

Improving mammography efficiency and workflow through Artificial Intelligence and SmartSlices

Hologic has announced the commercial availability in Europe of its 3DQuorum Imaging Technology, powered by the company's Genius AI algorithm. The innovation was designed to help improve mammography efficiency and workflow, which is becoming increasingly critical as clinics strive to manage the backlog of women whose routine breast screening has been delayed due to the COVID-19 lockdown.

Hologic's 3DQuorum imaging technology uses their Genius AI-powered analytics to reconstruct high-resolution 3D data to produce 6mm "SmartSlices". These analytics identify clinically relevant regions of interest and preserve important features during reconstruction of the SmartSlices, which expedite read time by reducing the number of images for radiologists to review, without compromising image quality, sensitivity or accuracy. With 3DQuorum technology, the number of 3D images to review is reduced by two-thirds, saving an average of one hour per eight hours of daily image interpretation time.

"As we continue to operate in this new landscape, radiologists are facing the dual challenge of a serious backlog of women who need routine breast screening as well as a screening process that is lengthier due to COVID-19 protection measures," said Jan Verstreken, Hologic's Group President, International. "The more efficient workflow of 3DQuorum is urgently necessary to help radiologists meet this challenge. This solution is a strong example of how Hologic continues to streamline workflow for radiologists by improving the reading experience without sacrificing accuracy or quality of work - a balance that our customers have come to expect."

In addition to the implications associated with the COVID-19 virus, radiologists are facing a growing need for improved workflow efficiency as digital breast tomosynthesis (DBT) becomes the gold standard for screening in Europe.

Recently, the European Commission Initiative on Breast Cancer (ECIBC) guidelines on breast cancer screening and diagnosis recommended for the first time the use of either DBT or digital mammography in screening.

However, DBT creates an influx of large file sizes and images that can lengthen the image reading process for radiologists. This creates a need for solutions like 3DQuorum technology to help streamline workflow where possible.

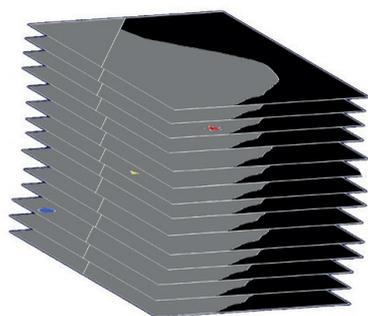
Complete information on the 3DQuorum Technology can be found in a Hologic White Paper [1]. The salient points are summarized below:

DESIGN GOALS FOR 3DQUORUM

The most commonly used slice thickness in commercial breast tomosynthesis systems is 1 mm. For a common breast thickness of 60 mm,

Design Goals

- Faster radiologist reading time
- Reduced number of tomosynthesis slices
- Reduced data storage space and network traffic



Original 1-mm slices

- ▲ Bright spots (calcifications)
- ★ Radiating lines (spiculated masses and AD)
- Round dense object (lobulated and round masses)

Figure 1. The 1-mm thin slices are searched for features of clinical interest, and their locations are noted

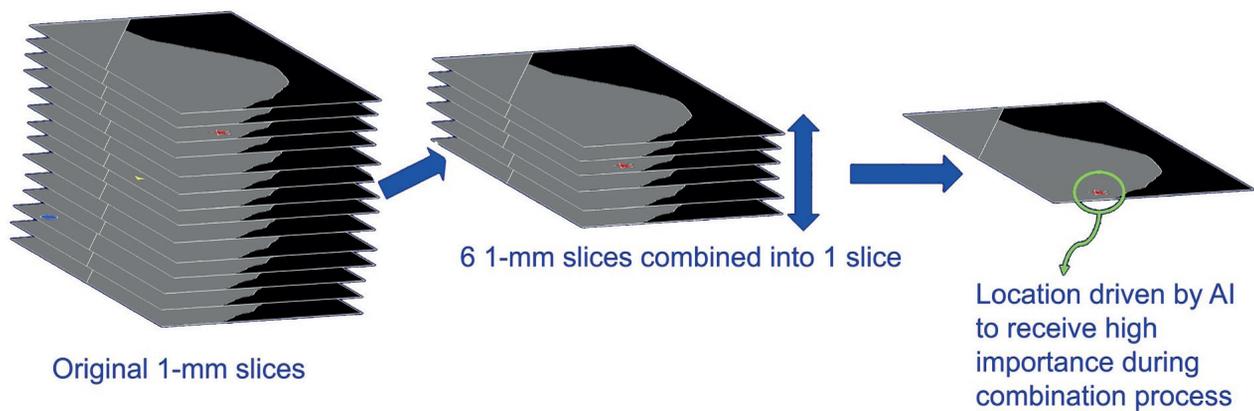


Figure 2. Six 1-mm slices are combined into one 6-mm SmartSlice, giving extra weight to AI-located objects of interest

the radiologist needs to review 240 image slices in a standard 4-view screening mammogram set. The design goal of 3DQuorum is to provide fewer, thicker slices for review which speeds up interpretation time, uses smaller files for ease of transfer and storage, and at the same time maintains clinical performance compared to 1-mm breast tomosynthesis datasets.

HOW SMARTSLICES ARE CREATED

Commonly used methods of creating thicker slices, such as simple summing of adjacent thin slices, or Maximum Intensity Projection (MIP) algorithms can create blurring and can also degrade the visibility of low-contrast and smaller objects due to the effect of overlapping tissues. That is why Hologic developed the

technology of SmartSlices, designed to ensure the visibility in the 6-mm slices of subtle and important objects seen in the 1-mm slices. The basic philosophy is similar to what is used in Hologic’s synthesized 2D images Intelligent 2D (I2D) and relies on artificial intelligence and machine learning.

In the SmartSlice generation process, the input data are 1-mm slices, and a high performance CAD-like algorithm searches each slice for details that may be clinically relevant, such as bright spots that could represent calcifications, radiating lines that could represent spiculations or architectural distortions, and rounded dense objects that might represent lobulated and round lesions. As it finds these objects, it makes a list of their x,y locations and slice numbers. This is shown schematically in Figure 1.

After the search through the 1-mm slices is complete, the 6-mm SmartSlices are created. Information found and marked during the AI search of the 1-mm slices are used in the combining of the 6 slices that are the components of each given SmartSlice. Figure 2 illustrates this process.

This step is repeated, ensuring a 3-mm overlap between successive SmartSlices. Because of the overlap, it can be seen that the number of SmartSlices is about 1/3 of the number of 1-mm thick slices. The way the overlap is arranged is shown in Figure 3. In the instances where the original number of slices are not divisible by 3, an extra 1 or 2 slices are reconstructed in order to complete the slabbing process.

CLINICAL STUDY REVIEW

The performance of the 3DQuorum (3DQ) images, compared to 1-mm tomosynthesis, was demonstrated in a multi-reader, multi-case clinical study. Specifically, 3DQuorum plus synthesized 2D images (I2D) were compared to 1-mm tomosynthesis with C-View synthesized 2D images. All clinical study endpoints were met. The primary endpoints were as follows:

- The diagnostic accuracy averaged among all readers reading the 3DQ/I2D (6-mm 3D slices along with high

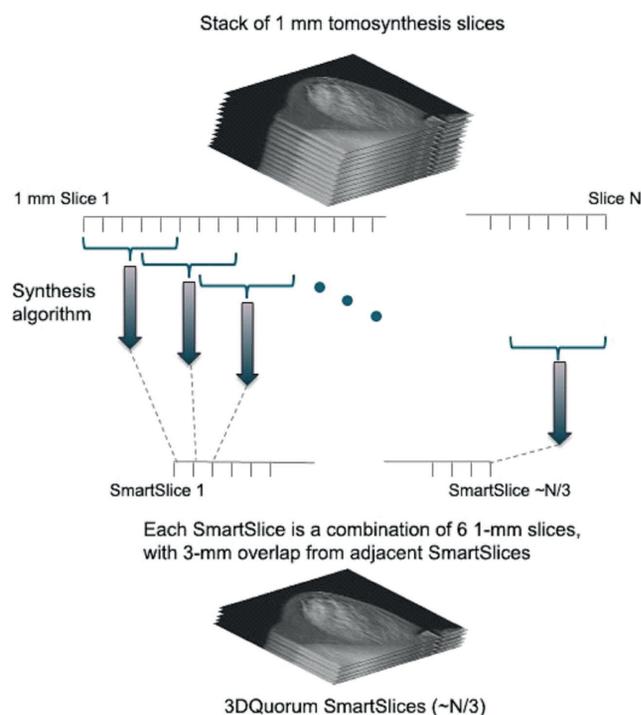


Figure 3. Each SmartSlice is computed from six 1-mm slices, and successive SmartSlices each have an overlap of three 1-mm slices from the previous SmartSlice.

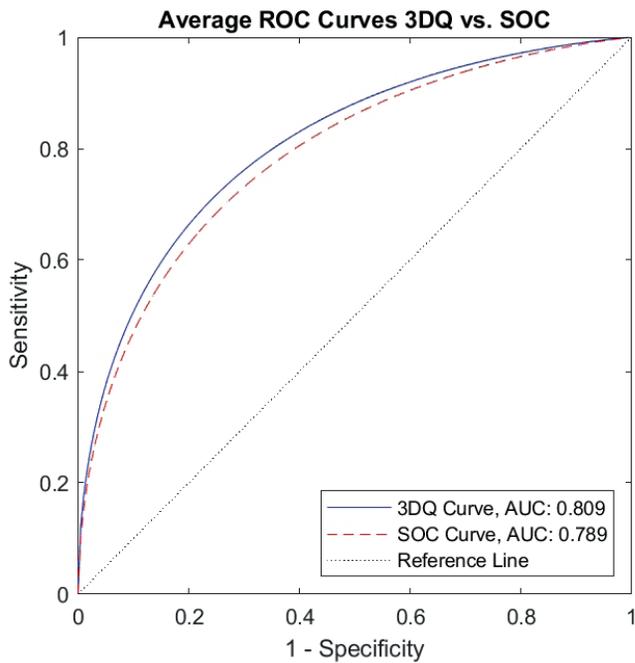


Figure 4. The 3DQuorum plus I2D and SOC (Standard of Care) pooled ROC curves averaged across the 15 readers

resolution synthesized 2D image) is non-inferior to that of 1 mm 3D slices along with C-View images, as measured by area under the ROC curve.

- The recall rate of cancer cases by readers (i.e. specificity) using 3DQ/I2D is non-inferior among calcification-only cases to the recall rate using 1 mm 3D slices along with C-View images, on average across all readers.

The reader study consisted of 391 cases and 15 readers with a range of clinical and tomosynthesis experience. The study used a fully-crossed reader study design. It comprised 2 sessions, separated by a minimum of a 4 week wash out period. In the first session, the reader read a randomized mix of the two modalities. The selection of cases under each modality to be read in each session was random, as was the order of their presentation to the reader. In the second session, the reader read the opposite exam type in a different random order. Through this design, each case was read using both

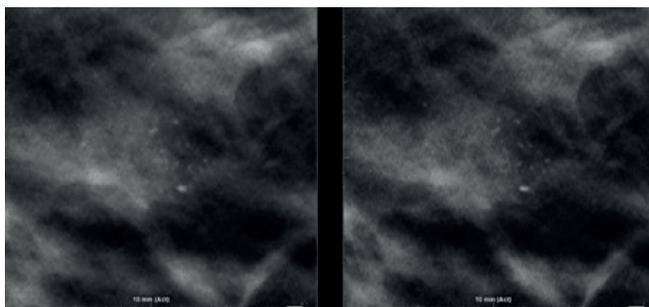


Figure 5. Example of clinical images. SmartSlice generation for a calcification cluster. The image on the left is a single 1-mm slice and the image on the right is the 6-mm SmartSlice.

modalities by each reader. In addition to the clinical scoring of each case (BI-RADS scores and lesion detection), the interpretation/image-view time was recorded for each case for each reader.

CONCLUSIONS OF CLINICAL STUDY

The average ROC curves for the performance of 3DQuorum and standard 1-mm tomosynthesis set can be seen in Figure 4. The difference in AUC for the two modalities was +0.027 (p-value = 0.027) in favor of 3DQuorum. Thus the first primary endpoint of the design goals was reached.

The second primary endpoint was demonstration of a non-inferior recall rate of calcification-only cancer cases by readers (i.e. specificity) when reviewing the 3DQ/I2D image set relative to the standard 1-mm tomosynthesis image set with a pre-specified non-inferiority margin of -0.05 of the 95% confidence interval. Mixed regression demonstrated a +0.047 recall rate difference (p-value=0.08) in calcification - only cancers in favor of 3DQuorum, thus the second primary endpoint of non-inferior recall rate for cancers presenting as calcifications only was met.

The average image read time for 3DQ/I2D and for the standard 1-mm tomosynthesis set was calculated. The standard 1-mm tomosynthesis set mean read time was 61.9 seconds and the 3DQ/I2D mean read-time was 54.5 seconds. This corresponds to about a 13% reduction in

read time when using 3DQuorum, and translates into an average time savings of 1 hour per 8 hour day.

The clinical study results indicate that all the design goals for the use of 3DQuorum plus synthesized 2D imaging have been met, namely a significant reduction in reading time and with approximately 1/3 the

number of slices compared to 1-mm tomosynthesis.

CLINICAL IMPLEMENTATION

Hologic understands that some customers may want to gain confidence in SmartSlices before using them in their clinical practice to replace their current mode of 1 mm tomosynthesis slices. Therefore, the company's acquisition station (AWS) will allow a configuration where both tomosynthesis slices as well as SmartSlices are created. The AWS also can be configured to send either or both the modes of slices to review workstation and PACS. Thus, customers can continue to generate 1 mm slices in addition to SmartSlices and send both of them to the review workstation until the users gain confidence on SmartSlices. During this period, they can choose to send either of the images to the PACS storage and decide to completely switch to SmartSlices when they are ready

REFERENCE

1. Keller B, Kshirsagar A & Smith A. 3DQuorum™ Imaging Technology: improving radiologist performance through Artificial Intelligence and SmartSlices. White Paper www.hologic.3dimensionsmammography.eu/3dquorum/