Improvements in locoregional treatment of breast cancer
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SURGICAL COMPLICATIONS OF SKIN SPARING MASTECTOMY AND IMMEDIATE PROSTHETIC RECONSTRUCTION AFTER NEOADJUVANT CHEMOTHERAPY FOR INVASIVE BREAST CANCER


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ABSTRACT

Background
Neoadjuvant chemotherapy is gaining acceptance as an option for breast cancer treatment, particularly in young women. These women may seek immediate breast reconstruction after mastectomy even though it is not known whether such preoperative chemotherapy may be detrimental to post-reconstruction wound healing. Therefore, we set out to assess the influence of neoadjuvant chemotherapy for invasive breast cancer on the short-term complications after skin sparing mastectomy and immediate prosthetic reconstruction.

Patients and methods
The short-term surgical outcome of 48 immediate breast reconstructions in 37 women treated with neoadjuvant chemotherapy from 2006 through 2009 was prospectively compared to that of 215 immediate reconstructions in 176 women who were operated in the same period without neoadjuvant chemotherapy.

Results
The overall rate of short-term postoperative complications was significantly less among neoadjuvantly treated women (15% vs. 29%; p = 0.042) but this did not result in a reduction of loss of prostheses (8% vs. 11%; p = 0.566).

Conclusion
Because neoadjuvant chemotherapy is not associated with an increase in short-term complications after skin sparing mastectomy and immediate prosthetic reconstruction in patients with invasive breast cancer, such combined surgical therapy may be offered as treatment option for this particular group of patients also.
INTRODUCTION

Neoadjuvant chemotherapy is defined as adjuvant systemic therapy administered prior to, rather than following, locoregional treatment. It is also known as primary, induction or preoperative therapy, all of which terms indicate that subsequent treatment is intended. Neoadjuvant chemotherapy regimens are equivalent with conventional adjuvant chemotherapy regimens in terms of overall survival and permit the assessment of response of the primary tumour to a particular cytotoxic regimen. In breast cancer patients, the resulting preoperative decrease of tumour load may allow breast conserving therapy in 25–32 percent of women who were initially scheduled for mastectomy. Hence, a majority of women still have to undergo mastectomy following neoadjuvant chemotherapy. In case immediate reconstruction is oncologically feasible, many of these women will be candidates for a combined skin sparing mastectomy and immediate breast reconstruction by use of a temporary or permanent implant. Out of concern that the neoadjuvant chemotherapy might hamper postoperative wound healing, however, such combined treatment is less likely to be offered to them. Still, the influence of neoadjuvant chemotherapy for invasive breast cancer on the rate of surgical complications after combined skin sparing mastectomy and immediate prosthetic reconstruction has hardly been studied to date. Therefore, we compared the short-term surgical outcome in women treated with neoadjuvant chemotherapy to the surgical outcome of a control group of women who underwent skin-sparing mastectomy with immediate prosthetic reconstruction without neoadjuvant chemotherapy. To assess the short-term surgical outcome, postoperative complications that occurred within six weeks after surgery were recorded.

PATIENTS AND METHODS

Patients
From January 1st, 2006, through December 31st, 2009, 659 women underwent 864 skin-sparing mastectomies combined with immediate breast reconstruction by subpectoral prosthetic implantation in the Netherlands Cancer Institute-Antoni van Leeuwenhoek hospital. Forty-four of these women (57 mastectomies) had had neoadjuvant chemotherapy and the data on the remaining 615 women was considered for inclusion in the control group. Data on women who underwent skin sparing mastectomy for other reasons than an invasive malignancy in that breast was excluded, except when this mastectomy was combined with a contralateral skin-sparing mastectomy for an invasive tumour. Furthermore, the data on women who had undergone previous breast surgery, previous radiotherapy, or previous chemotherapy other than the neoadjuvant chemotherapy for breast cancer, was excluded (Fig. 1). Consequently, we were able to include the prospectively gathered data of 37 women (48 mastectomies) who were treated with neoadjuvant chemotherapy and the data of 176 women (215 mastectomies) as controls. We included the data on all these women even though this resulted in a much larger number of women in the control group as compared to the number of neoadjuvantly treated women. This was done to prevent any bias that might have occurred with the selection of a case-matched control group. The study was approved by the institutional ethical committee.
Neoadjuvant chemotherapy

Neoadjuvant chemotherapy was given for histologically proven infiltrating breast cancer with either a primary tumour of over 3 cm in clinical size, or cytological proven spread to the axillary lymph nodes, in accordance to protocol. Treatment consisted of six courses of dose-dense doxorubicin and cyclophosphamide (ddAC) (n = 23) or six courses of capecitabine and docetaxel (CD) (n = 2). If the therapy response was considered unfavourable by contrast-enhanced MRI evaluation after three courses, ddAC was changed to CD or vice versa. Patients with HER2+ tumours received three 8-week courses of trastuzumab, paclitaxel and carboplatin (PTC) (n = 9). Three women had been treated in other hospitals with comparable neoadjuvant regimens. The median interval between the last cycle of neoadjuvant chemotherapy and surgery was 4.4 weeks (range, 2.4–7.7 weeks).

Surgical technique

All women were operated in the standardized fashion previously reported by our group. The mastectomy included resection of the areolar complex. Because the periareolar incision usually did not allow adequate entrance to the glandular and axillary tissue to be resected, it was extended in most patients. For cosmetic reasons, this extension was preferably directed caudally or laterally. Care was taken to optimally resect all mammary glandular tissue. Apart from the areolar complex, this involved resection of the inframammary ligament and filleting of the mammary skin at the level
of the superficial thoracic fascia. In 29 of the 263 mastectomies in both groups, an axillary lymph node dissection was performed en bloc with the mastectomy in accordance with the preoperative plan, whereas 176 mastectomies were combined with a sentinel lymph node procedure. Because 26 of these 176 sentinel node procedures led to additional axillary lymph node dissection, a total of 55 axillary lymph node dissections were performed (Table 1).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Neoadjuvant group</th>
<th>Controls</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (SD)</td>
<td>40 year (10.9)</td>
<td>47 year (9.7)</td>
<td>0.001</td>
</tr>
<tr>
<td>BMI (SD)</td>
<td>22.9 kg/m² (2.9)</td>
<td>23.3 kg/m² (3.4)</td>
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<tr>
<td>Smoking</td>
<td>0.14 (5/37)</td>
<td>0.20 (36/176)</td>
<td>0.332</td>
</tr>
<tr>
<td>Co-morbidity</td>
<td>0.05 (2/37)</td>
<td>0.14 (24/176)</td>
<td>0.166</td>
</tr>
<tr>
<td>Bilateral surgery</td>
<td>0.30 (11/37)</td>
<td>0.23 (39/176)</td>
<td>0.324</td>
</tr>
<tr>
<td>Fellow oncologic surgeon</td>
<td>0.17 (8/48)</td>
<td>0.18 (38/215)</td>
<td>0.869</td>
</tr>
<tr>
<td>Resident plastic surgeon</td>
<td>0.23 (11/48)</td>
<td>0.21 (45/215)</td>
<td>0.761</td>
</tr>
<tr>
<td>Weight of specimen (SD)</td>
<td>509 gr (251.2)</td>
<td>513 gr (263.1)</td>
<td>0.919</td>
</tr>
<tr>
<td>Axillary dissection</td>
<td>0.44 (21/48)</td>
<td>0.16 (34/215)</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Table 1. Patient-related and procedure-related characteristics of the 37 women in the neoadjuvantly treated group and the 176 women in the control group. Please, note that patient-related characteristics may be expressed as a fraction of the number of women in each group, whereas the procedure-related characteristics may be expressed as a fraction of the number of mastectomies. Significant p-values are depicted in bold print.

SD: standard deviation; BMI: body mass index

Immediately following the skin sparing mastectomy, a subpectoral cavity was created to allow for implantation of a permanent endoprosthesis (n = 224) or a temporary tissue expander (n = 39). To prevent cranial displacement of the implants and to allow for a more naturally projecting lower part of the reconstructed breast, the origin of the major pectoral muscle was detached from the lower costal arch and the caudal part of the sternum. The mean weight of the implanted BioDimensional, textured, high-cohesive gel-filled prostheses (Natrelle style 410; Allergan, Marlow, Buckinghamshire, United Kingdom) was 400 g (range, 170–625 gr) in the neoadjuvantly treated group and 420 gr (range, 170–775 gr) in the controls. The mean intraoperative filling volume of the tissue expanders (Natrelle style 133; Allergan, Marlow, Buckinghamshire, United Kingdom) was 173 cc (range, 100–200 cc) in the neoadjuvantly treated group and 215 cc (range, 50–450 cc) in the controls. The caudal edge of the major pectoral muscle was subsequently sutured to the subcutaneous tissue of the caudal skin flap. In women in whom the periareolar incision had been extended, the skin was closed in a double-breasted fashion to create an extra covering layer over the lower part of the implant that was not covered by the muscle flap. Antibiotic prophylaxis and wound drainage were routinely applied in all patients. The mean operation time of the combined procedure was 146 min (range 55–250 min) in the intervention group and 149 min (range, 65–300 min) in the controls.

Outcome measures
All complications that occurred during the first 6 postoperative weeks were recorded for each reconstructed breast as outcome measures of surgical therapy. This fixed period was accepted because adjuvant treatment in general starts after 6 weeks. Still, the time period between surgery and the start of possible adjuvant radiotherapy was recorded to assess whether there was any significant difference between both treatment groups in time between surgery and adjuvant
irradiation. We considered adjuvant radiotherapy to have been delayed in cases where it was started later than six weeks postoperatively due to wound healing or patient’s non-compliance. For the present analysis no distinction was made between permanent or temporary implants as this has previously been proven not to influence the short-term surgical outcome in our hands. Data on this outcome was included in the prospectively maintained database by two of the plastic surgeons of our institute (JJH and LAEW). We considered the surgical outcome to have been complicated in cases where seroma, haematoma, skin necrosis, or infection was diagnosed by the plastic surgeon. Seroma was defined as a clinically obvious collection of serous fluid within the surgical cavity requiring aspiration. Haematoma was defined as any collection of blood requiring surgical re-intervention. Necrosis was scored when local loss of circulation and viability of the mammary skin indicated conservative or surgical treatment. Infections were clinically diagnosed or proven by bacterial cultures and led to antibiotic or surgical treatment. Clinically, however, the loss of an implant is the most relevant measure of the outcome of breast reconstruction.

Statistical analysis
To establish comparability between the neoadjuvantly treated women and the controls, we statistically compared the distribution among both groups of women, of the patient-related potential risk factors age, general health risk factors, smoking habits, body mass, and whether the patient was operated on unilaterally or bilaterally. As procedure-related potential risk factors we compared the distribution over both groups of the level of experience of the oncologic surgeon (staff versus fellow) and the plastic surgeon (staff versus resident), of the weight of the resected specimen, and of complementary axillary lymph node dissection. The Student’s t-test was used for continuous variables, and the two-tailed \( \chi^2 \) test for dichotomous variables. The prevalence of postoperative complications and loss of implant among both groups was statistically compared using the \( \chi^2 \) test. Odds ratios and 95% confidence intervals (95% CI) were computed using logistic regression analysis. A p-value of 0.05 was accepted as indicative of statistical significance.

RESULTS

Patient-related and procedure-related factors
Except for the neoadjuvant chemotherapy and the fraction of axillary lymph node dissections, the age of the 37 women in the intervention group was the only pre-operative or procedure-related characteristic that differed significantly from that of 176 women in the control group (Table 1). The distribution of histopathological types of tumours among both groups was similar although, obviously, other tumour-related characteristics significantly differed between neoadjuvantly treated and non-neoadjuvantly treated women (Table 2). There was no difference in terms of level of experience of the surgeon or plastic surgeon or other procedure-related characteristics between both groups (Table 2).
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Neoadjuvant group</th>
<th>Controls</th>
<th>$p$-value</th>
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<tbody>
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<td><strong>Clinical tumor stage</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>0.19 (9/48)</td>
<td>0.13 (29/215)</td>
<td>0.350</td>
</tr>
<tr>
<td>T1</td>
<td>0.10 (5/48)</td>
<td>0.49 (106/215)</td>
<td>0.000</td>
</tr>
<tr>
<td>T2</td>
<td>0.63 (30/48)</td>
<td>0.32 (69/215)</td>
<td>0.002</td>
</tr>
<tr>
<td>T3</td>
<td>0.06 (3/48)</td>
<td>0.00 (0/215)</td>
<td>0.002</td>
</tr>
<tr>
<td>Tis</td>
<td>0.02 (1/48)</td>
<td>0.05 (11/215)</td>
<td>0.364</td>
</tr>
<tr>
<td><strong>Clinical nodal stage</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0.75 (36/48)</td>
<td>1.00 (215/215)</td>
<td>0.000</td>
</tr>
<tr>
<td>N+</td>
<td>0.23 (11/48)</td>
<td>0.00 (0/215)</td>
<td>0.000</td>
</tr>
<tr>
<td>Nx</td>
<td>0.02 (1/48)</td>
<td>0.00 (0/215)</td>
<td>0.034</td>
</tr>
<tr>
<td><strong>Tumor histopathology</strong></td>
<td></td>
<td></td>
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<tr>
<td>Ductal carcinoma</td>
<td>0.63 (30/48)</td>
<td>0.70 (152/215)</td>
<td>0.267</td>
</tr>
<tr>
<td>Lobular carcinoma</td>
<td>0.02 (1/48)</td>
<td>0.08 (17/215)</td>
<td>0.150</td>
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<td>Other invasive type</td>
<td>0.13 (6/48)</td>
<td>0.07 (15/215)</td>
<td>0.203</td>
</tr>
<tr>
<td>In situ carcinoma</td>
<td>0.06 (3/48)</td>
<td>0.02 (4/215)</td>
<td>0.088</td>
</tr>
<tr>
<td>No malignancy</td>
<td>0.17 (8/48)</td>
<td>0.13 (27/215)</td>
<td>0.449</td>
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<tr>
<td><strong>Receptor-based subtype</strong></td>
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<td></td>
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<tr>
<td>ER- / PR- / Her2-</td>
<td>0.35 (17/48)</td>
<td>0.08 (17/215)</td>
<td>0.000</td>
</tr>
<tr>
<td>ER+ / Her2-</td>
<td>0.27 (13/48)</td>
<td>0.62 (134/215)</td>
<td>0.000</td>
</tr>
<tr>
<td>Her2+</td>
<td>0.15 (7/48)</td>
<td>0.15 (33/215)</td>
<td>0.894</td>
</tr>
<tr>
<td>No invasive malignancy</td>
<td>0.23 (11/48)</td>
<td>0.14 (31/215)</td>
<td>0.147</td>
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</tbody>
</table>

Table 2. Tumor-related characteristics of the 48 mastectomies in the 37 women of the neoadjuvantly treated group compared to those of the 215 mastectomies in the 176 women of the control group. Please note that the 50 contralateral mastectomies that were done for preventive reason or in situ carcinoma are included in both groups. Significant $p$-values are depicted in bold print.

Tis: in situ carcinoma; No: no clinical evidence of lymph node metastasis, including a negative ultrasound; N+: Axillary lymph node metastasis diagnosed by fine needle aspiration; Nx: lymph node status unknown; ER: estrogen receptor; PR: progesterone receptor; Her2: human epidermal growth factor receptor.

* Receptor-based subtype as established on the pre-chemotherapy biopsy in the neoadjuvantly treated group and on the surgical specimen in the controls.

**Short-term surgical outcome**

The short-term postoperative course was uneventful in 41 of the 48 mastectomies performed after neoadjuvant chemotherapy (Table 3). Three of the 7 implants subject to a complicated postoperative course could be salvaged by additional conservative (n = 1) or surgical (n = 3) treatment. In the control group, an eventful postoperative course was observed significantly more often (62 out of 215). Seven of the 62 implants involved could be salvaged by additional conservative treatment, while 31 were salvaged by re-operation.

The loss of the implant encountered after neoadjuvant chemotherapy (4 out of 48) did not differ significantly from that in the control group (24 out of 215).
Characteristics | Neoadjuvant group | Controls | Odds Ratio (95% CI) | p-value
--- | --- | --- | --- | ---
Uneventful | 41/48 (0.85) | 153/215 (0.71) | 0.421 (0.179 - 0.990) | 0.042
Seroma | 1/48 (0.02) | 4/215 (0.02) | 1.122 (0.123 - 10.27) | 0.918
Haematoma | 0/48 (0.00) | 11/215 (0.05) | 5.455 (0.316 - 94.18) | 0.160
Infection | 4/48 (0.08) | 29/215 (0.013) | 0.583 (0.195 - 1.744) | 0.330
Skin necrosis | 4/48 (0.08) | 29/215 (0.017) | 0.218 (0.050 - 0.931) | 0.025
Salvaged cons. | 1/48 (0.02) | 7/215 (0.03) | 0.632 (0.076 - 5.262) | 0.670
Surgical re-int. | 6/48 (0.13) | 55/215 (0.26) | 0.416 (0.168 - 1.031) | 0.052
Salvaged by re-op. | 2/6 (0.33) | 31/55 (0.56) | 0.387 (0.065 - 2.293) | 0.287
Implant loss | 4/48 (0.08) | 24/215 (0.11) | 0.724 (0.239 - 2.191) | 0.566
by infection | 4/48 (0.08) | 23/215 (0.11) | 0.759 (0.759 - 2.305) | 0.626
by necrosis | 0/48 (0.00) | 1/215 (0.00) | 0.678 (0.027 - 16.91) | 0.636

Table 4. Short-term surgical outcome of the 48 mastectomies in the neoadjuvantly treated group (37 women) and the 215 mastectomies in the control group (176 women). Please note that the numbers are expressed as a fraction of the number of mastectomies. Odds ratios under 1.00 indicate a risk reduction in favor of the neoadjuvantly treated women. Significant p-values are depicted in bold print.

OR: odds ratio; 95% CI: 95% confidence interval
Salvaged cons. = Salvaged conservatively; Surgical re-int. = Surgical re-intervention; Salvaged by re-op. = Salvaged by re-operation

Delay in start of the adjuvant radiotherapy
Adjuvant chest wall radiotherapy was indicated in seven of the 37 neoadjuvantly treated women and in nine of the 176 women in the control group. Because we limited our observations to the first six weeks after surgery, such therapy did not influence our observations. The median time between surgery and the start of adjuvant radiotherapy did not differ significantly in both groups. The start of radiotherapy was not delayed in any of the neoadjuvantly treated women, whereas it was delayed in three of the 176 women in the control group. One of these women initially refused radiotherapy while for the other two women radiotherapy was postponed because of implant-related wound healing problems.

DISCUSSION
Although chemotherapy is increasingly being applied in a neoadjuvant setting for the treatment of breast cancer, little is known of its possible influence on short-term outcome of the breast surgery to follow. Recently, Hu et al. reported the odds of undergoing immediate reconstruction to be significantly reduced in women treated with neoadjuvant chemotherapy, even after controlling for age, disease stage and treatment with postoperative radiotherapy. This difference was irrespective of the length of the chemotherapy or complications during the neoadjuvant chemotherapy treatment. Furthermore, no increase of the number of delayed reconstruction was observed among these women. According to these authors, the difference might be explained by the surgeon’s fear for increased postoperative complications after treatment with neoadjuvant chemotherapy.

Surgical complications after neoadjuvant chemotherapy
Some twenty years ago, a comparison of the outcome of mastectomies in 106 neoadjuvantly treated women to that of the mastectomies in 91 women not treated with neoadjuvant chemotherapy showed no significant difference in postoperative rates of wound infection, wound ischemia, or delay of
adjuvant chemotherapy.14 The authors even reported that the prevalence of seroma formation was significantly less among the neoadjuvantly treated women. A later review of the relevant literature showed some preclinical animal models to suggest that neoadjuvant chemotherapy might cause significant wound healing complications, but the authors concluded that this has not been borne out in clinical practice.15 Their review showed that neoadjuvant chemotherapy did not increase the morbidity associated with breast surgery when the operation was scheduled during or after the third week after chemotherapy when the white blood cell count had returned to appropriate levels.15 A subsequent meta-analysis showed that a significantly lower rate of chemotherapy-related infectious complications may be found after breast surgery in neoadjuvantly treated women.3 Another study, however, contradicted this observation as a higher rate of seroma development was observed.16 Still, none of these studies regarded the outcome of mastectomy in combination with immediate breast reconstruction.

Complications of immediate reconstruction after neoadjuvant chemotherapy
Immediate reconstruction is increasingly being offered to women who need to undergo mastectomy.17 In a study on complications of skin sparing mastectomy and various techniques of immediate reconstruction following neoadjuvant chemotherapy, Mitchem et al6 observed the loss of 13 out of 39 (0.33) implants in 30 stage II/III breast cancer patients receiving a uniform neoadjuvant chemotherapy regimen. Gouy et al17 reported the need of additional surgery in 24 of the 48 (0.50) women after some sort of immediate breast reconstruction following neoadjuvant chemotherapy. Because both these reports lacked information on the rate of complications in woman who underwent immediate reconstruction without receiving neoadjuvant chemotherapy, it remained unknown to what extent these rates could be attributed to the neoadjuvant treatment. Azzawi et al18 concluded that neoadjuvant chemotherapy did not influence the rate of severe postoperative complications of 58 immediate breast reconstruction done by various techniques in comparison to 140 immediate reconstructions in women who had not been treated neoadjuvantly. The same applies to the analysis performed by Liu et al19 of the effects of neoadjuvant chemotherapy on the outcome of 12 immediate breast reconstructions that were compared to the outcome of 63 immediate reconstructions in women who had not had chemotherapy preoperatively. These data seem to be consistent with ours but are difficult to interpret as various techniques of reconstruction were included and only a minority of patients was reconstructed with an implant.

Hence, our analysis is unique since it focuses solely on immediate prosthetic reconstruction in a large cohort of identically operated patients of whom part was treated neoadjuvantly, and part was not. We observed significantly less postoperative complications among woman treated with neoadjuvant chemotherapy compared to the controls but this did not result in a significant difference of the most relevant outcome measure: loss of implant.

Potential methodological limitation
Before we present the clinical implication of this observation, a potential limitation of our methodology needs to be addressed. As such, the selection of women to undergo neoadjuvant chemotherapy may have influenced our observations. In our study, these women were significantly younger than the women in the control group. Furthermore, the initial clinical tumour stage of the neoadjuvantly treated women was unfavourable compared to that of the controls and a higher rate of axillary lymph node dissections was performed in this group. This is in line with the differences observed by Azzawi et al.18 The effect of the patients’ age is the most likely explanation for our
counterintuitive observation. Previously, we found only age to be positively correlated with the prevalence of short-term complications and loss of implant after combined skin sparing mastectomy and immediate prosthetic reconstruction. In the current study, we observed a non-significant trend towards a lower percentage of co-morbidity and smoking after neoadjuvant chemotherapy. The impact of the differences in initial clinical tumour stage and rate of axillary dissections between both groups, again, appears to be counterintuitive. The explanation for this impact remains unclear. The initially unfavourable tumour stages and axillary lymph node dissections among the neoadjuvantly treated women may negatively influence the healing conditions. However, a pathological complete response to neoadjuvant chemotherapy was observed in 12 of the 37 (0.32) breasts with invasive malignancy, whereas all pathological specimens of the controls contained tumour cells.

**CONCLUSION**

Although neoadjuvant chemotherapy may permit breast conserving surgery in some women who were initially scheduled for mastectomy, this is still not an option for the majority of the women with locally advanced breast cancer. Like other women who have to undergo mastectomy, this particular group of woman can potentially benefit from skin sparing mastectomy combined with immediate prosthetic breast reconstruction. We found that neoadjuvant chemotherapy is not associated with an increase of short-term postoperative complications or implant loss.
REFERENCES


