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## A Pilot Study To Investigate Concerns In Patients Undergoing Neck Dissection Surgery

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A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Health and Rehabilitation Sciences

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A Pilot Study To Investigate Concerns In Patients Undergoing Neck Dissection  
Surgery

(Thesis format: Integrated Article)  
by

Daniel Sundar Raj Arulananda Doss

Graduate Program in Health and Rehabilitation Science (Physical Therapy)

A thesis submitted in partial fulfillment  
of the requirements for the degree of  
Master of Science

The School of Graduate and Postdoctoral Studies  
The University of Western Ontario  
London, Ontario, Canada

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## **Abstract**

This study investigates concerns in patients undergoing neck dissection surgery. Forty patients were recruited at Pre-surgery, Discharge and 1-month Post-surgery. The Patient Concerns Inventory - Level of Importance questionnaire (PCI-LOI), Shoulder Pain and Disability Index (SPADI), Neck Dissection Impairment Index (NDII) and the University of Washington - Quality of Life questionnaire (UWQOL) were used.

The study identified "Anxiety" at Pre-surgery and "Appearance" at Discharge and 1-month Post-surgery as the important patient concerns. Patients' concerns were found to change over time. Support for cross-sectional convergent validity of the PCI-LOI was evidenced by significant correlations between the PCI-LOI and the UWQOL ( $r = -0.48$  and  $-0.43$ ), and the PCI-LOI and the SPADI ( $r = 0.45$  and  $0.57$ ), at Discharge and 1-month Post-surgery, respectively.

Identification of patient concerns and the importance of these concerns should assist health care professionals to respond to the needs of patients undergoing head and neck cancer surgery.

### **Keywords**

head and neck cancer, neck dissection surgery, patient concerns, quality of life

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### **Dedication**

This work is dedicated to my family who have loved me and supported me throughout the adventures of the last two years.

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# CHAPTER 1

## 1 Introduction

Head and neck cancer (HNC) is a broad term that includes carcinomas arising from the head and neck region. The most common type of HNC is the squamous cell carcinoma (Argiris, Karamouzis, Raben & Ferris, 2008). The important risk factors causing head and neck carcinoma are tobacco and alcohol consumption (Ariyawardana & Johnson, 2013). Treatment decisions are often complex and involve specialists from various fields in health care.

Surgery and radiotherapy are widely accepted treatment options for HNC. The type of surgery is based on the location and extent of the malignancy. Surgery is often associated with post-surgical morbidity that affects quality of life (Vanwilgen, Dijkstra, van der Laan & Plukker, 2004). Shoulder and neck problems are two commonly recorded physical morbidities post-surgery (McNeely et al., 2008).

Head and neck carcinoma can cause patients to suffer both physically and emotionally due to its sheer complexity and severity. Patients undergo stress and have a wide array of concerns as they go through different phases of treatment (Kanastas, Ghazali, Lowe & Rogers, 2012). These concerns might range from psychological to social concerns and are influenced by treatment decisions and acute problems they might face during the treatment period. It is important to recognize these patient concerns as it will help health care professionals to better understand and cater to the needs of their patients (Ghazali, Roe, Lowe & Rogers, 2013). Furthermore, patient concerns may vary depending upon the stage of the treatment period. Hence it is also important to identify the patient's primary concerns at different phases of the treatment period. This will enable clinicians to track how patients' priorities change over time. To identify patient issues researchers have used methods like direct interview, phone interview, surveys and questionnaires.

The World Health Organization (WHO) has come up with the International Classification of Functioning, Disability & Health (ICF). It is a classification of health and health related domains. It is a biopsychosocial model which focuses on the consequences of the disease. This is the most widely accepted conceptual model used for describing an outcome measure

(World Health Organization, 2001). Previous research has suggested development of tools specific to the HNC population using the ICF framework will help in clinical decision making (Tschiesner, 2011).

Patients' concerns are often missed during regular consultation, due to factors like the busy nature of the outpatient clinic, or a patient's hesitancy to discuss their concerns. Researchers have developed patient-reported outcome measures that can help people identify peoples' concerns which can then be used to inform their health care (Rogers, El-Sheikha & Lowe, 2009). The Patient Concerns Inventory (PCI) is a patient-reported outcome measure which has been used to identify any patient concerns (Ghazali et al., 2013, Kanastas et al., 2012).

We have modified the original PCI by adding a response scale for each item in the questionnaire which allows patients to rate the importance of each concern. We refer to this modified tool as the Patient Concerns Inventory – Level of Importance questionnaire (PCI-LOI). Using this tool over time will help clinicians and researchers understand how the importance of each patient's priority varies during treatment. As an initial step in the evaluation of this modified tool, it is important to assess its validity by determining its relationship with other valid quality of life tools used with persons who have HNC.

With these concepts in mind this thesis is intended to explore and identify the different concerns of patients with HNC. It will also provide initial estimates of mean importance ratings for these concerns as measured by the modified version of the PCI (PCI-LOI) at three different time points (Pre-surgery, Discharge and 1-month Post-surgery). Finally, the thesis project will provide preliminary evidence of the validity of the modified version of the PCI, the PCI-LOI.

## **1.1 Etiology**

The term head and neck cancer (HNC) includes a range of malignant neoplasms originating from soft tissues of the oral cavity including the lips, nasal cavity, paranasal sinuses, pharynx, larynx and salivary glands. About 95% of HNC fall under the category of squamous cell carcinoma. Risk factors for HNC include both environmental and lifestyle factors including tobacco use, smoking and exposure to smoking, heavy alcohol consumption (Argiris et al., 2008), diets with poor anti-oxidant supplements, ultra-violet light and occupational exposure

to radiation and chemical carcinogens (Ariyawardana & Johnson, 2013). Viruses that are sexually transmitted, notably the human papillomavirus (HPV 16 &18), can cause cancers originating from the tonsils and the oropharynx (Ariyawardana & Johnson, 2013).

In 2010, there were an estimated 3400 new cases of oral cancers in Canada of which approximately 2200 were found in males and 1200 in females. Thyroid and larynx cancers accounted for about 5200 and 1150 new cases, respectively. Incidence of thyroid cancer is dominant in females whereas in larynx cancer, males are the dominant group (Canadian cancer statistics 2010). Recent research has suggested that oropharynx cancer is increasing in incidence in Canada with an improvement in survival rate. Incidence of oropharynx tumors increased in 2010 with an annual percent change of 1.5% in men and 0.8% in women. Survival for patients with oropharynx cancer increased by 1.5 %, with a significant change in mortality among men. Survival rate of oral cavity cancers and other HNC has increased in males (Hwang, Johnson-Obasek, McDonald, Connel & Corsten, 2013).

## **1.2 Surgeries**

Head and neck cancer can metastasize and in these scenarios surgery is considered the primary treatment option. Cervical metastasis is usually treated with neck dissection surgery. The type of surgery depends on the level and location of the tumour (Martin, Del Valle, Ehrlich & Cahan, 1951).

Crile initially described excision of HNC (i.e. radical dissection surgery) (Crile, 1906) (Silver, Rinaldo & Ferlito, 2007). Since then, the procedure has undergone various developments and has become the standard treatment option for HNC. The different types of neck dissection surgeries are summarized in Table 1.1. A brief description of these surgeries (Ferlito, Robbins, Silver, Hasegawa & Rinaldo, 2009) follows.

**Table 1.1: Currently used terminology and definitions for neck dissection surgery.**

Terminology	Definitions of neck dissection surgeries
Radical	Removal of lymph node levels I–V, sternocleidomastoid muscle, spinal accessory nerve, and internal jugular vein.
Modified	Removal of lymph node levels I–V (as in radical neck dissection), but preservation of at least one of the non-lymphatic structures (sternocleidomastoid muscle, spinal accessory nerve, and internal jugular vein). Each non-lymphatic structure that is removed should be named.
Selective	Preservation of one or more lymph node levels relative to a radical neck dissection.
Extended	Removal of an additional lymph node level or group or a non-lymphatic structure relative to a radical neck dissection (muscle, blood vessel, nerve). An example of other lymph node groups can be superior mediastinal, parapharyngeal, retropharyngeal, peri-parotid, post auricular, sub occipital, or buccinator. An example of other non-lymphatic structures can be the external carotid artery, hypoglossal or vagus nerves.

### **Radical Neck Dissection**

A radical excision is the removal of all the lymphatic structures on the ipsilateral side of the neck. This surgery would result in the removal of all lymphatic and non-lymphatic structures from the mandible to the clavicle and between the platysma and the pre-vertebral fascia. The carotid arteries, hypoglossal, lingual, vagus and phrenic nerves, and brachial plexus are the

important structures that are preserved in this type of surgery. The boundaries of the surgery are the anterior border of the trapezius muscle laterally, midline of the neck medially, superficial to the infrahyoid muscles and the opposite digastric muscles superficial to the suprahyoid (mylohyoid) muscle (Shaha, 2004). The current definition of radical neck dissection is the "Removal of lymph nodes levels I-V, sternocleidomastoid muscle, spinal accessory nerve and internal jugular veins" (Ferlito et al., 2009).

### **Modified Neck Dissection**

An alternate technique to neck dissection was suggested by Suarez in 1952 (Ferlito & Rinaldo, 2004). This technique was more conservative than the radical neck dissection surgery. It preserves the sternocleidomastoid muscle, the omohyoid muscle, the internal jugular vein and the spinal accessory nerve. This technique was named "functional neck dissection". Within a few years another technique was developed by Jesse and Ballantyne (Jesse, Ballantyne & Larson, 1978). The intention of this technique was to identify the high risk lymph nodes that could contain metastases and by removing them, this surgery was termed as a "modified neck dissection". This surgery was further improved by the removal of the aponeurotic compartments of the neck while simultaneously preserving the sternocleidomastoid muscle, the omohyoid muscle, the internal jugular vein, the spinal accessory nerve and the common facial veins (Ferlito et al., 2009).

### **Selective Neck Dissection**

Selective neck dissection is considered a modified extension of the more invasive radical neck dissection and modified radical neck dissection. It is a highly functional-preserving surgical option for cervical metastases and considered to cause less post-surgical morbidity. Selective neck dissections (SND) evolved from a conservative approach adapted by Suarez in 1950, later termed functional neck dissection (Ferlito & Rinaldo, 2004). Selective neck dissection is considered as an extension of functional neck dissection. Identification of the pattern of lymph node metastases and the development of a nodal staging system has helped surgeons to selectively remove lymph nodes (Lindberg, 1972). Selective neck dissection is

therefore used to selectively remove nodes of high risk metastases. It also allows removal of sub-clinical and sub-pathological metastases, thus paving the way for more accurate staging. It helps to treat the disease and allows for better counseling of the patient (Ferlito et al., 2006; Teyamoortash, Hoch, Eivazi & Werner, 2010). In order to selectively remove lymph nodes, the lymph nodes are classified by the region where they are present (Table 1.2). For more accurate resection of potential high risk lymph nodes the neck region has been divided into sub-levels based on major anatomical structures that are located near the lymph nodes (Table 1.3)

**Table 1.2: Cervical lymph nodes levels**

Level of Cervical Lymph Nodes	Description
Level I (Sub Mandibular Triangle)	Nodal tissue in the triangle bounded by the anterior and posterior bellies of the digastric muscle and inferior body of the mandible.
Level II (Upper Jugular)	Nodal tissue around the upper portion of the jugular vein extending from the base of the skull to the bifurcation of the carotid (radiological landmark) or the hyoid bone (clinical landmark), with the posterior border of the sternocleidomastoid muscle being the posterior limit and the anterior border being the lateral border of the sternohyoid muscle.
Level III (Middle Jugular)	Nodal tissue extending from the inferior border of the level II to the omohyoid muscle or the cricoid cartilage (clinical landmark), with anterior and posterior borders similar to level II.
Level IV (Posterior Jugular)	Nodal tissue extending from the inferior border of the level III to the clavicle, with anterior and posterior borders similar to level II and level III.
Level V (Posterior Triangle)	Nodal tissue around the lower border of the spinal accessory nerve and the transverse cervical vessels, bounded by a triangle formed by the clavicle, posterior border of the sternocleidomastoid muscle and the anterior border of the trapezius muscle.

---

(Chummun, McLean, & Ragbir, 2004)

**Table 1.3: Cervical nodes specific sub-levels**

Sub-levels	Group of nodes
Level Ia	Submental nodes
Level Ib (Upper Jugular)	Submandibular nodes
Level IIa (Middle Jugular)	Upper jugular, anterior to Cranial Nerve IX
Level IIb (Posterior Jugular)	Upper jugular, posterior to Cranial Nerve IX
Level III (Posterior Triangle)	Middle jugular nodes
Level IVa (Posterior Triangle)	Lower jugular nodes (behind clavicular head of sternocleidomastoid)
Level IVb (Posterior Triangle)	Lower jugular nodes (behind sternal head of sternocleidomastoid)
Level Va	Posterior triangular nodes (spinal accessory group)

---

(Chummun et al., 2004)

Though this procedure causes less physical morbidity, it is yet to be the standard of treatment for cervical metastasis. Selective neck dissection was first implemented to serve as a staging or diagnostic procedure but research suggests that selective neck dissection will have a significant therapeutic role for patients with HNC (Ferlito et al., 2009; Ferlito et al., 2006; Givi et al., 2012).

### **Reconstructive Surgeries**

Head and neck carcinoma treated with neck dissection surgeries can lead to cosmetic and functional problems for the patient. Surgical resection of the oral cavity often leads to difficulties with swallowing, speech, mastication and cosmetic problems. Hence oral reconstruction and its rehabilitative phase are considered as essential components of the treatment plan by the health care team (Skolnik, Yee & Keyes, 1976).

The amount and extent of oncologic resection will determine the type of reconstructive procedures that need to be carried out. Reconstructing mandibular defects dates back to the beginning of the century. It involved plaster of paris and paraffin wax. Later, metals like gold, silver and brass were used in the surgery (Jacobs, 1995). The advent of free flaps has brought about big advances in reconstructive surgeries. A free flap includes a vascular pedicle, soft tissue and parts of bone. The microvascular free flap is now considered as the gold standard of reconstructive procedures owing to its high success rate. There are different types of free flap surgery are categorized by the donor site: scapula, fibula, radial forearm and anterolateral thigh flap (Mitchell, 2012). In recent years, flap reconstruction surgeries are done along with neck dissection surgeries. Reconstruction surgeries along with the original neck dissection surgeries can lead to potential complications due to the presence of multiple variables (Clark et al, 2007). The reconstructive surgeries can act as confounding factors in post operative issues faced by the HNC population.

### **1.3 Patient Concerns**

Even with advancements in medicine, technology, treatment techniques and with increased survival rate, cancer remains an emotionally distressing condition. Head and neck cancer patients are generally known to have significant psychological issues (Horney et al., 2011). It

has been estimated that 58% of them have a mild to severe bout of depression before radiation therapy, with this percentage increasing to 67% on the final day of treatment (Buchmann, Conlee, Hunt, Agarwal & White, 2013). Head and neck cancer treatment regimens, either surgical or chemo/radio therapy, are found to have effects on patients post-treatment. These effects can be physical, psychological and social in nature. Surgical resection can alter appearance and render functional limitations due to the involvement of vital structures (Fingeret et al., 2013). It often results in physical morbidities like difficulties in swallowing and speech, shoulder and neck dysfunction, and loss of taste. Research has also suggested that the quality of life of patients with HNC is affected after neck dissection surgery (Inoue et al., 2006).

Research has shown that it is important for health care professionals to identify, understand and resolve patients' priorities and concerns (Kanastas et al., 2012). Mismatch between the patient's priorities and that of health care providers will lead to regret and lack of trust and miscommunication which might further negatively impact the patient's problems. Identifying patient concerns and understanding their emotional state will lead to a better relationship with the patient.

Head and neck cancer and the various surgeries used to treat it can give rise to a host of issues. Some of the important concerns that have been documented in previous studies are listed below.

Pain is considered as one of the most common complaints associated with HNC. While advances in neck dissection and reconstructive surgeries have improved the long term survival of patients, these surgeries also cause considerable pain during the acute post-operative period (Gil, Smith, Marouani, Khafif & Fliss, 2006). Surgeries can also cause nerve and soft tissue damage which might eventually lead to pain around the surgical area. Up to 30-80% of people with cancer experience some sort of pain (Whale, Lyne & Papanikolaou, 2001).

Physical morbidity is considered to be a complication that arises either directly because of the disease or from post-surgical effects. The most common post-surgical complication of neck dissection surgery is shoulder dysfunction (Oz & Memphis, 2009). One of the first to

report shoulder morbidity post neck dissection surgery was Ewing in 1952 (Givi et al., 2012). One of the causes of shoulder dysfunction is the surgical damage or complete resection of the spinal accessory nerve (SAN). Injury to this nerve leads to a series of signs and symptoms such as trapezius atrophy, restricted shoulder abduction, scapular dyskinesia, and shoulder girdle depression. Typically they are caused by palsy of the SAN (Bradley, Ferlito, Silver & Takes, 2011). Secondary to neck dissection, adhesive capsulitis, pain, post-surgical tightness and the effects of radiotherapy can also contribute to shoulder and neck morbidities (Merve, Mitra, Swindell & Homer, 2009).

Swallowing is a complex process which involves co-ordination of neural and muscular structures. Oral functions such as swallowing, speech, chewing and eating are influenced either by the location of the tumour or the different methods used to treat the tumour. Surgery and radiotherapy to the oral and oropharyngeal region causes significant impairments to speech and swallowing functions (Zuydam et al., 2005). It has been reported that 75% of patients with HNC may complain of swallowing problems post treatment (Dwivedi et al., 2012).

Various factors contribute to the psychological burden on patients with HNC. Most notably fear of cancer and fear of declining health are the major worries of the patients. Fear of cancer might include fear of recurrence of the disease, or of the diagnosis itself, as well as undergoing the diagnostic tests. Other fear include fear of survival (Devins et al., 2013).

Other consequences of HNC and its treatment can be related to the appearance of patients, such as body image problems and facial disfigurement. These factors cause anxiety and depression which in turn may lead to poor motivation, inability to focus and poor compliance with treatment regimens (Veer, Kia & Papesch, 2010).

While HNC and its treatments are associated with a number of complications, and declines in function and quality of life; it is important to determine whether these issues are a concern from a patient's perspective. Hence identification of patients' concerns through a holistic approach is essential.

## **1.4 Objectives of the study**

The objectives of this thesis project were:

1. To identify patient-reported concerns and the importance of these concerns at three time points during treatment: Pre-surgery, Discharge, and 1-month Post-surgery.
2. To identify changes in patient-reported concerns across the three time points during the treatment period.
3. To provide initial estimates of the cross-sectional validity of the Patient Concerns Inventory - Level of Importance questionnaire.

## CHAPTER 2

### **2 Introduction**

The study aims to explore and identify the different concerns of patients with HNC. It also seeks to provide initial estimates of mean importance ratings for these concerns as measured by the modified version of the PCI (PCI-LOI) at three different time points (Pre-surgery, 1-week after surgery at Discharge and 1-month Post-surgery). Finally, it hopes to yield preliminary evidence of the validity of the modified version of the PCI, the PCI-LOI.

### **2.1 Methods**

The project used a prospective cohort study design. It was conducted between March 2013 to August 2013 at the London Health Sciences Centre - Victoria Hospital campus. Ethics approval for the study was obtained from the Health Sciences Research Ethics board of Western University and from the Clinical Research Impact Committee (CRIC) of London Health Sciences Centre (LHSC) [see appendix A and B]. All participants provided informed written consent.

#### **Inclusion Criteria**

To be included in the study, persons had to be a patient at LHSC - Victoria Hospital campus with cancer of the head and neck area, over 18 years of age and scheduled for neck dissection surgery alone or in conjunction with various reconstruction flap procedures.

#### **Exclusion Criteria**

Patients with language and comprehension barriers were excluded.

## **2.2 Outcome Measures**

### **Patient Concerns Inventory – Level of Importance (PCI-LOI)**

The Patient Concerns Inventory (PCI) is a patient-reported questionnaire which is used to identify the concerns that are important to patients. The PCI consists of a battery of concerns which were identified from other health-related quality of life questionnaires and in consultation with patients, multidisciplinary health care team members and other patient support groups.

For this study, we incorporated an importance of rating scale for each concern listed in the original version to form the Patient Concerns Inventory - Level of Importance questionnaire (PCI-LOI). Each level of importance scale uses a 7-point adjectival rating scale that varies from No importance (1) to Very great importance (7). Therefore the PCI-LOI allows the patient to identify their concerns as well as rate the importance of each concern. [see appendix E]. The PCI-LOI has four domains: Physical and Functional Well-being (30 items; min-max 30-210; least to most important); Social Care and Social Well-being (9 items; min - max 9-63; least to most important); Psychological, Emotional and Spiritual Well-being (12 items; min-max 12-84; least to most important); and Treatment Related Concerns (2 items; min-max 2-14; least to most important). In addition, the PCI-LOI includes an "other concerns" section allowing the patient to include any concerns and an importance rating for these other concerns that might have been missed in the questionnaire. It also includes an open text box for patients to list their "top 3 concerns" as their most important issues. In this thesis project, we calculated domain scores for the first three domains and then summed these three values for a total PCI-LOI score.

### **University of Washington - Quality of Life scale (UWQOL)**

The University of Washington - Quality of Life scale (UWQOL) is one of the most commonly used patient-reported outcome measures for persons with HNC. The UWQOL questionnaire is a well validated instrument (Kazi et al., 2008) and it has been revised three

times from its original version which was introduced in 1993. The UWQOL has been extensively validated with other quality of life tools supporting its convergent validity (Laraway & Rogers, 2012). The tool has been widely used for almost two decades and is both simple and easy to administer (Rogers et al., 2009, Pusic et al, 2009).

The UWQOL version-4 has four components consisting of 12 items (pain, appearance, activity, recreation, swallowing, chewing, speech, shoulder, taste, saliva, mood and anxiety), an importance rating scale, general quality of life questions and a free-text section where patients can add their own comments. The response scale for each item can vary from 0 (worst) to 100 (best). In a separate item patients are also asked to identify the top three concerns that were the most important to them within the past seven days. The UWQOL version has been found to accurately compare treatment effects in the management of HNC. It was found to be valid, reliable and reproducible in patients with HNC (Weymuller, Alsarraf, Tueh, Deleyiannis & Coltrera, 2001).

### **Shoulder Pain and Disability Index (SPADI)**

The SPADI is a patient-reported assessment tool used to measure shoulder pain and disability. The SPADI consists of two subscales, pain (5 items) and disability (8 items). Each item is scored with a visual analog scale ranging from 0 to 10 (No pain/No difficulty to Worst pain imaginable/So difficult required help). The total SPADI score is calculated by averaging the total pain and disability subscale scores. The SPADI is a valid and reliable tool which demonstrates good internal consistency and has the ability to detect change in patient status over time (Angst, Schwyzer, Aeschlimann, Simmen & Goldhahn, 2011). The SPADI is short, easy to understand and a responsive shoulder instrument (Roach, Budiman-Mak, Songsiridej & Lertratanaku, 1991). The SPADI is one of the most common tools used to evaluate shoulder dysfunction and pain in patients undergoing neck dissection for HNC. It is also considered to be a valid instrument for identifying shoulder dysfunction and pain in patients undergoing neck dissection (Marchese et al., 2012, McNeely et al., 2004)

## **Neck Dissection Impairment Index (NDII)**

The NDII is a valid and reliable tool (Taylor et al., 2002). The tool is designed specifically to evaluate shoulder and neck function and quality of life in patients following neck dissection surgery. The NDII consists of 10 questions; each with a 5 level ordinal scaled response option ranging from “not at all” to “a lot”. The response for each item is then scored from 1 to 5, with 5 denoting higher quality of life (Not at all) and 1 being the least (A lot). The scores are then standardized to a 0-100 scale, worst to best state (Taylor et al., 2002, Murer, Huber, Haile & Stoeckli, 2011, Scott et al., 2007).

## **2.3 Procedure**

Potential study participants were identified by the Ear, Nose and Throat surgeons at the Head and Neck Clinic in Victoria Hospital - LHSC campus. The identified persons were then met by the graduate student investigator (D.A.D) at the Pre-admission clinic prior to surgery and written consent was obtained. Patients who had given their consent were then provided with the four patient-reported outcome measures (PCI-LOI, UWQOL, SPADI and NDII) in a self-addressed and stamped envelope and instructed to complete the forms and return them by mail. They were subsequently provided with the same packages during each of the next two time points (Discharge and 1-month Post-surgery). Participants were asked to complete the questionnaires within a couple of days of receiving it. They were instructed to return the envelope within a week after their visit to the hospital. If patients did not mail back their questionnaires, phone calls were made to remind them.

## **2.4 Sample Size Calculation**

Sample size calculation was based on an *a priori* decision about the number of subjects that could be obtained for this pilot study given a specific recruitment timeline and the rate of surgeries conducted at the hospital. The number of surgeries was estimated to be 6-8 per

week. With 20 weeks available for recruitment, a target of 40 eligible consenting patients (20 x 2) was determined to be achievable for this pilot study.

## **2.5 Analysis:**

Data analysis was done using SPSS software version 21 (IBM corp., USA). Means, standard deviations, frequencies and percentages were used as appropriate, to describe the sample at the Pre-surgery time point.

**Analysis for Objective 1** - Identify patient-reported concerns and importance of concerns at Pre-surgery, Discharge, and 1-month Post-surgery.

For the first objective we determined the median pre-surgical level of importance at the item level (i.e. for each concern) for the Physical and Functional Well-being domain, the Social Care and Social Well-being domain, the Psychological, Emotional and Spiritual Well-being domain and the Treatment Related Concerns domain of the PCI-LOI (n=32). At each time point, we described the mean and standard deviation for the PCI-LOI, the SPADI, the NDII and the UWQOL total scores.

**Analysis for Objective 2** - Identify changes in patient-reported concerns across the three time points during the treatment period.

Using a subset of study participants who provided patient-reported outcomes data at all three time points (n=13), we first described the mean and standard deviation for the PCI-LOI, the SPADI, the NDII and the UWQOL. Then we used one-sample t-tests to determine if the mean values for the patient-reported outcomes obtained from this smaller dataset (n=13) were significantly different than the values obtained using the full dataset that varied in sample size across the three time points because of non-response (Pre-surgery n=32, Discharge n=25, 1-month Post-surgery n=22). To determine if there was any significant difference in the patient-reported outcomes across the three time points, we used a Kruskal-Wallis test. Finally, we determined the top three concerns across the three time points using the UWQOL item that requested participants to rate their top 3 concerns.

**Analysis for Objective 3** - Provide initial estimates of the cross-sectional validity of the Patient Concerns Inventory - Level of Importance questionnaire.

For cross-sectional convergent validity, at all three time points, we estimated the association between the PCI-LOI and the other patient-reported outcomes using Spearman's Rank Correlation Coefficient. More specifically we examined the relationship between the PCI-LOI total, PCI-LOI domain scores and the UWQOL scores; and we examined the relationship between the PCI-LOI total score, the PCI-Physical and Functional and Well-being domain score and the SPADI and the NDII scores.

## **2.6 Results**

### **Patient Characteristics**

A total of 42 patients were approached, out of which 40 patients (23 males, 17 females) agreed to participate in the study (Figure 2.1). The mean age of the participants at the time of recruitment was 62.1 (range 32-90) years. There were seven (18.4%) patients who underwent radial neck dissection, 24 (63.2%) patients who underwent modified neck dissection and six (15.8%) patients who had a selective neck dissection procedure. There were 18 patients who did not undergo any reconstructive procedures along with the neck dissection surgery. Five patients underwent supraclavicular flap reconstructive procedure, five more underwent radial forearm flap procedure and four patients had a scapular flap procedure. Table 2.1 describes the patients' characteristics.

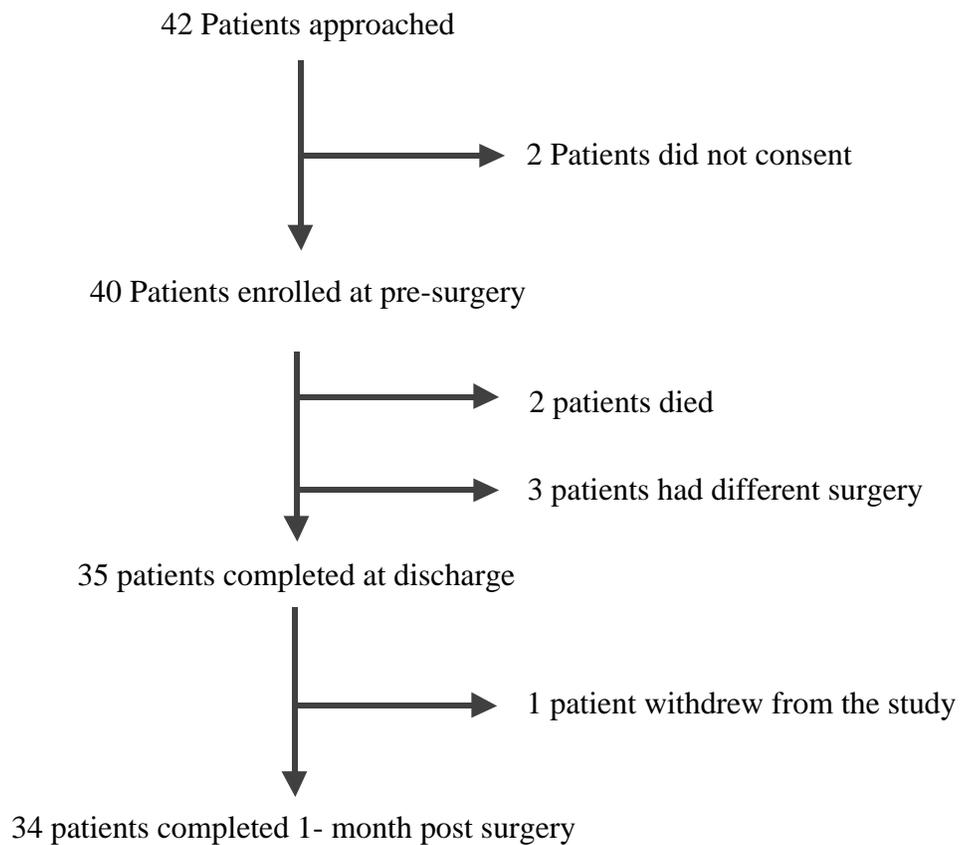
**Objective 1** - Patient-reported concerns and importance of concerns at Pre-surgery, Discharge, and 1-month Post-surgery.

Thirty-two patients completed the PCI-LOI at Pre-surgery. In the Physical and Functional Well-being domain, 20/30 (67%) concerns were identified to be of "Moderate" to "Great Importance" (Figure 2.2). In the Social Care and Social Well-being domain, 7/9 (78%) concerns were identified to be of "Moderate" to "Fairly Great Important" (Figure 2.3). For the Psychological, Emotional & Spiritual Well-being domain, 9/14 (64%) concerns were identified to be of "Moderate" to "Fairly Great Important" (Figure 2.4). For the Treatment Related domain, Feeding Tube Concerns and Wound Healing had median values of 4 and 5.5 respectively. There were only two concerns: Well-being of My Dependents/Children and

Feeding Tube Concerns, which were left empty by more than 10% of patients (4/32 or 12.5% for both items).

The descriptive statistics for the four patient-reported outcomes for all the patients who completed the questionnaires in a given time point is provided in Table 2.2

**Figure 2.1 Patient Enrollment**



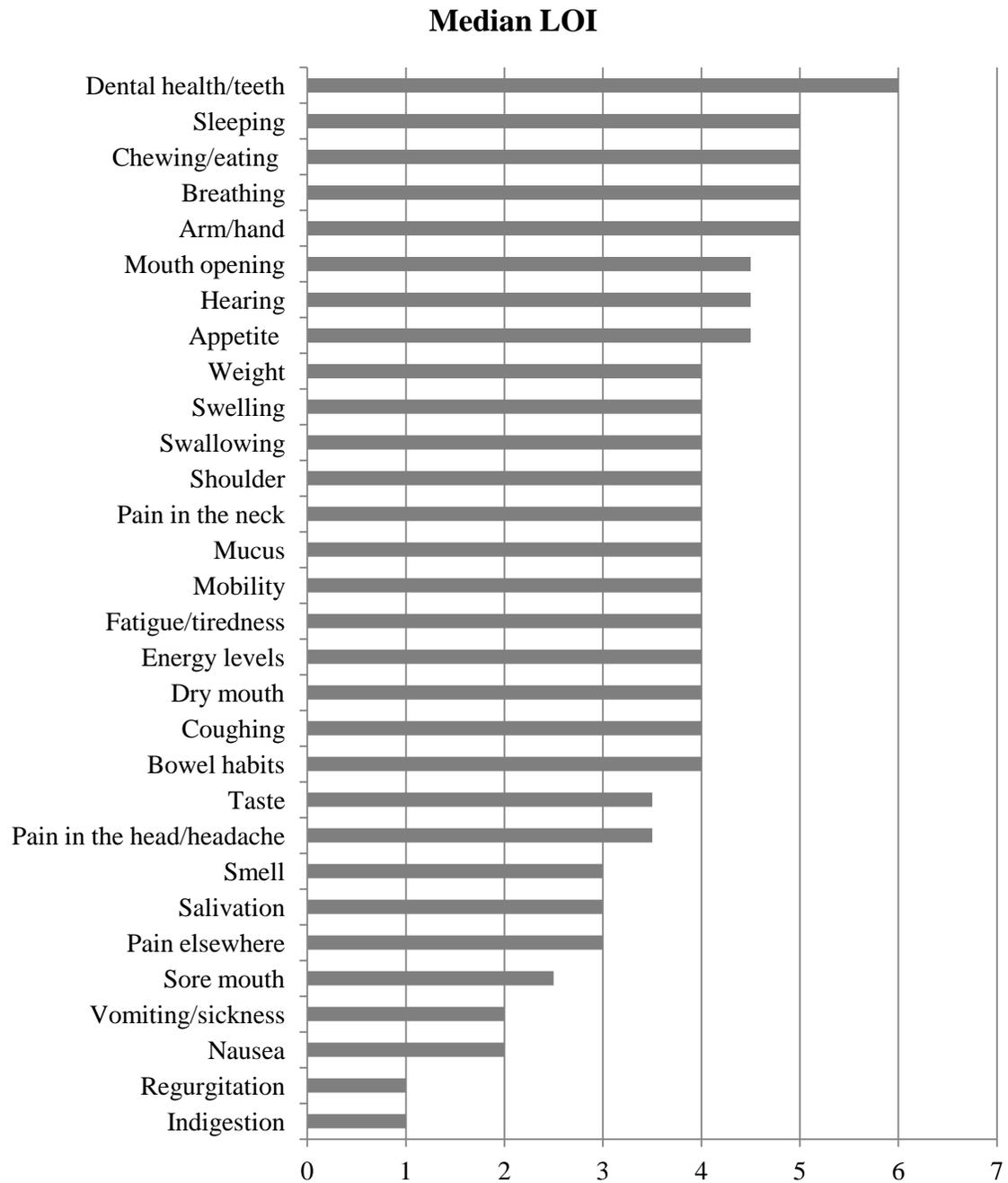
**Table 2.1 Patient Characteristics (means and percentages)**

Demographics	Total Participants (n=40)
<b>Age, years</b>	
Mean (minimum-maximum)	62.1 (32.0 – 90.0)
<b>Gender, n (%)</b>	
Male	23 (57.5)
<b>Dominant Side, n (%)</b>	
Left	3 (7.5)
Right	33 (82.5)
Ambidextrous	4 (10.0)
<b>Surgery<sup>a</sup>, n (%)</b>	
Radical	7 (18.4)
Modified <sup>b</sup>	24 (63.2)
Selective <sup>b</sup>	6 (15.8)
<b>Reconstructive Flap, n (%)</b>	
Supraclavicular	5 (13.2)
Radial Forearm	5 (13.2)
Scapular	4 (10.5)
Local Rotational Flap	3 (7.9)
Thigh	2 (5.3)
Fibular	1 (2.6)
No Flap	18 (47.4)
<b>Pain, n</b>	
Reported before Surgery	10
Reported after surgery <sup>c</sup>	22
<b>Painful side Post-Surgery, n</b>	
Left	10
Right	10

<sup>a</sup> total surgeries (n=38), <sup>b</sup>one patient had both modified and selective neck dissection,

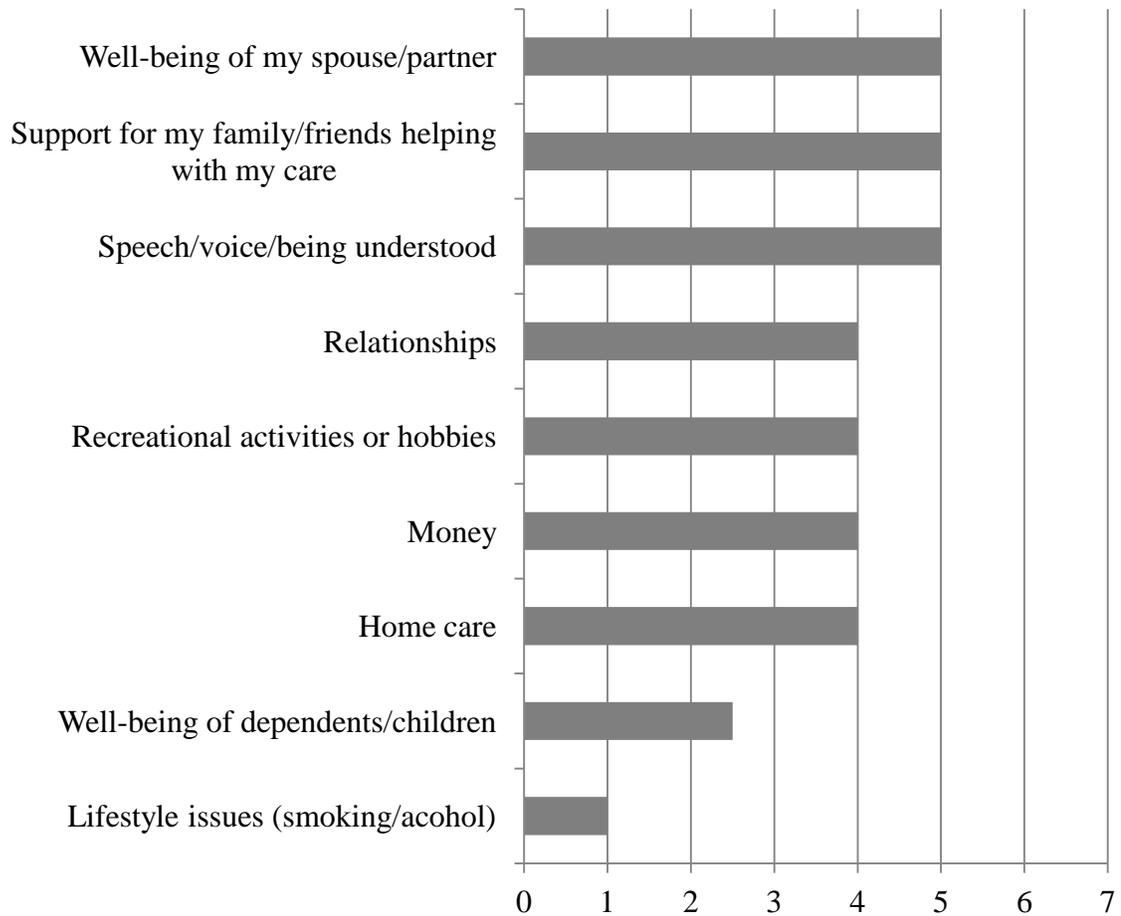
<sup>c</sup> participants followed up post-surgery (n=30)

**Figure 2.2 Patient-rated Level of Importance for Pre-surgical Concerns in the Physical & Functional Well-being Domain of the PCI-LOI, ranked by median Level of Importance (n=32)**



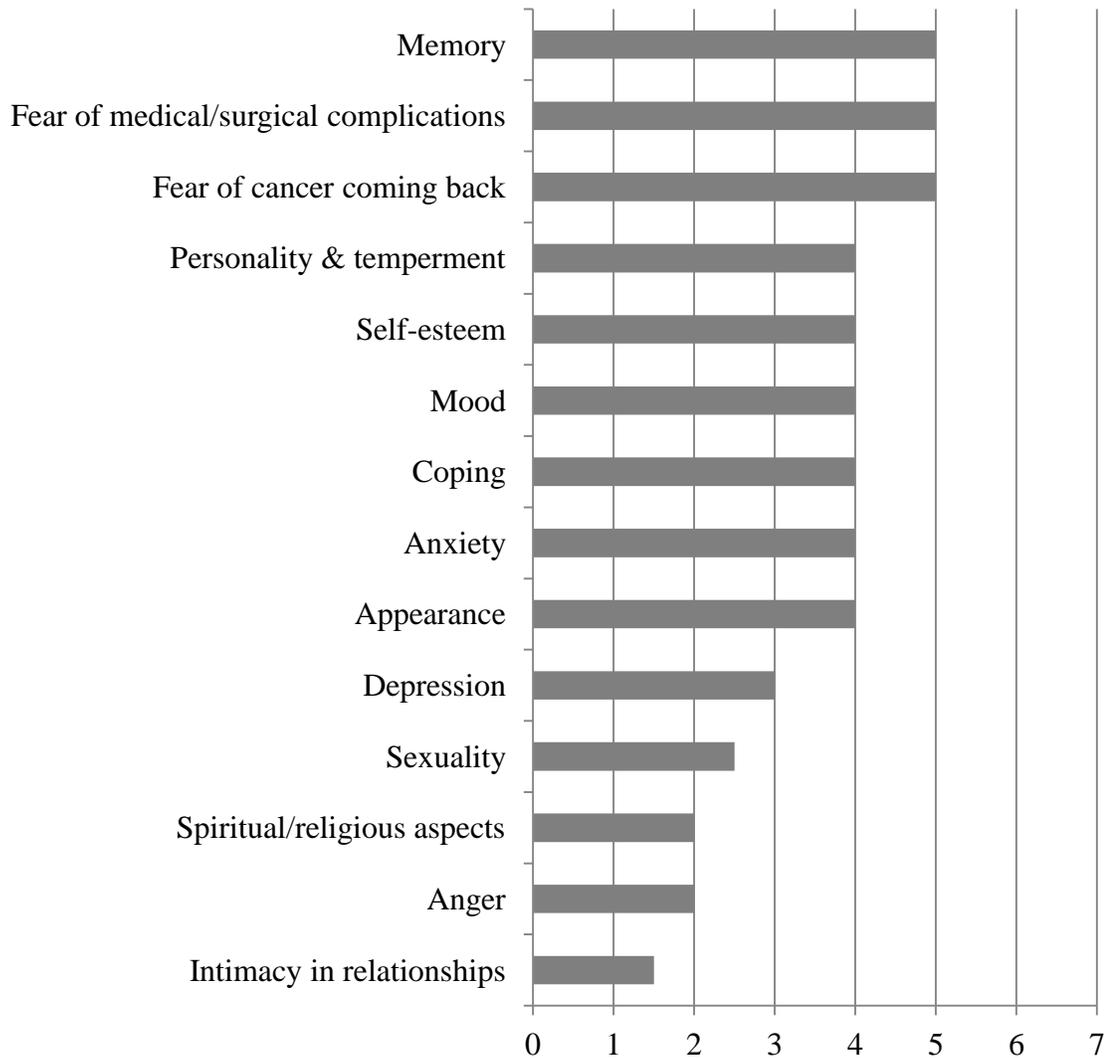
PCI-LOI = Patient Concerns Inventory – Level of Importance Questionnaire  
 Level of importance scale = 1 (None), 2 (Very Small), 3 (Small), 4 (Moderate), 5 (Fairly Great), 6 (Great) & 7 (Very Great)

**Figure 2.3 Patient-rated Level of Importance for Pre-surgical Concerns in the Social care and Social Well-being Domain of the PCI-LOI, ranked by median Level of Importance (n=32)**



PCI-LOI = Patient Concerns Inventory – Level of Importance Questionnaire  
Level of importance scale = 1 (None), 2 (Very Small), 3 (Small), 4 (Moderate), 5 (Fairly Great), 6 (Great) & 7 (Very Great)

**Figure 2.4 Patient-rated Level of Importance for Pre-surgical Concerns in the Psychological, Emotional & Spiritual Well-being Domain of the PCI-LOI, ranked by median Level of Importance (n=32)**



PCI-LOI = Patient Concerns Inventory – Level of Importance Questionnaire  
Level of importance scale = 1 (None), 2 (Very Small), 3 (small), 4 (Moderate), 5 (Fairly Great),  
6 (Great) & 7 (Very Great)

**Objective 2** - Identify changes in patient-reported concerns across the three time points during the treatment period.

The statistics for patients who completed the questionnaires at all three time points (n=13) are described in Table 2.3. In one-sample t-testing, only the SPADI total score at pre-surgery was found to be significantly different between the smaller subset (Table 2.3) and the full sample (Table 2.2),  $p < 0.05$ . The Kruskal-Wallis test determined that there was a significant difference between Pre-Surgery, Discharge and 1-month Post-surgery scores of the SPADI (chi-square 12.8), NDII (chi-square 13.5) and UWQOL (chi-square 6.5). Mean ranks are shown in Table 2.7.

The top 3 concerns on the UWQOL identified at the three time points are provided in Table 2.4. While “Anxiety” was the most selected concern at Pre-surgery, it was “Appearance” that was most selected at Discharge and 1-month Post-surgery. “Pain” was identified as one of the top 3 concerns at Discharge and “Shoulder” was identified as a top concern at Discharge and 1-month Post-surgery. Only “Appearance” and “Activity” were selected to be among the top 3 concerns across all the three time points. Prior to surgery 13/32 (40.7%) patients identified their concerns. At discharge 13/24 (54.2%) of patients identified their concerns. At 1-month Post-surgery 13/23 (56.6%) of patients identified their concerns.

**Table 2.2 Descriptive statistics of patient-reported outcomes**

Patient-Reported Outcomes	Pre-Surgery <sup>a</sup>		Discharge <sup>b</sup>		1 Month <sup>c</sup>	
	Mean	SD	Mean	SD	Mean	SD
<b>PCI</b>						
Physical & Functional Well-being	114	56	112	50	97	58
Social Care & Social Well-being	32	17	33	17	30	17
Psychological, Emotional & Spiritual	50	23	49	25	46	27
Treatment Related	9	4	7	4	5	4
Total score	203	91	201	85	178	101
<b>SPADI</b>						
Total Percentage	13	19	44	28	41	40
<b>NDII</b>						
Total Standardized Score	81	19	40	26	63	25
<b>UWQOL</b>						
Total Score	952	181	755	232	885	225

<sup>a</sup> Pre-Surgery (n): PCI-LOI - 32, UW-QOL - 32, SPADI - 29, NDII - 25, <sup>b</sup> Discharge (n) PCI-LOI - 24, UW-QOL - 24, SPADI - 24, NDII - 20, <sup>c</sup> 1-month (n) : PCI-LOI - 22, UWQOL - 22, SPADI - 21, NDII - 20  
PCI-LOI - Patient Concerns Inventory-Level of Importance, SPADI - Shoulder Pain and Disability Index, NDII - Neck Dissection Impairment Index, UWQOL - University of Washington Quality of Life Scale, SD- standard deviation

**Table 2.3 Descriptive statistics of patient-related outcomes completed at all three time points (n=13)**

Patient-Reported Outcomes	Pre-Surgery		Discharge		1 Month	
	Mean	SD	Mean	SD	Mean	SD
<b>PCI-LOI</b>						
Physical & Functional Well-being	115	63	114	49	103	64
Social Care & Social Well-being	34	16	33	17	30	19
Psychological, Emotional & Spiritual	52	27	50	26	49	28
Treatment Related	10	5	7	4	6	4
Total score	211	106	204	94	189	113
<b>SPADI</b>						
Total Percentage	7	10	40	24	37	30
<b>NDII</b>						
Total Standardized Score	82	16	47	25	64	23
<b>UWQOL</b>						
Total Score	988	144	745	260	872	212

PCI-LOI - Patient Concerns Inventory-Level of Importance, SPADI - Shoulder Pain and Disability Index, NDII - Neck Dissection Impairment Index, UWQOL - University of Washington Quality of Life Scale

SD - standard deviation

**Table 2.4 Top three concerns identified by patients at three time points**

Rank	Concerns (frequency)		
	Pre-Surgery <sup>a</sup>	Discharge <sup>b</sup>	1-month <sup>b</sup>
1	Anxiety (6)	Appearance (7)	Appearance (8)
2	Appearance+Activity (4)	Pain+Speech (6)	Shoulder (6)
3	Mood+Swallowing (3)	Shoulder+Activity (4)	Swallowing+Activity (5)

<sup>a</sup> n=11<sup>b</sup> n=13

**Objective 3** - Initial estimates of cross-sectional validity for the Patient Concerns Inventory - Level of Importance questionnaire.

The PCI-LOI demonstrated moderate correlations at Discharge and 1-month Post surgery (Table 2.5 & 2.6). At Pre-surgery, there was no significant correlation between the PCI-LOI and the other three questionnaires (Tables 2.5 and 2.6 provide the correlations). At Discharge, the PCI-LOI total scores and domain scores were correlated significantly with UWQOL total scores. The correlation between PCI-LOI and the UWQOL (Figure 2.5) had a moderate negative correlation of -0.48 ( $p < .05$ ), while correlation between the Physical Function Domain of PCI-LOI and UWQOL produced a significant moderate correlation of -0.55 ( $p < .05$ ). The correlation between the other two domains of PCI-LOI also produced significant negative correlations with UWQOL (see Table 2.5). Between PCI-LOI and SPADI at Discharge there was a moderate positive correlation of 0.45 ( $p < .05$ ), while the correlation was 0.40 ( $p < .05$ ) between Physical Function Domain of PCI-LOI and the SPADI. There was no significant correlation between PCI-LOI and NDII. The Physical Function of the PCI-LOI had a weak negative correlation of -0.31 ( $p > .05$ ) with the NDII (Table 2.6).

At 1-month Post-surgery, there were significant correlations between PCI-LOI, UWQOL and SPADI total scores. However only the Psychological, Emotional & Spiritual Domain of the PCI-LOI had a significant correlation of 0.45 ( $p<.05$ ) with the UWQOL (Table 2.5). The strongest correlation at 1-month Post-surgery was found between the PCI-LOI and the SPADI total scores (Table 2.6, Figure 2.6) with 0.57 ( $p<.05$ ) and Physical Function Domain of PCI-LOI and SPADI had a correlation of 0.62 ( $p<.05$ ).

**Table 2.5 Correlations between PCI-LOI and UWQOL**

PCI-LOI	UWQOL		
	Pre-surgery	Discharge	1-Month
	n=32	n=25	n=22
Total Score	-0.156	-0.483 <sup>a</sup>	-0.429 <sup>a</sup>
Physical Function	-0.195	-0.550 <sup>a</sup>	-0.417
Social & Social Care	-0.096	-0.427 <sup>a</sup>	-0.422
Psychological, Emotional, Spiritual	-0.111	-0.446 <sup>a</sup>	-0.453 <sup>a</sup>

<sup>a</sup>  $p<.05$

PCI-LOI - Patient Concerns Inventory Level of Importance, UWQOL - University of Washington Quality of Life scale

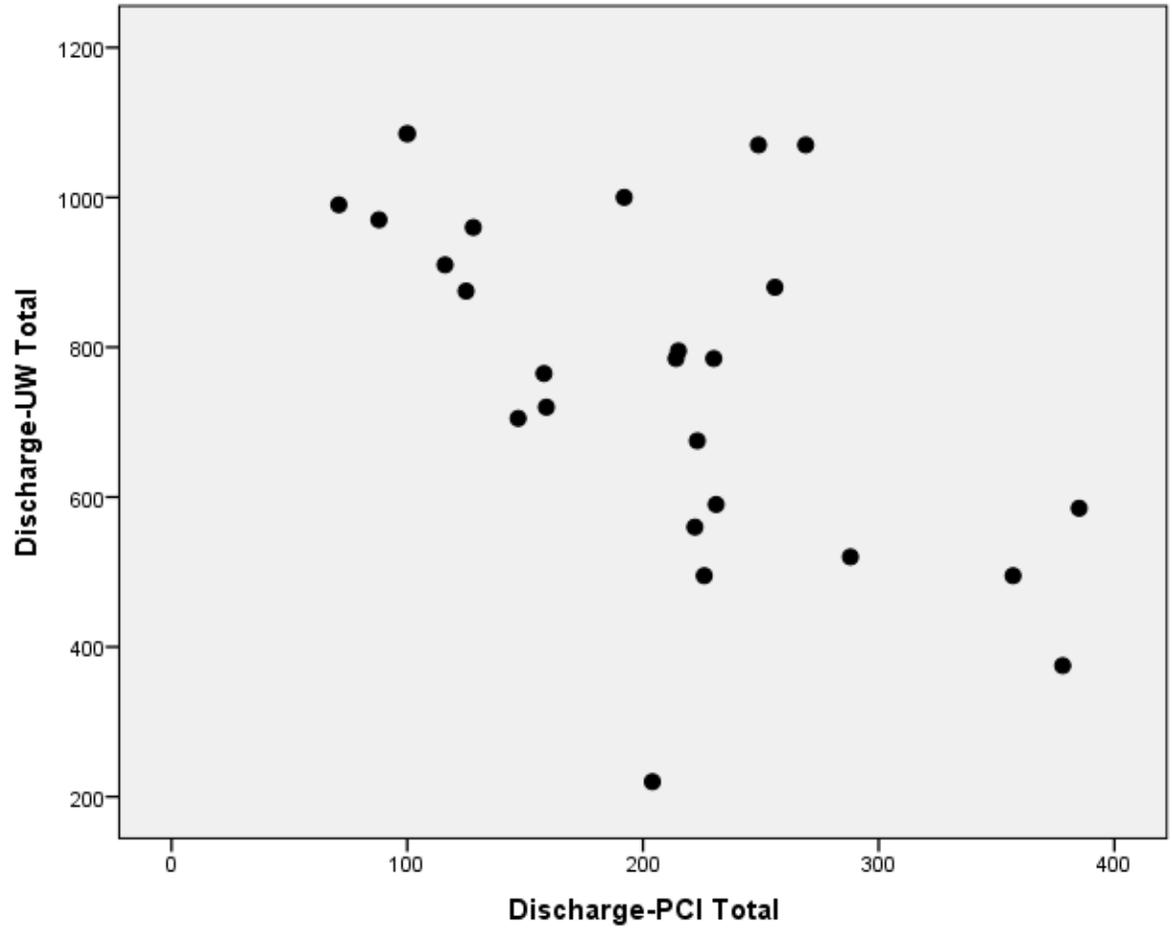
**Table 2.6 Correlations between PCI-LOI, SPADI and NDII**

PCI-LOI	SPADI			NDII		
	Pre-surgery	Discharge	1-Month	Pre-surgery	Discharge	1-Month
	n=29	n=25	n=21	n=25	n=21	n=20
Total Score	0.306	0.446 <sup>a</sup>	0.573 <sup>a</sup>	-0.242	-0.243	-0.252
Physical Function	0.266	0.400 <sup>a</sup>	0.618 <sup>a</sup>	-0.130	-0.308	-0.325

<sup>a</sup> p<.05

PCI-LOI - Patient Concerns Inventory-Level of Importance, SPADI - Shoulder Pain and Disability Index, NDII - Neck Dissection Impairment Index

**Figure 2.5 Scatter plot for PCI-LOI and UWQOL at Discharge**

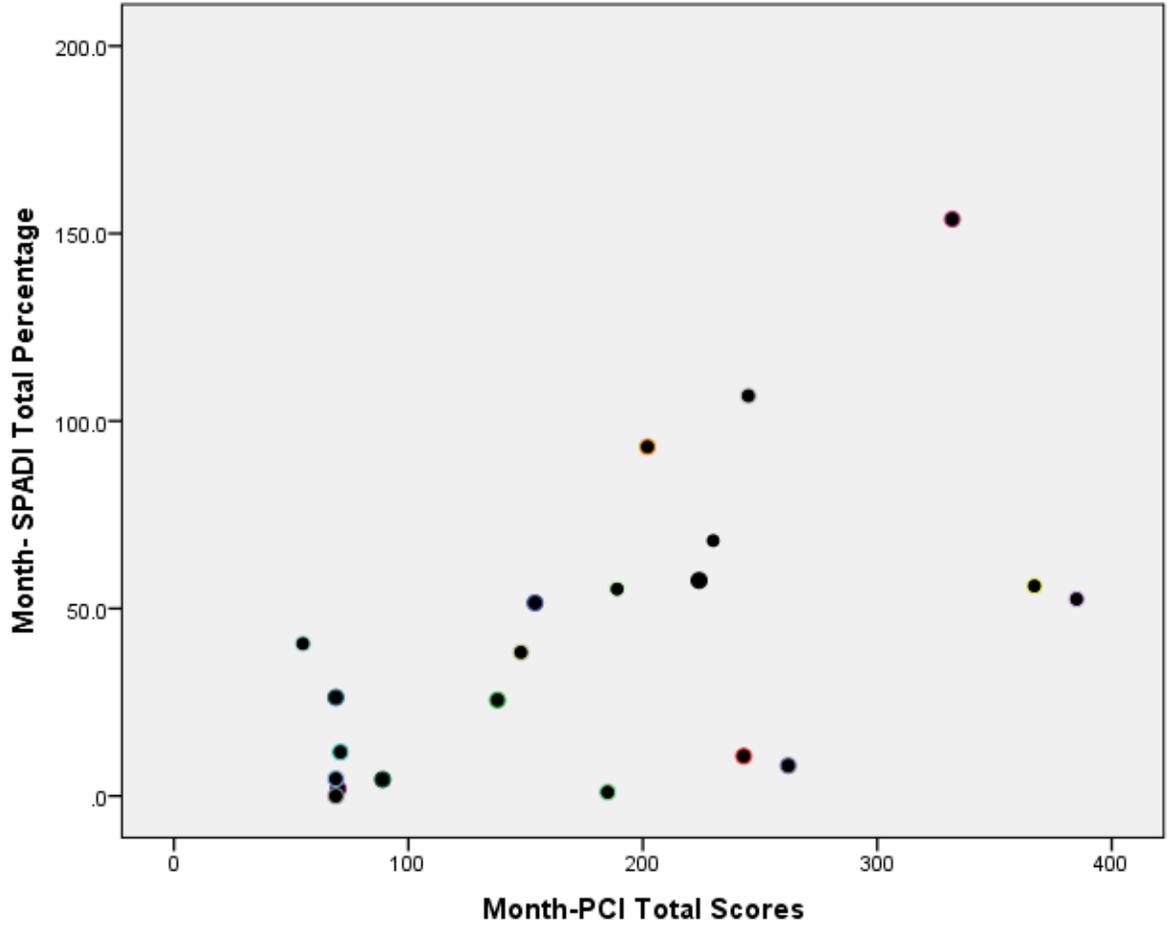


X-AXIS - PCI-LOI Total Score

Y-AXIS - UWQOL Total score

PCI-LOI - Patient Concerns Inventory Level of Importance, UWQOL - University of Washington Quality of Life scale

Figure 2.6 Scatter plot for PCI-LOI and SPADI at 1-month Post-surgery



X-AXIS - PCI-LOI Total Score

Y-AXIS - SPADI Total Percentage Score

PCI-LOI - Patient Concerns Inventory Level of Importance, SPADI - Shoulder Pain and Disability Index

**Table 2.7 Kruskal-Wallis test involving the patient-reported outcomes across the three time points (n=13)**

Patient-reported Outcomes	Mean Ranks			Chi square	p value
	Pre-Surgery	Discharge	1-month		
PCI-LOI					
Total Score	21.42	20.42	18.15	0.56	0.76
Physical Function	20.54	20.85	18.62	0.30	0.86
Social Care	21.65	19.73	18.62	0.47	0.79
Psychological, Emotional	21.46	19.88	18.65	0.38	0.82
SPADI	10.88	25.69	23.42	12.77	0.002
NDII	28.58	12.23	19.19	13.48	0.001
UWQOL	25.65	14.27	20.08	6.49	0.039

PCI-LOI - Patient Concerns Inventory-Level of Importance, SPADI - Shoulder Pain and Disability Index, NDII - Neck Dissection Impairment Index, UWQOL - University of Washington Quality of Life scale

## 2.7 Discussion

In this study we examined concerns of the patients undergoing neck dissection surgery. We identified various issues the patients were worried about at Pre-surgery, Discharge and 1-month Post-surgery and examined the change in patient concerns across the three time points. The study also investigated the relationship between the PCI-LOI with other patient-reported outcome measures used in patients with HNC.

### Patient concerns

The most significant finding of this pilot was the identification of patients' concerns at Pre-surgery, Discharge and 1-month Post-surgery. "Anxiety" was the most important concern at Pre-surgery. At Discharge and 1-month Post-surgery, "Appearance" was the most important

concern. This is the first study to identify patient-reported concerns at three different phases of the treatment period in patients with HNC. These self-identified concerns enable us to determine that patient-reported outcome measures can be used to gain insight about the issues that the patients are actually worried about.

"Anxiety" in patients with HNC can be attributed to numerous factors. Several studies have found that patients undergo considerable psychological distress during the course of the treatment for HNC (Pandey, et al., 2007; Buchmann, Conlee, Hunt, Agarwal & White, 2013). A study by Joseph and colleagues (2013) concluded that anxiety score was highest at pre-treatment and depression was highest at the completion of treatment in patients who underwent a radical radiotherapy treatment. Anxiety scores showed significant difference when comparing pre-surgery to treatment completion. This result supports our study's findings in which "Anxiety" was identified as the most important concern reported by patients at Pre-surgery, but was not among the top 3 concerns at Discharge and 1-month Post-surgery. Patients have numerous stressful factors due to the complex nature of the HNC and its treatment methods. It is highly distressing for patients who are awaiting their results for the investigative procedure and it is evident during their consultation (Veer, et al., 2010). In addition, whatever the type of treatment the patient might undergo for HNC there are always physical, psychological and social consequences. Hence it is understandable that patients are more anxious before treatment than at any other time point during the course of their treatment period.

"Appearance" was identified as one of the top 3 concerns at all three time-points and it is the most important concern at Discharge and 1-month Post-surgery. (Fingeret, et al., 2012) conducted a cross-sectional study, and obtained data from participants at different time points and concluded that at least 75% of the patient population was feeling concerned with respect to bodily changes related to the treatment for HNC and at least 38% of them avoided social interaction due to their body and image concerns, supporting the results from our study. The possible explanation for "Appearance" as an important concern for the HNC population may be due to surgical intervention, the primary method of treatment for HNC. The type and extent of surgeries depend on the location and size of the tumor (Scarpa, 2009) and surgical management can be extensive. The surgical site is mostly around the neck and facial region for most individuals with HNC and this can be quite distressing for patients. At Post-surgery,

the fear of facial appearance and body image concerns are high, due to the aftermath of the surgeries. In addition, patients with large tumors may undergo reconstructive surgeries. Despite advancement in surgeries, appearances of the patients are often changed thus sparking concerns over appearance and body image. Fear of social stigma is often found to be the cause of patients to be reclusive post-reconstructive surgery due to change in their appearance due to scarring and/or disfigurement (Bonanno & Esmaeli, 2012).

One other important trend is that the patients identified at least one of the oral functions at all three time points. Recent research suggests that patients with eating and speech concerns found significantly higher level of appearance concerns (Fingeret, Hutcheson, Jensen, Yuan & Urbauer, 2013). These findings agree with results of our study where oral functions such as "Swallowing" and "Speech" were identified as one of the top 3 concerns at all three time-points with "Appearance" as the top concern. Swallowing outcomes are better with chemo-radiation than with surgery and radiation in oropharyngeal cancer (Gillespie, Brodosky, Day, Lee & Martin-Harris, 2004). Swallowing was found to be difficult in patients who underwent oropharyngeal resection and primary closure (Barata, de Carvalho, Angelis, de Faria & Kowalski, et al, 2013). Patients might also have swallowing and speech issues if tumours exist in tongue, larynx and pharynx. The severity on the oral function depends on the size and location of the tumour.

Post-surgical physical morbidity is one of the major issues post-surgery in HNC patients. Physical morbidity can curtail patient's mobility and activities depending on the extent of surgery and its damage on the soft tissue structures. We showed that "Activity" was identified as one of the top 3 concerns at all three time-points. This indicates that patients are concerned about surgery's effect on "Activity". One of the most important physical morbidities post-surgery is shoulder dysfunction (Van Wilgen, et al., 2003, Merve, Mitra, Swindell & Homer, 2009). Out of our three time points, "Shoulder" was not identified as a concern by any of the 11 patients at Pre-surgery. At Discharge, 4/13 patients and at 1-month Post-surgery, 6/13 patients have identified "Shoulder" as a concern to them. There is a trend that "Shoulder" concerns do increase over time and this can also be a factor that patients start to worry more about the shoulder dysfunction more than being worried about "Activity" levels. Laverick and colleagues (2004) conducted a study to compare quality of life between surgical and non-surgical patient populations and found that there was dramatic increase in

shoulder dysfunction up to 6-months post-surgery followed by a slight improvement over time. Our results showed that "Shoulder" was one of the top concerns and reiterates that shoulder dysfunction does cause concerns for HNC patient population. Research has provided the evidence about prevalence of shoulder morbidity in patients who underwent neck dissection surgery (van Wilgen et al., 2004, Scott, Lowe & Rogers, 2007). In recent years, research (McNeely et al., 2008, McGarvey, Osmotherly, Hoffmann & Chiarelli, 2013) has been done to examine the effect of physiotherapy on shoulder morbidity and found that physiotherapy and exercises have reduced pain and mobility issues and improved the overall functional ability of the shoulder and quality of life of the patients. The information from our study can be used to get a better understanding of patients shoulder concerns and if required the patients may be referred to physiotherapist for assessment.

More patients started to identify their concerns at Discharge and 1-month Post-surgery. The percentage of people who identified their concerns increased from 40.7% at Pre-surgery to 56.6% at 1-month Post-surgery. An increased incidence of issues after surgery affects the patients and these are reported because they are a concern for the patients. A contributing factor to the increase in percentage might also be due to the smaller sample size at Discharge and 1-month Post-surgery.

Our results provide a good idea about the priorities of patients with respect to their concerns at three different time points. Overall, it is clear that "Appearance" is considered very important across all the three time points. Oral functions (speech/swallowing) identified at three time points agrees with previous results about the surgery and its effect on oral function. "Activity" decreased as a concern whereas "Shoulder" concerns were identified over time. If a trend in increase of shoulder concerns continues, physiotherapy can be considered as an integral part of post-surgical management of HNC patients. Future studies can consider assessing patients with physical measures along with the patient-reported outcome measures to gain better knowledge about patients' shoulder problems.

This study was able to provide important insight about patient concerns and priority at early phases of patient treatment. We also showed subtle trends among the identified patient concerns across the three time points. With an improved sample size and following patients

for a longer time, we may find further information on patient concerns in HNC population undergoing a surgical treatment.

#### **Validity of Patient Concerns Inventory-Level of Importance:**

We examined the validity of the modified Patient Concerns Inventory PCI – Level of Importance. The PCI-LOI had a moderate negative correlation with the UWQOL (a valid and reliable instrument used in patients with HNC). This indicated that patients with less QOL had higher levels of concern post-surgery as measured by their importance ratings. Patients with HNC have many factors affecting them physically, psychologically and socially and hence the lower QOL scores. Patients have a considerable post-surgical physical morbidity especially body image issues that affected them both psychologically and socially. This can be explained by the stronger correlation ( $r = -0.55$ ) of the PCI-LOI Physical and Functional Well-being domain with the UWQOL. We also showed a moderate correlation between PCI-LOI and UWQOL at 1-month Post-surgery ( $r = -0.42$ ).

We found no significant correlations between these measures at Pre-surgery. This may be explained by the fact that the questionnaires' instructions to patients may not both be applicable at this time point. The PCI-LOI instructions indicate to patients "*We would like to know what is important to you with respect to undergoing Neck Dissection Surgery. Please indicate how important the following items are to you during the last week*". The first instruction asks the patients to think about the possible issues or factors related to neck dissection surgery which might be a concern to them. In contrast, the UWQOL provides the following instruction, "*The questionnaire asks about your health and quality of life over the past seven days. Please answer all of the questions by checking one box for each question*". There is no mention of the surgery in the instruction and hence the information provided by patients might be only about their quality of life issues for the "past seven days". This may explain the weak non-significant correlation between the PCI-LOI and its domains with the UWQOL.

A study by Chen and colleagues (2011) examined the short form, head and neck cancer-specific, Chinese version of the Cancer Needs Questionnaire (CNQ-SF-hn) by determining its relationship with the UWQOL subscale score. The authors concluded that with a moderate correlation ( $r = -0.42$  to  $-0.34$ ), between the subscale scores and the QOL scores, people who

need a higher level of care and need have a lower quality of life and inferred that the unmet needs identified by the CNQ-Sf-hn are important predictors of QOL. Our PCI had a similar correlation with the UWQOL. We agree that people reporting a higher level of importance for their concerns may be predictors of a low quality of life, suggesting that identifying and resolving patient concerns could result in a better quality of life.

Our PCI-LOI had a moderate correlation with the SPADI at Discharge ( $r = 0.45$ ) and a higher correlation at 1-month Post-surgery ( $r = 0.57$ ). There was no significant correlation at Pre-surgery. The SPADI asks questions specific to shoulder function and quality of life and the PCI-LOI asks the patient to report the level of importance of each of the issues listed in the tool. The mean age of the population was 62.1 yrs, suggesting that some patients might have had a pre-existing shoulder problem that might have been detected by the SPADI, but was not necessarily a patient concern at Pre-surgery. Around Discharge the patients may be overwhelmed by many issues related to surgery and recovery; there is a good chance that the shoulder is not probably among the most important concerns at that point in time, whereas the SPADI picked up the difference and hence we saw the moderate correlation rather than a stronger correlation. However 1-month Post-surgery is when patients are more active and are hence more stable than at Discharge. Shoulder problems with pain and mobility issues can be easily identified which is reported in both the PCI and SPADI and hence we saw a better correlation. This study also did identify that patients selected "Shoulder" as one of their top 3 concerns at Discharge and 1-month Post-surgery when more people identified it as an important concern. This supports the correlation findings between the PCI-LOI and SPADI.

Patient Concerns Inventory-Level of Importance was able to demonstrate that majority of the issues listed in the questionnaire were of moderate to great importance to the patients at Pre-surgery. The fact that only two issues were not selected by more than 10% of the patients demonstrates that the PCI-LOI can become a practical tool that is appropriate for the HNC population. Due to the sharp decline in sample size at the follow up time points, we did not analyze the item level values for Discharge and 1-month Post-surgery.

Patients failing to send back their questionnaires during their follow-up time points increased. This resulted in a smaller sample size. Some of the patients failed to mail back the documents within the specified timeline. These are the major factors that have contributed to the weaker

correlation between the outcomes measures. Larger sample size and better data collection and follow up with patients will help to improve the correlation and level of agreement between the PCI-LOI and the other patient-reported questionnaires. Collection of additional information like pre-surgical morbidities will be helpful in a longitudinal analysis.

**Difference between time-points:**

We wanted to determine the presence of significant differences between Pre-surgery, Discharge and 1-month Post-surgery with respect to the patient-reported outcome scores. The one sample t-tests confirmed that the total scores at each time point for this small group within the sample who had complete data (n=13) was no different than the total score of our cross-sectional values with variable sample sizes at each time point. The exception was at Pre-surgery for the SPADI score. Thus our sub-sample of 13 with complete data can be considered to be representative of the larger sample at each time point.

Kruskal-Wallis tests confirmed the presence of significant differences between Pre-surgery, Discharge and 1-month Post-surgery with respect to the total scores of the UWQOL, SPADI and NDII scores. The study was able to identify the difference in the quality of life of patients as reported in the outcome measures across the three time-points. This confirms that QOL of patients does change over time. With better sample size and increased follow up-period, the study will be more effective to identify the specific QOL changes over time.

We have showed that patients are concerned about issues that are directly or indirectly related to HNC. These issues and their importance tend to change at different time points of the treatment period. The study was also able to find specific issues that were identified as important concerns across all the three time points. This information from this study can be used in further analysis of patients concerns following a neck dissection with a longer follow-up period of the HNC patients. For the health care team this information will be useful to understand and alleviate the various problems faced by the patients.

## Chapter 3

### 3 Conclusion

Patient concerns can be identified at different phases of the treatment using patient-reported outcome measures. Our results show that "Anxiety" at Pre-surgery and "Appearance" at Discharge and 1-month are the most important concerns for our participants. We also showed that patients' perception on the importance of these concerns varies at different time points (the top 3 concerns selected by the patients were different at each time point). Patient Concerns Inventory - Level of Importance has shown to correlate negatively with UWQOL and positively with SPADI at Discharge and 1-month Post-surgery. When the patients' quality of life decreases post-surgery, this is shown by increases in patient concerns and when shoulder issues are reported on the SPADI, it also results in increases in patient concerns. Although this result cannot be used as conclusive evidence for the validity of PCI-LOI, there is scope for the PCI-LOI to evolve and this information from this can be useful for future studies with better sample size to test the measurement properties.

By identifying patient concerns, the information can be used to understand the factors affecting the patients during the different phases of the treatment. The multi-disciplinary health care team can use this information to plan their patient management that caters to the patient-identified needs.

## Chapter 4

### 4 Limitations

Our study had some limitations. The first one is on the sample size. This study was designed as a pilot study on the recruitment timeline along with the number of surgeries performed at the hospital. The goal was to have 40 patients in the study within a period of six months. We did achieve the numbers of having 40 patients at baseline, but our numbers fell sharply as the study progressed. Some patients did not return the questionnaire within a specific timeframe and some of the patients completely failed to return the questionnaire.

The original plan was to get the participants to complete all the patient-reported outcome measures either at the pre-admission clinic or at the head and neck clinic. However there were four questionnaires and given the busy nature of the clinics it was not possible to get the patients to complete them at the clinic. We provided them with a stamped self-addressed package so that they could fill them out at home and mail it back to us. We made efforts to remind the patients through phone calls to return the package if we did not receive it within a specific time period. However, despite our efforts the number of patients who answered all the four outcome measures at the three time points fell sharply.

The next limitation was related to the specific time frame the patients were required to return the questionnaires so that their data actually reflected the specific follow-up time points mentioned in the study. However some patients returned their package later than expected.

With a smaller sample size our study is under-powered to make conclusions on the identification of patient concerns and validation of the PCI-LOI. Increased sample size with better data collection strategies will allow for more certainty in our results.

## Chapter 5

### 5 References

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## **Appendix A- Ethics approval forms**



Use of Human Participants - Ethics Approval Notice

Research Ethics

Principal Investigator: Dr. Boff Chesworth  
 File Number: 103096  
 Review Level: Delegated  
 Approved Local Adult Participants: 50  
 Approved Local Minor Participants: 0  
 Protocol Title: Patient Concerns Following Head and Neck Surgery for Cancer  
 Department & Institution: Schulich School of Medicine and Dentistry/Epidemiology & Biostatistics, Western University  
 Sponsor:  
 Ethics Approval Date: October 25, 2012 Expiry Date: August 31, 2013  
 Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Letter of Information	Appendix - A contains the Letter of Information to the patients	2012/09/21
Other	Appendix B, contains the Consent form for the patients.	2012/09/21
Other	Appendix C, contains the Pre-Surgical data collection form for the study.	2012/09/21
Other	Appendix D, contains the Post-Surgical data collection form for the study.	2012/09/21
Other	Appendix E, contains the Surgical details data extraction form, for the study	2012/09/21
Other	Appendix F, contains the Shoulder Pain And Disability Index (SPADI).	
Other	Appendix G, contains the Neck Dissection Impairment Index (NDII)	
Other	Appendix H, contains the Patient Concerns Inventory (PCI).	

Western University  
Protocol

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/CH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request Form.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

## **Appendix B - CRIC Approval**

**LAWSON FINAL APPROVAL NOTICE**

RESEARCH OFFICE REVIEW NO.: R-12-485

PROJECT TITLE: Patient Concerns Following Head and Neck Surgery for Cancer

PRINCIPAL INVESTIGATOR: Dr. Bert Chesworth

LAWSON APPROVAL DATE: November 22, 2012

Health Sciences REB#: 103096

Please be advised that the above project was reviewed by the Clinical Research Impact Committee and the project:

**Was Approved**

**PLEASE INFORM THE APPROPRIATE NURSING UNITS, LABORATORIES, ETC. BEFORE STARTING THIS PROTOCOL. THE RESEARCH OFFICE NUMBER MUST BE USED WHEN COMMUNICATING WITH THESE AREAS.**

Dr. David Hill

V.P. Research

Lawson Health Research Institute

All future correspondence concerning this study should include the Research Office Review Number and should be directed to Sherry Paiva, CRIC Liaison, Lawson Health Research Institute.

## **Appendix C - Letter of Information**



Letter of Information

Research Study: Patient Concerns Following Head and Neck Surgery for Cancer

<p><b>Study Investigators:</b> Bert M. Chesworth, PhD Associate Professor &amp; Joint-Supervisor School of Physical Therapy</p>	<p>Tom Overend, PhD Associate Professor &amp; Joint-Supervisor School of Physical Therapy</p>
<p><b>Co-Investigators:</b> Cathy Anderson, PT, MSc Physiotherapist London Health Sciences Centre,</p>	<p>John Yoo, MD, Chief - Dept. of Otolaryngology Victoria Hospital, London Health Sciences Centre</p>
<p>Kevin Fung, MD Associate Professor Dept. of Otolaryngology Victoria Hospital, London Health Sciences Centre</p>	<p>Anthony Nichols, MD, Assistant Professor, Dept. of Otolaryngology Victoria Hospital, London Health Sciences Centre</p>
<p>Danielle Macneil, MD Dept. of Otolaryngology, Victoria Hospital, London Health Sciences Centre</p>	<p>Tara Keating, PT, BScPT Physiotherapist Victoria Hospital, London Health Sciences Centre.</p>
<p><b>Graduate Student Investigator</b> Daniel Arulananda-Doss, B.P.T, MSc Candidate Graduate Program in Health and Rehabilitation Sciences, Western University</p>	

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Page 1 of 5

**Background Information and Purpose:**

You are being invited to participate in a research study to determine the concerns of patients before and after the neck dissection surgery scheduled by your surgeon in the Otolaryngology Clinic at Victoria Hospital, London Health Sciences Centre. The purpose of this letter is to provide you with information that will allow you to make an informed decision about participating in this study.

**Details of the study:**

We are asking you to participate because we wish to determine what your concerns are before and after the surgery. We would like to know how your concerns change after the surgery and during your follow-up visits. In addition we would like to know the effect of surgery on your shoulder and neck by evaluating your shoulder and neck function and your shoulder strength, before and after surgery and during the course of your follow-up visits.

We are giving this letter of information only to people who are scheduled for neck dissection surgery at Victoria Hospital. If this situation does not apply to you, we would request you not to take part in this study.

This study is being conducted under the direct supervision of Dr. Bert Chesworth, who works at the School of Physical Therapy at Western University. He will supervise this study along with the following co-investigators: Dr. Tom Overend, Graduate supervisor, Associate professor, School of Physical Therapy; Dr. John Yoo, Chief, Dept. of Otolaryngology, Victoria Hospital, London Health Sciences Centre; Dr. Kevin Fung, Associate Professor, Dept. of Otolaryngology LHSC; Dr. Danielle Macneil, Assistant Professor, Dept. of Otolaryngology, LHSC; Dr. Anthony Nichols, LHSC, Assistant Professor, Dept. of Otolaryngology, LHSC; Cathy Anderson, Physiotherapist, LHSC; Tara Keating, Physiotherapist, LHSC; and Daniel Arulananda-Doss, graduate student, Health and Rehabilitation Sciences program, Faculty of Health Sciences, Western University.

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Page 2 of 5

If you agree to participate in this study you will be initially contacted by a nurse or surgeon in the head and neck clinic at Victoria Hospital, LHSC. The nurse or surgeon in the head and neck clinic will introduce you to Daniel Arulananda-Doss our co-investigator, who will be collecting the information for this project. They will assist Daniel Arulananda-Doss with the consent process for patients willing to volunteer for the study.

The data collection will start prior to your scheduled neck dissection surgery. Following the neck dissection surgery data will be collected at 4 different time points.

- 1 week post-surgery prior to discharge from hospital (data collected in-hospital)
- 3 to 4 weeks post-surgery prior to radiation treatment (data collected at the follow-up clinic visit)
- 3 months post-surgery after radiation treatment (data collected at the follow-up clinic visit)
- 6 months post-surgery (data collected at the follow-up clinic visit)

The study will include the following questionnaires which you are required to complete during the data collection time points to achieve the primary and secondary objectives.

1. Patients Concerns Inventory-Level of Importance (PCI-LOI) - Primary objective
2. Shoulder Pain And Disability Index (SPADI) - Secondary objective
3. Neck Dissection Impairment Index (NDII) - Secondary objective
4. University of Washington Quality of Life Scale – Secondary Objective

Daniel Arulananda-Doss will also be evaluating your shoulder and neck movements and shoulder strength using specific instruments to achieve the Secondary objective.

1. Shoulder Movements - Universal Goniometer
2. Neck Movements - Cervical Inclinator (CROM device)
3. Shoulder Strength – Hand-held Dynamometer

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Page 3 of 5

**Risk and Benefits:**

You will not be placed at any risk or harm in this study. You are expected to have some stiffness and pain in the shoulder and neck areas caused by the surgery, and there might be some discomfort while completing the questionnaires or while Daniel Arulananda-Doss measures the shoulder and neck movements and shoulder strength, but this is expected to be relatively mild and should abate quickly following the completion of the outcome measure tools.

There are no direct benefits to you due to your participation in the study but the results of the study can be helpful for future research and researchers. The results of the study will also help the clinical fraternity and patients in the future to have a better understanding about patients' concerns and surgical effects on their neck and shoulder function following surgery. Your participation in this project will not involve any additional costs to you, and you will not receive compensation for your participation.

**Confidentiality:**

Your confidentiality will be respected. Your name and chart number are collected so that your hospital chart can be retrieved to obtain the details of your surgery. Your year of birth is obtained to calculate your age, since age is considered to be an important aspect of shoulder and neck mobility and function. This information will always be kept in a locked cabinet once Daniel Arulananda-Doss has completed collecting your data. No information that discloses your identity will be released or published, without your explicit consent to the disclosure. All records will be given a code number to be used on all data collection forms.

If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your explicit consent to the disclosure. All of the information collected will be kept in locked filing cabinets and shredded after seven years.

Representatives of Western University's Health Sciences Research Ethics Board may contact you or require access to your study related records to monitor the conduct of the research.

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Page 4 of 5

**Voluntary Nature of Study/Freedom to Withdraw or Participate:**

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study with no effect on your future care at any time while in hospital or within one month following the conclusion of your involvement with the study. You do not waive any legal rights by signing the consent form.

If you agree to participate in this project, please sign the attached consent form, complete the contact information requested and return it to the person who gave this letter to you. You may keep this letter of information. A copy of your signed consent form will be made for you.

If you have any questions about this study, please contact Dr. Bert Chesworth or Daniel Arulananda-Doss.

**Questions:**

If you have any questions about your rights as a research participant or the conduct of the study you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute.

**Primary Investigator**  
**Bert M. Chesworth**  
**BA, BScPT, MCIScPT, PhD**  
**Associate Professor**  
**Department of Physical Therapy**  
**University of Western Ontario**  
**London, Ontario**

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Page 5 of 5

## **Appendix D – Consent Form**

**Consent Form**

"Patient Concerns Following Head and Neck surgery for Cancer"

**Principal Investigator:**

Dr. Bert M. Chesworth, School of Physical Therapy, Western University

I have read the Letter of Information, have had the nature of the study explained to me and I have agreed to participate. All questions have been answered to my satisfaction.

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Name of participant (Print)

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Signature of participant

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Date

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Name of person obtaining consent (Print)

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Signature of person obtaining consent

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Date

## **Appendix E - Patients Concerns Inventory-Level of Importance**

## Head & Neck Cancer

### Patient Concerns Inventory – Level of Importance Rating

We would like to know what is important to you with respect to undergoing Neck Dissection Surgery.

Please indicate how important the following items are to you ‘during the last week’.

For each item, please tick the box to indicate how important the issue is to you.

PHYSICAL AND FUNCTIONAL WELL-BEING							
Concerns	LEVEL OF IMPORTANCE						
	None 1	Very Small 2	Small 3	Moderate 4	Fairly Great 5	Great 6	Very Great 7
<b>Appetite</b>							
<b>Arm / hand</b>							
<b>Bowel habits</b>							
<b>Breathing</b>							
<b>Chewing / eating</b>							
<b>Coughing</b>							
<b>Dental health / teeth</b>							
<b>Dry mouth</b>							
<b>Energy levels</b>							
<b>Fatigue/tiredness</b>							
<b>Hearing</b>							
<b>Indigestion</b>							
<b>Mobility</b>							
<b>Mouth opening</b>							
<b>Mucus</b>							
<b>Nausea / vomiting / sickness</b>							
<b>Pain in the head / headache</b>							
<b>Pain in the neck</b>							
<b>Pain elsewhere</b>							
<b>Regurgitation</b>							
<b>Salivation</b>							
<b>Shoulder</b>							
<b>Sleeping</b>							
<b>Smell</b>							
<b>Sore mouth</b>							
<b>Swallowing</b>							
<b>Swelling</b>							
<b>Taste</b>							
<b>Weight</b>							

## Social Care & Social Well-being

Concerns	LEVEL OF IMPORTANCE						
	None	Very Small	Small	Moderate	Fairly Great	Great	Very Great
	1	2	3	4	5	6	7
Home care							
Lifestyle issues (smoking / alcohol)							
Money							
Recreational activities or hobbies							
Relationships							
Speech / voice / being understood							
Support for my family or friends helping with my care							
Well-being of my dependents / children							
Well-being of my spouse / partner							

## Psychological, Emotional & Spiritual well-Being

Concerns	LEVEL OF IMPORTANCE						
	None	Very Small	Small	Moderate	Fairly Great	Great	Very Great
	1	2	3	4	5	6	7
Appearance							
Anger							
Anxiety / depression / mood							
Coping							
Fear of the cancer coming back							
Fear of medical or surgical complications							
Intimacy in relationships							
Memory							
Self-esteem							
Sexuality							
Spiritual / religious aspects							
Personality & temperament							

Treatment Related							
LEVEL OF IMPORTANCE							
Concerns	None 1	Very Small 2	Small 3	Moderate 4	Fairly Great 5	Great 6	Very Great 7
Feeding tube							
Wound healing							

**OTHER CONCERNS: (Please indicate below)**

Have we missed anything?

*Please indicate in your own words anything else that is important to you; but was not covered in the above sections*

LEVEL OF IMPORTANCE							
Other Concerns	None 1	Very Small 2	Small 3	Moderate 4	Fairly Great 5	Great 6	Very Great 7

**TOP 3 CONCERNS: (Please indicate below)**

*In the space provided below, using your own words, please tell us your TOP 3 CONCERNS in the past week*

Thank you for taking the time to complete this questionnaire.  
 Your assistance in providing this information is very much appreciated.  
 Adapted with the approval of The Evidence-based Practice Research Centre, Edge Hill University and the Aintree University Hospitals.

## Appendix F – SPADI

**SPADI (SHOULDER)**

Please place a mark on the line that best represents your experience during the last week attributable to your shoulder problem.

PAIN SCALE	
How severe is your pain: (Circle the number that best describes your pain)	
1. At its worst.	No pain 0 1 2 3 4 5 6 7 8 9 10 Worst Pain Imaginable
2. When lying on involved side.	No pain 0 1 2 3 4 5 6 7 8 9 10 Worst Pain Imaginable
3. Reaching for something on a high shelf.	No pain 0 1 2 3 4 5 6 7 8 9 10 Worst Pain Imaginable
4. Touching the back of your neck.	No pain 0 1 2 3 4 5 6 7 8 9 10 Worst Pain Imaginable
5. Pushing with the involved arm.	No pain 0 1 2 3 4 5 6 7 8 9 10 Worst Pain Imaginable
DISABILITY SCALE	
How much difficulty did you have: (Circle the number that best describes your experience)	
1. Washing your hair.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
2. Washing your back.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
3. Putting on an undershirt or pullover sweater.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
4. Putting on a shirt that buttons down the front.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
5. Putting on your pants.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
6. Placing an object on a high shelf.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
7. Carrying a heavy object of 10 pounds.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
8. Removing something from your back	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help

## **Appendix G – NDII**

**Neck Dissection Impairment Index**

Study Number \_\_\_\_\_

Date \_\_\_\_\_

Time point \_\_\_\_\_

As a result of the cancer **TREATMENT OF YOUR NECK**, how much have you been bothered by the following over the past **4 WEEKS**? (Circle appropriate response)

1. Are you bothered by the neck or shoulder **pain or discomfort**?

Not at all    a little bit    a moderate amount    quite a bit    a lot

2. Are you bothered by neck or shoulders **stiffness**?

Not at all    a little bit    a moderate amount    quite a bit    a lot

3. Are you bothered by difficulty with **self-care** activities because of your neck or shoulder (For example, combing hair, dressing bathing, etc)?

Not at all    a little bit    a moderate amount    quite a bit    a lot

4. Have you been limited in your ability to **lift light** objects because of your shoulder or neck?

Not at all    a little bit    a moderate amount    quite a bit    a lot

5. Have you been limited in your ability to **lift heavy** objects because of your shoulder or neck?

Not at all    a little bit    a moderate amount    quite a bit    a lot

6. Have you been limited in your ability to **reach above** for objects because of your shoulder or neck (for example, from shelves, tables, or counters)?

Not at all    a little bit    a moderate amount    quite a bit    a lot

7. Are you bothered by your **overall activity** level because of your shoulder or neck?

Not at all    a little bit    a moderate amount    quite a bit    a lot

8. Has the treatment of your neck affected your participation in **social activities**?

Not at all    a little bit    a moderate amount    quite a bit    a lot

9. Have you been limited in your ability to do **leisure or recreational activities** because of your neck and shoulder?

Not at all    a little bit    a moderate amount    quite a bit    a lot

10. Have you been limited in your ability to do **work** (including **work** at home) because of your neck or shoulder?

Not at all    a little bit    a moderate amount    quite a bit    a lot

## **Appendix H - UWQOL**

## University of Washington Quality of Life Questionnaire (UWQOL)

This questionnaire asks about your health and quality of life **over the past seven days**. Please answer all of the questions by checking one box for each question.

1. **Pain.** (Check one box: )

I have no pain.

There is mild pain not needing medication.

I have moderate pain - requires regular medication (codeine or nonnarcotic).

I have severe pain controlled only by narcotics.

I have severe pain, not controlled by medication.

2. **Appearance.** (Check one box: )

There is no change in my appearance.

The change in my appearance is minor.

My appearance bothers me but I remain active.

I feel significantly disfigured and limit my activities due to my appearance.

I cannot be with people due to my appearance.

3. **Activity.** (Check one box: )

I am as active as I have ever been.

There are times when I can't keep up my old pace, but not often.

I am often tired and have slowed down my activities although I still get out.

I don't go out because I don't have the strength.

I am usually in bed or chair and don't leave home.

4. **Recreation.** (Check one box: )

There are no limitations to recreation at home or away from home. There are a few things I can't do but I still get out and enjoy life.

There are many times when I wish I could get out more, but I'm not up to it.

There are severe limitations to what I can do, mostly I stay at home and watch TV. I can't do anything enjoyable.

5. **Swallowing.** (Check one box: )

I can swallow as well as ever.

I cannot swallow certain solid foods.

I can only swallow liquid food.

I cannot swallow because it "goes down the wrong way" and chokes me.

6. **Chewing.** (Check one box: )

I can chew as well as ever.

I can eat soft solids but cannot chew some foods.

I cannot even chew soft solids.

7. **Speech.** (Check one box: )

My speech is the same as always.  
 I have difficulty saying some words but I can be understood over the phone.  
 Only my family and friends can understand me.  
 I cannot be understood.

8. **Shoulder.** (Check one box: )

I have no problem with my shoulder.  
 My shoulder is stiff but it has not affected my activity or strength.  
 Pain or weakness in my shoulder has caused me to change my work.  
 I cannot work due to problems with my shoulder.

9. **Taste.** (Check one box: )

I can taste food normally.  
 I can taste most foods normally.  
 I can taste some foods.  
 I cannot taste any foods.

10. **Saliva.** (Check one box: )

My saliva is of normal consistency.  
 I have less saliva than normal, but it is enough.  
 I have too little saliva.  
 I have no saliva.

11. **Mood.** (Check one box: )

My mood is excellent and unaffected by my cancer.  
 My mood is generally good and only occasionally affected by my cancer.  
 I am neither in a good mood nor depressed about my cancer.  
 I am somewhat depressed about my cancer.  
 I am extremely depressed about my cancer.

12. **Anxiety.** (Check one box: )

I am not anxious about my cancer.  
 I am a little anxious about my cancer.  
 I am anxious about my cancer.  
 I am very anxious about my cancer.

---

Which issues have been the most important to you during the past 7 days?

**Check  up to 3 boxes.**

Pain	Swallowing	Taste
Appearance	Chewing	Saliva
Activity	Speech	Mood
Recreation	Shoulder	Anxiety

## GENERAL QUESTIONS

**Compared to the month before you developed cancer**, how would you rate your health-related quality of life? (check one box: )

- Much better
- Somewhat better
- About the same
- Somewhat worse
- Much worse

In general, would you say your **health-related quality of life** during the past 7 days has been: (check one box: )

- Outstanding
- Very good
- Good
- Fair
- Poor
- Very poor

Overall quality of life includes not only physical and mental health, but also many other factors, such as family, friends, spirituality, or personal leisure activities that are important to your enjoyment of life. Considering everything in your life that contributes to your personal well-being, rate your **overall quality of life** during the past 7 days. (check one box: )

- Outstanding
- Very good
- Good
- Fair
- Poor
- Very poor

---

Please describe any other issues (medical or nonmedical) that are important to your quality of life and have not been adequately addressed by our questions (you may attach additional sheets if needed).

## **Appendix I - Surgical Details Form**

**Surgical Details Data Extraction Form**

**Patient Concerns Following Head and Neck Surgery for Cancer**

**Study ID.....**

**Extraction Date:.....**

**Type of Surgery:.....**

**Date of Surgery:.....**

**Details of Surgery:**

## CURRICULUM VITAE

Daniel Arulananda Doss BPT. MSc(cand)  
Graduate Student,  
Health and Rehabilitation Sciences Program  
Western University

### **1. Education**

<b><u>Year</u></b>	<b><u>Institution</u></b>	<b><u>Degree</u></b>
2011-	University of Western Ontario	Master of Science (HRS)
2005-2010	TN Dr.MGR Medical University	Bachelor of Physiotherapy

### **2. Employment and Training**

2010 - 2011	Community Physiotherapist - Rural Health Centre, Trichy, India
2010	Physiotherapist Intern - PSG Multi-speciality Hospitals, Coimbatore, India.
2010	First Aid and CPR - PSG Hospital, Coimbatore, India
2008-2009	Physiotherapist in Training - PSG Rural Health Centre, Coimbatore, India

### **3. Student Placements**

2012 - 2013	Dept. of Physiotherapy and Dept. of Otolaryngology London Health Sciences Centre, Canada
2008 - 2010	Dept. of Physiotherapy PSG Hospitals, India

### **4. Scholarships, awards, distinctions**

2012	Recipient of Graduate Student Bursary Award (\$ 1000)
2011	Western Graduate research Scholarship (\$ 12,000 per year for 2 years)
2010	Recipient of "Best Intern of the Year" award - Dr.MGR Medical University
2010	Gold Medalist - University Topper in senior year

### **5. Publication and Presentations**

2010	Effectiveness of End Range Mobilization Techniques in Patient with Adhesive Capsulitis - An Experimental Study. Under Grad Project presented at Dr.MGR University, India
2009	Analysis of loss of vibration and proprioception in diabetics - Correlation study. Paper presented at - Annamalai University, India
2008	Effect of Ankle tapping technique in sports injuries - Experimental Study. Presented at Manipal University, India