# 6011

# Dynamic Optical Breast Imaging: A non-invasive, adjunctive method to detect breast cancer

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## Introduction

It has been established that increased vascularity associated with the growth of malignant lesions (neo-angiogenesis) is inherently different from the vascularity seen in normal healthy tissue. Recent technological developments make it possible to identify and distinguish non-invasively between vascular changes associated with benign and malignant growth in the breast. The DOBI Medical ComfortScan™ system detects one of the differences by evaluating light absorption when a slight external pressure stimulus is applied on the breast over time. As a result of this stimulus, the dynamic behavior of tissue optical properties creates different dynamic signatures for areas of abnormal vascularization relative to those of surrounding normal breast tissue. The potential of the ComfortScan system as a diagnostic tool is to differentiate between specific optical patterns of vascularized and non-vascularized areas (i.e., to differentiate between malignant and benign lesions by the detection of neo-angiogenesis). This provides the physician with additional physiological information on the angiogenic status of a suspicious area.

## Patients and Methods

From March 2003 to January 2004 - as part of a larger prospective international pilot study aimed at developing data acquisition methods and dynamic signature interpretation rules - a total of 105 patients, aged 23-79, scheduled for open biopsies (palpable and non-palpable lesions) were entered into this study from this site. All patients were scanned with the ComfortScan system preoperatively and findings were compared with those of the definite histology report and previous imaging. Approximately 50% of the patients were included in the training phase for the investigating physician.

For the study cases, a blinded reader was requested to interpret each scan as "malignant" or "benign" - no undecided or dubious scores were allowed. The blinded reader was given information regarding the location of the lesion as indicated in the mammography or sonography reports (quadrant and depth) and the age of the patient. A set of standards, compatible with the most recent acquisition hardware and proprietary software, and with the most recent reading application and interpretation rules, was used to filter the database. The data sets with values falling outside these rules were not included in the analysis.

The following standard filter rules applied to exclude some data sets:

- the number of saturated pixels >20;
- light intensity (detected by the CCD camera) <400 counts;
- illuminated area to breast area ratio ≤25%

After application of the filter, the database returned 41 data sets. Of these data sets, 6 were excluded from the analysis due to incomplete documentation.

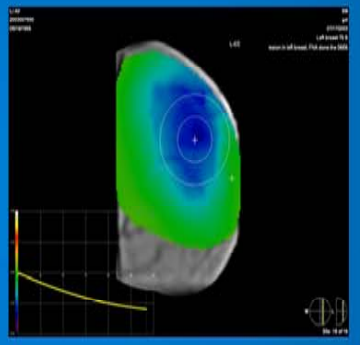
A total of 35 data sets were available for interpretation. Of these scans, 30 were from lesions determined to be malignant by biopsy and 5 were from lesions determined to be benign. (Table 1)

*Table 1*

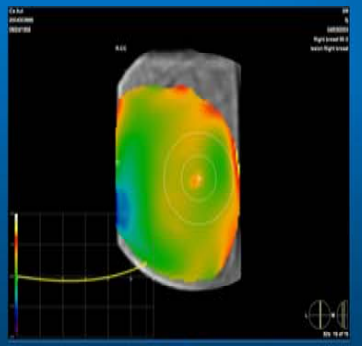
| | |
|---|---|
| **TOTAL DATA SETS** | **105** |
| *Reason for exclusion* | |
| Acquisition error or system malfunction | 28 |
| Over or under illumination | 36 |
| Incomplete documentation | 6 |
| **S/T** | **(70)** |
| **Remaining datasets after filtering** | **35** |

## Results

Calculated sensitivity and specificity to discriminate between malignant and benign lesions were 100% and 80%, respectively. (Table 2)



Case 1
Malignant lesion



Case 2
Benign lesion

*Table 2*

| | |
|---|---|
| **N** | 35 |
| *Biopsy Results* | |
| Malignant | 30 |
| Benign | 5 |
| *Blinded Reader* | |
| Malignant | 31 |
| Benign | 4 |
| *Metrics* | |
| True Positive | 30 |
| True Negative | 4 |
| False Positive | 1 |
| False Negative | - |
| Sensitivity | 100.0% |
| Specificity | 80.0% |
| PPV | 96.8% |
| NPV | 100.0% |

## Conclusion

Results from this selected dataset indicated that the ComfortScan system could be a valuable tool in breast cancer diagnosis when paired with other imaging methods. In addition, the system provides the physician with information obtained through a dynamic, physiological method to distinguish non-invasively between benign and malignant lesions, which may avoid unnecessary interventions. Further studies are needed to support these data.

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