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Original Article

Impact of procedure type on revisional surgery and secondary reconstruction after immediate breast reconstruction in a population-based cohort

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Abstract

Background: Women considering immediate breast reconstruction require high-quality information about the likely need for secondary reconstruction and the long-term risk of revisional surgery to make fully informed decisions about different reconstructive options. Such data are currently lacking. This study aimed to explore the impact of reconstruction type on the number of revisions and secondary reconstructions performed 3, 5, and 8 years after immediate breast reconstruction in a large population-based cohort.

Methods: Women undergoing unilateral mastectomy and immediate breast reconstruction for breast cancer or ductal carcinoma *in situ* in England between 1 April 2009 and 31 March 2015 were identified from National Health Service Hospital Episode Statistics. Numbers of revisions and secondary reconstructions in women undergoing primary definitive immediate breast reconstruction were compared by procedure type at 3, 5, and 8 years after index surgery.

Results: Some 16 897 women underwent immediate breast reconstruction with at least 3 years' follow-up. Of these, 14 069 had a definitive reconstruction with an implant only (5193), latissimus dorsi flap with (3110) or without (2373) an implant, or abdominal free flap (3393). Women undergoing implant-only reconstruction were more likely to require revision, with 69.5 per cent (747 of 1075) undergoing at least one revision by 8 years compared with 49.3 per cent (1568 of 3180) in other reconstruction groups. They were also more likely to undergo secondary reconstruction, with the proportion of women having further reconstructive procedures increasing over time: 12.8 per cent (663 of 5193) at 3 years, 14.3 per cent (535 of 3752) at 5 years, and 17.6 per cent (189 of 1075) at 8 years.

Conclusion: Long-term rates of revisions and secondary reconstructions were considerably higher after primary implant-based reconstruction than autologous procedures. These results should be shared with patients to support informed decision-making.

Introduction

Breast cancer affects over 55 000 women every year in the UK[1] and, despite improvements in treatment, approximately one-third undergo mastectomy as part of their treatment[2]. Immediate breast reconstruction (IBR) is offered routinely in the UK to improve outcomes for women after mastectomy[3], but decision-making for breast reconstruction can be complex owing to the range of procedures that may be offered. Breast reconstruction surgery can be divided broadly into procedures involving implants alone and those involving autologous techniques in which the patient's own tissue is used to recreate the breast mound, sometimes with the assistance of an implant. Different procedures are associated with different short- and long-term outcomes[4,5], and, as the majority of women become long-term breast cancer survivors[1], high-quality information about the long-term outcomes of different types of reconstruction is important to help them make fully informed decisions about what type of procedure, if any, may be right for them.

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Information about the long-term surgical burden of different IBR procedures, however, is lacking and the need for long-term outcome data has been highlighted as a research priority[6,7]. Specifically, there is insufficient evidence about the long-term need for revisional surgery to improve the appearance of the reconstruction or address complications, or the need for further reconstructive procedures to completely replace the reconstruction initially performed (that is secondary reconstruction) because the initial reconstruction has either failed or resulted in a poor outcome. Few studies have reported clinical outcomes beyond 2 years[8]. Studies that have reported long-term outcomes are small, often retrospective, single-centre cohort studies[9] that often only considered one procedure type[10–12], so comparison of outcomes between procedures is not possible. In studies that have compared implant-based and autologous procedures, the reported impact of procedure type on revisions and secondary reconstructions has been inconsistent[8]. Further high-quality research regarding the long-term need for revisional surgery and secondary reconstruction is therefore required to support informed decision-making.

The NHS Hospital Episode Statistics (HES) Admitted Patient Care (APC) data set includes information on all operations funded by the UK National Health Service (NHS) in hospitals in England, and allows longitudinal tracking of patients over time[13]. Analysis of this nationally representative data set therefore provides an excellent opportunity to explore the long-term surgical burden in a population-based cohort of women undergoing different types of IBR. The aim of the present study was to use these data to investigate revisional surgery and secondary reconstruction performed at 3, 5, and 8 years after operation in patients undergoing different types of IBR following mastectomy for breast cancer.

Methods

Data sources

The NHS HES APC database was used for this analysis[14]. The HES APC database, including information on data quality and its comprehensiveness and validity for use in research studies, has been described elsewhere[13]. In brief, HES APC contains records on all NHS patients receiving hospital treatment in England and uses a unique patient identifier to allow admissions for each patient to be linked for longitudinal follow-up. Each record contains demographic and clinical information including diagnoses and operative procedures. Diagnoses are recorded using the WHO ICD-10 and surgical procedures are coded using OPCS-4[13].

Cohort identification

NHS HES APC[13] data were obtained for all women aged 16 years and over, who had undergone a unilateral mastectomy (OPCS-4 code B27x (total excision of breast) with OPCS Subsidiary Classification of Sites of Operation codes Z94x (laterality of operation)) for invasive breast cancer or preinvasive disease (ductal carcinoma *in situ*, DCIS) (ICD-10 codes C50x (malignant neoplasm of breast) or D05x (carcinoma *in situ* of breast)) between 1 April 2009 and 31 March 2015.

Women were considered to have undergone IBR if OPCS code B27x and ICD codes C50 or D05 were present together with a code for a reconstructive procedure, performed on the same side and on the same day as the index mastectomy. OPCS codes (summarized in *Table S1*) were used to define five types of IBR, reflecting those most commonly performed in the UK during the study interval: two-stage expander-implant reconstruction; single-stage implant-only reconstruction; autologous latissimus dorsi (LD) flap reconstruction (without the use of an implant); LD flap reconstruction with use of an implant; and abdominal free-flap reconstruction.

Single-stage and two-stage implant reconstruction groups were considered separately because the practice of prosthetic breast reconstruction changed over the study interval. At the start of the study (April 2009), most prosthetic reconstructions were performed as two-stage expander–implant procedures requiring two operations as standard practice. During the study, however, the use of acellular dermal matrices and other meshes became widespread. These allowed a definitive fixed-volume implant to be placed at the first operation, facilitating single-stage implant-based procedures. Single-stage, direct-to-implant mesh-assisted reconstruction became standard of care by 2014–2015 as demonstrated by the findings of the UK iBRA study[15,16]. As primary expander reconstructions were, by definition, two-stage procedures, whereas direct-to-implant procedures were planned as a single stage, the two groups should not be combined when estimating surgical burden.

The cohort also included women undergoing other types of IBR, including pedicled transverse rectus abdominus myocutaneous (TRAM), gluteal artery perforator (superior gluteal artery perforator (SGAP)/inferior gluteal artery perforator (IGAP)), transverse upper gracilis, and profunda artery perforator flap procedures. Pedicled TRAM flaps are now rarely used in the UK[17] owing to high rates of abdominal morbidity[18,19], and other types of free-flap reconstruction are offered only in a small number of highly specialized centres. The numbers of these patients would therefore be very small[17]. As this would preclude meaningful comparisons, these groups were excluded from the analysis.

Complete HES APC data were available for all women up to and including 31 March 2019 such that all women in the cohort had a minimum of 3 years' follow-up data.

This work was undertaken as part of the wider Brighter long-term breast reconstruction outcomes study[20]. No ethical approval was required for this analysis as studies using non-identifiable records from HES are exempt from research ethics committee approval.

Outcomes

The primary outcomes were revisional procedures performed to the index breast reconstruction or donor site (if applicable) and secondary reconstruction. Revisional procedures were defined as any procedure performed to the index breast reconstruction to improve the appearance of the reconstruction and/or correct complications after the patient had been discharged following the index reconstructive procedure. A comprehensive list of procedure codes was developed and refined iteratively in collaboration with expert breast and plastic surgeons and the existing literature to include all potentially relevant procedures (*Table S2*). Any procedures to the ipsilateral breast or donor site (if applicable) were considered revisions. Procedures undertaken during the initial inpatient stay were considered to be for immediate postoperative complications and were excluded from the analysis.

Secondary reconstruction was defined as the replacement of the index reconstruction with another, usually different, type of reconstruction with or without reconstruction failure (when the index reconstruction was removed and not replaced). Women who underwent a subsequent expander–implant reconstruction having had a period without a reconstruction (reconstruction failure), when the index implant was removed but not replaced, were considered to have undergone a secondary reconstruction. Women who underwent an exchange of implant, in which one

Table 1 Demographics of study cohort

	Implant (*n* = 5193)	Expander (*n* = 2828)	Autologous LD (*n* = 2373)	LD-implant (*n* = 3110)	Abdominal flap (*n* = 3393)	Whole cohort (*n* = 16 897)	P‡
Age at index mastectomy (years), mean(s.d.)	52.9(10.6)	51.9(10.3)	53.3(9.9)	52.5(9.7)	52.1(8.5)	52.5(9.9)	<0.001§
Year of index mastectomy							<0.001
2009–2011	1579 (21.9)	1231 (17.1)	1299 (18.0)	1733 (24.0)	1367 (19.0)	7209 (100)	
2012–2015	3614 (37.3)	1597 (16.5)	1074 (11.1)	1377 (14.2)	2026 (20.9)	9688 (100)	
Duration of follow-up (days), mean(s.d.)	2321.9(610.0)	2536.3(612.4)	2690.1(613.9)	2687.7(590.2)	2466.1(631.2)	2505.8(629.1)	<0.001§
Ethnicity							<0.001
White	4559 (30.3)	2577 (17.2)	2154 (14.3)	2870 (19.1)	2866 (19.1)	15 026 (100)	
Other	426 (32.4)	147 (11.2)	155 (11.8)	160 (12.2)	425 (32.4)	1313 (100)	
Not known	208 (37.3)	104 (18.6)	64 (11.5)	80 (14.3)	102 (18.3)	558 (100)	
PHE region*							<0.001
East Midlands	454 (32.5)	348 (24.9)	181 (13.0)	232 (16.6)	183 (13.1)	1398 (100)	
East of England	560 (26.4)	216 (10.2)	121 (5.7)	328 (15.5)	898 (42.3)	2123 (100)	
London	945 (34.8)	205 (7.6)	244 (9.0)	343 (12.6)	977 (36.0)	2714 (100)	
North East	283 (36.7)	282 (36.5)	77 (10.0)	73 (9.5)	57 (7.4)	772 (100)	
North West	701 (30.4)	555 (24.1)	293 (12.7)	587 (25.5)	170 (7.4)	2306 (100)	
South East	862 (32.5)	265 (10.0)	357 (13.5)	688 (25.9)	481 (18.1)	2653 (100)	
South West	475 (30.2)	340 (21.6)	299 (19.0)	320 (20.4)	138 (8.8)	1572 (100)	
West Midlands	524 (31.4)	256 (15.4)	360 (21.6)	254 (15.2)	274 (16.4)	1668 (100)	
Yorkshire and Humber	389 (23.1)	360 (21.3)	441 (26.1)	285 (16.9)	212 (12.6)	1687 (100)	
Index of Multiple Deprivation score†							<0.001
1 (most deprived)	1036 (30.7)	648 (19.2)	500 (14.8)	600 (17.8)	596 (17.6)	3380 (100)	
2	1079 (31.9)	554 (16.4)	446 (13.2)	593 (17.6)	706 (20.9)	3378 (100)	
3	1051 (31.1)	501 (14.8)	483 (14.3)	632 (18.7)	712 (21.1)	3379 (100)	
4	977 (28.9)	572 (16.9)	481 (14.2)	644 (19.1)	704 (20.8)	3378 (100)	
5 (least deprived)	1050 (31.1)	552 (16.3)	463 (13.7)	641 (19.0)	672 (19.9)	3378 (100)	
Chemotherapy	1752 (31.7)	956 (17.3)	786 (14.2)	968 (17.5)	1071 (19.4)	5533 (100)	0.044
Radiotherapy	366 (36.2)	148 (14.6)	115 (11.4)	169 (16.7)	213 (21.1)	1011 (100)	<0.001
Nodal involvement	1594 (30.7)	1001 (19.3)	792 (15.2)	926 (17.8)	883 (17.0)	5196 (100)	<0.001
Disease status							<0.001
Invasive cancer	4116 (31.0)	2321 (17.5)	1916 (14.4)	2401 (18.1)	2545 (19.1)	13 299 (100)	
DCIS	1077 (29.9)	507 (14.1)	457 (12.7)	709 (19.7)	848 (23.6)	3598 (100)	
RCS CCI score, mean(s.d.)	0.23(0.50)	0.22(0.53)	0.21(0.50)	0.19(0.48)	0.19(0.45)	0.21(0.49)	<0.001§

Values are *n* (%) unless otherwise indicated. *Public Health England (PHE) centre of residence at time of mastectomy. †Quintiles of lower super output area (of residence at mastectomy) national rank. LD, latissimus dorsi; DCIS, ductal carcinoma *in situ*; RCS, Royal College of Surgeons; CCI, Charlson Co-morbidity Index. ‡χ^2 test, except §ANOVA.

implant was removed but immediately replaced with another prosthesis in the same episode, were considered to have had a revision of the reconstruction rather than a secondary reconstruction (*Table S3*). Small batches of individual patient records were reviewed at various points during the development of the analysis to ensure that the codes and patterns of codes identified the outcomes of interest, and were valid within the context of the index procedure performed.

Statistical analysis

Simple summary statistics were used to describe participant demographics for the cohort overall, and by type of IBR performed. Categorical data were summarized by counts and percentages and continuous variables as mean(s.d.). Data for IBR groups were compared using χ^2 tests for categorical variables and ANOVA for continuous data.

Analyses were undertaken for women with a minimum of 3, 5, and 8 completed years of follow-up to allow trends in revisional surgery and secondary reconstruction to be explored over time. Only women undergoing a primary definitive reconstruction (that is a procedure to reconstruct the breast mound, which, if successful, would not require further revisional surgery to the ipsilateral reconstruction) were included in the analysis. Those receiving a tissue expander as first procedure were considered to be undergoing a planned two-stage reconstruction and were excluded from the analysis.

For each time point, the number of revisional procedures (including secondary reconstructions) and proportion of patients undergoing secondary reconstruction alone in each procedure group were summarized and compared using χ^2 statistics. The ORs for requiring revisions and secondary reconstructions in different reconstruction groups were compared.

Multivariable binary linear regression was used to explore clinicopathological variables hypothesized to be associated with revisions and/or secondary reconstruction. These included patient-, procedure-, and treatment-related factors, namely age at the time of index mastectomy (under 50, 50–59 *versus* 60 years and over); ethnicity (white, other, not known), Royal College of Surgeons' Charlson Co-morbidity Index score[21], Public Health England region, socioeconomic status based on the Index of Multiple Deprivation, type of immediate reconstruction performed (implant only, autologous LD, LD with implant, and abdominal free flap); year of mastectomy (2009–2012 *versus* 2013–2015); disease status (invasive disease *versus* DCIS); nodal involvement (based on OPCS/ICD codes in HES); and receipt of chemotherapy (defined as whether an OPCS code for delivery or infusion of chemotherapy was seen in HES) and radiotherapy.

Time to secondary reconstruction was calculated by immediate reconstruction type, using secondary reconstruction as the event. Kaplan–Meier survival plots were used to compare the rate and timing of secondary reconstructions by type of reconstruction performed.

Results

Between 1 April 2009 and 31 March 2015, 16 897 women underwent IBR following a mastectomy for invasive breast cancer or DCIS (*Table 1*). This

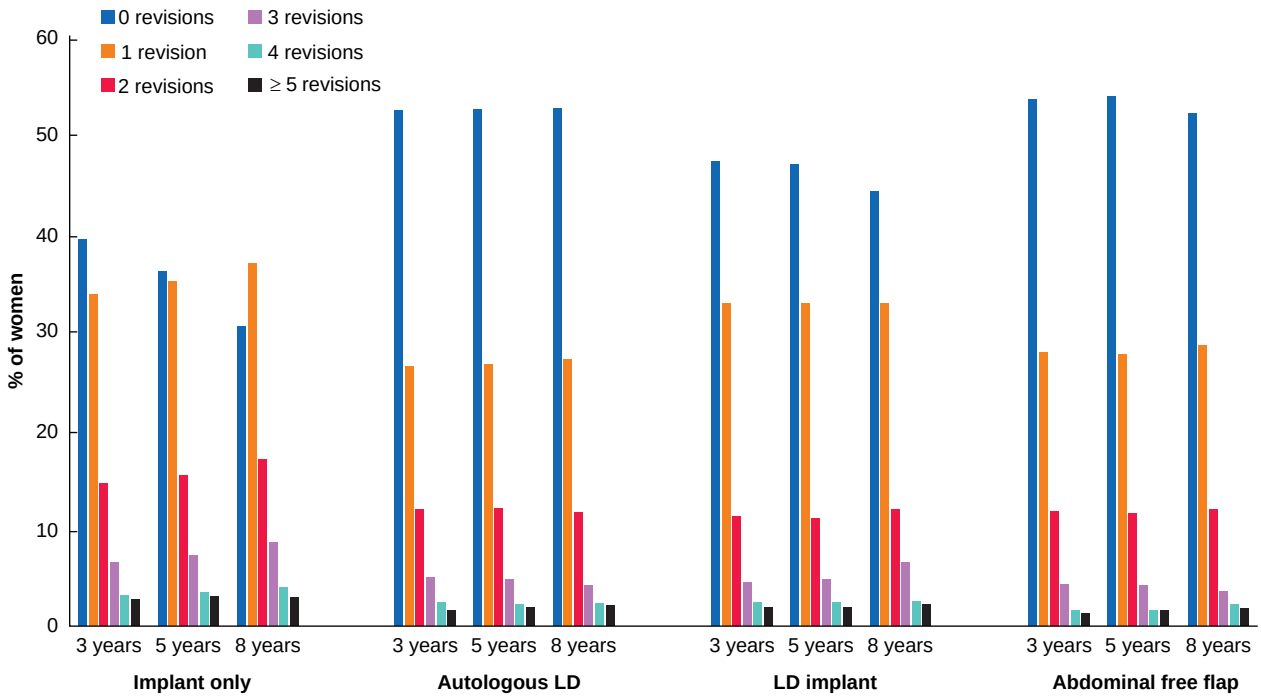

Fig. 1 Numbers of revisions performed at 3, 5, and 8 years after index reconstruction, by procedure type

included 5193 women (30.7 per cent) receiving implant-only reconstructions, 5483 (32.4 per cent) having LD flaps with (3110) or without (2373) an implant, and 3393 (20.1 per cent) undergoing abdominal free-flap procedures. Some 2828 women (16.7 per cent) received a temporary tissue expander as the first stage of the reconstructive process. The mean(s.d.) age at the time of the index mastectomy was 52.5(9.9) years. Type of reconstruction varied with patient age, ethnicity, geographical region, socioeconomic deprivation, Royal College of Surgeons' Charlson score, disease status, node positivity, and receipt of chemotherapy and radiotherapy (*Table 1*). As described previously[17], proportions of women undergoing implant-only reconstruction increased from 22 per cent (1579 women) between 2009 and 2011 to 37 per cent (3614 of 9688) from 2012 to 2015, and the proportions of LD flaps performed with and without implants decreased over the same interval (autologous LD from 1299 of 7209 (18.0 per cent) to 1074 of 9688 (11.1 per cent); LD–implant from 1733 of 7209 (24.0 per cent) to 1377 of 9688 (14.2 per cent)). The numbers of patients receiving postmastectomy radiotherapy in this cohort, however, were much lower than would be expected based on other contemporaneous UK-based reconstruction studies[22]. Radiotherapy was therefore considered to be unreliably recorded in the HES data set and was not included as a co-variable in further analysis.

Of the 16 897 women in the cohort as a whole, 14 069 (83.3 per cent) underwent a definitive primary reconstruction and all had a minimum of 3 years' complete follow-up; 11 347 women (implant only 3752, autologous LD 2105, LD–implant 2786, and abdominal free-flap reconstruction 2704) had at least 5 years' complete follow-up, and 4255 (implant only 1075, autologous LD 994, LD–implant 1236, and abdominal free-flap reconstruction 950) had at least 8 years' complete follow-up data.

Revisional surgery at 3, 5, and 8 years

The numbers of revisional procedures performed by 3, 5, and 8 years according to reconstruction type are illustrated in *Fig. 1* and summarized in *Table S4*. At 3 years, over 60 per cent of women (3147, 60.6 per cent) undergoing an implant-only reconstruction had undergone at least one revisional procedure compared with 46 per cent (1574, 46.4 per cent) of those receiving an abdominal free-flap reconstruction, and approximately half of those having an LD flap reconstruction with or without an implant ($P < 0.001$) (*Table S4*). By 8 years, the proportion of women in the implant-only group who had undergone at least one revision had increased to approximately 70 per cent (747, 69.5 per cent), with almost one-third (349, 32.5 per cent) undergoing two or more revisions (*Table S4*). By comparison, the proportion of women undergoing revision after primary autologous reconstruction remained static after 3 years and did not appear to increase over time (*Fig. 1*).

In the unadjusted analysis, at all three time points, women undergoing implant-based reconstruction were significantly more likely to require revisional surgery than those who received other types of primary reconstruction, and the odds of needing at least one revision increased over time (*Table S5*). At 3 years, women undergoing implant reconstruction were between 1.4 and 1.8 times more likely to undergo one or more revisions than those who had other primary reconstructive procedures (compared with autologous LD: OR 1.67, 95 per c.i. 1.54 to 1.87, $P < 0.001$; compared with LD–implant: OR 1.38, 1.26 to 1.51, $P < 0.001$; compared with abdominal free-flap reconstruction: OR 1.78, 1.63 to 1.94, $P < 0.001$). At 5 years, this had increased to between 1.6 and 2.1 times (compared with autologous LD: OR 1.97, 1.77 to 2.19, $P < 0.001$; compared with LD–implant: OR 1.58, 1.43 to 1.74, $P < 0.001$; compared with abdominal free-flap reconstruction: OR 2.08, 1.88 to 2.30, $P < 0.001$). At 8 years, the odds of undergoing at least one revision were between 1.8 and 2.6 times higher than for other primary reconstruction types (compared with autologous LD: OR 2.55, 2.13 to 3.05, $P < 0.001$; compared with LD–implant: OR 1.81, 1.52 to 2.15, $P < 0.001$; compared with abdominal free-flap reconstruction: OR 2.49, 2.07 to 2.98, $P < 0.001$) (*Table S5*).

Women undergoing an LD flap procedure with an implant were more likely to require one or more revisions than those having LD

Table 2 Multivariable binary logistic regression for one or more revisions at 3, 5, and 8 years after reconstruction

	Revisions by 3 years (*n* = 14 066)		Revisions by 5 years (*n* = 11 345)		Revisions by 8 years (*n* = 4254)	
	Adjusted OR	*P*	Adjusted OR	*P*	Adjusted OR	*P*
Reconstruction type		<0.001		<0.001		<0.001
Implant only	1.00 (reference)		1.00 (reference)		1.00 (reference)	
Autologous LD	0.54 (0.49, 0.60)	<0.001	0.48 (0.43, 0.54)	<0.001	0.37 (0.31, 0.45)	<0.001
LD–implant	0.67 (0.61, 0.74)	<0.001	0.61 (0.55, 0.67)	<0.001	0.52 (0.44, 0.62)	<0.001
Abdominal flap	0.55 (0.55, 0.61)	<0.001	0.48 (0.43, 0.53)	<0.001	0.40 (0.33, 0.48)	<0.001
Age (years)		<0.001		<0.001		0.002
<50	1.00 (reference)		1.00 (reference)		1.00 (reference)	
50–59	0.94 (0.87, 1.02)	0.134	0.91 (0.84, 1.00)	0.041	0.93 (0.80, 1.07)	0.306
≥60	0.75 (0.68, 0.82)	<0.001	0.76 (0.68, 0.84)	<0.001	0.75 (0.63, 0.88)	0.001
Year of mastectomy		<0.001		0.010		
2009–2012	1.00 (reference)		1.00 (reference)			
2013–2015	0.84 (0.78, 0.90)	<0.001	0.89 (0.82, 0.97)	0.010		
Ethnicity		<0.001		<0.001		0.02
White	1.00 (reference)		1.00 (reference)		1.00 (reference)	
Other	0.79 (0.69, 0.90)	<0.001	0.81 (0.70, 0.93)	0.004	0.89 (0.70, 1.14)	0.369
Not known	0.78 (0.65, 0.95)	0.013	0.70 (0.56, 0.88)	0.003	0.54 (0.34, 0.85)	0.008
PHE region		<0.001		<0.001		0.077
London	1.00 (reference)		1.00 (reference)		1.00 (reference)	
East Midlands	0.96 (0.83, 1.12)	0.635	0.97 (0.82, 1.15)	0.750	1.03 (0.77, 1.36)	0.862
East of England	0.73 (0.65, 0.83)	<0.001	0.74 (0.64, 0.85)	<0.001	0.84 (0.67, 1.05)	0.131
North East	1.03 (0.84, 1.26)	0.790	1.05 (0.83, 1.32)	0.694	1.51 (0.95, 2.38)	0.080
North West	0.77 (0.68, 0.88)	<0.001	0.79 (0.68, 0.92)	0.002	1.04 (0.81, 1.34)	0.736
South East	1.01 (0.89, 1.14)	0.881	1.00 (0.87, 1.14)	0.980	1.05 (0.84, 1.31)	0.671
South West	0.91 (0.78, 1.05)	0.179	0.94 (0.80, 1.10)	0.453	1.10 (0.85, 1.43)	0.480
West Midlands	0.81 (0.71, 0.93)	0.003	0.82 (0.71, 0.96	0.014	0.81 (0.63, 1.04)	0.092
Yorkshire and Humber	1.06 (0.92, 1.23)	0.400	1.05 (0.90, 1.24)	0.515	1.10 (0.85, 1.41)	0.482
Index of Multiple Deprivation score		0.081		0.308		0.997
Most deprived quintile	1.00 (reference)		1.00 (reference)	1.00 (reference)		
Least deprived 4 quintiles	0.92 (0.85, 1.01)	0.081	0.95 (0.86, 1.05)	0.308	1.00 (0.85, 1.18)	0.997
Chemotherapy received	1.14 (1.05, 1.23)	0.002	1.13 (1.04, 1.24)	0.006	1.13 (0.98, 1.31)	0.099
Nodal involvement	1.02 (0.94, 1.10)	0.655	1.02 (0.93, 1.12)	0.646	0.99 (0.86, 1.15)	0.927
Disease status		0.346		0.138		0.189
DCIS	1.00 (reference)		1.00 (reference)		1.00 (reference)	
Invasive disease	1.04 (0.96, 1.14)	0.346	1.08 (0.98, 1.18)	0.138	1.11 (0.95, 1.30)	0.189
RCS CCI score	1.15 (1.07, 1.24)	<0.001	1.19 (1.10, 1.29)	<0.001	1.12 (0.98, 1.29)	0.091

Values in parentheses are 95% confidence intervals. LD, latissimus dorsi; PHE, Public Health England; DCIS, ductal carcinoma *in situ*; RCS, Royal College of Surgeons; CCI, Charlson Co-morbidity Index.

Table 3 Number of patients undergoing secondary reconstruction at 3, 5 and 8 years by reconstruction type

	Patients undergoing secondary reconstruction					
	3 years	P*	5 years	P*	8 years	P*
Reconstruction type		<0.001		<0.001		<0.001
Implant-only	663 of 5193 (12.8)		535 of 3752 (14.3)		189 of 1075 (17.6)	
Autologous LD flap	43 of 2373 (1.8)		40 of 2105 (1.9)		24 of 994 (2.4)	
LD–implant	66 of 3110 (2.1)		63 of 2786 (2.3)		31 of 1236 (2.5)	
Abdominal flap	73 of 3393 (2.2)		62 of 2704 (2.3)		25 of 950 (2.6)	

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

procedures with no implant at all three time points (at 3 years: OR 1.23, 1.10 to 1.37, $P < 0.001$; at 5 years: OR 1.25, 1.11 to 1.40, $P < 0.001$; at 8 years: OR 1.41, 1.19 to 1.67, $P < 0.001$). They were not more likely to undergo subsequent revisional procedures at 3 or 5 years but, at 8 years, the odds of undergoing two or more (OR 1.26, 1.03 to 1.55, $P = 0.031$) or three or more (OR 1.35, 1.02 to 1.80, $P = 0.039$) revisions increased in the LD–implant group (*Table S4*).

Among women undergoing purely autologous primary reconstructions, there were no differences between autologous LD and abdominal free-flap procedures in the receipt of one or more compared with two or more revisions at 3, 5 or 8 years after primary surgery. Women undergoing autologous LD reconstructions, however, were more likely than women receiving abdominal free-flap procedures to undergo multiple revisions (3 or more) at 3 years (OR 1.39, 1.14 to 1.68, $P < 0.001$) and 5 years (OR 1.25, 1.01 to 1.55, $P = 0.007$), but not at 8 years after the initial surgery (*Table S5*). This may reflect the need to address the loss of volume in the reconstruction owing to atrophy of the LD muscle over time.

Multivariable binary logistic regression demonstrated a strong association between the receipt of one or more revisions and the patient's age at the time of index surgery and the type of reconstruction performed in all cohorts (*Table 2*). Ethnicity, region, receipt of chemotherapy, and Charlson Co-morbidity

Table 4 Multivariable binary logistic regression for secondary reconstruction at 3, 5 and 8 years

	Secondary reconstruction at 3 years ($n = 14\,066$)		Secondary reconstruction at 5 years ($n = 11\,345$)		Secondary reconstruction at 8 years ($n = 4254$)	
	Adjusted OR	P	Adjusted OR	P	Adjusted OR	P
Reconstruction type		<0.001		<0.001		<0.001
Implant only	1.00 (reference)		1.00 (reference)		1.00 (reference)	
Autologous LD	0.11 (0.08, 0.15)	<0.001	0.11 (0.08, 0.15)	<0.001	0.11 (0.07, 0.17)	<0.001
LD–implant	0.13 (0.10, 0.16)	<0.001	0.13 (0.10, 0.17)	<0.001	0.11 (0.07, 0.16)	<0.001
Abdominal flap	0.15 (0.12, 0.20)	<0.001	0.15 (0.11, 0.19)	<0.001	0.13 (0.08, 0.20)	<0.001
Age (years)		<0.001		<0.001		<0.001
<50	1.00 (reference)		1.00 (reference)		1.00 (reference)	
50–59	0.92 (0.78, 1.08)	0.311	0.92 (0.77, 1.10)	0.356	0.91 (0.68, 1.21)	0.518
≥ 60	0.52 (0.42, 0.64)	<0.001	0.51 (0.40, 0.64)	<0.001	0.40 (0.26, 0.60	<0.001
Year of mastectomy		<0.001		<0.001		
2009–2012	1.00 (reference)		1.00 (reference)			
2013–2015	0.61 (0.53, 0.71)	<0.001	0.71 (0.59, 0.85)	<0.001		
Ethnicity		<0.001		0.002		0.036
White	1.00 (reference)		1.00 (reference)		1.00 (reference)	
Other	0.78 (0.59, 1.04)	0.093	0.79 (0.58, 1.09)	0.146	0.88 (0.53, 1.46)	0.615
Not known	0.39 (0.22, 0.68)	0.001	0.37 (0.19, 0.74)	0.005	0.15 (0.02, 1.10)	0.062
PHE region		<0.001		<0.001		0.047
London	1.00 (reference)		1.00 (reference)		1.00 (reference)	
East Midlands	1.08 (0.79, 1.48)	0.616	1.10 (0.78, 1.55)	0.581	1.14 (0.64, 2.05)	0.655
East of England	0.83 (0.62, 1.11)	0.215	0.86 (0.63, 1.18)	0.353	1.07 (0.66, 1.73)	0.790
North East	1.56 (1.10, 2.21)	0.013	1.46 (0.99, 2.15)	0.053	1.38 (0.62, 3.07)	0.434
North West	0.83 (0.61, 1.12)	0.227	0.79 (0.56, 1.11)	0.176	0.99 (0.56, 1.75)	0.982
South East	1.51 (1.18, 1.93)	0.001	1.53 (1.16, 2.01)	0.002	1.50 (0.95, 2.36)	0.079
South West	1.14 (0.84, 1.56)	0.395	1.27 (0.91, 1.77)	0.159	1.60 (0.94, 2.71)	0.083
West Midlands	1.34 (1.02, 1.76)	0.038	1.33 (0.99, 1.80)	0.060	1.72 (1.09, 2.72)	0.020
Yorkshire and Humber	0.83 (0.59, 1.16)	0.264	0.79 (0.54, 1.14)	0.207	0.64 (0.33, 1.23)	0.178
Index of Multiple Deprivation score		0.056		0.016		0.067
Most deprived quintile	1.00 (reference)		1.00 (reference)		1.00 (reference)	
Least deprived 4 quintiles	0.84 (0.70, 1.00)	0.056	0.78 (0.64, 0.96)	0.016	0.74 (0.53, 1.02)	0.067
Chemotherapy received	1.44 (1.22, 1.69)	<0.001	1.42 (1.18, 1.69)	<0.001	1.59 (1.19, 2.14)	0.002
Nodal involvement	1.39 (1.18, 1.63)	<0.001	1.36 (1.14, 1.63)	0.001	1.08 (0.81, 1.45)	0.584
Disease status		<0.001		0.003		0.003
DCIS	1.00 (reference)		1.00 (reference)		1.00 (reference)	
Invasive disease	1.52 (1.21, 1.91)	<0.001	1.45 (1.14, 1.85)	0.003	1.82 (1.21, 2.74)	0.003
RCS CCI score	1.17 (1.02, 1.35)	0.023	1.13 (0.97, 1.32)	0.118	0.96 (0.74, 1.26)	0.789

Values in parentheses are 95% confidence intervals. LD, latissimus dorsi; PHE, Public Health England; DCIS, ductal carcinoma *in situ*; RCS, Royal College of Surgeons; CCI, Charlson Co-morbidity Index.

Index score were strongly associated with the receipt of one or more revisions at 3 and 5, but not 8 years. Cancer-related factors, including disease status and nodal involvement, were not associated with revisional surgery at any time point (*Table 2*). Women undergoing reconstruction more recently (2013–2015) were less likely to have undergone one or more revision than those who had surgery during the earlier time period after adjusting for other factors.

Secondary reconstructions at 3, 5, and 8 years

The number of women requiring at least one secondary reconstruction by primary reconstruction type at 3, 5, and 8 years is summarized in *Table 3*. In the unadjusted analysis, women undergoing implant-based reconstruction were more likely to undergo secondary reconstruction than those undergoing autologous procedures at every time point ($P < 0.001$), with the proportion of women undergoing surgery in the implant-only group increasing over time from 12.8 per cent at 3 years to 17.6 per cent at 8 years (*Table 3*). By contrast, the proportion of women undergoing secondary reconstruction following autologous procedures was approximately 2 per cent, and remained static after 3 years (*Table 3* and *Fig. S1*). Overall, women undergoing implant-based procedures were 6.8–7.9 times more likely to undergo secondary reconstruction than those having other reconstructive procedures by 3 years, 7.2–8.6 times more likely to undergo secondary reconstruction at 5 years, and 7.9–8.6 times more likely to have undergone replacement of the index reconstruction by 8 years after the initial surgery. There were no differences in the likelihood of secondary reconstruction between the other reconstruction types (*Table S6*).

Multivariable binary logistic regression demonstrated that, in addition to undergoing implant-based primary reconstruction, younger age at time of index surgery (under 50 *versus* 60 or more years), invasive *versus* preinvasive disease, and receipt of chemotherapy were strongly associated with increased rates of secondary reconstruction at all three time points (*Table 4*). By contrast, nodal involvement was strongly associated with increased secondary reconstruction at 3 and 5 years, but not 8 years. Women having immediate reconstruction more recently (2013–2015) were less likely to have undergone secondary reconstruction than those having surgery between 2009 and 2012. The effect of region was more complex. At 3 years, women in the North East, South East, and West Midlands were more likely to have undergone secondary reconstruction than those treated in London. At 5 years, only women treated in the South East underwent more surgery, whereas at 8 years, only women treated in the West Midlands were more likely to have undergone secondary reconstruction.

Discussion

This study has explored revisional surgery and secondary reconstruction performed by 3, 5, and 8 years after IBR in a large population-based cohort of women undergoing mastectomy for breast cancer. It has demonstrated that both the need for revisional surgery and secondary reconstruction are strongly associated with the type of primary reconstruction performed, and that women undergoing primary implant-based reconstruction are more likely to require one or more revisions over time than those undergoing other types of reconstruction. Furthermore, by 8 years after the primary reconstruction, almost one in five women who initially received an implant-based procedure had undergone a secondary reconstruction. Other factors associated with revisions and secondary reconstruction included age at mastectomy, ethnicity, geographical region of residence, and disease- and treatment-related factors, such as whether surgery was performed for invasive or preinvasive disease and the receipt of chemotherapy. The need for further surgery over time is likely to be an important consideration for most women making decisions about breast reconstruction and, following recent changes in UK standards for informed consent[23], it is essential that this information is shared with women considering IBR to help them make fully informed decisions about the surgery.

This large study has robustly evaluated the long-term impact of procedure type on the need for revisional surgery after IBR. Previous studies have generated conflicting results regarding the impact of procedure type on the need for revisional surgery[8], but this is likely to reflect heterogeneity in the definitions of revision used and the duration of follow-up in the included studies. Two recently published large North American studies[24,25] have both suggested that revision rates are higher after autologous reconstruction. The first[25] included 1996 women from the Mastectomy Reconstruction Outcomes Consortium prospective cohort with 2 years' postoperative follow-up. Although complications after autologous reconstruction, such as fat necrosis or wound healing problems, occur in the early postoperative phase[24], implant-related complications including malposition or capsular contracture are more likely to occur several years after surgery. Two years would not be sufficient to capture the impact of these issues, which may explain the results. The second population-based study[24] from Canada reported the outcomes from 3066 women, 1714 of whom underwent IBR with up to 10 years' follow-up. Women in this study underwent surgery as early as 2002 and the authors reported a 50 per cent unplanned surgery rate in the microsurgical group in the early study period. Reoperation rates in this cohort may therefore not reflect the UK, where the reoperation rate after microsurgical reconstruction is approximately 7 per cent[26]. A more recent Australian single-centre retrospective study[9] of 390 women, with a median of 61 months' follow-up, suggested that complication rates after direct-to-implant reconstruction were higher than those following autologous reconstruction. The autologous reconstructions were largely pedicled TRAM flaps, so this may not reflect UK practice.

This work has provided further evidence to suggest that autologous reconstruction may offer better outcomes[4,27,28] and reduced long-term surgical burden to women who are suitable for the procedure than implant-based techniques. This is because autologous techniques, in particular abdominal free-flap reconstruction, uses the patient's own tissue to reconstruct the breast, essentially replacing 'like with like'. This means that the reconstruction will age naturally over time in a similar way to the natural breast and alter in size if the patient's weight changes. Thus, once any initial revision or symmetrizing procedures have been carried out, most women electing to undergo autologous reconstruction are unlikely to require any further surgery over time. By contrast, implants are foreign bodies. Although they can be used to recreate the breast mound, they are not the same as the natural breast. They have a fixed shape, and women undergoing unilateral implant-based procedures will become increasingly asymmetrical as the natural breast ages or they gain weight. Implants are also more likely to develop complications over time, including the development of scar tissue leading to capsular contracture, which has an adverse impact on the cosmetic outcome of the reconstruction, malposition, and, even with new-generation devices, leakage and rupture requiring replacement.

This study has provided high-quality evidence to suggest that women who choose implant-based procedures are likely to be committing themselves to future surgery and that the likelihood of undergoing surgery, including secondary reconstruction, increases over time. It also has significant implications for healthcare providers and commissioners, many of whom in recent years have placed restrictions on the number of procedures that can be performed after immediate reconstruction and the time frame in which further surgery may take place[29]. These data suggest that such restrictions are largely inappropriate and that women who elect to receive implant-based reconstruction should have ongoing access to surgery as required without time limits. Furthermore, this work provides strong evidence that the provision of free-flap reconstruction should be extended so that all women who wish to have autologous reconstruction should have access to the procedure. This may lead to fewer women electing to undergo implant-based procedures, one in five of which are ultimately converted to tissue-based reconstructions, and allow best use of scarce resources while optimizing outcomes for individual patients.

This study has generated much needed long-term data regarding the need for further surgery after IBR, but there are several limitations that require consideration. First, the study has used HES data to identify the cohort, and expert knowledge to iteratively develop lists of OPCS codes to identify revisions and secondary reconstruction. Although every attempt was made to generate an inclusive list of codes indicative of revisions, it is possible that some procedures undertaken to revise the reconstruction were missed as they had been coded in an unanticipated way, or that some procedures (especially with regard to donor-site issues such as hernias) were misclassified as revisions when they were unrelated to the reconstruction. Furthermore, the OPCS coding system is not exhaustive and patterns of codes need to be used to identify or deduce the occurrence of specific events. There were specific issues relating to the identification of reconstructive failure in the autologous group, for example, as there is no OPCS code for removal of a tissue flap. Reconstruction failure could therefore not be included as an outcome in this study. Secondary reconstructions must also be deduced by exploring and interpreting the patterns of codes that follow the index procedure. Reconstructive failure in the expander–implant group can be identified when a code for an expander–implant removal is not accompanied by a code for expander–implant insertion or a code for another form of reconstruction, but this requires accurate coding; exploration of

the data set demonstrated that the codes for expanders and implants were sometimes used interchangeably and that codes for implant–expander removal were not always used when an implant-based procedure was revised.

The present analysis therefore represents an informed interpretation of the HES data but is open to some error. A major limitation is that HES does not contain information on key variables such as patient smoking status and BMI, or important oncological data such as tumour and treatment factors. Radiotherapy, for example, is likely to be an important determinant of the need for revisions and secondary reconstruction, particularly in women undergoing implant-based reconstruction[9,30], but was poorly coded within the HES extract even when outpatient data were explored. In addition, this study has only reported the procedures that were actually performed. It could not evaluate any procedures that patients would have wanted, but were unable to receive owing to local restrictions on the provision of surgery in the UK[29]. This may explain the regional and temporal variation seen but, similarly, it is not possible to determine from HES data why the procedure was undertaken and whether this was driven by the surgeon's desire to improve the outcome of the reconstruction or the patient's request. Indeed, many reconstructive surgeons take the opportunity to 'tidy up' the reconstruction when they symmetrize the contralateral breast and/or reconstruct the nipple. These revisions would not be done in isolation should the patient not have elected to have completion surgery and, as such, the surgical burden in this group may have been overstated. Finally, HES only covers NHS-funded procedures undertaken in England, so privately funded surgery or surgery performed outside of England would not have been captured. It is not possible to know definitively how many such procedures were performed, but, as the UK has a comprehensive publicly funded healthcare system, it is likely the number of privately funded procedures was very small. As such, any missing data are unlikely to have significantly affected the outcomes of the analysis. Therefore, despite these limitations, the present study has generated much needed data to support women making decisions about reconstructive surgery and represents a sound start in establishing the evidence base in this important area.

Information regarding the need for further surgery is only one of many outcomes that women may wish to consider when making decisions about breast reconstruction. Other key outcomes include satisfaction with the outcome of surgery, and the impact that different procedures may have on health-related quality of life and physical and psychological well-being. This work is part of the ongoing UK Brighter study[20], which will explore the patient-reported outcomes of different approaches to reconstruction approximately 12 years after index surgery and the costs associated with different procedure types. Although these data will be extremely valuable, they are cross-sectional and do not capture change in outcomes over time. There is an urgent need for high-quality prospective studies and ideally registries to accurately capture baseline and patient- and procedure-specific data, and create cohorts that can be efficiently and effectively followed up through routinely collected data sets supplemented with routine assessment of patient-reported outcomes.

Breast reconstruction is performed to improve outcomes for women undergoing mastectomy, but it is only possible to determine whether the procedures currently offered are beneficial if appropriate patient-centred outcomes, for example, the breast reconstruction core outcome set[31], are collected and evaluated routinely. High-quality short- and long-term outcome data are also vital in supporting women making informed decisions about reconstructive surgery and allowing them to form realistic expectations of what surgery may achieve to minimize the risk of decisional regret[32,33]. The need for such work has recently been identified as a research priority by patients and professionals as part of a James Lind Alliance Priority Setting Partnership in breast cancer surgery[7]. Recognition of the importance of this area will hopefully provide the necessary incentive for clinicians, patients, and funders to work together to generate much needed long-term breast reconstruction outcome data to support modern patient-centred surgical practice.

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Disclosure

The authors declare no conflict of interest.

Supplementary material

Supplementary material is available at *BJS* online.

Data availability

The study is based on NHS HES data and was provided within the terms of an NHS Digital data-sharing agreement. The data do not belong to the authors and may not be shared by the authors, except in aggregate form for publication. Data can be obtained by submitting a research request via the NHS Digital Data Access Request Service.

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