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**13. ABSTRACT** *(Maximum 200 Words)*

The imaging technology of Dynamic Functional Optical Mammoscopy (DFOM) has been used to scan patients scheduled for biopsy of breast lesions. These patients were scheduled for core or excisional breast biopsy on the basis of equivocal mammographic and ancillary clinical findings within ACR BI-RADS™ categories 3 or 4. Analysis of test results of 47 patients shows that the DFOM detected cancer in nine of the 11 patients in whom biopsies confirmed malignant lesions giving a sensitivity of 82%. DFOM also correctly identified 24 of 36 benign lesions giving a specificity of 67%. In clinical practice, the adjunctive use of DFOM would have decreased the percentage of biopsies that turn out to be benign from 36/47 (77%) to 12/47 (26%). The negative predictive value, the chance that a negative DFOM result truly indicates a benign lesion, was 24/26 (92%).

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# Introduction

The imaging technology of Dynamic Functional Optical Mammoscopy (DFOM) is a breast scan based upon transmission/absorption of infrared light, which measures the dynamic patterns of breast reactivity of various physiological states in response to soft pressure. DFOM produces a functional rather than a morphological image and the dynamic pattern of tissue reactivity after mild compression is charted. Pilot study results suggested that this innovative DFOM imaging technique has the potential to determine which of the mammographically and clinically indeterminate lesions are benign vs. carcinoma and distinguish those lesions thereby avoiding biopsy. The purpose of the study reported here is to extend the preliminary results of the pilot study at Columbia Presbyterian Medical Center, using DFOM between mammography and biopsy to further evaluate the efficacy of DFOM in evaluation of breast lesions, using biopsy results to confirm diagnosis.

# Body

A total of 117 patients scheduled for biopsy were scanned with the identical protocol between June 1, 2000 and September 30, 2000. The study was performed on women scheduled for core or excisional breast biopsy on the basis of equivocal mammographic and ancillary clinical findings within ACR BI-RADS™ categories 3 or 4. Women who met the selection criteria were enrolled from the normal caseload from both screening and diagnostic mammography. Each woman signed an informed consent prior to being scanned.

The scan procedure required approximately 5 minutes. During examination, the breast was placed in the soft breast holder of the system. The breast was then softly compressed by a thin transparent silicone rubber membrane using an applied pressure of approximately 10 mm Hg. For each scan, the breast was symmetrically centered on the illuminator. When the breast was correctly positioned, illumination adjustment and image recording took place following the requirements of the pressure profile.

Optical illumination was provided by an array of red light emitting diodes (LEDs) attached to the bottom surface of the soft breast holder. Light transmitted through the breast was recorded as a temporal sequence for approximately 30 seconds by a highly sensitive digital CCD camera. The image sequences were accumulated in digital memory and processed by proprietary software to accentuate differences in the temporal variations of intensity between normal/benign and malignant tissue.

Each woman was scanned by a trained technologist prior to biopsy. The scans were read by an experienced reader trained in interpreting the scans. Results were reported as either a recommendation for biopsy or a recommendation that the woman be sent to interval follow-up.

Recommendations on the basis of DOFM were compared to pathology reports of malignant or benign which were used as the gold standard. Sensitivity, specificity, and negative predictive value were calculated.

Table 1 gives the patient accounting for the 117 patients reported on during this period.

**TABLE 1 – Patients Scanned June 1 – September 30, 2000**

| | |
|---|---|
| Excluded patients* | = 40 |
| Unacceptable scans** | = 20 |
| Scans to be interpreted | = 10 |
| Interpreted scans | = 47 |
| | |
| Total scans performed | = 117 |

*Patients who did into meet the selection criteria for the development study protocol.
**Patients whose scans were not acceptable to be interpreted.

Table 2 presents the reasons for scans determined to be unacceptable.

| TABLE 2 – Unacceptable Scans | |
|---|---|
| Lesion sub areolar or located where it cannot be properly illuminated | = 5 |
| Inadequate illumination in area of pathology | = 6 |
| Device related | = 4 |
| Incorrect illumination | = 2 |
| Not enough breast tissue in holder | = 2 |
| Excessive patient movement | = 1 |
| | |
| Total | = 20 |

Below, Table 3 lists reasons for excluding from our study selected patients.

| TABLE 3 – Excluded Patients | |
|---|---|
| Lesion sub areolar or located where it cannot be properly illuminated | = 12 |
| Previous surgery in ipsilateral breast | = 9 |
| BI-RADs 5 lesion | = 4 |
| Post-menopausal with palpable lesoin | = 3 |
| Relevant record(s) not available oat site of review | = 2 |
| Small breast that could not be properly positioned | = 2 |
| Patient could not remain still | = 1 |
| Biopsy of ipsilateral breast within 3 months | = 1 |
| Biopsy to be performed at another facility | = 1 |
| Not recorded | = 5 |
| | |
| Total | = 40 |

Table 4 presents patient demographics of race and age.

**TABLE 4 – Patient Demographics**

| Race | |
|---|---|
| White | = 58 |
| African American | = 5 |
| Hispanic White | = 34 |
| Hispanic Black | = 16 |
| Asian | = 2 |
| Other | = 2 |
| | |
| Total | = 117 |

AGE: Average = 56
Range = 35-82

Table 5 presents the results of scan interpretation.

**TABLE 5 – Results of 47 Patients Scheduled for Biopsy**

| | | Pathology | | |
|---|---|---|---|---|
| | | Malignant | Benign | Total |
| **DFOM Recommendation** | Biopsy | 9 | 12 | 21 |
| | Interval Follow-Up | 2 | 24 | 26 |
| | Total | 11 | 36 | 47 |

Sensitivity: 9/11 (82%)
Specificity: 24/36 (67%)
Negative Predictive Value (NPV): 24/26 (92%)

The analysis of test results on the 47 patients with interpreted scans shows that the DFOM detected cancer in 9 of the 11 patients in whom biopsies confirmed malignant lesions ("true positives"). This results in a sensitivity of 82%. The system also correctly identified 24 of 36 benign lesions ("true negatives"). In other words, the specificity of the DFOM is 24/36 (67%).

## Key Research Accomplishments

Below we summarize our accomplishments in the context of the original Statement of Work, as described in the proposal.

**TASK 1. Develop substructure for implementing study (months 1-3).**

(a) Obtained Institutional Review Board (IRB) Approval, including patient consent form.

(b) Trained three consecutive research associates in protocol and procedures:
Patricia Ogiliva 11/30/98 – 6/3/99,
Homyra Hadavand 6/14/99 – 11/30/99 and
Behnaz Mesbah 12/13/99 – 8/31/01.

(c) Develop database program to enable data entry and to allow compilation of results.

**TASK 2. Develop a database of DFOM dynamic imges and signatures of various pathologic lesions (months 3-34).**

(a) Recruited patients undergoing evaluation of lesions to have DFOM scan prior to tissue sampling or biopsy.

(b) Correlated DFOM information evaluated for acquired dynamic images and signature types with pathologic lesion by type, grade (Bi-Rads scale) and size. Compared appearance with parenchymal density.

**TASK 4. Interim analyses (months 12-26).**

(a) Interim analysis has been presented in this report for the fist phase of the study, and is currently being collected for analysis in the next annual report.

## Reportable Outcomes

The effectiveness of the DFOM in discriminating between benign and malignant breast lesions has been further evaluated and the preliminary results have been corroborated.

## Conclusions

While the number of patients reported on is small, the indications of effectiveness are very encouraging. The results reported above indicate that the adjunctive use of the DOFM in clinical practice would have decreased the percentage of biopsies that turn out to be benign from 36/47 (77%) to 12/47 (26%). The negative predictive value, the chance that a negative DFOM result truly indicates a benign lesion, is 24/26 (92%).

Thus, we are encouraged by these early findings. We will continue to accrue patients and analysis data during the next phase.

## References

None.

## Appendices

Summary Tables of Scanned Patients - First Year of Study

CPMC

| | Patient ID | Protocol | Press. P | Acceptable | Blind | Adjunct | BiRads | Unblind | Biopsy | S.conf |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 19980915A-L | post-biopsy | E | NO - NC | | | | | | y |
| 2 | 19980915A-R | post-biopsy | E | NO - NC | | | | | | y |
| 3 | 19981001A R | 8408 | E | YES | | | 3 | TN | FA + FC, non-proliferative | y |
| 4 | 19981001B L | 8408 | E | YES | | | 1 | TN | Focal fibrosis, focal fibrocytic chg | y |
| 5 | 19981005A R | 8408 | E | YES | | | 3 | TN | microfibroadenoma | y |
| 6 | 19981008A R | 8408 | D | YES | | | 3 | TN | FC, epithelial hyperplasia, f. atypia | y |
| 7 | 19981013A L | 8408 | D | YES | | | 4 | TP | DCIS, multifocal, cribif. NG2-S0 | y |
| 8 | 19981013B R | 8408 | D | YES | | | 4 | TN | FC, non-proliferative | y |
| 9 | 19981014A L | 8408 | E | YES | | | 4 | TN | FC with microcalcifications | y |
| 10 | 19981022A L | 8408 | E | NO - NB | | | | | | |
| 11 | 19981023A | volunteer | G1 | NO - NC | | | | | | |
| 12 | 19981023B L | 8408 | E | YES | TP | TP | 5 | TP | mxd:DCIS, ID, lobular SIII | y |
| 13 | 19981028A L | 8408 | H | YES | TN | TN | 4 | TN | FC | y |
| 14 | 19981110A L | post-biopsy | H | NO - NC | | | | | | |
| 15 | 19981110B | volunteer | H | NO - NC | | | | | | |
| 16 | 19981124A L | 8408 | H | YES | FN | TP | 5 | TP | ID and in situ ductal carcinoma | y |
| 17 | 19981124B L | 8408 | H | YES | TN | TN | 3 | TN | FC, FA | y |
| 18 | 19981125A L | 8408 | G1 | YES | TN | TN | 3 | TN | FC, proliferative , no atypia | y |
| 19 | 19981125B R | 8408 | G1 | YES | TN | TN | 3 | TN | FF, FC, Intraductal papilloma | y |
| 20 | 19981130A | 8408 | G1 | PENDING | | | | | *fna only….* | |
| 21 | 19981130B - L-SAR | 8408 | G1 | PENDING | | | | | *just had biopsy (5-21-99)* | |
| 22 | 19981201A R | 8408 | G1 | YES | TP | TP | 4 | TP | DCIS+FC (proliferative. +atypia | y |
| 23 | 19981202A L | 8408 | G1 | YES | TN | TN | 2 | TN | FF, aprocrine cyst | y |
| 24 | 19981202A-R | 8408 | G1 | YES | INDET. | FP | 2 | FP | FF, lobular hyperplasia, adenosis | y |
| 25 | 19981202B L | 8408 | G1 | YES | FN | FN | 5 | FN | Invasive ductal +focal DCIS | y |
| 26 | 19981202B-R | 8408 | G1 | YES | FP | FP | 3 | FP | FF, epithelial hyperplasia | y |
| 27 | 19981207A R | 8408 | G1 | YES | TN | TN | 3-4A | TN | FC+FAH | y |
| 28 | 19981207B R | 8408 | G1 | YES | TN | TN | 3 | TN | Adenosis, fibrosis | y |
| 29 | 19981209A L | 8408 | G1 | YES | TN | TN | 3 | TN | FC, FF | y |
| 30 | 19981209B L | 8408 | G1 | YES | TN | TN | 2 | TN | FD, Intraductal papilloma | y |
| 31 | 19981216A L | 8408 | G1 | YES | INDET. | FN | 5 | TP | ID G2-3 focal tubular features. | y |
| 32 | 19981221A | 8408 | G1 | YES | TN | TN | 3 | TN | FC + microcalc. | y |
| 33 | 19981223A L | 8408 | G1 | YES | TN | TN | 3 | TN | FC | y |
| 34 | 19990104A R | 8408 | G1 | NO-WP | | | | | | y |
| 35 | 19990104B L | 8408 | G1 | YES | TN | TN | 3 | TN | FC | y |
| 36 | 19990106A R | 8408 | S3 | YES | TN | TN | 3 | TN | FA, FC, FF, | y |
| 37 | 19990106B R | 8408 | S2 | YES | TN | TN | 4A | TN | FF+OSCIFICATION | y |
| 38 | 19990106C L | 8408 | G1 | YES | TP | TP | 5 | TP | ID (NOS) poorly differentiated | y |
| 39 | 19990111A L | 8408 | G1 | YES | TN | TN | 3 | TN | FC | y |
| CP | Patient ID | Protocol | Press. P | Acceptable | Blind | Adjunct | BiRads | Unblind | Biopsy | S. conf |

| 40 | 19990111B R | 8408 | S3 | YES | TN | TN | 3 | TN | Adenosis | y |
|---|---|---|---|---|---|---|---|---|---|---|
| 41 | 19990112A L | 8408 | G1 | NO - WP | | | | | | y |
| 42 | 19990113A | 8408 | G1 | NO - WP | | | | | | |
| 43 | 19990113B- - L-TRE | vol-infl.ca | LS6-RS4 | NO - NC | | | | | | |
| 44 | 19990120A | 8408 | Not compl | NO - IP | | | | | | |
| 45 | 19990120B L | 8408 | G1 | NO - WP | | | | | | y |
| 46 | 19990121A R | 8408 | G1 | YES | TN | TN | 4 | TN | FC | y |
| 47 | 19990121B R | 8408 | G1 | NO - WP | | | | | | y |
| 48 | 19990121C | 8408 | LS1-RS1 | PENDING | | | | | *cancelled biopsy only F/U in 6 mths* | |
| 49 | 19990122A L | 8408 | S4 | YES | INDET | TN | 3 | TN | FC | y |
| 50 | 19990122A-R | 8408 | G1 | YES | TN | TN | 3 | TN | FC | y |
| 51 | 19990125A | 8408 | LS2-RS2 | PENDING | | | | | | |
| 52 | 19990127A R | 8408 | | YES | TN | TN | 3 | TN | Fibroadenoma | y |
| 53 | 19990127B L | 8408 | G1 | YES | FP | FP | 4A | FP | FC+LS in one lobule | y |
| 54 | 19990128A R | 8408 | G1 | YES | FN | FN | 5 | FN | FA+DCIS (4mm) | y |
| 55 | 19990201A L | 8408 | EUG | NO - EUG | | | | | | |
| 56 | 19990203A R | 8408 | G1 | NO - WP | | | | | | |
| 57 | 19990203B - H-MAL | 8408 | EUG | NO - EUG | | | | | | |
| 58 | 19990203C R | 8408 | G1 | YES | TN | TN | 3 | TN | SA | y |
| 59 | 19990204A R | 8408 | EUG | NO - EUG | | | | | | |
| 60 | 19990204B R | 8408 | G1 | YES | FP | FP | 3 | FP | FC | y |
| 61 | 19990208A L | 8408 | EUG | NO | | | | | | |
| 62 | 19990209A L | 8408 | G1 | YES | FN | TP | 5 | TP | DCIS | y |
| 63 | 1990209B | 8408 | | PENDING | | | | | *cancelled biopsy only F/U in 6 mths* | |
| 64 | 19990209C L | 8408 | S3 | YES | INDET | FP | 4 | FP | FF + PT | y |
| 65 | 19990209D R | 8408 | EUG | NO - EUG | | | | | | |
| 66 | 19990210A L | 8408 | EUG | NO - EUG | | | | | | |
| 67 | 19990210B-R - I-KAT | 8408 | G1 | YES | TP | TP | 4A | TP | ID | y |
| 68 | 19990210C L | 8408 | EUG | NO - EUG | | | | | | y |
| 69 | 19990216A R | 8408 | G1 | NO - WP | | | | | | y |
| 70 | 19990217A R | 8408 | S2 | YES | TN | TN | 4 | TN | FA (4mm) | y |
| 71 | 19990218A-R - M-HAL | 8408 | S6 | NO-WP | | | | | | y |
| 72 | 19990222A-L - L-SAN | 8408 | EUG | NO-EUG | | | | | | |
| 73 | 19990222B-L - G-BLU | 8408 | S2 | NO-WP-WI | | | | | | y |
| 74 | 19990223A-L - A-ROG | 8408 | S2 | YES | FP | FP | 3 | FP | FF | y |
| 75 | 19990223B-L | 8408 | S3 | YES | INDET | TP | 4 | TP | Invasive ductal with tubular featues | Y |
| 76 | 19990224A-R - L-ALB | 8408 | EUG3 | NO - EUG | | | | | | y |
| 77 | 19990225A-L - M-HAR | 8408 | E1 | NO - WP,WI | | | | | | y |
| 78 | 19990301A-R - B-UBI | 8408 | S2 | YES | TN | TN | 3,4 | TN | Lactacional activity+microcals | y |
| 79 | 19990301B-L - A-MOR | 8408 | S2 | NO-WP-WI | | | | | | y |
| **CP** | **Patient ID** | **Protocol** | **Press. P** | **Acceptable** | **Blind** | **Adjunct** | **BiRads** | **Unblind** | **Biopsy** | **S. conf** |
| 80 | 19990302A-R - C-COL | 8408 | G1 | YES | FN | FN | 5 | FN | ID | |

| 81 | 19990302B R | 8408 | G1 | YES | TN | TN | 3 | TN | FF | y |
|---|---|---|---|---|---|---|---|---|---|---|
| 82 | 19990302C-L - M-TOR | 8408 | S4 | YES | TN | TN | 4A | TN | CD+focal atypia+microc+vasculitis sm. Vessels | |
| 83 | 19990302D-R - E-WEI | 8408 | G1 | YES | TN | TN | 4A | TN | FC+ALH+ADH+DH | |
| 84 | 19990303A-L - G-JOH | 8408 | S3 | YES | INDET | FP | 4A | FP | ADH+FC(prolif)+microc | y |
| 85 | 19990303B-L - E-SIL | 8408 | G1 | YES | TN | TN | 3 | TN | Duct dilation with microcal. | y |
| 86 | 19990309A-R - E-KAS | 8408 | S3 | YES | TN | TN | 4A | TN | FA | y |
| 87 | 19990312A - R-PEN | | | PENDING | | | | | | |
| 88 | 19990312B-R - A-PEG | 8408 | S2 | YES | TN | TN | 3,4 | TN | FC+FF+microcal. | y |
| 89 | 19990316A-R - M-BRU | 8408 | G1 | YES | FP | FP | 3 | FP | FF+FC+AD+DH | y |
| 90 | 19990316B-R - M-MCG | 8408 | G1 | YES | TN | TN | 4A - 4B | TN | RS, SA, FA | y |
| 91 | 19990323A | | | PENDING | | | | | | |
| 92 | 19990324A-R - L-LES | 8408 | S3 | YES | TN | TN | 4A | TN | CD | y |
| 93 | 19990325A-L | 8408 | | YES | | FN | | | | |
| 94 | 19990325B-R | 8408 | | YES | | TN | | | | |
| 95 | 19990325C | | | PENDING | | | | | | |
| 96 | 19990326A | | | PENDING | | | | | | |
| 97 | 19990329A-L - G-DAV | 8408 | 805 | YES | INDET | NS | 4A | NS | FC+microcal+sclerosed papilloma | |
| 98 | 19990330A-R - A-FRA | 8408 | 805 | YES | INDET | INDET | 4A | INDET | DE+FC+FF+microcal.+FA | y |
| 99 | 19990330B-R | 8408 | | YES | | YN | | | | |
| 100 | 19990401A-R - B-KIN | 8408 | G1 | YES | FP | FP | 4 | FP | FF+FC | |
| 101 | 19990401B-R - A-CHO | 8408 | G1 | NO-MV | | | | | | y |
| CP | | | | | | | | | | |
| 102 | 19990405A-R - S-LOV | 8408 | S3 | YES | INDET | TN | 3 | TN | FF+FC | |
| 103 | 19990406A-R - C-TES | 8408 | s2 | YES | NS | INDET | 5 | INDET? | DS | |
| 104 | 19990406B-L - W-FOG | 8408 | G1 | YES | FP | FP | 4A | FP | DE+FA+microc. | y |
| 105 | 19990406C-L - A-WHI | 8408 | S3 | NO-WI | | | | | | y |
| 106 | 19990407A-R - P-MOU | 8408 | G1 | YES | TN | TN | 4B | TN | FC non-proliferative | |
| 107 | 19990412A-R - P-LAF | 8408 | G1 | PENDING | | | | | awaiting cc location of lesion | |
| 108 | 19990412B | | | PENDING | | | | | | |
| 109 | 19990413A | | | PENDING | | | | | | |
| 110 | 19990416A- -K-ATH | 8408 | | PENDING | | | | | | |
| 111 | 19990419A | | | PENDING | | | | | | |
| 112 | 19990421A-L - M-DIA | 8408 | S5 | YES | TN PR | TN PR | 4A | FP | SA+microc. | |
| 113 | 19990421B-R - S-COR | 8408 | G1 | YES | FP | FP | 4A | FP | FC+FA+SA | |
| 114 | 19990422A-L - E-WEI | 8408 | G1 | YES | TN | TN | 4A | TN | FN | |
| 115 | 19990422B-L - R-RIC | 8408 | S3 | YES | TN | TN | US | TN | FA | Y |
| 116 | 19990426A | | | PENDING | | | | | | |
| 117 | 19990426B | | | PENDING | | | | | | |
| 118 | 19990427A-R - A-AAR | 8408 | S3 | YES | NS | FN | 5 | | DCIS+ID | |
| **CP** | **Patient ID** | **Protocol** | **Press. P** | **Acceptable** | **Blind** | **Adjunct** | **BiRads** | **Unblind** | **Biopsy** | **S. conf** |
| 119 | 19990427B-R - NO-UTT | 8408 | G1 | YES | TN | TN | 4A | TN | FA+FC+LS+microcal | |
| 120 | 19990428A | | | PENDING | | | | | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 121 | 19990428B | | | PENDING | | | | | | |
| 122 | 19990503A | | | PENDING | | | | | | |
| 123 | 19990504A | | | PENDING | | | | | | |
| 124 | 19990506A | | | PENDING | | | | | | |
| 125 | 19990506B - L-SAR | 1130B+C37 | | PENDING | | | | | | |
| 126 | 19990510A | | | PENDING | | | | | | |
| 127 | 19990510B | | | PENDING | | | | | | |
| 128 | 19990511A | | | PENDING | | | | | | |
| 129 | 19990511B | | | PENDING | | | | | | |
| 130 | 19990512A | | | PENDING | | | | | | |
| 131 | 19990513A | | | PENDING | | | | | | |
| 132 | 19990514A | | | | | | | | | |
| 133 | 19990514B | | | PENDING | | | | | | |
| 134 | 19990517A | | | PENDING | | | | | | |
| 135 | 19990518A | | | PENDING | | | | | | |
| 136 | 19990518B | | | PENDING | | | | | | |
| 137 | 19990519A | | | PENDING | | | | | | |
| 138 | 19990519B | | | PENDING | | | | | | |
| 139 | 19990520A | | | PENDING | | | | | | |
| 140 | 19990520B | | | PENDING | | | | | | |
| 141 | 19990524A | | | PENDING | | | | | | |
| 142 | 19990525A-L - I-REY | 8408 | S2 | YES | TN | TN | 3 | TN | FA | |
| 143 | 19990527A-R | 8408 | | YES | | TN | | | | |
| 144 | 19990527B-L | 8408 | | NO-MV | | | | | | |
| 145 | 19990527C-R | 8408 | | NO-MV | | | | | | |
| 146 | 19990601A | | | PENDING | | | | | | |
| 147 | 19990602A | | | PENDING | | | | | | |
| 148 | 19990603A | | | PENDING | | | | | | |
| 149 | 19990603B | | | PENDING | | | | | | |
| 150 | 19990603C - VOL | | | PENDING | | | | | | |
| 151 | 19990615A | | | PENDING | | | | | | |
| 152 | 19990615B-L - D-MES | 8408 | G1 | YES | TN | TN | 4A | TN | Intraductal papilloma | |
| 153 | 19990616A-R - M-TAV | 8408 | G1 | YES | ~~TN~~ FP | ~~TN~~ FP | 3 | FP | FC+microcal | |
| 154 | 19990616B-L - M-IZS | 8408 | G1 | YES | TP | TP | 4B | TP | DC+ID | |
| 155 | 19990617A | | | | | | | | | |
| 156 | 19990621A | | | | | | | | | |
| 157 | 19990621B | | | | | | | | | |
| 158 | 19990621C | | | | | | | | | |
| **CP** | **Patient ID** | **Protocol** | **Press. P** | **Acceptable** | **Blind** | **Adjunct** | **BiRads** | **Unblind** | **Biopsy** | **S. conf** |
| 159 | 19990623A-L - R-NIV | 8408 | G1 | YES | TN | TN | 4A | TN | FC | |
| 160 | 19990623B-R - NO-BUC | 8408 | G1 | YES | FP | FP | 4A | FP | FC | |
| 161 | 19990625A | | | NO-VOLUNT | | | | | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 162 | 19990625B | | | NO-VOLUNT | | | | | | |
| CO | | | | | | | | | | |
| 163 | | | | | | | | | | |
| 164 | | | | | | | | | | |
| 165 | | | | | | | | | | |
| 166 | | | | | | | | | | |
| 167 | | | | | | | | | | |
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| | | | | | | | | | | |

| COLUMBIA | | | | | | |
|---|---|---|---|---|---|---|
| Scan Tracking | | | | | | |
| ID | EXCLUDED | ACCEPT | PATHOLOGY | AGE | RACE | INTERPRETATION |
| June-00 | | | | | | |
| 06-01A | 11 | 99 | Benign | 61 | HW | |
| 06-01C | 11 | 99 | Benign | 35 | HB | |
| 06-05A | 0 | 0 | Benign | 61 | HW | TN |
| 06-05B | 0 | 26 | Benign | 66 | HW | |
| 06-07A | 0 | 0 | Benign | 71 | W | TN |
| 06-07B | 11 | 99 | Benign | 35 | HB | |
| 06-07C | 26 | 99 | NK | | AA | |
| 06-08A | 8 | 99 | Benign | 52 | W | |
| 06-08B | 0 | 0 | Benign | 50 | HW | TN |
| 06-08C | 0 | 27 | Benign | 64 | W | |
| 06-08D | 0 | 30 | Benign | | W | |
| 06-08E | 0 | 26 | Malignant | | HW | |
| 06-12A | 0 | 0 | Benign | 49 | W | TN |
| 06-12B | 0 | 0 | Benign | 56 | HW | TN |
| 06-13A L | 0 | 0 | Benign | 40 | HW | TN |
| 06-13B R | 0 | 0 | Benign | 40 | HW | TN |
| 06-14B | 0 | 0 | Benign | 63 | HW | FP |
| 06-15A | 26 | 99 | NK | | HB | |
| 06-19A | 2 | 99 | Benign | 39 | HW | |
| 06-20A | | | | | AA | |
| 06-21A | 0 | 0 | Malignant | 44 | HW | TP |
| 06-22A | 0 | 0 | Benign | 82 | W | TN |
| 06-22B | 0 | 0 | Benign | 48 | HB | FP |
| 06-27A | 0 | 26 | Benign | 64 | W | |
| 06-27B | | | | | HW | |
| 06-28A | 0 | 0 | Benign | 52 | HW | FP |
| 06-29A | 6 | 99 | Malignant | | W | |
| 06-29B | 0 | 0 | Benign | 50 | HW | TN |
| | | | | | | |
| JUNE TOTALS: | | | | | | |
| TOTAL SCANS: | | | | | | |
| ACCEPTABLES | | (12 benign/1 malignant) | | | | |
| UNACCEPTABLES | | | | | | |
| EXCLUDED PTS | | | | | | |
| TBI | | | | | | |

| July-00 | | | | | | |
|---|---|---|---|---|---|---|
| 07-03A | 6 | 99 | Benign | 46 | W | |
| 07-05A | 22 | 99 | NK | | W | |
| 07-05B | 19 | 99 | NK | 68 | HB | |
| 07-05C | 0 | 17 | Benign | 59 | W | |
| 07-06A L | 0 | 0 | Benign | 65 | HW | FP |
| 07-06A R | 0 | 0 | Benign | 65 | HW | TN |
| 07-11A | 0 | 17 | Benign | 37 | W | |
| 07-11B | 11 | 99 | Benign | 57 | W | |
| 07-13A | 0 | 21 | Malignant | 54 | W | |
| 07-13C | 11 | 99 | Benign | 38 | OTHER | |
| 07-17A | 12 | 99 | NK | | W | |
| 07-17B | 1 | 99 | Benign | 43 | HW | |
| 07-17C | 0 | 11 | Malignant | 46 | HB | |
| 07-18A L | 0 | 10,11 | Benign | 49 | W | |
| 07-18B R | 0 | 10,11 | Benign | 49 | W | |
| 07-24A | 0 | 11 | Benign | 38 | W | |
| 07-24B | | | | 61 | W | |
| 07-26A | 0 | 11 | Benign | 73 | OTHER | |
| 07-27B | 6 | 99 | Malignant | 81 | AA | |
| 07-28A | 0 | 0 | Benign | 57 | W | TN |
| 07-31A | 6 | 99 | Malignant | 66 | W | |
| | | | | | | |
| JULY TOTALS: | | | | | | |
| TOTAL SCANS: | | | | | | |
| ACCEPTABLES | | 3 benign | | | | |
| UNACCEPTABLES | | | | | | |
| EXCLUDED PTS | | | | | | |
| TBI | | | | | | |

| August-00 | | | | | | |
|---|---|---|---|---|---|---|
| 08-01A | 1 | 99 | Malignant | 64 | W | |
| 08-01C | 11 | 99 | NK | 51 | W | |
| 08-01D | 0 | 0 | Benign | 53 | W | FP |
| 08-02A | 0 | 0 | Benign | 69 | HW | TN |
| 08-02B | 0 | 0 | Malignant | 46 | W | TP |
| 08-02C | 0 | 0 | Benign | 44 | HB | FP |
| 08-04A | 0 | 21 | Benign | 40 | HB | |
| 08-09A | 26 | 99 | Benign | 36 | W | |
| 08-09B | 1 | 99 | Malignant | 76 | W | |
| 08-09C | 0 | 0 | Benign | 54 | HW | TN |
| 08-10A | 0 | 0 | Malignant | 63 | W | TP |
| 08-10B L | 0 | 13 | Benign | 55 | W | |
| 08-10C R | 6 | 99 | Benign | 55 | W | |
| 08-14A | 0 | 0 | Benign | 48 | W | TN |
| 08-14B | | | | | HB | |
| 08-15A | 0 | 0 | Benign | 50 | AA | TN |
| 08-15B | 0 | 0 | Benign | 55 | W | FP |
| 08-16A | 11 | 99 | Benign | 36 | HB | |
| 08-17A | 1 | 99 | Malignant | 63 | W | |
| 08-17B | 0 | 0 | Malignant | 68 | W | TP |
| 08-21A | 0 | 0 | Benign | 48 | HW | TN |
| 08-21B | 10 | 99 | Atypia | 49 | ASIAN | |
| 08-21C | | | | | W | |
| 08-21D | | | | 80 | HB | |
| 08-21E | 0 | 21 | Benign | 60 | W | |
| 08-23A | 4 | 99 | Malignant | 68 | HW | |
| 08-28A | 11 | 99 | Benign | 69 | W | |
| 08-29A | 3 | 99 | Benign | 51 | W | |
| 08-29B | 0 | 0 | Benign | 43 | W | TN |
| 08-29C | 0 | 0 | Benign | 49 | HW | TN |
| 08-31A | 0 | 0 | Benign | 61 | HW | TN |
| 08-31B | 0 | 0 | Benign | 51 | W | TN |
| 08-31C | 2 | 99 | Benign | 40 | HW | |
| 08-31D | 0 | 0 | Malignant | 82 | HB | TP |
| 08-31E | 11 | 99 | Benign | 40 | HW | |
| 08-31F | 6 | 99 | Malignant | 54 | HW | |
| 08-31G | 0 | 21 | Benign | 42 | HW | |
| 08-31H | 4 | 99 | Benign | 47 | W | |
| | | | | | | |
| AUGUST TOTALS: | | | | | | |
| TOTAL SCANS: | | | | | | |
| ACCEPTABLES | | (12/4) | | | | |
| UNACCEPTABLES | | | | | | |
| EXCLUDED PTS | | | | | | |
| TBI | | | | | | |

| September-00 | | | | | | |
|---|---|---|---|---|---|---|
| 09-05A | 4 | 99 | Malignant | 80 | W | TN |
| 09-05B | 0 | 0 | Benign | 52 | W | TN |
| 09-05C | 0 | 0 | Benign | 60 | W | |
| 09-05D | 11 | 99 | NK | 45 | HB | |
| 09-06A | 6 | 99 | Benign | 79 | W | |
| 09-06B | 0 | 0 | Benign | 43 | W | FP |
| 09-07A | 0 | 0 | Malignant | 74 | HW | TP |
| 09-07B | 0 | 21 | Benign | 69 | AA | |
| 09-11A | 0 | 0 | Benign | 54 | ASIAN | TN |
| 09-11B | 0 | 0 | Malignant | 68 | HW | TP |
| 09-11C | 0 | 0 | Benign | 70 | W | TN |
| 09-13A | | | | | HW | |
| 09-13B | | | | | HW | |
| 09-14A | 0 | 0 | Malignant | 48 | W | TP |
| 09-14B | 0 | 21 | Malignant | 50 | W | |
| 09-14C | 7 | 99 | Benign | | W | |
| 09-14E | 0 | 0 | Benign | 46 | HW | FP |
| 09-14F(8) | 4 | 99 | Benign | 42 | HB | |
| 09-18A | 0 | 0 | Malignant | 80 | W | FN |
| 09-18B | 0 | 0 | Benign | 42 | HB | FP |
| 09-19A | 6 | 99 | Malignant | 74 | W | |
| 09-19B | | | | | HW | |
| 09-20A | 0 | 0 | Malignant | 67 | W | TP |
| 09-20B | | | | | W | |
| 09-20C | 0 | 0 | Malignant | 75 | W | FN |
| 09-21A | 0 | 0 | Benign | 63 | HB | FP |
| 09-21B | 0 | 16 | Benign | 51 | W | |
| 09-25A | 11 | 99 | Benign | 45 | W | |
| 09-28A | 11 | 99 | Benign | 56 | W | |
| 09-28B | 0 | 0 | Benign | 57 | HW | FP |
| | | | | | | |
| SEPTEMBER TOTALS: | | | | | | |
| TOTAL SCANS: | | | | | | |
| ACCEPTABLES | | (9/6) | | | | |
| UNACCEPTABLES | | | | | | |
| EXCLUDED PTS | | | | | | |
| TBI | | | | | | |
| | | | | | | |
| OVERALL TOTALS | | | | | | |
| TOTAL SCANS: | | 117 | | | | |
| ACCEPTABLES | | 47(36 benign/11 malignant) | | | | |
| UNACCEPTABLES | | 20 | | | | |
| EXCLUDED PTS | | 40 | | | | |
| TBI | TBI | 10 | | | | |
| | AVERAGE AGE | 55.68 | | | | |

## PATIENT SCREENING EXCLUSION CODES

CLINICAL

01 Outside of BI-RADS categories 3 and 4
02 Not all records available at site for review
03 Biopsy at another facility
04 Post-menopausal with a palpable lesion
05 Pregnant or lactating
06 Breast surgery in ipsilateral breast
07 Biopsy of ipsilateral breast (core or excisional) within past three months
08 Surgical clips or scarring in or on ipsilateral breast
09 Patient refused consent.

IMAGING

10 Small breasts that, in the judgment of the technologist, cannot be properly positioned
11 Lesion is subareolar or located where it cannot be properly illuminated (e.g. lesions visible on MLO view that *cannot also* be visualized on the CC view)
12 Patient unable to stand still

## CODES FOR UNACCEPTABLE SCANS

BREAST POSITIONING:

13 Breast too small
14 Soft holder not closed properly
15 Non-symmetrical positioning
16 Not enough breast tissue in holder

ILLUMINATION

17 Size of illumination too small
18 Size of illumination too large
19 Intensity too high
20 Intensity too low
21 Inadequate illumination in area of pathology
22 Ambient light leakage

DEVICE RELATED

23 Computer error
24 Air leakage
25 Other error: Copy error message number from screen
26 Other Device Related: Describe

PATIENT RELATED

27 Excessive patient movement
28 Patient complaint/refusal after scan has started
29 Other Patient Related: Describe

OTHER

30 Other: Describe