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The UK radiology workforce census — a warning message for all

The just-published report commissioned by the UK’s Royal College of Radiology (available at www.rcr.ac.uk/system/files/publication/field_publication_files/bfcr166_cr_census.pdf) contains a wealth of up-to-date information and data about the status of clinical radiology in the UK. By definition limited to the UK, the census report nevertheless contains findings which European radiologists outside the UK will surely recognize.

The main take-home message from the UK census is the alarmingly insufficient number of radiologists in the country. True? The UK has traditionally always been low in the number of radiologists per head of population with only 7 radiologists per 100,000 population compared to a European mean of 12 radiologists per 100,000. What is more worrying are the future developmental trends of the profession. The rate of recruitment into the profession is significantly lower than the rise in clinical demand for radiology services. Over the last five years the consultant radiology work-force in the UK has grown at an average rate of 3% per annum but over the same period, the demand for CT scans has increased by 29% and for MRI by 26%. The vast majority of all radiology departments stated that they were unable to meet their diagnostic reporting requirements in 2015. The report clearly points out the recruitment crisis in the profession, with unfilled consultant positions now being the norm. Approximately one in ten radiologist positions cannot be filled with some 41% of unfilled posts remaining vacant for more than a year. What’s worse is that in the UK, diagnostic reporting requirements. This has led to radiology departments in the UK are at a stage where the majority of time will be spent rading-room.

The difficulty of attracting enough young graduates into radiology is resulting in a situation in the UK where the profession is greying. It is expected that a quarter of new recruits — they are out-sourcing their reporting work to commercial companies. This involves outflows of money which could be used to pay in-house radiologists. We have big problems.

While the situation in the UK may be extreme, it is not unique.

The UK radiology workforce census — a warning message for all

for Multi Disciplinary Team Meetings (MDMTs), for interventions, departmental fixer or problem solving and for complex image analysis. I am using my recently retired locums and international radiologists. We have big problems.”

The difficulty of attracting enough newly graduated medical staff into radiology is one that will ring bells in many countries. Despite the key and increasingly important role of radiology in modern medicine, too often new graduates perceive a future role in radiology as being one in which the majority of time will be spent in a darkened reading room in front of a display monitor and with little or no direct contact with patients. Even participation in MDTMs, which can widen perspectives for the radiologist, can have its drawback since all too often time taken to attend MDTMs simply means that there is a growing backlog of cases waiting to be read back in the reading-room.

The difficulty of attracting enough young graduates into radiology is resulting in a situation in the UK where the profession is greying. It is expected that a quarter of new recruits — they are out-sourcing their reporting work to commercial companies. This involves outflows of money which could be used to pay in-house radiologists. We have big problems.

While the situation in the UK may be extreme, it is not unique.
COMING IN THE NOV ISSUE:
Radiation dose reduction

COVER STORY - Hospital focus
The Radiolor group is the principal provider of radiology services in the north eastern French region of Lorraine. In addition the group has just invested in TeraRecon’s enterprise viewing solution linking all the imaging centers in the group.

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Diagnostic yield of CTA better than RBC Scintigraphy for Localizing Lower GI Bleeding

In a recently published retrospective study the diagnostic yield of computed tomography angiography was found to be higher than that of technetium-tagged red blood cell (RBC) scintigraphy for evaluating acute lower gastrointestinal (GI) bleeding. (Feuerstein JD et al. Localizing Acute Lower Gastrointestinal Hemorrhage: CT Angiography Versus Tagged RBC Scintigraphy. AJR Am J Roentgenol. 2016 Sep;207(3):578-84).

In this single-center retrospective study, researchers compared the yields of 45 consecutive CTA studies and 90 consecutive RBC scintigraphic studies performed for acute lower GI bleeding; only 9 patients underwent both studies. The presumed bleeding site was identified significantly more often in patients who underwent CTA than in those who underwent RBC scintigraphy (53% vs. 30%). Average time from request to scan completion was significantly shorter for CTA than for RBC scintigraphy (1.7 hours vs. 3.2 hours). Clinical outcomes (e.g., length of hospital stay, number of transfusions, mortality) were similar in the two groups. The researchers concluded that both CTA and RBC scintigraphy can be used to identify active bleeding in 38% of cases. However, the site of bleeding is localized with CTA in a significantly higher proportion of studies.

Dr A S Brett commented on the paper “In general, CTA is more available around the clock, but it exposes patients to more radiation than does RBC scintigraphy. The absence of proven final diagnoses to which all CTA and RBC scintigraphy findings could be compared is an understandable limitation of this study. Lower GI bleeding often stops spontaneously, and in some cases, no additional intervention is required to precisely identify the bleeding source. Moreover, CTA or RBC scintigraphy is not required in every case”.

http://tinyurl.com/Feuerstein-et-al-paper

First Head-to-Head Comparison of Non-Invasive Coronary Artery Imaging Modalities

For patients presenting for the first time with suspected coronary artery disease (CAD), clinicians have had a number of non-invasive diagnostic tests to choose from, but little evidence for which is best. Now, findings from the PACIFIC trial may offer some guidance. The first head-to-head comparison of the most commonly used non-invasive techniques to evaluate myocardial perfusion or coronary artery stenosis severity found that positron emission tomography (PET) had more diagnostic accuracy than either single photon emission computed tomography (SPECT) or coronary computed tomography angiography (CCTA), researchers reported at the recent ESC Congress 2016.

“At present, there is little consensus about the choice of non-invasive imaging modality, and European and US guidelines do not advocate any one over another,” said Prof I Danad, from VU University Medical Center, Amsterdam, who presented the findings. “The vast majority of studies used invasive coronary angiography as a reference standard, which may lead to erroneous interpretations. These data represent the first comprehensive evaluation of coronary artery disease and will help to guide the clinician to choose the appropriate non-invasive test for his or her patients.”

PACIFIC (Prospective Head-to-Head Comparison of Coronary CT Angiography, Myocardial Perfusion SPECT, PET, and Hybrid Imaging for Diagnosis of Ischemic Heart Disease using Fractional Flow Reserve as Index for Functional Severity of Coronary Stenoses) was a single centre study that included 208 patients with suspected CAD. Initially, all patients underwent the gold standard diagnostic test – invasive coronary angiography - which requires threading a catheter into the coronary artery to obtain x-rays and assess intracoronary pressure (fractional flow reserve, or FFR). This test showed that 44.2% of patients had hemodynamically significant CAD. Patients then received non-invasive PET, SPECT and CCTA as well as some “hybrid” combinations of PET and CCTA or SPECT and CCTA designed to combine functional and anatomical assessments.

Comparing results of these non-invasive results to the gold standard results, investigators showed that PET was significantly more accurate (85%) for diagnosing coronary ischemia as compared to CCTA (74%, p<0.01) and SPECT (77%, p < 0.01). Sensitivity of the non-invasive approaches was 87% for PET, 90% for CCTA, and 57% for SPECT, whereas specificity was 60%, 94%, and 84%, respectively.

Additionally, diagnostic accuracy was not enhanced by either hybrid CCTA/SPECT or CCTA/PET, and instead resulted in an increase in false negatives and decrease in false positive results, noted Professor Danad.

“This study’s findings are novel and, to our knowledge, represent the first of its kind to evaluate diagnostic performance of non-invasive imaging modalities against a widely considered reference standard for functionally significant CAD.”
“The results will definitely spark further research. There is always a lot of discussion whether we need to choose SPECT or PET as the initial functional test for our patients. I think that we need to invest more in clinical PET imaging, which will be future. It is more convenient for patients in terms of time, accuracy and radiation dose.”
http://tinyurl.com/Danad-presentation-at-ESC

Canadian study shows healthcare providers do not fully understand cancer risk from CT scans

Knowledge of radiation dose and associated risks varies among referring physicians, radiologists, and technicians, according to a new study in the Journal of Medical Imaging and Radiation Sciences.

Computed tomography (CT) scans are an invaluable diagnostic tool in modern medicine, but they do come at a price: exposing patients to potentially dangerous ionizing radiation. Clinicians and other healthcare professionals may not be fully aware of a CT scan’s effect on lifetime malignancy risk. A new study surveyed doctors, radiologists, and imaging technologists regarding their beliefs about radiation exposure from CT (Irving B, Leswick DA et al Knowing the Enemy: Healthcare Provider Knowledge of CT Radiation Dose and Associated Risks J Med Imaging and Rad Sci. 2016(Sept); 47 Issue 3) The survey found that while most respondents recognized there is an increased risk of cancer from CT, many underestimated the actual radiation dose.

The researchers wanted to assess healthcare providers’ knowledge regarding radiation dosing from CT scans so surveyed medical professionals in Saskatchewan, Canada. They found that 73% of physicians, 97% of radiologists, and 76% of technologists correctly identified that there is an increased cancer risk from one abdominal-pelvic CT. However, only 18% of physicians, 28% of radiologists, and 22% of technologists were able to correctly identify the dose in relation to chest x-rays. Although 48% of physicians, 78% of radiologists and 63% of technologists either accurately estimated or overestimated this dose, many respondents underestimated the dose level.

“Underestimating radiation dose from a CT scan is more concerning than knowing the exact dose level, particularly when it is a vast underestimation, as this may lead to minimization of the risk estimate when considering a test,” explained lead investigator Dr D Leswick, of the Dept. of Medical Imaging, College of Medicine, University of Saskatchewan.

The issue of radiation exposure is significant as doctors continue to order CT scans with increasing frequency. In Canada alone, there were an estimated 4.4 million CT scans conducted in 2011-2012. Measured in millisieverts (mSv), the average radiation dose from an abdominal-pelvic CT is 10 mSv, compared to 0.02 to 0.2 mSv from one chest x-ray, meaning that a radiation dose from a CT scan is best approximated as between that from 100-250 chest radiographs.

“Although the risk from radiation dose levels in the range of medical imaging procedures is small, it is real — as evidenced from atomic bomb survivors and nuclear industry workers showing significantly increased risk of malignancy after exposure to doses in the range of diagnostic CT,” said Dr. Leswick.

“The risk of fatal malignancy may be as high as 1 in 1000 for a 10 mSv exposure (approximate dose of an abdomen-pelvis CT). This risk is significant on a population basis, with up to 2% of cancers in the United States population possibly attributable to CT.”

With such a clear risk relationship between radiation exposure and cancer, it is imperative that healthcare providers understand the facts to ensure the benefits outweigh the possible danger when ordering a diagnostic CT. The survey indicated that 93% of respondents were interested in radiation dose feedback when considering ordering a CT scan. Automated dose calculation software and radiology information systems can be integrated into electronic ordering, which would give doctors immediate access to information when considering ordering a scan.

“Unfortunately, healthcare providers including physicians, radiologists, and medical imaging technologists are often not aware of radiation doses for common CT scans,” concluded Dr. Leswick. “It is important for healthcare professionals (including referring physicians, radiologists, and technologists) to be aware of radiation dose levels and risks from imaging tests for several reasons, including the ability to weigh the risks and benefits of tests, counsel patients on relevant risks, optimize protocols to minimize radiation dose, and select appropriate protocols to minimize radiation dose.”
http://tinyurl.com/Irving-et-al-paper

Research shows MRI-based Computer Simulation can Spare Children from Heart Surgery

Children with congenital heart defects often undergo a battery of strenuous examinations and interventions. In the EU CARDIOPROOF project, Fraunhofer researchers have developed software to simulate certain interventions in advance. Preliminary results point to a reduced need to perform numerous interventions. It can come as a shock to parents: when coarctation of the aorta affects a newborn, the aorta is so narrow that associated heart problems could threaten the life of the child. Fortunately, these heart defects can now be successfully treated with stents. Multiple treatments, however, are often spread over many years, which can be exhausting for child and parent. The Fraunhofer Institute for Medical Image Computing (MEVIS) in Bremen, Germany has developed software to simulate and compare various types
of interventions. This could improve therapy quality and help determine the necessity of an intervention, thereby sparing some young patients from having to undergo an operation. The research was completed as part of the EU CARDIOPROOF project, which will conclude at the end of 2016.

The computer simulation is based on images of a patient’s heart taken with an MRI scanner. These images show not only the shape of the blood vessels, but also portray blood flow. “Our algorithms can detect which blood pressure conditions are found in the vessels,” according to Dr. A Hennemuth, researcher at MEVIS. “What is important is the degree to which the blood pressure differs before and after a vascular constriction.” Based upon a blood flow simulation, experts can replicate and estimate different types of interventions on a computer and determine their effect on patients’ blood flow and pressure. With these advances, researchers can inflate a virtual balloon catheter and assess its effects on blood flow and pressure or plan the insertion of a variety of stents on a computer. This so-called “virtual stenting” helps choose the most suitable stent and its placement. “With the help of our software, clinicians can make informed decisions about which type of intervention is most appropriate and whether the intervention can be delayed or even forgone,” states Hennemuth.

CARDIOPROOF aims to develop a real-world system for clinical use. The research team in Bremen worked closely with the project’s partner clinics to discover how the new software could best be integrated into hospital routine. “To test how realistic the computer simulations were, the scientists conducted clinical studies at the German Heart Center in Berlin. In addition, young patients were examined after the interventions using an MRI scanner. This allowed blood flow before and after their intervention to be calculated and compared to the simulation. The results show accurate predictions of blood flow and pressure.

“The next steps include quality assurance, certification, and transfer into a commercial solution.” Lynkeus, one of CARDIOPROOF’s industrial partners, has already submitted a follow-up project proposal to the EU.

http://tinyurl.com/Cardioproof-project

LDCT screening for lung cancer not associated with undue stress

A new study shows that the introduction of lung cancer screening could significantly reduce deaths in high risk groups, without causing participants the undue stress sometimes associated with medical tests (Brain K, Lifford KJ et al. Long-term psychosocial outcomes of low-dose CT screening: results of the UK Lung Cancer Screening randomized controlled trial. Thorax. 2016 Jul. pii: thoraxjnl-2016-208283). The trial, carried out by researchers from Cardiff University, UK, was aimed at studying long-term psychosocial outcomes of CT screening for lung cancer and found that it did not cause unnecessary anxiety, even though fear and stigma can sometimes be barriers to participation in screening.

Lung cancer is the leading cause of cancer-related mortality in the UK, killing almost 40,000 people per year. Additionally, around three quarters of patients are diagnosed at a late stage when fewer treatment options are available. With early detection of lung cancer about seven out of ten patients survive for a year or more.

Dr K Brain from Cardiff University said:

“With the UK’s 5-year survival rate for lung cancer being lower than many other countries with comparable healthcare systems, it is important that we do more to introduce early detection strategies that help to ensure treatment is delivered before patients present at an advanced stage of the disease.

“Sometimes, fear of medical procedures and the results they might bring can prevent people from seeking life-saving tests. However, what our trial shows is that CT lung cancer screening actually has no long-term negative psychosocial impact on patients, making it an excellent tool for catching lung cancer earlier when there is a better chance of survival.”

The UK Lung cancer screening trial (UKLS) recruited over 4,000 men and women, aged 50-75, at high risk of lung cancer. This group was randomized into two groups: one of which received a CT screen and one that didn’t. Participants in both groups were assessed two weeks into the study and again two years later. To assess people’s emotional responses to CT lung screening, standard measures of lung cancer distress, anxiety, depression and satisfaction were used. The research showed that lung cancer screening did not cause undue worry when people were followed up over the two year period. Participants who needed to have a repeat scan reported slightly higher cancer distress, but this was temporary. The results revealed that at both points more participants from the group that didn’t receive scans were dissatisfied with their decision to take part in the trial. It also found, regardless of group allocation, cancer distress was higher in women, participants under 65, current smokers and those with lung cancer experience.

The evidence produced from the trial should contribute to clinical and policy decisions regarding the successful and equitable implementation of potential future low-dose CT lung screening for high-risk individuals.

http://tinyurl.com/Brain-et-al-paper
Study shows Cardiovascular MR gives fewer unnecessary invasive angiography

Among patients with suspected coronary heart disease (CHD), rates of invasive angiography are generally considered too high. For this reason a group of UK researchers set out to test the hypothesis that among patients with suspected CHD, cardiovascular magnetic resonance (CMR)–guided care is superior to the UK’s National Institute for Health and Care Excellence (NICE) guidelines–directed care and myocardial perfusion scintigraphy (MPS)–guided care in reducing unnecessary angiography. (Greenwood JP et al CE-MARC 2 team. Investigators Effect of Care Guided by Cardiovascular Magnetic Resonance, Myocardial Perfusion Scintigraphy, or NICE Guidelines on Subsequent Unnecessary Angiography Rates: The CE-MARC 2 Randomized Clinical Trial. JAMA. 2016 Sep 13;316(10):1051-60). The group designed a multicenter, 3-parallel group, randomized clinical trial using a pragmatic comparative effectiveness design. From 6 UK hospitals, 1202 symptomatic patients with suspected CHD and a CHD pretest likelihood of 10% to 90% were recruited. Patients were randomly assigned (240:481:481) to management according to the UK NICE guidelines or to guided care based on the results of CMR or MPS testing.

The primary end point was protocol-defined unnecessary coronary angiography (normal fractional flow reserve >0.8 or quantitative coronary angiography [QCA] showing no percentage diameter stenosis ≥70% in 1 view or ≥50% in 2 orthogonal views in all coronary vessels ≥2.5 mm diameter) within 12 months. Secondary end points included positive angiography, major adverse cardiovascular events (MACEs), and procedural complications.

The results showed that in patients with suspected angina, investigation by CMR resulted in a lower probability of unnecessary angiography within 12 months than NICE guideline-directed care, with no statistically significant difference between CMR and MPS strategies. There were no statistically significant differences in MACE rates.

Prof Greenwood later commented that CMR is an established advanced cross-sectional imaging modality for the functional and anatomical assessment of a wide range of cardiovascular diseases. CMR is safe, does not use ionizing radiation, provides diagnostic and prognostic information, and guides patient management. However, the relative duration of the scan time, expense and lack of portability, puts the onus on CMR to demonstrate superiority over other imaging modalities.

http://tinyurl.com/Greenwood-et-al-paper

MRI quantifies liver response in nonalcoholic steatohepatitis (NASH) patients

Researchers at the University of California San Diego School of Medicine have found that MRI based measures of fat density in the liver corresponds with histological responses in patients with nonalcoholic steatohepatitis (NASH).

The recently published finding, suggests the imaging technique can be useful in future NASH clinical trials and in treatment (Patel J et al. Association of noninvasive quantitative decline in liver fat content on MRI with histologic response in nonalcoholic steatohepatitis. Therap Adv Gastroenterol. 2016 Sep;9(5):692-701). NASH is an advanced form of nonalcoholic fatty liver disease (NAFLD), which occurs when fat accumulates in liver cells due to causes other than excessive alcohol use. The precise cause is not known, but diet and genetics play substantial roles. The condition is relatively common. — NAFLD occurs in roughly 20 percent of non-obese persons and in more than 60 percent of obese persons. NAFLD often has no symptoms, but can progress to NASH and, ultimately, to cirrhosis or liver cancer. “NAFLD and NASH are invisible diseases. In most cases, adverse effects are not noticeable until the disease is well-advanced,” said senior author Dr R. Loomba, director of the Nonalcoholic Fatty Liver Disease Research Center at UC San Diego Health, USA. “The ability to accurately quantify liver fat content, without resorting to needle biopsies, represents a significant advance, in the lab and in the clinic.”

Loomba and colleagues looked at how the form of MRI, known as MRI-estimated proton-density-fat-fraction (MRI-PDFF), compared to liver biopsies in 35 patients with confirmed NASH diagnoses. Patients were assessed with both techniques before and after treatment. The researchers found that a 29 percent reduction in liver fat, as measured by MRI-PDFF, corresponded to a clinically important improvement in liver histology. “MRI-PDFF has the potential to be a cost-effective and convenient method for liver fat quantification. It requires only a single, 20-second breath hold and an estimated time of about five minutes in an MRI scanner,” said Loomba.

http://tinyurl.com/Patel-et-al-paper
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Working Face-to-Face for Pediatric CT Dose Reduction: A Community Toolkit

Although children are especially vulnerable to the health risks of ionizing radiation, approximately 8 million CTs are performed on children in the USA. Widespread dose variation is common, particularly in non-pediatric focused facilities. In this article we present our rationale and hands-on approach in developing and refining a toolkit aimed at helping a community hospital with pediatric CT dose reduction.

INTRODUCTION

"Is this a private fight or can anyone join in?"
— Unknown Irish man who saw a fight and inquired [1]

In the USA concerns about potential radiation-induced cancer from CT scans continue to intensify in the public domain, as evidenced by recent articles in the New York Times [2] and Washington Post [3]. Over the past three decades the number of CT scans has increased dramatically, with current estimates at almost 5 million scan per year in the UK and about 85 million per year in the US [4]. U.S. population doses are at a historic high, with radiation exposure from medical sources having increased 600% since the 1980s [5,6]. The greatest contributor to the striking increase in population exposure in the US is the CT scan [7]. Dose levels for CT of the body in the USA remain substantially higher than those in Europe [8]. In the US, the average person has a CT every four and a half years and receives an annual dose from medical exposure of 3.2 mSv, in comparison with the UK where the average citizen has a CT every 17-18 years and the average annual dose from medical exposure is 0.4 mSv [8]. Dose variations between countries may be secondary to normative differences and cultural contexts. For example, in the USA, the practice of defensive medicine to reduce the threat of litigation [9] promotes high levels of image quality which may exceed diagnostic requirements. Coupled with this constraint is the absence of formal consideration of radiation dose in the justification process for each patient. In Europe, radiation dose is enshrined in medical exposure legislation and “requires optimization to be undertaken using diagnostic reference levels (DRLs)
... and the inclusion of patient dose in the justification of each examination” [8].

Children are especially vulnerable to the harmful effects of radiation [10,11]. Although quantification of cancer risk from CT in children is complex and contentious [12], two large, longitudinal analyses in the UK and Australia showed similar results: a 24% increase in cancer in children and adolescents exposed to ionizing radiation from CT [13-15]. Such epidemiologic estimates of lifetime risks based on direct analyses and electronic record linkage from national health registries, an approach which would be exceptionally difficult in the USA, are compatible with lifetime risk estimates that are derived from atomic bomb survivor data [16].

The practice of using the same radiation exposure factors for CT examinations as those for adults is not uncommon, resulting in much higher doses of radiation than are necessary for an adequate level of image quality [17,18]. A recent study canvassing a large research network of health maintenance organizations in the USA found that many children received high radiation doses from CT scans [19]. This finding was attributed to both the greater use of higher-dose CT examinations, such as scans of the abdomen and pelvis, and to substantial variability in radiation doses [5]. The investigators projected that if radiation doses nationwide reflect the doses they observed for CT scans of the head, abdomen/pelvis, chest, and spine for children, then the scans performed in one year in the United States might cause 4,870 future cancers [5]. The investigators suggested that if the highest 25% of doses can be reduced to the median dose, then 43% of those cancers might be prevented [5]. Of the estimated 8 million CTs performed on children in the USA, up to 6.8 million are performed at sites outside the auspices of a dedicated pediatric facility [20,21]. Studies continue to show that CT dose optimization for children is particularly challenging at these non-pediatric focused sites [20,22,23].

**OUR WORK**

In our pilot study [24] we conducted a retrospective analysis of de-identified CT dose estimates from 20 community hospitals (CH) and radiology practices during a 6-month period in 2012. Based on this analysis, we identified 12 sites with pediatric dose estimates 2-10 times higher than corresponding age-based protocols at our academic medical center (AMC), a public, tertiary care Level I adult and pediatric trauma center. [See Figure 1 for graphical representation].

Following this analysis, we partnered with a general, non-pediatric community CH, to develop a toolkit for pediatric dose reduction, *The ABCs of Childcare in CT: Awareness, Belief, Change* [24]. [See Figures 2 for a sample of information provided within the toolkit.] The toolkit contained selected examples of AMC pediatric protocols with as low as reasonably achievable (ALARA) doses; medical literature regarding practical strategies; interactive Image Gently [25] pediatric CT dose calculation charts; a glossary of definitions and terms; selected educational links; tips, contacts and links provided by the Imaging 3.0 program[26]; and a list of direct contacts at AMC. The novelty of our approach existed in the collaborative effort of physicists, physicians, public health researchers, and CH imaging stakeholders. During this process, we used surveys and semi-structured interviews to develop, evaluate, and refine our toolkit for generalizability over different manufacturers and platforms, and tailoring to meet the individual needs of small CHs. In addition to developing a physical toolkit, we also conducted an educational session with various members of the imaging
Radiation Dose Reduction

“Things should be made as simple as possible. But no simpler.”
— Albert Einstein

We used questionnaires to explore staff opinions and familiarity with CT risks and best practice guidelines in pediatric CT dose reduction. We also used semi-structured interviews to evaluate the content of the educational intervention and toolkit. These interviews were transcribed and reviewed for insights [24]. Finally, to establish baseline data for a future intervention, we collected dose data from CH pediatric CT scans for comparison to benchmarks, including the vendor and scanning parameters from the DICOM dose reports [24].

**What We Found**

“We all know that dose reduction is important, and in a small hospital that may be where it ends.”
— Interviewee from CH

**Educational Session Evaluation**

One of the benefits of our educational session was the facility-specific information that we presented. Baseline data from CH revealed approximately 2 to 3 times higher doses than matched patients at AMC. [See Table 1 for a comparison of CH and AMC pediatric CT doses and Figure 3 for the introductory slide to our presentation]. By presenting this information and describing our own struggles with dose reduction, the need for dose reduction became less of an abstract idea and more of a practical example with room for incremental improvement. “Just because we’re small is not an excuse not to implement good dose reduction strategies,” stated one interviewee. Following the session, we found an increase in knowledge and opinions towards CT risks, a strong willingness and readiness to implement change, and a positive utility of the session [24].

**Toolkit Evaluation**

Interviewees uniformly reported that our toolkit is a very useful resource. However, there were still opportunities for improvement. For example, because of the low volume of pediatric patients, interviewees suggested that the toolkit contains some information and sample protocols that they may not use.

**Risk Communication**

Patients, caregivers and providers alike are not fully aware of the risks that CTs present to patients [10]. Thus, we asked about the discussion of the risks and benefits of CT scans with patients before ordering or performing a study. One interviewee reported, “We try to, yes, but my opinion is most people come in the hospital and [a CT is] what they want.”

**Making an Impact**

Though some may wish to use lower doses, this implementation relies heavily on commitment from radiologists since they will have to read lower quality images. “I have to make sure that the radiologists understand where we are going and I have their buy-in,” stated one interviewee. Because many CHs are small, equipment maintenance and updates that include better dose optimization methods are other important barriers. The relatively low volume of CT scans in CHs, particularly for pediatric patients, provides CH staff with limited experience in practicing dose reduction technique and was a topic broached by all interviewees.

**Discussion**

**The Big Picture**

“There are no small problems. Problems that appear small are large problems that are not understood.”
— Santiago Ramón y Cajal

There is a worldwide, critical need for continuing pediatric CT quality improvement, including assessment and reduction of unnecessary dose variation which does not contribute to positive patient outcomes and may jeopardize children’s health and safety [25, 27]. A most recent review of US healthcare quality measurement cited several issues which have limited improvement, including the lack of alignment in the use of measures and improvement strategies, and the lack of centralized national electronic systems for measurement, reporting, benchmarking, and improvement [28]. Radiation protection is a priority for the American College of Radiology (ACR), and systematic improvements in CT utilization, dose optimization, and patient safety are being realized through the power of national pooled data in the ACR’s Dose Index Registry, and up-to-date educational resources for radiologists and referring clinicians through the Image Wisely initiative [29, 30].

**The Smaller Picture**

“Enjoy the little things, for some day you may look back and realize they were the big things.”
— Robert Brault

Our motivation for the present research project was threefold, namely: 1) our long, personal, trial-and-error, ongoing experience in a large academic medical center for pediatric CT dose reduction, 2) the recognition that small hospitals in our own neighborhood may struggle with high radiation doses in children’s CT, and 3) the belief that we can help them to reduce these doses. Our rationale was that changing practice patterns related to pediatric CT dose reduction is complex, requiring a hands-on, evidence-based approach to dissemination and implementation [31, 32]. By closely interacting with CH imaging staff, we learned that operational barriers to dose reduction include: 1) limited resources such as software and equipment upgrades, 2) the complex and counter-intuitive nature of dose-reduction techniques on scanners, 3) lack of educational support for pediatric protocol oversight and quality management, 4) the possibility that...
CH radiologists who do not routinely interpret children's CT scans may order images acquired at higher doses in order to increase diagnostic confidence and to offset the increased noise that accompanies lower dose scans, and 5) the relatively small number of pediatric patients [21,22,33]. We experienced CH leadership-in-action through their open mindedness regarding the need for dose reduction measures, their responsiveness involving our CT toolkit booklet, and their eagerness for dose reduction implementation and ongoing consultative support from a larger academic institution. A plan to present our research findings to a statewide healthcare imaging consortium to seek administrative support for implementation is in process.

CONCLUSION

Our research partnership revealed that one of the most challenging aspects for CHs to overcome when attempting to optimize pediatric CT doses is the limited number of pediatric patients. The small number of pediatric patients creates a need for educational interventions to raise awareness of radiation risks and to formalize pediatric CT protocols.

Acknowledgements

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REFERENCES

A province-wide approach to CT dose optimisation in Québec, Canada

Several studies have linked an increase of lifetime risk of cancer to the radiation exposure in CT examinations. This has prompted many countries to take action and to consider CT exposure as a public health problem. The province of Québec (Canada) has created the Center of clinical expertise in radiation safety (Centre d’expertise clinique en radioprotection, CECR) to gather knowledge and communicate best practices related to the use of ionizing radiation in a medical context. Since 2011, the CECR has conducted a province-wide tour of 180 CT installations in order to evaluate the performance of CT scanners and to initiate, with local stakeholders, a CT dose optimization process. This paper presents the multidisciplinary and collaborative approach developed by the CECR.

INTRODUCTION

CT is the largest source of population exposure to medical ionizing radiation around the world [1, 2] and recent studies have shown a statistically significant increase of lifetime risk of radiation-induced cancer from CT examinations [3,4,5]. In 2008, CT was responsible for 52% of the medical exposure to ionizing radiation in the province of Québec (Canada) [6]. Data collected from the provincial universal health care program showed a continuous augmentation in CT studies since then, with an increase of 45% between 2008 and 2013. The degree of population exposure can be expressed in terms of diagnostic reference levels (DRLs), obtained through national or regional surveys. In the field, these DRLs values are often used as dose limits rather than guidelines. For an efficient optimization of patient doses, DRLs must be used with other parameters such as the capabilities of CT equipment, patient size, and diagnostic image quality requirements. This is not a trivial, one-size-fits-all task and significant efforts must be made to achieve an optimal use of dose in CT.

In order to promote a more rational use of radiation in medicine, the province of Québec has created the Centre de compétence clinique en radioprotection (CECR), a provincial center of clinical expertise in radiation safety with the mandate to support the Ministry of Health and Social Services in reducing medical radiation exposure. As part of its mandate, the CECR initiated in 2011 a province-wide tour of 180 CT sites in order to: (i) evaluate the technical and functional performance of CT scanners, (ii) evaluate and improve radiation safety practices and (iii) initiate a dose optimization process of routine CT protocols [7]. Over a period of four years, ending in 2015, 112 installations have been optimized.

ON-SITE VISITS

The tour consisted of two-day visits to CT facilities conducted by a team of medical physicists (or biomedical engineers) and medical imaging technologists. Weeks prior to the visit, the CECR contacted the facility to gather information on the equipment and the CT protocols used. The objectives of the tour and the overall progress of the visit were explained during this first contact, and the CECR asked the hospital to designate technologists, managers and radiologists to participate during the visit.

The visits began with a meeting between CECR experts and local technologists, managers and radiologists to explain the approach and the objectives of the visit. The emphasis was put on the collaborative nature of the approach, so that local stakeholders do not wrongly believe that this was a formal inspection. Then, CECR experts performed quality assurance tests on monitor display (AAPM TG18) as well as on CT equipment [8, 9]. They also evaluated local radiation safety practices and analyzed 30 recent adult studies and 15 pediatric studies provided by the hospital. Acquisition and reconstruction technical parameters, CTDIvol, dose length products, noise levels, scan ranges and image artifacts were verified.

The second day also began with a meeting with the local team where the CECR presented its observations and recommendations, notably regarding ways to improve the clinical practice and to optimize CT protocols. With the consent of local radiologists, optimized CT protocols were used for CT studies.
scheduled on this second day. Finally, at the end of the visit, a report summarizing all CECR observations and recommendations was delivered to the local team as well as to the head of the institution.

In the weeks following the visit, the local team of radiologists were asked to evaluate up to 30 CT exams performed with the optimized protocols. This evaluation was conducted with quality scoring forms and sent back to the CECR.

1. QUALITY ASSURANCE PROGRAM

The vast majority of CT devices inspected achieved the CECR performance criteria, with only 9% of them failing to meet one or two performance criteria. However, the data collected showed that there is room for improvement in quality control (QC) practices, which varied significantly from one facility to another. For this reason, the CECR published in 2013 a QC and radiation safety manual for CT installations [9] to help CT facilities to progressively implement standardized QC practices.

2. DOSE REDUCTION THROUGH GOOD CLINICAL PRACTICE

Clinical practices, under the responsibility of radiologists and executed by technologists, have a significant impact on the overall radiation dose delivered to the patients. Based on the analysis of 30 routine studies provided by the hospital, the recommendations of CECR experts regarding clinical practices included items such as reducing the scan coverage to the minimum required for diagnostic purpose, centering the patient adequately in the CT gantry and using bismuth shielding when there is no medical contraindications. The analysis of clinical studies showed that: i) scanning beyond predefined anatomical landmarks recommended by the CECR occurred in 25%, 39% and 25% of hospitals visited for the head, chest and abdomen-pelvis protocols respectively. Overscanning ranged from 10 to 40 mm, ii) patient positioning was not adequate in 15% of CT facilities visited and iii) about 25% of visited CT hospitals did not own bismuth shielding for breast, thyroid and eyes. 43% of hospitals visited did not use this shielding when available and 22% used it occasionally.

3. DOSE REDUCTION THROUGH SCAN PROTOCOL OPTIMIZATION

The success of CT protocol dose optimization relies on two important factors. The first one is the acknowledgement of radiologist’s expectations for image quality: spatial resolution, noise and contrast-to-noise ratio. The second is the comprehension of how different acquisition and reconstruction parameters influence, independently and together, image quality and associated radiation dose. Full consideration of these expectations along with the knowledge of CT device capabilities are essential in the judicious choices of acquisition and reconstruction parameters that achieve an adequate image quality for a particular indication and patient morphology, at the lowest achievable radiation dose. Published guidelines [10] suggesting technical parameters for specific CT devices constitute a good starting point for optimization, but in general this process requires fine-tuning and discussions with radiologists. More than 80% of routine adult head, chest and abdomen-pelvis protocols were modified during on-site visits. Table 1 reports the statistics on dose reduction achieved for protocols that were modified. Overall, significant dose reductions were achieved, in some cases with values as high as 60%.

**CONCLUSION**

The objective of the CECR CT tour was to initiate a dose optimization process within each hospital visited, with the hope that local teams would take over in the long run. The CECR approach to optimize CT doses is based on the active participation of all stakeholders in the process and takes into account the performances of CT scanners, the opinion of radiologists and the availability of dose reduction tools (current modulation, iterative reconstruction). The diagnostic quality required by local radiologists remained central in the optimization process. This multidisciplinary and collaborative approach, based on support, guidance and the physical presence of CT imaging experts, was very well accepted and led to significant dose reductions. The CECR continues to support hospitals remotely and with follow-up visits, with the objective of promoting a rationale use of ionizing radiation in medicine.

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Created more than 25 years ago, the Radiolor group is now the principal provider of radiology services in the north eastern French region of Lorraine, with the group currently present in eight of the principal hospitals and medical centers in the area. Providing easy access for patients, most of whom are referred by local medical prescribers, Radiolor has an experienced staff of more than 100 medical professionals, including 16 radiologists, as well as radiographers and support personnel. Currently Radiolor offers all principal imaging modalities and has five CT scanners and four MRI systems. To ensure that the imaging systems are always state-of-the-art, the group has a policy of regular hardware renewal. In addition the group has just invested in TeraRecon’s enterprise viewing solution linking all the imaging centers.

We wanted to find out more about the group and the equipment in particular so we spoke to Dr Frédéric Lefèvre, radiologist.

**Q** DI Europe readers may not all be familiar with the Radiolor group, so please tell us about your organization

Radiolor is a medical imaging group that provides imaging services to three private hospitals (Louis Pasteur Clinic in Essey les Nancy, Clinic of the Blue Line in Epinal, and Jeanne d’Arc Clinic in Luneville). We also partner with three public hospitals (University Hospital of Nancy, Luneville, and CH of Pont-à-Mousson). We serve patients coming mainly from Lorraine and the nearby regions in the east of France, with a total population of 2.3 million. Each site cooperates closely with the local health care services in its own area to ensure that quality care is provided to patients in an environment close to home. Only highly specialized examinations, such as cardiac exploration and interventional radiology services, involve patients having to travel to more specialized facilities. Radiolor itself reviews about 200,000 cases annually – 22% of those exams are CT scans, 11% MRI, 6% Mammography, 20% Ultrasound and the rest X-ray. Radiolor also closely partners with other private groups in the region and in total reviews nearly 500,000 cases annually. Our centers have seen that the demand for MRI and CT studies in particular has been increasing steadily over the last few years. This growth in CT and MRI is not unique to our area, but is true in almost all the other regions in France.

**Q** Now let’s turn to how you keep up with this demand. What equipment do you have to provide the service expected of you? What imaging hardware available?

We have all the main imaging modalities. We have built up a large platform comprising 11 CTs, 5 MRIs, 21 X-ray systems (CR, DX, and radiography/fluoroscopy), 18 ultrasound units, and 11 Mammography systems. The healthcare system in France is administered by the government. Scanners such as CT and MRI require government approval and must be renewed every 5 years.
We at Radiolor and our partners try our best to meet the demands of a rising patient population while also being compliant with government regulations.

**Q** And what about software? I understand you have TeraRecon’s enterprise viewing system. How long have you had this? What viewing system did you have before?

Our information systems are shared with our main imaging partner in Lorraine (SOLIME) and as I said, the total annual number of studies is near 500,000. This platform was created 10 years ago by pairing RIS with various storage archives. We did not have a traditional PACS. Advanced Visualization and other non-DICOM data were managed on “stand-alone” workstations, generally provided by the scanner suppliers at the time of each hardware acquisition.

We had reached our limits of being able to manage all the scattered imaging data that the previous set-up generated and we desperately needed to increase accessibility possibilities without compromising the RIS +Archive model.

Against this background, we came to the decision to go for an enterprise viewing system in order to have a common platform to access image data. An “Invitation to tender” process was initiated so that demonstrations could be organized and, in particular, that a “Proof of Concept” could be established. All this and the bidding process took about 18 months. All vendors demonstrated their solutions in a real environment and with extensive testing to measure their capabilities and flexibility.

We carefully reviewed all major outcomes and challenges of this large transition with specially constituted teams covering the areas of project management, IT and change management. Of course, we also carefully considered the objectives for our clinical workflows.

In the end, this intensive evaluation process allowed us to select a “short-list” of 3 possible vendors. We decided to purchase TeraRecon in December 2015 and installed the system May 2016. The choice was not easy because in fact there was no single system that could, off the shelf, solve all our problems!

However, the consistency, commitment, and clinical tools of the TeraRecon team assigned to the project showed our entire radiology personnel that their solution could fulfill the requirements and challenges of our project.

In terms of project and change management, TeraRecon’s value proposal consistently took into account and in detail all the challenges that we had identified for what was after all a drastic workflow change for our community.

After a few months of use, the transition to TeraRecon is now almost complete.

The contextual integration with RIS was quickly implemented, even with an archive housing over 3 million exams.

The ability to access all the modalities within the same GUI is a big advantage. We are now using one GUI for all our image review and we can access all image data across our organization. This has allowed us to be much more efficient.

We have not yet perfected the very technical workflows (CT angio, Monitoring... RECIST) nor some complex operations (multi-MR, patient comparison to different PID), but we are currently working on these aspects.

**Q** What about the impact of the new system on workflow and the effect on radiologist productivity and efficiency? Ease of access from the various sites of the group?

It is still too soon to make an exhaustive and final, quantitative assessment of these aspects, however, it is already clear that the TeraRecon system has

The group provides imaging services to three private hospitals in Lorraine and also partners with three public hospitals and two medical centers in the region.
HOSPITAL FOCUS

definitely helped our radiologists to be more efficient in their daily tasks, even within our complex environment.

There is still work to be done for our technicians to expand their knowledge of, and familiarity with, the new system in order to take full advantage of all of the many capabilities the system offers. So advanced training is needed and an in-depth training program is currently scheduled to take place over the upcoming months.

Given the geographical locations of the various hospitals in the Radiolor group, the possibility of interoperability between remote sites is important for us. TeraRecon’s Overlay PACS Viewer now allows our organization to provide seamless workflow between acute and specialty care sites — a feature which was not possible prior to the installation of the new system.

TeraRecon’s enterprise imaging solution provides a tool box for IT infrastructure that has helped us to dramatically improve image sharing between our six sites and, as a result, make our patient care much better. It also reduced the number of extra-solutions that we needed previously to archive our data.

We are now looking forward to significantly extending our image and information sharing even further — an activity that was absolutely painful in the past.

This is a very important advantage, especially, when compared to PACS solutions. We are still receiving some support from TeraRecon to finalize customization and help us to incorporate more seamless workflows. Also, TeraRecon trained our local IT team during the Proof of Concept and implementation phases. The complete transparency between the two teams allowed a true partnership and it has been a real benefit whenever new challenges arise.

It is important to note that what TeraRecon offers is not a PACS solution, but a totally customizable enterprise viewing system that meets the facility’s specifications and needs. At the end of the day, TeraRecon’s devoted support in this transition and change management phase has been — and continues to be — a vital, key point in the success of the project.

Q: Do you have any metrics regarding patient impact, e.g. clinical outcomes?

It’s still early to say, but the quality system (ISO 9001) that we’ve been using for 12 years will be able to identify and quantify the impact on patient satisfaction soon.

Q: How is all this software kept up-to-date? In-house software engineers or support from TeraRecon?

We have not received any software updates yet, but we expect one at the end of the year, which will improve our viewing workflow even further. TeraRecon constantly offers updated tools that add value to our practice.

Q: So how do you envision the future?

Radiolor would like to grow our practice and also expand our clinical network. France has a very complex system of medical and health records and we would like to establish new and efficient workflows to improve the patient care system.

We would like to champion vendor neutral enterprise viewing systems, like the TeraRecon solution, that doesn’t limit our data and its workflow, regardless of the hardware vendors. We have several ongoing projects with TeraRecon, such as ZEP viewer for internal and external diffusion. Also, in order to improve the quality of our patient care, we want to develop courses that would provide more specially trained technicians who would be focussed on each speciality instead of having general technicians.

For example, we would like to establish 3D labs like those in the US since that model doesn’t exist in France. As a start, we want to deploy TeraRecon solutions to other partner sites with whom we share our RIS-Archives.

All these possibilities make the future a challenging, exciting but ultimately rewarding prospect.
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Neuro technology collaborate to develop MRgFUS Neuro technology

INSIGHTEC, a global leader in MR-guided Focused Ultrasound (MRgFUS) therapy, announced the signing of a strategic agreement with a global leader in MRI, Siemens Healthineers. The strategic collaboration will involve the development of compatibility between Exablate Neuro and Siemens’ leading 1.5T and 3T clinical MRI systems, namely the MAGNETOM Aera and Skyra. Both parties will work towards providing access to Exablate Neuro for installed base, as well as new product installation customers.

Exablate Neuro is the world’s first and only CE- and FDA-approved device for the non-invasive application of MR guided focused ultrasound to treat essential tremor and other conditions. Clinical research, development and regulatory approvals are ongoing for additional neurosurgical applications and markets. Exablate Neuro uses focused ultrasound waves to precisely target and accurately ablate tissue deep within the brain with no incisions, and while minimizing damage to adjacent healthy tissue. Siemens MR imaging plans to provide patient-specific treatment planning and continuous temperature monitoring for assessing treatment outcome in real-time during Exablate Neuro procedures.

“Our agreement with Siemens Healthineers will allow us to significantly expand Exablate Neuro’s market presence. Siemens has embraced our technology and together we will bring our therapy to significantly more patients and providers,” said Dr. Maurice Ferré, CEO of INSIGHTEC. “INSIGHTEC is committed to continue investing in research and development of MRgFUS technology. The strategic collaboration with Siemens Healthineers will allow more patients and researchers globally to benefit from the unique MRgFUS technology,” he concluded.

Dr Christoph Zindel, General Manager of SIEMENS Healthineers’ Magnetic Resonance business further highlights the importance of the agreement: “This strategic partnership of two leading organizations is exciting and further underlines Siemens Healthineers’ strategy of enabling better patient outcomes by broadening its diagnostic imaging portfolio into advanced therapies in the area of neurological and other disorders. Together with INSIGHTEC and its innovative technology, we will jointly drive healthcare further together with our strong research and clinical customer network worldwide.”

INSIGHTEC TIRAT CARMEL, ISRAEL
www.insightec.com

Carestream’s Cone Beam CT System gets FDA clearance

CARESTREAM’s OnSight 3D Extremity System that uses cone beam CT (CBCT) technology to capture weight-bearing and other types of extremity exams has received FDA 510(k) clearance. This affordable, compact system offers high-quality, lower-dose 3D imaging studies for use by orthopedic and sports medicine prac-
tices, hospitals, imaging centers, urgent care facilities and other healthcare providers. “Our extremity imaging system can help in treating a host of orthopedic conditions that affect the biomechanical behavior of the joints such as arthritis, meniscus loss, instability and malalignment syndromes,” said Helen Titus, Carestream’s Worldwide Marketing Director for Ultrasound & CT Solutions. “This new system offers less radiation than traditional CT systems while delivering excellent image quality.”

Orthopedic imaging is a major focus for Carestream because of the prevalence of musculoskeletal conditions among people of all ages. “Youth and adults often suffer sports-related injuries to their knees, ankles and feet while older adults experience arthritis, joint instability, meniscus loss and other conditions,” Titus explains.

Carestream’s new extremity imaging system enables healthcare providers to capture high-quality 3D images and conduct a patient consultation in a single visit—which helps improve productivity and convenience for both specialists and patients. An additional benefit is the ability for patients to view a 3D image that illustrates their condition or injury to help them understand the reason for a treatment or surgical procedure.

CARESTREAM ROCHESTER, NY, USA
www.carestream.com

POC ultrasound helps enhance maternity services in Africa

A unique collaboration between the charity Health Improvement Project Zanzibar (HIPZ) and the Zanzibar government has seen point-of-care ultrasound systems introduced into the country’s hospitals, helping to improve maternity services. Dr Ru MacDonagh, founder of HIPZ and a consultant urologist at Musgrove Park Hospital in Taunton, Somerset, UK explained: “In a drive to improve healthcare services, the Zanzibar government approached HIPZ to run its Makunduchi Hospital and, later on, a larger hospital at Kivunge. One big problem was the lack of ultrasonography, which is particularly important in a maternity unit. The large cart systems we used initially were not practical for use in Africa, and so we looked for an alternative solution.”

“SonoSite point-of-care ultrasound systems are used at Musgrove Park, and an anaesthetist colleague
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had also used them in the earthquake zone in Nepal during the 2015 disaster relief effort, describing them as ‘bullet proof’. This robustness made them ideal for use in Africa. We bought two NanoMaxx systems, which deliver exactly what we need. They are compact, lightweight and portable, with good image quality. They are also straightforward to operate, and I learned how to use them in a very short period of time. Point-of-care ultrasound has made a dramatic difference to our maternity unit. Patients really appreciate seeing the baby, and attendance rates at our antenatal clinics have now grown from just 20 to 30% to around 70%. Ultrasound has proved a huge success. It’s a real life saver.”

FUJIFILM SONOSITE
TOKYO, JAPAN
www.sonosite.com

Mallinckrodt Sells Its Nuclear Imaging Business

The specialty pharmaceutical company Mallinckrodt has announced that it has agreed to sell its Nuclear Imaging business to IBA Molecular (IBAM), for approximately $690 million.

“Mallinckrodt’s Nuclear Imaging operation has a long history going back 50 years, and has been a strong cash-generating business over time,” said Mark Trudeau, President and CEO of Mallinckrodt. “But with our strategic priorities focused on enlarging our portfolio in the high-growth specialty pharmaceuticals space,” Trudeau continued, “we believe the sale of our Nuclear Imaging portfolio to IBAM is the best solution for both the business itself and Mallinckrodt.”

Renaud Dehareng, Chief Executive Officer of IBAM, said, “We are very excited about this acquisition. IBAM’s and Mallinckrodt’s Nuclear Imaging business’ complementary footprint and capabilities will substantially broaden our ability to serve patients globally. We are very pleased to welcome our new colleagues to IBAM upon closing and look forward to working together in this next chapter of our company’s development.”

Mallinckrodt’s Nuclear Imaging business includes a portfolio of diagnostic imaging products. The business is a prominent global producer of the key medical isotope molybdenum-99, from which technetium-99m (Tc-99m) is derived. Tc-99m is used in roughly 80% of all nuclear medicine procedures worldwide, and Mallinckrodt is a significant global supplier of this radioisotope.

MALLINCKRODT
CHESTERFIELD, UK
www.mallinckrodt.com

Contrast enhanced ultrasound agent approved in Mexico

Bracco Imaging has announced that its Sonovue (Sulphur Hexafluoride Microbubbles) product has been approved by Mexican regulatory authorities for use in echocardiography and Doppler ultrasonography. The approval is aimed at improving the assessment of the heart during echocardiographic procedures and at increasing the detection or exclusion of abnormalities during Doppler ultrasonography of the macrovasculature or in individual organs in the microvasculature.

BRACCO IMAGING
MILAN, ITALY
www.braccoimaging.com

MRI-guided radiation therapy system gets CE Mark Approval

ViewRay the Ohio-based company manufacturer of radiation therapy systems, has announced that it has received CE Mark approval for its next generation linear accelerator-based MRI-guided radiation therapy system, the MRIdian Linac. The MRIdian Linac builds on the first generation MRIdian system, but replaces cobalt with linear accelerator technology. The MRIdian is the world’s first and only clinical MRI-guided radiation therapy system. Using a patented combination of magnetic resonance imaging (MRI) and radiation therapy delivery technology, the MRIdian system provides high-qual-
UK's first spectral-detector CT scanner installed

Philips have announced that the Ulster Independent Clinic in Northern Ireland has invested Euro 1.7m in a Philips iQon, the world's first and only spectral – detector CT which delivers multiple layers of retrospective data in a single, low-dose scan, helping to improve clinical confidence, by removing the need to prospectively make diagnostic decisions. Consultant Radiologist Dr. Peter Ball from Ulster Hospital in Belfast and Ulster Clinic comments: “This advanced technology is effectively redefining how we scan patients and the subsequent course of treatment. It will enable us to deliver significant benefits for patients both diagnostically and prognostically as we can now provide faster, safer diagnostic screening which gives us a clear breakdown of the scanned tissue, for faster treatment planning. For example, in a case where a patient has renal stones the iQon scanner will illustrate what type of stones we are dealing with, enabling prompt, confident diagnosis and improved clinical outcomes."

“The iQon scanner has effectively taken CT technology to another level,” Dr. Ball continues: “We are only beginning to discover what we can do with the multiple layers of information it provides, and we are excited about its ability to help us deliver enhanced patient care in the future.”

By delivering spectral results 100% of the time in a single scan, the valuable clinical insights allows the physician to influence clinical workflow, patient care and economic outcomes by decreasing the number of patient findings that are indeterminate. It also allows expansion of clinical capabilities to all patients, even for the most challenging scenarios by facilitating enhanced tissue characterisation and visualization and also full use of dose management tools.

Chairman of the Ulster Independent Clinic, Dr. Kieran Fitzpatrick added, “This is a significant investment for the Clinic, which is very much aligned with our aim to provide an unrivalled level of care for our patients. As a leading private healthcare provider in Northern Ireland, we are committed to investing in the most advanced technology available, and the iQon scanner is set to transform our diagnostic capabilities. We are currently taking part in a collaborative network with the other iQon users worldwide, sharing vital information which will enable us to maximise the full potential of the technology and further benefit our patients.”

PHILIPS
EINDHOVEN, THE NETHERLANDS
www.philips.com

Agfa awarded its fourth U.S. Government DIN-PACS agreement

Agfa has been awarded the U.S. government’s DIN-PACS IV (Digital Imaging Network/Picture Archiving and Communication System) contract. The contract term includes one five-year base period and one five-year option period. The potential maximum value for Agfa’s contract is up to US $768 million over the ten years. The DIN-PACS IV contract allows U.S. government healthcare providers to purchase diagnostic imaging IT and related technology solutions on-demand, providing flexibility, cost savings, and quality enhancement in service to its healthcare consumers. Under the previous three DIN-PACS contracts, Agfa HealthCare has delivered more than $600 million in products and services. The new DIN-PACS IV contract includes departmental (e.g., radiology, cardiology, etc.) and enterprise imaging informatics solutions (e.g. VNA, image sharing, etc), integration services, and support programs to be used by U.S. Federal agencies.

Over its 18-year relationship, Agfa HealthCare has developed a strong DIN-PACS presence across a wide range of U.S. government facilities, advancing the quality of healthcare delivery with solutions installed at more than 200 Department of Defence (DoD) and Veterans Affairs. A medical treatment facilities, including 14 DoD/NATO sites in Europe, four of the VA’s multi-facility Veterans Integrated Service Networks, and more than 30 Navy ships. Agfa has the longest-standing DIN-PACS license agreement relationship with the Federal government.

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Recent study suggests UK guidelines on breast MRI recall rates too low

Breast MRI is a useful tool for screening women at high risk of developing breast cancer and has been shown to have a higher sensitivity for detection of invasive breast cancer when compared with traditional mammography alone. Although breast MRI is associated with high sensitivity, the specificity is less than that of mammography. This can lead to the detection of indeterminate lesions, requiring recall for further imaging. In the majority of cases, the area of concern represents a benign finding. With increasing use of breast MRI in surveillance programmes, the potential high rate of false positives when compared to mammography is a cause for concern. High recall rates generate additional costs and also serve to increase patient anxiety.

In a recent study carried out by researchers in Dublin, Ireland (Healy NA, O’Keeffe SA. Determination of recall rates for assessment in high-risk women undergoing annual surveillance breast MRI. Clin Radiol. 2016 Nov;71(11):1143-7) a review was made of all surveillance breast MRI examinations carried out over a 6-year period at the Irish national centre to determine the recall rate, the biopsy rate and cancer-detection rates. The team compared their results with the guidelines of the UK National Health Service Breast Screening Programme (BSP) which set a maximum recall rate following breast MRI in high-risk women to be 10% with an expected recall rate < 7%. The Irish results showed a 5-year recall rate of 10.9% so slightly higher than the recommended maximum rate. The recall rate of 8.5% in the incident rounds of screening, although lower, was still not less than the target recall rate of 7% recommended by the NHS BSP.

These recent Irish results are similar to those from other international studies. In fact no studies to date have achieved the target of <7%. Aiming for this target could risk lowering the cancer-detection rate, similar to findings for screening mammography. The Irish team suggest that a maximum recall and a target of <15% for the prevalent round and a maximum recall of 12% and target of <10% for incident rounds, respectively, may be more appropriate. Further studies from larger screening populations would be of benefit to validate these suggestions. http://tinyurl.com/Healy-O-Keeffe-paper

Study of breast lesions not seen on mammography but detected by ultrasound

Dense breast most likely reason for mammographically occult lesions

In the majority of cases, invasive breast cancer presents as an uncalcified mass that appears dense on mammography. Detection is therefore compromised in women with a high mammographic density. It has been reported that the sensitivity can be as low as 57–63% in women with dense breasts with mammographic density being defined as >30% of the breast area. Interval cancers have also been reported to be more common in women with dense breasts.

A recently published article described a study carried out by a group of researchers from Germany and the USA, to estimate the probability of a tumor being visible on ultrasound but not on mammography in hospital-based diagnostic mammography units, and investigated several factors, including density as predictors of the desirability to carry out additional ultrasound (Häberle L et al. Mammographic density is the main correlate of tumors detected on ultrasound but not on mammography. Int J Cancer. 2016 Nov 1;139(9):1967-74.).

Although mammography screening programs do not include ultrasound examinations, some diagnostic units do provide women with both mammography and ultrasonography, thus providing a unique opportunity to investigate the likelihood that a patient’s invasive breast cancer might be detectable on ultrasound, but not on mammography. The group looked at several factors that might be useful as predictors of lesions able to be picked up on ultrasound but missed on mammography. Mammographic density was found to be the main predictor of masking, but age, BMI and previous breast surgery also had additional value in the prediction model. For example, mammographic density and the risk of masking were positively associated, implying that breast cancer patients with a masked tumor had on average a denser breast than patients with a visible tumor.

Currently there are no clear recommendations as to which women should be selected for additional ultrasonography on the
Grant given for development of photoacoustic imaging in breast cancer diagnosis

A large European research consortium headed by the University of Twente in The Netherlands is to receive grants of more than five million euros from the EU, to develop a new imaging device for the diagnosis of breast cancer. A prototype of the device will be ready for large scale testing and production in four years. Not only will it provide improved photoacoustic and ultrasound imaging, it will also be able to combine the images generated by both techniques. The expectation is that the new imager will improve and accelerate the diagnosis of breast cancer, and also be applicable for younger women.

Current techniques for detecting breast cancer – x-ray mammography, ultrasound and magnetic resonance imaging (MRI) – have shortcomings, such as occasionally failing to detect tumors as well as sometimes requiring unnecessary and stressful biopsies to be carried out. The large European research consortium, aims therefore to develop a completely new device for the diagnosis of breast cancer. The proposed device is expected to shorten the time to accurate diagnosis substantially. The device does not use radiation or contrast media which are potentially harmful, and does not cause any pain to the woman being examined. Project leader Srirang Manohar calls the proposed device, which has been dubbed ‘PAMMOTH’, a ‘dream imager’. “We will be working on this prototype with the best partners in Europe and actively involving doctors and patient associations for their inputs and advice in the design and testing processes.”

PAMMOTH will combine existing photoacoustic and ultrasound imaging techniques, and elevate both to a higher level at the same time. Manohar said: “The images from the two systems will be combined. This will result in simultaneous three-dimensional information about disease specific optical contrast, as well as about the ultrasound properties which provide anatomic information within the breast. Further we wish to do this combined imaging in real time.” Although photoacoustics is a relatively new imaging technique in the medical world, the University of Twente has, for some time now, been conducting research in its application to breast imaging, which is called photoacoustic mammography or PAMmography. In PAMmography, the breast is illuminated with laser light, which is converted into ultrasound in regions where higher concentrations of blood are present, such as the areas around malignant tumours. Various colours of laser light will be used to improve visualisation of the tumor and to yield information about the oxygen saturation of the blood in tumours, which can indicate whether they are malignant or benign.

The researchers are also hoping to take significant steps in the field of ultrasound. They will develop technology which will yield a three-dimensional image, with the ultrasound waves being generated in an unconventional manner. Contrary to regular ultrasound imaging, handheld scanners will not be used in this project so as to avoid images from being affected by the operator of the device.

In long-term follow-up, study looks at prognostic factors for breast cancer after breast-conserving therapy

A new study published online in JAMA Oncology describes long-term analysis of prognostic factors among some patients with breast cancer who were treated with breast-conserving therapy in the EORTC “boost no boost” trial, which evaluated the influence of a “boost” dose in radiotherapy. (Vrieling C, et al. Prognostic Factors For Local Control in Breast Cancer After Long-term Follow-up in the EORTC Boost vs No Boost Trial: A Randomized Clinical Trial. JAMA Oncol. 2016 Sept ) With a median follow-up of 18 years among 1,616 patients, Dr Conny Vrieling, of the Clinique des Grangettes, Geneva, Switzerland, and coauthors report that young age and the presence of ductal carcinoma in situ (DCIS) adjacent to the invasive tumor were associated with increased risk of ipsilateral breast tumor recurrence (IBTR) at long-term
follow-up. Also, high-grade invasive tumors relapsed more frequently only during the first five years, according to the findings. The 20-year cumulative incidence of IBTR was 15 percent with 160 cases found. “Patients with high-grade invasive tumors should be monitored closely, especially in the first five years. The impact of DCIS remained constant over time, indicating that long-term follow-up is necessary. The boost significantly reduced IBTR in these patients,”
http://tinyurl.com/Vrileing-et-al-paper

Breast MRI — prone or supine?

New research from Brigham and Women’s Hospital (BWH) finds changes in patient positioning for MRI from imaging to surgery can result in deformation and displacement of the tumor during surgery.

MRI has been used as an effective tool for cancer evaluation and is highly sensitive in detecting breast tumors, but there is no evidence that pre-operative MRI translates into improved outcomes following breast conserving surgery. Traditionally, patients who are scheduled to undergo breast-conserving lumpectomy for breast cancer undergo a breast MRI prior to surgery to help inform the surgeon about the size, shape, and location of the tumor. These MRIs are performed with the patient lying prone while the surgery is performed with the patient lying supine. A new phase I clinical trial from Brigham and Women’s Hospital evaluated the differences between pre-operative prone and supine MRI exams in 12 women undergoing lumpectomy for breast cancer. (Gombos E et al Intraoperative Supine Breast MR Imaging to Quantify Tumor Deformation and Detection of Residual Breast Cancer: Preliminary Results. Radiology. 2016 Jun 22;2151472). The researchers demonstrated that considerable deformity of the breast and tumor position occurs when patients are imaged in the prone position.

“Accounting for change in size and shape caused by displacement and deformation of the tumor between standard imaging in the prone position and operative supine position, our analysis highlights that supine MRI before surgery may provide surgeons with more detailed and accurate information and could lead to effective tumor removal,” stated Dr Eva C. Gombos, radiologist at BWH and lead author of the study. “Supine MRI, when performed in addition to standard prone breast MRI, may help detect a remnant tumor and ensure clear margins to prevent re-operation. Among women undergoing breast conserving surgery, 15–40 percent need to have a second operation to remove remnant tumor,” said senior author Dr Mehra Golshan, distinguished chair in surgical oncology at BWH. Between April 2012 and December 2014, a total of 15 women were enrolled in the trial in the Advanced Modality Image Guided Operating Suite (AMIGO) at BWH, an operating room and interventional suite facility with a full array of imaging modalities for use during surgical procedures. All images and information relevant to the procedure are accessible in the operating suite, allowing radiologists and surgeons to continuously view relevant imaging data.

Patients in the study underwent standard diagnostic MR imaging in the usual prone position as an outpatient preceding surgery. Twelve patients underwent lumpectomy and post-surgical supine MRI during the operation. Half had pre-procedure supine imaging. Researchers measured differences found in size, position, and shape of tumor between prone and supine imaging. Researchers found that specifications of the tumor, including size and location in the breast, were substantially different depending on the position of the women when she had her MRI. All patients underwent successful removal of their tumor with clear margins for invasive breast cancer.

“If validated in future large studies, intra-operative, and, more importantly, pre-operative supine MRI could be expected to help the surgeon in accurately planning removal of the tumor and reducing the need for re-operation which negatively impacts the patient emotionally, delays post-operative therapy and increases infection rates and cost,” stated Gombos.

http://tinyurl.com/Gombos-et-al-paper

MRI parenchymal enhancement in breast tissue is not an indicator for increased cancer risk

Women with certain gene mutations are among the high-risk patients for breast cancer. With MRI it is possible to detect tissue with measurable active blood supply which indicates an increased breast cancer risk. The molecular biologist and radiologist, Barbara Bennani-Baiti and the radiologist Pascal Baltzer of the Clinic for Radiology and Nuclear Medicine of MedUni Vienna, Austria are now exploring whether tissue with measurable active blood supply which indicates a clearly increased cancer risk according to current findings and should be considered in the decision-making process for any preventive measures.

http://tinyurl.com/Bennani-Baiti-et-al-paper
Mammography may miss 1/3 of cancer in dense breasts

Four out of ten women have dense breast tissue. Dense breasts make a woman up to 4-6 times more likely to develop breast cancer. And they make it very difficult to detect cancer with standard mammography.

The Invenia™ ABUS (Automated Breast Ultrasound System) from GE Healthcare improves invasive cancer detection by a 57% relative increase over mammography in women with dense breasts. It looks at dense breasts differently to find cancer that mammography may not see. The result: enhanced confidence for you and your patients.

Contact your GE Sales Representative and visit us at gehealthcare.com/inveniaabus to learn how the GE Invenia ABUS can help you give your patients with dense breasts personalized care and the peace of mind they need.


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Quantitative Breast Density Measurement Using Low Dose Chest CT

In this article, we briefly review the background to the increasing interest in the measurement of breast density and point out limitations of the current methods of quantitative measurement of breast density using two dimensional mammography. We describe the emergence of various three dimensional imaging methods for the quantification of breast density and present the results of the use of low dose chest computed tomography (LDCT) to measure breast density. LDCT is increasingly being used, e.g. in lung cancer screening, so the use of an already existing imaging data set may represent an efficient opportunity to provide quantitative 3D breast density determinations.

THE NEED FOR QUANTITATIVE MEASUREMENT OF BREAST DENSITY

The United States is so far the only country in the world to have passed laws mandating that women be informed if they are found to have dense breasts and that they be made aware of the limitations this might impose on mammography examinations. Such limitations include the possibility that suspicious lesions could be masked in mammographic examination of dense breasts. Ever since the first US state - Connecticut - implemented breast density legislation in 2009, such legislation has steadily become more widespread in the USA. In October 2011, the Breast Density and Mammography Reporting Act was passed in the U.S. Congress, requiring that every mammography report should provide information regarding the patient’s breast density. As of May 2006, 27 states in the USA had passed breast density notification legislation and several more states have bills in progress. Other regions throughout the world including the European Union, Canada and Japan have also shown interest in such legislation although as yet no laws have been passed. While all this indicates the growing interest in the issue of breast density, it should be noted that the legislation can have unintended consequences, one of which can be confusion and anxiety on the part of the women if the notification process itself is unclear and if recommended future action is not clearly explained.

One other major problem is how to consistently and accurately measure breast density in the first place. Current studies of breast density have mostly used methods based on 2D mammographic density (MD) determination and have significantly advanced our understanding of the association between breast density and cancer risk. Nevertheless, there are fundamental concerns regarding the assessment of breast density using this approach. The assessment of MD based on a qualitative method, such as BIRADS categorization, is observer-dependent and reliability is thus a major concern, with high inter- or intra- reader inconsistency. Even with quantitative methods, the fundamental issue remains that 2D mammography relies on projection images that can be affected by the tissue-overlapping problem and so might not be able to differentiate accurately and with high sensitivity between fatty and fibroglandular tissues. The positioning of the subject and the degree of breast compression during the image acquisition process may result in different projection views and thus different measured densities. The 2D MD quantification technique is also subjective, requiring as it does the operator to interactively select overall threshold values for the whole breast and the fibroglandular tissue area. This can result in large intra- and inter-operator measurement variability. Calibration of the mammography unit itself is of course extremely important to control the X-ray exposure in quantitative analysis. Even a small variation in calibration may render unreliable the evaluation of small changes in the image. Indeed, the accuracy of breast density as determined by mammography has been seriously questioned in one paper [1] which pointed out that several studies suggesting a link between MD and the risk of breast cancer may have methodological flaws, and concluded that studies showing only small percentage differences between groups are likely to be inaccurate.

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Recently two automated breast density assessment tools have been approved by FDA and are increasingly being used in mammography. One is the Quantra system from Hologic (www.hologic.com); the other is from Volpara (www.volparadenisty.com). Both quantitative tools give an objective estimate of the total volume of fibroglandular tissue as well as the total volume of the breast tissue, expressed in cubic centimeters, and avoid the subjectivity associated with the judgment of human operators. However, despite the advances brought about by the development of these new analytical tools, they still suffer from the intrinsic problem of overlapping tissue, since the analysis is still based on 2-dimensional projection acquisition. Ideally measurement of breast density probably would require a standardized true isotropic three-dimensional (3D) capture of the whole breast.

**Quantitative Density Measurement Using 3D Modalities**

Because of the problems of mammography-based measurement, other emerging new technologies are being developed for assessing breast density, including other X-ray-based modalities, MR imaging, optical imaging modalities, and ultrasound-based imaging. Over the last ten years, our research group has focussed intensive effort in the development of 3D imaging tools, for the quantitative assessment of breast density including MRI [2, 3], 3D ultrasound [4], and low dose chest CT [5].

Of these 3D imaging modalities, MRI has been the most studied, but its clinical role in density assessment has been limited by its high cost and the consequent limited number of women who have been examined using this modality.

Still in the early stages of development, the use of 3D US for the quantitative measurement of breast density faces challenges such as separating the chest wall from the breast area, and fatty tissue from the fibroglandular tissue [4].

In contrast, CT is a widely used diagnostic modality in the clinical setting and chest CT is routinely employed for many pathologies in the thoracic, pulmonary, and cardiovascular fields.

The large number of clinical chest CT examinations that are carried out presents an opportunity to evaluate the potential of this modality for assessing breast density in female subjects. In recent years, several CT modalities have been studied, including clinical chest CT [6], low dose chest CT (LDCT) [5], cone beam CT, and dedicated breast CT [7]. LDCT is increasingly being used for lung cancer screening. The overall average effective radiation dose of LDCT is much lower than that of a typical standard-dose chest CT examination (2 mSv vs. 7 mSv) [8]. In Western countries, LDCT is increasingly being used to screen patients at high risk of lung cancer such as heavy smokers. The use of LDCT in such applications has resulted in a 20 percent reduction in deaths from lung cancer among current or former heavy smokers as compared with those screened by chest X-ray [9]. In addition, in several Asian countries, for example Korea and Taiwan, many non-high-risk subjects are examined by LDCT because of a general perceived risk of radiation-associated cancer with standard CT. Against the general background of concern regarding radiation in CT, LDCT is considered a safe screening tool. Its clinical use is thus anticipated to increase, not only for lung cancer screening but also for the diagnosis of other pulmonary diseases. As many of the patients undergoing such chest LDCT are female, the modality has the potential to provide additional information about breast density of use in the personalized management of breast cancer screening.

**Figure 1.** Quantitative measurement of breast density using low dose chest CT (LDCT). (a), original LDCT image; (b), segmentation of breast area; and (c) segmentation of fibroglandular tissue. The acquired breast volume, fibroglandular tissue volume, and percent breast density are 750.9 mL, 53.8mL, and 7.2% respectively for the right breast; and 810.9 mL, 63.9 mL, and 7.9% respectively for the left breast.
Because of the relatively noisy nature of LDCT images, accurate segmentation of fibroglandular tissue and thus quantification of breast density using the modality is challenging. To have consistent results, robust segmentation algorithms are required. The method we have adopted for breast segmentation on LDCT [5] is derived from an automatic 3D MR-based method using sophisticated computer-assisted algorithms which we have developed for breast density segmentation [10]. In the overall segmentation procedure, two aspects have to be addressed. First, the segmentation of the breast volume and secondly, the segmentation of the fibroglandular tissue [Figure 1].

For breast segmentation, since breast fatty tissue is continuous with the body fat, and there is no "real" boundary of the breast, the anatomic landmark used for the segmentation of the breast may affect the calculation of the percentage breast density. The anatomic landmark to segment the breast can be determined in different ways but must retain all the fibroglandular tissue within the breast. In practice, for simplicity and consistency, we usually trace a horizontal line on an image acquired at the aortic arch level. The line is immediately posterior and parallel to the sternum or is a line connecting the lateral margin of the bilateral pectoralis muscle. Since LDCT images are acquired with the subject in the supine position, the breast may shift laterally due to gravity and the shape of the thoracic cage. Accordingly, the fibroglandular tissue is also shifted to the lateral-posterior side of the chest. Depending on the extent of such shifting of the breast, the horizontal line we trace may have to be moved to a more posterior position to ensure that all the fibroglandular tissue in the acquired CT images is included. When the anatomic landmark is determined in this way, the breast area in all the images can then be segmented.

For fibroglandular tissue segmentation, we use fuzzy C-means (FCM) algorithms to separate adipose and fibroglandular tissue. FCM is currently implemented in several freely downloadable software for image processing, such as Medical Image Processing, Analysis, and Visualization (MIPAV). Several references in the literature describe the use of thresholding and clustering-based algorithms such as FCM, or K-means clustering, for quantitative fibroglandular tissue segmentation.

For mammographic density studies, interactive thresholding methods are used more often than FCM. Klifa et al. compared breast density results based on MR imaging using manual, thresholding, and FCM methods to segment the fibroglandular tissue in the breast [11]. They noted that inter-operator variability using FCM was around 7%, while that using the thresholding method was >15% and that using manual segmentation was >18%. Intra-operator variability showed the same trend, thus suggesting that the FCM clustering-based algorithm is the optimal method to minimize operator-related variability. In our recent published study of LDCT using FCM [5], the intra- and inter-operator reproducibility for the measurement of breast volume, fibroglandular tissue volume, and percent density all yield highly consistent results, with all intraclass correlation coefficients > 0.95. (In the absence of an absolute method for validation, the statistical parameters used to evaluate the approach measure reproducibility rather than accuracy). One problem with FCM is that the choice of FCM clusters does affect the segmentation results, which can subsequently affect the density measurement. For this reason we fix the cluster numbers to minimize the bias effect. The cluster numbers were adjusted in only a few cases when the segmentation results were unsatisfactory as judged by a radiologist’s inspection.

Breast density acquired in LDCT was in general lower than that of mammographic density both qualitatively and quantitatively [12]. This is to be expected since CT is based on 3D analysis and not on 2D projection views. Breast density acquired via LDCT was well correlated with that of MRI (r>0.95) [5]. However, due to the positional difference of the two imaging modalities, breast volume and fibroglandular tissue volume acquired with LDCT were in general higher than those of MRI, but percentage density results were very similar.

CONCLUSIONS

The clinical use of LDCT has been steadily increasing, especially after the announcement last year by the US. Centers for Medicare and Medicaid Services (CMS) that LDCT can be reimbursed, particularly in current clinical applications in lung cancer. It seems common sense to take advantage of chest LDCT in female subjects to measure breast density through use of the same imaging data set.

We have proven the technical feasibility of the use of LDCT images in the measurement of breast density and have shown consistent intra- and inter-operator results. The full realization of the future clinical potential of chest LDCT to provide density information which can then be used to improve the quality of screening for breast cancer will however depend on several issues. These include the familiarity of clinical personnel with the segmentation algorithms, how consistent the density results measured by this approach are as compared to the currently established mammographic density and generally how popular this new application of an established modality turns out to be in clinical routine.

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Experience exceptional 2D and 3D biopsy imaging.
Fast and easy access to challenging lesion locations.
Significantly improved breast biopsy workflow.

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GE Healthcare’s 3D ABUS detects 57% more invasive breast cancers

Adding 3D automated breast ultrasound to mammography screening in women with heterogeneously and extremely dense breasts: report from a hospital-based, high-volume, single-center breast cancer screening program.

New findings [1] show a 57% relative increase in the detection rate of invasive breast cancer in women with dense breasts, with an acceptable low recall rate, when the 3D Automated Breast Ultrasound (ABUS) system from GE Healthcare is used as an adjunct to full field digital screening mammography (FFDSM).

The findings come from a study led by Dr Brigitte Wilczek at Unilabs Capio St Göran’s Hospital in Stockholm. The aim of the study was to evaluate the impact of 3D ABUS and FFDSM in breast cancer detection in asymptomatic women with dense breasts. The recall rate of the 3D ABUS in conjunction with FFDSM was found to be only +0.9% in comparison to FFDSM alone. This is an acceptable low recall rate that is well within the recommendations of the European guidelines for quality assurance in breast cancer screening. The first generation of ABUS equipment used in the study, was designed to make it easier for doctors to detect breast cancers in women with dense breast tissue when used as a complement to mammography and with no additional radiation dose to the patient.

“The study shows that it is feasible to implement 3D ABUS into a high volume mammography screening center and increase the cancer detection rate, in women aged 40-74 years, while maintaining a low recall rate well within the range of the recommendation of the European guidelines.

If ABUS were a part of our national screening programs in dense breasts, more cancers could be detected at an earlier stage, which makes a difference to overall survival. Many countries are working to try to optimize screening so that each woman can get examinations according to her assessed risks,” said Dr Wilczek.

Breast cancer is by far the most common type of cancer amongst women in Europe [2], and for women with dense breast tissue it is particularly difficult to detect. Generally speaking dense breasts are more common in younger women as many women will have fatty replacement of dense glandular tissue as they age. However, on average 74% of women in their 40s, 57% of women in their 50s, 44% of women in their 60s, and 36% of women in their 70s have dense breast tissue.

Breast tissue consists of fatty and fibroglandular tissue and if a woman has more than 50% of fibroglandular tissue within the breasts then they are classified as dense. Having dense breasts increases the likelihood of developing cancer by four to six times [3] and makes the cancer more difficult to detect in mammography. This is because the breast tissue, as well as any potential lumps, appear white in the mammogram which makes the search for lumps like a search for a snowball in a snowstorm.

This represents a significant problem since 40% of women have dense breast tissue [4] and mammography may miss over 1/3 of cancers in dense breast. Smaller tumors are harder to detect in dense breasts when only using mammography and the stage of the tumor at diagnosis still appears to significantly affect the overall survival in women with breast cancer. Mammography is still the gold standard for conducting breast exams but women with dense breast tissue may need supplemental imaging in addition to mammography.

STUDY DESIGN

The 1,668 women who took part in the study all had to be asymptomatic, 40 years or older and have either heterogeneously dense parenchyma or extremely dense breast on assessment. Anteroposterior AP and Lateral volumes. Coronal and transversal plane show invasive ductal carcinoma.
by the radiographer at the screening. For the full breast examination in the study, FFDSM was first performed using standard cranio-caudal (CC) and mediolateral oblique (MLO) views followed by anteroposterior (AP), lateral (LAT) and medial (MED) acquisitions of 3D ABUS in both breasts. The 3D ABUS screening took 15 minutes to complete per patient. Women were excluded if they were pregnant or breastfeeding, had undergone breast surgery or had a history of cancer diagnosis or breast cancer treatment 12 months prior to the initial assessment.

The FFDSM equipment used in the study was in all cases either a FFDM Microdose Senographe (Philips Solna, Sweden) or a Senographe DS FFDM (GE Healthcare, Milwaukee WI, USA). The 3D ABUS equipment was provided by U-Systems Inc. Sunnyvale, CA USA (now GE Healthcare), and was equipped with a linear broadband transducer 6-14 MHz. The 3D ABUS examination was carried out with the patient in a supine position and the fibroglandular tissue being flattened by applying gentle compression to the chest wall. The radiographers, who had received specific training in the operation of the system, always performed at least three views of each breast: LAT, AP and MED. The first reader of the results interpreted the FFDSM with a reading time of 1-2 minutes followed by 5-7 minutes reading time for the 3D ABUS. The second reader then interpreted the FFDSM blinded to the first reader’s assessment. If the readers expressed any concerns on the interpretation of the results, the findings were discussed to reach a consensus.

RESULTS
The study concluded that the addition of ABUS to FFDSM helps detect more cancers in women aged 40-74 years with dense breasts as mammography on its own may not be enough.

The recently launched new generation of Automated Breast Ultrasound, Invenia ABUS, shifts traditional Ultrasound from hardware- to software-based processing which results in excellent image quality, reproducibility and easy operation. The ABUS also includes intelligent imaging algorithms to help produce better image quality for easier identification of lumps, such as the tissue equalisation algorithm, nipple shadow compensation, breast border detection and chest wall detection.

Invenia ABUS’s Reverse Curve Transducer is designed to shape a woman’s anatomy and enhances patient comfort during the exam as well as breast coverage. The 15 cm wide field-of-view, high-frequency transducer automatically creates uniform compression across the entire breast for enhanced anatomical detail and consistent image quality independent of the operator.

The ABUS workstation displays 3D volumes and tools for efficient interpretation and analysis.

“We are seeing a significant shift in breast cancer screening – with breast tissue density becoming an important consideration in decision making for the physician and the patient. In simple terms, different tests for different breasts. The addition of ABUS provides clinicians with a new, powerful tool to customise their screening protocols and detect breast cancer earlier and more accurately,” said Sankar Suryanarayanan, General Manager of ABUS at GE Healthcare.

The economic benefits associated with the use of ABUS are also found to be substantial as cancers can be found at earlier stages which makes it easier to treat. This is especially the case when considering long-term 24-month therapy costs.

Mammography machines that follow GE’s Senographe, introduced in 1966, remain the standard for breast cancer screening today. “GE Healthcare is committed to the fight against breast cancer and will continue making available clinically robust and accessible ABUS technology as healthcare providers seek to improve breast cancer detection and care, especially for women with dense breasts,” said Mr Suryanarayanan.

REFERENCES
‘Deep Learning’ Technology applied to Diagnostic Ultrasound Imaging

To meet the growing need for faster and more efficient diagnostic imaging solutions, Samsung is for the first time applying ‘Deep Learning’ technology to ultrasound imaging in breast lesion analysis. The company’s premium ultrasound RS80A system now includes ‘S-Detect for Breast,’ which employs specially developed Deep Learning algorithms.

The S-Detect for Breast module utilizes large data sets collected from numerous breast exam cases and provides the characteristics of displayed lesion as well as a suggestion as to whether a selected lesion is benign or malignant. By adopting a deep learning algorithm in the processes of lesion segmentation, analysis of characteristics and assessment, users are now provided with more accurate results with all this information being made available in a single report.

The S-Detect system has been built upon nearly 10,000 pages of data, which represent the accumulated experience and experience of the Samsung Medical center over the last 20 years.

“Samsung is moving forward in the healthcare market by not only utilizing its IT and display technology but also bringing new software solutions to ultrasound diagnosis like S-Detect,” said Dongsoo Jun, President of Health & Medical Equipment Business at Samsung Electronics and CEO of Samsung Medison.

“With our leading software technology, we will continue to develop advanced imaging functions for users to experience faster and more confident diagnosis.”

“We saw a high level of conformity in the analysis and detection lesion in various cases by using the S-Detect,” said Professor Boo-Kyung Han, a radiologist at Samsung Medical Center. “Users can reduce the number of unnecessary biopsies and residents and less experienced radiologists will have more reliable support in accurately detecting malignant and suspicious lesions.”

The RS80A system is of course not intended only for breast ultrasound through its S-Detect for Breast module. Other key upgrades of the latest version (RS80A with Prestige) include:

Enhanced Workflow and Imaging for Radiologists
- S-Fusion — Now provides ‘Respiration Auto’ function that minimizes registration gap between real-time ultrasound and recorded CT/MRI images, which is caused by the difference in images when the patient inhales and exhales.
- CEUS+ — Applies Samsung’s ‘VesselMax’ and ‘FlowMax’ to generate clear visualization of vessels and blood flow when viewing ultrasound images with contrast agents.
- S-3D Arterial Analysis — Enables 3D imaging of vessels and provides volume measurement of artery plaque in a simplified way. Users can also track the morphological changes of the artery.

Advanced Display Technology
- S-Harmonic — Generates greater image conformity from near to far field while reducing signal noise based on wider bandwidths and higher frequency.
- HQ Vision — Visualizes anatomical structures with improved clarity. It helps make a reliable diagnosis especially for MSK (Musculoskeletal) imaging such as tendon and muscles.

The system uses BI-RADS scores for standardized analysis and classification of suspicious breast lesions. For thyroid cases the RS80A system provides diagnoses based on K-TIRADS (Korean-Thyroid Imaging Reporting and Data System), the TIRADS scoring system from Dr Gilles Russ) and the American Thyroid Association (ATA) guidelines.

Since its launch in 2014, the RS80A has been providing users with easy, fast, and accurate diagnosis around the world including in various prestigious medical institutions such as the Mayo Clinic (U.S.) and the Charité University Hospital (Germany). The latest RS80A model is now available in European and Middle Eastern markets and will launch in the Americas, China, and Russia shortly.
The clinical performance of the S-Detect system

We discussed the data currently available on the clinical performance of the S-Detect with Prof Boo-Kyung Han who is a radiologist at the Samsung Medical Center.

The S-Detect was developed using a database accumulated over 20 years in the Samsung Medical Center. Presumably this involved principally Korean or other Asian women. What about differences in breast characteristics between Asian and say Caucasian women, for example breast density? Does this affect the performance system?

It's true that certain breast characteristics may differ between Asian and Caucasian women and indeed the proportion of women in Asia who have dense breasts is much greater than that say with women in the United States. However we consider that in already detected abnormal lesions, the echogenicity of the background parenchyma would have little or no effect on the morphologic characteristics of the lesions. Nevertheless we do plan to add cases from a global database to the S-Detect in near future to enhance accuracy.

What is the performance of the S-Detect system in validation trials, e.g. compared to experienced breast radiologists and/or histologically confirmed lesions? Regarding the feature of the system which allows the sensitivity or selectivity settings to be adjusted, in practice what is most often selected? High sensitivity mode / High accuracy mode / High specificity mode?

We are currently carrying out a retrospective comparative study in which experienced breast radiologists use S-Detect in histologically confirmed lesions. Sensitivity and specificity were found to be much better in the S-Detect system as compared to radiologists’ standard performance without the systems, especially when used in High-Sensitivity mode and High-Accuracy mode.

It is good to have the option to be able to change the sensitivity specificity parameters but personally, I prefer high accuracy mode, because I think it is much more important to reduce the number of unnecessary biopsies for screening purposes — the use of High-Sensitivity mode could result in an increased number of unnecessary biopsies. In addition, just because US-guided biopsies are in practice easier to carry out than mammography-guided biopsies, we should nevertheless be careful not to overuse US-guided biopsy. A decision to take a biopsy due to an increased suspicion from S-Detect findings should only be taken if the suspicion of the lesion is very high, as based on the clinical condition or mammographic findings.

Hand-held breast ultrasound is notoriously operator-dependent. Of course, intuitively standardization would be a great advantage in this respect. How do you actually quantify this advantage? That is exactly the challenge we are aiming to overcome. Thus, in order to alleviate the relatively higher user-dependency of ultrasound imaging in general, the S-Detect was developed to produce the best-quality static images obtained by highly-qualified radiologists. Of course we cannot guarantee the same-level performance in every real clinical environment; the results of the multi-institutional validation study may provide information on user-dependency and help substantiate ultrasound diagnosis.

The new system can suggest interpretation of a suspicious lesion, a feature which looks to be of great advantage to less experienced users. What about the reaction of experienced users? Do they resent the idea that the system suggests interpretation of the image? Do they feel threatened?

We radiologists are accustomed to making decisions using real-time scanning and we evaluate a sonographic finding by integrating mammography and US information, as well as taking into account the clinical situation. That's one of the possible reasons why the radiologists performed less well than S-Detect in the retrospective study which was evaluated using static images. Also, S-Detect can play the role of providing a second opinion, which doctors mostly appreciate in that overall it makes decision-making more accurate.

One measure of the performance of the S-Detect system could be the reduction in the number of unnecessary biopsies. Do you have data on this?

The data describing the performance of the S-Detect is currently being collated and we expect publication later on this year. Information on biopsies will be included so I don't want to anticipate the results, but for example if BI-RADS 4A masses were shown to be reliably assessed by S-Detect as being benign, then there could be a significant effect on a decreased number of unnecessary biopsies.

In short, what would be the overall possible clinical benefits of S-Detect? There are many, but one example would be the use of S-Detect to help in deciding between short term follow-up or biopsy in equivocal lesions, such as in BI-RADS 4A masses.
What exactly is “Deep Learning”?

We wanted to find out more about Deep Learning so we spoke with Dr Yeong Kyeong Seong and Dr Moon Ho Park, who are principal engineers at Samsung and responsible for the development of the RS80A and the implementation of deep learning in the system.

Q Let’s start at the beginning. Can you give a simple description of deep learning?

Well Deep Learning is the latest rapidly developing subject in the overall field of artificial intelligence (AI). As Prof Y Bengio, from the University of Montreal, Canada, one of the world leaders in deep learning — and a consultant to Samsung in the early stages of the development of the RS80A — put it in a recent paper (Machines who learn, Scientific American Jun 2016 p41 -48), AI started as a field of serious study as far back as in the 1950s but its potential was never realized as the algorithms and computing power of the period were simply not up to the task. However in the past few years a revival of interest in AI has taken place as software patterned roughly after networks of neurons in the brain showed that the potential of AI might be realized. Deep Learning — a technique that uses complex neural networks is already reaching amazing performance levels.

With Samsung’s capabilities in computing science and display technologies, we believed we could adopt Deep Learning principles to enable fast and accurate decision-making. Samsung has an on-going commitment to innovation and this is a core element in the development of our medical equipment with the objective of making diagnoses ever more reliable and ultimately improving patient outcomes. As far as ultrasound–based medical diagnosis is concerned we concluded after evaluation of all options, that the use of Deep Learning technology was the optimal choice for better reproducibility and accuracy.

Recently there has been a lot of publicity about several applications of machine learning. For example a computer recently won a game of “Go” against expert humans. It should be noted that although the basic principles used in such applications are the same as those we use in the S-Detect for Breast module of the RS80A, the network structures and applied algorithms are quite different.

Q In what way are your algorithms different? Were specific modifications needed to apply the principle to the recognition of lesions in ultrasound breast images?

We use customized convolutional neural networks in S-Detect for Breast. When segmenting lesions automatically from a seed point specified by a user, input images are transformed in the software to enable better recognition of various–sized lesions. This transformation involves several steps such as shifting, resizing and warping of the input images, and these transformations are included into our deep neural network as customized layers. Moreover, in order to optimize our convolutional network, some additional layers were added and modified to provide even better performance in terms of accuracy and processing time.

Q In convolutional neural networks, is it true that the software itself “learns” to improve recognition of an image without human input?

Convolutional neural networks can learn to classify an image by itself from a large amount of training data — and this is the great advantage of convolutional neural networks compared with conventional learning methods. Convolutional neural networks consist of many convolutional layers so that in each convolution layer, meaningful features can be extracted automatically from input data. These features are then integrated by going through the deep layers. A learnable classifier is added at the end of the convolutional neural network. So, instead of using hand–crafted features designed by developers, convolutional neural networks can extract optimal features from the data and make the classifier from the features at the same time during the learning process. This is precisely the reason why we adopted the convolutional neural network approach for the recognition of breast lesions.

We plan to continuously upgrade the S-Detect with more and more meaningful cases. While it is not possible for users to input such cases themselves, Samsung will regularly upgrade the software for continual machine learning. As more data accumulate, the S-Detect will yield even more accurate results.

Q How did you validate the software?

We used well-known cases whose medical diagnosis was established and whose benign/malignant status had been determined by biopsy. When evaluating the S-Detect’s practical performance, actual diagnoses of each lesion were made to make sure that the learning was processing correctly.

Q Presumably the process needs powerful computing calculation processors. Does this mean that there is a time delay while the processing is going on?

It’s true that in general, a lot of time can be needed to process deep neural networks. We knew that this drawback had to be overcome in clinical applications so a priority for us was to optimize the convolutional neural networks used in S-Detect by finding optimal input size and network structure, so streamlining the process. In this way there is absolutely no time delay for users and, what’s more to achieve the speed performance no compromises were made as regards accuracy.
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Pressure controlled compression of the breast in mammography

Current mammography procedures require compression of the breast by a compression paddle. Such procedures involve application of a certain force with generally no account being taken of the size of the breast. The process can result in various levels of pain and discomfort.

This article describes the rationale behind the development of a pressure-based compression system, i.e. one that takes into account the contact area of the breast with the paddle. Validation studies of the new system show that the use of standardized pressure-based compression not only provides high quality images at the same radiation dose but also significantly reduces the pain and discomfort reported by the women undergoing mammography examinations.

Recent results show that the performance of mammography, in terms of detectability of cancerous lesions can be affected by the compression pressure at which the examination is carried out.

Mammography is a widely used diagnostic modality in radiology and is the starting procedure in almost every work-up in breast imaging whether this is diagnostic, i.e. initiated by clinical signs or in asymptomatic subjects in screening programs. Screening mammography is widely considered as one of the major medical successes of the past decades, and the decline in breast cancer mortality that has been observed in many countries throughout the world has been attributed at least in part to screening programs. Each year, an estimated 125 million women throughout the world are imaged using mammography, a process which involves each woman routinely undergoing two compressions of each breast.

A certain level of compression of the breast is required in mammography for several reasons:
• Immobilization of the breast is needed to avoid movement and the consequent blurring of images.
• Flattening of the breast enables a more homogeneous exposure and a better dynamic range of luminance.
• Superimposing structures at different depths and those with different degrees of stiffness can be better depicted in a compressed breast.
• Last but not least, compression enables a quality image at a lower radiation dose.

However, despite the key role of compression, attempts to standardize the procedure have to date been limited to either the subjective judgement of the radiographer (“compress until skin is taut”) or the use of a set amount of force (“apply 130N of force”), which does not take into consideration whether the breast is small or large. Compression which is too great can lead to a painful experience with the woman being less likely to continue to participate in the screening program.

To date, efforts to help radiographers achieve the optimal compromise between the pain felt by the woman and image quality have not been successful [1].

In this article we describe the advantages of introducing a more objective, scientific approach to breast compression with the ultimate aim of maintaining high image quality, low radiation dose and at the same time ensuring the most comfortable experience for the woman.
determined by the viscoelasticity (2) and the volume (3) of the breast. These three factors determine a dynamic contact area (4) which increases as the compression increases, until it reaches a level which can be quantified by the mean contact area pressure (5), namely the force/contact area.

- The concept of force (expressed in the SI unit newton (N), as used in standard mammography is not suitable to describe or quantify the degree to which a body is affected by mechanical stress (which is what in fact causes the pain).
- Stress is a measure of the average amount of force exerted per unit area of a surface within a deformable body on which internal forces act. The SI-unit for stress is the pascal (Pa) which is also the unit of pressure (in medicine the unit of millimeter mercury (10 kPa = 75 mm Hg) is often still used).

Therefore, what standard mammographic procedures exert on the female breast is a force and what the female experiences is deformation of her breast. Since the breast has elastic properties, the contact area will vary in size during the increasing phase of the compression process. There are many factors influencing the viscoelastic behavior of the breast, but in the process of flattening the breast only the force can be controlled externally, since the other confounders, namely size and viscoelastic properties of the breast are individually determined. Since the breast can be flattened but only a little compressed, there is a limit to what can be achieved by increasing the force.

Some people have the misconception that the higher the force, the flatter the breast and thus the better the image.

A (more or less) standardized range of force between 12 and 18 daN (18 decanewtons = 180 N) as described in European and US guidelines will result in totally variable levels of the mean contact area pressure [Figure 1], depending on the individual properties of the breast. Ideally, to achieve a standardized and rational effect for an optimal mammographic image, individually determined amounts of force should be applied depending on the breast size and properties.

**OPTIMIZING THE “COMPRESSION” PROCESS**

In mammography, the acquisition of images of sufficient quality at the lowest radiation dose, requires compression of the breast. Since, as shown above, the amount of force applied is basically meaningless and in fact is the incorrect parameter to monitor, we defined the following research questions:

1. Can we develop a new method of compression that can be introduced in every currently commercially available mammographic unit and those of the future?
2. Can the frequent individual complaints from women regarding pain during and after mammography be correlated with and explained (at least in part) by large differences in applied pressure?
3. Is there an optimal pressure in mammography which not only allows optimal imaging and detection of lesions at a low radiation dose, but which is also comfortable for the woman.

**INVESTIGATION**

A multi-site study was carried out using data from a site in the USA and a larger sample from the Dutch breast screening program [2]. In the study, software from Volpara Analytics was used to record average force, pressure, breast thickness, breast volume, volumetric breast density and average glandular dose as a function of the size of the contact area between the breast and the compression paddle.
so that differences between sites and within individual sites could be quantitatively estimated. It was found that there was a large variation in the mean tissue force used during imaging [Figure 2]. These variations covered the range from the level of venous pressure up to several times systolic blood pressure and can be explained by the large individual differences in breast dimensions and elasticity. These in turn lead to differences in the size of the contact area between the breast and the paddle, which can vary by as much as a factor of 10 and consequently may result in differences in pressure of a factor of 10.

In an observational study we analyzed the standard compression procedure used in mammography [3]. We plotted the time course of the compression against the breast thickness, measuring the contact area and the force as a function of time [Figure 3]. By dividing the force by the contact area, the mean pressure can be derived and plotted versus time. The particular compression example shown in Figure 3 took about 5 – 10 seconds followed by a hold period of 10 – 15 seconds to allow the radiographer to reach the control desk and make the X-ray image acquisition. It can be seen that the compression is nonlinear, i.e. the rate of thickness reduction is reduced at higher forces. Since the parameters were measured during the whole compression period, these data enabled the breast tissue thickness, contact area (as well as the pain level reported by the woman) to be modelled. This model allows estimates of pain for any force and pressure to be made.

VALIDATION

The validation of our new compression procedure based on guidance by pressure rather than force was carried out via an intervention study performed within a unit of the Dutch national screening program and involving 500 women [4]. In this study, the pain experience as reported by the women, diagnostic image quality and dose were all recorded. Two compression protocols were used for each woman, one based on force with a target force of 14 decanewton (daN) and the other on pressure with a target pressure of 10 kilopascal (kPa). The different protocols were carried out in a random order for each woman and the technicians were blinded to the protocol. The majority of women considered the pressure-based protocol to be less painful than the one using 14 daN of force. One third of the women reported the same level of pain, and a relatively small group of women with large breasts (10%) reported more pain with the pressure-based protocols.

Four radiologists blinded to the protocol scored the diagnostic image quality. No statistically significant difference was found in image quality and the number of retakes between the force- and pressure-based protocols. In the pressure-standardized compression protocol, the average glandular dose (AGD) was reduced by 4.2% in cranial view and 0.5% in media lateral oblique MLO, as a result of filter switching and of a slightly harder energy X-ray beam.

Altogether these positive results were not really surprising to us since we anticipated that the introduction of a pressure-standardized procedure would improve quality. In fact the current lack of standardization throughout the world [Figure 5] results in many different local guidelines and differences in positioning training without taking into account quantitative breast sizes.

EFFECT OF PRESSURE ON SCREENING PERFORMANCE

The recent availability of Volpara Analytics software [5], enables the estimation of the contact area of the breast under compression during image acquisition. Hence the pressure can be computed retrospectively, opening up the possibility of analyzing established databases containing DICOM information and unprocessed images. Such analysis enabled the establishment of a relation between compression pressure and screening performance in a series of 113,464 screening exams [6]. The exams were categorized into five equal groups of increasing applied pressure, in such a way that each group contained 20% of the exams. Pressure thresholds between the groups were 7.7, 9.2, 10.7 and 12.8 kPa. Measures of screening performance were then determined for the exams in each group. It was found that PPV and the cancer detection rate varied significantly within the five groups. There was a clear indication that the group with a moderate pressure (around 10 kPa) had a better performance than those in lower and higher pressure categories [Figure 4].

DISCUSSION

We propose the use of a new compression procedure in mammography, based on a standard mean contact area pressure. To achieve this, we measure in real time the contact area which is related to the volume of the breast and the stiffness. The target pressure we aim for is 10 kPa (75 mmHg), the rationale behind this being that very little additional flattening of the breast can be expected at or above arterial blood pressure, as was shown in our prospective observational study [3]. It is not easy to show how our pressure-based compression relates to the conventional way of working because there is no single, conventional way of working. But we can compare our procedure to the most extreme compression protocols. In protocols with high target force (18-20 daN) serious over-compression will occur even if the technicians take, to some extent breast size into account. At the other extreme, a low target force (8-10 daN) protocol will produce serious under-compression in the larger breast. The most fundamental difference with a pressure-based protocol is...
that every woman receives a personalized amount of force related to the contact area and stiffness and so makes mammographic compression predictable and repeatable.

Over-compression may result in unnecessary pain and discomfort, but the question is not if there is unnecessary pain in a 10 daN or a 18 daN protocol, but to what extent. It is obvious that in a country where the norm is to use a mean force of 10 daN, the number of complaints will be lower than in a country with a mean of 18 daN force. But with the use of a pressure-based protocol, the extremes namely over-compression in small breasts and under-compression in large breasts will be avoided.

If it is possible to image the breast with pressures varying between 5 and 20 kPa, it may be asked if there is an optimal pressure. From a large study that was carried out, it appears that such an optimal pressure lies somewhere around 10 kPa.

Compression appears to be a “black hole” in mammography without any underlying rationale or standardization. This has resulted in completely different ways of carrying out mammography throughout the world [Figure 5]. In some countries, even the guidelines for machine or phantom testing (between 10-20 daN) have been simply transferred into guidelines for the female population. Under-compression has an obvious effect on image contrast and will play a role in diagnostic performance. That over-compression plays a role not only in pain and discomfort but also in diagnostic performance, might surprise some readers but was already acutely known to many radiologists who were used to use cone down views, with disappearing distortions and tumors.

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HOW DOES IT WORK?
In mammography a C-arm of the X-ray source and a x-ray detector is used to acquire mammograms. A plastic paddle is used for compression of the breast tissue during exposure in order to immobilize and flatten the breast so as to produce an optimal image and a minimal dose. The compression force is automatically measured in the C-arm of the mammography machine and is displayed, together with other parameters including the thickness of the breast tissue between the paddle and the detector cover.

To calculate the mean pressure — which is the basis of the new system —, the force

A commercially available pressure-based compression paddle system

The new Sensitive Sigma Paddle uses multiple sensors to enable optimal breast compression for every breast, every time. Clinical trials of the system have shown positive clinical results and improved patient experience. In practice, the operation of the system is carried out in a few, simple steps:

• The mammography technologist positions the breast and starts the compression;
• During compression, the real time pressure value is calculated automatically by the system and can be visualized from the built-in LED monitor lights;
• At the start of the procedure, i.e. with no breast compression, only the first LED is lit;
• As the pressure increases, additional LED’s will light up;
• When the target pressure of 75 mmHg is reached the sixth LED will light up;
• The target pressure is chosen as being the optimal compression for this particular breast in this position;

To automatically measure the contact area of the breast with the compression paddle, the Sensitive Sigma Paddle incorporates a proprietary thin (0.1mm) film containing silver nano-wires to measure capacitance. The film is fitted in the paddle and has minimal effect on X-ray transmission and scattering.

The homogeneous foil (0.1 – 0.2 mm) adds only approximately 4 – 8 % to the absorption and scatter of X-rays which already occur from the approx. 2.5 mm thick paddle material. Repercussions on the image quality have been shown to be minimal. The retrofittable paddle contains proprietary load cells and electronics to measure the force and the contact area. The ratio of the force and contact area is then automatically computed and visually portrayed on the rear of the paddle by LEDs, with each LED representing a mean pressure of 2 kilopascal (15 mmHg).

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Breast tomosynthesis — the optimal screening modality?

A recent study from Malmö, Sweden suggests that 3D imaging could replace conventional 2D imaging in screening mammography.

The recently published interim results of a large cohort study carried out in Malmö, Sweden, suggest that breast tomosynthesis, the relatively new imaging modality for 3D depiction of the breast, could replace conventional 2D mammography in the future and thereby change the practice of breast cancer screening internationally [1].

“Tomosynthesis is the better mammography method,” explains radiologist and senior author of the study Sophia Zackrisson of Lund University. “The method offers significant advantages, particularly for screening.” Two-view digital mammography is currently the world’s gold standard for breast cancer screening. However, it is known that the X-ray technique does not detect all breast tumors; in fact, up to one-third of all cancers may remain undetected, especially in women with very dense breast tissue [2]. One reason is that overlapping breast tissue can cover tumors, resulting in them not being easily visible on the 2D mammogram. With tomosynthesis, on the other hand, the X-ray tube moves in an arc over the breast, taking low-dose images across a range of angles. These imaging data are used to calculate one-millimeter-thin layers of the entire breast tissue, which is displayed as a stack that the radiologist can scan through like in a flip book.

NOT A MIX OF TECHNOLOGIES, BUT A RATIONAL STRATEGY

Studies over the past few years have shown that more tumors are discovered when tomosynthesis is used in addition to mammography [3]. However the Malmö study used a different approach. “We did not want to simply add different technologies, but rather develop a strategy for screening that is as rational and efficient as possible,” states Zackrisson. The clinical trial, which began in 2010 in Malmö, was therefore designed from the very beginning to examine whether tomosynthesis is superior to mammography as a stand-alone procedure in the screening process and could replace it as the standard method.

According to the preliminary results, this appears to be the case. An interim analysis of 7,500 of the planned 15,000 study participants shows that one-view tomosynthesis detects up to 43% more cancers than two-view mammography and, at the same time, reduces the radiation exposure. Furthermore, the force needed to compress the breast could also be significantly reduced. “For many women breast compression during the mammogram is very painful,” comments Zackrisson’s colleague, Kristina Lång. It is therefore possible that tomosynthesis screening could also lead to higher participation in screening programs.

OUTSTANDING ISSUES SHOULD BE RESOLVED IN THE NEXT FEW YEARS

It remains to be seen whether the new method actually detects particularly aggressive cancers better. Another
possible scenario is that additionally detected tumors are actually changes posing little risk to the woman, and tomosynthesis could occasionally lead to overdiagnosis. One other aspect is that the time needed for the reading and assessment of tomosynthesis is higher due to the large number of slices displayed for each breast. In addition, the preliminary results show that more women needed to be called back for additional diagnostic testing to clarify the results. However, this recall rate increased in proportion to the cancer detection rate, which is consistent for those screening programs, where the recall rate with 2D was already very low.

“... We observed that the recall rate, as well as the time to read the images, decreased with the radiologist’s increased experience. There is apparently a significant learning curve here...”

“We also observed that the recall rate, as well as the time to read the images, decreased with the radiologist’s increased experience,” reports Lång. “There is apparently a significant learning curve here.” The definitive assessment of the procedure will be made in the years ahead, after the study is completed. The Malmö researchers also plan to present a detailed analysis of the cost efficiency of the new method.

AN INTERNATIONAL COMPARISON OF SCREENING PROGRAMS

According to a 2012 survey by the International Cancer Screening Network, more than two dozen countries worldwide have organized breast cancer screening programs [4]. Since the first pilot projects in 1977 in Japan, the approach spread in the 1980s and 1990s to North America, Europe and Australia, and more recently to countries such as China, Singapore, Saudi Arabia, and some parts of Brazil [5]. In a global comparison there are differences as well as similarities.

For example, women in the Scandinavian countries, the United Kingdom and Germany receive a personal invitation for screening at predetermined intervals. In contrast, participants in other countries are also recruited through media campaigns or referred by their GP. In addition, screening programs are only available in limited regions of China, Saudi Arabia, Spain and Switzerland.

One special case is “opportunistic screening,” in which women undergo the exam at their request or as part of routine medical care. Opportunistic screening plays an important role in the United States, for example. In Latin America, where there are national screening recommendations but no organized mammography programs, most screenings are performed at the patient’s request, and often by a private-sector doctor [6]. The main problems with opportunistic screenings are that on average the necessary intense training of personnel and the quality assurance of imaging, image interpretation and further work-up are often not at the same level as those with organized screening programs, which in general leads to higher risks of side effects and higher costs without proof of a comparable effect.

Mammography is the standard screening technology around the world, being sometimes supplemented by breast palpation or ultrasound examination. Special centers, general medical facilities and occasionally mobile screening units carry out the examinations, most often at two-year intervals. Many organized programs concentrate on patients between the ages of 50 and 70, but women are routinely screened starting at the age of 40 and after the age of 70 in Sweden, Australia, South Korea, Japan and the United States. Participation rates also vary considerably: from only 20 percent in Japan and Saudi Arabia, around 50 percent in Canada and Switzerland to more than 80 percent in the Netherlands and Finland.

THE GROWING WORLD MARKET FOR SCREENING

Worldwide, breast cancer is the most common cancer in women and the number of women affected continues to
countries like India, public screening programs are barely the private healthcare sector in emerging and developing nations [8]. By 2018, the total number of women worldwide who qualify for a breast cancer screening could total around 250 million [9].

One driving force behind this development is the aging of the world population. It is well known that the probability of developing breast cancer increases with age. A rising standard of living with greater education opportunities for women, and the resultant later births and shorter lactation periods, lead indirectly to a higher risk of breast cancer due to changing hormonal influences.

As a result, China is one of the largest markets for breast cancer screening, along with the United States, Brazil, Japan and Germany. China has experienced a rapid increase in disease rates since the early 1990s. Various regional screening programs have been developed in China since then; however, experts do not anticipate nationwide mammography screenings based on Western-style models in the near future. In fact, it is possible that ultrasound screening will play a role, as the procedure offers advantages for Asian women, who frequently have denser breast tissue, small breasts and often develop cancer at an earlier age [10].

While there are frequently screening services offered by the private healthcare sector in emerging and developing countries like India, public screening programs are barely affordable in these countries [11]. Cultural barriers can also stand in the way of breast examinations carried out for early detection [12].

On the other hand, in industrialized countries with organized screening programs, the services are paid for through taxes or by health insurance companies (sometimes with a co-payment from the patient) at predetermined rates. The total cost of the German mammography screening program, for example, which screens around half of the women who are entitled to use the program, amounts to approximately US$200 million to US$250 million per year, corresponding to about 70-80¢ per screening mammogram including double reading, centralized quality assurance and subsequent assessment examinations [13].

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Breast Density Assessment Methods: A Historical and Clinical Review

Epithelial cells in the breast are the nexus of breast cancer [1] and the presence of a greater number of glandular cells may put women at higher risk. Furthermore, the surrounding fibrous connective tissue has a stimulatory influence on glandular cell proliferation and can promote carcinogenesis [2, 3]. High amounts of fibroglandular tissue pose a primary breast cancer risk, which makes its quantification of high importance.

Fibroglandular tissue, including glandular tissue without disease, is also of interest because it can mask the presence of cancer in X-rays, reducing the sensitivity of mammography [4, 5] and increasing the rate of false positive callbacks [6, 7].

There is growing legislative pressure for breast composition, known as breast density, to be described in mammography reports, especially in the United States. But it is also well known that inter- and intra-operator variability is very large when assessing density visually, as Ren [8], and more recently, Sprague [9] reported.

As breast cancer risk prediction models, such as Tyrer-Cuzick, have recently begun to include breast density, it is critical for clinicians to understand the different density assessment methods and how to best obtain density information in a reliable and repeatable manner. This article summarizes recent studies that have reviewed different breast density assessment models.

THE HISTORY OF BREAST DENSITY

In 1976, Wolfe associated the visually scored appearance of parenchymal patterns in X-rays of the breast with the risk of developing cancer [10, 11]. Wolfe reported a 37× higher incidence of disease in breasts of P1 pattern vs DY pattern (the lowest vs highest density pattern), although this result has never been repeated in part because of the subjective manner in which mammographic pattern was categorized. Boyd [12] demonstrated a 4.7× risk associated with the area of density measured by Cumulus. Boyd's approach had the advantage of using semi-automated software to assess the proportion of breast by area that enclosed fibroglandular tissue, removing most human subjectivity. However, Cumulus required a human to manually threshold the image, which limits its throughput and makes it impractical for clinical use.

BREAST DENSITY IN CLINICAL PRACTICE

When the BI-RADS Atlas 4th Edition was published by the American College of Radiology in 2003, it recommended reporting breast composition, and it provided four quantitative categories, based on area of the breast covered by dense tissue [4]. The densest category, 75-100%, description included the words “which may limit the sensitivity of mammography”. However, no guidance was provided as to what should happen for a specific woman if sensitivity was limited in her case.

ACR later clarified that area-based measures, whether achieved by a human observer or software, were imprecise. In the BI-RADS Atlas 5th Edition [5], ACR required “an overall assessment of the volume of attenuating tissues in the breast” and stated: “We further recognize that both subjective estimates and planimetry measurements of breast density based on area as depicted on (2-D) mammograms are imprecise indicators of the volume of breast density.” The category descriptions were also updated [Figure 1], removing the quantitative categories and the cautionary note was changed to “which lowers the sensitivity of mammography”. There was also an increased focus on the masking risk posed by density, with the definition of the third BI-RADS category (C) changing to “heterogeneously dense, which may obscure small masses”. However, what constitutes a “small mass” is not defined and this may lead to disagreement in density assessments by radiologists.

RADIOLOGIST-ASSESSED BREAST DENSITY VARIES CONSIDERABLY

In their study, Brian Sprague and members of the PROSPR Consortium examined data from three breast cancer screening research centers to review radiologist breast density assessment. [9] Radiologists reviewed 216,783 mammograms from a total of 145,123 women and gave them a BI-RADS 4th Edition density score. Of particular interest was the percentage of images that each radiologist examined and deemed to be “dense” (classified as BI-RADS 3 or 4).

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The outcome was a striking highlight of the inherent subjectivity of BI-RADS. Considering the readings of all 83 radiologists, the median percentage of mammograms that were classified as "dense" was 38.7%. However, there was significant variation — one radiologist only considered 6.3% of all mammograms as dense, while another gave this classification to 84.5% of the images (Figure 2).

One possibility for this discrepancy could be the fact that the patient set seen by each radiologist may vary considerably in terms of their breast density. However, after adjusting for age, race/ethnicity and BMI, the overall results barely changed, suggesting this may not explain the variability.

Furthermore, longitudinal assessment of a subset of women who had consecutive studies available suggested that inter-radiologist variation was the issue. Of the women whose density was re-assessed by the same radiologist after an average period of 1.2 years, 10% changed in their density classification. However, when a different radiologist performed the re-assessment over the same time period, 17.2% of women received a different classification—a 72% increase in discrepancy. It is unlikely that this increased discrepancy arose due to other factors that affect density, such as age-dependent breast involution [13].

Considering the increased importance of breast density reporting, this discrepancy between radiologist readings could illustrate a serious issue with the way that density is commonly measured. The authors point out that “a woman’s likelihood of being told she has dense breasts varies substantially on the basis of which radiologist interprets her mammogram.”

Figure 1. BI-RADS Atlas 5th Edition Breast Composition Categories
A. The breasts are almost entirely fatty. B. There are scattered areas of fibroglandular density. C. The breasts are heterogeneously dense, which may obscure small lesions. D. The breasts are extremely dense, which lowers the sensitivity of mammography.

Figure 2. The distribution of density assessment among 83 radiologists in the PROSPR Consortium. Displayed is the fraction of mammograms (in terms of percentage) that each radiologist assessed as being “dense”. The percentage labels below the plot display the minimum, median and maximum estimation of “dense” mammograms amongst radiologists.
**Can Automation Remove Subjectivity From Breast Density Estimates?**

As the breast is not a two-dimensional organ, explained well by Kopans [14], it is necessary to consider the volumetric density of the breast – that is not easily done by human observers looking at two-dimensional images. Therefore, the use of computer algorithms to quantify density with objective measures is one possible means of removing subjectivity. VolparaDensity, one such tool, has been tested in a number of peer-reviewed studies that proved its clinical utility and association with breast cancer risk.

One such study, by Eng et al. [15], provides a comprehensive comparison of six methods of measuring mammographic density and their association with breast cancer risk. Three area-based methods (BI-RADS, Cumulus, and Imagel) and three fully-automated volumetric methods (Volpara, Quantra and SXA) were evaluated to quantify their association with breast cancer risk. Each method was tested using digital images from 414 cases and 685 controls. All methods showed that density was inversely associated with age and BMI, and that mammographic density offers the potential, alone or in combination with other factors, to improve breast cancer risk prediction.

![Figure 3. Kappa agreement values for Volpara vs Radiologists on Two- and Four-Category Scales.](image)

Of the six methods studied, the association of breast density with risk was highest for Volpara and Cumulus. Additionally, Volpara was better at identifying women at low risk than other methods. Volpara and Cumulus were the only tools that produced breast density measures for all images in the study, with other methods failing to produce readings for up to 11% of the participants. The authors conclude that fully-automated methods are valid alternatives to the labor-intensive Cumulus for quantifying density in digital mammography.

**Automated Density Assessment Provides More Consistent Readings**

In light of the subjectivity and variation that Sprague et al. described, reliable breast density measurement is needed to personalize screening. Katarina Holland [16] and a team from the Radboud University Medical Center in The Netherlands investigated the categorization of pairs of subsequent screening mammograms into density classes by human readers and by an automated system. Holland used VolparaDensity software and the observations of four readers, including three specialized breast radiologists, to categorize 1000 mammograms belonging to 500 pairs of subsequent screening exams into either two or four density classes. Volpara identified a significantly higher proportion of women who did not exhibit a change between two-point density categories (90.4% of women) compared to the radiologists (86.8%). Volpara produced more consistent density readings than the radiologists; Volpara’s readings between serial exams were significantly higher than the radiologists’ readings were to each other. Volpara maintained higher kappa agreement values on both two- and four-category scales [Figure 3].

**Conclusion**

The use of an automated density measurement algorithm like VolparaDensity may prove effective in screening practice, as it is objective and not subject to the variation of a radiologist’s visual assessment. The triage of women to supplemental screening to overcome the reduced sensitivity of mammography in dense breasts should not be subjective. It is now well-established that automated quantitative methods can provide objective density assessment that is not subject to the intra- and inter-reader variability of human density assessment. Furthermore, VolparaDensity will further personalize breast cancer risk assessment and help assess the temporal change of breast density, perhaps for monitoring the occurrence of age-related involution or response to neoadjuvant therapies.

**References**

First reviews of new Hologic Affirm Prone Biopsy system are very positive

Breast tomosynthesis exams — Hologic calls them 3D Mammography — have shown to be an advance over digital mammography, with higher cancer detection rates and fewer patient recalls for additional testing. The new Affirm Prone Biopsy system, which was installed for the first time in Europe earlier this year, is widely considered as one of the most significant advances in biopsy technology since the first prone biopsy system was introduced more than 20 years ago.

The Affirm Prone Biopsy system uses the same proven detector technology as the Hologic Selenia Dimensions breast tomosynthesis system, a top selling breast cancer screening and diagnostic system in the U.S. and in many other countries around the world. With a significantly larger field of view than the MultiCare Platinum system, along with its translucent paddles, the new prone system is designed to deliver exceptional 2D and 3D images and better target lesions found during 3D Mammography exams, as well as other screening modalities. In addition, the Affirm Prone Biopsy System allows full 360° access to the breast to accommodate most lesion locations. Users can go from a standard to lateral needle approach in seconds to accelerate procedures and ensure reaching targeted lesions.

Doctors in Spain report handling with the new system complex biopsies that they were only able to see with breast tomosynthesis imaging

As Doctor Tejerina, a radiologist with the Centro de Patologia de la Mama, Tejerina Foundation, in Madrid, Spain, reports, feedback from the first wave of patients is very positive. “We used to suffer in the handling of complex biopsies of subtle lesions like faint calcifications or distortions that we were only able to see on 3D images,” Dr. Tejerina says. “Older breast biopsy systems are restricted to 2D imaging with a narrow window for targeting the lesions. Often they require multiple X-ray exposures to find and position the suspect tumor for the biopsy needle. With tomosynthesis imaging on the new Affirm Prone System, there is a much wider field of view. So the biopsy device can be positioned anywhere in a 360-degree circle, and areas of suspicion seen only with 3D imaging can be easily biopsied.”

Dr. Tejerina also notes that with the previous Hologic biopsy table, the tube head of the biopsy device had to be positioned manually. “The new system does this for us automatically, which saves time,” he says. “The software really streamlines our workflow, so the procedure goes faster.” And he adds, the Affirm Prone table, with its translucent paddles and wider detector, “helps us see lesions in the first scout and significantly reduce the number of images needed to get to the lesion.”

The Centro de Patologia de la Mama, Tejerina Foundation has been leading the way in women’s breast health for over 40 years. In 1997, the Centre was first center in Spain to install a stereotactic guided prone biopsy table. In 2010 the Centre installed a Hologic Selenia Dimensions breast tomosynthesis system, the first site in Spain to use the innovative technology. In 2010 the Centre was also the first site in Spain to combine the Hologic Affirm upright biopsy system with the Hologic tomosynthesis system. And now, in 2016, the Centre is one of the first sites in the world to offer prone biopsies on the new Affirm system from Hologic.
Doctors in the Netherlands say Affirm system is fast and comfortable for patients

Dr. Henebiens, a radiologist at Spaarne Gasthuis Hospital in Hoofddorp—the first Affirm prone user in the Netherlands—commented on how fast doctors can do a procedure on the Affirm system and how comfortable the new system is for patients.

“We make fewer exposures on the new Affirm Prone Biopsy system, compared to the older MultiCare Platinum table,” she notes. “And because the table uses 3D technology, we use fewer steps getting to the target and getting biopsies.”

Dr. Henebiens also likes how easy it was to get up to speed on the table. “The learning curve for the new table was very fast. Training was scheduled for two days, but in just one day, the staff knew how to use it.”

The Spaarne Gasthuis Hospital staff have completed over 60 procedures on the table in their first 7 months of use.

Doctors in Italy report faster and lower patient dose biopsies with the new system

Doctor Gianfranco Scaperrotta, Chief of the Breast Imaging and Interventional Radiology at Fondazione IRCCS Istituto Nazionale dei Tumori (INT) in Milano, Italy was an early adopter of the Affirm Prone Biopsy system.

“The Affirm Prone Biopsy System is a quick, effective and easy to use system,” he says. “The image quality is high, comparable to the Hologic Selenia Dimensions digital mammography system. Workflow is quick thanks to a dedicated workstation and the system’s fully integrated C-arm and automated tube-head. Procedures are faster and safer with the new system thanks to the programmed needle parameters and automated calculations such as the display of safety margins and relative distance in real time.”

After 73 procedures on the new system, INT has seen a 20% reduction in the time needed for performing a biopsy (patient time under compression) and approximately a 50% drop in the mean glandular patient dose when they compare the new system to the older Hologic system.

The Fondazione IRCCS Istituto Nazionale dei Tumori is the largest oncology site in Lombardia, the most populous region in Italy. The research and cancer treatment site draws patients from throughout Italy.

Conclusion

In sum, doctors at the first three European Affirm prone install sites report that the new system offers significant benefits to the patient, the doctor and the technologist. No wonder Hologic says the Affirm Prone Biopsy system is the most significant advance in biopsy technology since Hologic introduced the first prone biopsy system more than 20 years ago.

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Breast cancer is one of the most common cancers in women worldwide, with a reported number of 1.7 million being diagnosed in 2012 [1]. In recent years, the incidence of breast cancer has increased by 20% with a particular increase in diagnosis before the age of 50 [1]. Nowadays mammography is the only breast imaging modality with a demonstrated ability to reduce mortality. However, the method has a population-based sensitivity of only approximately 80% [2], with a much lower sensitivity that this in women with dense breasts. The sensitivity of mammography in young women with dense breasts can be as low as 40% [3-5].

For these reasons, there has been an increased research focus in Europe and in the United States on the evaluation of other imaging modalities to improve diagnostic accuracy in breast cancer diagnosis. Over the last few years, several methods, with or without the use of contrast media have been developed and evaluated in the effort to extend the capability of mammography and to detect more breast cancers. Examples of such techniques which have been proposed as adjunct breast imaging screening methods are ultrasound for dense breasts and digital breast tomosynthesis [6].

Breast cancer screening methods using contrast media are commonly based on the biological principle of the rapid formation of tumoral microvessels that render malignancy-associated vessels more permeable to contrast agent than normal tissue, resulting in tumor enhancement [7]. Contrast-enhanced spectral mammography (CESM) is a new imaging technique based on this principle. Thus CESM is based on the use of mammography in combination with iodine-based contrast agents to increase diagnostic capability via the detection of areas of increased vascularization in the breast [8]. A review of contrast-enhanced mammography techniques showed encouraging preliminary results, with a mean sensitivity of 85.2% (range 62.0-96.0%) and a mean specificity of 66.1% (range 50.0-83.3%) [7-9].

However, until now studies estimating the diagnostic performance of CESM have involved relatively small sample sizes or had mixed inclusion criteria, large confidence intervals for estimates of performance and yielded heterogeneous results.

We have therefore recently carried out a study whose purpose was to assess the potential role of CESM by estimating its diagnostic capabilities from an evaluation of the already published evidence; we performed a systematic literature review and meta-analysis. (see Reference section for details of our original paper)

**Material and methods**

Our review methods followed the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

**Search strategy**

We identified relevant studies that assessed the accuracy of CESM through a literature search of the major medical databases available: PUBMED, Embase ( ISI Web of Science, SpringerLink, ScienceDirect and Cochrane library). Searches were performed independently by two reviewers with the assistance of a hospital librarian and were carried out up to 1st December 2015.

**Inclusion & exclusion criteria**

**Inclusion criteria:**

1. Patients older than 18 years who had undergone assessment of the breast for cancer.
2. Existence of an acceptable reference standard (surgery or pathology) for the characterisation of any lesions
3. The availability of (or possibility of deriving adequately) [at least one of the following pairs: the absolute numbers of true-positive results and false-negative results; or the numbers of true-negative results and false-positive results].

**Exclusion criteria:**

1. Case report or case series, review articles, letters, or comments
2. Duplicate publications

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**This article summarizes the findings of a recent survey and meta-analysis of publications on Contrast-Enhanced Spectral Mammography. The sensitivity of CESM was found to be high, underscoring the potential of the modality whose diagnostic performance could rival that of MRI, but with added advantages of improved accessibility and lower cost.**
Studies of Diagnostic Accuracy Studies

studies using the Quality Assessment of the screening and eligibility evaluation read the full text of studies included in the screening and eligibility evaluation process. We also assessed the quality of the eligible studies using the Quality Assessment of Studies of Diagnostic Accuracy Studies (QUADAS-2) checklist.

Study selection

Two authors independently reviewed article titles and abstracts for study selection, based on the pre-defined inclusion criteria. The same authors independently read the full text of studies included in the screening and eligibility evaluation process.

RESULTS

From 643 screened articles, 33 studies were submitted for full-text review. Out of these, 8 eligible articles reporting the accuracy of CESM were included in the systematic review. The 25 articles excluded did not meet the predefined inclusion criteria.

A number of the studies were performed in Poland (3/8) by the same group. All studies were observational: five studies enrolled participants prospectively and three studies were carried out retrospectively. In the majority of these studies, the patients had already known mammographic abnormalities; had suspicious lesions; were patients already with a confirmed diagnosis of breast cancer or were having additional imaging as part of screening or diagnostic work-up. A total of 994 lesions were evaluated in 920 patients.

Sensitivity

A very high pooled test sensitivity of 0.98 (95% CI: 0.96-1.00) was found.

Specificity

Specificity was based on six studies reporting raw data, and was calculated as 0.58 (95% CI: 0.38-0.77).

Summary ROC

The pooled ROC curve showed an area under the curve of 0.93.

Mean Lesion size

The mean size of the cancerous lesion cancer was 21.2 mm (range: 0.1-77 mm).

DISCUSSION

We estimated the sensitivity and specificity of CESM for the detection of breast cancer using a meta-analytic approach. From the evaluation of 994 lesions evaluated in 920 patients, we found that the sensitivity of the technique was very high (98%). On the other hand, specificity was relatively low (58%) and the specificity confidence intervals were very broad, indicating a large variability in specificity across the studies.

The high sensitivity of CESM is giving rise to optimism regarding the potential of the technique and its superiority over conventional mammography. The extended information obtained from the use of contrast media together with the large experience and capacity of existing mammography, means that CESM could possibly be comparable with MRI, but much more accessible.

In fact CESM can be immediately implemented in the mammography suite with minimal loss of time [9]. Therefore, CESM might be an alternative cost-effective imaging method for MRI, especially when MRI availability is limited [9]. Contrast enhanced mammography is emerging as a combined application of full-field digital mammography with intravenous injection of iodinated contrast medium. CESM also has the potential for improved lesion detection in dense breasts where the tumor could be obscured by the fibroglandular (dense) tissue.

We believe that CESM could be comparable to MRI in terms of diagnostic feasibility. CESM and MRI could have similar diagnostic performance in the diagnosis and staging of breast cancer, but most patients seem to prefer the experience of CESM to that of MRI. Indeed, in addition to the cost and accessibility issues there can also be problems with MRI such as contraindications in patients with pacemakers and in claustrophobic patients. For these reasons, it is likely that the role of CESM will grow in the near future. However, it should be pointed out the studies published so far on the evaluation of the diagnostic performance of CESM had relatively large confidence intervals on the estimates of diagnostic performance and several discrepancies especially regarding specificity.

If CESM is going to be used in screening, or if CESM is to be considered as a potential alternative to diagnostic MRI, it will be necessary to have accuracy data derived from studies with more robust designs. However the current evidence provides some insights on the potential of CESM to replace or complement the existing array of imaging modalities in breast cancer diagnosis.

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ACKNOWLEDGEMENT

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Models for Assessment of Breast Cancer Risk

The so-called Tyrer-Cuzick (or IBIS) model was developed to predict the risk of developing breast cancer, initially for women with an elevated risk [1,2]. It is widely used and has now been validated in several studies, including with women at average risk attending routine breast screening [3,4]. The computer program of the model displays a chart to show a woman's risk of breast cancer until age 85 in comparison with the risk for a typical woman of the same age, together with estimates of the 10-year and lifetime risks. The risk factors that have been used to make this estimate are also recorded in a printable summary. The latest software is freely available for non-commercial research use from the website www.ems-trials.org/riskevaluator.

The model works by using a novel hybrid of a segregation model for familial risk and a proportional hazards model. The segregation model is used to estimate the chance that the woman carries a mutation in two high risk genes (BRCA1 and BRCA2) and an unknown gene. The unknown gene is included to account for further inheritable genetic factors. The segregation model is combined with age and other risk factors through a proportional hazards model. The risk factors chosen for the model were those most supported by the literature. They include age, a detailed family history of breast and ovarian cancer in first and second degree relatives with age at onset, prior proliferative benign breast disease or atypical hyperplasia, hormone replacement therapy use, height, weight at menopause and parity including age at first child birth. Examples of lifetime risks associated with risk factors for a woman aged 50 are shown in Table 1 along with information on their prevalence. A useful feature to simplify data entry is that population average values are used if a factor is not known or not entered for any reason.

Additional Factors Planned for the Next Software Update (V8)

Various improvements are planned for the next version of the program (version 8). The most important of these is the inclusion of mammographic density. Previous research indicates that this is the single most important factor and has a high population attributable fraction for breast cancer, particularly younger women [5]. This is because of the strong impact on risk (roughly fourfold between dense and fatty breasts) and the fact that dense breasts are not uncommon in the general population. Introduction of this factor was delayed because of the large number of ways in which density can be measured, and the different resultant scales on which it can be reported. In the end we decided to not require one specific method, but will accept one of three standard methods and calibrate the risk according to the method cited. These are:

1. A visual analogue scale [3];
2. BI-RADS density categories (4th edition) [6];
3. Volpara density [7].

Of these methods number (2), the BI-RADS density classification (fourth edition) is widely used, especially in the United States and has four categories: fatty (0-25% dense), scattered (25-50%), heterogeneous (50-75%) and extremely dense (75-100%) [5]. The third density method to be included in the next update (v8) of our software is a volumetric measure of percent density based on the Volpara algorithm [7] which has the advantage of being fully automated and objective. The best results appear to be obtained by using percent density adjusted for age and BMI. The Volpara method has been predictive of risk in high-risk and average risk women in several studies, but despite being more reproducible than visually-assessed density from an expert radiologist, its relationship with risk does not appear to be any stronger [8].

Perhaps the most noticeable density method omitted is CUMULUS [5]. This is a semi-automated method, but it still has a subjective component due to the way in which thresholds for dense and total breast tissue are chosen. It has mainly been used in research settings, but appears to be less often used now, partly because it is very labour intensive.

Another variable which appears to be useful, but is currently mostly used only in research circumstances, is a risk score given from a panel of genetic alterations, or single nucleotide polymorphisms (SNPs) [9]. Panels with between 7 and 94 SNPs have been investigated and shown to improve the performance of risk models based on phenotypic factors. The Tyrer-Cuzick model will be updated to accommodate such panels that provide a relative risk compared to a women of average risk of the same age.

Future extensions beyond v8 will explore the value of including additional lifestyle factors such as alcohol consumption and physical activity. A common problem...
with these is to obtain accurate reporting as alcohol consumption tends to be under-reported and physical activity over-reported. They are also more difficult to accurately code since alcohol consumption needs to be extracted from the type of alcoholic beverage consumed and physical activity depends both on the duration and the vigourousness of the exercise, which is complex to report in a simple manner.

**CONCLUSION**

In summary, accurate estimation of increased risk is important for determining the need for additional screening — either by shortening intervals between mammograms or more expensive modalities such as MRI. They also may be used for identifying women at a lower risk of breast cancer, where screening intervals might usefully be lengthened or screening even avoided altogether. Breast screening is an attractive time to counsel woman about breast cancer prevention and to advise them on their risk both in absolute and relative terms.

**REFERENCES**


The use of digital breast tomosynthesis in the post-treatment breast cancer surveillance setting

Several studies have confirmed the advantages of the use of digital breast tomosynthesis (DBT) as an adjunct to digital mammography (DM) in population-based breast cancer screening studies. However, the use of DBT in the surveillance of patients who have had breast cancer treatment has not been extensively investigated. This article summarizes the findings of a first prospective study of the use of DBT in addition to 2D imaging in patients with a history of breast cancer treatment. It was found that the use of adjunct DBT in addition to DM in such patients reduced the rate of indeterminate findings and hence unnecessary investigations compared to DM alone.

THE CURRENT LANDSCAPE FOR THE USE OF DIGITAL BREAST TOMOSYNTHESIS

In recent years there has been a rapid increase in efforts to investigate the place of digital breast tomosynthesis (DBT) as standard of care in breast cancer screening, either as an adjunct to conventional digital mammography (DM) or as a stand-alone modality [1,2].

DBT is a mammographic technique whereby the X-ray tube and digital detector are rotated in a limited arc to create multiple low-dose projection images through a compressed breast, which are then tomographically reconstructed into a series of thin-slice images to provide three-dimensional (3D) information for radiology reporting. The main advantage of DBT lies in its ability to circumvent the limitation of DM where superimposed breast tissue can either masquerade as a suspicious lesion or obscure a malignant lesion. Additionally, a two-dimensional (2D) image can be digitally reconstructed from the 3D data acquired in DBT to mimic a conventional DM. This 2D synthesized mammogram (SM) is termed C-view by the initial developers of the technique (Hologic, Bedford, MA, USA).

Indeed the theoretical benefit of DBT is well corroborated in the clinical setting. The early clinical studies tested DBT in cancer-enriched populations, which were either test sets of selected subjects, or patients who were recalled for suspicious lesions found on initial screening mammography. Many of these studies showed that the addition of DBT to DM improved accuracy, reduced recall rates, reduced false positive rates, and increased cancer detection rates [1,2]. These early clinical studies however were limited by potential selection biases due to the use of cancer-enriched test sets. Multiple, large population-based studies have since been undertaken to address this limitation. While there is some heterogeneity in results owing to differences in the screen-reading approaches employed, these population screening studies largely confirm the benefit of adjunct DBT for the reduction in false positive rates and improvement in cancer detection rates [3-6].

Current evidence supports the adjunct use of DBT in addition to 2D imaging rather than as a stand-alone imaging modality. DBT alone without an integrated 2D image (either in the form of DM or SM) has not been shown to reduce false positive rates [7-9]. There are also concerns that microcalcification clusters are not readily detected on DBT images alone [10-12], and that accurate comparison with prior studies may be difficult without 2D imaging. Therefore, currently most protocols specify the use of DBT in addition to DM, at the expense of doubling of radiation exposure to the breast compared to DM alone. Synthesized 2D images reconstructed from DBT data however could potentially replace DM and make redundant the separate DM acquisition, thereby eliminating this major downside of DBT. While an initial investigation [13] concluded that the diagnostic quality of the tested SM images was inferior to...
DM, technology for synthetically reconstructing 2D images has been progressing. Indeed, subsequent studies with updated versions of image reconstruction software, notably including the large Oslo and STORM 2 trials, have shown comparable performance between DM and SM [14-16]. It should be noted that all these studies used Hologic DBT systems. Other DBT platforms exist and their proprietary reconstruction software must be evaluated separately.

THE PERFORMANCE OF DIGITAL BREAST TOMOSYNTHESIS IN THE POST-TREATMENT SURVEILLANCE SETTING

While the everyday clinical use of adjunct DBT has rapidly proliferated to include almost all occasions of breast imaging, a review of published literature will reveal that the major DBT investigations relate to its application in population screening. The incremental benefit of DBT in surveillance after breast cancer treatment is much less well-defined, recognizing that mammographic appearances after breast conserving surgery and radiation therapy differ from treatment-naïve breasts. In particular, benign changes in the breast after breast conserving surgery and breast radiotherapy include breast edema, skin thickening, fluid collections, architectural distortion and calcifications [17,18]. These changes may impact on breast imaging by causing limited compressibility of the breast, and by mimicking or hiding tumor recurrences on mammographic appearances. It is unclear whether these changes would affect the performance of DBT on imaging of the treated breasts in patients who had breast conserving therapy.

We undertook what is, to our knowledge, the first prospective study investigating the performance of DBT in addition to 2D imaging for surveillance of a pure cohort of patients with a history of prior breast cancer treatment [19]. In this prospective study, patients who were scheduled to have mammography for routine surveillance after breast cancer treatment, which included breast conserving surgery or mastectomy with or without post-operative radiotherapy, were invited to participate in the study.

The primary objective of the study was to compare the rates of indeterminate findings between adjunct DBT (in combination with DM) and DM alone. An indeterminate finding was defined as a lesion detected using either modality that necessitated additional imaging studies for clarification. We also compared the rate of cancer detection between adjunct DBT and DM alone, assessed the impact of breast density on the rate of indeterminate findings with adjunct DBT, and compared the rates of indeterminate findings between DM and SM.

All study patients underwent both DM and DBT, and SM images were reconstructed from DBT data for each patient. The DM, SM and DBT images for each patient were read in one of the two pre-defined sequences by a single radiologist in a single sitting [Figure 1]. DM was read before SM in one sequence and the order was reversed for the other sequence. DBT was read after DM and SM in both sequences. True randomization of sequences was not possible due to logistical limitations in the reporting workflow, but the sequences were alternated weekly to reduce reading biases in the comparison of DM and SM. Imaging findings were documented after the reading of each image set and before the next step of the reporting sequence for the week. No retrospective documentation or amendment of imaging findings was permitted.

We enrolled 618 patients in the study over a 12 month period. We found that DBT in addition to DM resulted in a significantly lower rate of indeterminate findings when compared to DM alone (10.5% versus 13.1%, p=0.018). This improvement was similarly observed when analysis was confined to breasts treated with both breast conserving surgery and whole breast radiotherapy (4.9% versus 6.9%, p=0.039). We could not show a difference in cancer detection rates between adjunct DBT and
Breast Imaging

study size. Regardless, we suggest surveillance setting with our smaller cancer detection rates in treatment-als show adjunct DBT to improve eradicated in very dense breasts, suggesting that other breast imaging masonry: a comparison of diagnostic accuracy. Br J Radiol 2012;85:e1074–82.

There was no difference in indeterminate findings when DM was compared with SM in our study (13.1% and 11.5% respectively, p=0.1). Increased breast density was found to be associated with an increase in the rate of indeterminate findings on adjunct DBT. In addition, the benefit of adjunct DBT in resolving indeterminate lesions detected on DM was compromised in patients with dense breasts (15.9% versus 16.9%, p=0.752 in patients with BI-RADS breast density categories 3 and 4, compared to 7.8% versus 11.2%, p=0.018 in patients with BI-RADS breast density categories 1 and 2). Results from screening studies that have reported comparisons across different breast density strata have been conflicting in this regard [3,5,16].

CONCLUDING REMARKS

We hereby provide support for the use of adjunct DBT in addition to DM in patients after breast cancer treatment to reduce the rate of indeterminate findings and hence unnecessary investigations compared to DM alone [19]. The magnitude of relative reduction in the rates of indeterminate findings in our study (about 20%) is in fact consistent with published literature in the treatment-naïve screening population (about 15-20%) [3-5]. This benefit however is potentially negated in very dense breasts, suggesting that other breast imaging modalities should still be considered in patients with very dense breasts.

While prospective screening trials show adjunct DBT to improve cancer detection rates in treatment-naïve breasts [3,4,16], we are unable to verify this in the post-treatment surveillance setting with our smaller study size. Regardless, we suggest that the key benefit for DBT is the improvement in resolving indeterminate findings, reducing false positive recalls, and minimizing over-investigation. An increase in cancer detection rate does not necessarily indicate a breast cancer mortality benefit. It is also unclear whether the increased cancer detection rates seen with DBT in studies will translate into a reduction in interval breast cancer rate [1].

Our study has also shown that the rate of indeterminate findings on SM (using the Hologic DBT platform) is not significantly different compared to conventional DM, lending further support to the increasing acceptance of SM as being of adequate diagnostic quality, which may potentially eliminate the need for an extra DM acquisition with DBT, at least for the Hologic platform. We emphasise however that more studies should corroborate this proposition before DM is abandoned altogether in the setting of DBT, especially for the post breast cancer treatment surveillance setting.

REFERENCES

Ultra-High Performance Ultrasound Transducers

Expanding its suite of next generation ultrasound transducers based on semiconductor technologies, Kolo Medical has introduced three new SiliconWave transducers which are designed to deliver an unprecedented level of performance in the areas of ultra-high resolution imaging and offer the first-ever practical alternative to traditional PZT ultrasound transducers.

Compatible with existing and next generation ultrasound systems, the proprietary SiliconWave transducer technology delivers an unprecedented level of performance in the area of ultra-high resolution and ultra-wide bandwidth imaging for such applications as Thyroid, Breast, Small The company is working with several OEM partners to test the new transducers with commercial ultrasound systems. “This provides an opportunity to evaluate our advanced semiconductor technology for use in clinical imaging as well as its current use in research and academic institutions,” said Dr. Yongli Huang, President of Kolo Medical.

The transducer arrays resemble tiny silicon drums, each smaller than the width of a human hair, that are fabricated on a silicon wafer and incorporated into the transducer giving superior acoustic response that forms the basis for better ultrasound images. The technology used in the new transducers overcomes the fabrication limitations of bulk piezoelectric transducers.

Diagnostic quality web-based echo reporting

Philips have announced the launch of IntelliSpace Cardiovascular 2.1, the latest version of its next-generation Cardiovascular Image and Information Management System. The new system provides clinicians with a single point of access anytime and virtually anywhere and allows for web-based echo reporting, delivering diagnostic quality viewing of echo images.

The World Health Organization has stated that in 2015 cardiovascular diseases accounted for 17.5 million deaths annually. As part of Philips’ commitment to providing the latest advanced technology and integrated cardiology solutions to prevent, diagnose and treat cardiovascular disease the new IntelliSpace Cardiovascular provides cardiologists with an interoperable, patient-centric repository of comprehensive cardiovascular information to help support clinical decision-making, streamline workflows and reduce costs.

“Now, the cardiologist doesn’t have to search for images and reports from earlier tests or open multiple screens. Everything is presented in a unified view, on a chronologically ordered timeline,” said Wally Wonnink, Supervising Physician on Echocardiography at the Elisabeth - Tweesteden Hospital Tilburg, the Netherlands. “This will give caregivers access to the patient’s history of diagnosis and treatment and can help prevent unnecessary examinations.”

According to the Future Health Index, a recent study commissioned by Philips, 81% of cardiology patients surveyed feel it is important that the healthcare system in their country is integrated so that they do not have to have the same test or screening run multiple times due to visiting different facilities, further demonstrating the need for a fully integrated cardiology solution like IntelliSpace Cardiovascular.

IntelliSpace Cardiovascular also features expanded vendor agnostic web application programming interfaces (WebAPI) to provide customers with easier access to third-party applications. The latest iteration of IntelliSpace Cardiovascular delivers seamless access to EMR data, scheduling systems and any web-based application supporting the clinician. The increased interoperability further centralizes patient data from multiple sources to streamline workflows, provide a more comprehensive patient view, and foster collaboration by adding clinical depth instead of information overload. Having a holistic view into the patient’s history spanning diagnosis, treatment and therapy can improve patient care.

“Cardiovascular diseases are the leading cause of death, and account for more cost than any other chronic illness across the globe. Finding ways to speed the path to treatment for patients, while improving workflow productivity and enhancing patient outcomes, are critical to transforming cardiology care,” said Yair Briman, Senior Vice President and General Manager of Healthcare IT for Philips. “IntelliSpace Cardiovascular expands the ability for cardiologists to deliver care from virtually anywhere by giving them power to access diagnostic quality echo images remotely.”

PHILIPS HEALTHCARE
EINDHOVEN, THE NETHERLANDS
www.philips.com/newscenter
High-frequency, high-resolution transducers are potentially easier to fabricate with SiliconWave technology, thus making ultrasound available for a wider range of applications. There are several models in the new range:

- The L38-22 linear array transducer with a center frequency of 30MHz enables high performance superficial imaging in dermatology and can also be used to image superficial tendons and nerves as well as joints of the wrist, hands, and feet.
- The M17-4 1.5D array transducer with a 120% bandwidth and frequencies from 4-17 MHz is the ultrasound industry’s first single-probe solution. With this frequency range, the M17-4 is able to replace multiple linear array transducers for imaging small parts to deep vascular applications.
- The new L30-14 linear array transducer can be used for Neonatal, Pediatric, and MSK applications. The L30-14 transducer has a center frequency of 22 MHz.

The development of capacitive micromachined ultrasound transducer (CMUT) technology was initiated many years ago by a team at Stanford University that included the Kolo Medical founders. The modern transducers offer designs that overcome many initial CMUT limitations such as sensitivity.

KOLO MEDICAL
SAN JOSE, CA, USA
www.kolomedical.com

New family of Detectors for high quality DR imaging

Carestream is now shipping its new DRX Core family of DRX detectors designed to make reliable, high-quality DR imaging affordable for imaging centers, small to mid-size hospitals, urgent care facilities, specialty clinics and providers that perform mobile imaging exams. The DRX Core portfolio includes wireless gadolinium (GOS) and cesium (CsI) scintillators in 35 x 43 cm and 43 x 43 cm sizes—as well as fixed 43 x 43 cm detectors with both scintillators. DRX Core detectors can be used with Carestream’s DRX-Ascend System, DRX-Mobile Retrofit Kits and DRX-Motion Mobile X-ray System. Up to two DRX Core detectors can be registered with each system at any time. Facilities can combine DRX Plus, DRX-1 and DRX Core detectors to have a combination of eight detectors registered with DIRECTVIEW Software on each imaging system for simultaneous use.

“The ability to integrate DRX Core, DRX Plus and DRX-1 detectors offers exceptional flexibility for healthcare providers of all sizes. Providers can select a detector that offers the desired features and budget requirements for each imaging area,” said Sarah Verna, Carestream’s Global Marketing Manager for X-ray Solutions.

DRX Core detectors deliver a preview image in three seconds and full-resolution display in 12 seconds. These detectors use the same battery as DRX Plus and DRX-1 detectors to maximize return on investment and streamline imaging operations.

DRX Core detectors offer a Level 4 liquid rating that provides protection against water spray from any direction. Tri- and bi-color LED lights offer improved feedback of detector status.

CARESTREAM
ROCHESTER, NY, USA.
www.carestream.com

MRI contrast agent approved for whole body imaging

Bracco Imaging have announced that their MultiHance (gadobenate dimeglumine) contrast agent has been approved for whole body MRI in adults and pediatric patients (> 2 years).

MultiHance was already approved in the European Union for use in MRI of the Central Nervous System (CNS) in adults and pediatric patients older than 2 years of age, and in MRI of the liver, breast and Magnetic Resonance Angiography (MRA) of renal and aorto-ilio-femoral occlusive diseases in adult patients.

The new indications for MultiHance are MRI of the brain and spine in adults and children above the age of 2 years, where it improves the detection of lesions and provides diagnostic information additional to that obtained with unenhanced MRI; MR imaging of the whole body in adults and children (above the age of 2 years) including head and neck region, thoracic space (including the heart and female breast), abdomen (pancreas and liver), abdomen (gastrointestinal tract), retroperitoneal space (kidney, adrenal glands), pelvis (prostate, bladder and uterus) and musculoskeletal system where it facilitates identification of abnormal structures or lesions and helps in differentiating normal from pathological tissues;

With the EU’s Mutual Recognition Procedure successfully completed, the new labeling with expanded indications will be implemented in the following 15 European countries: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Spain, Sweden, and the United Kingdom.

BRACCO IMAGING
MILAN, ITALY
www.bracco.com
Premium Ultrasound system for Women’s Health

The result of Toshiba Medical’s 50 years of dedication to ultrasound and partnerships with leading obstetricians from around the world the company’s Aplio i-series combines superior image quality with the most advanced clinical applications. Together with the current Aplio 500/400/300 Platinum series and the Xario 200/100 Platinum series Toshiba now offers a broad range of attractive ultrasound products in the field of OB/GYN. The new iBeam-forming architecture provides enhanced image quality thanks to sharper, more homogeneous ultrasonic beams. This further strengthens Toshiba Medical’s leading position in 2D image quality, which is most important in first trimester scanning and early detection of abnormalities. Simplified controls, a visual guided user interface and automated image optimization features help to boost productivity, even during the more complex examinations, without compromising on accuracy and precision. Newly developed transducers for the Aplio i-series are again setting a new standard for routine scanning and advanced prenatal diagnosis by utilizing.
Cloud-based Ultrasound Enables Instant Collaboration Among Clinicians

GE Healthcare and Trice Imaging, Inc, a cloud-based medical imaging solutions provider, have announced a commercial partnership to provide a new way for clinicians to connect with their colleagues and patients. This solution — called Tricefy — adds cloud-based image sharing, diagnostic collaboration, remote reviewing, archiving and Electronic Health Record (EHR) integration to GE Healthcare’s Ultrasound Women’s Health product portfolio. The system enables collaboration among physicians through one-click ultrasound sharing and secure archiving. “With clinicians and patients increasingly demanding seamless access to medical imaging, we’re committed to providing simple solutions that are not only clinically intuitive, but also make the care process more fluent,” commented Roland Rott, General Manager of Women’s Health Ultrasound for GE Healthcare. “The Tricefy solution does just that, as it meets a growing need by clinicians to collaborate with remote colleagues and share examination results with patients.”

Tricefy seamlessly integrates with GE Healthcare’s Women’s Health ultrasound offerings – including the Voluson E series product line and ViewPoint 6 reporting software – and will ultimately align with GE Health Cloud. Tricefy improves the clinical, hospital and patient experience in several ways:

• CLINICIANS can now access images and reports from anywhere, and remotely collaborate with other physicians via cost-efficient, secured storage.

• HOSPITALS can see economic benefits as well, given that Tricefy integrates into existing PACS Systems, saving on implementation costs. In addition, the solution eliminates the need for DVDs or thumb drives.

• Receiving their baby’s first images is among the most exciting moments for expectant parents. With Tricefy, PATIENTS will receive high quality images, videos and reports easily and directly on their phones/emails during the course of a routine ultrasound exam.

“Tricefy is an invaluable tool for me, for my colleagues, and for patients,” added Dr. Greggory DeVore, Specialist in Maternal Fetal Medicine in Pasadena, California. “Within moments, I can consult with a referral source or send the images to remote pediatric colleagues and cardiologists prior to meeting with the patient when it comes to congenital heart defects or other similar issues. Tricefy is a powerful research tool when collaborating with other institutions in which DICOM images and clips are exchanged for evaluation. I can also provide images via mobile phone or tablet to my patients almost instantaneously.”

GE HEALTHCARE
CHICAGO, IL, USA
www.gehealthcare.com

DR Retrofit portfolio expanded with introduction of 17x17 inch detector

Agfa has expanded its DX-D Retrofit line with the introduction of the versatile, vendor-neutral direct radiography (DR) DX-D 60 detector which easily fits into existing radiography rooms and provides DR workflow without the higher cost of room replacement. In addition to virtually instant image access, technologists do not have to rotate the 17x17 inch DX-D 60 for radiology exams that would otherwise require portrait and landscape detector rotations, thus greatly improving image acquisition speed and workflow. The new system is cassette sized, 17x17 inch (43 x 43 cm) detector and fits into existing x-ray bucky trays. DX-D 60 is available with either gadolinium (GOS) or cesium (CsI) based scintillators.

This and other retrofit options are key components to Agfa’s Fast Forward to DR program. Retfolios allow healthcare providers to upgrade their technology economically, circumventing the need for costly complete room replacements, while enhancing technological capabilities. When healthcare providers retrofit existing units with DR, they benefit from improved image quality, the potential for lower doses of radiation when used with cesium (CsI) detectors and realize exceptional value while still being responsive to government regulations that maximize reimbursement.

Louis Kuitenbrouwer, Vice President Imaging Division. Said “We created our Fast Forward to DR Program and creative acquisition strategies specifically for customers who are struggling to find capital funding.”

AGFA HEALTHCARE
MORTSEL, BELGIUM
www.agfahealthcare.com
Hand-Carried Ultrasound System

Mindray has announced the launch of its new M6 hand-carried ultrasound system. Configured with full range transducers, advanced clinical functions, and intelligent measurement tools, the M6 makes ultrasound scanning and diagnosis accurate and versatile in extremely compact size. “Health care within reach is always the promise made by Mindray,” said Mr. He Xujin, General Manager of the Medical Imaging System Business Unit. “Benefitting from technology migrated from established hand-carried ultrasound systems, the M6 offers the best balanced performance with a super wide range of tools that maximize diagnostic capability. Covering general imaging, OB/GYN and point of care, the M6 provides advanced and complete solutions including HR Flow, UWN Contrast Imaging, Natural Touch Elastography, 4D imaging, TDI & TDI QA and Free Xros M/CM.

The M6 is also equipped with automatic measurement, intelligent workflow, onboard education software and flexible connectivity solutions, reducing repetitive steps and button strokes, thus enabling diagnoses to be made in a smart way. Application-specific auto-measurement packages include Auto IMT, Auto LV, Smart OB etc., and all maximize scanning comfort. With the tutorial function iScanHelper, practitioners can learn basic scanning skill during real time scanning. iStorage and Medsight are software/App supporting transferring clinical images to PC or even smart phone to maximize the clinical efficiency. MINDRAY SHENZHEN, CHINA www.mindray.com

Imaging Diagnostics for Women’s Health

Samsung Medison has introduced a comprehensive diagnostic solution for women from family-planning to cancer screening, helping accurate diagnosis for health issues that women may experience throughout their lifetime. Dongsoo Jun, President of Health & Medical Equipment Business of Samsung Electronics and CEO of Samsung Medison said “Samsung is committed to creating solutions that provide clinicians with better imaging and help them make better management decisions for their patients.”

- Crystal Clear — Defining women’s lifetime diagnostic challenges into four repetitive categories from family-planning, healthy pregnancy, healthy birth to Gynecology & breast health, Crystal Clear is Samsung’s comprehensive ultrasound imaging solution that provides continuous diagnostic tools designed for each stage. With one Samsung ultrasound system, clinicians can provide proper diagnosis to any Obstetrics and Gynecology patients.
- IOTA-ADNEX — In collaboration with the International Ovarian Tumor Analysis (IOTA) group, Samsung has incorporated the ADNEX (Assessment of Different NEoplasias in the adnexa) decision support tool for the classification of ovarian tumors into the ultrasound system. The ADNEX model not only accurately classifies ovarian masses as benign or malignant, but also sub-classifies malignancies, thus giving the opportunity for more nuanced management decisions. Once the straightforward ultrasound variables have been entered into the model, ADNEX automatically gives a graphical representation of the risks of ovarian cancer to the clinician, enabling instant feedback to the patient. Prof. Tom Bourne, from Imperial College, London, UK and a member of the steering committee of the IOTA group said, “The ADNEX model is based on data from over 5,900 women from 24 centers in ten different countries. It is a decision support tool that has both a high sensitivity and specificity for ovarian cancer, but can also sub-classify malignancies to help personalize management for patients. Integrating the model into the ultrasound machine makes it easy to use and in effect builds intelligence into the machine.”
- Crystal Vue Flow — Samsung also introduced new Crystal Vue Flow, by adopting the existing Crystal Vue which is an advanced 3D volume rendering technology (and featured on the front cover of the Ultrasound in Obstetrics & Gynecology (UOG) journal earlier this year). In addition to innovative volume rendering technology, it now adds flow information that shows vascular structures with increased depth perception and demonstrates vessels in different imaging planes. Prof. Christoph Lees, visiting Professor at KU Leuven, Belgium and Reader in Obstetrics and Fetal Medicine at Imperial College in the U.K., said, “For visualization of fetus, evaluation of fetal face and CNS, we found that Crystal Vue may provide more anatomical information than the conventional 2D or 3D ultrasound and can give imaging comparable to MRI”. He added, “Crystal Vue Flow combines morphological information with hemodynamic flow, and allows a deeper understanding of fetal vascular anatomical variants and neighboring vessels, particularly valuable in our experience for morbidity adherent placenta.”

SAMSUNG MEDISON SEOUL, KOREA www.samsungmedison.com
Incredible things happen when you layer one medical imaging viewer across your enterprise.

Our unified and yet flexible viewing technology offers the ability to adapt to the specific needs of your department while bridging the workflow gaps which are common to multi-specialty imaging workflows. We’ve designed our solutions with the speed and interoperability you need to work with the systems you own and to prepare your organization for the future. We offer integrations for VNA, HIE, RIS, PACS and other interfaces to make it possible. Of course, we are a world-leader in advanced visualization tools, too. We’ve designed our solutions with the speed and interoperability you need to work with the systems you own and to prepare your organization for the future. Learn more at www.terarecon.com.