



Long-term patient-reported outcomes of immediate breast reconstruction after mastectomy for breast cancer: population-based cohort study

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Preliminary analysis presented to the Association of Breast Surgery Conference, Liverpool, UK, May 2022; European Journal of Surgical Oncology, 2022;48(5):e191–e192. doi:10.1016/j.ejso.2022.03.031; and full results presented to the San Antonio Breast Cancer Symposium, San Antonio, Texas, USA, December 2022: Cancer Res. 2023;83(5_Supplement):PD15-09. doi:10.1158/1538-7445.SABCS22-PD15-09.

Abstract

Background: Breast reconstruction is offered to improve quality of life for women after mastectomy for breast cancer, but information regarding the long-term patient-reported outcomes of different reconstruction procedures is currently lacking. The Brighter study aimed to evaluate long-term patient-reported outcomes after immediate breast reconstruction (IBR) in a population-based cohort.

Methods: Women who underwent mastectomy with IBR for breast cancer in England between 1 January 2008 and 31 March 2009 were identified from National Health Service Hospital Episode Statistics. Surviving women were invited to complete the BREAST-Q, EQ-5D-5L™, and ICECAP-A at least 12 years after the index procedure. Questionnaires were scored according to developers' instructions and compared by IBR type.

Results: Some 1236 women underwent IBR; 343 (27.8 per cent) had 2-stage expander/implant, 630 (51.0 per cent) latissimus dorsi, and 263 (21.3 per cent) abdominal flap reconstructions, with a mean(s.d.) follow-up of 13.3(0.5) years. Women who underwent abdominal flap reconstruction reported higher scores in all BREAST-Q domains than those who had other procedures. These differences remained statistically significant and clinically meaningful after adjusting for age, ethnicity, geographical region, socioeconomic status, smoking, BMI, and complications. The greatest difference was seen in scores for satisfaction with breasts; women who had abdominal flap reconstructions reported scores that were 13.17 (95 per cent c.i. 9.48 to 16.87) points; $P < 0.001$ higher than those among women who had two-stage expander/implant procedures. Women who underwent latissimus dorsi reconstruction reported significantly more pain/discomfort on the EQ-5D-5L™, but no other differences between procedures were seen.

Conclusion: Long-term patient-reported outcomes are significantly better following abdominal flap reconstruction than other traditional procedure types. These findings should be shared with women considering IBR to help them make informed decisions about their surgical options.

Introduction

Despite improvements in breast cancer treatment, up to 40 per cent of women undergo a mastectomy^{1,2}. Mastectomy can significantly affect women's well-being and body image, and breast reconstruction is offered to address this³. Decision-making for breast reconstruction, however, can be challenging. There are many types of reconstruction, and women require detailed, accurate information about the outcomes of different techniques to help them choose. Furthermore, as most women become long-term breast cancer survivors⁴, information about the

long-term outcomes of different procedures, and particularly how these are perceived from the patient perspective, are becoming increasingly important.

Although multiple studies^{5–8} have compared the short-term patient-reported outcomes (PROs) of implant-based and autologous procedures, and suggested that the outcomes of tissue-based reconstructions may be superior, few studies have undertaken long-term follow up. The studies that have compared long-term PROs are often small or single-centre analyses^{9–12}. Larger North American studies have reported

Received: April 23, 2023. Revised: June 27, 2023. Accepted: August 10, 2023

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Table 1 Respondent demographics by reconstruction type

	Expander/implant (n = 343)	LD flap (n = 630)	Abdominal flap (n = 263)	All patients (n = 1236)	P*
Age at index mastectomy (years), mean (s.d.)	52.10 (9.47)	51.20 (9.14)	50.58 (7.73)	51.32 (8.96)	0.105†
Ethnicity					0.568
White	328 (97.9)	606 (97.4)	249 (96.5)	1183 (97.4)	
Other	7 (2.1)	16 (2.6)	9 (3.5)	32 (2.6)	
Region					< 0.001
East Midlands	31 (9.0)	61 (9.7)	22 (8.4)	114 (9.2)	
East of England	37 (10.4)	73 (11.6)	82 (31.2)	192 (15.5)	
London	45 (13.1)	56 (8.9)	30 (11.4)	131 (10.6)	
North East	13 (3.8)	20 (3.2)	7 (2.7)	40 (3.2)	
North West	41 (12.0)	84 (13.3)	20 (7.6)	145 (11.7)	
South East	61 (17.8)	110 (17.5)	40 (15.2)	211 (17.1)	
South West	44 (12.8)	80 (12.7)	23 (8.8)	147 (11.9)	
West Midlands	26 (7.6)	56 (8.9)	21 (8.0)	103 (8.3)	
Yorkshire and Humber	34 (9.9)	83 (13.2)	16 (6.1)	133 (10.8)	
Other	11 (3.2)	7 (1.1)	2 (0.8)	20 (1.6)	
Indices of Multiple Deprivation					0.729
1 (most deprived)	25 (7.6)	56 (9.0)	21 (8.1)	102 (8.4)	
2	61 (18.4)	85 (13.7)	43 (16.5)	189 (15.6)	
3	69 (20.9)	141 (22.7)	51 (19.5)	261 (21.5)	
4	85 (25.7)	157 (25.2)	69 (26.4)	311 (25.6)	
5 (least deprived)	91 (27.5)	183 (29.4)	77 (29.5)	351 (28.9)	
Smoking status					0.010
Yes	44 (13.0)	80 (12.9)	17 (6.6)	141 (11.6)	
No	292 (86.1)	537 (86.5)	235 (90.7)	1064 (87.3)	
Prefer not to say	3 (0.9)	4 (0.6)	7 (2.7)	14 (1.2)	
BMI (kg/m ²), mean (s.d.)	24.14 (4.30)	24.33 (3.59)	25.80 (3.96)	24.59 (3.93)	< 0.001†
Marital status					0.062
Single	39 (11.7)	57 (9.3)	15 (5.9)	111 (9.3)	
Married	209 (62.3)	411 (67.2)	173 (68.4)	793 (66.1)	
Divorced or separated	44 (13.2)	72 (11.8)	38 (15.0)	154 (12.8)	
In a relationship	35 (10.5)	69 (11.3)	26 (10.3)	130 (10.8)	
Prefer not to say	7 (2.1)	3 (0.5)	1 (0.4)	11 (0.9)	
Complications resulting from surgery					< 0.001
Yes, managed in clinic or by GP	43 (12.9)	139 (22.8)	63 (24.7)	245 (20.5)	
Yes, I needed further surgery	93 (27.9)	111 (18.2)	25 (9.8)	229 (19.1)	
No	197 (59.2)	358 (59.0)	167 (65.5)	723 (60.4)	
Further surgery					0.504
Yes	233 (67.9)	418 (66.4)	185 (70.3)	836 (67.6)	
No	110 (32.1)	212 (33.7)	78 (29.7)	400 (32.4)	

Values are n (%) unless otherwise indicated. LD, latissimus dorsi; GP, general practitioner. * χ^2 test, except †ANOVA.

Table 2 Unadjusted BREAST-Q scores by reconstruction type

	Satisfaction with breasts (n = 1084)			Psychosocial well-being (n = 1177)			Physical well-being (n = 1055)			Sexual well-being* (n = 800)		
	n	Mean score	P†	n	Mean score	P†	n	Mean score	P†	n	Mean score	P†
Implant/expander	293	54.7 (52.4, 56.9)	< 0.001	328	72.2 (70.0, 74.5)	0.006	296	82.1 (80.0, 84.1)	< 0.001	225	44.7 (41.4, 47.9)	0.013
LD flap	555	59.0 (57.2, 60.7)		597	73.3 (71.5, 75.0)		532	79.5 (77.8, 81.3)		390	47.4 (44.8, 50.0)	
Abdominal flap	236	67.6 (65.0, 70.3)		252	77.6 (74.9, 80.2)		227	87.8 (85.6, 89.8)		185	51.2 (47.7, 54.8)	

Values in parentheses are 95% confidence intervals. *The sexual well-being scale was an optional part of the questionnaire and a proportion of respondents elected not to complete this section. LD, latissimus dorsi. †ANOVA.

outcomes at 4¹³ and 8¹⁴ years, but significant proportions of these women had undergone bilateral mastectomy and reconstruction, so the generalizability of these results to other settings is unclear. Furthermore, only the outcomes of implants and abdominal flaps have been compared. Both the UK Association of Breast Surgery¹⁵, and the patients and professionals participating in the UK breast cancer surgery James Lind Alliance Research Priority Setting Partnership¹⁶ have identified the need for long-term breast reconstruction outcome data as a key research priority.

The aim of the Brighter study was, therefore, to explore the impact of procedure type on the long-term PROs of immediate breast reconstruction (IBR) in a population-based cohort to provide much needed evidence to support informed decision-making for women considering breast reconstruction.

Methods

This population-based cohort study received full ethical approval from the UK Health Research Authority and Confidentiality

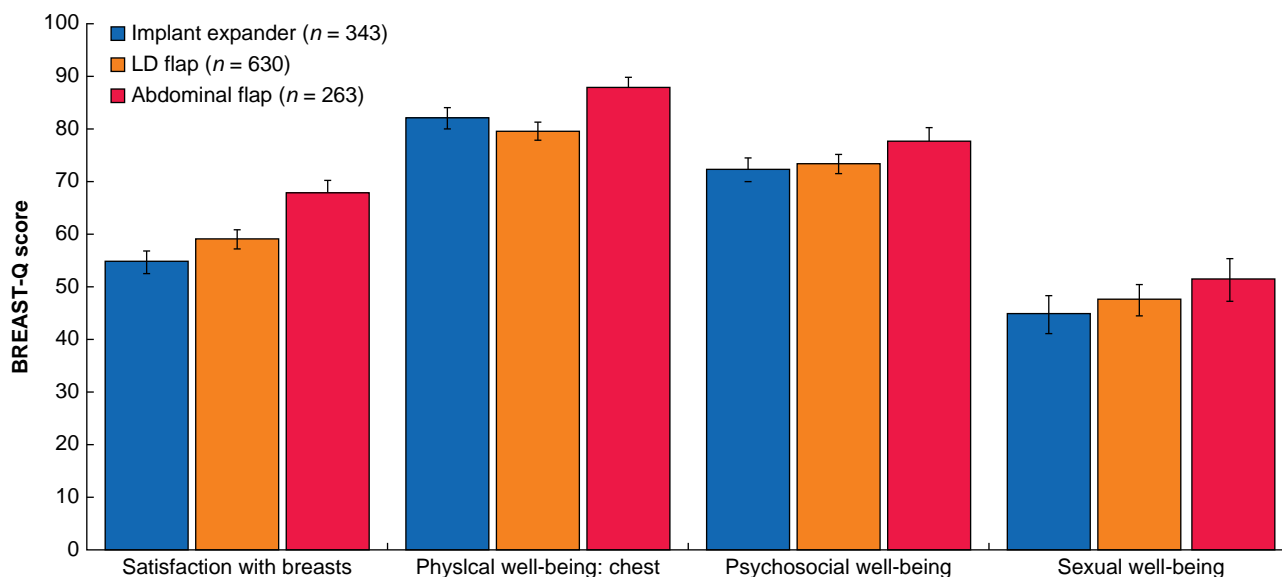


Fig. 1. Unadjusted BREAST-Q score by procedure type

Values are mean with 95% confidence interval.

Advisory Group (CAG) (REC reference 20/SW/0020, CAG reference 20/CAG/0021; IRAS ID 276030). The Brighter protocol provides a full description of the study design and methodology¹⁷. This article reports the PROs of the IBR cohort. The clinical outcome and cost analyses¹⁸ will be reported elsewhere.

Cohort identification and participant recruitment

Women undergoing unilateral mastectomy for breast cancer or ductal carcinoma *in situ* between 1 January 2008 and 31 March 2009 with or without breast reconstruction were identified by National Health Service (NHS) Digital and up-to-date contact details for the surviving cohort obtained from the NHS Personal Demographic service following Section 251 approval from the CAG. This cohort was selected to include all women who would have been included in the UK National Mastectomy and Breast Reconstruction Audit (NMBRA) for comparative purposes^{17,19}.

Women aged less than 90 years, living independently (not nursing or care home residents) without evidence of cognitive impairment, defined as having codes for dementia in their Hospital Episode Statistics data record, were contacted and invited to complete validated PRO questionnaires either by post or online via a secure REDCap²⁰ link according to participant preference. A second invitation letter was sent approximately 6 weeks after the first to optimize study participation. If no response was received after the second invitation, women were considered to have declined participation in the PRO study.

Receipt of IBR and type of reconstruction performed were determined by patient self-report. Only women who reported undergoing the three most commonly performed procedures—two-stage subpectoral expander/implant only reconstruction (without the use of mesh), latissimus dorsi (LD) flap with or without an implant, and abdominal flap reconstruction—were included in the analysis. This is because preliminary work suggested that other types of reconstruction were carried out infrequently, and small numbers of these reconstructions would preclude meaningful comparisons between procedure types.

Questionnaires

Participants were asked to complete three validated questionnaires: BREAST-Q, ED-5D-5L™ (EuroQol Group, Rotterdam, the Netherlands), and ICEpop CAPability measure for Adults (ICECAP-A), together with a study-specific questionnaire including participant demographics and details of surgery and treatments received. Respondents were also asked to complete a single item assessment of overall satisfaction with the outcomes of surgery on a five-point Likert scale (excellent, very good, good, fair, poor), consistent with the assessment made as part of the NMBRA²¹.

BREAST-Q

The BREAST-Q is a validated questionnaire that has been developed robustly for use in patients undergoing breast reconstruction surgery^{22,23}. It consists of four main scales: satisfaction with breasts, physical well-being (chest), sexual well-being, and psychosocial well-being. Each scale is Rasch-transformed to give a score out of 100, with higher scores reflecting better outcomes. The minimum clinically important difference in BREAST-Q scores has recently been defined as being 4 points for the satisfaction with breast, psychosocial and sexual well-being domains, and 3 points for the physical well-being domain²⁴.

ED-5D-5L™

The EQ-5D-5L™²⁵ is a generic measure of health-related quality of life consisting of a descriptive system with five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The scores on the five dimensions can be presented as a health profile, or can be converted to a single index reflecting a preference-based quality-of-life score (utility) anchored at 1 (best health) and 0 (death) using a UK National Institute for Health and Care Excellence-recommended value set²⁶. It also includes the EQ VAS, a vertical visual analogue scale on which patients self-report their health on a scale from 'the best health you can imagine' to 'the worst health you can

Table 3 Multivariable regression of BREAST-Q scores

	Satisfaction with breasts (n = 1009)			Psychosocial well-being (n = 1103)			Physical well-being (chest) (n = 990)			Sexual well-being (n = 760)		
	Coefficient (95% c.i.)	P*	P†	Coefficient (95% c.i.)	P*	P†	Coefficient (95% c.i.)	P*	P†	Coefficient (95% c.i.)	P*	P†
Procedure												
Expander/implant (reference)												
LD flap	4.86 (1.92, 7.81)	0.001	< 0.001	1.60 (-1.26, 4.45)	0.273	0.011	-2.02 (-4.73, 0.68)	0.143	< 0.001	3.27 (-0.84, 7.37)	0.119	0.029
Abdominal flap	13.17 (9.48, 16.87)	< 0.001		5.41 (1.80, 9.01)	0.003		5.65 (2.22, 9.09)	0.001		6.79 (1.69, 11.90)	0.009	
Age (years)												
< 50 (reference)												
50-59	2.81 (0.06, 5.56)	0.045	0.002	6.15 (3.46, 8.85)	< 0.001	< 0.001	3.51 (0.95, 6.06)	0.007	0.001	3.64 (-0.12, 7.40)	0.058	0.002
≥ 60	6.39 (2.76, 10.02)	0.001		11.30 (7.85, 14.75)	< 0.001		5.82 (2.52, 9.11)	0.001		9.37 (3.82, 14.91)	0.001	
Ethnicity												
White (reference)												
Other	4.36 (-4.39, 13.12)	0.328	0.328	-1.40 (-9.42, 6.61)	0.731	0.728	-11.92 (-19.29, -4.55)	0.002	0.002	5.95 (-7.38, 19.28)	0.381	0.381
Region												
London (reference)												
North East	1.63 (-6.15, 9.41)	0.681		-0.37 (-8.01, 7.28)	0.925		-5.24 (-12.63, 2.16)	0.165		-5.89 (-16.97, 5.20)	0.298	
North West	0.69 (-4.62, 5.99)	0.799		-1.96 (-7.14, 3.22)	0.458		-1.81 (-6.74, 3.12)	0.471		-2.24 (-9.60, 5.12)	0.551	
Yorkshire and Humber	0.10 (-5.33, 5.53)	0.971		0.09 (-5.37, 5.18)	0.973		-2.71 (-7.85, 2.42)	0.300		-1.76 (-9.29, 5.77)	0.647	
East Midlands	1.72 (-3.92, 7.35)	0.550	0.984	0.77 (-4.72, 6.27)	0.782	0.951	-2.59 (-7.77, 2.58)	0.326	0.741	0.32 (-7.60, 8.23)	0.937	0.925
West Midlands	-0.22 (-5.97, 5.53)	0.940		-2.34 (-7.93, 3.24)	0.410		-3.72 (-9.05, 1.60)	0.170		-1.04 (-8.87, 6.79)	0.794	
East of England	-1.42 (-6.46, 3.62)	0.580		0.17 (-4.72, 5.06)	0.945		-1.74 (-6.40, 2.93)	0.466		-2.31 (-9.38, 4.77)	0.523	
South East	-0.25 (-4.68, 5.19)	0.920		0.53 (-4.24, 5.31)	0.827		-0.88 (-5.38, 3.62)	0.702		-3.82 (-10.61, 2.97)	0.270	
South West	1.54 (-3.79, 6.86)	0.571		1.34 (-3.81, 6.49)	0.610		0.63 (-4.27, 5.54)	0.800		-2.77 (-10.19, 4.66)	0.464	
Other	-0.09 (-10.66, 10.48)	0.987		0.72 (-9.43, 10.86)	0.890		-3.24 (-12.65, 6.18)	0.500		-8.44 (-22.65, 5.78)	0.244	
IMD												
Most deprived quintile (reference)												
Least deprived four quintiles	1.08 (-3.65, 5.80)	0.654	0.654	6.31 (0.007)	0.007	1.71, 10.91	-0.70 (-5.09, 3.69)	0.753	0.753	5.22 (-1.24, 11.67)	0.113	0.113
Smoker												
No (reference)												
Yes	-6.51 (-10.49, -2.54)	0.001	0.005	-7.88 (-11.75, -4.02)	0.000	< 0.001	-6.78 (-10.48, -3.08)	0.000	0.001	-9.34 (-14.72, -3.96)	0.001	0.001
Prefer not to say	-0.52 (-12.00, 10.96)	0.929		-11.21 (-22.86, 0.43)	0.059		2.65 (-8.33, 13.64)	0.636		-13.85 (-29.18, 1.47)	0.076	
BMI (kg/m²)												
≤ 30 (reference)												
> 30	-0.78 (-3.86, 2.30)	0.619	0.619	-2.48 (-5.43, 0.48)	0.100	0.096	-3.39 (-6.28, -0.50)	0.022	0.022	-3.81 (-8.21, 0.59)	0.090	0.090
Marital status												
Married (reference)												
Single	-8.06 (-12.52, -3.61)	0.000		-6.86 (-11.06, -2.65)	0.001		-2.81 (-6.85, 1.23)	0.172		-17.34 (-23.96, -10.71)	0.000	
Divorced or separated	-0.96 (-4.74, 2.82)	0.617	0.002	-3.94 (-7.60, -0.28)	0.035	< 0.001	-1.33 (-4.84, 2.17)	0.455	0.602	-14.11 (-19.73, -8.48)	0.000	< 0.001
In a relationship	-4.20 (-8.29, -0.10)	0.045		-4.62 (-8.63, -0.61)	0.024		0.02 (-3.84, 3.88)	0.992		-4.32 (-9.58, 0.95)	0.108	
Prefer not to say	7.59 (-6.41, 21.60)	0.288		14.79 (-0.45, 30.02)	0.057		3.74 (-9.05, 16.54)	0.566		18.89 (-2.50, 40.27)	0.083	
Complications after surgery												
No (reference)												
Yes, managed in clinic or by GP	-5.73 (-8.89, -2.58)	< 0.001	< 0.001	-3.16 (-6.26, -0.06)	0.046	< 0.001	-6.02 (-8.97, -3.08)	< 0.001	< 0.001	-2.63 (-7.02, 1.76)	0.240	0.110
Yes, I needed further surgery	-8.50 (-11.94, -5.06)	< 0.001		-6.89 (-10.15, -3.63)	< 0.001		-6.58 (-9.69, -3.47)	< 0.001		-4.53 (-9.08, 0.31)	0.052	
Further surgery to breasts												
Yes (reference)												
No	-0.08 (-2.83, 2.67)	0.955	0.955	2.39 (-0.27, 5.05)	0.078	0.074	3.51 (1.01, 6.02)	0.006	0.006	3.52 (-0.38, 7.43)	0.077	0.072

LD, latissimus dorsi; IMD, Indices of multiple deprivation. *P for coefficients of co-variable within each category; †P for likelihood ratio test of impact of co-variable on regression model.

imagine'. The EQ-5D-5L™ has been used in previous breast reconstruction studies^{27,28}.

ICECAP-A

ICECAP-A²⁹ is a measure of well-being defined in a broader sense than health and covers five attributes: attachment, stability, achievement, enjoyment, and autonomy. A set of UK index values for ICECAP-A has been estimated using best-worst scaling³⁰. It was hypothesized that ICECAP-A may be more sensitive to breast reconstruction-related concerns than the EQ-5D-5L™ and so it was used as an exploratory measure in this study.

Statistical analysis

Demographic characteristics are summarized as counts with percentages for categorical variables, and mean (s.d.) for continuous variables. These were compared in the responder and non-responder groups, and by the type of reconstruction received, using ANOVA and χ^2 test for continuous and categorical variables respectively.

All questionnaires were scored according to the developers' instructions, and scores for each of the main BREAST-Q scales, ICECAP-A score, individual EQ-5D-5L™ dimensions, utility, and the EQ VAS were compared by type of reconstruction performed. Multivariable linear regression was used to adjust

Table 4 Overall satisfaction with outcome of surgery by immediate breast reconstruction type

	Implant expander (n = 330)	LD flap (n = 615)	Abdominal flap (n = 254)	P*
Good, fair, poor	155 (47.0)	226 (36.8)	67 (26.4)	< 0.001
Excellent, very good	175 (53.0)	389 (63.3)	187 (73.6)	

Values are n (%). LD, latissimus dorsi. * χ^2 test.

for factors hypothesized from the literature^{13,31-33} to influence BREAST-Q scores, including age at mastectomy, ethnicity, socioeconomic deprivation assessed using Indices of Multiple Deprivation, geographical region of residence, smoking status, marital status, BMI at the time of mastectomy, surgical complications, and receipt of further surgery.

The single item concerning overall satisfaction with the outcome of surgery was dichotomized into 'excellent, very good' versus 'good, fair, poor' and compared across procedure types using χ^2 statistics.

Results

Of 11 977 women invited to participate in the study, 4207 (35.7 per cent) completed the PRO questionnaires. Of these, 1236 (29.4 per cent) reported undergoing IBR with 1 of the 3 procedures of interest. This included 343 2-stage expander/implant reconstructions (27.8 per cent), 630 LD flap procedures (51.0 per cent), and 263 abdominal flap reconstructions (21.3 per cent). Responders were more likely to be older, white, and from the higher socioeconomic groups than non-responders (Table S1).

Demographic characteristics of the IBR cohort are summarized in Table 1. There were no differences between surgical groups with regard to age at the time of index mastectomy, socioeconomic or marital status, ethnicity or the receipt of further surgery (Table 1). Women who had an abdominal flap reconstruction had slightly higher BMIs, but were significantly less likely to have smoked at the time of reconstruction, than women who had expander/implant or LD flap reconstructions. There were also significant differences between the groups in postoperative complications; women who had two-stage expander/implant reconstruction more likely to have experienced complications requiring further surgery than those who underwent other types of reconstruction (93 women (27.9 per cent) in expander/implant group, 111 (18.2 per cent) in LD flap group, and 25 (9.8 per cent) in abdominal flap group; $P < 0.001$) (Table 1). Mean(s.d.) follow-up for the cohort was 13.3(0.5) years.

BREAST-Q and overall satisfaction with outcome

Women who received an abdominal flap reconstruction reported higher unadjusted mean scores across all BREAST-Q domains than those having other breast reconstruction procedures (Table 2 and Fig. 1). These differences in satisfaction with breasts (13.17 (95 per cent c.i. 9.48 to 16.87) points; $P < 0.001$), psychosocial well-being (5.41 (1.80 to 9.01) points; $P = 0.003$), physical well-being (5.65 (2.22 to 9.09) points; $P = 0.001$), and sexual well-being (6.79 (1.69 to 11.90) points; $P = 0.009$) remained statistically significant, and the means exceeded the established minimum clinically important difference for each domain²⁴ after adjusting for potential confounders (Table 3). In the

Table 5 EQ-5D-5L™ dimension scores by reconstruction type

	Implant expander (n = 343)	LD flap (n = 630)	Abdominal flap (n = 263)	P*
Mobility				
No problems	265 (80.6)	450 (74.1)	193 (76.9)	0.184
Slight problems	28 (8.5)	93 (15.3)	36 (14.3)	
Moderate problems	21 (6.4)	42 (6.9)	14 (5.6)	
Severe problems	15 (4.6)	21 (3.5)	8 (3.2)	
Unable to walk about	0 (0)	1 (0.2)	0 (0)	
Total	329 (100)	607 (100)	251 (100)	
Self-care				
No problems	304 (92.7)	559 (92.2)	235 (94.0)	0.723
Slight problems	16 (4.9)	27 (4.5)	6 (2.4)	
Moderate problems	7 (2.1)	17 (2.8)	9 (3.6)	
Severe problems	1 (0.3)	2 (0.3)	0 (0)	
Unable to wash/dress	0 (0)	1 (0.2)	0 (0)	
Total	328 (100)	606 (100)	250 (100)	
Usual activities				
No problems	232 (70.5)	421 (69.5)	181 (72.4)	0.874
Slight problems	61 (18.5)	120 (19.8)	46 (18.4)	
Moderate problems	24 (7.3)	49 (8.1)	15 (6.0)	
Severe problems	10 (3.0)	14 (2.3)	8 (3.2)	
Unable to do	2 (0.6)	2 (0.3)	0 (0)	
Total	329 (100)	606 (100)	250 (100)	
Pain/discomfort				
None	145 (44.2)	237 (39.2)	133 (53.0)	0.008
Slight	134 (40.9)	239 (39.5)	79 (31.5)	
Moderate	32 (9.8)	96 (15.9)	24 (9.6)	
Severe	13 (4.0)	26 (4.3)	12 (4.8)	
Extreme	4 (1.2)	7 (1.2)	3 (1.2)	
Total	328 (100.0)	605 (100)	251 (100)	
Anxiety/depression				
None	193 (58.7)	353 (58.4)	145 (57.8)	0.897
Slight	99 (30.1)	169 (27.9)	75 (29.9)	
Moderate	31 (9.4)	61 (10.1)	22 (8.8)	
Severe	5 (1.5)	18 (3.0)	8 (3.2)	
Extreme	1 (0.3)	4 (0.7)	1 (0.4)	
Total	329 (100)	605 (100)	251 (100)	

Values are n (%). LD, latissimus dorsi. * χ^2 test.

multivariable analysis, higher scores in all BREAST-Q domains were also strongly associated with older age at the initial reconstruction (aged 60 or over versus under 50 years), whereas lower scores in all domains were strongly associated with smoking at the time of reconstruction and experiencing postoperative complications (Table 3). Higher psychosocial well-being scores were strongly associated with higher socioeconomic status, whereas non-white ethnicity and higher BMI were strongly associated with lower physical well-being scores. The impact of marital status at the time of reconstruction was complex (Table 3).

Considering overall satisfaction with the outcome of the reconstruction, almost three-quarters of women who underwent abdominal flap reconstruction (187 of 254, 73.6 (95 per cent c.i. 67.8 to 78.9) per cent) considered their outcome to be excellent or very good compared with just over half of those who had two-stage expander/implant procedures (175 of 330, 53.0 (47.5 to 58.5) per cent) ($P < 0.001$) (Table 4).

EQ-5D-5L™ and ICECAP-A

There were no differences in EQ-5D-5L™ VAS or overall utility scores, irrespective of the type of procedure performed (Tables S2 and S3). Comparison of individual EQ-5D-5L™ dimension scores across procedure types, however, showed that women who underwent LD reconstructions reported significantly more

moderate or severe pain/discomfort than those who had other types of reconstruction (129 of 605 (21.3 per cent) *versus* 49 of 328 (14.9 per cent) for expander/implant and 39 of 251 (15.5 per cent) for abdominal flap reconstructions; $P=0.008$) (Table 5). There were no differences in other dimensions of the EQ-5D-5L™, and ICECAP-A scores were similar across all procedure groups (Table S4).

Discussion

This large population-based cohort study evaluated long-term PROs at a mean of 13.3 years after IBR, and compared outcomes following the three procedures most commonly performed at that time. It demonstrated that women who had abdominal flap reconstruction reported higher long-term levels of satisfaction with breasts, and physical, psychosocial, and sexual well-being than those who underwent other types of reconstruction. Women who had LD flap reconstruction reported greater satisfaction with breasts than those who had two-stage subpectoral expander/implant reconstruction, but there were no other differences between the groups. Women who received a traditional two-stage expander/implant reconstruction reported the lowest scores across all BREAST-Q scales 13 years after surgery. This important and novel information highlights how different IBR procedures continue to affect the well-being of women treated for breast cancer many years after surgery and for a significant amount of their remaining 22–28-year life expectancy³⁴. As such, it should be shared routinely with women considering surgery to allow them to make fully informed decisions about reconstructive options.

These findings are consistent with those of other shorter studies^{13,14} suggesting that the PROs of abdominal flap reconstruction are superior to those after implant-based procedures. A large single-centre North American cohort study¹⁴ of 3268 women suggested that adjusted scores for satisfaction with breasts were 16.77 and 22.02 points higher at 5 and 7 years after surgery after abdominal flap reconstruction compared with implant-based procedures. These differences are much higher than the 13-point difference at 13 years in the present study. Notably, almost two-thirds of patients in the North American cohort had bilateral surgery, which may partially explain these findings. Furthermore, these women all had surgery at a single large specialist centre, so the extent to which the results are generalizable is unclear and the outcomes of LD flap reconstruction were not assessed. This present population-based cohort included women who had the three most commonly performed IBR procedures in England. It should, therefore, be more representative of long-term outcomes of IBR in a wider group of patients.

Similar findings were noted in a small cross-sectional North American study³⁵ that evaluated aesthetic satisfaction with breast reconstruction over time in 219 women, with a median follow-up of 6.5 years. In that study, although women who had implant-based procedures were initially more satisfied with the outcome of the reconstruction, satisfaction decreased markedly over time, whereas women who underwent autologous reconstruction became more satisfied with the results. Approximately 40 per cent of women who had implant-based procedures reported being satisfied with the cosmetic outcome of the reconstruction at 10 years, compared with approximately 75 per cent of those who underwent autologous procedures³⁵. These findings are consistent with those at 13 years reported here.

The reason for the superiority of autologous procedures is likely to be that tissue-based reconstructions behave more like a

natural breast, developing ptosis over time and changing with the weight of the patient. By contrast, for women with unilateral implant-based reconstruction, asymmetry will become more marked over time and complications such as capsular contracture are more likely to develop, requiring further interventions to maintain acceptable cosmetic results.

Despite the marked differences between procedure types highlighted with the BREAST-Q, there were no differences between the surgical groups in overall scores for either the generic measures of health (EQ-5D-5L™) or well-being (ICECAP-A). The lack of discriminatory value has previously been reported for the EQ-5D-5L™^{27,28}, but this is a novel and unanticipated finding for the well-being measure. These results are likely to reflect the brevity of both generic measures as they do not include aspects of outcome, such as satisfaction with breast appearance, that differ between procedure types and are important to women. In addition, both measures compress all aspects of health/well-being into a single scale anchored at 0 and 1. This means that small but potentially important differences are not evident, even in large sample sizes. When individual dimensions of the EQ-5D-5L™ were compared, however, differences were seen in the levels of pain/discomfort reported in the LD group. This was notable, and suggests that chronic pain may be a more significant long-term issue for these women than previously reported³⁶.

This work has several limitations that require consideration. First, even though every attempt was made to optimize engagement and response rates, including co-developing study materials with patients, only 1236 women participated in the study. Although it is not possible to determine response rates precisely owing to UK legislation mandating that participants are given the opportunity to opt out of having their routinely collected healthcare data used in research, based on the numbers of women who had IBR registered in the UK 2007–2008 NMBRA^{19,37} and allowing for a 20–25 per cent mortality rate at 12 years⁴, it could be estimated that response rates in this study were between 40 and 50 per cent. This is lower than ideal, but reasonable given that invitations to participate were sent 12–13 years after the initial surgery. Women who completed the questionnaires, however, were older, more affluent, and more likely to be white than non-responders. This response bias has been reported in other breast reconstruction studies³⁸, and may mean that the views reported here may not be representative of the breast reconstruction community more generally.

Previous PRO data for this cohort were not available, meaning that it is not possible to make any definitive comments regarding how outcomes have changed over time. The initial aim of the study was to link these data to the original NMBRA cohort¹⁷ that included 18-month PROs, but changes in UK data protection legislation meant that the NMBRA data were no longer available for linkage. Without NMBRA data, patient self-report of IBR and the type of procedure received was used as the basis for this study. This introduces the possibility of recall bias as women may not accurately remember details of procedures and events that occurred over 12 years previously. Although this is possible, breast cancer and breast reconstruction are highly salient events in any woman's life. This would make significant issues with recall bias unlikely.

Patient satisfaction and health-related quality of life are complex constructs that are likely to be influenced by multiple factors. Although attempts were made to control for several potential confounders, it is acknowledged that other factors may have been important. Specifically, the impact of cancer

stage and adjuvant treatments could not be assessed as it was not possible to obtain linked oncological or treatment data.

Finally, it could be argued that this study evaluated the outcomes of historical procedures that do not reflect current practice. This is particularly relevant to women in the implant-based group, all of whom would have received two-stage subpectoral expander/implant reconstructions without the use of mesh, which is no longer the standard of care in the UK³⁹. Indeed, the practice of implant-based reconstruction has evolved significantly over the past 12–13 years with the introduction of mesh-assisted subpectoral³⁹ and, more recently, pre-pectoral⁴⁰ techniques, aimed at improving patient-reported and cosmetic outcomes of implant-based procedures⁴¹. Evidence to support the benefits of mesh-assisted reconstruction, however, remains limited, and BREAST-Q scores at 18 months after one- and two-stage prosthetic procedures were shown to be broadly comparable in a large prospective cohort study⁴², irrespective of whether mesh was used. Long-term outcome data for these techniques are also currently lacking. A recent small retrospective study⁴³, with a median of 62 months follow-up, suggested that women who had mesh-assisted reconstruction were significantly more satisfied with the outcomes of reconstruction (BREAST-Q scores 62 *versus* 55) than those who had reconstruction using standard two-stage submuscular techniques. It should be noted, however, that the study was very small and there was a high proportion of bilateral procedures in the mesh-assisted group. Further evolution of the technique has resulted prepectoral mesh-assisted implant reconstruction becoming the new standard of care in the UK. Again, although short-term outcomes of prepectoral and subpectoral mesh-assisted reconstructions appear to be broadly comparable⁴⁴, work is needed to evaluate long-term PROs prospectively in this group. Despite these limitations, particularly with regard to the applicability of the findings to modern implant-based techniques, the present study has generated much needed information regarding the long-term PROs of IBR, and how they vary by procedure performed, to support informed decision-making.

Several decision aids have been developed to help women make decisions about breast reconstruction surgery⁴⁵ including, most recently, BRECONDA⁴⁶ and PEGASUS⁴⁷. These, in particular, BRECONDA, have been shown to improve satisfaction with information and reduce decisional conflict in well designed clinical trials⁴⁶. Neither of these tools, however, include long-term outcomes, which may influence patient decision-making. Integration of information about the need for further surgery over time and how different types of reconstruction are perceived in the longer term from a patient perspective may therefore add to their value. Determining how best to communicate and share this complex information with patients, however, is challenging and further qualitative work with patients and key stakeholders is needed to determine how best to use these findings to support informed decision-making.

The present study has added significantly to the evidence regarding long-term breast reconstruction outcomes, but well designed, large-scale prospective longitudinal studies are still needed in this area. Such studies are time-consuming and expensive, so pragmatic registry-based approaches, including routine PRO assessment and linkage to routinely collected clinical outcome data, is essential. In the UK, the Flap Registry⁴⁸ already collects PROs at 12 months, but further work is needed to extend the PRO timeline and consider how the PROs of implant reconstruction could also be assessed. Breast

reconstruction is performed to improve quality of life after mastectomy, so it is vital that this information is collected moving forward to support women in making fully informed decisions about reconstruction options.

Funding

This work was funded by a National Institute for Health Research (NIHR) Research for Patient Benefit Programme Grant (PB-PG-0817-20020), and supported by the NIHR Biomedical Research Centre at University Hospitals Bristol and Weston NHS Foundation Trust and the University of Bristol and the NIHR Applied Research Collaboration West. S.P. is an NIHR Clinician Scientist (CS-2016-16-019). The views expressed in this publication are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Acknowledgements

The authors thank all the patients who participated in the Brighter study.

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Disclosure

The authors declare no conflict of interest.

Data availability

Data will be made available on reasonable request from the corresponding author.

Supplementary material

Supplementary material is available at *BJS* online.

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