Topics in plastic surgery of the breast

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PATHOLOGICAL FINDINGS IN PRIMARY CAPSULECTOMY SPECIMENS: ANALYSIS IN 2531 PATIENTS
ABSTRACT

Background: Following breast augmentation, reoperations are often needed for revision or explantation; the surgeon may elect to leave the capsule in situ. If excised, capsule tissue may be submitted for pathological examination.

Objectives: To assess the pathological findings seen in breast implant capsules submitted for histopathological examination.

Methods: Using PALGA, the Nationwide Network and Registry of Histopathology and Cytopathology in the Netherlands, a search was done for the years 2003–2012 for primary capsulectomy specimens. This was performed using the keywords “capsule, implant, augmentation, silicone, rupture and foreign body”, using wildcards for different spelling options. Patients were excluded if previous examinations were compatible with a history of breast cancer, prophylactic mastectomy or prophylactic ovariectomy. The pathological reports were manually scanned for their relevance. The diagnoses were registered.

Results: A total of 6803 reports of 4948 patients were available. We included 2574 reports of 2531 patients. Age was 51.2 ± 12.0 years. We found four invasive carcinomas (0.16%) in patients aged 44, 66 and two aged 54. Furthermore, four cases of ductal carcinoma in situ (0.16%) were identified in patients aged 48, 51, 56 and 68, and one case of lobular carcinoma in situ (0.04%) in a patient aged 57 years. Metaplasia was seen in 51 cases (2.0%), calcifications in 375 (14.6%), and silicone was present in 701 (27.2%).

Conclusions: The incidence of occult invasive and in situ carcinoma in capsulectomy specimens is low. It is oncologically safe to leave capsule tissue in situ.

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INTRODUCTION
Breast augmentation is the most popular surgical procedure with 330,631 procedures in 2012 in the United States [1]. It is estimated that more than 1.2 million procedures performed worldwide that in 2011 [2]. Patients with breast implants frequently require revision surgery for different reasons, the most common being capsular contracture [3, 4]. There are various options for the management of capsular contracture, some of which may call for a partial or full capsulectomy [5-7].

Previous studies have demonstrated that patients with breast implants do not have an increased risk of breast cancer. Nevertheless, due to the high incidence of breast cancer in women it is possible that an undiagnosed occult breast cancer may be found in a capsulectomy specimen (Figure 1). There are no guidelines mandating capsulectomy or the submission of capsule material for histopathological examination [7].

Roth et al. performed a study assessing 434 capsulectomy specimens from 264 patients at one institution [7]. They concluded that it is not necessary to submit capsulectomy specimens for pathological examination.

The aim of this study was to assess the pathological findings in primary capsulectomy specimens using a national histopathology database covering multiple centers.

MATERIALS AND METHODS
Data were obtained from the “Nationwide Network and Registry of Histo- and Cytopathology in the Netherlands” (PALGA); the pathology results obtained by all 58 Dutch pathology departments (academic and non-academic) are stored in this database. Retrieval is performed in accordance with the ethical guidelines of the Code for Proper Secondary Use of Human Tissue in the Netherlands [8].

A search was performed for the years 2003–2012. Due to the fact that there is no specific code for capsulectomy specimens, a search was implemented using the gender “female” and the anatomic location “breast” and any of the following keywords in the text of the reports: “implant, augmentation, foreign, silicon, silicone, prostheses, capsule, contracture, mammoplasty, extravasation, rupture or leakage”. Wildcards were used to perform truncation searching. The patient demographics and histopathology reports were obtained, as well as previous pathology reports for breast or ovarian tissue.

Reports were excluded if the samples were not consistent with a capsulectomy. Patients were excluded if it was identified in the data that they had previous breast histopathology examinations or if they had previously undergone bilateral oophorectomy, which is consistent with being a BRCA gene carrier with a higher risk of breast cancer.

When two unilateral specimens from the same patient were submitted on the same day, the data were combined and considered to be a bilateral specimen.

The query retrieved 6589 reports from 4759 patients; 3255 reports were excluded, (Figure 2) and 3334 reports were selected as being relevant. Of these, 474 had previous
pathology reports of the breast. In 143 patients bilateral specimens were submitted separately and these were combined. A total of 2574 reports were ultimately included, from 2531 patients, 43 of whom had undergone multiple capsulectomy procedures. The mean age of the cohort was 51.2 ± 12.0 years, with a range of 15–88 years (Figure 3).

Descriptive statistics were used to present the data.

RESULTS

We examined 2574 specimens from 2531 patients. The average age of the patients was 51.2, ± 12 years, with a range of 15–88 years (see Figure 3). In the majority of cases there were no pathological findings. In 2134 cases (82.9%) the reports were compatible with normal capsules and did not mention the presence of malignancy, metaplasia, and calcifications. Silicone deposition in the capsule or leakage or rupture of the implant was noted in 701 reports (27.2%). Calcifications were present in 375 cases (14.6%) with a mean age of 57.3 ± 9.2 years, and metaplasia in 51 cases (2.0%) with a mean age of 49.3 ± 11.7 years.

There were 4 cases of invasive carcinoma (0.16% of patients) and 5 cases of in situ carcinoma (0.2% of patients), of which 4 were ductal and one lobular (see Table 1).
**Figure 2.** Flow diagram of the patient selection

**Figure 3.** Age distribution of the patients

No carcinomas were diagnosed in the 151 reports consistent with being a BRCA gene carrier.

**DISCUSSION**

Breast cancer is the most common cancer seen in women. In the Netherlands it has an incidence of 1.58 per 1000 women and a prevalence of 11.61 per 1000 women, meaning that 1 in 7 women in the Netherlands will develop breast cancer during their lifetime [9, 10].
Table 1. Demographics of the patients with invasive and in situ carcinomas

<table>
<thead>
<tr>
<th>Case</th>
<th>Age</th>
<th>Unilateral or bilateral procedure</th>
<th>Diagnosis</th>
<th>Side</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>56</td>
<td>Bilateral</td>
<td>DCIS, stage III</td>
<td>Left</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>68</td>
<td>Bilateral</td>
<td>DCIS, stage II</td>
<td>Right</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>57</td>
<td>Bilateral</td>
<td>LCIS</td>
<td>Right</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>54</td>
<td>Bilateral</td>
<td>Invasive carcinoma</td>
<td>Left</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>54</td>
<td>Bilateral</td>
<td>Invasive carcinoma</td>
<td>Left</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>44</td>
<td>Unilateral</td>
<td>Invasive carcinoma</td>
<td>Right</td>
<td>*</td>
</tr>
<tr>
<td>7</td>
<td>48</td>
<td>Unilateral</td>
<td>DCIS, stage III</td>
<td>Right</td>
<td>* **</td>
</tr>
<tr>
<td>8</td>
<td>66</td>
<td>Bilateral</td>
<td>Invasive carcinoma</td>
<td>Right</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>51</td>
<td>Bilateral</td>
<td>DCIS, stage I</td>
<td>Left</td>
<td></td>
</tr>
</tbody>
</table>

DCIS = ductal carcinoma in situ  
LCIS = lobular carcinoma in situ  
* Stated as a unilateral lumpectomy procedure; possible erroneous inclusion  
** The carcinoma was detected in a separately excised lump during the capsulectomy procedure

Due to this high incidence it is possible that one may detect an unexpected occult carcinoma at the pathological examination following an elective breast operation such as a capsulectomy. In fact, occult carcinomas are known to be found in breast reduction specimens. The incidence reported varies from 0.06 to 4.6%. This may also be dependent on the technique used during the pathological examination as well as the indication for reduction mammaplasty [11]. On the other hand, it has been reported that patients with breast implants have a lower incidence of breast cancer [12, 13]. This may be attributed to several factors, one may hypothesize that patients with a family history of breast cancer are less inclined to opt for augmentation.

The possibility of breast cancer arising within or next to a capsule has been described [14]. Recently, the diagnosis of anaplastic large cell lymphoma (ALCL) has received attention. Although it is believed to be rare, it is estimated to develop in 1:500,000 women with breast implants [15]. Other forms that have been described include squamous cell carcinoma and desmoid metaplasia [16].

Our findings demonstrate that the incidence of occult tumors in capsulectomy specimens is low. This can be attributed to the fact that patients with suspect lesions have a work-up and receive the appropriate treatment, which will include cytological and histological examination before a capsulectomy will be performed, and such patients were excluded from our series.

It should also be kept in mind that the amount of breast tissue included in a capsulectomy specimen is small and that there is no uniform protocol for the examination of these specimens. It is possible that, as in breast reduction, a more meticulous examination will yield more pathological findings [11]. On the other
hand, this incidence may in fact be lower than what we have described since not all surgeons submit capsulectomy specimens for examination [7]. The strength of this study is the use of a national database with input from many centers, which can correct for local bias in patient selection and treatment. Since there is no specific code for capsulectomy, we used a sensitive search strategy, which had a low specificity. Nevertheless, it is possible that some cases were not included. We did not find cases of anaplastic large cell lymphoma in our series, however, in 14 reports the pathologists specifically mentioned the fact that they did not find ALCL, and ALCL was found in one of the excluded patients who had received implants for breast reconstruction.

Another strength of this study is the fact that we excluded patients with a history of breast cancer which could otherwise have biased our data, as was the case in the study by Roth et al. [7]. We also elected to exclude patients with a possible familial risk of breast cancer as indicated from previous benign mastectomy specimens or bilateral oophorectomies.

However, pooling data from multiple laboratories also has its disadvantages. The examinations had been performed by a number of different pathologists who possibly did not use uniform examination and reporting protocols, the national guidelines require a minimum number of 2 specimens, but pathologists may take more samples if deemed necessary. In addition, we were dependent on the decision of the surgeons to perform a capsulectomy and to submit the capsule for pathological examination, and on the communication of the surgeons with the pathologists. As there is no central registration of procedures performed as well as the fact that capsulectomies can be coded as part of different procedures we have no way of knowing how many of the capsules excised were ultimately submitted for histopathological examination. The cost of sending specimens is low around €30 ($40), and uniform across the country, in cases of surgeries covered by the insurance it is included in the global fee paid to the hospital by the medical insurance, and will most probably not influence the decision to submit material for pathological examination.

Due to the design of the study we did not have additional information about the patients, or the implants used and their anatomic location, and how long they had been present. It should be mentioned that the moratorium on silicone gel implants was not implemented in Europe; we can therefore assume that the vast majority of the implants were filled with silicone gel. One may also expect to find less breast tissue in a capsule of an implant that had a subpectoral or dual plane placement, and therefore a lower probability of finding breast cancer. This could unfortunately not be retrieved from the available data.

Our results demonstrate that the incidence of occult carcinoma in the capsulectomy specimens of patients without a previous history of breast pathologies is low.

CONCLUSIONS
Our results show a low frequency of occult malignancies, both invasive and in situ, in capsulectomy specimens. This may be due to several factors: for example, evident
tumors are mostly detected during the preoperative work-up and the amount of breast tissue excised during a capsulectomy is small. However, our findings may also represent an overestimation since not all capsules are excised or submitted for pathological examination.

We conclude that it is oncologically safe to leave breast capsule tissue in situ.

REFERENCES