Digital Breast Tomosynthesis: A Planning Guide to Integrating the Latest Advancement into Your Imaging Center

By Diella Mrnaci

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Since the early 2000s, there have been numerous reports promoting the increased cancer detection benefits from tomosynthesis. This 3D imaging technology has been hailed by many in the research and clinical communities for providing radiologists with images that enable them to examine the breast layer by layer and identify more cancers. After many years of anticipating the new technology, The Food and Drug Administration (FDA) finally approved tomosynthesis for use in breast screening and diagnostic tests in 2011.

Although numerous studies claim that tomosynthesis provides greater clarity than 2D digital imaging and saves more lives; many researchers initially held back their enthusiasm, and in some cases, criticized the use of tomosynthesis for breast cancer screening and detection. Some of that restraint and opposition was a result of what critics cited as a lack of convincing research, as well as reports that tomosynthesis exposes patients to higher doses of radiation than 2D mammograms.

At Stamford Hospital, our leadership carefully studied the available research and ultimately decided in 2011 to implement tomosynthesis, in addition to 2D imaging, to screen and diagnose patients for breast cancer. Our breast imaging specialists were bullish that this technology would enable us to see inside the breast more clearly, find tumors at an earlier more treatable stage, and reduce the time women spent returning for additional imaging. We were right. Our own research demonstrates a significant increase in our cancer detection rate. This technology significantly validates the benefits to our patients.

We began using our first tomosynthesis unit at our Tully Breast Imaging Center in October 2012 and became just the second imaging center in the state of Connecticut to adopt 3D imaging for mammography. Embracing this new technology and the promise it held for our patients' health was incredibly exciting for our team. But, as anyone who works for an institution such as a university or hospital knows – dramatic change, even when it's positive, is hard.

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Like everyone else who studies to become a licensed clinical specialist, radiologists spend years building their knowledge and honing their skills. Adopting a new technology entails a learning curve and an abrupt change in how radiologists have interpreted breast cancer screens throughout their careers. The introduction of tomosynthesis is as disruptive as when radiologists who interpreted film screens made the transition to reading 2D digital images. Integrating tomosynthesis also is a massive cultural change for the rest of the imaging team, including the technologists and office staff.

Unsurprisingly, adding a new advancement to our environment introduced a whole new world of challenges. Even though our team was well prepared, we still had to progress along a learning curve and contend with the inevitable uncertainties. At Stamford, we faced a variety of challenges in integrating the new technology and its usage into a workflow we were accustomed to. Throughout this process we learned many lessons, which you can benefit from as you implement tomosynthesis at your hospital or practice.

The Journey Begins

Our journey to integrate tomosynthesis into our imaging centers began with the installation of our first tomosynthesis unit at Tully Breast Imaging Center, our outpatient facility with the largest volume of breast cancer screenings. The system vendor, Hologic, Inc., trained our team and installed the tomosynthesis unit.

To become certified to use tomosynthesis, our radiologists underwent eight mandatory credit hours of training. Physicists were trained on-site for an additional eight hours and technologists had three days of intensive applications training.

The Hologic team integrated the tomosynthesis unit and software with one of our 2D units at Tully over the course of a weekend. Their installation team started on Friday night after our last patient screening and the unit was ready for use when we opened our offices Monday morning.

My team of technologists and office staff were excited to begin using tomosynthesis immediately, but the transition wasn't like flipping a switch. In fact, it took about three months until we could say that our operations were running smoothly. It was an exciting time, but those are three months none of us will ever forget.

At First, the Tomosynthesis Unit Collected Dust

Adoption of tomosynthesis by our radiologists didn't take off immediately. After training, about 50% of our radiologists were on board seeing this as a fantastic opportunity and the other 50% were skeptical. It didn't help that many reports from researchers, doctors, and the media still questioned the ability of tomosynthesis to save more lives or improve upon what 2D mammography offered.

At first 3D images do not look as sharp or defined as traditional 2D images. 3D images display as layers, unlike the single bird's-eye view afforded by 2D. As in CT-Scan, radiologists view 3D images slice-by-slice whereas 2D displays as one solid image with all the tissue superimposed. It takes a while for both radiologists and technologists to adjust to viewing 3D. This makes it especially challenging in the beginning to detect motion – which, when found, requires taking another image of the patient's breast.

Some of our radiologists were concerned about reports that tomosynthesis subjected patients to additional, potentially dangerous radiation. Much of this misunderstanding came about because 3D tomosynthesis is used in conjunction with 2D imaging. This exposes the patient to radiation for seconds longer than conventional digital imaging. However, the dose of that combined radiation is well within FDA safety guidelines. More recent studies support tomosynthesis and give physicians a better understanding of why the technology is safe and beneficial to patients.

So at first, the tomosynthesis machine kind of sat alone in its room, underutilized. Fortunately, a champion emerged from the ranks of the radiologists to lead in the use of tomosynthesis – Dr. David Gruen, clinical director of our imaging centers. His influence and leadership eventually led to 100% adoption by our radiologists.

Dramatic Workflow Changes Quickly Emerged

With Dr. Gruen leading the charge with the doctors, my colleagues and I focused on keeping everything humming from the technology and administrative support side. I handled the workflow and technical aspects as well as managed the scheduling and operational changes within the department.

Our technologists, who spend the most time with the patients, were eager to start using tomosynthesis right away. The biggest differences for them were new touch screens, fingerprint access, and bilateral hand switches. However, the most disruptive change for technologists wasn't the introduction of the technology, but in how they had to adapt their workflow – not just once, but a few times.

Our Tully operations are in full swing 12 hours per day, Monday through Friday. The schedule, which is usually packed every day, includes four 15-minute 2D/3D screens

per hour for a total of 60 per day. With a busy schedule like ours, clearly there is no margin for error.

A month after installation, our radiologists were interpreting both 2D and 3D images and were still adjusting to the differences in reading 3D. This created some bottlenecks that had an impact on our ability to keep up with the number of scans we could perform daily.

The combined 2D/3D screening room became overloaded because as technologists adjusted to the new technology and process, they were now averaging 20 minutes to complete a tomosynthesis screening. Many of them fell in love with the technology and would also slip into the tomosynthesis room whenever they could for diagnostics – disrupting the schedule even further.

Our patients have time constraints and expect our breast cancer screenings to be something we can manage quickly so they can get back to work or pick up their children at school. Due to the initial learning curve associated with implementing this new technology, that wasn't happening – and it was time to again look for opportunities to improve our workflow.

Exams had to be cut down from 20 to 15 minutes, so we could still accommodate volume and maintain the availability to our patients. Each technologist has their own way of establishing rapport with their patients, but they've had to adapt and process everything quicker. However, the unexpected (such as walk-in patients, emergency add-on procedures, and equipment issues) has the potential to occur on a daily basis and directly impact workflow.

The stress levels of our technologists, understandably, went through the roof during this period of accelerated change. We revised our workflow several times, using approaches such as creating separate diagnostic and screening schedules. Some technologists were assigned to the screening room, others assigned to the diagnostic room, and the rest picked up the slack as needed such as answering patients' questions and helping to guide them through the process.

With all the changes Tully endured to implement tomosynthesis, we decided to keep our skin marking protocol intact. **With so much more tissue detail visible on the 3D image, the use of skin markers help to map out an area on the breast that either identifies or rules out some questionable findings. For example, on a 2D image, some scars 5 years old or older are barely visible; but when viewing a scar on 3D, architectural distortion from scarring is much more noticeable and causes questions.** By marking this area, the scar marker helps clarify findings reducing the possibility of additional imaging and potentially even biopsies. Keeping our same skin marking protocol alleviated some of the stresses associated with our transition to 3D.

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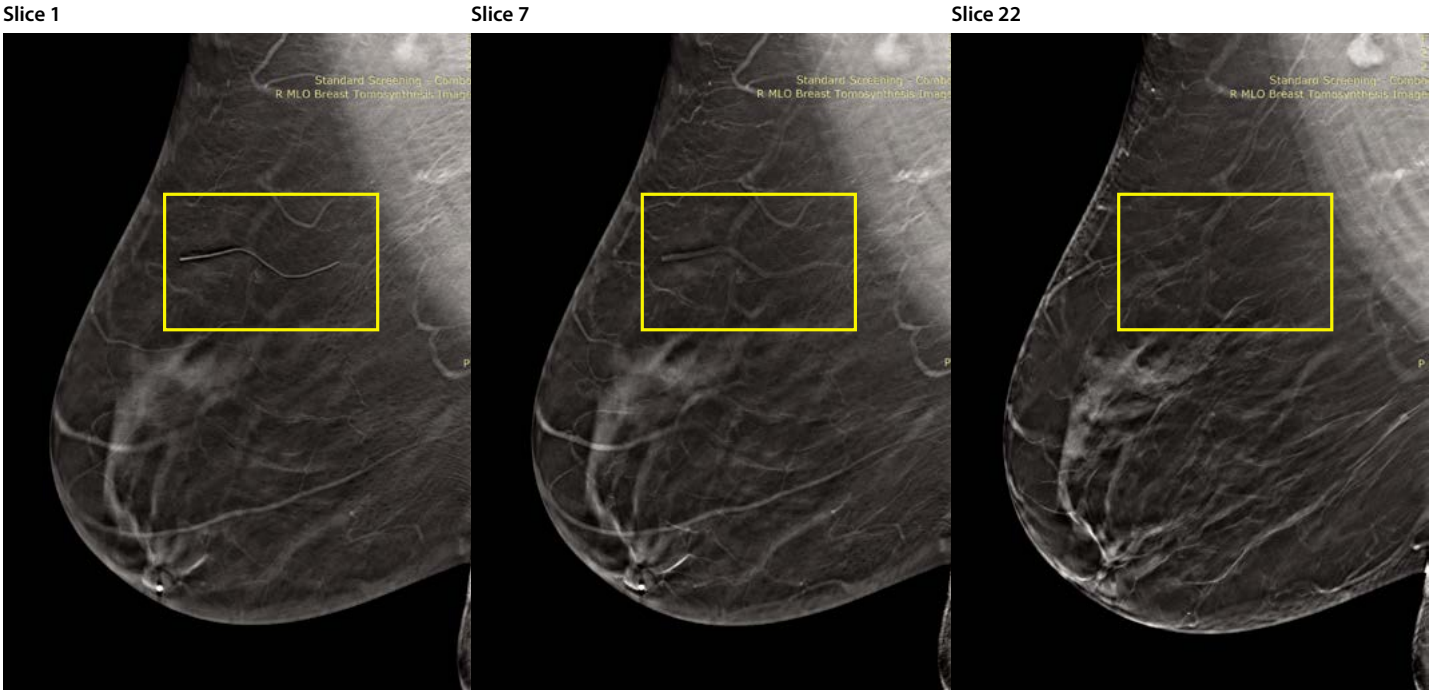

Figure 1
Breast tomosynthesis image – standard screening right MLO view. **Slice 1** shows linear TomoSPOT™ scar marker (Beekley Medical®) at its clearest resolution. **Slice 7** shows linear TomoSPOT scar marker beginning to fade when scrolling through the tomosynthesis dataset slices. **Slice 22** is the point at which the linear TomoSPOT scar marker is no longer visible (see highlighted boxes).

Eventually we fine-tuned our workflow to the point where we were back on track and able to better manage our standard of 60 patients per day. We reached that milestone in about three months and no sooner did we accomplish that, we discovered things were about to get even more interesting.

As the Department Fires on All Cylinders, Screening Volume Soars

After three months, the results were impressive. The number of tomosynthesis screenings was back to 60 per day. With radiologists up to speed and sold on the technology and technologists following a successfully revised workflow, many of the outcomes we had hoped for had become a reality. The number of diagnostics and call-backs for re-imaging plummeted. Biopsies were increasing because our team was identifying more calcifications and tiny structures. It was exactly what we as a hospital had dreamed of. In some ways, though, the struggles in our journey were just entering a new phase.

Because the radiologists had greater faith in the technology, many of them began insisting that everything, from screenings to diagnostics, be handled with 3D. And with patients hearing more and more about the benefits of tomosynthesis in the news, coupled with our hospital's outreach and promotional campaigns – demand was exploding.

At the three-month mark, we were handling 60 tomosynthesis screens per day and were ecstatic. Patient number 61, though, was the straw that broke the camel's back. With such vigorous demand, the capacity of our one tomosynthesis room was exceeded. After our initial success, we were determined not to let this progress in improving patient satisfaction and restoring our technologists' peace of mind head in the opposite direction. Clearly, it was time to introduce another tomosynthesis room at Tully as well as add a tomosynthesis room at our other busy outpatient imaging center at Darien.

After some fits and starts, our success was undeniable – and we had the data to prove it. When we showed the numbers on patient satisfaction, the adoption rates by our radiologists and technologists, and the reductions in false positives, false negatives, and call-backs for additional imaging – hospital leadership was instantly sold.

They were more than happy to accommodate our request to meet the incredible surge in demand for screens and approved funding for additional tomosynthesis rooms for both centers.

All of our hard work and sacrifices paid off as we had hoped. **In fiscal year 2013, with three tomosynthesis units in operation across the Stamford Hospital system, we performed 14,000 screens. In the first six months of 2014 alone, we were already up to 16,000 screenings. Patient complaints have fallen dramatically and our Press Ganey® scores have increased.** As we continue to engage more women at health expos and through our community outreach, the demand for tomosynthesis only continues to expand. It has grown so much that the hospital is close to approving a mobile tomosynthesis unit that we can use to serve even more women throughout Fairfield County.

More and more research is emerging regarding the benefits of tomosynthesis. It's highly likely you're not considering whether to implement tomosynthesis, but when.

When your facility transitions to tomosynthesis, be sure that your current PACS system is compatible with the technology. Certain PACS versions are not able to integrate correctly, resulting in images being inverted, degraded, and facing the wrong direction. In addition, do not forget that to maintain FDA accreditation; you have to submit your QA/QC within 6 months of your initial approval.

You should also keep in mind that due to the heightened sensitivity of 3D imaging, dense materials can cause an artifact through the tomosynthesis slices. Some of these artifacts can obscure or overshadow underlying structures, so it is important that you use a compatible tomosynthesis skin marker for marking moles, nipples, scars, palpable areas, or points of pain.

I hope this account of our experiences at Stamford Hospital helps you transition smoothly to tomosynthesis and helps your patients lead healthy lives and enjoy greater peace of mind.