Breast cancer is recognized as the most common cancer in women worldwide and a leading cause of cancer-related mortality.\textsuperscript{1} Despite improvements in screening and diagnosis and advances in treatment of breast cancer, mastectomy remains an important surgical option.\textsuperscript{2} Prophylactic mastectomy is offered to decrease the risk of gene mutations,\textsuperscript{3} notably the risk associated with \textit{BRCA1} or \textit{BRCA2}.\textsuperscript{4} However, mastectomy undoubtedly adds a traumatic burden to the lives of women diagnosed with breast cancer.\textsuperscript{5} Psychological changes may often be detected.\textsuperscript{6} Besides the obvious concerns over physiologic health, breast cancer sufferers are also apprehensive about their appearance following a disfiguring operation.\textsuperscript{7} This perception may impact their social, personal, and sexual relationships.\textsuperscript{8} Half of all women who undergo mastectomy perceive a negative self-image and experience negative changes in their sexuality.\textsuperscript{9} For such women, particularly younger ones for whom physical appearance carries more significance, breast reconstruction, in its various forms, should be considered as a possible solution.\textsuperscript{10}

A retrospective study by Rowland et al.\textsuperscript{11} concluded that there were no significant differences
in quality of life of women who underwent either mastectomy alone, lumpectomy, or mastectomy with reconstruction. However, only one-third of the women replied to the self-reported questionnaire. Chen et al.\textsuperscript{12} concluded that rigorous patient-reported outcomes data are essential and should be the focus of future research. A systematic review by Winters et al.\textsuperscript{13} revealed that most of the studies were poorly designed, retrospective with significant limitations, and potentially biased. Furthermore, the studies were underpowered and they used generic quality-of-life instruments that were neither sensitive nor specific for breast reconstruction. We may conclude that published data on quality of life in women after breast reconstruction are inconsistent and point out various limitations.

The aim of this cross-sectional study was to determine whether successful breast reconstruction improves quality of life in women following mastectomy. For that, we performed a survey among women who underwent surgery for breast cancer at our university hospital and compared the quality of life in women with breast reconstruction to women with mastectomy alone. In addition to the RAND-36, we used the recently published BREAST-Q questionnaire to appraise the outcome of breast reconstruction as perceived by the patients themselves.\textsuperscript{14} This is currently one of the few instruments in reconstructive breast surgery that meets international standards in terms of development and validation.\textsuperscript{15} Naturally, we were also interested in learning of our patients’ experiences. This knowledge would empower the future breast cancer sufferers and enable them to make a more informed decision. This decision would rely on an evidence-based protocol designed according to the patient’s psychological and social needs.

PATIENTS AND METHODS

Study Population

The study population consisted of women who had undergone mastectomy for either breast cancer or prophylaxis resulting from genetic predisposition. These patients were treated at the University Medical Center Groningen between 2006 and 2010. The patient selection procedure is shown in Figure 1. The study population consisted of two groups of women: mastectomy alone and mastectomy with successful breast reconstruction. We received approval from the medical ethics committee before conducting the study.

The inclusion criteria included female breast reconstruction patients, mastectomy patients (unilateral or bilateral), patients with a good understanding of the Dutch language, and signed consent. We excluded patients younger than 18 years, severely ill patients, women who were legally incompetent, and women who did not sign the consent form; also, 12 patients were excluded because of flap or prosthesis loss. In these patients, emotional trauma and disappointment were clear. We considered it unethical to ask women with failed reconstruction to answer questions about the new reconstructed breast.

The initial number of patients considered for the study was 301. As depicted in the flow diagram, 264 of them were deemed eligible and thus approached to participate in the study. Of the 264 patients, 139 women had undergone mastectomy and a breast reconstruction, whereas 125 women had only mastectomy performed. We received signed informed consent from 149 subjects; nonetheless, 12 were still excluded as detailed in the flow diagram. Thus, a total of 137 patients with completed questionnaires and consent forms were included: 92 subjects with breast reconstruction and 45 in the mastectomy-alone group.

Methods

Clinical data were retrieved using digital patient recording by Poliplus software (Poliplus Software, Waterloo, Ontario, Canada). Where necessary, we turned to paper-based documentation. Demographic information (Table 1) such as employment, educational level, marital status, and the time interval since last treatment were obtained using the demographic questionnaire formerly used in the study by van den Beuken-van Everdingen et al.\textsuperscript{16} In addition, all patients completed the Hospital Anxiety and Depression Scale\textsuperscript{17,18} and a Dutch language version of the Concerns About Recurrence Scale.\textsuperscript{19} The Hospital Anxiety and Depression Scale appears to be a good means of assessment of anxiety disorder (Cronbach alpha, 0.68 to 0.93) and depression (Cronbach alpha, 0.67 to 0.90).\textsuperscript{18} The Dutch language version of the Concerns About Recurrence Scale measures the influence of fear of cancer recurrence on the quality of life in women with breast cancer.\textsuperscript{19} Comorbidities noted included diabetes mellitus, fibromyalgia, hypertension, and psychological instability. American Society of Anesthesiologists classification was noted. In addition, we used tumor, node, metastasis staging. To further condense our population, we divided the tumors into two categories: stage 0 to IIB and stage III to IIIC. Two self-reported questionnaires were used to measure the quality of life in our patients: the BREAST-Q and the RAND-36.
BREAST-Q

The BREAST-Q patient-reported outcome instrument is designed to gauge the impact of mastectomy and breast reconstruction on quality of life and satisfaction, from the patient’s perspective. The BREAST-Q reconstruction module (postoperative) consists of nine scales. The BREAST-Q mastectomy module (postoperative) consists of five scales. Each scale consists of three to five items. The score from each scale is transferred into a 100-point scale. Thus, each scale displays a score from 0 (very dissatisfied) to 100 (very satisfied). The BREAST-Q reconstruction module has good internal consistency (Cronbach alpha, 0.88)

Fig. 1. Patient selection flow diagram.
The BREAST-Q mastectomy module was only recently released. However, we understand that this is similar to the reconstruction module. Before commencing the study, the questionnaires had a Dutch translation validated in accordance with the agreement with the MAPI Trust (http://www.mapi-trust.org/). The translated version was approved by Pusic, the author of the BREAST-Q.

**RAND 36-Item Health Survey**

The RAND-36 questionnaire consists of 36 items for assessing various topics related to health and quality of life concentrated under eight domains: physical functioning, physical role functioning, emotional role functioning, vitality, mental health, social role functioning, bodily pain, and general health. The Dutch translation has been validated. The internal consistency of the domains is high (Cronbach alpha, 0.71 to 0.92).

**Statistical Analysis**

To present baseline characteristics, we distinguished the following groups of women: prophylactic mastectomy alone, reconstruction following prophylactic mastectomy, therapeutic mastectomy alone, and reconstruction following therapeutic mastectomy.
mastectomy. We used the medians and ranges or proportions. Multivariate analysis made a distinction between mastectomy alone and reconstruction. The data on the BREAST-Q and the RAND-36 were presented by means and standard deviations. Differences on the BREAST-Q and the RAND-36 between mastectomy alone and reconstruction were tested by using linear regression modeling. For each dimension of the BREAST-Q and the RAND-36, we compared mastectomy alone versus reconstruction. To adjust for differences in baseline to each comparison, the covariates as measured at baseline were added, and in case of any significant effect, these covariates were included in the model. In these multiple models, the variables mastectomy and reconstruction were always included. The regression analyses were tested with a 95 percent confidence interval and a 5 percent significance level ($\alpha = 0.05$) (Table 2). The statistical analysis was performed using SPSS version 18.0 (SPSS, Inc., Chicago, Ill.). Lastly, we reviewed all recorded intraoperative and postoperative complications in both groups.

### RESULTS

This cross-sectional study compared two cohorts in which 45 women underwent mastectomy alone and 92 women underwent successful breast reconstruction. The overall response rate was 56.44 percent (149 of 264). Only two women preferred to undergo mastectomy alone for preventive indications (Table 1). The median age was 50.5 years at the time of completing the questionnaires. At the time of mastectomy, both subjects were aged 47 years. Both had $BRCA1$ or $BRCA2$ gene abnormality and both underwent bilateral mastectomy. However, 26 women underwent prophylactic mastectomy and reconstruction. The median age of the patients at the time of completing the questionnaire was 43 years (range, 26 to 57 years). The median age of the patients at the time of mastectomy was 40.5 years (range, 25 to 54 years). Existing comorbidity was noted in 11.5 percent of patients. The median body mass index at the time of reconstruction was 23 kg/m$^2$ (range, 20 to 34 kg/m$^2$). All women had a bilateral mastectomy. $BRCA1$ or $BRCA2$ gene mutation

<table>
<thead>
<tr>
<th>Variables†</th>
<th>$\beta$</th>
<th>SE</th>
<th>95% CL for $\beta$</th>
</tr>
</thead>
<tbody>
<tr>
<td>BREAST-Q</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfaction with breasts‡</td>
<td>None</td>
<td>10.12</td>
<td>3.33</td>
</tr>
<tr>
<td>Psychosocial well-being‡</td>
<td>None</td>
<td>8.89</td>
<td>3.29</td>
</tr>
<tr>
<td>Sexual well-being‡</td>
<td>None</td>
<td>11.59</td>
<td>4.26</td>
</tr>
<tr>
<td>Physical well-being: breast region</td>
<td>Unilateral or bilateral mastectomy; partner</td>
<td>4.55</td>
<td>2.88</td>
</tr>
<tr>
<td>Satisfaction with the surgeon‡</td>
<td>Chemotherapy</td>
<td>11.34</td>
<td>3.02</td>
</tr>
<tr>
<td>Satisfaction with the medical team</td>
<td>Unilateral or bilateral mastectomy; education</td>
<td>1.99</td>
<td>3.56</td>
</tr>
<tr>
<td>Satisfaction with the administration team</td>
<td>Age at completion of questionnaires; education</td>
<td>4.87</td>
<td>4.14</td>
</tr>
<tr>
<td>RAND-36</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical functioning†</td>
<td>Comorbidity</td>
<td>7.65</td>
<td>3.00</td>
</tr>
<tr>
<td>Social functioning</td>
<td>Comorbidity; partner</td>
<td>1.61</td>
<td>3.08</td>
</tr>
<tr>
<td>Physical role problem</td>
<td>Time interval between the last operation and questionnaires completed; comorbidity: $BRCA$ mutation</td>
<td>7.47</td>
<td>6.44</td>
</tr>
<tr>
<td>Emotional role problem</td>
<td>Comorbidity; TNM staging</td>
<td>−0.07</td>
<td>7.45</td>
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<tr>
<td>Mental health</td>
<td>Partner</td>
<td>2.86</td>
<td>2.53</td>
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<tr>
<td>Vitality</td>
<td>Comorbidity</td>
<td>−1.82</td>
<td>3.11</td>
</tr>
<tr>
<td>Pain†</td>
<td>BMI &gt; 30</td>
<td>9.73</td>
<td>3.56</td>
</tr>
<tr>
<td>General health</td>
<td>Comorbidity</td>
<td>6.05</td>
<td>3.36</td>
</tr>
<tr>
<td>Health change</td>
<td>None</td>
<td>−5.44</td>
<td>4.64</td>
</tr>
</tbody>
</table>

$\beta$, coefficient for main effect (mastectomy alone)/reconstruction in the model; SE, standard error for $\beta$; CL, confidence limits; TNM, tumor, node, metastasis; BMI, body mass index.

*Coded as 0 for mastectomy alone and 1 for reconstruction.

†Variables are the variables included in the model except the main effect (mastectomy alone/reconstruction), age at mastectomy, age at breast reconstruction, age when quality of life reported, period between mastectomy and breast reconstruction in months, time between breast reconstruction and reporting quality of life, mastectomy indication, tumor/node/metastasis classification, comorbidity, body mass index, body mass index > 30, smoking, radiotherapy, chemotherapy, unilateral or bilateral mastectomy, unilateral or bilateral breast reconstruction, $BRCA$, primary/secondary breast reconstruction, education level, partner, nipple reconstruction, areola reconstruction, complications (asymmetry, scar, seroma, ptosis, wound healing), and secondary corrections.

†Statistically significant.
was detected in 88.5 percent of the subjects in the said group.

Forty-three women had mastectomy alone for malignant disease (Table 1). Reconstruction following mastectomy for malignant indications was performed in 66 women. Patients undergoing only mastectomy had a significantly higher median age (58.0 years; range, 40 to 76 years) at the time of completing the questionnaire ($p < 0.001$) than subjects in the breast reconstruction group (50.0 years; range, 26 to 78 years). Also, the age at the time of mastectomy in the former group was significantly higher ($p < 0.001$) (57.0 years; range, 38 to 74 years) than in the reconstruction group (45.5 years; range, 21 to 72 years). Despite some differences in scores between mastectomy-alone and the reconstruction group, neither the Hospital Anxiety and Depression Scale nor the Dutch language version of the Concerns About Recurrence Scale produced any significant results. However, 73 percent of the mastectomy-alone group did not consider reconstruction.

No measured variables could explain the higher score of patients with reconstruction on satisfaction with breasts, psychosocial well-being, and sexual well-being (Table 2). Patients with mastectomy alone were less satisfied with their surgeon than breast reconstruction patients, regardless of whether the patients received chemotherapy or not. Breast reconstruction patients had a higher score on physical functioning, regardless of whether their body mass index was greater than 30 or not.

Table 3 details the score of both the BREAST-Q and RAND-36 questionnaires. The score for satisfaction with breasts was a mean of 60.3 in the mastectomy-alone group, whereas in the breast reconstruction group this value was statistically significantly higher (70.5; $p = 0.003$). Similarly, the score for psychosocial well-being was a mean of 66.6 in the former group. This value was again statistically significantly higher in the latter group (75.5; $p = 0.008$). Breast reconstruction patients reported less pain regardless of whether their body mass index was greater than 30 or not.

Breast reconstruction patients showed a lower score on physical functioning, regardless of whether the patients had a comorbidity or not. The scores for subgroups with therapeutic indications had similar significant differences in the same areas of the BREAST-Q, as in comparison between the mastectomy and the reconstruction groups. Comparing results from the RAND-36 questionnaire, two important domains showed a marked difference between the mastectomy and the reconstruction groups. Both physical functioning and pain domain scores were higher with breast reconstruction. These results were statistically significant ($p = 0.012$ and $p = 0.007$, respectively). In other areas, striking differences were not observed between the two groups, as detailed in Table 3.

We looked at complications (e.g., bleeding, seroma formation, delayed wound healing)
associated with mastectomy itself. The incidence of such complications was comparable between the two groups. However, as expected, additional complications were identified directly as a result of breast reconstruction. The most notable complications were related to the anastomosis, partial or total flap necrosis, and the loss of prosthesis. In total, 12 patients (7.9 percent) were excluded because of flap loss (five patients) and implant loss (seven patients).

**DISCUSSION**

Women with successful breast reconstruction were significantly more satisfied with the appearance of their chest/breasts \( (p = 0.003) \). They also fared better psychosocially \( (p = 0.008) \) and sexually \( (p = 0.007) \) than women with mastectomy alone. Furthermore, they functioned better physically \( (p = 0.012) \), experiencing less pain and fewer limitations \( (p = 0.007) \).

Mastectomy is potentially a very traumatic event. Besides immediate concerns over health and longevity associated with breast cancer, patients most likely agonize over their future appearance, social interactions, and sexual life. For these women, breast reconstruction is proposed as a possible solution. In this study, we investigated whether there was a difference in satisfaction and quality of life between women with mastectomy alone and women with mastectomy and successful breast reconstruction. Among the self-report questionnaires, the BREAST-Q in particular added extra strength to this study, as it is currently the only validated, condition-specific instrument for breast reconstruction surgery.

A previous systematic literature review by Lee et al. could not find any evidence of disparity in satisfaction between patients with mastectomy alone and those undergoing breast reconstruction. However, they do point out the various limitations associated with most studies that make it very doubtful whether the above conclusion is justified. The results from our questionnaires do conclude that women with breast reconstruction are more satisfied with their appearance than women with only a mastectomy. They are also more content with their psychosocial and sexual well-being. Physical functioning in women following breast reconstruction was superior to that in patients with a mastectomy alone. Furthermore, they also experienced less pain and disability. These observations emphasize our proposition that breast reconstruction does facilitate breast cancer sufferers to better cope with various aspects of their lives following completion of their treatment.

In general, women with breast cancer surgery are content with the medical care they receive. However, in our study, breast reconstruction patients were more satisfied with their breast surgeon than were women with mastectomy alone. Nonetheless, this discrepancy may be because comparison is being drawn between possibly two different subspecialties and at different stages of treatment. The systematic review by Guyomard et al. has reported high satisfaction rates with breast reconstruction, but the authors advised that more robust and evidence-based research is needed with validated quality-of-life measures.

Whether unilateral or bilateral breast reconstruction was undertaken also influenced the results in various domains of the BREAST-Q. This can be explained by the possible resultant asymmetry. Waljee et al. drew a similar conclusion, emphasizing the importance of breast symmetry or the lack of it in psychosocial functioning of breast reconstruction recipients.

Educational level also correlated with satisfaction with the overall outcome. In our study, women with low educational background were more satisfied with the outcome than women with higher education. Similar findings were reported by Medina-Franco et al. Perhaps patients with higher education have a higher expectation from breast reconstruction procedures.

We found that chemotherapy affected the BREAST-Q score. Although the comorbidity affected the RAND-36 scores, patients with reconstruction had a higher score on physical functioning. Patients who were overweight (body mass index > 30) and underwent reconstruction reported less pain. Lower quality of life is associated with the presence of other diseases. This may be explained by the fact that those parts of questionnaires focused on the overall picture of the patient’s condition; they were not designed specifically for breast reconstruction surgery.

This study has some limitations. To begin with bias by indication, the reconstruction technique and study population were not randomized. However, randomization would have been difficult, because it is the patient who will make the decision on reconstruction. We identified only two BRCA-positive patients, who chose to undergo mastectomy alone without reconstruction. Therefore, we decided to include prophylactic and therapeutic mastectomy patients in one group and performed multivariate regression analyses to control for differences in our population. The sample size was not sufficient to control for all biases. However, the power of the outcome “satisfaction with breasts”
was 80 percent. A total of 115 women chose not to participate in this study. Their reasons and their characteristics were not clear. We cannot exclude that the nonparticipation might have influenced the findings in this study. The low response rate (56.44 percent) could be a potential selection bias. Furthermore, we excluded 12 patients who had flap or implant loss. However, features of failed breast reconstruction patients did not match the features of the breast reconstruction group. The BREAST-Q is a condition-specific instrument, and the reconstruction module measures satisfaction with questions about the breast (e.g., softness, size, implant). We found it inappropriate to ask women those questions after such a traumatic event. The quality-of-life study of Bellino et al. excluded patients with cancer recurrences and subjects with breast reconstruction complications. Zhong et al. reported a 20 percent rate of major postoperative complications, but no flap loss. After adjusting for complications, the gains in satisfaction with breast, psychosocial well-being, and sexual well-being remained significant.

The study reflects findings from a single institution treating a homogenous population. However, “homogenous population” can be considered as an advantage. In contrast, a multicenter study targeting various ethnic groups would add weight to our findings. Furthermore, we had little information on the emotional background of our patients. The median time between surgical intervention and completion of the questionnaire was 24 months (range, 4 to 52 months). The analysis showed that the time effect was not significant. The retrospective nature of our study could not possibly record the likely variations in perceived quality of life over time. Some women are still in the process of nipple reconstruction or nipple tattooing or are awaiting secondary correction. However, nipple reconstruction showed a positive effect on satisfaction. Previous studies have revealed that the time elapsed since surgery influences the quality of life in women with breast surgery. Therefore, we currently are conducting a prospective study in which patients periodically complete a questionnaire. Nonetheless, to the best of the authors’ knowledge, the BREAST-Q has never been used to evaluate satisfaction and quality of life in patients following mastectomy alone or combined with breast reconstruction. Furthermore, combining the validated BREAST-Q with the RAND-36, the Hospital Anxiety and Depression Scale, and the Dutch language version of the Concerns About Recurrence Scale in one study is also unique.

CONCLUSIONS

Breast reconstruction, in its various forms, has become an appropriate option offered to women diagnosed with breast cancer. Breast reconstruction may be accomplished in one sitting, but more often than not, it is a multistage process. As such, many months may lapse before the final intended aesthetic result is achieved. It may also be associated with additional surgical complications and higher costs. However, it is evident that patients do benefit from breast reconstruction following mastectomy. Of course, careful patient selection and ample patient education are important in empowering patients to make an informed decision in view of their treatment plan. Larger, more comprehensive studies are needed; nevertheless, results from this study will be helpful to both care providers and patients during that decision process.

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