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# THE EFFECTS OF ROCKING CHAIR MOTION ON POSTOPERATIVE ILEUS DURATION, SUBJECTIVE PAIN, PAIN MEDICATION USE AND TIME TO DISCHARGE FOLLOWING ABDOMINAL SURGERY

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by

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# Dedication

I wish to dedicate this project to all the patients I have cared for during the past twentysix years, my wife Mona, my mother-in-law Jeannine Molles, daughter Sarah and son Brett. I also wish to dedicate this to my late mother who always encouraged me to continue to grow and learn both as a person and scholar.

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# THE EFFECTS OF ROCKING CHAIR MOTION ON POSTOPERATIVE ILEUS DURATION, SUBJECTIVE PAIN, PAIN MEDICATION USE AND TIME TO DISCHARGE FOLLOWING ABDOMINAL SURGERY

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Rocking motion may be useful in resolving postoperative ileus (POI) in cancer patients who have undergone abdominal surgery. Operations of the abdomen result in gastrointestinal dysmotility, to some extent, in all patients because abdominal surgical procedures to remove abdominal tumors require large abdominal incisions, extensive dissection, and manipulation of the bowel that initiates a surgical induced stress response commonly known as, postoperative ileus. In this study, the effects of a rocking chair motion as a moderator of the surgical stress response and mediator of the gas and distention effects of POI in abdominal surgery cancer patients compared to standard care was examined. Two groups of postoperative abdominal surgery cancer patients were randomly assigned to the rocking or non-rocking groups. The outcome variables assessed were duration of time to first flatus, subjective pain, total pain medication received and time to discharge. The hypotheses tested were there were no differences in duration of time to first flatus indicating resolution of POI, subjective pain, total pain medication received and time to discharge from the hospital. The rocking group had a reduction in time to first flatus and no differences in subjective reports of pain, total pain medication received and time to discharge from the hospital. Results indicated the rocking chair motion is effective in postoperative abdominal surgery cancer patients reducing the duration of postoperative ileus.

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## **CHAPTER 1: INTRODUCTION**

#### **1.1 THE PROBLEM**

The purpose of this chapter is to introduce the problem that was studied, discuss its significance to the discipline of nursing and suggest the contributions its findings may make to promoting changes in nursing practice protocols that have the potential to improve patient outcomes following abdominal surgery. The aims, hypotheses, background and significance sections of this chapter reveal the basic assumptions, conceptual perspectives, and limitations that directed and influenced this study.

Postoperative ileus (POI) is a form of gastrointestinal dysfunction that commonly occurs in patients after abdominal surgery and results in absent or delayed gastrointestinal motility, food intolerance, gas retention, and pain. POI may last for four to five days and complicate the full and timely recovery of the patient. Literature suggests that the duration of POI is in part related to the degree of surgical trauma and is most severe following extensive surgeries of the colon (Holte & Kehlet, 2000; Kehlet, 1997). Other studies suggest there are multiple contributing causes of POI and to date no specific interventions have been discovered that prevent and successfully resolve POI (Luckey, Livingston & Tache, 2003; Miedema & Johnson, 2003).

POI is a major health problem because it places postoperative abdominal surgery patients at increased risk for development of circulatory and pulmonary complications associated with reduced physical activity due to pain and other immobilizing symptoms. Previous research provides overwhelming evidence that POI extends the affected patient's post-surgical recovery period for several days (Prasad & Matthews, 1999), significantly delaying the healing process (Barnes, Resch & Ernst, 1997; Clark, 2002; Le

Blanc-Louvry, Costaglioli, Boulon, Leroi & Ducrotte, 2002; Livingston & Passaro,1990; Luckey et al. 2003; Miedema & Johnson, 2003; Schuster & Montie, 2002), and adds more than \$1 billion annually to the costs of related health care to treat the problem.

POI is hypothesized to be the body's sympathetic-induced response to over stimulation and stress imposed by large abdominal incisions and extensive manipulation and dissection of the bowel (Holte & Kehlet, 2000; Holte & Kehlet, 2002; Le Blanc-Louvry et al. 2002; Luckey et al., 2003; Miedema & Johnson, 2003; Prasad & Mathews, 1999; Shelton, 1999; Schuster & Montie, 2002; Wood, 1981). Factors reported to contribute to its onset and persistence are activation of the body's inflammatory mediators, secretion of gastrointestinal hormones, various forms of anesthesia used during the surgery, and opiates given for pain control (Kalff, Schraut & Billar, 2000; Kalff, Schraut, Simmons & Bauer, 1998; Kehlet & Holte, 2001; Luckey et al., 2003; Miedema & Johnson, 2003; Prasad & Matthews, 1999; Shaheen, 2002). The immobilizing effects of POI are associated with absent, abnormal, or disorganized motor function of the stomach, small bowel, and colon resulting in the accumulation of gas that cannot be dissipated, abdominal distention, nausea, vomiting, and debilitating pain (Brooks-Brunn, 1997; Moore, Shannon, Richard & Vacca, 1995; Platell & Hall, 1997; Thomas, Ptak, Giddings, Moore & Opperman, 1990).

Although POI has been recognized as a post-operative phenomenon since 1899, little progress has been made towards its prevention and treatment during a century in which other significant advancements in surgical techniques and postoperative care were made (Agostini, Chinnock & Daly, 1975; Barnes et al., 1997; Bayliss & Starling, 1899; Cisar & Ruppert, 1999; Le Blanc-Louvry et al., 2002; Luckey et al., 2003; Miedema & Johnson, 2003; Schuster & Montie, 2002). To date, physicians and nurses have little to offer patients other than reassurance that the incapacitating symptoms will resolve in time and bowel function will return (Matros et al., 2006).

Currently, clinical standards for determining the prevention, treatment, and resolution of POI continue to be as confounding as the multiple combinations of contributing factors that cause it. In addition, agreement among practitioners regarding the assessment and evaluation of signs and symptoms of POI has been difficult to establish until the last decade. Today's standard clinical practice protocols recommend that the assessment of postoperative patients for POI include daily auscultation of the patient's abdomen for the return of bowel sounds, plus monitoring the patient for the passage of gas through the rectum; a phenomenon commonly called "surgeons' music" (Prasad & Matthews, 1999). Historically, hearing bowel sounds following surgery was thought to be proof that POI was absent or resolved. However, there remain inconsistencies in the research and clinical literature about whether or not the return of bowel sounds is indeed the most reliable indicator of complete and proper bowel function in postoperative abdominal surgery patients. Some researchers argue that the absence of abdominal distention and vomiting must also accompany the presence of bowel sounds and "surgeons music" (Davis, Pisters, Dovial & Donat, 2002).

Other researchers and practicing clinicians argue that findings from studies that used implanted barostats support suspicions that bowel function never fully ceases during or after surgery, thereby introducing doubt about the validity of using the presence of bowel sounds as an indicator of proper bowel functioning (Davis et al., 2002; Huge, Kreis, Zittel, Becker, Starlinger & Jehle, 2000; Le Blanc-Louvry et al. 2002; Luckey et al., 2003; Miedema & Johnson, 2003; Schuster & Montie, 2002; Shaheen, 2002; Waldhausen, Shaffrey, Skenderis, Jones & Schirmer, 1990). Further complicating the assessment and treatment of POI are other research findings that suggest that some postoperative patients with normal active bowel sounds also suffer from symptoms of POI.

Despite conflicting research findings over the past several decades, the clinical community does agree that the standard measure to evaluate the resolution of POI is the actual passage of flatus from the rectum (Barnes et al., 1997; Madsen et al., 2005; Prasad & Matthews, 1999; Waldhausen & Schirmer, 1990). This agreed-upon standard was used in this dissertation to determine the resolution of POI in the sample. While this standard provides clinicians with tools to assess and evaluate POI, more studies are needed that employ low-risk, non-invasive interventions that can bring about effective resolutions to the problem and reduce its complications and costs.

One common non-invasive postoperative standard of care intervention that is believed to prevent and resolve POI is early ambulation of the patient followed by orders to increase the time spent sitting in a chair and walking (Waldhausen & Schirmer, 1990). Evidence to support the effectiveness of these interventions remain unchallenged and unconvincing (Brieger, 1983; Holte & Kehlet, 2002; Schuster & Montie, 2002). The need for controlled studies of other interventions using randomized comparison treatment groups set into motion the design and conduct of this dissertation.

In this dissertation, standard postoperative care including regular ambulation and sitting in a chair was provided to one treatment group and a comparison treatment group was given the rocking chair intervention. Specific aims and the overview of methods employed in this study are discussed in the following sections of this chapter. Chapter 2 discusses the review of literature, Chapter 3 reports methods used, Chapter 4 is a

presentation of findings, and Chapter 5 discusses findings, conclusions, and recommendations.

### **1.2 THE OVERALL AIM**

Given that POI remains a stubborn, painful, and costly postoperative patient care problem (LeBlanc-Louvry et al. 2002; Livingston & Passaro, 1990; Luckey et al. 2003; Schuster & Montie, 2002), more studies are needed to examine and test safe, costeffective interventions for its prevention and treatment. The overall aim of this experimental posttest only control group study was to examine differences in the duration of POI symptoms [postoperative time to first passage of flatus from the rectum (TTFF)], subjective reports of type, duration, intensity and interference of postoperative abdominal pain [Brief Pain Inventory – Short Form (BPI-SF)], pain medication use [total milligrams received per 24 hours], and postoperative patient recovery time [time to discharge] among and between two groups of cancer patients recovering from abdominal surgery. One treatment group received standard postoperative care that included ambulation and sitting up out of bed beginning the first postoperative day and the other received the postoperative protocol that included the use of a rocking chair motion.

#### **1.3 Hypotheses and Specific Aims**

The null hypothesis (H0) tested in this study was: There are no differences in the duration of return to flatus, subjective reports of postoperative abdominal pain, total pain medication use, and postoperative recovery time among cancer patients recovering from abdominal surgery who receive the rocking intervention vs. the standard of care. Patients randomized to the rocking arm were instructed to get out of bed and begin rocking in a rocking chair and ambulating beginning the first postoperative day. Patients randomized to the nonrocking standard of care arm were instructed to get out of bed beginning the

first postoperative day and sit in a nonrocking chair and ambulate beginning the first postoperative day.

The research hypotheses evaluated in this study were:

**SPECIFIC AIM 1**: To assess whether the rocking intervention reduces the mean time in days to passage of first flatus from the rectum in postoperative abdominal surgery patients compared to standard postoperative care patients.

**HYPOTHESIS 1:** There will be a difference in postoperative mean time to the passage of first flatus from the rectum between those patients who receive the rocking intervention and those who receive standard postoperative care.

**SPECIFIC AIM 2:** To assess whether mean pain intensity and interference scores could be reduced to a greater extent by rocking motion compared to standard postoperative care.

**HYPOTHESIS 2:** There will be a difference in mean postoperative subjective reports of pain intensity (worst, least, average and pain right now) and pain interference (general activity, mood, walking ability, relations with others, sleep and enjoyment of life) between those patients who receive the rocking intervention and those who receive standard postoperative care.

**SPECIFIC AIM 3:** To assess whether the rocking motion is more effective in reducing total mean pain medication milligrams received compared to standard postoperative care.

**HYPOTHESIS 3:** There will be a difference in the mean total pain medication in milligrams received between those patients who receive the rocking intervention and those who receive standard postoperative care.

**SPECIFIC AIM 4:** To assess whether mean time in days to hospital discharge is reduced by treatment with rocking motion compared to standard postoperative care.

**HYPOTHESIS 4**: There will be a difference in mean time to discharge between those patients who receive the rocking intervention and those who receive standard postoperative care.

### **1.4 THE TARGET POPULATION**

The target population of cancer patients recovering from abdominal surgery was chosen for this study. The high occurrence rates of digestive cancers in the United States (Jemal et al. 2005), the potential risks that complications of abdominal surgeries and POI present to this group (Miedema & Johnson, 2003), and the threats these phenomena present to further increasing the already high costs of health care significantly influenced this research.

The majority of patients with digestive system cancers undergo surgical interventions that involve large abdominal incisions, extensive tissue dissection, and manipulation of the bowel required to diagnose stage or remove lesions (Miedema & Johnson, 2003). Among this group of patients, POI is a common transient and debilitating sequel to the surgery. Patients themselves have described the worst aspect of abdominal surgery as the period between loss of bowel function and actual return of bowel function, indicated by flatus or stool expelled from the rectum (Behm & Stollman, 2003; Schwenk, Bohn, Haase, Jughans, & Muller, 1998; Shaheen, 2002). Helping patients achieve quick and uncomplicated recovery from POI remain a significant challenge for the health care team.

### **1.5 ETIOLOGY AND CLINICAL SIGNIFICANCE OF POI**

A key physiologic factor in the development of POI is the body's response to the stress of surgery (Desborough, 2000; Desborough & Hall, 1993; Kehlet, 1997). This surgical stress response is not limited to patients who undergo abdominal surgeries. Other surgical procedures such as hip replacement and thoracic surgeries also are implicated as stimuli for the surgical stress response and POI that is associated with abdominal dysfunction, dysmotility and disorganization of neural stimuli that normally are responsible to coordinate propulsion within the gastrointestinal tract (Behm & Stollman, 2003; Bowling, 1994; Delaney, 2004; Holte & Kehlet, 2002; Kehlet, 1997; Kehlet & Holte, 2001).

POI has been linked to the uncomfortable and disabling symptoms (gas retention, abdominal distention, pain, nausea and vomiting) that curtail the physical activity of postoperative patients and place patients at increased risk for circulatory and pulmonary complications, increased length of hospital stay, and higher costs of care (Behm & Stollman, 2003; Bowling, 1994; Brooks-Brunn, 1997; Davis et al., 2002; Delaney, 2004; Livingston & Passaro, 1990; Miedema & Johnson, 2003; Moore et al. 1995; Prasad & Matthews, 1999; Schuster & Montie, 2002; Shaheen, 2002; Thomas et al., 1990). Awaiting the resolution of POI is the primary reason why many postoperative patients have longer than expected hospital stays.

#### **1.6 ASSESSMENT AND DYNAMICS OF POI**

While POI is known to be a transient impairment in gastrointestinal (GI) motility among postoperative patients, no standard grading system or nomenclature exists to assist clinicians with the assessment, reporting, and treatment of symptoms (Behm & Stollman, 2003; Fukuda, Tsuchida, Koda, Miyazaki, Pappas & Takahashi, 2005; Holte & Kehlet, 2000). The review of the literature for this study revealed a lack of consensus about how frequently postoperative patients should be assessed for symptoms, what treatment protocols should be, and which criteria should be used to determine when POI has resolved. Although POI is among the most common and troublesome side effects of abdominal surgery, it is the criterion most often used to determine if the postoperative patient is ready for discharge from the hospital (Luckey et al., 2003).

To date, there are no data in the literature to suggest that POI-related delays in recovery and discharge from the hospital present any benefits to the patient (Behm & Stollman, 2003; Huge et al., 2000; Holte & Kehlet, 2000). Instead, POI remains detrimental to postoperative patients because it places them at risk for complications, prolongs recovery time, and increases the costs of care.

It is documented in the literature that the postoperative return of bowel functioning varies by location. That is, the return of functioning appears to occur first in the small intestine within several hours after surgery, the stomach in 24-48 hours, and the colon within 3-5 days (Huge et al., 2000; Le Blanc-Lowery et al., 2002; Schuster & Montie, 2002; Waldhausen et al., 1990). POI can last for up to four to five days and significantly extend the patient's Time to Discharge and increase risks of complications (Barnes et al., 1997; Le Blanc-Louvry et al., 2002; Luckey et al., 2003; Miedema & Johnson, 2003; Schuster & Montie, 2002). It has been noted that impaired bowel motility may last longer when the surgery involves the distal rather than the proximal digestive tract, especially if there has been distal colonic reanastomosis (Huge et al., 2000).

### **1.7 PATHOPHYSIOLOGY OF POI, SOURCES OF COMPLICATIONS AND RISKS**

Studies of post-surgical patients have consistently demonstrated a postoperative period of gastric hypomotility associated with irregular and disorganized electrical activity after abdominal surgical procedures (Clevers, Smout, Van der Schee, & Akkermans, 1991). Several mechanisms are thought to have roles in the pathology of POI. All are thought to contribute to the disorganized electrical activity and lack of coordinated propulsion of the gastrointestinal system after abdominal surgery. Mechanisms involved include: (1) spinal and local sympathetic neural reflexes, (2) local and systemic inflammatory mediators, and (3) exacerbating factors such as opioid analgesics, intraperitoneal surgery, degree of bowel manipulation, open surgical procedure, and hypokalemia (Behm & Stollman, 2003). Abnormal gastric propulsion and emptying related to a shortening of the migrating motor complex (MMC) also occurs following surgery (Condon et al., 1986; Wilson, 1975). Random, disorganized bursts of electrical activity contribute to additional gastric motility problems because they increase pyloric tone (Dauchel, Schang, Kachelhoffer, Elroy, & Grenier, 1976) and stimulate retrograde contractions (Miedema et al., 2000).

The health risks presented by POI are the circulatory and pulmonary complications that are primarily triggered by surgical pain discomfort that restricts physical activity (Brooks-Brunn, 1997; Moore et al., 1995; Platell & Hall, 1997; Thomas et al., 1990). Patients report feeling very uncomfortable after abdominal surgery, are more hesitant to get up and walk around, and do less deep breathing (Lasser, Bond, & Levitt, 1975). The discomfort associated with the build-up of intestinal gas further limits chest excursion and mobility thus increasing the patient's potential for increased morbidity, recovery time, length of hospitalization, and the costs of care (Moore et al., 1995; Thomas et al., 1990).

Overall, POI can extend the post-surgical recovery period more than a week and add more than \$1 billion annually to health care costs (Luckey et al., 2003). Delaney (2004) noted that, "approximately 161,000 Medicare patients who underwent abdominal surgery stayed 1.8 million extra days in the hospital at an additional cost of \$1.75 billion as a result of the complications associated with POI" (p. 61). With the same concerns, Barnes et al. (1997) noted that delays in the resolution of POI were responsible for additional morbidity and delays in recovery from bowel surgery.

Despite the fact that progressively increasing ambulation times and time spent out of bed for post-surgical patients have been the standard of care since the early 1900s, little progress has been made in preventing POI and effectively treating it (Barnes et al., 1997; Cisar & Ruppert, 1999; Le Blanc-Louvry, et al., 2002; Luckey et al., 2003; Miedema & Johnson, 2003; Schuster & Montie, 2002; Waldhausen et al., 1990; Waldhausen & Schrimer, 1990). Among studies of POI interventions and outcomes found in the literature, no randomized, posttest control group experiments are reported that used rocking alone as an intervention. It is this gap in the research literature that this dissertation was designed to address.

#### **1.8 ROCKING AS INTERVENTION: THEORY AND RESEARCH**

A relatively new non-invasive clinical intervention that is hypothesized to mediate the surgical stress response is a rocking motion delivered using a rocking chair (Kehlet, 1997; Moore et al., 1995; Thomas et al., 1990). However, this intervention needs more testing to determine its effectiveness in resolving POI. For this dissertation, the physiologic stress response and Benson's (1975) Relaxation Response Theory were sources of hypotheses and interventions. The non-invasive rocking motion delivered using a rocking chair is currently not part of the standard of care that has prevailed in the treatment of postoperative patients for over a century. Hypothesized to stimulate relaxation, the back and forth momentum of rocking was found by Moore et al. (1995) and Thomas et al. (1990) to reduce intestinal gas accumulation, abdominal distention, and pain associated with POI in abdominal surgery patients. Thomas' research group found that rocking helped mothers, after cesarean birth, to feel more relaxed and less anxious. These mothers were also found to relate to their infants in a more relaxed manner when compared to non-rocking mothers. They reported less pain, passed flatus one day earlier than the non-rocking mothers, and had a reduced length of hospital stay by one day. Moore et al. (1995) reported similar findings among postoperative abdominal hysterectomy patients. Concomitant clinical observations and data analysis revealed that rocking in ten to 20 minute increments for at least 60 minutes per day also reduced gas pain scores, promoted earlier ambulation and expulsion of gas, and facilitated the patient's discharge from the hospital an average of one day earlier than patients in the non-rocking group.

Throughout a growing body of literature, rocking is discussed as a stimulus to relaxation because it mediates and moderates stress response mechanisms (Benson, 1975; Benson, 1979; Benson, 1985; Benson, 1996). In addition to Moore and Thomas, several other researchers have identified roles that rocking motions play in offsetting the negative effects of stress, illness, and surgery (De Marco-Sinatra, 2000; Houston, 1993; Roberts & Fitzpatrick, 1983; Snyder et al., 2001; Talmadge, 1996). These studies will be discussed in Chapter 2. Even though we have known for some time that stress is unavoidable (Selye, 1976; Selye, 1978; Benson, 1975; Benson, 1979), Cannon (1914) reminds us that stress reduction and positive responses to stress are essential for survival. While the exact physiological mechanisms that are influenced by rocking motions are not well known, several theorists and researchers hypothesize that the gentle, rhythmic, repetitive motion of rocking stimulates the vestibular nerves to send signals of pleasure and alertness to the

Reticular Activating System (RAS), which is the body's "flight or fight" response center (Moore et al., 1995). From Benson's perspective, it is the gentle motion of rocking that inhibits the sympathetic response to stressful stimuli and facilitates the Relaxation Response. Both of these interpretive perspectives on the effects of rocking were instrumental in guiding the aims, hypotheses, interventions and choices of outcomes measures employed in this study.

### **1.9 SUMMARY**

POI poses serious risks for postoperative abdominal surgery patients and warrants more rigorous study to determine the effectiveness of non-invasive, low cost interventions for its prevention and treatment. The background and significance of this problem and its effect on patients and health care costs formed the basic rationale for the design and conduct of this dissertation study, while two primary theoretical perspectives on surgical stress response and relaxation provided the platform for intervention and measurement.

The phenomenon of POI and its resolution needs to be studied from a nursing perspective to promote quality care, theory-guided practice, and healing among postoperative abdominal surgery patients. Cost-effective, efficient and non-invasive care strategies need to be tested and compared for their abilities to contribute to lowering risks and bringing about positive patient outcomes.

The next Chapter presents a review of relevant literature and serves to establish the state of knowledge about POI, stress responses and mediators, and interventions that are important to the recovery of postoperative patients.

# CHAPTER II: LITERATURE REVIEW / THEORETICAL FRAMEWORK

#### 2.1 DEFINITIONS AND DESCRIPTIONS OF POI

The purpose of this chapter is to present definitions of terms, a review and critique of published works that form the basis of knowledge about POI, and the theoretical framework that guided this study. The presentation is organized according to the definitions and descriptions of the problem, its causes and treatments, and related issues regarding the assessment, duration, and resolution of POI. Following the review of literature, the theoretical framework is presented along with evidence that this framework is a good fit for guiding the conduct of this study and interpreting the findings.

There are staggering statistics about numbers of abdominal surgeries performed each year in the United States. Given that POI is a potential post-surgical complication that threatens the well being of patients and drives up the costs of health care, more knowledge is needed about why it occurs and how we can safely, efficiently and effectively manage the problem. According to the National Center for Health Statistics, approximately 43.9 million surgical procedures were performed in the United States in 2003. Twelve million of those surgeries involved opening the abdomen to explore, correct, or remove sources of disorders and diseases of the digestive system (National Center for Health Statistics, 2003).

In the most general sense, POI is a frequently occurring complication of abdominal surgery. It occurs in response to the sympathetic stimulus of the bowel by various mechanical and psychological stressors (Schuster & Montie, 2002). Behm and Stollman (2003) clarified that POI is a transient impairment of gastrointestinal motility for which there is no existing standard to grade, quantify, or describe its intensity and expected duration. Using both Schuster and Montie's definition of POI and Behm and Stollman's description of its transient nature, there is agreement that POI can be distinguished as different from an episode of ileus. Ileus suggests that there is an obstruction in the bowel rather than there being an inhibition of propulsive activity as happens when POI is the problem (Kehlet, 1997; Kehlet & Holte, 2001; Livingston & Passaro, 1990; Luckey et al., 2003; Dorland's Illustrated Medical Dictionary, 2003). Delaney (2004) and Fukuda et al. (2005) also described the transient nature of POI. However, controversies about which specific parameters should be used to define the onset, duration, and resolution of this transient phenomenon persist throughout the literature. While controversies and disagreements remain, Holte and Kehlet (2000) concluded that POI was an obligatory transient impairment in bowel motility that could not be linked to any benefit for the postoperative abdominal surgery patient.

### 2.2 CAUSES, RISKS, AND COSTS OF POI

A common and debilitating sequel to abdominal surgery, two types of reflexes are thought to be responsible for the sympathetic-induced gastrointestinal dysmotility of POI. Both afferent and efferent stimulation of the intestines are recognized in the POI response (Holte & Kehlet, 2000; Holte & Kehlet, 2002; Kehlet, 1997; Kehlet & Holte, 2001; LeBlanc-Louvry et al., 2002; Luckey et al., 2003; Miedema & Johnson, 2003; Schuster & Montie, 2002; Wood, 1981). Cancer patients undergoing abdominal surgery are especially prone to the development of POI because the dissection of bowel tumors typically involves excessive stimulation of the bowel. It is also believed that cancer patients experience higher levels of psychological stressors that may further stimulate the sympathetic response to stress and exacerbate symptoms of POI (Schuster & Monte, 2002). Although sympathetic activity related to the stress response is considered the primary cause for the onset of POI, other factors appear also to contribute to the development of this common and troublesome complication (Prasad & Matthews, 1999; Shelton, 1999).

Other factors recognized as contributing to POI include activation of inflammatory mediators, use of opiates for pain control, nitric oxide, gastrointestinal hormones and anesthesia (Luckey et al., 2003; Kalff et al., 2000; Kalff et al., 1998; Miedema & Johnson, 2003; Prasad & Matthews, 1999; Shaheen, 2002). Inflammatory mediators result in decreased bowel activity (Kalff et al., 1998). Opiates, frequently used for pain control in the postoperative patient, are known to increase the nonpropulsive bowel contractions and can trigger constipation and gas retention (Kurz & Sessler, 2003; Luckey et al., 2003; Miedema & Johnson, 2003). Anesthetics appear to exert their effects on the part of the bowel that depends on neural integration, most notably, the large intestine (Livingston & Passaro, 1990). Despite recent research into the multiple factors that contribute to POI, the primary cause remains the surgical stress response. This primary cause is the premise upon which the aims, design, and interventions of this dissertations research were based.

In addition to the circulatory and pulmonary complications that POI can precipitate because of pain and immobility (Brooks-Brunn, 1997; LeBlanc-Louvry et al., 2002; Luckey et al., 2003; Moore et al., 1995; Platell & Hall, 1997; Schuster & Montie, 2002; Thomas et al., 1990), POI also extends a patient's recovery time, hospital stay, and costs of care. It is estimated that POI adds approximately one billion dollars annually to healthcare costs when its effects on patients are tallied (Koller, Haug & Brügger, 2006; Livingston & Passaro, 1990; Prasad, 1999). More studies are needed to test non-invasive, low-cost interventions that reduce the incidence of POI and decrease time to resolution and discharge (Brooks-Dunn, 1997).

### 2.3 HISTORY OF POI, STANDARDS OF CARE, AND TREATMENT EFFECTS

Despite significant advancements in surgical techniques and postoperative care over the past century, progress in the prevention and treatment of POI is less impressive (Agostini et al., 1975; Barnes et al., 1997; Bayliss & Starling, 1899; Cisar & Ruppert, 1999; LeBlanc-Louvry et al., 2002). There are various interventions reported in the literature as useful in mediating and relieving POI, yet none is overwhelmingly effective. Reported interventions include decompression of the gastrointestinal tract and resting the bowel through use of nasogastric tubes, pharmacologic agents, early postoperative resumption of feeding, early nasogastric tube removal, abdominal massage, pulsed electromagnetic energy, gum chewing, homeopathy, progressive ambulation and increased time out of bed sitting in a chair (Asao et al., 2002; Baker, Allcutt & McCollum, 1984; Luckey et al., 2003; Miedema & Johnson, 2003; Schuster & Montie, 2002; Waldhausen & Schrimer, 1990). Nasogastric tubes have been implemented as an intervention to decompress and rest the bowel since 1921 as one attempt to relieve POI (Sagar, Kruegner & MacFire, 1992).

There is a significant lack of evidence to support the effectiveness of nasogastric tubes in the resolution of POI. Outweighing the continued use of this intervention for POI are the many complications of gastroesphageal reflux, fluid and electrolyte imbalances, otitis media, sinusitis, and potential gastric perforation commonly associated with nasogastric intubation (Cheatham, Chapman, Key & Sawyers, 1995; Davis et al., 2002; Luckey et al., 2003; Miedema & Johnson, 2003). As a result of the complications and risks associated with nasogastric intubation, this intervention is used much less frequently

today. Nasogastric intubations are still currently used during the surgical procedure itself, but are removed prior to or just as the patient is being awakened from anesthesia.

Findings from randomized clinical trials and meta-analyses of extant research both conclude that nasogastric decompression and bowel rest does not shorten the time to first passage of flatus and stool from the rectum following abdominal surgery (Cheatham et al., 1995; Sagar et al., 1992). Subjects in both the control (standard of care) and intervention (rocking motion) treatment groups of this dissertation study had nasogastric intubation during and after their surgeries due to preferences among the surgeons involved. However, since subjects were randomly assigned to the two groups, the effects of intraoperative nasogastric intubation upon symptoms and duration of POI were minimized, as were effects on internal validity (Campbell & Stanley, 1963; Huck & Cormier, 1996).

The most commonly used current standard of care intervention specific to the postoperative patient is the doctor's order to be out of bed ambulating and sitting in a chair beginning on the first postoperative day. However, research findings do not support a relationship between the time spent ambulating and sitting in a chair and the resolution of POI (Barnes et al., 1997; Brieger, 1983; Waldhausen & Schirmer, 1990; Waldhausen, et al., 1990), thus making continued research into the effectiveness of such interventions an important goal.

One non-invasive intervention that does show promise in resolving POI is a rocking motion that is hypothesized to induce a Relaxation Response (Benson, 1975) that Moore et al. (1995) and Thomas et al. (1990) suggest serves as a moderator of the surgical stress response and mediates the gas and distention effects of POI. Findings from the Thomas et al. study describe rocking mothers as more relaxed and less anxious about

the psychological and physical aspects of their cesarean birth and seemed to relate to their infants in a more relaxed manner compared to non-rocking mother. Treatment protocols that emerged from these clinical observations and research findings suggest that rocking in ten to 20 minute increments for at least 60 minutes per day can reduce the gas pain scores among rocking patients, promote earlier ambulation and expulsion of gas, and facilitate discharge from the hospital an average of one day earlier than the non-rocking patients. Moore et al. found similar results when they conducted a rocking chair intervention study with abdominal hysterectomy patients. Both the Thomas and Moore teams of researchers hypothesized that the gentle, rhythmic, repetitive motion of rocking stimulated the vestibular nerves in their subjects that resulted in pleasant signals being sent to the Reticular Activating System (RAS) to modulate the neuroendocrine stress response.

Several studies found in the literature further support the hypotheses and theoretical explanations of findings put forth the by the Thomas and Moore teams. Malcuit, Pomerleau and Brossou (1998) demonstrated cardiac deceleration and motor quieting in three month-old infants in response to the gentle motion of being rocked in a rocking chair. Linear movements, such as the back and forth motion of rocking in a rocking chair, were believed to have a calming effect on young irritable infants by inhibiting the RAS via vestibular stimulation (Bonndonna, 1981; Clark, Cordero, Goss & Goss, 1989; Di Gangi, 1991; Korner & Thoman, 1972; Vrugt & Pederson, 1973).

Watson, Wells & Cox, (1998) found that rocking affects psychosocial well-being and balance through stimulation of the vestibular-proprioception system. These researchers used a crossover design to study 25 demented elderly patients over a sixweek period, during which the subjects rocked an average of 101 minutes per day, five days per week, for six weeks. A non-rocking comparison group of subjects sat in nonrocking chairs for at least 60 minutes per day for six weeks. Although there were only small positive changes in scores on psychosocial well-being and balance measures in the rocking group, researchers found significant reductions in anxiety scores in the rocking when compared to the scores in the non-rocking group. A unique secondary effect was a decrease in non-scheduled intermittent pain medication doses delivered, suggesting that rocking may be a non-pharmacologic intervention to reduce pain in this study's sample. Similar findings from studies by other researchers support the hypothesis that the release of endorphins associated with prolonged rhythmic exercise, such as rocking and walking, may effectively reduce pain (Bautch, Malone & Vailas, 1997; McCaffery, 2002; Thomas, Lee, Franks & Paffenbarger, 1981; Thoren, Flora, Hoffman & Seals, 1990).

Throughout a growing body of literature, activities such as rocking are identified as stimuli that induce relaxation by moderating and mediating various stress response mechanisms and initiating what is described as the Relaxation Response (Benson, 1975; Benson, 1985; Benson, 1996). As previously discussed, rocking has been found by several researchers to offset the negative effects of stress, illness, and surgery (De Marco-Sinatra, 2000; Houston, 1993; Moore et al., 1995; Snyder et al., 2001; Roberts & Fitzpatrick, 1983; Talmadge, 1996; Thomas et al., 1990; Watson et al., 1998) and contribute to the resolution of POI. Previous studies (Thomas et al., 1990) used rocking in combination with medications as an intervention. This dissertation study evaluated the effects of rocking chair motion as the only intervention in order to reduce clouding of results due to covariation from other interventions.

The phenomenon of POI and its resolution need to be studied from a nursing perspective to promote quality care, theory-guided practice, and healing among

postoperative abdominal surgery patients. The primary delay in the convalescence after abdominal surgery is the slow return of normal gastrointestinal function ending in prolonged hospital stays (Koller et al., 2004). Cost-effective and efficient care strategies need to be tested for their outcomes and contributions to well-being and healing. Testing the effects of rocking as an intervention in stress-induced POI was the primary aim of the research reported in this study.

The increasing interest in prevention and early treatment of POI is not only related to patient comfort and goals to hold down the costs of health care. The absence or resolution of POI in abdominal surgery patients is a primary consideration in determining the time for discharge of the patient, suggesting that interventions and clinical standards of postoperative care must change based on findings of evidence-based research. Koller et al. (2004) performed a systematic review of POI literature and reported that there are multiple treatment strategies that have been investigated for their potential to shorten the duration of POI. While more data are needed to refute and support the various interventions currently available for clinical use, those that appear more frequently in the literature are related to the use of epidural and local anesthetics rather than general anesthesia, homeopathy, relaxation, and multi-modal interventions such as sham feeding, early feeding, early ambulation (Barnes et al., 1997; Holte & Kehlet, 2002; Jorgansen, Wettersley, Moiniche & Dahl, 2001; Kehlet & Holte, 2001) to address the duration and effects of POI. Nevertheless there remain gaps in the literature regarding research studies that test non-invasive POI interventions. A need exists to assess old, longstanding interventions as well as newer clinical approaches to POI prevention and treatment.

### 2.4 Assessing and Evaluating POI

One significant milestone that is celebrated among postoperative abdominal surgery patients and their care providers is the return of gastrointestinal motility following POI. However, after more than a century of concern about the absence and return of this important functional phenomenon, there is still confusion and disagreements about the standard to use to definitively conclude that POI is resolved.

Return of bowel sounds has been a longstanding indicator of the return of bowel function in the postoperative abdominal surgical patient. Nevertheless, some researchers argue that the absence of abdominal distention, nausea and vomiting must also accompany the presence of bowel sounds as an endpoint for resolution of POI (Davis et al., 2002). Other researchers and clinicians argue that recordings from implanted barostatic and monometry instruments confirm that bowel function never fully ceases after abdominal surgery, thereby introducing further doubt into the use of the presence of bowel sounds as an endpoint of POI (Davis et al., 2002; Luckey et al., 2003; Waldhausen et al., 1990).

Standard clinical practice protocols recommend the daily auscultation of the abdomen for a minimum of five minutes in each of four quadrants to determine the return of bowel sounds (Prasad & Matthews, 1999). Waldhausen et al. (1990) and Huge et al. (2000) found that some patients with normal, active postoperative bowel sounds also reported experiencing abdominal distention, pain, nausea and vomiting. Although there are no hard and fast agreements about POI symptomatology, the medical community continues to use the passage of flatus from the rectum as the practice standard that determines the return of gastrointestinal function in the postoperative patient (LeBlanc-Louvry et al., 2002; Luckey et al., 2003; Miedema & Johnson, 2003; Prasad & Matthews,

1999; Schuster & Montie, 2002; Shaheen, 2002). This practice standard became the operational definition for the resolution of POI used in this study.

While the return of bowel sounds has been a longstanding indicator of the return of bowel function in the postoperative surgical patient recovering from abdominal surgery (Holte & Kehlet, 2000; Prasad & Matthews, 1999), controversies about the reliability of this indicator remain. Because bowel sounds are generated in multiple segments of the small and large bowel, sounds heard during auscultation of the abdomen cannot be assumed to represent full and functional peristalsis. Just as controversial is the use of the passage of stool from the rectum as an indicator of bowel functioning in postoperative patients. It has been argued that this milestone merely indicates that the lower bowel has emptied (Davis et al., 2002).

Waldhausen et al. (1990) failed to find any positive correlations between the passage of flatus, bowel sounds and actual propulsive bowel movements, thereby lending even more doubt to the questionable reliability of bowel sounds as indicators of bowel functioning. However, other researchers have posited that the absence of abdominal distention and vomiting must accompany bowel sounds to be considered a reliable indicator of the resolution of POI (Davis et al., 2002). In fact, Davis and associates used the absence of both abdominal distention and vomiting and the return of bowel sounds as their endpoint for POI in their study of 31 postoperative retroperitoneal node dissection patients.

In their landmark study, Waldhausen and Schirmer, (1990) evaluated if early ambulation hastened the return of bowel function following laparotomy in 35 patients; ten of whom were randomly assigned to an ambulatory regimen beginning on the first postoperative day and 25 controls that began ambulating on the fourth postoperative day. All patients underwent implantation of seromuscular bipolar recording electrodes on their stomachs, jejunums, and colons at the time of their abdominal surgeries. Recordings of myoelectric activity were performed on fasting patients, on postoperative days one through five, then again on every other day until discharge. Results showed that continuous electrical activity was observed as early as twenty-four hours after surgery in the stomach, within the first twelve hours in the small intestine and within forty-eight hours in the colon. While the electrical activity in the digestive system was disorganized after abdominal surgery, recordings revealed that the origin of bowel sounds randomly emanated from both the small and large bowel. Together these findings suggest that bowel functioning may not completely cease during surgery and the postoperative period, but instead the sounds of bowel functioning may be muffled and unable to be heard by a clinician using a stethoscope to ascultate bowel sounds. The researchers conducting this study also concluded that walking was not an effective method to reduce the time until return of bowel function but was recommended to prevent the side effects of prolonged bedrest after abdominal surgery.

The findings of the Waldhausen and Schirmer, (1990) study have stimulated additional investigations that challenge the traditional use of bowel sounds to indicate the resolution of POI. Huge et al. (2000) evaluated postoperative colonic activity and tone among nineteen patients using barostat and monometry recordings after left colonic surgery. Recordings were made intraoperative and twice daily from the first through the third postoperative day. In this study group, POI was found to occur first in the small intestine, then the stomach and lastly in the colon. The majority of patients showed no relationships between propagated contractions of the colon and flatus or defecation. Despite these findings, it is interesting to note that bowel sounds were present in two-

thirds of the patients on postoperative day one and in all patients on postoperative day three. All subjects in the study group had a first postoperative flatus or bowel movement on day three except for one patient who had this occurrence on day four. The findings of this study add more evidence to support the questioning of bowel sounds as a reliable indicator of bowel functioning.

One recent evidenced-based study completed by nurses evaluated the best indicators of returning gastrointestinal motility in patients who had undergone abdominal surgery (Madsen et al., 2005). The aim of the study was to determine if bowel sounds were reliable indicators to use to determine resolution of POI. The team completed an extensive search of the literature then selected, reviewed, critiqued and synthesized the evidence available. The literature did not provide them with definitive support for the use of bowel sounds, so the investigators turned to the practitioners. Questionnaires were sent to general nurses, specialist nurses, advance practice nurses and physicians requesting that they describe the criteria they use to determine the resolution of POI. Nurses responded that the most useful indicators of failure to resolve POI were vomiting, distention, pain, wound drainage and firmness of the abdomen. Physicians responded that return of flatus (89%) was the primary indicator of returning bowel functioning, followed by having a bowel movement (44%) and feeling hungry (44%).

A majority (78%) of the surgeons in the Madsen et al. (2005) study responded that the monitoring of bowel sounds by nurses was not helpful to them in planning patient management. The five nursing assessments most valued by surgeons included noting the return of flatus (78%), bowel movement (67%), distention (44%), nausea (44%), and vomiting (44%). Return of flatus and passage of stool were positive indicators of recovery from POI and distention, nausea and vomiting were considered negative indicators or signals that the patient had not yet recovered from POI. As a result of this study, the nurses who participated changed their practices away from the traditional listening to and assessing bowel sounds in each of four quadrants of the abdomen for a minimum of five minutes and toward assessing the two indicators that include the passage of flatus and passage of stool. They also changed their practices by establishing that the three negative indicators of nausea, vomiting and abdominal distention would serve to validate that POI remained an active problem for the patient. This evidence-based change in practice is still being studied and evaluated.

Despite a variety of treatments used in an attempt to resolve POI, most studies used small sample sizes, were retrospective, and had a variety of endpoints that made drawing conclusions and making comparisons difficult (Behm & Stollman, 2003). However, time to passage of flatus or stool appears to be the most often cited as endpoints. Thomas et al. (1990) used the expulsion of gas as an endpoint in a study of post cesarean section patients (N = 290) comparing rocking, diet modifications and antiflatulent medications. Moore et al. (1995) evaluated length of time until passage of flatus and the first postoperative bowel movement as endpoints in an unpublished study of 34 patients undergoing abdominal hysterectomy.

Holte and Kehlet (2000) reported difficulties with using the passage of flatus and stool as evidence that POI has reached its endpoint or has been resolved. They purport that the passage of flatus is highly subjective and based on subjects' self-report, while the passage of stool may indicate that only the distal bowel has emptied. These authors concluded that the occurrence of one phenomenon alone cannot adequately provide evidence that complete gastrointestinal tract functioning has returned. Rather, they believe that the most accurate measure of POI resolution is the combined return of normal food intake and bowel function in the patient.

A study by Yukoikab, Bogod and Rosen, (1987) refuted Holte and Kehlet's (2000) conclusions and demonstrated the accuracy of patients subjective self-report of the time of first flatus is passed while recovering from the effects of sedative medications after surgery. Yukoikab, Bogod, and Rosen also reported that time to first flatus was an indicator of resolution of POI indicating comprehensive return of gastrointestinal motility throughout the digestive system. A small amount of carbon dioxide is expelled when patients pass flatus from the rectum. Yukoikab, Bogod and Rosen compared the time to first flatus reported by the patient and simultaneously measured amounts of carbon dioxide released with the first flatus recorded by a carbon dioxide analyzer in 20 patients aged 60 years and older. In sixteen of the 20 patients (80%), the two observed times (patient report of first flatus and recorded first flatus carbon dioxide recording) coincided and there were no false reports. Two of the four patients fell asleep and did not report TTFF and two others the sampling tube attached just outside the rectum became obstructed yielding no carbon dioxide recordings. Analysis revealed close correlations between the time to first flatus as estimated by both methods (r = 0.999, p < 0.001). Disbrow, Bennett and Owings, (1993) studied the effects of instruction on postoperative gastrointestinal motility and successfully used the self-report of TTFF as described by Yukioka et al., (1987) as their outcome variable indicating resolution of POI. Both of these studies provided guidance in this dissertation for determining the method to use for recording the primary outcome indicator, TTFF.

POI endpoints found by Shaheen (2002) in his review of studies of treatments and interventions published in the Journal of Gastroenterology were most often time to

passage of first flatus, time to first bowel movement, and time to discharge as endpoints. Some unexpected findings reported by Waldhausen et al. (1990) and Huge et al. (2000) suggest that some patients with normal active bowel sounds postoperatively fail to be free of the clinical symptoms of POI, such as bloating, distention, pain, nausea and vomiting, until the actual passage of flatus and stool from the rectum.

Despite the variations in findings across the reported research studies discussed in this chapter, clinicians and researchers alike agree that the standard measure of the resolution of POI must be the actual passage of flatus from the rectum (Huge et al., 2000; LeBlanc-Louvry et al., 2002; Luckey et al., 2003; Miedema & Johnson, 2003; Prasad and Matthews, 1999, Schuster & Montie, 2002; Shaheen, 2002). Based on this agreement, the outcome measure of POI resolution used in this study was passage of flatus from the rectum.

### 2.5 THEORETICAL FRAMEWORK FOR THE STUDY

Benson's Relaxation Response Theory (1975) provided the theoretical framework for this study of the effects of (rocking motion) on POI experienced by abdominal surgery cancer patients. The relaxation response is a set of physiologic changes that moderate the effects of stress and mediate the effects of increased sympathetic nervous system activity. The relaxation response facilitates physiologic changes by reducing sympathetic activity that is stimulated by stress and allowing an increase in parasympathetic nervous system activity that may support the expression of acquired coping behaviors (Houston, 1993). The relaxation response is also an inducible, physiological state of quietude, leading to the ability to "heal and rejuvenate" our bodies (Benson, 1975, p. 9). It serves as a natural method to counteract increases in sympathetic nervous system activity and associated stress. The relaxation response is a powerful and evidenced-based nontraditional complementary and alternative intervention that can elicit very powerful healing resources within each of us.

To fully understand Benson's (1975) theoretical propositions about relaxation and the roles that relaxation-inducing interventions can have as mediators of stress, it is necessary to review human responses to stressful stimuli. Cannon (1914) proposed that mammals have the ability to react to stress by way of the "flight or fight" survival mechanism. That is, when faced with a stressor, humans enter into either a fight or flight mode. If the fight mode is initiated, the person mobilizes internal physiological and psychological activities to confront the stressor. The flight mode is a set of physiologic and psychological activities that are mobilized to distance one from the stressor. Either one can be used separately or they can be used together. Both involve activation of the sympathetic and parasympathetic components of the autonomic nervous system.

In another view of stress and human responses to stress, Selye (1976) suggests that it is an unavoidable environmental stimulus that precipitates a coordinated response in an individual. The coordinated response, called the General Adaptation Syndrome (GAS), mobilizes physiologic forces against the stressor by activating the sympathetic nervous system. The effect a stressor has on an individual depends on certain mediating factors such as general state of health, prior exposure to stress, personality and how the person perceives the stress.

Even though the exact physiological responses to relaxation-inducing stimuli such as rocking motions are not completely understood, it is hypothesized that the gentle, rhythmic, repetitive motion of rocking stimulates the vestibular nerves to send signals of pleasure and alertness to the Reticular Activating System (RAS), the body's "flight or fight" response center (Guyton & Hall, 1997; Moore et al., 1995). Inhibition of sympathetic responses and stimulation of para-sympathetic responses triggered by the relaxation response that results from rocking was a guiding principle for this study and set the stage for the development of relevant aims and hypotheses.

#### 2.6 FIT OF BENSON'S THEORETICAL FRAMEWORK AND STUDY AIMS

Surgical patients frequently have an altered general state of physical and psychological health that results from the disease process or trauma that establishes the need for surgical intervention, past surgical experiences, and altered coping abilities (Desborough, 2000; Kehlet, 1997). In addition to the stressful conditions mentioned above, the stress response to the actual surgery (Desborough, 2000) and the effects of interventions that lower or mediate this stress response continue to be of interest to scientists and practitioners (Holte & Kehlet, 2002; Kehlet, 1997; Kehlet & Holte 2001).

The stress response to surgery is characterized by a multimodal response that includes increased secretion of pituitary hormones and activation of the sympathetic nervous system (Desborough & Hall, 1993; Holte & Kehlet, 2002). Hypothalamic activation of the sympathetic nervous system results in increased secretion of catecholamines from the renal medulla and release of norepinephrine for presynaptic nerve terminals. The increased sympathetic activity results in alterations in function of certain visceral organs that have long been understood as part of the flight or fight response and the GAS (Cannon, 1914; Desborough, 2000; Selye, 1976, 1978). Although these collective responses have evolved to operate as an advantage for survival, if they are prolonged or amplified they can erode body cell mass and physiologic reserve capacity (Kehlet, 1997). Organs that function primarily because of stimulation by the parasympathetic nervous system, such as the gastrointestinal track, are inhibited by the increased sympathetic activity during stress. It is the prolonged, increased and combined

sympathetic stress-induced activity that is thought to influence the intensity and duration of POI in abdominal surgery cancer patients.

Interest in the use of alternative and complimentary therapies to reduce the sympathetic response of surgical and non-surgical stress has grown since the 1970s (Good, 1996; Houston, 1993; Le Blanc-Louvry et al., 2002). Benson's (1975) Relaxation Response Theory helped to promote traditional western medicine to begin thinking outside of the box and seriously begin to consider and evaluate alternative and complimentary therapies. That is, Benson formulated a four-component guideline for inducing a relaxation response in human subjects. The four components are: (1) a quiet environment, (2) a mental device, (3) a passive attitude, and (4) a comfortable position. Benson purported that the relaxation response could easily be evoked by any number of techniques that are recognized as alternative and complementary to medicine. Examples of techniques he recommended are yoga, walking, swimming, knitting or rowing and rocking in a rocking chair (Benson, 1975, 1979, 1985 & 1996). In on-going research efforts to further develop and refine his theory, Benson (1975, 1985, & 1996) later discovered that only two of the four components he originally proposed were necessary to evoke a relaxation response. The mental device and passive attitude are considered the two most important and effective activities and those techniques continue to be used today.

The mental device involves focusing on a sound, word, phrase, prayer repeated silently or aloud, or a fixed gaze on an object. Passive attitude involves not worrying about how well one is performing the technique and simply putting aside any distracting thoughts in order to retain one's focus. Therefore, a person could be performing any physical activity in any environment and still elicit the relaxation response if they can maintain a mental focus and are able to return to his or her focus when distracting thoughts interfere. Benson's guidelines make it clear that relaxation can be induced without sophisticated equipment, invasive interventions, drugs, or any other substantive object. In cases where the reduction of surgical stress through the use of relaxation is desired, there is room for investigators to test interventions that are sometimes called alterative and complementary therapies. Examples of such investigations are presented later in this section.

Alternative and complementary therapies that include relaxation techniques are stress management strategies that elicit what Benson (1975, 1979) calls the relaxation response. Rocking motion and other hypothesized mediators of stress can and do affect the surgical stress response, the GAS response, sympathetic activity, and gastric motility (Kehlet, 1997; Kehlet & Holte, 2001). While use of alternative and complementary therapies in the United States have grown in popularity over the past decade (Good, 1996; Houston, 1993; Le Blanc-Louvry et al., 2002; Tracy et al., 2006), most techniques require considerable training and cooperation from patients that may be unrealistic in the postoperative setting. Even so, alternative and complementary interventions that mediate responses to surgical stress continue to be of interest to scientists, including the principal investigator of this study.

An example of alternative nursing interventions aimed at POI resolution was carried out in a randomized study of 130 patients undergoing their first elective colorectal operation (Tusek, Church, Strong, Grass & Fazio, 1997). In that study conducted by Tusek and associates (1997), one group of patients received guided imagery as an alternative intervention to the standard pre- and postoperative care typically provided for abdominal surgery patients. The aim of the Tusek et al. study was to determine if guided

imagery affected total narcotic consumption, time to first bowel movement, worst and least pain preoperatively and postoperatively, and Time to Discharge in patients undergoing abdominal surgery. Patients randomized to Group 1 (n = 65) received standard perioperative care and Group 2 (n = 65) listened to guided imagery tapes three days before surgery and listened to music during the induction of anesthesia, during surgery, and while they were in the recovery room and a guided imagery tape during the experimental group's first six days post surgery. Between groups comparisons were made using Wilcoxon rank-sum tests and within groups using Wilcoxon signed-rank test. Unfortunately, the authors did not provide the actual test estimates and mean ranks. Total narcotic consumption was significantly lower in the imagery group (Mdn = 185, Range 55 - 908) mg compared to the control (*Mdn* = 326, range 63 - 1,108) mg; Wilcoxon rank-sum (p < .001). Time to first bowel movement was significantly less in the imagery group (Mdn = 58, Range 16 – 288) hours than the control (Mdn = 92, Range 8 – 264) hours; Wilcoxon rank-sum (p < .001). Median Time to Discharge on days for the imagery group (Mdn = 6.2, Range 4 - 31) days and not significantly different (Wilcoxon rank-sum) from the control group (Mdn = 6.2, Range 4 - 31) days. Differences between worst and least pain preoperatively and postop were two key outcomes reported in the Tusek et al. (1997) article that are being evaluated in this study. Differences between worst pain preop and on Day 1 after surgery was significantly different (Mdn = 72.5) for the control compared to (Mdn = 42.5) for the imagery group Wilcoxon singed-rank (p .001). Least pain median score increases was also different between groups pre (Mdn =30.0) and postoperatively (Mdn = 12.5); Wilcoxon signed-rank (p.001). This study was designed to determine whether guided imagery in the perioperative period could improve outcomes in colorectal surgical patients. The study by Tusek et al. (1997) was beneficial

to this dissertation because it measured similar outcomes to include duration of POI, narcotic consumption, Time to Discharge and worst and least pain. Worst and least pain differences were described as ordinal data and tested using appropriate non-parametric statistics instead of interval data.

Disbrow, Bennett and Owings (1993) demonstrated the value of psychological preparation in the return of POI in patients undergoing abdominal surgery. Forty patients were randomized to a control group (n = 20) that received instructions unrelated to the return of gastrointestinal function and an intervention group (n = 20) that received specific instructions for resolving POI. Time to passage of first flatus was used as a measure of resolution of POI. One-way analysis of variance (ANOVA) demonstrated a difference between the groups. Mean time to first flatus for the POI return instruction group was 2.6 days (SD = 1.6) compared to 4.2 days (SD = 2.4). There was a significant effect of instruction on for POI return, F(1, 38) = 5.63, p < .05. Although not statistically significant F(1, 37) = .60, p > .05, an overall decrease in duration of hospital stay by 1.5 days was identified in those who received the intervention instructions; Time to Discharge for the experimental group was 6.6 days (SD = 7.2) compared to 8.1 days (SD = 5.3) for the controls. Analysis of covariance (ANCOVA) was also performed to investigate the effects of other factors on time to first flatus. These included duration of operation, amount of narcotics given postoperatively and degree of bowel manipulation. Analysis revealed only rank of intraoperative bowel manipulation and amount of postoperative narcotics were correlated with the dependent variable time to first flatus (r [39] = .58, p < .05; r [39] = .37, p = .05 respectively). This study showed that there is an association between preoperative instruction and duration of POI. To control for this potential confounder in the dissertation study, both the control and intervention groups

received the same instruction sheets without mention of the effects of either the standard of care or rocking on return of POI. This was deemed important in order to reduce instructional bias that may have otherwise affected internal validity.

Le Blanc-Louvry et al. (2002) examined the effectiveness of mechanical abdominal massage on POI in patients (N = 50) with colon cancer who underwent abdominal surgery. They hypothesized that parietal abdominal stimulation has the potential to counteract induced pain and POI through common spinal-sensitive pathways, with nociceptive visceral messages. The aim of this study was to determine if 15 minutes of mechanical abdominal massage once daily during the first seven postoperative days after colectomy was effective in reducing postoperative abdominal pain and ileus. Patients also walked twice daily beginning the second postoperative day. Twenty-five patients were randomized to receive mechanical massage and 25 patients did not receive mechanical massage. Visual analog pain scores, doses of analgesics and delay between surgery and the time to first passage of flatus were assessed.

The Le Blanc-Louvry et al study demonstrated through one-way analysis of variance a difference in pain scores on the second and third postoperative day (p < 0.001) and doses of analgesics (p < 0.05) were lower in patients receiving the mechanical massage intervention. Time to passage of first flatus was less in the active massage group ( $1.8 \pm 0.3$  days vs.  $3.6 \pm 0.4$  days, Mann-Whitney U (p < 0.001). The day of the first passage of flatus and/or stool was used to define the duration of POI. However, flatus preceded the emission of stool in all patients. Duration of POI (hours) was defined as the interval between the end of surgery and the first passage of flatus or stool through the anus. Time to discharge from the hospital did not differ between the two groups (8.1  $\pm 0.1$ ) days in the active massage and ( $7.6 \pm 0.1$ ) days in the placebo group. This study

suggests that mechanical abdominal massage may be effective in comparison to standard management for reducing the duration of POI and intensity of postoperative pain in colon cancer patients who underwent abdominal surgery. The study also demonstrated that massage was well tolerated among colon cancer patients after abdominal surgery as evidenced that none of the patients complained of acute abdominal pain during massage. This is important for this dissertation because of the concern the rocking motion may increase acute abdominal pain as a result of the contraction and relaxation of the abdomen during the rocking motion. The study demonstrated the therapeutic benefit of massage on pain and ileus duration. Nevertheless, due to high pain levels (7 to 8 on 0-10 scale) in the early postoperative period, patients received consistent doses of pain medication (6 grams) in combination with massage due to ethical reasons thereby confounding the specific effectiveness of massage on pain reduction.

A limitation of many relaxation techniques is the difficulty involved with performing them after surgery. Guided imagery requires training and a facilitator, massage requires someone knowledgeable in massage therapy, and Reiki therapy requires training. Despite the difficulties, Good, Anderson, Stanton-Hicks, Grass and Makii, (2002) evaluated (N = 311) patients using three relaxation interventions (jaw relaxation, music or combination of relaxation or music taught preoperatively) after gynecologic surgery. Good, Anderson, Ahn, Cong and Stanton-Hicks, (2005) also evaluated (N = 167) patients using three relaxation interventions (relaxation, chosen music and their combination) for pain relief following intestinal surgery. Although subjects experienced significant decreases in perceptions of pain by post hoc MANOVA (p = .022 - .001) and (p = .24 - .001) respectively, there were inconsistencies among patients' patterns of uses

of the identified interventions although they deemed to be simple techniques by the investigators.

Rocking has been used in a variety of settings as an intervention to reduce stress. It requires little effort or training to perform and typically involves only the individual who has been instructed to rock. The gentle motion of rocking or being rocked is something almost everyone has experienced and researchers have shown can stimulate a relaxation response (Houston, 1993; Moore et al., 1995; Thomas et al., 1990). Thomas et al. (1990) successfully used rocking to reduce the stress response in post cesarean section mothers. Moore et al. (1995) initiated the rocking motion in post hysterectomy patients. Each observed reductions in the duration of POI, pain medication use, and length of hospital stays in their samples. Because rocking has demonstrated promise as an intervention in the postoperative abdominal surgical patient, it was used as the study intervention with one of two comparison groups of postoperative cancer patients in this dissertation.

#### **2.7 SUMMARY**

POI is a common clinical outcome associated with abdominal surgery and is thought to occur primarily through the activation of the sympathetic nervous system. Described as a stress response to the opening of the abdomen, extensive dissection of abdominal tumors and manipulation of bowel, POI has presented challenges to many researchers, clinicians, and patients for over a century. The body's response to the stress of abdominal surgery has been likened to the fight or flight (Cannon, 1914) response and the GAS described by Selye (1976).

Methods to reduce the sympathetic response of surgical and non-surgical stress responses have received frequent attention in the literature since the 1970's. In addition to conventional treatments, alternative and complementary therapies that include relaxation techniques to reduce stress have joined the scientific and clinical communities as viable interventions to measure and evaluate (Benson, 1975, 1979). While there is a growing body of nursing literature that examines the effects of interventions such as guided imagery and massage, more nursing studies are needed to provide evidence for the use of relaxation techniques in everyday practice. The next Chapter presents the methods used to address the aims and hypotheses put forth in this study.

# **CHAPTER III: METHODOLOGY**

This chapter addresses the research design and methods employed to achieve the aims and test the hypotheses put forth by this investigator. Included in the discussion of design and methods are operational definitions of variables, descriptions of sampling and group assignments, details about instrument performance, instructions given to enrolled subjects, staff training protocols, and the types of statistical tests that were run to address the hypotheses. Findings will be presented and discussed in Chapters 4 and 5.

## **3.1 OVERALL AIM AND RESEARCH DESIGN**

The overall aim of this study was to examine differences in the duration of POI symptoms [postoperative time to passage of first flatus the from rectum], subjective reports of type, duration, intensity and interference of postoperative abdominal pain [Brief Pain Inventory – Short Form (BPI-SF)], pain medication received [in milligrams per 24 hours], and postoperative patient recovery time [time to discharge] between two groups of patients recovering from surgery performed to remove cancerous gastrointestinal tumors.

The experimental design used in this study was Campbell and Stanley's (1963) post-test only control group design with random assignment of subjects into treatment groups. In this study there were two treatment groups. The control group received standard postoperative care that included ambulation and sitting up out of bed beginning the first postoperative day and the experimental group received the rocking chair intervention that included motion in addition to the standard postoperative protocols. According to Campbell and Stanley (1963) and others (Huck & Cormier, 1996; Whittemore & Grey, 2006), the essential elements of research experiments are

randomization, control, and manipulation. These important properties permit the researcher to control for biases and to probabilistically estimate the effects of interventions or treatments at specified levels of confidence (Huck & Cormier, 1996). They also provide a basis for anticipating similar results upon subsequent replication of the study. While true experiments are often difficult to conduct in real life patient care settings where professional nursing is practiced (Maas, Buckwalter, Reed & Pringle-Specht, 1998), alternative experimental designs that resemble true experiments and employ rigorous controls over threats to internal and external validity are feasible and necessary to conduct if evidence-based nursing practice is to prevail.

The posttest-only control group design is composed of two groups randomly (R) assigned to a control (O1) and experimental group (O2) involving a single independent variable (X) manipulated by the researcher introduced only to the experimental group; however, neither group is pretested or measured as in classic experimental designs (Huck & Cormier, 1996; Whittemore & Grey, 2006). This design does not assure that the experimental and control groups are equal before differential experimental treatment due to the lack of pretest measurements. Nonetheless, the most adequate all-purpose assurance of lack of initial biases between the groups is randomization and within the limits of confidence stated by tests of significance, randomization can suffice without pretest (Campbell & Stanley, 1963, p. 25), especially in studies where the pretests in the ordinary sense are not plausible.

According to Campbell and Stanley (1963, p. 8), the posttest-only control group design accounts for the same eight threats (history, maturation, testing, instrumentation, regression, selection bias, mortality and selection-maturation interaction) to internal validity as the true experimental pretest-posttest control group design. The posttest only

control group design also accounts for the three threats (interaction of testing and X but is questionable in controlling interaction of selection and X, and reactive arrangements) to external validity. This design allows for statistical testing through use of the *t*-test, analysis of variance (ANOVA) and covariate analysis (ANCOVA) and blocking on subject variables such as pre- and postoperative pain location and type and intensity and interference, in order to increase power of the significance tests similar to pretest effects (Campbell & Stanley, 1963). However, as with all experimental designs, internal validity is a basic minimum requirement for a study to be considered acceptable (Campbell & Stanley, 1963, Pedhazur & Schmelkin, 1991). Only after the minimum requirements of internal validity are met can there be speculation about a study's external validity or its generalizability.

The post-test only experiment conducted by this investigator used randomization of subjects into control and treatment groups and the manipulation of specified variables by the designated interventions to meet two of the three criteria required of experiments. The control features used in this study included: (1) when interventions were delivered, (2) when observations were made, and (3) which of the treatment groups under study received the specific interventions under examination (Campbell & Stanley, 1963; Huck, Cormier & Bounds, 1974; Huck & Cormier, 1996). Although this study was designed as a post-test only experiment, it was necessary to pre-test existing pain using the BPI-SF (Cleeland, 1989; Cleeland, 1997) on the dimensions of location, intensity and interference because of its potential to co-vary with and confound the assessment of postoperative pain in both groups of subjects. Sources of existing preoperative abdominal pain experienced by patients with gastrointestinal cancers include tumor encroachment on abdominal organs, gas retention, and bowel obstruction.

The discussion of internal and external validity, sources of error, and the investigator's strategies employed to manage error and threats to the validity of this study are presented in table format in section 3.15 at the end of this chapter. Discussed there are specific issues related to history, maturation, testing, instrumentation, regression, differential selection, and experimental mortality and selection-maturation interactions.

## **3.2 Hypotheses and Specific Aims**

The null hypothesis (H0) tested in this study was: There are no differences in the duration of return to flatus, subjective reports of postoperative abdominal pain, total pain medication use, and postoperative recovery time among cancer patients recovering from abdominal surgery who receive the rocking intervention vs. the standard of care. Patients randomized to the rocking arm were instructed to get out of bed and begin rocking in a rocking chair and ambulating beginning the first postoperative day. Patients randomized to the nonrocking standard of care arm were instructed to get out of bed beginning the first postoperative day and sit in a nonrocking chair and ambulate beginning the first postoperative day.

The research hypotheses evaluated in this study and their related aims are presented below:

**SPECIFIC AIM 1:** To assess whether the rocking intervention reduces the mean time in days to passage of first flatus from the rectum in postoperative abdominal surgery patients compared to standard postoperative care patients.

**HYPOTHESIS 1:** There will be a difference in postoperative mean time to the passage of first flatus from the rectum between those patients who receive the rocking intervention and those who receive standard postoperative care.

**SPECIFIC AIM 2:** To assess whether mean pain intensity and interference scores could be reduced to a greater extent by rocking motion compared to standard postoperative care.

**HYPOTHESIS 2:** There will be a difference in mean postoperative subjective reports of pain intensity (worst, least, average and pain right now) and pain interference (general activity, mood, walking ability, relations with others, sleep and enjoyment of life) between those patients who receive the rocking intervention and those who receive standard postoperative care.

**SPECIFIC AIM 3:** To assess whether the rocking motion is more effective in reducing total mean pain medication milligrams received compared to standard postoperative care.

**HYPOTHESIS 3**: There will be a difference in the mean total pain medication in milligrams received between those patients who receive the rocking intervention and those who receive standard postoperative care.

**SPECIFIC AIM 4:** To assess whether mean time in days to hospital discharge is reduced by treatment with rocking motion compared to standard postoperative care.

**HYPOTHESIS 4:** There will be a difference in mean time to discharge between those patients who receive the rocking intervention and those who receive standard postoperative care.

#### **3.3 VARIABLES AND OPERATIONAL DEFINITIONS**

The variables used in this study and their operational definitions are listed and discussed below:

<u>Time to first flatus (TTFF)</u> was operationalized as the difference measured in days between the date and time noted in the electronic medical record as the end of the surgical procedure and the date and time of the subject's report that he or she passed flatus (gas) from the rectum the first time since the surgical procedure ended.

<u>Postoperative surgical site pain</u> was defined as the patient's subjective recognition and report of intense discomfort at the surgical site each morning of every postoperative day beginning with the first and ending when the subject reported the passage of first flatus from the rectum.

<u>Postoperative gas pain</u> was defined as the patient's subjective recognition and report of intense discomfort due to gas buildup within the bowel each morning of every postoperative day beginning with the first and ending when the subject reported the passage of first flatus from the rectum.

<u>Worst Pain</u> is defined as the one number that best describes the subject's most intense pain in the immediate past 24-hour period on a 0 -10 scale with 0 = no pain and 10 = pain as bad as you can imagine.

<u>Least Pain</u> is defined as the one number that best describes the subject's least intense pain in the immediate past 24-hour period on a 0 - 10 scale with 0 = no pain and 10 = pain as bad as you can imagine.

<u>Average Pain</u> is defined as the one number that best describes the subject's average pain intensity during the immediate past 24-hour period on a 0 - 10 scale with 0 = no pain and 10 = pain as bad as you can imagine.

<u>Pain Right Now</u> is defined as the one number that best describes the subject's pain intensity at the moment on a 0 - 10 scale with 0 = no pain and 10 = pain as bad as you can imagine. <u>General Activity Pain Interference</u> is defined as the one number that best describes how, during the past 24 hours, pain has interfered with the subject's general activity on a 0 - 10 scale with 0 =Does not interfere and 10 =Completely interferes.

<u>Mood Pain Interference</u> is defined as the one number that best describes how, during the past 24 hours, pain has interfered with the subject's mood on a 0 - 10 scale with 0 = Does not interfere and 10 = Completely interferes.

<u>Walking Ability Pain Interference</u> is defined as the one number that best describes how, during the past 24 hours, pain has interfered with the subject's walking ability on a 0 - 10 scale with 0 = Does not interfere and 10 = Completely interferes.

<u>Relations with other people pain interference</u> is defined as the one number that best describes how, during the past 24 hours, pain has interfered with the subject's relations with other people on a 0 - 10 scale with 0 = Does not interfere and 10 =Completely interferes.

<u>Sleep pain interference</u> is defined as the one number that best describes how, during the past 24 hours, pain has interfered with the subject's sleep on a 0 - 10 scale with 0 = Does not interfere and 10 = Completely interferes.

Enjoyment of life pain interference is defined as the one number that best describes how, during the past 24 hours, pain has interfered with the subject's enjoyment of life on a 0 - 10 scale with 0 = Does not interfere and 10 = Completely interferes.

<u>Pain Medication</u> received is the total amount of narcotic analgesia, expressed in total milligrams that the patient received for pain control in a 24-hour period, captured once each morning of every postoperative day beginning with the first and ending at the subject's report of passage of first flatus from the rectum.

<u>Time to discharge</u> was operationalized as the difference measured in days between the date and time noted in the electronic medical record that the surgical procedure ended and the electronically recorded date and time the patient was officially discharged from the hospital by doctor's order.

<u>One rock cycle</u> was operationalized as one backward and one forward motion in a rocking chair completed by the subject in one second. At one rock cycle per second, 3600 rock cycles equal sixty minutes of rocking.

<u>One pedometer measured rock cycle</u> was operationalized as one combined backward and forward motion in a rocking chair completed by a subject in one second of time. At one rock cycle per second, 3600 rock cycles equal sixty minutes of rocking. However, the pedometer counted each forward and backward motion and therefore the total number recorded by the pedometer was divided by two in order to determine the actual number of rock cycles completed.

<u>Time spent rocking</u> was operationalized as the amount of time that subjects spent rocking in a rocking chair. Time spent rocking was important to discern in this study because previous POI research did not calculate nor present the amount of time spent in the rocking chair.

<u>Time spent in the non-rocking chair</u> was operationalized as the amount of time spent sitting in a non-rocking chair. Time sitting in the non-rocking chair was important to discern in this study because previous research did not calculate nor present the amount of time spent in the non-rocking chair.

<u>Number of steps</u> was operationalized as the number of steps recorded by the pedometer worn by the subject during ambulation around the nursing unit in a twenty-four hour period.

<u>Number of laps</u> was operationalized as the number of laps around the nursing unit completed by the subject during ambulation around the nursing unit in a twenty-four hour period.

Lap Distance was operationalized as one lap around the nursing unit was equal to 56 steps or 121.6 feet.

<u>Pedometer distance ambulated</u> for the specific pedometer used in this study was operationalized as the number of steps recorded during each twenty-four hour period. One mile or (1.61 km) was defined as equivalent to1935 steps for the specific pedometer used in this study.

<u>Lap distance ambulated</u> was operationalized as the number of laps around the nursing unit completed in a twenty-four hours period times 121.6 feet.

## **3.4 INSTRUMENTS AND MEASURES**

This section describes the primary instruments used to collect data in this study and discussion of the reliability and validity of the respective tools is presented. Critique of the reliability and validity data is presented to establish the rationale for selection and use of the tools in this study.

The BPI-SF (Appendix A) is a pain assessment and quality of life measure that is widely used to examine the intensity (sensory dimension) and functional effect (reactive dimension) of pain in individuals with cancer or other diseases (Cleeland, 1997; Cleeland & Ryan, 1994; Daut & Cleeland, 1983; Zalon, 2004). The sensory component is considered to be equivalent to pain severity (worst, least, average and pain right now) and the reactive dimension measures pain's interference with function in areas (general activity, mood, walking, work, relationships with others, sleep and enjoyment with life) of daily life (Zalon, 2004). The BPI-SF was selected for use in this study because it has a

sound psychometric performance history in the cancer medical and surgical patient populations, measures the concept of pain in a manner appropriate for this study, and can be completed by subjects in less than five minutes keeping the burden for completion of the instrument to a minimum.

The BPI-SF was the tool used to measure the location, type, intensity, and duration of each subject's pain and identify each subject's estimation of the level of interference the pain imposed upon performance of daily activities. The BPI-SF was administered pre-operatively and then once each day following the reported ending of the surgical procedure until the time of each subject's report of the passage of first flatus from the rectum. The BPI-SF was the only tool administered preoperatively and again postoperatively. Given that the overall aim of this study focused on determining if the rocking and non-rocking groups differed on mean scores on worst pain and pain right now and on surgical site and gas pain intensity and interference items, it was necessary for the investigator to measure these specific items preoperatively as well as postoperatively. A preoperative BPI-SF assessment was completed on each subject in order to identify if preexisting pain location, type, intensity, duration and interference would confound postoperative pain interpretation. Establishing preoperative pain intensity and interference levels for each subject was one strategy used to reduce and control error. All subjects in this study completed the BPI-SF every morning beginning the first postoperative day until the passage of first flatus from the rectum.

In this study, the intensity or sensory dimension scores for the subjects allowed for the determination of the extent of pain relief, pain quality, and the subject's perception of the causes or sources of pain. These data were important to the examination of the effects of rocking motion on experiences with and perceptions of pain that may be related to POI in subjects in both intervention groups. That is, it was important in this study to know the subject's perceptions about sources and types of pain in order to distinguish between postoperative pain at the surgical site and pain believed to be related to gas retention and bloating associated with POI. The BPI-SF inquires about the location of pain. However, it does not specifically distinguish the specific type of pain the patient is reporting. Distinguishing whether the patient was experiencing surgical site and gas pain from POI was deemed vital because a major patient complaint after abdominal surgery is the gas pain they experience until resolution of POI.

Previous studies identified and measured specific gas pain associated with the bowel distention caused by POI (Moore et al., 1995; Thomas et al., 1990). Patients who incur surgical incisions also have pain associated with the wound healing response at the surgical site. The rocking intervention has been implicated in previous research to mitigate the gas pain associated with POI through proposed relaxation induced by the rocking motion (Moore et al., 1995; Thomas et al., 1990). Therefore, in order to distinguish between the two types of pain, operational definitions of surgical site pain and gas pain were provided to each subject in order to assure consistency of subject responses in order to enhance reliability and validity.

The quality of life (pain interference) subscale of the BPI-SF allowed for determination of the effects of surgical or gas pain on the subject's functional abilities by assessing interference of pain in a patient's life (reactive dimension) with general activity, mood, walking activity, work, relations with others, sleep and enjoyment of life. The three key elements of pain interference for this study were determined to be general activity, walking ability and sleep. Pain interference with general activity occurs whenever the patient is attempting to get out of bed to and from the rocking and nonrocking chairs. A condition of this study was the ability to be able to get out of bed beginning the first postoperative day and sit in either the rocking or non-rocking chair. It was important to discern whether pain was interfering with this vital postoperative recovery intervention and standard of care activity.

The literature reveals no evidence whether pain interference with general activity affects the frequency of time spent in the chairs. Interference with walking was important to measure in order to assess the effects pain may have on the postoperative abdominal surgical patient's ability to ambulate. Ambulation is a vital component of both the standard of care after surgery and the rocking intervention. Pain interference with sleep was also considered an important measure because sleep has been identified as an important factor affecting wound healing (BaHamman, 2006; Lower & Bonsack, 2003; Nadolski, 2005). Rocking is proposed to induce a relaxation response that may mitigate the amount of pain experienced by subjects in this study. Comparing pain interference with sleep was therefore measured in this study preoperatively and daily until time to first flatus.

The BPI-SF instrument includes a pain location diagram, 10-point rating scales, checklists, and open-ended questions. After obtaining informed consent and basic demographic information at the time of admission prior to surgery, the investigator asked each subject to indicate whether he or she was having pain at the time, other than a headache, sprain or toothache. If yes, the subject was asked to identify the location of the pain on the pain location diagram of the body by placing an "X" on the area that hurt the most. Following this question, a 10-point pain rating scale is presented to ascertain the subject's perception of the pain intensity. The rating scale is anchored by the terms "no pain" and "pain as bad as you can imagine" and aimed to learn about the worst, least and

average pain the patient has experienced during the past 24 hours and how much pain he or she was presently having right now.

An open-ended question follows the pain rating scale. It asks the subject to describe the medications and treatments he or she is currently taking to relieve pain. Next, a rating scale anchored by the terms "no relief" and "complete relief" using percentages from 0% - 100% allows the subject to quantify his or her perception of how effective the medication or treatment is regarding relief of pain. Subjective quantification of pain relief effectiveness was important to this study because a hypothesized outcome of the rocking motion intervention was that pain medication use between the rocking motion and standard of care intervention groups would differ because of the effects of rocking.

The final component of the BPI-SF asks the subject to describe how pain in the last 24 hours has interfered with his or her general activity, mood, walking ability, normal work, relations with others, sleep and enjoyment of life. A 10-point rating scale anchored by the terms "does not interfere" to "completely interferes" describes choices subjects can make regarding their interpretations of the amount of interference the pain imposes on their desired quality of life.

Concerns this investigator had about using the BPI-SF both pre- and postoperatively were related to recall. That is, the actual accurate ability to recall specifically the item one is measuring. To address these concerns, pilot assessments of worst pain were conducted. Findings revealed that patients reported a much more vivid recollection of the worst pain compared to the least pain and average pain. Patients complained it was difficult to remember the least and average pain levels they were experiencing but they could readily recall the worst pain they had experienced. This was also found to be true while conducting the full study.

Without a set algorithm for scoring the BPI-SF, the investigator made the following decisions based on the pilot and study data discussed above. The mean score of three items (general activity, walking ability and sleep) related to interference with daily life was used as a pain interference score in this study. For pain interference, the primary pain focus was the interference of pain with general activity, walking ability and sleep. Scores for the questions regarding "worst", "least", "average" pain in the last 24 hours and "pain right now" were used to identify pain severity. Pain intensity was formed by mean scores on items assessing the "worst" pain and "pain right now." It was also decided that the assessment of "pain right now" was the most accurate measure of the actual level of pain the patient was experiencing each morning when he or she was interviewed by the investigator. In response to the investigator's question about level of "pain right now," patients described the level of pain in relationship to the location of the pain, i.e. gas pain and surgical site pain. The decisions to focus on "worst pain" and "pain right now" were vital to this investigator's ability to accurately assess the effectiveness of the rocking intervention on gas and surgical site pain.

The BPI-SF has demonstrated strong reliability and validity when used in multiple cancer populations to measure different types of pain including chronic nonmalignant pain, medical and surgical pain (Tan, Jensen, Thornby & Shanti, 2004; Tittle, McMillan & Hagan, 2003; Zalon, 1999). Psychometric performance standards suggest that a Cronbach  $\alpha$  of greater or equal to .70 reflects acceptable internal consistency for scale validation for research purposes and Cronbach  $\alpha$  greater or equal to .80 is considered an adequate measure to compare groups (Nunnally & Bernstein, 1994).

According to these standards and reports of psychometric performance of the BPI-SF when used in populations similar to this study, this investigator concluded that this tool was appropriate for assessing pain in the abdominal surgery cancer patient.

In addition to being used to measure specific types of pain in postoperative cancer patients, the psychometric properties of the BPI-SF have also been evaluated during its use in studies that aimed to understand the experience of pain among patients undergoing medical treatments for cancer. Tittle et al. (2003) examined the psychometric characteristics of the BPI-SF for surgical patients with cancer (N = 388) comparing the validity and reliability results between surgical (n = 159) and medical (n = 229) patients with cancer in a descriptive correlational study conducted in two veterans hospitals. A variety of cancer diagnoses were reported in the study including 35 (22%) patients with colorectal cancer who underwent abdominal surgery as a treatment intervention. The BPI-SF was administered to patients once and a Visual Analog Scale (VAS) pain scale three times to both medical and surgical patients. The main research variables were pain at its worst and least, current pain intensity (pain right now), average pain intensity and pain relief. Means for both groups were similar for items on the BPI-SF. Cronbach's alpha was used to examine the reliability of the BPI in medical and surgical patients with cancer. Validity was estimated using Pearson correlation coefficients between tools and items. Correlations between the VAS and pain interference subscales of the BPI-SF were equally high for medical (r = 0.70, p < 0.01) and surgical (r = 0.73, p < 0.01) patients. Reliability evaluated by coefficient alpha was very robust for the medical (r = 0.95) and surgical (r = 0.97) groups without the work item. Correlations between the VAS pain intensity and pain interference scales of the BPI-SF were similar except the walking ability item was significantly higher for surgical patients (r = 0.70, p < .01) than medical patients (r = 0.60, p < 0.01). Small slightly higher differences (p < 0.01) were noted in general activity, mood, relationships, sleep and enjoyment with life for surgical patients.

The Tittle et al. (2003) study found that the BPI-SF is sensitive to the effects of different pain intensity levels on interference and can be useful in determining the amount of interference that pain from gas retention in POI may have on these same items. However, it is important to note that Tittle and associates eliminated the BPI-SF item that asks about the pain's interference with work because it was deemed inappropriate for hospitalized patients. Tittle et al. also found that the BPI-SF, originally developed for use with medical oncology patients, is reliable and valid for use with surgical patients when the work item is eliminated. The interference items measured by the BPI-SF are mood, walking, physical activity, work, social activity, relations with others and sleep. The Cronbach alpha reported by Tittle et al. for the BPI-SF Pain Interference Subscale, minus the work interference item, used with medical patients was (0.95). It was (0.97) for the surgical patient cohort. Therefore, it was decided that this dissertation study would use the modified BPI-SF, without the work interference subscale, to measure pain interference in both the rocking intervention and nonrocking standard of postoperative care groups. An interesting note is that single item Visual Analog Scales used by Tittle et al. (2003), are ordinal level measures and correlations with the BPI-SF with any other interval or ordinal variable should have used Spearman's rho  $(r_s)$  and not Pearson' r and the results would likely not have been as robust (Field, 2005). Coefficient alpha requires interval data and both the VAS and BPI-SF are ordinal.

Cleeland (1997) examined the test-retest reliability of pain rating items on the BPI-SF at one and seven days with 22 patients from a subject pool of 1200 that had primary cancer sites of breast, colon-rectal and gynecologic. Correlations of r = 0.93,

0.78 and 0.59 were considered satisfactory. However, a second sample of 56 patients with breast, colon-rectal and gynecologic cancers re-tested on the same items at a mean 91.5 days after the first measure produced less favorable correlations of r = 0.34, 0.24 and 0.22 respectively for the same items. Also found were relatively high percentages of agreement between responses to questions about initial pain (76%), worst pain ever (81%) and pain in last month (67%) and reports of total increases in use of pain medication. For the most part and for purposes of this study, the BPI-SF appears to be satisfactorily reliable over short durations of time.

Recently, the BPI-SF was found to be valid for use with patients who experience chronic non-malignant pain as a primary problem. Tan et al. (2004) examined the psychometric properties in a sample of patients (N = 440) with chronic intractable pain who were referred to a chronic pain clinic at a veterans hospital. Subjects completed the BPI-SF Intensity and Interference subscales before being seen the first time and at follow-up appointments. Acceptable internal consistency was determined by a Cronbach  $\alpha$  coefficient of .85 for the intensity items and .88 for the interference items. Construct validity of the BPI was evaluated through factor analysis on BPI items to determine the presence of two distinct dimensions (intensity and interference). Result identified two distinct and independent factors, supporting validity of the 2-factor structure (intensity and interference) of the BPI. Zero order correlations provided concurrent predictive validity of the 2 BPI pain scales (Pain Intensity and Interference) and indicated an association with a measure of disability that was significantly higher for BPI interference (r = 0.57) than BPI intensity (r = 0.40, t = 5.71, p < .01) and the correlation with BPI interference was not more than 0.80, providing support that the scales are related but measure two distinct dimensions. It was expected that the BPI pain intensity score would have a low correlation with pain-related disability because pain intensity and interference are viewed as two distinct dimensions. Knowing that the BPI assesses two distinct dimensions of pain intensity and interference is important for this dissertation because the gas pain associated with POI has been implicated to increased levels of pain intensity and to potentially immobilize patients through interference with activities such as ambulation and getting out of bed.

An important factor for this dissertation is the responsivity of the BPI scales to change in expected directions as a result of surgical site and gas pain experiences of subjects over time. Paired t tests were used to compare the BPI pain intensity (worst, least and average) scores across three clinic visits with the assumption that significant differences between scale scores would support responsivity of the BPI scale for detecting treatment-related change in pain over time. Paired t test values for BPI intensity (worst, least, average and pain right now) were 2.52 for visit 1 and 2 at ( p <.01); 2.83 for visit 2 and 3, (p < .01); 5.33 (p < .001) for visit 1 and 3. BPI interference (general activity), paired t test values were 3.56, (p < .001) for visit 1 and visit 2; 1.12, (p = .001)> .01) for visit 2 and 3; 5.33, (p < .001) for visit 1 and 3. Tan and associates found that the BPI was capable of measuring changes in expected directions from visit one to visit three in patients experiencing pain that was not cancer pain. This observation was important for this dissertation because pain intensity and interference were measured preoperatively and repeated measures were obtained beginning the first postoperative day until the patient passed flatus from the rectum. An interesting note is that single item BPI-SF pain intensity and interference scales are ordinal level measures and correlations with the BPI-SF with any other interval or ordinal scale should have used Spearman's rho  $(r_s)$  and not Pearson' r and the results would likely not have been as robust (Field, 2005).

Non-parametric tests (Mann-Whitney U) were also indicated versus t test for this ordinal data.

Another recent use of the BPI-SF was in a study of the effects of pain, depression, and fatigue on the older adults (60 years of age and older) return to functional status and perceptions of recovery immediately after abdominal surgery, the first three to five postoperative days, one month and three months after discharge from the hospital (Zalon, 2004). Evidence of the BPI-SF's ability to measure pain intensity and interference the first three to five days after surgery for older abdominal surgical patients was considered important to this investigator as it was presumed a significant number of subjects would have repeated measures of pain intensity and interference post surgery during the duration of POI. Pain intensity and interference data were collected by Zalon preoperatively and the first three to five days after abdominal surgery (N= 141) using the BPI-SF and Cronbach alpha reliability coefficients for the sample ranged from (0.90 – 0.95). As noted earlier, the single item BPI-SF pain intensity and interference scales are ordinal level measures and correlations with the BPI-SF with any other interval or ordinal variable should have used Spearman's rho  $(r_s)$  and not Pearson' r in this study as well. Hence, the robustness of the results are similarly questioned (Field, 2005).

Zalon's (2004) study also provides support for the reliability and validity of the BPI-SF when used among a population of older adults that undergo major abdominal surgery. The majority of the subjects in her study underwent abdominal surgery that required large incisions and extensive manipulation and dissection of the bowel. The BPI-SF means and standard deviations comparisons immediately after abdominal surgery and during the three to five days after surgery for pain decreased (M = 39.93, SD = 24.43) and (M = 20.68, SD = 20.50) indicating the BPI-SF measured expected changes in pain

over time. The study also found that 59.2% of the subjects reported preoperative pain that was usually associated with chronic co-morbid conditions. A key focus of this dissertation was to determine if the rocking group reported different *worst pain* and *right now pain* levels than the nonrocking group, specific to intensity and interference of surgical site pain and gas pain. It was decided that in the dissertation study, the identification of preoperative painful conditions would allow for differentiation of pre-existing pain from surgical pain and allow the consideration of the masking of postoperative pain by the pre-existing pain.

The BPI-SF has also withstood validity comparisons to other pain measures used with postoperative patients (Zalon, 1999). The BPI-SF, the McGill Pain Questionnaire Short Form, and two Visual Analog Scales (one for pain at rest and one for pain during movement) were administered to 155 patients at two points after surgery. Correlations among the BPI-SF, McGill Pain Questionnaire Short Form and the two visual analog scales ranged from (0.33 – 0.76), providing evidence of construct and convergent validity when used with postoperative patients. Again, parametric analyses (e. g., Pearson's *r* versus Spearman's rho ( $r_s$ ), that involved the single item BPI-SF pain intensity and interference scales or the BPI-SF (ordinal level measures) were inappropriate and raise questions about the strengths of these results (Field, 2005). Alpha also requires interval data and both the VAS and BPI-SF are ordinal.

In conclusion and based on generally satisfactory psychometric examinations of BPI-SF, the modified BPI-SF was used in this dissertation to assess pain location, type, intensity, duration and interference reported by the subjects preoperatively and each day following abdominal surgery until resolution of POI (time of first flatus). The investigator measured these criteria daily in order to compare whether there were differences between the rocking motion intervention group and the standard of care intervention group on the variables of interest.

Measurement of physical activity is a complex phenomenon characterized by intensity (rate), duration of each session, frequency of occurrences (per hour, per day) and surrounding environmental and social conditions (Montoye, 2000). Greater emphasis on studies of the relationship of activity and health has driven the need for more accurate and reliable methods to asses and measure physical activity. A variety of methods have been employed in and out of the healthcare setting to measure physical activity. These include energy consumption, biochemical techniques, observation and time-motion analysis, diaries, questionnaires, interviews, recordings of physiologic responses to activity, and the use of portable monitoring devices such as pedometers and accelerometers (Montoye, 2000). All of these methods mentioned have varying degrees of accuracy and feasibility for use in estimating physical activity in the postoperative patient.

The simple method of measuring the physical distance properties of the rocking cycle and ambulation in this study was accomplished through the use of a Yamax Digi-Walker SW-200 pedometer (Yamax, Inc., Tokyo, Japan). The SW-200 pedometers are designed with a pivot-armature motion detector, coil spring tension for the lever arm, brass counterweights and rubber-sheathed conductive posts to prevent corrosion. A copper ground plane also inhibits electrical interference and a screw lock maintains the level of sensitivity.

Validity and reliability of the SW-200 was demonstrated in studies measuring physical activity in a variety of settings (indoors and outdoors), with different population age groups (young and older), and over a variety of activity abilities (high activity levels

and low activity levels). The SW-200 was considered the best measure to use in this study because the postoperative population of subjects ranged from 21 through 85 years of age, they were indoors during the entire length of the study, and they represented a wide range of activity levels due to age, co-morbidities, pain, and postoperative physical capabilities.

Bassett, Cureton, and Ainsworth (2000) compared measurements of daily walking distances using both the College Alumnus Questionnaire (CAQ) and a pedometer. Ninety-six men and women (25 to 70 years of age) with a wide range of physical activity capabilities were studied. The investigators found that the subjects underestimated their daily walking distance on the CAQ as compared with the pedometer ( $1.43 \pm 1.01$  vs.  $4.17 \pm 1.61$  km·d-<sup>1</sup>) recordings. These findings made a significant effect upon the design of this study as they pointed out that subjective reports of distances rocked or walked may not be reliable. The pedometer became an important instrument in obtaining and validating accurate and reliable data about rocking cycles and ambulation distances.

Pre-study testing of the pedometer used in the Bassett et al. (2000) study produced exceptionally strong reliability and validity results in that the number of walking steps measured by the pedometer were within one to two percent of the actual measured walking distances during a 4.88 km walk and over a wide range of walking speeds. For this study it was important to use an instrument to accurately measure the physical activity of walking because while ambulation is a postoperative standard of care, literature revealed that it was never calibrated and measured in real distances before now.

Welk et al. (2000) evaluated the utility of the Digi-Walker step counter to assess daily physical activity patterns among 31 adults (17 men, 14 women) in two specific studies. Study 1 determined the number of steps to complete a mile under two different conditions (treadmill and track) and at three different paces. While stride length was expected to vary by size, gender, and pace, it was important to understand the effects of these variables on the step counter readings. Findings revealed that there were no differences in step counts between the treadmill and the track, but step counts were inversely related to pace, with values ranging from1330 steps to 1996 steps. The review of Welk et al.'s study was important to this study in that surgical patients vary in size, gender, and possibly postoperative walking pace due to wound pain and energy level following the recent surgery.

In the second study reported by Welk et al. (2000), a field-trial was conducted to examine relationships between daily step counts and other indices of physical activity recall (PAR). Reliability of the pedometers for accurately and repeatedly recording steps was established by comparing measured step counts with those recorded by two independent observers in an indoor hallway (37.4 m long). Mean step counts among all participants were within three to five percent of recorded values. For the walk condition the step counts were within ten percent of observed steps for 81% of the trials (26 of 32) and intra-class reliability was moderate (R = 0.56). Step counts at a specific pace were negatively correlated with height, weight, leg length, and stride length but positively correlated with body fatness. Three-way repeated-measures ANOVA revealed non-significant differences (no interaction or main effects) with site suggesting that similar results were obtained under both treadmill and track conditions. Step counts were found to decrease with pace for both genders with a slightly steeper effect for females. However, the mean number of steps to complete one mile (1.61 km) approximated 1935.

Also in Study 2, participants were found to have daily step counts of 11,603 when structured vigorous activity was required and 8265 when only light and moderate activity

was performed (Welk et al., 2000). Lack of strong correspondence between daily step count totals and measures from the PAR was evident in the modest correlations observed between the different measures. Averaged daily step count values for both conditions 1 (r = 0.34) and condition 2 (r = 0.49) indicated less error with the pedometer than the PAR instrument supporting the inaccuracy of recall as a method to assess actual steps taken.

The Welk et al. study identified the importance of using calibrated, tested, and standardized pedometers to accurately measure steps taken and distance walked. Easton, Rowlands and Ingledew (1998) reported strong correlations (r = 0.92) between step counts using the Digi-Walker and a scaled measure during unstructured low intensity activity in children. Welk et al. (2000) reported average correlations of 0.76 in their study between the Digi-Walker and another pedometer across seven days of data collection.

Vincent and Sidman (2003) evaluated measurement error in 24 Digi-walker SW-200 pedometers on 11 adults (8 women, 3 men) ages 27 -54 in walking and shake tests. The purpose of their study was to determine the amount of measurement error in a random sample of pedometers before and after heavy use in a large research study. Pretests and posttests were conducted with subjects wearing two pedometers left and right of the navel while walking 100 steps until each wore all 24 pedometers. Participants walked in a gym while counting their own 100 steps. Researchers recorded the pedometer readings after the 100 steps. Shake tests of each pedometer were conducted after each was placed in a box and shaken 100 times. Mean deviations from the 100 steps and shakes were calculated and considered the dependent variable for each pedometer. Pretest and posttest comparisons were made of absolute error deviations from 100 and a repeated measures factorial analysis of variance. The mean deviation of the walking test was 2.26

 $\pm$  .80 ( $M \pm SD$ ) 1.71  $\pm$  .88 on pretests and posttests. Mean deviations for the shake tests were 0.39  $\pm$  0.29 and 0.60  $\pm$  .62 for the pretests and posttests. The largest mean walking error for any pedometer was 4.2 steps and the largest mean shake error was 1.1. No pedometer exceeded a 5% error on any of the tests. No significant differences were found between the pretests and posttests (F (1, 46) = 1.49,  $p \ge$  .229). However, a significant difference was found between walking and the shake tests (F (1, 46) = 109.04,  $p \le$  .01.) An interaction was significant (F, (1, 46) = 7.76,  $p \le$  .008). As a result of these findings, researchers can assume confidence that the scores obtained using the Digi-Walker SW-200 Yamax pedometer is accurate.

Time and time again, studies reporting the use of the SW-200 discuss its high reliability, consistency, and accuracy over time. However, an important determination that had to be completed before commencing with this study was how a rocking cycle (number of rocks) would be defined, how the number of rocks and steps taken (distance ambulated) in a 24-hour period could be recorded. There were no previous reports of procedures or evidence found in the literature to assist with establishing these standards, therefore this investigator set out to create one. Previous researchers (Moore et al., 1995; Thomas et al., 1990) had tried to calibrate and measure rocks using observation and a mercury counter. However, mercury is banned from use in healthcare settings and therefore not able to be used to measure rock cycles. Direct observation of rocking distance ambulated of postoperative patients over a 24-hour period is also not practicable or feasible. Consultation by this investigator with experts in institutional biomedical services failed to yield a comparable method to count rocks and steps other than through direct observation for each twenty-four hour period. Direct observations for purposes of

counting rocks and steps were cost prohibitive. Therefore, an alternative method to record these rocks and steps was needed.

The procedures set forth by this investigator to develop SW-200 measurements of rock cycles are described in the following paragraphs. According to Vincent & Sidman (2003) and Welk et al. (2000), sufficient reliability and validity data were available to support the appropriate use of the device for recording rock cycles of study subjects. The SW – 200 pedometer records a step each time the person wearing the pedometer takes a normal stride while walking. An armature in the pedometer is displaced with the rise and fall of the ileac crest as the person completed a stride when walking. When the pedometer was placed on the leg of the rocking chair in the investigators garage and a person rocked in the chair, the combination of the backward and forward motion of the rocking chair resulted in the pedometer counting and recording two steps, one for the backward motion of the rocking chair. As a result, in order to obtain the actual number of rocks in each rock cycle (one combined backward and forward motion of the rocking chair), it became necessary to divide the pedometer recordings by two to yield one rock cycle.

To pilot the SW-200 before use in this study, ten nursing staff was instructed to walk ten laps around the study unit while wearing the pedometer. Steps were counted and averaged to yield a mean number of steps it took to navigate one lap around the unit where the study was to be conducted. An average of 56 steps was identified as the number required navigating one lap around the unit. Each pod was measured with an electronic sound wave device that the investigator used to determine the accurate distance in feet and kilometers around the unit. The actual distance for one lap around the nursing unit was 121 feet 6 inches. Each triangular-shaped pod measured 0.02 miles or 0.037

kilometers. This measure provided for a comparison of the average distance ambulated in by subjects in this study. The measurement of distance ambulated had not previously been identified or tested in previous research despite the long established practice of having patients begin ambulation the first postoperative day and continue to increase the distance each day thereafter. This researcher wanted to determine if there may be a correlation between the distances ambulated and the time to return of first flatus.

Nurses who pilot-tested the SW-200 and subjects who participated in the study were instructed to maintain a diary of the time spent in the rocking and non-rocking chairs and the numbers of laps they walked around the nursing unit as a secondary means of activity measurement and comparison. These data provided an alternative form of step, rocking, and time spent in the rocking and non-rocking chair for comparison in case the pedometer failed to capture steps walked and the number of rocks in the rocking chair. The number of rocks was important to determine in order to evaluate whether there was a correlation between the total rocks and the time to return of first flatus, the primary outcome variable in this study. The time spent in the non-rocking chair had never been evaluated in previous research and therefore no correlation evidence exists in the literature as to whether this time honored standard of postoperative care affects the time to return of first flatus and resolution of POI. Questions remain as to whether the time spent sitting in the non-rocking chair and the number of rocks performed affect the return of first flatus.

### 3.5 SETTING, TARGET POPULATION, AND SUBJECT RECRUITMENT

The setting for this study was a 32-bed postoperative surgical oncology unit at a large academic cancer center located in the southwestern Unites States. This setting was chosen because it offered the type of patient population, nursing, and medical staff

required to ensure the completion of the study. Over 90% of the patients on this unit undergo abdominal surgery for various gastrointestinal cancers and their average Time to Discharge is 7.6 days.

Subjects were recruited from the study site's gastrointestinal and anesthesia preoperative clinics where patients were screened for preoperative evaluations. As described previously, patients with gastrointestinal cancers were chosen as the target population for this study specifically because removal of all or part of the stomach, pancreas, liver, small bowel, colon and rectal structures requires a large abdominal incision, extensive dissection of the tumor, and manipulation of the bowel. These gross excisions and manipulations are thought to be primary reasons for the development of POI in this patient population (Schuster & Monte, 2002; Huge et al., 2000). The focus on gastrointestinal cancers also allowed for a more homogeneous population, as far as type of surgery, and offered greater opportunities to control threats to internal and external validity.

Historical data regarding numbers of admissions to the unit following abdominal surgeries ensured the investigator that there would be adequate numbers of consenting subjects screened and qualified to complete this study. The unit's population was sufficient to allow over-sampling to compensate for replacement of subjects lost to attrition and to correct any group disparities. Correction of group disparities was important from the perspective of concluding group equivalence and establishing internal validity (Campbell & Stanley, 1963; Huck & Cormier, 1996).

To reduce sources of error and protect confidentiality of enrolled subjects, all were admitted into private rooms for the duration of their hospital stays. To control for treatment bias effects and contamination of data, spatial separation of the control group and the treatment group was accomplished (Maas et al., 1989). That is, subjects randomized to the standard postoperative care group and those randomized to the postoperative rocking intervention group resided on two different 16-bed pods on the 32-bed unit. Six rocking chairs purchased for use in this study were standardized and calibrated prior to use in the study as a treatment in the experimental protocol group. Only the subjects in the experimental group used the rocking chairs. They were maintained, re-calibrated and tested for proper functioning throughout the study. The subject informed consent process and determinations of eligibility for participation are discussed in detail in the following section.

#### **3.6 PROTECTION OF HUMAN SUBJECTS AND INFORMED CONSENT**

Approval to conduct this study was granted by appropriate Institutional Review Boards. Written informed consent was required and completed of all participants prior to enrolling in the study. In a private meeting room, the investigator shared the goals and objectives of the study with all patients arriving at the cancer center's gastrointestinal clinic to be admitted for abdominal surgery. If the patient expressed an interest in participating in the study, they were given the consent form to read or it was read to them. After reading the informed consent, the investigator provided time for questions and explanations as needed. When all questions were answered to the satisfaction of the potential subject and he or she agreed to participate by signing the consent form, the individual was screened for his or her eligibility to participate. A copy of the signed consent form was provided to the subject and, if requested, a copy was provided to his or her significant other. If the consenting individual met the criteria for eligibility, he or she was enrolled in the study, a code number was assigned, and the subject's information was entered into the randomization program discussed elsewhere in this chapter in the section 3.9 marked *Randomized Group Assignments*.

Subjects were informed that the risk of injury for study participants was minimal. The primary potential injury was that of a fall while transferring to or from the bed to chair and while ambulating. However, it was explained that for the first 72 hours after surgery a member of the staff would assist patients to and from the bed to the chair and while walking.

Confidentiality of each subject's information was guarded through use of a threedigit code that was assigned at the time he or she agreed to participate. Only the individual subject and the investigator knew the assigned subject code. Only subject code numbers appeared on documents that were used to collect data from subjects' records, notebooks, charts, and research tools. Each code number was then used to identify data collected and recorded for that subject.

The record book of subject codes remained locked in the investigator's office in a locked file drawer. Study data were handled in the same ways. The computer where data files were stored was password protected and locked in the investigator's office. Data files used the subjects' code numbers as case identification tags.

### **3.7 SUBJECT INCLUSION AND EXCLUSION CRITERIA**

To be considered for inclusion in this study, potential subjects had to have been scheduled to undergo abdominal surgery for a gastrointestinal cancer, be at least 21 years of age, ambulatory, cognitively intact, able to give informed consent, and scheduled to receive either intravenous or epidural patient controlled analgesia postoperatively for pain control. Eligible participants also had to be free of specific co-morbidities that might present an increased risk for harm during the performance of the ambulation and rocking protocols in the study. Details about such risks are discussed in the next paragraph along with exclusion criteria.

Individuals excluded from participation in this study were those who were not scheduled for and did not have abdominal surgery for a gastrointestinal cancer, were not at least 21 years of age, were not ambulatory and cognitively intact, and not scheduled to receive either intravenous or epidural patient controlled analgesia for postoperative pain control. In addition, patients with neuromuscular diseases, cardiovascular diseases, prior rectal surgeries involving bowel re-anastamosis, pacemakers, inner-ear disturbances, severe peripheral vascular diseases, and those taking sympathetic inhibitory or mood altering drugs were not eligible to participate. These patients were excluded because they were considered to be at increased risk for harm during the performance of activities specified in each of the arms of the study.

Ineligibility of patients who were cognitively impaired was based on their inability to comprehend and give informed consent as well as problems they might have had carrying out the instructions for participation. Reasons to disqualify patients who did not receive the standard intravenous or epidural patient-controlled postoperative analgesia with morphine, hydromorphone or fentanyl were based on research findings that show that pain medications that differ from these standards present systemic effects that confound the occurrence and resolution of POI (Carli et al. 2002; Liu, Carpenter & Neal, 1995; Steinbrook, 1998). All of the exclusion criteria addressed above were carefully identified, studied, and selected in order to reduce the potential for interaction effects and threats to internal validity (Cook & Campbell, 1979).

#### **3.8 DETERMINATION OF SAMPLE SIZE AND OVER-SAMPLING**

Preparing the parameters for power calculation for this study was based on the primary endpoint of time to first passage of flatus from the rectum used by Disbrow, Bennett, and Owings, (1993) in their study of the effects of specific instructions for early return of gastrointestinal motility with time to first flatus from the end of the surgical procedure as an endpoint of POI duration. The null hypothesis for their first comparison was that instruction would be equivalent to the standard care (no specific instruction of early gastrointestinal motility) and the alternate hypothesis was that they would not be equivalent. The null hypothesis for their second comparison was that instruction group would be equivalent to the standard of care (non instruction) therapy, although the alternative hypothesis stated these two therapies would not be equal.

Given the similarities in aims and hypotheses between the Disbrow et al. (1993) study and this dissertation, the investigator used SPSS Sample Power<sup>®</sup>2. (Borenstein, Rothstein & Cohen, 2006) software to perform the sample size calculations by setting the criterion for significance (alpha) at 0.050 for 2-tailed tests (an effect in either direction was accepted) and power at 0.80. A total sample size of 54 subjects was determined necessary to yield statistically significant results.

One goal of the dissertation study was to test the null hypothesis that the two population means were equal. The mean difference in time to first flatus in the Disbrow, Bennett, & Owings (1993) study was 1.6 days (corresponding to means of 4.2 nonrocking versus 2.6 rocking) and the common within group standard deviation was 2.0 (based on *SD* estimates of 2.4 and 1.6). This effect was selected as the smallest effect that would be important to detect, in the sense that any smaller effect would not be of clinical or substantive significance. It was also assumed that this effect size d ((4.2-2.6) / 2.0) = 0.80

was reasonable based on current knowledge, in the sense that an effect of this magnitude could be anticipated in this field of research.

A second goal of this dissertation study was to estimate the mean difference between the two populations. On average, a study of this design would detect a mean difference with a precision (95% confidence interval) of plus/minus 1.11 points. For example, an observed difference of 1.6 would be reported with a 95% confidence interval of 0.49 to 2.71. Precision will vary as a function of the observed standard deviation (as well as sample size), and in any single study will be narrower or wider than this estimate. Calculating (95% confidence intervals) within which the true value of the population mean may fall provides another method to assess the accuracy of the sample mean (Field, 2005). The goal is that 95% of the time the true value of the population mean will fall within these limits.

#### **3.9 RANDOMIZED GROUP ASSIGNMENTS**

At the time when informed consent of each subject eligible to participate in this study was obtained, the investigator assigned a three-digit code (ranging from 001 - 120) to each to protect confidentiality and provide an identifier for all documents and data specific to each participant (Lynn, 1986). Eligible and consenting subjects were randomly assigned to either the rocking motion intervention group or the standard postoperative care intervention group using the Protocol Database Management System (CORe, *Copyright* 2000-2007) at the institution where the study was conducted. The CORe is a clinical research management system supporting clinical trials at the institution where this research was conducted and collaborative sites across the United States. This computer program and system facilitates the random assignment of research subjects to treatment groups without researcher bias.

Thirty-two subjects were randomly assigned to the standard postoperative care intervention group and another 34 to the rocking motion intervention group. The randomization process for this study was capable of handling the assignment of up to 120 subjects in order to allow for 10% over-sampling covering attrition and a potential enrollment of 60 subjects in each group. In order to ensure gender was distributed equally, the investigator monitored random assignment to treatment groups.

Random assignment offered each subject an equal chance of being assigned to the control or experimental group and allowed for elimination of systematic bias in the groups with respect to attributes that may affect the dependent variables under study (Campbell & Stanley, 1963; Huck & Cormier, 1996; Whittemore & Grey, 2006). Random assignment in this study also aimed to make the two groups' equivalent, in a probabilistic sense, on subject attributes or characteristics at the times the groups were formed. However, the magnitude effect of random assignment may be reduced in this study compared to studies with larger sample sizes. Equal numbers of subjects were randomly assigned to the control and intervention groups. While the diversity in demographic characteristics of persons with gastrointestinal cancers did not allow for the creation of truly equivalent groups, the creation of comparison groups rather than equivalent groups was factored on the assumption that any important intervening variables were equally distributed between the groups, thereby minimizing variance and decreasing selection bias (Huck & Cormier, 1996).

## 3.10 PRE-STUDY STAFF EDUCATION AND TRAINING

Prior to the start of the study the principal investigator met with the nursing staff and medical staff to describe the purposes of the study and the procedures involved in conducting the study. They were informed they would be notified verbally about which subjects were assigned to either the rocking motion group or the standard of care group and that forms pertinent to the study could be found in the participating subjects' charts. Blinding was not an option in this study within the surgical unit whereby the study was conducted because rocking chairs are not the standard chair used on the unit where the study was conducted. However, the surgeons who performed the surgeries were not aware until the postoperative period who was randomly assigned to the rocking or standard of care group limiting bias.

Each subject randomly assigned to the rocking motion intervention group had his or her bedside chair removed and replaced with a rocking chair. Subjects randomly assigned to the standard of care (non-rocking) group kept and used the standard bedside chair provided for each patient admitted to the unit. These institutional chairs are from the same stock and all have the same features. No rocking chairs were made available to any patients on the unit other than those assigned to the rocking motion intervention group. The spatial separation of group members on one of the unit's pods or the other was the researcher's attempt to reduce potential contamination between groups.

Procedures that involved the staff in observation and validation of distances ambulated by each subject and the recordings of pain medication used were repeatedly reviewed with the staff to secure satisfactory levels of interrater reliability and reduce errors. Newly hired nursing staff for the unit (research setting) were oriented to the study by the investigator. Daily patient care assignments of the staff nurses working on the unit did not crossover the two pods. This reduced the chances of errors associated with observer bias and data contamination.

#### **3.11 PROTOCOL INSTRUCTIONS FOR THE ROCKING CHAIR GROUP (ARM 1)**

Subjects in the rocking chair intervention group (Arm 1) were given an instruction sheet (Appendix B) that identified the activities required for their participation. The investigator provided each subject with a demonstration of how to properly follow the instructions and use the rocking chair according to the protocol. Subjects were instructed to begin by getting out of bed on the first postoperative day, sit in the rocking chair and rock, and ambulate.

The instructions and the demonstration included placing the pillow to sit upon, placing the lumbar support pillow with help from the staff, positioning of both feet on the floor, and rocking at the rate of one rock cycle (one backward and one forward motion taken together is the equivalent of one rock cycle) per second in ten to 20-minute increments for at least sixty minutes per day. The rock cycle configurations and the duration of rocking activities established for use in this study were modeled after the recommendations put forth by Benson, (1975) and Moore et al. (1995) as minimally necessary to stimulate the relaxation response.

A calibrated pedometer was attached to each rocking chair to digitally record the number of rock cycles completed during each 24-hour period. Approximately 3600 rock cycles is equal to 60 minutes of rocking and that standard was used to determine the time each subject spent rocking. Each subject was instructed to progressively increase the time spent rocking each day, as his or her condition allowed, until passage of first flatus.

Ambulation instructions were to begin ambulating on the first postoperative day, at least twice daily, and to increase the time, distance, and frequency each additional day as their condition allowed until passage of first flatus. In order to obtain an accurate determination of the number of steps taken during ambulation and total distances covered in a 24-hour period, each subject wore a calibrated pedometer on a gait belt while ambulating. The distance ambulated was calculated using the total number of steps recorded each day. Previous research has suggested that walking 1935 steps is equivalent to one mile (1.61 km) for the YAMAX Digi-Walker pedometer used in this study and this was the standard used to determine the ambulation distances achieved by each of the subjects (Welk et al., 2000).

Each subject was given a pad and a pencil and asked to record the date and time when they passed the "first flatus" following surgery. Each morning the investigator recorded all rocking chair and ambulation data onto the Rocking Study Demographic/ Data Sheets (Appendix C) and reset the calibrated pedometers. Time spent ambulating and number of laps (distance) around the unit was also recorded on the Rocking Chair Time and Lap Data Sheets (Appendix D) using notations made by trained staff nurses who observed the activities of the subjects. Nursing staff observations and recordings were compared to pedometer recordings to evaluate accuracy. It was determined that an average of 56 steps (121.6 ft or 37.06 meters) was required to navigate (one lap) around the triangle shaped unit where each subject resided during their postoperative hospitalization.

Each day the investigator asked the subjects in the rocking chair intervention group if they had any questions. When they presented questions, the investigator answered them to the satisfaction of the subject.

### **3.12 PROTOCOL INSTRUCTIONS FOR THE STANDARD OF CARE GROUP (ARM 2)**

Subjects in the nonrocking standard of care group (Arm 2) were given an instruction sheet (Appendix B) that identified the activities required for their participation. Subjects were instructed to get up out of bed on the first postoperative day,

sit in a nonrocking chair and ambulate at least twice daily. They were further instructed to increase chair sitting time and frequency each additional day as their condition allowed, until passage of first flatus. They were further instructed to increase ambulation time, frequency, and distance each additional day as their condition allowed, until passage of first flatus. The investigator provided each subject with a demonstration of how to safely and properly get out of bed, sit in the chair and ambulate according to the protocol.

The instructions and the demonstration included placing a pillow on the seat of the nonrocking chair, sitting and placing a lumbar support pillow with help from the staff, positioning both feet on the floor, and repeating this set of activities in ten to 20-minute increments for a total of at least 60 minutes per day beginning the first day after surgery until passage of first flatus. Ambulation instructions were to begin ambulating on the first postoperative day, at least twice daily, and to increase the time, distance, and frequency each additional day as their condition allowed until passage of first flatus. In order to obtain an accurate determination of the number of steps taken during ambulation and total distances covered in a 24-hour period, each subject wore a calibrated pedometer on a gait belt while ambulating. The distance ambulated was calculated using the total number of steps recorded each day. Previous research has suggested that walking 1935 steps is equivalent to one mile (1.61 km) for the YAMAX Digi-Walker pedometer used in this study and this was the standard used to determine the ambulation distances achieved by each of the subjects (Welk et al., 2000).

Each subject was given a pad and a pencil and asked to record the date and time when they passed the "first flatus" following surgery. Each morning the investigator recorded all nonrocking chair and ambulation data onto the Rocking Study Demographic/ Data Sheets (Appendix C) and reset the calibrated pedometer used for ambulation. Time spent ambulating and number of laps (distance) around the unit was also recorded on the Nonrocking Chair Time and Lap Data Sheets (Appendix E) using notations made by trained staff nurses who observed the activities of the subjects. Nursing staff observations and recordings were compared to pedometer recordings to evaluate accuracy. It was determined that an average of 56 steps (121.6 ft or 37.06 meters) was required to navigate (one lap) around the triangle shaped unit where each subject resided during their postoperative hospitalization.

Each day the investigator asked the subjects in the nonrocking chair intervention group if they had any questions. When they presented questions, the investigator answered them to the satisfaction of the subject.

#### **3.13 DATA COLLECTION PROCEDURES**

All demographic and study data were collected and recorded on the Rocking Study Demographic and Data Sheet (Appendix C) for each subject by the investigator. All coded subject data were stored in data notebooks kept in a locked file in the investigator's locked office. Demographic data collected included age, gender, marital status, diagnosis, and surgical procedure, date and time of surgery, and date and time of discharge from the hospital. Surgical characteristics collected included type of surgical procedure, anesthesia time, surgical time and previous abdominal surgery. A preoperative assessment of pain presence, location, type, intensity and quality of life pain interference rating during the last 24 hours was completed by administering the Brief Pain Inventory-Short Form (BPI-SF) at the time the subject provided informed consent to participate.

Each day the investigator met with each subject in each of the study groups and recorded the amount of pain medication used during the last twenty-four hour period from pain infusion devices and the medical record, converted the amount to milligrams, and recorded the number on the data sheet. The time spent in the rocking chair and nonrocking chair was also collected from the patient and nurse kept diaries located in each subject's room. The number of steps ambulated was also collected each day from the pedometer each subject wore while ambulating over the past twenty four hours. Calculation of distance walked was based on 1935 steps comprising an equivalent to one measured mile (1.61km). Patients and nursing staff also recorded the number of laps around the triangular shaped nursing unit in diaries maintained at the bedside.

Once all data were gathered each morning and transferred to the Rocking Study Demographic and Data Sheet from pedometers, assessments, and subjects' and nurses' notes, the investigator reset each pedometer for the next 24-hour period. The number of rocks was calculated from the pedometer readings and distances ambulated were calculated from the number of laps recorded on the patient and nurse diary. The details of these calculations are explained in the operational definitions discussed in section 3.3 and in the protocol instructions for each arm presented in section 3.11 and 3.12.

Data collected each day in this study also included findings from the investigator's daily assessment of the presence, location, type and intensity of pain and pain interference for each subject during the past 24-hours. Self-report of each subject was captured using the BPI-SF every postoperative morning until actual passage of first flatus from the rectum.

Subjects were also provided a pad and pencil so they were ready to record the day, date, and time of the first postoperative passage of flatus from the rectum. This method was chosen based on a study by Yukioka et al., (1987) who demonstrated that patient estimates of time of first flatus in a group of patients 60 years and older was a reliable method when compared to simultaneously carbon dioxide measurement after

surgical procedures. In 16 patients (80%), the observed patient estimate and simultaneous carbon dioxide measures coincided and there were no false reports. Two patients were asleep and did not report TTFF and in two the tube measuring carbon dioxide malfunctioned. The investigator also reviewed each subject's chart each day and used the nursing and medical notes to validate data in the diaries and on the patients' notepads. All data were saved in the investigator's data notebook that was kept in the investigator's locked office in a locked file cabinet. All study data were transposed from the coded data sheets and investigator's notebook into an SPSS 12.0 data file for data analysis.

#### **3.14 DATA ANALYSIS PROCEDURES**

Statistical analysis of demographic characteristics (age, gender, and marital status) and clinical characteristics (diagnosis, surgical procedure) were summarized using descriptive statistics. The two intervention groups (rocking and nonrocking standard of care) were compared with respect to various demographic and clinical characteristics using the appropriate statistical *t*-tests for interval data and chi-square analyses for ordinal data. The sample was heterogeneous for age, gender, and total postoperative pain medication used, rocking time and ambulation distance. The sample was not homogeneous for any other characteristics other than abdominal surgery for cancer.

To examine group differences in the duration of POI [postoperative time to first passage of flatus from the rectum], pain medication use [total doses in milligrams used per 24 hours], and postoperative patient recovery time [time to discharge], the two sample *t*-test was used if assumptions of normality and homogeneity of variance on the dependent variable were upheld (Field, 2005). Subjective reports of type, duration, and intensity of postoperative abdominal pain [Brief Pain Inventory – Short Form (BPI-SF)]

of this ordinal data was completed using non-parametric Mann – Whitney U tests (Field, 2005). Both groups were independent and assigned to either the rocking group or the nonrocking group through randomization using the Protocol Database Management System (CORe, *Copyright* 2000-2007) a component of the Surgical Oncology Research Database. It is important to note that all patients passed flatus from the rectum prior to being discharged from the hospital. The first passage of flatus was also the end point of the study and each subject's enrollment was terminated when this milestone was achieved.

Descriptive statistics (mean, medium, mode, range, standard deviation) were used to summarize each outcome of interest (time to first flatus, subjective reports of surgical and gas pain, total pain medication used and time to discharge). If assumptions underlying the two-sample *t*-test were violated, appropriate non-parametric tests were run for the involved variables (Mann-Whitney U). In addition, when significant differences between groups on demographic, independent, or outcomes variables or significant relationships between them arose, appropriate regression and ANCOVA tests were scheduled to be performed. A significance level of 0.05 was used.

#### **3.15 THREATS TO VALIDITY AND SOURCES OF ERROR**

This section presents the identification and management of sources of error and threats to internal and external validity. Internal validity is described as the degree to which the study establishes the cause and effect relationship between the treatment and observed outcome (Campbell & Stanley, 1963; Slack & Draugalis, 2001). Potential extraneous variables identified by this investigator were history, maturation, testing, instrumentation, regression, differential selection, and experimental mortality and selection-maturation interactions. External validity is addressed by delineating inclusion and exclusion criteria, describing subjects in terms of relevant variables and assessing generalizability. Each will be discussed in the sections that follow and discussion will include the strategies employed by the investigator to control for the threats and reduce sources of errors.

Threat	Specific Study	Potential Source of	Actions to Reduce
Tineat	Threat	Error	Threat
History	1) Repeated measurement of pain intensity and interference scores.	Stability of instrument over time.	BPI-SF demonstrates reliability and validity over time in research with surgical patients (Cleeland, 1997; Tittle et al. 2003).
		Variation in administration of instrument.	Administered at same time each morning by primary investigator.
	2) Estimate of Time To First Flatus, total pain meds received and Time to Discharge.	TTFF subjective report by patient.	Research by Yukioka & Rosen, (1987) first identified and validated this method of patient estimate of TTFF. Disbrow et al. (1993) used method in study of TTFF. Operational definitions of each item and how to calculate TTFF, total pain meds received and LOS developed prior to study.

Table 1 Threat to Internal Validity

Threat	Specific Study Threat	Potential Source of Error	Actions to Reduce Threat
	3) Past surgical experience postoperative pain intensity and interference.	Past surgical pain experience has been demonstrated to potentially affect new experiences.	Preop and post-op assessment of pain and past surgery compared among groups (Burton & Cleeland, 2001; McCaffery, 2002).
Maturation	1) Non-treatment events between pre and post testing.	Pre-surgical evaluation and preparation for participating in study.	All individuals received the same preoperative instructions and preps on day prior to surgery reducing length of time for potential non- treatment events to occur prior to testing.
	2) BPI-SF internal consistency.	Changes in pain intensity and interference scores due to patient being tired, bored or less motivated.	BPI-SF well established internal consistency in previous research involving repeated measures over time (Tittle et al. 2003).
Testing	1) Test scores changing due to repeated testing and not due to the intervention.	Preop testing of BPI-SF. Total pain meds received each day.	Instrument has demonstrated test- retest reliability in studies involving surgical and non- surgical patients (Tittle et al. 2003; Zalon, 1999).
			Potential for error reduced by using only one person to collect data, pre study calculations.

Threat	Specific Study Threat	Potential Source of Error	Actions to Reduce Threat
		TTFF and LOS.	TTFF and LOS were one time tested events.
Instrumentation	1) Changes in instrument calibration or observer changes.	Pedometers used in study.	One type of pedometer used based on accuracy in prior activity measurement research (Vincent & Sidman, 2003; Welk et al. (2000.
		Distance ambulated.	Use of pedometer 1935 steps equal 1 mile and counting laps (121.6 ft.) equal distance around unit used to confirm distances (Welk et al. 2000).
		Rocks, rock time and time in non- rocking chair.	Rocks counted using pedometer attached to chair. Patients and staff trained to record time in chair.
Regression	1) Occurs when subjects selected based on high or low scores.	Preop scores such as preop pain not used to select patients.	Not a factor in this study because all subjects selected due to meeting inclusion criteria.

Threat	Specific Study Threat	Potential Source of Error	Actions to Reduce Threat
Differential Selection (Bias)	1) When subjects selected are not randomly assigned to treatment groups.	Unequal groups with respect to relevant variables (age, gender, etc.) due to lack of random assignment.	Patients randomly assigned to treatment groups although small sample size is limiting factor.
Experimental Mortality	1) Attrition, withdrawals and dropouts prior to randomization.	Differential loss of subjects from rocking and nonrocking comparison groups.	All subjects were randomized to groups prior to abdominal surgery.
		Attrition limit set at 10% based on previous research.	Over sampling was incorporated into study to compensate for those who dropped out of the study.
		Selecting patients of variety of surgical procedures.	All subjects scheduled to have abdominal surgery.
		Potential bias due to mortality. Groups no longer equivalent in terms of known and unknown factors.	Intention to treat analysis in which all subjects randomized to groups are included in analysis.
Selection Interactions	Differential assignment of subjects to groups in a way that relates to the subjects maturation.	Patients with similar disease indicators at start of study had worsening of disease process postop assigned to one group.	Subjects were randomly assigned and not assigned to groups based on potential progression of disease process.

The deliberate choice of research design for this study (e.g., post test only) and the operational procedures employed (random assignment) were the investigator's attempts to affect a high level of confidence in internal validity. The posttest only control group design used in this dissertation meets all the criteria for a true experimental study except for pretest measurement that has been argued as not an essential element in true experiments as put forth by Fischer (Campbell and Stanley, 1963). Random assignment to parallel groups was performed to control for the majority of the threats to internal validity with the exception of experimental mortality (Slack & Draugalis, 2001). However, in studies with small sample sizes, as is the case in this dissertation, the effectiveness of randomization in assuring the equal distribution may be limited. This limitation is posed by both known and unknown variables among subjects that interfere with determining outcome effects of interventions among and between the groups.

Differential selection was addressed and controlled in this study not only by random assignment but also by the researcher's monitoring of gender distributions in each group, with the goal of ensuring equal representation of gender in both groups. As a result of the previously discussed controls, the most significant threat to internal validity was mortality. There was no mortality except for two subjects in the rocking group who could not continue to rock beyond the second postop day, but still passed flatus shortly thereafter and were included in the data analysis based on the principle of intention-to-treat. Intention-to-treat is an important factor. Potential loss of the value of random assignment occurs if subjects are dropped from the analysis because the two groups are no longer considered equivalent in terms of known and unknown factors. Therefore, the preferred procedure for preventing bias is to use the intention-to-treat analysis, in which all subjects randomized are included in the analysis (Everitt & Pickles, 1999; Slack & Draugalis, 2001).

Detailed explanations of this investigator's actions to control for threats and errors are found in each section that speaks to methodology as well as in Table 1 and Table 2 presented here. All are important to establishing the effects of treatment and drawing conclusions from study findings. Practically speaking, the central issues that demonstrate internal validity and establishing the effects of a treatment are ensuring that the comparison groups are equivalent in all variables except the independent treatment variable. It has been established that the groups in this study were similar demographically, did not differ in severity and type of disease or surgical procedure (gastrointestinal cancer and undergoing extensive abdominal surgery), had similar prognoses, received equal treatments for comorbidities, and received equal treatment for postoperative care (adherence to protocol), except for the experimental treatment delivered in the course of this study (rocking intervention).

Threat	Specific Study Threat	Potential Source of Error	Actions to Reduce Threat
Interaction of selection biases and treatment.	1) People who agreed to participate may differ from those who refuse.	Reduces generalization of results to those who did not participate.	Validity of statistical conclusion. Difference is real and not likely to chance variation. Assess Statistical significance ( <i>p</i> value) and statistical results are valid.
			External validity can only be established if internal validity is established (Slack & Draugalis, 2001).

Table 2 Threats to External Validity

Threat	Specific Study Threat	Potential Source of Error	Actions to Reduce Threat
Reactive effects of experimental arrangements.	1) Results obtained in one setting may not be obtained in another.	Use of multiple units to conduct study could bias protocol adherence affecting results.	One postoperative surgical unit used to conduct study. Treatment bias addressed by locating rocking and nonrocking subjects on separate pods in the unit where study conducted.
Interaction of effect testing.	1) Pretest might increase or decrease respondent's sensitivity or responsiveness to the experimental variable.	Potential for BPI-SF preop testing to exert effects on pain intensity and interference. Potential for pre and post test interactions with TTFF, total	Instrument has demonstrated test- retest reliability in studies involving surgical and non- surgical patients (Tittle et al. 2003; Zalon, 1999). Posttest only randomized design reduces potential for
Multiple-treatment interference.	Multiple treatments applied to same subjects.	meds received, and LOS. Effects of prior treatments are not usually erasable.	Prior standard of care (nonrocking) could have been received after prior surgery. However, rocking intervention was only new intervention introduced to this sample reducing effects of multiple treatment interference.

External validity threats identified in this study include interaction of selection bias and treatment, reactive effects of experimental arrangements, interaction of effect testing, and multiple treatment interference. Table 2 describes the threats pertinent to this study, controls introduced by this investigator, and sources of information that guided the decisions made to enhance external validity. Generalizability, or the ability to extrapolate results to other patient populations, is a goal of many researchers that cannot be met without a rigorous estimate of a study's satisfactory level of external validity. Studies that use random selection of subjects are generally considered to have an increased chance of being generalized beyond the study groups. However, random selection does not guarantee generalizability (Slack & Draugalis, 2001) when sample sizes are not large enough to adequately represent the larger population.

As was the case in this dissertation, clinical studies are often unable to use random selection because it is difficult for clinicians to identify every potentially eligible patient in the target population prior to the start of the study. Clinicians cannot identify in advance patients who will require abdominal surgery or anticipate any of the other clinical events that will influence a patient's eligibility before a clinical trial begins. To adjust for the aforementioned barriers to employing random selection in this study, the investigator monitored the composition of the rocking and the nonrocking groups, following random assignments, to assess the degree to which the groups were representative of the population of persons with digestive system cancers.

All efforts were made though the inclusion and exclusion criteria and investigator monitoring to ensure that a homogenous group of patients was chosen to participate in this study. The study protocol was adhered to in all cases and analysis of data was completed with significant detail in order to assure the results were not by chance alone. Within the methods and results sections, inclusion and exclusion criteria provide clarity about which population the findings under discussion apply. Additional information considering generalizability of the findings is found in discussions of the demographic, surgical, surgical procedures, diseases and other characteristics of study subjects. Examination of the subject characteristics allows readers to estimate if they would likely obtain similar outcomes in their own study's population.

Establishing the validity of this study's findings was guided by the procedures outlined in the three steps identified by Slack and Draugalis (2001). First, it was necessary to establish statistical conclusion. Only when the statistical conclusion drawn was valid was it appropriate to move to the assessment of internal validity. Only when internal validity was established was it appropriate to assess external validity (Campbell & Stanley, 1963; Cook & Campbell, 1979). In the second step, in cases where no significant differences were found, differences detected could not be interpreted as valid, no treatment effect was recognized, and no cause and effect relationship could be said to exist. Under these conditions, the examination of threats to internal validity was carried out to determine any contributions they made to extraneous variance. Third, the appropriateness of claiming external validity for the study was based first on the recognition of internal validity. If internal validity could not be established, there could be no decisions about treatment effects and therefore no generalizability. Throughout all chapters of this dissertation, the investigator used this three-step process to establish validity and generalizability.

## **CHAPTER IV: RESULTS**

#### **4.1 PURPOSE AND HYPOTHESES TESTED**

The purpose of this chapter is to describe the results of this post-test two group randomized study of the effects of relaxation induced by the rocking motion on duration of POI (time to first flatus in days), subjective reports of postoperative pain intensity (worst and pain right now) and interference (general activity, walking ability and sleep), pain medication used (total milligrams received) and postoperative recovery time (time to discharge in days). General results, actual sample size, demographics and attributes of study participants are also included within this chapter.

The null hypothesis (H0) tested in this study was: There are no differences in the duration of return to flatus, subjective reports of postoperative abdominal pain, total pain medication use, and postoperative recovery time among cancer patients recovering from abdominal surgery who receive the rocking intervention motion vs. the standard of care. Patients randomized to the rocking arm were instructed to get out of bed and begin rocking in a rocking chair and ambulating beginning the first postoperative day. Patients randomized to the nonrocking standard of care arm were instructed to get out of bed beginning the first postoperative day and sit in a nonrocking chair and ambulate beginning the first postoperative day.

The research hypotheses evaluated in this study were:

**SPECIFIC AIM 1:** To assess whether the rocking intervention reduces the mean time in days to passage of first flatus from the rectum in postoperative abdominal surgery patients compared to standard postoperative care.

**HYPOTHESIS 1:** There will be a difference in postoperative mean time to the passage of first flatus from the rectum between those patients who receive the rocking intervention and those who receive standard postoperative care.

**SPECIFIC AIM 2:** To assess whether mean pain intensity and interference scores could be reduced to a greater extent by rocking motion compared to standard postoperative care.

**HYPOTHESIS 2**: There will be a difference in mean postoperative subjective reports of pain intensity (worst, least, average and pain right now) and pain interference (general activity, mood, walking ability, relations with others, sleep and enjoyment of life) between those patients who receive the rocking intervention and those who receive standard postoperative care.

**SPECIFIC AIM 3:** To assess whether the rocking motion is more effective in reducing total mean pain medication milligrams received compared to standard postoperative care.

**HYPOTHESIS 3:** There will be a difference in the mean total pain medication in milligrams received between those patients who receive the rocking intervention and those who receive standard postoperative care.

Specific Aim 4: To assess whether mean time in days to hospital discharge is reduced by treatment with rocking motion compared to standard postoperative care.

**HYPOTHESIS 4**: There will be a difference in mean time to discharge between those patients who receive the rocking intervention and those who receive standard postoperative care.

#### **4.2 GENERAL RESULTS**

Between July 2005 and February 2007, a total of 66 patients with digestive system cancers who were scheduled to have abdominal surgery met inclusion criteria, provided informed consent, and were randomized into either the rocking intervention group or the nonrocking standard of care group. Thirty-two subjects were randomly assigned to the standard of care (nonrocking) group and 34 to the rocking intervention group for a total N = 66. All sixty-six subjects completed the study. Two subjects in the rocking group could not continue the rocking intervention after the second postop day but met criteria for intent-to-treat discussed previously in Chapter 3. One male rocking subject developed dizziness at the end of the second postoperative day while rocking in the rocking chair. However, he passed flatus early on postoperative day number three and was not an outlier. A female rocking subject required a second surgery within twenty-four hours of her first surgery and could not continue to rock after the second surgical procedure due to the inability to maintain an adequate blood pressure when out of bed sitting in the rocking chair. She too passed flatus by the third day after the second surgery. Both were included in the final analysis of data based on the intention-to-treat principle (Slack & Draugalis, 2001). Nevertheless, over-sampling by two more subjects was performed for randomization into the rocking group thereby increasing the number of rocking participants to thirty-four.

#### **4.3 DEMOGRAPHICS**

The demographics of the study participants presented in Table 3 include age, gender, ethnic group, marital status, and diagnosis.

Table 3 Demographics
----------------------

Charactoristics	Roc	king	Nonro	cking	
Characteristics	n	%	п	%	р
	34	51.5	32	48.5	
Age (Years)	56.2	<u>+</u> 10.1	54.8 <u>+</u>	<u>-</u> 11.4	
Mean Age (Min, Max)	(32	, 77)	(32,	70)	0.600
Gender					
Male	14	41.2	19	59.4	0.218
Female	20	58.8	13	40.6	
Ethnic Group					
White Non Hispanic	26	76.5	27	84.4	
African American	2	5.9	1	3.1	0.875
Hispanic	3	8.8	2	6.3	
Asian	3	8.8	2	6.3	
Marital Status					
Single	5	14.7	3	9.4	
Married	27	79.4	25	78.0	0.757
Divorced	1	2.9	2	6.3	
Widowed	1	2.9	2	6.3	
Diagnosis					
Colon Cancer	19	55.9	22	68.8	
Liver Cancer	4	11.8	4	12.5	

Characteristics	Roc	king	Nonro		n
	n	%	n	%	p
	34	51.5	32	48.5	
Sarcoma	5	14.7	3	9.4	0.752
Gastric Cancer	2	5.9	2	6.3	
Pancreatic Cancer	3	8.8	1	3.1	
Adrenal Cancer*	1	2.9	0	0.0	

\*Note: Had colon resection at time of adrenalectomy.

The combined mean age for both the rocking and nonrocking groups was 55.6 (SD = 10.7). Age, as a whole, was normally distributed as evidenced by  $(D \ (66) = .096, p > .200)$ . There were no significant differences between groups on age, gender, ethnic group, marital status and diagnosis as evidenced by the nonsignificant *p* values in Table 3. Overall, male participants in this study were significantly older (M = 59.09, SE = 1.716) than female participants (M = 52.03, SE = 1.808) (*t* (64) = 2.832, *p* < .006) but demonstrated only a small effect size (d = 0.33).

Although gender was equally represented in the total sample (N = 66), distributions across study conditions were somewhat dissimilar (rocking 41.2% males versus 58.8% females; nonrocking 59.4% males versus 40.6% females) although this pattern failed to reach statistical significance (p = .218).

Ethnic group distributions were predominantly white (n = 53, 80.3%) in both study conditions with very small representation across African Americans (n = 3, 4.5%), Hispanics (n = 5, 7.6%), and Asians (n = 5, 7.6%). There were no significant differences between groups on ethnic composition (p = 0.875). The majority of the individuals who participated in this study were married and the distribution across the study groups was homogeneous and nonsignificant. Distributions across diagnoses were again very similar between both arms of the study with no significant differences between groups.

# **4.4 SURGICAL ATTRIBUTES**

The surgical attributes of the study participants presented in Table 4 include surgical procedure, American Society of Anesthesia (ASA) status, and previous abdominal surgery.

$\frac{n}{34} \frac{0}{51.5} \frac{n}{32} \frac{0}{48.5}$ Procedure	р
Procedure	
Colectomy 13 38.2 10 31.3	
Liver Resection 8 23.5 12 37.5	0.668
Small Bowel         1         2.9         1         3.1	
Exploratory Lap         12         35.3         9         28.1	
ASA Status	
ASA 1 0 0.0 1 3.1	
ASA 2 19 55.9 17 53.1	0.533
ASA 3 15 44.1 13 40.6	
ASA 4 0 0.0 1 3.1	
Previous Abdominal Surgery	
Yes 30 88.2 25 78.1	0.333
No 4 11.8 7 21.9	

Table 4 Surgical Attributes

There were no significant differences between the study groups on surgical procedure types (p = 0.668) and ASA categories (p = .533). The ASA status designations were used because they provided a simple and concise way to determine the patient's preoperative physical health status prior to receiving anesthesia in each arm of this study (Barbeito, et al., 2006). Developed in 1941, the ASA rating scale is an ordinal scale (1 through 4) with a higher score indicating higher levels of health status complexity. Assessing ASA status of patients in this study was important because anesthesia has been implicated in the literature as a potential contributor to POI (Holte & Kehlet, 2002; Kehlet & Holte, 2001).

Numbers of previous abdominal surgery experiences were recorded and analyzed in order to assess the potential effects they might have on the time to first flatus and Time to Discharge outcomes in this study. Historically, patients who had previous abdominal surgeries were determined to be more difficult to manage during any current surgery because of challenges presented by adhesions, changes in anatomy, and potentially longer surgical operating and anesthesia time. Each factor has been implicated as a potential contributor to increased length of POI and length of hospital stay (Behm & Stollman, 2003; Holte & Kehlet, 2000). Participants in both arms of this study, overall, had higher numbers of previous abdominal surgeries than in the general population, however there were no significant differences between the groups (p = .333).

## 4.5 SPECIFIC RESULTS FOR EACH MEASURE

Preliminary analyses of all data were completed to determine any coding and data entry errors and to clean the data. Descriptive statistics (percentages, means, median, mode and standard deviation) were calculated for all variables. Tables were prepared and high points noted and any potential limiting issues such as small sample size were examined. Potential relationships and associations that might affect analyses or might indicate anemic cell sizes and violations of assumptions (expected frequencies) were explored using Pearson's and Spearman's correlations as appropriate for interval and ordinal data.

Subgroups were ruled out using tests of differences on study variables (dependent variables across subgroups) within extraneous categorical variables (e.g., gender differences on pain meds or LOS). Data were also analyzed to determine if assumptions for independent samples *t*-tests were violated and included tests for normality, homogeneity of variance and independence of continuous data (Field, 2005). If homogeneity of variance was violated then a non-parametric Mann-Whitney U test was performed. Ordinal data such as the pain intensity and interference data were analyzed using Mann-Whitney U tests. When data were poorly distributed and reflected small sample sizes, the exact method was employed to determine significance of the Mann-Whitney U tests in this study. The exact method allowed for a more accurate calculation of the significance of the Kruskal-Wallis test (Field, 205). Ordinal data correlations were performed using Spearman's correlations and interval data correlations were performed using Pearson's correlation (Field, 2005). If there were statistical differences between extraneous subgroup categories, then a two-way ANOVA was performed. If there were significant correlations between interval level variables then a one-way ANCOVA or a two-way ANCOVA were performed.

### **4.6 BOWEL SOUNDS**

	Rocking		Noni	rocking	
	n	%	n	%	р
Mean Time to Bowel Sounds (Days)					
Day 1	1	2.9	1	3.1	
Day 2	25	75.3	22	68.8	0.909
Day 3	8	23.5	9	28.1	

Table 5 Return of Bowel Sounds

Time to first bowel sounds data were normally distributed, homogeneous for both groups and indicated no significant differences (p < .909) between the rocking and nonrocking groups (Table 5). On average, there were no differences in time to first bowel sounds between the nonrocking (M = 2.25, SE = .090) and rocking (M = 2.21, SE = .082) groups (t (64) = .363, p = .718, d = .04). Pearson's correlation between time to first flatus and return of bowel sounds for combined groups was not significant (r = .231, p = .062) indicating that return of bowel sounds and time to first flatus were not associated. Bivariate correlations for each group revealed the nonrocking arm time to first flatus and return of bowel sounds were not correlated (r = .102, p = .579). However, the rocking group revealed a weak correlation between return of bowel sounds and time to first flatus and time to first flatus in the rocking group may be confounded by the shortened duration of POI in the same group whereby the time to first flatus was found to average 3.16 days.

## **4.7 PREOPERATIVE PAIN**

The preoperative baseline pain comparisons reported in Table 6 were conducted to determine differences between the rocking and nonrocking groups on preoperative pain and to identify painful conditions that may have confounded the accurate assessment of postoperative pain (abdominal surgical site and gas pain). The BPI-SF was administered preoperatively to all participants who signed an informed consent to participate in the study. Patients who agreed to participate in the study were asked if they were experiencing any type pain other than a headache or toothache. Distributions of location and type of preoperative pain and absence thereof were equal across both the rocking and nonrocking groups.

	Roc	king	Noni	rocking	72
	п	%	п	%	р
Pre-op Pain					
No (42, 63.6%)	22	64.7	20	62.5	1.000
Yes (24, 36.4%)	12	35.3	12	37.5	
Pre-op Med					
0 mg	33	97.1	30	93.7	0.477
10mg	1	2.9	2	6.3	
Pain Location					
None	23	67.6	22	68.8	
Neck	0	0.0	1	3.1	
Shoulder	2	5.9	1	3.1	

Table 6 Preoperative Pain Assessment

	Roc	king	Nonr	ocking	
	n	%	n	%	р
Pain Location (Cont'd)					
Hand	0	0.0	1	3.1	0.703
Knee	1	2.9	2	6.3	
Leg	1	2.9	2	6.3	
Chest	0	0.0	1	3.1	
Abdomen	3	8.8	2	6.3	
Back	4	11.8	2	6.3	
Type Pain					
None	23	67.6	20	62.5	
Sharp/Stabbing	2	5.9	1	3.1	
Burning	0	0.0	1	3.1	0.608
Pins/Needles	1	2.9	0	0.0	
Aching	8	23.5	10	31.3	

Total preoperative pain medication used each day, including narcotic pain medication, was analyzed to determine whether preoperative pain and medication use confounded the interpretation of postoperative pain and medication use. There were no differences between the rocking and nonrocking groups in the use of preoperative narcotic pain medication (p = .477). Thirty-three (97.1%) subjects in the rocking group and 30 (93.7%) in the nonrocking group reported no use of preop narcotic pain

medications preoperatively. Only one subject (2.9%) in the rocking group and two (6.3%) in the nonrocking group reported taking preop narcotic pain medication preoperatively.

If a patient reported that he or she was having pain at the time of assessment by the investigator, then the next question on the BPI-SF referring to pain location was presented. The patient was asked to place a mark on the body drawing illustration in order to show the location of the pain currently being experienced. Since the majority of both groups (rocking, n = 23, 67.6%; nonrocking, n = 22, 68.8%) indicated that they were not having pain at the time of assessment by the investigator, very few illustrations of body pain locations were marked.

For the few subjects who did report having pain (n = 12 in both groups) and marked the location on the illustration provided, there was a slightly greater modal distribution for abdominal and back pain in the rocking group (n = 3 and 4 respectively) compared to the nonrocking group (n = 2 and 2 respectively). Surprisingly, for this patient study group of individuals experiencing abdominal surgery due to digestive system cancers, there were very few who identified preoperative abdominal pain. The abdominal pain being experienced by each was described as vague pain that they were once told (not by this investigator) was related to the cancerous lesion and not the surgical site or gas pain. In one case, a rocking arm participant reported leg pain secondary to the effects of preoperative adjuvant chemotherapy. In another case, one nonrocking arm participant reported experiencing preoperative chest pain due to a fall he had taken at home just prior to arriving for his preoperative evaluation. Overall, there were no significant differences between the two groups on pain location (p = .703).

The types of preoperative pain descriptions accessed and recorded were those identified in the BPI-SF. The four pain types were sharp/stabbing, burning, pins/needles

and aching. The primary investigator asked each participant to report the type of pain they were experiencing if they were having pain. Of those reporting pain, the overwhelming majority in both groups (rocking, n = 8, 23.5%; nonrocking, n = 10, 31.3%) reported aching pain. Only one nonrocking patient reported burning pain resulting from peripheral neuropathies associated with side effects of preoperative adjuvant chemotherapy. Just one rocking participant reported pins/needles pain. However, pain types were not different between the two groups (p = .608).

## **4.8 TIME TO EVENTS**

The durations of surgery and anesthesia in hours for each group are summarized in Table 7. The duration of the surgery and anesthesia were important data points in this study because they have been implicated in reports of previous research as potential factors that may contribute to increased duration of POI (Behm & Stollman, 2003; Holte & Kehlet, 2000; Holte & Kehlet, 2002). The theoretical foundations of this study included the premise that the duration of POI is influenced by the body's sympatheticinduced response to over stimulation and stress imposed by large abdominal incisions and extensive manipulation and dissection of the bowel (Behm & Stollman, 2003; Holte & Kehlet, 2000; Holte & Kehlet, 2002). Both the duration of anesthesia and surgical procedures have been implicated as factors associated with surgical stress and are understood as being capable of increasing POI duration. Therefore, comparison of these two factors in this study was deemed vital to the determination of treatment effects.

Table 7 Anesthesia	and Surgery	7 Time
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Characteristics	Rocking	Nonrocking	р
	<i>n</i> = 34	n = 32	
Anesthesia Time (Hours)	4.77 + 2.50	4.03 + 2.13	
Mean (SD)	3.82	3.24	0.204
Median (Min, Max)	(2.10, 12.19)	(1.24, 9.36)	
Surgery Time (Hours)	3.61 + 2.35	3.01 + 2.08	
Mean (SD)	3.03	2.05	0.280
Median (Min, Max)	(1.02, 10.44)	(0.56, 7.23)	

Anesthesia time was not normally distributed for either group (nonrocking: D (32) = .238, p < .001; rocking: D (34) = .184, p < .005). However, Levene's test for homogeneity was not violated (F (1, 64) = .420, p = .519) and therefore the variances are equal. While the rocking group participants experienced slightly lengthier anesthesia times (M = 4.77, SE .429), than nonrocking participants (M = 4.03, SE = .376), this difference was not significant (t (64) = -1.284, p = .204, d = 0.15).

Surgery time was not normally distributed for either group (nonrocking: D(32) = .253, p < .001; rocking: D(34) = .165, p = 0.020). Levene's test for homogeneity was not violated (F(1, 64) = .055, p = .816) and therefore the variances are equal. While rocking participants experienced slightly lengthier surgical times (M = 3.60, SE .403), than nonrocking participants (M = 3.01, SE = .368), this difference was not significant (t (64) = -1.089, p = .280, d = 0.13).

Previous research indicates that one of the most distressing events of POI is the gas pain experienced by patients recovering from abdominal surgery (Moore et al. 1995; Thomas et al. 1990). During completion of the BPI-SF each morning all subjects were asked if they were experiencing gas pain. Table 8 presents the actual number and percent of patients in each group who experienced gas pain days 1-5 respectively.

Gas Pain	n	%	<i>MRank</i> Rocking	n	%	<i>MRank</i> Non Rocking	р	d
Day 1	0	0.0	33.00	1	3.1	34.03	0.485	-0.13
Day 2	6	18.0	33.32	6	19.0	33.69	1.000	-0.01
Day 3	10	29.4	30.21	16	50.0	37.00	0.130	-0.20
Day 4	5	15.0	29.85	12	38.0	37.38	0.049*	-0.26
Day 5	0	0.0	32.00	3	9.4	35.09	0.108	-0.22

Table 8 Percent Patients per Treatment Group with Gas Pain

The nonrocking participants, as a group, reported slightly higher, non-significant amounts of gas pain than the rocking group during Days 1, 3, and 5. During Day 2 no differences were detected and on Day 4 reports of gas pain were significantly higher (p = .049) in the nonrocking group. Among this study's participants, gas pain appears to have been minimally reported as the primary source of postoperative pain.

Patients recovering from abdominal surgery normally experience surgical site or incision pain. Surgical site pain was recorded as part of the BPI-SF each morning for both

groups. During completion of the BPI-SF each morning, all subjects were asked if they were experiencing surgical pain. Table 9 presents the actual number and percent of patients in each group who experienced surgical site pain days 1-5 respectively.

		Rockin $(n = 3)$	•		Nonroo $(n = 1)$	U		
Surgical Site Pain	n	%	MRank	n	%	MRank	р	d
Day 1	30	88.2	36.62	22	68.8	30.19	0.055	-0.24
Day 2	22	64.7	33.35	21	65.6	33.66	0.938	-0.01
Day 3	13	38.2	33.62	12	37.5	33.38	0.951	-0.01
Day 4	3	8.8	30.91	8	25.0	36.25	0.080	-0.22
Day 5	1	2.9	33.97	0	0.0	33.00	0.332	-0.12

Table 9 Percent Patients per Treatment Group with Surgical Site Pain

The rocking participants, as a group, reported slightly higher amounts of surgical site pain than the nonrocking group during Days 1, 3, and 5. The difference was found to be only marginally significant (0.055) on Day 1. On Days 2 and 4, the pain reported by the nonrocking group was slightly higher than in the rocking group. The difference between the groups on Day 4 was found to be only marginally significant (0.080). Among this study's participants, surgical site pain appears to have been equally reported as the primary source of postoperative pain and not gas pain as reported in previous research (Thomas et al., 1990).

## **4.9 Hypotheses Results**

The next section will discuss the four primary hypotheses of this dissertation in detail. The null hypothesis tested in this study was: There are no differences in the duration of POI, subjective reports of postoperative abdominal pain, total pain medication use, and postoperative recovery time among cancer patients recovering from abdominal surgery who receive the rocking intervention vs. the standard of care.

**SPECIFIC AIM 1:** To assess whether the rocking intervention reduces the mean time in days to passage of first flatus from the rectum in postoperative abdominal surgery patients compared to standard postoperative care patients.

**HYPOTHESIS 1:** There will be a difference in postoperative mean time to the passage of first flatus from the rectum between those patients who receive the rocking intervention and those who receive standard postoperative care.

Characteristics	Rocking $n = 34$	Nonrocking $n = 32$	р
Time to First Flatus (Days)			
Mean	3.16 <u>+</u> .86	3.88 <u>+</u> .80	
Median	2.96	3.82	0.001*
(Min, Max)	(1.4, 5.0)	(2.7, 5.7)	

Table 10 Times to First Flatus

Note: Significant p < .05.

The combined mean TTFF for both groups was 3.5 (SD = .90) days. Time to first flatus was normally distributed for both groups (nonrocking: D (32) = .115, p > .200; rocking: D (34) = .140, p = .092). Levene's test of homogeneity was not violated (F (1, 64) = .091, p = .764) indicating equal variances. The nonrocking group, on average, 106

experienced significantly longer time to passage of first flatus from the rectum (M = 3.88, SE = .1420), compared to the rocking arm (M = 3.15, SE = .1479), (t (64) = -3.542, p = .001) with the difference of medium effect size d = 0.40. Therefore, the null hypothesis that the means were equal was rejected and there was a significant difference between the means of the rocking and nonrocking times to first flatus providing support for Hypothesis 1.

**SPECIFIC AIM 2:** To assess whether mean pain intensity and interference scores could be reduced to a greater extent by rocking motion compared to standard postoperative care.

**HYPOTHESIS 2:** There will be a difference in mean subjective reports of postoperative pain intensity (worst, least, average and pain right now) and pain interference (general activity, mood, walking ability, relations with others, sleep and enjoyment of life) between those patients who receive the rocking intervention and those who receive standard postoperative care.

Each subject's pain was assessed for intensity and interference using the BPI-SF preoperatively and during each postoperative day. The purpose was to determine whether the mean pain intensity and interference ratings were affected by the rocking intervention and therefore different than the standard nonrocking arm. The pre-study assumption was that the rocking motion could possibly increase pain intensity ratings and may also result in limited rocking because of pain interference. Pain intensity and interference ratings were obtained each morning and recorded by the primary investigator to reduce error. Pain intensity and interference ratings were also collected in order to determine whether pain interfered with the ability of subjects to actually perform the

activities of getting out of bed to the rocking and nonrocking chairs and the ability to ambulate.

Characteristics	Rockin n = 34	•	Nonrock $n = 3$	•	р	d
Worst Pain	Mean/SD	Mrank	Mean/SD	Mrank		
Preop	1.21 <u>+</u> 2.17	34.51	1.06 + 2.15	32.42	0.592	-0.06
Day 1	6.74 <u>+</u> 2.93	36.16	5.91 + 3.17	30.67	0.242	-0.14
Day 2	5.15 <u>+</u> 2.88	33.18	5.25 + 2.86	33.84	0.887	-0.02
Day 3	3.38 <u>+</u> 3.14	29.59	4.66 + 2.71	37.66	0.084	-0.21
Day 4	1.53 <u>+</u> 2.50	30.74	2.38 + 2.84	36.44	0.171	-0.17
Day 5	0.18 <u>+</u> 1.02	32.03	0.47 + 1.29	35.06	0.162	-0.17
Least Pain	Mean/SD	Mrank	Mean/SD	Mrank		
Preop	0.38 <u>+</u> 1.01	35.31	0.13 <u>+</u> .421	31.58	0.205	-0.15
Day 1	2.18 <u>+</u> 2.22	35.40	1.69 <u>+</u> 1.75	31.48	0.395	-0.10
Day 2	0.97 <u>+</u> 1.24	30.54	1.41 <u>+</u> 1.43	36.54	0.174	-0.17
Day 3	0.56 <u>+</u> 1.05	31.25	1.00 <u>+</u> 1.48	35.89	0.253	-0.14
Day 4	0.35 <u>+</u> 0.69	31.53	0.69 <u>+</u> 1.20	35.59	0.281	-0.13
Day 5	0.06 <u>+</u> .24	32.38	0.19 <u>+</u> .54	34.69	0.328	-0.12

Table 11 Pain Intensity

			•	р	d
Mean/SD	Mra <i>nk</i>	Mean/SD	Mrank		
0.91 <u>+</u> 1.55	34.79	0.66 <u>+</u> 1.26	32.13	0.480	-0.08
3.97 <u>+</u> 2.14	37.06	3.19 <u>+</u> 2.19	29.72	0.117	-0.19
2.71 <u>+</u> 1.34	34.82	2.66 <u>+</u> 2.03	32.09	0.556	-0.07
1.59 <u>+</u> 1.52	29.26	2.28 <u>+</u> 1.51	38.00	0.056	-0.23
0.68 <u>+</u> 1.20	30.35	1.13 <u>+</u> 1.45	36.84	0.118	-0.19
0.09 <u>+</u> .51	32.03	0.19 <u>+</u> .54	35.06	0.162	-0.17
Mean/SD	Mrank	Mean/SD	Mrank		
0.47 + 1.13	34.29	0.31 + .74	32.66	0.606	-0.06
3.41 + 2.69	36.63	2.47 + 2.56	30.17	0. 165	-0.17
1.85 + 2.08	32.09	2.19 + 2.26	35.00	0. 528	-0.08
1.00 + 1.47	30.96	1.31 + 1.40	36.20	0. 237	-0.14
0.47 + 1.19	29.32	1.34 + 1.99	37.94	0. 027*	· -0.27
0.12 + .69	32.03	0.25 + .72	35.06	0. 162	-0.01
	$n = 34$ Mean/SD $0.91 \pm 1.55$ $3.97 \pm 2.14$ $2.71 \pm 1.34$ $1.59 \pm 1.52$ $0.68 \pm 1.20$ $0.09 \pm .51$ Mean/SD $0.47 \pm 1.13$ $3.41 \pm 2.69$ $1.85 \pm 2.08$ $1.00 \pm 1.47$ $0.47 \pm 1.19$	$0.91 \pm 1.55$ $34.79$ $3.97 \pm 2.14$ $37.06$ $2.71 \pm 1.34$ $34.82$ $1.59 \pm 1.52$ $29.26$ $0.68 \pm 1.20$ $30.35$ $0.09 \pm .51$ $32.03$ Mean/SDMrank $0.47 \pm 1.13$ $34.29$ $3.41 \pm 2.69$ $36.63$ $1.85 \pm 2.08$ $32.09$ $1.00 \pm 1.47$ $30.96$ $0.47 \pm 1.19$ $29.32$	$n = 34$ $n = 3$ Mean/SDMrankMean/SD $0.91 \pm 1.55$ $34.79$ $0.66 \pm 1.26$ $3.97 \pm 2.14$ $37.06$ $3.19 \pm 2.19$ $2.71 \pm 1.34$ $34.82$ $2.66 \pm 2.03$ $1.59 \pm 1.52$ $29.26$ $2.28 \pm 1.51$ $0.68 \pm 1.20$ $30.35$ $1.13 \pm 1.45$ $0.09 \pm .51$ $32.03$ $0.19 \pm .54$ Mean/SDMrankMean/SD $0.47 \pm 1.13$ $34.29$ $0.31 \pm .74$ $3.41 \pm 2.69$ $36.63$ $2.47 \pm 2.56$ $1.85 \pm 2.08$ $32.09$ $2.19 \pm 2.26$ $1.00 \pm 1.47$ $30.96$ $1.31 \pm 1.40$ $0.47 \pm 1.19$ $29.32$ $1.34 \pm 1.99$	$n = 34$ $n = 32$ Mean/SDMrankMean/SDMrank $0.91 \pm 1.55$ $34.79$ $0.66 \pm 1.26$ $32.13$ $3.97 \pm 2.14$ $37.06$ $3.19 \pm 2.19$ $29.72$ $2.71 \pm 1.34$ $34.82$ $2.66 \pm 2.03$ $32.09$ $1.59 \pm 1.52$ $29.26$ $2.28 \pm 1.51$ $38.00$ $0.68 \pm 1.20$ $30.35$ $1.13 \pm 1.45$ $36.84$ $0.09 \pm .51$ $32.03$ $0.19 \pm .54$ $35.06$ Mean/SDMrankMean/SDMrank $0.47 \pm 1.13$ $34.29$ $0.31 \pm .74$ $32.66$ $3.41 \pm 2.69$ $36.63$ $2.47 \pm 2.56$ $30.17$ $1.85 \pm 2.08$ $32.09$ $2.19 \pm 2.26$ $35.00$ $1.00 \pm 1.47$ $30.96$ $1.31 \pm 1.40$ $36.20$ $0.47 \pm 1.19$ $29.32$ $1.34 \pm 1.99$ $37.94$	$n = 34$ $n = 32$ $p$ Mean/SDMrankMean/SDMrank $0.91 \pm 1.55$ $34.79$ $0.66 \pm 1.26$ $32.13$ $0.480$ $3.97 \pm 2.14$ $37.06$ $3.19 \pm 2.19$ $29.72$ $0.117$ $2.71 \pm 1.34$ $34.82$ $2.66 \pm 2.03$ $32.09$ $0.556$ $1.59 \pm 1.52$ $29.26$ $2.28 \pm 1.51$ $38.00$ $0.056$ $0.68 \pm 1.20$ $30.35$ $1.13 \pm 1.45$ $36.84$ $0.118$ $0.09 \pm .51$ $32.03$ $0.19 \pm .54$ $35.06$ $0.162$ Mean/SDMrankMean/SDMrank $0.47 + 1.13$ $34.29$ $0.31 + .74$ $32.66$ $0.606$ $3.41 + 2.69$ $36.63$ $2.47 + 2.56$ $30.17$ $0.165$ $1.85 + 2.08$ $32.09$ $2.19 + 2.26$ $35.00$ $0.528$ $1.00 + 1.47$ $30.96$ $1.31 + 1.40$ $36.20$ $0.237$ $0.47 + 1.19$ $29.32$ $1.34 + 1.99$ $37.94$ $0.027^*$

\* Significant p < .05

Preop pain intensity and postop mean scores for pain intensity for days 1 - 5 were evaluated in both the rocking and nonrocking groups using a 0 -10 scale anchored by 0 = no pain and 10 = pain as bad as you can imagine. Data analysis results for the ordinal data representing worst, least, average and right now pain intensity are presented in Table 11. Non-parametric tests (Mann-Whitney U) were used to evaluate the pain intensity data.

There were no significant differences in *worst* pain intensity between the rocking and nonrocking groups both on the preoperative measure and on postop days 1 - 5 respectively, except for Day 3 when the nonrocking mean score was marginally significantly higher (p = .08) than the mean score for the rocking group.

There were no significant differences in *least* pain intensity between the rocking and nonrocking groups preoperatively and on Days 1-5, respectively. The pattern of least pain between the groups was slightly higher preop and on Day 1 for the rocking group and then lower Days 2-5 compared to the nonrocking group.

There were no significant differences in *average* pain intensity between rocking and nonrocking groups preoperatively and on Days 1-5 respectively, except for Day 3 when the nonrocking mean score was marginally, significantly higher (p = .056) than the rocking group.

Pain right now is the pain one was experiencing at the time the BPI-SF pain assessment was administered by the primary investigator each morning after surgery. There were no significant differences in *pain right now* intensity between the rocking and nonrocking groups at the preoperative assessment and on Days 1 - 5 respectively, except Day 4 when the nonrocking mean score (*Mrank* = 37.94) was significantly (*MW-U* = 402.00, z = -2.207, 2-tailed Exact p = .027) higher than the rocking (*Mrank* = 29.32) and displayed a small effect size (d = -0.27). Therefore, the null hypothesis that the means and mean ranks were equal was not rejected for the preoperative time and for Days 1, 2, 3 & 5. There was no significant difference between the mean ranks of the rocking and nonrocking pain in regard to worst, least, average and pain right now pain intensity, respectively. Although the alternate hypothesis regarding the detection of significant differences was accepted for Day 4, the number of analyses conducted and test-wise error considerations strongly support a conservative and limited interpretation of this finding.

Pain interference is the second pain dimension evaluated by the BPI-SF. It includes general activity, mood, walking ability, relations with other people, sleep and enjoyment of life. Pain interference was assessed preoperatively and on each postoperative day until the passage of first flatus. Preop and postop mean scores for pain interference by treatment groups were evaluated for Days 1 - 5 using a 0 -10 scale anchored by 0 (does not interfere) and 10 (completely interferes). Data analysis results for the ordinal data representing (general activity, mood, walking ability, relations with other people, sleep and enjoyment of life) interference are presented in Table 12. Non-parametric tests (Mann-Whitney U) were used to evaluate the pain interference data.

Characteristics	Rocking (n	a = 34)	Nonrocking	( <i>n</i> = 32)	р	d
General Activity	Mean/SD	Mrank	Mean/SD	Mrank		
Preop	1.03 + 2.34	34.74	0.66 <u>+</u> 1.94	32.19	0.406	-0.10
Day 1	4.50 + 4.02	33.50	4.53 <u>+</u> 3.93	33.50	1.000	-0.00
Day 2	3.68 + 3.16	31.56	4.34 <u>+</u> 3.23	35.56	0.390	-0.10
Day 3	1.97 + 2.61	31.47	2.59 <u>+</u> 2.96	35.66	0.349	-0.11
Day 4	0.53 + 1.81	31.84	1.06 <u>+</u> 2.34	35.27	0.264	-0.14
Day 5	0.18 + 1.03	33.97	$0.00 \pm 0.00$	33.00	0.332	-0.12

Table	12 Pa	in Inter	ference
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Characteristics	Rocking (r	<i>i</i> = 34)	Nonrocking	( <i>n</i> = 32)	р	d
Mood	Mean/SD	Mrank	Mean/SD	Mrank		
Preop	0.91 <u>+</u> 2.79	34.44	0.34 <u>+</u> 1.49	32.5	0.410	-0.10
Day 1	3.26 <u>+</u> 3.68	37.03	01.88 <u>+</u> 3.21	29.75	0.087	-0.21
Day 2	1.56 <u>+</u> 2.51	32.60	1.88 <u>+</u> 2.72	34.45	0.657	-0.05
Day 3	1.62 <u>+</u> 2.69	35.87	0.88 <u>+</u> 1.95	30.98	0.211	-0.15
Day 4	0.41 <u>+</u> 1.35	33.85	0.41 <u>+</u> 1.39	33.13	0.773	-0.04
Day 5	0.15 <u>+</u> 0.86	33.97	$0.00 \pm 0.00$	33.00	0.332	-0.12
Walking Ability	Mean/SD	Mrank	Mean/SD	Mrank		
Preop	0.53 <u>+</u> 1.64	32.85	0.72 <u>+</u> 1.85	34.19	0.636	-0.05
Day 1	4.41 <u>+</u> 4.16	36.22	3.38 <u>+</u> 4.23	30.61	0.213	-0.15
Day 2	3.32 <u>+</u> 3.20	29.16	4.84 <u>+</u> 3.22	38.11	0.056	-0.24
Day 3	1.50 <u>+</u> 2.23	32.09	2.00 <u>+</u> 2.66	35.00	0.497	-0.08
Day 4	0.62 <u>+</u> 2.06	31.44	1.13 <u>+</u> 2.60	35.69	0.182	-0.02
Day 5	$0.00 \pm 0.00$	33.00	0.06 <u>+</u> 0.35	34.03	0.303	-0.13

Characteristics	Rocking (n	= 34)	Nonrocking	( <i>n</i> = 32)	р	d
Relations with Others	Mean/SD	Mrank	Mean/SD	Mrank		
Preop	0.82 + 2.53	34.44	0.28 + 1.17	32.50	0. 410	-0.10
Day 1	2.85 + 3.74	37.25	1.22 + 2.34	29.52	0.060	-0.23
Day 2	1.44 + 2.63	30.26	2.38 + 2.99	36.94	0. 109	-0.20
Day 3	0.91 + 2.11	33.22	0.91 + 1.77	33.80	0. 871	-0.02
Day 4	0.29 + 1.09	34.31	0.31 + 1.26	32.64	0. 479	-0.08
Day 5	0.00 + 0.00	33.50	0.00 + 0.00	33.50	1.000	-0.00
Sleep	Mean/SD	Mrank	Mean/SD	Mrank		
Preop	1.03 + 2.69	33.46	0.88 + 2.43	33.55	0.975	-0.003
Day 1	3.06 + 4.01	32.51	3.38 + 3.84	34.55	0.643	-0.06
Day 2	2.15 + 3.36	31.28	3.06 + 3.38	35.86	0.293	-0.13
Day 3	1.15 + 1.70	32.99	1.81 + 2.92	34.05	0.799	-0.03
Day 4	0.21 + 0.78	30.74	1.09 + 2.36	36.44	0.063	-0.23
Day 5	0.00 + 0.00	32.50	0.13 + 0.49	34.56	0.142	-0.18

Characteristics	Rocking (n	= 34)	Nonrocking (	(n = 32)	р	d
Enjoyment of Life	Mean/SD	Mrank	Mean/SD	Mrank		
Preop	0.91 + 2.71	33.47	0.63 + 2.01	33.53	0.982	-0.003
Day 1	4.32 + 4.34	35.50	3.34 + 3.75	31.38	0.360	-0.11
Day 2	2.24 + 3.07	33.13	2.53 + 3.52	33.89	0.860	-0.02
Day 3	1.56 + 2.66	32.97	1.84 + 3.06	34.06	0.789	-0.03
Day 4	0.56 + 1.93	31.91	0.72 + 1.92	35.19	0.286	-0.13
Day 5	0.12 + 0.69	33.47	0.13 + 0.71	33.53	0.966	-0.005

There were no significant differences in pain interference with *general activity* between rocking and nonrocking groups preoperatively and on Days 1-5, respectively. The pattern of interference between the groups was slightly higher preoperatively and on Day 5 for the rocking group and then lower on Days 1-4 compared to the nonrocking group.

There were no significant differences in pain interference on the *mood* dimension between the rocking and nonrocking groups preoperatively and on Days 1-5, respectively. On Day 1 the rocking mean score was marginally, significantly higher (p =.087, d = -0.21) than the nonrocking group. There was a pattern of higher mood interference in the rocking group at the preop and Days 1, 3, 4 and 5 for the rocking group and was lower on Day 2 compared to the nonrocking group.

There were no significant differences in mean and mean rank scores for pain interference with *walking ability* preoperatively and on Days 1-5 respectively, except for Day 2 when the nonrocking pain interference with walking ability mean rank scores (*Mrank* = 38.11) were marginally, significantly higher than in the rocking group (*Mrank* = 29.16), (*MW-U* = 396.50, z = -1.915, 2-tailed Exact p = .056), but with a minimal effect size (d = -0.24). The pattern of higher pain interference with walking ability between the groups occurred preop and Days 3, 4 and 5 nonrocking and did not hold for Day 1 when scores in the rocking group were higher.

There were no significant differences in mean and mean rank scores for pain interference with *relations with others* preoperatively and on Days 1-5 respectively, except for Day 1 when the nonrocking mean rank scores (*Mrank* = 29.52) were marginally, significantly lower than in the rocking group (*Mrank* = 37.25), (*MW-U* = 416.50, z = -1.887, 2-tailed Asymptotic p = .06), but with a minimal effect size (d = -0.23). The pattern of higher between group interference with relations with others occurred preoperatively and on Days 1 and 4 for the rocking group but was lower on Days 2 and Day 3 and equivalent to the nonrocking group on Day 5.

There were no significant differences in pain interference with sleep between the rocking and nonrocking groups preoperatively and on Days 1-5, respectively except for Day 4 when the nonrocking pain interference with sleep mean rank scores (*Mrank* = 36.44) were marginally, significantly higher than in the rocking group (*Mrank* = 30.74), (*MW-U* = 450.00, z = -1.858, 2-tailed Asymptotic p = .06), but with a minimal effect size (d = -0.23).. The pattern of higher sleep interference for the nonrocking group compared to the rocking group occurred preoperatively and on Days 1 – 5 respectively.

There were no significant differences in pain interference with enjoyment of life between rocking and nonrocking groups preoperatively and on Days 1-5, respectively. The pattern of higher enjoyment of life interference between the groups occurred at Day 1 in the rocking group compared to the nonrocking group, which experienced higher levels of pain interference with enjoyment of life preoperatively and on Days 2, 3, 4 and 5.

**SPECIFIC AIM 3:** To assess whether the rocking motion is more effective in reducing total mean pain medication milligrams received compared to standard postoperative care.

**HYPOTHESIS 3:** There will be a difference in the mean total pain medication in milligrams received between those patients who receive the rocking intervention and those who receive standard postoperative care.

Total pain medication in milligrams was obtained preoperatively and each twentyfour hour period postoperatively until the subject passed first flatus from the rectum for both the rocking and nonrocking groups. Data are presented in Table 13.

Characteristics	Rocking $n = 34$	Nonrocking n=32	р
Pain Medication Received (Mgs.)			
Mean	29.35 <u>+</u> 58.99	36.48 <u>+</u> 51.66	
Median	5.16	6.31	0.604
(Min, Max)	(0.58, 275.0)	(0.86, 168.9)	

Analysis of total pain medication received revealed non-normality for both groups (nonrocking, D (32) = .298, p < .001; rocking D (34) = .335, p < .001). However, Levene's test for homogeneity was not violated (F (1, 64) = .243, p = .624) and therefore the variances are assumed to be equal. The total pain medication in milligrams received was, on average, greater for the nonrocking group (M = 36.48, SE = 9.13), compared to

the rocking arm (M = 29.35, SE = 10.11) but this difference was not statistically significant (t (64) = .521, p = .604, d = 0.06). Therefore, the null hypothesis that the means were equal was not rejected and there was no significant difference between the means of the rocking and nonrocking groups on total pain medication in milligrams received indicating a lack of support for Hypothesis 3.

**SPECIFIC AIM 4:** To assess whether mean time in days to hospital discharge is reduced by treatment with rocking motion compared to standard postoperative care.

**HYPOTHESIS 4:** There will be a difference in mean time to discharge between those patients who receive the rocking intervention and those who receive standard postoperative care.

Characteristics	Rocking $n = 34$	Nonrocking $n = 32$	р
Time to Discharge (Days)			
Mean	7.69 <u>+</u> 4.57	7.89 <u>+</u> 3.20	
Median	5.95	6.96	0.837
(Min, Max)	(3.1, 23.8)	(3.9, 15.9)	

Analysis of time to discharge revealed non-normality for both groups (nonrocking, D(32) = .181, p = .009; rocking, D(34) = .251, p < .001). However Levene's test for homogeneity was not violated (F(1, 64) = .736, p = .394) and therefore the variances are assumed equal. The time to discharge data with the outliers included indicated that the nonrocking group experienced an essentially equal number of days in

the hospital (M = 7.89, SE = .56), compared to the rocking arm (M = 7.69, SE = .78), (t (64) = .206, p = .837, d = 0.02).

Removal of outliers with a time to discharge greater and equal to ten days improved normality (D(25) = .160, p = .098) for the nonrocking group (n = 25) as well as for the rocking group (n = 28) (D(28) = .156, p = .081). The Levene's test for homogeneity was nonsignificant (F(1, 51) = .137, p = .712). The data without the outliers revealed that the nonrocking group experienced slightly more days in the hospital (M = 6.43, SE = .29), compared to the rocking arm (M = 5.95, SE = .27) although this difference was not significant (t(51) = 1.196, p = .237; d = 0.17). Therefore, the null hypothesis that the means were equal was not rejected and there was no significant difference between the means of the rocking and nonrocking time in days to discharge from the hospital providing a lack of support for Hypothesis 4.

This concludes the presentation of findings by order of specific aims and hypotheses. The discussion of the findings is presented in Chapter V along with conclusions, recommendations, and implications.

# **CHAPTER V: CONCLUSIONS**

#### 5.1 REVIEW OF THE GOALS AND OBJECTIVES

The overall aim of this randomized, experimental posttest only control group study was to examine differences in the duration of POI, subjective reports of postoperative pain intensity and interference, pain medication use and postoperative recovery time between two groups of postoperative abdominal surgery cancer patients; one receiving standard postoperative care and one receiving the rocking chair intervention.

The null hypothesis (H0) tested in this study was: There are no differences in the duration of return to flatus (POI), subjective reports of postoperative abdominal pain, total pain medication use, and postoperative recovery time among cancer patients recovering from abdominal surgery who receive the rocking intervention vs. the standard of care. Patients randomized to the rocking arm were instructed to get out of bed and begin rocking in a rocking chair and ambulating beginning the first postoperative day. Patients randomized to the nonrocking standard of care arm were instructed to get out of bed beginning the first postoperative day and sit in a nonrocking chair and ambulate beginning the first postoperative day.

# 5.2 SUMMARY OF INDIVIDUAL HYPOTHESES AND FINDINGS

A brief summary of the findings and their meanings is presented in the following sections, organized by the study's hypotheses and aims.

**HYPOTHESIS 1:** There will be a difference in postoperative mean time to the passage of first flatus from the rectum between those patients who receive the rocking intervention and those who receive standard postoperative care.

**SPECIFIC AIM 1:** To assess whether the rocking intervention reduces the mean time in days to passage of first flatus from the rectum in postoperative abdominal surgery patients compared to standard postoperative care patients.

A significant difference in the group means (p < .001) on TTFF, reported in Chapter IV, directed the investigator to reject the null hypothesis and conclude that the rocking intervention played a role in shortening POI recovery time. The rocking motion tested previously by Thomas et al. (1990) and Moore et al. (1995) also was found to mitigate POI duration under similar conditions but with different postoperative samples of patients. Although the sample size for this study was small, there was significant clinical support for the use of rocking motion as a mediator of the surgical stress response. An effect size (d = .40) supported the clinical implication that a reduction in duration of .7 day (16.8 hours) is of significant magnitude for both patients with POI and the clinicians managing them. The findings of this study support Hypothesis 1 and make a contribution to the growing body of evidence that suggests the rocking motion may shorten time to passage of first postoperative flatus in postoperative abdominal surgery cancer patients.

**HYPOTHESIS 2:** There will be a difference in mean postoperative subjective reports of pain intensity (worst, least, average and pain right now) and pain interference (general activity, mood, walking ability, relations with others, sleep and enjoyment of life) between those patients who receive the rocking intervention and those who receive standard postoperative care.

**SPECIFIC AIM 2:** To assess whether mean pain intensity and interference scores could be reduced to a greater extent by rocking motion compared to standard postoperative care.

Using the Brief Pain Inventory Short Form (BPI-SF) preoperatively for baseline data and daily following surgery to assess each patient's pain severity and interference (Daut & Cleeland, 1983; Zalon, 2006), it was found that the distributions of preoperative pain location, type, intensity and interference and absence were equal across both the rocking and nonrocking groups and failure to reject the null hypothesis. Rocking motion made no detectable differences in subjects' reports of perceived pain intensity and interference. Reports of preoperative, lesion-related pain and discomfort that the investigator anticipated hearing about from subjects during the preoperative administration of the BPI-SF did not materialize. This finding can be considered important to clinical practice in that it introduces variability into the assumptions and generalizations that practitioners make about most, if not all, patients with digestive system cancers have lesion-related pain. Implications for patient teaching about cancer symptom recognition and nursing assessments of patients with abdominal lesions are important to translate into practice.

Findings on Day 4 related to the marginally significant difference in worst pain intensity (higher in the nonrocking group) warrant further investigation as do the findings that reveal a pattern of lower pain intensity in the rocking group during Days 2 through 5. While these patterns were not statistically significant findings, patterns can contribute to the clinical significance of findings if investigated further in replication studies and studies that use larger samples and more rigorous controls. The significant finding of higher pain right now mean scores on Day 4 in the nonrocking group and their higher pain-related sleep interference scores (non-significant) add to this investigator's curiosity about Day 4 in the life of a recovering postoperative abdominal surgery patient. However, caution is exercised to avoid the over-interpretation of any patterns of nonsignificant findings as well as any single significant result.

Pain interference with general activity was slightly higher preoperatively and on Day 1 for the rocking group. Scores were lower on Days 2-5. While not statistically significant, clinicians can use this finding to begin to explore postoperative pain control and manipulation of pain interference more extensively on Day 1. Given the significant findings for Aim 1 and the knowledge that early activity following surgery reduces the patient's risks for complications, controlling early postoperative pain and pain interference may be fruitful areas for more research. A question might be, "If pain is better controlled on Day 1, will patients rock more often and effectively?" This question is not yet in the form of a research question complete with hypotheses and aims, but it represents a beginning thought process that follows the interpretation of this study's findings. This investigator's curiosity about Day 1 pain interference also extends to include the marginally, statistically significant higher pain interference with mood scores in the rocking group on Day 1 and the higher pattern of pain interference with enjoyment of life. It is the Day 1 findings about several dimensions of pain measured by the BPI-SF that, examined together, stimulate new ideas for further research to promote interventions that potentially increase Day 1 postoperative pain control and activity for abdominal surgery cancer patients.

Despite marginal significance and patterns found among several dimensions of pain and discomfort, overall, there were no significant differences in pain interference between the groups and therefore Hypothesis 2 was not supported. **HYPOTHESIS 3:** There will be a difference in the mean total pain medication in milligrams received between those patients who receive the rocking intervention and those who received standard postoperative care.

**SPECIFIC AIM 3:** To assess whether the rocking motion is more effective in reducing total mean pain medication milligrams received compared to standard postoperative care.

Findings for total pain medication used each 24 hour period until passage of first flatus revealed that, on average, more milligrams of medication were used by the nonrocking group compared to the rocking group. While a pattern of higher use is clinically supported, the findings were not statistically significant and therefore the null hypothesis that the means were equal was not rejected and Hypothesis 3 was not supported. There are several conclusions that can be drawn from these findings; however caution is necessary to avoid over-interpretation. Of course the tendency is to support rocking as an intervention that not only significantly reduces TTFF in postoperative abdominal surgery cancer patients, but may influence a reduction in need for pain medication in those who rock. Speculation about the physiologic surgical stress response and its mediation by relaxation-induced rocking requires further investigation using larger samples and more rigorous controls.

**HYPOTHESIS 4**: There will be a difference in mean time to discharge between those patients who receive the rocking intervention and those who receive standard postoperative care.

**SPECIFIC AIM 4:** To assess whether mean time in days to hospital discharge is reduced by treatment with rocking motion compared to standard postoperative care.

The time to discharge data with the outliers included indicated that the nonrocking and rocking groups experienced essentially an equal number of postoperative days in the hospital. Removal of outliers with a time to discharge of greater than or equal to ten days improved normality for both the nonrocking and the rocking groups, respectively. With outliers removed, the nonrocking group experienced slightly more days in the hospital although this difference was not statistically significant (p = .237). Therefore, the null hypothesis that the means were equal was not rejected and Hypothesis 4 was not supported. It remains clear that more investigations of rocking and time to discharge are required before conclusions can be drawn. Several variables in this study beg further investigation of relationships as well as differences. Patterns across days regarding pain intensity and dimensions of pain interference and time to discharge may be priorities for future research in this area of inquiry.

## **5.3 DISCUSSION**

The problem of postoperative ileus (POI) remains a troubling phenomenon that complicates the comfort and recovery of abdominal surgery patients. It has not been an overwhelmingly popular focus of clinical trials over the past century, despite its role in extending the patient's hospital stay and increasing the costs of health care. While much of the theory and research literature describe POI as a transient problem for postoperative patients, its complications and costs can have far-reaching consequences (Waldhausen et al., 1990).

The results of this study indicate that the rocking intervention was successful in reducing the duration of POI as evidenced by shorter times to first passage of postoperative flatus for patients who followed the rocking protocol rather than the nonrocking standard of care. Thomas et al. (1990) first described the successful use of

alternative and complimentary therapy such as rocking chair motion to mitigate the effects of POI but did not specifically measure time to passage of first flatus. However, they did report that patients did in fact pass flatus more rapidly than the nonrocking group allowing the rocking group to be discharged from the hospital one day earlier. Disbrow et al. (1993) utilized specific instructions for the early return of gastrointestinal motility versus standard of care instruction as the intervention in their randomly assigned comparison study after intra-abdominal surgery and a significantly shorter time to return on intestinal motility was obtained (2.6 versus 4.1 days) respectively for the instruction and standard of care group (p < .05). The results of this dissertation revealed an average reduction in time to passage of first flatus after abdominal surgery of .7 days (16.8 hours) that was less than the Disbrow, Bennett and Owings study (1.5 days, 36 hours) conducted in 1993. The pathogenesis of POI is multifactorial and requires a multimodal set of interventions (Holte & Kehlet, 2002). Numerous interventions have been tried to date in order to reduce the duration of POI with minimal effect. The results of this dissertation does demonstrate clinical support due to a medium effect size (d = .40) that the rocking motion indeed has potential as a low cost easy to apply intervention to reduce duration of POI requiring future study with larger samples and different populations.

However, rocking had no effect on reducing the amount of milligrams of pain medication used for surgical pain relief. In fact, in some cases milligrams used were found to be higher among the rocking group versus the nonrocking group. The results of this dissertation validated the results reported by Thomas et al. (1990) that rocking motion did not reduce the amount of narcotic consumption between the rocking. Tusek et al. (1997) compared the use of randomly assigned guided imagery to patients undergoing colorectal surgery and measured total narcotic consumption. The guided imagery group used less (Mdn = 185) mg narcotic than the nonimagery group (Mdn = 326) mg (p < .001). Disbrow et al. (1993) reported the suggestion group received (M = 108.7, SD = 117.5) milligrams compared to the control group (M = 87.0, SD = 67.5) milligrams and did act as a covariant (r (39) = .37, p < .05). The subjects in this dissertation did not receive only one method of pain management (patient controlled intravenous analgesia) as in the Disbrow, Thomas and Tusek studies. Due to lack of significant differences between the rocking and nonrocking groups' narcotic consumption there was also no indications of covariation with time to first flatus. Subjects in this dissertation study also received patient controlled epidural analgesia and patient controlled intravenous analgesia and this may have contributed to the lack of differences in total narcotic consumption. The results of this dissertation on total pain medication received provide for future research using a homogeneous population of one pain medication route of delivery in order to more reliably determine the effects of rocking motion on narcotic pain medication received.

Pain intensity and interference ratings did not demonstrate any statistically significant decreases as a result of the rocking motion. However, once again in some instances, the rocking group experienced worse pain intensity and interference than the nonrocking group. Nurses need reliable and valid instruments to use in pain assessment (Tittle et al., 2003). Evidence of the BPI-SF's ability to measure pain intensity and interference the first three to five days after surgery for older abdominal surgical patients was considered important to this investigator as it was presumed a significant number of subjects would have repeated measures of pain intensity and interference post surgery during the duration of POI. Tittle et al. (2003) examined the psychometric characteristics of the BPI-SF for surgical patients with cancer (N = 388) comparing the validity and

reliability results between surgical (n = 159) and medical (n = 229) patients with cancer in a descriptive correlational study conducted in two veterans hospitals. A variety of cancer diagnoses were reported in the study including 35 (22%) patients with colorectal types who underwent abdominal surgery as a treatment intervention. The BPI-SF was administered to patients once and a VAS pain scale three times to both medical and postoperatively in surgical patients. The main research variables were pain at its worst and least, current pain intensity (pain right now), average pain intensity, and pain relief. The first three postop days mean worst pain intensity for the Tittle et al. study was higher for the surgical patients (M = 8.3, SD = 2.8) compared to rocking (M = 3.4, SD = 2.94) and nonrocking (M = 3.7, SD = 2.57) groups combined five day mean worst pain intensity levels indicated in this dissertation. Least and average pain combined mean scores for the rocking and nonrocking groups compared to the least and average pain scores in the Tittle study were similar. Pain right now scores for this dissertation were (M = 1.37, SD = 1.62) rocking and (M = 1.52, SD = 1.78) nonrocking compared to (M = 1.52, SD = 1.78)5.2, SD = 2.6) in the Title et al. study surgical patients. Worst pain and pain right now were slightly higher in the surgical patients than least and average pain intensity which was higher in the medical patients in the Tittle et al. study. This finding indicates that measuring worst and pain right now are more reflective of surgical patient pain and this method was used as the primary pain intensity outcomes for this dissertation. Collectively, lower levels of pain right now were recorded in this dissertation patient population and may be due to the aggressive pain management that included all patients receiving continuous patient controlled analgesia provided by an acute pain management team at the institution where this dissertation study was conducted. The Tittle et al. study participants received as needed pain management techniques that may have led to higher

overall pain intensity scores versus the continuous basal and patient controlled analgesia methods of pain management provided to participants in this dissertation. Tittle et al. reported correlations of pain interference with visual analog scales but did not report means or mean ranks and therefore not allowing for comparison with the results of this dissertation. Other studies included in the literature review failed to report the means and standard deviations for pain interference and instead reported correlations with other instruments and concepts (Good, et al. 2000; Zalon, 1999; Zalon, 2004). Evidence of the BPI-SF's ability to measure pain intensity and interference the first three to five days after surgery for older abdominal surgical patients was considered important to this investigator as it was presumed a significant number of subjects would have repeated measures of pain intensity and interference post surgery during the duration of POI. Tan et al. (2003) recorded seven pain interference mean scores and standard deviations of patients with chronic non malignant pain. General activity (M = 7.70, SD = 2.38), walking ability (M = 7.39, SD = 2.73) and sleep (M = 7.67, SD = 2.56) for the Tan et al. study were higher than the general activity, walking ability and sleep interference results recorded for the rocking and nonrocking groups in this dissertation. Chronic nonmalignant pain is a different type of pain compared to acute post surgical pain and may account for the disparity (Burton & Cleeland, 2001). For this dissertation, it was important to determine if the subjects experienced pain interference with general activities that may involve transferring to and from the bed to chair, rocking, walking ability and the healing value of sleep. The results of pain interference recorded in this dissertation indicate that this was not the case for this patient population.

Rocking also did not reduce the amount of time to discharge from the hospital in this study. There was wide variation in the time to discharge and multiple factors were probably involved in affecting Time to Discharge. Previous research by Thomas et al., (1990) a greater proportion of the rocking group versus the nonrocking group (Chi-square = 15.89, p = .0012) were discharged at least one day earlier. Disbrow et al. (1993) reported a mean duration of time to discharge 6.6 days (SD = 7.2) for the information group compared with the control 8.1 days (SD = 5.3) using ANCOVA that was not significant (F (1, 37) = .60, p > .05). Tusek et al. (1997) reported median Time to Discharge for the imagery patients 6.2 (range 4-31) days that was not significantly different from the control group (6.4, range, 2.9 - 30.1) days. Mean time to discharge for the rocking group (M = 7.69, SD = 4.57) and nonrocking (M = 7.89, SD = 3.20) were not significantly different and appeared to be affected by the similar issues with the minimum and maximum (rocking 3.1 - 23.8, nonrocking 3.9 - 15.9) ranges of time until discharge results in this dissertation therefore leading to the conclusion that future research is needed to determine what, if any, effects the duration of POI has on time to discharge.

Two variables that were thought to potentially affect the time to first flatus were time spent rocking in the rocking chair or sitting in the nonrocking chair, and the distance each subject ambulated. However, there were no differences between the two study groups regarding time in the chair (rocking or nonrocking) and ambulating. Reports of prior research do not address the exact amount of time subjects spent rocking in rocking chairs, although recommendations to rock in 10 - 20 minute increments for at least 60 minutes to affect a relaxation response were put forth and designed as interventions in this study (Moore et al. 1995; Thomas et al. 1990).

Since the early 1900s, post-surgical patient orders and suggestions to patients by physicians have included getting out of bed, sitting in a chair and ambulating beginning the first postoperative day and increasing the amount of time spent out of bed in the chair and distance ambulated each day following. Waldhausen and Schirmer (1990) were the first to identify the positive effects of being out of bed and ambulating after abdominal surgery and praised the positive effects but did not suggest optimal amounts spent completing each activity. Others have more recently included these two activities as components of the concept that a multi-modal approach is needed to resolve such a multi-factorial phenomenon as POI (Holte & Kehlet, 2001; Kehlet & Holte, 2002). However, none have maintained and or presented any data of the amount of time spent in the rocking and nonrocking chair nor the distance ambulated for these two potential covariates. This study attempted to quantify the amount of time spent in the rocking and nonrocking chairs and distance ambulated.

In studies like this one and those cited throughout the dissertation, time out of bed and type of out-of-bed activity following surgery are important to patient outcomes and health care costs. Unfortunately, performances of instruments and other measures are prone to failure and error. In this study, measuring number of rocks (rock cycles) and distances walked (ambulation) proved to be problematic. That is, the use of the pedometers to track the numbers of rocks rocked and steps taken did not work. The alternative, less accurate measure of time spent sitting up in the chair and laps taken around the nursing care unit were recorded in bedside diaries that required patient and nurse recall. The skewness of these data informed the investigator that they had no use in data analysis and therefore are not reported. While other researchers have reported successfully using pedometers to measure activity in like studies (Montoye, 2000; Welk et al. 2000; Vincent & Sidman, 2003) and while this investigator calibrated and piloted the use of the pedometers the use of the pedometers in preparation for this study, their performance was unreliable. Other researchers have also struggled with selecting sensitive, specific, and reliable tools when conducting reliable studies (Moore et al, 1995). Moore et al. (1995) recommended counting the number of rocks using mercury counters; however, mercury has been banned from hospital use in the United States and therefore was not an option. There were no other non mercury counters available for use by this investigator despite extensive and exhaustive searching and inquiry with the institutional biomedical division. Observations made by this researcher reveal that the pedometer worn at the waist line is not appropriate for use with the post abdominal surgical patient as a recorder of activity distance. The patients walk very cautiously and not vigorous enough to present a consistent rise and fall of the iliac crest which is essential to stimulate the armature that records steps by the Yamax Digi-Walker pedometer (Welk et al. 2000).

Yet another controversial measure reported in the literature related to using the return of bowel sounds as an indicator of the return of gastrointestinal motility came to the fore in this study (Davis et al., 2002; Huge et al. 2000; Le Blanc-Louvry et al., 2002; Luckey et al., 2003; Madsen et al. 2005 Miedema & Johnson, 2003; Schuster & Montie, 2002; Shaheen, 2002; Waldhausen, et al., 1990). While bowel sounds were decidedly not the indicator of choice used in this study to evaluate the resolution of POI, the standard of care for all postoperative patients requires that nurses assess and record the absence and presence of bowel sounds on a regular basis each postoperative day. Thus, records of each patient's postoperative bowel sound status were available to this investigator and were tested on a trial and error basis to ascertain any correspondence between them and

TTFF. Given the lack of statistical evidence to support any correspondence between TTFF and the presence of bowel sounds in this study, the earlier decisions of this investigator to not include the return of bowel sounds as an outcome measure of POI's presence and resolution are further reinforced and supported. Most recently, Madsen et al. (2005) also found similar results.

Another unique finding from this dissertation involved the type of pain reported. Thomas et al, (1990) reported that gas pain secondary to the build-up within the intestinal tract due to POI and the rocking group experienced less gas pain than the nonrocking groups. In general the Thomas et al. study reported lower rank scores in the rocking than the nonrocking group, based on mean scores for pain and analyzed mean gas pain scores to determine if a significant difference existed between gas pain scores for the rocking and nonrocking groups using t test. A significant difference in mean gas pain scores for the rocking and nonrocking groups on Day 1 (p = .002), Day 2 (p = .0001), and Day 3 (p= .0005) was reported and the greatest difference between mean gas pain scores for the rocking and nonrocking chair groups was Day 2 indicating the rocking participants reported less gas pain (Thomas et al., 1990). The nonrocking participants in this dissertation, as a group, reported slightly higher, non-significant amounts of gas pain than the rocking group during Days 1, 3, and 5. During Day 2 no differences were detected and on Day 4 reports of gas pain were significantly higher (p = .049) in the nonrocking group. Among this study's participants, gas pain appears to have been minimally reported as the primary source of postoperative pain. The finding from this dissertation supports the Thomas et al. study that the nonrocking groups rank gas pain higher than the rocking groups but does not support gas pain as the most reported pain causing distress as hypothesized and reported by Thomas et al. Surgical site pain was the most often cited

pain type in this dissertation and not gas pain. Unfortunately, the Thomas et al. study used parametric statistics to evaluate ordinal pain data and their outcomes may not have been as robust if the appropriate non-parametric stats had been used.

In conclusion, there were no adverse events reported during this study. All patients had been instructed regarding the potential for falling while transferring to and from the bed to chair and while ambulating. However, all followed the unit policy that they would receive assistance from unit personnel for the first three days postop in order to reduce the risk of falling. There were no issues with the rocking chairs used in the study and none had to be removed due to breakage. Initially, there was confusion among the nursing staff whether participants were in the rocking or nonrocking cohorts. However, there were no instances whereby there was a mix up and a rocking patient did not receive a rocking chair and vice versa for the nonrocking group. There were significant issues with recording time spent in the chairs and number of laps ambulated and therefore that data was not presented in this report. Newer technology in now available in the form of electronic accelerometers and pedometers that one can wear around the neck to record distance and for use to measure rocks are now available. Unfortunately, the costs are prohibitive and will require grant funding in order to use in future research. Obtaining the amount of pain medication received was somewhat of a challenge due to incomplete recording of pain medication received on the nursing patient controlled analgesia intravenous and epidural forms. However, the investigator was able to extract from the infusion devices themselves the total pain medications received per twenty-four hours. Otherwise, the primary investigator was involved directly with all other measurements thereby reducing error. All participants were also separated by group on one of the two pods that make up the surgical oncology unit the study intervention was conducted assuring a lack of contamination bias.

#### **5.4 LIMITATIONS OF THE STUDY**

Limitations of this study include the small sample size, flaws in the observed and calibrated measurements of time spent rocking, sitting in chairs, and distances ambulated. Pedometer failures compounded measurement flaws and related data were eliminated to reduce error presented by unreliable tools. Other limitations include the lack of homogeneity in the sample related to surgical procedures performed, wide variation in types of pain medications used and routes administered, and distances ambulated.

Although subjects were randomly assigned to groups allowing for equal chance to participate in either the rocking or nonrocking group and equal distribution of the sample population characteristics, small sample sizes tend to limit the fair and equitable distribution of sample population characteristics compared to larger samples that may contribute to error (Field, 2005). Therefore interpretation of the results of this study must be interpreted with caution.

Measurement of time in rocking chairs, rocks completed, and distance ambulated based on the step counts of the pedometers is the most compelling disappointment for this investigator. However, at the time this study was conducted, funding for an accelerometer was not available and the brand of pedometer used was the most researchtested, reliable and valid method available to measure physical movement activities under study. The strategy of having postoperative abdominal surgery patients wear the pedometer around their waists was not successful due to irritation of the surgical wound by the gait belt. As measurement instruments, the pedometers failed to record the short, staccato and shuffling steps that surgical patients tend to perform while ambulating during the first few days following surgery. The smaller steps contributed to the reduction of the rise and fall of the iliac crest, which is essential for the armature of the pedometer to react and record a step. The pedometers also failed to record the number of rocks each patient completed, for similar reasons, and therefore pedometer data are not used or reported in the findings of this study. Nevertheless, newer pedometers are on the market now that can be worn around the neck versus the waist. These new products should be pilot-tested against similar conditions addressed in the reasons given here for their failures before they are employed in other research.

The sample for both groups was comprised of patients who had surgeries for colon cancer, pancreatic cancer, liver resections, and exploratory laparotomy. Limitations posed by the diversity in types of surgeries are related to the inability to control for variations in extent of abdominal wounds, pre-existing oncologic condition of the patient, prior chemotherapies and radiation treatments that may have altered overall physical conditions, and tolerance for postoperative activity. Ideally, future studies need to specify and limit the types of surgical procedures and pre-existing conditions of the surgical patients to minimize variations that cannot be controlled statistically or by other conditions. In addition, variations in pain management strategies need to be minimized in future studies. For example, enrolling only patients that receive intravenous or epidural patient-controlled analgesia (PCA) can control better for factors that affect pain variances. PCA epidural analgesia is believed to be the ideal system of pain medication delivery because most users have been found to effectively avoid peaks and valleys in pain and pain relief experiences. They achieve a more reliable "steady state" between pain and relief from pain (Delaney, 2004; Vallejo et al., 2000). Large variances in pain intensity and interference based on different types, schedules, and amounts of administered pain medications may have precluded an ability to detect relationships between pain states, rocking motion, and time to passage of first postoperative flatus.

Another limitation that needs to be overcome prior to future studies is related to the need to reduce error in the recognition and reporting of first postoperative flatus. Determining a method that provides more reliable data than what patients, nurses, and the investigator were able to provide through recall is necessary. Although the findings of this study show that 92.4% of patients, when asked, recalled the approximate time they first passed flatus and recorded it, 7.6% had difficulty with recall and documentation of the event. Yukoikab et al. (1987) compared self-report of time to first flatus to carbon dioxide gas analysis and reported a statistically significant accuracy rate in 16 out of 20 cases. While accuracy rates in this study are similar to those found by Yukoikab et al. stronger results are desired and deemed possible. That is, subjects in this study were vigilant in monitoring themselves for passage of first flatus because they were asked about it numerous times each day. Creating better forms for recording such events may make significant contributions to reducing error in future studies where the accurate measure of this vital outcome variable that signals the end of POI is paramount.

As a final observation, no instrument was employed to measure relaxation. This could be considered a limitation of this study. Repeatedly, subjects in the rocking arm of the study informed the investigator they felt very relaxed as a result of the rocking motion. Many rocking subjects remarked that they could only rock for ten to twenty minutes before falling asleep. All rocking participants attributed relaxation as a consistent response to rocking chair motion. Conversely, subjects in the nonrocking standard of care group did not identify relaxation at any point during study participation. However, since relaxation was not measured no specific conclusions can be drawn. Overall and in

consideration of the limitations, this study was conducted without incident and subjects were more than willing to participate.

#### 5.5 IMPLICATIONS FOR NURSING PRACTICE AND FUTURE RESEARCH

This study provides an initial exploration into the use of a nursing administered and controlled alternative and complementary therapy for the resolution of POI. The pathogenesis of POI has been proven multifactorial and therefore a one-size fits all approach to its resolution is out of step with advances in practice (Holte & Kehlet, 2002). This study provides a clear opportunity for nursing to explore alternatives to traditional standard of care protocols that call for getting patients out of bed on the first postoperative day, having them sit in a chair, and encouraging them to ambulate. The standard of care that was challenged in this study has rarely been evaluated in a randomized control clinical trial. This study does make several contributions to evidencebased practice from the standpoint of its statistically and practically significant findings as well as the limitations discussed herein as guides for the design and conduct of future, more rigorous investigations.

This study and those that will follow will continue to challenge the traditional knowledge that the return of bowel sounds is the first sign that bowel function has returned to the patient following surgery. Historically, all clinicians are trained to assess the presence or absence of bowel sounds by auscultation as an indicator of the return of gastrointestinal motility. Recent and past evidence suggests that this practice may be less important than other indicators, such as passage of stool or flatus (Disbrow et al., 1993; Madsen et al., 2005).

Evidenced-based evaluation by Madsen et al. (2005) identified that listening to bowel sounds may not be a clear indicator of the return of bowel function after abdominal surgery. Disbrow et al. (1993) reported the mean time to first postoperative bowel sounds was slightly less at 1.22 days for the relaxation-intervention group and 1.9 days for the control group. In this study, comparisons were 2.21 days for the rocking group and 2.25 days for the nonrocking group. With more studies, it may be possible to have enough evidence to support a change in nursing practice related to the auscultation of bowel sounds as a measure of return of postoperative bowel function.

Although there were no significant reductions in time to discharge (in days) in the rocking group in this study, clinically speaking any reduction in time to discharge is beneficial for the patient, the institution, and health care costs overall. Keeping outliers in the mix, one might suggest that a reduction in hospital stay of 0.19 days or 4.56 hours for the rocking group subjects presents marginal benefit. However, if one views this from the patients' and families' perspectives, leaving the hospital earlier than expected can be interpreted as a positive psychological and emotional event. The institution also benefits in revenues gained because they can turn the bed over sooner than anticipated and keep it filled with patients. If one were to consider the 11.52 hour decreased time to discharge that is revealed when outlier data are removed, positive benefits are even more significant for the patients, families, and the institution. Although there were no statistically significant differences and the effect size was small, benefits mentioned for reduced time to discharge remain important considerations. It may be helpful for future research to include long-term effects of rocking on post-surgical recoveries of patients following discharge from the hospital. Thus far, there are no reports of this type of follow-up in the literature.

Implications for future nursing research studies that plan to use the BPI-SF to assess pain include determining the appropriate levels of data that scores on the instrument's items and its subscales represent. In this study, the analyses of the BPI-SF pain intensity and interference scales were completed using non-parametric tests. Munro (1997) posits that scales such as pain scales with arbitrary zero points and no accepted units of measurement are "technically, really ordinal, yet in practice researchers often think of them as interval" (p. 5). Historically, healthcare researchers involved in the study of pain have used the concept of "*meaningfulness*" as their rationale for interpreting and analyzing scores on ordinal pain scales as if they were interval level data (Knapp, 1990). Attempting to establish the "*meaningfulness*" of a patient's interpretation of his or her pain has led to the violation of a technical canon, but in many instances, the outcomes may be useful (Stevens, 1968).

Unfortunately, the healthcare literature demonstrates extensive misinterpretation of ordinal data as interval data because most healthcare providers continue to measure abstract and complex multidimensional concepts, such as pain, with instruments such as visual analog scales (VAS) that are single item and easy to use. The true limitations of tools such as the VAS are that they do not measure the multidimensional aspects of the concepts and offer no means to establish intervals between dimensions. Therefore, in order to appropriately assess (statistically) the pain intensity and interference experienced by the subjects in this study, the decision was made to treat the BPI-SF scores as ordinal data and analyze those data using non-parametric statistics. A future comparison of parametric analysis of supposed interval BPI-SF data to the non-parametric analyses performed in this study is beyond the scope of this dissertation and may take place in a different venue. The caveat offered here may be appropriate to consider in other research when similar debates about levels of data are important to conduct. Generalization beyond this patient population is limited to cancer patients recovering from abdominal surgery in this study. However, concerning future research, replication of this study with larger sample sizes, multi-site comparison groups, homogeneity in surgical procedures, and same-method pain control are next steps. It is important to understand that conducting a randomized post-test only intervention study in a clinical setting is rather difficult and requires the investigator to anticipate and control many threats to validity and sources of error. Setting-specific research with human subjects is far more difficult to control than studies conducted in laboratory settings. However, it is the belief of this investigator that more clinical trials of this nature are necessary to test longstanding medical and nursing practice traditions that may need to change, based on evidence, to promote better outcomes for our patients and control costs of health care.

#### 5.6 CLOSING REMARKS

This study attempted to explore a method to resolve POI in postoperative abdominal cancer surgery patients using randomized assignment of subjects to either the standard of care group or the rocking motion group. The goal of this study was to explore the effects of an alternative and complementary intervention, "rocking chair motion," on POI, based on premises of stress response theories that purport that relaxation techniques can mediate stress. More research is needed to investigate these premises and interventions further to determine the effectiveness of relaxation and its ability to moderate the sympathetic effects of the surgical stress and alter the duration of POI. All in all, this investigator thinks that this initial study will provide the fuel for future research by nurses regarding this and other clinical issues faced by our postoperative patients.

# **APPENDIX** A

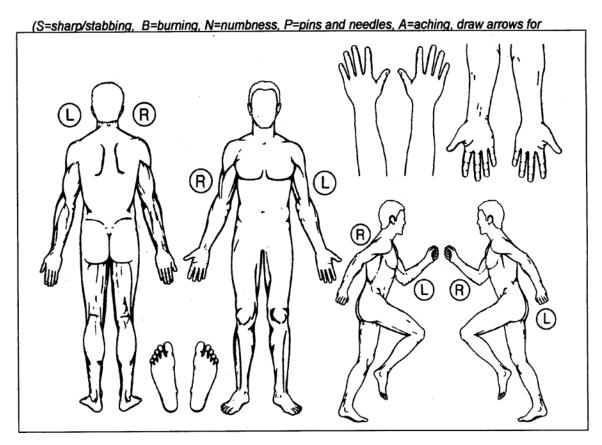
### **BRIEF PAIN INVENTORY (SHORT FORM)**

 Code #:\_\_\_\_\_
 Date: \_\_\_\_\_\_

Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains and toothaches). Have you had pain other than these everyday kinds of pain today?

1. Yes 2. No

On the diagram below, shade in the areas where you feel pain. Put an "X" on the areas where it hurts the most.



Please rate your pain by circling the one number that best describes you pain at its WORST in the past 24 hours.												
No Pain	0	1	2	3	4	5	6	7	8	9	10	Pain as bad as you can imagine
3.	<b>3.</b> Please rate you pain by circling the one number that best describes your pain at its <b>LEAST</b> in the past 24-hours.											
No Pain	0	1	2	3	4	5	6	7	8	9	10	Pain as bad as you can imagine
4.	<ol> <li>Please rate your pain by circling the one number that best describes your pain on the AVERAGE.</li> </ol>											
No Pain	0	1	2	3	4	5	6	7	8	9	10	Pain as bad as you can imagine
5.	<ol> <li>Please rate your pain by circling the one number that tells how much pain you have RIGHT NOW.</li> </ol>											
No Pain	0	1	2	3	4	5	6	7	8	9	10	Pain as bad as you can imagine
6.	What	treati	ments	or me	edicati	ions ar	e you	curren	tly red	ceiving	g for you	r pain?

7. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that shows most how much **RELIEF** you have received.

No **0 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%** Complete Relief

**9.** Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

## a. General Activity

Does not interfere	0	1	2	3	4	5	6	7	8	9	10	Completely Interferes
<b>b. Mood:</b> Does not interfere	0	1	2	3	4	5	6	7	8	9	10	Completely Interferes
c. Walking A	bilit	v:										
Does not interfere	0	1	2	3	4	5	6	7	8	9	10	Completely Interferes
d. Relations	with	oth	er po	eople	;							
Does not interfere	0	1	2	3	4	5	6	7	8	9	10	Completely Interferes
e. Sleep:												
Does not interfere	0	1	2	3	4	5	6	7	8	9	10	Completely Interferes
f. Enjoyment o	of life	e										
Does not interfere	0	1	2	3	4	5	6	7	8	9	10	Completely Interferes

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# **APPENDIX B**

#### **INSTRUCTIONS TO SUBJECTS**

Thank you for participating in this study of the effects of rocking and its effect on the return of your bowel function after your surgery. I need your assistance in order to ensure that the study proceeds in the manner it is intended to. Therefore, I must ask you to try to the best of your ability to follow these instructions.

## CONTROL GROUP: \_\_\_\_\_

You have been randomly chosen to participate in the study in the group that will spend increasing amounts of time out of bed sitting in a chair and walking. Please follow these instructions beginning the first day after surgery as we discussed when obtaining your consent to participate in this study.

- 1. Beginning the first day after surgery you will be assisted to get out of bed and sit in a chair at the side of your bed.
- 2. The goal is for you to sit in the chair at least twice during the first day and every day thereafter.
- 3. The nursing staff will also encourage you to begin to walk on the unit with assistance for the first 72 hours after surgery at least twice a day beginning the first day after your surgery.
- 4. Prior to your walking please place the belt with the pedometer around your waist as instructed (pedometer over right hip area). This will allow me to assess the distance you have walked using the number of steps counted.
- 5. It is important you are out of bed sitting in a chair and walking on the first day after surgery and to continue to increase the time sitting and walking each every day.
- 6. Every morning I will personally come to your room and have you complete a pain inventory called the Brief Pain Inventory-Short Form.
- 7. I will review and record the number of steps the pedometer has recorded and reset the pedometer.
- 8. I will also ask you if you have passed any gas from your rectum and if you have recorded the date and time this occurred using the pencil and pad I left for you.
- 9. I will also review your medical record and record the total amount of pain medication you have received in the last twenty-four hours.

If for any reason you do not understand the instructions or, you have questions, please feel free to have the nursing staff on P5 or page me (Robert L. Massey) at (713)404-1135 or you may call me directly at my office (713) 792-3704 or at home (281) 538-1949.

## **INSTRUCTIONS TO SUBJECTS**

Thank you for participating in this study of the effects of rocking and its effect on the return of your bowel function after your surgery. I need your assistance in order to ensure that the study proceeds in the manner it is intended to. Therefore, I must ask you to try to the best of your ability to follow these instructions.

## **ROCKING INTERVENTION GROUP:**

You have been randomly chosen to participate in the study in the group that will spend increasing amounts of time out of bed rocking in a rocking chair and walking. Please follow these instructions beginning the first day after surgery as we discussed when obtaining your consent to participate in this study.

- 1. Beginning the first day after surgery you will be assisted to get out of bed and sit in a rocking chair at the side of your bed and to **gently rock backward and forward** at a rate of at least one rock per second.
- 2. Please try to rock in the rocking chair at least twice a day for at least ten to twenty minutes at a time for a total of sixty minutes per day.
- 3. The nursing staff will also have you begin to walk around the unit beginning the first day after surgery (with assistance for the first seventy-two hours) at least twice a day beginning the first day after surgery.
- 4. Prior to your walking please place the belt with the pedometer attached around your waist as instructed (pedometer over the front of you right hip). This will allow me to assess the distance you have walked using the number of steps counted.
- 5. I will also place a pedometer on the rocking chair in order to determine the number of rocks you complete during a twenty four hour period.
- 6. It is important you are out of bed sitting in a chair and walking on the first day after surgery and to continue to increase the time participating in each every day.
- 7. Every morning I will personally come to your room and have you complete a pain inventory called the Brief Pain Inventory-Short Form.
- 8. I will review and record the number of steps and rocks the pedometer (s) has recorded and reset the pedometers.
- 9. I will also ask you if you have passed any gas from your rectum during the day and if you recorded the date and time using the pencil and pad I left for you.
- 10. I will also review your medical record and record the total amount of pain medication you have received in the last twenty-four hours.

If for any reason you do not understand the instructions or, you have questions, please feel free to have the nursing staff on P5 page me (Robert L. Massey) at (713)404-1135 or you may call me directly at my office (713) 792-3704 or at home (281) 538-1949.

# **APPENDIX C**

## **ROCKING STUDY DEMOGRAPHIC/DATA SHEET**

Date \_\_\_\_\_ Code # \_\_\_\_\_

Randomized Arm: \_\_\_\_\_ Rocking \_\_\_\_\_ Non Rocking

Age \_\_\_\_\_ Gender \_\_\_\_\_ Male \_\_\_\_\_ Female

**Ethnic Group** 

\_\_\_\_\_ White/Non-Hispanic \_\_\_\_\_ African American \_\_\_\_\_ Hispanic \_\_\_\_\_ Middle Eastern

\_\_\_\_\_ Asian \_\_\_\_\_\_ Other

**Marital Status** 

\_\_\_\_\_ Single \_\_\_\_\_ Married \_\_\_\_\_ Divorced/Separated \_\_\_\_\_ Widow/Widower

Diagnosis \_\_\_\_\_\_ Surgical Procedure \_\_\_\_\_

Date/Time of Surgery \_\_\_\_\_ Date/Time of Discharge \_\_\_\_\_

DATA SHEET Code # \_\_\_\_\_

Day # \_\_\_\_\_ Date \_\_\_\_\_

Flatus \_\_\_\_ Yes \_\_\_\_ No \_\_\_\_\_ Time

Pain Medication Route \_\_\_\_\_ Type \_\_\_\_ Total Mgs/24 hours \_\_\_\_\_mg. MED

# Rocks/ 24 hours \_\_\_\_\_ # Steps/24 hours \_\_\_\_\_ Distance (miles) \_\_\_\_\_

Comments

Day # Date
Flatus Yes No Time
Pain Medication Route Type Total Mgs/24 hoursmg. MED
# Rocks/ 24 hours # Steps/24 hours Distance (miles)
Comments
Day # Date
Flatus Yes No Time
Pain Medication Route Type Total Mgs/24 hoursmg. MED
# Rocks/ 24 hours # Steps/24 hours Distance (miles)
Comments
Day # Date
Flatus Yes No Time Pain Medication Route Type Total Mgs/24 hoursmg. MED
# Rocks/ 24 hours # Steps/24 hours Distance (miles)
Comments
Day # Date
Flatus Yes No Time
Pain Medication Route Type Total Mgs/24 hoursmg. MED
# Rocks/ 24 hours # Steps/24 hours Distance (miles)

Comments
Day # Date
Flatus Yes No Time
Pain Medication Route Type Total Mgs/24 hoursmg. MED
# Rocks/ 24 hours # Steps/24 hours Distance (miles)
Comments
Day # Date
Flatus Yes No Time
Pain Medication Route Type Total Mgs/24 hoursmg. MED
# Rocks/ 24 hours # Steps/24 hours Distance (miles)
Comments
Day # Date
Flatus Yes No Time
Pain Medication Route Type Total Mgs/24 hoursmg. MED
# Rocks/ 24 hours # Steps/24 hours Distance (miles)
Comments

# **APPENDIX D**

# **ROCKING GROUP**

# \_\_\_\_\_

Date	Time Rocking Started	Time Rocking Stopped	Total Time Rocking	Number of Laps Walked

# **APPENDIX E**

### NON ROCKING GROUP

# \_\_\_\_\_

Date	Time in Chair Started	Time in Chair Stopped	Total Time in Chair	Number of Laps Walked

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## VITA

#### **Robert Lee Massey**

Robert was born on October 5, 1949 in Stephenville, Texas to Minnie Lee and James Henry Massey. He is married to Mona Rosanne Willingham Massey, has one son Brett L. Massey and one daughter Sarah Nicole Massey. His professional work experience includes 26 years as a Registered Professional nurse in a variety of clinical and administrative positions from staff nurse to his present role as Clinical Director, of Nursing at The University of Texas MD Anderson Cancer Center in Houston, Texas. In his present position he is the leader of four inpatient surgical units and the wound ostomy section.

#### Education

B.S.N., December 1981, The University of Texas at San Antonio School of Nursing M.S.A., December 1989, Central Michigan University, Mt. Pleasant, MI.

#### Publications

Massey, R. L., & Rodriguez, G. (2002). Case report: Human scrotal myiasis. Urologic Nursing, 22(2), 315-317.

Description of second reported case in medical literature of male with scrotal myiasis infestation after a trip to Costa Rica, Central America was misdiagnosed by multiple healthcare providers due to unusual nature of illness. Article describes the need for advance practice nurses to be alert to potential to see patients in clinical setting with unusual tropical disease infestations.

Massey, R. L., Haylock, P. J., & Curtis, C. P. Constipation, in Yarbro, CH, Goodman, M. (Eds): Cancer Symptom Management (Ed 3). Boston: Jones and Bartlet, 2003. © Jones and Bartlett Publishers.

Chapter provided up to date information on the pathophysiology and clinical signs and symptoms associated with constipation in cancer patients and methods nurses can use to develop a plan of care. Included are treatment options and a daily diary patients can maintain to assist in the reduction of constipation among this vulnerable patient population. Mick, J. & Massey, R. (2007). Implementing the Good Catch pilot program: A positive patient safety culture increases potential error reporting. The Journal of Nursing Administration accepted for publication November 2007 issue.

Article provided description of innovative process implemented at a major cancer center to increase the reporting of close call potential error events through use of a change in terminology and senior nursing leadership involvement. Changing the terminology from "close call" which implied one almost made an error to a more positive focus "Good Catch" which implies one did a good job identifying potential errors has demonstrated a positive response. Prior to implementation of the Good Catch concept, approximately 175 close calls had been reported in a 2 ½ year time period. To date, since implementation in 2005, over 17,000 Good Catch reports have been recorded. That data has been evaluated using a variety of techniques to include human factors concepts. Significant system and process changes have occurred reducing the potential for errors to actually reach patients.

#### Summary of Dissertation

Rocking motion may be useful in resolving postoperative ileus (POI) in cancer patients who have undergone abdominal surgery. Operations of the abdomen result in gastrointestinal dysmotility, to some extent, in all patients because abdominal surgical procedures to remove abdominal tumors require large abdominal incisions, extensive dissection, and manipulation of the bowel that initiates a surgical induced stress response commonly known as, postoperative ileus.

In this study, we examined the effects of a rocking as a moderator of the surgical stress response and mediator of the gas and distention effects of POI in abdominal surgery cancer patients compared to standard postoperative care. The outcome variables assessed indicating resolution of POI was duration of time to first flatus, subjective reports of pain intensity and interference, total pain medication received and time to discharge. The hypotheses tested was there were no differences in duration of time to first flatus, subjective reports of pain intensity and interference, total pain medication received and time to first flatus, subjective reports of pain intensity and interference, total pain medication received and time to discharge from the hospital. Two groups of postoperative abdominal surgery cancer patients were randomized to the rocking or non-rocking groups.

We found that the rocking group had a significant reduction in time to first flatus and no differences in subjective reports of pain, total pain medication received and time to discharge from the hospital. Our results indicated rocking chair motion is effective in reducing the duration of postoperative abdominal surgery cancer patients. Permanent address: 2101 Spinnaker Drive, League City, TX 77573 This dissertation was typed by Linda F. Bohannon