Published in final edited form as:

J Plast Reconstr Aesthet Surg. 2013 September ; 66(9): 1202–1205. doi:10.1016/j.bjps.2013.04.052.

Nipple Reconstruction After Implant-Based Breast Reconstruction – A “Matched-Pair” Outcome Analysis Focusing on the Effects of Radiotherapy

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Abstract

Background—The major focus of research when addressing nipple reconstruction has been on developing new techniques to provide for long-lasting nipple projection. Rarely, has the outcome of nipple reconstruction as it relates to postoperative morbidity, particularly after implant-based breast reconstruction, been analyzed.

Methods—A “matched-pair” study was designed to specifically answer the question whether a history of radiotherapy predisposes to a higher complication rate after nipple reconstruction in patients after implant-based breast reconstruction. Only patients with a history of unilateral radiotherapy who underwent bilateral mastectomy and implant-based breast reconstruction followed by bilateral nipple reconstruction were included in the study.

Results—A total of 17 patients (i.e. 34 nipple reconstructions) were identified who met inclusion criteria. The mean age of the study population was 43.5 years (range, 23 – 69). Complications were seen after a total of 8 nipple reconstructions (23.5 percent). Of these, 7 complications were seen on the irradiated side (41.2 percent) ($p = 0.03$).

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 procedure with a significant increase in postoperative complication rate.

An area of limited outcomes research is nipple reconstruction. While considered a minor procedure, its profound implications on patient satisfaction after post-mastectomy breast reconstruction have been demonstrated (1, 2). The bulk of contributions related to nipple reconstruction focus on surgical techniques. The major focus of articles has been on ways to prevent the inevitable loss of nipple projection (3–8). This is in contrast to the limited number of studies analyzing risk factors and complication rates after nipple reconstruction (5, 9). It is prudent, however, to not only focus on preservation of nipple projection but also analyze and identify factors that predict poor outcome, as complications after nipple reconstruction can have devastating consequences for patients.

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Conflict of Interest: None

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The authors previously performed a cross-sectional study in which radiotherapy was identified as a risk factor for the development of complications after nipple reconstruction (10). Acknowledging the inherent limitations of a cross-sectional study, the authors then designed a “matched-pair” analysis to specifically answer the question whether a history of radiotherapy predisposes to a higher complication rate after nipple reconstruction in patients after implant-based breast reconstruction.

Methods

Institutional Review Board (IRB) approval was obtained prior to conducting the study. 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 (11), was utilized to identify patients with a history of unilateral breast radiation who underwent bilateral mastectomy and implant-based breast reconstruction with subsequent bilateral nipple reconstruction. This study design allowed patients to act as their own internal control, thus, “matching” radiated to non-radiated breasts. Only patients who underwent nipple reconstruction by means of local flaps were included in the study. Other modes of reconstruction, such as tattoo-only, nipple-sharing, skin grafting, etc. were excluded. Our primary outcome measure was complication rate. Further parameters retrieved included age, final implant volume, time-interval from radiotherapy to nipple reconstruction, time-interval from placement of final implant to nipple reconstruction, and length of follow-up.

The aim of the study was to analyze the impact of radiotherapy on complication rate after nipple reconstruction in patients with a history of implant-based breast reconstruction.

Statistical analysis

Final data analysis was performed in STATA 9.0 (STATA Corporation, College Station, TX, 2006). 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 17 patients (i.e. 34 nipple reconstructions) met inclusion criteria. All patients had a history of unilateral radiation, underwent bilateral mastectomy and implant-based breast reconstruction followed by bilateral nipple reconstruction. The mean age of the study population was 43.5 years (range, 23 – 69). The mean implant volume was 530 cc (range, 370 – 800 cc). The mean time interval from radiotherapy to nipple reconstruction and from implant placement to nipple reconstruction was 24.9 months (range, 6 – 156 months) and 7.6 months (range, 2 – 22 months), respectively. The mean follow-up period was 11.1 months (range, 2 – 36 months) (Table 1). Table 2 displays the techniques chosen for nipple reconstruction.

Complications were seen after a total of 8 nipple reconstructions (23.5 percent). A statistically significant increase in complication rate was observed after nipple reconstruction in an irradiated field (41.2 percent vs. 5.8 percent [$p = 0.03$]). Only one case of cellulitis was seen after nipple reconstruction in the non-irradiated setting (5.9 percent). Of note, this was successfully treated with oral antibiotics as an outpatient. The remaining complications included cellulitis (responsive to oral antibiotics; $N = 2$), infection with loss of implant without further reconstruction ($N = 1$), infection with loss of implant with subsequent autologous reconstruction ($N = 1$), infection requiring implant exchange ($N = 1$),

wound dehiscence with implant exposure requiring surgical intervention (N = 1), and nipple necrosis (N = 1) (Figure 1).

In order to investigate whether implant volume had an impact on the occurrence of complications in patients with a history of radiotherapy, patients were grouped into those who had implant volumes of <500 cc and those with implant volumes of ≥ 500 cc. A volume of 500 cc was chosen as this represented the median implant volume used in the study population. Although a trend towards a higher complication rate was seen in patients with implant volumes ≥ 500 cc, statistical significance was not reached (p = 0.08).

Discussion

The paucity of high-quality studies with a particular focus on nipple reconstruction has been demonstrated (12). Acknowledging the impact of nipple reconstruction on patient satisfaction, the authors critically analyzed patient outcome after nipple reconstruction. A particular focus was to identify predictors of poor outcome.

In a cross-sectional analysis, the authors previously identified radiotherapy as a factor that displayed a statistically significant association with poor outcome (10). In an attempt to address limitations inherent to such a study design, the present study was conducted.

The present study design, which represents a true “matched-pair” analysis, allowed us to attribute changes in outcome to radiotherapy, as this was the only characteristic that did not apply to both breasts. A statistically significant increase in complication rate was observed after nipple reconstruction in an irradiated field (41.2 percent vs. 5.8 percent [p = 0.03]). Thus, our previous study finding was confirmed using a higher quality study design (i.e. level III evidence) (10, 13). Similarly, the previously reported trend of higher implant volumes being associated with a higher rate of complication was seen in the present study (p = 0.08) (10). Inability to demonstrate statistical significance may have been secondary to small sample size.

The relevance of this study’s finding becomes evident when considering recent trends in breast cancer care. With the pendulum of surgical care swinging towards breast conservation, an increasing number of patients are undergoing radiotherapy as part of their initial management (14). Yet, it is well known that re-excision rates after breast conservation can be as high as 60 percent, with greater than 10 percent of these patients eventually undergoing mastectomy (15–18). These numbers along with an increased incidence of breast cancer explain the increasing number of patients who present for consultation regarding breast reconstruction. Radiotherapy, however, is particularly problematic if implant-based reconstruction is desired (19, 20).

Draper et al observed a complication rate of 25 percent after nipple-areolar reconstruction in an irradiated field (9). While the authors felt this was “acceptable” we feel that problems occurring in 1 in 4 patients seems rather high. A higher complication rate was found in this study, i.e. 41.2 percent. This confirms previous study findings, which demonstrated a complication rate of 51.7 percent (10).

While nipple reconstruction is an overall rather safe procedure with complication rates ranging between 5 to 7 percent in non-irradiated patients (5, 10), radiotherapy converts it to a high-risk one, with potentially devastating complications, including revision surgery and implant loss. Surgeons are cautioned to offer nipple reconstruction in patients with a history of radiotherapy and implant-based reconstruction. Given these recommendations, it is critical to discuss these issues before embarking on a particular mode of breast reconstruction. Acknowledging the risks associated with nipple reconstruction in an

irradiated field, patients may then choose to undergo autologous reconstruction with nipple reconstruction rather than implant-based reconstruction without nipple 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 procedure with a significant increase in postoperative complication rate.

Acknowledgments

Funding:

STRIDE (Stanford Translational Research Integrated Database Environment) is a research and development project at Stanford University to create a standards-based informatics platform supporting clinical and translational research.

The project described was supported by the National Center for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health, through grant **UL1 RR025744**. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

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Figure 1.
Complications after nipple reconstruction

Table 1

Patient characteristics (N=17, i.e. 34 nipple reconstructions)

Age	
- Mean	- 43.5 years
- Range	- 23 – 69 years
Final implant volume	
- Mean	- 530 cc
- Range	- 370 – 800 cc
Time interval from radiotherapy to nipple reconstruction	
- Mean	- 24.9 months
- Range	- 6 – 156 months
Time interval from final implant placement to nipple reconstruction	
- Mean	- 7.6 months
- Range	- 2 – 22 months
Length of follow-up	
- Mean	- 11.1 months
- Range	- 2 – 36 months

Table 2

Techniques of nipple reconstruction

Technique of nipple reconstruction	Number of reconstructions
Star flap	8
Bowtie flap	16
Double opposing tab	6
Skate flap	4