

PAIN AND POSTOPERATIVE HEALTH-RELATED QUALITY OF
LIFE IN INGUINAL HERNIA PATIENTS

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COLLEGE OF NURSING

BY
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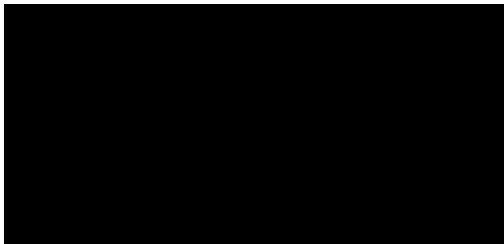
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To the Dean of Graduate Studies and Research:

I am submitting herewith a dissertation written by Cheryl B. Rowder titled "Pain and Postoperative Health-Related Quality of Life in Inguinal Hernia Patients." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy with a major in Nursing.


Margaret Beard, Ph.D., Major Professor

We have read this dissertation
And recommend its acceptance:



Accepted: 

Dean of Graduate Studies and
Research

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DEDICATION

This dissertation is dedicated first to my hero, Richard E. Rowder, who endured 10 years of continuous academic demands enabling me to earn three degrees from Texas Woman's University. His belief in my ability to recover from cancer amidst a career and doctoral work empowered me to complete my dream.

This dissertation is dedicated to my children, Nicholas J. Rowder, MD, and Margo C. Rowder, Art Director, who tolerated my studying on all occasions without complaint and who never wavered in their belief in my ability to finish.

This dissertation is dedicated to my sister, Annette B. Tucker, Ph.D., who led the way and whose physical and emotional assistance during my illness were invaluable to my recovery and persistence.

Lastly, this dissertation is dedicated to my parents, Edward E. and Margaret M. Bauer, who instilled in me a love of knowledge and a belief in the accomplishment of dreams. I know they are celebrating in Heaven.

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ABSTRACT

PAIN AND POSTOPERATIVE HEALTH-RELATED QUALITY OF LIFE IN INGUINAL HERNIA PATIENTS

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The purpose of this study was to explore the relationship between selected variables (i.e., pain issues, hernia characteristics, and personal attributes) and postoperative health-related quality of life in inguinal hernia patients. This study identified preoperative variables predictive of lower postoperative health-related quality of life.

The study entailed non-experimental retrospective analyses of variables generated during an ongoing longitudinal cooperative clinical study to examine patient outcomes after inguinal hernia repair. Fourteen Veterans Affairs Medical Centers in the continental United States participated in the study. Data were collected from eligible participants upon entry into the project and at 3 months post-surgery.

The sample consisted of 560 veteran participants. Canonical analyses were used to examine the relationship of pain issues, hernia characteristics, and personal attributes with postoperative health-related quality of life. High preoperative pain predicted lower postoperative health-related quality of life. Fear of injury and pain avoidance did not uniquely contribute to this relationship. This finding supported a singular difference in chronic and acute pain. Hernia characteristics were not associated with postoperative health-related quality of life. Age and functional limitations were predictive of

postoperative outcomes. Younger age predicted physical recovery while older age predicted mental recovery. High functional limitations were associated with lower health-related quality of life regardless of other factors.

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CHAPTER 1

INTRODUCTION

The final decades of the 20th century have been marked by an explosion of new medical technologies offering an increasing array of treatment options to a population expecting positive outcomes. A shift in economic resources and health care delivery have forced a concurrent focusing on documentation of treatment outcomes, health promotion, and risk reduction within the confines of cost containment. It is no longer sufficient to offer treatment options without attempting to describe their impact on resultant patient disease burden and quality of life.

Quality of life is not just health status, but a totality of human perception regarding the value of all aspects of life (Covinsky et al., 1999). Several difficulties arise in describing this multidimensional construct. First, quality of life is personal and must be individually defined. Second, people do not separate perceptions of quality of life into medical and non-medical realms. Third, physical capacity to accomplish goals, adequacy of financial resources, and levels of social support interact with health status compounding obstacles in isolating a single definition of quality of life (Ormel, Lindenberg, Steverink, & Vonkorff, 1997). In spite of these descriptive dilemmas, the driving force behind a person's decision to seek medical care remains the belief that adherence to prescribed restorative, palliative, or preventive interventions will result in improvement in quality of life. Caregivers' recommendations for treatment are often based on impressions of these expected results. Consequently, outcome data in this area are viewed as

essential in determining the value of healthcare to society, the healthcare system, and the individual.

Several factors contribute to inadequate outcome data assessment. Among these factors are movement of the recuperative process from inpatient to multiple outpatient settings, increased numbers of health-care personnel involved in care delivery, standardized care that does not account for variability of needs, and the subjective nature of perceptions of health (Jones, Burney, Peterson, & Christy, 1998). Assessment of outcome data improves when physical examination findings are integrated within the context of perceived health rather than solely based on symptoms and functional limitations that may not be directly proportional to physical abnormalities. Because literature supports a link between physical functioning and quality of life, factors affecting physical capacities require examination (Laforge et al., 1999).

Physical functioning is directly impacted by postoperative pain. Pain, a protective response, is an expected experience following surgery and is anticipated to affect many aspects of normal physiology and activity including eating, walking, sleeping, moving, and communicating. The individuality of pain tolerance, however, increases necessity of evaluation of its effect on health-related quality of life of surgical patients. People undergoing inguinal hernia repair are at risk for postoperative pain and activity intolerance (Callesen et al., 1998). An understanding of this risk begins with a description of the presenting physical abnormality and its operative treatment.

A hernia is defined as the protrusion of "a viscus through an opening in the wall of the cavity in which it is contained" (Wantz, 1999, p. 1585). Inguinal hernias are a common health problem and are associated with male gender, age, and strenuous activity (Eubanks, 1997). The natural progression of a hernia is one of increasing size

with the potential of incarceration or obstruction of the intestine or the vascular supply to the bowel. Hernias do not resolve spontaneously or improve with time, but require surgical intervention for resolution (Eubanks, 1997).

Each year more than 700,000 patients undergo inguinal herniorrhaphies. This procedure is accomplished through an open incision or by laparoscopic approach. Either repair requires extensive invasion of the tissues of the groin area. "The groin is the area of junction of the lower abdomen and the thigh" (Wantz, 1999, p. 1587). Because of the invasiveness of the procedure and its location, the potential for disruption in postoperative mobility from pain and discomfort is clear.

Despite its invasiveness, this procedure is routinely accomplished on an outpatient basis. With early discharge, smooth recovery is typically assumed unless significant complications occur (Jones et al., 1998). The validity of these assumptions is not established.

Lack of opportunity for postoperative assessment increases importance of identification of people at risk for pain-related reductions in activity prior to discharge. Examination of predictor variables of postoperative health-related quality of life provides a potential method for such identification.

Selection of predictor variables starts with consideration of humans and their response to change. Invasive surgical procedures result in adaptive responses to rapid changes in comfort levels. Degree of individual change hinges on a totality of factors descriptive of the preoperative person. Previous experience and reactions to pain, resources that buffer stress, and factors that affect wound healing impact recovery. These human aspects are represented in three groups of variables, preoperative pain issues, hernia characteristics, and personal attributes.

Pain issues, level of sensation and maladaptive behaviors, that predict avoidance of activities are variables that may potentially identify patients at risk for increased postoperative disease burden. Vlaeyen, Seelen et al. (1999) found that avoidance of activity led to maintenance or exacerbation of fear of movement. Preoperative existence of such behaviors may be predictive of a postoperative continuation of avoidance behaviors.

An individual's resources and physical condition also influence recovery. Hernia characteristics describe an abnormal physical condition that may impact health perceptions. Likewise, personal attributes, age and level of functioning, contribute to a person's current state of health (Keister & Blixen, 1998). Educational level and marital status represent resources in knowledge and emotional support that can assist patients during recovery (Berkman et al., 1999).

Age predicts differing responses to medical treatment. Kleinpell (1991) reported that satisfaction with health declined with age. Older people expected poorer health as a result of the normal process of aging. Functional status was found to directly impact patient satisfaction with care. Through its ability to buffer stress, social support contributed to positive perceptions of health-related quality of life (Kleinpell, 1991). These findings clarify relevance of an investigation of age, education, marital status, and functional limitations on the postoperative recovery of inguinal hernia patients. This project sought to examine selected easily discernible variables as potential predictors of lower postoperative health-related quality of life.

Problem of the Study

The following question constituted the problem of study:

Do some patients experience higher postoperative disease burden accompanied by greater difficulty with adaptive efforts after inguinal hernia surgery, and can these patients be identified prior to surgery?

Purpose

While thousands of patients undergo inguinal hernia repair, a paucity of studies has been directed to postoperative pain and prediction of patient recovery (Jones et al., 1998). The purpose of this study was to examine the impact of pain issues, hernia characteristics, and personal attributes on health-related quality of life of inguinal hernia patients. The expected result was determination of predictor variables for lower postoperative health-related quality of life.

Rationale

In this current era of accountability, health professionals are obligated not only to relieve pain and ease fear, but also to improve general functioning and well being. Quality of life, an abstract concept, is used in many disciplines to describe overall perceptions of health; a more precise concept is health-related quality of life. Health-related quality of life is an accepted end point in clinical research (Dijkers, 1999).

Response to postoperative pain is personal and predictable from past reactions (Drain, 1984; Gupta & Staats, 1997; Melzack & Wall, 1965). While nurses are ideally situated to assist patients in pain, difficulties exist in providing appropriate pain management when decisions are based on incomplete or incorrect knowledge. While identification of variables that distinguish patients at risk for negative pain-related postoperative outcomes would improve nursing

assessment, this investigator found no studies that focused on the impact of pain on health-related quality of life in inguinal hernia patients (Kate, McWhinnie, Jenkinson, & Coulter, 1997).

Even when pain is expected as in postoperative patients, inappropriate initial and follow-up assessments along with erroneous attitudes and beliefs have hampered nurses in adequately providing comfort (Salerno & Willens, 1996). Identification of variables that distinguish inguinal hernia patients at risk for negative pain-related postoperative outcomes would provide such scientific data. This study will provide such a set of predictor variables through the examination of data generated during an ongoing national Veterans Affairs cooperative study designed to examine postoperative outcomes of patients undergoing inguinal hernia repair.

Theoretical Framework

The concepts of primary interest for this study are health-related quality of life, pain issues, hernia characteristics, and personal attributes. The following model describes the relationships that this investigator believes exist for postoperative inguinal hernia patients. In Figure 1, the theoretical model of health-related quality of life in inguinal hernia patients has three independent variables and one dependent variable. The independent variables are pain issues, hernia characteristics, and personal attributes. The dependent variable is postoperative health-related quality of life.

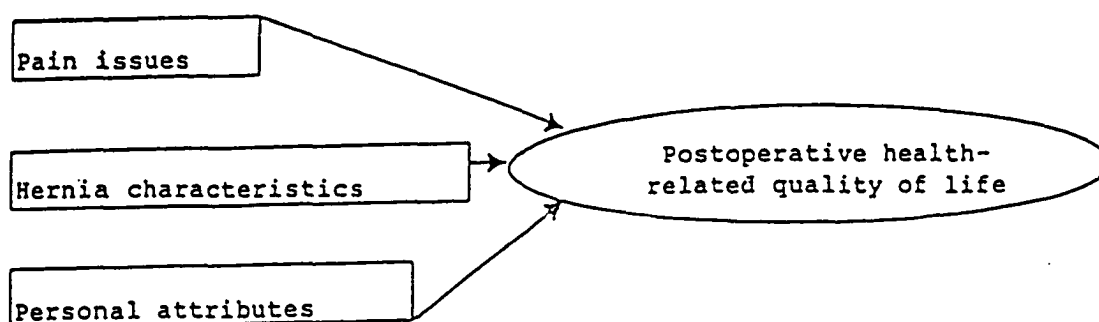


Figure 1. Theoretical model of health-related quality of life in inguinal hernia patients.

This model is derived from Sister Callista Roy's theory of adaptation (Roy & Andrews, 1991). This systems-based theory describes human survival as dependent on ability to adjust to changing stimuli in the environment. Concepts of input, throughput, and output describe reactions to stimuli. Humans, bio-psycho-social systems, receive information from their external and internal environment in the form of stimuli. Stimuli, input information, trigger throughput or activation of the regulator and cognator systems. The regulator control system responds to stimuli through physiological effectors, chemical/electrical impulses, and results in the sensory component of pain. The reactions of the cognator control system, perception and learned responses encompassed in higher brain functions, result in aversive drives that produce the affective reactions to pain. Both systems are necessary for the adaptive efforts of humans (George, 1985; Roy & Andrews, 1991; Torres, 1986).

These systems respond to three types of stimuli. Focal stimuli are predominant stimuli of immediate importance. Contextual stimuli are background stimuli in the environment that do not command immediate

attention. Residual stimuli are attitudes and traits of humans that may not be readily changed. Postoperative pain is a focal or contextual stimulus (Fawcett, 1995; Torres, 1986).

The regulator and cognator processes utilize four adaptive effectors. Three effectors are described through abstract concepts including role function, self-concept, and interdependence. The fourth effector, the physiological mode, encompasses all biological, hormonal, and neural interactions. The regulator process potentially stimulates the cognator process.

The output for this holistic system is either ineffective or adaptive behaviors that lead to mastery, reproduction, and overall integration of the individual (Fawcett, 1995). Adaptive behavior is a function of the level of stimulus and the adaptive zone of the person. The adaptive zone is the zone where positive adaptation may occur.

Because pain represents an extremely strong and compelling stimuli, modification of behavior by this stimulus would seem inevitable. This modification in postoperative patients takes the form of guarding and reticence to move the injured body part. A natural focusing of attention on the source of pain assists the organism to organize protective behavior (Caldwell & Chase, 1977). While this is beneficial to the patient in the early phases of wound healing, prolonged immobilization may put patients at risk for decreased activity levels that lead directly to decreased health-related quality of life (Caldwell & Chase, 1977).

The ability to recognize these at-risk patients prior to an event assists nurses to identify interventions to avoid this outcome. This project sought to provide such research-based variables for assessment of risk for lower post-operative health-related quality of life in inguinal hernia patients.

Hypotheses

This study examined the hypotheses that among inguinal hernia patients:

1. Pain issues (i.e., increased intensity of sensation and presence of preoperative maladaptive behaviors) predict lower postoperative health-related quality of life.
2. Selected hernia characteristics predict lower postoperative health-related quality of life.
3. Personal attributes predict lower health-related quality of life.

Table 1 depicts the major variables with identification of the assessment tool providing these data.

Table 1

Variables and Measurements

Variables	Measurement
<u>Dependent variable:</u>	
Health-related quality of life	SF-36 (see Appendix A)
1. Physical Components	
2. Mental Components	
<u>Independent variables:</u>	
1. Pain Issues:	
a. Intensity of sensation--	Visual Analogue (see Appendix B)
b. Maladaptive behavior--	Preoperative Activities (see Appendix C)
2. Hernia Characteristics:	Hernia Assessment (see Appendix D)
3. Personal Attributes:	Patient Assessment (see Appendix D)

Definition of Terms

1. Health is a perception of the current level of physical, mental, and emotional well being of the individual.

2. Quality of life is a multidimensional phenomenon that encompasses the totality of the biological, psychological, social, interpersonal, economic, and cultural experiences of the individual.

3. Health-related quality of life is the patient's perception regarding his well being in the areas of physical, mental, and social functioning, bodily pain, and ability to fulfill roles as defined operationally with the SF-36.

4. Postoperative health-related quality of life is the individual's perception of health-related quality of life 3 months after surgery.

5. Pain is an unpleasant sensation with multiple dimensions that has an impact on the mental and physical functioning of the individual as measured by visual analog scales.

6. Pain intensity is the level of sensation experienced by the individual as operationally defined by visual analog scales (VAS).

7. Maladaptive behavior is identification of preoperative fear of injury or pain avoidance as the identified reason for preoperative difficulty with activities as measured by the Preoperative Activity Form.

8. Pain issues are intensity of sensation and maladaptive behaviors.

9. Hernia is defined as the protrusion of "a viscus through an opening in the wall of the cavity in which it is contained" (Wantz, 1999, p. 1585).

10. Hernia characteristics are descriptors that delineate the patient's experience including change in size, length of time from onset

of symptoms, and number of times of repair as reported on the Screening Form.

11. Personal attributes are the characteristics that could impact the individual's ability to recover, operationally defined as chronological age, marital status, preoperative functional limitations, and formal education as reported on the Screening Form.

Assumptions

The following statements are assumed to be true:

1. Humans can accurately remember and report intensity of sensation associated with recent pain.
2. Humans can differentiate pain associated with their hernia from pain in other areas of their body.

Limitations

This study was limited to those individuals served by the selected 14 Veterans Affairs Medical Centers. Additionally, this study was limited to males who required an inguinal hernia repair.

Delimitations

Male inguinal hernia patients entered as a part of Veterans Affairs Cooperative Study 456. Persons, age 18 years and above, were included in the study.

Summary

Reactions to pain such as avoidance behavior may be adaptive after acute injury. These changes in behavior allow tissue healing during the early recuperative period. However, the long-term effects of behavioral avoidance can be negative (Phillips, 1987). Vlaeyen, Kole-Snijders, Boeren, and Eek (1995) identified fear of movement as a precursor to

avoidance behavior. A consequence of avoidance may be lower postoperative health-related quality of life.

The goal of surgery is enhancement of health-related quality of life. Because postoperative activity level directly influences this outcome, it is important to identify patients at risk for decreased postoperative activities. While fear of injury and pain avoidance have been implicated in formation of a chronic pain response, these behaviors have not been examined as predictors of patients likely to experience decreased activities in response to postoperative pain.

By examining selected predictor variables, pain issues, hernia characteristics, and personal attributes, identification of variables that differentiate patients likely to experience lower health-related quality of life may be established. Strategies to prevent potentially negative outcomes may then be instituted.

CHAPTER II

REVIEW OF LITERATURE

This literature review is organized around quality of life and selected variables that may impact patients' perceptions of this outcome after surgery. Assisting humans to maintain quality of life following medical treatments recognized to cause discomfort requires understanding of potential variables that impact recovery. Recognizing the pervasive multidimensional influence of pain after operative procedures, an in-depth examination of the phenomena of pain will be included.

Selected variables to be discussed include personal attributes and hernia characteristics. The review begins with quality of life and health-related quality of life followed by health-related quality of life of inguinal hernia patients. A representative sample of studies that have examined health-related quality of life will initiate this review.

Quality of Life

Concern for human happiness and well being has existed since the days of Socrates (469-399 B.C.) who thought of happiness as the result of living the good life (Audi, 1995). Contemporary psychologists and sociologists describe quality of life in terms of expectations and perception of their fulfillment. Even though all humans share beliefs relevant to components of quality of life, these components must be defined subjectively and from an individual perspective. "Satisfaction or happiness with life is determined by the difference between one's perceived needs or expectations in each domain compared to what one

actually possesses or achieves in that domain" (Anderson & Burkhardt, 1999, p. 300).

Padilla and Frank-Stromborg (1997) reported the World Health Organization's definition of quality of life (QOL) as an individual's perception of position in life relative to cultural and value systems as related to personal goals, expectations, standards, and concerns. Expressed as domains within this concept are physical health, psychological state, level of independence, state of well being, social relationships, environmental features, and spiritual concerns. Health-related quality of life was defined by the United States Public Health Service as the value assigned to life duration as modified by impairments, functional states, perceptions, and social opportunities influenced by disease, injury, or treatment policy (Padilla & Frank-Stromborg, 1997). Thus, the focus on quality of life is within the context of health and illness.

Health-Related Quality of Life

Quality of life, a multidimensional abstract construct, encompasses fundamental values and philosophical issues so complex that finding one definition to satisfy all people remains problematic. "The use of the term 'quality of life' to encompass the values and perceptions of the patients has created doubt, confusion, and misunderstanding among practitioners, researchers, policymakers, and patients" (Leplege, 1997, p. 47). Consequently, health-related quality of life, a more precise concept, is utilized to represent perceptions of the patient relative specifically to physical and mental well being. The emphasis is on health-related components of quality of life that are important to patients, such as improvement in mobility or ability to return to work, as well as improvement in mental state.

This more precise term, however, has not resolved all issues relevant to the examination of this outcome. Different beliefs exist pertaining to appropriate methods for ascertaining health-related quality of life. One view is that subjective information is the only legitimate methodology for measurement, while another view stipulates that health-related quality of life must be objectified to be legitimate. Investigators must address the issue that this multidimensional construct requires both types of measures to fully represent all facets of life (Dijkers, 1999). Additionally, due to personal assumptions of instrument creators, development of value free measures of health-related quality of life is an elusive goal. Furthermore, once administered, interpretation of results remains an issue requiring resolution.

Health-related quality of life is composed of multiple facets representing physical and mental well being. This discussion will begin with a brief description of components of mental well being: vitality, social functioning, role-emotional, and mental health. Following this will be a description of the physical components of well being: physical functioning, role-physical, bodily pain, and general health.

Vininga (1997) equated morale to vitality and stated that protection of health preserves vitality. Henningsen and Priebe (1999) examined modern disorders of vitality. "Embedded in these complaints (loss of vitality) is a perceived incapacity to perform daily activities in the usual way, so that incapacity becomes an essential and primary characteristic of the illness" (Henningsen & Priebe, 1999, p. 209). Through its affect on ability to perform activities, postoperative pain contributes to perceived incapacity (Gelling, 1998).

Ware, Snow, Kosinski, and Gandek (1993) described social functioning as the impact of either physical health or emotional

problems on social activities. Postoperative pain potentially elicits physical and emotional responses in some patients, with resulting effects on social functioning (Gelling, 1998). Role-emotional is defined as difficulty with work or other daily activities as a result of emotional problems (Ware et al., 1993). Through its ability to impact emotional well being, pain impacts ability to fulfill emotional roles (role emotional) as well as mental health, a current feeling state of either happiness or nervousness (Ware et al., 1993).

Health-related quality of life contains components of physical well being including physical functioning, role-physical, bodily pain, and general health. Kim, Wolde-Tsadik, and Reuben (1997) examined effects of hospitalization on physical functioning. Impact of physical functioning on quality of life was extremely important during the immediate recovery period following hospitalization, a time when pain is most likely to occur. Pain was an identified critical factor in physical recovery, and consequently impacted health-related quality of life.

Comparison of physical and mental components of health-related quality of life across populations allows evaluation and comparison of outcomes from different investigations (Hays, Sherbourne, & Mazel, 1993). A representative sample of studies examining health-related quality of life follows.

Health-related Quality of Life General Studies

Jette and Downing (1994) examined health-related quality of life in patients participating in cardiac rehabilitation programs in 13 hospitals including 3 rural, 5 suburban, and 5 urban. Seven hundred eighty-nine people agreed to participate. The participants' ages averaged 59.7 ($SD = 11$), and individuals had completed an average of 13 years of school ($SD = 3$). Demographic information, exercise tolerance tests, and psychological profiles were collected upon admission to the

study. Quality of life as measured by the SF-36 was assessed at baseline and upon completion of the program.

Results of this study showed that physical problems impacted role performance more than mental health. Cardiac rehabilitation participants were limited in the kind of activities, time spent on activities, as well as level of difficulty they could tolerate. Restrictions placed on patients by health care providers or family members were thought to contribute to this. "Fatigue" and "worn out" feelings also were reported demonstrating that these participants did have psychological needs that could be met by learning to pace daily activities. Bodily pain was not an issue.

Physiological variables along with reduction of risk factors for cardiac disease had previously defined outcomes for cardiac rehabilitation programs. Addition of measures of health-related quality of life provided evaluation of psychological well being and physical and social functioning that constituted aspects of health that cardiac rehabilitation sought to affect (Jette & Downing, 1994).

Forbes et al. (1998) investigated differences in health-related quality of life in aneurysm patients recovering from corrective surgery from those treated with periodic ultrasonographic aneurysm surveillance. Impact of health service choices and costs were examined with patient survival the primary trial endpoint. Patient perception of quality of life while existing with a life-threatening disorder was compared to perception of quality of life following corrective surgery.

Early surgery resulted in a small but significant impact to health perception and pain. Concurrent reporting of descriptive data on quality of life alongside the main trial endpoint of survival assisted medical caregivers to avoid imposing arbitrary or unjustified treatment decisions (Forbes et al., 1998).

Chetter et al. (1998) examined changes in health-related quality of life in 55 individuals (28 women and 27 men) following infrainguinal arterial reconstruction for critical limb ischaemia. Individuals reported a median age of 71 (range 41 to 86) with median symptom duration of 12 months (range 2 months to 30 years). Health-related quality of life as measured by the SF-36 was assessed prior to surgery, and at 1, 3, 6, and 12 months. Kolmogorov-Smirnov goodness of fit established that quality of life scores were not normally distributed.

Arterial reconstruction was found to improve physical functioning, pain, vitality, and social functioning. No improvements were noted in the domains of role physical, general health, role emotional, or mental health. Subgroup analysis by graft patency revealed that a patent graft immediately improved physical functioning, role physical, pain, and social functioning. After graft occlusion, pain, vitality, and social functioning were the only domains that improved at 6 months. No improvements in physical functioning and role physical were found at any follow-up visit if graft occlusion occurred. At 12 months, only patients with a patent graft gained any benefit in physical functioning and role physical.

Critical limb ischemia was detrimental to patients' perceptions of health-related quality of life. Previously enumerated domains improved immediately following surgery with some requiring 6 months for such enhancement. Psychological benefits and improvement in pain were noted in individuals after secondary amputation following non-redeemable graft occlusion. Regardless of the severe restrictions faced in physical functioning, it was surmised that individuals benefited from the knowledge that symptoms of ischemia would no longer occur. This study supported use of health-related quality of life measures as evidence of improvement following surgery for critical limb ischemia.

Because quality of life measures have been established as superior predictors of survival compared to measures of depression or lung transplant status, MacNaughton, Rodriguez, Cicale, and Staples (1998) assessed quality of life in 17 individuals following lung transplantation. Fifty-three percent were male, with a mean age of 51 ($SD = 8.8$), and all were Caucasian. These participants were compared to individuals from a normal population with Welch's t -statistic. Preoperative and postoperative differences were examined with dependent t -tests. Bonferroni correction was used to reduce Type I error. Except where this correction was made, p value $< .05$ was considered significant.

Results of analysis revealed that time from transplant was correlated with pain ($r = 0.58$) and mental health ($r = 0.50$). Actual lung functions were correlated with social functioning ($r = 0.56$) and vitality ($r = -0.56$). Repeated measures analysis revealed that physical functioning, general health, vitality, social functioning, and mental health improved significantly after transplantation. Interestingly, even though individuals reported dramatic declines in breathing difficulties, symptom frequency increased. The relationship between pre-transplant pulmonary status and post-transplant health-related quality of life was not particularly strong. Pre-transplant levels of mental health and role emotional were comparable to normal populations and did not change after transplantation. These investigators concluded that consideration of health-related quality of life extended evaluation of success of transplantation beyond survival. Additionally, consideration of possible changes in health-related quality of life provided useful clinical information to weigh benefits and costs associated with lung transplantation.

Seabrook, Cambria, Freischlag, and Towne (1999) conducted an investigation of functional outcomes and quality of life following limb salvage surgery. Six months after successful bypass grafts to restore lower limb perfusion, 70 patients (58 men and 12 women) with a mean age of 69.1 years (range 45-87) were chosen from a group of 287 patients being followed in a longitudinal surveillance protocol. A control group of 70 patients who participated in a health screening was matched for age and gender. The control group, while disease free, was found to have similar hemodynamics and served as a standard for excellent hemodynamic outcomes. The groups differed for history of coronary artery disease and for smoking with these conditions being more prevalent in the patients requiring limb salvage.

This study sought to determine if limb salvage to avoid amputation actually improved perception of quality of life. Health-related quality of life was defined as the functional ability to participate in activities of daily living and the degree of happiness or sense of well being associated with mastery of these tasks. Health status, on the other hand, was measured in four categories including symptoms, perception of well being, functional capability, and life quality.

Results of a comparison of the two groups revealed that both had similar perceptions of health-related quality of life. The bypass group, however, continued to have a disadvantaged extremity and lower functional ability than the control group. This study documents that perceptions of quality of life may exceed functional ability and that baseline information is valuable in predicting expected functional outcomes.

Moy, Ingenito, Mentzer, Evans, and Reilly (1999) evaluated health-related quality of life following pulmonary rehabilitation and lung volume reduction surgery. Objectives included examination of

changes in health-related quality of life after pulmonary rehabilitation and 6 months after lung volume reduction surgery with contributions of these two treatments on health-related quality of life. Nineteen patients met inclusion criteria with clinically diagnosed emphysema and hyperinflation and were admitted to pulmonary rehabilitation in preparation for lung reduction surgery. Health-related quality of life as measured by the SF-36 was evaluated 3 months prior to rehabilitation, upon admission to the hospital after rehabilitation but prior to surgery, and 6 months after surgery. One-way analysis of variance with repeated measures and the Duncan's test of multiple comparisons of pair-wise means were used to compare between change in scores.

Results revealed that health-related quality of life was not significantly changed from baseline to after pulmonary rehabilitation. vitality improved at 6 months following lung reduction surgery. After rehabilitation and surgery, however, improvements were noted in 4 areas including physical and social functioning, role limitations due to physical functioning, and vitality. Although both treatments contributed to improvement in health-related quality of life, each contributed uniquely. Rehabilitation accounted for 90% of improvement in role limitations due to physical function while lung reduction accounted for all improvements in physical function and vitality. Non-physiological factors such as anxiety and depression were found to contribute to reductions in exercise capacity.

Health-related Quality of Life and Inguinal Hernia Patients

Linden and Engberg (1994) assessed quality of life in individuals after inguinal herniorrhaphy in a Swedish ambulatory surgery facility. Forty patients who averaged 47 years of age were contacted by phone to evaluate postoperative pain, orthostatic hypotension, constipation, and

urinary retention after surgery. Correlation of biologic, physical, psychological, and mental feelings provided subjective information concerning the individual's feeling of health. This study did not utilize instruments with tested reliability or validity, limiting interpretation of results. However, common problems reported included pain and constipation. Patients who reported "feeling bad" during the first postoperative day also expressed that being at home resulted in feeling troubled and worried. The experience of pain decreased the individual's ability to participate in self-care and contributed to decreased satisfaction with the ambulatory surgery experience.

Filipi et al. (1996) assessed pain and return to normal activities in 53 postoperative inguinal hernia patients ranging in age from 20 to 83. Kolmogorov's statistic determined normality of data distribution. A repeated measures analysis of variance was performed as well as student's t-test on data collected during hospitalization and follow-up. A less invasive repair, laparoscopic, did not influence postoperative convalescence or disability (Filipi et al., 1996).

Studies involving inguinal hernia repair have predominantly concentrated on comparisons of surgical techniques. One study, however, examined recovery of inguinal hernia patients in a day surgery setting. Inguinal hernia patients were chosen for this study because it was anticipated that they would have reduced postoperative functional status. The focus of the study was an examination of clinically significant but non-life-threatening patient outcomes. Swan, Maislin, and Traber (1997) reported several unexpected findings. Intermediate activities of daily living were reduced for a longer period than expected following surgery. Additionally, good preoperative functioning did not predict adequate functioning after surgery.

Lawrence, Jenkinson, McWhinnie, and Coulter (1997) evaluated health-related quality of life as measured by the SF-36 in 144 inguinal hernia patients undergoing laparoscopic or open hernia repair. These investigators found no difference associated with surgical procedure in postoperative health-related quality of life as measured by the SF-36 reported at 3 months or 6 months. Clinically important improvements in pain, role limitation due to physical restriction, and physical functioning were found at 6 months. The benefits of a minimally invasive technique, laparoscopic repair, were found to last 6 weeks. After this time, there were no significant differences in the groups.

Callesen et al. (1998) examined pain in 466 postoperative inguinal hernia patients. Total pain scores during rest, cough, and mobilization were reported for 4 weeks postoperatively. Maximum pain occurred during the first postoperative week with 42% of patients requiring additional analgesics to those normally prescribed. Spearman rank order correlation revealed a negative relationship between total pain scores and age during the activity of coughing. The correlation between age and total pain was present in all groups for pain during coughing and mobilization regardless of surgical technique. There was no difference in total pain associated with type of hernia. The entire cohort reported significantly lower pain at rest than during coughing or mobilization ($F = 298$, $p < 0.001$, Friedman test). No differences were found between pain during coughing or mobilization (Callesen et al., 1998, p. 1413).

Sixty percent of patients reported moderate to severe pain during functioning on day 1, 33% on day 6, and 11% after 4 weeks (Callesen, 1998). "Postoperative pain was not prevented despite extensive incisional local anaesthesia for the surgical procedure" (Callesen, 1998, 1414). After 4 weeks, 11% of patients continued to report moderate to severe pain associated with functioning. Additionally, 100

consecutive patients reported pain as the primary reason for extension of convalescence, demonstrating a unique observation between pain and duration of recovery.

Younger patients reported more pain related to functioning when compared to the entire population as well as when compared within specific surgical procedures. Prevalence of higher activity level in this age group with different postoperative expectations may account for this finding. An important conclusion of the study was that planning postoperative inguinal hernia treatment for young patients should incorporate consideration of higher activity levels associated with greater pain.

Stengel and Lange (1998) prospectively surveyed 269 patients undergoing inguinal hernia repair. General health perception, pain, and physical activity were significantly improved regardless of surgical procedure chosen. Difficulty in examining these outcomes in inguinal hernia patients was attributed to choice of day surgery for these procedures.

Current health care is often delivered in boluses in one setting with recovery occurring in multiple settings including home care. Functional health status, clinical outcomes, patient satisfaction, cost, and utilization require direct collection of data from the consumer. Because individuals treated in day surgery are not available for postoperative assessment in the hospital setting, little information regarding outcomes exists (Jones et al., 1998). This study highlighted that lack of postoperative assessment opportunity placed greater importance on ability to preoperatively predict those likely to experience difficulty after discharge.

Jones et al. (1998) proposed that quality of life as measured by the SF-36 be used as part of an overall measurement system that included

personal attributes, demographics, co-morbidities, patient satisfaction, and condition-specific data. Health-related quality of life as measured by the SF-36 was assessed in a convenience sample of individuals undergoing cholecystectomy, parathyroidectomy, and inguinal hernia repair. Results suggested that as a measure of quality of life, the SF-36 was sensitive to improvements in health status in all three operative procedures. For inguinal hernia repair, the responses on the SF-36 at 6-months showed a statistically significant reduction in role limitations related to physical problems.

In summary, postoperative pain potentially alters role performance through its impact on physical ability to perform activities of daily living (Ware et al., 1993). The literature supports a link between these abilities and perceptions of quality of life (Kim et al., 1997). Intensity of sensation experienced postoperatively can impact general health and sense of well being. Because intensity of sensation, pain, is commonly associated with surgical procedures, a more detailed explanation of this multidimensional phenomenon follows.

Pain

Understanding the impact of pain on postoperative health-related quality of life starts with a clear understanding of the multidimensional pain experience. The negative connotations of pain can be clearly found in the origins of the word "pain" in Webster's New World Dictionary (Guralnik & Friend, 1962). Its Latin derivative, "poena" translates to penalty (p. 1050). pain has been defined as "a sensation of hurting, or strong discomfort, in some part of the body caused by an injury, disease, or functional disorder and transmitted through the nervous system" (p. 1050). McCaffery (1979) defined pain as whatever the patient reported it to be, existing whenever the patient said that it did. These definitions, while appropriate for the general

population, do not fully describe this phenomenon. Historical explanations and biological theories and laws provide further understanding of this complex phenomenon.

Specificity, pattern theory, and the gate-control theory have all contributed to current understanding of the movement and response to pain impulses. McCance and Huether (1990) described specificity theory as including four categories of cutaneous sensation: touch, warmth, cold, and pain. These sensations were thought to result from stimulation of nerve endings of pain receptor sites on the skin. The transmission of stimuli was believed to travel to the spinal column cross over the substantia gelatinosa to the opposite side and ascend to the brain through the spinothalamic tract. The thalamus and cerebral cortex were sites for perception of pain. This theory not only failed to explain the actual cause of pain after tissue damage, but did not account for such phenomena as phantom pain.

The pattern theory postulated that sensation of pain depended on summation of impulses of varying intensity. The level of intensity was believed to be a function of the tissue involved and the strength of the stimulus (McCance & Huether, 1990, p. 396). Pattern theory further posited that impulses traveling to the brain were not sent individually but as a pattern of impulses emanating from one type of nerve ending. A debate remained as to where this summation took place, the spinal cord or the brain. This debate and the premise of the existence of one universal receptor have been refuted by the work of Perl (1984) who identified various types of receptive units.

The gate-control theory, formulated by Melzack and Wall in 1965, grew from specificity and pattern theories (Melzack, 1973). A summary of this theory would be that impulses of pain travel to the brain via two pathways, small and large fibers. These fibers located throughout the

tissues depend on stimulation for activation. Small fibers require minimal but continual stimulation. This transmission "opens" the gate to the dorsal horns and allows the transmission of pain to the brain. Large fiber stimulation provides a flooding effect that overloads the dorsal horn, closing the "gate." This closure retards or prevents the transportation of stimuli to the brain, reducing pain perception. (Melzack, 1973).

Central to an understanding of the gate-control theory of pain is an understanding of how a pain stimulus is transmitted to the brain and perceived by the patient. Nociception is the reaction to noxious stimulus. The resulting pain phenomenon is a perception of the stimuli by the person. This perception, according to Salerno and Willens (1996), is received through nociceptors located in the periosteum, skin, arterial walls, joint surfaces, subcutaneous tissue, muscle, fascia, and viscera. The response of nociceptors to tissues damage is release of serotonin, H⁺, K⁺, histamine, bradykinin and cholecystokinin from the plasma, and substance P from the nerve terminals. These substances depolarize adjacent nociceptors.

Depolarization described by Guyton (1991) occurs when a membrane becomes permeable to sodium ions, allowing large numbers of sodium ions to flow to the interior of the axon. Depolarization changes the permeability of the nerve cell membrane allowing sodium ions to enter the cell. Increased permeability allows release of neurotransmitters across adjacent synaptic clefts sending nerve impulses in a unidirectional path.

Several propositions underlying the gate-control theory of pain were described by Watt-Watson and Donovan (1992) to clarify how pain impulses are transmitted:

1. The transmission of nerve impulses from afferent fibers, those traveling from the periphery, is modulated by the gating mechanism in the dorsal horn. The gating mechanisms are several layers of laminae with the specialized function of accepting input from the body before transmission to the brain.

2. The gating mechanism is influenced by the amount of activity in large-diameter (L) and small diameter (S) fibers. Large fibers inhibit transmission, while small fibers facilitate transmission.

3. A specialized system of large-diameter rapidly conducting fibers activates higher cognitive processes that influence the modulating properties of the spinal gating mechanism.

4. When output of the spinal cord transmission cells exceeds a critical level, activation of an action system occurs. This action system predicts the behavior and experience characteristic of that individual as a response to pain.

In addition to these propositions, several systems have been shown to influence the perception and reaction of organisms to pain. Among these systems are:

1. The sensory-discriminative dimension of pain is influenced by the rapidly conducting spinal systems. Brain stem projections, cortical projections, and central control triggers are part of this system. Brain stem projections exert a powerful inhibitory control over information projected by the spinal transmission cells. Neuropharmacological systems are involved in descending control.

2. The motivational drive and unpleasant affect characteristic of pain are controlled by activities in the reticular and limbic structures, and are influenced by the slowly conducting spinal systems (Watt-Watson & Donovan, 1992). Fibers of the entire cortex project into the reticular formation. Through this connection, cognitive processes of

previous experience are able to influence spinal activities. Cognitive processes also influence the gating mechanisms by means of large pyramidal fibers that project to the dorsal horns.

3. Neocortical processes, higher central nervous system processes, evaluate input in terms of past experience, and exert control over activity in both the discriminative and motivational systems (Watt-Watson & Donovan, 1992). The central control triggers activate selective brain processes, memories of previous experience, as well as present response strategies, that influence information that is still arriving over slowly conducting fibers.

Pain: Applicable Laws and Theorems

To understand how a peripheral pain stimulus can influence behavior of an entire organism, it is necessary to explore pertinent laws and theorems. Adaptation, homeostasis, and the principle of least interaction contribute to this understanding.

Central to consideration of adaptation is knowledge of the concept of stress. Webster's New World Dictionary defined stress as "strain" or "pressure" (Guralnik & Friend, 1962). Initially utilized by engineers to explain the amount of force a substance could endure prior to breaking or deforming, Selye (1946) later expanded its application to describe effects of physiological stress on humans. Selye defined stress as any chemical or physical disturbance in the cells or tissue fluid produced by a change, either in the external environment or within the body, requiring a response to counteract the disturbance. The result of stress was termed the general adaptation syndrome (GAS) consisting of three stages: alarm, resistance, and exhaustion.

The purpose of the GAS response is to preserve the organism. The alarm phase triggers the body's defenses to prepare for phase two, the fight or flight stage. The third stage, exhaustion, marks breakdown of

compensatory mechanism and homeostasis. Adaptation is an identified outcome of this stage.

Adaptation is the characteristic of all sensory receptors to change over time either partially or completely in response to stimuli. While receptors initially respond at a high rate, progressively lower reaction rates occur until there is finally no response. This change in response rate is responsible for fatigue at the nerve synapses that causes further depression of sensitivities of the circuits. Fatigue and recovery from fatigue "constitute an important short-term means of moderating the sensitivities of the different nervous system circuits, helping to keep them operational in a range of sensitivity that allows effective function" (Guyton, 1991, p. 505). While fatigue can lead to the demise of the organism, it is also this fatigue that allows the nervous system to recover. Thus, adaptation allows homeostasis and preservation of the organism.

Guyton (1991) defined homeostasis as "the maintenance of static, or constant, conditions in the internal environment" (p. 3). According to this law, all systems of the body should perform their functions so as to maintain the stability of the organism. Each system is organized to promote homeostasis and to operate in harmony with other systems. Of particular importance to an understanding of pain is an understanding of the functioning of the nervous system.

The interconnected control mechanisms of the nervous system are both simple and complex. Simple feedback systems produce complex interactions. Unlike the negative feedback that exists in the other systems of the body, the firing of nerve cells depends on a positive feedback loop.

When the membrane of the nerve is stimulated, a leakage of sodium ions passes through the sodium channels to the interior of the cell. The

addition of sodium ions changes the charge of the interior of the cell causing further opening of the cell membrane to sodium. This positive feedback loop allows large shifts of sodium creating a nerve action potential. This action potential continues until the nerve signal extends to the ends of the nerve fiber (Guyton, 1991). The positive feedback system stimulates multiple negative feedback systems the goal of which is maintenance or homeostasis of the organism.

While adaptation and homeostasis explain reactions to a painful stimulus, they do not explain how complex systems are able to process information quickly and efficiently. One such explanation comes from the work of Bernstein (1966) in Models of the Structural-Functional Organization of Biological Systems. Human organisms, according to Bernstein, are composed of expedient systems combined into a complex controlling system. The work of each subsystem is determined by the environment as well as the complex whole. At each moment, the subsystem solves its particular problem without depending on the whole.

Bernstein (1966) stated that systems with minimal interaction are the most stable. Further, the expediency of these systems contributes to new stable behavior that guarantees minimal interaction in a changed environment. Minimal interaction is part of the principle of homeostasis and assists in explaining how complex systems function in a coordinated continuum.

Bernstein (1966) described the central nervous system as containing multiple nerve centers to control effectors. A change in one center involves a change in the remaining centers. Each nerve center represents an expedient working system (Bernstein, 1966). Consequently, the centers can be considered systems. Interaction among these systems replaces consideration of complex individual connections.

The nervous system is arranged along the principle of the least interaction. "For each external situation the problem of the nervous system is an output into the sort of working behavior in which afferentation is minimal" (Bernstien, 1966, p. 20). This condition eliminates the necessity of detailed control by one center, resulting in expediency and flexibility. Corrections can be introduced by a series of nerve centers rather than requiring coordination among all systems.

In summary, the goal of adaptation, homeostasis, and minimal interaction is to preserve the existence of the organism in a stable state. These theories and laws correspond with the adaptation theory proposed by Sister Callista Roy (Roy & Anderson, 1991). Pain, input, necessitates processing of throughput via regulator and cognator systems to produce a change in the organism predicated by these three principles. Pain has perceived consequences that guide the protective mechanisms of the organism away from danger. Understanding how this response impacts postoperative inguinal hernia patients is the focus of this project.

Health-related Quality of Life and Pain Issues

Maladaptive Behaviors

Prevention programs based on early interventions assume early identification of potential problems (Linton & Hallden, 1997). This early identification relies primarily on establishment of potential risk factors of the condition to be prevented. Little is established concerning the risk that sub-acute pain can develop into a chronic pain problem. Similarly, while fear of injury and pain avoidance have been implicated as precursors to the development of chronic pain, their use in identifying patients at risk for decreased postoperative activity has not been examined.

Vlaeyen, Kole-Snijders et al. (1995) presented two studies that examined fear of injury in chronic pain patients. Findings indicated that fear of injury was more closely related to catastrophizing and depression and less to extent of pain coping and pain intensity (Vlaeyen, Kole-Snijders et al., 1995).

Fear of injury and pain avoidance are reactions associated with chronic pain. Vlaeyen, Kole-Snijders et al. (1995) examined these behaviors and their contribution to pain disability. Fear of injury was implicated in activity avoidance leading to disuse of the musculature. Disuse, in turn, augmented deficits in social, vocational, and motor skills. A shift from mechanical to cognitive reactions to pain can occur within a 4 to 8 week period. Increased arousal in response to pain stimulation contributes to reduction in pain tolerance with subsequent increases in functional limitation and pain disability (Vlaeyen, Kole-Snijders et al., 1995). One such disability is described as activity avoidance.

Activity avoidance refers to a patient's refusal to perform activities because of anticipated pain and suffering. During an acute pain episode, such as postoperative recovery, this may reveal itself as limping, resting, or use of supportive equipment. While these may be acceptable behaviors immediately after surgery, long lasting avoidance of activities can have detrimental consequences, both mentally and physically (Vlaeyen, Kole-Snijders et al., 1995).

Fear of injury was a second identified reason for activity avoidance. Vlaeyen, Seelen et al. (1999) found that avoidance behaviors were not associated with age, gender, number of surgeries, use of medication, or reported pain intensity. Instead, behavioral performance was significantly predicted by pain avoidance and fear of injury.

Katz (1997) investigated postoperative pain and its transition in some patients to chronic pain. The contribution of preoperative pain, intraoperative trauma, and postoperative injury and inflammation in formation of long-term pain was not established (Katz, 1997).

Hart (1998) examined the relationship of health-related quality of life and chronic work-related pain syndromes in a convenience sample of 42 patients in one industrial rehabilitation clinic. Analysis revealed that pain intensity or its interference with activities was not significantly related to perception of level of functional ability. A poor to non-existent relationship was found between perception of reported function compared with actual measurement of performance. Results of this study support the complex relationships between actual functional abilities, perceived functional abilities, and pain intensity or impact of pain in people with chronic pain syndrome.

Gureje, Von Korff, Simon, and Gater (1998) examined data from a World Health Organization survey of 5,447 cross-national primary care patients to determine the association of persistent pain with health perceptions, psychological distress, and activity limitations. The study utilized stratified random sampling with weighted data. Prevalence of persistent pain ranged from 5% to 21.5% and was associated with psychological disturbance and activity limitations.

Keen et al. (1999) examined perception of physical activity by individuals with low back pain. Even though physical activity was viewed as beneficial to health, participants continued to avoid activity because of fear that pain would return. This study supports the importance of early detection of avoidance of activity and/or fear of pain as a method to prevent decreases in levels of physical activity.

Intensity of Sensation

Joris, Hinue, Laurent, Desai, and Lamy (1998) prospectively examined postoperative pain and pulmonary function after gastropasty performed laparoscopically and with an open repair. Because this procedure is frequently recommended for obesity that is resistant to dietary treatment, all patients were comparable for this condition. Fifteen of these consecutive obese patients underwent elective laparoscopic gastropasty and an equal number had open gastropasty.

Many facets of the patients' care were controlled including anesthetic technique and postoperative analgesia. Measures of pain were recorded on a 100-mm visual analogue scale at rest, during mobilization, and during coughing. pain intensity was measured 4 hours after surgery, and at 08:00, 13:00, and 18:00 on day 1, and at 08:00 on day 2 after surgery.

Pain at rest was similar for both groups except at 18:00 on day 1 when patients who had laparoscopic repair reported less pain. Pain during mobilization and coughing was significantly more intense for the group who had an open laparotomy. This corresponds to a higher opioid use in this group. This study provides preliminary evidence of an association between intensity of sensation and activity after surgery.

Gelling (1998) examined two dimensions of quality of life, physical and functional recovery, following liver transplantation. Physical recovery was sub-divided into sleep, pain, and mobility. Pain was found to be an important influencing factor on physical recovery and health-related quality of life. An acceptable degree of mobility was essential to role fulfillment and high perceptions of quality of life.

Functional aspects of recovery were found to be composed of interconnected sub-dimensions that have individualized meanings. All

sub-dimensions were impacted by physical recovery, with return to normal functioning positively contributing to health-related quality of life.

Lichtenstein, Dhanda, Cornell, Escalante, and Hazuda (1998) examined pain and its effect on physical functional limitations. Eight hundred thirty-three Mexican American and European American participants, 65 to 79 years of age, were surveyed. Association of pain frequency, intensity, and location with levels of physical functional limitation was reported. Backwards elimination logistic regression was utilized to determine variables to be included in a final stepwise forward regression model examining the association between pain and physical functional limitations.

A strong association existed between pain and total physical functional limitation. Persons without pain reported functional limitation scores of 2.43 (SD = 2.42) compared to persons with pain who reported functional limitation scores of 4.30 (SD = 2.64). Pain frequency and intensity were highly correlated; however, pain intensity was more strongly associated with physical functional limitations than with pain frequency. Greatest pain was reported in the upper leg. An individual reporting three painful areas in the upper leg was 6.53 times more likely to have difficulty getting out of a chair than an individual without pain. Pain in the upper leg was strongly associated with difficulty with both upper and lower extremity tasks.

Olsson and Thelin (1999) examined health-related quality of life in 76 patients 7 to 76 months following thoracic aortic surgery. Values of $p < 0.05$ were considered significant for the Mann-Whitney U and t-tests used to compare surgical to normal populations. No differences were found for bodily pain. General and mental health, vitality, and social function were lower in the participants prior to surgery, but relatively close to values for normal populations. Emotional and

physical role functioning were significantly lower for participants than the normal population.

After surgery, participants improved mentally more than physically. Unexpectedly, bodily pain was not a reported problem. Significant differences in health-related quality of life were not established for varying acuity, surgical procedure, complications, or dysfunction. Thus, health-related quality of life failed to provide preoperative risk-stratification. After surgery, individuals were found to have similar patterns of health-related quality of life to those who had coronary artery bypass grafts, diabetes, or hypertension.

Atroshi, Gummesson, Johnsson, and Sprinchorn (1999) investigated health-related quality of life after surgery for carpal tunnel syndrome. Before surgery, patients with carpal tunnel had lower health-related quality of life than the normal population particularly for physical functioning, role physical, pain, vitality, and the general physical health component. After surgery, role physical and physical component summary scores remained lower for the carpal tunnel patients when compared to the normal population; however, the mental health and mental component summary score showed improvement (Atroshi et al., 1999).

Higher preoperative pain scores with carpal tunnel syndrome were associated with greater symptom improvement. Correlation of these findings across studies was established. Advocacy of health-related quality of life as integral to evaluation of newly introduced surgical treatments was established. Jones et al. (1998) described quality of life as appropriate to examine surgical preparation, evaluation of practice changes, analysis of longitudinal outcomes after clinical interventions, as well as monitoring overall health status over time.

Shields, Enloe, and Leo (1999) examined the quality of life of 43 patients preoperatively and at 3 and 6 months following total hip or

total knee replacement. Quality of life as measured by the SF-36 was compared to quality of well being, a preference-weighted measure of an individual's health status at one point in time. The highest correlation between these measures occurred preoperatively in individuals with total hip replacement for the health concept of bodily pain. The highest correlation for participants with total knee replacement was also for bodily pain but occurred at 3 months. Physical health was more highly correlated in both groups than mental health. The greatest improvement for these two patient groups in quality of life and quality of well being occurred at 3 months with little change at 6 months. The exception to this was perception of ability to perform role-activity. Those with hip osteoarthritis were found to have lower preoperative perceptions of ability to perform roles, but exhibited greater improvements in this by 3 months when compared to those with knee osteoarthritis. This was posited to have occurred because participants with hip replacement were younger.

Both patient groups exhibited greater difficulty associated with physical recovery than with mental recovery. Both groups perceived their health to be significantly reduced when compared to the general population. Health-related quality of life as measured by the SF-36 was sensitive to changes in patients' perceptions of health after hip or knee replacement.

Gaston-Johansson, Ohly, Fall-Dickson, Nanda, and Kennedy (1999) described the relationship between pain, psychological distress, and coping in 83 persons prior to bone marrow transplant. In this population, significant correlations were observed between physical and role functioning ($0.65, p < 0.001$). Pain, depression, and catastrophizing were all significantly correlated to total health status. "Regression results from the model explained an overall variance

of 65% ($R^2 = 0.65$, $F = 22.48$, $p < 0.05$) of the total health status based on the covariates in the chosen model" (Gaston-Johansson et al., 1999, p. 1343). Because this patient population was treated in a fast-paced ambulatory care setting prior to transplant, these investigators emphasized the importance of focused assessments of patient anxiety, altered physical and role functioning, coping, and cognitive restructuring in order to change perception of pain prior to surgery.

Celia (2000) described age and gender differences in pain management following coronary artery bypass surgery. Three hundred eighty-two participants' charts were retrospectively reviewed from a 554-bed urban university-affiliated medical center in the north-east. T-tests were used to test for postoperative differences between men and women and between ethnic participants. Analysis of variance tested for differences among three different age groups with an alpha chosen of 0.05. A mean patient age was reported as 63.9 with 122 patients reporting ages of 60 or less, 133 reporting ages between 61 and 69, and 122 reporting ages of 70 or older.

No significant differences in prescribed pain medications were reported; however, few of the prescribed medications were administered. During the first 3 days, patients 60 or younger received more pain medications than other age groups. Men and patients with no complications received greater amounts of medication than women and those with complications. Fear of narcotic overdose in elderly patients, along with beliefs regarding pain as an inevitable consequence of aging, contributed to under evaluation of pain in the elderly.

By the year 2020, Celia (2000) reported that individuals aged 65 or greater would comprise 16% of the population. Patients 85 or older were identified as the fastest growing group in this older population.

This demonstrated a clear indication of the necessity for increased skill in assessment of pain in the elderly.

Health-related Quality of Life and Hernia Characteristics

Hernia characteristics are descriptors of a physical abnormality. The number of times experienced, recent changes in size, or how long the patient has had the abnormality are unique to each individual. While the ability of these descriptor variables to predict postoperative outcomes has not been examined in inguinal hernia patients, investigators have determined that a relationship exists between descriptor variables and outcome measures. For example, descriptor variables were found to be associated with poorer quality of life in AIDS patients (Vogl et al., 1999).

Mozes, Cohen, Olmer, and Shabtai (1996) examined patient characteristics related to benign prostatic hypertrophy and factors affecting change in quality of life. This project examined correspondence of personal attributes of patients with surgical outcomes. Four hundred eighty-four consecutive patients who underwent prostatectomy in three medical centers were evaluated for preoperative symptom effect that varied from mild or moderate to severe. Independently related variables were associated with postoperative symptom effects scores and included preoperative socio-demographic factors (age), urology factors, co-morbidity, and quality of life preoperatively. These investigators predicted subgroups of patients who would not improve postoperatively.

None of the subgroups of patients categorized by preoperative symptom effects (mild, moderate, and severe) experienced significant differences in postoperative symptoms. A preoperative indwelling urinary catheter was more predictive of results than type of operative

procedure. Interaction of prostate size or operation type did not enter the model.

Health-related Quality of Life and Personal Attributes

Advances in technology have led to a seemingly limitless expansion in treatment options including an increasing number of elective operations performed on the elderly (Lacey, Meier, Krumholz, & Gusberg, 1995). This expansion increases the importance of assessing outcomes in elderly patients within the context of improving or maintaining optimal quality of life.

Cox, Sprio, and Sullivan (1988) studied social factors leading to perceived health status of the elderly. An association was found between decreased social contacts and increased mortality. Marriage, intimate family ties, and informal associations of church or group membership were found to be strong predictors of perception of health in the elderly. Pain contributed to decreased ability of the elderly to travel outside the home, resulting in isolation and a negative impact on health-related quality of life.

Magnani (1990) explored the relationship between self-perceived health and activity in independently functioning older adults. Higher levels of hardiness and self-perceived health were predicted to be associated with higher activity levels. The combination of hardiness and perceived health were posited to explain more of the variance in activity than each variable considered individually. One hundred fifteen volunteers who were between 60 and 90 years of age were entered in the study. Of the 30 men and 85 women, 41 were married, 55 widowed, 5 separated, 5 divorced, and 9 single. None were recently separated, divorced, or widowed.

Data supported the hypotheses. The correlations between hardiness and self-perceived health were -0.293 ($p < 0.001$) and 0.210 ($p < 0.01$). Perceived health alone explained 4.4% of the variance while perceived health and hardiness explained 10%. This led to the conclusion that other variables contribute to activity besides hardiness and perceived health. To assist the elderly, these investigators recommended that nurses encourage appropriate forms of activity in the elderly.

Sherman, Hughes, and Tavakoli (1995) examined the relationship between health status, functional status, and chronic illness in a nationally representative sample of adults between 18 and 65 years of age. Effects of age, gender, and race on the variables of interest were also examined. Data from 17,688 non-institutionalized individuals were entered in a stratified multistage probability design. Persons with and without chronic illness were compared to measure the influence of functional limitations on perception of health and well being. A strong positive correlation (0.54) was found between perceived health and level of functional status. A moderate correlation between presence of chronic illness and perceived health status also was noted. The correlations varied with age, race, and gender. Individuals with no functional limitations reported a higher percentage of excellent and good health perception as compared to those with functional impairments. Chi-square analysis revealed that perceived health status and functional impairments were related in the total sample and by subgroups of age, gender, and race.

Results of this study indicated that health status is perceived in the context of functional abilities. A stronger correlation existed between functional status and perceived health than between perceived health and chronic illness. This led to the conclusion that functional status was related more closely to perception of health than to presence

of chronic illness. Exploration of programs to improve health outcomes and quality of life by incorporating programs that provide life-enhancing health care services designed to encourage optimal functioning were recommended as a result of this study.

Meir et al. (1996) evaluated the response of older individuals with a mean age of 65 to various painful inpatient hospital procedures. This study reported that pain ratings as measured by visual analog scale decreased with age for procedures involving insertion of intravenous lines or phlebotomy. Pain with urethral catheter insertion was not associated with age. Ratings of amount of discomfort associated with pain suggested that the sensory-discriminative aspects of pain were affected by age.

Sharma et al. (1996) investigated ability of baseline physical functioning, medical, psychosocial, and demographic variables to predict functional outcomes for those undergoing total knee replacement. Baseline physical, psychological, and social functioning, gender, and other medical and demographic variables, as well as self-assessed functional outcomes, were assessed 3 months after surgery. Fifty-two patients aged 55 or older who reported preoperative pain and functional decline were enrolled. A t -test compared baseline and 3 month health-related quality of life as measured by the SF-36. A hierarchical regression analysis was performed with 3-month postoperative health-related quality of life as the dependent variable.

Improvement in strength was significantly associated with physical and social functioning, and bodily pain, but not associated with role or emotional functioning and mental health. Furthermore, demographics and psychosocial factors accounted for 23% of the variance in postoperative health-related quality of life. Psychosocial variables uniquely accounted for 19% in this same variance ($F(3,35) = 4.14$, $p = .020$).

These investigators concluded that while preoperative physical functioning was important, psychological and social functioning were more closely associated with outcomes after total knee replacement. Prior to total knee replacement, physical therapy was thought to optimize patient outcomes. With findings of this study, psychosocial interventions to address psychological welfare and use of support groups were recommended. "Psychological and social status evaluation may be used to identify patients at risk for worse outcomes" (Sharma et al., 1996, p. M156).

Waltz, Kriegel, and Bosch (1996) examined social contributors of individual variability in pain severity associated with rheumatoid arthritis. Two hundred thirty-four participants were predominantly unemployed middle-aged females. Initially, multivariate analysis with hierarchical regression models was utilized to examine predictive relationships between education and pain outcome. Level of formal education was inversely correlated to functional status, depression, and pain severity. While these correlations were weak to moderate (-0.20 to -0.30 , $p < 0.01$), they suggest that formal education is related to clinical outcomes such as pain in individuals with rheumatoid arthritis.

Social support was found to predict less severe depression and fewer pain symptoms. Additionally, negative behavior by a spouse was correlated with depression. This was the only direct association between the social environment and pain outcomes. A major finding was the direct relationship between stressful spouse behavior, pain outcome, and future health status in this patient population. The relationship between pain severity and social functioning was direct and remained even after the effects of baseline pain had been accounted for.

These investigators concluded that an individual's social environment affects the experience of pain severity and health outcomes

via several pathways. Absence of strong rather than weak social ties was linked to perception of pain severity. The association between social factors and pain severity was mediated by psychological functioning at baseline. "Not only the status of being married but also the quality of the relationship in terms of long-term stress and emotional support may be useful prognostic factors in rheumatoid arthritis" (Waltz et al., 1996, p. 356).

Heller, Lim, Valenti, and Knapp (1997) evaluated health-related quality of life as measured by the SF-36 to identify markers that predict future health-related quality of life after hospital admission for heart attack or angina. This study tested the hypothesis that health-related quality of life can be predicted by a number of factors including patient characteristics and severity of disease. Analysis of variance (ANOVA) was used to compare emotional, physical, and social factors at 6 months for variables including sex, age, marital status, employment, previous experience with cardiac disease, and level of baseline health-related quality of life. Variables that showed an association at the $p < 0.10$ were entered into a multiple regression analysis as independent variables, with health-related quality of life as the dependent variable. The sensitivity, specificity, and positive predictive value of each variable was determined relative to a low 6-month health-related quality of life score. Results indicated that selected variables were associated with the lower third of health-related quality of life 6 months after hospitalization. Additionally, interventions produced improvement in 81% of those who would otherwise would have been in the lower third of health-related quality of life at 6 months.

Wisloff and Hjorth (1997) evaluated ability of measures of health-related quality of life to reflect impact of chemotherapy on

survival of patients with multiple myeloma. Before chemotherapy, physical, role, and cognitive functioning, global quality of life, and pain were predictors of survival. Emotional and social functioning had less prognostic capability. In the first 1-2 years of follow up, physical functioning emerged as a powerful prognosticator coupled with general quality of life. Quality of life assessment was found to be an aid in selecting treatment options and in comparing clinical trial results.

Helme and Gibson (1997) reviewed differences in pain tolerance in elderly people. One thousand randomly selected Australian persons 65 or older were interviewed to ascertain demographic and social information, active diseases, functional limitations, and attitudes about health. Questions on pain, its expectation, frequency, site, severity, presumed cause, and treatment were analyzed. Results revealed that pain described as persistent, bothersome, or that of limited activities was the same for all people 65 or older. Forty-four percent of participants reported no pain. The number who reported acute pain was stable across the entire age range. Factors associated with increased pain were low educational level and a history of unpaid employment.

Individuals with a recorded age greater than 80 years and residing in the community reported pain experiences similar to institutionalized individuals of the same age. Older persons were found to underrate pain and its impact on health-related quality of life because of effects from other life events that led to downgrading the importance of pain. These investigators also reported that pain increased with age only up to the 7th decade of life. Maintenance of a steady pain state after this age was unexplained. It was concluded, however, that pain was more prevalent in older persons than those who were young and middle aged. No further increases in pain occurred in extremely old individuals. Persons likely

to emerge with a chronic pain syndrome cluster, "high pain, high functional impact, and high mood disturbance," averaged 51.5 years. This cluster was less likely to occur in older patients.

Padula (1997) studied predictors of health promotion activities in elderly couples. Partnership relationships were described as an important source of support that increased level of interdependence over time. Caregiving was part of everyday relationships and was related to actions found within established roles. A convenience sample of 59 couples who had been married for 35 years or longer was selected to participate from three senior centers. The purpose of the study was to identify predictors of participation in health promoting behaviors. Perceived health status was one of three cognitive-perceptual factors selected for study. Three interpersonal variables, relationship quality, social support, and spousal influence along with selected demographics were proposed as potential predictor variables.

Ages of participants ranged from 54 to 86 with a mean of 72.5. Thirty-six percent of the individuals had less than a high school education. Seventy-three percent rated their health as good with the same percentage reporting a happy marriage. Regression analysis identified five independent variables that explained 30.5% of the variance. These five were relationship quality, perceived health, educational level, social support, and health locus of control. Perceived health status and social support were found to be strong predictors of health behavior. However, the strongest predictor was relationship quality, leading to the recommendation that this be considered prior to planning intervention strategies.

Bennahum, Forman, Vellas, and Albarede (1997) examined life expectancy, co-morbidity, and quality of life of elderly cancer patients. Cognition and freedom from pain were found to be essential to

quality of life with the balance between the two determined by the individual. Age influenced quality of life through assignment of different meanings to similar disease processes. For example, heart disease had devastating consequences for young people with continuing income requirements compared to older retired individuals without such requirements. Equally, age exerted an influence on ability to adapt to stress, illness, and its treatment. Loss of independence meant unemployment for young people compared to older people who believed that loss of independence meant inability to drive. With such differences, quality of life assessment as part of management of elderly patients with cancer was recommended.

Patients receiving dialysis are prone to experience diminished physical working capacity and difficulty in coping with family and social activities. A study designed by Klang and Clyne (1997) examined well-being and functional ability in uremic patients before and after initiation of dialysis treatment. Fatigue, decreased sense of health and functional ability, and emotional distress were analyzed in individuals prior to and after dialysis. Twenty women and 18 men who averaged 54 years of age were entered in the prospective study.

Health in comparison to other people, fatigue, lack of energy, sleep disturbance, mobility, sense of loneliness, mood, and compliance with medications were considered measures of quality of life. Increased fatigue and lack of energy were expected with renal anemia; however, in this study these attributes remained even with correction of anaemia. Notably, patients' dysfunction in recreation decreased after dialysis, while fatigue and lack of energy increased. The participants perceived themselves as ill or well irrespective of whether they had started dialysis treatment. Perception of function and well being could be identified and labeled in three distinct groups including severely

decreased, moderately decreased, or intact quality of life. These levels were not associated with symptoms, metabolic control, or presence of other diseases like diabetes but more with sense of coherence. As with operative procedures, uremia resulted in individualized reactions. The results of this study emphasized that assessment of quality of life is needed to allocate support to patients in need.

Effects of age on quality of life have not been clearly established. Ross and Crook (1998) examined pain, disability, and functional competence in the elderly. The extent to which pain was related to disability and social, physical, or emotional functioning was not established. "This dearth of knowledge about pain may be compromising the health and well-being of an increasing population of vulnerable and frail older adults" (Ross & Crook, 1988, p. 1119).

Recognizing that health care costs occur when the elderly lose functional independence, Cochrane, Davey, Munro, and Nicholl (1998) studied exercise, physical function, and health perceptions in this population. Results of this study indicated that subjects who participated in a 1-hour exercise program an average of 1.4 times per week exhibited significant improvement in physical function tests. These changes were accompanied by improvements in self-reported health status. Changes in health perceptions showed a moderate effect size. Similarly, Myers et al. (1999) measured health-related benefits of exercise participation in older adults. The benefits of exercise programs included improved emotional and physical feelings.

Ghusn, Stevens, and Attasi (1998) surveyed 135 outpatient and 53 inpatient veterans who were between 65 and 97 years of age to examine psychosocial issues in an effort to understand enhancements to quality of later life. Frequency and reciprocity of contact with family and friends were hypothesized to be positively associated with later life

satisfaction of older veterans. Also predicted to be positively associated with later life satisfaction were ongoing respect, meeting one's own expectations, and a sense of usefulness.

Older inpatients were found to have later life satisfaction predicated by respect and sense of usefulness, while outpatients reported interpersonal involvement as a greater contributor to later life satisfaction. Meeting one's expectation was important to both populations. Generally, support systems were important and when unavailable, placed greater importance on enhancement of continuity in respect and sense of usefulness.

Covinsky et al. (1999) examined health status and health-related quality of life in older patients. Because of differing expectations and adaptations, older patients assigned different meanings to the same level of health. The capacity to adapt to declines in health status varied depending on personality traits, psychological status, social support, and characteristics of the environment. Adaptation was predicted through a complex interaction between dimensions of life impacted by medical treatments.

Ellingson and Conn (2000) examined exercise and health-related quality of life in the elderly. These investigators posited that exercise influenced two components of health-related quality of life, physical functioning and well being. The cited benefits of exercise were increased resistance to disease, enhanced functional independence, improved muscle strength, joint flexibility, and general endurance. Psychosocial benefits of exercise included enhancement of social and emotional well being as well as improved cognitive ability to take part in social activities. Self-esteem increased with exercise. A review of current literature conducted by these investigators revealed that a bi-directional relationship exists between exercise and health-related

quality of life. High levels of exercise enhance health-related quality of life and those who experience a high degree of health-related quality of life are more likely to exercise.

An analysis of 5 descriptive and 11 experimental studies that examined the relationship between exercise and health-related quality of life revealed that in one case, measured pain, affect, and physical functioning after exercise did not lead to changes in quality of life. Two studies that used specific measures of health-related quality of life found no significant differences in perception of health-related quality of life after exercise. The remaining studies documented that exercise delayed progression of functional decline in older adults. Evidence linking exercise and health-related quality of life suggested that assessment of risk for declines in health-related quality of life with interventions to promote exercise are important nursing activities.

Kurtz, Kurtz, Stommel, Given, and Given (2000) explored symptomology and loss of physical functioning in geriatric patients with lung cancer. Of these patients, 60% to 90% with advanced lung cancer reported pain that was severe enough to impair physical functioning. To examine the relationship between symptomology and physical functioning, 133 patients (58% male and 42% female) from 26 sites in southern Michigan were entered in a longitudinal study. Surveys were conducted between 4 to 6 weeks after surgery and within 2 to 4 weeks following subsequent radiation or chemotherapy.

Physical functioning was measured by one sub-scale of the SF-36 related to physical functioning. The 10 items that make up this sub-scale were found to have a Cronbach's alpha of 0.89 and were thought to distinguish groups differing in severity for chronic medical conditions and to be a distinct measure of physical health.

Results of analysis of covariance (ANCOVA) "revealed that loss of physical functioning was positively correlated with prior physical functioning and negatively correlated with patient age" (Kurtz et al., 2000, p. 252). Patients suffering greater losses in physical functioning tended to be younger and had high pre-diagnosis levels of physical functioning. Patients reporting high baseline physical functioning generally were younger, suffered from fewer co-morbid conditions, and reported lower symptom severity.

ANCOVA revealed that baseline physical functioning ($\beta = 0.52$, $p < 0.001$), symptom severity ($\beta = 0.30$, $p < 0.001$), and patient age ($\beta = -0.18$, $p < 0.032$) were significant predictors of loss of physical functioning. Younger patients and those patients with higher baseline levels of functioning suffered greater losses in physical functioning. Stage of disease, gender, treatment type, or any interaction of these characteristics impacted physical functioning.

Summary

Postoperative pain requires an adaptive response from patients that is unique and predicated by the adaptive zone and capabilities of each patient. An examination of the theorems and laws that form a basis for understanding the multidimensional phenomenon, pain, includes adaptation. This concept explains the body's level of response to stimuli as well as accomplishment of the ultimate goal of survival. Adaptation is the central focus for the theoretical foundation for nursing as proposed by Sister Callista Roy and provides the basis for this research project.

An adaptive response results in either optimal or lower health-related quality of life. Health-related quality of life is thought to be composed of at least eight sub-divisions which can be described by two main summary domains of physical and mental

functioning. The two domains, physical and mental components, represent more levels of health than any of the eight sub-divisions consequently providing greater precision in evaluating health-related quality of life (Kazis, 1998). The physical and mental components correspond to the regulator (physiological) and cognator (higher brain functions) systems proposed by Sister Callista Roy (Roy & Andrews, 1991). Thus, they provide a link to theoretically based nursing assessment.

CHAPTER III

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

Design

The design for this study was a non-experimental retrospective analysis of variables generated during an ongoing longitudinal cooperative clinical study designed to examine patient outcomes after inguinal hernia repair. The executive committee for this Veterans Affairs Cooperative Study approved the use of the data for this project (see Appendix F).

Setting

Data were collected in 14 Veterans Affairs Medical Centers located in the continental United States. Initial randomization took place in the clinical setting. The surgical procedure was conducted as day surgery.

More than 90 variables including screening: pain intensity, preoperative activities, and health-related quality of life are contained in the data set. The staff at the Hines Veterans Affairs Medical Center are responsible for the data set.

Population and Sample

The target population was all competent adult males presenting to be evaluated for inguinal hernia repair. A non-probability sample of patients were approached and screened for eligibility. Females and patients with particular co-morbidities were excluded. Among those excluded were patients with an American Society of Anesthesia (ASA) class IV or V, a hernia that could not be detected on physical exam,

presence of bowel obstruction or local/systemic infection, contraindications to pelvic laparoscopy, recurrent mesh repair of hernia, or participation in another clinic trial. At the time of this study, 560 patients had completed baseline and 3 month data.

Instruments

Four instruments used in this study contributed to the analyzed data.

1. A Screening form (see Appendix B) included demographic data and was collected to ascertain appropriateness of participants.

2. The Preoperative Activity Form (see Appendix C) provided information regarding the identified reason patients experienced difficulty with activities prior to surgery. Reliability and validity estimates were determined.

3. Sensory Intensity (see Appendix D) was measured with four visual analog scales (VAS). Pain at rest, pain with normal activities, pain during work, and how bothersome the worst pain was were measured with horizontal lines 150 millimeters long. Verbal anchors indicated extremes of the sensory intensity experienced by the patient. Interval level data were obtained by measuring the distance of the patient's mark from no pain at one end to most intense pain imaginable at the other end. A VAS is considered a sensitive measure of pain intensity. Reliability of the VAS on repeated measures has been reported as $r = 0.95$, $p = < 0.001$ (Frank-Stromberg, 1992).

4. The SF-36 (see Appendix A) contained 36 questions that evaluated patients' beliefs regarding health in eight areas including limitations in activities due to health or emotional problems, limitations in role activities due to health problems, bodily pain, general mental health, limitations in social activities due to physical or emotional problems, vitality, and general health perception. The

SF-36 was derived from a long-form measure of general health status (Reed, 1988).

Development of the SF-36

Outcome measurement relies on rules for assignment of numbers to objects to represent the amount of an existing attribute. A methodological debate exists on the reporting of data. Should scores be summarized into one overall score, or should they be reported as component summary scores? A profile approach, inclusion of separate sub-categories, ensures that the domains of life are treated as incomparable.

A debate remains concerning the value of using disease-specific measures sensitive to changes in a specific population versus generic measures that compare outcomes across patient populations. Generic instruments have been thoroughly researched, however, increasing the predominance of their selection. Development of a well-documented generic measure, the SF-36, encourages use of this type of measure. Dijikers (1999) described the SF-36 as offering a profile approach that includes objective and subjective measures of health-related quality of life.

The Medical Outcomes Study (MOS), a precursor to the SF-36, was developed in response to a need for information on impact of health care systems on patient outcomes. Tarlov et al. (1989) utilized the MOS to examine impact of type of care on an array of patient-reported outcomes in patients with hypertension, coronary heart disease, diabetes, and depression. Comparison of these outcomes to independent physical and laboratory examinations was performed at the beginning and end of the study. Replication occurred at three geographical sites, Boston, Chicago, and Los Angeles. The MOS was found to be a reliable

instrument to understand how health care policies affect medical management decisions and patient outcomes.

Stewart, Hays, and Ware (1988) described development of an instrument that represented a compromise between lengthy instruments and single-item measures of health perception. Eleven thousand one hundred and eighty-six adults answered 20 items that were located in the middle of a 75-item self-administered questionnaire. The short form was evaluated to assure similarity of patterns to those patterns observed with the long-form measures. "Reliability coefficients for the multi-item health scales ranged from 0.81 to 0.88" (Stewart et al., 1988, p. 728). Internal consistency reliabilities of the short forms were only slightly lower than the long form. The potential of the short form to evaluate the effects of health care within practical constraints was established.

The population served by the Veterans Affairs (VA) Medical Centers are older with a predominance of chronic disease. The goals of patient care within the Veterans Affairs Medical system are no longer focused solely on survival or curing disease, but on optimizing patient's functional health and well being (Kazis et al., 1996). For postoperative inguinal hernia patients, functional health assessments are important indicators of the postoperative disease burden experienced by patients.

The long-form measure of health status that served as the foundation for the SF-36 captures two major dimensions of health, physical and mental health (Reed, 1998). The eight sub-category concepts represented in the SF-36 contribute to two main domains of interest, physical and mental components of health (PCS and MCS). These measures contribute to a uniform approach for assessing patient health status (Kazis et al., 1996).

Kazis et al. (1996) analyzed the physical and mental components of health-related quality of life in veterans. This analysis provided information now advocated as performance measures for the year 2000. As such, the two domains represented by the physical and mental components of health-related quality of life are proposed as a preferred method to evaluate efficiency and effectiveness of care delivery. Thus, the physical and mental components of health-related quality of life are appropriate outcome measures for the veteran population.

Validity and Reliability of the SF-36

Mahler and Mackowiak (1995) evaluated the ability of the SF-36 to measure health-related quality of life in patients with chronic obstructive pulmonary disease (COPD). Fifty male patients with COPD were recruited from one out-patient clinic at Dartmouth-Hitchcock Medical Center. Strong evidence for validity of the SF-36 in measuring health-related quality of life in this patient population was established by comparing the relationship of dyspnea ratings and lung function with scores for the separate components of the SF-36. Physiologic variables were helpful to clinicians in assessing COPD patients; however, patients reported greater concern with symptoms, ability to function, and general well-being (Mahler & Mackowiak, 1995). Use of the SF-36 with scales to measure specific symptoms was supported as superior to use of physiological measures alone in providing complete patient assessment.

Kyes, Franklin, and Weaver (1997) utilized several subscales of the SF-36 including physical functioning, role limitation, bodily pain, general mental health, and general health perceptions to assess injured workers. These subscales were found to be reliable and valid as outcome measures for these workers.

Husted, Gladman, Farwell, and Long (1997) validated the use of the SF-36 in its entirety with psoriatic arthritis. Health status measures

usually focus on functional status and well being rather than traditional clinical endpoints (Husted et al., 1997). Reliability of the SF-36 was examined by assessing its ability to differentiate between individuals with psoriatic arthritis and those from a general population. Validity was examined by comparing the degree to which the SF-36 correlated with traditional measures of function, disease, activity, and severity of illness (Husted et al., 1997). Physical function, pain, and vitality scales of the SF-36 were determined to be good indicators of overall physical functioning and disease activity. Further, the SF-36 was deemed appropriate for use with arthritic patients and for comparison of health status across different patient populations.

Ruta, Hurst, Kind, Hunter, and Stubbings (1997) examined the reliability, validity and responsiveness of the SF-36 with British rheumatoid arthritis patients. Test-retest methods were used to assess reliability. The scores for repeated tests were examined for patients who reported that their arthritis had not changed in two weeks. "The standard deviations of within-subjects differences over time were used to calculate the size of score differences detectable with repeated measurements in an individual patient with 95% confidence" (Ruta et al., 1998, p. 426). Additionally, Goodman and Kruskal's kappa measured reliability for ordinal scales. For this population, the values of kappa for social function, role limitations-physical, and role limitations-emotional indicated poor test-retest reliability. Intra-class coefficients for the physical summary score were high. These investigators emphasized that transformation of the SF-36 scores into physical and mental component summary scores gave distributions that were nearly Gaussian and reduced the marked floor or ceiling effects noted in the sub-scale score distributions.

To examine construct validity of the SF-36 as a measure of health status, stepwise multiple regression was used to model the relationship between the scales of the SF-36 with other clinical and sociodemographic variables, and condition-specific measures simultaneously. Condition-specific measures should enter the regression model simultaneously to support construct validity. The advantage of utilizing summary scores, for which a t or z score may be calculated, is facilitation of comparison with published population norms.

A Spearman rank correlation coefficient matrix revealed correlation between the eight SF-36 sub-scales and specific measures of impairment. The physical and mental summary scores correlated more with pain and disability than with measures of impairment and disease process. Further, forward stepwise regression revealed that "disease activity, VA-pain and joint tenderness scales, together with age, years of education, drug side-effects, duration of arthritis, and co-morbidity were able to explain a substantial proportion of the observed variation in five of the SF-36 scores" (Ruta et al., 1998, p. 431). These variables remained in the model at 3 months and explained 76 to 86% of the variance in the physical and mental summary scores. The regression equations remained stable at the 3 month follow-up (Ruta et al., 1998). This study supported use of the physical and mental summary scores for assessment of health-related quality of life. While they did not discriminate between patients with increasing disability, they were less likely to reflect the floor and ceiling effects that occurred when examining the eight sub-scales. The SF-36 scales met the reliability standards required of a measure when used to compare groups of patients (Ruta et al., 1998).

Kazis (1998) concurred emphasizing that the physical and mental summary scores "define many more levels of health than any of the eight

SF-36 scales individually and consequently provide greater precision" (p. 226). Further, reliability estimates of the physical and mental summary scores by age, race, education, and marital status "ranged from 0.90 to 0.95 for physical summary and 0.85 to 0.90 for mental summary scores" (Kazis, 1998, p. 226).

Reed (1998) utilized factor analysis to examine the assumption that the item groupings of the SF-36 are invariant across groups. Through structural equation modeling (SEM) "the cross-loading of general mental health onto Physical Health suggests that a person's perception of Physical Health has a greater effect on that person's general mental health than has been predicted" (Reed, 1998, p. 1376). This implies importance of the physical impact of surgical procedures on the mental health of patients. This association is epitomized by considering the impact of pain on the physical and emotional well being of patients.

Protection of Human Subjects

The Veterans Affairs Cooperative Study was approved by the Institutional Review Board (IRB) of all participating Veterans Affairs Medical Centers (see Appendix E for an example of approved consent of Dallas IRB). The Human Subjects Committee of Texas Woman's University approved the study (see Appendix G).

Data Collection

Data for this VA cooperative study were collected at 14 geographically represented Veterans Affairs Medical Centers in the continental United States. In order to control for potentially confounding variables inherent with use of multiple sites, only trained site coordinators were involved with data collection. Ongoing training via conference calls ensured similar data collection techniques. This is an ongoing longitudinal cooperative study that began in January 1999 and

will culminate in January 2004. This data set represents the first third of the accrual of patients.

Treatment of Data

The Statistical Package for Social Sciences (SPSS) version 10.0 was accessed via a personal computer. Descriptive statistics were utilized to describe characteristics of the population. Canonical correlation analyses examined the relationships between pain issues, hernia characteristics, and personal attributes and postoperative health-related quality of life.

Canonical correlation analysis examines the different dynamics in the ability of a set of variables to explain different portions of another variable set (Thompson, 1984). This project sought an explanation of a set of several aspects of the dependent variable by a set of independent variables. Yielded from this investigation was information related to combinations of dependent variables and their relationship to combinations of independent variables (Levine, 1977). The variates generated are similar to principle components with factor loadings that are examined as to the signs and sizes of the loadings (Beard, Edwards, Curry, Marshall, & Johnson, 1996). The benefit of this technique is that it reflects reality where most outcomes have multiple causes and most contributing variables have multiple effects (Thompson, 1984). Pillais criterion tested for significance of main effects and interactions (Tabachnick & Fidell, 1996).

Seven questions can be answered with canonical analysis. First, the extent that one set of variables can predict another variable set. Second, the contribution of one variable to the set to which it belongs. Third, the contribution of one variable to the variable set to which it does not belong. Fourth, the dynamics involved in one set of variables predicting different portions of another variable set. Fifth, the power

of different canonical functions to predict or explain relationships. Sixth, the stability of canonical results across a variety of sample sub-groups. Seventh, how closely the observed and predicted values correspond to each other (Thompson, 1984).

Assumptions were met for canonical correlation including minimal error in variable measurement, non-restricted variances, and no substantial attenuation associated with distribution differences. A fourth distribution assumption is applied for population parameters. Driven by the multivariate central limit theorem, this assumption is considered met with a large sample size (Thompson, 1984). Table 2 describes selected variables of interest for this study along with the instrument utilized for its measurement.

Dependent Variable

The eight aspects, as well as the mental and physical components of health-related quality of life, were measures of the dependent variable. Health-related quality of life was reported at baseline and 3 months.

Independent Variables

Pain issues were reported as intensity of sensation and maladaptive behaviors. Four visual analog scales (VAS) measured in millimeters produced interval level data used to represent intensity of sensation.

Table 2

Study Variables and Their Measurements

Variables	Measurement
Dependent Variable	
Health-related Quality of Life:	SF-36 3 month postoperative-preoperative
MCS	
1. Vitality	MCS calculated predominantly from scores on 1-4 for baseline and 3 months.
2. Social functioning	
3. Role-emotional	
4. Mental health	
PCS	
5. Physical functioning	PCS calculated predominantly from scores on 5-8 for baseline and 3 months.
6. Role-physical	
7. Bodily pain	
8. General health	
Independent Variables	
1. Pain Issues:	
a. Intensity of Sensation--	Visual Analogue 150 mm
Pain at rest	
Pain with normal activities	
Pain with work	
Worst pain	
b. Maladaptive Behavior:	Preoperative Activities
Fear of injury	D
Pain avoidance	E
No difficulty	
2. Hernia Characteristics:	Hernia Assessment
Time from onset	'1' = < 6 weeks; '2' = 6 weeks to 1 year; '3' = > 1 year; '4' = unknown
Recent increased in size	'1' = no increase in past 6 weeks; '2' = yes increase in past 6 weeks
Primary or recurrent repair	P = primary repair or R = recurrent repair
3. Personal Attributes	Patient Assessment
Age	Chronological
Marital status	Single = 1; Married = 2; Divorced = 3; Separated = 4; Widowed = 5
Education	Number of years of school completed
Functional limitation	'1' = Independent '2' = Partially dependent '3' = Totally dependent

Maladaptive behavior was reported categorically on the Preoperative Activity Form as either no difficulty with activity or as difficulty with activity due to one of the following reasons: (a) advised to refrain from activity from medical caregivers or family members, (b) necessity for help with activities, (c) pain avoidance, (d) fear of injury, or (e) other. Because few patients reported receiving advice, needing help, or other, only pain avoidance or fear of injury was considered for this project.

Hernia characteristics were categorically reported as primary or recurrent. No increase in size in the past 6 weeks, or increase in size of the hernia in the past 6 weeks were reported. How long the hernia had been present was reported as less than 6 weeks, 6 weeks to 1 year duration, greater than 6 weeks, or unknown.

Personal attributes were reported with an interval level measure for age and three categorical measures including highest grade of school completed, marital status, and functional limitations. Marital status was reported as single, married, divorced, separated, or widowed. Functional limitations were reported as independent, partially independent, or totally dependent.

Canonical correlation analyses were utilized to examine each set of independent variables, pain issues, personal attributes, and hernia characteristics, with postoperative health-related quality of life. Health-related quality of life was assessed at baseline and at 3 months. Although structure coefficients (cross-loadings) of 0.300 may be considered, 0.400 or higher was treated as meaningful (Tabachnick & Fidell, 1996).

Summary

Nurses are in an ideal position to assess and treat patients in pain. Preoperative assessment of reactions to pain has been advocated.

These assessments have not included risk variables identified through the research process. By establishing variables associated with pain and lower health-related quality of life in inguinal hernia patients, patients at risk may be identified. This knowledge provides an opportunity for treatment decisions prior to operative procedures.

The Physical and Mental Component Summary Scores generated from the SF-36 are indications of impact to physical and mental components of health-related quality of life. These scores correspond to the regulator and cognator systems described in Roy's adaptation theory. Through this link, this project will provide theoretically based nursing assessment and intervention, as well as optimal health-related quality of life for inguinal hernia patients.

CHAPTER IV

ANALYSIS OF DATA

The major purpose of the study was to explore relationships between selected preoperative variables and postoperative health-related quality of life. Roy's theory of adaptation provided the underlying theoretical framework. This chapter presents the results of canonical correlation analyses examining postoperative health-related quality of life and potentially influential variables.

This chapter is divided into three sections. The first describes the population sample. Frequencies, means, and standard deviations are reported. The second section examines the validity of the SF-36. The third section contains the findings related to the three hypotheses. Relationships of personal attributes, hernia characteristics, and pain issues to postoperative health-related quality of life are evaluated to address these hypotheses. Pillais criterion was chosen to test the significance of main effects and interactions. When there is an expectation that separation of significant groups will be distributed over many dimensions, Pillais criterion is robust and represents the pooled effect variance (Tabachnick & Fidell, 1996). A value of 0.400 or greater was then chosen to distinguish covariates that contributed to profiles associated with significant outcome clusters.

For each hypothesis, the independent variables were analyzed with canonical analyses to determine how they were associated with the dependent variable. The dependent variable, postoperative health-related quality of life as measured by the SF-36, was considered in two different ways. First, the eight aspects of health-related quality of

life included: bodily pain, general health, physical function, role physical, vitality, mental health, role emotional, and social function of health-related quality of life. Secondly, the two components, physical and mental, formed from the eight aspects of health-related quality of life were examined.

Patient Sample

The non-probability sample for this study was chosen from male patients who presented at one of the participating Veterans Affairs Medical Centers for repair of an inguinal hernia. Of the total available population, 560 participants completed baseline and 3-month data. Participants were entered who met the study criteria, were able and willing to participate, had no identified exclusionary factor, and were at least 18 years of age.

Although 560 participants completed baseline and 3 month data, not all respondents completed all questions. Patients not participating in strenuous work or lifting, were told to skip the visual analog scale (VAS) measuring intensity of sensation during work or lifting on the intensity of sensation instrument. After randomness of this event was established, these participants were eliminated leaving 508 participants for the analysis of Pain Issues.

Table 3 depicts the ages of this male population as ranging from 24 to 85 with the majority, 435 (77.7%), between 49 and 78; the mean was 60.76 (SD = 12.27) which compares with national averages for veterans of 63.4 (SD = 12.7) (Kazis, 1996). The greatest number of participants were either currently married (51.3%) or had been married and were now divorced (21.8%). This compares to national averages for veterans of 60.9% married. Fifteen percent of the study population were single, and nearly equal numbers were either separated (5.5%) or widowed (6.6%).

Table 3

Demographic Characteristics of the Sample

Variable	N	Percent
Personal Characteristics:		
Age 18-33	10	1.8%
Age 34-48	83	14.8%
Age 49-63	215	38.4%
Age 64-78	220	39.3%
Age 79-100	32	5.7%
Marital Status:		
Single	83	14.8%
Married	287	51.3%
Divorced	122	21.8%
Separated	31	5.5%
Widowed	37	6.6%
Education:		
Elementary School	15	2.7%
High School	319	56.8%
College	193	34.4%
Post Graduate	33	6.1%
Functional Limitation:		
Independent	541	96.6%
Partially dependent	18	3.2%
Total dependent	1	.2%
Hernia Characteristics:		
Recent increase in size:	288	51.4%
No	270	48.2%
Yes		
Primary or recurrent:		
Primary	500	89.3%
Recurrent	60	10.7%
Time from onset:		
< 6 weeks	54	9.6%
6 weeks - 1 year	267	47.7%
> 1 year	203	36.3%
unknown	35	6.3%
Maladaptive Behavior:		
No difficulty	265	47.3%
Yes difficulty	295	62.7%
Reason for difficulty		
D - fear of injury	107	19.2%
E - pain avoidance	148	25.7%
Other	40	7.1%

Most participants reported having a high school education (56.8%) with 2.7% reporting elementary school education. This compares to 59.7% for the national average of veterans who reported completing high school. Thirty-four percent of participants had either attended or completed college. Six percent had pursued postgraduate education.

Predominantly, participants reported that they could function independently (96.6%). Eighteen (3.2%) stated that they were partially dependent, and 1 patient reported total dependence.

Two hundred seventy (48.2%) of participants reported an increase in size of hernia in the previous 6 weeks. Fifty-one percent reported no increase in hernia size. Over 89% of individuals reported no experience with previous hernia repair of the identified hernia. Two hundred sixty-seven participants (47.7%) reported that the hernia had existed for 6 weeks to 1 year. Two hundred three participants (36.6%) reported a hernia history of longer than 1 year. Fifty-four (9.6%) reported a hernia present for less than 6 weeks, and 35 (6.3%) did not know how long the hernia had been present.

Two hundred sixty-five (47.3%) of participants reported no difficulty with activities; the remaining 295 (62.7%) individuals reported difficulty with activities. Of the 295 reporting difficulties with activities, 107 (19.2%) stated that they feared injury and 148 (25.7%) stated that they avoided activities due to pain. Twenty-seven (4.8%) individuals reported that they had been told to avoid activities by a medical caregiver or family member, or that they required help with activities. Thirteen (2.3%) listed "other" as the most important reason for difficulties with activities.

Table 4 describes average pain at rest as 22.7mm out of 150mm with SD = 30.26mm. Pain with normal activities averaged 35mm with SD = 37.4mm; pain with work revealed a mean of 58mm with SD = 48.9mm. Average

disturbance by worst pain was reported at 40mm with SD = 42mm. Clearly, activity level increase was accompanied by greater pain. Increasing VAS scores with increasing levels of activity provides preliminary indications that preoperative activities and pain are positively associated.

Baseline health-related quality of life revealed that role physical exhibited the greatest range and lowest mean within participants. The physical components of health-related quality of life average 50 for non-veterans and 36.91 for veterans compared to 41.7 in the sample (Perlin et al., 1999). Participants of this study reported higher overall physical health than average veterans, but lower overall physical health than average non-veterans.

Baseline mental components of health-related quality of life averaged 50 for non-veterans, 45.08 for veterans compared to 43.3 (Perlin et al., 1999). The study population had lower mental health than average veterans or non-veterans.

Three-month postoperative health-related quality of life revealed that the study population averaged less (43.17) for physical components of health-related quality of life compared to non-veterans (50) but were higher than veterans (36.91) (Perlin et al. 1999). Mental components of health-related quality of life at 3 months revealed that study participants were lower (43.17) than veterans (45.08) and non-veterans (50) for overall mental health (Perlin et al., 1999).

Table 4

Distribution of Age, Pain, and Health-related Quality of Life

Variable	Mean	<u>SD</u>	Range	Skewness	Kurtosis
Age	60.76	12.27	61	-0.273	- .0528
Pain at rest	22.70	30.26	150	1.92	3.45
Pain with normal activity	35.35	37.42	153	1.106	.373
Pain with work	58.25	48.89	155	.35	-1.23
Pain disturb	40.05	42.14	151	.99	- .13
Baseline body pain	57.64	24.57	100	- .05	- .69
Baseline general health	70.81	20.99	90	- .565	- .44
Baseline physical function	63.07	27.66	100	- .40	- .893
Baseline role physical	28.31	40.72	100	.962	- .853
Baseline mental health	58.38	12.11	60	- .548	- .361
Baseline role emotional	50.92	45.84	100	.0002	-1.841
Baseline social function	64.69	24.70	100	- .756	- .596
Baseline vitality	54.51	13.01	60	- .089	- .188
Baseline PCS	41.71	10.45	51.7	.100	- .649
Baseline MCS	43.39	9.24	46.9	- .154	- .895
3-month bodily pain	75.28	25.44	100	- .834	- .149
3-month general health	70.58	21.64	100	- .69	- .187
3-month physical function	78.62	26.09	100	-1.243	- .537
3-month role physical	52.14	45.23	100	- .09	-1.81
3-month mental health	60.32	12.14	56	- .78	- .03
3-month social function	72.61	21.49	100	-1.31	.734
3-month vitality	56.68	12.32	60	- .163	.284
3-month role emotional	63.75	44.15	100	- .548	-1.53
3-month PCS	48.43	10.92	48.7	- .63	- .696
3-month MCS	43.17	8.495	46	- .68	- .438

Health-related quality of life improved from baseline to three months in the areas of bodily pain, physical functioning, and role physical, but decreased in general health. Overall physical components of health-related quality of life improved slightly.

Slight improvement in health-related quality of life at three months was evident in the areas of mental health, social functioning, and vitality. Greatest improvement was noted in role-emotional. However, overall mental health components of health-related quality of life declined. In general, physical gains were greater than mental gains with the largest change recorded in physical functioning and ability to accomplish roles. General health and overall mental component revealed an overall loss from baseline to 3 months postoperative.

Validity of Instruments

The Short Form 36 (SF-36) used to measure preoperative and postoperative health-related quality of life contained 36 items. These 36 items contributed to eight sub-category scores that, in turn, contributed to two component summary scores. The Pearson correlation coefficient alpha for the four sub-category baseline scores that contributed to the physical component summary score (physical function, role physical, bodily pain) was 0.777. The four sub-category scores that contributed to the baseline mental component summary score (vitality, social function, role emotional, mental health) was 0.715. A correlation of 0.50 to 0.75 suggested moderate validity (Portney & Watkins, 1993). The correlation coefficient for the physical and mental component summary scores was 0.204 supporting that the two component summary scores are measures of different constructs.

The Pearson correlation coefficient for the postoperative physical components was 0.81 and for the mental components summary was 0.73. Values above 0.75 are indicative of good validity (Portney & Watkins,

1993). The postoperative mental and physical component summary scores had a correlation of 0.32 again supporting that these scores measured different constructs.

Findings

Hypothesis 1 stated: Pain issues (i.e., increased intensity of sensation and presence of preoperative maladaptive behaviors) predict lower postoperative health-related quality of life. Hypothesis 1 was examined through two canonical analyses. Canonical analysis was first performed on pain issues and the aspects of health-related quality of life. Subsequently, canonical analysis examined pain issues and postoperative mental and physical components of health-related quality of life.

Table 5 reports the canonical analysis of pain issues and the postoperative aspects of health-related quality of life. While formation of six variate pairs was possible, only one variate pair was significant. The variate pair formed was interpreted from factor loadings of 0.400 or greater. Negative factor loadings for all aspects of health-related quality of life contributed to a description of the dependent variate set as low postoperative health-related quality of life. Positive factor loadings for the independent variate set led to a description of this variate set as high pain issues. Preliminarily, a high pain issues variate set associated with a low postoperative aspects of health-related quality of life variate set supported Hypothesis 1.

The standardized weight for bodily pain indicated its unique contribution to the dependent variate set. High loadings for bodily pain and social function indicated the importance of these two variables to the underlying dimensions of the low postoperative healthy-related quality of life variate set.

Redundancy is a measure of how much variance one variate set (dependent variate set) extracts from the other set of variables (independent variables) $(\bar{S}^2)(r_c^2)$. In this case, redundancy was the amount of variance the health-related quality of life variate set extracted from the pain issue variables; and vice versa, the amount of variance the pain issues variate set extracted from the health-related quality of life variables (Stewart & Love, 1968).

As noted in Table 5, the postoperative health-related quality of life variate set extracted half (50%) of the variance in the postoperative health-related quality of life variables. The canonical variate set formed from the individual aspects of health-related quality of life extracted a small (5%) percentage of the variance from the set of pain issue variables.

Highest loadings were identified for pain at rest and pain disturbance indicating that these two variables made the strongest contribution to the underlying dimension of the high pain issues variate set. The canonical variate set composed from pain issues extracted over half (55%) of the variance from the independent variable of pain issues and a small portion (6%) from the set of individual aspects of health-related quality of life. High pain issues associated with low postoperative health-related quality of life supported Hypothesis 1.

Table 5

Canonical Analysis of Pain Issues and the Postoperative Aspects of Health-related Quality of Life

<u>Dependent Variables</u>	<u>Canonical Variate Pair</u>	
	Loading	Weight
Post physical function	-.717	-.210
Post role physical	-.583	.096
Post bodily pain	-.870	-.564
Post general health	-.681	-.139
Post vitality	-.612	.180
Post social function	-.823	-.333
Post role emotional	-.618	-.137
Post mental health	-.717	-.336
% of variance	50.28	
Redundancy	5.176	
<u>Independent Variables</u>		
Pain at rest	.867	.514
Pain with normal activities	.774	.092
Pain with work or lifting	.760	.118
Pain disturbance	.827	.304
Problems with activities	.614	.225
Difficulties = pain avoidance/fear of injury	.533	.007
% of variance	54.54	
Redundance	5.614	
Canonical correlation	.321***	

Note. Weights are standardized canonical weights; the loadings are the structure coefficients.

Overall Pillais = .812, $p < .001$.

Percentage of variance accounted for within the set by the canonical variates for the set.

*** $p < .001$.

Table 6 reports the results of canonical correlation analysis of pain issues and postoperative physical and mental components of health-related quality of life. Of the two possible canonical variate pairs only one pair was significantly correlated. Both variables, physical and mental components of health-related quality of life, contributed to this variate set. Physical components contributed the stronger underlying dimension to this variate set. More than half (58%) of the variance in postoperative physical and mental components of health-related quality of life was explained by the physical components variate set with a small portion (5%) of variance in pain issues explained by this variate set.

A profile of people who reported low pain issues prior to surgery were expected to experience high postoperative physical and mental health-related quality of life. Pain at rest contributed the greatest amount to the underlying dimension of this variate pair. Difficulty with activities contributed the least. The size of the weight for pain at rest ($-.557$) indicated the importance of this variable to the pain issue variate set. More than half (54%) of the variance in pain issues was captured by the pain issues variate set with a small portion (5%) of postoperative health-related quality of life explained by the pain issues variate set. Low preoperative pain issues associated with high postoperative physical and mental components of health-related quality of life supports Hypothesis 1.

Table 6

Canonical Analysis of Pain Issues and the Physical and Mental Components of Health-related Quality of Life

<u>Dependent Variables</u>	<u>Canonical Variate Pair</u>	
	<u>Loading</u>	<u>Weight</u>
Post physical component summary	.882	.796
Post mental component summary	.622	.478
% of variance	58.26	
Redundance	5.034	
<u>Independent Variables</u>		
Pain at rest	-.865	-.557
Pain with normal activities	-.788	-.184
Pain with work	-.791	-.227
Pain disturbance	-.716	-.016
Difficulty with activities	-.656	-.341
Difficulties = pain avoidance/fear of injury	-.546	.074
% of variance	53.93	
Redundancy	4.66	
Canonical correlation	.294***	

Note. The weights are standardized canonical weights; the loadings are the structure coefficients.

Overall Pillais = .095, $p < .001$.

Percentage of variance accounted for within the set by the canonical variates for the set.

*** $p < .001$.

Hypothesis 2 stated: Hernia characteristics (length of time from onset, enlargement of hernia, or number of times repaired) predict lower postoperative health-related quality of life. The canonical analysis of hernia characteristics and postoperative aspects of health-related quality of life produced no significant canonical variate pairs ($F(24, 1647) = .9995, p = .463$). Likewise, canonical analysis of hernia characteristics and postoperative physical and mental components of

health-related quality of life produced no significant canonical variate pairs ($F(4,990) = .4921, p = .742$). Hypothesis 2 was not supported.

Hypothesis 3 stated: Personal attributes (age, education, marital status, and functional limitations) predict lower postoperative health-related quality of life. Two canonical analyses were utilized to examine this hypothesis. Personal attributes were first correlated with the postoperative individual aspects of health-related quality of life and subsequently correlated with postoperative mental and physical components of health-related quality of life.

Table 7 reports the results of canonical analysis of personal attributes and postoperative aspects of health-related quality of life. Of a possible seven covariate pairs, two were significant. The first variate set contained high physical function, role physical, general health, and vitality. The weight for physical function indicated that this variable was the most significant to the first canonical variate pair. The loadings and weights for low age, low functional limitations, and high education indicated the important contribution of these variables to the underlying dimension of this variate pair as well as the canonical variate set.

Examination of the second canonical variate pair revealed that social function (.982) contributed the most to this variate set with high bodily pain, general health, vitality, social function, and mental health making the greatest contribution to the underlying dimension of this health-related quality of life variate set. A profile of people described as older with low functional limitation were expected to experience high postoperative health-related quality of life except for physical functioning, role physical, and role emotional. Functional limitations contributed the most to this variate set.

Table 7

Canonical Analysis of Personal Attributes and Individual Aspects of Health-related Quality of Life

<u>Dependent Variable</u>	<u>Canonical Variate Pair 1</u>		<u>Canonical Variate Pair 2</u>	
	<u>Loadings</u>	<u>Weights</u>	<u>Loadings</u>	<u>Weights</u>
Post physical function	.850	1.085	.214	-.270
Post role physical	.458	.188	.027	-.528
Post bodily pain	.163	-.589	.464	.398
Post general health	.444	.065	.501	.282
Post vitality	.485	.241	.410	.041
Post social function	.343	.024	.762	.982
Post role emotional	.174	-.293	.219	.393
Post mental health	.184	-.088	.568	.176
% of variance	19.67		20.40	
Redundancy	1.883		1.589	
<u>Independent Variables</u>				
Age	-.679	-.511	.544	.639
Single	.320	.256	-.259	.104
Married	-.004	.180	.060	.111
Divorced	.177	-.136	-.014	.019
Separated	.047	.041	.122	.200
Education	.529	.401	-.138	.081
Functional limitations	-.615	-.542	-.729	.807
% of variance	17.928		13.559	
Redundancy	1.716		1.056	
Canonical correlation	.309***		.279***	

Note. The weights are standardized canonical weights; the loadings are the structure coefficients.

Overall Pillais = .229, $p < .001$.

Percentage of variance accounted for within the set by the canonical variates for the set.

*** $p < .001$.

Less than half (40%) of the variance in the postoperative health-related quality of life variables was explained by the two postoperative health-related variate sets, with a small portion (3%) of the variance in personal attributes explained by the postoperative health-related quality of life variate set. A modest portion (31%) of the variance in personal attributes was explained by the identified independent variate sets, and less than 1% (0.59%) of postoperative health-related quality of life was explained by the personal attribute variate sets.

The first identified profile of people were described as highly educated younger people with few functional limitations who were expected to have high postoperative health-related quality of life in the areas of physical function, role physical, general health, and vitality. This provided partial support for Hypothesis 3 by predicting that these people may not experience postoperative health-related quality of life in the areas of bodily pain, social function, role emotional, or mental health. Equally, older people with high functional limitations and low education may experience low levels of physical functioning, role physical, general health, and vitality.

A second canonical profile described people who are older but highly functional who were predicted to experience high bodily pain, general health, vitality, social function, and mental health. This provides partial support for Hypothesis 3 by predicting that older people with low functional limitations may not experience postoperative health-related quality of life in physical functioning, role functioning, or role emotional. Equally, younger people with high functional limitations are not predicted to experience health-related quality of life in areas of bodily pain, general health, vitality, social function, or mental health.

Table 8 reports the results of canonical analysis of personal attributes and postoperative physical and mental components of health-related quality of life. Two covariate pairs were possible and both were significant. The first variate pair contained dependent variables with high loadings and weights for physical components, and the second significant variate pair contained dependent variables with high loadings and weights for mental components. Together, these variate sets explained 100% of the variance in postoperative health-related quality of life. A small amount (4%) of the variance in personal attributes was explained by the postoperative health-related quality of life variate sets.

Low age and functional limitations contributed the greatest amount to the underlying dimension of the first independent variate set, and high age, low education, and low functional limitations contributed the most to the second independent variate set. Together these two independent variate sets explained a moderate amount (34%) of the variance in personal attributes. A small portion (1.4%) of the variance in physical and mental components of health-related quality of life was explained by the personal attribute variate set.

The first variate pair described a profile of younger people with few functional limitations who were expected to experience high postoperative physical, but not mental components of health-related quality of life. Likewise, older people with high functional limitations were predicted to experience low postoperative physical components of health-related quality of life. The second profile of people was described as older people with low levels of education and functional limitations who were expected to experience high postoperative mental, but not physical, components of health-related quality of life. Similarly, younger people with high levels of education and functional

limitations were not expected to experience high postoperative mental components of health-related quality of life. These canonical variate pairs provided support for Hypothesis 3 by predicting improvement in only one component of health-related quality of life for specific profiles of people.

Table 8

Canonical Analysis of Personal Attributes and Postoperative Physical and Mental Components of Health-related Quality of Life

<u>Dependent Variable</u>	<u>Canonical Variate Pair 1</u>		<u>Canonical Variate Pair 2</u>	
	Loadings	Weights	Loadings	Weights
Post physical components	.999	.992	-.038	-.241
Post mental components	.236	.039	.972	1.020
% of variance	52.7077		47.293	
Redundancy	2.742		1.508	
<u>Independent Variables</u>				
Age	-.538	-.382	.547	.362
Single	.252	.009	-.352	-.484
Married	-.183	-.246	.196	-.360
Divorced	-.091	-.301	.089	-.188
Separated	.178	.051	-.349	-.430
Education	.331	.193	-.536	-.500
Functional limitations	-.823	-.787	-.519	-.578
% of variance	17.316		16.398	
Redundancy	.901		.523	
Canonical correlation	.228***		.179**	

Note. The weights are standardized canonical weights; the loadings are the structure coefficients.

Overall Pillais = .307, $p < .001$.

Percentage of variance accounted for within the set by the canonical variates for the set.

** $p < .02$; *** $p < .001$.

Summary

In Chapter IV, the results of canonical analyses were presented. A description of the sample from 14 Veterans Affairs Medical Centers contained information pertaining to age, marital status, level of education, functional limitations, hernia characteristics, and maladaptive behavior. Intensity of sensation and health-related quality of life as measured by the SF-36 were reported with means and standard deviations. Comparison of the mental and physical components of health-related quality of life in the study population with national averages for other veterans and non-veterans were reported.

The results of canonical analyses of each set of independent variables with the individual aspects and physical and mental components of health-related quality of life were reported. The resultant profiles were described with interpretation of support of hypotheses.

CHAPTER V

SUMMARY OF THE STUDY

The major purpose of the analysis of retrospective data generated from the Veterans Affairs Cooperative study was to explore the relationships that exist between postoperative health-related quality of life and selected variables. The selected variables included pain issues (intensity of sensation & maladaptive behaviors), hernia characteristics (recent increase in size, length of time from onset, & number of times repaired), and personal attributes (age, education, marital status, and functional limitations). Three hypotheses were proposed and examined through canonical analyses.

Hypothesis 1 stated that pain issues are associated with lower postoperative health-related quality of life. The first two canonical analyses supported this hypothesis. Hypothesis 2 stated that hernia characteristics are associated with lower postoperative health-related quality of life. Neither of the canonical analyses yielded significant correlations for this set of variables; therefore, the second hypothesis was not supported. Hypothesis 3 stated that personal attributes are associated with lower postoperative health-related quality of life. In specific profiles, age, functional limitations, and education were personal attributes associated with lower postoperative health-related quality of life. This association supported Hypothesis 3. It appeared that marital status was not associated with lower postoperative health-related quality of life. This chapter summarizes and discusses the findings of the study. Conclusions, implications, and recommendations are presented for future studies.

Summary of Findings

A correlational descriptive design was used to explore the association of sets of independent variables and postoperative health-related quality of life. The theoretical framework of the study was Roy's (1991) adaptation theory. Health-related quality of life as measured by the SF-36, Visual Analog Scales (VAS) of intensity of sensation, preoperative activities assessment, personal assessment, and hernia assessment were utilized for data collection. Each participant completed the VAS, Hernia Assessment, and Patient Assessment upon entry in the study. Health-related quality of life of participants was again assessed 3 months after surgery.

Approximately 1,000 people entered the study during the first year of this 5-year study. Of these patients, 560 completed baseline and 3-month data required for inclusion in this project. Fifty-two of the 560 did not complete all questions related to pain. Participants were told to "not answer" the VAS concerning "pain with work or lifting" if they were currently not working or lifting. Consequently, 52 participants had no score associated with this variable and were eliminated for the analysis of pain issues. The study setting was 14 Veterans Affairs Medical Centers located in the continental U.S.

The Statistical Package for Social Sciences (SPSS) version 10.0 was used to enter and store the data set for statistical analyses. Frequencies and measures of central tendency were used to examine the demographic data.

Discussion of Findings

Pain Issues and Postoperative Health-related Quality of Life

Preoperative pain issues, intensity of sensation and maladaptive behaviors, were inversely related to postoperative health-related

quality of life. Low measures for pain issues at baseline predicted high postoperative physical and mental components of health-related quality of life. This repeated the positive association between pain and functional limitations reported by Lichtenstein et al. (1998). Additionally, Gelling (1998) found that pain was an influencing factor on physical recovery and health-related quality of life in patients having liver transplant. This corresponds to the current findings of an inverse relationship between pain issues (particularly pain at rest and pain disturbance) and postoperative health-related quality of life.

Three studies reported that postoperative patients improved mentally more than physically (Atroschi et al., 1999; Olsson & Thelan, 1999; Shields et al., 1999). This was replicated for older people after inguinal hernia surgery but not for younger people. It is possible that outcomes such as health-related quality of life vary with differing procedures.

The discussion thus far has focused on pain intensity, a variable often reported by investigators. The canonical analyses reported in this study revealed that pain behaviors (fear of injury and pain avoidance) do not uniquely contribute to postoperative health-related quality of life. This did not replicate the findings of Vlaeyen, Kole-Snijders et al. (1995) or Vlaeyen, Seelen et al. (1999). These studies revealed that pain behaviors were not associated with pain intensity, but rather with depression. These differences may be due to differences inherent in chronic and acute pain experience. Separation of maladaptive behaviors and pain intensity may be a marker for a basic difference in these patient populations and warrants further study.

Hernia Characteristics and Postoperative Health-related Quality of Life

Hypothesis 2 stated that hernia characteristics predict lower health-related quality of life. Few studies have examined descriptive characteristics of a physical abnormality and postoperative quality of life. Of these Mozes et al. (1996) found that preoperative symptoms did not predict postoperative improvements or postoperative symptoms. This corresponds to the lack of correlation in this study between hernia characteristics and postoperative health-related quality of life. Studies specifically designed to examine the predictive capacity of symptom descriptions are necessary to clarify these findings.

Personal Attributes and Postoperative Health-related Quality of Life

Examination of Hypothesis 3, personal attributes and postoperative health-related quality of life, yielded profiles of highly educated young people with few functional limitations associated with improvements in role physical, physical functioning, general health, and vitality. Additionally, older people with low levels of education and high functional limitations were predicted to experience low vitality, physical functioning, role physical, and general health. This corresponds in part to findings by Cox et al. (1988) who described isolation in the elderly as predictive of negative perception of health-related quality of life. These authors additionally identified marital status as important to positive outcomes, a finding not supported in the current study.

Sherman et al. (1995) found a positive correlation between functional status and perceptions of health and well-being unrelated to presence of chronic illness. This was partially replicated by canonical analysis in this study that revealed an inverse relationship between

functional limitations and perceptions of postoperative health-related quality of life.

The findings of Sharma et al. (1996) predicted that preoperative psychological and social functioning were more important than physical functioning for people having knee replacement. Importance of high preoperative physical functioning and lack of contribution of marital status to any profile in the current canonical analysis contradicts this finding.

Waltz et al. (1996) found level of education to be inversely correlated to functional status and pain severity in people with rheumatoid arthritis. This was supported by the conclusions of Helme and Gibson (1997) who found that factors associated with increased pain were low educational status and unpaid employment. The canonical analysis of personal attributes and postoperative aspects of health-related quality of life resulted in a variate set that included high education describing a profile of people expected to experience high postoperative physical function, role physical, general health, and vitality. Contrary to this, a second profile resulting from canonical analysis of personal attributes and physical and mental components of health-related quality of life described people with low levels of education who were predicted to experience high physical but not mental components of health-related quality of life. It appears that high levels of education are associated with physical recovery while lower levels of education are associated with mental recovery.

The findings of Bennahum et al. (1997) revealed an association between age and perception of quality of life. The way that older and younger people adapt to stress along with different meanings assigned to change brought on by illness contributed to the differences in perceived quality of life in cancer patients. Older people assigned less

importance to loss of independence but had fewer resources to cope with stress. Younger people possessed greater resources to cope with stress but assigned greater importance to loss of independence.

These findings corresponded to the profiles that resulted from canonical analyses of personal attributes and postoperative mental and physical components of health-related quality of life. Older age was strongly associated with high postoperative mental components of health-related quality of life while younger age was associated with high postoperative physical components of health-related quality of life. Gains were predicted for physical and mental components of health-related quality of life for younger people with low functional limitations. Older people with high functional limitations were predicted to experience lower postoperative physical and mental components of health-related quality of life. These findings did not correspond to Chetter et al. (1998) who found that after infrainguinal arterial reconstruction for critical limb ischemia older patients experienced improvement in physical functioning, pain, vitality, and social functioning but not in general health, role emotional and physical and mental health. Preoperative intensity of sensation was not assessed in these patients limiting comparisons for this variable.

Kurtz et al. (2000) found that in patients with lung cancer, greater losses in physical function were associated with younger age and high pre-diagnosed levels of physical functioning. This finding was partially replicated in the canonical analysis of this study that correlated postoperative mental and physical components of health-related quality of life and personal attributes. Younger people with high functional limitations and low levels of education were predicted to experience high mental but not physical components of health-related quality of life.

In summary, older people with high functional limitations were predicted to experience lower postoperative health-related quality of life. People who were younger were predicted to improve in physical components of health-related quality of life while those who were older were predicted to improve in the mental components of health-related quality of life. Marital status was not significant to any profile, and education was only a significant predictor of outcomes when personal attributes were correlated with the physical and mental components of health-related quality of life. The importance of preoperative physical functioning to outcomes did not replicate previous findings by Sharma et al. (1996) who found that functional status was less important to outcomes than psychological and social functioning. Without information on preoperative psychological and social functioning in the current study, a comparison of the relationship of these variables with physical functioning and postoperative health-related quality of life with previous studies was not possible.

Callesen et al. (1998) discovered that younger patients reported higher postoperative pain related to higher physical functioning. This was not replicated in the current study but did indicate a need for further investigation of this relationship for younger postoperative inguinal hernia patients.

A strong inverse relationship between education and pain was reported by Helme and Gibson (1997) and Waltz et al. (1996). This was not replicated in the current study. Education was included in the profile associated with personal attributes and aspects of health-related quality of life but was not associated with bodily pain.

Absence of marital status in any profile generated by the canonical analysis of personal attributes and the physical and mental components or individual aspects of health-related quality of life does

not replicate the findings of Waltz et al. (1996) who reported that social support predicted less severe pain and depression. According to Waltz et al., social factors impact effects of pain intensity. This relationship is mediated by baseline psychological functioning, a variable not examined in the current study.

Theoretical Implications

Roy's theory of adaptation (Roy & Andrews, 1991) posits to explain the reaction of humans to changing stimuli through two effector systems. The regulator system resembles the physical components while the cognator system resembles the mental components of health-related quality of life described in this project. Enhancement of both components results in adaptation, optimal postoperative health-related quality of life.

To achieve this positive outcome, inguinal hernia patients must adapt to noxious stimuli, pain. Those who are unable to adapt are predicted to experience lower health-related quality of life. Results of canonical analysis of pain issues and physical and mental components of health-related quality of life indicated that patients with high preoperative pain (particularly pain at rest) will need assistance to achieve optimal health-related quality of life. Changing contextual or environmental stimuli such as the addition of relaxation techniques or music therapy prior to and after surgery would provide such assistance.

Equally, canonical analysis of personal attributes and health-related quality of life revealed two distinct profiles, one associated with physical components (regulator) and the second associated with mental components (cognator) of health-related quality of life. A profile of younger people with low functional limitations were expected to experience optimal physical components of health-related quality of life, while a profile of older people with low education and functional

limitations were predicted to experience optimal mental components (cognator) of health-related quality of life. From this information, it is clear that for optimal postoperative adaptation, younger physically fit people will need assistance with mental (cognator) components of health-related quality of life. Likewise, older people with low education and functional limitations will need assistance with physical (regulator) aspects of health-related quality of life.

Conclusions

A link was found in this study between pain and postoperative health-related quality of life in inguinal hernia patients. Pain is known to produce multidimensional responses linked to depression (Vlaeyen, Kole-Snijders et al., 1995). Considering this, additional evaluation of psychological state prior to surgery would add important predictive information concerning postoperative outcomes for inguinal hernia patients.

Marital status was not clearly predictive of postoperative health-related quality of life in inguinal hernia patients. Several investigators found that quality of relationship was more important to outcomes than marital status (Heller et al., 1997; Waltz et al., 1996). With this in mind, including assessment of quality of relationship in addition to marital status would add more precise information on the impact of social relationships on postoperative health-related quality of life of inguinal hernia patients.

It seems reasonable to assume that younger physically fit individuals will experience high postoperative health-related quality of life. This canonical analysis only partially supported this conclusion. Further examination of impacts to postoperative mental components of health-related quality of life would yield clues to potential interventions for younger people.

Ellingson and Conn (2000) discovered a bi-directional relationship between exercise and health-related quality of life. High levels of exercise enhanced perceptions of health-related quality of life, and high perceptions of health-related quality of life predicted higher levels of exercise. Instituting interventions either prior to surgery or postoperatively with comparison to current findings would contribute a potentially appropriate intervention to prevent lower health-related quality of life.

This study was conducted on data from a totally male veteran population. Replication with females and with non-Veterans would add substantially to the predictive profiles. Similarly, examination of postoperative outcomes after a variety of ambulatory surgical procedures would expand application of these findings.

Recommendations for Further Studies

Based on the findings of this study, further research is recommended in these areas:

1. The study should be expanded to include female patients as well as non-veterans.
2. Replication of the study should include outcomes for a variety of ambulatory surgery procedures.
3. Future studies should include assessment of preoperative psychological state as well as quality of relationships.
4. Future studies should include additional variables representing baseline activity levels as well as co-morbidities.
5. Additional studies should examine postoperative outcomes for patients who report pain at rest and/or pain disturbance prior to surgery.

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APPENDIX A

SF-36

VA COOPERATIVE STUDY #456
Tension-Free Inguinal Hernia Repair: Comparison of Open
and Laparoscopic Surgical Techniques

**HEALTH-RELATED QUALITY
 OF LIFE (SF-36)
 STANDARD VERSION**
 (FORM 11)

Site # Randomization # Form
 Record ₁₀ Encounter ₁₁ - Date ₁₅
01 = 8
 05 = 3 mo.
 07 = 1 yr.
 09 = 2 yr.
 11 = 6 yr.
 06 = 6 mo.
 08 = 3 yr.
 10 = 4 yr.
 MM DD YEAR

Patient's Initials _____

A. This is: an original screening a rescreening *(All forms completed after baseline are 'original')*

**YOUR HEALTH AND WELL-BEING
 STANDARD VERSION**
**TO BE COMPLETED AT BASELINE, 3-MONTH, 6-MONTH, AND ANNUAL
 FOLLOW-UP VISITS.**

Thank you for completing this survey.

This survey asks for your views about your health. This information will help keep track of how
 you feel and how well you are able to do your usual activities.

**HEALTH-RELATED QUALITY
OF LIFE (SF-36)
STANDARD VERSION**

(FORM 11)

Site #

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Randomization #

--	--	--

Patient's Initials _____

1. In general, would you say your health is: **(Circle the box that best describes your answer.)**

Excellent	Very good	Good	Fair	Poor
1	2	3	4	5

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
1	2	3	4	5

HEALTH-RELATED QUALITY
OF LIFE (SF-36)
STANDARD VERSION
(FORM 11)

Site #

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Randomization #

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Patient's Initials _____

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (**Circle the box that best describes your answer.**)

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. <u>Vigorous activities</u> , such as running, lifting heavy objects, participating in strenuous sports.	26 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
b. <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	27 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
c. Lifting or carrying groceries.	28 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
d. Climbing <u>several</u> flights of stairs.	29 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
e. Climbing <u>one</u> flight of stairs.	30 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
f. Bending, kneeling, or stooping.	31 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
g. Walking <u>more than a mile</u> .	32 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
h. Walking <u>several hundred yards</u> .	33 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
i. Walking <u>one hundred yards</u> .	34 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
j. Bathing or dressing yourself.	35 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>

**HEALTH-RELATED QUALITY
OF LIFE (SF-36)
STANDARD VERSION
(FORM 11)**

Site #

Randomization #

Patient's Initials _____

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the <u>amount of time</u> you spent on work or other activities.	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>
b. <u>Accomplished less</u> than you would like.	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>
c. Were limited in the <u>kind of</u> work or other activities.	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>
d. Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort.)	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the <u>amount of time</u> you spent on work or other activities.	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>
b. <u>Accomplished less</u> than you would like.	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>
c. Did work or other activities <u>less carefully than usual</u> .	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>

**HEALTH-RELATED QUALITY
OF LIFE (SF-36)
STANDARD VERSION**
(FORM 11)

Site #

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Randomization #

--	--	--

Patient's Initials _____

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
1	2	3	4	5

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
1	2	3	4	5	6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
1	2	3	4	5

**HEALTH-RELATED QUALITY
OF LIFE (SF-36)
STANDARD VERSION**

(FORM 11)

Site # Randomization #

Patient's Initials _____

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life?	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
b. Have you been very nervous?	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
c. Have you felt so down in the dumps that nothing could cheer you up?	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
d. Have you felt calm and peaceful?	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
e. Did you have a lot of energy?	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
f. Have you felt downhearted and depressed?	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
g. Did you feel worn out?	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
h. Have you been happy?	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
i. Did you feel tired?	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

HEALTH-RELATED QUALITY
OF LIFE (SF-36)
STANDARD VERSION
(FORM 11)

Site #

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Randomization #

--	--	--

Patient's Initials _____

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people.	1	2	3	4	5
b. I am as healthy as anybody I know.	1	2	3	4	5
c. I expect my health to get worse.	1	2	3	4	5
d. My health is excellent.	1	2	3	4	5

Thank you for completing these questions!

APPENDIX B
Visual Analogue

VA COOPERATIVE STUDY #456
Tension-Free Inguinal Hernia Repair: Comparison of Open
and Laparoscopic Surgical Techniques

PREOPERATIVE PAIN AND DISCOMFORT (FORM 09)	Site #	[] [] []	Randomization #	[] [] []	Form	[0] [9]
	Record ¹⁰	[1]	Encounter ¹¹	[0] [1] - [0] [0]	Date ¹²	[] [] [] [] [] []
					MM	DD
						YEAR

Patient's Initials _____

A. This is: ²² [1] an original screening ²³ [2] a rescreening

We want to know how much pain or discomfort you had within the last 24 hours as a result of your hernia. Use a pen or pencil to draw an "X" on the lines below to indicate the average amount of pain or discomfort you experienced. For instance, if you did not have much pain today you would draw an "X" down near the **No Pain Sensation** end of the line. If you had a lot of pain today, you would make an "X" up towards the **Most Intense Pain Imaginable** end of the scale.

1. What was the average amount of pain or discomfort you experienced when you were at rest?

No Pain Sensation		Most Intense Pain Imaginable
	²⁴ [] [] [] mm	

2. How much pain did you have during your normal activities (for example, walking, climbing stairs, driving a car, getting up from a chair)?

No Pain Sensation		Most Intense Pain Imaginable
	²⁷ [] [] [] mm	

3. How much pain did you have when you were exercising, doing strenuous work, or lifting objects you used to be able to lift comfortably?

No Pain Sensation		Most Intense Pain Imaginable
	³⁰ [] [] [] mm	

4. How unpleasant or disturbing was the worst pain that you had today?

Not Bad at All		Most Intense Bad Feeling Imaginable
	³³ [] [] [] mm	

APPENDIX C
Preoperative Activities

VA COOPERATIVE STUDY #456
Tension-Free Inguinal Hernia Repair: Comparison of Open
and Laparoscopic Surgical Techniques

PRE-OPERATIVE ACTIVITIES ASSESSMENT (FORM 06)	Site #	Randomization #	Form	06
	Record	Encounter	Date	
	1	01 - 00	MM DD YEAR	

Patient's Initials _____

A. This is: ☒ 1 an original screening ☐ 2 a rescreening

We want to know how much your hernia has interfered with your ability to perform various activities. Please read the examples given below and circle the box that corresponds to how difficult it was for you to engage in that activity within the last 24 hours. Please circle "8" if you were able to perform that activity but did not do so, or if you do not ordinarily engage in that activity.

How much difficulty did you have performing the following activities within the last 24 hours as a result of your hernia?

Activity	No difficulty at all	A little difficulty	Some difficulty	A lot of difficulty	Not able to do it	Did not do it for other reasons
1. Lying in bed.	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 8
2. Sitting.	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 8
3. Getting in or out of bed or chair.	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 8
4. Reaching or stretching.	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 8
5. Lifting 3 to 5 pounds.	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 8
6. Walking around inside.	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 8
7. Climbing up or down stairs.	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 8
8. Walking outside or at work.	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 8
9. Engaging in sedentary activities such as typing, talking on the phone, playing cards, watching TV.	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 8
10. Engaging in light physical activities, such as cooking, dusting, clerical work, visiting friends.	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 8
11. Engaging in sexual intercourse.	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 8
12. Engaging in moderate physical activities such as sweeping, washing the car, dancing, playing golf, hiking.	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 8
13. Engaging in vigorous physical activities such as construction work, shoveling, playing tennis or basketball, weight lifting.	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 8

**PRE-OPERATIVE
ACTIVITIES ASSESSMENT
(FORM 06)**

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Patient's Initials _____

REASONS FOR AVOIDING ACTIVITIES

1. Have you had difficulty performing usual daily activities, work activities, recreational activities, social activities, or sexual activities due to the presence of your hernia?

37 ☐ 1 No ☐ 2 Yes

If you answered "No" please skip the following questions. If you answered "Yes", please circle "Yes" or "No" for each of the following:

- | | No | Yes |
|---|-----------------------------------|--------------------------------|
| a. I was told to avoid certain activities by a doctor, assistant, or nurse: | 36 <input type="text" value="1"/> | <input type="text" value="2"/> |
| b. I was told to avoid certain activities by a family member or friend: | 38 <input type="text" value="1"/> | <input type="text" value="2"/> |
| c. I can't perform certain activities without help: | 40 <input type="text" value="1"/> | <input type="text" value="2"/> |
| d. I am concerned I might injure myself: | 41 <input type="text" value="1"/> | <input type="text" value="2"/> |
| e. I felt pain when I tried to do certain activities: | 42 <input type="text" value="1"/> | <input type="text" value="2"/> |
| f. Other reason (explain): _____ | <input type="text" value="1"/> | <input type="text" value="2"/> |

2. Put the letter of the most important reason in this box:

Reason ☐

APPENDIX D
Hernia Assessment and Patient Assessment

Screening #

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Phone () _____

PATIENT SCREENING
(FORM 01)

Site #

Screening #

Patient's Initials _____

1. Was the purpose of the patient's visit to the doctor related to hernia? 42 ☐ No ☐ Yes
2. Has patient had any episode of hernia-related bowel obstruction? 43 ☐ No ☐ Yes
3. Characteristics of hernia:

Side(s) of hernia <i>[Circle all that apply]</i>	Left	Right
a. Primary/Recurrent	<input type="checkbox"/> 1 Primary <input type="checkbox"/> 2 Recurrent	<input type="checkbox"/> 1 Primary <input type="checkbox"/> 2 Recurrent
b. Has hernia enlarged in past 6 weeks?	<input type="checkbox"/> 1 No <input type="checkbox"/> 2 Yes	<input type="checkbox"/> 1 No <input type="checkbox"/> 2 Yes
c. How long has hernia been present?	<input type="checkbox"/> 1 Less than 6 weeks <input type="checkbox"/> 2 6 weeks to 1 year <input type="checkbox"/> 3 Longer than 1 year <input type="checkbox"/> 4 Unknown	<input type="checkbox"/> 1 Less than 6 weeks <input type="checkbox"/> 2 6 weeks to 1 year <input type="checkbox"/> 3 Longer than 1 year <input type="checkbox"/> 4 Unknown
d. Reducibility	<input type="checkbox"/> 1 Reduces spontaneously <input type="checkbox"/> 2 Reduces easily <input type="checkbox"/> 3 Reduces with difficulty <input type="checkbox"/> 4 Not reducible	<input type="checkbox"/> 1 Reduces spontaneously <input type="checkbox"/> 2 Reduces easily <input type="checkbox"/> 3 Reduces with difficulty <input type="checkbox"/> 4 Not reducible
e. If not reducible, how long has hernia been "out"?	<input type="checkbox"/> 1 Less than 6 weeks <input type="checkbox"/> 2 6 weeks to 1 year <input type="checkbox"/> 3 Longer than 1 year <input type="checkbox"/> 4 Unknown	<input type="checkbox"/> 1 Less than 6 weeks <input type="checkbox"/> 2 6 weeks to 1 year <input type="checkbox"/> 3 Longer than 1 year <input type="checkbox"/> 4 Unknown
f. Findings:	<input type="checkbox"/> 1 Hernia is palpable on impulse but is not visible when standing (without straining). <input type="checkbox"/> 2 Hernia is visible when standing (without straining) but does not extend into scrotum. <input type="checkbox"/> 3 Hernia extends into scrotum. <input type="checkbox"/> 4 Hernia by history - not evident on exam.	<input type="checkbox"/> 1 Hernia is palpable on impulse but is not visible when standing (without straining). <input type="checkbox"/> 2 Hernia is visible when standing (without straining) but does not extend into scrotum. <input type="checkbox"/> 3 Hernia extends into scrotum. <input type="checkbox"/> 4 Hernia by history - not evident on exam.

PATIENT SCREENING
(FORM 01)

Site #

Screening #

Patient's Initials _____

COMORBIDITIES CHECKLIST

A. CARDIOVASCULAR

1. CHF* (within past 6 months): 11 ☐ 1 No ☐ 2 Yes
2. Myocardial Infarction* (within past 6 months): 12 ☐ 1 No ☐ 2 Yes
3. Angina* (within 1 month): 13 ☐ 1 No ☐ 2 Yes
4. Hypertension requiring medication (current)*: 14 ☐ 1 No ☐ 2 Yes

B. CENTRAL NERVOUS SYSTEM (circle most severe occurrence)

- ☐ 1 No events
- 15 ☐ 2 History of TIA*
- ☐ 3 CVA w/no residual neurological defect*
- ☐ 4 CVA w/residual neurological defect*

C. GASTROINTESTINAL

1. Chronic constipation: 16 ☐ 1 No ☐ 2 Yes

D. HEPATIC

1. Ascites*: 17 ☐ 1 No ☐ 2 Yes
2. Cirrhosis*: 18 ☐ 1 No ☐ 2 Yes

E. NUTRITIONAL/IMMUNE/OTHER

1. Greater than 10% loss body weight in last 6 months*: 19 ☐ 1 No ☐ 2 Yes
2. Chronic steroid use*: 20 ☐ 1 No ☐ 2 Yes
3. AIDS*: 21 ☐ 1 No ☐ 2 Yes

F. PERIPHERAL VASCULAR

1. Revascularization/amputation for occlusive PV disease*: 22 ☐ 1 No ☐ 2 Yes
2. Claudication*: 23 ☐ 1 No ☐ 2 Yes

*= Definitions in Operations Manual

PATIENT SCREENING
(FORM 01)

Site #

Screening #

Patient's Initials _____

Record 3

G. PULMONARY

1. History of severe COPD*: 23 1 No 2 Yes
2. Chronic cough*: 24 1 No 2 Yes

H. RENAL

1. Renal failure requiring dialysis: 25 1 No 2 Yes
2. Prostatism*: 26 1 No 2 Yes
3. Recurrent UTIs*: 27 1 No 2 Yes

I. GENERAL

1. Is patient taking Coumadin, Tyclid, ASA or NSAIDS? 28 1 No 2 Yes
If answer is 'Yes', follow protocol.

2. Diabetes mellitus requiring medication*:

- 29 1 No diabetes
 2 Oral hypoglycemics
 3 Insulin

3. Diabetes mellitus with complications* : 30 1 No 2 Yes
4. Smoked cigarettes in past year* : 31 1 No 2 Yes
If yes, number of pack-years :* 32

5. Alcohol Use ->2 drinks/day in past 2 weeks 33 1 No 2 Yes

6. Functional Health Status*:

- 34 1 Independent
 2 Partially dependent
 3 Totally dependent

7. ASA Classification:

- 37 1 Healthy patient
 2 Mild systemic disease
 3 Severe systemic disease - not incapacitating
 4 Life-threatening disease
 5 Moribund

* = Definitions in Operations Manual

PATIENT SCREENING
(FORM 01)

Site #

Screening #

Patient's Initials _____

SCREENING SUMMARY

A. EXCLUSION CRITERIA

Men will be eligible for enrollment into the study if all answers in this section are "No".

- | | | |
|---|----------------------------------|--------------------------------|
| 1. Hernia cannot be detected on physical examination: | 38 <input type="checkbox"/> 1 No | <input type="checkbox"/> 2 Yes |
| 2. ASA Class IV or V, or contraindications to general anesthesia: | 39 <input type="checkbox"/> 1 No | <input type="checkbox"/> 2 Yes |
| 3. Presence of bowel obstruction, strangulation, peritonitis, or perforation: | 40 <input type="checkbox"/> 1 No | <input type="checkbox"/> 2 Yes |
| 4. Presence of local or systemic infection: | 41 <input type="checkbox"/> 1 No | <input type="checkbox"/> 2 Yes |
| 5. Presence of contraindications to pelvic laparoscopy such as previous pelvic procedures (e.g. radical prostatectomy and/or pelvic irradiation): | 42 <input type="checkbox"/> 1 No | <input type="checkbox"/> 2 Yes |
| 6. Recurrent hernia where previous repair was with mesh: | 43 <input type="checkbox"/> 1 No | <input type="checkbox"/> 2 Yes |
| 7. Participation in another clinical trial: | 44 <input type="checkbox"/> 1 No | <input type="checkbox"/> 2 Yes |

B. INCLUSION CRITERIA:

Men will be eligible for enrollment into the study if all answers in this section are "Yes".

- | | | |
|--|----------------------------------|--------------------------------|
| 1. Patient is 18 years of age or older: | 45 <input type="checkbox"/> 1 No | <input type="checkbox"/> 2 Yes |
| 2. Has a diagnosis of inguinal hernia: | 46 <input type="checkbox"/> 1 No | <input type="checkbox"/> 2 Yes |
| 3. Has given informed consent for randomization: | 47 <input type="checkbox"/> 1 No | <input type="checkbox"/> 2 Yes |

If patient meets the enrollment criteria, immediately FAX the completed consent form to Hines Coordinating Center at (708) 216-2116 or (708) 216-2324.

C. RANDOMIZATION INFORMATION

- | | | |
|---------------------------------|---|--|
| 1. Study Number: | 48 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Site # | 49 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Randomization # |
| 2. Treatment assignment: | 50 <input type="checkbox"/> 1 Open | <input type="checkbox"/> 2 Laparoscopic |
| 3. Scheduled date of operation: | 51 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> MM DD | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Year |

Form Completed by _____

Physician of exam _____

I have examined patient and confirm the presence of inguinal hernia _____

Attending Physician

APPENDIX E

Approved Consent of the Dallas Institutional
Review Board

Subject Name: _____ Date: _____
 Title of Study: CSP #456 – Tension-free Inguinal Hernia Repair: Comparison of Open and Laparoscopic Surgical Techniques
 Principal Investigator: Lawrence T. Kim, M.D. VAMC: Dallas
 Co-Investigators: Richard H. Turnage, MD, Patricia Bergen, MD, Thomas Anthony, MD, Fiemu Nwariaku, MD, George Sarosi, MD, Robert Gibbons, MD.

Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed procedures. This statement describes the alternative procedures, benefits, risks, discomforts, and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. It is important for you to understand that no guarantees or assurances can be made as to the results of the study.

THE PURPOSE OF THE STUDY AND HOW LONG IT WILL LAST:

You are being asked to participate in a clinical research study. The purpose of this study is to determine whether an inguinal hernia is best repaired using an open tension-free operation or a new approach, known as laparoscopic hernia repair.

An inguinal hernia is an abnormal space between the abdominal cavity and the groin. The abnormal space allows abdominal contents to enter the groin and travel as far down as the scrotal sac. It is the presence of abdominal contents in the groin that accounts for the bulge that you see when you have a hernia.

There are many ways to repair inguinal hernias. Two of the most common involve placing a piece of mesh (plastic net) to help close the space. In the open tension-free repair, a 4-6 inch incision is made in the groin, the hernia found and the piece of mesh is placed over the hole and sewed in place, closing the hole from the outside. In the laparoscopic tension-free repair, the space is closed from the inside. Access to this space is obtained by placing telescopes and the operating instruments through hollow tubes that are inserted temporarily via several 1/4 inch incisions. The hernia is then found and the piece of mesh is placed and tacked in place with metal staples. The telescopes and hollow tubes are then removed. In both types of operations, the plastic net is permanent, as are the sutures or staples that hold it in place.

Both the open and laparoscopic procedures have been shown to be effective and neither are considered experimental options. The purpose of this research project is to determine when it is best to recommend one operation or the other for an individual patient.

SUBJECT'S IDENTIFICATION (I.D. plate of give name - last, first, middle)

APPROVED BY THE SUBCOMMITTEE
 ON HUMAN STUDIES *06/28/2000*

Subject's Initials _____

Date _____

VA FORM Rev. 06/00
 JAN 1990 10-1086

Subject Name: _____

Date: _____

Title of Study: CSP #456 – Tension-free Inguinal Hernia Repair: Comparison of Open and Laparoscopic Surgical Techniques

Principal Investigator: Lawrence T. Kim, M.D.

VAMC: Dallas

Co-Investigators: Richard H. Turnage, MD, Patricia Bergen, MD, Thomas Anthony, MD, Fiemu Nwariaku, MD, George Sarosi, MD, Robert Gibbons, MD.

We expect to enroll an average of 50 to 60 patients per year for three years from this and 13 other hospitals for a total of 2200 patients. After your operation, you will be followed for 2 to 5 years (at 1 to 2 weeks, 3 and 6 months, and yearly thereafter depending on how long the study has been going on at the time of your enrollment). Each day for the 7 to 10 days between your operation and your first follow-up visit you will be asked to record the amount of pain you experience.

This study is being sponsored by the VA Cooperative Studies Program.

DESCRIPTION OF THE STUDY INCLUDING THE PROCEDURES TO BE USED:

You will undergo a history and physical examinations to determine the presence of a hernia and how many symptoms you are having from it. You will also be asked to fill out several forms before the operation, requiring 20 to 30 minutes of your time. These forms will help us assess your activity level, the amount of pain and discomfort you are having as well as how bothersome this hernia is for you. You will undergo either an open tension-free repair or a laparoscopic repair of your hernia. Assignment to one of these groups will be done randomly (like flipping a coin). If the laparoscopic operation is to be used, you will undergo general anesthesia. If an open operation is to be used, you along with the anesthesiologist and surgeon will decide on the type of anesthesia to use (local with intravenous sedation, spinal or general).

The open repair involves making a 4-6 inch incision just above your groin crease. Several layers of tissue including muscle are then opened and the abnormal space identified and repaired by placing a sheet of plastic netting (mesh) over the defect and sewing it in place.

The laparoscopic repair involves first accessing the groin area from the inside. This is done by entering the abdominal cavity through a small incision near your navel. Carbon dioxide gas is used to inflate your abdomen allowing the surgeon to insert the telescope. The telescope will either be inserted into the abdominal cavity or in to the layer just above that. While watching through the telescope, two hollow tubes will be inserted through small (1/4 inch) incisions in the right and left lower sides of the abdomen. The surgeon uses these to introduce the patch, the stapler and various instruments to manipulate the patch. After the patch is placed in to the abdomen through one of the hollow tubes, it will be manipulated to cover the hernia defect in your groin. Fine metal staples will be used to fix the patch in to position, closing the hernia from the inside of the abdomen. After the patch is secured in place, gas will be allowed to escape and all three wounds will be closed and dressed.

Subject's Initials _____

Date _____

Subject Name: _____ Date: _____
 Title of Study: CSP #456 – Tension-free Inguinal Hernia Repair: Comparison of Open and Laparoscopic Surgical Techniques
 Principal Investigator: Lawrence T. Kim, M.D. VAMC: Dallas
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Fiemu Nwariaku, MD, George Sarosi, MD, Robert Gibbons, MD.

Both open and laparoscopic repairs are usually performed on an outpatient basis, that is you come in and go home on the same day as your surgery. Occasionally, your doctor may decide to keep you in the hospital overnight.

DESCRIPTION OF PROCEDURES THAT MAY RESULT IN DISCOMFORT OR INCONVENIENCE:

Participation in this study will add no risk over and above that of open or laparoscopic hernia repair since neither are experimental operations. You may be inconvenienced by having to complete some forms, and the repeat hernia examinations may cause a minimal amount of momentary discomfort. In addition more frequent followup than usual may cause some inconvenience.

DESCRIPTION OF EXPERIMENTAL PROCEDURES WHICH ARE ASSOCIATED WITH FORESEEABLE RISKS:

Many of the complications from these two types of hernia repair are similar. These complications include recurrence (the hernia comes back), which is thought to occur in about 4 out of 100 patients who undergo laparoscopic repair and somewhere between 1 and 10 out of 100 for the open repair. There can also be damage to the tube that carries sperm or damage to the blood supply to the testicle. Infection, sometimes requiring removal of the mesh is also a risk. Blood vessels and nerves in the area of the operation can also be damaged and may result in long term pain after the operation. In addition, the laparoscopic repair can result in hernias through the incisions where the hollow tubes are placed. Although very rare, injury or damage to the intra-abdominal organs can occur which could involve another operation, or prolonged hospital stay. With either operation, there is a less than 0.5% risk of death.

The open tension-free repair can be performed using several different types of anesthesia including local (like what is used at the dentist's office) that is usually given in addition to some medicine given in your veins to make you a little more comfortable. Usually this procedure is performed using a regional (spinal or epidural) or a general anesthetic. The laparoscopic repair is almost always performed using a general anesthetic since the air used to keep the tissues separated while the surgeon is operating can cause discomfort that is not easily taken care of with injections of local numbing medicine. There are risks associated with the type of anesthesia used. These risks are very small, but include the chance of having nausea, vomiting or a sore throat. With a spinal or epidural anesthetic, there is also a very small risk of headache. With a general or regional anesthetic, there is also a small chance you would not be able to empty your bladder after surgery, in which case a catheter would be inserted to drain the urine and then taken back out. With a local anesthetic, there is a risk of getting too much of the medicine and this can cause a reaction. On rare occasion, you could have an allergic reaction to one of the medicines.

Subject's Initials _____ Date _____

Subject Name: _____ Date: _____
 Title of Study: CSP #456 – Tension-free Inguinal Hernia Repair: Comparison of Open and Laparoscopic Surgical Techniques
 Principal Investigator: Lawrence T. Kim, M.D. VAMC: Dallas
 Co-Investigators: Richard H. Turnage, MD, Patricia Bergen, MD, Thomas Anthony, MD, Fiemu Nwariaku, MD, George Sarosi, MD, Robert Gibbons, MD.

Hernia repair, like any operation involves risks of death, bleeding, and infection. Both of the procedures used in this study are accepted techniques of hernia repair. Participation in this study should not involve any additional risk to you beyond the usual risks of hernia repair.

ALTERNATIVE TREATMENTS:

If you do not want to participate in this study, you can have your inguinal hernia repaired by whichever method you and your surgeon feel is best for you.

BENEFITS TO THE PATIENT OR OTHERS:

The proposed study will help doctors learn which, if any, of these methods of hernia repair is better. You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others. Subjects do not pay for treatment associated with participation in a VA research program.

CONFIDENTIALITY OF RESEARCH RECORDS:

The investigators maintain confidentiality of your research records in the same way as your other medical records. No one has access to your records except as required by law. You are, however, authorizing the Veterans Administration, the Food and Drug Administration (FDA), and the Dallas VA Institutional Review Board to inspect your medical and research records. Your name as a subject in this study is confidential, and will not be included in any publication prepared as a result of this study.

COMPENSATION FOR ANY RESEARCH-RELATED INJURY:

The investigators will make every effort to prevent injury that could result from this research. While there is no requirement for the VA to provide compensation for injuries related to research, it will provide reasonable medical treatment for injuries related to research in accordance with Federal Law.

You do not give up any legal rights to compensation for injuries related to research by signing this form. The Federal Tort Claims Act is a way to request compensation from the government for injuries related to research in VA research subjects. Investigators at the VA will advise you about medical treatment available at the Dallas VA Medical Center in case of bad effects, which you should report to them promptly. Investigator's phone numbers are at the end of this form.

Subject's Initials _____ Date _____

Subject Name: _____ Date: _____
 Title of Study: CSP #456 – Tension-free Inguinal Hernia Repair: Comparison of Open and Laparoscopic Surgical Techniques
 Principal Investigator: Lawrence T. Kim, M.D. VAMC: Dallas
 Co-Investigators: Richard H. Turnage, MD, Patricia Bergen, MD, Thomas Anthony, MD
Fiemu Nwariaku, MD, George Sarosi, MD, Robert Gibbons, MD.

If you have any questions about your rights as a participant in this study, you may contact the Chairman, Subcommittee on Human Studies at the Dallas VA Medical Center: (214) 857-0291

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above.
 Dr. _____ has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled. The study physician can stop my participation at any time if it appears to be medically harmful to me, if I fail to follow directions for participation in this study, if it is discovered that I do not meet the study requirements, or if the study is cancelled.

In case there are medical problems or questions, I have been told I can call Dr. Kim at (214)857-1811 during the day and the surgical doctor on call at (214)742-8387 or (800)849-3597 after hours.

I understand my rights as a research subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I will receive a signed copy of this consent form.

 Subject's Signature

 Date

 Signature of Subject's Representative*

 Subject's Representatives (print)

 Signature of Witness

 Witness (print)

For the Investigator or Designee: I certify that I have reviewed the contents of this form with the person signing above, who, in my opinion understood the explanation. I have explained the known side effects and benefits of the research

 Signature of Investigator

 Date

*Only required if subject not competent.

Subject's Initials _____ Date _____

APPENDIX F

Approval of the Executive Committee of VA
Cooperative Study #456



**DEPARTMENT OF VETERANS AFFAIRS
Medical Center
500 Foothill Boulevard
Salt Lake City UT 84148-9998**

March 13, 2000

In Reply Refer To:

Texas Woman's University
College of Nursing
1322 Oakland
Denton, TX

This letter allows Cheryl Rowder, RN to examine the partial data sets generated by Cooperative Studies Program #456 entitled, "Tension-Free Inguinal Hernia Repair: Comparison of Open and Laparoscopic Surgical Techniques."

If there are any questions in regard to this matter, please call Leigh Neumayer, M.D.,

[REDACTED]

[REDACTED]

LEIGH NEUMAYER, M.D.
Chair, CSP #456

APPENDIX G

Texas Woman's University Human Subjects Committee
and Graduate School Permission to Conduct Study

████████████████████

TEXAS WOMAN'S
UNIVERSITY

DENTON / DALLAS / HOUSTON

HUMAN SUBJECTS
REVIEW COMMITTEE
P.O. Box 425619
Denton, TX 76204-5619
Phone: 940/898-3377
Fax: 940/898-3416

March 21, 2000

Ms. Cheryl Rowder
████████████████████
████████████████████

Social Security ██████████

Dear Ms. Rowder:

Re: Pain and Postoperative Quality of Life in Inguinal Hernia Patients

The above referenced study has been reviewed by a committee of the Human Subjects Review Committee and was determined to be exempt from further TWU HSRC review.

If applicable, agency approval letters obtained should be submitted to the HSRC upon receipt prior to any data collection at that agency. Because you do not utilize a signed consent form for your study, the filing of signatures of subjects with the HSRC is not required.

Another review by the HSRC is required if your project changes. If you have any questions, please feel free to call the Human Subjects Review Committee at the phone number listed above.

Sincerely,

████████████████████
Dr. Linda Rubin, Chair
Human Subjects Review Committee - Denton

cc. Dr. Carolyn Gunning, College of Nursing
Dr. Margaret Beard, College of Nursing
Graduate School

A Comprehensive Public University Primarily for Women
An Equal Opportunity/Affirmative Action Employer

018-36-7058

TEXAS WOMAN'S
UNIVERSITY
DENTON/DALLAS/HOUSTON

THE GRADUATE SCHOOL
P.O. Box 425649
Denton, TX 76204-5649
Phone: 940/898-3400
Fax: 940/898-3412

June 15, 2000

Ms. Cheryl B. Rowder
[REDACTED]

Dear Ms. Rowder:

I have received and approved the prospectus entitled "Pain and Postoperative Health-Related Quality of Life of Inguinal Hernia Patients" for your *Dissertation* research project.

Best wishes to you in the research and writing of your project.

Sincerely yours,
[REDACTED]

Leslie M. Thompson
Associate Vice President for Research and
Dean of the Graduate School

LMT/sgm

cc Dr. Margaret Beard, Nursing
Dr. Carolyn Gunning, Nursing

A Comprehensive Public University Primarily for Women
An Equal Opportunity/Affirmative Action Employer

Cheryl B. Rowder, RN

Curriculum Vita

EDUCATION

<u>Date</u>	<u>Degree</u>	<u>Major</u>	<u>Institution</u>
5-96	M. S.	Nursing	Texas Woman's University
5-92	B. S.	Nursing	Texas Woman's University
5-68	B. S.	Elementary Education	University of Illinois

PROFESSIONAL EXPERIENCE

<u>Date</u>	<u>Position</u>	<u>Institution</u>
1/99	Site Coordinator VA Cooperative Study #456.	VANTHCS
1/96-1/99	Educator Served on Recruitment and Retention Task Force Co-Chair Education/Research Council Diabetic Education Task Force	VANTHCS
4/95-1/96	Staff Nurse MICU	VANTHCS
5/92-4/95 Dallas	Staff Nurse CCU	Presbyterian Hospital of Dallas

PROFESSIONAL ORGANIZATIONS AND COMMUNITY SERVICE ACTIVITIES

Professional Organizations

1992- present	Sigma Theta Tau, International Nursing Honor Society Beta Beta Chapter activities: Awards Committee 2000
1992- present	Mortar Board
1992- present	Alpha Chi Honor Society
1992- present	Golden Key Honor Society
1992-1995	Association of Critical Care Nurses
1995-1999	Metroplex Nursing Staff Development Organization
1999-present	Association of Clinical Research Professionals (National)
1999-present	Nursing Organization of Veterans Affairs (National)

Community Service

1991-present	Red Cross Volunteer Emergency Preparedness
1996-1997	Greiner's Business/Mentor Shadow Program
1996-1997	Artist- Patient Paint-a-long, Dallas VA Medical Center
1996-1999	CPR Instructor
1996-1999	Volunteer at State Fair of Texas VA Booth

HONORS/AWARDS

4/1997	Dallas Fort Worth Great 100 Nurse
5/ 99	Research Grant, Sigma Theta Tau International Honor Society 'Postoperative Pain and Respiratory Effort in Abdominal and Thoracic Surgery Patients'
1997	Inducted as Great 100 Nurses
1997	Outstanding Poster Eleventh Annual Nursing Research Conference
1996	Idea of the Month- Dallas VA Medical Center

RESEARCH AND FUNDED PROJECTS

<u>Date</u>	<u>Title</u>	<u>Agency</u>
<u>7/1997</u>	Back Safety	North Texas Veterans Affairs Health Care System
5/1996	Geriatric Evaluation & Management	Eleventh Annual nursing Research Conference
4/1997	Professional Growth	Poster Presentation Thirty-third Annual Clinical Nursing Conference

WORKSHOPS/SEMINARS/PROFESSIONAL DEVELOPMENT ATTENDED

1996	Nurse Manager Traineeship Program
1997	Innovations in Medical/Surgical Nursing
1997	Exploring New Opportunities
1997	Board of Nurse Examiners Workshop
1998	Alternative Therapies
1998	Nursing Research: Reaching Into the Next Millennium
2000	Nursing Research Seminar