Augmented intelligence enhances breast screening and cancer treatment.

In the fight against breast cancer, dense breast tissue causes diagnostic problems, but continuing development of augmented intelligence technology is helping radiologists better detect, investigate, and, in the best of cases, arrest the insidious invader. The problem thus far has been that breast cancer has run rampant "under the cover of darkness, like a thief in the night." But that metaphor doesn't accurately convey the problem. It's not the darkness that's the problem; it's the light.

"A large amount of dense breast tissue can result in a falsely reassuring negative mammogram," says Sian E. Iles, MD, FRCPC, section head of breast imaging in the Central Zone/IWK Health Centre and an associate professor in the department of radiology at Dalhousie University in Nova Scotia, Canada. "We now know that dense breast tissue can obscure breast cancers, as the breast tissue shows up white and the breast cancers also show up as white. Data reveal that sensitivity is much lower in women with dense breast tissue."

Iles adds a key reminder. "Another important fact is that women with dense tissue are at a higher risk of cancer," she says. "It's proven that in the overall population, mammography does save lives, but the problem is the procedure is less effective in women with dense tissue, and these are the women at higher risk."
Iles reports that advocacy groups are trying to ensure that dense breast information is given to both referring physicians and patients. "In this way, the patient will be more aware of the implications of her dense breast tissue," she explains.

Women with dense breasts are often advised to have digital breast tomosynthesis (DBT), and for good reason: It boasts a higher detection rate and fewer false-positive findings, resulting in fewer unnecessary breast biopsies.

"With the advocacy came a trend toward looking at other methods, in addition to mammography, of screening women with dense breast tissue," Iles says. "These include handheld ultrasound, automated breast ultrasound, breast MRI, and contrast-enhanced mammography. For those women with the densest breasts, either automated or handheld ultrasound may be better at improving cancer detection. And advocacy groups are recommending that supplemental screening be performed."

Recent technological developments related to a shift to 3D imaging with DBT, automated ultrasound procedures, and functional imaging with contrast-enhanced mammography are helping to eliminate paradigm-changing problems, such as too much data to scroll through. In addition, physicians aver that patients who could best benefit from supplemental screening are better identified by delivery of automated and reproduceable assessment.

**Automation Takes a Step**
Densitas Inc, a medical device software company that develops mammography screening products, announced in April 2018 that it received FDA clearance for DENSITAS|density, an automated breast density software that analyzes digital mammograms and generates automated reports. Iles has hands-on experience with the Densitas product and indicates that its impact rests on two levels: daily work and its larger impact when it comes to looking at breast density in the larger screening population.
"The problem with breast density assessment is that it can be very subjective," she says. "On the same patient, two radiologists can come up with a different assessment. As such, there's been a push toward trying to standardize methods of measuring breast density. The Densitas method involves an algorithm based on hundreds of mammograms and trying to use that to develop a new augmented intelligence algorithm. It involves a much more standardized measure of breast density, and it can take out radiologist variability. [The technology] allows us an automatically generated breast density assessment that can be used as a preliminary assessment to generate a more objective, reproducible measurement of breast density."

As Iles points out, when health care professionals read mammograms, trying to focus intently upon images—and what these images may or may not reveal—the extra time involved in trying to assess breast density potentially distracts from the most important task: finding a lesion. The integration of automation into augmented intelligence is an important move forward.

"Automation helps provide a standardization that removes a time-consuming step," Iles says. "Because it is a software program with an output, there is a potential to integrate that within a reporting system and the radiologist doesn't even have to dictate the breast density. So, it takes out a step.

"Here's another thing," Iles points out. "Because of the reproducible element, and an applicability to large numbers of mammograms, we can use it to evaluate a patient population, to look at the distribution of breast density across a broad population. We can then tailor according to a specific population. For example, in general, it is considered that if you have dense tissue, you could apply a category C or category D descriptor. When you apply this to a population, we have more knowledge of breast density in the general population that helps us tailor our approach to how many women are within the population, what we need to address, and at what level should we be thinking of doing something extra."

Furthermore, she takes it from the broader population picture to the
individual patient case. "The automation of breast density assessment allows us to better consider other existing risk factors, now that we have an improved screening program," Iles says. "We're able to do a more personalized screening to a woman's specific needs. That's what we're looking toward in the future. Breast density is only one factor we're looking at."

Looking ahead, Iles says, "What we see [potentially happening] is something better than the current one-size-fits-all regimen. The emerging technology is leading the way to a more personalized screening."

**An Edge at the Margins**

Last November, Kubtec Medical Imaging, a firm focused on breast specimen tomosynthesis, launched its Mozart Supra Specimen Tomosynthesis System, an imaging tool for breast cancer surgery. The new product, Kubtec's latest generation of the 3D imaging system for breast cancer surgery, is built on its already existing and proprietary specimen tomosynthesis technology. This augmented intelligence technology aids radiologists with image interpretation and reduces the need for repeat surgeries.

Instead of generating a single 2D planar view of multiple tissue layers, the system employs 3D tomosynthesis technology to eliminate tissue interference by digitally removing overlying or underlying tissue in 1 mm slices, providing greater clarity. Three-dimensional breast tomosynthesis is increasingly becoming the recognized standard for specimen mammography, rather than 2D technology; the improved clarity of 3D tomosynthesis improves accuracy in diagnosis and reduces false-positives.

Cary S. Kaufman MD, FACS, an associate clinical professor of surgery at the University of Washington and medical director of the Bellingham Regional Breast Center, says 3D specimen tomosynthesis enables better evaluation of surgical margins and a more accurate determination of what exactly needs to be removed from the patient's anatomy. Whereas a 2D image reveals the suggestion of a lesion, a 3D image shows the exact location and extent of the lesion, he notes.
As far as technological development, Kaufman says, "Three-dimensional breast tomosynthesis appears to be the obvious, evidential evolution in breast screening and surgery. Researchers made it clear that tomosynthesis for dense breast anatomy was a much better method to identify lesions, and, from evidence gained, many centers throughout the country have gone from [2D] to 3D. Others are in the process of doing that. It's become clear that, to have the optimal specimen mammogram method, the 2D imaging was inadequate in comparison.

"It's not that it allows us to do something that we couldn't do before; rather, it's that we can now do what we have been trying to do even better," Kaufman continues. "There are two reasons to do the specimen mammogram: to identify the lesion and to capture the cancer. Previously, it was done with 2D mammography, and we thought we were doing great. Now, we have a much more detailed view of tumor orientation within the specimen—exactly how close the tumor is to every margin, not just the two margins you see on the periphery of the horizon. We now have a much more comprehensive view of the margins and a more comprehensive view of the cancer."

Tomosynthesis, he continues, enables the user to scroll through multiple slices of the specimen and, as a result, see more detail. More importantly, if the patient has a dense breast with a cancer within, the physician has much better capability to determine the exact cancer location.

"Essentially, the cancer is not obscured by the dense breast tissue that surrounds the cancer," Kaufman says. "[But] let's be clear—it's not valuable to every patient. Other modalities provide valuable information. But [tomosynthesis] helps identify which patients would be best served."

**Two Views**
Kaufman was involved in research to determine the value of 3D specimen tomosynthesis. He relates that the 18-month clinical study began in mid-2015, with results being published last year. The study included 210 patients and involved a side-by-side comparison of 2D and 3D specimen images for
intraoperative margin assessment. The researchers compared results gleaned from patients who had image-guided lumpectomies using both intraoperative 2D imaging and intraoperative 3D tomosynthesis. Specifically, the study compared 3D intraoperative specimen tomosynthesis (IDST) with intraoperative digital specimen mammography (IDSM). The study was conducted with Kubtec technology.

"Two orthogonal views of each specimen were taken with each machine," according to the researchers. "For patient management, intraoperative review of all images was available to the operating surgeon for their immediate action as appropriate. Comparison data was accumulated as to ease of use, time to first image, handling issues, re-excisions, mechanical issues, as well as image comparisons."

The researchers forwarded all imaging from the operating room to the radiologists and permanent recording via a standard PACS system. They categorized breast lesion images into the following three groups:
- densities (61%);
- clips (26%); and
- calcifications (13%).

The researchers found that the primary difference was within the density group: "In 70% of patients with densities or spiculated lesions, the IDST provided more information than the IDSM. It was possible to see the target lesion more often with IDST than IDSM. Comparing the same image orientation, overlapping tissue was avoided and spiculations could be seen more easily using IDST."

IDST was more precise in 43% of all lesions examined. That led the researchers to conclude that the use of specimen tomosynthesis improved accuracy. They added, "Further use by others should validate these early findings."

The average re-excision rate for specimen assessment in the United States
falls in the 30% range. The researchers found that re-excision rates dropped during the study period, and the average overall re-excision rate for the entire period was 12%. Kaufman, who led the study, and colleagues determined that IDST enables breast surgeons to significantly reduce their re-excision rates from 19% to 9% compared with IDSM. Obviously, this is heartening news, as the ultimate goal of specimen tomosynthesis is to remove the entire tumor in a single procedure with maximum breast conservation. The results suggest that it's possible to achieve a reduction in health care cost as well as an increase in patient satisfaction and quality of life with this technology. Kaufman expects IDST to become standard.

"As it was with screening mammography, it takes time for the message to get across, but we could see a lessening of re-excision. The message just needs to be recognized by breast surgeons. When they do, they will find that their performance will improve, not for every patient, but at least for patients determined to need re-excision," he says. "In my experience, I use it on every patient, because at this point, it indicates the potential to benefit every patient, even if we don't know right now where it will provide more information in each case."

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