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Swedish Version of the Latissimus Dorsi Modules of Breast-Q: Translation and Psychometric Properties

Degree Project in Medicine

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Abstract

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Title: Swedish Version of the Latissimus Dorsi Modules of Breast-Q: Translation and Psychometric Properties.

Background:

At the Sahlgrenska University Hospital; Department for Plastic Surgery, around 350 breast reconstructions are performed every year. The latissimus dorsi flap is a popular autologous flap technique which may be performed with or without implants in an immediate (at the same time as the mastectomy) or delayed setting.

A disease-specific instrument, the Breast-Q, has been developed to evaluate patient-related outcome measures (PROMs) after breast reconstruction. The subscales of the Breast-Q reconstruction module; 'Satisfaction with Back' and 'Physical Well Being: Shoulder and Back' have been used to measure and collect patient subjective information regarding their well-being and health related quality of life after reconstruction with the latissimus dorsi flap.

Aim:

To assess whether the self assessment subscales 'Satisfaction with Back' and 'Physical Well Being: Shoulder and Back' are suitable for use as a form of evaluation for breast reconstruction with latissimus dorsi flap in Sweden.

Method:

The study is a validation of a PROM questionnaire for breast reconstruction with latissimus dorsi in Sweden. Every woman > 18 years old who had undergone reconstructive surgery with autologous latissimus dorsi flap within the past 10 years (2007-2017) at Sahlgrenska University Hospital as well as all women who were awaiting reconstructive surgery of the breast with autologous latissimus dorsi flap were included in the study.

Results:

Statistical analysis of the subcscales through a validation process, reliability testing and correlation testing to one another proved to be satisfactory.

Conclusion:

The subscales 'Satisfaction with Back' and 'Physical Well Being: Shoulder and Back' have shown good results and has satisfied the hypothesised outcome for this study. However, in order to increase its strength for use in the setting of breast reconstruction with latissimus dorsi flap, more comparative studies within this area are of interest.

Key words:

Breast Cancer, Breast Reconstruction, Breast-Q, Latissimus-Dorsi, Patient Reported Outcomes

1. Background

1.1 Breast cancer

1.1.1 Epidemiology

Breast cancer is the leading cause of death in women globally and, the most frequent cancer among women (WHO). According to WHO 2018 estimation, more than 600 000 women died from breast cancer constituting approximately 15% of all deaths caused by cancer in women. Breast cancer rates are higher in developed regions (WHO). In Nordic countries the number of cases reported per year between 2012-2016 in females was 20132 with the incidence in Sweden being 7240 (NORDCAN). It is the leading cause of cancer in women in Sweden and as of 2018 the total number of cases reported was 10063 (Socialstyrelsen, 2018). The survival rate for patients diagnosed with breast cancer in Sweden today is high. 2016 statistics show that approximately 100 000 women live with breast cancer, with the five and ten year relative survival rates being 92% and 86. % respectively (Socialstyrelsen, 2018).

1.1.2 Etiology

Hereditary high and medium penetrating genes such as BRCA1 or BRCA2 exist in 2-3% of women who are diagnosed with breast cancer in Sweden (Cancercentrum). It is known and well-presented through large epidemiological studies that women with a family history of breast cancer have an increased risk of developing breast cancer as compared to women without the disease in the family (Cao et al., 2017). Apart from inherited genetic mutations, other risk-factors for breast cancer include environmental, reproductive and lifestyle factors.

(ROJAS and STUCKEY, 2016). Enviromental factors such as exposure to tobacco smoke (both active and passive exposure), dietary factors (i.e high fat foods), alcohol consumption and environmental carcinogens (i.e exposure to ionising radiation), lack of physical excercise has all shown to increase the risk of breast cancer (Howell et al., 2014, Coughlin and Smith, 2015). Child bearing before the age of 30 has shown to decrease the risk of breast cancer. Early menarche or women who have not had children have shown an increased risk of developing breast cancer (Hinkula et al., 2001). Being overweight has also shown an increased risk for devloping post-menopausal breast cancer. Conversely, being overweight or obese in young adulthood has demonstrated a somewhat decreased risk of developing pre-menopausal breast cancer (Amina Amadou et al., 2013).

1.1.2 Classification

There are different types of classification of breast cancers and they form the basis for the choice of treatment and the prognosis. They are divided into histological subtypes based on which structure they originate in, for example ductal cancer originating in the milk ducts and lobular cancer, originating in the milk producing glands. Furthermore, cancers of the breast are classified into in situ (CIS), where the cancerous cells proliferate within the ducts or lobules without invading the surrounding stromal tissue, and invasive cancer, as given in the name, describes any form of breast cancer which has spread (invaded) beyond the boundaries of the ducts and spread into the surrounding tissue. Tumours are also classified according to hormone recepter status and based on whether the tumour has spread to other tissues or not (Weigelt et al., 2010).

1.1.3 Treatment

Surgical treatment is usually the primary step in a line of multimodal treatment for most women with carcinoma of the breast. The two types of surgical procedures performed are partial mastectomy, where the tumour is excised with an adequate margin, and mastectomy where all breast tissue is removed with or without dissection of the axilla. The latter is performed if partial mastectomy is assessed to not give satisfactory cosmetic results, in case of an inflammatory tumour or another T4-tumour after pre-operative treatment, large tumours that continue to progress during pre-operative treatment, in case of local relapse after performed partial mastectomy with radiotherapy, if there are contraindications to postoperative radiotherapy, and more. During pre-operative treatment in patients with no confirmed axillary metastasis it is recommended that the sentinel node biopsy be performed after the pre-operative treatment. The indication for axillary dissection is if there is known metastasis of the tumour to the axilla, if there are multifocal tumours, if there exist macrometastasis to the sentinel lymph node and if there is locally advanced breast cancer (regardless of size) after pre-operative systemic treatment (Cancercentrum, 2019). Neoadjuvant chemotherapy is sometimes given before the surgery. Depending on the type and size of the tumour and whether it has spread to the lymphnodes, adjuvant treatment may include chemotherapy, radiotherapy and endocrine therapy (Cancercentrum, 2019, McDonald et al., 2016).

1.2 Breast Reconstruction

1.2.1 Scope

When the patient is operated on with a mastectomy she may opt to have a breast reconstruction. It can be performed at the same time as the mastectomy (‘immediate breast reconstruction’) or later in a separate operation (‘delayed breast reconstruction’). The principle aim of breast reconstruction after mastectomy is to restore cosmesis and improve physical and psychological health (Veronesi et al., 2011).

1.2.2 Techniques

The techniques for breast reconstruction can be divided into implant based techniques, autologous techniques, mainly deep inferior epigastrica performator flap (DIEP) and latissimus dorsi flap, and a combination of implant based and autologous techniques. According to the Swedish national medical indications, implant based reconstructions are offered to non-radiated patients and autologous alternatives to radiated patients (Anna Elander et al., 2011). The focus of this thesis will be the evaluation of breast reconstruction with latissimus dorsi with or without implants.

1.2.3 The latissimus dorsi flap

The latissimus dorsi muscle is a flat and triangular muscle which covers the posterior trunk. Its superior medial portion rests deep into the trapezius muscle. The remainder of the LD rests inferiorly to the surroundning subcutaneous tissue. The muscle has its origin in the spinous

processes of thoracic T7-T12, thoracolumbar fascia, iliac crest and inferior 3 or 4 ribs and the inferior angle of the scapulae. The insertion of the muscle is on the floor of the intertubercular groove of the humerus (Bhatt et al., 2013). The latissimus dorsi flap is used for soft tissue coverage providing form and function during breast reconstruction. It may be used in immediate or delayed reconstruction, with implant based immediate reconstruction, as an autologous flap or in combination with tissue expanders. (Sood et al., 2018). The LD flap method is usually offered to patients who are poor candidates for breast recontruction with microsurgical technique.

The aim of the operative technique is to be able to maximise and thus provide the target chest area with sufficient non-radiated soft tissue coverage provided by the flap. All while trying to minimise the magnitude of donor site defect and donor site complications (Ismaïl et al., 2014, Lee and Miteff, 2014). The latissimus dorsi is dissected along with a pedicle of vascularized muscle (thoracodorsal artery and vein). This technique may include overlying fat and skin, making it a musculocutaneous flap. Once it has been elevated from its site of origin, the latissimus dorsi is tunneled subcutaneously under the axilla and transfered into a breast pocket where it is sutured into place (Smith, 2014).

According to Blackburn et al. (2018), there appears to be a disparity between scientific consensus within literature regarding problems associated with LD reconstructive surgery. Nonetheless, common problems associated with the flap includes infection, flap necrosis, seroma formation and shoulder dysfunction (Bittar et al., 2012, Giordano et al., 2011, Cattelani et al., 2019). According to a review by Ismaïl et al. (2014) several studies reported

shoulder dysfunction which included deficiency in range of motion, decreased strength and endurance in extension and adduction, decreased mobility, rigididty and pain. (Ismaïl et al., 2014). However, Ismaïl et al. (2014) goes on to describe that the studies show divergent results which may be affected by the variable follow-up and use of different techniques. Conclusively, they go on to mention that the removal of the muscle may provoke pain and lead to functional sequelae but which seem to fade with time thanks to rehabilitation by utilising of other muscle groups.

1.2.4 Evaluation of the outcome – PROMs

1.2.4.1 Development of PROMs

Before the 21st century there were limited studies providing patient subjective information. Health outcome measure research was focused on traditional outcome measures such as patient morbidity and mortality (Cordova et al., 2019, Cohen et al., 2016). As the main aim of a breast reconstruction is to increase the patients quality of life, it is crucial to use instruments that include the direct perspective of the patient when measuring the surgical outcomes, so called patient-reported-outcomes (PROs) (Cordova et al., 2019, van Egdom et al., 2019b). PROMs or patients-related-outcome-measures are validated instruments (questionnaires) that measure the patients perception of their functional well-being and health related quality of life (HRQoL) through self-assessment of their functional well-being and health status (Ghilli et al., 2020, Dahlbäck et al., 2017). The development of PROMs has helped clinicians improve patient tailored care which in turn leads to improved care delivery.

PROMs are divided into generic and disease specific instruments. In simple terms, a generic instrument is a wide-range questionnaire that measures health related quality of life in a diverse patient population (Cano et al., 2009). Moreover, according to Cano et al, although such instruments may be reliable they may not be sensitive enough to measure changes as a consequence of surgical intervention. They may also miss to capture all aspects of a specific outcome to the condition of interest.

Disease specific instruments (i.e Breast-Q) are developed to address those aspects of outcome that are important for a specific patient population. Patients will be asked questions which are relevant and meaningful to them through addressing relevant areas of concern for the study group. The downfall of disease-speicifc instruments is the lack of comparability across diseases making it a particular issue for assessing i.e the comparative benefits of treatment reimbursements across disease areas (Lo et al., 2001).

1.2.4.3 The core outcome set for PROMs in breast reconstruction

According to Santosa et al. (2018) a shared decision making is essential in choosing high quality breast reconstruction techniques which seldom is the case when left to the patient alone. Santosa writes that a collaboration between the physician and the patient can aid in contributing to a well-grounded choice which stems from evidence based, patient-centred data in combination with patient preferences. Such data has not previously been available due to a lack of well-developed valid, disease-specific PROMs.

Furthermore, van Egdom et al. (2019a) highlights in a systematic review on the implementation of patient-reported-outcome-measures in clinical breast cancer care, the importance of taking into account that several studies consist of a heterogenous study population, have differences in PROMs collection methods/frequencies or have combined interventions (i.e enhanced patient care with education and coaching) which further challenges the attempt to develop profound interpretation of the impact of PROMs collection for comparative studies.

Due to marked heterogenity of published studies on patient-reported-outcome-measures on reconstructive breast surgery, it is fundamental and essential to select and develop an appropriate core outcome set (Potter et al., 2015). The aim of the BRAVO study (Breast Reconstruction and Valid Outcomes) which was conducted in the UK, was to develop a core outcome set to be used in studies in reconstructive breast surgery. The use of a robust consensus methodology to develop a core outcome set for effectiveness in reconstructive breast surgery studies would according to Potter et al. (2015) improve quality of outcome assessment and the value of work to patients and surgeons within the reconstructive community. The core outcome set for breast reconstruction, includes patient reported outcomes that should be measured and used in all breast reconstruction studies. Hence, it is of particular importance that instruments used to measure these outcomes as a part core measurement set are well grounded and validated (Davies et al., 2020).

1.2.4.2 Generic PROMs in breast reconstruction

The 36-Item Short-Form Health Survey is a generic PROM which aims to asses general health status through limitations in physical, social, usual role activities and general health perceptions (Korus et al., 2015). According to a systematic review by Korus et al. (2015), The 36-Item Short-Form Health Survey is one such generic PROM which has shown great success in assessing change in health status prior to and after breast reconstruction.The instrument has been able to present statistical improvements in social function, emotional role, mental health and general health.

The review goes on to mention the use of other generic proms such as the Hospital Anxiety and Depression Scale, which in the setting of breast reconstruction has shown the greatest use in correlation of anxiety and depression with patients experiencing postoperative complications.

The Hopwood Body Image Scale (10-question scale PROM) and the Rosenberg Self-Esteem Scale (10-item scale PROM), have both been able to show a spectrum of change in body image and self-esteem respectively when comparing mastectomy alone to mastectomy with reconstruction and then to breast-conserving surgery. However, the Rosenberg Self-Esteem Scale has never been formally validated in a breast reconstruction population. The Hopwood Body Image Scale, originally developed to be used in assesment of cancer patiens, has presented trends in improving body image when comparing mastectomy to reconstruction to breast-conserving surgery and has shown that poorer body image is associated with regret in decision making (Korus et al., 2015).

1.2.4.3 Disease-specific PROMs, including Breast Q

There are several disease-specific validated instruments, for example Breast-Q and EORTC-Q30/Q-23 (Cordova et al., 2019). In regards to the question at issue for this thesis, solely the Breast-Q will be discussed further. The Breast-Q has since its founding in 2006 increased the use of PROMs in breast surgery and has been used to provide a better understanding of the impact that surgical decision and failures has on the patient (Cohen et al., 2016). The breast cancer Breast-Q is divided into; the mastectomy module, the reconstruction module, the breast reconstruction expectations module and the breast conserving therapy module. The prior mentioned modules each consists of a pre-operative and post-operative version with multiple scales that can be used independently (Pusic et al., 2009).

1.2.4.4 The latissimus dorsi specific Breast-Q modules

Recently, a specific reconstruction to evaluate breast reconstruction with a latissimus dorsi flap has been developed (Pusic et al., 2017): 'Satisfaction with Back' and 'Physical Well Being: Shoulder and Back'. The aim of the 'Satisfaction with Back' scale is to appreciate the degree to which the patient is satisfied or dissatisfied with the appearance of their back after reconstructive breast surgery. The scale consists of 8 questions. Each question has a scale of five numbers; 1-5. The recall period for each question is the "past week".

The outline for 'Physical Well Being: Shoulder and Back' scale is the same in regards to the recall period and scoring (1-5) as previously described. The scale consists of 11 questions. This subscale aims at measuring to which degree the patients well-being has been affected by

the surgical procedure, i.e it asks about weakness of the arm, pain in the shoulder, stiffness of the shoulder, etc.

1.2.4.4 Validation of PROMs

There are three important aspects when evaluating PROM questionnaires. These are reliability, validity, and responsiveness (Alrubaiy et al., 2014). Where reliability means the abilitiy to produce consistent and reproducible scores, where validity is the ability to measure what is intended to be measured and, responsiveness is defined as the abilitiy of a measure to accurately detect change. The science which is used to measure the previously mentioned properties of a PROM is called psychometrics. Modern day psychometric methods in use are i.e Rasch measurement or Rasch analysis (Pusic et al., 2011). This will be discussed further under *validation process and statistics*.

1.2.4.5 Translation and validation for different cultures

In the process of translation and adaption of instruments for the use in research it is important to achieve a conceptual equivalent in the targeted country or culture. By means, the aim should not be to achieve a word-to-word translation. There is a well established method which consists of forward and backward translation in order to achieve a cross-cultural and conceptual version in the target language. The first step, the forward translation, involves a translator whos mother tongue should be in the target language but who fully grasps the English-speaking language culture. The translator should also be familiar with the terminology which is covered in the area. The backward translation is similar to the former mentioned, however in this case an independent translator whos mother tongue is in English and who is not acquainted with the questionnaire will translate the paper back to English.

Forward and backward translation is followed by pre-testing in the target population and a cognitive interview before the final version is produced (MAPI, 2017).

Since the inception of the Breast-Q and commencement of use in clinical practice, the breast reconstruction module has been translated into 42 languages, the majority of the translations being local academic translations. (Drs Andrea Pusic, 2017). The Breast-Q reconstruction questionnaire has already been translated into Swedish. An example of a Breast-Q translated questionnaire can be found in a recently published article by Willert et al. (2020) which presented the achieved goal of the production of the Danish-translated and conceptually equivalent version to all 5 of the Breast-Q modules. Thus, creating a possibility to include the direct perspective of the patient through achieving translation and linguistic validation of the Breast-Q. A cultural difference regarding questions about office staff was notable. Several patients pointed out the difficulty in responding to questions regarding office staff due to the lack of contact with them.

1.2.4.6 Translation and semantic validity of the latissimus modules of Breast-Q

Permission to translate and validate the latissimus modules of Breast-Q was granted by the Mapi Research Trust. Two independent translations from the English original to Swedish were performed by professional Swedish mother tongue translators. The researches in the Department of Plastic and Reconstructive surgery then created a single Swedish version thorugh discussion. A back-translation from Swedish to English was performed by a professional Enligsh mother tongue translator. The authors of the original latissimus modules of Breast-Q reviewd the back-translated version and considered it equivalent to the original version in meaning. The translated version was tested in 5 women awaiting breast

reconstruction with latissimus and 5 women who have had the operation. All of the women were native speakers of Swedish. They were interviewed regarding how they understand the questionnaires and interpret the items. A report on the linguistic validation process was sent to the Mapi Research Trust and the final Swedish version was established.

2. Aim

The aim of this study is to assess whether the self-assessment subscales ‘Satisfaction with Back’ and ‘Physical Well Being: Shoulder and Back’ of the Breast-Q reconstruction module are suitable for use as a form of evaluation for breast reconstruction with latissimus dorsi flap in Sweden.

2.1 Study Objective

The primary objective for this study is to validate the Breast-Q - Latissimus Dorsi Module regarding:

- Internal validation
- External Validation
- Reliability Test-Retest

3. Material and Methods

3.1 Study design and protocol

The study is a validation of a PROM questionnaire for breast reconstruction with latissimus dorsi for Sweden. It is one of studies described in the Reconstruction with Back Donor Site Flaps and Validation of Quality of Life Scales study protocol (ClinicalTrials.Gov identifier NCT04526561).

3.2 Setting

The research setting is based in Sweden, Gothenburg at The Sahlgrenska University Hospital. It is one out of seven university hospitals in Sweden. At the Department for Plastic Surgery around 350 breast reconstructions are performed every year. The hospital consists of a system of hospitals associated with "Sahlgrenska Academy" at the University of Gothenburg. All research and clinical aspects of the study i.e surgical interventions were conductucted at the Department for Plastic Surgery.

3.3 Participants

Every woman > 18 years old who had undergone reconstructive surgery with autologus latissimus dorsi flap within the past 10 years (2007-2017) at Sahlgrenska University Hospital as well as all women who are awaiting reconstructive surgery of the breast with autologus latissimus dorsi flap were included in the study. Participants were identified through the surgery scheduling systems Orbit and Operätt by using operation codes HAE05 and HAE10.

Subjects home addresses were retracted from the time booking system ELVIS.

Inclusion criteria: Female, over 18 years of age, written consent to participate in study, unilateral LD reconstruction.

Exclusion criteria: Deceased, metastatic spread of cancer or relapse, inability to give written consent, insufficient language skills in Swedish, bilateral mastectomy and reconstruction other than LD.

3.4 Validation process and statistics

Two modules of the Breast-Q - Latissimus Dorsi Module will be validated: 'Physical Well Being: Shoulder and Back', 'Satisfaction with Back Appearance'.

3.4.1 Validations

It will be tested how different parts of the survey, specifically subscales of the Breast-Q reconstruction module, correlate with each other.. The two latissimus scales 'Satisfaction with Back' and 'Physical Well Being: Shoulder and Back' scale have been designed and will be validated with Rasch analysis.

Internal Validation

For internal validation the Cronbach's alpha will be calculated. Cronbach's alpha is a measure of internal consistency. By means. it measures the correlations between the items in the two scales. That is, how closely related a set of items are as a group.

External validation

The external validation will be mainly based on Convergent and Discriminant validity between these two scales and Western Ontario osteoarthritis of the shoulder index (WOOS) scale, sub scales and questions.

Convergent and Discriminant validity

Convergent validity demonstrates that two measures that are supposed to be measuring the same construct are related i.e correlations between PROMs measuring similar constructs. Discriminant validitiy shows that two measures that aren't supposed to be related, are not.

The scale 'Physical Well Being: Shoulder and Back' is expected to have:
Strong correlation (convergent validity) with the WOOS sub scale physical symptoms. The Spearman correlation coefficient will be calculated for these correlations and compared with the theoretical pre-specified correlation we assumed.

3.4.2 Reliability

The same test is conducted on the same group of people at two different points in time. Some of patients who responded to the questionnaire postoperatively received the 'Satisfaction with Back' and 'Physical Well Being: Shoulder and Back' scale on two occasions to test that the answers were constant. The method used to test reliability is called Test-Retest Reliability. For both the test and the re-test values we present the distributions of the latissimus scales for each group with mean, SD, median, minimum and maximum. For the change from test to re-

test we give mean, SD, median, minimum and maximum, 95 % confidence interval for the mean difference between the two groups, p-values with Wilcoxon Signed Rank test for paired differences between test and retest, intra individual SD (IISD), repeatability = IISD*1.96*sqrt(2) and Intra-Class Correlation Coefficient (ICC).
Interpretation: If we get a value on one of the scales then the true value will lie within +-1.96*IISD of that value in 95% the measurements. If we let the subjects answer to the questionnaire a second time then the difference between the two measurements will lie with the repeatability in 95%. The results for the test re-test reliability will be presented in a Bland-Altman Plot.

3.4.3 Distribution of questionnaires

Patients were sent an envelope including information regarding the study, a questionnaire containing: 'Satisfaction with Back' and 'Physical Well Being: Shoulder and Back' scale, 'Western Ontario Osteoarthritis of the shoulder index (WOOS)'.

A consent form and information about the study was enclosed together with the questionnaires that were sent. Please see illustrations for clarification of the distribution of questionnaires in Figure 1.

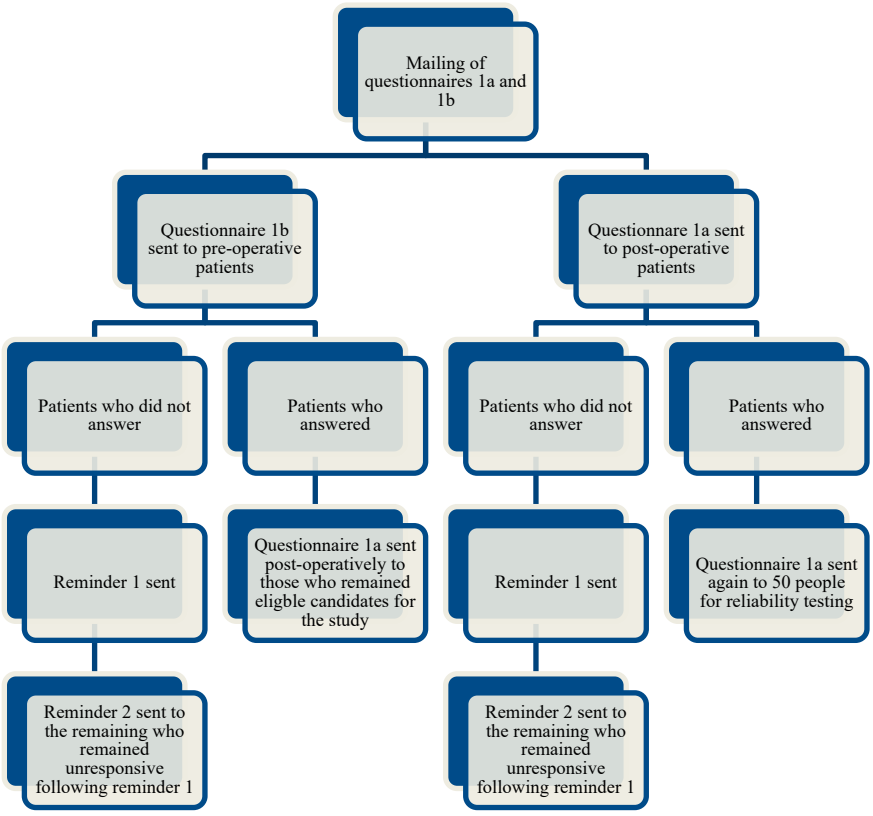

Figure 1: Questionnaire 1a refers to the specific questionnaire sent to post-operative patients. Questionnaire 1b refers to the specific questionnaire sent to pre-operative patients where certain sub-scales were excluded which could only be answered post-operatively.

The time interval between sending out the first questionnaire followed by the first reminder (to patients who we did not receive a response from) was two weeks. The time interval between the first reminder and the second reminder was approximately two weeks. Within the time that the first questionnaire and the first reminder was sent, duplicates were sent out to 50 people who had successfully responded to the first questionnaire.

The ‘Western Ontario Osteoarthritis of the Shoulder Index (WOOS)’ is a disease-specific tool to evaluate the quality of life in people with shoulder discomfort (Griffin, 2001). It consists of four parts:

Part A: Questions relating to physical symptoms

Part B: Questions relating to sport/hobbies/work

Part C: Questions relating to lifestyle

Part D: Questions relating to feelings

Each question is given a linear horisontal line. The patient is asked to draw a line on the part of the horisontal line which they feel best reflects the degree of their perceived condition in response to the question of interest. The Western Ontario Osteoarthritis of the Shoulder (WOOS) was produced in 1998 by A Kirkely MD, S. Griffin, CSS (Lo et al., 2001). It was reproduced into a Swedish-translated version in 2004 using forward and backward translation in accordance with MAPI guidelines (Sousa and Rojjanasrirat, 2011).

3.5 Ethics

The Regional Ethical Committee of Gothenburg reviewed and approved the study (254-18). Procedures followed were in accordance with the Helsinki Declaration and the Good Clinical Practice (GCP) guidelines (WMA, 2013, Otte et al., 2005). All participants gave their written informed consent.

4 Results

4.4 Participants

Postoperative group

A totalt of 235 patients were assessed for eligibility. Those who were not considerd eligible and who were excluded were the following: Deceased (n = 33), had metastasis of the disease (n = 9), total flap necrosis (n = 1), a flap technique other than LD (n = 3).

The questionnaire was sent to a total of 189 eligbile candidates for the study. The following were excluded: Did not respond to the questionnaire (n = 40), did not sign the consent form (n = 7), bilateral mastectomy (n = 8).

A total of a 134 eligble candidates responded and were included in the study.
The same questionnaire was sent a second time to 50 candidates for reliability testing. A total of 44 patients responded. Figure 1 in Appendix: Study Overview presents an overview of this information in form of a flow-chart.

4.5 Psychometric Properties

4.2.1 Internal consistency

Internal consistency was satisfactory for both subscales. Cronbach's α was 0.96 for 'Satisfaction with Back Appearance' and, *a* = 0.95 for 'Physical Well Being: Shoulder and Back' .

4.2.2 Correlation between questions in subscales

Pearson's correlation among the different questions was high for both modules (Table 1 and 2). All correlations were significant.

Table 1. Correlations among question in the "Satsifaction with Back Appearance"

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Q1	1.00							
Q2	0.82*	1.00						
Q3	0.65*	0.74*	1.00					
Q4	0.71*	0.69*	0.71*	1.00				
Q5	0.74*	0.71*	0.74*	0.90*	1.00			
Q6	0.70*	0.64*	0.66*	0.87*	0.91*	1.00		
Q7	0.75*	0.83*	0.77*	0.75*	0.78*	0.70*	1.00	
Q8	0.71*	0.80*	0.67*	0.71*	0.73*	0.64*	0.86*	1.00

*p<0.0001

Table 2. Correlations among question in the ”Physical Well Being: Shoulder and Back”

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11
Q1	1.0										
Q2	0.84*	1.0									
Q3	0.60*	0.62*	1.0								
Q4	0.52*	0.40*	0.55*	1.0							
Q5	0.50*	0.42*	0.60*	0.85*	1.0						
Q6	0.50*	0.49*	0.56*	0.69*	0.74*	1.0					
Q7	0.61*	0.53*	0.72*	0.75*	0.79*	0.79*	1.0				
Q8	0.58*	0.46*	0.58*	0.59*	0.67*	0.63*	0.67*	1.0			
Q9	0.54*	0.48*	0.65*	0.56*	0.64*	0.58*	0.68*	0.80*	1.0		
Q10	0.48*	0.43*	0.43*	0.73*	0.75*	0.70*	0.74*	0.70*	0.73*	1.0	
Q11	0.48*	0.50*	0.50*	0.67*	0.72*	0.80*	0.76*	0.57*	0.60*	0.73*	1.0

*p<0.0001

Tables 1 and 2 display how well questions answered from the same module, ‘Satisfaction with Back Appearance’ and ‘Physical Well Being: Shoulder and Back’, correlate with

eachother when comparing data from two surveys. Values closer to one imply that there is a stronger relationship.

4.2.3 Test-Retest Reliability

The analyses revelaed a good test-retest stability for the two subscales, r_{icc}=0.8 (CV% 10.95) for the 'Satsifaction with back appearance' and r_{icc}=0.8 (CV% 12.21) for the 'Physical Well Being: Shoulder and Back'. In both cases the coefficient was above 0.7, this indicates evidence that there exist test-retest reliability (Tavakol and Dennick, 2011). The mean absolute difference between the two measurements was 2.70 (SD 12.68) for the 'Satisfaction with Back Appearance' module and -1.28 (SD 11.80) for the 'Satisfaction with Shoulder and Back Function' module. According to the Bland-Altman plots (Figures 1 and 2), the overall assessment of comparisons of the first and second measurement shows that the direction of the mean difference is fairly close to zero for the 'Satiscation with shoulder and back function' module and for the 'Satsifaction with back appearance' module. The Bland-Altman plot recommends that 95% of the dotted points should lie within ± 2 SD of the mean difference. Also, if there is agreement we expect the values in Figure 1 and 2 to cluster around the mean of the differences (termed the bias). If the differences are normally distributed, this would result in a 95% prediction interval (termed the limits of agreement). In Figure 1 and 2, 3 points lie outside the limits of agremment out of a total of 27 and 39 points respectively.

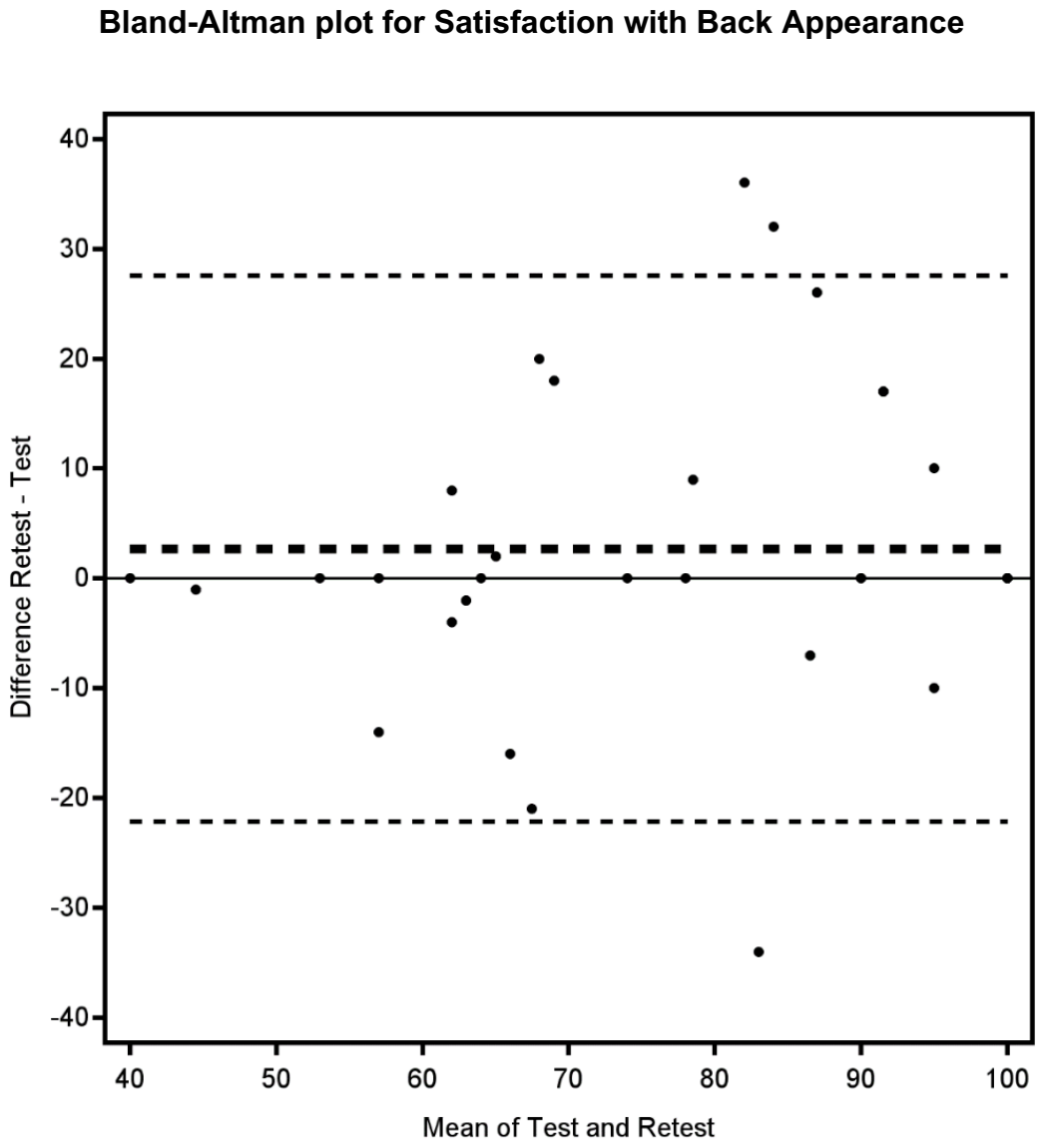

Figure 2: This figure illustrates the a plot of the different scores of the two measurments against the mean for each item.

Bland-Altman plot for Physical Well-Being: Shoulder and Back

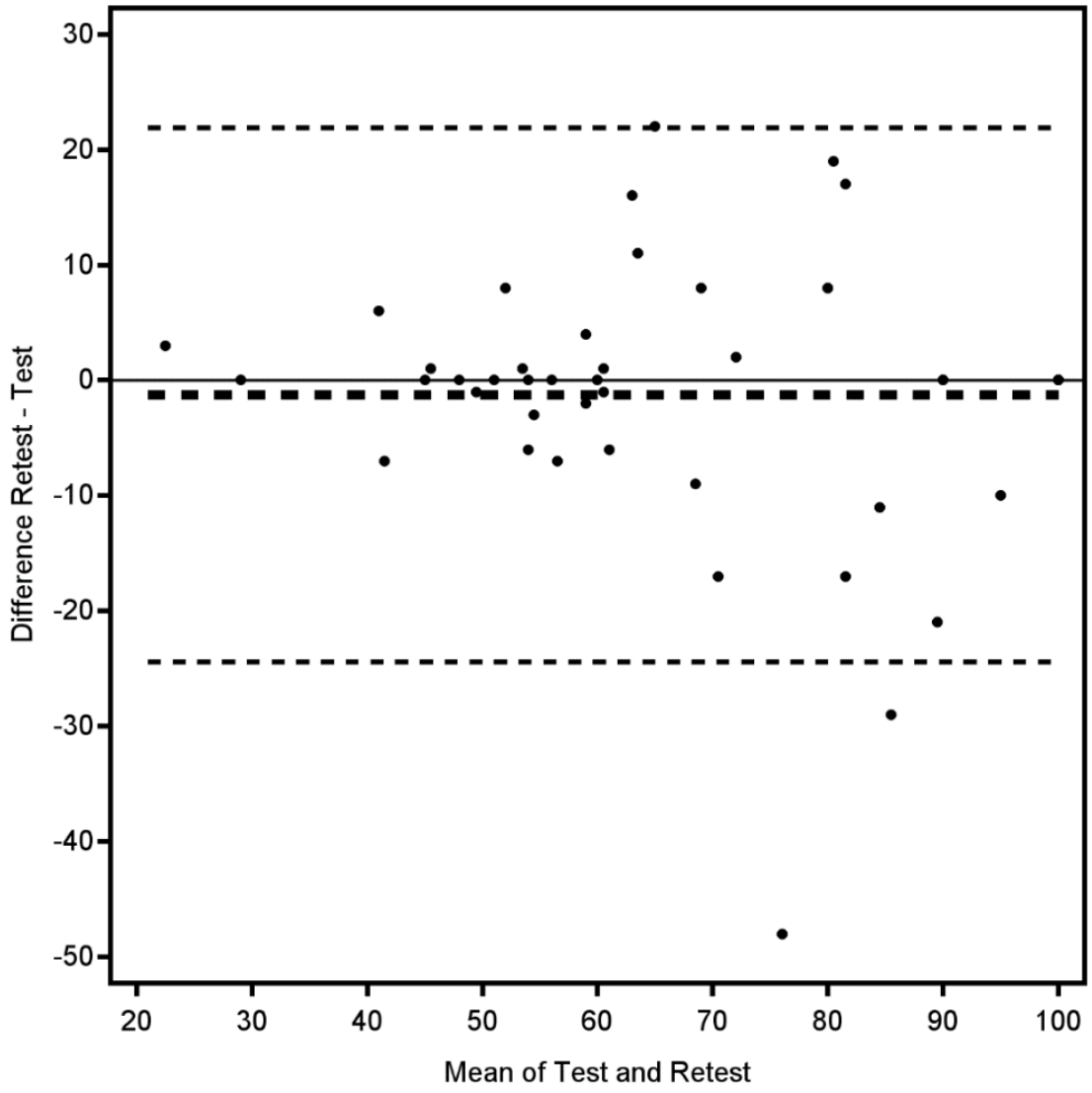

Figure 3: This figure illustrates the a plot of the different scores of the two measurments against the mean for each item.

5 Discussion

The aim of the present study was to validate the latissimus modules of Breast-Q for Swedish circumstances. Compared with the original latissimus dorsi modules, the Swedish version showed comparatively satisfactory results when compared to the validation of the original Breast-Q version (Cano et al., 2012). In a multicenter study conducted by Browne et al. (2018) in the United Kingdom, the 8-item version of the 'Satisfaction with Back Appearance' presented a high internal consistency with (Cronbach's alpha coefficient = 0.95) a totel item correlation of range of 0.75 to 0.86, similar to our own range of 0.64 to 0.91.

The 11-item version of the 'Physical Well Being: Shoulder and Back' scale had good internal consistency (Cronbach's alpha coefficient = 0.94) and all items were highly correlated presenting a range score from 0.61 to 0.83. For the same analysis, our study was up to par presenting a coefficient of 0.96 and a total item correlation range of 0.40 to 0.85.

As previously mentioned in the results, a score of $a = 0.96$ was obtained for 'Satisfaction with Back Appearance' and, $a = 0.95$ for 'Physical Well Being: Shoulder and Back'. A score of around 0.7 and more is deemed acceptable. Although a high level of alpha may mean that the items are highly correlated, alpha is also sensitive to the number of items of the test (Tavakol and Dennick, 2011).

Cronbach's alpha coefficient is strongly correlated to the number of items. The issue wich may arise due to this is that a larger number of items can result in a larger coefficient and vice versa. If the coefficient is high, this may mean that there are redundant questions. In other words, several questions that ask the same thing. On the other hand, a low value for alpha may mean that there aren't enough questions on the test.

In addition, other factors that will have an affect on the coefficient is whether the analysis has been performed on a unidimensional measurement scale. Unidimensionality assumes that the questions are only measuring one dimension (i.e height of people, age of people or in our case a psychocological concept such as satisfaction with the back appearance). The scales measured in this study are a Likert scale which is a type of unidimensional scale where respondents are asked to rate items according to a level of agreement. Unidimensional data will maximise the alpha.

In the Spearmann correlation, the strength of the relationship is presented by the value of the correlation coefficient (r_s) which varies between +1 and -1. A value of +1 indicates a strong correlation between the two variables. If the correlation goes towards 0, this indicates a weaker relationship between the two variables. +1 indicates a positive relationship and -1, a negative relationship.

The relationships later displayed on a scatterplot should be montotonic. This means that when the value of one variable increases, so does the other value or, if the value of one variable increases, the other variable decreases.Since the Spearmans coefficient measures the strength

of a monotinic relationship berween paired data, if $r_s = 0$ this would indicate that there is no correlation between the two scales (Schober et al., 2018).

As we hypothesized the 'Physical Well Being: Shoulder and Back' was positively correlated with the Western Ontario osteoarthritis of the shoulder index (WOOSI) (Spearman correlation coefficient 0.69, $p<0.001$). The subscale 'Satisfaction with Back Appearance' was also positively correlated with WOOSI.

Thus, for the 'Satisfaction with Back Appearance' scale this suggests a moderate, positive correlation with WOOS. For the the 'Physical Well Being: Shoulder and Back' scale this suggests a strong, positive correlation with WOOS. In both cases the convergent validity is significant.

As for the Test Re-Test reliability, intraclass correlation coefficient or ICC was of acceptable reliability for 'Satisfaction with Back Appearance' and for 'Physical Well Being: Shoulder and Back' scale.

Furthermore, the Rasch analysis was not re-done. As it could result in a conversion table different to the original conversion table and thereby complicate comparison of results from different countries.

A notable limitation within the study is that of the PROM instrument itself. The Breast-Q does not discriminate between the source which may have caused any physical sequelae.

Whether the symtoms be the subsequent result following implications of surgical intervention or if they have arised due to other reasons remains unknown. In addition to this, the response rate consequently adds to the limitations of the study as we are not able to know if the participants who responded differ from those who did not respond to the survey.

6 Conclusion

The Breast-Q reconstruction module is a well-known instrument for use in measuring patient related outcomes after breast reconstruction. For the Breast-Q latissmus dorsi module's continued use in Sweden it has undergone a validation process; testing its psychometric properties such as construct validity with it being a translation of the original version. The subscales 'Satisfaction with Back' and 'Physical Well Being: Shoulder and Back' have shown good results in the validity, correlation and reliability testing as well as having satisfied the hypothesised outcome for this study.

Future Perspectives

However, in order to increase it's strength for use in the setting of breast reconstruction with latissimus dorsi flap, more comparative studies with other internationally validated Breast-Qs which have been used in independent clinical studies within this area are of interest. This may also strengthen the validation of the Breast-Q and what is intended to be measured through its use by studying and comparing any differences and similarities which may arise when comparing the results from different countries. Thus, providing clinicians and researchers

with an increased understanding of the patient related outcome measure in the setting of breast reconstruction with the latissimus dorsi flap. This may help contribute to improved tailored patient care and/or surgical approaches.

Populärvetenskaplig sammanfattning på svenska

Namn: Lynne Kamya

Titel: Svensk Version av Breast-Qs Latissimus Dorsi Moduler: Översättning och Psykometriska Egenskaper

I Sverige får cirka 9500 kvinnor en bröstcancerdiagnos årligen, och då fem- och tioårsöverlevnaden idag är mycket hög lever ungefär 100 000 kvinnor med sjukdomen i landet. Detta betyder att många kvinnor har ett behov av bröstrekonstruktion. Det finns många olika tekniker för bröstrekonstruktion men mycket lite evidens för vilka metoder som ger bäst resultat.

Studier inom de flesta typer av bröstrekonstruktion är grundläggande för att denna stora patientgrupp ska kunna erbjudas evidensbaserad och säker behandling. När patienten har fått strålbehandling mot bröstkorgen för sin bröstcancer är oftast tillförsel av icke-strålad vävnad nödvändig för att man ska kunna åstadkomma en acceptabel bröstrekonstruktion.

Latissimus dorsilambån är den äldsta och mest använda tekniken för att tillföra ny vävnad vid bröstrekonstruktion. Trots detta är det vetenskapliga underlaget för långtidseffekter vid bröstrekonstruktion med latissimus dorsilambå mycket litet. För att kunna skapa evidens för bröstrekonstruktion krävs att vi har validerade utvärderingssätt. Ett viktigt utvärderingssätt är att använda patient related outcomes measures, förkortat till PROMs. Det mest använda PROM instrumentet vid bröstrekonstruktion är Breast-Q och det har nyligen tagits fram moduler, “the Back Appearance scale” och ”the Back and Shoulder Function scale”, för långtidsutvärdering av effekterna av lattisimus dorsilambårekonstruktion.

Den här studien utfördes på Sahlgrenska Universitetssjukhuset, avdelningen för plastikkirurgi. Studiens syfte var att validera Breast-Q subskalorna ’the Back Appearance scale’ och ’the Backand Shoulder Function scale’ för svenska förhållanden. Patienternas svar på dessa subskalor i enketärna bearbetades statistisk med avseende på validitet, reliabilitet och responsivness.

Resultaten visade god validitet (Cronbach’s alpha a = 0.95 för ’Satisfaction with Back Appearance’ och a = 0.96 för ’Physical Well Being: Shoulder and Back’) samt god korrelation till varann (Pearson’s correlation och Spearman’s Correlation). Test-re test

reliabilitet, vilken testade pålitligheten i svaren av enkäterna gav godkända resultat. Inom ramen för denna studie uteblev slutförandet av den statiska analysen för responsivness då mer tid behövs för ett komplettera resultatet.

Studien har härmed bekräftat att utvärderings instrumentet Breast-Q går att använda och fungerar som det skall i svenska förhållanden. Det kan fortsätta användas med förtroende för att mäta samt utvärdera långtidseffekterna vid bröstrekonstruktion med lattisimus dorsi lambå.

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Appendices

Appendix: Study Overview

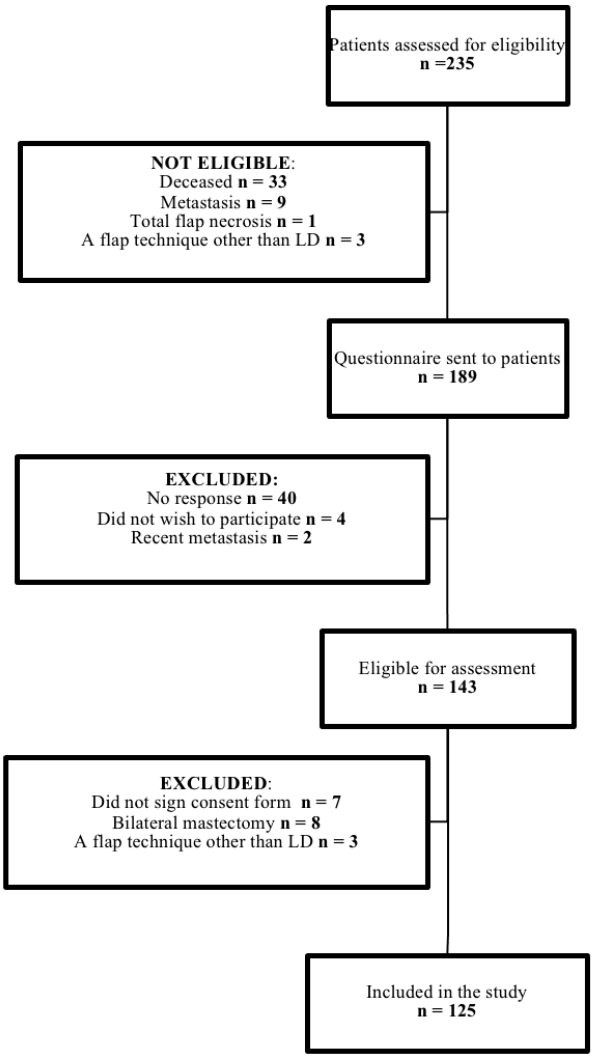

Figure 1: Flow-chart post-operative group