Salvage of the failed implant-based breast reconstruction using the Deep Inferior Epigastric Perforator Flap: A single centre experience with tertiary breast reconstruction

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Summary *Background:* The longevity and durability of implant-based reconstruction is limited and many patients who develop complications seek alternative reconstruction. Recent studies have shown tertiary reconstruction with autologous tissue to be safe in the short term. But no study has looked in-depth at the motivation for seeking referral and its long-term outcome.

Methods: This was a retrospective study using patient case-notes and a prospectively-collated database. One hundred and fifteen patients underwent tertiary breast reconstruction with a Deep Inferior Epigastric Perforator (DIEP) flap between 1998 and 2016.

Results: Mean age was 49 (23-67). The predominant initial reconstruction was expander (71%). Twenty nine percent received a definitive reconstruction (implant with acellular dermal matrix or pedicled latissimus dorsi). The proportion of patients who received post-mastectomy radiotherapy (PMRT) to their implant was 72%. Thirty four percent underwent surgical salvage prior to referral for autologous tissue and this was significantly higher in the group that did not receive PMRT (29% vs 40, $p = 0.04$). Predominant motivation for autologous reconstruction was poor cosmesis (62%) and/or grade III/IV capsular contracture (27%). Mean time from

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implant to DIEP was 4 years 5 months. Ten percent had complications requiring re-operation. Flap loss was 0.7%. Fifty five percent required an additional ipsilateral procedure and 47% required symmetrization. Median follow-up was 20-months (6-months to 7-years).

Conclusions: We present the largest UK series of tertiary breast reconstruction. Tertiary reconstruction is safe with a surgical outcome comparable to delayed autologous reconstruction. Patients with implant complications often had multiple failed attempts at salvage prior to referral. We advocate careful consideration of implants in the setting of PMRT and early referral for autologous tissue once complications become apparent.

Introduction

Implant-based breast reconstruction continues to be the most common form of immediate breast reconstruction performed in the UK.[1] Immediate reconstruction continues to rise nationally and is now 33%.[2,3] UK-based prospective audits report a 25% re-operation rate and nine percent implant loss at 3-months.[1,4] US clinical trials demonstrate failure rates of implant-based breast reconstruction in the range of 50% at 7-years.[5] Furthermore, 28% of patients are not satisfied with the appearance of their breasts 18-months following immediate reconstruction.[1] Thus, there exists a large population of women with either a failed reconstruction or a poor cosmetic outcome who are seeking salvage reconstruction.

Tertiary breast reconstruction is the salvage of a failed prosthetic reconstruction with autologous tissue.[6] Recent literature has shown that tertiary breast reconstruction with autologous tissue is a viable option for women who have known complications of implant-based reconstruction (IBR) and can produce subjective early results comparable to secondary autologous reconstruction.[6-9] These published articles present low patient numbers and reconstructions with a myriad of autologous flaps – latissimus dorsi (LD), transverse rectus abdominis (TRAM) and deep inferior epigastric (DIEP) flaps.[6,7,10-12] No study has looked in-depth at the drivers of tertiary reconstruction, the motivation for referral and the natural history of referral.

The aims of our study were to look at the natural history of patients who underwent tertiary reconstruction with a single autologous flap and understand:

- The rationale for immediate IBR.
- The motivation for seeking tertiary reconstruction.
- The number of salvage ancillary procedures prior to tertiary reconstruction referral.
- The number of secondary surgeries following tertiary reconstruction required to achieve a satisfactory result.
- The outcome of tertiary breast reconstruction.

Methods

Patient population

We retrospectively analysed the case notes of patients who underwent tertiary autologous breast reconstruction with a DIEP flap in a single-institution (North Bristol NHS Foundation Trust) from 1998 to 2017.

Inclusion and exclusion criteria

We included all patients who underwent a DIEP flap tertiary reconstruction, having previously undergone an immediate based reconstruction that included the insertion of an implant/expander with or without acellular dermal matrix (ADM), LD and or local flap/dermal slings.

We excluded:

- Previous autologous-only reconstruction.
- Patients with a successful IBR who underwent contralateral prophylactic mastectomy and bilateral autologous reconstruction.
- Patients who had IBR and developed recurrence.
- Patients who had a successful delayed-immediate reconstruction defined as replacement of the tissue expander with autologous tissue within 6-months.

Data collection

Data were extracted from the clinical notes; from comprehensive written notes and supporting letters or from a detailed proforma completed at the time of the original consultation. Patient demographics were recorded along with operative, oncological and post-operative data. We used both digital and paper notes to collect data on any pre-operative and post-operative systemic therapy, the number and type of subsequent breast procedures and outcome of the implant reconstruction. Complications were assessed using Baker's classification and documented history of infection, implant-related complications and subjective patient reports of pain and poor cosmesis.

We recorded the number of salvage procedures performed prior to referral. We also recorded the motivation for referral for tertiary reconstruction, the complication rate of autologous reconstruction, and subsequent number of adjuvant ipsilateral procedures required to achieve a result that enabled discharge from the reconstructive service. We excluded nipple reconstruction and nipple tattoo. Contralateral surgery included any non-oncological surgery to the contralateral breast following tertiary reconstruction.

Minor complications following DIEP flap were defined as complications that could be treated conservatively, and major complications were defined as complications that required surgical intervention. Additional ipsilateral procedures were defined as any operative intervention designed to improve the aesthetic appearance of the autologous reconstructed breast. Length of follow-up was
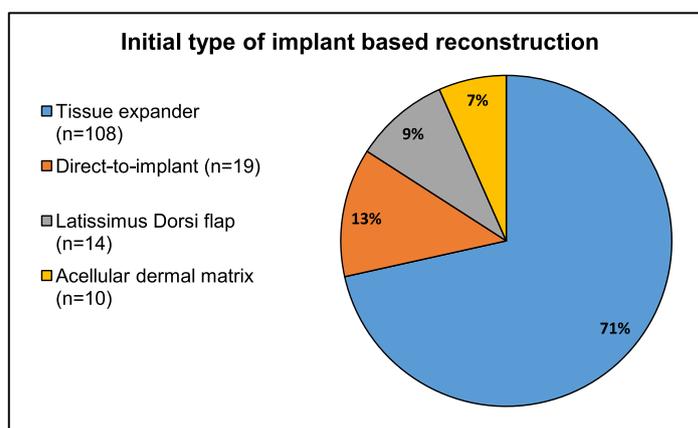
Figure 1 Pie chart showing type of initial implant-based reconstruction. 29% received a definitive reconstruction.

determined from the date of last clinic appointment or date of discharge.

Results

From 1998 to 2017, a total of 151 patients underwent tertiary reconstruction with DIEP flap. Mean age was 47 (23-67).

Invasive ductal carcinoma was the most common pathology ($n=83$) followed by ductal carcinoma in situ ($n=25$), lobular carcinoma in situ ($n=8$), and invasive lobular carcinoma ($n=18$). Ten patients were considered high-risk and offered prophylactic surgery. Eight patients had no histology available.

Tissue expander was the most common form of initial reconstruction ($n=108$) 71%. Direct-to-implant was performed in 13% ($n=19$). Ten percent ($n=14$) of patients underwent reconstruction with a LD flap in combination with an implant. ADM's were used in six percent of IBRs ($n=10$) (Figure 1).

Seventy two percent of patients received post mastectomy radiotherapy (PMRT) ($n=108$). Four percent of patients had previously received radiotherapy prior to mastectomy ($n=6$).

Rationale for IBR at the time of initial mastectomy was varied. Autologous was not offered at the time of reconstruction in 62% ($n=94$). Planned delayed approached was planned in 14% ($n=21$) followed by patient choice in 11% ($n=16$). Nine percent had unknown reasons. Four percent ($n=6$) were denied autologous reconstruction at the time of mastectomy due to patient factors such as anaesthetic risk, smoking status, BMI > 30 (Figure 2).

Thirty four percent of patients required additional ipsilateral procedures prior to referral for tertiary reconstruction ($n=48$). These patients underwent total of 105 additional procedures, median 2 (range 1-10). The primary reason for additional surgery was for explanation following infection ($n=33$) followed by capsule procedures ($n=28$), size adjustment ($n=25$), planned tissue expander exchange ($n=15$), and device failure ($n=4$) (Figure 3).

Patient were more likely to undergo additional procedures prior to tertiary reconstruction referral if they had not received PMRT (48.7% vs 29%) Figure 4).

Motivation for autologous reconstruction was multifactorial for many patients – the most common *primary* cause was poor cosmesis 62%, followed by grade IV capsular contracture 29%. Total implant loss accounted for 9% of referrals (Figure 5).

Median time from mastectomy to DIEP reconstruction was 3 years 9 months and ranged from 7 months to 11 years. Median time from mastectomy to DIEP for patients who received an expander prosthesis was 2 years 10 months and ranged from 7 months to 11 years.

Median BMI at time of surgery was 26 (18-34). 12% were ex-smoker ($n=16$) and only 7% had two or more co-morbidities.

Ten percent ($n=14$) had complications requiring re-operation. 12 of these were flap related and consisted of anastomosis salvage ($n=4$) or evacuation of haematoma ($n=8$). Two major complications were related to the donor site. 25% of patients suffered minor complications that were managed conservatively ($n=36$). The most common was delayed wound healing ($n=16$) followed by fat necrosis ($n=8$) and seroma ($n=7$). Flap loss was 0.7% (1/151).

The number of additional procedures patients underwent after tertiary reconstruction ranged from 0-5 with a mean of 1.5. The overall tertiary reconstruction re-operation rate (adjuvant contralateral and ipsilateral procedures undertaken at the same time points) was 63%. Sub-analysis revealed 55% of tertiary reconstructions required one additional ipsilateral procedure, median 1 (range 1-3) ($n=77$). The most commonly performed ipsilateral procedure was lipofilling ($n=41$) followed by scar revision ($n=37$), reduction ($n=18$) and mastopexy/flap adjustment ($n=8$).

Forty seven percent required a symmeterization procedure. Median follow-up was 20-months (4-months-7-years). By the time of manuscript submission 88% of patients had been discharged from the reconstructive service.

Discussion

Rationale for original IBR

It is important to recognise that whilst 62% of patients said they were not offered autologous reconstruction at the time of their initial reconstruction, this is a retrospective
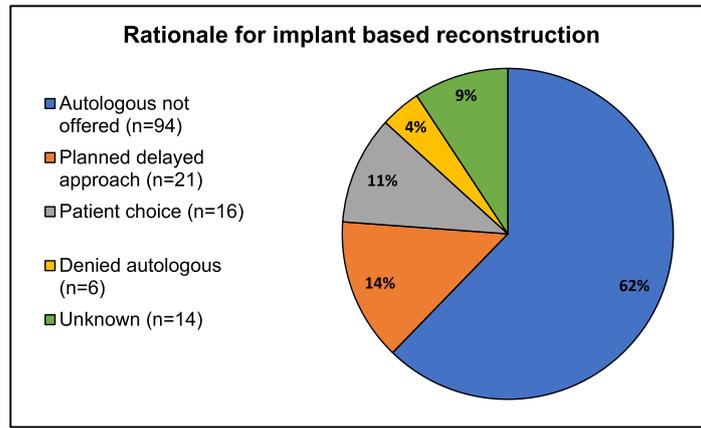
Rationale for implant based reconstruction

- Autologous not offered (n=94)
- Planned delayed approach (n=21)
- Patient choice (n=16)
- Denied autologous (n=6)
- Unknown (n=14)

9%
4%
11%
14%
62%

Figure 2 Pie chart showing rationale for implant based reconstruction. $n = 151$.

Reasons for ipsilateral procedures

- Explantation following infection (n=33)
- Capsule procedures (n=28)
- Size adjustment (n=25)
- Planned expander exchange (n=15)
- Device failure (n=4)
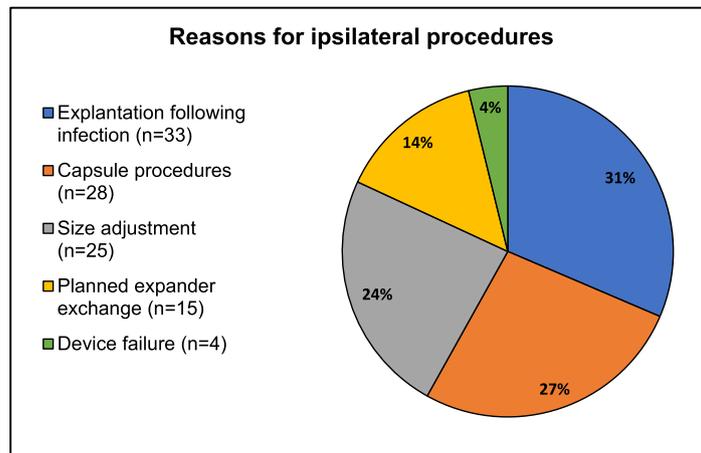
4%
14%
24%
31%
27%

Figure 3 Reasons additional ipsilateral procedures were required prior to referral for tertiary reconstruction. 34% of patient underwent additional procedures $n = 48$. There was a total of 105 procedures performed.

Proportion of patients requiring additional procedures
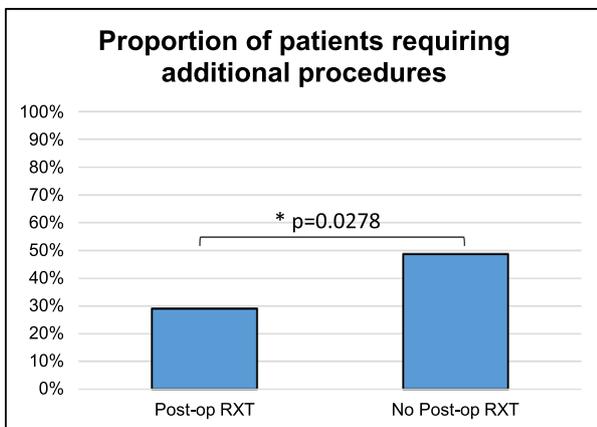
* p=0.0278

Post-op RXT   No Post-op RXT

Figure 4 Graph comparing proportion of patients who had received post-mastectomy radiotherapy and went on to require additional procedures, with those who had not received post-mastectomy radiotherapy ($p = 0.0278$).

analysis spanning 20 years where both reconstructive techniques and the modern oncological management of breast cancer, has and continues to evolve. The DIEP has undergone refinements in this time and the indications for radiotherapy continues to expand and cannot always be predicted pre-operatively. Our unit uses sentinel lymph node biopsy in selected patients as a procedure before the mastectomy to help the multidisciplinary team stage the axilla and inform decisions on those who will require radiotherapy or not. We therefore acknowledge that there is still a role for the use of primary IBR in some instances when the clinical situation dictates, and that the conclusions drawn here are based on what has been published so far. IBR continues to be the most common form of breast reconstruction for women undergoing mastectomy and immediate reconstruction.[1] Until recently, surgical dogma has long-held vascularized muscle coverage as a proponent method to mitigate implant complications observed with PMRT. There is emerging data to support pre-pectoral IBR as an effective technique in the setting of PMRT, with morbidity rates similar to those experienced with complete sub-muscular or "traditional" dual-plane (partial sub-muscular) coverage techniques with PMRT.[13] Whilst other institutions have been able to achieve similar results with IBR in the setting of PMRT, long-term results are still lacking.[14-16] Limits are therefore placed on the external validity of these studies and it is still unclear
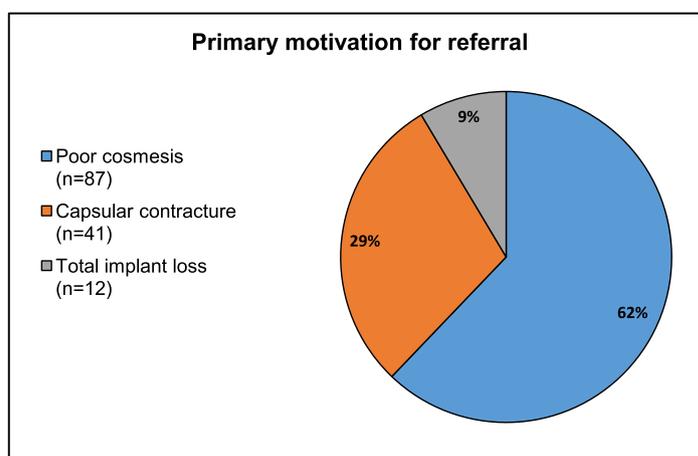
Figure 5 Primary factor motivating referral for tertiary reconstruction. Missing data $n = 11$.

what type of long-term effects PMRT will have on the reconstructed breasts, especially when an ADM is present. Among the increasing number of studies on the use of ADM in breast reconstruction, few studies specifically examine the effect of them in the irradiated breast, with only a few studies including irradiated subgroups. Results are conflicting however, with some authors reporting excellent cosmetic results and relatively low complication rates and others have suggested an increase in implant infections, seroma and implant loss.[17,18]

However, in the era of shared decision making, concern remains that women undergoing a mastectomy are not being given enough information pre-operatively to make an informed decision about their breast reconstruction as reported by the 2002 NICE document 'Improving Outcomes in Breast Cancer'.[19] More recently The National Mastectomy and Breast Reconstruction Audit (NMBRA) 2010 reported that ten percent of women were unhappy with pre-operative information given to them.[20] The reason for such a high proportion of patients not being offered autologous in our study is unclear. There is the possibility of surgeon preference and the unwillingness to discuss an option that they did not feel was clinically appropriate or available locally. Furthermore, many of these patients were treated prior to the publication of our national guidelines mandating that all patients receive information on all types of breast reconstruction.[21] But these results must be interpreted with caution. Recall bias is possible, as many patients were seen long after the initial mastectomy consultation. Nevertheless, our data suggests that a significant proportion of patients were not adequately counselled pre-operatively.

Fourteen percent of patients were scheduled for a delayed-immediate approach ($n = 21$). Of these patients, 15 underwent radiotherapy (71%). The delayed immediate approach advocated by Kronowitz relies on a streamlined referral system with important timeline considerations.[22] The purported advantage of this approach is that the patient maintains a breast mound and mastectomy skin is preserved. None of the patients, in our study, scheduled for delayed immediate approach, received their autologous reconstruction within the timeline advocated by Kronowitz. The mean time between insertion of an expander to

autologous reconstruction in our delayed-immediate group was 2-years. Poor cosmesis was the main motivation for referral in this group. Why these 15 patients did not have a successful delayed-immediate approach is unclear. One possibility is the patient deciding not to proceed to autologous reconstruction following expander insertion. Another reason, and indeed this has been our experience, is the difficulty in providing this precise timeline due to delayed referral, the large geographical area covered by our tertiary unit, and the lack of theatre resources. Two patients in our delayed immediate-approach suffered implant loss (9%). Kronowitz reported a 14% implant loss with his approach; most failures occurring at the time of initial implant placement.[22] Furthermore, we found that mastectomy skin was not maintained. Out of the 60 of patients who had their mastectomy flap quality documented in our study, only ten percent (6/60) had preservation of their mastectomy flaps. Our data shows that the placement of a skin expander does not translate into preserved mastectomy skin when the there is a significant delay between the two stages.

In our unit, we do not offer DIEP flap to anyone who is a current smoker, BMI > 30, or lacks abdominal resource. Relative contra-indications for autologous reconstruction include uncontrolled diabetes, haematological disorders, or significant atherosclerotic heart disease. Taking these factors into account only four percent of patients in our series were deemed not suitable for immediate autologous reconstruction at the time of mastectomy. All of these were due to modifiable risk factors.

Motivation for referral

Poor cosmesis was the primary reason for referral in 62% of patients. The median time from implant reconstruction to referral was 3-years. This suggests that the poor cosmesis occurred too early to be attributed to age-related changes. Poor cosmesis following implant reconstruction is well recognized. The NMBRA 2011 found that 62% were not 'very satisfied' with the cosmetic appearance following immediate IBR at 18-months.[23] Satisfaction is known to deteriorate over time up to 18-years when compared to autologous
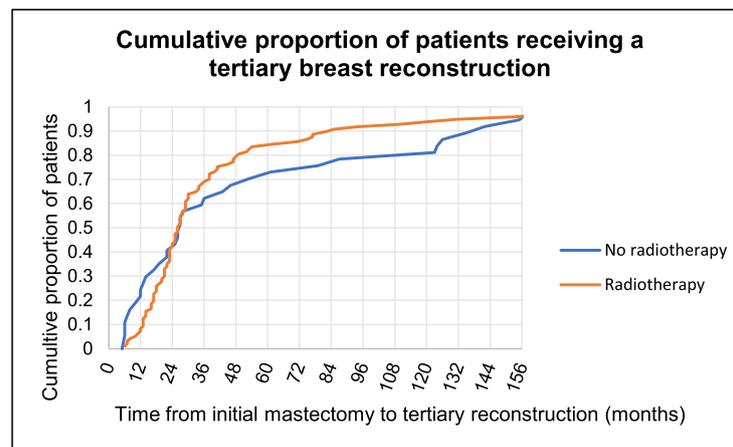
Figure 6 Graph demonstrating referral delay from initial reconstruction to tertiary reconstruction. Patients who received radiotherapy were referred earlier than those who did not receive radiotherapy. Those patients who received radiotherapy had less salvage procedures performed prior to referral ($p = 0.04$).

reconstruction.[24] We found that most patients who presented with poor cosmesis had undergone more ancillary salvage procedures prior to referral and were often referred at a much later date as compared to those who had implant loss or early complications related to radiotherapy (Figure 6). Poor cosmesis was the main motivator in the largest series of tertiary breast reconstruction published by Levine et al.[9] They found 64% of patients sought tertiary reconstruction for a more natural appearance, although their rate of radiotherapy was much lower at 20%.

The next most common reasons for referral to tertiary reconstruction were grade IV capsular contracture and implant loss in 29% and 7% of patients respectively. Most these women had received radiotherapy to their implant or had undergone immediate implant reconstruction in a previously irradiated field. The concerns regarding radiotherapy and implant complication are well documented and a recent systematic review found a reconstruction failure rate of 20% at 15-months.[25] Levine et al. reported a similar rate of implant loss being a motivator for tertiary breast reconstruction.[9] Attempted salvage of a failed implant reconstruction with a further implant has a reported failure rate of 18–35%.[11,26,27] Importantly, these studies do not comment on aesthetic outcome of a successful salvaged implant reconstruction with a further implant, and, as detailed above, many of our patients in the poor cosmesis group were the victims of a successful salvage reconstruction with a further implant.

Ancillary procedures and time to referral

Median time from mastectomy to DIEP reconstruction was 3-years 9-months (7-months–11-years) and median time from mastectomy to DIEP for patients who received an expander prosthesis was 2-years 10-months (7-months–11-years). This is in keeping with the timeline for the development of complications and the number of ancillary/salvage procedures performed. Those referred early were the patients with implant loss (9%) and those late were due to capsular contracture (29%) and poor cosmesis (62%). Those who had received radiotherapy were more likely to be referred earlier – due

to early onset of complications and the fewer salvage attempts. This would support the fact that patients who had radiotherapy received less adjuvant ipsilateral salvage procedures that those who did not (49 vs 29% $p = 0.04$) prior to referral.

The role of radiotherapy in implant complications

Our study found that 76% of patients had received radiotherapy. Radiotherapy has been implicated in up to 86% of all patients undergoing tertiary reconstruction.[8,9,12] Radiotherapy is a well-known risk factor for implant-related complication and failure and has recommendations that, IBR in the setting of radiotherapy, should be the exception and not the rule.[28] Our results suggest that this is also true for an attempted salvage with a further implant procedure.

Twenty nine percent of patients in our series had a definitive reconstruction with either ADM, LD or direct-to-implant. We found that ADM use increased over time as LD decreased. Most patients with ADM underwent tertiary reconstruction because of implant loss. A recent meta-analysis found that ADMs are associated with a higher rate of implant failure.[29] Patients with an ADM have been shown to have much higher complications rates following radiotherapy.[30] The provisional results of the UK iBRA study show that ADM use is increasing.[4] As ADM use continue to rise, and new products marketed, this cohort of patients will increase.

Tertiary reconstruction complications

Flap loss in our study was 0.7% and total complication rate was 25%. This compares with the NMBRA reported flap failure rate of 1% in the delayed setting.[20] We did not see increased flap failure as reported by Mohan et al. (6%) or complications attributed to vessel scarring reported by Roostaeian and coworkers.[7,10] Only ten percent of patients required re-operation following tertiary reconstruction. This is less than the 19% re-operation reported by Visser et al. and 17.4% reported by Roostaeian and coworkers.[8,10]
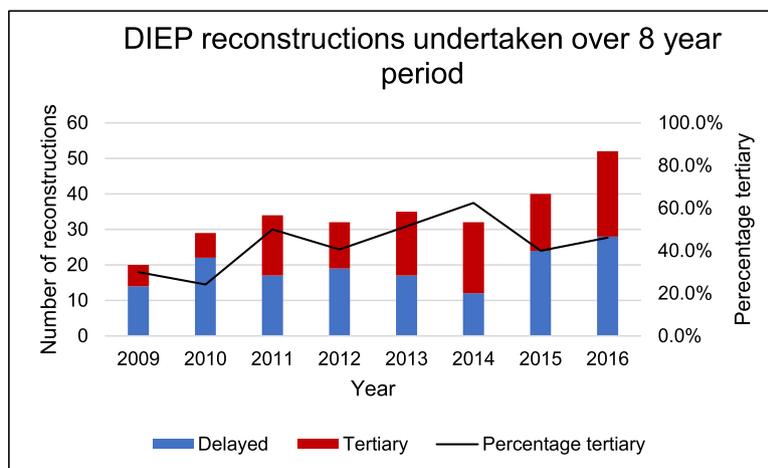
Figure 7 Graph demonstrating number of delayed and tertiary breast reconstructions completed over an 8-year period. Percentage of tertiary reconstructions is represented by the black line. This data does not include immediate autologous reconstruction.

We suggest that our low complication and re-operation rate were due to our patient selection criteria. No patient in our series had a BMI >30 or was an active smoker. The median number of significant comorbidities was 0 (range 0-2).

Ipsilateral procedures occurred in 55% of cases and were usually done at the time of symmetrization surgery. Lipofilling to the central mound for projection and minor scar revision were the most common procedures. Lipofilling was performed primarily to improve mound projection, especially when a contralateral symmetrizing mastopexy/reduction was done. The scar adjustment was performed in patients who developed minor flap complications such as delayed wound healing or scar tethering. Median number of surgeries required was 1 (range 1-3) at a median follow up of 20-months (range 6-months-7-years). One patient suffered from a failed tertiary reconstruction (flap loss 0.7%). She was salvaged with a LD only flap reconstruction.

Forty seven percent of patients in our cohort required symmetrizing procedures following DIEP. The most common procedure was a mastopexy with or without a small reduction. Our contralateral symmetrization rate of rate of 47% is very similar to the 45% reported for delayed reconstruction in the NMBRA 2010.[20] Visser et al. also found that 47% of patients who had tertiary reconstruction required further surgery.[8] We agree with their conclusion that these patients represent a disappointed and cosmetically cognizant group of unsuccessful previous breast reconstruction with an appetent to achieve the best possible result. Whilst symmetrization surgery involved an additional anaesthetic, there is now a trend to perform contralateral symmetrizing surgeries at the time of autologous reconstruction.[31]

Study limitations

Our study is retrospective. Some patient's datasets were missing or illegible and had to be excluded. Ancillary and/or salvage procedures were categorised and may not represent the full complexity of the additional procedures required for each patient.

For those patients who received radiotherapy we were unable to determine whether the radiotherapy was anticipated prior to mastectomy. Adjuvant radiotherapy was performed at regional breast oncology centres and not standardized.

Our study is looking at a highly-motivated subset of patients with failed implant reconstruction. Studies suggest 50% of patients choose to forego any further reconstructive attempts after even one severe complication.[11,25] It is therefore likely that we are underestimating the size of the problem. But with no denominator to our study, the results must be interpreted with caution.

Conclusions

We present the UK's largest series of tertiary reconstruction and the largest series of tertiary reconstruction with a single autologous flap. We have shown that tertiary breast reconstruction can be successful with only 55% requiring a further ipsilateral procedure. Importantly we show that radiotherapy is a factor in 71% of all reconstructive failures and that many patients are subjected to multiple failed salvage operations prior to referral. Tertiary reconstruction is increased and now comprises of 40% of all our delayed reconstructions (Figure 7). This is due to:

- Improved access to microsurgical expertise.
- Increased use of ADM with its associated complications.[29]
- Increasing indications for radiotherapy in early stage breast cancer.[32]
- Increased patient demand due to growing concerns over long-term safety of implants.[33]
- Increasing trend towards decreased aesthetic satisfaction with implant reconstruction over time.[24]

In the era of shared decision making, patients need to be aware of the short and long-term complications of implant-based immediate reconstruction. This is especially important in those patients who are likely to undergo radiotherapy. Whilst implants may be an appropriate option, these patients must also be given information on all types of breast reconstruction at the time of mastectomy. We would advocate prompt referral for consideration of autologous reconstruction in all cases of failed reconstruction, prior

to consideration to adjuvant salvage attempts, and would caution against the use of implant reconstruction when radiotherapy is planned, or the concept of delayed-immediate reconstruction, unless the streamlined staged protocol can be meticulously followed.

Financial support

None.

Conflicts of interest

None.

Institutional ethical approval

Local ethics approval was sought prior to the commencement of this study.

Reporting standards

This manuscript has been written in accordance with the STROBE guidelines.

Authorship

All listed authors contributed to; (1) conception and design, acquisition of data, analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; (3) final approval of the version to be published; (4) agreement to be accountable for all aspects of the work.

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