Residual Breast Tissue After Skin-Sparing Mastectomy: A Retrospective Review

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Acknowledgement Page

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Abstract

Background

Skin-sparing mastectomy (SSM) is an accepted surgical option for patients diagnosed with early stage breast cancer. Advantages of the technique include preservation of the native skin envelope, improved cosmesis, and the ability to avoid radiation therapy. SSM was initially described in 1991, and although there were initial concerns regarding increased rates of recurrence due to residual breast tissue being left behind, large retrospective series have not demonstrated that this is an ongoing concern. There continues to remain, however, a paucity of data regarding the frequency of residual breast tissue left behind following SSM, how to predict which patients are most likely to have residual breast tissue after SSM, and the oncologic implications of residual breast tissue post SSM.

Method

Retrospective review was performed to identify all patients undergoing SSM at a tertiary, comprehensive, academic cancer center. Initially, 288 charts were reviewed. Patients who had undergone SSM with excision of additional skin for immediate reconstruction purposes only, either at the initial oncologic surgery or at subsequent reconstruction revision, were included in the final study group. Careful pathologic analyses by fellowship trained pathologists were performed to evaluate all residual skin removed for assistance with the reconstruction. Data regarding demographics, tumor pathology, and treatment was obtained. Comparison between the groups who had residual breast tissue left behind and those who did not was subsequently performed.
**Results**

When comparing women with residual breast tissue to those with no residual breast tissue after SSM, all measures (age at diagnosis [$p = 0.806$], BMI [$p = 0.531$], tumor size [$p = 0.922$], and estrogen receptor status [$p > 0.999$]) were found to have non-significant differences between the groups.

**Conclusions**

After SSM, 6% of patients had residual breast tissue left behind. This analysis, contrary to some previous reports, did not reveal any patients with residual tumor. Although these specimens were routinely sent for pathologic analysis, the value of this protocol is questionable in light of this series and current limited healthcare resources. Nearly $11,220$ of pathologic reimbursement and approximately $22$ hours of pathologic analysis time could have been saved if routine examination of these specimens was not performed. The study also reveals no evidence of an increased risk of cancer recurrence due to residual breast tissue after SSM to date from $13$ to $48$ months postoperatively.
Residual Breast Tissue After Skin-Sparing Mastectomy: A Retrospective Review

Scope of the Problem

Breast cancer is the second leading cause of death in American women, and the American Cancer Society (ACS) estimates that approximately 192,370 new cases of breast cancer and 40,170 deaths from breast cancer will occur in 2009 (ACS, 2009). Options for the surgical treatment of breast cancer include partial mastectomy followed by radiation therapy or total mastectomy.

Traditionally, a mastectomy includes the removal of a large ellipse of skin that includes the nipple-areolar complex (NAC). In 1991 however, Toth and Lappert first described a mastectomy preserving the skin envelope surrounding the tissue of the breast. This skin-sparing mastectomy (SSM) entails removing the NAC, any tumor or biopsy scar, and all tissue of the breast through a periareolar (i.e., keyhole) incision (Singletary, Robb, & Hortobagyi, 2004). Skin conservation decreases the need for additional procedures to harvest skin for breast reconstruction and improves overall cosmesis (Vaughan et al., 2007; Mustonen et al., 2004).

The goal of the SSM is to completely excise all breast tissue, decreasing the risk of residual disease, and it has become an accepted approach in the treatment of breast cancer (Singletary et al., 2004). The increasing numbers of these procedures being performed drives the need for clinicians to identify the overall rate of residual breast tissue post procedure, describe the factors associated with this remaining tissue, and measure the frequency of breast cancer recurrence in patients with residual breast tissue.
Description of Population

Women with breast cancer who had undergone SSM with immediate reconstruction within the University of Texas Southwestern Medical Center system were the population of focus for this scholarly project.

Setting

A retrospective chart review of patients who had undergone SSM in the University of Texas Southwestern Medical Center system was performed. The institutions that compose this system include Parkland Health and Hospital System, Zale Lipshy Hospital, and St. Paul Hospital, all located in Dallas, Texas.

Expected Outcomes

While there is a scarceness of literature regarding how often residual breast tissue is left behind after SSM and factors associated with it, it is expected that this retrospective analytical evaluation will reveal minimal occurrences of residual breast tissue following SSM. The variables of age at diagnosis, BMI, tumor size, and estrogen receptor status were specifically addressed in relation to the differences in those women with residual breast tissue and those without. It is presumed that there will be no association of these factors with increased rates of residual breast tissue and no differences between these groups. It is not expected that there will be instances of breast cancer recurrence in those patients with residual breast tissue.

A cost-benefit analysis will be performed if the incidence of residual breast tissue is found to be negligible following interrogation of the database and statistical examination. Given limited resources within the healthcare system at present, the importance of identifying appropriate cost cutting opportunities that can be instigated without compromising the focus of
patient care is imperative. This scholarly project presents a prospect for accomplishing this specific objective.

**Definition of Terms**

*Body mass index (BMI).* According to the Center for Disease Control and Prevention ([CDC]), 2009), BMI is an indirect indicator of a person’s body fat measurement. BMI is calculated using a person’s weight and height and can be employed to detect weight problems in adults (CDC).

*Tumor size.* Cancer staging is based on guidelines set forth by the American Joint Committee on Cancer (AJCC) and is referred to as the TNM Staging System (AJCC, 2010). Tumor size (T), extent of spread to lymph nodes (N), and presence of metastasis (M) are the three main factors in which this staging is determined (AJCC). The T category describes the size of the original primary tumor (AJCC). The tumor size can be measured either clinically (i.e., physical examination, mammography, sonography) or pathologically. This study utilized pathological staging.

*Estrogen receptor status.* An estrogen receptor is a protein molecule that is present within a cell, and it contains a specific site that is receptive only to estrogen molecules or those similar to it (National Cancer Institute [NCI], 2006). The tissues that contain these receptors and are the main targets of estrogen are the breast and uterus (NCI). Estrogen influences the tissues of the brain, bone, liver, and heart as well (NCI).

**Purpose**

The purpose of this capstone project was to identify the percentage of patients who have breast tissue remaining following SSM, evaluate factors (i.e., age at diagnosis, BMI, tumor size, and estrogen receptor status) associated with increased rates of residual breast tissue, assess the differences between those women with and without residual breast tissue based on these factors,
and to ultimately determine the incidence of breast cancer recurrence in those women with residual breast tissue after SSM. If the frequency of residual breast tissue is found to be negligible, a cost-benefit analysis will be performed regarding the necessity of sending skin specimens for pathological evaluation following reconstructive surgery.

Research Questions

The following research questions were addressed: 1. In women diagnosed with breast cancer who have undergone treatment with SSM and immediate breast reconstruction, how often is residual breast tissue left behind; 2. In women diagnosed with breast cancer who have undergone treatment with SSM and immediate reconstruction, is there an association between (a) age at diagnosis, (b) BMI, (c) tumor size, and (d) estrogen receptor status and the presence of residual breast tissue; 3. In women diagnosed with breast cancer who have undergone treatment with SSM and immediate reconstruction, is there a difference in women with and without the presence of residual breast tissue in relation to (a) age, (b) BMI, (c) tumor size, and (d) estrogen receptor status; and 4. What is the frequency of breast cancer recurrence among those women with remaining breast tissue following SSM? Analyses of data obtained from these research questions will assist in examination of cost and benefit of the current practice of pathological evaluation of skin specimens following SSM.

Null Hypotheses

The null hypotheses that were addressed are: 1. In women diagnosed with breast cancer who have undergone treatment with SSM and immediate breast reconstruction, there is no association with (a) age, (b) BMI, (c) tumor size, and (d) estrogen receptor status and the presence of residual breast tissue; 2. In women diagnosed with breast cancer who have undergone treatment with SSM and immediate breast reconstruction, there is no difference
between women with and without residual breast tissue in relation to (a) age, (b) BMI, (c) tumor size, and (d) estrogen receptor status; and 3. In women diagnosed with breast cancer who have undergone SSM and immediate breast reconstruction, there will be no breast cancer recurrence in those women with residual breast tissue after SSM. It is expected that there will be few instances of residual breast tissue left behind following SSM.

**Conceptual Framework**

*Halstead Theory of Cancer Metastasis*

The conceptual framework that will be used to guide this project is the Halstead Theory of Cancer Metastasis (Punglia, Morrow, Winer, & Harris, 2007). Dr. William Halstead’s theory prevailed as the explanation for the physiology of cancer spread during the first half of the twentieth century. This theory proposed that breast cancer begins as local disease within the breast and spreads from the primary site to adjacent sites through the lymphatic circulation. Dr. Halstead believed that distant metastases are the result of expansion of local disease affecting the breast, chest wall, axillary lymph nodes, and supraclavicular lymph nodes. Aggressive local therapy for control of breast cancer is based on Dr. Halstead’s propositions about the nature of cancer.

A meta-analysis of local therapy by the Early Breast Cancer Trialists’ Collaborative Group (EBCTCG) provided evidence supporting Dr. Halstead’s propositions (Clarke et al., 2005). This analysis indicated that improved local control of disease substantially reduced the rate of local recurrence, thus decreasing breast cancer mortality and increasing overall survival of women experiencing the malignancy. This capstone project provided further evidence about effects of SSM, a procedure most often performed as a means of local control (Torresan et al, 2005). Because the skin envelope surrounding the breast remains intact with SSM, local control
of an initial breast lesion theoretically could be compromised if residual breast tissue remained following surgery. The frequency of residual breast tissue after SSM was measured. Exploration of possible factors associated with the presence of residual breast tissue in women post SSM were evaluated and compared to those women without residual breast tissue following SSM. Incidence of recurrence of breast cancer in those women with residual tissue was determined. Information gleaned from this research effort will contribute to the existing body of knowledge concerning the spread of cancer as proposed by the Halstead Theory, and to the efficacy of SSM as a treatment for breast cancer.

Cost/Risk Benefit Analyses

Risk-benefit analysis in health care compares the possibility of adverse outcomes or side effects with prospective positive outcomes of a particular treatment (Policy 10: Cost-Benefit Analysis in Health Care, 2004). This capstone project identified the frequency of residual breast tissue in patients who had undergone SSM. Differences in women with and without residual breast tissue following SSM in relation to age, BMI, tumor size, and estrogen receptor status were evaluated. Through this study, factors that could be associated with increased rates of residual breast tissue were assessed. This risk could then be compared to traditional surgical alternatives to determine the best treatment in a specific practice situation. These results can be used to calculate potential risk of SSM in certain populations (i.e., age, BMI, tumor size, and estrogen receptor status). This knowledge will then supply healthcare providers with the ability to better tailor surgical procedures according to the presence/absence of these factors, thus minimizing risk and allowing for the most beneficial immediate and long term results.

The current research identified minimal residual breast tissue; therefore, a cost-benefit analysis was performed. A cost-benefit analysis is an evaluation of resource expenditures comparative to possible medical benefits (Policy 10: Cost-Benefit Analysis in Health Care,
Assessment of the economical advantages or disadvantages of sending skin specimens obtained during reconstruction procedures following SSM for histological evaluation was considered when performing future surgeries. Because the incidence of remaining breast tissue following SSM was negligible, the cost of further pathological analyses of these specimens could be greater than potential benefits for this patient population.

Review of Literature

Databases of scholarly and scientific publications were accessed via Texas Woman’s University and University of Texas Southwestern Medical Center libraries. The databases evaluated included PubMed, Ovid, Scopus, and Academic Search Complete. Specific search terms used were: (a) mastectomy, (b) breast cancer, (c) breast neoplasms/surgery and skin-sparing, (d) residual breast tissue and breast cancer recurrence, and (e) residual tissue and skin-sparing mastectomy. Articles reviewed were limited to publications in English and those pertaining to females. Approximately 160 articles were obtained. Only those concerning SSM, residual breast tissue, factors related with cancer recurrence, oncologic safety, and variables related to residual breast tissue were evaluated. In order to expand the breadth of the reviewed literature, articles dating back to 1991 were included in the examined publications. Studies regarding (a) oncologic safety and factors associated with cancer recurrence following SSM, (b) patient and surgeon attitudes concerning SSM, and (c) frequency of residual breast tissue after SSM were reviewed.

Oncologic Safety of Skin-Sparing Mastectomy and Factors Associated with Recurrence

Although some breast surgeons express apprehension regarding the oncologic safety of the skin-sparing approach for mastectomy, several case series have documented low local recurrence (LR) rates with SSM (0% to 7%). Recurrence is of significant concern for providers treating patients with breast cancer; therefore, determining the oncologic safety of procedures
performed to treat this disease is imperative. One of the principle concerns regarding the skin-sparing approach is the potential for incomplete excision of tumor and/or breast tissue resulting in a possible focus for eventual LR.

Ho et al. (2003) conducted a study in order to evaluate the mode and incidence of skin involvement in women with invasive breast cancer. Only patients who underwent treatment of breast cancer with total mastectomy were included. Those patients who had SSM were excluded because the purpose of this research was to assess the pattern of skin involvement in breast malignancies. Between March 1996 and October 1997, thirty consecutive patients with invasive breast cancer were indentified. The clinical size of the primary tumor ranged from 1 to 7 cm. Upon pathologic analysis of the mastectomy specimens, tumor involvement of the dermis and subcutaneous tissue was documented with special attention to any tumor detected in the subcutaneous fat within 5 mm from the skin surface. This data was crucial because of the potential for residual tumor on the skin flap following SSM. Six of the 30 patients had skin involvement, which was significantly related to the site of the tumor ($p < .02$), clinical tumor staging ($p < .05$), skin tethering ($p < .02$), pathologic tumor size ($p < .02$), and perineural infiltration ($p < .01$). The nipple areola complex (NAC) is routinely removed in SSM, and this study supported this practice. The incidence of NAC tumor involvement was 57% (23% had infiltration of the dermis, 33% had tumor within 5 mm of the skin, and 17% had ductal carcinoma in situ [DCIS] in the lactiferous ducts). Of the above-mentioned six patients with skin involvement, tethering of the overlying skin was noted in three patients and big tumors (T3) were appreciated in the other three patients. The authors deduced that SSM is safe if there is no evidence of skin tethering, and special attention should be given to those patients with large tumors (T3).
Newman and associates (1998) conducted a retrospective review of women who had undergone SSM at the University of Texas M. D. Anderson Cancer Center between 1986 and 1993. Four hundred and thirty-seven SSMs were performed for 372 invasive T1 and T2 breast cancers. A LR rate of 6.2% (23 of 372) was identified with a median time to recurrence of 25 months. The authors deduced that SSM is a satisfactory alternative for the treatment of early stage breast cancer.

Toth, Forley, and Calbria (1999) studied 50 consecutive patients who had SSM and immediate breast reconstruction between 1985 and 1991 in order to assess the oncologic safety of the procedure. The median follow up time was 51.5 months. No LR was discovered; however, active distant disease was present in five patients.

Kroll and associates (1999) reviewed the records of women treated for T1 and T2 invasive breast cancers at the University of Texas M. D. Anderson Cancer Center between March of 1986 and November of 1990. This research evaluation included 174 patients of which 114 underwent SSM and 40 who had nonskin-sparing mastectomies. Only patients with a documented LR or a minimum follow up of 72 months or longer were included. There was a 7% LR rate for the SSM group and a 7.5% LR rate in the nonskin-sparing mastectomy group. SSM was found to be clinically safe as a treatment for early stage breast cancer.

A retrospective review was performed by Carlson et al. (2003) at Emory University Hospital from January 1, 1989 to December 31, 1998. Five hundred thirty-nine patients treated for 565 cases of breast cancer with SSM and immediate reconstruction were evaluated. Chi-square analysis was used to determine factors related with the 36-month recurrence rate. Thirty-one patients developed LR, and tumor grade ($p = .001$) as well as lymphovascular invasion ($p =$
were found to be independent predictors. LR after SSM was also influenced by advanced tumor stage \( (p = .002) \) and estrogen receptor negativity \( (p = .002) \).

Speigel and Butler (2003) studied LR rates in 221 patients who had been treated for DCIS with SSM between 1985 and 1994. One hundred seventy-seven patients had invasive carcinoma and 44 patients had DCIS. A LR rate of 0\% (0 of 44) was detected in patients with DCIS and a LR rate of 5.6\% (10 of 177) was detected in patients with invasive carcinoma. Mean follow up time was 9.8 years. The authors concluded that SSM was an oncologically safe procedure for the treatment of women with DCIS; however, long term follow up is important to assess for the possibility of breast cancer recurrence.

Two groups, Patani and Mokbel (2008) and Cunnick and Mokbel (2006), conducted literature reviews analyzing the oncologic safety of SSM due to the persistent controversies regarding the preservation of the native breast skin and inframammary fold. These thorough evaluations of the literature concluded that SSM is an oncologically appropriate technique when patients are correctly selected for the procedure. Suitable patient characteristics include an invasive tumor size of less than 5 cm, multicentric tumors, DCIS, and prophylactic risk reduction surgery. Patients with skin involvement and/or inflammatory breast cancers exhibited a high risk of LR with the use of SSM.

Vaughan et al. (2007) carried out a retrospective database review in order to identify the patterns of LR and risk factors associated with SSM. Two hundred and six patients who underwent 210 SSMs with immediate breast reconstruction (tissue expanders/implants, latissimus dorsi flaps, and transverse abdominus myocutaneous flaps) for both invasive and non-invasive breast cancer were identified. Only those patients with a primary, ipsilateral recurrence were included. LR was detected in 5.3\% of these patients with a follow up time ranging from
13.1 to 132.5 months. There was no statistically significant difference in subjects who experienced LR and those who did not with respect to type of reconstruction, tumor stage, tumor size, margin status, lymph node metastases, presence of lymphovascular space invasion, hormone receptor status (estrogen, progesterone, Her2/neu), and treatment with radiation therapy ($p > .05$). Tumor grade was the only factor that predicted LR ($p = .0035$). Patients with grade 3 invasive tumors or high-grade DCIS were more likely to experience cancer recurrence than patients with grade 1 or 2 invasive tumors or low or intermediate grade DCIS. Nine of eleven (82%) patients who recurred did so in the same quadrant as their primary tumor locations.

Medina-Franco et al. (2002) analyzed data from 173 patients with invasive breast cancer who underwent SSM, followed by immediate reconstruction, from June 1986 to December 1997. The purpose of this study was to identify incidence of LR and factors associated with it in this particular patient population. This series differed from the others in that only cases of invasive cancer were included. Tumor size was found to be one of the most significant predictors of LR ($p = .0001$) along with tumor stage, poor tumor differentiation, and negative progesterone receptor status. With a median follow up of 73 months, the authors indicated a local recurrence rate of 4.5% in this population, and concluded that LR after SSM is low. This surgical modality, therefore, should be considered oncologically safe in the use of treatment for early breast cancer.

Cao et al. (2008) conducted a study at John Hopkins Hospital in order to assess the frequency and implications of superficial specimen margin in SSM. Surgical pathology files of 168 SSMs with additional superficial margin (ASM) excised directly over the tumor were evaluated by a single surgeon for residual breast tissue. Sixty-four (38%) of these tissue specimens had a positive superficial margin, and 89 (53%) contained benign breast tissue. Multivariate analysis demonstrated that a positive deep margin ($p = 0.01$) was the only
prognostic marker for a positive superficial specimen margin excluding other variables such as hormone receptor status (i.e., estrogen, progesterone, Her2/neu). Thicker ASM was of borderline significance \((p = 0.05)\) in predicting positive superficial specimen margins. Residual carcinoma was found in 14 of the 168 (8.3%) ASMs. DCIS was present in all specimens that had positive superficial specimen margins and residual carcinoma in ASMs.

*Patient and Surgeon Attitudes Concerning Skin-Sparing Mastectomy*

Improved aesthetic results have been reported with SSM. Omranipour, Bobin, and Esouyeh (2008) conducted a retrospective chart review of 95 patients with stage 0, 1, and 2 breast cancers who received SSM from April 1995 to April 2003. One surgeon who followed the patients 6 months postoperatively classified final aesthetic results into 1 of 3 categories according to the Lowery Scaling System. The surgeon described 35.8% as excellent cosmesis, 56.8% as good cosmesis, and 7.3% as fair cosmesis.

Patani and Mokbel (2008) reported that patients indicated positive aesthetic and economic considerations related to the use of the SSM approach. With this procedure, a smaller incision is made, and the skin envelope of the breast is retained. Therefore, there is less chest deformity than conventional total mastectomy procedures. Because multiple staged procedures are not indicated with SSMs, this approach to cancer treatment is more economical than conventional surgeries. Patani and Mokbel proposed that patient satisfaction is increased because of both benefits.

An investigational effort by Shen, Ellenhorn, Quian, Kulber, and Aronowitz (2008) utilized postal questionnaires in order to establish general surgeons’ attitudes toward SSM. Twenty-seven hundred surgeons were mailed a questionnaire targeting their practice patterns and opinions concerning the feasibility, safety, and cosmetic outcomes of SSM. Four hundred and fourteen questionnaires were returned with 370 of these surgeons stating they performed breast
cancer surgery. Three hundred and thirty-one of these surgeons performed mastectomy with immediate reconstruction, and 256 of these 370 respondents used the skin-sparing approach. Seventy-one percent felt that SSM is an oncologically sound procedure; however, 25% expressed apprehension over a potential elevated risk of skin flap necrosis. Ninety percent of general surgeons agreed that the risk of LR did not increase with SSM, and overall it is an oncologically safe procedure. Fisher’s exact test was used to assess comparisons between groups (surgeons in the settings of private practice [70%], academics [8%], mixed private practice/academics [7%], and health maintenance organizations [15%]) based on the above-mentioned factors. Statistically significant differences were found between those general surgeons who worked in private practice settings compared to other settings. Surgeons in private practice performed the SSM much less often than surgeons in academia, mixed settings, or health maintenance organizations (61% versus 83%, $p = 0.02$; 88%, $p \leq 0.01$; and 93%, $p \leq 0.01$ respectively). Fewer private practice surgeons believed that the SSM is an oncologically safe procedure when compared with those surgeons in the academic (67% versus 80%, $p =$ non-significant) and health maintenance organization settings (67% versus 89%, $p \leq 0.01$). Surgeons encompassing all practice settings agreed that LR is not increased with the use of SSM. Overall, while surgeons believed that SSM is cosmetically superior and oncologically dependable, only 61% are performing SSM when immediate breast reconstruction is planned. These authors concluded that surgeons need to be educated regarding the safety of this procedure in order for SSM to be deemed the standard of care in patients undergoing immediate reconstruction.

Shen et al. (2008) obtained results consistent with the conclusions of Bleicher, Hansen, and Giuliano in an earlier, yet larger, study performed in 2003. The goal of this study was to determine SSM attitudes and biases among disciplines worldwide. These authors polled 11,485
individuals within the disciplines of surgical, medical, and radiation oncology via email. One thousand twenty-seven individuals responded, but only 1008 felt they had an appropriate knowledge base to complete the survey. Fifty-two countries were represented by physicians who returned the questionnaire, and the specialties which comprised this group included: 43.3% surgeons, 37.3% medical oncologists, 14.5% radiation oncologists, and 5% from other fields. Sixty-two percent of these physicians stated SSM was performed at their institution, but 19.1% did not exhibit understanding of the procedure (i.e., they believed that the nipple-areola complex was left intact). This opinion was increased outside of the United States \( (p < 0.0001) \). While 77.8% agreed that SSM does not have an increased LR rate, 25% of the respondents did not believe the literature was a true representation of the clinical findings. These authors concluded that despite a developing body of literature regarding the SSM, there is lack of knowledge about the procedure itself and unfamiliarity with available literature. Bleicher et al. (2003) encouraged education about SSM across these disciplines.

**Frequency of Residual Breast Tissue After Mastectomy**

There is a paucity of literature regarding percentages of residual breast tissue. Only four studies reported rates of residual breast tissue after mastectomy, and only a single study specifically discussed residual breast tissue in SSM (Torresan, Cabello dos Santos, Okamura, & Alvarenga, 2005; Tewari, Kumar, Kumar, & Shukla, 2004; Carlson, Grossl, Lewis, Temple, & Styblo, 1995; Barton, English, Kingsley, & Fietz, 1991).

Barton et al. (1991) conducted a study comparing residual breast tissue after total glandular mastectomy (TGM) and modified radical mastectomy (MRM). Twenty-seven breasts were evaluated in the TGM group and 28 in the MRM group. Patients in each group were matched for age and breast volume. Six open biopsies were obtained and sent for histological
Residual breast tissue was discovered in 8 of 161 (4.97%) specimens from the TGM group and 8 of 159 (5.03%) specimens from the MRM group. All biopsy sites portrayed residual breast tissue at least once, except for the infracavicular chest wall biopsy site. Six of 16 specimens that revealed residual breast tissue came from the skin flap. Generally, residual breast tissue was detected in 25% of patients after TGM and 21% of patients after MRM. The authors concluded that TGM can be as successful as MRM in removing breast tissue, but the significance of residual breast tissue concerning either procedure remains unknown.

Carlson et al. (1995) evaluated the inframammary fold (IMF) at the time of traditional mastectomy. Preservation of the IMF facilitates breast reconstruction. Twenty-four specimens acquired from 22 female patients, ages 44 to 88, from March 1993 to August 1994 at Emory University Hospital were the focus of study. The IMF specimens were removed separately following the mastectomy, which preserved the fold. In 12 of the cases only a representative sample was sent for histological evaluation while in the other 12 cases the entire sample was submitted for pathological analysis. Breast tissue was identified in 13 of the 24 specimens. Where breast parenchyma was discovered, the exact area was measured by computer image analysis in order to obtain a percentage of the total area inspected. While over 50% of the specimens indicated evidence of the presence of breast tissue, computer image analysis established the amount to be less than 0.02% of the total tissue area. There were no malignancies appreciated in any of these samples, and the authors concluded that mastectomy with preservation of the IMF is safe.
Tewari et al. (2004) evaluated the presence of residual breast tissue following the Patey mastectomy (modified radical mastectomy). This study was conducted in Varanasi, India from January 1998 to March 2002. Thirty-seven consecutively selected women with breast cancer treated by the Patey mastectomy performed by one surgeon (excluding those who had received any type of neo-adjuvant treatment) were included in the study. Following the mastectomy, a 1 cm by 1 cm section of subcutaneous tissue from beneath the skin flap was excised for evaluation by the pathologist. Residual breast tissue was found in 8 (21.6%) of these cases. In three (37.5%) of these patients, malignant cells were also detected.

Torresan et al. (2005) evaluated 42 women with stage 0, I, II, and III breast cancer without clinical skin involvement who underwent SSM from June 2003 to January 2004 in Campinas, Brazil. All of these surgeries were performed by the same two surgeons. The patients were marked prior to surgery with a continuous line representing SSM and a dotted line representing a traditional mastectomy. The skin flap that would remain after SSM was removed and histologically evaluated. The presence and number of terminal duct lobular units (TDLUs) were evaluated by pathology. Relationship between the existence of TDLUs, residual disease, skin flap thickness, age, BMI, menopausal status, clinical and pathologic staging, breast volume, mammographic density, neoadjuvant chemotherapy, type of surgery, and the presence of a widespread in situ component was calculated using Fisher’s exact test. The prevalence of residual breast tissue in these samples was 59.5%, and the presence of TDLUs was only significantly associated with skin flaps thicker than 5 mm ($p = .05$). As skin flaps became thinner, the quantity of TDLUs decreased. Residual disease was found in 9.5% of women and was also associated with skin flaps greater than 5 mm thick. The authors deduced that surgical
technique, not just biological tumor factors (i.e., tumor size, estrogen receptor status, histologic grade, lymphovascular invasion), related to skin flap thickness should be a focus of attention.

Many retrospective studies have been performed regarding SSM. Most of these investigative efforts have been focused on the oncologic safety of this particular technique as well as the superior cosmetic results it provides. While SSM has been established as an oncologically appropriate procedure for early stage breast cancer, gaps in the literature still exist on the subject of SSM and residual breast tissue left behind following the procedure. This scholarly research project focused on the identification of residual breast tissue in patients who have undergone SSM with immediate reconstruction for the treatment of breast cancer.

Project Implementation and Results

Project Objectives and Evaluation

At the University of Texas Southwestern Medical Center, patients who undergo SSM with expander-based reconstruction usually experience a second procedure for the placement of permanent implants. Typically redundant skin is excised and sent for histological analysis following one or both of these procedures. Due to the paucity of literature available regarding residual breast tissue following SSM, this capstone project focused on the following objectives: (a) to detect the frequency of patients who have breast tissue left behind following SSM as evaluated through the calculation of simple frequencies demonstrated through the histological assessment of skin specimens removed at the time of reconstructive surgery; (b) to assess the differences that exist between those women with and without residual breast tissue, as related to the chosen variables age, BMI, tumor size, and estrogen receptor status, as evaluated by Mann-Whitney U for continuous variables and Fisher’s exact test for the dichotomous variable if incidence of women with residual breast tissue is sufficient to allow the performance of
statistical tests; (c) to identify factors (age, BMI, tumor size, and estrogen receptor status) related to increased rates of residual breast tissue through the performance of retrospective chart reviews as evaluated by point biserial correlation coefficient for continuous variables and chi-square for the dichotomous variable if incidence of women with residual breast tissue is sufficient to allow the performance of statistical tests; (d) to determine the frequency of breast cancer recurrence in women with residual breast tissue as evaluated through the calculation of simple frequencies obtained through retrospective chart review; and (e) to analyze the cost and benefit of pathological assessment of skin specimens following SSM as evaluated through the appraisal of healthcare dollars spent for pathologic assessment as well as expert time spent studying breast tissue specimens.

Project Timeline and Methodology

The project timeline includes implementation processes described in Appendix A. Prior to initiating the research process, the National Institutes of Health Office of Extramural Research training course, Protecting Human Research Participants, was completed (see Appendix B). An application for Institutional Review Board (IRB) approval was submitted to the University of Texas Southwestern Medical system (see Appendixes C and D). Upon approval of this application, the author submitted an application to the Texas Woman’s University IRB (see Appendixes E, F, and G). Once both approvals were obtained, the Plastics and Reconstructive Department’s Reconstruction and Implant Registry, which consists of patients within the University of Texas Southwestern system (Parkland Health and Hospital System, Zale Lipshy Hospital, St. Paul Hospital, and the affiliated outpatient centers) were queried by the author in order to detect patients who have undergone breast reconstruction between August 2005 and May 2009.
A retrospective review of these identified patient charts was conducted through Parkland’s Epic® and Clinical Data Repository (CDR) systems over a 3-month period in order to ascertain those who underwent SSM for which a skin specimen was sent by the plastic surgeon at the time of reconstruction, as well as to assess the variables contained in the data collection tool (see Appendix H). The information collected from this sample population included patient demographics, pathological evaluation, and treatment course. The data was entered into a de-identified Excel® database spreadsheet. The skin specimens of these patients submitted to the laboratory following SSM were reviewed by a fellowship-trained pathologist for detection of any remaining breast tissue. Ultimately, statistical analyses were performed, with the assistance of a doctoral prepared bio-statistician, in order to assess the frequency of residual breast tissue and to evaluate for relationships with patient and tumor factors. Differences between the group with and without residual breast tissue were also examined. The incidence of breast cancer recurrence in women with residual breast tissue following SSM was assessed as well. After this data exploration, cost benefits were analyzed.

A retrospective review of data from 288 patients was completed. No exclusions were made based on age, ethnic background, life expectancy, nutritional status, or performance status. Only females were included in this project. Ninety-two of the 288 patients were found to have had SSM, and 66 of these patients had SSM with skin sent to pathology for analysis at the time of breast reconstruction. A cost-benefit analysis was ultimately conducted in order to evaluate the expense of pathological assessment of the skin sent for examination following breast reconstruction surgery as well as the necessary time spent by the pathologist to evaluate these specimens.
The methodology employed to complete this research project has been presented in sufficient detail to enable replication of this study. The data and results obtained during retrospective review of patient records that underwent SSM with reconstruction will provide value to advanced practice nursing, the institutions performing this procedure, as well as policy makers, surgeons, and organizations supporting the advancement of breast health such as the ACS and the Susan G. Komen Foundation.

Site Support, Necessary Resources, and Project Requirements

Overall support was needed from the institutions that constitute the University of Texas Southwestern Medical Center in order for this project to be complete and comprehensive. Admission to the Plastics and Reconstructive Department’s Reconstruction and Implant Registry was necessary in order to identify appropriate patients for subsequent retrospective chart review. In house as well as remote access to the Epic® and CDR computer systems was obtained through the assistance of Parkland Health and Hospital System’s Information Technology Department. The access allowed for chart review to be completed outside of the work place and thus enabled the author an expedited method of study. All information pertaining to this study was kept in a locked office cabinet within the division of Surgical Oncology at the University of Texas Southwestern Medical Center. Contribution and cooperation from the Department of Pathology was also necessary for histological review of the tissue specimens as well as in obtaining information regarding time spent analyzing tissue specimens. Assistance from the coding and billing departments was elicited for Current Procedural Terminology (CPT) codes and financial data pertaining to specimen examination.
Evaluation of Objectives

Initial review of the Epic® and CDR systems was time consuming because of the amount of data present and the complex graphic-user interface of the systems. The researcher gradually developed a method (looking first at the surgical procedure note for type of surgery performed then at the pathology reports for types of specimens sent for evaluation) allowing for more efficient identification of those patients who had SSM performed and thus the frequency of patients who had breast tissue left behind following SSM.

In order to identify factors related with increased rates of residual breast tissue, several screens needed to be accessed in order to obtain age, BMI, tumor size, and estrogen receptor status. Age at diagnosis and BMI were ascertained from breast surgeon and/or medical oncology progress notes. Tumor size and estrogen receptor status were obtained from the pathology and tumor profile reports of the specimens sent for evaluation following SSM.

The obtained data were entered into an Excel® spreadsheet then exported into SPSS to facilitate the evaluation of differences that exist between those women with and without residual breast tissue. This method was chosen because of professional practice mentor preference and familiarity with Excel®. In addition, Excel® is available on the computer system at Parkland Health and Hospital System and allows the author increased opportunity and ease of data entry. In order to examine the incidence of breast cancer recurrence in women with residual breast tissue following SSM, data from the Excel® spreadsheet were evaluated. Once the particular patients with residual breast tissue were determined, surgical pathology reports as well as progress notes for each individual patient were reviewed in order to establish the presence/absence of recurrent breast cancer.
Statistical analyses were performed on the data obtained from the retrospective chart review. The Fisher’s exact test was utilized in order to evaluate the differences between the dichotomous variables of presence/absence of residual breast tissue and the factor of estrogen receptor status. Differences among women with and without residual breast tissue with regards to the interval level data of age, BMI, and tumor size were evaluated using the Mann-Whitney U test.

The number of women with residual breast tissue following SSM was found to be negligible. This extremely small number precluded statistical evaluation for relationships between the chosen variables and women in this group. The frequency of breast cancer recurrence was evaluated among these women from data obtained through medical records.

A cost benefit analysis pertaining to the pathological assessment of skin specimens following SSM was conducted. Discussions with personnel in the billing and coding departments regarding the method these specimens are coded and subsequently charged took place in order to estimate cost for skin specimen evaluation. Conversation with an Associate Professor of Pathology at the University of Texas Southwestern Medical Center assisted in approximating time necessary to expertly analyze these specimens.

**Expected Results/End Products**

The University of Texas Southwestern Medical Center encompasses Parkland Health and Hospital System, Zale Lipshy Hospital, and St. Paul Hospital. The mission statement of this institution as a whole is to improve healthcare from a local to an international level through affording innovative education in patient care, biomedical science, and disease prevention, performing research acknowledged world-wide and providing care to patients that exhibits scientific developments focusing on quality, safety, and service (University of Texas
Southwestern Medical Center, 2010). Approximately 450 individuals are treated for breast cancer within this healthcare system annually (Parkland Health and Hospital System, 2009; K. Pratt, personal communication, February 23, 2010).

This research effort provided important data that will be considered when planning future surgical interventions in the treatment of patients with breast cancer. In this institution breast cancer patients will be receiving guidance and treatment from Doctor of Nursing Practice (DNP) prepared advanced practice nurses who will use these results as part of advanced practice in a specialty area and patient education. Improved understanding of SSM will be gleaned from this research endeavor and will positively impact the institutions involved through the care they render, benefiting those individuals diagnosed with breast cancer. This investigation will also lead to prospective breast cancer trials and interventions pertaining to SSM.

Initial expectations were that following this treatment modality, low rates of residual breast tissue would be found. It was also expected that there would be no difference among women with and without residual breast tissue following SSM in relation to age, BMI, tumor size, and estrogen receptor status. Appraisal of economic advantages through cost-benefit analysis was a product of this study because insignificant occurrences of residual breast tissue were found. Cost benefit analysis will allow for effective and efficient use of laboratory resources for the benefit of the greatest number of patients. Study findings were consistent with expected outcomes.

Once data entry was completed, statistical evaluation was performed and a report of findings compiled to assess the stated purposes of the study. A report will be presented to the participating institutions as well as Texas Woman’s University. This data will also be submitted for publication in a professional journal and clinical findings implemented in the treatment of the
patients cared for by the facilities that compose the University of Texas Southwestern Medical Center System, thus providing for enhancement in healthcare delivery to women diagnosed with breast cancer.

Project Evaluation and Recommendations

Plan/Rationale for Evaluating Collected Data

The objectives were evaluated with appropriate statistical analyses to produce evidence-based measures. These measures will subsequently be used as a basis for future practice and research in caring for patients with breast cancer. The evaluation plan included statistical consultation for analysis and interpretation as presented.

Detect the frequency of patients who have breast tissue left behind following SSM. In order to assess the rates of breast tissue left behind after SSM, simple frequencies and percentages were calculated. This data was obtained from the patient information gleaned during retrospective chart review.

Assess the differences that exist between those women with and without residual breast tissue, as related to the chosen variables age, BMI, tumor size, and estrogen receptor status. Because both the presence/absence of residual breast tissue and the factor of estrogen receptor status are dichotomous, assessment of the differences within this objective in women with and without residual breast tissue was performed using the Fisher’s exact test. Age, BMI, and tumor size are interval level data; therefore, the differences among women with and without residual breast tissue with respect to these variables were evaluated using the Mann-Whitney U test.

Identify factors (age, BMI, tumor size, estrogen receptor status) related to increased rates of residual breast tissue. If insufficient cases of women with residual breast tissue did not preclude statistical evaluation of the relationship between the presence of residual breast tissue
and the factors age, BMI, tumor size, and estrogen receptor status, point biserial correlation coefficient would have been used to evaluate the relationship between interval level data and residual breast tissue and chi-square used to assess the relationship between nominal level data and residual breast tissue.

Determine the incidence of breast cancer recurrence in women with residual breast tissue following SSM. Very few patients were found to have residual breast tissue left behind following SSM; therefore, simple frequencies were appropriate measures for analyses. This data was easily accessed and evaluated through review of each woman’s specific chart.

Analyze the cost and benefit of pathological assessment of skin specimens following SSM. A cost-benefit analysis was performed in order to estimate if an economic advantage exists within the current healthcare environment in sending skin specimens removed during reconstruction for histologic evaluation. Discussions with individuals in the University of Texas Southwestern Medical Center’s billing department as well as with one of the associate professors of pathology within this system assisted the researcher in estimating both the cost of histological analyses as well as pathologist time spent examining tissue specimens.

Statistical Analyses and Final Results

Group comparisons for continuous measures (age at diagnosis, BMI, tumor size) were conducted using independent samples t-tests or Mann-Whitney U tests, as appropriate. When parametric analyses were used, mean and standard deviations for the data were provided; otherwise medians and range (low – high) for each measure were presented (see Appendix I1). For the dichotomous measure (estrogen receptor status: positive/negative), chi-square or Fisher’s exact test, as appropriate, was used for group comparison. Assumptions of all statistical tests were checked for violations (normality, variances, and percentage of cells with expected counts
There were a total of 66 patients evaluated in this study; four patients (6%) had residual breast tissue (RBT) and 62 (93.9%) did not have residual breast tissue (NRBT) detected by pathologic analysis in the skin specimen sent following SSM. Forty-four (66.6%) patients were Caucasian (3 [75%] in the RBT group and 41 [66%] in NRBT group), 8 (12%) were African American (1 [25%] in RBT group and 7 [11%] in NRBT group), and 7 (11%), 2 (3%), and 5 (8%) patients in the NRBT group were Hispanic, Asian, and other respectively. With the small number of women with RBT, further statistical evaluations regarding this group were not possible.

The assumptions for the continuous measures were reviewed. The tests for normality were found to be violated for BMI (Kolmogorov Smirnov \( p = 0.001 \)) and tumor size (Kolmogorov Smirnov \( p = 0.001 \)). While the test for variance for age at diagnosis was not significant \( (p = 0.129 \) ), the variances for the 2 groups were considered different (26.25 for RBT versus 133.143 for NRBT), and the small sample size for the RBT group results in a lack of power to detect the difference between the variances. Mann-Whitney U tests were conducted for all continuous measures. The assumptions of the chi-square test were also reviewed. Fifty percent of the cells for estrogen receptor status had expected frequencies less than 5; therefore, a Fisher’s exact test was conducted.

The median patients age in years (median, range) at diagnosis for patients in the RBT group (53.0, 47 – 58) were slightly older than in the NRBT group (50.5, 25 – 76), but not significantly (Mann-Whitney U test \( p = 0.806 \)). The median BMI was larger in the RBT group than in the NRBT group (29.7, 20.9 – 34.0; 24.9, 19.8 – 38.3, respectively), but not significantly
(Mann-Whitney U test $p = 0.531$). The median tumor size in cm was smaller in the RBT group (0.8, 0.7 – 6.0) than in the NRBT group (1.5, 0.2 – 9.0), but not significantly (Mann-Whitney U test $p = 0.922$). For the dichotomous measure, estrogen receptor status, 3/3 (100%) of the patients in the RBT group had positive test results and 36/48 (75%) patients in the NRBT group had positive test results. The Fisher’s exact test resulted in non-significant results ($p > 0.999$).

With the exception of age, not all variables were available for chart review in every patient. Only 3 of 4 patients in the RBT group and 48 of 62 patients and 46 of 62 patients in the NRBT group were evaluated with regards to estrogen receptor status and tumor size respectively. One patient in the RBT group and twelve patients in the NRBT group had a prophylactic SSM along with SSM performed for treatment for breast cancer on the contralateral side. Also, in the NRBT group one patient had SSM for a recurrent seroma, and one patient had SSM for lobular carcinoma in situ; therefore, no test for estrogen receptor status was carried out and no tumor diameter assessed on these benign tissue specimens. Additionally, in two patients in the NRBT group, pathologic tumor size was not located in the medical record. BMI was not available for 7 of 62 patients in the NRBT group.

**Discussion of Results**

The great disparity in the quantity of women in each group (4 women in the RBT group and 62 women in the NRBT group) was a major factor affecting statistical analyses of the data obtained for this study. While the number of individuals in the RBT group was drastically less than the number of individuals in the NRBT group, no statistically significant differences were detected between the two groups based on age, BMI, tumor size, and estrogen receptor status. However, BMI was noted to be substantially greater in the RBT group and consideration as a focus in future studies is suggested. In addition, because the RBT group was small, the ability to effectively evaluate relationships of the four variables on women with residual breast tissue left
behind was unfeasible. Of the four patients in the RBT group, none have experienced breast cancer recurrence to date which is a range of 13 to 48 months post SSM. One of these patients was diagnosed in 2006, two were diagnosed in 2007, and one was diagnosed in 2009. All null hypotheses were ultimately supported. Acceptance of these null hypotheses contributes to the body of clinical knowledge and affects practice in the surgical oncology setting.

The present investigation studied a greater number of subjects (66 versus 42) yet found a decreased frequency of residual breast tissue following SSM (6% versus 59.5%) than did the only other study investigating frequency of residual breast tissue after SSM by Torresan et al. (2005). The current study additionally revealed no patients with residual tumor compared to 9.5% of patients with residual tumor in the Torresan et al. study.

Factors associated with residual breast tissue following SSM should be further evaluated with a larger sample size. Several studies have evaluated variables that are associated with breast cancer recurrence. Carlson et al. (2003) looked at nodal status, histologic grade, lymphovascular invasion, tumor stage, and estrogen receptor status in relation to LR. Vaughan et al. (2007) evaluated relationships of LR with type of reconstruction, tumor stage, tumor size, margin status, lymph node metastases, presence of lymphovascular space invasion, hormone receptor status (estrogen, progesterone, Her2/neu), and treatment with radiation. Medina-Franco et al. (2002) found tumor stage, poor tumor differentiation, and negative progesterone receptor status to be significant predictors of LR. Torresan et al. (2005) incorporated menopausal status, breast volume, mammographic density, neoadjuvant chemotherapy, and skin flap thickness in the evaluation of the association with residual disease following SSM. These factors included in past studies should be incorporated into future, prospective, research investigations of larger populations regarding residual breast tissue following SSM.
Given that the prediction of negligible residual breast tissue following SSM was substantiated through this research effort, a cost-benefit estimate related to pathological analysis of the skin specimens was subsequently performed in order to detect if cost of pathological analyses outweighs potential benefits related to risk assessment. This financial analysis was implemented with the assistance from Parkland Health and Hospital System, as well as the University of Texas Southwestern Medical Center’s billing and coding departments. The financial appraisal conducted was based on the CPT code 88302 (T. Vuong, personal communication, February 23, 2010). This code pertains to the reconstructive portion of the procedure where skin is excised and sent for pathologic examination following the SSM. For each piece of skin removed, the code is applied and subsequent charges incurred. These charges can vary from $85 per specimen if the procedure is performed in the main operating room and/or the patient is classified as an inpatient versus $190 per specimen for those procedures performed in the ambulatory surgery setting and/or the patient is classified as an outpatient (S. Minter, personal communication, February 23, 2010). In the current study, between 1 and 4 skin specimens per patient were sent following reconstruction with 2 skin specimens per patient being the usual number submitted. The majority of patients undergoing SSM are operated on in the inpatient setting. The compilation of these figures resulted in the approximate value of $11,220 spent for histologic analyses of the skin specimens.

Support from the pathologists who examine these skin specimens was also critical in calculating time spent studying the specimen following excision. Discussion with an Associate Professor of Pathology at the University of Texas Southwestern Medical Center confirmed the time necessary for complete evaluation of each skin specimen is roughly 10 minutes (V. Sarode,
personal communication, February 23, 2010). Therefore, on average approximately 22 hours of pathological expertise was necessary for skin specimen evaluation in this study.

While these skin specimens are routinely sent for pathologic analysis, the value of this protocol is questionable in light of the present study findings and current limited healthcare resources. For this study, in 66 patients diagnosed with breast cancer who underwent SSM with reconstruction, approximately $11,220 was spent on pathological analyses that were not related to risk assessment of breast cancer recurrence 13 to 48 months post SSM.

Project Limitations

The current study is limited by several factors including those inherent within a retrospective chart review method. A few charts were missing key pieces of information being studied in this research effort. Potential for author error in data collection and data entry is present in this retrospective assessment as well. No formal system to ensure accuracy was employed during this review; however, future studies will utilize an official method to minimize errors throughout the study process.

Interrogation of the database and subsequent patient chart evaluation produced results that were expected (i.e., few patients with residual breast tissue left behind following SSM). Due to this finding, however, the number of patients in each group is greatly different (i.e., 62 women in the NRBT group and 4 women in the RBT group following SSM), which limited inferential statistical conclusions. Because of this considerable diversity between the groups and the overall lack of power in the RBT group, assumptions for the utilization of parametric tests were violated. Therefore, nonparametric statistics were employed to evaluate differences between the two groups based on the continuous variables age, BMI, and tumor size, as well as the dichotomous variable estrogen receptor status.
The objectives of the study focused on the ability to assess the factors associated with residual breast tissue, as well as to evaluate the incidence of breast cancer recurrence in women with residual breast tissue. Examination of these objectives was limited owing to the number of patients in the RBT group. Nevertheless, this is believed to be the largest study of this patient population to date.

The literature review completed revealed LR rates following SSM ranged from 0% to 7% with follow up ranging from 26 to 132 months after diagnosis (Vaughan et al., 2007; Cunnick & Mokbel, 2006; Kroll et al., 1999; Newman et al., 1998). While the four patients belonging to the RBT group have exhibited no recurrence to date (i.e., approximately 13 months is the patient with the shortest duration of follow up and 48 months is the patient with the longest duration of follow up in the RBT group), longer follow up and further research is necessary in order to confidently make any finite conclusions regarding the association of residual breast tissue and breast cancer recurrence. Post-diagnosis evaluation is the standard plan of care for all women diagnosed with breast cancer.

**Recommendations for Future Projects and Future Practice**

There are similarities and differences between the present study and the Torresan et al. series (2005) that are important to note and that can be used as a foundation for future research in the healthcare setting. While the reference study focused on factors associated with residual disease, these factors could also be considered as part of future studies evaluating residual breast tissue following SSM. Both research efforts were comprised of rather small sample sizes (66 and 42 breast cancer patients), and the surgeons performing the SSMs were all from the same facilities (University of Texas Southwestern Medical Center in Dallas, Texas and Women’s Integral Healthcare Center of the State University of Campinas, Brazil). A multicenter effort could be beneficial in identifying an increased number of patients who have undergone SSM.
with immediate reconstruction allowing for a more statistically sound analyses of the factors associated with residual breast tissue and the differences between the women with and without the presence of residual breast tissue following SSM.

While in this study the frequency of residual breast tissue following SSM was found to be minimal and, therefore, did not lend to optimal statistical analyses and results, this discovery is encouraging for the providers rendering these services. Minimal residual breast tissue leads one to believe that techniques employed by these surgeons are extremely effective in successfully removing all breast tissue during this procedure. A multicenter endeavor would include SSMs performed by a variety of surgeons whose basic methods could potentially differ from one another. Multicenter research studies would permit a broader assessment of this topic as well as limit potentially confounding factors within this study performed at a single institution. With access to larger populations from multicenter research investigations, statistically valid analyses would be possible between cancer recurrence in women with residual breast tissue following SSM compared to those women without residual breast tissue.

There is need for evidence based guidelines regarding SSM in order to increase wider practice of SSM. According to the reviewed literature, only 61% of surgeons are performing SSM when immediate reconstruction is planned (Shen et al., 2008). These guidelines should be constructed in a multidisciplinary fashion. Providers who directly participate in the care of patients with breast cancer such as breast surgeons, pathologists, radiologists, medical oncologists, radiation oncologists, and nurse practitioners would be included. Considering present and past research regarding SSM, residual tissue, and factors associated with LR as well as residual disease following procedures performed for the treatment of breast cancer, suitable types of patients (e.g., BMI, tumor size, histologic grade, hormone receptor status) for SSM
could be identified. Techniques in performing the SSM, such as how thick the skin flap should be made, should also be outlined thus imparting a process of standardizing procedure methods to be utilized by all providers. Presenting concrete, evidence based guidelines would assist providers in confidently distinguishing patients who would most benefit from SSM. This assurance in the suitable selection of patients would subsequently lend to the more extensive practice of SSM.

The DNP prepared advanced practice nurse will be an integral participant in future research and practice efforts. The DNP will participate as a part of the multidisciplinary team caring for patients with breast cancer. Counseling patients concerning diagnosis and ensuing treatment options is a responsibility of the advanced practice nurse. Incorporating evidence based information obtained from this research project (i.e., concern for residual breast tissue following SSM) in examinations and discussions with patients will allow the patient to make more informed decisions regarding their plan of care.

The DNP prepared advanced practice nurse will also participate in creating clinical pathways and protocols within the clinical practice setting. These pathways and protocols will again comprise evidence from this research endeavor as well as others pertaining to the standardization of the care of patients with breast cancer and those with the history of breast cancer. This will include guidelines for routine care, medical and surgical treatments, as well as short- and long-term follow up. DNP advanced practice nurses will act as a liaison between physicians and management in creating and completing these pathways and protocols.

Conclusion

After SSM, 6% of patients had residual breast tissue left behind. This analysis, contrary to some previous reports, did not reveal any patients with residual tumor. Nearly $11,220 of
pathologic re-imbursement and approximately 22 hours of pathologic analysis time could have possibly been saved if routine analysis of these specimens was not performed. The study also reveals no evidence of an increased risk of cancer recurrence due to residual breast tissue after SSM from 13 to 48 months post SSM.

The DNP advanced practice nurse will ultimately be an essential piece in the process of evidence based, cost efficient healthcare practices of the future. The DNP will participate in formulating ideas for new research studies regarding SSM, especially designs for prospective studies, given that most investigations to date have been retrospective reviews and analyses. The DNP advanced practice nurse will also integrate evidence from these studies into daily practice and utilize this evidence in educating patients and staff, devising clinical protocols and pathways as well as employing resourceful utilization of healthcare assets and funds. The findings from this research effort will be submitted for publication consideration in a professional journal and disseminated to policy makers, surgeons, and agencies advocating for breast care such as the ACS and Susan G. Komen Foundation, permitting high quality patient support in today’s world and in times to come.
References


Appendix A

Project Timeline
## Project Timeline

<table>
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<tr>
<th>Date</th>
<th>Event Description</th>
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<tr>
<td>June 25, 2009</td>
<td>Complete NIH <em>Protecting Human Research Participants</em> training course</td>
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<tr>
<td>September 18, 2009</td>
<td>Submission to University of Texas Southwestern Medical Center IRB and receipt of approval</td>
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<tr>
<td>September 28, 2009</td>
<td>Proposal defense</td>
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<tr>
<td>October 2009</td>
<td>Submission to Texas Woman’s University IRB and receipt of approval</td>
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<tr>
<td>November 2009</td>
<td>Begin data collection (database review/chart review)</td>
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<tr>
<td>February 2010</td>
<td>Complete data collection</td>
</tr>
<tr>
<td>February-March 2010</td>
<td>Statistical evaluation/data analysis with the assistance of professional practice mentor and statistician</td>
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<tr>
<td>March 29, 2010</td>
<td>Capstone final defense</td>
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Writing the Capstone paper will be ongoing throughout this process.
Appendix B

Certificate of Training Completion
Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that Julie Dreadin successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 06/25/2009
Certification Number: 248719
Appendix C

IRB Form University of Texas Southwestern Medical Center
Residual Breast Tissue 51

The University of Texas Southwestern Medical Center at Dallas
Institutional Review Board

IRB Form NR1 - EXP: Application for Review of Expedited Research
(Revised April 2005)

Title of Research

Residual breast tissue after skin-sparing mastectomy

Sponsor and Grant Number

None

Assurances of the Principal Investigator and Sub-investigators

• To safeguard human subjects involved in this research, I agree to use procedures that conform to the policies of the University of Texas Southwestern Medical Center at Dallas and the regulations of the Department of Health and Human Services and the Food and Drug Administration.

• Unless it is necessary to eliminate apparent immediate hazard to a human subject, I shall seek prior approval from the Institutional Review Board (IRB) for substantive changes in the investigative procedures involving human subjects that may be called for during the research covered by this application.

• I shall agree to follow the advice of the IRB.

• I agree to report immediately to the IRB any unanticipated, life-threatening, or fatal complications with respect to human subjects.

• My signature certifies that I assure compliance with the ethical principles and institutional policies regarding the protection of human subjects in research as stated in Title 45 Code of Federal Regulations Part 46 (revised June 18, 1991; reprinted April 2, 1996) and the Federal Wide Assurance.4

Assurances of Department and Collaborating Chairs

• I understand that responsibility for assessing the quality of research must be shared by both the department and the IRB.

• My signature certifies that I assure compliance with the ethical principles and institutional policies regarding the protection of human subjects in research as stated in Title 45 Code of Federal Regulations Part 46 [revised June 18, 1991; reprinted April 2, 1996] and the Federal Wide Assurance, and that I have reviewed the proposed research for the proper use of human subjects.

• This review encompassed experimental design, scientific merit, and accuracy of the proposed research.

Date of Application:

1The IRB reviews all research involving human subjects for Children's Medical Center, Parkland Health & Hospital System, Texas Scottish Rite Hospital for Children, and the University of Texas Southwestern Medical Center at Dallas. The Board also reviews all research conducted at the Presbyterian Hospital of Dallas, The Retina Foundation of the Southwest and the Veteran's Affairs Medical Center of Dallas for which a member of the faculty at UT Southwestern serves as principal investigator.

2Title printed on the cover of the protocol, including the sponsor's protocol number, version, and date

3Complete name of the organization(s) funding the research

4Available as an electronic file at http://www8.utsouthwestern.edu/utsw/cda/dep131018/files/41623.html
Investigators' and Chairmen's Signatures

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<td>Robert Rege, MD</td>
<td>Surgery</td>
<td>MD</td>
<td>Prof.</td>
<td>214-648-3030</td>
<td>9031</td>
<td><a href="mailto:Robert.rege@utsouthwestern.edu">Robert.rege@utsouthwestern.edu</a></td>
<td></td>
</tr>
<tr>
<td>Department Chairperson²</td>
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<tr>
<td>Peggy Mancuso, RN, PhD, CNM</td>
<td>OB TWU Faculty</td>
<td>RN, PhD, CNM</td>
<td>Prof./Midwife</td>
<td>214-680-6552</td>
<td>7208</td>
<td><a href="mailto:pmancuso@twu.edu">pmancuso@twu.edu</a></td>
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<tr>
<td>Consultant for project</td>
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Please note that to qualify for expedited review, the research must present no more than minimal risk to human subjects and cannot explore sensitive topics. Designate below the category that qualifies this proposal for expedited review, and justify this designation by responding to the statements below each category.

(Category #) The IRB will review your justification and decide if this study can be approved on an expedited basis. If it is decided that it doesn’t meet expedited criteria completely, then you will be informed and submission of an NR1 form will be necessary.

Category #: 5

Information Required for Justification (specific information in attachments):

1. All information has already been collected for the tumor registry, this is a retrospective study.

2. Source of the material is a pre-existing database. Patients signed a previous consent for their information to be input into the database.

1. PROBLEM UNDER INVESTIGATION:

Medical condition or scientific problem to be studied: Breast Cancer treatment: Mastectomy

Describe the research in simple language by attaching a project summary (template available on the IRB website). If this is a retrospective chart review (Category 5), (health records research), all of the following must be

¹Investigator responsible for the global aspects of the research. The IRB acknowledges one PI for a study.

²Chairman of the PI's or faculty sponsor's department (or center director).
addressed: a) describe specifically what data (variables) will be extracted from each medical record, whether or not subject identifiers (name, medical record number, social security number, etc.) will be present, and at what point in time identifiers (if used) will be destroyed. Clarify how subject confidentiality will be protected. b) State why the research could not practicably be carried out without access to and use of the protected health information.
2. SUBJECTS:

a) General Inclusion:

Approximate number of subjects:

Age range (indicate whether months or years): 18-90 years of age

Gender: Male ( ) Female ( X )

Explain below if either gender is excluded: Due to the small numbers of men with breast cancer, only women will be eligible for this study.

Will all racial/ethnic groups be included? Yes ( X ) No ( ) (If no, explain in project summary)

Please note that a consent document in the subject’s own language will need to be provided.

Expected time to completion of enrollment or conclusion of study: No enrollment as it is a retrospective study, however total study time should be about 5-6 months.

b) Protocol inclusion criteria: Any patient undergoing mastectomy with reconstruction between August 2005 and May 2009 at Parkland Memorial Hospital (PMH) or a UT Southwestern hospital/clinic may be included in the database.

c) Protocol exclusion criteria: Patients who did not undergo treatment at PMH or a UT Southwestern Hospital will be excluded as this is the primary location of practice for the investigators.

Specify all classes of subjects included in the research:

Healthy volunteers: Medical students ( ), Center employees ( ), Minors (<18 yrs) ( ), Men ( ), Women ( )

Patients: Outpatients ( X ), Inpatients ( )

Vulnerable Subjects: Pregnant women ( ), Minors (<18 yrs) ( ), Men ( ), Women ( X ) Cognitively impaired ( ), Terminally ill ( ), etc.

Other: Other class ( ) please explain below

3. RECRUITMENT:

Specify procedures for recruiting subjects: This is a retrospective review; obtaining informed consent would be impossible because the subjects will not be seen by research personnel. Patients will be identified by querying a reconstruction and implant registry database, therefore some patients may be known to Dr. Rao and Julie Dreadin. After patients are identified, Dr. Rao and Julie Dreadin will personally review patient’s charts for information that was gathered in the process of their standard of care. This information will be de-identified and moved into a database that only Dr. Rao and Julie Dreadin will have access to.

4. CONSENT OF SUBJECTS: Describe the method used to obtain informed consent. Prospective research ordinarily requires written informed consent. If any special subject classes are eligible to participate, discuss how the consent process will differ. Inclusion of children in minimal risk research requires permission of at least one parent and the assent of the child.

No informed consent will be obtained, as this is a retrospective study.
If requesting a waiver or alteration of informed consent, justify such in accordance with the following four criteria established under 45CFR46.116(d)(1-4):

1) The research involves no more than minimal risk* to the subjects? Yes (X) No ( ) AND

2) The waiver or alteration will not adversely affect the rights and welfare of the subjects? Yes (X) No ( ) AND

3) The research could not practically be carried out without the waiver or alteration? Yes (X) No ( ) AND

4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation? Yes (X) No ( )

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR 46).

Please note that the IRB will make the final determination if waiver of consent is appropriate.

5. RISKS AND BENEFITS:

Specify the risks and benefits to the subjects and/or society:

There is minimal risk associated with this study, including a risk for loss of confidentiality for participants. However, it may provide valuable insight into residual breast tissue after skin-sparing mastectomy. In addition, this data may be used for the creation of a prospective study evaluating this type of surgery.

6. RESEARCH PERSONNEL:

Is there a conflict of interest between any investigator and the sponsor?

Yes ( ) explain below and notify the Conflict of Interest Office
No (X)

Have all research personnel completed the required human subject protection training? (X) yes (name(s) and completion date(s) under Comments) (enclosed with current submission)

Have all research personnel completed the required HIPAA training? (X) yes (name(s) and completion date(s) under Comments) (enclosed with current submission)

Is this study industry sponsored? ( ) yes (X) no (please skip the next question)

Have all research personnel completed the required Good Clinical Practice training? (X) yes (name(s) and completion date(s) under Comments) (enclosed with current submission)
7. PERFORMANCE SITES:

Specify the sites where (1) study procedures will be conducted, (2) patients will be seen, and (3) resources (equipment, supplies, personnel, etc.) will be utilized. Indicate whether Form NR3 has been sent to the appropriate authority at the performance site.

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<th>Form NR3 sent</th>
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<td>Children’s Medical Center</td>
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<td>UT Southwestern University Hospital-Zale Lipshy</td>
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<tr>
<td>Other (specify below)</td>
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Other approvals needed:
- Environmental Health & Safety Committee
- Radiation Safety Committee
- IRB at the Veteran’s Affairs Medical Center
- IRB at Presbyterian Hospital of Dallas
- Grants Management (UT Southwestern)
- General Clinical Research Center
- Form NR3
- Other (specify below)

Have all approvals been requested?  
- Yes
- No (explain below)
8. OTHER PAPERWORK REQUIRED:

a) Project summary including any questionnaires, surveys, telephone scripts, etc.

Also, when applicable:

b) Complete grant application, with budget (when project is federally funded). Block out confidential salary information and total dollar amount.

c) Consent form, information sheet, brochure, and/or letter, script for verbal consent.

d) Recruitment materials (e.g., posted notices, advertisements, telephone script, letters, etc.)

COMMENTS:

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<tr>
<th>Roshni Rao, MD</th>
<th>HIPAA</th>
<th>HSP</th>
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<td>Michel St. Cyr, MD</td>
<td>08/18/2005</td>
<td>03/04/2003</td>
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<td>Robert Rege, MD</td>
<td>04/11/2007</td>
<td>09/08/2005</td>
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<td>Julie Dreadin, RNC, MS, WHNP</td>
<td>08/08/2008</td>
<td>09/19/2000</td>
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<td>Peggy Mancuso, PhD, CNM</td>
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<tr>
<td>Expedited Review</td>
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<td>Date:</td>
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<td>o Approved As Submitted</td>
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<tr>
<td>o Approved - Minor Changes (may be verified by designee)</td>
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<td>o Deferred - Substantive Issues (needs IRB Chair approval)</td>
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<tr>
<td>o Refer for Full Board Review</td>
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</table>
Residual Breast Tissue 59

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS
CHILDREN'S MEDICAL CENTER OF DALLAS, PARKLAND HEALTH & HOSPITAL SYSTEM
RETINA FOUNDATION OF THE SOUTHWEST, TEXAS SCOTTISH RITE HOSPITAL FOR CHILDREN
ZALE LIPSHY UNIVERSITY HOSPITAL, ST. PAUL UNIVERSITY HOSPITAL
THE UNIVERSITY OF TEXAS SOUTHWESTERN MONCIEF CANCER CENTER

REQUEST FOR WAIVER OF HIPAA PRIVACY AUTHORIZATION FOR RESEARCH

IRB Number: 072009-033
Study Title: Residual breast tissue after skin-sparing mastectomy

Principal Investigator: Roshni Rao, MD
Principal Investigator Mail Code: 9155
Research Coordinator: Julie Dreadin, RNC, WHNP
Research Coordinator Phone #: 214-590-5071
Research Coordinator Mail Code/Address (if applicable): UTSW 9155; PMH 720B

SEE INSTRUCTION PAGE FOR GUIDANCE AND EXAMPLES

1. I am requesting this waiver of authorization for the following purpose:
   <Please select only one>
   □ The collection of initial screening data to recruit potential research subjects, or to determine study eligibility only. (Authorization is required for the remainder of the research study.)
   ☑ Retrospective reviews, research database or repository, or other research study where obtaining a signed authorization is not practical.

2. The following protected health information will be created, collected, used and/or disclosed for the purpose of conducting this research: (Please list the specific protected health information)
   Data collected from this registry will be utilized to perform a chart review, which will include medical/surgical history, as related to breast cancer, evaluating tumor data, demographic, radiologic, clinical, pathologic, and treatment information. A review of the histological sample and pathological report of the redundant skin removed at the second operation will be performed. This data will then be entered into a de-identified database and undergo statistical analysis to evaluate the factors which contributing to residual breast tissue being left behind.

3. I certify that the use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals based on at least the following elements:
   a. An adequate plan is in place to protect the identifiers from improper use and disclosure. The plan is as follows:
      <Select all that apply. Include additional information when applicable.>
      ☑ All electronic study data will be password protected.
      ☑ Passwords will be changed on a regular basis.
      ☑ Access to study data will be restricted to the following authorized study personnel only,
        Roshni Rao, MD, Michel Saint Cyr, MD, Venetia Sarode, MD, and Julie Dreadin, RNC, WHNP.
      ☑ All paper study records will be kept in locked file cabinets and access limited to authorized study personnel only.

Revised August 2006
Page 1 of 2
□ Other: ____  

b. An adequate plan is in place to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. The plan is as follows:  
   All personal health identifiers will be destroyed before patient health information is moved from the reconstruction and implant registry database to the second database, this process will take about two weeks. Therefore, all personal identifying information will be removed from this study about two weeks after it begins. In the interim, data will be in a double locked area in the primary investigators office.  
c. The protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by HIPAA regulations.

4. I certify that the research could not practicably be conducted without this requested waiver.
5. I certify that this research could not practicably be conducted without access to and use of the protected health information.
6. I certify that I will only access the minimum amount of PHI necessary to accomplish the purpose(s) of the research described under this waiver.

I attest that the above statements are correct and complete to the best of my knowledge.

__________________________________________  __________________________
Signature of Principal Investigator  Date

Printed name of Principal Investigator

For IRB Office Use Only

This waiver was approved under:  Full Review  Expedited Review  

__________________________________________
Signature of IRB Administrative Representative or Board Member  Approval Date

Revised August 2006
Appendix D

University of Texas Southwestern Medical Center IRB Approval Letter
TO: Roshni Rao, MD  
c/o Victoria Warren  
Surgery - 9031

FROM: Ahamed Idris, MD  
Institutional Review Board 4 Chairperson  
IRB - 8843

DATE: July 30, 2009

RE: Expedited Approval of NR1-Exp, Protocol/Project Summary and HIPAA Waiver  
IRB Number: 072009-033  
Title: Residual breast tissue after skin-sparing mastectomy

The Institutional Review Board reviewed this research activity via an expedited review procedure in accordance with 45 CFR 46.110(a)-(d)(1), 63 FR 60364, and 63 FR 60353. Having met the conditions as set forth by the IRB Chairman on July 30, 2009 your research protocol is now approved for a period of 12 months. This approval period will begin July 30, 2009 and last until July 29, 2010. If the research continues beyond approval period, the study will require continuing review from the IRB and a reminder will be mailed to you 60 days prior to the expiration date stated above.

The use of consent form is waived in accordance with 45 CFR 46.116(d).

Federal regulatory law requires that you report to the Institutional Review Board any unexpected and/or serious adverse events/unanticipated problems, as defined on the IRB website at http://www.utsouthwestern.edu/irb, that occur to research subjects or others during the course of your study.

In the future, should you require a change or need to modify the research, including the informed consent document(s) and HIPAA Authorization, per federal regulation you must obtain prospective review and approval of the Institutional Review Board. For any change to the research, prior review and approval before implementing such changes is mandatory except when prompt implementation is necessary to eliminate apparent immediate hazard to a subject.

Enc: NR1-Exp  
Protocol/Project Summary  
HIPAA Waiver

Al/cl

5323 Harry Hines Boulevard, Cl. 206 / Dallas, Texas 75390-8843 / 214-648-3060 Fax 214-648-2171  
www.utsouthwestern.edu
Appendix E

IRB Form Texas Woman’s University
Texas Woman's University, Dallas Campus
Application to Institutional Review Board
Cover Page
Mailing Address: TWU School of Physical Therapy, 8194 Walnut Hill Dallas Texas 75231-4363
IRB Chair: Suh-Jen Lin, PT, PhD (Phone: 214-706-2461)

Title of Study: Residual Breast Tissue After Skin-Sparing Mastectomy

Name of Principal Investigator (PI) #: Julie Dreadin/Roshni Rao Phone: 817-821-2201
Status of PI: ☑ faculty ☐ student ☐ staff ☐ other: X E-mail: jdreadin@bcglobal.net

Address where correspondence is to be sent: 9439 Timberleaf Dr.
Dallas, TX 75243

If the Principal Investigator is a student, provide the following student information:
Colleague ID #: 0571002 Department: Doctor of Nursing Practice Program
Name & Phone # of Research Advisor: Peggy Mancuso 214-689-6552

Estimated beginning date of the study: November 1, 2009

Research being conducted for (check appropriate box):
☐ thesis ☐ student professional paper
☐ dissertation ☐ faculty research
☐ class project ☑ other Capstone Project

If this research is, or may be, supported by a grant or an outside sponsor, list name(s) of sponsor(s):

Mark the application review level most appropriate for your study. (See the first page of these materials for a description of application review levels.)
Exempt: ☑
Expeditied: ☐
Full review: ☐

Required Signatures

Principal Investigator

[Signature]

[Date] 9/25/09

Faculty Research Advisor (if applicable)

[Signature]

[Date] 1/21/09

Dean, Department Head, or Program Director

[Signature]

[Date] 10/5/09

* If more than one investigator is involved in the project, complete a separate Cover Page for each investigator.

March 2007 (updated 9/28/08)
Appendix F

Letters Accompanying Texas Woman’s University IRB Form
MEMORANDUM FOR: Texas Woman’s University (TWU) Institutional Review Board (IRB).

SUBJECT: Request for acceptance of IRB approval

1. PURPOSE: The purpose of this memorandum is to request that the TWU IRB accept the IRB approval from the University of Texas Southwestern Medical Center at Dallas for the study entitled “Residual Breast Tissue After Skin-sparing Mastectomy” IRB number 072009-033. The study was approved on July 30, 2009. All participants involved in the research are located at the site where this IRB approval was obtained.

2. If there are any questions or concerns, please contact me at 817-821-2201 or jdreadin@sbcglobal.net.

Julie Dreadin, RNC, MS, WHNP
Parkland Health and Hospital System
Surgical Oncology
MEMORANDUM FOR: Texas Woman’s University Institutional Review Board.

SUBJECT: Doctor of Nursing Practice Capstone Project.

1. PURPOSE: The purpose of this memorandum is to inform the Institutional Review Board that the study entitled “Residual Breast Tissue After Skin Sparing Mastectomy” will serve as the topic for Julie Dreadin’s Capstone Project, and she will be conducting the research in order to complete this portion of the project.

2. If there are any questions or concerns, please contact me at 214-648-5647 (office) or Roshni.rao@utsouthwestern.edu.

Roshni Rao, MD
Assistant Professor
University of Texas Southwestern Medical Center
Surgical Oncology
Appendix G

Texas Woman’s University IRB Approval Letter
October 20, 2009

Ms. Julie Dreadin
9439 Timberleaf Dr.
Dallas, TX 75243

Dear Ms. Dreadin:

Re: Residual Breast Tissue After Skin-Sparing Mastectomy

Your application to the IRB has been reviewed and was approved on . This approval is valid for one (1) year. The study may not continue after the approval period without additional IRB review and approval for continuation. It is your responsibility to assure that this study is not conducted beyond the expiration date.

Any changes in the study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participant's safety or willingness to continue in your study.

Remember to provide copies of the signed informed consent to me at the Presbyterian campus when the study has been completed. Include a letter providing the name(s) of the researcher(s), the faculty advisor, and the title of the study. Upon receipt of these consent forms the committee will issue a statement ending its involvement with this project. Graduation may be blocked unless consents are returned.

The Institutional Review Board is pleased to acknowledge your sense of responsibility for ethical research. If you have any questions concerning this review, please contact me at (214) 706-2461 or email SL.in@twu.edu.

Sincerely,

Dr. Suh-Jen Lin, Chair
Institutional Review Board - Dallas

cc. Dr. Stephanie Woods, College of Nursing - Dallas
Dr. Peggy Mancuso, College of Nursing - Dallas
Graduate School
Appendix H

Data Collection Tool
Residual Breast Tissue After Skin-Sparing Mastectomy
Data Collection Tool

**Patient Demographics**

1. Patient Code: _________________________

2. Race
   1. White
   2. Black
   3. Hispanic
   4. Asian
   5. Other

3. Date of birth _____/_____/_______

4. Age at Diagnosis ______

**Basic Patient/Background Information**

5. Patient weight ______

6. Patient height ______

7. BMI ______

8. Date of 1st surgery ____/_____/______

9. Date of 2nd surgery _____/_______/______

**Factors Related to Tumor**

10. Tumor size (in cm) ___________

11. Estrogen receptor status
   1. Positive
   2. Negative
   3. Unknown

**Factors Related to Reconstruction**

12. Type of immediate reconstruction
   1. Expanders
   2. Latissimus
   3. TRAM
   4. Other
Factors Related to Surgery

13. Excess/non-viable skin taken at initial surgery by Plastic Surgeon
   1. Yes
   2. No

14. Skin taken at 1st surgery with residual breast tissue
   1. Yes
   2. No
   3. NA

15. Excess skin taken at second reconstructive procedure
   1. Yes
   2. No
   3. NA

16. Skin taken at 2nd surgery with residual breast tissue
   1. Yes
   2. No
   3. NA
Appendix I

Statistical Tables and Graphs
Table II

*Comparison of RBT and NRBT Groups*

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Table I2

*Tests of Normality for Continuous Variables Age, BMI, Tumor Size*

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</tr>
</tbody>
</table>

a. Lilliefors Significance Correction

*. This is a lower bound of the true significance.
Figure 13. Box and whisker plot for the variable BMI.
Figure 14. Box and whisker plot for the variable tumor size.
Figure I5. Box and whisker plot for the variable age.