parts are blurred. In the anterior image the sternum is seen in detail (green arrow) as well as the anterior ribs (pink arrow).

In terms of radiation exposure, posterior-anterior and lateral chest radiographs would result in a radiation dose of 0.01 mSv and 0.15 mSv, respectively¹¹. DTS related dose would be approximately 0.1–0.2 mSv^{12 13}. When compared to CT, the advantage of DTS is in a pronounced reduced radiation dose to patients [4–8 mSv in chest CT¹⁴ and 1.5 mSv in low-dose CT^{12 13 15}.

As mentioned, DTS is emerging as a promising technology for the diagnosis of equivocal or suspected pulmonary lesions¹⁶.

The use of DTS would entail less waiting time for the workup of the suspected lung lesion that then turns out to be benign, non-pulmonary, or a false positive nodule. Prospectively, DTS could replace CT scan in the characterization of incidental chest lesions identified by conventional radiography¹⁷. Chest DTS highlights the potential to follow up known nodules¹⁸. It also has applications in cystic fibrosis¹⁹ tuberculosis²⁰ and asbestos-related diseases²¹.

COVID-19

C OVID-19 has already infected more than 200M and killed many millions worldwide. Despite global vaccination efforts, the 4th surge is at its peak in extensive geographical areas and new variants are worrisome. Studies have shown that although CT scanning is more sensitive than conventional X-ray and is a valuable tool in severe COVID, practically, it is used only in a minority of COVID patients. While more studies are required, it is proposed that DTS can serve as a replacement for some indications where CT would otherwise be required^{22 23}.

Orthopaedic and Rheumatological Imaging

Fractures

The adult human skeleton is made up of 206 bones (270 at birth). These include the bones of the skull, spine (vertebrae), ribs, arms and legs. Fractures are incredibly common and in fact, globally, the person-yearly fracture incidence rate is 1.2%^{24 25}. In the US alone, 2 million fractures occur each year, including those related to osteoporosis. Many radiologists, especially those in Emergency Departments and Urgent Care settings agree that missing a fracture on 2D X-ray is the most common misdiagnosis accounting for approximately 80% of missed diagnoses^{25 26}.

DTS therefore can offer significant improvement over X-ray diagnosis, either as an additional tool or as a routine for fracture diagnosis (Figure 2,3). Due to its innate advantages over 2D X-ray, DTS has been described in the literature as offering improved detection of not only routine fractures but also of micro and occult bone fractures, which can typically be detected only by CT or MRI²⁷. This modality has been noted to be especially useful in delineating certain complex anatomical structures, including skull, TMJs, facial bones, atlanto-axial joints and as well as carpal and tarsal bones²⁸.



Figure 2. Hand phantom (with human bones) images. Conventional radiograph (A), Nanox.ARC DTS system* (B,C). On the 2D image (A) the carpal bones are superimposed on each other. On the DTS images, at different layers, the Pisiform is decluttered from the triquetrum (B) and the hook of the hamate can be clearly evaluated (C). The out of plane bones are blurred.



Figure 3. Knee phantom (with human bones) images. Conventional radiograph (A), Nanox.ARC DTS system* (B, C, D). An anterior reconstructed image (B) demonstrated the patella while the tibiofemoral joint is blurred. A more posterior image (C) details the medial and lateral tibiofemoral joints. There is a subchondral lucency in the posterior aspect of the medial femoral condyle that is seen only on the DTS (D).

Joint imaging in Rheumatology

The most utilized imaging modality for evaluation of bones and joints is plain radiography. However, this is also the least sensitive technique for abnormalities compared to CT and MRI. CT of bones and joints is a significant burden on the radiologists since these studies contain hundreds of images and is an expensive and not always readily available tool. MRI, while an unmatched modality for the demonstration of soft tissues, including ligaments, menisci and tendons, has significant limitations in the evaluation of the bone itself. DTS is a good solution for addressing these limitations.

A useful application for arthropathies has also been demonstrated, with outstanding imaging of joint spaces and erosions, suggesting it may become an important element in screening and monitoring of arthropathies²⁸⁻³⁰. Several studies have noted that DTS can improve the detection of degenerative and inflammatory arthritis including subtle findings such as erosions. Further studies are needed but it would seem likely that DTS may become the modality of choice for the evaluation of various common conditions in this category including osteoarthritis, rheumatoid arthritis and gout²⁸⁻³⁰.

Abdominal Imaging

DTS abdominal imaging has been demonstrated to be remarkably successful in aiding in the diagnosis of urinary tract calculus disease^{31 32}. In fact, studies have demonstrated that DTS improves the detection of and location of urinary calculi when compared to digital radiography with only a minimal increase in patient effective radiation exposure dose.

Additionally, it has been shown that DTS abdominal imaging demonstrated improved evaluation of various other abdominal anatomical structures, such as pancreato-biliary, and gastrointestinal tracts. Specifically, it has been demonstrated to improve evaluation of these organ systems when the patient has significant superimposition of bowel gas, and these are notoriously difficult to assess without contrast and/or associated with invasive procedures, and in the evaluation of tumours of the biliary tract in percutaneous transhepatic cholangiography examinations⁷.

Head & Neck and Dental Applications

According to the National Ambulatory Medical Care Survey the prevalence of sinus disease is estimated to be approximately 14% in the general adult population and DTS has already been used with success for accurate detection of sinus disease. Studies have shown that DTS is useful in delineation of complex anatomic structures⁷. X-ray evaluation of these structures is usually limited and DTS can contribute to diagnosis of TMJ dislocations, orbital fractures, etc. DTS dental applications have also achieved success, including for the purposes of implant planning^{7 33}.

Other Applications

Additional applications of DTS are being evaluated. Of them, to mention a few, in the field of radiotherapy and oncology for determining patient positioning and treatment follow-up³⁴, as well as for its use intraoperatively^{35 36}.

More studies are needed but the evidence base is evolving rapidly.

The Nano-X solution

The vast majority of imaging is X-ray based (X-ray, CT, fluoroscopy***, mammography*** etc.). Nano-X has embedded its unique digital X-ray source in its multiple-source Nanox.ARC DTS device. This new technology will not only enable the manufacturing of a DTS device more readily and inexpensively but will also form the basis of a revolutionary ecosystem based on source and device, with a unique business model and cloud-based platform. Therefore Nano-X has the potential to make a significant global impact.

In addition, Nano-X integrates the concept of MSaaS (Medical-Scanning-As-A-Service) to improve the accessibility and affordability of medical imaging services worldwide. The MSaaS business model enables removal of barriers of large upfront capital expenditure, lease payments and significant service expenses associated with traditional systems.

A New Standard of Care

It is clear from a host of studies that DTS offers superior performance to conventional X-rays in a wide variety of clinical applications, including some of the most common ones, e.g., thoracic, breast, orthopaedic, head & neck, abdominal and emergency and intra-operative imaging. It appears to offer the prospect of a cost-effective, relatively low radiation dose imaging approach to the early diagnosis and monitoring of disease. More studies are needed – and many are underway – to establish optimum imaging parameters and sensitivity and specificity indices. For many clinical applications, DTS can overcome the limitation of an X-ray and obviate a need for a CT scan which is expensive and carries high radiation dose. It has the potential to improve workflow and reduce the cost of imaging.

Conclusion

Digital Tomosynthesis is a promising imaging modality that acquires multiple low dose projections over a limited arc of movement of the X-ray tube and produces a stack of slices in the acquisition plane using image reconstruction. Through this, it provides depth resolution and reduces the degree of obscuration by overlying structures.

DTS bridges the gap between 2D (“conventional” or “plain” X-ray) and CT, with a lower radiation dose compared to CT, and with higher yield of clinical information compared to conventional radiography. The Nanox.ARC*, which is currently under development, is intended to offer the necessary link between the two with a projected lower cost than current expensive imaging devices. This will aid in stationing it in many facilities, offering advanced imaging to many more patients.

In conclusion, Nano-X is developing a pioneering new concept of medical imaging technology and infrastructure. Once cleared, Nano-X will introduce a unique digital X-ray source embedded in the Nanox.ARC DTS device, coupled with the MSaaS business model and cloud-based radiology services platform. This will enable the company to revolutionize the imaging world, by creating a comprehensive accessible and affordable imaging ecosystem globally.

Disclaimers:

- Device pending US FDA 510k clearance, image of a phantom, image provided for educational purposes only.
- Device pending US FDA 510k clearance, discussion provided for educational purposes only.
- Nanox.ARC is not intended to support fluoroscopy and breast tomosynthesis.

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