The results of a retrospective CESM study of a large cohort of patients/lesions show that the technique provides high diagnostic performance and should be considered a useful technique for the local staging of breast cancer.
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Dr. Constantino S. Peña, Medical director of Vascular Imaging, Baptist Hospital, Miami, FL, USA
The ethics of Artificial Intelligence in radiology

It’s hard to believe it now, but once upon a time, the concepts of convolutional neural network, machine learning, deep-learning and artificial intelligence were confined to academic faculties of computing science who produced very few, mostly arcane publications. The only references to eventual practical applications of this relatively obscure technology (obscure at least to non-computer scientists) were being made by a few future-looking gurus, who were largely unidentified, or ignored by people outside the field.

Now all that has changed out of all recognition. In recent years, there has been an explosion in the growth of artificial intelligence research in the field of medicine, radiology in particular lends itself to AI research because of its large digital data sets. In response, the radiology community has largely embraced AI research as has been shown by the growing number of publications focusing on such research and the ever-increasing attention it is given at large radiology society meetings. A recent paper (West E, Mutasa S, Zhu Z, Ha R. Global Trend in Artificial Intelligence-Based Publications in Radiology From 2000 to 2018. AJR Am J Roentgenol. 2019 Aug 15;3. doi: 10.2214/AJR.19.21346) tried to analyze and quantify the trend in AI-based radiology publications. They found that the global growth trend was indeed literally exponential. The top 12 most productive countries were, in decreasing order of productivity, the United States, China, Germany, the United Kingdom, Canada, Japan, The Netherlands, France, India, Italy, South Korea, and Australia. As for individual organizations, the most productive were NIH and Harvard in the USA, while in Europe outstanding centers in AI radiology were the University of London, UK; INSERM in France; Radboud University, Nijmegen, in The Netherlands and the German Helmholtz Association. Neuroradiology was the sub-specialty most prolific in such publications, followed by chest, nuclear medicine, breast and MSK. Of course such research publications are far being indicators of the actual use of the technology in clinical routine, but, increasingly, research papers are appearing which report real clinical studies where the performance of AI-based algorithms is certainly non-inferior and frequently superior to the performance of human radiologists, in terms of classical parameters such as sensitivity, specificity, diagnostic accuracy, etc. However an infallible indicator of the imminent arrival of a technology poised to enter into routine clinical use is when the appropriate professional bodies and learned societies start issuing guidelines regarding how the technology should be managed. Two such papers have recently appeared: an ESR Statement paper (What the radiologist should know about Artificial Intelligence — an ESR white paper) European Society of Radiology (ESR), Insights Imaging. 2019 Apr 4(1):44. doi: 10.1186/s13244-019-0738-2) and a joint statement from European and North American multisocieties (Geis JR et al. Ethics of artificial intelligence in radiology: summary of the joint European and North American multisociety statement. Insights Imaging. 2019 Oct 1;10(1):101. doi: 10.1186/s13244-019-0785-8), with the latter being produced by the the ACR, European Society of Radiology, RSNA, Society for Imaging Informatics in Medicine, European Society of Medical Imaging Informatics, Canadian Association of Radiologists, and the American Association of Physicists in Medicine. Key points coming out of these weighty publications are that AI should respect human rights and freedoms, including dignity and privacy. It should be designed for maximum transparency and dependability. Crucially the ultimate responsibility and accountability for AI should be with its human designers and operators for the foreseeable future.

The radiology community should start now to develop codes of ethics and practice for AI that promote any use that helps patients and the common good and should block use of radiology data and algorithms for financial gain without those two attributes.

More colloquially, the ESR position statement suggests that, ethically, Isaac Asimov’s famous three laws for robots could equally be applied to AI just by exchanging AI for the word robot. Asimov’s laws are: a robot should not injure a human being; a robot should obey orders given by humans; a robot must protect its own existence.

Some radiologists have been heard muttering “can the threat of losing one’s job be construed as injury to a human being?”
Front Cover Story
There are many steps in a breast cancer patient’s journey, from a routine screening mammogram all the way through pathology and treatment. It’s important for healthcare professionals to approach a patient’s journey with a holistic view—as a singular continuum of care, from screening through treatment, rather than in isolated procedures and individual patient visits.
One way of positively impacting the patient journey and clinician’s workflow is through technological innovation....

REPORTS

A retrospective study of 644 breast lesions was carried out to accurately evaluate the performance of CESM compared to that of FFDM, either alone or accompanied with breast ultrasound (BUS). It was found that CESM significantly increased sensitivity, specificity, positive predictive value, and accuracy.

Deep-learning AI software for digital breast tomosynthesis: experience and results from a leading European cancer center. Widely recognized as one of the premier European cancer centers, the Gustave Roussy Cancer Campus (GRCC) in Paris, France has recently acquired iCAD’s ProFound AI platform

A recent study found that LV hypertrophy was an independent predictor of significant CHD events, including myocardial infarction, coronary artery disease-related death and heart failure

BREAST IMAGING ARTICLES

The usefulness of pre-operative MRI in the management of patients with Invasive Lobular Carcinoma.

Breast MRI in the management of the discordant-benign core biopsy.

Breast density data in overall breast cancer risk assessment: the experience of an Australian breast imaging group.

The growing recognition of the impact of breast density.

Evaluation of a new system for automated and integrated breast density assessment.

Breast Elastography.

AI-based reading of breast tomosynthesis images: the experience of a dedicated private women’s imaging center in Athens, Greece.

AI improves efficiency and accuracy of digital breast tomosynthesis.

Study shows mammography unlikely to benefit older women with chronic illnesses

Ultrasound yields similar cancer detection rates after digital mammography or after tomosynthesis

Updated guidelines on BRCA-related genetic counseling and testing

Combination of AI & radiologists more accurately identified breast cancer

Study provides insights on treatment and prognosis of male breast cancer

New technique may significantly reduce breast biopsies study provides

IMAGING NEWS

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BOOK REVIEW

INDUSTRY NEWS

TECHNOLOGY UPDATE
Fast MRI offers alternative to CT scans for pediatric head injuries

Traumatic brain injury (TBI) is a common reason for children to seek emergency care. Despite a relatively low incidence of clinically significant injury in these children, 20% to 70% of them undergo CT examinations, exposing them to ionizing radiation and increased risk of cancer. A recent study (Lindberg DM et al. Feasibility and Accuracy of Fast MRI Versus CT for Traumatic Brain Injury in Young Children. Pediatrics. 2019 Oct;144(4). doi: 10.1542/peds.2019-0419) shows that “fast MRI” is effective in identifying traumatic brain injuries in children, and can avoid exposure to ionizing radiation and anesthesia. “We found that fast MRI is a reasonable alternative to CT,” said Dr. D Lindberg, “Nearly all - 99 percent - of fast MRIs were completed successfully, with accuracy that was similar to CT, while avoiding the harms of radiation exposure.”

Conventional MRI can identify injuries without radiation exposure, but requires the child to remain motionless for several minutes. Conventional MRI requires anesthesia, which is not practical in many injured children and may expose them to mild cognitive injury. Fast MRI avoids the need for sedation by using faster, and more motion-tolerant imaging techniques.

Between June 2015 and June 2018, the researchers recruited participants to their study. Children less than six years old who had already undergone CT scans during their emergency care were eligible to participate and those enrolled received fast MRI as soon as possible, usually within 24 hours of the CT scan.

Out of the 225 children enrolled, fast MRI was completed in 223 cases. The median imaging time in fast MRI was 6 minutes, 5 seconds. Fast MRI results matched those of CT in more than 90 percent of cases, CT showed better accuracy for identifying fractures or breaks to the skull, while fast MRI did a better job of imaging the brain and the space between the brain and skull.

One limitation of the study is that it may not apply to other settings without access to cutting-edge MRI scanners or experienced pediatric radiologists. “We were fortunate to be using newer scanning equipment and highly experienced technicians and pediatric radiologists,” Lindberg said. “While we believe our findings reveal a feasible alternative to CTs in pediatric specialty centers, further study is necessary to test the results in other settings.”

doi: 10.1542/peds.2019-0419

Lower magnetic field MRI developed for cardiac and lung imaging conditions

NIH researchers, along with researchers at Siemens, have developed a high-performance, low magnetic-field MRI system that vastly improves the image quality of the lungs and other internal structures of the human body. (Campbell-Washburn AE et al Opportunities in Interventional and Diagnostic Imaging by Using High-Performance Low-Field-Strength MRI. Radiology. 2019 Nov;293(2):384-393. doi: 10.1148/radiol.2019190452)

The new system is more compatible with interventional devices which could greatly enhance image-guided procedures that diagnose and treat disease. The system makes medical imaging more affordable and accessible for patients. The low-field MRI system may also be safer for patients with pacemakers or defibrillators, quieter, and easier to maintain and install.

The trend in recent years has been to develop MRI systems with higher magnetic field strengths to produce clearer images of the brain. But, researchers calculated that using those same state-of-the-art systems — at a modified strength—might offer high quality imaging of the heart and lungs. They found that metal devices such as interventional cardiology tools that were once at risk of heating with the high-field system were now safe for real-time, image-guided procedures such as heart catheterization.

“We continue to explore how MRI can be optimized for diagnostic and therapeutic applications,” said Dr. Robert Balaban., “The system reduces the risk of heating — a major barrier to the use of MRI-guided therapeutic approaches that have hampered the imaging field for decades.”

The researchers also found that lung imaging improved and that oxygen itself can be observed in tissue and blood much better at a lower magnetic field, providing a unique view of the distribution of this vital molecule in the body.

“MRI of the lung is notoriously difficult and has been off-limits for years because air causes distortion in MRI images,” said

A 4-year-old boy was transferred because of persistently altered mental status (grogginess) after a fall down stairs despite a negative head CT result (Left Panel). Fast MRI (Right panel) identified a small, posterior subarachnoid haemorrhage. Images reproduced from Lindberg et al. Pediatrics doi: 10.1542/peds.2019-0419

Lung cysts and surrounding tissues in a patient with lymphangioleiomyomatosis (LAM) seen more clearly using high-performance low field MRI (Right Panel) compared to standard MRI (Left panel) Credit: Campbell-Washburn A E, et al.. Radiological Society of North America, 2019.
Dr. A Campbell-Washburn “A low-field MRI system equipped with contemporary imaging technology allows us to see the lungs very clearly. Plus, we can use inhaled oxygen as a contrast agent. This lets us study the structure and the function of the lungs much better.”

The researchers modified a commercial MRI system, Siemens Healthcare’s MAGNETOM Aera, with a magnetic field strength of 1.5T to operate at 0.55T, while maintaining the modern hardware and software needed for high-quality images. Researchers first tested the new imaging procedure using objects that mimic human tissues, then quickly applied the procedure to healthy volunteers and patients with disease.

“This research helps us to define new strategies that may improve accessibility and affordability of MRI as an imaging modality,” said Dr. Arthur Kaindl, head of MR at Siemens Healthineers. “We believe that the high-performance, low-field MRI will have a great impact on clinical care.”

When compared with images obtained at 1.5T, researchers saw lung cysts and surrounding tissues in patients with lymphangioleiomyomatosis, or LAM, more clearly. In addition, researchers found that inhaled oxygen could increase the brightness of lung tissue more effectively using the lower magnetic field strength when compared to the higher field strength. These results show how useful low-field MRI can be in helping identify problems in the lungs.

Researchers found similar advantages using low-field MRI during heart catheterization, a procedure used to diagnose and treat some heart conditions, or LAM, more clearly. In addition, researchers found that inhaled oxygen could increase the brightness of lung tissue more effectively using the lower magnetic field strength when compared to the higher field strength. These results show how useful low-field MRI can be in helping identify problems in the lungs.

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The new generation of low-field MRI allows increased flexibility in image acquisition, said Campbell-Washburn, and researchers can apply the technology for new clinical applications that could change how MRI is used in the future.

“We can start thinking about doing more complex procedures under MRI-guidance now that we can combine standard devices with good quality cardiac imaging,” said Campbell-Washburn, who noted that the results are also encouraging for imaging of the brain, spine, and abdomen. Imaging the upper airway with this system, she said, may also offer valuable clinical information for both sleep and speech disorders.

doi: 10.1148/radiol.2019190452

Patients say “ask before using medical records for research”

With electronic medical records creating an ideal source of data to inform quality care and new discovery, a key question emerges: how much say should patients have in how their data are used?

A new study finds that even when patients understand the overall benefit to society, they still want to be able to give consent at least once before their de-identified data is used for research (Jagsi R et al. Effect of Public Deliberation on Patient Attitudes Regarding Consent and Data Use in a Learning Health Care System for Oncology. J Clin Oncol. 2019 Oct 2. doi: 10.1200/JCO.19.01693).

“What we heard was a resounding sense that people want to be able to control their data,” says lead study author Dr. RJagsi, director of the Center for Bioethics and Social Sciences in Medicine at the University of Michigan.

“Many patients indicated they fully intended to allow for their data to be used, but they wanted the respect of being told and having the chance to say no. Programs trying to facilitate use of data collected in routine patient care encounters for other purposes — even highly worthy ones like improving the quality of care and research — need to be mindful of transparency and clarity in the communication of their goals and activities so patients don’t feel violated when they find out how their data was used,” Jagsi says.

While previous research suggested patients had some unease with their data being used for research without their permission, these earlier studies often did not focus on making sure patients understood how this research could improve care or the importance of including all possible data to maximize benefit to the community.

In this new study, researchers used a novel approach called democratic deliberation. Participants were given information about why and how data are used, followed by facilitated small group discussions about the benefits and concerns. Participants were surveyed throughout the process to assess their attitudes toward use of de-identified patient data for research. Altogether, 217 cancer patients participated at four diverse sites in day-long democratic deliberation sessions.

The vast majority of participants — 97% — thought it was important to conduct medical research using de-identified electronic health records. Support for academic medical centers or community hospitals seeking to improve quality was high, but fewer people were comfortable with insurance companies or drug companies using their data, as well as hospitals using their data for marketing purposes.

Initial surveys showed 84% of participants thought it was important for doctors to ask patients at least once whether their de-identified data could be used for...
future research. That number dropped to 66% after discussion. A month later, 75% wanted to give permission.

Race and ethnicity played a significant role. White participants were less likely than non-white participants to value consent. Half of the minority participants expressed wanting to give consent every time their medical records were used, compared to a quarter of white participants. Jagi says this discrepancy likely reflects historical injustices experienced by minority populations in the context of clinical research. She emphasized that systems must be structured in ways that all patients feel respected so that they do provide access to their data — especially since minorities are often underrepresented in research. “Including data from diverse patient populations is crucial for quality improvement and discovery,” Jagi says. “At the same time, we do not want patients to feel they gave their information for one purpose and that — albeit with good intentions — we are using it for another purpose. Policies around learning health care systems must be grounded in and respectful of public opinion if we are to realize the great promise of big data in health care.”

doi: 10.1200/JCO.19.01693

Radiology organizations publish statement on ethics of AI in Radiology

Experts in the use of artificial intelligence (AI) in radiology, from many of the world’s leading radiology, medical physics and imaging informatics groups, have published an aspirational statement to guide the development of AI in radiology.

Simultaneously published in the Journal of the American College of Radiology, Radiology, Insights into Imaging and the Canadian Association of Radiologists Journal, the paper also sought to address and incorporate feedback received from patients, radiologists, regulators and other stakeholders during a comment period that ended in April 2019 (Geis JR et al. Ethics of Artificial Intelligence in Radiology: Summary of the Joint European and North American Multisociety Statement. Can Assoc Radiol J. 2019 Oct 1. doi: 10.1016/j.carj.2019.08.010.)

The authoring societies include the American College of Radiology (ACR), European Society of Radiology (ESR), Radiological Society of North America (RSNA), Society for Imaging Informatics in Medicine (SIIM), European Society of Medical Imaging Informatics (EuSoMII), Canadian Association of Radiologists (CAR) and American Association of Physicians in Medicine (AAPM).

As a new technology, AI lacks clear standards guiding its development and use. Authors emphasize that ethical use of AI in radiology should promote well-being and minimize harm resulting from potential pitfalls and inherent biases. It should also ensure that benefits and harms are distributed among stakeholders in a just manner that respects human rights and freedoms, including dignity and privacy.

“Radiologists remain ultimately responsible for patient care and will need to acquire new skills to do their best for patients in the new AI ecosystem,” said Dr. J. Raymond Geis, one of the paper’s leading contributors. “The radiology community needs an ethical framework to help steer technological development, influence how different stakeholders respond to and use AI, and implement these tools to make the best decisions for — and increasingly with — patients.”

“Developments in artificial intelligence represent one of the most exciting, and most challenging, changes in how radiology services will be delivered to patients in the near future,” said Dr. Adrian Brady, Chairperson of the ESR Quality, Safety and Standards Committee and co-author. “The potential for patient benefit from AI implementation is great, but there are also significant risks of unexpected or unplanned harmful effects of these changes. It’s incumbent on professionals working in this area to ensure that patient and public benefit and safety are paramount.”

“The application of AI tools in radiological practice lies in the hand of the radiologists, which also means that they have to be well-informed not only about the advantages they can offer to improve their services to patients, but also about the potential risks and pitfalls that might occur when implementing them,” said Dr. Erik R. Ranschaert, president of EuSoMII. “This paper is therefore an excellent basis to improve their awareness about the potential issues that might arise, and should stimulate them in thinking proactively on how to answer the existing questions.”

Dr. Cynthia McCollough, president of the AAPM emphasized that “in order for AI technology to positively impact human health, it is crucial that robust and reproducible data, methods, guidelines, and tools are developed and made available. As quantitative and interdisciplinary scientists, medical physicists are playing an essential role in the development of these essential resources — we need to ensure that variability and bias are minimized in the data used to answer compelling medical questions.”


Review of vaping-associated lung injury findings

A recent article summarizes common imaging manifestations of electronic nicotine delivery systems (ENDS) (Henry TS et al Imaging Findings of Vaping-Associated Lung Injury. AJR Am J Roentgenol. 2019 Oct 8:1-8. doi: 10.2214/AJR.19.22251). “Because there is not a standardized case definition for vaping-associated lung injury,” said Dr TS Henry “the diagnosis of lung injury due to vaping may be made by establishing a temporal relationship between change in vaping habits and onset of lung disease, exclusion of other causes of lung disease (e.g., infection, other drug or exposure, connective tissue disease, and..."
so on), and stabilization or improvement with cessation of vaping and possibly with corticosteroid treatment.”

Stressing the importance of recognizing the following patterns seen with ENDS, Henry noted that the radiologist may be the first person to prompt the clinical team to ask about relevant exposures:

**Hypersensitivity Pneumonitis** Typical findings on CT include symmetric upper lung-predominant and midlung-predominant ground-glass opacity (GGO), poorly defined centrilobular nodules, and occasionally mosaic attenuation reflective of air trapping. Henry and team observed improvement after cessation of antigen inhalation.

**Diffuse Alveolar Hemorrhage** Although chest radiography or CT alone is not sufficient to distinguish from other causes of acute lung opacities — aspiration, edema, infection, etc. — patients may be anemic, and bronchoalveolar lavage (BAL) with persistent or increasingly bloody aliquots can confirm diagnosis.

**Acute Eosinophilic Pneumonia** Often bloody aliquots can confirm diagnosis. (BAL) with persistent or increasingly bloody aliquots can confirm diagnosis.

**Organizing Pneumonia** A common response to lung injury characterized by fibroblast proliferation and collagen deposition, the most typical CT findings are bilateral patchy GGO, consolidation, or both in peripheral or perilobular distribution. Henry and colleagues noted that the “reverse halo” or “atoll” sign is also associated with organizing pneumonia.

**Lipoid Pneumonia**

Although the basic content of ENDS flavoring agents are juices, agent constituents like glycerin may produce in the form of endogenous phospholipidosis. However, macroscopic fat attenuation within consolidation (< -30 HU) does not present in all cases, so the presence of lipid-laden macrophages on BAL or foreign body reaction around lipid at histology can confirm diagnosis.

**Giant Cell Interstitial Pneumonia**

With hard metal contamination of vaping aerosols well documented, Henry et al. encountered one pathologically proven case of this rare pneumoconiosis, attributable to trace amounts of cobalt in the patient’s vape pen.

“Because of the heterogeneity of both the construction of e-cigarettes and the substances aerosolized, there are likely many other pulmonary manifestations not covered in this article,” Henry acknowledged.

“For instance, ENDS mixtures may also contain compounds such as diacetyl, known to cause other lung injury patterns, including constrictive bronchiolitis,” he concluded.

doi: 10.2214/AJR.19.22251

**Autoantibody test followed by CT imaging may reduce lung cancer mortality**

A combination of the EarlyCDT-Lung Test followed by CT imaging in patients at risk for lung cancer resulted in a significant decrease in late stage diagnosis of lung cancer and may decrease lung cancer specific mortality, according to research presented at the recent IASLC 2019 World Conference on Lung Cancer. The research was presented by Prof. Frank Sullivan, University of St Andrews, Scotland, UK.

Scotland has one of the highest rates of lung cancer in the world — approximately 460 men and 340 women for every 100,000 Scottish citizens are diagnosed with lung cancer every year. Fewer than 9 percent of all lung cancer patients reach their five-year survival mark.

The EarlyCDT-Lung Test is a novel autoantibody diagnostic test for the early detection of lung cancer that allows stratification of individuals according to their risk of developing lung cancer. The test identifies 41 percent of lung cancers with a high specificity of 90 percent, compared to CT scanning, which identifies 67 percent of lung cancers but with a low specificity of 49 percent. Sullivan and his team sought to determine whether using the EarlyCDT-Lung Test, followed by X-ray and CT scanning, could identify those at high risk of lung cancer.

They randomized 12,208 participants aged 50 to 75 who had a high risk of developing lung cancer over the next 24 months. Test positive patients were offered a chest X-ray followed by a non-contrast thoracic CT scan. If the initial CT scan revealed no evidence of lung cancer, then subsequent CT scans were offered monthly for 24 months. Individuals with abnormalities were referred up over the study period or referred to clinical care as appropriate. Sullivan’s team discovered that 127 lung cancers were diagnosed in the study period (56 in the intervention group and 71 in the control arm) and 9.8 percent of the intervention group had a positive EarlyCDT-Lung test and 3.4 percent (n=18) of these were diagnosed with lung cancer in the study period.

Sullivan said that significantly fewer participants in the intervention group were diagnosed at a late-stage compared with the control group (33 vs 52).

“Our results show that the combination of the EarlyCDT-Lung followed by CT imaging in those with a positive blood test, results in a significant decrease in late stage diagnosis of lung cancer and may decrease all cause and lung cancer specific mortality”.

https://tinyurl.com/Sullivan-at-IASLC
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The usefulness of pre-operative MRI in the management of patients with Invasive Lobular Carcinoma

By Dr. S J Barker, Dr. E Anderson & Dr. R Mullen.

This review summarises the results of a recent retrospective study of patients diagnosed with Invasive Lobular Carcinoma of the breast. The objectives of the study were to assess the impact of pre-operative MRI on the management of such patients and to evaluate whether high breast density was associated with an increased likelihood of additional disease being found on MRI.

Around 54,900 new cases of invasive breast cancer are diagnosed each year in the United Kingdom alone [1]. Proportionally similar incidence rates are found in many Western countries. Invasive Lobular Carcinoma (ILC) is the second most common histological type of breast cancer, accounting for more than 1 in 10 cases [1]. ILC is often not apparent on mammography due to its non-cohesive histologic growth pattern, low opacity and low likelihood of producing calcifications. As a result ILC can present diagnostic and therapeutic challenges due to its potentially occult and multifocal nature [2].

The multifocality of ILC also makes it more likely that surgical excision is incomplete; reported re-excision rates after Breast Conserving Surgery (BCS) range from 29-67% and conversion to mastectomy after failure of BCS range from 20-49% [3, 4].

The use of contrast-enhanced magnetic resonance imaging (MRI) determines tumor extent more accurately than mammography and ultrasound [3]. MRI is highly sensitive (nearly 100%) but has lower specificity (65-79%), with a false negative rate of 4-12%. MRI has been shown to improve visualization of ILC tumors [5], and there is some evidence that MRI reduces re-excision surgery in patients with ILC, although at the expense of increased mastectomy rates [6]. Current UK guidelines recommend the use of MRI if BCS is being considered for ILC patients as well as when breast density precludes accurate mammographic assessment — it is well established that mammographic sensitivity is reduced in dense breasts [7, 8]. Mammographic density is also, in itself, a strong independent risk factor for the development of breast cancer, with malignant breast tumors more likely to arise in the areas of greatest mammographic density [9].

The aim of our study [10] was to assess the impact MRI had upon further investigation and subsequent management of patients who had a diagnosis of ILC and who were being considered for BCS. A second aim was to evaluate whether, in such patients, additional findings on MRI were associated with increased mammographic breast density.

STUDY MATERIALS AND METHODS

Patients diagnosed with ILC between January 2013 and December 2016 were identified from our database containing electronically stored records of the information from the multi-disciplinary team (MDT) meetings discussing the cases. The data so harvested were analyzed retrospectively. In our hospital, patients deemed suitable for BCS undergo an MRI scan which is then reviewed at the MDT meeting. All patients underwent MRI scans in the prone position using dedicated breast coils and in the same hospital (Phillips Achoeva 1.5T).

Using the hospital online results system (SCI Store v8.3, NHS National Services Scotland), patient characteristics and details of pathology results were collected, as well as the outcomes of MRI scans and the findings of any additional biopsies performed as a result of the MRI findings. A consultant breast radiologist with extensive experience in both screening and symptomatic work assessed each patient’s mammograms to determine their breast density, using the ACR BI-RADS scale for mammographic breast composition to grade breast density. The radiologist was blinded as to the purpose of the assessment [11].

By carefully analyzing the electronic records in the database, the impact of MRI and secondary biopsy findings on surgical decision-making could be ascertained. The relationship between mammographic breast density and the number of additional findings on MRI was also examined.

The NHS Highland Research and Ethics Committee which has responsibility for our hospital, considered our project as a service improvement and audit study; so formal management approval was not required; a letter of no objection was issued.
provided by the NHS Highland Research and Development Team. Statistical analysis was carried out using VassarStats:Website for Statistical Computation [12]. Chi-squared tests were used to compare the relationship between breast density and MRI findings. A P value of <0.05 was considered statistically significant.

**RESULTS**

110 women with ILC were identified; 68 from a symptomatic pathway and 42 from a screening pathway. In this cohort 95 patients (86.4%) underwent surgery and 69 patients (72.6%) were deemed potentially suitable for BCS following review at the MDT meeting.

Of the patients judged suitable for BCS 84.1% of cases (58 patients) underwent MRI. In 11 patients, claustrophobia, a high BMI or a preoperative diagnosis of ductal carcinoma excluded the carrying out of MRI examinations. New findings not seen with mammography or ultrasound were detected in 22 patients following MRI (37.9%). Figure 1 outlines the outcomes of these patients. Nine had no further abnormality detected with second-look USS but 13 patients required further core biopsy.

Following review of all MRI scans at the MDT meeting, seven patients (12.1%) were considered no longer suitable for BCS due to tumor size (two patients) or multifocality (five patients). Further surgery due to positive margins was required in 13 patients (26.5%). Seven patients had margins re-excised and six patients underwent completion mastectomy.

The findings of preoperative MRI examinations of patients requiring further surgery did not appear to correlate with residual multifocal disease at final pathology.

In 49% of cases, the size of the tumor as reported on MRI was found to be accurate to within 5 mm of that found on pathology.

When assessing mammographic breast density a BI-RADS category of A-B was found in 37 patients (63.8%) while 21 patients (36.2%) had a BI-RADS score of C-D. There was no association between increased breast density and further disease as identified on MRI [Table 1]. However, the number of malignancies identified on second-round core biopsy was noted to be higher in patients with dense-breasts: 12.5% in BI-RADS category D patients compared to 7% in BI-RADS category A patients. There was no correlation between increased breast density and the risk of needing further surgery; of the 13 patients who required further surgery for positive margins, 10 patients had low-density breasts (BI-RADS, categories A-B).

**DISCUSSION**

Preoperative MRI assessment of the breast is known to detect additional disease but there is currently no evidence that it affects recurrence rates or disease-free survival [6, 13-15]. The improved sensitivity of MRI comes at the expense of reduced specificity [14, 16]. In our group of patients, preoperative MRI resulted in additional investigations in 37.9% of patients so delaying their initially planned surgical intervention. This delay to surgery is unlikely to affect the patient’s long-term survival but there is likely to be an additional psychological burden associated with treatment delay and with the need for further investigations as a result of the MRI findings. Previous research has found that a diagnosis of breast cancer causes considerable anxiety and psychological distress in “waiting” patients and this could be exacerbated by patients needing to wait even more for additional investigations necessitated by MRI [17]. A study by Berg et al. found that the need to undergo additional tests due to MRI findings influenced the patients’ choice to undergo mastectomy so as to avoid such tests. This resulted in a 12% rate of “unnecessary mastectomies” [16, 18]. In our cohort of patients, 13 women chose mastectomy despite being offered BCS. Since our study was retrospective it is not possible to ascertain the specific reasons for which patients chose mastectomy but one reason could be

**Figure 1.** Patient outcomes. After second-look US, nine patients had no further detected abnormality but 13 patients required further core-biopsy.
that they simply wished to avoid further tests and treatment delay.

MRI examinations have costs related not only to the scan itself but also to the additional workload it generates in patients requiring further investigations as well as to MTI review. There are limited data available regarding the precise cost-effectiveness of MRI in such situations but the resource burden associated with its use needs always to be recognized [9, 17]. The percentage of our patients whose management changed from BCS to mastectomy was 10.1%, which is in keeping with the results from a meta-analysis of non-randomized studies assessing the clinical value of preoperative MRI [6, 19, 20]. After reviewing final pathology specimens for multifocality and tumor size it was found that one of our patients had undergone a mastectomy that on, the basis of the pathology findings, was avoidable, which is of course concerning. However our sample size is modest and a larger sample may have borne out our original hypothesis.

In addition to the sample size, our study has several limitations. Firstly, the non-randomized and retrospective nature of this study should be taken into account. Secondly, women undergoing MRI had a mean age of almost 10 years younger than those who did not undergo MRI. We have to consider whether this is selection-bias towards BCS in younger patients and whether this was a preference of surgeons or of the patients. It is unknown if the need for MRI played a role in the patient’s decision-making process regarding the choice of undergoing BCS but this may be an important factor to be considered in further research. We know that 19% of the women in our group who were considered for BCS ultimately chose mastectomy. It is important to take into account that the patients in our study group tended overall to have less dense breasts (63.8%). To assess this further we would recommend that a larger sample size of patients with high density breasts be reviewed before definitive conclusions are drawn. Our group of patients had pathology-confirmed diagnoses of ILC, so care must be taken when extrapolating our findings to other types of breast cancer.

CONCLUSION

We found that the identification by MRI of additional lesions in the assessment of ILC patients scheduled for BCS rarely changed the surgical approach. In our sample of patients, breast density did not predict the likelihood of subsequent MRI findings and therefore breast density should not be a factor used to justify MRI in this setting. Further prospective studies with larger patient populations are needed to confirm our findings and to further assess the role of MRI in the management of ILC patients.

<table>
<thead>
<tr>
<th>BI-RADS A-B</th>
<th>Normal MRI (%)</th>
<th>Abnormal MRI (%)</th>
<th>Chi-squared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bi-RADS C-D</td>
<td>7 (12.1)</td>
<td>15 (25.9)</td>
<td>22 (37.9)</td>
</tr>
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</table>

Table 1: MRI findings and mammographic breast density
Breast MRI in the management of the discordant-benign core biopsy

By Dr. L M Sanders

This article summarizes the results of a recent retrospective study evaluating the use of contrast-enhanced MRI (CE-MRI) in the management of discordant benign core biopsy results. The results showed that CE-MRI facilitated the successful triage of patients, permitting 68.9% of patients with a discordant benign pathology result to avoid surgery [1].

A necessary aspect of the core biopsy process is the evaluation of concordance by the breast interventionalist — the pathologic results of the biopsy must be compared to the imaging characteristics of the lesion sampled. If the pathology matches, the results are judged to be concordant. However, if the pathology results are benign for a lesion with moderate to highly suspicious imaging (or clinical) characteristics, the biopsy should be deemed discordant-benign. The standard of care for lesions that fall into this category following core biopsy has traditionally been surgical excision [2,3]. The American Society of Breast Surgeons performance and practice guidelines enumerates accepted surgical standards for excisional biopsy and includes discordance biopsy results as a valid indication for surgery [4].

Contrast-enhanced MRI (CE-MRI) has become widely accepted as the most sensitive imaging modality for the detection of breast malignancy compared to digital mammography and ultrasound [5]. Over the past two decades, CE-MRI has been found useful in a wide variety of clinical circumstances, including high risk screening, extent of disease evaluation in newly diagnosed breast cancer, locating mammographically occult breast malignancy, in monitoring response to neoadjuvant chemotherapy, and in the evaluation of bloody nipple discharge after negative conventional imaging [6-9].

The purpose of our retrospective study was to determine whether CE-MRI was useful in the triage of patients to definitive surgery or follow-up after ultrasound or stereotactically guided discordant-benign core biopsy results.

Our study population included 45 women who underwent CE-MRI after a discordant-benign biopsy (identified by that phrase in the history field of MRI reports). Biopsies were performed under ultrasound guidance using a non-vacuum assisted device (Monopty, Bard) or under stereotactic guidance using an Eviva

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Figure 1. A 57 year-old woman with palpable concern in her left retroareolar region. Ultrasound (A) revealed a vague hypoechoic lesion (white arrow) behind the nipple. Pathology of ultrasound guided core biopsy showed stromal fibrosis, felt to be discordant-benign. CE-MRI (B) demonstrated an enhancing mass involving the nipple-areolar complex (white arrow), interpreted as a suspicious finding. Repeat ultrasound-guided biopsy revealed invasive ductal carcinoma.
system (Hologic). MRI examinations were performed with a 1.5T system (Ingenia, Philips Healthcare) and a 16-channel breast coil. Sequences included: T1 weighted nonfat-saturated, T2 weighted fat-saturated, and dynamic sequences using T1 weighted fat-saturation prior to and then following intravenous gadolinium by patient weight. K-space was centered at 90 seconds.

Three dedicated breast radiologists with 11-24 years of experience in breast imaging and intervention performed the biopsies and interpreted the MRIs.

The 45 patients (46 lesions) with discordant results were grouped into two categories: those with suspicious findings at CE-MRI and those without suspicious findings.

The suspicious group was comprised of 14 lesions in 14 patients. Mean patient age was 62.0 years, mean lesion size was 13.7 mm. A second site of suspicious enhancement was identified in 3 patients (one ipsilateral and two contralateral to the side of the discordant core biopsy). In 4 patients, core biopsy of the original lesion was repeated after MRI, revealing malignancy. All patients with suspicious findings on CE-MRI underwent surgery. Pathologic results of the 14 discordant lesions included: 6 invasive ductal carcinomas, two ductal carcinomas in situ (DCIS), one lobular carcinoma in situ, classic type (LCIS), three papillomas, one sclerosed fibroadenoma, and one stromal fibrosis with fat necrosis. In total there were eight malignancies, four borderline lesions and two benign lesions. The three incidental lesions found at MRI included one contralateral IDC, one contralateral LCIS and one ipsilateral DCIS. For the purposes of statistical analysis of the sensitivity/specificity/positive predictive value and negative predictive value for MRI of 12/12 or 100%, 28/30 or 93.3%, 12/14 or 85.7% and 28/28 or 100% respectively. The false negative rate was 0/12, or 0%. The false positive rate was 2/30 or 6.7% The use of CE-MRI in the triage of patients following discordant benign biopsies successfully allowed avoidance of surgical management in 31 of the original 45 patients (68.9%).

Contrast enhanced MRI of the breast has been shown to be the most sensitive imaging modality for the detection of breast malignancy [5]. Although detractors of the modality have pointed to its high false positive rate during the early era after its introduction, over the ensuing decades, the technique has improved with regards to its spatial-temporal resolution and standardization of imaging protocols. With experience, breast imagers have developed greater skill interpreting the imaging characteristics of both benign and malignant disease. Incorporation

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Figure 2. A 78 year-old woman with remote history of surgery in uncertain location in the left breast. Left craniocaudal mammogram image (A) showed medial asymmetry (white arrow). Ultrasound (B) demonstrated an irregular lesion with shadowing (white arrow). No prior studies were available for comparison and core biopsy was recommended. Pathology of biopsy revealed stromal fibrosis, felt to be possibly discordant. CE-MRI was recommended. T1 weighted sequence (C) showed the irregular lesion (white arrow) which was non-enhancing on post-contrast dynamic sequence (D) in the medial left breast (white arrow). Follow-up imaging at 18 months confirmed stability of lesion.
Our aim was to evaluate the use of CE-MRI in the management of the discordant benign core biopsy, relying on evidence that non-enhancement on breast MRI was reliable in excluding malignancy.

This evidence is based on an important prospective study published in 2015 by Strobel et al. [10] of BI-RADS category 4 lesions identified by mammography and ultrasound that were subsequently assessed by MRI. In that study, MRI was shown to have a false-negative rate of 0% and a negative predictive value of 100% in the evaluation of all lesions, except pure clustered microcalcifications. In their study, there was a 12% false negative rate for MRI for pure clustered microcalcifications due to non-enhancement in three cases of low-grade DCIS. Strobel et al. emphasize that for BI-RADS 4 lesions seen on mammogram or ultrasound (excepting pure clusters microcalcifications), MRI performed prior to biopsy would help to avoid 92% of unnecessary biopsies.

Malignancy may be able to avoid surgery by incorporating CE-MRI with the work published by Strobel et al. [10]. We recommend further research to evaluate the use of MRI in specific diagnostic settings, particularly those that the American Society of Breast Surgeons considers indications for surgical excision. The immediate goal should be to reduce the frequency of surgery on benign lesions. The goal over the longer term should be to reduce the frequency of benign core biopsies by incorporating CE-MRI into the management algorithm of BI-RADS 4 lesions.

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Integrating technology into the breast care continuum can enhance patient experience

By Lori Fontaine

There are many steps in a breast cancer patient’s journey, from a routine screening mammogram all the way through pathology and treatment. Each of these steps is tied to the one before it – for example, patients do not get a biopsy until they have accurate, clear images taken of their breasts. Furthermore, clinicians are accountable for much more than clinical accuracy at each point in the patient journey. In today’s healthcare environment, they are also responsible for the growing priority of improving the patient experience, such as comfort level, as well as working more efficiently, a combination of priorities which can be challenging. As a result, it’s important for healthcare professionals to approach a patient’s journey with a holistic view—as a singular continuum of care, from screening through treatment, rather than in isolated procedures and individual patient visits.

One way of positively impacting the patient journey and clinician’s workflow is through technological innovation.

SCREENING
Consider the screening portion of the breast cancer journey.

The key purpose of the screening exam is to detect suspicious tissue, ideally as early as possible, making the capability of capturing clear, accurate images necessary.

In the broader picture, there are also other factors to keep in mind, such as patient anxiety and extra workflow for clinicians when patients are called back for a diagnostic exam before a biopsy can occur. With the introduction of digital breast tomosynthesis (DBT), more invasive cancers can be detected and callbacks are reduced. Hologic’s 3D Mammography Exam, for example [Figure 1], is clinically proven to detect 20-65 percent more invasive breast cancers compared to 2D mammography alone [1] and reduces recalls by up to 40 percent compared to 2D mammography alone. [2,3].

While European clinicians are still adopting DBT as the standard of care, in the United States, clinicians are receiving so much information from the 3D images in the initial routine screening.

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Figure 1. Designed to be the fastest, highest resolution breast tomosynthesis system, the 3Dimensions system from Hologic is designed to provide higher quality 3D images for radiologists, a more comfortable mammography experience for patients and enhanced workflow for technologists.
phase that some facilities are able to forgo having the diagnostic mammogram before a biopsy. Instead, some patients are able to go straight from their screening exam to biopsy, accelerating their care pathway on the breast care continuum so they can get started on the next step sooner – a huge feat given the long road cancer patients have lying ahead of them. In turn, clinicians can move on to help the next patient rather than re-screening the same one.

BIOLOGY

When looking at the next step in the care pathway, the breast biopsy procedure, the goal is to obtain the tissue from the area of concern so that it may be sent to pathology for diagnosis. When viewing this procedure in the larger context of the continuum, though, additional priorities arise.

After the biopsy, the patient may receive a breast cancer diagnosis and need to start treatment. Due to this concern, her anxiety level is likely to be heightened during the biopsy, making a shorter procedure desirable.

Additionally, if the clinician does not extract breast tissue samples from the correct location, he or she will have to remove more tissue, potentially adding to the patient's discomfort and making the procedure time longer. In many locations where biopsies are performed, the tissue samples need to be verified on imaging equipment in a separate room. After the biopsy procedure, core samples need to be properly handled and delivered to pathology—maintaining sample integrity is crucial in order for the samples to be successfully analyzed by pathology. Otherwise the biopsy will need to be repeated.

Fortunately, new technology can help streamline the process to address both patients' and clinicians' needs during and after the procedure. For example, Hologic's Brevera Breast Biopsy System with CorLumina imaging technology [Figure 2] is designed to eliminate five steps in the biopsy process by combining tissue acquisition, imaging, verification, and sample preparation, with the potential to save 10 minutes on average per patient [4]. Fast procedures mean less time under compression and can result in a more positive patient experience, while clinicians can have a greater confidence in the biopsy workflow.

PRE-SURGICAL BREAST LESION LOCALIZATION

If pathology determines that the patient has a cancer requiring surgical removal, the radiologist will need to mark the tumor in the breast for surgical resection. Traditionally, a wire would be inserted into the patient's breast the same day as her surgery, potentially creating logistical hurdles for health care teams which need to schedule the wire procedure on the same day as the surgery. The wire localization procedure can cause patient discomfort and anxiety as the wire protrudes from the skin. If the surgical resection does not achieve tissue margins that are clear of tumor, patients often need to return for a second resection. This scenario is yet another example of how the integration of technology may be able to enhance the patient and clinician experience.

Consider the LOCAlizer wireless radio frequency identification (RFID) breast lesion localization system [Figure 3]. The RFID tag can be implanted up to 30 days prior to a surgery, providing increased flexibility for providers and a better experience for patients, who no longer need to walk around with a wire sticking out from their breast while they wait for their surgery. The technology is designed to improve workflow for clinicians to help reduce the complexity of scheduling for the healthcare team and aims to deliver added convenience for an enhanced patient experience, as it provides an opportunity to disconnect the radiology localization procedure from the surgery. Following placement, the miniature implantable tag can be detected by a portable, handheld reader that indicates the location and distance in millimeters from the skin to the lesion in the breast, enabling the surgeon to
pinpoint the correct area of breast tissue for removal. While the primary goal of the surgical procedure is to remove the cancer, it’s important to once again look ahead in the continuum of care to enhance the patient experience from treatment through recovery. While complete cancer removal is crucial, it’s also important to recognize the emotional value of helping a woman maintain the desired contour of her breast.

**Implantable Markers**

Fifty years ago, the principal treatment for breast cancer was a radical mastectomy, a deforming surgery that involved removing not only the breast but also all the underlying chest muscles and lymph nodes in the armpit. With advances in screening technology and increased awareness, breast cancer can be detected earlier, giving women alternative possibilities, such as breast-conserving surgery, which allows the cancer to be removed while conserving the surrounding breast tissue, leaving the breast looking as natural as possible. For such a procedure, 3D implantable markers, such as the BioZorb® 3D Bioabsorbable Marker [Figure 4] can help the clinicians involved in the patient journey from surgery through radiation treatment and radiological follow-up.

Thus, the innovation of technology to support the breast continuum of care comes full circle, as initial screening capabilities can improve early detection, which ultimately can influence treatment and recovery. This cycle demonstrates the importance of approaching breast cancer detection and treatment from a holistic view, not only taking into consideration what each step entails from a clinician’s perspective, such as precision and confidence, but also from a patient’s perspective, focusing on comfort and anxiety reduction.

Healthcare providers should be seeking solutions to improve the continuum of care, and it’s clear that technological innovations can help make a meaningful impact on what matters most—patients.

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Study shows mammography unlikely to benefit older women with chronic illnesses

*Mortality due to chronic illness greatly exceeds breast cancer risk*

Regular screening mammograms are unlikely to benefit women aged 75 and older who have chronic illnesses such as cardiovascular disease or diabetes. New data suggest they would likely die due to other health conditions before they developed breast cancer.

That is the finding of a recently published study based on data from more than 220,000 women (Demb J et al. Screening mammography outcomes: risk of breast cancer and mortality by comorbidity score and age J Natl Cancer Inst. 2019 Sep 6. pii: djz172. doi: 10.1093/jnci/djz172)

“Our findings shed light on what age may be the best stopping point for mammography. If you have chronic illnesses after age 75, our findings do not support continuing mammograms,” said senior author Dr. Dejana Braithwaite, an associate professor of epidemiology and oncology at Georgetown Lombardi Comprehensive Cancer Center.

Using data from Medicare claims and the Breast Cancer Surveillance Consortium — which gathers the largest set of data in the world on older women who receive mammograms, as the United States is one of the few countries to continue screening women into their 80s and sometimes 90s — the researchers found that for women who lived past age 75, fewer cases of new invasive breast cancer and ductal carcinoma in situ (DCIS), the non-invasive pre-malignant growth, occurred.

“This study examined who is not likely to benefit from screening mammography after 75 years of age,” said co-author, Dr. Karla Kerlikowske, professor of medicine at UCSF and physician at UCSF-affiliated San Francisco VA Medical Center. “We hope that future research efforts can build on our evidence and inform discussions about optimal screening strategies for older women.”

The investigators looked at breast cancer incidence and death from breast cancer and other causes over a period of 10 years among 222,088 women who had one or more mammograms between 66 and 94 years of age; they found that 7,583 women were diagnosed with invasive breast cancer and 1,742 with DCIS. Over the 10 years, 471 women died from breast cancer and 42,229 died from other causes, a nearly 90-fold difference.

The investigators also noted:
- Women aged 75 to 84 were 123 times more likely to die of causes other than breast cancer; this estimate was even higher among women age 85 and older.
- The risk of dying from breast cancer stayed steady as the risk of dying from non-breast cancer causes increased; conversely, the risk of being diagnosed with breast cancer decreased slightly after age 75 regardless of women’s overall health status.
- The 10-year risk of dying from breast cancer was small and did not vary by age; it stayed about the same from age 66 to 94, accounting for just 0.2% -0.3% of all deaths.

The United States Preventive Services Task Force notes that there is not enough evidence to recommend for or against screening women age 75 or older. Many breast cancer programs in Europe stop screening women between the ages of 69 and 74.

“Our research underscores the need to individualize screening decisions among older women,” said Dr. Joshua Demb, a post-doctoral researcher at the University of California San Diego. “To that end, we hope that our analyses contribute to developing effective tools that older women can use in consultation with their health care providers to decide a screening strategy that is best for them.”

doi: 10.1093/jnci/djz172

Ultrasound yields similar cancer detection rates after digital mammography or after tomosynthesis

*Dense breast ultrasound screening after digital mammography — versus after digital breast tomosynthesis — yielded ‘no significant difference’ in additional cancer detection rate*

The majority of data available on screening breast ultrasound are from patients screened after digital mammography (DM), and not after digital breast tomosynthesis (DBT). Compared to DM, DBT improves detection of breast cancer in women with dense breasts. The value that US screening adds in patients who have already undergone mammographic screening with DBT remains unclear.

Given the enhanced cancer detection with DBT, a group of researchers from Brown University hypothesized that fewer cancers would be identified by US after DBT compared to after DM. They carried out a study to compare the yield of dense breast US screening after DM versus after DBT by comparing additional cancers or other findings requiring biopsy in patients with dense breasts who undergo US screening after DM or DBT (Dibble EH et al. Dense Breast Ultrasound Screening After Digital Mammography Versus After Digital Breast Tomosynthesis. AJR Am J Roentgenol. 2019 Sep 25; 1-6. doi: 10.2214/AJR.18.20748). Lead investigator Elizabeth H.
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2. Hologic FDA approved submissions files P080003, P080003/S001, P080003/S004, P080003/S005.
Dibble of Brown University and colleagues retrospectively searched databases at two tertiary breast imaging centers and an office practice, focusing on 3183 screening breast US examinations performed from October 2014 to September 2016—1434 (45.1%) after DM and 1668 (52.4%) after DBT. The purpose of the study was to compare the yield of dense breast US screening after DM versus after DBT by comparing additional cancers or other findings requiring biopsy in patients with dense breasts who undergo US screening after DM or DBT.

Of these 3183 examinations, 81 (2.5%) had no prior mammogram available. Of the 122 DM and DBT patients for whom biopsy or cyst aspiration was recommended — all BI-RADS assessment category 4 or 5 studies — 118 (96.7%) had biopsy or cyst aspiration results available.

Of the 36 biopsies or aspirations after DM, 6 (16.7%) were malignant, and 30 (83.3%) were benign. Of the 82 biopsies or aspirations after DBT, 11 (13.4%) were malignant, and 71 (86.6%) were benign (p = 0.8583).

Overall, the additional cancer detection rate by US after DM was 5/1434, or 3.5 per 1000 women screened; after DBT, the detection rate was 5/1668, or 3.0 per 1000 women screened (p = 0.9999).

Dibble concluded: “DBT does not obviate additional US screening in women with dense breast tissue. No evidence was found of a difference in additional cancer detection rate with screening US after DM versus after DBT. Knowing that the cancer yield of screening US is similar after DBT versus DM may help inform clinical practice, because questions abound about whether DBT is sufficient screening for women with dense breast tissue.”

doi: 10.2214/AJR.18.20748

Updated guidelines on BRCA-related genetic counseling and testing

A recent update to the USPSTF guidelines recommends that providers use a risk assessment tool for all women with personal or family history of breast and ovarian cancer.

Potentially harmful mutations of the breast cancer susceptibility 1 and 2 genes (BRCA1/2) are associated with increased risk for breast, ovarian, fallopian tube, and peritoneal cancer. In the Western world, breast cancer is the most common cancer after non-melanoma skin cancer and the second leading cause of cancer death. In the general population, BRCA1/2 mutations occur in an estimated 1 in 300 to 500 women and account for 5% to 10% of breast cancer cases and 15% of ovarian cancer cases.

In 2013, the U.S. Preventive Services Task Force (USPSTF) recommended referral to genetic counseling only for women with a family history of breast, ovarian, tubal, or peritoneal cancer.


The key recommendations of the recent update are:
- Primary care providers should screen patients who have a personal history or family history of breast and ovarian/ peritoneal/tubal cancers.
- One of the seven available risk assessment tools should be used to estimate the likelihood of carrying a pathogenic BRCA mutation.
- Women with a positive screen should be referred for genetic counseling and, if indicated, testing.
- Routine screening and genetic testing are not recommended among the general population without a history suggestive of BRCA mutation.

Many professional oncology societies have already adopted genetic testing guidelines that address family history and...
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¹. Data on file and from public sources, 2017. ². Results from Friedewald, SM, et al. “Breast cancer screening using tomosynthesis in combination with digital mammography.” JAMA 311.24 (2014): 2499-2507; a multi-site (13), non-randomized, historical control study of 454,000 screening mammograms investigating the initial impact of the introduction of the Hologic Selenia® Dimensions² on screening outcomes. Individual results may vary. The study found an average 41% increase and that 1.2 (95% CI: 0.8-1.6) additional invasive breast cancers per 1000 screening exams were found in women receiving combined 2D FFDM and 3D™ mammograms acquired with the Hologic 3D™ Mammography System versus women receiving 2D FFDM mammograms only. ³. In an internal study comparing Hologic’s standard compression technology to the SmartCurve™ system (18 x 24cm).
personal history of cancer; now, this USPSTF update expands the obligation to the primary care arena. Among assessment tools, the Gail Model is not appropriate for calculating risk for BRCA mutation; either the Referral Screening Tool or Tyrer Cuzick is preferable. Clinicians can use a few simple red flags in a patient’s history to generate a referral for genetic testing; these include personal or family history of breast cancer with Ashkenazi Jewish ancestry, breast cancer diagnosis before age 45, male breast cancer, tubal or ovarian cancer at any age, or breast and ovarian cancer in the same individual. Direct-to-consumer genetic testing (e.g., 23andMe) only looks for 3 Ashkenazi Jewish founder mutations in BRCA genes and does not identify the other 98% of BRCA mutations.

These days, genetic testing typically involves multiple gene panels beyond BRCA; the National Comprehensive Cancer Network provides guidelines for such tests.


Combination of AI & radiologists more accurately identified breast cancer


The study examined the ability of a type of AI machine learning computer program, to add value to the diagnoses reached by a group of 14 radiologists as they reviewed 720 mammogram images.

“... an extraordinarily large dataset for the AI tool to train on, consisting of 229,426 digital screening mammography exams and 1,001,093 images. Most databases used in studies to date have been limited to 10,000 images...”

“Our study found that AI identified cancer-related patterns in the data that radiologists could not, and vice versa,” says senior study author Dr. Krzysztof J. Geras, “AI detected pixel-level changes in tissue invisible to the human eye, while humans used forms of reasoning not available to AI,” adds Dr. Geras, “The ultimate goal of our work is to augment, not replace, human radiologists.”

In 2014, more than 39 million mammography exams were performed to screen women asymptomatic for breast cancer. Women whose test results yield abnormal mammography findings are referred for biopsy.

In the new study, the research team designed statistical techniques that let their program “learn” how to get better at a task without being told exactly how. Such programs build mathematical models that enable decision-making based on data examples fed into them, with the program getting “smarter” as it reviews more and more data.

Modern AI approaches, inspired by the human brain, use complex circuits to process information in layers, with each step feeding information into the next, and assigning more or less importance to each piece of information along the way.

The authors trained their AI tool on many images matched with the results of biopsies performed in the past. Their goal was to reduce the number biopsies needed. This can only be achieved, says Dr. Geras, by increasing the confidence that physicians have in the accuracy of assessments made for screening exams (for example, reducing false-positive and false-negative results).

For the current study, the research team analyzed images collected at NYU Langone Health over seven years, sifting through the collected data and connecting the images with biopsy results.

This effort created an extraordinarily large dataset for the AI tool to train on, consisting of 229,426 digital screening mammography exams and 1,001,093 images. Most databases used in studies to date have been limited to 10,000 images.

Thus, the researchers trained their neural network by programming it to analyze images from the database for which cancer diagnoses had already been determined. This meant that researchers knew the “truth” for each mammography image as they tested the tool’s accuracy, while the tool had to guess. Accuracy was measured in the frequency of correct predictions.

In addition, the researchers designed the study AI model to first consider very small patches of the full resolution image separately to create a heat map, a statistical picture of disease likelihood. Then the program considers the entire breast for structural features linked to cancer, paying closer attention to the areas flagged in the pixel-level heat map.

Rather than have the researchers identify image features for their AI to search for, the tool discovers on its own which image features increase prediction accuracy. The team plans to further increase this accuracy by training the AI program on more data, perhaps even identifying changes in breast tissue that are not yet cancerous “The transition to AI support in diagnostic radiology should proceed like the adoption of self-driving cars — slowly and carefully, building trust, and improving systems along the way with a focus on safety,” says first author Nan Wu, a doctoral candidate at the NYU Center for Data Science.

doi: 10.1109/TMI.2019.2945514

Study provides insights on treatment and prognosis of male breast cancer

Male breast cancer (MBC) is a rare disease for which there is limited understanding of treatment patterns and prognostic factors.

A recent analysis reveals that treatment of male breast cancer has evolved over the years. In addition, certain patient-, tumor-, and treatment-related
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- Available with the only mammogram superior for women with dense breasts compared to 2D mammography alone.1,2

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1. FDA submissions P080003, P080003/S001. 2. Results from Friedewald, SM, et al. "Breast cancer screening using tomosynthesis in combination with digital mammography." JAMA 311.24 (2014): 2499-2507. A multi-site (13), non-randomized, historical control study of 454,000 screening mammograms investigating the initial impact of the introduction of the Hologic Selenia® Dimensions® on screening outcomes. Individual results may vary. The study found an average 4% increase and that 1.2 (95% CI: 0.8-1.6) additional invasive breast cancers per 1,000 screening exams were found in women receiving combined 2D FFDM and 3D™ mammograms acquired with the Hologic 3D™ Mammography System versus women receiving 2D FFDM mammograms only.

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Male breast cancer (MBC) comprises one percent of all breast cancer cases, yet no prospective randomized clinical trials specifically focused on MBC have been successfully completed. Some studies suggest that the incidence of MBC may be rising, however, and there is an increasing appreciation that the tumor biology of MBC differs from that of female breast cancer.

To examine how MBC has been treated in the United States in recent years, and to identify factors associated with patient prognosis, a team led by Dr. Kathryn Ruddy and Dr. Siddhartha Yadav at the Mayo Clinic in Rochester, analyzed information from the National Cancer Database on men diagnosed with stage I-III breast cancer between 2004 and 2014.

A total of 10,873 patients with MBC were included, with a median age at diagnosis of 64 years. Breast-conserving surgery was performed in 24 percent of patients, and 70 percent of patients undergoing breast conservation received radiation. Forty-four percent of patients received chemotherapy, and 62 percent of patients received anti-estrogen therapy. During the study period, there was a significant increase in the rates of total mastectomy, contralateral prophylactic mastectomy, and post-breast conservation radiation, as well as an increase in the rate of genomic testing on tumors and the use of anti-estrogen therapy. Tamoxifen is the standard anti-estrogen medication recommended for treatment of hormonally sensitive MBC.

Factors associated with worse overall survival were older age, black race, multiple comorbidities, high tumor grade and stage, and undergoing total mastectomy. Residing in higher income areas; having tumors that express the progesterone receptor; and receiving chemotherapy, radiation, and anti-estrogen therapy were associated with better overall survival.

Research estimates the post-mammography recall rate for women to be more than 10 percent in the United States (although it is generally lower in Europe).

“The callback rate with mammography is much higher than ideal,” said the study’s first author, Dr Karen Drukker, “There are costs associated with recalls, and our goal is to reduce these costs but not miss anything that should be biopsied.”

Dr. Drukker and colleagues recently studied a new technique called three-compartment breast (3CB) imaging. By measuring the water, lipid and protein tissue composition throughout the breast, 3CB might provide a biological signature for a tumor. For instance, more water in the tumor tissue might indicate angiogenesis. For the study, the researchers acquired dual-energy mammograms from 109 women with breast masses that were suspicious or highly suggestive of a malignancy immediately prior to biopsy, and the ensuing biopsies showed 35 masses to be invasive cancers, while the remaining 74 were benign.

3CB images were derived from dual-energy mammograms and analyzed along with mammography radiomics, a method developed by Dr. Maryellen L. Giger and her team at the University of Chicago. The method uses artificial intelligence algorithms to analyze features and patterns in images. The combination of 3CB image analysis and radiomics improved the positive predictive value in breast masses deemed suspicious by the breast radiologist. The combined method improved PPV from 32 percent for visual interpretation alone to almost 50 percent, with an almost 36 percent reduction in biopsies. The 3CB-radiomics method missed one of the 35 cancers, for a 97 percent sensitivity rate.

New technique may significantly reduce breast biopsies

A novel technique that uses mammography to determine the biological tissue composition of a tumor could help reduce unnecessary breast biopsies, according to a recent study (Drukker K et al Combined Benefit of Quantitative Three-Compartment Breast Image Analysis and Mammography Radiomics in the Classification of Breast Masses in a Clinical Data Set. Radiology. 2019; 290(3):621-628. doi: 10.1148/radiol.2018180608).

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“These results are very promising,” Dr. Drukker said. “Combining 3CB image analysis with mammography radiomics, the reduction in recalls was substantial.”

Dr. Drukker said the combined 3CB-radiomics approach has the potential to play an increasingly prominent role in breast cancer diagnosis and perhaps also screening. She noted that 3CB can easily be added to mammography without requiring extensive modifications of existing equipment.

“The patient is already getting the mammography, plus we get all this extra information with only a 10 percent additional dose of radiation,” she said.

The researchers plan to study how the combined approach will help radiologists make their final determinations. They also want to study the approach using digital breast tomosynthesis, which reduces the problem of overlapping breast tissue inherent to regular mammography. A tumor’s unique water-lipid-protein signature might be even clearer with tomosynthesis, Dr. Drukker said.

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Images in 71-year-old woman with 1.6-cm invasive ductal carcinoma (Breast Imaging Reporting and Data System category 5, with category C breast density). Low-energy mammogram and corresponding regions of interest for mammogram (top) and breast tissue composition images (bottom two rows). CREDIT Radiological Society of North America
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Breast density data in overall breast cancer risk assessment: the experience of an Australian breast imaging group

In the field of breast imaging, the implications of breast density are increasingly being appreciated, not just because of the effect on the sensitivity of mammography, but also because breast density in itself is recognized as an independent risk factor for the development of breast cancer.

Imaging Associates, a leading independent Australian radiology organization, has recently incorporated quantitative measurements of breast density as determined by the VolparaDensity software into a general breast cancer risk assessment provided to women undergoing screening mammography. We wanted to find out more about Imaging Associates in general and their experience with the breast density software and cancer risk assessment in particular, so we spoke to Dr. Daniel Lee, Clinical Director and breast radiologist at Imaging Associates.

Q Let’s start with some background about yourself and Imaging Associates

Imaging Associates are based in Melbourne, Australia, but we also provide imaging services in south-western New South Wales (NSW). Between all our sites, we provide a large range of imaging services, including 3D mammography, CT, MRI, nuclear medicine and a large range of imaging-guided procedures.

I am clinical director of our practice in Mitcham Private Hospital in Melbourne. We also have comprehensive private radiology practices in Box Hill, Melbourne and Wagga Wagga, NSW. Imaging Associates also provides radiologist services to Eastern Health in Melbourne (Box Hill, Maroondah and Angliss Hospitals) and the Murrumbidgee Local Health District in NSW (including Wagga Wagga and Griffith Base Hospitals).

Q Now, focusing purely on breast imaging, how many breast exams do you carry out annually?

In the last 12 months we have performed a total of approximately 3500 3D mammograms (including some contrast enhanced mammograms) in our private sites in Mitcham and Wagga. We are not part of the Australian national breast cancer screening program, BreastScreen Australia, so our screening mammograms are usually for women who have either a past history or family history of breast cancer. The split between screening and diagnostic mammography is approximately 50/50. The women we see are generally referred to us by breast surgeons and general practitioners (GPs).
In terms of equipment, we have the latest Hologic HD 3D mammography/tomosynthesis with Intelligent 2D (synthetic 2D) and contrast enhanced mammography capabilities at both of our private breast sites. We offer Hologic tomosynthesis-guided vacuum assisted breast biopsy and hookwire localisation, with the option of lateral arm attachment. We also have Philips 3T breast MRI and Bard MRI-guided vacuum assisted breast biopsy available at Maroondah Hospital.

Now let’s get on to the issue of breast density.

We consider the issue of mammographic breast density as being very important, not only for its potential masking effect but also as a potentially strong independent risk factor for breast cancer. Thus having reliable software that can objectively quantify density is important for us to be able to provide the best possible clinical practice.

This need for dependable density data was all the more pressing since, prior to getting the VolparaDensity software, breast density was assessed visually by our radiologists, with the usual, inevitable drawback that the results were subjective and potentially variable.

We installed the Volpara software in our private breast sites in November 2016. From the radiologist’s point of view, the system simply provides an extra screen of information that shows breast density expressed as a category (a, b, c, or d) and volumetric percentage. The system also gives some information on the average compression used by the mammographer and average radiation dose.

In practice the installation of Volpara into our system presented no major issues, nor was it difficult to learn how to interpret the Volpara information. The reproducibility of the Volpara readings is good although occasionally we find that the Volpara category seems to be initially discrepant from the subjective BI-RADS category determined visually by the radiologist but these rare discrepancies can usually be explained by factors such as positioning or the effect of synthetic 2D mammogram.

Introducing Volpara into our practice has had no major negative impact on our workflow.

And how has the system performed so far?

Overall, I believe Volpara does its job well. It is simple to use, does not have a negative impact on workflow, and most importantly, provides a reproducible objective quantitative measure of mammographic breast density.

The Volpara online software gives a good snapshot of patient demographics of our mammograms. Thus, we have many women aged in their 40s, many of whom have a family history of breast cancer. We also have many women aged 55 to 70, with a past history of breast cancer. Taking into consideration the breast density I give recommendations regarding supplementary screening possibilities as a part of this service.

What about breast cancer risk assessment?

At our private breast sites we offer a breast cancer risk assessment service whenever this is specifically requested with the mammogram. Referrers usually ask for this for women who have a family history of breast cancer. Breast cancer risk assessment is also often carried out for women in their 40s who are not covered by BreastScreen Australia, which only targets women aged 50 to 74 with a recommendation for screening mammograms every two years.

The assessment of breast cancer risk is based on the use of the Tyrer-Cuzick/IBIS model which uses anamnesis data of the patient as well as the breast density.

The main reason for starting this breast cancer risk assessment service was that I would often receive calls from GPs asking what my screening recommendation would be for certain patients, many of whom had dense breasts and a family history of breast cancer. We chose the Tyrer-Cuzick/IBIS model principally because it is well-validated, easy to use, and incorporates mammographic breast density — it allows the direct input of Volpara volumetric breast density percentage values.
In practice, our mammographers get all the information that is required to perform a risk assessment from the patient just before performing the mammogram. This data entry only takes a few minutes. After the mammogram, provided nothing is found on imaging that requires further investigation or management, the breast radiologist will have a discussion with the patient regarding their breast density and how a risk assessment is carried out.

If the patient then agrees to have a risk assessment, it is then calculated on the basis of the data already accumulated. The final result and screening recommendations are then included in the mammogram report for the referring doctor.

**Q** How do you see developments in the future?

In this age of rapidly advancing Artificial Intelligence (AI) applications in radiology, I believe radiologist phone- and face-time with referrers and patients is more important than ever. In this context, I have found our experience in carrying out the breast cancer risk assessment service with patients and referrers to be very rewarding. I hope this type of role will in the future become more common for breast radiologists, and that mammographic breast density and its significance remains as an important area of expertise.

**Q** How do the women react to the information they get regarding their breast density on its own or as part of an overall risk assessment algorithm?

If it is explained well, I find that women usually react appropriately to information regarding their breast density; in fact, I believe they often feel empowered by receiving the information. I have had only very few negative encounters when having this discussion with patients. It’s true that many women are surprised to hear that breast density is a cancer risk factor. Some women mistake mammographic breast density with the way their breasts feel.

**Q** And how do the primary care referrers react to receiving the risk assessment?

Since, as I said, we only perform the risk assessment when it is requested by the referring doctor, they are never surprised to see it on the mammogram report. In fact, we have had very positive feedback from the referring doctors regarding our risk assessment service on our surveys.

**Q** In practice how does the risk assessment affect follow-ups?

If a woman is found to have a moderately increased risk of breast cancer and has dense breasts (Volpara category c or d), we would typically recommend annual screening with 3D mammography +/- breast ultrasound to the age of 50, and then every two years after this. If their density is category d we would often suggest incorporating contrast enhanced mammography or breast MRI.

If a woman is found to be at a potentially high risk of breast cancer, they usually have dense breasts. For these women we usually recommend annual screening with 3D mammography +/- breast ultrasound to the age of 60, and then every two years after this. We also usually recommend review by a breast surgeon or at the familial cancer centre as well as incorporation of contrast enhanced mammogram or breast MRI for screening.

Whenever the appropriate follow-up programme has been established on the basis of the risk assessment we find that the vast majority of women do in fact return to us for follow up appointments. Without the risk assessment, most would probably not have returned.
The growing recognition of the impact of breast density

With an estimated 562,500 new cases per year, breast cancer remains the most common cancer impacting women across Europe [1]. National breast screening programs for women of average risk are offered in nearly all European countries based on the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis and The European Society of Breast Imaging (EUSOBI) attributes a 40% reduction in breast cancer mortality to population-based screening [2].

**USING RISK TO TRIAGE WOMEN TO THE RIGHT SCREENING TOOLS**

Mammography has been proven to save lives by finding cancers when they are small enough to treat. However, because of the possibility that not only can dense breasts mask the detection of lesions by mammography but also are a risk factor for cancer in their own right, there is growing recognition that population-based screening with mammography alone may not be enough. Due to its clinical importance, breast density has been recently incorporated into the Tyrer-Cuzick and Breast Cancer Surveillance Consortium risk models. This raises an important question — can we reduce the cancers that might be missed due to dense breast tissue using risk-based screening protocols, by triaging women to supplemental screening tools, such as automated breast ultrasound (3D ABUS)?

“In order to overcome the limitations of mammography for women with dense breasts, a risk-based strategy improving the utilization of supplemental screening approaches must be considered,” says Dr. Athina Vourtsis, director and radiologist at Diagnostic Mammography in Greece.

Breast density is a critical factor in triaging women to the appropriate screening tool based on their personal risk. The use of a breast cancer risk model that includes family history, prior breast biopsies, gynaecological history, breast density and chest or mantle radiation therapy to identify those women at higher risk of developing breast cancer, can help clinicians to introduce personalized screening strategy that have shown to improve early diagnosis of the disease.

“As we get results from more trials designed to evaluate what cancers are found by which imaging modalities, we start to have evidence that shows benefit for using a risk-based approach rather than just our population approach,” says Professor Fiona Gilbert, University of Cambridge, UK. “The next step is to look at how we would implement risk-based screening so that when women go to the Imaging Center, they know: ‘This is my risk. This is the imaging test I should be getting and how frequently.’ Hopefully within a five-year period, breast density measurement and risk assessment will be a more robust automated process.”

Dr. Stephan Seitz, Senior Gynecologist, University Medical Center Regensburg, Caritas Krankenhaus St. Josef in Regensburg, Germany agrees, “We are one of 21 academic centers assigned to deliver the high-risk screening program in Germany. The recommendation for all women at high risk is to perform an annual MRI and breast ultrasound starting at age 25 because of a potential early incidence and higher breast density in younger women, on average.”

Results from multiple large-scale screening ultrasound studies involving thousands of women demonstrate that ultrasound improves cancer detection as a supplement to mammography. The EASY Study (European Asymptomatic Screening Study) published in European Journal of Radiology shows that it is feasible to implement 3D ABUS in a high-volume mammography center and increase the cancer detection rate by 57 percent while maintaining a low recall rate, well within the recommendations of the European guidelines for quality assurance in breast cancer screening and diagnosis [3].

**EDUCATION IS KEY**

“We have to continually educate our patients that breast diagnosis is sometimes like a puzzle, where you need to use all the parts of a puzzle, from medical history, clinical exams, follow-up information, mammography, ultrasound, MRI and histology results correlation,” says Dr. Ruta Briediene of Affidea and the National Cancer Institute, Lithuania. “Recently, we introduced ABUS to our patients and their physicians as an important new technique, especially for dense breast evaluation. Working with ‘Women Go Tech’ we launched a campaign called #differentyetstrong, where 50 members of ‘Women Go Tech’ had ABUS exams, shared their experience and explained why it is important to find time for yourself and to take care of your own health.”

In the US, advocacy groups have improved awareness and understanding through breast density reporting legislation. In the UK and Australia, advocacy groups are working to encourage the density discussion and to educate the public and healthcare professionals about the importance of breast density.

“Many women are still not aware of the composition of their breast and how increased breast density may lead to a delayed diagnosis. When this important information is not delivered to women, it compromises their access to supplemental screening and its benefits,” adds Dr. Vourtsis.
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To help improve breast density education across Europe, Dr. Vourtsis has joined efforts with the US-based non-profit DenseBreast-info.org as the organization's European Liaison along with Cheryl Cruwys, who serves as the European Education Coordinator. Medically-sourced, DenseBreast-Info/Europe is the only educational website on the topic developed specifically for European medical healthcare professionals. The focus of DB-I/Europe throughout 2019 and 2020 will be on sharing the educational tool within the European health care community via conference attendance, linking agreements with societies and universities, and increasing the number of countries represented by an Education Ambassador and included in a European Screening Guidelines Map [Figure 1].

INVENIA ABUS 2.0: IMPROVING EARLY DETECTION AND THE PATIENT EXPERIENCE

As the breast care community continues to evolve protocols to personalize breast care for better outcomes, there is a growing need to develop a parallel path to advance technology. Supplemental screening with automated breast ultrasound (ABUS) transforms breast care from reactive to proactive, helping clinicians to be more confident, and allowing patients to avoid potential delayed diagnosis. Invenia ABUS 2.0 is the only FDA-approved ultrasound supplemental breast screening technology, specifically designed for detecting cancer in dense breast tissue.

“The new Invenia ABUS 2.0 was designed to help improve the exam experience for both operators and patients, to enhance the reading experience for radiologists and to advance image quality through a new software-based image formation processor called cSound. We had a lot of input from users on the improvements they were looking for. The system’s new features and updates help further customize each exam, provide improved workflow and help bring the standardization and consistency that is needed in the screening environment,” says Luke Delaney, General Manager of Automated Breast Ultrasound at GE Healthcare.

IMPROVING PATIENT COMFORT

“In the era of new medical technologies, patients must have the opportunity to access the newest imaging tools to get the best diagnostic results. ABUS is a perfect tool for screening and we have had very positive feedback from our ABUS patients - most of whom indicated that the exam is painless, fast and informative. I believe that ABUS is a big step forward personalized breast cancer screening in dense breast population,” added Dr. Briediene.

Dr. Seitz adds, “ABUS is a technology that is very suitable for the early detection of breast cancer because of the global visualization of the breast. The storage of the complete data set to evaluate the breast at a later stage, to compare it with priors and to make a potential double reading in suspicious cases are the most valuable advantages in a breast center like ours.”

“We integrated the Invenia ABUS into our clinical practice in 2016 and have performed more than 5,750 exams with it. Our experience working with the new Invenia ABUS 2.0 is that the image processor is faster, providing even more efficient image interpretation and reporting,” says Dr. Vourtsis. “The image quality has been upgraded so providing higher contrast and higher spatial resolution and better penetration for larger and denser breasts. Since no two women are identical, this improves patient comfort while it increases image quality and decreases the creation of artifacts.”

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Figure 1. Interactive map available at https://eu.densebreast-info.org/eumap.
Clicking on a country will trigger a pop-up panel containing a summary of the characteristics of breast screening programs available in the country.
Breast density plays an important role in mammographic imaging for the detection of breast cancer. It is well known that a high breast density can reduce sensitivity in X-ray mammography, which is by far the most widespread imaging modality used for breast cancer screening. In addition, it has been shown that, in its own right, a higher breast density leads to an increased risk of breast cancer [1]. Both these aspects have resulted in the determination of breast density becoming a major factor when it comes to determining appropriate personalized breast cancer screening workflows.

Traditionally, breast density is evaluated visually by the radiologist after the mammography examination and is most commonly reported on a four-point scale (a,b,c,d) as defined by the ACR BI-RADS guidelines [2]. However, the actual categorization of visual breast density depends heavily on the radiologist. In a study conducted by Sprague et al. [3], it was found that the distribution of the breast density categories varied substantially across radiologists as illustrated in Figure 1. The interquartile range of percent mammograms rated as dense (two highest breast density categories) was 28.9-50.9% [3].

To overcome such subjective influences, automated breast density assessment by computer software is increasingly being used to assist radiologists. With the aid of the software, breast density can be reported more objectively and consistently.

In this article we summarize a recently published study by Fieselmann et al. [4] evaluating the performance characteristics of the Insight BD software application (Siemens Healthcare, Forchheim, Germany) for the automated measurement and classification of volumetric breast density. The software is built into the acquisition workstation of the MAMMOMAT Revelation mammography system (Siemens Healthcare, Forchheim, Germany).

The new system measures the percentage volumetric breast density (VBD) as the ratio of the volume of fibroglandular tissue to the total volume of the breast by analyzing the unprocessed full-field digital mammogram (FFDM) or the raw central (0°) projection in digital breast tomosynthesis (DBT). The VBD value is then used for classification of the breast into one of the four breast density categories by means of pre-defined percentage threshold values.
EvAluATIOn OF INSIGhT BD

EvaluATIon CriterIa

In their publication, Ng and Lau [5] defined the requirements and criteria that software for automated breast density assessment should fulfill. Following these recommendations, our evaluation of Insight BD was based on measuring the following parameters:
1. accuracy
2. reproducibility
3. consistency
4. agreement with visual assessment

Fuller description and definitions of these parameters are given below.

Methods

For each of the four criteria above, at least one evaluation was performed, with a total of more than 8,000 anonymized mammographic examinations (32,000 individual images) from four different institutions being analyzed during the evaluation.

Accuracy. A measurement can be said to be accurate if its average value is close to the true value of the quantity being measured. To evaluate accuracy, measurements were carried out in phantoms. In these measurements mammography images of breast tissue-equivalent phantoms of known breast density values were acquired and analyzed using the software.

Reproducibility is the term used when measurements repeated under similar, but not identical, conditions deliver similar, but not necessarily identical, results. To test if Insight BD delivers reproducible results, images of both breasts from the same woman, different mammographic views of the same breast, images from different imaging techniques (FFDM, DBT), and images of the same breast and mammographic view at different time points were analyzed with Insight BD.

Consistency of measurements is shown if the results depict behavior that is expected from prior study results or existing knowledge. To test consistency, breast density measured with Insight BD was evaluated with respect to the woman's age at examination. The expectation is that measured breast density decreases with age [6].

Agreement between density categories. Finally, in order to evaluate the level of agreement between the methods, the categories of breast density as determined by the new software were compared to those determined by radiologists' visual assessment.

To this end, a reading study was carried out by 32 experienced radiologists from the US and Canada and involved 600 anonymized FFDM examinations. For each examination the majority vote of the panel of radiologists was compared to the category of breast density as determined by Insight BD.

RESULTS

The phantom-based experiments to evaluate accuracy showed a mean absolute percentage error of 3.84% of the measured VBD with respect to the known value in the phantom.

The evaluation of the reproducibility of the measurements resulted in Pearson correlation values of 0.900 to 0.995, indicating strong to almost perfect correlation.

It was found that the category of measured breast density decreased with age of the woman at the time of examination [Figure 2]. This is consistent with prior studies [6].

Figure 1: Results from a recent study [3] showing distributions of mammograms rated as dense or nondense by different radiologists. The data illustrate the subjectivity of density assessments derived by radiologists' visual examination of mammograms.

Figure 2: Results for breast density categorization as a function of age at examination. [4]
The data used to evaluate the level of agreement between the Insight BD results and those from radiologists’ visual density assessment are shown in Table 1. In this table first the agreement based on all 4 breast density categories (a-d) is shown. The overall percentage agreement (OPA, i.e. the relative sum of the values along the diagonal) is 69.5%. When results are dichotomized into nondense (a, b) and dense (c, d) categories, the OPA increases to 88.5%.

**DISCUSSION AND CONCLUSION**

Several tests were carried out to evaluate the performance of Insight BD with respect to the various criteria described above. The first series of tests (the phantom-based measurements) confirmed that the software does indeed quantify breast density accurately. Whereas these tests were performed under laboratory conditions all other tests used mammographic images (FFDM or DBT examinations) from clinical routine. The density results from these clinical images were found to be reproducible not only on a population level but also on an individual basis. For example, if a woman is examined twice under similar conditions (e.g., same woman but other breast, same breast but different mammographic views, same breast but different imaging techniques) the results of the measured density are strongly correlated. Such tests are important, for example to verify that the Insight BD system can be reliably used for the assessment of breast density over time.

The categorization of breast density, either into one of the four individual density categories or as nondense/dense is important not just for the determination of the appropriate clinical workflow to be followed but also for legal reasons in certain countries [7]. The nondense/dense classification is important whenever a binary decision is required, e.g., when determining if additional imaging such as breast ultrasound should be offered.

With an OPA of 88.5%, Insight BD showed a very high agreement with the average opinion of the radiologists for this binary task. The disagreement of 11.5% can be partially attributed to the intrinsic variability in breast density as assessed by the radiologist. Even if a majority vote of a panel of radiologists may appear to be an objective ground truth, it is nevertheless still based on individual, subjective assessments of breast density. For example, if five radiologists rate a breast as being dense and five other radiologists rate the breast differently, the software results will inevitably disagree with one of the two groups. The fact that Insight BD makes a volume-based assessment, as opposed to the predominantly area-based assessment of breast density used by radiologists, is a further factor that could explain the deviations.

To conclude, the findings of our evaluation studies show that Insight BD delivers accurate, reproducible, and consistent results that agree well with the visual assessment of breast density by radiologists.

**BREAST DENSITY ASSESSMENT IN CLINICAL WORKFLOW**

In general, there are several reasons that justify the incorporation of automated breast density assessment tools into the clinical screening workflow, ranging from reducing the time radiologists spend reading mammograms to other factors such as providing reliable risk stratification.

After the evaluation of the technical performance characteristics of Insight BD as described above, we now highlight one potential clinical application of the automated breast density assessment tool, namely the contribution of breast density data to determining the optimal subsequent imaging workflow for individual patients. This application of the breast density information is particularly valuable when it is performed at the time of the original screening examination. The time at which breast density is assessed can have a considerable impact on the efficiency of the subsequent screening workflow. Currently, a mammographic examination (including breast density assessment) is usually interpreted by the radiologist after the woman has already left the screening center. If the assessment of breast density shows that a need for supplemental imaging is indicated, in practice this would require that the woman be recalled for the supplementary examination at a later date.

However, if an automated breast density assessment was incorporated into the workflow to provide density information during the first step of the screening examination, then any supplementary exams could be carried out right away. In this way, the overall workflow could become more personalized, less time-consuming, and could possibly result in less stress and anxiety for the woman. Thus, an automated breast density score could indicate a need for supplemental imaging (e.g. ultrasound) instantly after the original mammography image acquisition...
could then be initiated before the woman leaves the screening center [Figure 3]. Ideally, the women could also get the result of the supplemental imaging test on the day of screening, thus reducing psychological distress and improving clinical management. Of course, any changes in screening procedures towards such a more personalized approach would also require an operational change in the organization of the screening center. Such a change would require careful evaluation since it would affect many women participating every day in breast cancer screening programs.

In a more personalized screening procedure, automated breast density assessment could play a vital role by providing important, objectively generated information on breast density.

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COMMERCIAL AVAILABILITY
Insight BD and MAMMOMAT Revelation are not commercially available in all countries. Due to regulatory reasons, future availability cannot be guaranteed.

Book Review
Hendee’s Physics of Medical Imaging, 5th Edition
By E Samei & DJ Peck

the extensively revised fifth edition of Hendee’s Medical Imaging Physics, offers a guide to the principles, technologies, and procedures of medical imaging. Comprehensive in scope, the text contains coverage of all aspects of image formation in modern medical imaging modalities including radiography, fluoroscopy, computed tomography, nuclear imaging, magnetic resonance imaging, and ultrasound. Since the publication of the fourth edition, there have been major advances in the techniques and instrumentation used in the ever-changing field of medical imaging. The fifth edition offers a comprehensive reflection of these advances including digital projection imaging techniques, nuclear imaging technologies, new CT and MR imaging methods, and ultrasound applications. The new edition also takes a radical strategy in organization of the content, offering the fundamentals common to most imaging methods in Part I of the book, and application of those fundamentals in specific imaging modalities in Part II.
Mammography continues to be the imaging modality of choice for the study of breast lesions in symptomatic patients over 40 years of age, and also as a screening technique for the general population [1]. It is fast, economic and widely available, with a large number of mammography systems installed and operational in many types of healthcare facilities. However, numerous studies indicate that mammography yields both a high percentage of false positives, which leads to unnecessary recalls for complementary studies that generate great anxiety in women, and false negatives, with a number of cancers that are not detected early [2].

The implementation of full-field digital mammography (FFDM) has allowed the development of further advanced applications, such as Contrast-Enhanced Spectral Mammography (CESM). The principle of CESM is based on the acquisition of images at two energies. A low energy acquisition is carried out with a tube voltage below the k-edge of iodine (33.2 keV) so that even though there is iodine in the breast, the low energy image resembles that of FFDM. A higher energy image acquisition is obtained at a voltage above the k-edge of iodine. Then CESM applies a subtraction algorithm to depict only contrast-enhanced lesions, which could otherwise have been hidden on standard unenhanced mammography [3].

Thus, in CESM, two images are obtained, examples of which are shown in Figure 1. The low-energy image of CESM provides the same information as FFDM and the recombined image only shows specifically contrast-enhanced structures [Figure 1]. In other words, in a quick procedure lasting only approximately seven minutes, CESM combines the simplicity and low cost of mammography with the diagnostic power of specific contrast enhancement of the neovascularization of breast lesions.

Although it was launched almost a decade ago, CESM is still a relatively little known technique; it is estimated that as of today there are only about 1000 units installed world-wide. It is estimated that only around a total of 200,000 CESM examinations have as yet been performed in both research and clinical settings [4]. This relatively low up-take may be due to
the fact that until 2017 the marketing of the technology was carried out by a single company (GE Healthcare). Nevertheless, although the availability of CESM is currently relatively low, it is possible that in the near future a more widespread adoption of CESM could occur relatively rapidly, not just because of the performance characteristics of the technique but also since many mammography systems of the current generation are now being delivered with the filters and software necessary for carrying out CESM already incorporated as standard.

**STUDY DESIGN AND METHODS**

The purpose of our retrospective study [5] was to accurately calculate the performance parameters of CESM and compare them to those of FFDM, alone or combined with breast ultrasound (BUS). We deliberately decided to study a large series of patients/lesions (465/644), including both benign and malignant breast lesions, since up till now the available studies in which the diagnostic performance of the technique has been evaluated, involved on average a relatively modest number of 160 patients/study for a cumulative total in all the studies of approximately 3000 patients [6-12]. Indeed, a recent comprehensive review of the technique underlined the need for further studies with larger series of patients in order to validate the encouraging initial results [13].

In our hospital, we have been performing CESM as a complementary technique since 2013. Although we have also employed the technique as a first-line imaging tool for patients with clinical indications or abnormalities, for the purposes of this current study we included only those patients for whom CESM was employed for the staging of their breast cancer or for clarifying previous abnormalities observed in FFDM and/or BUS. Thus, 283 patients (367 lesions) had a previous FFDM examination and 180 patients (277 lesions) had both FFDM and BUS exams. All imaging studies were performed within an 8-day period. Both CESM and FFDM were performed using a Senographe Essential digital mammography unit (GE Healthcare), equipped with the Senobright application, while BUS was carried out using a LOGIQ E9 ultrasound system (GE Healthcare).

Five experienced radiologists reviewed the images. First, three radiologists, completely blinded to the medical history of the patients, evaluated the FFDM, FFDM plus BUS, and CESM images independently, leaving a time interval of at least three weeks between their reviews of the three imaging modalities to avoid any case memorization effect. The radiologists were provided with a template in which they could classify the related information in a standardized manner. In a second stage, two other senior radiologists with more than 15 years of experience in breast pathology reviewed all discrepant cases and provided a consensus opinion. For evaluation of the diagnostic performance of FFDM, FFDM + BUS, and CESM, lesion images classified 1 to 3 were considered as “benign”, and 4-5 as “malignant”, using the appropriate BI-RADS system.

Depending on the lesion type, the true status of the disease in each patient was assessed either by the histopathological result, from surgery or biopsy, when these were available, or by the histopathological analysis of the aspiration of the contents of cysts. Some lesions were not biopsied/operated/aspirated, and an imaging follow-up every 6 months was recommended up to 24 months.

**RESULTS**

In our study the great majority of the malignant lesions (96.5%) were enhanced by the contrast medium. It is also interesting to note that the majority of the lesions that were not contrast-enhanced were benign (86.4%), and that only 14 out of 411 malignant lesions were not contrast-enhanced (3.4%). However, the mere uptake of contrast medium does not in itself indicate malignancy, since up to almost 60% of benign lesions were also enhanced by the contrast medium. Previous studies, by our group and by others, have indicated that the employment of appropriate descriptors is necessary for the correct classification of the lesions as benign or malignant; the use of the MRI-BI-RADS lexicon has been proposed for such interpretation of CESM images [14,15]. Although certain discrepancies in the interpretation of descriptors existed, these do not influence the final score of the BI-RADS scale. In addition the inter-observer agreement was high, both for lesions enhanced by contrast and for those not enhanced (global Fleiss-Cohen kappa = 0.805). Thus, the radiologists in our study...
were able to classify 90.3% of lesions correctly. Even so, this means that there were almost 10% of misclassified lesions, with 15.1% of benign lesions that were classified as malignant (false positives), and 7% of malignant lesions that were classified as benign (false negatives). Similar results have been also reported in previous studies which found broadly similar percentages of misclassified lesions, which are also similar to those described for breast MRI. It appears that certain tumor types, such as infiltrating ductal carcinoma, ductal carcinoma in situ, or angiosarcoma are more prone to yield false negatives; these are frequently reported in dense breasts. Other authors have also reported false positives with CESM due to certain benign lesions, such as fibroadenoma, hamartoma, intramammary nodules, diabetic mastopathy, fat necrosis, infected cysts, or radial scars [13].

Regarding the diagnostic accuracy of CESM compared to the FFDM alone, of FFDM + BUS, we found a general and significant improvement in all the parameters [Figure 2]. Thus, CESM significantly increased sensitivity to 93.2% (+ 10.7% and + 3.4%, compared to FFDM and FFDM + BUS respectively); specificity was increased to 84.4% (+ 15.8% and + 1.7%, vs FFDM and FFDM + BUS, respectively); positive predictive value increased to 92.3% (+ 26.8% and + 3.6%, vs. vs FFDM and FFDM + BUS, respectively); and accuracy increased to 90.2% (+ 15.8% and + 3.2%, vs FFDM and FFDM + BUS, respectively).

With their added advantage of being based on a large number of patients/lesions, our results confirm those so far obtained from other studies and indicate that CESM is a valuable diagnostic tool, which could allow the initial evaluation of lesions, at least in the clinical setting, and is also of an undoubted utility for the staging of breast cancer. We also consider that the capability of CESM to quickly rule out the presence of malignancies is very important. Our results showed that, had CESM been employed as the initial imaging technique, it would have allowed the correct classification of 89 benign lesions from a total series of 644 lesions (14%). If CESM were applied in routine, such a performance level could avoid delays in diagnosis, so minimizing the patient stress associated with waiting, as well as avoiding the additional costs of performing complementary tests.

Finally, we also studied the behavior of CESM in relation to the accuracy of the pre-surgical estimation of the size of the lesion. In comparison to FFDM and/or BUS, we found that CESM gave a more accurate size estimate with a generally high agreement with the size of the surgical sample as determined histopathologically. Nevertheless, we also found that CESM tends to overestimate the size of the lesion (+ 2.9 mm, average) [Figure 3]. In a previous study, we also reported that the estimation of the lesion size by CESM seems to be more precise in larger tumors and in

Figure 2. Histogram showing the comparison of the performance parameters of the three techniques studied. Abbreviations PPV: mpositive predictive value. NPV: negative predictive value...
patients in whom there is nodal involvement. This observation supports the hypothesis that the accuracy of the determination of tumor size increases with the degree of tumor malignancy, probably due to the fact that malignant tumors are much more active metabolically. In the same publication, we also reported that the accuracy of CESM decreases with high breast density, as well as with breasts of greater volume [23].

CONCLUSION

The high values of sensitivity, specificity, PPV, NPV and accuracy that we found in our large cohort study, taken together with the simplicity of the technique, confirm our view that CESM is not only a suitable second-line technique for the staging of breast cancer, but could also be employed as an initial technique for symptomatic patients, and even as a screening modality in high-risk patients.

REFERENCES

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Deep learning cancer detection software for breast tomosynthesis

Widely recognized as one of the premier European cancer centers, the Gustave Roussy Cancer Campus (GRCC) in Paris, France, not only provides patient care, but also carries out cutting-edge research and teaching activities. Patients with all types of cancer are diagnosed and treated in the institute, whose motto is to put innovation at the heart of a human, scientific and technological revolution in the fight against cancer. The breast cancer unit in GRCC is particularly active, conducting numerous research projects and performing thousands of breast imaging examinations annually.

The unit has recently acquired a deep learning-based, cancer detection software for breast tomosynthesis, the ProFound AI system from iCAD.

We spoke to Dr. Corinne Balleyguier, Senior Radiologist and Head of Department about her unit's experience with, and opinion of the new software.

Before we get on to the ProFound AI system itself, please give us a brief overview of the breast cancer unit at Gustave Roussy.

In part due to the reputation of the Institut Gustave Roussy (now known as Gustave Roussy Cancer Campus) and of our breast imaging service, we receive many patient referrals — we see more than 12,000 patients per year. We are well equipped to deal with this number of patients: we have three mammography systems, all of which can carry out tomosynthesis and also contrast-enhanced spectral mammography (CESM) as well as a stereotactic vacuum-assisted biopsy machine, three ultrasound scanners, and two MR imaging systems. In addition to the imaging modalities, we also perform ultrasound-guided microbiopsies, stereotactic biopsies, fine needle aspirations and MRI-guided core biopsies, as well as pre and post-operative patient management.

Let’s now focus on the ProFound AI system

It should be said right from the outset that, over several years, I have had a long and fruitful relationship with the iCAD company. However, this doesn’t mean that we in the breast unit at GRCC blindly accept all products without first being able to extensively evaluate any new system. This is the same procedure that we adopt for all our new equipment or systems introduced into our department.

Thus, we have had the ProFound AI system since May of this year, but prior to putting the system into routine clinical use, we of course carried out an evaluation study. This study was all the more rigorous since we previously had an old Computer-Aided Detection software which was disappointing in its performance principally because the level of false positives it flagged was too high.

However, this experience did not at all close my mind completely to other applications, particularly to the newer algorithms based on deep learning artificial intelligence (AI) which have been trained on large digital breast tomosynthesis (DBT) datasets. These systems have the potential to further improve reader accuracy while also improving reader efficiency.

The ProFound AI system in particular was developed by iCAD in a data-driven manner by using an expertly annotated tomosynthesis image dataset collected independently, unlike conventional CAD systems, this AI system acquired knowledge necessary for lesion detection directly from
the training data provided and did not rely on explicit encoding or replication of human expert decision processes.

One feature of ProFound AI is that it has an operating point controlling the trade-off between the detection sensitivity and specificity of the algorithm. This operating point can be selected by the user. At the beginning we chose the highest sensitivity, in order to get maximum detection of lesions, while accepting that this could increase the level of false positives.

In practice, this AI system, which is based on a deep convolutional neural network algorithm that processes individual reconstructed DBT images, presents the readers with outlines and locations of breast lesions. In addition, the algorithm assigns a “certainty of finding” score for each lesion and for each case in its entirety.

Certainty of Finding Scores or lesion scores are assigned to each lesion detected by the ProFound AI algorithm and represents how confident the algorithm is that the detection is malignant. In addition the algorithm assigns case scores which represents how confident the algorithm is that a case is malignant. All cases, including those without lesion detections, are assigned a case score.

Q And how did the evaluation process go?

The very fact that we have now proceeded to the implementation of ProFound AI in our clinical routine is an indication that indeed the results of the evaluation process were positive.

Of course, in this process we looked at a large number of cases and assigned several of our breast radiologists to be involved. In our department we have a total of 19 radiologists (including residents) although not all of them are full-time. The overall conclusions of the evaluation were based on the totality of the cases but there was one particular case that impressed me. This was a case in which the radiologist on the original images had missed a very small spiculated lesion in an extremely dense breast. The lesion was detected by the ProFound AI system and later confirmed by MRI. When we looked back at the original tomosynthesis images, we realized that this was indeed the sort of lesion that we estimate eight out of ten readers would also have missed. After this case, I thought I’d better look more closely at the system.

Q And now that the system is in routine use?

Since we installed the software, we have used it in approximately 5,000 cases. We use tomosynthesis as the front line-modality for all the symptomatic cases we see except for high-risk cases such as BRCA gene carriers, which are imaged using MRI. (In France, screening with tomosynthesis is not approved). A typical case work-up involves first of all reading the synthetic 2D mammography. On our workstation, if any lesions are contoured by the algorithm, one click on the image will bring the reader directly to the tomo slice where the flagged lesion will be best visualized.

Although we do not oblige all of our radiologists to use the system, the vast majority do. While the installation of the software was without problem and its use is straightforward and intuitive, one aspect did require a little bit of getting used to. This was the need to familiarize ourselves with the lesion and case scores that ProFound AI provides. These are relative scores computed by the algorithm and represent the algorithm’s confidence that a lesion or case is malignant. The scores are represented on a 0% to 100% scale, with a higher score indicating a higher level of confidence in the malignancy of the lesion or the case as a whole and so aids in determining if a suspicious finding or case needs further workup. These scores are really useful, but they are a separate system from the BI-RADS score and do not correlate mathematically with BI-RADS.

"... the increased assurance of high sensitivity in an 'AI system that works' is what we appreciate the most..."

Q And the overall impression of the system?

We are very satisfied with ProFound AI, and the main reason for our satisfaction is the increased level of assurance that the system provides that we have detected all suspicious lesions, with a minimum number of false positives. In addition, the system saves us time in the reading of our tomo cases. The time needed to read all the slices of a tomosynthesis examination is, of course, a drawback of the modality compared to mammography. This reduction in tomosynthesis reading time that ProFound AI brings, particularly with straightforward cases, frees us up to focus on more complicated cases.

Lastly, what we appreciate the most is having the increased assurance of high sensitivity in an ‘AI system that works.’
Breast Elastography

By Dr RG Barr

Both high sensitivity and specificity can be achieved in the characterization of breast lesions by combining results from strain elastography and 2D shear wave elastodraphy; this has clear implications for patient management with the potential of significantly decreasing the number of negative breast biopsies. Careful attention to technique is however critical to ensure accurate and reproducible outcomes.

This article summarizes the current status of breast elastography

Breast elastography has been clinically available for over 15 years. However, elastography has not been widely accepted as a standard procedure in breast imaging. This is likely due to variations in technique, a relatively steep learning curve for some types of elastography, and differences in methodology in systems from different vendors. Both strain elastography (SE) and 2D-shear wave imaging (2D-SWE) have been used to evaluate breast lesions; numerous studies have reported improvement in characterization of breast lesions to various degrees using elastography [1-12]. Based on elastography of in vitro breast tissue, elastography should be highly sensitive and specific for characterizing breast lesions as the stiffness of malignant lesions is significantly greater, with very little overlap, than benign lesions [13]. Elastography is mentioned in the most recent BI-RADS but not required [14]. The most common application of breast elastography is to upgrade or downgrade BI-RADS category 3 lesions or downgrade BI-RADS category 4A lesions.

STRAIN ELASTOGRAPHY

Strain imaging is a relative technique. The elastogram does not provide a specific value of the lesion stiffness but instead reflects relative stiffness compared with other tissues in the field of view (FOV)[15]. A unique feature of breast elastography for both SE and SWE is that malignant breast lesions appear larger on elastography than on B-mode ultrasound images while benign breast lesions appear smaller on elastography [15]. The mechanism of this difference in size is poorly understood. For SE, three techniques have been proposed for interpretation of the elastogram [Figure 1].

Firstly, a 5-point color scale can be used with a score of 1 if the lesion is soft, a score of 2 both soft and stiff components, a score of 3 if the lesion is stiff and smaller than on the B-mode image, a score of 4 if the lesion is stiff and the same size as on B-mode and a score of 5 if the lesion is stiff and larger than on the B-mode image.

Secondly, a semi-quantitative method, the fat to lesion ratio (FLR), also known as the strain ratio, has been proposed. Since fat in the breast has a relatively constant stiffness between patients, it can be used as a reference standard. In this technique, a region of interest (ROI) is placed on the lesion and also in an area of fat, preferably at the same depth of the lesion. The ultrasound system then calculates the ratio of lesion stiffness compared to fat.

The third method compares the size of the lesion on elastography and B-mode imaging by measuring the length of the lesion on the elastogram in the longest dimension and dividing by the length of the lesion on the B-mode image, yielding the E/B ratio. For the 5-point method, a cut-off score of 3 is usually considered most accurate in differentiating benign from malignant lesions. For the FLR method, each vendor has their own method of calculating the strain value of a ROI and the FLR is very vendor dependent [2]. Additionally, compression of the tissue will also add variance to the measurement as the stiffness of fat increases faster than other tissues in the breast with compression [15]. The E/B method requires that the lesion be accurately measured on both the B-mode and elastogram which are obtained and displayed simultaneously. An E/B ratio of >=1 is reported as malignant, while an E/B ratio of <1 is reported as benign. A meta-analysis of the literature on strain elastography found that the E/B ratio is more sensitive and specific than the other two methods [Table 1].
identifying the length of the lesion becomes problematic. In benign lesions and fibroglandular tissue is similar. Therefore, change is present in fibroglandular tissue, the stiffness of these tumours will be easily identified as it is substantially stiffer than the fibroglandular tissue [Figure 2].

**SE TECHNIQUE**
Most systems have linear transducers from 9 MHz to 18MHz that can be used for SE breast imaging. The systems vary in the amount of compression/release needed, some require none at all and others small movements of the transducer up and down. Most systems have a bar or number that allow the operator to apply the appropriate pressure of the transducer.

The most important technical factor is to not compress the breast with the transducer [16]. After obtaining the B-mode image, the transducer is lifted until the probe just barely contacts the skin to ensure that the breast is not compressed by the transducer when the elastogram is obtained.

When a benign lesion such as a fibroadenoma or fibrocystic change is present in fibroglandular tissue, the stiffness of these benign lesions and fibroglandular tissue is similar. Therefore, identifying the length of the lesion becomes problematic. In this situation, comparing the stiffness to the fibroglandular tissue is helpful. If the lesion is benign, the stiffness is similar to the fibroglandular tissue, whereas if it is malignant, the lesion will be easily identified as it is substantially stiffer than the fibroglandular tissue [Figure 2].

**SHEAR WAVE ELASTOGRAPHY**
Shear wave elastography (SWE) provides a quantitative estimate of the lesion stiffness based on the speed of shear waves generated by applying an acoustic radiation force impulse (ARFI) push pulse. The shear wave movement is tracked by B-mode tracking pulses [2]. SWE can be performed in a single ROI (point-SWE) or over a larger FOV (2D-SWE). A color map is used to display the shear wave velocities in 2D-SWE. As breast cancer stiffness is very heterogeneous, point shear wave elastography (p-SWE) should not be used as the area of maximum stiffness cannot be readily identified. With 2D-SWE the various stiffness values within the breast cancer or adjacent few millimeters can be visualized, and the area of maximal stiffness selected for measurement. Several papers have demonstrated improvement in breast lesion characterization using SWE. However, shear wave propagation does not occur in many breast cancers. These will not be color coded as the system cannot estimate a shear wave speed. There may be a ring of high stiffness surrounding the tumor. In some cancers only noise is identified, and the ultrasound system, therefore, estimates this as a slow shear wave speed which could be interpreted as a false negative finding. The addition of a quality map which evaluates the quality of the shear waves is helpful in identifying these false negative cases [3] [Figure 3].

**2D-SWE TECHNIQUE**
A linear probe should be used that is optimized for breast elastography. The frequency varies by vendor and can be from 9MHz to 18MHz. With a higher frequency transducer imaging of denser or large breasts may not provide shear wave results greater than 4cm deep. As in SE, pressure from the transducer markedly affects the elastography results. A method of obtaining consistent results has been described[16]. Breast cancers often are not color coded or give false negative results due to the marked stiffness of breast cancers[3, 17]. These are sometimes referred to as “blue cancers” or “soft cancers” (i.e. very stiff cancers may look soft on SWE). The use of a quality map is helpful in identifying this artifact. This artifact is discussed in detail elsewhere [3]. We use a cut-off value of B/B ratio calculated in this case is 0.69/0.82 equal to 0.84 which is suggestive of a benign lesion.

(A) Using the 5-point color scale with blue as stiff and red as soft, the lesion (dotted line) is stiff while the fatty tissue is soft. The lesion appears smaller than the B-mode image. Therefore, this would have a score of 3. (B) To calculate the strain ratio, an ROI is placed in the lesion and in fatty tissue. In this case the strain of fat is 0.675 while the strain of the lesion is 0.082 giving a ratio of 8.2 suggestive of a malignant lesion. This measurement is highly dependent on the amount of pre-compression and the specific ultrasound vendor. (C) To calculate the E/B ratio, the lesion is measured on B-mode and on the elastogram. The ratio calculated in this case is 0.69/0.82 equal to 0.84 which is suggestive of a benign lesion.

**Table 1.** Results of a meta-analysis of the 3 methods of characterizing breast lesions with strain elastography[11].

<table>
<thead>
<tr>
<th>Method</th>
<th>N of study</th>
<th>N of benign</th>
<th>N of malignant</th>
<th>Sens (95% CI)</th>
<th>Spec (95% CI)</th>
<th>PlR (95% CI)</th>
<th>Spec (95% CI)</th>
<th>SROC (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>E/B</td>
<td>7</td>
<td>5954</td>
<td>512</td>
<td>90 (64.06)</td>
<td>68 (6560)</td>
<td>0.69 (0.16)</td>
<td>0.90 (0.28)</td>
<td>0.03 (0.11-0.23)</td>
</tr>
<tr>
<td>SF</td>
<td>40</td>
<td>71.73</td>
<td>3830</td>
<td>77 (79.79)</td>
<td>87 (79.79)</td>
<td>0.33 (0.44-0.3)</td>
<td>0.24 (0.13-0.3)</td>
<td>0.59 (0.90)</td>
</tr>
<tr>
<td>SE</td>
<td>35</td>
<td>33.44</td>
<td>1257</td>
<td>4 (95.40)</td>
<td>91 (79.43)</td>
<td>0.4 (0.65-0.3)</td>
<td>0.24 (0.1-0.33)</td>
<td>0.62 (0.88-0.90)</td>
</tr>
</tbody>
</table>
Breast Imaging for Improved Accuracy

The maximum values is used as the final result. The stiffest value in the ROI is used. The average of the three should only include the area of highest stiffness. The ROI (3mm) in the area of the highest stiffness. The ROI in characterization of breast lesions as benign or malignant [3].

Combining Strain and Shear Wave Elastography for Improved Accuracy

SE has higher sensitivity while 2D-SWE has higher specificity in characterization of breast lesions as benign or malignant [3].

However, it is important to recognize that SE and 2D-SWE are complementary imaging techniques. A major interpretation problem with SE is that benign lesions have similar stiffness to fibroglandular tissue. Therefore, benign lesions are often difficult to identify in glandular tissue making it difficult to perform accurate E/B measurement. On the other hand, if the lesion is significantly stiffer than the surrounding glandular tissue, it has high probability of malignancy. Also, these lesions can be identified with 2D-SWE as benign as these lesions all have low stiffness values even though they may not be clearly distinguished from the fibroglandular tissue based on the color map. An example of this is presented in Figure 2. On the other hand, 2D-SWE often does not provide a stiffness value or may provide a false negative stiffness value in malignant lesions [3]. Often these false negatives can be detected using a quality map that evaluates the displacement curves used to estimate the stiffness value. However, in solid lesions where the velocity map is not color-coded or soft, but the quality map is poor SE should be considered positive. In these cases, the SE results suggest malignancy. Thus, the use of both SE and 2D-SWE can overcome the problems of each individually. Hence, SE and 2D-SWE are best considered as complementary techniques.

When both SE and 2D-SWE suggest that a breast lesion is malignant, biopsy should be performed regardless of the BI-RADS category score. False positives include fat necrosis [18], mastitis [19], complex sclerosing lesion (radial scar) and a small number of fibroadenomas [18]. Some cases of fat necrosis and all cases of mastitis have surrounding edema which is poorly visualized on B-mode but substantially increases the stiffness of the surrounding tissue. If the patient has clinical symptoms of mastitis, the patient is treated and in 3-6 months a follow-up examination is obtained to confirm complete resolution. If the patient’s mammogram has calcifications suggestive of fat necrosis, a 6-month follow-up is advised. Also, if the patient has had surgery at the site and fat necrosis is suspected, consideration of a 6-month follow-up is recommended.

When both SE and 2D-SWE are suggestive of a benign lesion with a BI-RADS category score of 4A or less, the lesion is classified as benign. For BI-RADS category 4B lesions with SE and 2D-SWE findings consistent with a benign lesion, either a 6-month follow-up or biopsy is advised based on the patient’s preference. Our previous published results confirm that with a pre-test probability of 50% (all BI-RADS category 4B and lower lesions) and a SE suggestive of a benign lesion, the post-test probability of malignancy is 2%[11]. BI-RADS 4C and 5 lesions are biopsied even if elastography results are suggestive of benign pathology. The only false negative that we have observed is lymphoma. Lymphoma in the breast, whether primary or secondary, presents as a well-circumscribed hypoechoic lesion with markedly increased blood flow on color or power Doppler[20] and are soft on elastography.

Lesions with these characteristics of lymphoma are biopsied, especially if the patient has a known diagnosis of lymphoma.

If SE is suggestive of a malignant lesion and 2D-SWE is suggestive of a benign lesion but the 2D-SWE results are of poor

Figure 2. When a benign lesion such as fibrocystic change is present surrounded by glandular tissue the stiffness values of both are similar and it is difficult to identify the lesion on SE. On this SE image (A) of a 60-year-old with a palpable lump and a negative mammogram, the lesion (dotted line) is seen in the B-mode image (left). On SE the lesion is difficult to identify. The dotted line on the B-mode image has been copied to the SE image. This is because the lesion has similar stiffness to the surrounding tissue. However, on 2D-SWE (B) it has a benign stiffness with a stiffness value of 2.42m/s. If the lesion is malignant, it would be stiffer than the surrounding glandular tissue as in another patient (C). Note that the white arrows point to the glandular tissue while the dotted line measures the mass on B-mode and SE. The malignant lesion is clearly identified on SE as black; the glandular tissue is light grey; fat is white. In this case, the E/B ratio is 1.51 concordant with the biopsy result of an invasive ductal cancer.

Table 1. Comparison of BI-RADS categories 4A and 4B with SE and 2D-SWE results.

<table>
<thead>
<tr>
<th>BI-RADS Category</th>
<th>SE Results</th>
<th>2D-SWE Results</th>
<th>BI-RADS Category Score</th>
</tr>
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<tbody>
<tr>
<td>4A</td>
<td>Suggestive of benign</td>
<td>Suggestive of benign</td>
<td>4A</td>
</tr>
<tr>
<td>4B</td>
<td>Suggestive of benign</td>
<td>Suggestive of benign</td>
<td>4B</td>
</tr>
<tr>
<td>4C</td>
<td>Suggestive of benign</td>
<td>Suggestive of benign</td>
<td>4C</td>
</tr>
<tr>
<td>5</td>
<td>Suggestive of benign</td>
<td>Suggestive of benign</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 2. Comparison of BI-RADS categories 4A and 4B with SE and 2D-SWE results.

<table>
<thead>
<tr>
<th>BI-RADS Category</th>
<th>SE Results</th>
<th>2D-SWE Results</th>
<th>BI-RADS Category Score</th>
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<tbody>
<tr>
<td>4A</td>
<td>Suggestive of benign</td>
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<td>4A</td>
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<tr>
<td>4B</td>
<td>Suggestive of benign</td>
<td>Suggestive of benign</td>
<td>4B</td>
</tr>
<tr>
<td>4C</td>
<td>Suggestive of benign</td>
<td>Suggestive of benign</td>
<td>4C</td>
</tr>
<tr>
<td>5</td>
<td>Suggestive of benign</td>
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If SE is suggestive of a benign lesion and 2D-SWE is suggestive of malignancy, biopsy is recommended whether or not the 2D-SWE image is consistent with a benign lesion with high 2D-SWE quality or malignant lesion.

CONCLUSIONS

Both high sensitivity and specificity for breast lesion characterization can be obtained by combining results from SE and 2D-SWE which has significant implications for patient management with the potential of significantly decrease the number of negative breast biopsies, thereby improving patient care, reducing patient anxiety and saving health care dollars. Knowledge of false positive and false negative lesions also improves accuracy of interpretation. Careful attention to technique is critical to ensure accurate and reproducible outcomes.

REFERENCES


DISCLOSURES

RGB has the following Conflicts of Interest.: Research grants from Philips Ultrasound, Siemens Ultrasound, Mindray, GE Ultrasound, SuperSonic Imagine, B and K Ultrasound. He is on the speaker's bureau of Philips Ultrasound, Mindray, Siemens Ultrasound, and Bracco Diagnostics. He is on the advisory board of Bracco Diagnostics and Lantheus Medical. He receives royalties from Thieme Publishers.
Situated in Athens, Greece, the Delta Digital Imaging Center is a privately-owned clinic which has a well-established reputation in the field of breast imaging. Recently the center has acquired the iCAD ProFound AI system — an artificial intelligence-based software platform for the reading of digital breast tomosynthesis images. We wanted to know more about the Delta Digital Imaging Center in general and their experience with the ProFound AI system in particular, so we spoke to chief radiologists Dr. Nikolas Dimitropoulos, Medical Director of the Center, and Dr. Mariana Ioannidou, CEO.

Q Before we get down to details, please give us some general background regarding the Delta Digital Imaging Center.

Yes, let’s start with a bit of the history of our center, the Delta Digital Imaging Center. Together with a group of doctors, all of whom were specialized in women’s imaging, we set up the center in 2007. All of our colleagues have 20 years’ experience in private and public health services not just in Greece but also throughout Western Europe. We chose the title of “Delta Digital” for our center because at the time of the founding of our center, digital technology was the pioneering technological development in breast imaging.

The center is situated in a very pleasant location in the center of Athens next to several large university hospitals, with whom we have a very close and mutually fruitful relationship.

We pride ourselves on the fact that right from the beginning, we set the mission of our center to be the provision of medical services at the highest quality and technological level, while at the same time always being aware of, and reactive to, each woman’s particular personality, psychology and sensitivities, especially since, almost by definition when our patients come to us, they are often going through a stressful time.

Our center operates as an exclusively private institution, so we don’t have any contracts with insurance organizations. Since there is no national centralized, mammographic screening system in Greece, our patients come for routine examination based on their personalized needs (after self-referral on their own initiative or on medical advice/referral). The majority of women we see are dealt with on an outpatient basis, but we do have some in-patients, mostly for interventional reasons such as breast biopsies or for pre-surgical breast lesion localization. Each year, we see approximately 9,000-10,000 patients for breast-related issues and examinations, both diagnostic/symptomatic and screening. Although breast cases represent the majority of the women we see, we also carry out other interventions and examinations in the wider field of women’s health, such as transvaginal ultrasound, abdominal ultrasound and bone densitometry. Of the patients we see, 70% come from the city of Athens itself, the rest from the surrounding provinces and the Greek islands.

Q Overall, we are well equipped to deal with the patients we see — we have a digital mammography system, a digital breast tomosynthesis (DBT) system and several ultrasound systems, fitted with 3-D probes and with breast elastography capabilities, as well as a bone densitometry system. For any patients who may need additional imaging modalities such as MRI or CESM these are carried out in the nearby university hospitals and diagnostic centers, with whom, as
we said, we have a very close and regular collaboration.

We carry out about 50-60 breast interventional procedures per month such as pre-surgical localizations, by mammography or ultrasound of impalpable breast lesions as well as ultrasound-guided biopsies.

As for stereotactically guided breast biopsies for microcalcifications and also MRI-guided biopsies and lesion localizations by MRI, we refer these patients to our colleagues in the appropriate specialized departments of the hospitals and diagnostic centers with whom we collaborate. The overall clinical management and surgery of our patients are carried out by these large university and private sector hospitals which have specialized breast units and clinics. These patients then come back to us for postsurgical evaluation so that approximately 10-15 percent of all our patients are actually being examined as part of postsurgical follow-up program.

What is the typical work-up for breast patients in your center?

The typical management of our patients is relatively standard with the underlying principle being to be able to communicate the results of the examination back to the referring physician as quickly as possible. Of course, the process starts by the patient coming to the center for their pre-arranged appointment. The programmed exam is then carried out, as well as any supplementary exams that may be needed. At this stage the patient waits in the lounge while the report is being prepared, which typically takes 15 - 20 minutes, after which the patient is called back into the doctors’ office, so that her situation can be explained to her. She receives the report with any specific recommendations and appointments for an appropriate follow-up, depending on the diagnosis and the estimated personalized risk of developing breast cancer.

In low risk patients, a digital mammography is usually performed as the first line examination, supplemented by ultrasound if the patient has dense breasts. If for such patients prior mammograms are available, then DBT is carried out. For example, if suspicious lesions have been detected on mammography, DBT is carried out usually followed by ultrasound. In women with increased risk, or in women with basic risk but with very dense breasts, DBT is performed from the outset. When we do carry out DBT, we always use 2D synthetic views and when we investigate clinical or mammographic abnormalities, we perform both 2D views and tomosynthesis views. The total time for the tomosynthesis exam, including the actual exam itself and the reading, lasts about 30-40 minutes, of which 20 minutes is needed for the reading and preparation of the report. We find our patients have a positive opinion of tomosynthesis itself and the reading, lasts about 30-40 minutes, of which 20 minutes is needed for the reading and preparation of the report.

Taking the information provided by the AI system into account, we have been able to appreciate the advantages and reassurance that the system gives us for our tomosynthesis cases. With the new system, we now only have one radiologist reading the tomosynthesis images, in parallel with the ProFound AI System. Taking the information provided by the AI system into account, we now only have one radiologist reading the tomosynthesis images, in parallel with the ProFound AI System. The final reports are now available for the patients in 10 minutes.

This is not our first time with CAD — about 15 years ago, we had some previous experience with earlier CAD systems in 2D mammography, but overall that experience was not satisfactory because the level of false positive results was too high. However, since then we have had close scientific collaboration with the Department of Informatics and Medical Imaging at the University of Athens, who convinced us that the application of modern deep-learning technology could provide much more powerful and accurate algorithms and could indeed bring about a revolutionary change in the methods of studying and reporting medical imaging exams. Thus, we were open to the idea of investigating and eventually accepting new, reliable applications.

ProFound AI offered the solution we were looking for as it really shortens the reading time, frees up the second reader, and offers us the assurance that even when our radiologists are tired or overworked by handling too many exams, they can be assisted in finding cancers, even small lesions.

The operation of the ProFound AI system is simple and intuitive so there is virtually no learning curve regarding the

Since when have you had the iCAD ProFound AI software?

The installation of the iCAD ProFound AI System took place four months ago and even in that relatively short period of time, we have been able to appreciate the advantages and reassurance that the system gives us for our tomosynthesis cases. With the new system, we now only have one radiologist reading the tomosynthesis images, in parallel with the ProFound AI System. Taking the information provided by the AI system into account, which is analyzed by the algorithm in under two minutes and available at the workstation immediately, the radiologist evaluates the images and composes the report. The final reports are now available for the patients in 10 minutes.

A view of the waiting lounge in the Delta Digital Imaging Center. The use of ProFound AI system shortens the reading time of breast tomosynthesis images so that patients typically have to wait for no more than 20 minutes in the lounge before receiving their report.
operation of the system. Moreover, the longer a radiologist uses ProFound AI, the more he or she becomes confident in the algorithm’s capabilities. The radiologist has to gain experience of the functioning of the system in different types of cases and evaluate his or her results along with the analysis provided by the software.

Before using the system in routine, we carried out a validation process involving known cases in order to be sure of not missing any cancers. We have chosen to operate the system in high sensitivity mode, in order to be absolutely sure not to miss any lesions, although some of these detected lesions have turned out to be sonographically benign. In routine practice, ProFound AI works rapidly and enables the routine case workflow to be accelerated.

We have found that the system is of special help in the characterization of very small breast nodules that sometimes can be missed or characterized wrongly as benign (e.g. lymph nodes). The ProFound AI system is also helpful in identifying small architectural distortions and in the evaluation of small areas with microcalcifications.

We have by now already studied a total of about 500 of both previous and new cases; we now use ProFound AI in every tomosynthesis exam that we carry out. Of course, individual radiologists can initially have varying degrees of skepticism regarding the system and so, for such radiologists a longer time may be needed for validation and for confidence to be built. But we are sure that the routine use of the system will convince even the most skeptical of radiologists and widen the future horizons.

Q Clinically what advantages does the system bring you?

That’s easy to answer. On the basis of the experience we have acquired so far, we can say that the incorporation of ProFound AI into our workflow has enabled us to:

- Reduce false negatives (fewer cancers missed)
- Reduce false positives (fewer additional exams and negative biopsies)
- Improve overall patient management
- Free up more time for interventional procedures and discussion of reports and appropriate future management with patients
- Have quick and accurate tomosynthesis exam results for patients waiting in the lounge
- Identify interesting cases for educational and scientific use
- Be at the cutting edge of technology
- Offer a better service to our patients
- Have a new, useful (and experienced) partner in our center

Q So you are content with the new AI system?

Well as you can judge from the previous comments, we are indeed positively excited by the application of ProFound AI. Our satisfaction with the current system has spurred us on to actively assess the usefulness of ProFound AI in 2D mammography and in the evaluation of breast density.

As for other possible future developments, it would be useful if the AI systems could enable us to correlate lesions and images with prior 2D or 3D exams. In addition, worldwide multicenter studies and international meetings of experts in the field would also be useful to continue to study the capabilities of ProFound AI in screening and diagnosis.

Q How do you see the future? Any thoughts on extending the use of tomosynthesis to screening?

It is well established that breast tomosynthesis is a more sensitive modality than 2D mammography for screening. However, for the time being at least the use of tomosynthesis is not practical because the reading of the images is very time-consuming, a problem that is exacerbated by the current lack of radiologists experienced in the field.

Both these drawbacks can be overcome by use of the ProFound AI technology in that reading time can be significantly reduced (by more than 50%) and in our opinion, the need for a second reader can be avoided, as the system is more sensitive than the average experienced radiologist in identifying small lesions.

Thus tomosynthesis-based screening could be envisaged if all the tomosynthesis systems were equipped with AI.

Q What are your thoughts on AI in radiology in general? Opportunity or a threat?

We are convinced that the next generation of imaging systems — not just mammography — will have to have AI technology built-in. The new generation of radiologists will simply have to become familiar with these new technologies and how to use them in routine workflow. The advantages AI offers for radiologists is increased confidence in the diagnosis and decreased time and effort.

The everyday collaboration of radiologists and AI-based systems will result in an on-going educational process that will increase the ability level of every radiologist. Thus, we are convinced that AI is a great opportunity, especially for the younger radiologists. In contrast to the opinion held by some commentators that AI-based systems are only suitable for a small percentage of experienced radiology users in large hospitals and centers with lots of cases, we believe that AI is for everybody, it can be especially helpful for younger, less experienced radiologists practicing on their own or for small centers where there are only very few radiologists available.

Another area where we believe that AI-based applications have a role to play is as an educational tool. Indeed, we plan to incorporate this aspect in the continuing educational processes and workshops that are run by the Hellenic Society of Breast Radiologists. This is an organization in which we are major instructors, founding and council members (Dr. N. Dimitropoulos - President, Dr. M. Ioannidou - Member).
AI improves efficiency and accuracy of digital breast tomosynthesis

Artificial intelligence (AI) helps improve the efficiency and accuracy of an advanced imaging technology used to screen for breast cancer, according to a new study (Conant EF et al. Improving Accuracy and Efficiency with Concurrent Use of Artificial Intelligence for Digital Breast Tomosynthesis Radiology Artificial Intelligence Jul 31 2019 doi.10.1148/ryai.2019180096).

Digital breast tomosynthesis (DBT) is the advanced method for cancer detection in which an X-ray arm sweeps over the breast, taking multiple images in a matter of seconds. Research has shown that DBT improves cancer detection and reduces false-positive recalls compared to screening with digital mammography (DM) alone. However, the DBT exam can take almost twice as long to interpret as DM due to the time it takes for the radiologist to scroll through all the images. This increased time is likely to be more consequential as DBT increasingly becomes the standard-of-care for mammographic imaging.

For the study, researchers developed a deep learning system, a type of AI that can mine vast amounts of data to find subtle patterns beyond human recognition. They trained the AI system on large DBT data sets to identify suspicious findings in the DBT images.

After developing and training the system, the researchers tested its performance by having 24 radiologists, including 13 breast subspecialists, each read 260 DBT examinations with and without AI assistance. The examinations included 65 cancer cases.

Use of AI was associated with improved accuracy and shorter reading times. Sensitivity increased from 77 percent without AI to 85 percent with it. Specificity increased from 62.7 percent without AI to 69.6 percent with it. The recall rate for non-cancers, or the rate at which women were called back for follow-up examinations based on benign findings, decreased from 38 percent without AI to just 30.9 percent with it. On average, reading time decreased from just over 64 seconds without AI to only 30.4 seconds with it.

“Overall, readers were able to increase their sensitivity by 8 percent, lower their recall rate by 7 percent and cut their reading time in half when using AI concurrently while reading DBT cases compared to reading without using AI,” said study lead author Dr. Emily F. Conant, chief of breast imaging at the Perelman School of Medicine at the University of Pennsylvania in Philadelphia.

Also showing improvement was the area under the receiver operating characteristic curve (AUC). Radiologist performance, measured by mean AUC, increased from 0.795 without AI to 0.852 with AI.

“We know that DBT imaging increases cancer detection and lowers recall rate when added to 2-D mammography and even further improvement in these key metrics is clinically very important,” Dr. Conant said. “And, since adding DBT to the 2-D mammogram approximately doubles radiologist reading time, the concurrent use of AI with DBT increases cancer detection and may bring reading times back to about the time it takes to read DM-alone exams.”

The researchers expect the deep learning approach to improve as it is exposed to larger and larger data sets, making its potential impact on patient care even more significant.

“The results of this study suggest that both improved efficiency and accuracy could be achieved in clinical practice using an effective AI system,” Dr. Conant said.

doi.10.1148/ryai.2019180096)
The Breast Clinic in the Sint Lucas hospital in Bruges, Belgium has recently retro-fitted one of its mammography machines with a new breast compression system from the Dutch company Sigmascreening. Based on measuring the pressure applied during breast compression rather than an arbitrary force applied by the radiographer, the new system allows a standardised pressure to be applied during the compression phase of mammography. We wanted to find out more about Sint Lucas’ experience with the system so we spoke to Dr. Hilde Goris, specialised breast radiologist.

Q Before we get on to the new compression system, please give us a brief introduction to your hospital and facilities.

Sint Lucas is a medium-sized hospital with more than 400 beds. We’re located just outside Bruges, so our patients are referred to us from the city itself and also the surrounding area in the Belgian province of West Flanders. To add to our in-patients we handle more than 25,000 out-patients per year.

In addition to our general radiology capabilities, we have always been specially focussed on breast imaging, and are proud to say that we were actually the first hospital in Belgium to set up a dedicated Breast Clinic, which was inaugurated as far back as 1999.

The idea behind the Breast Clinic is to gather together all the disciplines needed for the optimal treatment of women being examined for, or diagnosed with, breast cancer. Thus, in addition to radiologists, our multi-disciplinary team includes pathologists, oncologists, surgeons, and a psychologist for the optimal treatment of our breast cancer patients.

Q What imaging modalities do you have in the Breast Clinic?

We are relatively well equipped to handle the number of patients we see, which is approximately 4000 women, per year. Of these roughly half are referred to us for diagnostic mammography and the rest are women undergoing screening examinations. The majority of women who come to us for screening mammography do so in the context of the Flemish Health ministry’s organized breast screening program while the remainder come after referral by a general practitioner or gynecologist.

As regards equipment, we have one mammography unit (GE Essential) and a brand-new tomosynthesis system (GE Pristina) which can also carry out Contrast Enhanced Spectral Mammography (CESM). We intend to use CESM for our high-risk, more elderly patients, but we also have a GE MRI machine for high-risk patients such as women with BRCA mutations. We have Aplio hand-held ultrasound systems from Canon.

Q Let’s turn to the Sensitive Sigma paddle.

We have had this now for more than two years. The basic principle behind the system is actually quite simple: rather than measuring the force applied to the breast during the compression phase of the mammography procedure, the Sensitive Sigma system calculates the actual pressure, i.e. the force applied divided by the area of the breast on which this force is exerted. If the same compression force is applied to a small breast as to a large breast, it is clear that the pressure applied to the small breast is greater than that for a large breast. The result is that women with small breasts can experience unnecessary discomfort.

The Sensitive Sigma paddle from Sigmascreening measures the pressure applied to the breast during the compression process as opposed to the usual force. A system of LED lights indicates when the optimal compression is reached.
In practice, in the Sensitive Sigma Paddle, the measurement of the area of the breast in contact with the paddle is made automatically through use of a special, X-ray transparent conductive coating on the paddle.

The mammography procedure is initiated as usual by the mammography technologist positioning the breast on the bucky cover and compressed by the paddle. During compression, the real time pressure value is calculated and displayed using a series of LED lights which are built into the system. At the start of the procedure, when there is no applied breast compression, only the first LED is lit up. As pressure increases, additional LED’s light up sequentially. When the optimal target pressure is reached, which has been determined to be the equivalent of 75 mmHg, the sixth LED is lit up. These LED lights are clearly visible, not just by the technologist but also by the patients. The time taken for the mammography examination is not affected by the use of the new paddle systems.

The actual retrofitting of the new paddles system to the mammography unit does not involve significant modification.

Q And how has the new system performed in practice?

In short, very well. Of course different members of the mammography team have different criteria for evaluating the system.

Thus, as a radiologist, one of my priorities is to be sure that the quality of images isn’t in any way affected by the use of the new paddles. (In fact this was one of the aspects that was evaluated in the independent “Type” assessment which is required by the authorities before any new imaging system is introduced to the market in the Flemish region of Belgium. See Side Panel). In addition, the use of consistent and optimal breast compression not only enables high-quality images, but also means that the images are acquired at low doses of radiation. The radiation dose in the GE Essential mammography system is already quite low, but optimal compression enables the dose to be slightly lowered even further, which is important, especially when we are dealing with healthy women in the screening process.

As for the radiographers/technologists, after an initial period during which they wondered about the impact the new system would have regarding their work practices, they are now very positive. Technologists are aware of the importance of good compression in mammography, but are of course reluctant to increase any discomfort that the woman may be undergoing during the process by increasing the compression. These two aspects can be mutually contradictory. By providing a visual indication of when the 75 mm Hg optimal compression is attained, the new paddle system provides an objective way of resolving these potentially conflicting aspects.

As for the patients, the feedback is overwhelmingly in favor of the new paddles system. (In fact this was one of the aspects that was evaluated in the independent “Type” assessment which is required by the authorities before any new imaging system is introduced to the market in the Flemish region of Belgium. See Side Panel).

Q What kind of quality assurance testing does your department carry out?

The majority of the tests we carry out for breast imaging systems are regular quality control evaluations which are carried out at various levels. These include daily evaluation of standard phantoms whose images are sent automatically to our lab every day. These are backed up by six monthly visits by a team of physicists from our lab to each installation where a complete QC protocol is carried out to monitor compliance with the European Guidelines. In addition to these routine tests, the authorities require that “Type” testing be carried out on each new type of imaging equipment introduced into the region. This involves several teams of independent physicists who develop a unique testing protocol appropriate for the system being introduced to the market. Our lab was assigned this task for the Sigmascreening Sensitive Sigma system.

Q What type of tests did you decide on?

In addition to the routine QC, several specific tests were carried out:
1) To verify that the display system accurately and reproducibly indicates the true pressure.
2) To verify whether the compression paddle produces a constant and left-right, anterior-posterior symmetrical compression.
3) To verify that the new paddle does not show abnormal absorption of radiation.
4) To verify that the operation of the Automatic Exposure Control (AEC) system is not affected by the new paddles.
5) To verify that the compression paddle does not induce any extra noise in the images as measured from the noise power in a standard test block.
6) In addition we carried out a comparative study of 100 women imaged both with the new paddles and standard paddles.

Q And the results?

All test results were acceptable and a full report was submitted to the Flemish authorities. Although the type test protocol was carried out on the GE Essential mammography system at Sint Lucas in Bruges, it was judged that the results of the acceptability of the Sensitive Sigma paddles could be applied also to mammography systems from other manufacturers, which would therefore not require any further type testing.
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Patient First - Back to Basics
One-Stop Breast Cancer Diagnostic Center set up in the U.S. to give women same-day results

GE Healthcare and Premier Inc have announced a collaboration to develop a workflow model to bring a same-day breast cancer diagnosis and treatment model to the United States. A similar model has already proven highly effective at the Gustave Roussy Cancer Campus in Paris, France.

Launched in 2004, the One-Stop Clinic at the Gustave Roussy Institute in France offers a coordinated patient journey from the initial appointment through diagnosis and treatment plan in one place, on one day and with one team. With a multimodality approach that includes the GE Healthcare Senographe Pristina mammography system, the SenoBright Contrast Enhanced Spectral Mammography (CESM) and biopsy, the program has proven to be successful, with an 80 percent patient satisfaction rating.

“We’ve seen the benefit of taking a personalized approach to breast care that includes different modalities and a multidisciplinary team to ensure we get answers to our patients as quickly as possible,” said Dr. Joseph Russo, section chief of women’s imaging at St. Luke’s University Health Network, and a member of the Advisory Board with GE Healthcare and Premier. “The One-Stop Clinic takes this a step further to offer proven same-day results that are incredibly impactful for patients and clinicians. I couldn’t be more excited to work with GE Healthcare and Premier to bring similar outcomes to life in the United States.”

“Premier is eager to explore the U.S. adoption of the One-Stop Clinic model, which decreases anxiety, aims to improve accuracy and speeds up the time it takes to diagnose breast cancer and establish a treatment plan,” said Denise Juliano, Group Vice President for Premier Applied Sciences. “We are proud to bring together the various expertise needed to evaluate this model’s potential and improve the patient experience in a way that has not been widely available to women in this country.”

To support the effort, Premier conducted a Rapid Evidence Review, one of the first comprehensive evaluations of expedited diagnosis for patients with breast cancer. Based on the results of the first phase of the collaboration, GE Healthcare and Premier will next evaluate the potential and merits associated with adopting the One-Stop Clinic model in the United States. The companies have convened an advisory board to provide insight on the One-Stop Clinic model, as well as guidance and counsel on best approaches to redesign it for the U.S. market.

“It is incredibly worrying for patients to hear they have a suspicious finding on their mammogram,” added Ben Newton, General Manager of Global Oncology at GE Healthcare. “In some cases, they have to anxiously wait for a follow-up exam that could take weeks to happen. The One-Stop Clinic is a unique model for cancer centers, offering immediate answers to patients and their loved ones. Based on the success of the clinic in France, we are excited to work with the Premier Applied Sciences team to explore opportunities to develop a similar model in the United States.”

To date, more than 20,000 women have participated in this program, and 75 percent of women leave with their diagnosis on the same day. The idea and design of the clinic were pioneered by Suzette Delaloge, MD, an oncologist and head of the Breast Cancer Department at Gustave Roussy.

GE HEALTHCARE CHALFONT ST GILES, UK. www.gehealthcare.com

Philips and Braun combine to launch needle tip tracking system

Philips and B. Braun have announced the launch of Onvision, a breakthrough ultrasound guidance solution for real-time needle tip tracking in regional anesthesia. Available on the latest version of the B. Braun and Philips Xperius ultrasound system, Onvision gives anesthesiologists the confidence to accurately position the needle tip inside the body. The introduction is part of a multi-year strategic alliance between Philips and B. Braun to innovate in ultrasound-guided regional anesthesia, a rapidly growing alternative to general anesthesia.

Accurate needle placement is critical to the success of regional anesthesia procedures, such as peripheral nerve blocks, both in terms of effective pain relief and the avoidance of unintended nerve and vessel punctures or collateral damage to surrounding tissue. While real-time ultrasound imaging has proved to be a valuable tool for needle guidance, failure to optimally visualize the needle tip remains a challenge for both novice and experienced anesthetists. Currently, 10-20% of all peripheral nerve blocks are ineffective on the first attempt. By simplifying alignment between the needle and ultrasound probe, Onvision reduces the effort needed to interpret the ultrasound image. This allows the anesthesiologist...
# Fill out this form, answering all questions – and be sure to include your signature.

## MEDICAL DOCTORS (respond below)

1. What is your occupation? (check only one)
   - 50 q Diagnostic Radiologist
   - 51 q Other Physician (please specify)
   
   1a. What is your radiology sub-specialty? (check only one)
   - 52 q General Radiology
   - 53 q Nuclear Medicine
   - 54 q Nuclear Radiology
   - 55 q Cardiovascular Diseases
   - 56 q Other (please specify)
   
   1b. I am a Head of my department
   - 58 q Yes
   - 59 q No
   
   Please continue with question #2 below

## NON-PHYSICIAN PROFESSIONALS (respond below)

1c. What is your occupation? (check only one)
   - 60 q Radiology Administrator
   - 61 q Radiology Business Manager
   - 62 q PACS Administrator
   
   Executive:
   - 63 q Chief Information Officer/IT Manager
   - 64 q Chairman/Managing Director/Executive Director
   - 65 q Chief Financial Officer/Other executive titles

Please continue with question #2 below

## ALL RESPONDENTS reply to the questions below

2. In what type of facility do you work? (check only one)
   - 20 q Private Clinic
   - 21 q Hospital (check number of beds):
     - a q More than 500 beds
     - b q 200-299 beds
     - c q 100-199 beds
     - d q 50-99 beds
     - e q 0-99 beds

3. With what technologies or disciplines do you work? (check all that apply)
   - 01 q Diagnostic X-ray
   - 06 q MRI
   - 02 q Nuclear Imaging
   - 10 q Mammography
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   - e q 4
   - f q 5
   - g q 6 or more

5. Please describe your involvement in the decision to purchase medical imaging equipment/products for your department.
   - (Check all that apply)
   - 32 q Recommend purchase of product
   - 33 q Approve purchase of product
   - 34 q Specify type of product to purchase
   - 35 q None of the above

---

**Signature:**

**Date:**

**First Name:**

**Last Name:**

**Title:**

**Hospital/Office Name:**

**Address:**

**City:**

**Postal Code/Country:**

**Business Phone:**

**E-mail:**

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to more confidently guide the tip of the needle to its target.

“Regional anesthesia is a rapidly growing alternative to general anesthesia and has the potential to improve patient outcomes as well as increase workflow efficiency in the hospital,” said Bert van Meurs, Chief Business Leader, Image Guided Therapy at Philips. “By combining B. Braun’s expertise in needle design with Philips’ capabilities in real-time image guidance, we’ve created a solution to one of the biggest challenges in regional anesthesia – accurate positioning of the needle tip in the body. Our alliance with B. Braun is a strong example of our commitment to partner with industry leaders to grow our footprint in the therapy market.”

Together, B. Braun’s Stimuplex Onvision needles and Philips’ Onvision needle tip tracking technology indicate the position of the needle tip in relation to the ultrasound viewing plane to an accuracy of better than 3mm. A sensitive micro-sensor placed on the needle, combined with advanced signal processing and visualization techniques on the Xperius system, indicate the real-time location of the needle tip in relation to the 2D ultrasound viewing plane. The solution provides greater flexibility in needle trajectory and can reduce procedure times. The increased confidence and predictability offered by Xperius and Onvision will empower more anesthesiologists to embrace regional anesthesia as a viable and effective alternative to general anesthesia.

Regional anesthesia or analgesia involves the injection of an anesthetic in the proximity of a nerve, targeting areas of a patient’s body that are subject to surgical intervention. Regional anesthesia can have significant advantages over general anesthesia for both patients and hospitals. Patients undergoing regional anesthesia typically benefit from reduced opioid consumption and fewer side-effects, such as nausea. Moreover, regional anesthesia may lead to faster post-surgical recovery, allowing patients to ambulate or leave the hospital sooner, which benefits both patients and hospitals.

Volpara Solutions and ScreenPoint Medical have announced that they had come to an agreement under which Volpara will sell ScreenPoint’s Transpara products to breast imaging clinics in the United States, Australia, New Zealand, and parts of Asia.

Transpara is designed to assist radiologists with the reading of mammograms and is one of the first next-generation artificial intelligence (AI) applications for detecting breast cancer in screening mammograms to gain 510(k) clearance from the US Food & Drug Administration (FDA) which was supported by the results of a multi-reader, multi-case reader study (Rodriguez-Ruiz A et al Detection of Breast Cancer with Mammography: Effect of an Artificial Intelligence Support System. Radiology. 2019; 290: 305. doi: 10.1148/radiol.2018181371). This study demonstrated that radiologists using Transpara significantly improved detection accuracy without increasing reading times and showed that radiologists’ performance consistently improved independently of their level of experience. In the ground-breaking publication that followed (Rodriguez-Ruiz A et al. Can we reduce the workload of mammographic screening by automatic identification of normal exams with artificial intelligence? A feasibility study. Eur Radiol. 2019; 29(9): 4825. doi: 10.1007/s00330-019-06186-9), it was reported that when compared to 101 radiologists, the stand-alone performance (in terms of sensitivity and specificity) of Transpara was as accurate as the radiologists. This suggests that the system gives an objective second opinion similar to that of a second radiologist. Transpara gained European regulatory approval (CE) for use with multi-vendor mammography (2018) and digital breast tomosynthesis (DBT) images (2019) and is already installed at leading breast imaging centers in Europe.

“Based on the published research to date, we strongly believe that Transpara will deliver both improved mammographic cancer detection and enhanced workflow,” said Dr. Ralph Highnam, Volpara CEO. “We are delighted to have ScreenPoint join our common cause and bring this powerful software to our customers.”

Prof. Nico Karssemeijer, ScreenPoint Medical CEO, said: “I am excited that ScreenPoint and Volpara will now partner to bring Transpara to the United States and other markets, as Volpara is well established in the breast space globally. Together, the two companies will help breast care teams detect cancer earlier, streamline mammography reading, and personalize screening for women.”

**VOLPARA SOLUTIONS**

WELLINGTON, NEW ZEALAND

www.volparasolutions.com

**SCREENPOINT MEDICAL**

NIJMEGEN, THE NETHERLANDS

www.screenpoint-medical.com

Siemens expert on UHF MRI nominated for the German Future Prize

Christina Triantafyllou, Ph.D., an employee at Siemens Healthineers, has been nominated for the German Future Prize for her work on Magnetom Terra, the first ultra-high field magnetic resonance scanner approved for clinical use. Nominated with her are Professor Arnd Dörrler, MD, Head of University Hospital Erlangen’s Department of Neuroradiology, and Professor Mark E. Ladd, Head of the Division of Medical Physics in Radiology at the
The work of physicist Christina Triantafyllou, Ph.D., at Siemens Healthineers was a driving force behind the development of Magnetom Terra, which laid the technical foundations for the clinical application of 7 Tesla imaging.

German Cancer Research Center in Heidelberg. They are one of three research teams in contention for the award. The prize, awarded by the President of Germany, is one of the country’s highest distinctions for technology and innovation.

Thanks to the efforts of the team led by Christina Triantafyllou, imaging at a magnetic field strength of 7 Tesla – previously used only in basic research – has been available as a novel and effective diagnostic tool for clinical use since 2017. This development is a breakthrough for precision medicine and brings immediate benefits for patients. Because of its ability to accurately image even tiny structures measuring down to 0.2 mm, Magnetom Terra opens up new opportunities for early diagnosis and personalized treatment of neurological diseases such as multiple sclerosis (MS), epilepsy, and Parkinson’s disease in particular.

The German Future Prize will be awarded by Germany’s federal president, Dr. Frank-Walter Steinmeier, on November 27, 2019, in Berlin.

“Along with the entire team at Siemens Healthineers, I am delighted by this nomination for the German Future Prize. The choice underlines our successful cooperation with research partners around the globe,” said Dr. Bernd Montag, CEO of Siemens Healthineers. “The development and clinical approval of Magnetom Terra are illustrative of the strengths of Siemens Healthineers. Clinical use of 7 Tesla imaging helps neuroradiological experts detect pathological changes such as MS or Parkinson’s disease at an early stage and offer targeted treatment. This is an outstanding example of the benefits that can be achieved by expanding precision medicine,” said Montag.

The field strength of 7 Tesla – which is around 140,000 times stronger than the Earth’s magnetic field – yields remarkable results: While in the past clinical imaging could only detect pathological changes in the advanced stages of MS, at 7 Tesla these changes can be observed early on.

In terms of key achievements in hardware technology, Magnetom Terra uses a specially developed, innovative actively shielded magnet. Despite its higher performance, it weighs only half as much as the magnets used in previous generation of 7 Tesla systems. Another innovation is its dual mode functionality, that allows users to seamlessly switch between clinical use and research applications. The system is therefore an ideal platform for translational research. Numerous installations in leading hospitals around the world suggest that 7 Tesla imaging will become an integral part of many large teaching and research hospitals in the medium term.

SIEMENS HEALTHINEERS
ERLANGEN, GERMANY
www.siemens.com

GE Healthcare and Theragnostics to partner on late stage PSMA diagnostic for prostate cancer

GE Healthcare and Theragnostics have entered into a global commercial partnership for a new Prostate-Specific Membrane Antigen (PSMA) PET/CT imaging agent. Theragnostics will lead the development of the tracer, GalliProst, while GE Healthcare will lead all pre-approval commercial preparations and as and when approval is received, all subsequent commercial and distribution activities.

Theragnostics has reported data from a phase two clinical study which met its primary and secondary endpoints, demonstrating that one third of newly diagnosed prostate cancer patients — and over 50% of patients with biochemically recurrent disease — had their treatment plans modified as a result of a GalliProst scan. The change in patient management increased to 75% in a post-radical radiotherapy setting.

“We are excited to partner with Theragnostics on GalliProst to give vital insights into prostate cancer,” said Sanka Thiru, Global Product Leader, Molecular Imaging Oncology in GE Healthcare’s Pharmaceutical Diagnostics business. “We believe that this partnership enables both parties to leverage each other’s key areas of expertise in order to accelerate the development of GalliProst and ultimately improve patient care.”

Greg Mullen, CEO of Theragnostics added “This agreement is validation of the potential for our novel prostate cancer Gallium-68 (68Ga) diagnostic tracer, GalliProst which can benefit the treatment of prostate cancer patients around the globe. We are very pleased to sign our second agreement with GE Healthcare following our agreement last year for a diagnostic tracer for imaging kidney function and scarring.”

GE HEALTHCARE
CHALFONT ST GILES, UK
www.gehealthcare.com

THERAGNOSTICS
BRACKNELL, BERKS, UK
https://theragnostics.com
New ultrasound system with advanced applications

Siemens Healthineers has launched the ACUSON Redwood, a new ultrasound system built on the company’s new platform architecture and features advanced applications for greater clinical confidence, AI-powered tools for smart workflows and has shared services cardiology features used by different hospital departments.

These features, along with a portable and lightweight design, offer clinicians an affordable and efficient high-performing imaging solution.

“Globally, we are seeing an increased demand for cost-effective medical imaging services being driven by the growing healthcare needs of an aging population, particularly in regard to chronic diseases,” says Robert Thompson, Head of Ultrasound at Siemens Healthineers.

“Chronic diseases often require more imaging and additional follow up which drives costs. To meet this challenge, we worked together with input from users to transform care delivery with the ACUSON Redwood. This system is designed to deliver premium image quality, exceptional performance, and greater workflow efficiency within the constraints of limited resources and tightening budgets.”

The ACUSON Redwood’s advanced applications, including Contrast Enhanced Ultrasound (CEUS) and Shear wave Elastography, are available for the first time from the company in this segment and support precise lesion detection and characterization as well as potentially reducing the need for invasive procedures.

A full portfolio of high-performance transducers including compact micro-pinless technology and single crystal transducers support superb image quality. With our coherent image formation (CIF) technology, the ACUSON Redwood maintains B-mode image quality performance even in complex modes and the system’s UltraArt Universal Image Processing provides several image choices right on the touch screen avoiding manual adjustment of multiple image parameters.

With a suite of AI-powered tools, the ACUSON Redwood delivers smart workflows for greater efficiency. Designed to go beyond the radiology department and bring precision imaging to more patients, lightweight and portable with 13 transducers, the ACUSON Redwood is easy to move and delivers premium imaging capabilities to the various clinical departments within an organization, such as radiology, cardiology and OB/Gyn.

The ACUSON Redwood is a comprehensive shared services cardiac solution. In this environment it is crucial to address the needs of a broad range of cardiac assessments which is why the system includes applications such as syngo Velocity Vector Imaging (VVI) technology, an advanced 2D quantitative tool for assessment of global and regional myocardial motion and mechanics, stress echo with a complete wall motion scoring analysis package and Left Ventricular Opacification (LVO) mode to enable cardiac contrast agent imaging.

SIEMENS HEALTHINEERS
ERLANGEN, GERMANY
www.siemens-healthineers.com/ultrasound

Breast Imaging Workstation

Candels recently launched its Advanced Breast Imaging Workstation as an enhancement to the company’s ImageGrid platform. In additional to supporting mammography and tomosynthesis images from Hologic, GE, Siemens, Fuji, Planmed, and Giotto, ImageGrid’s Advanced Breast Imaging Workstation supports viewing and analysis of 3D breast ultrasound images acquired by GE, Siemens, Hitachi, and iVu.

“ImageGrid has long served as the industry benchmark for mammography workflow. With the Advanced Breast Imaging Workstation, ImageGrid is now the best informatics platform in breast imaging,” said Robert Van Uitert, Vice President of Marketing.

The Advanced Breast Imaging Workstation includes:

3D Breast Ultrasound Support

ImageGrid now provides support for 3D breast ultrasound images acquired by GE Invenia ABUS, Siemens Acuson ABVS, Hitachi and iVu Sophia with diagnostic tools for reading and interpretation. The updated breast imaging workstation offers superior image quality with tools for a more accurate and thorough diagnosis.

Enhanced Mammography Prefetch

These tools further reduce the time required before studies can be read and eliminates all information that can cause a patient mismatch. The advanced features include:

• Retrieval of prior studies from multiple PACS
• Ensuring consistency between current and prior patient studies
• Delivery of prior studies to the workstation during non-peak hours
• Caching exams on the workstation to minimize fetching activities during reading
• Prerendering prior exams for visualization resulting in quicker reading of studies
• Delivery of both current and prior exams simultaneously to workstation

“All of these added features are a huge improvement for breast imaging workflow. This will further allow imaging centers and clinics to focus on patient care,” added Van Uitert.

CANDELIS
NEWPORT BEACH CA, USA
www.candelis.com
Improved ergonomics for Mobile X-ray system

Carestream's DRX-Revolution Mobile X-ray System now features an improved ergonomic design and workflow based on customer feedback. The system has a lighter, balanced tube head and collimator with enhanced, responsive display screens located at both the tube head and main display; new functional LED lighting providing the technologist with another point of visibility of the system's status; and In-Bin detector charging that means the system is always at the ready. With patients in mind, the system's brakes and drive motors are quiet to enable noiseless navigation in hallways, elevators and rooms.

CARESTREAM
ROCHESTER, NY, USA
www.carestream.com

New low-dose drug-coated balloons to broaden treatment options for peripheral artery disease patients

Stellarex's unique coating enables a low therapeutic drug dose and has demonstrated a significant treatment effect and high safety profile.

Philips has introduced two new balloons to its Stellarex 0.035” low-dose drug-coated balloon (DCB) portfolio. The new 200mm and 150mm Stellarex 0.035” low-dose DCBs have received approval from the U.S. Food and Drug Administration (FDA) for the treatment of de novo and restenotic lesions in native superficial femoral or popliteal arteries, both arteries in the upper leg. The new balloons broaden physicians’ treatment options for peripheral artery disease (PAD) patients with a high risk of restenosis and expand the Stellarex portfolio, which has a proven significant treatment effect and high safety profile. The 200mm and 150mm Stellarex 0.035” low-dose DCBs are now available in the U.S. and will be rolled out to other markets in due course.

PAD affects more than 200 million people worldwide. If left untreated, it can result in critical limb ischemia (CLI). In patients with CLI, 34% undergo amputation within one year of diagnosis. Broadening physicians’ treatment options helps ensure more PAD patients will receive treatment before the disease progresses.

“By expanding our range of Stellarex balloons, we are adding to the treatment options that physicians can use to provide optimal care for each patient with peripheral arterial disease. With its unique coating, Stellarex is unlike any other DCB in the industry for the treatment of PAD,” said Chris Landon, General Manager, Image Guided Therapy Devices at Philips. “Stellarex is the only low-dose drug-coated balloon with a proven treatment effect at three years compared to the existing standard of care in the U.S. and Europe. By expanding our range of Stellarex balloons, we are adding to the treatment options that physicians can use to provide optimal care for each patient with peripheral arterial disease.”

All Philips’ Stellarex DCBs feature EnduraCoat technology, a unique coating consisting of a polyethylene glycol excipient with amorphous and crystalline paclitaxel particles dispersed in it. The coating provides efficient drug transfer and effective drug residency coupled with high coating durability and minimal particulate loss, thereby enabling a low therapeutic drug dose. The Stellarex balloon is now available in 40, 60, 80, 100, 120, 150, and 200mm lengths for the treatment of lesions in the superficial femoral and popliteal arteries with vessel diameters of 4-6mm.

The results of third-party analyses of patient-level data from worldwide clinical trials of the Philips Stellarex 0.035” low-dose DCB in lengths under 150mm were recently published in Circulation, a peer-reviewed journal of the American Heart Association. Primary safety analysis of Philips Stellarex DCB three-year data, comprising a large published, pooled set of randomized controlled trial (RCT) data for a single paclitaxel-based device, showed no difference in mortality between patients treated with the Philips Stellarex DCB and those treated with percutaneous angioplasty, the current standard of care. The analyses represent one of industry’s most extensive and rigorous safety assessments of a paclitaxel-based device.

In addition to Stellarex DCBs, Philips has leading positions in IVUS (intravascular ultrasound) catheters that produce ultrasound images of the interior of blood vessels, as well as FFR (fractional flow reserve) and iFR (instantaneous free wave) catheters that are used to assess the blood flow. iFR technology is unique to Philips. Our integrated solutions advance minimally invasive procedures for patients with coronary artery disease, peripheral artery disease and lead extraction indications.

PHILIPS
BEST, THE NETHERLANDS
www.philips.com
FDA clearance for AI algorithms to prioritize critical chest X-ray review

GE Healthcare has announced the FDA’s clearance of Critical Care Suite, an industry-first collection of artificial intelligence (AI) algorithms embedded on a mobile X-ray device. Built in collaboration with UC San Francisco (UCSF), using GE Healthcare’s Edison platform, the AI algorithms help to reduce the turn-around time it can take for radiologists to review a suspected pneumothorax. “X-ray – the world’s oldest form of medical imaging – just got a whole lot smarter, and soon, the rest of our offerings will too,” says Kieran Murphy, President & CEO, GE Healthcare.

“GE Healthcare is leading the way in the creation of AI applications for diagnostic imaging and taking what was once a promise and turning it into a reality. By integrating AI into every aspect of care, we will ultimately improve patient outcomes, reduce waste and inefficiencies, and eliminate costly errors. Critical Care Suite is just the beginning.”

Even a prioritized “STAT” X-ray can sit waiting for up to eight hours for a radiologist’s review. However, when a patient is scanned on a device with Critical Care Suite, the system automatically analyzes the images by simultaneously searching for a pneumothorax. If a pneumothorax is suspected, an alert – along with the original chest X-ray – is sent directly to the radiologist for review via PACS. The technologist also receives a subsequent on-device notification to give awareness of the prioritized cases. Quality-focused AI algorithms simultaneously analyze and flag protocol and field of view errors as well as auto rotate the images on-device.

Critical Care Suite and the quality algorithms were developed using GE Healthcare’s Edison platform – which helps deploy AI algorithms quickly and securely – and deployed on the company’s Optima XR240amx system.

“Clinicians are always looking for clinically proven methods to increase outcomes and improve the patient experience,” says Dr. Rachael Callcut, Associate Professor of Surgery at UCSF, a surgeon at UCSF Health and Director of Data Science for the Center for Digital Health Innovation, who partnered in the development of Critical Care Suite. “When a patient X-ray is taken, the minutes and hours it takes to process and interpret the image can impact the outcome in either direction. AI gives us an opportunity to speed up diagnosis, and change the way we care for patients, which could ultimately save lives and improve outcomes.”

Additionally, embedding Critical Care Suite on-device offers several benefits to radiologists and technologists. For critical findings, GE Healthcare’s algorithms are a fast and reliable way to ensure AI results are generated within seconds of image acquisition, without any dependency on connectivity or transfer speeds to produce the AI results. These results are then sent to the radiologist at the same time that the device sends the original diagnostic image, ensuring no additional processing delay. Also, automatically running quality checks on-device integrates them into the technologist’s standard workflow and enables technologist actions – such as rejections or reprocessing – to occur at the patient’s bedside and before the images are sent to PACS.

“Currently, 62 percent of exams are marked ‘STAT’ or for urgent reading, but they aren’t all critical. This creates a delay in turnaround for truly critical patients, which can be a serious issue,” adds Jie Xue, President & CEO, X-ray, GE Healthcare. “Not only does Critical Care Suite flag images with a suspected pneumothorax with impressive accuracy and enable radiologists to prioritize those cases immediately, but it also makes AI accessible. Our embedded AI algorithms offer hospitals an opportunity to try AI without making investments into additional IT infrastructure, security assessments or cybersecurity precautions for routing images offsite.”

GE Healthcare’s Edison offering comprises applications and smart devices built using the Edison platform. The platform uses an extensive catalog of healthcare-specific developer services to enable both GE developers and select strategic partners to design, develop, manage, secure and distribute advanced applications, services and AI algorithms quickly. Edison integrates and assimilates data from multiple sources, applying analytics and AI to not only transform data, but provide actionable insights that can be deployed on medical devices, via the cloud or at the edge of the device.

GE HEALTHCARE
CHICAGO, IL, USA
www.gehealthcare.com
Early evaluations of interventional imaging system suggest potential for 50% dose reduction to patients

Within a year of its launch into the European market, the new Alphenix family of interventional imaging systems from Canon Medical Systems has received its first evaluations of dose reduction rates as compared to previous systems and against UK National Diagnostic Reference Levels (NDRLs).

The dose audit on the Alphenix system was undertaken between February and July 2019 assessing coronary angiography, pacemaker and single stent PCI procedures. All median Dose Area Product (DAP) for the dose audits were lower than national levels.

“These early findings show how the amount of dose delivered to patients during interventional procedures can be lowered using the Alphenix system. They are really encouraging and bring to life how excited we are about this innovation being able to make the invisible visible,” states Daniel Parr, XR Modality Manager at Canon Medical Systems UK.

“Being able to display dose accurately and in real time is unique to the Alphenix and a giant leap for interventional radiology. Clinical procedures that are performed less invasively offer many benefits over alternative surgical options such as faster recovery times, improved patient outcomes and a reduction in total cost of hospital stays. But with this innovation comes a renewed focus on the best strategies for managing ionizing radiation for staff and patients,” he continues.

The Alphenix Dose Tracking System (DTS) is a simple, colour-coded visual that is displayed on the system interface. It tracks x-ray beam movement and provides real-time visual feedback on skin dose information, mapping it visually on the system monitor at the same time.

Improving uptime, and extending lifetime of displays

Healthcare organizations are challenged to improve patient care while controlling costs. Therefore, it is important to ensure that the displays they invest in provide the best performance they can – and continue to do so for as long as possible.

Barco’s ExtendedCare program helps these organizations ensure clinical efficiency by safeguarding their investment. When combined with the product guarantee, the Extended Care program is the cost-effective way to make sure that the displays are always calibrated, compliant to standards, used effectively, and always current with the latest features and software.

The benefits of ExtendedCare include

- Maximized uptime of the diagnostic displays
- Assured quality and compliance
- Optimized lifetime

By extending the useful life of their display systems, healthcare organizations can mitigate risks associated with unplanned downtime, unbudgeted costs and outdated technology.

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* Last minute fee for EACVI Silver Members (Young and Allied Professionals) compared to standard last minute fee for non-members
Introducing

Invenia ABUS 2.0

Proven to find 57% more cancer in dense breasts than mammography alone, \(^1\) supplemental screening with Invenia™ ABUS 2.0 transforms breast care from reactive to proactive.

The new Invenia ABUS 2.0 combines powerful cSound™ Imageforming and an intelligent design to deliver superb, consistent imaging performance. New features enhance the exam experience for both operators and patients. Workflow advancements further streamline scanning, reading, reporting and archiving.

**How many cancers are being missed in dense breast tissue?**
Invenia ABUS 2.0 is helping clinicians be more confident, and helping women with dense breasts avoid potential delayed diagnosis.

To learn more, contact your GE Healthcare Sales Representative and visit [gehealthcare.com/products/ultrasound/abus-breast-imaging](gehealthcare.com/products/ultrasound/abus-breast-imaging)

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