Assistive Intervention in the Characterization of Muscle Activity During Bed Rising and Assessment of Self-Perceived Recovery Measures for Abdominal Surgery Patients in Postoperative Care

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(ABSTRACT)

Previous literature has indicated that nursing personnel face the second highest rate of occupational injury and illness. Assistive equipment, such as lift and transfer aids, has helped lower work task demands and reduce back stress on patient handlers. However, limited attention has been paid to the safety, comfort and dignity of the patient in postoperative care. Research on the efficacy of self-transfer aids for patients who require limited or no assistance by nursing personnel is insufficient. Ratings of comfort and security have only been evaluated for nursing home residents in a pilot field study, in which residents rated assistive devices as generally equal to or more secure and comfortable than manual transfer methods.

The first study reports the laboratory evaluation of bed rising with the use of two self-transfer aids and bed rising unassisted. The objective was to determine muscle activity during bed rising tasks with and without the use of a bed assistive device using surface electromyography (EMG). Twenty male (n = 9; age, 33.7 ± 8.0 years) and female (n = 11; age, 34.5 ± 23.9 years) participants, with normal body mass index (BMI) ranging from 18.4 to 24.9, took part in the study. Mean and peak activity was recorded from three abdominal muscle sites. The results indicated bed rising with the use of a self-transfer device significantly reduced muscle activity compared to bed rising unassisted. Anchoring the devices at a higher height and elevating the torso further reduced muscle activity. Although no differences were observed between devices using EMG, results from the usability survey and final ranking indicated favorable ratings for the ABNOSTRAIN™ prototype compared to the Bed Pull-up.

A second study was conducted to determine the efficacy of a bed assistive device in a patient population. The objective was to compare self-perceived recovery measures and usage of pain medication between patients in the control (n = 8; age, 34.0 ± 6.3years) and device (n = 7; 40.7 ± 12.4) groups. A total of fifteen female participants undergoing either abdominal hysterectomy (n = 6) or Cesarean-section (n = 9) procedures were recruited for the study. Both groups completed a total of twelve questionnaires over a five-week recovery period. Responses to self-perceived recovery measures were significantly different. In general, the device group reported higher levels of energy, less pain interference, lower perceived pain, less reliance on pain medication and returned to activities of daily living faster than the control group.

The results from the study provide clinicians or other practitioners information on the benefits of bed assistive devices for patients during postoperative recovery. Age and surgery differences should be considered when suggesting bed movement patterns with assistive intervention.

Thoughts and Dedication

(5.04.2004)

i have found a getaway that seemingly remains hidden in this small town. yet in time, i know that this place will be a secret place for all. but for now, at least i can smell the scent of fresh pine chips and the budding landscape that will soon flourish into something of greater magnitude. better yet, i call it a place of my own where no one can find me.

it's amazing how much blacksburg has changed and tonight will be marked as one of my favorites. the evening has turned into the brisk of fall and soon the hour will become darker, but at least i can still see green in the grass and birds singing as if it were day.

i am taking a short break before approaching the last stretch of my hardest cross-country race yet. and then i hear the sounds of the cheering section. *to my parents for their love and support.* shirt drenched. i pick up the pace. muscles aching. my entire body burning. but my legs are still drudging through the hard and soft terrain. focus. focus. *to my brother for making me snort coca-cola up my nose when we were tater tots.* focus..! the end is finally in sight. my heart pumping. arms in full swing and feet full speed ahead. wanting to beat the time count on the loud speakers. only several more yards before crossing the finish line…

but then i stop cold.

and hesitate. my legs cramping, but i scan the crowd and take a detour. i see my family in the distance and run to them. *to my grandmother who has always and continues to inspire me through example*. i flash a smile and give them each a big, warm hug. i turn around again and begin my sprint towards the finish line.

how you climb up the mountain is just as important as how you get down the mountain. and, so it is with life, which for many of us becomes one big gigantic test followed by one big gigantic lesson…it's how you accept winning and losing, good luck and bad luck, the darkness and the light.

- cristina carlino

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CHAPTER 1. INTRODUCTION

1.1 Work-Related Musculoskeletal Disorders and Patient Safety Concerns in Healthcare

Patient handling (lifting, repositioning, and transferring of patients) has been a growing ergonomic concern over the past decade. Back injuries and shoulder strains can be attributed to events that occur during the handling of patients, and have been identified as the primary cause for musculoskeletal disorders among the nursing workforce by the American Nursing Association (ANA, 2003). According to the 2001 Bureau of Labor Statistics, nursing personnel face the second highest rate of occupational injury and illness. Nurses and nursing aides have both high prevalence rates of back pain and high incidence rates of workers' compensation claims for back injuries (Zhuang et al., 1999).

ANA initiated an ergonomics campaign in 2003 in efforts to reduce the risk of musculoskeletal injury and establish a safe environment of care for nurses and patients. The campaign continues to seek action and implement policies that eliminate manual patient handling (ANA, 2003). The development of assistive equipment, such as lift and transfer aids, has helped lower the physical demands and reduce back stress on patient handlers (Zhuang et al, 1999; ANA, 2003; Keir and MacDonnell, 2004). With the effective use of assistive equipment and devices during patient-handling tasks, the risk for musculoskeletal injury can be significantly reduced for nursing personnel; however, a comprehensive evaluation of transfer devices has yet to ensure the safety, comfort and dignity of patients in postoperative care. Nursing home residents in a pilot study indicated promising results and rated assistive devices as generally equal to or more secure and comfortable than manual transfer methods used in the healthcare system (Zhuang et al, 2000).

1.2 Approaches to WMSD Problem

Though addressing the prevalence of back injuries in nursing personnel remains a concern, the aim of this user-centered research was to evaluate a self-transfer device that would meet the immediate

needs of patients following surgery, and potentially inspire a safe environment of care for nursing professionals as a result.

Human factors engineering and ergonomics research can help identify the psychological and physiological stresses of surgery that affect the performance of activities of daily living (ADLs) for postoperative patients. Characterizing the physical requirements and perceptions of patients using biomechanical and survey methods may provide a framework in designing and/or suggesting proper use of assistive products to improve postoperative patient care. The scope of this research was to evaluate the efficacy of self-assistive intervention in characterizing abdominal muscle activity, self-perceived recovery measures and administration of oral pain medication.

1.3 Rationale for the Study

From the case studies in Chapter 4, patients following major abdominal surgery reported discomfort and extreme pain during bed rising. Torso movements associated with the use of bed rails exacerbated the pain across the surgical site. Similarly, patients felt pain when transferred during patient-handling tasks by nursing personnel.

The efficacy of assistive intervention on the safety and comfort of patients during bed rising has not yet been supported by both quantitative and qualitative measures. The goals of this study were to initiate research and assess the efficacy of self-transfer devices for patients following major abdominal surgery. The use of self-transfer aids was hypothesized to facilitate independent bed rising for postoperative patients in the hospital and during recovery at home, and other activities requiring trunk stability or movement such as sitting and standing using their own strength and abilities. As a result of not having to rely on nursing personnel or others for assistance, patients were hypothesized to maintain a sense of independence and self-esteem, perform ADLs earlier in postoperative recovery, and return to their preoperative level of self-care faster.

1.4 Research Objectives and Framework

The objectives of the study were to: 1) quantitatively assess the activation of abdominal muscles during bed rising with and without assistive intervention; and 2) qualitatively compare self-perceived recovery measures and administration of pain medication of patient groups with and without assistive intervention.

Study One

The first phase of the study was conducted on a healthy population in a laboratory setting. Participants were asked to perform three repetitions of tasks involving manual bed rising and bed rising with the use of an assistive device. Surface electromyography (EMG) was recorded from the right upper and lower rectus abdominis, and external oblique during both concentric and eccentric phases of the bed-rise movements. Subjective ratings on the usability of the assistive devices were also collected.

Study Two

The second phase of the study consisted of a patient population undergoing major abdominal surgery. Participants were randomly assigned to one of two groups: 1) no assistive device or training (Control), and 2) assistive device with no training (Device). Subjective measures of recovery status and usage of pain medication were evaluated using a total of twelve self-report questionnaires over a five-week recovery period.

CHAPTER 2. RESEARCH BACKGROUND

2.1 Clinical-Related Research

2.1.1 Abdominal Surgery Overview

Statistics have indicated the high prevalence of gynecologic surgeries, including cesarean section and abdominal hysterectomy procedures. Cesarean section rates have nearly quintupled in the United States to 23.8% in the past twenty years, where the International Childbirth Education Association reported 81.5% of women in the United States with a previous cesarean had a repeat cesarean in 1989. From 1988 to 1990, approximately 1.7 million women underwent hysterectomy procedures (ACOG, 2001). Over 600,000 hysterectomy procedures were performed annually in the United States (ACOG, 2001). According to the National Uterine Fibroid Foundation, approximately 144 million work hours are lost for patients undergoing hysterectomy and require an average recovery period of six weeks (NUFF, 2002). Cesarean-section patients also require on average six weeks of recovery time to heal from the surgical incision (CBO, 2001).

Cesarean section (C-section) is the surgical delivery of a baby and is typically performed when the health of the baby or mother is at risk, or if the baby is breeched. Cesarean rates, influenced by non-medical factors, are higher for women who have private medical insurance, are private rather than public clinical patients, are older, are married, have higher levels of education and are in a higher socio-economic bracket (ICEA, 2001).

Hysterectomy is the surgical removal of the uterus to treat various uterine diseases such as fibroids (leiomyomas), endometriosis, cancer or premalignant disease, genital prolapse, abnormal uterine bleeding and severe pelvic infection. The highest rates of hysterectomies performed are on women aged 30 to 54 years, with 100 hysterectomies per 10,000 women performed annually (ACOG, 2001). The most common conditions requiring hysterectomy procedures before the age of menopause include uterine leiomyoma or endometriosis, which account for two-thirds of all noncancerous hysterectomies (Wilcox et

al., 1994). Approximately 75% of all hysterectomies performed in the United States are abdominal hysterectomies (ACOG, 2001).

2.1.2 Invasiveness of Surgery to Abdominal Cavity

Both gynecologic surgeries require an incision to the abdominal cavity, approximately five-inches in length in the vertical (vertical incision) or horizontal (Pfannenstiel or "bikini") plane of the lower abdomen. The Pfannenstiel incision is made approximately one inch above the pubic bone, and the vertical incision is made in the midline from the umbilicus to just above the pubic bone. The incision cuts into the anterior wall of the rectus sheath, transecting neuromuscular pathways in the skin of the abdominal wall and requires partial or complete transection of the rectus abdominis (Wheeless, 1997). In a cesarean delivery, the baby is removed from the uterus, and the tissues of the abdominal wall are then closed in layers with sutures, and the skin is closed with sutures or staples.

In an abdominal hysterectomy, cardinal and uteroscaral ligaments (ligaments that attach the uterus to the pelvic wall) are separated and the uterus is removed. The vaginal cuff is then sutured and the peritoneal layers (tissues of the abdominal wall) are closed. Staples or stitches, depending on the type of incision, are used to close the skin.

2.1.3 Effects of Surgery on Postoperative Patients

Although Cesarean sections and hysterectomies are considered safe operations, risks and severe complications can occur (Lacey, 2002; MOD, 2004). Abdominal surgery patients must ambulate after surgery to reduce the risk for blood clotting in the lungs (known as pulmonary embolism), which extend from blood clotting in the legs. Postoperative patients, however, cannot voluntarily perform activities of daily living (ADLs) due to the pain associated with the invasiveness of the surgery. Computed topography (CT) showed denervation of the oblique abdominal and illipsilateral rectus abdominis muscle, and atrophy of the oblique abdominal muscles following abdominal surgery (Balough et al., 2002). ADLs such as bed rising would exacerbate the trauma to the surgical site since supine-to-sit or sit-to-

supine movements require trunk strength, coordination and balance (Miller and Medeiros, 1987; Alexander, 2000).

Patients following hysterectomy procedures also face the pain and emotional stresses of surgery including depression, sense of loss (removal of organ, inability to conceive), urinary and sexual dysfunction and stress incontinence (De Leo et al., 1999). In addition, women are dissatisfied with their body image due to the abdominal scar (Gutl et al., 2002). Depression is common especially for patients who undergo surgical procedures for cancer or severe illness rather than as an elective operation.

The level of pain sensitivity and abdominal muscle function vary among abdominal surgery patients depending on the type of incision. Incisional hernias are more frequent with the vertical incision, but minimal blood loss is observed and major nerves are avoided with this incision (Mattingly and Thompson, 1985). The Pfannenstiel incision is associated with a higher frequency of femoral nerve injury, in addition to longer time for incising and re-approximating the abdominal muscles, and more local anesthesia. The Pfannenstiel incision has a cosmetic advantage since the scar is located in the lower abdomen or hidden near the margin of the pubic hairline (Mattingly and Thompson, 1985; Wheeless, 1997), and reported to entail less postoperative discomfort (Mattingly and Thompson, 1985). Various physical and emotional factors therefore affect cesarean and abdominal hysterectomy patients, who may require immediate assistance in coping with the trauma of surgery.

2.1.4 Patient Handling in Postoperative Care

Common patient handling tasks include transferring patients from bed to chair, repositioning patients in bed, and lateral transfer from the bed to stretcher. Nursing personnel may also be confined to physical spaces that do not allow adequate room in supporting patient handling tasks (Garg and Owen, 1994). Patient handling devices were reported to be time consuming, difficult to use, not accessible or disliked by patients (Garg and Owen, 1994). In addition, in-patients including abdominal hysterectomy and Cesarean patients, typically remain in the hospital, on average, two to three days. As a result of relatively short hospital stays, patients must ambulate earlier in postoperative care. Although ambulation

avoids complications such as deep vein thrombosis, patients (depending on the level of care) often require the assistance of nurses in performing self-transfer tasks. Patient dependency levels are contingent on the patient characteristics such as body weight, height, upper extremity strength and medical condition (Table 1).

Table 1. Patient dependency levels and appropriate assistive devices (PSCI, 2001).

Dependency Level	Definition	Assistive Device
Total Dependence	▪ Full staff assistance for activity during entire 7-day period ▪ Requires total transfer at all times.	▪ No manual lifting is recommended ▪ Should be lifted and transferred between beds, chairs, toilets, bathing and weighing devices by full sling mechanical device
Extensive Dependence	▪ Can perform part of activity, follow simple directions, has some upper body strength and some ability to pivot transfer	▪ Full body sling appropriate for all transfers ▪ Stand assist may be appropriate ▪ Should be lifted (described above) with aid of mechanical device
Limited Dependence	▪ Highly involved in activity, ability to pivot transfer, can sit up well, but may need assistance	▪ Electric height adjustment on bed may be used to assist in transfer ▪ Stand assist may be appropriate
Supervision	▪ Non-powered devices appropriate (gait belts with handles or transfer belts) ▪ Provides safety and support while allowing patients to use and strengthen their own abilities	▪ Use of gait belts for health provider to provides stability and control patient ▪ Non-powered devices may be useful to allow patients strengthen own abilities ▪ Sliding boards to slide patients from bed to chair
Independent	▪ Can ambulate normally without assistance, may need limited assistance ▪ Capable of bearing own weight	▪ Mechanical assistance for transferring, lifting or repositioning not required normally

Even with manual and mechanical devices available to the nursing staff, patient handling remains a leading cause of back injuries observed in the nursing industry (Goldman et al., 2000). The American Nursing Association (ANA) initiated an ergonomics campaign in 2003 to encourage and implement ergonomic interventions in providing a safe environment for nurses and patients. Psychophysical and biomechanical assessments of assistive devices have indicated favorable results for nursing personnel during patient-handling tasks (Zhuang et al., 1999; Zhuang et al., 2000; Kier and MacDonell, 2004). Nursing home residents also indicated positive ratings on comfort and feeling secure during patient-handling tasks involving assistive devices (Zhuang et al, 2000).

2.1.5 Implications of Assistive Intervention for Patients in Postoperative Care

From the case studies in Chapter 4, patients following major abdominal surgery performed bed rising tasks using bed rails for leverage and support. Patients were forced to rotate the torso in carrying out the movement, which further induced pain at the incision site. Pain sensitivity was also heightened for patients when assisted by nursing personnel (given that patients did not have the ability to control the pace during bed rising).

Movement patterns used during bed rising varied across age groups (Alexander et al., 1992; Ford-Smith and VanSant, 1993; Alexander et al., 1995). Alexander et al. (1995) found that older women (mean age = 73.8 years) were more likely to bear weight on their hip/gluteal area and use a broad pivot base consisting of the hip and elbow during supine-to-sit movements than younger women (mean age = 23.8 years). Differences in rising movements were also supported by Ford-Smith and VanSant (1993).

The most common form of rising for the subjects in the 30-39 year old age group usually involved a double push pattern with the left upper limb, as the right upper limb grasped and pushed off the edge of the bed (Ford-Smith and VanSant, 1993). Common forms of rising for older participants in the 40-49 and 50-59 year old age groups only varied in the lower limb movement to that of their younger counterparts in the 30-39 year old age group. In the come-to-sit from supine position and come-to-stand from sitting position, the older groups were observed to lift and move their lower limbs synchronously across the bed, and lowered to the floor simultaneously (Ford-Smith and VanSant, 1993). The younger age group demonstrated asynchronous patterns in lifting the lower limbs off the bed, before moving their legs across the bed and lowering to the floor either asynchronously or synchronously.

Joint range of motion, strength (Alexander et al., 1995) and body dimensions (Ford-Smith and VanSant, 1993) are additional factors that have been reported to influence rising action variability. Bed rails are most often the only form of support for patients in performing bed rising while in the hospital. However, Bail et al. (1997) suggest that bed rails will impede the independence of the majority of elderly patients, particularly those who already find it difficult to get off their bed. The ethos of rehabilitation is to encourage independence, where barriers or obstacles are removed or overcome (Bail et al., 1997). A

bed rail is one such unnecessary obstacle, as no clearly demonstrated benefits and some potential harm were associated with their use (Bail et al., 1997).

Past literature has documented different types of assistive devices used by the elderly population and quadriplegic patients for bed rising. Past examples include a bed hoist, looping transfer system, bed-ladder and Bedside assist, devices designed to assist users help themselves move in and out of bed. Most often the devices require assembling, such as the Bedside assist. Although Tipton (1983) indicated that the Bedside assist "offers the patient a secure hand hold and encourages him to move independently" and "eliminate the need for side rails unless the patient is restless," recommendations for the use of the product were not supported by any reliability measures or evidence.

2.1.6 Effects of Preoperative Physical Factors on Postoperative Recovery

Returning to preoperative ADLs or work is often a milestone for patients to achieving recovery (Graff et al., 1992). Fitness level was a preoperative factor that was found to predict postoperative recovery measures (Schilling and Molen, 1984). Results indicated individuals who were physically active had a faster rate of recovery then those who were not physically fit.

Training can benefit the patient, especially since there is an increased risk of injury to the musculoskeletal system when various muscles groups normally not used for specific tasks, are recruited to compensate for the injured muscles (Marras et al., 1998). Strategies aimed at increasing muscle mass, such as preoperative physical training, may be ineffective in improving the postoperative strength of older patients (age, 77 ± 5 years) (Watters et al., 1993). While age-related differences in preoperative strength are attributable to differences in muscle mass, as well as to presumed changes in muscle fiber type, preoperative levels of strength were lowered after surgery, but failed to predict impaired postoperative recovery of strength (Watters, 1993).

Alexander et al. (2001) proposed task-specific training (learning an activity through practice) as a more effective method to increase the ability of older adults to perform bed-rise tasks than typical isolated resistance strength training exercises in a rehabilitation setting. Training effects were observed in

musculoskeletal capacities, particularly in trunk range of motion, strength and balance at twelve weeks, depending on the maximum number of tasks successfully completed. The training effect, however, decreased as the total number of tasks increased (Alexander et al., 2001).

2.1.7 Additional Factors Affecting Postoperative Recovery

Other preoperative measures have been found to affect the rate of recovery of patients after surgery, including behavioral preparation, coping style, and outlook on life (Wilson, 1981; Miro, 1999). Studies in behavioral medicine have found preoperative instruction helped patients cope with the complications of surgery (Wilson, 1981; Oetker-Black et al., 1997; Miro and Raich, 1999). The rate of recovery was significantly improved when patients were informed of what will happen or how to cope more effectively with stress in the preoperative stage (Wilson, 1981; Oetker-Black et al., 1997). However, behavioral preparation for surgery may not be favorable for patients in denial of experiencing pain; more pain medication usage and a higher frequency of complaints were observed for those in denial (Wilson, 1981). Preoperative preparation therefore has the potential to increase efficacy expectations for the patient during surgery, decrease anxiety and improve postoperative outcomes; however, the mechanism by which preoperative instruction benefits patients is still unknown (Wilson, 1981).

Additional studies have indicated the benefits of using relaxation techniques on postoperative recovery and pain. Postoperative patients exposed to various relaxation techniques required less oral narcotics and analgesics than those in the control group (Levin et al., 1987).

2.1.8 Common Recovery Measures

The general need for reliable and valid criterion measure of patient welfare for has been recognized for some time, and a wide variety of measures and indices of postoperative condition have been used (Wolfer and Davis, 1970). Common measures for postoperative recovery of surgery include: length of hospitalization, time to ambulation stage, amount of physical activity, number of narcotics, analgesics and sedatives, urinary retention, pain and comfort ratings (Wolfer and Davis, 1970; Wilson,

1981; Schilling and Molen, 1984). Other postoperative indicators such as levels of epinephrine and norepinephrine, and index of mood have been evaluated less frequently (Wilson, 1981). Usually one or two recovery indicators have been included in surgery studies (Wolfer and Davis, 1970), but additional recovery measures have been used depending on the objective of post-operative assessments in clinical settings (Graff et al., 1992).

Researchers have utilized pain assessments to evaluate methods of controlling pain, and to investigate the effects of experimental and therapeutic interventions for pain in clinical studies (Melzak, 1991). Response to pain is defined as self-reported sensation and distress (Levin et al., 1991), which is affected by emotional, experiential and environmental factors. Patients undergoing abdominal surgery experience acute pain, a dynamic process of great physical and emotional stress (Doyle, 1999). As such, attention to pain beliefs and pain coping is a critical component of a cognitive-based approach to understanding pain and maximize response to treatment (DeGood and Tait, 2000).

Pain thresholds for abdominal hysterectomy patients are lowered as a result of metabolic responses from nerves being cut and smooth muscles become spasmodic (Bray, 1986). Lowered thresholds intensify pain sensation, increase anxiety and cause the release of more pain neurotransmitters, yet the degree of pain experienced by the patient remains characteristic to the individual (Bray, 1986). Anxiety levels can increase in patients as the level and duration of pain after surgery cannot be anticipated, especially for those who have not undergone previous surgery. Additional factors such as the operative site, intra-operative analgesics, the concomitant use of regional anesthetic techniques and the patient's personality and state of mind may influence the amount of pain experienced (Doyle, 1999).

Age and interethnic differences have also been studied in pain perception. Pain tolerance has been observed to decrease with age (Woodhill, 1972), while measures of pain sensation, pain described in affective terms, varied among ethnicities (Greenwald, 1991). Caucasian individuals tolerate more pain than Asians, and African-American individuals occupy an intermediate position (Greenwald, 1991).

2.2 Electromyography Research

2.2.1 Overview

Electromyography is commonly used in biomechanical studies with applications in three domains: to detect muscle activation, estimate a muscle force-EMG relationship, and as an index of fatigue through spectral analysis of the signal (DeLuca, 1997). The intent of the present research is in the first of the three applications—characterizing abdominal muscle activity during assisted and unassisted bed rising tasks. Muscle activity during unassisted and assisted bed rising tasks has not yet been examined. Past studies have used surface electromyography (EMG) extensively to quantify the activation levels of the rectus abdominis and oblique muscles during abdominal exercises.

Abdominal exercises are generally prescribed for rehabilitation of low back injury and as a component of fitness training programs (Axler and McGill, 1997). For this study, understanding the effects of abdominal exercises from previous research helped provide the groundwork in developing the experimental methods, and potential implications for patients in postoperative care.

2.2.2 Abdominal Exercises and Low Back Pain (LBP)

The presence of chronic low back pain (LBP) is highly correlated with weak torso musculature, in which reduced abdominal and spinal extensor strength is a factor in the recurrence and/or persistence of chronic LBP (Axler and McGill, 1997). Though abdominal exercises are most often recommended for their capacity to maximize muscle activity (Flint, 1965), the load cost on the lumbar spine have not been sufficiently examined (Axler and McGill, 1997). Concern has been raised regarding the safety of abdominal exercise programs. Researchers have suspected that tissue damage can occur through compressive loading on the lumbar spine (Axler and McGill, 1997).

2.2.3 Levels of Abdominal Activity and Compressive Spinal Loading

Axler and McGill (1997) conducted a comprehensive evaluation of twelve different abdominal exercises to identify abdominal exercises that challenge the rectus abdominis and obliques (internal and

external) and minimized loading to the lumbar spine. Of the abdominal variations, curl-ups effectively provided lower compressive loads while maximizing abdominal musculature. The curl-up exercises were described being similar to a bent-leg sit-up, with torso movement in flexion until the scapula is just lifted from the mat/bench (Halpern and Bleck, 1979; Axler and McGill, 1997).

In general, full sit-ups generated the highest compressive forces, followed closely by the cross-knee curl-ups and hanging leg raises (Axler and McGill, 1997). Performing sit-ups with knees bent did not lower lumbar spine compression (Axler and McGill, 1997) and had little impact on muscle activity (Flint, 1965). Sit-ups with feet unanchored, legs elevated or twists of the torso did not increase abdominal activity levels (Axler and McGill, 1997). However, curl-ups with trunk twists required the most activity throughout the exercise cycle for all of the abdominal muscles than any of the other exercises (Flint, 1965).

Anchor effects influenced differences in muscle activation levels (Flint, 1965; Guimaraes et al., 1991; Axler and McGill, 1997). Peak muscle activity for the straight leg sit-up (legs straight, feet anchored) were relatively high at the upper rectus (Axler and McGill, 1997) and lower rectus (Flint, 1965) compared to abdominal exercises with feet unanchored, legs extended or knees bent. Sit-ups with legs extended (feet unanchored) and curl-ups with trunk twist (unanchored) elicited the most activity at the external oblique (Flint, 1965).

Axler and McGill (1997) suggested that different abdominal exercises were best suited for different individuals, depending on variables such as fitness level, training goals, and history of previous spinal injury. Exercises that had the highest (optimal) challenge-to-compression-cost indices may be suitable for someone with LBP, but may not challenge the abdominal musculature for an athlete seeking muscle challenge. On the other hand, exercises that optimize muscle activity vs. the spinal load index may still produce dangerously high levels of L4/L5 compression for the injured. Given these findings, Axler and McGill (1997) recommended a list of abdominal exercises for specific purposes to provide clinicians and trainers with a useful tool in selecting the most appropriate exercises for individuals for rehabilitation or training.

2.2.4 Abdominal Activity in the Concentric and Eccentric Movements

Muscle activity was generally greater during the rising (concentric) than in the lowering (eccentric) portion of the sit-up exercises (Flint, 1965; Andersson et al., 1998). Despite the activation differences between phases, similar muscle patterns were observed across the phases. A peak usually occurred between 30° and 45° of torso flexion in the upward and downward movements (Flint, 1965). In addition, movement patterns were also characterized by a drop in activity level with the trunk in 75° and 90° flexion (Flint 1965; Halpern and Bleck, 1979).

2.2.5 Muscle Differences and Electrode Placement

Lehmen and McGill (2001) found that the upper and lower portions of the rectus abdominis were equally active, but controversy exists (Ng et al., 1998). A difference in fiber orientation between the upper and lower rectus abdominis was observed, which implies that differences in muscle activation would exist between the two regions. Ng et al. (1998) suggested alternative electrode placements for the lower and upper rectus abdominis and external obliques, contrary to what has been published and accepted as standard practice.

Differences in muscle activity were observed between the right and left oblique muscles (Halpern and Black, 1979). Results from the study indicated that the right oblique muscles were active for 25% of the sit-up cycle, while the left side was active for 20% of the time. Although differences in muscle activity at the opposing sites remain unclear, researchers have characterized muscle activity with electrodes placed solely on the right-hand side (Flint, 1965; Lehman and McGill, 2001).

2.2.6 Normalization Procedures

Normalization of EMG data is generally necessary to make comparisons of activation levels between muscle sites and across participants (Andersson et al., 1998; Vezina, 2000; Lehman and McGill,

2001). In comparing between maximal and near maximal exertions, Andersson et al., (1998) emphasized that different methods of normalizing EMG results have different consequences and the methods selected should be dependent on the objective and task at hand.

When the intention is to compare variation in EMG patterns for a certain muscle across situations, any recorded EMG could be used as a reference value. Given that the selected reference value is not at its peak, the consequence of using a sub-maximal value may lead to relative values that may exceed 100% (Andersson et al., 1998). Maximum voluntary exertion levels have been found to be relatively constant across conditions, but eliciting maximal efforts are often difficult to obtain (Andersson et al., 1998). Studies typically assume that subjects produced maximal effort during the normalization procedures. However, if participants did not reach maximal effort, then the reported relative amplitudes would be overestimated and provide stronger evidence to support conclusions related to strengthening potential than with submaximal contractions (Vezina, 2000).

2.2.7 Factors Affecting EMG Signal

Numerous factors can influence the magnitude of the EMG signal. The amount of subcutaneous adipose tissue under the electrodes, changes in electrode spacing during movement, muscle movement relative to the electrodes during changes in limb position and change in muscle length during movement can interfere with optimal EMG signals. Participants have been considered to have minimal excess adipose tissue around the abdomen with a "normal" body fat range (BMI, 18.0 – 24.9), and are generally recruited for abdominal-related EMG studies. Rate of performance also has an effect on muscle recruitment during an abdominal exercise. Exercises performed at a faster rate will generate higher accelerations requiring higher muscle forces (Axler and McGill, 1997).

2.3 Electromyography and Clinical Relationship

Generative research (i.e., observational analysis) has primarily been applied in studying bed rising movements and bed devices, whereas evaluative research (i.e., usability, electromyography) has

commonly been employed for studies on abdominal exercises. However, the application of both qualitative and quantitative research methods has not yet been conducted on bed rising movements, specifically with assistive intervention. The synthesis of electromyography and clinical assessments provided the impetus for the present study in determining the effective use of assistive devices in health care. Various studies were therefore explored, which included research on common bed rising movements (Ford-Smith and VanSant, 1993; Alexander et al., 1995), abdominal exercises (Flint, 1965; Axler and McGill, 1997; Lehman and McGill, 2001; Vezina, 2001), implications of abdominal surgery, and self-perceived recovery measures (Wolfer and Davis, 1970; Wilson, 1981; Bray, 1986; Doyle, 1999.

CHAPTER 3. EXPERIMENTAL METHODS FOR ELECTROMYOGRAPHY STUDY

3.1 Introduction

Previous studies have not examined the efficacy of self-transfer devices during bed rising. The scope of the laboratory study was to characterize muscle activity during bed rising movements assumed in a clinical setting. The exercise task, adopted from Ford-Smith and VanSant (1993), was selected to represent bed rising movements for participants in the clinical study. Muscle activity was collected from three abdominal sites (upper rectus, lower rectus and external oblique) and the usability of the devices was rated using a 7-point Likert Scale.

3.2 Experimental Design

A laboratory study was conducted to measure muscle activity during the concentric and eccentric phases of bed rising tasks. A within-subject design was used to test whether the effects of bed-rise configuration, bed elevation angle, in addition to age and gender, affected muscle activity at the upper rectus abdominis (URA), lower rectus abdominis (LRA), and external oblique (EO) sites. The order of the treatment combinations was randomized following a Latin Square (Table 2).

Table 2. Latin Square order of exposure for configuration and angle conditions.

	Treatment Conditions*									
Participants	UA		A1	A2	A1	A2	B1	B2	B1	B2
	0°	30°	0°		30°		0°		30°	
1/11	1	2	3	4	5	6	7	8	9	10
2/12	2	3	4	5	6	7	8	9	10	1
3/13	10	1	2	3	4	5	6	7	8	9
4/14	3	4	5	6	7	8	9	10	1	2
5/15	9	10	1	2	3	4	5	6	7	8
6/16	4	5	6	7	8	9	10	1	2	3
7/17	8	9	10	1	2	3	4	5	6	7
8/18	5	6	7	8	9	10	1	2	3	4
9/19	7	8	9	10	1	2	3	4	5	6
10/20	6	7	8	9	10	1	2	3	4	5

*Note: UA = unassisted; A1 = ABNOSTRAIN™ at low anchor height; A2 = ABNOSTRAIN™ at high anchor height; B1 = Bed Pull-Up at low anchor height; B2 = Bed Pull-Up at high anchor height

3.3 Participants

A sample size of ten was estimated from pilot data to approach power at 0.8. Previous EMG reliability studies have suggested experimental designs to obtain at least 80% power in identifying significant differences with an alpha level of 0.05 (Cichetti, 1999).

Potential participants were screened for any past or recent musculoskeletal conditions that would hinder their performance or place them at risk during the study. Those who exhibited excess adipose tissue around the abdomen or had a body fat percentage over 25% were excluded from the study (normal BMI = 18.0 – 24.9). Advertisement for participants was primarily conducted through posters on campus, nearby gyms, and list-serves affiliated with the university with compensation at $7.00/hour.

3.4 Independent Variables

The independent variables for this study were bed-rise configuration and head elevation angle. The bed-rise configuration included unassisted bed-rise (UA), bed-rise with the ABNOSTRAIN™ (A1, A2), and bed-rise with the Bed Pull-Up (B1, B2). In order to support a full-factorial design, the device conditions were combined with anchor height, the position to which the device was pinned to the footboard frame. Both device conditions were assigned numbers to denote the low and high anchor positions (P1 and P2, respectively).

3.4.1 Experimental Equipment

The exercise task required participants to perform a sit-up with legs extended and unrestrained during manual bed rising with no device (UA), and bed rising with a self-transfer device (A1, A2, B1 and B2). The ABNOSTRAIN™ and Bed Pull-Up assistive devices were selected as products potentially available to the patient population. The ABNOSTRAIN™ prototype contained a series of six handles with rubber grips approximately 4-inches in length and 1-inch in diameter. The ABNOSTRAIN™ attached to the footboard frame by adjusting the nylon webbing and secured with the plastic buckle (Figure 6). The Bed Pull-up was made of cloth webbing and consisted of four rungs sewn 10-inches

apart. The device attached to the footboard by adjusting the webbing and secured with the small metal clasp (Figure 1).

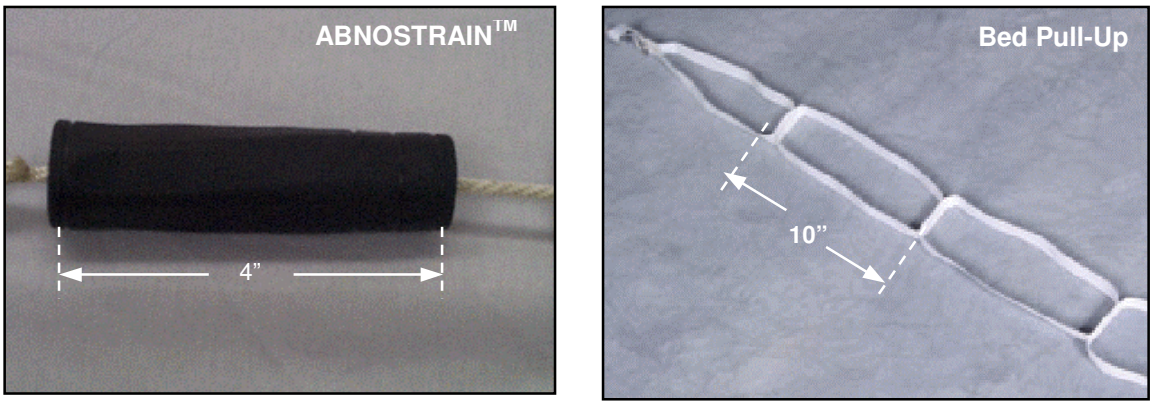


Figure 1. Close-up image of the (L) ABNOSTRAIN™ device, and (R) Bed Pull-Up devices.

Two anchor heights, P1 (attached to the footboard horizontal) and P2 (6 inches above P1), were chosen arbitrarily, but with the intent to simulate a number of different footboard heights. Both assistive devices were secured at the middle of the footboard frame (Figure 2).

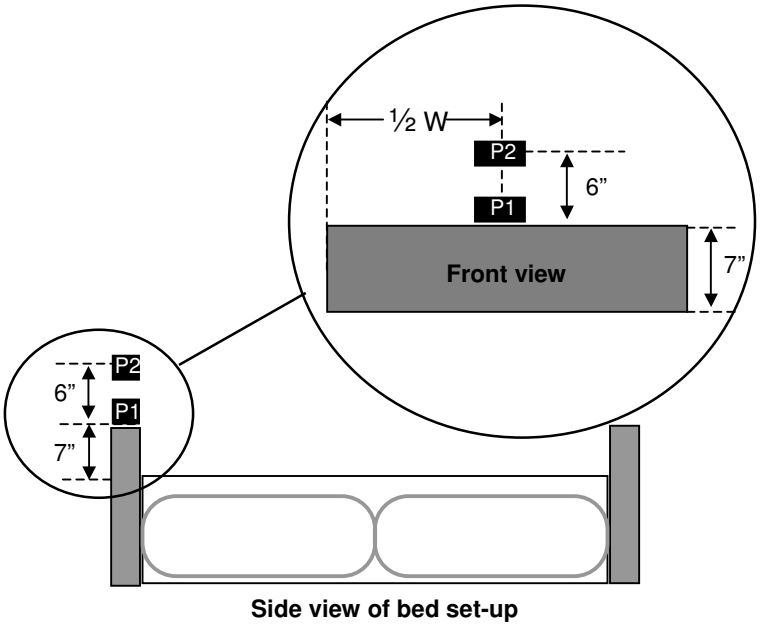


Figure 2. Schematic of bed for device set-up (Note: P1 = Low anchor point; P2 = High anchor point; W = width of footboard).

Participants performed bed rising at two different head elevation angles: 0° and 30° (Figure 3). For the treatment conditions at the 0° position, participants started the exercise task by lying supine on a fully reclined hospital bed. At the 30° angle treatment conditions, participants were asked to perform bed rising with the bed surface elevated 30^{o} above horizontal. The variation in evaluation angles was selected to represent a range of possible head angles for patients following abdominal surgery.

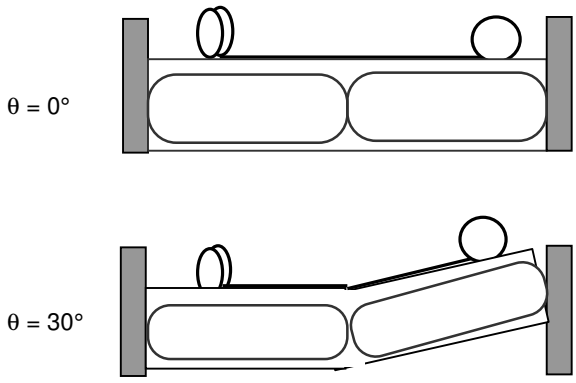


Figure 3. Side-view of bed schematic at 0° and elevated to 30°.

3.5 Dependent Variables

The dependent measures consisted of mean and peak normalized root-mean-square (RMS) EMG, and subjective ratings for device usability. EMG was collected using an EMG amplifier (Measurement Systems, Inc., Ann Arbor, MI, USA) and multiplied by 100 with a preamplifier with a band-pass filter of 10-500Hz. RMS EMG data was sampled at 64 Hz using 110 ms time constant. Given a 10-second exercise window for both the concentric and eccentric phases, RMS data was collected, processed and low-pass filtered with a Butterworth filter (cutoff frequency at 3 Hz) using a program developed in LabView 5.1 (National Instruments).

The concentric and eccentric phases were separated using an event marker in a LabView program, in which the on-off timing activation of the muscles was also estimated (noise was calculated as 2 standard deviations from mean value in 10ms window). Mean and peak RMS_{ij} for each trial i and

muscle *j* in the different phases were then normalized to $RMSmvc_j$ over a 5-second sample, as shown in Figure 4.

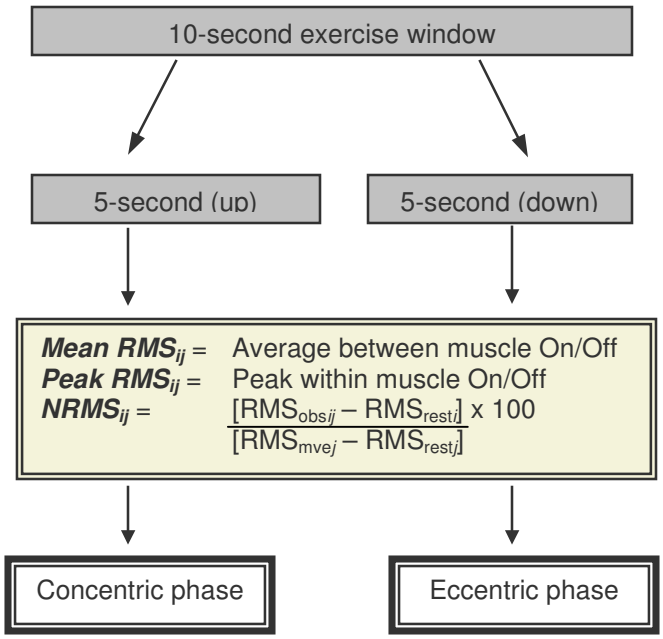


Figure 4. Schematic of signal processing where $NRMS_{ij}$ is the normalized value for muscle *j* and trial *i*.

3.5.1 Electrode Placement and Preparation

Three pairs of Ag/Ag Cl (3 cm) surface electrodes were placed in a bipolar arrangement over the muscle sites at a distance of 3 cm, center-to-center. The three abdominal muscle sites of interest included: (1) the lower rectus abdominis (LRA), centered on the muscle belly midway between the pubis and umbilicus (Gilleard et al., 1994); 2) upper rectus abdominis (URA), centered on the muscle belly midway between the sternum and the umbilicus (Gilleard et al., 1994); 3) external oblique (EO), approximately 15cm lateral to the umbilicus (Vezina, 2000). To keep the inter-electrode resistance below 10kΩ and ensure good skin-electrode contact, the skin was shaved, lightly abraded with a polishing stone, and cleansed with 70% rubbing alcohol. Muscle activity using surface EMG was collected from the right side of the abdomen. A reference electrode was placed over the right iliac crest as the ground signal.

Following a 10-minute stabilization period to ensure a stable temperature and impedance (Redfren, 1992), resting muscle (baseline) activity was collected over a 5-second period.

3.5.2 Maximum Voluntary Exertions

Maximal voluntary isometric exertions (MVEs) were performed to estimate the maximum EMG activity at the three abdominal sites and to normalize EMG data during the experimental trials. The largest RMS value at each muscle site was considered as the participant's MVE regardless of the normalization procedure from which it was obtained.

MVE procedures were adopted from Vezina (2000) as exercises intended to produce the maximal activity for the URA, LRA and EO sites. To assume better comparisons between the bed-rise conditions, slight modifications were made to the MVE postures to represent the task-specific nature of the exercise trials. Large Velcro straps were placed across the hips and ankles to prevent leg movement with hands placed under the lower back for support. Lehman and McGill (2001) suggested that placing the hands under the lower back would prevent the lower back from rounding out (press flat to the floor) during the exercises. Compressive loading on the lumbar spine may contribute to degenerative changes of the lumbar disk with repeated sit-up activity (Halpern and Bleck, 1979) and increase the risks associated with low back injury (Axler and McGill, 1997). Participants with minimal shoulder flexibility were asked to extend arms with their palms facing their legs.

Participants were instructed to exert as much resistance as possible against the padded strap placed across the chest. Intended to elicit maximal URA and LRA activity, participants raised the trunk in flexion against the chest strap for the "Restrained Sit-Up Effort." Intended to elicit maximal EO activity, participants raised the trunk and rotated to the left against the chest strap during the "Trunk Rotation to the Left" procedure. Participants practiced the MVE procedures for one minute to ensure proper execution of the ramp-up to maximum, hold and ramp down method. Following a two-minute rest period after the practice session, participants performed a minimum of two MVC trials for each normalization exercise. In cases where muscle activity at the respective abdominal sites displayed greater

values than the preceding trial, additional MVE trials were performed until a decrease in muscle activity was observed in the following trial. The order of the normalization trials was randomized. MVEs were collected over a 7-second period with a 2-minute rest period between each trial. Participants were encouraged to exert maximum activity with verbal cues, "Push, Push, Push," repeated by the experimenter.

3.6 Experimental Procedures

Participants received a verbal and written description of the project, its objective and procedures and completed informed consent forms approved through the Virginia Tech Institutional Review Board. A screening questionnaire and minimum sit-up test were conducted to determine the eligibility of the participant on the day of testing (Appendix A). Participants who met all inclusion criteria completed a demographic questionnaire, including information on age, height, weight, and fitness level (Appendix B).

3.6.1 Experimental Task

The handles of the bed devices were adjusted to be within reach of the participant's hand while lying supine. After completing the MVEs, participant practiced the bed rise conditions at the 0° angle (and devices fixed at P1 anchor height) for five minutes. The practice session was intended to minimize any learning effects and warm-up the muscles before the experimental trials. Participants were instructed prior to each trial to concentrate on using the upper extremity and minimize abdominal activity during bed rising. Verbal instructions remained consistent throughout the testing session in efforts to simulate the impaired mobility of postoperative patients. Additional trials were required if inconsistent EMG readings were observed.

A two-minute rest period was given prior to testing. Participants performed the experimental task for approximately two and a half hours with recurrent rest periods. On verbal command, "Ready, set, one," participants were asked to raise the trunk to 90° flexion over a five-second time duration, maintain the posture for two seconds (to indicate end of concentric phase), and lower the trunk to resting position

over another five-second exercise window. A metronome was used to control the rate of the exercise, set at 60 beats per minute. During the unassisted condition, participants were asked to perform manual bed rising without the aid of any devices. For the assisted conditions, participants were asked to perform the concentric phase of the bed-rise task using the following movements: 1) grab first handle with right-hand and pull, 2) shoulders lift from bed surface, 3) extend left-hand to second handle and pull, 4) extend right-hand to third handle and pull; 5) complete movement until 90° torso flexion.

Verbal instructions were emphasized throughout the testing session: " Focus on using the upper extremity only and minimize any movement below the waist." Participants were asked to complete three trials for each treatment condition with one-minute rest periods between each trial, and two-minute rest periods between each treatment condition. Subjective usability ratings were obtained at the end of each treatment condition using a 7- and 11-point Likert scale. Participants also provided short-answers and final rankings on the bed rise-conditions in the exit survey.

3.6.2 Usability and Exit Survey

Usability ratings on the comfort and security of the devices were based on a 7-point Likert Scale (0 = Strongly Agree and 6 = Strongly Disagree), and overall performance on an 11-point Likert Scale (0 = poor and 10 = excellent). Participants were also asked to complete an exit survey and provide additional answers on whether they liked or disliked the devices, on bed elevation angle ("Did the higher starting angle help you perform the assisted task much easier, easier, about the same, harder, or much harder than in the flat, horizontal position?") and whether any discomfort was experienced ("Did you experience any additional discomforts or pain? If so, please indicate where."). In addition, participants provided a final ranking on a scale from 1 = Best Condition to 3 = Worst Condition, for the unassisted, ABNOSTRAIN™ and Bed Pull-Up conditions.

3.7 Statistical Analysis

A program developed in LabView 5.1 was used to separate the concentric and eccentric phases for data analysis. Statistics were calculated for each dependent variable using JMP (version 5.0) and SAS. In testing whether the data fit a normal distribution, the Shapiro-Wilk test for normality was used on all dependent variables. A total of six two-way repeated measures analyses of variance (ANOVA) models (including both concentric and eccentric phases) were employed to determine any significant differences of the main effects and all two-way interactions on the responses variables at each muscle site. The statistical model used was as follows: $Y_{ijklm} = \alpha_i + \beta_j + \chi_k + \phi_l + \gamma_{(kl)} + \varepsilon_{m(ijkl)} + \alpha\beta_{ij} + \alpha\chi_{ik} + \alpha\phi_{il} + \beta\chi_{jk} + \beta\phi_{jl} + \chi\phi_{kl}$; where α = Device Configuration; β = Angle; χ = Gender; ϕ = Age; γ = Subject; ε = Error.

Subjective ratings from the usability survey and final rankings were compared using ANOVA and the test of homogeneity respectively. All post-hoc analyses were conducted using Tukey's Honestly Significant Difference (HSD) to identify the differences within the significant findings. All results were reported significant at an alpha level of 0.05.

3.8 Results

3.8.1 Participants

A total of twenty participants, between the ages of 18 to 55 years old, were recruited to represent a sample population of different ages and varying fitness levels (Table 3). Twenty-two participants were originally screened for the study; however, two subject files could not be used due to hardware problems. Nine men (age, 33.7 ± 8.0; BMI, 23.3 ± 3.2) and eleven women (age, 34.5 ± 12.9; BMI, 21.0 ± 1.5) completed the study as described. Nine participants, less than 30 years old, were classified as the young group (26.9 ± 4.6 years). Eleven of the participants, who were 30 years old or above, were classified as the older group (40.9 ± 8.8 years). Participants did not report any musculoskeletal conditions that would have hindered their performance or place them at risk during the experimental tasks. Those who exhibited excessive subcutaneous abdominal adipose tissue or had a body fat percentage outside the

normal body fat range were not considered eligible for the study. All participants were right-hand dominant, and passed the 10 minimum sit-up test with legs extended and unrestrained.

Fitness level was defined as the average number of workout sessions per week, which included 30 minutes of cardiovascular activity at minimum. The young group averaged approximately 2.5 sessions/week (fitness level, 6.0 ± 1.8) and the older group averaged 2.0 sessions/week (fitness level, 5.7 ± 1.6). Both age groups participated in activities including aerobics, running, walking, weight lifting, and abdominal exercises (i.e., sit-ups, leg lifts and crunches). The testing session required approximately 2.5 hours.

Table 3. Descriptive summary of participants.

	Young (n = 9)	Older (n = 11)
Age, years	26.9 ± 4.6	40.9 ± 8.8
Height, m	1.8 ± 0.1	1.7 ± 0.1
Weight, kg	66.5 ± 10.9	65.2 ±12.6
Body mass index, kg/m^2	21.4 ± 2.1	22.5 ±3.0
Fitness level (1-7)	6.0 ± 1.8	5.7 ± 1.6
Included abdominal training (n = 12)	6	6
Gender:		
Male (n = 9)	4	5
Female (n = 11)	5	6
Occupation:		
Student/Researcher	8	3
Supervisory	0	4
Homemaker	0	2
Other	1	2

3.8.2 Electromyography (EMG)

EMG data were found to approximate a normal distribution ($p > 0.05$). Since three trials were performed for each treatment condition, and a Latin Square order sequence was applied, trial and order effects were tested. ANOVA results indicated that trial and order effects were not significant for both mean and peak activity in the concentric or eccentric phases.

Results from the mixed factors ANOVA are presented in Table 4 for mean and peak muscle activity in the concentric and eccentric phases. Overall, exercises performed in the concentric direction

produced greater muscle activity than in the eccentric phase. Gender or age effects did not influence differences in muscle activity in either the concentric or eccentric phases; however, age interactions were predominantly evident in the concentric direction ($p < 0.05$). The age by configuration interaction was significant for mean URA, and for mean and peak EO activity. Additionally, differences in mean and peak EO activity were evident in the age by angle interaction.

The effects of configuration, angle and their two-way interaction contributed to differences in muscle activity in both the concentric and eccentric phases ($p < 0.05$). The effects were generally observed for mean and peak activity at the URA and LRA sites. A summary of the descriptive statistics and post-hoc comparisons are summarized in Tables 5-7 for the concentric phase, and Tables 8-9 for the eccentric phase.

Table 4. Significant terms (shaded areas) from mixed factors ANOVA for both phases.

Muscle	Source	Mean		Peak	
		Up	Down	Up	Down
URA	Gender	0.6538	0.6626	0.8723	0.6576
	Age	0.1536	0.0986	0.1447	0.1283
	Gender x Age	0.1033	0.2336	0.3213	0.4157
	Configuration	**<.0001***	**<.0001***	**<.0001***	**<.0001***
	Gender x Configuration	0.6839	0.7864	0.1899	0.8815
	Age x Configuration	**0.0449***	0.3356	0.1383	0.1624
	Angle	**0.0095***	0.0911	**0.0075***	**0.0227***
	Gender x Angle	0.8574	0.5423	0.7006	0.3338
	Age x Angle	0.2586	0.2154	0.1047	0.3743
	Configuration x Angle	**<.0001***	**0.0007***	**<.0001***	**0.0422***
LRA	Gender	0.3683	0.4701	0.3237	0.1167
	Age	0.7706	0.3459	0.9576	0.6905
	Gender x Age	0.1480	0.0823	0.2528	0.4922
	Configuration	**<.0001***	**0.0047***	**<.0001***	**<.0001***
	Gender x Configuration	0.0712	0.1424	0.0801	0.2425
	Age x Configuration	0.3429	0.4007	0.4539	0.9776
	Angle	**0.0025***	0.4111	**0.0092***	**0.0058***
	Gender x Angle	0.5082	0.2021	0.7614	0.6338
	Age x Angle	0.5264	0.3524	0.3772	0.4164
	Configuration x Angle	**0.0001***	0.1977	**0.0271***	**0.0138***
EO	Gender	0.3270	0.1253	0.1994	0.0707
	Age	0.1411	0.7699	0.0658	0.8884
	Gender x Age	0.1360	0.3612	0.2505	0.4081
	Configuration	**<.0001***	**0.0009***	**<.0001***	**0.0220***
	Gender x Configuration	0.2080	0.8512	0.4737	0.6314
	Age x Configuration	**0.0003***	0.1787	**0.0003***	0.9992
	Angle	**0.0199***	0.1075	**0.003***	0.3160
	Gender x Angle	0.6807	0.4511	0.4556	0.4519
	Age x Angle	**0.0143***	0.6758	**0.0442***	0.4179
	Configuration x Angle	0.9252	0.6010	0.2418	0.5939

Table 5. Means (SD) of mean and peak activity during the concentric phase (%MVE).

Variable		Mean activity			Peak activity		
		URA	LRA	EO	URA	LRA	EO
Gender	Female	9.6 (8.5)	12.1 (8.6)	12.6 (7.4)	26.7 (23.6)	30.2 (25.1)	28.0 (14.9)
	Male	11.2 (13.4)	9.6 (8.1)	9.8 (8.8)	25.5 (29.9)	21.9 (22.3)	20.8 (18.1)
Age	Young	12.2 (12.8)	11.1 (7.1)	13.2 (7.9)	31.1 (30.4)	26.1 (19.9)	29.8 (16.8)
	Old	8.3 (7.8)	11.1 (9.8)	9.7 (7.9)	21.4 (20.4)	27.6 (28.1)	20.4 (15.2)
Configuration	UA	21.2 (15.0)	19.7 (8.9)	15.4 (10.0)	52.9 (33.9)	47.7 (25.3)	34.2 (19.9)
	A1	9.4 (8.4)	11.1 (7.4)	12.8 (8.1)	24.8 (23.4)	26.2 (20.8)	27.9 (16.6)
	A2	4.8 (5.4)	6.0 (5.2)	9.3 (7.3)	14.0 (19.7)	15.8 (20.2)	20.7 (16.4)
	B1	9.7 (7.4)	11.3 (7.0)	10.9 (6.6)	25.0 (20.0)	27.3 (21.8)	23.2 (15.5)
	B2	6.1 (5.9)	7.5 (6.4)	9.0 (6.4)	14.6 (13.8)	17.3 (19.1)	19.6 (12.8)
Angle	0°	11.0 (11.9)	11.6 (8.9)	11.7 (8.3)	28.8 (30.4)	28.8 (25.9)	26.2 (16.8)
	30°	9.5 (9.5)	10.6 (8.1)	11.3 (8.0)	23.7 (21.1)	24.9 (22.5)	24.1 (16.5)
Configuration by Angle (0°)	UA	24.5 (15.6)	21.9 (9.2)	15.7 (10.8)	63.6 (38.0)	53.7 (24.5)	35.0 (20.6)
	A1	9.2 (9.1)	10.8 (7.0)	12.8 (7.8)	24.0 (19.9)	26.1 (21.1)	28.1 (16.0)
	A2	5.0 (5.7)	6.4 (5.5)	9.8 (7.6)	16.6 (26.0)	18.8 (24.7)	23.5 (16.7)
	B1	10.0 (8.0)	11.6 (6.7)	11.1 (6.3)	24.8 (18.4)	28.2 (22.4)	23.6 (12.8)
	B2	6.2 (6.5)	7.5 (6.5)	9.3 (6.6)	15.0 (14.8)	17.4 (19.5)	20.7 (13.1)
Configuration by Angle (30°)	UA	18.0 (13.8)	17.4 (8.2)	15.1 (9.1)	42.2 (25.4)	41.7 (24.9)	33.5 (19.3)
	A1	9.6 (7.7)	11.4 (7.9)	12.8 (8.5)	25.5 (19.7)	26.3 (20.7)	27.7 (17.4)
	A2	4.7 (5.1)	5.6 (4.9)	8.9 (7.0)	11.3 (10.7)	12.8 (14.0)	17.9 (13.8)
	B1	9.5 (6.7)	11.0 (7.4)	10.8 (7.0)	25.2 (18.7)	26.4 (21.3)	22.7 (13.7)
	B2	5.9 (5.4)	7.5 (6.3)	8.7 (6.2)	14.2 (12.9)	17.2 (19.0)	18.4 (12.4)

Table 6. Post-hoc comparisons for (L) configuration, and (R) configuration by angle interaction in the concentric phase. Note: Shaded regions were not summarized in the results.

EMG Variable	Condition	Mean (%MVE)			
URA mean	U1	21.6	A		
	B1	9.7		B	
	A1	9.5		B	
	B2	6.2		B	C
	A2	5.0			C
LRA mean	U1	19.2	A		
	A1	11.0		B	
	B1	10.9		B	
	B2	7.3			C
	A2	6.0			C
EO mean	U1	19.2	A		
	A1	11.0		B	
	B1	10.9		B	
	B2	7.3			C
	A2	6.0			C
URA peak	U1	19.2	A		
	A1	11.0		B	
	B1	10.9		B	
	B2	7.3			C
	A2	6.0			C
LRA peak	U1	46.3	A		
	B1	26.2		B	
	A1	25.2		B	
	B2	16.4			C
	A2	16.1			C
EO peak	U1	33.9	A		
	A1	26.8		B	
	B1	22.4		B	C
	A2	20.0			C
	B2	18.9			C

EMG variable	Interaction	Mean (%MVE)					
URA mean	U1,0	24.8	A				
	U1,30	18.4		B			
	B1,0	9.9			C		
	A1,30	9.7			C		
	B1,30	9.5			C		
	A1,0	9.3			C		
	B2,0	6.4				D	
	B2,30	6.0				D	
	A2,0	5.2				D	
	A2,30	4.9				D	
LRA mean	U1,0	21.4	A				
	U1,30	17		B			
	A1,30	11.3			C		
	B1,0	11.1			C		
	A1,0	10.6			C		
	B1,30	10.6			C		
	B2,30	7.3				D	
	B2,0	7.3				D	
	A2,0	6.4				D	
	A2,30	5.6				D	
URA peak	U1,0	64.3	A				
	U1,30	42.7		B			
	A1,30	24.7			C		
	B1,30	24.5			C		
	B1,0	24.1			C		
	A1,0	23.3			C	D	
	A2,0	17.3			C	D	
	B2,0	14.7			C	D	
	B2,30	13.8			C	D	
	A2,30	11.9				D	
LRA peak	U1,0	52.4	A				
	U1,30	40.3		B			
	B1,0	27.1			C		
	A1,30	25.3			C	D	
	B1,30	25.2			C	D	
	A1,0	25.2			C	D	
	A2,0	19.1			C	D	E
	B2,0	16.5				D	E
	B2,30	16.3				D	E
	A2,30	13.1					E

Table 7. Post-hoc comparisons for the (L) age by configuration, and (R) age by angle interactions during the concentric phase. Note: Shaded regions were not summarized in the results.

EMG variable	Interaction	Mean (%MVE)				
URA mean	O,U1	26.9	A			
	Y,U1	16.3		B		
	O,A1	11.6		B	C	
	O,B1	11.5		B	C	
	O,B2	8.1			C	D
	Y,B1	7.9			C	D
	Y,A1	7.4			C	D
	O,A2	6.4			C	D
	Y,B2	4.4				D
	Y,A2	3.6				D
EO mean	O,U1	20.7	A			
	O,A1	14.8		B		
	O,B1	11.8		B	C	
	O,A2	10.4		B	C	
	Y,A1	10.2		B	C	
	Y,U1	10.1		B	C	
	O,B2	9.3			C	
	Y,B1	9.2			C	
	Y,B2	8.1			C	
	Y,A2	7.5			C	
EO peak	O,U1	45.5	A			
	O,A1	31.5		B		
	O,B1	25.9		B	C	
	O,A2	24.5		B	C	D
	Y,U1	22.4		B	C	D
	Y,A1	22.2		B	C	D
	O,B2	21.2			C	D
	Y,B1	18.8			C	D
	Y,B2	16.6			C	D
	Y,A2	15.4				D

EMG variable	Interaction	Mean (%MVE)			
EO mean	O,0	13.9	A		
	O,30	12.9		B	
	Y,30	9.0			C
	Y,0	9.0			C
EO peak	O,0	31.5	A		
	O,30	27.9		B	
	Y,0	19.5			C
	Y,30	18.6			C

Table 8. Means (SD) of mean and peak activity during the eccentric phase (%MVE).

Variable		Mean activity			Peak activity		
		URA	LRA	EO	URA	LRA	EO
Gender	Female	6.5 (6.6)	8.3 (6.6)	9.2 (8.1)	15.8 (17.8)	18.8 (18.5)	19.5 (31.5)
	Male	7.6 (9.7)	6.8 (25.9)	5.4 (4.9)	14 (16.0)	9.2 (9.8)	9.6 (8.1)
Age	Young	8.8 (9.7)	8.3 (23.1)	7.8 (5.4)	17.9 (18.6)	13.4 (10.0)	15.5 (11.5)
	Old	5.1 (5.1)	7.1 (7.3)	7.6 (8.7)	12.2 (14.9)	16.5 (20.6)	15.6 (34.1)
Configuration	UA	12.1 (11.7)	11.0 (7.7)	9.4 (10.4)	27.6 (25.0)	24.2 (23.5)	22.8 (49.6)
	A1	7.0 (6.7)	10.4 (36.2)	8.5 (6.5)	14.4 (11.2)	15.6 (13.7)	15.6 (10.4)
	A2	3.8 (4.8)	3.7 (3.3)	5.7 (5.5)	8.4 (16.3)	7.7 (8.4)	9.9 (8.4)
	B1	7.6 (6.6)	8.5 (6.0)	8.3 (7.0)	16.0 (11.6)	16.7 (13.7)	17.3 (20.4)
	B2	4.5 (5.2)	5.0 (5.0)	6.6 (5.0)	8.8 (8.6)	10.5 (13.0)	12.0 (9.5)
Angle	0°	7.3 (8.6)	7.3 (6.2)	8.1 (8.0)	17.1 (20.4)	16.0 (16.4)	17.1 (33.9)
	30°	6.6 (7.3)	8.1 (23.5)	7.3 (6.4)	13 (12.7)	13.9 (16.0)	14 (11.8)
Configuration by Angle (0°)	UA	14.0 (13.6)	11.8 (8.0)	10.3 (12.9)	33.1 (29.4)	27.1 (23.8)	27.7 (68.7)
	A1	6.3 (5.9)	6.8 (4.6)	8.3 (5.8)	15.1 (12.5)	15.1 (12.4)	15.7 (10.3)
	A2	4.4 (5.7)	4.4 (3.5)	6.4 (5.8)	10.8 (22.3)	9.1 (8.9)	11.1 (8.6)
	B1	7.5 (5.6)	8.5 (5.7)	8.4 (7.1)	17.2 (11.9)	17.7 (13.8)	18.5 (25.8)
	B2	4.4 (5.3)	5.1 (5.5	7.0 (5.3)	9.2 (9.1)	10.9 (13.1)	12.3 (9.7)
Configuration by Angle (30°)	UA	10.2 (9.3)	10.1 (7.5)	8.5 (7.0)	22.1 (18.3)	21.4 (23.1)	18.0 (14.4)
	A1	7.6 (7.5)	14.0 (50.9)	8.6 (7.3)	13.7 (9.9)	16.1 (14.9)	15.6 (10.7)
	A2	3.1 (3.5)	2.9 (2.8)	5.0 (5.1)	6.0 (5.2)	6.3 (7.7)	8.8 (8.1)
	B1	7.7 (7.6)	8.4 (6.4)	8.1 (7.0)	14.8 (11.4)	15.7 (13.6)	16.1 (13.1)
	B2	4.5 (5.2)	4.9 (4.6)	6.1 (4.5)	8.4 (8.1)	10.1 (12.9)	11.7 (9.3)

Table 9. Post-hoc comparisons for (L) configuration, and (R) configuration by angle interaction in the eccentric phase. Note: Shaded regions were not reported in the results.

EMG Variable	Condition	Mean (%MVE)			
URA mean	U1	12.3	A		
	B1	7.7		B	
	A1	7.0		B	C
	B2	4.7		B	C
	A2	3.8			C
LRA mean	A1	10.9	A		
	U1	10.4	A		
	B1	8.1	A	B	
	B2	4.8	A	B	
	A2	3.5		B	
EO mean	U1	9.0	A		
	A1	8.2	A	B	
	B1	7.8	A	B	C
	B2	6.2		B	C
	A2	5.3			C
URA peak	U1	27.4	A		
	B1	15.6		B	
	A1	14.2		B	
	B2	9.0		B	
	A2	8.2		B	
LRA peak	U1	22.7	A		
	B1	15.5		B	
	A1	14.8		B	
	B2	9.8		B	C
	A2	7.2			C
EO peak	U1	21.1	A		
	B1	16.2	A	B	
	A1	14.9	A	B	
	B2	11.3	A	B	
	A2	9.2		B	

EMG variable	Interaction	Mean (%MVE)						
URA mean	U1,0	14.2	A					
	U1,30	10.4		B				
	B1,30	7.7		B	C			
	B1,0	7.6		B	C	D		
	A1,30	7.6		B	C	D		
	A1,0	6.3			C	D	E	
	B2,30	4.8			C	D	E	
	B2,0	4.7				D	E	
	A2,0	4.5					E	
	A2,30	3.1					E	
URA peak	U1,0	32.8	A					
	U1,30	22		B				
	B1,0	16.6		B	C			
	A1,0	14.7		B	C	D		
	B1,30	14.5		B	C	D		
	A1,30	13.6			C	D		
	A2,0	10.5			C	D	E	
	B2,0	9.3			C	D	E	
	B2,30	8.7				D	E	
	A2,30	5.9					E	
LRA peak	U1,0	25.5	A					
	U1,30	19.9		B				
	B1,0	16.6		B	C			
	A1,30	15.3		B	C			
	B1,30	14.5			C	D		
	A1,0	14.3			C	D	E	
	B2,0	10.1				D	E	F
	B2,30	9.4					E	F
	A2,0	8.5						F
	A2,30	5.9						F

3.8.2.1 Muscle Activity in the Concentric Phase

3.8.2.1.1 Configuration

Mean Activity. Differences in mean muscle activity were significantly influenced by configuration effects ($p < 0.05$). The unassisted configuration (UA) required the most muscle activity across the URA, LRA and EO sites at 21.2%, 19.7% and 15.4% MVE, respectively ($p < 0.05$). Conditions A1 and B1 significantly lowered muscle activity at the URA and LRA sites, with moderate activity ranging from 9.5% to 11.0% MVE. Further reductions in muscle activity was supported by conditions A2 and B2 at the LRA and EO sites, and only A2 at the URA site, with muscle activity ranging from 5.0% to 9.3% MVE.

Peak Activity. Similar results were obtained for peak muscle activity, in which maximum activity was observed at the UA condition, and resulted in 52.9%, 47.7% and 34.2% MVE across the URA, LRA and EO sites, respectively ($p < 0.05$). Reductions in muscle activity were observed with the assisted conditions. The lowest activity was achieved with conditions A1, A2, B1 and B2 (14.0% to 24.8%MVE) at the URA site, and with conditions A2 and B2 at the LRA and EO sites (15.8% to 20.7% MVE). The results for both mean and peak activity are shown in Figure 5.

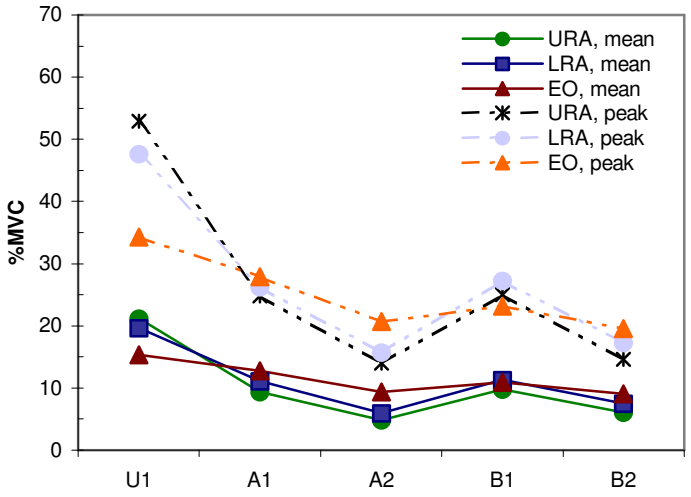


Figure 5. Significant configuration effects for mean and peak activity.

3.8.2.1.2 Angle

Angle effects contributed to significant differences in mean and peak activity across the individual sites (Figure 6). Maximum muscle activity was observed at the 0° angle across all of the muscle sites, with mean activity varying from 11.0% to 11.7% MVE. Muscle activity at the 30° elevation angle ranged from 9.5% to 11.3% MVE.

The 0° angle also affected peak activity for all muscle sites, and resulted in the most activity ranging from 26.2 to 28.8% MVE. Peak activity was significantly reduced at the 30° angle, with muscle activity that varied from 23.7% to 24.9%MVE.

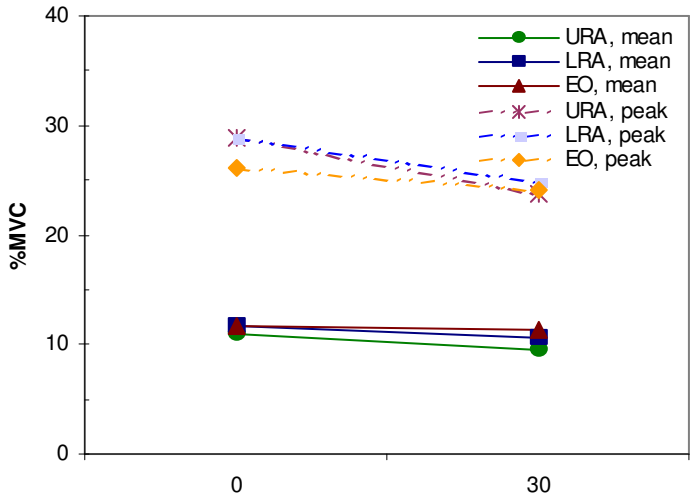


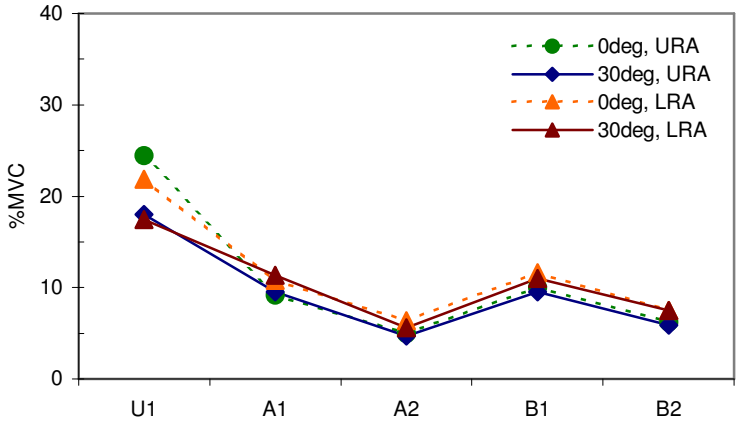
Figure 6. Significant angle effects for mean and peak activity ($p < 0.05$).

3.8.2.1.3 Configuration by Angle Interaction

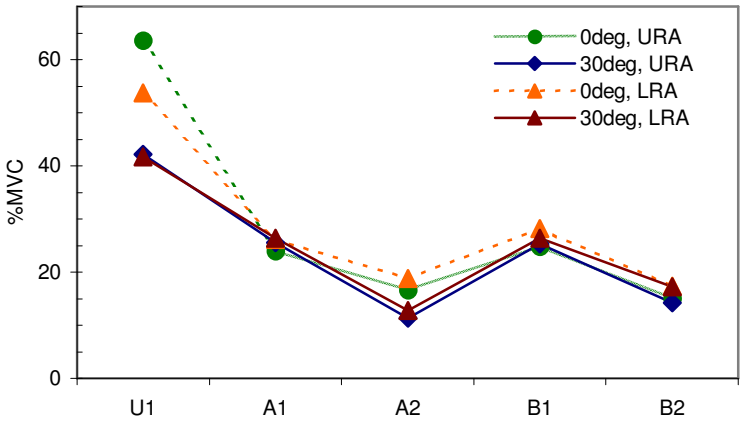
Mean Activity. Differences in mean activity were characterized by the configuration by angle interaction at the URA and LRA muscle sites (Figure 7a). Maximum muscle activity was obtained by UA, 0° angle at the URA and LRA sites (24.5 % and 21.9% MVE, respectively). Mean activity for UA, 30° was significantly reduced to 18.0% and 17.4 % MVE at the URA and LRA sites, respectively.

Regardless of elevation angle, A2 and B2 contributed to the least muscle activity at the URA (4.7% to 6.0% MVE), and LRA (5.6% to 7.6% MVE) sites.

Peak Activity. Similar results were obtained for peak activity in which the highest activity was observed at UA, 0° across the URA and LRA sites (63.6% and 52.4%MVE) (Figure 7b). Significant reductions in muscle activity were associated with UA, 30°, where URA and LRA activity was lowered to 42.2% and 40.3% MVE. Further reductions in muscle activity were observed, specifically B1, 0° at the LRA site (27.1% MVE), and A2, 30° resulting in the least URA and LRA activity (11.3% and 13.1% MVE).



(a)



(b)

Figure 7. Significant configuration by angle interaction for (a) mean and (b) peak activity.

3.8.2.1.4 Age by Angle Interaction

Significant differences in muscle activity were found for the age by angle interaction for mean and peak EO activity. Older participants at 0° had greater mean and peak activity levels (13.9% and 31.5% MVE, respectively). Muscle activity was significantly lowered to 12.9% and 27.9% MVE for the older age group at 30°. Further mean and peak muscle reductions were observed for the younger group, regardless of bed elevation angle (9.0% and 19.0% MVE, respectively).

3.8.2.1.5 Age by Configuration Interaction

Mean Activity. Significant differences in mean activity were found for the age by configuration interaction at the URA and EO sites (Figure 8). Older participants during UA required the highest URA and EO activity (26.9% and 20.7% MVE). Young participants at A2 and B2 resulted in the least URA activity (3.6 and 4.4% MVE), whereas young participants at A2, B1 and B2 (in addition to older participants at B2) required the least EO activity ranging from 7.5 to 9.3% MVE.

Peak Activity. The effects of the age by configuration interaction affected muscle activity at the EO site only. Older participants at UA required maximum activity (45.5% MVE), and younger participants at A2 obtained the least muscle activity of 15.4%.

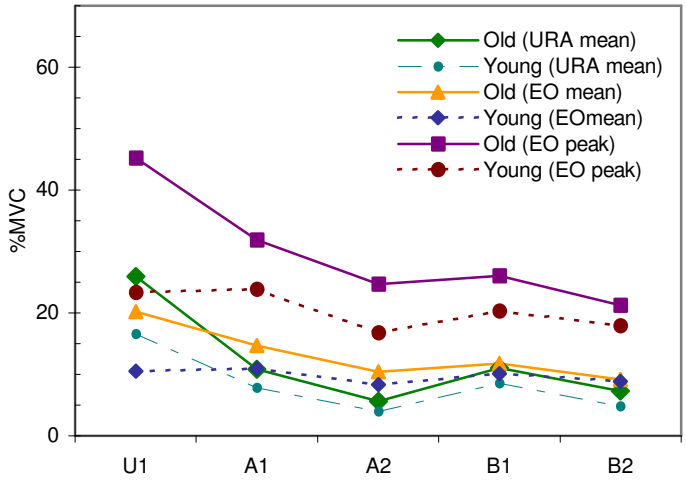


Figure 8. Significant age by configuration interaction for mean and peak activity ($p < 0.05$).

3.8.2.2 Muscle Activity in the Eccentric Phase

3.8.2.2.1 Configuration

Mean Activity. The effects of configuration significantly affected mean muscle activity at all of the sites (Figure 9). UA resulted in the most muscle activity at the URA, LRA and EO sites (21.2%, 19.7% and 15.4% MVE, respectively). Reductions in muscle activity were observed with the assisted conditions; A2 was consistent across all of the sites and required the least activity (3.8% to 5.3 % MVE).

Peak Activity. Similarly, differences in peak muscle activity were found for configuration at the URA, LRA and EO sites. Maximum activity across all of the muscle sites was observed for UA. Although the least muscle activity at the URA site was characterized by all of assisted conditions, A2 resulted in the lowest activity specifically at the LRA and EO sites (7.2% and 9.2% MVE, respectively). The results are summarized in Figure 13, below, for both mean and peak activity. A summary of the descriptive statistics for the effects of configuration is also provided in Table 8.

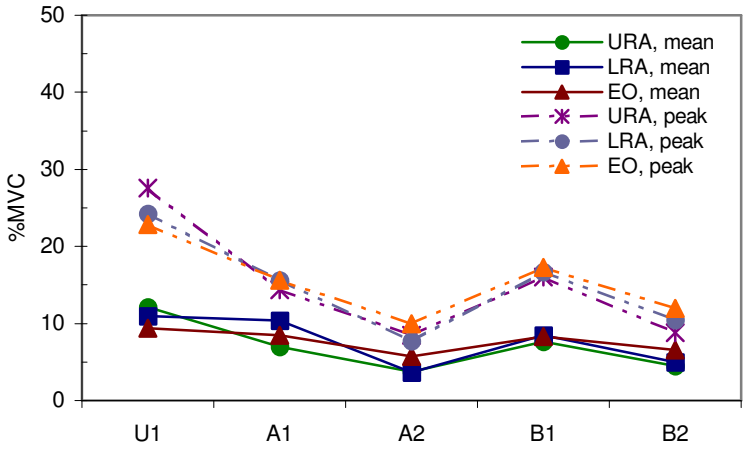


Figure 9. Significant configuration effects during the eccentric phase.

3.8.2.2.2 Angle

The effects of angle significantly affected peak muscle activity at the URA and LRA sites (Figure 10). Maximum activity was observed at 0° at both sites (16.0% and 17.1% MVE), and lower muscle activity was achieved during exercises at the 30° angle (13.9% and 14.0% MVE).

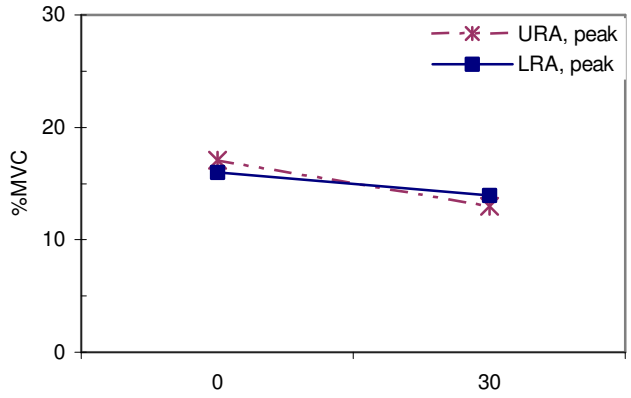
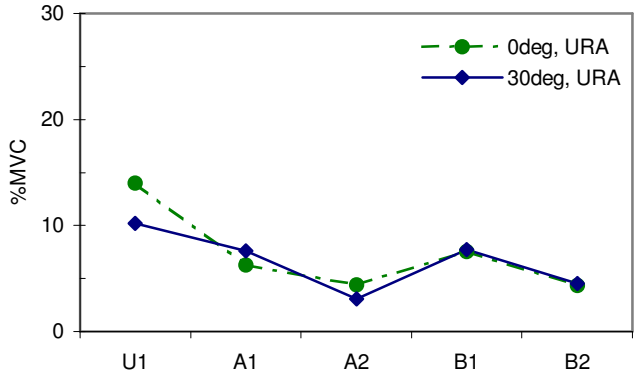


Figure 10. Significant angle effects in the eccentric phase.

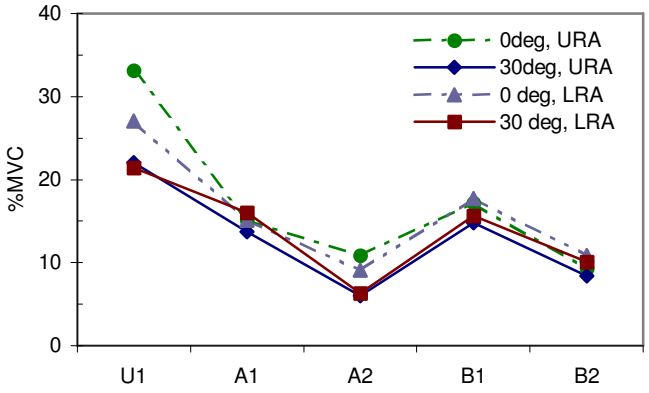
3.8.2.2.3 Configuration by Angle interaction

Differences in mean muscle activity were significant in the configuration by angle interaction at the URA site (Figure 12a). UA, 0° required the most muscle activity at 13.4% MVE, with mean activity lowered to 10.4% MVE at UA, 30°. Regardless of angle, A2 resulted in the least mean URA activity ranging from 3.0 to 4.5% MVE.

For peak activity, the configuration by angle interaction was significant at the URA and LRA sites (Figure 12b). Maximum activity was characterized by UA, 0° (URA = 32.8% and LRA = 25.5% MVE), where peak activity was significantly lowered at UA, 30° (URA = 22.0% MVE, LRA = 19.4% MVE). The least muscle activity, which ranged from 5.9% to 8.5% MVE, was obtained at A2, 30° for peak URA activity, and A2 (regardless of angle) for peak LRA activity.



(a)



(b)

Figure 11. Configuration by angle interaction for (a) mean and (b) peak activity in the eccentric direction.

3.8.3 Usability Survey

3.8.3.1 Device Effects

Ratings on the usability of assistive devices were based on a 7-point Likert Scale, where 0 = Strongly Agree to 6 = Strongly Disagree. Effects of device were significant, specifically questions related to ease of use, comfort of handles, abdominal strain, would use regularly, and recommend to others. Participants reported ratings in support of the ABNOSTRAIN™ for ease of use, comfortable handles, and would use the device regularly (Table 10). Participants also felt that the ABNOSTRAIN™ did not strain the abdominal muscles and would recommend the device to others. In contrast, participants felt less secure using the Bed Pull-Up. The ABNOSTRAIN™ resulted in the highest rating for overall

performance of 8.1 (compared to 5.9 for the Bed Pull-up), where 0 = Worst and 10 = Best condition. A summary of the results is shown in Figure 12.

3.8.3.2 Anchor Effects

Responses to the usability survey were affected by anchor height (Figure 13a). Specifically, participants reported less strain at the abdominal muscles and easier use of the devices at P2 than P1. Participants also indicated a higher overall rating when performing conditions at P2 (7.2 ± 2.2) than P1 (6.8 ± 2.3) on a scale from 0 = worst to 10 = best.

3.8.3.3 Angle Effects

The results, as shown in Figure 13b, indicated that angle effects significantly affected responses in the usability survey. Conditions at the 30° angle resulted in less strain at the abdominal muscles and less soreness in the upper body, compared to conditions at 0°. The 30° angle also allowed participants to use the devices with ease, and improved perception of handle comfort. Participants supported the higher elevation angle in recommending the use of the devices to others.

Table 10. Significant means (SD) for responses in the usability survey (in shaded areas). Responses were based on 0 = Strongly Agree and 6 = Strongly Disagree.

	Device		Anchor		Angle	
	ABNOSTRAIN™	Bed Pull-Up	P1	P2	0°	30°
Q1 Ease of use	**1.01(0.93)**	**2.53 (1.68)**	**1.90 (1.63)**	**1.64 (1.48)**	**1.94 (1.63)**	**1.60 (1.46)**
Q2 Did not strain abdominal muscles	**1.14 (1.00)**	**2.06 (1.39)**	**1.71 (1.33)**	**1.49 (1.25)**	**1.80 (1.31)**	**1.40 (1.26)**
Q3 Did not feel secure	**4.94 (1.52)**	**3.60 (1.90)**	4.24 (1.83)	4.30 (1.87)	4.15 (1.81)	4.39 (1.88)
Q4 Soreness in upper body	**5.03 (1.42)**	**4.34 (1.68)**	4.65 (1.61)	4.71 (1.58)	**4.44 (1.76)**	**4.93 (1.37)**
Q5 Would use regularly	**1.28 (1.04)**	**2.78 (1.72)**	2.13 (1.64)	1.93 (1.57)	2.11 (1.52)	1.94 (1.69)
Q6 Handles are comfortable	**1.23 (1.23)**	**3.88 (2.04)**	2.54 (2.17)	2.56 (2.13)	**2.64 (2.18)**	**2.46 (2.12)**
Q7 Handles too close	4.55 (1.46)	4.94 (1.51)	4.83 (1.41)	4.66 (1.57)	4.90 (1.36)	4.59 (1.61)
Q8 Would recommend to others	**1.45 (1.36)**	**2.88 (1.81)**	2.23 (1.80)	2.10 (1.70)	**2.28 (1.76)**	**2.05 (1.73)**
Q9 Overall performance[a]	**8.06 (1.58)**	**5.93 (2.31)**	**6.84 (2.33)**	**7.15 (2.15)**	6.88 (2.13)	7.11 (2.36)

[a] Based on 0 = Worst condition; 10 = Best condition

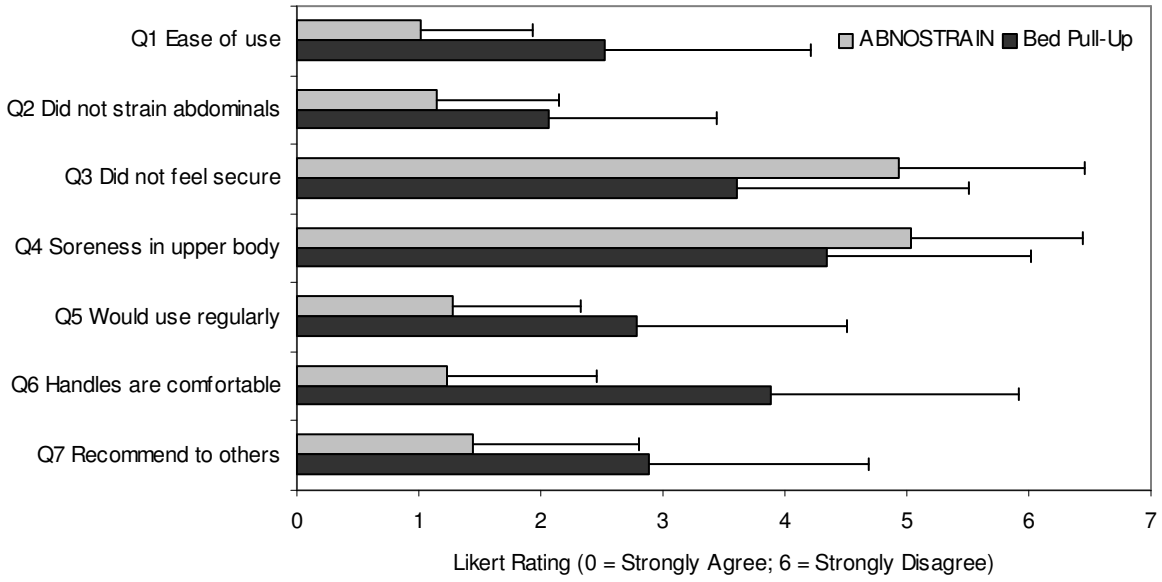
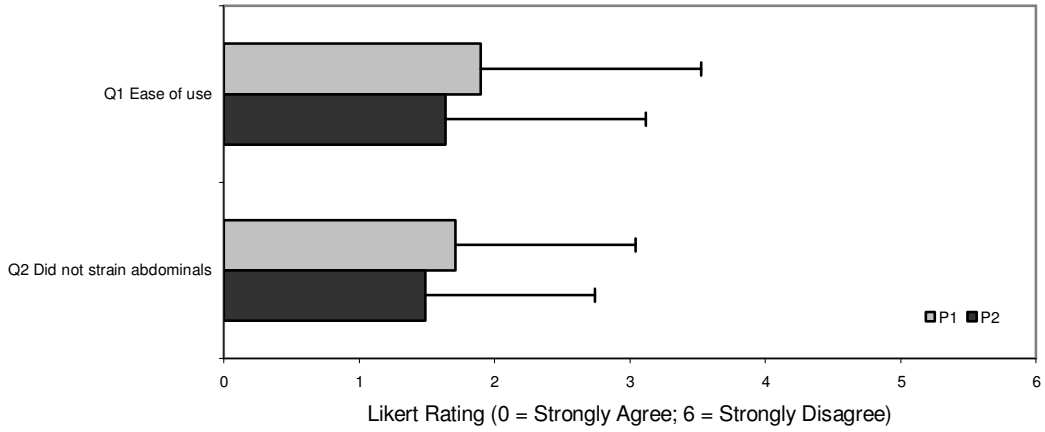
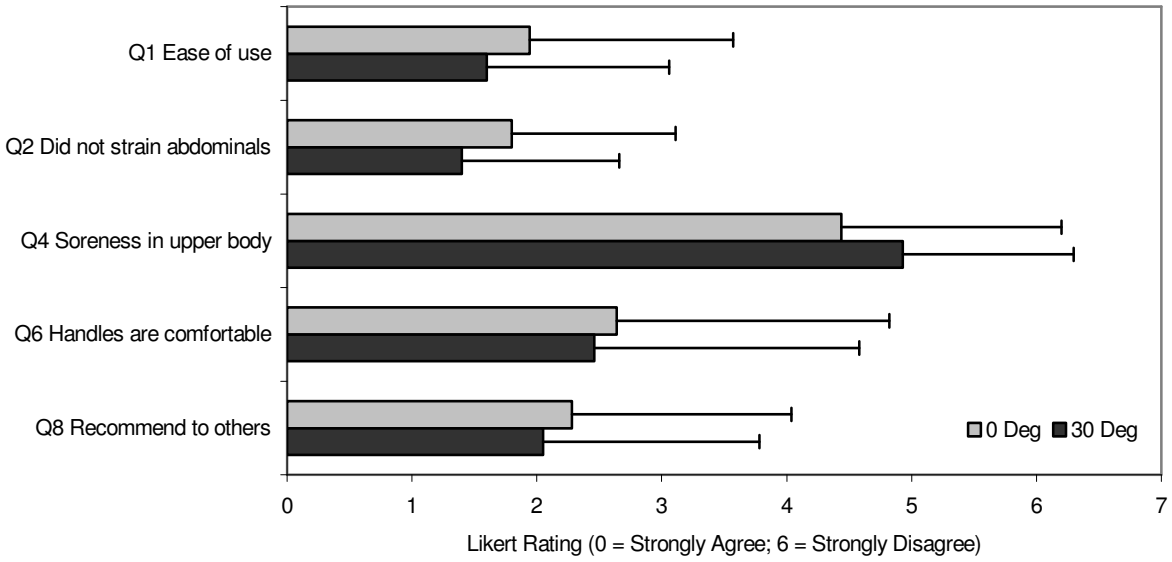


Figure 12. Device effects on usability survey ($p < 0.05$).



(a)



(b)

Figure 13. Effects of (a) age and (b) angle on device usability ($p < 0.05$).

3.8.4 Exit Survey

3.8.4.1 Perceived Angle

A chi-square test was used to determine significant differences in whether "the higher angle was easier to use, much easier or the same" (Figure 14). Given a one-third probability for each response, no significant differences were observed ($p > 0.39$).

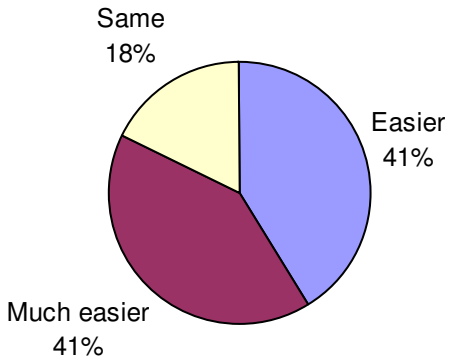


Figure 14. Summary of perceived angle ($p > 0.39$)

3.8.4.2 Final Rankings

The distribution of final rankings across condition was significant (Figure 15). The ABNOSTRAIN™ received the highest ranking (1 = Best condition) indicated by 94.4% of the participants. The Bed Pull-up was reported as the second best condition by 78.8% of the participants. Lastly, 78.8% of the participants ranked the unassisted condition as the worst condition.

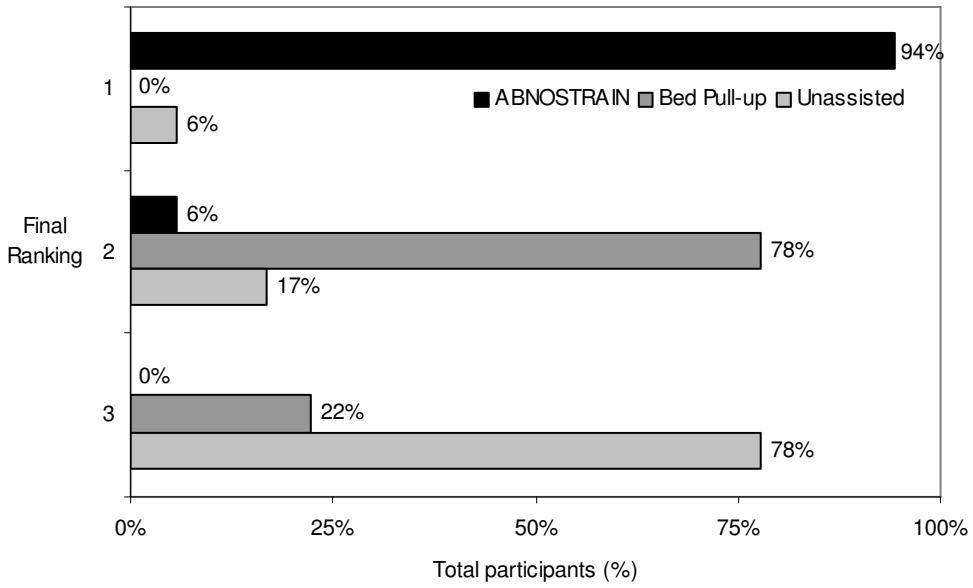


Figure 15. Distribution of final rankings, where 1 = Best condition and 3 = Worst condition.

3.9 Discussion

The study was conducted to characterize abdominal muscle activity during bed rising with and without assistive intervention. All of the participants were considered in the normal body fat range, with a BMI ranging from 17.7 to 23.5 for females, and 18.3 to 24.7 for males. Participants were involved in, on average, two physical activity sessions per week (which included 30 minutes of cardiovascular exercise). The variability in reported fitness levels and physical activity provided a good representation of a healthy population for both age (young and old) and gender groups.

3.9.1 Normalization Procedures

Normalization of EMG recordings is generally necessary in order to make comparisons of activation levels between individuals (Andersson et al., 1998). In addition, muscle activity in the concentric phase is often not equally the same for conditions performed in the eccentric direction (Andersson et al., 1988). Since maximum voluntary activation levels are relatively constant across

conditions, MVEs were suitable in measuring muscle activity in both the concentric eccentric phase for this study.

The normalization exercises used in the study were assumed to elicit maximum activity at the URA, LRA and EO sites, using evidence supported by previous research (Guimarares et al., 1991; Axler and McGill, 1997; Vezina, 2001). Controversy exists in constraining the torso and hips during MVE assessments, with inferences leading to inaccurate measurements (overestimation of MVEs) and thus affecting characterization of muscle activity during task performance. The protocols developed for this study, however, were intended to represent the simulated bed conditions of patients after abdominal surgery and minimize contributions from surrounding muscles (i.e., hip flexors are active with lower limb movement). Any confounding variables associated with constraining the legs would be consistent across the testing conditions, and minimize any potential influences in characterizing muscle activity.

Potential concerns using static MVE procedures to study dynamic tasks were also considered. Due to changes in muscle length and orientation to the electrodes, dynamic EMG tasks are often normalized using a reference task to compare muscle patterns. In the present study, however, comparing the reference task (bed rising unassisted) to the device conditions was of interest, and static MVE tasks were employed in normalizing EMG data. Although significant differences between the two devices were not observed in this study, the assignment of dynamic MVE tasks may provide a better means for making comparisons between the assisted tasks. Variations in body position and movement velocity would be minimized with task-specific normalization procedures (vs. static MVEs), and attribute to potential design differences not originally observed.

3.9.2 Electromyography

The higher muscle activity observed during the concentric phase compared to the eccentric phase supported results from past literature (Flint, 1965; Andersson et al., 1998). Reasons for lower muscle activity in the eccentric phase are subject to variability in the biomechanics field. However, one contributing factor for lower activity observed during the eccentric phase could be due to the increase in

antagonist muscle activity (i.e., lower back muscles) or contributions from surrounding muscle activity (i.e., hips flexors). Flint (1965) suggested that movement in the lowering phase was primarily hip flexion, and that activity in the lower rectus does not record as great as decline in action potential as do the other muscles.

Assistive intervention was expected to reduce abdominal muscle activity during bed rising tasks compared to manual bed rising. Referring to a free-body diagram (FBD) as an example, the reaction forces acting on the abdominal muscles would be comprised of forces primarily in the vertical direction during unassisted bed rising. However, biomechanical loading would change with assisted bed rising; the reaction forces would no longer be acting solely in the vertical direction. The reaction forces during assisted bed rising would also consist of a horizontal component, contributed by upper limb movement in the horizontal direction. The resultant force would serve as an advantage in minimizing abdominal activity with forces distributed along the horizontal; forces in the vertical direction would thus be minimized during assisted bed rising, and in turn, contribute to reductions in abdominal muscle activity.

Considering moments from a free-body example, assisted bed rising was expected to lower the moment about the hip compared to manual bed rising. The higher anchor height was also expected to lower the moment about the hip. Additional research would be needed, however, to determine the optimal anchor range that would allow users to transfer themselves independently with a bed assistive device.

Reductions in muscle activity were expected at the higher bed elevation angle following the reasoning from the length-tension relationship. In general, the length-tension relationship states that isometric tension in skeletal muscle is a function of the magnitude of overlap between actin and myosin filaments (UCSD, 2004). As such, changes in muscle length, which is generally accompanied by changes in joint angles, are known to affect force output. The exchange of overlapping filaments was therefore lower (in theory) with torso elevation at 30° than in the horizontal plane (0°). As a result of the shorter muscle length, lower abdominal muscle activity was observed.

Inferences from previous studies using observational analysis provide support for the age effects during bed movement patterns obtained in the current study using EMG; as such, the age by configuration interaction was of particular interest. The present study indicated that young participants required lower abdominal muscle activity during bed rising, and even less muscle with the use of an assistive device. The reason for lower abdominal muscle usage may be supported with the results obtained by Ford-Smith and VanSant (1993); younger participants were likely to use more upper body movements in the supine-to-sit task compared to their older counterparts. Further inferences may be drawn such that younger participants are more likely to support their upper body with the use of a device during bed rising and in turn, require lower abdominal muscle usage (observed in the present study).

Understanding the effects of age during bed rising tasks may provide practical information for clinicians or physical therapists in recommending preoperative strategies for patients undergoing abdominal surgery in postoperative care. Preoperative training, for example, may include task-specific exercises that help strengthen the upper body for older patients with the use of a device, especially since older participants bear more weight in the hip/gluteal area and use a broad pivot base during bed rising (Alexander et al., 1995).

3.9.3 Subjective Ratings

Participants indicated favorable usability ratings and preferred the ABNOSTRAIN™ compared to the Bed Pull-Up. Most importantly, participants felt less abdominal strain and more secure using the ABNOSTRAIN™ device in part of its product design. The ABNOSTRAIN™ allowed participants to grip the handles firmly and support their body weight during bed rising. The Bed Pull-Up, however, did not have rigid handles like the ABNOSTRAIN™. As a result, participants had to accommodate to the design of the device, rather than the device fitting to the user, with each hand-over-hand motion. The reliability of the subjective tests was supported in the overall and final rankings of the devices. The ABNOSTRAIN™ received the highest overall rating of 8.1 on a 10-point scale and was ranked the best condition by 94% of the participants.

3.9.4 Study Limitations

A few limitations of the study are worth noting. The exercises performed in the study were task-specific. Verbal instructions were highly emphasized to simulate the impaired conditions of a patient population, especially since participants had no experience with the trauma of abdominal surgery and its implications on physical activity. Therefore, the results may not reflect real situations used in a clinical environment. Differences in bed movement patterns and movement velocities associated with bed rising in clinical situations may result in muscle activity requirements other than that obtained from this study. Similarly, different body positions and movement velocities with other forms of maximal or sub-maximal exertions (static or dynamic) could produce different findings.

Bed rising tasks consisted of unassisted and assisted conditions. The movements adopted for the protocol may not resemble other modes of support, such as the use of bed rails or assistance from nursing personnel. Additional comparisons used in the actual hospital and home environments may support a stronger need for the use of self-transfer devices.

Participants in the study may not reflect the physical fitness level or body fat index of patients undergoing abdominal surgery, especially for patients who exceed the normal body fat index of 18.5 to 24.9%. Although fitness and obesity effects were not studied, the use of assistive devices may prove beneficial to individuals who are less physically active and/or considered overweight or obese (BMI > 24.9%). Additional research is needed to determine the trend and/or correlation between abdominal muscle activity during bed rising and variables such as preoperative fitness and strength level.

Previous studies indicated that the right side of the body elicited higher muscle activity than the left-hand side (Halpern and Black, 1987), and therefore, EMG electrodes were only recorded from the right side of the body to deduce muscle activity of the abdominal region (Flint, 1967; Halpern and Black, 1987). However, bed rising movement was asynchronous for the 30-39 years old age group and more synchronous for the 40-59 year age group (Ford-Smith and VanSant, 1993). Therefore, placing EMG electrodes on the right side of the body may be considered a limitation in drawing assessments for the entire abdominal region.

Finally, two questions on the usability were omitted due to poor questionnaire design. In most cases, participants were not able to provide accurate responses to "The device was easier to perform at this height" or " I had a difficult time starting at this angle. " Participants could not make a fair comparison especially during the first exposure relative to the question.

3.10 Conclusions

Although previous research studies have only included a comprehensive evaluation of assistive devices for nursing professionals during resident-transferring methods (Zhuang et al., 1999; Zhuang et al., 2000; Keir and MacDonnell, 2004), this study provides preliminary research on characterizing muscle activity during bed rising with and without the use of an assistive device. The preliminary results were positive.

Self-transfer devices required significantly less mean and peak activity during bed-rising tasks on the abdominal muscles than during manual bed rising. In comparing muscle activity between the ABNOSTRAIN™ and Bed Pull-Up studied, no objective differences were found. However, subjective assessments indicated differences in the perceived comfort, security, and usability between the two devices, in which participants favored the design and usability of the ABNOSTRAIN™. In addition, angle and anchor effects affected reductions in muscle activity.

The implications of reduced muscle activity with the use of a self-transfer device may benefit users such as patients following major abdominal surgery. By minimizing the physical stress imposed on the abdominal region after surgery, patients would be more likely to ambulate with a greater sense of independence, and in turn, return to activities of daily living (ADLs) faster.

CHAPTER 4. CLINICAL ASSESSMENT

4.1 Introduction

Literature indicated that modifications to self-report assessments were appropriate to meet specific research goals (DeGood and Tait, 1999; Doyle, 1992). A clinical assessment from Doyle (1992) was adopted and modified to design a self-report questionnaire appropriate for this study. The intent of the first case study was to understand the experience of an abdominal surgery patient. The interview provided groundwork for designing a self-report questionnaire for the clinical study, and acknowledges a potential need for self-transfer aids in postoperative care.

In the second case study, a preliminary questionnaire design was tested to determine whether questions on self-perceived recovery were relevant to abdominal surgery patients. The participant was an abdominal hysterectomy patient, who was given a device prototype (ABNOSTRAIN^{TM}) to use during her postoperative recovery. She was asked to complete twelve self-report questionnaires over a four-week period and usability survey on the device. Revisions to the self-report questionnaire were made, with results from the pilot work reflected in the final design.

4.1.1 Case Study One

The participant underwent an abdominal hysterectomy two months after being diagnosed with uterine cancer. In the discourse of her experience, she recalls how the pain (from surgery) afflicted her emotional and physical sense of independence from the start of her postoperative recovery.

The participant received in-patient care for three days and was required to ambulate after surgery to reduce the risk of vein thrombosis. The sensation of pain across the surgical area hindered her desire and ability to rise in and out of the hospital bed. Specifically, she required assistance from nursing personnel to accommodate her from the bed to the bathroom. The participant felt rather inept by needing the physical support of others, but the pain was “extreme, like hot needles poking inside the stomach” and limited her ability to perform bed rising on her own. The use of bed rails or rolling onto her side became

an alternative means of rising (to nurses), but having to perform movement in the transversal plane caused pain to the surgical area, and when pulling the body into an upright position.

After the participant was discharged from the hospital, she had difficulties adapting to her home environment, particularly since she did not have the conveniences of an adjustable hospital bed. She felt pain and discomfort when lying in the supine position, and adjusted to the situation by using pillows to elevate the torso and provide support for the lower back. Although the arrangement was more comfortable and minimized abdominal strain, greater satisfaction was achieved when she used pillows to support her back while sitting in a chair.

The participant returned to activities of daily living (ADLs) after the first week of surgery, specifically driving. In the third week of recovery, she was able to perform light household chores such as cleaning and vacuuming, and returned to work by the fourth week. Two months after surgery, she no longer felt pain at the surgical area and was able to resume her preoperative level of ADLs.

Postoperative recovery for abdominal surgery patients is typically four to six weeks (CBO, 2001; NUFF, 2002). From this case report, the patient felt that her positive outlook and conscious effort in avoiding the use of oral narcotics (and related side-effects) aided in her ability to perform ADLs independently after the first week, and return to work in the fourth week. She attributed her ability to maintain a positive attitude with the help and social support from friends and family, even with the administration of pain medication circumvented. However, the first week of postoperative recovery in the hospital and home environments could have been more desirable if assistance from nursing personnel was optional. She indicated that independent patients, such as herself, would value an assistive device that supports the performance of ADLs by using and strengthening their own abilities.

4.1.2 Case Study Two

The participant underwent an abdominal hysterectomy as an elective procedure primarily for abnormal bleeding. Approximately a week before surgery, the participant was given a questionnaire packet and asked to complete a total of twelve self-report questionnaires following a specific reporting

schedule during a 4-week recovery period (Table 11). A prototype of the ABNOSTRAIN™ was also given to the patient with verbal instructions on the proper set-up of the device. Suggestions on the use of the device were provided, and any preoperative training with the device was left to the discretion of the patient.

In the first week of the reporting period, the participant was unable to complete the self-assessment independently for Day 1 due to the anesthesia. She relied on her daughter to read the questions out loud while recording the appropriate responses on the form. Physical activity following surgery was primarily limited to walking in her room. She required the assistance of nursing personnel in helping her transfer her in and out of bed. She moved with caution as any movement caused pain around the surgical site.

The participant was discharged from the hospital on the third day of recovery. Although she managed to experience less pain at the surgical area when rolling onto the side of her body first (and complete the bed rise movement in the transversal plane), the patient benefited from the ABNOSTRAIN™ in helping her ambulate at home. In rising in and out of bed, she used the device as an anchor in one hand while letting her body slide to the edge of the bed (to get out of bed), or while lifting her legs from the floor to the bed surface and then lowering her body (to get in). The participant felt secure and safe using the device and did not report any muscle soreness in the upper extremity. She used pain medication to cope with postoperative pain and remained on analgesics for three weeks. In her sixth week of recovery, the patient was able to return to work half-days and resumed full workdays in the seventh week.

In an interview following the completion of the questionnaires, the participant indicated the self-perceived recovery measures (i.e., perceived pain, mood, energy level, pain medication, and ability to perform specific ADLs) were relevant to her postoperative experience. Moreover, self-perceived recovery measures related to bowel and urine movements were also appropriate and did not invade her privacy. She reported positive results in the use of the ABNOSTRAIN™ from the usability survey, and felt inspired to be more physically active during postoperative recovery than she had anticipated. The

reporting schedule was modified, however, to account for the mental state of participants on Day 1 of surgery, and individual differences in postoperative recovery periods. Changes to the reporting schedule are shown in Table 11.

Variables not originally included in the preliminary questionnaire (i.e., reason for surgery and if preoperative instructions were provided), were reconsidered as factors that may potentially affect the overall trend in the reporting process. Patients who are given expectation of surgery or preoperative care have been reported to recovery faster (Owens, 1992). Typically, abdominal hysterectomy patients are advised by their physician to refrain taking vitamins and from eating after 10PM before surgery to avoid gastrointestinal disruptions and prevent the risk of excess bleeding during surgery.

Table 11. Reporting schedule for questionnaires

Preliminary schedule		Modified schedule	
Week	Day(s)	Week	Day(s)
1	1, 2, 3, 4, 5, 6	1	2, 3, 4, 6
2	10, 13	2	8, 10, 12
3	17, 20	3	16, 20
4	24, 27	4	23, 27
		5	33

From the results obtained from both case studies, the research questions for this clinical assessment included: 1) is there a difference in self-perceived recovery measures for patients provided with and without the use of a bed-assistive device; and 2) is there a difference in the type and daily dosage of pain medication for patients provided with and without the bed-assistive device?

4.2 Experimental Design

Since the number of prospective participants could not be predetermined in an 8-month recruitment period, a stratified randomization scheme was used to assign abdominal surgery patients to the control or device experimental groups. Strata sampling consisted of surgical procedure (abdominal hysterectomy and Cesarean-section) and age group (young and old) as strata. The young group was comprised of abdominal hysterectomy patients less than 45 years and Cesarean patients less than 30

years. The older age group consisted of abdominal hysterectomy patients 45 years or older and cesarean patients 30 years or above. The randomization scheme is shown in Table 12.

Table 12. Recruitment of participants based on surgery and age strata.

Participant	Cesarean-section		Abdominal Hysterectomy	
	Young (< 30)	Older (30+)	Young (< 45)	Older (45+)
1	Device	Control	Control	Control
2	Control	Device	Device	Device
3	Control	Control	Device	Device
4	Device	Device	Control	Control
5	Device	Control	Control	Control
6	Control	Device	Control	Device
7	Device	Control	Control	Control
8	Control	Device	Device	Device
9	Device	Control	Control	Control
10	Control	Device	Device	Device
11	Control	Control		

4.2.1 Participants

A pilot study was conducted to determine the reliability of the self-report questionnaires. Clinical studies typically require a large sample size to minimize the sampling and non-sampling errors associated with survey-based research. For this assessment, a minimum of 50 subjects was required to obtain power above 0.80; however, a sample size of 15 was selected arbitrarily for exploratory purposes. With two normal equally varying populations and samples of different sizes ($n_{control} = 8 \neq n_{device} = 7$ and $\sigma_A = \sigma_B$), and assuming a large effect size (d = 0.8), power analysis following Cohen (1988) resulted in 40% power at an alpha level of 0.1.

4.2.2 Independent and Dependent Variables

The dependent variables were responses to incisional pain (VAS, 0-10), emotional distress (VAS, 0-10), pain interference (VAS, 0-10), energy level (VAS, 0-10), pain medication type and daily dosage (Class 1 and 2), ADLs (frequency counts for bathroom use, chores and meal preparation) and self-

perceived recovery measures (total days reporting ability to eat solid foods, urinate, perform bowel movement, shower, drive and work).

Participants were the independent variable for response variables tested across recovery week (VAS measures, usage of pain medication and frequency of ADLs). Experimental group (device or control) was the independent variable for self-perceived recovery measures based on total days (ability to eat solid foods, urinate, perform bowel movement, shower, drive and work).

4.2.3 Experimental Task

Self-report questionnaires were completed during a five-week recovery period beginning from the date of surgery. The questionnaire designed for this study consisted of four parts. In the visual analogue scale (VAS) section, patients were asked to rate their perceptions on incisional pain (0 = No incisional pain; 10 = Worst possible pain), emotional distress (0 = No emotional distress; 10 = Worst possible distress), pain interference during bed rise (0 = No interference; 0 = Extreme interference) and energy level (0 = Extremely low energy; 10 = Extremely high energy).

Administration of pain medication was collected, in which participants listed the type of pain medication received, dosage (mg) and frequency. Data on pain medication was sorted into Class type and daily dosage by the researcher. Class type was categorized by oral narcotics (Class 1) and non-steroidal anti-inflammatory (Class 2). Mean equivalent daily dosage (MEDD) to morphine was used to standardize the different oral narcotics across participants as follows: MEDD calculation = [Dose] x [MEDD factor] x [Frequency]. MEDD factors for Demerol (0.05), Endocet (0.833), Percocet (0.833) and Lortab (0.667) were obtained from the assessment tools at the Palliative Care Program (Edmonton, Alberta). Class 2 dosages were calculated given: Ibuprofen Daily Dosages (IBDD) = [Dose] x [Frequency].

The frequency of activities of daily living (ADLs), specifically bathroom use, household chores and meal preparation were recorded. Additionally, participants were asked to provide Yes/No responses on whether or not they were “Able to eat solid foods,” “Urinate without discomfort,” “Shower,” “Drive”

and “Return to work” on the reporting days. A total of twelve questionnaires were provided to the participants, to be completed according to the schedule shown previously in Table 7 (page 55).

4.2.4 Experimental Procedure

Abdominal hysterectomy and Cesarean patients were initially informed of the study with the aid of a local physician. With their consent, the researcher contacted participants by phone to schedule an informational meeting. Participants received a verbal and written description of the project, and signed informed consent forms approved through both the Virginia Tech Institutional and Montgomery Regional Hospital Review Boards prior to any data collection. A screening questionnaire was also provided to the participants to determine eligibility, and obtain additional information in the demographic questionnaire (Appendix B). Participants were excluded from the study if they were not scheduled for the Pfannenstiel incision in the abdominal hysterectomy or Cesarean section. Based on the stratified sampling scheme (with surgery and age as strata), participants were assigned to the control or device group. Each participant received a packet containing twelve self-report questionnaires and was asked to follow the reporting schedule accordingly. Participants in the device group were provided with a prototype of the ABNOSTRAIN™ and verbal instructions on how to attach the device to a bed and recommended handling techniques as demonstrated by the researcher. The researcher made follow-up phone calls once a week for follow-up purposes.

4.2.5 Statistical Analysis

Mean responses were summarized by experimental, age and surgery groups and analyzed using either within-subject or between-subject ANOVAs. Data for repeated-measures ANOVA were compared across recovery week (Week 1, 2, 3, 4 and 5), which consisted of responses in the VAS (pain perception, emotional distress, interference with activities, energy level), daily dosages (MEDD and IBDD), and frequency of ADLs sections. Between-subjects ANOVA was used to test for questions relating to pain class, usability of assistive device, and self-perceived recovery measures based on total days or percent

recovery time. Experimental group, age and surgery effects were also tested in all of the analyses to determine if significant differences existed. Finally, regression analysis was used to indicate trends in device frequency. Since the clinical study was exploratory in nature (and the total number of participants would be based on a pilot-scale), findings were considered significant at alpha = 0.1.

4.3 Results

4.3.1 Participants

Eighteen participants were originally recruited to take part of the study; however, three participants did not complete the study for reasons including non-response, family emergency and change in surgical procedure (to vaginal hysterectomy). Participants were screened for any musculoskeletal conditions affecting the upper extremity or trunk and chronic or acute back pain. Eight participants were assigned to the control group (age, 34.0 ± 4.0 years) and seven participants were assigned to the device group (age, 37.3 ± 6.4 years). Descriptive statistics of the participants are detailed in Table 13.

Table 13. Preoperative statistics for participants in the clinical study.

Variable	Control (n = 8)	Device (n = 7)
Body Mass Index (BMI)	33.0 ± 4.0	37.3 ± 6.4
Body Weight (kg)	82.3 ± 10.4	108.8 ± 21.5
Pre-pregnancy weight (kg)	58.1 ± 10.5	68.2 ±6.4
Height (m)	1.6 ± 0.1	1.7 ± 0.1
Age (y)	34.0 ± 6.3	40.7 ±12.4
Surgery type:		
Abdominal hysterectomy (n= 6)	3	3
Cesarean section (n= 9)	5	4

4.3.2 Visual Analogue Scale (VAS) Measures

In general, all of the VAS measures were significantly affected by recovery week (Table 14). VAS ratings across participants, specifically Weeks 1 and 2, ranged from 3.1 to 6.7 (where 0 = Lowest perception of measure; 10 = Extreme perception of measure) on responses to incisional pain, emotional distress, pain interference and energy levels. Although not significant, age effects seemed to affect VAS

measures with the young participants resulting in higher ratings (more extreme) on incisional pain, emotional distress and pain interference observed, and the old participants reporting higher energy levels.

Incisional pain was significantly influenced by the effects of group and surgery, with higher levels of incisional pain for the control group and abdominal hysterectomy patients. For the emotional distress measure, significant effects were found for surgery and in the surgery by group interaction. Abdominal hysterectomy patients, particularly in the control group, experienced greater emotional distress than Cesarean patients in either the control or device groups.

Differences in pain interference during bed rising were characterized by group, surgery and their interaction effects. Levels of pain interference were typically higher for abdominal hysterectomy patients in the control group than in device group, and compared to Cesarean patients in either the control or device groups ($p < 0.05$). Differences in pain interference were also found for the week by group interaction, with both groups indicating lower pain interference in the subsequent weeks. Of particular interest, the control group responded with greater pain interference for Weeks 2 and 4 than the device group.

Perceived levels of energy were significantly different across participants by surgery, and for the surgery by week and age by week interactions. Cesarean patients indicated higher energy levels than abdominal hysterectomy patients across Weeks 1, 3, 4 and 5. Although older patients indicated lower energy levels than their young counterparts, energy levels generally increased as participants progressed in their recovery period. Specifically, higher levels of energy were observed in Weeks 3, 4 and 5 for the older age group compared to Week 1.

Table 14. Summary of significant terms (in non-shaded areas) from repeated measures ANOVA. Values provided in means (and standard deviations).

VAS measures	Group		Age		Surgery		Week*				
	Control	Device	Old	Young	AH	CS	1	2	3	4	5
Incisional pain	**3.7** (2.7)	**2.9** (2.5)	3.2 (2.7)	3.4 (2.6)	**3.7** (2.7)	**3.0** (2.5)	**5.9** (2.1)[a]	**3.1** (1.9)[b]	**2.0** (1.7)[c]	**1.1** (1.0)[d]	**0.8** (0.9)[d]
Emotional distress	3.4 (2.5)	2.8 (2.2)	2.7 (2.3)	3.5 (2.5)	**3.8** (2.5)	**2.5** (2.1)	**4.7** (2.4)[a]	**3.1** (1.9)[b]	**2.4** (2.0)[b]	**1.4** (1.5)[c]	**1.1** (1.5)[c]
Pain Interference	**4.5** (2.9)	**3.1** (3.0)	3.5 (2.9)	4.3 (3.1)	**4.4** (3.2)	**3.4** (2.8)	**6.7** (2.3)[a]	**3.7** (2.5)[b]	**2.0** (1.7)[c]	**1.7** (2.1)[cd]	**1.0** (1.3)[d]
Energy Level	4.9 (2.6)	5.2 (2.5)	5.3 (2.5)	4.8 (2.6)	**3.7** (2.4)	**6.2** (2.1)	**3.9** (2.5)[a]	**4.8** (1.8)[b]	**5.8** (2.4)[c]	**6.0** (2.7)[c]	**6.6** (2.8)[c]

* Levels are not significant if connected by the same letter.

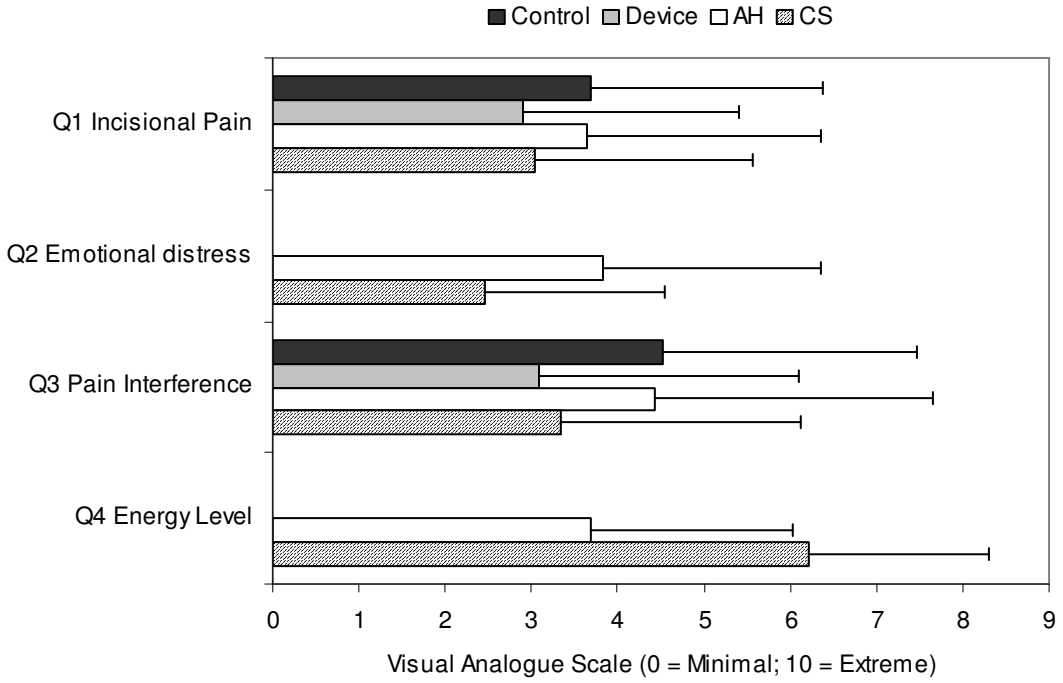


Figure 16. Plot of significant VAS responses ($p < 0.1$).

4.3.3 Usage of Medication by Pain Class

The results in Table 15 indicated that no one or two-way interactions were significant for pain medication class (Figure 17).

Table 15. Means (SD) for usage of pain medication by class type (% reporting period).

Pain Medication	Group		Age		Surgery	
	Control	Device	Old	Young	AH	CS
Class 1	46.9 (27.1)	31.9 (8.2)	38.5 (14.7)	43.1 (30.5)	35.7 (29.5)	45.2 (10.6)
Class 2	51.4 (32.7)	35.6 (15.7)	38.1 (26.3)	48.6 (25.0)	36.1 (29.7)	48.8 (21.2)

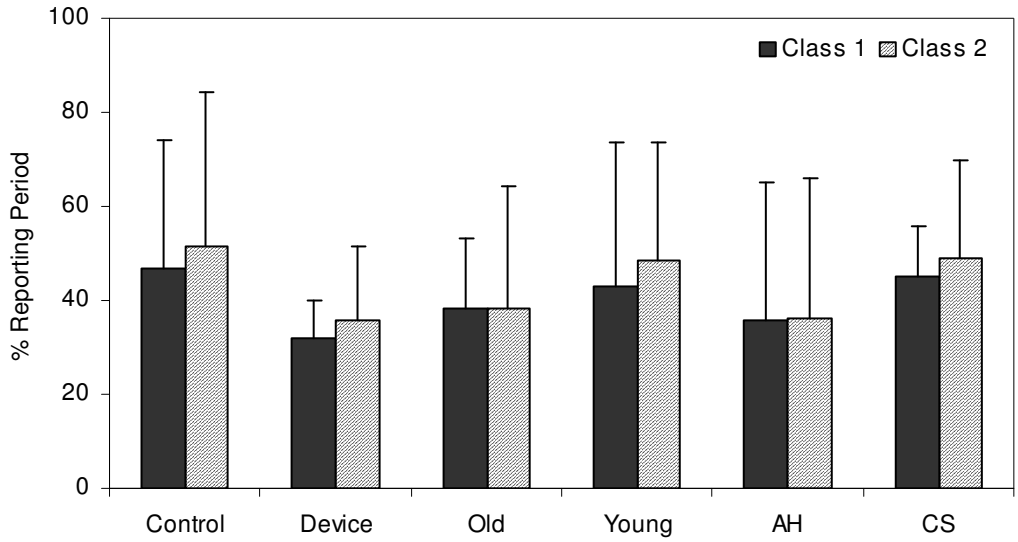


Figure 17. Non-significant comparisons on usage of medication by pain class during the reporting period.

4.3.4 Daily Dosages of Pain Medication Types

Some participants did not require the administration of Class 1 and/or Class 2 pain medications throughout the five-week recovery period. In this particular case, repeated-measures ANOVA could only be tested during Weeks 1 and 2, of which daily dosages were significantly higher in Week 1 than Week 2, regardless of pain class (Table 16).

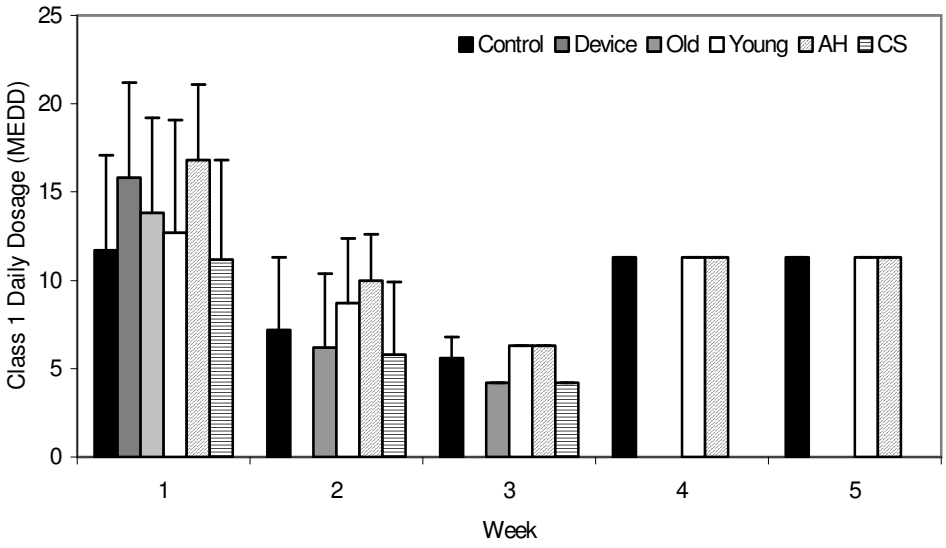
Surgery group was significant for MEDD (Figure 18a). Abdominal hysterectomy patients had MEDDs of 13.6 ± 4.8 mg compared to 9.0 ± 5.0 mg for Cesarean patients. Group effects characterized differences in MEDD with a p-level that approached significance ($p = 0.104$); the device group received higher MEDD with an average of 14.5 ± 4.7 mg, compared to 9.6 ± 5.0 mg for the control group in Week 1. Additionally, the device group did not take Class 1 pain medication after Week 1 (whereas participants in the control group responded to using Class 1 medication through Week 5).

Significant differences in IBDD were found for the week by surgery interaction. Specifically, abdominal hysterectomy patients required higher IBDD in Week 1 with 1540 ± 719 mg compared to 1030 ± 526 mg in Week 2. Higher daily dosages were observed for the control group in IBDD compared to the device group; however, the results were not significant (Figure 18b).

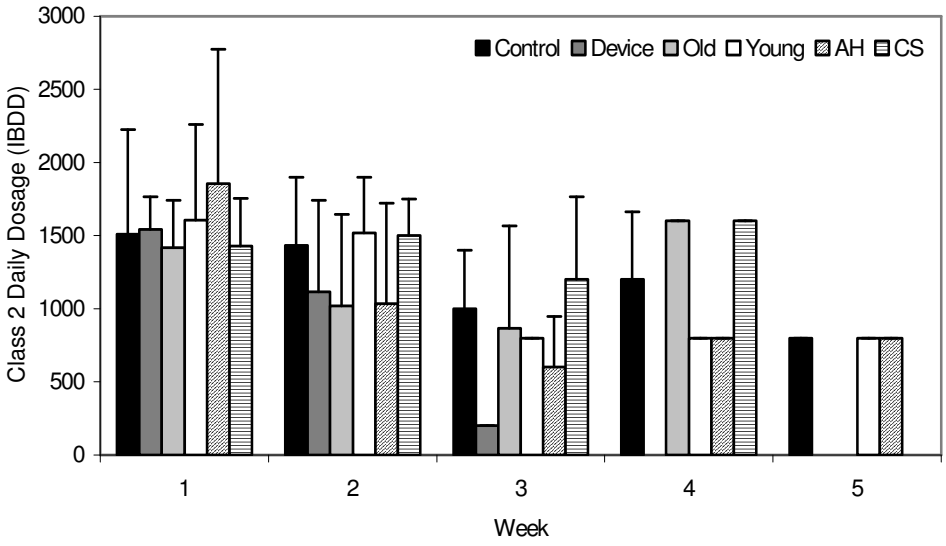
Table 16. Significant means (SD) for MEDD and IBDD (in shaded areas).

Daily Dosage	Group		Age		Surgery*		Week	
	Control	Device	Old	Young	AH	CS	1	2
Class 1 (MEDD)	**9.6 (5.0)**	**14.5 (4.7)**	10.9 (5.5)	11.3 (5.4)	**13.6 (4.8)**	**9.0 (5.0)**	**13.4 (5.8)**	**7.2 (4.1)**
Class 2 (IBDD)	1320 (515)	1270 (511)	1230 (484)	1370 (533)	1130 (652)	1460 (210)	**1480 (506)**	**1300 (428)**

*Note: AH = Abdominal hysterectomy; CS = Cesarean patients



(a)



(b)

Figure 18. Means for (a) MEDD and (b) IBDD during recovery period. Significant terms were observed during Weeks 1 and 2 only.

4.3.5 Frequency of ADLs

Significant differences were only found in the surgery by week interaction. Comparing between recovery Week 1 and 5, Cesarean patients increased the frequency of bathroom use by 1.2 times/day from the beginning towards the latter phase of the recovery period.

The performance of chores was significant by week (Table 17). The average (SD) number of chores performed was 1.3 ± 1.6 times/day during Week 1, and steadily increased from 3.1 ± 2.3 to 4.6 ± 3.1 times/day for Weeks 2 to 5, respectively. The group by week interaction was also significant for the frequency of chores. With means ranging from 0.9 to 5.0 chores/day, the control group was able to conduct more activity in Weeks 3 to 5 compared to Week 1.

Significant differences in meal preparation were contributed by age, surgery, and week effects and in the surgery by group interaction. Overall, the device group, older participants and Cesarean patients prepared a higher number of meals than the control group. Tukey's post-hoc analysis for the two-way interaction indicated higher meal preparation activity for CS patients in either the control or device groups (1.7−1.9 meal/day) than the AH device group (1.1 meal/day).

Table 17. Significant means (SD) (in shaded regions) for activities of daily living (ADLs)

ADL	Group		Age		Surgery		Week*				
	Control	Device	Old	Young	AH	CS	1	2	3	4	5
Bathroom	6.1 (1.8)	6.4 (1.7)	6.4 (1.8)	6.0 (1.7)	5.6 (1.3)	6.8 (1.9)	6.0 1.8)	6.2 (1.8)	6.2 (1.7)	6.2 (1.9)	6.6 (1.8)
Chores	3.2 (2.5)	3.5 (2.8)	4.1 (2.9)	2.4 (2.0)	2.7 (1.8)	4.0 (3.1)	**1.3 (1.6)[a]**	**3.1 (2.3)[b]**	**3.8 (2.4)[c]**	**4.1 (2.5)[d]**	**4.6 (3.1)[e]**
Meal Prep	1.6 (1.1)	1.7 (1.1)	**1.9 (1.2)**	**1.3 (0.9)**	**1.5 (1.1)**	**1.7 (1.1)**	0.3 (0.4)	1.4 (0.9)	2.0 (1.0)	2.1 (0.8)	2.3 (0.9)

*Levels are not significant when connected by the same letter.

4.3.6 Self-Perceived Recovery Measures

Differences in the "Ability to eat solid foods" variable were significantly affected by surgery ($p < 0.08$). Cesarean patients reported a greater ability to eat normal foods (31.1 days total) compared to AH patients (30.0 days total). In addition, significant differences were observed for the ability to "Pass bowel movements." The device group reported the ability to pass bowel more regularly (28.6 total days) than the control group (26.6 days total). Group, age and surgery effects were not significant on the remaining

recovery measures including ability to return to work, drive, shower, and urinate without discomfort (p = 0.22–0.69). Age effects, however, contributed to slight differences in the "Ability to shower" with a *p*-level approaching significance (p = 0.13). The young participants were able to shower for a total of 27.8 days compared to older participants (27.3 days total).

4.3.7 Usability Survey

Usability responses were given on a 7-point Likert Scale, where 0 = Strongly Agree, and 6 = Strongly Disagree for the usability survey. Significant differences were not found on whether if the device was easy to use, had comfortable handles, required upper body strength, increased sense of independence, and was preferred than having to rely on others (Figure 19).

The effects of age contributed to significant differences in "I did not feel pain in the surgical area" ($p < 0.08$). Participants in the old age group (Likert, 2.0 ± 0.7) reported less pain while using the ABNOSTRAIN™ than the young participants (Likert, 4.4 ± 0.8). Surgery effects also appeared to affect responses to pain, though this finding was not significant. Abdominal hysterectomy patients reported less pain than Cesarean patients while using device, as indicated by a p-value that approached significance (p = 0.126).

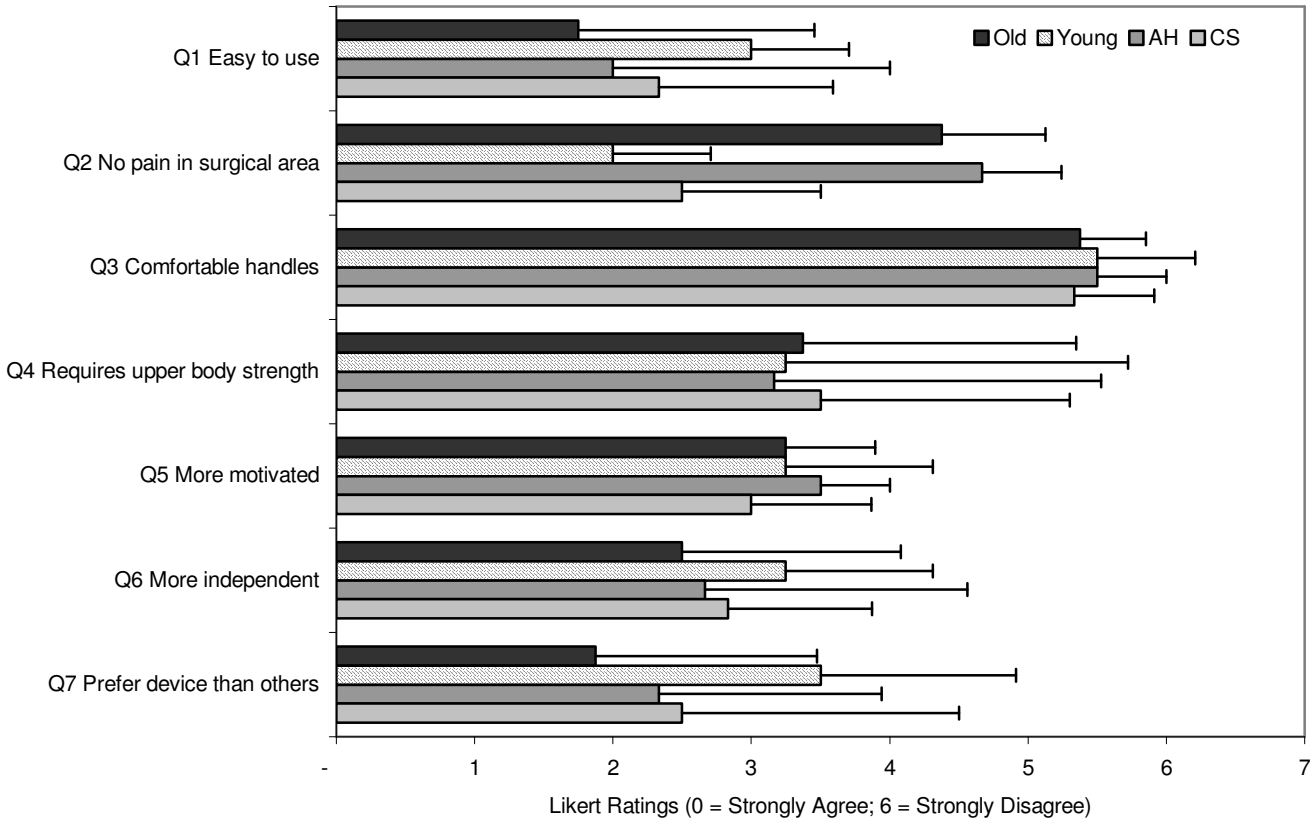


Figure 19. Significant and non-significant results on device usability ($p < 0.1$).

Participants indicated the number of times the device was used for each reporting day. From the trend analysis, a non-linear model was used to project the frequency of the device over a 33-day reporting period (Figure 20). Participants were predicted to use the device the most often in the first week (approximately 3-4 times/day), and progress to a lower frequency near Day 20 (approximately 1-2 times/day) of the postoperative recovery period.

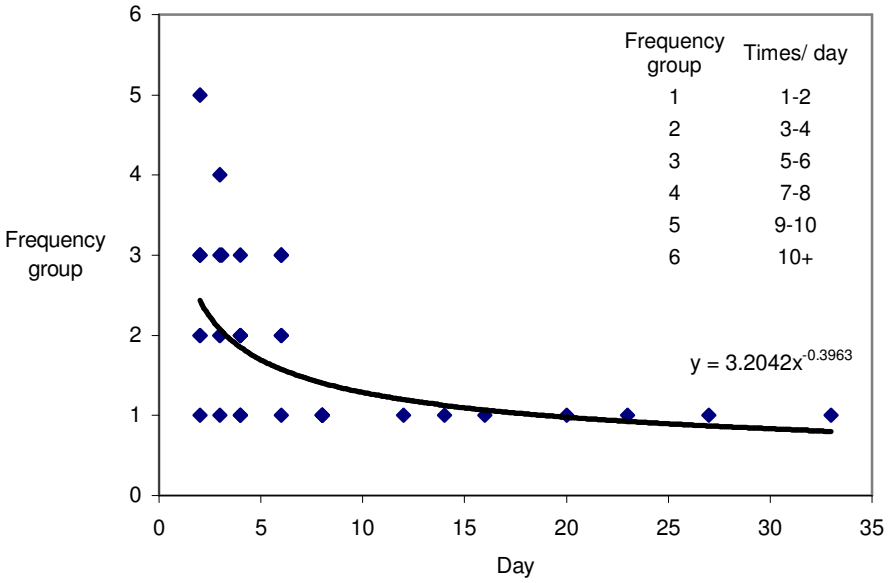


Figure 20. Trends analysis for device frequency over 5-week recovery period (33 reporting days).

4.4 Discussion

The study consisted of a small sample size and relatively low power, yet significant results were still obtained ($p < 0.1$). Statistical analyses were initially performed by testing the main effects and all two-way interactions on the dependent measures. However, the addition of interactions in a model (when not of particular interest) increased the degrees of freedom and variance about the means, and therefore, non-significant interactions were excluded from the model to increase the power of the test. In cases where significant interactions were observed though main effects were *not* significant, all main effects still remained in the model.

Time effects had to be considered using repeated-measures ANOVA since participants completed twelve of the same questionnaire over a 5-week postoperative recovery period. Time was indicated by recovery week (Week 1, 2, 3, 4 and 5) for questions specifically relating to VAS, pain dosage and frequency of ADLs sections. The repeated measures were compared using autoregressive symmetry (feature in SAS that assumes the correlation between repeated measure and time follows a decreasing trend) since postoperative welfare was hypothesized to improve over time. (Note: sections on pain class and self-perceived recovery status were analyzed using between-subject ANOVAs since time was based on percent recovery or total days). Therefore, time effects were expected, which were indicated in the results: responses to VAS measures, MEDD, IBDD and frequency of ADLs were more favorable in Week 2 compared to Week 1.

Participants in the control group generally reported lower levels of energy and frequency of ADLs (i.e., meal preparation) with higher levels of emotional distress, incisional pain, pain interference (during bed rising) and administration of pain medication than the device group. The outcome was expected particularly since abdominal muscle activity was reduced with assistive intervention in the laboratory study (Phase 1). The implications of lower abdominal activity and less pain interference with assistive intervention could also reinforce the sense of independence for participants—the device group had the freedom to reposition themselves in bed or out of bed without having to rely on the physical support from nurses and/or family members. With the ability for patients to use their own strength and abilities, assistive intervention was assumed to allow patients adjust faster to their postoperative emotional and physical recovery measures than the control group.

Variables such as body weight and age may have confounded the results, but the benefits of assistive intervention still yielded promising results. The device group had a higher body mass (37.3 ± 6.4 kg) than the control group (33.0 ± 4.0 kg), and yet the device group reported a more positive reporting period. Findings from Woodrow et al. (1972) may explain the effects of age observed in the study. Although participants in the device group (40.7 ± 12.4 years) were older than the control group (34.0 ±

6.3 years), pain tolerance may have differed between the age groups. Woodrow et al. indicated that the 40-59 year age group reported a higher pain tolerance than the 30-39 year group (1972). In such a case, having a higher tolerance to pain may have influenced the positive recovery period for the device group. Other confounding effects could include other physical and psychological factors such as physical fitness level, strength and coping style.

Surgery effects were also of interest in the study. Abdominal hysterectomy participants reported a higher sensitivity to pain and emotional measures, more pain medication usage and slower adjustment in postoperative recovery than Cesarean patients. In addition, abdominal hysterectomy participants in the control group experienced greater emotional distress than Cesarean patients in either the control or device group. In comparing differences between surgical procedures, social and emotional factors relative to the invasiveness or diagnoses of surgery could be among the confounding variables. Hysterectomy patients were likely exposed to higher levels of fear and anxiety, which attributed to a less favorable recovery than Cesarean patients. Hysterectomy participants may not have elected their surgical procedure due to complications such as abnormal bleeding, pelvic pain or uterine cancer. In addition, although the same Pfannenstiel incision was used for both Cesarean and hysterectomy participants, hysterectomy procedures are typically considered more invasive than cesarean sections, particularly since ligaments and nerves are cut in removing the uterus.

Responses to the usability survey provided insight to the actual physical and psychological condition of postoperative patients than the results from Phase 1. Clinical participants experienced soreness in the upper extremity using the device during postoperative recovery. Even if participants were relatively fit, muscle soreness in the upper extremity was expected, especially since overall postoperative strength decreased most noticeably on postoperative day 2 (Watters et al., 1993). Task-specific training with the bed-assistive device would likely help participants prepare and develop specific muscle coordination during postoperative recovery. Task-specific exercises improved the ability for nursing residents to perform ADLs such as in the bed-to-sit task (Alexander et al., 2000), which may serve as a prognosis for participants following major abdominal surgery.

The results from the study could be generalized for patients undergoing other types of abdominal surgery, in addition to back surgery or those in a rehabilitation setting. Findings were not consistent, however, specifically on responses to the usability and VAS sections reported by the device group. Abdominal hysterectomy patients in the device group experienced less pain than Cesarean patients from the usability survey, and the opposite result was obtained in the VAS section. Additional research would be needed to study the effects of surgery for participants in the device group.

4.4.1 Study Limitations

Sample size was a main imitation in the study. Survey-based research typically requires a sample size of 50 (or greater) to obtain power above 0.80. A small number of participants were involved with this study. The statistical power was relatively low (approximately 0.40) based on an alpha level of significance of 0.1. Though the findings were useful for exploratory purposes, a larger sample size would increase the validity of the tests. Results would not be as sensitive to sampling and non-sampling errors (i.e., respondent errors-faulty recollections, non-response errors—respondent not completing all questionnaires) compared to that with a small number of participants.

Significant differences were observed between surgery groups, which may affect comparisons between experimental groups. If the recruitment was not constrained by time or fiscal pressure, obtaining a larger population of patients undergoing the same surgical procedure could reduce variability in the experimental group results.

Abdominal surgery patients who undergo procedures with the vertical incision could yield different results presented in the current study. Although assistive intervention was hypothesized to benefit abdominal surgery patients, only patients undergoing Cesarean or hysterectomy procedures were recruited with the horizontal incision. Additional research would be necessary to verify that assistive intervention can result in a more positive recovery period for patients undergoing other types of abdominal surgery or in a rehabilitation setting.

The involvement of additional physicians would benefit the recruitment process for the study. Since recruitment patterns were sporadic with the assistance of one local physician, participants were only given, on average, a 6-day advanced noticed in meeting with the researcher. The shortened lead-time may not have allowed patients to prepare or gain familiarity with the questionnaires beforehand, which could have affected responses.

4.5 Conclusions

A study was conducted to determine if bed assistive devices influenced self-perceived recovery measures and on the administration of pain medication in a clinical field setting. Participants in the control group reported recovery measures associated with a more difficult postoperative convalescence. Lower ratings on incisional pain and pain interference during bed rising were supported with the use of assistive devices, and provided preliminary evidence in benefiting patients in postoperative care. Less medication usage was observed for the device group, although a larger study should be conducted to reflect stronger evidence on assistive intervention and administration of pain medication.

Furthermore, the intent of the preliminary study was to study the effects of surgery, age and experimental group on a larger number of postoperative recovery measures. Only one or two recovery indicators have been included in previous surgery studies (Wolfer and Davis, 1970). In understanding the varying levels of, for instance, pain or frequency of ADLs in postoperative care, patients may be better prepared to cope with and adjust to the trauma of surgery. Wilson (1981) indicated that knowledge in the form of accurate expectations about the future and in the form of ability to cope with that future, promotes positive convalescence. Conversely, the greater the fear and apprehension, the poorer the recovery (Wolfer and Davis, 1970).

CHAPTER 5. FINAL SUMMARY AND FUTURE RESEARCH

A comprehensive evaluation on the efficacy of self-transfer aids and its implications on rehabilitative patients have not been supported in previous literature. With assistive intervention, results from the EMG study indicated reductions in abdominal muscle activity compared to unassisted bed rising. Further reductions in abdominal activity were supported by a higher bed elevation angle and/or anchor position. The efficacy of self-transfer aids also demonstrated positive benefits in the clinical environment. Patients in the device group reported lower pain and emotional recovery measures and usage of pain medication, with higher levels of energy and frequency of ADLs during the five-week postoperative period.

In response to the 2003 ergonomic campaign by the American Nursing Association (ANA), the use of self-transfer aids showed promising results for abdominal surgery patients during their postoperative recovery period. Additional research is needed to demonstrate a stronger assertion for assistive intervention in the health care system. Future research may involve additional clinical studies with a larger sample size and a sample population including patients undergoing other types of surgery or in a rehabilitation or nursing-home setting. Employing device-training methods would also be of interest since preoperative variables have significantly affected levels in postoperative recovery (Wilson, 1981; Watters et al., 1995). Correlations could also be tested to determine if inverse and/or linear relationships exist between preoperative levels on postoperative recovery and adjustment.

Future studies using EMG could include additional comparisons of support devices during bed rising, muscle activity requirements on the upper body, and determining EMG-force relationships on the abdominal and/or upper body muscles.

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APPENDIX A: INFORMED CONSENT FORMS

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERISTY
Informed Consent Form for:

Project: "Electromyography Evaluation of a Bed-Assistive Device During Bed-Rising Tasks"

Investigators: Kari Babski-Reeves, Ph.D., Assistant Professor, Grado Department of Industrial and Systems Engineering and Grace Tran, Graduate Research Assistant

I. Purpose

You are being asked to participate in a study aimed at determining the amount of abdominal muscle activity is required to sit up from a supine position in a bed. A number of medical procedures require incisions to the abdominal muscles causing pain and discomfort in this region during recovery, especially during bed rising and lying down. Very few studies exist that have investigated the benefits of using assistive devices for raising and lowering the torso in bed. The objectives of this study are to: (1) measure muscle activity required to rise from a supine position in a bed and (2) measure muscle activity required to rise from a supine position in a bed when using assistive devices (ABNOSTRAIN^{TM} and Bed Pull-up). Muscle activity will be determined using surface electromyography (EMG) of the abdomen and selected upper arm and shoulder muscles.

II. Procedures

You will first be provided with a verbal and written description of the project, its objectives, and the protocols, and complete informed consent documents. You will then complete a questionnaire to determine if you have any pre-existing conditions (such as previous abdominal surgery, chronic or acute back pain, and tendonitis of the shoulder, wrist or elbow) which may influence the results, and about your physical activity level. Over the past three months, you will need to have participated in an average of 3-30minute cardiovascular sessions per week (such as running, power walking, or aerobics), otherwise you will be excluded from this study. Finally, you will be asked to stand on a weight scale that will be used to measure you weight and body fat percentage. You must have a body fat percentage of less than 30% to continue as a participant.

Muscle activity will be measured using surface electromyography (EMG) of the right abdomen (upper and lower rectus abdominis and the external oblique). Because EMG requires the application of small self-adhesive circles to be applied directly to the skin, you will be asked to wear a sports bra and gym shorts during testing.

The skin will be prepared by cleansing with alcohol, lightly abrading using a polishing stone, and shaving as needed. A pair of electrodes (with diameter 3cm) will be placed 3cm apart over each site per standard clinical practice. Following a 10-minute stabilization period, resting muscle activity (over a 5-second period) will be collected while you are lying in a standard hospital bed. You will perform a minimum of 3 maximal voluntary contractions separated by a 1-minute rest period for each muscle. You will be instructed to raise your upper torso to the desired position and hold that position for 1 second.

Active muscle activity will be measuring during both unassisted (no device) and assisted (using the devices) sit-ups. First you will lie on the cot with legs extended. The hands will be placed behind the head or neck (fingers unlocked) or crossed across the chest, depending on your preference. You will then perform a standard bed rise, rising until you are able to sitting upright. You will then lower yourself back down, and repeat the bed-rise task 3 times. Computer generated tones will be used to control the rate of the exercise. You will have 30 seconds of rest between sit-ups.

You will then repeat the procedures described above, however, you will now be using each of the assistive devices following a training period on their usage. During the training session, you will practice

raising yourself while minimizing the use of your abdominal muscles. A researcher will be monitoring your muscle usage and provide you with feedback on how you are doing. After completing three trials where you have minimized your abdomen muscles, you will complete a total of 30 trials for the unassisted and assisted procedures. All trials will be completed within a single testing session with total testing time projected to be 1.5 hours per participant.

You will also be asked to complete a short questionnaire for each of the assistive devices. An example question is "The AbnoStrainTM was easy to use. 0 = Strongly Agree to 6 = Strongly Disagree". You will be asked to complete the questionnaire immediately following the trials associated with each device.

III. Risk and Benefits
Although there are risks associated with performing any exercise, you are encouraged to inform the researcher if you experience any discomfort. You will be compensated monetarily for their participation at a rate of $7.00 per session.

IV. Confidentiality/Anonymity
The results of the study will be kept strictly confidential. Your data will be numbered without the use of any names on the data collection forms or any other data-recording medium.

V. Compensation
You will be compensated for your participation at a rate of $7 per session.

VI. Freedom to Withdraw
You are free to not respond to experimental situations you choose and withdraw from this study at any time for any reason with no penalty.

VII. Approval of Research
This research project has been approved, as required, by the Institutional Review Board (IRB) for research involving human subjects at Virginia Polytechnic Institute and State University and by the Department of Industrial and Systems Engineering.

VIII. Subject Responsibilities
I voluntarily agree to participate in this study. I have the following responsibilities:
Provide an honest level of effort.
Report any injuries to Virginia Tech Health Services medical personnel if you are a Virginia Tech student. Otherwise, obtain appropriate medical evaluation and treatment from your personal physician.
To notify the investigator at any time about a desire to discontinue participation.
To notify the investigator of any medical conditions which may be negatively influenced by the research study. This may include any medical problems that may interfere with results or increase the risk of Injury or illness.
To inform the investigator of any discomfort experienced during testing.

_____ _____
Participant's Signature Date

IX. Subject's Permission
Before you sign the signature page of this form, please make sure that you understand, to your complete satisfaction, the nature of the study and your rights as a participant. If you have question, please ask the

investigator at this time. Then if you decide to participate, please sign your name above and on the following pages (one of which will be for your records).

Signature Page

I have read the description of this study and understand the nature of the research and my rights as a participant. I hereby consent to participate with the understanding that I may discontinue participation at any time if I choose to do so.

_____ _____

Signature Date

_____

Printed Name

You may contact Dr. Kari Babski-Reeves at any time at the following address and phone number:

Grado Department of Industrial Systems and Engineering
250 Durham Hall
Blacksburg, VA 24061
(540) 231-9093

In addition, if you have any detailed questions regarding your rights as participant in University Research, you may contact the following individual:

Dr. David Moore
IRB Chair
Assistant Vice Provost Research Compliance Director, Animal Resources
CMV Phase II
Virginia Tech (0442)
Blacksburg, VA 24061
(540) 231-9359

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
Informed Consent for Participants in Research Projects.

Title of Project: "Clinical Assessment of a Bed Assistive Device on Self-Perceived Recovery Measures and Pain Medication Usage"

Investigators: Kari Babski-Reeves, Ph.D., Assistant Professor, Virginia Tech, Grado Department of Industrial and Systems Engineering and Grace Tran, Graduate Research Assistant

I. Purpose

You are being asked to participate in a study that will investigate the benefits of using an assistive device for rising from bed following hysterectomy procedures. Discomfort and pain in the abdominal region are common following these procedures, yet no studies have looked at reductions in recovery time, increases in independence, less reliance on pain medication, etc. associated with using assistive devices to help in rising and lowering for lying or seated positions. The objectives of this study are to: (1) observe you during bed transfer tasks without the use of the ABNOSTRAIN™ in the hospital, and (2) assess your recovery rates. Participation in this study will involve a visit in the hospital during visiting hours where you will be videotaped as you rise and lower from the bed, and verbal responses from you to several questions on your state of health. We will also need your permission to ask the nursing staff for information on the type and dosage of pain medication you are receiving. When you return to home, you will be asked to complete a set of questionnaires at specific dates in your recovery period and mail them back in self addressed stamped envelopes for a 5-week period following your return to home. These questionnaires will need to be completed, on average, two times per week.

To participate in the study, you should not have any conditions that may affect upper limb and trunk mobility (i.e., previous abdominal surgery within 6 months, chronic or acute back pain, and tendonitis of the shoulder, wrist or elbow, etc.).

II. Procedures

When you first meet with us, you will receive a verbal and written description of the project, its objectives, procedures, and have completed informed consent documents approved through the Institutional Review Board for Research Involving Human Subjects at Virginia Tech, as well as consent documents approved through the Montgomery Regional Hospital Review Board.

In-Hospital Stay

First, we need your permission to observe you in the hospital during normal visiting hours and video you during bed transfer tasks. During this time, a researcher will also be writing notes about difficulties and postures you assumed when attempting to rise and return to bed. We will not invade your privacy in any way and will not video you in a compromising situation. Also, you will be verbally asked a set of questions to describe your perception on pain based on a scale (e.g., 1= none to 7 = extreme). These questions will relate to subjective ratings of pain and discomfort, the number of times out of bed (daily), and self-perceived recovery status (i.e., strength, energy, bowel condition, ability to urinate). We also need your permission to ask nursing personnel to provide us with information on the type and dosage of pain medication used. This will help us to identify how long you needed stronger medication during recovery. Finally, you will be asked to provide an estimate of the number of times medication was taken to alleviate pain.

Questionnaires

You will be provided with a packet of questionnaires, self-addressed return envelopes, and a schedule for completing the questionnaires during your at-home recovery period (the 5 weeks following your return to home). The questionnaires include questions pertaining to subjective ratings of pain, mobility, self-

perceived recovery status, and medication (type and dosage), similar to the questions asked while you were in the hospital.

III. Risks and Benefits
There is not more than minimal risk associated with the above procedures that extends beyond what you would normally experience following hysterectomy procedures. The benefits to you will be in initiating research studies to improve the self-transfer performance of patients during postoperative recovery. Specific information obtained from this study will be used to assess patient perceptions of their ability to function independently during at home recovery.

IV. Extent of Anonymity and Confidentiality
The results of this study will be strictly confidential. Your data will be numbered without the use of any names on the data collection forms or any other data-recording medium. Data will be secured and kept in a locked filing cabinet.

All videotapes will be coded by a number with no identifying information displayed on them. The videotapes will be used to take retrospective assessments of body postures (e.g., upper limb, torso, cervical spine). At no time will the tapes be released or viewed by anyone other than the researchers. If clips or snapshots from the tapes are used in documents produced from this research, all faces will be smudged so identification of the persons will be impossible.

V. Compensation
You will be compensated monetarily for your participation at a rate of $50.

VI. Freedom to Withdraw
You are free to not respond to experimental situations as you choose and withdraw from this study at any time for any reason with no penalty. You will be compensated proportionally for the amount of time you spent performing the experimental protocols.

VII. Approval of Research
This research project has been approved, as required, by the Institutional Review Board (IRB) for research involving human subjects at Virginia Polytechnic Institute and State University and by the Department of Industrial and Systems Engineering.

VIII. Subject Responsibilities
I voluntarily agree to participate in this study. I have the following responsibilities:
Provide an honest level of effort.
Report any injuries to Virginia Tech Health Services medical personnel if you are a Virginia Tech student. Otherwise, obtain appropriate medical evaluation and treatment from your personal physician.
To notify the investigator at any time about a desire to discontinue participation.
To notify the investigator of any medical conditions which may be negatively influenced by the research study. This may include any medical problems that may interfere with results or increase the risk of Injury or illness.
To inform the investigator of any discomfort experienced during testing.

_____ _____

Participant's Signature Date

IX. Subject's Permission

Before you sign the signature page of this form, please make sure that you understand, to your complete satisfaction, the nature of the study and your rights as a participant. If you have question, please ask the investigator at this time. Then if you decide to participate, please sign your name above and on the following pages (one of which will be for your records).

Signature Page

I have read the description of this study and understand the nature of the research and my rights as a participant. I hereby consent to participate with the understanding that I may discontinue participation at any time if I choose to do so.

_____ _____

Signature Date

_____

Printed Name

You may contact Dr. Kari Babski-Reeves at any time at the following address and phone number:

Grado Department of Industrial Systems and Engineering
250 Durham Hall
Blacksburg, VA 24061
(540) 231-9093

In addition, if you have any detailed questions regarding your rights as participant in University Research, you may contact the following individual:

Dr. David Moore
IRB Chair
Assistant Vice Provost Research Compliance Director, Animal Resources
CMV Phase II
Virginia Tech (0442)
Blacksburg, VA 24061
(540) 231-9359

APPENDIX B: DEMOGRAPHIC FORMS

FORM A: EMG Screening Questionnaire

1. Do you presently have low back pain?

❑ Yes ❑ No

2. Have you ever had low back pain requiring medical attention or work loss in the past year?

❑ Yes ❑ No

3. Indicate your normal physical activity level on the following scale.

❑	❑	❑	❑	❑	❑	❑
1	**2**	**3**	**4**	**5**	**6**	**7**
Avoid walking or exertion		Work out regularly once a week (1x)		Work out regularly twice a week (2x)		Work out three or more times a week

4. If you answered above "1," please list the type of activities (i.e., running, walking, weight-training) and in the table below.

Type of activity	duration (min)	times per week	less than one month	less than two months	Three months or more
			❑	❑	❑
			❑	❑	❑
			❑	❑	❑

5. Do you train your abdominal muscles (i.e., sit-ups, curl-ups, leg-lifts)?

❑ Yes ❑ No

6. If "yes" to the above question, please list the type of abdominal exercises in the table below.

Type of abdominal exercise(s)	Times per week	Less than one month	Less than two months	Three months or more
		❑	❑	❑
		❑	❑	❑
		❑	❑	❑

7. Have you ever fainted, experienced shortness of breath or chest discomfort with any physical exertion or activity?

❑ Yes ❑ No If "yes", please explain: _____

8. Are there any orthopedic limitations you have that may restrict your ability to perform exercise?

❑ Yes ❑ No If "yes", please explain: _____

9. Do you smoke cigarettes?

❑ Yes ❑ No If "yes", please explain: _____

FORM B: Medical and Health History (for both laboratory and clinical studies)

Please indicate any current or previous conditions or problems you have experienced or have been told by a physician you have had:

	Yes	No
Heart disease or any heart problems:	❑	❑
Rheumatic Fever:	❑	❑
Respiratory disease or breathing problems (e.g. asthma):	❑	❑
Circulation problems:	❑	❑
Kidney disease or problems:	❑	❑
Urinary problems:	❑	❑
Musculoskeletal problems (i.e. orthopedic injuries, osteoporosis):	❑	❑
Fainting and Dizziness:	❑	❑
High Cholesterol:	❑	❑
Diabetes:	❑	❑
Thyroid problems:	❑	❑
Mental illness:	❑	❑
Hypoglycemia:(i.e. low blood sugar)	❑	❑
Epilepsy or seizures:	❑	❑
Blood clotting problems (e.g. hemophilia):	❑	❑
Liver disorders (e.g. hepatitis B)	❑	❑
Allergies	❑	❑

1. **If you answered "yes" to any of the previous questions, please indicate the date and describe:**

   _____

   _____

   _____

2. **Please list any hospitalizations/operations/recent illnesses/number of pregnancies in the table below.**

Type of surgery	Date

FORM C: Subject Data (for both laboratory and clinical studies)

Name: _____
First Middle Last

Address: _____
Street Apt #

_____
City State Zip Code

Contact number: (Home) _____ (Work) _____

Occupation: _____

E-mail: _____

Birth date: _____

Dominant-hand: ❑ Right ❑ Left

Ethnicity: ❑ African American ❑ Asian American ❑ Caucasian

❑ Hispanic/Latino ❑ Native American ❑ Asian

❑ Other: _____

Person to Contact in Case of an Emergency: _____

Relationship: _____ Phone: _____

Prithe patient Care Physician: _____ Phone: _____

Medical Insurance Carrier: _____

Are you employed by Virginia Tech? ❑ Yes ❑ No

APPENDIX C: EMG USABILITY AND SURVEY FORMS

FORM A: EMG Usability Survey

Testing Condition:	A3	A4	A5	A6	B7	B8	B9	B10

	Strongly Agree						Strongly Disagree
Q1. The assistive device was easy to use	0	1	2	3	4	5	6
Q2. The device did not strain my abdominal muscles	0	1	2	3	4	5	6
Q3. I did not feel secure using the device	0	1	2	3	4	5	6
Q4. My upper extremity felt sore after using the device	0	1	2	3	4	5	6
Q5. I would use this device regularly	0	1	2	3	4	5	6
Q6. The handles were comfortable to grab	0	1	2	3	4	5	6
Q7. The handles are spaced too close together	0	1	2	3	4	5	6
Q8. I would recommend this device to others	0	1	2	3	4	5	6

Q9. Rate the overall performance of this device on a scale from 0 = poor; 10 = excellent _____

FORM B: EMG Exit Survey

1. Provide any additional comments about the ABNOSTRAIN™ that you would change.

2. Provide any additional comments about the Bed Pull-up that you would change.

3. Did the higher starting angle help you perform the task much easier, easier, about the same, harder, or much harder than in the flat, horizontal position?

4. Did you experience any additional discomforts or pain?

5. Rank the following that allowed you to perform successful bed-rise on a scale from 1 = best; 3 = worst

____No device ____ABNOSTRAIN™ ____Bed Pull-up

APPENDIX D: CLINICAL SELF-REPORT QUESTIONNAIRE PACKET

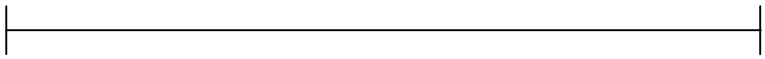
Section 1: Visual Analogue Scale (VAS)

Date: _____ Time of day: _____AM PM

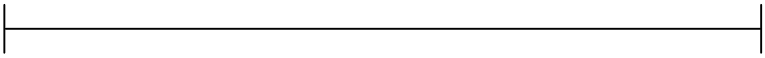
Please complete the form for each of these days and mark the day below with a circle:

2 3 4 6 8 12 14 16 20 23 27 33

In the following 2 questions, place a mark on the line that best describes your perception of pain and emotional distress.

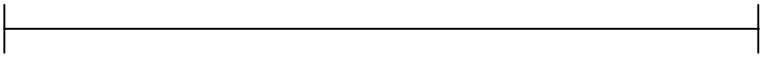


No incisional pain Worst possible pain

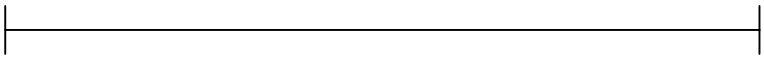


No emotional distress Worst possible distress

For the following 2 questions, place a mark on the line that best describes how the pain interferes with your ability to rise in and out of bed and your level of energy at the present moment.



Extreme interference No interference



Extremely low energy Extremely high energy

Section 2: Pain Medication

In the following 2 questions, you will be asked about your medication. Please fill in the blank where appropriate to indicate how that specific question applies to you.

1. What kind of pain-relief medication are you currently using? Please specify type and dosage, if possible.

Type of pain medication:	Dosage (mg):

2. How many times do you take your medication per day? Please mark with "X."

- ❑ 0-1 times
- ❑ 2-3 times
- ❑ 4-5 times
- ❑ 6-7 times
- ❑ 8-9 times
- ❑ 10+ times

Section 3: Self-Perceived Recovery Measures

In the following 3 questions, you will be asked about your self-perceived recovery status. Read each question carefully and then mark your answer in the blank space to indicate how that specific question applies to you.

1.	**Are you able to eat solid foods at this time?**	❑ Yes	❑ No
2.	**Have you been able to pass a bowel movement at this time?**	❑ Yes	❑ No
3.	**Are you able to urinate without any discomfort at this time?**	❑ Yes	❑ No

Section 4: Activities of Daily Living

Listed below are common daily activities. Please indicate *how many times* you do each of these activities by circling a number on the scale listed below each activity.

1. Use the bathroom.

❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑
0 1 2 3 4 5 6 7 8 9 10+

2. Sit up in bed (for approximately 30 minutes).

❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑
0 1 2 3 4 5 6 7 8 9 10+

3. Walk around the house (for approximately 30 minutes).

❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑
0 1 2 3 4 5 6 7 8 9 10+

4. Perform light household chores (i.e., cleaning, dusting, vacuuming, etc.)

❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑
0 1 2 3 4 5 6 7 8 9 10+

Please list type of household chores AND duration of activity:

_____ _____

_____ _____

5. Prepare a meal.

❑ ❑ ❑ ❑ ❑ ❑ ❑
0 1 2 3 4 5 6+

6. Shower.

❑ ❑ ❑
0 1 2+

7. Are you able to drive at this time? ❑ Yes ❑ No

8. Are you able to return to work at this time? ❑ Yes ❑ No

Section 5: Usability Survey (for Device group only)

In the following 7 questions, you will be asked about the ABNOSTRAIN™. Under each question is a scale to record your answer. Read each question carefully and then circle a number on the scale under that question to indicate how that specific question applies to you.

1. The ABNOSTRAIN™ is easy to use.

0 1 2 3 4 5 6
Strongly agree Strongly disagree

2. When I sit up using the ABNOSTRAIN™, I do not feel pain in the surgical area.

0 1 2 3 4 5 6
Strongly agree Strongly disagree

3. Rate the level of comfort of the grip handles.

0 1 2 3 4 5 6
Not comfortable Extremely comfortable

4. The ABNOSTRAIN™ requires a lot of upper body strength.

0 1 2 3 4 5 6
Strongly agree Strongly disagree

5. I am more motivated to get out of bed using the ABNOSTRAIN™.

0 1 2 3 4 5 6
Strongly agree Strongly disagree

6. I feel more independent using the ABNOSTRAIN™.

0 1 2 3 4 5 6
Strongly agree Strongly disagree

7. I prefer using the ABNOSTRAIN™ than having to rely on someone else.

0 1 2 3 4 5 6
Strongly agree Strongly disagree

APPENDIX E: SUPPLEMENTAL ELECTROMYOGRAPHY RESULTS

Mean and Peak Concentric Activity

Table E1. Multiple comparisons by configuration and angle during the concentric phase (%MVE).

conditions compared	Mean activity			Peak activity		
	URA	LRA	EO	URA	LRA	EO
U1-A1	**12.1***	**8.22***	**2.87***	**29.5***	**21.1***	**7.10***
U1-A2	**16.6***	**13.2***	**6.44***	**38.9***	**30.2***	**14.0***
U1-B1	**11.9***	**8.32***	**4.87***	**29.2***	**20.2***	**11.6***
U1-B2	**15.4***	**11.9***	**6.67***	**39.3***	**30.0***	**15.0***
A1-A2	**4.45***	**4.96***	**3.57***	9.39	**9.12***	**6.88***
A1-B1	-0.24	0.10	2.00	-0.31	-0.93	4.47
A1-B2	**3.27***	**3.65***	**3.80***	9.75	**8.83***	**7.90***
A2-B1	**-4.69***	**-4.86***	-1.57	-9.70	**-10.0***	-2.41
A2-B2	-1.18	-1.31	0.23	0.35	-0.29	1.02
B1-B2	**3.51***	**3.55***	**1.80***	10.1	**9.76***	3.43
0°-30°	**1.42***	**1.01***	**0.46***	**5.24***	**4.03***	**2.22***

Mean and Peak Eccentric Activity

Statistical Model:

Table E2. Multiple comparisons by configuration and angle during the eccentric phase (%MVE).

conditions compared	Mean activity			Peak activity		
	URA	LRA	EO	URA	LRA	EO
U1-A1	**5.33***	-0.52	0.76	**13.26***	**7.89***	6.27
U1-A2	**8.47***	**6.92***	**3.63***	**19.21***	**15.46***	**11.91***
U1-B1	**4.63***	2.35	1.12	**11.86***	**7.12***	4.95
U1-B2	**7.57***	5.63	**2.74***	**18.42***	**12.88***	9.85
A1-A2	3.14	**7.45***	**2.87***	**5.95***	**7.57***	5.64
A1-B1	-0.69	2.87	0.36	-1.40	-0.77	-1.32
A1-B2	2.24	6.16	1.98	5.16	4.99	3.58
A2-B1	**-3.84***	-4.58	-2.51	-7.35	**-8.34***	-6.96
A2-B2	-0.90	-1.29	-0.89	-0.79	-2.58	-2.06
B1-B2	2.93	3.29	1.62	6.56	5.76	4.90
0°-30°	0.75	-1.09	0.78	**3.80***	**1.99***	2.64

Usability Survey

Table E3. Analysis of final ranking data from exit survey using test of homogeneity.

	Rank[a]			Total
	1	2	3	
ABNOSTRAIN™	17	1	0	18
	6	6	6	
	31.5	1.9	0	33.3
	94.4	5.6	0	
Bed Pull-Up	0	14	4	18
	6	6	6	
	0	25.9	7.4	33.3
	0	77.8	22.2	
Unassisted	1	3	14	18
	6	6	6	
	1.9	5.6	25.9	33.3
	5.6	16.7	77.8	
Total	18	18	18	54
	33.3	33.3	33.3	100

[a] Row 1: Actual response
Row 2: Expected Response (Given 33% probability)
Row 3: Row 2 ÷ Row 1 = Chance (%)
Row 4: Row 1 ÷ Total = Actual (%)

APPENDIX F: SUPPLEMENTAL CLINICAL RESULTS

Visual Analogue Scale (VAS)

Table F1. Means (SD) for on VAS response variables (0 = Minimal; 10 = Extreme).

VAS variable	Week	Group		Age		Surgery	
		Control	Device	Old	Young	AH	CS
Q1 Incisional pain	1	6.0 (2.2)	5.8 (1.9)	6.1 (1.8)	5.6 (2.3)	6.6 (2.0)	5.3 (1.9)
	2	3.8 (2.2)	2.3 (1.1)	3.0 (1.8)	3.2 (2.1)	3.1 (1.5)	3.1 (2.3)
	3	2.5 (2.1)	1.3 (0.8))	1.5 (1.4)	2.4 (1.9)	1.9 (1.5)	2.0 (1.9)
	4	1.3 (1.2)	0.9 (0.7)	0.8 (0.6)	1.5 (1.3)	1.5 (1.2)	0.7 (0.6)
	5	1.1 (1.2)	0.5 (0.3)	0.5 (0.3)	1.2 (1.3)	1.2 (1.2)	0.4 (0.2)
Q2 Emotional distress	1	4.6 (2.6)	4.9 (2.1)	4.6 (2.4)	4.8 (2.5)	5.6 (2.5)	3.9 (2.0)
	2	3.8 (2.3)	2.4 (0.9)	2.5 (1.5)	3.9 (2.2)	3.6 (2.1)	2.7 (1.8)
	3	2.8 (2.4)	2.0 (1.4)	1.8 (1.5)	3.2 (2.4)	3.3 (2.2)	1.7 (1.6)
	4	1.7 (1.5)	1.1 (1.5)	1.3 (1.6)	1.6 (1.4)	2.1 (1.8)	0.9 (1.0)
	5	1.3 (1.7)	0.9 (1.3)	0.7 (1.3)	1.7 (1.6)	1.9 (1.8)	0.4 (0.3)
Q3 Pain interference	1	7.0 (2.2)	6.3 (2.3)	6.3 (2.1)	7.1 (2.4)	7.6 (2.1)	5.8 (2.0)
	2	4.7 (2.2)	2.5 (2.3)	3.4 (2.5)	4.0 (2.5)	3.9 (2.5)	3.5 (2.5)
	3	2.6 (2.0)	1.3 (1.1)	1.7 (1.5)	2.3 (2.0)	2.4 (1.9)	1.6 (1.6)
	4	2.6 (2.5)	0.7 (0.8)	1.3 (1.8)	2.2 (2.4)	2.1 (2.4)	1.4 (1.7)
	5	1.6 (1.6)	0.3 (0.4)	0.5 (0.4)	1.7 (1.8)	1.6 (1.6)	0.3 (0.3)
Q4 Energy Level	1	3.8 (2.6)	4.0 (2.5)	3.7 (2.2)	4.1 (2.9)	2.2 (1.7)	5.4 (2.2)
	2	4.9 (1.9)	4.8 (1.8)	4.9 (1.8)	4.8 (1.9)	4.3 (1.9)	5.3 (1.7)
	3	5.5 (2.6)	6.2 (2.3)	6.4 (2.3)	5.1 (2.4)	4.3 (2.5)	7.2 (1.4)
	4	5.7 (2.9)	6.5 (2.5)	6.5 (2.6)	5.6 (2.8)	4.4 (2.6)	7.5 (1.8)
	5	6.1 (3.1)	7.1 (2.6)	7.6 (2.6)	5.2 (2.5)	5.1 (3.0)	8.1 (1.6)

Pain Class and Daily Dosage

Table F2. Means (SD) of daily dosages for Class 1 and Class 2 medication.

Daily Dosage	Week	Group		Age		Surgery	
		Control	Device	Old	Young	AH	CS
Class 1 (MEDD)	1	11.7 (5.4)	15.8 (5.6)	13.8 (5.4)	12.7 (6.4)	16.8 (4.3)	11.2 (5.6)
	2	7.2 (4.1)	N/A	6.2 (4.2)	8.7 (3.7)	10.0 (2.6)	5.8 (4.1)
	3	5.6 (1.2)	N/A	4.2 (0.0)	6.3 (0.0)	6.3 (0.0)	4.2 (0.0)
	4	11.3 (0.0)	N/A	N/A	11.3 (0.0)	11.3 (0.0)	N/A
	5	11.3 (0.0)	N/A	N/A	11.3 (0.0)	11.3 (0.0)	N/A
Class 2 (IBDD)	1	1511 (713)	1541 (223)	1417 (323)	1605 (654)	1856 (919)	1426 (330)
	2	1433 (464)	1115 (626)	1017 (625)	1520 (377)	1033 (688)	1500 (249)
	3	1000 (400)	200 (0)	867 (702)	800 (0)	600 (346)	1200 (566)
	4	1200 (462)	N/A	1600 (0)	800 (0)	800 (0)	1600 (0)
	5	800 (0)	N/A	N/A	800 (0)	800 (0)	N/A

Activities of Daily Living (ADLs)

Table F3. Means (SD) of activities of daily living (ADLs) by week.

ADL	Week	Group		Age		Surgery	
		Control	Device	Old	Young	AH	CS
Bathroom	1	5.7 (2.2)	6.3 (1.9)	6.3 2.1)	5.6 (2.0)	5.9 (2.2)	6.1 (2.0)
	2	6.0 (1.9)	6.5 (1.8)	6.4 1.9)	6.1 (1.9)	5.8 (1.6)	6.7 (2.0)
	3	6.0 (1.9)	6.5 (1.5)	6.5 1.6)	5.9 (1.8)	5.4 (0.9)	6.9 (2.0)
	4	6.1 (2.0)	6.4 (1.9)	6.5 1.8)	5.9 (2.0)	5.5 (1.2)	6.9 (2.2)
	5	6.7 (1.7)	6.4 (2.1)	6.5 2.0)	6.7 (1.8)	5.6 (1.3)	7.6 (1.8)
Chores	1	0.9 (1.9)	1.6 (2.0)	1.4 2.1)	1.1 (1.9)	0.5 (0.8)	1.9 (2.5)
	2	2.9 (2.5)	3.4 (2.7)	3.7 2.8)	2.5 (2.2)	2.8 (1.6)	3.5 (3.2)
	3	3.6 (2.6)	3.9 (2.7)	4.4 2.5)	3.0 (2.6)	3.0 (1.3)	4.4 (3.2)
	4	4.0 (2.4)	4.2 (3.1)	5.1 2.8)	3.0 (2.3)	3.6 (1.7)	4.6 (3.4)
	5	5.0 (3.2)	4.3 (3.3)	6.1 3.4)	2.7 (1.0)	3.4 (1.8)	5.9 (3.8)
Meals	1	0.3 (0.7)	0.3 (0.7)	0.3 0.8)	0.3 (0.5)	0.1 (0.4)	0.4 (0.8)
	2	1.4 (1.0)	1.5 (1.0)	1.7 1.1)	1.1 (0.9)	1.4 (1.1)	1.4 (1.0)
	3	2.0 (1.1)	2.1 (0.9)	2.5 1.1)	1.5 (0.5)	1.8 (0.9)	2.3 (1.1)
	4	2.0 (0.9)	2.2 (0.9)	2.5 0.7)	1.6 (0.8)	2.1 (0.8)	2.1 (1.0)
	5	2.3 (1.0)	2.3 (1.0)	2.5 0.9)	2.0 (0.9)	2.0 (1.0)	2.6 (0.8)

Self-Perceived Recovery Measures

Table F4. Means (SD) on self-perceived recovery measures (Total days).

Recovery measure	Group		Age		Surgery	
	Control	Device	Old	Young	AH	CS
Pass bowel movement	26.8 (1.3)	28.4 (1.8)	27.6 (1.9)	27.4 (1.6)	27.4 (2.0)	27.6 (1.6)
Eat solid food	30.4 (1.4)	30.9 (0.4)	30.9 (0.4)	30.3 (1.5)	30.1 (1.5)	31.0 (0.0)
Urinate w/o discomfort	28.5 (3.3)	29.7 (2.2)	29.6 (2.0)	28.4 (3.6)	29.9 (1.6)	28.4 (3.5)
Drive	20.7 (3.1)	20.1 (2.8)	21.0 (3.4)	19.7 (2.1)	20.0 (3.0)	20.8 (2.9)
Shower	30.8 (0.5)	30.3 (0.8)	30.3 (0.7)	30.9 (0.4)	30.3 (0.8)	30.8 (0.5)
Return to work	16.3 (8.9)	19.0 (0.0)	19.5 (5.7)	12.5 (9.2)	19.0 (0.0)	16.8 (7.8)

Clinical Usability Survey

Table F5. Means (SD) on clinical usability summary based on 7-point Likert Scale where 0 = Strongly Agree; 6 = Strongly Disagree.

Question	Age		Surgery	
	Old	Young	AH	CS
Q1 Easy to use	1.8 (1.7)	3.0 (0.7)	2.0 (2.0)	2.3 (1.3)
Q2 No pain in surgical area	4.4 (0.8)	2.0 (0.7)	4.7 (0.6)	2.5 (1.0)
Q3 Comfortable handles	5.4 (0.5)	5.5 (0.7)	5.5 (0.5)	5.3 (0.6)
Q4 Requires upper body strength	3.4 (2.0)	3.3 (2.5)	3.2 (2.4)	3.5 (1.8)
Q5 More motivated	3.3 (0.6)	3.3 (1.1)	3.5 (0.5)	3.0 (0.9)
Q6 More independent	2.5 (1.6)	3.3 (1.1)	2.7 (1.9)	2.8 (1.0)
Q7 Prefer device than others	1.9 (1.6)	3.5 (1.4)	2.3 (1.6)	2.5 (2.0)