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Research Article

Does delayed immediate breast reconstruction lead to improved patients' satisfaction?

Abstract

Background: Immediate Breast Reconstruction (IBR) offers the best psychological and aesthetic outcome if radiotherapy is not required. If radiotherapy is required, Delayed Breast Reconstruction (DBR) may be preferable as there is less risk of complications.

It is challenging to predict the need of radiotherapy preoperatively.

Delayed-Immediate Breast Reconstruction (DIBR) can resolve this problem because definitive reconstruction is performed after completion of radiotherapy.

DIBR is a compromise between the psychological advantages of IBR and the benefit of delaying reconstruction until after completion of radiotherapy.

Therefore, it is expected that DIBR is also associated with high levels of patient satisfaction.

Aim: The aim of the study was to assess patient satisfaction outcomes following DIBR, and to compare these to patient satisfaction outcomes following DBR and IBR. The hypothesis was that patient satisfaction following DIBR would be better than patients undergoing DBR, with similar satisfaction to patients undergoing IBR.

Methods: 78 patients undergoing DIBR, DBR and IBR were reviewed retrospectively and included in this study.

Anonymous Breast Q satisfaction questionnaires used by the Royal College of Surgeons of England were posted to DIBR patients and to patients who underwent DBR following stage 2 and IBR 6 months after surgery.

Analysis: Outcome measures included breasts appearance, psychosocial, sexual and physical wellbeing. These were evaluated using a categorical scale then converted to a 0 to 100 scale with greater values indicating higher levels of satisfaction

Conclusion: Breast reconstruction successfully improved body image, physical, psychosocial and sexual well-being in all 3 cohorts of patients. However the DIBR group showed that scores for satisfaction with the breast were higher than for the IBR group.

Level of Evidence: Level III, well designed cohort analytic study.

Background

Researchers have widely reported the positive effects of Immediate Breast Reconstruction (IBR) on psychological health, self-esteem, sexuality, body image and the several advantages over delayed reconstruction [1-5]. In particular retrospective studies noted that IBR serves as a preventing measure to avoid the postoperative psychological problems frequently observed in women with early diagnosed breast cancer after mastectomy [6-9].

However, prospective studies have not been as universal in supporting the benefits of immediate reconstruction at the time of mastectomy, as patients can still experience distressing alterations in body image at 1-year follow-up [10,11].

It is conceivable that women who choose IBR may be

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significantly compromised in their emotional and behavioural functioning given that they are coping with a recent diagnosis of breast cancer. Indeed, there is evidence that women who pursue IBR, compared with those undergoing DBR, are more distressed about the effects of mastectomy on their feelings of femininity and sexuality [12,13].

Of particular relevance is the evidence that preoperative psychological disturbance, such as depression and anxiety, is associated with negative emotional and functional outcomes after mastectomy and following breast reconstruction [14-17].

This is also reported in women seeking DBR, who similarly had to cope with a prior history of breast cancer and mastectomy [10,11].

Therefore, patient selection is critical in determining the optimal time to consider breast reconstruction in newly diagnosed breast cancer patient [18-20].

Another important factor in this choice, which deserves special attention, is the use of adjuvant radiotherapy.

Its use in selected patients with early breast cancer has increased in frequency and this contribute to impaired cosmetic outcomes and higher complication rates, in particular following implant based reconstruction. Autologous tissue is preferable to implant within an irradiated operative field, however, even autologous tissue reconstructions can be adversely affected by Post-Mastectomy Radiotherapy (PMRT).

Therefore the need for radiotherapy may be viewed as a relative contraindication to immediate reconstruction. Several studies have shown both short and long-term post-reconstruction complications of PMRT [21-26]. Furthermore, previous research has suggested that reconstruction may negatively impact PMRT quality and delivery by increasing dose to the heart and lungs and by impairing chest wall and regional nodal coverage and overall outcome [27,28]. Given both the potential benefits and risks of reconstruction within the radiotherapy field, there continues to be a significant amount of controversy regarding the timing of breast reconstruction relative to radiation treatment. There is a lack of prospective data supporting the optimal reconstructive approach for women requiring PMRT and there is a variety of departmental preferences for the timing and type of reconstruction in breast cancer patients needing radiation.

There is little evidence that other systemic adjuvant treatment such as chemotherapy or endocrine therapy has a detrimental effect on immediate breast reconstruction [29,30].

Therefore the most important consideration in determining patients' suitability for IBR is whether or not they are likely to require PMRT. It is challenging to accurately determine pre-operatively the need for PMRT, especially in a symptomatic breast cancer unit. Also, an increasing number of patients are being offered PMRT, as NICE 2009 guidelines [31] advocate that PMRT should be offered to all patients with early invasive breast cancer at a high risk of local recurrence.

Kronowitz, et al., [32] implemented the DIBR approach to avoid the negative effect of radiotherapy on the final reconstruction. A temporary tissue expander is inserted at the same time as the skin sparing mastectomy and a definitive reconstruction is carried out as a second stage procedure, after completion of adjuvant treatment including PMRT if required, avoiding the potential unwanted consequences of radiotherapy on the final aesthetic outcome of the breast reconstruction [33,36].

DIBR is a compromise between the psychological advantages of IBR and the benefit of delaying reconstruction until after the completion of PMRT.

Therefore, it is expected that DIBR could also be associated with higher levels of patient satisfaction.

There is limited literature on patient satisfaction outcomes following DIBR and to our knowledge this is the first study to address patient satisfaction following DIBR.

The purpose of the present study was to compare the satisfaction outcomes and complications rate among a cohort of patients undergoing single-stage IBR, versus two-stage DIBR and DBR.

Participant selection criteria and number

The study patient population included female patients who underwent breast reconstruction at Northumbria NHS Foundation Trust from Jan 2016 to March 2017.

Inclusion criteria to be eligible for our study were the following:

- Patient age over 18.
- Undergoing unilateral or bilateral skin sparing mastectomy for breast cancer or risk reducing mastectomy and reconstruction (IBR, DIBR or DBR).
- DIBR and DBR group must have completed their definitive reconstruction (2nd stage) within 6 months.

Exclusion criteria

- Patients undergoing simple mastectomy.
- Patients undergoing breast conserving surgery.
- Stage IV or Metastatic breast cancer.
- Unable to speak English.
- Otherwise unable to complete research assessment (eg: cognitive impairment).

Patients were identified retrospectively from an electronic hospital database.

78 patients undergoing DIBR, DBR and IBR were identified who met the criteria to be included in this study.

Patient demographic data included age, race, smoking

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status, BMI and ASA grade (Table 1). Clinical information obtained included reconstructive procedure type, timing (IBR, DIBR or DBR), whether patients underwent symmetrisation or nipple reconstruction procedures, if the mastectomy and reconstruction was unilateral or bilateral, incidence of complications and whether patients received radiotherapy, chemotherapy or both.

Bilateral procedures included operations which were carried out on the contralateral breast as a simultaneous procedure with the initial reconstructive procedure for either prophylactic reasons or contralateral breast cancer. Symmetrising procedures were any procedure carried out in the contralateral breast to enhance symmetry and included reduction, mastopexy or augmentation. Major complications were defined as any patients requiring unplanned return to theatre and included partial or total flap necrosis, implant infection, extrusion or evacuation of haematoma. Minor complications were defined as complications which were managed non-operatively and included wound infections treated with antibiotics, seromas aspirated in clinic or delayed healing by secondary intention.

Table 1: Patient Demographics.

Patient Demographics Total	Total Patients N= 70	IBR N=20	DIBR N=25	DBR N=25
Ethnicity				
British White	67	18	25	24
Other	3	2	0	1
Age (years)				
Range (Mean)	34-75 (54)	34-73 (54)	34-75 (52)	37-72 (55)
BMI				
Range (Mean)	17-38 (27)	19-38 (27)	17-36 (27)	19-33 (26)
Smoker				
Y	3	2	1	0
Ex	11	1	3	7
N	56	17	21	18
ASA grade				
1	5	4	1	0
2	65	16	24	25
3	0	0	0	0

No BMI for 1 patient in the DBR category.

Data collection

Patients who met the inclusion criteria were contacted by phone to inquire about participating in the survey. Verbal or written informed consent was obtained from patients before sending the Breast Q post reconstruction module by post.

The breast Q post reconstruction questionnaire is a well validated Patient-Reported Outcome (PROM) instrument developed by Memorial Sloan Kettering Hospital and the University of British Columbia in 2009 [37], which encompasses two main themes, namely, patient satisfaction and Health Related Quality of Life (HRQoL). Separate subdomains within these two themes include satisfaction with the breast, satisfaction with overall outcome, psychological, sexual and physical well-being.

The same breast Q satisfaction module was used by the Royal College of Surgeons of England in the National Mastectomy and Breast Reconstruction Audit [38].

This survey was posted to patients who underwent DIBR following completion of their second stage reconstruction and to patients who underwent DBR and IBR at 6 months after surgery and asked to return them in a stamped addressed envelope. If the questionnaire was not received after 5 weeks, participants were sent a reminder letter with an additional questionnaire.

Each participant was assigned a research number to protect confidentiality.

Statistical analysis

Statistical analysis was supported by the statistical package SPSS (IBM Corp, Armonk, NY, USA, version 23).

The purpose of the analysis was to assess the factors which may influence the quality of life after reconstruction from the patient's perspective.

Categorical data were summarised using measures of frequency and proportion and scale/ordinal data using either the mean and standard deviation or the median and inter-quartile range. Inferential analysis was undertaken using the Chi-square test (categorical variables) and the Mann-Whitney U test (ordinal variables).

Despite the small sample size, we wanted to determine as to whether any of the observed differences were significant and due to this we had to use a binary logistic regression modelling which allowed us to investigate the independent impact of eight key factors (operation timing, operation type, symmetrising surgery, nipple reconstruction, complications, radiotherapy, chemotherapy, unilateral or bilateral) on outcomes. For the analysis, the data were dichotomised into: Breast Q score of <70 (moderate/poor outcome) and ≥70 (good outcome).

The analysis was undertaken by the principal investigator (senior author MPS), Breast reconstruction Nurse (BRN) and Statistician. Significance was set at 5% and two tailed tests used throughout.

Results

Patient demographic and tumour features are presented in Tables 1,2.

A total of 78 patients were identified by code from an electronic operative database that underwent breast reconstruction from January 2016 to March 2017 of whom 76 consented to participate in the survey and 2 declined.

70 patients responded, 20 IBR, 25 DIBR and 25 DBR group.

2 IBR, 2 DIBR and 2 DBR patients did not return the questionnaire.

Treatment undergone by our study population is presented in Table 3 (type of surgery) and Table 4 (adjuvant treatment).

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Table 3 provides details of the surgical procedures undertaken by each group of patients. 55(78.5%) patients had unilateral breast reconstruction, 49(70%) patients underwent symmetrising procedures (involving mastopexy, augmentation or prophylactic mastectomy), 17(24.2%) had nipple reconstruction. 18(25%) patients experienced minor complications and none experienced major complications. Implant based reconstruction was performed in 27 patients (38%), whereas autologous tissue reconstruction was performed in 31 patients (44%) and combined procedures (LD flap with implant) in 12 patients (17%).

Table 4 provides details of adjuvant treatments undergone by each group of patients.

In the IBR group 5 patients had prior adjuvant radiotherapy following breast conserving surgery for their initial breast cancer.

Table 2: Clinical data of study population (Tumour Features).

Clinical Variables Total	Total Patients N=70	IBR N=20	DIBR N=25	DBR N=25
Tumour Type				
Invasive (all types)	49	7	22	20
DCIS	11	6	2	3
N/A	10	7	1	2
Receptor Status				
ER +ve only	34	5	13	16
HER2 +ve only	6	1	2	3
ER + HER2 +ve	7	1	4	2
Triple -ve	6	0	4	2
N/A	17	13	2	2
Tumour Grade				
1	5	1	1	3
2	30	3	15	12
3	12	3	6	3
N/A	23	13	3	7
Nodes				
Positive	19	2	9	8
1-3	14	1	8	5
4+	4	1	1	2
Unknown	1	0	0	1
Negative	40	11	14	15
N/A	11	7	2	2

Table 3: Treatment undergone by our study population (Surgery).

Clinical Variables Total	Total Patients N=70	IBR N=20	DIBR N=25	DBR N=25
Surgery Type (Final operation)				
Implant	27(38%)	10(50%)	13(52%)	4(16%)
DIEP Flap	31(44%)	9(45%)	11(44%)	11(44%)
LD Flap	12(17%)	1(5%)	1(4%)	10(40%)
Unilateral	55 (78.5%)	11(55%)	21(84%)	23(92%)
Bilateral	15 (21.4)	9(45%)	4(16%)	2(8%)
Symmetrising Procedure				
Y	49(70%)	12(60%)	18(72%)	19(76%)
N	21(30%)	8(40%)	7(28%)	6(24%)
Nipple Reconstruction				
Y	17(24.2%)	4(20%)	11(44%)	2(8%)
N	50(71.4%)	13(65%)	14(56%)	23(92%)
N/A	3(4%)	3(15%)	0(0%)	0(0%)
Complications				
None	52(74%)	16(80%)	21(84%)	15(60%)
Major	0(0%)	0(0%)	0(0%)	0(0%)
Minor	18(25%)	4(20%)	4(16%)	10(40%)

Table 4: Treatment undergone by our study population (adjuvant treatment).

Clinical Variables Total	Total Patients N=70	IBR N=20	DIBR N=25	DBR N=25
Radiotherapy	24	2*	6	16
Chemotherapy	38	6	16	16
Tamoxifen	33	6	14	13
Aromatase Inibitors	16	4	4	8
Herceptin	13	1	6	6

* 5 patients undergoing IBR for recurrent breast cancer had prior adjuvant radiotherapy following breast conserving surgery for their initial breast cancer.

In the DIBR group all 6 patients had radiotherapy after the 1st stage reconstruction with expander, before undergoing the 2nd stage definitive reconstruction. In the DBR group 16 patients received radiotherapy before undergoing delayed reconstruction and the average time to proceed to reconstruction after radiotherapy was 2 years.

Breast Q score calculation

Analysis of the results following DIBR, DBR and IBR were evaluated at 6 months using a categorical scale (i.e., poor, fair, good, very good, and excellent). Each subdomain is scored individually and a raw score is generated through a Q-score statistical program. Scales used were satisfaction with breasts appearance, satisfaction with outcome, emotional psychosocial well-being, sexual well-being, and physical well-being. The Q-score software translates this raw score to a score on a scale. For each scale, items will be summed and transformed on a 0 to 100 scale, with greater values indicating higher levels of satisfaction and health-related quality of life.

Table 5 provides scores of patient satisfaction with their breast reconstruction. The average satisfaction with respect to the appearance of the breast was as followed: in the IBR group, it was 76.1 for implants, 76.11 for DIEP flaps and 63for LD flaps.

In the DIBR group, it was 78.9 for implants, 84.18 for DIEP flaps and 70 for LD flaps.

In the DBR group, it was 79 for implants, 88.81 for Diep flaps and 76.9 for LD flaps.

All DIEP and LD flap were performed by MPS, whilst implants by both MPS and MY.

Clinical variables

The total satisfaction with the breast score was calculated and descriptive statistics were presented divided into each of the key predictors of outcome: a) timing of surgery, b) type of surgery, c) radiotherapy or chemotherapy, d) symmetrising procedures, e) bilateral or unilateral reconstruction, f) nipple reconstruction, g) complications.

In evaluating clinical variables, there was equal representation of all reconstructive types in our study population, apart from the DBR group where implant based reconstruction was much lower compared to DIEP and LD flaps, because most of the patients in this group had adjuvant radiotherapy post mastectomy for which the use of implant only reconstruction was not feasible.

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Correlation between satisfaction and study variables

Due to the small sample size, a binary logistic regression modelling was used to investigate the independent impact of the 8 key predictors of outcome. For the analysis the data were dichotomised into <70 (moderate/poor outcome) and >70 (good outcome). This analysis showed that scores for satisfaction with the breast were significantly higher for the DIBR group than for the IBR group, after adjusting for all other factors (Table 6). There was no significant difference between the IBR and DBR group or between the DIBR and DBR groups.

There were no significant predictors of the satisfaction outcome with psychosocial or physical well-being from the model variables with regards to type of surgery, radiotherapy or chemotherapy, symmetrising procedures, nipple reconstruction and bilateral or unilateral reconstruction. Patients in the sexual well-being domain who experienced complications had higher scores than those without complications. However most of the complications experienced by these patients were minor and did not have a detrimental effect on their cosmetic appearance.

Although there was no statistically significant difference between patients who underwent different type of reconstructions, autologous tissue reconstruction with DIEP flap coincided with slightly higher levels of satisfaction with the breast in the DIBR (Figures 1,2 and Table 5) and DBR groups and slightly higher level of psychosocial well-being in the DIBR, whilst satisfaction with psychosocial well-being, was slightly better for implant based reconstruction in the IBR (Figures 3,4) and DBR groups (Table 5).

Table 5: Breast Q post-reconstruction Module Score in the satisfaction of the breast and HRQoL Domains.

Implant	Breast Q score	Satisfaction with breast	Psychosocial Well-Being	Physical Well-Being	Sexual Well-Being
		Total (mean)	Total (mean)	Total (mean)	Total (mean)
IBR(10)		761(76.1)	871(87.1)	507(50.7)	529(75.5)
DIBR(13)		1026(78.9)	1085(83.4)	657(50.5)	722(72.2)
DBR(4)		316(79)	335(83.75)	200(50)	266(66.5)
DIEP					
IBR(9)		685(76.11)	699(77.6)	450(50)	375(62.5)
DIBR(11)		926(84.18)	946(86)	550(50)	397(56.71)
DBR(11)		977(88.81)	896(81.45)	549(49.9)	447(74.5)
LD					
IBR(1)		63(63)	53(53)	50(50)	n/a
DIBR(1)		70(70)	50(50)	50(50)	63(63)
DBR(10)		769(76.9)	502(50.2)	502(50.2)	408(58.28)

Table 6: Binary logistic regression modelling.

Satisfaction with breast	B	S.E.	Wald	Df	Sig.	Exp(B)	95% C.I. for EXP(B)	
							Lower	Upper
IBR			4.938	2	0.085			
DIBR	1.823	0.874	4.356	1	0.037	6.192	1.117	34.316
DBR	1.039	0.719	2.087	1	0.149	2.827	0.690	11.577
Constant	0.619	0.469	1.744	1	0.187	1.857		
Satisfaction with sexual well being								
Complications	1.463	.673	4.729	1	.030	4.320	1.155	16.153
Constant	-.875	.376	5.410	1	.020	.417		

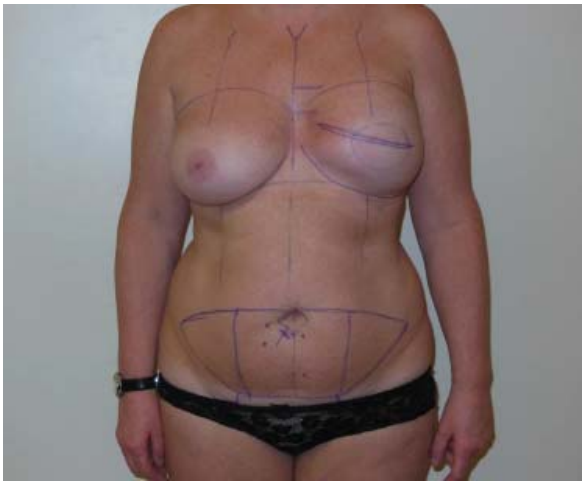

Figure 1: Left mastectomy and immediate reconstruction with expander (DIBR).

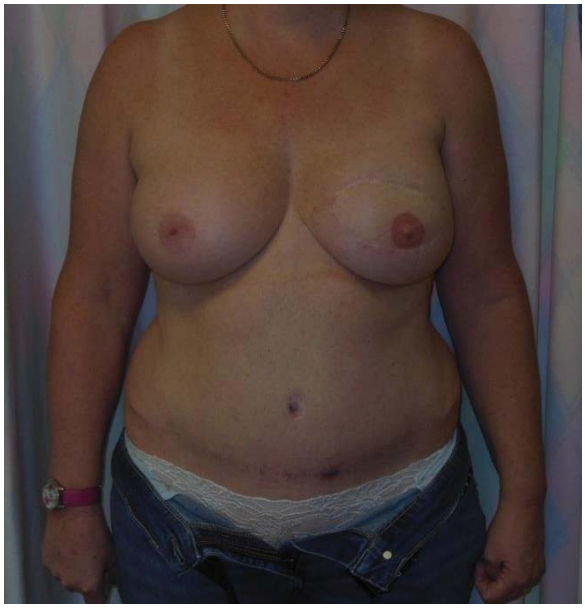

Figure 2: Replacement of left expander with free Diep flap and NAC reconstruction.

Discussion

In this study breast reconstruction generally improved body image, physical, psychosocial and sexual well-being and these benefits could be appreciated as early as 6 months following reconstruction, in accordance with Eltahir, et al., [39].

However a longer follow-up is warranted to determine any changes in body image after an extended period of time, as psychosocial benefit of breast reconstruction continue to manifest even after 2 years post reconstruction [40,41] .

Although we are aware of the limitations of a single Breast Q analysis in a short period of time, our study showed that patients who had shorter F-U time (IBR) had similar scores to patients with longer F-U (DIBR and DBR), suggesting that observed outcomes are maintained over time.

Furthermore as this study was conducted only retrospectively, it could not analyse the multiple preoperative

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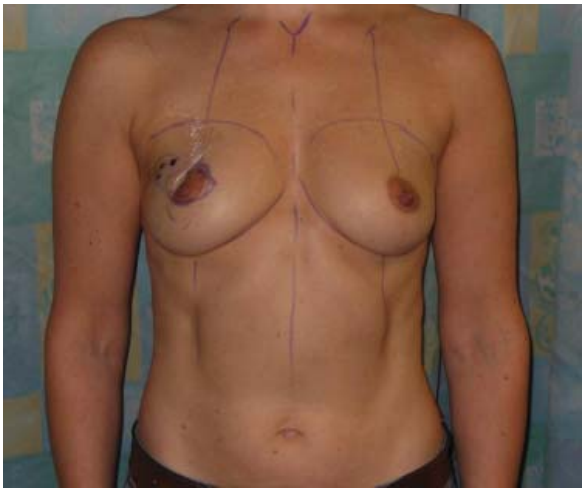

Figure 3: Preoperative IBR.

Figure 4: Postoperative: IBR with implant and NAC reconstruction Right breast and Left breast augmentation.

factors that contribute to lower the satisfaction score such as psychological distress related to breast cancer diagnosis which may persist after reconstruction, regardless of the type or timing [42].

Therefore it is not surprising that surgical outcomes for IBR may be adversely affected by psychological distress associated with breast cancer diagnosis [43], as showed in our study where satisfaction rates following IBR were lower when compared with DIBR and DBR.

However it is possible that assessment of patient satisfaction after a longer period of time following their surgery and cancer diagnosis may mitigate against this.

Indeed an accurate and methodical pre surgical assessment with multiple clinical reviews carried out by the Consultant Surgeon, psychologist and BRN, is essential to identify potential emotional or psychological distress which might jeopardize satisfactory outcomes after reconstructive surgery.

The option of IBR, DIBR and DBR was routinely offered to all women presenting to our surgical practice and the process of discussion and consent allowed women to understand the potential risks and benefits to make an informed decision. All patients underwent a detailed discussion of the pros and cons of the different reconstructive approaches, as well as the relevant complications, both with the breast reconstruction nurse specialists and also with the consultant surgeon, and were offered further appointments when necessary.

Patients were informed about the possibility of dissatisfaction with the aesthetic results following IBR, and that this could be generally worse when PMRT was required [44].

Impact of unilateral versus bilateral procedures

Interestingly in our study there was no statistically significant difference between patients who underwent symmetrising surgery or not, however patients who had bilateral reconstruction scored slightly better than those who had unilateral reconstruction in the domain of psychosocial and sexual well-being.

This suggests that patients who had bilateral reconstruction were more satisfied due to improved symmetry and superior aesthetic appearance. Furthermore as the number of bilateral mastectomy and subsequent need for reconstruction increases [45], in particular in the setting of prophylactic mastectomy, it seems to be reassuring for the patients that bilateral procedures are often perceived favourably by most of them.

Impact of PMRT

Another key variable which may influence the satisfactory outcome of surgery is PMRT.

The impact and extent of the radiotherapy adverse effect on cosmetic outcome, patient's satisfaction and quality of life are not very well understood. Some studies have observed high rates of undesirable aesthetic results and dissatisfied patients, while others have shown minimal deleterious effects in these domains [46-54].

We found no statistical difference in our group of patients between those who received radiotherapy pre or post reconstruction and those who did not require it.

Impact of chemotherapy

No statistical difference was found between patients who had chemotherapy and those who did not received it.

Influence of different timing of reconstruction

Patients who had DIBR scored significantly higher in the domain of satisfaction with the breast than the IBR group.

Influence of Procedure type on body image

As we found in our 6 months analysis, the 15 months data indicate that procedure type has a limited effect on psychosocial outcomes, in accordance with other studies [55].

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However, several studies have shown that autologous tissue reconstruction patients, especially with an extended period of time, fare better on this measure in terms of aesthetical superiority and patient satisfaction when compared with implant reconstruction [56].

The early improvements in HRQoL domains with the choice of implant reconstruction within the first 6 months postoperatively, may diminish over time as shown in previous studies [57]. One of the limitations of this study is the short follow up period, given the fact that satisfaction may well change over time.

Surgical complications

All complications were minor, with no major complications as experienced by any patients in this study.

In our study the women were generally fit, non-smokers of healthy body weight and this is a carefully selected group of patients who would be likely to experience very few surgical complications.

Conclusion

Differences in outcome between our three groups were identified only with the retrograde analysis and the key findings showed that patients who had DIBR scored significantly higher in the domain of satisfaction with the breast than the IBR group, after adjusting for all factors and this was despite the small number involved. There was no significant difference between the IBR and DBR group or between the DIBR and DBR groups.

We speculate that the higher satisfaction rate of DIBR patients was due to the combination of the advantages of immediate and delayed breast reconstruction, allowing patients' more time to obtain and process information regarding breast reconstruction so that they could make an informed decision about the final reconstruction.

However, these results may be occurred by chance, therefore caution in the interpretation of the analysis is required and we should reassess the satisfaction outcomes within a defined long-term postoperative period to identify any changes of the result.

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Ethical approval

1) FMH Research Ethics Committee approval was obtained.

2) Approval from the NHS Research and Development department in Northumbria was also obtained.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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