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Canon acquires Toshiba

Last year, the Japanese tech giant Canon acquired Toshiba Medical Systems Corporation in a move that propels Canon deep into the global health-care market and promises a host of synergies for delivering world-class medical devices and solutions.

DIAGNOSIS · TECHNOLOGY · THERAPY · PREVENTION

NOVEMBER 2017

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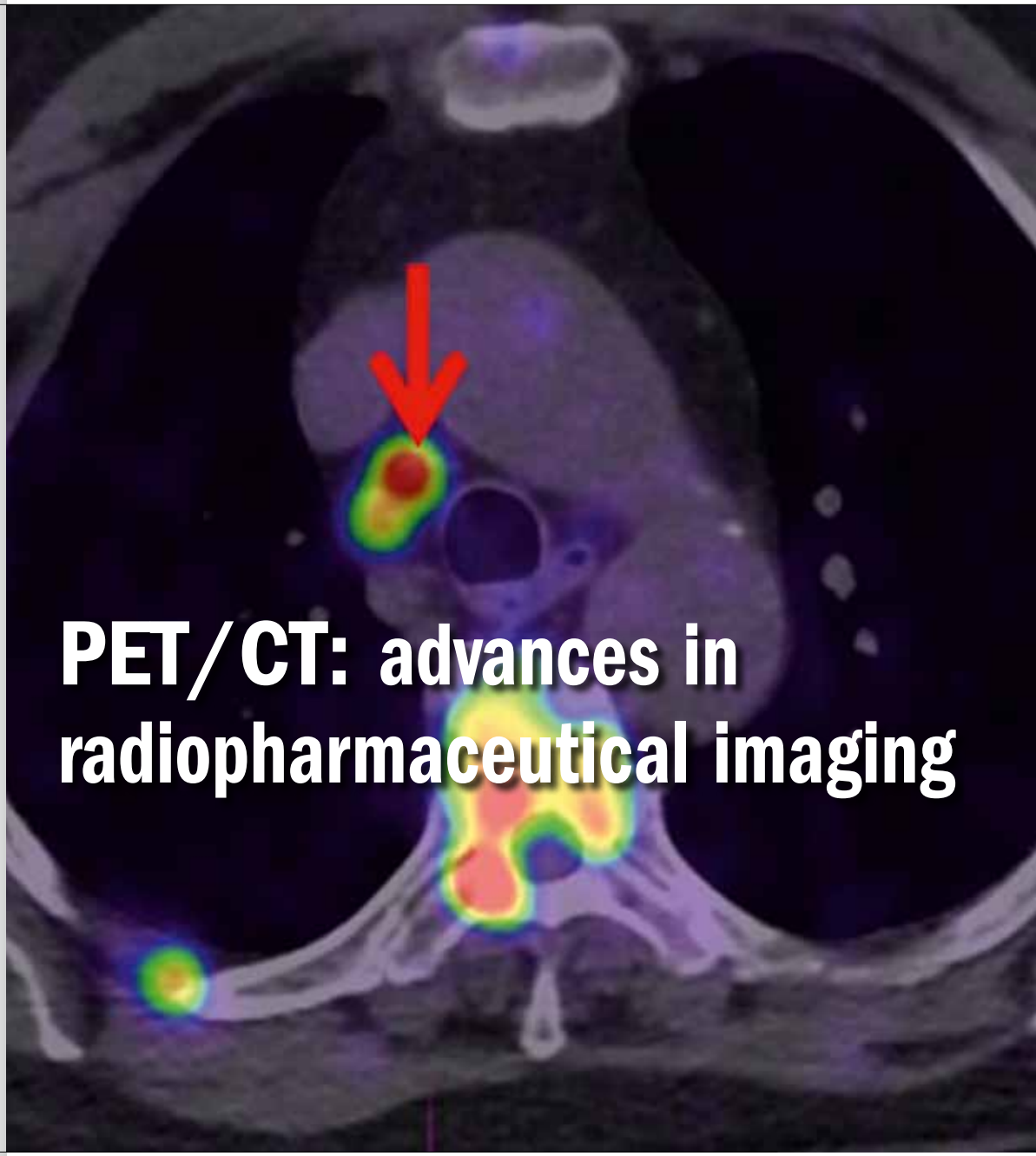

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BY ALAN BARCLAY, Ph.D.

The potential of AI in radiology and the fear of accepting new technology

The evidence is inescapable, at least if the number of peer-reviewed papers with the key-words Artificial Intelligence (AI) and Radiology accessible in PubMed is anything to go by. AI seems to be the "next big thing" in radiology. There is an exponentially growing number of scientific papers being published on the subject of AI in some form or another in the medical literature — as opposed to the more arcane branch of computing science where for many years most of developers active in the field of machine learning published the results of their fundamental research. Now remarkable advances in the development of convoluted neural networks and computer network architectures, not to mention the ever-increasing power of computing hardware, especially graphics processing units, have meant that artificial intelligence and machine learning are at last coming out of the purely academic discipline where up until recently they were mostly restricted.

It's true that the vast majority of the publications dealing with AI in radiology are still limited to evaluation or clinical validation studies. There are very few AI applications running in routine, day-to-day radiology.

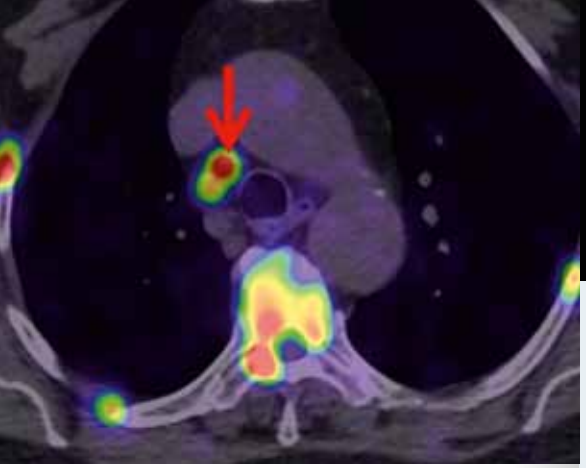
However the sheer head of steam being built up by the development of AI approaches means that almost certainly, sooner or later, AI applications will enter into the mainstream of radiology, driven by the promise of huge improvements in the efficiency of radiology workflows. The ideal future outcome is portrayed as something like "the machine-learning algorithms will take care of the routine, humdrum activities of the vast majority of relatively simple examinations that the typical front-line radiologist currently deals with, so freeing up the radiologist to deal with more complex cases, which in addition have the advantage of being more interesting and professionally rewarding".

And there is no question that most such radiologists in the trenches need such help. One study (*McDonald RJ, et al. The effects of changes in utilization and technological advancements of cross-sectional imaging on radiologist workload. Acad Radiol. 2015; 22(9): 1191*) estimated that in one institution (the prestigious Mayo clinic) imaging volumes had grown at such a disproportionate rate that the average radiologist reading CT or MRI examinations had to interpret one image every 3-4 seconds in an 8-hour workday to meet workload demands. This already dire situation is exacerbated by the fact that the demand for radiology exams continues to increase inexorably. In addition, in several countries (the UK is a prime example) many radiologists are retiring and leaving the profession, without sufficient compensatory inflow of new resident radiologists.

Against this background, the real intriguing question is why not all radiologists are welcoming the approach of AI with jubilant open arms, in the manner of the sight of a relieving army coming to the aid of a beleaguered city. Instead, the promise of a bright new future has been tinged with fundamental doubts as to whether AI actually presents a threat to the very existence of the profession, with human radiologists being outmatched by the speed and accuracy of machines and relegated to some sort of maintenance role in the upkeep of the systems, which could even by-pass the radiologist entirely by sending results directly to the referring physicians. And it's not as though radiology has up until now been somehow totally unaffected from software developments bringing significant improvements to quality of images or ease of workload., to such an extent that without powerful computer systems a modern radiology department would basically stop dead in its tracks (as many did several months ago when their systems were infected by ransomware viruses).

But artificial intelligence seems to some too big a step. Could it be that the simple reason behind the scepticism of some radiologists is that they simply have an intrinsic fear of accepting new technology? In fact just like most humans.

However, again like many examples of the introduction of disruptive technologies in other fields, once these human radiologists get familiar with the real advantages that AI can bring them the welcome mats will be put out.



The 68Ga-THP-PSMA PET/CT modality offers a significant step forward in the management of prostate cancer. ^{68}Ga-THP-PSMA-PET also allows the visualisation of metastatic lymph nodes not detectable with conventional CT. **Front cover image courtesy of Theragnostics.**

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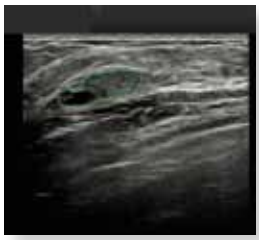
COVER STORY

^{68}Ga-PSMA-PET/CT imaging has rapidly emerged as a practice-changing imaging modality in prostate cancer. A novel PET tracer known as ^{68}Ga-THP-PSMA can be produced quickly and on-demand in the clinic using a simple single step kit much in the same way as traditional nuclear medicine Tc-99m radiopharmaceuticals are produced.

..... by Dr Greg Mullen

REPORTS



Categorization of focal breast lesions according to the BI-RADS US lexicon: the role of a CAD making support system (S-Detect)

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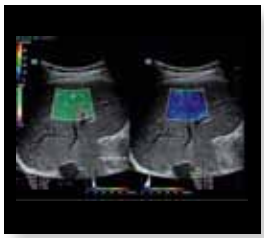

Ultrasound and elastography: a Greek center of excellence

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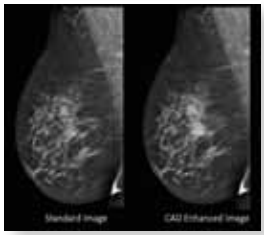

CAD in breast imaging A thriving women's health radiology practice at the technological top

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IMAGING NEWS

FEATURE ARTICLES

DI EUROPE

COMING IN THE NEXT ISSUE:
Enhancing MRI logistics

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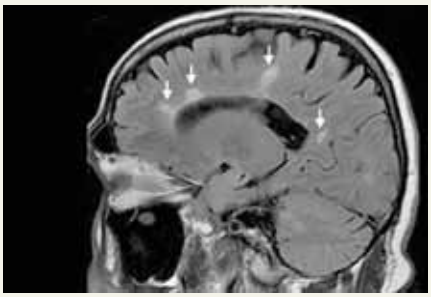
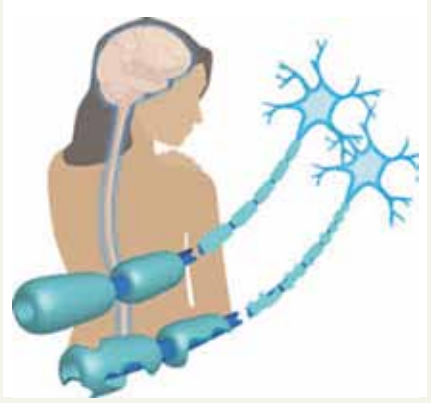
Guidelines for brain and spinal cord MRI protocols updated in light of GBCA findings

The Consortium of Multiple Sclerosis Centers (CMSC), the U.S.-based organization committed to the development and advancement of best practices in multiple sclerosis has proposed updates to the standardized MRI protocol used when evaluating people suspected of having MS and for following individuals undergoing treatment for MS. CSMC



is the leading U.S. educational, training, and networking organization for MS healthcare professionals and researchers. The CMSC's mission is to promote high quality MS care through educational programming and accreditation including live and online events, research grants, technical journals and papers, and targeted advocacy efforts. The CMSC member network includes more than 11,000 international healthcare clinicians and scientists committed to MS care.

The guidelines and indications that have been proposed for updating are those for standardized brain and include attention to the use of gadolinium, based on new data, survey results and expert opinion.



Clinical guidelines from the CMSC for the diagnosis and follow-up of MS had previously recommended the routine use of gadolinium-based contrast agents (GBCA) in brain MRI for the diagnosis and follow-up of patients with MS. Soon after the publication of these recommendations in 2015, the CMSC became aware of the concerns regarding gadolinium deposition in the brain and the recommendations of the FDA to limit GBCA use to appropriate clinical circumstances. In Europe the regulatory authorities have proposed the withdrawal from the market of certain, linear GBCAs.

The proposed 2017 revised guidelines that are posted on the CMSC website (www.mscare.org), now state, "While there is no known central nervous system toxicity, GBCAs should be used judiciously, recognizing that gadolinium continues to play an invaluable role in specific circumstances related to the diagnosis and follow-up of individuals with MS." This is an important change compared to the earlier recommendation. Other key changes to the MRI protocols since the 2009 include emphasis on 3D sequences for brain MRI, Progressive Multifocal Leukoencephalopathy (PML) specific monitoring protocol, and optional orbit MRI protocol for severe optic neuritis.

Key changes to the clinical guidelines since 2009 includes more specific timing of brain MRI for monitoring patients on disease modifying therapy, specific timing for brain MRI for PML surveillance, updated evidence on the value of MRI changes in determining treatment effectiveness, and inclusion of radiologic isolated syndrome.

"The CMSC's goal in posting these guidelines is to standardize the MRI protocol and make these recommendations a useful guideline for neurologists, neuroradiologists, and related healthcare professionals during initial evaluations and during follow-up of patients with MS, and ultimately provide optimum care for those individuals dealing with this unpredictable disease," said June Halper, Chief Executive Officer of the CMSC.

The 2017 Proposed Revised Guidelines of the CMSC MRI Protocol for the Diagnosis and Follow-up of MS can be found under the "Resources" section on the CMSC website at wwwms-care.org. The 2017 guidelines are subject to change since the CMSC Task Force is in the process of review. The 2015 MRI Guidelines from the CMSC Task Force published in the American Journal of Neuroradiology can also be accessed from this page.
wwwmscare.org/page/MRI_protocol.

U.S. study aims to prove value of mobile CT stroke units

Roughly every 40 seconds, someone in the United States will have a stroke (similar statistics apply in Europe). Almost every four minutes, one of those people will die as a result. Against that backdrop, the UCLA Health in Los Angeles has officially launched the first mobile stroke unit on the West Coast of America, enabling rapid delivery of brain-saving medications to stroke patients who might otherwise face debilitating delays in treatment.

"Rapid response is critical, because the sooner a stroke is treated, the better the patient's outcome," said Dr. May Nour, medical director of the UCLA Arline and Henry Gluck Stroke Rescue Program. "We know from research at UCLA that in a typical stroke, for every minute that goes by without treatment, 2 million brain cells die."

A mobile stroke unit is a unique type of ambulance equipped with a mobile CT scanner, which allows doctors to diagnose and treat strokes in the field with appropriate medications. Within the unit are a mobile blood-testing laboratory, as well as a neurologist, critical care nurse, CT technologist and paramedic.

"With the UCLA Health Mobile Stroke Unit, we are bringing the hospital to the patient instead of the patient to the hospital, in order to save as much brain as possible," said Dr. Jeffrey Saver, director of the UCLA Comprehensive Stroke Center.

The UCLA unit is the first such unit to operate in California. although MSUs have been deployed in other U.S. cities and in Europe. It will be the West Coast anchor of the first national demonstration project to gather data on the degree of improved patient outcomes and cost-effectiveness with accelerated field treatment. Positive results from the study could enable the U.S. Federal Centers for Medicare and Medicaid Services and other insurers to reimburse emergency medical service and hospital systems for mobile stroke clinical activities. Nour is optimistic. "To be able to take care of stroke patients in the very first minutes after onset, when there is the most brain to save, is our ultimate goal," she said. "Recovery and quality of life for stroke survivors is of utmost importance. By providing treatment in the most efficient timing, we offer patients the greatest possibility of improved clinical recovery."

In the initial phase of the pilot program, a neurologist specializing in stroke treatment will be riding in the unit. As the program develops, however, a neurologist will oversee care more efficiently via a live video and voice connection from the Ronald Reagan UCLA Medical Center.

"Definitive treatments for acute stroke can only be started after a head CT is done and shows the type of stroke the patient is having," Nour said.

This past summer, the Los Angeles County Board of Supervisors voted to provide additional funding of nearly $1.5 million to enable the state-of-the-art vehicle to operate every week, instead of the original plan to operate every other week, and to extend the life of the pilot program from 18 to 30 months. The additional funding also will increase the geographic reach of those served by the unit and enhance the quality of data gathered through the project.

"Minutes matter when it comes to treating strokes," said Supervisor Janice Hahn, who wrote the motion for funding. "With a mobile stroke unit operating in L.A. County, doctors will be able to diagnose and treat stroke patients faster than ever before — making it more likely that they not only survive, but go on to live longer, healthier lives."
www.uclahealth.org/

New lung cancer screening guidelines proposed

Each year, more people die of lung cancer than of colon, breast and prostate cancers combined, and low-dose CT (LDCT) screening for lung cancer has become a standard practice mostly due to the results of the U.S. National Lung Cancer Screening Trial whch showed a reduction in cancer-related mortality with LDCT screening. Evidence continues to evolve, in turn informing the benefits and risks of LDCT in clinical practice.

Lung cancer experts have proposed new lung cancer screening guidelines. Key recommendations and shifts from previous guidelines include:

- For asymptomatic smokers and former smokers age 55 to 77 who have smoked 30 pack-years or more and either continue to smoke or have quit within the past 15 years, it is suggested that annual screening with low-dose CT should be offered.
- For asymptomatic smokers and former smokers who do not meet the smoking and age criteria above but are deemed to be at high risk of having/developing lung cancer based on clinical risk prediction calculators, it is suggested that low-dose CT screening should *not* be routinely performed.
- For individuals who have accumulated fewer than 30 pack-years of smoking or are younger than age 55 or older than age 77, or have quit smoking more than 15 years ago, and do not have a high risk of having/developing lung cancer based on clinical risk prediction calculators, it is recommended that low-dose CT screening should *not* be performed.
- For individuals with comorbidities that adversely influence their ability to tolerate the evaluation of screen-detected findings, or tolerate treatment of an early stage screen-detected lung cancer, or that substantially limit their life expectancy, we recommend that low-dose CT screening should *not* be performed.

"This guideline differs from our previous guideline as we went beyond discussing harms and benefits," said Dr Peter Mazzone, guideline chair. "We addressed implementation of low-dose CT screening, including who to screen, how to identify appropriate patients for screening, how to conduct a shared-decision-making visit, how to perform LDCT and how to manage abnormal findings."

"The potential benefit of cancer screening to reduce the number of cancer-related deaths must be balanced with potential harms of screening," said Dr Gerard Silvestri, guideline panelist and CHEST immediate past president. "Current evidence suggests that even within groups at high risk of developing a cancer, only a small fraction of those screened will benefit, while everyone screened is exposed to potential harms including physical and psychosocial consequences of identifying and subsequently evaluating a screen-detected nodule, radiation exposure, overdiagnosis and overtreatment. For this reason, our recommendations for screening have evolved to be even more selective and specifically target those highest risk populations. The evidence currently does not support widespread adoption of lung cancer screening outside of those patients described in our recommendations."
https://tinyurl.com/Guideline-report

Improving pancreatic cancer survival through use of MR-guided adaptive radiation

Data presented at the recent 2017 Annual Meeting of the American Society for Radiation Oncology (ASTRO). showed compelling early results on the use of an MR-guided adaptive radiation system for the treatment of inoperable, locally advanced pancreatic cancer.

The MRIdian system (commercialized by Viewray) allows clinicians to visualize the tumor and nearby soft-tissue anatomy throughout radiation treatments using real-time diagnostic MR-visualization. As a result, the on-table adaptive radiation therapy allows doctors to respond to subtle anatomical changes observed on a day-to-day basis and reshape the dose to better match the current contours of the tumor. By more accurately targeting the tumor, and reducing treatment radiation dose to surrounding organs such as the duodenum, small bowel, stomach and liver, a higher and potentially more effective radiation dose may be delivered without increasing the risks of side effects and complications for the patient.

Key data points and findings from the presentation included the following:

• The study detailed a retrospective review of 42 locally-advanced pancreatic cancer patients treated with MRIdian at four institutions.

• The authors examined survival and toxicity rates for two unique cohorts of patients. One sample received a higher biologically effective dose (maxBED10 >90), primarily enabled by MRIdian MR-guided on-table adaptive radiotherapy. The other sample received a lower, more conventional biologically effective dose (maxBED10 <90), using non-adaptive therapy.

• The cohort receiving the higher dose demonstrated a near doubling of median overall survival (Kaplan-Meier estimated median overall survival of 27.8 months compared to 14.8 months).

• Patients treated with higher radiation doses reported no grade 3 or higher toxicities (0 percent). In comparison, those patients receiving lower doses via non-adaptive treatments experienced 15.8 percent grade 3 or higher toxicities.

"*High-definition MR now enables oncologists to detect the slightest anatomical changes that occur from one day to the next and in real-time while the patient is being treated. Coupled with new adaptive radiation therapy software tools, we create new customized plans in minutes, all while the patient is on the treatment table,*" said Percy Lee, M.D., senior author and Associate Professor and Vice Chair of Education for the Department of Radiation Oncology at the David Geffen School of Medicine at UCLA. "*The data suggest that higher radiation doses with adaptive MR guided radiation therapy may improve survival in pancreatic cancer while maintaining a very favorable toxicity profile. These outcomes warrant further investigations.*"

www.astro.org

Brain imaging reveals ADHD as a collection of different disorders

Researchers have found that patients with different types of attention-deficit/hyperactivity disorder (ADHD) have impairments in unique brain systems, indicating that there may not be a one-size-fits-all explanation for the cause of the disorder. Based on performance on behavioral tests, adolescents with ADHD fit into one of three subgroups, where each group demonstrated distinct impairments in the brain with no common abnormalities between them. The study, (*Stevens MC et al. Functional Neuroimaging Evidence for Distinct Neurobiological Pathways in Attention-Deficit/Hyperactivity Disorder, Cognitive Neuroscience and Neuroimaging. 2017*) has the potential to radically reframe how researchers think about ADHD. "This study found evidence that clearly supports the idea that ADHD-diagnosed adolescents are not all the same neurobiologically," said first author Dr. Michael Stevens, of the Olin Neuropsychiatry Research Center, Hartford, CT, and Yale University. Rather than a single disorder with small variations, the findings suggest that the diagnosis instead encompasses a "constellation" of different types of ADHD in which the brain functions in completely different ways.

The researchers tested 117 adolescents with ADHD to assess different types of impulsive behavior — a typical feature of ADHD. Three distinct groups emerged based on the participants' performance. One group demonstrated impulsive motor responses during fast-moving visual tasks (a measure of executive function), one group showed a preference for immediate reward, and the third group performed relatively normal on both tasks, compared to 134 non-ADHD adolescents.

"These three ADHD subgroups were otherwise clinically indistinguishable for the most part," said Dr. Stevens. "Without the specialized cognitive testing, a clinician would have had no way to tell apart the ADHD patients in one subgroup versus another." Dr. Stevens and colleagues then used functional magnetic resonance imaging (fMRI), which that allows researchers to make connections between behavior and brain function, to investigate how these different impulsivity-related test profiles related to brain dysfunction.

"Far from having a core ADHD profile of brain dysfunction, there was not a single fMRI-measured abnormality that

could be found in all three ADHD subgroups," said Dr. Stevens. Instead, each subgroup had dysfunction in different brain regions related to their specific type of behavioral impairment.

"The results of this study highlight that there are different neural systems related to executive functions and reward processing that may contribute independently to the development of ADHD symptoms," said Dr. Cameron Carter, Editor of Biological Psychiatry: Cognitive Neuroscience and Neuroimaging.

It will take more research to prove that ADHD is a collection of different disorders, but this study provides a big step in that direction. "*Ultimately, by being open to the idea that psychiatric disorders like ADHD might be caused by more than one factor, it might be possible to advance our understanding of causes and treatments more rapidly*", said Dr. Stevens.

The findings suggest that future approaches using clinical assessments to identify the specific type of brain dysfunction contributing to a patient's symptoms may allow a more targeted approach to treatment. For example, medications that may not appear to work well in a group of ADHD patients as a whole, may be effective for one particular subgroup that arises from a specific causal pathway.
www.biologicalpsychiatrycnni.org

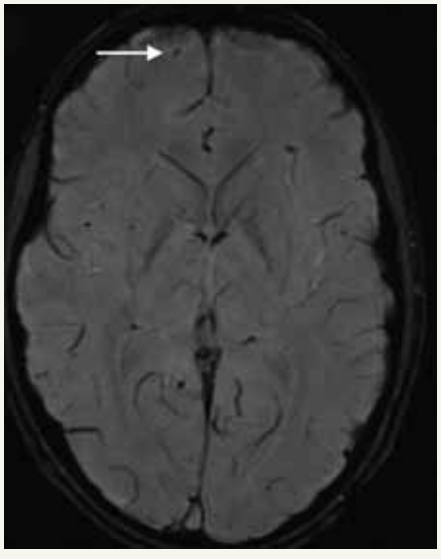
Is MRI needed in children with a sports-related concussion?

A new study reviewed more than 5 years of records of pediatric patients treated for sports concussion, the most common form of traumatic brain injury (TBI) among children, to determine if MRI revealed structural changes to the brain that may be related to persistent symptoms. The findings are reported in a recently published article (*Bonow RH et al. Prevalence of Abnormal Magnetic Resonance Imaging Findings in Children with Persistent Symptoms after Pediatric Sports-Related Concussion. J Neurotrauma 2017; 34: 1*)

Unlike more severe forms of TBI, sports concussion is characterized by functional disturbance rather than overt structural injury, and symptoms rapidly resolve in most cases. However, whereas the vast majority of adults are symptomatic for less than 1 week, recovery can sometimes be more protracted in children and adolescents; post-concussive effects such as headaches, irritability, and cognitive difficulties may persist for a month or more in about 25-30% of children.

The precise aim of the recent study was to characterize the use and utility of structural brain imaging with MRI in children with persistent symptoms post-concussion (PCS). Specifically, the researchers aimed to identify which patients with concussion were selected for MRI and to describe the pathologies identified on these scans. Because comprehensive brain MRI scans are costly and time-intensive, the researchers also sought to test the hypothesis that a limited brain MRI consisting of T2 fluid-attenuated inverse recovery (FLAIR) and susceptibility weighted imaging (SWI) would achieve a yield for abnormal results similar to that of a full scan.

Structural injury is uncommon in sports concussion in children, although nearly 13% of the children in the recent study underwent MRI. The current study indicated that MRI in children with persistent symptoms after concussion rarely identified brain injury.



"This is an important communication," says Prof J T Povlishock, Medical College of Virginia Campus of Virginia Commonwealth University, Richmond. "It provides important guidance for those clinicians caring for children with persistent symptoms of concussion. The large sample size and the rigor of the retrospective analyses strongly support the validity of the study's finding that only a small fraction of these children present with routine MRI-detectable intracranial lesions. While not endorsing a prescriptive approach, this report does provide important insight for those clinicians considering conventional MRI in children with persistent concussive symptoms."
https://tinyurl.com/Bonow-et-al-paper

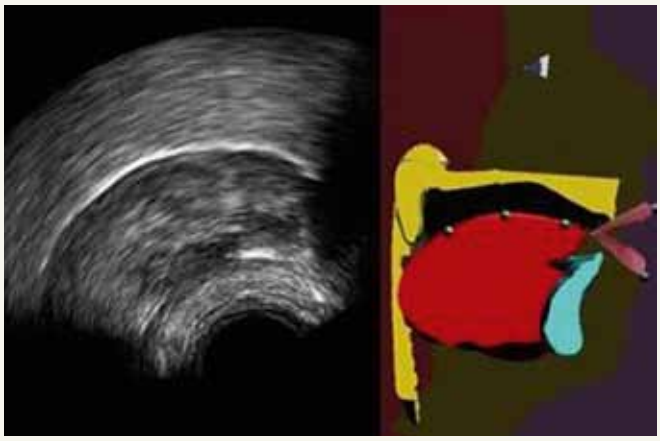
Augmented tongue ultrasound for speech therapy

A team of researchers in the French GIPSA-Lab in (CNRS/Université Grenoble Alpes/Grenoble INP) and at INRIA Grenoble Rhône-Alpes has developed a system that can display the movements of our own tongues in real time (*Fabre D et al. Automatic animation of an articulatory tongue model from ultrasound images of the vocal tract. Speech Communication, 2017 ; 93 : 63)*

Captured using an ultrasound probe placed under the jaw, these movements are processed by a machine learning algorithm that controls an "articulatory talking head." As well as the face and lips, this avatar shows the tongue, palate and teeth, which are usually hidden inside the vocal tract. This "visual biofeedback" system, which ought to be easier to understand and therefore should produce better correction of pronunciation, could be used for speech therapy and for learning foreign languages.

For a person with an articulation disorder, speech therapy partly uses repetition exercises: the practitioner qualitatively analyzes the patient's pronunciations and orally explains, using

drawings, how to place articulators, particularly the tongue: something patients are generally unaware of. How effective the therapy is depends on how well the patient can integrate what they are told. It is at this stage that "visual biofeedback" systems can help. They let patients see their articulatory movements in real time, and in particular how their tongues move, so that they are aware of these movements and can correct pronunciation problems faster.



Example of tongue model animations of the GIPSA-Lab articulatory talking head from ultrasound images, using the Integrated Cascaded Gaussian Mixture Regression algorithm for the sound [ata]

For several years, researchers have been using ultrasound to design biofeedback systems. The image of the tongue is obtained by placing under the jaw a probe similar to that used conventionally to look at a heart or fetus. This image is sometimes deemed to be difficult for a patient to use because it is not very good quality and does not provide any information on the location of the palate and teeth. In this new work, the team of researchers propose to improve this visual feedback by automatically animating an articulatory talking head in real time from ultrasound images. This virtual clone of a real speaker, in development for many years at the GIPSA-Lab, produces a contextualized — and therefore more natural — visualization of articulatory movements.

The strength of this new system lies in a machine learning algorithm that researchers have been working on for several years. This algorithm can process articulatory movements that users cannot achieve when they start to use the system. This property is indispensable for the targeted therapeutic applications. The algorithm exploits a probabilistic model based on a large articulatory database acquired from an "expert" speaker capable of pronouncing all of the sounds in one or more languages. This model is automatically adapted to the morphology of each new user, over the course of a short system calibration phase, during which the patient must pronounce a few phrases.

This system, validated in a laboratory for healthy speakers, is now being tested in a simplified version in a clinical trial for patients who have had tongue surgery. The researchers are also developing another version of the system, where the articulatory talking head is automatically animated, not by ultrasound, but directly by the user's voice.

http://www2.cnrs.fr/en/

Development of CT-based AI algorithms for diagnosis of neurological conditions

The National Neuroscience Institute (NNI) and Nanyang Technological University, Singapore (NTU Singapore) are collaborating to develop innovative technologies to better diagnose and treat patients with neurological conditions such as Parkinson's disease and brain injuries. These include developing an artificial intelligence system that can accurately identify types of traumatic brain injuries from CT scans. Another project involves coming up with a computing algorithm for more precise identification of tissues during brain surgeries. It aims to restore the neurological functions of patients suffering from various conditions such as Parkinson's disease. Over the next three years, the collaboration will also foster closer working relations between medical practitioners and engineers through annual fellowships and student attachment programmes..Associate Professor Ng Wai Hoe, Medical Director of the National Neuroscience Institute, said, "Innovation occurs at intersections of disciplines, knowledge and expertise. Doctors have a deep understanding of clinical needs from their everyday interactions with patients. Our unique collaboration brings these medical needs to engineering laboratories – an environment where imagination is encouraged in the form of technological advances and capabilities.

"The rapidly ageing population will lead to a significant rise in neurological diseases globally. By harnessing the power of the human brain, neurotechnology can provide solutions to revolutionise the treatment of brain disorders. This partnership has great potential to be an innovation launchpad for neurotechnology."

Professor Lam Khin Yong, NTU's Chief of Staff and Vice President for Research, said, "This collaboration creates a unique multidisciplinary research environment by integrating healthcare with both medical and engineering expertise from NTU's Lee Kong Chian School of Medicine and College of Engineering.

"This will not only nurture next-generation doctors armed with a multidisciplinary skillset to meet Singapore's healthcare needs, but also enhance medical technologies to diagnose and treat neurological conditions more effectively."

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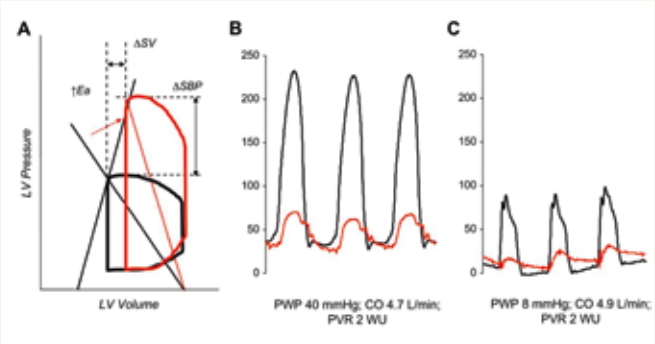
Non-invasive diagnosis of diastolic heart failure by cardiovascular magnetic resonance

Two new studies on diastolic heart failure are starting at the German Centre for Cardiovascular Research (DZHK). They will investigate whether this form of heart failure can be better diagnosed and its causes clarified by cardiovascular magnetic resonance imaging (CMR).

Diastolic heart failure, also called heart failure with preserved ejection fraction (HFpEF), is a disease whose name appears contradictory at first glance. Patients exhibit the symptoms of systolic heart failure; for example, they suffer from dyspnoea and water retention. Yet unlike with systolic heart failure, the pumping power of the heart is not impaired. In fact, the problem with HFpEF is that the left ventricle is stiff and does not sufficiently fill with blood. Whether the heart is insufficiently filled with blood is hard to measure with the non-invasive methods currently used, such as an ultrasound examination, and is often only identified late. Invasive methods are more exact, but expensive, onerous, and they cannot identify the causes of the disease.

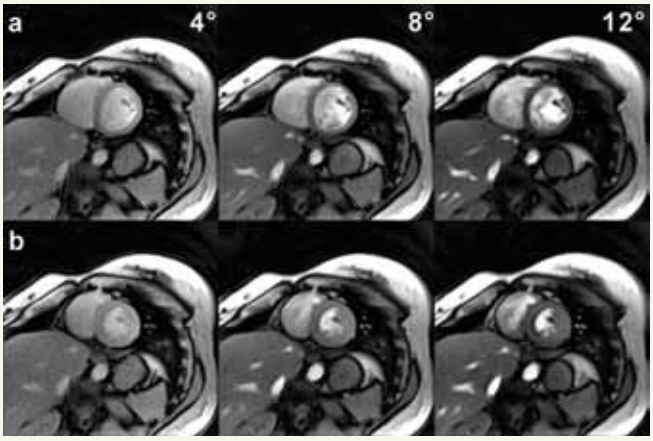
The multicentre study DECIPHER HFpEF DZHK headed by Prof. E Nagel of the University Hospital Frankfurt aims to establish cardiovascular magnetic resonance imaging (CMR) of the heart as the standard method for diagnosing HFpEF. To this end, the study will compare the CMR data with the results of the present gold standard in the diagnosis of HFpEF, namely invasive hemodynamics, where patients are examined using a cardiac catheter. In order to obtain a comprehensive picture of the validity of CMR, Nagel and his colleagues are also comparing the CMR measurements to the results of ultrasound examinations and analyses of myocardial tissue samples.

Using these data, the researchers aim to investigate whether CMR can help clarify why the disease arises, especially since the underlying cause of diastolic heart failure can vary greatly. For example, it can be caused by an inflammation of the heart muscle (myocardium), thickening of the myocardium, or decreased blood flow to the myocardium due to changes to the smallest blood vessels. CMR procedures developed in recent years enable these parameters to be assessed and are for the first time merged in a combined examination in the study. This is because, unlike an ultrasound examination, these new procedures can not only measure the flow and filling of the ventricle, but also visualize whether the heart muscle is inflamed, whether there is a pathological proliferation of the connective tissue, or whether there is a change to the small vessels.



The current "gold standard" method for diagnosis of HFpEF is by hemodynamic metyhods.Shown above are PV Loops measurements in HFpEF. From Borlaug and Kass. Heart Fail Clin 2010

"Only once the causes are clear can patients receive targeted medicinal therapy, because the treatment of myocardial inflammation differs entirely to that of a circulatory disorder", explains Nagel. "Significant therapeutic studies are only possible once we can distinguish between the various patient subgroups." DECIPHER HFpEF-DZHK12 aims to lay the foundation for this. It is the first multicentre study on the diagnosis of HFpEF worldwide. In addition to Frankfurt am Main, the DZHK sites in Berlin, Heidelberg, Göttingen, and Bad Nauheim are also participating. If the results are positive, the study could lead to a modification of the guidelines for diagnosing HFpEF.



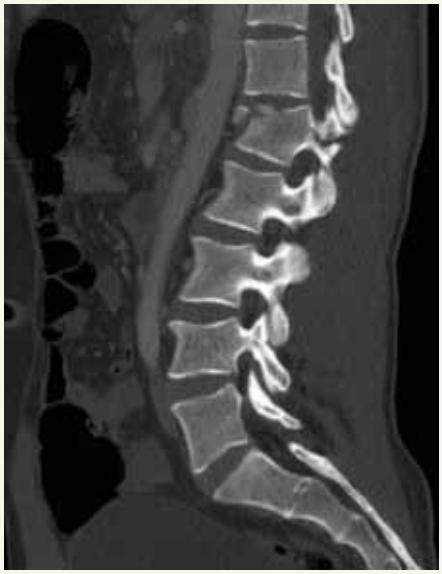
The second study evaluating the use of CMR for HFpEF will use a real-time CMR which does not require patient breath-hold and so allows exercise to be carried out during the CMR scan.

Complementing this work, a pilot study on a novel method of diagnosing HFpEF that goes one step further is also starting, this time at the Göttingen DZHK site. Headed by Dr. Andreas Schuster, researchers will test whether the newly developed real-time CMR technology is suitable for the early and safe diagnosis of HFpEF. This pioneering technology was developed by Professor Jens Frahm of the Max Planck Institute for Biophysical Chemistry in Göttingen and is currently only available in a few centers worldwide. It enables patients to create physical stress on their bodies during CMR measurements since with real-time CMR the patients can breathe freely during the examination. They do not have to hold their breath during measurements as they have to with standard techniques. This is made possible through an unprecedented acceleration of the MR system, whereby entire recordings of the heart movement are captured in one to two heart beats. With the help of this technology, the researchers at the Göttingen site now aim to define CMR parameters that can replace a hemodynamics stress test of the right ventricle. This stress test is usually conducted using a cardiac catheter and is one of the most sensitive and specific diagnostic procedures for HFpEF.

"When you do physical work or exercise, the heart beats faster. Thus, the time in which the heart is filled with oxygen-rich blood is reduced and any difficulty with the filling of the ventricle that may exist becomes even clearer", Dr. S Backhaus of the Heart Center Göttingen explains the concept of the stress test. In the study, the patients must ride a bike for the stress test during the CMR. To do this, a kind of stationary exercise bike is installed on the examination couch, so that patients can cycle while lying down during the CMR. In the process, the researchers measure the heart rate, which should reach between 100 and 110 beats per minute, in order to establish more clearly where the difficulty with filling the ventricle lies. The CMR examination will also be carried out at rest and will be compared with the results of the invasive hemodynamics, also conducted at rest and under stress. The advantage of the stress test during the CMR for the patients is that it is non-invasive, there is no exposure to radiation and yet it still produces detailed images with a high resolution for a precise diagnosis.

http://www.cardiac-imaging.org/decipher--hfpef.html

Clinically undiagnosed but radiologically evident spine fractures in older men



Fewer than a quarter of new vertebral fractures are clinically diagnosed, yet they often cause symptoms. Prior data in women suggest that incident clinically undiagnosed radiographic vertebral fractures (VFs) often are symptomatic, but misclassification of incident clinical VF may have biased these estimates. There are no comparable data in men. In a study of older men in the general population now published in the Journal of Bone and Mineral Research, clinically undiagnosed vertebral fractures that were evident on X-rays were associated with higher likelihood of back pain and limited physical activity. (F*ink HA et al, Association of Incident, Clinically Undiagnosed Radiographic Vertebral Fractures With Follow-Up Back Pain Symptoms in Older Men: the Osteoporotic Fractures in Men (MrOS) Study. J Bone Miner Res. 2017. doi: 10.1002/jbmr.3215*

The findings build on similar results previously reported in older women and point to the need for more effective strategies to detect and prevent vertebral fractures.

"Preventing these fractures may reduce back pain and related disability in older men," wrote the authors.

https://tinyurl.com/Fink-et-al-paper

MR guided focused ultrasound shows promise for treating Parkinson's tremor

An initial test to determine if a scalpel-free form of brain surgery can reduce tremor caused by Parkinson's disease has produced encouraging results. Further research is warranted, the researchers conclude in a paper published recently (*Bond AE et al. Safety and Efficacy of Focused Ultrasound Thalamotomy for Patients With Medication-Refractory, Tremor-Dominant Parkinson Disease: A Randomized Clinical Trial. JAMA Neurol. 2017 Oct 30*)

The small pilot study was led by Dr Jeff Elias of the University of Virginia School of Medicine, and was also conducted at Swedish Neuroscience Institute in Seattle. Twenty-seven participants with tremor-dominant Parkinson's disease were enrolled in the study; the research team randomly assigned 20 to be treated with focused ultrasound waves on their brains, while the others received a fake procedure, to account for any potential placebo effect. (They were later offered the opportunity to have the actual procedure). All had tremor that had resisted medical treatment, and all continued taking their existing Parkinson's medication. The trial participants who received the focused ultrasound procedure had a 62 percent median improvement in their hand tremor three months later. Those who underwent a sham procedure also improved but to a lesser degree, however, suggesting some placebo effect. Additional testing is needed to better establish the effectiveness of focused ultrasound for Parkinson's tremor, the researchers concluded.

The median age of trial participants was 67.8 years, and 26 were male. The most significant side effects reported were mild numbness on one side of the body, which later improved, and numbness of the face and finger, which were persistent. Two subjects also experienced partial weakness that recovered or improved during the study. The researchers believe that a larger, multicenter study is needed to better define the potential role of focused ultrasound in managing Parkinson's disease.

"Our findings suggest that the patients likely to benefit from this approach are those for whom tremor reduction is enough to improve their quality of life," said UVA researcher Dr Binit Shah.

https://tinyurl.com/Bond-et-al-paper

"Unfixable" things in current radiology workflows — that AI can fix

Over the past few months, the inescapable buzz in the world of radiology has been the growing realization that Artificial Intelligence (AI) technologies actually do have potential to address some of the current inefficiencies in typical radiology workflows. The interest in AI is not a passing fashion or technological flash in the pan — algorithms developed using AI appear to have a permanent place in the future of medical image analysis and interpretation.

One indication of the interest that AI is generating in radiology is the recently announced acquisition of the young startup company, McCoy Medical Technologies, by TeraRecon — a leading provider of medical image viewing solutions. We wanted to learn more about the acquisition and developments in the field, so we spoke to Dr. Steven Rothenberg, co-founder and currently Chief Medical Officer of TeraRecon's new spin out company, EnvoyAI.

Steven Rothenberg, MD, is Chief Medical Officer at EnvoyAI. Dr. Rothenberg is a physician entrepreneur with 13 years of experience in the medical industry and over 8 years of experience with various startup endeavors. He received a bachelor's degree in Physics from the University of Maryland and a medical degree from George Washington University. He is a radiology informatics fellow at the Baltimore VA Medical Center in located in Maryland, USA

Q *Let's start with the new startup company. Please tell us about EnvoyAI and how, and why, it started.*

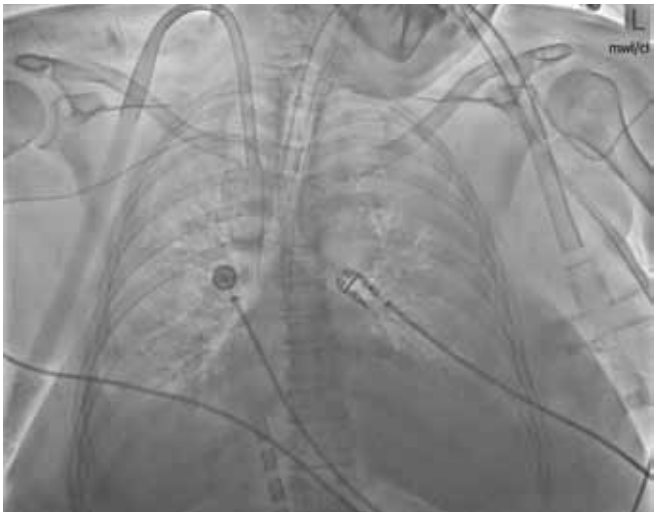
We founded McCoy Medical Technologies, now EnvoyAI, on the basis of a simple yet powerful idea about how to better leverage and clinically implement AI in Healthcare. Specifically, the idea for the company was to streamline the translational process for distribution and commercialization of AI algorithms from research into practice. Typically, such algorithms are developed in advanced clinical research institutions or start-up companies, which often lack the infrastructure to build and support the integration of a machine into the clinical workflow. A "machine" is what we call a trained algorithm that is wrapped in a software container with well-defined inputs and outputs; our platform hosts machines. The EnvoyAI platform builds upon the original codebase from McCoy and leverages TeraRecon's intellectual property, global salesforce, and implementation experience to turn our vision into a reality.

Q *AI has been an academic discipline for many years now. Why has there recently been such an explosion of interest in the field?*

There is a scientific answer as well as a business answer to that question. The scientific answer is that recent technological advances, particularly in the use of certain network architectures, have substantially improved the state of computer vision within the broader field of artificial intelligence. This has decreased the need for pre-processing steps, allowing for improved results with far less training data. As you would expect, better and cheaper hardware, particularly GPU hardware, has also contributed to research efforts.

"…. AI has a great potential to decrease intra/inter-reader variability and provide consistent diagnostic interpretation and error detection…."

As for the business reason AI is now taking off, I believe the focus is shifting to more pragmatic applications of the technology. The last five years were consumed by people falling into the hype and trying to use AI to solve every problem all at once, with poor results – in effect they were wide but not deep. More recently, we are starting to see people get past the hype and start focusing on more approachable, focused, practical applications. In practice, people are starting to aim at achieving high performance for a narrow problem with each application, and choosing to focus on building applications with real added clinical benefits. The focus on depth rather than breadth for applications is what is going to allow this technology to be adopted by doctors.



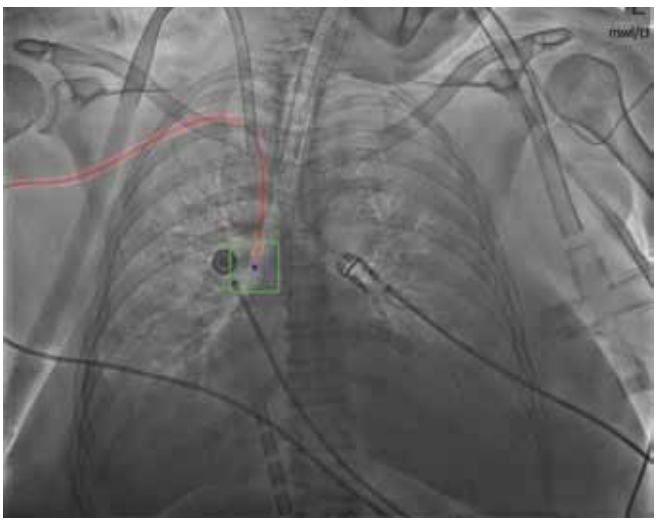


Figure 1. Example of a machine learning application for appropriate placement of support lines and tubes – the location assessment, with color visualization overlay, of the termination of a Peripherally Inserted Central Catheter (PICC) line. Images courtesy of Synho Do, PhD., Lab of Medical Imaging and Computation (LMIC), Massachusetts General Hospital and Harvard Medical School. *http://lmic.mgh.harvard.edu*

Q *There is a lot of hype about AI and Machine Learning. How do you see AI actually improving the current diagnostic environment in practice?*

This definitely connects closely to my answer above, and at a high level, I can say that the answer is all about the specific examples, rather than trying to do too much all at once. As a radiologist, I am constantly amazed by the power and sophistication of our technology, such as all the various imaging modalities that actually generate the images. I am simultaneously frustrated by the inefficiencies in the current workflow. Sub-optimal processes not only slow us down but — what's worse — they can also make the interpreting physicians more prone to errors. As I analyze my own day-to-day workflow, many problems spring to mind

"…. Data security is of primary concern, so we make it easy to keep data on-site, or to de-identify it before it is processed in the cloud …."

as troubling but relatively easy to solve with AI. Many of the problems seem to fall into the categories of: inefficient interpretation workflow, image annotation, and patient triage. It is helpful to break the examples into categories for discussion, but I think it is also important to emphasize that the value of AI isn't in trying to tackle all of image annotation at once – it is in finding specific problems where AI can add the most value. I will be sure to highlight specific examples rather than focusing on the abstract.

INEFFICIENT INTERPRETATION

A specific example here is lung nodule interpretation and follow up, which will be much more efficient with the use of AI embedded in the interpretive workflow. Correctly identifying and comparing lung nodules on chest CTs is an arduous task that can be dramatically improved with advances in computer vision. Using a combination of advanced co-registration and machine learned annotation algorithms, the change in volume of nodules could be better assessed in three dimensions and reported in an easily consumable way for referring physicians. The ability to easily review change in volume provided by machines will be a major leap forward. This will allow for improved efficiency and image annotation, which will enable physicians to consistently deliver optimal patient management.

IMAGE ANNOTATION

AI represents the dawn of a new era of quantitative image analysis. Instead of only reporting that a patient has mild or moderate emphysema, machines could present the actual quantitative data. For example, an algorithm could accurately segment lung volumes and provide quantitative insights, using routine acquisitions, concerning the underlying disease process. This can lead to better disease evaluation and treatment planning. It is important to note that each different disease context and imaging modality will also be handled by an algorithm focused on that task, so it is again important for algorithm developers to work with a very focused approach.

Along with the quantitative insights themselves, AI systems will show the most relevant content to physicians depending on clinical context. In the future, machines will show findings on the appropriate sequence with pre-calculated associated measurements so that the radiologist can spend more time with interpretation and higher-level thinking. In turn, this will reduce intra/inter-reader variability and facilitate an objective, standardized way to communicate with referring physicians.

PATIENT TRIAGE

AI can also help determine which studies need to be escalated to specialists for immediate attention. Instead of a RIS or EMR-driven workflow, we can create findings-driven workflows. Studies with critical findings such as a pneumothorax can already be identified by algorithms with high accuracy. Another example, as shown in Figure 1, is Dr. Do's PICC algorithm, which can alert the radiologist that a support line is misplaced and aid in diagnostic interpretation. We can use the critical findings in medical images to drive STAT prioritization in concert with input from the ordering physician. Again, a critical note about AI applied to triage is that each algorithm tackles a specific part of the challenge.

"…. Instead of RIS or EMR-driven workflows, we can create findings-driven workflows…."

AI will undoubtedly be a game-changer in problem areas that can be easily and drastically improved, such as those above. In particular, it seems that there is a lot of value to be gained as more and more highly focused and effective algorithms become available. A combination of many more specific algorithms will make a much bigger difference than all of the past "boil the ocean" initiatives combined.

Q *To realize the full potential of AI, what are the current challenges facing the development process?*

There is a growing amount of ground-breaking AI research being published all the time, including more than 3,000 PubMed-referenced articles in the last year alone. However, there are very few working machines actually being tested in clinical validation studies, and even fewer already in routine clinical use today. The problem is that the usual translational processes don't work well for this technology.

Lack of interoperability is part of the problem. The integration cost makes it difficult to validate algorithms prospectively, which is a major roadblock preventing an algorithm's adoption into clinical practice.

In addition to translational problems on the implementation side, there are important bottlenecks on the business side as well, which hinder the ability of algorithm/machine developers to scale their business. There are a large number of non-algorithm components to both a software product and, more generally, a software company. Many of the challenges, such as marketing, sales to hospitals, regulatory concerns, and customer support may be too difficult, time-consuming, or costly for small companies and research scientists to manage themselves.

Furthermore, for many researchers, it is simply too much extra work and too much of a risk to create a whole company in order to commercialize their research. The colossal effort required to create a successful software company in the healthcare space is a significant part of the reason that so many of the potentially useful algorithms are shelved rather than implemented clinically.

Aside from the business challenges, there is also a major clinical workflow issue that needs to be addressed in order to facilitate adoption: who is ultimately going to be in the driver's seat? Who do we trust, the physician or the robot? AI needs to help physicians make decisions, not make decisions for physicians. Arguments to the contrary misunderstand the state of modern technology to a significant extent. For the foreseeable future, we want doctors making decisions, and having the option to select certain specific tools to extend their capabilities. Therefore, it is crucial that AI results are reviewed and accepted or rejected, prior to sending them to PACS.

Otherwise, there is the potential for unintended downstream clinical and medicolegal consequences.

Q *So how can these problems be addressed?*

We saw a broken translational model in this industry, so we created the EnvoyAI Exchange, to enable and expedite algorithm implementation and development. This allows the overhead of commercializing algorithms to be shared across machines, which dramatically reduces the cost of commercialization for any given algorithm to a fraction of what it is today. The lower overhead costs allow lower pricing for hospitals, while still allowing for algorithm developers to quickly scale to a profitable position.

Inside of the Exchange, the actual developer of the machine no longer has to worry about, or be responsible for, machine-independent functions, such as: data privacy, security, HIPAA compliance, administration privileges, sales, marketing, workflow integrations, and technical support. Another advantage of the EnvoyAI Exchange is that it allows for both algorithm developers and distribution partners, such as TeraRecon, to use a machine's functionality with existing User Interface and User Experience (UI/UX) components.

This allows both for profitable commercialization of existing algorithms, and for the justification of new research to create machines that would not otherwise be worth creating. The future of medical image analysis will involve hundreds, or thousands, of algorithms working in tight coordination. It is impossible to imagine a hospital interacting and integrating with so many independent parties, so an ecosystem with an integration pipeline will be crucial for managing these functions and sharing machines.

Q *If the "Exchange" provided by EnvoyAI contains lots of individual machines from separate developers, how are data security and intellectual property handled?*

Data security is a key concern, so we make it easy for hospital customers to use machines in a configuration that they are comfortable with. Hospitals can choose to keep their data on-site with an "on premise" deployment using an instance of our Inference Appliance, or they can choose to de-identify their data with the EnvoyAI Liaison before it is processed in the Inference Cloud at lower cost.

With regard to the machine developer's intellectual property, in the cloud model, hospitals only have access to machine results, so stealing the code would be nearly impossible. In the "on premise" deployment, it will be extremely difficult to steal the code, not to mention illegal, and in violation of multiple contracts. We take our IP protection and data security responsibilities extremely seriously, and are more than willing to work with developers to ensure that they feel comfortable using us as a go-to-market approach. Thankfully, we have had the guidance of our new parent company, TeraRecon, in our corner while we figured this out. They have deployed hardware and software in thousands of hospitals, and have worked with many partners, so their expertise has proven invaluable as we have worked toward our official launch. We have also worked with regulatory consultants to make sure that we get this part of the model right.

"....The future of medical imaging analysis will involve hundreds, or thousands, of algorithms working in tight coordination. It is impossible to imagine a hospital interacting and integrating with so many independent parties...."

However, the most important part of our ecosystem development has been our conversations with dozens of algorithm developers over the last year, during which we were able to really dig into some of the greatest concerns and work on solutions that work for everyone involved. Over the last few months, as we have been starting to work on closing content deals, we have been blown away by how enthusiastic most algorithm developers are to work with us in the model that we put forward. After so many of these conversations, we are very confident that our system really does address the needs of the people who are building the AI systems that we believe are going to fix all of those traditionally unfixable problems in radiology.

Q *Now to the TeraRecon funding. What was the rationale behind TeraRecon's venture with EnvoyAI and how are you positioned with TeraRecon?*

That is a question I am asked a lot. To boil it all down, TeraRecon strategically funded EnvoyAI because we were a strong team with a great platform and we had a well-aligned, synergistic long-term vision. From our perspective, we wanted to partner with TeraRecon because nobody has more experience with advanced image processing than them. We also saw their positioning as a vendor-neutral 3D viewer parallel to how we see our open platform. EnvoyAI operates alongside TeraRecon as an independent company with a split board of directors that ensures independence. Our company has no natural competitors, which allows us to give access to our Exchange services and integration tools to any distributor or machine developer who wants to get involved.

More info at
https://envoyai.com
www.terarecon.com

Novel PET/MRI technology for enhanced breast cancer diagnosis

By Dr C. Kuhl, Dr V. Schulz, Dr T. Helbich, Dr D. Schaart, Dr. E Wandelmann, Dr D Schaart, Dr E Wardelmann, M. Crean & Dr P. Zolda.

In this article, we present our EU-funded project to develop a cutting edge hybrid PET/MRI technology for breast cancer detection and we report on the progress made during its first phase of research/development.

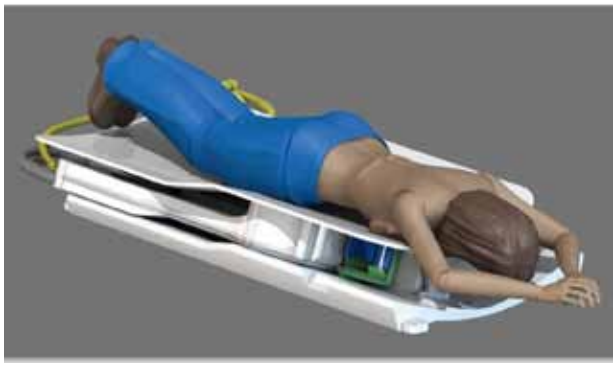


Figure 1. A patient model on the patient rest.

Breast cancer is the most common type of cancer and one of the main causes of cancer death in women. Despite the advances made in modern medicine and contemporary targeted therapies, the stage of breast cancer at the time of diagnosis is still the most important indicator of patient survival.

This means that there is a clear and urgent need for improved methods not just for early breast cancer diagnosis but also for the application of more personalised medicine. The concept of targeted therapies requires not only knowing about the presence or absence of cancer, but also an in-depth analysis of a given cancer to select and guide appropriate treatment. PET and MRI are diagnostic tools which provide functional and molecular information that is of vital importance for such treatment concepts. However, current approaches to PET/MR imaging lack the necessary sensitivity that is essential for the type of information needed to guide tailored therapies.

In our project *Digital Hybrid Breast PET/MRI for Enhanced Diagnosis of Breast Cancer (HYPMED)*, we aim to develop a hybrid system combining MRI and PET that facilitates earlier diagnosis of breast cancer and personalised therapy control.

To achieve this, we are designing and testing a combined PET-radiofrequency (RF) insert that can be connected to a conventional clinical MR scanner, thus transforming the device into a high-resolution PET/MRI hybrid system. This PET-RF insert can be used to identify even the smallest breast cancer foci and to better characterise the cancer, as well as its response to therapy. Another key benefit of this technology for patients is that the radiation dose of the new technology will, unlike other PET-MRI examinations, be comparable to the low dose of a regular digital mammogram.

HYPMED's new hybrid imaging technology will have a significant impact on breast cancer diagnosis and therapy, as the accuracy and reliability of the non-invasive detection of breast cancer, and the delineation of its extent, will be vastly improved. Apart from merely diagnosing the presence or absence of breast cancer, HYPMED will improve the non-invasive biological classification of breast cancers. In other words it will improve the assessment of its aggressiveness and so facilitate a better selection of the appropriate

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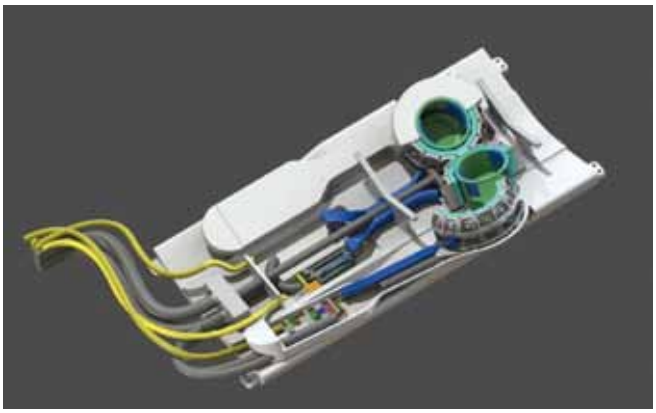


Figure 2. A close-up of the HYPMED PET-RF insert mechanics.

treatment. The expected improvement in response prediction, response assessment and establishing prognoses in patients undergoing therapy will allow earlier adaption of the therapy in case of treatment failure.

Project partners also expect that the HYPMED technology can be transferred to other clinical applications, such as the detection of prostate cancer, hybrid cardiac and brain imaging, so making the potential impact of the project extremely broad. The introduction of the breast PET-RF insert will reduce the overall economic costs associated with breast cancer, further bolstering the sustainability of the European healthcare system. The successful completion of the HYPMED project will also create new markets that will initially be served by the industry partners participating in the project. In addition to the clinical and academic collaborators, there are four industrial partners, namely Philips Electonics (The Netherlands), Futura Composites (The Netherlands), Noras MRI Products (Germany) & Intrasense (France).

PROGRESS SO FAR

To date, as the project reaches its second year, the design of the PET-RF insert mechanics has been completed, which is a solid basis for the design of the highly sensitive radiofrequency coil, as well as the development of the MR-compatible PET detector modules. This mechanical design is the result of extensive research in the areas of material science, nuclear science, radiofrequency technology and medical science, with each project partner putting their extensive expertise into the project. By drawing on the different disciplines, the result is that a design has been created that carefully balances all the necessary requirements. This had not been achieved previously for technical reasons.

Initial experiments on the subcomponents have already been successfully conducted, proving the viability of the newly designed subcomponents in the harsh environment of MRI, while good progress has also been made in implementing the Myrian software required to visualise the images produced by the HYPMED device, with the project's radiologists giving their feedback to ensure that it meets routine clinical needs.

Testing the clinical use of the PET-RF insert and its diagnostic utility will be carried out in a multicentre study scheduled to begin in early 2019. The study will involve 200 patients and will be carried out at the University Hospital Aachen in Germany and the Medical University of Vienna, General Hospital in Austria.

During the project's first 18-month period, preparatory patient studies for the development of the multimodality image processing software were conducted successfully. In addition, the preliminary drafts of the study protocol, patient information and informed consent forms as well as the documents necessary for ethical approval were prepared. For the correlation of multiparametric functional imaging information with established and novel tissue-based biomarkers, a control series of different breast lesions has been generated to define different types of immune infiltrate and other components of the tumor microenvironment.

With a consortium of ten partners from across Europe, including major universities, research institutes, SMEs and the industry corporations, the HYPMED project brings together a wide range of expertise. Prof. Christiane Kuhl from the University Hospital Aachen in Germany serves as the scientific coordinator of the HYPMED project while the European Institute for Biomedical Imaging Research (EIBIR) in Vienna, Austria acts as project coordinator and is responsible for HYPMED`s overall management. Other countries involved in the project include the Netherlands and France. Experts from the disciplines of radiology, engineering and image processing and computing are working together to produce this ground-breaking technology.

More information

For more information about HYPMED visit the project website:
www.hypmed.eu

The HYPMED Project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 667211

Bracco Imaging acquires SurgVision in expansion into the field of real-time fluorescence image-guided surgery

Bracco Imaging, a leading global company in diagnostic imaging, recently announced the acquisition of the Dutch company SurgVision, a high-tech start-up focused on a real-time Fluorescence Image Guided Surgery platform based on the combination of targeted imaging agents and a device for the efficient visualization of tumors during oncological surgical procedures.

More than 3.6 million people are diagnosed with solid malignant tumors every year in the US and the European Union. Surgery remains the primary curative option for most solid cancers: the scientific literature has long documented that complete tumor resection and tumor-specific debulking can significantly improve prognoses. But distinguishing healthy from unhealthy tissue has always been a difficult and recurring challenge during surgical procedures because visual inspection and palpation by hand — the only methods currently widely available — are limited in their diagnostic capability. Fluorescence Image Guided Surgery is an innovative intraoperative optical technique aimed at assisting surgeons in distinguishing tumors from surrounding tissue, using a combined infrared camera and contrast agent approach. In this context, SurgVision's innovative targeting solution is expected to provide significant improvements versus competing modalities and products, due to the extremely advanced features of its optical camera and the very sensitive targeting performance of its new imaging agent.

"*With the acquisition of SurgVision, already one of the most advanced companies in a very promising field, we intend to address a relevant, unmet medical need for oncology patients who have to undergo tumor removal surgery,*" said Fulvio Renoldi Bracco, Chief Executive Officer at Bracco Imaging. "The *SurgVision platform expands our imaging solutions for healthcare professionals in oncology and reinforces our long-lasting commitment to patient care,*" he concluded.

"*The investment in SurgVision provides Bracco Imaging with key competencies and technologies strategically adjacent to our core business,*" said Micol Fornaroli, Chief Strategy Officer at Bracco Imaging "*and, at the same time, this acquisition will accelerate the development of the projects currently in scope of our Research and Development efforts.*"

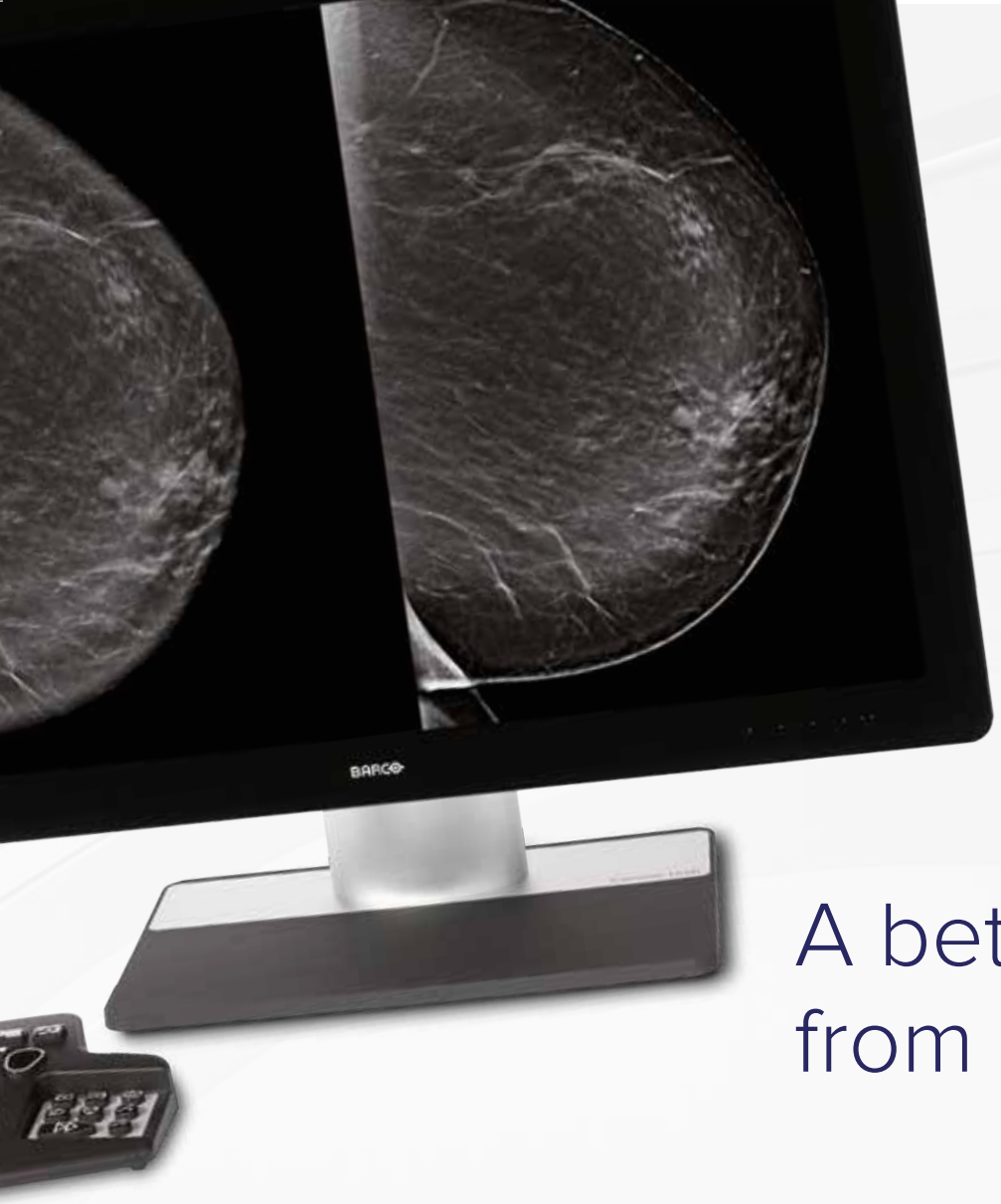
"*The acquisition of SurgVision by Bracco is a vote of confidence for the field of fluorescence image-guided surgery and for the achievements so far by the SurgVision team,*" said Ton van den Hoven, Chief Executive Officer at SurgVision. "*The expertise and commitment from Bracco will allow SurgVision to continue developing a solution that delivers on the potential of important clinical benefits for patients.*"

Bracco Imaging

Bracco Imaging S.p.A., part of the Bracco Group, is one of the world's leading companies in the diagnostic imaging business. Headquartered in Milan, Italy, Bracco Imaging develops, manufactures and markets diagnostic imaging agents and solutions that meet medical needs. Bracco Imaging offers a product and solution portfolio for all key diagnostic imaging modalities: X-ray Imaging (including Computed Tomography, Interventional Radiology, and Cardiac Catheterization), Magnetic Resonance Imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers. The compamy's diagnostic imaging offer is complemented by several medical devices and advanced administration systems for contrast imaging products in the fields of radiology. www.braccoimaging.com.

SurgVision

SurgVision is a high-tech innovative start-up company specialized in developing Fluorescence Image Guided Surgery platform solutions using high-definition cameras and tracers. The company was founded in August 2013, as a spin-off of the Technical University of Munich and is funded by De Friesland Participatiefonds and BioGeneration Ventures. SurgVision is headquartered in 't Harde, The Netherlands. www.surgvision.com.



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1. Results from Friedewald, SM, et al. "Breast cancer screening using tomosynthesis in combination with digital mammography." JAMA 311.24 (2014): 2499-2507; a multi-site (13), non-randomized, historical control study of 454,000 screening mammograms investigating the initial impact of the introduction of the Hologic Selenia® Dimensions® on screening outcomes. Individual results may vary. The study found an average 41% increase and that 1.2 (95% CI: 0.8-1.6) additional invasive breast cancers per 1000 screening exams were found in women receiving combined 2D FFDM and 3D™ mammograms acquired with the Hologic 3D™ Mammography System versus women receiving 2D FFDM mammograms only. **2.** Hologic data on file, 2017.

Categorization of focal breast lesions according to the BI-RADS US lexicon: the role of a computer aided decision making support system (S-Detect)

By Dr T.V. Bartolotta & Dr A.A.M. Orlando

Breast ultrasound (US) is a widespread imaging tool, often used as an adjunct to mammography with the aim of characterizing focal breast lesions (FBLs), in order to improve cancer detection rates and to reduce the number of false negatives in breast cancer diagnosis. However, breast US requires extensive experience, making it an extremely operator-dependent procedure which yields lower reproducibility, specificity and positive predictive value than mammography.

The Breast Imaging-Reporting and Data System (BI-RADS) lexicon was first developed by the American College of Radiology (ACR) in 2003, and provided descriptors for focal breast lesions (FBLs) on breast US imaging, which standardized the reporting terminology and clinical management.

Computer-aided detection (CAD) system, such as the S-Detect system from Samsung, has been developed as a supporting tool in the classsification of FBLs, and allows seamless recording, processing and reviewing of US images.

This article summarizes a study carried out to assess the role of the novel computer-guided decision-making support (S-Detect) in the categorization of FBLs based on the BI-RADS US lexicon.

METHODS

CAD examination was performed on US images of 160 consecutive FBLs between December 2014 and June 2015. Indications for breast US included a palpable mass detected on physical examination, dense breasts or lesions detected from adjunct mammography examination, patients with mastodynia and young patients having family history or in a follow-up for benign breast nodules or cysts. Two radiologists classified by consensus 160 FBLs (size range: 2.6 – 47.2 mm; mean: 11.5 mm ± 6.5 SD) in 123 patients (121 women and 2 men; age range: 13-98 years; mean 50.1 years ±14.4 SD) into 4 categories:

(1) BI-RADS 2 benign;
(2) BI-RADS 3 probably benign;
(3) BI-RADS 4 suspicious;
(4) BI-RADS 5 highly suggestive of malignancy.

The classification was based on the BI-RADS US descriptors such as shape, orientation, margin of the mass, boundary, echo pattern and posterior acoustic feature. FBLs were detected by a high resolution ultrasound system, RS80A (Samsung Medison Co., Ltd, Seoul, Korea). A third independent reader also assessed the same 160 FBLs off-line while using S-Detect, a built-in dedicated US-BIRADS classification software which is capable of a semi-automated lesion extraction and guided classification based on the descriptors above.

The patient's age, family or personal history of breast cancer and previous US investigations were available to the investigator in order to reproduce a more realistic clinical situation. Mammographic findings of FBLs were not taken into consideration for this BI-RADS US classification. US-guided core-biopsy and fine-needle aspiration cytology (FNAC) served as a standard of reference (SOR) for all the FBLs classified as either BI-RADS 4 or 5.

US findings at 6 months follow-up were available for all the 45 lesions classified as BI-RADS 3 both before and after S-Detect assessment. Sensitivity, specificity, positive and negative predictive values (PPV, NPV) were calculated while considering BI-RADS 4 and 5 FBLs as malignant and BI-RADS 2 and 3 FBLs as benign mass.

RESULTS

Table 1 shows the differences in the BI-RADS categorization of the 160 FBLs assessed by the two radiologists in consensus and the third reviewer using S-Detect.

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BI-RADS CATEGORY	RADIOLOGISTS' ASSESSMENT (number of lesions)	S-Detect GUIDED ASSESSMENT (number of lesions)
BI-RADS 2	70	70
BI-RADS 3	54	51
BI-RADS 4	21	26
BI-RADS 5	15	13
TOTAL	160	160

Table 1. Categorization of 160 FBLs before and after S-Detect assessment. The concordance between S-Detect assisted radiologist and the two reviewers not performing S-Detect was 89.4 %.

It can be seen that the S-Detect-assisted radiologist changed the initial BI-RADS classification in 17 of 160 (10.6%) FBLs: 9 FBLs were upgraded from BI-RADS 3 to BI-RADS 4 [Figure 1] whereas 6 FBLs were downgraded from BI-RADS 4 to BI-RADS 3 [Figure 2], and 2 FBLs were downgraded from BI-RADS 5 to BI-RADS 4. No differences were noted in classification of FBLs BI-RADS 2.

Histological diagnoses [Table 2] was obtained for 45 lesions classified as BI-RADS 4 or BI-RADS 5 with or without S-Detect:

- 7 Benign lesions: fibroadenoma (2), usual ductal hyperplasia (2), granuloma (1), corpuscular cyst (1), abscess (1);
- 2 High risk lesions: atypical ductal hyperplasia (1), sclerosing adenosis (1);
- 36 malignant lesions: invasive ductal carcinoma (27), invasive lobular carcinoma (6), mucinous carcinoma (1), malignant phyllodes tumor (1), chondrosarcoma (1)

The two radiologists classified 160 FBLs as BI-RADS 2 (n = 70), BI-RADS 3 (n = 54), BI-RADS 4 (n = 21), BI-RADS 5 (n = 15), with Sensitivity, Specificity, PPV and NPV of 81.6%, 95.9%, 86.1% and 94.3%, respectively. S-Detect assisted radiologist classified 160 FBLs as BI-RADS 2 (n = 70), BI-RADS 3 (n = 51), BI-RADS 4 (n = 26), BI-RADS 5 (n = 13), with Sensitivity, Specificity, PPV and NPV of 92.1%, 96.7%, 89.7% and 97.5% respectively.

In cases of malignancy, S-Detect-guided re-classification was correct in 12 of 17 cases (70.6%): 6 of 9 malignant FBLs and 1 of 9 high risk FBLs were properly upgraded from BI-RADS 3 to BI-RADS 4, 3 of 6 benign FBLs were downgraded from BI-RADS 4 to BI-RADS 3.

Furthermore, 2 FBLs were downgraded from BI-RADS 5 to BI-RADS 4, but the course of management for these cases wouldn't have undergone any variations.

On the other hand, 2 of 9 benign FBLs were erroneously upgraded to BI-RADS 4 and 2 of 6 malignant FBLs and 1 of 6

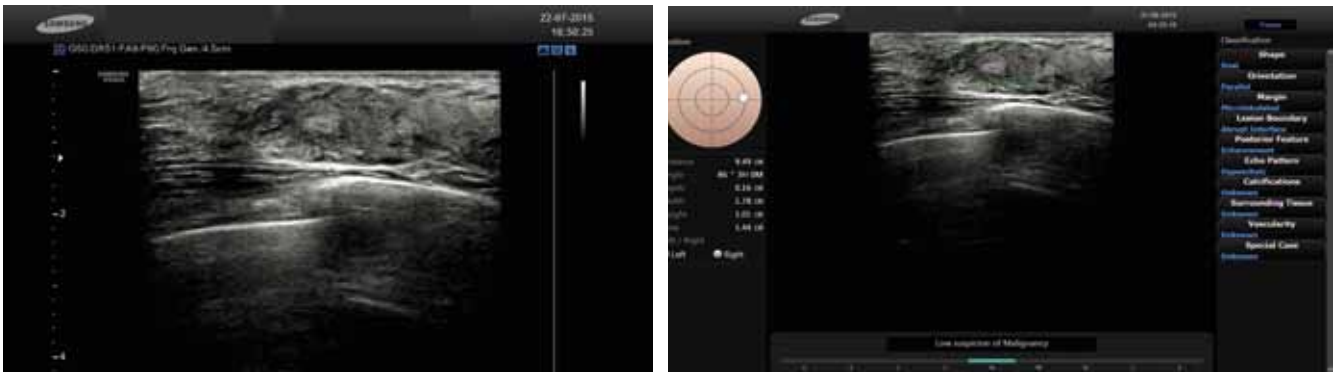

Figure 1. In a 57-year-old woman, B-mode US (Left Panel) depicted an oval-shaped mass, slightly hypoechoic with a central area of hyperechogenicity, parallel orientation and a slightly posterior acoustic enhancement. The two reviewers assessed margins as circumscribed, The S-Detect guided radiologist (Right Panel) as microlobulated, thus the lesion was upgraded from BI-RADS 3 to BI-RADS 4A. Core-needle biopsy confirmed the lesion as an invasive ductal carcinoma.

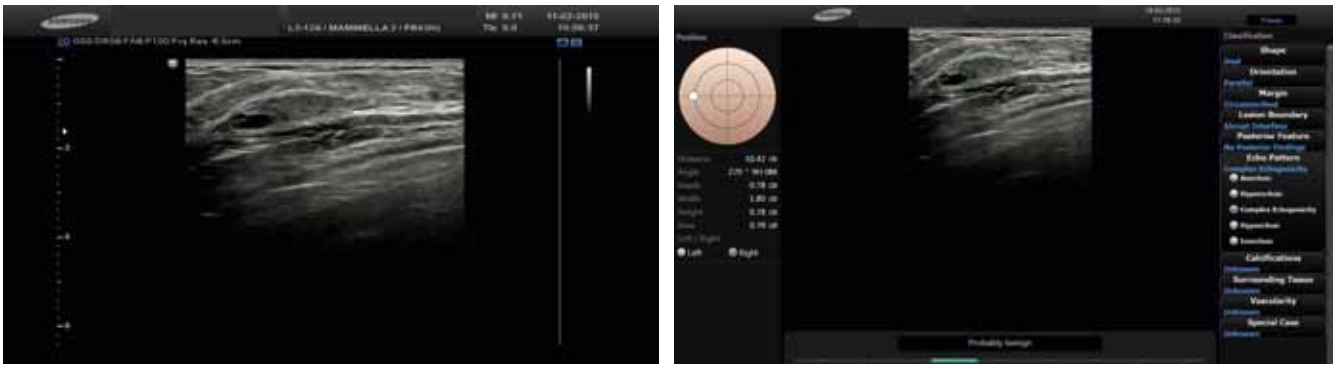

Figure 2. A 43-year-old woman with dense breasts undergone breast sonography. US image (Left Panel) displays an isoechoic mass with an eccentric anechoic area, oval shape, parallel orientation and circumscribed margins. The S-Detect assisted radiologist (Right Panel) changed this FBL from BI-RADS 4 to BI-RADS 3. Core needle biopsy revealed a usual ductal hyperplasia (fibrocystic changes)

DIAGNOSIS	HISTOLOGY	No	Radiologists' Assessment	S-Detect	Radiologist S-Detect assisted
Benign Lesion (n=7)	Fibroadenomas	2	1 BI-RADS 3 1 BI-RADS 4A	PM PB	1 BI-RADS 4A 1 BI-RADS 3
	Corpuscular cyst	1	BI-RADS 4A	PB	BI-RADS 3
	Granuloma	1	BI-RADS 4B	PM	BI-RADS 4C
	Usual Ductal Hyperplasa	2	BI-RADS 3 BI-RADS 4A	PM PB	BI-RADS 4 BI-RADS 3
	Abscess	1	BI-RADS 4A	PM	BI-RADS 4B
Malignancy (n=36)	Invasive ductal carcinoma	27	4 BI-RADS 3 23 BI-RADS 4 or 5	All PM 3 PB e 20 PM	All BI-RADS 4 or 5 All BI-RADS 4 or 5
	Invasive Lobular carcinoma	6	2 BI-RADS 3 4 BI-RADS 4 or 5	All PM	All BI-RADS 4 or 5
	Mucinous carcinoma	1	BI-RADS 4A	PB	BI-RADS 3
	Chondrosarcoma	1	BI-RADS 4B	PM	BI-RADS 4B
	Malignant Phyllodes tumour	1	BI-RADS 4A	PB	BI-RADS 3
High risk lesion (n=2)	ADH Sclerosing adenosis	1 1	BI-RADS 3 BI-RADS 4A	PM PB	BI-RADS 4B BI-RADS 3

Table 2. PB = possibly Benign; PM = Possibly Malignant ; ADH = Atypical Ductal Hyperplasia

high risk FBLs were erroneously downgraded to BI-RADS 3.

DISCUSSION

In this study, S-Detect assisted radiologist reached higher sensitivity, specificity, NPV and PPV compared to the reviewers without S-Detect. Among 36 malignant FBLs, only 2 were interpreted as "probably benign" (BI-RADS 3) by the S-Detect assisted radiologist. Histological diagnosis for these cases were mucinous carcinoma and malignant phyllodes tumor, respectively. These masses showed relatively circumscribed margins, and the phyllodes tumor in particular, presenting with no more than three lobulation, was considered of oval morphology. The S-Detect assisted radiologist classified only one high risk lesion as BI-RADS 3 for which pathologic diagnosis was sclerosing adenosis. Six malignant (2 invasive lobular carcinoma and 4 invasive ductal carcinoma) and 1 high risk (atypical ductal hyperplasia) lesions missed by the two reviewer were correctly recognized as suspicious by radiologists' S-Detect assisted readings. These lesions showed non-irregular morphology and margins were not completely circumscribed, thus assessed as microlobulated. The two benign lesions that were erroneously upgraded as BI-RADS 4 by the radiologist with S-Detect assistance were histopathologically proved to be one fibroadenoma and one usual ductal hyperplasia. In these two cases descriptors which led the radiologist to upgrade were shadowing as posterior acoustic finding and round morphology, respectively. One abscess and one granuloma were the only two lesions inaccurately assessed as BI-RADS 4, both with and without performing S-Detect. This is due to the presence of indistinct margins for the first lesion and non-parallel orientation for the second one.

CONCLUSIONS

Our experience validated S-Detect as an effective computer-aided decision-making tool for classification of FBLs as it improves breast cancer detection rate, specificity, NPV and PPV, even when compared with to the results of the experts.

The importance of a patient-centered approach

By Rob Cascella

It is not a surprise: the healthcare industry is shifting towards a more value-based and patient-centric care model, requiring clinicians to deliver high-quality care while managing costs and enhancing the patient's experience. Innovators are experiencing increased demand for equipment designed to address not just quality care, but solutions that keep human empathy in mind. Healthcare is becoming a more customer-centric focused industry as more clinicians and healthcare executives realize the impact that the patient experience has on clinical outcomes, financial results, consumer loyalty, community reputation and broader staff engagement.

According to the Beryl Institute (the global community of practice dedicated to improving the patient experience through collaboration and shared knowledge), 82% of health systems recognize patient experience as a top priority, and 89% of consumers reported that their experience is extremely important (*www.theberylinstitute.org*). Patients have begun acting as customers, and we need to think of them as such when it comes to their care. They're making decisions on where to receive treatment based on service expectations and various preferences – with some even starting to choose radiology locations that can provide a less stressful experience, over those that are more convenient. Now more than ever, we need to shift our approach to be inclusive of the consumer mindset.

THE IMPACT OF ANXIETY ON IMAGING

All too often, the stress a patient may feel when coming in for an imaging scan is overlooked. For clinicians, the imaging suite and scanners are something they're comfortable around. But this could be a patient's first scan, a patient that may be afraid of enclosed spaces, or a patient who has heard a friend's own stressful or negative experience and has a preconceived idea of what their experience will be like.

Patient anxiety and discomfort throughout the diagnostic imaging process can significantly impact outcomes, ranging from stress-related movement that impedes high-value scans in MRI, to the physiological effects of stress on image acquisition in PET/CT. In some cases, it can even result in patients missing the appointment all together – about 10%-12% of all radiology appointments are no-shows or last-minute cancellations, creating problems for daily schedules and contributing to lost revenue.

In fact, patients who feel comfortable and secure are less likely to engage in behavior that compromise the quality of the imaging study, making it easier for staff to acquire high-quality images and for radiologists to accurately interpret them. It also reduces the need for rescans (and their accompanying radiation exposure and costs) and helps workflow to continue to run smoothly. According to a recent study, 61% of patients indicated that obtaining an accurate scan in the least amount of time to reduce physical discomfort is important to them.

It's also important to consider staff satisfaction and its impact on the patient experience. Radiologists typically report feeling burnt out. When their days get longer and more stressful, they are burdened by reporting requirements, or the equipment is challenging to maneuver, it adds to the problem. Design that makes their job easier will lead to an improved staff and patient experience, which subsequently contributes to a better ROI at the end of the day.

EXPANDING COMFORT BEYOND THE SCANNER

According to a recent study, some of the most significant barriers standing in the way of a truly integrated and seamless health experience are centered on the technology itself. However, expertise in design, clinical and operational consulting, and technology can help innovate not just the facility's look and feel, but the clinicians' and staff's approach to patient care. Using a people-centric design methodology to better meet the challenges of care delivery through the entire process is key. While patients generally have more positive experiences in the early phases of the imaging process, a recent study found that 23% have less than average experiences during the exam prep phase, with the number rising to 25% during the scan itself. Integrating technology, spatial design and workflow improvements can create a comfortable and stress-reducing environment for patients, as well as an efficient, clutter-free workspace for staff.

The newest imaging suite designs go beyond just scanners to support improved waiting areas and control rooms in various departments. But most importantly, they allow experiences to be personalized by the patient. Customizable audio and visual components provide patients with a sense of control, allowing them to select the themes that make them comfortable, less anxious and more at ease with the imaging process. The combination of improved workflows, processes and procedures can lead to increased patient and staff satisfaction and improved imaging outcomes.

Ultimately, in being sensitized to patient needs, we can support healthcare organizations in achieving the triple aim of reducing costs, achieving a timely and confident diagnosis, and improving the patient experience by minimizing anxiety across the imaging ecosystem.

THE AUTHOR
Rob Cascella,
Chief Business Leader, Diagnosis & Treatment, Philips

Why vendors bring what they do to the RSNA

By Greg Freiherr

The 2017 RSNA exhibit floor will have a hint of years past with the coming together of **Canon** and **Toshiba Medical Systems**. The already merged company will feature **Canon** equipment at one end of a shared booth, **Toshiba** equipment in the middle, and **Vital Images** at the other end. (Acquired years ago by **Toshiba, Vital Images** has sought a quasi-independent position in the marketplace.)

"There will be dual branding at RSNA just because of registration (issues)," said Satrajit Misra, vice president of marketing and strategic development at what used to be Toshiba America Medical Systems. "As of Jan. 4, 2018, we will be 100 percent Canon branded."

When registrations in the U.S. and other countries are complete, Toshiba will become Canon Medical — but the Vital Images brand will remain, according to Misra.

The merger has little or no chance of triggering other big mergers and acquisitions (M&A) like the ones 20 years ago that recast the landscape of medical imaging. M&A remains an important part of major vendors' growth strategy. But, unlike the tsunami of mega-mergers two decades ago, there are no big gaps to fill in the product lines of major multimodality vendors — and no large or midsize companies with attractive product portfolios, according to industry executives.

Likely having greater impact will be the tumultuous reshaping of healthcare in the U.S. and its long awaited transition from volume- to value-based medicine. But even this will be muted at RSNA 2017 by the international character of the meeting. **GE Healthcare** estimates that the traffic to its booth is split about evenly between visitors from North America and elsewhere. That mix has changed a lot.

GLOBAL MARKET SHIFT

Decades ago, when volume-based medicine in the U.S. and the introduction of glitzy new technologies were in high gear, the U.S. market predominated. Its influence has since diminished in lockstep with cost containment efforts that today take the form of value-based medicine. Yet, with the U.S. accounting for 32 percent of global revenue the country remains the dominant market of all global markets, according to Mark Phillips, chief marketing officer for GE imaging,

When it comes to growth, however, China is in front. According to Mark Phillips, China's 6 to 7 percent growth is two to three times that in the U.S. There is some crossover, however, in that rural America presents opportunity for sales as does rural China.

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Making its first appearance at the RSNA meeting but launched at ECR in March, Siemens' 3T Magnetom Vida illustrates how product availability and timing influence the choice of meeting for a product unveiling. Photo courtesy of Siemens Healthineers

"This is good because the solutions that we are developing that drive efficiency will help our customers in North America being able to have more productivity," he said. "Then in the emerging markets it is about helping to maximize the number of radiologists."

R&D decisions predate every professional meeting. The development of products largely determines what will be brought. When developing a new product, **Philips** tries to imbue the ability to improve outcomes, reduce cost and enhance patient experience, according to Rob Cascella, chief business leader for diagnosis and treatment at **Philips Healthcare.** "Our delivery of seamless care is really based on our ability to satisfy those requirements," Cascella said.

THE ROLE OF TIMING

As the premier radiology show in the world, the RSNA meeting "becomes the tip of your spear. It is where you showcase state-of-the-art technology in all modalities," **Toshiba's** Misra said. "But then you start looking at using (the RSNA meeting) to build up to a variety of the regional shows throughout the year."

Siemens Healthineers has twice the booth space at the RSNA meeting compared to the ECR and about four times the space as Arab Health in Dubai. "So RSNA continues to be our main show for all of our radiology offerings," said Raghavan Dhandapany, Siemens vice president of marketing, sales operations and communications in diagnostic imaging. Sometimes, however, the RSNA meeting and development cycles don't mesh.

Siemens' decision to launch the 3T Vida at ECR in March was because the company "didn't want to lose the whole year" waiting for RSNA, he said.

Time will not be an issue this year for the debut of

GE's Senographe Pristina enables women receiving a mammogram to control compression using a wireless remote control. (see inset) Photos courtesy of GE Healthcare

Siemens' three-room OR-imaging solution called the nexaris Therapy Suite (comprised of x-ray angiography, MR and CT); the launch of two new members of the Somatom go family (the first two — the go.Now and go.Up — were launched at RSNA 2016); and major new features on two long-standing CT scanners, Somatom Force and Somatom Edge.

Toshiba's Misra predicts the **Canon/Toshiba/Vital** booth will feature major launches in all modalities, "including information technology." Particularly relevant will be synergies between Canon and Toshiba. These are likely to occur in digital radiography, he said, "and also potentially and some of the emerging areas around clinical laboratories and genomics."

Decisions about what to exhibit this year are more focused than they were in the past, said Cascella. "There is a lot of emphasis on bringing tools not just gantries," he said. "We bring tools that allow you to do a better job."

As in past years, vendors will present themselves as being on the leading edge of technology and, therefore, likely to keep their clients up-to-date. "People want to know that they are partnering with (a company) that is leveraging the latest technology," said GE exec Phillips. "You need to be perceived as a technology leader."

AI INSIDE

In past years, vendors have alluded to "black boxes" with mysterious mechanisms that accomplish remarkable feats. The black box of the 2017 RSNA will be artificial intelligence (AI).

Philips Healthcare will devote an entire section of its booth to AI. **Siemens** will be showcasing AI as well.

"Probably we have the largest amount of patents among large imaging players," Dhandapany said. "And we have many new artificial intelligence-based products in the pipeline."

Some of these will be shown as prototypes on the Siemens RSNA 2017 booth in its "Future Lounge." The company may show prototypes designed to assist radiologists as well as technologists. The most advanced will automatically annotate structures in images and even bring up regions of interest on which the radiologist should focus. (One caveat -- before entering the lounge, visitors will have to sign a nondisclosure agreement.)

In keeping with the push on AI, GE will feature its Applied Intelligence Suite. "We will start to show from our perspective how we think this can be integrated into the radiology infrastructure," he said.

Building out that infrastructure message in the GE booth will be the evolution of the company's "digital ecosystem," which leverages developments in AI, as well as the cloud and the company's Edge computing technology, which crunches data in-house.

"In this day and age there are different levels of comfort our customers have with what goes outside the network and what doesn't. So I think you have to be smart with how you design (products) and how these things run," he said.

M&A — METHOD NOT MANIA

The **Canon/Toshiba** deal — valued at $6.5 billion — combines two big players. The merger went forward despite EU regulators that have threatened to fine Canon about $3 billion for allegedly breaking procedural rules regarding the submission of information.

Misra describes reports of a possible fine from the European Union as a "press-related item." "The EU has similar questions with other mergers with other companies as well," he said. "So right now my understanding is that Canon has responded and (the fine) is still being discussed."

More important, he said, is the message the combined company will project at the meeting. "It is a message about partnership with our customers -- our hospitals and our patients," Misra said.

Combined **Canon** and **Toshiba** generate about $6 billion annually in healthcare. The goal, according to Misra, is to grow that to $10 billion in the next few years. "You cannot just achieve that through organic growth; you have to make inorganic moves," he said.

PRODUCTIVITY AND EFFICIENCY

Technologies that allow more to be done with less will be at a premium. Chipping a few seconds off a scan will matter less than techniques that reduce the overall time of examination, as these support higher volumes. To get to this grail, automation will take the driver's seat. Look for "zero click" technologies that automate time-consuming or skill-dependent post processing functions. They may increase both efficiency and reproducibility, said Dhandapany.

Toshiba equipment, such as this 1.5T Vantage MR scanner, will be "dual branded" by Canon and Toshiba in a booth shared by the now combined companies. The brand is expected to be uniformly Canon, when registrations take effect globally on Jan. 4, 2018. Photo courtesy of Toshiba America Medical Systems

"Reproducibility has been a major concern -- a major R&D focus — the development of enabling technologies that reduce the expertise needed from operators," he said.

High-level automation promises to not only reduce variability in exams done at different times and places within a provider network (for example, an integrated delivery network), but minimize the need for operator training, according to Dhandapany.

Looking for ways to save times is nothing new. Two years ago Siemens came out with GOBrain, which promised to cut MR brain scans to five minutes. This year the company will show a new CT feature built around an innovative 3D-camera-assisted automated patient positioning. Mounted on the ceiling of the CT suite, the camera will relay optical images for the assessment of patient anatomy. Smart algorithms will analyze the optical images and communicate their assessment to the scanner. The auto-positioning system is designed to save time, reduce cost coming from patient handling, and improve throughput.

"The technologist selects the organs and the reason for the scan," Dhandapany said. "From there on, everything is done automatically."

Automation through AI will be apparent at Philips' RSNA booth, where the company will use AI to enhance patient comfort and streamline machine set up, according to Cascella.

OUTCOMES RISE AGAIN

Attendees this year will see a resurgence of outcomes in the context of cost containment. What **Siemens** brings to the RSNA exhibit floor reflects the company's focus on developing products that "should enable providers to either improve outcomes or lower cost or both," said Dhandapany.

Vendors are moving away from their one-time focus on clinical outcomes in favor of outcomes that are easier to measure and document. GE's Mark Phillips breaks outcomes into three categories -- clinical, financial and operations. The basic metrics of all three are efficiency and productivity. The trick is achieving them along with reduced cost.

This year Philips will promote ways its equipment can reduce scan times in MR by between 20 and 30 percent. "Another thing we will say is that (our equipment) will be able sense when a patient moves and correct for that movement in a scanner so you don't have to do a rescan," Cascella said. AI will figure prominently in each, he said.

Patient experience can be enhanced by minimizing the time patients spend waiting to get on — and off — the scan table. Patient centricity also includes safety.

When it comes to ionizing radiation, reduced dose translates into patient safety. The concept of patient dose is a metric also in clinical outcomes, Cascella said: "In my world that is an outcome that resonates with both radiology and hospital administration."

Philips Healthcare wants to show new equipment in the light of what's important to users but also in terms of what Rob Cascella describes as "very high-value applications." These applications are disease focused, said Cascella.

"When a person brings you over to the modality (in the Philips booth), in addition to showing you what is unique about (the equipment), they will stress how it is to be used relative to a specific disease category."

Disease-specific applications relate naturally to patient centricity, which gained prominence four years when the RSNA made "Patients First" its meeting theme. The idea has finally taken hold and will be an strong undercurrent at this year's RSNA meeting.

Philips publicly kicked off the idea in mid-October with the release of results from its Patient Experience in Imaging Study. In the study, 603 patients in the U.S. and Germany were surveyed about their satisfaction, expectations, preferences and unmet needs regarding diagnostic imaging procedures. Patients' top priorities, as reported by Philips, "were to get through the scan as quickly as possible and to minimize exposure to harmful radiation and contrast agents."

GE's take on patient centricity at this year's RSNA will include Pristina Dueta, an extension of the Senographe Pristina mammography system. Using wireless remote control, Dueta lets patients control their own breast compression during mammography. Released earlier this year in Europe, the feature was only cleared by the FDA in September.

THE END GAME

Canon and Toshiba will show integrated products -- but the merger will not likely spark a surge in M&A, certainly not one like the mega-mergers of the 1990s. Instead, efficiency and productivity will take center stage, as the industry grapples to find a common denominator for emerging markets with high single-digit growth rates and mature markets that show a couple percent or less growth.

As it has in past years, the RSNA meeting will provide vendors a world stage on which they can showcase their technology — and their engineering prowess. "The right formula for RSNA is to show people where you are going; how your vision is different; and what you can do for them," said GE's chief marketing officer Phillips.

Some years down the road, RSNA 2017 may be recognized as AI's coming out party. Disappearing is the Musk-Gates-Hawking bred fears of smart robots replacing people. Taking shape is an embrace of smart, time-saving algorithms that make professional lives more manageable and patients happier.

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Digital Breast Tomosynthesis (DBT)

Several presentations at the ECR Breast Care Day, which traditionally takes place on the first day of the annual ECR meeting and is sponsored by Siemens Healthineers, in cooperation with Bayer Healthcare, were this year devoted to the current status and potential of DBT. More than 1300 radiologists were treated to detailed presentations given by specialists experienced in the tomosynthesies field. This article summarizes the presentations.

Clinicial perfomance of synthetic mammograms (Insight 2D) and its role in screening procedures.

Dr Maria Bernthova

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To set the scene, Dr Bernathova reminded the audience that synthetic mammograms are developed from the data acquired during DBT acquisition, so a synthetic mammogram is NOT a Full Field Digital Mammogram (FFDM), a difference which can be clearly seen just by looking at the images [Figure 1].

Since several studies of DBT (e.g. the Malmö Breast Tomosynthesis Screening Trial) have shown that 3D tomosynthesis increases the number of lesions detected, it has been proposed to use DBT as a simple "stand-alone" imaging modality. The problem with such a scenario comes when comparisons with previous 2D mammograms have to be carried out. Likewise comparison of the right and left breast and the detection of asymmetries, distortions and calcifications can be challenging if only 3D data are available.

Several studies (*e.g. Lotti et al., ECR 2015*) were carried out to examine the need for 2D images in DBT and have shown that the addition of a synthetic 2D image to DBT was overall rated beneficial and useful particularly in the assessment of distortions and asymmetries.

Expectations for synthetic 2D

However although the benefits of synthetic 2D mammography seem clear, the situation is complicated by the fact that different users have different expectations for synthetic 2D. For example, some users want synthetic 2D only as a guide to the breast density, others want to have the image quality of synthetic 2D to be equivalent to that of digital mammography. The result of this lack of clarity as to what the users want is that different vendors are adopting different approaches to the issue.

A priority is therefore to define exactly what the role of synthetic mammograms should be, in both screening and diagnostic settings. However it shouldn't be forgotten that the advantage of using SM + DBT is that there is a significant reduction in radiation dose compared to DM and DBT. Radiation reduction is always important but is particularly so in screening situations.

Evidence for usefulness of SM.

There is an increasing body of evidence regarding the usefulness of SM. One early study, the Tommy trial (*Gilbert et al*, 2015) compared three reading arms, namely (i) 2D alone; (ii) 2D + DBT and (iii) SM +DBT. The conclusions were:

- that the specificity of 2D or SM with DBT was improved compared to 2D alone;
- there was an improvement in sensitivity of 2D + DBT in women with dense breasts, but not for SM plus DBT in such women;
- 2D and SM with DBT had higher sensitivity for women with cancers greater than 1 cm
- The "problem child" remains calcifications, where SM with DBT had a lower sensitivity than that of 2D + DBT and 2D alone

In another small study (*Zuley et al 2014*) the performance of SM and FFDM alone were compared in terms of Area Under Curves (AUCs) of the Receiver Operating Curves (ROC) and found to be equivalent, while the combination of SM with DBT also showed very comparable performance compared to FFDM + DBT. Of course, the specificity of 2D or SM with DBT was improved compared to 2D alone. The overall conclusion of this trial was that "*the use of SM instead of FFDM, either alone or in combination with DBT does not result in any clinically meaningful differences in diagnostic accuracy and may eliminate the need for FFDM in routine clinical studies*". The fact that this study was relatively small means that it is however dangerous to extrapolate this clear message. Nevertheless, it shouldn't be forgotten

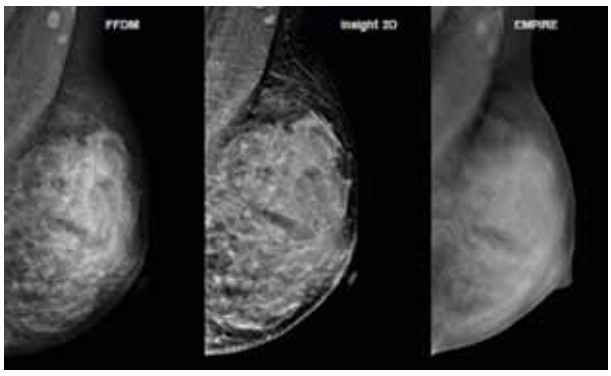

Figure 1. The appearance of the FFDM image (left panel) is different from that of the synthetic 2D image (Center panel) which is generated , in this case by the Siemens Insight 2D system, from 3D tomosynthesis data. Right Panel is the mage after processing by Siemens EMPIRE reconstruction algorithm.

2017 Breast Care Day Video recordings
Videos of all presentations are available at www.siemens.com/breastcareday

that DBT and SM are continually improving so it is very likely that in the future SM may actually provide better performance than FFDM.

The current evidence regarding SM — a summary:

- Its use allows reduction in radiation dose
- The performance of DM+ DBT is similar to that of SM + DBT
- When interpreting the evidence from such trials, it should always be remembered that differences in study designs, in the actual DBT systems used and the cases examined means that, sometimes conflicting results can be produced.

However the key, fundamentally important question is whether there is a danger of missing cancers if SM were to replace DM in combination with DBT for screening. Right now there is no absolutely definitive reply to this question, so in Austria it was recently decided to set up a study with the express purpose of evaluating the diagnostic accuracy of SM generated from data acquired in tomosynthesis compared to DM.

In this study, the Siemens Mammomat Inspiration system is used (the system has a wide, 50 degree angle), the DBT reconstruction is carried out using Siemens' EMPIRE algorithm and synthetic mammograms are generated by Siemens' Insight 2D system.

Secondary aims of the trial are to compare the diagnostic accuracy of DM versus 1 view S2D + DBT vs 1 view DM + DBT; to compare the image quality of S2D vs DM; and to compare the readers' confidence and reading times.

In this study 200 cases will be examined, with each examination involving DM, DBT and SM 2D for both breasts, in two views (CC and MLO). The cases are a mixture of histologically defined malignant (40%); benign (35%) and negative (25%), and cover all breast densities. Four readers blinded to the clinical history will read the images.

The study is still ongoing, so final results are not yet available, but already several individual cases show the usefulness of SM. It is planned to present more detailed results at RSNA

Conclusions

- The use of SM allows dose reduction and also means that, with SM, the transition to 3D is less abrupt than just 3D alone
- the role of SM in a diagnostic setting is still questionable since there are very few data available
- Since the appearance of SM images is different from that of DM, there is an inevitable learning curve needed for the interpretation of SM images
- Quality criteria are needed by which the quality of SM images can be evaluated

The overall take-home message is however that synthetic mammography is a significant advance and looks set to play an important future role, especially in screening applications.

Practical challenges in screening with digital breast tomosynthesis (DBT)

Prof. Chantal Van Ongeval

Just like other advances in the history of the evolution of mammography, the implementation of new technological advances is frequently accompanied with new challenges which have to be addressed. Thus, while digital breast tomosynthesis (DBT) in its current form (i.e. DBT + 2D Full Field Digital Mammography, FFDM) brings many advantages, there are also several disadvantages. These include increased acquisition time, increased radiation dose and increased reading time, which have been described in detail elsewhere. In addition, the use of DBT in practice is accompanied by other issues, e.g. comparison with prior 2D FFDM images; the comparison of DBT images generated by systems from different manufacturers; and the evaluation of morphology and the extent of microcalcifications.

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Comparison with prior images

As for the comparison of DBT with prior screening images from 2D FFDM, the synthetic mammogram (SM) generated from the DBT projections has a role to play, since, using this, there is no need for an additional FFDM. This means that overall there is only a slightly higher radiation dose and a slightly longer acquisition time. Exactly what the impact on the reading time still isn't clear — some people maintain that simply reading the synthetic mammogram (SM) is sufficient and that there is no need to look at the DBT images unless there is an indication from the SM to do so. This is short-sighted.

Quality of SM

Reporting on the quality of SM is all the more important in the context of DBT systems with different geometries and specifications from different manufacturers. One method for describing the quality of SM could simply be via measures of detection accuracy and characterization, but there is a case for the retention of a visual grading system based on contrast, sharpness and noise, which works well for FFDM [Figure 2]

A small two arm study was carried out at the University Hospital of Leuven on 29 women attending the clinic every year for follow-up after breast cancer. In one arm of the study, 4-view FFDM images taken in 2015 were compared with FFDM images taken in 2016. In the other arm of the study 2DFFDM images from 2015 were compared with SM 2D generated in DBT carried out in 2016. All images were acquired on the Siemens Inspiration System. The images were evaluated by three readers not only using BI-RADS categorization, density evaluation but also using visual grading parameters namely contrast, sharpness, noise, presentation of microcalcifications and masses and overall image quality.

The results showed that there was a low level of inter-reader agreement, especially as far as the SM images (Insight 2D) were concerned.

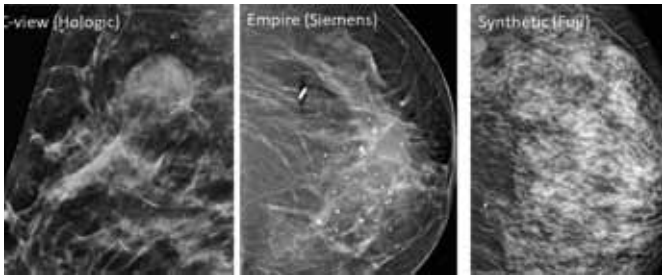

Figure 2. The need for a system to enable evaluation of the quality of SM images is illustrated in these images, which are SMs generated using the systems of three different vendors. It can be seen that the image from one system appears noisier, another system has bright microcalcifications and the third appears to be of lower contrast. Image quality could be determined by detection accuracy and characterization, but there is also a role for classical visual quality grading (which functions well for FFDM) using parameters such as contrast, sharpness and noise.

There were statistically significant differences in the classification of density between the FFDM and the SM (Insight 2D) image, with the density derived from the SM tending to be higher than that from the FFDM. As for BI-RADS lesion characterization there was no significant difference. Regarding the overall image quality scores, the FFDM was considered better.

These results are not surprising, since it must be remembered that the synthetic mammogram is derived ultimately from the individual projections of the DBT taken at a low dose, which also explains the fact that overall the SM image quality is lower compared to FFDM, especially in the presentation of microcalcifications. This latter conclusion regarding microcalcifications was confirmed by a recent study (*Peters et al., Invest Radiol, 2016*) carried out by medical physicists using anthropomorphic phantoms including simulated microcalcifications. It was found that FFDM was superior to SM in the detection of such microcalcifications.

Thus the overall conclusion from such studies is that synthetic mammograms should only be seen as an overview of the DBT and should not be used as stand-alone image for evaluation. In addition there is a requirement for additional training before SM can be used optimally and compared meaningfully with FFDM.

High quality displays can help a lot — the latest FDA-approved monitors can eliminate motion blur and increase luminance. It is necessary to be able to scroll all the images at a rapid frame rate, without skipping frames, through all the slices for all the views displayed on the large 5MO display required for mammography. Ideally this should be synchronized with same size contralateral and prior views.

Data Handling.

The large amount of data generated by DBT means that the data handling systems, e.g. PACS and storage must be fast and large enough to deal with the data. This is not limited to just exporting the data, e.g. during the night but also within each department. For example, the data exchange rate governing the transfer of data from the acquisition and reconstruction (tomo) modules to the PACS is more efficient at 1 Gb/sec than at the standard network rate of 100Mb/sec. Special PACS are required and should be compatible so that, for example, images generated by a screening department can also be read by a diagnostic department.

Radiographers

Currently there is discussion regarding the possibility of reducing compression force, but care should be taken regarding this since reduced compression can result in greater dose. The radiographer has an important role to play in this aspect. Regarding the positioning of the breast, it is important that the radiographer ensures that the whole breast is covered during the tomo process and that compression is maintained during the longer tomo synthesis acquisition time.

Conclusion

- In comparison to FFDM + DBT, the use of SM + DBT will lower acquisition time and radiation dose, but will only have a small impact on reading time.
- SM can only be used in combination with DBT
- The performance of SM regarding microcalcifications is still not clear.
- It should also be remembered that once an X-ray dose has been administered, the radiologist is legally responsible for all the images generated including those DBT projections of which many may not be looked at
- Monitor must be 5 MP
- Adequate training of radiographers and radiologists is necessary.

Technical aspects of breast tomosynthesis:

are all DBT systems the same?

Dr Wayne Lemish

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Dr Lemish explained that recently his practice in Melbourne Australia had expanded which meant that they had ended up with two breast tomosynthesis units, each from a different manufacturer, so this enabled comparison between the two systems. Both systems had of course regulatory approval and the results of clinical trials have shown that the use of each system enables the detection of an increased number of cancers.

One particular case showed however that the performance of the systems could differ. A 55 year old woman with a clear palpable lump on her left breast presented to the practice. The first tomosynthesis analysis did not show clear evidence of any lesion corresponding to the palpable lump, so it was decided to repeat the tomosynthesis scan, which this time happened to be carried out using the tomosynthesis system from the other manufacturer. A spiculated mass was seen, and was followed up by ultrasound which showed a lesion that was ultimately confirmed histologically as an invasive ductal carcinoma Grade II.

The significance of such differences in the performance of tomosynthesis systems from different manufacturers was the subject that Dr Lemish wanted to explore in more detail.

First of all he recapped on the various design factors which constrain the actual performance of tomosynthesis systems.

These include:

- Total radiation dose, which should be as low as possible and should in any case be in the realms of the dose involved in standard 2D mammography
- Detectors should have high quantum efficiency. Tomosynthesis involves multiple low dose exposures with each individual exposure only the fraction of the dose of a standard 2D mammogram so the detectors need to provide rapid read-out and no lag
- Movement of the X-ray tube (XRT). In tomosynthesis there is of course mechanical motion of the XRT which can be done continuously. However this method runs the risk of having focal spot blurring. The alternative is the "step and shoot" option which means the XRT moves to a defined position, stops and then takes an exposure. Overall, however this approach takes more time.
- Scan Time. This should of course be as short as possible. Even with standard 2D mammography there can be motion artefacts, and the risk of this is greater in tomosynthesis. In practice reducing motion artefacts depends greatly on the ability and experience of the radiographer in positioning the breast.
- Whole Breast. The systems need to be able to image the entire breast in one scan.

In designing systems to deal with such aspects there are many

parameters involved, which frequently involve design trade-offs and compromises, but the two key factors are :

1) The number of projections. This is directly analogous to CT: the more projections, the fewer artifacts

2) The scan angle. Increasing the scan angle results in higher depth or z-axis resolution, so there is less tissue superimposition, less anatomical noise as well as the increased z-axis resolution [Figure 3]. All tomosynthesis manufacturers produce images with slices that are 1mm apart but this does not mean that all slices are actually 1 mm in thickness. In fact the thickness of the slice is poorly defined in the z direction. What is clear however is that the greater the scan angle, then effectively the thinner the slice. So, in theory, it would be ideal to have an increased number of projections and a wider scan angle for increased z-axis resolution. In practice this ideal is constrained by the detector performance, the need to limit radiation dose exposure and the scan time.

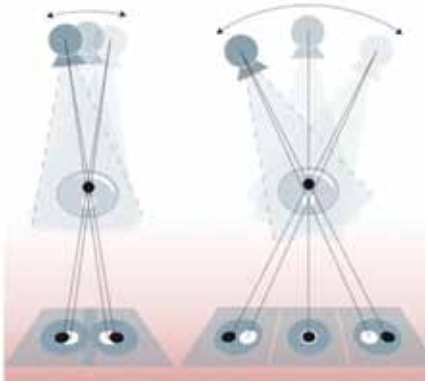

Figure 3. The effect of scan angle. An increased scan angle results in increasaed tissue separation, with less superimposition, less anatomical noise and increased z-axis resolution. This design can be constrained by the need to reduce radiation dose and scan time.

In view of all this, it is not surprising that different manufacturers have ended up with different combinations of design parameters, with consequent differences in image characteristics.

Take-home message

- A number of DBT systems from different manufacturers have regulatory approval.
- Manufacturers have used different combination of techniques and technologies
- The optimal combination of factors has not been determined
- Differences between systems could:

-potentially result in different clinical outcomes

-make comparison between clinical trials problematic

New tomo reconstruction algorithms: clinical experiences

Prof. Detlev Uhlenbrock

Prof. Detlev Uhlenbrock, Dortmund, Germany
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Dr Uhlenbrock started his presentation by pointing out that although digital breast tomosynthesis (DBT) is by now a validated and well-proven method there is still room for improvement, notably to overcome several current restrictions.

Tomosynthesis Angle

One of these is the question of the tomosynthesis angle. DBT systems developed by different manufacturers have different tomo angles, with the Siemens' system having the widest angle, (namely a total angle of 50°) and the largest number of projections (25).

Laboratory experiments can be used to examine the precise impact of the tomo angle. Thus, in experiments to study resolution using a PMMA phantom containing two steel balls of 1mm diameter situated 6mm apart, it is found that a wider scan angle can show separation of the steel balls, while a narrower angle cannot.

Iterative reconstruction

The Enhanced Multiple Parameter Iterative REconstruction (EMPIRE) is a new reconstruction algorithm introduced by Siemens for their tomo system. It operates in several steps:

• Artifact Suppression

There are several high attenuation structures which cause so-called artifacts, e.g. macrocalcifications; microcalcifications; dense tissue; and metal structures, such as clips or biopsy needles. In practice, the EMPIRE system uses outlier detection to eliminate an artefact. Normally with FBP the values of pixels are back projected to reconstruct the voxel, so if the pixel has a different value due to an artefact, this will be included in the back-projected voxel. The EMPIRE system uses statistically based machine learning algorithms to identify such a pixel as an outlier and thus enables suppression of the pixel by carrying out the back projection only with the remaining pixels.

• Super-resolution reconstruction.

Step 2 of the EMPIRE system involves artefact reduction using super-resolution reconstruction. In experiments using 1 mm thick slices the "normal" non-EMPIRE reconstruction results in "smearing" of microcalcification into the slices above and below a particular slice. Such smearing is retained in the voxel reconstruction and so the image quality is reduced, with the result that in the final images, the calcifications appear faded and details are lost.

With the new EMPIRE technology 0.2 mm slices are reconstructed and merged into 2 mm slices without smearing so that the contrast of calcifications is preserved in the 2 mm slice. The overall result is that the calcifications look brighter and details are retained.

• Iterative Noise Filtering.

In the third step of EMPIRE reconstruction, a system of iterative noise filtering is applied to every slice of the tomosynthesis volume. It preserves edges and microcalcifications as the algorithm has been manually optimized on clinical data sets.".

Take-home Message

The take-home message is that EMPIRE is an important advance in providing improved image quality, especially in terms of handling artefacts and in improvement of signal-to-noise ratio, [Figure 4].

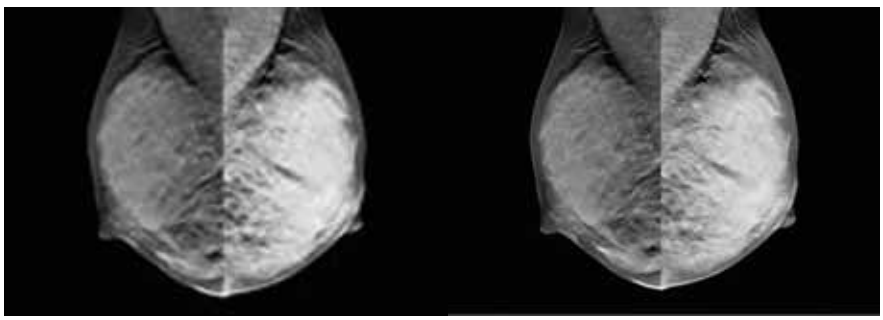

Figure 4. The effect of the new EMPIRE iterative reconstruction algorithm. Left Panel without EMPIRE. Right Panel with EMPIRE

Can enhancing the MRI in-bore experience reduce the need for patient sedation?

By Dr J. Kesseböhmer

During an MRI scan a patient has to lie still, all alone in the bore of the MRI scanner for often as much as 20 to 45 minutes, depending on the indication.

We found in our practice that a focus on improving this "in-bore" experience helps us increase patient satisfaction and reduce the need for sedation.

The capabilities of MRI are remarkable, providing insights that no other commonly used imaging technology can offer and making it an invaluable tool in diagnosing a broad range of conditions.
However, for patients, MRI exams can be long, stressful, noisy, anxiety-filled experiences, making it sometimes hard to complete the procedures appropriately. Particularly for patients who are anxious, restless or in pain, it is difficult to remain still during scans, thus increasing the likelihood of in-bore movement. This movement can lead to motion artifacts in the images, which therefore require rescans or even exam cancellations We then often have to plan a new MRI examination that incorporates the administration of sedation to relax the patient.

Sedation is a commonly used approach to allow patients to undergo an MRI examination without major patient movement. In our practice, we see three scenarios of patients needing sedation for a successful MRI examination:

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for patients with a history of requiring sedation, we know beforehand that they will need it and so are prepared; secondly, there is a group patients who get very anxious upon entering the MRI room. They are offered sedation right at that moment. A third, and fortunately small, group are patients who actually start a scan but then appear incapable of completing it.
The need to sedate patients can pose significant operational disruptions and administrative burdens for imaging centers. Evaluating whether a patient needs sedation takes time, as well as the additional handling and constant monitoring, needed because of the risk of respiratory depression. For the patient, there are also practical considerations, such as dizziness, nausea and the advice/requirement not to drive directly after their MRI exam. These factors can negatively affect both the patient and staff experience, and raise costs.
Patient satisfaction has always been a priority at our practice, in Lübeck, Germany, with our patients

With the Philips Ambient Experience patient in-bore solution for MR, engaging visuals are displayed on the back wall and can be seen via a mirror on the head coil, while patients can listen to music/sound through the headphones.

Anxiety before or during an MRI examination can lead to reduced diagnostic accuracy, aborting of the scan and unwillingness to undergo another MRI examination in the future.

accustomed to having a high degree of comfort during scans. When our practice made the decision to purchase a new MRI system, we wanted to continue to provide at least the same high level of patient comfort for which we are known and we wanted our new system to be a clear differentiator from other practices in the area.

We purchased the Philips Ingenia 1.5T S with its in-bore solution to adhere to our high standard of patient comfort. The room lighting and the in-bore experience provide a relaxing environment through an immersive video experience during the scan, that we expected to enhance patient comfort and cooperation, as well as improve workflow.

Like other practices, we had accepted sedation as an unavoidable aspect of reaching a definitive diagnosis in certain cases. However, we understood the value of Philips' Ingenia solution in providing a relaxing environment and we believed we could have a measurable impact on patient anxiety due to the distracting nature of the in-bore solution.

"... We scanned more than five hundred patients during a five-week period, and found a significantly lower need for sedation among patients scanned with the Philips system..."

Six months after installing the system, we conducted a retrospective survey on patient experience, and also reviewed practice data. Those retrospective preliminary data suggested that we were using much less anxiolytic and sedative medication for patients in the Ingenia MRI system with in-bore solution.

We then decided to conduct a study to compare the Philips Ingenia 1.5T S with MRI In-Bore Experience with our institution's two short-bore 1.5T systems. All three systems had a 70 cm wide bore diameter.

Using the need for anxiolytics as an indicator of the anxiety experienced by the patient during the exams in each system, we initiated a study to confirm our retrospective observation that the Philips system would decrease patient anxiety. We scanned more than five hundred patients during a five-week period, and found a significantly lower need for sedation among patients scanned with the Philips system. The number of patients requiring sedation while being scanned with the Philips MRI In-Bore Experience decreased by 80% versus the average of the two short-bore systems [1]. We discovered that our patients were calmer and more compliant when scanned using the Philips MRI In-Bore Experience, in addition to an observed improvement in our already generally low cancellation rates.

What's most exciting for us, collectively as a practice and as individual radiologists, is seeing how continued innovation helps us maintain and improve the patient experience.

We now know that use of anxiolytics is not an inevitability in MRI and this is great news for our patients.

A calming, comfortable patient experience can lead to a smoother exam and increased patient satisfaction.

REFERENCES:

1. 2017 case study in Radiologisches Zentrum am Kaufhof, Lübeck, Germany (n=583).

DISCLAIMER

Results represent a case study performed at single location. Results from case studies are not predictive of results in other cases. Results in other cases may vary.

The tranquilizer referred to is the valium-based derivative "Diazepam".

Greek center of excellence in ultrasound and elastography

The Diagnostic Echotomography/Echomed Day Clinic in Kifissia, Athens, Greece has a deserved and well-established reputation of being a center of excellence in the field of ultrasound and elastography imaging.

The Center has recently acquired a new Mindray elastography system. We wanted to find out more about the center in general and how the new elastography system was performing in particular, so we spoke to Dr Pavlos Zoumpoulis MD, PhD radiologist and director of the Day Clinic.

Dr Pavlos Zoumpoulis MD, Ph.D., is radiologist and director of the Echomed Day Clinic in Kifissia, Athens, Greece.
email p.zoumpoulis@echomed.gr

Q *Let's start with your Center in general. How many patients do you see annually? From which geographical area do the patients come? Is your center associated with any particular hospital?*

Founded in 1985, Echomed is an independent medical company that is, as the name suggests, focussed on and specialized in ultrasound (US). We see approximately 20,000 patients per year in Echomed, and this number is steadily increasing year-on-year by about 10%. Our patients mainly come from all over Greece, but in addition we have a small number of patients who come from neighboring and Eastern European countries, such as Albania, the Former Yugoslav Republic of Macedonia (FYROM), Bulgaria, Kosovo, Ukraine and Moldavia).

Although Echomed is a stand-alone institute we have close working associations with the hepatology departments of the Laiko and Ippokrateio University Hospitals, both of which are in Athens and are specialized in all liver disorders. Likewise we have close relations with the oncology unit in the University Hospital of Patras to the west of Athens. This unit is specialized in prostate cancer.

We see 50-70 cases of Chronic Liver Disease (CLD) of different causes per week. Approximately 45% of those cases are suitable for incorporation in the many clinical trials we are running, requiring either a liver biopsy, a Fibroscan (classical elastography scan) or a Fibrotest (measurement of serum markers of liver disorders). We carry out 8-12 US/Shear Wave Elastography (SWE) -guided or US/MRI fusion-guided prostate biopsies per week. We also perform approximately 4-6 US-guided fine needle thyroid biopsies per week.

"...All this generates an exciting feeling that we are entering a spectacular new era in US imaging..."

Q *Now, what about the equipment you have in order to deal with all these patients — ultrasound of course but what about other imaging modalities?*

At Echomed we are entirely focussed on ultrasound — whether it be preventive, diagnostic or therapeutic US -guided interventions. We also have an endoscopy unit but, apart from the ultrasound and endoscopy, we don't have any other imaging modality. We have six examination rooms which are all interconnected so our medical teams always have the possibility of easily getting a second opinion on any challenging cases.

We have recently implemented a new RIS/PACS system, which we find particularly useful since the scientific module of the system helps us to store data for the protocols of the examinations we are carrying out and also for the clinical trials we are involved in. The RIS/PACS has a module for transmitting images, videos and reports to the referring physicians including dictated oral comments from the examiner.

It also includes a web-app that can be accessed by the patient via the patient's own mobile phone. This helps us in offering personalized services to our Echomed patients. The PACS/RIS of course also includes an archive of all exams performed in Echomed and allows easy comparison between new and prior images.

Q *And the personnel to run the equipment?*

We have a total of 11 doctors comprising six radiologists, two gastroenterologists, one cardiologist, one gynecologist, one pathologist and one anesthesiologist, each one dealing with a specific field of diagnostic and interventional US, e.g.. US/ MRI fusion-guided biopsies,

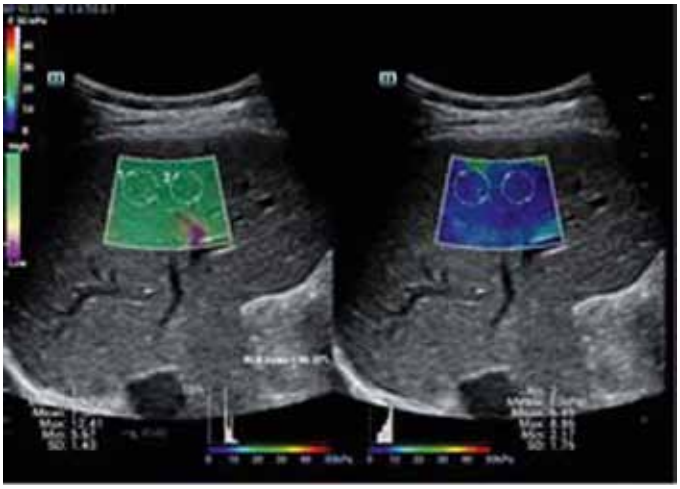
contrast-enhanced ultrasound (CEUS), cardiology, vascular, musculo skeletal imaging (MSK), urogenital/prostate, breast, thyroid/lymph nodes.
We also have an in-house software specialist who mainly deals with the RIS/PACS system support and Echomed's internet presence (websites, social media, etc.).
In addition there is a medical physicist who deals with our research activities, as well as with the communication and collaboration with the R&D departments of the US equipment constructors who are associated with Echomed. A Senior Data Scientist supervises the collection of data, especially for the clinical trials and research projects as well as collating our scientific publications. Our personnel numbers are rounded off by a nurse and all this structure is supported by five staff members dealing with the necessary administration.

Q *Let's turn more specifically to elastography. Since when have you had your system? What were the reasons for its purchase? Was there a significant learning curve? For what type of cases do you use it?*

We have been working in US Elastography for ten years now, during which period we have used many different elastography technologies. As for hepatology, we started off using Fibroscan and we are now continuing using the recent Shear Wave Elastography (SWE) applications. Regarding the prostate, we started using the first Strain Elastography technique that was introduced to the market but now are currently using the recent SWE applications for reliable guidance of prostate biopsies.

Q *So why this focus on — and invesment in — elastography?*

Ever since the early years of US, we have accumulated a lot of experience with the technology and since then we have followed and evaluated many US-based innovations and applications. Some of these developments are of undoubted clinical value, some are important research tools, and some are only "gadgets" of doubtful value.
We have however thankfully progressed from the early days of the introduction of elastography, during which constructors generally claimed that elastography was the answer to all problems.
We are now confident that the recent SWE applications with dedicated transducers belong to the first category, namely that of the most clinically important group of technologies.
The precise usefulness of these applications varies depending on the different pathologies, e.g. cancer vs. chronic disease, and also on the organ being examined, e.g. superficial organs such as the breast or thyroid vs. more deeply situated organs such as liver, kidney, or prostate.



LIver examination using SWE. The Shear Wave Elastography technology of Mindray's Resona 7 system is based on the company's exclusive Ultra Wide Beam Tracking for faster and more precise imaging. It realizes real time imaging with comprehensive quantification metrics for enhanced diagnostic confidence.

The investment we have made in elastography is directly related to the importance we attribute to its use in a number of crucial SWE applications:
1. **Liver.** Staging and grading of CLD and Non Alcoholic Steatohepatitis (NASH)
2. **Breast.** Down-grading borderline lesions seen in mammography
3. **Prostate.** Improved biopsy guidance by applying elastographic criteria to tumor-suspicious lesions. In this application elastography can play an important role in differentiating types of prostate adenocarcinoma. Such differential diagnosis is important not just to optimize the patient's well-being and outcome but also for the emotional and socio-economic consequences of the over-diagnosis and over-treatment frequently associated with prostatic adenocarcinoma.
4. **Thyroid and Lymph nodes.** Discrimination of the suspicious "hard" segment of a nodule and appropriate guidance of the biopsy needle.
5. **MSK/Skin**. Guiding therapeutic or cosmetic interventions.

"...SWE has been added to the imaging arsenal of the physician and is here to stay..."

Thus, now that we are convinced of the realistic uses and benefits of SWE in the above applications, we are in a position to be able to invest in appropriate elastography technology, equipment and probes. Choosing the equipment is not easy since various constructors propose several different elastography solutions in the respective anatomical application.

Finally and taking into account the B-Mode, Color Doppler and Elastography performances we opted for the Mindray's Resona 7.

Q *What were the reasons for that choice?*

The criteria we applied were the ability of the system to routinely handle the above anatomy/pathology applications for the organs we are interested in, namely, liver, breast, prostate, thyroid, & MSK.

There are currently a small number of specialized US machines on the market on which one can depend for reliable answers to crucial questions concerning the stiffness of certain specific tissues with different properties and in different anatomical situations.

But what we were looking for was a heavy-duty, multi-purpose US equipment able to carry out all US exams of the whole body, from head to toe. SWE alone can provide stiffness measurements in a number of organs.

We are no longer in the era of the single-line, non-guided elastography measurement offered by Fibroscan.

In stark contrast to the old Fibroscan, with modern high-end US/SWE machines a physician or clinician can, with the same system, acquire:

1. High-definition B-Mode images for a precise anatomical morphologic visualization of all organs
2. High quality color and pulsed Doppler images for reliable hemodynamic evaluation of the vasculature of the organs.

"...B-mode and Color Doppler are crucial, and related, aspects of the uinderlying technology. Elastography can now be added as the third, vital facet..."

These two features, i.e. B-Mode & Color Doppler, are crucial, and related, aspects of the same underlying technology. Elastography can now be added as the third vital facet.

However for SWE to be in practice applicable to every organ and in all anatomic regions — some of which can be technically difficult — it must come in an US/SWE machine with solid B-Mode and Color Doppler functionality. The three components together form a powerful multiparameter US/CD/SWE imaging tool.

To realize the full potential of SWE and its applications there is however a learning curve to be climbed. This can be long, depending mainly on the level of already acquired US education and training. We find that courses on the theory and physical principles behind SWE are vital since an understanding of the actual production of Shear Waves helps the practitioner considerably in the acquisition of reliable diagnostic images. In our experience, we have found that a six-months training course with the system carrying out 4-6 SWE exams every day under the supervision of an experienced practitioner is sufficient to attain an appropriately high level of expertise.

We at Echomed fully acknowledge that there can be complex educational and training issues associated with elastography. Our response to this need is the organization of theoretical and practical elastography courses which are in practice carried out by Echonet, our affiliate company. Echonet uses Echomed's teaching and training facilities in order to achieve its educational purpose.

Q *And the future? How do you see technological or other developments in the future?*

SWE has been added to the imaging arsenal of the physician and is here to stay. SWE has already been shown that it can provide useful information in the imaging of many, if not all organs that are accessible by US. We are already working on prototypes for imaging in MSK, vessels and the kidneys. All this generates an exciting feeling that we are entering a spectacular new era in US imaging.

However as regards innovation in US, it shouldn't be considered that SWE is the only new area of development:

In fact, B Mode US is now pushing new frontiers regarding the quality of the US image. Likewise, SW image analysis can in many organs now provide more detailed information concerning their fat, fibrotic tissue and heavy metal content. The technology of Color Doppler is also progressing rapidly, particularly with the involvement of, and collaboration between specialized clinicians on the one hand and medical physicists and biomedical engineers on the other. Such collaborative approaches have already generated promising results on the hemodynamic characterization and behavior of all organs. The technology of CEUS and its applications are also expanding dramatically.

US alone, or with SWE as a hand-in-hand companion, is already becoming the "*sine qua non*" diagnostic tool for all health professionals, including doctors of all specialties. This trend, along with the continued miniaturization of the instrumentation looks set to keep US at the leading edge of all health services, ranging from the patient's bedside at home to the advanced surgical operating room of a university hospital. Hand-held equipment and mobile based wireless US transducers may produce crucial preventive, diagnostic and therapeutic analysis of symptoms.

One of the central guidelines for the education of medical students, nurses and midwives has to be the inclusion, early in the study curriculum, of appropriate training in US. Recognizing this, the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) has initiated the implementation of traditional and web-based courses to meet the need.

"...US.. with SWE as a hand-in-hand companion is already becoming the "sine qua non" diagnostic tool for all health professionals...."

The broad expansion of US could also be accelerated with the onset of the era of "Big Data" and Artificial Intelligence. The implementation of "Real World Data" could revolutionize the field of medical health, not just in terms of research but also for improving the outcomes of almost all acute or chronic medical conditions. Machine Learning technologies, along with the revolution of the "Internet of Things" , is in general making knowledge ever-more accessible.

In particular this should promote US even further as a key factor in improving the cost-effectiveness of medicine in the years to come.

Guidance issued on radiation dose monitoring software

The mission of the U.K.'s National Institute for Health and Care Excellence (NICE) is to provide national guidance and advice to improve health and social care. A recent innovation briefing (MIB127) issued by NICE in NOVEMBER 2017, provides advice on the use of radiation dose monitoring software for medical imaging with ionising radiation to aid local decision-making. The technologies described in the briefing are eight radiation dose monitoring software technologies from different suppliers. The sytems automatically gather and analyse information on patients' exposure to ionising radiation from medical imaging and X ray-guided procedures.

The systems described and the producing company are DOSE (Qaelum); DoseM (Infinitt); DoseMonitor (PACS Health); DoseTrack (Sectra); DoseWatch (GE Healthcare); DoseWise (Philips); OpenREM (OpenREM); Teamplay (Siemens Healthineers). Dose-related data from medical imaging with ionising radiation can be systematically collected, monitored and analysed in a largely automated way with the systems. The technologies are designed to improve image quality while minimising radiation exposure to the patient. The intended use of the systems is to replace manual radiation dose data collection for people undergoing medical imaging with ionising radiation. The key points from the evidence summarised in this briefing are from ten studies investigating three of the technologies. Most of the evidence comes from retrospective observational studies, four of which are available as conference abstracts only. The software varies in technical features, allowing for various ways to acquire and analyse data from different kinds of imaging. Key uncertainties of the briefing are that published evidence is only available for three of the included technologies. None of the studies were comparative. The cost of the technologies ranges from no cost to £20,000 per year, depending on local requirements. Some companies also charge a fee per modality price that varies according to patient numbers, whereas some offer the software as free and open source. With adequate resource input and time to implement the technologies, the resource impact may be faster and more detailed audits of radiation exposure data compared with standard manual audits.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE)
LONDON, U.K.
www.nice.org.uk/advice/mib127

Dutch national breast cancer screening program decides on mammography systems

Hologic has announced that, in partnership with Tromp Medical, Hologic's distributor in the Netherlands, it will provide all mammography systems for the Dutch Breast Cancer Screening program. Under the tender, Hologic's new, state-of-the-art 3Dimensions mammography systems will be installed in mobile and stationary screening facilities across the country, starting in 2018. The multi-year agreement is the result of a comprehensive public procurement process conducted by Facilitaire Samenwerking Bevolkingsonderzoeken (FSB) on behalf of the five regional screening organizations responsible for nationwide breast screening in the Netherlands. The Dutch Breast Cancer Screening program provides women between 50 and 75-years-old with a mammogram once every two years. Through the program, approximately 1.3 million women in the Netherlands are invited for screening each year. "*Hologic is grateful for the opportunity to extend access to its new, state-of-the-art 3Dimension system to Dutch women starting in 2018,*" said Jan Verstreken, Hologic's Regional President for EMEA and Canada. "*We were proud to learn that during the procurement process, the 3Dimensions system was ranked number one in ergonomics and patient comfort by clinicians and screening participants, and are hopeful that all Dutch women will take advantage of the invitation to get screened on this system.*" On behalf of the five regional screening organizations, the FSB launched a public procurement process in 2016. A special prioritization was placed on finding new digital mammography systems that would improve the ergonomics of the screening experience for clinicians and the participating women. In addition to extensive testing among clinicians, a group of 30 participants in the screening program underwent tests on the equipment of all bidders. Both clinicians and participants ranked the 3Dimensions system number one in ergonomics and patient comfort.

In Europe, the 3Dimensions system is available in both 3D and 2D configurations. The 2D system is easily upgradeable to Hologic's 3Dimensions, which has been shown to detect up to 65 percent more invasive breast cancers and is the only mammogram approved by the U.S. Food and Drug Administration as superior for women with dense breasts compared to 2D alone.

HOLOGIC,
MARLBOROUGH, MA, USA
www.hologic.com

CE approval for capsule endoscopy system

The Silicon Valley-based company CapsoVision has announced CE Mark approval for its CapsoCam Plus System in patients ages 2 and above. The systems is the only wire-free capsule endoscopy system on the market that provides a full 360° panoramic lateral image of the small bowel mucosa.

"*Gastroenterologists and patients have told us that CapsoCam Plus provided them with comfort and convenience compared to other capsule endoscopy systems,*" CapsoVision President Johnny Wang said. "*Since CapsoCam Plus does not require patients to wear a data recorder as with ordinary capsule endoscopes, these benefits are more pronounced for use with younger patients and their caregivers.*"

The incidence of Inflammatory Bowel Disease (IBD) in pediatric patients worldwide is on the rise, particularly in Europe. According to a recent report commissioned by United European Gastroenterology (UEG), childhood onset of IBD now accounts for 20-30% of all IBD cases. Capsule endoscopy is one of the tools that pediatric gastroenterologists use to identify abnormalities of the small bowel that may lead to an IBD diagnosis.

Dr. Salvatore Oliva, pediatric gastroenterologist at the Sapienza University of Rome, Italy, gave a presentation discussing the use of CapsoCam Plus in patients ages 2 and above at the recent United European Gastroenterology Week (UEGW) in Barcelona on October 31, 2017.

CapsoVision mission is defined as being to strive to empower physicians and patients with innovative technologies that will provide superior clinical outcomes and improve quality of life. CapsoVision is currently working in 70+ countries through strong distribution partners. The innovations embedded in the CapsoCam Plus system are seen to enhance physician experience in observing and diagnosing small bowel abnormalities while providing unparalleled comfort, convenience, and freedom to patients.

CAPSOVISION
SARATOGA, CA, USA
www.capsovision.com

PSV football club uses portable ultrasound to evaluate its players' injuries

Philips has announced that the Dutch football team PSV Eindhoven will be the first professional soccer club in the world to use Philips' Lumify portable ultrasound for the diagnosis of injuries and the acute care of its players.

When using current ultrasound options in the hospital to analyze a player's injury, the process of transportation, consulting a clinician and reaching a diagnosis can take several hours, delaying the treatment plan and creating anxiety for the patient. With the Lumify portable, smart-device based ultrasound solution, PSV's medical staff will be able to make an initial diagnosis of suspected injuries immediately, at the point of care.

"*Philips Lumify is an extremely beneficial tool, and particularly useful in an environment where immediate injury analysis is needed,*" said PSV's Medical Director Wart van Zoest. "*We can now make diagnoses and decisions much faster, anywhere in a sports complex and even when we're traveling to remote training locations with no hospital nearby. This enables us to offer better care to our players and address injuries as soon as they happen.*"

Lumify is Philips' first app-based mobile ultrasound device that offers diagnostic capabilities for compatible smartphones and handheld devices.

With advanced ultrasound processing built into Lumify hand-held ultrasound transducers, a physician simply needs to download the Lumify app to a compatible tablet or smartphone, connect the transducer and initiate the scan. The Lumify enables physicians to make fast, informed decisions where needed, to facilitate more expeditious care.

Featuring exceptional image quality, Lumify has a variety of clinical applications, including cardiology, abdominal, musculoskeletal, lung and obstetrics/gynecology exams. Equipped with the full range of transducers, physicians have the ability with Lumify to assess a number of different potential injuries.

"*Philips' app-based ultrasound delivers exceptional image quality through a compatible smart device*", said Carmen Silverstandt, Business Manager Ultrasound at Philips Benelux. "*This supports our vision of putting high-quality*

ultrasound in the hands of more professionals to serve more patients in more locations."

Philips and PSV Eindhoven have a unique partnership that spans more than a hundred years. Philips employees founded PSV in 1913, and since then the soccer club, which is based in Eindhoven, has played in both national and European leagues. Philips has been closely involved with PSV's activities, not only as sponsor but also by providing cutting-edge technologies to support the club.

PHILIPS
EINDHOVEN, THE NETHERLANDS
www.philps.com

Three new subspecialty radiology journals launched

The Radiological Society of North America (RSNA) has announced that it will begin publication of three new subspecialty journals in 2019. The journals will be published solely online and will cover the topics of cancer imaging, cardiothoracic imaging and machine learning/artificial intelligence.

The cancer imaging journal will address cancer screening, differential diagnosis and treatment planning across imaging subspecialties, organ systems and modalities and present an interdisciplinary perspective on cancer imaging.

The cardiothoracic imaging journal will emphasize research advances and technical developments in imaging that drive cardiothoracic medicine.

The machine learning/artificial intelligence journal will highlight the emerging applications of machine learning and artificial intelligence in the field of imaging across multiple disciplines.

"The RSNA Board of Directors is tremendously excited about the society's new journals," said board chair, Dr Valerie P. Jackson. "These will build upon RSNA's long tradition of publishing the premier journals in our field".

RSNA currently publishes two peer-reviewed journals. Radiology is the authoritative reference for the most current, clinically relevant and highest quality radiology research. RadioGraphics, with its educational content, is a leading source for earning continuing medical education credits. The new journals will complement Radiology and RadioGraphics and provide a way to keep practicing physicians and imaging researchers up-to-date on the best emerging science in each subspecialty.

RSNA members will receive access to all of these journals as a benefit of membership.The subspecialty journals will accept new submissions in 2018 and will also provide a forum for transferred submissions within the family of Radiology journals. Each journal will contain a mix of original research and topical reviews. The search for editors for the journals will begin in November 2017.

www.rsna.org

No end in sight for UK's radiologist staffing crisis

Figures recently released by The Royal College of Radiologists (RCR) underline the increasingly desperate situation in UK radiology, with the ongoing shortage of imaging doctors making late hospital diagnoses and delayed scan results a very real likelihood for patients.

In 2016 the NHS paid out an estimated £88 million for out-of-hours reporting of X-rays and CT scans, while nearly two-thirds of vacant radiologist posts sat empty for 12 months or more.

Key findings of the Clinical radiology UK workforce census 2016 report include;

Nearly one-in-ten UK radiologist posts (8.5%) were vacant during 2016, nearly two-thirds of which (61%) were unfilled for a year or more

The need for scans continues to grow. In England from 2013-16 the number of computed tomography (CT) and magnetic resonance imaging (MRI) scans respectively rose by more than 30% - three times more than the rate of workforce growth. Technological advances mean that these scans are more complex than ever before and take longer to interpret

The high proportion of retirements versus new consultant numbers means the UK's radiologist workforce will expand by just 1% year-on-year

The Royal College of Radiologists

Last year, only 3% of NHS imaging departments were able to report all their patient scans within normal working hoursThe NHS spent nearly £88 million in 2016 paying for backlogs of radiology examinations to be reported – the same amount could have paid for at least 1,028 full-time consultants.

The workforce report highlights the critical UK-wide problem of not have enough imaging doctors to fill hospital vacancies.

Across the UK as a whole, 8.5% of radiologist posts are unfilled. In Wales, 13.1% of posts are vacant, whereas Northern Ireland has the highest vacancy rate, with 20% of posts now empty.

Around a fifth of the radiologist workforce is going to retire across the UK, England and Scotland within the next five years, whereas in Wales that number jumps to 30%.

Region	Number of radiologists (part- and full-time workers)	Radiologists per 100,000 (consultants only)	2016 Vacancy level	Retirement rate over next 5 years	2016 Estimated NHS outsourcing cost
UK	4970	4.9	8.5%	22%	£87.9m
England	4131	4.8	7.4%	22%	£71.1m
Scotland	454	5.5	10%	19%	£4.6m
Wales	216	4.9	13.1%	30%	£4.5m
Northern Ireland	169	6.0	20%	13%	£6.5m

The UK has the third lowest number of radiologists per population of 31 audited EU countries, with 7.5 clinicians (radiology trainees and consultants combined) per 100,000 patients. The EU average is 12.7 per 100,0002.

Meanwhile, the NHS continues to spend millions to cover the shortfall in radiologists. Last year, the UK spent an estimated £87.9m on paying for its backlog of radiology examinations to be reported, with the bulk spent by English hospitals (£71.2m). Northern Ireland spent £6.5m in 2016, Scotland £4.6m and Wales £4.5m.

Dr Nicola Strickland, President of The Royal College of Radiologists, said:

"So much of modern healthcare depends upon diagnostic imaging scans and interventional radiology.

"The UK Government seems intent on sticking its proverbial head in the sand, constantly failing to invest in the much-needed trainee radiologists who will become the consultants of tomorrow. Instead, it is content to waste millions of pounds of NHS funds paying for scans and X-rays to be reported out-of-hours, as well as paying for expensive locum consultants just to keep hospital imaging departments afloat.

"Previous RCR workforce figures have made grim reading, and sadly 2016 numbers show there is no end in sight for the UK's ongoing shortage of radiologists. The only lasting way to sort out this problem is to invest now in training many more radiologists, which will more than pay for itself in the near future".

"Scans are integral to patient care, and demand for X-rays, MRI and CT scans is growing every year. As well as doctors having more scans to report, improving imaging technology means these scans are becoming ever more complicated, taking longer to interpret. Cutting-edge radiology, such as life-altering stroke intervention and cardiac imaging, can only keep pace if we have enough radiologist doctors to do it. Without more radiologists, more patients will miss out on vital new interventional procedures, and they will wait even longer for diagnoses of cancer and serious diseases."

www.rcr.ac.uk

Clinical trial results published of intraoperative imaging technology in breast cancer surgery

Lightpoint Medical, a medical device company focused on developing innovative imaging technologies to improve cancer surgery, today announced positive clinical trial results for its intraoperative imaging technology in breast cancer surgery. The first-in-human clinical trial showed that intraoperative molecular imaging was a feasible, low-risk, and accurate procedure for assessing tumor margins intraoperatively. The study was conducted by Guy's and St Thomas' Hospital London, UK and published in the Journal of Nuclear Medicine. Breast-conserving surgery (BCS), also called lumpectomy, is the primary treatment for early-stage breast cancer yet approximately 1 in 4 patients undergoing BCS will need to undergo repeat surgery. Repeat operations are required so frequently because surgeons lack a means to precisely detect the cancer in the initial surgery. Intraoperative molecular imaging potentially provides a means to assess the extent of cancer during surgery and reduce the need for repeat operations.The study's Principal Investigator, Professor Arnie Purushotham from King's College London and Guy's

Hospital, commented: "We're delighted to present these exciting first-in-human results on the use of intraoperative molecular imaging in breast-conserving surgery. This clinical trial showed that molecular imaging agreed strongly with gold standard pathology and was straight-forward to interpret. Although the technology is still in its early days, we believe intraoperative molecular imaging holds considerable promise for improving clinical outcomes in breast cancer patients."

Dr David Tuch, CEO of Lightpoint Medical, said: "These pilot clinical trial results are an important step in Lightpoint Medical's mission to provide clinicians with more accurate tools to guide cancer surgery. We look forward to undertaking further clinical trials to validate these results in larger patient populations."

The LightPath Imaging System is CE Marked and approved for sale in the European Union. The clinical trial was supported by funding from Innovate UK, Cancer Research UK King's Health Partners Experimental Cancer Medicine Centre, Guy's and St Thomas' Charity, and the National Institute for Health Research (NIHR) Biomedical Research Centre at Guy's and St Thomas' NHS Foundation Trust and King's College London.

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www.lightpointmedical.com

Canon makes a splash in global healthcare

Last year, the Japanese tech giant Canon Inc. acquired Toshiba Medical Systems Corporation, a leading manufacturer and seller of medical imaging devices. The move propels Canon deep into the global healthcare market and promises a host of synergies for delivering world-class medical devices and solutions.

Fujio Mitarai, Chairman and CEO, Canon

The first president of Canon, the global camera and printer giant, was an obstetrician named Takeshi Mitarai. And since its establishment in 1937 in Tokyo, Canon manufactured digital radiography and ophthalmic equipment, but had never developed a large global presence in medical devices. Last year, the company returned to its roots with verve. In a whopping 665.5bn yen (5.47bn US dollar) deal, Canon acquired Toshiba Medical, a leading manufacturer of medical imaging devices, propelling the group into the global healthcare business.

"*As Canon's first president was a doctor, there was always a yearning to make healthcare one of our main businesses*," says Fujio Mitarai, Canon's Chairman and CEO. "*We are delighted that Toshiba Medical is joining our group; it feels as if our dream of launching into the global healthcare market has been achieved, all in one fell swoop*."

CANON'S FOUR NEW GROWTH AREAS

The latest acquisition is certainly not mere nostalgia, but an integral step in the transformation of the $29.3bn-revenue company (as of 2016). In recent years, the markets for office equipment and cameras – which have for long been Canon's core businesses – have undergone structural changes, including market maturation and the proliferation of smartphones. In response, the company has been pursuing a multi-pronged strategic shift of its business model. Its latest five-year plan focuses on pivoting away from consumer electronics to business clients in its traditional domains, while searching for new growth areas with affinity to its core competencies. The plan is ambitious: group revenues are targeted to increase to over 5 trillion yen ($44bn) with operating profit margins over 15 per cent and net profit margins of over 10 per cent for the Canon group by 2020.

Toshio Takiguchi, President and CEO, Toshiba Medical

The purchase of Toshiba Medical, finalized in December of last year, completes the re-alignment of the tech company and is expected to serve as a primary engine towards this medium-term goal.

"*We have now lined up new businesses in four key growth areas – commercial printing, network cameras, industrial devices, and healthcare,*" says Chairman and CEO Mitarai. "*From this year, we plan to redouble our efforts, particularly in healthcare.*"

Indeed, the purchase of Toshiba Medical comes fast on the heels of a series of industry-shaping M&As by Canon. In 2010, the company purchased Dutch Océ, expanding laterally into the digital commercial printing domain. Canon has also committed deeply to the burgeoning video surveillance market with purchases of Danish Milestone Systems in 2014 and Sweden-based Axis Communications in 2015. The Japanese company now has the largest network camera business in the world.

Although no major purchases have taken place in its third target area of industrial devices, the company's subsidiary in that domain is in rude health. Canon Tokki Corporation's production capacity is being expanded to meet strong demand for equipment used in producing organic electroluminescent displays (OLED) found in smartphones.

PIVOTING TOWARDS HEALTHCARE

And now Canon has set its sights firmly on healthcare. Chairman and CEO Mitarai believes this to be "an area of the greatest potential", in light of global population growth and its affinity to Canon's technologies and corporate goals.

In both developed and developing markets, greater longevity and an expanding geriatric base of patients with chronic diseases related to the brain, and respiratory and cardiovascular systems are driving demand for diagnostic equipment. The market

for diagnostic imaging equipment was valued at $32bn in 2016, and is expected to grow at a compound annual growth rate of around 6 per cent in the next five years to $42.6bn in 2021, according to industry research . Currently, Siemens, General Electric, and Philips dominate, taking roughly three-quarters of the global market share, followed by Toshiba Medical and several smaller Japanese makers.

The purchase of Toshiba Medical puts Canon in an ideal position to compete in the medical imaging systems market. As one of the most profitable divisions within the Toshiba group, Toshiba Medical has over 86 years of history in developing and supplying medical diagnostic devices, technology, and services in 140 countries and regions across the world. The company is dominant in Japan for diagnostic imaging devices including CT (computed tomography), MRI (magnetic resonance imaging), X-ray radiology, ultrasound, and nuclear medicine. It also offers cutting-edge medical imaging solutions and in-vitro diagnostics aimed at precision medicine. The company is vying to become the second largest supplier of CT systems globally and is currently the fourth largest supplier of MRI systems in the world.

MADE FOR LIFE

"*Toshiba Medical has developed a lot of technologies and products which are Japan-first or world-first in diagnostic imaging,*" says Toshiba Medical's president and CEO Toshio Takiguchi.

The company developed the world's first super-quiet MRI system as well as pioneered non-contrast-enhanced imaging to ease the burden of patients undergoing examination. The company's lower radiation dose technology is standard in all its CT systems, which are constantly evolving to more rapidly, widely, and accurately diagnose patients

"*All of this product development is driven by our corporate philosophy – 'Made for Life' – which is focused squarely on the patient. Our mission is to listen to the needs of clinicians and help them to more efficiently diagnose their patients,*" says President and CEO Takiguchi.

In a fortuitous echo to Toshiba Medical's slogan, Canon is guided by its corporate philosophy of kyosei that "focuses on living and working together for the common good". Chairman and CEO Mitarai believes the company world-views are compatible, a vital point when integrating the two companies: "*I believe we have been able to share smooth conversations and develop plans together because our thinking overlaps in many areas.*"

SYNERGIES IN EXPANSION, EFFICIENCY, AND R&D

Such overlap, however, does not extend to the two companies' products and technologies, leaving plenty of room for synergies. Although acknowledging that these are still early days in the integration, the two executives expressed excitement over a wide range of future benefits from the deal.

The first area in which Canon is hoping for synergies is further acceleration into new healthcare businesses. Leveraging Toshiba Medical's strength in imaging diagnostics, Canon hopes to expand its presence in different healthcare businesses through strategic investing and M&A.

"*Canon has been in a small pond, unlike Toshiba Medical which has been in a large ocean, in terms of competing in medical devices,*" says Chairman and CEO Mitarai. "*So, we expect Toshiba Medical to take initiatives, including in the selection of M&A candidates, with the full backing and funding from the Canon group.*"

Canon is pleased to inherit the global sales network of healthcare providers developed by Toshiba Medical over decades. While President and CEO Takiguchi is hopeful that Canon's brand and sales network – know-how in customer relations, sales, and marketing – will open up new sales routes for Toshiba Medical's devices.

A second set of synergy gains is expected in improved production quality and cost-efficiencies. As government reforms tighten national health budgets in mature markets and newcomers drive down prices in emerging ones, competitive pricing in medical imaging devices will be critical. By applying Canon's know-how in optimizing design, manufacturing, and production, Toshiba Medical's existing offerings could be made more cost-competitive. Moreover, savings in production processes will then be used to fund next-generation medical technology.

And finally, there are the R&D synergies. President and CEO Takiguchi believes that the possibilities for innovations from joint development will be many: "*I am very curious about what kind of chemical reaction will result from applying Canon's optics and materials know-how to our products.*"

Indeed, Canon boasts a rich stock of cutting-edge technologies that could be combined with Toshiba Medical's capabilities. Notable ones include: high-speed dynamic X-ray imaging sensor technology, among other imaging devices, along with associated elemental technologies; photoacoustic tomography technology selected by Japan's national ImPACT program ; medical robotic system technologies; and minimally invasive technologies.

"*We are asking Toshiba Medical to make an inventory of all our technologies and see what they can use to create concrete synergies*," says Chairman and CEO Mitarai.

DATA HEALTHCARE AND PRECISION MEDICINE

As in almost all industries, healthcare is being reshaped by ICT, an explosion of digitized data, and the potential for AI applications. This so-called "data healthcare" trend has swept through the industry in the past year. Siemens partnered with IBM to jointly develop population health management tools that provide better prevention and diagnosis through cognitive computing. GE rolled out a medical cloud service which will use deep-learning algorithms to help doctors more effectively diagnose patients.

Even before joining the Canon group, Toshiba Medical had also been gearing itself up for this "data healthcare" revolution by purchasing medical imaging and software companies such as US ViTAL images, French Olea, and Canadian Karos. The group is keeping an eye out for further opportunities to expand and develop medical IT

solutions.

"*We recognize that doctors are overwhelmed by an explosion of medical data. We believe it is our mission to not just collect this data, but to collate, analyze and then deliver it to them in a way that helps doctors make accurate and efficient decisions,*" says President and CEO Takiguchi. "*The use of AI would play a significant role in achieving this mission.*"

Another related and key market trend of "precision medicine" – medical treatment tailored to patients based on their individual genes, lifestyle, and environment – is also part of the new medical group's plans. In this area, Canon had already established Canon BioMedical in New York State in 2015, and hopes to use this facility to commercialize genetic diagnostic equipment together with Toshiba Medical assets.

OVERSEAS STRATEGY

Although dominant in Japan, Toshiba Medical – which will be renamed Canon Medical Systems Corporation from the beginning of 2018 – remains a challenger globally. The company generated roughly 417bn yen ($3.6bn) in the year ending March 2016, which is considerably smaller than the annual sales of the top three healthcare device makers. Nevertheless, the two company executives are bullish about challenging the overseas titans.

"*Our global marketing strategy is to maintain a dominant market share domestically, strengthen our business base in US and European markets, and use this influence to generate growth in emerging markets,*" says President and CEO Takiguchi.

In general, the group hopes to expand its global network by focusing on university hospitals, high-end medical facilities, and participation in collaborative research with local institutions. In the US, the group will heighten its brand awareness through joint research and emphasis of "Japan quality". In Europe, it is focusing on the top-end device market in the West, while hoping to expand market share in the East and Russia with its standard models.

Its basic strategy in emerging markets is to approach influential top hospitals and secure government-driven large-scale orders. New products that match emerging market conditions will also be developed. Toshiba Medical is already enjoying stronger sales after recently adding subsidiaries in Turkey, South Korea and Malaysia. As an overall business priority, however, the group's goal is to develop and pursue "*universal global products and solutions,*" adds President and CEO Takiguchi.

The new healthcare group faces diverse markets abroad, with varying levels of economic development and demographics. Healthcare business is also particularly sensitive to government policies and regulations, points out Chairman and CEO Mitarai. "*We hope to expand into different markets matching the country's developmental phase and adjusting to government policies,*" he explains.

INNOVATION AND COMPETITIVENESS FROM JAPAN

In conclusion, Canon's timely move into healthcare is indicative of the broader, underlying resilience of Japanese industry. For some time, critics have claimed that Japan's manufacturing prowess has been losing its edge. Chairman and CEO Mitarai, however, does not share in the pessimism.

"*Innovation is the key for Japan's future. In that sense, the country still has comparatively very high levels of technological assets, companies are focused on R&D, and the Japanese government is promoting innovation,*" explains Chairman and CEO Mitarai. The Canon group itself commits more than 8 per cent of its revenues on average to R&D, from what used to be around 5 per cent.


X-Ray Angiography Systems

"*I am optimistic that Japanese companies have the potential to adapt to the changes of the time," he says. Canon's latest leap into the rapidly evolving and critical global healthcare market is strong evidence of that confidence.*

A thriving women's health radiology practice at the technological top

The "CSE Imagerie Médicale Numérique" center located in the heart of Paris is one of the most successful and dynamic private women's health radiology practices in France. Ever since its creation 28 years ago, the center has adopted a policy of always using the most technologically advanced and up-to-date equipment not just for the imaging equipment itself but also for the, just as important, accessory equipment.

Dr Philippe Benillouche, co-founder and current CEO of CSE Imagerie Médicale

The latest addition to the center's impressive arsenal of systems is a new Computer-Aided-Detection (CAD) software package for use in the detection of suspicious lesions in mammography and in digital breast tomosynthesis.

We wanted to find out more about the center in general and their experience with the new CAD system in particular, so we spoke to Dr Philippe Benillouche, co-founder, CEO, and practising radiologist.

Q *Let's start with your center in general. How many patients do you see annually?*

In our center as a whole we see more than 100 000 patients a year for a complete range of indications and radiological examinations, but since we are principally focussed on women's health we actually carry out more than 40 000 mammograms per year, a total which is constantly increasing from year to year.

Our center is located right in the center of Paris, not far from the famous Place de la République so most of our patients come from the city of Paris itself, but we're proud to say that, thanks to the reputation that our center has built up since its creation, a substantial proportion of our patients come from further afield, such as the outer suburbs of Paris and even from other regions in France,

The patients are mostly referred to us by specialists such as gynecologists, surgeons, etc. from private practices and hospitals.

At the foundation of our practice in 1989, CSE was exclusively focussed on womens' health imaging, and this still remains one of our principal activities even though over the years we have developed other imaging indications and introduced appropriate new imaging modalities as new radiologists specialised in fields other than that of womens' health have joined the group. However, as I said breast cancer screening and diagnostic mammography remain our principal activity.

We are an independent private practice but we are very well aware that while radiology plays a vital role in the diagnosis and follow-up of patients receiving treatment, the discipline should not be a stand-alone, isolated activity.

It is for this reason that we are an active participant in one of the biggest multi-disciplinary network in France, focused on breast cancer

Thanks to its high reputation, the CSE Imagerie Médicale deals with 100 000 patients per year. Although the center itself is located in the heart of Paris, the patients come not only from Paris itself, but also from the suburbs and further afield.

and connecting private practice specialists with hospital-based specialists.
Known as the SLRS (*Saint Louis Réseau Sein* or *Saint Louis Breast Network*) the network is based on the Saint Louis Hospital in Paris and is particularly active in the management of breast cancer patients.
I am currently vice-president of the SLRS, whose mission can be simply stated as being to "improve the care of breast cancer patients and their family through care, prevention, screening and support".
The Saint Louis hospital is one of the largest hospitals in the Paris-wide group of hospitals (the AP-HP) which itself is the biggest association of hospitals in Europe.
In addition to our close contacts with Saint Louis, we also have close working relationships with the breast cancer departments in other Parisian hospitals.

Q *Now, what about the equipment you have in order to deal with all your patients?*

When in 1989 we started our small women's health imaging centre in the same street as we are now, we only had one analogic mammography system and 2 ultrasounds.
We moved to our current location— which has a total floor space of 2000 m^2 — in 1999 because the original premises were too small. We are now well equipped — we have four Pristina digital mammography systems from GE Healthcare. In addition to mammography, these systems are capable of carrying out digital breast tomosynthesis (DBT), contrast enhanced spectral mammography (CESM). We also have the computer-aided detection (CAD) system from the US company iCAD.
Other equipment we have include:
1 Invenia Automated Breast Ultrasound system (ABUS).
1 breast biopsy stereotactic unit.
2 general and bone radiology units,
12 ultrasounds units
1 bone densitometry equipment.
1 dental radiology unit with cone beam 1 CT Scanner and a 1.5T MRI system

Q *And the personnel to run all this?*

There are a total of 60 people in our team and that includes 15 radiologists, of whom ten are specialized in breast imaging;. We also have one obstetrician for pregnancy ultrasound; 15 X ray technicians one executive secretary; 24 secretaries; 4 Management and accounting staff

Q *Let's turn more specifically to breast imaging and tomosynthesis*

We carry out Digital Breast Tomosynthesis (DBT) on all of our breast examinations including screening.

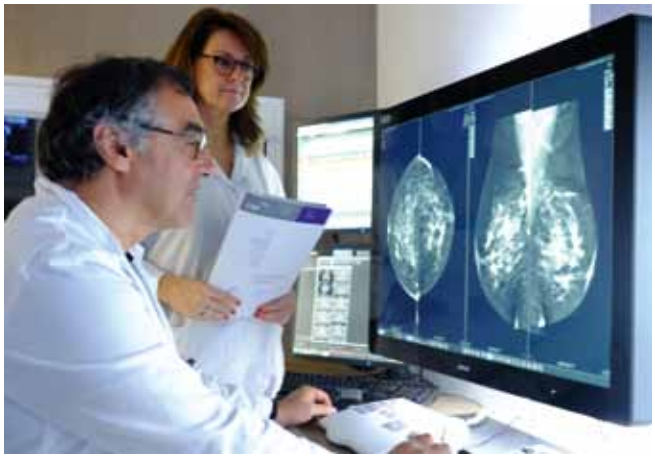
The advantage of DBT is of course that the number of lesions that can be detected is increased compared to standard mammography. DBT is also useful in the examination of dense breasts, where some lesions can be occluded in standard mammography.

"... The results...showed that the combination of 3D CAD with DBT resulted in a reduction of reading time by 28%..."

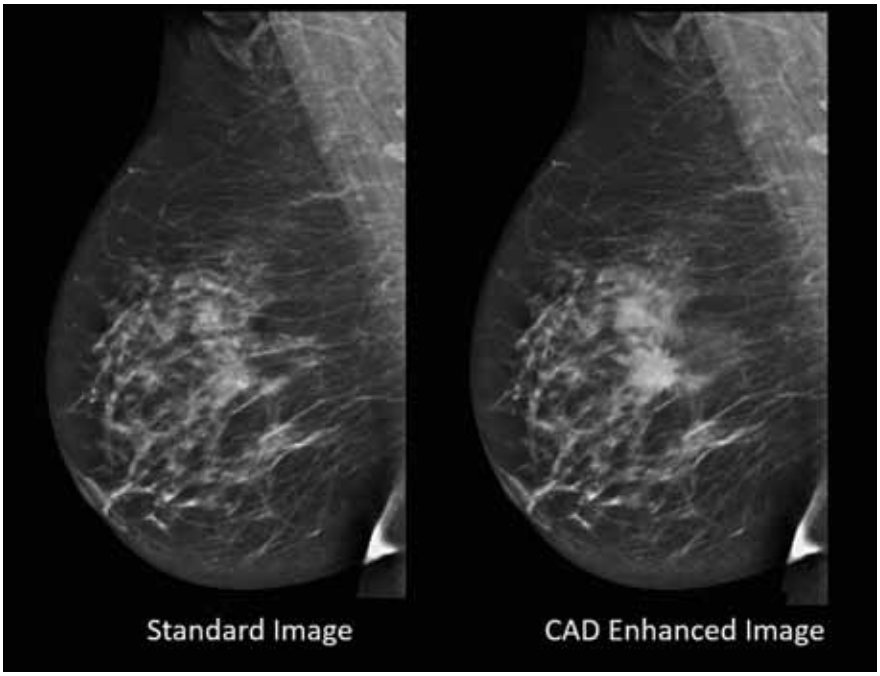
However before we started to use DBT in routine we had to consider the fact that it would significantly increase our reading time. Which is where we became interested in the role that Computer-Aided Detection (CAD) could play. I have to say that we have been using CAD in one form or another for a long time now (our first CAD system dates from the year 2000) so we have had time to be able to appreciate the potential of the approach.
However regarding the exact contribution of the use of CAD to the problem of the increased reading time associated with DBT, last year we carried out a study initiated by iCAD on exactly this question. The results were presented at RSNA and showed that the combination of 3D CAD with DBT resulted in a reduction of reading time by 29.2%, so increasing our efficiency significantly.

Q *So what CAD system do you use now?*

We have been using the new iCAD Powerlook Tomo Detection for the last two years and in fact we now collaborate in the deep learning development process run by iCAD by flagging and sending our images every day to iCAD's development team. Given the significant increase of the reading time involved in reading all the projections of a DBT examination, we knew we needed a solution to improve our clinical workflow.
It was totally natural for us to choose the use of a 3D CAD system to provide a solution to this issue.
Once the software was installed the learning curve for



The center has a policy of investing in up-to-date technology, which, with a staff of 60 personnel, including 16 radiologists, enables the center to handle an ever-increasing number of patients.



iCAD's PowerLook Tomo Detection, built on the latest deep learning technology, is being used at CSE Imagerie Médicale to improve the digital breast tomosynthesis reading workflow and assist radiologists in finding cancers quickly. The advanced Tomo Detection deep learning algorithm detects potential cancers by scanning each DBT plane and blending those regions onto GE's V-Preview 2D synthetic image, so creating an Enhanced V-Preview image. The detected regions visible in the Enhanced V-Preview 2D synthetic image are linked back to the DBT planes where they were detected creating an efficient and effective navigation tool for radiologists when reading tomosynthesis exams. iCAD's PowerLook Tomo Detection is CE marked and being used by several mammography facilities throughout Europe.

our radiologists to be able to get up to speed and to use the software to its full capacity was not difficult at all, but as with any change in work routine involving reporting of clinical results we had to go through a validation period, which however didn't take a long time.

Our radiologists were not resistant to this change or at all sceptical of the potential benefits perhaps because over several years our team had already been used to, and trained in, the reading of mammograms using 2D CAD.

The Power Look Tomo detection is now used routinely by all our team of radiologists in since, as I said, we carry out tomosynthesis on every patient for each of whom we also carry out a 3D CAD reading.

The impact on our work flow since we added CAD to our DBT examinations has been significantly positive, as we can read more mammograms with the help of 3D CAD.

The Enhanced V-Preview images are additional V-Preview images (2D synthetic views) provided to the radiologist, in which the V-Preview images are blended with regions from their corresponding DBT projections.

In these Enhanced V-Preview images, regions of interest detected by the CAD system are overlaid on to the corresponding segment of a DBT image containing the structure of the detection.

"... The impact on our work flow since we added CAD to our DBT examinations has been significantly positive..."

The system also provides new tools that leads directly to the CAD marks and allows to navigate in the adjacent planes.

As for the second reading you may be surprised to learn that this is carried out using film prints in a separate independent second reading center elsewhere in Paris that unfortunately is not equipped for reading digital images on work stations and has no access to the DBT images. I hope this set-up will change.

I am sure that our screening programs will in the future benefit greatly from the use of 3D CAD.

So to sum up, we are very satisfied with our 3D CAD. We are looking forward to the next software release that will include a risk score indicating the certainty of the findings.

Q *And the future? How do you see technology or other developments?*

Recently there has been a debate about the impact of technological advances, such as Artificial Intelligence on the profession of radiology. However, right from the setting up of our center, we have always been open to innovation and have never considered technology developments as a threat, so long of course as there are advantages for the patients and that the developments help us by increasing confidence in our diagnoses. We are all already using AI in our everyday lives, sometimes without knowing it, and today, image recognition by computers trained using deep learning is getting better than humans. If we accept the idea of driverless cars we should be at ease with the use of neural networks that simulate the radiologist's decision making, which would be particularly useful in an automated breast cancer screening program with the aim of improving preventive healthcare.

Likewise in breast imaging there is the ongoing debate about overdiagnosis/overtreatment. It is a fact that we now detect small lesions more frequently, which we would not have been able to detect without using DBT. I firmly believe that such a scenario is a direct consequence of the essential goal of the radiologist, which of course is to make diagnoses. So the problem is not one of over-diagnosis but rather the subsequent over-treatment, where some developmental advances are needed.

In the future, the breast screening program in France should be adapted to accommodate all the technologic developments of mammography. By offering more widespread access to recent technologies such as DBT and 3DCAD we should be able to optimize diagnoses and increase the number of women participating in the screening program.

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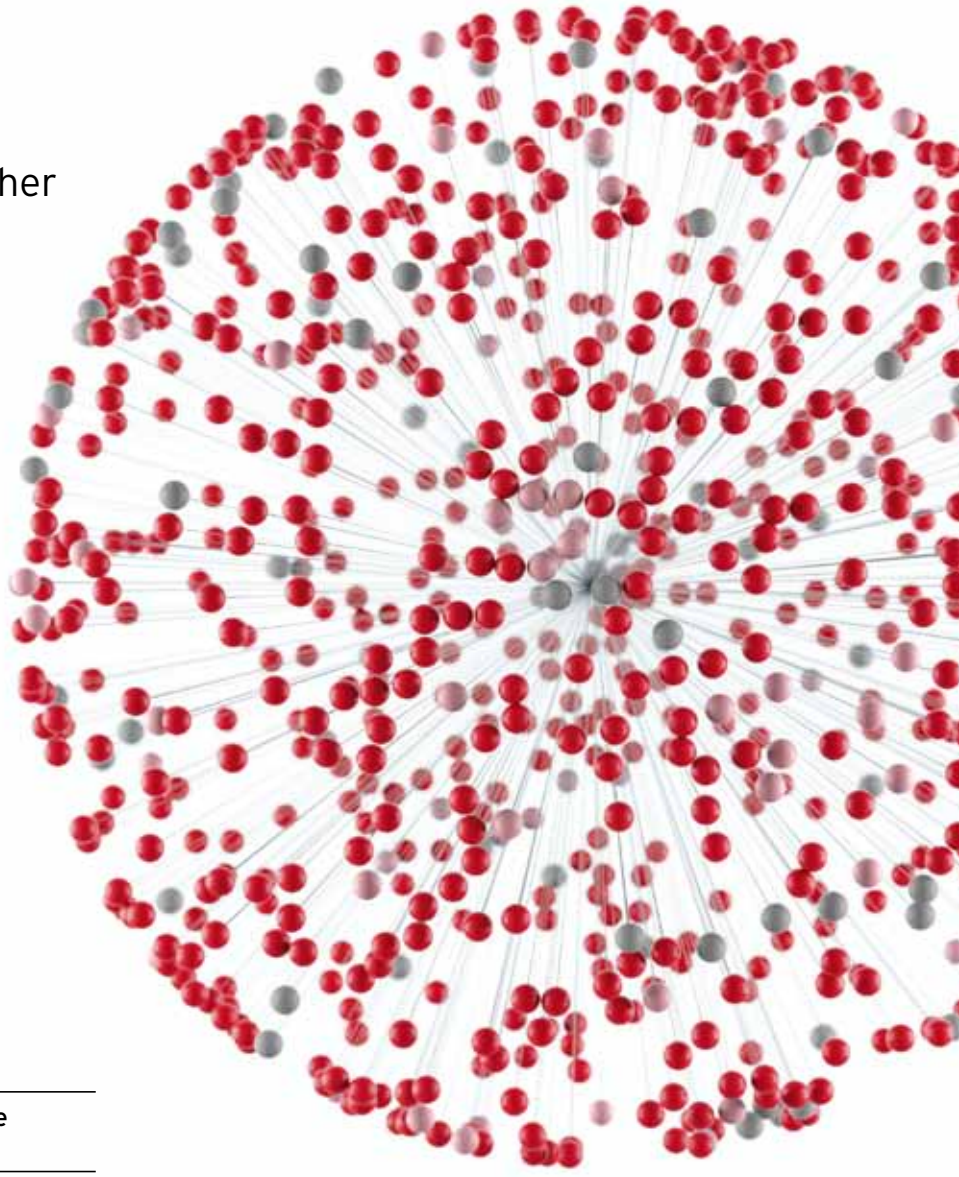

Spotlight:
Valvular
Heart
Disease

Key dates:

Mid Dec - 14 Feb	Abstract submission
Mid Jan - 1 March	Clinical Case submission
Mid March - 21 May	Late-Breaking Science submission
31 May	Early registration deadline
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EUROPEAN SOCIETY OF RADIOLOGY

Philips gets (even more) serious in the image-guided therapy business

The major acquisition by Philips three months ago of the US-based Spectranetics Corporation was significant enough. Spectranetics is a leader in vascular intervention systems but when that deal is put into the context of another major Philips acquisition, this time the purchase nearly three years ago of the Volcano Corporation, another US-based company leading in the field of catheter-based imaging in cardiovascular applications, it is clear that Philips is getting serious about the image-guided therapy field.

Bert van Meurs is leader of Philips' Image Guided Therapy Business Division,

We wanted to know more about the thinking behind these acquisitions and Philips' strategy regarding image-guided therapy in general, so we spoke to Bert Van Meurs, business leader of the Image-Guided Therapy Business Division.

Q *So two major acquisitions in three years. What's the rationale behind this M & A activity?*

Yes it's true that the acquisition of Volcano and, more recently, that of Spectranetics were major headline events for us, but you shouldn't think that these were out-of-the-blue purchases to suddenly get an introductory foothold in the image-guided therapy field.

The fact is that Philips has been involved in the image-guided business for many, many years, in fact right since the time that the first Percutaneous Transluminal Coronary Angioplasty (PCTA) procedures were being carried out. It is sometimes forgotten that the very first PCTA procedure was actually carried out by Gruentzig now nearly 40 years ago. Even before then Philips was involved in the coronary angiography imaging field.

Of course since then there have been huge developments in the field and Philips has been active in the introduction of many innovations in the field from dedicated X-ray tubes for digital cardiac applications, and quantitative analysis right up to the current brand-new top-of-the range Azurion platform, which provides interventional staff with all the control and information they need to perform modern procedures efficiently.

This track record has meant that Philips has traditionally occupied a market-leading position in the interventional imaging field — a position which, I am proud to say, we maintain to this day.

But several years ago we realized that we had a strategic decision to take. Should we sit tight and remain solely focussed on the purely imaging side of interventional procedures, where we were, and are, firmly established or should we focus more on the entire procedure and overall enable our customers to treat patients more effectively and efficiently. Therefore getting fully into the minimally invasive interventional field, which is currently undergoing dramatic development, such as that of smart catheters and devices, was, in the end, a logical step forward for us.

Q *What exactly are these developments in the minimally invasive surgery fields?*

Simply put, this is the now widespread acceptance by the surgical and interventional world of the benefits of minimally invasive surgery over classical surgery. Of course well-established classical surgical procedures can't be abandoned overnight but when minimally invasive procedures are appropriate, the benefits are enormous. And although such benefits may seem intuitively obvious, there are also now hard objective metrics which support the advantages of the approach. Such metrics range from proven improvements in clinical outcomes for the patient, to significant reductions in the length-of-stay of the patient in the hospital. In fact nowadays many minimally invasive interventional procedures are actually not even

carried out in the hospital, but on an out-patient basis in office-based labs. There is even a subset of patients where, because of co-morbidities or other clinical reasons, classical open surgery is contra-indicated, so minimally invasive surgery is in fact the only procedure possible.

So not just clinical improvement but significant socio-economic benefits as well.

And while the roots were originally based in interventional cardiology, minimally invasive interventional procedures have extended to many other applications, For example, the treatment of strokes or of aneurysms in the brain, by endovascular coil insertion via a catheter. Even further, minimally invasive procedures in interventional radiology are now established in the field of oncology, with procedures such as Trans Arterial Chemoembolisation (TACE) designed to restrict the blood supply to a tumor, and apply local chemotherapy, with minimal effect on healthy tissue.

Other applications are in the field of spinal surgery in cases of spinal trauma. Here the exact placement of pedicle screws (used as a means to allow fusion of a spinal segment) can be difficult in open surgery — with potentially devastating consequences if wrongly placed. By image guidance 3D reconstruction of the spine, using cameras integrated into the system an augmented reality approach can be adopted which has been validated successfully in centers of surgical excellence around the world.

Or more recently, the possibility of treatment of drug-resistant hypertension via renal denervation, although it's still early days for this approach.

Of course all these applications are at different stages of acceptance but there is no doubt that in general the future potential of the approach is tremendous

Q *So how in practice how do you realize this potential ?*

The first thing we recognized was that, despite all the expertise and competencies we in Philips have in-house in image-guided therapy, we were not present in the entire procedure optimizing effective patient treatment. Hence the business rationale behind our acquisition, now nearly three years ago, of the Volcano Corporation, a US company based in San Diego.

With a head-count of approximately 1800 persons, Volcano is a leader in catheter-based imaging and measurements for minimally invasive diagnostics for the treatment of coronary artery disease and peripheral artery disease. Volcano is the only company in the industry with leading positions in both IVUS (intravascular ultrasound) catheters that are capable of producing ultrasound images of the interior of blood vessels and FFR (fractional flow reserve) catheters that are used to assess blood flow which can help to decide whether a patient should be treated with a stent or not.

Incorporating a tiny ultrasound transducer mounted on the tip of a catheter, the Volcano Intravascular Ultrasound (IVUS) catheter is a triumph of miniaturised engineering. IVUS catheters can be used to assess vessel/lumen diameter, lesion length, atherosclerotic plaque build-up and composition.

The development, manufacture, regulatory approval and marketing of such disposable devices require skill sets that Volcano has developed over the years

These skill sets complement perfectly the expertise that Philips has in its existing portfolio of interventional X-ray and ultrasound imaging equipment, navigation systems and software and services,

Q *But you didn't stop at the acquisition of Volcano.*

No that's right. Earlier this year we completed the acquisition of the US-company Spectranetics, based in Colorado Springs, USA.

The business logic behind this acquisition was quite simple: to further complement the Image-Guided Business unit formed by Philips and Volcano via

The development, manufacture, regulatory approval and marketing of disposable devices such as the catheters used in minimally invasive surgery require skill sets that Volcano has developed over the years

Azurion is Philips' next generation image-guided therapy platform and the new core of its integrated solutions portfolio. Azurion supports a full range of configurations across a broad spectrum of image-guided therapy procedures. These include configurations for high volume routine procedures and flexible configurations for advanced procedures. Harnessing vital procedural information from various sources, such as imaging systems, interventional devices, navigation tools and patient health records, the system provides interventional staff members with the control and information they need to perform procedures efficiently.

an entry to the field of minimally invasive therapeutic devices.

Spectranetics' device portfolio includes a range of catheters to treat coronary and peripheral artery disease, and the removal of implanted pacemaker and implantable cardioverter defibrillator leads.

The company's drug-coated balloon, Stellarex, is a key growth driver in this portfolio. It is a next generation drug-coated balloon that provides proven peripheral artery disease treatment and is backed by robust clinical evidence. The Stellarex drug-coated balloon is CE-marked and recently obtained U.S. FDA Pre-Market Approval.

This clearly brings us into areas of expertise such as not only designing and manufacturing devices — under GMP clean room conditions — but also designing and managing clinical trials to deliver evidence on outcomes as well as obtaining regulatory approval. All this requires highly specialised expertise and experience. Spectranetics has these capabilities.

Q *So in practice how is the integration of Volcano and Spectranetics into the Philips Image-Guided Therapy division going?*

Having only completed the acquisition a few months ago, it's still a bit early in the integration process for Spectranetics, but I'm happy to say that now nearly three years down the road with Volcano, we're very satisfied with the way things are going.

Of course, as with any acquisition, there is always a bit of initial caution or wariness on the part of the people in the company being acquired. This is all the more so since the people at Volcano — and Spectranetics too — are, justifiably, very proud of the success they have had in building up their respective companies.

From Philips' point of view, the key is to make it quite clear that such accomplishments are recognized and acknowledged and to ensure that the people get engaged.

This is not a problem when it is realized by everyone that the overall plan is to grow the business and that the synergies between the various groups in the Image-Guided Therapy division actually make that aim easier to attain. The proof is that we have already hit the objectives of growing the business that we set ourselves at the time of the Volcano acquisition.

Q *So what about the future?*

Well, the advantage of having a clear and thought-through vision of the future is that it's easy to answer such a question. Our vision at Philips is to improve healthcare delivery, not just in terms of the purely clinical perspective and improved outcomes for the patients but also in terms of economic benefits. We believe that image-guided therapy will play an ever-increasing role in attaining such objectives since the trend to minimally invasive therapy away from open surgery is growing dramatically.

We look at the field in a holistic way, so we don't just content ourselves with the contribution that imaging can bring to the party. Instead we are focusing on bringing innovations in the entire procedure through solutions comprised of our imaging systems combined with devices, software and services, that benefit patients.

We will continue to invest and innovate in the development of clinically relevant smart devices, for example those with even better, smarter guidance.

The Stellarex drug coated angioplasty balloon (DCB) from Spectranetics has just received FDA PMA approval. The device is designed to restore and maintian blood flow to the superficial and popliteal arteries in patients with peripheral arterial disease. Stellarex uses the proprietary EnduraCoat technology, a durable, uniform coating designed to maximize drug transfer to the vessel wall and minimize downstream drug loss during transit and upon inflation. Stellarex has shown safety and efficiacy both in a US IDE trial and in a European randomized controlled trial

Mobile health tools, sensors, and portable imaging devices: high resolution approaches for Point-of-Care assessment of structural heart disease

By Dr M Tokodi, Dr SP Bhavnani, Dr R Khedraki & Prof PP Sengupta

Newly developed smartphone-connected mHealth devices represent promising methods to diagnose common diseases in resource-limited areas. However, the impact of technology-based care on long-term outcomes has not been rigorously evaluated.

This article summarizes a recently published study which sought to determine whether mobile health (mHealth) device assessments used as clinical decision support tools at the point-of-care can reduce the time to treatment and improve long-term outcomes among patients with rheumatic and structural heart diseases (SHD).

The results showed that an initial mHealth diagnostic strategy was associated with a shorter time to definitive therapy among patients with SHD in a resource-limited area and was associated with improved outcomes.

HIGH RESOLUTION HEALTHCARE

Due to the increasing burden of cardiovascular diseases and growing demands in healthcare, there is an emerging need for easily accessible and cost-efficient techniques for diagnosis and treatment. The rapid technological advances in the 21st century heralded by smartphone development could provide solutions to this need. The exponential increase of computing power and the progressive miniaturization of diagnostic instruments into wireless mobile health (mHealth) devices are creating a new era of data-driven and high resolution healthcare. This will enable the assessment and the management of a variety of conditions — remotely and at the point-of-care — with the potential of improving healthcare accessibility and affordability [1].

mHealth is defined as the practice of medicine supported by portable diagnostic devices including smartphone health 'apps', smartphone-connected devices, pocket-sized portable echocardiography (PPE), lab-on-a-chip devices, and miniaturized sensor-based technologies [2]. Important design features of mHealth include lower cost and high portability thereby making such devices accessible to a wide range of clinicians in different practice settings. These design factors are particularly appropriate to the health systems of resource-constrained areas of low and middle-income countries. In such areas, new technologies may bridge common healthcare inequities resulting from the low availability of traditional diagnostic devices and adequately trained healthcare practitioners [3, 4].

On the one hand, there is the promise of the transformation of healthcare delivery facilitated by advances in new technologies and data handling. However, on the other hand, several questions arise as to just how new devices should be used at the point-of-care. Such questions include: how are the new devices and sensors integrated into healthcare systems? What are the methods for data transmission? How are devices used pragmatically particularly in resource-limited areas? And finally, what is the overall impact on healthcare quality and outcomes?

AMERICAN SOCIETY OF ECHOCARDIOGRAPHY GLOBAL HEALTH INNOVATION TRIALS

To begin to answer these questions, the American Society of Echocardiography (ASE) has undertaken a series of sequential global health clinical trials – ASE-REWARD, ASE-VISION, and ASE-VALUES – to determine the usability of the new technologies and specifically the utilization of PPE devices in structural heart disease. Through these

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clinical trials, new methods for cloud-based image transfer and new educational modules for PPE image acquisition and interpretation have emerged. By leveraging cellular, broadband, and smartphone technologies these investigations have begun to evaluate the effectiveness of PPE used as a clinical decision support tool. In the aggregate, such efforts are creating new hierarchical structures to increase the yield of PPE and to determine its impact on healthcare access and outcomes.

PORTABLE POCKET-ECHOCARDIOGRAPHY

Pocket-sized portable echocardiography has significant potential to facilitate earlier disease detection, improving triage for high-risk patients, and enhancing the diagnostic capacity at the point-of-care [5]. The current generation of devices can provide two dimensional and color Doppler imaging in real time but are not capable of spectral Doppler or M-mode imaging [6]. The accuracy of PPE has been evaluated in various structural abnormalities such as left ventricular (LV) dysfunction, LV hypertrophy, pericardial effusion, and valvular heart disease [7-9]. Many studies have demonstrated a moderate-to-high degree of correlation between images acquired with PPE and those acquired by standard transthoracic echocardiography (TTE), especially with regards to LV function and valvular abnormalities [10-12]. Although a useful extension of clinical examination, PPE does not substitute for TTE due to its limited technical capabilities and lack of quantified findings with Doppler interrogation [6]. It should also be kept in mind that there is a learning curve for the use of these pocket-sized devices that could result in significant differences in both sensitivity and specificity of diagnostic findings and intra- and inter-observer variation between experienced and non-expert imagers [8, 13].

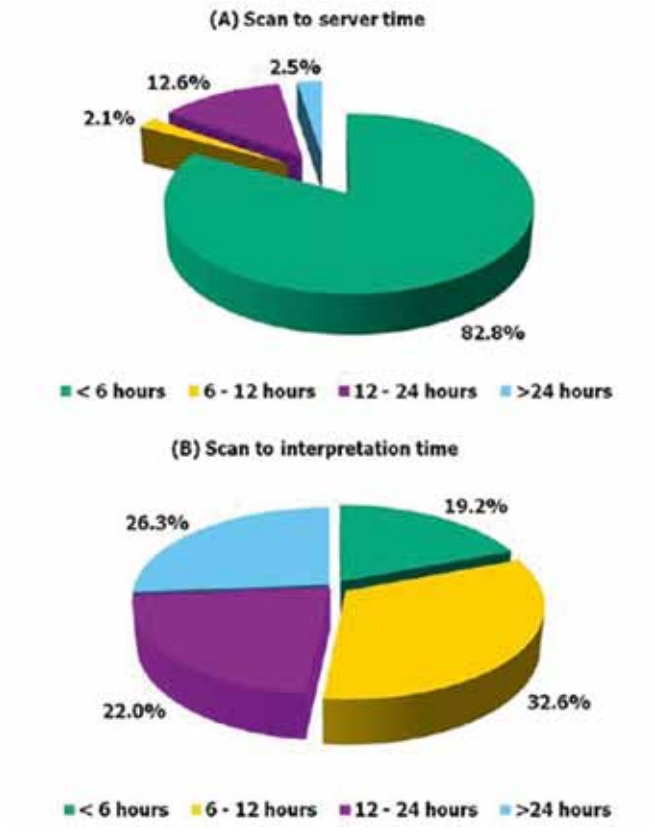

Figure 1. Time from PPE image acquisition to study upload (A) and time to study interpretation (B) via cloud-based image transfer.

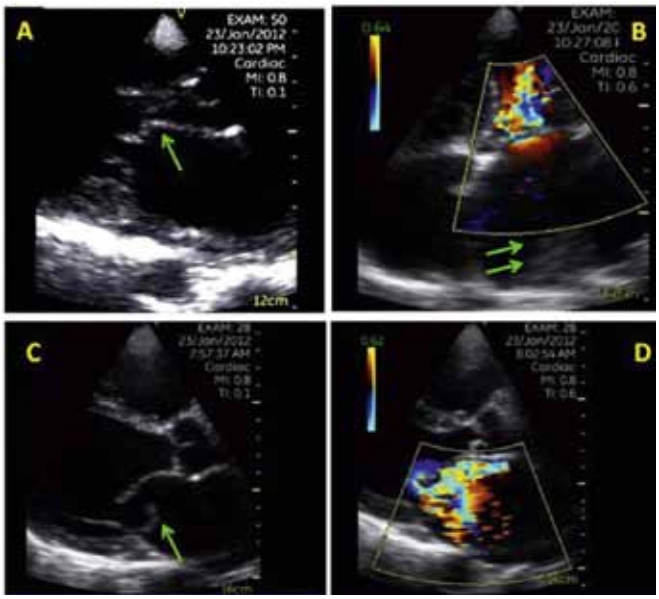

Figure 2. Results of complex SHD including systolic heart failure, and rheumatic and congenital heart disease were delivered back to local physicians for clinical decisions

ASE-REWARD – EXPEDITING PPE IMAGE INTERPRETATION WITH CLOUD COMPUTING

The ASE-REWARD (Remote Echocardiography with Web-Based Assessments for Referrals at a Distance) study was the first investigation to determine the feasibility of 'cloud computing' and Internet-based echocardiographic image transfer [14]. In 2012, ASE investigators, physicians, and sonographers screened >10,000 patients in rural India and imaged over 1,000 study subjects within 48 hours. The study methodology linked images obtained with PPE at the point-of-contact to the cloud with wireless broadband support brought directly to the study site. On average, each study consisted of 18 clips which were acquired according to ASE focused ultrasound guidelines. The provision of Internet-based communications in remote locations enabled upload of the digitized studies within 4 hours. The studies were then interpreted by a global consortium of 75 cardiologists scattered over four countries within the following 12 hours [Figure 1]. Results of complex structural heart disease (SHD) including systolic heart failure, and rheumatic and congenital heart disease were delivered back to local physicians for clinical decisions [Figure 2].

Readily available Internet connections and a systematic approach for image acquisition, transfer, and interpretation provided new methods for accessing expert consultation at the point-of-care.

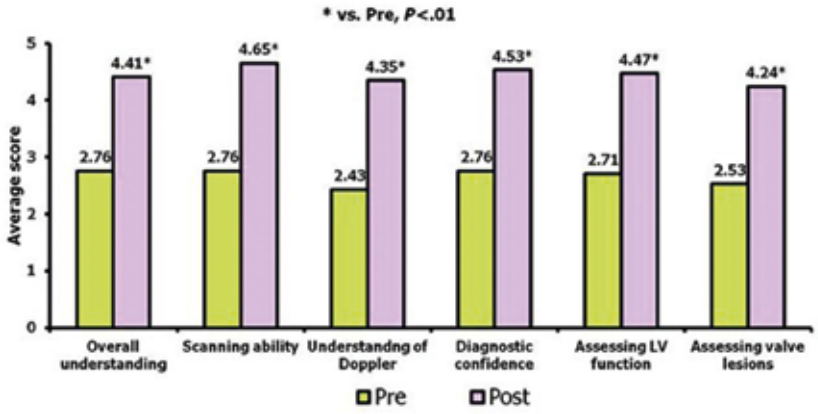

Figure 3: Overall impact of training on the self-perceived competence of the physicians in different components of PPE performance. All scores were derived using a five-point modified Likert-type scale.

ASE-VISION – INTERNET-BASED TELE-ECHOCARDIOGRAPHIC TRAINING

Recognizing that echocardiography requires expertise in both image acquisition and interpretation — common barriers limiting wider use in community settings — to standardize PPE image acquisition and reporting, the follow-up ASE-VISION (Value of Interactive Scanning for Improving Outcomes of New Learners) study was conducted in 2014 [15] and had several aims:

1) To test the feasibility of a Web-based training module for remote ultrasound training in which physicians learn from ASE-educators by transmitting their PPE images in real-time during scanning sessions;

2) To compare the Web-based trained physicians with a group of physicians trained on-site on markers of PPE efficiency and proficiency using studies performed in community settings.

After recruitment into the study a combination of 17 physicians were provided focused PPE training by ASE-sonographers on-site and remotely via a Web-based tele-echocardiography system. The remote Web-based training included live-echocardiography streaming with images accessed in real-time via Web-portals. These images were simultaneously accessed by expert sonographers in the United States who provided feedback for machine settings, transducer position, and for guideline-based image interpretation. During the trial period 900 PPE studies were performed of which 660 were used for validating physician competencies. Overall, there was adequate agreement between the two physician groups, i.e. on-site versus remotely trained, for image interpretation of major structural cardiac abnormalities obtained on PPE devices. The majority of physicians reported high satisfaction with Web-based training and significant improvements in measures of echocardiographic proficiency, including scanning ability, diagnostic confidence, and quantification of structural abnormalities on pre- and post-competency assessments [Figure 3].

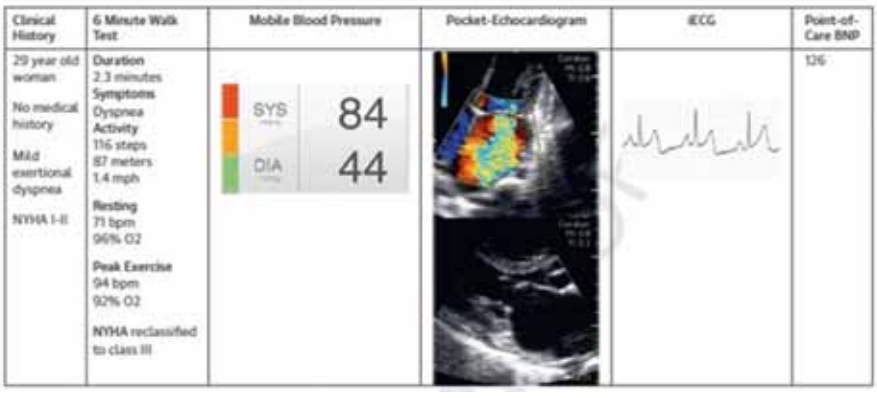

Figure 4 Comprehensive mHealth and PPE derived assessment of a 29-year old with symptomatic rheumatic mitral valve disease. Mobile diagnostics demonstrated NYHA III symptoms, hypotension, severe mitral regurgitation, and sinus rhythm. The patient was referred for mitral valve replacement.

ASE-VALUES – MHEALTH INTEGRATED PPE ASSESSMENTS & CLINICAL OUTCOMES

Using the above experiences as a foundation for the potential applications of new mHealth technologies sensors, and PPE devices, the ASE-VALUES (Valvular Assessments Leading to Unexplored Echocardiographic Stratagems) randomized clinical trial was undertaken in 2014 and completed follow-up in 2015 [16]. The primary objective of this investigation was to compare the outcomes of mHealth-derived assessments of structural heart disease with PPE and a variety of smartphone-connected devices to standard-care on medical decision making and treatment outcomes among patients with rheumatic and structural heart disease.

STUDY METHODS

To obtain comprehensive assessments of the severity of structural heart disease, 253 patients were randomized within 72 hours to either standard-care or mHealth clinics. These latter were equipped with new portable devices, including smartphone-connected iECG, activity monitors for quantification of 6-minute walk test, PPE for qualitative assessments of structural heart disease, wireless blood pressure and oximetry, and fingerstick BNP. All study subjects underwent comprehensive transthoracic-echocardiography for the quantification of valvular disease and for diagnostic comparison to PPE studies. Physician-derived mHealth assessments were conducted at the time of enrollment for point-of-care clinical decision. The primary outcome of interest was the time to treatment with valvuloplasty or valve replacement after the initial clinical evaluation with secondary outcomes being the occurrence of cardiovascular hospitalization or death over 12 months.

STUDY RESULTS

Overall, the mean age of the study population was 39±14 years. Comprehensive mHealth assessment was performed in 139 subjects and standard care evaluation in 114. The study population had a substantial burden of disease with 57%, 42%, 23%, and 32% of echocardiographic studies exhibiting mitral stenosis, mitral regurgitation, aortic stenosis, and/or aortic regurgitation, respectively. The prevalence of severe mitral and/or aortic valve disease was similar between the

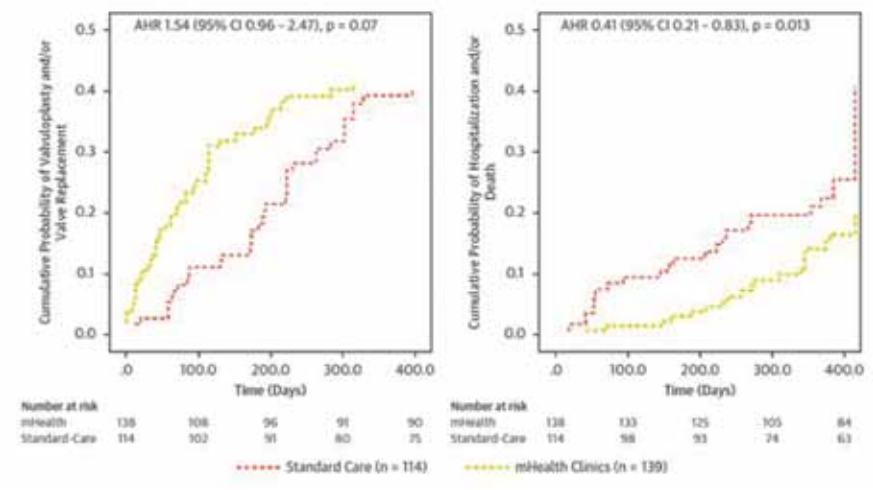

Figure 5: (A) Outcomes of percutaneous valvuloplasty or valve replacement, and (B) hospitalization and/or death stratified by mHealth with PPE or standard-care.

mHealth and standard-care randomized groups.

Ninety-six percent of PPE studies were rated to have good image quality and demonstrated adequate diagnostic correlation with transthoracic echocardiography for moderate or severe mitral or aortic valve disease (areas under the ROC curve of 0.74 and 0.79, respectively). More than one third of the study population exhibited severe mitral and/or aortic valvular disease on PPE with one in four patients having combined mitral and aortic valve pathologies. An example of an initial mHealth and PPE assessment is illustrated in Figure 4.

At 12 months, 34% of the study population underwent treatment with valvuloplasty or valve replacement. Compared to standard care, a shorter time from initial evaluation to primary outcome was observed with mHealth (83±79 days vs. 180±101 days, p<0.001) with twice as many patients in the mHealth arm receiving treatment within 90 days (20% vs 10%, p<0.01). Compared to standard-care, subjects randomized to mHealth were more likely to undergo valvuloplasty or valve replacement (AHR 1.54 [95% CI: 0.96 to 2.47], p=0.07) and were associated with a lower probability of hospitalization and/or death at on follow-up (AHR 0.41 [95% CI: 0.21 to 0.83], p=0.013. [Figure 5].

PRINCIPAL FINDINGS

Within a community cohort with advanced structural heart disease mHealth and PPE can be used as clinical decision support tools at the point-of-care to assess symptoms, structural, and functional abnormalities. Compared to standard care an initial diagnostic strategy with mHealth was associated with a shorter time to referral for valvular interventions, resulting in improved morbidity and survival.

TRANSLATIONAL PERSPECTIVES

Newly developed PPE devices and smartphone-connected mHealth technologies have emerged as potentially transformative innovations capable of reducing common health care disparities by providing diagnostic information and to support clinical decisions at the point-of-care. The ASE innovation clinical trials aimed to advance our knowledge of the potential of PPE for diagnosis, treatment, and patient-related outcomes. To do so, the key components of PPE that were evaluated included the following:

- Identification of heuristic factors and evaluation methods that lead to appropriate use of new portable imaging devices,
- Determination of the integration of PPE derived device findings into existing information systems and health records,
- Identification of patterns of utilization that lead to earlier diagnostic and treatment decisions.

CONCLUSION

Our ability to understand and longitudinally measure health parameters and cardiovascular function at high resolution with new PPE devices, coupled with new mHealth technologies that consider the multidimensional aspects of disease, accelerates medical decision-making at the point-of-care.

Demonstrating the incremental and additive value of new technologies in endemic communities with high burden of disease should remain a focus of future studies evaluating the outcomes of such technology-enabled care in resource-limited areas.

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Diagnosing prostate cancer: advances in radiopharmaceutical imaging

By G Mullen

Prostate cancer is an enormous global burden and one of the most prevalent cancers in men. Although the vast majority of men diagnosed with prostate cancer do not die of the disease, it still kills more than 300,000 men each year and in high- and middle-income countries it is considered to be the third most common cause of cancer-associated mortality in men [1].

Although there have been great strides in the management of prostate cancer over the last few decades, the prevalence of undiagnosed disease and the mortality rate lag behind some other types of cancer, raising the question as to why this should be. There are many factors at play, but among the most crucial are deficiencies in the diagnosis and accurate staging of prostate cancer.

DIAGNOSIS AND STAGING — CURRENT APPROACHES AND CHALLENGES

The initial presentation of prostate cancer patients is usually as a result of issues related to urination e.g. frequency, lack of or difficulty in urinating. The typical prostate cancer diagnostic pathway begins with measurement of prostate specific antigen (PSA) levels, followed by a digital rectal examination. These techniques can only indicate whether there might be a problem with the prostate and not the specific nature of that problem. PSA levels increase with age even in the absence of prostate cancer, and high levels are merely an indication that an issue may exist with the prostate gland [2]. A firm diagnosis of prostate cancer relies on sonography-guided needle biopsy, which of course is an invasive procedure, with a risk of bleeding and infection. Anterior tumors tend to be missed by transrectal ultrasound-guided biopsy until they grow to a substantial size and reach within 15–20 mm of the posterior margin of the prostate [3]. A template biopsy might only sample a proportion of the lesions in a diseased prostate gland. The histology of each of these lesions is not necessarily the same, which can often lead to under- or over-staging of the disease. A further limitation of biopsy is that the histological findings may come back as negative, even though PSA levels are high. In intermediate- or high-risk patients imaging will then be used.

Imaging can be used to detect and visualize prostate lesions. MRI, especially multiparametric MRI (mpMRI) has greatly improved the diagnostic and staging pathway in prostate cancer patients, but it is only appropriate for detecting prostate and local lymph node lesions that are >5 mm in diameter. Lesions smaller than this may be missed.

When prostate cancer is confirmed histologically the patient is typically assigned a risk category, based on his initial rectal examination, histological findings and serum PSA level. After a risk category has been assigned, the guidelines recommend CT, MRI and bone scintigraphy for detecting primary tumors, recurrent and/or metastatic disease and monitoring treatment response [4,5]. Other imaging modalities, such as PET with choline-based tracers or fluorodeoxyglucose, have been investigated, but they do not always reliably identify local recurrence, lymph node involvement or visceral metastases, and arguably have low value in overall patient management [6].

The over-arching problems with this current approach for the detection and staging of prostate cancer are three-fold.

- Firstly, digital rectal examinations and PSA tests only reveal if there is a problem with the prostate gland, without specifically ruling out or ruling in cancer.
- Secondly, prostate cancer is very heterogeneous – some cancers are slow-growing and non-aggressive, while others are extremely malignant. The inability to resolve this heterogeneity is a serious shortcoming as it may lead to over-treatment in which many men receive treatment that they may not have needed, for a cancer that may not have harmed them. Under-treatment also occurs. [2].

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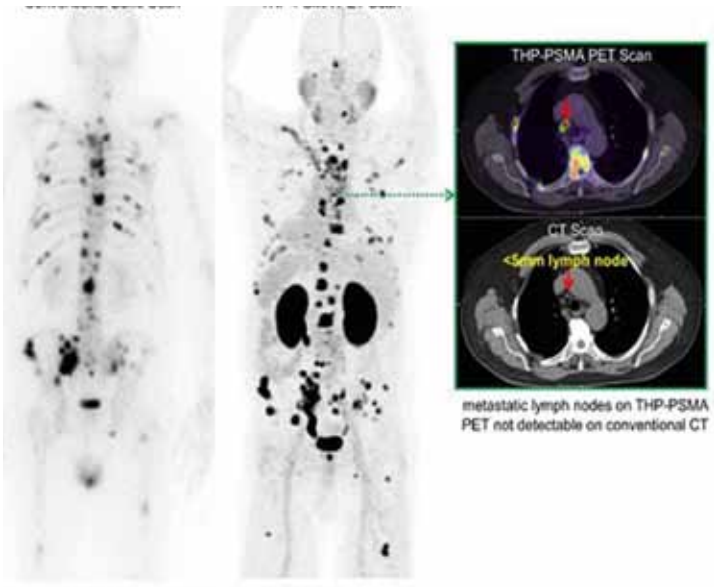
• Thirdly, moving through the disparate elements of the patient management pathway takes time; time to obtain a false negative, time to schedule further appointments and time for further procedures. In patients with aggressive disease this extended time scale is a luxury they simply do not have. In the weeks between an initial consultation and a firm diagnosis, the cancer may have already metastasized to distant parts of their body.

A NEW APPROACH: PSMA PET/CT IMAGING

A single, non-invasive imaging modality that improves diagnosis and disease staging and which can be used to assess disease progression and treatment response has the potential to transform the management of prostate cancer. Such an imaging modality is already available – PET/CT imaging with prostate cancer-specific tracers.

^{68}Ga-PSMA PET/CT is a rapidly emerging targeted imaging modality in the field and involves the use of an injectable ^{68}Ga-labeled urea-based small molecule, which binds with high affinity to the extra-cellular domain of the prostate-specific membrane antigen (PSMA). Increased PSMA expression is seen in a variety of malignancies, most notably in prostate cancer. Adenocarcinomas of the prostate demonstrate PSMA expression in the great majority of primary and metastatic lesions. ^{68}Ga-PSMA-PET/CT imaging has rapidly emerged as a practice-changing imaging modality with significant advantages compared to conventional imaging such as CT, MRI or bone scanning.

^{68}Ga-HBED-PSMA-11 PET/CT has demonstrated significant clinical utility in both the staging of newly diagnosed patients and restaging. More accurate staging of high-risk patients may enable better selection of the most appropriate management strategy and avoid futile locoregional surgery or radiotherapy in patients with metastatic disease. However, the cumbersome production of the ^{68}Ga-HBED-PSMA-11 tracer, which has to be performed at the hospital site because of the short half-life of the ^{68}Ga, is an impediment to its standard, widespread use.



Compared to conventional bone scans, ^{68}Ga-THP-PSMA-PET enables better visualisation of widespread bony metastases. ^{68}Ga-THP-PSMA-PET also allows the visualisation of metastatic lymph nodes not detectable with conventional CT. (Conventional Bone Scan on left; THP-PSMA PET on right)

^{68}Ga-THP-PSMA PET/CT Phase 1 study design

The results of a phase 1 study were recently published in the Journal of Nuclear Medicine [7]. The paper described a promising solution to overcoming some of the production challenges of existing technologies. The new approach is based on the use of a tris(hydroxypyridinone) (THP) chelator to form a novel ^{68}Ga PSMA PET tracer known as ^{68}Ga-THP-PSMA. This tracer can be produced quickly and on-demand in the clinic using a simple single step kit much in the same way as traditional nuclear medicine Tc-99m radiopharmaceuticals are produced [7].

"...The 68Ga-THP-PSMA tracer can be produced quickly and on-demand in the clinic using a simple, single-step kit..."

In this Phase 1 study, fourteen patients with biopsy proven adenocarcinoma of the prostate were recruited; eight in Group A and six in Group B. Safety and biodistribution of ^{68}Ga-THP-PSMA were assessed in all patients. In Group A, additional aims were to define whole body radiation dose and plasma radiotracer clearance, and correlate the uptake with tumor PSMA expression on histopathology. In Group B, the aim was to compare physiologic and pathologic biodistribution in patients with PSMA-avid malignant disease on ^{68}Ga-HBED-PSMA-11 PET/CT.

In Group A, patients had no prior treatment for prostate carcinoma and were scheduled for prostatectomy. In Group B, inclusion criteria additionally mandated patients with prior clinical ^{68}Ga-HBED-PSMA-11 PET/CT demonstrating at least one unequivocal PSMA-avid focus considered to represent metastatic prostate cancer.

^{68}Ga-THP-PSMA PET/CT Phase 1 study results

This study is the first-in-human validation of ^{68}Ga-THP-PSMA, the first clinical tracer to utilise the novel THP chelator, which enables labelling to be carried out in less than five minutes at room temperature. In contrast, the DOTA chelator, incorporated in the widely used DOTATATE, requires pH adjustment, heating followed by cooling, and sometimes a purification step, necessitating either significant manual handling or the use of an automated synthesis device [7,8]. This increases expense and may not be compliant with Good Manufacturing Practices (GMP). Furthermore,

cartridge-based automated synthesis typically takes more than 45 minutes, which is suboptimal for a short half-life radionuclide such as ^{68}Ga. HBED chelation can be performed at room temperature but this produces a mixture of cis/trans geometric isomers [9]. ^{68}Ga-THP-PSMA has been developed as a single step kit-formulated GMP radiopharmaceutical, requiring only the addition of unprocessed, unfractioned generator eluate (with low Ge-68 breakthrough) to a single vial.

The study demonstrated that ^{68}Ga-THP-PSMA is comparable with ^{68}Ga-HBED-PSMA-11 in terms of safety, biodistribution and visualization of malignant tissue. Indeed, ^{68}Ga-THP-PSMA had significantly lower background physiologic uptake compared to ^{68}Ga-HBED-PSMA-11. Specifically, uptake in the salivary (parotid and submandibular) and tear glands (lacrimal), liver, spleen, duodenum and small bowel was significantly lower for ^{68}Ga-THP-PSMA.

THE FUTURE OF PSMA PET/CT IMAGING

The recent study has a number of important implications for the detection and management of prostate cancer. First and foremost is the fact that ^{68}Ga-THP-PSMA can be produced simply, quickly and on demand in the clinic, thus offers significant efficiencies (e.g. days instead of months of validation and a few minutes instead of hours of preparation and production time) when compared with the production of ^{68}Ga-HBED-PSMA-11. This advance could facilitate and underpin a more widespread use of PSMA-PET imaging for prostate cancer patients. Combining ^{68}Ga-THP-PSMA-PET with mpMRI instead of CT also promises to improve the detection, localization or exclusion of malignant foci within the prostate, owing to the excellent anatomical and zonal resolution of the prostate obtained by MRI [10]. A further possibility is the use of this modality to detect and localise suspicious lesions and PSMA-positive tissue. This ability would be extremely useful, especially in those patients who have undergone several biopsies, all of which have been negative on inspection. Imaging with ^{68}Ga-THP-PSMA-PET in these patients could be used to pinpoint the area a biopsy must target to collect cancerous tissue.

^{68}Ga-THP-PSMA-PET may also improve the evaluation of the metastatic spread of the disease to lymph nodes, bone or viscera in patients with primary intermediate/high risk disease [10]. In this setting, ^{68}Ga-THP-PSMA-PET imaging enables a whole staging procedure to be performed in a single examination, therefore obviating the need for further cross-sectional imaging or bone scintigraphy [10]. This potential is in line with ^{68}Ga-PSMA-PET imaging generally, as recent results have shown that this approach increases the diagnostic accuracy in primary staging, which might influence the subsequent management of the disease [10]. This is particularly relevant to surgical treatment. Often, the prostate gland is removed unnecessarily when the cancer has already spread to distant parts of the body although surgical removal offers no benefit. In this scenario, the patient would be better treated with androgen deprivation therapy (ADT) chemotherapy/radiotherapy. Removing the prostate gland is an invasive procedure that can result in bleeding, infection, incontinence and erectile dysfunction, so any modality that can inform the most appropriate treatment decision would be a step forward. Conversely, PSMA-PET imaging could underpin new salvage treatment options in those patients with oligometastatic disease who are suitable for PSMA-radioguided surgery. In castration-resistant prostate cancer it is possible to envisage an approach where radionuclide-tagged PSMA inhibitors could be used to treat the lesions [10].

To date, the majority of PSMA-PET data have come from studies on patients with recurrent prostate cancer. In this setting, PSMA-PET improves the detection of metastatic prostate cancer compared with conventional, cross-sectional imaging or bone scintigraphy [10]. Moreover, PSMA-PET increases the detection of lesions (even at very low serum PSA values) compared with conventional imaging or PET using different tracers [10]. This has important implications for salvage radiotherapy as this treatment is most effective at low serum PSA values. PSMA-PET imaging could therefore be used to optimize and guide radiotherapy.

CONCLUSIONS

The ^{68}Ga-THP-PSMA PET/CT modality offers a significant step forward in the management of prostate cancer. PSMA-PET scanning is fast becoming the imaging modality of choice in high-risk and recurrent prostate cancer because of the simplicity of its preparation. The advance promises to make this imaging technique more widely available to men with prostate cancer. Pending further data and regulatory approval, ^{68}Ga-THP-PSMA PET/CT can make a real difference in the management of this disease.

ACKNOWLEDGMENTS

^{68}Ga-THP-PSMA PET/CT was invented at King's College London and the clinical trial was conducted at the Peter MacCallum Cancer Centre in Victoria, Australia. The trial was funded by Theragnostics.

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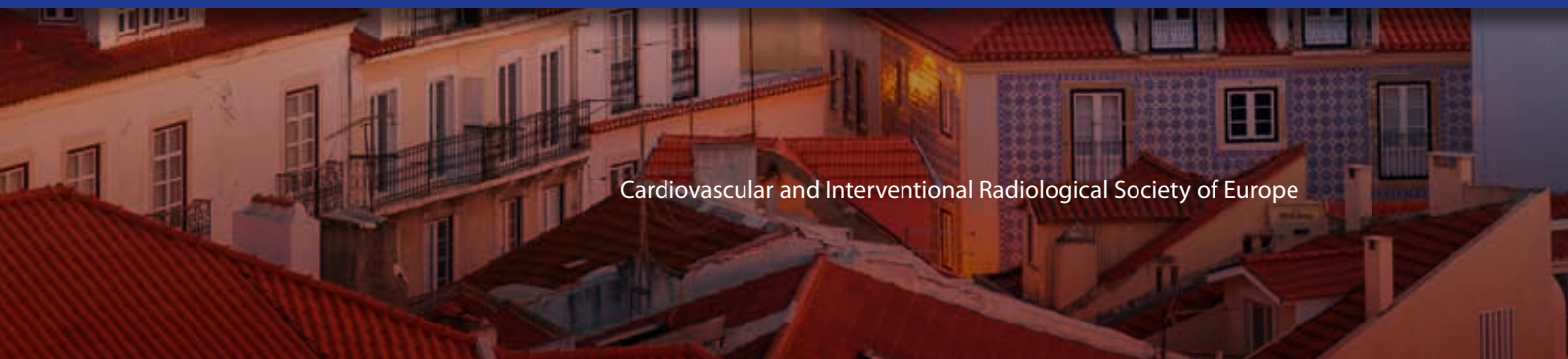

Cardiovascular and Interventional Radiological Society of Europe

Radio-wave imaging: a new modality for breast imaging

By Dr Peter Bannister

Although X-ray based mammography is the most widely used technique for breast cancer screening and diagnostic imaging, the technology has several disadvantages, such as the risk of false negatives — especially in dense breasts — not to mention the use of ionizing radiation.

The imaging modality based on the use of radio-waves has the potential to overcome such drawbacks.

This article describes the basic principles of radio-wave imaging and summarizes the preliminary clinical results generated by a commercially available radio-wave breast imaging system.

Breast cancer is the most prevalent cancer in women, with approximately 1.7m new cases worldwide in 2012. It is the leading cause of death from cancer for women in many countries. According to the American Cancer Society, 2017 estimates, worldwide breast cancer causes over 500,000 deaths each year [1] with an estimated economic impact of $88 billion each year. It is the most common cause of death in the EU for women aged between 35 and 55, with 1 in 8 contracting the disease in their lifetime. Around 80% of women will be the first in family to have been diagnosed with breast cancer. Since the 1970s, incidence has increased by 64% and in the UK is predicted to rise by a further 2% between 2014 and 2035 [2] where it is the most frequently occurring cancer in women with approximately 55,000 new cases diagnosed, and over 11,000 deaths in 2014.

The early diagnosis of breast cancer is of paramount importance, with a 5-year survival rate of 97% if the cancer is detected "locally", This survical rate deteriorates to 79% if detected in the "axillary" lymph nodes, and to 23% if it has metastasised to the rest of the body. Unfortunately at diagnosis, most cancers are well established with a palpable tumor size. The surgical removal of small breast lesions (lumpectomy) is a straightforward, minimally invasive procedure, but a partial or full mastectomy is more complex, entails greater risk and results in considerable disfigurement, frequently requiring cosmetic surgery. Today 75% of patients diagnosed with breast cancer go on to have major surgical resection.

Apart from regular self-examination, the most important early detection system is provided by the numerous national asymptomatic breast screening programmes in place around the world. These are backed up by various follow-up diagnostic imaging and biopsy procedures for women whose screens have produced suspicious results.

Recent advances in screening and treatment have led to a decline in the mortality rate from breast cancer. Studies in Italy, the Netherlands, Sweden and the UK have demonstrated that screening programmes could reduce mortality by 22%. Analysis of survival rates in 16 European countries has concluded that improvement in mortality was due to both screening programmes and developments in treatment. However despite the encouraging decline in mortality, there are still issues with screening programmes. For example, the uptake of screening in the UK has fallen slightly since 2010/11. A study from 2013 demonstrated that up to 46% of women in England who did not re-attend the screening program cited pain associated with their previous mammogram as the main reason for their decision [3].

BREAST SCREENING PROGRAMMES

Screening programmes utilising x-ray mammography (XRM), were introduced in several countries in the 1980s. Today 10 countries of the European Union have a national screening programme in place. While the USA does not have a national screening programme, women are encouraged to have regular mammograms, reimbursed by health insurance. Evidence collected from screening programmes suggests that women between 50 and 69 years benefit from screening. The evidence is weaker for women between 40 and 49, due to technology limitations, although trials are ongoing in this population [4]. The predictive value of an abnormal mammogram increases with age, such predictive values being higher amongst women with a family history of breast cancer. The interval between screenings varies between countries. Most European countries with

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screening programmes offer XRM every 2 years; 3 years in the UK. In the USA women are advised to have a mammogram every 1 to 2 years with shorter intervals for women under 50 due to more rapid cancer growth and poorer mammogram sensitivity, as a result of the low contrast between lesions and fibro-glandular or dense tissue exhibited by younger women and women of Far Eastern origin. Around 80% to 90% of abnormal screening mammograms are false positives. These require follow up testing and procedures such as breast biopsy, resulting in significant additional medical costs as well as anxiety, inconvenience and discomfort. Screening becomes more effective with the addition of other imaging modalities such as ultrasound or MRI. Together with invasive cytology or needle biopsy, these additions increase the accuracy to better than 90%. False negatives result in around 20% of cancers being missed, often in younger women with denser tissue. "Interval cancers" are those cancers that have become detectable since the last screening. Retrospective analysis of women who developed cancer after screening indicate that between 33% and 50% of lesions were, in fact, visible, but missed, on the initial mammogram. A recent study [5] reported XRM misses every other cancer in dense tissue, so whilst screening programmes are a positive activity they are still ineffective at finding cancer, particularly in dense tissue.

Diagnosis is currently achieved through clinical examination, imaging with XRM and/or ultrasound (US) and needle biopsy. XRM is dependent upon adequate breast compression to allow greater contrast differentiation between tissue structures, this is not only uncomfortable, but in younger women with dense breast tissue the contrast difference between normal tissue and tumor is minimal despite compression. Furthermore XRM uses ionising radiation, which means that a risk/benefit calculation is weighted against repeated or frequent use. Often it is necessary to use additional imaging such as ultrasound or MRI for diagnostic support.

FIGURE 1: The MARIA system, showing the Signal and Data Processing cabinet (containing the radiowave array) and patient bed. The patient lies with their breast pendulous though the hole in the bed, thereby avoiding the uncomfortable breast compression associated with XRM.

DIELECTRIC CONTRAST

Limitations of XRM have resulted in research into alternative methods for imaging of breasts with radio-wave detection of breast tumors being a potential non-ionising alternative [6]. Breast tumors have an additional attributes that can distinguish them from normal tissue which are defined by their dielectric properties. These includes two components – the dielectric constant (or relative permittivity), which affects the velocity of propagation of radio waves and therefore their wavelength, and the conductivity, which affects the rate of attenuation. Typically a tumor has a dielectric constant of 45-50 and a conductivity of 2S/m, whereas breast fat is 5-15 and 0.2-1S/m respectively but with considerable range. Normal glandular tissue falls between these two sets of ranges. The differences in dielectric constant can be exploited to aid breast cancer diagnosis. Initial results of radio-wave radar-based imaging have been presented [7-14] whose approaches rely on a difference in the dielectric properties of normal and malignant breast tissues [15-22] giving rise to varied changes to an applied radio-wave signal (which occupies the Ghz or "microwave" band). The breast as an organ is unique in the human body in that basic structure consists of glandular tissue (high dielectric constant, high conductivity and is radio-opaque) in a fat-based matrix with low dielectric constant, low conductivity and relatively radio-lucent. Inclusions such as a tumor are also of high permittivity, enhanced by the angiogenic increase in vascularity; cysts contain fluid which also has very high permittivity.

RADIO-WAVE IMAGING

Radio waves are part of a spectrum that includes visible light. Just as with light, we can 'see' with radio beams: a radio antenna shines radio waves like a torch beam. Radio telescopes and RADAR use radio to make images: they focus the radio like a lens to create an image. A radio-wave imaging scanner works in a similar way – directing radio beams from antennas into the body and focusing the reflections to form an image. Most soft body tissues are more or less transparent to radio, so radio can shine into the body and create images of what is inside. The way in which radio waves pass through is related to the electrical property called impedance. Inside the body, changes in impedance reflect radio waves, so the image created from a radio-wave imaging scanner relates to the basic property of bio impedance. A radio-wave imaging array [Figure 2] works by focusing – in a very similar manner to how a lens focuses an image

Figure 2. The scanner consists of an array of radio antennas arranged around the inside of a hemispherical bowl. The array is located below a hole in the scanner bed and is covered by a round cup that fits the breast when the patient is in the prone position

in a camera, but also controlling the generation of the radio waves as well as receiving them. This is used to create an image in 3D rather than the conventional two.

A radio-wave scan shows reflections from objects inside the body. As with light, reflections happen at the surfaces of objects. So at its simplest, radio-wave imaging shows the surfaces of objects inside the body. Specifically, the brightness of the reflection is determined by the difference in bio impedance either side of the surface, so radio-wave imaging shows the change in impedance across a surface. Impedance describes how the tissue impedes the progress of radio waves leading to changes in their size and timing. The bio impedance is determined by a number of factors to do with the mix of tissue types – fat, tumor, water – and the details of each tissue's water content. Bio impedance has been measured and analysed for more than 150 years. A body of evidence shows that tumors have a lower impedance than normal breast tissue: so the surface of a tumor embedded in normal tissue reflects radio-waves brightly and can be seen.

BREAST CANCER DETECTION WITH MARIA

Micrima's MARIA (Multistatic Array processing for Radio-wave Image Acquisition) radio-wave breast imaging system has a number of key advantages that make it ideally suited for the diagnosis and screening of breast cancer. Unlike XRM which is only accurate for women with lucent (fatty) breast tissue, MARIA is accurate in dense tissue typically associated with women below the age of 50. The technology is very low dose (exposure for a complete scan is equivalent to a few minutes mobile phone use), making repeated scanning safe, and the system is far more comfortable for the patient than XRM.

MARIA measures very different physical parameters to those exploited by XRM and is hence able to provide new diagnostic information. The scanner consists of an array of radio antennas arranged around the inside of a hemispherical bowl. The system uses a conformal array – designed to fit round the shape of the breast and with antennas that look at the breast from all sides in a closely packed pattern. The array is located below a hole in the scanner bed and is covered by a round cup that fits the breast when the patient lies face down. The scanner is operated by a radiographer, who is trained in carrying out imaging investigations. They control the scanner using a computer. Unlike an MRI or a mammogram, the radiographer is in the room with the patient during the procedure. The procedure is comfortable, painless and safe and takes just a few minutes

CLINICAL PERFORMANCE

MARIA has been used in the assessment of 86 women attending a symptomatic clinic in Bristol, UK in the so-called M4 study [2] and subsequently in a 227 patient multi-centre symptomatic trial in the UK (the M5 Study) [23,24,25]. The principal findings of these studies are:

i) **M4 Study** – Pre-CE Mark evaluation on 86 patients, single centre trial in symptomatic breast clinics. Lesion detection sensitivity of 74%. A blind read of mammograms from 66 patients demonstrated MARIA found 12% of index lesions missed by XRM alone. [26]
ii) **M5 Study** – Post-market study on 232 patients, 3 centre trial in symptomatic breast clinics. Lesion detection sensitivity of 77%, increasing to 84% for carcinoma in dense tissue and 100% (5 cases) for carcinoma in BI-RAD d (very dense) tissue. Blind read of first 30 cases using 4 independent readers demonstrated XRM found 90% of lesions and MARIA detected remaining 10%. [5]

FUTURE WORK

New studies centred around MARIA are due to commence at major EU centres and will consider several distinct groups of patients including symptomatic dense cases, high risk (BRCA1/2 screening) and women receiving neo-adjuvant chemotherapy who can be safely and comfortably imaged across therapeutic intervals of only a few weeks. MARIA is also demonstrating an increasingly accurate ability to automatically identify the type of lesion being imaged based on the inherent radio-wave "signature" of targets [8] and also provide direct measurements of local breast density [9].

CONCLUSION

This diagnostic modality could prove to be a major step forwards in cancer detection, initially as a complementary source of information that can increase confidence in results obtained from established technologies that are routinely deployed in the clinic.

MARIA also has the potential to make safe and effective screening available to women from a younger age, due to the absence of ionising radiation and unlike XRM not being limited by 'dense' tissue, enabling the application of current clinical interventions that are known to lead to overwhelmingly positive 5-year outcomes when the tumor is less than 10mm in diameter [7].

MARIA at RSNA 2017

Oral Paper: SST01-08 A reader study of MARIA radio-wave breast imaging compared with x-ray mammography for the symptomatic breast
Date and Time: 12/1/17, 11:40 AM - 11:50 AM

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Book Review

MRI-Essentials.com: a textbook of orthopedic MRI. Second edition

by Fischer, Guermazi, Roemer, Carrino, Crema, Grainger, Kijowski & Steinbach

Published by MRI-Publisher 2017 Eur 189/USD 199 *www.mri-publisher.com*

MRI-Essentials.com covers all aspects of musculoskeletal MRI with an emphasis on orthopedics and sports medicine. The text is highly compressed and enhanced by more than 4000 MR images of outstanding quality. Examples of some complex pathologies are included, but without straying from the subject. Learning in radiology, like all learning, is a combination of knowledge acquired from those around us, knowing the science and personal experience. Presentation and analysis of actual MR images is of fundamental importance to such personal experience beyond the daily exposition of cases. The images included in this book were chosen to provide the opportunity for such analysis, but the most important criterion for their use was that the images be relevant to clinical practice.

MRI-Essentials.com can be studied and read from the beginning to the end to gain a deeper insight into musculoskeletal MR imaging, but it can also be dipped into for information on specific topics. Basic knowledge of MRI is helpful to take full advantage of its content. The structure of the book is as logical as possible to allow easy access to its contents so that it can be of use in daily radiology practice. Finally, any non-radiologists involved in the diagnosis and treatment of orthopedic conditions will profit from this book, as knowledge of MRI is always important for communication and decisions about treatment.

Compared to the 1st edition, the 2nd has grown by 70 pages, 750 images and a large number of literature references. During the revision, the authors constantly asked themselves whether this expansion was justified. On the one hand, they wanted to offer the reader as much as possible and provide all relevant information. On the other hand, the claim of this book is to be short and concise, and to be reduced to the clinically relevant facts.

The 2nd edition is a good compromise between these difficult and conflicting objectives and promises to be a valuable tool in daily radiological work.

The book is available at *www.mri-essentials.com*

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Machine learning identifies breast lesions likely to become cancer

This article summarizes a recently published paper describing the development of a machine learning model that allows high-risk breast lesions (HRLs) diagnosed with image-guided needle biopsy that require surgical excision to be distinguished from HRLs that are at low risk for upgrade to cancer at surgery. The results provide a proof of concept that a machine learning model can be applied to predict the risk of upgrade of HRLs to cancer. Use of this model could decrease unnecessary surgery by nearly one-third.

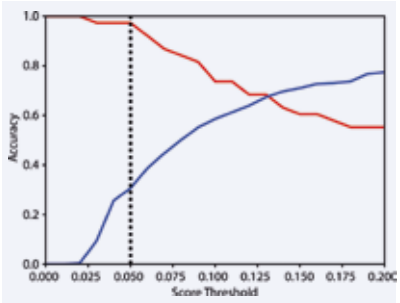

Figure 1. The above graph shows the accuracy achieved with the machine learning model for independent test set as a function of model output score, both for patients with malignancy (red line) and for patients without malignancy (blue line), in an independent test set. Vertical dotted line indicates 5 percent threshold

A machine learning tool can help identify which high-risk breast lesions are likely to become cancerous, according to a new study published in the journal Radiology [1]. The researchers carrying out the work said the technology has the potential to reduce unnecessary surgeries.

High-risk breast lesions are biopsy-diagnosed lesions that carry an increased risk of developing into cancer. Because of that risk, surgical removal is often the preferred treatment option. However, many high-risk lesions do not pose an immediate threat to the patient's life and can be safely monitored with follow-up imaging studies, sparing patients the costs and complications associated with surgery.

"*There are different types of high-risk lesions*," said Dr Manisha Bahl from Massachusetts General Hospital (MGH) and Harvard Medical School, Boston, MA, USA "*Most institutions recommend surgical excision for high-risk lesions such as atypical ductal hyperplasia, for which the risk of upgrade to cancer is about 20 percent. For other types of high-risk lesions, the risk of upgrade varies quite a bit in the literature, and patient management, including the decision about whether to remove or survey the lesion, varies across practices.*"

Dr Bahl and colleagues at MGH studied the use of a machine learning tool to identify high-risk lesions that are at low risk for upgrade to cancer. The study resulted from a close collaboration between researchers at the Massachusetts Institute of Technology's (MIT) Computer Science and Artificial Intelligence Laboratory in Cambridge, Mass., and breast imaging experts at MGH.

"*Because diagnostic tools are inexact, there is an understandable tendency for doctors to over-screen for breast cancer,*" said Dr Regina Barzilay, the Delta Electronics Professor of Electrical Engineering and Computer Science at MIT. "*When there's this much uncertainty in data, machine learning is exactly the tool that we need to improve detection and prevent overtreatment.*"

Machine learning is a type of artificial intelligence in which a model automatically learns and improves based on previous experiences. The model developed by researchers analyzed traditional risk factors such as patient age and lesion histology, along with several unique features, including words that appear in the text from the biopsy pathology report. The researchers trained the model on a group of patients with biopsy-proven high-risk lesions who had surgery or at least two-year imaging follow-up. Of the 1,006 high-risk lesions identified, 115, or 11 percent, were upgraded to cancer.

"... the model correctly predicted 97 percent of the lesions that were upgraded to cancer...."

After training the machine learning model on two-thirds of the high-risk lesions, the researchers tested it on the remaining 335 lesions. The model correctly predicted 37 of the 38 lesions, or 97 percent, that were upgraded to cancer. The researchers also found that use of the model would have helped avoid almost one-third of benign surgeries.

The machine-learning model identified the terms "severely" and "severely atypical" in the text of the pathology reports as associated with a greater risk of upgrade to cancer.

"*Our study provides 'proof of concept' that machine learning can not only decrease unnecessary surgery by nearly one-third in this specific patient population, but also can support more targeted, personalized approaches to patient care,*" said the paper's senior author Prof. Constance Lehman, of Harvard Medical School and Director of Breast Imaging at MGH.

"*Our goal is to apply the tool in clinical settings to help make more informed decisions as to which patients will be surveilled and which will go on to surgery,*" Dr. Bahl added. "*I believe we can capitalize on machine learning to inform clinical decision making and ultimately improve patient care.*"

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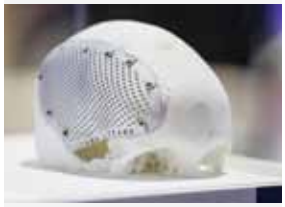

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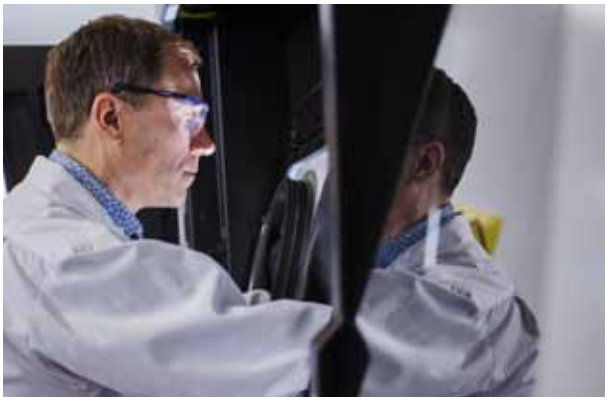
GE Healthcare opens first European 3D printing center

GE Healthcare has opened its first 3D printing lab, called the Innovative Design and Advanced Manufacturing Technology Center for Europe, in Uppsala, Sweden. The center will use technologies including 3D printing and robotics to speed up the launch of new innovative products for the healthcare industry. The center combines advanced manufacturing technology such as metal and polymer printers and collaborative robots, or "cobots", with traditional machining equipment. A key in realizing the advantages of 3D printing is ensuring the technology is considered at the start of the innovation process with Research and Design teams working with advanced manufacturing engineers and in collaboration with customers. The new center in Uppsala will ensure additive expertise is available from the start of product design. Advanced manufacturing techniques like 3D printing can bring significant benefits to manufacturing processes. For example, a 3D printed part can combine 20 parts into a single part and improve performance. Reducing parts in a manufacturing process



benefits industries like the biomanufacturing industry where the processes and manufacturing equipment are complex and made up of hundreds different parts.

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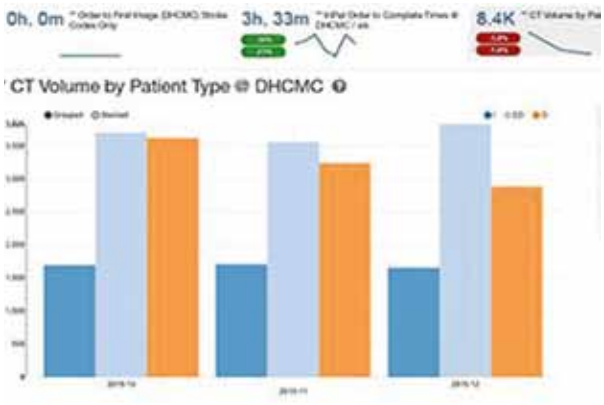
Analytics software integrates financial and imaging data

Formerly known as Imaging Resource Planning, Vital's Practice Management, version 1.4, software introduces the ability to integrate financial data with data generated by EMR, RIS, PACS and imaging equipment. Adding this financial dimension enables imaging leaders to uncover critical insights into the economics of their operations. Utilizing the current Practice Management applications, users benefit from a self-service toolset for building KPI (Key Performance Indicator) dashboards and on-demand reports. This package of modules is part of the newly branded Vitrea Intelligence solution.

"*To provide high quality imaging services for patients, healthcare leaders have to make wise financial decisions with respect to their business and clinical operations. Our Practice Management solution ensures the right people have the right information to assess the whole picture,*" says Ben Slater, Analytics Product Line Director.



Vital's analytics solutions are further supported by 'Evidence-based Management Services.' Vital tailors these consultative services to meet customer needs and focuses on value creating process improvements.

"*Helping organizations navigate the path to being truly data-driven is the primary focus of our Evidence-based Management Services. This begins in our initial conversations with new customers and continues through to improvement planning and execution,*" asserts Ben.

Vital Images, Minnetonka, MN, USA
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Real-time dosimeter

The RaySafe i3 realtime dosimeter visualizes X-ray exposure in real time using easy-to-read bar graphs. Instant feedback empowers medical staff to learn and adapt their behavior to minimize unnecessary radiation exposure. The measurements are simultaneously stored for post-procedure analysis, to facilitate continued learning as well as to enable comparisons over time or between labs.

The Real-time Dosimeter measures and records radiation every second. Data is transferred wirelessly to the Real-time Display. A hidden USB connector connects the Real-time Dosimeter to the Dose Viewer software, which can be used to change settings and to view and export dose data. The dosimeter is easy to wear, requires minimal maintenance and is designed to be personalized.

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MEDICAL DOCTORS (respond below)

1. What is your occupation ? (check only one)
   50 ❑ Diagnostic Radiologist
   51 ❑ Other Physician (please specify) _____

1a. What is your radiology sub-specialty ? (check only one)
   52 ❑ General Radiology
   04 ❑ Nuclear Medicine
   53 ❑ Nuclear Radiology
   54 ❑ Pediatric Radiology
   55 ❑ Neuroradiology
   56 ❑ Vascular & Interventional
   03 ❑ Cardiolovascular Diseases
   57 ❑ Other (please specify) _____

1b. I am a Head of my department
   58 ❑ Yes 59 ❑ No

Please continue with question #2 below

NON-PHYSICIAN PROFESSIONALS (respond below)

(non-physician may qualify based on the criteria listed below)

1c. What is your occupation ? (check only one)

Adminstrator/Manager :
60 ❑ Radiology Administrator
61 ❑ Radiology Business Manager
62 ❑ PACS Administrator

Executive :
63 ❑ Chief Information Officer/IT Manager
64 ❑ Chairman/Managing Director/ Executive Director
65 ❑ Chief Financial Officer/ Other excutive titles

Other :
22 ❑ Medical Physicist
67 ❑ Academic
66 ❑ Chief Technologist/ Senior Radiographer
27 ❑ Manufacturer
28 ❑ Business Consultant
29 ❑ Distributor/Dealer
30 ❑ Please specify _____

Please continue with question #2 below

ALL RESPONDENTS reply to the questions below

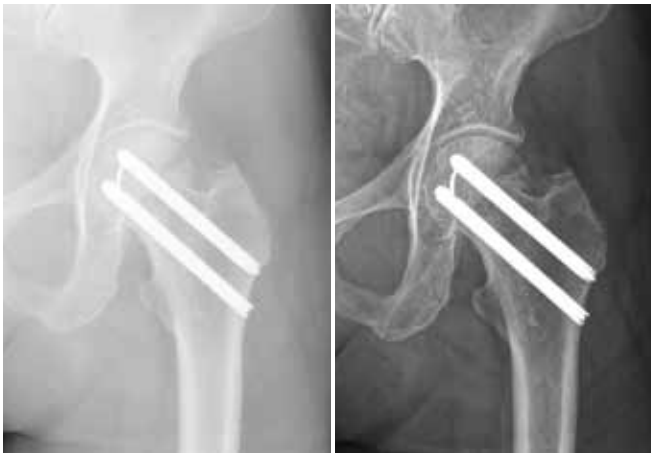
2. In what type of facility do you work ? (check only one)
   20 ❑ Private Clinic
   21 ❑ Hospital (check number of beds):
   a ❑ More than 500 beds
   d ❑ 200-299 beds
   b ❑ 400-499 beds
   e ❑ 100-199 beds
   c ❑ 300-399 beds
   f ❑ 0-99 beds

3. With what technologies or disciplines do you work ? (check all that apply)
   01 ❑ Diagnostic X-ray
   06 ❑ MRI
   02 ❑ Nuclear Imaging
   10 ❑ Mammography
   03 ❑ Interventional Radiology
   11 ❑ Bone Densitometry
   04 ❑ CT
   12 ❑ PACS/Teleradiology
   05 ❑ Ultrasound
   70 ❑ Cardiac Imaging
   71 ❑ PET 72 ❑ Angio
   73 ❑ Radiation Therapy
   74 ❑ Oncology
   75 ❑ Women's Imaging
   76 ❑ Molecular Imaging
   77 ❑ None of the above

4. If you currently receive Diagnostic Imaging Europe, how many other people read your copy ?
   a ❑ 0 g ❑ 1 b ❑ 2 c ❑ 3
   d ❑ 4 e ❑ 5 f ❑ 6 or more

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

Orthopedic image enhancement software and visualization for hand-held ultrasound systems



The latest development of ContextVision's flagship product, GOPView XR2Plus the system is an Orthopedic package. GOPView XR2Plus is the gold standard image enhancement solution for digital radiography and provides excellent image quality results, great durability and robustness in daily use. Addressing the specific requirements for both pre- and postoperative orthopedic imaging, the new Orthopedic package also facilitates low dose exposures with highest image quality. It provides extended product flexibility enabling excellent "white-bone" look, gives great visibility of trabecular structures and has no image artifacts around implants.

Another new product from Context Vision is VolarView which offers state-of-the-art image enhancement for the handheld ultrasound market segment. The new system allows for efficient implementation on smart phone and tablet based systems as well as special designed compact devices. VolarView is designed to meet the new requirements for efficiency and optimization for a variety of hardware and software platforms.

The increased availability of handheld devices makes ultrasound examinations applicable to more application areas and users outside traditional clinics.

The excellent image quality of VolarView gives diagnostic confidence and enables a fast and precise workflow by making images easier to read. VolarView provides adaptive algorithms continuously analyzing each pixel in real-time to optimize image quality as well as intelligent noise suppression with simultaneous contrast and edge enhancement presenting clear visibility of all clinical structures.

CONTEXTVISION
STOCKHOLM, SWEDEN
www.contextvision.com

Total radiology conference at Arab Health 2018

From 29th January to 1st February 2018, the Emirate of Dubai will welcome more than 4,000 exhibiting companies and over 102,600 attendees from 160+ countries at the 2018 Arab Health Exhibition and Congress; in what is clearly the largest gathering of healthcare and trade professionals in the MENA region. With 90% of exhibitors at the 2017 event rebooking their space for the 2018 edition of the show, the success and strength of the event as the region's leading exhibition and conference in the healthcare industry has been validated beyond doubt.

Accompanying the exhibition will be 19 business, leadership and Continuing Medical Education (CME) conferences providing the very latest updates and insights into cutting-edge procedures, techniques and skills. Arab Health Congress 2018 is one of the largest multi-track medical conferences accredited to CME worldwide and will see the participation of more than 8,000 delegates and 500 speakers from the region and around the world as it aims to bridge the gap in medical knowledge.

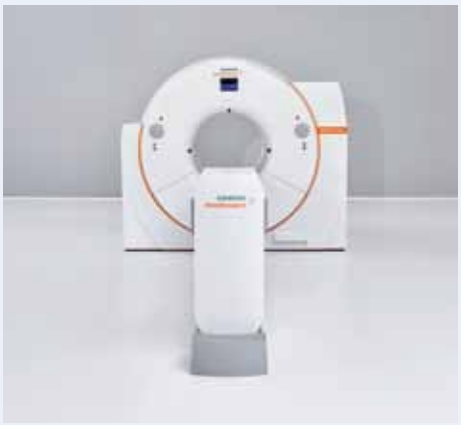
As one of the most awaited and popular conference tracks, Arab Health's 18th Imaging and Diagnostics - Total Radiology conference will present the latest advances in medical imaging, accurate imaging diagnosis and improvement of care quality for radiology patients. Held under the theme, 'Advances in the Art of Radiology', these scientific sessions will identify disease imaging and diagnostics for oncology, breast, abdominal, emergency and respiratory, gastrointestinal, cardiovascular, nervous systems including a comprehensive discussion of the diagnostic imaging procedures utilized in demonstrating diseases and conditions.

New topics for the 2018 edition include radiology in sports medicine and radiology in emergencies. Participants can also examine the impact of new initiatives to prevent occupational exposure in radiology, identify how to translate academic research to evidence-based diagnostic radiology; and evaluate how to reduce radiation while maintaining good image quality with different modalities; amongst others.
www.ahcongress.com/imaging

Powerful new PET/CT system & software platform

Siemens Healthineers have introduced the Biograph Vision, a positron emission tomography/computed tomography system designed to deliver a new level of precision in PET/CT imaging. Together with this, Siemens have unveiled new software features designed to bring advanced clinical capabilities to the Biograph Vision as well as the company's established Biograph mCT and Biograph mCT Flow PET/CT systems.

The Biograph Vision PET/CT system features new Optiso Ultra Dynamic Range (UDR) Detector Technology, which is based on silicon photomultipliers (SiPMs) rather than the photomultiplier tubes (PMTs) that have up till now been the industry standard. This new system design enables the reduction of the size of the detector's lutetium oxyorthosilicate (LSO) crystal elements from 4 x 4 mm to 3.2 x 3.2 mm, resulting in higher spatial resolution, which may improve lesion detectability. Utilizing these extremely small LSO crystals and covering 100 percent of the area of the scintillator array with SiPMs, the Biograph Vision is designed to deliver the industry's fastest time-of-flight (TOF), with a temporal resolution of just 249 picoseconds. The Biograph Vision also has a large 78 cm bore that offers 24 percent more space than the industry standard. This larger bore is designed for improved patient comfort and positioning, and for advanced applications in radiation therapy (RT) planning.



The new Biograph Vision is designed to fit in a facility's existing Biograph mCT family of PET/CT systems room with no need for costly renovations.

The new software platform contains four optional features that are designed to provide optimal performance to the new Biograph Vision PET/CT system. These software features also will be available as options on the existing Biograph mCT family of PET/CT systems.

The QualityGuard feature is designed to self-calibrate the PET detector by tapping natural background radiation from the LSO detectors to run daily and weekly quality control (QC) procedures during off-hours, saving up to 30 minutes of staff time per day. Self-calibration eliminates the need to use a radioactive source for daily and weekly manual calibration, thereby reducing the technologist's radiation exposure, in addition to eliminating the need to manipulate the radioactive source, which can weigh more than 11 Kg.

A second software feature, FlowMotion Multiparametric Suite, is a fully automated solution designed to deliver whole-body PET images of tracer uptake rate and distribution volume, in addition to the standard static PET images.

The OncoFreeze feature is designed to provide images that are virtually free of respiratory motion. Traditionally, respiratory gated images use only select information from a specific portion of the patient's respiratory cycle, and the rest of the data acquired from the PET/CT scan is discarded. OncoFreeze is designed to use 100 percent of acquired information from the respiratory cycle and potentially allows for reduced acquisition time.

Finally, CardioFreeze addresses issues associated with cardiac PET/CT image acquisitions. The software is designed to correct for respiratory and cardiac motion. With CardioFreeze, each individual cardiac gate is reconstructed with 100 percent of the data acquired, eliminating variability from respiratory and heartbeat motion.

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

High end ultrasound platform launched

MyLab9 is Esaote's new flagship platform in its ultrasound portfolio and defines a new standard in image clarity smart workflow and solid performance. Developed to provide ultra-quality ultrasound technology for hospitals, clinics and private practices, the MyLab9 eXP offers smart upgradability, remote serviceability, long-term maintenance options and transducer compatibility.

"*The MyLab9 platform represents a new chapter for Esaote*" said Luca Bombino, High-End Ultrasound Product Marketing Manager. "*We invested in technologies that have a real clinical impact, improving image acquisition, diagnostic confidence and patient throughput. Our multi-modality approach allows quick access to other imaging modalities and PACS systems, for immediate clinical follow up and fusion imaging. At Esaote, we believe this is an important step for a more informed and efficient healthcare system.*"

The MyLab9 takes advantage of cutting-edge manufacturing to offer an ultra-ergonomic experience, such as the easyMode unique touch-tool for image optimization. "*In everyday clinical practice, it's crucial to be precise, and confident at the same time. The easyMode technology allows the operators to conduct the examination*

with a focus on the patient, without distractions or complex technical routines of the system", said Carlo Biagini, MD, Radiologist, Florence, Italy.

Massimo Rosa, Esaote's Chief Global Marketing Officer said "T*oday economic constraints, and the increase in average life expectancy, are opposing forces. The MyLabTM9 eXP provides advanced diagnostic capabilities and clinical efficacy to respond effectively to the most demanding healthcare needs expanding the access to innovative technologies for more customers.*"

ESAOTE,
GENOA, ITALY
www.esaote.com

Custom workflow and advanced toolsets for enterprise imaging

Konica Minolta has introduced new functionalities including performance dashboards on its Exa enterprise imaging solution. The recent enhancements, including non-DICOM data viewing capabilities and a customized workflow engine, along with the existing advanced technology now make Exa Enterprise Imaging one of the most advanced healthcare IT platforms available on the market today.

With the addition of performance dashboards, facilities can measure daily exam volume, radiologist performance, and referring physicians ordering preferences. Administrators and department managers can easily create their own customized reports to efficiently get the data that are most relevant for their practice or organization. Exa also facilitates the sharing of multispecialty medical images

and reports via referring physician, patient, and attorney portals. The platform enables outside facilities to safely access pertinent patient data via Image Exchange, which eliminates the need for sending or bringing image CDs.

Exa is the only Enterprise Imaging solution that offers a diagnostic-quality zero footprint universal viewer for DICOM and non-DICOM images, including nuclear medicine and echocardiograms; Server-side rendering for fast access to large files, such as 3D mammography, with no prefetching required; and cybersecurity with no data transferred to or stored on workstations to minimize unwanted exposure to patient data. For women's health departments and clinics seeking to consolidate viewing, it offers universal viewing of images from a single workstation.

The Exa platform, comprised of multiple modules including PACS, RIS, EHR and specialty viewers, was developed to enable each site to design its own preferred imaging workflow, very simply, with drag and drop tools.

"*Throughout this past year, we've continued to explore, invent and transform Exa into a true Enterprise Imaging solution,*" says Steve Deaton, President of Konica Minolta HCIT. "*Our investment in a modular platform enables us to rapidly implement advanced technologies and deliver innovative functionality such as non-DICOM viewing, portals for image sharing and Performance Dashboards. This approach also enables facilities to maximize their investments in healthcare IT while tapping into administrative reports that can help achieve maximum clinical and business efficiencies.*"

KONICA MINOLTA,
TOKYO, JAPAN
www.konicaminolta.com

Advanced multi-parameter ultrasound system

SuperSonic Imagine has introduced a new version, the Ultimate, of its premium ultrasound system, Aixplorer. "*We are very proud to introduce Aixplorer Ultimate to radiologists and physicians. We work closely with the scientific and medical community so that our technology will become a standard in expert imaging of diseases of the breast and liver to improve the treatment of patients diagnosed with cancer or chronic liver diseases such as fibrosis or steatosis (NASH),*" said Michèle Lesieur, CEO of SuperSonic Imagine. The SuperSonic Imagine technology, whose acquisition frame rates are 200 times faster than conventional ultrasound systems, has opened up the possibility of new imaging modalities which are now in daily use in hospitals and clinics.

The Aixplorer Ultimate has a new streamlined look and intuitive user interface. It incorporates new architecture boasting 4.5 times more computing power than previous Aixplorer models. Supersonic Imagine optimizes the development of non-invasive evaluation tools to evaluate non-alcoholic steatotic hepatitis (NASH).

Ultimate also incorporates the very latest UltraFast innovation – Needle PL.U.S – enabling simultaneous visualization of anatomical structures, biopsy needle and the trajectory with a high level of precision. These innovations provide fast and reliable access to diagnostic information, an essential resource for the diagnosis and assessment of major diseases such as chronic liver disease, breast and prostate cancers. SuperSonic Imagine provides physicians an increased reliability of interventional procedures using ultrasound guidance while improving patients' safety and comfort.

Needle PL.U.S. joins other modalities introduced over the past 8 years by Supersonic Imagine: ShearWave Elastography (SWE), used to view and measure the stiffness of tissue in real time using color mapping; UltraFast Doppler, which combines Pulsed Doppler and Color Doppler in a single sweep; Angio PL.U.S., offering unrivalled resolution for imaging micro vascularization in lesions; and TriVu (B mode + SWE + Color+), a new triplex

modality combining three types of diagnostic information into a single image. In the management of breast cancer, Aixplorer Ultimate helps to improve the identification of malignant or benign lesions and helps to reduce the number of biopsies.

The advantages of ShearWave Elastography in the diagnosis of mammary lesions has been demonstrated in more than 100 articles in peer-reviewed journals, including an international study involving more than 1,600 patients. When this technology is combined with conventional ultrasonography, diagnoses can be more accurate, significantly reducing the number of false positives, and thus the number of unnecessary biopsies.

"*ShearWave Elastography, integrated with morphological characteristics, improves the diagnostic performance of ultrasonography by enhancing the characterisation and boosting the specificity of mammary lesions. It makes it possible to decrease unnecessary follow-ups and negative biopsies,*" explains Dr. Cohen-Zarade, radiologist at IRP (Paris Radiology Institute).

In the liver, Aixplorer Ultimate can assess liver stiffness for the assessment of liver fibrosis severity and NASH without a biopsy

"*Aixplorer is a comprehensive, non-invasive diagnostic tool for chronic diseases of the liver. It makes it possible both to quantify liver fibrosis by assessing liver stiffness and projected changes with ShearWave Elastography and to quantify steatohepatitis of alcoholic or non-alcoholic origin (NASH) through the hepatorenal index*," emphasized Dr. Mona Munteanu, Anti-Fibrosis Diagnosis Centre, Pitié Salpêtrière Hospital Group, Paris.

More than 120 articles in the international literature have demonstrating the reliability and effectiveness of ShearWave Elastography in the NASH field.

SUPERSONIC IMAGINE
AIX-EN-PROVENCE, FRANCE
www.supersonicimagine.com

Faster, breast tomosynthesis system with higher resolution for increased clinical confidence

The newly introduced 3Dimensions mammography system from Hologic is the fastest, highest resolution breast tomosynthesis system ever, and is now available in Europe. The new product offers a variety of groundbreaking features designed to provide higher quality 3D images for radiologists, enhanced workflow for technologists, and a more comfortable mammography experience, with low-dose options, for patients. "*We are excited to introduce our new 3Dimensions mammography system, a major advance in Hologic's mission to expand our leadership in breast health through transformational technology that is rooted in meaningful customer insights and supported by superior clinical evidence,*" said Pete Valenti, Hologic's Division President, Breast and Skeletal Health Solutions. "*The 3Dimensions system offers a number of innovative features that improve image clarity and help manage dose, setting it apart from every other screening technology on the European market.*"

The new 3Dimensions system features Clarity HD high-resolution 3D imaging, which is designed to clearly reveal subtle lesions and fine calcifications to help pinpoint cancers early. The advanced detector and innovative 3D imaging algorithm work together to deliver exceptional 3D images, regardless of breast size or density. Designed to increase clinical confidence and achieve more accuracy the first time, Clarity HD reduces recalls by up to 40 percent compared to 2D alone. "*Clinicians across Europe have made clear their desire for breast cancer screening technology that offers improved accuracy, clarity and workflow*", said Jan Verstreken, Hologic's Regional President for EMEA and Canada. "*We are thrilled to introduce this comprehensive solution, which will undoubtedly make a positive impact on European radiologists, technologists and patients alike.*"

In addition, the 3Dimensions system offers Intelligent 2D imaging technology, which works with Clarity HD technology to deliver unprecedented clarity, contrast and detail at a lower dose. Intelligent 2D imaging technology features smart mapping, which enables radiologists to instantly move from suspicious areas detected on the 2D image to the point of interest on the 3D slice, saving time and optimizing workflow.

The 3Dimensions system also includes the new SmartCurve breast stabilization system, which is clinically proven to deliver a more comfortable mammogram without compromising image quality, workflow or dose and has been shown to improve comfort in 93 percent of women surveyed who reported moderate to severe discomfort with standard compression. The system features a curved compression surface that mirrors the shape of a woman's breast to reduce pinching and allow uniform compression over the entire breast.

HOLOGIC
MARLBOROUGH, MA, USA
www.hologic.com.

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Vienna, Austria

www.ecio.org

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siemens.com/mammomat-revelation

SIEMENS Healthineers