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Nipple Reconstruction: Risk Factors and Complications after 189 Procedures

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Abstract

Background—A multitude of different approaches have been proposed for achieving optimal aesthetic results after nipple reconstruction. In contrast, however, only a few studies focus on the morbidity associated with this procedure, particularly after implant-based breast reconstruction.

Methods—Using a cross-sectional study design all patients who underwent implant-based breast reconstruction with subsequent nipple reconstruction between 2000 and 2010 at Stanford University Medical Center were identified. The aim of the study was to analyze the impact of the following parameters on the occurrence of postoperative complications: age, final implant volume, time interval from placement of final implant to nipple reconstruction, and history of radiotherapy.

Results—A total of 139 patients with a mean age of 47.5 years (range, 29 to 75 years) underwent 189 nipple reconstructions. The overall complication rate was 13.2 percent (N = 25 nipple reconstructions). No association was observed between age ($p = 0.43$) or implant volume ($p = 0.47$) and the occurrence of complications. A trend towards higher complication rates in patients in whom the time interval between final implant placement and nipple reconstruction was greater than 8.5 months was seen ($p = 0.07$). Radiotherapy was the only parameter that was associated with a statistically significant increase in postoperative complication rate (51.7 percent vs. 6.25 percent; $p < 0.00001$).

Conclusion—While nipple reconstruction is a safe procedure after implant-based breast reconstruction in patients without a history of radiotherapy, the presence of an irradiated field converts it to a high-risk one with a significant increase in postoperative complication rate. Patients with a history of radiotherapy should be informed about their risk profile and as a result may choose autologous reconstruction instead.

Level of Evidence—IV

Post-mastectomy breast reconstruction is considered complete after successful reconstruction of the nipple-areola complex (NAC). The influence of an appealing NAC on patient satisfaction has been demonstrated (1, 2). In fact, the NAC has been described as the defining element of the female breast (3). Reflecting the importance attributed to this procedure is a multitude of different approaches that have been proposed for achieving optimal aesthetic results (4–9). The overriding problem, however, has been an up to 75 percent loss of nipple projection over time (7). Thus, a particular focus of prior studies has been the development of techniques to overcome the tendency of nipple projection loss (10, 11).

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In stark contrast, there is a paucity of studies focusing on complications after nipple reconstruction (7, 12). No study has attempted to specifically identify risk factors associated with the occurrence of complications after nipple reconstruction.

By virtue of their limited soft tissue envelope, patients undergoing implant-based breast reconstruction are at particular risk for adverse events following nipple reconstruction. In the face of an ever-increasing incidence of breast cancer along with the fact that implant-based reconstruction represents the most common mode of reconstruction, plastic surgeons will increasingly face this particular patient population that demands nipple reconstruction (13, 14).

Given these trends, we were interested in identifying predictors of poor outcome in patients who underwent implant-based breast and subsequent nipple reconstruction.

Methods

The Stanford Translational Research Integrated Database Environment (STRIDE), which is a research and development project at Stanford University to create a standards-based informatics platform supporting clinical and translational research (15), was utilized to identify all patients who underwent mastectomy, implant-based breast reconstruction, and subsequent nipple reconstruction between 2000 and 2010 at Stanford University Medical Center. Institutional Review Board (IRB) approval was obtained prior to conducting the study. Only patients who underwent nipple reconstruction with local flaps were included in the study. Patients who underwent other modes of reconstruction, such as nipple-sharing, tattoo-only, etc. were excluded. Parameters retrieved included age, history of radiotherapy, final implant volume, time interval from placement of final implant to nipple reconstruction, length of follow-up, and occurrence of complications.

The aim of the study was to analyze the impact of the following parameters on the occurrence of complications: age, final implant volume, time interval from placement of final implant to nipple reconstruction, and history of radiotherapy.

Statistical analysis

Final data analysis was performed in STATA 9.0 (STATA Corporation, College Station, TX, 2006). Exploratory analyses of continuous data included histograms, means, and standard deviations for normally distributed data and medians and inter-quartile ranges for non-normally distributed data. The significance of the difference between two categorical variables was assessed using logistic regression analysis. For all statistical tests, a critical p-value of 0.05 was used.

Results

A total of 139 patients with a mean age of 47.5 years (range, 29 to 75 years) were included in the study. Unilateral and bilateral nipple reconstructions were performed in 89 and 50 patients, respectively (N = 189 nipple reconstructions). Twenty-nine patients had a history of chest wall radiation prior to nipple reconstruction. Of these, all patients underwent unilateral nipple reconstruction. The mean final implant volume was 450 cc (range, 120 to 870 cc). The mean time interval from final implant placement to nipple reconstruction was 8.5 months (range, 0 to 60 months). Mean follow-up time was 12.8 months (range, 1 to 72 months) (Table 1).

Complications were seen after 25 nipple reconstructions, thus, accounting for an overall complication rate of 13.2 percent (Figure 1). Of these, the vast majority was secondary to

infection (N = 21 [83 percent]). In almost half of these cases surgical intervention was indicated (N = 9 [42.9 percent]), consisting of implant exchange (N = 4), implant removal without further reconstruction (N = 3), and implant removal with subsequent autologous breast reconstruction (N = 2). Twenty-four percent (N = 6) of all complications were related to problems with wound healing (i.e. wound dehiscence [N = 1], delayed wound healing [N = 2], and nipple necrosis [N = 3]) (Figure 1). No case of implant loss, need for implant replacement or implant removal with subsequent autologous reconstruction was seen in non-irradiated patients.

Radiotherapy was the only parameter that was associated with a statistically significant increase in postoperative complication rate (51.7 percent vs. 6.25 percent; $p < 0.00001$) (Table 2).

No significant association was observed between age and the occurrence of complications after nipple reconstruction ($p = 0.43$) (Table 3). Similarly, implant volume did not display a significant association with complications ($p = 0.47$). Merely a trend was seen towards higher complication rates in patients with implants greater than 450 cc and a history of radiotherapy ($p = 0.1$) (Table 4). Another observed trend was a higher complication rate in patients in whom the time interval between final implant placement and nipple reconstruction was greater than 8.5 months (25 percent) vs. less than 8.5 months (10.1 percent) ($p = 0.07$) (Table 5). This trend appeared to be independent of the effects of chest wall irradiation ($p = 0.36$).

Discussion

Although surgery continues to represent a cornerstone of modern breast cancer treatment, the trend over the past decades has been away from radical surgery (i.e. mastectomy) and towards a combination of breast-conserving approaches with radiotherapy. Some authors have, in fact, proposed breast-conserving surgery (BCS) as a quality measure (16). It is estimated that 60 to 75 percent of breast cancer cases undergo BCS as initial treatment (17). Re-excision, however, is a common procedure in women undergoing BCS with reported rates of re-excision varying between 30 and 60 percent (18–20). Of these patients greater than 10 percent undergo mastectomy (21).

As plastic surgeons, we are increasingly faced with patients who have undergone unsuccessful attempts at breast conservation and eventually present for evaluation regarding reconstructive options; either at the time of planned mastectomy or in a delayed fashion. The deleterious effects of radiotherapy, however, particularly in the context of implant-based breast reconstruction, are well documented (22, 23). The pathophysiologic basis for adverse effects seen after surgical interventions within an irradiated field is attributed to depletion of parenchymal and stem cells as well as progressive fibrosis (23, 24).

The importance of critically analyzing complication rates after nipple reconstruction is surprisingly not reflected by the number of articles addressing this topic. Furthermore, no attempts have been made to identify risk factors and as such recognizing patients who should possibly not be offered nipple reconstruction; a discussion one ought to have prior to embarking on breast reconstruction.

Draper et al retrospectively reviewed their experience with nipple-areola reconstruction following chest wall irradiation in 28 patients (12). Although the reported complication rate was 25 percent, the authors felt that this complication rate was “acceptable” and concluded that nipple reconstruction after implant-based reconstruction in patients with a history of radiation “can be successful” (12). Certainly, nipple reconstruction within an irradiated field is possible, but the question is whether it should be performed and what indeed can be

considered an “acceptable” complication rate. Given the profound implications, most notably risk of implant loss after nipple reconstruction, this topic deserves a critical evaluation and discussion.

In the present study 15 of 29 patients with a history of radiotherapy experienced complications. Of these, 9 patients required either permanent implant removal, implant replacement, or implant removal with subsequent autologous reconstruction. One could legitimately argue that, although nipple reconstruction undoubtedly increases patient satisfaction (1, 25), loss of the entire reconstruction may not be worth the risk. The importance of this discussion cannot be overstated as an increasing number of patients are expected to present for breast reconstruction (and ultimately nipple reconstruction) after failed BCS.

The effects of radiotherapy furthermore appear to be relevant in patients in whom reconstruction with larger implants is planned. While implant volume itself did not appear to correlate with postoperative complication rate, the combination of implant volume greater than 450 cc and radiotherapy displayed a strong trend towards development of postoperative complications ($p = 0.1$). An explanation for this observation may be that the combination of a large implant and radiotherapy inflicts a “double insult” to the soft tissues of the chest wall, thus, resulting in a higher rate of postoperative complications.

Interestingly, the time interval between final breast implant placement and nipple reconstruction displayed a strong trend toward higher complication rates in those patients whose time interval exceeded 8.5 months ($p = 0.07$). This finding does not appear intuitive at first glance as a prolonged waiting period typically permits for soft tissue equilibrium. A possible explanation for this observation, however, may have been a particularly tenuous soft tissue envelope with thinner mastectomy skin flaps. Thus, the treating surgeons may have been inclined to intentionally wait for a prolonged period of time prior to performing nipple reconstruction (i.e. selection bias). The increased complication rate may, thus, be reflective of a less robust soft tissue envelope rather than the time interval between implant placement and nipple reconstruction. Interestingly, the effect of time interval between final breast implant placement and nipple reconstruction appears to be independent from a history of radiotherapy ($p = 0.36$).

Nipple reconstruction is an overall rather safe intervention with low complication rates. Zhong et al retrospectively analyzed their experience of 422 nipple reconstructions in 292 patients with a follow-up of at least 1 year (7). Minor complications in their series occurred in 7.2 percent of patients. Of note, the authors excluded patients with a history of chest wall radiation. The complication rate in non-irradiated patients in the present study was 6.25 percent, thus, supporting the observations made by Zhong et al (7).

The implications of our study findings relate to the discussion surgeons ought to have with the patient at the time of initial consultation. Particularly patients with a history of radiotherapy, a significant number being those after failed BCS, should be informed that the decision to proceed with an implant-based reconstruction exposes them to a significantly higher risk of complications after nipple reconstruction. It should be openly discussed that implant loss is a real risk when choosing to perform nipple reconstruction in the setting of radiation. Another parameter to consider is implant size. The patient needs to be made aware that if larger implant volumes are necessary to achieve an aesthetically appealing result, the risk for developing complications is further augmented in the setting of radiation. Changes in patient decision-making regarding the mode of reconstruction may be seen as a result of such a thorough discussion, as some may not be willing to choose an “incomplete” implant-

based reconstruction (without nipple reconstruction) and instead may opt for autologous reconstruction.

Conclusion

While nipple reconstruction is a safe procedure after implant-based breast reconstruction in patients without a history of radiotherapy, the presence of an irradiated field converts it to a high-risk one with a significant increase in postoperative complication rate. Patients with a history of radiotherapy should be informed about their risk profile and as a result may choose autologous reconstruction instead.

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Figure 1.
Complications observed after nipple reconstruction (of note, some patients experienced more than one complication)

Table 1

Patient characteristics

Patients	139
- Unilateral reconstruction	- 89
- Bilateral reconstruction	- 50
- Total number of nipple reconstruction	- 189
Chest wall radiation	
- Yes	- 29 patients (29 nipple reconstructions)
- No	- 110 patients (160 nipple reconstructions)
Final implant volume	
- Mean	- 423.9 cc
- Range	- 120 to 870 cc
Time interval from final implant placement to nipple reconstruction	
- Mean	- 8.5 months
- Range	- 0 to 60 months
Length of follow-up	
- Mean	- 12.8 months
- Range	- 1 to 72 months

Table 2

Influence of chest wall radiation on occurrence of postoperative complications

Chest wall radiation	Yes	No	p - value
Complication (%)	15 (51.7)	10 (6.25)	< 0.00001
No Complication (%)	14 (48.3)	150 (93.75)	

Table 3

Influence of age on occurrence of postoperative complications

Age	47 years	> 47 years	p - value
Complication (%)	11 (11.3)	14 (15.2)	0.43
No Complication (%)	86 (88.6)	78 (84.8)	

Table 4

Influence of implant volume (chest wall radiation) on occurrence of postoperative complications

Implant volume	450 cc	> 450 cc	p - value
Complication (%)	9 (9.9)	12 (13.3)	0.47
No complication (%)	82 (90.1)	78 (86.7)	
XRT			
Complication (%)	5 (31.3)	6 (66.7)	0.1
No complication (%)	11 (68.7)	3 (33.3)	

Table 5

Influence of time interval between final breast implant placement and nipple reconstruction (and chest wall radiation) on occurrence of postoperative complications

Time interval between implant placement and nipple reconstruction	8.5 months	> 8.5 months	p - value
Complication (%)	13 (10.1)	12 (20)	0.07
No complication (%)	116 (89.9)	48 (80)	
Chest wall radiation			
Complication (%)	6 (42.9)	9 (60)	0.36
No complication (%)	8 (57.1)	6 (40)	