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 findings[5]. 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 applications[6].

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 neck[7]. For example, DTS provides improved visibility of anatomical structures in the chest, such as lungs, airways, sternum and ribs with more accuracy[8].

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 are generally expensive), market and radiologists' education, are considered to form the major obstacles for mass adoption of the technology. These issues, in parallel to the common use of other advanced imaging modalities, have led tomosynthesis to find its place only in specific niches.

Tomosynthesis Applications

Digital Breast Tomosynthesis (DBT)

In clinical practice, DTS has been extensively researched and developed for breast imaging. 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 (Figure 1).
Compared to standard radiography, DTS of the chest has several advantages including improved lesion detection. Recent reports have shown that the use of DTS, as an alternative to conventional chest radiography, leads to considerable improvement in diagnostic content[7].

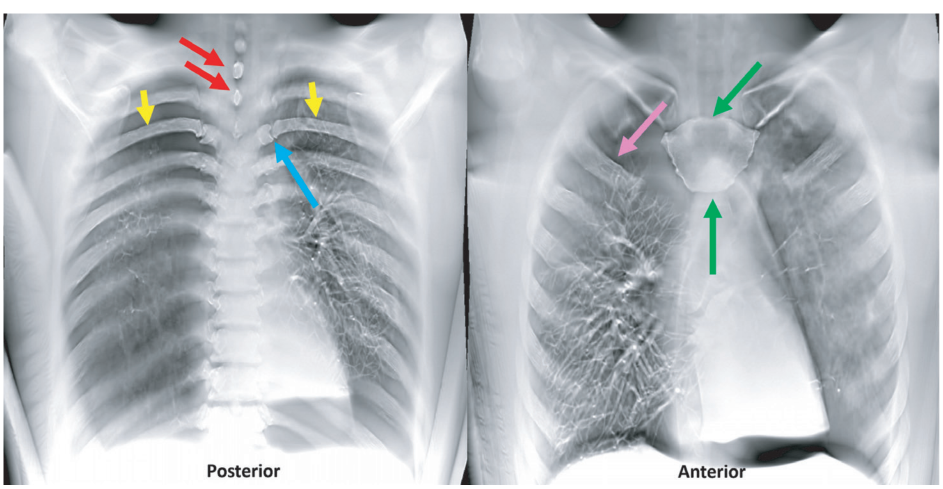

Figure 1. Anthropomorphic chest phantom (Lungman, Kyoto Kagaku, Japan) images by Nanox.ARC DTS system*. On the posterior image the spinous processes of the upper thoracic vertebra (red arrows), the upper posterior ribs (yellow arrows) and the posterior costovertebral junctions (blue arrows) are sharp 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, respectively[11]. DTS related dose would be approximately 0.1–0.2 mSv[12, 13]. When compared to CT, the advantage of DTS is a pronounced reduced radiation dose to patients [4–8 mSv in chest CT[14] 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 lesions[16].

It has been suggested that chest DTS can be used as a case solving technique in the workup of equivocal or suspected pulmonary lesions on chest radiography. Chest DTS can contribute additional information on the suspected lesion, and rather than sending patients directly to CT, DTS can eliminate false positive cases in which the lesion can be characterized as extrapulmonary or benign[17] .
Chest DTS highlights the potential to follow up known nodules[18]. It also has applications in cystic fibrosis[19] tuberculosis[20] and asbestos-related diseases[21].

COVID-19

COVID-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 MRI[27]. This modality has been noted to be especially useful in delineating certain complex anatomical structures, including skull, TMJs, facial bones, atlanto-axial joints and carpal and tarsal bones[28].

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 Pisifom is decluttered from the triquetrum (B) and the hook of the hamate can be clearly evaluated (C). The out of plane bones are blurred.

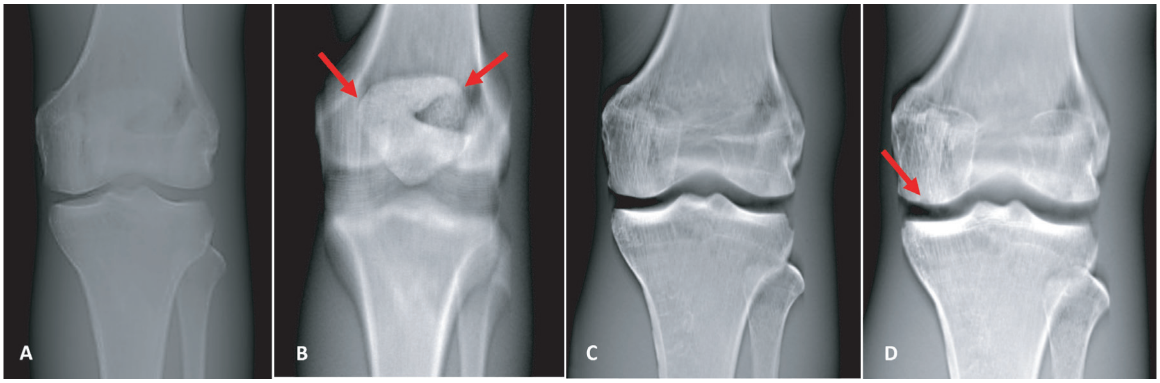

Figure 3. Knee phantom (with human bones) images. Conventional radiograph (A), Nanox.ARC DTS system* (B, C, D). An anterior reconstructed image (B) demonstrated the patella while the tibiofemoral joint is blurred. A more posterior image (C) details the medial and lateral tibiofemoral joints. There is 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 arthropathies[28-30]. 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 gout[28-30].

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 examinations[7].

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 structures[7]. 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. For example, in the field of radiotherapy and oncology for determining patient positioning and treatment follow-up[34], as well as for its use intraoperatively[35, 36].

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

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 under development, image of a phantom, image provided for educational purposes only.

**Device under development, discussion provided for educational purposes only.

***Nanox.ARC is not intended to support fluoroscopy and breast tomosynthesis.

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