# Breast Cancer Diagnosis and Prognosis in Women Following Augmentation with Silicone Gel-filled Prostheses

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62 healthy women were studied mammographically before and after augmentation mammoplasty. Postaugmentation mammograms were done using both the implant compression and implant displacement technique. The amount of visualisable tissue was measured in all films before and after augmentation. We concluded: State-of-the-art film-screen mammography is extremely difficult to obtain in most patients augmented with silicone-gel-filled prostheses. On average, there is a decrease in measurable visualised breast tissue after augmentation mammoplasty with silicone-gel-filled prostheses. The area of mammographically measurable tissue is no different whether smooth or textured implants are used. Textured implants are less likely to form an early capsular contracture and are therefore preferred. However, the cancer-causing potential of polyurethane in humans is currently unknown. Anterior breast tissue is generally seen better with displacement mammography; posterior breast tissue with compression mammography. Better films are generally obtained when the implant is in the subpectoral position rather than subglandular. The more severe the capsular contracture, the poorer the mammogram. In addition 42 previously augmented patients developed breast carcinomas an average of 8.4 years after augmentation with silicone-gel-filled impants; 95% had palpable lesions (only 60% of which could be seen on mammography), 90% had infiltrating carcinomas, 45% had metastases to axillary nodes, and 7 patients have recurred, 5 of whom have died. We concluded: Augmented women who develop breast cancer are similar, in terms of tumour size and nodal positivity, to non-augmented breast cancer patients who present with palpable masses. When compared with non-augmented women whose breast cancers are found with screening mammography, augmented patients with breast cancer present with a higher percentage of invasive lesions and involved axillary lymph nodes, resulting in a poorer prognosis. The 40% false negative rate for mammography in this series is unduly high and alarming. Augmentation mammoplasty with silicone-gel-filled implants should be discouraged in women with a high risk of developing breast cancer.
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## INTRODUCTION

THE MOST favourable breast carcinomas, those with 90–95% 5-year survivals, are occult (non-palpable) lesions found in asymptomatic women undergoing screening mammography [1–5]. Any procedure which decreases the sensitivity of mammography may lead to a delay in diagnosis, and in some cases to decreased survival. Recently, augmentation mammoplasty with silicone-gel-filled (SGF) prostheses has been accused of affecting breast cancer diagnosis (mammography) and prognosis in a detrimental fashion [6–11].

In the United States, more than 150 000 women undergo augmentation mammoplasty annually [11] and the number is increasing. Current estimates suggest that more than one and a half million women have already been augmented [12]. Since as many as 11% of all American women, including those who have undergone augmentation mammoplasty, can expect to develop breast cancer during their lifetime, there is an obvious need to investigate the effect of silicone-gel-filled prostheses on breast cancer diagnosis, treatment, and prognosis.

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In section 1 of this paper, we present mammographical measurement data on 62 healthy women both before and after augmentation. In section 2, we present detailed follow-up of 42 different women who developed breast cancer an average of 8.4 years after augmentation with silicone-gel-filled prostheses.

## SECTION 1. MAMMOGRAPHICAL MEASUREMENTS BEFORE AND AFTER AUGMENTATION MAMMOPLASTY WITH SILICONE-GEL-FILLED IMPLANTS

*Patients and methods*

62 patients, all of whom had preaugmentation film-screen mammography and postaugmentation compression mammography, were studied. 52 of these patients also had implant displacement mammography; in 6 women, displacement mammography was not possible due to severe capsular contracture [13], in 4 women, displacement views were not obtained.

Implant compression mammography was done using standard mediolateral oblique and exaggerated craniocaudal views, with the implant included in the compression field. Implant displacement mammography [11] was done by pulling the anterior breast tissue forward while displacing the implant posteriorly, flattening it against the chest wall. The tissue which was pulled anteriorly was then compressed between the film holder and the

compression paddle of the mammography machine. The same mediolateral oblique and exaggerated craniocaudal views were obtained.

The mammographically visualised area was measured using a transparent grid calibrated to one tenth of 1 $cm^2$. The pectoralis major muscle was used as the posterior boundary for the purpose of measurement in the mediolateral view.

*Results*

Mammographical measurement data was available in 62 patients; in 32 the implant was subglandular (anterior to the pectoralis major muscle) (Fig. 1a–c), in 30 the implant was submuscular (posterior to the pectoralis major muscle). 34 augmentations were performed with smooth-walled single or double lumen silicone-gel-filled implants, 28 augmentations were performed with polyurethane covered silicone-gel-filled implants.

The average measurable area in the preaugmentation films was 83.8 $cm^2$, in the postaugmentation implant compression films it was 54.8 $cm^2$, a 35% decrease. The average measurable area in the postaugmentation implant displacement films was 62.8 $cm^2$, a decrease of 25% when compared with preoperative films.

The patients were grouped by implant position: subglandular versus submuscular (Table 1). In subglandular augmentation mammoplasty patients, compression mammography revealed an average decrease in measurable area of 43%; displacement mammography revealed a 37% decrease. In submuscular augmentation, the average decrease using compression mammography was 26%; with displacement mammography, it was 15%.

The patients were further subdivided by mammographic view (Table 2): mediolateral versus craniocaudal. The mediolateral views were reduced in subglandular augmented patients using the compression technique by 42%. Using displacement mammography, they were reduced by 38%. With submuscular augmentation, the mediolateral views using compression were reduced by 30%; with displacement, there was a 10% decrease in measurable area.

The craniocaudal views were similar, although less area overall was measured in this view. In patients with subglandular implants, compression mammography yielded a reduction of 44%, displacement mammography a reduction of 36%. In women with submuscular implants, compression mammography yielded a reduction of 22% while displacement mammography resulted in a reduction of 20%.

Detailed subset analysis comparing smooth versus polyurethane covered implants by both position and mammographical view revealed no significant differences in measurable area. Anterior breast tissue was seen best using displacement mammography; posterior breast tissue was seen best using compression mammography. No damage was caused to any implant by breast compression during mammography.

*Discussion*

Improved mammography and directed breast biopsy has led to a dramatic increase in the detection of non-palpable cancers, many of which are non-invasive and have extremely good prognoses. At facilities using screening mammography, the percentage of occult breast carcinomas is now 20–30% [4, 5,14] and increasing. Most centres report rates of axillary node metastases well below 20% for occult breast cancers compared with more than 40% for palpable carcinomas [1, 4, 5, 14]. Any factors that decrease mammographical utilisation may adversely affect the diagnosis of early breast cancer.

Using an American College of Radiology phantom to simulate microcalcifications and soft-tissue masses, Gumucio and associates [10] took radiographs with various implants resting on the phantom. An empty silicone shell had a minimal effect on artifact resolution; but when filled with silicone-gel, it completely obscured all phantom artifacts. Hayes and associates [9] using calibrated planimetry and solid geometric calculations reported that augmentation mammoplasty obscured 22–83% of visualisable breast volume. Both of these studies casted serious doubt on the reliability of routine mammography in the augmented patient.

In an attempt to see more breast tissue in the augmented patient and see it better, Eklund *et al.* [11] popularised displacement mammography. This type of mammography yielded improved films in terms of image area and quality. Unfortunately, since the implant cannot be completely flattened against the chest wall, posterior breast tissue is often seen better with standard implant compression views. Anterior breast tissue is almost always seen better with displacement mammography. The exception occurs when severe capsular contracture does not allow any significant posterior displacement of the implant. Since both techniques have advantages and disadvantages, and they vary with position of the implant and degree of capsular contracture, it is often necessary to use both methods when imaging an augmented breast. This means routine evaluation may require four films of each breast, rather than two, doubling the X-ray exposure.

Capsular contracture is a major problem for displacement mammography. The more intense this reaction, and it is significant in 30–50% of patients augmented with smooth-walled implants [13, 15], the more difficult displacement mammography is to perform. Severe capsular contracture makes posterior displacement of the implant almost impossible and often extremely painful. In 6 out of 62 patients with preaugmentation films in this series, a complete set of displacement mammograms could not be performed due to the rigidity of the capsules. If these films had been done, they would have shown little measurable breast tissue and would have further reduced the measured area in the displacement subgroup. Capsular contracture also makes compression mammography, breast self-examination and physician examination more difficult. Currently, capsular contracture is markedly decreased in patients with textured-silicone [16] and polyurethane [17] covered implants. Unfortunately, laboratory studies suggest an increase in both breast and liver cancer in susceptible rodents fed 2,4-toluenediamine, a possible polyurethane breakdown product [18]. No such cases have been reported in humans. The Food and Drug Administration (FDA) is studying this problem and feels the risk is extremely small [19].

Prior to 1988, there was little discussion in the medical literature regarding augmentation mammoplasty and any effect the procedure might have on mammography. Since most augmentation patients were relatively young, few received routine preaugmentation mammography, explaining why only 62 out of 311 (20%) augmented patients evaluated at our facility during the course of this study had preaugmentation mammograms available for measurement.

In this study, most postaugmentation mammograms yielded decreases in measurable area. However, a decrease in measurable area does not necessarily mean an equivalent decrease in the amount of tissue visualised. During compression mammography
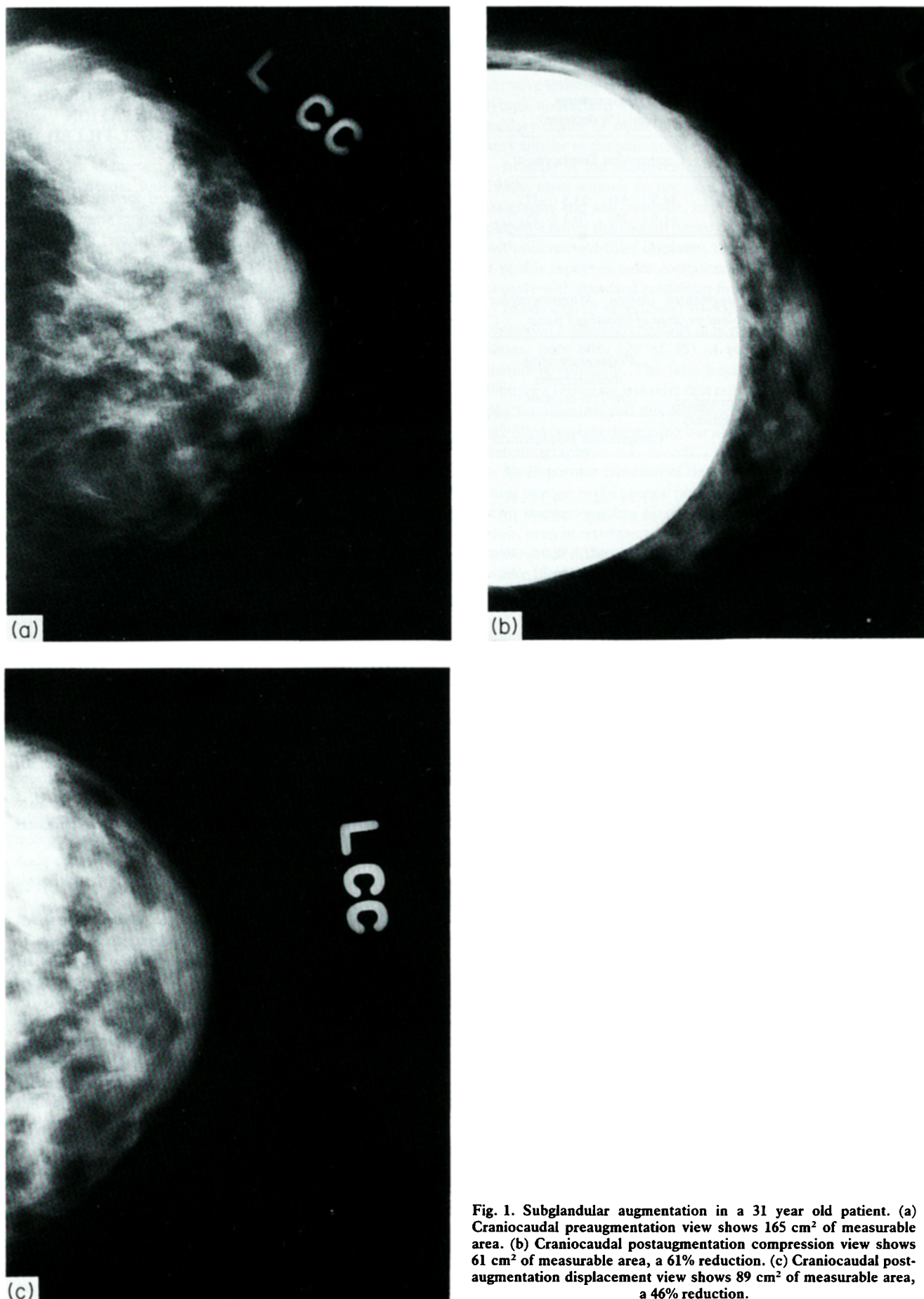
Fig. 1. Subglandular augmentation in a 31 year old patient. (a) Craniocaudal preaugmentation view shows 165 cm² of measurable area. (b) Craniocaudal postaugmentation compression view shows 61 cm² of measurable area, a 61% reduction. (c) Craniocaudal post-augmentation displacement view shows 89 cm² of measurable area, a 46% reduction.

*Table 1. Mammography in augmented women. Position of implant vs. area of visualised tissue*

| Implant position | Preaugmentation measurements (cm²) | Postaugmentation measurements (cm²) (% decrease) | |
|---|---|---|---|
| | | Compression | Displacement |
| Glandular | 84.9 | 48.5 (−43) | 53.3 (−37) |
| Submuscular | 82.8 | 61.0 (−26) | 70.1 (−15) |

*Table 2. Mammography in augmented women. Mammographic view and position of implant vs. area of visualised tissue*

| Implant position by view | Preaugmentation measurements (cm²) | Postaugmentation measurements (cm²) (% decrease) | |
|---|---|---|---|
| | | Compression | Displacement |
| Mediolateral views | | | |
| Glandular | 88.0 | 51.2 (−42) | 54.3 (−38) |
| Submuscular | 87.8 | 61.8 (−30) | 78.7 (−10) |
| Craniocaudad views | | | |
| Glandular | 82.1 | 45.6 (−44) | 52.7 (−36) |
| Submuscular | 77.1 | 59.8 (−22) | 61.7 (−20) |

in an augmented patient, the implant may force a larger volume of breast tissue into a smaller space, resulting in a measurable area which may not correlate precisely with the amount of tissue visualised. In other words, more tissue may be imaged in a smaller space; this may cause more superimposition of structures, resulting in lower image quality. The extent of this artifact is impossible to quantitate.

Currently, we appraise all women considering augmentation mammoplasty of the mammographical measurement data and its potential implications. Consideration should be given to recommending against augmentation in patients with an increased likelihood of developing breast cancer; for example, patients with a strong family history of breast cancer, patients with a history of previous contralateral breast cancer, and patients with a previous breast biopsy revealing severe atypical epithelial hyperplasia.

For those patients who elect augmentation mammoplasty, in spite of the data suggesting a reduction in mammographically measurable tissue following augmentation, we would suggest the use of textured-implants to decrease or delay capsular contracture, and when practical, submuscular placement of the implant to yield the best quality mammogram under the circumstances.

We are strongly against the insertion of an implant for cosmetic reasons in women who have undergone segmental resection (lumpectomy) and radiation therapy and have achieved a poor cosmetic result. The advantage of breast conservation is that it saves the breast. But that breast must be closely and carefully followed due to a local recurrence rate of at least 10% to 20% in most series [20–22]. Currently we perform mammography on the irradiated breast every 6 months. Any procedure, such as augmentation, which decreases the accuracy

of mammography must be carefully considered and is contraindicated in most cases.

## SECTION 2. PROGNOSIS IN WOMEN DEVELOPING BREAST CANCER AFTER AUGMENTATION MAMMOPLASTY WITH SILICONE-GEL-FILLED IMPLANTS

*Patients and methods*

All previously augmented patients treated for breast cancer between 1981 and 1990 were included. Tumours were divided into four major histological types of breast cancer: infiltrating ductal, infiltrating lobular, duct carcinoma *in situ* (DCIS), and lobular carcinoma *in situ* (LCIS). Film-screen mammography was performed using an overpenetrated implant compression technique [1]; beginning in 1988, the posterior displacement technique was also employed [11].

Patients whose tumours could be excised with microscopically clear surgical margins and an acceptable cosmetic result were treated with excision and radiation therapy. Patients with larger tumours, involved surgical margins, and poor cosmetic results underwent mastectomy. All patients treated with radiation therapy received 180–200 cGy/fractions via a 4 or 6 Mev linear accelerator 4 or 5 times a week to a dose of 4500–5000 cGy. 19 of 23 patients who underwent radiation therapy received a 1500 to 2000 cGy boost with either orthovoltage, 4 MeV photons or an iridium implant.

*Results*

The study group consisted of 42 previously augmented patients with biopsy proven breast cancer. 22 biopsies were performed at The Breast Center, 20 at other institutions prior to referral. All outside biopsy material and mammograms were reviewed prior to definitive treatment. The patients ranged in age at the time of diagnosis from 31 to 67 years (average 44).

All augmentations had been performed with smooth-surfaced silicone-gel-filled implants, either single or double lumen, 6 months to 20 years (mean 8.4, median 8.5 years) prior to the diagnosis of breast cancer. The implant was anterior to the pectoralis major muscle (subglandular) in 37 of 42 (88%) patients and posterior to the muscle (submuscular) in 5 patients (12%).

*Clinical findings*

40 of 42 (95%) patients were symptomatic, presenting with a palpable mass which they reported having been present from 5 days to 3.5 years (median 42 days). 2 patients with intra-ductal carcinoma were asymptomatic, abnormal screening mammograms leading to their diagnosis.

Standard implant compression mammography was performed prior to biopsy in all 22 patients biopsied at The Breast Center and in 15 of 20 patients biopsied elsewhere. In 21 of 35 (60%) mammographically evaluated patients with palpable masses, the lesion was visualised. In the remaining 14 patients with palpable lesions, the tumour could not be seen, even in retrospect; a false negative mammography rate of 40% for palpable lesions.

7 patients had prebiopsy mammograms taken with both the standard compression technique and the implant displacement technique [11]. In 5 patients the abnormality was seen with both techniques; in 1 patient, the cancer could not be seen with either technique. In the final patient, a posterior lesion could be seen easily with compression mammography but not with displacement mammography.

## Pathology

38 cancers were invasive: 34 infiltrating ductal, 4 infiltrating lobular. Four cancers were non-invasive: two were occult intraductal carcinomas found by mammographical calcifications, a third was a palpable DCIS with mammographic calcifications, and the fourth was lobular carcinoma *in situ* found in a thickened mass-like section of capsular scar. The average tumour measured 2.3 cm in diameter. Fine needle aspiration (FNA) biopsy or Tru-Cut needle biopsy was attempted in 13 patients; in 9, malignant cells were seen. No injury to any of the underlying impants was caused by needle biopsy.

There was sufficient tumour present to perform oestrogen and progesterone receptor analysis on 32 specimens. 17 patients had both receptors positive, 5 had one positive receptor and one negative receptor, and 10 patients had both receptors negative.

Lymphatic invasion, within or around the tumour, was seen in 13 patients, 10 of whom had positive nodes. Seven additional patients in whom intramammary lymphatic invasion could not be demonstrated also had positive axillary lymph nodes. 19 of 38 (50%) patients who underwent axillary dissection had involved nodes: 13 patients had 1–3 positive nodes, 3 patients had 4–9 positive nodes, and 3 patients had 10 or more involved nodes.

## Treatment

15 patients with infiltrating carcinomas were treated by modified radical mastectomy. 1 patient with LCIS and a family history of breast carcinoma was treated with bilateral mastectomies; her contralateral breast also revealed foci of LCIS which were not suspected prior to mastectomy.

26 patients were treated with breast preservation: 22 patients with infiltrating carcinomas and one patient with DCIS underwent excision of the tumour, axillary node dissection and radiation therapy. An additional patient with DCIS was treated with radiation therapy without axillary dissection and a third patient with DCIS was treated with excision only. The final patient with an infiltrating duct carcinoma refused further therapy after excisional biopsy and was lost to follow-up at 46 months without evidence of local or distant recurrence.

17 of 19 patients with positive axillary lymph nodes received adjuvant chemotherapy. Both patients who did not had a single micrometastases and refused chemotherapy. In addition, four node negative patients with unfavourable biochemical prognostic indicators also received chemotherapy.

## Recurrences

7 patients have recurred; 1 locally, 6 metastatic. 4 recurrences were in patients treated by mastectomy, 3, including the local recurrence, were in patients treated with breast conservation. All 6 patients with metastatic disease had involved axillary nodes at the time of initial treatment. All 6 received adjuvant chemotherapy following initial treatment, 4 had histologically demonstrable lymphatic invasion in or around the tumour; in four, both the ERA and PRA were negative.

5 patients with recurrent disease have died, 4 treated by mastectomy and one treated with breast conservation. The actuarial disease-free and overall survival at 6 years are 76% and 80%, respectively. The median follow-up time 60 months.

## Discussion

The average breast carcinoma diagnosed in the 1970s in the United States was palpable, discovered by the patient, 2.7 cm in mean diameter, and had more than a 40% rate of axillary metastases [23]; a description very similar to the 42 augmented breast cancer patients in this series. The Los Angeles County Cancer Surveillance Program logged 5876 women with breast cancer aged 45–54 years between 1972 and 1985: 7% had non-invasive lesions, 50% had invasive lesions with negative axillary lymph nodes, and 43% had invasive lesions with metastases to axillary nodes or other distant sites [24, 25]. Again, a group very similar to the patients in this series.

In spite of the improvements in mammography during the 1980s, most women do not take advantage of screening mammography and will continue, in the near future, to present with palpable rather than occult breast cancer. For women augmented with silicone-gel-filled implants, the problem as stated in section 1 of this report is more complicated than just getting them to comply with standard guidelines for screening mammography.

In our overall experience, 90–95% of palpable cancers can be visualised mammographically in non-augmented women. In this series, only 60% (21 of 35) of palpable cancers were seen mammographically. The false negative rate of 40% is unduly high for a centre such as ours that relies heavily upon mammography for diagnosis and this difference is likely due to the silicone-gel-filled implant decreasing our ability to perform and interpret mammography.

An important criticism of this paper is that our patients, like most women in the general population, were not screened yearly with mammography. Since 14 palpable cancers could not be seen, even in retrospect, it is unlikely that screening would have made much difference. For the 21 patients with palpable lesions whose tumours could be imaged mammographically, screening would likely have led to earlier diagnosis.

Women considering augmentation mammoplasty should be apprised that mammography is more difficult after augmentation. If breast cancer develops, it may be palpable rather than occult when diagnosed. Compared with state-of-the-art mammographical diagnosis in non-augmented patients, the chances of nodal metastases will be increased, thereby worsening prognosis.

In high risk patients who elect augmentation, very careful informed consent must be obtained. Postoperatively the patient should be followed by physicians experienced with augmented patients. We perform mammography yearly after the age of 35 with the radiologist present. Appropriate compression, displacement and cone-down views should be obtained at the radiologist's direction. We obtain preaugmentation mammography in all women over the age of 30 contemplating the procedure. We admit that there is no data to suggest that this is beneficial or cost-effective in this age group. However, this is likely to be the last chance to obtain high quality mammography in these patients. All palpable lesions in augmented patients, even those of minimal suspicion, and all mammographic abnormalities in augmented women must be biopsied.

The augmented patients with breast cancer in this series presented similarly to patients seen in the 1970s; that is, predominantly with palpable primary lesions and almost 50% nodal positivity. From an oncologist's point of view, these figures are no longer acceptable in the 1990s. The state-of-the-art in breast cancer diagnosis is mammographical discovery of non-palpable lesions. These occult tumours have a much lower percentage of nodal positivity and a far superior survival rate [1, 4]. With high quality mammography available throughout the United States and Western Europe, we should no long accept the routine diagnosis of breast cancer by palpation alone. We should be wary of any cosmetic procedure that decreases the accuracy of mammography.

From a patients point of view, she must weigh the potential psychological, emotional, and physical benefits of augmentation, comparing them carefully with the negatives. The final choice must always rest with the patient.

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