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The Effect of Radiotherapy on Implant-based Breast Reconstruction in the Setting of Skin-sparing Mastectomy: Clinical Series and Review of Complications

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Abstract. *Background:* With the increasing popularity of skin-sparing mastectomy techniques, implant-based breast reconstruction and use of perioperative radiation therapy, there is a growing need to scrutinize the effects they have on breast reconstruction. This study examined the effect of radiation on implant-based breast reconstruction in patients who had skin-sparing or conventional mastectomies in terms of complication, reoperation, and capsular contracture rates. *Patients and Methods:* A retrospective review of 227 implant-based breast reconstructions in 132 mastectomy patients by a single surgeon was undertaken. All cases occurred over a four-year period (2006-2009) at a single institution. Complication, re-operation, and capsular contracture rates were tabulated against immediate and delayed reconstruction, skin-sparing and conventional mastectomy implant-based reconstruction, and irradiated and non-irradiated groups. Chi-square test was performed for statistical analysis. *Results:* The overall complication and reoperation rates of 15% and 10% in these 227 reconstructions compare favorably to reviewed series. Delayed reconstruction, skin-sparing mastectomy and irradiation were all associated with a significantly increased rate of re-operation, but not to an increase in complication or capsular contracture rates. *Conclusion:* The results of this study were more favourable than those of similar studies reported in the current literature, suggesting an increased role for implant-based reconstruction in the setting of adjuvant radiotherapy for patients that undergo skin-sparing mastectomy.

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Undergoing mastectomy has implications for the psychosocial well-being of the patient and every attempt should be made to reconstruct the breast in suitable patients (1). Skin-sparing mastectomy (SSM) is one of the techniques developed to improve the aesthetic result of breast reconstruction. The concept of preoperative plastic surgery planning together with SSM was first brought to the forefront by Toth *et al.* in 1991 (2). It involves the preservation of a native skin envelope with the removal of the breast, nipple-areolar complex, biopsy scars and skin overlying any superficial tumours (2). The ideal SSM would have a skin flap devoid of all breast tissue but having an adequate blood supply to prevent flap necrosis and delayed wound healing. It is believed that the preservation of the skin architecture and intact infra-mammary fold, allows for immediate breast reconstruction, thereby reducing the number of reoperations and improving the cosmetic appearance of the breast.

For many years, the expander/implant option was not available as a reconstructive option post mastectomy and autologous tissue was the mainstay of treatment. Various studies also suggested that tissue expansion was associated with a significantly higher complication rate (3-6). In fact, in a study by Kroll and Baldwin, in 325 post-mastectomy reconstruction patients reported, the failure rate for tissue expansion was as high as 21% whilst the failure rate for transverse rectus abdominis myocutaneous (TRAM) flaps was only 3% (4). Other studies have been more favorable towards implants, with one study by Rosen and colleagues finding that the complication rates were similar between TRAM and tissue expander/implant reconstruction for breast reconstruction (7), a finding echoed in other series (8, 9).

While there are studies which have demonstrated the efficacy of SSM and autologous reconstruction (5), SSM with expander/implant reconstruction has been scarcely evaluated in the literature. A PubMed search of 'skin sparing mastectomy' and 'tissue expansion' or 'implant' revealed 30

original articles, with the first articles of any relevance being published within the last 10 years.

This study explores the outcome of breast implants following conservative mastectomy and SSM. It also examines the complication and reoperation rates in patients who underwent delayed *versus* immediate reconstruction, as well as patients who did and did not undergo radiation therapy. The main hypothesis is that there is no difference in outcome between patients undergoing SSM *versus* conventional mastectomy. The secondary hypotheses include that there is no difference in complication rate in patients undergoing delayed *versus* immediate reconstruction, but an increased complication rate in patients who undergo radiotherapy of the affected breast and axilla.

Patients and Methods

A retrospective review was performed of 132 patients undergoing 227 implant-based breast reconstructions over a four year period at a single institution, by a single surgeon (RK). Follow-up ranged from 12 to 36 months postoperation. All patients had reconstructions with either Mentor (Irving Texas, USA) or Inamed/Allergan (Irvine California, USA) expanders (subpectoral) together with either SSM or conventional mastectomy (see Figure 1). The creation of a sling was performed with Alloderm (LifeCell, Branchburg New Jersey, USA), FlexHD (Ethicon, Somerville New Jersey, USA), Neoform (Mentor, Irving Texas, USA) or Strattice (LifeCell, Branchburg, New Jersey, USA). No attempt was made to standardize initial fill volumes, time to full expansion, or final volumes achieved

Data collected included type of surgery (immediate *versus* delayed, SSM *versus* conventional mastectomy), history of radiotherapy treatment and complications. Complications include reoperation, capsular contracture, infection, seroma formation, post-operative haematoma, implant exposure and delayed wound healing. The modified Baker classification of capsular contracture was used (10). All personal identifiers were removed from the data as stipulated by the Human Subjects Review Committee. Results were recorded and tabulated using Microsoft Access (Microsoft Corporation, Redmond Washington, USA). Chi-square tests were performed on the data, and *p*-values were used to evaluate the data for statistical significance.

Results

A total of 132 patients received 227 mastectomies, of whom 64% (145 patients) had conventional mastectomy skin envelope excisions, 33% (75 patients) were SSMs, and 3% (7 patients) were of Wise pattern excisions. The average age of patients was 52 years with the following ethnic breakdown: 84% White, 5% African-American, 5% Hispanic, 1% Asian and 5% other. 2% were current smokers, 18% had a history of smoking, and 80% were nonsmokers. A total of 8% of the patients were diabetic. With regard to radiation exposure in this study, 12% had a remote history (>1 year prior to surgery), 9% had immediate preoperative radiation, and 15% had postoperative radiation.

The overall complication and re-operation rates were 15% and 10% respectively (Tables I-III). Of the patients who had infected implants, half were managed conservatively with antibiotics whilst the remaining half necessitated surgical removal of the implants. A total of 6/8 implant exposures were treated with removal of implant, whilst the remaining 25% received irrigation and closure. Two out of the three hematomas required surgical drainage.

SSM vs. conventional mastectomy. Overall, the SSM group had a lower complication rate (12% *vs.* 18%) but a greater reoperation and capsular contracture rate than the conventional mastectomy group (Table I). Of these, only the reoperation rate was statistically significant ($p<0.01$).

Immediate vs. delayed. Delayed breast reconstructions were associated with a significantly greater number of reoperations ($p<0.0001$) than immediate reconstructions, but the overall complication rates were similar (Table II). The immediate group had a higher rate of capsular contracture (5% *vs.* 0%), although this difference was not statistically significant ($p=0.21$).

Influence of radiation. The irradiated group had higher rates of complications and re-operations (Table III), but only the rate of reoperation between the two proved significant statistically ($p=0.02$). Capsular contraction was similar in the two groups.

Discussion

The field of implant-based reconstruction is constantly undergoing changes. These changes include the advent of dual chambers, anatomic and cohesive variations, texture modifications, and ever-evolving proprietary manipulation. As a result, implant-based reconstruction data are difficult to standardize over any prolonged period of time. Similarly, size of implant, initial volume, final volume, and rapidity of expansion are tailored to meet patient goals and expectations and can never be fully standardized. The development of skin-sparing and, more recently, nipple-sparing techniques also adds a distinct element to the gamut of variability.

The overall complication rate of our implant-based reconstruction was 15%, with a reoperation rate of 10%. This is lower than the percentage reported by Rosen *et al.* in 1990, who had a complication rate of 23% in their tissue expander group and 24% in their TRAM flap group (7). It is also much lower than the rate reported by a large study of 165 immediate reconstructions in 1986 by Bailey *et al.*, who had a 22% implant and 15% expander loss, and an overall complication rate of 57% (11). This may reflect not only differences in the implants and expanders themselves, but also



Figure 1. A: smooth saline implant; B: smooth, cohesive silicone gel implant; C: saline tissue expander. Images supplied by Mentor (California, USA). Reproduced with permission from Rozen *et al.* (22).

Table I. Comparison of skin sparing mastectomy (SSM) and conventional mastectomy.

			Chi-square value	p-value
	Complication	None		
SSM	8	66	0.7539	0.39
Conventional	23	130		
	Reoperation	None		
SSM	18	56	6.6772	<0.01
Conventional	17	136		
	Capsular contraction	None		
SSM	6	68	2.534	0.11
Conventional	5	148		

Table II. Comparison of immediate and delayed reconstruction of the breast.

			Chi-square value	p-value
	Complication	None		
Immediate	30	167	0.4442	0.5
Delayed	6	24		
	Reoperation	None		
Immediate	16	181	24.4675	<0.0001
Delayed	12	18		
	Capsular contraction	None		
Immediate	10	187	1.593	0.21
Delayed	0	30		

a learning curve where it is presumed that over the last 30 years, surgical techniques have improved over time (12, 13).

Breast reconstruction may be performed immediately postmastectomy or delayed for up to years following the initial mastectomy. Immediate breast reconstruction is often recommended for psychosocial benefits, but obviously this needs to be weighed against the judgment of the patient and surgeon, and individual oncologic needs (including further operation and adjuvant radiotherapy) (1). This study has demonstrated that not only is implant-based reconstruction associated with a low complication rate, but immediate reconstruction is also associated with a statistically significant lower reoperation rate.

There are two major concerns regarding implant reconstruction following SSM. The first is that most breast reconstructions occur in the anterior chest skin and therefore SSM may increase the risk of recurrence (1). The breast

Table III. Comparison of radiotherapy and no radiotherapy.

			Chi-square value	p-value
	Complication	None		
Radiotherapy	14	69	1.5212	0.22
No radiotherapy	16	128		
	Reoperation	None		
Radiotherapy	16	67	5.8316	0.02
No radiotherapy	12	132		
	Capsular contraction	None		
Radiotherapy	2	81	0.028	0.87
No radiotherapy	4	140		

surgeon must balance the risk of skin necrosis in the residual skin flap to the risk of recurrence if breast tissue is left behind in the SSM flap. A multitude of studies has demonstrated that there are no differences in local recurrence rate and overall survival between mastectomy and reconstructed groups (1). Secondly, studies have shown that there is a severe complication rate of approximately 20% in patients who undergo immediate implants following SSM (14-16). Another study has suggested that careful selection of patients could result in a complication rate as low as 5% (17). Our complication rate was at the lower end of that reported in the literature, again perhaps reflecting the learning curve in the skin-sparing paradigm.

Overgaard *et al.*'s landmark trials in 1997 resulted in radiation therapy becoming increasingly used as adjuvant therapy (18), shown to reduce the local recurrence rate, prolong disease-free survival and increase the overall survival rate (1). One would expect breast irradiation to be associated with higher postoperative complication due to radiation associated damage to surrounding tissues (1). Some researchers have classed patients who have had irradiation to be similar to heavy smokers and have recommended SSM to be avoided in such patients (14). Other studies have shown that radiation therapy is associated with an unacceptably high rate of capsular contracture and rupture of the implant envelope or capsule (1, 19, 20). A study by Spear and Onweyu in 2000, comprising of 40 consecutive patients undergoing staged expander/implant placement and radiotherapy during a seven year period, demonstrated a capsular contracture rate of 21% in the irradiated group vs. 0% in the control group (21). However, our study has not shown this. One could argue that as capsular contracture develops over months to years, this study does not have the long-term follow-up to evaluate the overall contracture rate. Spear and Onweyu's study also reported complications to be more common in the irradiated group (36%) than in the control group (7%) (21). The infection rate was also higher at 4% in the irradiated group and 0% in the control group (21). Finally, 32% of irradiated breasts with implants ultimately needed the addition of a flap (21). Our study has demonstrated somewhat different results, with irradiated breasts having a statistically higher reoperation rate, but a similar complication rate as non-irradiated breasts. This could also be due to improvement in the targeting of radiotherapy in order to limit damage to surrounding tissue, improved surgical techniques, or better quality of implants.

A word of clarification should be entered on the nature of the capsular contracture. None of the patients were observed to have any greater than Baker grade II capsular contracture, and the overwhelming majority were classified as grade I. An additional group of patients remained in relatively early follow-up period after implant placement (<6 months). As such, capsular contracture rates from the latter group were excluded from all calculations.

Conclusion

The goal of the current study was to determine complication, reoperation, and capsular contracture rates in implant-based reconstruction after SSM and adjuvant radiotherapy. While the study showed a trend toward SSM being associated with lower complication rates compared to conventional mastectomy, the study did not reveal an effect on the reoperation rate or rate of capsular contracture. Radiation exposure negatively impacted reoperation rates but, oddly, did not lead to any increase in capsular contracture or overall complication rates. The complication, reoperation and capsular contracture rates are lower than what has been traditionally reported in literature, and may reflect the increased surgical expertise, more targeted radiation therapy and improved implants being used for the patients. Immediate reconstruction with implants in patients who have undergone SSM, even in irradiated tissue, appears to be a viable option in breast reconstruction.

Conflicts of Interest

None.

Disclosures

None.

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