# How to Follow the Cancer Risk of Women with Breast Implants

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## Abstract

**Background:** Breast implants are now recognized to be associated with a variety of potential problems, including inflammatory changes – both locally and systemically–precancerous and cancerous changes. Monitoring these changes are particularly problematic in the face of breast implants. Molecular breast imaging (MBI) using FMTVDM\* provides a unique method for measuring changes in breast tissue in these individuals. This study examines that potential.

**Methods:** Eighteen breast implants were evaluated in women who had undergone implantation for a variety of reasons. These women underwent measurement of regional blood flow (RBF) and metabolism differences to determine the extent of inflammation, precancerous and cancerous changes.

**Results:** Measured changes in RBF and metabolism were not influenced by breast implants. Among the 18 breast implant studies; there were 4 instances of inflammation (22%), 5 (28%) instances of precancerous changes and 1 (5%) instance of breast cancer.

**Conclusions:** MBI using FMTVDM provides a non-invasive ability to measure changes in breast tissue in women who have undergone breast implantation. The measured monitoring of these changes allows clinicians a tool to make clinical decisions regarding either the need to remove the breast implant or provide alternative treatment options.

**Keywords:** FMTVDM; Breast Cancer; Inflammation; Breast Implants

**Abbreviations:** FMTVDM: The Fleming Method for Tissue and Vascular Differentiation and Metabolism

## Introduction

The risk of inflammatory changes, potential autoimmune diseases and breast cancer in women with breast implants are now well recognized [1-6]. Given the prevalence of breast implants and the likelihood that they will not become a thing of the past, it is important that clinicians be able to monitor the overall health of the women and men with breast implants by measuring changes in breast health [7-9]. This study investigated the prevalence of inflammatory changes in women with breast implants and monitored those changes by measuring metabolic and Regional Blood Flow (RBF) differences associated with inflammatory and cancerous breast changes using The Fleming Method for Tissue and Vascular Differentiation and Metabolism molecular breast imaging.

## Methods

### Patient Enrollment

Eighteen breast implants were interrogated in women with breast irregularities. The women volunteered to undergo FMTVDM Molecular Breast Imaging (MBI), to measure changes in breast tissue RBF and metabolism, to determine if there was evidence of inflammation, precancerous changes or cancer. Their mammography findings were compared along with the information already known about the extent of their breast health. All components of FMTVDM are already FDA approved - including the enhancement of Regional Blood Flow (RBF) and metabolic differences, isotopes and camera. Each woman signed an informed consent agreeing to participate in the nuclear imaging protocol. All personal identifying information was redacted to protect patient identification.

## Breast Imaging

Prior to imaging, the nuclear technologist calibrated the Siemens Orbiter camera according to patent instructions to guarantee quantitative calibration of the camera in addition to customary qualitative controls. Patients arrived in the overnight fasting state and were prepared for imaging with placement of an intravenous catheter through which a vasodilator (enhancement) was given, followed by the imaging isotope and flush as previously described [7-9].

## Patient Records

Patients provided inter alia detailed medical records, including prior biopsy results, mammography results, family history of cancer, any prior False Positive or False Negative (FPFN) results from prior testing including but not limited to mammography, smoking history, current medications, any diagnosis of dense breasts and breast implants.

## Measurement of RBF and Metabolic Differences - Maximal Count Activity (MCA)

Following image acquisition, Regions of Interest (ROI) were drawn around the acquired breast images and the measured scintillation activity of RBF and metabolic differences was obtained (MCA).

## Results

The diagnostic information obtained from these 18 breast implants and patient medical records/information are shown in Table 1, including specific details for each Region of Interest (ROI) measured, along with the patient number and breast involved. The measured MCA for each ROI is shown, along with tissue information, the presence or absence of breast implants, dense breasts and FP mammography results. The MCAs were compared with the previously published [7,8] values for breast tissue including women without inflammation or cancer (MCA 144 $\pm$ 30; 95% CI 138-150), women with inflammation (MCA 229 $\pm$ 50; 95% CI 219-240) and women with breast cancer (MCA 446 $\pm$ 80; 95% CI 404-489). Later research [7,9] showed pre-cancerous and DCIS tissue to have MCA values of 307 $\pm$ 29; 95% CI 270-340. Of the 18-implants, there was evidence of inflammation in 4 (22%), five had evidence of precancerous changes (28%) and 1 (5%) had evidence of breast cancer. Examples of FMTVDM breast implant imaging results are shown in Figure 1, including (A) no evidence of inflammation or cancer (normal), (B) inflammatory changes, (C) ductal carcinoma in-situ and (D) breast cancer.



(A) – No evidence of inflammation (B) – Breast Implant with Inflammation

(C) – Breast Implant with DCIS (D) – Breast Implant with Cancer
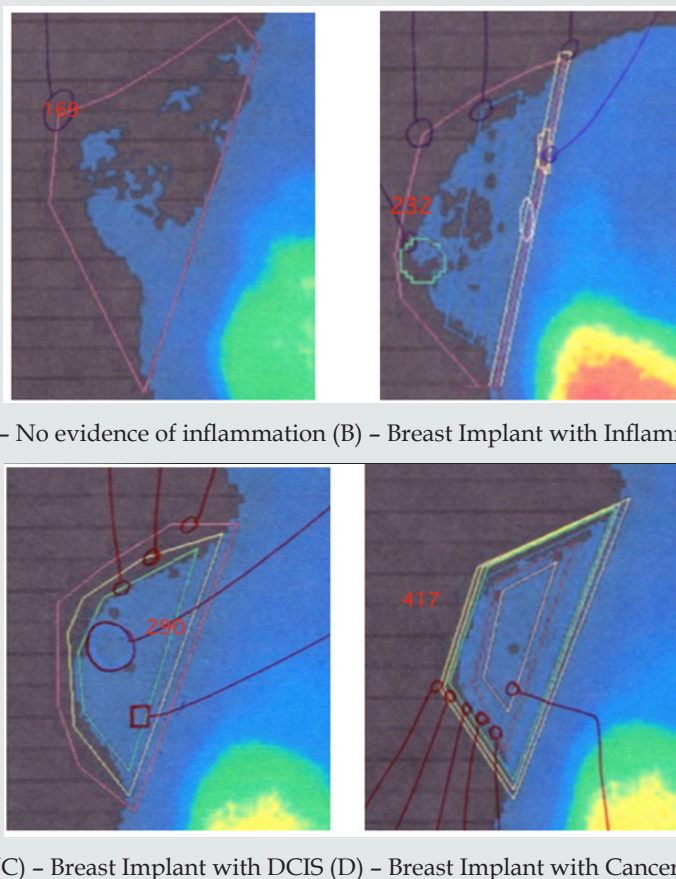
**Figure 1**. Results of FMTVDM measurements in women with breast implants

**Table 1:** Patient data and diagnostic information for 18-breast implants.

| Initial-Breast | MCA | Tissue Data | Other |
|---|---|---|---|
| 1-R | 54 | Lumps | Implants, Not Dense |
| 2-L | 74 | Lumps | Implants, Not Dense |
| 3-L | 92 | No CA | Breast Implant |
| 4-R | 103 | None CA Lumps | Breast Implant |
| 5-L | 144 | No CA | Breast Implant |
| 6-L | 146 | Irregularities | Dense Breasts, Implants |
| 7-R | 158 | No CA | Breast Implant |
| 8-R | 169 | Lumps | Implants, Not Dense |
| 9-L | 173 | Non-CA Lumps | Breast Implant, Taking HT |
| 10-L | 180 | Lumps | Implants, Not Dense |
| 11-L | 232 | No CA | Breast Implant |
| 12-R | 238 | No CA | Breast Implant |
| 13-R | 245 | Lumps | Implants, Not Dense |
| 14-L | 259 | Irregularities | Dense Breasts, Implants |
| 15-R | 270 | Not tested yet | ? |
| 16-R | 290 | CA with marker left | Dense Breasts, Implants |
| 17-L | 297 | Lumps | ? |
| 18-R | 417 | CA with marker left | Dense Breasts, Implants |

DB = Dense Breasts (Yes, No? =Uncertain), FP=incorrect mammogram, HT=Hormone Therapy

## Discussion

While the sample size was relatively small, it provided adequate information to demonstrate that changes in breast tissue inflammation, precancerous and cancerous changes are measurable in women with breast implants. In this study, one-third of the implants were associated with precancerous or cancer changes in the breast and twenty two (22%) percent were associated with inflammation. There was one instance of breast cancer. While the purpose of this study was not to conclude that the breast implants were the cause of the changes in breast tissue, it demonstrated the ability to measure the tissue changes occurring behind the breast implants. Women will undoubtedly continue to have breast implants for a variety of reasons. Perhaps the most clinically important are women who have undergone reconstructive surgery post mastectomy for the treatment of breast cancer. In these women there is a particular risk for recurrence of cancer, which becomes more difficult to evaluate in the presence of breast implants presenting a special challenge for clinicians [10,11]. Breast implants do not affect MCA measurement as the isotope is not taken up into the implants, allowing clear measurements to be obtained in the presence of breast implants [7]. Thus, allowing these women, and men, to be safely monitored for evidence of tissue change in the face of breast implants.

## Conclusion

Using FMTVDM, women and men with breast implants can be monitored for changes in breast tissue including inflammation, precancerous and cancer change–alerting clinicians to possible concerns and the need for implant extraction [2] or other treatment The Fleming Method for Tissue and Vascular Differentiation and Metabolism.

## Acknowledgment

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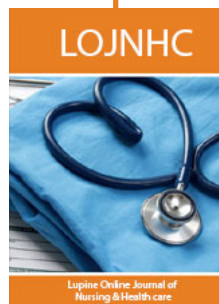
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