

Functional Analysis of a User Driven Non – Surgical Spinal Decompression System

by

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Abstract

Surgery is a common treatment for low back pain, but is a significant undertaking. An emerging non – surgical alternative, noted as spinal decompression therapy has evolved into an effective non – surgical treatment. This research focuses on the development and implementation of a user driven non – surgical spinal decompression (USD) system, a first of its kind prototype. The USD system’s function is validated through experiments performed on a dummy subject. In addition, a pilot study was performed on 4 human participants analyzing performance results and user feedback in regards to pedaling options, loading characteristics, restraint combinations, human response characteristics, safety features and overall comfort. Users imparted an average rating of 7.5 on a scale of 1 to 10 in terms of ease of utilization. In addition, 75% of users indicated the therapy underwent in the USD system felt like mild exercise, while 25% indicated it felt like a relaxation session.

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Chapter 1: Introduction

1.1 Motivation

Back problems are among the most common chronic conditions in Canada. According to Statistics Canada, four out of five Canadian adults will experience at least one episode of back pain at some time in their lives [1]. During the last 20 years, disability due to back pain has increased greatly, where 7 – 14% of adults in the USA experience disabling back pain during the course of a year, and just over 1% will be permanently disabled [2]. Back pain has been identified as one of the most costly disorders among the worldwide working population and it comprises approximately 40% of all compensation claims in the United States [3].

Surgery is a common treatment for low back pain, but is a significant undertaking as every surgical procedure carries the risks of failure and complications; along with financial loss and irreversible modification to the structure of the spine. Spinal surgery is a common treatment for disc herniation and disc degeneration [2]. An emerging non – surgical alternative, *spinal decompression therapy* has evolved into a cost-effective nonsurgical treatment for herniated and degenerative spinal disc disease. Non – surgical spinal decompression therapy consists of a specially designed table providing a unique form of intermittent motorized traction to the human spine [4]. This procedure lightly stretches the spine through a logic control mechanism thereby reducing the intradiscal pressure of the intervertebral disc commencing healing of the disc [5]. Non – surgical spinal decompression systems are utilized in clinics and operated by chiropractors, physiotherapists or trained professionals [6]. Figure 1.1, [7], below, displays an

example of the spinal decompression therapy, where the lumbar spine segment is isolated by two restraints.

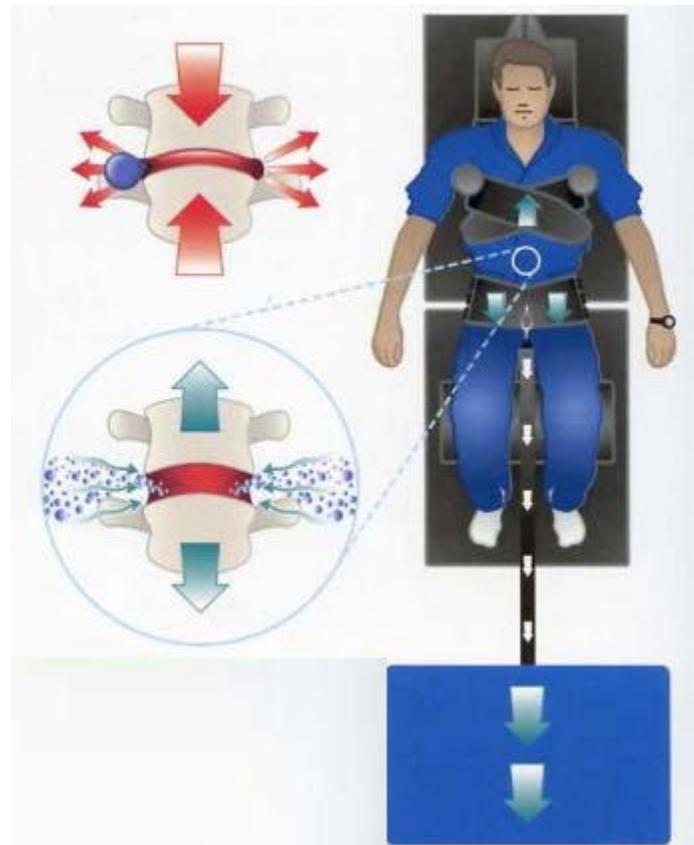


Figure 1.1: Non-Surgical Spinal Decompression Example

Non-surgical spinal decompression devices have risen in popularity over the last few decades, a study has shown that the presence of units has increased from 1991 to 2003, where as many as 5000 new devices among chiropractors in the U.S. [4]. Non-surgical spinal decompression devices are not to be confused with traction devices, such as inversion tables or non – intermittent form of back stretching without the implementation of a logic control mechanism. Although, the downside of these systems is that there is no direct input from the patient and the patient remains passive during the therapy, thus the patient has no control and must rely on the

chiropractor in the clinic to operate the device. Non-surgical spinal decompression devices are also generally bulky, heavy, immobile and most importantly very costly; where pricing ranges from \$9,000 to over \$100,000 [4]. Thus, the non – surgical spinal decompression devices are not meant for home use.

Research has shown back pain to be a recurrent problem for an individual rather than of a progressive nature. Thus, with the rise of back pain and its recurrent nature it seems evident to prototype an enhanced version of existing non – surgical spinal decompression devices and traction devices that is more readily available for the patient. This prototype shall be the first user driven spinal decompression (USD) system to enable user application of traction force with a logic control mechanism. In addition, this prototype should aim to be modular, lightweight, portable, and low-cost compared to comparable systems to enable an autonomous in-home therapy with the possibility of remote health monitoring. The new development will include user-driven inputs in addition to machine-set limits that minimize the potential for higher pain or excessive force, thus minimizing the potential for injury.

The motivation behind prototyping the first user-driven spinal decompression (USD) system is not only due to the evident need but due to the collaboration of the Broadview Spine and Health Center with its lead Dr. Lawrence. Dr. Lawrence is a licensed chiropractor with sufficient knowledge and insight about non – surgical spinal decompression therapy.

1.2 Thesis Objective

The objective of this thesis is to implement the first prototype of a user driven spinal decompression (USD) system, and perform functional experiments to analyze the functionality of the system to guide the future developments. The USD system shall include the following:

- A transmission system where the user comfortably generates the load utilizing their feet via a pedaling mechanism with an incorporated reduction ratio without the use of an electric motor.
- A pedaling mechanism that contains numerous options for the user to choose from.
- Machine-set limits that minimize the potential for higher pain or excessive force, thus minimizing the potential for injury.
- A control system that controls the cycles of force build up and release while simultaneously overseeing safety features.
- Ability to be utilized in the following anatomical positions: supine or prone.
- Ability to provide spinal decompression therapy to the following spinal regions: lumbar and cervical to lumbar.
- New restraining components to restrain and isolate the spinal region(s) of interest and its corresponding anatomical position.
- Appropriate sensors for the collection of test data.
- A researcher graphical interface intended for researcher use with the purpose of user data logging, safety checks and real time data display to monitor sensor output during the therapy; the interface shall include easy-to-operate features incorporating requirements for a simple transition to a USER graphical interface in regards to future development and possibly of health remote monitoring.
- The ability to be powered by a battery or electrical outlet.
- Portability and modularity features to ensure in home therapy accessibility.
- A structure that shall accommodate a wide range of people.
- Be aesthetically pleasing to encourage participants for functional trials.

The functionality experiments are implemented to validate the USD system and use as a guideline for the future development of the USD system. Two categories of functionality experiments, denoted as preliminary experiments and pilot study are implemented, where preliminary experiments are performed on a dummy subject and the pilot study on human participants. The preliminary experiments serve to validate the USD system's functionality in terms of anticipated function in accordance to implemented design. The pilot study serves to validate the USD system's function in accordance to human interaction and their feedback. The development of the USD prototype follows the generic engineering design process as medical devices should [8], which is incorporated in the following steps that must be taken to achieve the objective of producing the USD prototype:

- Requirements identification,
- Constraints identification,
- Follow the mechanical design process including concepts, detail computer-aided drawing (CAD) models and analysis,
- Procure all components including structural elements, mechanical actuation parts, hardware, sensors, and data acquisition system,
- Coordinate the bulk of manufacturing with Carleton University's machine shop,
- Assemble the device with the manufactured and purchased parts, and
- Interface mechanical structure with electronics and control software.

1.3 Platform Introduction

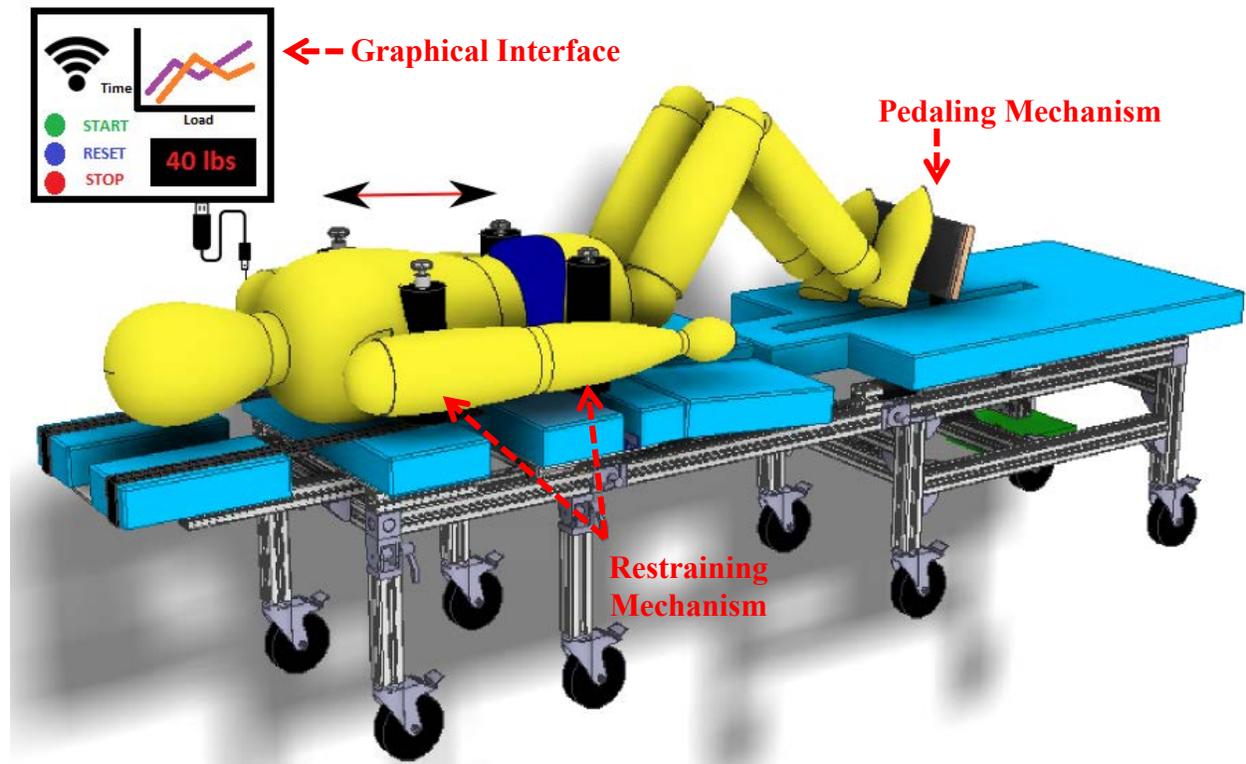


Figure 1.2: 3D CAD Design

Figure 1.2, displays the USD prototype in 3D CAD, while Figure 1.3, displays the built prototype. The USD system consists of a table that is capable of performing non – surgical spinal decompression through a user driven methodology. The main components include a transmission system, graphical interface, hardware box, restraining mechanisms and structural table capable of several adjustments for varying anatomical positions and spinal segments.



Figure 1.3: USD Built Prototype

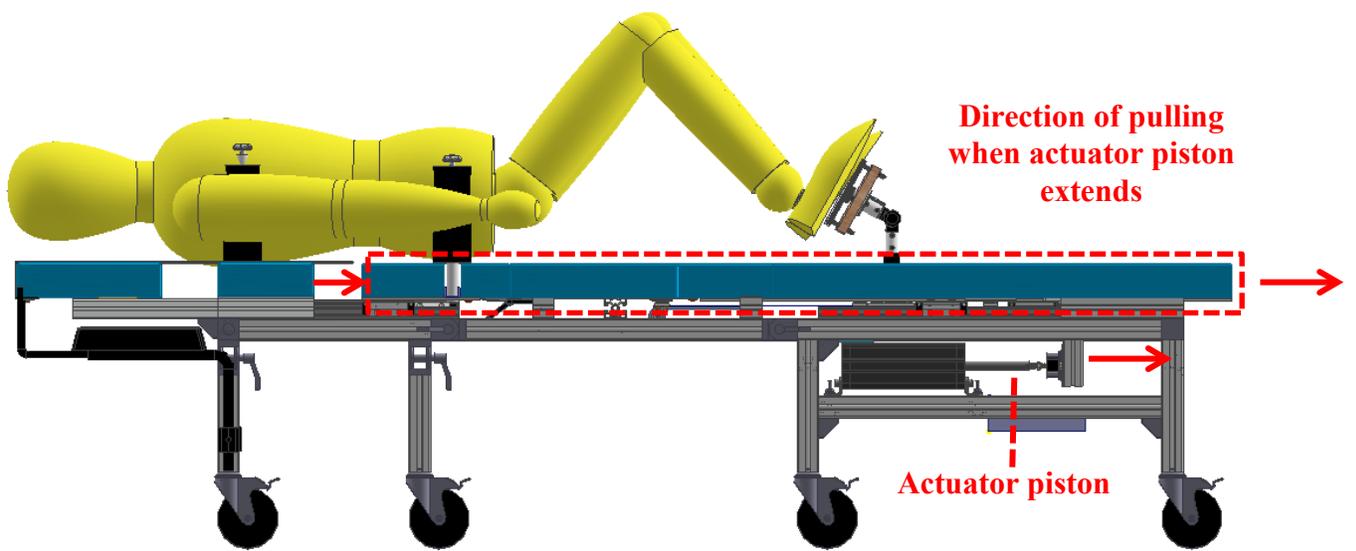


Figure 1.4: USD System Movement

1.4 Significant Contributions

The work presented in this thesis resulted in the following contributions:

1. The first design of a User-Driven Non-Surgical Spinal Decompression (USD) system capable of performing controlled cyclic intermittent form of spinal decompression therapy, which allows the user to set one's own pace in the application of loading. Novel attributes to the USD system design includes an original transmission system along with integrated sensors and safety features, novel restraining components, and an original mechanism to allow structure adjustment for different individual heights and different anatomical positions integrated in one structure.
2. A prototype of the USD system is implemented utilizing commercially-available parts, custom made components and assemblies.
3. Two categories of functional experiments were performed, preliminary experiments and a pilot study. The preliminary experiments performed tests on a dummy subject concentrating on USD system function and safety precautions. The pilot study is subcategorized into two categories and was performed on 4 healthy participants concentrating on user feedback and feasibility.

1.5 Thesis Outline

This thesis is divided into seven chapters.

Chapter 1: Introduction

Chapter 1 introduces the problem by discussing the motivation, states the objectives, introduces the platform and summarizes the contributions.

Chapter 2: Literature Review

Chapter 2 provides the literature review. It includes an overview of back pain. Follows with an analysis of the evolution of traction to non – surgical spinal decompression and differentiating between different types of devices. Lastly, details of non – surgical spinal decompression therapy in terms of application and design as specified in the literature to aid in the development of the USD.

Chapter 3: Mechanical Design

Chapter 3 discusses the mechanical design. It includes the constraints and requirements anticipated with specific concentration on the transmission design, restraining mechanisms design and structural design. It discusses the development attributes and components utilized.

Chapter 4: Electrical and Software Design

Chapter 4 discusses the electrical and software design. It includes the constraints and requirements anticipated with specific concentration on the hardware design, calibration of sensors and graphical interface design.

Chapter 5: Preliminary Experiments

Chapter 5 discusses the objective of the preliminary experiments and its meant to serve as a safety pre–caution to human experimentation. It includes an overview of the dummy subject design, design analysis verification, overview of the preliminary experiments and coinciding results.

Chapter 6: Pilot Study

Chapter 6 discusses the objective of the pilot study, selection of experiments, the methodology of the experiments and participant information. In addition, the results are analyzed and discussed.

Chapter 7: Conclusion

This chapter summarizes the accomplishments of this thesis, possible improvements to the design or implementation, and recommendations for future work.

Chapter 2: Literature Review

2.1 Introduction

The following chapter includes an overview of back pain. Following with a section on the evolution of traction to non – surgical spinal decompression, this is an important section to understand the origin of traction, to distinguish between different types and to analyze the current devices commercially available in the market. The last section is an overview of non – surgical spinal decompression therapy in terms of mechanical effects, physiological effects, application factors, clinical studies and its utilization/regulation.

2.2 Back Pain

The following section outlines how back pain is classified, the risk factors associated, causes and the treatments available.

2.2.1 Classification

Back pain is generally classified into low back pain and neck pain, pain in the lumbar region of the spine and pain in the cervical region of the spine, respectively, according to Statistics Canada 2006 report [1]. Figure 2.1, below, illustrates the various regions of the spine [9]. Figure 2.2, below, illustrates various conditions related to the intervertebral disc such as herniated disc, degenerated disc, etc. [10].

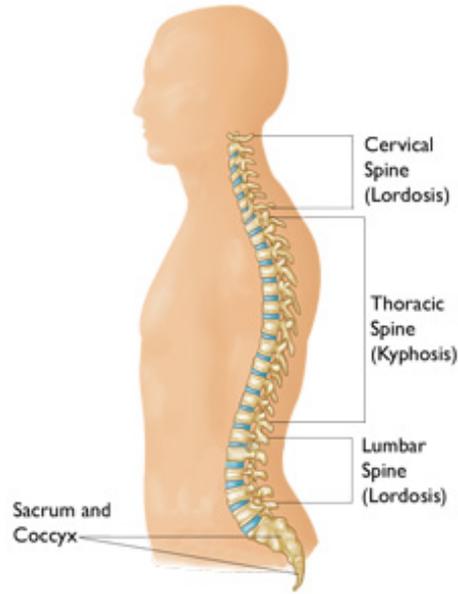


Figure 2.1: Spine Segments



Figure 2.2: Spine Conditions

Back pain symptoms are classified as acute, lasting between six weeks to three months, or chronic, lasting longer than three months [1], [2]. In addition to classifying back pain symptoms as acute or chronic, recent research has shown that back pain is a recurrent problem rather than a progressive nature; refer to Figure 2.3 for an example of how this is displayed [2].

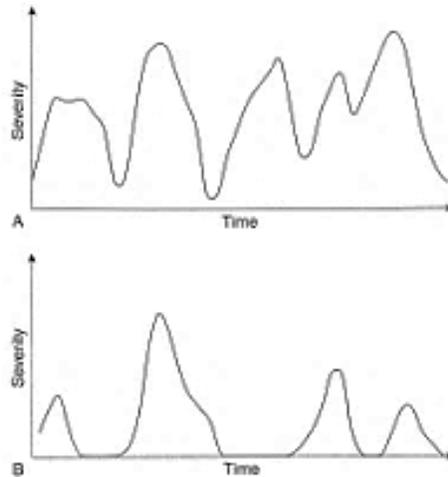


Figure 2.3: Recurrent Back Problem - Severity versus Time

2.2.2 Risk Factors

The risk factors of back pain have been subdivided into four categories genetic, individual, environmental and psychosocial [2]:

- Genetic
 - Genes inherited from parents such as small intervertebral discs, defective collagen or proteoglycans could weaken spinal tissues so that they are more vulnerable to injury
 - Epidemiological studies suggest that up to 60% of back pain and 50 – 75% of disc degeneration is associated with genetic inheritance
- Individual
 - Includes body height, weight, flexibility, strength, fatigability and fitness
 - Presumably tall people with long backs tend to lift weights at the end of greater lever arms and this may explain why tall people have a greater risk of disc prolapse
 - Obese individuals have a greater risk in developing back pain due to the extra bodyweight acting on the spine

- Environmental
 - Occupation, sporting activities, smoking, etc.
 - Incidents that require sudden muscular efforts
 - Physical demands of work (manual materials handling, lifting, bending, twisting and whole body vibration)
- Psychosocial
 - Depressive mood, somatization, attitudes/beliefs about the activity/pain/damage relationship, and occupational psychosocial interactions

2.2.3 Causes

Back pain could arise from any of the ligaments, muscles, fasciae, joints or discs of the lumbar spine. Back pain is a symptom that afflicts most people at some points in their lives, although, usually in the absence of a relevant, clinically detectable source. Aside from the noted risk factors, distinct causes of back pain remain obscure [2]. Low back pain is the most prevalent type of back pain with common conditions including intervertebral disc herniation and degeneration, zygapophysial joint osteoarthritis, spinal stenosis, spondylolisthesis and segmental instability; where disc herniation is the major cause of nerve root, most commonly experienced as sciatica [2].

Low back pain is the most prevalent type of back pain because the lumbar spine endures greater compressive loading in comparison to the rest of the spine. By age 50, 97% of all lumbar discs are degenerated, and the most degenerated segments are L3 – L4, L4 – L5 and L5 – S1 [11]. The rise of low back pain is attributed to prolonged sitting, in industrialized countries, 75% of workers sit for long periods of time [3]. A greater compressive force and average intradiscal pressure acts on the intervertebral discs of the lumbar spine when in the sitting position as

compared to standing or lying posture [2], [11]. The compressive force is about 150 – 250 N when lying, to 500 – 800 N when standing and 700 – 1000 N when sitting [2]. Average intradiscal pressure is about 154 KPa in prone, 550 KPa when standing and 700 KPa when sitting [11].

2.2.4 Treatment

The treatment of back pain is split into two categories, surgical and non-surgical.

Surgical

Surgery is a common form of treatment for low back pain, but it is a momentous undertaking. Unlike other interventions, it involves modifying the structure of the spine. This requires invading the body and disrupting the surrounding tissues in order to gain access to the target structure. Its effects are irreversible; once anatomy has been altered it cannot be restored. Every surgical procedure carries the risks of failure and of complications. Spinal surgery for back pain has included resection, fusion and disc replacement. Surgical intervention is generally considered to be appropriate in cases of sciatica due to lumbar disc herniation, but is regularly performed for back pain in the presence of other lumbar pathologies such as disc degeneration (and associated spinal stenosis), spondylosis, spondylolisthesis and so-called instability [2].

Non-Surgical

Non-surgical methods for back pain are referred to as conservative /non – invasive methods in comparison to surgical methods [2], [12]. Non – surgical methods can be as simple as exercise therapy, active therapy such as yoga or Pilates. Passive therapy such as massage, superficial or deep heat, transcutaneous electrical nerve stimulation

(TENS), traction or spinal manipulation administered by a chiropractor [12]. In addition, non-surgical spinal decompression, a method that has become more common in the last few decades to treat disc degeneration and disc herniation [5].

2.3 Evolution of Traction to Non–Surgical Spinal

Decompression

2.3.1 History

Ancient Times and Pre 19th Century

Spinal traction has been used as a medical intervention since ancient times [13]. Several ancient references have been found and identified the popular use of spinal traction to treat spinal deformity, such as scoliosis and kyphosis. The oldest reference available is in ancient Hindu mythological epics, written between 3500 BC and 1800 BC, where it is mentioned Lord Krishna corrected the hunchback of one of his devotees. Later, several spinal traction devices were invented by Hippocrates, ‘father of medicine’, documented between 460 BC and 377 BC. Galen, a follower of Hippocrates took spinal traction one step further by applying direct pressure, between 131 AD – 201 AD. Years later, Ibn Sena, in the Middle East, between 980 AD – 1037 AD, used Galen’s methods and further developed his own instruments. Lastly, several depictions of spinal traction methods were found in Turkey during medieval times. An illustrative timeline is put together of discovered spinal traction references in historic manuscripts; refer to Figure 2.4 below. The vast use of spinal traction to treat spinal deformity in ancient times gradually went into disrepute due to the invariable production of paraplegia [14]. Despite the disrepute, spinal traction did not fully disappear, but received a renewed popularity, specifically, in the last

century [14], [6].

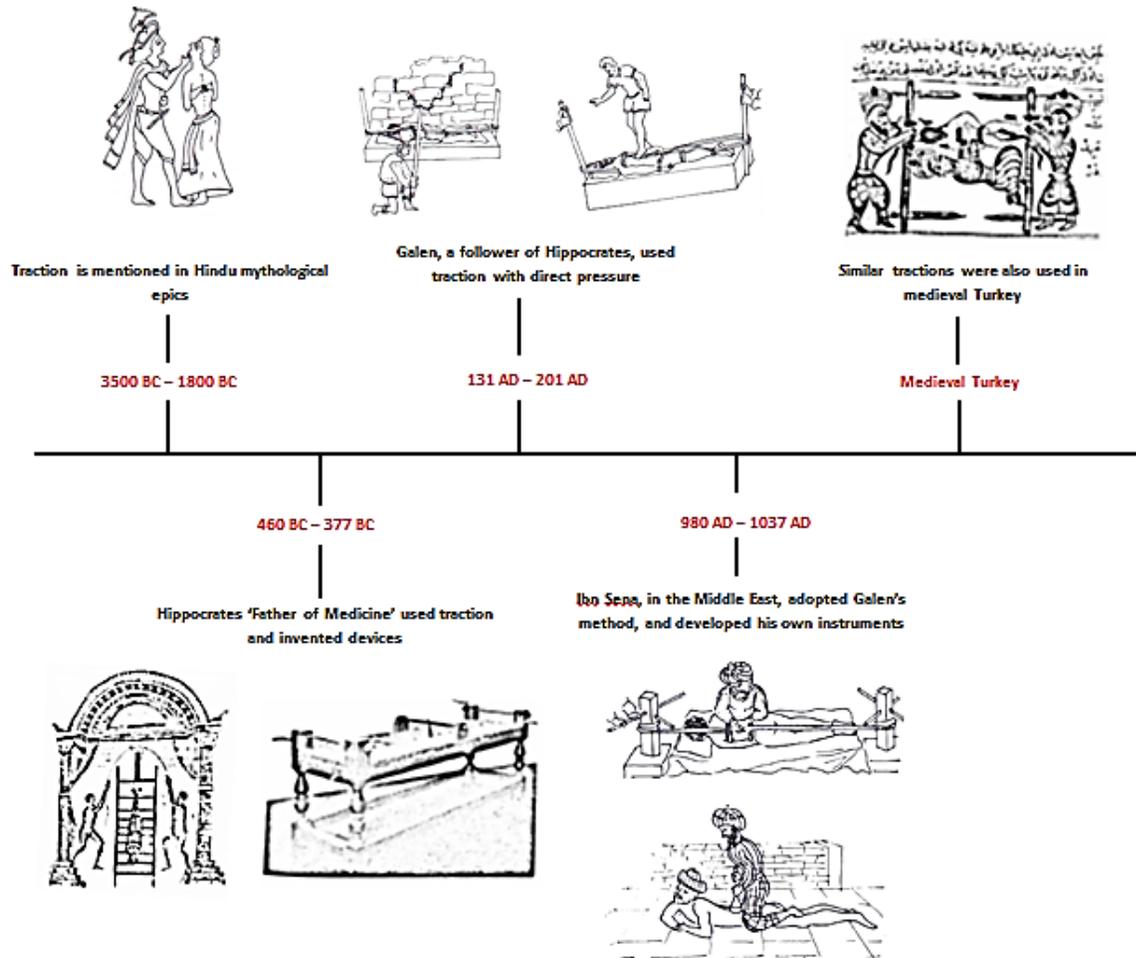


Figure 2.4: Timeline of Ancient References to Spinal Traction

19th Century and Beyond

Fast forward to the 19th century, the traction bed was used to treat scoliosis, backache, rickets, and spinal deformity, and traction corsets, traction chairs, and body suspension were promoted by individual practitioners. Traction became a common treatment for chronic low back pain (CLBP) in the early 20th century and opinions developed regarding how traction should be applied, including debates about the ideal amount of force, degree of pull, duration of pull, and timing of force intervals [6].

The renewed popularity briefly initiated when William Mixter in 1934 presented a paper, which mentioned intervertebral disk pathology as a possible cause for low back pain, where this led a new interest in traction therapy relieving pain via widening of the intervertebral discs [15]. Its popularity rose higher in the 1950's and 1960's with James Cyriax's findings on the efficacy of spinal traction for not only the treatment of CLBP, but theorizing that traction would produce negative pressure in the disc and thereby reduce disc herniation's [6], [16]. In 1974, Gertrude Lind developed auto traction [17]. In 1976, the Gravity Lumbar Reduction Therapy Program was developed at the Sister Kenny Institute in Minneapolis where a user controlled method for lumbar traction was initiated. The FDA approved the first powered traction unit in 1977 [18]. HD Saunder's further popularized the use of intermittent spinal traction in the 1980's and 1990's through the development of improved stabilization belts and split table technology. In the 2000's several advancements have been made with improved instrumentation and development of computer driven spinal decompression tables to apply traction to the spine [16]. Figure 2.5, below, visually highlights some of the milestones of the last century noted in the literature incorporated in a visual timeline.

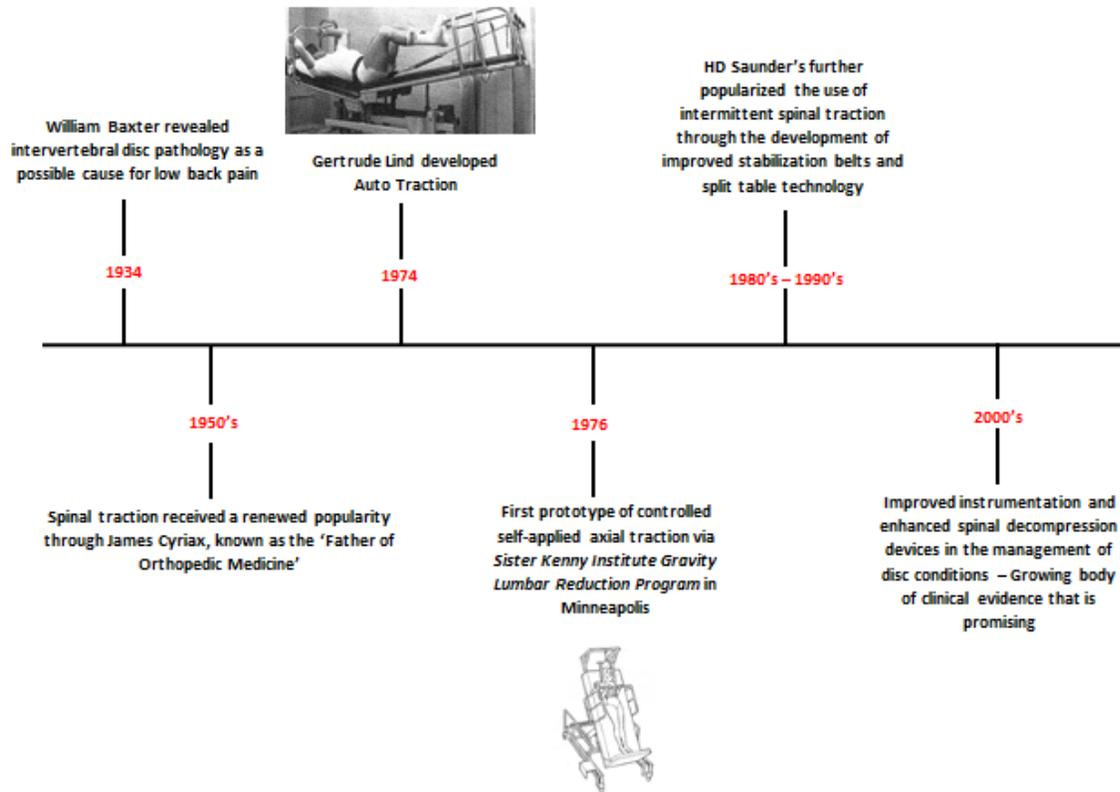


Figure 2.5: 19th Century and Beyond Timeline of Spinal Traction

2.3.2 Classification of Systems

There are numerous types of spinal traction systems with varying features described in the literature that are still in use today aside from the commonly utilized non – surgical spinal decompression systems. There is not a distinct classification system that describes these systems, but based on a review of the literature, spinal traction/non – surgical spinal decompression therapy are generally classified based on duration, application method and direction of force [13], [6]. Figure 2.6, below, outlines the general classification as described in the literature.

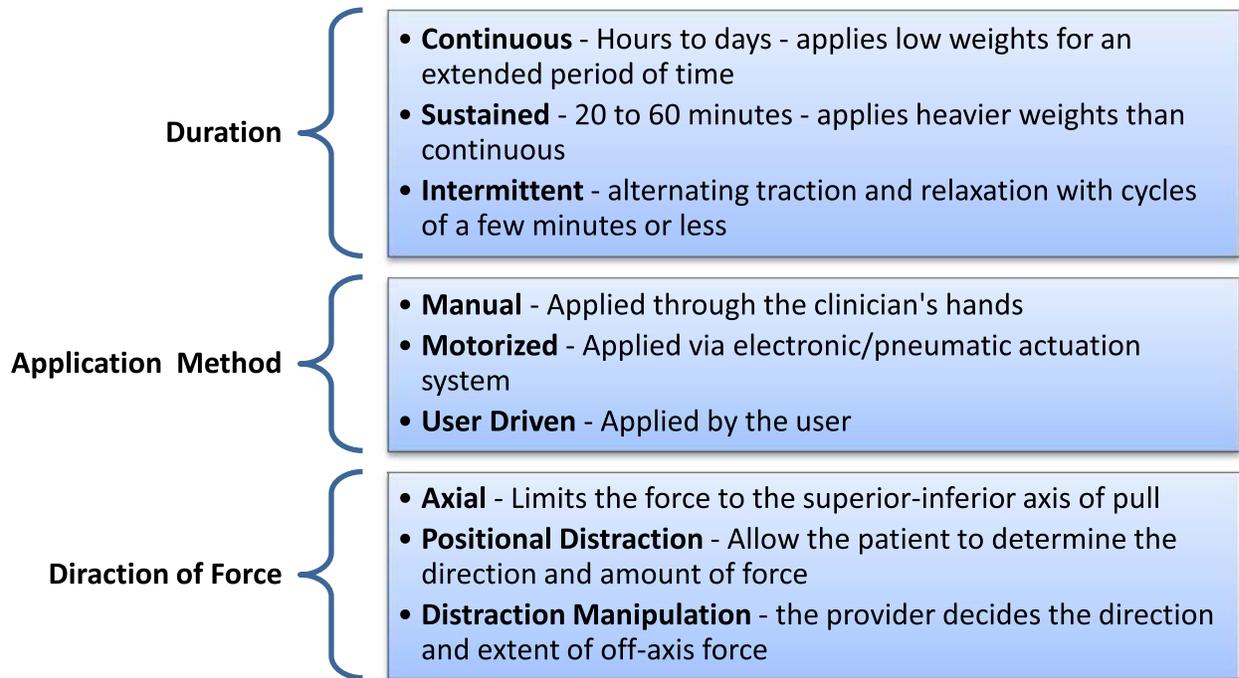


Figure 2.6: Classification Attributes of Spinal Traction/Non - Surgical Spinal Decompression Therapy

To further comprehend the described classification system, Figure 2.7, displays various systems and how they vary in duration, application and direction of force [6], [19], [20], [21], [22].

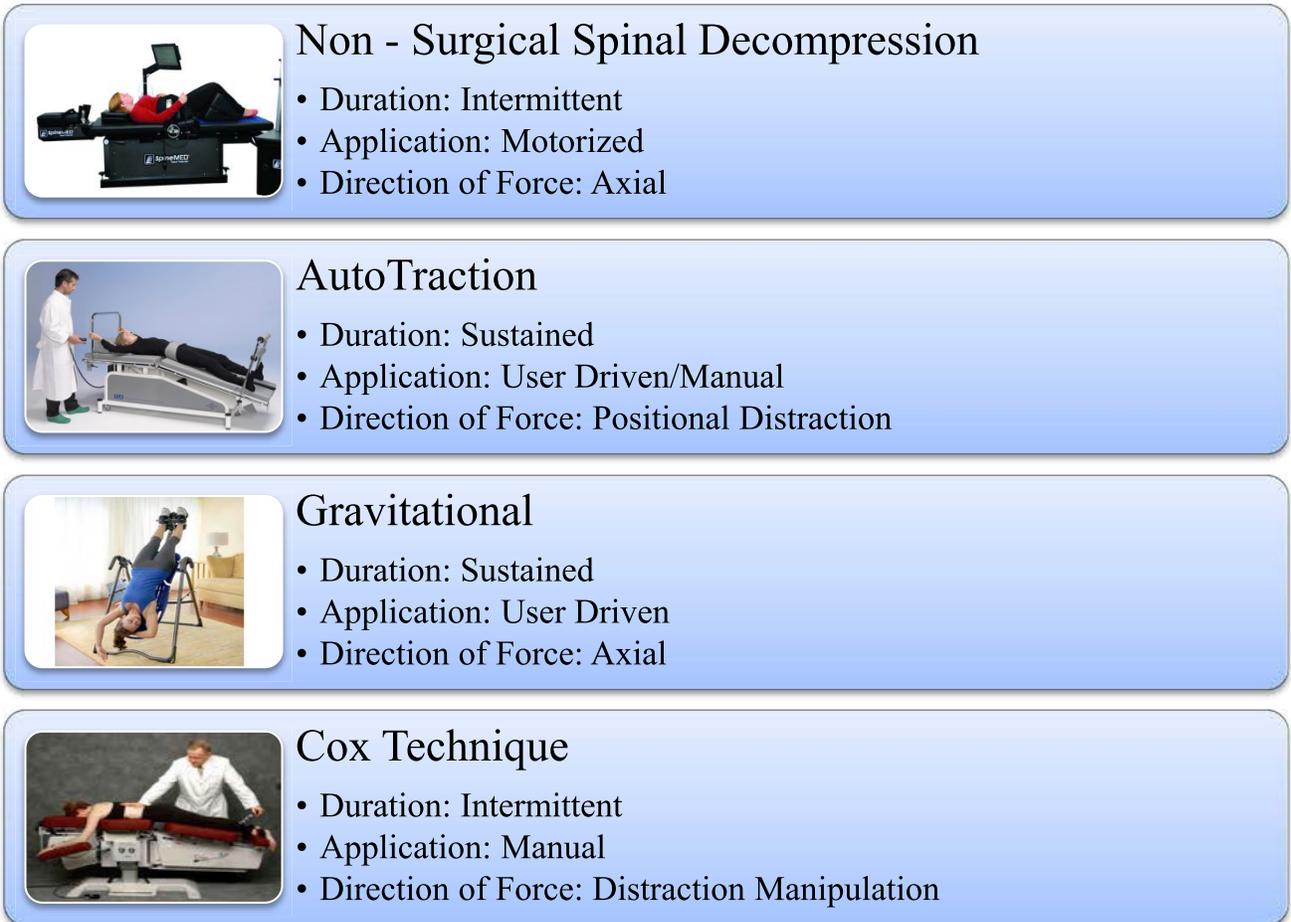


Figure 2.7: Classification of Various Spinal traction Systems

2.3.3 Survey of Devices in the 21st Century Market

The following section outlines the devices currently available to the consumer market categorized by non – surgical spinal decompression devices and user driven home devices while discussing the short comings of both. A Venn diagram is produced below, Figure 2.8, outlining the current available and non-available device categories based on the findings through the survey. This further demonstrates the need to develop a non – surgical spinal decompression user driven home device.

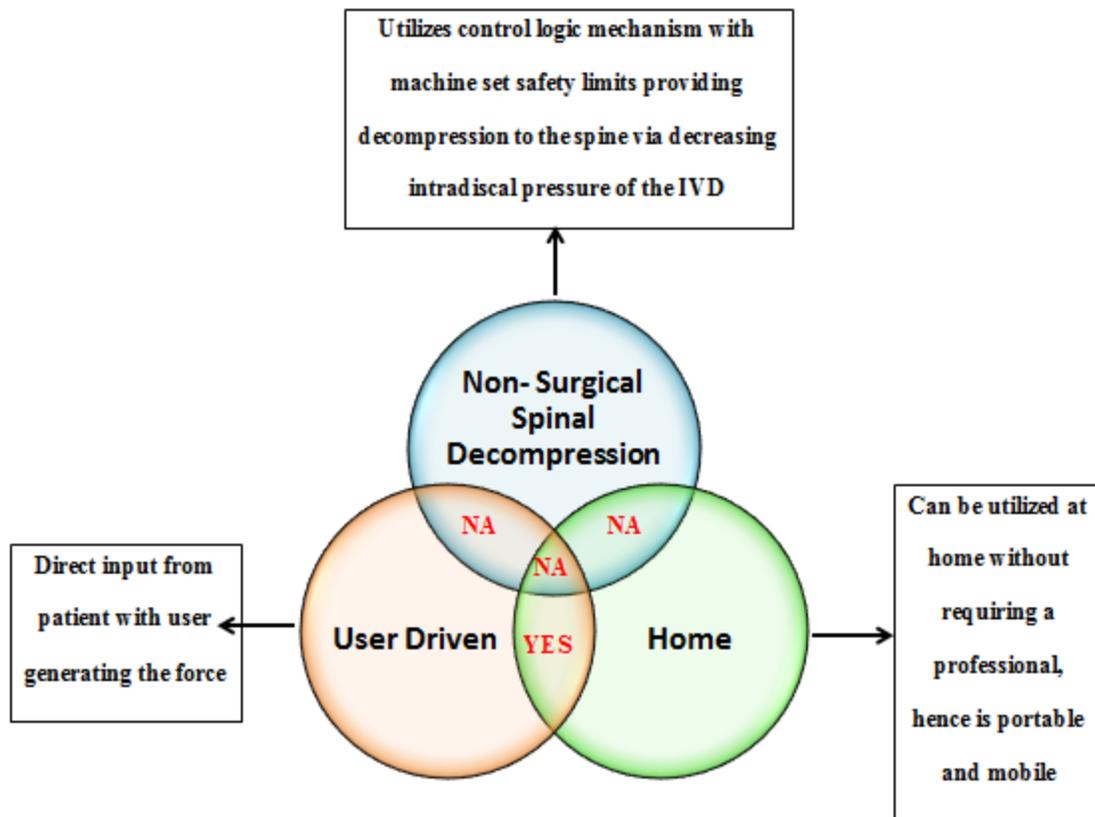


Figure 2.8: Venn diagram of Spinal Traction Devices

Non – Surgical Spinal Decompression Devices

By searching through the FDA database, it is clear there are 68 non – surgical spinal decompression under device name ‘Equipment, Traction, Powered’ [23]. It should be noted that FDA considers non – surgical spinal decompression devices as a form of traction. There are numerous devices currently commercially available, but too much to list all down; the following is a list of the commonly advertised devices:

- VAX-D
- Decompression Reduction Stabilization (DRS) System
- DRX2000, 3000, 5000, 9000
- Accu-Spina System
- Tru Tac 401 (Henley International)

- DRX 9000C
- Lordex Power Traction Equipment
- SPINEdex
- Triton DTS

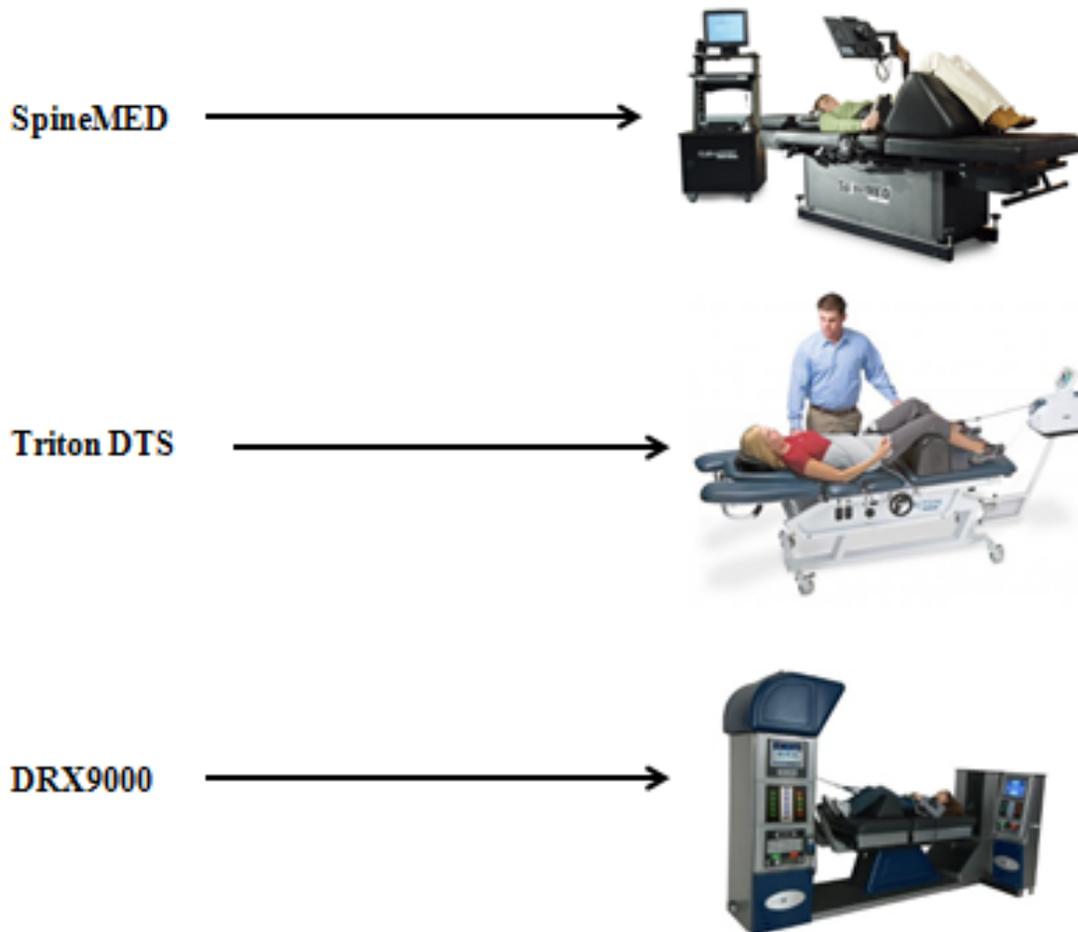


Figure 2.9: Commonly Advertised Non - Surgical Spinal Decompression Devices

Figure 2.9, above, displays some of the commonly advertised non – surgical spinal decompression devices [24], [25], [26] .

Non-surgical spinal decompression devices utilize a logic control mechanism (discussed in section 2.4.3.3) stated to decrease the patients' protective proprioceptive response to distraction allowing distraction of the spinal segment. The shortcomings of these devices are that they are costly, non-portable, immobile, no direct input from the user and require an operator.

User-Driven Home Devices

The user-driven home devices that are currently advertised in the market are commonly referred to as traction devices. User-driven traction devices efficacy has not been as promising as non-surgical spinal decompression devices [27]. Nonetheless, the user driven aspect allows the user to control the force it applies to its spine where this direct input is a safety feature. The ability to utilize the device at home makes treatment readily available to the patient. The following is a list of user-driven home traction devices:

- Inversion Table
- Saunders Lumbar Home Traction Device
- Teeter Spinal Stretch
- Saunders Cervical Home Traction Device
- Nubax Trio
- Over the Door Cervical Traction Unit
- 3D Denneroll Traction Table System
- Pronex Pneumatic Cervical Traction Device
- Horizontal Back Decompression at Home

Inversion Table (Teeter Hang Ups)



Teeter Spinal Stretch



Figure 2.10: Commonly Advertised User Driven Home Traction Devices

Figure 2.10, above, displays some of the commonly advertised user drive home traction devices [28], [29], [30].

2.4 Non–Surgical Spinal Decompression Therapy

Non–surgical spinal decompression is described as a unique form of intermittent motorized traction utilizing variable force, variable traction/relaxation time and in some units variable angles of pull [4]. Non–surgical spinal decompression devices utilize a computer to control the applied distractive tension, or stretching along the spinal axis. These devices are meant to provide gradual and controlled stretch designed to overcome muscle resistance, thereby allowing effective distraction of the intervertebral discs. Non–surgical spinal decompression is more frequently used by physical therapists, chiropractors, neurosurgeons, and orthopedists in clinical practice because of its greater standardization and repeatability in trials as compared with other types of traction [27]. Literature states that when traction is applied, the pull force of traction may elicit the body’s protective proprioceptive response to distraction resulting in contraction of the paravertebral muscle, causing reduction of the distraction force. It’s noted that the use of non – surgical spinal decompression can decrease patients’ protective proprioceptive response to distraction allowing distraction of the spinal segment [27].

2.4.1 Understanding the Mechanical and Physiological Effects of Non–Surgical Spinal Decompression

The clinical effects of non–surgical spinal decompression are a combination of mechanical and physiological effects, where the mechanical effects induce physiological effects [31].

Mechanical Effects of Non–Surgical Spinal Decompression

The mechanical effects are as follows [13], [31], [11], [32]:

- Distraction to increase intervertebral disc space
- Reduction of intradiscal pressure

- Enlargement of intervertebral foramen
- Flattening of the lordosis
- Distraction of the apophyseal joint
- Stretching of the spinal musculature
- Stretching of the spinal ligaments

The mechanical effects of non-surgical spinal decompression have been well documented in the literature with strong backing evidence [13]. The decrease in intradiscal pressure of the intervertebral disc is fundamental to achieving decompression of the spine. A previous study has reported that pressures inside L4 – L5 intervertebral disc were significantly decreased to – 150 to -160 mm Hg when spinal decompression via VAX – D was delivered to patients who had a subligamentous herniation and were candidates for percutaneous discectomy [33], [27].

It should be noted that not all forms of spinal traction, such as auto traction, decrease intradiscal pressure as demonstrated in a previous study [34]. Thus, the specifics of the application of non-surgical spinal decompression must be considered.

Physiological Effects of Non-Surgical Spinal Decompression

The increase in intervertebral disc space and decrease in intradiscal pressure will result in a central vacuum/suction to reduce a herniated disc and diminish a disc protrusion or prolapse [13], [11], [32]. This will also result in the release of entrapped synovial membrane and enhanced circulation of blood flow. The reduction of intradiscal pressure via spinal decompression system creates a diffusion gradient into the damaged discs allowing nourishment to proceed, ultimately promoting disc metabolism and restoration [35], [36]. The enlargement of the intervertebral foramina will allow the nerve root more space relieving any nerve root compression. In addition, the stretch of a tight or painful capsule will relieve pain [13], [11]. The

stretching of the spinal musculature will result in the relaxation of the muscles and muscle spasms. Lastly, the stretching of spinal ligaments, such as the posterior longitudinal ligament will result in tension reducing of herniated disc [13], [11], [32].

2.4.2 Indications and Contraindications for Non–Surgical Spinal Decompression

Indications for Non–Surgical Spinal Decompression

Indications for non–surgical spinal decompression include spinal pain associated with [13], [37]:

- Herniated nucleus pulposus with disc protrusion
- Degenerative disc disease
- Foraminal stenosis
- Joint dysfunction/hypomobility/impingement
- Contracted connective tissue
- Adhesions
- Muscle spasms

It's also suggested in the literature that patients with spinal pain who have not responded to more conservative spine treatments such spinal manipulation, physical therapy, etc. are ideal candidates for non–surgical spinal decompression [6], [32].

Contraindications of Non–Surgical Spinal Decompression

Commonly listed contraindications include [13], [6]:

- Spinal malignancy
- Spinal cord compression
- Uncontrolled hypertension

- Cardiovascular disease
- Osteoporosis
- Severe hemorrhoids,
- Abdominal hernia
- Pregnancy
- Aortic or iliac aneurysm
- Inflammatory spondyloarthritis
- Severe Respiratory disease
- Abdominal Hernia
- Acute Fracture

2.4.3 Non–Surgical Decompression Application Factors

2.4.3.1 System Design and Components

2.4.3.1.1 Split Table Design

In 1955, Judovich discussed dissipated forces in traction devices specifically noting the surface traction resistance of the body. Through live subject and cadaver studies, Judovich revealed that the average surface traction resistance of the body in a hospital bed is approximately 54% of the total body weight. The lower body segment weighs approximately 49% of the total body weight. It also requires 54% of the weight of the lower body segment to overcome its own surface traction resistance. This is equal to approximately 26% of the total body weight. Thus, the force dissipated with lumbar/pelvic traction is approximately 26% of the entire body weight.

Therefore, the traction force applied must be an excess of the 26% body weight amount to obtain an effect on the lumbar spine [38].

Judovich proposed a ‘split table’ design to overcome surface resistance. The design encompasses the table to be built into two sections, where the upper section is fixed and the lower section is mobile upon roller bearings, and is transported by a motorized intermittent traction unit. Thus, the resistance of the lower body is no longer a factor since it is transported mechanically [38]. Ever since Judovich’s revelations regarding surface resistance, most devices after 1955 incorporated the split design, most evident in today’s most popular non – surgical spinal decompression devices such as SpineMED, DRX9000, VAX-D, etc.

2.4.3.1.2 Restraining Mechanisms

Restraining components in non–surgical spinal decompression devices are one of the most integral in terms of ensuring an effective therapy. The criteria of the restraining components must satisfy comfort and non – slippage. For example, non – surgical spinal decompression targeting the lumbar spine should ensure the pelvic restraint component and the chest restraint component satisfy comfort and non–slippage [39].

2.4.3.2 Treatment Technique

The treatment technique of cervical and lumbar non–surgical spinal decompression in terms of force, duration and application factors varies considerably in the literature [13] [31]. The literature recommends using the minimum duration, force and frequency to achieve desired outcomes [31]. Table 2.1 and Table 2.2 outline defined treatment factors found in the literature for cervical and lumbar non – surgical spinal decompression.

Table 2.1: Cervical Non – Surgical Spinal decompression Treatment Factors

	Posture	Neck Position	Force	Duration
<i>Cervical Spine</i>	Supine or sitting [40]	- 0° to 30° positioned in flexion [41] - 20° to 30° for best clinical results [40]	- 9.9 lbs. to 14.74 lbs. for Muscle Relaxation - 24.75lbs. to 29.7 lbs. for mechanical elongation [40]	Minimum of 2 minutes for clinical benefits [40]

Table 2.2: Lumbar Non – Surgical Spinal Decompression Treatment Factors

	Posture	Force	Duration	Knee Position
<i>Lumbar Spine</i>	Supine or Prone [13]	- >20% body weight [38], [31] - 20 % to 50% body weight for IVD separation [31]	Minimum of a few minutes [13]	Knees in flexion up to maximum 90° for hip relaxation and increase separation [39], [31]

In correlation with Table 1 above, it's proven a direct relationship exists between the angle of neck flexion and the posterior vertebral separation. The purpose of neck flexion is to stretch the

posterior neck muscles and provide intervertebral separation, including the enlargement of the intervertebral foramina. Muscle relaxation is best accomplished with 10 lbs. to 15 lbs. If the objective is to produce an effective mechanical elongation of the cervical spine, a minimum force of 25 lbs. to 30 lbs. is required. For an effective duration, the literature reports as low as 7 seconds to several hours. Most investigators agree mechanical benefits to occur in the first few minutes of non – surgical spinal decompression. Lastly, most investigators agree that the supine position is the most comforting and relaxing in comparison to the sitting position [40].

In correlation with Table 2 above, the literature states that lumbar non – surgical spinal decompression can be performed in the supine or prone position depending on the patient's preference [13]. The force applied must be at least 20% of the patient's body weight to achieve the mechanical attributes of spinal decompression that is when used with a split table [38], [31].

In terms of the duration, the literature values vary from a few minutes to 40 minutes with optimal timing between 8 to 10 minutes [13]. Investigators also suggest flexing the knee to provide hip relaxation and increase separation to increase lumbar spine length [31], [39].

2.4.3.3 Logic Control Mechanism

Non – surgical spinal decompression therapy is administered via an automated logic control mechanism, which systematically applies distractive tensions and rest periods in a cyclic fashion. The typical therapy session varies depending on the device and disorder. For the VAX-D, a commonly utilized non – surgical spinal decompression device, the typical therapy session consists of 15 cycles of tensions and relaxation. This periodic process allows patients to withstand stronger forces than can be tolerated when static techniques are used and it promotes accommodation and relaxation during the therapy session [5].

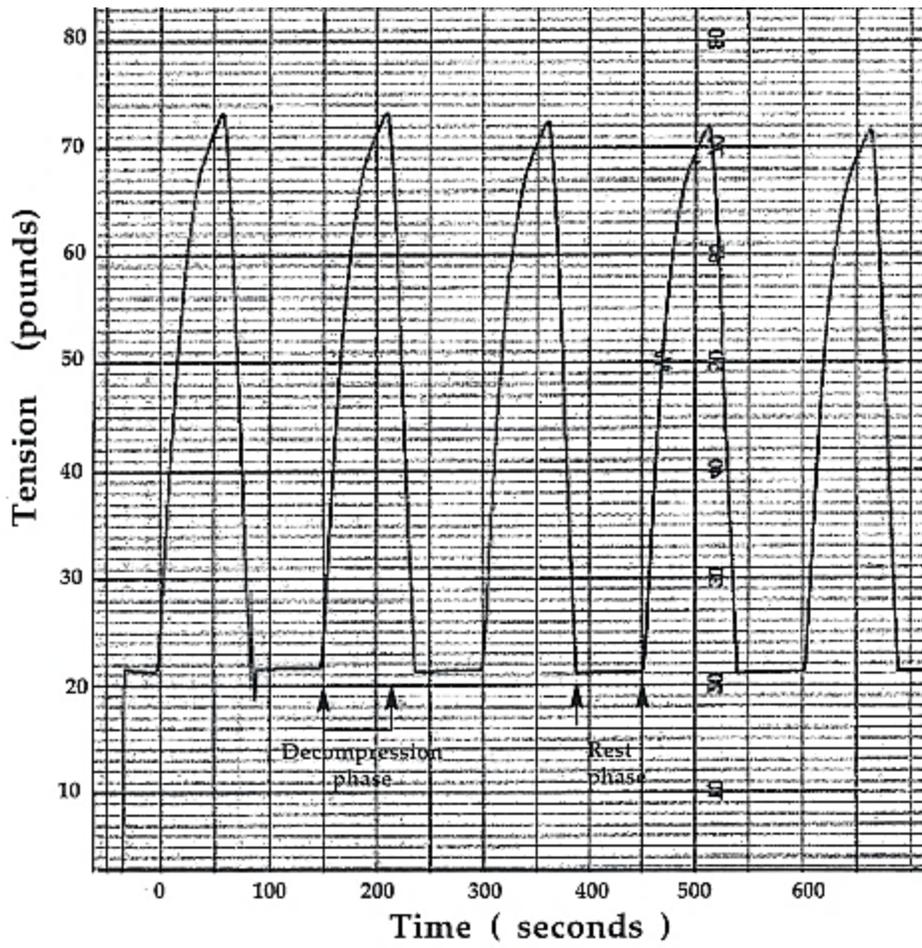


Figure 2.11: Typical Chart of VAX - D for Tensile Loading

Figure 2.11: Typical Chart of VAX - D for Tensile LoadingFigure 2.11, displays a portion of a typical chart recording of the tensile force applied to a patient's spine as a function of time administered via the VAX – D [5]. This is an example of the cyclic loading applied in non – surgical spinal decompression therapy, although, it should be noted that exact detail regarding decompression phase, rest phase, total cycles, etc. vary from patient to patient, and also depending on the device itself.

2.4.4 Clinical Efficiency Studies of Non – Surgical Spinal

Decompression

The following clinical studies are based solely on the utilization of non – surgical spinal decompression therapy and do not include studies on spinal traction.

1. Vertebral axial decompression therapy for pain associated with herniated or degenerated discs or facet syndrome: An outcome study, Journal of Neurological Research, 1998:
The treatment was successful in 71% of the 778 cases; improvements in mobility and activities of daily living correlated strongly with pain reduction [5]
2. Decompression, Reduction, and Stabilization of the Lumbar Spine: A Cost-Effective Treatment for Lumbosacral Pain, Journal of Pain Management, 1997:

86% of ruptured intervertebral disc (RID) patients achieved good (50-89% improvement) to excellent (90-100% improvement) results with decompression. Sciatica and back pain were relieved. Of the facet arthrosis patients, 75% obtained good to excellent results with decompression [42]

3. Surgical Alternatives: Spinal Decompression, Journal of Orthopedic Technology Review, 2003:

Results showed that 86% of the 219 patients who completed the therapy reported immediate resolution of symptoms, while 84% remained pain-free 90 days post-treatment [43]

4. A Clinical Trial on Non-Surgical Spinal Decompression Using Vertebral Axial Distraction Delivered by a Computerized Traction Device, The Academy of Chiropractic Orthopedists Journal, 2004:

All but two of the patients in the study improved at least 30% or more in the first three weeks, concludes that this form of decompression reduces symptoms and improves activities of daily living [44]

5. Treatment of 94 outpatients with chronic discogenic low back pain with the DRX9000: a retrospective chart review, Journal of Pain Practice, 2008:

Concluded that chronic low back pain may improve with DRX9000 spinal decompression; there is a need for randomized double-blind trials are needed to measure the efficacy of such systems [45]

6. Prospective Evaluation of the Efficacy of Spinal Decompression via the DRX9000 for Chronic Low Back Pain, Journal of Medicine, 2008:

16 out of 18 patients reported clinically significant pain improvement after noninvasive spinal decompression via utilizing the DRX9000 for 20 treatment sessions being enrolled in a 6 week course [46]:

7. The Effect of Motorized Spinal Decompression Delivered Via SpineMED Combined with Physical Therapy Modalities for Patients with Cervical Radiculopathy:

The study suggests that the use of motorized spinal decompression delivered via SpineMED combined with physical therapy modalities appears to be a safe and efficacious, noninvasive treatment modality for patient with cervical radiculopathy [27]

The following studies are literature reviews regarding studies of non – surgical decompression.

1. Systematic Literature Review of Spinal Decompression Via Motorized Traction for Chronic Discogenic Low Back Pain, Journal of Pain Practice, 2006:

Literature search was performed from 1975 to October 2005; 10 studies were fully analyzed; concluded that scientifically more rigorous studies (better randomization, control groups and standardized outcome measures) are needed to overcome limitations [47]

2. Non-surgical spinal decompression therapy: does the scientific literature support efficacy claims made in the advertising media?, Journal of Chiropractic & Osteopathy, 2007:

Literature search was performed from January 1990 to September 2006; 9 studies were analyzed; concluded that evidence is limited to confirm efficacy of non – surgical spinal decompression due to quality of trials [4]

2.4.5 Utilization Factors

2.4.5.1 Regulation

In the U.S., non – surgical spinal decompression devices are regulated by the Food and Drug Administration (FDA) as class II medical devices granted 510(k) approval under device classification name ‘Equipment, Traction, Powered’ [6].

2.4.5.2 Practice, Setting and Availability

Non – surgical spinal decompression therapy can be applied by chiropractors, physical therapists, or medical physicians trained in the use of these specific devices. Non – surgical spinal decompression devices are widely available in the United States and Canada, although, their utilization seems to be limited to the hands of trained and licensed individuals, due to their high cost and operator requirement. Thus, the therapy session setting is inclined to occur in a chiropractic/medical clinic [6].

2.4.5.3 Cost

The cost of non – surgical spinal decompression devices are priced from \$9,000 to well over \$100,000 each [4]. The typical cost for a session of non – surgical spinal decompression is \$50 to \$100. Most insurance plans cover this therapy that is prescribed by a licensed health provider, though there may be limits on the number of sessions allowed per episode or year [6].

2.5 Chapter Summary

Chapter 2 presents a comprehensive review of the literature, specifically concentrating on back pain, the evolution of traction to spinal decompression devices and spinal decompression therapy with an overview on mechanical effects, physiological effects, indications, contraindications, application factors, clinical studies and utilization factors. Distinguishing between different types

of devices and an analysis on current devices commercially available in the market is presented. Through this review, the need for user driven non – surgical spinal decompression therapy investigation and accessibility of such devices is identified. Non – surgical spinal decompression therapy has become a popular alternative for surgical back pain methods, although, the lack of user driven elements limits its potential.

Chapter 3: Mechanical Design

3.1 Introduction

The mechanical design chapter concentrates on three categories that include transmission design, restraining mechanisms design and structural design. The transmission design consists of the specific actuation arrangement and driving components to drive and control the USD system. The restraining mechanisms are the physical components involved in isolating specific spinal regions including the lumbar spine and the cervical to lumbar spine. The structural design of the USD system consists of the components involved in holding the table together, the strategic design for accommodating various individual heights, anatomical positions and compact ability. The following chapter includes a section on design constraints that concerns the mechanical design in general, a section on each of the three categories mentioned above, along with embedded requirements, experiments that took place and the outcome of the final design.

3.2 Design Constraints

Constraints guide the design process; the following is a list of constraints associated with the mechanical design of the USD prototype:

- Anthropometry: It is encouraged for medical devices to be sized to accommodate adult users who range from a 5th-percentile female to a 95th-percentile male in size, theoretically providing coverage for 90% of the user population [48]. Thus, the USD system shall be sized accordingly, utilizing the recommended NASA Man – Systems Integration Standard of Anthropometry and Biomechanics for human dimensions and joint range of motions [48],

[49]. The range of stature heights the USD will accommodate is from 148.9 cm, 5th percentile female, to 190.1 cm, 95th percentile male [49]. In addition, the USD system should be capable of bearing the weight of a 5th percentile female to a 95th percentile male, which is 90.4 lbs. to 217.2 lbs., respectively, according to the NASA Man – Systems Integration Standard of Anthropometry and Biomechanics [49].

- Human Performance Capabilities: The USD system requires the user to perform certain physical actions, thus human performance capabilities shall be taken into account by utilizing the Handbook of Manufacturing Engineering for certain standards and values [50].
- Split Table Design: The USD system shall encompass a split table design. The significance of a split table design in non – surgical spinal decompression systems is outlined in Section 2.4.3.1.1.
- Cost: The cost of components and manufacturing required affects the overall design. The USD system is supposed to be cost effective in the long run. Thus, components utilized to create the USD system shall be kept to a minimum, which is considered during the design process.
- Manufacturing: All required machining shall be produced in Carleton University's Mechanical and Aerospace Engineering department machine shop by the researcher due to the high costs of local machine shops. In addition, the assembly of the USD system will take place in Carleton University's ABL lab. Manufacturing is considered in the design process to ensure design can be produced with machines available in the noted facilities.

3.3 Transmission System

3.3.1 Design Requirements

The transmission system must be driven by the user who comfortably generates the load utilizing their feet through a pedaling mechanism without the use of an electric motor. As the user increases their pedaling, a greater force should be produced by the actuator. This force mechanism acts through a reduction ratio where the displacement is reduced and the force reflected by the actuator is increased. As stated in Section 1.2, a required objective is for the pedaling mechanism to contain numerous options for the user to choose from. Thus, the pedaling mechanism incorporated shall have the following requirements:

- Full pedal plate able to accommodate one or both feet adhering to individuals who may only be able to utilize one foot,
- Pedal joint that can be operated at a fixed position or freely rotating adhering to user preference,
- Pedal joint that can accommodate the feet in the plantar or dorsi flexion position adhering to different anatomical positions,
- Stroke length that can be achieved by both the 5th percentile female and 95th percentile male, in the event that a user prefers to do full pedal strokes,
- The ability to automatically return or manually return the pedal by the user, where an automatic return refers to a spring return mechanism and manual return is the user pulling the pedal back by having their feet strapped in, and
- The ability to provide the foot force reading as user is pedaling.

The actuator incorporated will not only be required to provide a load to the spine, but must be capable of displacing enough to stretch the spine.

The transmission system will incorporate components for communication to control the load limits and precisely release the load when specified. In addition, it will be able to adhere to machine set limits minimizing the potential for injury. The transmission system shall also be able to maintain a specific load for any time requirement.

3.3.2 Design Overview

3.3.2.1 System Selection

The system utilized for the transmission system must contain the least number of components to produce the required function as a requirement of simplicity in design. Several options were considered for the transmission system, although, a pneumatic system was selected due to the feasibility in easily replacing a compressor with a user operated pump to control a pneumatic actuator. In addition, pneumatic systems require air to operate successfully, where air is abundant and free. The utilization of air reduces hazards significantly as there is a limited occurrence of fires, and leakages in the system do not negatively affect the outside environment. In addition, pneumatic systems are known for their low cost, high power to weight ratio, ease of maintenance, cleanliness, readily available and cheap power source [51]. On the downside, pneumatic systems are known to be loud during operation where this is reduced through the application of ‘silencers’, as is discussed below.

3.3.2.2 Preliminary Design Experiment

A small scale experiment is set up as a means to validate the choice in utilizing a pneumatic system with a user operated pump. The experimental apparatus is set up based on the anticipated

design for the transmission system to analyze how and if a user operated pump can provide compressed air to build up pressure in the pneumatic cylinder, which can then ‘stretch’ the spine through load application and displacement. In addition, a leakage analysis is performed. The main components of the set up include a miniature pneumatic cylinder *Airpel Anti – Stiction Air Cylinder*, a foot pump from Canadian Tire, a load cell from *Transducer Techniques*, a linear guide from *Igus*, a DAQ from *National Instruments* to read load data, a tension spring to act as the restrained spine and a cylindrical block to act as ‘body weight’. Refer to Figure 3.1, below, for the experiment setup.

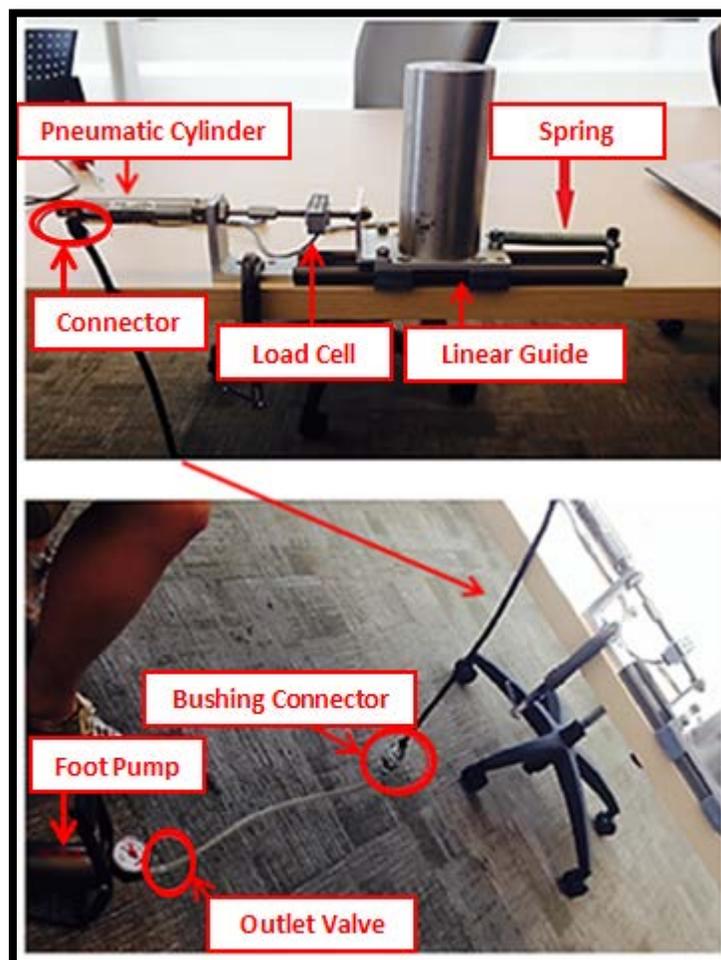


Figure 3.1: Preliminary Design Experiment of a Pneumatic Setup

For the experiment, the user pumped compressed air into the pneumatic cylinder, where the increase in pressure in the pneumatic cylinder caused the piston to be pushed. The piston's attachment to the linear guides caused them to slide with force simultaneously stretching the attached spring with the corresponding load cell capturing the data.

The setup is tested when the pneumatic cylinder is in extension and also tested when it is in retraction to analyze its leakage prevention abilities. Figure 3.2, displays when a pneumatic cylinder is in extension and when in retraction [52]; the red circular shapes in the figure are the locations where possible leakage occurs between the two configurations if the sealants are not sufficient. It is illustrated that in the retraction configuration, there is more potential for possible leakage.

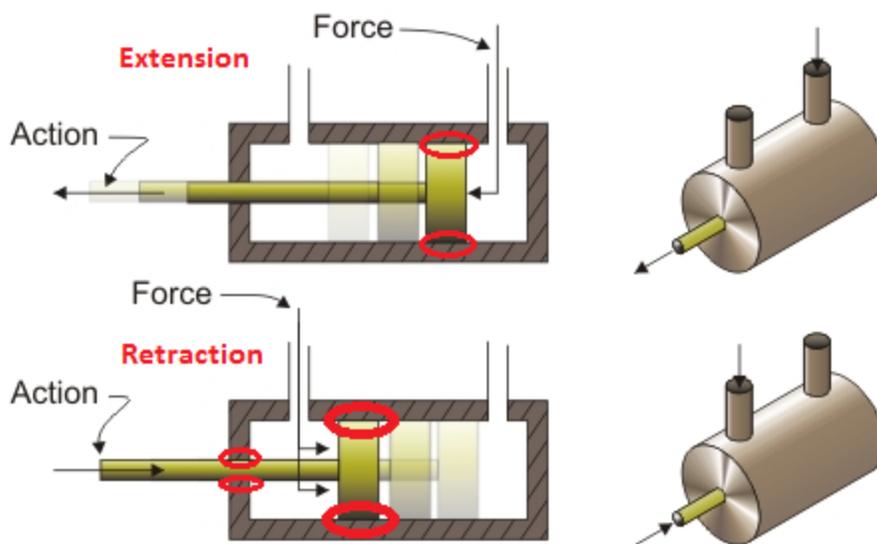


Figure 3.2: Double Acting Pneumatic Cylinder in Extension and Retraction

As the anticipated design is required to have a non-back drivable system, leakage prevention is a must. Any sort of leakage will result in pressure loss and hence will dismiss the non-back drivable requirement.

The experiment proved the system was capable of delivering an applied load and displacement through a user operated pump, which was one of the major goals set for the actuation system. However, the following observations were detected, and implemented solutions for the final design are noted:

- Observation #1: The pneumatic cylinder leaked in extension and retraction, but more so in retraction due to more exposable areas. The specific cylinder utilized is classified as anti – stiction which contains little to no sealant reducing friction
 - Implemented Solution: A high quality pneumatic cylinder with incorporated sealants is acquired to act as actuator and utilized in extension
- Observation #2: The foot pump leaked some air before reaching its outlet valve when not pumping fast enough. This is due to little or no sealant
 - Implemented Solution: Off the shelf foot pump is not utilized, but a custom designed foot pump including a high quality pneumatic cylinder with incorporated sealants and coordinated valves
- Observation #3: There is evident leakage where there are connections, specifically, where thread is involved
 - Implemented Solution: Thread seal tape, also known as Teflon tape, is utilized on connections in the final design

3.3.2.3 Pneumatic Circuit and Components

The pneumatic circuit of the final design for the transmission system is represented in Figure 3.3; it contains numerical labeling to coincide with the actual 3D components of the transmission system as shown in Figure 3.4. All components were purchased from *Festo Canada*.

Descriptions of the components utilized are noted in Figure 3.1. The final design of the

transmission system took into account the outcomes of the pre – design experiment. The main components of the final design include a ‘pumper’, an ‘actuator’ and a solenoid valve to regulate the system. Secondary components include pneumatic connections, silencers and a gauge meter.

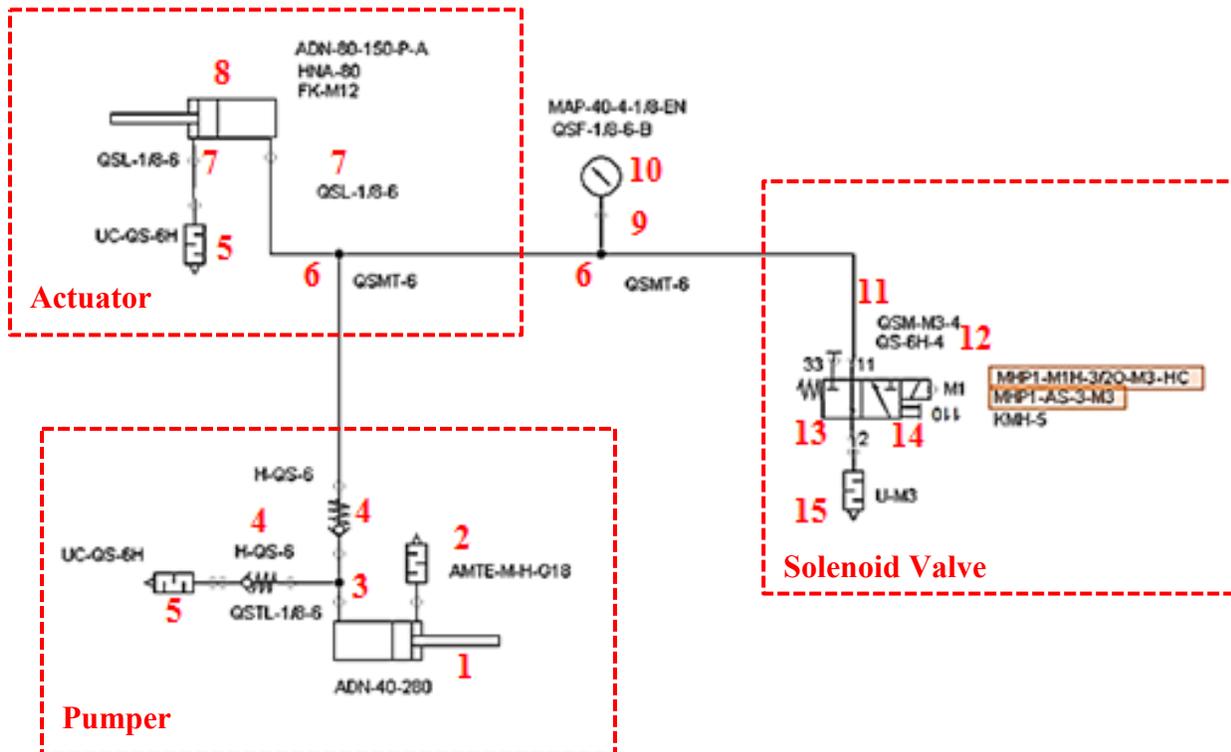


Figure 3.3: Pneumatic Circuit of the USD System

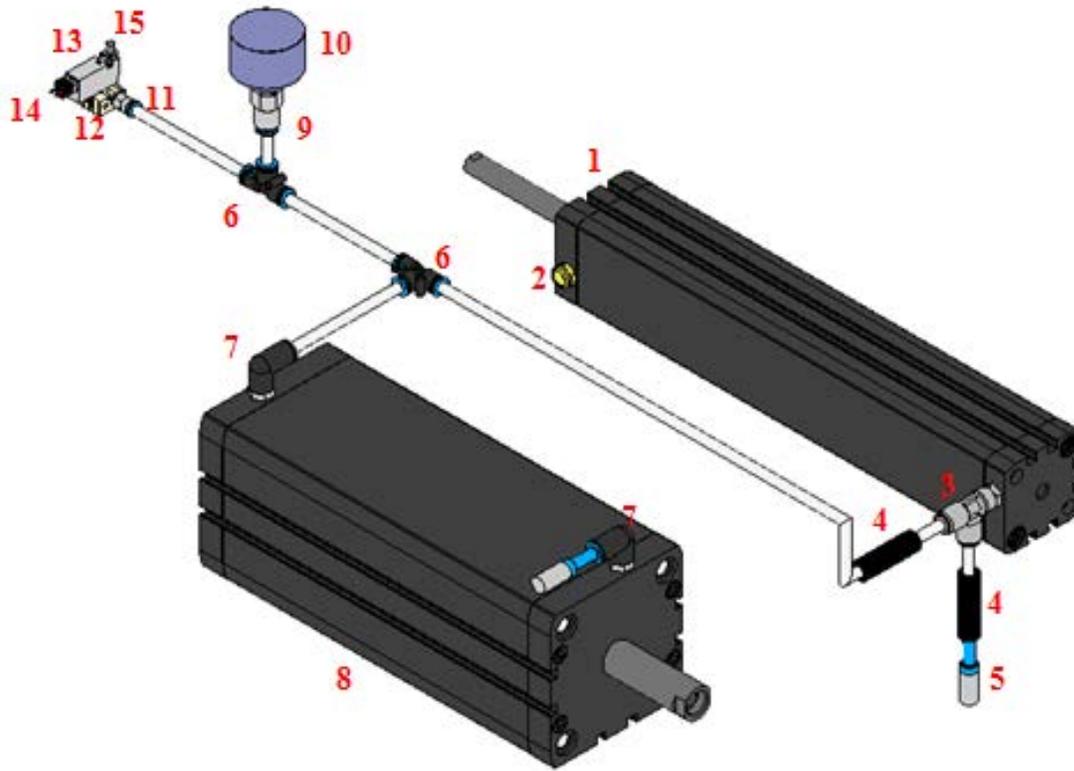


Figure 3.4: USD Assembly of Pneumatic Components

Table 3.1: Pneumatic Components for USD System

<i>Part Number</i>	Name	Description
<i>1</i>	ADN – 40 – 280 – I – P – A Compact Double Acting Cylinder	Diameter of 40 mm, stroke length of 280 mm and female thread for piston rod
<i>2</i>	AMTE-M-H-G18 Silencer	Reduces sound of air pressure at opening
<i>3</i>	QSTL-1/8-6 Push – Pull Fitting	Pneumatic connector

4	H-QS-6 Non – Return Valve	Air can flow only in one direction; part of the ‘pumper’ design
5	UC-QS-6H Silencer	Reduces sound of air pressure at opening
6	QSMT-6 Push – Pull Fitting	Pneumatic connector
7	QSL-1/8-6 Push – Pull Fitting	Pneumatic connector
8	AND – 80 – 200 – I – P – A Compact Double Acting Cylinder	Diameter of 80 mm, stroke length of 200 mm and female thread for piston rod
9	QSF-1/8-6-B Push – Pull Fitting	Pneumatic connector
10	MAP-40-4-1/8-EN Pressure Gauge	Manual pressure gauge reading
11	QSM-M3-4 Push – Pull Fitting	Pneumatic connector
12	MHP1-AS-3-M3 Individual Sub Base	Component integrated with solenoid valve
13	MHP1-M1H-3/2O-M3-HC Solenoid Valve	3 port 2 position, 5V operated valve, normally open, does not require a minimum pressure to

		operate
<i>14</i>	KMH-5 Connector Plug	Electrical plug
<i>15</i>	U – M3 Silencer	Reduces sound of air pressure at opening

The ‘pumper’ design follows the conventional off the shelf foot/bike pump, but with higher quality components to ensure leakage prevention. Foot/bike pumps usually contain a piston, compression chamber, an inlet valve and outlet valve. As one raises the piston, the inlet valve opens up to grab air from the atmosphere with the outlet valve closed, as one pushes down on the piston, the outlet valve opens and compressed air is pushed through to the tire. It must be noted as the air is compressed further, in each step of pumping, larger resistance forces are expected, thus larger input forces should be exerted by the pumper (user’s feet).

Aside from the pneumatic connectors and silencers, the ‘pumper’ design for the transmission system consists of a double acting pneumatic cylinder and two non – return valves; one acting as an inlet valve and the other as an outlet valve positioned in opposite direction; refer to Figure 3.5, which provides an illustrative explanation.

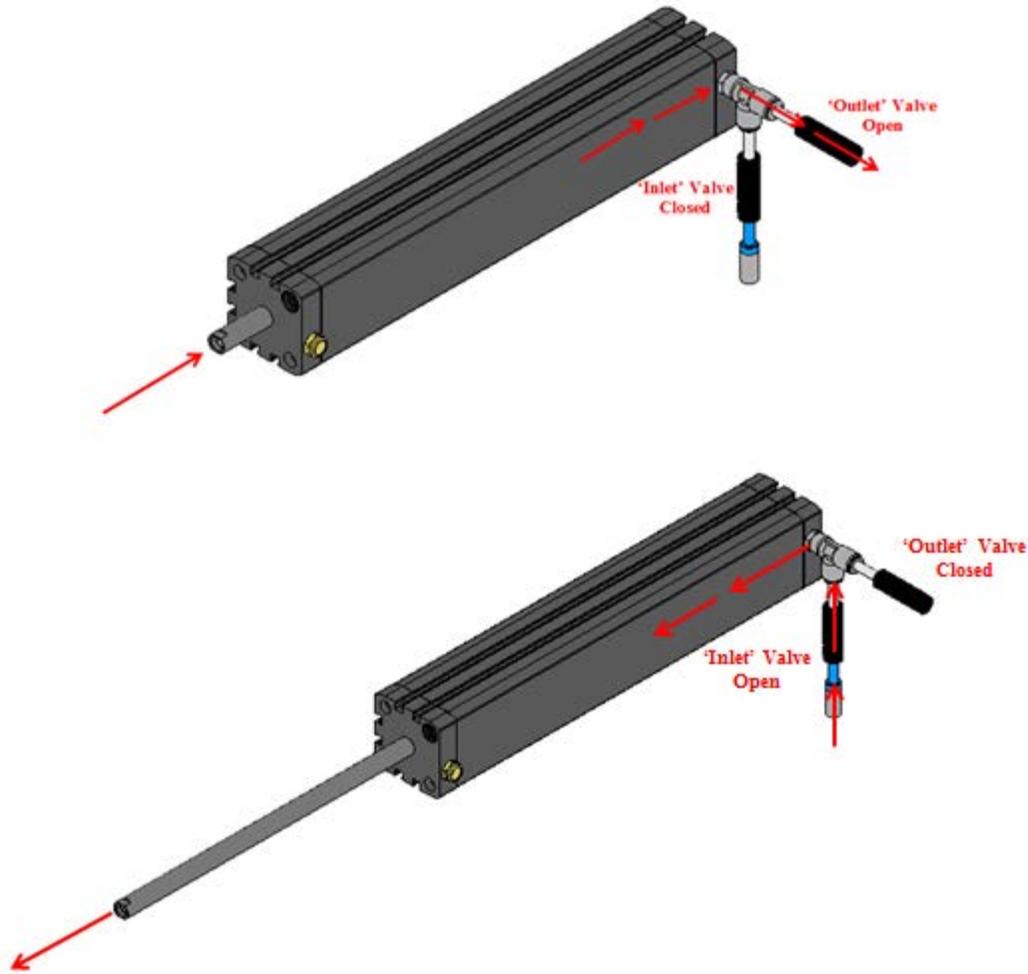


Figure 3.5: Analysis of the USD 'Pumper'

The solenoid valve is an integral part of the transmission system in terms of implementing the logic control mechanism anticipated for the USD. Specifically in maintaining the pressure at a distinct load, releasing pressure to reduce to a specific load and to ensure releasing all load safely when required. The solenoid valve is normally open meaning that when the USD system is not in 'start' mode any pressure build up by the user accidentally pumping is dissipated to the atmosphere. In addition, it does not require a minimum operating pressure as most commercial valves do, this is important for the USD system, as pressure accumulation in the actuator is required upon initial push from the user.

A graphical explanation of how the transmission system functions when the solenoid valve is open is displayed in Figure 3.6. The flow of air is highlighted red and shows that air pushed via pumper or air that has been accumulated in the actuator will escape through the opening of the solenoid valve.

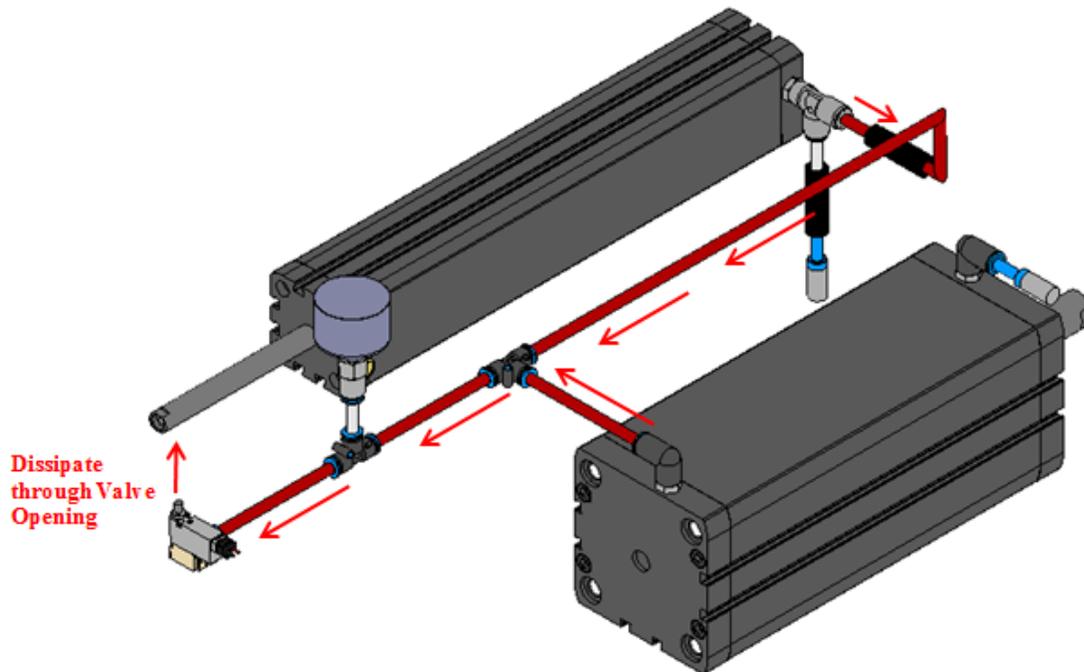


Figure 3.6: Flow of Pressure when the Solenoid Valve is Open

A graphical explanation of how the transmission system functions when the solenoid valve is closed is displayed in Figure 3.7: Flow of Pressure when the Solenoid Valve is Closed. All air pushed in will accumulate in the actuator, which is the larger of the two double acting pneumatic cylinders.

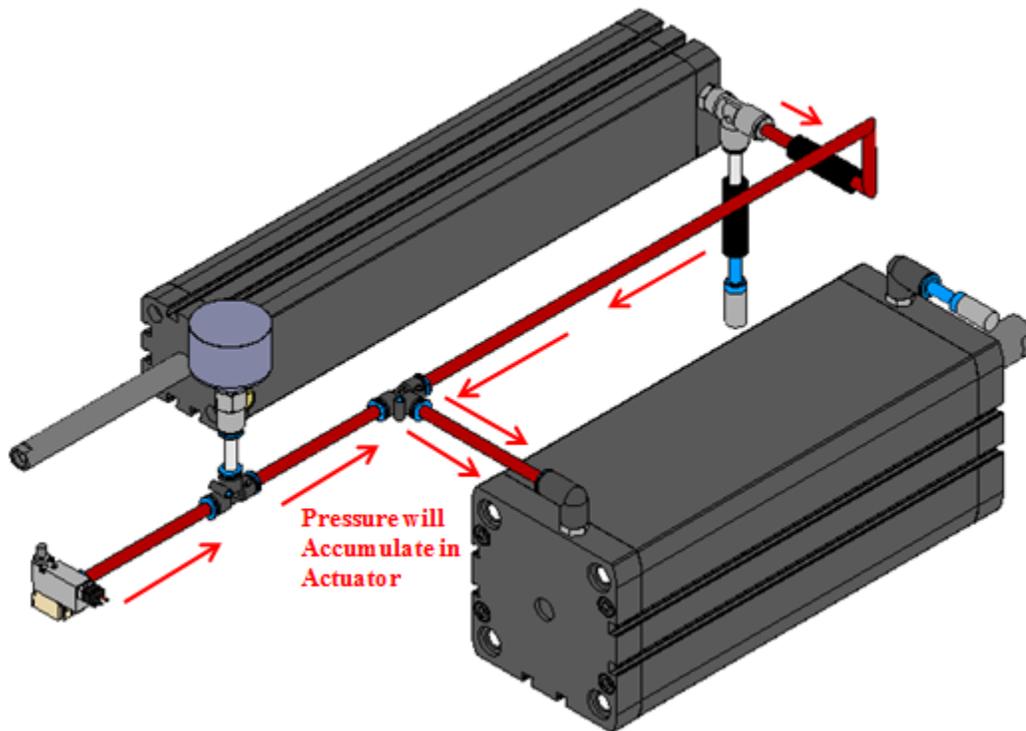


Figure 3.7: Flow of Pressure when the Solenoid Valve is Closed

3.3.2.4 Development of Parameters

The following parameters for the transmission system are developed based on anthropometry and human performance capabilities as discussed in Section 3.2 Design Constraints:

- Pedal Stroke Distance,
- Foot Force Capability,
- Actuator Stroke Length (USD Displacement),
- Maximum Loading, and
- Reduction Ratio – Sizing of Pneumatic Cylinders.

Pedal Stroke Distance and Foot Force Capability

In the USD system, the user must linearly pedal to create a force build up. The pedal stroke distance is the distance an individual pushes the pedal, thus, it is specifically the length of the ‘pumper’ piston, pneumatic double acting cylinder. As the system is designed to accommodate from the 5th percentile female to the 95th percentile male, the pedal stroke distance shall be the minimum capable stroke distance by this group, which is based on the 5th percentile female. Data regarding leg strength, comfortable starting knee angle and limiting knee angle is taken from the Handbook of Manufacturing Engineering, specifically utilizing the *Leg Strength at Various Knee and Thigh Angles* chart for a 5th percentile male, refer to Figure 3.8 [50]. The angles are depicted for the 5th percentile male, but can also be utilized for the 5th percentile female, although, in terms of strength, it is noted for lower extremities; women’s strength is 64.2 % of men’s.

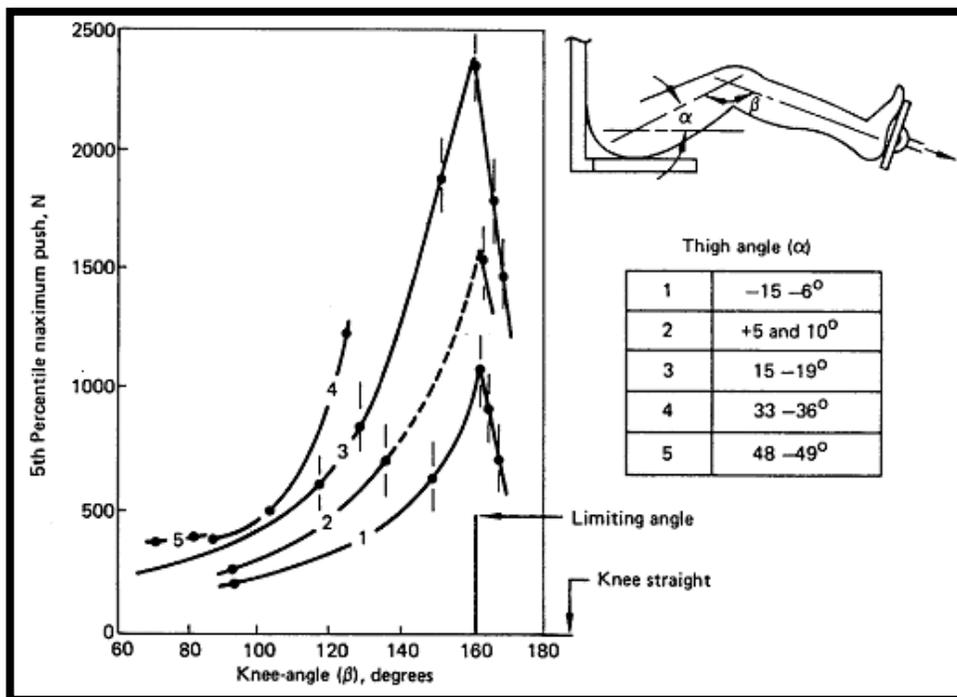


Figure 3.8: Leg Strength at various Knee and Thigh Angles

Analyzing Figure 3.8, a safe starting angle of 75° is selected and the limiting angle of 160° is selected as the ending angle to determine the pedal stroke distance. The thigh length is 35.1 cm and tibial length is 35.9 cm with a total trochanteric height of 71 cm for a 5th percentile female, refer to Figure 3.9.

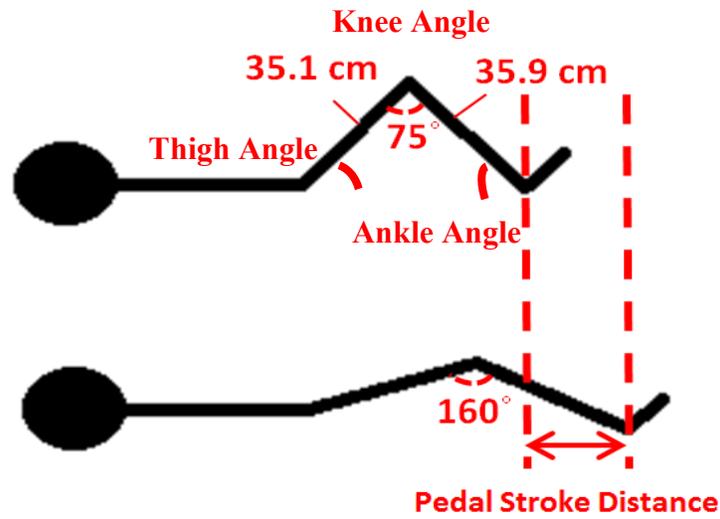


Figure 3.9: Pedal Stroke Distance Depiction

A simulation of the anticipated thigh angle, ankle angle, knee angle with corresponding pedal stroke distance is displayed in Figure 3.10, where trigonometry is utilized. The anticipated pedal stroke distance capability of the 5th percentile female is calculated to be 27.6948 cm, thus a rounded pedal stroke distance of 28 cm is utilized suiting industry available sizes.

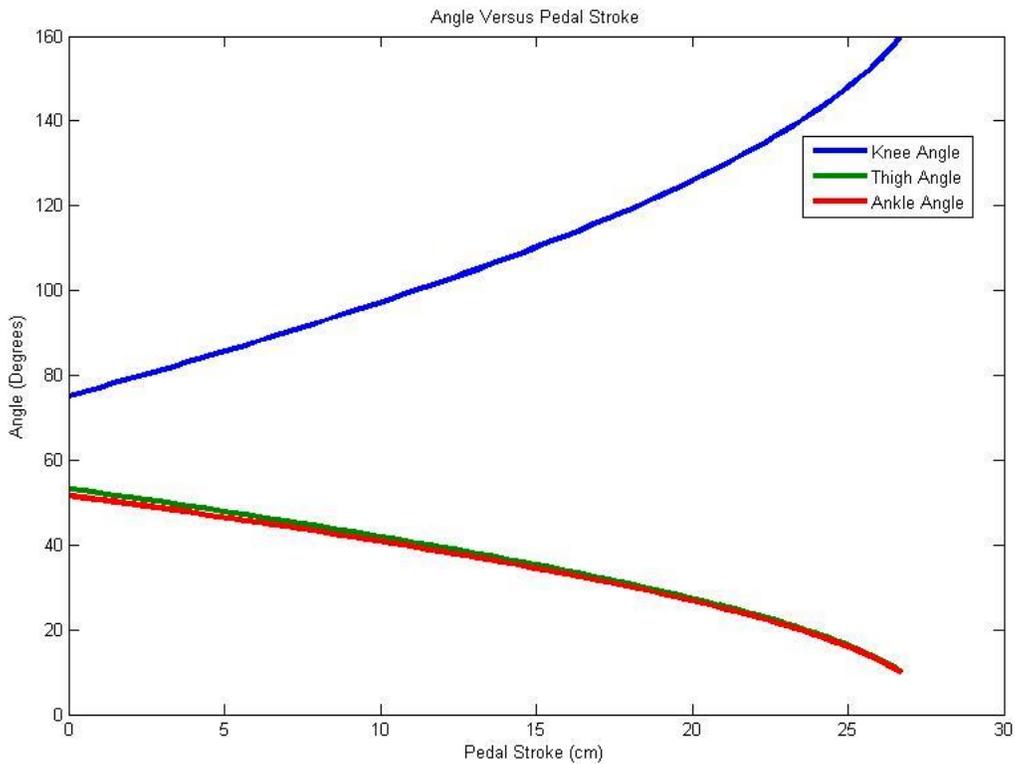


Figure 3.10: Angle versus Pedal Stroke

In terms of foot force capability, the thigh angle is anticipated to range from approximately 53° to 10° with a 75° to 160° knee angle, respectively, through a full pedal stroke, thus, analyzing the chart above, the 5th percentile male can produce a force range of approximately 400 N to 1600 N, equivalent to approximately 90 lbs. to 360 lbs. As noted, for lower extremities, women's strength is 64.2 % of men's, thus, 5th percentile female leg strength is approximately 58 lbs. to 231 lbs. Thus, for the USD design, the 5th percentile female shall not need to exert a force over 58 lbs. to reach desired load.

Actuator Stroke Length and Maximum Loading

In the USD system, displacement of the table along with an axial load is essential to stretch the spine, the total allowable displacement is guaranteed through the actuator stroke length via the piston of the pneumatic double acting cylinder. The actuator stroke length shall take into account the gripping distance, spine displacement in tension and slipping distance.

As the spine is seldom subjected to a full tensile load under normal physiological activities, there are few experiments that have been done to determine the tensile properties of the Intervertebral disc and hence the spine displacement in tension [11]. One notable experiment where a longitudinal tensile load is applied to cadaver segments, “Sustained Lumbar Traction an Experimental Study of Long Spine Segments”, depicts the greatest displacement as 16 mm under a load of 9 kg. Although, it is noted that the lordosis of the lumbar spine has been already straightened prior to loading, which can be a considerable length to account for [53]. Thus, an estimate of 5 cm will be added for precaution to the 16 mm length.

As for the ‘gripping’ distance, this is noted as the distance it takes for the restraints such as the pelvic or upper body restraint to fully grasp on the intended body part. There is no official data, but it’s approximated to range anywhere from 0 – 5 cm with appropriate placement of the restraint.

A total of 11.6 cm is approximated for required displacement for the USD system, for precaution this value is raised to 20 cm to account for ‘slipping’, which is the distance due to the restraint slipping during spinal decompression.

In terms of maximum loading, as the literature review states that 20 – 50 % of body weight loading is required to provide intervertebral separation and some papers state higher than that [31]. Thus, in terms of loading the USD system shall accommodate the 95th percentile male; the

95th percentile male weighs 217.2 lbs. [49], thus 50% of this weight is 108.6 lbs. For feasibility of the USD system in terms of loading capability, it shall be able to accommodate up to 150 lbs. for precaution.

Reduction Ratio – Sizing of Pneumatic Cylinders

The reduction ratio depends on the diameter sizing of the pneumatic cylinders incorporated. Specifically, the pumper diameter must be smaller than the actuator diameter, for a greater actuator force to be reflected. That is the foot force applied to the pump will result in a higher actuator load by a multiplication of the ratio of areas.

As discussed earlier, literature states that 20 % - 50% of body weight loading is required [31], thus, Table 3.2, represents the maximum prescribed loading anticipated for the USD system from the 5th percentile female to the 95th percentile male, 45.2 lbs. to 108.6 lbs., respectively. In addition, available sizes of pneumatic cylinders sold in the market are also taken into account when selecting the reduction ratio.

Table 3.2: Range of Loading Prescription

	Weight (lbs.)	20 - 50 % of Weight (lbs.)	Maximum Prescribed Loading (lbs.)
<i>5th Percentile Female</i>	90.4	18.08 - 45.2	45.2
<i>95th Percentile Male</i>	217.2	43.44 - 108.6	108.6

In terms of the above, a pumper diameter of 4 cm and actuator diameter of 8 cm is a suitable match. The corresponding areas are 1.95 in² and 7.79 in², respectively, resulting in a reduction ratio of 4. When a force is applied to the pumper and the outlet valve opens these results in a confined fluid where any pressure change occurs, it will occur everywhere throughout this space

following Pascal’s principle, refer to (3.1), where the designation 1 refers to the ‘pumper’ pneumatic cylinder and the designation 2 refer to the ‘actuator’ pneumatic cylinder; P, F and A represent the pressure inside the pneumatic cylinder, resulting force and cross sectional area of the pneumatic cylinder, respectively.

Thus, to reach a maximum load of 45.2 lbs. for a 5th percentile female, the user must apply a feet force of 11.3 lbs., similarly, for a 95th percentile male to reach a maximum load of 108.6 lbs., the user must apply a feet force of 27.15 lbs.

$$P_1 = \frac{F_1}{A_1} = P_2 = \frac{F_2}{A_2} \tag{3.1}$$

Application of 11.3 lbs. feet force to reach the maximum anticipated prescribed loading of 45.2 lbs. for a 5th percentile female is low in comparison to their capable strength of 58 lbs. [50]. This is implemented because the reduction ratio analysis is implemented neglecting any loss or outside forces. Thus, the low application of forces is to compensate for any unforeseen losses in the integrated final design; this is discussed in Section 5.3.1.

Overview of Parameters and Preliminary Analysis

Table 3.3, provides an overview of the parameters discussed above.

Table 3.3: Overview of Parameters for Transmission System

<i>Parameter</i>	
<i>Pedal Stroke Distance</i>	28 cm
<i>Actuator Stroke Length</i>	20 cm
<i>Reduction Ratio Area of Pump Area of Actuator</i>	4 1.95 in ² 7.79 in ²

A preliminary analysis is performed to analyze how many pedal strokes it takes the user to reach their maximum load. The ideal gas law is utilized. Each pedal stroke transfers a specific amount of moles to the actuator, which is presented by equation (3.2), where n represents number of moles, p is absolute pressure, V is volume, R is gas constant and T is temperature. Thus, the total number of strokes required is the required number of moles to reach maximum loading divided by the number of moles a pedal stroke provides, which is presented by equation (3.3), and results in equation (3.4), where p , A and h , represent the absolute pressure, cross sectional area and height of the designated pneumatic cylinder, respectively.

$$n = pV/\bar{R}T \quad (3.2)$$

$$N = \frac{n_{MaximumLoading}}{n_{PedalStroke}} \quad (3.3)$$

$$N = p_2A_2h_2/p_1A_1h_1 \quad (3.4)$$

Utilizing equation (3.4), the number of strokes calculations for the 5th percentile female to attain 45.2 lbs. is 2.31 strokes and for the 95th percentile male to attain 108.6 lbs. is 3.23 strokes, which is very conservative, but this is maintained due to anticipated friction loss and unforeseen forces.

3.3.2.5 Pedal Design

The pedal design consists of an incremental angle position hinge that has a 220° range of motion with adjustment increments of 10° to lock in place [54]; refer to Figure 3.11. Thus, the pedal can be utilized in plantar flexion or dorsi – flexion. In addition, the joint can be clamped in making it freely rotatable. Thus, the pedal joint can be operated at a fixed position or freely rotated. For a manual return, straps are incorporated for user to pull pedal back; refer to Figure 3.12. For an automatic return, a constant spring is incorporated that brings the pedal back automatically; refer to Figure 3.13. For inquiry regarding plate design of pedal, refer to Section 4.2.1.2.

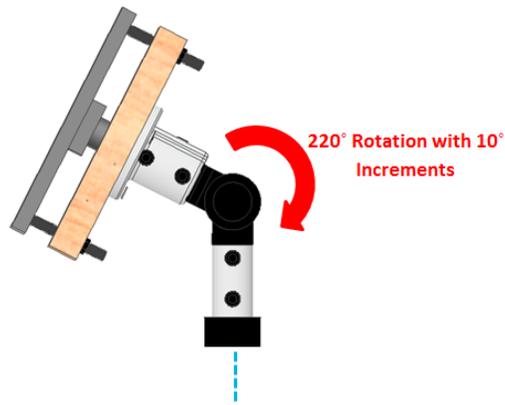


Figure 3.11: Pedal Joint Range of Motion

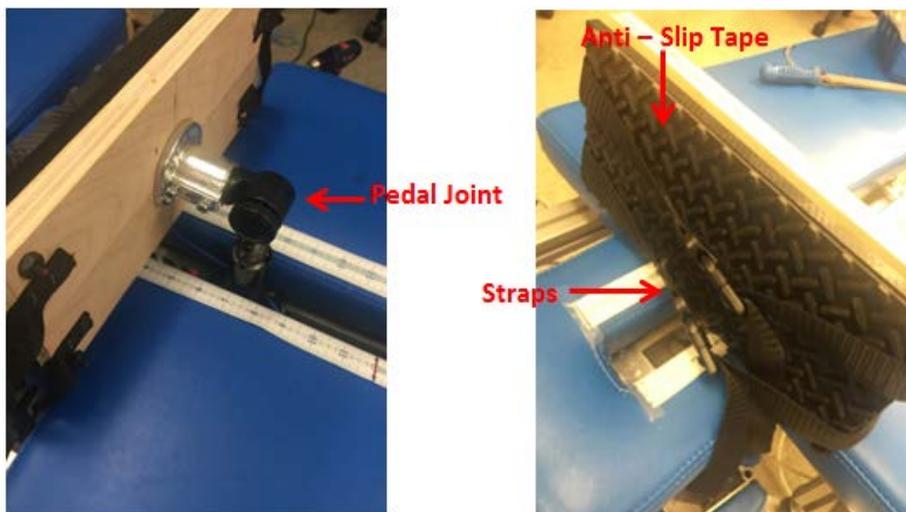


Figure 3.12: Pedal Design Attributes

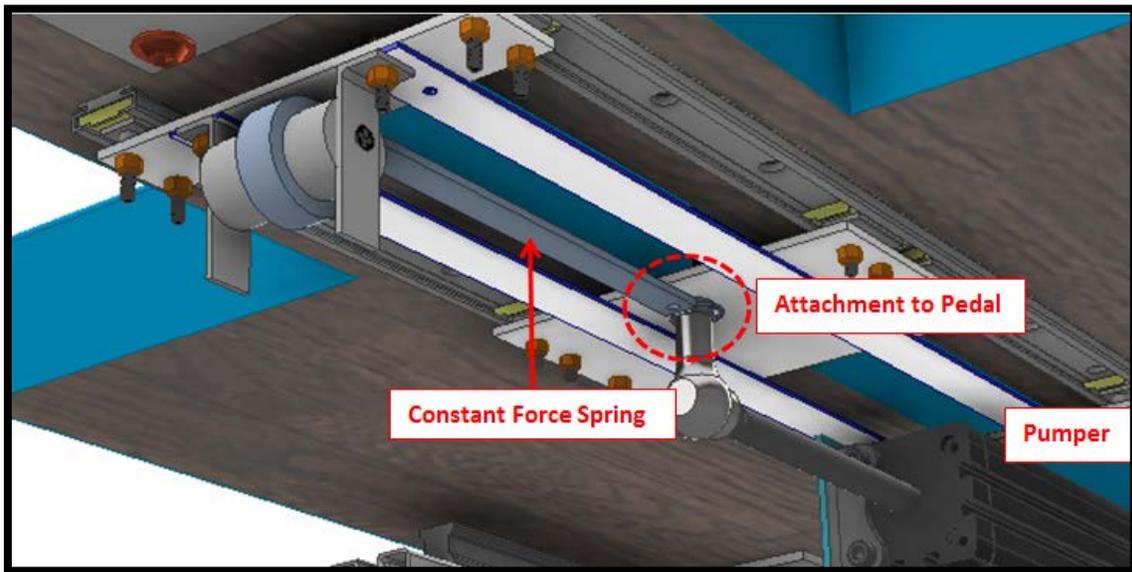


Figure 3.13: Constant Force Spring Attachment to Pedal

3.4 Restraining Mechanisms Design

The restraining mechanisms are physical components involved in isolating specific spinal segments for spinal decompression where one part of the spinal segment is held in place and another part is pulled through cyclic application of desired forces. Different restraint combinations are required to accommodate for different anatomical positions in the USD system that include the supine position and the prone position. In addition, different restraint combinations are required to accommodate for different spinal segment treatments in the USD system that include the lumbar spine and the ‘full’ (cervical to lumbar) spine. Permissible combinations of spinal segment and anatomical position with the required restraints for acceptable spinal decompression treatment are displayed in Figure 3.14. Lumbar spinal decompression can be performed in the supine or prone position, both requiring an upper body and lower body restraint. While the full spine spinal decompression can only be performed in the supine position, which requires a neck and lower body restraint. Each required restraint such as

upper body or lower body category has various options of restraints to choose from in the USD system, which are discussed in this section.

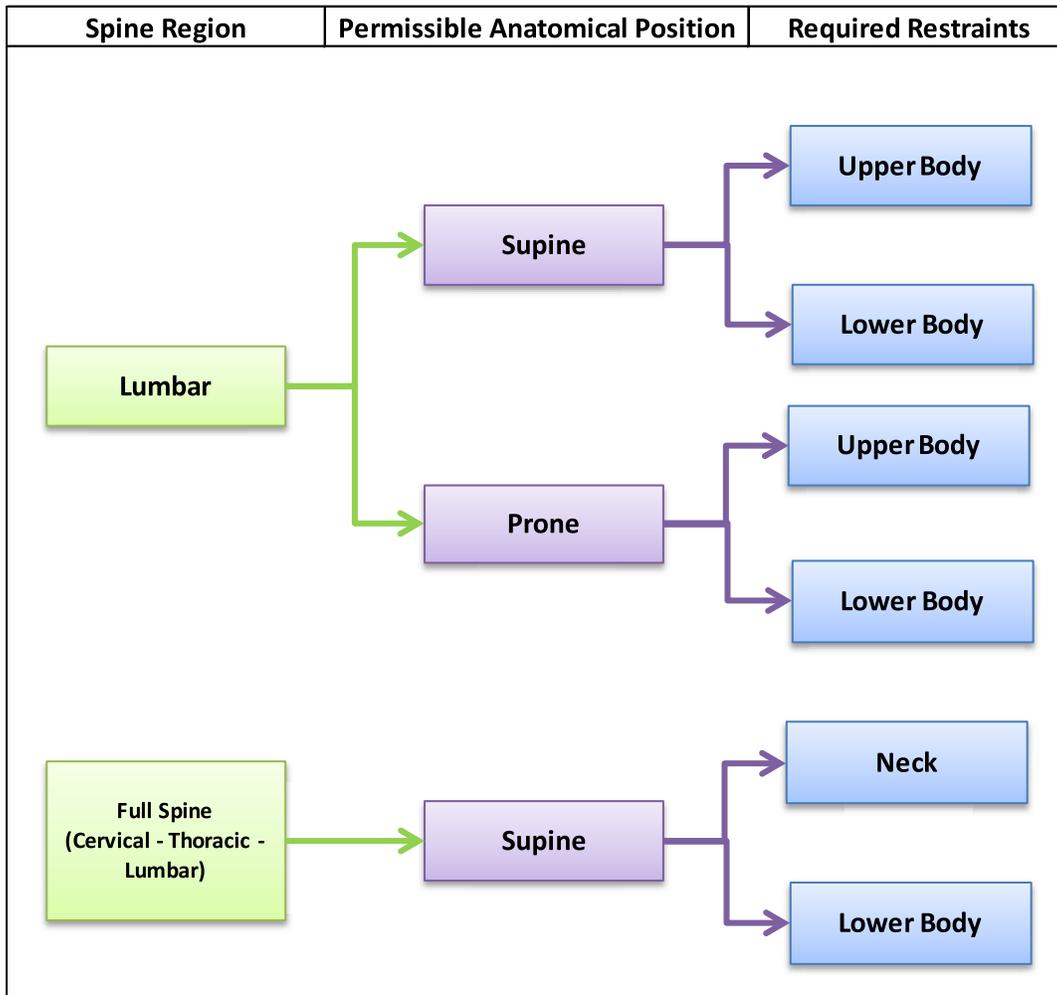


Figure 3.14: Permissible Combinations with Required Restraints

The following generic requirements are essential for the design of the restraints and they include:

- Point of contact to body must be soft ensuring user comfort;
- Easy adjustability to accommodate for the 5th percentile female to the 95th percentile male;
- Non – slip material resulting in firm grip resisting pulling force; and
- Novelty in design.

The following restraining components are utilized in the USD system and their design is discussed in upcoming subsequent sections:

- Upper body restraint
 - Axilla posts
 - Upper body strap
 - Axilla posts + upper body strap
 - Hand posts
- Lower Body Restraint
 - Pelvic Posts
 - Lower Body Strap
 - Pelvic posts + lower body strap
- Neck Restraint

To distinguish between which restraints combinations such as which distinct upper body and lower body are utilized for specific spinal regions/anatomical positions, refer to Figure 6.3 in section 6.1.

3.4.1 Upper Body Restraint

The upper body restraint is fixed right below one's shoulders, specifically under one's armpits. It is utilized to fix the upper mid portion of the human spine, specifically, for spinal decompression

treatment to the lumbar spine. The upper restraints to be experimented with are upper body strap, axilla posts and hand restraints.

Upper Body Strap

The upper body strap exhibits novelty in design, it utilizes a stretchable non – slip material, where the inside is of Teflon texture. It is permanently connected to the unmovable upper body table piece through two connections, one is the orange straps stapled to the wood and two is the adjustable buckle straps also connected to the wood. The strapping mechanism ensures a distributed grip. It's non – slip material is crucial in ensuring the upper end of the lumbar spine is intact during spinal decompression. The intactness of the upper body strap is analyzed during experiments; refer to chapter 6. Lastly, the straps are adjustable to accommodate various sizes; refer to Figure 3.15. In addition, refer to section 6.5, for visualization of a user encompassed with restraining mechanism.



Figure 3.15: Upper Body Strap

Axilla Posts

The axilla posts are widely utilized in commercially available non – surgical spinal decompression devices to restrain the upper mid portion of the human spine, specifically, for lumbar spinal decompression. They are two posts where each post is fixed right under the armpit of the individual. Its wide usage evokes effectiveness, its design is known to provide an effective grip, although, there is incentive for further effectiveness in terms of user comfort.

Axilla Posts plus Upper Body Strap

The combination of utilizing the axilla posts with an upper body strap as one upper body restraint for lumbar spinal decompression exhibits novelty. The reasoning behind combining the two components is based on a predicament that the utilization of both will provide better grip and less slippage during spinal decompression. The axilla posts contact point is concentrated on the armpit, while the strap’s contact point on the human body is distributed across the upper body, it is predicted that the combination of the two will incite user preference.

The utilization of axilla posts, upper body strap or both for upper body restraint during spinal decompression therapy is analyzed in chapter 6.

Hand Restraint

In the prone anatomical position for lumbar spinal decompression treatment, the user lays flat on their stomach in the USD system. The upper body restraints mentioned above are not suitable in the prone position. The majority of non – surgical spinal decompression devices utilize ‘hand restraints’, although the current designs are limited in their adjustability, specifically providing only one degree of freedom in hand grasping. Examples of such hand restraints can be found utilized by well – known non – surgical spinal decompression devices that include the Kennedy Table and the Triton DTS [55], [56].

The upper body hand restraint for the USD prone lumbar treatment is displayed in Figure 3.16. It consists of an arm rest that can easily slide through the aluminum profile grooves. It is conjoined with an in house manufactured 90° elbow for the hand to grasp on with a non – slip covering. The new design has many forms of adjustability to pertain to the user’s desired setting ensuring comfort; the forms of adjustability and locking methods are displayed.



Figure 3.16: Hand Restraint Design for USD System

3.4.2 Lower Body Restraint

The lower body restraint is utilized to grasp the pelvic area of the human body, and it is required for both lumbar and cervical to lumbar spinal decompression treatment. In addition, it is required for both anatomical positions, supine and prone. While all restraints play a significant role in restraining the spinal segment of interest, the lower body restraint is the most challenging in ensuring an effective design, due to the likelihood of slippage as a result of the pelvic shape in comparison to upper body obstructions. The lower body restraint not only needs to have a tight holding grip on the pelvis, but must ensure its integrity and grip on the pelvic while the restraint is being pulled via actuator. During this ‘pulling’, the restraint’s tight grip on the pelvis should simultaneously pull the pelvis along producing the stretching action.

Pelvic Posts

For the USD system, a new design is implemented that is not currently commercially utilized with non – surgical spinal decompression or traction devices. The novelty in the design is the use of a post component that clamps in place to fixate above the iliac crest of the pelvis, also known as the ‘pelvic bone’. As the lower body restraint is pulled via actuator, the restraint gets closer in to the iliac crest, once a tight grip is obtained; the pelvis is pulled simultaneously with the restraint, where the restraint is clamped to the table component of the USD system.

The pelvic posts restraint design and the components it utilizes is displayed in Figure 3.17. The pelvic restraint can be easily adjusted by the user through sliding the two pieces in the groove until a desirable fit is attained and can lock through tightening the knob, thus fitting a range of widths to suit the 5th percentile female to the 95th percentile male. The point of contact from the restraint to the body is high density foam. It is soft enough to ensure user comfort, but not too

soft for the body to feel the metal rod encompassed. Lastly, its texture also provides a non – slip attribute.

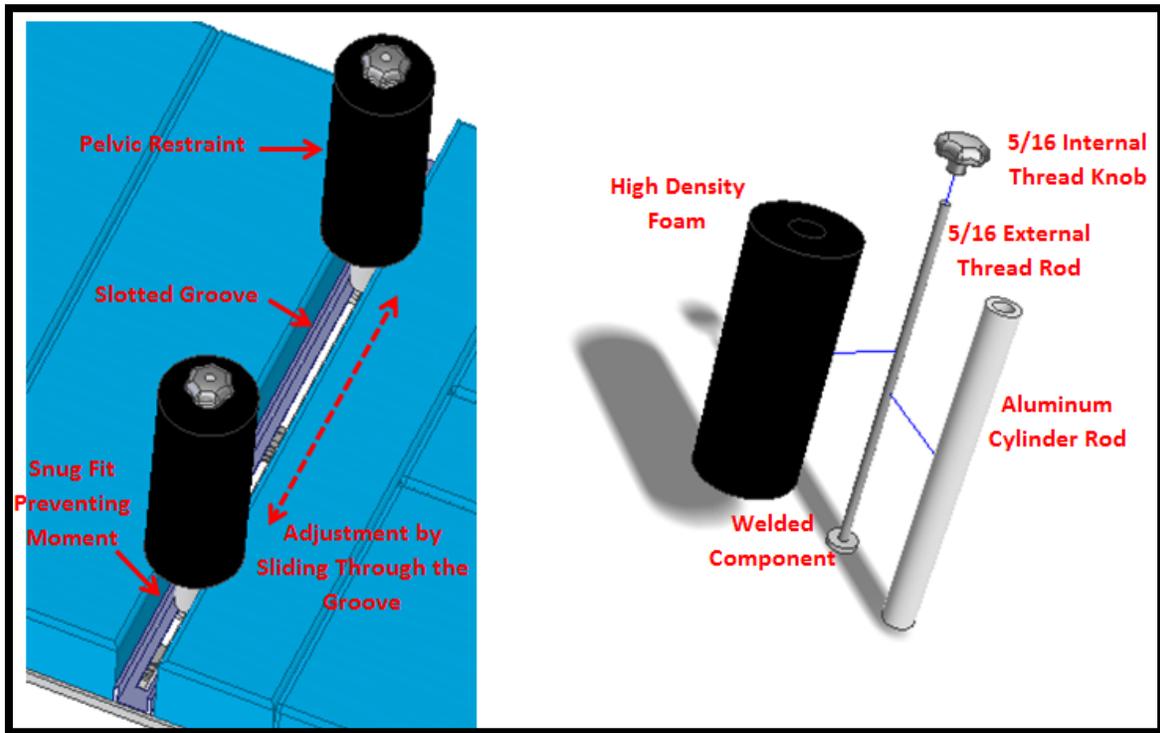


Figure 3.17: Posts Restraint Design

Lower Body Strap

The lower body strap design is identical to the upper body strap discussed above with the exception of the permanent attachment is to the movable table piece as opposed to the unmovable table piece of the USD system.

Pelvic Posts plus Lower Body Strap

Similarly, the combination of utilizing the pelvic posts with a lower body strap as one lower body restraint for lumbar or cervical to lumbar spinal decompression exhibits novelty. The reasoning behind combining the two components is based on a predicament that the utilization of both will provide better grip and less slippage of the pelvic during spinal decompression. The

combination of utilizing both the pelvic posts and lower body strap is displayed in Figure 3.18. The utilization of pelvic posts, upper body strap or both for lower body restraint during spinal decompression therapy is analyzed in chapter 6.

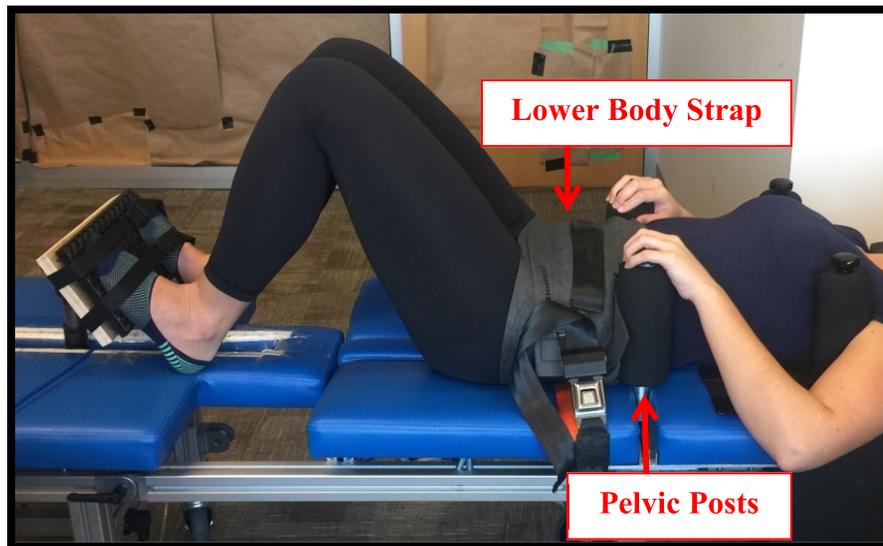


Figure 3.18: Pelvic Restraint Design with Strap

3.4.3 Neck Restraint

The neck restraint utilized for cervical to lumbar ‘full’ spine treatment in the USD system is positioned to restrain the cervical spine in place, it is implemented to not move during spinal decompression treatment. The components utilized for the restraint design include commercially available cervical restraint by Kennedy Decompression Technique and integrated components for suitable integration in the USD system. As the literature review suggested, the cervical spine must angled between 0° - 30° anteriorly, with 20° - 30° for best practice [40], [41], thus, in the USD system the restraint is implemented accordingly by manufacturing components to angle the restraint precisely; refer to Figure 3.19.

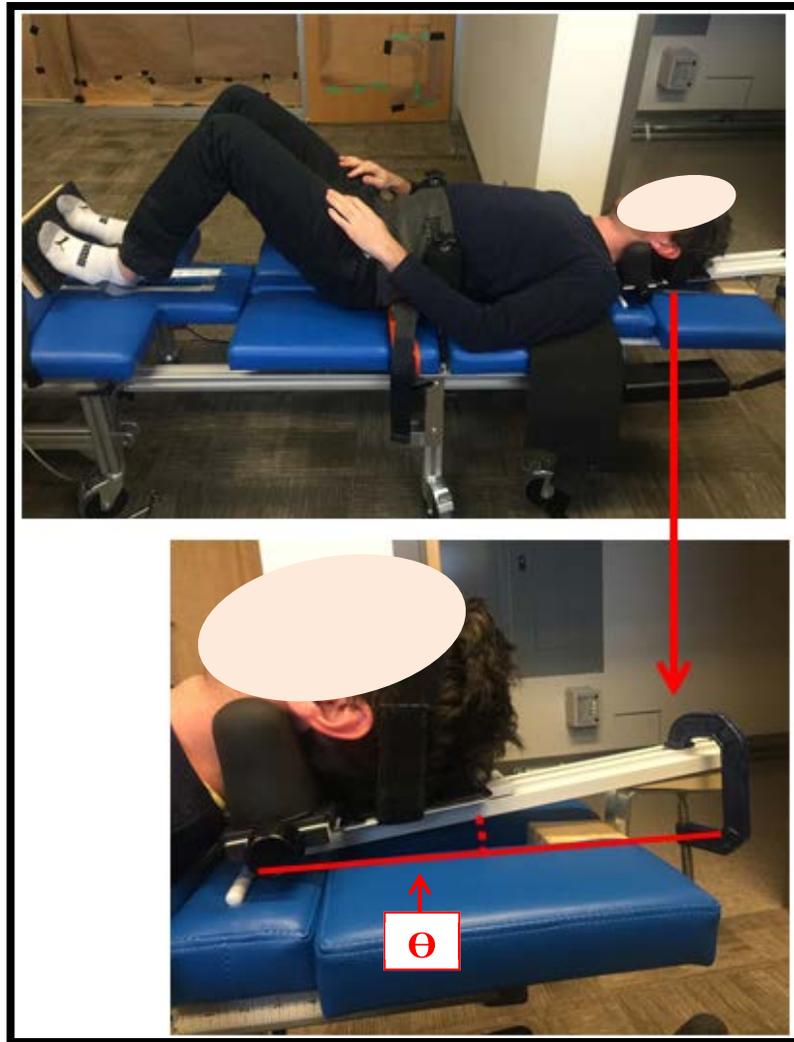


Figure 3.19: Adjusted Cervical Restraint

3.5 Structural Design

The following are requirements for the structural design of the USD system:

- Positional Adjustments: The structure shall contain adjustments to position for different body heights, specifically, from the 5th percentile female to the 95th percentile male; and the structure shall also contain adjustments to position for anatomical positions that include supine or prone.

- Aesthetics and Material: The USD prototype treatment table shall be aesthetically pleasing with comfortable material as a means to encourage participants to participate in the functional experiments.
- Modularity and Portability: These features are a must for the final version of the USD system to ensure in home therapy accessibility. Although, for the first prototype, this is not mandatory, as it is not the main attribute, thus, the requirement is to incorporate some modularity and portability features to experiment with. For the USD to be modular, it must be easily assembled with flexible arrangement. For the USD to have a portability aspect, it means it must be easily carried from one location to another. Thus, the device is to be mobile, mobility guidelines for medical devices include lightweight, as carrying components should not weigh more than 19 kg for short distance walking, up to 10 meters [48]. The USD system shall not be utilized during mobility.
- Integrity: The USD shall be able to sustain the weight of the 5th percentile female to the 95th percentile male. The design shall utilize components that will be easy to disassemble and reassemble through prototyping phase ensuring sustained integrity such as utilizing metal inserts, aluminum grooved profiles, etc.

3.5.1 Positional Adjustments and Accommodation

To accommodate for a range of heights in the USD system, specifically, from the 5th percentile female to 95th percentile male, 148.9 cm to 190.1 cm, respectively, there are positional adjustments that the user can adjust to fit their needs. In the USD system, the pelvic posts restraint is fixed longitudinally, thus, adjustments are made available for the upper body and the lower body. Figure 3.20, displays the upper body adjustment consisting of a 15 cm shift

capability and a lower body adjustment consisting of a 35 cm shift capability. When the adjustments are not utilized and remain in the zero shift position, the USD can accommodate a 5th percentile female with lower extremities ready to pedal, but when the adjustments are fully extended, the USD is intended to fit a 95th percentile male with lower extremities ready to pedal; partial adjustments fit the population between the two extremes.

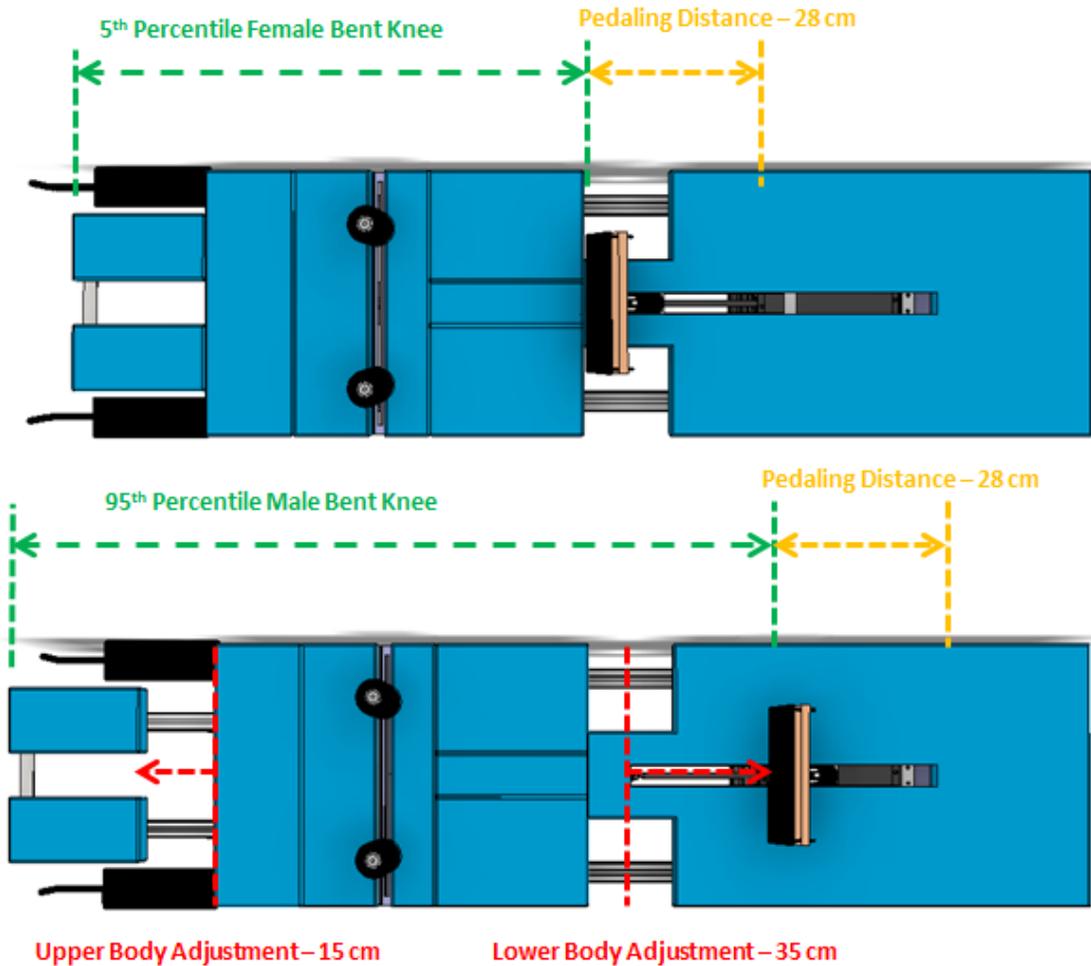


Figure 3.20: Upper Body and Lower Body Adjustment for USD

The ‘table pieces’ refer to each blue block in the USD system and they are all sized appropriately in accordance to available anthropometric data from the NASA Man – Systems Integration Standards Anthropometry and Biomechanics for human dimensions. Refer to References

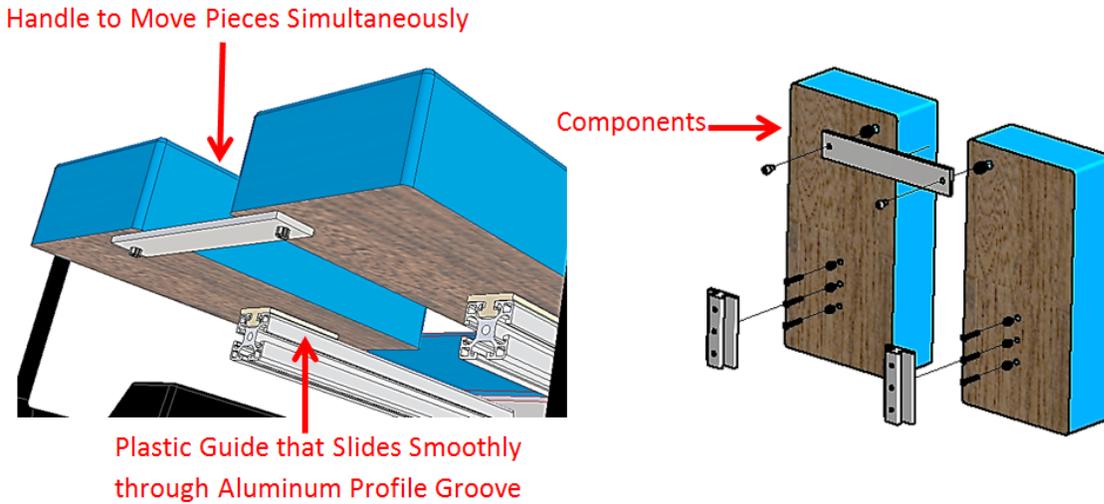


Figure 3.22: Upper Body Adjustment Assembly



Figure 3.23: Measurement Ruler for Upper Body Adjustment

Lower Body Adjustment

The lower body is considered the trochanteric height. Thus, the USD lower body adjustment is the difference in trochanteric height between the 5th percentile female and 95th percentile male, 71 cm and 102.9 cm, respectively, which results in 31.9 cm. Since space permits, this value is increased to 35 cm for precaution.

Figure 3.24 demonstrates the components utilized and design in making the lower body adjustment possible, while having the user still being able to pedal the anticipated distance. In

Figure 3.24, there are images grouped together with the last image having several components made invisible to provide clarity in the components utilized for the lower body adjustment. The user is to manually slide the pedal to the desired location and lock in place through rotating the threaded knobs in the linear guide rail. When the rotating knobs are loose, linear guide plates 1 through 4 are all connected as one. Thus, if one linear guide plate is moved, all linear guides plates move simultaneously making it possible for the user to adjust for their height. Specifically, linear guide plates 3 and 4 are connected as one through their connection to the pumper, linear guide 1 is connected to linear guide 3 through the 'connector' indicated in Figure 3.24 and linear guide 2 where the pedal sits is connected to the pumper piston. Although, if the rotating knobs are rotated in, linear guide plates 1, 3 and 4 will be locked in place. Thus, leaving linear guide plate 2 constrained to move within range of the pumper piston, which is 0 to 28 cm.

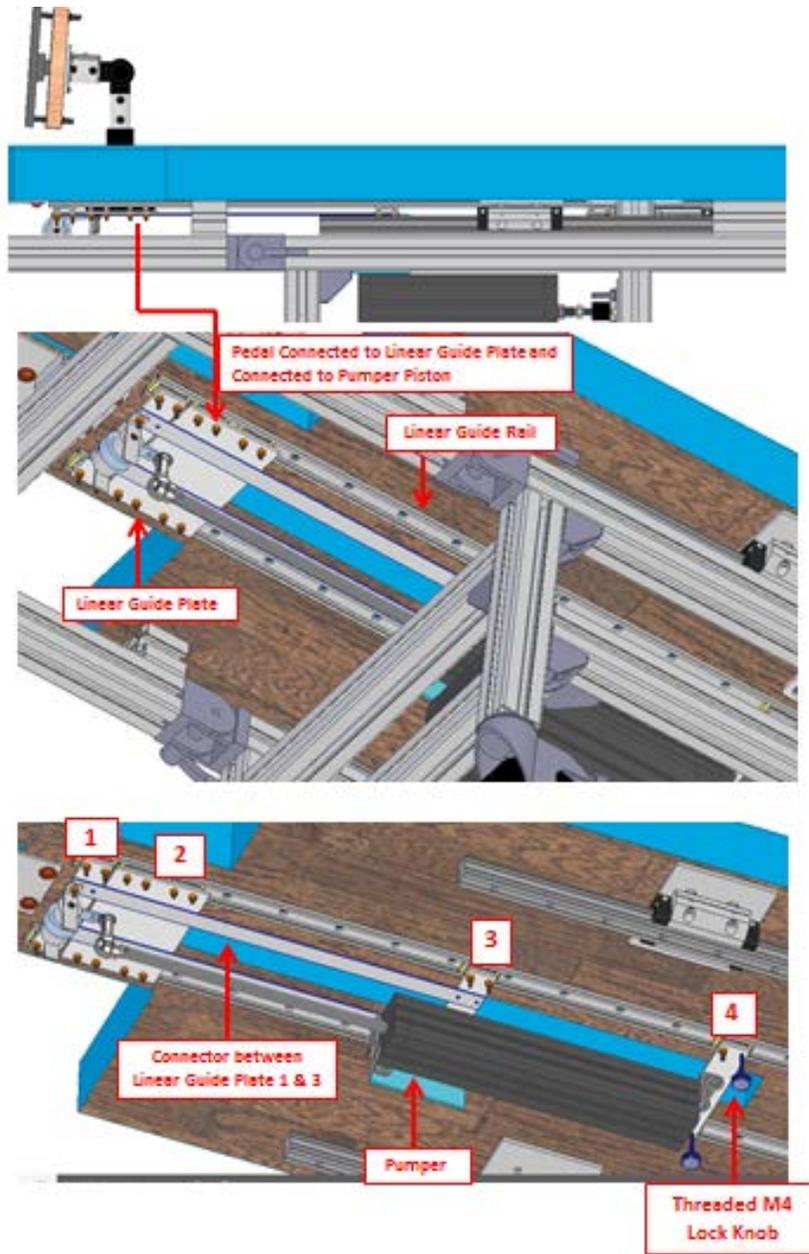


Figure 3.24: Lower Body Adjustment Assembly

Ruler markers are implemented to indicate the exact length of the displacement; refer to Figure 3.25: Lower Body Adjustment Ruler.



Figure 3.25: Lower Body Adjustment Ruler

Accommodations for Supine and Prone Anatomical Positions

The USD system must accommodate the user in the supine position or prone position.

Figure 3.26, displays which USD table components adjust position to make the table suitable for the user to pedal in the prone position, which is the user laying on their stomach as opposed to lying on their back (supine).

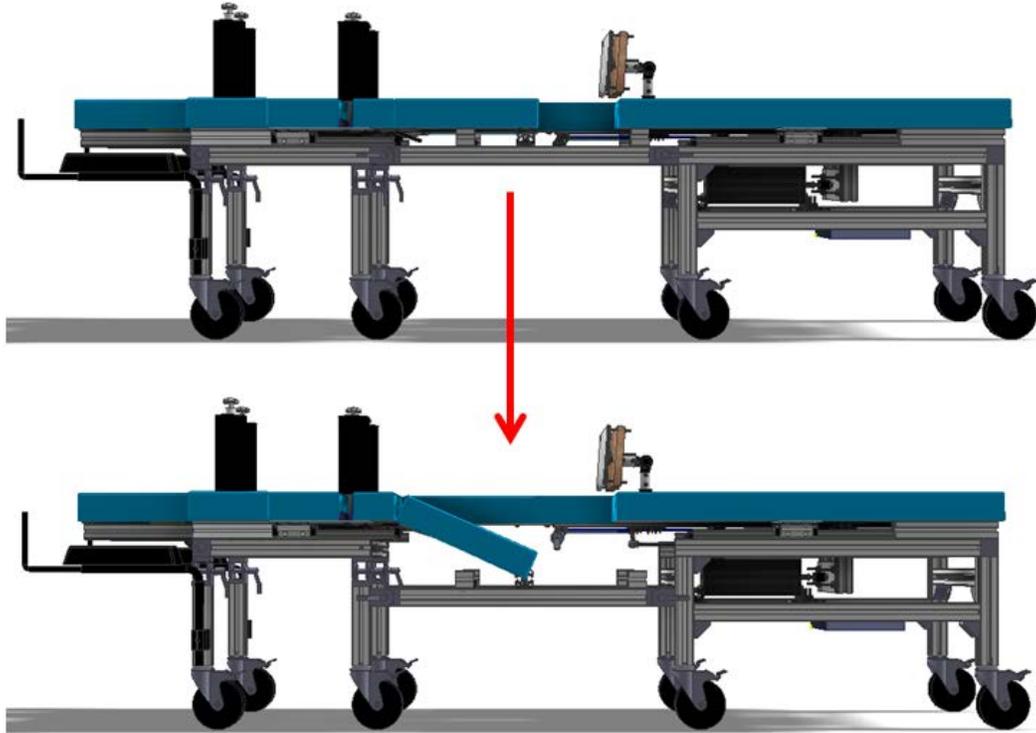


Figure 3.26: Supine to Prone Conversion

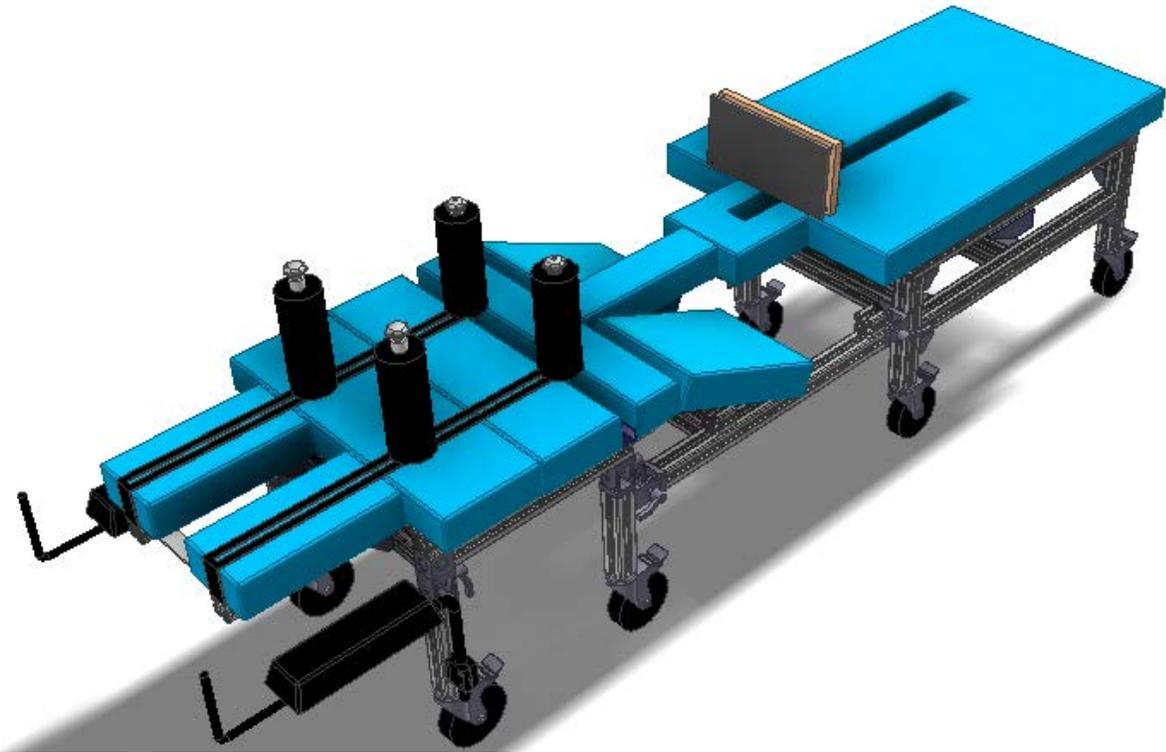


Figure 3.27: USD Prone Setup

The prone adjustment is made possible by lowering the mid – section metal structure and adjusting the angle of the lever lock hinges applied as can be seen in Figure 3.28: Lever Lock Hinge to Accommodate Prone Adjustment.

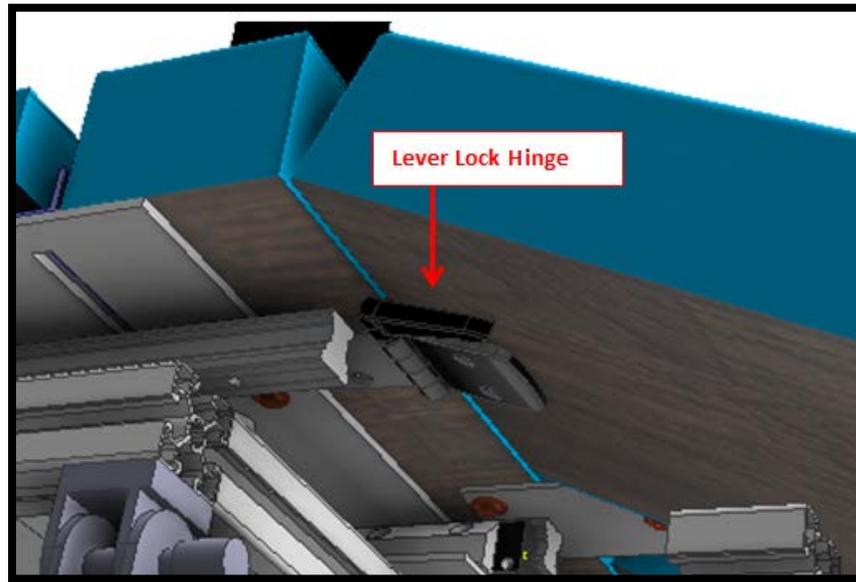


Figure 3.28: Lever Lock Hinge to Accommodate Prone Adjustment

3.5.2 Modularity and Portability

As the system is to contain modular features, the USD is designed to be broken up into several components that can be assembled comfortably. The unassembled version of the USD system is displayed in Figure 3.29. The broken up assemblies each don't weigh more than 19 kg as is noted in the literature review to be lift able. Castor wheels with lock option from Bosch Rexroth are incorporated in the design so the device can be mobile. The wheels are heavy duty and can sustain a force of 1100 N each making the USD feel very light weight when being slid.

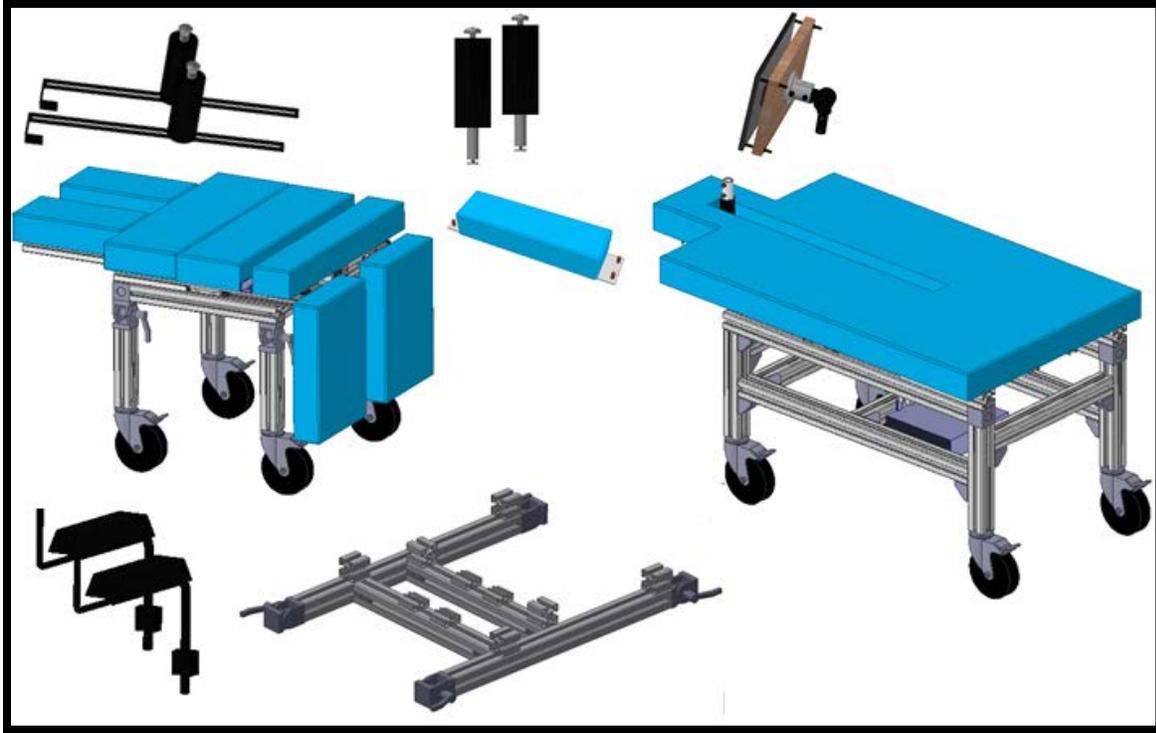


Figure 3.29: Modularity and Portability Features

3.5.3 Integrity

The integrity of the design is the structural analysis and capability to withstand specific loads.

For the first prototype of the USD system, participants are anticipated for functional testing, thus, a conservative approach is taken to ensure failure does not occur. The structure is designed to intake the vertical loading of the human body, specifically when the user:

- Is in the upright sitting position on the USD table getting ready to orient themselves for testing
- Is lying flat on the USD table during testing

The structural design is designed to withstand the weight of the 5th percentile female to the 95th percentile male with a minimum safety factor of 2. In addition to meeting the safety factor, the following is implemented for the structural design to ensure effectiveness:

- Metal sheets/plates are incorporated under wooden pieces where large forces are anticipated such that if the wood fails the metal is there for backup
- Metal inserts are utilized for any screw placement in the wooden components ensuring integrity
- Lightweight aluminum profiles of 45X45 (mm) weighing 1.6 kg/m are utilized for their ease in incorporating various connections; in addition, their weight is suitable in terms of preventing a wobbly/unstable structure
- Specialized connection elements for aluminum profiles are utilized to ensure rigidity such as tensioning connectors, brackets, t – nuts, t – bolts, cubic connectors, central bolts, etc. with load ratings acquired from the Bosch Rexroth manual [57]

The figures below display the exploded assemblies of the main assembled components of the USD system and an emphasis on the parts utilized ensuring a rigid system.

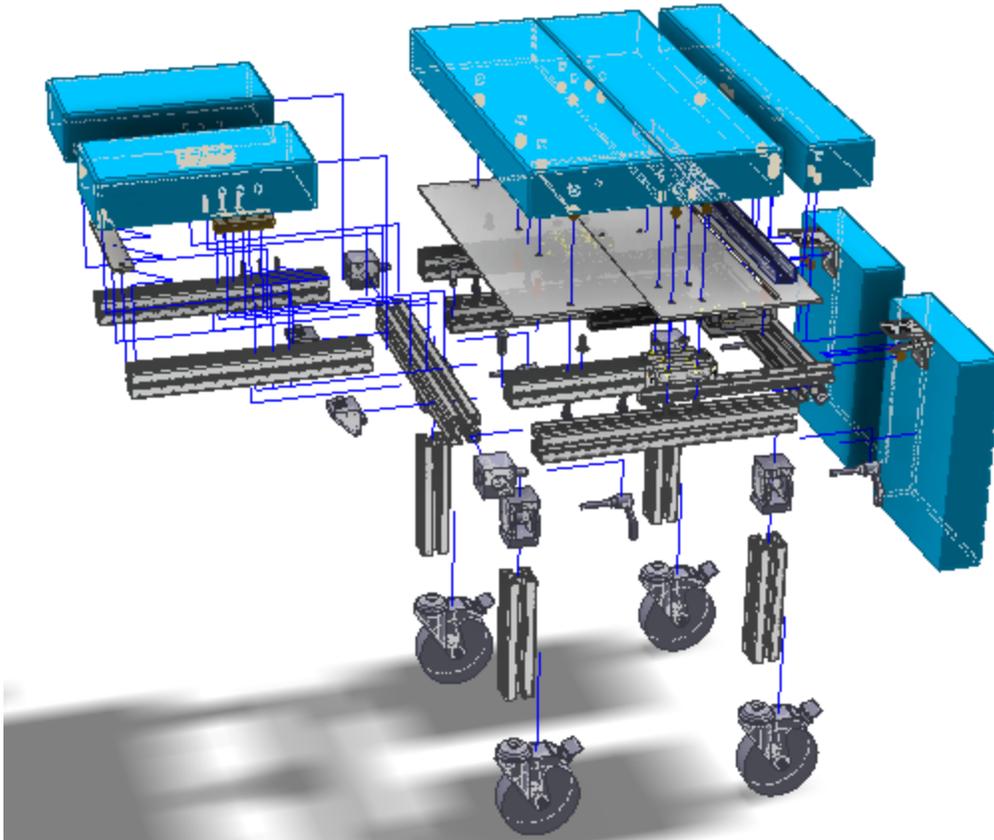


Figure 3.30: Exploded Assembly of Upper Part of Table

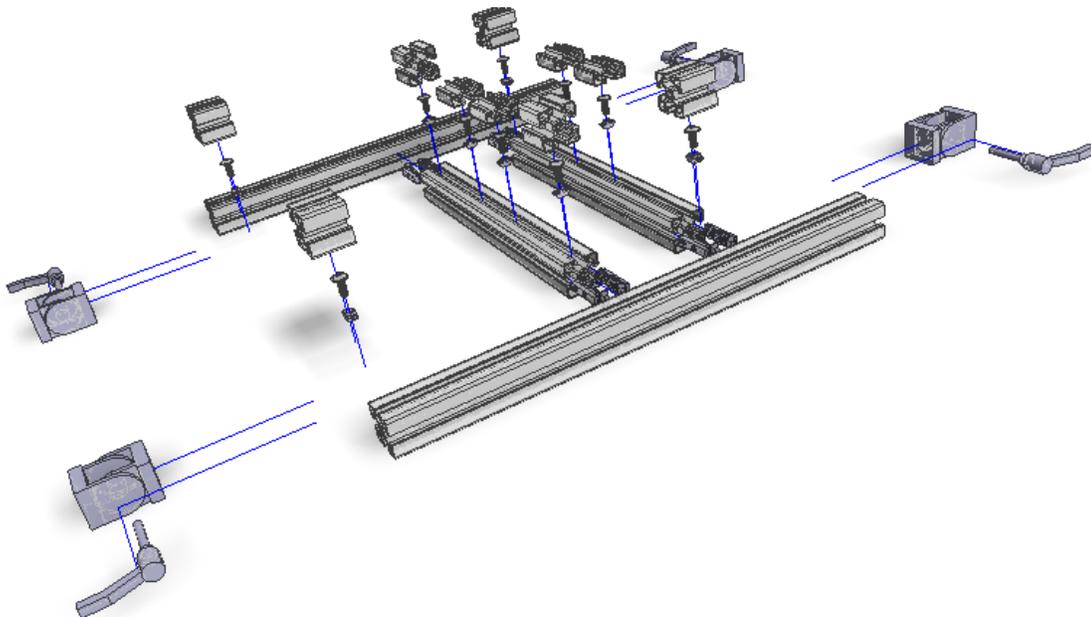


Figure 3.31: Exploded Assembly of Mid Structure

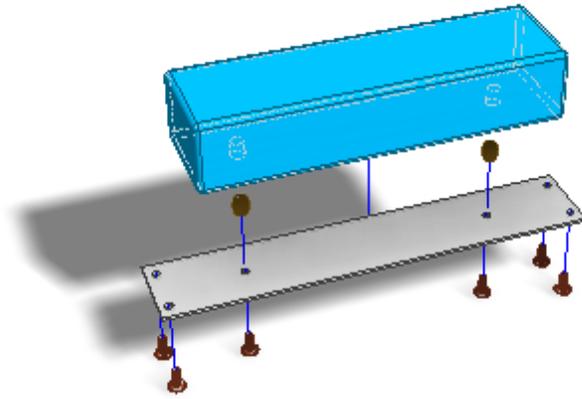


Figure 3.33: Exploded Assembly of 'Connection' Between Upper and Lower Part of Table

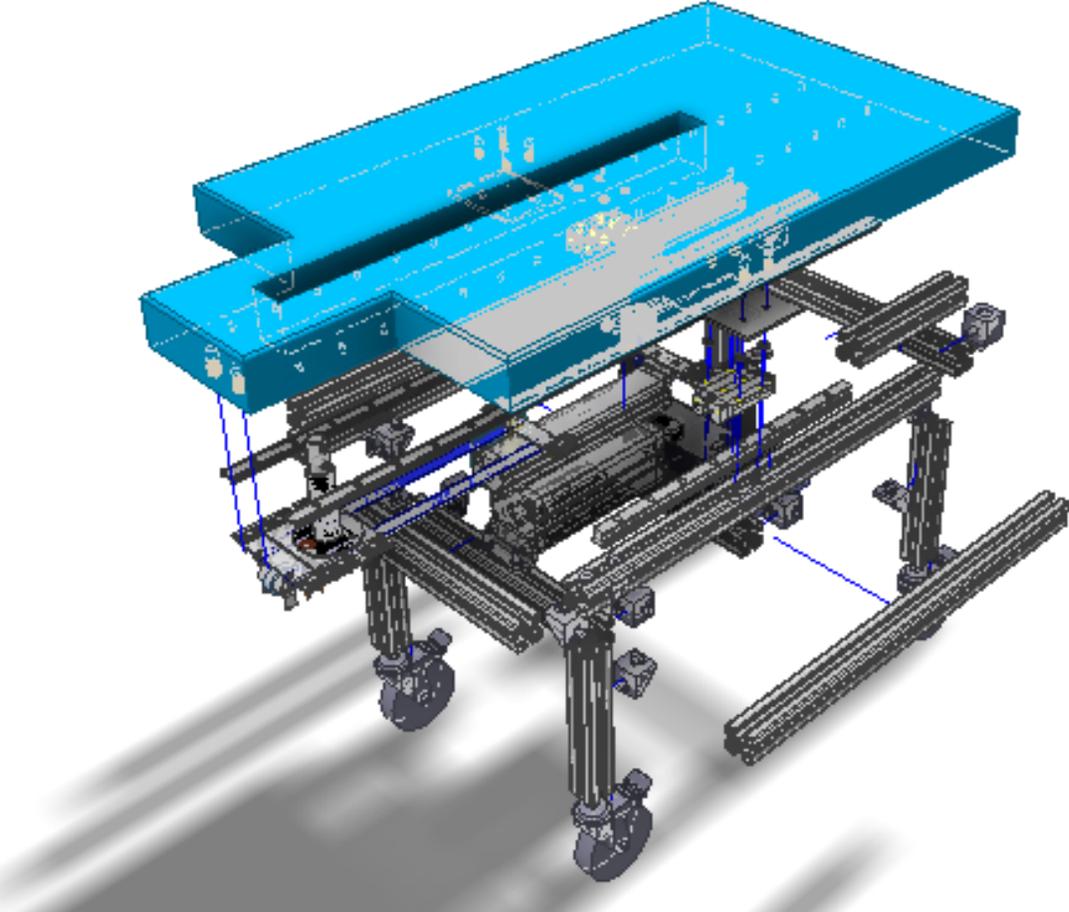


Figure 3.32: Exploded Assembly of Lower Part of Table

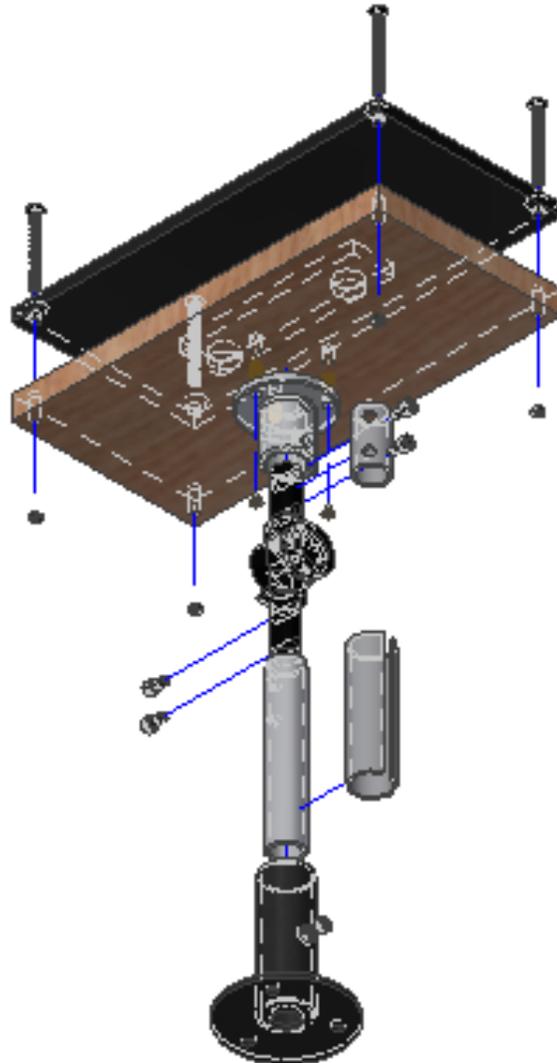


Figure 3.34: Exploded Assembly of Pedal Design

3.6 Chapter Summary

Chapter 3 presents a comprehensive overview of the mechanical design of the USD system. The chapter concentrated on three categories including transmission design, restraining mechanisms design and structural design. An overview of the transmission design is presented concentrating on system selection, pneumatic circuitry, parameter development and preliminary experiments. Parameters discussed in detail included the pedal stroke distance, foot force capability, actuator

stroke length, maximum loading and reduction ratio of the pneumatic cylinders implemented. An overview of the restraining mechanisms design is also discussed in detail concentrating on which restraints are required for the USD system, which included upper body restraint, lower body restraint and neck restraint with distinct combination depending on anatomical position and spinal segment treatment. Lastly, an overview of the structural design is presented concentrating on the positional adjustments to accommodate for the 5th percentile female to the 95th percentile male, positional adjustments for different anatomical positions, modularity and portability features and overview of structural integrity.

Chapter 4: Electrical and Software Design

4.1 Introduction

The USD system is a dynamic device with movement and force application where such attributes must be measured and recorded. This involves sensors, data acquisition and corresponding software to log the data. All of these devices require a power source and wiring for the power and data signals. In addition, a graphical interface is required for the USD system where software is involved for implementation. This chapter will provide an overview of the sensors, power, control systems and graphical interface of the USD system.

It should be noted that all design requirements for electronics and software are completed by the author. Specifically, operational requirements, graphical interface design, sensor calibration and sensor integration along with mechanically designed components within USD system is performed by the author. While the hardware and software design and the implementation of the graphical user interface are performed by fellow ABL lab researcher Mr. Omar Masaud.

4.2 Electrical Design

4.2.1 Design Requirements

The following is required for the electrical design of the USD system:

- Power to the USD system shall be through a standard electrical outlet or via a rechargeable battery; thus can function as a standalone system

- Strain relief, heat shrinks, proper connectors, fuse implementation and electrical box to encase all hardware.
- Control hardware with integrated I/O
- Sensors for instrumentation:
 - Displacement sensor for pedal stroke distance,
 - Displacement sensor for USD spine displacement,
 - Force sensor for foot load application to the pedal, and
 - Force sensor for actuator loading.
- Emergency button for instantaneous relief of force once pressed and resetting of system.
- Power switch, safety lock and operational indicators on electrical box.

4.2.1.1 Overview of Electronics

The integration of the electrical components utilized for the USD system excluding the physical sensors and emergency button are displayed in Figure 4.1. The myRIO by National Instruments is utilized to implement the control logic required for the USD system, in addition, to reading in the analog signals of the sensors implemented and converting to digital signals for interpretation. Also, being the source of control to the solenoid valve and data acquisition.

The solenoid valve selected is the MHP1-M1H-3/2O-M3-HC by Festo Canada, which is normally open and requires an input voltage of +24V DC to switch positions from open to close to allow the releasing or enclosing of pressure. The solenoid valve is controlled through the myRIO via a solid state relay through a digital output.

Sensors and their respective circuitry along with signal conditioners are discussed in section 4.2.1.2: Sensors. Data acquisition is implemented through a USB connection to the myRIO where text files of each experiment are saved, simultaneously, data can be saved right off

the graphical interface; see section 4.3.1: Graphical Interface. An emergency button is incorporated as a safety feature for whenever the user feels uncomfortable, pressing on the emergency button causes the solenoid valve to open and release all the pressure relieving any load and resetting the system.

The external features of the electrical box such as the safety features that include a lock out key to lock out the system from operating even if power is on, light indicator for valve operation, light indicator for emergency button and light indicator for spinal decompression therapy mode are displayed in Figure 4.2. In addition, a switch to indicate the power source, battery or external plug. Lastly, it indicates the connection to the usb stick and usb connection to desktop/laptop source.

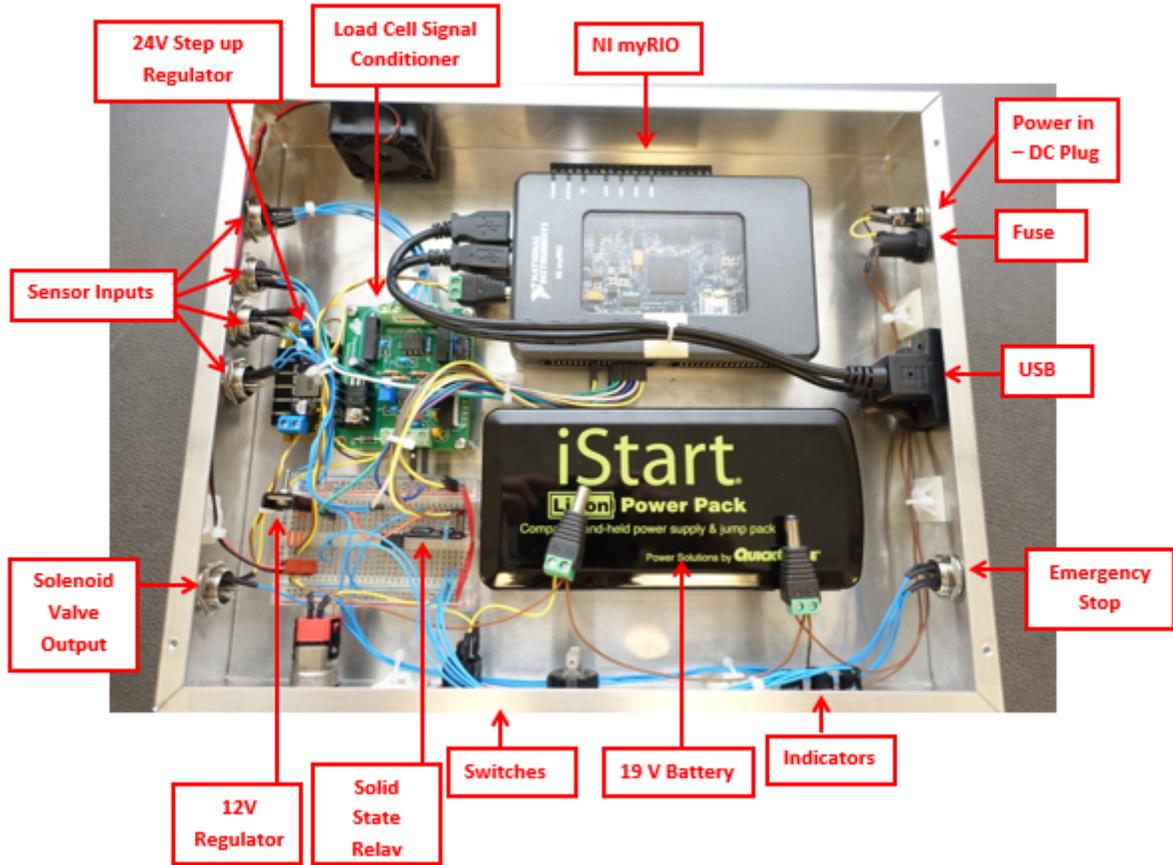


Figure 4.1: Overview of Electrical Components

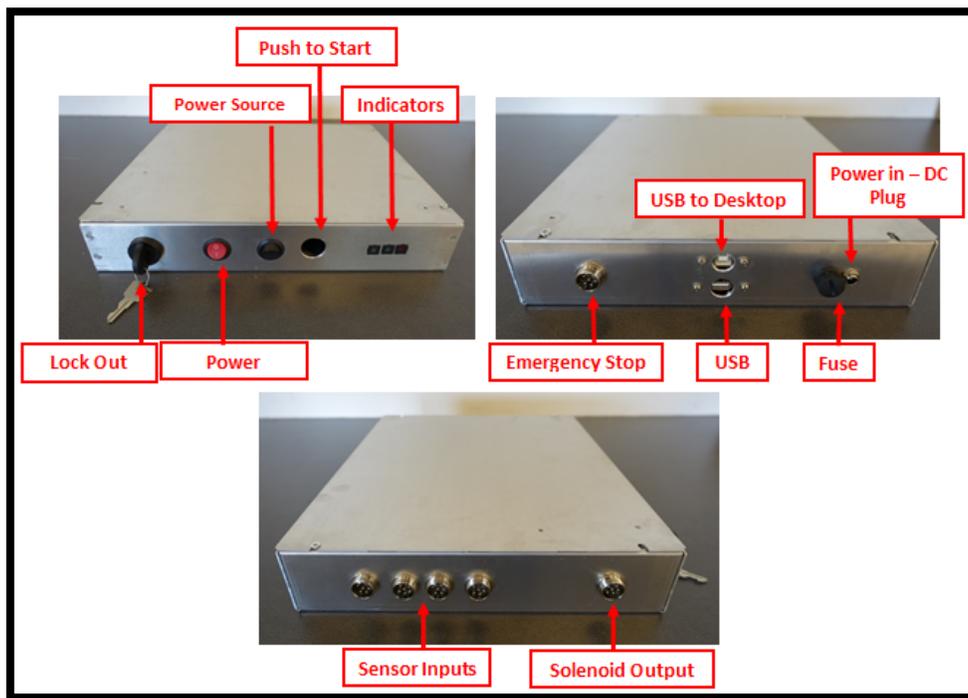


Figure 4.2: Electrical Box - External

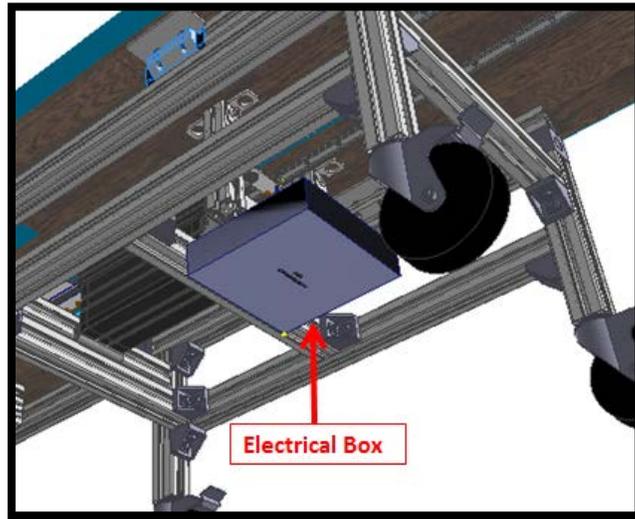


Figure 4.3: Placement of Electrical Box in USD

4.2.1.2 Sensors

Force Sensor for Foot Load Application to the Pedal

Two FlexiForce sensors model A401 are utilized to measure the load applied to the pedal by the feet. The sensor loading is an important criterion to consider in the application of the FlexiForce sensor. The sensing area is the silver circle on the top of the sensor only where the entire sensing area of the sensor is treated as a single contact point. The FlexiForce sensor reads forces that are perpendicular to the sensor plane. Shear forces are not favored. If the footprint of the applied load is larger than the sensing area then a specifically designed plate must be utilized to ensure the entire load applied goes only through the sensing area and not outside of it. Thus, since the sensing area has a diameter of 1 inch and the 5th percentile female's foot is much larger, a plate design is in order.



Figure 4.4: FlexiForce A401 Sensors with Plate Design

Utilizing one FlexiForce A401 sensor does not make a feasible design due to their small size, thus two sensors are implemented to measure the foot force. The placement of the FlexiForce Sensors in the pedal design is displayed in Figure 4.4, where a specifically designed plate is implemented to be placed on top of the sensors ensuring all the foot load is sensed by the FlexiForce A401 sensors. Figure 4.5, displays how the load is distributed to the sensors.

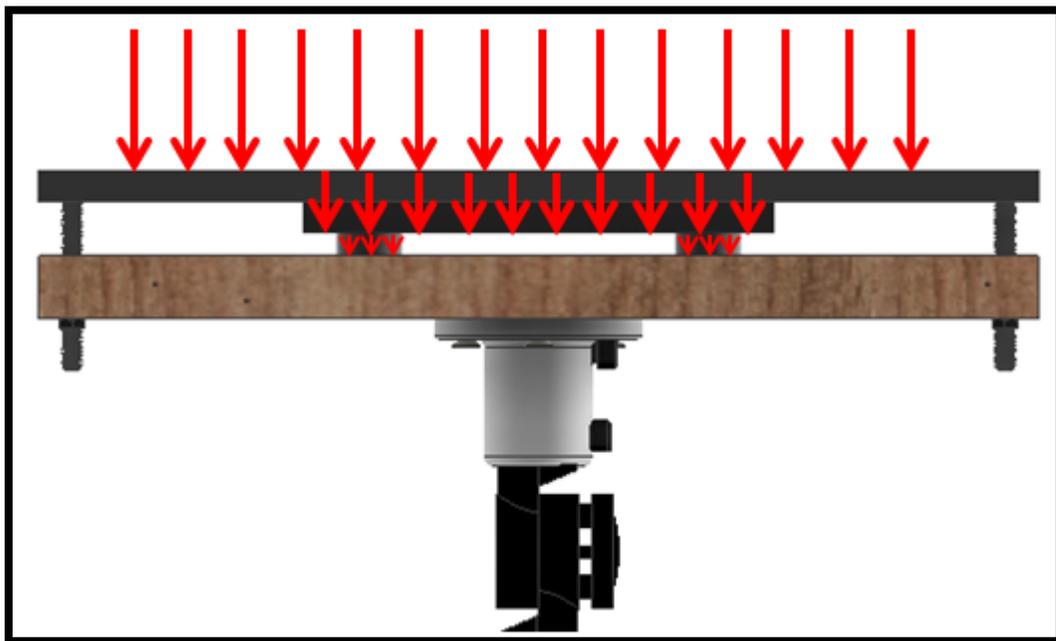


Figure 4.5: Force Distribution on Pedal Plate

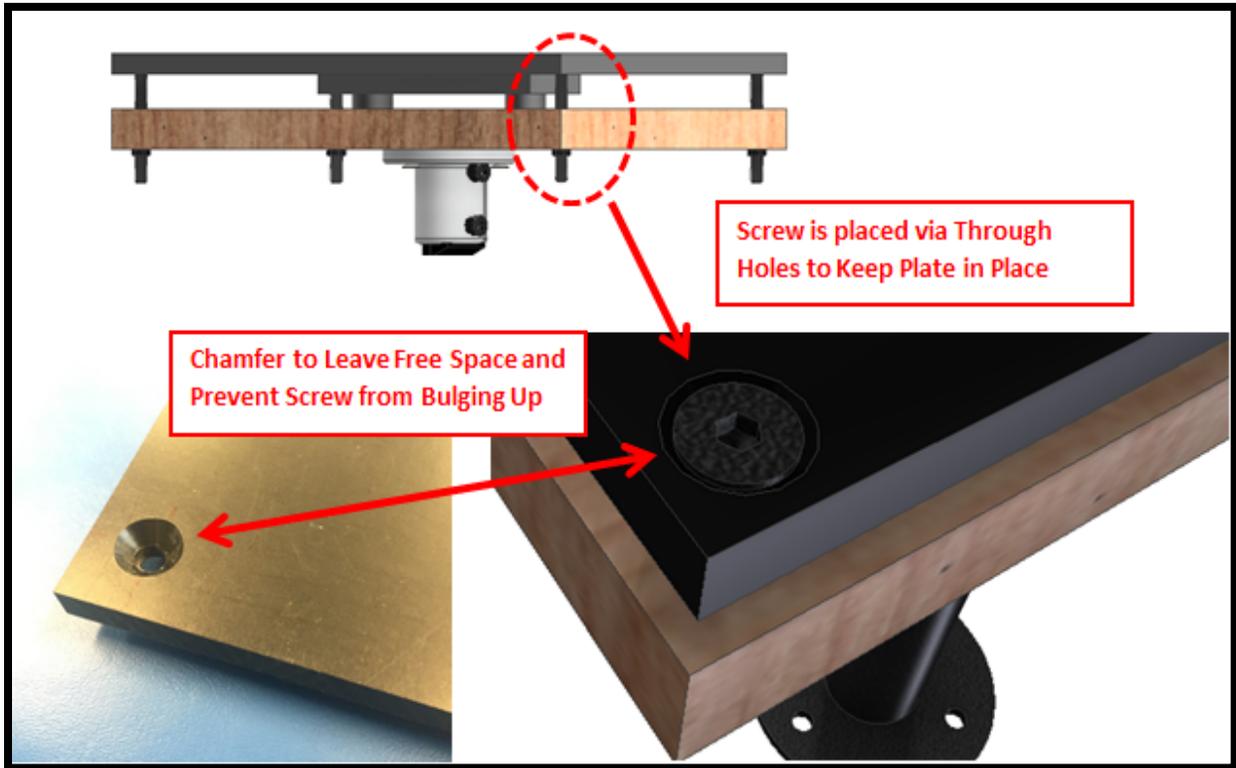


Figure 4.6: Pedal Plate Design - Screw Alignment

The implementation of the four screws in the pedal design is to maintain the pedal plate in place, but not act to have it rigid, thus allowing the plate push down on the sensors through load application. The screws are placed via through holes and the nuts incorporated are implemented to prevent the screws from falling out.

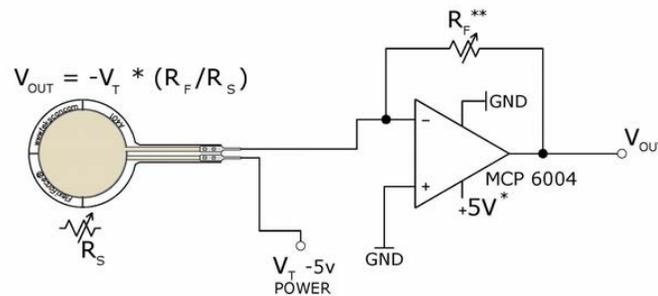


Figure 4.7: FlexiForce Sensor Recommended Circuit

The circuitry implemented for the FlexiForce A401 sensors is based on the recommended circuit by Tekscan [58]; refer to Figure 4.7: FlexiForce Sensor Recommended Circuit.

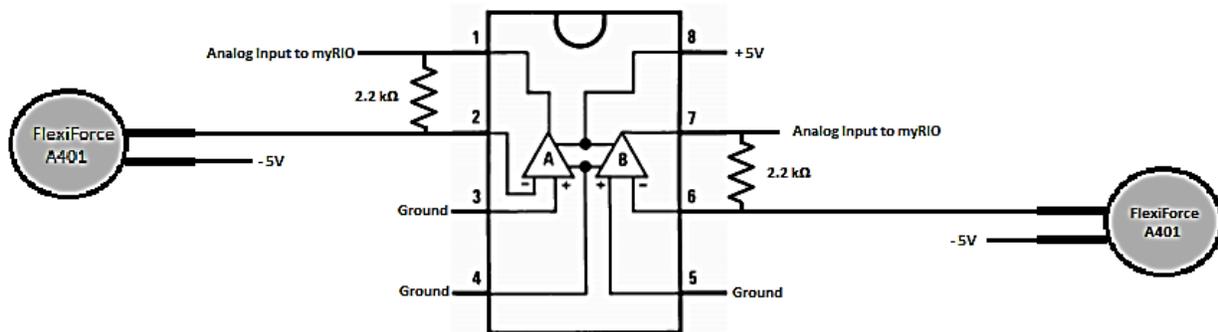


Figure 4.8: Circuitry for FlexiForce Sensors

The circuit implemented for the two FlexiForce A401 sensors is displayed in Figure 4.8, which includes a dual op amp, LM358N, +5V is supplied to the dual op amp, -5V is supplied to each sensor and a reference resistor of 2.2 kΩ incorporated for each sensor. The reference resistor is selected through various trials to accommodate a suitable voltage range for the anticipated loading.

Each FlexiForce A401 sensor is calibrated separately; refer to Figure 4.9 and Figure 4.10.

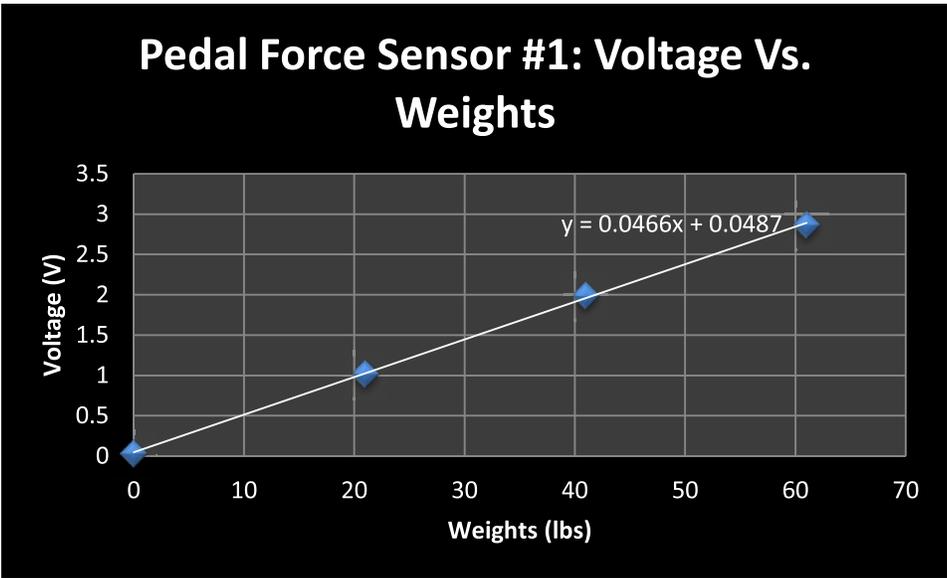


Figure 4.9: Calibration Plot for Pedal FlexiForce Sensor #1

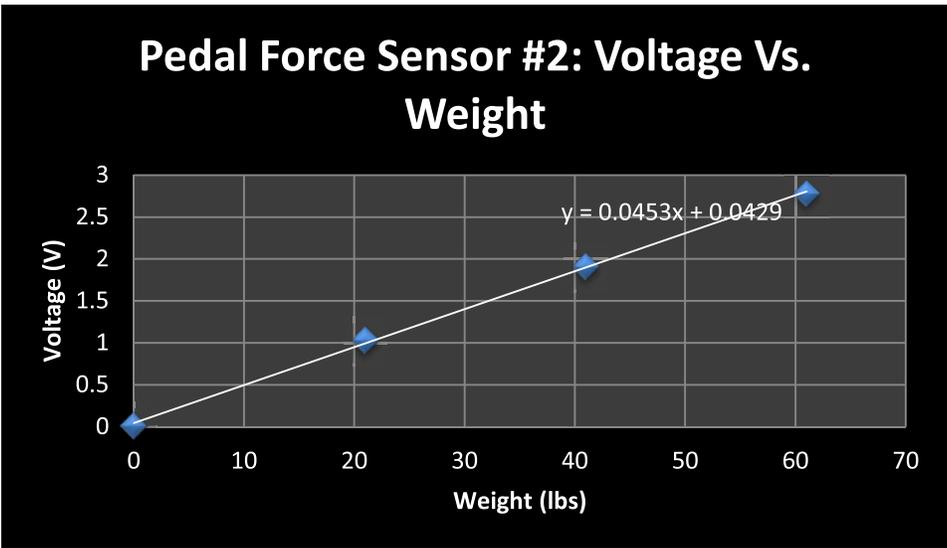


Figure 4.10: Calibration Plot for Pedal FlexiForce Sensor #2

Force Sensor for Actuator Loading

The force sensor utilized to record the force applied by the actuator to the spine via table is the MLP – 300 load cell by Transducer Techniques. The load cell can detect a force of 0 – 300 lbs. The load cell signal must be signal conditioned prior to integrating with the myRIO. The signal conditioning process is important in this case so that the signal will be accurately processed as it goes through analog to digital conversion. The load cell signal conditioner circuit implemented is the TMO-1-24 VDC by Transducer Techniques. The load cell is mounted between the actuator and the metal plate that is connected to the USD table; refer to Figure 4.11. Figure 4.12, displays the integration of the load cell and signal conditioner.

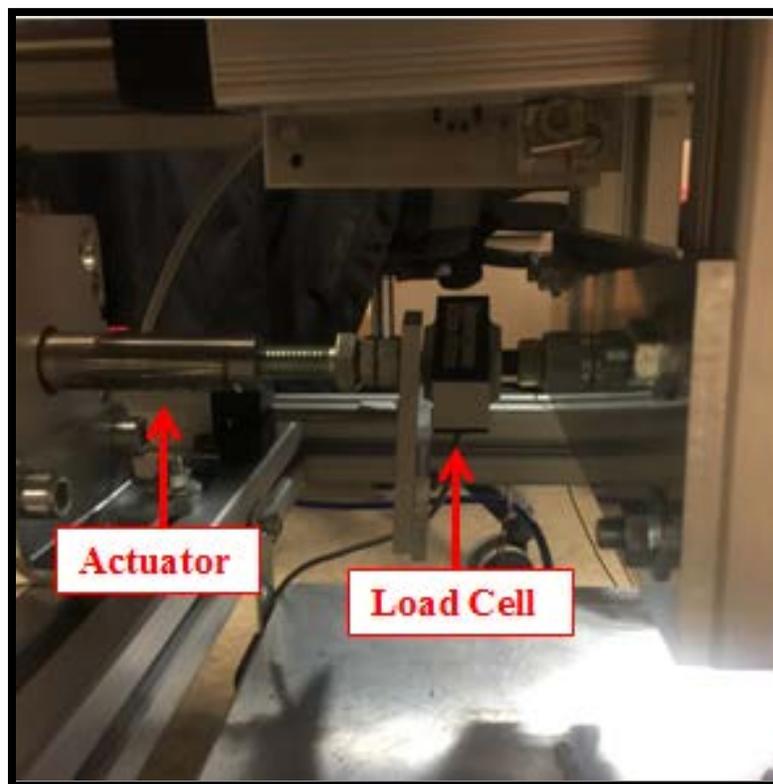


Figure 4.11: Mounting of Load Cell

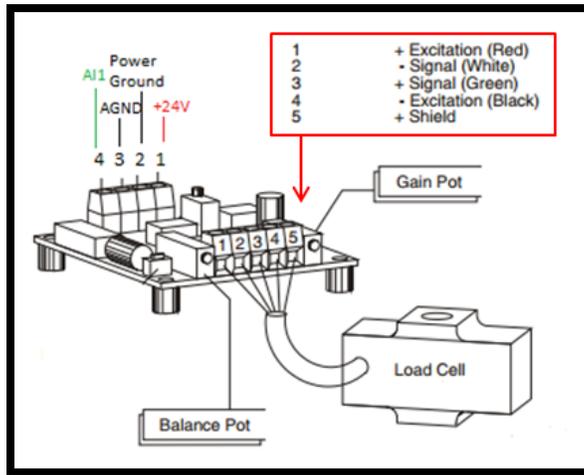


Figure 4.12: Load Cell and Signal Conditioner Integration

The load cell is calibrated by following ‘METHOD 1 Shunt calibration with TTI transducers’ as recommended by the operators manual of Transducer Techniques [59].

Displacement Sensor for Pedal Stroke Distance

A linear potentiometer of model KTC – 300 mm by MINOR is utilized to measure the pedal stroke distance [60]. It has a capability of measuring up to 300 mm where the USD design requires 280 mm, thus, this a 300 linear potentiometer is suitable.

The KTC 300 mm requires +5V of power and outputs an analog output between 0 – 5 V.

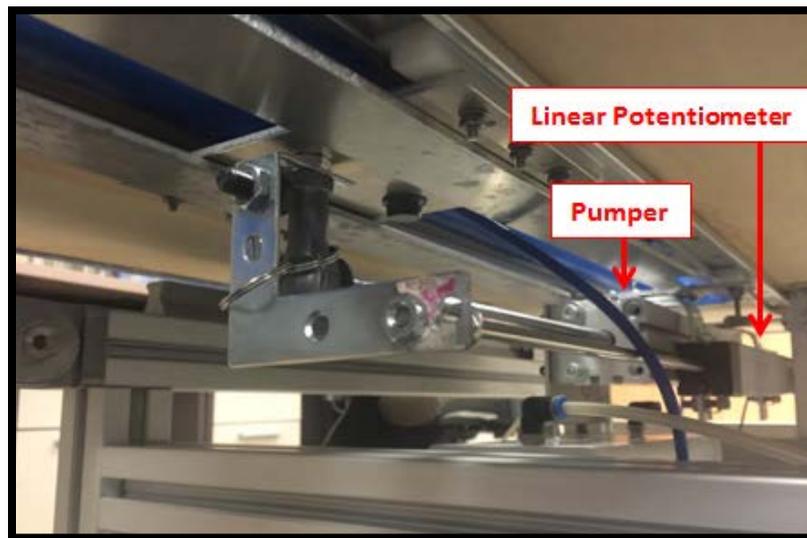


Figure 4.13: Potentiometer Alignment with Pumper

How the potentiometer is aligned with the pumper is displayed in Figure 4.13, such that when the piston of the pumper elongates so does the piston of the potentiometer.

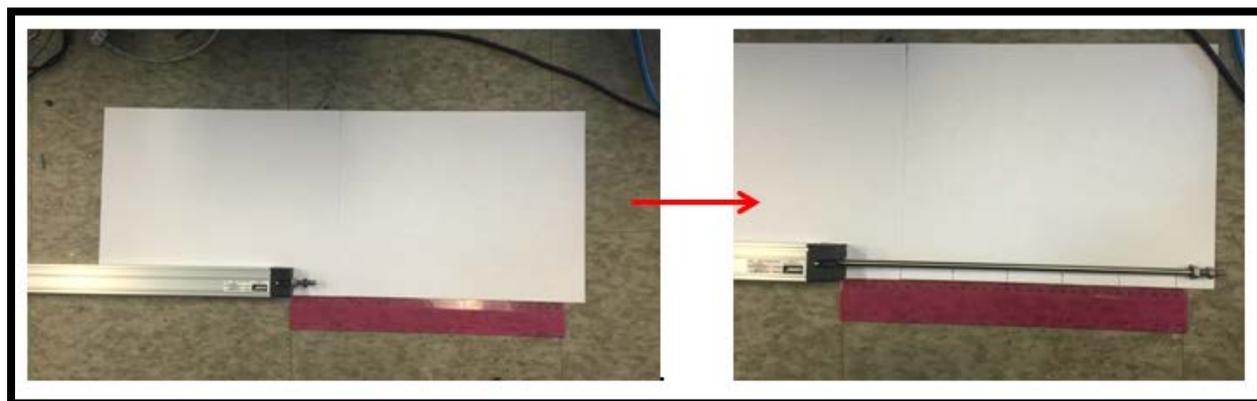


Figure 4.14: Calibration of Potentiometer (KTC - 300 by MINOR)

The potentiometer is calibrated as displayed in Figure 4.14; refer to Figure 4.15, for calibration plot.

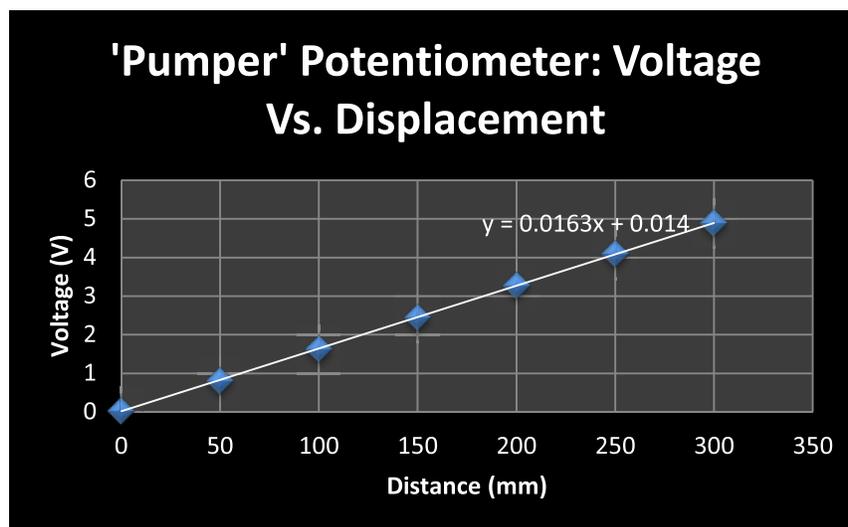


Figure 4.15: Calibration Plot for 'Pumper' Potentiometer

Displacement Sensor for USD Spine Displacement

The sensor utilized to measure the actuator displacement is the KTC 300 by MINOR, potentiometer, same model utilized for the ‘pumper’. Figure 4.16, displays how potentiometer is aligned with the actuator to acquire correct measurements.

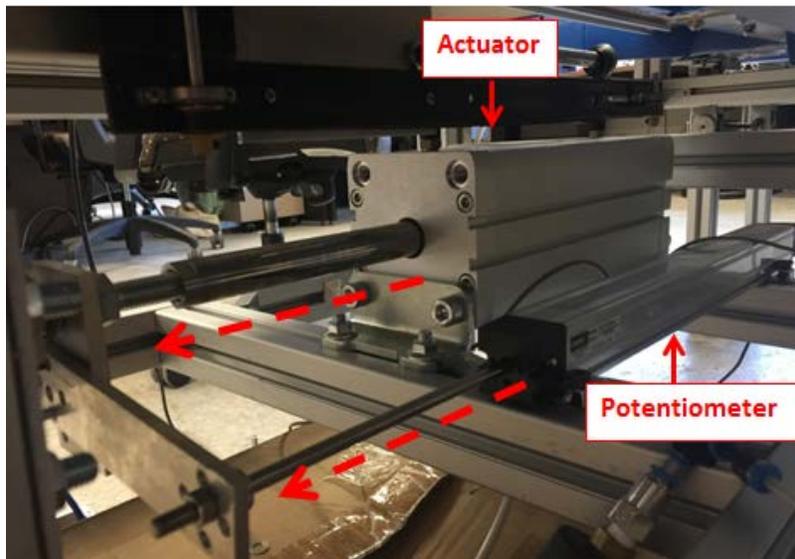


Figure 4.16: Alignment of Potentiometer to Actuator

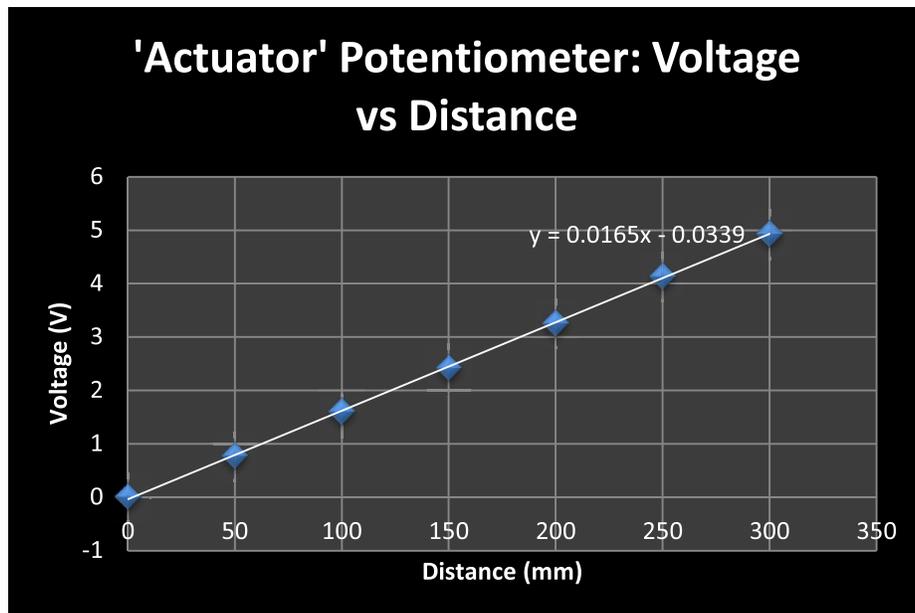


Figure 4.17: Calibration Plot for 'Actuator' Potentiometer

The potentiometer is calibrated in the same manner as the potentiometer utilized to measure the ‘pumper’ displacement; refer to Figure 4.17.

4.2.1.3 Power Distribution

The requirements for the electrical design include having the USD system operate on a rechargeable battery or electrical outlet power. Figure 4.18, displays the distribution of power. A single pole double throw switch is utilized to switch between using the electrical plug via outlet or the chargeable battery as the main power source. The chargeable battery supplies 19V and its input specification is 14V, thus an electrical plug of 14V is chosen to simultaneously power the system and recharge the battery. A fuse is integrated as a safety precaution. A +24V step up regulator is incorporated to boost the +19V/14V to +24V to power the components that require +24V such as load cell signal conditioner, solenoid valve, etc. A 12V regulator is incorporated to regulate the 19V/14V down to supply the myRIO with 12V without overpowering it.

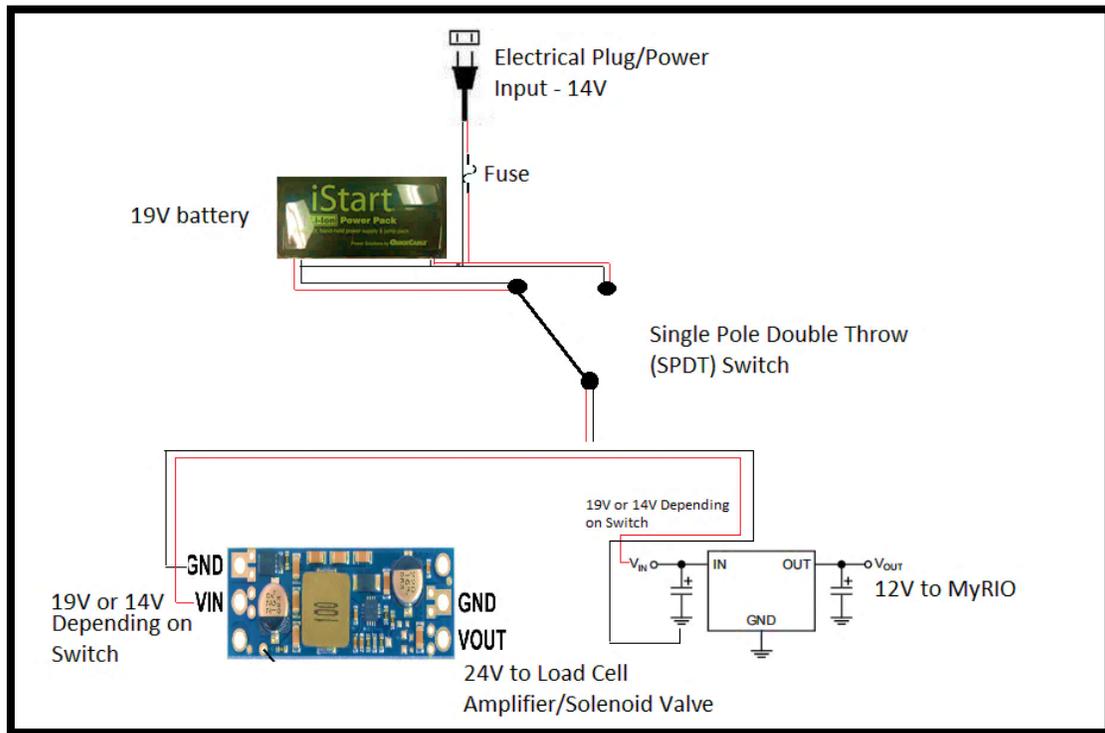


Figure 4.18: Power Distribution of USD System

The following is a list of the components requiring power, the required power and the power source:

- MyRIO receives +12V from battery (+19V) or electrical outlet(+14V) which is first regulated down to +12V via voltage regulator before passed to myRIO
- Two FelxiForce A401 sensors each receive +5V from the myRIO voltage output pin of +5V
- Two KTC 300 by MINOR potentiometer receives +5V from the myRIO voltage output pin of +5V
- Load call signal conditioner receives +24V from battery (+19V) or electrical outlet (+14V) which is first boosted up to +24V by a +24V step regulator

- Solenoid valve receives +24V from battery (+19V) or electrical outlet (+14V) which is first boosted up to +24V by a +24V step regulator
- Emergency button receives +5V from the myRIO voltage output pin of +5V

4.3 Software Design

The software design consists of implementing the required control logic mechanism, data collection and the graphical interface for the USD system.

The graphical interface for the USD system is a *researcher* graphical interface that is designed based on requirements for making a suitable transition to a *user* graphical interface, which is the end goal for the USD system. Thus, the researcher graphical interface shall contain a series of safety checks and operational features that would in turn be required for a user graphical interface.

The researcher graphical interface shall display the following in sequential order:

- Device initialization where all sensor signal readings are displayed,
- Pre – operational checks that require the user/operator ensures all necessary mechanisms are in place such as restraining components, emergency button check, etc.,
- Patient data configuration file setup,
- Initiation/start tab,
- Graphs displaying real time data of all sensor readings and cyclic timing.

The logic control mechanism shall follow the intermittent cyclic loading required in non – surgical spinal decompression therapy with consideration of user driven aspects.

4.3.1 Graphical Interface

The graphical interface is designed into several steps incorporating safety features, acts as a methodological checklist and displays real time data. The graphical interface is split into two tabs where the first tab is experimental set up and the second tab is real time data display; refer to Figure 4.19. The experimental set up is split into six steps with four of them requiring checks in chronological order to be able to move on to the next step. The first step is to evaluate the sensors functionality by analyzing their signal and ensuring the measurement is accurate. This is done by visually analyzing the sensor signals on the left hand side of the graphical interface; this step is performed by the researcher and does not require a check mark. Figure 4.20, and, Figure 4.21, displays the graphical interface when no steps have been completed and when all steps are completed, respectively.

The second step is operation step up by selecting mode of operation, restraints and emergency button verification. Only specific combinations of operation modes can be selected and they include:

- Supine and Lumbar
- Supine and Cervical
- Prone and Lumbar

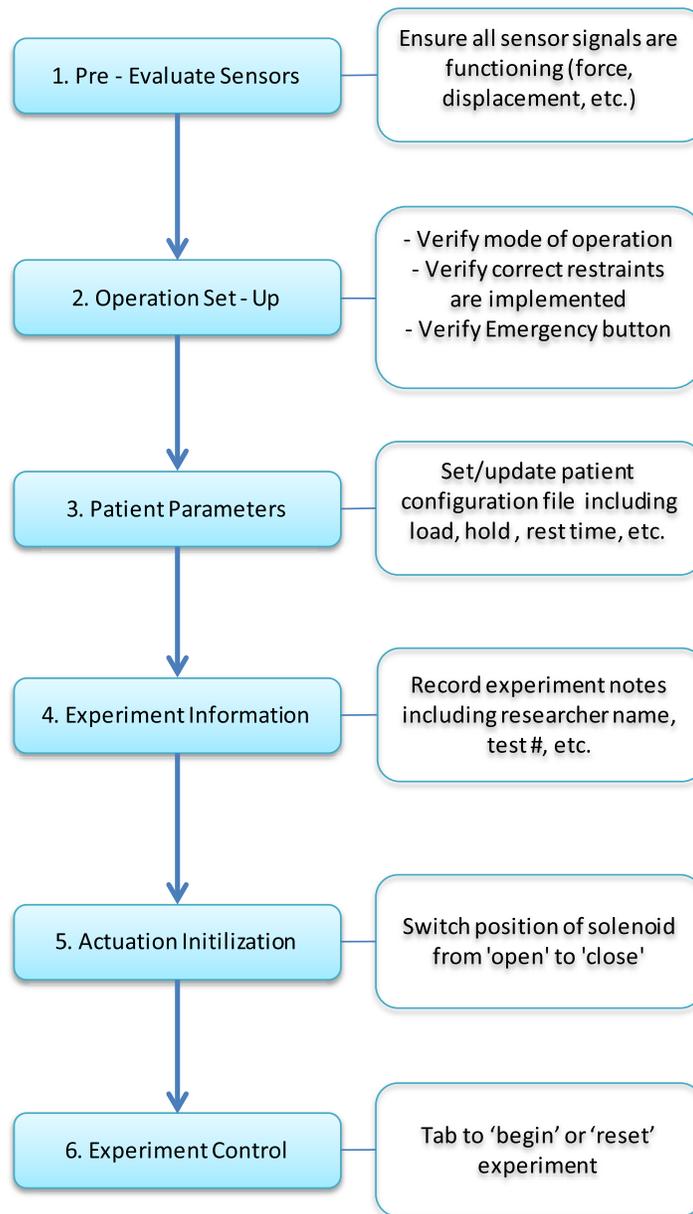
If a different combination than the above is chosen the system prevents researcher from moving to the next step until a correct combination is selected. Subsequently, each combination has distinct restraining mechanisms to select from which the system is programmed to incorporate. An emergency button check is verified by having the user pushing it and unlocking it with the interface acknowledging this step.

The third step is the patient parameters where the researcher sets up a new file for new patients, updates or utilizes the same file for recurrent patient doing another test. The patient parameters include prescribed load, notes on physical attributes such as body weight etc. In addition, the therapy parameters such as the duration time, hold time and rest time.

The fourth step is experiment information noting test number, researcher name, etc. The fifth step is actuator initialization, by the user decompressing the pedal, the solenoid valve closes and the testing data is ready to be recorded. The last step is experiment control, by either clicking begin to start spinal decompression or reset to restart test set up.

After clicking begins, the graphical interface navigates to the data collection tab; refer to Figure 4.22. Data is displayed in real time in plots for the researcher to ensure the system is functioning accurately. The 'data collection' tab displays when the user should pedal and when the user should not pedal in accordance to the cyclic procedure of spinal decompression therapy.

Graphical Interface 'Tab' #1



Graphical Interface 'Tab' #2

Real Time Data Display with timers, sensor readings, etc.

Figure 4.19: Graphical Interface 'Tab' #1 and 'Tab' #2

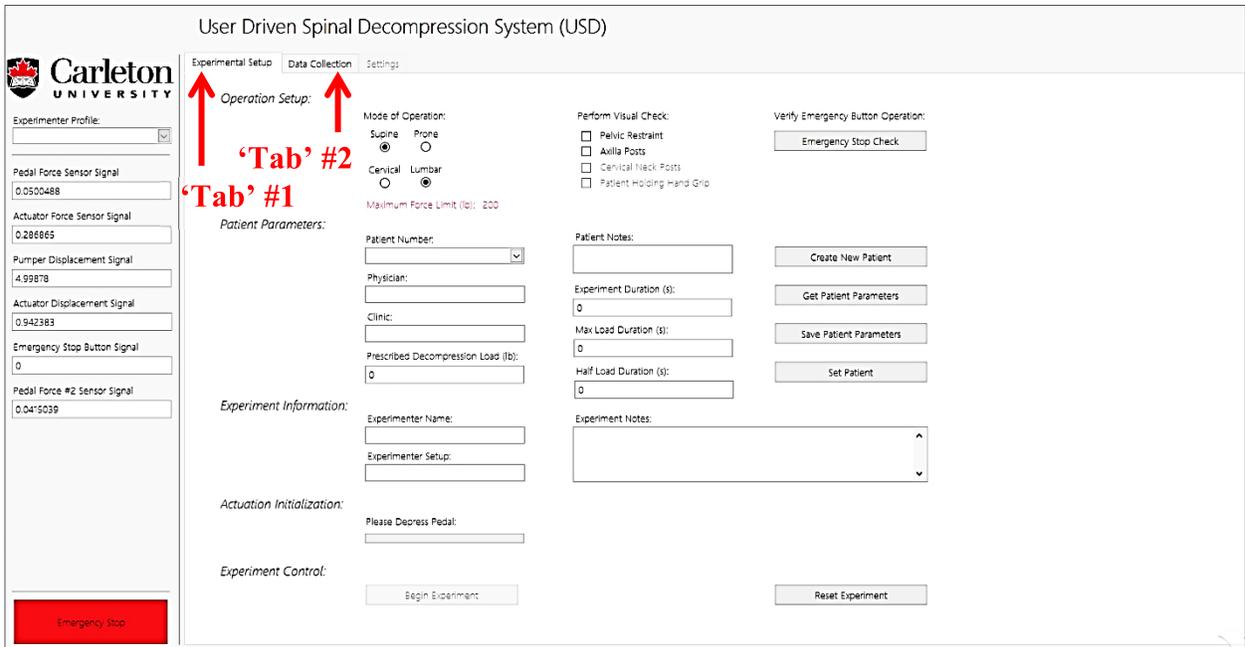


Figure 4.20: Graphical Interface without Check Marks

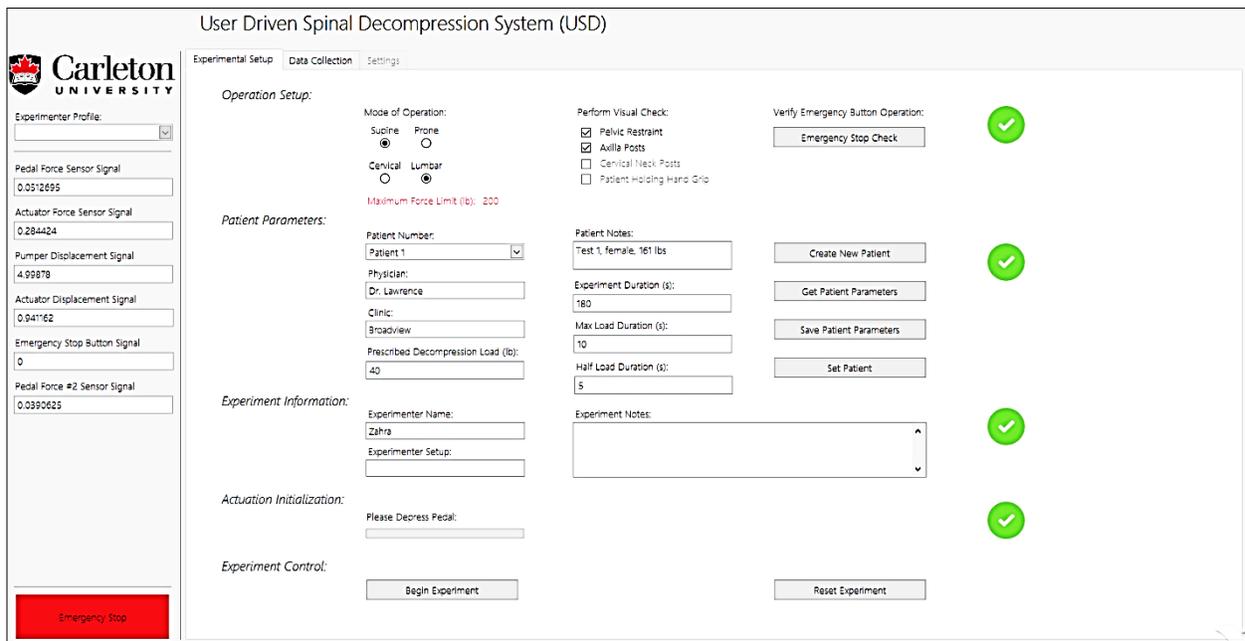


Figure 4.21: Graphical Interface with Check Marks

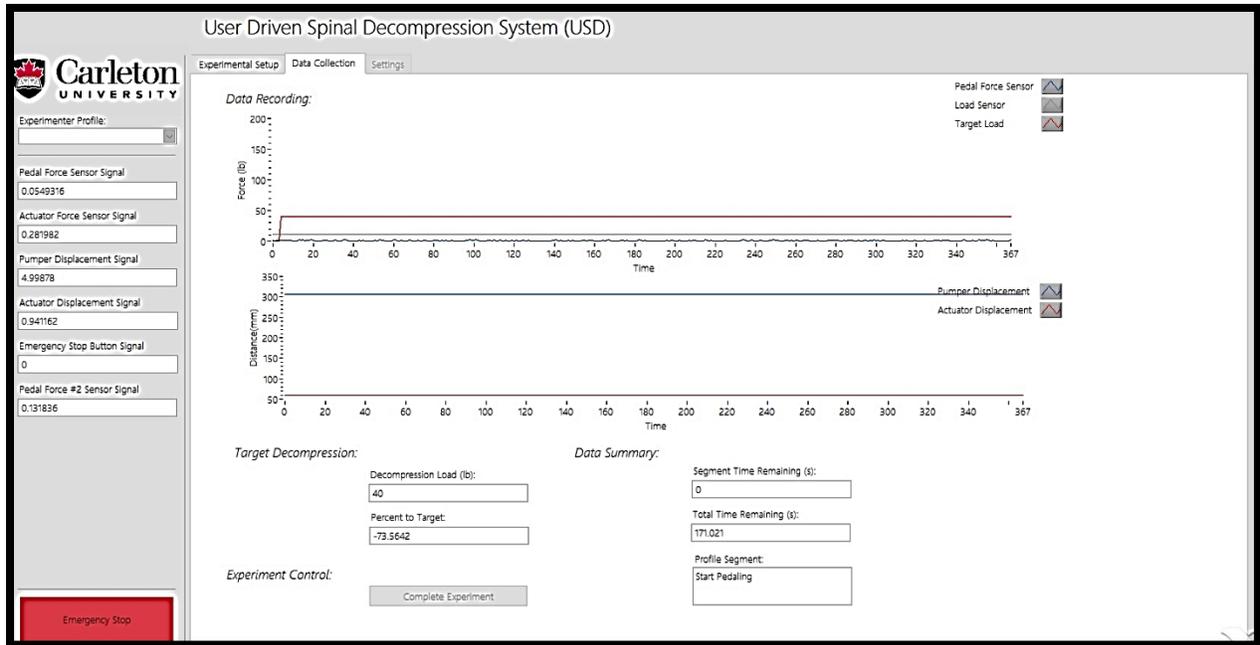


Figure 4.22: Graphical Interface Data Collection Tab

4.3.2 Control Logic Mechanism

The USD system requires logic control mechanism to implement the intermittent cyclic spinal decompression therapy. The logic control mechanism of non – surgical spinal decompression therapy is described in Section 2.4.3.3: Logic Control Mechanism. In the commercial non – surgical spinal decompression devices, the cycles of loading is machine controlled where timing to reach maximum load, half load, etc. is pre-set. While in the USD system, since it is user driven, the user pedals to reach their maximum load, this will vary between users due to capability, preference in speed, etc. In the USD system, it is programmed for the therapy to last for a specific duration independent of cycles reached. It is also programmed to not let the load go above the maximum prescribed load, if this occurs, the solenoid valve is programmed to release pressure and close once it is at prescribed load. Figure 4.23, displays the anticipated cycle outlook for the USD system. The user starts from 0 lbs. load and pedals to reach their prescribed

load; the duration of this step is unknown. The system holds this load for an allotted 'hold' time, preventing the user from increasing this load. Then the system dissipates pressure to reach half of the prescribed load, the duration of this step depends on the rate of dissipation by the solenoid valve. The system holds this load for an allotted 'rest' time. After this time is up, the user then again pedals to reach their maximum prescribed load. This cycle continues until the set duration of the therapy is finished, or the emergency button is pressed by the user or researcher.

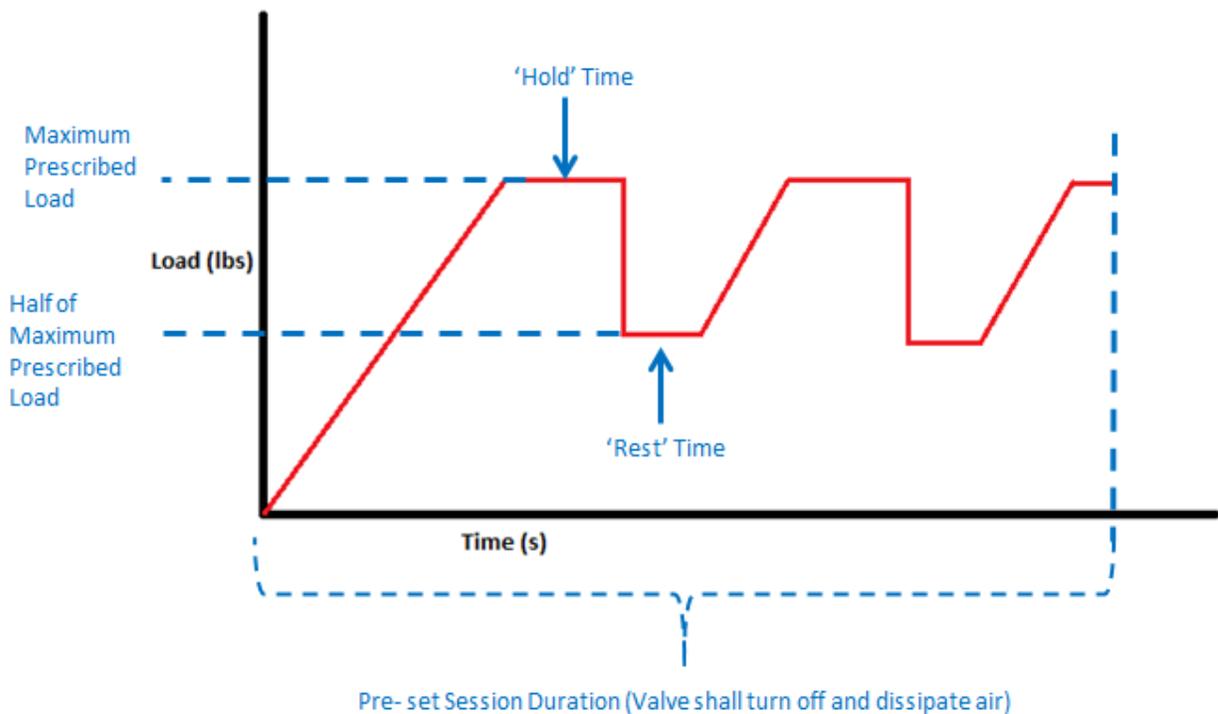


Figure 4.23: Anticipated Cycles of the USD Spinal Decompression Therapy

4.4 Chapter Summary

Chapter 4 presents a comprehensive overview of the electronics and software design of the USD system. The hardware components of the electronics design are discussed that include power distribution, operational indicators, safety features, power switches, sensors incorporated and data collection components. The USD system can be powered via external outlet plug or rechargeable battery. The five sensors utilized for data collection include a load cell integrated to read actuator load, two flexi-force sensors to read feet load, one linear potentiometer to read pedal stroke distance and one linear potentiometer to read actuator distance. The data is collected via usb stick or directly from the graphical interface plots. The researcher graphical interface is designed with requirements that would be implemented for the future user graphical interface that include clear sequential steps and safety features. Lastly, the logic control mechanism for non – surgical spinal decompression therapy is discussed and distinct implementation with incorporated user driven aspects for the USD system is discussed.

Chapter 5: Preliminary Experiments

The preliminary experiments are a series of experiments performed on a dummy subject prior to human experimentation. The preliminary experiments serve two objectives:

1. Acts as a safety validation prior to human experimentation, and
2. Provides an assessment of the technical performance of the USD system. Specifically in terms of:
 - A mechanical loading analysis of the load distribution verifying any force losses.
 - Structural components acting in accordance to USD performance criteria (components repositioning in the right places during spinal decompression therapy).
 - Operational validation of all steps preceding and during spinal decompression including safety features, graphical interface functions, data collection, etc.

This chapter includes:

- An overview of the dummy subject design,
- Presentation of a static analysis to compare experimental results and verify force losses through the mechanical loading analysis, and
- Overview of preliminary experiments and coinciding results.

5.1 Design of Dummy Subject

The utilization of a ‘dummy’ subject will verify the functionality of the USD system without risking injury to a human subject. The ‘dummy’ subject is designed and manufactured based on the behavior of the lumbar spine in spinal decompression. Stiffness specifications and material selection is discussed below.

5.1.1 Stiffness Specifications

As noted in section 3.3.2.4, the spine is seldom subjected to a full tensile load under normal physiological activities. Thus, the stiffness specifications for the dummy subject are based on the findings in “Sustained Lumbar Traction an Experimental Study of Long Spine Segments”, where a longitudinal tensile load is applied to cadaver segments. For this design, the data from young healthy male subjects with ‘good’ non – degenerated discs are utilized. The greatest elongation resulted in 16 mm at initial traction with an applied load of 9 kg [53], thus, approximating a stiffness of 31.42 lb/in to be utilized for the dummy subject.

5.1.2 Materials Utilized

Two blocks of wood are sized and cut into rectangular pieces, where they are utilized as the bases. In addition, straps of about a stiffness of 4.467 lb/in are utilized to act as the lumbar spine. Thus, a total of 7 straps are utilized to provide an overall stiffness of 31.42 lb/in. Lastly, metal hooks are also implemented to connect the straps with the wooden blocks. Figure 5.1, displays built design of the dummy subject, with Figure 5.2, displaying how it is situated in the USD system.

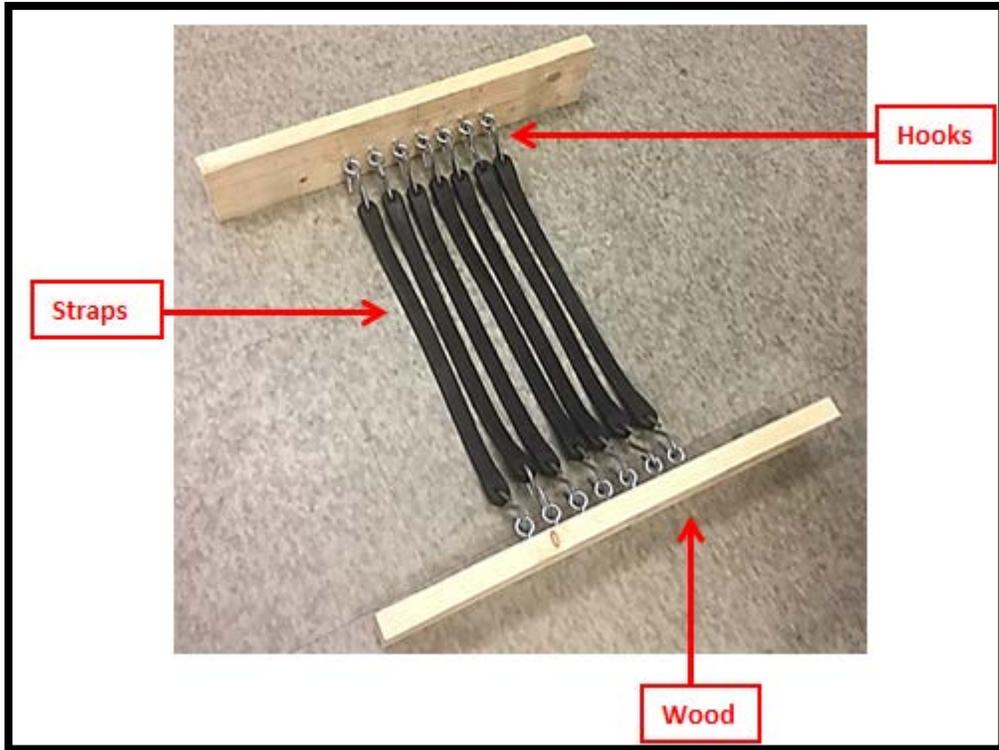


Figure 5.1: Dummy Subject



Figure 5.2: Dummy Subject Incorporated in USD System

5.2 Design Analysis

The following design analysis is a static analysis based on the built USD prototype. This analysis discusses the load distribution during the spinal decompression process, specifically; it discusses the major loads in play and factors contributing to force loss that were unknown in the design phase, such as friction, etc. The design static analysis is utilized to compare with the experimental results ensuring all major loads are accounted for.

The following is explored with the static analysis:

- How much of the applied foot load transpires to the resultant pneumatic actuator force?
- Which factors contribute significantly to force loss?

5.2.1 How much of the Applied Foot Load Transpires to the Resultant Pneumatic Actuator Force

The objection of this section is to present the forces acting during pedaling that decrease the overall force produced by the pumper, due to pressure accumulation. Equation (5.1) below represents the 'pumper' pneumatic cylinder and all associated loads involved in producing the pressure accumulation inside the pumper:

$$\sum F_X = 0; \quad F_{PF} + F_{LG} + F_S + F_P - F_F \cos \theta = 0; \quad (5.1)$$

The pressure accumulated in the pumper transpires to the actuator, which is how the pumper and actuator are intertwined. The abbreviations in equation (5.1) are expanded on below, where an analysis on how much foot load transpires to the resultant pneumatic actuator force is delved in. A specific free body diagram relating to equation (5.1) is represented in Figure 5.3: FBD of 'Pumper' and Associated Loads.

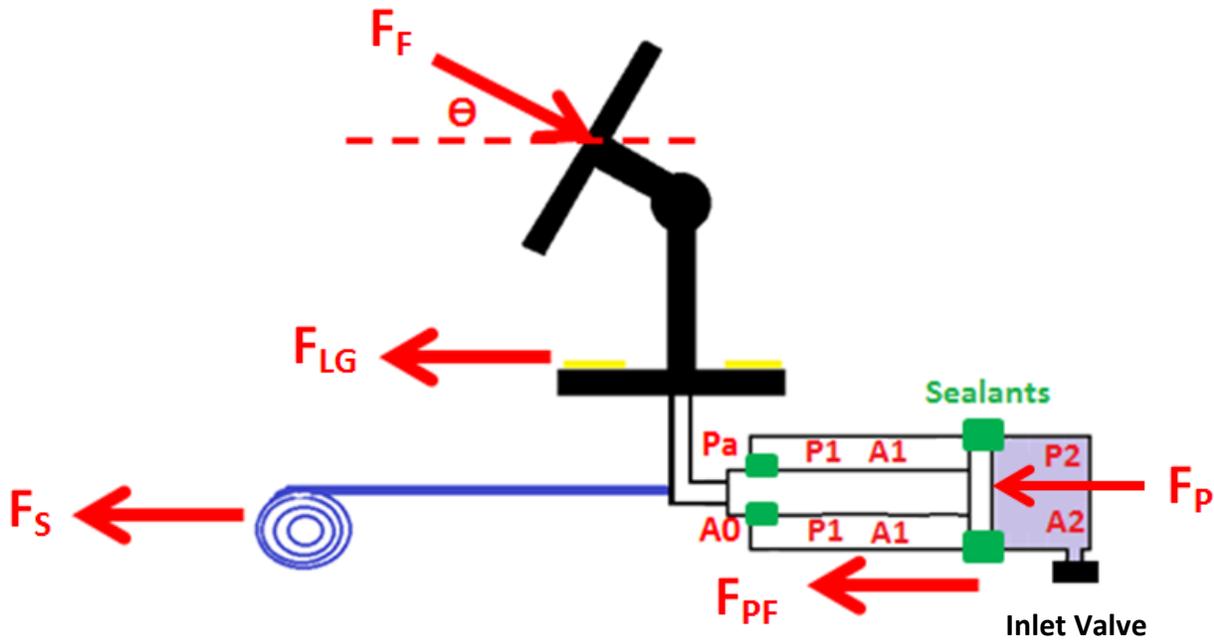


Figure 5.3: FBD of 'Pumper' and Associated Loads

The abbreviations in equation (5.1) stand for:

- F_{PF} represents the force due to the pump friction, 'PF', specifically, it is the dry friction of the pumper as a result of the sealants incorporated for leak prevention and is denoted as '*Friction of Pumper*' in Figure 5.3. The dry friction is determined experimentally as there is a lack of information in catalogs covering friction characteristics. The dry friction is determined to be approximately 3.5 lbs.
- F_{LG} represents the frictional force due to the linear guides, 'LG', by Igus DryLin 'low profile guides' attached to the pedal plate, denoted as '*Friction of Linear Guide*' in Figure 5.3. The frictional force is a result of the vertical component of the feet load and the moment applied to the pedal. The frictional coefficient of the Igus DryLin low profile guide is $\mu = 0.12$, and is denoted as ' μ_{LG} '. F_{LG} is represented by equation (5.2) and Figure 5.4.

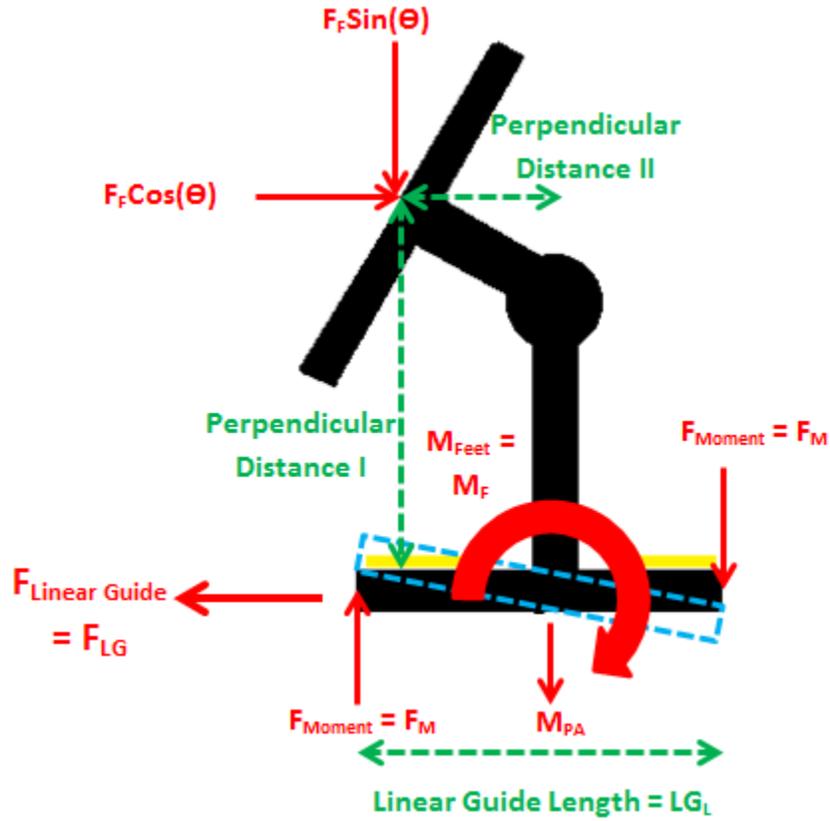


Figure 5.4: FBD of Loads Acting on Pedal Assembly

$$F_{LG} = (F_F \sin \theta + M_{PA} + F_M) \times \mu_{LG} \quad (5.2)$$

$$F_M = \frac{M_F}{LG_L} \quad (5.3)$$

$$M_F = ((F_F \cos \theta \times PD_I) - (F_F \sin \theta \times PD_{II})) \quad (5.4)$$

$$F_{LG} = \left(F_F \sin \theta + M_{PA} + \left(\frac{((F_F \cos \theta \times PD_I) - (F_F \sin \theta \times PD_{II}))}{LG_L} \right) \right) \times \mu_{LG} \quad (5.5)$$

Equation (5.2) presents the forces contributing to the friction load of the linear guides, where $F_F \sin(\theta)$ is the vertical feet load component acting on the linear guides and M_{PA} is the weight of the pedal assembly, 'PA' acting on the linear guides. F_M is represented by equation (5.3), denoted as ' F_{Moment} ' in Figure 5.4, which is the vertical force acting on the linear guides due to the applied moment, ' M_F ', and the Linear Guide Length, ' LG_L ', is the length of two linear guides in series. The F_M is distributed between two guides on separate sides, thus, it is divided by two. Equation (5.4) represents the applied moment during pedaling, where PD_I and PD_{II} represent, perpendicular distance I and perpendicular distance II, respectively in Figure 5.4: FBD of Loads Acting on Pedal Assembly. Equation (5.4) substituted into equation (5.3), and then substituted into equation (5.2) yields the resulting equation (5.5).

- F_S represents the force acting due to the constant 10 lbs. load spring, 's'; the spring load is considered when the optional automatic pedal feature is incorporated. 10 lbs. is enough to overcome the 6 lbs. static friction of the pneumatic cylinder and return the pedal to its initial position at a moderate rate. A constant load spring of 7 lbs. was initially tested, but the pedal return was very slow resulting in delays.
- F_P represents the force created in the pump, 'P', due to the pressure accumulated in the pneumatic chamber denoted as P_2 in Figure 5.3. The pump force created inside pressure chamber 2 of the pneumatic cylinder is represented by equation (5.6):

$$F_P = P_2A_2 - P_1A_1 - P_aA_r \quad (5.6)$$

Where P_a , P_1 and P_2 are absolute pressures, since the air port of pressure chamber 1 is always open, P_1 is atmospheric pressure. P_a is the pressure around the exposed piston rod which is also denoted by atmospheric pressure. A_r , A_1 and A_2 are the cross sectional areas of the respective chambers. Thus, F_P can be represented by equation (5.7):

$$F_P = P_2A_2 - P_1A_1 - P_aA_r = P_2A_2 - P_aA_2 = P_{2G}A_2 \quad (5.7)$$

Where P_{2G} is the gauge pressure inside pressure chamber 2 of the ‘pumper’ pneumatic cylinder

- $F_F \cos(\theta)$ is the feet load applied in the longitudinal x – direction measured by the pedal sensor

An expanded equation (5.1) with equations (5.5) and (5.7) substituted in results in equation (5.8):

$$\begin{aligned} \sum F_X = 0; F_{PF} & \quad (5.8) \\ & + \left(F_F \sin \theta + M_{PA} \right. \\ & \left. + \left(\frac{\left(\frac{(F_F \cos \theta \times PD_I) - (F_F \sin \theta \times PD_{II})}{LG_L} \right)}{2} \right) \right) \times \mu_{LG} + F_S \\ & + P_{2G}A_2 - F_F \cos \theta = 0; \end{aligned}$$

The unknown component in equation (5.8) is P_{2G} the gauge pressure in chamber 2, which is the component of interest. Rearranging equation (5.8) in terms of P_2 gives equation (5.9):

$$P_{2G} = \left(F_F \cos \theta - F_{PF} \right. \\ \left. - \left(\left(F_F \sin \theta + M_{PA} \right. \right. \right. \\ \left. \left. \left. + \left(\frac{\left((F_F \cos \theta \times PD_I) - (F_F \sin \theta \times PD_{II}) \right)}{2 LG_L} \right) \right) \right) \times \mu_{LG} - F_S \right) \\ / A_2 \quad (5.9)$$

When the inlet valve is open, P_{2G} is equal to P_{3G} , refer to Figure 5.5, thus, the resultant pneumatic actuator force is represented by equation (5.10):

$$F_A = P_{3G} A_3 \quad (5.10)$$

Where P_{3G} is equal to P_{2G} when the inlet valve is open, thus, substituting equation (5.9) into equation (5.10) yields equation (5.11):

$$F_A = \left(\left(F_F \cos \theta - F_{PF} - \left(F_F \sin \theta + M_{PA} + \left(\frac{((F_F \cos \theta \times PD_I) - (F_F \sin \theta \times PD_{II}))}{2} \right) \right) \right) \times \right. \\ \left. \left(\mu_{LG} \right) - F_S \right) / A_2 \times A_3 \quad (5.11)$$

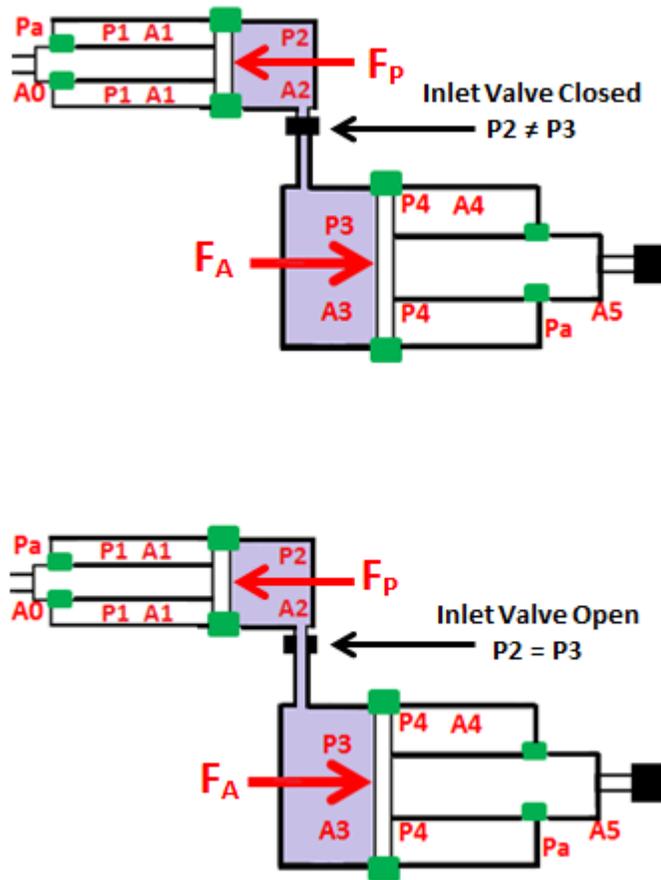


Figure 5.5: Inlet Valve Effect on Pressurization

- F_A is the force produced as a result of the pressure build up in chamber 3 and its associated cross sectional area. F_A can be expressed as follows:

$$F_A = P_3A_3 - P_4A_4 - P_aA_5 = P_3A_3 - P_aA_3 = P_{3G}A_3 \quad (5.12)$$

Where P_a , P_3 and P_4 are absolute pressures, since the air port of pressure chamber 4 is always open, P_4 is atmospheric pressure. P_a is the pressure around the exposed piston rod which is also denoted by atmospheric pressure. A_3 , A_4 and A_5 are the cross sectional areas of the respective chambers

- F_{AF} represents the actuator friction, 'AF', specifically it is the dry friction of the actuator pneumatic cylinder as a result of the sealants incorporated for leak prevention and is denoted as '*Friction of Actuator*' in Figure 5.6. The dry friction is determined experimentally as there is a lack of information in catalogs covering friction characteristics. The dry friction is determined to be approximately 8lbs.

It should be noted that the load cell reading in the USD system is the actuator force subtracted by the actuator friction and is represented by equation (5.13), where F_{RAF} stands for the resultant actuator force; refer to Figure 5.6:

$$F_{RAF} = F_A - F_{AF} \quad (5.13)$$

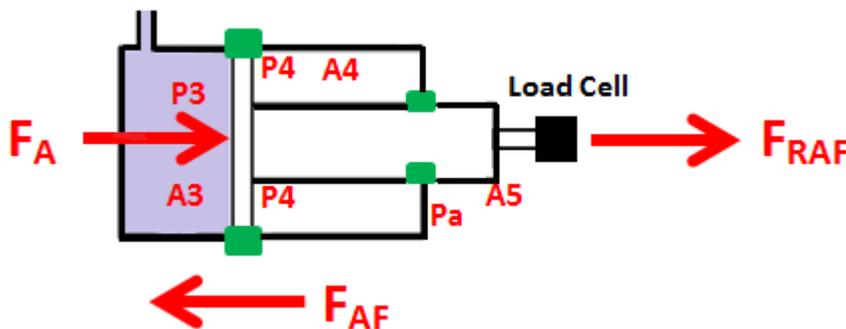


Figure 5.6: FBD for Resultant Actuator Force

Substituting equation (5.11) into (5.13) yields:

$$\begin{aligned}
 F_{RAF} = & \left(\left(F_F \cos \theta - F_{PF} \right. \right. \\
 & - \left(\left(F_F \sin \theta + M_{PA} \right. \right. \\
 & \left. \left. + \left(\frac{((F_F \cos \theta \times PD_I) - (F_F \sin \theta \times PD_{II}))}{LG_L} \right) \right) \right) \\
 & \left. \left. \times \mu_{LG} - F_S \right) / A_2 \right) \times A_3 - F_{AF}
 \end{aligned} \tag{5.14}$$

5.2.2 Which Factors Contribute Significantly to Force Loss

The significant factors contributing to force loss are outlined in section 5.2.1, above, and they include pneumatic cylinder friction, constant spring force (optional), linear guide friction and linear bearings friction. These factors are considered significant if the prescribed load is low. It is demonstrated in section 5.3.1, below; as the prescribed load increases the force loss factors become less significant.

It should be noted that a greater pedal angle will result in less force being transferred to actuator and greater force adding to the friction of the pedal linear guides, hence greater force loss.

5.3 Experiments Overview

The experiments performed on the dummy subject were coordinated by the researcher where the researcher pedals by hand in the standing position to reach the prescribed load. Note that the researcher did not sit on the USD system during the experiments ensuring the dummy subject is the only additional external weight on the system. The experiments explore the following:

- Do the experimental results match the calculated results?
- Can the USD system maintain a load for a specified time?
- Is the solenoid valve dissipation exact in reaching a desired pressure?

The experiments performed on the dummy subject employ the same variable factors that are employed in the pilot study, such as experiment duration, hold time and relaxation time. Unless otherwise indicated, the experiment duration is 3 minutes long, the hold time is 10 seconds and the rest time is 5 seconds. In addition, unless otherwise indicated, the ‘prescribed load’ will be based on 25% of the 95th percentile male body weight, which is 53 lbs. A ‘target load’ will be visible in all force data plots; the target load indicates what load the user should be at.

5.3.1 Do the Experimental Results Match the Design Analysis

Four experiments are performed on the dummy subject with target loads of 33 lbs., 53 lbs., 73 lbs., and 93 lbs. Each experiment was performed with a pedal angle of 20° and a manual pedal return, hence 0 lbs. of spring load as outlined in [Table 5.1](#).

Figure 5.7, below, displays when the prescribed load is reached along with the required hand load.

In addition, all four plots of the varying loads are displayed in Figure 5.8.

Table 5.1: Dummy Subject – Calculated Versus Experimental Results

Exp #	Prescribed Load (lbs.)	Hand Load (lbs.)	Pedal Angle (°)	Spring Load (lbs.)	Calculated Resultant Actuator Load (lbs.)	% Error	Ratio
1	33	17.7	20	0	37.5	12	1.9
2	53	22.0	20	0	52.1	1.7	2.4
3	73	29.8	20	0	78.7	7.2	2.5
4	93	34.0	20	0	93.3	0.3	2.7

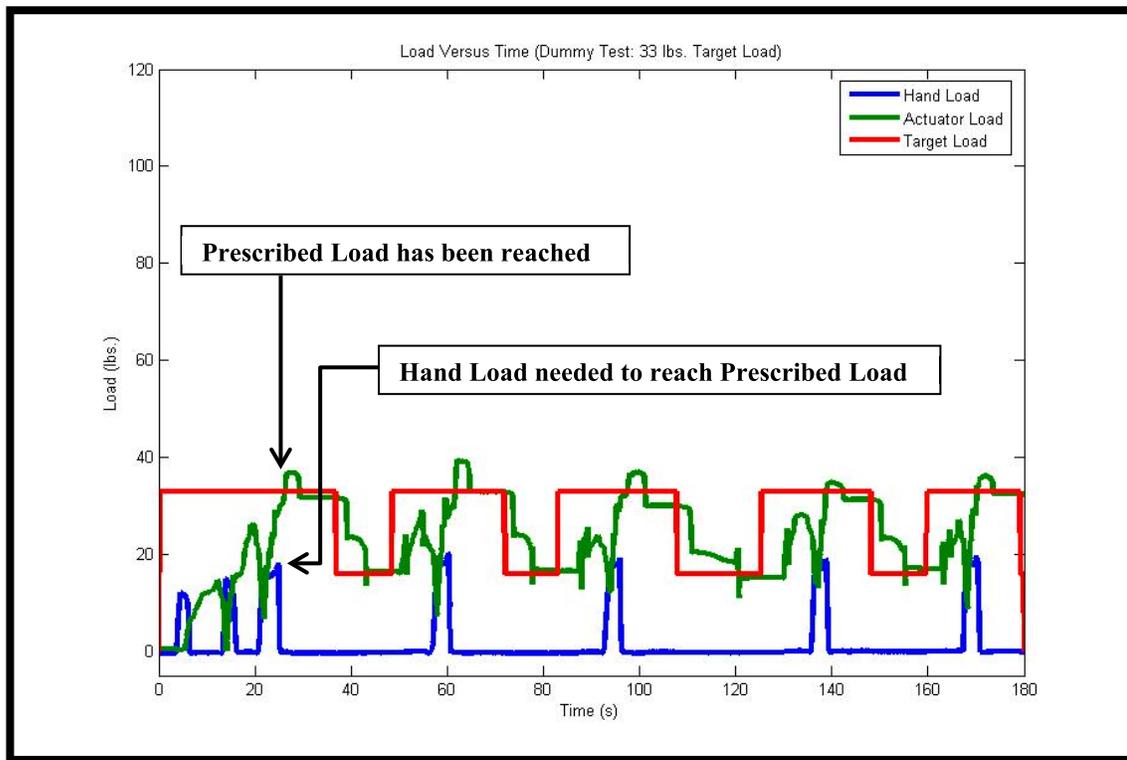


Figure 5.7: 33 lbs. Spinal Decompression Therapy on

The calculated resultant actuator load is calculated using equation (5.13), where the hand load is replaced for the F_F component, specifically the average hand load across all cycles is taken.

The *percent error* displayed in Table 5.1: Dummy Subject – Calculated Versus Experimental Results is calculated using equation (5.15):

$$\% \text{ Error} = \left| \frac{\# \text{Prescribed} - \# \text{Calculated}}{\# \text{Calculated}} \right| \times 100 \quad (5.15)$$

The % error is the difference of the prescribed load from the calculated load, is a measure indicating if all forces are accounted for in the analysis. It can be concluded that the design analysis is valid due to the low percent error. The average percent error between the calculated and prescribed load results is 5.3 %. The design analysis is a conservative analysis and variation of the how user applies the load with their feet is unaccounted for and may become more visible in the pilot study.

The *Ratio* displayed in Table 5.1: Dummy Subject – Calculated Versus Experimental Results is calculated using equation (5.16) :

$$\text{Ratio} = \frac{\text{Prescribed Load}}{\text{Hand Load}} \quad (5.16)$$

It is demonstrated that as the prescribed load increases, the ratio of the actuator load to hand load increases. This is so because the forces contributing to force loss became less apparent as a greater prescribed load is required. Without any force loss, the ratio of actuator load to hand or feet load would be 4, as this value is the ratio between the area of the pneumatic actuator and pneumatic pumper. In addition, it is demonstrated that as the prescribed load is increased by 20

lbs., as it is between the varying experiments displayed in Table 5.1: Dummy Subject – Calculated Versus Experimental Results, an average increase of 5.4 lbs. of hand load is required. This verifies the sizing ratio of the pneumatic cylinders implemented, since a prescribed load of 20 lbs. requires 5 lbs. supplied by the pumper.

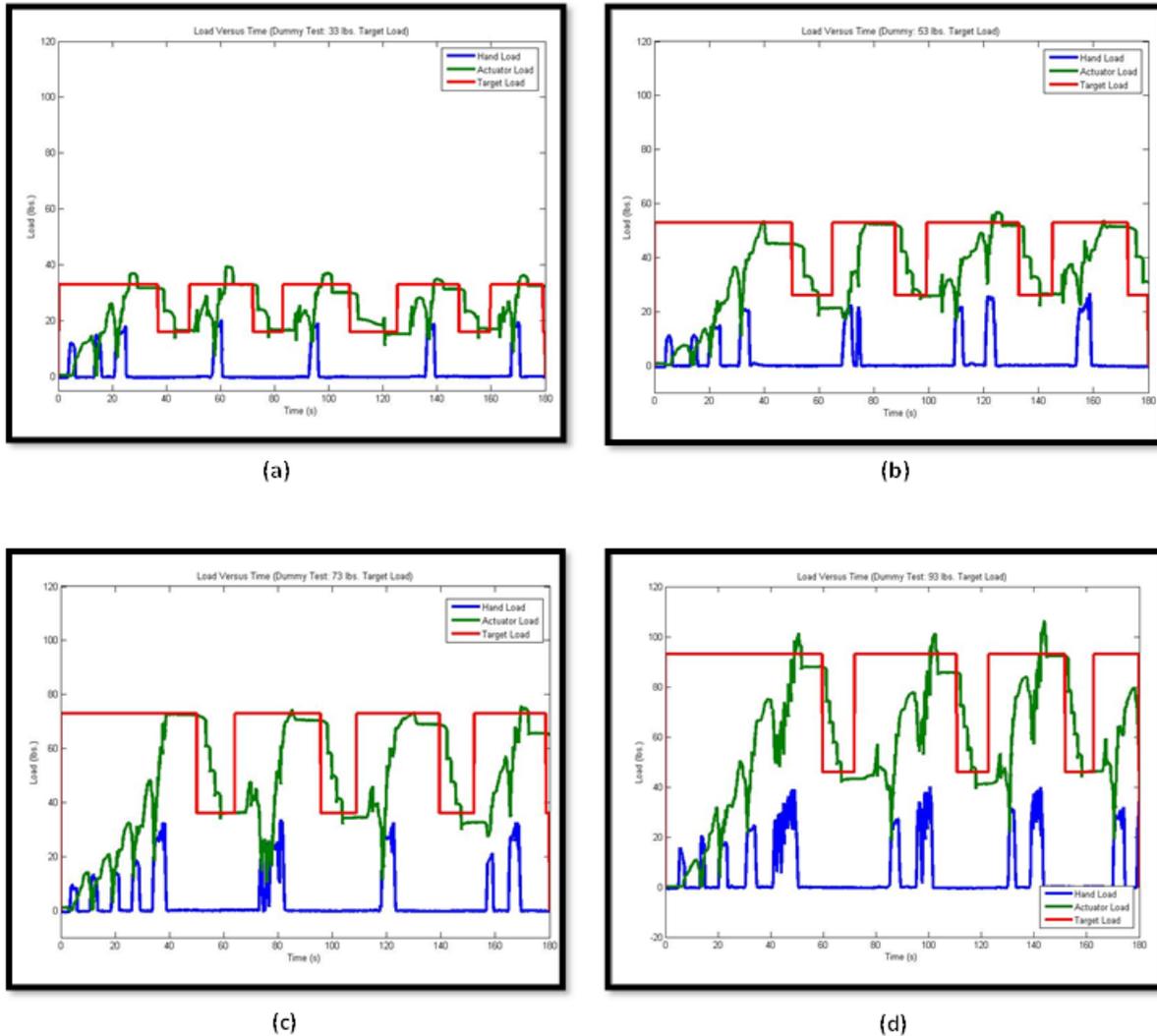


Figure 5.8 Four Different Prescribed Loads of Spinal Decompression Therapy on a Dummy Subject - (a) has a prescribed load of 33 lbs., (b) has a prescribed load of 53 lbs., (c) has a prescribed load of 73 lbs. and (d) has a prescribed load of 93 lbs.

5.3.2 Can the USD System Maintain a Load for a Specified Time

An experiment with extended hold and rest times is performed on the dummy subject to verify the USD system can maintain a load for a specified time. The hold time is extended from 10 seconds to 30 seconds and the rest time is extended from 5 seconds to 15 seconds. The results are plotted and displayed in Figure 5.9. The results verify that the USD system is capable of maintaining a load for a specified time with no disruptions.

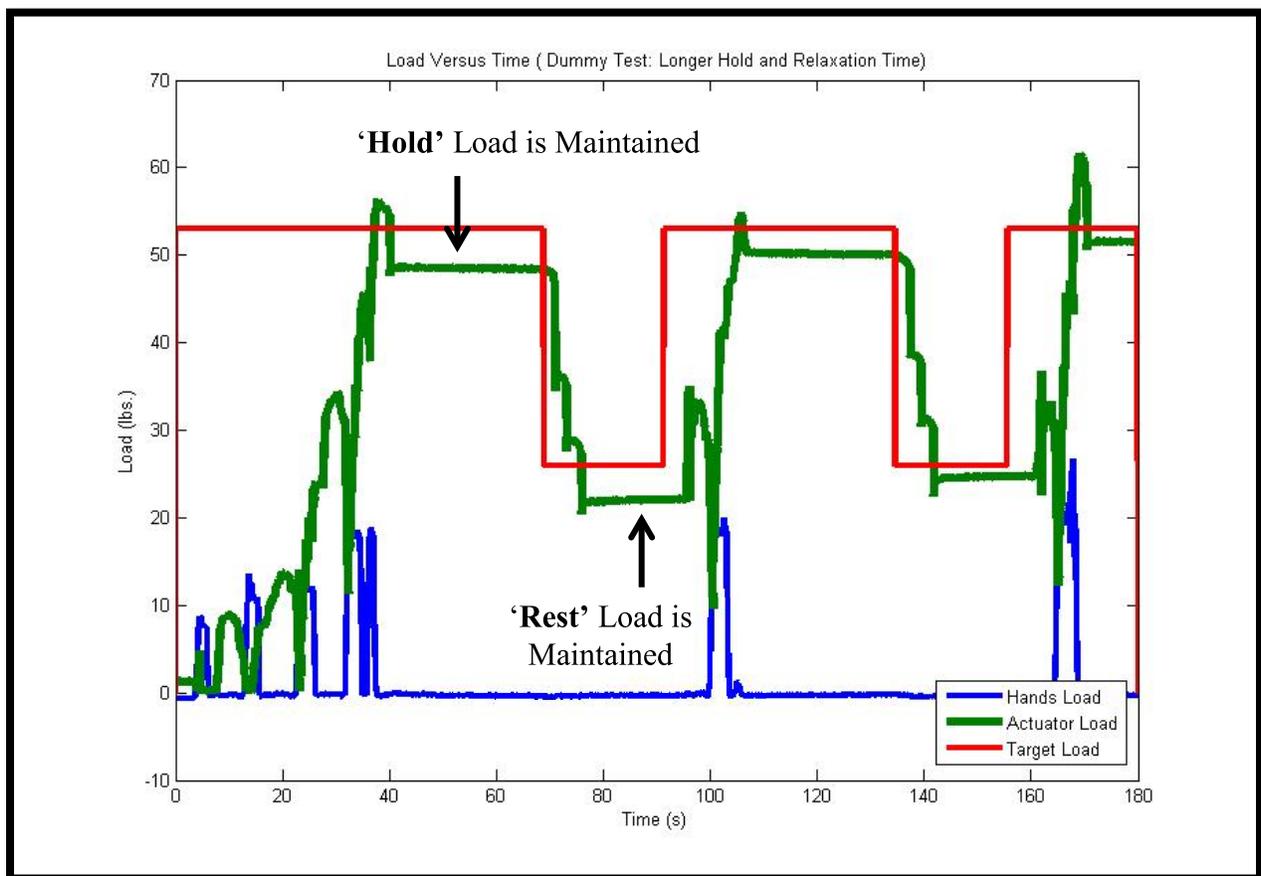


Figure 5.9: Spinal Decompression Therapy on Dummy Subject with Extended Hold and Rest Times

5.3.3 Is the Solenoid Valve Dissipation Exact in Reaching Desired Pressure

When the target load is reached the results indicate that the actuator load does not always settle on the specified target load. This can be perceived from Figure 5.8, and Figure 5.9.

The reason for the misalignment is due to the valve exit port being too large in this circumstance.

On the contrary its dimensions are quite small in general, with a diameter of 0.7 mm [61], although, with a high flow rate, this presents a slight hindrance.

A simple solution is to implement a manual flow control valve to reduce the diameter of the solenoid valve, and hence reduce the dissipation rate. The results are plotted and displayed in Figure 5.10. It is evident from the results that the use of a flow control valve in the USD system is an improvement in terms of the actuator load precisely settling on the target load. Although, this preciseness comes with a slower dissipation rate, which vastly increases the time it takes to reach half of the prescribed load during each cycle. Thus, a flow control valve will not be utilized in the pilot study experiments and a slight hindrance of actuator load settling is acceptable for the pilot study experiments.

Literature has indicated the difficulties in obtaining position and force control of pneumatic components due nonlinearities, where methods have been investigated and solutions proposed [51] . This is an area that can be explored in the second prototype of the USD system.

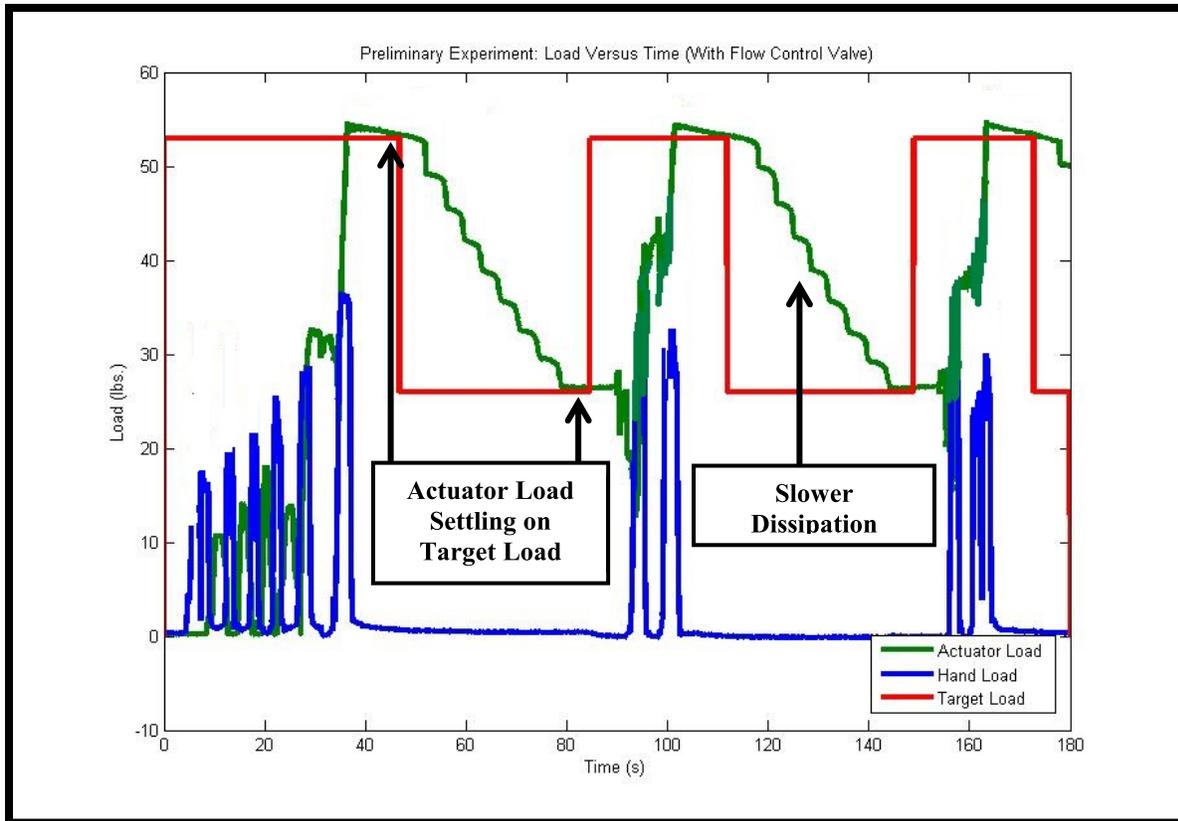


Figure 5.10: Experiment with Flow Control Valve Attached to Solenoid Valve

5.3.4 Meniscal Load Fluctuation

In the plots it is apparent a slight load fluctuation occurs during pedal return, specifically, when the user returns the pedal during pedaling there is a slight decrease in load when it should have maintained constant. This is due to a moment applied causing a disturbance to the load cell reading, as a result of the pedaling system and conjoining linear rail system mounted on the same wooden component as the load cell mount. An experiment is performed where the pneumatic pumper is disconnected from the linear rail system, resulting in Figure 5.11. The results indicate the disturbance during pedal return is now absent.

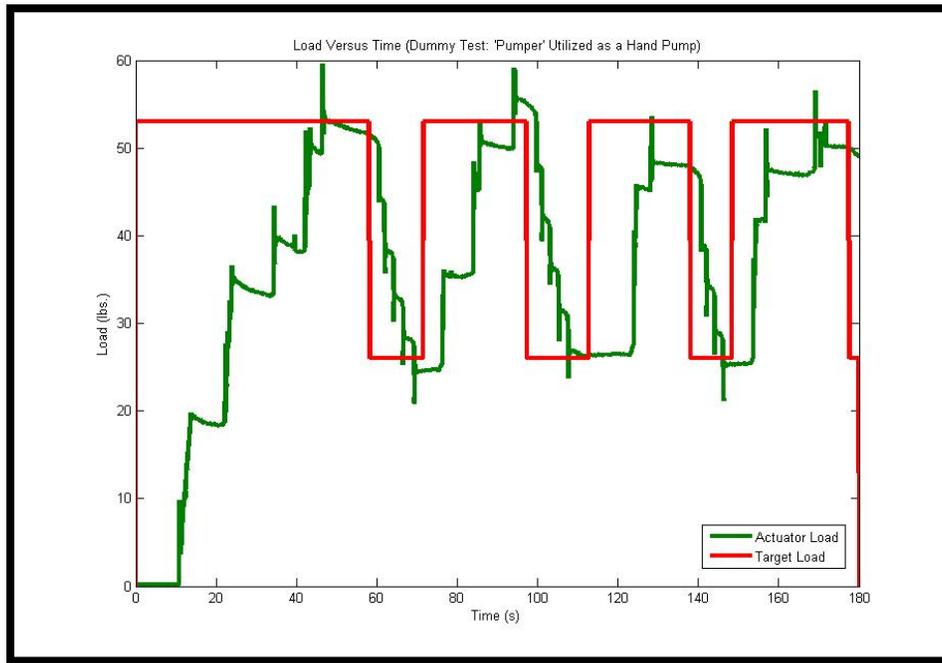


Figure 5.11: Pneumatic Pumper is disconnected from Linear Rail

5.4 Chapter Summary

Chapter 5 discussed the significance behind performing preliminary experiments on a dummy subject prior to human experimentation with an overview of the dummy subject design. In addition, a design analysis of the load distribution during spinal decompression therapy in the USD system is presented to verify experimental results. An overview of the preliminary experiments and specific objectives were outlined.

The design analysis presented is deemed successful with a percent error of 5.3% in comparison to experimental results. The USD system is able to maintain a load for a specified time. Lastly, the solenoid valve's preciseness in terms of reaching a desired pressure is analyzed, where the current setup is deemed satisfactory for the pilot study, but areas for improvement are suggested and can be explored in the future. Overall, the experiments performed on the dummy subject are deemed successful and no abnormal issues arose. The USD system is deemed functional to perform experiments on human subjects.

Chapter 6: Pilot Study

6.1 Introduction

The pilot study, consisting of a series of experiments, is designed to validate the functionality of the USD system concentrating on user interaction and user feedback. The pilot study experiments with healthy participants and investigates the capability of the system rather than its therapeutic effectiveness.

The following chapter presents an overview of the pilot study by providing an overview of possible experiments, experiments objectives, ethical clearance, protocol, results and discussion. The results provide a quantitative assessment based on the numerical data collected, and a qualitative assessment based on the feedback of the participants through their answers to a customized USD system questionnaire.

6.2 Selection of Experiments

As discussed in the previous chapters, the USD system is the first prototype conforming to a user driven non – surgical spinal decompression system and is developed with various features to enable experiments in order to narrow down the specifications for the next generation system. Thus, due to numerous features incorporated in the system, there are several categorical experiments to be performed. A selection of these experiments are performed and focused on in this pilot study. The following section provides an outline of the various features available in the USD system and the experiments selected that are focused on in this pilot study. The USD system is designed with different options for different sections of the overall system, including

spine region, anatomical positions, restraints, and pedaling options; these features are outlined in Figure 6.1.

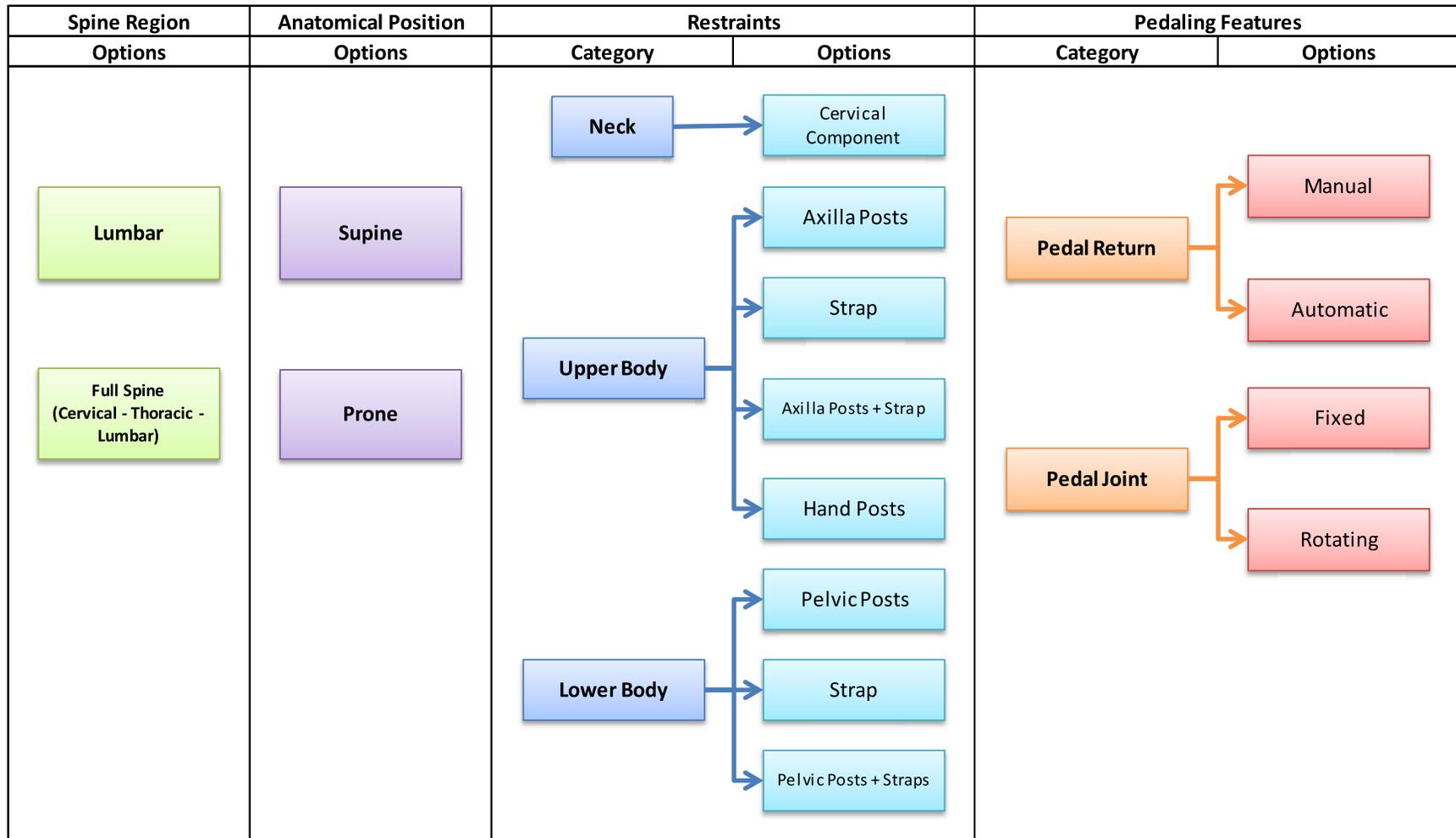


Figure 6.1: USD Sections and their Respective Options

Although, as noted in section 3.4, not all options of the various sections can be combined during therapy. The permissible combinations among the various available sections within the USD system are displayed in Figure 6.2, with the combinations to be experimented on are highlighted in red. Lumbar spinal decompression can be performed in the supine or prone position, both requiring an upper body and lower body restraint. While the full spine spinal decompression can only be performed in the supine position, which requires a neck and lower body restraint. Each required restraint has various options of restraints to choose from, which are indicated in Figure 6.3, with the restraint options to be experimented on are highlighted in red.

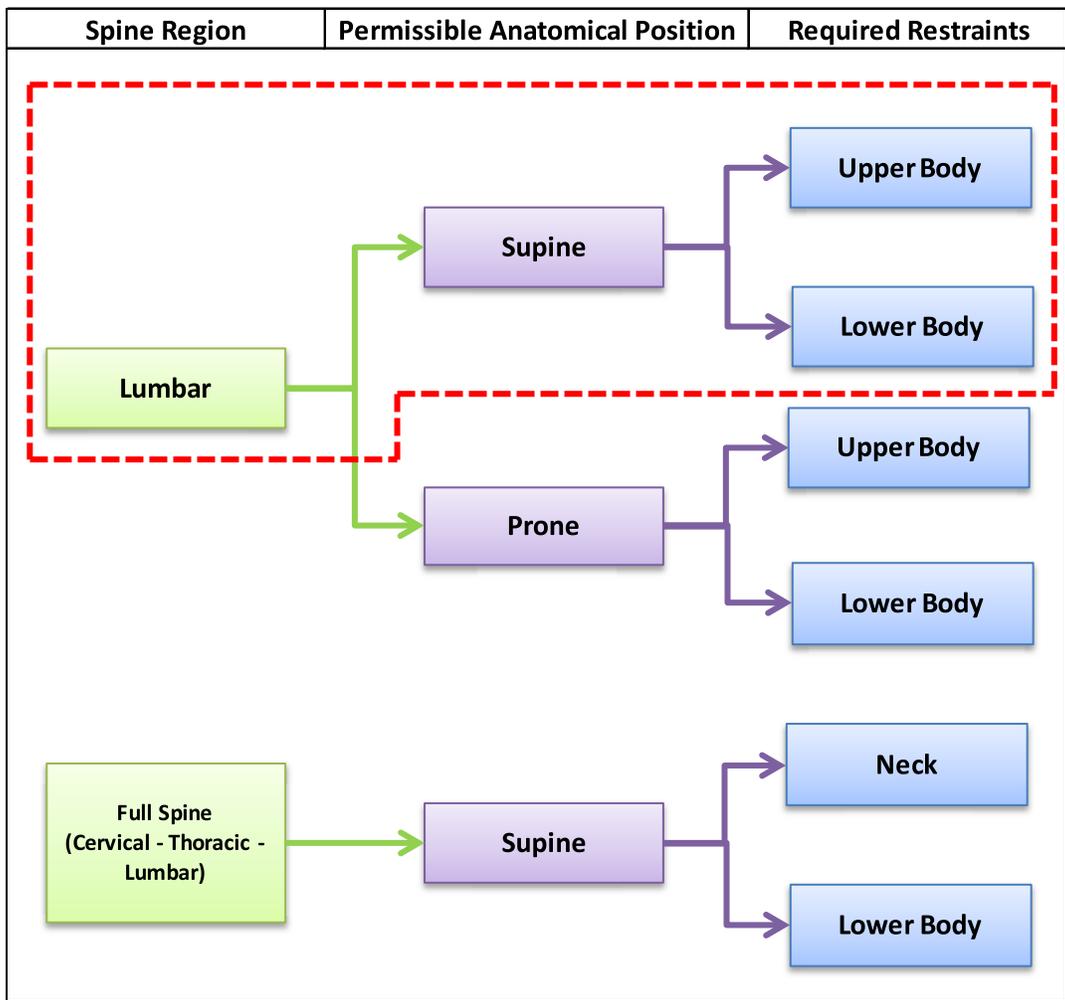


Figure 6.2: Permissible Combinations – USD Pilot Study Experiments

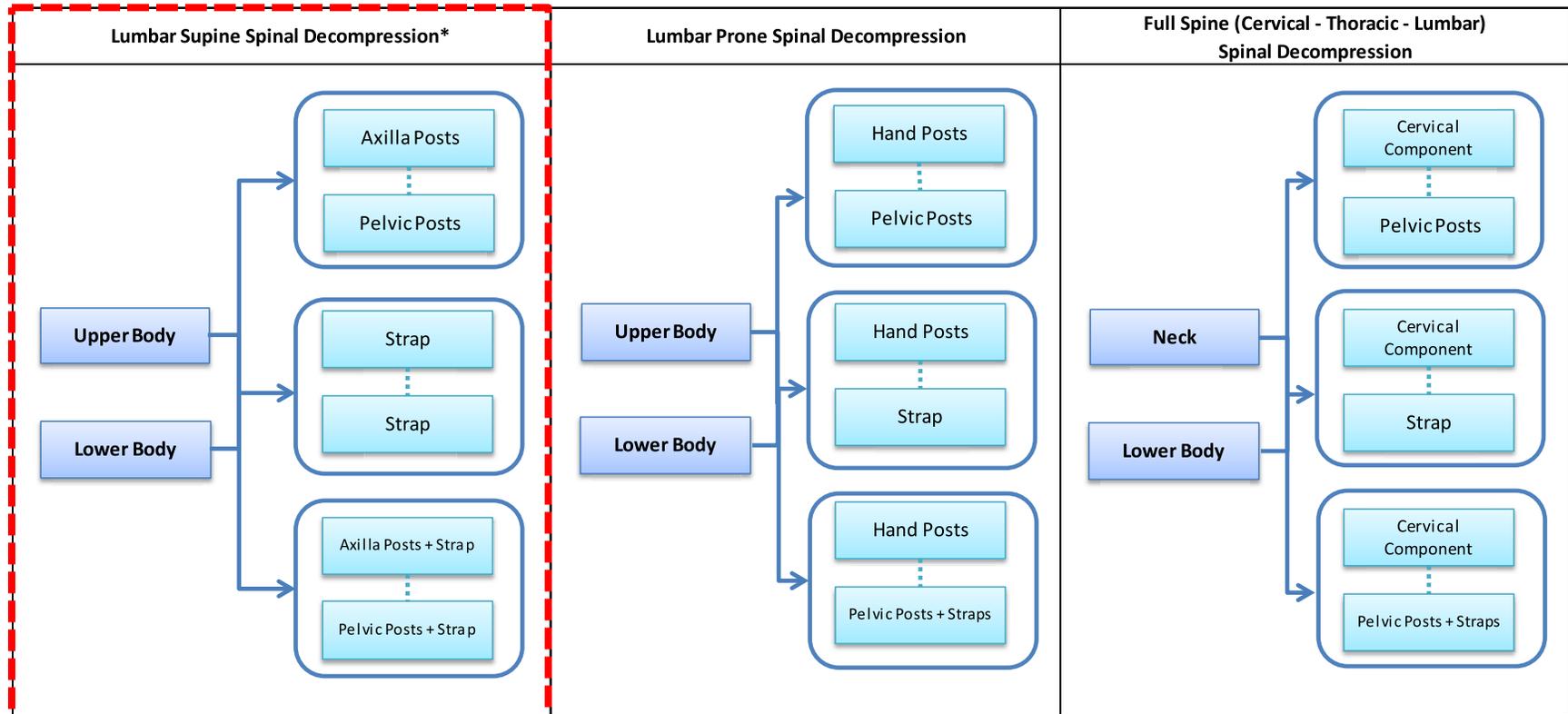


Figure 6.3: Restraint Combinations for the Specific Spinal Region and Anatomical Position

The various combinations of restraint options permissible for the specific spinal region and anatomical position are displayed in Figure 6.3. It should be noted that for the lumbar spinal supine decompression therapy, there are three upper body restraint options and three lower body restraint options, resulting in a possibility of nine combinations. Although, the primary three combinations presented are based on design equivalency of upper body restraint to lower body restraint. The three combinations are posts based combination, strap based combination and a posts and strap combination.

For the lumbar prone spinal decompression, there is one available option for the upper body restraint, which is the hand restraint, and there are three lower body restraints, resulting in three combinations to experiment with. Although, as there is one upper body restraint, the hand restraint, in itself has various positions and adjustments to work with, this results in the exploration of more combinations and thus, more potential experiments.

Lastly, for the full spine supine spinal decompression therapy, there is one available option for the neck restraint, which is the cervical component, and there are three lower body restraints, resulting in three restraint combinations to experiment with.

The available pedaling features for the USD system are displayed in Figure 6.4. There are two categories of mandatory features to select, which includes the type of pedal return and the type of pedal joint. There are four possible combinations of the pedal return and pedal joint, although, the combination of an automatic pedal return and a rotating joint is doable; the feasibility of the combination in the USD system is not. Thus, this leaves three permissible pedaling features combinations to experiment with. The three pedaling features combinations can be utilized with any of the spinal regions, anatomical positions and restraints.

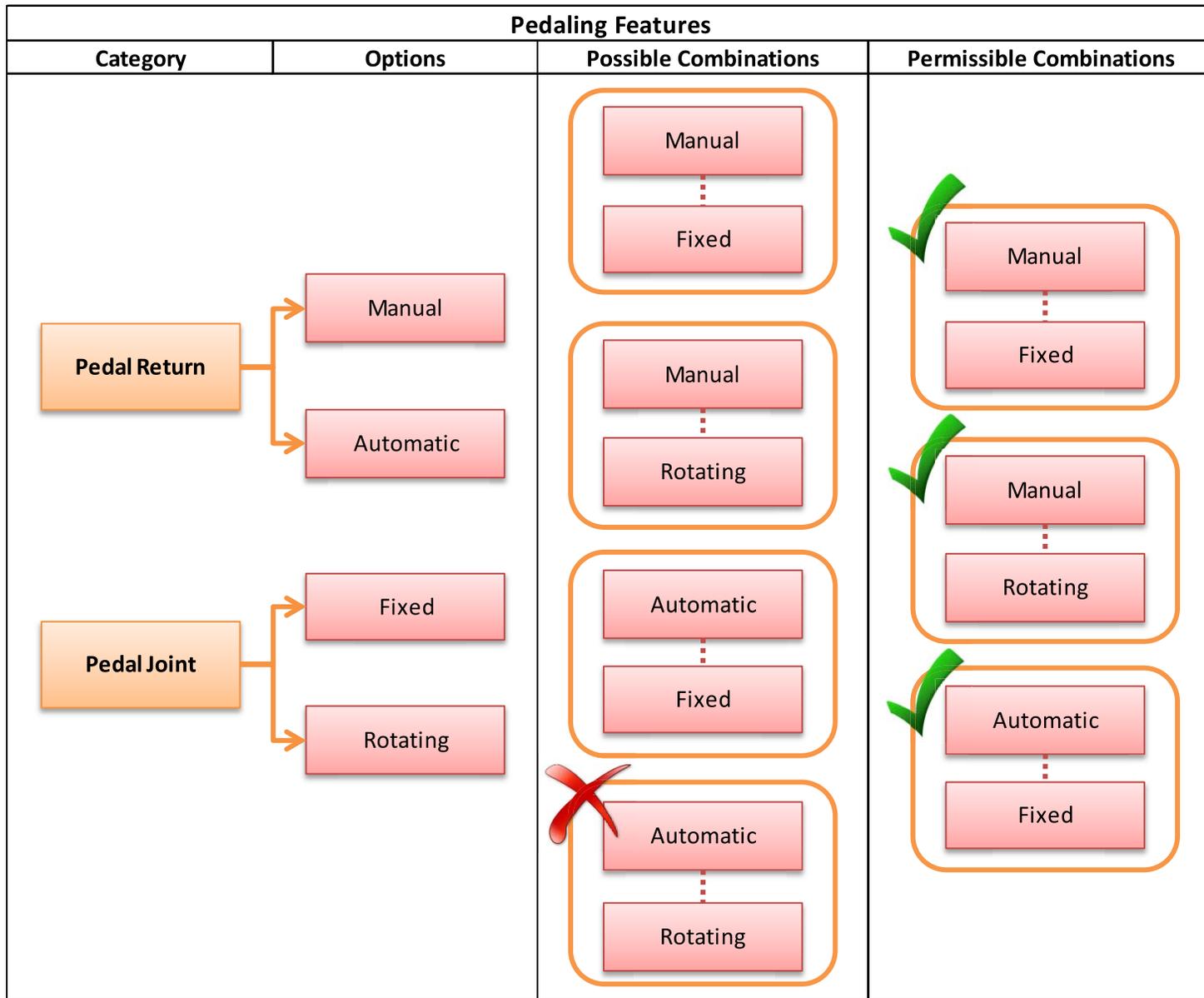


Figure 6.4: Pedal Features Combinations

To simplify the experiments assortment, there will be two categories of experiments. Category 1 will be *Exploration of Pedaling Options* and category 2 will be *User Driven Non – Surgical Spinal Decompression*, refer to Table 6.1 and Table 6.2, respectively. Experiments performed in this study are highlighted in red and the protocol is discussed in section 6.5. For category 1, experiment numbers 1 to 3 in Table 6.1 are performed, for category 2, experiment numbers 1 to 3 in Table 6.2 are performed.

Table 6.1: Category 1 - Exploration of Pedaling Options

Experiment #	Anatomical Position	Pedal Return	Pedal Joint
1	Supine	Manual	Fixed
2	Supine	Manual	Rotating
3	Supine	Automatic	Fixed
4	Prone	Manual	Fixed
5	Prone	Manual	Rotating
6	Prone	Automatic	Fixed

Table 6.2: Category 2 - User Driven Non – Surgical Spinal Decompression Experiments

Experiment #	Spine Region	Anatomical Position	Upper Body/Neck Restraint	Lower Body Restraint	Pedal Return	Pedal Joint
1	Lumbar	Supine	Axilla Posts	Pelvic Posts	User Preference	User Preference
2	Lumbar	Supine	Strap	Strap	User Preference	User Preference
3	Lumbar	Supine	Axilla Posts + Strap	Pelvic Posts + Strap	User Preference	User Preference
4	Lumbar	Prone	Hand Posts	Pelvic Posts	User Preference	User Preference
5	Lumbar	Prone	Hand Posts	Strap	User Preference	User Preference
6	Lumbar	Prone	Hand Posts	Pelvic Posts + Strap	User Preference	User Preference
7	Full Spine (Cervical - thoracic - Lumbar)	Supine	Cervical Component	Pelvic Posts	User Preference	User Preference
8	Full Spine (Cervical - thoracic - Lumbar)	Supine	Cervical Component	Strap	User Preference	User Preference
9	Full Spine (Cervical - thoracic - Lumbar)	Supine	Cervical Component	Pelvic Posts + Strap	User Preference	User Preference

6.3 Experiments Objective

The experiments described in this chapter investigate the following questions:

1. *Do users have specific pedaling characteristics and do they have a preference to specific pedaling features?* The USD system's method of producing a load to decompress the spine is through user pedaling, thus, pedaling is a significant aspect of the overall system. The users' feedback regarding the pedal features will be utilized to assess the efficiency of the current designs. In addition, the users' feedback is to determine which features are more favored and to assess the need of having more than one option in the final USD version. In addition, the pedaling characteristics of users will be assessed in terms of stroke length and speed.
2. *What are the loading characteristics in the USD system and the user feedback regarding its associated attributes?* A design requirement of the USD system is the user applies a low load to the pedal to produce a high load in the actuator. The preliminary experiments performed on a dummy subject verified the design analysis with the experimental results. The pilot study experiments further analyzes the design analysis with human subjects, simultaneously, analyzing any factors that were unnoticed in the preliminary experiments. In addition, user feedback regarding characteristics of the force ratio in regards to incremental loading and ratio attributes will be analyzed.
3. *Which upper body and lower body restraint combination is most suitable for supine lumbar spinal decompression in the USD system?* There are three combinations to experiment with, which include a post based design, a strap based design and a combination of posts and strap based design. The suitability of restraint combinations is based on the ability of the restraints to effectively grip and prevent slippage of the required spine region during spinal

decompression. A comparison of displacement data between the three combinations will be analyzed. In addition to performance based criteria, the suitability of the restraint combinations will also be based on user preference and comfort. Thus, user feedback will be utilized in the suitability of the restraint combinations' analysis.

4. *Are there user specific response characteristics during the spinal decompression process? Specifically, how does user response time vary in the cyclic pedaling process during spinal decompression in the USD system?* As discussed in chapter 2, the current non – surgical spinal decompression devices are machine controlled and the attainment of target load and half target load are implemented at a preset time. While in the USD system, the first user driven non – surgical spinal decompression system, the process of reaching target load during each cycle is based on the user response time to initiate pedaling and user specific rate of pedaling. There are known advantages and disadvantages in comparing the capabilities of human versus machine. After initial cognitive processing is finished, humans have limitations in response capabilities in comparison to machines [48]. This will be further analyzed in the results and discussion section with an analysis on the advantages of setting one's own pace in non – surgical spinal decompression devices.
5. *What is the user feedback regarding the overall USD system in terms of ease of utilization?* The USD system is intended to be easy to use with the purpose of sole operation for in home use. Thus, user feedback regarding ease of use of the USD system is important in this stage of design.

6.4 Ethical Clearance and Participant Information

6.4.1 Ethical Clearance and Eligibility Criteria

The subject recruitment, screening, and informed consent procedures were reviewed by and received ethics clearance through the Carleton University Research Ethics Board – B (CUREB – B). CUREB-B is constituted and operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2). The ethics identification number of this approved research is # 105344 15-275.

By signing the consent form, the participants consent to the following eligibility criteria:

- Between 18-60 years of age
- Comfortable with and physically capable of performing tasks required for the study
- In good physical condition with no prior history of back pain
- Or patients from Broadview Spinal and Health Centre with minor back pain
- Not pregnant
- Do not have a history of or currently have cancer, osteopenia, aortic aneurysm, artificial discs, severe arthritis and/or abdominal surgery

6.4.2 Participant Information

Four healthy participants were recruited to participate in the experiments. Details regarding the participants are outlined in [Table 6.3](#).

Table 6.3: Pilot Study Participant Information

Participant #	Gender	Age	Weight (lbs.)	Height (in.)
1	Male	32	170	70
2	Male	27	185	67
3	Male	25	153	68
4	Female	26	157	57

6.5 Protocol

All experiments were conducted at the Advanced Biomechanics and Locomotion Laboratory at Carleton University. The participants were provided an overview of the experiments along with a safety briefing. Each participant had the USD system accustomed to their height, where upper body and lower body adjustments were implemented. The following categories of experiments were executed, where a debriefing and questionnaire followed.

6.5.1 Pedaling Options Exploration Experiments

As outlined in Table 6.1, there are three pedaling options experiments for each participant to perform. For the first experiment, the pedal is secured for a manual return and fixed joint. The participant was instructed to lay on the USD system in the supine position, where their feet were strapped in at a comfortable pedaling angle of their choice. The participant is then instructed to pedal for one minute in length. The second experiment consisted of a manual return and a freely rotating joint, and the third experiment consisted of an automatic return with a fixed joint, where the participant pedaled for one minute in length for each experiment. After the three experiments

the participant chooses their preferred pedal features combinations to be implemented in the non-surgical spinal decompression experiments in the USD system.

It should be noted that in the pedaling experiments the spinal decompression therapy is not implemented and the participant is not strapped in.

6.5.2 Non – Surgical Spinal Decompression Experiments

As outlined in Table 6.2, there are three non – surgical spinal decompression experiments. All three experiments were similar in procedure with the exception of different upper body and lower body restraint combination for each experiment. The preferred pedaling features were implemented in all three experiments. The participant was instructed to lay in the supine position, where the anticipated restraints combinations were strapped on the individual with the researcher's aid. The series of safety measures are executed at the beginning of each experiment, refer to section 4.3.1. A target load of 25 % of each participant's body weight was applied, a hold time of 10 seconds, a rest time of 5 seconds and duration of 3 minutes for the total therapy time was applied via graphical interface. Subsequent to execution of safety measures and experiment set up, the researcher pressed 'start' and advised participant to pedal. Participant pedals from 0 lbs. until he/she reached their target load, once target load was reached, the researcher advised the participant to 'hold' for 10 seconds. After 10 seconds was up, the system automatically dissipated to half of the target load, once this specific load was reached the system 'rest' (maintain this load) for 5 seconds. After the 5 seconds was up, the researcher advised the participant to pedal to reach their target load again. This cycle of reaching target load, 'resting' and 'holding' continues for the duration of the therapy which was set to 3 minutes or if the user/researcher pressed the emergency button.

The upper body and lower body restraints combination utilized for experiment 1 is displayed in Figure 6.5. The upper body and lower body restraints combination utilized for experiment 2 is displayed in Figure 6.6. The upper body and lower body restraints combination utilized for experiment 3 is displayed in Figure 6.7. Each participant's conditions for each experiment are outlined in

Table 6.4: Participant Set - Up Information Table 6.4.

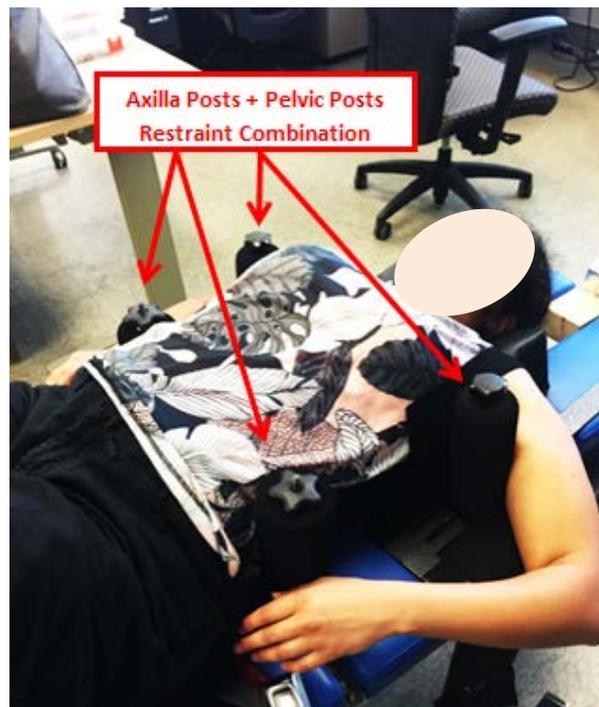


Figure 6.5: Posts Restraint Combination for Experiment #1

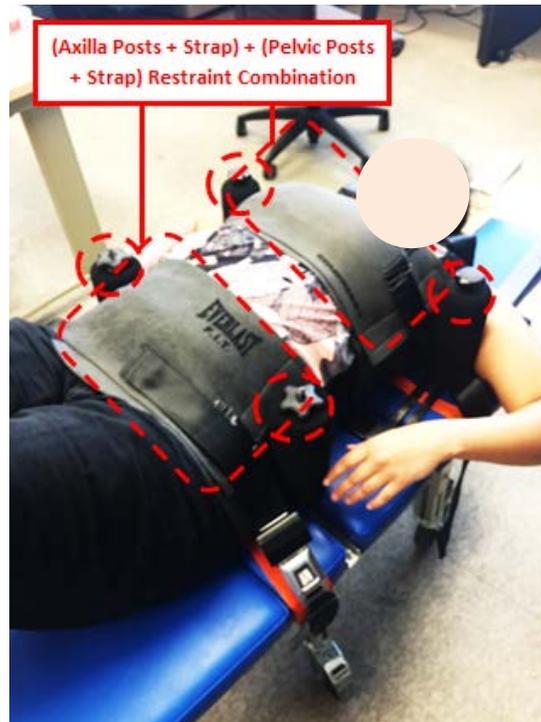


Figure 6.6: Posts + Straps Restraint Combination for Experiment #2



Figure 6.7: Straps Restraint Combination for Experiment #3

Table 6.4: Participant Set - Up Information

<i>Participant #</i>	<i>Target Load (lbs.)</i>	<i>Lower Body Adjustment (in)</i>	<i>Upper Body Adjustment (in)</i>	<i>Starting Knee Angle (°)</i>	<i>Pedal Angle (°)</i>
1	43	10	3	73.9	20
2	38	7	3	74.2	20
3	39	7	3	81.1	20
4	46	5	3	81.9	30

6.6 Results and Discussion

All results from the six experiments performed are discussed below, interconnecting quantitative and qualitative results. The results and discussion aim to answer the questions of interest as outlined in Section 6.3.

6.6.1 Pedaling Characteristics Analysis

The following section answers the question ‘*Do users have specific pedaling characteristics and do they have a preference to specific pedaling features?*’ The results from category 1 and category 2 experiments are discussed below along with participant feedback.

6.6.1.1 Category 1 Experimental Results: Exploration of Pedaling

Options

The three experiments regarding exploration of pedaling options were performed by each participant. All four participants favored an automatic pedal return with a fixed joint. Thus, all

participants performed category 2 experiments with an automatic pedal return with a fixed joint. Participant feedback regarding the pedaling options is discussed in Section 6.6.1.3.

6.6.1.2 Category 2 Experimental Results: Non – Surgical Spinal Decompression Experiments

The following section discusses the pedaling characteristics as per data collected in the non – surgical spinal decompression experiments. Sample pedaling data is displayed in Figure 6.8, which includes an indication where pedal strokes, pedal rest and pedal extract or return occur in the plot.

The data shows that the pedaling characteristics vary among the participants in speed and pedal stroke distance. Not only do the characteristics vary among the different participants, but also among the specific participants' themselves. The pedaling distance data depends on the participant's desire to go fast or slow and desire to make full pedal strokes or not, plots for all three experiments of one participant are displayed in Figure 6.10, Figure 6.9 and Figure 6.11.

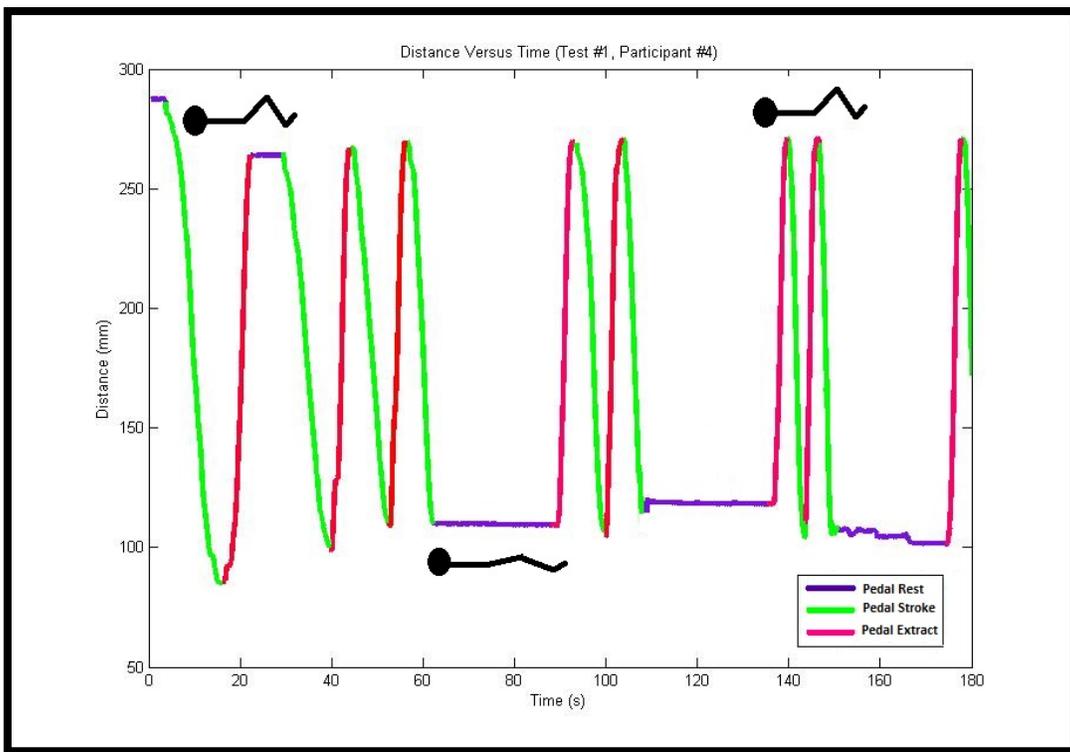


Figure 6.8: Pedaling Distance of Experiment #1 for one Participant (Explanation)

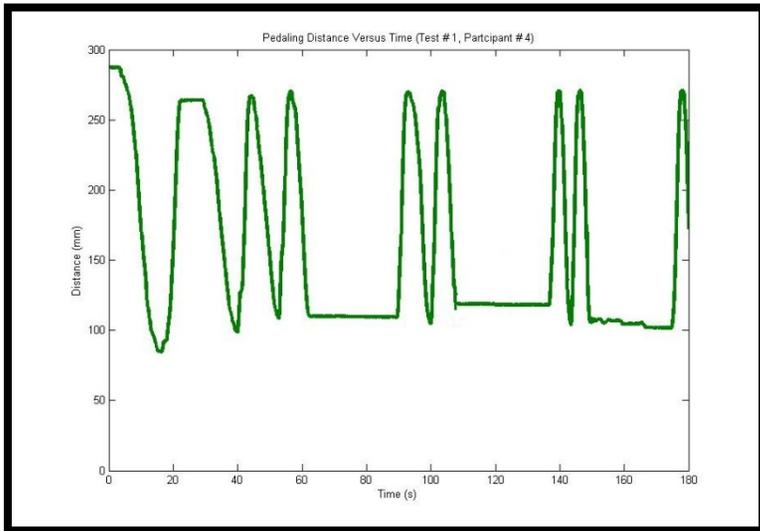


Figure 6.9: Pedaling Distance of Experiment #1 for one Participant

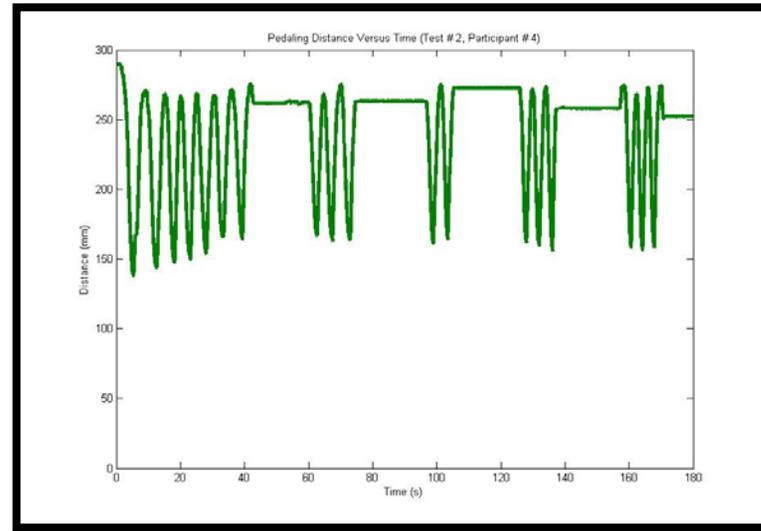


Figure 6.10: Pedaling Distance of Experiment #2 for one Participant

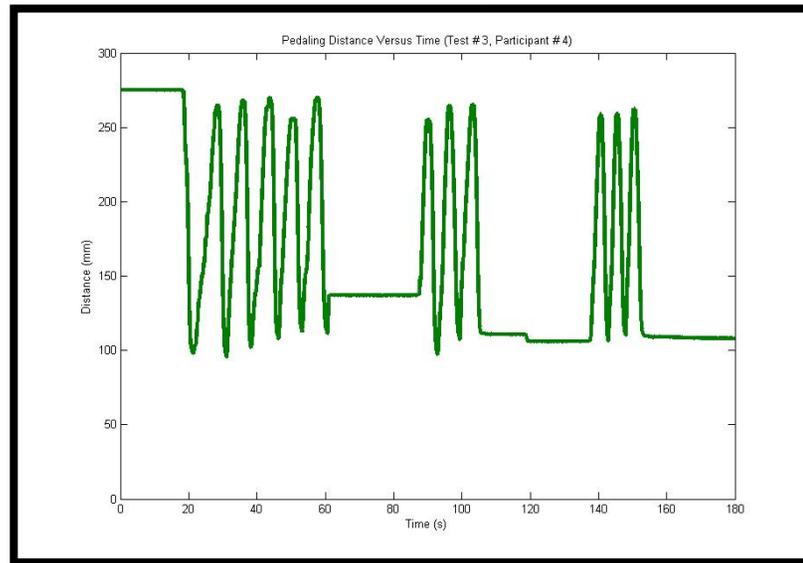


Figure 6.11: Pedaling Distance of Experiment #3 for one Participant

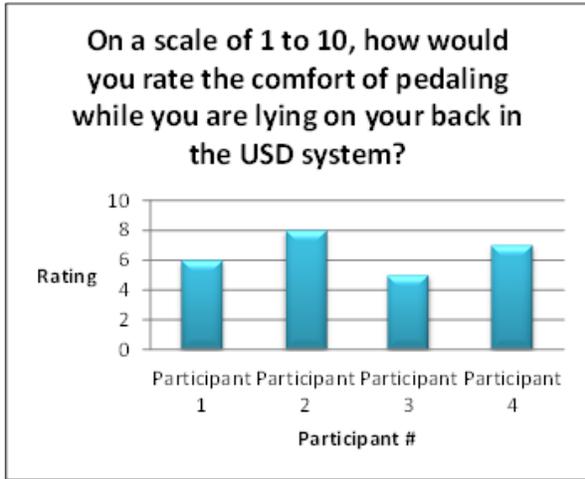
6.6.1.3 Participants Feedback

A series of questions related to the pedaling characteristics of the USD system were included in the questionnaire and answered by each participant; for the specific questions and answers refer to plots (a) to (e) in Figure 6.12.

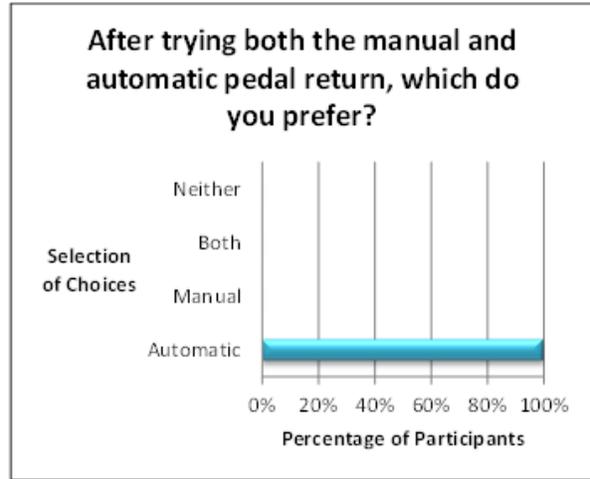
The general level of comfort of pedaling in the supine position is inquired about and the participants imparted an average rating of 6.5 on a scale of 1 to 10; refer to plot (a). The ratings varied from 5 to 8, the participants opting for a lower rating commented on an occasional locking effect, feeling of slight discomfort when performing linear pedaling and a participant wanting to spread their feet apart more.

All participants preferred the automatic pedal return over the manual return; refer to plot (b).

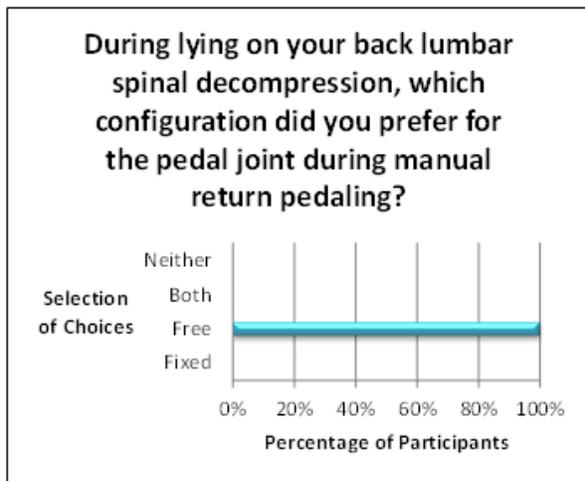
Participants imparted an average rating of 2.5 on a scale of 1 to 10 regarding the comfort level of manually returning the pedal, refer to plot (d), where participants commented on feet sliding from straps and the return process feeling like a workout. All participants preferred a free pedal joint over a fixed pedal joint in the manual return configuration, refer to plot (c), where participants commented that a free pedal joint was more comfortable when pushing the pedal. All participants liked the automatic pedal return, where 25% of participants described the return speed as 'comfortable' and 75% of participants described the return speed as 'slow'; refer to plot (e).



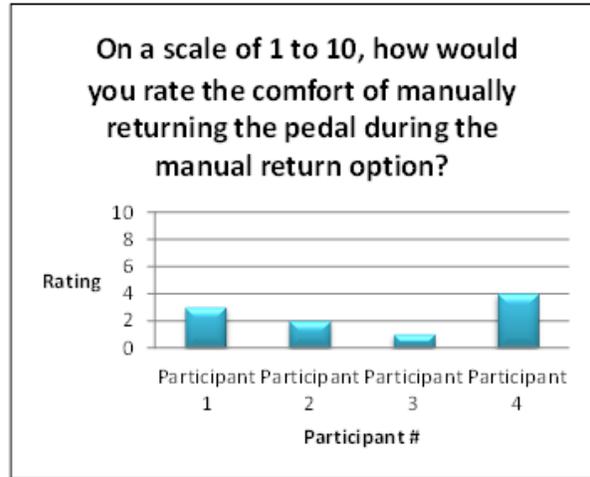
(a)



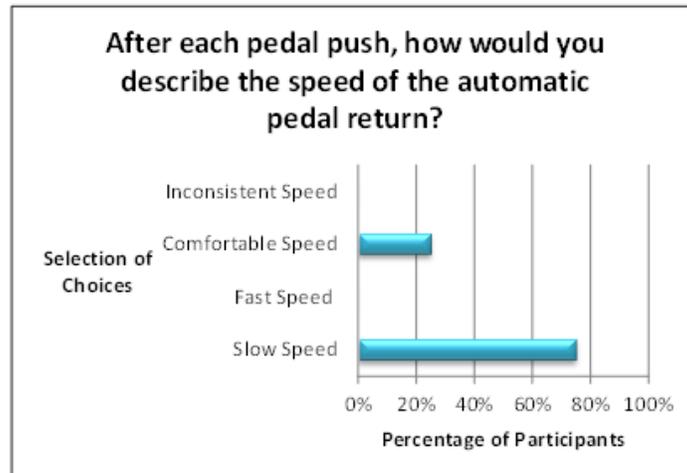
(b)



(c)



(d)



(e)

Figure 6.12: Pedaling Features Participant Feedback

6.6.2 Loading Characteristics in the USD System

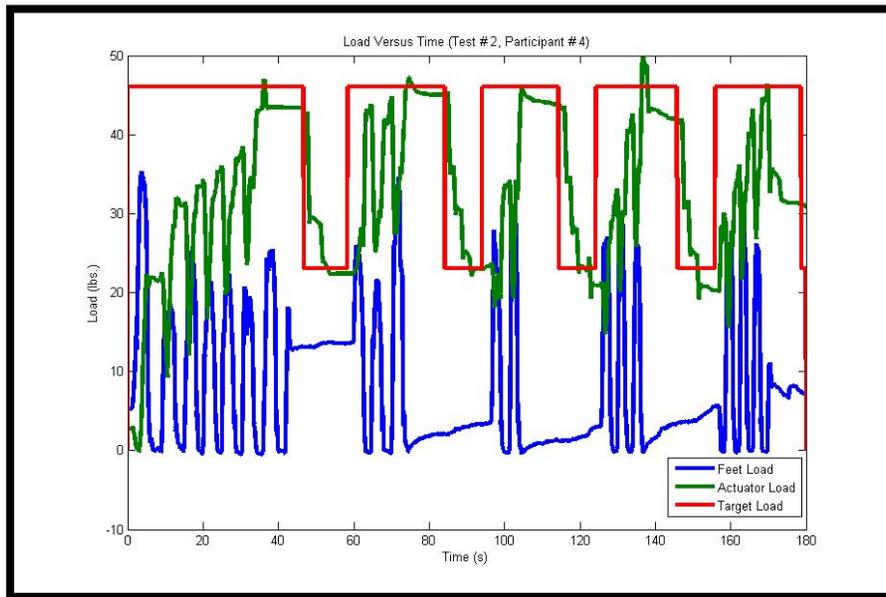
The following section answers the question ‘*What are the loading characteristics in the USD system and the user feedback regarding its associated attributes?*’ The results from category 2 experiments are discussed below along with participant feedback.

6.6.2.1 Category 2 Experimental Results: Non – Surgical Spinal

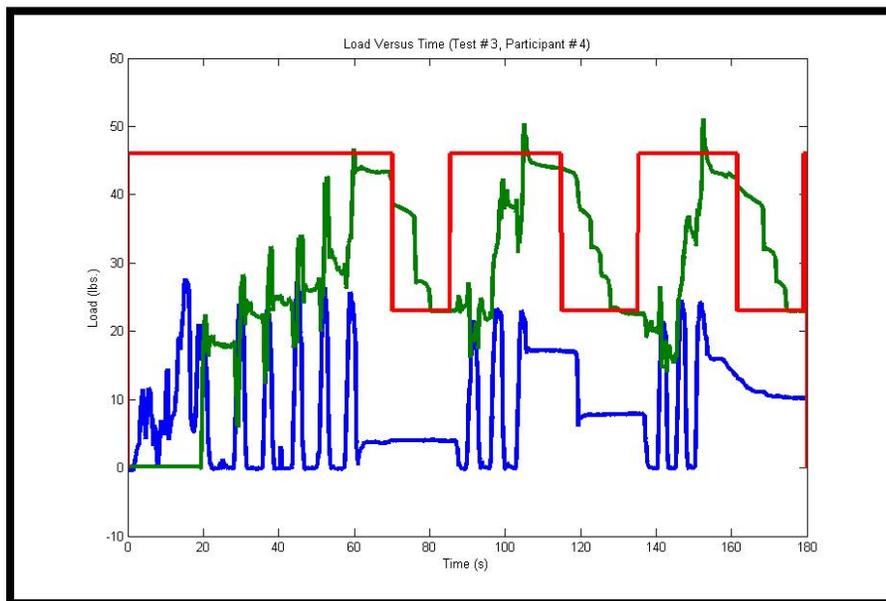
Decompression Experiments

The following section discusses the loading characteristics as per data collected in the non – surgical spinal decompression experiments. The primary focus is to observe any factors that were unnoticed in the preliminary experiments. Sample results of loading data from one participant are displayed in Figure 6.13.

The main observations noticed are concerning the feet loading data, which do not show the same loading characteristics as in the preliminary experiments. Specifically, the feet loading data is supposed to show an increase in load after each subsequent pedal; although, the increase in feet loading data is slightly inconsistent as shown in Figure 6.13. The reasoning behind this is due to the application of the feet on the pedal. In the preliminary experiments, the researcher applies the load optimally ensuring accuracy in results, while in the pilot study; this is not always the case with participants, resulting in a slight discrepancy of feet loading readings.



(a)



(b)

Figure 6.13: Loading Plots of one Participant, (a) Experiment #2, (b) Experiment #3

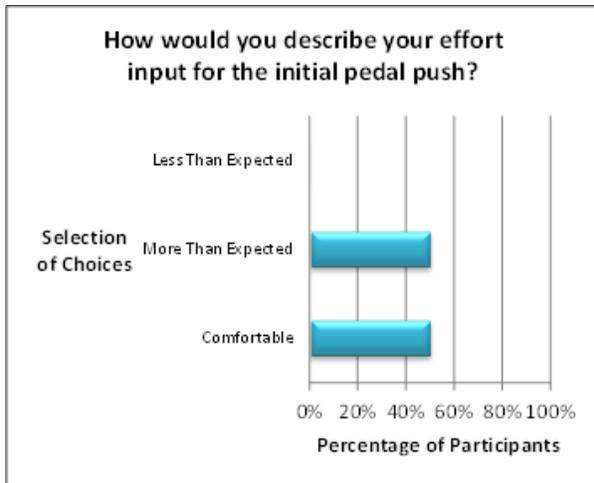
6.6.2.2 Participants Feedback

A series of questions related to the loading characteristics of the USD system were included in the questionnaire and answered by each participant; for the specific questions and answers refer to plots (a) to (e) in Figure 6.14.

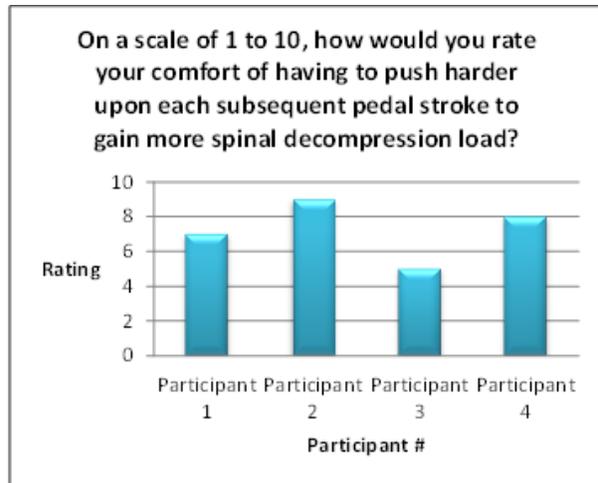
The contentment of the pedaling load to actuator load ratio aspect is inquired about indirectly, where participants are asked about their effort input for their first pedal push. Half of the participants, 50%, selected that the effort was 'comfortable', while the other 50% selected 'more than expected'; refer to plot (a) of Figure 6.14. The general comfort of having to push harder upon each subsequent pedal is also inquired about, where the average rating is 7.25, on a scale of 1 to 10; refer to plot (b).

On a larger scale, the feedback indicates that individuals have different preferences for loading ratios, and having viable options for the future generation of the USD system is to be considered. The participants are asked regarding their liking to the user driven process versus non – user; refer to plot (c). A quarter of the participants, 25%, have indicated they prefer to not 'work', thus, non – user preferred, while 75% have indicated they prefer to utilize a user driven system. Participants indicating favor to the user – driven system, have indicated it feels safer and would only feel comfortable having the load applied automatically if the loads are low. In addition, participants have indicated they enjoy participating during the therapy, as it feels like a fun and mild workout.

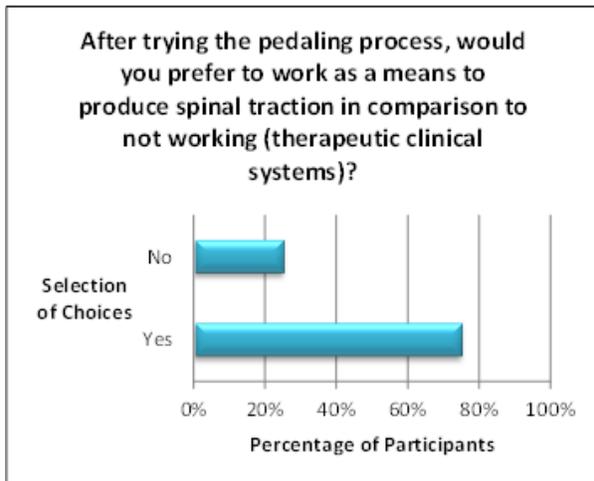
As the USD system is user driven, one of the primary objectives of the system is to provide control to the user, thus, the participants were asked how in control they felt about applying load during the process; refer to plot (d), an average rating of 7.25 on a scale of 1 to 10 is provided.



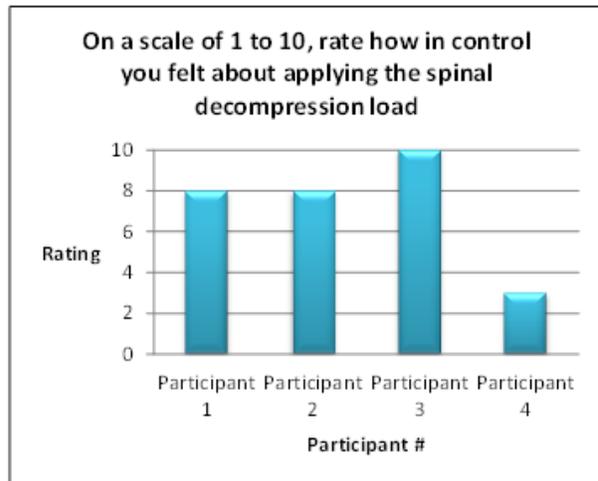
(a)



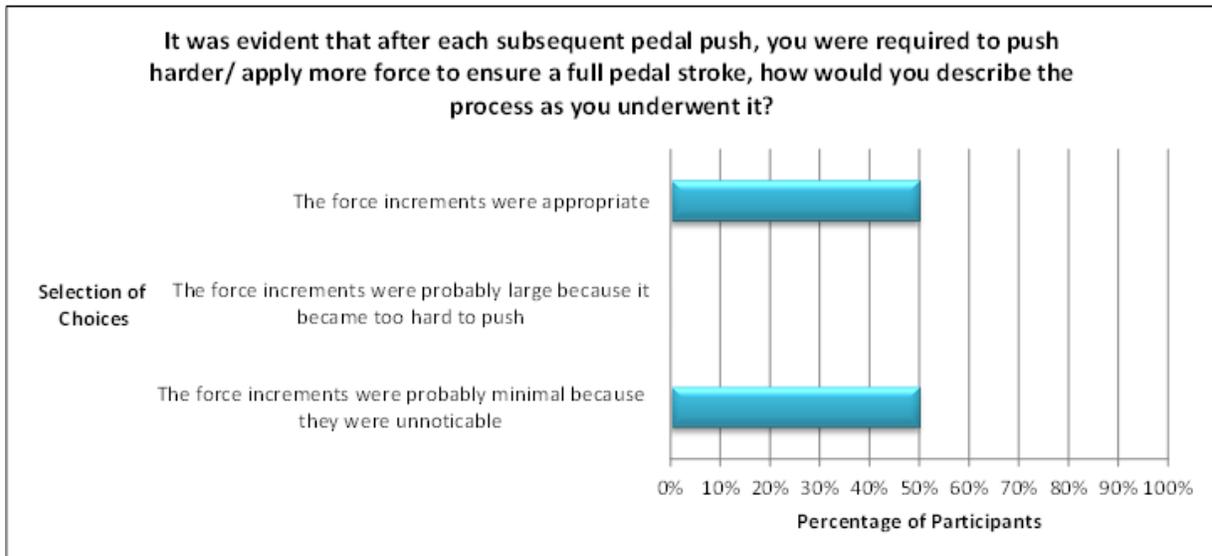
(b)



(c)



(d)



(e)

Figure 6.14: Loading Characteristics Participants Feedback

6.6.3 Restraint Combinations Analysis

The following section answers the question ‘*Which upper body and lower body restraint combination is most suitable for supine lumbar spinal decompression in the USD system?*’ The results from category 2 experiments are discussed below along with participant feedback.

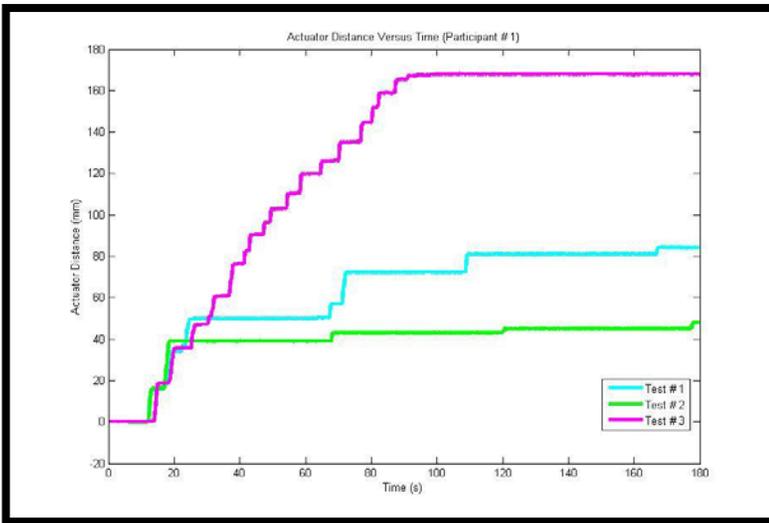
6.6.3.1 Category 2 Experimental Results: Non – Surgical Spinal

Decompression Experiments

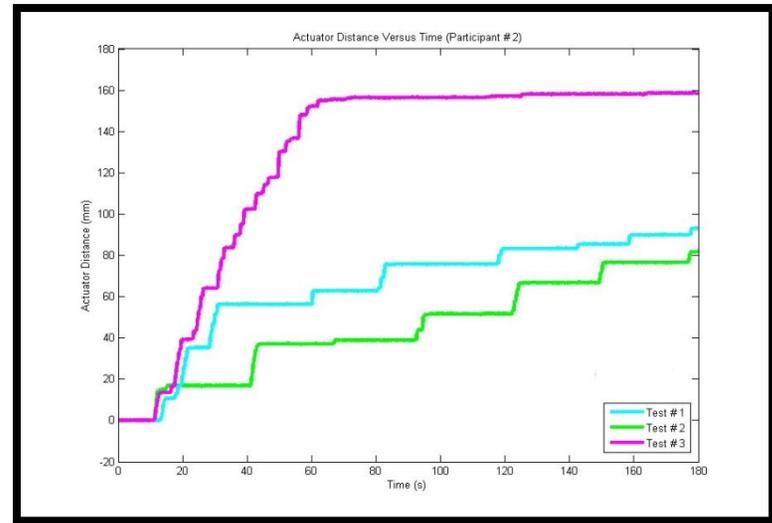
The actuator distance displacement is analyzed for all three experiments for each participant. The actuator distance displacement is a combinational result of the gripping distance, spine displacement and slipping distance. The gripping distance is the distance it takes for the restraint combination to optimally grip the spine region of interest. The spine displacement is the distance the spine region of interest displaces. Lastly, the slipping distance is the distance due to the slipping effect to occur between the restraint and human body as a result of ineffective gripping. Plots of actuator distance versus time for each participant are displayed in Figure 6.15. Based on the resulting data, for all participants, it is evident the restraint combinations with the greatest ability to effectively grip and prevent slippage are as follows:

1. (Axilla Posts + Upper Body Strap) + (Pelvic Posts + Lower Body Strap)
2. Axilla Posts + Pelvic Posts
3. Upper Body Strap + Lower Body Strap

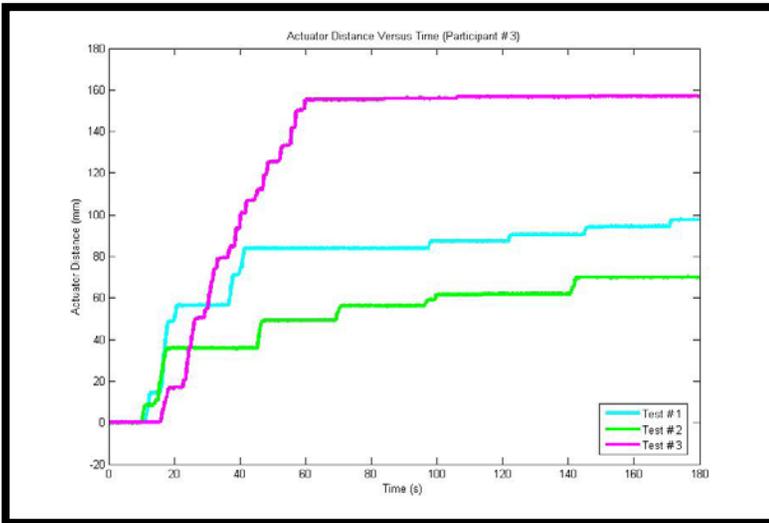
Thus, from a performance outlook, the posts plus strap combination is the best combination, although, the suitability of a restraint combination for supine lumbar decompression is based on performance and user preference. Thus, the participant feedback is taken in consideration below.



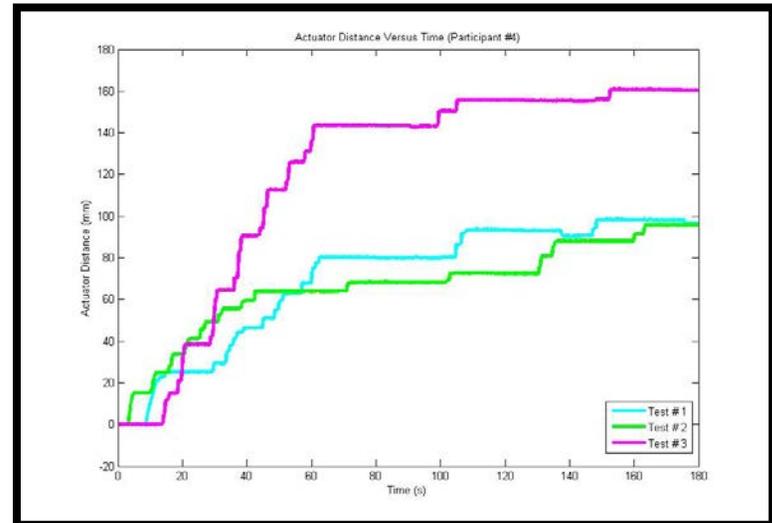
(a)



(b)



(c)



(d)

Figure 6.15: Actuator Distance versus Time for Each Experiment of Each Participant, (a) Participant #1, (b) Participant #2, (c) Participant #3, (d) Participant #4

6.6.3.2 Participants Feedback

The participants are asked to order the restraint combinations on the basis of feeling most secure in terms of slippage prevention. As discussed earlier, slippage is not desired as it proves ineffective gripping ability of the restraining mechanism. Table 6.5, displays the participants results, where 75% of participants ranked the posts plus strap based combination as their first choice for slippage prevention and 25% of participants ranked the posts based combination as their first choice, while all participants ranked the strap based combination as their last choice. Thus, the participants ranking align with the performance results.

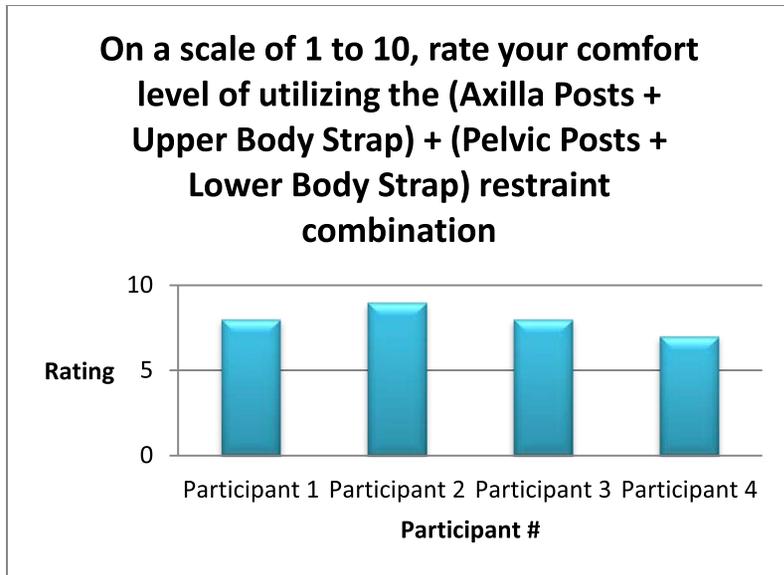
Table 6.5: Participant Ranking of Restraint Combination in terms of Slippage Prevention

	RESTRAINT COMBINATION		
	Axilla Posts + Pelvic Posts	(Axilla Posts + Strap) + (Pelvic Posts + Strap)	Upper Body Strap + Lower Body Strap
Choice of Placing	Percentage of Participants		
#1 Choice	25%	75%	0%
#2 Choice	75%	25%	0%
#3 Choice	0%	0%	100%

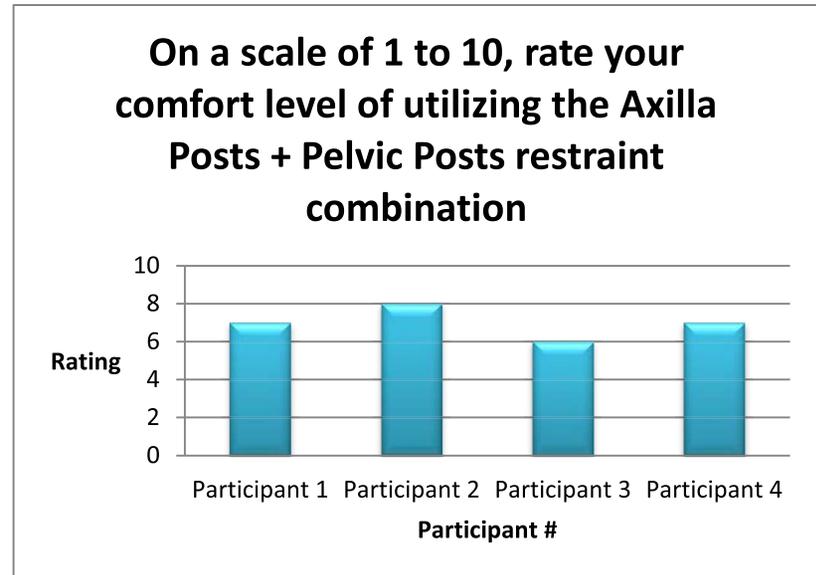
The participants are also asked to rate the comfort level of each restraint combination, where on a scale of 1 to 10, the participants provided an average rating of 7 for the posts based restraint combination, an average rating of 8 for the posts plus straps based restraint combination and an average rating of 7.4 for the strap based restraint combination; refer to Figure 6.16.

The comfort ratings for the restraint combinations are all close in proximity. Participants had varying comments for the restraint combinations. Participants commented that the straps felt comfortable, specifically concerning the material, and their placement did not feel awkward. Although, participants did not feel secure enough utilizing the straps on their own due to the slippage it caused and could not feel the spinal decompression load as effectively as with the other restraint combinations. On the other hand, participants commented that utilizing the straps with the posts provided a more distributed load feel. As utilizing the posts on their own, the load felt concentrated in specific areas.

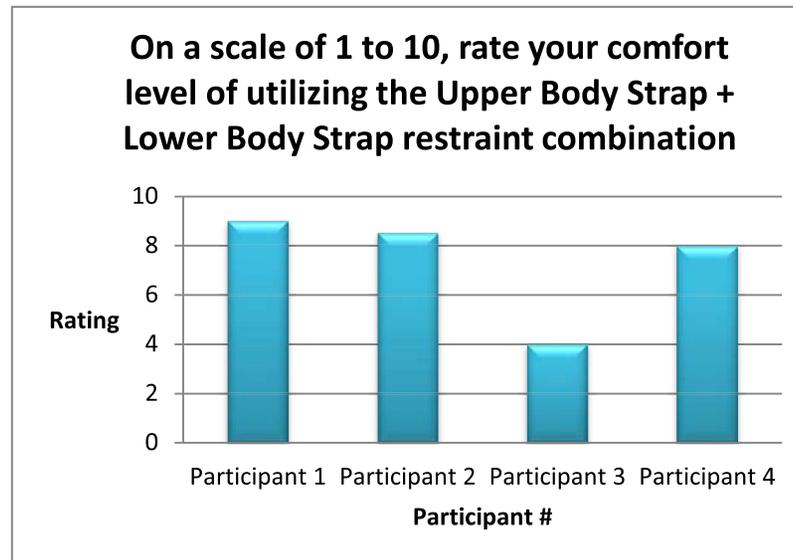
Thus, analyzing the performance of the restraint combinations and the participants' feedback, it is clear that the most suitable restraint combination for supine lumbar spinal decompression is the posts plus strap combination. It is clear that an effective gripping component is required, such as the posts and an integrated strapping belt component to simultaneously distribute the load and add an additional restraining mechanism is most effective. An improvement to the current design for the next generation of the USD system can be an integrated design of the two components.



(a)



(b)



(c)

Figure 6.16: Comfort Level Rating of the Restraint Combinations

6.6.4 Human Response Characteristics Analysis

The following section answers the question ‘*Are there user specific response characteristics during the spinal decompression process? Specifically, how does user response time vary in the cyclic pedaling process during spinal decompression in the USD system?*’ The results from category 2 are discussed below.

6.6.4.1 Category 2 Experimental Results: Non – Surgical Spinal

Decompression Experiments

A primary objective of the USD system is to have the user be in control of the application of loading; specifically, apply the load at a rate of one’s desire. In section 2.4.3.3, a typical spinal decompression chart of the VAX – D is presented, a well-known non – surgical spinal decompression system. The VAX – D chart is presented in Figure 6.17, where the chart data is based on an automated machine response and the cycles are equivalent in shape. This is true of current commercially available non – surgical spinal decompression systems. This section compares the charts of machine automated response of non – surgical spinal decompression systems and direct human actuated response chart of the USD system.

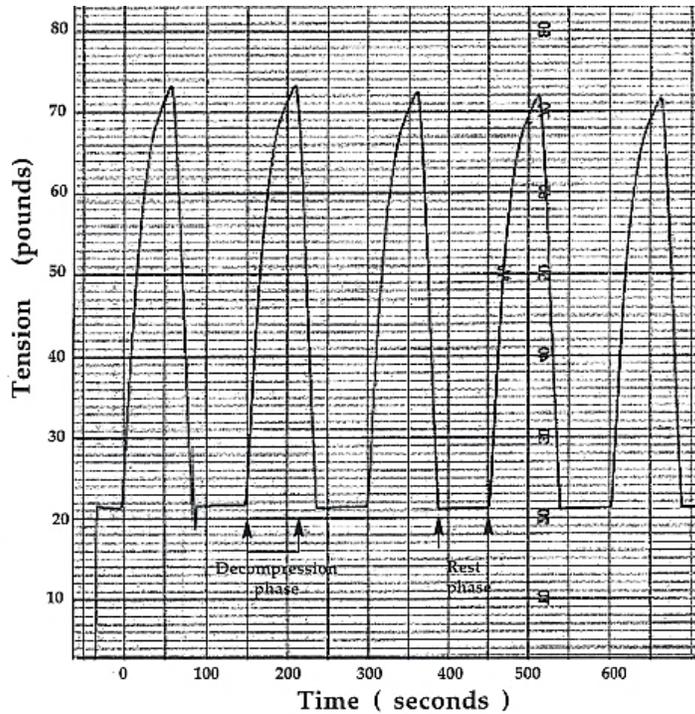


Figure 6.17: Non - Surgical Spinal Decompression Therapy Logic Control Chart

The USD system is the first to explore the implementation of non – surgical spinal decompression based on direct human actuated response. The anticipated cycle response is displayed in Figure 6.18.

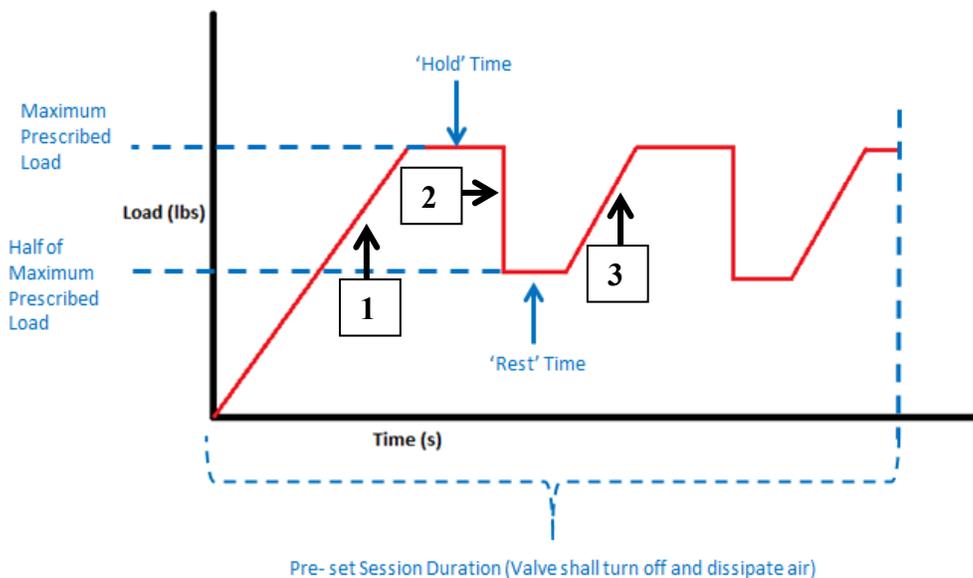


Figure 6.18: Anticipated Cycles of the USD System

Sample loading data from one participant in the USD system based on direct human actuated response is displayed in Figure 6.19, where the maximum prescribed load and half of maximum prescribed load are indicated.

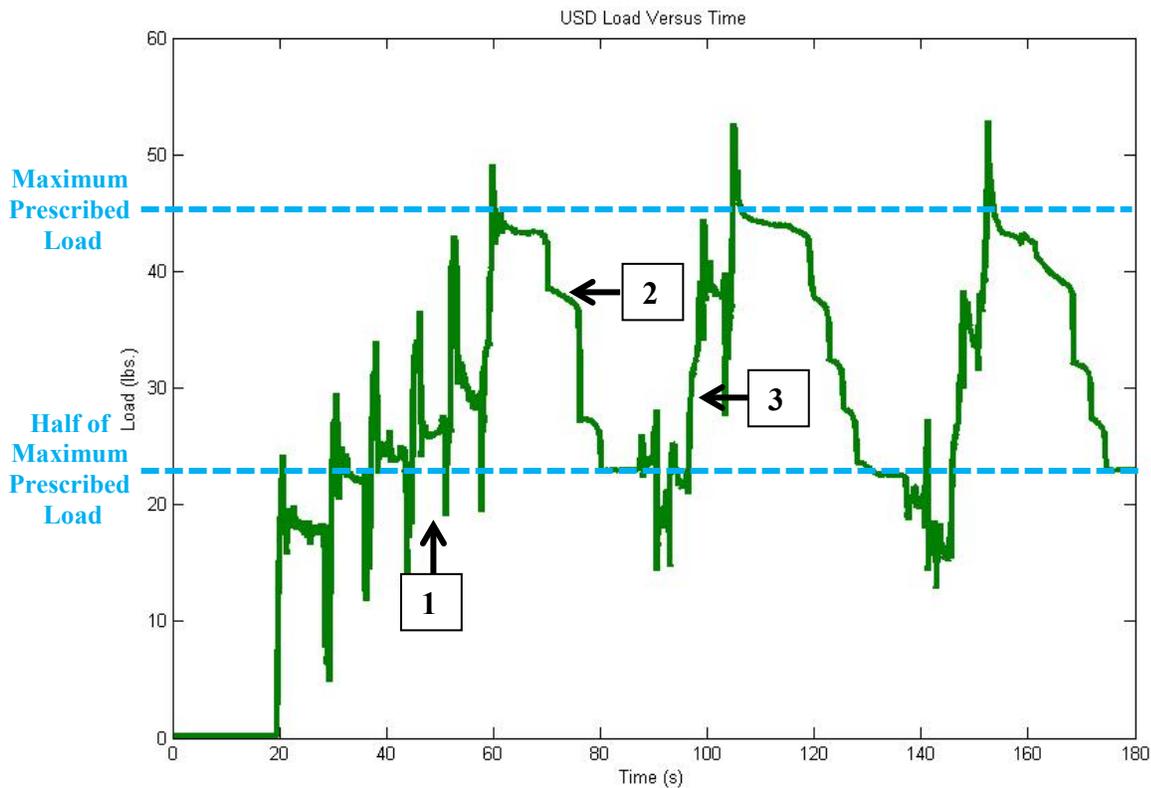


Figure 6.19: Sample Loading Data from one Participant - Direct Human Actuated Response

In the human response plot, it is clear that cycles are not equivalent and the response is not instantaneous through interchanging between loads as can be seen in machine response plots.

The specific attributes between cycles in the human response plots, specifically, Figure 6.18 and Figure 6.19, are numbered and correspond to the following:

1. This is the time it takes for the user to pedal from 0 lbs. load to 'hold' load and it is based on:

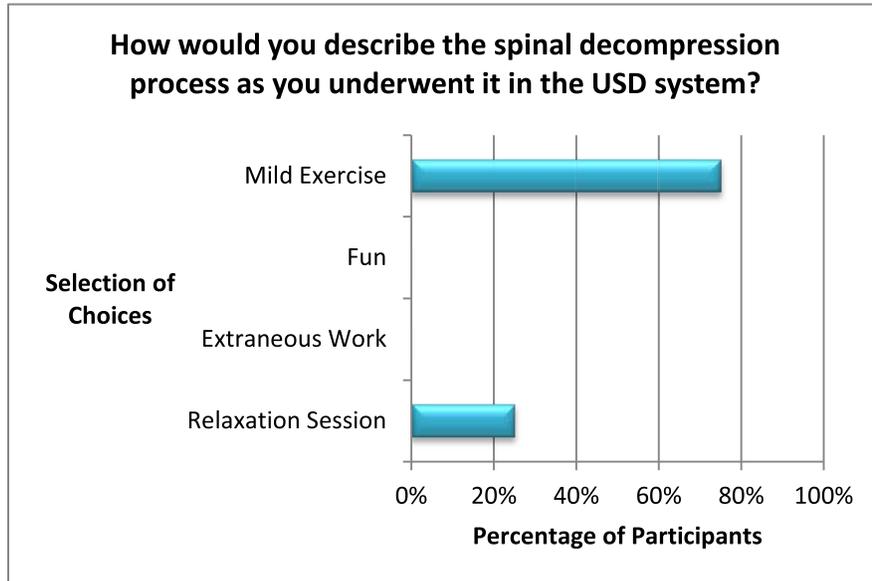
- The response time it takes for the user to recognize he/she must pedal
 - The pedaling rate of the user
2. This is the time it takes for the system to dissipate from ‘hold’ load to ‘rest’ load and is uncontrolled by the user during the therapy itself
 3. This is the time it takes for the user to pedal from ‘rest’ load to ‘hold’ load and it is based on:
 - The response time it takes for the user to recognize he/she must pedal
 - The pedaling rate of the user

In terms of how user response characteristics vary during therapy within the USD system is dependent upon each individual’s response capabilities and their preferred pedaling rate as was seen in the data. According to the Handbook of Human Factors for the Design of Medical Devices, it is important to accommodate user needs and preferences, specifically, in enabling users to set the pace. It is stated that human beings become annoyed when machines set the work pace and often the pace will be too slow or too fast because of individual performance differences [48]. This is what the USD system provides to the user, an ability to set one’s own pace in the application of loading.

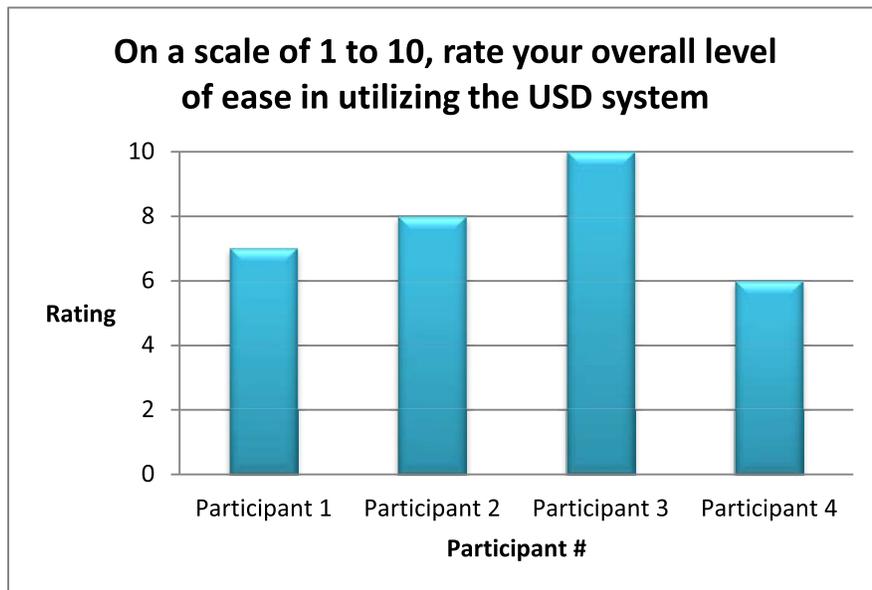
6.6.5 Overall USD System Participant Feedback

The participants are asked about the USD system in general, specifically, how they would describe the spinal decompression process as they underwent it, 75% of participants described it as ‘mild exercise’, while 25% of participants described it as a relaxation session; refer to plot (a) of Figure 6.20.

The participants are also asked to rate their overall level of ease in utilizing the system, an average rate of 7.5 is acquired on a scale of 1 to 10; refer to plot (b) of Figure 6.20.



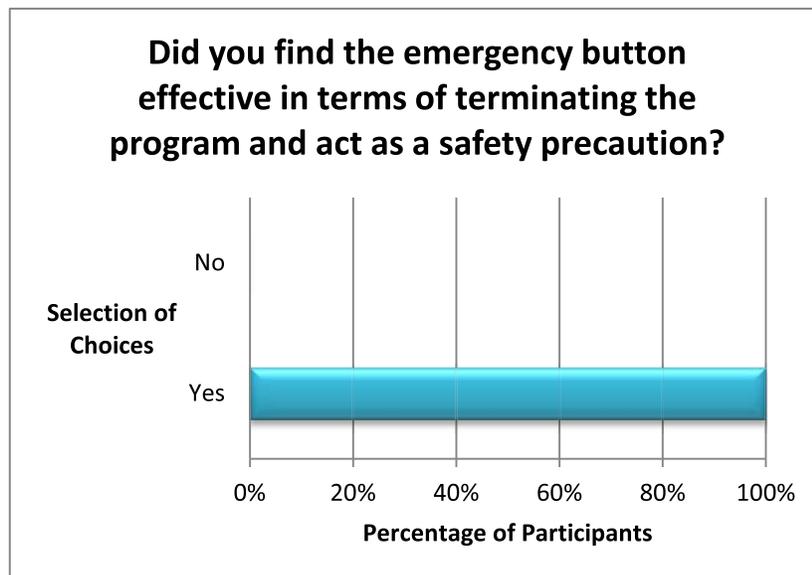
(a)



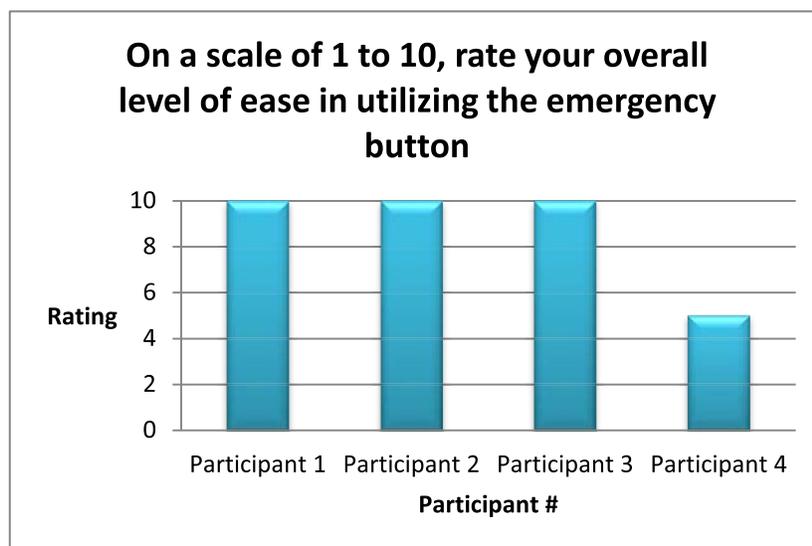
(b)

Figure 6.20: General Participant Feedback

The emergency button is an important safety feature in the USD system, and the participants were asked regarding its effectiveness of acting as a safety precaution, 100% of participants answered yes; refer to plot (a) of Figure 6.21. In addition, participants were also asked to rate the level of ease in utilizing the emergency button, an average rating of 8.75 is acquired on a scale of 1 to 10; refer to plot (b) of Figure 6.21.



(a)



(b)

Figure 6.21: Emergency Button Participant Feedback

6.7 Chapter Summary

Chapter 6 discussed all primary areas of the pilot study including an overview of experiments selection, the experiments objectives, ethical clearance, protocol, results and discussion.

The pilot study was carried out for four human participants. Participants performed a total of six experiments, three for each sub category. All experiments for the non – surgical spinal decompression therapy category were based on the supine anatomical position and lumbar spine. Overall, the following is concluded:

1. Participants described the spinal decompression therapy in the USD system between mild exercise and a relaxation session, with an average level of 7.5 on a scale of 1 to 10 for their ease in utilizing the system.
2. Participants described the pedaling force required during therapy between comfortable and more than expected, indicating users have different preferences, where a customized loading ratio would be beneficial or different reduction ratio sizes to be implemented for consideration in the next generation USD.
3. Participants described the emergency button as an effective safety measure with an average level of 8.75 on a scale of 1 to 10 for their ease in utilization, although placement within the USD system seemed awkward.
4. All participants preferred an automatic pedal return as opposed to a manual pedal return due to the work required during manually returning; although, a majority of the participants indicated the automatic return to be too slow for their liking. This can be modified by replacing the spring with a higher load, but this in turn will require a higher load to overcome during pedaling. A strategic design should be considered for the next generation USD.

5. During manual return pedaling, all participants preferred a free joint as opposed to a fixed joint. This shows great potential for an automatic pedal return and free joint as a successful combination.
6. An analysis of the pedaling characteristics revealed that participants have varying characteristics and an individual can have varying characteristics between trials depending on their preference.
7. Three different restraint combinations were experimented with, performance based results suggested the posts plus straps combination prevented slippage the most and acquired the best grip of the spine segment. Majority of participants also ranked the posts plus straps based combination as their first choice in preventing slippage, and an average level of 8 on a scale of 1 to 10 for overall comfort exceeding the other two restraint combinations.
8. The human response characteristics during pedaling and their modification to the general spinal decompression logic control chart were analyzed in this study. It was revealed that the response characteristics are dependent upon each individual's response capabilities and their preferred rate of pedaling in their desire to go fast or slow. The USD system is the first non – surgical spinal decompression system to allow the user to set one's own pace in the application of loading.

Chapter 7: Conclusion and Future Work

7.1 Conclusion

As part of this thesis, a comprehensive review of the literature on non – surgical spinal decompression is presented, where back pain, evolution of traction to non – surgical spinal decompression and current devices have been touched on. Through this review, the need for user driven non – surgical spinal decompression therapy investigation and accessibility of such devices is identified. Non – surgical spinal decompression therapy has become a popular alternative for surgical back pain methods, although, the lack of user driven elements limits its potential. As recent research has indicated back pain to be of a recurrent problem rather than of a progressive nature, it is beneficial to explore more accessible back pain technologies such as user driven non – surgical spinal decompression systems. To address this gap in research, a prototype of a user driven non – surgical spinal decompression (USD) system is developed and implemented for investigation.

The development of the prototype took in consideration system design, components and treatment techniques identified in the literature review of current non – surgical spinal decompression systems. Standard elements for the USD prototype to be categorized under non – surgical spinal decompression are incorporated including required restraining components to isolate particular spine segments that include the lumbar spine and cervical to lumbar spine. In addition, a transmission system to provide load and displacement to the isolated spine segment, and an integrated cyclic logic control mechanism. In addition to standard elements, the USD integrates user driven components demonstrating novelty, specifically, a transmission system where the user accumulates the load through a reduction ratio mechanism by utilizing their feet

through a pedaling process without the use of an electric motor. The pedaling mechanism is designed with multiple options to experiment with.

The mechanical design of the USD system is based on anthropometric and standard human performance capabilities, where the prototype is designed to accommodate users from the 5th percentile female to the 95th percentile male, as is recommended for standard medical devices.

The mechanical design incorporated modularity and portability elements for in home use expectation of a user driven system. The USD system's hardware includes sensors for data collection, safety switches and a researcher graphical interface that is designed to be transitioned to a user graphical interface.

The USD system first generation prototype is developed not limited to its ability to provide non – surgical spinal decompression through a user driven process, but is also developed to be performed in the supine or prone anatomical positions and to be performed on multiple spinal segments including lumbar spine and cervical to lumbar spine. In addition, multiple restraining components are incorporated, a mixture of novel designs and recognized components, to investigate their feasibility in a user driven system. Due to its multiple features, the USD system serves to investigate numerous research factors.

The USD system is validated through two categories of experiments, denoted as preliminary experiments and pilot study. The preliminary experiments served to validate the USD system's functionality in terms of anticipated function in accordance to implemented design. The pilot study served to validate the USD system's function in accordance to human interaction and their feedback; it is subcategorized into two categories, pedaling options exploration experiments and non – surgical spinal decompression experiments.

7.1.1 USD System Function in Accordance to Implemented

Design through Dummy Subject Experimentation

The preliminary experiments were performed on a dummy subject; through these experiments a design analysis is compared to experimental results, which resulted in a percent error of 5.3%, signifying that most loads and factors contributing to load loss are accounted for. It is observed the USD system can maintain a load for a specified time. In addition, it is observed the degree of preciseness regarding the current solenoid valve's dissipation is not the desired level anticipated, but nonetheless suitable for the current prototype; enhancements are explored and are available. Lastly, the preliminary experiments indicated all components function as planned, specifically, all safety features, switches, sensors, hardware, structure and researcher graphical interface perform as required.

7.1.2 USD System Human Experimentation

The pilot study was carried out for four human participants. Participants performed a total of six experiments, three for each sub category. All experiments for the non – surgical spinal decompression therapy category were based on the supine anatomical position and lumbar spine.

Overall USD System Feedback

Overall, participants described the spinal decompression therapy in the USD system between mild exercise and a relaxation session, with an average level of 7.5 on a scale of 1 to 10 for their ease in utilizing the system.

USD System Loading Analysis

Participants described the pedaling force required during therapy between comfortable and more than expected, indicating users have different preferences, where a customized loading ratio

would be beneficial or different reduction ratio sizes to be implemented for consideration in the next generation USD. In addition, in comparison to preliminary experiments, it is exhibited that the application of feet loading by users hinder more reduction of feet load transcribed to the pneumatic actuator. This is an area to be considered for future generation of USD.

USD System Emergency Button Effectiveness

Participants described the emergency button as an effective safety measure with an average level of 8.75 on a scale of 1 to 10 for their ease in utilization, although placement within the USD system seemed awkward, a suitable placement regarding participant feedback should be taken in consideration.

USD System Pedaling Options Analysis

The general level of comfort of pedaling in the supine position is inquired about and the participants imparted an average rating of 6.5 on a scale of 1 to 10. The ratings varied from 5 to 8, the participants opting for a lower rating commented on an occasional locking effect, feeling of slight discomfort when performing linear pedaling and a participant wanting to spread their feet apart more. All participants preferred an automatic pedal return as opposed to a manual pedal return due to the work required during manually returning; although, the majority of participants indicated the automatic return to be too slow for their liking. This can be modified by replacing the spring with a higher load, but this in turn will require a higher load to overcome during pedaling. A strategic design should be considered for the next generation USD. During manual return pedaling, all participants preferred a free joint as opposed to a fixed joint. This shows great potential for an automatic pedal return and free joint as a successful combination. An analysis of the pedaling characteristics revealed that participants have varying characteristics and an individual can have varying characteristics between trials depending on their preference.

USD System Restraint Combinations Analysis

Three different restraint combinations were experimented with, performance based results suggested the posts plus straps combination prevented slippage the most and acquired the best grip of the spine segment. Majority of participants also ranked the posts plus straps based combination as their first choice in preventing slippage, and an average level of 8 on a scale of 1 to 10 for overall comfort exceeding the other two restraint combinations.

USD System Direct Human Actuated Response Characteristics

The human response characteristics during pedaling and their modification to the general spinal decompression logic control chart were analyzed in this study. It was revealed that the response characteristics are dependent upon each individual's response capabilities and their preferred rate of pedaling in their desire to go fast or slow. The USD system is the first non – surgical spinal decompression system to allow the user to set one's own pace in the application of loading.

7.2 Future Work

As stated earlier, the USD system's integrated multiple features serves to explore numerous research areas. The functional analysis and experimental validation of the USD system presented in this thesis has laid a foundation for future studies. The list below focuses on recommendations for additional experiments in the current prototype and improvements for the next generation prototype:

- The USD system is ready to be experimented on in the prone anatomical position and lumbar spine combination for human subjects, in addition, in the supine anatomical position and cervical to lumbar (full) spine combination. It's recommended to perform the noted experiments in the current USD system as outlined in Table 6.1: Category 1 - Exploration of Pedaling Options, experiments #4 to #6, and as outlined in Table 6.2: Category 2 - User

Driven Non – Surgical Spinal Decompression Experiments, experiments #4 to #9. An analysis and validation can be made regarding the usage of the USD system for the specific anatomical position and spine segment.

- The hand restraints are intended to be utilized as the upper body restraint for the prone anatomical position and the lumbar spine combination and they are a novel design in terms of the configuration options they present. It's recommended to define specific experiments for the hand restraints to observe optimal configuration and analyze the need to provide the user with multiple configuration options.
- The pilot study concentrated on healthy subjects, and the next step is to concentrate on the target population who are patients. It would be beneficial to perform experiments with a wide variety of patient populations for understanding which populations are best suited to use the device, specifically:
 - It would be beneficial to perform experiments with human subjects that have utilized non – surgical spinal decompression therapy devices, which in turn will provide valuable feedback in comparing user driven to non – user driven non – surgical spinal decompression devices from a participant point of view
 - It would be beneficial to perform experiments on patients with varying back pain and back pain conditions, age, gender, etc.
- Testing protocol should be improved in incorporating methods on determining the therapeutic effects of the USD system, specifically when testing on patients. This should be done in coordination with a licensed chiropractor in implementing standard protocol as would be taken when utilizing current non – user driven non – surgical spinal decompression systems.

- The researcher graphical interface should be replaced with the anticipated user graphical interface. The current researcher graphical interface was designed with specifications that would semi replicate the requirements for the user graphical interface to result in simple transition, in addition to incorporating a screen ‘arm’ for the user interface
- A user operating manual should be developed with instructions on how to set up the device and operate it, as one of the main anticipated objectives of the USD system is for the device to be solely operated by the user.
- Once the user graphical interface is implemented and the operating manual is developed, experiments should be defined and developed to test the feasibility of the user operating the device on their own, specifically, analyzing the effectiveness of incorporated modularity and portability features for in home use.
- Enhance the transmission system, where the user can select the loading ratio; this is deemed favorable as the pilot study shows varying views by the participants in regards to the degree of loading.
- Precision of the solenoid valve dissipation should be enhanced for the next generation of the USD system. A few solutions were proposed and recommendation is to explore more solutions.
- Enhance the overall pedal design, where the user can select an automatic pedal return with a rotating joint, and limit locking effects of the current design, as suggested by feedback received from the pilot study.
- Enhance the posts plus strap restraint combination design to be more integrated as one
- Explore the physiological effects as a result of a modified logic control spinal decompression chart due to human response in a user driven non – surgical spinal decompression system.

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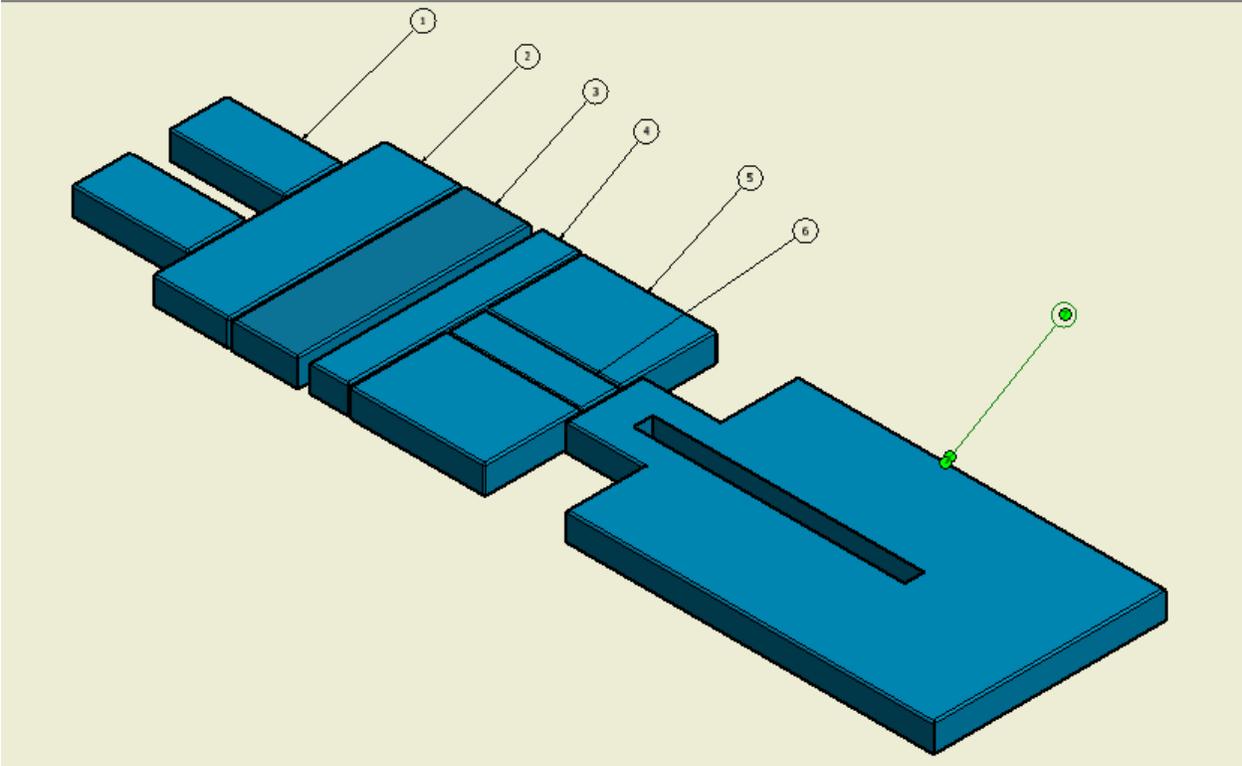
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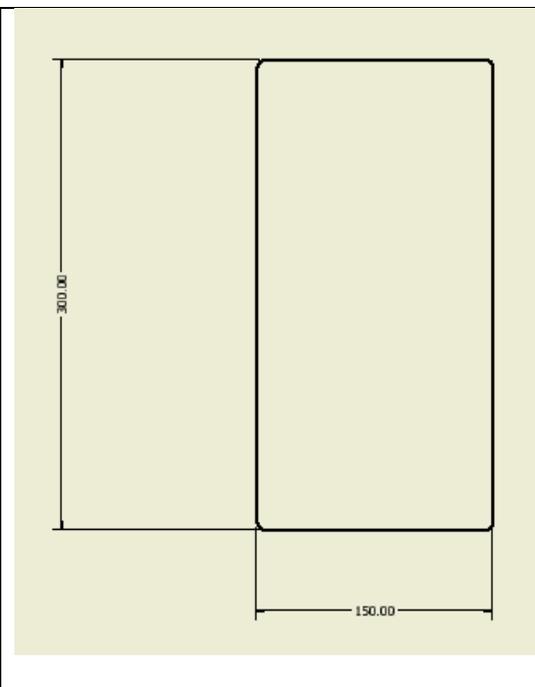
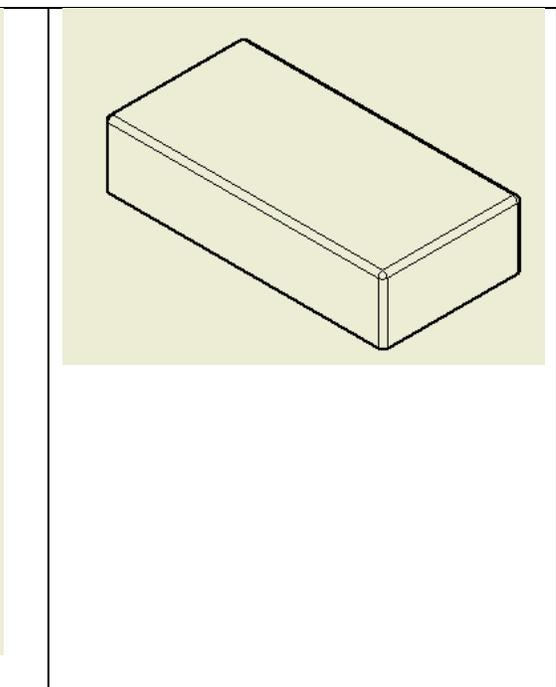
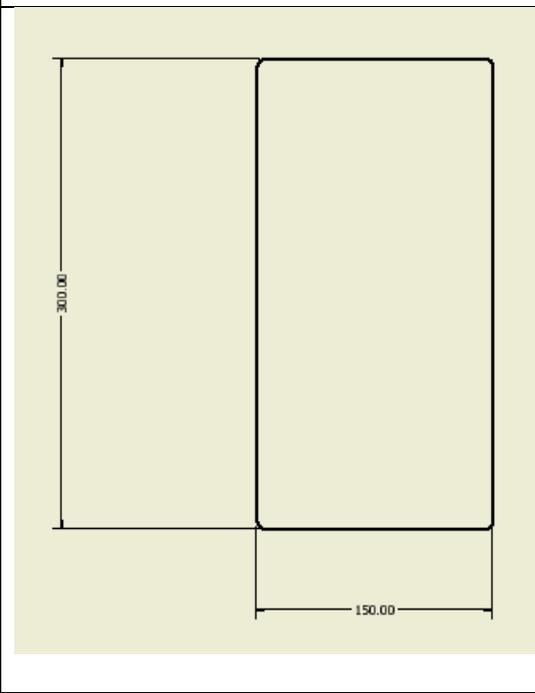
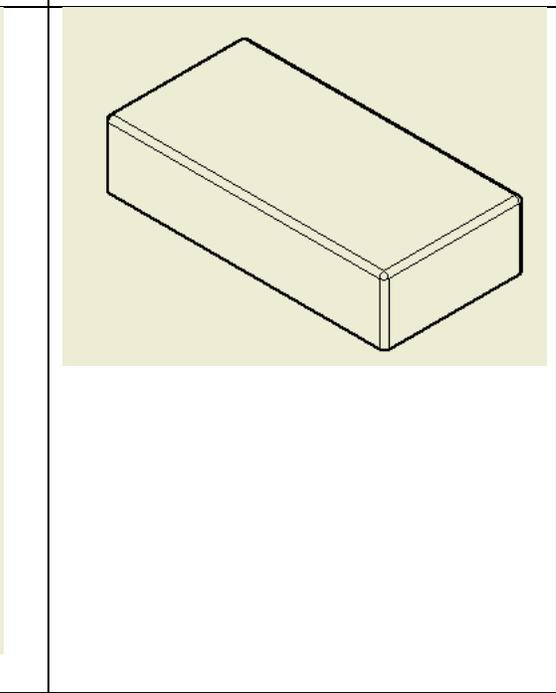
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Appendix A: Anthropometry in USD System Mechanical Design

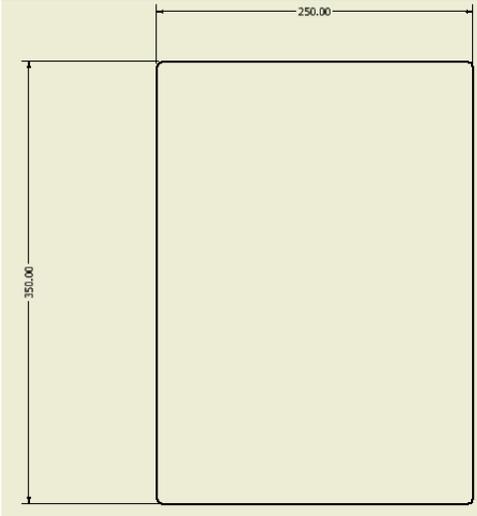
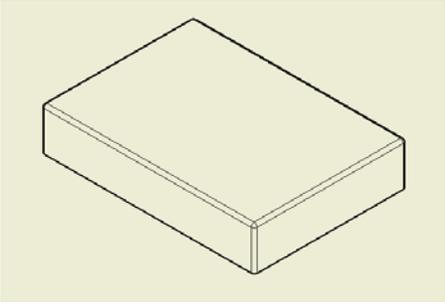
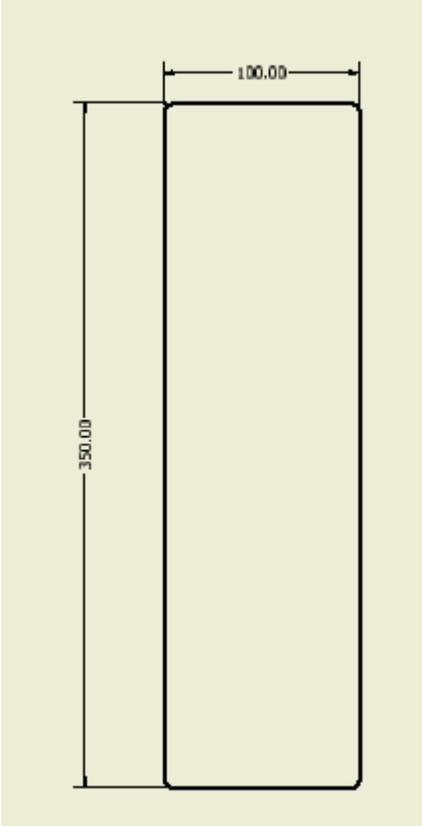
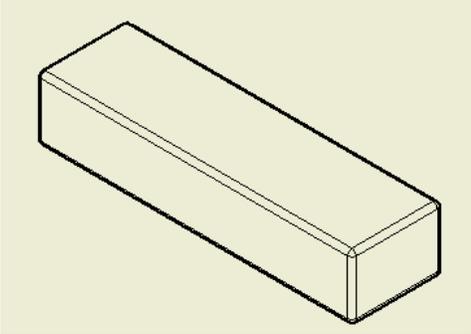
All 'table' pieces in the USD system are specifically dimensioned in accordance to anthropometry standards.



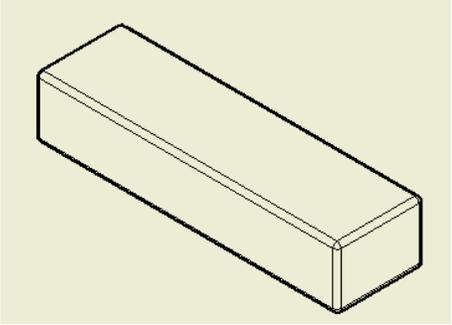
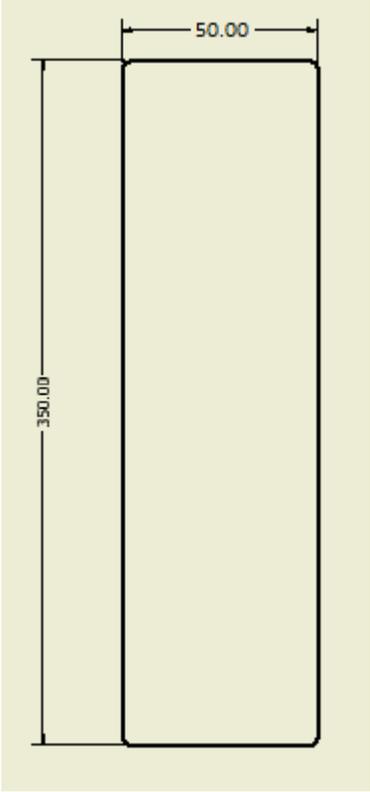
#	Dimensions (mm)	3D Orientation
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1	 <p>Technical drawing of a rectangular block. The drawing shows a front view on the left and a side view on the right. The front view is a vertical rectangle with a height dimension of 300.00. The side view is a horizontal rectangle with a width dimension of 150.00. The two views are aligned at their bottom edges.</p>	 <p>A 3D perspective view of a rectangular block, showing its length, width, and height. The block is oriented horizontally, with the length extending towards the right and the width extending towards the viewer.</p>
1	 <p>Technical drawing of a rectangular block, identical to the one above. It shows a front view with a height of 300.00 and a side view with a width of 150.00.</p>	 <p>A 3D perspective view of a rectangular block, identical to the one above, showing its length, width, and height.</p>

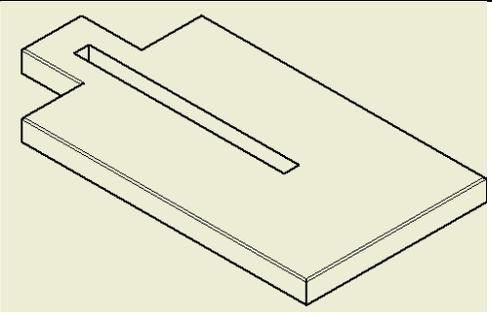
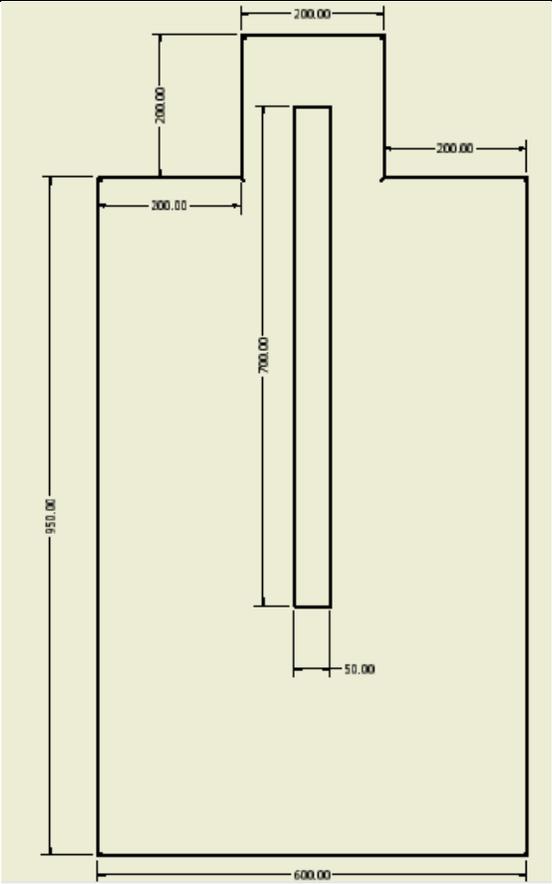
2	<p>600.00</p> <p>200.00</p>	
3	<p>400.00</p> <p>170.00</p>	
4	<p>600.00</p> <p>100.00</p>	
5	<p>350.00</p> <p>250.00</p>	

5	 <p>Technical drawing of a rectangular block. The width is labeled as 250.00 and the height is labeled as 350.00.</p>	 <p>3D perspective view of a rectangular block.</p>
6	 <p>Technical drawing of a rectangular block. The width is labeled as 100.00 and the height is labeled as 350.00.</p>	 <p>3D perspective view of a rectangular block.</p>

6



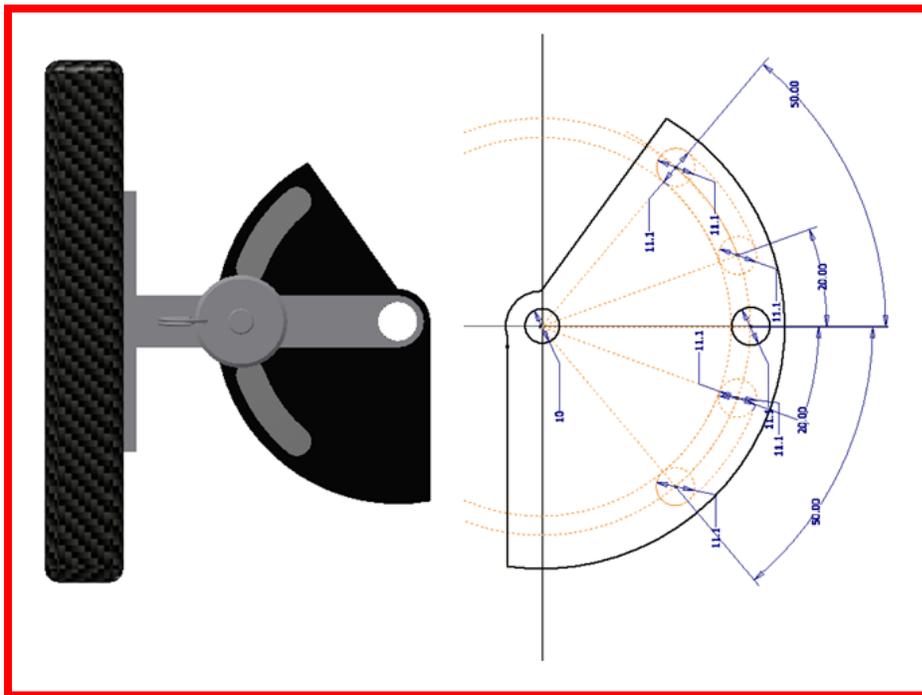
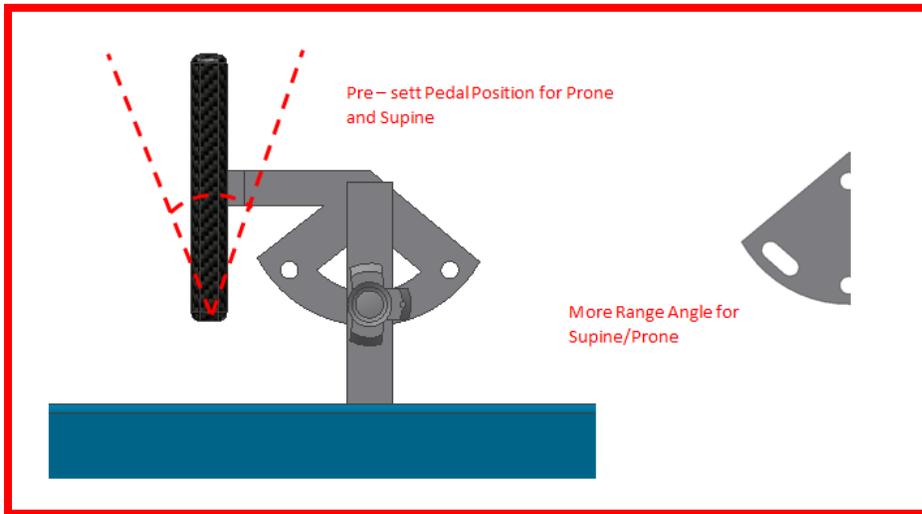
7



Appendix B: USD System Mechanical Design Progress

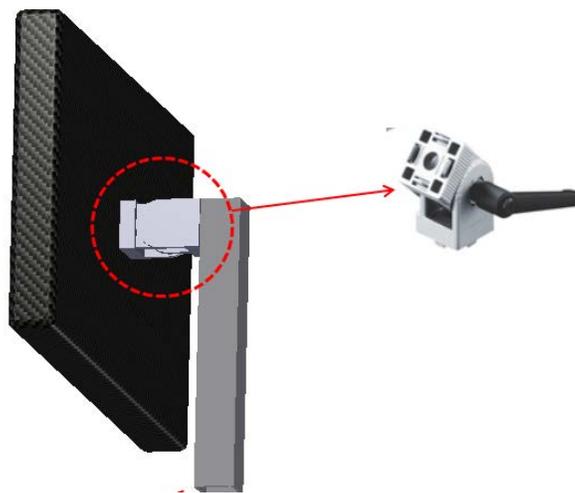
The final USD system presented in this thesis consisted of a road with numerous conceptual designs. This appendix presents designs explored for the pedaling mechanism and coinciding linear guides.

Pedaling Mechanism Conceptual Designs



The above pedaling conceptual designs were not implemented due to the extensive machining involved, where simplification of design is a must.

Pedaling Mechanism Implemented Design



The above pedaling mechanism design was implemented, although, its function was not as successful as anticipated due to ineffectiveness of joint locking and heaviness of material. The utilized pedaling mechanism in the final USD system is discussed in chapter 3.

Linear Guide Exploration Implemented Design

A new design manufactured in the MAAE machine shop utilizing the milling machine is implemented and explored with. Its design was a temporary success as its properties seemed to erode overtime. The Igus linear guides were resorted to use in the final USD system.

