Deep learning cancer detection software for breast tomosynthesis

Widely recognized as one of the premier European cancer centers, the Gustave Roussy Cancer Campus (GRCC) in Paris, France, not only provides patient care, but also carries out cutting-edge research and teaching activities. Patients with all types of cancer are diagnosed and treated in the institute, whose motto is to put innovation at the heart of a human, scientific and technological revolution in the fight against cancer. The breast cancer unit in GRCC is particularly active, conducting numerous research projects and performing thousands of breast imaging examinations annually.

The unit has recently acquired a deep learning-based, cancer detection software for breast tomosynthesis, the ProFound AI system from iCAD.

We spoke to Dr. Corinne Balleyguier, Senior Radiologist and Head of Department about her unit's experience with, and opinion of the new software.

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Q *Before we get on to the ProFound AI system itself, please give us a brief overview of the breast cancer unit at Gustave Roussy.*

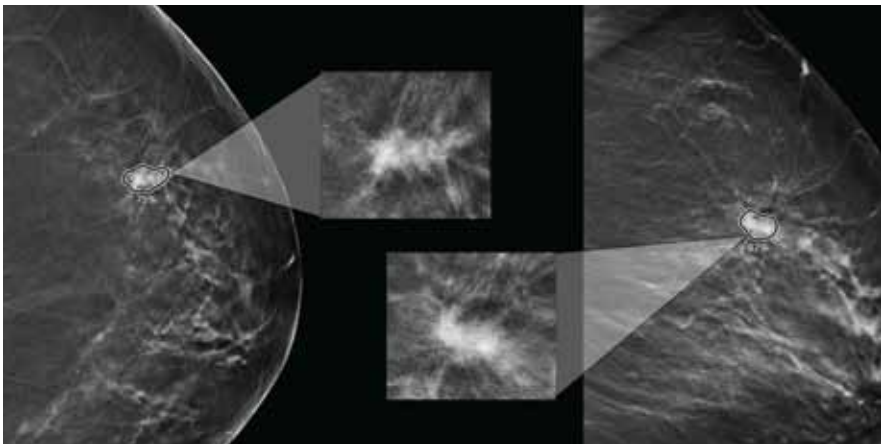
In part due to the reputation of the Institut Gustave Roussy (now known as Gustave Roussy Cancer Campus) and of our breast imaging service, we receive many patient referrals — we see more than 12,000 patients per year. We are well equipped to deal with this number of patients: we have three mammography systems, all of which can carry out tomosynthesis and also contrast-enhanced spectral mammography (CESM) as well as a stereotactic vacuum-assisted biopsy machine, three ultrasound scanners, and two MR imaging systems.
In addition to the imaging modalities, we also perform ultrasound-guided microbiopsies, stereotactic biopsies, fine needle aspirations and MRI-guided core biopsies, as well as pre and post-operative patient management.

Q *Let's now focus on the ProFound AI system*

It should be said right from the outset that, over several years, I have had a long and fruitful relationship with the iCAD company. However, this doesn't mean that we in the breast unit at GRCC blindly accept all products without first being able to extensively evaluate any new system. This is the same procedure that we adopt for all our new equipment or systems introduced into our department.
Thus, we have had the ProFound AI system since May of this year, but prior to putting the system into routine clinical use, we of course carried out an evaluation study. This study was all the more rigorous since we previously had an old Computer-Aided Detection software which was disappointing in its performance principally because the level of false positives it flagged was too high.

However, this experience did not at all close my mind completely to other applications, particularly to the newer algorithms based on deep learning artificial intelligence (AI) which have been trained on large digital breast tomosynthesis (DBT) datasets. These systems have the potential to further improve reader accuracy while also improving reader efficiency.

The ProFound AI system in particular was developed by iCAD in a data-driven manner by using an expertly annotated tomosynthesis image dataset collected independently, unlike conventional CAD systems, this AI system acquired knowledge necessary for lesion detection directly from



Certainty of Finding Scores or lesion scores are assigned to each lesion detected by the ProFound AI algorithm and represents how confident the algorithm is that the detection is malignant. In addition the algorithm assigns case scores which represents how confident the algorithm is that a case is malignant. All cases, including those without lesion detections, are assigned a case score.

the training data provided and did not rely on explicit encoding or replication of human expert decision processes.

One feature of ProFound AI is that it has an operating point controlling the trade-off between the detection sensitivity and specificity of the algorithm. This operating point can be selected by the user. At the beginning we chose the highest sensitivity, in order to get maximum detection of lesions, while accepting that this could increase the level of false positives.

In practice, this AI system, which is based on a deep convolutional neural network algorithm that processes individual reconstructed DBT images, presents the readers with outlines and locations of breast lesions. In addition, the algorithm assigns a "certainty of finding" score for each lesion and for each case in its entirety.

Q *And how did the evaluation process go?*

The very fact that we have now proceeded to the implementation of ProFound AI in our clinical routine is an indication that indeed the results of the evaluation process were positive.
Of course, in this process we looked at a large number of cases and assigned several of our breast radiologists to be involved. In our department we have a total of 19 radiologists (including residents) although not all of them are full-time. The overall conclusions of the evaluation were based on the totality of the cases but there was one particular case that impressed me. This was a case in which the radiologist on the original images had missed a very small spiculated lesion in an extremely dense breast. The lesion was detected by the ProFound AI system and later confirmed by MRI. Finally the lesion was confirmed as malignant by MRI-guided biopsy. When we looked back at the original tomosynthesis images, we realized that this was indeed the sort of lesion that we estimate eight out of ten readers would also have missed. After this case, I thought I'd better look more closely at the system.

"... the increased assurance of high sensitivity in an `AI system that works` is what we appreciate the most..."

Q *And now that the system is in routine use?*

Since we installed the software, we have used it in approximately 5,000 cases. We use tomosynthesis as the front line-modality for all the symptomatic cases we see except for high-risk cases such as BRCA gene carriers, which are imaged using MRI. (In France, screening with tomosynthesis is not approved). A typical case work-up involves first of all reading the synthetic 2D mammography. On our workstation, if any lesions are contoured by the algorithm, one click on the image will bring the reader directly to the tomo slice where the flagged lesion will be best visualized.

Although we do not oblige all of our radiologists to use the system, the vast majority do. While the installation of the software was without problem and its use is straightforward and intuitive, one aspect did require a little bit of getting used to. This was the need to familiarize ourselves with the lesion and case scores that ProFound AI provides. These are relative scores computed by the algorithm and represent the algorithm's confidence that a lesion or case is malignant. The scores are represented on a 0% to 100% scale, with a higher score indicating a higher level of confidence in the malignancy of the lesion or the case as a whole and so aids in determining if a suspicious finding or case needs further workup. These scores are really useful, but they are a separate system from the BI-RADS score and do not correlate mathematically with BI-RADS.

Q *And the overall impression of the system ?*

We are very satisfied with ProFound AI, and the main reason for our satisfaction is the increased level of assurance that the system provides that we have detected all suspicious lesions, with a minimum number of false positives.
In addition, the system saves us time in the reading of our tomo cases. The time needed to read all the slices of a tomosynthesis examination is, of course, a drawback of the modality compared to mammography. This reduction in tomosynthesis reading time that ProFound AI brings, particularly with straightforward cases, frees us up to focus on more complicated cases.

Lastly, what we appreciate the most is having the increased assurance of high sensitivity in an "AI system that works."