**Ultrasound-Guided Diffuse Optical Tomography for   
Fast, Low-Cost Functional Imaging of Breast Lesions**

**Technology Description**

Researchers have pioneered a compact, low-cost ultrasound-guided optical tomography system designed to differentiate between benign and malignant breast lesions and reduce the need for costly and invasive biopsies. This technology enables fast, robust image reconstruction for diffuse optical tomography (DOT) in near infrared spectrum, providing objective, quantitative functional images for characterizing suspicious lesions identified through ultrasound and mammography.

Currently, it is difficult to distinguish the appearance of malignant vs. benign lesions with conventional breast imaging modalities and up to 80% of breast biopsies are performed on benign lesions. DOT could improve diagnostic accuracy and reduce the number of benign biopsies by providing complementary functional information. However, in the past, DOT has suffered from slow and difficult image reconstruction complicated by low accuracy and artifacts due to intense light scattering, presenting a bottleneck for wide clinical use. This technology addresses that problem with a combination of software and hardware to produce fast, high-fidelity images.

The compact hardware can be easily combined with any commercial ultrasound transducer for DOT imaging. The user-friendly software includes computational techniques for: automated ultrasound image segmentation for DOT reconstruction guidance; automated DOT data pre-preprocessing; and conditioning for improved signal-to-noise ratio; and fast image reconstruction. Collectively, the system generates optimized functional images for quantifying hemoglobin concentration and blood oxygen saturation in the lesion. Because higher levels of hemoglobin are associated with angiogenesis and malignancy, a conservative hemoglobin threshold could reliably identify many benign lesions, greatly reducing benign breast biopsies without compromising cancer detection sensitivity. In addition, functional imaging with DOT could predict response to neoadjuvant chemotherapy for breast cancer.



(a) (b)

Figure 1. Reconstructed hemoglobin map of a benign but proliferative lesion. Image (a) is a co-registered ultrasound image. Image (b) is a center slice of the reconstructed hemoglobin distribution.

**Stage of Research**

* **Prototype and prospective testing:** The inventors have developed a fourth-generation prototype US-guided Optical Tomography system that is currently being used at a university hospital for a prospective clinical trial.
* **Image reconstruction software:** Software currently provides imaging results in 20-30 minutes. The inventors plan to improve the software and develop it for near real-time imaging read out.
* **Retrospective studies:** The inventors conducted a retrospective study of 288 patients and estimated that using the US-guided Optical Tomography system would reduce the number of patients referred for biopsy by 45%. In a different study, the inventors used the system to predict treatment response to neoadjuvant chemotherapy.

**Applications**

Breast cancer imaging:

* Adjunct to mammography and ultrasound to characterize suspicious lesions, particularly in dense breast tissue
* Treatment monitoring/assessing response to neoadjuvant chemotherapy
* US-guided Optical Tomography reconstruction algorithms could be adapted for use with MRI or X-ray guided imaging

**Key Advantages**

* **Reduce benign biopsies:**
  + Objective, quantitative criteria to predict likelihood of malignancy
  + Potentially reduce 40-50% of benign breast biopsies by combining functional image with traditional ultrasound to identify false positive screens
  + Lowers total healthcare costs and subjects fewer patients to the risks of costly and an invasive procedure or an aggressive management plan
* **Compact, portable, low-cost, compatible device:**
  + DOT technique is non-invasive and does not require any contrast agents
  + DOT probe can be easily combined with any commercial ultrasound transducer
  + User-friendly operation and interface
* **Fast, robust image reconstruction:**
  + Preprocessing and imaging reconstruction algorithms currently generate images in 20-30 minutes with ongoing improvements aimed at achieving near real-time imaging read-outs
  + Automated data processing to improve consistency and facilitate clinical translation
  + Improved lesion quantification accuracy from ultrasound-guided image reconstruction techniques