

Limiting complication rates in implant-based breast reconstruction

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ABSTRACT

BACKGROUND: External beam radiotherapy (XRT) to the breast has been shown to increase complication rates in women undergoing implant-based breast reconstruction (IBBR). Owing to concerns about high complication and failure rates, our department began to favour autologous reconstructive in patients requiring XRT in 2013. This study assesses the outcomes of IBBR prior to and following this policy change.

METHODS: The records of all patients who underwent first-stage IBBR in 2012 and 2013 in our department were reviewed. Patients undergoing peri-operative XRT were identified. Complications and failure rates were analysed.

RESULTS: Over two years, 77 IBBRs were performed in 53 patients. In 2012, 11 patients underwent peri-operative XTR compared with five in 2013. Radiotherapy was significantly associated with higher reconstructive failure rates while pre-operative XRT was associated with more complications overall ($p=0.0099$). Over the two years, the number of IBBRs with any complication fell from 16 (43.2%) to 11 (27.5%) while reconstructive failure fell from six (16.2%) to four (10%).

CONCLUSIONS: Peri-operative XRT increases complication rates and reconstructive failure with IBBR. Our current policy of recommending autologous reconstruction if they have had pre-operative XRT seems to be resulting in decreased complication rates and increased reconstructive success.

Breast cancer is the most prevalent cancer of women in New Zealand and around the world. Breast reconstruction is commonly undertaken after mastectomy, to improve the quality of life and functional wellbeing of affected women. Treatment with external beam radiation therapy (XRT) to the breast has been shown to increase complication rates and associated morbidity in women undergoing implant-based breast reconstruction (IBBR).¹⁻³ Both prior and post-operative XRT has also been shown to negatively affect implant-related outcomes (Figure 1A and B).^{4,5} While XRT is not an absolute contraindication to IBBR, concern over complications rates in our department resulted in surgeons encouraging such patients to favour autologous reconstructive options if XRT was planned. To facilitate this, since 2012 all referrals to our department for breast reconstruction must be accompanied by an oncological appraisal, detailing the probability of XRT by classifying the patient's risk of requiring

post-mastectomy XRT into 'Certain', 'Likely', 'Possible' or 'Unlikely'.

As breast reconstruction is often a staged procedure and complications can occur weeks to months after surgery, it is only now appropriate to analyse data from the time period around this policy change, to allow capture of all complications through the entire reconstructive process. The aim of this study was to assess the outcome of IBBR at Counties Manukau District Health Board (CMDHB) Plastic and Reconstructive Surgery Department for two years, between January 2012 and December 2013. This department includes six breast reconstructive surgeons. Primary endpoints include assessment of the proportion of patients who underwent IBBR received either pre- or post-operative adjuvant XRT, as well as the development of any acute complication associated with their reconstructive surgery and final reconstructive success overall.

Figure 1: Patient undergoing IBBR at a different surgical unit following left breast XRT, showing challenges in expansion of left breast tissue.



A: Expansion was able to be progressed to 375mL on the right but only 250mL on the left.

B: The same patient as 1A following expander to implant exchange with 300cc round silicone implants in situ, showing poor cosmetic result of IBBR due to pre-operative XRT.

Patients and methods

Institutional approval for this project was obtained from the CMDHB Research Office (#2139). All patients treated with first-stage of their immediate reconstruction in 2012 and 2013 in our department were identified from our prospective records. After reviewing available electronic notes, all patients who underwent adjuvant XRT were identified. We stratified our cohort by year, to identify those prior to and immediately after the introduction of our new departmental guidelines. Those treated with XRT were sub-classified into whether treatment was delivered prior to undertaking reconstruction ('pre-operatively') or following completion of reconstruction ('post-operatively') for the purpose of outcome analysis. Length of follow up was conservatively defined as the time from insertion of first expander to the date last seen in our clinic. Complication was defined as an adverse outcome noted in the records, regardless of how this was managed. Despite the presence of a complication, these patients were still considered to have had successful reconstructions. Reconstructive failure was defined as removal of expander or implant for clinical or aesthetic reasons with abandonment of this reconstructive method.

All patients underwent reconstructive surgery by a plastic surgeon who sub-specialised in breast reconstruction. All mastectomies were performed by oncological breast surgeons. Our department

does not have access to technologies for intra-operative perfusion assessment of the mastectomy skin flaps, therefore all intra-operative surgical decision making was clinically based.

Descriptive statistics of demographics were reported as a mean or percentage of patients. Categorical variables were compared using the Student's t-test and Fishers Exact Test with two-sided probability as appropriate using GraphPad InStat v3.10 (San Diego, CA, USA). Past3 (Palaeontologica Electronica, Oslo) statistical software was used for Kaplan-Meier analysis. Significance was set at $p \leq 0.05$.

Results

Patient characteristics

In 2012, 27 patients underwent immediate IBBR on 37 breasts. Thirty-three of these were two-stage, expanded to implant only reconstructions, and four involved a latissimus dorsi (LD) flap plus an implant. In 2013, 26 patients underwent immediate IBBR on 40 breasts, of which only one involved a LD flap plus an implant. No patients had acellular dermal matrix.

Demographic data are summarised in Table 1. The groups were well matched for age. Follow up was significantly longer for the earlier (2012) cohort. A greater percentage of patients in 2012 underwent pre- or post-operative XRT than in 2013, but this was not statistically significant ($p=0.1699$).

Table 1: Patient demographics, radiotherapy treatment and outcomes.

	2012	2013	p value
Number of patients	27	26	
Number of breasts	37	40	
Mean age at surgery (years)	48	47	p=0.75
Age range (years)	31–64	30–68	
Ethnicity			
New Zealand European	18	15	
Māori	2	3	
Asian	3	4	
Other/not stated	4	4	
Mean follow-up (months)	28	20	p=0.002*
Radiotherapy (n (%))	11 (29.7%)	5 (12.5%)	p=0.091
Pre-operative	6	0	
Post-operative	5	5	
Median radiotherapy dose# (Gy)	50	50	
Range (Gy)	45–50	50	
Overall outcome (n (%))			
No complication	21 (56.8%)	29 (72.5%)	p=0.1614
Complication	10 (37%)	7 (17.5%)	
Reconstructive failure	6 (16.2%)	4 (10%)	p=0.5074

Gy = Grey. * = statistically significant. # = Where known; data only available for 7 of 11 patients in 2012 and 4 of 5 patients in 2013.

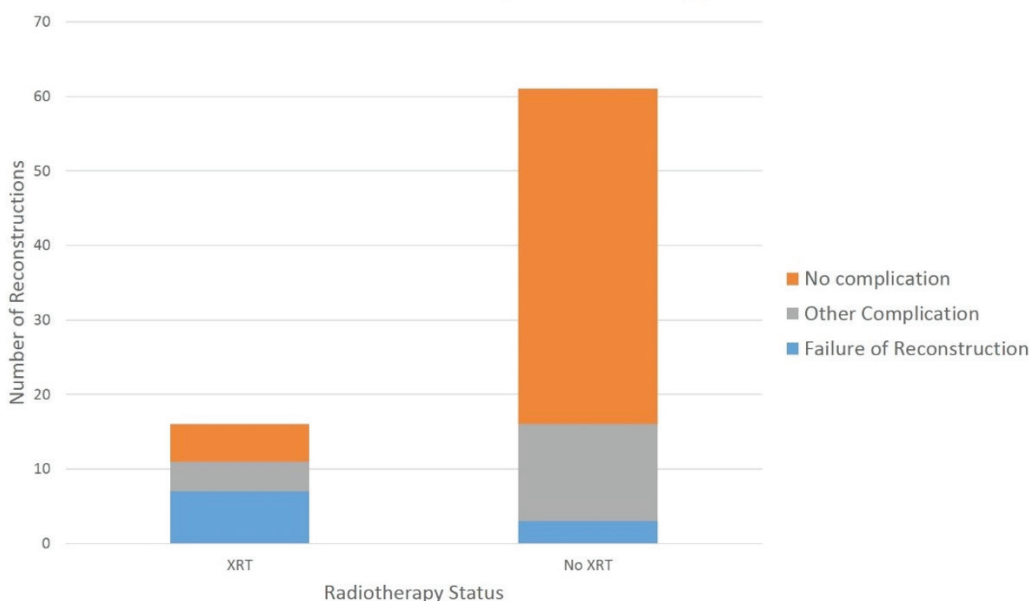
XRT = external beam radiotherapy.

Primary outcomes

Both the complication rate and the reconstructive failure rate was higher in the 2012 cohort than the 2013 cohort, but this was

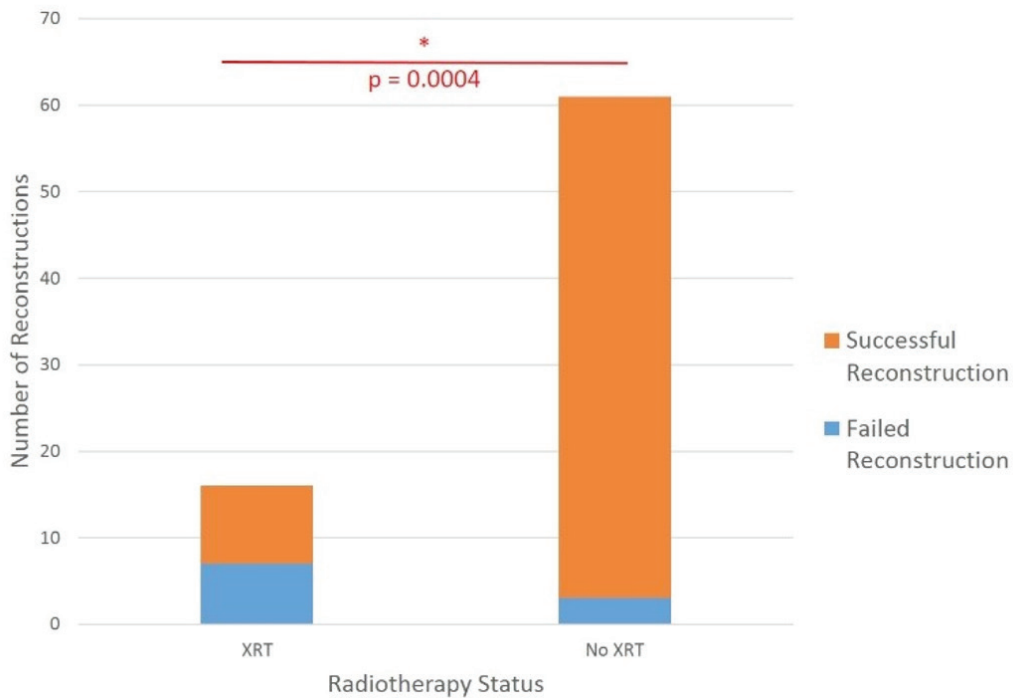
not statistically significant. However, when analysed by the presence or absence of XRT and by timing of XRT, there were significant differences. Overall outcome by radiotherapy status is shown in Figure 2.

Figure 2: Overall outcomes by radiotherapy status.



XRT = external beam radiotherapy.

Figure 3: Rate of failure of implant-based breast reconstruction by radiotherapy status.



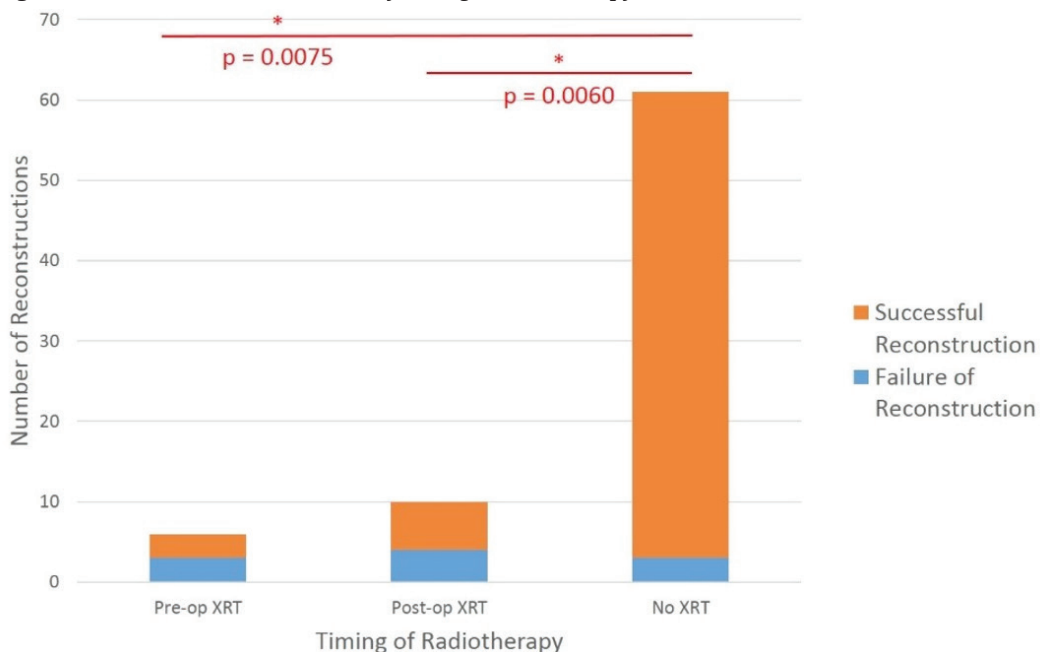
XRT = external beam radiotherapy.

Taken together, a history of perioperative XRT was significantly associated with the development of a reconstructive complication including failure ($p=0.0027$) and failure of IBBR alone ($p=0.0004$, Figure 3).

A history of pre-operative XRT or the requirement for post-operative XRT were both significantly associated with higher

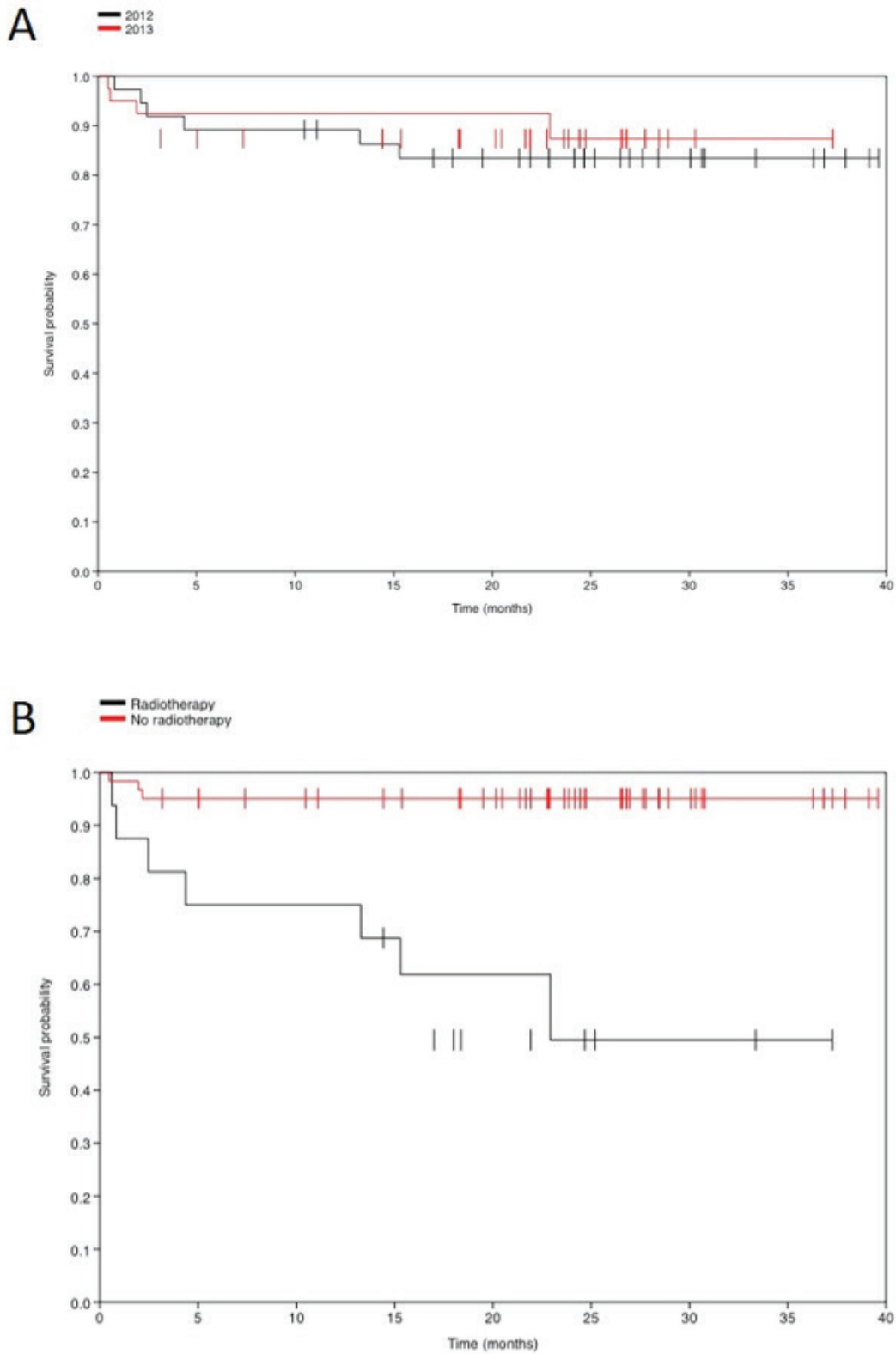
reconstructive failure rates ($p=0.0075$ and 0.0060 respectively, Figure 4) while pre-operative XRT was also associated with higher rates of any complication, including reconstructive failure ($p=0.0099$). The difference between the yearly cohort groups and by presence or absence of peri-operative XRT can be clearly seen in Kaplan-Meier survival curve depictions, Figure 5.

Figure 4: Outcome of reconstruction by timing of radiotherapy.



XRT = external beam radiotherapy.

Figure 5: Kaplan-Meier survival curves for each group.



A: By year cohort group. B: By radiotherapy status.

Discussion

IBBR is still commonly provided in the setting of peri-operative XRT, either due to a lack of autologous options or patient or surgeon preference. While this may accomplish a reasonable reconstruction,⁶ meta-analysis suggests that XRT results in higher complication and morbidity when compared with non-irradiated cohorts, while autologous reconstruction in the setting of XRT results in lower morbidity.¹ It is not possible to predict with absolute certainty which patients will require post-operative XRT, so any immediate IBBR patient may potentially require XRT. In our series, five IBBR patients per year were unexpectedly subject to post-operative XRT. However, where there is already a previous history of XRT treatment or a high suspicion of post-operative XRT being required, our departmental guidelines now suggest that these patients be steered away from IBBR. The success of this policy can be seen in the 2013 patient cohort, of which no patients undergoing IBBR had previously received XRT.

Our data shows a significant association between peri-operative XRT and the development of a complication or reconstructive failure from IBBR, in line with other literature on this topic.⁶⁻⁸ Uncertainty exists in the literature over whether pre-operative or post-operative XRT is the bigger risk factor for complications. Our data support the idea that pre-operative XRT poses more of a problem, with both higher operative complication rates and overall failure of IBBR in this group. While post-operative XRT was significantly associated with long-term failure of IBBR, it did not result in an increased acute complication rate, presumably due to the fact that XRT was commenced after surgical healing had occurred. Our radiation oncology colleagues will not irradiate a tissue expander with an integrated metallic fill port due to concerns that this may compromise their optimal adjuvant treatment plan.⁹ Therefore, any patient identified as requiring post-operative XRT either has their expander removed (hence relegating the reconstruction to the 'Failed' category—one patient in the 2013 cohort) or is rapidly expanded and changed to

a definitive cohesive gel breast implant prior to undergoing XRT, similar to the "fast track exchange" used by Cordeiro and colleagues.¹⁰ While a recent systematic review found that failure rates in both groups were not statistically different,⁵ Cordeiro feels that the long-term result is better if it is the final implant which is irradiated, rather than the expander.¹⁰

Expressing these results from a patient viewpoint, if no XRT is required, the patients chance of successful IBBR is 95.1%. However, this rate falls to only 56.2% for patients undergoing XRT. This XRT-related failure rate is high compared with published literature, where implant loss ranges from 20–30% for irradiated patients compared with 5–14% for non-irradiated controls.^{2,7,8,11} Cordeiro, whose outcomes are among the best published, has an 11.1% implant failure rate for irradiated patients and 6.1% for non-irradiated controls.¹⁰ In contrast, our failure rate in the non-irradiated control cohort of 4.9% compares very favourably. While the small sample size limits to conclusions we can draw from this, we believe that the improvement in our complication rate (43.2% in 2012 vs 27.5% in 2013) and failure rate (16.2% in 2012 vs 10% in 2013) is positive reinforcement of our departmental policy and in line with the first tenet of medicine, *primum non nocere*.

There is a difference in follow-up periods between our two cohorts, as is commonly seen when cohorts are separated by a date range, with the earlier patients having a longer follow-up period. As radiation-associated damage can take several years to develop, it is possible that the lower rate of complications in the 2013 cohort reflects the shorter follow-up period. However, this study was not designed to identify long-term complications from IBBR, but rather success of the reconstructive method employed. As most reconstructive failures occur from acute problems such as failure of expansion, wound breakdown or early implant infection, we believe that the 20-month follow-up period for our 2013 patient cohort is long enough to identify all cases of reconstructive failure. Similarly, the retrospective nature of some of our data collection can result in decreased identification of complications. However, as all patients were seen in our clinic for a lengthy follow-up

period as above, we are confident that any significant complications would have been identified. Another limitation of our study is the lack of comparative data from patients with pre-operative XRT who underwent autologous reconstruction under this new policy. It is possible that their complication rate from autologous reconstruction was no different than it would have been with IBBR, and this policy has simply transferred their complications to a different reconstructive pathway. However, the literature suggests this would not be the case.¹

Our department currently relies on predictions from the breast surgery team to determine the future risk of XRT. To limit the risk of XRT-related complications, the threshold for immediate reconstruction based on the estimated likelihood of needing future XRT could be lowered, for example, only accepting patients who are rated as 'Unlikely' to need XRT, rather than those rated as 'Unlikely' and 'Possible'. For these latter patients, reconstruction could be

delayed until post-mastectomy histopathology results are reported or autologous reconstruction offered. However, we do not feel these changes are warranted in our department at this time, as our current policy seems to have resulted in an improving complication profile for the 2013 patient cohort to a level which is felt to be acceptable.

Conclusions

Our data shows that both pre-operative and post-operative XRT are associated with increased complication rates from IBBR, while pre-operative XRT is also associated with increased failure of this form of breast reconstruction. We recommend that patients with a history of previous XRT or a high likelihood of requiring post-operative XRT be counselled regarding the high risk of complications of XRT and IBBR and be steered instead to favour autologous reconstructive options.

Competing interests:

Nil.

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