PATIENTS' IMPRESSION OF BREAST SYMMETRY FOLLOWING UNILATERAL OR BILATERAL IMMEDIATE TO IMPLANT RECONSTRUCTION, AND THEIR TENDENCY TOWARD REPEAT SURGERIES

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A Dissertation submitted to the Faculty of Science, University of the Witwatersrand, in fulfilment of the requirements for the degree of Master of Medicine (MMED)

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(I) Declaration

I, Dr Gareth Tjasink declare that this dissertation is my own, unaided work. It is being submitted for the Degree of Master of Medicine (MMED) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other university.

Signed 

2nd day of November 2022 in Johannesburg

(I) Acknowledgements

I would first like to thank my supervisor, Professor Carol Benn, for her guidance and support, for being available on short notice, and for always having the time to steer me in the right direction.

To my wife, your unwavering and selfless support has made this all possible. You have been the keystone in our bridge, bearing the load. This is as much your victory as it is mine.

(II) Abstract

The aim of this study was to compare patient-reported outcomes in female breast cancer patients who opted for contralateral prophylactic mastectomy with bilateral immediate implant-based reconstruction, or who had unilateral skin–sparing mastectomy with an immediate prosthetic reconstruction, in terms of patients' impression of breast symmetry and satisfaction with their breasts, as well as the number of repeat surgeries these patients underwent for cosmetic purposes. The study utilised an established, valid, and reliable patient-reported outcome tool - the BREAST-Q - and employed a descriptive cross-sectional questionnaire-based study design. The question posed was whether immediate reconstruction following an elective bilateral mastectomy, while having little oncological benefit, may have other benefits including increased patient satisfaction and/or a superior cosmetic result compared to patients who opted for a unilateral implant-based reconstruction. The results of this study do not support this assumption. They, instead, indicate that the satisfaction levels were comparable and not as obviously disparate as predicted and the tendency to repeat surgeries for cosmetic reasons was parallel among the two groups. However, due to small and uneven sample sizes the findings of this research are not statistically conclusive and further research is necessary to corroborate the results.

Word count: 10,279

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(VI) Nomenclature

ASCO: American Society of Clinical Oncology

BREAST-Q: Breast Questionnaire 1.0

BRCA: BReast CAncer gene 1/2

CPM: Contralateral Prophylactic Mastectomy

DIEP: Deep Inferior Epigastric Perforators

IQR: Inter-Quartile Range

NSABP: National Surgical Adjuvant Breast and Bowel Project

MRI: Magnetic Resonance Imaging

OSM: Opposite Side Matching

PRO: Patient-reported outcomes

TRAM: Transverse Rectus Abdominis Myocutaneous

1. Chapter One: Introduction

1.1 General Introduction

A substantial number of female breast cancer patients with unilateral invasive breast cancer opt for elective contralateral prophylactic mastectomy (CPM), even in cases where these patients are at low risk for cancer recurrence and where there is no proven oncological advantage of CPM, and the trend appears to be rising[1,2,3]. Little is known about the extent to which women who have had a unilateral skin–sparing mastectomy for oncological reasons with an immediate prosthetic reconstruction elect to have further surgical procedures to the opposite uninvolved "healthy" breast and, if so, why they choose to do so. Patient-reported outcomes (PRO) are not typically collected post-procedure. The aim of this study was to compare PRO in female breast cancer patients who either opted for CPM or who had unilateral skin–sparing mastectomy with an immediate prosthetic reconstruction, both in terms of patients' impression of breast symmetry and satisfaction with their breasts.

1.2 Objectives

Major Objectives:

- To ascertain patients' impressions of breast symmetry two years or more after the index procedure.
- To determine patient satisfaction with their breasts using a standardised questionnaire.

Minor objectives:

- To determine the average number of repeat surgeries, for cosmetic purposes, carried out.

- To describe any further surgeries undertaken with the average time interval between the index procedure and the subsequent procedure/s.

1.1 Literature Review

Over the course of the last century, breast cancer surgery has progressed from a considerably "mutilating"[4] procedure to one that gives the surgeon, and patient, a variety of options for reconstruction. These advances in surgical reconstruction continue to evolve as the understanding of, and management options for, breast cancer surgery are explored. Studies such as the National Surgical Adjuvant Breast and Bowel Project (NSABP) B04[5], B06[6], Milan 3[7], together with a host of other such studies, have demonstrated that oncological surgery for breast cancer has entered a new paradigm. Minimally aggressive surgery (breast conserving surgery with radiation) has gained favour and has been shown to have equivalent outcomes with some studies showing better cancer survival when compared with its more aggressive predecessor (mastectomy).

Breast conserving surgery is a marked improvement on the radical mastectomy originally described by Halstead in the 1890s and on the modified radical mastectomy of the 1960s[8]. The introduction of the skin-sparing mastectomy in the latter part of the twentieth century has seen a wide selection of reconstruction options become available to surgeons and patients who chose to undergo mastectomies for a variety of oncological and other reasons.

Breast cancer survival rates have further improved due to advances in other disciplines associated with the treatment of breast cancer patients. Non-surgical therapies such as chemotherapy, hormonal therapy and other targeted therapies have also played a significant role in increased survival rates. Improvements in

imaging modalities and the addition of Magnetic Resonance Imaging (MRI) have resulted in earlier detection of disease and earlier intervention, which in turn allows for a far more conservative surgical approach.

Treatment decisions for breast cancer now involve multi-disciplinary teams, which focus not only on the surgical but the psychological aspect of the disease and the patient's own experience and perspective. Complementary approaches such as psychological counselling have been integrated into the modern breast unit. This new awareness of the patient's perspective has altered the relationship between the surgeon and patient from a dictatorial one to one more closely resembling a partnership. It has consequently given the patient a voice in the treatment-related decision-making process.

It has been well established in recent literature that there has been a significant increase in the number of female breast cancer patients opting for CPM, even in cases where these patients are at low risk for opposite side malignancy and where there is no proven oncological advantage of CPM[1,9,10]. Morrow[11], in a 2011 conference report for the American Society of Clinical Oncology (ASCO), noted that "less than 0.5% of breast cancers now spread to the second breast". Nonetheless, many patients choose this option. These patients are typically younger, more educated women, who research their condition and, together with their surgeon, select an approach that they feel best suits them. The reasons these patients opt for CPM are not well understood and involve a myriad of contributing factors from over reporting of risk lesions on radiological assessments (particularly MRI)[12], oncological fears, psychological cancer anxiety to cosmetic concerns. Whether patients consider

the outcome successful, depending on their motivation for CPM, is even less well understood[11].

Studies suggest several factors may play a role. Fear of recurrence and perceived survival benefit are often cited as reasons for CPM[1]. For example, in a longitudinal study of 707 women, more than 80% of patients who underwent CPM were not at high risk for recurrent breast cancer. The study found that a major contributing factor to treatment choice was the patient's mental state at the time of choice. Patients who opted for CPM were approximately three times more concerned about recurrence than patients who did not opt for CPM[11]. Other cited reasons for patients' electing for CPM include testing positive for a BRCA genetic mutation, undergoing a preoperative MRI, and the availability of immediate reconstructive surgery[1].

As the rate of elective CPM increases in breast cancer patients, more patients are opting for immediate bilateral breast reconstruction[13]. This suggests that the increase in contralateral mastectomies may be at least partially ascribed to the development and refinement of skin-sparing mastectomies. Studies have found that breast cancer patients who undergo a reconstructive procedure following mastectomy place significant emphasis on the symmetry of their breasts post-reconstruction[14]. For example, a study of 910 breast reconstructions in 702 breast cancer patients found similar scores in terms of general and aesthetic satisfaction in unilateral and bilateral mastectomy patients but concluded that symmetry was crucial for patient satisfaction in cases where patients had opted for bilateral reconstruction[15]. Perceived aesthetic benefit may therefore be a factor in some patients' choice to opt for CPM with immediate bilateral reconstruction.

It is important that, as we continue to improve patient care and reconstruction in breast cancer, we investigate the implications of elective CPM with reconstruction.

For example, Khan[9], in an editorial in the Journal of Oncology, notes that,

"…there is a great need for… studies of the short- and long-term complications of mastectomy with reconstruction, particularly the frequency of additional surgery and the overall satisfaction with the results of reconstruction compared with expectations."

Some longitudinal studies have shown that a number of women who have elective CPM opt for reconstruction at some point after the initial mastectomies. For example, in a retrospective review of 382 women, followed over a four year period, Nahabedian et al[10] found that a contralateral procedure was performed in 20% of these women. The review found that women were more likely to undergo secondary procedures more frequently after autologous reconstruction than after an implant, and it demonstrated that women were more likely to have a secondary procedure after delayed reconstruction (59%) versus immediate reconstruction (36%)[10].

Nahabedian[16] found very few studies examined "…the management of the reconstructed breast to facilitate symmetry" and cited two studies that looked at symmetry following unilateral breast reconstruction. In the first report, Losken et al reviewed 1394 mastectomy patients of which 705 had immediate reconstruction and 689 had delayed reconstruction. The report found that 67% of women had a contralateral symmetry procedure after delayed reconstruction versus 22% after immediate reconstruction[17]. The study also, interestingly, found that those women who opted for prosthetic reconstruction had a higher incidence of contralateral procedures (89% delayed and 57% immediate) compared with Tram Flap

reconstruction (59% delayed and 18% immediate)[17]. In the second report, Giacalone et al reported on 683 mastectomy patients who had delayed reconstruction, followed over 17 years. The report found that 33.5% of patients with transverse rectus abdominis musculocutaneous reconstruction, 37.8% of patients with latissimus dorsi reconstructions, and 27.6% of patients with implant reconstructions went on to have contralateral symmetry procedures[18]. From this review, Nahabedian concluded that autologous reconstruction was superior to implant reconstruction in terms of symmetry, with particular reference to contour and shape.

Smith et al[15] similarly found that "Patients having unilateral breast reconstruction often require a second stage procedure on the contralateral breast to improve symmetry." The authors opted to perform "…simultaneous contralateral balancing operations at the time of initial reconstruction" to ensure instant symmetry and reduce the need for secondary procedures. They found the approach was safe and particularly effective with autologous reconstruction, with 87% of the patients not requiring a further operation to address symmetry.

On the other hand, another study found that differences exist in the symmetry achieved depending on type of reconstruction. For example, unilateral autologous breast reconstruction has been shown to result in significantly higher patient satisfaction when compared with unilateral prosthetic reconstruction. In comparison, bilateral reconstruction has been shown to result in similar satisfaction levels when comparing, autologous reconstruction, autologous reconstruction with implants, or isolated implant reconstruction[15].

A 10-year longitudinal review[19] of 178,603 mastectomy patients compared unilateral, contralateral prophylactic, and bilateral prophylactic patient groups who had

undergone either autologous or implant reconstructions. The report found that patients who had CPM were the only group who had increased rates of reconstruction over the period of the study. It also found that implant use was greatest in patients who had bilateral mastectomies, and in patients who had CPM, although it also increased over the study period for other types of mastectomy. The report concluded that changing patterns in mastectomy are one of the factors associated with a move away from autologous tissue reconstruction towards reconstruction with implants.

Cordeiro and McCarthy[20] noted that very few studies have looked at the long-term outcomes of two-stage implant reconstruction. Their study, based on a single surgeon's experience with expander/implant reconstruction in 1221 patients over 12 years, evaluated the long-term aesthetic outcome, complications, and satisfaction in a cohort of 315 of these patients who, collectively, had 410 reconstructions. The study found that 88% of these patients had a good to outstanding aesthetic outcome and 95% reported satisfaction with their reconstruction. Laterality of the reconstruction was a significant predictor of general cosmetic outcome, with bilateral reconstruction having higher aesthetic grades than unilateral reconstructions.

Considering that so many mastectomy patients are increasingly opting for reconstruction with implants, whether immediate or delayed, and considering that bilateral reconstructions have been found to have higher aesthetic grades than unilateral reconstructions, the question at this stage is whether, in low-risk patients, offering bilateral mastectomy with immediate reconstruction is ethical, or even preferable. Though immediate reconstruction following an elective bilateral mastectomy may have little oncological benefit, there may be other benefits

including increased patient satisfaction, and/or a superior cosmetic result. If immediate reconstruction does spare the patient from further surgeries, and lead to an improved long-term cosmetic outcome, along with an increase in patient satisfaction, then perhaps a case can be made for justifying this procedure.

The literature suggests that unilateral reconstruction with natural autologous tissue would probably change shape and age much closer to a natural breast than reconstruction with an implant. However, in cases where patients have bilateral reconstruction, it suggests that the specific type of reconstruction used may matter less than the fact that the reconstruction method is matched. However, there is a paucity of information in the literature about whether matching procedures are a factor in ultimate patient satisfaction and overall aesthetic result. In addition, there is very little information about how to advise a patient regarding the management of the contralateral side.

As a result, this study aimed to investigate what percentage of women who had a unilateral skin–sparing mastectomy for oncological reasons with an immediate prosthetic reconstruction, elected to have further surgical procedures to the opposite, uninvolved “virgin” breast and, if so, why they chose to do so. The study anticipated that the reconstructed breast would age differently to the contralateral natural “virgin” breast and that this may potentially result in women who have not had opposite-side matching procedures (OSM) opting for further corrective surgeries.

The remainder of this report outlines the study methods and materials before delving into the study results, followed by a discussion and conclusions for the study.

2. Chapter Two: Methods and Materials

This chapter provides an overview of the methods, sample, and materials (BREAST-Q questionnaire) used for the study. The study was implemented at the medical practice of Professor Carol Benn, in private practice in Johannesburg, South Africa. The study design was a descriptive cross-sectional questionnaire-based study. The questionnaire utilised was an established, valid, and reliable patient-reported outcome tool - the BREAST-Q[21]. The study was approved by the University of Witwatersrand Ethics Committee (Approval number:

M140883).

2.1 Materials

The BREAST-Q questionnaire[Error! Reference source not found.] post-operative reconstruction module looks at patient's perceptions of their breasts following breast reconstruction using quality of life and satisfaction domains. The conceptual framework and questionnaire items for the BREAST-Q were developed through interviews with patients, panel interviews with experts, focus group discussions and a literature review[Error! Reference source not found.]. The study utilised the post-operative reconstruction module of the BREAST-Q, which was designed "…to quantify different aspects of a woman's quality of life and satisfaction with breast reconstruction surgery"[22].

The BREAST-Q reconstruction module has eight post-operative scales within the two domains (quality of life and satisfaction). Under the quality of life domain, the scales include Psychosocial Wellbeing, Sexual Wellbeing, and Physical Wellbeing. Under the satisfaction domain, the scales include Satisfaction with Breasts,

Satisfaction with Nipples, Satisfaction with Abdomen, Satisfaction with Outcome, and Satisfaction with Care (including Satisfaction with Information, Satisfaction with Plastic Surgeon,

Satisfaction with Medical Team (other than surgeon), and Satisfaction with Office Staff). In validation studies, the reconstruction module scales had test-retest reliability intraclass correlation coefficients between 0.90 and 0.96, internal consistency scores (Crobach coefficient alpha) of between 0.92 and 0.96, and both content and construct validity[Error! Reference source not found.].

In addition to the BREAST-Q questionnaire, patients were asked several demographic questions and questions relating to the type of reconstructive surgery they underwent. They were asked whether they had considered further surgery for purely cosmetic reasons, whether they underwent further surgery for purely cosmetic reasons, and if so, how long after their initial surgery they had had the following surgery. They were asked which side they had the second procedure, and whether they had had any further (i.e., multiple) surgeries.

2.2 Sample

The study population included female breast cancer patients who underwent skin-sparing mastectomies with immediate prosthetic reconstruction on at least one breast over the period January 2012 to December 2018. The sample frame included patients treated by multiple reconstructive surgeons and two oncological surgeons in a dedicated private breast care practice.

Patient files from January 2012 to December 2018 in the practice were reviewed. Patients who had previous prosthetically augmented breasts, previous mastopexies,

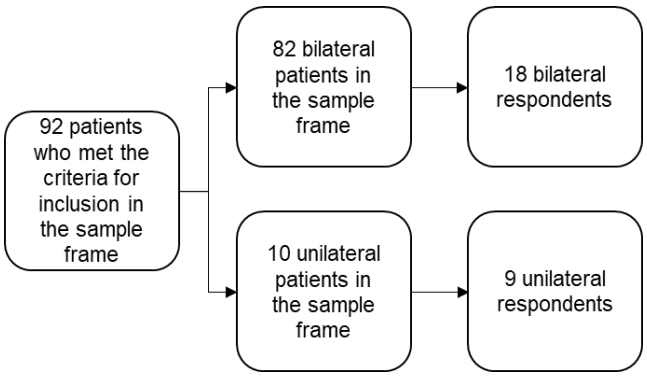
or previous breast reduction surgery were excluded. Only patients who provided consent to file review for research purposes in the practice were included in the sample frame.

All patients meeting the criteria for inclusion within the study period, and included in the sample frame, were approached to complete the post-operative reconstruction module of the BREAST-Q questionnaire. The questionnaire was designed and delivered in RedCap, pre-tested by the researcher, and made available in English. The patients were contacted via email and were asked to complete the questionnaire via RedCap (a link was sent to each patient). Instructions for answering the survey were included in the email, including a notification to prospective respondents that their responses were both voluntary and confidential. The respondents provided electronic consent prior to taking part in the study. Respondents were guaranteed anonymity and confidentiality in reporting.

Patients that had not responded after a period of 7 days were reminded of the survey and were followed up via a RedCap-generated email notification. There was a total of 92 patients in the original sample frame.

Below is a flow diagramme describing how the final sample was achieved:

Figure 1: Flow Diagramme Depicting Sample Selection



2.3 Analysis

The study results were analysed using the BREAST-Q built-in data analysis function, which used scoring software, QScore (available at http://qportfolio.org/score-breast-q-breast-cancer-2/). First, the raw scores for each respondent were transferred from an Excel spreadsheet produced via RedCap into the QScore reconstruction post-operative Excel template. Next, the scores were imported to the QScore scoring software. The individual responses of each patient on each scale (raw scores) were converted into continuous scores, which ranged from 0-100, with a higher number indicating better quality of life or higher satisfaction. The BREAST-Q does not produce an overall score[23].

The demographic questions, and questions relating to whether the patients had considered and/or had further procedures for purely cosmetic reasons after the initial reconstruction procedure, were analysed separately. Categorical variables were assessed using Pearson's chi-square test. A Students t-test was used for variables with a normal distribution to compare mean score changes, using a p-value < 0.05 to indicate a significant result.

To summarise, the study was descriptive in nature and used a reliable and valid tool with a built-in data analysis function.

3. Chapter Three: Results

This chapter provides the summary results from the QScore programme and additional questions for each group of questionnaire respondents: the unilateral skin–sparing mastectomy with an immediate prosthetic reconstruction group (unilateral implant-based reconstruction group) and the contralateral prophylactic

mastectomy with bilateral immediate implant-based opposite side matching reconstruction group (bilateral with OSM group).

Separate summary scores were produced for the unilateral implant-based reconstruction group (n = 9 respondents) and the bilateral with OSM group (n = 18 respondents). In addition, basic descriptive statistics were used to relay the overall findings of the study and the findings for each group.

Of the patients with valid email addresses, there were 29 unique respondents representing a response rate of 20 percent. This is fairly low in comparison with the results of a systematic review, which found a response rate of between 32 percent to 100 percent across thirty-eight studies[24].

3.1 Demographic Details

The mean age of the respondents was comparable at 55.67 (range 31–70) and 53.94 (range 35–74) months, in the unilateral implant-based reconstruction and bilateral with OSM groups respectively (p = 0.690, Table 1). Similarly, most of the respondents were White in both groups. No other demographic data were collected.

There are no major differences in the basic demographic data that might influence the decisions made regards type of surgery and the responses to the surgery. The similarity of the respondents to the non-responders is unknown. A well-resourced group with medical insurance and the ability to access and complete the computer assessments using the RedCap system is inferred but was not directly captured in the survey.

Table 1: Demographic Details

	Unilateral Group (n=9)	**Bilateral Group (n=18)**
Mean age (in years)	55.67 (Range 31 - 70)	53.94 (Range 35 - 74)

	Unilateral Group (n=9)	Bilateral Group (n=18)
Race		
Black African	1	0
White	7	17
Asian	0	1
Coloured	0	0
Unspecified	1	0

3.2 Patient Characteristics

The numbers of patients who considered further surgery following their initial reconstruction was similar between the groups (5 of 9 in the unilateral implant-based reconstruction group and 8 of 18 in the bilateral with OSM group, p = 0.585, Table 1). The number of patients that underwent a second procedure following initial reconstruction was also comparable across the groups (3 of 9 in the unilateral implant-based reconstruction group and 4 of 18 in the bilateral with OSM group, p = 0.534, Table 1). The number of patients that underwent more than two surgeries was the same in both groups (1 of 3 in the unilateral implant-based reconstruction group and 1 of 4 in the bilateral with OSM group, p = 0.809, Table 1). In both groups, a similar number of patients considered undergoing any other breast surgeries (7 of 9 in the unilateral implant-based reconstruction group and 10 of 18 in the bilateral with OSM group, p = 0.333, Table 1).

Table 2: Patient Characteristics

	Unilateral Group (n=9)	Bilateral Group (n=18)	p-value	Statistic
Considered further surgery following initial reconstruction			0.585957	Chi Square
-Yes	5	8		
-No	4	10		
Time from first surgery to considering second surgery			0.980104	Chi Square
- < 6 months	2	3		
- 6 months - 1 year	1	1		
- 1 year - 2 years	1	2		
- > 2 years	1	2		
Underwent second surgery following initial reconstruction			0.534561	Chi Square
-Yes	3	4		
-No	6	14		
Had more than two surgeries following initial reconstruction			0.80915	Chi Square
-Yes	1	1		
-No	2	3		
Any other breast surgeries considered			0.333804	Chi Square
-Yes	7	10		
-No	2	7		

3.2 Summary Scores

The QScore programme returned summary scores for the unilateral implant-based reconstruction group (Table 2) and the bilateral with OSM group (Table 3). Higher scores indicated better quality of life or higher satisfaction.

Table 3: BREAST-Q Reconstruction Post-Operative Module Summary Scores - Unilateral implant-based reconstruction group

Patient ID	1. Satisfaction with Breasts	3. Satisfaction with Outcome	4. Psychosocial Wellbeing	5. Sexual Wellbeing	6. Physical Wellbeing: Chest	7.Physical Wellbeing: Abdomen	10. Sat isfaction with Nipples	11. Satisfaction with Information	12. Satisfaction with Surgeon	13. Satisfaction with Medical Staff	14. Satisfaction with Office Staff
1	30	67	39	16	68	N/A	N/A	41	39	25	58
2	29	0	50	22	50	N/A	N/A	31	17	100	85
4	100	100	100	69	100	N/A	N/A	100	100	100	100
5	36	32	46	22	85	N/A	N/A	53	77	100	100
7	85	100	100	83	91	N/A	N/A	65	91	59	100
16	81	86	65	53	71	89	N/A	67	100	100	85
17	91	55	79	71	85	100	67	77	100	100	100
18	33	86	100	55	100	N/A	N/A	36	0	69	91
20	55	75	100	63	77	N/A	45	50	71	79	80

Table 4: BREAST-Q Reconstruction Post-Operative Module Summary Scores - Bilateral with OSM Group

Patient ID	1. Satisfaction with Breasts	3. Satisfaction with Outcome	4. Psychosocial Wellbeing	5. Sexual Wellbeing	6. Physical Wellbeing: Chest	7.Physical Wellbeing: Abdomen	10. Sat isfaction with Nipples	11. Satisfaction with Information	12. Satisfaction with Surgeon	13. Satisfaction with Medical Staff	14. Satisfaction with Office Staff
3	69	67	92	90	91	N/A	N/A	71	100	36	100
6	43	100	23	31	50	N/A	N/A	100	100	100	100
8	40	51	79	43	85	N/A	N/A	43	42	100	100
9	57	47	65	57	77	N/A	61	51	100	59	58
10	85	47	100	100	100	N/A	N/A	100	100	100	100
11	91	100	100	83	91	N/A	N/A	100	100	100	100
12	27	55	14	16	33	21	0	60	100	100	100
13	85	21	0	0	60	N/A	N/A	37	100	100	75
14	57	39	100	22	68	N/A	N/A	32	45	100	58
15	61	75	86	57	77	N/A	N/A	50	60	91	100
19	40	35	48	32	53	N/A	N/A	47	51	59	58

Patient ID	1. Satisfaction with Breasts	3. Satisfaction with Outcome	4. Psychosocial Wellbeing	5. Sexual Wellbeing	6. Physical Wellbeing: Chest	7.Physical Wellbeing: Abdomen	10. Sat isfaction with Nipples	11. Satisfaction with Information	12. Satisfaction with Surgeon	13. Satisfaction with Medical Staff	14. Satisfaction with Office Staff
21	100	100	100	100	100	N/A	N/A	100	100	100	100
22	67	47	52	41	74	N/A	N/A	46	33	39	49
23	41	39	60	29	74	N/A	N/A	69	100	28	45
24	64	55	60	60	71	N/A	N/A	64	56	100	100
25	52	39	53	52	85	N/A	N/A	36	42	0	58
26	91	100	82	100	77	N/A	N/A	65	100	74	91
27	78	75	73	100	85	N/A	N/A	60	58	55	49

3.3 BREAST-Q Results

Given the small and unequal sample sizes, the data was not eligible for inferential statistical analysis. Instead, each item in the BREAST-Q reconstruction module was interpreted using box plots to visualise the data. The study used descriptive data analysis to interpret the results. Where available, normative values are presented as a point of comparison with the study results.

Box plots statistically summarise the data using the median and interquartile range, which "…are robust in the presence of skewness and outliers and require no

assumptions about the population"[25]. The centre line represents the median, and the extremes of the box represent the 1st and 3rd quartiles. The vertical lines outside of the boxes lines represent the most extreme data points in the dataset; outliers are excluded.

3.3.1 Satisfaction with Breasts

The boxplot below represents the overall BREAST-Q reconstruction module scores for Satisfaction with Breasts, comparing unilateral implant-based reconstruction and bilateral with OSM groups. No outliers were found in the dataset.

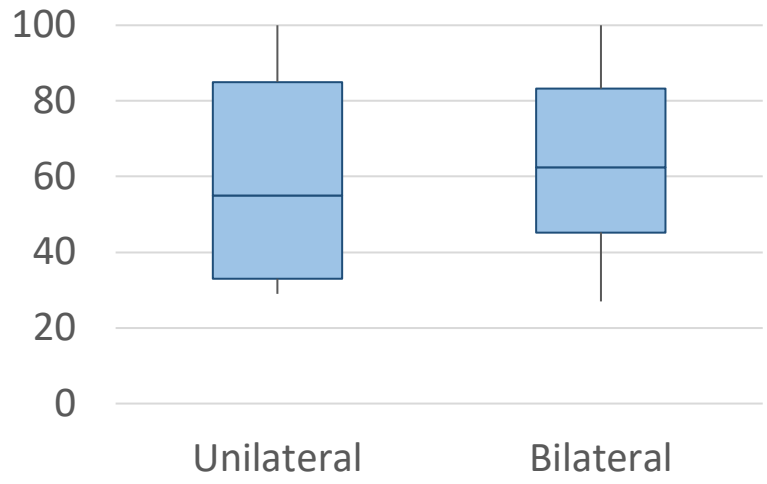


Figure 2: Box plot of patients' Satisfaction with Breasts, comparing unilateral implant-based reconstruction and bilateral with OSM groups

Patients' Satisfaction with Breasts was slightly higher in the bilateral with OSM group with a median of 62.5 out of 100, and a higher lower quartile, compared to the unilateral implant-based reconstruction group (median = 55). The lower interquartile range (IQR) in the bilateral with OSM group (IQR =38, compared with an IQR = 52 in the unilateral implant-based reconstruction group) suggests that that the bilateral with OSM group varied less in response and was more consistent.

3.3.2 Satisfaction with Outcome

The boxplot below represents the overall BREAST-Q reconstruction module scores for Satisfaction with Outcome, comparing unilateral implant-based reconstruction and bilateral with OSM groups. One outlier (defined as a data point that lies beyond 1.5 IQRs below the first quartile or above the third quartile in the dataset) was removed in the unilateral implant-based reconstruction group.

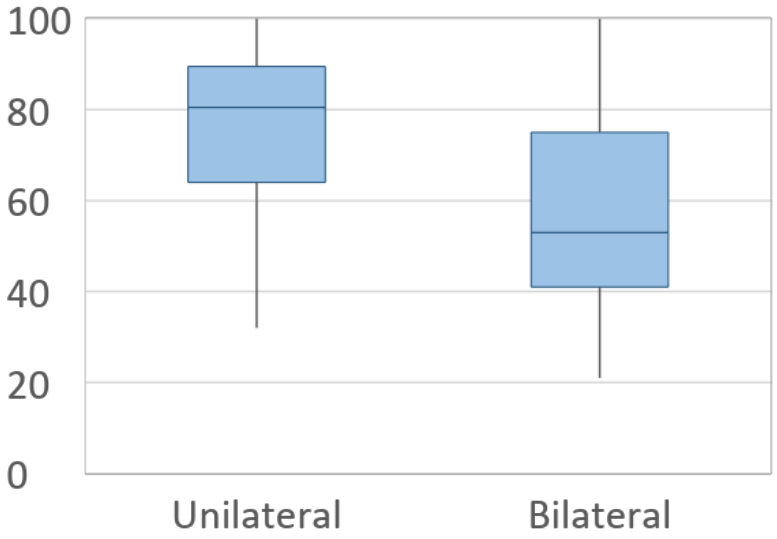


Figure 3: Box plot of patients' Satisfaction with Outcome, comparing unilateral implant-based reconstruction and bilateral with OSM groups

Patients' Satisfaction with Outcome was higher in the unilateral implant-based reconstruction group with a median of 80.5 out of 100, and higher lower and upper quartiles, compared to the bilateral with OSM group (median = 53). The lower IQR in the unilateral implant-based reconstruction group (IQR =25.5, compared with an IQR = 34 in the bilateral with OSM group) suggests that that the unilateral implant-based reconstruction group varied less in response and was more consistent.

3.3.3 Psychosocial Wellbeing

The boxplot below represents the overall BREAST-Q reconstruction module scores for Psychosocial Wellbeing, comparing unilateral implant-based reconstruction and bilateral with OSM groups. No outliers were found in the dataset.

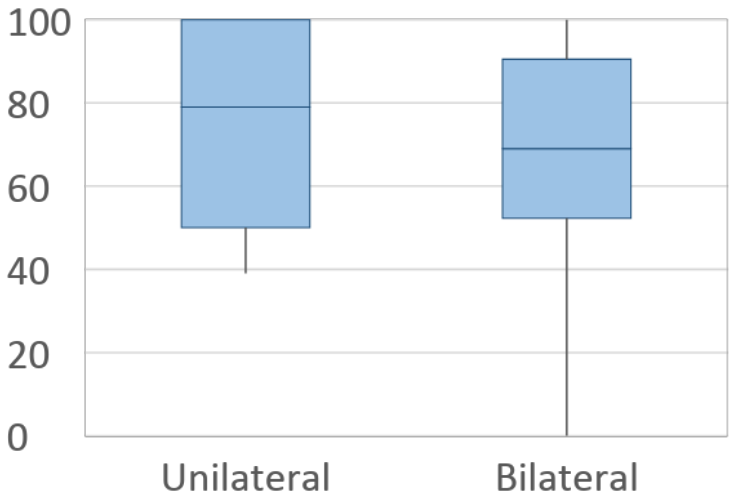


Figure 4: Box plot of patients' Psychosocial Wellbeing, comparing unilateral implant-based reconstruction and bilateral with OSM groups

Patients' Psychosocial Wellbeing was slightly higher in the unilateral implant-based reconstruction group with a median of 79 out of 100 compared to the bilateral with OSM group (median = 69). The lower IQR in the bilateral with OSM group (IQR =38, compared with an IQR = 50 in the unilateral implant-based reconstruction group) suggests that that the bilateral with OSM group varied less in response and was more consistent.

3.3.4 Sexual Wellbeing

The boxplot below represents the overall BREAST-Q reconstruction module scores for Sexual Wellbeing, comparing unilateral implant-based reconstruction and bilateral with OSM groups. No outliers were found in the dataset.

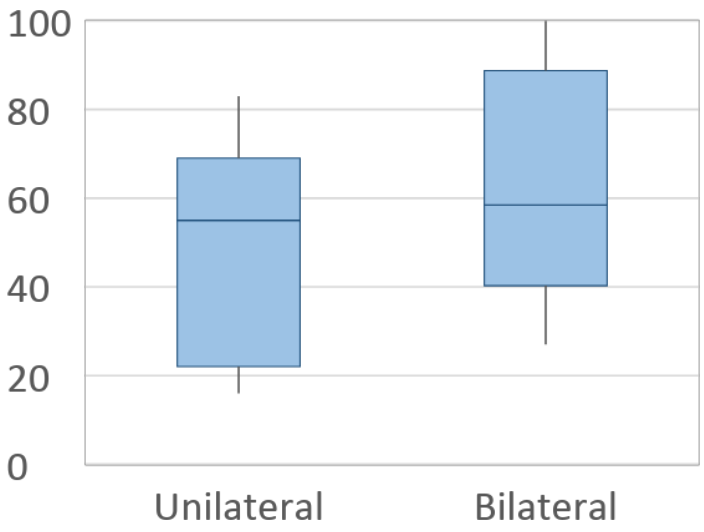


Figure 5: Box plot of patients' Sexual Wellbeing, comparing unilateral implant-based reconstruction and bilateral with OSM groups

Although the median value was similar, patients' Sexual Wellbeing was higher in the bilateral with OSM group with a median of 58.5 out of 100, and higher lower and upper quartiles, compared to the unilateral implant-based reconstruction group (median = 55). The IQR was similar in both groups (48 and 47.5, consecutively).

3.3.5 Physical Wellbeing: Chest

The boxplot below represents the overall BREAST-Q reconstruction module scores for Physical Wellbeing: Chest, comparing unilateral implant-based reconstruction and bilateral with OSM groups. One outlier (defined as a data point that lies beyond 1.5 IQRs below the first quartile or above the third quartile in the dataset) was removed in the bilateral with OSM group.

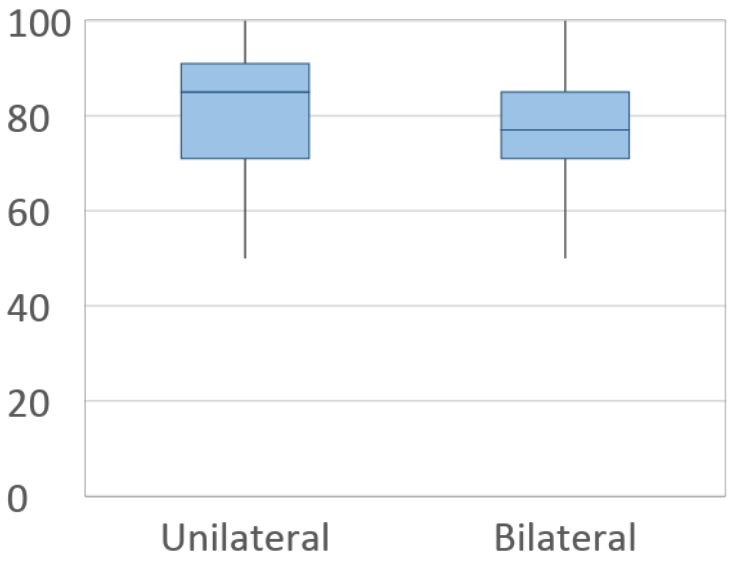


Figure 6: Box plot of patients' Physical Wellbeing, comparing unilateral implant-based reconstruction and bilateral with OSM groups

Patients' Physical Wellbeing: Chest was higher in the unilateral implant-based reconstruction group with a median of 85 out of 100 compared to the bilateral with OSM group (median = 77). The lower IQR in the bilateral with OSM group (IQR =14, compared with an IQR = 20 in the unilateral implant-based reconstruction group) suggests that that the bilateral with OSM group varied less in response and was more consistent.

3.3.6 Physical Wellbeing: Abdomen

There were too few respondents (n = 2 in the unilateral implant-based reconstruction and n = 1 in the bilateral with OSM group) to run descriptive analyses on this item. This was because only three respondents reported having a TRAM or DIEP flap at some point in their reconstruction journey. The bilateral with OSM respondent reported low Physical Wellbeing (with a score of 21 out of 100) compared with the two unilateral implant-based reconstruction respondents (with scores of 89 and 100

out of 100). These scores were not included in the discussion as they did not pertain to this study.

3.3.7 Satisfaction with Nipples

There were too few respondents (n = 2 in the unilateral implant-based reconstruction and n = 2 in the bilateral with OSM group) to run descriptive analyses on this item. The bilateral with OSM respondents reported varied Satisfaction with Nipples (with scores of 0 and 61 out of 100) compared with the two unilateral implant-based reconstruction respondents (with scores of 45 and 67 out of 100). These scores were not included in the discussion as they did not pertain to this study.

3.3.8 Satisfaction with Information

The boxplot below represents the overall BREAST-Q reconstruction module scores for Satisfaction with Information, comparing unilateral implant-based reconstruction and bilateral with OSM groups. No outliers were found in the dataset.

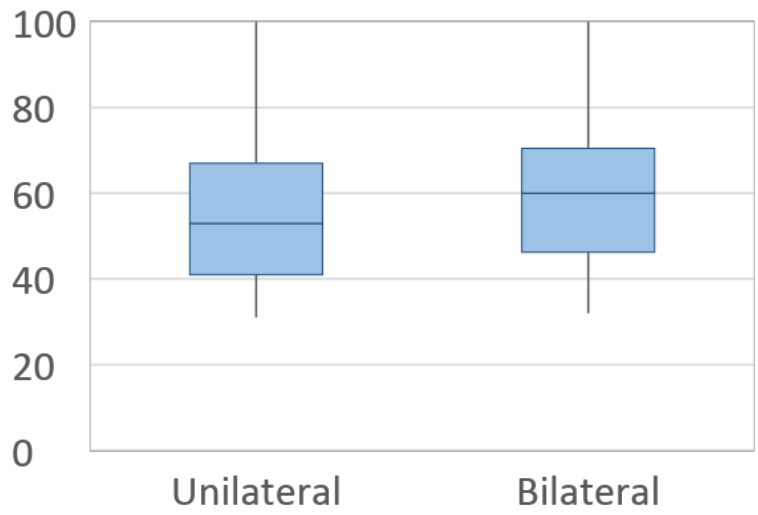


Figure 7: Box plot of patients' Satisfaction with Information comparing unilateral implant-based reconstruction and bilateral with OSM groups

Patients' Satisfaction with Information was slightly higher in the bilateral with OSM group with a median of 60 out of 100 compared to the unilateral implant-based reconstruction group (median = 53). The IQR was similar in both groups (26 and 24, consecutively).

3.3.9 Satisfaction with Surgeon

The boxplot below represents the overall BREAST-Q reconstruction module scores for Satisfaction with Surgeon, comparing unilateral implant-based reconstruction and bilateral with OSM groups. No outliers were found in the dataset.

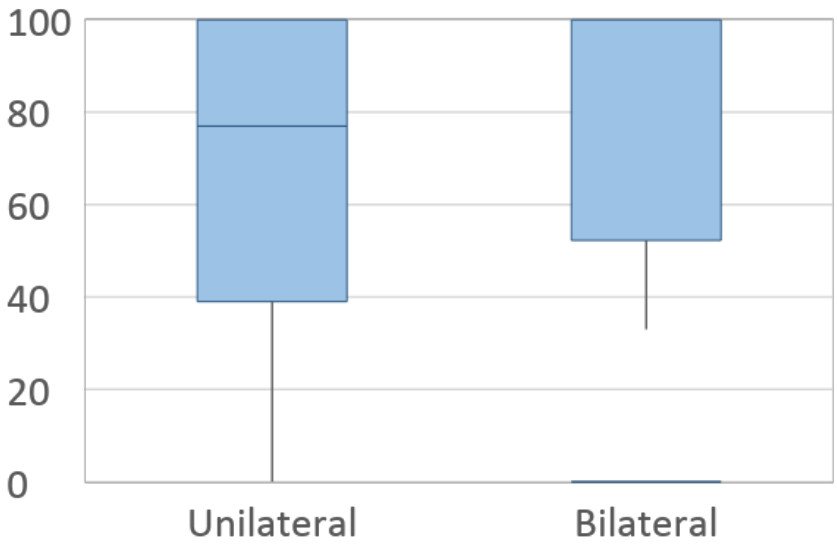


Figure 8: Box plot of patients' Satisfaction with Surgeon, comparing unilateral implant-based reconstruction and bilateral with OSM groups

Patients' satisfaction with the surgeon was substantially higher in the bilateral with OSM group with a median of 100 out of 100, and a higher lower quartile, compared to the unilateral implant-based reconstruction group (median = 77). The lower IQR in the bilateral with OSM group (IQR =48, compared with an IQR = 61 in the unilateral implant-based reconstruction group) suggests that that the bilateral with OSM group varied less in response and was more consistent.

3.3.10 Satisfaction with Medical Staff

The boxplot below represents the overall BREAST-Q reconstruction module scores for Satisfaction with Medical Staff, comparing unilateral implant-based reconstruction and bilateral with OSM groups. No outliers were found in the dataset.

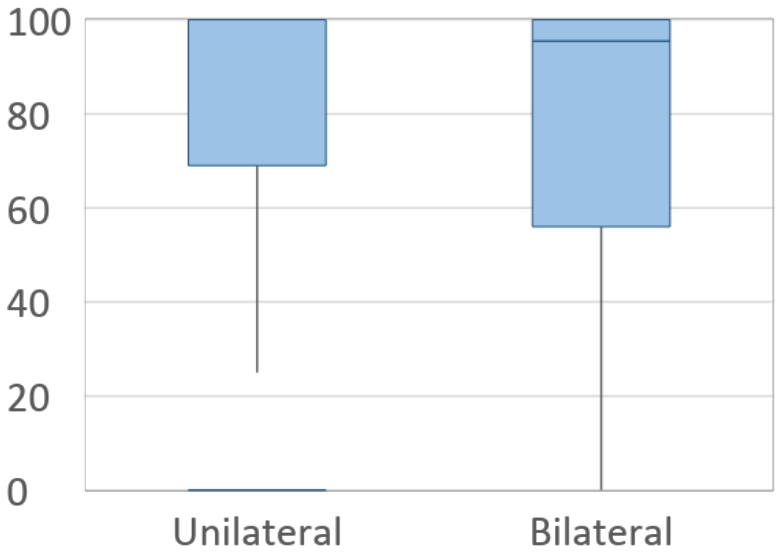


Figure 9: Box plot of patients' Satisfaction with Medical Staff, comparing unilateral implant-based reconstruction and bilateral with OSM groups

Patients' Satisfaction with Medical Staff was marginally higher in the unilateral implant-based reconstruction group with a median of 100 out of 100, and a higher lower quartile, compared to the unilateral implant-based reconstruction group (median = 95.5). The lower IQR in the unilateral implant-based reconstruction group (IQR =31, compared with an IQR = 44 in the bilateral with OSM group) suggests that that the unilateral implant-based reconstruction group varied less in response and was more consistent.

3.3.11 Satisfaction with Office Staff

The boxplot below represents the overall BREAST-Q reconstruction module scores for Satisfaction with Office Staff, comparing unilateral implant-based reconstruction and bilateral with OSM groups. One outlier (defined as a data point that lies beyond 1.5 IQRs below the first quartile or above the third quartile in the dataset) was removed in the unilateral implant-based reconstruction group.

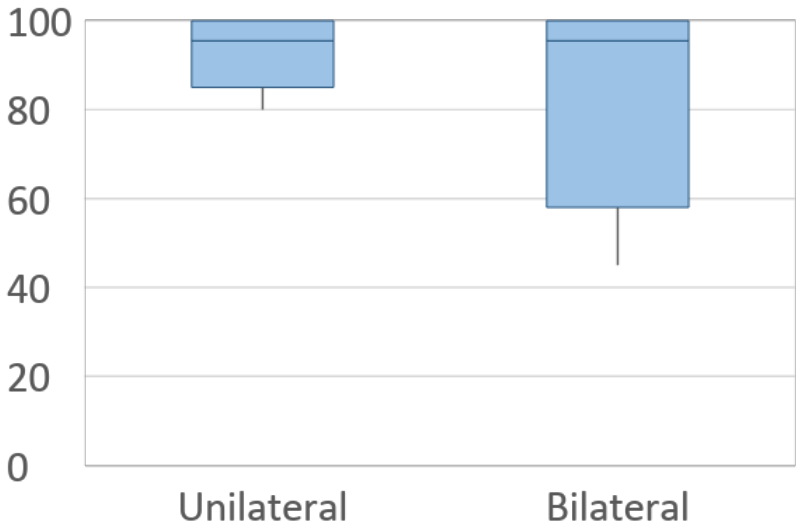


Figure 10: Box plot of patients' Satisfaction with Office Staff, comparing unilateral implant-based reconstruction and bilateral with OSM groups

Although the median values were the same (95.5 of 100), patients' Satisfaction with Medical Staff had a higher lower quartile in the bilateral with OSM group compared to the unilateral implant-based reconstruction group. The lower IQR in the unilateral implant-based reconstruction group (IQR =15, compared with an IQR = 42 in the bilateral with OSM group) suggests that that the unilateral implant-based reconstruction group varied less in response and was more consistent.

To summarise, this chapter showed the difference in BREAST-Q scores between the bilateral with OSM and unilateral implant-based reconstruction mastectomy groups.

The response rate was fairly low in comparison to other studies, with the final sample representing approximately 20 percent of the sample frame. In the next section, the results are interpreted and discussed in this context.

4. Chapter Four – Discussion and Conclusion

4.1 Discussion

4.1.1 Major Objectives

The major objectives of this research were to “ascertain patients’ impressions of breast symmetry two years or more after the index procedure” and to “determine patients satisfaction with their breasts using a standardised questionnaire’: the BREAST-Q.”

As described in the introduction, there is a paucity of research comparing long-term Patient Reported Outcomes (PRO) in unilateral prosthetic reconstruction compared to bilateral prosthetic based reconstruction with a contralateral prophylactic mastectomy. This study hypothesised that a patient undergoing a unilateral procedure with an implant would likely, at some stage in the future, be dissatisfied with the symmetry of her breasts, prompting her to seek further symmetrising procedures. The underlying hypothesis was based on the expectation that the implant-based reconstruction, over time, would age differently to the natural contralateral breast. The prosthesis would be expected to behave in a different manner longitudinally to that of autologous tissue and would eventually result in a significant disparity between the two breasts.

Prosthetic-based reconstruction contradicts the well-known plastic surgery adage of “replace like with like” and creates a more rounded and projected breast with medial

upper pole fullness that a natural breast does not have. The study therefore anticipated that patients opting for bilateral immediate reconstruction with prostheses would have higher satisfaction levels, both initially and in the long term, than those opting for a unilateral procedure as the bilateral prosthetic reconstructions would initially be more symmetrical and age in a similar way.

Weight fluctuation is another consideration when considering patients' perceptions of their breasts after reconstruction, particularly regarding the anticipated differential outcomes between unilateral implant-based reconstruction and bilateral with OSM patients. Natural breast tissue is subject to the normal influences of a high caloric diet or the hormonal effects of menopause, pregnancy, and hormonal ablation therapy, whereas prosthetic reconstruction is not. Patients opting for bilateral immediate reconstruction with prostheses would be anticipated to have higher satisfaction levels compared with patients opting for a unilateral procedure in the context of weight fluctuation in the natural breast.

The Satisfaction with Outcome module in the BREAST-Q assesses patients' perceptions of the overall outcome of the surgery including the patient's experience of the procedure and whether the patient, in hindsight, would undergo the procedure again (versus not having a reconstruction). The module also queries whether the patient would recommend the procedure to other women and whether, or not, the surgery met their expectations.

The unilateral implant-based reconstruction group had an overall Satisfaction with Outcome median score of 80.5 compared with a median of 53 in the bilateral with OSM group. This result is not in keeping with the study hypothesis. The large score difference could arguably relate to patient expectations due to pre-operative

counselling, metering expectations, and preparing the patient for possible asymmetries. Previous research has shown that patients' satisfaction with preoperative information and interaction with their plastic surgeon may significantly affect their satisfaction with their breasts and with their overall significantly affect their satisfaction with their breasts and with their overall outcome[26,27]. However, the unilateral implant-based reconstruction group was less satisfied with their surgeon and the information received than the bilateral with OSM group and therefore this may not have been such an influential factor in this study.

It is possible that the unilateral implant-based reconstruction group may have been averse to multiple surgeries prior to selecting their choice of reconstruction and may have been relieved to have only had one surgical procedure. This conservative approach may have initially dissuaded them from the contralateral matching procedure at the outset and therefore contributed to overall Satisfaction with Outcome post-operatively.

Another contributing factor could be the baseline anxiety levels among women opting for bilateral reconstruction, which have been found to be significantly higher pre-operatively compared with versus unilateral implant reconstructions. This may indicate that "…these patients have a distinct set of concerns that differentiates them from those choosing autologous tissue."[28] Therefore, their experience could be affected accordingly.

A study looking at the trade-offs associated with CPM in women opting for breast reconstruction[Error! Reference source not found.] found a higher rate of complications following bilateral autologous and bilateral implant reconstructions. Should the patients in the bilateral with OSM group have experienced complications, this may also explain the

lower Satisfaction with Outcome scores for this group compared with the unilateral implant-based reconstruction group in this study.

The Satisfaction with Breasts module in the BREAST-Q assesses women's perceptions of how matched/symmetrical they believe their breasts to be, how they feel about their breasts (clothed and unclothed), and how they feel about the appearance of their breasts. The study results showed slightly higher patient Satisfaction with Breasts, including symmetry, in the bilateral with OSM group compared to the unilateral implant-based reconstruction group, which was in keeping with our hypothesis. What was interesting however is that these scores were not as vastly different as expected (median of bilateral with OSM group = 62.5 vs 55 in the unilateral implant-based reconstruction group). Razdan et al[29] cautioned that the baseline Satisfaction with Breasts could positively or negatively influence post-operative BREAST-Q scores and that future studies should account for these influences.

Comparing these data against normative values, which were obtained from a sample of more than 1,200 women with demographic and physical characteristics representing "…the diverse population of women undergoing breast cancer treatment and reconstruction"**Error! Reference source not found.**, the unilateral implant-based reconstruction group median score (55) was slightly below the normative mean of 58, while the bilateral with OSM group median score (62.5) was slightly higher. In other words, in the sample of women in this study, those who opted for bilateral implant-based reconstruction had a better impression of their breasts post-operatively than the average women has of her virgin breasts.

The latter finding is in keeping with previously published BREAST-Q Data from the Mastectomy Reconstruction Outcomes Consortium (MROC) study of post-operative implant-based reconstruction patients, whose mean score on the Satisfaction with Breasts scale was 63 – also above the normative mean. Mundy et al. concluded from the MROC study that, "Breast reconstruction can now be associated with a 'return to normalcy', a clinically relevant finding, and a finding that mastectomy alone has not demonstrated." **Error! Reference source not found.**

The BREAST-Q Psychosocial Wellbeing module assesses women's perceptions of their body, including how confident and accepting they are of their body, how confident they feel in a social environment, and how emotionally healthy they feel. The study found higher Wellbeing median scores in the unilateral implant-based reconstruction group (79) compared to the bilateral with OSM group (69). Comparing these results against normative data**Error! Reference source not found.**, the unilateral implant-based reconstruction group median score of 79 was higher than the normative mean of 71, while the bilateral with OSM group median score of 69 was approximately on par. Again, pre-operative differences between the groups, including anxiety levels, could be a contributing factor.

The BREAST-Q Sexual Wellbeing module assesses women's perceptions of their sexual attractiveness (clothed and unclothed), how confident they feel sexually and their comfort and ease during sexual activity. The study found similar sexual satisfaction scores between the two groups, with the bilateral with OSM group having a marginally higher median score (58.5) compared to the unilateral implant-based reconstruction group (median = 55). Comparing these results against normative data**Error! Reference source not found.**, the unilateral implant-based reconstruction group

median score of 55 was on par with the normative mean of 56, while the bilateral with OSM group median score of 58.5 was marginally higher.

The BREAST-Q Physical Wellbeing module asks about women's perceptions of physical discomfort (pain), and other issues in the breast area, such as tenderness and limitations in activity, as well as difficulties with sleep due to discomfort. The study found that patients' Physical Wellbeing in the chest area was higher in the unilateral implant-based reconstruction group with a median of 85 compared to the bilateral with OSM group with a median of 77. Comparing these results against normative data[30], both the unilateral and the bilateral OSM group scores were lower than the normative mean of 93, which is to be expected.

The BREAST-Q Satisfaction with Care modules cover several areas including how well patients felt they were informed about the surgery (information and options provided by the surgeon), how competent and comfortable they felt their surgeon to be, how satisfied they were with the wider medical team, and how satisfied they were in their interactions with the office staff. The study found that patients in the bilateral with OSM group were more satisfied with the information they received, with a median score of 60, compared to the unilateral implant-based reconstruction group with a median score of 53. Again, bilateral with OSM patients were substantially more satisfied with their surgeon, with a median score of 100, compared with the unilateral implant-based reconstruction group, with a median score of 77. When it came to Satisfaction with Medical and Office Staff, the groups were generally very satisfied with their care from medical staff (median of 100 in the bilateral with OSM group compared with 95.5 in the unilateral implant-based reconstruction group) and office staff (median of 95.5 in both groups).

4.1.2 Minor Objectives

The minor objectives of this study were to determine the average number of repeat surgeries carried out for cosmetic purposes and to describe any further surgeries undertaken with the average time interval between the index procedure and the subsequent procedure/s.

The numbers of patients who considered further surgery following their initial reconstruction, for purely cosmetic reasons, was similar between the groups (5 of 9 in the unilateral implant-based reconstruction group and 8 of 18 in the bilateral with OSM group) and the numbers of patients that then underwent a second procedure, for purely cosmetic reasons, was also comparable (3 of 9 in the unilateral implant-based reconstruction group and 4 of 18 in the bilateral with OSM group). This translates to a conversion rate (from considering surgery to undertaking a procedure) of 60% in the unilateral implant-based reconstruction group and 50% in the bilateral with OSM group. Of the three unilateral patients who underwent a second procedure, two did so within six months of the index procedure and one did so within one to two years of the index procedure. Of the four bilateral patients who underwent a second procedure, two did so within six months to a year of the index procedure, one did so within one to two years of the index procedure, and one did so more than two years after the index procedure. This trend is remarkably similar.

The numbers of patients that underwent more than two surgeries, for purely cosmetic reasons, was the same in both groups (1 in each group). Respondents were also asked whether they would currently consider further surgery to improve their symmetry and 2 of 9 patients in the unilateral implant-based reconstruction

group, compared to 7 of 17 patients in the bilateral with OSM group (one patient opted not to respond), indicated they would do so.

4.1.3 Study Limitations

The study limitations include the fact that the data was retrospective, the sample size was small and uneven, and there were no preoperative scores against which to compare post-operative findings. The small numbers prevent observations having statistical significance. There is no pathological data so the influence of stage on selection of reconstructive procedure selected is not evaluated.

Due to the low response rate, non-response bias could be a factor influencing the results of the study. The respondents may differ from non-respondents in terms of their outcomes, and these characteristics may be underrepresented in the study. In addition, due to the difference in response rates between those having bilateral (22% of bilateral patients) as opposed to unilateral (90% of unilateral patients) mastectomies, the characteristics of the bilateral group may be underrepresented in the study.

However, as a small study, the study results raise some interesting questions for future research.

4.2 Conclusion

The question posed upfront in this study was whether immediate bilateral implant-based reconstruction following an elective bilateral mastectomy, while resulting in little oncological benefit, may have other benefits including increased patient satisfaction and/or a superior cosmetic result compared to patients who opted for a unilateral implant-based reconstruction. The original working hypothesis was that the unilateral

implant based reconstruction group would have lower satisfaction scores with regards to their breast symmetry and would therefore seek further corrective procedures at some stage in their breast reconstructive journey. The results of this study do not support this assumption. They, instead, indicate that the satisfaction levels were comparable and not as obviously disparate as predicted and the tendency to repeat surgeries for cosmetic reasons was parallel among the two groups.

The BREAST-Q outcomes module favoured the unilateral implant based reconstruction group, while the breast symmetry module favouring the bilateral with OSM group, but only marginally. Psychological and physical wellness modules favoured the unilateral implant-based reconstruction group, while the sexual Wellbeing module had higher satisfaction scores in the bilateral with OSM group. What is striking about the reported results is the narrow differences in satisfaction levels. With the increased rate of CPM in modern, educated women, it is interesting to note the similar satisfaction scores across the two groups.

Furthermore, the number of patients considering further surgeries was high (55% in the unilateral implant-based reconstruction group and 44% in the bilateral OSM group) despite high reported levels of satisfaction in both groups. In the unilateral implant-based reconstruction group, 33% underwent a cosmetic procedure and, in the bilateral with OSM group, 22% underwent a secondary procedure. The timing of the procedures was similarly dispersed.

Due to small and uneven sample sizes the findings of this research are not conclusive. Although there were some differences between the groups on certain BREAST-Q modules, this may be related to sample size differences rather than reflecting a true difference. Further research is necessary to explore these findings.

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