THE EFFECT OF WEIGHT OF RESECTION IN REDUCTION MAMMOPALSTY ON THE SYMPTOMS AND QUALITY OF LIFE IN PATIENTS WITH BREAST HYPERTROPHY IN NAIROBI, KENYA

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LIST OF ABBREVIATIONS AND ACRONYMS

AKUH	Aga Khan University Hospital
ASPS	American Society of Plastic Surgery
BH	Breast Hypertrophy
BMI	Body Mass Index
BREAST Q	Breast Q questionnaire
COVID –19	Coronavirus Disease 2019
g	Grams
Kg	Kilograms
KNH	Kenyatta National Hospital
MBSRQ	Multi-dimensional Body Self Relation Questionnaire
NAC	Nipple Areolar Complex
NH	Nairobi Hospital
PRAS	Plastics Reconstructive and Aesthetic Surgery
PROM	Patient Reported Outcomes Measurements
QOL	Quality of Life
Q Score	BREAST-Q Score
RM	Reduction Mammoplasty
SF 36	Short Form 36
UON	University of Nairobi

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ABSTRACT

Background

Breast hypertrophy (BH) is a psychologically and physically debilitating condition characterized by abnormal enlargement of the breast tissue. Studies have shown that reduction mammoplasty (RM) results in improvement of symptoms and quality of life (QOL). Whether improvement in symptoms and QOL correlates to the weight of tissue resected or not, remains unknown as there is paucity of data.

Broad objective: To determine the effect of resected weight in RM on BH symptoms and QOL in Nairobi, Kenya

Materials and Method:

This was a multi-centre, prospective, observational study carried out between July 2020 and April 2021 in KNH, AKUH and NH hospitals in Nairobi. It involved females aged 16-55 years with symptomatic BH. BREAST-Q questionnaire was administered preoperatively and 6 weeks postoperatively. Intraoperatively, resected tissue for each breast was weighed separately. Data derived was coded and input into SPSS (version 23) from where descriptive data was summarized into means, modes and frequencies. Paired T test was calculated to assess statistical significance in the differences between the pre and post reduction Q scores. Pearson correlation was used to correlate the weight resected to differences in the pre and post-reduction Q score.

Results

A total of 76 patients were followed up to the completion of the study. The mean age, weight and BMI of the patients were 32 years, 90kgs and 30kg/m^2 respectively. Statistically significant improvement in quality of life was observed in the pre and post reduction Q scores. Pearson correlation test, revealed a weak positive correlation between weight resected and the differences in the pre and post reduction Q scores.

Conclusion

Reduction mammoplasty leads to improvement in breast hypertrophy symptoms and quality of life. This improvement is evident regardless of the weight resected and has a weak positive correlation to the weight of breast tissue resected.

1.0 INTRODUCTION

Breast hypertrophy is defined as excessive breast tissue of more than 3% of total body weight[1]. There is currently no consensus on the classification of breast hypertrophy; however, some use absolute weight of the breast tissue resected during reduction mammoplasty, or according to cause, management and prognosis while others prefer percentage of body weight[1-3]. It is a frequent condition but with low diagnostic rates. Aetiology is idiopathic in most cases with few familial cases suggesting a genetic basis[4].

To the woman, the breasts are an important external identification of feminity[5]. Poor body image brought about by breast hypertrophy or breast asymmetry has been linked to psychosocial symptoms such as low self-esteem, anxiety, eating disorders, depression and negative impact on sexual well-being. Breast hypertrophy is also associated with physical symptoms which include headache, neck pain, shoulder pain, bra strap grooving, breast pain, upper and lower back pain, arm pain, inframammary intertrigo[6]

Reduction mammoplasty is a surgical procedure in which volumetric reduction of the breast bulk is done on patients with symptomatic breast hypertrophy. The main goal is to attain substantial breast volume reduction while preserving the nipple areolar complex and attaining an aesthetically acceptable breast with minimal scar[7]. It does help reduce symptoms and improve quality of life. The measurements of symptoms reduction and improvement of quality of life can be done using patient reported outcome measures (PROM)

Several PROM questionnaires regarding breast surgery have been formulated. Among the questionnaires developed for breast hypertrophy are the Short Form 36 (SF-36), breast related symptom questionnaire (BRSQ), Rosenberg self-esteem scale, EuroQol, Multidimensional Body self-relation Questionnaire (MBSRQ) among others. These tools however, have been criticized for lack of condition specificity and validation. Particularly for breast hypertrophy, they fail to assess all the important aspects of quality of life and satisfaction among reduction mammoplasty patients[8.] BREAST-Q questionnaire is a validated, reliable and specific patient satisfaction assessment tool which was developed through a rigorous process of psychometric evaluation, conceptual framework formation and item generation[9.]

This study sought to find out the effect of weight resection on the symptoms and quality of life for breast hypertrophy in selected hospitals in Kenya.

2.0 LITERATURE REVIEW

2.1 Breast hypertrophy definition, aetiology and classification

Breast hypertrophy is a psychologically and physically debilitating condition characterized by abnormal enlargement of the breast tissue. This enlargement could be excessive glandular tissue or excessive fatty tissue and in some cases, both[1]. The aetiology is mostly idiopathic and there are a few familial cases that have been reported suggesting a genetic cause[4]. It is also thought to be associated with hormonal changes during puberty and pregnancy[10.] Histology done has showed an increase in oestrogen receptors and receptor hypersensitivity of both oestrogen and progesterone receptors. Drug induced breast hypertrophy has been related to penicillamine, antiretroviral especially efavirenz and cyclosporine where cessation of the drug halted the breast hypertrophy[3].

There is currently no universal classification of breast hypertrophy. For this study, we based the classification on weight of breast tissue resected as defined by Regnault et al [2]; mild less than 200g, moderate 200-500g, major 500-1500g and gigantomastia above 1500g of weight of breast tissue resected. Hoda S.A et al differentiated macromastia from gigantomastia by the weight of breast tissue resected, where macromastia is between 1500g -2500g, and gigantomastia is resected weight above 2500g[11]

2.2 Reduction mammoplasty

Reduction mammoplasty also known as breast reduction surgery is one of the common plastic surgery breast procedures performed in Western countries. According to the American Society of Plastic Surgeons national plastic surgery statistics, 46,340 and 33,574 breast reduction procedures were done in 2019 and 2020 respectively[12]. In Kenya, over the last decade reduction mammoplasty has become a very popular procedure with the growth of plastic surgery in the country. The financial implication on the patient is high and most insurance companies do not have policies that cover the procedure, regarding it as a cosmetic procedure[13]. This is despite significant relief of preoperative physical and psychological symptoms related to breast hypertrophy. In a systematic review by Lonie et al looking at patient reported outcomes post reduction mammoplasty, they found that there was significant improvement of macromastia related symptoms[14]. Scott et al showed that in 518 patients, 97% of the patients achieved complete resolution of preoperative symptoms and were satisfied with their results[15]. The burden of breast hypertrophy related symptoms and quality of life is similar in all women requiring

reduction mammoplasty. Women requiring resection of <1000g and >2000g had similar disease burden before surgery[16].

Behmand et al compared physical functioning of patients originally suffering from macromastia related symptoms 9 months after reduction mammoplasty to non-patient controls and found that physical functioning was similar[17]. In a study by Neto et al they found patients with breast hypertrophy who underwent reduction mammoplasty had improved self-esteem, functional capacity and relieved lower back pain[18].

There are several studies that have described improvement in outcome following reduction mammoplasty[14-19] but very few have stratified patients by weight of breast tissue resected or correlated symptom outcome to the resected weight. Spector J et al looked at outcomes after breast reduction in terms of physical symptoms and quality of life and correlated it to the weight of resection. He divided the participants into cohorts based on the volume before resection as from <1000g to >2000g. They found that reduction mammoplasty resulted in improved physical symptoms and quality of life across the groups. He also found that the percentage of greater satisfaction was higher in patients with severe breast hypertrophy[16]. In this study there was a correlation between increasing Body Mass Index and increasing amount of breast tissue resected, suggesting that thinner, more active women are more sensitive to lesser degrees of breast hypertrophy and lesser degrees of breast volume resection. A limitation to this study is that they used a custom designed questionnaire that was not validated.

In another study Spector J et al focused on reduction mammoplasty where the resection volume was less than 1000g to see if there was any improvement in macromastia symptoms or quality of life [20]. Physical symptoms analysed in the study were upper back pain, lower back pain, neck pain, arm pain, shoulder pain, breast pain, headache, inframammary fold rashes, itching and bra strap grooving. For resections <750g they found improvement of all the above symptoms except for hand pain where there was no statistically significant improvement. For the same cohort of <750g, improvement of quality of life was realised. Resections between 750g-1000g were associated with a decrease in all the symptoms including hand pain. There was also significant improvement in quality of life.

Wagner et al in their study primarily set out to determine the relationship between various levels of obesity (determined by BMI) symptom relief and complication rates[21]. In addition, also looked at the relationship between volume of tissue resected with symptom relief and the rate of

complications. They found no relationship between obesity, resected volume on symptom relief and complications.

Despite several studies showing that reduction mammoplasty is efficacious in providing symptom relief as well as quality of life improvement, [15-21] most third party payers consider it a cosmetic rather than a functional procedure and majority give a minimum total weight resection of 1000g to consider reimbursement [16-21, 23]. Total weight of less than 1000g is considered cosmetic and above 1000g is considered functional [16,23].

2.3 BREAST-Q

The BREAST-Q questionnaire was introduced by Pusic et al [22]. It is a Patient Reported Outcome Measures (PROM) instrument designed to evaluate outcomes among women undergoing different breast surgery. The BREAST-Q contains 5 modules for the different breast surgery procedures. The reduction mammoplasty module comprises 2 themes; that is, patient satisfaction and health related quality of life. Under these themes are subthemes. The patient satisfaction domain subthemes include, satisfaction with breasts, overall outcomes and care. The quality of life domain subthemes include, physical symptoms, psychosocial and sexual well-being. Each sub theme contains BREAST-Q scales that are psychometrically linked hence used for comparison between different patient groups. The patient responses are analysed through the Q-score. The Q score has a sum score that is collected using a scale from each subtheme in the different domains. Each sum score has an equivalent Rasch transformed score from 0-100 available through a conversion table where 0 is the worst and 100 the best. A higher score reflects a better outcome.

Gonzalez et al in a 10 year retrospective study determined if there is improvement in the quality of life, and whether weight resected influenced the outcome using the BREAST –Q questionnaire. They concluded that 95% of the patients were satisfied and quality of life was improved; however, this improvement was independent of the volume resected or patients' body weight[23].

Studies have been done to determine when patients experience symptom improvement post reduction mammoplasty. In a randomized control trial conducted by Thoma et al, reported improvement as early as one month and this was observed throughout the postoperative period[24]. Coriddi et al found symptom improvement by 6 weeks post operatively[25]. Cohen et al used the

validated BREAST-Q questionnaire to determine if time after reduction mammoplasty affected patients' satisfaction and health related quality of life. He compared postoperative symptoms within the first 3 months and after the 3 months. There was marked improvement noted within the first 3 months that was sustained up to 6 months postoperatively[26].

3.0 STUDY JUSTIFICATION

Current debate with insurance policies is that reduction mammoplasty is a cosmetic rather than a functional procedure. Firms use weight of resection to set this guideline. In Kenya, insurance carriers either have absent medical policy or total exclusion from coverage of all forms of reduction mammoplasty rendering it a cosmetic procedure. The blanket consideration of all reduction mammoplasties as cosmetic, leaves a significant financial burden onto the patients with clinical symptomatology requiring surgical intervention. This also limits access to care for many with this debilitating condition. With the growth in the field of plastic surgery in Kenya, an increase in public awareness of the health burden of gigantomastia and improved patient knowledge, more patients will seek care. There will be increased demand for the insurance companies to be involved. This study provides local data useful to our insurance firms when formulating policies on breast hypertrophy and reduction mammoplasty.

To the best of our knowledge, there is currently no study in Africa that has used the validated BREAST-Q questionnaire to correlate symptoms by stratifying patients' preoperative symptoms and quality of life to the weight of breast tissue resected.

3.1 RESEARCH QUESTION

How does weight of resection in reduction mammoplasty correlate with symptoms and quality of life in patients with breast hypertrophy in Nairobi, Kenya?

Null Hypothesis

Reduction mammoplasty does not change quality of life and symptoms in symptomatic breast hypertrophy

Weight of resection in reduction mammoplasty has no effect on breast hypertrophy symptoms and quality of life

3.2 OBJECTIVES

3.2.1 Broad Objective

- To determine the effect of resected weight in reduction mammoplasty on breast hypertrophy symptoms and on quality of life in Nairobi, Kenya

3.2.2 Specific Objectives

1. To determine breast hypertrophy symptoms and quality of life preoperatively and 6 weeks post reduction mammoplasty
2. To determine the correlation between weight of resected breast tissue to breast hypertrophy symptoms and quality of life

4.0 MATERIALS AND METHODS

4.1 Study design

This was a prospective observational study

4.2 Study Area Description

The study was carried out in the surgical departments of 3 collaborating hospitals: Kenyatta National Hospital (KNH), the Aga Khan University Hospital (AKUH) and the Nairobi Hospital (NH).

4.3 Study population

The study population was female patients, aged between 16 and 55 years with symptomatic breast hypertrophy

4.3.1 Inclusion criteria

1. Females aged between 16 and 55 years with symptomatic breast hypertrophy

4.3.2 Exclusion criteria

1. Unilateral breast hypertrophy
2. Fibroadenoma, phyllodes tumor
3. Previous history of oncologic surgery/radiotherapy/chemotherapy
4. Previous breast reconstruction surgery
5. Patient with known psychiatric disorders

4.4 Sample size calculation

Sample size was calculated using the [27]Fischer formula: $N= Z^2P (1-p) / D^2$; where:

N = total number of samples

P = estimated proportion of study outcome

D = margin of error

Z = z score

Therefore, Z = 1.96, D is taken at 0.05. A study on patients' satisfaction with breast reconstruction and reduction mammoplasty revealed that 96% of patients who underwent reduction mammoplasty thought that the outcome of the operation was good (Tykka et al [28]) Since we also aim to determine patient satisfaction following the procedure, we set our P at 0.88. Therefore P = 0.96 and 1-p = (0.04), hence:

$$\frac{1.96^2 \times 0.96 \times 0.04}{0.05^2} = 59$$

Therefore N = 59.

4.5 Sampling procedure

Convenience sampling

4.6 Variables

4.6.1 Independent variables

1. Patient factors
    a) Age
    b) Weight
    c) Height
    d) Physical breast hypertrophy symptoms
    e) Psychosocial and sexual symptoms
    f) Breast anthropometric measurements

4.6.2 Dependent variables

1. Resected weight of each breast

4.7 Data collection Tools

1. Calibrated Digital Weighing scale
2. Custom designed Questionnaire
3. BREAST-Q questionnaire (licence to use obtained)
4. Plastic tape measure (metric)

4.8 Data collection method

Females aged between 16 and 55 years with symptomatic breast hypertrophy who presented to the outpatient clinic, wards and theatres in the stated study sites were recruited by either the principal investigator or the operating plastic surgeon. Informed consent was sought to join the study. For participants between 16 and 18 years, assent was sought in addition to the consent from the guardians. A history and physical examination was conducted and those who met the exclusion criteria exited the study. Those who met the inclusion criteria were then subjected to the study questionnaires; a custom designed questionnaire that captured the demographics of the

patients and the preoperative BREAST-Q questionnaire. Surgery was performed within one week of recruitment in the respective study site.

During surgery, the resected breast tissue was weighed immediately to avoid sample dehydration. It was done using a non-sterile standard digital weighing machine. Each breast was weighed separately in grams and findings recorded.

Six weeks from the day of surgery the participants were subjected to the postoperative BREAST-Q questionnaire through a phone call.

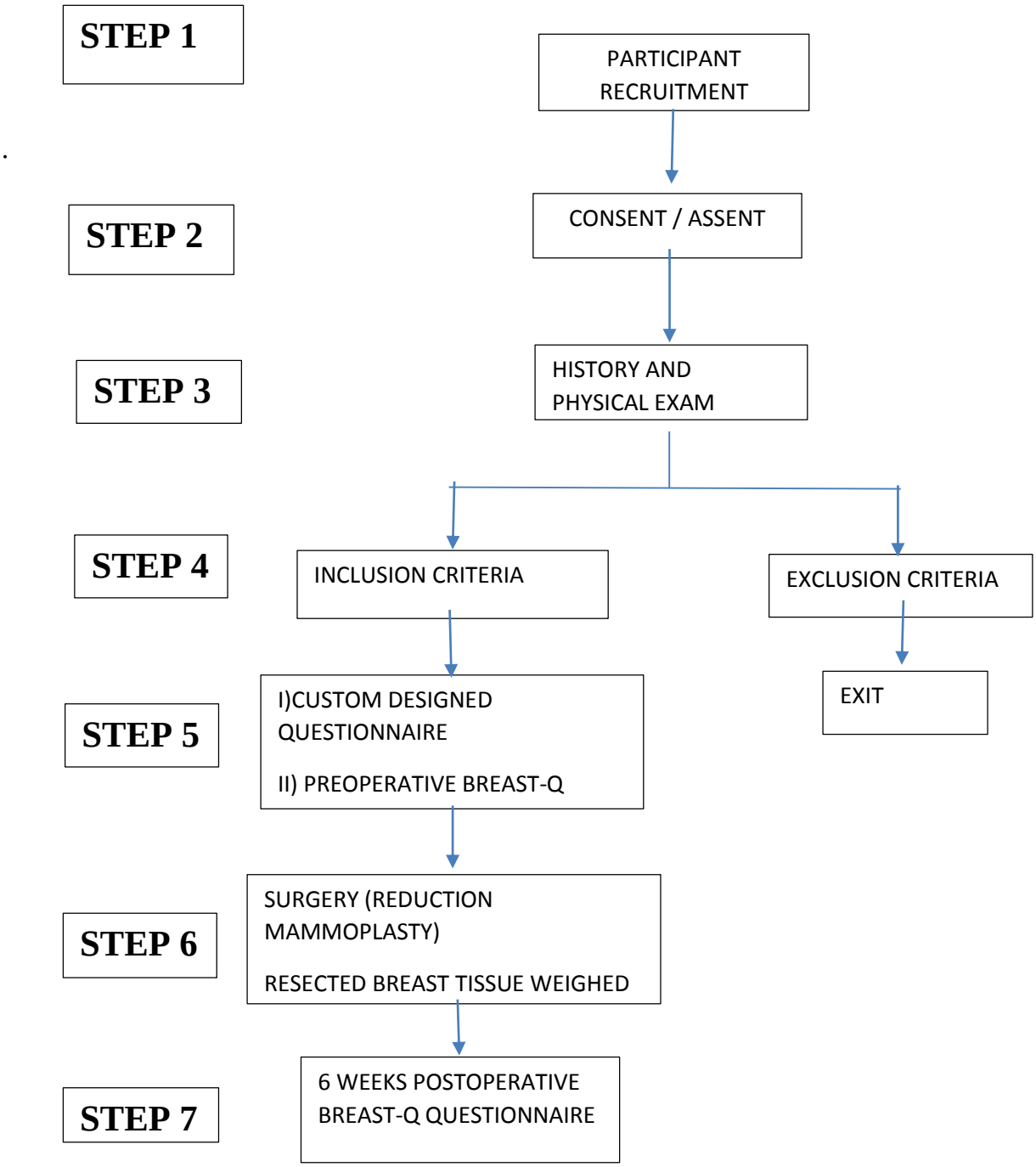

Figure 1: Flowchart of study procedure

4.8 Data Management

All data derived was handled with confidentiality. Participants were given codes that bore no relation to their names or contacts. The principal investigator retrieved the data from the completed questionnaires and entered it into Microsoft access database on a password protected computer. At the end of the study, the raw data was destroyed and deleted from any soft copy storage devices including computers, flash discs and hard disks.

4.9 Data Analysis

Data derived was coded and input into SPSS (version 23) from where descriptive data was summarized into means, modes and frequencies. The differences between the pre and post reduction quality of life Q scores were calculated. Statistical significance between the pre and post reduction Q score differences was then assessed using the paired T test. P value of ≤ 0.05 was considered statistically significant at 95% confidence interval. In addition, Pearson correlation test was used to correlate the difference in the pre and post Q score to the weight of breast tissue resected (1 = perfect positive; -1 = perfect negative; 0 - 0.3 weak positive; 0.3 - 0.7 moderate positive; 0.7 - 1 strong positive) Data derived was summarized in figures and tables.

4.10 Quality Control

Quality control was a continuous process throughout the study to maximize validity and reliability of the study findings.

A pre-test of the structured questionnaires was carried out by clarifying grammar and language used so as to avoid bias and misinterpretation of the questions.

The data collection tools were standardized for all participants. The qualitative and quantitative data collected was cross checked for completeness, inconsistencies and then rectified.

4.11 Ethical considerations

Ethical approval was obtained from the Kenyatta National Hospital/ University of Nairobi Ethical Review Committee (KNH/UON ERC)

Permission was obtained from Kenyatta National Hospital, Aga Khan University Hospital and Nairobi Hospital administration before commencement of the study pursuant to ethical approval. An introductory letter from department of surgery seeking permission to collect data in the various institutions was presented to each institution prior to data collection.

The recruited participants received full disclosure of the nature of the study before any informed consent/assent was taken. They were informed that participation in the study was voluntary and they could withdraw from the study at any time without giving any reason and this would not affect the quality of care that they received. Patients who declined to participate were not discriminated against and received the same quality treatment as those participating. Utmost confidentiality was maintained. No extra cost was incurred by the participants for participating in the study. The questionnaire was filled on the day of admission or on their routine plastic surgery outpatient clinic visit. They were not reimbursed for transport to and from clinic visits. There was no conflict of interest, financial or otherwise in this study.

The results of the study would be disseminated through scientific presentations at conferences, departmental academic meetings, through publications in peer reviewed scientific journals and even regular newspapers where necessary.

At the end of the study, the raw data was destroyed and deleted from any existing hard copies by paper shredding; formatting and deleted from any soft copy storage devices including computers, flash disks and hard disks.

Infection prevention measures were taken to safeguard the participants during the COVID-19 pandemic. This included but was not limited to hand hygiene (hand washing or hand sanitizing) cough and respiratory hygiene (use of the recommended masks at all times), keeping a distance of more than 3 feet apart. To minimize contact, the principal investigator or the operating surgeon administered the questionnaire as they were part of the team involved in caring for the patient. To maintain social distancing, the postoperative BREAST-Q questionnaire was administered via a phone call. In addition, Ministry of Health guidelines on Infection, prevention and control recommendations for COVID-19 in healthcare settings[29] and protocols from the specific stated study sites regarding COVID-19 measures were strictly adhered to.

4.12 Study limitation and delimitation

4.12.1 Study limitation.

1. Six week follow up led to patients dropping out of the study. Eighty participants were recruited, four dropped out of the study.

4.12.2 Delimitations

1. Increased number of study sites and a longer period of study aided in recruiting more patients.
2. An informed and detailed description of the purpose of the study was done during the recruitment phase and emphasis made on the importance of follow up clinic visits throughout the postoperative phase.

5.0 RESULTS

A total of eighty patients were recruited for the study; however, 76 completed both the pre-reduction survey and post-reduction survey. The mean age, mean body weight and BMI of the patients was 32 years (13years - 48 years), 90kgs and 30 kg/m^2 respectively. (Table 1)

Table 1: Distribution by Age and BMI

(n=76)		
	Frequency	**Percentages**
Age grouping		
15-20	16	21.05
21-25	12	15.79
26-30	13	17.12
31-35	10	13.15
36-40	11	14.47
41-45	9	11.84
46-50	5	6.5
BMI		
<20	21	27.6
21-25	15	19.7
31-35	22	28.9
>35	18	23.6

5.1 Distribution by weight of breast resected, diagnosis and technique used

The least amount of breast tissue resected per participant was 280g and the highest was 6715g with an average of 2527g. Common diagnosis was pubertal gigantomastia at 79%. The Wise-pattern and superomedial pedicle was the commonly used technique. (Table 2)

Table 2: Distribution by weight resected, diagnosis and technique used

	Frequency	**Percentage**
Average weight of breast resected per person		
<500	6	7.89
501-1000	22	28.94
1001-1500	21	27.63
1501-2000	21	27.63
2001-2500	3	3.94
2501-3000	1	1.31
3001-3500	2	2.66
Diagnosis		
Physiological gigantomastia	8	10.53
Gestational gigantomastia	8	10.53
Pubertal gigantomastia	60	78.94
Pedicle		
Superomedial	70	92.11
Inferior	6	7.89
Skin excision		
Wise Pattern	63	82.9
Vertical scar	13	17.1

5.2 Pre and post reduction Q scores for quality of life sub themes specific variables

The quality of life sub themes assessed were psychosocial well-being, sexual well-being and physical well-being. Under quality of life sub-theme specific variables were assessed for the pre and post reduction Q scores. As illustrated below.

5.21 Pre and post reduction Q scores for psychosocial well-being variables

Pre and post reduction Q scores for psychosocial well-being specific variables were assessed for statistical significance using the Wilcoxon test. There was statistical significance in all variables (p value = 0.000). (Table 3)

Table 3: Pre and post reduction psychosocial well-being Q score and P value

Psychosocial well-being	**Pre-reduction Q score**	**Post-reduction Q score**	**P value (Wilcoxon test)**
Confident in social setting	1	5	0.000
Equal worth to other women	1	5	0.000
Good about yourself	1	5	0.000
Self-assured	1	5	0.000
Confident in your clothes	1	5	0.000
Accepting of your body	1	5	0.000
Appearance matches who you are inside	1	5	0.000
Confident about your body	1	5	0.000
Attractive	1	5	0.000

5.22 Pre and post reduction Q scores for sexual well-being variables

Pre and post reduction Q scores for sexual well-being specific variables were assessed for statistical significance using the Wilcoxon test. There was statistical significance in all variables (p value = 0.000). (Table 4)

Table 4: Pre and post reduction sexual well-being Q score and P value

Sexual well-being	Pre-reduction Q score	Post-reduction Q score	P value (Wilcoxon test)
Comfortable during sexual activity	1	5	0.000
Confident sexually	1	5	0.000
Satisfied with your sexual life	2	5	0.000
Sexually attractive in your clothes	1	5	0.000
Sexy when unclothed	1	5	0.000

5.23 Pre and post reduction Q scores for physical well-being variables

Pre and post reduction Q scores for physical well-being specific variables were assessed for statistical significance using the Wilcoxon test. There was statistical significance in all variables (p value = 0.000). (Table 5)

Table 5: Pre and post reduction physical well-being Q score and P value

Physical well-being	Pre-reduction Q score	Post-reduction Q score	P value (Wilcoxon test)
Breast Pain	1	3	0.000
Neck Pain	1	3	0.000
Shoulder Pain	1	3	0.000
Painful grooves in shoulders from bra straps	1	3	0.000
Difficult doing vigorous activities running; exercise	1	3	0.000
Inframammary intertrigo	1	3	0.000

5.3 Pre and post reduction Q scores for quality of life and satisfaction with breasts sub themes

Pre and post reduction quality of life and satisfaction with breast sub themes were analysed. The differences in the Q score, pre and post reduction was calculated. These differences were then assessed for statistical significance using the paired T test. Statistically significant improvement was observed in all sub themes (p value=0.000) (Table 6).

Table 6: Differences between the pre and post reduction Q score and p values

Score	Q reduction score (Pre)	Q reduction score (Post)	Differences	p-value
Physical well-being	33	93	60	0.000
Sexual well-being	41	86	45	0.000
Psychosocial well-being	41	92	51	0.000
Satisfaction with breast outcome	38	86	48	0.000

5.4 Correlation between weight resected and differences in Q score pre and post reduction

The differences in the pre and post reduction Q scores was correlated to weight of breast tissue resected using the Pearson correlation test. This was done for both the average weight resected and total weight resected. It revealed a weak positive correlation. (R values = 0 - 0.3) (Table 7)

Table 7: Correlations between weight and differences in Q score pre and post reduction

		Psychosocial well-being	Sexual well-being	Physical well-being	Satisfaction with breast outcome
Average breast weight per person	Pearson Correlation	.348	.276	.357	.169
Total breast weight per person	Pearson Correlation	.348	.276	.357	.169

6.0 DISCUSSION

Reduction mammoplasty is one of the rigorously studied surgical procedures in plastic surgery. It is commonly performed for improvement of symptoms and quality of life associated with breast hypertrophy that is the physical, sexual and psychosocial well-being. Several studies have demonstrated that breast reduction results in significant improvement in breast hypertrophy symptoms[15-21].

This study demonstrated statistically significant improvement in the psychosocial well-being. Patients reported feeling more confident in social setting, of equal worth to other women, good about themselves and self-assured. It demonstrated statistically significant improvement in sexual well-being; the patients were more at ease during sexual activity, felt confident sexually, attractive sexually and satisfied with sex life post the reduction. It also demonstrated statistically significant improvement in the physical well-being; patients reported decreased pain in the back, shoulder and neck. They were at more ease carrying out vigorous activities like running and exercise. This study also demonstrated statistically significant improvement in satisfaction with breasts post reduction. These findings were similar to Crittenden et al, where they looked at outcomes of breast reduction surgery using the BREAST-Q[30].

Symptom improvement was observed as early as 6 weeks after the surgery as our post-reduction survey was administered six weeks post-surgery. This was similar to Corridi et al who reported symptom improvement six weeks postoperative[25].

Several studies describe improvement of symptoms; however, few correlate the weight resected to quality of life and symptoms. This study demonstrated a weak positive correlation between the weight resected and the difference in the pre reduction and post reduction Q scores. There was improvement of symptoms following reduction mammoplasty regardless of the weight resected as seen in the differences between the pre reduction and post reduction Q scores. The minimum weight resected was 280g and the maximum weight was 6715g. This difference in scores was higher with higher resection weights but then this was a weak positive correlation. Similarly Gonzalez et al, in their study found a positive correlation of breast tissue resected and patients' response in regards to quality of life, but was not statistically significant. The study was retrospective and only correlated one sub theme in the BREAST-Q (outcome of the surgery) [23] Spector J et al, in a prospective study demonstrated improvement of symptoms in weights resected between 1000g-2000g[16]. Greater satisfaction was observed in patients with higher resected weights, however they used a non-validated custom designed questionnaire. Our study

findings were different from Wagner et al, who reported no relationship between volume of breast tissue resected and the relief of symptoms[21]. This study was retrospective and used a non-validated three point scale that only assessed degree of symptom relief as significant pain relief, mild and no pain relief.

Despite the proven benefits of breast reduction surgery, studies demonstrate that coverage of reduction mammoplasty is often denied by majority of the third party payers, who require at least a total 1000g weight resected for reimbursement[16 & 23]. This study demonstrates improvement of symptoms and quality of life regardless of weight resected and a weak positive correlation between weight resected and quality of life. Weight of resection should not be the only factor used to determine third party coverage policies for reduction mammoplasty.

7.0 CONCLUSION

Reduction mammoplasty leads to improvement of breast hypertrophy symptoms and quality of life that is physical well-being, psychosocial well-being and sexual well-being. This improvement is evident regardless of the weight resected and has a weak positive correlation to the weight of breast tissue resected.

8.0 RECOMMENDATIONS

Reduction mammoplasty should be offered to all patients with symptomatic breast hypertrophy.

Third party payers should not deny reduction mammoplasty coverage for patients with symptomatic breast hypertrophy based on weight of resection alone.

A follow up study with a larger sample size for comparison.

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APPENDICES

APPENDIX I: PATIENT INFORMED CONSENT/ASSENT FORM
PARTICIPANT INFORMATION AND CONSENT FORM

Title of study: THE EFFECT OF WEIGHT OF RESECTION IN REDUCTION MAMMOPALSTY ON THE SYMPTOMS AND QUALITY OF LIFE IN PATIENTS WITH BREAST HYPERTROPHY IN NAIROBI, KENYA

Principal investigator Dr. Waithaka A.W

Institutional affiliation: Department of Surgery, School of medicine, University of Nairobi

Co-investigators and institutional affiliation: Dr. Nangole F.W, Prof. Khainga, Dr. Ojuka D. K department of Surgery, School of medicine, University of Nairobi

This informed consent has three parts:

1) Information sheet (to share information about the research with you)
2) Certificate of consent (for affirmation/ signatures if you agree to take part)
3) Statement by the researcher

You will be given a copy of the full informed consent

PART 1: INFORMATION SHEET

INTRODUCTION

My name is Dr. Anne Wangui Waithaka, a post graduate student in Plastic, Reconstructive and Aesthetic Surgery at the University of Nairobi. I am carrying out a research to determine the effect the weight of **breast tissue removed during surgery** has on the symptoms and quality of life associated with the **having abnormally enlarged breasts**.

PURPOSE OF THE STUDY

Having abnormally enlarged breast is a physically and debilitating condition characterized by physical symptoms such as back pain, neck pain, bra strap grooving among others. It is also associated with psychosocial symptoms such as low self-esteem, anxiety, depression and has a negative impact on sexual well-being. **The treatment for this is a surgical procedure to reduce the size of the breasts.** The weight of the **breast tissue removed** aids insurance companies in setting guidelines on how to provide insuarance coverage for the surgery. This study therefore aims to find out the relationship between the weight of **breast tissue removed** and quality of life of the patients. These findings may be used to help insurance companies come up with guidelines on the said condition.

I am going to give you information and invite you to be a participant in this research. There may be some words that you do not understand or that you may need clarification. Please ask me to stop as we go through the information and I will clarify.

Name of proposed procedure: breast reduction surgery

BREAST-Qquestionnaire
Weighing of breast tissue removed

Description of procedure
A BREAST-Q questionnaire shall be administered to you, the questionnaire will be asking about **how the size of your breast** has affected your physical health, social life and sexual well-being. Six weeks after surgery the same questionnaire will be administered through a phone call. The **breast tissue removed** shall be weighed d uring surgery and subsequently disposed of as directed by the operating plastic surgeon. This study shall not change the course, mode or manner of your condition. The final findings of the project shall be shared with you the patient. Photographs will be taken to illustrate the procedure described.

Voluntary participation/right to refuse or withdraw
You are free to participate or decline participation in this study. Whether you choose to participate or not will not change your current management and treatment, that is routinely offered in this hospital for your particular condition. You have a right to refuse or withdraw from this study at any point.

Confidentiality
The information obtained shall be treated with utmost confidentiality and only be available to the principal investigator and her research team. Your name will not be used and you shall remain anonymous. We shall not be sharing the identity of anyone participating in this research.

Sharing the results
The knowledge that we get from this study shall be shared with the internationally and locally, policy makers in the government and non-government institutions in health care, insuarance, the medical professionals and the public through publications, conferences, journals and presentations. Confidential information shall not be shared with any third party.

Risks
There are no risks in this study. All parameters are verbal and observations of your current management. No invasive investigations shall be used during the course of this study.

Cost and compensation
There will be no extra cost incurred for participating in this study.

Please read the following:
I understand that you cannot guarantee me that a particular person will perform the procedure. The person undertaking the procedure will however, have appropriate experience
I understand that any photographs taken and tissue removed as part of the procedure will remain anonymous and may be used for teaching or quality control and stored or disposed of in a manner regulated by appropriate, ethical, legal, and professional standards.

I understand that this research has been approved by the Kenyatta National Hospital/ University of Nairobi Ethics Review Committee (KNH/UON-ERC) and undertaken in accordance with appropriate ethical, legal and professional standards.
I understand that data about me will be held electronically and may be passed between the Kenyatta National Hospital, University of Nairobi; Nairobi hospital, Agakhan University Hospital and any other university/ hospital, research institute collaborating with KNH/UoN, to facilitate research and my care
I understand that my involvement in this research will be through clinical evaluation and that you will not expose yourself to any risks if I consent to participate
I understand that there will be **NO** financial benefits
I understand that results from this study may be published to enhance scientific knowledge
I understand that refusal to participate or withdrawal from the study will not in any way compromise the quality of care and treatment given to me

Please tick the box below to indicate if you either

agree ☐ **disagree** ☐

Contacts
Participant
Telephone number:

Alternative telephone number:

KNH/UoN-ERC
This study has been reviewed and approved by the KNH/UoN-ERC which is a committee whose work is to make sure research participants are protected from harm. The contact information is given below if you wish to contact any of them for whatever reason:

Secretary:
KNH/UoN-ERC,
P.O. Box 20723-00202 KNH, Nairobi
Tel: 020-726300-9
Email: KNHplan@Ken.Healthnet.org , uonknh_erc@uonbi.ac.ke

Principal investigator:
Dr. Anne Wangui Waithaka
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University of Nairobi research supervisors:
Prof. Stanley Ominde Khainga
MBChB, M.MED (Surg.), Cert. Microvascular Surgery (MEDUNSA), FCS (Plast), FCS (CoSECSA)
Consultant Plastic, Reconstructive and Aesthetic Surgeon
Associate Professor of Surgery and Thematic Unit Head of Plastic Surgery,
Department of Surgery, School of Medicine, University of Nairobi
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Dr. Ferdinand Wanjala Nangole
MBChB, M.MED (Surg.), FCS (UCT), Fellow of EBOPRAS (Brussels, Marseille)
Consultant Plastic, Reconstructive, Hand and Hair Transplant Surgeon and Senior Lecturer
Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 2212-00202 KNH, Nairobi
Mobile: 0733864249
Email: nangole2212@yahoo.com

Dr. Daniel Kinyuru Ojuka
MBChB, MMED Surg, Consultant General Surgeon, Breast Oncoplastic and Endocrine Surgeon
Senior Lecturer Department of Surgery, University of Nairobi.
P.O. BOX 19676-00202 Nairobi
Mobile: 254722322246
Email: dkinyuru@yahoo.com

PART II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research. I hereunder impress my signature / thumbprint as proof of my consent.

Patient/parent/guardian signature: ..... Date: .....
Name (PRINT): .....

Witness' signature: ..... Date: .....
Name (PRINT): .....

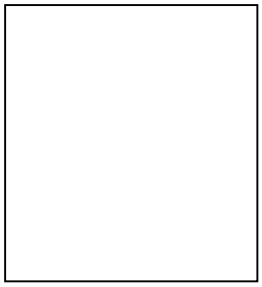
Statement of the interpreter (if appropriate)
I confirm that I have interpreted the information to the best of my ability, and in a way in which I believe she/he has understood:
Interpreter's signature ..... Date: .....
Name (PRINT): .....

If Illiterate:

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Witness' signature: ..... Date: .....
Name (PRINT): .....

Thumb print of participant:



PART III: Statement by the researcher

I have accurately read out the information sheet to the patient and/or guardian(s), and to the best of my ability made sure that the patient or guardian understands the following:

- Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- All information given will be treated with confidentiality.
- The results of this study might be published to enhance the knowledge and understanding of medical professionals regarding the subject of the study.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Researcher's signature ..... Date: .....
Name (PRINT): ..... Designation: .....

ASSENT FORM

Title of the Study: THE EFFECT OF WEIGHT OF RESECTION IN REDUCTION MAMMOPLASTY ON THE SYMPTOMS AND QUALITY OF LIFE IN PATIENTS WITH BREAST HYPERTROPHY IN NAIROBI, KENYA

This informed assent form is for patients who shall be **undergoing a surgery to reduce the breast size**. I am inviting you to participate in this research on a voluntary basis.

Principal investigator: Dr. Waithaka A.W
Institution: Department of Surgery, School of Medicine, University of Nairobi
Supervisors: Prof. Stanley O. Khainga, Dr. Ferdinand W. Nangole and Dr. Daniel K. Ojuka

This Informed assent form has four parts:

1) Information Sheet (to share information about the research with you).
2) Certificate of assent (for affirmation/signatures if you agree to take part).
3) Statement by the researcher.
4) Informed assent

You will be given a copy of the full informed assent form.

PART I: Information Sheet

INTRODUCTION

My name is Dr. Anne Wangui Waithaka, a post graduate student in Plastic, Reconstructive and Aesthetic Surgery at the University of Nairobi. I am carrying out a research to determine the effect the weight of **breast tissue removed** during surgery has on the symptoms and quality of life associated with **the having abnormally enlarged breasts**.

PURPOSE OF THE RESEARCH

Having abnormally enlarged breast is a physically and debilitating condition characterized by physical symptoms such as back pain, neck pain, bra strap grooving among others. It is also associated with psychosocial such as low self-esteem, anxiety, and depression and has a negative impact on sexual well-being. **The treatment for this is a surgical procedure to reduce the size of the breasts**. The weight of the **breast tissue removed** aids insuarance companies in setting guidelines on how to provide insuarance coverage for the surgery. This study therefore aims to find out the relationship between the weight of **breast tissue removed** and quality of life of this patients. These findings may be used to help insuarance companies come up with guidelines on the said condition.

I am going to give you information and invite you to be a participant in this research. There may be some words that you do not understand or that you may need clarification. Please ask me to stop as we go through the information and I will clarify.

Name of proposed procedure: breast reduction surgery
BREAST-Qquestionnaire
Weighing of breast tissue removed

Description of procedure

A BREAST-Q questionnaire shall be administered to you, the questionnaire will be asking about **the effect the size of the breasts** has had on your physical health, social and sexual well-being. Six weeks after surgery the same questionnaire will be administered through a phone call. The **breast tissue removed** shall be weighed during surgery and subsequently disposed of as directed by the operating plastic surgeon. This study shall not change the course, mode or manner of your condition. The final findings from the project shall be shared with the patient. Photographs will be taken to illustrate the procedure described.

Voluntary participation/right to refuse or withdraw

You are free to participate or decline participation in this study. Whether you choose to participate or not, will not change your current management and treatment, that is routinely offered in this hospital for your particular condition. You have a right to refuse or withdraw from this study at any point.

Confidentiality
The information obtained shall be treated with utmost confidentiality and only be available to the principal investigator and her research team. Your name will not be used and you shall remain anonymous. We shall not be sharing the identity of anyone participating in this research.

Sharing the results
The knowledge that we get from this study shall be shared with the internationally and locally, policy makers in the government and non-government institutions in health care, insuarance, the medical professionals and the public through publications, conferences, journals and presentations. Confidential information shall not be shared with any third party.

Risks
There are no risks in this study. All parameters are merely observations of your current management; no invasive investigations will be used during the course of this study.

Cost and compensation
There will be no extra cost incurred for participating in this study.

Please read the following:
I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.
I understand that any photographs taken and tissue (including blood) removed as part of the procedure or treatment will be anonymous and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.
I understand that this research has been approved by the Kenyatta National Hospital/University of Nairobi Ethics Review Committee (KNH/UoN-ERC) and undertaken in accordance with appropriate ethical, legal and professional standards.
I understand that data about me will be held electronically and may be passed between the Kenyatta National Hospital, the University of Nairobi, Nairobi Hospital, Agakhan University Hospital and any other University/ Hospital/ Research Institute collaborating with KNH/UoN, to facilitate research and my care.
I understand that my involvement in this research will be through clinical evaluation and that you will not expose yourself to any risks if you consent to participate.
I understand that there will be **NO** financial benefits.
I understand that results from this study may be published to enhance scientific knowledge
I understand that refusal to participate or withdrawal from the study will not in any way compromise the quality of care and treatment given to me

Please the tick box below to indicate if you either AGREE ☐ DISAGREE ☐

Contacts
Participant
Telephone number:

Alternative telephone number:

KNH/UoN-ERC
This study has been reviewed and approved by the KNH/UoN-ERC which is a committee whose work is to make sure research participants are protected from harm. The contact information is given below if you wish to contact any of them for whatever reason:

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Principal investigator:
Dr. Anne Wangui Waithaka
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University of Nairobi research supervisors:
Prof. Stanley Ominde Khainga
MBChB, M.MED (Surg.), Cert. Microvascular Surgery (MEDUNSA), FCS (Plast), FCS (CoSECSA)
Consultant Plastic, Reconstructive and Aesthetic Surgeon
Associate Professor of Surgery and Thematic Unit Head of Plastic Surgery,
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Email: skhainga@yahoo.com

Dr. Ferdinand Wanjala Nangole
MBChB, M.MED (Surg.), FCS (UCT), Fellow of EBOPRAS (Brussels, Marseille)
Consultant Plastic, Reconstructive, Hand and Hair Transplant Surgeon and Senior Lecturer
Department of Surgery, School of Medicine, University of Nairobi
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Dr. Daniel Kinyuru Ojuka
MBChB, MMED Surg, Consultant General Surgeon, Breast Oncoplastic and Endocrine Surgeon
Senior Lecturer Department of Surgery, University of Nairobi.
P.O. BOX 19676-00202 Nairobi
Mobile: 254722322246

Email: dkinyuru@yahoo.com

PART II: Certificate of Assent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I assent voluntarily to participate in this research. I hereunder impress my signature / thumbprint as proof of my consent.

Patient/parent/guardian signature: ..... Date: .....
Name (PRINT): .....

Witness' signature: ..... Date: .....
Name (PRINT): .....

Statement of the interpreter (if appropriate)
I confirm that I have interpreted the information to the best of my ability, and in a way in which I believe she/he has understood:
Interpreter's signature ..... Date: .....
Name (PRINT): .....

If Illiterate:
I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.
Witness' signature: ..... Date: .....
Name (PRINT): .....

Thumb print of participant:

PART III: Statement by the researcher

I have accurately read out the information sheet to the patient and/or guardian(s), and to the best of my ability made sure that the patient or guardian understands the following:

- Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- All information given will be treated with confidentiality.
- The results of this study might be published to enhance the knowledge and understanding of medical professionals regarding the subject of the study.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Assent Form has been provided to the participant.

Researcher's signature ..... Date: .....
Name (PRINT): ..... Designation: .....

PART IV: INFORMED ASSENT

I have read this information (or had the information read to me). I have had my questions answered and know that I can ask questions later if I have them.
I do not wish to take part in the study and I have not signed the assent below.

…….. (initialled by child/minor)

Only if child assents:

Print name of child: ……Signature of child: ……..

Date: …….
I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Print name of witness (not a parent): …… Signature of witness: ……..

Date: ……

Statement of the researcher
I have introduced myself to the child and have:

□ Clearly stated what the study is about, why it is being done and why we are informing him/her
□ Informed the child that I have spoken to his/her parents and that parental consent is also necessary.
□ Let him/her know that they can speak to anyone they choose about the research before they make up their mind
□ Checked with the child and they understand that participation is voluntary
□ Explained how the procedure is to be performed, follow up procedures and how data will be collected
□ Checked with the child and they understand the procedures involved

□ Checked with the child and they understand the risks and or discomforts involved
□ Checked with the child and they understand any benefits
□ Explained the contents of the recipient consent form

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving assent, and the assent has been given freely and voluntarily.

Reasearcher's signature: ..... Date: .....
Name (PRINT): ..... Designation: .....

Parent/Guardian has signed an informed consent: Yes □ **No** □

Appendix I (b): Consent Form (Swahili)

IDHINI

ATHARI YA UPUNGUZAJI WA UZITO WA KILO KWA TITI KWA DALILI YA MAUMIVU NA UBORA WA AFYA

Fomu ya Idhini ya _____ _____

Mpelelezi mkuu ni Daktari Anne Wangui Waithaka chini ya usimamizi wa Daktari Ferdinand Nangole, Profesa Khainga Ominde na Daktari Daniel Ojuka katika utafiti wa kuangalia athari ya upunguzaji wa uzito wa kilo kwa titi kwa dalili ya maumivu na ubora wa afya. Hi fomu ya idhini ina sehemu mbili:

● Sehemu ya Maelezo (kukuelezea zaidi kuhusu utafiti)

● Shahada ya Idhini (sahihi ikiwa umekubali kujihusisha na utafiti huu)

SEHEMU YA I: **Maelezo**

Mimi ni mwanafunzi katika chuo kikuu cha Nairobi, ninasomea shahada kuu kwenye Idara Upasuaji wa kujenga upya. Ningependa pamoja na wasimamizi wangu kuangalia athari ya upunguzaji wa uzito wa kilo kwa titi kwa dalili na ubora wa afya. Kando na haya utapewa maalezo zaidi kuhusu mada na pia una uhuru wa kuuliza maswali yoyote ili kuelewa uafiti huu zaidi.

Nia

Uzito wa matiti una madhara mengi kama uchungu kwa mgogngo, mabega, titi, kisaikolojia kama kujithamini chini, kuwa na huzuni. Upasuaji wa kupunguza uzito wa matiti unahusiana na uboreshaji wa dalili na ubora wa afya. Utafiti huu utaangalia uhusiano wa uzito wa kilo na dalili na ubora wa afya.

Hatari

Hakuna hatari yoyote itakayotarajiwa utakaposhiriki utafiti huu.

Faida ya utafiti

Utafiti utasaidia wagonjwa wanao uzito wa matiti na madhara yake kusaidika na upasuaji. Na pia bima za afya zitapata fursa ya kujua faida ya upasuaji na kusaidia wagonjwa wanaohitaji hii upasuaji kifedha

Kushiriki

Kushiriki utafiti huu utakuwa kwa njia ya kujitolea na kwa hivyo hakuna malipo yoyote atakayolipwa mshiriki wa utafiti huu. Iwapo hungependa kushiriki ,uamuzi huu hautakuathiri kwa njia yoyote iwe matibabu yako au utakavyiohudumiwa.

Maelezo kuhusu mchakato

Iwapo utakubali kushiriki utaulizwa maswali machache kuhusu ubora wa afya. hali ya kufafanua zaidi juu ya upasuaji na nia ya utafiti amabayo itajazwa kwenye fomu. Wakati utakaotumika utahitaji dakika ishirini tu kukuuliza maswali nakujaza fomu. Wiki sita baada ya upasuaji utajaza fomu hiyo tena.

Usiri

Matokeo ya utafiti huu yatawekwa siri wala hayatapatiwa mtu yeyote asiyehusika na utafiti huu. Zaidi ya hayo badala ya jina, numbari zitatumiwa kutambulisha wahusika

Haki ya kutoshiriki Kushiriki utafiti huu ni kwa kujitolea na iwapo hungependa kushiriki, uamuzi wako utaheshimiwa na pia hautathiri kwa njia yoyote matibabu yako. Bali utaendelea kupokea matibabu na huduma ya hospitali hii kama hapo awali. Pendekezo hili limeangaliwa na kuidhinishwa na Idara ya upasuaji wa urekebishaji ya Chuo kikuu cha Nairobi na kamiti ya maadili ya utafiti katika hospitali ya Kenyatta inayohakikisha kuwa haki za wanaoshiriki utafiti wowote inchini,zinazingatiwa . Iwapo utakuwa na swali lolote kumbuka una uhuru kuuliza.

Sehemu Ya II: Shahada ya Idhini

Nambari Maalum:_____
Nimesoma maaelezo yote ya utafiti huu au nimesomewa maaelezo haya na nimekuwa na fursa ya kuuliza maswali .Maswali yangu yamejibiwa kadri na matarajio yangu kwa njia ya kuridhisha.Kwahio kama mzazi/ mlezi wa : _____ ningependa kupeana idhini yangu na pia kujitolea kushiriki kwa utafiti huu .

Jina la mshiriki: _____ Sihihi la mshiriki:_____
Nambari ya simu mshiriki:

Mtafiti mkuu: Dkt Anne Wangui Waithaka Sahihi ya mtafiti mkuu: _____
Tarehe: _____ Tarehe: _____

Kwa maelezo zaidi hata baada ya utafiti huu una uhuru wakuwasiliana na watu wafuatao kupitia anwani na numbari za simu zilizoandikwa hapa chini.

Jina: Dkt Anne Wangui Waithaka (Mtafiti mkuu)

Numba ya simu: 0724936958

Barua pepe: qawangui@gmail.com

Prof. Stanley Ominde Khainga
P.O. Box 19679, Nairobi
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Dr. Ferdinand Wanjala Nangole
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Barua pepe: nangole2212@yahoo.com

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numbari ya simu: 254722322246
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FOMU YA KUTIWA SAINI NA WATOTO
ATHARI YA UPUNGUZAJI WA UZITO WA KILO KWA TITI KWA DALILI YA MAUMIVU NA UBORA WA AFYA

Fomu ya kutiwa saini na watoto _

Fomu hii ni ya kutiwa sahihi na watoto wenye umri wa miaka kumi na nane chini wanao hudumiwa kwa upasuaji upunguzaji wa uzito wa titi. Mpelelezi mkuu ni Daktari Anne Waithaka chini ya usimamizi wa Daktari Ferdinard Nangole, Profesa Khainga na Daktari Daniel Ojuka katika utafiti wa kuangalia athari ya upunguzaji wa uzito wa kilo kwa titi kwa dalili ya maumivu na ubora wa afya. Utafiti utafanyika chini ya Idara ya upasuaji wa kujenga upya katika Chuo Kikuu cha Nairobi. Hi fomu ya kutiwa sahihi na watoto ina sehemu mbili:

- Sehemu ya Maelezo (kukuelezea zaidi kuhusu utafiti)
- Shahada ya Kutiwa sahihi na watoto (sahihi ikiwa umekubali kujihusisha na utafiti huu)

Utapewa nakala ya maalezo ya utafiti huu.

Maelezo

Mimi ni mwanafunzi katika chuo kikuu cha Nairobi, ninasomea shahada kuu kwenye Idara ya upasuaji wa urekebishaji. Ningependa pamoja na wasimamizi wangu utafiti wa kuangalia athari ya upunguzaji wa uzito wa kilo kwa titi kwa dalili ya maumivu na ubora wa afya. Kando na haya utapewa maalezo zaidi kuhusu mada na pia una uhuru wa kuuliza maswali yoyote ili kuelewa uafiti huu zaidi.

Nia

Uzito wa matiti una madhara mengi kama uchungu kwa mgogngo, mabega, titi, kisaikolojia kama kujithamini chini, kuwa na huzuni. Upasuaji wa kupunguza uzito wa matiti unahusiana na uboreshaji wa dalili na ubora wa afya. Utafiti huu utaangalia uhusiano wa uzito wa kilo na dalili na ubora wa afya.

Hatari

Hakuna hatari yoyote itakayotarajiwa utakaposhiriki utafiti huu.

Nimethibitisha kuwa mtoto ameelewa ya kwamba hakuna hatari yoyote ile itayomkabili _____ (sahihi)

Faida ya utafiti

Utafiti utasaidia wagonjwa wanao uzito wa matiti na madhara yake kusaidika na upasuaji. Na pia bima za afya zitapata fursa ya kujua faida ya upasuaji na kusaidia wagonjwa wanaohitaji hii upasuaji kifedha

Nimethibitisha kuwa mtoto ameelewa faida ya utafiti _____ (saini)

Waanaoalikwa kujihusisha na utafiti

Mtafiti anawakaribisha wagonjwa wote watakaofanyiwa upasuaji wa upunguzaji wa uzito wa titi katika Hospitali

Kushiriki

Kushiriki utafiti huu utakuwa kwa njia ya kujitolea na kwa hivyo hakuna malipo yoyote atakayolipwa mshiriki wa utafiti huu. Iwapo hungependa kushiriki, uamuzi huu hautaathiri kwa njia yoyote matibabu yako au utakavyiohudumiwa.

Nimethibitisha kuwa mtoto ameelewa ya kwamba kujihusisha na hii utafiti ni kwa njia ya kujitolea _____ (saini)

Maelezo kuhusu mchakato

Iwapo utakubali kushiriki utapewa fomu ya kujaza iliyo na seti ya maswali hasa kuhusu hali ya afya ya watoto hawa na idadi ya nyakati za kulazwa hospitalini.

Nimethibitisha kuwa mtoto ameelewa maelezo kuhusu mchakato_____ (saini)

Wakati utakaotumika

Kwa ujumla,utafiti huu utachukua siku hamsini (50).Kwa wakati huu,tutahitaji dakika ishirini tu kujaza fomu na kuchukua maelezo mengine yatakayohitajika. Wiki sita baada ya upasuaji tutajaza hiyo fomu tena.

Usiri

Matokeo ya utafiti huu yatawekwa siri wala hayatapatiwa mtu yeyote asiyehusika na utafiti huu. Zaidi ya hayo badala ya jina la mtoto, numbari zitatumiwa kutambuliwa watoto hawa. Matokeo yatazungumziwa na idara ya afya ya watoto pekee wala sio mtu mwingine.

Haki ya kutoshiriki

Kushiriki kwa utafiti huu ni kwa kujitolea na iwapo hungependa kushiriki,uamuzi wako utaheshimiwa na pia hautathiri kwa njia yoyote matibabu yako. Bali utaendelea kupokea matibabu na huduma ya hospitali hii kama hapo awali.

Pendekezo hili limeangaliwa na kuidhinishwa na Idara ya upasuaji wa kurekebisha ya Chuo kikuu cha Nairobi na kamiti ya maadili ya utafiti katika hospitali ya Kenyatta inayohakikisha kuwa haki za wanaoshiriki utafiti wowote inchini,zinazingatiwa .

Iwapo utakuwa na swali lolote kumbuka una uhuru kuuliza.

SEHEMU YA II: Shahada ya Kutiwa Saini na Watoto **Nambari Maalum:_____**

Nimesoma maaelezo yote ya utafiti huu au nimesomewa maaelezo haya na nimekuwa na fursa ya kuuliza maswali ambayo yamejibiwa kadri na matarajio yangu kwa njia ya kuridhisha. Kwa hio ningependa kupeana saini langu na pia kujitolea kushiriki kwa utafiti huu.

Nakubali kujihusisha na utafiti huu.

AMA

Si kubali kujuhusisha na utafiti huu na sijatia saini lolote._____ (alama ya mshiriki)

Nambari ya simu ya mshiriki

Mtoto akikubali:

Jina la mtoto: _____

Sahihi la mtoto: _____

Tarehe:_____

Iwapo mtoto awezi akasoma:

Nimeona na ninaweza thibitisha ya kwamba mtoto amesomewa yaliyo kwenye hii fomu ya kutiwa saini na mtoto, na mtoto mwenyewe ameweza kuuliza maswali atakayo. Na thibitisha ya kwamba mtoto amekubali kwa hiari yake kushirikiana na hii utafiti.

Jina la shahidi (isiwe mzazi): _____ NA Alama ya Kidole ya Mshiriki

Saini la shahidi:_____

Nambari ya simu

Tarehe: _____

Nememsomea, nimeona na ninaweza thibitisha ya kwamba mtoto amesomewa yaliyo kwenye hii fomu ya kutiwa saini na mtoto, na mtoto mwenyewe ameweza kuuliza maswali atakayo. Na thibitisha ya kwamba mtoto amekubali kwa hiari yake kushirikiana na hii utafiti.

Jina la mpelelezi: Dkt Anne Wangui Waithaka

Sahihi ya mpelelezi: _____

Tarahe: _____

Nakala imepewa kwake mshiriki ____(alama ya mpelelezi)

Mzazi/Mgarini amaitia saini Shahada ya Idhini: Ndiyo_____ Hapana_____

Kwa maelezo Zaidi hata baada ya utafiti huu una uhuru wakuwasiliana na watu wafuatao kupitia anwani na numbari za simu silizoandikwa hapa chini.

Jina: Dkt Anne Wangui Waithaka (Mtafiti mkuu)

Numba ya simu: 0724936958

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barua pepe: dkinyuru@yahoo.com

APPENDIX II: QUESTIONNAIRE 1

SECTION 1: BIO DATA

1. PATIENT IDENTITY NUMBER
2. DATE
3. DATE OF BIRTH
4. AGE/YEARS
5. WEIGHT/KILOGRAMS
6. HEIGHT/CENTIMETERS
7. BODY MASS INDEX
8. TELEPHONE NUMBER
9. EMAIL ADDRESS

RISK FACTORS

1. Age of onset
2. Family history
3. Smoking

STUDY SITE

1. KENYATTA NATIONAL HOSPITAL
2. AGAKHAN UNIVERSITY HOSPITAL
3. NAIROBI HOSPITAL

SECTION 2: INTRAOPERATIVE

	RIGHT BREAST	LEFT BREAST	TOTAL
RESECTED VOLUME/KILOGRAMS			

DIAGNOSIS

1. GIGANTOMASTIA	
2. MACROMASTIA	
3. GYNECOMASTIA	
4. BREAST ASSYMETRY	

1. DATE OF PROCEDURE;

2. DURATION OF SURGERY:

1. SURGEON; CONSULTANT ☐

2. REGISTRAR ☐

SECTION 4 POSTOPERTIVELY

COMPLICATIONS

MINOR	MAJOR
1.	1.
2.	2.
3.	3.
4.	4.
5.	5.

APPENDIX III: BREAST Q QUESTIONNAIRE

Memorial Sloan Kettering Cancer Center

BREAST-Q Version 2.0©

Reduction/Mastopexy Module

Pre- and Postoperative Scales

English Version

THE UNIVERSITY OF BRITISH COLUMBIA

NOTE TO LICENSED USERS

Each scale in this booklet can be used independently of the other scales (i.e., you don't have to use them all). For each scale that you use, the patients or research participants DO NOT NEED TO SEE:

- title of each scale
- notes at the bottom of the scale
- scoring table for the scale

We are able to provide you with a Word version of this booklet if needed. Send an email to: qportfolioteam@gmail.com

Patients or research participants only need to see the instructions, items, response options and the copyright notice at the bottom of the scale. Here's an example:

With your body in mind, thinking of the past week, how much would you disagree or agree with each statement:

	Definitely Disagree	Somewhat Disagree	Somewhat Agree	Definitely Agree
1. I feel positive towards my body.	1	2	3	4
2. My body is not perfect but I like it.	1	2	3	4
3. I am happy with my body.	1	2	3	4
4. I am proud of my body.	1	2	3	4
5. I think my body is attractive.	1	2	3	4
6. I feel good about my body when I am naked.	1	2	3	4
7. I have the body I want.	1	2	3	4

AS A REMINDER: In the license you signed, you agreed to the following:

1. You will not change this questionnaire in any way
2. You will not translate this questionnaire without permission
3. You will not give this questionnaire to an unlicensed user
4. You will not reproduce this questionnaire in publications or other materials

BREAST-Q™ - REDUCTION MODULE (PRE- AND POSTOPERATIVE) VERSION 2.0: PSYCHOSOCIAL WELL-BEING

With your breasts in mind, in the past week, 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. Of equal worth to other women?	**1**	**2**	**3**	**4**	**5**
c. Good about yourself?	**1**	**2**	**3**	**4**	**5**
d. Self-assured?	**1**	**2**	**3**	**4**	**5**
e. Confident in your clothes?	**1**	**2**	**3**	**4**	**5**
f. Accepting of your body?	**1**	**2**	**3**	**4**	**5**
g. That your appearance matches who you are inside?	**1**	**2**	**3**	**4**	**5**
h. Confident about your body?	**1**	**2**	**3**	**4**	**5**
i. Attractive?	**1**	**2**	**3**	**4**	**5**

Note to Investigators: This scale can be used independently of the other scales.

BREAST-Q™ - REDUCTION MODULE (PRE- AND POSTOPERATIVE) VERSION 2.0: PSYCHOSOCIAL WELL-BEING CONVERSION TABLE

Instructions: If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best). Higher scores reflect a better outcome.

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
9	0
10	14
11	18
12	21
13	24
14	26
15	28
16	30
17	32
18	33
19	35
20	36
21	38
22	39
23	41
24	42
25	44
26	45
27	47
28	49
29	50
30	52
31	54
32	56
33	59
34	61
35	64
36	66
37	69
38	72
39	75
40	78
41	81
42	84
43	88
44	93
45	100

BREAST-Q™ - REDUCTION MODULE (PRE- AND POSTOPERATIVE) VERSION 2.0: SEXUAL WELL-BEING

Thinking of your sexuality, 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
a. Comfortable/at ease during sexual activity?	**1**	**2**	**3**	**4**	**5**
b. Confident sexually?	**1**	**2**	**3**	**4**	**5**
c. Satisfied with your sex life?	**1**	**2**	**3**	**4**	**5**
d. Sexually attractive in your clothes?	**1**	**2**	**3**	**4**	**5**
e. Sexy when unclothed?	**1**	**2**	**3**	**4**	**5**

Note to Investigators: This scale can be used independently of the other scales. The following statement can be added to the stem to provide an opportunity for the patient to decline completing this scale. 'The following questions ask about your sexual well-being. If you are uncomfortable answering these questions or do not feel that they apply to you, please check the box and skip the questions that follow.'

BREAST-Q™ - REDUCTION MODULE (PRE- AND POSTOPERATIVE) VERSION 2.0: SEXUAL WELL-BEING CONVERSION TABLE

Instructions: If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best). Higher scores reflect a better outcome.

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
5	0
6	18
7	23
8	28
9	31
10	34
11	37
12	39
13	42
14	44
15	47
16	50
17	53
18	56
19	60
20	65
21	71
22	76
23	82
24	90
25	100

BREAST-Q™ - REDUCTION MODULE (PRE- AND POSTOPERATIVE) VERSION 2.0: PHYSICAL WELL-BEING

In the past week, how often have you experienced:

	None of the time	Some of the time	All of the time
a. Headaches?	**1**	**2**	**3**
b. Pain in your breast area?	**1**	**2**	**3**
c. Lack of energy?	**1**	**2**	**3**
d. Difficulty doing vigorous physical activities (e.g. running or exercising)?	**1**	**2**	**3**
e. Feeling physically unbalanced?	**1**	**2**	**3**
f. Shoulder pain?	**1**	**2**	**3**
g. Difficulty sleeping because of discomfort in your breast area?	**1**	**2**	**3**
h. Neck pain?	**1**	**2**	**3**
i. Painful gouges or grooves in your shoulders from your bra straps?	**1**	**2**	**3**
j. Feeling physically uncomfortable?	**1**	**2**	**3**
k. Rashes under your breasts?	**1**	**2**	**3**
l. Back pain?	**1**	**2**	**3**
m. Arm pain?	**1**	**2**	**3**
n. Pain, numbness or tingling in your hands because of your breast size?	**1**	**2**	**3**

Note to Investigators: This scale can be used independently of the other scales.

BREAST-Q™ - REDUCTION MODULE (PRE- AND POSTOPERATIVE) VERSION 2.0: PHYSICAL WELL-BEING CONVERSION TABLE

Instructions: Items 'a' and 'b' are stand-alone items that are not included in the scale score. Recode items c, d, e, f, g, h, i, j, k, l, m, and n as follows: "None of the time" = 3; "Some of the time" = 2; "All of the time" = 1. If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best). Higher scores reflect a better outcome.

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
12	0
13	14
14	20
15	25
16	28
17	31
18	34
19	37
20	40
21	42
22	44
23	47
24	49
25	51
26	54
27	56
28	59
29	62
30	65
31	68
32	72
33	77
34	82
35	90
36	100

BREAST-Q™ - REDUCTION MODULE (PREOPERATIVE) VERSION 2.0: SATISFACTION WITH BREASTS

With your breasts in mind, in the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How your breasts look in clothes?	**1**	**2**	**3**	**4**
b. How your breast size matches the rest of your body?	**1**	**2**	**3**	**4**
c. The size of your breasts?	**1**	**2**	**3**	**4**
d. The shape of your breasts when you are wearing a bra?	**1**	**2**	**3**	**4**
e. How equal in size your breasts are to each other?	**1**	**2**	**3**	**4**
f. How comfortably your bras fit?	**1**	**2**	**3**	**4**
g. The shape of your breasts when you are not wearing a bra?	**1**	**2**	**3**	**4**
h. How you look in the mirror clothed?	**1**	**2**	**3**	**4**
i. How your breasts sit/hang on your chest?	**1**	**2**	**3**	**4**
j. How normal your breasts look?	**1**	**2**	**3**	**4**
k. How you look in the mirror unclothed?	**1**	**2**	**3**	**4**

Note to Investigators: This scale can be used independently of the other scales.

BREAST-Q™ - REDUCTION MODULE (PREOPERATIVE) VERSION 2.0: SATISFACTION WITH BREASTS CONVERSION TABLE

Instructions: If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best). Higher scores reflect a better outcome.

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
11	0
12	11
13	17
14	21
15	24
16	26
17	29
18	31
19	33
20	35
21	36
22	38
23	40
24	41
25	43
26	45
27	46
28	48
29	50
30	52
31	53
32	55
33	57
34	59
35	61
36	63
37	66
38	68
39	71
40	74
41	78
42	82
43	89
44	100

BREAST-Q™ - REDUCTION MODULE (POSTOPERATIVE) VERSION 2.0: SATISFACTION WITH BREASTS

With your breasts in mind, in the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How your breasts look in clothes?	**1**	**2**	**3**	**4**
b. How your breast size matches the rest of your body?	**1**	**2**	**3**	**4**
c. The size of your breasts?	**1**	**2**	**3**	**4**
d. The shape of your breasts when you are wearing a bra?	**1**	**2**	**3**	**4**
e. How equal in size your breasts are to each other?	**1**	**2**	**3**	**4**
f. How comfortably your bras fit?	**1**	**2**	**3**	**4**
g. The shape of your breasts when you are not wearing a bra?	**1**	**2**	**3**	**4**
h. How you look in the mirror clothed?	**1**	**2**	**3**	**4**
i. How your breasts sit/hang on your chest?	**1**	**2**	**3**	**4**
j. How normal your breasts look?	**1**	**2**	**3**	**4**
k. The location of your scars?	**1**	**2**	**3**	**4**
l. How your scars look?	**1**	**2**	**3**	**4**
m. How you look in the mirror unclothed?	**1**	**2**	**3**	**4**

Note to Investigators: This scale can be used independently of the other scales.

BREAST-Q™ - REDUCTION MODULE (POSTOPERATIVE) VERSION 2.0: SATISFACTION WITH BREASTS CONVERSION TABLE

Instructions: If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best). Higher scores reflect a better outcome.

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
13	0
14	11
15	16
16	20
17	23
18	26
19	28
20	30
21	32
22	33
23	35
24	37
25	38
26	40
27	41
28	43
29	44
30	46
31	47
32	49
33	50
34	51
35	53
36	54
37	56
38	58
39	59
40	61
41	63
42	64
43	66
44	68
45	70
46	73
47	75
48	78
49	82
50	86
51	92
52	100

BREAST-Q™ - REDUCTION MODULE (POSTOPERATIVE) VERSION 2.0: SATISFACTION WITH NIPPLES

In the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How high or low your nipples are on your breasts?	**1**	**2**	**3**	**4**
b. How your nipples are lined up in relation to each other?	**1**	**2**	**3**	**4**
c. The shape of your nipples and areolas?	**1**	**2**	**3**	**4**
d. How your nipples and areolas look?	**1**	**2**	**3**	**4**
e. The amount of sensation (feeling) in your nipples?	**1**	**2**	**3**	**4**

Instructions: These questions should be considered as stand-alone. Thus, the patient's response is taken as the score form each item. Higher scores reflect a better outcome.

Note to Investigators: This scale can be used independently of the other scales.

BREAST-Q™ - REDUCTION MODULE (POSTOPERATIVE) VERSION 2.0: SATISFACTION WITH OUTCOME

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

	Disagree	Somewhat Agree	Definitely Agree
a. Having surgery was the right decision for me.	**1**	**2**	**3**
b. I would encourage other women in my situation to have breast reduction surgery.	**1**	**2**	**3**
c. I would do it again.	**1**	**2**	**3**
d. Overall the surgery was a positive experience.	**1**	**2**	**3**
e. Having surgery changed my life for the better.	**1**	**2**	**3**
f. I have no regrets about having surgery.	**1**	**2**	**3**
g. The outcome perfectly matched my expectations.	**1**	**2**	**3**
h. It turned out exactly as I had planned.	**1**	**2**	**3**

Note to Investigators: This scale can be used independently of the other scales.

BREAST-Q™ - REDUCTION MODULE (POSTOPERATIVE) VERSION 2.0: SATISFACTION WITH OUTCOME CONVERSION TABLE

Instructions: If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best). Higher scores reflect a better outcome.

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
8	0
9	17
10	25
11	31
12	36
13	39
14	43
15	46
16	49
17	52
18	56
19	59
20	63
21	68
22	76
23	86
24	100

BREAST-Q™ - REDUCTION MODULE (POSTOPERATIVE) VERSION 2.0: PATIENT EXPERIENCE: SATISFACTION WITH INFORMATION

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 surgery was to be done?	**1**	**2**	**3**	**4**
b. Possible complications?	**1**	**2**	**3**	**4**
c. Healing and recovery time?	**1**	**2**	**3**	**4**
d. How to choose a breast size that would suit what you wanted?	**1**	**2**	**3**	**4**
e. The potential for loss of sensation in your nipples?	**1**	**2**	**3**	**4**
f. What size you could expect your breasts to be after surgery?	**1**	**2**	**3**	**4**
g. Potential for loss of blood supply to your nipple area?	**1**	**2**	**3**	**4**
h. How to care for your incisions after surgery?	**1**	**2**	**3**	**4**
i. What you could expect your breasts to look like after surgery?	**1**	**2**	**3**	**4**
j. What the scars would look like?	**1**	**2**	**3**	**4**
k. How the surgery could affect future breast cancer screening (e.g. mammogram, self-examinations)?	**1**	**2**	**3**	**4**
l. Options to help with scarring?	**1**	**2**	**3**	**4**
m. How the surgery could affect breast-feeding? (only answer if applicable)	**1**	**2**	**3**	**4**

Note to Investigators: This scale can be used independently of the other scales. Depending on the use of this scale, you may wish to add the following statement to the stem for clarity. 'These questions ask about the surgeon who performed your most recent surgery.'

BREAST-Q™ - REDUCTION MODULE (POSTOPERATIVE) VERSION 2.0: PATIENT EXPERIENCE: SATISFACTION WITH INFORMATION CONVERSION TABLE

Instructions: If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best). Higher scores reflect a better outcome.

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
13	0
14	13
15	19
16	23
17	26
18	29
19	31
20	33
21	34
22	36
23	37
24	39
25	40
26	41
27	42
28	44
29	45
30	46
31	47
32	48
33	50
34	51
35	52
36	53
37	55
38	56
39	57
40	59
41	60
42	62
43	64
44	66
45	68
46	70
47	72
48	75
49	79
50	84
51	90
52	100

BREAST-Q™ - REDUCTION MODULE (POSTOPERATIVE) VERSION 2.0: PATIENT EXPERIENCE: SATISFACTION WITH SURGEON

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

	Definitely Disagree	Somewhat Disagree	Somewhat Agree	Definitely Agree
a. Was professional?	**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**

Note to Investigators: This scale can be used independently of the other scales. This scale is exactly the same across all BREAST-Q Postoperative Modules. Depending on the use of this scale, you may wish to add the following statement to the stem for clarity. 'These questions ask about the surgeon who performed your most recent surgery.'

BREAST-Q™ - REDUCTION MODULE (POSTOPERATIVE) VERSION 2.0: PATIENT EXPERIENCE: SATISFACTION WITH SURGEON CONVERSION TABLE

Instructions: If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best). Higher scores reflect a better outcome.

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
12	0
13	16
14	21
15	24
16	26
17	29
18	30
19	32
20	34
21	35
22	36
23	38
24	39
25	40
26	42
27	43
28	44
29	46
30	47
31	49
32	50
33	52
34	54
35	56
36	58
37	60
38	62
39	64
40	67
41	69
42	72
43	75
44	78
45	81
46	86
47	92
48	100

BREAST-Q™ - REDUCTION MODULE (POSTOPERATIVE) VERSION 2.0: PATIENT EXPERIENCE: SATISFACTION WITH MEDICAL TEAM

These questions ask about members of the medical team other than the surgeon. 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**

Note to Investigators: This scale can be used independently of the other scales. This scale is exactly the same across all BREAST-Q Postoperative Modules. Depending on the use of this scale, you may modify the stem wording to fit your clinical environment. (e.g. medical team may include nurses, physician assistants, or other licensed independent practitioners)

BREAST-Q™ - REDUCTION MODULE (POSTOPERATIVE) VERSION 2.0: PATIENT EXPERIENCE: SATISFACTION WITH MEDICAL TEAM CONVERSION TABLE

Instructions: If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best). Higher scores reflect a better outcome.

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
7	0
8	0
9	11
10	20
11	27
12	32
13	36
14	40
15	43
16	46
17	50
18	53
19	57
20	61
21	65
22	69
23	73
24	77
25	82
26	86
27	92
28	100

BREAST-Q™ - REDUCTION MODULE (POSTOPERATIVE) VERSION 2.0: PATIENT EXPERIENCE: SATISFACTION WITH OFFICE STAFF

These questions ask about members of the office staff (e.g. secretaries). 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**

Note to Investigators: This scale can be used independently of the other scales. This scale is exactly the same across all BREAST-Q Postoperative Modules. Depending on the use of this scale, you may modify the stem wording to fit your office environment. (e.g. office or clinic nurse)

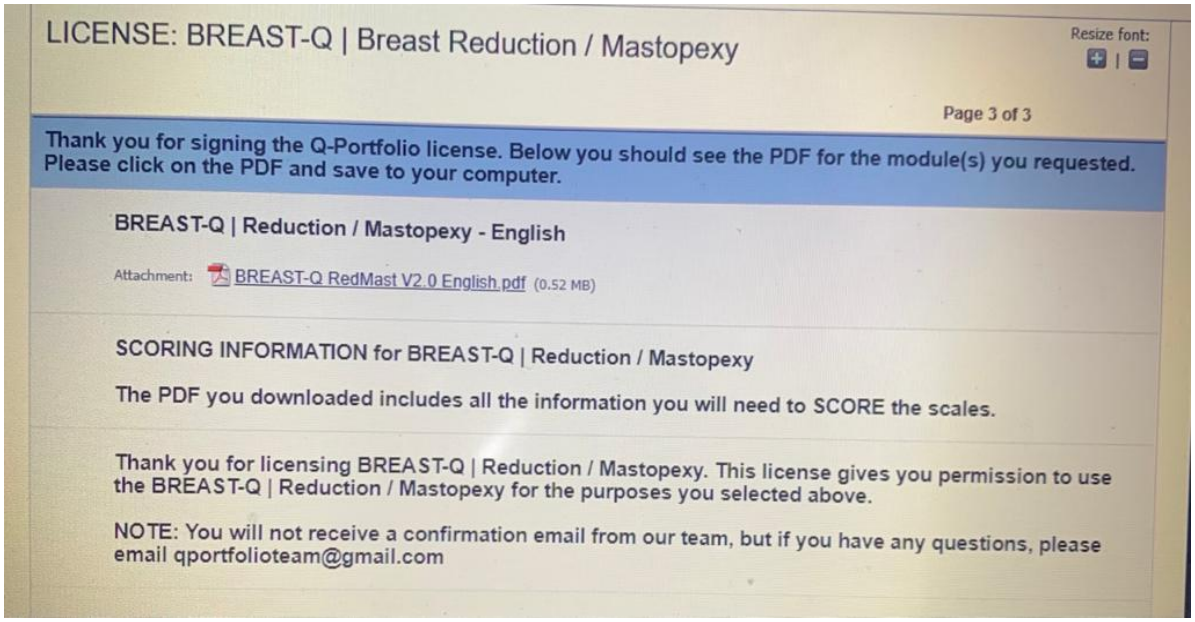
BREAST-Q™ - REDUCTION MODULE (POSTOPERATIVE) VERSION 2.0: PATIENT EXPERIENCE: SATISFACTION WITH OFFICE STAFF CONVERSION TABLE

Instructions: If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best). Higher scores reflect a better outcome.

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
7	0
8	17
9	24
10	28
11	31
12	34
13	37
14	39
15	41
16	44
17	46
18	49
19	51
20	54
21	58
22	61
23	65
24	70
25	75
26	81
27	89
28	100

Appendix 3 Licence: BREAST-Q/ Breast Reduction Module

APPENDIX IV: LICENCE TO BREAST-Q| Breast Reduction / Mastopexy Module



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Page 3 of 3

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