

# Prophylactic Mastectomy and Reconstruction: Clinical Outcomes and Patient Satisfaction

Scott L. Spear, M.D.  
Karl A. Schwarz, M.Sc., M.D.  
Mark L. Venturi, M.D.  
Todd Barbosa, B.Sc.  
Ali Al-Attar, M.D., Ph.D.

Washington, D.C.

**Background:** The purpose of this study was to evaluate both clinical outcomes and satisfaction in patients who have undergone prophylactic mastectomy and breast reconstruction.

**Methods:** A 5-year retrospective analysis of the senior author's (S.L.S.) experience with breast reconstruction following prophylactic mastectomy was performed. Timing, type of mastectomy and reconstruction, complications, and cancer occurrence/recurrence were examined. Patients reported their level of satisfaction and willingness to undergo the procedure again. Aesthetic outcomes were graded by an independent and blinded group of surgeons.

**Results:** There were 101 breast reconstructions performed in 74 patients following prophylactic mastectomy. With a mean follow-up of 31 months, there were three breast-site complications in this group (3 percent). Forty-seven patients in the study had a unilateral prophylactic mastectomy; on the contralateral side with cancer, there were five breast-site complications in reconstructions following therapeutic mastectomy (10 percent). Aesthetic outcome ratings by surgeons were higher in the bilateral prophylactic mastectomy and reconstruction patients compared with the cancer patients who had undergone a therapeutic mastectomy and reconstruction along with a contralateral prophylactic mastectomy; however, this difference did not reach statistical significance. Patient satisfaction was higher in the bilateral prophylactic group, with all of the patients completing the survey stating they would undergo the procedure again.

**Conclusions:** Breast reconstruction following prophylactic mastectomy was as safe as or more safe than that following therapeutic mastectomy, which has been shown in other studies to result in a high percentage of patient satisfaction. Although not statistically significant, the results from reconstruction after prophylactic mastectomy trended toward improved aesthetic outcome with a lower complication rate compared with reconstruction after therapeutic mastectomy. (*Plast. Reconstr. Surg.* 122: 1, 2008.)

**R**isk reduction or prophylactic mastectomy continues to attract increased interest by patients and physicians as more studies document its efficacy in reducing the risk of developing breast cancer by 90 percent or more.<sup>1-5</sup> Prophylactic mastectomy has been found to be effective in various patient populations, including those carrying the breast cancer-related genes *BRCA1* and *BRCA2*, and as a contralateral procedure in patients with breast cancer.<sup>2,4-9</sup> Prophylactic mas-

tectomy offers a number of advantages over more conservative therapy, including (1) a more comprehensive risk reduction, (2) the expectation for improved sense of well-being (because of decreased worry about breast cancer occurrence/recurrence), and (3) the potential for optimal cosmetic outcome and patient self-image.<sup>10-14</sup>

Although great advances have been made in identifying women at increased risk of developing breast cancer,<sup>15-18</sup> only a limited number of studies have addressed the technical issues surrounding

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the operation as it is currently practiced and its outcomes.<sup>3,14,19</sup> Critical questions relating to the choice of type of reconstruction, types and frequency of complications, aesthetic outcome, and patient satisfaction need further elucidation to help surgeons and patients better understand this rapidly evolving subject to make better informed decisions.

This study is a retrospective analysis of the senior author's (S.L.S.) experience with prophylactic mastectomy performed between 2000 and 2005. The 5-year period was chosen to provide data recent enough to be relevant to current practices and yet with sufficient follow-up for completion of the reconstruction, which often requires 6 to 12 months after the mastectomy. During this recent 5-year period, it was our impression that reconstruction for prophylactic mastectomy appeared to result in improved aesthetic outcomes and less frequent complications as compared with reconstruction after therapeutic mastectomy. To investigate these clinical suspicions, we undertook a survey of these affected patients and simultaneously collected data regarding outcomes, including complications. At the same time, aesthetic results were evaluated by blinded observers so that one group of patients could be simultaneously evaluated both objectively for risk and subjectively for appearance and satisfaction. The organized, retrospective data are presented here not as a final answer but as a step in forming the foundation for future studies on this increasingly important topic.

## PATIENTS AND METHODS

The records of all women who underwent mastectomy and immediate breast reconstruction at Georgetown University Hospital from January 1, 2000, through December 31, 2005, were reviewed. All patients whose mastectomy was prophylactic on one or both sides were identified. The type of mastectomy was classified as simple or nipple-sparing. Short-term outcomes were evaluated by tracking perioperative complications of either device-related or autologous tissue reconstructions. The unilateral prophylactic mastectomy group was used to compare complication rates between the breast reconstruction after prophylactic and therapeutic mastectomy. Donor-site complications were excluded. Clinical (aesthetic) outcomes were scored by a group of 14 blinded, independent surgeons in residency training. Surgeons were shown photographs that represented a final, stable surgical outcome for each patient, and were blinded to the type of surgery and reconstruction. Scoring was performed using a four-point scale,

and raters were asked to evaluate breast overall appearance, shape, position, and symmetry. Raters were advised to give a single comprehensive score of 4 for an "excellent result," 3 for a "good result," 2 for an "adequate result," and 1 for a "poor result." Patients were tracked by hospital records of their addresses and telephone numbers. Long-term patient outcomes were investigated by chart review and by mailing questionnaires to all identified patients, in which they were asked about complications and problems they perceived with their reconstruction. Patients were also asked to describe their level of satisfaction with the reconstruction, and whether they would choose to undergo the procedure again. To evaluate level of satisfaction, the questionnaire simply asked patients whether they were "highly satisfied," "very satisfied," "moderately satisfied," "satisfied," "disappointed," or "very disappointed" with their reconstruction. Note that although the patient questionnaire presents an asymmetric scale for satisfaction, with four of the six options representing some degree of satisfaction, it still did offer two options to express dissatisfaction. An effort was made to confirm the addresses of the nonresponding patients, and attempts were made to contact nonresponders a second time.

Complication incidence data are noncontinuous and are not assumed to be normally distributed with equal variances. Statistical analysis was performed using the Fisher's exact test for comparative evaluation of complications between reconstructions following prophylactic versus therapeutic mastectomy. Patient satisfaction data were derived from the mailed, asymmetric, six-point questionnaire. The data are nominal and noncontinuous, and the Kolmogorov-Smirnov test for two populations was used to analyze the difference. Independent surgeon scoring of aesthetic outcomes also resulted in nominal, noncontinuous scores; the median scores were compared using the Kruskal-Wallis test.

## RESULTS

From 2000 to 2005, reconstructions for 101 prophylactic mastectomies were performed in 74 patients by the senior author (S.L.S.). Forty-seven patients (64 percent) had unilateral prophylactic mastectomies; in 27 patients (36 percent), the procedure was bilateral. In patients undergoing unilateral prophylactic mastectomy, the contralateral side was performed as a therapeutic mastectomy. Table 1 summarizes the procedure characteristics, including whether the prophylactic mastectomy was unilateral or bilateral, the type of mastec-

**Table 1. Summary of Procedure Characteristics\***

	No. of Breasts	No. of Patients
No. of reconstructions	101	74
Unilateral vs. bilateral		
Unilateral prophylactic mastectomy	47	47
Bilateral prophylactic mastectomy	54	27
Type of mastectomy		
Simple	73	58
Nipple-areola complex sparing	28	16
Timing of reconstruction		
Immediate	91	66
Delayed	10	8
Type of reconstruction		
Tissue expander/implant	71	51
TRAM (free or pedicled)	20	16
Latissimus dorsi (with tissue expander/implant)	10	7

TRAM, transverse rectus abdominis musculocutaneous.

\*Including whether the prophylactic mastectomy was unilateral or bilateral, the type of mastectomy performed, and the timing and type of reconstruction.

tomy performed, and the timing and type of reconstruction.

The majority of these prophylactic mastectomy procedures (73 breasts in 58 patients) were performed as simple “skin-sparing” mastectomies—that is, including all glandular breast tissue and an ellipse of skin surrounding the nipple-areola complex, and the nipple-areola complex itself. The remaining 28 breasts (12 bilateral and four unilateral) underwent nipple-areola complex-sparing mastectomy, which is intended to remove as nearly as possible the same quantity of breast tissue as any therapeutic mastectomy but leaves behind the skin of the nipple-areola complex along with a minimal disk of breast tissue immediately underneath it.

Of the reconstructive procedures performed for patients, immediate reconstruction was selected by 66 of the patients, and delayed reconstruction was selected by the remaining eight patients (all unilateral prophylactic mastectomies). The majority of the women, 51 of the 74, had reconstruction with tissue expanders followed by implants. Of the 23 patients undergoing autologous reconstruction, 16 had transverse rectus abdominis musculocutaneous (TRAM) flaps (pedicled or free) and seven had latissimus dorsi flaps combined with tissue expanders and then implant exchange. Only one of the patients undergoing TRAM flap reconstruction had a nipple-sparing mastectomy; the procedure was bilateral in this patient. Only one of the latissimus dorsi reconstruction patients had a nipple-sparing mastectomy; this procedure was in a patient undergoing unilateral prophylactic mastectomy. In the aes-

thetic assessment by blinded observers, the median score for all patients was 3 of a possible 4 points. The median scores were 3 for both groups—those patients who underwent bilateral prophylactic mastectomy with reconstructions and those patients whose prophylactic procedures were unilateral.

Forty-three surveys of the 74 sent out were returned with responses. For nonresponders, efforts were made to confirm the correct mailing address and recontact the patients. Patients were queried about their degree of satisfaction using an asymmetric six-point scale as outlined earlier under Patients and Methods. Of the 11 patients who responded who underwent reconstruction following bilateral prophylactic mastectomy, all were satisfied (eight were “highly satisfied,” two were “very satisfied,” and one was “moderately satisfied”). Of the 32 survey responders who had reconstruction following unilateral prophylactic mastectomy, 30 of 32 were satisfied (17 were “highly satisfied,” eight were “very satisfied,” four were “moderately satisfied,” and one was “satisfied”). Only two were “disappointed” with their reconstructions. Patients were also asked whether they would undergo the reconstruction again. All respondents who had reconstruction following bilateral prophylactic mastectomies stated they would do so again. Of the 32 patients who responded who had a unilateral prophylactic mastectomy, 31 said they would have the procedures performed again. Table 2 reviews patient responses following both unilateral and bilateral prophylactic mastectomy. Although the trend suggests that those patients undergoing reconstruction following bilateral prophylactic mastectomy were more satisfied, the differences are not statistically significant, and neither is the difference in those willing to undergo reconstruction again.

Complication rates were recorded in patient charts and confirmed by responses on patient surveys. Complications were divided into breast-site and donor-site complications. A total of three breast-site complications were reported for the 101 breasts reconstructed following prophylactic mastectomy; all three complications occurred in patients undergoing unilateral prophylactic mastectomy (with a contralateral therapeutic mastectomy with reconstruction). Two patients who underwent skin-sparing mastectomies had infections; one patient underwent reconstruction with a tissue expander, and the second underwent reconstruction with a latissimus dorsi flap with a tissue expander. A third patient, who underwent nipple-areola complex-sparing

mastectomy followed by free TRAM flap reconstruction, had necrosis of the mastectomy flap. In addition, six patients had flap donor-site complications, all of which were seromas at the donor sites. Table 3 lists the breast-site complications in patients undergoing reconstruction following prophylactic mastectomies, by the types of reconstruction and resultant complications.

The 47 patients who had unilateral prophylactic mastectomies had therapeutic mastectomies with reconstructions performed on the other breast. Breast-site complications in reconstructions following therapeutic mastectomy occurred in five patients. The five breast-site complications were one hematoma, one cellulitis, one mastectomy flap necrosis, one partial flap necrosis, and one case of delayed healing of the nipple-areola complex. All complications occurred in reconstructions performed in an immediate fashion. In addition, seven donor-site complications occurred in reconstructions following therapeutic mastectomies; these donor-site complications were all seromas or hematomas.

All breast-site complications in reconstructions following prophylactic mastectomies or therapeutic mastectomies in this study are listed in Table 4. In this study, reconstructions following prophylactic mastectomy had a global breast-site complication rate of 3 percent; those following therapeutic mastectomy had a global breast-site complication rate of 10 percent. Note that this table only lists breast-site complications and does not include donor-site complications (of which all were seromas or hematomas that resolved nonoperatively). Although there was a difference in complication rates between reconstructions following prophylactic (3 percent) versus therapeutic (10 percent) mastectomy, this difference was not statistically significant ( $p = 0.065$ ).

Among all patients, no reconstructions failed and all of the complications were minor, self-limited, and managed in the outpatient setting without the need for hospitalization or reoperation. There were no deaths, and with a mean follow-up of 31 months (range, 2 to 29 months), there were no reported subsequent occurrences of cancer in

**Table 2. Patient Satisfaction with Reconstruction According to Whether the Prophylactic Reconstruction Was Unilateral or Bilateral\***

	Prophylactic Mastectomy		
	Unilateral ( $n = 32$ ) (%)	Bilateral ( $n = 11$ ) (%)	Total ( $n = 43$ ) (%)
Highly satisfied	17 (53)	8 (73)	25 (58)
Very satisfied	8 (25)	2 (18)	10 (23)
Moderately satisfied	4 (13)	1 (9)	5 (12)
Satisfied	1 (3)	0	1 (2)
Disappointed	2 (6)	0	2 (5)
Very disappointed	0	0	0
Willing to undergo reconstruction again	31 (96)	11 (100)	42 (98)

\*Contralateral therapeutic mastectomy was performed in patients undergoing unilateral prophylactic mastectomy.

**Table 3. Complications following Reconstruction after Prophylactic Mastectomy\***

Patient	Prophylactic Mastectomy	Reconstruction	Timing	Complication
1	Skin sparing	Tissue expander	Immediate	Hematoma and infection
2	Nipple-areola complex sparing	Free TRAM flap	Immediate	Mastectomy flap necrosis
3	Skin sparing	Latissimus dorsi flap and tissue expander	Delayed	Infection

\*All prophylactic mastectomy reconstruction complications were in patients who underwent unilateral prophylactic mastectomies (with a contralateral therapeutic mastectomy).

**Table 4. Complications in Reconstruction following Prophylactic versus Therapeutic Mastectomy\***

Reconstruction	Prophylactic Mastectomy		Therapeutic Mastectomy	
	No. of Complications	No. of Breasts	No. of Complications	No. of Breasts
Tissue expander/implant	1	71	2	28
TRAM flap	1	20	2	12
Latissimus dorsi with or without tissue expander	1	10	1	7
Total	3 (3%)	101	5 (10%)	47

\*The difference between the two groups is not statistically significant ( $p = 0.065$ ). Note that the listed complications only relate to those at the breast; donor-site complications (all of which were seromas or hematomas) are not included in this table.

any breast, nor was there any metastatic disease following prophylactic mastectomy. Figures 1 through 5 are representative photographs of patients following the plateau of their clinical course.

### DISCUSSION

The intent of this review was to critically examine reconstruction after prophylactic mastectomy from multiple perspectives and to look at how it might differ from reconstruction after therapeutic mastectomy. To add to the complexity of this task, we hoped to compare unilateral to bilateral prophylactic procedures and nipple-areola complex-sparing versus simple mastectomies. Despite the belief by many that prophylactic mastectomy should include removal of the nipple,<sup>20</sup> the landmark article by Hartmann and colleagues at the Mayo Clinic on the risk-reduction benefits of

prophylactic mastectomy included mostly nipple-sparing procedures.<sup>5</sup>

This topic has achieved increasingly critical importance for several reasons. To begin with, with the publications by Hartmann et al. and others, we have substantial evidence from multiple sources that prophylactic mastectomy reduces the risk of breast cancer in high-risk populations by 95 percent.<sup>2,4,5,8,9</sup> At the same time, we have improved methods of identifying patients at high risk either through genetic testing or computer modeling using various risk factors.<sup>15-18,21-25</sup>

What we do not have is a clear understanding of how reconstruction in these patients is similar to or different from reconstruction in patients after therapeutic mastectomy. Although it would be tempting, if not desirable, to compare similar or matched groups, the reality is that they are probably not similar or matchable, and that is one



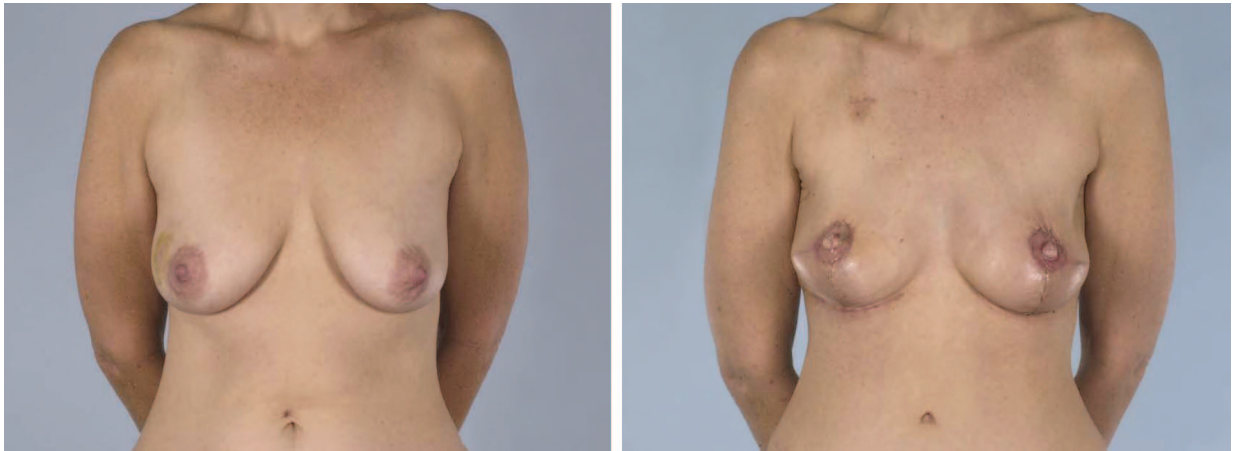
**Fig. 1.** A 51-year-old woman with unilateral, invasive ductal breast cancer underwent bilateral simple (skin-sparing) mastectomies and immediate reconstruction with bilateral free TRAM flaps. She was very satisfied with the result.



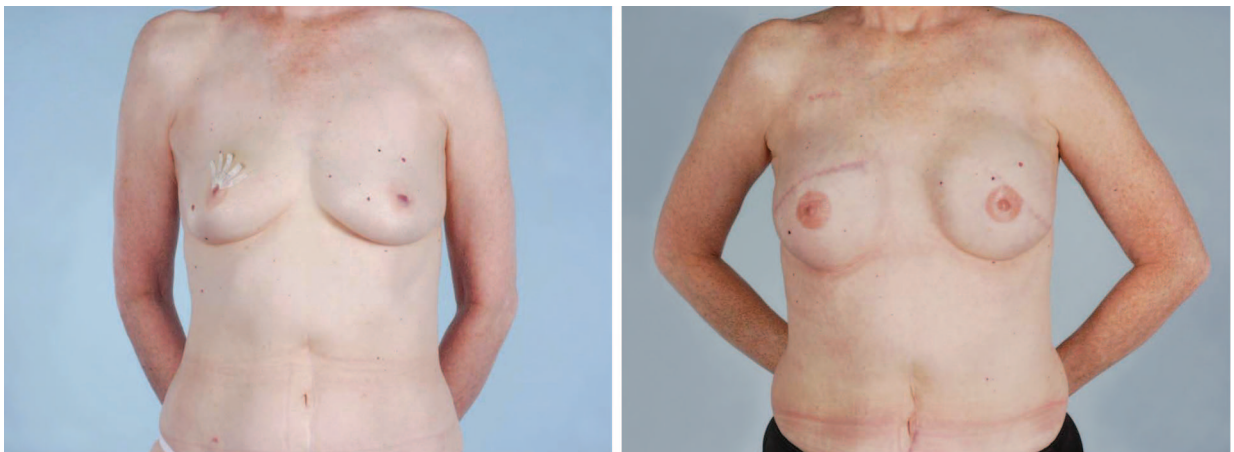
**Fig. 2.** A 43-year-old woman underwent bilateral prophylactic nipple-areola complex-sparing mastectomies and immediate two-stage reconstruction with tissue expanders followed by implants. She was highly satisfied with the result.



**Fig. 3.** A 42-year-old woman underwent bilateral prophylactic mastectomies and immediate two-stage reconstruction with bilateral latissimus flaps and tissue expanders followed by implants. Free nipple grafts were used. She was very satisfied with the result.



**Fig. 4.** A 45-year-old woman with unilateral, invasive ductal breast cancer underwent bilateral skin-sparing mastectomies and immediate bilateral reconstruction with TRAM flaps. Nipple reconstructions were also performed. She was disappointed with the result.



**Fig. 5.** A 54-year-old woman with a history of unilateral lobular breast cancer underwent bilateral skin-sparing mastectomies and immediate two-stage reconstruction with tissue expanders and AlloDerm (LifeCell Corp., Branchburg, N.J.), followed by implants. Bilateral nipple reconstruction and tattooing were later performed. She was highly satisfied with the result.

of the areas to consider in this report. To begin with, women with a diagnosis of breast cancer do not have the same latitude of choice as women without breast cancer but who are at high risk. Women with breast cancer are likely to undergo chemotherapy, and an increasing number are having postmastectomy irradiation. Prophylactic mastectomy is more likely to occur in younger women, in whom the risk reduction benefit is more powerful.<sup>15,26,27</sup> Younger patients are more likely to be healthier and thinner than older patients. The fact that women considering undergoing prophylactic mastectomy are likely to be thinner and healthier than women after therapeutic mastectomy, and will not be undergoing chemotherapy or radiation therapy, is part of the analysis and does not negate the value of looking at outcomes in the prophylactic group as compared with the therapeutic group even though they are or might be disparate. A patient or a surgeon wanting to analyze the value of prophylactic mastectomy would want to know the data relevant to that patient population, not to the general population.

Another significant difference between therapeutic mastectomy and prophylactic mastectomy is the inherent elective nature of the latter. The timing is elective, the choice of reconstructive technique is entirely elective, and the choices for incision and the option for nipple-sparing or areolar-sparing procedures are also available. In these patients, neither the location of a tumor, nor the need for margins, nor the possibility of postmastectomy radiation therapy needs to be considered. This luxury of being an elective procedure provided the widest possible latitude in counseling patients, selecting patients, planning incisions, and choosing the reconstructive technique. Such latitude could and probably should provide the opportunity for improved results, lower risk, and higher patient satisfaction. As protocols for patient selection and reconstructive techniques have evolved rapidly over the past decade, previous reports of the aesthetic outcomes, complication rates, and patient satisfaction ratings following prophylactic mastectomy—in particular, nipple-sparing mastectomy—might seriously overestimate the risk and underestimate the potential for superior aesthetic results.

Patients had the opportunity to describe their level of satisfaction in this study following either unilateral or bilateral prophylactic mastectomies. Patients who underwent bilateral prophylactic mastectomy tended to report increased satisfaction compared with those who had unilateral prophylactic procedures, although the results did not

reach statistical significance. The lack of a statistically significant difference may be a result of the small numbers and low power of this study sample size. We suspect that continued studies at our institution, with larger sample sizes and more refined evaluative instruments, may well show that superior patient satisfaction and aesthetic outcome are more likely following a bilateral procedure.

Similarly, breast-site complication rates following prophylactic mastectomy were found in this study to be less than those on the therapeutic mastectomy side, although again these differences were not statistically significant. Given the elective nature of the prophylactic mastectomy, we suspect that as the number of patients increases we will find statistically significantly lower complication rates in those patients undergoing reconstruction following prophylactic rather than therapeutic mastectomy, and we believe that this difference will be more dramatic in the bilateral prophylactic group.

Perhaps the most striking data in this review are related to the overwhelmingly positive level of patient satisfaction, with 100 percent of our bilateral group being moderately or more satisfied and 91 percent of our unilateral group responding similarly. Although we are pleased with these high satisfaction levels, we also note that they are higher than those found in other previous studies.<sup>7,10–13</sup> The survey instrument used in this project depends on an asymmetric scale (four of the six possible responses offer a satisfied outcome and two offer a dissatisfied outcome), which might contribute to an elevated number of satisfied responses. However, following a theme from our earlier publication on this topic,<sup>14</sup> it also seemed likely that data on patient satisfaction are likely to be center- and even surgeon-specific, much like mortality rates after cardiac surgery. The sophistication required in managing these patients cannot be overemphasized: it involves multiple surgical teams, often requires serial operations, and requires not one but two successful outcomes that are also symmetric.

Although the complication rates in this study are quite low and compare favorably with other published reports, the critical message is that final outcomes and patient satisfaction are more important considerations than transient minor perioperative complications. Thus, for example, although we did not document perioperative pain as a complication, we believe it is far more important and informative that 98 percent of our unilateral

respondents and 100 percent of our bilateral respondents stated that they would undergo their procedures again. Similarly, the fact that all of the procedures were ultimately successful, and that the cosmetic results were favorable, we believe, is more important than that numerous patients experienced short-term complications (such as donor-site seromas) without long-term sequelae.

This study did not selectively evaluate outcomes in patients who underwent nipple-sparing mastectomy and was not sufficiently powered to do so. However, the preliminary findings from this study are encouraging and suggest that further investigation into this option is also warranted. The most notable advantage of the nipple-sparing mastectomy is the possible opportunity for a unique aesthetic outcome; the critical notable risk is whether there is clinical significance from the amount of breast tissue that is left behind. As is characteristic of all of medicine and of plastic surgery in particular, the treatment plan needs to be individualized to each patient, and an appropriate strategy in one patient might be unwise in a second. Defining the correct role of nipple-sparing mastectomy in breast cancer risk reduction, particularly with the rise of genetic testing and identification of women at elevated risk, is important in refining outcome information that can give patients and surgeons what they need to make informed decisions. The questions that need to be addressed for the nipple-sparing prophylactic procedure are: (1) What is the actual risk of breast cancer development in the residual tissue? (2) How effective or useful are surveillance modalities (such as breast clinical examination, ultrasound, mammography, and magnetic resonance imaging) at detecting cancer in any remaining breast parenchyma? (3) Does the potential for improved aesthetic outcome justify the theoretical risk of leaving the nipple?

## CONCLUSIONS

Whereas the oncologic benefits of prophylactic mastectomy have been well established, there remains a significant lack of appreciation of how effective the surgery and reconstructive strategies can potentially be in these patients. Although recommending or performing prophylactic mastectomy should always be done with circumspection if not reluctance, it comes with a potential profile of extremely high effectiveness in terms of cancer risk reduction, but

also excellent cosmetic results, low surgical risk, and high levels of patient satisfaction.

Scott L. Spear, M.D.

Department of Plastic Surgery  
Georgetown University Hospital  
3800 Reservoir Road N.W.  
Washington, D.C. 20007  
spears@gunet.georgetown.edu

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