Core Clinical Study
Reconstruction Cohort
Malignant Breast Disease

CORE STUDY - RECONSTRUCTION

New Reports of Malignant Breast Disease After Implantation

Patient ID	Duration Following Implantation When Breast Malignancy Was Diagnosed	Tissue Type and Severity of Malignancy	Method of Diagnosis and Nature of How Diagnosis Was Made	Did Diagnosis Result in Removal? Was Replacement Performed?	Age of Patient at Diagnosis	Any Known Risk Factors for Breast Malignancy	If History of Malignancy Prior to Enrollment, Indication If New Malignancy is Recurrence of Same
	32 Months	Side/Quadrant: In lower outer quadrant of left breast Tissue type: Metastatic adenocarcinoma. Grade III of III. Ductal Invasive tissue; 5.5 cm nodule with 9 of 17 nodes involved and poor differentiation.	Mass detected by SBE initially. Abnormality noted on mammogram on 6/28/02 resulted in subsequent ultrasound and left breast MRI. Biopsy performed 7/8/02.	Implant was removed and no new implant placed.	47	Prior history of Grade III breast cancer in right side resulting in mastectomy in 1996. Patient refused some chemotherapy, radiation therapy and stem-cell infusion at that time against medical advice. Very strong familty history of breast cancer in mother, maternal aunts and maternal grandmother.	New malignancy. Previous cancer in opposite side, but same type of cell growth.
	Pathology report dated 1 day after enrollment surgery	Side/Quadrant: Throughout left breast Tissue Type: Invasive metastatic ductal carcinoma. Grade III. Multiple tumors up to 1.2 cm in size, with 4 or more nodes involved.	Tissue specimen was taken during enrollment surgery.	Implant was removed and no new implant placed.	54	Prior history of breast carcinoma in same breast in 1998; prior history of breast carcinoma in opposite breast in 1994. Mother also had breast cancer. Patient was a participant in the Herceptin trial.	This malignancy appears to be recurrence of same type of tumor in same breast as previous cancer in 1998.

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New Reports of Malignant Breast Disease After Implantation (cont.)

Patient ID	Duration Following Implantation When Breast Malignancy Was Diagnosed	Tissue Type and Severity of Malignancy	Method of Diagnosis and Nature of How Diagnosis Was Made	Did Diagnosis Result in Removal/ Was Replacement Performed	Age of Patient at Diagnosis	Any Known Risk Factors for Breast Malignancy	If History of Malignancy Prior to Enrollment, Indication If New Malignancy is Recurrence of Same
	14 months	Side/Quadrant: Left upper outer breast. Tissue Type: Seven lymph nodes positive for metastatic mammary carcinoma with extranodal tumor extension and embolization of lymphovascular spaces. Nodes ranged from 0.9-2.6 cm.	Mass palpated by SBE 3/01; 4/19/01 mammogram was unable to clearly visualize, so U/S was done. U/S found 2.4 cm mass and recommended biopsy. Biopsy pathology done 4/27/01.	Implant was not removed, as cancer was in lymph nodes and not breast.	52	Prior history of breast invasive ductal breast carcinoma in left breast in 1999 resulting in mastectomy. Paternal aunt with history of breast cancer as well.	While this is not a recurrence of the original breast cancer, as this occurrence is in the lymph nodes and not the breast itself, it does appear that these tumors are metastases of the original cancer.
	19 months	Side/Quadrant: Left upper outer quadrant Tissue Type: Recurrent residual tumor of original cancer. Ductal carcinoma in situ with high grade tumor. Multiple nodal involvement as well.	Diagnosed by biopsy in 11/01 and confirmed following tissue removal 2/02. Method of first detection uncertain, as she was treated by another physician not participating in the study.	Implant was removed by a surgeon not participating in study and no new implants were placed.	55	Prior history of breast carcinoma in same breast in 1999- ductal in situ. No family history of breast cancer.	The malignancy is a recurrence of the same type of tumor in the same breast as previous cancer in 1999

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New Reports of Malignant Breast Disease After Implantation (cont.)

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	19 months	Note: Cancer was in nonenrolled side. Side/Quadrant: Left breast in upper inner quadrant. Tissue Type: Adenocarcinoma grade 3/3. 1.2 cm tumor with no nodal involvement and poor differentiation. Ductal and invasive.	Diagnosed by incision biopsy resulting in mastectomy	N/A- no implant had been placed on this side.	44	Prior history of metastatic ductal invasive cancer in opposite breast in 1999. No family history.	New malignancy. Previous cancer in opposite side, but same type of tumor.