LA-UR-12-23472
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Title:	From Bombs to Breast Cancer Imaging: Los Alamos National Laboratory
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Intended for:	Innovation Magazine

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In the United States, one in eight women will be affected by breast cancer. According to the American Cancer Society, breast cancer is the most commonly diagnosed—as well as the second most fatal—cancer in American women. It is estimated that there will be nearly 200,000 diagnoses of breast cancer this year; more than 40,000 of these will be fatal. Although advances in medical technologies have greatly increased the odds of surviving the disease, the increase in screenings has not resulted in a significant reduction in the breast cancer mortality rate. Moreover, recent studies have even suggested that an increase in these methods might, in itself, cause cancer.

A new tool for early detection and diagnosis of breast cancer, supported by an award from the Breast Cancer Research Program (BCRP) of the Congressionally Directed Medical Research Programs of Department of Defense, could give women a new advantage in the fight against breast cancer. Lianjie Huang, Ph.D. (Los Alamos National Laboratory [LANL]), and his collaborators, Donald Ingber, M.D., Ph.D. (Harvard Medical School), and Michael Williamson, M.D. (University of New Mexico [UNM] School of Medicine), are recipients of the first BCRP Multi-Team Award project to support the creation of a safe, comfortable and cost-effective imaging modality for early detection and diagnosis of breast cancer.

This LANL-led project will integrate ultrasound tomography (UST) with recent discoveries in the field of cell and tissue biomechanics to improve breast cancer detection and characterization. UST uses ultrasound waves instead of X-rays to identify and characterize breast tumors. This technology reveals small mechanical-property changes within the breast. These changes are often the earliest signs of breast cancer. Additionally, UST is effective for women with dense breast tissue, who have a higher risk of developing breast cancer. Because the technology does not use radiation, UST can also be used as frequently as needed for women with a high risk of developing breast cancer. In contrast, mammography, the only routine breast-cancer screening tool currently available, is not effective for women with dense breast tissue and may come with unwanted side-effects caused by ionizing radiation. UST has great potential to become an alternative breast-cancer screening tool because of UST's advantages and benefits over mammography.

Currently, there is fierce debate surrounding the age at which breast cancer screening should begin, and once begun, how often it should occur. The American Cancer Society recommends yearly mammograms starting at age 40. On the other hand, the U.S. Preventive Services Task Force recommends against routine so early. Rather, the Task Force recommends biennial mammography screening for women aged 50 to 74 years. The ten-year discrepancy in the onset of screening results from recent data suggesting that the frequent use of X-ray radiation during screenings could potentially increase the likelihood of developing cancer. This danger is increased by the low sensitivity and accuracy of mammograms, which sometimes require multiple screenings to yield results. Furthermore, mammograms are often not only inaccurate, but average appalling misdiagnoses rates: about 80% false positives and 15% false negatives. These misdiagnoses lead to unwarranted biopsies at an estimated health care cost of $2 billion per year, while at the same time, resulting in excessive cases of undetected cancer. As such, the National Cancer Institute recommends more studies on the advantages of types and frequency of screenings, as well as alternative screening options.

The UST technology developed at LANL could be an alternative option to greatly improve the specificity and sensitivity of breast cancer screening without using ionizing radiation. LANL is developing high-resolution ultrasound tomography algorithms and a clinical ultrasound tomography scanner to conduct patient studies at

the UNM Hospital. During UST scanning, the patient lies face-down while her breast, immersed in a tank of warm water, is scanned by phased-transducer arrays. UST uses recorded ultrasound signals to reconstruct a high-resolution three-dimensional image of the breast, showing the spatial distribution of mechanical properties within the breast. Breast cancers are detected by higher values of mechanical properties compared to surrounding tissues. Thus, high-resolution breast images obtained using LANL's novel UST algorithms have the potential to detect breast cancer at its earliest stage. The goal of this Multi-Team Award project is two-fold: (1) develop a novel, safe and cost-effective breast-imaging technique, and (2) improve the specificity and sensitivity of breast cancer imaging. The project is expected to integrate basic research with clinical studies, perform substantive cross-disciplinary training among scientists on the teams and involve participation of consumer advocates. Those involved in the project are optimistic about future developments.

"I am very excited about this multi-team, collaborative and interdisciplinary research that could boost the efficacy of breast cancer screening and help save lives," said Principal Investigator Dr. Huang.

"As a survivor of breast cancer, I feel strongly that this innovative technology promises to have a dramatic effect on women's healthcare by providing a novel, cost-effective breast cancer screening tool; significantly improving early cancer detection for women in all ages and thus reducing the morbidity and mortality of this disease," said Dr. Erin Bouquin, M.D., a consumer advocate for the project.

To accelerate clinical translation, LANL has assisted with the formation of a start-up company: Mustomo, Inc. David Hadley, LANL's technology transfer representative spearheading the commercialization effort, spoke highly of the project's recent achievements, as well as the opportunities available for the future of the technology. Hadley hopes to fully develop the possibilities of the project through collaboration with industry expertise. He stated that success is founded through public-private partnerships like the one between LANL and Mustomo, Inc.

Affirmed Denis O'Connor, CEO of Mustomo, Inc., "We know that early detection is a critical factor in a successful long term prognosis, yet current methods are limited and not optimal. We are aggressively moving forward with this technology. I believe that it is, simply put, a major advancement for the assessment of breast cancer, worldwide."

Most recently, Mustomo applied for LANL's Venture Acceleration Funding (VAF). The VAF funding is intended to help companies reach their goals through business and technology development activities. The company has been awarded $100K in funding and is optimistic about the future of the program. David Pesiri, Technology Transfer division leader, also expressed his support of the program.

"We are pleased to work with Mustomo, Inc. and Denis O'Connor, an experienced CEO, on this project." said Pesiri, " Through the VAF we will be able to assist the company in the development of a commercial system based on the technology. This product has the potential to vastly impact how breast cancer is screened and detected and we are proud to be a part of that."