Single-Exposure, Digital, Dual-Energy Subtraction X-Ray Ushers in a New Era of Diagnostic X-Ray Imaging

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EXECUTIVE SUMMARY

- Dual-energy subtraction x-ray has been used clinically for the past two decades and has been shown to detect more solitary pulmonary nodules, pneumonia, pneumothorax, tuberculosis, and coronary calcium than digital (or analog) chest x-ray.
- The emergence of single-exposure, digital dual-energy subtraction detector technology creates an opportunity, for the first time, for both hospitals and healthcare systems to rapidly integrate DES x-ray into clinical imaging.
- The portability of single-exposure dual-energy subtraction detectors opens up new opportunities for point-of-care high-quality diagnostic imaging to increase access in underserved regions.

Abstract

Dual-energy subtraction (DES) x-ray has been used clinically for the past two decades and has been shown to detect more solitary pulmonary nodules,[1] pneumonia,[2] pneumothorax,[3] tuberculosis,[4] and coronary calcium[5] than digital (or analog) chest x-ray. The capability of DES to detect disease early can enable better patient health outcomes, upfront realization of hospital billing, and reduced exposure to malpractice claims and ultimately can result in making healthcare systems more efficient. Despite these attractive benefits, DES systems have not seen widespread adoption[6] due to (1) higher radiation relative to chest x-rays, which require changing imaging protocols; (2) limited views (eg, only AP/PA, no portable imaging); and (3) inconsistent image quality because of image motion artifacts. Recently, however, the emergence of single-exposure, portable, digital DES x-ray detector technology[7] that overcomes previous DES limitations has raised the possibility that DES can retrofit existing digital x-ray rooms. Moreover, the portability of single-exposure DES detectors opens up new opportunities for point-of-care high-quality diagnostic imaging to increase access in underserved regions.

Introduction

In conventional radiographic imaging, materials with different elemental compositions can demonstrate similar attenuation, making the discrimination of bone tissue from soft tissue challenging. Although contrast can be improved by using contrast agents, there are undesirable side effects and additional costs. An alternative is dual-energy subtraction (DES) x-ray, first developed in the late 1970s,[8] which makes use of the different attenuation characteristics of bone and soft tissue at two different x-ray spectra to generate soft tissue and bone images in addition to the conventional x-ray image.

There are two primary DES x-ray approaches[8]: single-exposure dual-layer DES detectors or dual-exposure DES systems based on energy (kV) or filter switching. In the former, a single radiation exposure generates two x-ray spectra: the top layer captures the original incident spectra, and the second layer detects a representation of the incident

spectra hardened (or filtered) by the preceding layers. In the latter, two distinct spectra are created by using two x-ray exposures either at different x-ray energies (eg, 60 kVp and 120 kVp) or by using a filter wheel to modify the incident beam.

The advantage of the single-exposure dual-layer DES detector is the reduced complexity for image registration since both images are acquired simultaneously within a single exposure. The disadvantages include a reduced detection efficiency, since achieving good-quality bone and soft tissue images requires good spectral separation in the incident x-ray beam, which is achieved by further hardening the incident beam via a copper mid-filter placed between the two x-ray sensing layers. The loss of photons in the copper layer, however, causes a trade-off between dose efficiency and image quality, resulting in a significantly lowered dose efficiency. As a result, these systems are no longer available clinically.

The advantage of the dual-exposure DES system is the improved dose efficiency relative to the two-layer DES detector, although two exposures does increase the patient dose relative to traditional x-ray.[8] In addition, any time delay between two exposures can cause image artifacts due to patient motion (eg, beating of the heart), which, even with modern motion corrections, leads to inconsistent image quality.[9] Also, the use of lower energy spectra (eg, 60 kV for energy switching) poses further limitations on the use of dual-exposure DES systems for the acquisition of lateral views because of a significant increase in patient dose compared to a traditional lateral chest x-ray exposure.

Recently, a third alternative[7,10] has emerged for DES that refines older-generation dual-layer detectors: a single-exposure, three-layer, DES detector design that replaces the copper mid-filter with a third sensing layer. Three sensing layers enable the simultaneous optimization of the spectral image without losing any of the incident photons in the copper mid-filter, thereby eliminating the trade-off between dose efficiency and spectral separation. The use of three layers enables the acquisition of a conventional digital x-ray image at very high dose efficiency (given that there are three sensing layers) while simultaneously generating motion-artifact-free bone and soft tissue DES images.[11] More importantly, the three-layer detector can operate at the radiation levels associated with a standard x-ray, teasing the possibility, for the first time, of replacing all mainstream digital x-ray detectors with higher-performance DES x-ray detectors. Figure 1 shows the different types of single- and dual-exposure DES systems.

Clinical applications and economic value of DES X-ray

Given that DES x-ray has been in regular clinical use for more than two decades, there is much clinical literature that describes the various applications where DES is useful or could be useful.[6] The focus in this work is on reviewing the potential economic value propositions for well-established and promising emerging use cases.

Solitary pulmonary nodules (SPN)

The prevalence of solitary pulmonary nodules is an early sign of lung cancer.[12] In the general population (ie, those patients who are not eligible for low-dose computed tomography (LDCT) screening but who require an x-ray for another purpose), the prevalence is around 0.1%–0.2%.[12] Compared to conventional x-ray, DES x-ray has been shown to have greater than an 18% accuracy and a 33% higher sensitivity[1] in finding pulmonary

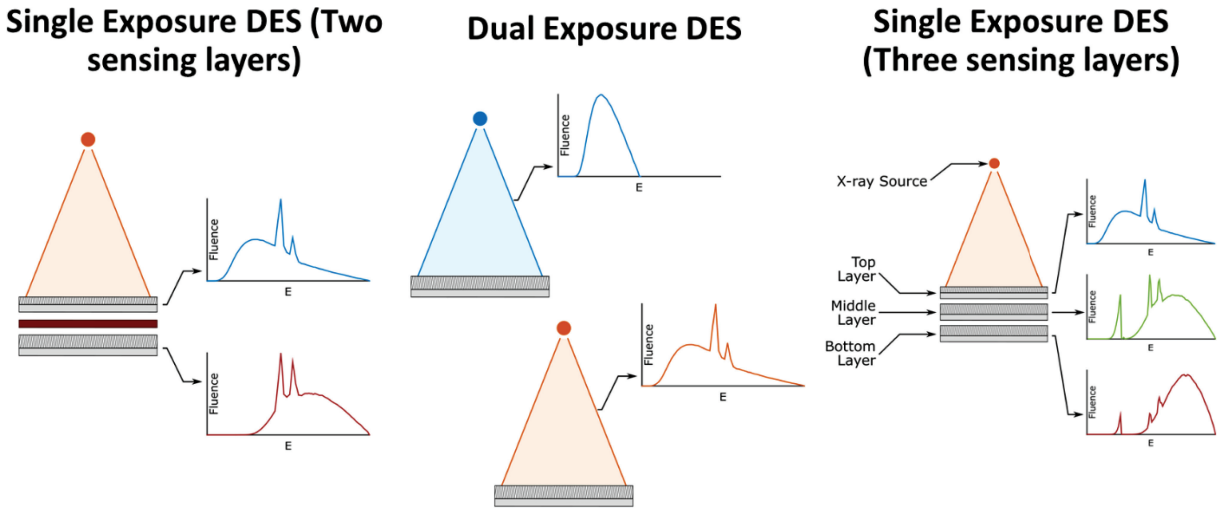

Figure 1 • Comparison of DES x-ray systems[11]

nodules, which are early indications of lung cancer. Early detection can save and extend patient lives because those additional patients identified via DES x-ray diagnostics can then benefit from follow-up CT scans and therapies depending on the stage of their cancer, which also increases procedure volume for healthcare providers. In many cases, early detection can extend the patient's life by reducing the probability of the patient requiring a late-stage costly cancer treatment[13] and leads to a stage shift in cancer detection, which allows for a more sustainable healthcare system.

In the United States, 150 million chest x-rays were performed annually in 2018, and given the 0.1%-0.2% prevalence for SPN in the general population, we can estimate that a total of 225,000 patients with SPN could have been found. A recent report indicated a rate of 1.66 claims filed per 1000 SPN patients where a SPN was missed,[14] implying that 374 patients filed a missed nodule malpractice claim. The total settlements and payout for SPN claims in the United States was 110 million American dollars[14]; thus we can estimate an average payout of $294,000 per claim.

For a typical site that carries out 120 x-ray scans daily, a simple calculation shows that an additional 12 patients could be found annually by employing the prevalence rate for SPN in the general population and the reported increase in accuracy of DES x-ray compared to conventional chest x-ray. These patients would be opportunistically discovered and are above and beyond the patients who would typically undergo LDCT screening. If the average charges associated with follow-up scans and therapies per SPN patient are estimated conservatively to be 10,000 American dollars[13] an additional $120,000 in hospital billing would be realized annually while simultaneously avoiding exposure to missed SPN claims.

Coronary calcifications

The presence of coronary calcium provides proof of coronary artery disease, and because providing patients with proof of immediate disease improves adherence to therapy, successful detection could positively impact healthcare for a very large number of patients. Detecting coronary calcium is significant because cardiac disease is America's costliest disease, with costs predicted to double to $1.1 trillion by 2035.[5] Work on the use of DES chest x-ray radiographs to detect coronary calcifications in the general population has been gathering momentum over the past decade.[5,6] In a recent RSNA 2020 publication from the US Naval Medical Center in San Diego, the benefits of DES lateral chest x-rays for the opportunistic detection of coronary calcium were reported.[15] A recent publication from Case Western University also demonstrated the clinical benefits of using DES x-ray for early detection of coronary calcium, including the possibility of calcium scoring with DES x-ray.[5] Lateral x-ray views are useful to image structures behind the heart; however, the key impediment for traditional two-exposure DES x-ray is the large increase in radiation dose for lateral views, which hinders widespread adoption. Lateral views on a single-exposure three-layer DES x-ray detector[16] use the same x-ray exposure as a conventional chest x-ray, potentially enabling the opportunistic detection of cardiac disease in the general population who are being sent for a conventional x-ray (ie, those who would not normally be recommended for a cardiac CT).

DES x-ray has been demonstrated to improve the visualization of lung parenchymal abnormalities associated with infectious and interstitial lung disease.

For a hospital scanning 90 older patients daily using x-ray and assuming a prevalence rate of 0.15% in the older population who require chest x-rays,[5] an additional 41 cases of coronary calcium can be discovered annually. Assuming average billings of 10,000 American dollars per patient discovered from follow-up scans and procedures for cardiac disease treatment,[17] 41 patients would benefit from early disease detection, and an increase in annual billings of up to 410,000 American dollars could be potentially realized.

Pneumonia

In the United States, 1 million people are hospitalized annually for pneumonia, and although 95% recover, there is a $9.5 billion cost to the hospitals[18] that is associated with the hospital stay and procedures (eg, ventilation), or roughly $10,000 per patient on average. Around 80% of the pneumonia patients present through the emergency room, 30% are either self-insured or not insured in the United States, and nearly 10% are readmitted within a month.[18] Thus, early identification of pneumonia can be part of a hospital and/or a healthcare system cost reduction strategy to reduce hospitalizations and intensive care unit (ICU) stays.[18] Early detection is also attractive because freeing up open beds enables space for additional patients with more serious illnesses or for patients who require a short-term stay due to day procedures.

DES x-ray has been demonstrated in the past[3] to improve the visualization of lung parenchymal abnormalities associated with infectious and interstitial lung disease. For example, DES showed a 50% greater sensitivity for identifying infectious consolidation and a three-times improvement in finding atelectasis compared to conventional x-ray.[3] In a recent study that employed the single-exposure, three-layer, DES x-ray detector for pneumonia, improved detection relative to chest x-ray was again observed along with increased clinician confidence in the diagnosis.[19] Based on the hospitalization

rate for pneumonia[18] in the United States (ie, 1 in 350), a site scanning 120 patients daily could find an additional 18 patients annually using DES relative to conventional x-ray, thus potentially averting at least $180,000 in hospital costs.

However, despite evidence indicating the benefits, DES x-ray is not yet a mainstream clinical imaging method for detecting pneumonia. One reason for the lack of adoption could be that pneumonia is most often found in emergency departments, where time is of the essence. The three images from a typical DES x-ray scan are often incorrectly perceived as requiring more time to interpret. In fact, just the opposite is true. A recent study[20] demonstrated up to a 30% reduction in reading time for DES x-ray compared to standard chest x-ray, likely due to a lesser need to window/level difficult cases. Other possible reasons for lack of adoption could be limited availability of DES x-ray since only a limited number of manufacturers offer a DES option with their x-ray rooms, and the inability to obtain DES x-rays on mobile x-ray machines, which are becoming more popular. It should be evident that emerging, three-layer, DES detector technology can address both these concerns.

Pneumothorax

Iatrogenic pneumothorax is defined as a "never" event; thus, it is not typically reimbursed by insurance or payers and is also the cause of medical lawsuits in the United States. The incidence of pneumothorax is about 1 in 1000 admitted hospital patients, and there are 36 million patients hospitalized annually in the United States, implying 36,000 pneumothorax US cases.[21] The attributable cost per pneumothorax ranges between $17,000 and $45,000 and can be estimated conservatively to be around 25,000 on average; pneumothorax-related malpractice suits (US related) have an annual median cost of around $143,250 per case.[21] Procedures required to help a patient recover from pneumothorax can range from a simple provision of oxygen to much more costly interventions. Thus, early detection is paramount, and although ultrasound has been demonstrated to be effective,[22] chest x-rays still remain a direct and time-efficient method to detect pneumothorax.

DES x-ray has been demonstrated to identify pneumothorax and, in particular, challenging small volume pneumothorax[2] in 15%-30% of cases where it was missed on conventional x-ray. These improvements were consistent across a variety of readers, including experienced radiologists, pulmonologists, residents, and interns, which is important because pneumothorax can occur in the hospital at all hours of the day, including off-hours when a radiologist is not available for immediate reading.

Again, although DES x-ray has demonstrated advantages at finding pneumothorax, it has not been widely adopted. This is likely due to the lack of portability of older-generation dual-exposure DES x-ray solutions, making them impractical for use in the ICU, where pneumothorax cases are usually discovered. However, the recent emergence of portable DES x-ray could change the adoption rate. For an ICU facility taking 30 x-ray scans of admitted ICU patients daily, an additional 2-3 pneumothorax cases could be found annually, $75,000 in savings and reducing the exposure to $429,750 in potential malpractice lawsuits.

Summary of Financial Impacts

DES x-ray is a demonstrated clinical tool for evaluating a wide range of cardiothoracic diseases and has shown greater sensitivity and accuracy at finding solitary pulmonary nodules, coronary calcium, pneumonia, and pneumothorax than standard x-ray imaging.

Late disease detection leads to adverse financial impacts, particularly in the case of misdiagnoses such as malpractice costs for missed pulmonary nodules and treatment costs to remedy "never" events such as pneumothorax that are typically not reimbursed by insurance companies.

TABLE 1. Summary of financial impacts for a typical clinical site adopting DES compared to if disease were not detected using standard digital x-ray imaging

	Projected extra cases found annually	Projected additional billings	Projected cost savings due to nonreimbursed procedures	Potential malpractice costs avoided
Pulmonary Nodules	12	$120,000		$3,528,000
Coronary Calcium	41	$410,000		
Pneumonia	18		$180,000	
Pneumothorax	3		$75,000	$429,750
Annual Total	74	$530,000	$255,000	$3,957,750

DES x-ray enables early detection relative to standard x-ray and thus allows for both cost savings and billings associated with finding disease early.

In Table 1, a summary of the financial impacts associated with the *additional* cases found using DES x-ray relative to standard x-ray imaging is shown. These numbers in Table 1 are calculated for a clinical site having at least one emergency and critical care facility with daily x-ray scan volumes of 120 patients or fewer as described in the previous sections. Based on the significant potential for cost savings, cost avoidance, and additional billings as described in Table 1, adding DES to a clinical site appears to be a low-risk opportunity to avail both better patient care and economic benefits simultaneously.

Since adding DES to a clinical site can require less than an additional $50,000 USD per unit in capital investment, the payback period for such a DES investment could occur within the first few months of use. The $50,000 USD number is based on the difference between a state-of-the-art digital x-ray detector and a single-exposure DES x-ray detector. Alternately, capital costs could be deferred if the DES upgrade is acquired on a monthly lease allowing for the additional billings and savings to fund the upgrade.

Conclusions

In the past, DES x-ray has not seen widespread adoption because of practical challenges with dual-exposure DES systems. These include: (1) poor image consistency due to motion and breathing artifacts, (2) higher patient radiation dose requiring alteration of existing clinical protocols, and (3) limited system availability from only select manufacturers. The emergence of single-exposure, digital DES detector technology creates an opportunity, for the first time, for both hospitals and healthcare systems to rapidly integrate DES x-ray into clinical imaging and avail the benefits of: (1) higher image quality and consistency, (2) maintaining the workflow and radiation levels of traditional x-ray, and (3) vendor agnostic detector retrofit solutions that can leverage existing hospital investments in both portable and fixed x-ray equipment.

Lastly, DES is inherently able to extract additional spectral data from the same x-ray spectrum used by traditional x-ray and glean information about the tissue type such as what is calcified and what is not. Thus, piggybacking on conventional digital x-ray, the extended functionality, ease of integration, and portability of newer DES x-ray solutions is expected to benefit in the future from integration with emerging artificial intelligence algorithms to improve clinical outcomes and greatly enhance the availability of point-of-care high-quality medical imaging.

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QUESTIONS

Instructions: Choose the answer that is most correct.

1. **Why is it difficult to discriminate bone from soft tissue in conventional x-ray imaging?**
   A. Materials with different elemental compositions demonstrate similar x-ray attenuation
   B. Bones are made of calcium
   C. There is more soft tissue than bone visible in a chest x-ray
   D. All of the above

2. **What decade was dual energy subtraction (DES) x-ray first developed?**
   A. In the 1950s
   B. In the 1960s
   C. In the 1970s
   D. In the 1980s

3. **How does DES x-ray distinguish bone from soft tissue?**
   A. DES uses artificial intelligence to separate bone and soft tissue
   B. DES uses the different x-ray attenuation characteristics of bone (calcium) and soft tissue (water) at two different x-ray energies to separate bone from soft tissue
   C. DES uses ultrasound to separate bone and soft tissue
   D. None of the above

4. **How many images are generated by DES x-ray?**
   A. Soft tissue and bone tissue
   B. Conventional and soft tissue
   C. Conventional, soft tissue, and bone tissue
   D. Conventional and bone tissue

5. **Which of the following is not a known approach to capturing a DES x-ray?**
   A. Single exposure multi-layer detector technology
   B. Dual exposure kV switching
   C. Dual exposure filter switching
   D. Ultrasound

6. **What are the two key advantages of single exposure DES approaches over dual exposure DES approaches?**
   A. Zero motion artifact and portability
   B. Zero motion artifact and high-speed image acquisition
   C. Portability and 3D images
   D. High-speed image acquisition and 3D images

7. **What is a key advantage of three-layer single exposure DES over two-layer single exposure DES?**
   A. Higher x-ray dose efficiency
   B. Better spectral separation for soft tissue and bone tissue images
   C. Maintains the same radiation dose as a standard chest x-ray
   D. All of the above

8. **Why are motion artifacts problematic when reading DES images?**
   A. It is challenging to interpret moving images
   B. Streaks in the DES images can lead to inconsistent image quality and challenges in interpretation
   C. Extra radiation is required to remove motion artifacts
   D. Extra time is required to remove motion artifacts

9. For which applications has DES x-ray shown improvements in detection over standard x-ray?

A. Solitary pulmonary nodules
B. Pneumonia
C. Pneumothorax
D. All of the above

10. The prevalence of solitary pulmonary nodules is an early sign of what disease?

A. Lung cancer
B. Constipation
C. Pneumothorax
D. All of the above

11. **How many x-ray exams were performed in the USA in 2018?**

A. 15 million
B. 150 million
C. 1.5 billion
D. 1.5 million

12. What are the benefits of early detection of solitary pulmonary nodules using DES x-ray?

A. Enrollment into lung cancer monitoring programs for asymptomatic patients
B. Reduction in the need for costly late-stage cancer treatments
C. Better patient outcomes
D. All of the above

13. The prevalence of coronary calcium is an early sign of what disease?

A. Pneumonia
B. Pneumothorax
C. Coronary artery disease
D. All of the above

14. Which DES image would coronary calcium be expected to appear in?

A. Bone
B. Soft tissue
C. Neither
D. Both (a) and (b)

15. What are the benefits of lateral chest x-rays compared to standard chest x-rays?

A. Less radiation dose
B. Higher-resolution images
C. Better visualization of structures located behind the heart
D. All of the above

16. Why is the dual-exposure DES approach not suitable for lateral chest x-ray imaging?

A. Large radiation dose compared to a standard lateral chest x-ray
B. Extra motion artifacts
C. Lack of portability
D. All of the above

17. How many people are typically hospitalized annually for pneumonia in the United States?

A. 100,000
B. 250,000
C. 500,000
D. 1,000,000

18. From which location are pneumonia patients typically admitted into a hospital?

A. Emergency department
B. Hospital outpatient imaging
C. Private imaging clinics
D. None of the above

19. How much time is required to read a set of DES x-rays relative to a standard x-ray?

A. 30% more
B. 30% less
C. About the same
D. Nobody reads x-rays anymore – AI is doing everything

20. What are the consequences of late (or missed) disease detection?

A. Increase in malpractice costs
B. Worse patient outcomes
C. Increase in non-reimbursed procedures
D. All of the above