# NOTE TO USERS

# Breast Cancer Surgery QOL Scale: Development, Validity, and Reliability

A thesis submitted to the Faculty of Graduate Studies
in partial fulfillment of the requirements for the degree of Master of Science

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## 1. Abstract

The SF-36 scale is widely used to evaluate the quality of life among breast cancer patients, but provides an inadequate reflection of their quality of life; therefore, we aimed to set up a new scale, a breast cancer surgery quality of life (BCSQOL) scale and to assess its reliability and validity. The analysis review showed that 75% to 91% of surgically treated patients (59/79) found that the questionnaire items were an accurate reflection of their feelings and were clear. The validity coefficient analysis showed a highly correlated extent of commonality ($\alpha = 0.778$) between BCSQOL and SF-36 and a significant strength of relationship ($\rho = 0.785$). Strong to moderate correlation reliability coefficient analysis ($\alpha = 0.779$-$0.351$) was observed for the association among all items of the scale. BCSQOL scale may help health care providers to better understand the health status of breast cancer subjects, rendering them more equipped to improve their quality of life.

## 2. Resume

L'échelle SF-36 ne reflète pas correctement la qualité de vie des personnes atteintes d'un cancer du sein malgré qu'elle soit couramment utilisée. Par conséquent, nous avons mis au point, validé et testé la fiabilité d'une nouvelle échelle d'évaluation appelée BCSQOL. Nos résultats ont montré que 75% à 91% des patients interrogés ont trouvé que le questionnaire se présente clairement et reflète précisément leurs sentiments. L'analyse du coefficient de validité a montré une forte corrélation entre BCSQOL et SF-36 ($\alpha = 0.778$) et une forte significativité??? ($\rho = 0.785$). L'analyse du coefficient de fiabilité a montré une corrélation modérée à forte ($\alpha = 0.779$-$0.351$) entre les différents items de l'échelle. L'échelle BCSQOL peut permettre aux professionnels de mieux comprendre l'état de santé des sujets atteints d'un cancer du sein, et ainsi de mieux les préparer à améliorer leur qualité de vie.

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4. Table of Contents

## 4. List of Abbreviations and Definition of Terms

| | |
|---|---|
| QOL | Quality of Life |
| BCSQOL | Breast Cancer Surgery Quality of Life |
| HRQOL | Health-Related Quality of Life |
| SF-36 | Medical Outcomes Survey Short Form 36 |
| EORTC-QLQ-C30 | European Organization for Research and Treatment of Cancer and the Functional Assessment of Cancer Therapy instrument |
| ALND | Axillary Lymph Node Dissection |
| DCIS | Ductal Carcinoma in Situ |
| LCIS | Lobular Carcinoma in Situ |
| ILC | Invasive or Infiltrating Lobular Carcinoma |
| IDC | Invasive or Infiltrating Ductal Carcinoma |
| cm. | Centimeter |
| $\rho$ | Spearman rank correlation |
| $\alpha$ | Pearson correlation, (Cronbach alpha) |
| vs | Versus |

# 6. Introduction

## *6.1. Definition of the Problem*

The evaluation of post-operative outcomes, either short or long term, for breast cancer is related firstly to the physical effect of the treatment on the patient, and secondly to the impact of the disease and the chosen therapy on the emotional well-being of the survivor. Contrary to the physical status, which requires indisputable direct physical examination on the operated area (scar and presence of tumor), the assessment of a breast cancer patient's quality life is indirect and controversial.

Surgical treatment-related side effects vary depending on the specific surgical procedures chosen. The change in shape of the affected breast is directly related to a) the size of breast tissue excised, b) the location of the excised tissue and c) the size of the breast in relation to the excised tissue. Physical disfigurement may lead to personality change such as irritability, depression, restlessness, and feelings of dependency that may eventually affect an individual's ability to perform routine daily activities.[1] Therefore, the psychological effect of breast cancer can affect a woman's life as well as the lives of those close to her.[2-6]

In surgical research, the measuring of Health Related Quality of Life (HRQOL) in clinical cancer trials has increased in recent years as more groups realize the importance of such endpoints. HRQOL instruments are increasingly being used as primary outcome measures, these some examples of such statements and a short description of each.

A key problem in the above tools has been missing data, is due to various factors: the assessment of HRQOL examines outcomes that are irrelevant to the patient's experience of the surgical treatment, the patients are too ill to complete the forms, the scales are too long, or there are too many scales to fill out. Another problem in the actual scales lies in establishing the clinical relevance of the scores obtained on the evaluation scale. It is simple to determine the statistical significance of changes in HRQOL, but placing the magnitude of these changes in a clinical context that is meaningful for health professionals has not been as easy.[7]

Therefore, there is a need for a HRQOL assessment tool designed for the evaluation of the effect of surgical treatment on patients QOL that will integrate the outcome assessment into clinical practice.

### *6.2. Why scale for Health Related Quality of Life for Breast Cancer Surgery?*

The existing outcomes fail to include all of the elements that can estimate the success or the failure of a surgical intervention. The existing scales use general physical and psychiatric symptoms that have no relation to the surgical intervention.

Recent research on gender and health has shown that women report more distress and chronic conditions than men. The amount of women's stressors combined with their personality traits may increase or diminish their stress response and affect their health. [8-10]

- Provide surgical treatment outcome evaluations of patients discharged and estimate the short or long term effects of the treatment on daily life.
- Trace the progress of the patient, and measure and demonstrate the side effects of the treatment, as surgical treatment for breast cancer may show an improvement on discharge followed by deterioration after discharge, or may also have long-term effects.
- Gain important information about the expected course of a particular disorder which will be helpful in selecting an appropriate follow-up intervention; follow-up data on all dimensions of surgical Health Related Quality of Life are useful in determining a complete picture of the benefits gained from the treatment.
- Link specific outcomes to breast surgery and establish its treatment value, as the integration into practice of a standardized outcome assessment for Breast Surgery will produce data legitimized for the development and the adoption of treatment guidelines.
- Use outcome assessment as a tool for surgical therapy outcome expectations.
- Reform and contain cost by improving Health Related Quality of Life and quality of care.

### *6.3. Review of literature*

#### *6.3.1. Breast Cancer Survivors and Quality of Life*

Breast Cancer survivors suffer physical and emotional difficulties. They have many concerns and fears about the recurrence of the disease that are unlikely to dissipate. A new physical pain, the anniversary of the breast cancer diagnosis, the return to a

treatment location for a follow-up exam, are all factors that may cause stress, depression, or concern to the patient.[9]

Little is known about the predictors of breast surgery health-related quality of life for breast cancer survivors. In one study, two generic and two disease-specific instruments were administered to patients with breast cancer. These were the visual analog scale from the EuroQOL EQ5D instrument, which is a patient-based generic questionnaire for health assessment; the Medical Outcomes Survey Short Form 36 (SF-36); the European Organization for Research and Treatment of Cancer (EORTC-QLQ-C30); and the Functional Assessment of Cancer Therapy instrument. While the EORTC-QLQ-C30 seemed to perform better than the SF-36,[11] researchers found that no single instrument had superior validity on all domains.

To date, there has been contradictory information on survival and disease-free survival rates for breast cancer patients. Some information has suggested that there is no difference in outcome,[12] while another study has supported a worse survival rate for breast cancer patients.[13] In two meta analysis studies on breast cancer surgery the evidence was statistically inclusive for global quality of life, physical health, sexual adjustments, psychological concerns and fear from the future[102,103]. In view of this fact, many survivors continue to experience negative effects of breast cancer disease and/or treatment on their daily lives well beyond the completion of therapy. One of the most profound emotional impacts that is experienced is the feeling of loss of femininity,[14] as it affects not only how a woman looks and feels about herself, but also how she perceives other people's reaction to her.[15] Woman's ability to function sexually, fear of marital disruption, and social functioning were also found to be concerns for many survivors. [3, 4, 8, 16-18]

The review of the literature clearly demonstrates that body image of the patient and the psychological aspects of the effects of breast cancer and its treatment are of great importance. The predominant symptoms reported in the literature are anxiety, depression, and fear of recurrence. Questionnaires assessing those variables such as the State-Trait Anxiety Inventory (STIA),[19-21] the Profile of Mood States,[22, 23] the Mental Health Inventory,[24,53] and the Symptom distress scale [25, 26] were reviewed. These questionnaires were developed for patients with psychiatric problems rather than for the evaluation of

patients who have undergone breast surgical treatment.[27] For example, fatigue and reduced activity levels are symptoms that characterize cancer patients, yet psychiatric questionnaires use the same symptoms to identify patients who are suffering from depression. This confirms the hypothesis that questionnaires developed for psychiatric patients are not optimal for breast cancer survivors.[27] The Hospital Anxiety and Depression Scale (HADS),[28] however, was developed specifically for somatically ill patients. It consists of fourteen items, seven concerning anxiety and seven concerning depression, and is reported to function well.[29, 30]

This literature review underlines the need for conducting further studies in order to better evaluate the breast surgery Health Related Quality of Life (HRQOL) for breast cancer survivors.

### *6.3.2. The Dilemma with the Existing QOL Measures*

In breast surgery Quality of Life research, collecting extensive data from large numbers of breast cancer survivors is expensive and labor intensive. Therefore, there is broad consensus that valid, specific outcome measures for breast surgery are needed in order to distinguish the effect of surgical intervention on breast cancer patients and to develop appropriate tools to reduce the negative effects of breast surgery on the patient's. [31] Consequently, a large variety of Quality of Life scales or questionnaires have been developed and used to evaluate disease specific outcomes and/or general QOL outcomes of breast cancer therapy (see Table 1, page 67). Some of the scales evaluate general health and include general variables (such as fear of recurrence, anxiety, bone pain, dry mouth, general fatigue, vaginal dryness, etc.) related to the disease of cancer, such as the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC C 30),[32-34] and the Chronic Illness Scale (PACIS).[35] General health after surgical treatment is evaluated by the SF-36,[33, 34, 36] the Summary Satisfaction Index (SSI),[37, 38] Health Related Quality of Life,[39] the Global Adjustment to Illness Scale, and the Linear Analogue Assessment Scale (LASA).[19] Other scales where treatment is modality oriented for chemotherapy include the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-BR 23)[9] and the Breast Cancer Treatment Outcome Scale.[9] Other surveys evaluating certain outcomes that are

related to or affected by surgical treatment include the McGill Pain Questionnaire, the Pain Disability Index,[9] the Body Image Scale (BIS),[41] the Functional Assessment of Cancer Therapy (FACT-B), the State-Trait Anxiety Inventory, [19] the Rosser scale, the Wilmoth Sexual Behaviors Questionnaire-Female, [24, 34, 42, 53] the Profile of Mood States, [22, 23] the Mental Health Inventory, [9] and the Symptom Distress Scale. [25, 26] Langenhoff et al found that there is not one Health Related Quality of Life (HRQOL) instrument that fits all the recommended conditions, not one that is suitable in all clinical situations. It has been demonstrated that using the appropriate instrument is essential to achieving a valid and clinically meaningful outcome measure. [9]

Testa and Simonson conclude that generic instruments are usually not specific to any particular disease state or susceptible population of patients, and are therefore most useful in conducting general health research surveys and making comparisons between disease states. Disease-specific instruments are most appropriate for clinical trials in which specific therapeutic interventions are being evaluated by focusing on the domains that are the most relevant to the disease or to the condition under study, and on the characteristics of patients in whom the condition is most prevalent. Batteries of scales and modular instruments combine the generic and the disease-specific approaches by maintaining a core module of questions that are applicable to diverse disease states and patient populations. Those questions that are the most relevant to the disease and to the therapy under study are added as needed.[44]

The generic Health Related Quality of Life measures, such as SF-36, have been used in a number of studies to assess Breast Cancer Related QOL. [10, 45-50] Even as these measures appear to have the advantage of permitting comparison across disease entities, [51] they are less suitable for measuring the effect of a specific disease or medical condition. Some sections of generic measures have little relevance for breast cancer survivors, while important domains affecting breast cancer survivors are omitted. For example, some symptoms and problems that are specific to breast cancer patients are not included, such as relationship with partner, fear of recurrence, loss of femininity, diet, and body image. All of these are areas not directly covered by generic instruments such as SF-36, but are of great importance to breast cancer survivors. Conversely, some items that are covered by the QLQ-C30, the QLQ-BR23, and the SF-36 are of less concern for the surgical

outcome of the majority of breast cancer survivors. In a study assessing the differences of Health Related Quality of Life for two different types of breast surgery, the SF-36 Health Survey was modified to include ten questions relevant to breast cancer surgery. The study's findings concluded that the SF-36 health survey detected few differences in Quality of Life measures between patients with lumpectomy and axillary lymph node dissection (ALND) and those with mastectomy, even though lumpectomy has been proven to have a more favorable impact than mastectomy on the way women dress, on comfort with nudity, and on sexual drive.[52] Janni et al conclude that the standard measuring instruments for QOL might fail to detect differences in satisfaction and adaptation (certain body image-related problems) due to the primary surgical treatment modality.[6] Stanton et al. find that the functional parameters have not been fully explored, although functional consequences of treatment, particularly of breast specific pain, are also significant influences on these patient HRQOL.[24, 53, 54]

### *6.3.3. Types of Scales Identified in Breast Surgical Research*

Thirty-three specific and generic Health Related Quality of Life scales (see Tables 1 and 2, pp. 67-68) that are used to evaluate quality of life from multiple perspectives and across many domains are identified. The assessment of the Health Related Quality of Life (HRQOL) is a rapidly developing area of research; therefore, many questionnaires have been constructed, validated, and translated.[32] The following are the most frequently used scales.

#### *6.3.3.1. The Medical Outcomes Survey Short Form 36 (SF-36).*

The SF-36 is a multi-item scale which assesses eight health concepts: physical functioning, role limitation due to physical health problems, bodily pain, mental health (psychological distress and psychosocial well being), social functioning and emotional role functioning limitation due to emotional problems, vitality, and general health perceptions. Item scores are summed for each scale and are transformed on a scale of 0 to 100, with higher scores representing better health.[51, 56] The SF-36 contains 36 questions, and can be self-administered or interview-assisted, in person or by telephone. It measures a patient's functioning and well-being by evaluating both the physical and mental components of health.[57] The Canadian version of the SF-36 has met reliability standards

for group comparisons.[58] The SF-36 is the most commonly used measure of health-related QOL.[51, 59, 60] The SF-12, which is a reduced version of the SF-36, measures similar outcomes in fewer questions. Previous studies have demonstrated that average scores on the SF-12 mirror those on the SF-36, although the standard error is almost always larger with the SF-12.[35]

*6.3.3.2. The EORTC QLQ-C30.*

The EORTC QLQ-C30 has been internationally developed and validated by the EORTC Study Group on Quality of Life.[32, 61, 62] It consist of 30 items which are divided into 6 scales of function (Physical Function, Social Function, Role Function, Emotional Function, Cognitive Function, and Global Health Status/Quality of Life), and three scales with six items about symptoms. The three scales are fatigue, pain, and nausea and vomiting, and the six items consist of loss of appetite, constipation, diarrhea, dyspnea, insomnia, and financial difficulties. In the function scales, a high score indicates a good function, and in the symptoms scales, a high score indicates many symptoms. This instrument is intended to be used in conjunction with disease specific supplementary models.

*6.3.3.3. The EORTC QLQ-BR23.*

The EORTC QLQ-BR23 is a 23-item breast cancer-specific questionnaire that measures the quality of life in breast cancer patients. The conceptual and methodological issues underlying the construction of the questionnaire are these:[62, 63] it incorporates two functional scales (body image and sexual functioning) and three symptom scales (arm symptoms, breast symptoms, and systematic therapy side effects). The remaining items assess sexual enjoyment and shock due to hair loss. This questionnaire has not yet been used to evaluate postoperative treatment for breast cancer.

*6.3.3.4. The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C33).*

The EORTC QLQ-C33 is used to evaluate the emotional functioning of patients with cancer, but has been found to be insufficient in measuring global Quality of Life. It is not used to evaluate surgical treatment as it is inadequate in its ability to measure depression, a predictor of psychological distress,[64] due to the fact that the questionnaire is more specific to chemotherapy treatment.

*6.3.3.5. McGill Pain Questionnaire.*

The McGill Pain Questionnaire is a type of scale that is timely in a fast-paced clinical setting; however, it does not address key factors such as the individual's expectations, the patient's daily pain patterns, and the effect of the environment on the patient. This renders the questionnaire inadequate for the purposes of ascertaining a HRQOL for breast cancer surgical treatment survivors as, for example, breast pain may be related to changes in the patient's hormone levels.

*6.3.3.6 Functional Assessment of Cancer Therapy (FACT-B)*

The FACT-B, is a Forty Four item instrument measured on five points rating scales, includes measures for physical health, body image related concerns, sexual functioning, social and family support, emotional concerns, and functional well being.

*6.3.3.7 The Hospital Anxiety and Depression Scale (HADS)*

Was developed specifically for somatically ill patients. It consist of fourteen items, seven concerning anxiety and seven concerning depression, and is reported to function well.

*6.3.3.8 Wilmoth Sexual Behaviors Questionnaire-Female (WSBQ-F)* [34, 42]

Consist of fifty-four items arranged in eight subscales. Items are rated on a likert-type scale, with high scores reflecting more consistent use of sexual behavior.

*6.3.4. Conclusion of literature review*

This literature review clearly demonstrates that the tools available are not adequate for the evaluation of the effects of the breast surgical treatment on the QOL of breast cancer survivals. In addition, it illustrates the advantage of studying the Health Related Quality of Life and treatment outcomes for breast cancer survivors may allow for more efficient strategies of follow-up treatment (psycho-social) and for the long term follow-up HRQOL measures may allow early detection of any recurrence of the disease. The implementation of a specific breast cancer surgery QOL scale will enable further clarification of the effect of the treatment outcome on the day-to-day activities of breast cancer survivors. It could also make possible a more efficient treatment strategy (for example lumpectomy versus mastectomy), or ease the diagnosis of recurrence patterns (for example identifying local pain or discomfort), and facilitate the determination of the

treatment or disease specific mortality rates of breast cancer (for example by identifying the variables related to the breast surgery or breast cancer). This specific post-surgical Health Related Quality of Life questionnaire developed for breast cancer survivors will diminish generalization and reduce the risks of lost information of the surgical treatment effect on the QOL which resulting from low interest of breast cancer survivors stemming from their reluctance to fill out the existing generic measures, which have little relevance for their post-surgical Health Related Quality of Life.

#### *6.3.5. Summary of Points from Literature Review*

- No relevant Health Related Quality of Life evaluation for the surgical treatment of breast cancer for women was detected. The questionnaires that were identified contain very limited information concerning surgical outcomes.
- There is no consensus regarding which QOL measurement is the most appropriate to evaluate the breast surgery Health Related Quality of Life.
- "Survival, whether measured overall, disease-free, progression-free, or event-free, is the most common outcome measured in the last three decades. Nevertheless, survival alone is not sufficient; the quality of survival and the effects of treatment on daily activities must also be assessed."[42]
- Quality of Life factors such as pain, apprehension, depression, and functional impairment add to the burden of the disease of breast cancer. These factors should be distinguished from surgical therapy outcomes by having more specific measures related to surgical therapy. A list of topics related to post-surgical outcomes was extracted from these articles and is shown in Table 2, p. 68.

## 7. Background

### *7.1. Health Related Quality of Life (HRQOL)*

#### *7.1.1. Definition*

The World Health Organization defines "health" as a state of complete physical, mental, and social well-being; not only as the absence of illness or disease. This characterization is complete and implies that outcome domains should include both physical and socio-psychological diminutions related to disease.

The terms "Quality of Life" and, more specifically, "Health Related Quality of Life" (HRQOL) refer to the functional effects of an illness and its consequent therapy upon a patient, as perceived by the patient. This is due to the fact that illness affects the physical, psychological, and social domains of health, which are seen as distinct areas that are influenced by a person's experiences, beliefs, expectations, and perceptions.[6] This definition emphasizes the multi dimensional aspect of HRQOL. Primary dimensions are physical, psychological, and social functioning; overall satisfaction and well-being; and perception of health status. Additional dimensions are pain, symptoms, personal productivity, sleep disturbance, intimacy, sexual functioning, and neuropsychological functioning.

### *7.1.2. History*

Pigou introduced the term "Quality of Life" in 1920 in his book about economics and welfare. He used the term to refer to the national impact of the government's financial support of the lower class.

The first article in a medical journal that used this term was entitled "Medicine and Quality of Life," and was written by Elkington on the subject of the responsibilities of medicine in the domain of Quality of Life.

According to the Ovid Medline database, the first appearance of the term Quality of Life in a breast cancer publication was in an abstract by R.S. Handley in 1975. [65]

### *7.1.3. Usefulness of HRQOL Measures in Clinical Research and Clinical Practice*

Clinical outcomes and Quality of Life domains are used to assess whether there has been improvement in the patients' post-surgical, pathological, and clinical status, and in the patients' feelings and functional ability. The following are the most common uses of Health Related Quality of Life measures in clinical research and practice: [66]

- Identifying and Prioritizing Problems: It is important to identify which problems are the most important to the patients, as the health care team must be able to prioritize when searching for a solution. This is particularly useful when patients have multiple problems, and when evaluating treatment outcome or efficacy.

- Evaluating the Outcome and Monitoring Changes or Responses to Treatment: This might be helpful in clinical practice, although it is now being used in most clinical trials as a primary or a secondary measure alongside other laboratory or clinical tests. It is important to evaluate the improvements that are relevant to the patient's adherence to treatment, and to identify the patient's perception of change and satisfaction.
- Detecting Details: Information that seems to have no apparent clinical relevance can clarify issues, such as disease severity or coping with problems, and can elucidate their relation to the treatment outcomes.
- Facilitating communication: The Health Related Quality of Life measure can contain clear information on a range of problems. It can provide patients with a tool to facilitate their communication and to explain their problems, as some issues (especially personal, psychological, and social problems) can be overlooked unless specifically inquired about by the health care providers. This may provide another screening method, while at the same time reducing the length of the clinical encounter and helping the health care team focus on the main concerns of the patient. [66]

### *7.1.4. Therapeutic Objectives of HRQOL*

Therapeutic objectives are best guided by the possibility that treatment will either restore lifestyle and pleasures or result in suffering.

The relation between the patients' clinical improvement with their prevalent satisfaction data that have an effect on therapeutic objectives can determine, the effect of the breast cancer surgery outcome on the Quality of Life of these patient's. These effects of which include body image and self-esteem, pain and suffering, dependence on family and friends, reduced life expectancy, heavy use of health care resources, accumulated stress, and social isolation.[11, 67]

Symptom assessment may be the best tool to measure the immediate clinical assessment; therefore, the collection of valid and reliable data concerning the intensity and the duration of pathological and clinical symptoms for breast surgery is the most essential tools.

Breast surgery psychological symptoms are measured by body image and by the level of the patients' acceptance of the new situation (i.e. scar disturbance).

Functional assessment is increasingly important, due to a growing recognition of the economic cost of post-surgical dysfunction and disability. Patients are interested in improving their capabilities, as functional status is more directly related to the patients' quality of life in multiple domains, especially interpersonal and domestic. The patients' ability to self-care, live independently, exhibit energy and zest, and maintain personal relationships and recreational pursuits are all important aspects of functional capacity that may continue to improve in the months after symptomatic recovery. The changes in functional status for longer term follow-up are excellent indicators for measuring any residual impairment from the breast surgery, and for determining the relationship of that impairment to the breast surgery.

## *7.2. Breast Cancer*

### *7.2.1. Definition*

Breast cancer is a cellular malignancy whose distinctive characteristics result in unregulated growth, lack of differentiation, and the ability to invade breast tissues and metastasize.[68] The tumor usually arises from the cells of the milk ducts. It may grow into the breast tissue as a mass which is usually very hard; however many patients find that particular types of tumors are soft.

### *7.2.2. Types of Breast Symptoms*

- Breast Pain: Pain in the breast(s) is most frequently associated with normal changes in hormone levels during the menstrual cycle, or with the presence of a non-cancerous breast cyst. The pain is usually treated upon treatment of its cause.
- Nipple Discharge: The most common cause of bloody discharge is an underlying intraductal papilloma. Nipple discharge is usually caused by medication (birth control pills or sedatives and tranquilizers), and may also be present after the cessation of breast feeding (galactorrhea). Cancer is the cause in < 10% of patients. The appearance of discharge is of little help in diagnosing an underlying cancer: in one study, only guaiac-positive secretions were associated with breast

cancer. In some cases, the cancer or benign tumor that is causing the discharge can be palpated or detected by mammography. Nipple discharge can be surgically treated by nipple-flap duct resection.

### *7.2.3. Types of Breast Disease*

The most common types of breast disease are as follows:

A) Benign breast disease:

- Fibroadenomas: This is the most common type of benign breast lump. It consists of round, soft, and moveable fibrous or granular tissue. The lump may be surgically removed, a procedure that is most commonly performed with the use of a local anesthetic. Fibroadenomas usually develop in young women, often in teenagers, and may be mistaken for cancer.
- Other benign solid breast masses include fat necrosis and sclerosing adenosis which can be diagnosed only by biopsy.
- Fibrocystic Changes: This is a generalized lumpiness of the breast the intensity of which varies with the menstrual cycle; painful cysts once usually present. Fibrocystic breast changes generally occur before menopause, and may be associated with brown or green nipple discharge.

B) Malignant breast disease:

- Ductal Carcinoma in Situ (DCIS): DCIS occurs in pre-menopausal and postmenopausal women. It forms a palpable mass and is commonly localized in one quadrant of a breast. It accounts for 43% of breast cancer diagnoses in women aged 40 to 49, and 92% of cases diagnosed in women aged 30 to 39. [67] It can be treated with a lumpectomy followed by radiation therapy or a mastectomy
- Lobular Carcinoma in Situ (LCIS): LCIS arises in lobules and occurs predominantly in pre-menopausal women. Its detection is usually incidental, as it does not form a palpable mass. Between 25% and 35% of patients with LCIS, develop invasive breast cancer after a latency of up to 40 years. LCIS may be treated with a bilateral prophylactic mastectomy, and is sometimes associated with the removal of the axillary lymph nodes. It may be followed by hormone therapy (Tamoxifen) to prevent the recurrence of cancer. [67]

- Inflammatory Carcinoma: This is an invasive, inflammatory cancer, which causes the skin structure of the breast to appear red (peau d'orange) and feel warm. Inflammatory carcinoma accounts for 5-10% of breast cancers.
- Invasive or Infiltrating Ductal Carcinoma (IDC): This accounts for 80% of invasive breast cancers and occurs in the milk ducts of the breast.
- Invasive or Infiltrating Lobular Carcinoma (ILC): This occurs in the milk producing glands of the breast and accounts for 15% of all invasive breast cancers.
- Invasive Mammary Carcinoma: This is a combination of IDC and ILC.
- Paget's Disease: This occurs in less than 1% of the cases of breast cancer. It is characterized by eczema-like changes in the nipple, or by discharge. Most patients have a palpable mass at diagnosis. The underlying cancer may be invasive or in situ. Standard treatment is identical to that of other forms of breast cancer; the prognosis depends on the level of invasiveness, on the size of the tumor, and on the presence or absence of histologic lymph node involvement.
- Tubular Carcinoma: This accounts for about 2% of all invasive cancers.

### *7.2.4. Stages of Breast Cancer*

Breast cancer can be staged according to the tumor size T (0-4), lymph nodes involvement N (0-3), and metastasis M (0-1). The treatment modalities and outcomes depend on the stage of the cancer.

- In **Stage 0**, the tumor is less than one inch and has no metastasis. It is sometimes called "noninvasive carcinoma" or "carcinoma in situ" (T< 1 inch, N = 0, M = 0).
- **Stage I** means that the tumor is no more than about one inch across, and that cancer cells have no metastasis beyond the breast. The tumor is further classified in 2 subtypes: **Stage I A**, where the tumor is less than 0.5 cm. and **Stage I B**, where the tumor is between 0.5 cm. and 1 cm.
- **Stage II A** means one of the following: either the tumor in the breast is less than 2 cm (or 1 inch) across and the cancer has metastasized to the axillary lymph nodes, or the tumor is between 2-5 cm (or 1-2 inches), with or without metastasis to the lymph nodes.

- In **Stage II B** the tumor is either larger than 5 cm (or 2 inches) in size without metastasis to the lymph nodes, or the tumor is smaller than 5 cm (or 2 inches) and metastasis to the axillary lymph nodes is present.
- **Stage III** is also called locally advanced cancer. In **Stage III A**, the tumor in the breast is large (more than 2 inches across) and the cancer may metastasize to the axillary lymph nodes. In **Stage III B**, the cancer has either metastasized to the chest wall, to the skin, and to the internal mammary lymph nodes on the same side of the chest, or the cancer has metastasized to the lymph nodes near the breast bone or to other tissues near the breast.
- **Stage IV** is metastatic cancer. The cancer has spread beyond the breast and the axillary lymph nodes to other parts of the body (bones, liver, lungs, brain, etc.)

### *7.2.5. Epidemiology*

In the last decade, medical research on breast cancer has advanced significantly and has contributed to the discovery of new methods of detecting, diagnosing, and treating the disease. Subsequently, the long-term survival rates for breast cancer patients are increasing; however, a rising number of women experience physical and psychological burdens of breast cancer.[15] Studies have shown that many disease-free cancer survivors still suffer from various kinds of problems including prolonged physical symptoms of cancer, delayed effects of cancer treatment, psychological distress including fear of recurrence and death, and alteration in social support.[2, 48, 70-71]

Breast cancer is the most frequently diagnosed cancer among Canadian women. It accounting for one in three cancer diagnoses. It is estimated that 20,500 Canadian women were diagnosed with breast cancer and 5,400 women died of the disease in 2002. [72] One in nine women is expected to develop breast cancer during her lifetime; one in 27 will die of it. [72] On average, 394 Canadian women will be diagnosed with breast cancer every week, and every week 104 Canadian women will die of the disease.

According to data provided by Statistics Canada, breast cancer survival rates have reached their highest levels in more than four decades. In 1995, 28.4 of every 100,000 females of all ages died of breast cancer, a figure that is down from 31.3 in 1990. From

1950 to 1990, the mortality rates remained relatively steady, fluctuating between 29.5 and 32.0 deaths per 100,000 females. Since 1990, there has been an overall decline.[72]

Age-specific survival rates in breast cancer patients have increased; between 1986 and 1995, statistically significant increases in breast cancer survival rates occurred in all age groups, from 30 to 70 years old. In 1995, only 57.4 in every 100,000 women in their fifties died of breast cancer, a figure that was down from 62.4 in 1990. Similarly, 80.4 in every 100,000 women in their sixties died of breast cancer in 1995; this is substantially lower than 103.5 in 1990[72] (see Table 3, page 68).

Breast cancer survivors are increasingly concerned about Quality of Life, particularly in terms of the loss of productivity, social functioning, health and well-being.

## *7.3. Breast Surgery*

### *7.3.1. Types of Operations*

Surgical procedures for breast cancer frequently consist of removing the malignant tumor from the breast. The different types of interventions are as follows:

A) Incisional / Diagnostic

- Fine Needle Aspiration: used to remove fluid or tissue from a breast lump for cytological assessment.
- Core Biopsy: the removal of a small suspicious tissue from the breast for histological assessment.
- Lumpectomy: only the tumor and a small amount of surrounding healthy tissue are removed.
- Partial Mastectomy: consists of removing the tumor with normal surrounding tissues combined with a dissection of a sample of axillary lymph nodes.
- Simple Mastectomy: the entire breast is removed, along with a sample of axillary lymph nodes. Occasionally sentinel lymph node biopsy is performed.
- Modified Radical Mastectomy: the whole breast including the nipple, the skin surrounding the nipple, and the axillary lymph nodes are removed.
- Radical Mastectomy: the entire breast, axillary lymph nodes, and pectoral major and minor muscles are removed.

### *7.3.2. Post Surgical Symptomatology*

Depending on the surgical intervention, the patient may feel local numbness, tickling, burning, or general weakness. These symptoms might disappear within 6 months to one year after the surgery. Since nerves are affected during the surgery, temporary sensations may occur on the inside part of the arm on the operated side. Presence of edema on the arm of the operated side may occur in patients who have had their axillary lymph nodes removed. Redness, heat, or swelling of the incision are the usual symptoms.

The patients' ultimate expectation of the treatment is the painless removal of the tumor, and the relief of primary symptoms that include pain and restricted motion. Most of the patients entering the surgeon's office want relief from the primary symptoms that led to their seeking treatment. These symptoms are typically problematic in their own right by preventing the patients from functioning personally, socially, and occupationally. From the patient's perspective, there are at least two desired outcomes of the medical care: relief from the primary symptom, and restoration of or improvement in the functional status. The reduction of symptoms, however, does not always guarantee the patient's goals.

### *7.3.3. Post-operative Care*

#### *7.3.3.1. Surgeon's Follow-up*

Depending on the surgical procedure, the patient's age, and the side effects of the operation, the patient can be released from the hospital anywhere from 24 hours to two to five days after surgery. The surgeon will want to see the patient seven to ten days after discharge from the hospital to follow up on the progress of the scar and to advise the patient as to when daily activities including work, sports, and driving a car can recommence.

#### *7.3.3.2. Oncologist's or Physician's Follow-up*

Depending on the results of the biopsy, the patient may need to undergo the following radiotherapy and/or chemotherapy or hormonotherapy treatments:

- Radiotherapy: X-ray, cobalt, or irradiation treatment may be used to decrease and destroy residual cancerous cells in the breast. Side effects are swelling and heaviness in the breast, skin irritation in the treated area, and, possibly, fatigue.

- Chemotherapy: This treatment is used to destroy residual cancer cells after surgery. Some patients may need a combination of chemotherapy, surgery, and/or radiation. Side effects are nausea and vomiting, loss of appetite, hair loss, mouth sores, changes in menstrual cycle, a higher risk of infection due to a shortage of white blood cells, and fatigue. Most of the side effects disappear when the treatment ends.
- Hormonotherapy: Anti-hormonal medication, such as Tamoxifen or Raloxefene, which blocks the estrogen receptors that are present in breast cancer cells, is used to prevent the growth and/or proliferation of cancerous cells. It is usually recommended for women with metastasis whose tumors are receptive to hormones.
- Immunotherapy (Herceptin): This is applied when hormone therapy or chemotherapy is no longer working.

*7.3.3.3. Physiotherapist's follow-up*

Physiotherapy is used for some patients who experience physical functioning problems (e.g. stiffness in the shoulder and the arm, lyphedema) after their breast surgery.

## 8. Rational

### *8.1. HRQOL in Surgical Research and Treatment Evaluation*

First, the surgical treatment outcome assessment impact on the Health Related Quality of Life for breast cancer women would be associated with a better or a worse outcome. In order to be fully aware of the impact of breast cancer surgical therapy on the patient's Quality of Life, and to be able to select the most beneficial post-surgical therapy, an overall Health Related Quality of Life assessment is vital. The need for this model of scale has been the impetus of this study; it has prompted the exploration of the patient as a rich source of information, and the identification of the five essential functions of case management programs:

- Assessment of the patient's needs
- Development of treatment plans for follow-up or for future patients (e.g. socio/psychological therapy).

- Linkage of patients to services (e.g. social services).
- Monitoring of the provision of services
- Evaluation of the patient's progress

Secondly, throughout surgical treatment and research, there is an increasing recognition of the importance of the patients' perspective on the outcome of their treatment, and a growing interest in the post-surgical effect on the Quality of Life. Consequently, the measurements of Quality of Life and the related constructs have increased dramatically in the last 30 years (see Table 4, pp. 69,70), thus acknowledging that QOL is a valid outcome measure, both in clinical research and in the evaluation of health care programs. However, due to the conceptual vagueness of QOL and its relation to surgical treatment outcomes, only 1% of the papers published on surgery mention assessment of well-being and Quality of Life in their abstracts. Quality of Life following surgery has been of secondary importance to mortality, morbidity, and operative complications.

Thirdly, applying a generalized questionnaire with diverse applications would measure other outcomes that are not treatment or disease related, or that are related to the disease but not to the breast surgical treatment outcomes. For example, the generalized questionnaire would not have a negative or a positive effect on measuring the breast surgical treatment success or failure, or on providing the proper guidelines for treatment follow-up. For this reason, there is a difference between applying the appropriate scales to evaluate the breast surgical outcomes and using them effectively. The feasibility and the credibility of Health Related Quality of Life questionnaires or surveys ultimately depends on whether they yield useful and meaningful information. There is controversy concerning which outcome survey is the most effective and whether there exists a valid measure that can be applied to the evaluation of the treatment outcome of breast surgery. Investigators have the responsibility of ensuring that the tests employed to measure QOL are more specific to the breast surgical treatment outcomes in order to evaluate the outcome effect on the quality of life for breast cancer survivors.

C. A. McHorney stated in his paper that "Quality of Life measures differ in content; [therefore] their appropriateness for different applications, populations, and settings varies considerably." [29] C. A. O'Boyle indicated that the generalized Quality of

Life and traditional indicators of outcomes becomes less relevant as anesthetic techniques improve and the impact of surgery on patients goes beyond impairment and disability.[39,73]

### *8.2. Importance of Health Related Quality of Life (HRQOL)*

Outcome research is generally enhanced by the treatment that allows for easier isolation of relevant variables and better methods of testing hypotheses. Patients will rate the outcome according to the changes that are experienced in their health and daily life. Physicians will rate the outcome based on changes relevant to or directly affecting their patients. The Physicians evaluate the outcome based on the degree of change occurring as a result of the therapeutic process. In clinical research, the outcome is based on the treatment's effect on the individual's ability to function. Surgeons will base the outcome on the success of the intervention.

The scientific demands of Health Related Quality of Life research based on patient self-assessment by means of questionnaires are well described.[74-76] The assessment of Health Related Quality of Life is becoming a crucial variable in clinical research, as clinicians are interested in the impact of the disease and treatment outcomes on the whole individual, and not in limiting their evaluations to the results of laboratory tests.[77, 78] An increasing number of Health Related Quality of Life measures are used to describe treatment outcomes and symptoms in order to facilitate decision making concerning the follow up treatment,[77] and, consequently, to enable patients to feel and function better in their day-to-day activities.[79]

Therefore, research is needed in breast surgery outcomes. Given the fact of the inexpensive nature of this study and the lack of a potentially harmful intervention, it is reasonable to pursue this investigation in order to establish better quality care, treatment, and prevention of treatment side effects for breast cancer survivors by identifying the variables that affect the QOL for breast cancer surgery survivals.

This study describes the development and the testing of the Health Related Quality of Life for patients of breast surgery; its goal is to assess the well-being of breast cancer survivors.

## 9. Objectives

General Objectives:

- To develop a scale that can allow the measurement of the post-operative quality of life relating to breast cancer surgery. It will be refer to as Breast Cancer Surgery Quality of Life scale (BCSQOL).

Measurement objectives:

- To evaluate the reliability and validity of the BCSQOL scale.

## 10. Hypothesis

Null hypothesis: The determinant outcomes of BCSQOL are not reliable or valid for measuring the HRQOL for beast cancer patients after their surgical treatment.

That means the correlation (R) between variable BCSQOL and individual BCSQOL domains are weakly or not at all correlated. The Pearson correlation (Cronbach alpha), and/or the Spearman rank correlation value is equal to or close to zero ($\alpha = 0$ and $\rho = 0$).

Ho: R = Ro versus Hi: R  Ro (where Ro < -0.30 or Ro > +0.30) at a 5% level of significance where R and Ro are their reliability and validity coefficients.

## 11. Method

### *11.1. Study Phases*

This is a five phase methodological study on the development of a standardized Health Related Quality of Life questionnaire for breast cancer surgery.

1. The first phase included creating a conceptual framework, performing a literature search, and selecting the topics and a HRQOL questionnaire for breast cancer surgery.
2. In the second phase, items were generated and set together in sequences to yield a first version of the questionnaire.
3. Third, the preliminary instrument was submitted, along with the conceptual framework, to reviewers for content validation and critical review.
4. Fourth, after the integration of modifications, the questionnaire was mailed out to the study population.

5. After the data collection and data entry, the assessment of reliability was carried out.

### *11.1.1. First Phase*

#### *11.1.1.1. Literature search.*

In order to identify Quality of Life measurements and measurable breast surgery treatment outcomes used to evaluate the quality of life for breast cancer surgery, the literature review was carried out. The review involved searching the Medline and the Ovid Medline databases for relevant articles using the keywords "Quality of Life," "Breast neoplasm," "breast neoplasm/surgery in the field MeSH terms," and "limits to human." It was carried out for the years 1966-2002, and reviewed existing scales and expert clinical opinions regarding the postoperative symptoms and problems reported by patients during clinical consultations in order to obtain a clear observation to breast cancer surgery symptoms, outcome evaluations, and Quality of Life issues.

#### *11.1.1.2. Selection of topics.*

According to the WHO and to the scientific literature for breast surgery, the main operational domains of outcomes assessment can be considered from two principal diminutions: symptomatic and functional. Consequently, the everyday life of the patient can be divided into measurement domains.

The measurable breast surgery outcomes, which may arise, based on the literature review, on practical experience, and on individually observed applications, are the following:

- Physical Health and Functioning:[31, 60, 80, 81] the performance of or the capacity to perform usual activities, the ability to perform daily self-care activities, and to function at work.
- Symptoms of Breast Surgery: [31, 80, 81] effects on the Quality of Life include redness at the surgical scar, of which heat or swelling of the incision are the usual early symptoms; pain, the sensation of numbness, tickling, burning, or weakness; and presence of edema on the arm may occur in patients who have had their axillary lymph nodes removed. Items referring to this topic are represented in Questions 2 & 5 of the BCSQOL.

- Mental Health Symptoms and Signs Effects:[1, 2, 5, 9, 67, 71, 82-85] behavior dysfunction and psychological status (distress or well being) are referred to in this topic. The patients' feelings and moods are referred to in items found in Question 3.
- Social functioning:[31, 60, 67] social contacts, interpersonal relationships, and resources are exemplified in items in Question 8.
- General health perception: [15, 35, 60, 67, 81, 86] self-perception (body image), global well-being, need for services, energy, and vitality are rated. Items referring to this topic are represented in Questions 4 & 7.
- Treatment satisfaction: [15, 31, 35, 60, 67, 80, 86] by inquiring after the patients' self-perception (body image), relation with the health care team, and social support, their satisfaction can be assessed. Items referring to this topic are represented in Questions 4 & 8.

Selected topics for breast surgery outcomes were identified from each article. Data regarding the Quality of Life impact that was defined as patient-experienced, the symptoms, and the negative effect of the treatment were extracted. Specialists in the domain of breast cancer treatment were consulted in order to ensure that the important topics characterizing treatment were included.

As is evident from the literature, the aspects of HRQOL that are the most relevant to beast surgery survivors are body image,[15, 35, 81, 86] and pain. [24, 80, 81, 87, 88] Social adjustment [2, 3, 11, 19, 38, 48, 67, 70-71, 86]and psychological aspects [5, 8, 9, 16, 18, 22-26, 90] are very well described, but not in sufficient details for breast surgery; therefore, they are not sufficiently sensitive to the precise evaluation of the impact of breast surgery on the patients.

In Table 1, p. 67, the different QOL scales to evaluate the topics identified in the literature are reported. The size of the topics selected from the list generated from the literature review was established according to the possible effects of the surgical treatment on the patient quality of life, and to any change that corresponds to the domain of interest which patients perceive as beneficial and which would affect the quality of life. They are described in Table 2, page 68.

*11.1.1.3. Measurement issues.*

Most measurements identified in the literature were largely restricted to impairments such as fatigue, pain, or anxiety: symptoms that are not exclusively associated with breast surgery treatment. Therefore, in conducting an outcome research study on the Health Related Quality of Life for breast cancer surgery, the QOL scale should be oriented toward care of and relief of breast cancer surgery symptoms, and aimed at improving function and preventing complications. In addition, a multidimensional, brief, valid, and significant measure of QOL with the purpose of identifying the relevant outcomes and variables that may influence the HRQOL for breast cancer surgery should be established. Understanding these elements that are relevant to the outcome is essential to the effective conceptualization of health related quality of life.

*11.1.2. Second Phase*

*11.1.2.1. Construction of Items and Development of Questionnaire.*

The Health Related Quality of Life questionnaire contains items identifying symptoms for post breast cancer surgery that were generated according to topics selected from the literature and the QOL questionnaires used in breast cancer surgery publications.

As shown in Tables 5.1a – 5.8b, pp. 71-78, some of the topics chosen for inclusion in the questionnaire were not covered by the standard questionnaires selected to evaluate the quality of life for breast cancer patients after surgery. These topics have, however, been referred to in the literature.

In order to construct the structure of the BCSQOL, the formats of the existing questionnaires applied in surgical research were examined in order to suit the BCSQOL for self-assessment (see Table 1, p. 67 for the list of scales identified in breast cancer surgical research publications). All items matching the topics selected from the literature were extracted from the existing questionnaire. The wording of the questionnaire was modified to specifically suit BCS symptoms and to render it more user-friendly, as having simple questions and response options facilitates a better understanding of the questionnaire by all levels of education and all social classes of patients.

- Topic 1: **Assessment of functioning** was derived from topics that might be affected by the breast surgical treatment. Questions concerning each post breast

cancer surgical symptom related to basic daily activities (i.e. pain in the operated area, and pain stimuli), were prepared. The physical functioning questionnaires are associated to the post surgical physical symptoms and their effect on physical daily activities. The sexual functioning questionnaire examines whether the surgical intervention had any effect on the sexual lifestyle, sexual communication, and perceived pleasure of the patient. The questions on physical health have been modified from the SF-36, the EORTC QLQ-30, the EORTC QLQ-BR23, and the Spitzer QOL index, all of which are shown in Tables 5.1 and 5.6, pp. 71, 72 and 76. The questionnaire on sexual functioning has been modified from the EORTC-QLQ-BR23.

- Topic 2: **Assessment of pain** as the major underlying cause of post surgical symptoms. Pain is assessed in items 2, 3, 4, 5, 6, & 7. Physical pain is discussed in Question 1.2, and in items 2 and 5. Disease-related psychological pain is questioned in item 3, psychological pain related to the surgery is assessed in item 4, and psychological pain due to other diseases or factors is discussed in items 6 & 7. Fatigue is also represented in the questionnaire. Questions concerning fatigue due to the treatment period are posed in item 1, while item 3 inquires after fatigue due to the nature of the disease. The questions on pain have been modified from the SF-36 and the EORTC QLQ-BR23, which are shown in Table 5.2, p. 73.
- Topic 3: The questionnaire in item number 3 examines the **psychological health symptoms and signs** effects like behavioral intention, attitude and self-efficacy. Psychological factors such as the patient's anxiety, depression, nervousness, fatigue, concern about recurrence, anger, psychological sexual effect, body image, general health perception, and relation with family and friends can be influenced by BCS symptoms. The questions concerning psychological factors have been modified from the SF-36, the EORTC QLQ-30, and the EORTC QLQ-BR23, which are shown in Table 5.3, p. 74.
- Topic 4: Measuring outcome status in the area of family and social relations is explored in item number 8. The questions on personal relations and social activities have been modified from the SF-36, the EORTC QLQ-30, and the Spitzer QOL index, which are shown in Table 5.8, p. 78.

- Topic 5 and 6: The questions in item number 4 examine general health self-perception and treatment satisfaction through examination of the body image of the patient. The questions on general health perception and treatment satisfaction have been adapted from the SF-36, the EORTC QLQ-30, the EORTC QLQ-BR23, and the multi-dimensional body self-relation questionnaire, all of which are shown in Table 5.4 and 5.7, pp. 75 and 77.

Overall, the resulting combination of questions consists of 51 items in eight Quality of Life domains, which were drafted to be coherent with impressions acquired from the literature. There are eight items concerning daily activities, seven items concerning pain, six items concerning feelings, three items concerning body image, seven items concerning physical health, six items concerning sexual functioning, seven items concerning general health, and seven items concerning social functioning. The short scale was used and the wording adapted in order to render the concepts more familiar to the study population. The questions were put in sequence; the responses and the questionnaire were pre-columned see the appendix on page 88.

*11.1.2.2. Scoring method and distributions.*

The answers were scored using a positively valued unipolar scale, with the value of zero assigned to the worst HRQOL status, and three to the best on the 4-point scale. On the 3-point scale, the score ranged from zero for the worst to two for the best. On the 2-point scale, the score ranged from zero for the worst to one for the best. More details are shown in Table 6, p. 79.

*11.1.2.3. Computation of scores.*

The algorithm for computing the BCSQOL summary scores was based on acquiring the score for each domain by adding the score for all the questions in each domain then dividing by the maximum best score for each domain. Each domain will have a final best value of one. For the BCSQOL summary score, the score of each domain is computed by adding the value of each domain then dividing by eight, that is, the

maximum best value of the scale. A final total of one is the maximum best value of the BCSQOL scale. The missing value was computed manually.

### *11.1.3. Third Phase*

#### *11.1.3.1. Reviewer's process.*

Several revisions followed the development of the preliminary version of this BSCQOL questionnaire. The first was derived from a series of individual consultations with external reviewers; the questionnaire was then presented first to the research committee for comments and feedback, then to the Department of Surgery at l'Hôpital Sacré-Coeur in Montreal. The questionnaire was presented to surgeons and physicians who were treating patients with breast cancer. They were asked to provide comments on the questionnaire, and to reflect on whether the proposed items adequately covered the domain of breast cancer surgery. After a period of two weeks, an individual meeting with the head of the Department of Surgery took place to summarize the comments on the questionnaire that were provided by surgeons and physicians at the hospital. The questionnaire was approved, with some corrections and suggestions. After this revision and consultation, a final version of the instrument was ready for pretest.

The second revision involved a test for language. Additional revisions were then conducted by the research team to ensure the judicious disposition of all suggested modifications. At this later phase, particular attention was given to the terminology of the instructions to respondents, to the questionnaire format, and to the data codifications. The final version that was prepared for the validity and reliability assessment is presented in the Appendix, p. 88.

### *11.1.4. Fourth Phase*

#### *11.1.4.1. Selection of QOL questionnaires.*

Based on the review of existing instruments shown in Table 1, p. 67, the SF-36 was found to be the most widely used health survey in clinical research; it has also been used as a validity gold standard QOL scale. It was therefore used in this study in combination with the BCSQOL as tool to assess the validity and the reliability of the BCSQOL. No instrument has been identified for post surgical quality of life for breast

cancer survivors that provide a global assessment of patient satisfaction, symptom severity, health status, and functioning; however, the SF-36 scale is easy to administer and provides a good orientation to outcome evaluation.

*11.1.4.2. Study population.*

All female patients who underwent breast cancer surgery between 1998 and 2002 were eligible for this study. Subjects were selected via random sampling from l'Hôpital Sacré-Coeur surgical registries and were mailed a questionnaire to self-administer.

*11.1.4.3. Ethical consideration.*

According to l'Hôpital Sacré-Coeur regulations, this study could be conducted at the breast clinic with neither the need for ethical approval, nor for patient consent due to the fact that the study questionnaire was anonymous and did not confer any privileges, such as special treatment by the breast clinic or by the hospital, to participant. The personal identification number of each participant was safeguarded, and could only be traced from the breast clinic at l'Hôpital Sacré-Coeur in order to gain access to personal data.

*11.1.4.4. Recruitment strategies.*

Patients were recruited from the Breast Cancer Clinic at l'Hôpital Sacré-Coeur. A letter inviting the patients to fill out the questionnaire was sent out, along with the questionnaire. It was estimated that the response rate would be 50% for unsolicited subjects. The aim was to send out 140 questionnaires; however the mailing was terminated after we received 79 responses out of 98 mailed questionnaires. The reply rate was 80.6%, which was a sufficient number of eligible responses for the questionnaire analyses.

*11.1.4.5. Field testing*

The current study was designed as a pilot project aimed at demonstrating that the BCSQOL questionnaire is relevant to breast cancer survivors.

A letter explaining the purpose of completing the questionnaire and inviting the survivors to fill it out was sent along with the BCSQOL and the SF-36 questionnaires. The package also included a stamped, self-addressed envelope in order to facilitate the expedient return of the completed questionnaires. McHorney has proven this method of mailed questionnaires to be as valid as are replies by telephone or in person.[91] Patients were asked to give the best answers they could, and to answer the questions with which they felt comfortable. In order to assess the content validity, two questions assessing the patients' opinions were included:

1. How do you think this questionnaire reflects on how you feel: poorly or well?
2. Did you feel that the questions are confusing or clear?

The patients were also asked to provide any comments about the questionnaire or about the disease.

The patients were blinded in that they didn't know which questionnaire was the BCSQOL and which was the SF-36.

For the study measures, the patients were asked to complete a short form which was a patient's demographics questionnaire regarding the age, marital status, education, employment status, and household income of each participant.

*11.1.4.6. The questionnaires and the data.*

Following the receipt of the questionnaires, all were reviewed for completeness and for clarity. Data were then entered on SPSS-11, verified for data entry errors, and stored on computer file and diskette for statistical analysis and for a backup copy of the data.

Descriptive statistics were completed for socio-demographical data, and the frequency distributions of responses were examined.

## 12. Statistical Analysis

### *12.1. Sample size*

Denner and M. Eliasziw developed a guide for the estimation of sample size requirement for reliability studies.[92] With two measurements per subject, a minimum of 70 subjects were required to provide 80% power to test Ho: R = Ro versus Hi: R  Ro or within the range of (-0.30 and +0.30) at a 5% level of significance where R and Ro are

their reliability and validity coefficients, and Ro value is more than 0.30 (R>0.30) or less than –0.30 (R<–0.30), that is considered to be acceptable for this study.

### *12.2. Study variables*

Four major considerations are important in the measurement of outcome:

1. Patient demographics: (Age, Education, Marital status, Occupation, Income). In order to obtain information, patients were provided with a self-report measure (patient information sheet).
2. Type of surgical treatment: Treatment type, i.e. Fine Needle Biopsy, Core Biopsy, Incisional Biopsy, Excisional Biopsy, Partial Mastectomy left, Partial Mastectomy right, Total Mastectomy, or Modified Radical Mastectomy, was extracted from the patients' files.
3. Time elapsed since breast cancer surgery operation: This is the elapsed time between the breast surgical treatment and the questionnaire evaluations. The surgical procedure date was extracted from the patients' files, and the patients provided the date of the assessment upon completion of the questionnaire. The difference between the two dates is computed as the length between the surgical intervention and the patient assessment.
4. Pathological diagnostic: this is defined as the diagnostic provided after examination of the extracted tissues of the breast.

### *12.3. Data Management*

For this study, statistical analyses were performed with SPSS-11 statistical software for Windows.

Before conducting the analyses, a 25% random sample of questionnaires was retrieved for verification of coding and data entry.

### *12.4. Data Analysis*

The frequency distribution was generated in order to provide an overview of the data. The differences in prevalence of age, treatment type, pathological diagnostic, and

duration of elapsed time since the operation, the mean, medians, mode, standard deviation, and proportion in each variable was computed.

- Patients' acceptance of the questionnaire: This refers to the patients' opinions of the questionnaire, to their comments, and to the number of surveys returned out of the total number of surveys sent.
- Questionnaire reliability: Reliability refers to the degree with which measurements taken under identical circumstances will yield the same results. The reliability of a measurement is based on an analysis of the correlation between individual BCSQOL domains obtained on the same group of patients and BCSQOL questionnaires, to evaluate the strength of reliability of each domain for breast cancer surgery survivors.

  The internal consistency of each of the eight QOL domains was devised to illustrate the QOL domains' reliability on the BCSQOL, and was assessed via the computation of Cronbach's standardized item coefficient alpha. Cronbach's $\alpha$ is an appropriate method to analyze the reliability of the questionnaire, as it estimates the reliability of a summation of items forming a scale; coefficient alpha is an optimal estimate of reliability and remains the most widely used and documented measure of internal consistency for the assessment of multiple item scales. Coefficient alpha tells us about the extent of commonality between all the items forming a scale; its calculation uses the average correlation of all the items. It can be interpreted as a correlation coefficient ranging in value from (-1 to 1); coefficients close to zero represent a weak relationship, and coefficients close to +1 or -1 represent a strong relationship.

  The Spearman rank correlation ($\rho$) between the BCSQOL and each of the eight QOL domains determines the strength of relationship between the QOL domains and the BCSQOL questionnaire.

  The sign of the coefficient indicates the direction of the relationship, and its absolute value indicates the strength, with larger absolute values indicating

stronger relationships. Possible values range from -1 to one, but a value of -1 or +1 can only be obtained from square tables.

- Questionnaire Validity: Validity refers to the degree with which the measure value reflects the characteristics it is intended to measure. The term "valid" implies that there is an external gold standard exemplified by the most commonly used QOL questionnaire (SF-36) against which the BCSQOL is being compared. To assess the validity, we computed the Spearman rank correlation of both the BCSQOL and the SF-36. The validity of a measurement is based on an analysis of the correlation between different parts of or questions in the BCSQOL and similar parts of or questions in the SF-36

  The Spearman rank correlation (ρ) between the BCSQOL and the SF-36 determines the strength of a relationship between the two scales.

  The Pearson correlation coefficient (α) was used to determine the degree of agreement between the BCSQOL and the SF-36 scale.

  The sign of the coefficient indicates the direction of the relationship; its absolute value indicates the strength, with larger absolute values indicating stronger relationships. Possible values range from -1 to one.

## 13. Results

### *13.1. Results of Literature Review*

In the last three decades, quality of life and treatment outcome evaluation research on breast cancer has advanced significantly and has contributed to define problem areas of quality of life and effect of each treatment modalities. The very first breast cancer surgery QOL publications were limited to survival rates, and then studies started to focus on the psychological effect and cosmetic outcome of the breast surgery. The last decade studies on QOL of breast cancer surgery publications have shown that many disease free cancer survivals still suffer from various kinds of problems including prolonged physical and psychological symptoms delayed effect of breast surgery.

The literature review underlines the need for the development of targeted HRQOL instruments containing items or scales which measure areas likely to be affected by breast cancer or by its treatment that are not captured by general or even breast cancer-specific instruments. These include HRQOL-specific areas such as body image, arm symptoms related to surgery and long-term survival after breast cancer surgery.[93]

The results of the literature search are summarized in Tables 1 and 2, pp. 67 and 68. Table 1 classifies reports of different measures used in breast cancer surgery, and Table 2 outlines symptoms and outcomes frequently experienced by BCS survivors, and QOL topics identified in the literature for breast cancer surgery quality of life.

### *13.2. Description of Participants*

The age of the participants ranges from 40 to 83 years; the mean is 61.36 years, the standard deviation is 9.79, the median age is 61 years, and the mode is 60 years (see Table 7, p. 79). Age ranged from 46-65 years old in 57% of the participants; 35.5% of the respondents received partial mastectomies. The most frequently performed procedure was the biopsy, represented in 50.8% of the respondents; 7.6% had total mastectomies, and 5.1% had modified radical mastectomies. The most commonly diagnosed breast cancer in the participants' population sample was invasive ductal carcinoma 63.3%, followed by intraductal cell carcinoma 10.1%. The elapsed time since the breast cancer surgery varies from 6 months to 42 months, with the mean and median around 24 months.

The participants reported various levels of education: 32.9% have their high school, 26.6% have a university degree, 16.5% have only primary school, 13.9% have trade school, and almost 9% have community college. Issues of functional literacy were addressed to resolve problems with self-reporting due to difficulties obtaining information regarding their condition resulting from illiteracy.

Most of the participants are married or live with a common-law partner (62%); 26.6% work full time, and another 26.6% are retired. The participants reported various levels of annual income, from less than $15,000 (14%), to between $15,000 and $25,000 (15.2%), to between $25,000 and $45,000 (almost 28%), to more than $45,000 (31.6%).

Figures 1-8, pp. 83-87 show the distribution of socio-demographic characteristics and the age categories, surgical treatment, pathological diagnostic, age categories since

the operation for breast cancer, employment status, house hold income, marital status and level of education of study participants.

Table 2, p. 68 presents the mean, standard deviation (SD), median and mode of the participant's age and the elapsed time since the operation for breast cancer.

### *13.3. Response rate*

The response rate to the BCSQOL questionnaire was 80.6%, which is considered high for unsolicited subjects. It was estimated that the response rate would be 50%. The aim was to send out 140 questionnaires; however, the mailing was terminated after 79 responses out of 98 mailed questionnaires were received. The reply rate led to a sufficient number of eligible responses for the questionnaire analyses, thus the BCSQOL questionnaire is feasible to administer and easy to complete as a self-assessment questionnaire for beast cancer surgery survivors.

### *13.4. Patients' Acceptance*

The majority of the respondents (74.7%, or 59 of 79) found the questionnaire to be relevant and its content appropriate to their feelings, while only 23.4% felt it a poor reflection of how they feel; 2.5% provided no comments.

A vast majority of the respondents (91.1%, or 72 of 79) found the questionnaire items to be clear, 3.8% found the questionnaires unclear, and 5.1% of the respondents provided no comments. Figures 9 and 10 on p. 87 and 88 present the findings of the questions concerning the clarity of the questionnaire and its appropriateness to the patients' post-surgical state.

### *13.5. Results of the Questionnaire Reliability and Validity*

Generally, correlations greater than 0.7 are considered strong, correlations less than 0.3 are considered weak, and correlations between 0.3 and 0.7 are considered moderate; the same range applies to the negative value. The coefficients close to (+1) or (–1) represent a strong relationship. Note that a p-value of 0.05 was considered significant for all our comparative analyses.

The values of α and ρ vary directly as a function of two factors: the average inter item correlation and the number of items forming a scale. The low value of α can generally be explained by one of three conditions: first, the QOL domains of BCSQOL may measure a single concept unequally; second, equally; or third, they measure more than one concept.

*13.5.1. Questionnaire Reliability*

The correlation between variable BCSQOL and individual BCSQOL domains obtained on the same group of patients varies between a strong correlation of the extent of commonality or association between all the items forming a scale of ($\alpha = 0.779$) and a moderate correlation of ($\alpha = 0.351$). The strength of the relationship between the BCSQOL and each of the eight QOL domains was determined by the Spearman rank correlation and ranged from ($\rho = 0.764$) to ($\rho = 0.286$). All the correlations were significant at the (p value 0.01) except for the Sexual Functioning QOL domain which was not significant. This concluded that the internal correlation identified in the sexual functioning QOL domain has contributed to lowering the alpha value and Spearman rank correlations. This could be, in part, due to the small sample sizes of participants, as only 23 of the 79 were eligible for the sexual functioning questionnaire (30% of participants had been sexually active before surgery). For this reason, another correlation analysis was conducted with the exception of the sexual functioning QOL domain, in which the Pearson correlation increased and varied between strong correlations of the extent of association between all the items forming a scale of ($\alpha = 0.806$) and a moderate correlation of ($\alpha = 0.401$). The strength of the relationship between the BCSQOL and each of the eight QOL domains also increased the Spearman rank correlation ($\rho = 0.782$) to moderate ($\rho = 0.452$).

Table eight, page 80, demonstrates that the null hypothesis (Ho: R = Ro) was rejected ($\alpha = 0.779\text{-}0.351$), ($\rho = 0.782\text{-}0.452$) $df = 77$, ($p < 0.01$) significant level, demonstrating that the BCSQOL questionnaire is reliable for breast cancer surgery survivors, and is well structured. Internal correlation measures for reliability with high correlation (R) of 0.70 or more indicate high reliability R of less than 0.70, and a moderate reliability of more than 0.30; these results are significant ($p < 0.01$).

Inspection of the subset questions within the items also revealed highly related subsets as well as subsets that do not relate to any of the others.

More detailed description of each QOL questionnaire is visible in the BCSQOL questionnaire, where their domains are analyzed by order of appearance.

- Physical Activity: ($\alpha$ = 0.650 and $\rho$ = 0.661), degree of freedom (77), and significance level (p value < 0.01) led to the rejection of the null hypothesis, which indicates substantial but moderate reliability. After removing the sexual functioning domain from the total domains of the BCSQOL, the $\alpha$ value decreased because it might be considered as physical activity: ($\alpha$ = 0.588 and $\rho$ = 0.560), degree of freedom (77), and significance level (p value < 0.01). Inter-item correlation revealed the highest correlation with the General Health domain and no correlation with Body Image. This QOL domain consists of 8 items measuring BCS symptoms which affect the daily activities and functions that are relevant to the location of the surgery, including the patient's return to employment (possible answers were: No, Yes, Sometimes, Yes, As before the treatment). All of participants responded to the questions in this domain that provided a mean score of (M = 0.86/1), a standard error of (SE = 0.022), and a standard deviation of (SD = 0.19).
- Pain: ($\alpha$ (76) = 0.767 and $\rho$ = 0.764), degree of freedom (76), and significance level (p value 0.01) led to the rejection of the null hypothesis. By removing sexual the functioning domain from the total BCSQOL domains, the correlations value for $\alpha$ and $\rho$ slightly decreased. The correlations indicate a substantial high reliability. The inter-item correlation revealed the highest correlation with the Psychological Functioning domain and the lowest with the Sexual Functioning domain. This seven-item QOL domain is designed to measure the presence and intensity of BCS pain relevant to the site of operation (possible answers were: Yes, severe; Yes, moderate; Yes, mild; None). 78 of the 79 participants responded to the questions in this domain, which provided a mean score of (M = 0.72/1), a standard error of (SE = 0.027), and a standard deviation of (SD = 0.24).
- Psychological Functioning: ($\alpha$ (77) = 0.779 and $\rho$ = 0.621), degree of freedom (77), and significance level (p value 0.01) led to the rejection of the null

hypothesis. After removing the Sexual Functioning domain from the total BCSQOL domains, the α value increased significantly (α = 0.806 and ρ = 0.782). This proved to be the highest correlation between the QOL domains and the BCSQOL, thus indicating substantially high reliability. The inter-item correlation revealed the highest correlation with the General Health domain and no correlation with the Sexual Functioning domain. This six-item QOL domain is designed to measure BCS psychological effect, whether it is disease- or surgery-related (possible answers were: All of the time, Most of the time, Some of the times, No). All participants responded to the questions in this domain, providing the following scores: (M = 0.70/1, SEM = 0.02, SD 0.20).

- Body Image: (α 76 = 0.504 and ρ = 0.440), degree of freedom (76), and significance level (p value 0.01) led to the rejection of the null hypothesis. After removing the Sexual Functioning domain from the total BCSQOL domains, the α value increased slightly. The inter-item correlation revealed a moderate correlation with the Symptoms domain, and almost no correlation with all QOL domains. The correlations indicate moderate reliability. This three-item QOL domain measures the awareness of the impact of the breast surgery on the respondents' perceptions of themselves and their bodies. In another way, this domain is meant to measure the psychological effect of BCS (possible answers were: No, Somewhat, Yes, A lot). 78 of 79 participants responded to the questions in this domain, which yielded the following scores: (M = 0.70/1,SEM = 0.03, SD 0.27).
- Symptoms: (α 76 = 0.637 and ρ = 0.562), degree of freedom (76), and significance level (p value 0.01) led to the rejection of the null hypothesis. After removing the Sexual Functioning domain from the total BCSQOL domains, the α value increased, but within moderate correlation range. The correlations indicate a substantial moderate reliability. The inter-item correlation reveals a moderate correlation with the Pain domain and no correlation with the Social Functioning domain. This section is an indirect measure to assess the presence of post-surgical symptoms and their effects (possible answers were: Yes, No). 78 of 79

participants responded to the questions in this domain, yielding the following scores: (M = 0.72/1, SEM = 0.26, SD 0.23).

- Sexual Functioning: (α (21) = 0.351 and ρ = 0.286), degree of freedom (21), the results were not significant ($p > 0.05$). The inter-item correlation revealed a moderate correlation with the Social Functioning domain of (α (21) = -0.424 and ρ = -0.463), degree of freedom (21); the results were significant ($p<0.05$). This negative direction moderate correlation indicates that the Sexual Functioning domain is reliable within the structure of the BCSQOL questionnaire since it has a moderate agreement with two domains, Social Functioning and Physical Functioning; a moderate strength with Social Functioning; and a moderate association with social functioning. In addition, this analysis identified a moderate agreement, and a positive direction correlation was found between the Physical and Sexual Functioning domains (α (21) = 0.492, $p < 0.05$). The Spearman rank correlations were moderate but not significant ρ (21) = 0.380, $p > 0.05$), indicating a weak strength of relationship between the domains of Physical Activity and Sexual Functioning; however, the Spearman rank was probably not significant for the small number of participants who were eligible for this portion of the questionnaire. The elements of this QOL domain consist of four items measuring BCS effect on sexual functioning compared to before surgery (possible answers were: Yes, No). The responses of patients who were not sexually active before the operation were eliminated. Twenty-three respondents were sexually active before the operation; their responses yielded the following scores: (M = 0.85/1, SEM = 0.04, SD 0.21).
- General Health: (α (76) = 0.660 and ρ = 0.545), degree of freedom (76), and significance level (p value 0.01) led to the rejection of the null hypothesis. After removing the Sexual Functioning domain from the total BCSQOL domains, the α value decreased slightly within the moderate correlation value. The correlations indicate a substantial moderate reliability. The inter-item correlation revealed a significant moderate correlation with the Psychological and the Physical Functioning domain, and no correlation with the Body Image, and Sexual and Social functioning domains. The General Health QOL domain consists of two

sections: the first section evaluates the participants' perception of their general health (possible answers were: Poor, Fair, Good, Very good), and the second has five items which evaluate the changes relevant to their general health lifestyle after the surgery (possible answers were: No; Yes, same as before the surgery; Yes, more than before the surgery). 78 of the 79 participants responded to the questions in this domain, yielding the following scores: (M = 0.75/1,SEM = 0.02, SD 0.16).

- Social Functioning: ($\alpha$ (76) = 0.370 and $\rho$ = 0.403); degree of freedom (76), and significance level (p value 0.01) led to the rejection of the null hypothesis. After removing the Sexual Functioning domain from the total BCSQOL domains, the $\alpha$ value increased significantly ($\alpha$ = 0.401 and $\rho$ = 0.452). The correlations indicate a moderate reliability. The inter-item correlation revealed a significant moderate correlation with the Sexual Functioning domain in the negative direction, and no correlation with the Symptoms and Body Image domains. This QOL domain consists of two sections. The first section is an indirect measure which evaluates participant satisfaction with health care services and with their family and friends by assessing the participants' perception of the support they are getting from the family or health care team (possible answers were: Not at all, Limited, Frequent, Very Frequent). The second section is also an indirect measure to evaluate the psychological effect of the treatment on the participants (possible answers were: All of the time, Most of the time, Some of the time, No). 78 of the 79 participants responded to the questions in this domain, which produced the following scores: (M = 0.73/1, SEM = 0.20, SD 0.18).

The internal correlation reliability analysis of the eight QOL domains with the total BCSQOL reliability analysis showed strong to moderate correlations ($\alpha$ = 0.779-0.351) concerning the extent of commonality between all of the items forming a scale. The strength of relationship between the BCSQOL and each of the eight QOL domains varies between strong and weak ($\rho$ = 0.764-0.286), indicating that the BCSQOL is well structured. Pearson's and Spearman's correlations indicate a value of more than 0.70, which is indicative of the substantial reliability of the BCSQOL.

*13.5.2. Questionnaire Validity*

The correlation between the BCSQOL and the SF-36 is a strong positive correlation, ($\alpha$ (77) = 0.778 and $\rho$ = 0.785), degree of freedom (77), and significance level (p value < 0.01) the null hypothesis was rejected.

The correlation between the BCSQOL and the SF-36 obtained from the same group of patients at the same time was significant, exhibiting a strong strength of association ($\alpha$ = 0.778) and a strong strength of relationship ($\rho$ = 0.785) between the two scales. The degree of freedom (77) and the correlation was significant at the (p value 0.01). This prompted the conclusion to reject the null hypothesis that the BCSQOL is a valid QOL scale to evaluate the surgical HRQOL (see Table 9.1, p.80).

To validate each QOL domain in BCSQOL the correlation analysis was computed via Pearson's and Spearman's correlations. Each Quality of Life domain from each scale was correlated with one another from the BCSQOL and the SF-36. Inspection of the subsets of questions from the BCSQOL also revealed highly related subsets from the SF-36, as well as subsets that do not relate to any of the others (see Tables 9.1 through 9.5, pp. 80-82). More detailed description of each QOL questionnaire in the BCSQOL and the SF-36 domains is presented by order of appearance in the BCSQOL questionnaire.

- Physical Activity from the BCSQOL had the best strength of association and relationship with limitation of activity from the SF-36 ($\alpha$ (77) = 0.806 and $\rho$ = 0.749), degree of freedom (77), and significance level (p value < 0.01); the null hypothesis was rejected, which indicates substantially high validity. The Physical Activity domain also had moderate correlations with other QOL domains from the SF-36, such as General Health, Physical Health, Energy and Emotions, and Social Activities.
- Pain: The inter-item correlation between the BCSQOL and the SF-36 revealed a moderate correlation with Energy and Emotions ($\alpha$ = 0.644 and $\rho$ = 0.639), with Pain ($\alpha$ = 0. 577 and $\rho$ = 0. 591), and with Limitation of Activities and Social Activities. The correlation was moderate and was correlated to other variables as the pain has an effect on these variables; also, the pain questions in the SF-36 are not specific to the operation site. The correlation was in the high moderate values

degree of freedom (77), and significance level (p value < 0.01); the null hypothesis was rejected, which indicates substantially high validity.

- Psychological Functioning: A moderate correlation with emotional health problems (α (77) = 0.582 and ρ = 0.584), degree of freedom (77), and significance level (p value < 0.01) led to the rejection of the null hypothesis. Another significantly moderate correlation was found with the Energy and Emotions domain (α (77) = 0.512 and ρ = 0.503), and with Social Activities (α (77) = 0.528 and ρ = 0.544). The soaring moderate correlation with all of the psychological domains of the SF-36 was in the high moderate values, degree of freedom (77), and significance level (p value < 0.01); the null hypothesis was rejected, which indicates substantially high validity.
- Body image: Although it was expected to have no correlation with the SF-36 since the scale does not have a section assessing this very important QOL domain after breast cancer surgery, a moderate correlation was detected with social activities at (α (76) = 0.348 and ρ = 0.327) and significance level (p value < 0.01). This correlation might be explained by the high importance of body image on the female population and its influence on their social activities. In the meantime, inter-item correlation revealed a moderate correlation with post-surgical symptoms from the BCSQOL (α (76) = 0.348 and ρ = 0.327), degree of freedom (76), significance level (p value 0.01) for strength of association (Pearson correlation), and (p value 0.05) strength of relationship (Spearman's correlation), which led to the rejection of the null hypothesis.
- Symptoms: This domain was validated by its correlation with the Social Activities and the Energy and Emotions domains from the SF-36. Due to the fact that the BCS symptoms could influence these QOL domains, the correlation was moderate: (α (76) = 0. 400 and ρ = 0. 395) and (α (76) = 0. 375and ρ = 0. 348) respectively, degree of freedom (76), and significance level (p value 0.01), which led to the rejection of the null hypothesis.
- Sexual functioning: The analysis identified a moderate agreement and association, one positive direction correlation with the Limitation of Activities domain (α 21 = 0.555, and ρ = 0.424, $p < 0.05$), a stronger negative direction correlation with the

last question of the SF-36 General Health domain ($\alpha$ (21) = -0. 489, and $\rho$ = -0.433, $p < 0.05$) was found between the Physical and Sexual Functioning domains ($\alpha$ (21) = 0.492, $p < 0.05$). The test results are significant, thus prompting the rejection of the null hypothesis.

- General Health: Although it was highly expected that this domain would be correlated with General Health domains from the SF-36 ($\alpha$ (77) = 0. 519 and $\rho$ = 0. 525), degree of freedom (77), and significance level (p value < 0.01), the correlation was moderate as the General Health items in the BCSQOL that assess this area are more specifically related to surgical treatment. The analysis identified a moderate agreement and association with other QOL domains from the SF-36 Limitations of Activities, Physical Health Problems, Pain, Emotional Health Problems, and Social Activities. The most significant correlation was found with Energy and Emotions ($\alpha$ (77) = 0. 568 and $\rho$ = 0. 527), as General Health influences these QOL domains. All correlations were significant at ($p < 0.05$) level; therefore, the null hypothesis was rejected.
- Social functioning: a moderate correlation was found with the Social Activities domain in the SF-36 ($\alpha$ (77) = 0. 313 and $\rho$ = 0. 315); degree of freedom (77), and significance level (p value 0.01); therefore, the null hypothesis was rejected.

This analysis reveals a strong to moderate inter-item correlation between the BCSQOL and the SF-36, which reveals a strong strength of relationship, and association between the two scales.

Tables 9.1-9.5, pp. 80-82, present internal correlation measures for validity with the highest validity correlation as ($\alpha$ (77) = 0.806 and $\rho$ = 0.749) for Physical Activity with the Limitation of Activity domain, and the lowest validity correlation of ($\alpha$ (77) = 0. 313 and $\rho$ = 0. 315) for Social Functioning with the Social Activities domain. All results were significant at ($p < 0.05$), which indicate high validity; the null hypothesis was rejected as a strong correlation was found, indicating that the BCSQOL questionnaire is a valid and reliable measure.

## 14. Discussion

The literature search and the interpretation of the treatment outcome studies is a difficult task that can be misleading; publications of such studies have often led to debate. The difficulty of interpreting the results increases with the incompleteness of the data that the studies are based on. It is important to determine what is to be measured and what purpose the measurement is going to serve. Long-term post-operative outcomes may be misleading, as surgery may worsen the patient's postoperative status, while improving the quality and duration of their life.

The BCSQOL was administered successfully in breast cancer subjects after surgical interventions. Research with this model deserves further examination and possible replication. This model allows for the continuous review of and improvement in treatment outcomes. It has also been found that the quality of information obtained from the patients can serve as a basis of a dynamic interplay for QOL improvement.

Through this model, outcome assessment can be conducted without sacrificing the patient's right to privacy and without placing undue burden on the operation of the clinical staff. As we aim at improving the quality of life of breast cancer survivors and ameliorating patient care, the need for a specific HRQOL questionnaire to efficiently cover the case of Quality of Life for breast cancer surgery survivors is clear. The form of the BCSQOL questionnaire was constructed to cover a large range of the topics concerning patients after the surgical treatment of breast cancer without the need for multiple scales to measure a study outcome. The scale was designed to have fewer items and aimed at having moderate reliability between the items to hamper respondent cooperation.

The items were constructed to form a scale that is timely in a fast-paced clinical setting and that addresses the individual's expectations, their daily activities and concern patterns, the effect of the environment, and the effect of treatment on the quality of life. The questionnaire was constructed to be a comprehensive measurement that can be performed outside the clinical research setting, and to have subscales that strike a balance between the efficiency and the comprehensiveness of the assessment of the main outcome effect on surgical therapy.

Both questionnaires yield different scores and similar ones for the mean score, and similar outcome responses for items measuring the same outcomes. The most significant of these was the Physical Activity domain from the BCSQOL and the Activity domain from the SF-36.

In the literature, the correlation between the SF-36 and the disease-specific QOL scales was reported as being low to moderate, and as varying from 0.22 to 0.65, thereby suggesting that the BCSQOL is indeed a valid and reliable scale for the measurement of HRQOL for beast cancer surgery survivors.

Another method of assessing questionnaire validity and reliability was asking the respondents to evaluate the questionnaire simply by indicating "clear" or "confusing," and by indicating whether it reflects their situation, "yes" or "no."

## 15. Future Research

The outcome according to the factor of interest might be investigated by random effects. In this case, the number of factors taken into account in the study is considered a random selection of all possible levels; it is the distribution, especially the variance, of these levels that is of interest. Since treatment outcome differences might be explained by the variability of access to health care resources; by the variability of the utilization of early detection programs, by the effectiveness of therapy (failure of surgical technique, ability of the surgeon "different of outcomes between surgeons"); by factors related to preoperative preparation of the patients, such as anesthetic management and location of the operation, or by the numerous aspects of postoperative care such as surgical scar care, etc. Other factors include differences in patient characteristics that have a strong relationship to the endpoint that could confound the outcome results, lifestyle, and socio-economic levels.

## 16. Conclusion

This study shows that the BCSQOL is a valid and reliable measure for the evaluation of surgical outcome Health Related Quality of Life. More importantly, the BCSQOL and the SF-36 are construct-related but are different measures.

This study illustrates that the BCSQOL and the SF-36 measure the same aspects of QOL because there is a high correlation between the total BCSQOL and the SF-36 total scores; however, the BCSQOL is superior to the SF-36 for the measurement of symptom severity of BCS that can affect these QOL domains. This raises the question of the use of generic quality of life questionnaires for measuring surgical symptoms that affect the Quality of Life of a narrow range of breast cancer survivors.

Overall, the high correlation coefficient value of ($\alpha$ (77) = 0.778 and $\rho$ = 0.785), the degree of freedom (77), and the significance level (p value < 0.01) led to the rejection of the null hypothesis, thereby providing strong evidence for the reliability and the validity of the BCSQOL. In previous similar validation and reliability studies, the correlation between the SF-36 and the disease-specific QOL scales was reported as being low to moderate and varied from 0.22 to 0.65.

The 8-item BCSQOL is proven to be reliable, internally consistent, and validly constructed. The resulting scale is suitable to use in clinical trials and to monitor patients in an outpatient setting or through mailings.

This instrument may be suitable for assessing different periods of recovery for different types of breast surgery; however, further studies are required in order to establish such possibilities.

## 17. Summary

- BCSQOL was administered successfully in breast cancer subjects after their surgical intervention.
- The questionnaire was constructed to cover a large range of the topics that concern patients after the surgical treatment of breast cancer without the need of multiple scales to measure a study outcome.
- The Pearson correlation coefficient direction is positive which estimates the reliability of a summation of items forming a scale. The strength is elevated, showing perfect internal consistency.
- The items were constructed to form a scale that is timely in a fast-paced clinical setting and that addresses the individual's expectations, their daily activities and

concern patterns, the effect of the environment, and the effect of treatment on the quality of life.

- The questionnaire was constructed to be a comprehensive measurement that can be performed quickly outside of the clinical research setting, and to have subscales that strike a balance between the efficiency and the comprehensiveness of the main outcome effect on the surgical therapy.
- In the literature, the correlation between the SF-36 and the disease-specific QOL scales was reported as being low to moderate, and as varying from 0.22 to 0.65 which suggests that the BCSQOL and the SF-36 are similar constructs.

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## 19. Tables

Table 1 *Symptoms and topics identified in the literature review from Medline since 1966 to June 2001*

| Topics identified in the literature/ outcome | Possible effect | | References Number Literature review | Topics in BCSQOL |
|---|---|---|---|---|
| | Clinical observation | Patient self-report | | |
| Physical activity | Morbidity/Mortality | Perceived fitness | 16, 21, 51, 94, , 100 | Q1 |
| | | Fatigue and ability to perform daily activities | | Q1.5 |
| Pain | Post-operative pain | Perceived Pain | 16, 21, 67, 68, 81, 94, | Q2 |
| | | Headache | | Q2.3 |
| | | Sleep problems | | Q2.4.1 |
| Psychological aspects | Neuro-psychological status/Symptoms and signs | Emotions/ Feelings/Moods | 13, 14, 20, 21, 24, 28, 30, 35-37, 48, 70-72, 81, 82, 97, 99 | Q3 |
| | | Sleep problems | | Q3.1 |
| | | Nervousness / irritability | | Q3.5 |
| | | Depression | 56 | Q3.2 |
| | | Anxiety | 56, 59, 64, 65 | Q3.3 |
| | | Difficulty concentrating | 70, 71, 72 | Q3.6 |
| | | Fatigue | 11, 90 | Q1.5 |
| Body image | Surgical scar, redness or swelling of the incision | Self-esteem and perception of body | 10, 16, 21, 28, 34, 38, 51, 101 | Q4 |
| Physical health/Physical symptoms | Severity of post-surgical symptoms | Numb, tingling fingers, and edema. | 16, 21, 94 | Q5, Q1 |
| | | | 73, 98, 100 | Q5.3 |
| Sexuality or Sex Behavior | Psychological or Sex Disorder | Less frequent intercourse | 21,35, 38, 51, 58, 80 | Q6 |
| | | | | Q6.1 |
| | Sexual functioning | Change in relation to spouse | | Q6.4 |
| | Reduced libido | Reduced satisfaction | 6 | Q6.3 |
| General health or Health Status | Overall health | Feeling ill | 10, 21, 28, 34, 51 | Q7 |
| | | Weight gain | | Q7.a |
| | Severity of illness | Need for health services | | Q7.c |
| Social Adjustment or Socialization | Social network functioning | Social behavior and Social support | 11-14, 16, 18, 23, 28, 51, 59, 62 | Q8 |
| | | Change in relation to spouse | | Q8.a.5 |

Table 2 *Selection of domains which were influenced by the literature review, the SF-36, the Spitzer QOL index, the Multi-dimensional body self-relation questionnaire, the EORTC QLQ-C30, and the EORTC QLQ-BR23*

| | QLQBC | | Topics selected from Existing Quality of life measures | | | | Reference Number from Literature Review |
|---|---|---|---|---|---|---|---|
| | QOL Domains | Number of items | Spitzer QOL index Item # | EORTC QLQ-C30 Item # | EORTC QLQ-BR23 Item # | SF-36 Item # | |
| 1 | Activity | 8 items | 1, 2 | 1-7 | 48, 1 | 1, 2, 4, 5, 8 | 21, 51, 94 |
| 2 | Pain | 7 items | | 19 | 38, 47, 50 | 7 | 21, 94 |
| 3 | Psychological functioning, Feelings | 6 items | | 18, 20, 22, 24, 25 | 43 | 9 | 13, 14, 28, 30, 35, 37, 97, 99 |
| 4 | Body image | 3 items | Multi-dimensional body self-relation questionnaire # 2 | 34, 39-42 | | | 10, 34, , 100 |
| 5 | Symptoms, Physical health | 7 items | | | 47-53 | | 16, 21, 94 |
| 6 | Sexual functioning | 4 items | | | 44, 46 | | 21, 35, 51, 58, 80, 101 |
| 7 | General health | 7 items | | 9, 11, 13, 15, 24 | 31, 32, 36, 38 | 1, 2 | 28 |
| 8 | Relationship with others | 7 items | 4 | 26, 27 | | 6 | 10, 28, 51 |

Table 3 *Decreased mortality of breast cancer*

| **Deaths due to Breast Cancer per 100,000 women** | | | |
|---|---|---|---|
| | **1995** | **1990** | **1950 to 1990** |
| **All ages** | 28.4 | 31.3 | 29.5 and 32.0 |
| **In their fifties** | 57.4 | 62.4 | |
| **In their sixties** | 80.4 | 103.5 | |

Table 4 *Scales identified in breast cancer surgical research publications*

| Quality of Life Scale/ Measurements | Scale Orientation | Reference Number |
|---|---|---|
| State-Trait Anxiety Inventory | Psychological | 38, 59, 64, 65 |
| Rosser Scale | Psychological | 66 |
| McGill Pain Questionnaire | Pain & Function | 52, 67, 68 |
| Pain Disability Index | Pain & Function | 52, 81 |
| Profile of Mood States | Psychological | 25, 47, 48, 69, 70, 96 |
| Mental Health Inventory | Psychological | 52, 82 |
| Symptom Distress Scale | Psychological | 71, 72 |
| Mental Adjustment to cancer Scale | Psychological | 96 |
| Hospital anxiety and Depression Scale | Psychological | 48 |
| Parenting Stress Index | Psychological | 80 |
| Cancer Fatigue Scale | Psychological | 48 |
| Psychosocial adjustment to illness scale | Psychosocial | 49 |
| Adaptation to survivorship experience | Psychosocial | 49 |
| Body Image Scale (BIS) | Body image & Self esteem | 75 |
| European Organization for Research and Treatment of Cancer Quality of Life Questionnaire EORTC QLQ-C30 | Cancer disease in general | 6, 15, 52, 54,77,78,82 |
| Adaptation to Surviving Cancer Profile | Cancer in general | 80 |
| Chronic Illness Scale (PACIS) | Cancer in general | 26, 73 |
| Breast cancer treatment outcome scale | Chemotherapy | 83 |
| Health-Related Quality of Life (HRQOL) | General health | 17 |
| SF-36 | General health | 69, 76-78 |
| Ferrans and Powers Quality of Life Index | General health | 80 |

| Quality of Life Scale/ Measurements | Scale Orientation | Reference Number |
|---|---|---|
| Global Adjustment to Illness Scale | General Health | 74 |
| Michel Uncertainty in Illness Scale | General Health | 96 |
| Quality of life index | General health | 69 |
| Summary Satisfaction Index (SSI) | General Health | 60, 61 |
| Linear Analogue Assessment Scale (LASA) | General Health | 38, 59, 62, 63 |
| Wilmoth Sexual Behaviors Questionnaire-Female | Sexual function | 34, 42, 79,81 |
| Functional Assessment of Cancer Therapy FACT-B.) | Chemotherapy | 82, 83, 96, 100 |
| Sickness Impact Profile | Functioning | 25 |
| Symptoms distress scale | Symptoms | 25 |
| Rotterdam Symptoms Checklist (RSCL) | Symptoms | 90, 95 |
| Brief Symptoms Inventory (BSI) | Symptoms | 40 |

Continue: Table 4 *Scales identified in breast cancer surgical research publications*

Table 5.1a *Construction of the Activity domain of the BCSQOL Questionnaire*

| 1 | Activity | EORTC QLQ-30 | EORTC QLQ-BR23 | SF-36 | Spitzer QOL index |
|---|---|---|---|---|---|
| | | | | Does your health now limit you in these activities? | |
| 1.1 | Can you dress and bathe yourself? | Do you need help with eating, dressing, washing yourself or using the toilet? | | Does your health now limit you in bathing or dressing yourself? | Ability to look after yourself. (able to eat, wash, go to the toilet, and dress) |
| 1.2 | Can you comb your hair? | | Was it difficult to raise your arm or to move it sideways? | | |
| 1.3 | Can you drive your car or use public transportation? | | | | Ability to look after yourself. (drive a car or use public transportation) |
| 1.4 | Can you lift or carry groceries or other light objects? | Do you have any trouble doing strenous activities, like carrying a heavy shopping bag or a suitcase? | | Does your health now limit you in lifting or carrying groceries? | |
| 1.5 | Can you practice mild sport activities? | Were you limited in pursuing your hobbies or other leisure time activities? | | | |

Table 5.1b *Continued Construction of the Activity domain of the BCSQOL Questionnaire*

| 1 | Activity | EORTC QLQ-30 | EORTC QLQ-BR23 | SF-36 | Spitzer QOL index |
|---|---|---|---|---|---|
| 1.6 | Do you socialize as before? | Has your physical condition or medical treatment interfered with your social activities? | | | |
| 1.7 | Can you work? | | | | What is your main activity (work, manage household, voluntary activity)? (as usual, can work but need help, can't work) |
| 1.8 | Is pain/physical impairment affecting your work? | Were you limited in doing either your work or your other daily activities? | | Have you had any of the following problems with your work or your other regular daily activities as a result of your physical health: Cut down the amount of time you spend on work or other activities? Accomplished less than you would like? Were limited in the kind of work or other activities? Had difficulty performing the work or other activities? | |

Table 5.2 *Construction of the Pain domain of the BCSQOL Questionnaire*

| 2 | Pain | EORTC QLQ-BR23 | SF-36 |
|---|---|---|---|
| 2.1 | Do you feel pain in your arm or shoulder? | Did you have any pain in your arm or shoulder? | How much bodily pain have you had? Not at all, A little bit, Moderately, Quite a bit, Extreme) |
| 2.2 | Do you feel pain at the surgical scar? | Have you had any pain in the area of your affected breast? | |
| 2.3 | Do you have frequent headaches? | Did you have headaches? | |
| 2.4 | How would you rank your level of pain when you are: | Did pain interfere with your daily activities? | |
| 2.4.1 | Lying in bed | | |
| 2.4.2 | Sitting | | |
| 2.4.3 | Standing | | |
| 2.4.4 | Walking | | |

Table 5.3 *Construction of the Psychological Functioning domain of the BCSQOL Questionnaire*

| 3 | Feelings | EORTC QLQ-30 | EORTC QLQ-BR23 | SF-36 |
|---|---|---|---|---|
| 3.1 | Do you feel tired? | Were you tired? | | Did you feel tired? |
| 3.2 | How often do you feel depressed lately? | Did you feel depressed? | | Have you felt downhearted and blue? |
| 3.3 | Do you worry about recurrence? | Did you worry? | Were you worried about your future health? | |
| 3.4 | Would you say you feel angry? | | | |
| 3.5 | Are you more nervous or stressed than before your treatment? | Did you feel tense? | | Have you been a very nervous person? |
| 3.6 | Do you have difficulty concentrating and/or memorizing lately? | Have you had difficulty concentrating on things, like reading a newspaper or watching television? | | |

Table 5.4 *Construction of the Body Image domain of the BCSQOL Questionnaire*

| 4 | BCSQOL | EORTC QLQ-BR23 | Multi-Dimensional Body-Self Relation Questionnaire |
|---|---|---|---|
| | Since your treatment, have your feelings changed when you are looking at yourself: | | How comfortable or unconfortable do you feel about each of the following items: |
| 4.1 | Fully dressed? | | Your general appearance fully dressed? |
| 4.2 | In a bathing suit? | Have you been dissatisfied with your body? | Your general appearance in a bathing suit? |
| 4.3 | Naked? | Did you find it difficult to look at yourself naked? | Your general appearance naked? |

Table 5.5 *Construction of Post-surgical symptoms and Physical functioning domain of the BCSQOL questionnaire*

| | BCSQOL | EORTC QLQ-BR23 |
|---|---|---|
| 5 | Post-surgical symptoms and Physical functioning | Did you have any pain in your arm or shoulder? Did you have a swollen arm or hand? Was it difficult to raise your arm or to move it sideways? |
| 5.1 | Has your handwriting changed? | |
| 5.2 | Can you button your blouse as easily as before? | |
| 5.3 | Do your fingers feel numb? | |
| 5.4 | Is the skin on your arm itchy or dry? | Have you had skin problems on or in the area of your affected breast (e.g. itchy, dry, flaky)? |
| 5.5 | Is your breast itchy? | |
| 5.6 | Is your skin sensitive, itchy, or dry in the area of surgery? | Was the area of your affected breast oversensitive? |
| 5.7 | Do you have numbness in the chest wall or armpit? | |

Table 5.6 *Construction of the Sexual Functioning domain of the BCSQOL Questionnaire*

| | BCSQOL | EORTC QLQ-BR23 |
|---|---|---|
| 6 | Were you sexually active before your surgery? | To what extent were you sexually active? |
| 6.1 | Do you find that you are not interested in sex lately? | To what extent were you interested in sex? |
| 6.2 | Have you modified your sexual style after surgery? | |
| 6.3 | Do you feel that your sexual desire has decreased? | To what extent was sex enjoyable for you? |
| 6.4 | Does your partner approach you like before? | |

Table 5.7 *Construction of the General Health domain of the BCSQOL Questionnaire*

| | BCSQOL | EORTC QLQ-30 | SF-36 |
|---|---|---|---|
| 7.A | How would you rate your health in general? | How would you rate your overall health? | In general, would you say your health is: Much better? Somewhat better? About the same? Somewhat worse? Much worse? |
| 7.B.1 | Do you use any dietary supplements or vitamins? | Did you feel ill or unwell? | |
| 7.B.2 | Do you use over-the-counter analgesics? | Have you had pain? Did you have headaches? | |
| 7.B.3 | Do you use prescription analgesics? | | |
| 7.B.4 | Do you use drugs to help you sleep or to relieve depression? | Have you had trouble sleeping? Did you feel depressed? | |
| 7.B.5 | Do you have a healthy diet? | Have you lacked appetite? | |
| 7.C | Have you lost weight recently? | | |

Table 5.8a *Construction of the Social Functioning Domain of the BCSQOL Questionnaire*

| | BCSQOL | Spitzer QOL index |
|---|---|---|
| 8.A | How do you rate the support you are getting from: | What support do you receive from others? I have good relationship with others and receive strong support from at least one family member and/or friend. The support I receive from family and friends is limited, occurs infrequently, or only when absolutely necessary. |
| 8.A.1 | Your family? | |
| 8.A.2 | Your Doctor? | |
| 8.A.3 | Your health care team? | |
| 8.A.4 | Your friends? | |
| 8.A.5 | Your spouse/significant other? | |

Table 5.8b *Construction of the Social Functioning domain of the BCSQOL Questionnaire*

| | BCSQOL | EORTC QLQ-30 | SF-36 |
|---|---|---|---|
| 8.B | Relationships with people | Has your physical condition or medical treatment interfered with your family life? | How much of the time have your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.): All of the time? Most of the time? Some of the time? A little of the time? None of the time? |
| 8.B.1 | Do you feel lonely? | Has your physical condition or medical treatment interfered with your social activities? | |
| 8.B.2 | Do you feel like avoiding people? | | |

Table 6 *Scoring BCSQOL*

| | QOL Domains | Number of items | Score per item | | Total score per items | Total score per domain |
|---|---|---|---|---|---|---|
| | | | Worst score | Best score | | |
| 1 | Activity | 8 items | 0 | 2 | 0-16 | 16/16 = 1 |
| 2 | Pain | 7 items | 0 | 3 | 0-21 | 21/21 = 1 |
| 3 | Feelings | 6 items | 0 | 3 | 0-18 | 18/18 = 1 |
| 4 | Body image | 3 items | 0 | 3 | 0-9 | 9/9 = 1 |
| 5 | Physical health | 7 items | 0 | 1 | 0-7 | 7/7 = 1 |
| 6 | Sexual functioning | 4 items | 0 | 1 | 0-4 | 4/4 = 1 |
| 7 | General health | 7 items | 0 | 2 | 0-14 | 14/14 = 1 |
| 8 | Relationship with others | 7 items | 0 | 2 | 0-21 | 21/21 =1 |
| | Overall score | 49 items | - | - | - | 0-8 |

Note: The answers were scored using a positively valued unipolar scale, with the value of 0 assigned to the worst HRQOL status, and 3 to the best on the 4-point scale. On the 3-point scale, the score ranged from 0 for the worst to 2 for the best. On the 2-point scale, the score ranged from 0 for the worst to 1 for the best. More details are shown in the accompanying table.

Table 7 *Description of participants*

| Participant Demographics | Mean | Standard deviation | Median | Mode |
|---|---|---|---|---|
| Age | 61.36 Years | 9.793 Years | 61 Years | 60 Years |
| Elapsed time since operation for breast cancer | 746 Days | 313 Days | 721 Days | 497 Days |

Table 8 *BCSQOL Reliability: Correlation assessment between individual QOL domains and the total correlations of the BCSQOL*

| QOL domain | | BCSQOL | | BCSQOL without sexual functioning domain | |
|---|---|---|---|---|---|
| | | Pearson α | Spearman (ρ) | Pearson α | Spearman (ρ) |
| 1 | Physical Activity | .650** | .661** | .588** | .560** |
| 2 | Pain | .767** | .764** | .758** | .758** |
| 3 | Psychological functioning | .779** | .721** | .806** | .782** |
| 4 | Body image | .504** | .440** | .517** | .457** |
| 5 | Symptoms | .637** | .562** | .659** | .606** |
| 6 | Sexual functioning | .351 | .286 | | |
| 7 | General health | .660** | .545** | .653** | .543** |
| 8 | Social functioning | .370** | .403** | .401** | .452** |

**Correlation is significant at the 0.01 level (2-tailed).

Pearson α: Pearson correlation, Cronbach alpha value

Spearman ρ: Spearman rank correlation

Note: Table 8 shows the correlation coefficient between QOL domains in the BCSQOL and the total BCSQOL High to moderate correlations can be seen for each of the individual QOL domains in the BCSQOL questionnaire. The Pearson correlation Coefficient alpha tell us about the extent of commonality between all the items forming a scale; its calculation uses the average correlation of all the items. The Spearman rank correlation determines the strength of relationship between the BCSQOL and each of the eight QOL domains.

Table 9.1 *BCSQOL Validity: Correlation assessment between the BCSQOL and the SF-36*

| Test | SF-36 QOL | |
|---|---|---|
| | Pearson α | Spearman's ρ |
| BCSQOL | .778** | .785** |
| BCSQOL without sexual functioning | .759** | .757** |

Table 9.2 *Correlation assessment between BCSQOL and SF-36 General Health Domains*

| SF-36 | | General Health (1) | | General Health (2) | | General Health (10) | |
|---|---|---|---|---|---|---|---|
| BCSQOL QOL domain | | Pearson α | Spearman's ρ | Pearson α | Spearman's ρ | Pearson α | Spearman's ρ |
| 1 | Physical Activity | .612** | .610** | .390** | .305** | | |
| 2 | Pain | .490** | .490** | | | | |
| 3 | Psychological functioning | .493** | .508** | | | | |
| 6 | Sexual functioning | | | | | -. 489* | -.433* |
| 7 | General health | .519** | .525** | | | | |

Table 9.3 *Correlation assessment between the BCSQOL domains and the SF-36 Limitations of Activities, Physical Health and Pain domains*

| SF-36 | | Limitations of Activities (3) | | Physical health problems (4) | | Pain (7) | |
|---|---|---|---|---|---|---|---|
| BCSQOL QOL domain | | Pearson α | Spearman's ρ | Pearson α | Spearman's ρ | Pearson α | Spearman's ρ |
| 1 | Physical Activity | .806** | .749** | .551** | .600** | .436** | .426** |
| 2 | Pain | .521** | .597** | .513** | .515** | .577** | .591** |
| 3 | Psychological functioning | .423** | .441** | .498** | .498** | .482** | .476** |
| 6 | Sexual functioning | .555** | .424* | | | | |
| 7 | General health | .508** | .430** | .486** | .438** | .480** | .450** |

Table 9.4 *Correlation assessment between BCSQOL domains and SF-36 Energy and Emotional health domains*

| SF-36 | | Emotional health problems (5) | | Energy and Emotions (8) | |
|---|---|---|---|---|---|
| BCSQOL QOL domain | | Pearson α | Spearman's ρ | Pearson α | Spearman's ρ |
| 1 | Physical Activity | | | .650** | .641** |
| 2 | Pain | .432** | .423** | .644** | .638** |
| 3 | Psychological functioning | .582** | .584** | .512** | .503** |
| 5 | Symptoms | .307** | .303** | . 375** | .348** |
| 7 | General health | .411** | .392** | .568** | .527** |

Table 9.5 *Correlation assessment between BCSQOL domains and SF-36 Social Activities domains*

| SF-36 | | Social activities (6) | | Social activities (9) | |
|---|---|---|---|---|---|
| BCSQOL QOL domain | | Pearson α | Spearman's ρ | Pearson α | Spearman's ρ |
| 1 | Physical activity | .479** | .518** | .312** | .283* |
| 2 | Pain | .566** | .544** | | |
| 3 | Psychological functioning | .528** | .544** | .452** | .455** |
| 4 | Body image | .348** | .327** | | |
| 5 | Symptoms | .400** | .395** | | |
| 7 | General health | .454** | .371** | .295** | .329** |
| 8 | Social functioning | .313** | .315** | | |

(α (76) = 0.348 and ρ = 0.327)

**Correlation is significant at the 0.01 level (2-tailed).

*Correlation is significant at the 0.05 level (2-tailed).

Pearson α: Pearson correlation, Cronbach alpha value

Spearman ρ: Spearman rank correlation

## 20. Figures

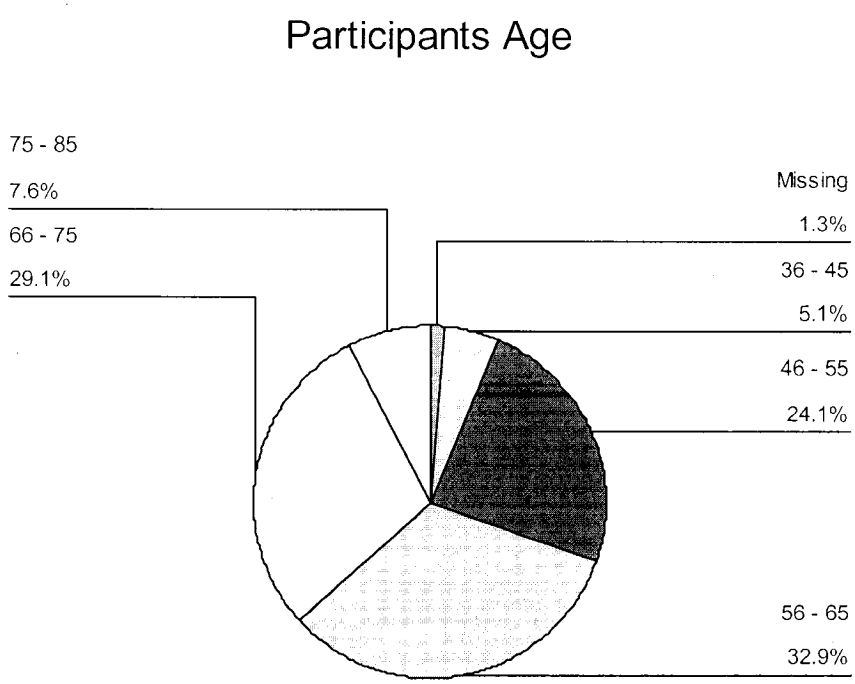


Figure 1 *Distribution of Study Population by Age*

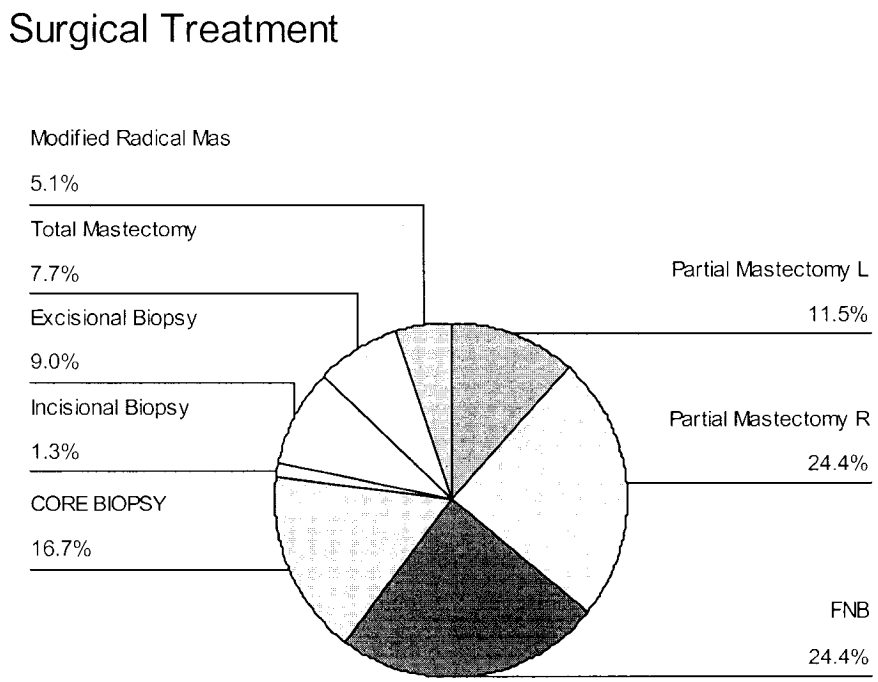


Figure 2 *Distribution of Study Population by Type of Operation*

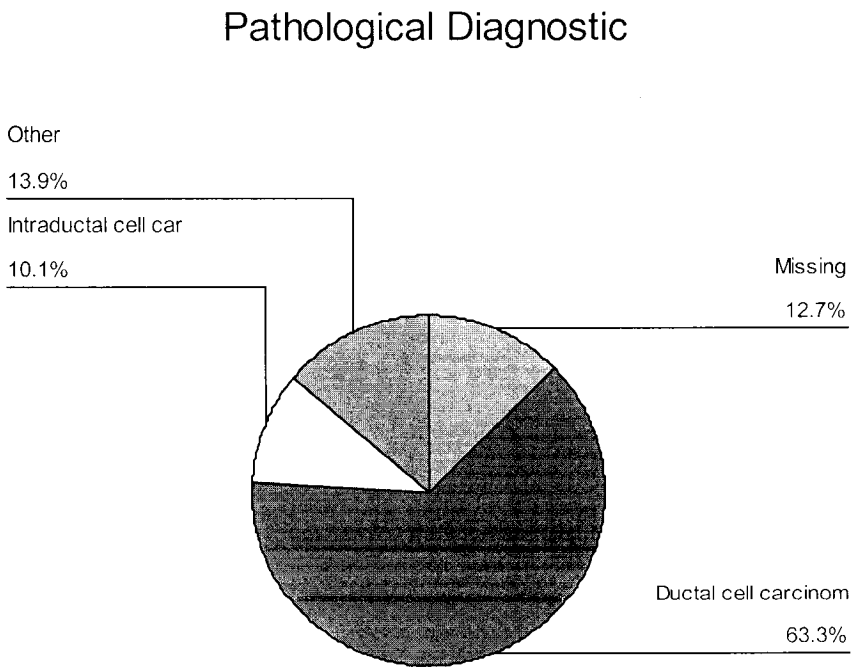


Figure 3 *Distribution of Study Population by Pathological Diagnostic*

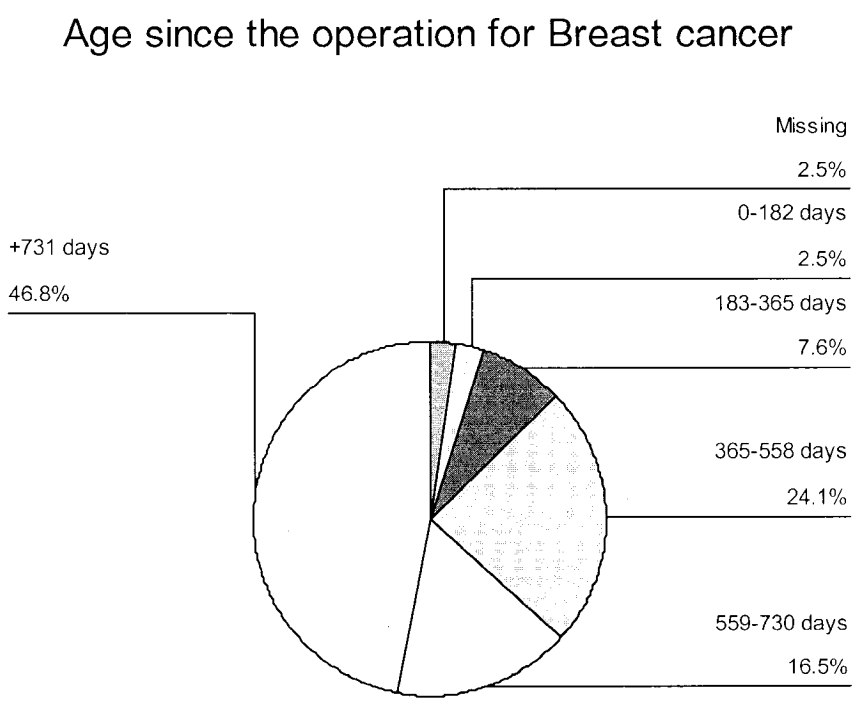


Figure 4 *Distribution of Study Population by Elapsed Time since Breast Cancer Surgery*

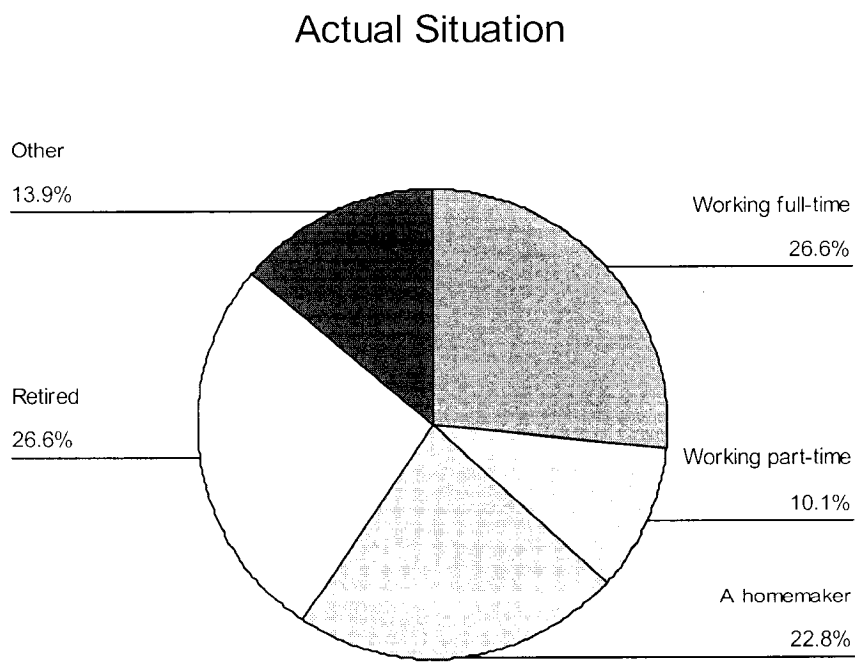


Figure 5 *Distribution of Study Population by Employment Status*

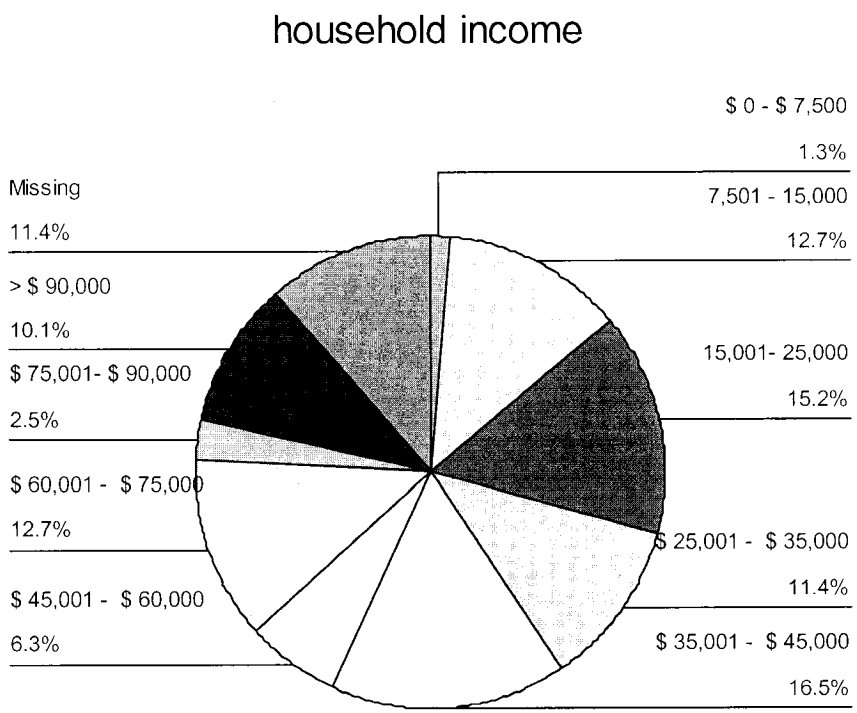


Figure 6 *Distribution of Study Population by Household Income*

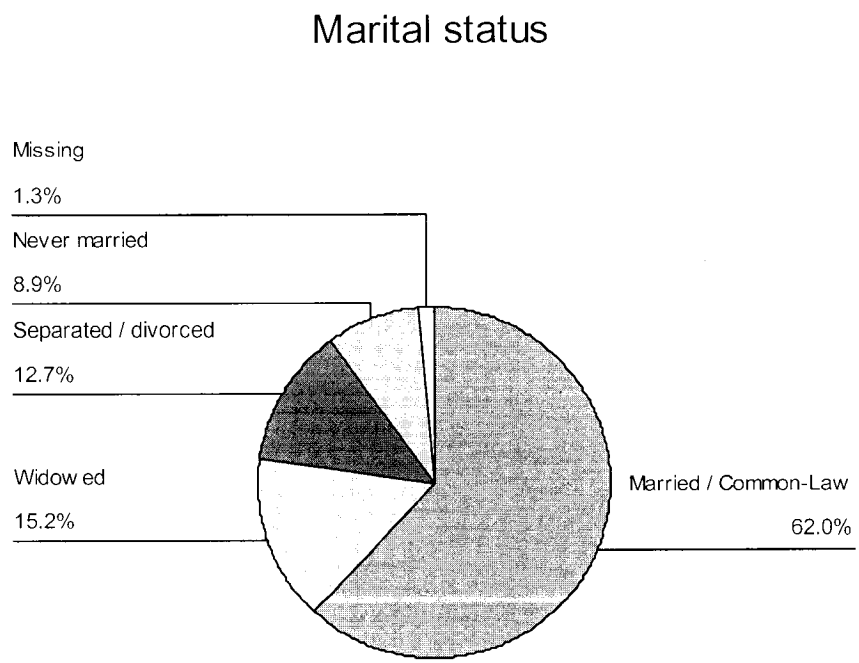


Figure 7 *Distribution of Study Population by Marital Status*

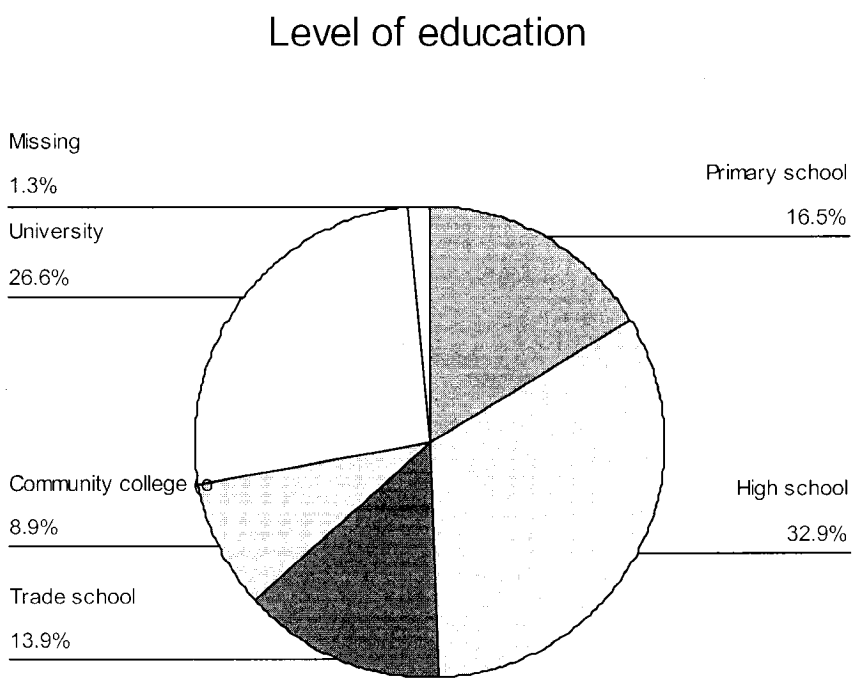


Figure 8 *Distribution of Study Population by Level of Education*

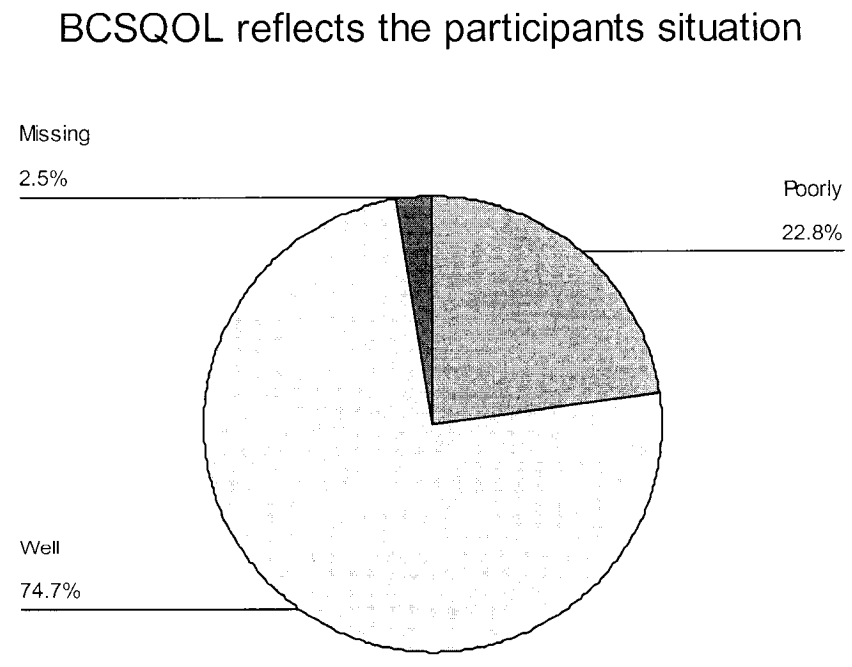


Figure 9 *How well does this questionnaire reflects on how you feel?*

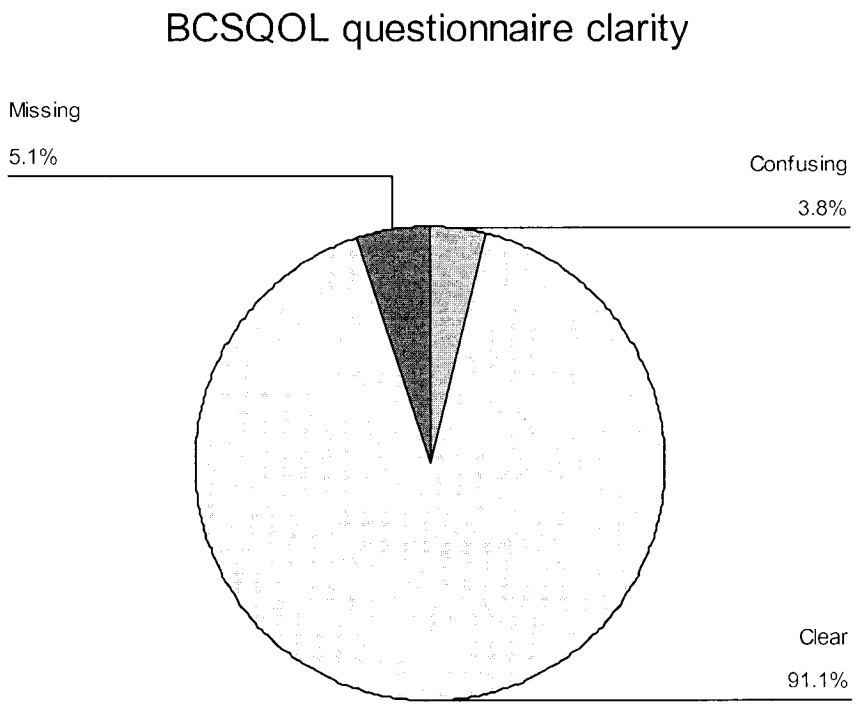


Figure 10 *How did you find the questionnaire items?*

## 21. Appendix

*Breast Cancer Quality of Life Questionnaire*

| 1 | ***Physical Activity*** | No | Yes, sometimes | Yes, as before the treatment |
|---|---|---|---|---|
| 1.1 | Can you dress and bathe your self? | 0 | 1 | 2 |
| 1.2 | Can you comb your hair? | 0 | 1 | 2 |
| 1.3 | Can you drive your car or use public transportation? | 0 | 1 | 2 |
| 1.4 | Can you lift or carry groceries or light objects? | 0 | 1 | 2 |
| 1.5 | Can you practice mild sport activities? | 0 | 1 | 2 |
| 1.6 | Do you socialize as before? | 0 | 1 | 2 |

| 1.7 | Can you work? | Retired | Not at all | Rarely | Part time | Full time |
|---|---|---|---|---|---|---|
| | | | 0 | 1 | 2 | 3 |

| If your working hours are reduced answer the following: | | | |
|---|---|---|---|
| 1.8 | Is pain/physical impairment affecting your work? | *Yes* | *No* |
| | | 0 | 1 |

| 2 | ***Pain*** | Yes, severe | Yes, moderate | Yes, mild | None |
|---|---|---|---|---|---|
| 2.1 | Do you feel pain in your arm or shoulder? | 0 | 1 | 2 | 3 |
| 2.2 | Do you feel pain at the surgical scar? | 0 | 1 | 2 | 3 |
| 2.3 | Do you have frequent headaches? | 0 | 1 | 2 | 3 |
| 2.4 | How would you rank your level of pain when you are: | Severe | Moderate | Mild | None |
| 2.4.1 | Lying in bed? | 0 | 1 | 2 | 3 |

| | | | | | |
|---|---|---|---|---|---|
| 2.4.2 | Sitting? | 0 | 1 | 2 | 3 |
| 2.4.3 | Standing? | 0 | 1 | 2 | 3 |
| 2.4.4 | Walking? | 0 | 1 | 2 | 3 |

| 3 | ***Feelings*** | All of the time | Most of the time | Some of the time | No |
|---|---|---|---|---|---|
| 3.1 | Do you feel tired? | 0 | 1 | 2 | 3 |
| 3.2 | How often do you feel depressed lately? | 0 | 1 | 2 | 3 |
| 3.3 | Do you worry about recurrence? | 0 | 1 | 2 | 3 |
| 3.4 | Would you say you feel angry? | 0 | 1 | 2 | 3 |
| 3.5 | Are you more nervous or stressed than before your treatment? | 0 | 1 | 2 | 3 |
| 3.6 | Do you have difficulty concentrating and/or memorizing lately? | 0 | 1 | 2 | 3 |

| 4 | Since your treatment, have your feelings changed when you are looking at yourself: | No | Somewhat | Yes | A lot |
|---|---|---|---|---|---|
| 4.1 | Fully dressed? | 3 | 2 | 1 | 0 |
| 4.2 | In a bathing suit? | 3 | 2 | 1 | 0 |
| 4.3 | Naked? | 3 | 2 | 1 | 0 |

| 5 | ***Post - Surgical symptoms and Physical functioning*** | Yes | No |
|---|---|---|---|
| 5.1 | Has your handwriting changed? | 0 | 1 |
| 5.2 | Can you button your blouse as easily as before? | 1 | 0 |
| 5.3 | Do your fingers feel numb? | 0 | 1 |
| 5.4 | Is the skin on your arm itchy or dry? | 0 | 1 |
| 5.5 | Is your breast itchy? | 0 | 1 |
| 5.6 | Is your skin sensitive, itchy, or dry in the area of surgery? | 0 | 1 |
| 5.7 | Do you have numbness in the chest wall or armpit? | 0 | 1 |

| 6 | Were you sexually active before your surgery? | Yes | No |
|---|---|---|---|
| | | 1 | 0 |
| 6.1 | Do you find that you are not interested in sex lately? | 0 | 1 |
| 6.2 | Have you modified your sexual style after surgery? | 0 | 1 |
| 6.3 | Do you feel that your sexual desire has decreased? | 0 | 1 |
| 6.4 | Does your partner approach you like before? | 1 | 0 |
| If you do not have a partner please check here | | | |

| 7.A | How would you rate your health in general? | Poor | Fair | Good | Very good |
|---|---|---|---|---|---|
| | | 0 | 1 | 2 | 3 |
| 7.B | ***General health*** | No | Yes, same as before | Yes, more than before | |
| 7.B.1 | Do you use any dietary supplements or vitamins? | 2 | 1 | 0 | |
| 7.B.2 | Do you use over-the-counter analgesics? | 2 | 1 | 0 | |
| 7.B.3 | Do you use prescription analgesics? | 2 | 1 | 0 | |
| 7.B.4 | Do you use drugs to help you sleep or to relieve depression? | 2 | 1 | 0 | |
| 7.B.5 | Do you eat a healthy diet? | 0 | 2 | 1 | |

| 7.C | Have you lost weight recently? | Yes | No |
|---|---|---|---|
| | | 0 | 1 |

| 8.A | How do you rate the support your are getting from: | Not Applicable | Not at all | Limited | Frequent | Very frequent |
|---|---|---|---|---|---|---|
| 8.A.1 | Your family? | N/A | 0 | 1 | 2 | 3 |
| 8.A.2 | Your Doctor? | N/A | 0 | 1 | 2 | 3 |
| 8.A.3 | Your health care team? | N/A | 0 | 1 | 2 | 3 |
| 8.A.4 | Your friends? | N/A | 0 | 1 | 2 | 3 |
| 8.A.5 | Your spouse/ significant other? | N/A | 0 | 1 | 2 | 3 |
| If you do not have a partner, please check here □ | | | | | | |

| 8.B | Relationships with people | All of the time | Most of the time | Some of the time | No |
|---|---|---|---|---|---|
| 8.B.1 | Do you feel lonely? | 0 | 1 | 2 | 3 |
| 8.B.2 | Do you feel like avoiding people? | 0 | 1 | 2 | 3 |

| ***Patient's Opinion*** | | |
|---|---|---|
| How do you think this questionnaire reflects on how you feel? | Poorly | Well |
| | 0 | 1 |
| Did you find the questionnaire items | Confusing | Clear |
| | 0 | 1 |