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| Authors | Browne, John P.;Jeevan, Ranjeet;Gulliver-Clarke, Carmel;Pereira, Jerome;Caddy, Christopher M.;van der Meulen, Jan H. P. |
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University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

**The association between complications and quality of life after mastectomy and breast reconstruction for breast cancer.**

*Quality of life after complications*

John P Browne, PhD[1]; Ranjeet Jeevan, MRCS[2]; Carmel Gulliver-Clarke, PhD[3]; Jerome Pereira, FRCS[4]; Christopher M Caddy, FRCS(Plast)[5]; Jan HP van der Meulen, PhD[6].

1. John P. Browne, PhD. Department of Epidemiology and Public Health, University College Cork.
2. Ranjeet Jeevan, MRCS. Clinical Effectiveness Unit, Royal College of Surgeons of England.
3. Carmel Gulliver-Clarke, PhD. Integrated Breast Service, Western Sussex Hospitals NHS Foundation Trust.
4. Jerome Pereira, FRCS. Department of General Surgery, James Paget University Hospitals NHS Foundation Trust.
5. Christopher M Caddy, FRCS(Plast). Department of Plastic Surgery, Sheffield Teaching Hospitals NHS Foundation Trust.
6. Jan HP van der Meulen, PhD. Department of Health Services Research, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine.

Correspondence to Professor John Browne, Department of Epidemiology and Public Health, University College Cork, Western Gateway Building, Western Rd, Cork, Ireland. Tel: +353 21 4205510. Fax: +353 21 4205469. Email: j.browne@ucc.ie

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Precis: Surgical complications are associated with little or no long-term impairment in quality of life in breast cancer patients undergoing mastectomy without reconstruction, or delayed reconstruction. The association is much larger for flap-related complications suffered during immediate reconstruction.

**Background:** Medical treatment for breast cancer is associated with substantial toxicity and patient burden. There is less known about the impact of surgical complications. Understanding this impact would provide important information for patients when considering surgical options.

**Methods**: Between 2008 and 2009, the UK National Mastectomy and Breast Reconstruction Audit recorded surgical complications for a prospective cohort of 17,844 women treated for breast cancer at 270 hospitals. 6,405 of these women were surveyed about their quality of life 18 months after surgery. Breast appearance, emotional well-being and physical well-being were quantified on 0-100 point scales. Linear multiple regression models were used to compare the scores of patients who had complications to those who did not, while controlling for a range of baseline prognostic factors.

**Results**: The overall complication rate was 10.2%. Complications were associated with little or no impairment in women undergoing mastectomy without reconstruction, or delayed reconstruction. The association was much larger for flap-related complications suffered during immediate reconstruction. The breast appearance (adjusted mean difference = -23.8; 95% CI, -31.0 to -16.6) and emotional well-being (adjusted mean difference = -14.0; 95% CI, -22.0 to -6.0) scores of these patients were much lower than any other patient group. Implant-related complications were not associated with lower quality of life in any surgical group.

**Conclusions:** There is a strong case for prospectively collecting flap complication rates at the surgeon and surgical unit level, and allowing patients to access this data when they make choices about their breast cancer surgery.

Key words: Breast cancer; mastectomy; breast reconstruction; postoperative complications; quality of life.

**Introduction**

After surgery most patients experience some degree of morbidity which can vary from minor discomfort and sleep disturbance to life threatening haemorrhage or infection. Unexpected morbidity is often referred to as a 'complication' and has been defined as "an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome".[1]

The association between surgical complications and quality of life was the subject of a 2016 systematic review. It found that in two-thirds of the 50 published studies reviewed, patients who suffered surgical complications had significantly worse quality of life and other psychosocial outcomes than those who had no complications and that this effect persisted in the long-term.[2]

Intuitively, one would expect surgical morbidity to affect the quality of life of patients undergoing breast cancer surgery despite attempts to reduce its impact. For example, on average, patients who suffer skin or flap necrosis following breast reconstruction should be at a higher risk of having an impaired aesthetic outcome, with associated harm to emotional well-being, even after corrective measures such as debridement or revision surgery have been performed. Information on the extent of this impairment would move our understanding of breast surgery complications beyond simple prevalence data and help patients and clinicians to weigh the harms and benefits of different surgical options.

To our knowledge there are only two previous studies of the impact of complications on patients undergoing breast cancer surgery. The first compared 233 breast reconstruction patients who suffered a complication to 483 patients who did not. This study, which was retrospective and assessed patients at varying time points after their surgery, found that aesthetic satisfaction was significantly lower in patients who had a complication.[3] The second compared 36 patients who suffered a complication after breast reconstruction to 136 patients with no complications and found no difference in clinician-rated aesthetic outcomes.[4] Both were single-centre studies that excluded patients undergoing mastectomy without reconstruction, and did not attempt to analyse the impact of different complication types. The paucity of literature may be because of methodological obstacles. The highest standard of evidence requires a large multi-centre study to identify a sufficient number of patients suffering different types of complications. It would also require the use of standardized definitions of complications across all centres, information about important clinical covariates, and the prospective collection of perioperative morbidity and patient-reported outcomes at standardized time points. All of the above are available from the UK National Mastectomy and Breast Reconstruction Audit. In this paper, we use data from the Audit to compare the quality of life of patients who had complications after breast cancer surgery to those who had no complications.

**Methods**

Patients were recruited between 1 January 2008 and 31 March 2009 at all 150 English NHS acute hospital trusts providing acute breast cancer treatment, six NHS acute hospitals in Wales and Scotland, and 114 independent hospitals in England. Staff at these treatment centres prospectively recorded clinical data on women aged 16 years and over with a diagnosis of invasive carcinoma of the breast or ductal carcinoma in-situ undergoing unilateral mastectomy with or without immediate reconstruction, or primary delayed reconstruction following a previous mastectomy. Local staff were also asked to obtain written consent from eligible women to allow them to be sent follow up questionnaires.

Because there is great variability in how different clinicians define complications we focused on post-surgical problems that required treatment. Clinicians recorded all surgical complications requiring some form of treatment during the hospital admission. In this paper, we describe three sets of perioperative complication that might be expected to have an impact on aesthetic outcome at the breast surgery site, with consequent impairment to other aspects of quality of life. First, mastectomy-site complications occurring during a mastectomy, mastectomy with immediate reconstruction, or delayed breast reconstruction. These comprised wound infection requiring intravenous antibiotics or surgical debridement, wound dehiscence requiring re-closure, skin flap necrosis requiring surgical debridement, and haematoma or seroma at the mastectomy site requiring aspiration or drainage. Second, flap-related complications occurring during breast reconstruction. These comprised impaired flap perfusion requiring re-exploration or revision of anastomosis, partial flap necrosis or failure requiring debridement, and total flap necrosis or failure requiring removal. Third, implant/expander-related complications occurring during breast

reconstruction. These comprised displaced implant/expander requiring re-positioning, infected implant/expander requiring intravenous antibiotic therapy, infected implant/expander requiring removal, and ruptured implant/expander requiring removal. A range of other clinical data items were recorded to account for confounding when patient groups were compared. These included details of surgical procedures, clinical risk factors and sociodemographic characteristics.

To collect data on long-term quality of life outcomes, questionnaires were sent to consenting patients at their home address 18 months after surgery. The questionnaires were sent by a co-ordinating team of researchers that did not include the treating hospitals or clinicians, once the team had confirmed the patient was still alive by cross-checking their details against mortality data held by the National Strategic Tracing Service. A prepaid envelope was enclosed to facilitate the return of the completed questionnaire. Questionnaires were marked only with a unique numeric patient identifier. Non-respondents were sent a single reminder letter and an additional copy of the questionnaire at a five week interval. Each patient's questionnaire data was linked to their associated clinical data using their unique numeric identifier. The questionnaire addressed patient satisfaction with their breast area appearance (4 items for mastectomy-alone patients, 16 items for reconstruction patients), emotional well-being (10 items) and physical well-being (16 items). The emotional well-being scale addressed issues such as confidence in a social setting, emotional health and self-esteem. The physical well-being scale addressed issues such as back and shoulder pain, breast pain and difficulty sleeping. A separate scale on sexual well-being was included on an optional basis. As nearly half of the follow-up sample (46%) declined to complete this section the results are not reported. The scales were

derived from the Breast-Q family of outcome measures[5,6] and were pre-tested with English breast cancer patients by the authors prior to their use to ensure that there were no issues with language, comprehension or acceptability. Each scale ranges from 0 to 100 with higher scores representing a better outcome. We defined the minimum important difference as 0.5 of a standard deviation, equivalent to 10 points for each scale.[7] Copies of the questionnaires and clinical proformas are available at https://www.rcseng.ac.uk/standards-and-research/research/clinical-effectiveness-unit/documents-and-publications/

Linear multiple regression models were used to compare the Breast-Q scale scores of patients who had complications to those who did not. Separate analyses were conducted for women who underwent mastectomy-alone, mastectomy with immediate reconstruction, and delayed reconstruction. The analyses were also separated for each of the three complication sets described above. Complications within each set were combined so that the set as a whole could be coded as either present or not present at the individual patient level. The denominator of patients varied depending on whether or not a particular complication was relevant to the surgical group being analysed. For example, patients who did not have an implant were excluded from analyses that examined the impact of implant-related complications. The regression models included a range of baseline variables likely to be associated with quality of life so that the independent impact of suffering a complication could be estimated. The models were constructed using a backward stepwise process with variables dropped from the models if the strength of their association with an outcome was weak ($p>0.05$). The initial variables in each model were the patient's age, socioeconomic deprivation[8], ethnicity (white or other ethnic group), smoking status, Body Mass Index (BMI), diabetes status, American Society of Anaesthesiologists (ASA) physical status

classification[9], Eastern Cooperative Oncology Group (ECOG) score[10], tumour type (invasive or ductal carcinoma in situ), ductal carcinoma in situ grade (low, intermediate or high) and invasive carcinoma grade (well, moderately, or poorly differentiated).

All statistical tests were two-sided and p-values less than 0.05 were considered to represent a statistically significant result. All statistical analyses were undertaken using STATA/MP 14.

At the time of the study national cancer audits were exempt from obtaining research ethics approval. Approval to prospectively collect patient identifiable data for analysis and reporting was obtained from the Patient Information Advisory Group under Section 60 of the Health and Social Care Act 2001. Informed written consent was obtained from women before they were sent follow-up questionnaires.

**Results**

18,216 eligible women were registered within the inclusion period of whom 17,844 had a complete record of any complications suffered in the perioperative period. The extent to which patients were successfully recruited to the patient-reported outcomes component of the study varied across treatment centres. Of the 18,216 patients registered in the study, 10,632 women (58%) were asked to consent to receive follow-up questionnaires. In some cases, hospital staff did not ask for consent due to legitimate concerns regarding poor eyesight (n=27), literacy or language comprehension issues (n=166), or cognitive impairment (n=202). However, a large number of women were not approached for this element of the study due to logistical problems with consent procedures. Among those women that were asked, 8,725 (82%) agreed to participate. After further excluding those women who died in the follow up period, 8,536 women (98%) had an 18 month questionnaire sent to their home address. 7,110 (83%) of these returned a completed 18 month questionnaire, of whom 6,405 successfully completed the breast appearance scale and had a complete record of their perioperative complications.

The characteristics of the 17,844 women with complete complications data and the sub-sample of 6,405 women with self-reported data about their breast appearance 18 months after surgery are shown in Table 1. The samples are very similar indicating that the sub-sample is likely to be representative of the larger cohort. The sub-sample was younger, healthier and less deprived than the cohort as a whole but the differences were small. The proportion of women undergoing breast reconstruction surgery was higher in the sub-sample (35%) than in the larger cohort (28%). Reassuringly, the proportion of women who

suffered a perioperative complication in the sub-sample (9.8%) was almost identical to that recorded for the larger cohort (10.2%).

The proportion of women suffering different types of complications is shown in Table 2 for the sub-sample of women with complete follow-up data. The overall complication rate was 10.1% for women undergoing mastectomy with no reconstruction, 10.0% for women undergoing mastectomy with an immediate reconstruction, and 7.6% for women undergoing a delayed reconstruction. The most commonly recorded complication was a haematoma or seroma requiring aspiration or drainage. 9.0% of women undergoing mastectomy-only suffered this complication compared to 4.5% of women undergoing immediate reconstruction and 2.3% of women undergoing delayed reconstruction. Flap-related complications were rare but slightly more frequent in women undergoing delayed (5.4%) versus immediate reconstruction (3.0%). Implant-related complications were infrequent in both groups and were recorded for 3.3% of immediate reconstruction patients and 1.4% of delayed reconstruction patients.

Unadjusted and adjusted differences in 18-month breast appearance scores between patients with and without complications are shown in Table 3. The effect of adjusting for baseline factors was minimal. A negative difference implies a worst breast appearance outcome for patients who suffered complications. In the mastectomy-only group, patient-reported breast appearance was significantly worse for patients who had suffered a mastectomy site complication (adjusted mean difference = -2.7; 95% CI = -4.7 to -0.7) but this difference was less than the pre-defined minimally important difference of 10 points. A similar result was observed in the immediate reconstruction group (adjusted mean

difference = -7.5; 95% CI = -11.5 to -3.4) but there was no significant difference among delayed reconstruction patients. Patients suffering a flap-related complication had significantly worse breast appearance scores in the immediate reconstruction group (adjusted mean difference = -23.8; 95% CI = -31.0 to -16.6) and this difference was much larger than the minimally important difference threshold. This finding was present when the analysis was separated for pedicled flap procedures ($p < 0.001$) and free flap procedures ($p < 0.001$). Flap-related complications were not associated with significantly lower breast appearance scores in the delayed reconstruction group. In both the immediate and delayed reconstruction groups, implant-related complications were not associated with significantly worse breast appearance scores.

A similar pattern was seen for the emotional and physical well-being scales (Tables 4 and 5). Mastectomy site complications were associated with small but statistically significant differences in favour of patients who had not had complications, but this effect was not seen with delayed reconstruction patients. In the immediate reconstruction group, flap related complications were associated with large differences in favour of those who did not have complications. This effect was not seen in the delayed reconstruction group. In both reconstruction groups implant related complications had no association with emotional and physical well-being.

**Discussion**

Surgical complications were associated with little or no impairment to the quality of life of women undergoing mastectomy without reconstruction, or delayed reconstruction. The association was much larger in women who suffered flap-related complications in the immediate reconstruction context. The breast appearance and emotional well-being scores of these patients were much lower than any other patient group, including women who had a mastectomy with no reconstruction. Implant-related complications were not associated with a lower quality of life in any surgical group. Physical well-being scores showed less of an association with complications across all groups.

The findings should be reassuring to women undergoing mastectomy with or without breast reconstruction. In contrast to the toxicities associated with medical treatments for breast cancer, which are reported as severe by 45% of patients and are associated with substantial impairment to quality of life, surgical complications are less frequent and associated with much less harm.[11] The one area of concern relates to flap-related complications in women undergoing immediate reconstruction. This finding requires careful interpretation. The impact of complications on quality of life is a function of the outcome for both the women who suffer complications and those who do not. Flap-based reconstructions have, at the overall group level, a superior outcome to implant-only procedures[12,13] and therefore the impact of flap-related complications is exacerbated because of the additional benefit that is lost when the operation fails. The role of patient expectations must also be considered. Flap-based reconstructions are more difficult to perform than implant-only procedures. They take longer to perform, and the recovery period is also longer. Women who choose this option may be trading the short-term harm hardship associated with recovering from

the procedure for a better long-term outcome. Reconstructive complications and subsequent failure usually results in an unanticipated mastectomy for a woman expecting the outcomes of a flap-based immediate reconstruction. This may lead to profound disappointment in the small number of women affected.

There was no association between flap-related complications and quality of life in the delayed setting. This could be for two distinct reasons. First, the initial reference point for delayed reconstruction patients is post-mastectomy, lowering expectations. Second, unlike women in the immediate reconstruction group, delayed reconstruction patients do not require adjuvant therapies, which may exacerbate the impact of a surgical complication, and are more likely to have undergone corrective secondary reconstruction after initial reconstructive complications or failure.

This study is the largest to date and has many strengths over the existing literature. Standardized definitions of complications were used and complication data was collected prospectively to reduce the risk of measurement error. Complete complication data was collected for 98% of eligible patients. Data on complications and quality of life were from different sources which reduces the risk that any observed associations were due to common method variance. The data was collected at 270 hospitals which increases the generalizability of the finds and reduces the risk that the results represent the unique practices of individual hospitals or surgeons. Follow-up was at 18 months which means the full impact of complications and any subsequent revision procedures and treatments is assessed. Our analysis provides separate answers for different surgical groups, including women who underwent mastectomy alone, a group that is often neglected by research in

this area. We also provide a detailed analysis of the impact of different complication types for the first time.

The main limitation is the attrition between baseline and follow up. The follow-up cohort was slightly younger, healthier and less deprived than the cohort as a whole. However, the most important baseline prognostic factor, complication rate, was almost identical in the two groups. Although we adjusted for a wide range of prognostic factors, and the adjusted and unadjusted differences between groups were very similar, it is still possible that the differences we observed are due to residual confounding. The analysis of implant procedures in the delayed reconstruction context involves only four patients who suffered a complication. This means that we may have missed a real effect due to an underpowered statistical test. Finally, our study is limited to perioperative morbidity and does not assess the impact of complications occurring after discharge.

Our findings are consistent with the previous literature but provide a more detailed analysis of specific complications and surgical groups. The results complement previous studies on the effectiveness of different breast reconstruction techniques: we are now able to characterise both the benefits and harms of these procedures. The main implication of our findings is that clinicians should discuss the risks associated with reconstruction procedures that use flaps to reconstruct the breast mound. Patients and clinicians should be aware that although flap procedures are, at the group level, associated with superior aesthetic outcomes, they carry a substantial risk for the small group of patients who suffer a flap-related complication in the immediate reconstruction context.[10,11] This risk goes beyond self-perceived aesthetic outcome: it also extends to emotional and physical well-being.

Given these consequences there is a strong case for prospectively collecting flap complication rates at the surgeon and surgical unit level, and allowing patients to access this data when they make choices about their breast cancer surgery. We have previously shown that this can be achieved in the United Kingdom and have also outlined the main statistical constraints when performing comparisons.[14,15] Women should be informed of the outcomes associated with both successful and failed reconstructive procedures, along with the likelihood of reconstructive failure locally. They should also be made aware of the likely delay before any secondary reconstructive procedure can be undertaken, and the risk that they will need to undergo a simple mastectomy, with its associated outcomes, if complications arise. Clinicians should continue to refine their patient and procedure selection processes and operative techniques to minimize the risk of flap-related complications in the immediate reconstruction context.

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**Table 1. Characteristics of full baseline sample and sub-sample with 18-month quality of life data.**

| Characteristic | Full sample (n = 17,844) | | Sub-sample (n = 6,405) | |
|---|---|---|---|---|
| | n | % | n | % |
| No reconstruction | 12,841 | 72.0 | 4,179 | 65.3 |
| Immediate reconstruction | 3,304 | 18.5 | 1,492 | 23.3 |
| Delayed reconstruction | 1,699 | 9.5 | 734 | 11.5 |
| Age>65 years | 6,188 | 34.3 | 1,972 | 30.8 |
| Missing data | 3 | 0.02 | 0 | 0 |
| Most deprived quintile | 2,614 | 14.6 | 807 | 12.6 |
| Missing data | 906 | 5.1 | 341 | 5.3 |
| Non-white ethnicity | 812 | 4.6 | 166 | 2.6 |
| Missing data | 2,131 | 11.9 | 624 | 9.7 |
| Smoker | 2,170 | 12.2 | 722 | 11.3 |
| Missing data | 882 | 4.9 | 167 | 2.6 |
| Diabetic | 1,067 | 6.0 | 307 | 4.8 |
| Missing data | 327 | 1.8 | 58 | 0.9 |
| Obese (BMI 30 or greater) | 4,451 | 24.9 | 1,579 | 24.7 |
| Missing data | 1,017 | 5.7 | 207 | 3.2 |
| Grade I (normal) ASA | 8,612 | 48.3 | 3,560 | 55.6 |
| Missing data | 715 | 4.0 | 84 | 1.3 |
| Grade 0 (fully active) ECOG | 11,887 | 66.6 | 4,845 | 75.6 |
| Missing data | 1,047 | 5.9 | 211 | 3.3 |
| Ductal carcinoma in situ | 2,643 | 14.8 | 1,049 | 16.4 |
| Missing data | 458 | 2.6 | 117 | 1.8 |
| High grade DCIS/poorly differentiated tumour | 7,805 | 43.7 | 2,720 | 42.5 |
| Missing data | 736 | 4.1 | 185 | 2.9 |
| Overall complication rate | 1,822 | 10.2 | 629 | 9.8 |

**Table 2. Complication rates in 6,405 patients who reported on their satisfaction with their breast appearance 18 months after their surgery.**

| Complication type (associated intervention) | Reconstruction group | | | | | |
|---|---|---|---|---|---|---|
| | Mastectomy (n = 4,179) | | Immediate (n = 1,492) | | Delayed (n = 734) | |
| | n | % | n | % | n | % |
| Wound infection (antibiotics) | 45 | 1.1 | 30 | 2.0 | 7 | 0.9 |
| Wound infection (debridement) | 6 | 0.1 | 4 | 0.3 | 2 | 0.3 |
| Wound dehiscence (re-closure) | 6 | 0.1 | 21 | 1.4 | 3 | 0.4 |
| Skin flap necrosis (debridement) | 3 | 0.1 | 2 | 0.1 | 0 | 0 |
| Haematoma/seroma (aspiration or drainage) | 378 | 9.0 | 67 | 4.5 | 17 | 2.3 |
| All mastectomy site complications | 423 | 10.1 | 113 | 7.6 | 26 | 3.5 |
| Impaired flap perfusion (re-exploration/revision) | NA | NA | 13 | 1.3 | 22 | 3.5 |
| Partial flap necrosis or failure (debridement) | NA | NA | 11 | 1.1 | 10 | 1.6 |
| Total flap necrosis or failure (removal) | NA | NA | 7 | 0.7 | 4 | 0.6 |
| All flap complications | NA | NA | 30 | 3.0 | 34 | 5.4 |
| Displaced implant/expander (re-positioning) | NA | NA | 5 | 0.6 | 3 | 1.1 |
| Infected implant/expander (intravenous antibiotics) | NA | NA | 9 | 1.1 | 1 | 0.3 |
| Infected implant/expander (removal) | NA | NA | 14 | 1.7 | 0 | 0 |
| Ruptured implant/expander (removal) | NA | NA | 2 | 0.2 | 0 | 0 |
| All implant/expander complications | NA | NA | 27 | 3.3 | 4 | 1.4 |
| All complications combined | 423 | 10.1 | 149 | 10.0 | 56 | 7.6 |

**Table 3: Breast-area appearance scores for patients with and without complications by type of complication and type of surgery at 18 months after surgery.**

| Surgical group/complication type | No complications | | Complications | | Adjusted difference (95% CI)* | *P* value | Covariates in multivariate linear regression model |
|---|---|---|---|---|---|---|---|
| | n | Mean (SD) | n | Mean (SD) | | | |
| *Mastectomy-only patients* | | | | | | | |
| Mastectomy site complications | 3,756 | 55.9 (20.3) | 423 | 53.2 (21.4) | -2.7 (-4.7 to -0.7) | 0.009 | Age, smoking status, BMI, ECOG, tumour type |
| *Immediate reconstruction patients* | | | | | | | |
| Mastectomy site complications | 1,379 | 62.1 (20.2) | 113 | 53.9 (18.1) | -7.5 (-11.5 to -3.4) | <0.001 | Deprivation, ASA, tumour type |
| Flap-related complications | 966 | 65.4 (19.2) | 30 | 42.2 (20.4) | -23.8 (-31.0 to -16.6) | <0.001 | Ethnicity |
| Implant-related complications | 786 | 59.1 (19.6) | 27 | 51.4 (23.4) | -8.3 (-17.1 to 0.5) | 0.06 | Deprivation, ASA |
| *Delayed reconstruction patients* | | | | | | | |
| Mastectomy site complications | 708 | 68.5 (19.8) | 26 | 67.0 (22.1) | -3.2 (-11.1 to 4.7) | 0.43 | Ethnicity, smoking status, ECOG |
| Flap-related complications | 594 | 70.7 (19.4) | 34 | 64.0 (21.1) | -2.8 (-9.7 to 4.0) | 0.42 | Ethnicity |
| Implant-related complications | 280 | 63.6 (19.6) | 4 | 70.0 (6.2) | 5.3 (-13.5 to 24.0) | 0.58 | Ethnicity, ECOG |

*Negative differences imply better outcomes for patients with no complications

**Table 4: Emotional well-being scores for patients with and without complications by type of complication and type of surgery at 18 months after surgery.**

| Surgical group/complication type | No complications | | Complications | | Adjusted difference (95% CI)* | *P* value | Covariates in multivariate linear regression model |
|---|---|---|---|---|---|---|---|
| | n | Mean (SD) | n | Mean (SD) | | | |
| *Mastectomy-only patients* | | | | | | | |
| Mastectomy site complications | 3,745 | 62.8 (21.3) | 421 | 59.5 (22.4) | -4.5 (-6.6 to -2.3) | 0<0.001 | Age, deprivation, smoking status, BMI, ASA, tumour type |
| *Immediate reconstruction patients* | | | | | | | |
| Mastectomy site complications | 1,374 | 69.7 (22.3) | 111 | 64.0 (23.3) | -4.9 (-9.4 to -0.3) | 0.03 | Age, deprivation, smoking status, BMI, ASA, ECOG |
| Flap-related complications | 963 | 71.9 (21.6) | 28 | 56.7 (23.8) | -14.0 (-22.0 to -6.0) | 0.001 | Age, deprivation, ECOG |
| Implant-related complications | 783 | 68.3 (22.1) | 27 | 63.7 (27.5) | -7.4 (-17.1 to 2.4) | 0.14 | Age, deprivation, ASA |
| *Delayed reconstruction patients* | | | | | | | |
| Mastectomy site complications | 703 | 74.4 (21.9) | 26 | 82.5 (20.6) | 6.7 (-2.2 to 15.7) | 0.14 | Ethnicity, smoking status, BMI, ASA, ECOG |
| Flap-related complications | 592 | 76.4 (21.2) | 34 | 73.1 (19.9) | 1.2 (-6.4 to 8.8) | 0.76 | Ethnicity, smoking status, ASA, ECOG |
| Implant-related complications | 276 | 71.7 (22.2) | 4 | 85.5 (18.0) | 15.4 (-5.9 to 36.8) | 0.16 | Smoking status, ECOG |

*Negative differences imply better outcomes for patients with no complications

**Table 5: Physical well-being scores for patients with and without complications by type of complication and type of surgery at 18 months after surgery.**

| Surgical group/complication type | No complications | | Complications | | Adjusted difference (95% CI)* | *P* value | Covariates in multivariate linear regression model |
|---|---|---|---|---|---|---|---|
| | n | Mean (SD) | n | Mean (SD) | | | |
| *Mastectomy-only patients* | | | | | | | |
| Mastectomy site complications | 3,742 | 73.6 (16.7) | 421 | 71.6 (17.7) | -2.6 (-4.4 to -0.8) | 0.004 | Age, deprivation, ethnicity, smoking status, BMI, ASA, tumour type |
| *Immediate reconstruction patients* | | | | | | | |
| Mastectomy site complications | 1,372 | 75.1 (15.3) | 113 | 71.2 (17.0) | -4.7 (-8.1 to -1.3) | 0.007 | Age, deprivation, ethnicity, BMI |
| Flap-related complications | 962 | 75.1 (15.6) | 29 | 69.2 (13.5) | -7.9 (-13.8 to -1.9) | 0.009 | Age, deprivation, ethnicity |
| Implant-related complications | 783 | 75.0 (15.4) | 27 | 76.7 (14.6) | -0.8 (-8.3 to 6.6) | 0.83 | Age, deprivation, ethnicity, ASA |
| *Delayed reconstruction patients* | | | | | | | |
| Mastectomy site complications | 706 | 76.7 (16.0) | 25 | 81.4 (17.9) | 3.5 (-3.2 to 10.2) | 0.31 | Deprivation, ethnicity, smoking status, ECOG |
| Flap-related complications | 593 | 77.0 (16.1) | 33 | 80.5 (15.6) | 5.9 (-0.1 to 12.0) | 0.06 | Deprivation, ethnicity, smoking status |
| Implant-related complications | 279 | 75.5 (16.2) | 4 | 67.0 (7.4) | -8.8 (-25.1 to 7.6) | 0.29 | Deprivation, BMI, ASA |

*Negative differences imply better outcomes for patients with no complications