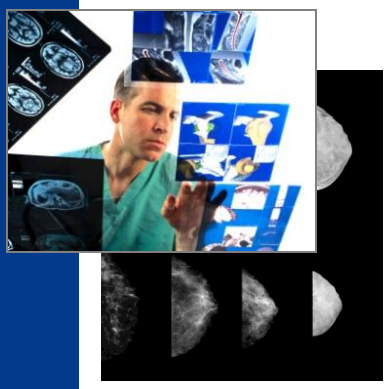
An Automated Mammographic Density Measure for Improved Breast Cancer Screening



Women with dense breast tissue have been shown to have elevated breast cancer risk, and dense breast tissue may also make lesions hard to detect. Our technology offers versatile algorithms to estimate mammographic density within full field digital mammography. These methods are fully automated, objective, reproducible, and are applicable across multiple imaging platforms. Our methods are easily modified to either correlate with breast cancer risk or to match established measures of assessing the potential for an hidden lesion, such as BI-RADS® (89% agreement with radiologists when determining which mammograms show dense breast tissue with a BI-RADS® score of 3 or 4).

COMMERCIAL OPPORTUNITY

- The American Cancer Society recommends that all women start annual breast cancer screening at age 40. More than 40% of women who undergo mammographic screening have dense breasts, which puts them at increased risk of cancer and decreased probability of early cancer detection.
- Breast density estimates are currently calculated to assess the whether a lesion may have been missed. Radiologists do this by visual scan of the mammogram, which is prone to significant subjectivity and variability between radiologists.
- Laws in CT, VA, TX, NY, and CA, as well as by proposed bills in 15-20 other state legislatures and the US House of Representatives call for mandates that high breast density measurements (BI-RADS® 3 and 4) be included in mammography reports, so the need for a reliable and standardized way of measuring breast density is growing.
- This market is attractive as evidenced by the recent introduction of volumetric breast density measurement software by Hologic, Inc. (Quantra®) and Matakina Technology Ltd. (Volpara®), which just surpassed 100 installations of Volpara® in healthcare facilities worldwide in March 2013.
- Our algorithm has >89% agreement with radiologists determining which mammograms show the highest density (BI-RADS® scores of 3 or 4), and this is better than the Volpara Density Grade algorithm that also measures breast density to provide a BI-RADS®-analagous breast density assessment. Our methodology can also be applied to existing breast density measurements.

TECHNOLOGY

We offer automated methods to estimate four breast density categories, analogous with BI-RADS scores, for full field digital mammography. Our methods are general and can be applied to raw mammograms, calibrated mammograms, or existing breast density measurements for breast cancer risk assessments or for evaluating the possibility that a lesion may be missed. The methods use either the variation (standard deviation) of pixel values within mammograms or simply the calibrated pixel values. According to our data, the risk for breast cancer (per one unit BI-RADS category-equivalent increase) was 2.13 (1.22; 3.72) for our technology, and 1.49 (0.99; 2.24) , suggesting our scoring system correlates better with risk. This work was validated with preliminary datasets using GE and Hologic instrument-generated mammograms.

PUBLICATION/PATENT

- US Non-provisional filed on 6/17/13, and a provisional patent application filed on 5/30/13 for Drs. Heine and Sellers
- Heine J.J. et al. JNCI 104(13): 1028-37, 2012, and manuscripts in press

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