AN EXPERIMENTAL STUDY OF SAFETY FOR A NEW DYNAMIC HEAD SUPPORT DEVICE FOR INDIVIDUALS WITH CHRONIC MUSCLE DISEASES

by

Devon Pessler

A Thesis

Submitted to the Faculty of Purdue University
In Partial Fulfillment of the Requirements for the degree of

Master of Science
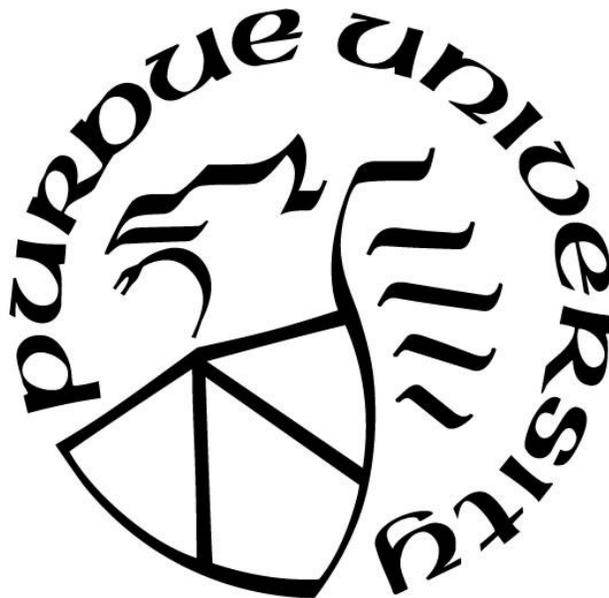
School of Engineering Technology

West Lafayette, Indiana

August 2019

THE PURDUE UNIVERSITY GRADUATE SCHOOL
STATEMENT OF COMMITTEE APPROVAL

Dr. Mark French, Co-Chair

    School of Engineering Technology

Dr. James Condron, Co-Chair

    School of Engineering Technology

Dr. Pam Karagory

    School of Nursing

Approved by:

    Dr. Duane Dunlap

        Head of the Graduate Program

To every teacher, professor, and advisor I have ever learned from. I would not be the student I am today without your humor, lessons, or guidance.

ACKNOWLEDGMENTS

I would like to express my appreciation to my fellow MET teammates, Lukas Jakub, Thibault Corens, and Jack Wigren, for their time and dedication to the creation of this device as well as the team of Purdue Nursing students, Jasmine Miles, Jacob Korba, and Natalie Sorenson, for making sure we had a device that had the patient's safety and needs in mind during the design processes. I am grateful to have been a part of this original senior capstone project with you all.

I would like to thank my committee for their guidance and patience through this journey. Dr. Pamela Karagory, you have been the difference-maker for this research topic. You have provided me with all the support I could ever ask for and need. I am so grateful that you agreed to continue this venture with me. Thank you for serving on my committee. Dr. James Condron, you have been with this project from the start, and I cannot express enough how much your advice has meant to me. You have always provided me with valuable insights regarding this study. Thank you for staying the course and serving on my committee co-chair. Dr. Mark French, I cannot express enough how grateful I am to you, not only for your perfectly timed words of wisdom but for believing in me when I didn't and encouraging me to study what I was passionate about. I sincerely thank you for serving as my committee co-chair.

I would like to give special recognition to David Gonzalez Rodrigez and Dr. Brittany Newell for volunteering their time and 3D printing the necessary components for this research. I would like to show my appreciation for Nancy Denton for guiding me through the ins and outs of using the UTM and helping video my test runs.

Finally, I would like to thank my family. My parents, Daryl and Michelle, for their endless encouragement through my academic career. I love you both so much and I can't wait to see what

comes next in this crazy life of ours. And my siblings, Samantha and Nicholas, for being there when I needed you and for the laughs we had along the way. Love you, little ones.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

ALS	Amyotrophic Lateral Sclerosis
CAD	Computer-Aided Design
DHS	Dropped Head Syndrome
FDA	Food and Drug Administration
ISO	International Organization for Standardization
NASCAR	National Association for Stock Car Auto Racing
PETG	Polyethylene Terephthalate Glycol
PLA	Polylactic Acid
RRS	Revolute-revolute-spherical
SITraN	Sheffield Institute for Translational Neuroscience
SOMI	Sternal Occipital Mandibular Immobilizer
USP	United States Pharmacopoeia
UTM	Universal Testing Machine

GLOSSARY

Amyotrophic Lateral Sclerosis	A progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord (ALS Association, 2018).
Brace	An appliance for supporting a body part (Merriam-Webster Dictionary, n.d.).
Dropped Head Syndrome	A disabling condition caused by severe weakness of the neck extensor muscles causing progressive reducible kyphosis of the cervical spine and the inability to hold the head up (Rahimizadeh, Soufiani, & Rahimizadeh, 2016)
ISO 10993	A standard that utilizes systemic toxicity and intracutaneous reactivity testing. It also includes additional cytotoxicity, genotoxicity, chronic toxicity and hemocompatibility tests, as well as more involved systemic toxicity testing (Foster Corporation, 2019).
Medical device	An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or

	other animals (Food and Drug Administration, 2018).
Medical-grade materials	Materials that have an FDA approval, USP Class VI approval, and adheres to the ISO 10993 standard of biocompatibility (Geneva Laboratories, 2019; Professional Plastics, 2019).
Myasthenia Gravis	A disease characterized by weakness and rapid fatigue of any of the muscles under your voluntary control (Mayo Clinic Staff, 2018).
Myopathy	A clinical disorder of the skeletal muscles. Abnormalities of muscle cell structure and metabolism lead to various patterns of weakness and dysfunction. In some cases, the pathology extends to involve cardiac muscle fibers, resulting in a hypertrophic or dilated cardiomyopathy (Muthusamy, Preetha & Tavee, Jinny, 2010)
Muscular Dystrophy	A group of diseases that cause progressive weakness and loss of muscle mass (Mayo Clinic Staff, 2018).
Orthotics	A device (such as a brace or splint) for supporting, immobilizing, or treating muscles, joints, or skeletal parts which are weak, ineffective, deformed, or injured (Merriam-Webster Dictionary, n.d.).

Pot Life   The amount of time it takes for an initial mixed viscosity to double, or quadruple for lower viscosity products (Epoxy Technology Inc., 2014).

Prototype   A first full-scale and usually functional form of a new type or design of a construction (Merriam-Webster Dictionary, n.d.).

Technology   The practical application of knowledge especially in a particular area (Merriam-Webster Dictionary, n.d.).

USP Class VI   One of six designations for plastics from General Chapter of the United States Pharmacopeia and National Formulary. It involves the following three in vivo biological reactivity evaluations, generally performed on mice or rabbits to mimic use in humans:

- Acute Systemic Toxicity (Systemic Injection) Test: Measures toxicity and irritation when a sample of the compound is administered orally, applied to the skin, and inhaled.
- Intracutaneous Test: Measures toxicity and localized irritation when the sample is in contact with live subdermal tissue (specifically, the tissue that the medical device is intended to contact).
- Implantation Test: Measures toxicity, infection, and irritation of an intramuscular implantation of the

compound into a test animal over several days.

(Foster Corporation, 2019).

ABSTRACT

Pessler, Devon, J. MS., Purdue University, August 2019. Using Expert and Patient Feedback to Validate a New Dynamic Head Support Device for Individuals with Chronic Muscle Diseases. Committee Chair: Mark French.

Neck braces and head supports used today do not allow wearers to rotate their head while maintaining the support they need. For people with chronic muscle diseases, such as ALS, DHS, Myasthenia Gravis, and Muscular Dystrophy, this inconvenience greatly affects their quality of life in that it hinders their abilities to perform activities of daily living, such as nonverbal communication and knowing their surroundings outside without having to move their entire body. There is a need for a head support device that allows individuals with chronic muscle diseases to rotate their heads, so they may better perform daily activities of living and thus live a more fulfilling life.

The purpose of this study was to assess the basic stance of safety of a dynamic head support device that allows individuals with chronic muscle diseases to rotate their heads left and right. The assessment includes an experimental procedure that will conclude whether this device can withstand the load equivalent to an average adult's head in a stationary position and a dynamic movement.

This research proposed a procedure that has a testing apparatus that will place a predetermined load onto the dynamic head support device to stabilize it and then continuously add weight that was checked incrementally. This load was placed on the device while it was centered and static first. The next step in this procedure is to assess whether or not the load on the device can be carried while dynamically moving on the race of the radial sliding track of the device. The data recorded from this experiment will provide the necessary information to

determine whether the basic safety requirement of load capacity for a medical device such as the

one in this proposed research is met.

CHAPTER 1. INTRODUCTION

1.1 Scope

The scope of this proposed research was to verify that the device in this experimental study was safe for an individual to wear. This was done by testing the load capacity of the dynamic head support device. The procedure had loads, with a predetermined starting load, incrementally applied to the chin rest, contact point for the load, until it is equivalent to that of an average human head. The experimental study looked to provide data of while the device is centered and static, as well as rotational both left and right.

1.2 Significance

The research was based on a new neck brace technology in the prototype stage. By analyzing and testing the safety of medically-common engineering materials, this research may provide additional approved options to what has already been established as medically trusted devices within the field of orthotics. With the exposure to the technologies within the prototype, existing neck braces or head supports in development can result in safer, more versatile, and more attractive to the wearers.

In healthcare, safety is one of the most, if not the most, important factor to consider when developing a device for any medical purpose. If or when a medical device fails to be safe for a patient, the consequences can be both economical for the company that developed the device and the healthcare institution that implemented the use of the device, as well as, and more devastatingly, it could lead to a worsened injury or death to the wearer of the device.

With more versatile neck braces and head supports, unable-bodied people can perform activities of daily living like they once used to when they were able-bodied. These activities of daily living include but are not exclusive to walking down a sidewalk, looking both ways before crossing the street without having to move one's entire body, talking without having to move one's entire head, and even just shaking one's head "yes" or "no" to give a nonverbal answer.

Medical external devices are bulky, including those that stabilize one's spine and/or immobilizes one's neck or head. These designs are unattractive. With a device that has all of its technology on the chest of a person, the device will be easier to conceal and not feel as bulky as other apparatuses.

Due to the newness of the device, this dynamic head support has never been studied before. Therefore, this research could bridge a gap between research in the neck and head motion testing and research in medical devices.

1.3   Research Question

Will this experimental design of a dynamic head support device be able to hold up the load equivalent of an average adult's head in a static position and a radial dynamic movement safely? An experimental procedure will provide quantitative data that will allow for this device to be considered for further research and testing involving human subjects.

1.4   Assumptions

The assumptions in this study are as follows:

1. The device will stay intact and functional throughout the entire experimental procedure.

2. The load placed on the device will remain consistent throughout the process; each starting load will be the same as the run before and the final load will be the same for each run of the experiment.

3. The contact load will not slip or fall off the chin rest.

4. The ball bearings in the radial sliding track will allow the load to move along the radial sliding track with minimal, uniform friction.

5. The ball bearings will cause negligible wear on the radial sliding track's surface.

6. The accuracy tolerance of the UTM will not significantly skew the experimental data.

7. The device will remain level and perpendicular to the top and bottom plates of the UTM.

8. The magnetic force of the small button magnets in the stabilizing fixture will have negligible interference with the axial compressive stress.

9. The bar magnet will have no effect on the axial compress stress.

1.5   Limitations

This study is limited by the design features of the device. These limiting factors include:

1. The device's chin rest has a surface area. This can be eliminated by making the chin rest large enough to withstand the compression of the load.

2. The load capacity of the shock absorbers that connected the chin piece to the base. This is eliminated by verifying that the spring constant and the length of the spring can handle the forces applied to the device.

3. The height range of the device limits the distance the load can travel. This is eliminated by having the vertical sliding track made at a length to fit an average adult's range of distance of their chest and chin.

4. The material strength of the 3D printed components. This is eliminated by choosing a strong material, PETG, which has a tensile strength of 53.0 MPa (MatWeb, 2019).

5. The 500-pound load cell has an accuracy tolerance of ±2.5 lbs. This is eliminated by having an experimental load set to high values, such as 300 lbs or greater, so that the tolerance causes little data inaccuracies.

1.6   Delimitations

The delimitations of this study are as follows:

1. No other healthcare criteria other than safety is being considered.

2. The mass of the device is not taken into consideration, as the gravitational force countering the axially compressive force is almost negligible.

3. The two forms of feedback are static load data and rotational load data.

4. Significance will be based on the integrity of the device design.

5. Only the compression loading of the UTM will affect the device.

6. The two conditions of testing are with the stabilizing fixture and without the stabilizing fixture.

CHAPTER 2. REVIEW OF LITERATURE

2.1   Introduction

Neck brace and head support devices have been observed in various fields of expertise. Athletic trainers and sports physicians use neck braces on athletes for preventative measures or rehabilitation tools for injuries or traumas to the neck or spine. Safety regarding athlete's neck and spine has been discussed extensively over the years, especially in contact sports like American football. Intended to prevent football players from sustaining serious neck injuries while in a game, Eugene J Ackerman (1975) patented a

> "rigid vertical member secured to the base of the athlete's helmet and extends downwardly
> therefrom into a telescoping support secured to the shoulder pad and which allows rotation
> of the helmet and head of the athlete upon an axis substantially close to the neck and
> parallel to the axis of the neck, and limits flexion and extension, thereby protecting the
> neck from trauma" (US Patent No. 3,900,896, 1975, p. 1).

Medics aiding a person in an ambulance use neck braces to stabilize a patient's neck when transporting them from one place to the next (Torlei, K., Matthews, E., Sparke, A., Benger, J., Voss, S., Harris, N., & Carter, J., 2013). Hospitals prescribe neck braces to patients' post-surgery or in place of surgery when a spinal cord injury occurs or neck strains and neck sprains (whiplash) are the results of an accident (Cleveland, 2018).

Due to the variety of causes of neck and spinal cord trauma, neck braces come in many different shapes, sizes, and materials. These constraints are based on the needs of the individual. A neck brace for the rehabilitation of the neck muscles requires a different composition than that of a brace trying to keep a person's spine completely immobile so that the person can recover from

a trauma to the neck or spine (Cleveland, 2018). The functionality of each brace can be determined by the designs of the brace, as well as the purpose or use of the brace.

2.2   Literature Review

2.2.1   Functionality

Neck braces have a multitude of functions due to the diversity of the population's needs. The three main functions of a neck brace are to immobilize one's spine during healing, stabilize injured areas, and control pain by restricting movement (Cleveland, 2018). Neck braces are most commonly in the form of cervical collars, the soft foam collar that doesn't allow one to move one's neck. Neck braces can also be head supports.

Head supports, like the SOMI brace in Figure 2.1, are more clinically called cervical-thoracic braces. Cervical meaning neck and thoracic meaning the back. This brace functions as a stabilizing agent for a person's neck but doesn't have the all-around support like a cervical collar. This type of support has the person immobilized and stabilized from a chest and back plate connected to a chin rest.

Figure 2.1 SOMI brace. (Cleveland, 2018)

Some neck braces have the sole function to completely immobilized one's upper body, torso, and head. These braces are most commonly seen after neck or spine fusions. To have a neck brace serve the need of the patient, the design has to come together and provide the necessary support.

2.2.2   Innovations in Designing a Neck Brace

Neck braces are known for being supportive and stiff. The design of the neck brace is large and noticeable, especially the cervical collar, the most common neck brace. The cervical collar is a large foam or plastic collar around a person's neck to protect after injury or prevent before the injury (Cervical collar, 2018). These collars are prescribed when a person suffers an injury to their neck or upper spine that requires them not to move their neck (Cervical collar, 2018). This design is rudimentary and most often uncomfortable. For example, the Philadelphia collar, most often seen in hospitals and ambulances or after leaving a hospital, requires the wearer to put on the brace while lying down by sliding up to a comfortable position and then strapping it down. Figure 2.2

illustrates the aftermath of adjusting the brace and Figure 2.3 depicts the man being strapped down

after the brace is appropriately positioned.

Figure 2.2 Adjusting Philadelphia Collar in the field (Wavebreak, n.d.)

Figure 2.3 Patient strapped down after the collar is adjusted (Wavebreak, n.d.)

This presents an issue because what is comfortable lying down may not be comfortable standing up (Cleveland, 2018). Scientists and medical professionals in the neurology and orthopedic concentrations continue to look for innovative alternatives to the existing design.

Designs for these supports and braces span from changing the existing solutions' materials or configuration to entirely new concepts. Foam cervical collars were part of the innovation process. The collars used today are mostly made from polyurethane foam because in 2006 this foam had characteristics that no other medical material possessed and there hasn't been a material since to compete with it. Polyurethane foam was applied to the medical field because it was good for filtration, absorption, wiping, and padding tasks that medical devices required (Myers, 2006).

The spring-loaded neck brace would take the place of the cervical collar. The brace never touches the patient's neck as seen in Figure 2.4. This is possible due to the brace resting on the patient's shoulder and being held with a headband (Zhang, Albee & Agrawal, 2018). Between the headband and shoulder rests is three revolute-revolute-spherical (RRS) chains (Zhang, Albee & Agrawal, 2018). These RRS chains assist head movement for the patient if needed (Zhang, Albee, & Agrawal, 2018). The RRS chains help the springs engage. Figure 2.5 has a close up of the composition of the three spring systems.
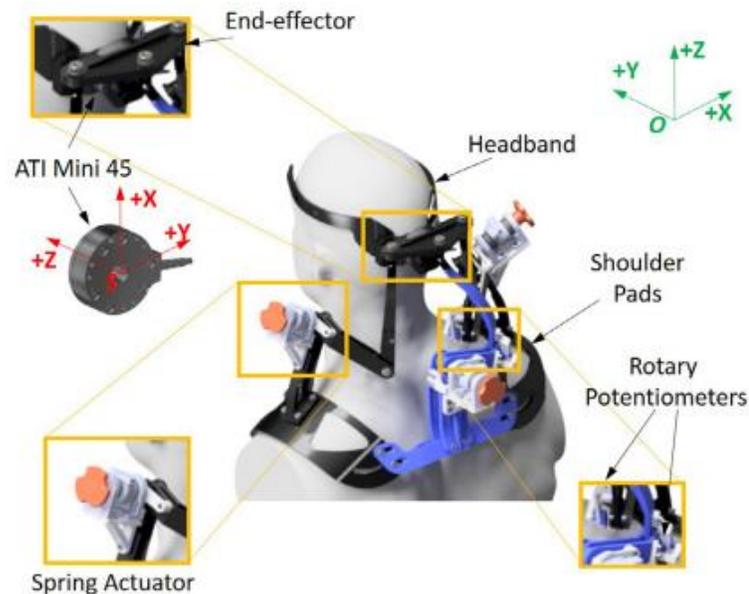
Figure 2.4. Detailed Image of Spring-Loaded Brace. (Zhang, Albee & Agrawal, 2018)
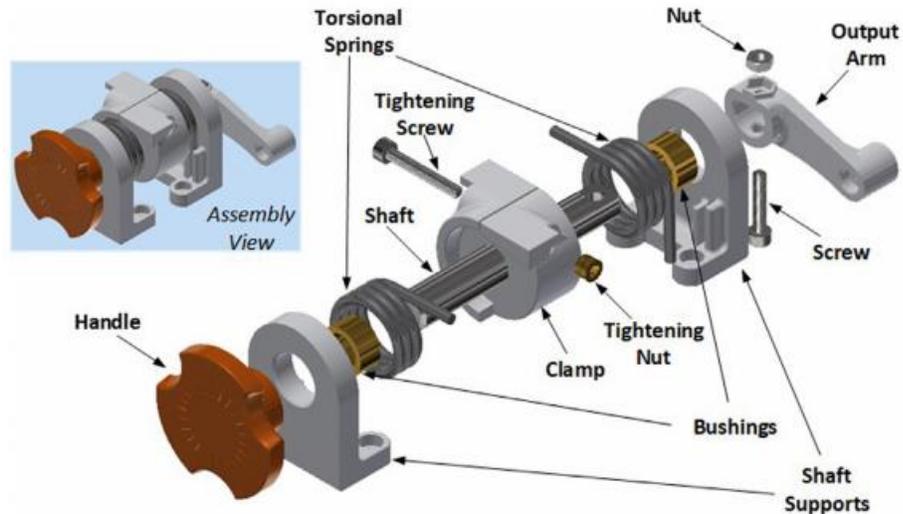
Figure 2.5. Detailed Exploded View of Spring Assembly. (Zhang, Albee & Agrawal, 2018)

This does not solve the noticeability; however, it allows motion that the cervical collar does not provide. The motion of looking up is important in today's active world, making this design concept an advancement in the concentration.

The next step forward was making a brace that was supportive, practical, and for those who have disabilities that do not allow them to do so would allow the patient's head to move slightly. There are multiple diseases and illnesses that ultimately cause one's neck muscles to deteriorate so that the patient is unable to hold up their head, Dropped Head Syndrome (DHS) being one of them. These diseases have such an impact in the medical field that interdisciplinary teams have been formed to develop new technologies for neck support braces. The Head-Up Project was created to research and start developing neck support for those with Motor Neurone Disease, a fast-progressing neurodegenerative disease that has no foreseeable cure, also known as ALS (Reed et al, 2015). The teams of designers, engineers, Sheffield Institute for Translational Neuroscience (SITraN) clinicians and researchers found through five workshops that neck support devices must be designed for specific tasks for the patient to get the most out of it (Reed et al, 2015).

2.2.3   Neck Braces Designed for Specific Causes

2.2.3.1   <u>Muscle Diseases.</u>

Neck braces can be used to enhance a patient's life by helping them correct muscular degeneration from a disease that they have (Calabrese, 2011). These diseases include DHS and ALS.

DHS is a disease that occurs when the muscles in a patient's neck deteriorate to the point where the muscles can no longer support the weight of the patient's head (Corens, Jakub, Pessler & Wigren, 2018). This disease has multiple causes, which include genetics, radiation therapies, impact trauma, ALS and Parkinson's and various myopathies (Corens, Jakub, Pessler & Wigren, 2018). ALS is "a progressive neurodegenerative disease that can lead to muscular weakness" (Glazener, 2014, p. 1). It "causes a deterioration of upper and lower motor neurons" that affects the entire body and can result in atrophy of the muscles among other symptoms (Glazener, 2014, p. 1).

New innovative neck braces have been designed and developed over the last decade to counteract the effects of diseases such as DHS and ALS. A study of five subjects with ALS, had the subjects wear a prototype neck brace on and test how it benefitted the subjects by utilizing surveys and other proven tests (Glazener, 2014). This neck brace was different from the ones that came before it because the mechanism was mainly behind the patient. The support harness had the support on the subject's back and used Velcro straps coming around to the front of the patient to keep it secure. The brace portion was also different. It was a plate that was placed behind the subject's head secured by a headband and an adjustable rod that connected to the harness/ backplate (Glazener, 2014).

Salvatore Calabrese developed and patented "an adjustable cervical collar designed to accommodate a broad range of prospective wearers with unique physical attributes" (Calabrese,

2011, p. 1). This brace, in Figure 2.6 and Figure 2.7, was adjustable in height and in tightness to conform to various wearer neck profile (Calabrese, 2011).
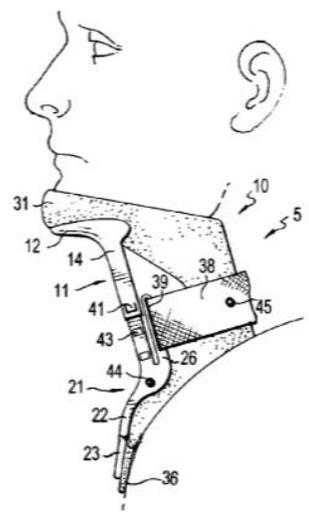

Figure 2.6. Front of Adjustable Brace. (Calabrese, 2011)
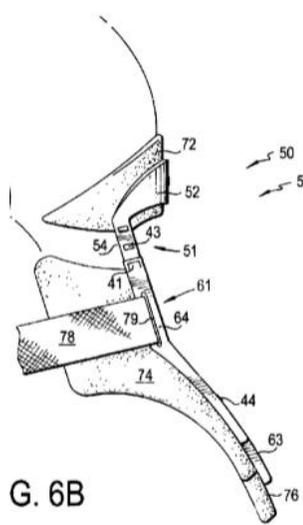

Figure 2.7. Back of Adjustable Brace. (Calabrese, 2011)

This brace also has two thoracic extenders. These extenders provide support and stability no matter what height or tightness that wearer needs. Calabrese has the first neck brace to have all

of these components in one brace, which opened up the field of neck braces to new possibilities, including those with DHS and ALS.

Innovations to the original cervical collar have been important to the progression of rotational movement for people with degenerative muscular diseases. Peter Gehlbach et al. (2018) developed and patented a cervical collar with the capability of rotating one's head left and right with a sliding chin piece built into the front of the collar (Gehlbach et al., 2008). With the quality of life for the patient being the main focus of this device, the mobility of the sliding piece had to accommodate the mobility of the patients. This mobile component of the cervical collar allowed the patients to have more freedoms in performing daily living activities (Gehlbach et al., 2008).

DHS is not as common as other diseases such as ALS, but still many advancements in assistive devices have been made in recent years. The newest advancements have been purely mechanical. The latest advancement has been revolutionary in that it is both internal and external. Not only has the existing brace been modified and improved but an internal surgical component was developed and implemented (Bronson, Moses & Protopsaltis, 2018).

The purely mechanical solution is a neck brace that rests on the shoulders of the patient. Figure 2.6 depicts a brace that has multiple hinges that connect the shoulder pads to the headband that keep the head up and stable. With the aid of actuators and motors, a joystick can control the horizontal and vertical movements of a DHS patient's head (Zhang & Agrawal, 2018). This way the patient can observe that world around him or her, with the smooth movement allowed by a motor and a joystick.
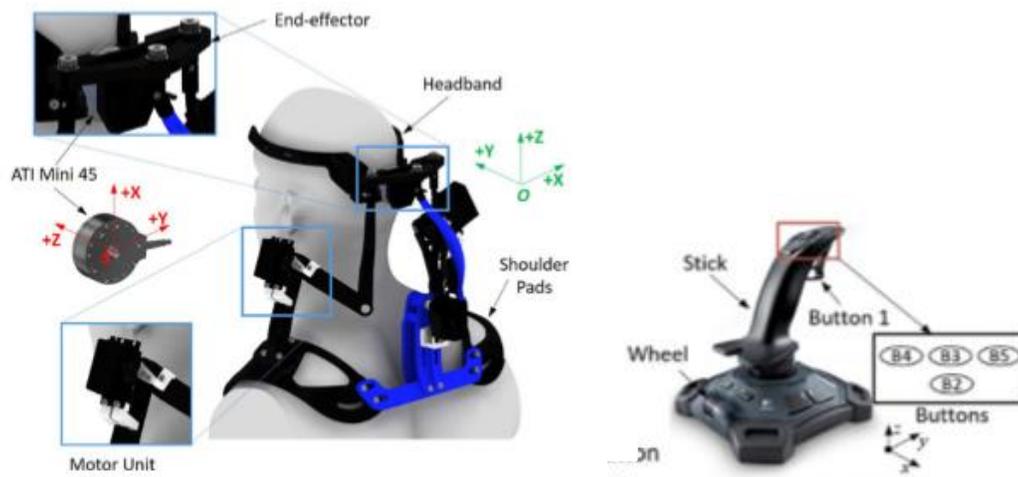
Figure 2.8. Motorized Neck Brace. (Zhang & Agrawal, 2018)

The internal and external solution is a quite different approach to a solution for DHS. First, surgery to take the parts of the discs that were deformed out of the patient, so the external correction will be more successful in lifting the patient's head off his chest (Bronson, Moses & Protopsaltis, 2018). The external correction is the introduction of screws into the patient's spinal column that will secure a plate that will keep the patient's head up (Bronson, Moses & Protopsaltis, 2018).

Advancements in neck braces for degenerative diseases come from multiple directions; however, the task is the same. With these new advancements, more people will benefit, and their limitations will diminish.

2.2.3.2   Sports Injury Prevention.

Sports cause unnecessary forces to the head, neck, and spine that don't usually occur in everyday life. In football, helmet-to-helmet collisions happen every weekend. In wrestling, an athlete's head can hit hard on the mat while being subjected to a takedown. Motocross riders get thrown from their bikes in all different direction and expose themselves to all kinds of injuries. NASCAR drivers have similar risks when they flip their racing cars.

Neck braces help prevent injury before and help recover and rehabilitate after. Many sports are now adopting some form of neck protection for the athletes while they are performing the actions necessary for their sport.

The motocross neck protection company, Atlas, produces a neck brace that is meant to reduce and possibly prevent head and neck injuries from quick impacts to the racer's head and neck while the wearer is actively participating in a race. The Atlas Brace is a revolutionary new device that aims to solve many of the problematic criteria that exist with neck protection today (Atlas, n.d.). Using advanced materials and breakthroughs in safety, the Atlas Brace challenges the traditional methods of neck protection by creating an innovative design that is stronger, safer, flexible, more adjustable, more comfortable, and extremely simplistic (Atlas, n.d.). The Atlas Brace provides advanced protection with none of the bulky trapped feelings.

2.2.4   New Technology

Because most neck braces are meant to immobilize and stabilize a person's movement, many of the components either surround the neck or are behind the head. There is very little research on how a neck brace or head support would function with moving parts and the important aspects of the device in the front of the individual. The SOMI brace has every purposeful part of the device in the front of the person; however, it does not allow easy movement for someone looking to live a close-to-normal life.

The advancements in mobility come from clunky robotic, motorized parts. And the brace is extremely noticeable, which makes it difficult for a person to wear it outside when performing activities of daily life. These innovations in neck braces and head supports are not completely practical for a user to wear for multiple hours a day too. The human body is not meant to hold a device on one's shoulders for multiple hours in a day.

2.2.4.1   <u>First Prototype</u>

As seen from Figure 2.9 below, the first physical prototype was composed of multiple 3D-printed pieces and a collection of different hardware. The chin piece at the top of the figure was set in a groove in the rotational track that allows for lateral, axial motion of the head. The rotational track was mounted to two pillars that surrounded two shock absorbers. The shock absorbers had the same purposes as those in the first version, to not have the device dig into the wearers jaw when going over uneven surfaces and to allow the wearer to talk moving their jaw instead of their entire head; however, the pillar provides more vertical stability by limiting the horizontal range of motion, giving the springs of the shock absorbers a more efficient purpose (Corens, Jakub, Pessler, & Wigren, 2018). The shock absorbers connected the pillars to the base of the device. The base was attached to the vertical sliding track. This connection allowed the device to be adjusted to more than one neck height so that it may be used to a broader audience. This first prototype was created so the team of Purdue Senior Capstone students could develop the foundation and the basic movements of the device.

Figure 2.9. First Sliding Track Prototype. (Corens, Jakub, Pessler, & Wigren, 2018)

Once the team found out how the simple parts of the new design should work, the team added more complex components that would make the device more comfortable for the patient (Corens, Jakub, Pessler, & Wigren, 2018). The design was changed from a 3-bar system to a 2-bar system. This would get rid of any head drop when the patient rotated their head. The team created a concept that consists of two bars that are stationary, but with added springs for lateral movement as well as a sliding track on top of the two bars for horizontal movement (Corens, Jakub, Pessler, & Wigren, 2018).

2.2.4.2   CAD Models of the Final Design Components.

Figure 2.10 shows a piece that serves as one of the main connection pieces. The radial sliding track sits on the top of this piece and the two are fastened together by M2 screws toward the end of the piece (Corens, Jakub, Pessler, & Wigren, 2018). This piece also provides a

connection point and housing for the shock absorbers and the spring spacers. The cylinder provides stability and direction for the shock absorbers; however, there was still room at top of the cylinder that had the shock absorbers wobbling (Corens, Jakub, Pessler, & Wigren, 2018). To combat this issue, spring spacers were added into the design to make the connection more stable.
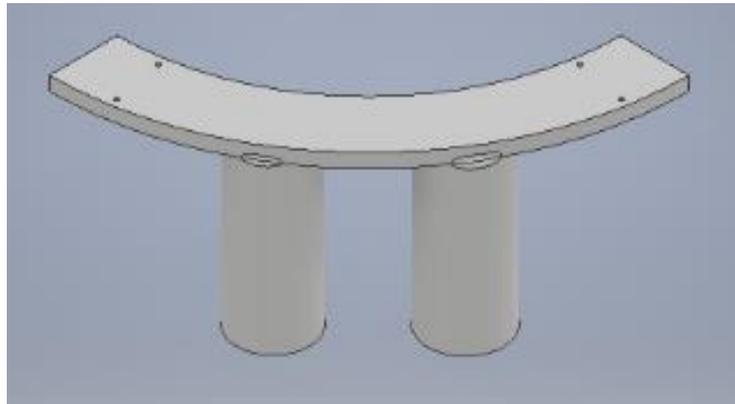
Figure 2.10. 3D CAD Model of the Radial Track Base. (Corens, Jakub, Pessler, & Wigren, 2018)

In Figure 2.11, the radial sliding track houses the chin rest in the groove. As mentioned above, this piece is fastened by screws to the bottom piece. This piece set up the radius for the chin rest and the bottom piece (Corens, Jakub, Pessler, & Wigren, 2018). To create this part, the radius of head rotation on the natural axis had to be calculated. The result was the radius of this piece (Corens, Jakub, Pessler, & Wigren, 2018). Inside the groove is space to have the chin rest supported by ball bearings glide for maximum rotation of 45-degrees each way (Corens, Jakub, Pessler, & Wigren, 2018). The radial sliding track piece will hold the chin piece to allow for lateral movement with the use of ball bearings.
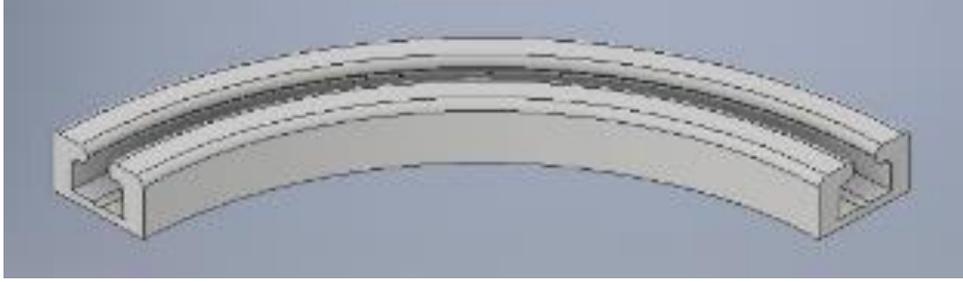
Figure 2.12. 3D CAD Model of the Radial Sliding Track. (Corens, Jakub, Pessler & Wigren, 2018)

In Figures 2.10 below shows two views of the sliding base. This is the most important component of the assembly (Corens, Jakub, Pessler, & Wigren, 2018). The sliding base was designed to hold the shock absorbers and secure each of them with a screw, provide housing for the springs that hold the locking tabs in constant outward pressure with the inward teeth of the vertical sliding track, provide a stable, straight path for the locking tabs so that the teeth of the locking tabs match up with the negative side of the sliding track teeth every time, and still look aesthetically pleasing so that the person wearing it wasn't too self-conscious about wearing it out in public (Corens, Jakub, Pessler, & Wigren, 2018). This design was the best possible solution without compromising any of the requirements.
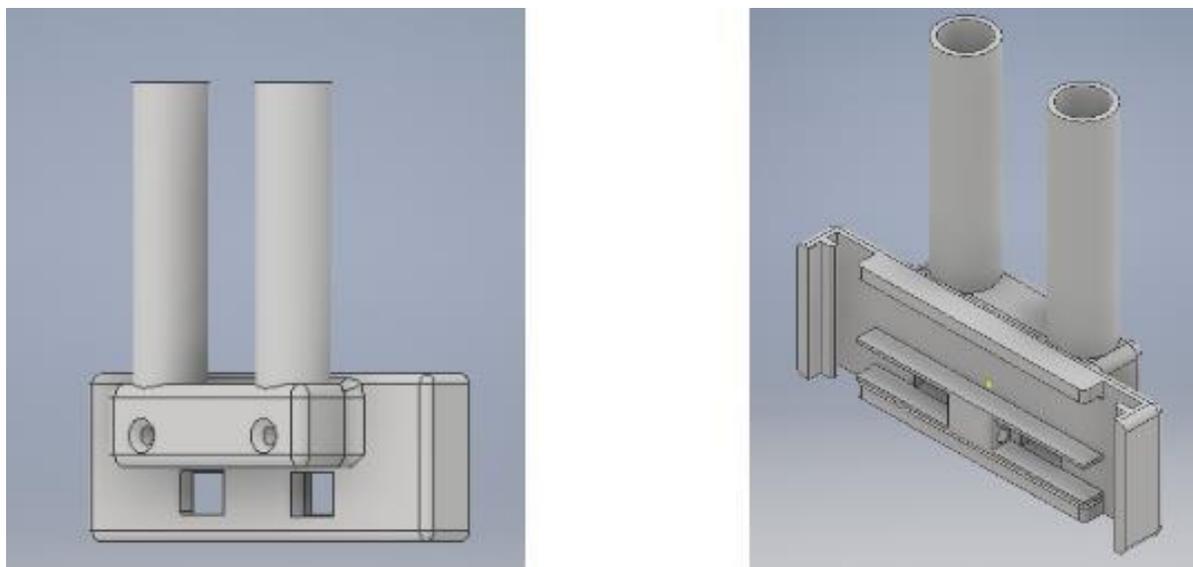
Figure 2.11. 3D CAD Model of the Sliding Base. (Corens, Jakub, Pessler & Wigren, 2018)

The sliding chin rest in Figure 2.13 serves as the moving piece in the track system where the chin rest is mounted on top for the comfort of the patient. Figure 12 shows two views of the sliding chin rest. It holds 10 small bearings for smooth movement (Corens, Jakub, Pessler, & Wigren, 2018). This piece is part of the sliding track as it sits in the radial sliding track. This design allows for easy movement as well as the needed surface area to mount the chin rest (Corens, Jakub, Pessler, & Wigren, 2018).
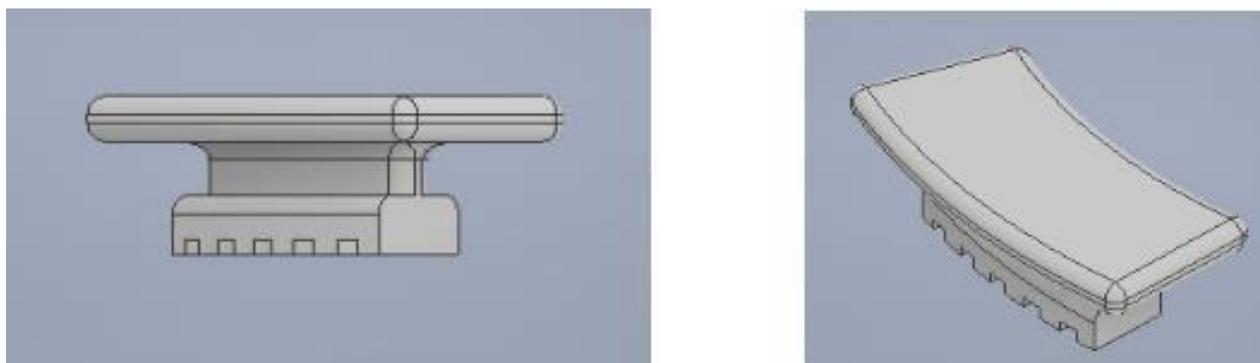

Figure 2.12. 3D CAD Model of the Sliding Chin Rest. (Corens, Jakub, Pessler & Wigren, 2018)

The locking tabs in Figure 2.14 are placed within the sliding base for easy height adjustment as well as an emergency protocol to take the system of the patient's chest. The locking tabs will be pushing against the track to lock the base in place with the use of two springs (Corens, Jakub, Pessler, & Wigren, 2018). The springs made it possible for the locking tab to stay in place and be easily compressed in case a height adjustment is needed. The original locking tabs only had one tab that rotated when the track moved up or down (Corens, Jakub, Pessler, & Wigren, 2018). That piece was mainly rejected because there was only one tooth and if that broke the whole system would experience a catastrophic failure (Corens, Jakub, Pessler, & Wigren, 2018). This part has four teeth for stability and redundancy, providing reassurance that if one tooth breaks, then the system would not be compromised. The teeth are a different width than the rest of the part as there is a gap on the adjustment track, and this will allow the system to compensate for a failed tooth (Corens, Jakub, Pessler, & Wigren, 2018).
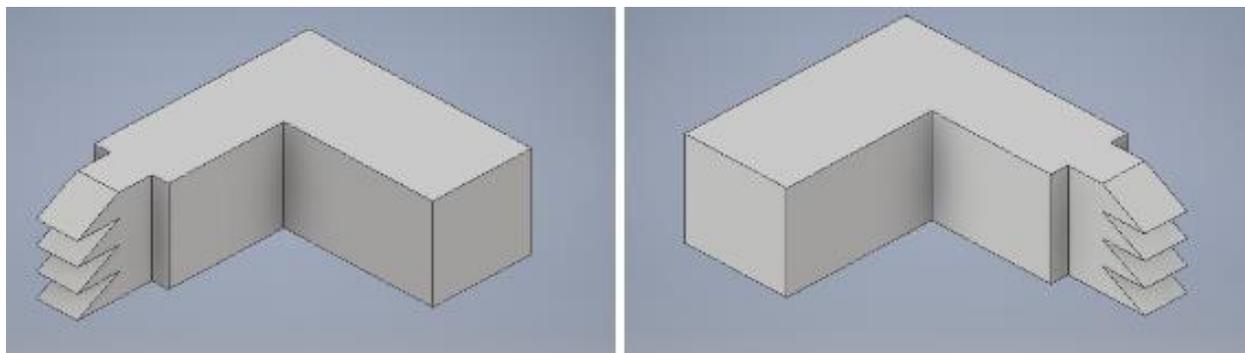
Figure 2.13. 3D CAD Model of the Locking Tabs. (Corens, Jakub, Pessler & Wigren, 2018)

The vertical sliding track in Figure 2.15 will be mounted to the chest plate via three screws. On top of the track will come the sliding base. The teeth are there for the locking tabs (Corens, Jakub, Pessler, & Wigren, 2018). Previously discussed above, the locking tabs will go into the spaces between the sliding track teeth and provide support to keep the patient's head the height

of their choosing for as long as they need (Corens, Jakub, Pessler, & Wigren, 2018). The external channels on the outside are for the inserts of the sliding base, preventing the sliding base from falling forward (Corens, Jakub, Pessler, & Wigren, 2018).
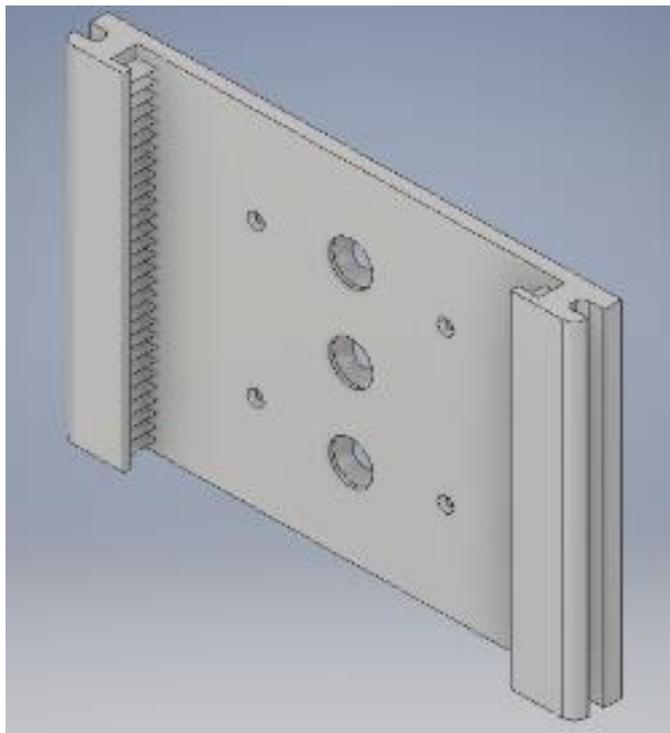
Figure 2.14. 3D CAD Model of the Vertical Sliding Track. (Corens, Jakub, Pessler & Wigren, 2018)

All pieces are 3D printed for the prototype version of the system except the springs, ball bearings, Teflon support or the front and backplate (Corens, Jakub, Pessler, & Wigren, 2018). This was not the intended material for the actual product but due to time constraints and manufacturing restrictions, no further research was conducted on adjusting the materials for each specific piece (Corens, Jakub, Pessler, & Wigren, 2018).

Therefore, this research is needed to make a dynamic head support device a possible option for individuals with chronic muscular degenerative diseases.

2.2.5   Summary

There are a large variety of neck braces and head supports in circulation today. Neck braces are made from various materials and have a multitude of purposes. These braces are designed for the needs of each individual that requires a neck brace or head support to immobilize and/or stabilized their neck as well as control the pain he or she may be experiencing.

Popular uses for neck brace are in sports, medicine, and therapy. Athletes use neck braces and head supports to support their neck during competition and immobilize their neck and head after a serious trauma to the head or neck region. Hospitals and ambulances use neck braces to stabilize an individual's spinal cord and control their pain. Neck stabilization devices in the form of head supports can be used for therapy. Depending on if rehabilitation is necessary or movement in order to control and/or stop muscle atrophy, then the support can be motorized or made to allow the individual to rotate their neck.

Neck braces have a variety of purposes. Two major uses are to support those that have weakened muscles due to muscular degenerative diseases, the other is to protect, prevent and rehabilitate sports injuries. Diseases like Amyotrophic Lateral Sclerosis and Dropped Head Syndrome eventually weaken the neck muscles to the point where one can no longer hold their head up. These braces and supports allow those individuals to keep their head up and live close to normal lives. Sports injuries to the spinal cord or to the neck and head can cause an athlete to need a neck brace and/or head support. Many neck brace/protection researchers are assessing what a soft brace can do while the athlete is performing on the field. Lastly, there are neck braces and supports for athletes that experience an injury and require an external device to help them heal and recover.

The FDA has strict regulation and laws. When a medical device violates those regulations and laws, they have to be recalled, usually reported by the manufacturer. There are three classes

of recalls. Class I is the most severe because the correction or the removal will have a high risk of serious injury or death. Class II is the intermediate classification because the correction or removal will cause temporary or reversible health problems and may lead to serious injury or death. Class III is the least severe because the correction or removal may cause temporary or reversible health issues and has a slight chance of serious injury or death.

New technologies are being developed that will make neck braces and head supports less noticeable and be more effective and comfortable for the people wearing them. The rotational head support prototype designed by the Purdue senior capstone group is just one example. It's one example that needs to be further explored. There is no previous research for materials of this kind of head support as there has never been a device of this nature before.

With research into new designs, head supports and neck braces will be constructed differently than they are now, better than they are now. Better in the fact that the device will not stifle the person wearing it as a cervical collar does. Better in the fact that the device will be more comfortable than braces similar to the SOMI brace. This research will take comfort and skin irritation into considerations, as well as independence, mobility, and cleanability. This will be beneficial to wearers today and wearers in the future.

CHAPTER 3. RESEARCH METHODOLOGY

This study involved safety testing a head support device that will allow individuals with chronic neck muscle diseases, like DHS and ALS, to rotate their head left and right. With no current design for this field of orthotics, the design in this study had purposeful testing concluding whether or not this new device for head support is appropriate based on the load capacity experimental procedure.

3.1   Hypothesis

The hypothesis for this study was straightforward since the problem has an explicit focus and anticipated outcome. The null hypothesis (H_0) was the dynamic head support device will hold up the load equivalent to that of an average adult's head in both a static position and a radial dynamic movement. Therefore, the alternative hypothesis (H_a) was the dynamic head support device will not hold up the load equivalent to that of an average adult's head in either a static position, radial dynamic movement or both.

3.2   Testing Apparatus

For this proposed research, the goal was to define the safety parameter of load capacity for the new dynamic head support device. The mechanism needed to achieve this goal has to able to compress the device and allow it to move along the race of the radial sliding track.

3.2.1   Original Testing Apparatus

The Purdue Senior Capstone's prototype testing apparatus was a testing device meant to simulate the features of a person, seen in Figure 3.1.

Figure 3.1. Testing Device for Original Project (Corens, Jakub, Pessler, & Wigren, 2018)

Multiple sheets of plywood were cut, shaped, and glued together to represent the shoulders, torso, and neck of a person. At the top of the neck, a hole was cut out for the neck of a drum stand. This piece of the testing device was meant to simulate the looseness and randomness of a person's neck without any muscles. Attached to the neck of the drum stand was a block of 2 by 4 that could be fastened to a motorcycle helmet. The motorcycle helmet allowed for any added weight to be added through the visor. The motorcycle helmet also modeled a person's chin's general shape and location with respect to a person's neck and head.

This original apparatus, however, would not have provided accurate data. The load would not have been located near the chin rest of the dynamic head support device. Therefore, the load capacity could not have accurately recorded.

3.2.2 Universal Testing Machine

Since this proposed research was dependent on a prototype device, a standard, rudimentary testing operation was the best option to validate the safety parameter of the load capacity of the device. A Universal Testing Machine (UTM) was the apparatus used in this proposed research.

Equipped with steel plates below and above the study's dynamic head support device, the UTM provided accurate data with respect to load capacity, rate of compression, and overall deflection of the dynamic head support device. The UTM was assembled with a 500-pound load cell, the lowest of the possible load cells the UTM is equipped for, because of the low load capacities of the experiment. Figure 3.2 shows a schematic of the testing apparatus that is not to scale. Figure 3.3 illustrates a front view of the testing apparatus.
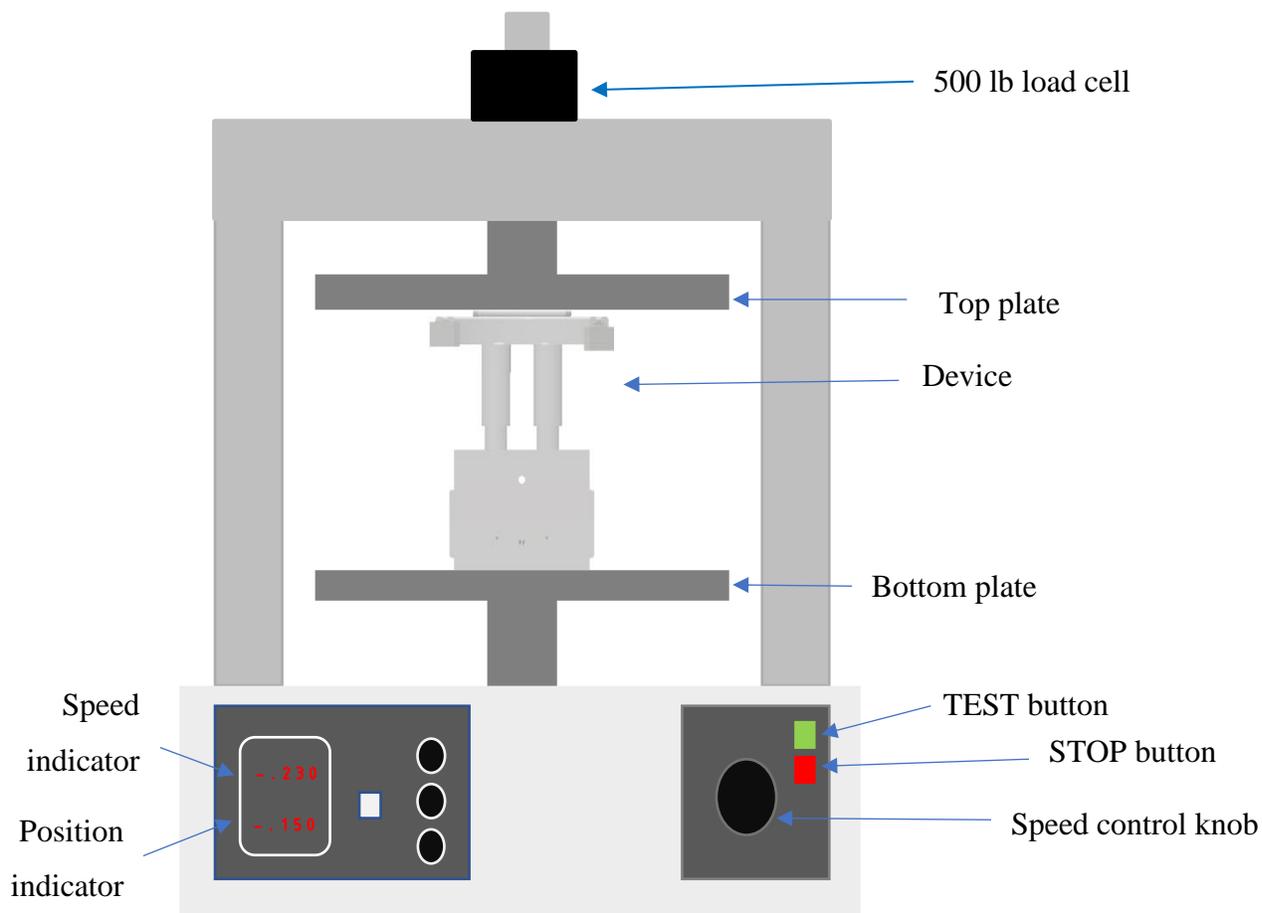
Figure 3.2 Schematic of Testing Apparatus, UTM.

Figure 3.3 Testing Apparatus, UTM.

The UTM was connected to a P-3500 strain indicator. The strain indicator allowed for the

load capacity to be digitalized and produce a value of load being compressed. The speed rate

percentage is determined by the size of the motor. The UTM in KNOY 106 is an

electromechanical UTM, meaning that it "uses an electric motor, gear reduction system and one,

two or four screws to move the crosshead up or down. A range of crosshead speeds can be

achieved by changing the speed of the motor" (Gedney, 2005). The percentages are based on how much of the motor capacity is being used. The motor rates of the UTM used in this study are 0.1 in/min at low speed at 100% and 1.0 in/min at high speed at 100%.

3.2.3   Stabilizing Fixture

Knowing the chin rest would only be attached to the top plate through friction, there needed to be a fixture that stabilized the chin rest so that it would remain centered and perpendicular to the top and bottom plates during the dynamic testing phase of the experiment.

The stabilizing fixture for this experiment was a 3D printed PLA insert with cutouts for the chin rest of the dynamic head support device and for the four button magnets. The dimensions of the button magnets are 3/16 in x 3/16 in. The purpose of the magnets was to connect the fixture to the steel top plate of the UTM. A ceramic bar magnet was placed on the backside of the fixture for redundancy and extra stabilization. The bar magnet dimensions are 2 in x 3/4 in x 3/8 in. The bar magnet was purposefully placed on the backside of the fixture so that it would not interfere with the movements during the dynamic testing of the experiment. Figure 3.4 depicts the fixture designed for this experiment in a 3D CAD model without the magnets. Figure 3.5 shows the actual fixture with the magnets.
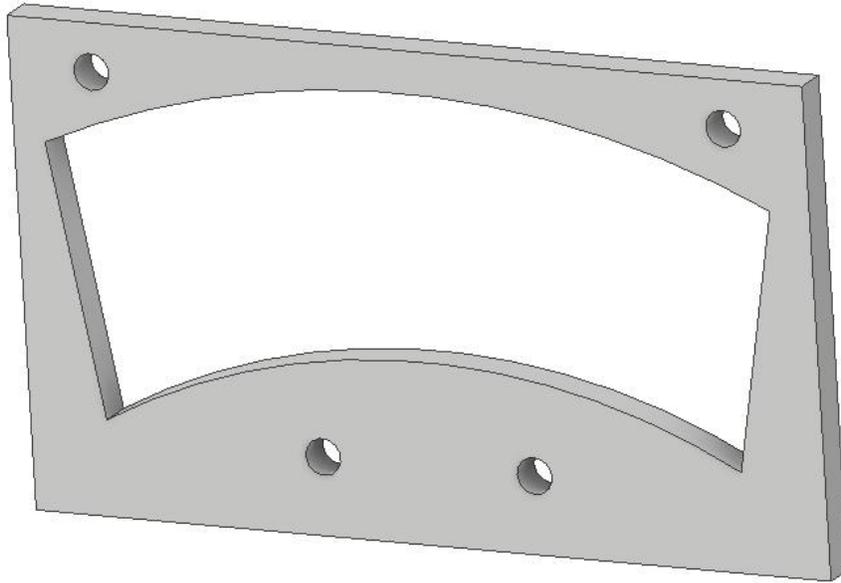
Figure 3.4 3D CAD Model of Stabilizing Fixture.

Figure 3.5 Stabilizing Fixture

3.3   Data Collection and Analysis

The data was collected via a checklist. At each phase of the testing cycle, a box labeled either

yes or no was checked. If the device performed the way it is expected, then the "yes" box was

checked, and the procedure continued to the next step; however, if the "no" box was checked then the procedure stopped and ended the testing cycle. The checklist had the following information:

1. The testing apparatus, UTM, is properly set up.

2. The device is secured in the UTM.

3. The device is stabilized with a starting load: 2 pounds.

4. The device is checked at each continuous increment of 1 pound until the total load is between 10 and 12 pounds.

5. The device is able to hold the total load for 10 minutes in a static position.

6. The loaded device moves along the radial sliding track to the left until it can no longer move the load.

7. Record distance of the chin rest from the end cap.

8. The device is returned to the center.

9. The loaded device moves along the radial sliding track to the right until it can no longer move the load.

10. Record distance of the chin rest from the end cap.

11. Return the device to center.

12. The device is successfully unloaded.

13. The device is successfully removed from the testing apparatus (still intact and functional).

If the device remained intact and functional throughout the entire procedure, then the experiment was measured as a success, thus allowed for a better understanding of the safety measures of the dynamic head support device concerning the wearer head and neck support.

3.4   Methodology

The methodology of the safety assessment was threefold: static load testing, radial dynamic movement to the left, and radial dynamic movement to the right. The dynamic head support device was placed into the UTM that will gradually apply a load onto the device until the load reaches that of an average adult's head, ten to twelve pounds.

Before the device was placed into the UTM, the wire connections to the P-3500 strain indicator had to be secured for proper output values. Once connected, the P-3500 strain indicator was set to full bridge configuration with the "AMP ZERO" value reading zero, the "GAGE FACTOR" value reading 1.6, and the "RUN" value reading zero because the UTM had yet to apply any load to the device. After the P-3500 strain indicator was properly calibrated, the next task was to make sure that the toggle switches on the UTM are on the correct settings. The first toggle switch was the on/off switch; this was off before the device was put into the UTM. The second toggle switch was the tension/compression switch; this was turned to compression so the top plate was compressed down on the device, thus applying a load. The third and last toggle switch was the high/low-speed range switch; this was turned to high so that the top plate of the UTM quickly came down to meet the chin rest of the device. Once the top plate was close, about three inches, to the chin rest, then the switch was turned to low.

Once the device was put into the testing apparatus and in a centered, static position, a predetermined starting load of two (2) pounds was applied to the chin rest to stabilize the device. From this starting load, the load was continuously increase. In increments of one (1) pound, the position was checked on the UTM. This process was recurrent until the load reaches the estimated maximum weight of an average adult's head, twelve pounds (Brian, Marshall, 2009). The speed at which this continuous load was applied to the chin rest was set using the speed control knob on the UTM. This knob controlled the rate at which the load compresses by percentages. The aim of

this proposed research was to set the speed rate between twenty (20) and thirty (30) percent. After the final load was applied, the device had to hold it for ten (10) minutes.

After the static hold testing, the dynamic movement assessment began. First, the chin rest rotated to the left, using ball bearings to move along the radial sliding track. This movement continued until the loaded chin rest stops against the end cap of the radial sliding track.

The chin rest then was centered again so the load could be rotated to the right. This movement continued until the loaded chin rest stops against the other end cap of the radial sliding track. After the movement to this end cap was completed, the chin rest was centered for a final time. Once centered, the load was taken off the device.

This experimental procedure was conducted with the stabilizing fixture fixed to the center of the UTM's top plate and without the stabilizing fixture.

3.5   Threats to Validity

There were three potential threats to validity in this proposed research. The first threat came from the accuracy of the testing apparatus and its load cell. The smallest possible load cell for the UTM was 500 pounds. This load cell had an accuracy tolerance of ±0.5% of the entire load cell. This meant the P-3500 strain indicator may have shown a value of the compression load of the UTM that was ±2.5 pounds from the actual load. This could have been avoided by having the load values large enough to where values of ±2.5 pounds did not affect the outcome of the proposed research. Since the load capacities of this proposed research were so small, maximum of twelve pounds, compared to that of the entire load cell, the values may have been skewed to where the final load value was inaccurate by 2.5 pounds. With small load values, this may have affected the recorded data.

The second threat came from the condition of the device. If the dynamic head support device had any flaws before testing, it could have impacted the experimental procedure. Since the device was mostly 3D printed from PETG, the device was theoretically strong enough to withstand the proposed load of this experiment. To avoid this, the parts of the device were examined thoroughly for cracks or blemishes that could have affected the experiment.

The third threat came from the magnets used in the stabilizing fixture. The magnetic pull of the electromagnetic field could have skewed the experimental data by creating a force in the opposite direction of axial compressive stress.

3.6   Summary

The goal of this endeavor was to study a new dynamic head support device and discover whether it was safe for a person to utilize. This parameter of safety was tested by having the device hold the load equivalent to that of an average adult's head, then have the device move the load right and left along with the race of the radial sliding track. The data was collected through a checklist of the procedure. After the data was collected and analyzed, the device would either be able to support an average adult's head safely or it would be another stepping stone for future research.

CHAPTER 4.   RESULTS

4.1   Device Prototype Design Modifications

The prototype device for this proposed research had the same key components as the prototype constructed by the Purdue Senior Capstone team. However, there were some modifications to the device. These modifications included adding stoppers or "caps" to the end of the radial sliding track so that the chin piece had a boundary that it could not pass. This will keep the participants safer as they will not be able to rotate their heads beyond the radial sliding track. Figure 4.1 and Figure 4.2 illustrates the comparison of the radial sliding track system with and without the end caps in 3D CAD models.

Figure 4.1 Original Radial Sliding Track System with no End Caps.

Figure 4.2 Radial Sliding Track System with End Caps.

Two modifications were made to the chin rest. One was enlarging the chin rest plate that sat above the radial sliding track. This modification was made because a larger chin rest will give the wearer more surface area in which to place their chin, thus giving them more stability. The other was making the neck of the chin rest longer. This was done by decreasing the thickness of the subcomponent that holds the ball bearings off the top. Making the neck longer allowed for the chin rest to move with minimal friction along with the race of the radial sliding track. The friction between the bottom of the radial sliding track overhang and the top of the ball bearing subcomponent of the original chin rest was causing undesirable fiction that made it difficult for the ball bearings to get across the race of the radial sliding track smoothly. Figure 4.3 and Figure 4.4 shows the differences of the chin rests in a 3D CAD model.
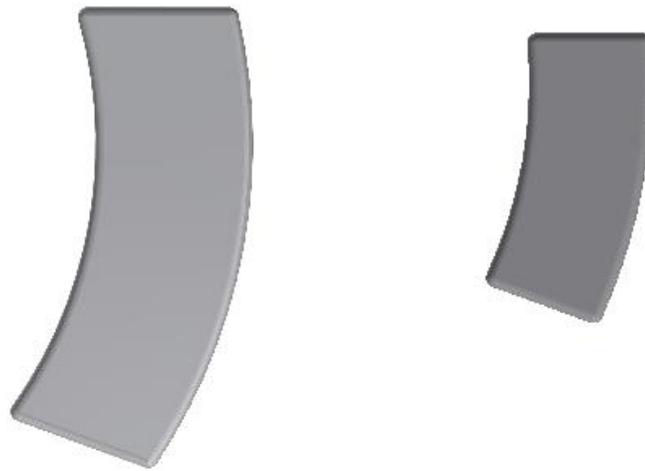
Figure 4.3 Top View of Chin Rests.

Figure 4.4 Side View of Chin Rests.

The last modification made to this study's device was that the engineering material for the

3D printing changed from PLA to PETG. The PLA was not strong enough to stay intact after

multiple uses, so this proposed research has a stronger material is PETG. PLA has a tensile

strength of 48.6 MPa (MatWeb, 2019), while PETG has a tensile strength of 53 MPa (MatWeb,

2019). Another reason the change of material was made to this study was due to PETG is

categorized as a medical-grade material and is commonly used in medical devices, while PLA is

not a medical-grade material.

4.2   Experimental Data

The experimental procedure checklist for testing without the stabilizing fixture can be found in Appendix A. The experimental procedure checklist for testing without the stabilizing fixture can be found in Appendix B.

4.2.1   Static Testing Data

The UTM recorded three variables throughout the experiment: speed rate, position, and load.

4.2.1.1   Experimental Data without the Chin Rest Stabilizing Fixture

Table 4.1 shows the load, speed rate, and position, deflection, of the device as it's being compressed. The three variable units were pounds for load, percentages for speed rate, and inches for position. The speed rate was constant and the load was recorded every whole pound, thus having the position as the only unknown variable.

Table 4.1 Load vs Speed Rate vs Position Table (Without Chin Rest Stabilizing Fixture)

Load (lbs, whole values)	Speed Rate (%)	Position (in)
2	0	0
3	-22	-0.116
4	-22	-0.342
5	-22	-0.442
6	-22	-0.453
7	-22	-0.457
8	-22	-0.461
9	-22	-0.462
10	-22	-0.465
11	-22	-0.466
12	0	-0.468
13	0	-0.469

After five pounds and more was applied to the device, the position, deflection,
differences of the device decreased exponentially. The load capacity for this experiment was
focused on targeting a maximum of twelve pounds. Due to a human reaction time factor, the load
surpassed that target load. The peak load was 13 pounds and the final load was 12.5 pounds. This
provides data that exceeded the expectations of the proposed research.

During this static testing, a bending failure between the outer columns of the radial
sliding base and the inner columns of the sliding base occurred with regards to the outer columns
of the radial sliding base. Figure 4.5 and Figure 4.6 show the device before and after
compression loading was complete. Figure 4.7 shows the device after the ten minute waiting
period. The figures compare the position of the chin rest, respectively, at the start of the static
test cycle and at the conclusion of the static test cycle.

No failure

Figure 4.5 Device Before Active Compressive Loading

Beginnings of bending failure

Figure 4.6 Device After Active Compression Loading

Complete bending failure
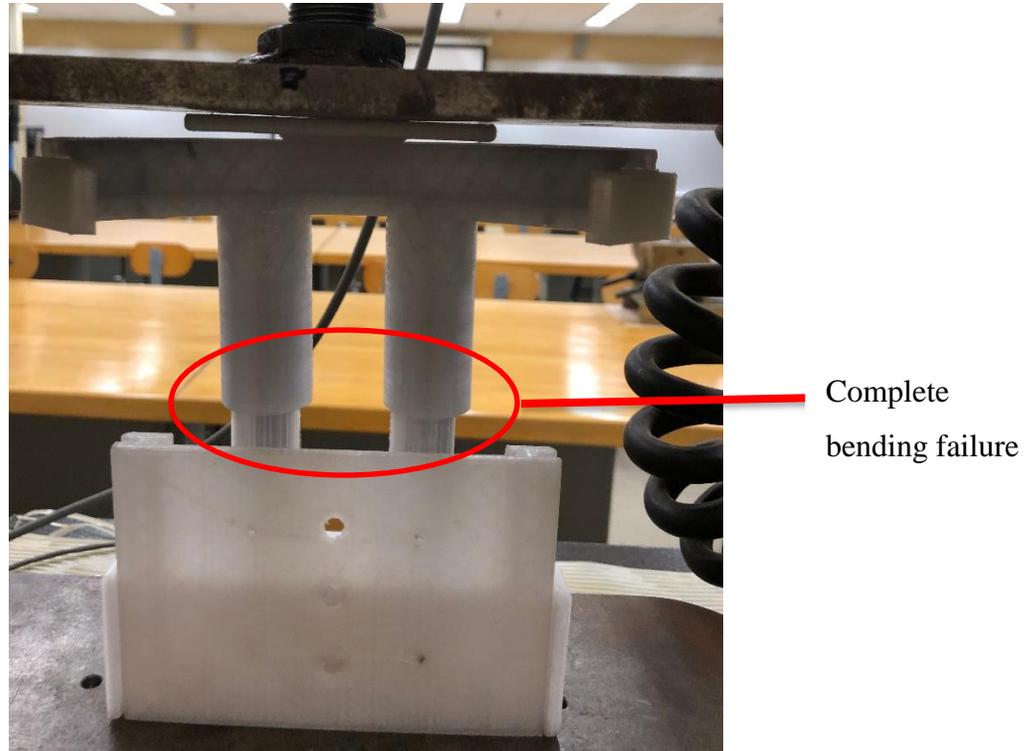
Figure 4.7 After 10-Minute Static Hold

Figure 4.7 shows a non-perpendicular forward tilt in the outer columns of the radial sliding base when compared to the inner column of the sliding base.

4.2.1.2   Experimental Data with the Chin Rest Stabilizing Fixture

Testing the device with the chin rest stabilizer provided ideal conditions for this experiment because the chin rest stabilizing fixture allowed for the chin rest to remain centered and perpendicular to the plates of the UTM. Table 4.2 shows the load, speed rate, and position of the device while being compressed with the chin rest stabilizer. The speed rate fluctuated between 24 and 25 percent, however, the position recorded almost always was recorded at a speed rate of 25 percent.

Table 4.2 Load vs Speed Rate vs Position Table (Without Chin Rest Stabilizing Fixture)

Load (lbs, whole values)	Speed Rate (%)	Position (in)
2	0	0
3	-24	-0.147
4	-25	-0.387
5	-25	-0.397
6	-25	-0.409
7	-25	-0.418
8	-25	-0.430
9	-25	-0.434
10	-25	-0.438
11	-25	-0.442
12	0	-0.445
12.6	0	-0.446

After four pounds and more was applied to the device, the position, deflection, differences of the device decreased exponentially. The target load capacity for this experiment was twelve pounds. The peak load recorded was 12.6 pounds and the final load was 12 pounds. This shows data that exceeded the expectations of the proposed research.

4.2.2   Dynamic Testing Data

The axially compressed chin rest required the body of the dynamic head support device move. This meant that the race of the radial sliding track moved along the ball bearings while the entire device was under the final load. This action was performed by moving the body of the device manually along the bottom plate of the UTM.

4.2.2.1   Experimental Data without the Chin Rest Stabilizing Fixture

When the chin rest made it to the left end cap, the body of the dynamic head support device experienced a height drop of 5/32 of an inch. The height drop was calculated by adding the gap distance between the top plate of the UTM at the chin rest and the gap distance from the top plate of the UTM to the top of the radial sliding track, and then subtracting the height of the

chin rest platform, the subcomponent of the chin rest that made contact with the top plate of the UTM. There was a load decrease when the chin rest was at the left end cap. The recorded load decrease was 3.1 pounds when the height drop occurred. Figure 4.8 illustrates the height drop of the device.

Figure 4.8 Height Drop

When attempting to move the chin rest back to center from the left end cap, the device could not remain perpendicular to the UTM plates, so it dislodged from the compressive load of the top plate of the UTM. This resulted in a failure and the experiment concluded.

These irregularities were direct results of the bending failure between the two sets of columns of the device while it was under the ten-minute static hold. The dynamic test commenced right after the ten-minute static hold during the static testing stages.

4.2.2.2   Experimental Data with the Chin Rest Stabilizing Fixture

Testing the device with the chin rest stabilizing fixtured provided ideal conditions for this experiment, similarly to that of the static testing. With the chin rest stable, the manually moved body of the device moved along the ball bearings of the chin rest as intended. The ball bearings moved along the race of the radial sliding track in both direction and made it back to the center starting position after touching each end cap. Thus, the chin rest was able to rotate the full 45 degrees each way when the device was level and perpendicular to the plates of the UTM. There was no height drop when the chin rest touched the end caps and there were no load fluctuations while the device was not centered.

4.2.3   Experimental Coup de Theatre

At the beginning of the first static load test, the top plate was not compressed against the chin rest enough to stabilize the device within the UTM. Due to this situation, the device leaned forward and eventually fell out of the UTM and onto the floor. The drop was approximately four feet. The result of this occurrence was a chin rest split in two at the neck, a column of the sliding base severed from the rest of the sliding base, and small cracks along with the right outer channel inserts of the sliding base.

The solution to this mishap was to glue the parts together with M-BOND 200 adhesive from Micro-Measurements. This adhesive is an ethyl-based cyanoacrylate adhesive. This type of adhesive has a modulus of elasticity of 1.26 GPa (H. Martinez, personal communication, July 15,

2019) when within the adhesive's pot life. Since the adhesive used to fix the dynamic head support device is past its pot life, the modulus of elasticity has decreased. This meant that the locations of the breaks and cracks were more flexible than they were before.

4.3   Summary

The static position testing showed that the dynamic head support device could withstand more than the load capacity of an average adult's head with the stabilizing fixture; however, the static testing without the stabilizing fixture experienced a bending failure after the ten-minute static hold. The dynamic movement testing showed that the device could move along the race when using the stabilizing fixture but could not move along the race back to center once the chin rest touched an end cap when not using the stabilizing fixture.

CHAPTER 5.   SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

5.1   Interpretations of the Results

The results of both the static and dynamic testing when the stabilizing fixture was attached to the top plate of the UTM were as expected. The static testing did not present with any buckling, and the dynamic testing did not exhibit height drops, load differentials, or failures in the middle of testing. However, when the final position of the dynamic head support device of this cycle of testing was compared to that of the testing cycle without the stabilizing fixture, the positions differed by twenty-three thousandths of an inch. The stabilizing fixture static test displayed less negative deflection than the static test that did not have the stabilizing fixture. This meant that the magnets of the stabilizing fixture had an effect on the dynamic head support device. The dynamic testing showed that the chin rest can slide along the race, touching both end caps and returning to the center of the race afterward. There were no load discrepancies during this stage of testing.

The results of both the static and dynamic testing when the stabilizing fixture was not attached to the top plate of the UTM showed flaws in the design of the device. The static testing resulted in the outer columns of the radial sliding base undergoing a bending failure with the inner columns of the sliding base. This issue was most likely the consequence of two flaws in the proposed research; one being design-based, the other being experiment-based. For the former, the gap between the inner diameter of the outer column of the radial sliding base and the outer diameter of the inner column of the sliding base was too wide, meaning the 2 mm space between the two columns caused the device to fail under direct axial compressive stress. For the latter, the device did not remain perpendicular to the plates of the UTM after the continuous compressive

loading stage of the static test began. The dynamic testing exposed that the presence of bending caused major issues such as significant load differentials, height drop, and instability. Since the bending failure began during the static testing stage, it was the root cause of the failures during the dynamic testing stage. This meant that with the correction of the bending failure, the device should perform as expected.

During both static active compressive load tests, the deflection of the dynamic head support device exponentially decreased. This was most likely caused by the resulting compression of the shock absorbers. During the first four pounds of continuous loading for the static test with the stabilizing fixture and first five pounds of continuous loading for the static test without the stabilizing fixture, the shock absorbers did not have enough load to feel the compression and collapse; therefore, the stiffness of the shock absorbers was strong until those marks. However, since neither test showed that the shock absorbers fully compressed to half an inch, the test proved that the device could hold up the weight of an average adult's head and more without the shock absorber completely retracting.

After analyzing the results, the current design of the dynamic head support device cannot hold up an average adult's head safely yet. The experimental data proved that the device cannot support an average adult's head up both in a stationary position and while rotating their head along the radial sliding track. It also shows that the device is not ready for the next step of research: human subject testing.

5.2   Conclusion

The dynamic head support device will not be able to hold up a load equivalent to that of an average adult's head in both a static position and a radial dynamic movement. Thus, the device is not safe for human subjects to wear it based on the experimental procedural checklists. This

experiment concludes that there will be any strain of the back of the neck when a person wears the device as the wearer's head will not be supported in an upright position in all directions.

5.3   Future Work

There are two ways this experimental study can improve. The first improvement would be to not have the device be subjected to failures that would not be possible if the device were to be worn by a person. During the beginning steps of the first static testing procedure, the device fell forward, and dropped approximately four feet to the floor, causing the device to break. The neck of the chin rest was split in two, the right column of the sliding base broke off, and the sliding base was cracked along the outer channel inserts. This instance of imperfection led to the gluing of the parts, and the testing of a blemished device.

The final improvement would be to widen the distance of the two columns of the sliding base. This alteration will provide a sturdier base for the radial sliding track and prevent height drops at the ends of the radial sliding track.

Once these changes transpire, the next step is to assess whether or not the device can meet other healthcare standards, such as comfort, mobility, independence, cleanability, and skin irritation tolerance. This would happen by giving it to able-bodied subjects and having them try it on and go through some movements.

5.4   Summary

This chapter summarizes the various nuances of the experiment. The conclusion was solely based on the experimental procedural checklists, and the future work of this proposed research will be dependent on the evolution of the dynamic head support device. Overall, the

experimental procedure answered the research question and the alternative hypothesis was

proven.

APPENDIX A. CHECKLIST FOR TESTING WITHOUT THE CHIN REST STABILIZING FIXTURE

Experimental Procedure Checklist

		YES	NO
1.	Testing apparatus properly set up.	☒	☐
2.	The device successfully fit in the testing apparatus.	☒	☐
3.	The device is able to withstand the load of the starting load: 2 lbs.	☒	☐
4.	The device is able to withstand the starting load and the first increment of 1 pound (total of 3 lbs).	☒	☐
5.	The device is able to withstand the starting load and two increments of 1 pound (total of 4 lbs).	☒	☐
6.	The device is able to withstand the starting load and three increments of 1 pound (total of 5 lbs).	☒	☐
7.	The device is able to withstand the starting load and four increments of 1 pound (total of 6 lbs).	☒	☐
8.	The device is able to withstand the starting load and five increments of 1 pound (total of 7 lbs).	☒	☐
9.	The device is able to withstand the starting load and six increments of 1 pound (total of 8 lbs).	☒	☐
10.	The device is able to withstand the starting load and seven increments of 1 pound (total of 9 lbs).	☒	☐
11.	The device is able to withstand the starting load and eight increments of 1 pound (total of 10 lbs).	☒	☐
12.	The device is able to withstand the starting load and nine increments of 1 pound (total of 11 lbs).	☒	☐
13.	The device is able to withstand the starting load and all incremental loads of 1 pound (total of 12 lbs).	☒	☐
14.	The device is able to hold the total load for 10 minutes in a static position.	☒	☐

15. The loaded device moves along the radial sliding track to the left until it stops at the end cap. ☒ ☐

16. The device is returned to center. ☐ ☒

17. The loaded device moves along the radial sliding track to the right until it stops. ☐ ☐

18. The device is returned to center. ☐ ☐

19. The device successfully is unloaded. ☐ ☐

20. The device is successfully removed from the testing apparatus still intact and functional. ☐ ☐

APPENDIX B. CHECKLIST FOR TESTING WITH THE CHIN REST STABILIZING FIXTURE

Experimental Procedure Checklist

		YES	NO
1.	Testing apparatus properly set up, including the stabilizing fixture.	☒	☐
2.	The device successfully fit in the testing apparatus.	☒	☐
3.	The device is able to withstand the load of the starting load: 2 lbs.	☒	☐
4.	The device is able to withstand the starting load and the first increment of 1 pound (total of 3 lbs).	☒	☐
5.	The device is able to withstand the starting load and two increments of 1 pound (total of 4 lbs).	☒	☐
6.	The device is able to withstand the starting load and three increments of 1 pound (total of 5 lbs).	☒	☐
7.	The device is able to withstand the starting load and four increments of 1 pound (total of 6 lbs).	☒	☐
8.	The device is able to withstand the starting load and five increments of 1 pound (total of 7 lbs).	☒	☐
9.	The device is able to withstand the starting load and six increments of 1 pound (total of 8 lbs).	☒	☐
10.	The device is able to withstand the starting load and seven increments of 1 pound (total of 9 lbs).	☒	☐
11.	The device is able to withstand the starting load and eight increments of 1 pound (total of 10 lbs).	☒	☐
12.	The device is able to withstand the starting load and nine increments of 1 pound (total of 11 lbs).	☒	☐
13.	The device is able to withstand the starting load and all incremental loads of 1 pound (total of 12 lbs).	☒	☐
14.	The device is able to hold the total load for 10 minutes in a static position.	☒	☐

15. The loaded device moves along the radial sliding track to the left until it stops at the end cap. ☒ ☐

16. The device is returned to center. ☒ ☐

17. The loaded device moves along the radial sliding track to the right until it stops. ☒ ☐

18. The device is returned to center. ☒ ☐

19. The device successfully is unloaded. ☒ ☐

20. The device is successfully removed from the testing apparatus still intact and functional. ☒ ☐

LIST OF REFERENCES

Ackerman, E. J. (1975). *U.S. Patent No. 3,900,896*. Washington, DC: U.S. Patent and Trademark Office.

ALS Association. (2018). *What is ALS?* Retrieved from http://www.alsa.org/about-als/what-is-als.html

Atlas. (n.d.) *About Atlas.* Retrieved from https://www.atlasbrace.com/about-atlas-brace/

Autodesk. (2019). Autodesk Inventor (Version 2019) [Computer Software]. Retrieved from https://www.autodesk.com/education/free-software/inventor-professional

Brace. (n.d.). In *Merriam-Webster Dictionary online*. Retrieved from https://www.merriam-webster.com/dictionary/brace

Brian, Marshall. (2009). *How much does the human head actually weigh?* Retrieved from https://www.brainstuffshow.com/blogs/how-much-does-the-human-head-actually-weigh.htm

Bronson, W., Moses, M., & Protopsaltis, T. (2018). Correction of dropped head deformity through combined anterior and posterior osteotomies to restore horizontal gaze and improve sagittal alignment. *European Spine Journal*, 27(8), 1992-1999. doi:10.1007/s00586-017-5184-6

Calabrese, S. (2011). US Patent No. US8,932,243 B2.

Cervical Collar. (2018, August 25). *Physiopedia*. Retrieved from https://www.physiopedia.com/index.php?title=Cervical_Collar&oldid=196544.

Cleveland, Lisa. (2018). *Braces for Your Neck and Back.* Mayfield Clinic. Retrieved from https://www.mayfieldclinic.com/PE-brace.htm

Corens, T., Jakub, L., Pessler, D., & Wigren, J. (2018). International Project: Rotational Head

    Support. Purdue University, West Lafayette, Indiana.

Epoxy Technology Inc. (2014). *Tech Tip 26: Pot Life, Working Life and Gel Time of Epoxies.*

    Retrieved from http://www.epotek.com/site/files/Techtips/pdfs/techtips_26_7.pdf

Food and Drug Administration. (2018). *Classify Your Medical Device: Is the Product a Medical*

    Device? Retrieved from

    https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyour

    device/ucm051512.htm

Foster Corporation. (2019). *USP Class VI.* Retrieved from

    https://www.fostercomp.com/stewardship/usp-class-vi/

Gedney, Richard. (January 2005). Tensile Testing Basics, Tips and Trends. *Quality.* Retrieved

    from https://www.admet.com/wp-

    content/uploads/2015/12/Tensile_Testing_Basics_Quality_Magazine.pdf

Gehlbach, P. L., Benson, B. C., Cortes, H. M., Davenport, M. S., Harrison, R. M., Hwang,

    K., . . . Wong, J. C. (2008). US Patent No. US20080004556 A1.

Gehlbach, P. L., Benson, B. C., Cortes, H. M., Davenport, M. S., Harrison, R. M., Hwang,

    K., . . . Wong, J. C. (2008). US Patent No. US20080004556 A1.

Geneva Laboratories. (2019). *Toxicology / Biocompatibility.* Retrieved from

    http://www.genevalabs.com/testing-services_toxicology-

    biocompatibility/?gclid=CjwKCAjw98rpBRAuEiwALmo-

    ygTZD7zjteJOsF6E3jy2adTsNO0TuZ_tGrxO9b-

    JByZn4RXJwmL_hBoCyIUQAvD_BwE

Glazener, P., & Glazener, P. (2014). Pilot study to determine the effectiveness of a new neck

brace design for patients with amyotrophic lateral sclerosis. *Journal of Nursing*

Education and Practice, 4(6). doi:10.5430/jnep.v4n6p1

MatWeb. (2019). *Clariant White Polyethylene Terephthalate Glycol 3D Printer Filament.*

Retrieved from

http://www.matweb.com/search/DataSheet.aspx?MatGUID=01c0de6d2c744230a277ab4

a0efe10cd&ckck=1

MatWeb. (2019). *Master Bond MB260NT Ethyl-based Cyanoacrylate.* Retrieved from

http://matweb.com/search/DataSheet.aspx?MatGUID=a121114b172e4f68bfc3ce43ee535

8a5&ckck=1

MatWeb. (2019). *Overview of materials for Polylactic Acid (PLA) Biopolymer.* Retrieved from

http://matweb.com/search/datasheet.aspx?MatGUID=ab96a4c0655c4018a8785ac4031b9

278

Mayo Clinic Staff. (2018). *Muscular Dystrophy: Overview.* Retrieved from

https://www.mayoclinic.org/diseases-conditions/muscular-dystrophy/symptoms-

causes/syc-20375388

Mayo Clinic Staff. (2018). *Myasthenia Gravis: Overview.* Retrieved from

https://www.mayoclinic.org/diseases-conditions/myasthenia-gravis/symptoms-

causes/syc-20352036

Muthusamy, Preetha & Tavee, Jinny. (2010). *Myopathy.* Retrieved from

http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/neurology/myop

athy/

Orthotic. (n.d.). In *Merriam-Webster Dictionary online*. Retrieved from https://www.merriam-webster.com/dictionary/orthotic

Professional Plastics. (2019). *Medical Products.* Retrieved from https://www.professionalplastics.com/Medical-Products

Prototype. (n.d.). In *Merriam-Webster Dictionary online*. Retrieved from https://www.merriam-webster.com/dictionary/prototype

Reed, H., Langley, J., Stanton, A., Heron, N., Clarke, Z., Judge, S., . . . Mcdermott, C. (2015). Head-Up; An interdisciplinary, participatory and co-design process informing the development of a novel head and neck support for people living with progressive neck muscle weakness. *Journal of Medical Engineering & Technology, 39*(7), 404-410.

Rahimizadeh, A., Soufiani, H. F., & Rahimizadeh, S. (2016). Cervical Spondylotic Myelopathy Secondary to Dropped Head Syndrome: Report of a Case and Review of the Literature. Case Reports in Orthopedics, 2016, 7. doi:10.1155/2016/5247102

Technology. (n.d.). In *Merriam-Webster Dictionary online*. Retrieved from https://www.merriam-webster.com/dictionary/technology

Torlei, K., Matthews, E., Sparke, A., Benger, J., Voss, S., Harris, N., & Carter, J. (2013). Design of Cervical Brace for Trauma Patients. Journal of Medical Devices, 7(2), 020928-020928-020922. doi:10.1115/1.4024341

Wavebreak. (n.d.). Ambulancemen healing injured man lying on a stretcher [Digital image]. Retrieved July 18, 2019, from https://dissolve.com/stock-photo/Ambulancemen-healing-injured-man-lying-royalty-free-image/101-D23-28-411

Zhang, H. & Agrawal, S. K. (2018). An Active Neck Brace Controlled by a Joystick to Assist

Head Motion. Robotics and Automation Letters, IEEE, 3(1), 37-43.

doi:10.1109/LRA.2017.2728858

Zhang, H., Albee, K., & Agrawal, S. K. (2018). A spring-loaded compliant neck brace with

adjustable supports. *Mechanism and Machine Theory, 125*, 34-44.