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Significantly reducing implant loss rates in immediate implant-based breast reconstruction: A protocol and completed audit of quality assurance☆

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Summary *Introduction:* Immediate implant-based breast reconstruction (IBR) rates have increased considerably with the advent of acellular dermal matrices. Implant loss is a significant complication and is costly to patients and the NHS. National Mastectomy and Breast Reconstruction Audit and Implant-Based Breast Reconstruction Audit data have demonstrated national implant loss rate of 9% at 3 months. National Oncoplastic Guidelines for Best Practice cite $a < 5\%$ target. We aimed to reduce implant loss by introducing a protocol with pre-, intra- and post-operative interventions.

Methods: Audit of IBR at a single oncoplastic breast unit was commenced and implant loss at 3 months was recorded (May 2012-July 2014). Patients were identified from a prospectively maintained database, and case notes were examined by identifying factors associated with implant loss.

A team involving microbiology, theatre staff, infection control and surgeons was established. A novel, evidence-based intervention bundle, including more than 25 protocol changes, was introduced.

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Prospective re-audit of IBR (April 2015–December 2017) was completed following introduction of the new protocol and implant loss was recorded at 3 months.
Results: The first retrospective audit of 77 reconstructions (54 patients) demonstrated 11 implant losses at 3 months (14%). Re-audit, post-intervention, comprised 129 reconstructions (106 patients) with no implant loss at 3 months. Fisher's exact analysis revealed statistically significant reduction in implant loss rate ($P < 0.00001$) following protocol introduction.
Conclusions: Implant loss rate following IBR can be reduced to an exceptionally low level, well below national targets, by adhering to this evidence-based intervention bundle. Our protocol could improve outcomes nationally.

Introduction

Since the advent of acellular dermal matrix (ADM), immediate implant-based breast reconstruction has become an increasingly popular option, rising from 30% of all immediate reconstructions in 2007 to 54% in 2013[1]. This facilitates a single-stage procedure, which benefits patients. Using an ADM improves cosmesis and ptosis compared with total submuscular placement.[2,3] Despite the advantages of this technique, it inevitably carries some risk, most notably implant failure and explantation,[4] which is costly to both the patient and providers. The National Oncoplastic Guidelines for Best Practice cite a target of less than 5% implant loss rate at 3 months post-operation.[5] The National Mastectomy and Breast Reconstruction Audit demonstrated an implant loss rate of 9% at 3 months in immediate breast reconstruction and 7% in delayed reconstruction.[6] More recent early data from the iBRA study (evaluating outcomes in implant-based reconstruction) are similar with loss rates of 9%.[7] Early results from the iBRA study also demonstrated significant variability in the provision of implant-based reconstruction nationally with regard to biological and synthetic mesh availability, patient selection criteria and peri- and post-operative management (notably duration of antibiotics and drain policy). Furthermore, very few units had written guidelines or management protocols, and only half prospectively audited their outcomes.[8]

In 2014, Lardi et al. published a two-centre retrospective cohort investigating factors affecting outcome in immediate breast reconstruction with ADM. The total complication rate was 32.5%, including a 12.5% implant loss rate at 3 months. Multivariate analysis demonstrated that several factors were associated with statistically significant increased risk of early complications: increased operative time, single stage procedure, body mass index (BMI) over 30, mastectomy weight more than 600 g and smoking. Although not statistically significant, neoadjuvant chemotherapy showed a trend of higher complication rates.[9]

In addition, Barber et al. (2015) published a retrospective analysis of outcomes in all breast reconstructions in their unit utilising ADMs. They found that the risk of unplanned explantation (reported as 9.5% at 3 months; 15.5% at 1 year) was significantly increased in smokers and when using an inframammary fold incision and to a lesser extent vertical incision. They found no statistical variation in explantation by the operating surgeon, type of ADM, patient weight, breast weight or nipple preservation.[10]

In 2013, the Association of Breast Surgery (ABS) in conjunction with The British Association of Plastic, Reconstructive and Aesthetic Surgery (BAPRAS) issued guidelines for ADM breast reconstruction procedures. These include a recommendation for auditing 3-month implant loss with a target of <5%. As yet, there is no set guidance or protocol about methods to improve loss rate despite evidence that this target is not being achieved by a significant number of centres in the UK.

Materials and methods

An original audit looking at implant loss rate in immediate implant-based reconstructions at a single oncoplastic breast unit comprising 11 surgeons (4 breast and 7 plastic) was performed. All patients having undergone immediate implant-based reconstruction from May 2012 to July 2014, were identified from a prospectively maintained database. Patients were excluded if the primary surgical intent was to do another form of breast reconstruction, if there was an LD reconstruction with implant or if a 2-stage reconstruction was planned. Case notes were then examined to identify potential factors associated with implant loss. For each case, the following were recorded:

- Operative factors:
  - Antibiotics used
  - Surgeon
  - ADM/dermal sling used
  - Size of implant
  - Concomitant axillary clearance
- Patient factors:
  - Smoking status
  - BMI
  - Mastectomy size
  - Diabetic status
  - Neoadjuvant chemotherapy
  - Radiotherapy
- Microbiological factors
  - Organisms identified

A literature review was also conducted to identify evidence regarding risk factors for implant loss.

A team was set up comprising a consultant microbiologist, a plastic surgery theatre sister, infection control lead nurse and three oncoplastic breast surgeons. A novel, evidence-based intervention bundle was produced,

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Table 1 A novel, evidence-based intervention bundle comprising multiple protocol points for pre-, intra-, and post-operative management of immediate implant-based breast reconstruction.

Pre-operative
Patient selection[11]:
No more than 1 risk factor from
• BMI >30
• Smoker
• Diabetes
• Radiotherapy
• Neoadjuvant chemotherapy
Concomitant axillary clearance was considered an additional risk factor, but 1 further risk factor was permitted if this was planned
Implants <500 ml only
MSSA[12] and MRSA[13] screening
No shaving or waxing for 48 h pre-operation[14]
Chlorhexidine shower the night before and morning of surgery[15]
Intravenous antibiotics at induction[16]: Teicoplanin & Gentamicin
Intraoperative
Reduce personnel in theatre and avoid opening doors (use of locks and signs)[17]
Reduce operative time - use 2 surgeons for all bilateral procedures[18]
All theatre personnel to wear facemasks when implant is opened
Patient to be warmed for the duration of surgery[19]
Nipple shields to be applied for unilateral cases[20]
Patient to be prepped with alcoholic chlorhexidine[21]
Surgeons and scrub staff to double glove[22]
Surgeons and scrub staff to change outer gloves to a clean pair prior to handling the implant
Clean drape to be placed before implant insertion
Open implant just before insertion
Implant only handled by surgeon (following glove change)
Implant cavity and skin washed and implant bathed in Vancomycin 1 g and Gentamicin 160 mg solution with sterile water[23]
Unused sterile instruments only post-implant opening
Drain to be tunnelled[24]
Trim skin edges
Bacteriostatic sutures and skin glue
High-risk patients - tissue expander and PICO dressing
Post-operative
Oral doxycycline 100 mg BD until it drains out
Drains out when <30 ml on 2 consecutive days or by day 10
Aggressive debridement of any small wound problems
Outpatient review by day 10

including more than 25 protocol changes (see Table 1), and implemented. A decision was made to limit the number of surgeons performing this procedure to 3 oncoplastic breast surgeons and theatre staff were educated about the change in practice. Surgeons were free to use their ADM of choice.

A prospective re-audit of all implant-based reconstructions, following implementation of the protocol, between April 2015 and December 2017 was completed and implant loss rate at 3 months was recorded. Risk factors were recorded for this group as before, to ensure protocol was being adhered to.

Results

In the original audit, 54 patients underwent 77 reconstructions (23 bilateral). These were all retro-pectoral and in 60 ADM was used (42 Strattice and 18 XCM), in 15 a dermal sling technique was used and in 2 a total sub-pectoral expansion technique was used. Mastectomy followed by immediate reconstruction was performed in response to invasive ductal carcinoma ($n=19$, 24.7%), invasive lobular carcinoma ($n=6$, 7.8%), ductal carcinoma in-situ ($n=20$, 26.0%) and in response to genetic factors indicating the need for risk-reducing mastectomy ($n=31$, 40.3%) (Figure 2).

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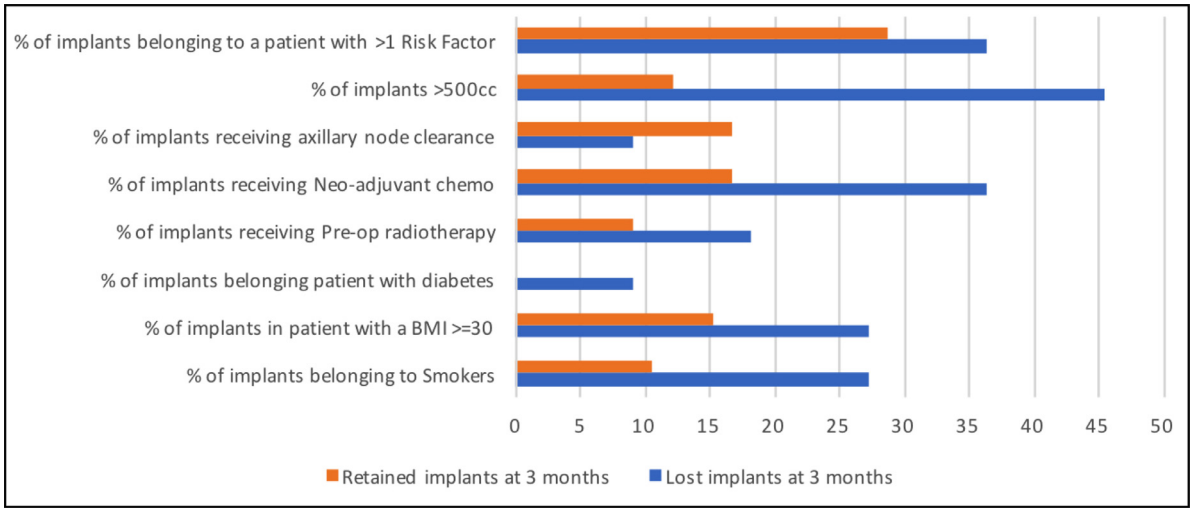

Figure 1 Original audit – prevalence of risk factors in patients who lost implants at 3 months compared to those who retained implants at 3 months.

Table 2 Original audit – prevalence of risk factors in patients who lost implants at 3 months versus those who retained implants at 3 months.

Risk factor	Prevalence risk factor % (*n*)		
	Lost implants at 3 months	Retained implants at 3 months	*P*-value
Smokers (*n*)	27.3 (3)	10.6 (7)	0.1296
BMI >=30 (*n*)	27.3 (3)	15.2 (10)	0.325
Diabetes (*n*)	9.10 (1)	0	N/A
Pre-operative radiotherapy (*n*)	18.2 (2)	9.10 (6)	0.3631
Neoadjuvant chemotherapy (*n*)	36.4 (4)	16.7 (11)	0.1707
Axillary node clearance (*n*)	9.10 (1)	16.7 (11)	0.523
Implants >500 cc (*n*)	45.5 (5)	12.1 (8)	0.0065
>1 risk factor (*n*)	36.4 (4)	28.8 (19)	0.6125
Total number of implants	11	66	N/A

Patients had a mean age of 49 years (range: 30–74 years), a mean BMI of 25.0 (range: 18–43) and a mean implant size of 383.4 cc (range: 150–690 cc). Within this group, there were a total of 11 implant losses in the first 3 months (14.3%). Retrospective analysis has shown a difference in the prevalence of 7 key risk factors between those who lost and those who retained their implants at 3 months (see Figure 1). Table 2 shows the trend observed within our study indicating a reduced prevalence of risk factors in the group retaining implants. Chi-squared analysis was used, and found that the group receiving implants >500 cc to have a statistically significantly increased risk of implant loss ($p = 0.0065$).

The re-audit comprised 129 reconstructions in 106 patients (46 bilateral). Twenty-seven of them were pre-pectoral reconstructions – 24 of which used Braxon and 3 Surgimend ADMs. A total of 102 were sub-pectoral: 52 of which used Surgimend, 31 Strattice, 5 Ti-loop, 10 dermal slings and 4 total sub-pectoral expander. Mastectomy was performed in patients with invasive ductal carcinoma ($n = 46$, 35.7%), invasive lobular carcinoma ($n = 17$, 13.2%), ductal carcinoma in-situ ($n = 21$, 16.3%), lobular carcinoma in-situ ($n = 1$, 0.78%), adenomyoepithelioma ($n = 1$, 0.78%) and risk reduction ($n = 43$, 33.3%) (Figure 2). Patients had a mean age of 50 years (range: 27–78 years), mean BMI of 24.2 (range: 17.7–34.7) and mean implant weight of 360.6 cc (range: 135–595 cc).

Patients were found to have fewer risk factors than in the original audit group. Analysis of our data has shown that during the re-audit, the selection of patients for immediate reconstruction was significantly reduced in those who are smokers ($P = 0.002$), have a BMI of greater than 30 ($P = 0.049$), who had pre-operative radiotherapy ($P = 0.013$) or who had greater than 1 risk factor ($P = 0.002$). Selection of patients who have diabetes, those requiring implants of >500 cc, and patients who had axillary clearance was also reduced, although not significantly (see Table 3).

A dramatic reduction in implant loss at 3 months was recorded in comparison to the original audit: 0 losses at 3 months versus 11 losses (14.3%). Fisher's exact analysis revealed this to be a statistically significant reduction in implant loss rate ($P < 0.00001$) and within the national target.

Data demonstrate that there has been a significant reduction in the number of patients with >1 risk factor and a reduction in those receiving implants >500 cc; however, some patients are still being offered implant-based

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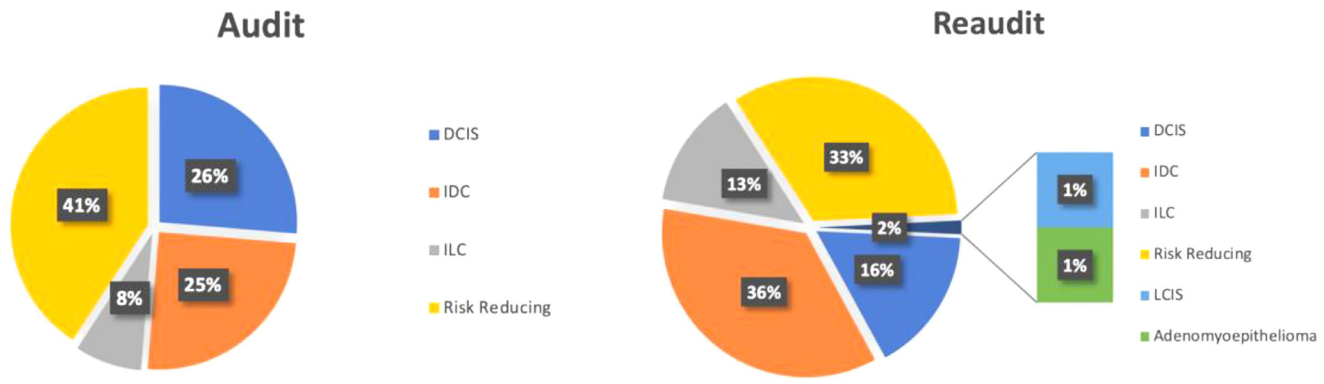

Figure 2 Indications for mastectomy were comparable in the original audit and re-audit groups.

Table 3 Prevalence of risk factors in the re-audit group compared with the audit group, demonstrating an overall reduction in the selection of patients with risk factors.

Risk factor	Prevalence risk factor % (*n*)		
	Audit	Re-audit	*P*-value
Smokers (*n*)	13.0 (10)	2.33 (3)	0.0024
BMI >=30 (*n*)	15.6 (12)	6.98 (9)	0.0485
Diabetes (*n*)	1.30 (1)	2.33 (3)	0.6054
Pre-operative radiotherapy (*n*)	10.4 (8)	2.33 (3)	0.013
Neoadjuvant chemotherapy (*n*)	19.5 (15)	22.5 (29)	0.6122
Axillary node clearance (*n*)	15.6 (12)	12.4 (16)	0.5178
implants >500 cc (*n*)	15.5 (12)	10.1 (13)	0.2437
>1 risk factor (*n*)	29.9 (23)	12.4 (16)	0.002
Total number of implants	77	129	N/A

reconstruction in these conditions despite the introduction of the protocol.

Conclusion

Implant loss rate following immediate implant-based reconstruction can be significantly reduced with the implementation of an evidence-based protocol incorporating pre-, intra- and post-operative measures.

Discussion

Initial audit of implant loss rate led to the unexpected and disappointing discovery that our unit had a high implant loss rate at 3 months sitting well above national reported standards and even further above the national target of <5%. It is clear from the evidence to date that multiple factors influence the risk of implant loss; hence, following close examination of our own data, we implemented a protocol that served to address as many of these as practically possible. The result has been a greatly reduced implant loss rate to 0 at 3 months. Furthermore, none of the measures implemented have come at any significant expense to the NHS. Given the financial burden of implant loss, this has measurable resource implications, quite apart from the impact for patients.

Our own initial audit certainly demonstrated outcomes in common with the Barber et al. study of 2015 and the Lardi et al. study of 2014. In these studies, as with our own findings, smoking status significantly increased the risk of implant loss at 3 months, and this is well supported by a number of studies in the literature.[11,25-27] In our audit, we simply recorded whether patients were smokers or non-smokers and according to our protocol, implant-based reconstruction can be permitted in smokers provided they have no other risk factors. Patients who had stopped smoking within 4 weeks of surgery were termed 'smokers'. However, given the widespread evidence regarding the negative impact of smoking, it may be prudent in the future to quantify the amount of smoking (current frequency and pack years), and investigate any variation in impact related to this.

Our own study demonstrated an increased risk, although not of significance attached to axillary node clearance and chemotherapy. Barber et al. propose that these risks are likely to be tied up in the fact that they indicate a greater burden of disease, and are likely confounded by the fact that these are also more likely to be undergoing chest wall radiotherapy because it is given routinely to those with the involvement of >3 lymph nodes. In their study, as well as others,[28] post-operative radiotherapy led to a significantly increased risk (Hazard ratio, 3.7), although pre-operative radiotherapy did not. As the requirement for post-operative radiotherapy is not always predictable when planning surgery and selecting patients, we did not include

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this in our analysis. In the initial audit, a greater proportion of those who had undergone pre-operative radiotherapy lost their implant (18% vs 9%), but as with the Barber study, this was not significant ($p = 0.36$). This finding has been supported elsewhere in the literature.[29] Interestingly, the Lardi et al. study did not find significant increase in complications associated with radiotherapy or adjuvant chemotherapy, on multivariate analysis. They did, however, find neoadjuvant chemotherapy to confer an increased risk.

As with the Barber study, obesity did not significantly increase the risk of implant loss in our study ($p = 0.3$), although other larger studies have demonstrated statistical significance here, despite the increase in risk being small.[26] Certainly the risk of less severe complications such as seroma formation and infection, not necessarily resulting in explantation, seem to be increased in this group.[30]

One quite different finding between our study and the Barber study related to implant size: we found that our most statistically significant increased risk was conferred by using implants greater than 500 cc ($p = 0.0065$). Although Barber et al. did not specifically look at implant size, the average reconstruction weight was 406 g with a range of 135–765 g, and they found no significant increase in risk related to excised breast weight. Lardi et al., however, found that a mastectomy weight of >600 g was associated with an increased risk of complications.

Barber's et al. main conclusion was that careful consideration should be given to the suitability of implant/ADM reconstruction in patients who are likely to need radiotherapy or chemotherapy and great caution should be exercised in smokers.

As with our study, the Lardi study found that by limiting patient selection to one risk factor (from BMI >30, smoking, >600 g estimated mastectomy weight), using an antibiotic solution (in their case just to rehydrate the ADM) and tunnelling drains they were able to significantly reduce their overall complication rate, including explantation rate at 3 months. Inspired by their results, achieved in a large teaching hospital environment, we have built on this to produce a more comprehensive protocol. There are clearly multiple factors in patient selection that may influence outcome and some of these, such as smoking, are more obviously significant than others. It seems that the more these factors are present the higher the risk; hence, reducing patient selection to 1 risk factor only seems to improve outcomes. Similarly, there are multiple small risks that can be introduced intraoperatively, and implementing a protocol that serves to address as many of these as possible has proven to be effective. We feel that by implementing this and achieving these results in a medium-sized oncoplastic unit, with a significant training commitment (one training registrar, one TIG fellow and one staff grade), this is a system that would be transferrable in the vast majority of reconstructive units nationally.

Implementation of the protocol has not only affected patient selection (as evidenced in the figures), but has also led to a cultural change in theatres with much greater care and concentration from all theatre staff during implant procedures. The surgeons performing these procedures now perform the entire procedure, whereas previously one surgeon would perform the mastectomy and another one would perform the reconstruction. Having one surgeon solely responsible for the operation means that an implant loss can only be attributed to that surgeon, and each surgeon pays huge attention to detail. There can be no debate between a reconstructive surgeon claiming the skin flaps were not viable or too thin, and the resectional surgeon wondering if the reconstructive surgeon's technique could be improved. If there is any concern regarding breast wounds that are slow to heal or areas of necrosis, patients are taken back to theatre for an early debridement.

One of the limitations of this study has been difficulty in assessing whether, beyond patient selection factors, all aspects of the protocol have been strictly adhered to. As the team reduced complication rates to a stable low level, by really limiting patient factors and becoming more confident with lower complication rates; some patients received reconstruction that had more than one risk factor, and bigger implants were used in some patients. Our next planned step in this process is to devise a protocol checklist with a pre-operative section to be completed in the clinic, an intraoperative section to be completed in theatre and a post-operative section to be completed at follow-up. Following its implementation in 2006, the WHO surgical safety checklist has proven to be effective in saving lives and reducing post-operative complications.[31,32] The impressive outcomes of the WHO checklist are thought to be in part because of the fact that the checks have resulted in addressing the surgical system and subsequently establishing the policy. However, the outcomes are also in part related to a change in team dynamics and a cultural change, whereby theatre staff are much more safety conscious. Haynes et al. demonstrated that an improvement in safety attitudes resulted in reduced morbidity and mortality following the implementation of a surgical safety checklist.[33] The use of a specific checklist for implant-based breast reconstruction has been previously suggested by Barr et al. and the Northwest Breast Surgical Collaborative following an extensive review of the evidence[34] – our aim is to implement a similar model but build on this to include the elements that we have found to make a significant difference to our own outcomes. The use of a checklist will not only serve to focus the surgical team on implementing best practices, but also serve as a data record to easily assess and audit practice in the future. Through this, we would also hope to record other complications such as haematomas, seromas and capsular contracture as well as delayed implant losses beyond 3 months.

Declaration of Competing Interest

There were no conflicts of interest to declare for any authors involved in this study.

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