QUALITY OF LIFE OUTCOMES AFTER BREAST RECONSTRUCTION IN WOMEN WITH A HIGH BODY MASS INDEX

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Quality of Life Outcomes after Breast Reconstruction in Women with a High Body Mass Index

Thesis for the Degree of Doctor of Philosophy

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THESIS SUMMARY

With the increased affluence of Western society, the prevalence of obesity in the population is climbing, with more than five million Australians, and 28.8% of Australian women, being classified as obese. This thesis presents a review of the literature on the role obesity plays in surgery, including its role in breast cancer risk, and post-operative complications. The literature review also explores the development and utilisation of the Breast-Q patient reported outcome measure, as well as its role and applications in the literature.

Obese patients have been shown to have a higher rate of post-operative complications. In Chapter 2, a case of an obese patient with a breast implant presenting with a late onset seroma is presented. Although the cause for the seroma was eventually found to be caused by an implant rupture, careful evaluation of patients presenting with a late onset seroma due to the growing concern for Breast Implant Associated Anaplastic Large Cell Lymphoma.

An obese woman seeking breast reconstruction can be limited in the options available for breast reconstruction. In Chapter 3, an alternative method for breast reconstruction, the Reverse Abdominoplasty is explored, with a case series of three patients undergoing the procedure. The procedure was found to be safe and satisfactory, and can be a viable option for breast reconstruction.

The diagnosis of breast cancer can have a tremendous psychological impact on a woman. In Chapter 4, a qualitative study was performed with an aim to explore the experiences and perspectives of obese women in relation to their cancer diagnosis, breast reconstruction journey, and perspectives into obesity. Some common themes that emerged included difficulties coping with external

breast prostheses, physical effects of breast cancer treatment, and the overwhelmingly positive experiences with breast reconstruction.

A study establishing the quality of life of obese women before and after breast reconstruction is detailed in Chapter 5. This is compared with the quality of life of non-obese women, as well as the relationship, to complications in the post-operative period. The study showed that obese women get the same, if not greater quality of life benefit when compared with non-obese women, despite a higher rate of minor complications.

A common theme expressed by women in Chapter 4 was the difficulty coping with external breast prostheses after mastectomy. Chapter 6 looks at the effect of the weight of the breast resected at mastectomy on the quality of life after breast reconstruction. It was found that women with a larger breast weight at mastectomy had a lower pre-operative quality of life, as well as a lower post-operative sexual well-being.

Chapter 7 was designed to study the effect of breast reconstruction using the latissimus dorsi (LD) flap on patient reported shoulder function, as well as quality of life, compared with a control group of women undergoing total mastectomy without breast reconstruction. It was found that women undergoing LD flap reconstruction had a higher quality of life outcome compared with women undergoing mastectomy without reconstruction, and there was no difference in patient reported shoulder function.

Declaration

I certify that this thesis:

1. Does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university; and
2. To the best of my knowledge and belief, does not contain any material previously published or written by another person except where due reference is made in the text.

Signed:

Dr Koh Zhi Yuan Eugene

MBBS, MSSc

Dated on 26th March, 2020

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Publications

The following is a list of publications which were generated from the work contained within this thesis:

1. Koh, E., Watson, D.I. and Dean, N.R., 2016. An uncommon presentation of breast implant rupture. *Plastic and Reconstructive Surgery Global Open*, *4*(5).

2. Koh, E., Watson, D.I. and Dean, N.R., 2016. Reverse Abdominoplasty, a Viable Option for Breast Reconstruction. *Plastic and Reconstructive Surgery Global Open*, *4*(9 Suppl).

3. Koh, E., Watson, D.I. and Dean, N.R., 2018. Quality of life and Shoulder Function after Latissimus Dorsi Breast Reconstruction. *Journal of Plastic, Reconstructive & Aesthetic Surgery*.

4. Koh, E., Watson, D.I. and Dean, N.R., 2019. Impact of Obesity on Quality of Life After Breast Reconstruction. *Annals of plastic surgery*.

Presentations

The following is a list of presentations which were generated from the work contained within this thesis:

1. Reverse Abdominoplasty, a Viable Option for Breast Reconstruction

   Presenter: Eugene Koh

   Poster presentation at Plastic Surgery, The Meeting 2016, Los Angeles, USA (international meeting)
2. Patient Reported Shoulder Function after Latissimus Dorsi Breast Reconstruction

   Presenter: Eugene Koh

   Verbal presentation at Plastic Surgery Congress 2017, Gold Coast, Australia
3. Effect of Obesity on Quality of Life after Breast Reconstruction

   Presenter: Eugene Koh

   Verbal presentation at Plastic Surgery Congress 2017, Gold Coast, Australia
4. Effect of Obesity on Quality of Life after Breast Reconstruction

   Presenter: Eugene Koh

   Verbal presentation at Don Robinson Prize Day 2017, Adelaide, Australia

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1 LITERATURE REVIEW

1.1 Introduction

With the increased affluence of Western society, the prevalence of obesity in the population is climbing, with more than five million Australians, and 30.1% of Australian women, being classified as obese (World Health Organisation, 2016). The World Health Organisation classifies overweight as a body mass index (BMI) of greater or equal to 25; and obesity as a BMI of more than 30. It goes on to further stratify this into three classes of obesity: class I obesity (BMI 30 to 34.9kg/m^2), class II obesity (BMI 35 to 39.9kg/m^2), and class III obesity (BMI more than 40kg/m^2) (Schaverien and McCulley, 2014, Fischer et al., 2013e).

Breast cancer has an enormous impact on the lives of affected women, threatening their very lives, and also affects their identity as a woman due to the loss of their breasts. Breast reconstruction is therefore an important step in the journey of women affected by breast cancer, as it often signifies the completion of their breast cancer journey and the beginning of the next phase of their lives.

The literature often reports outcomes as the rate of complications and how surgeons perceive an operation to be successful. However, an emerging outcome reporting tool is the use of patient reported outcome measures. There is no point in performing the most technically perfect operation when the patient is not happy or does not feel that their life has improved in any way. It is therefore important that while we look at complication rates of various procedures, we must also consider outcomes measured from the patient's point of view.

1.2 Comorbidities Associated with Obesity

Obesity is a disease that affects multiple systems in the body, which has implications when considering a patient for surgery. Obese patients often have a higher prevalence of comorbidities, including cardiovascular disease, respiratory disease, diabetes and insulin resistance, impaired wound healing and blood coagulation, and impaired immunity causing increased susceptibility to wound infections (Schaverien and McCulley, 2014, Pannucci et al., 2012, Wilson and Clark, 2004, Wilson and Clark, 2003). These factors are extremely important when calculating the perioperative risk for individual patients considering reconstructive surgery.

1.2.1 Cardiovascular Disease

As body weight increases, the volume of blood increases in proportion to body surface area (Messerli et al., 1982). This leads to increased preload and increased resting cardiac output. The heart adapts to this by increasing left heart diastolic filling volume and results in left ventricular hypertrophy, leading to altered mechanics of the heart. When the altered heart can no longer respond efficiently to increasing demands, congestive cardiac failure may ensue (Lauer et al., 1991, de Divitiis et al., 1981).

Obesity is also associated with an increase in cardiovascular comorbidities like hypertension, coronary artery disease, stroke, and myocardial infarction (Chen et al., 2006, Yusuf et al., 2005).

1.2.2 Respiratory Disease

Respiratory function is decreased in obese patients, especially when they are lying flat. Respiratory compliance is compromised by the mass effect of visceral adiposity, and also by a heavier chest wall (Canoy et al., 2004). There is also

decreased total lung capacity and functional residual capacity with increased airway resistance (Jubber, 2004).

Obstructive sleep apnoea is prevalent in the general population, with 9% of women and 24% of men affected by it. More than half of the prevalence of obstructive sleep apnoea is attributable to obesity (Young et al., 1993). This can lead to hypersomnolence, pulmonary hypertension, heart failure and respiratory failure. The odds ratio for developing obstructive sleep apnoea is 1.14 for each unit increase in BMI (Tishler et al., 2003).

There has also been an association recognised between obesity and asthma, which may be mediated by nocturnal gastro-oesophageal reflux (Gunnbjörnsdóttir et al., 2004). Obesity also causes the body to be in a state of low grade inflammation, which may affect the lung to exacerbate asthma (Shore, 2008).

1.2.3 Endocrine Disease

Obesity is strongly related to insulin resistance, it develops as body weight increases, and can be reversed with weight loss (Després, 2006). Hepatic steatosis is thought to be one of the mechanisms that could lead to insulin resistance. Fat deposition in the liver causes a decrease in hepatic glucose production, stimulating hyperinsulinaemia and increased fatty acid production from glucose (Taylor, 2008, Petersen et al., 2005).

Obese patients often have varying severity of metabolic syndrome, which is a group of clinical measures including; central obesity, raised triglycerides, reduced high-density lipoprotein cholesterol, raised fasting glucose and blood pressure. The components of the metabolic syndrome have been associated

with the development of cardiovascular disease and type 2 diabetes mellitus (Gami et al., 2007).

1.2.4 Immunity and Infection

Adipose tissue has been found to be an active participant in inflammation and immunity, producing and secreting a variety of pro-inflammatory and anti-inflammatory factors (Falagas and Kompoti, 2006).

As obese patients are at a higher risk of developing type 2 diabetes, the hyperglycaemia associated with diabetes can also affect neutrophil function (McManus et al., 2001). The hyperglycaemic state also causes an increased circulating level of pro-inflammatory cytokines, increases reactive oxygen species, oxidative stress, and free radicals. These factors can lead to attenuated immune cell function and an increase in the inflammatory response (Mooradian et al., 1991, Collier et al., 2008).

1.2.5 Thromboembolic Disease

Obesity has long been regarded as a risk factor for the development of thromboembolic disease. Visceral adiposity has been found to be particularly associated with increased circulating levels of inflammatory and pro-coagulant markers. It has been estimated that obesity doubles the risk of the development of thromboembolic complications like deep venous thrombosis and pulmonary embolism (Donohoe et al., 2011, Pannucci et al., 2012).

1.2.6 Psychosocial Comorbidities

Obesity is a chronic illness, it can thus have an enormous impact on the social and psychological functioning of a person. A study of 10,000 adolescents showed that obese males had lower rates of marriage when compared to non-obese males. Obese females had less schooling, lower income, lower rates of

marriage, and higher rates of household poverty when compared to non-obese females (Gortmaker et al., 1993).

Obesity can also severely impact the mental health of a person, with depression and low self-esteem common in this sector of the community. A study has found that patients would prefer to be of normal weight with significant physical disabilities, such as being blind, dyslexic, or having one leg amputated, to being morbidly obese millionaires (Rand and Macgregor, 1991, Flancbaum and Choban, 1998).

1.3 Breast Cancer and Obesity

Obesity has been found to be a risk factor for breast cancer in postmenopausal women. One hypothesis is that adipose tissue continues secreting oestrogen in the blood even after menopause, causing higher rates of breast tumour formation, especially hormone-sensitive tumours (Cleary and Grossmann, 2009). A large study by Morimoto et al. looked at the relationship of several anthropometric measures and risk of postmenopausal breast cancer in 85,917 women, and found that obesity was an important risk factor for postmenopausal breast cancer, but only in women who had never taken hormone replacement therapy (Morimoto et al., 2002). It has also been observed that obesity at the time of breast cancer diagnosis appears to decrease the chance for disease-free survival compared with that for non-obese patients at a similar stage (Senie et al., 1992).

Obesity is also associated with the development of insulin resistance, causing an increase in the circulating levels of insulin in the body. Longstanding hyperinsulinaemia has been posited to play a role in carcinogenesis. One

theory to explain this is that hyperinsulinaemia amplifies the bioavailability of insulin like growth factor-1, which acting together with insulin is known to promote human breast cancer (Sachdev and Yee, 2001). There are however conflicting views in the literature on whether measures of insulin resistance, such as insulin levels and C-peptide levels are associated with breast cancer risk, with some studies reporting no association (Eliassen et al., 2007, Garmendia et al., 2007), and some reporting an association with breast cancer risk (Fair et al., 2007, Yam et al., 1996).

A systematic review and meta-analysis of the literature found 22 studies looking at the association of components of insulin resistance and breast cancer. They found that higher levels of fasting insulin or C-peptide levels did not have an association with breast cancer risk (Hernandez et al., 2014). Another meta-analysis found small association between diabetes and breast cancer, with an odds ratio of 1.15, which was higher for postmenopausal women than for premenopausal women (Xue and Michels, 2007). Another meta-analysis also looked at the link between metabolic syndrome and breast cancer, and found a weak association between metabolic syndrome and breast cancer, with a relative risk of 1.23 (Esposito et al., 2012).

The rising rates of obesity around the world, along with an increased risk of obese postmenopausal women developing breast cancer, will certainly cause the rates of obese women being diagnosed with breast cancer to rise. This, in turn will be why plastic surgeons will be faced with more obese patients seeking breast reconstruction after mastectomy. It is therefore extremely important to investigate the efficacy and safety of the different reconstructive options in obese patients to deal with the increasing proportion of obese patients seeking

breast reconstruction (Hanwright et al., 2013).

1.4 Obesity and Surgery

A common cause of morbidity in obese patients after surgery is wound complications like infection, haematoma, fat necrosis, and dehiscence. Wound complications have been found to be significantly greater in patients undergoing cholecystectomy, duodenal ulcer surgery, coronary artery bypass grafting, hysterectomy, caesarean section, and renal transplantation. There are many factors contributing to a higher rate of wound complications in obese patients. Adipose tissue is relatively avascular, and hence has a poorer resistance to infection, a larger patient can also increase the operative time due to the increased complexity of the operation, and there can also be increased local trauma from more forceful retraction of a larger abdominal wall (Choban and Flancbaum, 1997).

Obese patients can also be challenging from an anaesthetic point of view. They often have short, thick necks and heavy chest walls, making standard oro-tracheal or naso-tracheal intubation and ventilation difficult. Due to the increased thickness of adipose tissue, normal anatomical landmarks can also be more difficult to locate in obese patients, making regional anaesthesia techniques like epidural anaesthesia more difficult. Normally easy tasks like inserting a venous cannula can also prove to be more challenging in obese patients due to the increased subcutaneous adiposity (Choban and Flancbaum, 1997, Buckley et al., 1983).

The literature is however mixed in whether there is a link between obesity and

post-operative complications.

Dindo et al. prospectively looked at 6336 consecutive patients undergoing elective general surgery under general or regional anaesthesia. They found that in their population, only American Society of Anaesthesiologists (ASA) classification, type of surgical procedure, and open surgery, were independent risk factors for post-operative complications but obesity was not. There was also no recorded difference in the types of post-operative complications between obese and non-obese groups (Dindo et al., 2003).

A retrospective review of 560 patients undergoing elective general surgery did not find a statistically significant difference in rates of post-operative complications between obese and non-obese patients, with an overall complication rate of 5.5% (Herrera et al., 2007).

The Determining Surgical Complications in the Overweight (DISCOVER) study is a prospective, multicentre cohort study currently underway in general surgical units across the United Kingdom and Republic of Ireland. The primary aim of this study is to determine whether obesity is associated with an increased risk of post-operative complications following gastrointestinal, bariatric, and hepatobiliary surgery (Nepogodiev et al., 2015).

1.5 Breast Cancer Surgery and Reconstruction

The loss of breast tissue following surgery for breast cancer deals a significant psychological blow to women. It is therefore pertinent to preserve or reconstruct the breast where possible, following removal, to aid not only in the physical recovery of women, but also psychologically and socially. Reconstruction of the breast has a positive impact on quality of life, as it restores appearance of the

chest area and significantly improves physical, psychological, and sexual well-being when compared with mastectomy alone (Schaverien and McCulley, 2014, Albornoz et al., 2014, Serletti et al., 2011).

It has also been found that women undergoing breast reconstruction were found to have higher levels of physical activity and quality of life compared to women who received mastectomy alone or breast-conserving surgery (Fontes et al., 2018).

1.5.1 Reconstructive Methods

Non-surgical and surgical methods can be employed to reconstruct a woman's breast after mastectomy. One non-surgical method of breast reconstruction is the use of an external breast prosthesis. This is sometimes used as a temporary measure between mastectomy and surgical reconstruction if immediate reconstruction is not undertaken. It is also used if a woman does not want to undergo any further surgery following mastectomy. Surgical methods of breast reconstruction can be divided into two categories, implant reconstruction, or autologous reconstruction.

1.5.1.1 Implant Reconstruction

Implant reconstruction involves inserting a breast prosthesis to reconstruct the breast mound. Most breast implants have a silicone shell, which is filled with a silicone gel. They come in a range of shapes, such as anatomic or round, and a range of sizes. Silicone implants have been in use since 1962 for breast augmentation and reconstruction. There were early concerns for the oncological risk of silicone and a possible relationship between silicone implants and autoimmune diseases, but epidemiological studies did not demonstrate any significant risk (Yoshida et al., 1995, Gabriel et al., 1994).

The most common long-term complication of silicone breast implants is capsular contracture. A fibroelastic capsule normally forms around a breast implant as part of the body's reaction to the foreign body. Capsular contracture is the consequence of the contraction of this capsule. It is present in about 11% of patients at two-year follow-up, and 15% of patients at five-year follow-up (Clough et al., 2001a).

Textured shells have been developed that are purported to decrease the rates of capsular contracture, which was demonstrated by Coleman et al. in a prospective study in a small patient group of 53 (Coleman et al., 1991). There have however been recent concerns about texturing breast implants due to an apparent association between a rare form of non-Hodgkin's lymphoma, anaplastic large cell lymphoma (ALCL) (Taylor et al., 2012).

Implant reconstruction is often performed as a two-stage procedure, with the use of tissue expanders in the first stage to form a suitable tissue pocket for the final implants (Petit et al., 2012).

1.5.1.2 Autologous Reconstruction

Autologous reconstruction involves using the patient's own tissue to reconstruct a breast mound. This method is used when the patient is deemed unsuitable to undergo implant reconstruction, such as if they have undergone radiotherapy, or the patient wishes to undergo autologous reconstruction. Some methods include Latissimus Dorsi breast reconstruction, and Transverse Rectus Abdominis Myocutaneous (TRAM) flap breast reconstruction (Serletti et al., 2011).

1.5.1.2.1 Latissimus Dorsi flap

Latissimus dorsi flap breast reconstruction involves harvesting a skin island on the back along with the underlying latissimus dorsi muscle, and transferring it to the anterior chest wall via the axilla. In obese patients with more fatty tissue, or in patients with smaller breasts, the flap is often of sufficient size to fully reconstruct the breast. In thin patients, a breast implant is often used to augment the tissue volume obtained from the flap (Mühlbauer and Olbrisch, 1977, Petit et al., 2012).

1.5.1.2.2 Abdominal Flaps

The Transverse Rectus Abdominis Myocutaneous (TRAM) flap is a myocutaneous flap utilising the rectus abdominis muscle and an overlying island of skin. It can either be used as a pedicled flap based on the superior epigastric vessels, or a free flap based on the inferior epigastric vessels anastomosed to the internal thoracic artery (Hartrampf et al., 1982).

As the rectus abdominis muscle is harvested during this procedure, the abdominal wall needs to be supported with a mesh to avoid a hernia. The rate of hernia after two months was found to be about 8.8% (Clough et al., 2001b). The tissue volume obtained from the TRAM flap is often of sufficient volume to reconstruct the breast without the use of implants. It also provides excellent cosmetic results in the long term (Petit et al., 2012).

Another abdominal flap gaining in popularity is the deep inferior epigastric pedicle (DIEP) flap, which is a modification of the free TRAM flap, where the rectus abdominis muscle is spared (Petit et al., 2012).

Fischer et al. conducted a study to compare tissue expander/implant based breast reconstruction with abdominally based free flap breast reconstruction. Two hundred and two patients who were suitable for both methods of breast reconstruction were included in the study. Patients who received free flaps were found to be older, have a higher BMI, and have higher rates of hypertension. They found that patients who received free flap breast reconstruction needed fewer surgical procedures, had fewer clinic visits, had lower rates of complications and reconstructive failures, and completed their reconstruction quicker than patients who received expander/implant-based breast reconstruction. An analysis of the cost also showed a trend toward lower cost in patients who received free flap breast reconstruction (Fischer et al., 2013a).

1.5.1.2.3 Other Flaps

There are also other flaps that are less commonly used in breast reconstruction. Such flaps described in the literature include the free transverse gracilis (TUG) flap, the superior gluteal artery perforator (SGAP) flap, and the inferior gluteal artery perforator (IGAP) flap (Arnež et al., 2004, LoTempio and Allen, 2010).

1.6 Breast Reconstruction Complications

Autologous breast reconstruction can be divided into pedicled flap reconstruction and free flap reconstruction. Flap complications can include total flap failure, partial flap failure, fat necrosis, haematoma, infection, or delayed wound healing. Because the flap is harvested from a site on the body away from the breast region, there is also a suite of complications involving the donor site, including seroma, haematoma, infection, hernia, or abdominal bulge.

Schaverien et al. performed a meta-analysis of 14 studies, including 6043

patients, undergoing free flap breast reconstruction. They found that there was an almost three-fold increase in the number of complications in obese patients compared with non-obese patients. However, the majority of those complications was minor and did not require re-operation. They also found that obese patients had an acceptable success rate when undergoing free flap breast reconstruction. Total flap failure rate was 2.2% in obese patients compared with 1% in non-obese patients, partial flap failure rate was 3.9% in obese patients compared with 1.3% in non-obese patients, and fat necrosis rate of 9.5% in obese patients compared with 8% in non-obese patients (Schaverien and McCulley, 2014).

A systematic review of the literature was carried out looking into fat necrosis in abdominally based breast reconstruction. The mean rate of fat necrosis across 70 studies was 11.3%. The authors also found that significant predictors for the development of fat necrosis after abdominally based breast reconstruction included: obesity, pre- and post-reconstruction irradiation, active smoking, and abdominal scars (Khansa et al.).

Fischer et al. performed a population based analysis of 15,937 breast reconstructions from 2005 – 2010 using the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database. They found that the rate of wound complications increased significantly as the class of obesity increased. The incidence of flap loss also increased significantly across the groups, from non-obese to class III obesity, (1.0% vs 1.5% vs 3.8% vs 2.7%). Obese patients were also found to experience a significantly higher rate of medical complications, such as pneumonia, pulmonary embolism, and urinary tract infection. One limitation of this study however, was that the ACS-

NSQIP did not include endpoints specific to autologous breast reconstruction, like seroma or fat necrosis, which can be significant in this population (Fischer et al., 2013b).

Spear et al. performed a retrospective review of 224 pedicled TRAM flaps in 200 patients over a 10-year period, split into normal weight, overweight, and obese groups. Overall, flap complications were seen in 43.5% of all patients, donor-site and other complications were seen in 35.5% and 7.5% of patients, respectively. They did not find a statistically significant difference in overall complications rates between the subgroups, but they did find that when compared with the normal weight and overweight subgroups, obese patients had a significantly higher incidence of multiple flap complications. Obese patients also had a significantly higher rate of donor-site complications when compared with normal weight patients (53.3% vs 31.9%) (Spear et al., 2007).

Chang et al. reviewed 936 free TRAM flaps in 718 patients over a nine year period, split into normal weight, overweight, and obese groups. They found that when compared with normal weight patients, obese patients had significantly higher rates of overall flap complications, total flap loss, flap seroma, and mastectomy flap necrosis. Donor-site complications were also significantly more common in obese patients than in normal weight patients. There was no significant difference in vessel thrombosis seen among the three groups, and they postulated that the higher rate of flap loss in obese and overweight patients were most likely because of less successful salvage of ischaemic flaps in these patients. One possible explanation was that the large and heavy flap in the obese patient stretches and attenuates the musculocutaneous perforators, causing compromise to the blood supply to the flap. There was no significant

difference in the incidence of fat necrosis across the three groups (Chang et al., 2000b).

Nelson et al. performed a retrospective study of 1,033 free flap breast reconstructions in 682 patients at a single institution with an aim to develop a risk model for delayed wound healing. Delayed wound healing was seen in 44% of the patient cohort. They found that patients with delayed wound healing were older, had a higher BMI, had higher rates of hypertension, diabetes, active smoking, and bilateral reconstruction. Obesity was found to have the highest risk scores of all the factors analysed, followed by current or previous smoking, bilateral reconstruction, and the use of vasopressors during surgery (Nelson et al., 2015).

Seidenstuecker et al. performed a prospective review of 624 free flap breast reconstructions with either deep inferior epigastric perforator (DIEP) or muscle-sparing TRAM flaps in 558 patients over a 2 year period. They found that flap complications were significantly more common in obese patients than in non-obese patients. They also had significantly higher rates of total flap loss and marginal necrosis. However, except for seroma formation, donor-site complications were not significantly higher in the obese group compared with the normal weight group. They also concluded that active smokers have a higher incidence of donor-site complications, whereas obese patients have a higher incidence of flap complications (Seidenstuecker et al., 2011).

Fischer et al. reviewed 1,258 free tissue transfers for breast reconstruction in 812 patients over a six-year period. They found that morbid obesity was associated with higher rates of total flap loss, delayed breast and donor-site

wound healing complications, hernia, and overall abdominal morbidity. They also found a trend towards higher rates of arterial thrombosis in obese patients. Additionally, more complicated flap harvest and vessel anastomosis in the obese patients created longer operative times and exposure to anaesthetics, greater intraoperative blood loss was also noted in the obese cohort. There was a total flap loss rate of 5% in class III obese patients compared with 1% in non-obese patients (Fischer et al., 2013c).

Garvey et al. retrospectively reviewed consecutive implant and abdominal-based free flap breast reconstructions performed in obese patients over a five-year period. Their analysis included 990 breast reconstructions (548 flaps vs 442 implants) in 700 patients. They found a significantly higher overall complication rate for flap reconstructions when compared with implant reconstructions, and a higher reconstruction loss rate for implant reconstructions when compared with flap reconstructions. They also found that the majority of implant reconstruction failures occurred in the group of patients who received immediate tissue expander plus implant reconstructions, rather than the group who received delayed tissue expander plus implant reconstructions (Garvey et al., 2012).

Nahabedian et al. reviewed 168 breast reconstructions using tissue expanders and implants in 130 women. They found a significant association between implant infection and radiation therapy. The chance for implant infection was 4.88 times greater for implants that were exposed to radiation therapy compared to those that were not. They did not find any other significant association with implant infection from patient groups receiving chemotherapy, lymph node dissection, tumour stage, smoking, or diabetes. BMI was not

included as a factor analysed in this study (Nahabedian et al., 2003).

Nguyen et al. performed a population-based study analysing 48,393 patients who underwent mastectomy, of whom 9,315 had immediate breast reconstruction, in the ACS-NSQIP database, with surgical site infection as a primary endpoint. They found that patients who received immediate breast reconstruction after mastectomy had a 1% increase in the incidence of surgical site infection when compared to those who underwent mastectomy without immediate breast reconstruction. While this was statistically significant, the authors concluded that this was not a clinically significant difference. Obesity was found to be a risk factor for developing surgical site infection, with the risk increasing with increasing degrees of obesity, with morbidly obese patients having a 2.8 fold increased odds of surgical site infection. An operative time of six or more hours was also found to be a significant risk factor for developing surgical site infection, which could compound the risk in obese patients as operative times tend to be longer in these women (Nguyen et al., 2012).

Hanwright et al. performed another population-based study analysing 12,986 patients who underwent breast reconstruction in the ACS-NSQIP database. They found that in patients who received autologous breast reconstruction, obese patients who underwent a latissimus dorsi flap were less likely to experience post-operative complications when compared with patients receiving pedicled TRAM or free flap reconstruction. Latissimus dorsi flap recipients had lower rates of overall surgical morbidity, overall medical morbidity, and wound infection when compared to TRAM and free flap recipients. The complication rate and rate of reconstruction failure was significantly higher in patients who received autologous breast reconstruction when compared with patients who

received implant reconstruction. Patients with higher BMI were found to have a higher rate of complications in implant, pedicled TRAM, and free flap reconstructions. There were also higher rates of re-operations, overall morbidity, surgical and medical complications in obese patients who received autologous breast reconstruction compared to obese patients who received implant based breast reconstruction (Hanwright et al., 2013).

1.6.1 Clavien-Dindo Classification of Surgical Complications

The Clavien-Dindo Classification (CDC) is a validated and simple classification of surgical complications; it classifies the extent of post-operative morbidity in correlation to therapy management. (Dindo et al., 2004, Panhofer et al., 2014) It provides a simple, objective and reproducible approach for comprehensive surgical outcome assessment, which can help the evaluation and comparison of surgical outcomes among different surgeons, centres and therapies. A five-year review of the CDC showed that this classification is valid and applicable worldwide in many fields of surgery, and is indeed reproducible, showing a 90% concordance rate when surgeons at different levels of training among different centres were asked to rank examples of complications. (Clavien et al., 2009)

1.7 Prevalence of and Policy on Post-Mastectomy Breast Reconstruction in Obese Women

Doren et al. found that women with a higher BMI were more likely to receive mastectomy alone without reconstruction when compared with women with a lower BMI. This was despite them having higher satisfaction with breast reconstruction and having similar satisfaction with breast conserving surgery. They recommended that all patients being considered for mastectomy should be referred to a plastic surgeon to discuss the possibility of breast

reconstruction. They also recommended that women with a higher BMI be offered abdominal flap reconstruction despite the higher rate of complications (Doren et al., 2014).

Some health providers have also placed a BMI limit on who can be offered breast reconstruction. For example, a woman must have a BMI of less than 35 to be able to undergo breast reconstruction in the public system, in Queensland, Australia (Queensland Government, 2015).

Kulkarni et al. performed a population-based study into the rates of breast reconstructive surgery in different BMI groups and found that rates of breast reconstruction were similar across the BMI groups. However, they found that obese patients were more likely to receive autologous reconstruction, especially abdominal based flaps, whereas patients with normal BMI were more likely to receive implant reconstruction. All BMI groups also reported similar satisfaction with the surgical decision-making and surgical outcome. The authors recommended that while breast reconstruction in obese patients was worthwhile, the patients need to be better informed and educated about the higher risk and possible complications of undergoing breast reconstruction (Kulkarni et al., 2012).

1.8 Breast Reduction Surgery

In women who undergo unilateral mastectomy and breast reconstruction, they often undergo breast reduction surgery or mastopexy on the contralateral breast as a means of achieving symmetry with the reconstructed breast. The complication profile of this procedure therefore also needs to be considered when considering any woman for surgery.

Access to bilateral breast reduction surgery is frequently restricted by healthcare providers based on BMI; for example, women are only able to access bilateral breast reduction if the BMI is less than 27.5kg/m^2 in the United Kingdom (British Association of Plastic Reconstructive and Aesthetic Surgeons, 2014).

Shah et al. conducted a retrospective review of 306 patients undergoing bilateral breast reduction at their institution, finding an overall complication rate of 53.9%. BMI had a significant association with increased rates of any complication and multiple complications. However, the incidence of major complications like haemorrhage, wound dehiscence, or total nipple loss was not correlated to BMI. Smokers were found to have increased complication and multiple complication rates. Even though there was an increased complication rate with increased BMI, there was no significant difference in final aesthetic outcome and in overall patient satisfaction across the BMI groups. The authors therefore argue that despite a higher rate of complications in women with a higher BMI, the majority of these complications are minor and seem to be acceptable to the patient group in terms of aesthetic outcome and patient satisfaction. Hence the use of BMI as an exclusion criterion should perhaps be reconsidered (Shah et al., 2011).

Another study also found that BMI did not significantly affect the quality of life improvement gained from bilateral breast reduction, with an average lifetime gain of 5.32 quality-adjusted life years, which equates to each patient living an additional 5.32 years in perfect health (Thoma et al., 2007).

1.9 Cost Analysis of Obesity in Breast Reconstruction

While the most important factor when evaluating a medical intervention is its safety and complication profile, another important factor in today's economic climate is cost.

On initial impressions, implant reconstruction appears to be a much less expensive operation when compared to free flap reconstruction. The former requires less operating time, less training, and can be performed by a wider group of surgeons; whereas the latter requires longer operating times, specialised equipment and training, longer stays in hospital and can only be performed by specialised surgeons. In the longer term however, implant reconstruction is associated with a higher rate of complications, like capsule formation, implant failure, and loss of symmetry. Autologous reconstructions also require significantly less revision surgery when compare to implant reconstructions. Therefore, in the long term, the financial advantage that implant reconstruction has over autologous reconstruction is lost (Kroll et al., 1996, Atherton et al., 2011).

Obesity and its related complications are associated with an added estimated cost of $11 billion per year in the United States (Fischer et al., 2013c).

Fischer et al. found that immediate major surgical complications after oncologic breast reconstruction added about two hospital days and over $9,000 in direct costs, similarly, medical complications added close to two hospital days and $7,000 in cost (Fischer et al., 2013d). Another paper by Fischer et al. found that obesity was associated with longer hospitalisations and greater hospital charges after abdominally based free tissue transfer for breast reconstruction.

However, operating room cost was no different with respect to obesity, but subsequent hospital stay and in-hospital resource use were significantly greater across the higher BMI groups (Fischer et al., 2013c).

1.10 Qualitative Research in Breast Cancer Surgery

Qualitative research has allowed us to learn what women experience when they go through breast cancer surgery. This enables the treating team to anticipate the needs of other women going through the same thing so that holistic care can be provided.

Jamison et al. found that the emotional impact of having a mastectomy far outweighed the physical impact in women. There was also loss of feelings of femininity, sense of mutilation, and fear of death. A strong indication that a woman was coping successfully with her diagnosis was found to be the presence of strong family or social supports (Jamison et al., 1978).

Landmark et al. conducted a study of ten women with newly diagnosed breast cancer, and the central theme that emerged from the study was the will to live, and the fight for existence. There was a diversity of emotions related to female identity and the loss of their breasts. Loss of femininity and deterioration of relationships with sexual partners was another theme. There was also concern in the beginning with the use of external breast prostheses with both technical and existential dimensions, but they gradually learned how to cope with them. There was also a need to regain their lives prior to the diagnosis, with the support of family, friends, as well as the medical team contributing greatly to them coping with the diagnosis (Landmark and Wahl, 2002).

Thewes et al. conducted a study of 18 women to study their psychosocial needs

after a breast cancer diagnosis, and to see if there were any differences in needs between older and younger women. There were ongoing needs for practical and emotional supports from family and friends, with younger women in particular voicing the need for professional counsellors as well. Another issue identified was the constant need for reassurance that any aches, pains, fatigue or minor problems were not from the cancer coming back. It was also found that younger women identified more unique needs compared to their older counterparts, for example, dealing with gynaecological and reproductive consequences of treatment, and impacts to their lifestyle and career (Thewes et al., 2004).

With Australia being a multi-cultural society, it is important to appreciate that women from different cultural backgrounds will have different needs when coping with a diagnosis of breast cancer. Ashing-Giwa et al. conducted a study interviewing a group of women from different cultural backgrounds, including Asians, African Americans, Latinas, and Caucasians. Some women found their spiritual beliefs central to how they coped with the diagnosis, while others found family more important in helping with practical and emotional support. Language barriers were also found to be an important aspect of how some women understood their diagnosis and treatment and affected their relationship to the treating medical team (Ashing-Giwa et al., 2004).

1.11 Patient-Reported Outcome Measures

An important outcome measure of breast reconstruction is the patient's perception of the outcome of surgery. A woman can have a technically perfect breast reconstruction, but she may not be satisfied with the outcome (Cano et al., 2009). It is therefore important to measure the psychological, emotional,

social, and functional benefits of breast reconstruction.

Patient-reported outcome measures are in increasing demand in plastic surgery due to a number of reasons. Firstly, there is increasing difficulty for patients to gain access to certain reconstructive procedures in North America and Europe. Scientifically sound data is therefore needed to show that surgery positively affects quality of life so that we can advocate for our patients. Secondly, with the evolution of reconstructive and aesthetic surgical techniques, quality of life data will be able to show if these new techniques are superior to others from a patient's perspective. Thirdly, there is also an increasing demand by regulatory bodies like the United States Food and Drug Administration for patient centred data that can only be provided by patient reported outcome measures (Cano et al., 2009).

1.11.1 Michigan Breast Reconstruction Outcome Study

The Michigan Breast Reconstruction Outcome Study (MBROS) was a 12 centre, 23-surgeon prospective cohort study of mastectomy reconstruction patients (Atisha et al., 2008a). Patients completed a series of questionnaires measuring quality of life, satisfaction, health status, general well-being, and psychosocial information. It was found that at two years post mastectomy reconstruction, general psychosocial benefits and body image gains continued to manifest.

Another paper stemming from MBROS found that obese patients who received expander/implant reconstruction had significantly lower aesthetic satisfaction than the normal BMI group. There was however no significant difference in aesthetic satisfaction across the groups in those who received TRAM flap reconstruction. Additionally, BMI had no effect on general satisfaction for either

expander/implant reconstruction or autologous TRAM flap reconstruction. Therefore, despite a higher associated risk of complications, obesity does not constitute an automatic contraindication for breast reconstructive surgery (Atisha et al., 2008b).

1.11.2 Other Studies on Patient-Reported Outcome Measures

Elder et al. conducted a prospective study of quality of life and patient satisfaction in 76 breast cancer patients after immediate breast reconstruction with tissue expanders and implants. The Medical Outcome Study 36-item Short Form (SF-36), which is a generic instrument to measure quality of life, was used to assess patient satisfaction. They found significant improvements in all domains by one year postoperatively as compared with the preoperative scores. The most common reason for women choosing to undergo immediate breast reconstruction reported by the authors was to avoid the need to wear an external breast prosthesis. In addition, breast reconstruction has had little impact on patients' relationships with their partners or their sexual lives (Elder et al., 2005).

A systematic review of the literature showed a small number of patient-reported outcome questionnaires that had been formally developed and validated in a cosmetic or reconstructive breast surgery population. However, only one questionnaire, the Breast-Related Symptoms Questionnaire, which is specific to breast reduction surgery, showed evidence of adequate development and validation. The authors also stipulated the importance of outcome measures that were condition or surgery specific so as to allow greater responsiveness to intervention-related change when compared with generic measures (Pusic et al., 2007).

1.11.3 Developing a Valid Outcome Measure

The Medical Outcomes Trust was formed in 1992 to promote the science and application of outcomes assessment. They defined eight attributes and criteria to be used when carrying out instrument assessments to ensure well developed and validated outcome questionnaires (Lohr, 2002).

- **Conceptual and measurement model**

The rationale for and description of the concept and the population that a measure is intended to assess and the relationship between these concepts.

- **Reliability**

The degree to which an instrument is free from random error.

- **Validity**

The degree to which the instrument measures what it purports to measure.

- **Responsiveness**

An instrument's ability to detect change over time.

- **Interpretability**

The degree to which one can assign easily understood meaning to an instrument's quantitative scores.

- **Burden**

The time, effort, and other demands placed on those to whom the instrument is administered (respondent burden) or on those who administer the instrument (administrative burden).

- **Alternative modes of administration**

These include self-report, interview-administered, trained observer rating, computer-assisted interviewer-administered, performance-based measures.

- **Cultural and language adaptations or translations**

Assessment of conceptual and linguistic equivalence and evaluation of measurement properties.

1.11.4 Three-Stage Approach for Developing a Health Outcomes Instrument

Cano and colleagues described a three-stage approach for development of a health outcomes instrument (Cano et al., 2009).

Phase 1 is item generation, where the conceptual model and preliminary items are developed from patient interviews, expert panels and literature. A pilot study is then conducted to test the item pool with a small sample of patients.

Phase 2 is item reduction, where the preliminary measure is field-tested in a large heterogeneous population to revise or eliminate items and to finalise the new measure.

Phase 3 is psychometric evaluation, where the new measure is evaluated with respect to validity and other psychometric properties.

1.11.5 The Breast-Q

The Breast-Q is a patient-reported outcome measure that was developed to assess the unique outcomes of breast surgery patients. It was developed using the three-stage approach as proposed by Cano above.

1.11.5.1 Development of the Breast-Q

In the first phase, semi-structured interviews were conducted with 48 patients who had undergone breast reconstruction, augmentation, or reduction (Klassen et al., 2009). A literature review of breast outcome measures was conducted by the authors to develop a list of topics to help guide the interviews. This was a dynamic topic list that was revised throughout the course of the study, with earlier interviews influencing and shaping its contents.

The interviews were used to collect detailed data about the personal experiences of breast surgery patients, generating 2,749 statements about patient satisfaction and health-related quality of life. Based on these statements, research literature, and expert opinion, the authors identified six key themes, forming the conceptual framework of patient satisfaction and health-related quality of life in breast surgery:

1.11.5.1.1 Satisfaction with breasts

This theme explores women's satisfaction with their breasts. Women described factors that affected their satisfaction with their breasts: breast size, shape, symmetry, cleavage, scars, positioning, how natural the breasts look and feel, and how their breasts fit in proportion to the rest of their body. Many women also discussed how surgery vastly improved their choice of clothing, being able to wear tops that were tighter fitting or lower cut. Those with breast implants brought up issues like rippling and how hard or soft the implants felt to touch.

1.11.5.1.2 Satisfaction with overall outcome

This theme explores the overall satisfaction women have with the outcome of their surgery. Thoughts that were brought up included whether they would

undergo surgery if they could do it all over again, whether they would recommend surgery to someone else, and whether they had any regrets about undergoing surgery.

1.11.5.1.3 Psychosocial well-being

This theme explores the effects that breast surgery has on their psychosocial well-being. Common themes that came up during interviews included feeling less embarrassed, more confident about their body and in a social setting and also feeling more self-assured. Breast surgery was also seen as a way of their bodies being more in line with what was perceived to be the “norm” for a woman’s body, enabling women to feel more normal, attractive, feminine, and good about themselves. Women who had undergone breast reconstruction after cancer also described being able to get back what was lost and to move on from the diagnosis of cancer.

1.11.5.1.4 Sexual well-being

This theme explores how a woman’s breast condition and surgery affects her sexual life. Not being satisfied with her own breasts may affect how sexually attractive a woman feels, as well as her sexual functioning and sexual pleasure. Many women described feeling more sexually attractive both when they were clothed and unclothed, and more satisfied with their sex life after post-mastectomy breast reconstruction.

1.11.5.1.5 Physical well-being

This theme explores how the physical function of women is affected both before and after surgery, issues relate mostly to chest and upper body symptoms and how they impact activities of daily living. Patients who underwent breast

reconstruction or reduction described symptoms such as pain in the arm, shoulder, neck, back, and breast, as well as pulling, tenderness, and discomfort. The symptoms were also related to how their activities were limited, such as difficulty moving their arms, playing sports, or performing everyday household chores.

1.11.5.1.6 Satisfaction with care

In the interviews conducted, satisfaction with their overall care was an important theme in the women's overall assessment of their experience with surgery. This theme was further subdivided into further subthemes: satisfaction with pre-operative information, satisfaction with care provided by the plastic surgeon, and satisfaction with the office staff and other members of the medical team.

Issues discussed around satisfaction with information included how the surgery was to be done, healing and recovery time, possible complications, breast appearance, risks, and scarring.

Another important aspect of care was the relationship the women had with their plastic surgeon. Themes discussed included how their surgeon made them feel comfortable, being caring and reassuring, answered all their questions, and involving them in the decision-making.

Satisfaction with the office staff and other members of the medical team were measured in terms of whether they were professional, kind, friendly, and treated them with respect (Klassen et al., 2009).

Using the above data, a list of potential items was generated for each domain within the conceptual framework. Separate modules were developed for breast

reconstruction, augmentation, and reduction patients based on interviews of patients who had undergone that particular type of surgery. Preliminary questionnaires were then presented to focus groups for evaluation, leading to the draft versions of the questionnaires.

In the second phase, questionnaires were sent to 2,715 patients, with a response rate of 72%. Additionally, 491 patients completed the questionnaires twice, for assessment of reliability. Item-reduction analysis was then carried out and items deemed nonspecific for the respective scales were deleted.

Finally, traditional psychometric analyses were carried out, and all scales exceeded criteria for acceptability, reliability, and validity. The final item-reduced questionnaires were reviewed by 30 patients, and they were found to be acceptable, comprehensive and clear (Pusic et al., 2009). The questionnaire that patients who have undergone breast reconstruction receive is included in Appendix 1.

1.11.5.2 Further Validation of the Breast-Q

The authors conducted further validation of the Breast-Q where they sought to test three aspects of validity of the questionnaire: intercorrelations between Breast-Q scales were assessed to examine the extent to which subscales measured separate but related constructs, correlations between Breast-Q subscales and other scales, and clinical validity was assessed by examining the ability of the Breast-Q to detect clinical differences between predefined subgroups. Reliability of the questionnaire was also examined, including internal consistency, and test-retest reliability.

Questionnaires were sent to 1,244 women, with a response rate of 66%.

Analysis of the results found that the Breast-Q satisfies and exceeds traditional psychometric criteria for valid measurement (Cano et al., 2012).

1.11.5.3 Applications of the Breast-Q

Atisha et al. conducted a large study looking into satisfaction with breast cancer surgery. Participants of the study were recruited from the Love/Avon Army of Women program that was launched in 2008 by the Dr. Susan Love Research Foundation to help connect scientists with study volunteers. Women with a history of breast cancer surgery were recruited and directed to fill in the Breast-Q module based on their most recent procedure.

Responses were received from 7,619 women, they underwent mastectomy alone, breast conserving surgery, or breast reconstructive surgery. Women who had mastectomies without reconstruction were found to have the lowest satisfaction scores. Those who underwent implant reconstruction had scores lower than those who underwent breast conserving surgery, while those who underwent abdominal flap reconstruction had higher satisfaction scores than those undergoing breast conserving surgery. Women who received latissimus dorsi flaps did not demonstrate any significant difference in satisfaction scores when compared to women who underwent breast conserving surgery.

The authors also found that women with a higher BMI had lower breast satisfaction scores than those with a normal BMI. Breast satisfaction scores in the entire cohort also decreased as time from surgery increased, however women who underwent abdominal and latissimus dorsi flap reconstruction maintained similar scores in the short and long-term. The overall results favour breast reconstruction using autologous tissue, and this will help guide the choice of women considering breast reconstructive surgery (Atisha et al., 2015).

The National Mastectomy and Breast Reconstruction Audit was a large audit conducted by the National Health Service (NHS) in England, and involved all NHS acute trusts and independent sector hospitals that provide mastectomy and breast reconstruction surgery. 18,216 patients participated in the audit during the 15 month data collection period. 16,485 underwent mastectomy, of whom 3,389 had immediate reconstruction. A further 1,731 women underwent delayed breast reconstruction following previous mastectomy. Patient satisfaction was evaluated using the Breast-Q questionnaire.

At 18 months post-surgery, it was found that women who underwent immediate breast reconstruction had higher satisfaction scores than those who underwent mastectomy without reconstruction. Autologous reconstruction also had higher satisfaction scores when compared with implant reconstruction (NHS Information Centre, 2011, Jeevan et al., 2014).

Cohen et al. conducted a review of the literature to look at how the Breast-Q has been used to improve the understanding and practice of plastic and reconstructive breast surgery. It was found that autologous breast reconstruction gives superior outcomes when compared with implant reconstruction, and while it is a more expensive procedure, it is worthwhile when cost and quality of life is factored together. Another important finding was that when a patient was satisfied with the information provided to her and also with the plastic surgeon, she was more likely to be satisfied with her surgical outcome. This highlights the importance of patient education and the provision of adequate information for the patient to make a fully informed decision about their treatment. One limitation proposed by the authors in the use of the Breast-Q is the introduction of an inherent selection bias, as patients who complete

questionnaires may be more likely to be either very satisfied or very dissatisfied (Cohen et al., 2015).

Mundy et al. conducted a large study recruiting 1201 without a history of breast surgery or breast cancer to complete the Breast-Q questionnaire. This has provided a set of normative scores for the Breast-Q breast cancer module to allow comparison in future studies. They found that women with a BMI of more than 30, cup size of D or greater, annual income of less than $40,000 and women younger than 40 years reported lower scores (Mundy et al., 2017).

1.12 Latissimus Dorsi Musculocutaneous Flap

The latissimus dorsi musculocutaneous flap was first described in the early 1900's by Italian surgeon Iginio Tansini. This versatile flap has since become widely used in breast reconstruction, head and neck reconstruction, free flap reconstruction, and chest wall coverage (Maxwell, 1980).

1.12.1 Function of the Latissimus Dorsi Muscle

The latissimus dorsi muscle, in its interaction with other muscles of the shoulder, plays an important role in shoulder adduction, extension, and internal rotation, as well as scapular depression and lateral flexion of the torso (Veeger and van der Helm, 2007). Daily activities that rely on the function of the latissimus dorsi include swimming, climbing stairs, rising with the aid of the arms, and walking on crutches (Adams et al., 2004, Spear and Hess, 2005, Koh and Morrison, 2009, Lee and Mun, 2014). There is therefore a concern that the latissimus dorsi flap procedure may impair shoulder function.

Russell et al. conducted a study to look at the cosmetic and functional problems associated with the latissimus dorsi muscle donor site. The study consisted of

24 patients undergoing both free and pedicled muscle and myocutaneous flap procedures for a wide variety of reconstruction problems. They found that there was measurable shoulder weakness in 19 out of 23 patients when compared to the opposite normal side. Total active shoulder range of motion was also decreased in most patients when compared to the non-operated side. Interestingly, while they found that most patients had to make adjustments to their physical activities and activities of daily living, the adjustments were minor and did not pose significant problems for most of the patients (Russell et al., 1986).

1.12.2 Latissimus Dorsi Breast Reconstruction

Breast reconstruction using the latissimus dorsi flap is one of the principal options for the reconstruction of post-mastectomy defects. It is a safe procedure and provides aesthetically pleasing results (Mühlbauer and Olbrisch, 1977, Malata et al., 2000, Sternberg et al., 2006).

A series of 54 immediate pedicled latissimus dorsi flap breast reconstructions with silicone implants were reviewed, and surviving patients were sent satisfaction surveys. 77.5% of 38 patients who completed the survey reported excellent or good satisfaction with their breast reconstruction (Winters et al., 2013).

Dutra et al. surveyed a cohort of 196 patients who underwent mastectomy and immediate breast reconstruction with a latissimus dorsi flap and implant, to assess the levels of patient satisfaction with the procedure. 178 patients out of the 196 responded, with 92% of them satisfied with the operation and 90% saying they would recommend the surgery to someone else. Older patients were found to be less satisfied than their younger counterparts (Dutra et al.,

2012).

A prospective cohort study was performed across six centres in the United Kingdom to assess health related quality of life after implant-assisted latissimus dorsi or tissue only autologous latissimus dorsi flap breast reconstruction, using a variety of patient reported outcome measure tools. They found that there was similar health related quality of life between the two types of latissimus dorsi breast reconstruction. Chemotherapy and early complications adversely affected quality of life, which improved between 3 and 12 months after surgery. They did however find that role functioning and pain scores were worse in the group who underwent tissue only autologous latissimus dorsi flap reconstruction when compared with the group who underwent implant-augmented latissimus dorsi flap reconstruction (Winters et al., 2013).

de Oliveria et al. performed a prospective study comparing the effects of mastectomy without breast reconstruction and mastectomy with immediate latissimus dorsi flap reconstruction on shoulder motion. They found that there was a 30% decrease in shoulder function in both groups of patients one month after surgery. Shoulder motion improved at the one-year mark, but did not reach baseline levels, with an average of 5-10% lower than baseline. Patients who underwent latissimus dorsi breast reconstruction were found to have superior shoulder flexion and abduction at the one-year mark when compared with those who underwent mastectomy without reconstruction. The authors hypothesised that the tissue manipulation performed during latissimus dorsi flap reconstruction, along with the extra skin provided by the flap helped reduce tissue adhesion, contributing to greater shoulder mobility seen in the group who underwent latissimus dorsi breast reconstruction (de Oliveira et al., 2010, de

Oliveira et al., 2013).

2 CASE REPORT: BREAST IMPLANT RUPTURE

A version of this chapter has been published in Plastic and Reconstructive Surgery (Global Open), and appended in Appendix 2.

2.1 Introduction

Obese patients have been shown to have significantly higher implant-related complications (Fischer et al., 2013b). Obese patients have been found to have a significantly higher seroma rate of up to 50% when compared to non-obese patients (Sforza et al., 2017).

Breast implant-associated anaplastic large-cell lymphoma (ALCL) is a concerning clinical entity that has been observed in recent years. A well-known mode of presentation for ALCL is late periprosthetic seroma. I present a case of late seroma occurring in the context of implant rupture, with no detectable ALCL in an obese patient.

2.2 Background

A 69-year-old woman with a BMI of 31 presented in late December 2014 with gross swelling of her reconstructed left breast and a maculopapular rash. She had undergone delayed bilateral implant-based reconstruction two years previously, after a right therapeutic and left prophylactic mastectomy. The reconstruction was performed in two stages with textured surface tissue expanders (PMT Integra, PMT corporation, Minn.), followed by imprint-textured surface, cohesive gel implants (Mentor Contour Profile Gel, Mentor Worldwide LLC., Calif.). There were no immediate postoperative complications, and all was well at a follow-up appointment 24 months after surgery, and follow-up photographs were obtained (Figure 2-1).

The patient then presented three weeks later with marked swelling of the reconstructed left breast and a maculopapular rash developed around the reconstructive scar on the same side over the previous week (Figure 2-2). For the rash, she had previously seen a dermatologist, who prescribed steroid cream and tablets, with no improvement. Ultrasound and magnetic resonance imaging were obtained. Ultrasonography revealed a large volume of fluid surrounding the left breast implant, and 840ml of viscous straw-coloured fluid was aspirated under ultrasound guidance, and sent for cytology. Magnetic resonance imaging of the reconstructed left breast revealed a rupture of the left breast implant, with a tear in the silicone rubber shell visible on its deep aspect, at the shell patch juncture (Figure 2-3). There were no systemic signs of infection, and the white cell count was normal. However, C-reactive protein was increased to 120mg/l.

Surgery was undertaken, and an obvious tear was seen at the interface of the smooth and textured parts of the posterior surface of the implant (Figure 2-4). The likely cause at that stage was considered to be implant rupture due to either mechanical forces or a one-off manufacturing fault. As the patient had not had any problems with the contralateral identical implant, a new implant of the same size and brand was inserted. Postoperatively, there was <20ml of output in the surgical drain across the first 12 hours after surgery, and the rash resolved within days of having the implant replaced. The ruptured implant was also returned to the manufacturer for testing, which did not reveal any manufacturing defects.

Analysis of the seroma fluid revealed an inflammatory exudate, and flow cytometry did not reveal any evidence of lymphoma or neoplasia. A skin biopsy

at that time showed tinea incognito and no neoplasia. There were no postoperative complications, and 12 months later, there has not been any recurrence of the swelling or rash.

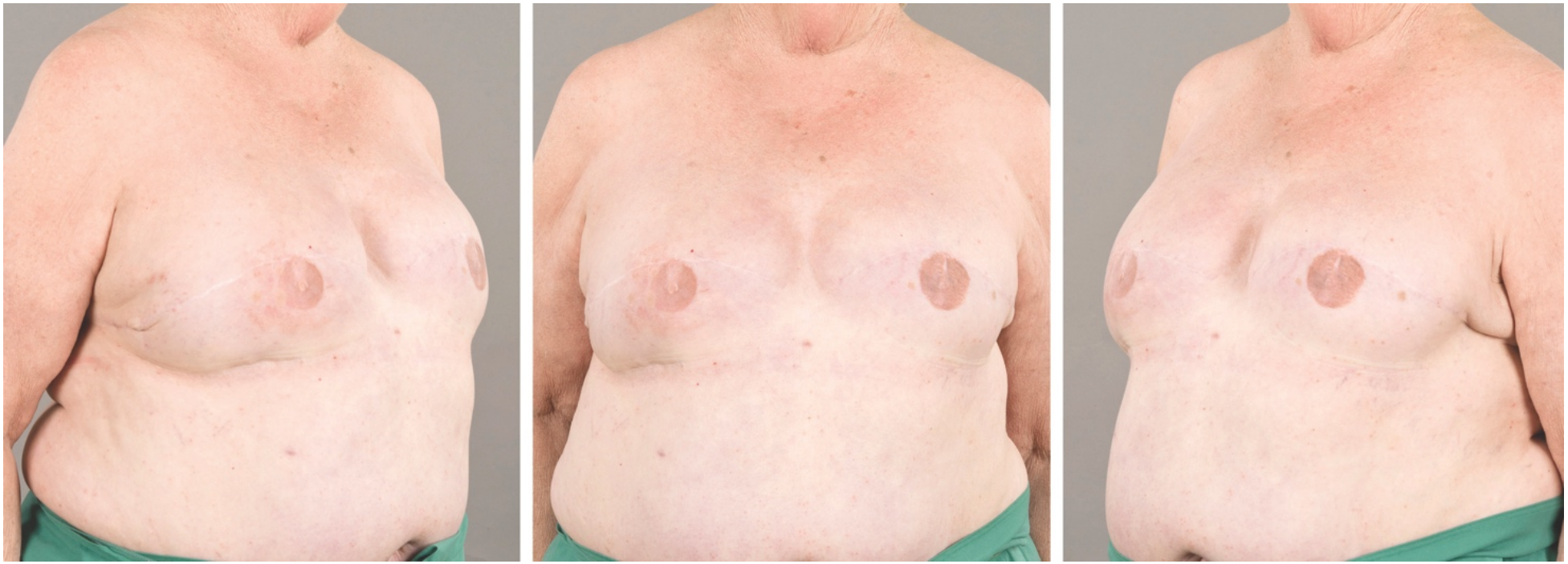


Figure 2-1 Follow-up picture obtained weeks before the onset of symptoms

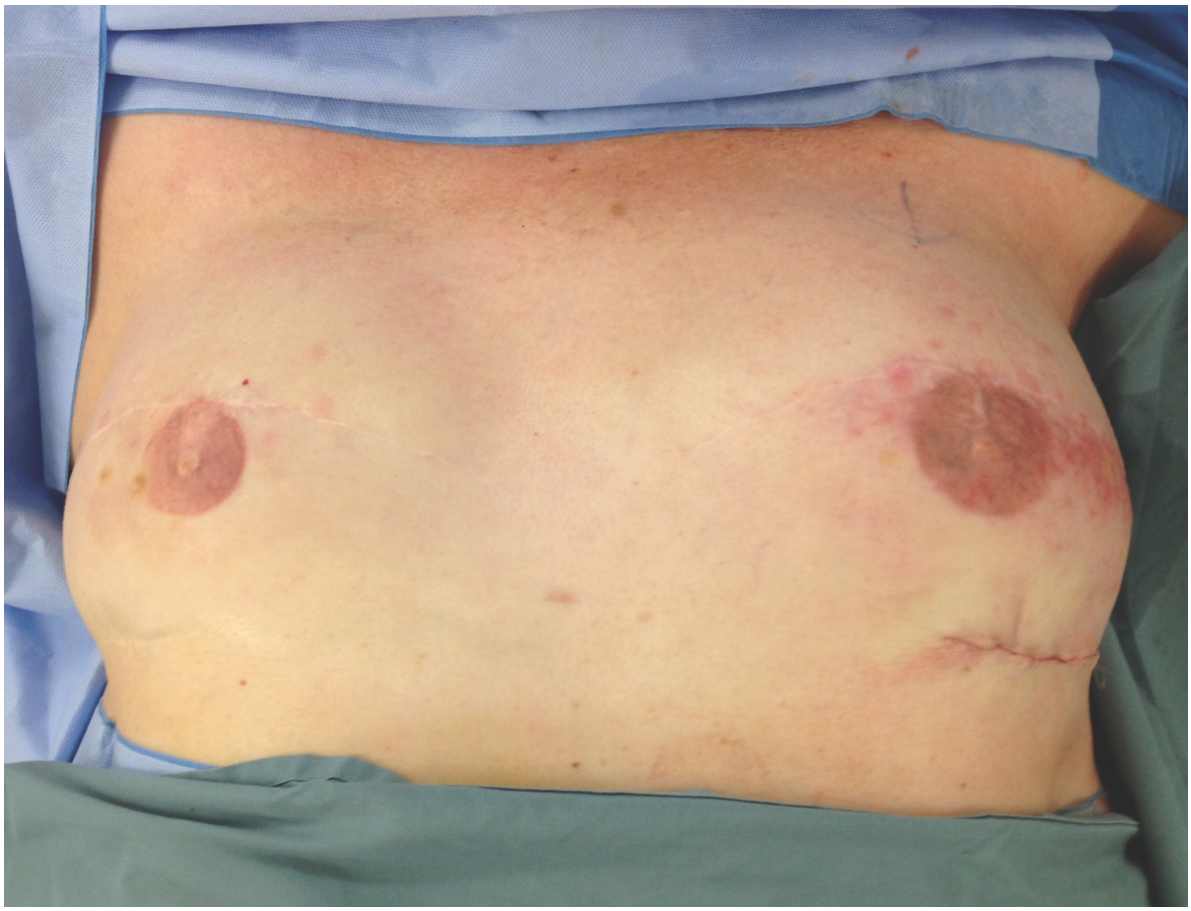


Figure 2-2 Picture obtained at the time of replacement of the left breast implant shows the maculopapular rash around the scar of the previous incision

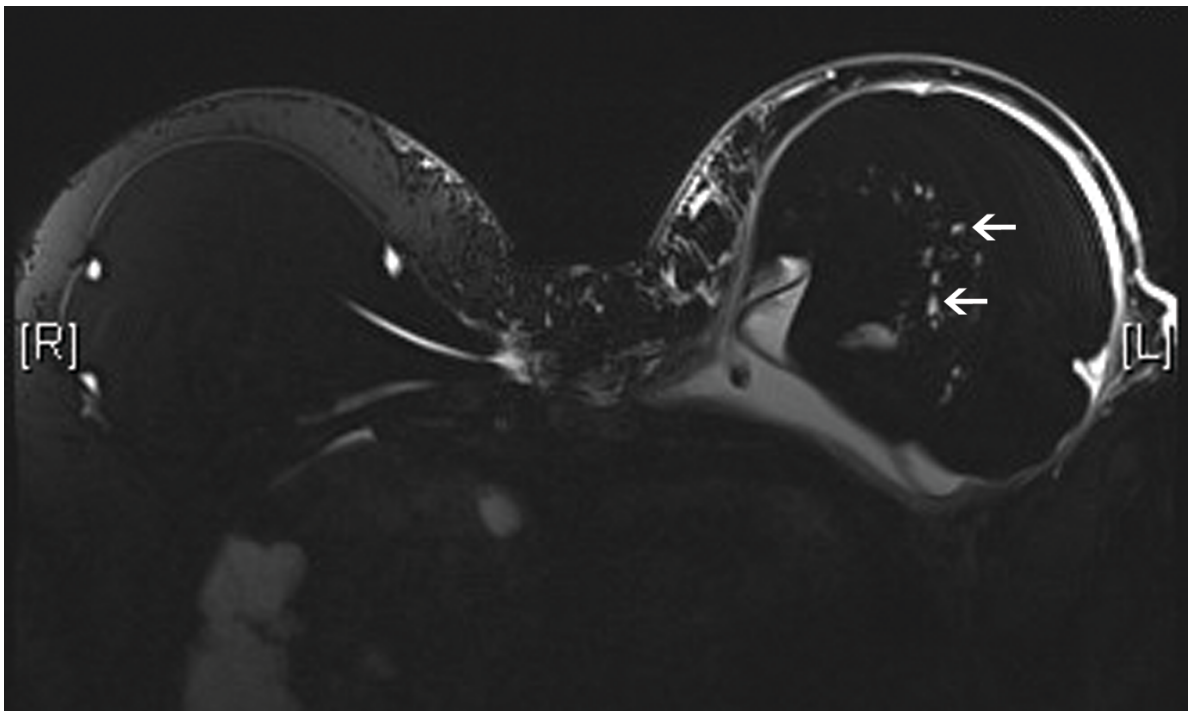


Figure 2-3 Magnetic resonance imaging showing the breach of the envelope at the deep aspect of the implant. Multiple areas of water signal content are noted within the silicone in the implant

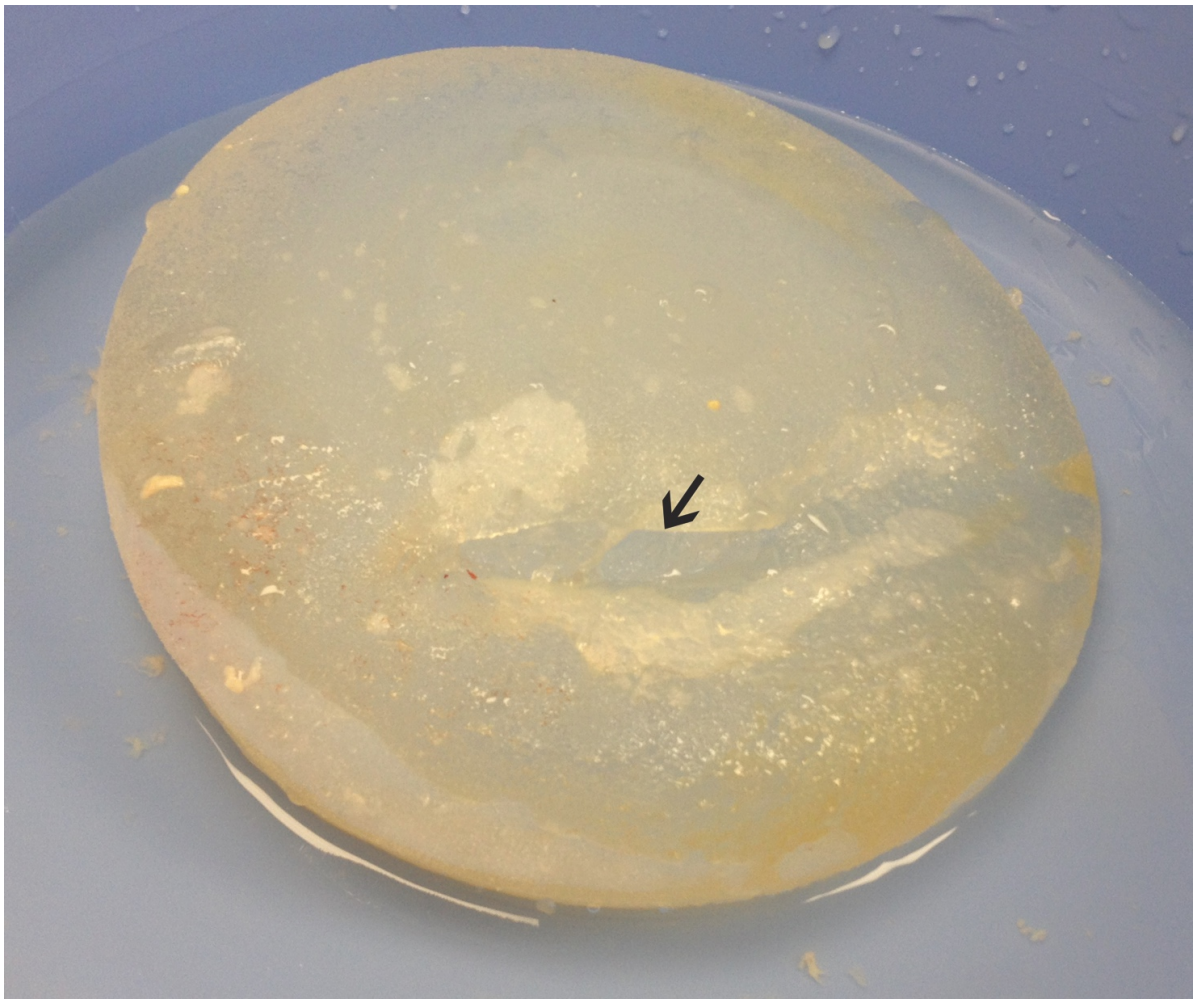


Figure 2-4 Arrow indicating 5-cm rupture of the deep surface of the implant at the shell patch juncture

2.3 Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

2.3.1 History of Silicone Breast Implants

Silicone-gel filled breast implants were first inserted in 1962, and have seen undergone changes in their composition and characteristics. (Cronin, 1964) The shells of early implants were composed of dimethylsiloxane, which were permeable to lower molecular weight oils within the gel, they were able to diffuse through the envelope into the surrounding breast and other tissue, including axillary lymph nodes, forming multiple benign granulomas. There were high rates of capsular contractures with these early implants.

In 1983, a layer of diphenyl siloxane was incorporated in the shell wall, allowing the gel to become more cohesive, which almost completely resisted diffusion. Rates of capsular contracture were reduced, but not eradicated. In 1987, it was noted that a particular brand of since discontinued polyurethane-sponge coated implants were apparently more resistant to capsular contracture, to reproduce this, texturing of the shell surface was introduced (Brody et al., 2015).

One of the major suppliers of implants, Allergan (Allergan Inc., Calif.) employs a ‘salt elution’ process. The completed shell is dipped into liquid silicone, coated with salt crystals, dipped again, and cured. The outer layer is then abraded by hand to expose the salt, which is then rinsed away. The resultant microscopic pits in the surface allow the ingrowth of tissue for attachment and rotational stability (Figure 2-5). Mentor Corp. uses a stamping technique, producing thick, irregular pillars, a mirror image of the pits on the surface of polyurethane implants (Figure 2-6) (Brody et al., 2015).

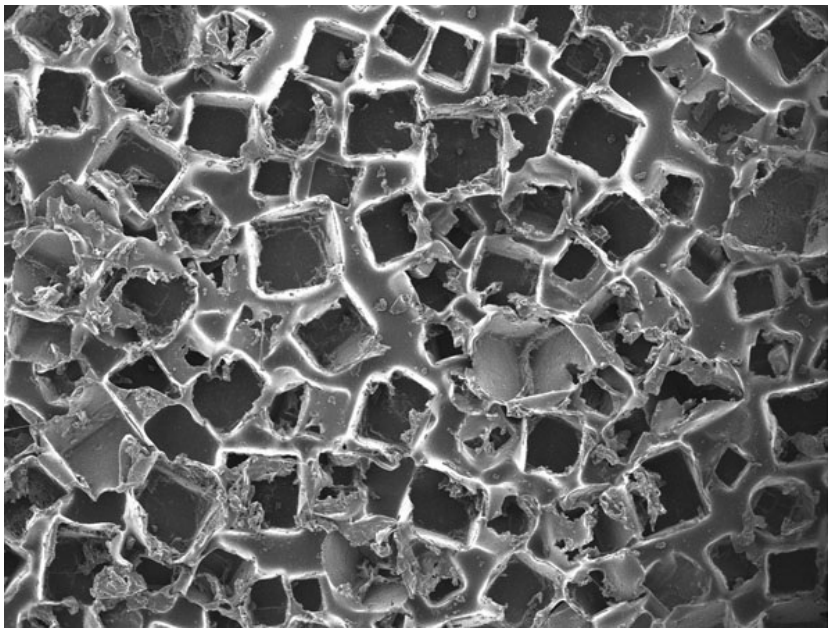


Figure 2-5 Electron microscopic photograph of Allergan textured shell surface (Brody et al., 2015)

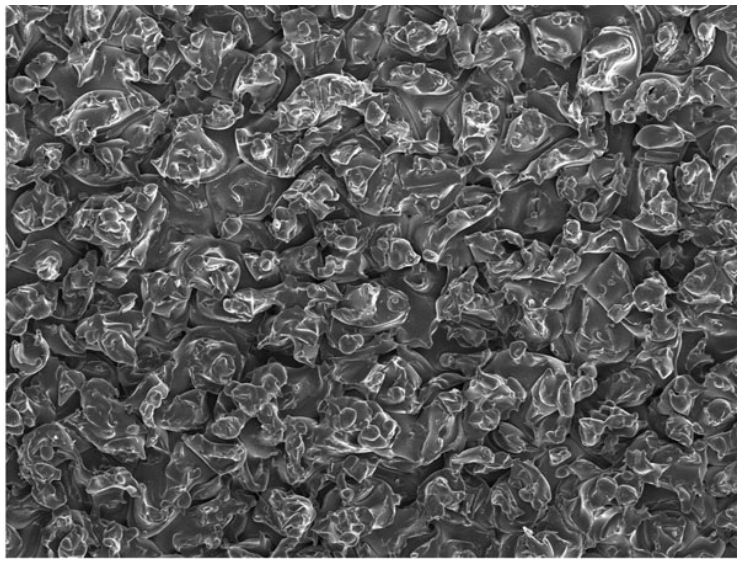


Figure 2-6 Electron microscopic micrograph of Mentor textured shell surface (Brody et al., 2015)

2.3.2 BIA-ALCL

BIA-ALCL is a rare disease; making up only two percent of all newly diagnosed non-Hodgkin's lymphomas worldwide. Despite that, multiple cases of BIA-ALCL developing next to breast implants have been reported (Kim et al., 2011, Brody et al., 2015). According to the World Health Organisation, it can be classified into two types: the systemic type, affecting lymph nodes and extranodal sites (causing systemic symptoms), and the cutaneous types (causing skin lesions) (Taylor et al., 2012). When a woman presents with a seroma or mass >6 months after insertion of a breast implant, the possibility of BIA-ALCL is of great concern. There has been a great deal of focus on BIA-ALCL more recently, but no work looking at possible links with previous immune reactions. It may be that understanding the broad areas of immune reactions to silicone gel and to late seromas in those without BIA-ALCL will be helpful in expanding the understanding of the disease itself.

2.4 Discussion

This patient developed a late seroma in a reconstructed breast after rupture of a silicone breast implant. Silicone has long been thought to be an inert material, which can be safely implanted in the human body. However, in the 1970s and 1980s, there was significant focus on the possibility of severe immune reactions to silicone gel. Ojo-Amaize et al found that 25% of women with silicone breast implants who were experiencing symptoms, such as muscle weakness and chronic fatigue, developed abnormal T-cell responses to silicone (Ojo-Amaize et al., 1994).

Narini et al found, in animal models, that injection of silicone gel induced an antigen-specific lymphocyte-mediated response in the animal, thereby causing

a delayed hypersensitivity (Narini et al., 1995). Dargan et al reported a delayed hypersensitivity reaction to a textured silicone implant within weeks of insertion, in a woman who had undergone removal of a prosthesis three years earlier, after wound dehiscence. Capsule biopsies demonstrated a large lymphoid cell reaction, consistent with a delayed type hypersensitivity reaction (Dargan et al., 2012). It is this hypersensitivity reaction that can lead to the release of inflammatory mediators like histamine and prostaglandins, causing the formation of seroma.

Late periprosthetic seroma is rare, with one series of 47,028 patients reporting an incidence of 0.13% of seroma formation occurring ≥1 year after implantation (Bengtson et al., 2011).

Ruptured breast implants can commonly cause a change in the breast shape, lumpiness, localised skin redness, tenderness, and sensitivity. Clinical examination has a reported 30% sensitivity of detecting a ruptured breast implant, whereas magnetic resonance imaging has the highest sensitivity at 90% (Institute of Medicine, 1999, Mallon et al., 2013).

There is only one other reported case of rash arising from a ruptured breast implant; however, this was involving rupture of Poly Implant Prothèse implants (Poly Implant Prothèse, France), whose silicone did not meet appropriate standards (Mallon et al., 2013).

2.5 Conclusion

I have reported on an uncommon presentation of breast implant rupture, with a skin rash and seroma forming two years after insertion of the implant in an obese patient. Although silicone has been thought to be inert and safe for

implantation into the human body, several studies have shown an immune response to silicone in a proportion of patients, even with intact implants. Careful evaluation of an obese patient presenting with a seroma is needed, due to the higher seroma rate in obese patients, and given the growing concern of BIA-ALCL, this must also be considered when surgeons are confronted with such a problem.

3 REVERSE ABDOMINOPLASTY, A VIABLE OPTION FOR BREAST RECONSTRUCTION

The work in this chapter was presented as a poster at Plastic Surgery, The Meeting 2016, Los Angeles, USA.

3.1 Introduction

The reverse abdominoplasty was first described in the 1970's, and since then, it has been described for thoracic wall defects, upper abdominal wall contouring, and augmentation mammaplasty. (Rebello and Franco, 1977, Baroudi et al., 1979, Halbesma and van der Lei, 2008) It has received little attention in the literature, it can however be a useful method of breast reconstruction in a select group of patients, such as those who are obese. We present a series of three patients who underwent post-mastectomy breast reconstruction with the reverse abdominoplasty flap after being found unsuitable for other methods of breast reconstruction.

3.2 Technique

3.2.1 Stage One

- Incisions are made above the costal margin (Figure 3-1), either at the level of an existing mastectomy scar or at the inferior limit of radiation therapy damaged skin of the chest wall. The incisions can be varied between the right and left side of the chest wall, depending on the pattern of existing scarring. The skin over the sternum should be preserved, with the aim of not breaching the attachment to the sternum, that results in the final 'cleavage' area.
- Laterally, the incisions should curve downwards to form a slight inverse 'U' shape for the whole flap. These near-vertical parts of the incision

should be in the mid-lateral line and should extend no further than the level of the umbilicus.

- The skin and subcutaneous fat are dissected away from the underlying fascia of the lower chest and abdominal wall, the same plane as in a standard abdominoplasty.
- The umbilicus is isolated as per a standard abdominoplasty.
- The extend of mobilisation can be varied depending on the distribution of excess skin required for import to the breast area. In the dissection, the natural inframammary fold is completely obliterated.
- The flap of skin and fat is mobilised superiorly, and the advancement is secured by 'gathering' sutures laterally (as per a rotation flap). A sub-pectoral pocket is dissected for each side and tissue expanders are placed. The wounds are closed with appropriate drainage.
- Note that there will be no inframammary fold at this stage

3.2.2 Stage Two

- The scar lines that were closed over the tissue expanders in Stage One will be re-opened at this stage.
- The tissue expanders are removed.
- Inframammary folds are formed by using deep permanent sutures anchoring the dermis of the skin flaps to the deep fascia, or even periosteum of the ribs.
- Definitive implants are placed.
- The wounds are closed over drains.

3.2.3 Stage Three

- Minor standing cone deformities or inframammary fold sutures can be

revised three to four months later if required.

3.3 Methods

Two patients underwent breast reconstruction with reverse abdominoplasty (Figure 3-1), and complication and Breast-Q data were obtained prospectively.

3.3.1 Patient 1

Patient 1 is a 55-year-old lady with a BMI of 48.30, who underwent two stage bilateral breast reconstruction with reverse abdominoplasty and insertion of tissue expanders.

3.3.2 Patient 2

Patient 2 is a 49-year-old lady with a BMI of 38.40, who underwent two stage bilateral breast reconstruction with reverse abdominoplasty and insertion of tissue expanders.

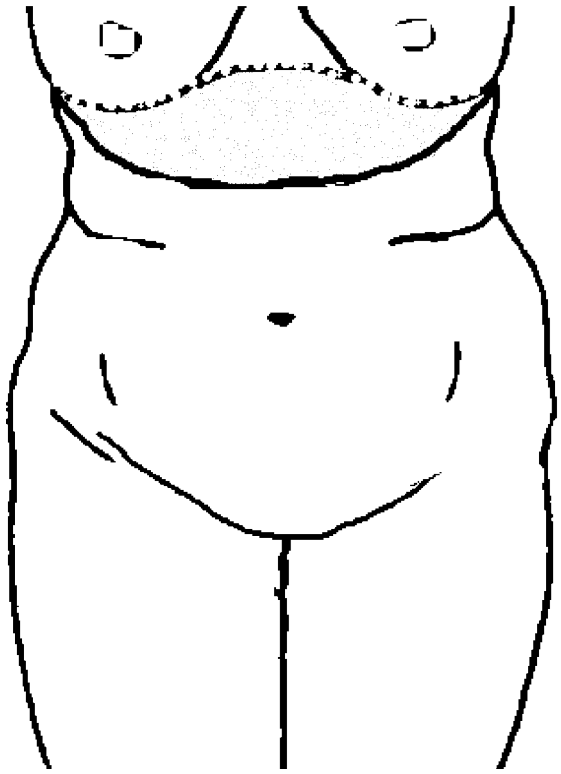


Figure 3-1 Schematic drawing of the reverse abdominoplasty. The dotted line represents the preoperative marking of the line of incision, the grey area represents the grey area planned to be resected.

3.4 Results

Patients 1 did not experience any post-operative complications, and Patient 2 experience minor wound healing problems. Both patients were satisfied with their outcomes, everyone having significant improvements in the Breast-Q scores across various domains. Their Breast-Q scores were also compared with those of patients who underwent conventional breast reconstruction or breast conserving surgery at our institution (Howes et al., 2016).

3.4.1 Patient 1 Results

Intra-operative photos from Patient one demonstrate the dissected reverse abdominoplasty flap (Figure 3-2), and also the flap being pulled up to cover the bilateral mastectomy defects (Figure 3-3).

Sequential postoperative photos (Figure 3-4) demonstrate Breast-Q scores at each time point, with a comparison to mean scores from women who underwent conventional breast reconstruction at our institution.

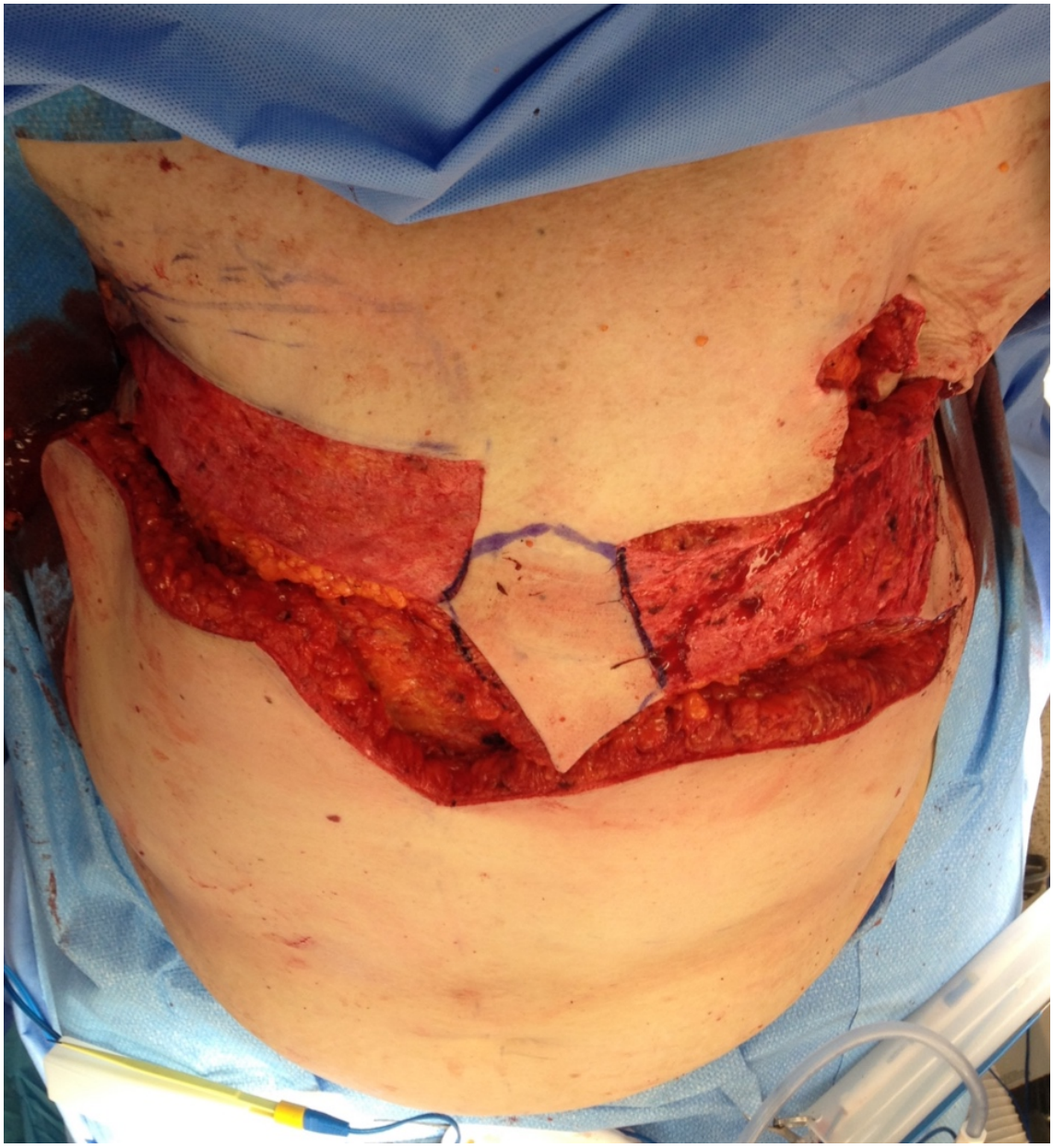


Figure 3-2 Dissected reverse abdominoplasty flap

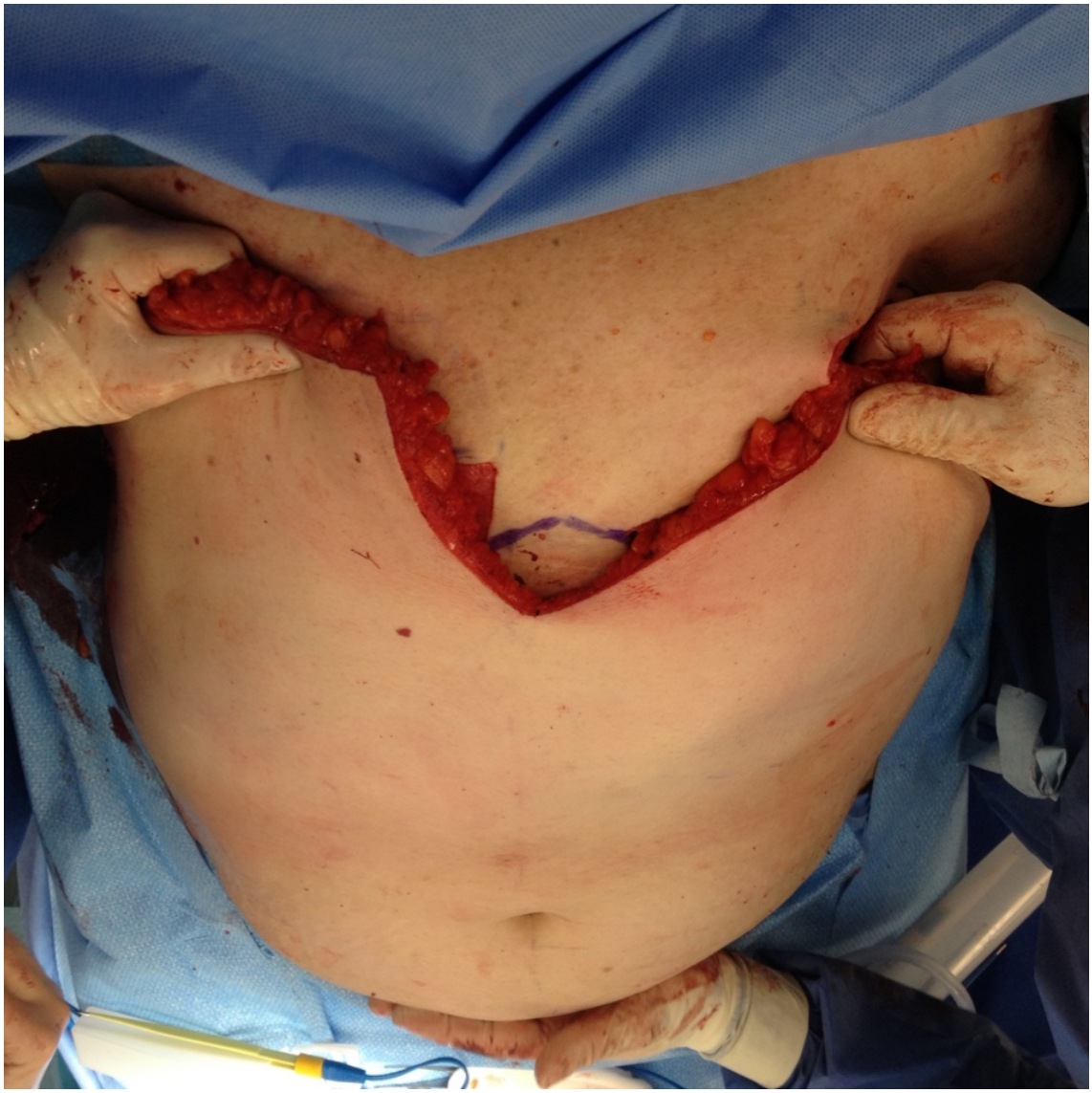


Figure 3-3 Reverse abdominoplasty flap pulled up to cover bilateral mastectomy defect

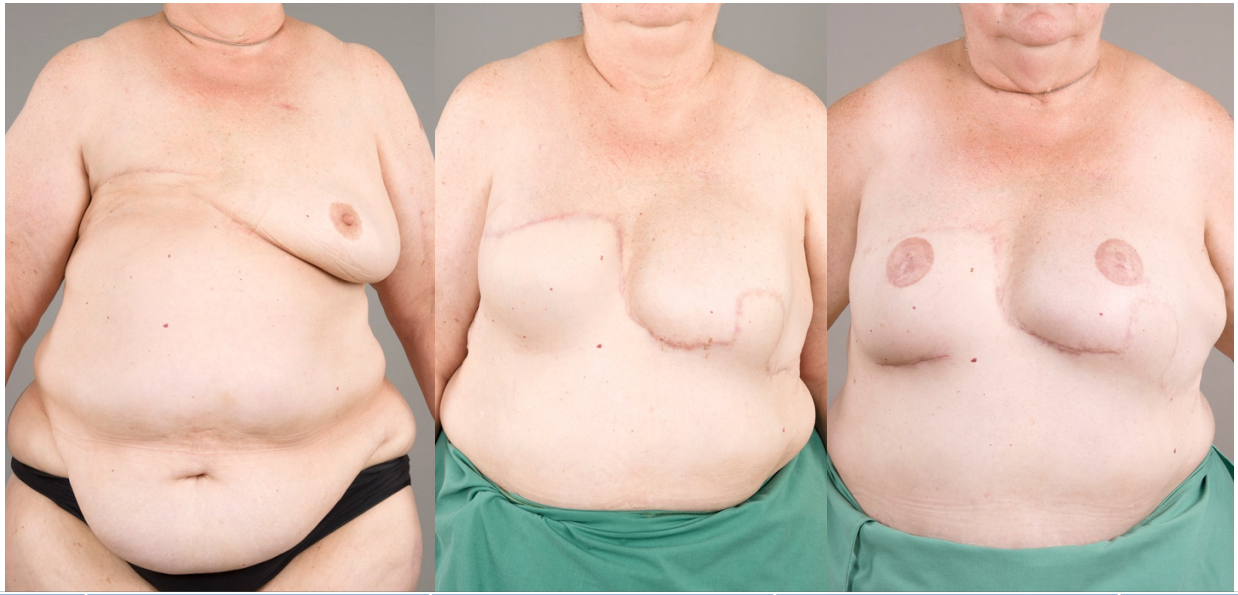


Figure 3-4 Post-operative photos of Patient 1 and corresponding Breast-Q scores

Breast-Q Domains (Out of 100)	Pre-Operative	10 months post-operative	26 months post-operative	Mean score post conventional total recon
Satisfaction with breasts	43	91	100	**78**
Psychosocial Well-Being	46	32	100	**81**
Physical Well-Being	91	100	91	**80**
Sexual Well-Being	0	N/A	N/A	**66**

3.4.2 Patient 2 Results

Sequential postoperative photos (Figure 3-5) demonstrate Breast-Q scores at each time point, with a comparison to mean scores from women who underwent conventional breast reconstruction at our institution.

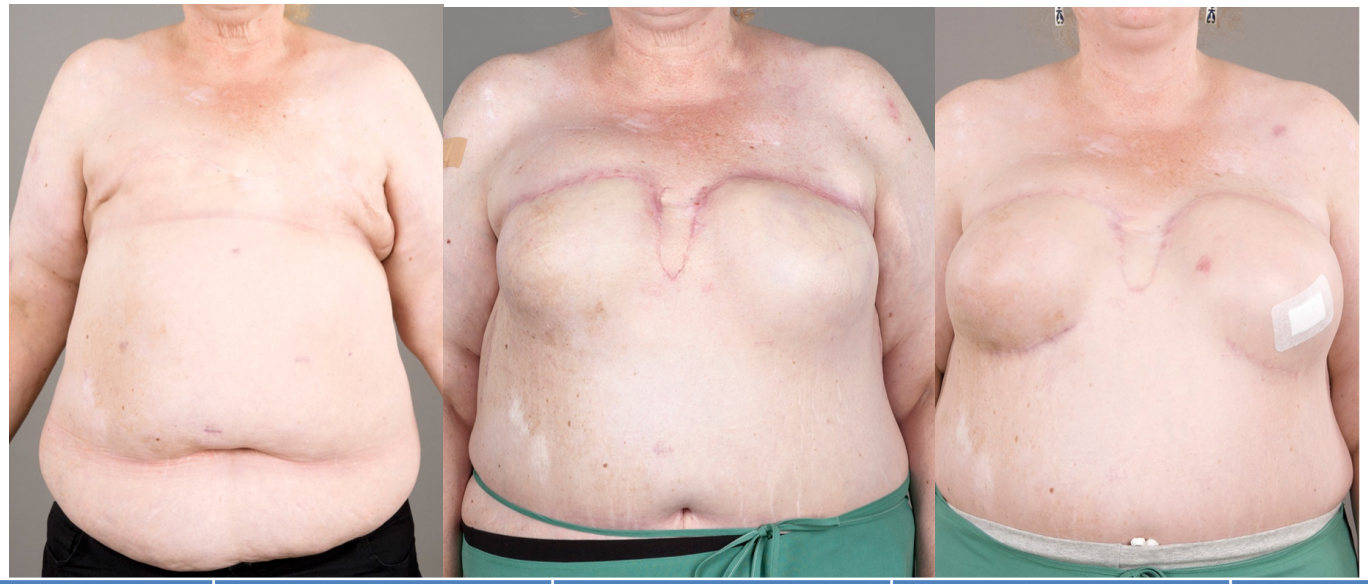


Figure 3-5 Post-operative photos of Patient 2 and corresponding Breast-Q scores

Breast-Q Domains (Out of 100)	Pre-Operative	1 month post-operative	9 months post-operative	Mean score post conventional total recon
Satisfaction with Breasts	0	76	78	**78**
Psychosocial Well-Being	14	58	53	**81**
Physical Well-Being	43	68	50	**80**
Sexual Well-Being	0	46	45	**66**

3.5 Conclusion

Reverse abdominoplasty is a safe and satisfactory option for breast reconstruction. Breast-Q scores for reverse abdominoplasty patients were comparable with those of women who underwent conventional breast reconstruction or breast conserving surgery. Reverse abdominoplasty can thus be considered when other options for breast reconstruction are unavailable, especially in the obese patient group.

4 QUALITATIVE STUDY OF OBESITY IN BREAST RECONSTRUCTION

4.1 Introduction

The diagnosis of breast cancer has a great psychosocial impact on women, threatening their very lives, as well as their self-image, and up to a quarter of women suffer significant psychological distress following the diagnosis of breast cancer (Glanz and Lerman, 1992). In this study, we aimed to explore the experiences and perspectives of obese women in relation to their cancer diagnosis, breast reconstruction journey, and perspectives into obesity.

4.2 Patients and Methods

Five patients with a BMI of more than 30 who had undergone breast reconstruction were identified from the breast reconstruction database of the Flinders Breast Reconstruction service, which is a prospectively maintained Access (Microsoft, Redmond, WA, USA) database including all patients attending the Breast Reconstruction Service at Flinders Medical Centre, Adelaide, South Australia.

They were contacted via phone call to explain the study and to seek their consent in participating in the study. A participant information sheet and consent form (Appendix 3) were then mailed to them.

Interviews were conducted in a one on one, semi-structured fashion, in a private interview room with the principal investigator. An audio recording of the interview was also obtained at the same time, which was transcribed verbatim at a later time. The transcripts were then analysed for any common themes, as well as differences in opinions amongst the different participants.

4.2.1 Participant Profiles

4.2.1.1 Participant 1

Participant 1 is a 53-year-old woman with a BMI of 34 who had previously undergone a delayed reconstruction of a unilateral mastectomy defect with a free transverse rectus abdominis myocutaneous (TRAM) flap.

4.2.1.2 Participant 2

Participant 2 is a 54-year-old woman with a BMI of 38.4 who had previously undergone a delayed reconstruction of bilateral mastectomy defects with reverse abdominoplasty and implant reconstruction with prior insertion of tissue expanders. Her reconstruction was described in Chapter 3 (patient 2).

4.2.1.3 Participant 3

Participant 3 is a 73-year-old woman with a BMI of 33.3 who had previously undergone a delayed reconstruction of bilateral mastectomy defects with bilateral extended latissimus dorsi flaps.

4.2.1.4 Participant 4

Participant 4 is a 52-year-old woman with a BMI of 33.0 who had previously undergone a delayed reconstruction of bilateral mastectomy defects with autologous fat grafting and implant reconstruction with prior insertion of tissue expanders.

4.2.1.5 Participant 5

Participant 5 is a 56-year-old woman with a BMI of 46.3 who had previously undergone a delayed implant reconstruction of a unilateral mastectomy defect with prior insertion of a tissue expander, as well as a contralateral breast reduction.

4.2.2 Data Collection and Storage

Audio recordings of interviews and transcripts were de-identified and stored on a password protected hospital computer server.

4.2.3 Ethics Approval

Ethics approval for this study was obtained from the Southern Adelaide Human Research Ethics Committee (approval number 474.15).

4.2.4 Analysis

A thematic analysis of the data was carried out (Joffe, 2011). Transcripts of the interviews were read several times to ensure familiarity of the data. Data were then analysed to identify predetermined themes that come up during the interviews that match with the interview topics. Meaningful quotes were extracted and organised according to the different themes. Constant comparison of the quotes was carried out in line with grounded theory. We were then able to identify similarities and differences in opinions within each theme (Tesch, 1990).

4.3 Findings

4.3.1 Emotional Experience around Cancer Diagnosis

The diagnosis of cancer is a potentially life-threatening diagnosis and has a tremendous psychosocial impact on a woman's life. One participant summed up her initial reaction to her cancer diagnosis:

"I immediately went into a sense of panic, and thought, what do I do?"

"When I was first told I had cancer, I asked three things, the first thing was am I going to die? The second thing was am I going to lose my hair? And the third thing was, will I still have my breast, and I thought that when I woke up without a

breast, I would be mortified, but I found that I was actually glad that the cancer had gone."

The cancer journey is an arduous one and there is often a sense of relief at the end of the journey amongst cancer survivors. Being diagnosed with a second cancer can therefore often deal a bigger blow compared with the initial diagnosis. One participant who was diagnosed with two separate breast cancers describes her experience after receiving the second diagnosis:

"My second cancer gutted me, because I had a fear that, okay, this is the second cancer in two years, like, I had a fear that it had gone right through my body, and that, you know, that gave me great sense of trauma, and I fell into depression going through that second one. I still try to be positive myself, but there was just all these, in my mind, that, oh my god, it's back. I'm probably, you know, you just sort of think I'm probably, I'm probably, yeah, it was, and I just didn't see it coming."

Participants described the support from their friends and family, both emotionally and practically, as being very important in helping them in their breast cancer journey. Another important source of support was friends or family who had suffered from breast cancer themselves as they could empathise with what the participants were going through.

"I have got a best friend, who has gone through breast cancer herself, since I've had my breast cancer. She's just had another scare yesterday, so, yeah, we supported each other. And I had a good boss at the time, he was very supportive as well."

There are also many support groups in the community providing support to

women going through breast cancer, they provide an important support network with people who are going through the journey themselves or people who have already completed their journeys. They often provide important emotional support, as well as social support. This is however not for everyone:

“just got one or two friends that supported me, but I did join one of these groups, but I’m going to be quite honest, it wasn’t for me. I didn’t want to go there talking about my breasts, and people exposing their breasts, I don’t think some of these support groups do you any good I’m going to be honest, but not me any good anyway.”

Besides the personal psychological impact of the diagnosis, it also had an impact on their family, causing breakdown of relationships:

“my marriage broke up, my husband left me, after 28 years.”

“when I got diagnosed the second time, and had my boobs off and got fat, he left.”

Besides breakdown of personal relationships, participants also described breakdowns of their social networks. A possible reason could be friends not understanding what participants were going through and preferring to keep their distance.

“I’m not as active as I used to be, and in a social way I’ve lost some of my close friends through the process, because they just, I don’t know, they just stopped coming to see me, or they just stopped their interactions.”

Having gone through and survived the cancer diagnosis gives some women a new outlook on life, with a fresh set of priorities:

“I don’t worry so much now about materialistic things, it’s not about the best car, the best house, how much money you can make, it’s more about living each life, living each day, getting the most you can out of each day. Like loving your family, developing your relationships, and being kind, and helping people and giving back to everyone that has been great to me.”

“it’s made me not sweat the small stuff, I really appreciate life, you really, really appreciate life.”

However, the spectre of cancer is not far from their minds:

“You can never consider yourself completely cancer free, because you just don’t know. Anytime you get like a pain somewhere, or you don’t feel right, you think, ‘oh s**t’ could that be cancer? Could that be cancer? You just worry that you’ve got the cells.”

“The cancer never leaves you, there’s always a bloody reminder.”

“I’m more worried when I get sick now, a small little pain or if I’ve got a headache that’s lasted a couple of days or something, you think, oh, cancer.”

“as soon as you get an ache or a pain, you think cancer is back”

4.3.2 Physical Effects of Cancer Diagnosis

Besides the emotional effects the diagnosis of cancer can have on a woman, it also affects their physical well-being, with fatigue being a big factor:

“I still suffer from overwhelming fatigue, I don’t just get tired, I just get completely fatigued to the point even my eyelashes are just aching tired.”

“I’m struggling working full time, I get very fatigued, and that has impacted me a

bit on the exercise that I can do."

"it is hard, we went to Hawaii last year with the boys as a post cancer holiday. I found that I was struggling with certain things, I'm like, I'm not enjoying this because I'm struggling with energy, unfortunately."

Another physical effect women experience is the side effect of medications taken as an adjunct to their cancer treatment:

"that would be a side effect from the cancer that I didn't think about, that's not very pleasant, these bloody hot flushes."

4.3.3 Experiences with External Breast Prosthesis

A non-surgical option for women after undergoing mastectomy of restoring their breast mound is to be fitted with an external breast prosthesis, which is often made of silicone, and is worn under clothing to recreate a breast mound. Women with higher BMI's often have bigger breasts, and these women often require bigger breast prostheses, leading to them being heavier.

A common theme that emerged during the interviews is the discomfort experienced by the participants wearing external breast prostheses. Being bigger and heavier, they often cause discomfort during wear, especially during the hot summers in Australia:

"they made me very hot, they just made me really hot all the time"

"I did purchase one of those prosthesis things, but I couldn't wear it, I just couldn't wear it. It didn't feel comfortable, and yeah, I didn't like it."

"they are sort of plastic at the back, in hot weather, oh my god, the sweat, and it

was so uncomfortable, and I found it was a lot heavier than my normal breast was, and it was horrible to wear."

"they were heavy, they were hot, sweat, you know"

"they were very weighty, I actually got myself a set of the heavy ones, and then just, some foam ones that patients normally wear soon after surgery, so I had two sets, so, yep, you know, if I was going somewhere official, I would wear the heavy ones, or if I was going you know, just around the neighbourhood just for a walk or something I would just wear the foam ones, the foam ones tended to ride up, so yep, they weren't something that I could wear all the time."

"I was using a prosthesis, and it was so heavy. I'd come home from work and I'd take it off, and then because I was lop-sided, and I was wobbling down, you know, if I was walking down the corridor, I'd wobble, and then I realised it just wasn't worth it."

Another frequently brought up issue was the difficulty traveling with external breast prostheses:

"If I went away somewhere, I'd have to put them in a box, the boxes were too big, so that's two boxes, took up nearly half my luggage room. Very inconvenient, hated them."

"the prosthesis was so uncomfortable, it really was. Plus, I'd planned a holiday overseas with my friend and we wanted to go swimming, and I just couldn't be bothered. I tried swimming in one, and you had to have another prosthesis to put in, and they'd come out of your swimsuit, and it was embarrassing."

4.3.4 Emotional Experiences around Breast Cancer Surgery

Breast cancer surgery can be a disfiguring operation and causes high levels of anxiety and depression in women about to go through surgery to treat breast cancer. (Harcourt et al., 2003)

“I got very depressed afterwards, um, I mean I had silly questions that I asked my doctor that because I’d had a complete hysterectomy, and now I’ve got no breasts, does that mean I’m a transvestite, or some word to that?”

This also affected their self-esteem, which also affected their relationships with friends and family:

“I would pull away if he went to hug me or I would turn around or um, I would like, run to get into the bathroom and close the door, and if I was in the shower I would lock the door, so that he couldn’t come in, just all those little things, um, but his love for me didn’t change, it was my perception of his love for me.”

In one instance, having to have a mastectomy also brought back traumatic memories as a child:

“I was abused as a kid and one of the things I remember distinctly was how my father used to touch my breasts. So, in that respect there was good and bad in it.”

On the other hand, having a mastectomy offered some comfort that the cancer was being removed:

“I thought that when I woke up without a breast, I would be mortified, but I found that I was actually glad the cancer had gone”

4.3.5 Motivations for Breast Reconstruction

Breast reconstruction restores the breast mound following mastectomy for breast cancer and greatly improves quality of life in women undergoing surgery. (Atisha et al., 2015) A common theme that emerged in this study is that one of the main motivations for women pursuing breast reconstruction is to allow themselves to feel like a woman again:

“I just wanted for my own sense of self-worth, and just to feel feminine again, rather than a shark attack victim, because I just, I hated, I hated having a shower, I hated going in the bathroom, and I just had such a poor self-image of myself.”

“I just wanted to feel like a woman again, and symmetrical, and I thought about having the other breast off, considering it was such a, you know, mammograms don’t pick up everything unfortunately.”

“The main reason I did it was for my self-esteem, and to make me feel like a woman again.”

“even though I am over 50, I think I’m young enough still to, I wanted to feel good in my bones, you know.”

Another common reason for pursuing breast reconstruction was the desire to appear normal wearing clothes again:

“I wanted to fill out a top, you know, I wanted to be able to fill out a T-shirt, before I was really flat.”

“It was really hard to find confidence to wear nice clothes because of my, um, mastectomy on my right side had left me with just a slight mound that way, and

this one had left me with bit of a dip."

An important source of support for participants thinking about breast reconstruction were their close family and friends:

"I wonder if I'm a candidate for that, and my husband's very supportive of me, and he's just happy for me to be, stay as I was, or to you know, to whatever I wanted to, but my mother was very negative, and said 'What are you chasing that for? You know, you don't need it, you know, you're older now, you don't need to go through anything else, you know, I don't understand why you're following this up.' So, I said look, I just want to do it for me, I want to go have a chat to see if this is a possibility for me."

One of the participants did not initially think of undergoing breast reconstruction:

"I didn't think there was a need, I'm single, I don't have anyone in my life, and I just thought it was a waste of time."

She however changed her mind after wearing external breast prostheses for a while:

"I wasn't going to have it done, but I was using a prosthesis, and it was so heavy. I'd come home from work and I'd take it off, and then because I was lop-sided, and I was wobbling down, you know, if I was walking down the corridor, I'd wobble, and then I realised it just wasn't worth it."

"the prosthesis was so uncomfortable, it really was. Plus, I'd planned a holiday overseas with my friend and we wanted to go swimming, and I just couldn't be bothered. I tried swimming in one, and you have to have another prosthesis to put in, and they'd come out of your swimsuit, and it was embarrassing, not that

other women would care. I know that, but it was just getting all too hard. I didn't realise I was getting a bit depressed, and it was the surgeon, actually, who noticed that. Then I thought about it, and I thought, let's get it done."

4.3.6 Experiences around Obesity

In this section, we explored the participants' weight and their experiences around their obesity. In some participants, their weight gain was put down as a consequence of the medical treatment for their breast cancer:

"I put on a lot of weight with the steroids, with the chemo, that's where I really stacked the weight on, when I was having my second lot of chemo, the heaviest I was was 95, I wasn't even 95 when I was pregnant with my kids."

Besides breast cancer treatment, weight gain was also attributed to other medical interventions:

"I did put on a lot of weight when my husband and I went through IVF (in-vitro fertilisation) for several years, which was unsuccessful, and I don't know if it was medication, but I put on a lot of weight in that period, like I'm talking 20+ kilos, probably more."

"I have tried everything to lose the weight, I've tried dieting, I was quite active, I was going to my doctor to say why am I not losing the weight? I did have polycystic ovarian syndrome, and so they thought that that plus the IVF may have caused that issue and I was finding it difficult to lose the weight. It just didn't seem to matter what I'd tried, I couldn't shift it."

"I had a hysterectomy. Once I had that, they found that I couldn't take the HRT (hormone replacement therapy), I started to get problems, with my weight, but

my weight does sort of fluctuate."

Some participants describe the impact obesity has on their physical health:

"I found that I couldn't play softball and sport anymore, but I was still walking my dog, you know, going down to the beach, that sort of thing."

"It's now causing problems, I can't walk properly, I have bad feet, and I struggle to walk."

Their body weight has also affected their personal and inter-personal lives:

"That is very embarrassing, that is the personal side, you can't get anything to fit you, you don't want to mix with people, um, yeah, weight has always caused me a problem."

"I think it contributed to my marriage breaking down."

"Only a sense of embarrassment, in you know, sexual embarrassment."

"I may be a little more reclusive than I used to be, but I think that has more to do with the weight than with the cancer."

One participant had especially strong views about the term 'obesity' and the implications surrounding it:

"I hate the word obese. I hate it and I loathe it, and when I'm called obese, which on their paper scale I am, I really get worked up."

"it's as if I am doing something wrong, I think people think you're sat there eating."

Another theme that emerged was while dealing with a diagnosis of cancer, their

body weight often becomes the last thing on their mind:

“since I got breast cancer, my weight just got put to the back of my mind, that was the last thing I cared about, and it slowly has got more and more, and I am the biggest I have ever been now.”

“my weight has just been put on hold, I just couldn’t be bothered with it.”

4.3.7 Experiences post Breast Reconstruction

The feedback from participants after their breast reconstruction was largely positive, and when asked if they would go through everything again, everyone replied in the affirmative:

“Far exceeded them, far exceeded them. You know I just can’t believe that the surgeon and the nurse have been able to achieve, they’re absolute angels, I love them.”

“Now that I am looking back, I’d still do it again. I’d still do it again, even though I’m, for me I’m forewarned.”

“it was a great procedure, horrible procedure, a long procedure.”

“I can actually walk around the house without a bra on, and a T-shirt, alright, you can see a little bit that it’s not quite perfect, but at least I can do that, where before with the prosthesis, you couldn’t do that. In the whole, I’m happy.”

“Oh yes, definitely, especially if I get the same team that I had before, with the nurse who was my saviour, every time I’d come in for, you know, being pumped up with the expansion, or whatever, she was wonderful to talk to, and the surgeon was fantastic. If I had to go through breast cancer again, they’re the

team that I would want."

4.4 Discussion

Some of the responses in this study illustrated the impact the diagnosis of breast cancer had on the lives of the participants, causing a certain amount of psychological distress, anxiety and uncertainty. It also caused the breakdown of personal relationships in some cases.

Several areas of impact have been identified in the literature, including physical, emotional, lifestyle, sexuality, as well as family and social supports (Ashing-Giwa et al., 2004, Fobair et al., 2006, Thewes et al., 2004). There are no studies discussing the impact of external breast prostheses on obese women, only one that briefly discusses women coping with external breast prostheses (Landmark and Wahl, 2002).

Biographical disruption, a concept first described by Bury in 1982, argues that chronic illness disrupts normality and starts a process of re-evaluating expectations for self, daily life, and future hopes and plans (Bury, 1982). In this study, the women have certainly described their lives being disrupted by the diagnosis of cancer, and their lives do not return to normal despite completing their breast cancer journey. This is evident by constant thoughts of the cancer has recurred whenever they experience any physical symptoms like aches and pains, as well as permanent changes to personal relationships in some cases (Trusson et al., 2016).

A study by Klassen et al. found that conditions affecting the breast, as well as breast surgery, affected women in six main areas: satisfaction with breasts; satisfaction with overall outcome; psychosocial well-being; sexual well-being;

physical well-being; and satisfaction with the process of care (Klassen et al., 2009). Most of the responses in this study certainly fit into one of these six areas.

Some common reasons for women electing to undergo breast reconstruction following mastectomy include: the ability to feel more balanced, and more feminine again; more freedom in the clothes they wear; not having to wear an external prosthesis anymore; and to have an endpoint to their cancer treatment (Handel et al., 1990, Jamison et al., 1978). These reasons were similarly echoed by the participants in this study, where they described external prostheses being hot and heavy, feeling unbalanced whenever they were not wearing their external prostheses, and being able to fill out their clothes.

Being overweight or obese can carry a certain stigma throughout a person's life, it can be present in school, work, or healthcare settings, as well as in traditional and social media. This can also be perpetuated by a person's own friends and family. It has been found that stigmatization of weight is a big source of stress for people who are overweight or obese, and this can work in a counter-productive way of causing more weight gain and increased risk of developing other medical conditions (Wu and Berry, 2018).

It has been shown that levels of physical activity decrease during breast cancer treatment, one study found that prior to beginning breast cancer treatment, 43% of breast cancer patients led an active lifestyle. However after beginning breast cancer treatment, that number dropped to 20% (Rhodes et al., 2001). Weight gain is a well-documented side effect of breast cancer treatment, along with that, women also suffer from low mood, fatigue, and poor body image (Pinto

and Maruyama, 1999). These effects have also been described by the participants in this study, particularly the overwhelming levels of fatigue described by our participants.

The participants in this study also describe being very self-conscious of their physical appearance after breast cancer treatment, such as not wanting to be seen by their partners or being afraid of being out in public areas such as the beach or swimming pools. This has also been found in the literature, with a significant proportion of women being treated for breast cancer becoming embarrassed to show their bodies or scars, and feeling uncomfortable with changes to their physical appearance for up to two years following diagnosis (Schain et al., 1994, Schag et al., 1993).

During this study, participants mentioned that during the course of breast cancer treatment, body weight became the last thing on their mind. However, it has been found that gentle to moderate levels of physical activity imparted great benefits, such as improving mood and levels of energy (Whitehead and Lavelle, 2009). This will be beneficial when counselling patients during treatment in the future. It has been found that strategies can be implemented to improve participation in activity programs amongst breast cancer patients: having an instructor that had knowledge in the area of cancer and its treatment, exercising in a private setting with other breast cancer survivors, and utilising a holistic approach that included nutritional information and support (Rogers et al., 2004).

As this study was designed as a pilot study, an arbitrary number of five participants was decided upon. This is one of the limitations of this study, having small sample size of only five women, which meant data saturation was

not reached, causing some views to potentially not be represented in this study. A future study can be designed to include a larger sample size of participants until data saturation is reached. A selection bias could also have occurred if only women who had a positive experience were willing to participate in the study. The participants in this study were all Caucasian Australian, and women from different ethnic backgrounds might not share the same viewpoints as the women in our study.

4.5 Conclusion

Although this was a small study, several common themes emerged from the data. There were common views on their experiences with external breast prostheses, physical effects of breast cancer treatment, as well as the overwhelmingly positive experiences with breast reconstruction. This will allow medical practitioners to have better insight into the experiences of obese patients undergoing treatment for breast cancer and their thoughts when thinking about breast reconstruction. This knowledge will allow us to better empathise with patients and counsel them about factors important to them, in order to provide better care to our patients.

5 IMPACT OF OBESITY ON QUALITY OF LIFE AFTER BREAST RECONSTRUCTION

A version of this chapter has been published in the Annals of Plastic Surgery, and appended in Appendix 4.

5.1 Introduction

In this study, we aimed to establish the level of quality of life of obese women before and after breast reconstruction, compared with non-obese women, as well as the relationship, if any, to complications in the post-operative period.

5.2 Patients and Methods

This study was designed as a 'RetroPro' study, a retrospective case-controlled, cohort study of prospectively collected data, to compare non-obese and obese women who had undergone breast reconstruction at our institution.

Ethics approval was obtained for this study from the Southern Adelaide Clinical Human Research Ethics Committee (approval number 369.14). Data were stored on a password protected hospital server. The STROBE statement and checklist (Institute of Social and Preventative Medicine, University of Bern) were used in the design of this study and preparation of the results.

Participants who underwent breast reconstruction from January 1st 2009 to July 31st 2016 were identified from the Flinders Breast Reconstruction database and participants undergoing immediate or delayed breast reconstruction following mastectomy were included in the study. All participants who had died or developed cancer recurrence were excluded, as well as those who attended the clinic for correction of partial mastectomy defects and those who did not go forward with breast reconstruction after initial consultation.

5.2.1 Data Collection and Storage

The breast reconstruction database of the Flinders Breast Reconstruction Service is a prospectively maintained Access (Microsoft, Redmond, WA, USA) database including all participants attending the service for a consultation on breast reconstruction at Flinders Medical Centre, Adelaide, South Australia. It includes participant demographics, procedure type and complications, BMI, previous radiotherapy, diabetic status, and BREAST-Q scores. This database is registered with the Southern Adelaide Clinical Human Research Ethics Committee (approval number 354.13).

Data for this study were extracted from the database and compiled into an Excel (Microsoft, Redmond, WA, USA) spreadsheet. This included participant demographics, procedure type and complications, BMI, previous radiotherapy, diabetic status, smoking status, and Breast-Q scores.

5.2.2 BREAST-Q

Breast-Q domains collected included Satisfaction with Breasts, Satisfaction with Outcome, Psychosocial Well-Being, Physical Well-Being – Chest, and Sexual Well-Being. These domains were scored from 0 – 100, with a larger number indicating more satisfaction, or better quality of life. The domains are also meant to function independently from the other, so domains which were not completed were not scored and excluded from analysis. Breast-Q scores from pre-operative assessments and at 12-months post-operative were collected.

Change scores were calculated for each domain by calculating the difference between the post-operative score and the pre-operative score for individual participants. The greater the change score, the greater the improvement in quality of life for that domain.

5.2.3 Clavien-Dindo Classification

Complications were classified using the Clavien-Dindo classification (CDC) of surgical complications (Table 5-1), it is a simple and well validated classification of surgical complications, and allows an objective and reproducible approach for comprehensive surgical outcome assessment, which can help the evaluation and comparison of surgical outcomes among different surgeons, centres, and therapies (Dindo et al., 2004, Clavien et al., 2009). For the purposes of this study, CDC grades I and II were classified as minor complications, and CDC grades III and above were classified as major complications, this included minor wound healing problems that just required dressing changes, as well as seroma.

Table 5-1 Clavien-Dindo Classification of Surgical Complications	
Grade	**Definition**
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at bedside.
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
Grade III	Requiring surgical, endoscopic, or radiological intervention IIIa: Intervention not under general anaesthesia IIIb: Intervention under general anaesthesia
Grade IV	Life threatening complication (including CNS complications) requiring intensive care unit management. IVa: Single organ dysfunction (including dialysis) IVb: Multiorgan dysfunction
Grade V	Death of a patient

5.2.4 Statistical Analysis

Analysis of data was performed using IBM SPSS statistical software v23.0 (IBM Corp., North Castle, NY, USA). Descriptive statistics, including means and 95% confidence intervals were computed to compare the obese and non-obese groups. Categorical data were analysed with Chi-square tests or Fischer's exact test. Continuous data were analysed with *t*-tests. Boxplots were used to illustrate Breast-Q scores for each domain separated into obese and non-obese groups. The median score is demonstrated as a bar, and the box demonstrates the interquartile range. Outliers are represented by circles on the plot and demonstrate points that lie three interquartile ranges away from the interquartile range. A value of $p < 0.05$ was considered to be statistically significant for all statistical tests used in this study.

5.3 Results

Three hundred and thirty-six participants underwent breast reconstruction between January 1st 2009 to July 31st 2015. Two hundred and nineteen participants were classified as non-obese, 76 participants were classified as having class I obesity, 16 participants were classified as having class II obesity, and 13 participants were classified as having class III obesity. Twelve participants did not have BMI data available, and they were excluded from the study. For analysis, participants were divided into obese (BMI $\geq$ 30) vs. non-obese (BMI < 30), due to the small number of participants who were classified as having class II or III obesity. The mean BMI of the non-obese group was 24.73 (17.4 – 29.8), and the mean BMI of the obese group was 34.50 (30.0 – 52.9).

The demographic details of the participants are presented in Table 5-2. There

were no statistically significant differences in age, smoking history, radiation history, or diabetic status. There were no significant differences in timing of the reconstruction between the two groups. A significantly higher proportion of obese participants received autologous reconstructions (i.e. Latissimus dorsi flap or abdominally based free flap) compared with non-obese participants. There were no significant differences in the proportion of participants receiving implant-based and mixed reconstructions (i.e. combination of autologous and implant) between the two groups. There was also no significant difference in laterality of the procedure.

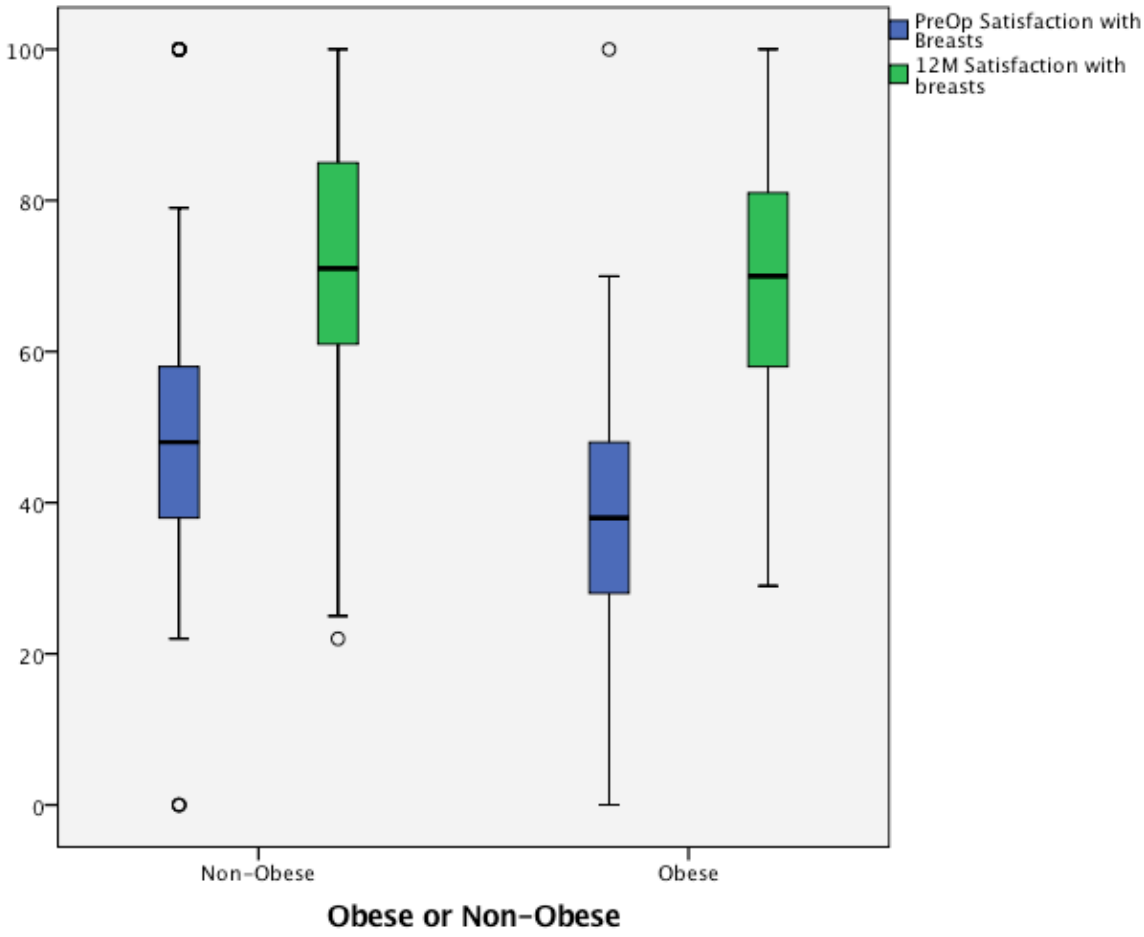
Table 5-2 Demographic Data			
	Non-Obese (n=219)	**Obese (n=105)**	**Significance of Difference Between Groups**
Median Age (range)	49 (19 – 79)	51 (26 – 73)	p = 0.08
Radiotherapy	71	35	p = 0.87
Diabetic	1	3	p = 0.07
Active or Reformed Smoker	72	43	p = 0.16
Timing of Recon			
Immediate	73	34	p = 0.87
Delayed	117	62	p = 0.34
Mixed	29	9	p = 0.22
Type of Recon			
Autologous	76	56	p < 0.01
Implant	88	32	p = 0.09
Mixed	55	17	p = 0.07

5.3.1 Breast-Q Scores

There were overall significant improvements in Breast-Q scores for all domains when pre-operative scores were compared to scores post reconstruction.

5.3.1.1 Satisfaction with Breasts

Figure 5-1 demonstrates the pre-operative and post-operative scores for the 'Satisfaction with Breasts' domain. 170 non-obese and 85 obese participants completed this domain pre-operatively, and 173 non-obese and 81 obese participants completed this domain post-operatively. Data shown in the table are mean scores with a 95% confidence interval (lower bound – upper bound).

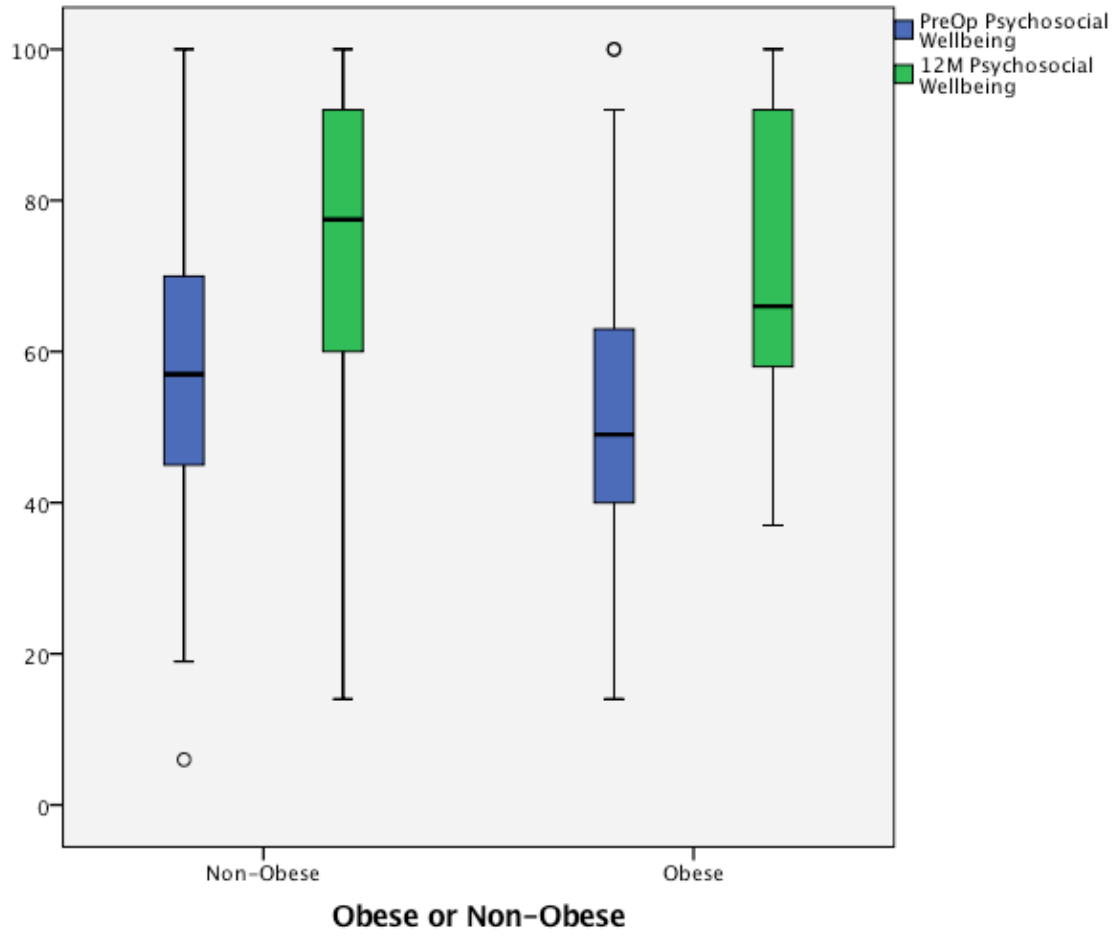


	Non-Obese	Obese	Sig. of difference between groups
Pre-Operative	48.14 (45.01 – 51.27)	40.18 (35.91 – 44.44)	p < 0.01
Post-Operative	72.01 (69.34 – 74.67)	69.14 (65.35 – 72.93)	p = 0.2

Figure 5-1 Pre-operative and post-operative scores for the 'Satisfaction with Breasts' domain

5.3.1.2 Psychosocial Well-Being

Figure 5-2 demonstrates the pre-operative and post-operative scores for the 'Psychosocial Well-Being' domain. 170 non-obese and 85 obese participants completed this domain pre-operatively, and 174 non-obese and 81 obese participants completed this domain post-operatively. Data shown in the table are mean scores with a 95% confidence interval (lower bound – upper bound).

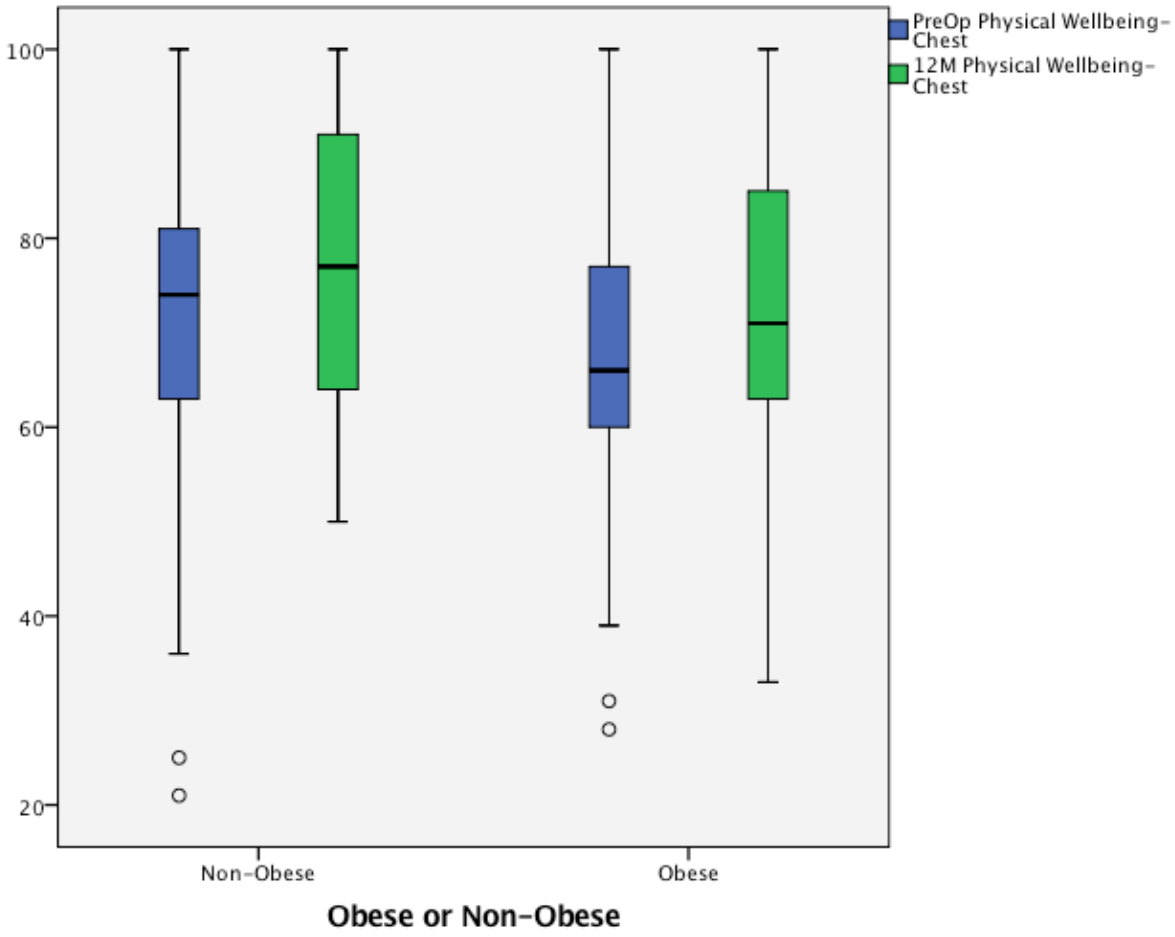


	Non-Obese	Obese	Sig. of difference between groups
Pre-Operative	57.10 (54.14 – 60.06)	51.62 (47.51 – 55.74)	$p < 0.05$
Post-Operative	75.67 (72.90 – 78.45)	71.38 (67.07 – 75.69)	$p = 0.09$

Figure 5-2 Pre-operative and post-operative scores for the 'Psychosocial Well-Being' domain

5.3.1.3 Physical Well-Being – Chest

Figure 5-3 demonstrates the pre-operative and post-operative scores for the 'Physical Well-Being – Chest' domain. 168 non-obese and 84 obese participants completed this domain pre-operatively, and 172 non-obese and 78 obese participants completed this domain post-operatively. Data shown in the table are mean scores with a 95% confidence interval (lower bound – upper bound).

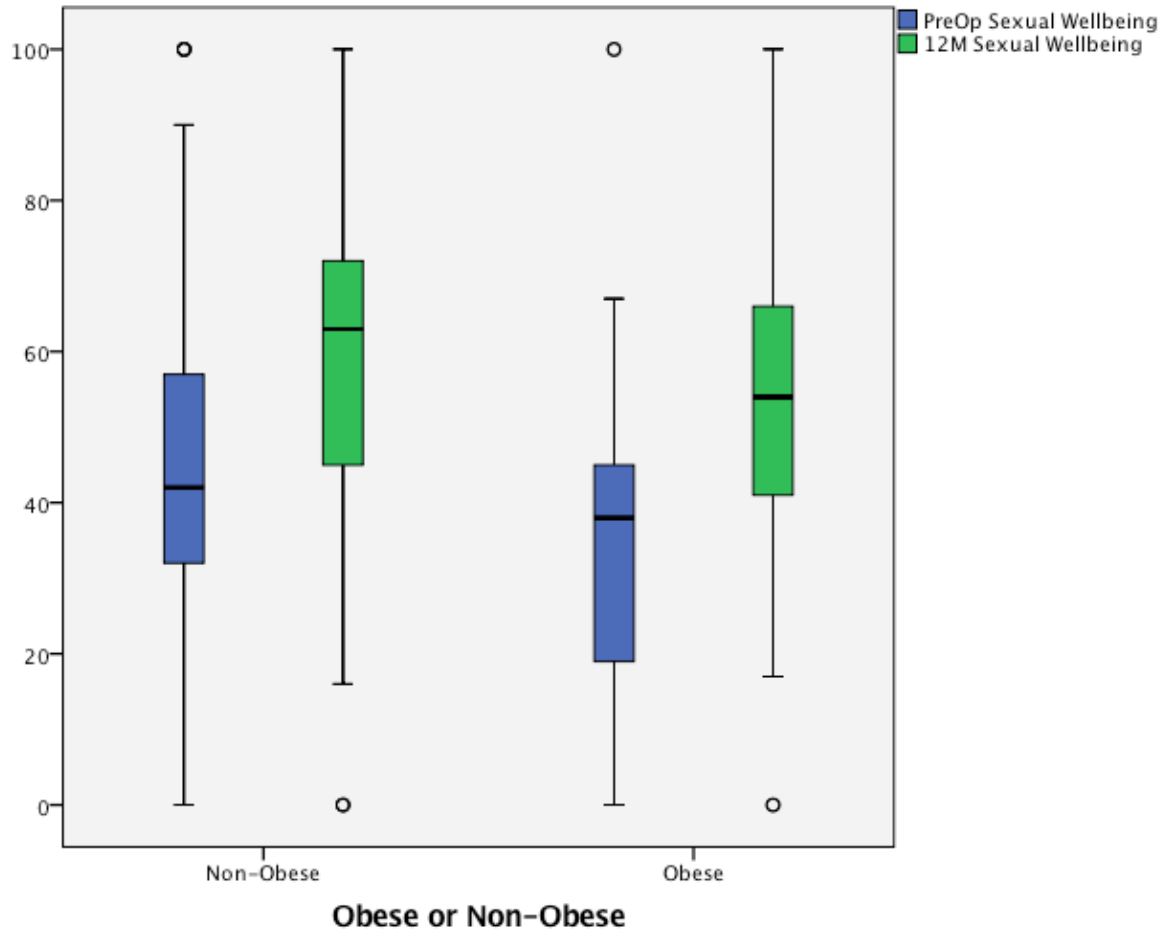


	Non-Obese	Obese	Sig. of difference between groups
Pre-Operative	72.15 (69.72 – 74.58)	68.48 (65.17 – 71.79)	p = 0.08
Post-Operative	77.09 (74.85 – 79.33)	75.37 (71.84 – 78.91)	p = 0.41

Figure 5-3 Pre-operative and post-operative scores for the 'Physical Well-Being - Chest' domain

5.3.1.4 Sexual Well-Being

Figure 5-4 demonstrates the pre-operative and post-operative scores for the 'Sexual Well-Being' domain. 165 non-obese and 77 obese participants completed this domain pre-operatively, and 160 non-obese and 68 obese participants completed this domain post-operatively. Data shown in the table are mean scores with a 95% confidence interval (lower bound – upper bound).



	Non-Obese	Obese	Sig. of difference between groups
Pre-Operative	40.72 (37.22 – 44.21)	34.30 (28.95 – 39.64)	$p < 0.05$
Post-Operative	59.84 (56.44 – 63.24)	54.76 (48.60 – 60.93)	$p = 0.13$

Figure 5-4 Pre-operative and post-operative scores for the 'Sexual Well-Being' domain

5.3.1.5 Change scores

Change scores were calculated for each domain by calculating the difference between the post-operative score and the pre-operative score for individual participants. The greater the change score, the greater the improvement in quality of life for that domain. Obese participants had a significantly higher mean change score for the domain ‘Satisfaction with Breasts’ when compared with non-obese participants ($p < 0.01$). There were no significant differences in the change scores for ‘Psychosocial Well-Being’, ‘Physical Well-Being – Chest’ and ‘Sexual Well-Being’ between the two groups (Table 5-3).

Table 5-3 Change scores in different domains between the two groups.
Change score was calculated by the difference between the post-op score and the pre-op score for individual participants. Mean change scores are shown with 95% confidence interval (lower-bound – upper-bound).

	Non-Obese	Obese	Significance of differences between groups
Satisfaction with Breasts	22.41 (18.58 – 26.25)	32.86 (27.39 – 38.33)	$p < 0.01$
Psychosocial Well-Being	16.18 (12.66 – 19.70)	20.59 (15.44 – 25.74)	$p = 0.16$
Physical Well-Being Chest	3.90 (1.52 – 6.27)	6.33 (2.10 – 10.55)	$p = 0.30$
Sexual Well-Being	16.25 (12.11 – 20.39)	21.29 (14.08 – 28.51)	$p = 0.21$

5.3.1.6 Satisfaction with Outcome

Scores for the domain ‘Satisfaction with Outcome’ were also calculated 12-months post mound reconstruction, and there were no significant differences in mean scores between the non-obese vs. obese groups (Table 5-4).

Table 5-4 Satisfaction with Outcome scores at 12 months post mound reconstruction

	Non-Obese n = 166	Obese n = 70	Sig. of difference between groups
Satisfaction with Outcome	82.19 (79.26 – 85.13)	79.84 (74.97 – 84.72)	p = 0.40

5.3.1.7 Complications and BREAST-Q Scores

Participants who experienced at least one complication were found to have significantly lower scores for the domain ‘Satisfaction with Outcome’ and ‘Sexual Well-Being’. There were no significant differences in scores for ‘Satisfaction with Breasts’, ‘Psychosocial Well-Being’, and ‘Physical Well-Being – Chest’ (**Table 5-5**).

Table 5-5 Mean Breast-Q scores of participants who experienced at least one complication					
	Satisfaction with Breasts	**Satisfaction with Outcome**	**Psychosocial Well-Being**	**Sexual Well-Being**	**Physical Well-Being Chest**
No Complications	71.3	84.2	75.8	60.3	77.1
At Least One Complication	70.6	78.6	73.1	54.6	75.7
Significance of Difference Between the Groups	$p = 0.71$	$p < 0.01$	$p = 0.19$	$p < 0.05$	$p = 0.34$

5.3.2 Complications

Overall, 149 (44.3%) participants experienced at least one complication within the 12 months following breast reconstruction. Obese participants had a significantly higher mean number of complications when compared to non-obese participants, 0.99 (CI 0.78 – 1.20) vs 0.60 (CI 0.48 – 0.72), $p < 0.01$.

The highest complication grade each participant attained was recorded and analysed (Table 5-6). There was a significantly higher proportion of non-obese participants with no complications when compared to obese participants. There was also a significantly higher proportion of obese participants who experienced minor complications when compared to non-obese participants. There were no significant differences in the proportions of obese and non-obese participants who experienced major complications.

Obese participants were found to have a higher rate of seroma when compared to non-obese participants, 31% versus 10% ($p < 0.001$).

When the participants were stratified according to their smoking status (Table 5-7), there was a significantly higher proportion of active or reformed smokers with major complications when compared to non-smokers. There were no significant differences in the proportions of active or reformed smokers and non-smokers who experienced minor or no complications. There was no significant difference in seroma rate between active or reformed smokers and non-smokers, 19% versus 14% ($p = 0.37$).

Table 5-6 Participants who experienced no complications, minor complications, or major complications by obesity status

	No Complications	Minor Complications	Major Complications
Non-Obese	132 (60.3%)	41 (18.7%)	46 (21.0%)
Obese	45 (42.9%)	34 (32.4%)	26 (24.8%)
Significance of difference between groups	$p < 0.05$	$p < 0.01$	$p = 0.45$

Table 5-7 Patients who experienced no complications, minor complications, or major complications by smoking status

	No Complications	Minor Complications	Major Complications
Non-Smoker	132 (60.8%)	49 (22.6%)	36 (16.6%)
Active or Reformed Smoker	55 (46.2%)	27 (22.7%)	37 (31.1%)
Significance of difference between groups	$p < 0.05$	$p = 0.98$	$p < 0.05$

5.4 Discussion

In summary, the key findings from this study were that obese participants undergoing either immediate or delayed breast reconstruction had a lower baseline quality of life in most of the analysed domains when compared to non-obese participants, and their quality of life improved post-operatively to a level which was similar to their non-obese counterparts, with no statistically significant difference between groups' scores at 12 months post mound reconstruction. Obese participants appeared to gain a larger quality of life benefit from breast reconstruction when compared to non-obese participants, due to the higher magnitude of change in their BREAST-Q scores. These findings are similar to those of Atisha et al. who also found that women with high BMI had a lower baseline satisfaction with breasts and yet a similar satisfaction with outcome to lower BMI women (Atisha et al., 2015). In contrast, it had previously been reported that obese women were less aesthetically satisfied with implant-based reconstruction, although they had similar levels of satisfaction with autologous methods of breast reconstruction to non-obese women (Atisha et al., 2008b).

This study found that a significantly higher proportion of obese participants underwent autologous breast reconstruction when compared with non-obese participants. This has been similarly reported in the literature, with obese participants more likely to undergo autologous reconstruction, particularly abdominal based flaps. In contrast, non-obese participants were more likely to undergo an implant-based reconstruction (Kulkarni et al., 2012). However, all BMI groups reported similar satisfaction with the surgical decision-making and surgical outcome.

This study found that a significantly higher proportion of obese patients underwent autologous breast reconstruction when compared with non-obese patients. This has been similarly reported in the literature, with obese patients more likely to undergo autologous reconstruction, particularly abdominal based flaps. In contrast, non-obese patients were more likely to undergo an implant-based reconstruction. However, all BMI groups reported similar satisfaction with the surgical decision-making and surgical outcome (Kulkarni et al., 2012).

This study found that there was a significantly higher proportion of non-obese participants who experienced no complications, and a significantly higher proportion of obese participants who experienced minor complications, but there was no significant difference in the proportion of participants who experienced major complications between the two groups. A meta-analysis of 14 studies, including 6043 participants, undergoing free flap breast reconstruction, reported similar findings. They found an almost three-fold increase in the number of complications in obese participants compared with non-obese participants. However, the majority of those complications were minor and did not require re-operations (Schaverien and McCulley, 2014). A large population-based analysis of 15,937 breast reconstructions by Fischer et al found that the incidence of wound complications (2.4% vs 5.3% vs 6.3% vs 10.4%, $p < 0.001$) and flap loss (1.0% vs 1.5% vs 3.8% vs 2.7%, $p < 0.001$) increased with the class of obesity. Obese participants were also found to experience a significantly higher rate of medical complications, such as pneumonia, pulmonary embolism, and urinary tract infection (1.2% vs 2.6% vs 2.3% vs 3.6%, $p < 0.001$), with increasing class of obesity (Fischer et al., 2013b). A few studies have reported higher rates of flap complications,

including delayed wound healing, and flap necrosis, in obese participants undergoing autologous breast reconstruction. Obese participants are also reported to experience higher rates of seroma formation, which is also reflected in our study (Fischer et al., 2013c, Chang et al., 2000b, Nelson et al., 2015, Seidenstuecker et al., 2011, Hanwright et al., 2013, Spear et al., 2007).

The finding of this study that active or reformed smokers experienced more major complications is in keeping with studies that found that smokers experience higher rates of complications, especially skin flap necrosis, infection, reconstructive failure, and perioperative complications, in both autologous and implant based reconstruction (Chang et al., 2000a, Goodwin et al., 2005).

It has been found that obese women were more likely to be offered mastectomy alone without reconstruction when compared with non-obese women. This was despite them having higher satisfaction with breast reconstruction and having similar satisfaction with breast conserving surgery (Doren et al., 2014). Some health providers have also placed a BMI limit on who can be offered breast reconstruction. For example, a woman must have a BMI of less than 35 to be able to undergo breast reconstruction in Queensland, Australia (Queensland Government, 2015).

The limitations of our study were the relatively small population size, which limited the ability to analyse sub-groups of BMI classes. Although there were high response rates to the Breast-Q questionnaires, we cannot account for the reasons for patients not completing the questionnaires or certain domains within the questionnaires, in particular the domain for ‘Sexual Well-Being’. This could potentially be a source of bias in this study (Eltahir et al., 2013). The

demographic data of patients who did not complete a single Breast-Q domain pre-operatively and post-operatively are compared in Table 5-8. There were no significant differences in age, obesity status, or smoking status between non-responders and responders pre and post operatively. Pre-operatively, there was a significantly higher proportion of patients who had undergone radiotherapy who were responders. In contrast, there was a significantly higher proportion of patients who had not undergone radiotherapy who were responders following surgery.

Table 5-8 Demographic data of non-responders			
	Pre-Operative		
	Non-Responders (n=69)	**Responders (n=255)**	**Significance of Difference Between Groups**
Age (Median)	50	50	p = 0.94
Obese	20	85	p = 0.49
Active or Reformed Smoker	25	94	p = 0.95
Radiotherapy	14	98	p < 0.01
	Post-Operative		
	Non-Responders (n=73)	**Responders (n=263)**	**Significance of Difference Between Groups**
Age (Median)	48	50	p = 0.77
Obese	24	81	p = 0.64
Active or Reformed Smoker	27	92	p = 0.75
Radiotherapy	32	80	P < 0.05

5.5 Conclusion

There is no doubt that breast reconstruction after mastectomy significantly improves a woman's quality of life. This study has shown that obese women get the same, if not greater, quality of life benefit from breast reconstruction, despite a higher rate of minor complications. Breast reconstruction in obese women appears to be worthwhile, although these participants need to be better informed and educated about the higher risk of minor complications. Health care policies which seek to exclude obese women from breast reconstruction should be questioned.

6 IMPACT OF BREAST WEIGHT ON QUALITY OF LIFE AFTER BREAST RECONSTRUCTION

6.1 Introduction

In chapter four, a common complaint expressed by the participants was the weight of the external breast prostheses they had to wear after mastectomy. External breast prostheses are designed to match the remaining breast in women who have had a unilateral mastectomy, therefore in women with bigger breasts, they need bigger, and naturally, heavier external breast prostheses to match their remaining breast. Similarly, in women who have undergone bilateral mastectomy, they are usually fitted with external breast prostheses closely matching the size of their resected breasts. Furthermore, women with a unilateral mastectomy who have heavy breasts pre-mastectomy are likely to have a greater subjective feeling of 'being lopsided' and having physical symptoms from this weight imbalance. In this study, we aimed to study the effect of the weight of the breast resected at mastectomy on the quality of life after delayed breast reconstruction.

6.2 Patients and Methods

This study was designed as a 'RetroPro' study, a retrospective case-controlled, cohort study of prospectively collected data, to investigate if there was any relationship between weight of the resected breast and quality of life outcomes measured by the Breast-Q in women undergoing delayed or mixed timing (i.e. delayed on one side and immediate on the other) breast reconstruction.

Ethics approval was obtained for this study from the Southern Adelaide Clinical Human Research Ethics Committee (approval number 369.14). Data were stored on a password protected hospital server.

Participants who underwent breast reconstruction from January 1st 2009 to July 31st 2016 were identified from the Flinders Breast Reconstruction database and participants undergoing delayed breast reconstruction following mastectomy were included in the study. All participants who had died or developed cancer recurrence were excluded, as well as those who attended the clinic for correction of partial mastectomy defects and those who did not go forward with breast reconstruction after initial consultation.

6.2.1 Data Collection and Storage

The breast reconstruction database of the Flinders Breast Reconstruction Service is a prospectively maintained Access (Microsoft, Redmond, WA, USA) database including all participants attending the service for a consultation on breast reconstruction at Flinders Medical Centre, Adelaide, South Australia. It includes participant demographics, procedure type and complications, BMI, previous radiotherapy, diabetic status, and Breast-Q scores. This database is registered with the Southern Adelaide Clinical Human Research Ethics Committee (approval number 354.13).

Data for this study were extracted from the database and compiled into an Excel (Microsoft, Redmond, WA, USA) spreadsheet. This included participant demographics, procedure type, BMI, and Breast-Q scores. Breast weight data were obtained from the histopathology report where the breast specimen was weighed in the pathology lab prior to histological analysis. The average weight was calculated if both breasts were removed.

6.2.2 Statistical Analysis

Descriptive statistics were used to describe the study population demographic, clinical features, and pre and post-op Breast-Q scores. Correlations between

breast weight with pre and post-op Breast-Q scores were examined using the pairwise Spearman correlation test.

All analyses were performed using Stata MP 14.0 (Stata Corp, Texas, USA). All tests were two sided and a p value <0.05 and non-overlapped 95% confidence intervals were regarded as statistically significant.

6.3 Results

A total of 299 participants with a mean age of 50 years were included in the analyses and their demographics and clinical are show in **Table 6-1**.

Table 6-1 Demographic Data
Total n = 299 and results are number (%) unless stated otherwise

	n (%)
Demographics	
Age, mean (standard deviation)	50.2 (9.4)
Clinical Features	
Laterality	
Unilateral	153 (51.2)
Bilateral	146 (48.8)
Timing	
Delayed	220 (73.6)
Mixed	79 (26.4)
Type of Reconstruction	
Autologous	128 (42.8)
Implant based	100 (33.4)
Mixed	71 (23.7)

In this population, 31.6% of participants were obese. Only 58% of participants had breast weight records, and among them, mean breast weight was 707 grams (SD 417) (**Table 6-2**). Breast weight had a mildly positive correlation with BMI, with an R^2 value of 0.46 (Figure 6-1).

Table 6-2 Breast Weight and BMI

	n (%)
BMI, n = 288	
Mean (SD)	27.7 (5.4)
Median (IQR)	26.6 (24.2 – 31.2)
BMI categories, n = 288	
<30	197 (68.4)
30 – 34.9 (Class I obesity)	65 (22.6)
35 – 39.9 (Class II obesity)	19 (6.6)
≥40 (Class III obesity)	7 (2.4)
Breast weight, n = 174	
Mean (SD)	707 (417)
Median (IQR)	594 (410 – 890)

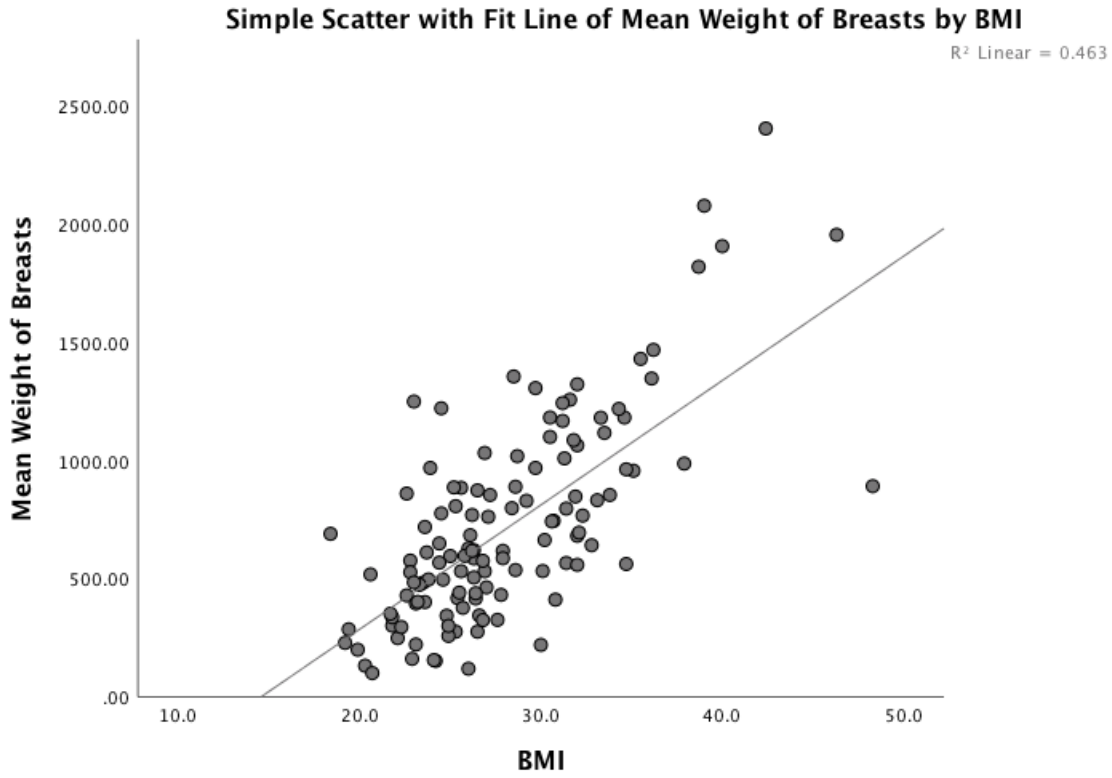


Figure 6-1 Correlation between breast weight and BMI

Breast weight was found to have a significant negative correlation with pre-operative Breast-Q scores in all domains, except for the domain Physical Well-Being – Chest, which approached, but did not achieve statistical significance (**Table 6-3**).

Table 6-3 Pearson correlation between breast weight and pre-operative Breast-Q scores

	Satisfaction with Breasts	Psychosocial Well-Being	Sexual Well-Being	Physical Well-Being (Chest)
Pearson Correlation Coefficient with Breast weight	-0.17	-0.23	-0.29	-0.16
Level of significance	p = 0.04	p = 0.005	p = 0.001	p = 0.06

At the 12-month post-reconstruction mark, Breast-Q scores had all improved to a point where there was no significant correlation in scores with mastectomy breast weight (**Table 6-4**). **Table 6-5** illustrates mean Breast-Q scores pre-operatively and at the 12-month post-reconstruction mark.

Table 6-4 Pearson correlation between breast weight and 12-month post-reconstruction Breast-Q scores

	Satisfaction with Breasts	Satisfaction with Outcome	Psychosocial Well-Being	Sexual Well-Being	Physical Well-Being (Chest)
Pearson Correlation Coefficient with Breast Weight	0.10	0.10	-0.03	-0.08	-0.04
Level of Significance	p = 0.23	p = 0.27	p = 0.76	p = 0.36	p = 0.68

Table 6-5 Mean Breast-Q scores pre-op and 12-months post-reconstruction with 95% confidence intervals

	Satisfaction with Breasts	Psychosocial Well-Being	Sexual Well-Being	Physical Well-Being (Chest)
Pre-operative	39.4 (36.5 – 42.2)	48.7 (45.8 – 51.6)	33.0 (29.8 – 36.1)	68.3 (65.6 – 71.0)
12-months post-reconstruction	71.1 (68.4 – 73.7)	71.9 (68.8 – 75.0)	55.6 (52.0 – 59.2)	74.9 (72.6 – 77.3)

6.4 Discussion

It has been found that breast weight generally increases as BMI increases, and having heavier breasts was found to correspond to lower pre-operative scores for satisfaction with breasts, and sexual well-being. The negative correlation with physical well-being – chest scores approached, but did not achieve statistical significance. It is well described in the literature that having big, heavy breasts can cause physical problems such as headache, back and neck pain, and poor body posture (Chadbourne et al., 2001, Hermans et al., 2005). It can also cause problems with body image and affect sexual relationships (Goin et al., 1977).

This is the first study of its kind looking at mastectomy breast weight and quality of life outcomes. A majority of studies in the literature pertains to macromastia and reduction mammoplasty. The influence of BMI and quality of life outcomes following breast reconstruction has already been discussed in chapter 5.

Post-reconstruction, participants who had heavier breasts resected had improvements to their scores to the point where there was no longer a correlation between the weight of the resected breasts and the Breast-Q scores. It can be inferred that they gained a bigger improvement in their Breast-Q scores to reach similar scores post-reconstruction with participants who had smaller breasts.

The limitations of this study include the small size of the population and only 58% of participants having breast weight data available. Breast weight data were extracted from histopathology reports from specimens that had already

been fixed in formalin. As formalin dehydrates tissue (Werner et al., 2000), the weight of the tissue will depend on the length of time it spends in the formalin, which is something we could not account for in this study. A future study can be performed where the breast is weighed immediately after mastectomy to obtain a fresh weight.

6.5 Conclusion

This study has shown that women with a larger mastectomy breast weight have a lower patient reported quality of life pre-operatively, but improved post-operatively to similar levels to that of participants who had a lower resected breast weight. It certainly warrants further investigation with a prospective study looking at fresh weights, as this area is currently lacking in the body of literature.

7 QUALITY OF LIFE AND SHOULDER FUNCTION AFTER LATISSIMUS DORSI BREAST RECONSTRUCTION

A version of this chapter has been published in the Journal of Plastic, Reconstructive and Aesthetic Surgery, and appended in Appendix 5.

7.1 Introduction

The primary objective of this study was to study the effect of breast reconstruction using the latissimus dorsi (LD) flap on patient reported shoulder function, as well as quality of life, using the Breast-Q questionnaire, compared with a control group of women who underwent total mastectomy without breast reconstruction. Women who had mastectomy without reconstruction were chosen as a control group as surgical treatment for breast cancer in itself has been theorised to affect shoulder mobility, possibly from scarring, tightness of the pectoralis muscle, or altered scapular kinetics (Yang and Kwon, 2017, Shamley et al., 2012).

7.2 Patients and Methods

This study was designed as a case controlled, cross-sectional study to compare women who have had LD flap breast reconstruction following mastectomy, and women who have had mastectomy alone without breast reconstruction.

7.2.1 Data Collection and Storage

Patients who underwent LD flap breast reconstruction, as well as those who underwent mastectomy alone from April 2007 to March 2015 were identified from the Flinders Breast Reconstruction database, and the Flinders Breast Unit database respectively. Patients who were deceased, as well as mastectomy

patients who had subsequently undergone breast reconstruction were excluded from the study. Demographic data such as time since surgery, age, laterality of procedure, and mailing address were recorded in an Excel spreadsheet (Microsoft, Redmond, WA, USA).

All LD flap breast reconstructive procedures at our institution are performed by two plastic surgeons. The first surgeon (Surgeon 1) employs the extended technique (harvesting the overlying fat), even when used in combination with a tissue expander, always dividing the tendinous insertion of the muscle, but not the thoracodorsal nerve. The second surgeon (Surgeon 2) employs the extended technique only when used in a purely autologous reconstruction without the use of a tissue expander, partially divides the tendinous insertion of the muscle, and divides the thoracodorsal nerve routinely.

Breast-Q questionnaires were mailed out to patients, along with participant information sheets (Appendix 6) and reply-paid envelopes. LD flap patients were given the post-operative reconstruction version, as well as satisfaction with back questionnaires (originally devised for the National Mastectomy and Breast Reconstruction Audit) (NHS Information Centre, 2011), and mastectomy patients were given post-operative mastectomy questionnaires. Both groups were also given the functional back and shoulder module of the Breast-Q. A second round of questionnaires were mailed out to non-responders after two months.

The raw data from the returned questionnaires were converted into domain scores (0 – 100) using the QScore (Memorial Sloan Kettering Cancer Institute, New York, USA) software programme. The domains scored included

Satisfaction with Breasts, Satisfaction with Outcome (LD flap only), Psychosocial Well-Being, Physical Well-Being – Chest, Sexual Well-Being, Satisfaction with Back (LD flap only), and Functional Back and Shoulder. Patients who did not complete any particular domain were not scored for that domain, but they were still scored for other domains they completed, as the domains are independent of each other.

7.2.2 Ethics Approval

Ethics approval was obtained for this study from the Southern Adelaide Clinical Human Research Ethics Committee (approval number 25.15). Data was stored on a password protected hospital server. The STROBE statement and checklist (Institute of Social and Preventative Medicine, University of Bern) were used in the design of this study and preparation of the results.

7.2.3 Statistical Analysis

Analysis of data was performed using IBM SPSS statistical software v23.0 (IBM Corp., North Castle, NY, USA). Descriptive statistics, including means and 95% confidence intervals were used to compare the LD flap and mastectomy alone groups. Categorical data were analysed with Chi-Square tests. Continuous data were analysed with *t*-tests, and correlations were analysed using Pearson's Correlation. A value of $p < 0.05$ was considered to be statistically significant for all statistical tests used in this study.

7.3 Results

Questionnaires were sent to 100 women who had undergone LD flaps and 121 patients who underwent mastectomy alone. After two rounds of mailing questionnaires, 60 out of 100 women who had undergone LD flaps, and 59 out of 121 women who had undergone mastectomy alone without reconstruction

returned completed questionnaires.

The demographic data of the patients are presented in Table 7-1. Patients in the mastectomy only group were significantly older than those in the LD flap group, with a median age of 62 vs 51. The LD flap group also underwent significantly more bilateral procedures when compared with the mastectomy alone group. There were no significant differences in the mean time since surgery between the two groups. The majority of women in either group had some form of axillary surgery, sentinel lymph node biopsy (SLNB), or axillary clearance. The difference of axillary surgery rates approached, but did not meet statistical significance between the two groups. Axillary surgery data were not available for 25 women in the study.

In this study, Surgeon 1 performed the reconstruction on 85 patients, and Surgeon 2 performed the reconstruction on 15 patients.

Table 7-1 Demographic data			
	Mastectomy Group (n = 121)	**Latissimus Dorsi Group (n = 100)**	**Significance of Difference Between Groups**
Median Age (Range)	62 (34 – 87)	51 (32 – 73)	p < 0.001
Mean Time since Surgery (months)	47.16	49.11	p = 0.56
Laterality			
Unilateral	104	64	p < 0.001
Bilateral	17	36	
Axillary Surgery			
None	9	12	p = 0.06
SLNB	48	20	
Axillary Clearance	64	43	

7.3.1 Breast-Q Scores

Patients who underwent LD flap breast reconstruction attained significantly higher mean scores than patients who underwent mastectomy alone in the domains of 'Satisfaction with Breast', 'Psychosocial Well-Being', 'Physical Well-Being – Chest', and 'Sexual Well-Being' (Table 7-2). There was no significant difference in the mean scores for both groups in the domain of 'Functional Back and Shoulder'.

Patients who underwent LD flap breast reconstruction were also generally satisfied with their outcomes. They scored a mean score of 75.42 (68.88 – 81.96) for the domain 'Satisfaction with Outcome'. There were also high levels of satisfaction with the appearance of their back following surgery, with a mean score of 81.18 (74.90 – 87.46) for the domain 'Satisfaction with Back'.

To ensure that time since surgery and the patient's age at surgery did not have an effect on the Breast-Q scores, correlations were tested with a Pearson Correlation (Table 7-3). There was no significant correlation between the time since surgery or patient's age at surgery and the scores for the domains of 'Satisfaction with Breasts', 'Psychosocial Well-Being', 'Physical Well-Being – Chest', 'Sexual Well-Being', and 'Functional Back and Shoulder'.

Table 7-4 and Table 7-5 illustrate the various Breast-Q domains in the mastectomy only group and LD flap group respectively stratified according to the laterality of the procedure. There were no significant differences in Breast-Q scores in patients having a unilateral or bilateral procedure.

When patients within the LD flap group were stratified according to the timing of breast reconstruction, there were no significant differences across the various

Breast-Q domains between patients who underwent immediate breast reconstruction and those who underwent delayed or mixed timing reconstruction (Table 7-6).

The functional back and shoulder scores were also analysed based on status of axillary surgery (Table 7-7). The mean scores trended downwards based on the extent of axillary surgery, from no axillary surgery to axillary clearance, but the differences were not statistically significant.

Responses were received from 53 patients operated on by Surgeon 1, and 5 patients operated on by Surgeon 2. There was no significant difference in the mean functional back and shoulder score between the two groups (69.34 vs. 66.40, $p = 0.77$)

Table 7-2 Breast-Q Scores in different domains vs type of surgery. All figures shown are mean (95% confidence interval, lower bound – upper bound)

	Satisfaction with Breasts	Psychosocial Well-Being	Physical Well-Being - Chest	Sexual Well-Being	Functional Back and Shoulder
Mastectomy Group (n = 59)	51.29 (46.22 – 56.35)	64.34 (58.99 – 69.69)	67.90 (63.73 – 72.06)	42.20 (35.40 – 49.00)	65.97 (61.69 – 70.25)
Latissimus Dorsi Group (n = 60)	67.20 (60.94 – 73.46)	78.35 (72.63 – 84.07)	74.50 (70.01 – 78.99)	59.42 (53.54 – 65.29)	68.17 (62.25 – 74.09)
Significance of Differences Between Groups	$p < 0.001$	$p < 0.01$	$p < 0.05$	$p < 0.001$	$p = 0.55$

Table 7-3 Pearson Correlation between time since surgery and Breast-Q scores					
	Satisfaction with Breasts	**Psychosocial Well-Being**	**Physical Well-Being (Chest)**	**Sexual Well-Being**	**Functional Back and Shoulder**
Pearson Correlation Coefficient with Time since Surgery	0.081	0.108	0.045	0.174	0.002
Level of Significance	p = 0.38	p = 0.24	p = 0.63	p = 0.10	p = 0.99
Pearson Correlation Coefficient with Age	-0.084	0.053	-0.094	0.029	-0.139
Level of Significance	p = 0.36	p = 0.57	p = 0.31	p = 0.78	p = 0.13

Table 7-4 Breast-Q scores in different domains in the mastectomy alone group separated by laterality of procedure. All figures shown are mean (95% confidence interval, lower bound – upper bound)

	Satisfaction with Breasts	Psychosocial Well-being	Physical Well-being (Chest)	Sexual Well-being	Functional Back and Shoulder
Unilateral (n = 46)	50.87 (44.93 – 56.81)	64.15 (58.30 – 70.00)	68.13 (63.15 – 73.11)	45.57 (38.20 – 52.94)	64.89 (59.67 – 70.11)
Bilateral (n = 13)	52.77 (41.94 – 63.60)	65.00 (50.43 – 79.57)	67.08 (58.99 – 75.17)	32.10 (15.28 – 48.92)	69.77 (63.00 – 76.54)
Significance of Differences Between Groups	p = 0.76	p = 0.90	p = 0.84	p = 0.08	p = 0.35

Table 7-5 Breast-Q scores in different domains in the latissimus dorsi group separated by laterality of procedure. All figures shown are mean (95% confidence interval, lower bound – upper bound)

	Satisfaction with Breasts	Satisfaction with Outcome	Psychosocial Well-being	Physical Well-being (Chest)	Sexual Well-being	Satisfaction with Back	Functional Back and Shoulder
Unilateral (n = 38)	65.11 (56.38 – 73.83)	74.08 (65.38 – 82.77)	78.37 (70.50 – 86.24)	74.66 (69.23 – 80.09)	60.80 (52.23 – 69.37)	80.63 (71.60 – 89.66)	68.47 (60.47 – 76.48)
Bilateral (n = 22)	70.82 (62.08 – 79.55)	77.73 (67.24 – 88.21)	78.32 (69.82 – 86.81)	74.23 (65.73 – 82.72)	56.72 (51.03 – 62.41)	82.14 (74.08 – 90.20)	67.64 (58.44 – 76.83)
Significance of Differences Between Groups	p = 0.71	p = 0.60	p = 0.99	p = 0.93	p = 0.42	p = 0.80	p = 0.89

Table 7-6 Breast-Q scores in different domains in the latissimus dorsi group separated by timing of reconstruction. All figures shown are mean (95% confidence interval, lower bound – upper bound)

	Satisfaction with Breasts	Satisfaction with Outcome	Psychosocial Well-being	Physical Well-being (Chest)	Sexual Well-being	Satisfaction with Back	Functional Back and Shoulder
Immediate (n = 16)	65.25 (54.55 – 75.95)	74.81 (61.07 – 88.55)	82.38 (72.28 – 92.47)	76.56 (68.99 – 84.13)	62.44 (51.47 – 73.41)	77.56 (63.88 – 91.24)	66.06 (57.46 – 74.67)
Delayed or Mixed (n = 44)	67.91 (60.08 – 75.74)	75.64 (67.90 – 83.37)	76.89 (69.82 – 83.95)	73.75 (68.13 – 79.37)	58.11 (50.86 – 65.36)	82.50 (75.21 – 89.79)	68.93 (61.32 – 76.55)
Significance of Differences Between Groups	p = 0.71	p = 0.91	p = 0.40	p = 0.58	p = 0.50	p = 0.49	p = 0.67

Table 7-7 Functional Back and Shoulder scores stratified by axillary surgery (95% confidence interval, lower bound – upper bound			
	No Axillary Surgery (n = 14) {a}	**Sentinel Lymph Node Biopsy (n = 36) {b}**	**Axillary Clearance (n = 51) {c}**
Functional Back and Shoulder Score	72.36 (62.11 – 82.60)	68.14 (62.70 – 73.58)	61.96 (56.04 – 67.88)
Significance of Difference Between Groups	{a} & {b} – p = 0.42 {a} & {c} – p = 0.10	{b} & {c} – p = 0.14	

7.3.2 Non-Responders

The demographic data for non-responders is summarised in Table 7-8. There were no significant differences between responders and non-responders in either the mastectomy only group or the LD flap group.

Table 7-8 Demographic data of non-responders

	Mastectomy Alone Group			Latissimus Dorsi Group		
	Responders (n = 59)	**Non-Responders (n = 62)**	**Significance of Difference Between Groups**	**Responders (n = 60)**	**Non-Responders (n = 40)**	**Significance of Difference Between Groups**
Median Age (Range)	63 (34 – 83)	62 (36 – 87)	p = 0.24	52 (32 – 73)	49.50 (32 – 70)	p = 0.51
Mean Time Since Surgery (Months)	45.58	48.66	p = 0.49	50.63	46.83	p = 0.45

7.4 Discussion

This study has shown that latissimus dorsi flap breast reconstruction gives a significant improvement in quality of life following mastectomy, compared to mastectomy without breast reconstruction. This is consistent with the published literature, with one study finding women who had mastectomies without breast reconstruction to have the lowest satisfaction scores out of women undergoing mastectomies without breast reconstruction, breast conserving surgery, or breast reconstructive surgery. Additionally, women who received LD flap breast reconstruction did not demonstrate any significant difference in satisfaction scores when compared to women who underwent breast conserving surgery (Atisha et al., 2015).

Patients who underwent LD flap breast reconstruction also reported high levels of satisfaction with the appearance of their back, despite the long scar that results from this surgery. This was similar to findings of the National Mastectomy and Breast Reconstruction Audit conducted by the National Health Service (NHS) in England, which found only about 1 in 10 women were bothered by the appearance of their back most or all of the time (NHS Information Centre, 2011).

The NHS audit also found that around 20% of patients who underwent LD flap breast reconstruction reported issues with activities involving use of their back or shoulder muscles most or all of the time (NHS Information Centre, 2011). In this study, there were no significant differences in patient reported outcomes of back and shoulder function in women who underwent LD flap breast reconstruction and those who underwent mastectomies without breast reconstruction. One possible reason for the variation of back and shoulder

function following LD flap breast reconstruction could be the different technical modifications some surgeons apply. For example, some surgeons divide the insertion of the muscle to the humerus, and some do not. Some surgeons also divide the thoracodorsal nerve that supplies the muscle (Hammond, 2009). Differences in technique could account for differences in outcomes, and future studies could evaluate this possibility.

A prospective study conducted by de Oliveria et al found that shoulder function decreased by about a third immediately after surgery in either patients who underwent mastectomy without breast reconstruction or who underwent mastectomy with immediate LD flap breast reconstruction. However, at the one-year mark, patients who underwent LD flap breast reconstruction were found to have superior shoulder flexion and abduction when compared to those who underwent mastectomy without reconstruction. The authors hypothesised that the tissue manipulation performed during LD flap reconstruction, along with the extra skin provided by the flap helped reduce tissue adhesion, contributing to greater shoulder mobility (de Oliveira et al., 2010, de Oliveira et al., 2013).

Even though the LD muscle is a significant muscle of the shoulder joint, its removal has not been found to detrimentally affect shoulder function, as other muscles of the shoulder, such as teres major often compensate for the loss of the LD muscle over time (Spear and Hess, 2005). A majority of studies have found that there may be an early deterioration in shoulder function following breast reconstruction using the LD flap, but most patients recover near normal shoulder function in the long term. A common recommendation in the literature is the significant role physiotherapy plays in the recovery period following surgery in allowing shoulder function to return as close to normal as possible

(Lee and Mun, 2014, Glassey et al., 2008, Smith, 2014).

Our study also found that LD flap patients had high scores for ‘Satisfaction with Outcome’, which is what has been found similarly in the literature. Dutra et al reported a 92% satisfaction rate with the operation and 90% of patients would recommend the surgery to someone else (Dutra et al., 2012).

This study also found no difference in Breast-Q scores between patients who received immediate or delayed breast reconstruction. This could be due to the cross-sectional nature of the study and some time has passed since the operation for most patients. The benefits of immediate breast reconstruction have been discussed previously, with patients experiencing lower psychological morbidity following mastectomy with immediate breast reconstruction (Dean et al., 1983).

In our institution, routine physiotherapy is not offered to patients undergoing mastectomy with LD flap reconstruction. Axillary surgery in the treatment of breast cancer is well known to cause morbidity of arm and shoulder function, commonly causing restricted shoulder mobility, oedema, pain, and numbness (Warmuth et al., 1998, Feuk, 2000). Post-operative physiotherapy has been shown to improve shoulder function and quality of life following breast cancer surgery, and is certainly worthy of consideration at our institution (Lauridsen et al., 2005, Beurskens et al., 2007).

Due to the cross-sectional nature of this study, there are a few limitations to this study. Firstly, the patients completed the questionnaires at varying time points following their surgery. We have tried to negate this factor by finding no correlation between time since surgery and the Breast-Q scores. Secondly, it

would be useful to obtain scores from different time points in a patient's treatment to assess the influence the treatment has on their score, which could be an area of further study.

Radiotherapy data was also not available for this patient cohort, which could be another confounding factor in this study.

Another potential source of bias is the significantly older age of the mastectomy only group. Age related impairment of shoulder function could cause a lower patient reported back and shoulder function score, as reflected by the negative correlation coefficient in Table 7-3, although not statistically significant, a larger population need to be studied to provide more statistical power.

There is also a potential selection bias between responders and non-responders to the postal questionnaires. Patients who complete questionnaires may be more likely to either be very satisfied or very dissatisfied (Cohen et al., 2015).

7.5 Conclusion

Our study has found that women who undergo LD flap breast reconstruction have a significantly higher quality of life when compared to women who undergo total mastectomy without breast reconstruction. Although there is a theoretical detriment to shoulder function after harvesting the LD for use in breast reconstruction, there is no significant difference in patient reported shoulder function between the two groups of women. There are also high levels of satisfaction with the aesthetics of the back despite scarring from harvesting the LD. LD flap breast reconstruction is therefore safe and improves the quality of life of women following total mastectomy.

8 THESIS CONCLUSIONS

With the increase in the prevalence of obesity in the population, the number of obese patients presenting with breast cancer and seeking breast reconstruction will certainly rise. It is therefore prudent to be able to counsel patients on their risks when considering breast reconstruction. A review of the literature explored the role obesity plays in surgery, as well as the theoretical risk obesity plays in the development of breast cancer. It was well documented in the literature that obese women experienced higher rates of complications when undergoing breast reconstruction, there was however a lack of data looking at the quality of life improvement obese women get after breast reconstruction.

A case of an obese woman with an implant-based reconstruction presenting with a late onset seroma was discussed. Although the cause for the seroma was eventually found to be caused by an implant rupture, careful evaluation of patients presenting a late onset seroma around a breast implant is needed due to the growing concern for Breast Implant Associated Anaplastic Large Cell Lypmhoma.

Obese women presenting for consideration of breast reconstruction can sometimes be limited in the options available to them, due to their body habitus or medical co-morbidities. The reverse abdominoplasty is a viable option for breast reconstruction especially in obese women due to the excess adipose tissue and skin present. A small series presented demonstrated satisfactory Breast-Q scores post-reconstruction comparable to scores post conventional reconstruction at our institution.

A small qualitative study was designed to explore the experiences of a small

group of obese women during their breast cancer and reconstructive journey. Common themes that emerged included the psychological impact the diagnosis had on them, as well as the impact on their social circle, including the importance of social supports in helping them cope with the diagnosis. One common point brought up was the trouble coping with using external breast prostheses, including the weight and cumbersome nature of the prostheses, as well as the discomfort experienced during hot weather. There was however an overwhelmingly positive experience with their reconstructive journey.

With this knowledge in hand, a ‘RetroPro’ study was designed to establish the quality of life of obese women before and after breast reconstruction. It was found that obese women had a lower baseline quality of life pre-operatively compared with non-obese women. However, at the 12-month post-operative mark, there was no significant difference in Breast-Q scores between obese and non-obese women. It can therefore be surmised that obese women gained a bigger quality of life benefit from breast reconstruction compared to non-obese women.

It was also found that obese women experienced a higher rate of minor complications compared to non-obese women, but the rates of major complications were comparable between the two groups. As expected, our cohort of women scored lower Breast-Q scores pre-operatively compared with normative data published by Mundy et. al. that surveyed women who had no history of breast cancer or breast surgery (Mundy et al., 2017).

A common theme that emerged from the qualitative study was the trouble in coping with external breast prostheses after mastectomy. To explore this

further, a study was developed to look at the effect of breast weight resected at mastectomy on quality of life after delayed breast reconstruction. Breast weight was found to have a mildly positive correlation with BMI, with obese women having bigger breasts than non-obese women. They will therefore require bigger and heavier external breast prostheses, which was a common complaint expressed during the qualitative study.

Women with heavier breasts were found to have a lower quality of life pre-reconstruction, however their scores improved to similar levels to that of women with lighter breasts. This warrants further study looking at breasts being weighed at the time of mastectomy to obtain fresh weights, which is currently lacking in the literature.

Obese women have been found to undergo autologous breast reconstruction more often than implant-based reconstruction, both in our study and in the literature. A common technique for autologous breast reconstruction is the Latissimus Dorsi (LD) musculocutaneous flap. A study was designed to look at the quality of life and patient reported shoulder function in women compared with a control group of women who underwent mastectomy without breast reconstruction. It was found that women who underwent LD flap reconstruction had a higher quality of life when compared to women who underwent mastectomy without breast reconstruction. Although there has been a theoretical detriment to shoulder function following harvesting of the LD flap in the literature, our study did not find any difference in patient reported shoulder function between the two groups.

The findings from this thesis will equip clinicians with the necessary knowledge

to adequately counsel obese women contemplating undergoing breast reconstruction about their risks, as well as benefits from undergoing surgery, so that they can be fully informed when making the decision to go ahead with surgery.

9 APPENDICES

Appendix 1. Breast Reconstruction Module of Breast-Q Questionnaire

The following questions are about your breasts and breast reconstruction surgery. After reading each question, please circle the number in the box that best describes your situation. If you are unsure how to answer a question, choose the answer that comes closest to how you feel. Please answer all questions.

1. With your breasts in mind, in the past 2 weeks, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How you look in the mirror clothed?	1	2	3	4
b. The shape of your reconstructed breast(s) when you are wearing a bra?	1	2	3	4
c. How normal you feel in your clothes?	1	2	3	4
d. The size of your reconstructed breast(s)?	1	2	3	4
e. Being able to wear clothing that is more fitted?	1	2	3	4
f. How your breasts are lined up in relation to each other?	1	2	3	4
g. How comfortably your bras fit?	1	2	3	4
h. The softness of your reconstructed breast(s)?	1	2	3	4
i. How equal in size your breasts are to each other?	1	2	3	4
j. How natural your reconstructed breast(s) looks?	1	2	3	4
k. How naturally your reconstructed breast(s) sits/ hangs?	1	2	3	4
l. How your reconstructed breast(s) feels to touch?	1	2	3	4
m. How much your reconstructed breast(s) feels like a natural part of your body?	1	2	3	4
n. How closely matched your breasts are to each other?	1	2	3	4
o. How your reconstructed breast(s) look now compared to before you had any breast surgery?	1	2	3	4
p. How you look in the mirror unclothed?	1	2	3	4

Please check that you have answered all the questions before going on to the next page

This question is about breast reconstruction using IMPLANTS. If you do not have an implant(s) please skip to question 3. If you do have an implant(s), please answer question 2 below.

2. In the past 2 weeks, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. The amount of rippling (wrinkling) of your implant(s) that you can see?	1	2	3	4
b. The amount of rippling (wrinkling) of your implant(s) that you can feel?	1	2	3	4

3. We would like to know how you feel about the outcome of your breast reconstruction surgery. Please indicate how much you agree or disagree with each statement:

	Disagree	Somewhat Agree	Definitely Agree
a. Having reconstruction is much better than the alternative of having no breast(s).	1	2	3
b. I would encourage other women in my situation to have breast reconstruction surgery.	1	2	3
c. I would do it again.	1	2	3
d. I have no regrets about having the surgery.	1	2	3
e. Having this surgery changed my life for the better.	1	2	3
f. The outcome perfectly matched my expectations.	1	2	3
g. It turned out exactly as I had planned.	1	2	3

Please check that you have answered all the questions before going on to the next page

4. With your breasts in mind, in the past 2 weeks, how often have you felt:

		None of the time	A little of the time	Some of the time	Most of the time	All of the time
a.	Confident in a social setting?	1	2	3	4	5
b.	Emotionally able to do the things that you want to do?	1	2	3	4	5
c.	Emotionally healthy?	1	2	3	4	5
d.	Of equal worth to other women?	1	2	3	4	5
e.	Self-confident?	1	2	3	4	5
f.	Feminine in your clothes?	1	2	3	4	5
g.	Accepting of your body?	1	2	3	4	5
h.	Normal?	1	2	3	4	5
i.	Like other women?	1	2	3	4	5
j.	Attractive?	1	2	3	4	5

5. Thinking of your sexuality, since your breast reconstruction, how often do you generally feel:

		None of the time	A little of the time	Some of the time	Most of the time	All of the time	Not Applicable
a.	Sexually attractive in your clothes?	1	2	3	4	5	N/A
b.	Comfortable/at ease during sexual activity?	1	2	3	4	5	N/A
c.	Confident sexually?	1	2	3	4	5	N/A
d.	Satisfied with your sex-life?	1	2	3	4	5	N/A
e.	Confident sexually about how your breast(s) look when unclothed?	1	2	3	4	5	N/A
f.	Sexually attractive when unclothed?	1	2	3	4	5	N/A

Please check that you have answered all the questions before going on to the next page

6. In the past 2 weeks, <u>how often</u> have you experienced:

		None of the time	A little of the time	Some of the time	Most of the time	All of the time
a.	Neck pain?	1	2	3	4	5
b.	Upper back pain?	1	2	3	4	5
c.	Shoulder pain?	1	2	3	4	5
d.	Arm pain?	1	2	3	4	5
e.	Rib pain?	1	2	3	4	5
f.	Pain in the muscles of your chest?	1	2	3	4	5
g.	Difficulty lifting or moving your arms?	1	2	3	4	5
h.	Difficulty sleeping because of discomfort in your breast area?	1	2	3	4	5
i.	Tightness in your breast area?	1	2	3	4	5
j.	Pulling in your breast area?	1	2	3	4	5
k.	Nagging feeling in your breast area?	1	2	3	4	5
l.	Tenderness in your breast area?	1	2	3	4	5
m.	Sharp pains in your breast area?	1	2	3	4	5
n.	Shooting pains in your breast area?	1	2	3	4	5
o.	Aching feeling in your breast area?	1	2	3	4	5
p.	Throbbing feeling in your breast area?	1	2	3	4	5

Please check that you have answered all the questions before going on to the next page

The following questions are about reconstruction using a TRAM or DIEP flap (i.e., reconstruction using skin and fat from you abdomen/tummy area). If you do not have a TRAM or DIEP flap, please skip to question 10. If you do have a TRAM or DIEP flap, please answer the following questions:

7. In the past 2 weeks, with your abdomen (tummy area) in mind, how often have you experienced:

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
a. Difficulty sitting up because of abdominal muscle weakness (e.g. getting out of bed)?	1	2	3	4	5
b. Difficulty doing everyday activities because of abdominal muscle weakness (e.g. making your bed)?	1	2	3	4	5
c. Abdominal discomfort?	1	2	3	4	5
d. Abdominal bloating?	1	2	3	4	5
e. Abdominal bulging?	1	2	3	4	5
f. Tightness in your abdomen?	1	2	3	4	5
g. Pulling in your abdomen?	1	2	3	4	5
h. Lower back pain?	1	2	3	4	5

8. In the past 2 weeks, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How your abdomen looks?	1	2	3	4
b. The position of your navel (belly button)?	1	2	3	4
c. How your abdominal scars look?	1	2	3	4

9. In the past 2 weeks, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How your abdomen feels now compared to before your surgery?	1	2	3	4
b. How your abdomen looks now compared to before your surgery?	1	2	3	4

Please check that you have answered all the questions before going on to the next page

This question is about NIPPLE reconstruction. If you did not have nipple reconstruction, please skip to question 11.
If you did have nipple reconstruction, please answer question 10 below.

10. In the past 2 weeks, how satisfied or dissatisfied are you with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. The shape of your reconstructed nipple(s)?	1	2	3	4
b. How your reconstructed nipple(s) and areola(s) look?	1	2	3	4
c. How natural your reconstructed nipple(s) look?	1	2	3	4
d. The color of your reconstructed nipple/areolar complex?	1	2	3	4
e. The height (projection) of your reconstructed nipple(s)?	1	2	3	4

Please check that you have answered all the questions before going on to the next page

The following questions are about reconstruction using skin and muscle from your back area. If you did not have this type of surgery, please skip to question 12.

11. In the past 2 weeks, with your back in mind, how often have you been bothered by:

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
a. How your back looks?	1	2	3	4	5
b. The shape (contour) of your back?	1	2	3	4	5
c. The sides of your back not matching?	1	2	3	4	5
d. How your back scar looks?	1	2	3	4	5
e. The location of your back scar?	1	2	3	4	5
f. The length of your back scar?	1	2	3	4	5
g. How noticeable your back scar is to others?	1	2	3	4	5
h. Having to wear certain clothes in order to hide your back scar?	1	2	3	4	5
i. Not being able to wear certain clothes because of your back scar (e.g. backless dress, bathing suit)?	1	2	3	4	5

Please check that you have answered all the questions before going on to the next page

12. How satisfied or dissatisfied were you with the information you received from your plastic surgeon about:

		Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a.	How the breast reconstruction surgery was to be done?	1	2	3	4
b.	Healing and recovery time?	1	2	3	4
c.	Possible complications?	1	2	3	4
d.	The options you were given regarding types of breast reconstruction?	1	2	3	4
e.	The options you were given regarding timing of your breast reconstruction (i.e. same time as your mastectomy versus later)?	1	2	3	4
f.	The pros and cons of the timing of your breast reconstruction?	1	2	3	4
g.	How long the process of breast reconstruction would take from start to finish?	1	2	3	4
h.	What size you could expect your breasts to be after reconstructive surgery?	1	2	3	4
i.	How much pain to expect during recovery?	1	2	3	4
j.	What you could expect your breasts to look like after surgery?	1	2	3	4
k.	How long after reconstruction surgery it would take to feel like yourself/feel normal again?	1	2	3	4
l.	How the surgery could affect future breast cancer screening (e.g. mammogram, self examinations)?	1	2	3	4
m.	Lack of sensation in your reconstructed breast(s) and nipple(s)?	1	2	3	4
n.	What other women experience with their breast reconstruction surgery?	1	2	3	4
o.	What the scars would look like?	1	2	3	4

Please check that you have answered all the questions before going on to the next page

13. These questions ask about your plastic surgeon. Did you feel that he/she:

	Definitely Disagree	Somewhat Disagree	Somewhat Agree	Definitely Agree
a. Was competent?	1	2	3	4
b. Gave you confidence?	1	2	3	4
c. Involved you in the decision-making process?	1	2	3	4
d. Was reassuring?	1	2	3	4
e. Answered all your questions?	1	2	3	4
f. Made you feel comfortable?	1	2	3	4
g. Was thorough?	1	2	3	4
h. Was easy to talk to?	1	2	3	4
i. Understood what you wanted?	1	2	3	4
j. Was sensitive?	1	2	3	4
k. Made time for your concerns?	1	2	3	4
l. Was available when you had concerns?	1	2	3	4

Please check that you have answered all the questions before going on to the next page

14. These questions ask about members of the medical team other than the surgeon (e.g. nurses and other doctors who looked after you in the hospital when you had your breast reconstruction surgery). Did you feel that they:

	Definitely Disagree	Somewhat Disagree	Somewhat Agree	Definitely Agree
a. Were professional?	1	2	3	4
b. Treated you with respect?	1	2	3	4
c. Were knowledgeable?	1	2	3	4
d. Were friendly and kind?	1	2	3	4
e. Made you feel comfortable?	1	2	3	4
f. Were thorough?	1	2	3	4
g. Made time for your concerns?	1	2	3	4

15. These questions ask about members of the office staff (e.g. secretaries, office or clinic nurses). Did you feel that they:

	Definitely Disagree	Somewhat Disagree	Somewhat Agree	Definitely Agree
a. Were professional?	1	2	3	4
b. Treated you with respect?	1	2	3	4
c. Were knowledgeable?	1	2	3	4
d. Were friendly and kind?	1	2	3	4
e. Made you feel comfortable?	1	2	3	4
f. Were thorough?	1	2	3	4
g. Made time for your concerns?	1	2	3	4

Please check that you have answered all the questions

Appendix 2. An Uncommon Presentation of Breast Implant Rupture (PRSGO)

OPEN

CASE REPORT
Breast

An Uncommon Presentation of Breast Implant Rupture

Eugene Koh, MBBS, MSSc*
David I. Watson, MD, FRACS†
Nicola R. Dean, MBChB, PhD, FRACS(Plas)*

Summary: Late periprosthetic seroma has lately been concerning for breast implant-associated anaplastic large cell lymphoma. The authors present an uncommon presentation of breast implant rupture with a seroma and skin rash forming 2 years after insertion of the implant. *(Plast Reconstr Surg Glob Open 2016;4:e719; doi: 10.1097/GOX.0000000000000699; Published online 26 May 2016.)*

Breast implant–associated anaplastic large-cell lymphoma (ALCL) is a concerning clinical entity that has been observed in recent years. A well-known mode of presentation for ALCL is late periprosthetic seroma. We present a case of late seroma occurring in the context of implant rupture, with no detectable ALCL.

CASE REPORT

A 69-year-old woman presented in late December 2014 with gross swelling of her reconstructed left breast and a maculopapular rash. She had undergone delayed bilateral implant based reconstruction 2 years previously, after right therapeutic and left prophylactic mastectomy. The reconstruction was performed in 2 stages with textured surface tissue expanders (PMT Integra, PMT Corporation, Minn.), followed by imprint-textured surface, cohesive gel implants (Mentor Contour Profile Gel, Mentor Worldwide LLC, Calif.). There were no immediate postoperative complications, and all was well at a follow-up appointment 24 months after surgery, and follow-up photographs were obtained (Fig. 1).

The patient then presented 3 weeks later with marked swelling of the reconstructed left breast and a maculopapular rash developed around the reconstructive scar on the same side over the previous week (Fig. 2). For the rash, she had previously seen a dermatologist, who prescribed steroid cream and tablets, with no improvement. Ultrasound and magnetic resonance imaging were obtained. Ultrasonography revealed a large volume of fluid surrounding the left breast implant, and 840 ml of viscous straw-colored fluid was aspirated under ultrasound guidance, and sent for cytology. Magnetic resonance imaging of the reconstructed breast revealed a rupture of the left breast implant, with a tear in the silicone rubber shell visible on its deep aspect, at the shell patch juncture (Fig. 3). There were no systemic signs of infection, and the white cell count was normal. However, C-reactive protein was increased to 120 mg/l.

Surgery was undertaken, and an obvious tear was seen at the interface of the smooth and textured parts of the posterior surface of the implant (Fig. 4). The likely cause at that stage was considered to be implant rupture due to either mechanical forces or a one-off manufacturing fault. As the patient had not had any problems with the contralateral identical implant, a new implant of the same size and brand was inserted. Postoperatively, there was <20 ml of output in the surgical drain across the first 12 hours after surgery, and the rash resolved

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Appendix 3. Participant information sheet and consent form for qualitative study

Participant Information Sheet

Non-Interventional Study – Adult providing own consent
Flinders Medical Centre

Title Qualitative Study of Obesity in Breast Reconstruction

Principal Investigator Dr Eugene Koh

Associate Investigators Dr Nicola Dean, Prof David Watson

Location Flinders Medical Centre

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, 'Qualitative Study of Obesity in Breast Reconstruction'. This is because you have previously had breast reconstruction surgery and have been identified as having a body mass index of more than 30. The research project is aiming to explore the experiences and perspectives of obese women in relation to their cancer diagnosis, breast reconstruction journey, and perspectives into obesity.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you

don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to the tests and research that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The aim of this project is to explore the experiences and perspectives of obese women in relation to their cancer diagnosis, breast reconstruction journey, and perspectives into obesity. This information will be useful for women in the future who are obese and considering breast reconstruction after mastectomy.

The results of this research will be used by the study doctor, Dr Eugene Koh to obtain a Doctor of Philosophy degree.

3 What does participation in this research involve?

Participants in this study will be required to attend the Flinders Medical Centre, where the project will be explained, and a consent form signed. A one on one semi structured interview will be conducted in a private interview room with Dr

Koh. The interview will last from 30 – 60 minutes. An audio recording of the interview will also be taken at the same time, which will later be transcribed. As the interview might be touching on some emotional aspects of your life, there is a possibility you might get upset during the interview process. You are welcome to stop the interview at any time should you wish not to continue. The Breast Reconstruction nurse will also be available if you wish to talk to someone.

The transcripts will be analysed for any common themes, as well as differences in opinions amongst the different participants.

There are no costs associated with participating in this research project, nor will you be paid. You will be reimbursed for car parking at the Flinders Medical Centre if you drive to the interview.

4 What do I have to do?

If you consent to participating in this study, please sign the consent form at the back of this info sheet and return it with the enclosed reply paid envelope. You will then be contacted by Dr Koh to arrange a suitable time for your interview at Flinders Medical Centre.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Flinders Medical Centre.

6 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research, but will benefit patients in the future who are considering breast reconstruction so that they will be well informed of what to expect following surgery.

7 What are the possible risks and disadvantages of taking part?

There are no expected risks of being a participant in this study.

Part 2 How is the research project being conducted?

8 What will happen to information about me?

The audio recordings and transcripts of the interview will be de-identified and stored in a secure file directory on the hospital's computer server. Any information obtained in connection with this research project that can identify you will remain confidential. It will be kept in a password-protected file in a secure file directory on the hospital's computer server. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

9 Who is organizing and funding the research?

This research project is being conducted by Dr Eugene Koh, and is being funded by Flinders University.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

10 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Flinders Medical Centre.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect the interests of people who agree to participate in human research studies.

11 Further information and who to contact

If you want any further information concerning this project, you can contact the principal study doctor on:

Dr Eugene Koh

Research Registrar, Plastic and Reconstructive Surgery

82045511 (via switchboard)

eugene.koh@health.sa.gov.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Petrina Kasperski

Executive Officer, Southern Adelaide Clinical Human Research Ethics Committee

82047433

research.ethics@health.sa.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC Name	Southern Adelaide Clinical Human Research Ethics Committee
HREC Executive Officer	Petrina Kasperski
Telephone	82047433
Email	research.ethics@health.sa.gov.au

Consent Form - *Adult providing own consent*

Title	Qualitative Study of Obesity in Breast
Coordinating Principal	Dr Eugene Koh
Associate Investigator(s)	Dr Nicola Dean, Prof David Watson
Location	Flinders Medical Centre

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print)_____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Appendix 4.

Koh, E., Watson, D.I. and Dean, N.R., 2019. Impact of Obesity on Quality of Life After Breast Reconstruction. *Annals of plastic surgery*, *83*(6), pp.622-628.

Can be accessed at:

https://journals.lww.com/annalsplasticsurgery/Abstract/2019/12000/Impact_of_Obesity_on_Quality_of_Life_After_Breast.5.aspx

Appendix 5.

Koh, E., Watson, D.I. and Dean, N.R., 2018. Quality of life and shoulder function after latissimus dorsi breast reconstruction. *Journal of Plastic, Reconstructive & Aesthetic Surgery*, *71*(9), pp.1317-1323.

Can be accessed at :

https://www.sciencedirect.com/science/article/abs/pii/S1748681518301657

Appendix 6. Participation information sheet for the Latissimus Dorsi study

Participant Information Sheet

Non-Interventional Study – Adult providing own consent
Flinders Medical Centre

Title Comparison of outcomes between women who have had Latissimus Dorsi breast reconstruction following mastectomy and women who have had mastectomy alone

Principal Investigator	Dr Eugene Koh
Associate Investigators	Dr Nicola Dean, Prof David Watson
Location	Flinders Medical Centre

Part 1 What does my participation involve?

4 Introduction

You are invited to take part in this research project, 'Comparison of outcomes between women who have had Latissimus Dorsi breast reconstruction following mastectomy and women who have had mastectomy alone'. This is because you have had a mastectomy or a Latissimus Dorsi breast reconstruction following a mastectomy. The research project is aiming to determine if there is any difference in outcome in women who have had mastectomy alone and women who go on to have a Latissimus Dorsi breast reconstruction after their mastectomy.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you simply have to answer the attached questionnaire and return it in the enclosed self-addressed envelope. By returning the questionnaire, you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to the tests and research that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information form to keep.

5 What is the purpose of this research?

The aim of this project is to determine if there is any difference in outcome in women who have had mastectomy alone and women who go on to have a Latissimus Dorsi breast reconstruction after their mastectomy. This information will be useful for ladies in the future who are considering breast reconstruction after a mastectomy.

The results of this research will be used by the study doctor, Dr Eugene Koh to

obtain a Doctor of Philosophy degree.

6 What does participation in this research involve?

Participants in this study will be required to fill in a Breast-Q questionnaire, which is a well validated tool for measuring outcomes following surgery. Participation in the research involves no tests or procedures. You will be mailed a copy of the questionnaire along with this participant information sheet, along with a self-addressed envelope, which will be used to return the completed questionnaire.

You will just need to commit about 15 minutes of your time in your own time to fill out the questionnaire and return it via a self-addressed envelope.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid.

4 What do I have to do?

You will just need to complete the enclosed questionnaire and return it via the included self-addressed envelope.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Flinders Medical Centre.

6 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research, but will benefit patients in the future who are considering breast reconstruction so that they will be well informed of what to expect following surgery.

7 What are the possible risks and disadvantages of taking part?

There are no expected risks of being a participant in this study.

Part 2 How is the research project being conducted?

8 What will happen to information about me?

By completing and returning the questionnaire, you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. It will be kept in a password-protected file in a secure file directory on the hospital's computer server. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

9 Who is organizing and funding the research?

This research project is being conducted by Dr Eugene Koh, and is being funded by Flinders University.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

10 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Flinders Medical Centre.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect the interests of people who agree to participate in human research studies.

11 Further information and who to contact

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Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC Name	Southern Adelaide Clinical Human Research Ethics Committee
HREC Executive Officer	Petrina Kasperski
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