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Mobility Device for Injured US Army Corp Engineer

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MOBILITY DEVICE FOR INJURED US ARMY CORP ENGINEER

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This Scholarly Project, submitted by Jessica Jones and Robert Whittaker in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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Title Mobility Device for US Army Corp Engineer

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Degree Doctor of Physical Therapy

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ACKNOWLEDGEMENTS

We would like to thank the engineering students Tyler Voegele, Tyler Bradley, and Ryan Hake as well as Dr. Neuberg for dedicating a great deal of time and effort into developing the device. We would also like to thank our client for taking the time to meet with us in order to optimize the device to best fit his needs as well as Dr. Flom-Meland, PT, Ph.D, NCS for providing us plenty of helpful feedback throughout the length of this project.
ABSTRACT

Background and Purpose: Low back pain affects 70-85% of American adults at some point in their life. Back pain can have a negative impact on a person’s quality of life. A group of three engineering students and two physical therapy students collaborated on designing a mobility device for a US Army veteran to aid him in transfers and pain management. The purpose of this research proposal would be to assess how our client would respond to an individualized mobility device. Case Description: Our client suffered lumbar disc injuries as a result of lifting and twisting a heavy object resulting in multiple impairments and limitations in activity and participation. The client has difficulties with transferring from the floor and has trouble tolerating positions such as sitting. Proposal: The client will receive the Short Form 36 (SF-36) and Oswestry Disability Questionnaire (ODQ) to complete before and after receiving the device to objectively measure changes in his function. We propose we will see most clinically significant improvements in the SF 36 physical functioning, role limitations due to physical and emotional health, and vitality subscales. We expect to see improvements in our clients back pain and improved social, occupational, and recreational functioning in the ODQ. Conclusion: Although there was limited contact with our client, we feel the completed device will meet his individual needs and improve his quality of life and will be supported through objective measures after he receives the device.
CHAPTER I
INTRODUCTION

Low back pain affects 70-85% of American adults during some point in their life.\(^1\) Approximately 60-85% of people will have recurrent back pain. However, 80-90% of disabling low back pain does not have a precise pathoanatomic diagnosis through imaging and other examination methods.\(^2\) Low back pain can have substantial impact on activities of daily living (ADLs) depending on the severity as well as efficiency and productivity at work.

There are several risk factors associated with low back pain which include heavy manual labor, repetitive lifting and twisting, whole body vibrations, weak trunk strength, low job satisfaction, poor physical fitness, and smoking.\(^1\) These risk factors can induce pathology of the vertebrae of the lumbar spine such as inflammation, joint compression, stenosis, and joint degeneration as well as injure the disc from faulty biomechanics causing a herniation. Education on appropriate body mechanics in work or other activities is crucial to reducing the occurrence of low back pain.

Modalities such as ultrasound, transcutaneous electrical stimulation (TENS), thermotherapy, and traction have been utilized to help alleviate symptoms of low back pain.\(^3\) In the comparison of traction, ultrasound, and low-power laser therapies on the treatment of lumbar disc herniation all three therapies showed improvement without a significant difference between therapies.\(^4\) Through the use of magnetic resonance imaging (MRI) and the Oswestry Disability Questionnaire (ODQ), along with other
questionnaires, there was no significant difference at any point during the study or three months post treatment. Results were seen as a reduction in pain and decreased disability on questionnaires and the MRI showed decreased size of herniation.\textsuperscript{4} Another comparison looked at the effectiveness between TENS verses percutaneous neuromodulation therapy (PNT) in the rehabilitation in patients with chronic low back pain.\textsuperscript{5} In the short term, two weeks, the study found that both TENS, conventional and low frequency, along with PNT were effective in reducing the patients' pain and increasing function and quality of life. Though, PNT was overall more effective than both types of TENS.\textsuperscript{5} Rehabilitation for low back pain also includes strengthening of the lumbar stabilizers and education on appropriate lifting and postures to prevent reoccurrence.\textsuperscript{6} Medications to alleviate pain include corticosteroids, nonsteroidal anti-inflammatory drugs (NSAIDs), and narcotics but all have deleterious effects with prolonged usage. If conservative measures are unsuccessful for low back pain, such as pain from degenerative disc disease (DDD), surgical interventions include discectomy, laminectomy, or spinal fusion.\textsuperscript{7}

In conjunction with the engineering department a client proposed the idea of fabricating a custom mobility device to increase his function. The three major components of the mobility device (see Figure 1) are to transfer our client from the floor to standing, a traditional powered wheelchair that can transition into standing, and an unweighting device. The lifting system is a detachable pillar attached over the front caster wheel powered by a small DC motor that lifts a padded bar vertically for the client to hold on to, when not in use the pillar can fold down along the device. The sit to stand portion of the device allows the seat to rise while the backrest stays in line to transition
into standing. The unweighting portion of the device allows pressure relief on his lower extremities and provides additional trunk stabilization, the device will unweight 20lbs and will support his body weight if he were to fall.

Figure 1. A final computer-aided design of the mobility device created by the engineering students.

All aspects of the device were intended to fit the client’s needs and to perform tasks in an analogous manner to what he is accustomed to performing as well as provide additional assistance to improve quality of life through decreased pain and increased mobility. The lifting device was designed in such a way to lift the client in a similar manner to how his wife assisted him from the floor to standing. She would crouch down with her forearm out in front of her and the client would hold on to her forearm and slowly lift him to kneeling and eventually to standing. Though this position puts the clients spine into extension he had familiarized himself with this motion and he was comfortable transitioning this way.
Problem Statement

The client suffers from extensive pain and increased limitations greatly affecting his quality of life. Our client was unsuccessful with physical therapy in the past for managing his symptoms and thus an assistive device was designed to optimize his function. The device is multidimensional in that it allows the client to transfer from prone on the floor to standing through the use of a vertical lifting pillar. From standing he is able to transfer to a sitting position on the device. The device is able to transfer him from sitting to standing and when standing he has the ability to be un-weighted in order to decrease load and pain within the spinal column and in his lower extremities. All aspects of the device are intended to increase his ability to interact with his family and in his recreational and occupational environments.

The client requested the device after an unsuccessful surgery and pain that would decrease his functional abilities in all aspects of his life. The initial traumatic incident took place in 1994 while he was working on a piping crew; he picked a pipe up from an excavation site, twisted and threw the pipe to his left side. He was buried in mud up to his waist as he threw the pipe and was unable to move his feet with the weight of the concrete pipe. As he threw the pipe he sustained a torque injury that was eventually surgically fixed.

As a result of the injury he was hospitalized many times. He was reluctant to have surgery but proceeded in 2002 with an L2-L3 spinal fusion. Prior to his torque injury he had worked in heavy industrial construction resulting in repeated compounding injuries that altered the stability and elasticity of the supporting structures of his lumbar spine. After his surgery the pain was not alleviated and he was unable to fully participate
in daily activities and work, this device is intended to increase his participation. He described his baseline pain as 5 on a 0-10 point scale and goes up to 15 when at its worst. The client described his pain as constant throbbing, sharp, shooting, and has experienced intermittent numbness in his legs. He tolerated sitting for up to 5 minutes to an hour before the pain became intolerable. Our client felt the pain at his surgical site and in his lower extremities has increased in sensitivity since the surgery.

Our client is currently taking prescribed medications for pain reduction, muscle relaxation, erectile dysfunction, depression, sleep, nausea, and acid reflux. He felt that the medications made him less productive and responsive so therefore waited for the pain to become intolerable before taking medication. He also wanted to avoid dependency on medications as he has a family history of addiction.

Purpose of the Study

The purpose of the study was to track the changes in quality of life and level of participation before and after the client uses the device through functional assessment questionnaires. The client states that on his worst days he is unable to move without maximal assistance from his family and on days he is not in very much pain he tends to perform too many activities and it causes an increase in pain later. The goals for the research proposal are to design a device that fits his body, navigates easily, increases participation, and avoids an increase in symptoms.

Significance of the Study

This study assessed the effectiveness of the mobility device with questionnaires to track objective progress overtime. The SF-36(tm) Health Survey and the revised Oswestry Disability Index (for low back pain/dysfunction) will be the two
questionnaires the client will be completed prior to using the mobility device and after he has used the device for two six week time periods.

Proposed Research Question

Can an individualized mobility device increase quality of life and participation with family and work activities?

Hypothesis

The individualized mobility device will reduce duration and intensity of pain, improve SF-36 subscale scores, and decrease Modified Oswestry Disability Index scores indicating overall improvement in function. We hypothesize we will see the most improvements in the SF 36 subscales role limitations due to physical health, role limitations due to emotional health, physical functioning, and vitality. We also hypothesize to see improvements in the pain and social questions on the ODQ.
CHAPTER II
LITERATURE REVIEW

The spinal column acts as the primary shock absorber for the trunk and neck, with about 80% of the load supported by the intervertebral discs and 20% through the apophyseal joints and laminae. The vertebrae of the lumbar spine have unique features compared to other segments of the spinal column. The apophyseal joints are oriented more vertically allowing more flexion and extension compared to other regions of the spine, but less axial rotation. About 50° of trunk flexion comes from the lumbar spine and 15° of trunk extension. During flexion the inferior articulating facets slide superiorly and anteriorly relative to the superior articulating facets, which transfers compressive forces from the apophyseal joints toward the discs and places tensile forces on the posterior spinal ligaments. Extension is essentially the opposite of flexion. The load on the apophyseal joints is increased with extension as the inferior articulating processes move posteriorly and inferior on the superior articulating processes. The intervertebral disc consists of an outer surrounding called the annulus fibrosus and an inner portion called the nucleus pulposus. The vertebral end plates are thin hyaline layers on the superior and inferior surfaces of the vertebral bodies that mesh with the fibers of the annulus fibrosus to connect the vertebrae. The nucleus consists mostly of water to function as a hydraulic shock absorber to transfer and attenuate loads between adjacent vertebrae. The annulus in the lumbar spine have about 10-20 concentric layers of
collagen fibers to surround and contain the nucleus with increased loading pressure. The collagen layers are oriented about 65° from the vertical with adjacent layers traveling in opposite directions. The disc has limited blood supply to the nucleus pulposus and relies on fluid moving in and out of the disc through diffusion with spine movements for nutrition. Compression of the disc stimulates matrix turnover. Only the outermost portion of the annulus fibrosus is innervated by proprioceptive and nociceptive nerves.²

Injuring the lumbar vertebrae disc and facet joints can occur from multiple causes. As humans age, the concentration proteoglycans in the nucleus decrease. Proteoglycans bind water in the nucleus pulposus of the intervertebral disc giving it hydrostatic properties to help support compressive loads. The nucleus becomes dryer, more solid, fibrous, and cracks appear resulting in the discs ability to bear weight to decrease.¹¹ There are several mechanical factors that can result in disc degeneration and injury. There are also many tissues that are subject to mechanical stress. Ligaments, facet capsules, periosteum of the vertebrae, muscles, anterior dura mater, dural sleeves, epidural areolar adipose tissues, and walls of blood vessels have nociceptive innervation that respond to mechanical stress. Distension or compression of the nociceptive nerve endings leads to pain, and if the stress exceeds the tissues support capabilities, the tissue will breakdown and can lead to inflammation. Removing these stresses is important to decrease inflammation and promote healing.⁶ Repetitive external mechanical forces can lead to fatigue failure of the matrix of the disc.⁷ Microtrauma can accumulate from many years of repetitive lifting or bending with an excessive flexed trunk. Fatigued structures are more apt to failure resulting in herniation or rupture. Our client worked in heavy industrial construction for multiple years and stated his initial injury occurred while
lifting a heavy object, twisting, and throwing it resulting in multiple ruptured discs. Repeated forward bending and lifting causes the posterolateral corners of the annulus to become strained causing radial fissures to develop. During lifting there is more trunk muscle activation increasing the hydrostatic pressure on the disc. Nutrition of the disc is also important in maintain its health. When a spine segment is immobilized or compressed for long durations, diffusion of nutrition to the cells in the nucleus is diminished decreasing the health of the disc. Compressive forces can also facture the vertebral end plate if it is sudden and tremendous load. Endplate damage can cause depressurization of the nucleus and increase stress to the posterior annulus due to not being able to help support the compressive load of the spine. Compression of the disc as a result of increased weight causes the oblique oriented lamellae to become more horizontal and the nuclear material to exert more tensile force on the lamellae. Torsional forces caused from twisting motions can cause tensile forces on the annulus collagen fibers as the lamellae have an oblique orientation in resting. Normally the facet joints aid in resisting rotation, but when the spine is flexed the facet joints are gapped offering less protection to rotational forces resulting in annular tears. During rotation the axis of rotation is in the posterocentral portion of the disc, but with extreme rotation the facets engage shifting the axis of rotation posteriorly and the vertebral bodies pivot around it. The force during extreme rotation places compression on the engaged facet while placing shear force on the disc as vertebrae pivot around the new axis. Forward flexion of the trunk places compression on the anterior portion of the annulus and tension through the posterior aspect of the annulus as the oblique oriented fibers become more vertical.
Trunk flexion combined with twisting places significant stress through the posterior annulus.\textsuperscript{2}

Degenerated discs are associated with spinal stenosis and degenerative spondylolisthesis. Decreases in intervertebral disc height cause the annulus to bulge circumferentially and buckling of the ligamentum flavum causing encroachment on the spinal canal, intervertebral foramen, and subarticular recesses. Increase compressive forces on the neural arch can cause osteoarthritis of the apophyseal joints and osteophytes around the vertebral body margins and articular processes.\textsuperscript{7} Trunk flexion increases the intervertebral foramen diameters about 19\% and the vertebral canal by about 11\% to reduce pressure on an impinged nerve root. However during flexion there are more compressive forces on the anterior portion of the disc which could shift the nucleus pulposus posteriorly. During extension the diameter of the intervertebral foramen is reduced by about 11\% and the volume of the vertebral canal by 15\%. However, extension can migrate the nucleus pulposus anteriorly to reduce a bulge that can be impinging vertebral structures.\textsuperscript{10}

For a degenerative disc surgical options are to remove the disc or disc fragments, laminectomy, and/or a spinal fusion if symptoms persist after conservative management.\textsuperscript{7} Philips et al\textsuperscript{12} found lumbar fusions are a viable treatment option to reduce pain and improve function when conservative treatment is ineffective and the diagnosis of disc degeneration is possible. However, our client's fusion was stated as being a failed fusion and his symptoms have not improved since. Degeneration that occurs at vertebral segments above or below the fused vertebrae is termed as adjacent segment disease (ASD). The most common pathology in a segment above or below the fusion is disc

\textsuperscript{10}
degeneration followed by listhesis, instability, hypertrophic facet joint arthritis, herniated nucleus pulposus, and stenosis. The exact mechanism of ASD is uncertain but altered biomechanics from a fusion are likely part of the cause. A fusion can change the center of rotation leading to increased stresses on the facets and disc of the adjacent mobile segment as well as increase the mobility of it as a result of the transfer of motion from the fused segment. There is up to 45% increase in intradiscal pressure of the disc immediately next to a fused segment, which can accelerate disc degeneration.

Asymptomatic ASD has varying rates from 8-100% whereas symptomatic ASD has a reported incidence of 5.2-18.5%. Increasing the amount of fused segments can promote ASD as the longer lever arm causes more stress at the free segments, and it was found that 78% of patients with ASD involved two or more fused segments. Other risk factors include the instrumentation of the fusion, sagittal alignment of the vertebral column, pre-existing degeneration of the discs at the adjacent level, lumbar stenosis, and age.13

Our client is able to reduce his pain by using his upper extremities to support his body weight thereby decreasing the load through his lower extremities and spine. Because of this, our client was taken to a physical therapy department to use the LiteGait® device to see if unweighting him on a body weight-supported treadmill (BWST) could help decrease his symptoms. With approximately 20 pounds of his weight supported, he felt relief. The device we helped design has an unweighting component to it using a MAGS Suspension Vest.14 A study by Whitman et al15 found greater perceived recovery in subjects with lumbar spinal stenosis receiving manual therapy, strengthening exercise tailored to each subjects needs, and BWST training compared to receiving flexion exercises, progressive treadmill walking, and therapeutic ultrasound group. In
this study the subjects were unweighted to the minimum amount required to decrease their symptoms and walk as comfortable as possible. At 6 weeks, 79% of subjects in the BWST group had perceived recovery compared to 41% of the subjects in the flexion exercise group. At one year, 62% of the subjects in the BWST group had perceived recovery and 41% in the flexion exercise group. At long term follow up, 38% in the BWST group had perceived recovery and 21% in the flexion exercise group. A case report on an ultra-marathon runner who suffered an L₄-L₅ right lateral disk extrusion showed improvements in symptoms after receiving rehabilitation using partially BWST running on a lower-body positive pressure device. The subject started at 50% of his body weight supported on the treadmill as well as performed quadriceps strengthening through electrical stimulation and core stabilization exercises. By six weeks post injury he was able to run comfortably on mountain trails. Both articles state the use of BWST can reduce axial loading forces and increase the cross sectional area of the neuroforamen and central spinal canal. There is also a decrease in ground reaction forces associated in gait when ambulating by decreasing the downward excursion of the center of gravity.

Decreasing the load on pathological tissues can allow them to recover more effectively. One downside to using BWST training is it can restrict respiration, although none of the subjects in the articles complained of that issue. Our client did not demonstrate any restrictions in respiration when wearing the harness or utilizing the LiteGait®.

Our client is currently taking multiple medications to manage his symptoms from his injury including narcotics and opioids, sleeping aids, muscle relaxants, antidepressants, NSAIDs, and many others. Adverse drug reactions (ADRs) can occur which is unintended or unwanted side effects of a drug even at the acceptable dose levels.
Polypharmacy and other comorbidities can increase the likelihood of ADRs. ADRs from opioids include sedation, depressed cognition, nausea and vomiting, and constipation. NSAIDs can cause increased risk of bleeding and gastrointestinal adverse effects. NSAIDs can also impact tissue healing by inhibiting COX enzyme necessary for repair.\textsuperscript{17} Since our client has so many medications he is at increased risk for ADRs and may be at risk for falling. The sedative side effects of many of the medications he is on can impact his activity levels. Our goal for the mobility device is to decrease his pain and reliance on his medications to improve his function.

Lumbar orthosis such as corsets or belts are commonly used after surgical procedures to stabilize spine. Other benefits of a lumbar orthosis include limitation in trunk flexion, increased intra-abdominal pressure to decrease disc pressure, postural control, spine stability, and adaptation of muscle activity. Calmels et al\textsuperscript{18} found using an elastic lumbar belt for the whole day for the 90 day duration of the study helped significantly improve function, pain level, and pharmacologic consumption in subjects with subacute (between 4 weeks and 3 months) low back pain. Using the harness could potentially reduce the amount of narcotics our patient is taking, although he has had chronic back pain for multiple years. A study by Yee et al\textsuperscript{19} showed no significant advantages of using a lumbar corset for 8 weeks full time after surgical intervention of a degenerative spinal condition compared to those who did not use it at one and two year follow up. Another study showed using a corset for chronic low back pain was helpful at one month to improve low back pain and increase muscle endurance but was not significant at 6 months. There was also no paravertebral muscle weakening at 6 months.\textsuperscript{20} Prolonged use can promote muscular atrophy of the spinal muscles and cause
psychological dependence. Lumbar corsets provide passive support to the lumbar region, but some patients tend to become dependent and continue to wear it after they have healed. It is better to strengthen the body’s deep abdominal core muscles to improve effective spinal mechanics. This review of literature suggests that using corsets to reduce pain and promote healing is useful up to 6 months, but could potentially weaken trunk musculature and have to rely on a corset for support. The MAGS harness we provided for the mobility device has three broad straps that are wrapped around the torso as snug as tolerable acting as an elastic corset. Our client felt the compression from the abdominal straps helped reduce his pain and provided lumbar stability.

Injuries resulting from Operation Iraqi Freedom, Operation New Dawn, and Operation Enduring Freedom had at least 51,809 service members injured causing a great need for assistive device following these injuries. At this time there is limited data on the outcomes of how these assistive devices have impact quality of life and activities of daily living. In conjunction with that there are more than 6.8 million people living in America using an assistive device for their mobility; there is a need for clarity on how to assist patients in navigating in the community with their assistive device. The need for mobility devices has been looked at by Walker et al with finding that suggest before a therapist gives a mobility device to a client, the client should be trained in community similar situations to increase safety. They found that some skills that were practiced in the clinic transferred well to the community while other more complex tasks were difficult to simulate in the clinic and are exclusive to the situation.

Objective data and tracking changes in a patient’s progress is necessary for monitoring improvement and effectiveness of treatment procedures. For our client in
particular that presented with low back pain and increased limitations in activities of
daily living and work objective data was gathered from the Short Form-36 (SF-36) and
the ODQ. The questionnaires were used before the client used the mobility device and
then again after he had used the device for (some time). The objective findings look at
many aspects of the client’s life from community activities to personal well-being and
overall health. In a comparison of the ODQ, the SF-36, and the Musculoskeletal
Outcomes Data Evaluation Management System (MODEMS) scale in the reactivity to
change for patients with low back pain and lower extremity pain, the researchers found
that the assessment of pain was more sensitive than the other aspects of the
questionnaires. The ODQ was best at discriminating with a condition specific function
while the SF-36 is able to differentiate in pain, function, and physical changes. The
MODEMS scale strongest aspect was discerning changed in pain.24 The findings suggest
that for our study the combination of using the SF-36 and the ODQ will show a good
differentiation of the clients change in status. Not only are we looking at the decrease in
limitations showing a change in score but understanding that the client’s pathology may
also cause deterioration in his ability to perform ADLs.

The client had a spinal fusion and research shows that patients may not perceive
improvement after the surgery; in fact, some state they have even declined in function
since their surgery.25 Though the ODQ has been shown to track changes in improvement,
tracking deterioration is a different way of using the questionnaire. If the client does
produce a higher disability number on the ODQ, that number may not be validated to
measure a decline in function.25
A study by Ferrari\textsuperscript{26} looked at the effect foot orthotics had on patients with low back pain and lower limb pain gauged by the SF-36 and the ODQ. The results of the study found that the physical component of the SF-36 and the ODQ both were statistically significantly in measuring the effects of the treatment, however, the ODQ (9.74) was more responsive than the SF-36 (0.24). The SF-36 and the ODQ should be able to track physical improvements from the use of the lifting device as the questionnaires did in the foot orthotics study. The use of assistive devices can be helpful in the management low back pain depending on the patient population.

Our client has difficulty with transferring when his pain flares up. Shum et al\textsuperscript{20} found that subacute low back pain alters the kinematics and joint coordination of the lumbar spine and hips during sit-to-stand and stand-to-sit. Subjects with low back pain had reduced trunk and hip motion during sit-to-stand and stand-to-sit transfers and the lumbar spine was found to have the least total movement. There was also a significant reduction in velocity in the lumbar spine and hips in subjects with low back pain. This suggests movement compensation to reduce pain, protect pathologic tissue, and to prevent provoking pain with fast movements.\textsuperscript{27} The device designed for him will assist in sit-to-stand transfers. There is also a lifting device to help him off the floor to simulate closely how he currently transfers from the floor. He does not tolerate sitting for longer periods of time. Depending on the sitting posture, certain parts of the spinal column can be affected. Sitting causes compressive forces and high intradiscal pressure. Sitting with lumbar extension reduces intradiscal pressure, decreases paraspinal muscle activity, increases compressive forces on apophyseal joints, and greater compromise of structures of the lateral and central canals. Sitting with flexion greatly increases intradiscal pressure.
and cause disc to bulge posteriorly.\textsuperscript{28} The device can be powered as a wheelchair so our client does not have to ambulate and have ground reaction forces transfer through his lower extremities and spine potentially causing pain.

With our knowledge of the spinal mechanics, pathological conditions and the various causes, reviewing the literature, the history of our client that was collected, and the engineering students expertise, we believe this device will alleviate symptoms that the client presents with. We were able to meet with our client to provide him means of gathering data on changes in his function and symptoms after he received the assistive device.
CHAPTER III
A RESEARCH PROPOSAL

Subject

An individualized mobility device was created as a senior design project by three UND mechanical engineering students in conjunction with two physical therapy students for a 40 year old male US Army Veteran. He was stationed in the Middle East working for the Army Corp of Engineers but now resides in the United States.

Methodology Proposal

The authors propose measuring change in the clients function through the use of the SF-36(tm) and ODQ functional questionnaires after the client has utilized the device. He will first complete them at the time of initiation of the project, after he received the device, six weeks post device use, and twelve weeks post device use. The ODQ will be scored by using the scoring criteria on the assessment9 and the SF-36(tm)8 assessment will be scored using the Scoring Exercise for the SF-36 Health Survey.29 Item answers in the SF-36(tm) will be rearranged to be ordered in most disabled to least disabled in each question after the assessments are completed. Depending on the amount of questions, the first item will receive a grade of 0 and go up by 1 point for each subsequent question. Scores for each scale will be summated and divided by the highest possible score. If the client selects multiple answers for a question on either of the surveys, the answer indicating more impairment will be selected to use for calculating the final score.
Since we only have one client (n=1), basic descriptive statistics will be used to analyze the data changes over time. The dependent variables will be the score on each assessment as discrete variables and the independent variable will be the use of the device. Data from both the ODQ and SF-36(tm) are ordinal data, the median will be used as the measure of central tendency, and the semi-interquartile range will be used to measure the variability. The range will be used to analyze the overall change in scores.

The client will be verbally instructed to use the device frequently as a means to decrease any episodes of intense pain.

Instrumentation

The client will be given the SF-36(tm) (see Appendix A) and the ODQ (see Appendix B) before receiving the device and again after using the device for six and twelve weeks for a total of four sets of data. SF-36 is reliable and valid in terms of responsiveness, and most responsive in categories bodily pain (BP) (Receiver Operating Characteristic (ROC)=0.773) and physical function (PF) (ROC=0.736). The SF-36(tm) consists of 36 items that measure physical function (PF), role limitations due to physical health (RP), bodily pain (BP), general health perceptions (GH), vitality (VT), social functioning (SF), role limitations due to emotional health problems (RE), mental health (MH), and one item dedicated to measuring the self reported change in health (HT). Higher scores in each scale would indicate less disability. The ODQ was found to be reliable and valid as a whole questionnaire (ROC=0.737). The ODQ consists of ten items that interprets the level of disability depending on the score which is categorized into minimal disability (0-20%), moderate disability (20-40%), severe disability (40-60%), crippled (60-80%), or bed bound (80-100%). Each question in the ODQ consists
of six answers where the first question is graded as 0 points and the sixth answer is graded as 5 points. The scores are summated and divided by 50 to indicate the disability percentage, so a higher score would indicate more disability.

The client will be instructed on donning and doffing the harness by the physical therapy students and provided with written instructions (see Appendix C). The engineering students will verbally instruct him on using the device as well as other aspects on the device mechanisms once the device complete.

Results Proposal

Following the use of the mobility device, we have reason to believe we will see a decrease in his painful symptoms as well as improvements in his functional assessment questionnaires.

With the ODQ scoring we believe he will decrease his score, which indicates decreased impairments associated with back pain, due to the device assisting him managing his symptoms. The device will help him unload his spinal column to decrease his pain intensity score as well as help him stand for longer periods of time. This will in turn allow him to improve his social life score as his wife will not have to assist him in transfers and increase his independence in recreational and occupational functioning. We also predict that he will have changes in his degree of pain due to having the device readily available when his symptoms start to occur or using the device as a preventative means of onset of pain. Activities such as traveling, personal care, and sitting may remain unchanged due to the nature of his back injury and prior traumatic events. Overall there should be a clinically significant improvement in his ODQ score twelve weeks post device use.
With the SF-36 scores we expect to see a clinically significant improvement in the total score and especially the PF, RE, RP, and VT subscales. In the PF subscale we expect improvements due to the ability to walk further, ascend more steps, and participate in more life activities if he is able to monitor his signs and symptoms of pain and use the device as needed. He will be able to use the harness to stabilize his spine during these activities to prevent onset of pain as well. We expect to see the greatest improvement in the RP subscale at the twelve week post use mark as his pain will be decreased so he is able to tolerate work. Hopefully he will rely less on the use of pain medications so his cognition is not altered or cause him to be drowsy. As discussed in the literature review, decrease in pain is associated with improvements in depression and will thus improve his RE subscale. We also expect his VT subscale to improve resulting in more zeal for life and increased energy levels. We do not expect to see much change in the other subscales.

Using the ODQ and SF-36 as objective findings we hope to analyze the functional status changes that take place when an individual uses a mobility device. The overall goals for this client are to optimize his function, decrease the severity and frequency of his debilitating days, and improve his quality of life.
CHAPTER IV

CONCLUSION

The mobility device that our client will receive will be able to meet his individual needs of his occupation. Factors such as ground clearance, tipping, the amount of charge the device can hold, safe driving speeds, device width and height for door clearance, and the ability to ride on outdoor terrain were considered when the device was designed as our clients job requires him to often be on construction sites. We proposed that through the use of the mobility device the client will show significant changes in his functional abilities through the SF-36 and ODQ assessments.

According to the Guide to Physical Therapy Practice\textsuperscript{30}, our client best fits in with pattern 4F: impaired joint mobility, motor function, muscle performance, range of motion, and reflex integrity associated with spinal disorders. The guide gives a prognosis of one to six months to gain optimal improvements in function. Within three months we expect to see improvements in his function.

There were limitations to designing the mobility device prior to the initiation our proposed study. Our client spent the duration of the design process oversees with limited availability for communication. We were able to meet with him once after the device was mostly fabricated, but he was in the process of moving multiple states away limiting our communication. We also will not be able to observe him using the device once he receives it. Since our client has an engineering background, we foresee him making
modifications himself changing our study variables. We also feel he will use the device when his pain becomes intolerable instead of the schedule use as we prescribed. We gathered one set of baseline data at the beginning of the fabrication process but due to unforeseen life circumstances further data collection was impeded thus, this study was made into a proposal.

We feel this device will meet the individual needs of the client and will be supported through objective measures once the device is utilized. We ascertain an individualized device will be more beneficial than the use of a premade generic device, however this could be costly for consumers. The majority of the devices fees were provided by the UND engineering and physical therapy department. For future senior engineer design projects, alterations to the device can be made such as improvements in car transportation or other suggestions from the client after use.
SF-36(TM) Health Survey

Instructions for completing the questionnaire: Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

Patient Name: __________________________
SSN#: ________________________ Date: __________________________
Person helping to complete this form: __________________________

1. In general, would you say your health is:
   - Excellent
   - Very good
   - Good
   - Fair
   - Poor

2. Compared to one year ago, how would you rate your health in general now?
   - Much better now than a year ago
   - Somewhat better now than a year ago
   - About the same as one year ago
   - Somewhat worse now than one year ago
   - Much worse now than one year ago

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?
   a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.
      - Yes, limited a lot.
      - Yes, limited a little.
      - No, not limited at all.
   b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?
      - Yes, limited a lot.
      - Yes, limited a little.
      - No, not limited at all.
   c. Lifting or carrying groceries?
      - Yes, limited a lot.
      - Yes, limited a little.
      - No, not limited at all.
   d. Climbing several flights of stairs.
      - Yes, limited a lot.
      - Yes, limited a little.
      - No, not limited at all.
   e. Climbing one flight of stairs.
      - Yes, limited a lot.
      - Yes, limited a little.
      - No, not limited at all.
   f. Bending, kneeling or stooping.
      - Yes, limited a lot.
      - Yes, limited a little.
      - No, not limited at all.
g. Walking more than one mile.
   ☐ Yes, limited a lot.
   ☐ Yes, limited a little.
   ☐ No, not limited at all.

h. Walking several blocks.
   ☐ Yes, limited a lot.
   ☐ Yes, limited a little.
   ☐ No, not limited at all.

i. Walking one block.
   ☐ Yes, limited a lot.
   ☐ Yes, limited a little.
   ☐ No, not limited at all.

j. Bathing or dressing yourself.
   ☐ Yes, limited a lot.
   ☐ Yes, limited a little.
   ☐ No, not limited at all.

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?
   a. Cut down the amount of time you spent on work or other activities?
      ☐ Yes ☐ No
   b. Accomplished less than you would like?
      ☐ Yes ☐ No
   c. Were limited in the kind of work or other activities?
      ☐ Yes ☐ No
   d. Had difficulty performing the work or other activities (for example, it took extra time)
      ☐ Yes ☐ No

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?
   a. Cut down the amount of time you spent on work or other activities?
      ☐ Yes ☐ No
   b. Accomplished less than you would like?
      ☐ Yes ☐ No
   c. Didn't do work or other activities as carefully as usual?
      ☐ Yes ☐ No

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
   ☐ Not at all
   ☐ Slightly
   ☐ Moderately
   ☐ Quite a bit
   ☐ Extremely

7. How much bodily pain have you had during the past 4 weeks?
   ☐ Not at all
   ☐ Slightly
   ☐ Moderately
   ☐ Quite a bit
   ☐ Extremely
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- Not at all
- Slightly
- Moderately
- Quite a bit
- Extremely

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

a. did you feel full of pep?
   - All of the time
   - Most of the time
   - A good bit of the time
   - Some of the time
   - A little of the time
   - None of the time

b. have you been a very nervous person?
   - All of the time
   - Most of the time
   - A good bit of the time
   - Some of the time
   - A little of the time
   - None of the time

c. have you felt so down in the dumps nothing could cheer you up?
   - All of the time
   - Most of the time
   - A good bit of the time
   - Some of the time
   - A little of the time
   - None of the time

d. have you felt calm and peaceful?
   - All of the time
   - Most of the time
   - A good bit of the time
   - Some of the time
   - A little of the time
   - None of the time

e. did you have a lot of energy?
   - All of the time
   - Most of the time
   - A good bit of the time
   - Some of the time
   - A little of the time
   - None of the time

f. have you felt downhearted and blue?
   - All of the time
   - Most of the time
   - A good bit of the time
   - Some of the time
   - A little of the time
   - None of the time
g. did you feel worn out?
   - All of the time
   - Most of the time
   - A good bit of the time
   - Some of the time
   - A little of the time
   - None of the time

h. have you been a happy person?
   - All of the time
   - Most of the time
   - A good bit of the time
   - Some of the time
   - A little of the time
   - None of the time

i. did you feel tired?
   - All of the time
   - Most of the time
   - A good bit of the time
   - Some of the time
   - A little of the time
   - None of the time

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?
   - All of the time
   - Most of the time
   - Some of the time
   - A little of the time
   - None of the time

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

   a. I seem to get sick a little easier than other people
      - Definitely true
      - Mostly true
      - Don't know
      - Mostly false
      - Definitely false

   b. I am as healthy as anybody I know
      - Definitely true
      - Mostly true
      - Don't know
      - Mostly false
      - Definitely false

   c. I expect my health to get worse
      - Definitely true
      - Mostly true
      - Don't know
      - Mostly false
      - Definitely false

   d. My health is excellent
      - Definitely true
      - Mostly true
      - Don't know
      - Mostly false
      - Definitely false
Appendix B
The Revised Oswestry Disability Index (for low back pain/dysfunction)

Patient name: ____________________________ Date: ____________________________

This questionnaire has been designed to give the doctor information as to how your back pain has affected your ability to manage everyday life. Please answer every section and mark in each section only the ONE box that applies to you. We realize that you may consider that two of the statements in any one section relate to you, but please just mark the box that most closely describes your problem.

SECTION 1-PAIN INTENSITY

☐ The pain comes and goes and is very mild.
☐ The pain is mild and does not vary much.
☐ The pain comes and goes and is moderate.
☐ The pain is moderate and does not vary much.
☐ The pain comes and goes and is very severe.
☐ The pain is severe and does not vary much.

SECTION 2-PERSONAL CARE

☐ I would not change my way of washing or dressing in order to avoid pain.
☐ I do not normally change my way of washing or dressing even though it causes some pain.
☐ Washing and dressing increases the pain, but I manage not to change my way of doing it.
☐ Washing and dressing increases the pain and I find it necessary to change my way of doing it.
☐ Because of the pain, I am unable to do some washing and dressing without help.
☐ Because of the pain, I am unable to do any washing and dressing without help.

SECTION 3-LIFTING

☐ I can lift heavy weights without extra pain.
☐ I can lift heavy weights, but it causes some pain.
☐ Pain prevents me from lifting heavy weights off the floor, but I manage if they are conveniently positioned (e.g., on a table).
☐ Pain prevents me from lifting heavy weights off the floor.
☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
☐ I can only lift very light weights at the most.

SECTION 4-WALKING

☐ I have no pain on walking.
☐ I have some pain on walking, but it does not increase with distance.
☐ I cannot walk more than one mile without increasing pain.
☐ I cannot walk more than 1/2 mile without increasing pain.
☐ I cannot walk at all without increasing pain.

SECTION 5-SITTING

☐ I can sit in my chair as long as I like.
☐ I can only sit in my favorite chair as long as I like.
☐ Pain prevents me from sitting more than one hour.
☐ Pain prevents me from sitting more than 1/2 hour.
☐ Pain prevents me from sitting more than 10 minutes.
☐ I avoid sitting because it increases pain right away.

SECTION 6-STANDING

☐ I can stand as long as I want without pain.
☐ I have some pain on standing, but it does not increase with time.
☐ I cannot stand for longer than one hour without increasing pain.
☐ I cannot stand for longer than 1/2 hour without increasing pain.
☐ I cannot stand for longer than 10 minutes without increasing pain.
☐ I avoid standing because it increases the pain right away.

SECTION 7-SLEEPING

☐ I get no pain in bed.
☐ I get pain in bed, but it does not prevent me from sleeping well.
☐ Because of pain, my normal night's sleep is reduced by less than 1/4.
☐ Because of pain, my normal night's sleep is reduced by less than 1/2.
☐ Because of pain, my normal night's sleep is reduced by less than 3/4.
☐ Pain prevents me from sleeping at all.

SECTION 8-SOCIAL LIFE

☐ My social life is normal and gives me no pain.
☐ My social life is normal, but increases the degree of pain.
☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g., dancing, etc.
☐ Pain has restricted my social life and I do not go out very often.
☐ Pain has restricted my social life to my house.
☐ I have hardly any social life because of the pain.

SECTION 9-TRAVELLING

☐ I get no pain while travelling.
☐ I get some pain while travelling, but none of my usual forms of travel makes it any worse.
☐ I get severe pain while travelling which compels me to seek alternative forms of travel.
☐ Pain restricts all forms of travel.
☐ Pain prevents all forms of travel except that done by lying down.

SECTION 10-CHANGING DEGREE OF PAIN

☐ My pain is rapidly getting better.
☐ My pain fluctuates, but is definitely getting better.
☐ My pain seems to be getting better, but improvement is slow at present.
☐ My pain is rapidly getting worse.
☐ My pain is gradually worsening.
☐ My pain is steadily worsening.
Instructions:
1. This is a self-report questionnaire: the patient is instructed to fill it out.
2. The patient follows the general instructions given at the top of the questionnaire.
3. Each section must be completed. If the patient leaves one blank, instruct them to complete the form. It must be completed in one sitting.
4. Each section has 6 possible answers. Statement 1 is graded as 0 points; statement 6 is graded as 5 points. A total score of 30 is thus possible and would indicate 100% disability. So, for example, a total score of 18 of a possible 30 would constitute a 60% disability.
5. The following interpretation of disability scores is excerpted from the developers of the Oswestry system (657):

0%-20%: Minimal disability
This group can cope with most living activities. Usually no treatment is indicated, apart from advice on lifting, sitting posture, physical fitness, and diet. In this group some patients have particular difficulty with rising, and this may be important if their occupation is sedentary, e.g., a typist or lorry (truck) driver.

20%-40%: Moderate disability
This group experiences more pain and problems with rising, lifting, and bending. Travel and social life are more difficult and they may well be off work. Personal care, sexual activity*, and sleeping are not greatly affected, and the back condition can usually be managed by conservative means.

40%-60%: Severe disability
Pain remains the main problem in this group of patients, but travel, personal care, sexual activity*, and sleeping are also affected. These patients require detailed investigation.

60%-80%: Crippled
Back pain impinges on all aspects of these patients' lives—both at home and at work—and positive intervention is required.

80%-100%: These patients are either bed-bound or exaggerating their symptoms. This can be evaluated by careful observation of the patient during medical examination.

6. It is recommended that clinicians focus their discussions of the results with patients in positive terms, rather than reporting disability scores. For example, point out the 10% improvement on a subsequent test.

* Note: in the revised Oswestry, sex life questions were replaced with recreation questions.
Appendix C
Donning the Mags Suspension Vest 695-SHBD Harness

CAUTION:
Inspect the harness prior to use. Do not use if harness straps are torn, if there is separation in the harness stitching, or if the Velcro is unable to adhere.
Make sure you are in a stable environment and on level surface.
It is important to stand with tall upright posture while securing harness straps.

1. Detach all Velcro attachments to open the vest (avoid letting Velcro attach to clothing).

2. Put your arms through the shoulder straps to put on the vest. The open side of the vest will face the front and the green mesh will be on the back.
3. Locate your pointy hip bones on the front of your pelvis. Place the top lower abdominal support strap directly below the bony points. Secure the Velcro strap as tight as you can tolerate (the stretchy straps on the sides should be loose right now).

4. Attach middle abdominal netting Velcro attachment next.
5. Attach the top abdominal strap by looping the strap through the cinch loop on the top left and secure the Velcro it back on itself.

6. Wrap the leg supports around the upper thigh and secure the straps tightly (prevents the whole harness from moving upward), if unable to do so have someone help so bending the torso is not required.
7. Tighten side stretchy straps on lower abdominal support next.

8. The 1" side vertical straps can be adjusted to allow shortening of the harness for the torso if necessary. Adjust the side vertical straps attached to the leg supports if needed. Adjust shoulder straps to comfort level.

9. If harness does not fit correctly repeat above steps before attaching to the unweighting device.
Removing the MAGS Suspension Vest 695-SHBD Harness

1. Release tension in shoulder straps from the lifting device.

2. Unbuckle from unweighting device

3. Remove Velcro attachments from stretchy side abdominal straps, top abdominal strap, middle netting abdominal strap, lower abdominal strap, and lastly the leg straps and step out.

If further help is required with the harness, contact the UND Physical Therapy Department

(701) 777-2831
UND SMHS Room 1510
501 N Columbia Road Stop 9037
Grand Forks ND 58202-9037

Cindy Flom-Meland, PT, PhD, NCS
Jessica Jones, SPT
Robert Whittaker, SPT
Medical Device Team

ME 487 Fall 2013

Ryan Hake
Tyler Bradley
Tyler Voegle
5/5/2014
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Executive Summary

This report details the summarized design objectives, constraints, experiments and testing, engineering analysis, and marketing and economic analysis for our team's medical device. The objective of our senior design team is to create a custom mobility device for [redacted].

The device has the ability to help our client get from a laying position on the floor and into a standing position. It also can transition from a traditional powered wheelchair into a standing powered chair. Finally, a traction device to ease the weight on [redacted] back. Our two largest constraints were that the device needs to be able to traverse a construction job site and that it need to be as inconspicuous as possible. We did testing of the rolling resistance of the device on different surfaces as well as tested the coefficient of friction for the drive tires on the same surfaces. For our engineering analysis we focused on the possibility of the device tipping while going up ramps and inclines and analysis on a few key components. We looked at tipping forward, backward, and sideways. We went over budget due to a misunderstanding of what our budget total was.
Introduction

Project Team

Tyler Voegele

I am originally from Minnesota, about 20 miles west of Minneapolis. My family moved to North Dakota about twelve years ago. I originally attended the College of St. Benedict & St. John’s University, a private college near St. Cloud MN, for a year as a physics major. I then transferred to North Dakota State University to pursue mechanical engineering. I stayed there for three semesters before transferring to the University of North Dakota also as a mechanical engineering major. I intend to graduate in May 2014.

I have experience working with welding equipment, manual milling machines, and manual lathes from my help at my father’s company Machine Design and Engineering. I also have undergraduate research experience working with Dr. Forrest Ames on turbine vane film cooling. I worked for 8 months taking and interpreting data and doing Infrared imaging of surfaces in wind tunnels. While working for Dr. Ames I had a number of small design and fabrication projects. I also am the current secretary of Tau Beta Pi, the only engineering honor society on campus, and I am involved in an on campus organization called VESTS [Volunteer Engineering Students]. When I graduate I hope to go to graduate school for product design.

Ryan Hake

I’ve bounced around to a couple schools until finally getting UND where I will be able to finish my degree, but I have no significant education experiences. My electives so far have been Gas Turbines, Intro to FEA, and Systems Dynamics and Control.

My work experience is possibly what I bring to the table, I’ve been in the US Air Force and my day to day duties include supervising a fabrication shop. My shop is responsible for manufacturing and repairing the structure of a squadron of 28 F-16’s. We also make parts for the aircraft’s ground support equipment. The unit is an almost fully equipped fabrication facility we have 5-axis milling centers, CNC lathes and Knee Mills. Welding equipment varying from SMAW, GMAW and GTAW. Heat treating ovens, sheetmetal brakes and other tools. Two paint booths one vehicle sized for smaller parts up to fuel tanks and some of the ground support equipment, and one larger paint booth that can fit one F-16 in it, or when we had them one A-10 if we pulled the wings off. Etc... etc...

This is my current position I also worked for the F-16 heavy repair depot facility (Ogden Air Logistics Center) at Hill AFB in Utah for five years. In that job we did crash/battle damage repair (aircraft with shrapnel holes in them or that had crashed but were repairable over the course of
1-5 years), and worked on some of the depot repair or modification assembly lines. I worked closely with the Air Forces structural design engineers in that job.

Tyler Bradley

I also have a 2 year liberal arts degree from Normandale Community College.

I started college in Minnesota at Normandale Community College and transferred to UNO to finish my major in Mechanical Engineering. The electives I have taken so far are Thermodynamics II and Composite materials.

This past summer I worked at an engineering consultant company called AAC Engineering. They specialize in airplane engineering and tech writing. I was the start of their research and development department. They had me research possible business endeavors. I also was in charge of their new 3D printer so I used SolidWorks to make prototypes and discovered what the machine was capable of. I also worked with electronics quite a bit. Using microcontrollers like the arduino and raspberry pi I made a slew of sensors, buzzers, displays, controls, and more.

Robert Whittaker

I have a B.S. Kinesiology and Health Promotion from University of Wyoming.

I completed 120 hour internship in outpatient physical therapy and took part in research experience in Perceptual-Motor Behavior Lab.

I taught supplemental instructions for General Physics I & II.

I have a general understanding of physics to aid in understanding some of the project design as well as some experience in research. I gained a general understanding of health promotion and human movement.

I am anticipating a Doctor of Physical Therapy degree in 5/2015 from University of North Dakota.

I completed my 1st clinical set August-October 2013 in acute care setting, currently doing clinical set in out patient from October-December.

I am gaining experience in the anatomy of the human body and how to evaluate injuries, understand how modalities/devices impact injuries/anatomy, and understanding of human movements. This will help me in providing feedback on what may/may not be appropriate for our client in terms of pain producing/eliminating.
Jessica Jones

I received a BS, Biology: Minor, Chemistry from University of Colorado at Colorado Springs.

I am working towards my DPT from University of North Dakota.

Clinical #1 August-October Avera Medical Clinic: Brookings; South Dakota Outpatient setting

Clinical #2 October-December Spearfish Regional Rehabilitation: Spearfish; South Dakota

During my first clinical affiliation I had the privilege of working with a very special lady that had Cuada Equina surgery. This experience has helped me understand some of the impairments associated with spinal cord injuries. I have been able to see the progression of therapeutic exercises.

At my second clinical I have been in the acute setting where I get to see patients using adaptive equipment more. I have been able to help a gentleman adapt his wheelchair to accommodate his different guidelines set by his surgeon and yet still fit him.

Background

Need for Project

[Patient] was injured on his job site. This left his back permanently injured. The bottom 3 vertebrae of his spinal cord were fused together. Normally can live a regular life getting around in his own. Some Days however he is barely mobile due to the pain he experiences. He is unable to stand up off the ground by himself. Getting around in this state is also quite hard. Our task was to create a mobility device similar to a wheelchair, but [Patient] will be standing in the device. The device also needs to be able to get[Patient] off of the floor with minimal pain.

Previous Work

This is the first time students have worked for [Patient] on this device. In the past [Patient] has tried physical therapy and it has been unsuccessful.

Design Constraints

The device needs to be compact, fit through doorways and indoor friendly. The device must also be outdoor friendly. The device also needs to be low enough to keep the center of gravity low to prevent tipping, but also give a high ground clearance to get around outdoors due to [Patient]'s profession being a civil engineer. The device needs to as visually simple and aesthetic as possible. The device needs to be able to run for a 8+ hour work day.
Relevant Literary Research
Other companies have made stand up wheelchairs before. Our group has learned a lot from researching other companies and what they have found to work. We have also used online resources to find information on center of gravity, battery power to wheel torque, wheelchair wheel research, harnesses to keep in the device.

Summarized Results

Status
We completed the product. We finished the vertical lift to help get from the ground into the device, the sit to stand mechanism to aid into a vertical position. We also added the unweighting/traction device to take a small amount of weight off of the back of.

Recommendations
Recommended use is for indoor and outdoor use. Avoid steep inclines or declines, due to this being a standing device it is subject to the possibility of tipping although we designed it to not tip in most scenarios. Use in heavy rain is strongly discouraged. This device was not made to be waterproof. Rainwater could cause a short in the electrical system possibly causing injury.

Our team assigned tasks each week to research one or more portions of the device. Each week we understood more and more of what decisions we need to make and the information required for those decisions. We weighed options based on cost, weight, energy output, efficiency, and visual aesthetics.

Marketing/Economic Analysis

Economic
Enclosed below is a Bill of Materials for our device. The items in yellow have been donated to our team reducing the total cost to $530.85 at this time. Our total budget for this project is $2K and we still have not accounted for some small miscellaneous items that we did not feel necessary to document, as well as some shipping costs.
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<td>PRO-TEC Powder Coating</td>
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</table>
There are multiple companies that make wheelchairs designed to move from a sitting or lying position to a standing position. Such as the PW-660ST three position wheelchair available from wheelchair88.com for $4K [1]. Our device is strictly a prototype not suitable for mass production but our current parts costs would put us competitive with this existing wheelchair. Our design is unique because of the device for getting the customer from a lying on the ground position to a standing position, mimicking his current method with his wife.

**Annual Production Rates**

Our device is a one of a kind prototype being fabricated to serve a particular customer’s needs. We are not designing for an annual production rate beyond the initial device.

**Project Description**

**Major Groups/Systems**

Our device will have 4 major subassemblies to include.

1. Base
2. Lifting System
3. Sit-To-Stand System
4. Traction System

---

**Unweighting Hardware**

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
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<th>Price 2</th>
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<td>Lifting Motor</td>
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<td>1</td>
<td>050ASA010R-36 Steinger.com</td>
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---

*Donated*
Assembly and Components

Function/purpose

The primary function of the base shall be to hold the wheels and motors that will propel the device. The base also serves to hold miscellaneous parts such as the controller and batteries, and allows a point to mount our other devices.

The lifting system will be a pillar attached over one of the front caster wheels enclosing an acme screw jack. This device will be powered by a small dc motor that when the screw is turned will raise a padded metal bar that the customer will hold onto and use to raise himself to a standing position. When not needed the pillar will fold down along the side of the device.

The sit-to-stand system shall be a wheelchair style seat powered by a smaller screw jack. When the seat part is lifted up the backrest will stay in line allowing a method to transition from sitting to standing while under power.

The traction system will be a cable system attached to the backrest that will pull the customers shoulders up relieving pressure off his lower back.

Fabrication

A current powered wheelchair base has been donated to us but it is designed for children and required modification before we were able to use it. The frame was cut and new sections were welded in to make it wider and longer. Second we installed larger drive wheels and casters as well as making new mounts to rotate the motors up giving us more ground clearance.

The lifting system was manufactured and assembled in Germany then shipped to North Dakota. Fabrication primarily involved TIG welding 6061-T6 aluminum plate together, and some use of a HAAS CNC Milling center. We also made use of a water jet to cut out some of the individual parts before welding together, and for making the sprockets.

The sit-to-stand system has a frame made from square steel tubing cut to length and bolted together with the hinges. The padding for seat and backrest were made from a wood backing with foam and a vinyl cover stapled on it.

The traction system was made our of 2"x2" aluminum square tubing. It was cut and welded to allow access to the strap inside. The straps were sewn onto the springs and hooks using a sewing machine.
Engineering Analysis

Structural Analysis

Tipping

This is the possibility of our client tipping forwards, backwards, or sideways. The structure is going to be made out of steel and there is little worry it will support our client without fail. The electronic components should also not have issue since we have space for very large batteries in the base. Our results for the tipping calculations are summarized below.

Wheelbase (length) 29 in (center-to-center)

Wheel track (width) 26 in (center of tire to center of tire)

CG when sitting is 20 in back from center of front tires centered left to right and 33.4 in from the ground.

CG when standing is 4.4 in back from center of front tires centered left to right and 64 in from ground.

For seated sideways tipping

Using the law of sines 
\[
\sin(\theta) = \frac{13}{35.8}
\]

\[\theta = 21.3^\circ\]

Using the same equations for other tipping scenarios.

Tipping forward while sitting \[\theta = 30.9^\circ\]

Tipping backwards while sitting \[\theta = 15.11^\circ\]

Tipping to the side while standing \[\theta = 11.5^\circ\]
Tipping forward while standing $\Theta = 3.93$

Tipping backwards while standing $\Theta = 21.0$

**Overhead Shaft Design**

The shaft is the part of the traction system that goes above the patient's head and is used to take off a small amount of weight from his back. The harness connects to the shaft and transfers his weight more comfortably. The physical therapy students helped us design this portion of the project.

Each shaft needed to only support about 10 lbs. as our patient was most comfortable when 20 lbs. total was relieved from him (10 lbs. per shaft). However, we also wanted to account for user error and extreme situations where our patient might supply a much larger amount of weight to the device.

From figure 1 and 2, we can see that the design is more than able to hold our patient's full weight. The test was done using the original 10 lb load and you can see it has a safety factor of more than 10.
Figure 1: Fixtures and Loads
The weak point on the 2"x2" aluminum tube is right where the strap is hanging down and supporting our patient.
**Sprocket Choice**

Available diameter for sprocket and chain is 2.92", Chose to use approx. 1.75" diameter sprockets. Chain spacing is 0.300", $1.75\times\pi/3=18.3260$ so will go with a 19 tooth sprocket. Sprocket outer diameter will be $19\times3/\pi=1.8144"$, with an ID of 1.5844".

**Screw Shaft Verification**

A 0.500" diameter by 0.100" pitch acme threaded screw shaft (figure 2) is chosen for purchase price and ease of manufacture with other components. We must verify the lift bar will not lower if something breaks from the control motor. Also the screw shaft must withstand the moment from the lift bar without binding up. A safety factor of 3 is used.

![Figure 2: Threaded Shaft](image_url)
To ensure the screw shaft is self-locking we use the equation

\[ T = \frac{F \times d_m}{2} \times \tan(\phi - \lambda) \]

\(d_m\) is the mean diameter
\(\phi\) is the angle of friction
\(\lambda\) is the lead angle

The screw shaft will be self-locking if the angle of friction is greater than the lead angle. Or \(\mu d_m > \angle 0.11 \times \pi \times 0.4306 = 0.1488\). With the pitch being 0.100" on this screw it will be self-locking and this verifies we could now have used the other option of a 0.250" lead.

**Stress on Mounting Point**

Applying a maximum moment of 4200 in-lb to the lifting device after a safety factor of 3 would result in a 1468.5 lbf force on the aft pin spread through three walls of the shaft housing and lower bearing support. The thinnest wall the pin passes through is 0.100" this would give a shear stress on that part of the support of 498.5 lbf / 0.025 in² = 19580 psi. This is well below the yield strength of 6061-T6 aluminum of 40ksi.

For other hand calculations see scanned images in appendix.

**Experimental Procedures and Testing**

**Experimental Setup**

We did our testing for our device during one of our other classes ME 483 Mechanical Measurements. For testing of our device we had two separate but related objectives.

- Find the rolling resistance of the cart with the approximate total weight. This will allow us to find the force needed to drive the cart. From this we will be able to accurately size the required battery.
- Find the static coefficient of friction of one of the drive tires on several different surfaces. This will allow us to prove that the cart will have enough force to overcome the rolling resistance and to start moving on different surfaces.

For the experiment, the following equipment was used:

1. Base Cart
2. Wheel
3. Wheel Mounting Fixture
First, we obtained all the necessary equipment as listed above. After obtaining all the necessary equipment we were able to start our experiment. We had to do a total of 6 tests; this included a test on tile, carpet, and in the sand pit for both setups. Our setups that we used were the base cart which can be seen in Figure 1 and Wheel with the Wheel Mounting Fixture which can be seen in Figure 2. When running the tests we had weight set on top of the fixtures which can be seen in Figure 3, this allowed us to test the rolling resistance and the coefficient of friction.

Figure 3: Base Cart
For each test we conducted the experiment 5 times, we did this to have a significant data set. Our first test that we did was the base cart on tile, this test we had to complete a few extra times to get our procedure exact. Our results from this test can be seen in the Experimental
Results: portion of this paper. The next test we did was the wheel with mounting fixture on tile; again results can be seen in the next portion. Following the tile tests, we moved to carpet, where we did our tests for both fixtures. The carpet the values were a lot higher than the values on the tile, this was expected. After the carpet tests, we went on a journey to the sand pit. We then conducted the experiments in the sand pit. We were able to conduct the wheel with mounting fixture in the sand pit and acquire the data expected. We were unable to conduct this test for the base cart, as it would not move in the sand pit.

Experimental Results

Results and Discussion

For this experiment we had two different measurements, the rolling resistance of the base cart while fully loaded and the coefficient of friction for a single tire loaded with a 4th of the weight of the cart. The rolling resistance measurements were used to calculate the minimum number of Amp-hours needed in a battery to drive the device. The coefficient of friction measurements were used to ensure there device will have enough driving force to overcome the rolling resistance.

To find the total power needed to drive the device we have to consider the power it takes to power the motors in addition to the losses of rolling resistance. The device is going to be powered by two 250 W motors, and we are going to assume eight hours of needed operation for an average workday. The rolling resistance was measured for two of the three different conditions: the cart on tile, carpet, and in sand. Unfortunately the sand we had access to was approximately three inches deep, and with the cart fully loaded we were unable to get the cart to move with a constant velocity. Therefore we have no data for the rolling resistance in deep sand. The following Table 1 shows the rolling resistance measured for the tile and carpet with five different trials for each. The cart was loaded with 401 lb to simulate being fully loaded with a full grown man, steel frame support structure, and batteries.

Table 1: The force needed to pull the fully loaded cart at a constant velocity of 3 mph (average walking speed).

<table>
<thead>
<tr>
<th>Trial</th>
<th>Cart on Tile (lb)</th>
<th>Cart on Carpet (lb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>13.8</td>
<td>12.6</td>
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<tr>
<td>2</td>
<td>12.8</td>
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<td>5</td>
<td>11.6</td>
<td>14.6</td>
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The average for the cart on tile is 12.2 lb, and the average for the cart on carpet is 13.2 lb. The batteries that will be used are assumed to be the 24V batteries and we are looking to find the number of Amp-hours needed for operation. Equation 3 shows how we will calculate the Amp-hours needed in the battery.

\[
\text{Force} \times \text{velocity} \times \text{hours of operation} + \text{Watts} \times \text{hours of operation} = 24V \times \text{Amp} \times \text{hours}
\]  

(3)

This equation needs consistent units so we need to convert the rolling resistance force from lbs to Newtons and the velocity from mph to meters per second. This gives a force for the cart on tile of 54.3 N and a force for the cart on carpet of 58.7 N and a velocity of 1.34 m/s. Putting these numbers into the above Equation 3 we get the following Equations 4 and 5.

\[
54.3 \text{ N} \times 1.34 \frac{\text{m}}{\text{s}} \times \text{6 hr} + 250 \text{ W} \times \text{6 hr} = 24 \text{ V} \times \text{Amp} \times \text{hours}
\]  

(4)

\[
58.7 \text{ N} \times 1.34 \frac{\text{m}}{\text{s}} \times \text{6 hr} + 250 \text{ W} \times \text{6 hr} = 24 \text{ V} \times \text{Amp} \times \text{hours}
\]  

(5)

This gives a needed Amp-hour rating of 107.6 A·hr for the cart on tile and 109.6 A·hr for the cart on carpet. Taking the larger of the two because we are looking for a minimum needed value we can assume we need a battery with at least 110 A·hr just to drive the device.

To calculate the coefficient of friction, we need to start with a free body diagram of the wheel. This is shown in Figure 4.

---

**Figure 6:** This is a FBD showing the applied force, weight load, normal force, and frictional force acting on the tire.
To find the coefficient of friction we need to sum the force in the X and Y directions which can be seen in Equations 7 and 8 below.

\[ \sum F_x = F_{ext} - F_f = ma \]  
\[ \sum F_y = F_n - W = 0 \]

Because we took our measurements right when the tire was starting to slip, we are going to assume that the acceleration in the X-direction is also zero. This allows us to set the frictional force equal to the normal force times the coefficient of friction which can be seen in Equation 8.

\[ F_{ext} - \mu F_n = 0 \]

The external force is what we measured in lab and is summarized for the wheel on tile, carpet, and sand in Table 2. The normal force is equal to the applied weight which was 115 lb.

<table>
<thead>
<tr>
<th>Trial</th>
<th>Wheel on Carpet (lb)</th>
<th>Wheel on Tile (lb)</th>
<th>Wheel on Sand (lb)</th>
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<td>1</td>
<td>180</td>
<td>132</td>
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<td>2</td>
<td>187</td>
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<tr>
<td>5</td>
<td>187</td>
<td>129</td>
<td>71</td>
</tr>
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</table>

The average value for the external force of the wheel on carpet is 185 lb; the average value of the wheel on tile is 130 lb; and the average value of the wheel on sand is 69 lb. These values make sense intuitively because one would expect it to be more difficult to push a rubber tire across carpet with no rolling than pushing the same tire across a tile floor or through lose sand.

Plugging the weight and external force into Equation 8 gives the following results for the coefficient friction:

Carpet = 1.61
Tile = 1.13
Sand = 0.60

This is also why it is more difficult to get traction in lose sand. The coefficient of friction between the tires and the sand is very low which doesn’t provide the needed force to move.
This also explains the difficulty we had in getting the loaded cart to move with a constant velocity in the sand. We simply did not have enough friction between the tires and the sand to move the cart.

These numbers also show that we have enough force to overcome the rolling resistance we measured earlier. With a fully loaded cart we will have more than enough force provided by the wheels to move the cart on tile and carpet with ease. It is also of note that we did not use a fully inflated tire for this test. This testing is being done for a medical mobility device and these generally do not use fully inflated tires because the ride is more comfortable for the passenger with "soft" tires.

Error Analysis

There are two experimental uncertainties that we can quantify, bias and precision. Bias (or systematic) error is classified as calibration error, recurring human error, error caused by defective equipment, and the limitation of system resolution. A Precision error is classified as error caused by disturbances to the equipment. Illegitimate error can't be quantified. Illegitimate errors are blunders and mistakes made during an experiment.

For the rolling resistance measurements, we wanted to find the Amp-hours need to power the cart on different surfaces. The surfaces were; tile, carpet, and sand. Table 3 shows the precision uncertainty of the cart on the different surfaces. Equations 9 through 11 were used to calculate the precision error with a 95% confidence level. "n" is the number of samples and "t" is from the Student's t-distribution tables.

\[ w_p = \frac{s_p}{\sqrt{n}} \]  
\[ x_m = \frac{1}{n} \sum_{i=1}^{n} x_i \]  
\[ \sigma = \left[ \frac{1}{n-1} \sum_{i=1}^{n} (x_i - x_m)^2 \right]^{1/2} \]
The tests on carpet had a higher arithmetic mean than the tests on the tile. This makes sense because more force was required to move the cart on carpet than tile. On tile the cart had a precision error of 2.935% and on carpet the cart had a precision error of 1.781%. One way to reduce the precision error is to collect more samples. With more samples, the Student’s t-distribution (t) will be less and therefore have a smaller error.

To find the Bias Uncertainty, we used the Uncertainty for Product Function. Table 4 shows the variables used to calculate the bias uncertainty. Equation 12 was used to find the bias uncertainty.

$$ \delta \equiv \left( \frac{\partial W}{\partial X_1} \right)^2 + \left( \frac{\partial W}{\partial X_2} \right)^2 + \ldots + \left( \frac{\partial W}{\partial X_n} \right)^2 \right)^{1/2} \quad (12) $$

Table 4: Bias Uncertainties for required Amp-hours

<table>
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<tr>
<th>Tile</th>
<th>Carpet</th>
</tr>
</thead>
<tbody>
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<td>X1 (Force)</td>
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<td>A1</td>
<td>1</td>
</tr>
<tr>
<td>W1</td>
<td>.89 N</td>
</tr>
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<td>X2 (Velocity)</td>
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</tr>
<tr>
<td>W2</td>
<td>.13 m/s</td>
</tr>
</tbody>
</table>

We calculated the bias error for tile to be 9.34% and for the carpet to be 9.82%. We were not able to collect data for the cart in sand. We tried to push the cart, but we were not able to keep the cart moving a constant velocity. In sand, we would have considered surface...
conditions as an error. This is because the sand was not the same throughout the testing site. The sand pit had different depths of sand and rocks.

To quantify the total uncertainty of a measurement, we need to include both precision and bias uncertainties. Equation 13 is used to calculate the total uncertainty. The total uncertainty for tile is 10.27% and 9.98% for carpet. This means our value for the required Amp-hours for the tile is 107.6 Amp-hours $\pm$ 10.27% or 107.6 $\pm$ 11.05 Amp-hours. The value for the carpet can be reported as 109.6 Amp-hours $\pm$ 9.98% or 109.6 $\pm$ 10.94 Amp-hours.

We also wanted to find the coefficient of friction of one of the drive wheels on different surfaces. The surfaces included; tile, carpet, and sand. Table 5 shows the precision uncertainty for the wheel on the different surfaces. Equations 9 through 11 and a 95% confidence level were used.

$$\frac{\mu}{\sigma} = \left(\frac{\mu}{P} \right)^2 + \left(\frac{\sigma}{P} \right)^2 \right)^{1/2}$$

(13)

### Table 5: Precision Uncertainties of the coefficient of friction

| Total | Coefficient of Friction | Arithmetic Mean (\mu) | Standard Deviation (\sigma) | Number of Samples (N) | W|C|O|F | W|C|O|F |
|-------|-------------------------|-----------------------|----------------------------|-----------------------|--------|--------|--------|
| Tile  | 0.14                   | 0.145                 | 0.12                       | 2                     | 29.09% | 29.09% | 29.09% |
| Carpet| 0.13                   | 0.135                 | 0.11                       | 2                     | 28.2%  | 28.2%  | 28.2%  |
| Sand  | 0.12                   | 0.125                 | 0.10                       | 2                     | 27.4%  | 27.4%  | 27.4%  |

Carpet had the highest average coefficient of friction while sand had the least. This makes sense because more force was required on carpet than tile and sand. For tile the precision error is 2.378%, 2.181% for carpet, and 4.501% for sand. A way to reduce the precision error is to take more samples.
To find the Bias Uncertainty, we used the Uncertainty for Product Function. Table 6 shows the variables used to calculate the bias uncertainty. Equation 12 was used to find the bias uncertainty.

<table>
<thead>
<tr>
<th>Tile</th>
<th>Carpet</th>
<th>Sand</th>
</tr>
</thead>
<tbody>
<tr>
<td>X1 (Fext)</td>
<td>130</td>
<td>X1 (Fext)</td>
</tr>
<tr>
<td>A1</td>
<td>1</td>
<td>A1</td>
</tr>
<tr>
<td>W1</td>
<td>0.2</td>
<td>W1</td>
</tr>
<tr>
<td>X2 (Fb)</td>
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<td>X2 (Fb)</td>
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</tr>
<tr>
<td>W2</td>
<td>0.5</td>
<td>W2</td>
</tr>
</tbody>
</table>

We calculated the bias uncertainty for tile to be .46%, .45% for carpet, and .52% for sand. There could have been an illegitimate error when gathering data in the sand pit. After each trial, we resurfaced the sand to try to get the most similar conditions possible. However, the surface conditions in the sand pit were not the same for every trial. An illegitimate error is not able to be quantified.

To quantify the total uncertainty of a measurement, we need to include both precision and bias uncertainties. Equation 13 is used to calculate the total uncertainty. The total uncertainty for tile is 2.42%, 2.23% for carpet, and 4.53% for sand. This means that our value for the coefficient of friction between the wheel and the tile is 1.13 +/- 2.42% or 1.13 +/- 0.027. The value for the coefficient of friction between the wheel and carpet can be reported as 1.61 +/- 2.23% or 1.61 +/- 0.036. The value of the coefficient of friction between the tire and sand is 0.60 +/- 4.53% or 0.60 +/- 0.027.

**Product Operations**

**Operating Procedures**

This device is recommended for eight hours of use a day with being fully charged again overnight. A general rule for batteries is to not run them lower than 50% power. This increases their working life.

This device is also not recommended for use above speeds of six mph as recommended by the Federal Drug Administration (FDA) [2]. The estimates for battery life seen in the previous Experimental Results sections assumes an average walking speed of 3 mph for the daily eight hours of use.
Scheduled Maintenance

Other than trying to avoid letting the batteries drop below 50% power before recharging this device should need little extra care and maintenance. The cushions are covered in material which is easy to wipe clean, and the steel will be coated so rust will not be an issue. All motors and linear actuators can be replaced if they wear out or break unexpectedly. The controls system is also self-contained and should not need any maintenance.

Disposal/Recycling

The batteries should be recycled according to the manufacture's recommendations. All of the steel can be recycled at a scrap metal collection site. The cushions, motors, actuators, and controls most likely cannot be recycled. The wiring may be able to be recycled if the plastic is stripped from it. The will not disassemble easily since it is primarily welded together, but all of the steel should be able to be taken together to be recycled.

Detailed Recommendations

was unable to test the device so many things will likely be fitted to his needs. Adjustments will need to be made to make the device as comfortable as possible.

Although we attempted to make the device so that could operate it by himself unassisted, he will likely require assistance on his "bad days" when he is more immobile than usual.

Detailed Conclusions

We have done a lot of manufacturing this semester and it has paid off. We have taken heavily from existing devices trying to improve on the existing designs. We did go over budget due to a misunderstanding of what our budget was. We would not have been able to do this project without the support of businesses that offered to help free of charge. This is a big part of our success so far.

The physical therapy students were a huge help. They advised the traction device. They also were a great resource for questions regarding the condition of
References


Appendix A1

The following pages are the detailed drawings of the different parts of the medical device. Shown directly below is the 3D assembly.
REFERENCES


15. Whitman JM, Flynn TW, Childs JD, et al. A comparison between two physical therapy treatment programs for patients with lumbar spinal stenosis: A randomized
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