Comparative study of the physical symptoms following bilateral mastectomy with immediate breast reconstruction and delayed breast reconstruction

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ABSTRACT

Breast reconstruction following a mastectomy can be done either immediately, at the time of the mastectomy, or following a recovery from the original surgery. This study compares the post-operative symptom experiences of these two groups of patients through secondary data analysis, using an existing survey, “How Women Decide” conducted at Texas Health Harris Methodist Hospital, Fort Worth (THFW). Statistical analysis was performed using SPSS 20. Tiredness/fatigue is the only symptoms which approached significance between the two groups; patients in the immediate breast reconstruction group experienced more tiredness/fatigue. No other aspects covered in the survey differed between the two groups. The study also found that hot flashes and tiredness/fatigue are the most common symptoms affecting the patients following bilateral mastectomy with breast reconstruction surgery. A larger sample size may have uncovered additional significant differences.
COMPARATIVE STUDY OF PHYSICAL SYMPTOMS FOLLOWING BILATERAL
MASTECTOMY WITH IMMEDIATE BREAST RECONSTRUCTION AND DELAYED
BREAST RECONSTRUCTION

Ritika Bhat, M.B.B.S

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Major Professor,

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Committee Member

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Dean, Graduate School of Biomedical Sciences
Comparative study of physical symptoms following bilateral mastectomy with immediate breast reconstruction and delayed breast reconstruction.

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the Graduate school of Biomedical Sciences University of North Texas Health Science Center at Fort Worth In partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE

By

Ritika Bhat, M.B.B.S

February, 2015
ACKNOWLEDGEMENTS

First of all, I would like to thank God, whose blessings have made me what I am today. There are several people with whom I am indebted for their contribution in my Master’s program.

I would like to express my gratitude to Dr. Patricia Gwirtz, for her kindness, support and guidance all the way through the course. She has been a great source of inspiration which encouraged me to work harder.

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I want to express my exceptional gratefulness to my mom, dad, my brother Dr. Nikhil Bhat and my sister in law Dr. Sangeeta Shenoy who stood by me during my tough times, encouraged me, and inspired me to pursue my goals. Last but not the least, I would like to thank my friends who have been extremely helpful, kind and supportive.
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CHAPTER 1
INTRODUCTION

Breast reconstruction following mastectomy involves rebuilding of the breast with the use of implants or using tissue from the other parts of the body, along with the reorganization of areola and nipple. It can be done immediately, i.e., along with mastectomy, delayed-immediately, in which case a tissue expander is placed after mastectomy and reconstruction is completed in the future or lastly, the reconstruction surgery can be delayed for some time (Kronowitz, 2010). The timing of breast reconstruction and the type of reconstruction to be performed is influenced by numerous factors. Principally, it is the patient’s decision after considering the other physiological and management factors which, include body mass index, original size of the breast, history of smoking, presence of autoimmune disorders and others. Furthermore, the need of post-operative radiotherapy also affects the outcome of breast reconstruction.

Complications can occur in both, immediate as well as delayed breast reconstruction. The common complications include wound breakdown, infection, loss of mastectomy flap, necrosis, capsular contractures, and others (Sabiston, 2012). The postoperative patient experiences may differ, depending on the other co-morbidities, lifestyle, use of adjuvant chemotherapy or radiotherapy with the surgical treatment, the type of breast reconstruction, use of implant or an autologous tissue for reconstruction and others. The present study is designed to examine and compare patients’ experiences following immediate versus delayed breast reconstruction with bilateral mastectomy. De-identified data, collected for other purposes were used in the present study. The primary endpoint of the study is the symptom experience.
CHAPTER 2
BACKGROUND AND LITERATURE

A review of the currently available literature was performed using PubMed search to learn about the physical symptoms experienced by the patient following breast reconstruction surgery. The search terms used were “breast reconstruction surgery,” “postoperative symptom experience,” “prophylactic mastectomy,” “immediate breast reconstruction” and “delayed breast reconstruction.” Articles reviewed were mainly pertinent to the advantages, disadvantages of different types of breast reconstruction and postoperative complications following breast reconstruction with a publication date after the year 2002. However, no studies have been performed in the past that examined the physical symptoms of the patients following bilateral mastectomy with breast reconstruction surgery.

Breast cancer is a disorder caused by multiple, known and unknown factors which can be of hereditary, hormonal or reproductive origin (DeBruin & Josephy, 2002). It is the most common cancer in women, but there are a few cases of breast cancer reported in men as well (Weiss et al., 2005). It is also the second leading cause of death in women. Research studies have shown that about 1 in 8 women develop breast cancer in the United States (DeSantis et al., 2014).

The clinical presentation of breast cancer is variable. The patient may present with generalized cancer symptoms or specific breast cancer symptoms. The pathology of cancer has an influence on the diagnosis, mode of treatment as well as the prognosis. Breast cancer can be managed by different modalities of treatment such as surgery, radiotherapy, chemotherapy, and hormone therapy. The choice of treatment depends on various factors like the stage of cancer, patient’s choice, history of co-morbidities and so on (U.S National Library of Medicine 2014).
The different surgical procedures performed for treating breast cancer are wide local excision, quadrantectomy and mastectomy of the breast. Chemotherapy is another treatment of choice in which cancer-killing drugs are administered intravenously or orally. It can be delivered before or after surgery (Hassan et al., 2010). Radiotherapy involves destruction of the cancerous growth using high-energy rays of particles. It is indicated in breast conserving surgery and also to treat the metastatic growth. Hormone therapy is given to eliminate and block the action of the hormones which promotes the growth of cancerous cells. Estrogen and progesterone stimulates the growth of hormone sensitive breast cancers. Hence, antiestrogens, selective estrogen receptor modulators, aromatase inhibitors and others are administered to prevent the tumorous growth (U.S National Library of Medicine 2014).

Mastectomy is a treatment of choice for majority of the breast cancer cases (Sabiston, 2012). In the past, women undergoing mastectomy suffered from emotional distress and depression due to the impaired body appearance and feeling of loss of femininity. With the advancement in the surgical techniques, breast reconstruction surgery following mastectomy became a worthwhile option as reconstruction involves rebuilding of breasts using autologous tissue or prosthetic implants (Joslyn, 2005). Breast reconstruction can be performed immediately with mastectomy or can be performed after a few months. The timing of the surgery mainly depends on the patient, but other influencing factors include the body mass index of patient, original size of breast, quality of skin over the breast, need of adjuvant therapy, history of smoking, presence of autoimmune disorders and so on.

Immediate breast reconstruction is known to be advantageous to overcome psychological symptoms, like depression, anxiety, lack of confidence and so forth (Howard-McNatt, 2013). It also has a positive impact on social outcomes like self-esteem, body image and sexual function.
These positive effects on the social behavior enhance the quality of life (Howard-McNatt, 2013). Studies have shown that immediate reconstruction of breast does not increase the rate of local recurrence of breast cancer and also is not a barrier to start chemotherapy (Lee et al., 2011). However, it is seen that post reconstruction radiotherapy can affect the cosmetic outcome of reconstructed breast due to fibrosis, volume loss, fat necrosis and capsular contractures (Mirzabeigi et al., 2013). Immediate breast reconstruction surgery also requires further postoperative corrections (Susarla et al., 2015).

Delayed - immediate reconstruction of breast is the procedure in which textured saline filled tissue is placed immediately after the skin sparing mastectomy and is followed by reconstruction using an autologous tissue or a permanent tissue expander in the future. This is the most suitable surgery if the requirement of radiotherapy following mastectomy is unknown (Kronowitz et al., 2004).

Delayed reconstruction of breast is done after completion of the adjuvant chemotherapy or radiotherapy. This approach is beneficial as the patient has sufficient time to decide if she needs breast reconstruction. Delayed surgery is also beneficial as the final pathology of the tissue is known. Patients can also choose to use prosthesis and decide if that is satisfactory for them (Greenall, 2007). A previous study has shown that delayed type of reconstruction has fewer complications when compared to immediate breast reconstruction including the patients requiring post mastectomy radiotherapy. Radiotherapy is completed before undergoing breast reconstruction so, the aesthetic outcome is satisfactory. (Seth, et al., 2014).

The complications associated with breast surgery can be categorized as immediate and delayed complications. Immediate complications can be further classified as local reversible complications (hemorrhage, or wound infection), irreversible complication (lymphedema), local
complications which need repair (scar deformity), and systemic complications (fever, nausea, vomiting, fatigue and so on) (Vitug & Newman, 2007). The delayed complications which may be seen are delayed wound healing, loss of sensation of breast, depression, and so forth. The physical symptoms the patient experiences postoperatively to an extent can depend on the above mentioned complications.

Both the types of breast reconstruction surgeries have their own advantages and disadvantages which can influence the physical symptoms experienced by the patient. The purpose of this study is to compare the physical symptoms following immediate and delayed breast reconstruction and to determine the appropriate timing for breast reconstruction.

CHAPTER 3

SPECIFIC OBJECTIVES

This practicum project tests the hypothesis that bilateral mastectomy followed by immediate breast reconstruction has a more positive outcome with respect to the physical symptoms than the delayed breast reconstruction following bilateral mastectomy.

CHAPTER 4

SIGNIFICANCE

With the increase in awareness among women regarding breast cancer, screening and early diagnosis of breast cancer has been increased. The risk of developing breast cancer and recurrence of breast cancer in high risk patients is decreased with the increasing trend of undergoing prophylactic mastectomies. With the improved surgical skills, reconstruction of the breast helps
women to retain their femininity, enhances the healing process, and reduces the chances of leaving an injured look which can be a result of the prophylactic mastectomy (Contant et al., 2002).

Patient experience should be one of the top priorities of the healthcare staff. (Rao, G.N., 2002). It is vital for the hospital to achieve a good feedback from the patient with regards to their experience in the hospital. Patient experience is a vital issue to define the quality of care provided by the institution. A good patient experience is beneficial to the medical staff and the institution with respect to the following factors:

- Improved quality and safety
- Improved financial performance
- Improved patient outcomes
- Enhanced market share and competitiveness
- Increased employee satisfaction and retention (Agency for Health Care Research and Quality, How patient and family engagement benefits your Hospital).

This study examines the potential differences in the postoperative symptomatic experiences of the patients, as determined by the timing of the breast reconstruction. It also provides important information for the medical staff, as the patients’ review about their experience is essential for them.
CHAPTER 5
MATERIALS AND METHODS

Study Design

This is a retrospective study using a limited, de-identified dataset from the “How Women Decide” study of women with breast cancer at Texas Health Harris Methodist Hospital Fort Worth (THFW) originally performed by Gayle Wilkins (MSN, RN, OCN, Clinical Education Specialist at THFW). Variables include the postoperative symptoms experienced by the patients’ and timing of breast reconstruction surgery.

Sample technique

The original study, ‘How Women Decide’ collected the information on patients from the Cancer Registry at THFW on the basis of their diagnosis and surgical treatment. All chosen subjects underwent bilateral mastectomy with one of the breasts removed prophylactically. A cover letter requesting participation in the study was mailed to the subjects along with the survey.

Population

The original study examined data from patients enrolled in the THFW Cancer Registry between January 1, 2011 and June 30, 2013, who underwent bilateral mastectomy in which one breast was removed prophylactically. This study included data of the cases that underwent breast reconstruction following bilateral mastectomy. The subjects were English speaking women in the Dallas/ Fort Worth area. The majority of the women in the Cancer Registry were Caucasians and few were African American, ranging in age from 35 to 90 years old.

Data collection

For the primary study, ‘How Women Decide’, Gayle Wilkins designed a questionnaire from two different validated surveys (Nissen, 2002 and Rosenberg 2013). The designed questionnaire
was validated by breast cancer experts. The main questionnaire included the following information: breast cancer background, treatment of breast cancer, information related to breast cancer, the physical symptoms following bilateral mastectomy, emotional and social support, details about breast reconstruction, and the correlation between the decision they made and the outcome obtained.

The data which were used for the present study are the physical symptoms that the patients experience following bilateral mastectomy with breast reconstruction. The two types of data that were analyzed were nominal data and ordinal data.

<table>
<thead>
<tr>
<th>Which of the following symptoms affected you the <strong>MOST</strong> in the past 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>O Soreness at incision site</td>
</tr>
<tr>
<td>O Pain at incision site</td>
</tr>
<tr>
<td>O Swelling of arm (lymphedema)</td>
</tr>
<tr>
<td>O Tiredness/fatigue</td>
</tr>
<tr>
<td>O Nausea/vomiting</td>
</tr>
<tr>
<td>O Limited range of motion in arms</td>
</tr>
<tr>
<td>O Flu-like symptoms</td>
</tr>
<tr>
<td>O Phantom breast sensations</td>
</tr>
<tr>
<td>O Hot flashes</td>
</tr>
<tr>
<td>Symptoms</td>
</tr>
<tr>
<td>----------------------------------</td>
</tr>
<tr>
<td>Soreness at incision site</td>
</tr>
<tr>
<td>Pain at incision site</td>
</tr>
<tr>
<td>Swelling of arm (lymphedema)</td>
</tr>
<tr>
<td>Tiredness/fatigue</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
</tr>
<tr>
<td>Limited range of motion in arms</td>
</tr>
<tr>
<td>Flu-like symptoms</td>
</tr>
</tbody>
</table>

Table 2. Ordinal data

PHYSICAL SYMPTOMS

Rank the following physical symptoms you have experienced within the past 12 months
The data were obtained from the Principal Investigator of the primary study ‘How Women Decide’. There were no patient identifiers in the data. They were then entered in an Excel spreadsheet and further imported into Statistical Package for the Social Sciences 20 (IBM SPSS Statistics 20) for analysis.

**Statistical Analysis**

The symptoms mentioned in Table No. 2 in a range of 1-5 were analyzed to determine if significant differences are present between the two groups of patients. Since the sample was not normally distributed, a non-parametric Mann Whitney U test was used for analysis. A post hoc power analysis was done using the mean of tiredness/fatigue score and the sample size of both immediate and delayed breast reconstruction group. To calculate the power for Mann Whitney U test, the Power Analysis and Sample Size (PASS) software was used. For the power analysis, the null hypothesis was the mean of the tiredness/fatigue score of immediate and delayed groups would be equal. An alpha value of 0.10 was used as a threshold of significance (90% level of confidence) to avoid missing any small effects in this poorly powered study. Group sample sizes

| Phantom breast sensations | | | | | |
| --- | --- | --- | --- | --- |
| Hot flashes | O | O | O | O | O |
| Tightness in chest | O | O | O | O | O |
| Itching at incision site | O | O | O | O | O |
| Numbness | O | O | O | O | O |
| Other | O | O | O | O | O |
of 25 for immediate breast reconstruction and 45 for delayed breast reconstruction achieved 79% power to detect a difference of 0.7 between the null hypotheses that both group means of tiredness/fatigue score would be equal and alternative hypothesis that the means would be unequal at a significance level of 0.10 using two-sided Mann-Whitney test. Data analysis included descriptive statistics to describe the responses to the survey. Internal consistency of the questionnaire was assessed by means of Cronbach’s alpha.

CHAPTER 6

RESULTS AND DISCUSSION

The nominal data in the survey measured the symptoms which frequently affected the patients in the past twelve months. The descriptive frequencies of the nominal data are shown in Table No. 3

Table 3: Descriptive frequencies for the symptoms in the past 12 months

<table>
<thead>
<tr>
<th>Symptoms experienced in the past 12 months</th>
<th>Percentage of patients experiencing the Symptom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soreness at incision site</td>
<td>8.7 %</td>
</tr>
<tr>
<td>Pain at incision site</td>
<td>5.4 %</td>
</tr>
<tr>
<td>Swelling of arm (lymphedema)</td>
<td>9.8 %</td>
</tr>
<tr>
<td><strong>Tiredness/Fatigue</strong></td>
<td><strong>50 %</strong></td>
</tr>
<tr>
<td>Nausea/Vomiting</td>
<td>7.6 %</td>
</tr>
<tr>
<td>Limited range of motion in arms</td>
<td>17.4 %</td>
</tr>
<tr>
<td>Flu-like symptoms</td>
<td>2.2 %</td>
</tr>
<tr>
<td>Phantom breast sensations</td>
<td>16.3 %</td>
</tr>
</tbody>
</table>
The occurrence presented in Table No. 3 show that hot flashes and tiredness/fatigue were the most frequent symptoms that affected the patients in the past twelve months.

The ordinal data includes the response of the patients for rating their symptom experience on a scale of 1-5. (1: Did not experience at all, 2: Experienced slightly, 3: Neutral, 4: Experienced moderately, 5: Experienced extremely). The descriptive statistics of the ordinal data analyzed is shown in Table No. 4

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Mean Score ± Std. Deviation after immediate breast reconstruction</th>
<th>Mean Score ± Std. Deviation after delayed breast reconstruction</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soreness at incision site</td>
<td>2.28 ± 1.40</td>
<td>2.13 ± 1.12</td>
<td>0.97</td>
</tr>
<tr>
<td>Pain at incision site</td>
<td>1.92 ± 1.32</td>
<td>1.93 ± 1.16</td>
<td>0.68</td>
</tr>
<tr>
<td>Swelling of arm (lymphedema)</td>
<td>1.52 ± 1.12</td>
<td>1.60 ± 1.11</td>
<td>0.48</td>
</tr>
<tr>
<td><strong>Tiredness/ Fatigue</strong></td>
<td><strong>3.72 ± 1.30</strong></td>
<td><strong>3.09 ± 1.53</strong></td>
<td><strong>0.10</strong></td>
</tr>
<tr>
<td>Nausea/Vomiting</td>
<td>1.68 ± 1.21</td>
<td>1.64 ± 1.20</td>
<td>0.88</td>
</tr>
<tr>
<td>Limited range of motion in arms</td>
<td>2.16 ± 1.28</td>
<td>2.25 ± 1.40</td>
<td>0.86</td>
</tr>
<tr>
<td>Flu-like symptoms</td>
<td>1.32 ± 0.62</td>
<td>1.61 ± 1.01</td>
<td>0.26</td>
</tr>
</tbody>
</table>
The Mann Whitney U test did not show any significant difference between the two types of breast reconstruction with regards to the symptom experience with the exemption of ‘tiredness/fatigue’. The p value obtained for ‘tiredness/fatigue’ was 0.10 showing the significant difference in both the groups.

The patients who underwent immediate breast reconstruction experienced more tiredness/fatigue compared to the patients who underwent delayed breast reconstruction.

**Discussion**

Breast reconstruction following mastectomy is a surgical procedure performed to rebuild the breast and nipple-areola complex. The desirable outcome is a symmetrical, aesthetically acceptable breast without intolerable post-operative symptoms. In this study, it was found that the most frequent symptoms experienced by the patients in the past twelve months were hot flashes and tiredness/fatigue.

Hot flashes involve an intermittent sensation of heat, sweating, and flushing of the face and chest. This symptom is commonly experienced by the breast cancer patients due to the hormone therapy that causes an estrogen deficiency (Morrow et.al, 2011). Chemotherapeutic agents also induce hot flashes due to the premature menopause (Morrow et.al, 2011). The pathophysiology of

<table>
<thead>
<tr>
<th>Phantom breast sensations</th>
<th>2.20 ± 1.38</th>
<th>2.67 ± 1.47</th>
<th>0.21</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hot flashes</td>
<td>3.28 ± 1.64</td>
<td>3.79 ± 1.45</td>
<td>0.19</td>
</tr>
<tr>
<td>Tightness of chest</td>
<td>2.84 ± 1.28</td>
<td>2.72 ± 1.47</td>
<td>0.69</td>
</tr>
<tr>
<td>Itching at incision site</td>
<td>2.38 ± 1.27</td>
<td>2.56 ± 1.37</td>
<td>0.75</td>
</tr>
<tr>
<td>Numbness</td>
<td>3.48 ± 1.38</td>
<td>3.36 ± 1.48</td>
<td>0.99</td>
</tr>
</tbody>
</table>
hot flashes is hypothesized to be associated with the thermoregulatory and neurochemical disruptions. Deficiency of estrogen levels leads to an increase in norepinephrine which stimulates the up regulation of the serotonin receptors, responsible for temperature regulation (Morrow et.al, 2011).

Tiredness/Fatigue was the other frequent symptom experienced by the patients and was consistent with the other finding that it was the only symptom which was significantly different between immediate and delayed breast reconstruction groups. The patients who underwent immediate breast reconstruction experienced more tiredness/fatigue compared to the patients who underwent delayed breast reconstruction. It is important to study the patient experience, as patient satisfaction defines the quality of care delivered by U.S hospitals.

There are numerous factors that influence the timing of breast reconstruction following bilateral mastectomy, and it is the patient’s choice to decide the timing of this surgery. The important physiological factors that are considered by the surgeons performing breast reconstruction are the age of the patient, original size of breasts, body mass index, availability of muscle donor sites, quality and thickness of the skin over the breast, stage of cancer, past history of autoimmune disorders, past history of smoking, and other co morbidities if present (Heller & Miller, 2004). The management factors, like the need for adjuvant chemotherapy and radiotherapy also are considered (Heller & Miller, 2004). Depending on the size of breast, one-stage, immediate breast reconstruction is suitable and convenient for all sizes of breast. Delayed breast reconstruction can be a lengthy two-stage procedure, depending on the size of the breast. Implant based breast reconstruction, which can be immediate or delayed, is suitable for small non-ptotic breasts, whereas autologous breast reconstruction is appropriate for large ptotic breasts and also if the chest wall does not meet the requirement for tissue expansion. (Dixon, 2014). The body mass
index of the patient also plays an important role. Studies have shown that the complication rates following immediate breast reconstruction are higher in obese patients; they experience higher donor site and flap related complications (Teymouri et al., 2006).

It is recommended that patients should quit smoking 4 weeks prior to the breast reconstruction surgery as smoking increases the post-operative complication rate (Teymouri et al., 2006). Smoking is mainly a concern with the immediate breast reconstruction, when autologous tissue is used. Smoking obstructs the microvascular distal circulation of the autologous tissues which leads to improper anastomosis. Smokers with autologous tissue reconstruction are at a higher risk of developing abdominal flap necrosis, skin flap necrosis, and hernia (Teymouri et al., 2006).

Studies have shown immediate breast reconstruction does not have any significant effect on chemotherapy. Hence chemotherapy does not influence the timing of breast reconstruction (Lee et al., 2011). Radiation, another mode of therapy, is an important deciding factor for timing of breast reconstruction. Berbers et al., (2014) concluded that use of radiotherapy with autologous tissue in immediate breast reconstruction does not increase the complication rates; however it can cause cosmetic defects. It was also determined that radiotherapy with implant-based immediate reconstruction leads to more postoperative complications (Berbers et al., 2014). Thus radiotherapy following immediate breast reconstruction affects the postoperative symptoms experienced by the patient.

According to the results found in this study immediate breast reconstruction patients experienced more tiredness/fatigue, compared to the patients with delayed breast reconstruction. Fatigue experienced due to cancer is predisposed by physical symptoms, comorbidities, and psychosocial factors (Bower, 2007). The claimed mechanisms leading to cancer-related fatigue are
release of pro-inflammatory cytokines and dysfunction of hypothalamic-pituitary axis (HPA) inhibiting cortisol production (Bower, 2007).

Cancer treatment also is known to cause fatigue. A study by Jacobsen et al., (1999) have shown that fatigue worsened with the beginning of chemotherapy treatment and also during chemotherapy (Jacobsen et al., 1999). Fatigue is one of the most common side effects of radiotherapy. Studies have shown that there was an increase in fatigue with the start of radiotherapy and decrease in fatigue after completion of radiotherapy (Smets et al., 1998).

As this study was based on a secondary analysis of de-identified data, it was not possible to obtain information about all the physiological and management factors, which affect the timing of breast reconstruction, and which influence the postoperative symptom experience. Furthermore, this study did not have information about the adjuvant chemotherapy and radiotherapy, so it is difficult comment that the timing of breast reconstruction surgery is the only factor which influenced the symptom experience with regards to tiredness/fatigue.

**Limitations**

The study was based on a very limited sample size and thus was inadequate to properly evaluate the various aspects of physical symptoms experienced following breast reconstruction with respect to the timing of breast reconstruction. Furthermore, the aforementioned factors contributing to hot flashes and tiredness/fatigue were not considered during the study.

This study has taken the data from the patients who underwent breast reconstruction when the plastic surgeons at THFW were not easily available. Hence delayed breast reconstruction surgery was commonly performed. The survey questionnaire used for the original study, ‘How Women Decide’ was designed using 2 validated surveys. This questionnaire was validated by breast cancer experts, but was not validated otherwise.
Moreover, the physical symptoms experienced by a patient is a subjective issue and there is no scale to measure it accurately.

CHAPTER 7
SUMMARY AND CONCLUSIONS

The conclusion of this practicum project is that hot flashes and tired/fatigue are the most common symptoms that typically affected the patients in the past twelve months. This study also concludes that the only postoperative symptom which was significantly different between the immediate breast reconstruction group and delayed breast reconstruction group in the past twelve months was tiredness/fatigue. The results of the study show that the patients who underwent immediate breast reconstruction experienced more tiredness/fatigue when compared to the patients with delayed breast reconstruction surgery. There were no significant differences in any other surveyed symptoms in the two groups.

The most suitable timing for breast reconstruction ultimately depends on the patient’s need and choice. The surgeon is responsible for delivering appropriate and adequate information regarding the treatment options that are available.

This is the only study that has compared the physical symptoms experienced by the patients following bilateral mastectomy with breast reconstruction. It clearly demonstrates the need for further research with significantly larger sample size to determine the symptom experience following different types of breast reconstruction surgery.
CHAPTER 8

INTERNSHIP EXPERIENCE

Internship site

The main site for the internship was Texas Health Harris Methodist Hospital Fort Worth (THFW). Texas Health Harris Methodist Hospital Fort Worth is a 726 bed facility located in the greater Tarrant county area. The internship also included Texas Health Specialty Hospital which is a 15 bed hospital within the campus of THFW that provides services to the chronic patients’ needing medical care longer than 25 days.

Journal Summary

During the internship at THFW, I led research projects by designing study protocols, submitting Institutional Review Board (IRB) applications, recruiting patients by obtaining their informed consent, collecting data, analyzing data, and theses writing. I worked on several clinical and non-clinical projects. Also, I attended the IRB meetings, research council meetings, focus group meetings, research poster days, and weekly meetings for THFW’s Interdisciplinary Breast Conferences and other conferences at Texas Christian University (TCU). I also attended certification courses such as, 'informed consent in research’, ‘privacy and confidentiality in research', 'adverse events in research', and ‘e - IRB application training’ at THFW.

By interning at THFW, I received valuable experience in the field of clinical research. Along with this experience, I also learnt other technical work such as recording an interview, scribing and transcribing notes, and so on. I was also exposed to many practical implications related to research which were new to me.
REFERENCES


19. Mary J. Nissen. (2002). Quality of Life after Postmastectomy Breast reconstruction Oncology Nursing Forum 29 (3) 547-553


Appendix A

INTERNERSHIP DAILY JOURNAL

AUGUST 2014

Tuesday, 19th August 2014
Mentor: Dr. Patricia Newcomb, PhD RN CPNP
Communicated with Dr. Newcomb regarding the various topics on which I had read up on the previous day. We listed the feasible options among them.

Thursday, 21st August 2014
Wrote a summary on the research topics I had enlisted. We also got in contact with the breast cancer registry in order to see the feasible options as far as the patients are concerned.

Friday, 22nd August 2014
Introduction to the tool of a study which is already in process. Reading up on the various research topics that could be studied based on the tool of the ongoing study.

Monday 25th August 2014
Discussed with Dr. Newcomb about the topic that can studied from the tool of the ongoing study. Finalized the research topic: ‘Comparative study of the patient experience with respect to symptom following bilateral mastectomy and patient experience with respect to symptom following bilateral mastectomy with breast reconstruction.’
Tuesday, 26th August 2014

I read up on the finalized topic and was working to write a summary on that topic. Also helped Dr. Newcomb with entry of some data.

Wednesday, 27th August 2014

I wrote a summary on the research topic and also made the necessary changes in it as told by Dr. Newcomb. I also did some data entry.

Thursday, 28th August 2014

Committee meeting

Learnt about how to prepare a poster when the research is yet to start and is in the preliminary stage.

Friday, 29th August 2014

Change in the topic to, ‘Comparative study of the patient experience with respect to symptom following bilateral mastectomy with immediate breast reconstruction and patient experience with respect to symptom following bilateral mastectomy with delayed breast reconstruction.’

I also did some data entry work.
SEPTEMBER 2014

Tuesday, 2nd September 2014

Did Data entry of Dr. Newcomb’s study.

Read articles for information of the newly framed question.

Thursday, 4th September 2014

Edited the data entered previously.

Worked on drafting the proposal.

Friday, 5th September 2014

Edited the data entered previously.

Worked on drafting the proposal.

Monday 8th September 2014

Edited the data entered previously.

Worked on drafting the proposal.

Tuesday 9th September 2014

Edited the data entered previously.

Worked on drafting the proposal.

Thursday 11th September 2014
Edited the data entered previously.
Worked on drafting the proposal.

Friday 12th September 2014
Edited the data entered previously.
Worked on drafting the proposal.

Monday, 15th September 2014
Edited the data entered previously.
Worked on drafting the proposal.
Submission of the immunization records.

Tuesday, 16th September 2014
Edited the data entered previously.
Worked on drafting the proposal.
Afternoon attended a lecture on ‘Adverse events’ in research.

Wednesday, 17th September 2014
Morning: Attended a poster presentation and a lecture on ‘The power of Patient Engagement’ in TCU.
Afternoon: Attended a lecture on Informed consent.
Thursday, 18th September 2014
Volunteer orientation in the morning.
Afternoon: Attended a lecture on ‘Professional confidentiality.’
Attended a research council meeting.

Friday, 19th September 2014
Worked on my proposal writing.

Monday, 22nd September 2014:
Introduced to the principal investigator of the project that I will be collecting my study data.
Worked on my proposal writing.
Attended a research meeting in the afternoon.

Tuesday, 23rd September 2014:
Edited the data entered previously.
Worked on drafting the proposal.

Wednesday, 24th September 2014:
Learnt data entry of a survey study using survey monkey.
Read literature about my study in school.

Thursday, 25th September 2014:
Completed the data entry of the survey study using survey monkey.

Attended the e IRB training.

Friday, 26th September 2014:

Worked on my proposal writing from school.

Monday, 29th September 2014:

Corrections in the proposal as discussed with Dr. Newcomb.

Editing the survey study which was designed last week using survey monkey

Reading a student’s proposal for editing.

Tuesday, 30th September 2014:

Worked on my own proposal writing.

Afternoon worked on Dr. Newcomb’s student’s proposal. Made the necessary changes and had a discussion of it with Dr. Newcomb.

Wednesday, 1st October 2014:

Was introduced to Dr. Jafari from UTD, he is planning to design a device which will help nurses communicate with their patients.

Afternoon had a meeting with Dr. Dory to review the proposal.
Thursday, 2nd October 2014:
Worked on my proposal. Made corrections as told by Dr. Dory. Had a discussion about it with Dr. Newcomb.
Also had a meeting with Dr. Newcomb and her student Cheryl Kirven to discuss about her study and IRB submission.
Afternoon attended a meeting with the research team who will be starting a new research study on ‘Tai Chi as a nursing intervention in heart failure patients’.

Friday, 3rd October 2014:
I attended an IRB meeting in the morning at THFW. Worked on my research proposal in School.

Monday, 6th October 2014:
I had to read the literature for writing the proposal of a new study ‘Effect of aromatherapy during mammography to relieve stress.’
Worked on the survey designed with survey monkey and discussed about the changes to be made in it with Dr. Newcomb.

Tuesday, 7th October 2014:
In the morning I had to record a video interview for the poster presentation which is coming up.
Later In the morning worked on my own proposal writing and also on the literature review of the Aromatherapy and Mammography study.
Attended a meeting with Dr. Newcomb to discuss about Robinsons study.

Wednesday, 8th October 2014:
Made the changes in the survey monkey as told by Dr. Newcomb. At school, worked on my own proposal draft.

Thursday, 9th October 2014:
Meeting with Cheryl Kirven to discuss about her proposal writing and IRB submission.
Record a video interview for the poster presentation.

Friday, 10th October 2014:
Meeting with Dr. Dory to discuss about the changes in the proposal as told by Dr. Gwirtz.
Meeting with Derrick to reserve room for the defense.
Worked on my proposal.

Monday, 13th October 2014:
Discussed about my proposal with Dr. Newcomb.
Wrote literature review Aromatherapy study.
Tuesday, 14th October 2014

Morning worked on my references for the research proposal.

Afternoon completed the literature review for aromatherapy and submitted to Dr. Newcomb.

Wednesday, 15th October 2014

Data entry of a new study done by Jason.

Meeting with Cheryl for her E-irb submission.

Afternoon meeting with Dr. Basu and Dr. Dory regarding the research proposal submission.

Thursday, 16th October 2014

Read up about a study which is going to be done in Cooks Hospital.

Had to make a few phone calls to review the E-irb submission.

Meeting with Cheryl to submit her proposal to IRB.

IRB meeting at COOK Children’s hospital in the afternoon.

Research Council meeting.

Friday, 17th October 2014

Morning read up a protocol on a new study of Patient experience of prescription of Narcotics in ER.

Video interview from 11.00 to noon.

Changes in the pre-review of the protocol which I read in the morning as told by IRB.
Monday, October 20, 2014

Prepared a worksheet on odds ratio for the afternoon lecture.

Assisted Dr. Newcomb with the preparations for the lecture.

Attended a lecture on Randomized Control Trial by Dr. Newcomb.

Video interview in the afternoon.

Tuesday, October 21st, 2014

Meeting with Dr. Dory and Dr. Basu. Submitted the proposal in school.

Literature review on Delirium study (Amanda).

Wednesday, October 22nd, 2014

Helped Dr. Newcomb assemble the posters.

Checked the list of the presenters who have not submitted their posters.

Made a poster for 1 presenter.

Attended meeting which discussed about the nonclinical research project.

Thursday, October 23rd, 2014

Collected data from Dr. Newcomb’s colleague.

Data entry of the collected data in a spreadsheet.

Monday, October 27, 2014

Helped Dr. Newcomb pack gifts for the students attending the poster reception.

Video shooting of interviews till noon.
Attended a conference on breast cancer cases.

Started working on my protocol submission at THR.

Meeting to design the consent form of a study on Barriers in breast feeding for NICU babies.

Video shooting for an interview.

Tuesday, October 28, 2014

Arranged the posters into another room.

Got print outs for the poster presentation reception.

Helped Dr. Newcomb to set the posters for hanging.

Went to recruit a patient for a study on vitamin D deficiency.

Data entry.

Wednesday, October 29, 2014

Conference of Journal club on Massive transfusion for trauma patients.

Thursday, October 30th, 2014

Arranged the posters with their hangers.

Set up the Posters in the presentation Hall.

Made ‘thank you’ cards for the participants of Dr. Newcomb’s study.

Set up the video for the poster presentation.

Arranged the tables and chairs for the guests.

Attended the poster presentation in the evening.
Friday, October 31st, 2014
Set up the food and sign-up sheets for the poster presentation.
Data entry of a new study (VaDS checklist).
Removed the posters from the hangers.
Rolled them up and placed them inside.
Cleaned up the auditorium.

**NOVEMBER 2014**

Monday, 3rd November 2014
Data entry of the Vads checklist continued.
Consenting of patients for the Vitamin D study with Cathy.
Multidisciplinary rounds in the ICU.
Attended the Breast cancer cases conference at noon.
Data entry of the VaDS study.
Meeting for a study on ‘wired to workplace’ in the afternoon with Dr. Newcomb and the other team.

Tuesday, 4th November 2014
Consenting rounds with Cathy for the Vitamin D study.
Data analysis of Vads Checklist study.
Preparation for Dr. Newcomb’s lecture to the nursing students on designing a research question.
Finding the alpha value for the Vads checklist study.
Wednesday, 5th November 2014

Attended a Nursing Congress at THR Arlington.

In the afternoon, I attended Dr. Newcomb’s lecture to the nursing students on ‘how to design a nursing question?’

Afternoon worked on the data entry and analysis of the Vads checklist study.

Friday, 7th November 2014

Attended the IRB meeting at THR.

Worked on the literature review of Aromatherapy study from school.

Monday, 10th November 2014

Went to the ICU for consenting with Cathy for her Vitamin D study.

Attended Breast cancer conference in the afternoon.

Worked on the protocol for submitting my research study proposal to THR.

Tuesday, 11th November 2014

Discussed about the data analysis of Vads checklist with Dr. Newcomb.

Started my e IRB submission process in THR

Wednesday, 12th November 2014

Completed my protocol writing for THR IRB in their format through school.
Thursday, 13th November 2014

Attended Defense of a PhD student in Arlington with Michelle.

Read and found more information for the literature review on Aromatherapy study.

Worked on the data entry of an ongoing study on the cardiac patients.

Monday, 17th November 2014

Created a survey monkey for Sally’s study.

Attended the Breast Cancer conference at noon.

In the afternoon, discussed and made the required changes in the survey monkey as told by Dr. Newcomb and Sally.

Dr. Newcomb discussed the required changes for my proposal submission in THR.

Made changes in the survey monkey as requested by Sally.

Tuesday, 18th November, 2014

Made a spreadsheet for Sally’s data and verified it with Dr. Newcomb.

Discussed the further sections of e IRB application for my study and entered the data.

In the afternoon, entered Sally’s data in the spreadsheet and emailed it to Dr. Newcomb.

Meeting with Dr. Newcomb to discuss about the changes to be made in the e IRB application.

Sent request to sign the conflict of interest and Bill form to the other study members.

Wednesday, 19th November, 2014

After receiving the COI forms, reviewed the whole e IRB application and submitted it.

Worked on the literature review to write the background of the Aromatherapy and mammography
Attended a grant writing defense in school in the afternoon.

Created a document showing the requirements for grant application for a research study, as it was required for a meeting on Thursday.

Thursday, 20th November 2014

Meeting with an RN who is to start a study on the anesthetic drugs given to the ventilated patients.
Meeting with Lesley to discuss about the application for her study on aromatherapy and mammography.
Meeting with an RN to discuss about the grant writing for a study on CPR.

IRB meeting at Cook’s Children’s Hospital
Research Council meeting at THR.

Friday, 21st November 2014

Attended a conference on 3D Mammography at THR.
Worked on the background writing for the Mammography and aromatherapy study.

Monday, 24th November 2014.

Got access to the data which was collected by Gayle for ‘How Women decide’ study.
Created a spreadsheet and started the data entry for my research study.
Completed the Data entry and discussed with Dr. Newcomb regarding its analysis.

Tuesday, 25th November 2014.
Had a discussion with Dr. Newcomb regarding the data analysis of ‘Breast Reconstruction Study’

Learnt how to use SPSS for the analysis of the same study.

Created a soft copy of a binder required for submission of various protocol of studies in THR.

Wednesday, 26th November 2014

Meeting with Dr. Dory to discuss about thesis writing.

Worked on the ‘Breast Reconstruction’ data in school using SPSS.

DECEMBER 2014

Monday, 1st December, 2014

Study protocol of aromatherapy.

Breast Conference Presentations.

Met with Kiebel to discuss about the aromatherapy study.

Meeting with the team initiating Breast Cancer Program.

Meeting with the research team on CPR study regarding grant writing and designing the study.

Tuesday, 2nd December 2014

Distributed the Genetic Competencies survey handouts in various departments at THFW.

Tested the ‘goto meeting’ with Dr. Newcomb and Jason.

Compiled the research study reports of nursing under THFW.

Discussed about the further data analysis of breast reconstruction data.
Wednesday, 3rd December 2014

Completed the compilation of nursing research reports under THFW.

Analyzed the breast reconstruction data using SPSS in school.

Thursday, 4th December 2014

Discussed the SPSS Results with Dr. Newcomb and noted the changes to be made.

Meeting with ‘Wired to workplace’ research study team to discuss about the focus meeting.

Meeting with Joy to discuss about the new study comparison in the intravenous line in high risk antepartum patients.

Worked on the breast reconstruction data using SPSS in school.

Friday, 5th December 2014

Discussed about the SPSS results with Dr. Newcomb

Preparation for the meeting i.e. to get print outs.

Meeting with ED narcotics research team.

Literature review on the high risk antepartum women study.

Monday, 8th December 2014

Read about high risk antepartum patients.

Breast Cancer Conference meeting.

Read about the different modes of intravenous lines.

Tuesday, 9th December 2014
Literature review of the high risk antepartum patients study.

Read the guidelines for theses writing.

Wednesday, 10th 2014

Discussed about the results obtained on SPSS and its conclusions with Dr. Newcomb.

Meeting with Allison regarding NIH funded study.

Meeting with Joy to decide if her study involves human subjects and hence the requirement for IRB approval.

Helped Joy with the document work to open the IRB account.

Read up on the types of breast reconstruction.

Thursday, 11th 2014

Helped Joy write her proposal and submit it to the IRB.

Worked on the abstract of my study.

Submitted Joy’s protocol to the IRB.

Friday, 12th December 2014

Collected the survey forms from the Texas Health Specialty Hospital.

Emailed my abstract to Dr. Newcomb.

Meeting with Dr. Newcomb to discuss about the abstract.

Worked on the descriptive frequency analysis of the ‘How Women Decide’ study. Emailed the results of my study to Dr. Dory.
Monday, 15th December, 2014

Made the required changes in the abstract and sent it to Dr. Dory for reviewing,
Meeting with Sunny and Dr. Newcomb to discuss about the data analysis of his study.
Meeting with Gayle to discuss my study results and to know her opinion about it.
Drafted the ‘introduction’ and emailed to Dr. Newcomb.

Tuesday, 16th December 2014

Meeting with Dr. Newcomb to discuss about the ‘introduction’.
Worked on the ‘introduction’ draft.
Edited the abstract as per the word limit of 150.
Meeting with Dr. Newcomb to discuss about the abstract.
Meeting with the ‘complaint department’ of THFW to discuss about their study based on the complaints filed by patients.

Wednesday, 17th December 2014

Worked on the Literature review for the study of patient complaints.
Also worked on my theses writing

Thursday, 18th December 2014

Worked on finding information on the grants for an interventional study on diabetes.
Discussed about those grants with Dr. Newcomb.
Meeting with the ED narcotics study team to discuss about the data extraction criteria.
Friday, 19th December 2014

Worked on SPSS for the descriptive frequencies of bilateral mastectomy data.
Data entry of the bilateral mastectomy in the electronic copy of the tool.

Monday, 22nd December 2014

Entered the data obtained from Sally’s survey study.
Discussed about the data analysis of Sally’s study with Dr. Newcomb and Sally.
Attended the breast cancer conference in the afternoon.
Started entering the results obtained from SPSS for the ‘How women decide’ study.

Tuesday, 23rd December 2014

Completed the data entry of ‘How Women Decide’ study and emailed it to Dr. Newcomb.
Performed data analysis on Sally’s data as discussed with Dr. Newcomb using SPSS.

Wednesday, 24th December 2014

Discussed about Sally’s study results.
Worked on Thesis writing for my study and emailed it to Dr. Newcomb.

Monday, 29th December, 2014

Read articles related to my study for theses writing.

Tuesday, 30th December, 2014
Worked on the theses writing of my study.

**JANUARY 2015**

Monday, 5th January, 2015

Discussed about the abstract writing to submit for conference.

Emailed my drafted abstract to Dr. Dory.

Worked on the corrections told by him.

Drafted an abstract for ‘Safe zone’ study and emailed it to Dr. Newcomb.

Tuesday, 6th January 2015

Started working on the introduction and background writing for my theses.

Meeting with Joy to help her do literature review.

Meeting with Kim and Sally to discuss about the work to be done to start their study on effect of skin to skin contact with neonatal screening.

Meeting with Chaplins to discuss about the study they want to start on the course they provide.

Wednesday, 7th January 2015

Drafted my introduction and background writing.

Emailed it to Dr. Newcomb.

Literature review on the study ‘effect of skin to skin contact with neonatal screening’.

Thursday, 8th January, 2015
Made copies of the data collected by Chaplins.
Meeting with a Nurse to discuss about a new study based on designing the robots.
Returned the data to the Chaplins.
Discussed about my background and introduction with Dr. Newcomb.

Friday, 9th January 2015
Performed SPSS analysis of data and emailed it to Dr. Newcomb.
Emailed background and introduction to Dr. Dory.
Drafted the materials and methodology section of my study.

Monday, 12th January 2015
Completed the materials and methodology section.
Meeting with Dr. Newcomb to discuss about theses writing.
Discussed the SPSS results obtained on Friday.
Attended the breast cancer conference.

Tuesday, 13th January 2015
Made changes in the abstract as told by Dr. Dory.
Prepared the cassettes for tape recording of Focus meeting.
Attended focus meeting.
Transcribed the notes of meeting.
Meeting with the research team working on a project on patient complaints.
Wednesday, January 14, 2015
Preparation for the focus group meeting of Managers.
Attended the meeting.
Cleared the meeting place.
Transcribed the meeting notes.

Thursday, January 15 2015
Discussed about the focus group meeting with Dr. Newcomb.
Completed transcription of meeting flipchart notes.
Meeting with ‘Wired to Workplace’ team to discuss about the focus group meeting.

Friday, January 16th 2015
Read through the articles related to my study.
Worked on theses writing from school.

Tuesday, January 20th 2015
Conducted 3 Focus group meetings in Dallas THR with Dr. Newcomb.
Scribed and also did the audio recording of the meeting.

Wednesday, January 21st 2015
Transcribed the notes of 3 focus group meetings conducted in Dallas.

Thursday, January 22nd 2015
Transcribed the audio recording notes of 3 focus group meetings conducted in Dallas.

Friday, January 23rd 2015
Meeting with Dr. Newcomb to discuss about the transcribed notes.
Started drafting the discussion for my study.
Read articles related to my study.

Monday, January, 26th 2015
Meeting with Dr. Newcomb to make changes in the theses draft as told by Dr. Dory.
Edited the draft and emailed it to Dr. Dory and Dr. Patricia.
Worked on theses draft.

Tuesday, January 27th 2015
Meeting with Dr. Newcomb to review the drafted discussion.
Read articles and papers to draft the corrections.
Emailed Joy to give an update on her study.

Wednesday, January 28th, 2015
Read articles from school library.
Started drafting the discussion section.

Thursday, January 29, 2015
Took print outs.

Read new articles.

Completed discussion writing and emailed it to Dr. Newcomb.

Scheduled an appointment with Joy to discuss about her study.

Meeting with Gayla to discuss about her study on intravenous catheters.

Friday, January 30th, 2015

Completed the limitations section of my theses writing.

Emailed the limitations section to Dr. Newcomb.

Did literature review for Gayla’s study and drafted an outline for the proposal.

FEBRUARY 2015

Monday, February 2nd, 2015

Read the proposal drafted by Gayle for her study.

Meeting with Dr. Newcomb to discuss about the progress in the theses writing.

Attended the breast cancer conference.

Made changes in Gayla’s proposal.

Tuesday, February 3rd, 2015

Meeting with Dr. Newcomb to discuss about the proposal writing for Gayla’s study.

Completed my theses writing and emailed to Dr. Dory.

Meeting with Joy, Nicolas and Dr. Newcomb to discuss about the data collection for Joy’s study.
Meeting with Dr. Dory on the phone to discuss about the changes in the theses.

Wednesday, February 4th, 2015

Read articles on my study and worked on my theses.

Made changes in my thesis as discussed with Dr. Dory.

Thursday, February 5th, 2015

Completed the theses draft and emailed it to Dr. Newcomb.

Meeting with the Narcotics study.

Made changes in Gayla’s study proposal and emailed it to her.

Friday, February 6th, 2015

Emailed my theses draft to Dr. Dory.

Read articles related to my study and biostatistics as told by Dr. Newcomb.

Monday, February 9th, 2015

Worked on the results of ‘How Women Decide’ study.

Attended Breast Cancer conference.

Emailed Kimberley to discuss about her study progress on skin to skin contact in neonates.

Meeting with Dr. Dory to discuss the final changes to be made in the theses.

Tuesday, February 10th, 2015
Worked on the changes to be made in the theses draft as told by Dr. Dory

Started working on the PowerPoint presentation for my defense.

Studied the data files sent to me by Nicholas.

Wednesday, February 11th, 2015

Performed data analysis for nominal data of my study using SPSS.

Drafted the results found through data analysis.

Discussed about statistical analysis with Dr. Newcomb.

Read the articles given by Dr. Newcomb for data analysis.

Thursday, February 12th, 2015

Discussed the results the nominal data analysis with Dr. Newcomb.

Made the changes in the result section as told by Dr. Newcomb.

Read articles on the new findings and accordingly made changes in the theses draft.

February 13th, 2015 to February 26th, 2015

Worked on the final part of the thesis, prepared my presentation for defense, and submitted my thesis to my committee.