Addressing The 80 Percent

NISTA Diagnostic brings non-invasive quantitative digital methodology to turn painful and time-consuming biopsies -- and squandered healthcare dollars -- into a non-invasive, same-day accurate diagnosis.

Approximately 39 million women get a mammogram in the United States each year. Over 20 million of those women are later informed that the mammogram discovered an anomaly that requires further analysis, and of those, about two million are advised to have biopsies of the suspicious tissue.

The good news is that only 20 percent of those women are found to actually have breast cancer, but the other 80 percent? They have endured a series of procedures, wrestled with severe anxiety, sleepless nights, ending with a painful procedure which often leads to complications. And all that amounts to a cost estimated at almost $8 billion annually.

It's a wasteful expense for everyone, yet the technology to eliminate the stress, pain, and costs exists today. And in fact, it has for over 20 years.

NISTA Diagnostic uses a different type of radiology data, which is digital and actually quantitative, and which has been completely overlooked when it comes to medical diagnosis, while widely known in other scientific areas.

X-ray diffraction allows to non-invasively and accurately determine structural status of the tissue. And with that approach, NISTA will turn days of multi-

ple appointments, biopsies and squandered healthcare dollars into a non-invasive, same-day diagnosis, simply by cutting down on unnecessary procedures.

"The turnaround time of using the NISTA Scan is just under 10 minutes," says Byron Aram, Chief Medical Officer of NISTA Diagnostic. "The instrument will take four to nine scans and the clinician would know if the patient has cancer immediately."

The computational algorithm processes the digital diffraction data and tells the doctor exactly what it is. The patient finds out whether the patient has breast cancer before leaving the clinic.

The process today is much different. If a mammogram reveals a tumor or a suspicious mass in the breast, that patient has to have a biopsy to extract a small piece of breast tissue. In recent years, 80 percent of breast cancer biopsies produce a negative result, leaving doctors and patients to ask, isn't there a better way to find the same answer?

NISTA's scan enables doctors to further analyze a patient's result. It uses x-ray diffraction to obtain objective information about the structure in the tissue on molecular level, specifically the structure of collagen and the Matrix within the tissue, and measures the immune response. If the scanned tissue contains a malignant tumor, the NISTA Scan will clearly identify it.

"This would alleviate all kinds of problems, from the stress level of the patient, to avoiding complications, scarring and bruising, to backlog for pathology labs, which receives so many tissue samples. And even for insurance companies, who won't have to pay for unnecessary biopsies," Dr. Aram says.

Alexander Lazarev, Chief Engineering Officer, says that in some cases, a biopsy would still be recommended. "We don't want to get rid of biopsy all together, just the unnecessary ones" he says. "We want to address the 80 percent."

A non-invasive technique would save time and money for everyone involved. "That's what it makes it so exciting. There's no waiting game," he says.

As anyone who has waited for mammogram or biopsy results can attest, the days and weeks of waiting and uncertainty are excruciating. The NISTA Scan provides digital certainty immediately. The idea of using this type of method was first tried in 1998.

"Way back then, with crude equipment, we still got very good results with 95% sensitivity to cancer after teaching the algorithm based on just 1,400 samples," says Lazarev, whose father, Pavel, first started the idea and now serves as Chief Technology Officer at NISTA. "The market environment has changed dramatically. In the past 20 years, lots of research groups agree that it works for diagnosis purposes. Equipment has advanced tremendously. We also now have global databases and cloud base SaaS platforms with on demand scalability. The time is right."

The former study became a start-up company based in Palo Alto just last year, actively fundraising with a new set of intellectual property and cooperation with Stanford University. And then COVID-19 hit.

"It's put a damper on everybody. It has slowed for everybody literally, but on the other hand, it has taught us to operate more efficiently. We operate though teleconference and it has illustrated how well we can operate," Lazarev says.

Some elements of the system, Dr. Aram says, have been easy to build because the software efforts are generally an online collaboration. "It has not affected our progress. It has been a relief to move forward more than most industries," he says.

Luckily, NISTA put the technology in the hands of Dr. Mark Pigram at Stanford before the pandemic struck. He and his team have been working to start the NISTA Scan clinical study at Stanford. Dr. Pegram hopes to objectively identify the 10-11 subtypes of breast cancer and open a new level of understanding the different nuances of each. NISTA is also in the agreement phase with prominent breast oncology departments at Shanghai and Cranfield universities. Once the team has a built the reference learning database, they hope to get NISTA out in the next 36-42 months.

"In the first 12 months of rolling this out, we hope to have up to 100 centers," Lazarev says. "The clinic that adopts it will have a competitive edge," adds Dr. Aram. Doctors will be able to offer a smooth, stress-free experience and order biopsies only when absolutely necessary. "Clinics and hospitals will benefit from cost-savings, only sending cancer-positive patients to biopsy. It's a huge advantage to any healthcare provider."

"Everyone I speak to has been affected by the breast diagnostic process," Dr. Aram says. "Yes, my mom and some friends have gone through the process and it was nerve-wracking. Whether it's the waiting, the discomfort of the biopsy or the time that it took. And then to receive a negative after all of the obstacles they had to jump through? NISTA will change all of that." — By Victoria Kertz, California Business Journal.