



A System for Computer-Aided Mammogram Interpretation

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Abbreviated Abstract

Screening mammography for early detection of breast cancer improves the chances of a cure and allows for less traumatic and less expensive treatment. Studies have shown that screening suffers from large variability in detection rates and that radiologists do not identify all breast cancers that are visible on retrospective review. The ultimate goal of the proposed project is to test and commercialize intelligent software for mammogram image analysis to assist radiologists in detecting early-stage breast cancer. The software prompts the radiologist to more carefully study computer-detected suspicious regions in the mammogram. This has been shown to improve detection rates of breast cancer.

The specific aim of this Phase II project is to test the safety and effectiveness of the system in a clinical setting in order to allow for obtaining the regulatory approval necessary before commercialization. The system is safe and effective and improves cancer detection rates without increasing the recall and biopsy rates.

Primary Investigator

Kevin Woods, Ph.D., Intelligent Systems Software, Inc., 311 Park Place Boulevard, Suite 240
Clearwater, FL 33759
Phone: (727) 799-4763
Fax: (727) 799-8707
E-mail: woods@ismd.com

Research Team & Affiliations

Kevin S. Woods, Ph.D., Principal Investigator, Intelligent Systems M.D., Inc. (ISMD)
Maha Sallam, Ph.D., ISMD
Alan Cantor, Ph.D., Biostatistician, H. Lee Moffitt Cancer Center and Research Institute

Total Budget

\$1,089,320

Research Objectives

AIMS

1. Refine a mammogram image analysis system.
2. Conduct clinical testing to prove the system's safety and effectiveness.

Theory/Hypothesis

Studies show that detection rates improve through double reading of mammograms by two radiologists. This is an expensive solution that becomes less feasible as the number of screening cases increases relative to the number of radiologists. Using computer-aided detection (CAD) systems to aid radiologists in reading mammograms can help alleviate the problem.



Experimental Design

Two studies were performed. The first is a Sensitivity Study designed to measure the extent to which the system helps detect cancers earlier. The second is a Specificity Study designed to measure the effect of using the system on the radiologist assessment of standard screening cases. Cases were collected at six different clinical sites in Florida. A total of 14 Mammography Quality Standards Act (MQSA)-certified radiologists participated in these studies. In the Sensitivity Study, each radiologist was asked to identify and then mark the location of each cancer in the prior exam, if visible. One of the radiologists was also asked to mark the location of the lesion(s) in the current exam. Each radiologist was also asked to make a subjective assessment of whether the lesion in the prior exam would be deemed actionable if the attention of the radiologist is drawn to the location of that lesion. For the Specificity Study, each radiologist compared the results of reading the same set of screening cases with and without use of the MammoReader. For each case, the number of aided readers and the number of unaided readers who considered that case to require recall was calculated.

Final Sample Size & Study Demographics

Sensitivity Study: Two sets of three experienced radiologists participated in this study. All six radiologists were MQSA certified, had an average of 17 (range of 12 to 24) years of experience in mammography, and had read an average of 6,328 (range of 2,078 to 16,000) mammograms in the year prior to the study.

Specificity Study: Ten radiologists affiliated with three different clinical sites participated in this study. The radiologists were MQSA certified, had an average of 10 (range of 1 to 20) years of mammography experience, and had read an average of 2,818 (range of 849 to 7,013) mammograms in the year prior to the study.

Data Collection Methods

Evaluation of mammograms

Outcome Measures

Detection of mammogram lesions (documented with a BI-RADS assessment).

Evaluation Methods

Accuracy of mammogram evaluations with and without the aid of the MammoReader was compared.

Research Results

The studies showed that use of the MammoReader could result in earlier detection, by an average of 14 months in 23 percent of women diagnosed with breast cancer who undergo screening. The system may result in an increase in the patient recall rate estimated at 3 percent (95% confidence interval = 1% to 5%). The recall rate is defined as the percentage of patients who would require additional imaging or biopsy because the radiologist assigned the case a BI-RADS assessment of 0, 4, or 5. This potential increase in recall is offset by the increase in sensitivity that results from the earlier detection of a certain percentage of cancers.

Barriers & Solutions



Product(s) Developed from This Research

M-Reader 2001: The MammoReader is a CAD system designed to detect potential cancer regions in mammogram images by digitizing mammogram films and then processing the resulting digitized images.