Final Report: Lower Extremity Loading Device During Magnetic Resonance Imaging

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BME 301: Section 302

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Abstract:

Hamstring strains injuries (HSIs) are one of the most common injuries in sports, exercise, and recreational activities. The client, Dr. Scott Crawford is currently conducting research into deciphering differences in neuromuscular control between individuals with and without hamstring strain injuries with the broader purpose of developing a more targeted physical rehabilitation strategy for HSIs. Within this research goal, we have been tasked with developing a lower extremity hamstring loading device that is MRI compatible that would enable a user to perform isometric movements while laying in a supine position. This device will allow for researchers to make connections between hamstring activation and the neuromuscular alterations that result in a higher risk of HSIs.

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Introduction:

Motivation:

Hamstring strains injuries (HSIs) are one of the most common injuries in sports, exercise, and recreational activities [1]. They generally occur during explosive motions, lower body weight lifting, and running, especially rapidly speeding up or slowing down [1]. Due to their high frequency of occurrence, the rehabilitation protocol for HSIs is well established and rather rudimentary. However, it is well documented that a previous HSI significantly increases the probability that the patient will experience another one, both in the same hamstring or in the other leg [1]. This trend is an indication that the current rehabilitation approach to HSIs and other musculotendinous injuries which yield similar reinjury rates may not be sufficient and thus requires amending.

Literature that has investigated HSI reinjury is currently focused on the biomechanical tissue properties of the hamstring itself [2][3]. It has been thought that reinjury risk is a result of direct tissue damage in the hamstring and the formation of scar tissue where the strain occurred [4]. Then, the reinjury risk in the other hamstring is explained by the patient compensating for a lack of strength and/or range of motion in their injured leg. While there is validity to this reasoning and ample research indicates this, recent studies are suggesting that a HSI can also affect the nervous system's control over the injured hamstring muscle and this increases future HSI risk.

The clients and their laboratory staff wish to explore this hypothesis and specifically determine if the alteration in neuronal signaling to the hamstring results from differences in central nervous system activation. The results of this study will be important in determining the full reaching effects of a HSI, and will definitely guide future research. Further, results of this study could outline specific changes to the current HSI rehabilitation protocol, preventing reinjury and increasing the ability for athletes and people to participate in their sports and recreation/exercise, respectively. In order to perform this study, a biomedical device is necessary to induce patient hamstring activation and collect biomechanical data.

Current Methods:

As this device is designed to facilitate research by the client, similar research studies and their setup are the majority of current methods. While there is extensive literature detailing recent studies conducted on soft tissue injuries, HSIs, and their rehabilitation, the use of functional magnetic resonance imaging, or fMRI, in such studies is more novel [5]. There are few studies describing methods similar to those outlined by the client, and those which are similar are recent [5].

The most similar research study that has been conducted and is detailed in literature was performed by the Emory University School of Medicine. As Figure 1 conveys, this study made use of simultaneous bilateral hamstring activation during fMRI of the brain.

Figure 1. Emory University illustration depicting their bilateral hamstring activation device and overall experimental setup with fMRI [6]. See also the motion capture optical markers and contraption to secure the upper body.

Emory used the fMRI imaging to compare brain activation during induced hamstring activation of patients who have suffered a hamstring strain injuries to healthy patients [6]. A detail in Figure 1 on the hypothetical patient's legs are passive optical markers for motion capture. Emory describes using a 12-camera array for motion capture in order to collect kinematic data on the patient's knee flexion angle, among other biomechanical data [6]. This kinematic data is then useful in observing how brain activation varies over the cyclic motion,

which is described by knee flexion angle data over time. As the Design Specifications section will discuss in detail, these features are key specifications for this design as well. In fact, client Dr. Scott Crawford referenced this study by Emory University as much of the basis for his design of experiment. Lastly, Figure 1 shows a design component for securing the upper body and stabilizing the head during imaging. Magnetic resonance, including fMRI, is susceptible to motion and this can negatively affect the quality of the imaging data as discussed in the Functional MRI section of the Background [6][7].

In order to induce hamstring activation for their study, Emory used the device as depicted in the SOLIDWORKS schematic in Figure 2 below. This device had patients perform a heel slide in order to activate their hamstring. The motion of a heel slide is effective at activating the hamstring and was considered as a preliminary design, as the Mechanical Preliminary Designs section and Proposed Final Design section outlines. Where Emory's design differs from this semester's design and experimental setup is that this design uses elastic bands to apply resistance to the hamstring, whereas this project requires a constant tension be applied.

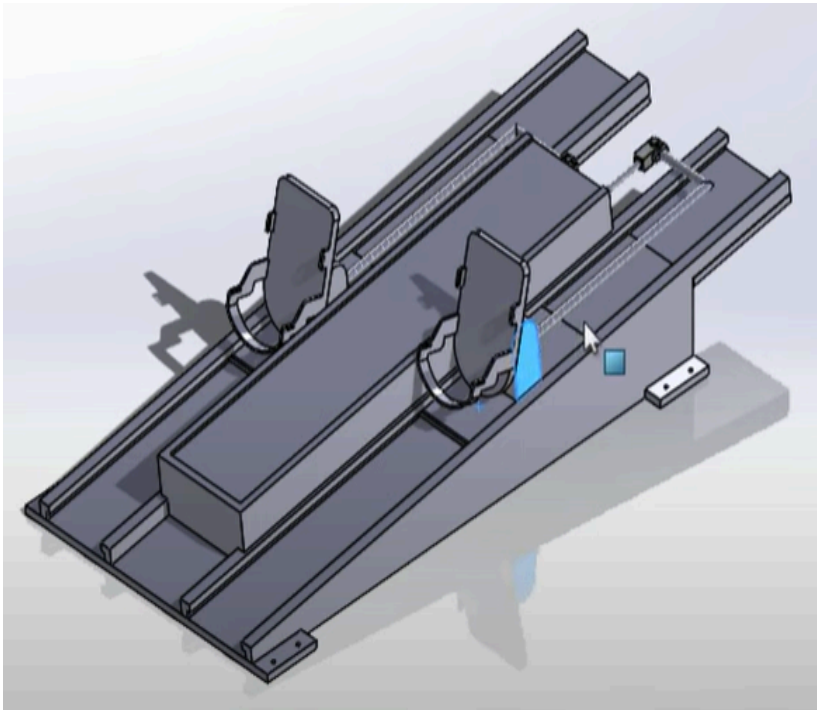


Figure 2. SOLIDWORKS schematic of the hamstring activation device used in the Emory study [6].

During a cyclic heel slide, there is an eccentric contraction phase as the patient moves their heel away from their body which activates the hamstring, but can also co-activate the quadriceps. Then, there is a concentric contraction phase as the patient moves their heel towards their body, thus activating the hamstring. As seen in Figure 2, the interface between the device and the patient occurs at the foot. Here, the design envelops the patient's heel and there appears to be a loop on each side of the foot for a strap. This strap secures the patient's foot during the motion [6]. Holes extending to the side on the bottom of the device indicate that it was screwed into the MRI table. A key feature of the device is that the tracks for the heel slide are inclined, and it is stated that this was an effort to increase the overall length of the heel slide in order to accommodate patients over the height of 72 inches of 6 feet [6].

Aside from the device that Emory used in their study which did not provide constant resistance, there is a commercially available product that does provide constant resistance. The Marsh-Bellofram Rolling Diaphragm as modeled in Figure 3 is used in providing constant, measurable force to a muscle [8]. This device is a pneumatic pressure vessel, meaning that it contains compressed air within a sealed volume. As a pneumatic mechanism, the resistance it applies is in the form of a reactionary force due to the attempted compression of the air inside the sealed volume. In order to provide constant resistance, the pressure is maintained constant within the rolling diaphragm. This constant pressure is achieved by a variable volume that changes directly with the piston compression/decompression [8]. While this device would effectively address the need for constant resistance applied to the patient's hamstring, it is not MR compatible as discussed in the Background section.

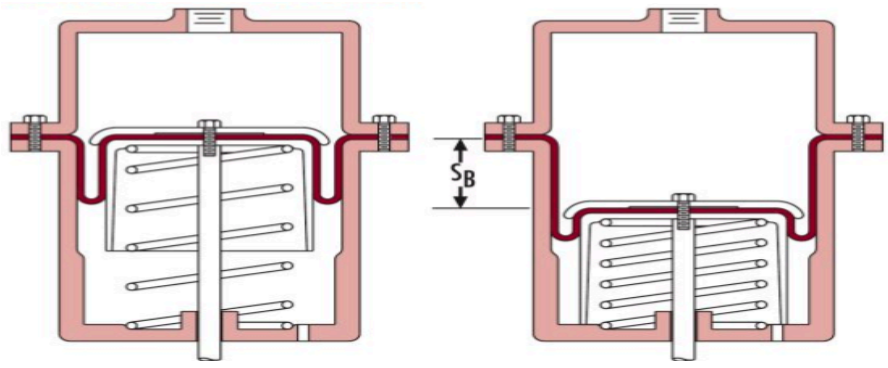


Figure 3. Marsh-Bellofram Rolling Diaphragm pneumatic pressure vessel design with the piston compressed (left) and decompressed (right) [8].

Problem Statement:

Hamstring strain injuries (HSIs) are the most common musculoskeletal injuries experienced in many sports and recreational activities [9]. Prior HSIs have been shown to significantly increase patients' risk for additional injury, due in part to neuromuscular alterations [9]. In order to research this phenomena and supplement the current rehabilitation process for HSIs in order to mitigate reinjury risk, a biomedical device is required. This device must be compatible with magnetic resonance imaging (MRI) and mechanically induce hamstring activation on a patient in the supine position in the MRI machine. The device will then collect knee flexion and resistance data that can be observed with the MR imaging.

Background:

Hamstring Anatomy:

As described in the Introduction section, the biomedical device will facilitate the client's research by causing hamstring activation. The hamstring is a major group of muscles in the upper leg which allow for knee flexion, as well as hip extension, which are demonstrated in Figure 4 [10]. These anatomical motions are important in walking and running, and hamstring activation is necessary for most lower body activities including squatting, climbing stairs, and weight lifting.

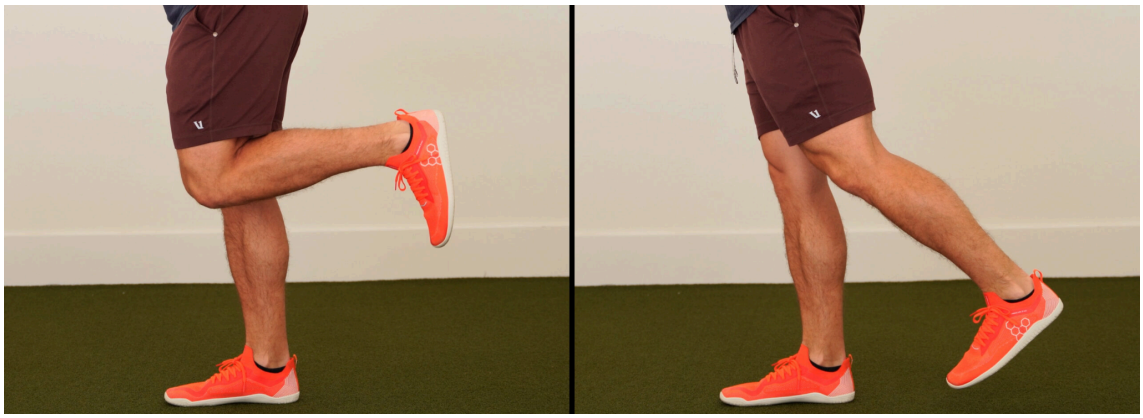


Figure 4. Demonstration of knee flexion (left) and hip extension (right) by the subjects left leg in the foreground [11].

The hamstring is commonly thought of as a singular muscle; however, it is composed of three distinct anatomical muscles which are the biceps femoris, semitendinosus, and semimembranosus which are illustrated in Figure 5 below. Each of the muscles within the hamstring are skeletal muscles, meaning they are composed of skeletal muscle tissue and require voluntary activation. The activation of the hamstring will be discussed in greater detail on page 10 in the Background section. For the purpose of the client's research study, the biceps femoris is prioritized because his experience in kinesiology has yielded that this hamstring muscle is most prone to HSIs and thus a majority of patients will encounter injury to this muscle.

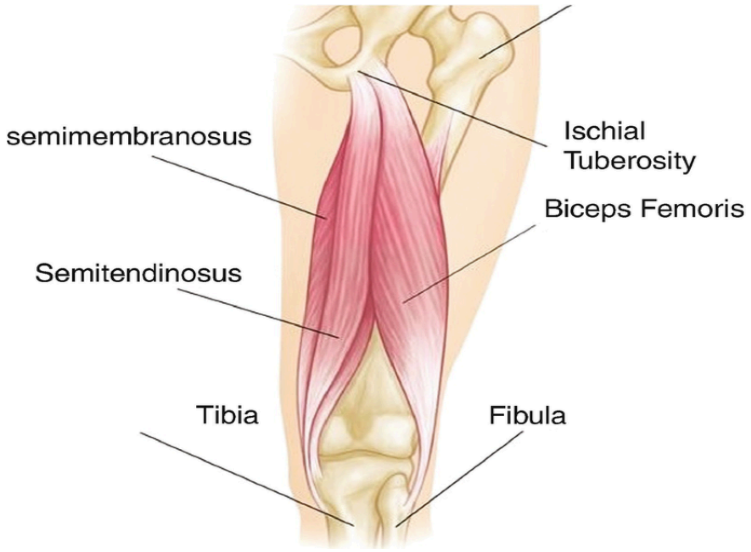


Figure 5. Diagram of the hamstring anatomy highlighting the three distinct muscles and their origin/insertion [12].

As shown in Figure 5, the biceps femoris is the most lateral hamstring muscle and approximately the largest by volume. The term 'lateral' is the anatomical direction meaning away from the midline of the body in the frontal plane. Opposite of lateral is medial, which is towards the midline of the body in the frontal plane. Other pertinent anatomical directions in describing the hamstring are posterior, meaning back or behind; proximal, meaning towards the origination of the structure; and distal, meaning away from the origination of the structure. For example, the hamstring is considered as a posterior leg muscle since it is in the back of the leg posterior to the femur.

The biceps femoris is made up of the two following parts: a long head and a short head. For kinesiology and exercise physiology purposes, the client generally focuses on the biceps femoris long head (BFLh). However, both parts are important for overall muscle functioning and are rather similar in that they both flex the knee and laterally rotate the lower leg [13]. The long head is responsible for hip extension and lateral rotation of the upper leg as well [13].

The long head and short head of the biceps femoris share insertion points, which can be thought of as where the distal part of the muscle attaches to the bone. Muscles attach to bone through stiff, collagen rich connective tissue structures called tendons. Specifically, tendons are made up of 70-80% Type I collagen by mass, proteoglycans to provide compressive strength, and glycoproteins elastin and fibronectin, which are common in the extracellular matrix [14]. The insertion point of the biceps femoris is on the lateral aspect of the fibular head, which is on the outside of the lower leg [14]. The biceps femoris tendon can be felt when flexing the knee behind the knee joint on the lateral side, and its insertion is approximately 50 mm from the axis of rotation of the knee. This value was determined on a 2 m tall male, and likely varies significantly for people of different heights, ages, and demographics. According to literature on lower leg and hamstring insertion anatomical values, the average insertion angle of the knee flexor tendon is 20.3° at an insertion distance from the tibial plateau of 41 mm and a tibial shaft length of 39.65 cm [15][16].

In order to contract the biceps femoris, voluntary activation is required as mentioned above. Throughout this report, use of the hamstring is broadly referred to as activation. The term ‘activation’ generally refers to contraction of the muscle, whether concentrically, eccentricity, or isometrically. Concentric contraction occurs during muscle shortening, eccentric contraction occurs during muscle lengthening, and isometric contraction occurs when the muscle length is held constant. Concentric contraction generally occurs when the force generated by the muscle exceeds that of the force acting on the muscle, and eccentric contraction occurs when the force applied on the muscle exceeds that of the force the muscle can generate.

Skeletal Muscle Physiology:

Muscles are able to generate the force required to produce a moment about the proximal joint (see Biophysics section of the Background below) and do work on a body segment due to their structure and physiology. Skeletal muscles are made up of thousands of individual muscle

fibers that are bound together by connective tissue into a structure called a fascicle [17]. Within muscle fibers are myofibrils, which contain parallel filaments of actin and myosin proteins. The ATP-mediated interaction between actin and myosin is known as the cross bridge cycle and allows a muscle to contract, thus applying a force to the bone it attaches to. The cross bridge cycle is made up of four repeating steps. First, ATP-bound myosin head domains bind actin, causing the release of an inorganic phosphate. Then, the myosin head domains bend, pulling the actin filament parallel to the myosin filament and causing the dissociation of ADP [18]. ATP binds to the myosin heads, severing the connection between actin and myosin, thus relaxing the muscle. The myosin heads hydrolyze the ATP and bend back to their original position with the energy released [16]. The net result of this process occurring between every actin and myosin filament within the tissue of the muscle allows for hundreds of Newtons to be generated.

The signal which allows myosin heads to bind to actin filaments and thus induce muscle contraction is from the motor neuron ending. Excitatory signals required to activate a muscle originate in the brain and propagate down a motor neuron, shown in pink in Figure 6 below, through the central nervous system.

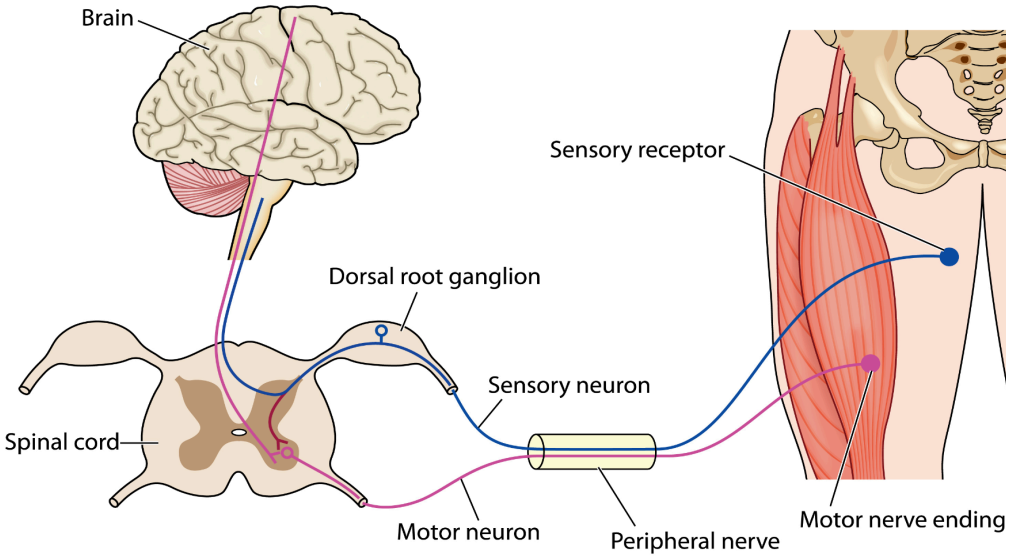


Figure 6. Diagram of how the nervous system propagates a signal to activate skeletal muscle [19].

Motor neurons exit the spinal cord where they become part of the peripheral nervous system and end within their affiliated muscle [19]. When the excitatory signal reaches the motor neuron ending, Ca^{2+} ions are released on the actin filaments, allowing myosin binding. As described, this myosin binding can then generate force.

Biomechanical Definitions:

Muscles are able to generate force through what can be modeled as a sum of moments diagram as exemplified in Equation 2 and Equation 3 below.

Equation 1. Equation for a moment M about an axis, where F_{app} is the force applied and r is the distance from the force to the axis.

$$\sum M_E = M_{Fb} + M_{wa} + M_{wb}$$

Equation 2. Sum of moments equation describing the net moment about the elbow in Figure 7 and 8 below..

$$\sum M_E = F_b(r_1) + w_a(r_2) + w_b(r_3)$$

Equation 3. Substituting Equation 1 into Equation 2 to obtain the full sum of moments equation describing the net moment about the elbow in Figure 6.

$$M = F_{app} * r$$

Since the insertion point of a muscle is not at the axis of rotation of the body segment, the shortening of length of the muscle applies a moment about the axis of rotation. This way, the muscle is able to induce movement of the segment via its tendinous connection to the bone and perform work. However, a force applied to the distal end of a body segment (w_b in Figure 7 and 8 below) also applies a moment about the axis of rotation.

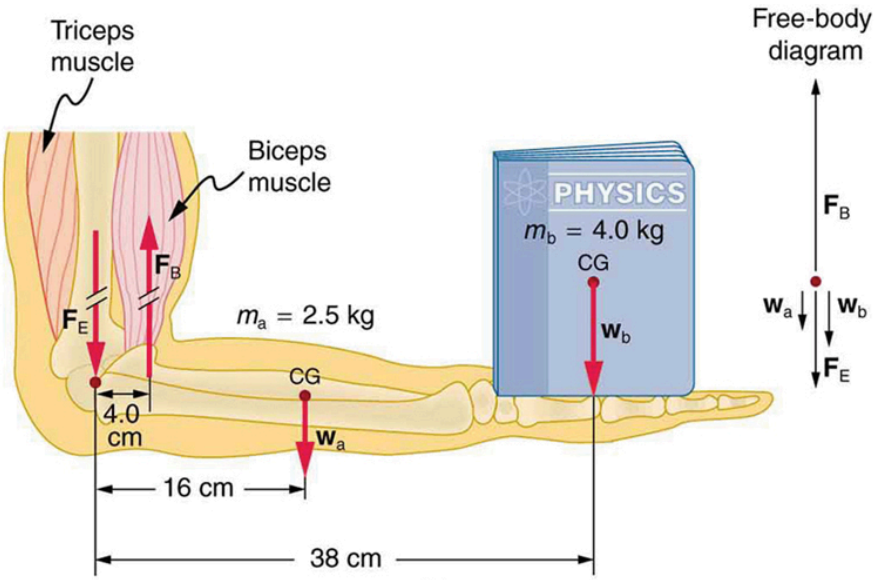


Figure 7. Free body diagram of the force considerations of a distally applied force, weight of the body segment, and force generated by the muscle [20].

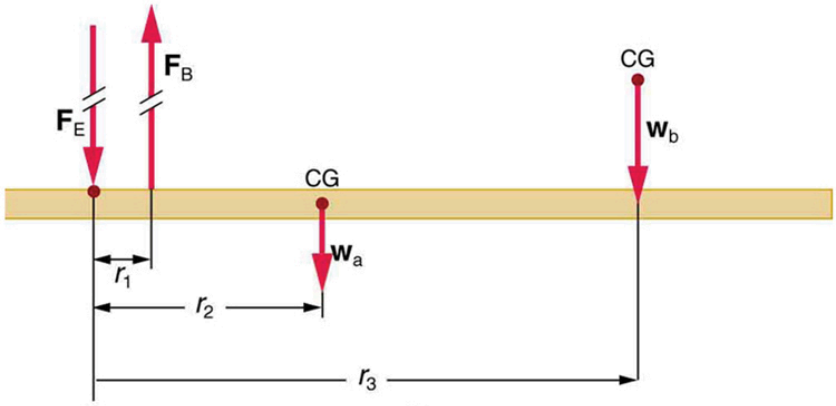


Figure 8. Simplified free body diagram from Figure 6 highlighting the moments applied about the axis of rotation [20].

Since the distance between the applied force and the axis of rotation is longer than the distance between the force generated by the muscle and the axis of rotation, the muscle must generate much more force than that of what is applied externally to the segment. This has an application to the design of the device, as it serves as a method for amplifying the weight provided by the device. In this way, less weight can be used in the design making for a more portable and compact device.

Functional MRI:

Figure 9. Image of an fMRI machine for brain imaging and how the patient is positioned during the imaging.

Dr. Crawford and his laboratory staff have a hypothesis that hamstring strain injuries can affect this process of excitatory signaling to activate the hamstring muscle, thus increasing reinjury risk and impairing function. In order to study if this alteration in nervous system activation originates within the brain, Dr. Meyerand is leading the application of functional magnetic resonance imaging, or fMRI. fMRI is a type of MRI that takes live images of the brain and sensitively measures the changes in blood flow within the brain that indicate neural functioning of a region [7]. The imaging results are exemplified by Figure 10, where hotspots of activity appear.

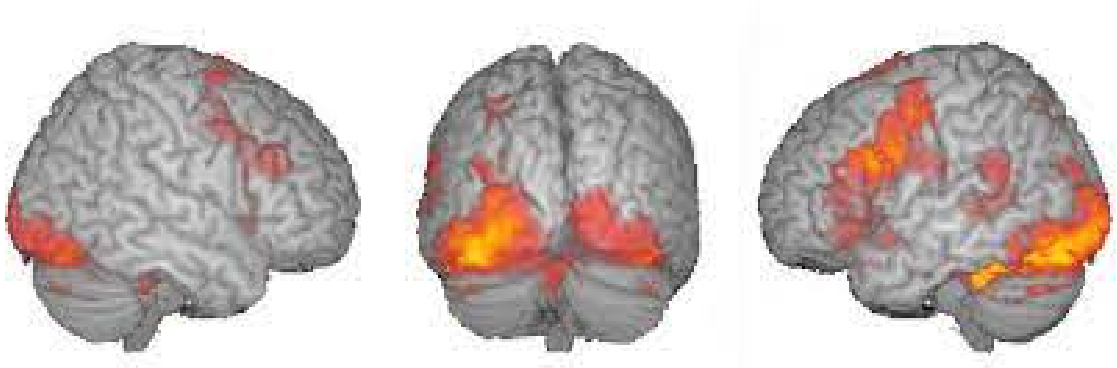


Figure 10. Brain fMRI showing neuronal activation [7].

For fMRI to produce quality images, the patient's upper body, especially head, must be completely still. If there is head movement even down to the millimeter scale, the result is what's called 'artifact of motion' or 'motion artifacts' and are shown in Figure 11 [21]. Artifacts occur when there is a low signal to noise ratio, usually meaning that there is simply increased noise in the imaging data. This can distort or blur images and generally leads to spatial errors and MRI misinterpretation.

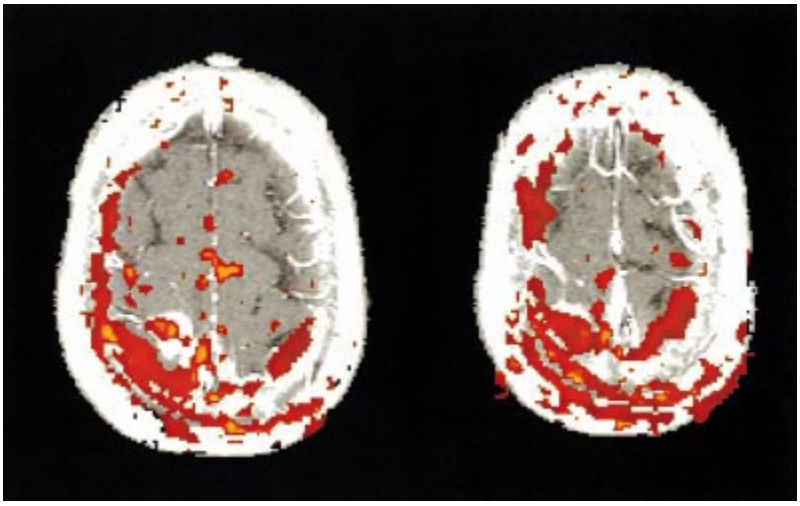


Figure 11. Severe motion artifact from patient movement during an fMRI [21].

Research Required to Design and Build Prototype

In order to consider all potential design options for this device and fabricate a prototype, the design team needs to determine what materials are feasible for the design. Initial material options will be reusable to allow for repeated patient testing, so one major component of this process is the cleaning of materials. The components of the design that come into contact with the patient are most notably the mechanism that secures the heel and foot. However, the patient's leg may come into contact with the body of the device, and the MR operator and/or researcher must adjust and position the device on the MRI table. Therefore, the presence of contaminants is likely. For the use of this device, sterilization is not necessary and general sanitizing or cleaning will suffice. Therefore, the materials' interactions with antimicrobial products must be known.

An additional material consideration that is imperative to the use and safety of the design is how the material interacts with the magnetic fields produced by MRI machines. ASTM International F2503 and IEC 60601-1-2 are standards for fabricating devices that are safe and

compatible in magnetic resonance environments or more broadly in the emission of electromagnetic disturbances [22][23]. ASTM F2503 categorizes devices into MR Safe, MR Conditional, MR Unsafe and when developing the hamstring loading device, it will be essential for us to refer to the set of guidelines for this categorization to ensure the device does not negatively interfere with the MRI readings or the patient's safety.

To ensure the device abides by experimental and laboratory standards, research was conducted surrounding the standards and specifications involved in the formulated design. This device must comply with National Safety Standard IEC 61010-031 Ed. 20 b: 2015, which specifies specific safety standards that electrical devices must follow in order to be utilized. Under IEC 61010-031, the device should be able to be utilized without risk of general mechanical hazards and excessive temperature hazards [24]. Certain materials have been observed to heat as a result of interaction with the magnetic and radiofrequency fields from the magnet used in MRI [25].

Client Information:

The clients for this design project are Dr. Scott Crawford and Dr. Beth Meyerand. Dr. Crawford is an assistant professor at UW-Madison in the kinesiology department. His research is focused on the effects of musculotendinous injury and how this relates to the rehabilitation process [26]. Dr. Beth Meyerand is a professor at UW-Madison in the medical physics and biomedical engineering departments. Her research pertains to the development and application of MRI technology. She has done research on neurological diseases such as epilepsy using magnetic resonance, and her lab currently is using MRI to track in vivo stem cells [27].

Design Specifications:

Preliminary Design Specifications (Appendix E) were formulated at the beginning of the project to lay out the pertinent criteria/constraints for the project. The device should be designed to activate the hamstrings (concentrically, eccentrically, isometrically) at around 20-30% of the maximum which correlates to an average of around 110.55 N [28]. This indicates that the device created should be able to withstand this amount of force on a regular basis during usage. Furthermore, while the device activates the hamstring, constant tension should be maintained throughout. The second major component is the ability of the device to be used within an MR

environment. Therefore, the device should be unaffected by the magnetic fields (static, radiofrequency and gradient) that are emitted by the MRI [29]. This indicates that no part of the device can be made of ferrous metals or other non-compatible materials [30]. Finally, in terms of size, the device must adhere to the standard width of MR tables (31 ⅞ in.) as well as be easily moved in and out of the MR room (less than 22.7 kg) [31].

Resistance Preliminary Designs:

Once the criteria for the device had been determined, the next step was to work on brainstorming distinct ideas for the resistance portion of the design. Ultimately, the three designs detailed in the sections below were taken into consideration in relation to the final prototype.

Resistance Design 1: Cable Stack

The first design (seen in Figure 12) that was developed is a design representative of cable systems within gym machines. This design would consist of a stack of weights, a pulley system and supports that hold the section of the device together. The pulley system would be activated by the movement of the subject, causing the weights to be lifted. As the weights are lifted, the hamstrings of the subject would be activated at a constant weight. This design presents a viable solution as it does allow for constant tension to be established. However, it also presents challenges in terms of the size of the design as well as finding ways of fabricating a similar design with all non-ferrous materials.

Figure 12. Representation of the cable stack design. Important features of the design include the pulley system to move the weights as well as the supports [32].

Resistance Design 2: Friction

The second design (seen in Figure 13) is the use of friction within the device in order to create resistance. This particular method of resistance would only apply to the Slider Design (Mechanical Design 1). This design would rely on the components of the design to create friction, which would then create the resistance desired of the device. This design provides excellent ease of fabrication but it may be challenging to determine if constant tension is achieved due to the complexity of calculations involved.

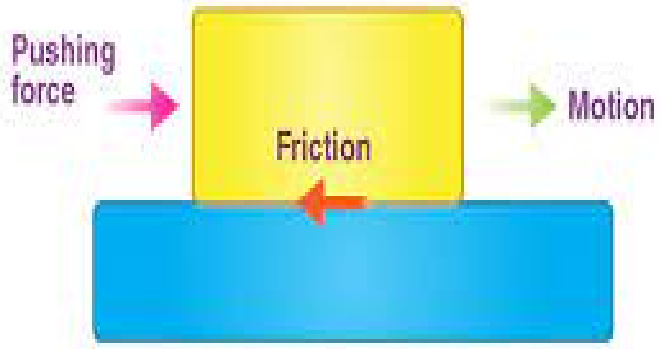


Figure 13. Representation of the friction design as a method of motion resistance [33]

Resistance 3: Elastic Bands

The third design relies upon elastic bands that are commonly used in exercise. These elastic bands would be connected to the device using the handles and would stretch as the subject utilizes the device. The stretching of the bands would then activate the subject's hamstrings in the direction desired, and return to a resting state when the movement is complete. The elastic bands also provide ease of fabrication as well as ease of use. However, they do not provide constant tension which, as shown in the Design Matrices below, was a major piece of criteria that was considered with respect to each design.

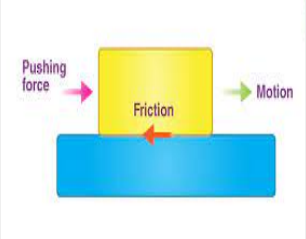
Figure 14. Representation of the elastic band design. Important features of this design include the handles which will attach the band to the device [34].

Resistance Design Evaluation:

When evaluating the resistance designs, important criteria was determined, as well as the weight each criterion would hold in. These criteria included hamstring activation, adjustability, size, ease of use, fabrication ability and safety which are thoroughly discussed and reasoned below.

Resistance Design Matrix

Table 1. Resistance design matrix comparing resistance designs to design criteria

Design Categories (Weight)	**Cable Stack** 		**Friction** 		**Elastic Band** 	
Hamstring activation (30)	5/5	30	2/5	12	0/5	0
Adjustability (20)	5/5	20	3/5	12	1/5	4
Size (15)	2/5	6	3/5	9	5/5	15
Ease of Use (15)	5/5	15	2/5	6	3/5	9
Fabrication Ability (10)	4/5	8	1/5	2	3/5	6
Safety (10)	3/5	6	4/5	8	4/5	8
Total (100)	**85**		**49**		**42**	

Resistance Design Category Descriptions:

Hamstring Activation:

The hamstring activation criteria for evaluating the preliminary designs is targeted at assessing the design's ability to address the crucial client requirements around hamstring activation and resistance. For the Resistance Design Matrix (Table 1), hamstring activation measures the designs' ability to provide constant resistance in order to induce hamstring activation, as well as the recording of resistance data. Constant tension is an emphasis of the client requirements and the method of providing resistance should reflect this. Similarly, for data

collection it is necessary to be able to record the force that is being applied to the hamstring. Since hamstring activation, constant resistance, and data collection is imperative to device functioning and the clients' research, the hamstring activation design category was weighted the highest at 30 in both matrices.

Adjustability:

The adjustability criteria refers to the designs' ability to conform to different patients that may use the device. This includes many factors, but specifically focuses on the device being compatible with different heights and strengths. For the Resistance Design Matrix (Table 1), adjustability focuses on the strength of the patient's hamstring. The component of the design responsible for providing resistance to activate the hamstring must do so with a force that is 20% -30% of the patient's maximum effort, and evidently this will vary significantly among people. Therefore, the resistance design must be easy to modulate the force it exerts. Since the overall functioning of the device is closely related to its ability to adjust to patient's of different heights/strengths, adjustability was weighted highly at 25.

Size:

As a result of the device being used in conjunction with an MRI machine, it is confined to only occupy the MR table and the space adjacent to it. The larger the design both in volume and mass, the more difficult it is for MR staff and researchers to work, as well as move the device. As a result of this, the Resistance Designs shown in Table 1 should be as compact and lightweight as possible. Size was weighted moderately high as this criteria is integral to the usability of the device, but less so than function and adjustability.

Ease of Use:

Since the device requires relocation, setup, and adjustment, as well as general use by the patient, researcher, and possibly MR staff, the ability of the device to be easily used in these operations is significant. Designs that are difficult to use would not be favorable by the mentioned parties and thus are less likely to be implemented. This criteria was weighted at 15, which is behind hamstring activation and adjustability. The reasoning for this is that hamstring activation is the core purpose of the device and ease of use does not matter if the device can't

effectively activate patients' hamstrings. Since adjustability is tied into the correct level of activation and knee flexion angle, this criteria was also above ease of use.

Fabrication Ability:

In order to realistically design and fabricate the device in the allotted semester, it is important that the designs are evaluated for ease of fabrication. This criteria accounts for the ability of the team to produce the design, the fabrication techniques necessary, and the availability of the materials that will be incorporated into the designs. In addition, this category also includes the overall cost of the design, specifically the cost of the fabrication techniques and materials as mentioned. A unique consideration for ease of fabrication and materials is the ability to use all non ferrous components in the design. This is applicable to the Resistance Designs shown in Table 1. Since these designs are intended to outline a research device, cost should be minimized without sacrificing quality. In addition, fabrication must be able to be completed within a semester as mentioned. Therefore, the fabrication ability criteria was weighted moderately at 15.

Safety:

An important consideration in any design, safety takes into account any risks posed to patient, researcher, or MR operator. For the Resistance Designs shown in Table 1, each design is already made with MR compatibility and non ferrous materials taken into consideration. As a result, the safety category does not address this potential risk because a design will not work in any way if it uses ferrous materials and thus has already been eliminated. Therefore, safety simply looks at other risks in operating each design. Since there are few remaining significant safety risks, this criteria was weighted rather low at 10.

Resistance Design Matrix Discussion

The cable stack design performed the best in hamstring activation for a couple of reasons. Most importantly, the cable stack design is the only one of the three designs that is able to maintain constant tension, an important requirement desired by the client. Additionally, the cable stack design will allow for accurate calculations to be made using free body diagrams and force

analyses to ensure the resistance provided by the design is as accurate as possible to the intended resistance.

In the adjustability portion of the matrix the cable stack predictably won, as the design would have a pin that would allow for the user to adjust the amount of weights/resistance the device was offering. The friction design would have little adjustability as it would be based on the resistance created by motion. Finally, the elastic bands would be very hard to adjust as the bands are set at an exact weight.

The elastic bands and friction performed similarly in size, as neither particularly affects the size of the device being fabricated, they are just added on. However, the cable stack introduces a significant addition in terms of size to the device. This would be paired with an increase in the amount of weight that has to be transferred in and out of the MR room which in turn makes it harder for the device to be used in a research setting.

The cable design also performed the best in the ease of use and fabrication ability aspects of the design matrix. This is due mostly to team as well as user familiarity with a similar design, as this design is comparable to cable machines in the gym. The friction and elastic band designs, however, would introduce new challenges in relation to both categories. Specifically, there would be more steps involved with the use of the machine in that it may be required to be set up in a particular way.

Finally, in terms of safety, the only concern is the dropping of weights that occurs as a result of the pulley system in the cable stack design. However, these weights will be relatively light so they should not pose too much of an issue.

Overall, due to its high performance in several of the categories presented in the design matrix, the cable stack design won by a large margin. It best met the criteria provided by the client as well as formulated by the team, and therefore will be a good fit moving forward.

Mechanical Preliminary Designs:

Following the team's careful consideration in relation to Resistance Designs, the mechanical portion of the design was now considered. Again, the design process was followed from the beginning in order to formulate a device that would serve as an effective prototype.

Mechanical Design 1: Slider

The slider design (as seen in Figure 15) is composed of a frictionless slider that will be placed parallel along the length of the MRI machine underneath a user's legs as they lay supine. The frictionless slider will range in length from the individual's heel in a full knee extension up until their gluteus maximus. Through one of the previously mentioned resistance designs, a force will be applied on the slider outwards away from the individual, and in turn as they pull the slider inwards using their heel and the bottom of their feet. The outwards force will generate a moment of knee extension and slight hip extension. This will thereby require the individual to activate their hamstrings and passively activate their rectus femoris in their quadriceps to generate an opposing moment of knee flexion and hip flexion. Due to the continuous outwards force on the slider, an individual can perform both isotonic and isometric knee flexion exercises ranging from full knee extension when the slider is farthest away, to full extension as the slider nears their gluteus maximus.

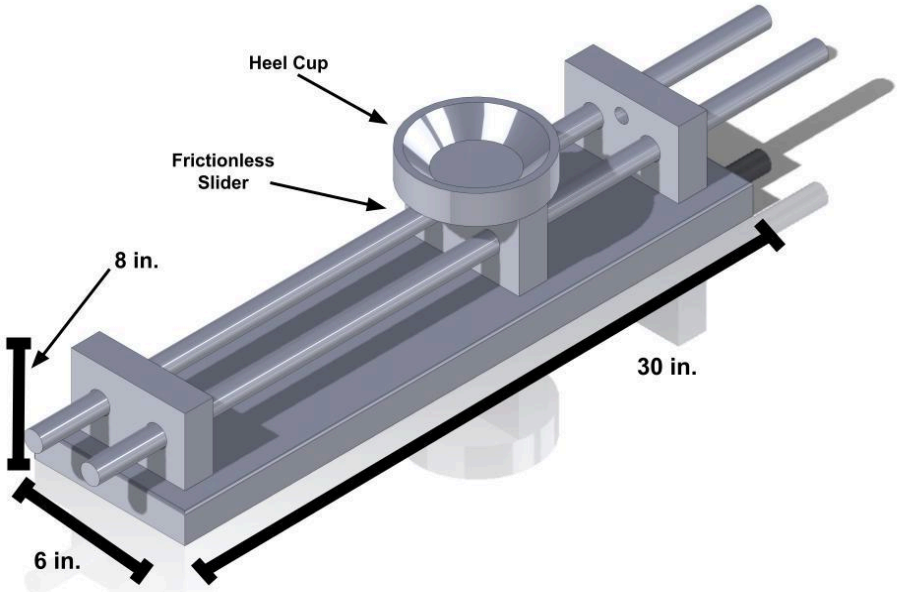


Figure 15. Slider Design. Important features of this design include the heel cup where the foot will be placed as well as the tract that this heel cup will move along during usage.

Mechanical Design 2: Bike Pedal

The bike pedal is composed of elevated bike pedals that will be mechanically supplied tension during rotation through one of the previously mentioned resistance designs. The bike pedals can be adjusted in their positioning along the length of the MRI such that the individual

only has to slightly flex their hip (<20 degrees) to pedal the bike pedals while laying in a supine position. The bike pedal will always apply an opposing force to its motion. As the individual pushes the pedal forward working to perform knee extension, the pedal will create an opposing moment of knee flexion, thereby activating their quadriceps. However, in converse, as an individual pulls the bike pedal inwards, the bike pedal will generate a moment of knee extension that will require an opposing moment of knee flexion. This will, in turn, activate the individual's hamstrings. With slight hip flexion and extension there may also be passive activation of the gluteus maximus and rectus femoris. The bike pedals can potentially be designed to have an adjustable path where an individual may have to pull or push the pedal for a longer length thereby altering the knee flexion range and total muscle contraction they perform.

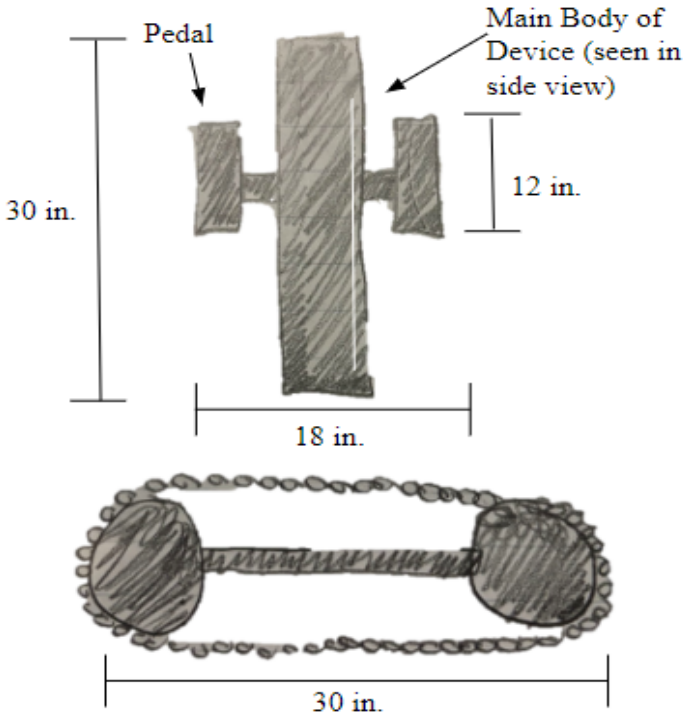


Figure 16. The bike pedal design. Important features of this design include the pedals and the system (similar to a bicycle) that allows for a cyclical motion.

Mechanical Design 3: Leg Support

In the Leg Support design an individual laying in a supine position will have their knees resting on an adjustable vertical device with the purpose of fixing their hip flexion angle and allowing the individual to perform isolated knee flexion and extension exercises. An ankle roller will extend from the vertical device to below the user's ankles. A user laying in a supine position will have to work to produce a moment of knee flexion that contracts the hamstring muscles as

they pull the leg roller inwards. This leg roller will rotate around a fixed pulley or extend an elastic band to generate an outwards opposing force. Regardless of the position of the ankle roller, the force will always be outwards thereby allowing activation of the hamstrings in both isotonic and isometric movements. Although there is adjustability in the vertical device that can be altered to adjust the knee flexion range of the performed movements, full extension or flexion of the knee is impractical in the design where the individual's legs for example will need to be completely extended vertically upwards which poses clear flexibility challenges. The knee flexion range in turn will most likely fall within less than 90 degrees in this design.

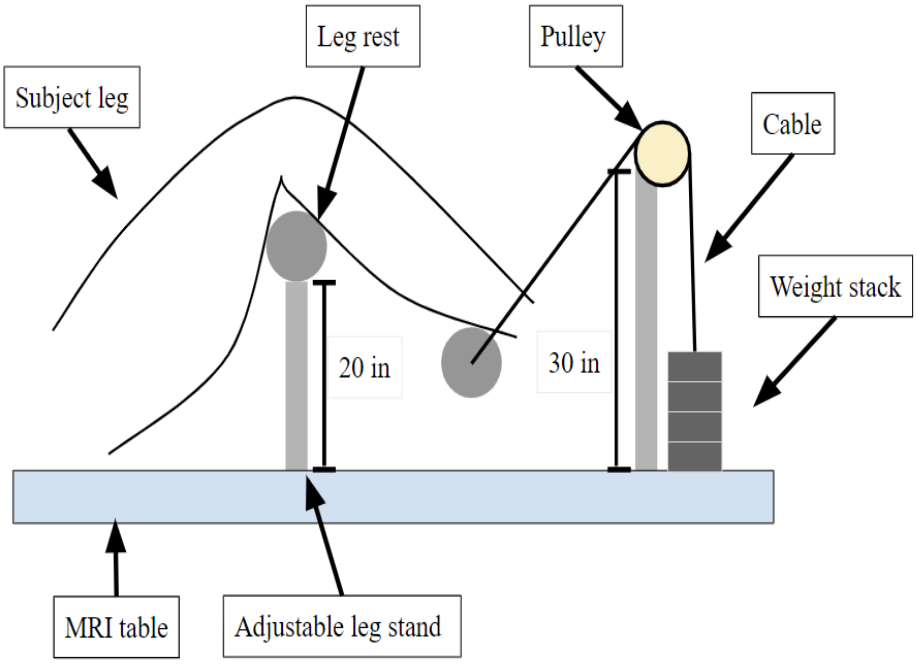


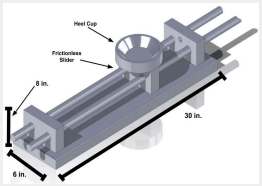
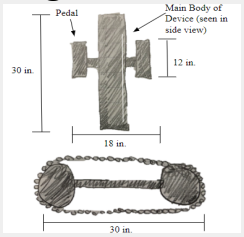
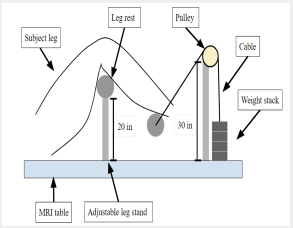
Figure 17. Leg Support Design. Important features of this design include the pulley system distributing forces and the ankle roller that allows for activation of the hamstring.

Mechanical Design Evaluation:

The design categories are identical for both the resistance and mechanical design matrices. However, there are subtle differences in the specific meaning and context of some criteria, as is explained in the Mechanical Design Category Descriptions below.

Mechanical Design Matrix

Table 2. Mechanical design matrix comparing mechanical designs to design criteria

Design Categories (Weight)	**Slider Design** 		**Bike Pedal Design** 		**Leg Support Design** 	
Hamstring activation (30)	5/5	30	3/5	18	4/5	24
Adjustability (20)	4/5	16	2/5	8	5/5	20
Size (15)	4/5	12	3/5	9	3/5	9
Ease of Use (15)	4/5	12	2/5	6	3/5	9
Fabrication Ability (10)	5/5	10	4/5	8	4/5	8
Safety (10)	3/5	6	2/5	4	4/5	8
Total (100)	**86**		**53**		**78**	

Mechanical Design Category Descriptions

Hamstring Activation:

The hamstring activation criteria for evaluating the preliminary designs is targeted at assessing the design's ability to address the crucial client requirements around hamstring activation and resistance. For the Mechanism Design Matrix (Table 2), hamstring activation measures the designs' ability to activate the hamstring efficiently and avoid co-activation of other muscles such as the quadriceps. This is dependent on the angle of force application and position the design places the patient's leg into. Since hamstring activation is imperative to

device functioning and the clients' research, the hamstring activation design category was weighted the highest at 30 in both matrices.

Adjustability:

The adjustability criteria refers to the designs' ability to conform to different patients that may use the device. This includes many factors, but specifically focuses on the device being compatible with different heights and strengths. For the Mechanism Design Matrix (Table 2), adjustability focuses on the height of the patient that will use the overall device. Since there is an ideal knee flexion for hamstring activation, each design must be adjustable to place the patient's leg into this position for testing regardless of the height of the patient. Since the overall functioning of the device is closely related to its ability to adjust to patient's of different heights/strengths, adjustability was weighted highly at 25.

Size:

As a result of the device being used in conjunction with an MRI machine, it is confined to only occupy the MR table and the space adjacent to it. The larger the design both in volume and mass, the more difficult it is for MR staff and researchers to work, as well as move the device. As a result of this, the Mechanism Designs shown in Table 2 should be as compact and lightweight as possible. Size was weighted moderately high as this criteria is integral to the usability of the device, but less so than function and adjustability.

Ease of Use:

Since the device requires relocation, setup, and adjustment, as well as general use by the patient, researcher, and possibly MR staff, the ability of the device to be easily used in these operations is significant. Designs that are difficult to use would not be favorable by the mentioned parties and thus are less likely to be implemented. This criteria was weighted at 15, which is behind hamstring activation and adjustability. The reasoning for this is that hamstring activation is the core purpose of the device and ease of use does not matter if the device can't effectively activate patients' hamstrings. Since adjustability is tied into the correct level of activation and knee flexion angle, this criteria was also above ease of use.

Fabrication Ability:

In order to realistically design and fabricate the device in the allotted semester, it is important that the designs are evaluated for ease of fabrication. This criteria accounts for the ability of the team to produce the design, the fabrication techniques necessary, and the availability of the materials that will be incorporated into the designs. In addition, this category also includes the overall cost of the design, specifically the cost of the fabrication techniques and materials as mentioned. A unique consideration for ease of fabrication and materials is the ability to use all non ferrous components in the design. This is applicable to the Mechanism Designs shown in Table 2. Since these designs are intended to outline a research device, cost should be minimized without sacrificing quality. In addition, fabrication must be able to be completed within a semester as mentioned. Therefore, the fabrication ability criteria was weighted moderately at 15.

Safety:

An important consideration in any design, safety takes into account any risks posed to patient, researcher, or MR operator. For the Mechanism Designs shown in Table 2, each design is already made with MR compatibility and non ferrous materials taken into consideration. As a result, the safety category does not address this potential risk because a design will not work in any way if it uses ferrous materials and thus has already been eliminated. Therefore, safety simply looks at other risks in operating each design. Since there are few remaining significant safety risks, this criteria was weighted rather low at 10.

Mechanical Design Matrix Discussion

The mechanical design that performed the best given the design criteria was the slider design for a number of principal reasons. First, although the leg support design allows for isolated knee flexion and hamstring activation the slider design maximizes hamstring muscle activation overall by enabling a user to perform the largest range of knee flexion from full leg extension to full knee flexion. There is one minor drawback in passive activation of the rectus femoris through slight hip flexion. In addition, the slider design has the highest ease of fabrication as the main design is composed of a linear frictionless slider as opposed to more complex and intricate rotational elements present in both the leg support/ankle-roller and bike

pedal design. This may be especially true due to more difficult to purchase materials or development of durable and reliable non-ferrous iterations of each design. When it comes to ease of use and size, the slider design performs best because although it makes up a portion of the length of the table, it has a low vertical height relative to the elevated bike pedals and vertical positioning stand of the leg support design. Furthermore, the additional rotational elements of the ankle roller and bike pedals create an unnecessary higher learning curve for a user to effectively activate their hamstrings when using the mechanical system.

Proposed Final Design:

The final mechanical design after evaluating the mechanical design matrix will be the slider design. The slider design will be created with a MR-compatible material (non-ferrous), HDPE (High Density poly(ethylene)), which will be the structural material. This slider design will be in combination with the cable stack design. This initial proposed resistance design will implement ceramic weights, non-ferrous pulleys made of HDPE, and a Dyneema cable.

Final Design

The final iteration of the frictionless slider system and the pulley weight stack is shown in Figures 18, 19, 20. The slider system will rest parallel along the length of the MRI table while the pulley and weight stack will be positioned on the ground at the end of the table. Specifically in operation of the slider, an individual lying supine in an MRI machine will place their heel centered in the divot of the slider bar. They will pull the slider proximally towards their glutes, activating their hamstring to produce a moment that induces knee flexion against the outwards cable force generating an opposing moment of knee extension.

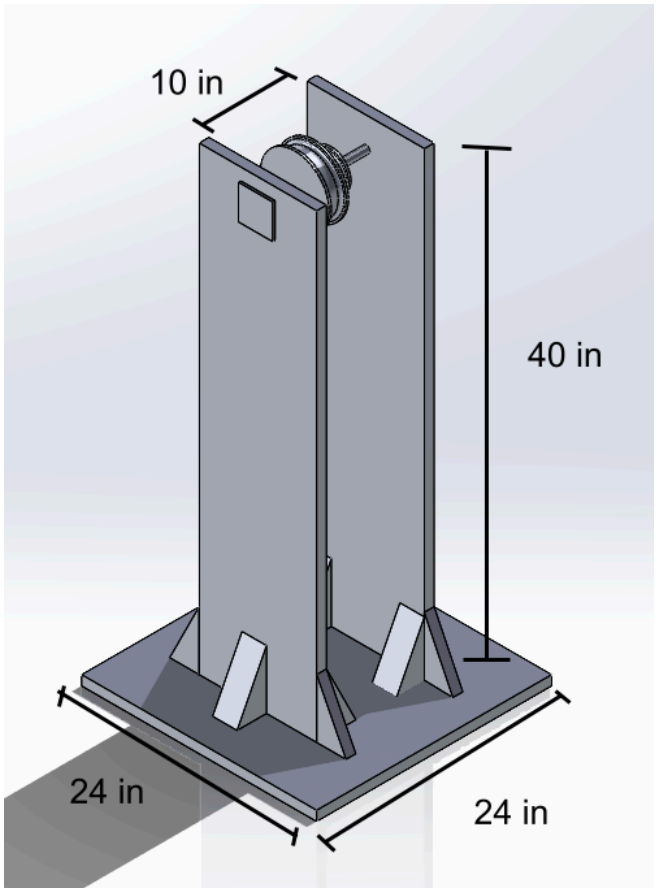


Figure 18. Final design iteration of pulley weight stack system

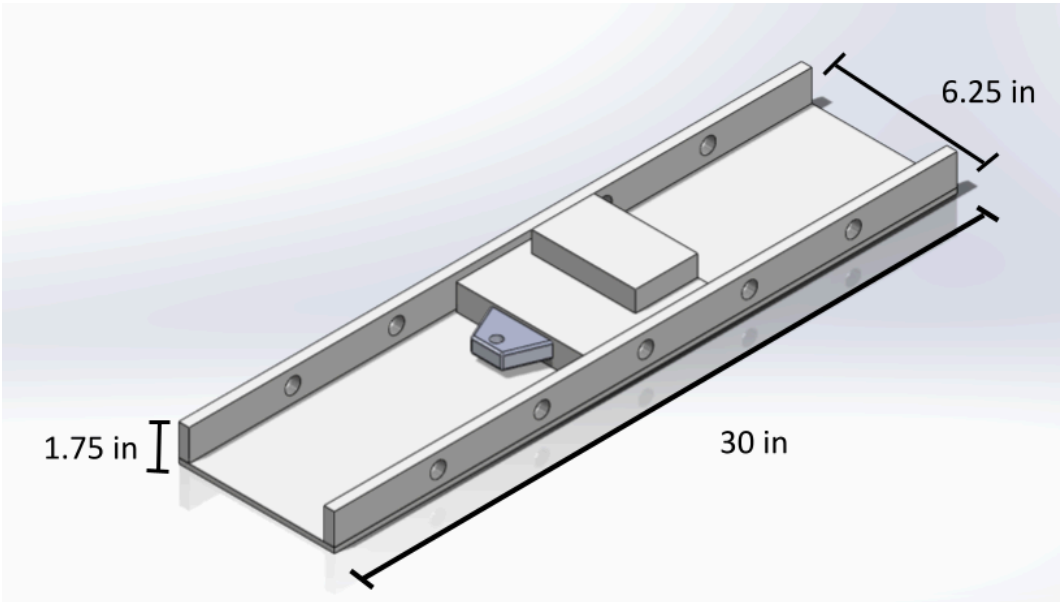


Figure 19. Final design iteration of slider system showing frictionless slider and slider heel bar

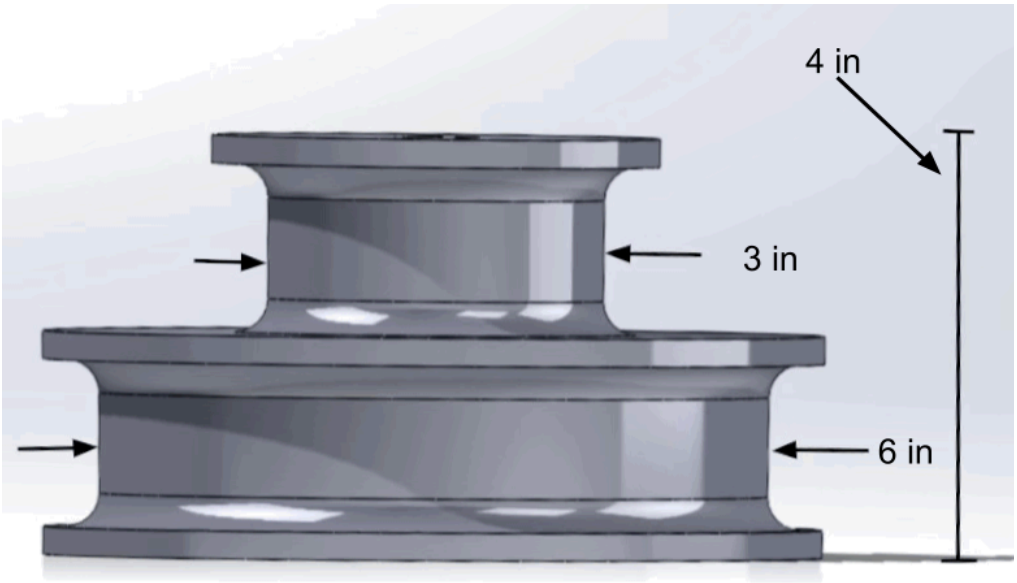


Figure 20. Final design iteration of step pulley with 2 times weight amplification

The lower theoretical force amplification is further detailed in the free body diagram shown below in Figure 21. As mentioned in the Background section, Figure 21 inherits from three notable studies on lower leg and hamstring insertion anatomical values giving an average insertion angle of the knee flexor tendon of 20.3° at an insertion distance from the tibial plateau of 41 mm and a tibial shaft length of 39.65 cm [15][16].

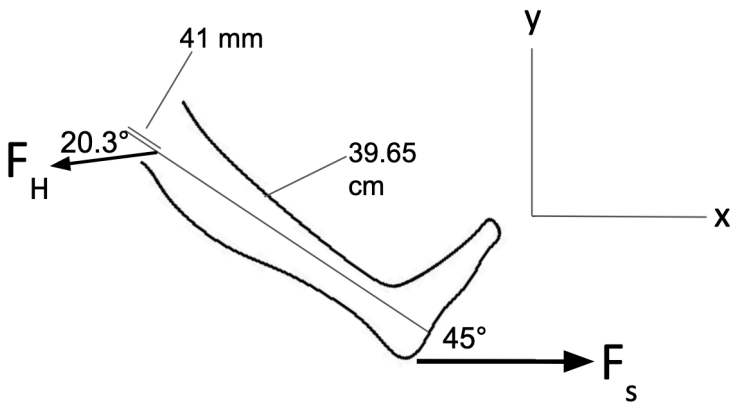


Figure 21. Side view free body diagram of lower leg in slider design context, F_H=Collective Hamstring Force, and F_s=Cable Force

Ranging from a 85° (near full extension) to a 5° (near full flexion) heel angle relative to the slider, the hamstring force will range from 2.43 to 27.8 times the cable force. Despite the

variation in hamstring activation throughout knee flexion, the client has validated that a constant cable force is suitable in alignment with the PDS criteria for constant tension.

Moreover, the pulley weight stack system will be the source of the cable load. A step pulley was designed with two different radii of a ratio of 2.0 to 1.0 thereby amplifying an attached weight by 2.0 times and minimizing the necessary weight to achieve a desired cable force. Specifically, the cable attached to the smaller radii will connect to the slider, and a weight will be hung on the cable connected to the larger pulley radii.

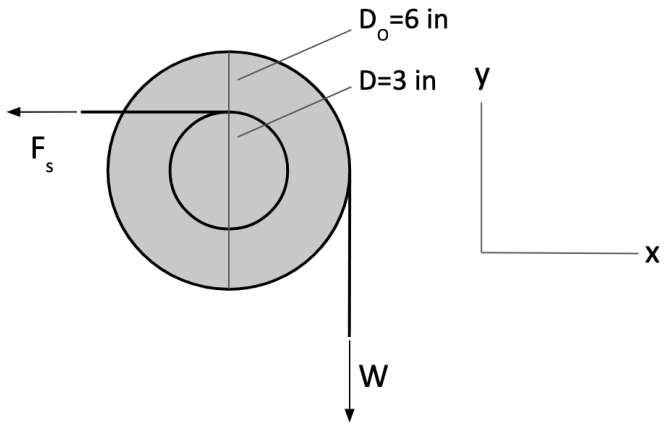


Figure 22. Side view step pulley showing radii ratio of 2.0

The pulley stands at a height that is level with that of the slider to ensure a level, 0 degree cable force on the pulley.

A shaft is used to support the pulley whose material selection is further discussed in the materials section of the fabrication and development section. There will be a press fit between the shaft and two bearings inlaid in each of the vertical posts to allow for frictionless rotation. Figure 23 shows a free body diagram of the shaft indicating the presence of bending, torsional, and transverse shear stresses throughout the shaft of which the bending stress will be the most critical at the ends of the pulley. Further calculations for a safety factor are conducted on the critical stress element for the shaft in the shaft materials selection process described in the fabrication and development process.

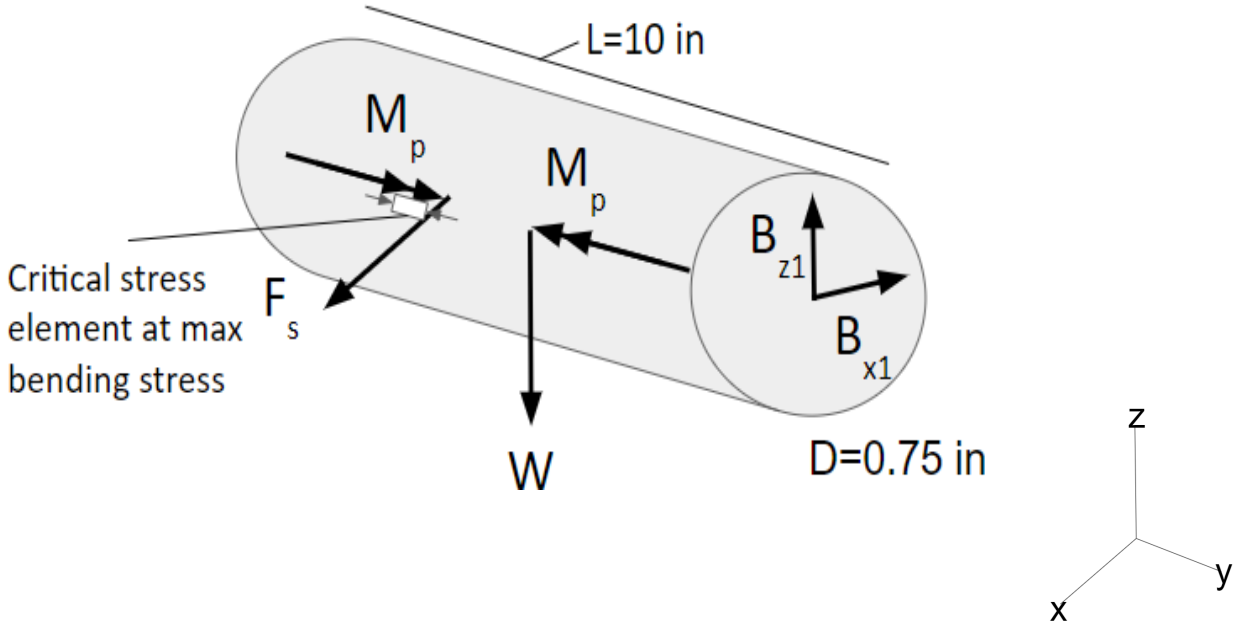


Figure 23. Free body diagram of carbon fiber shaft. F_s = Slider Cable Force, W=Attached weight force, M_p = moments due to amplified force and weight $B_{..}$ = bearing reaction force

Fabrication and Development

Materials Selection

The materials selection process was guided by a few primary criteria. First across the slider and pulley weight stack system each component had the hard constraint of being non-ferrous with a strong recommendation of also not using other metals for larger or dynamic components.

For the slider system, High Density Polyethylene (HDPE) was selected for the base sheet, rails, and slider foot bar for the slider system. Since these components were subject to distributed loads including the weight of the leg of the individual, strength was not critical. And HDPE was selected with a sufficient yield strength in the range of 20-33 MPa alongside its easy machinability and high accessibility. A hook was designed for the slider system which needed to support a potentially high load (>100 lbs), and was 3D printed at a 100% infill from polylactic acid (PLA) with a yield strength in the range of 45 to 60 MPa.

For the pulley weight stack system, HDPE was chosen for the base sheet, base supports and vertical supports where the yield strength (20-33 MPa) would be sufficient as the high load

(>100 lbs) would be distributed over larger cross sectional areas of HDPE thereby minimizing stresses. The pulley also was designed with a high cross sectional area to minimize stresses where for example the smallest radii in the pulley would have an area 22 times the cross sectional area of the shaft. In turn the pulley was 3D printed with a 100% infill to achieve a sufficient yield strength in the range of 45 to 60 MPa.

The material selection for the shaft was critical and encompassed notable criteria including ultimate tensile/compressive strength and density. Carbon fiber was selected with a tensile strength from 3500 to 5000 MPa, significantly stronger than that of HDPE, which is necessary given the need to support high bending stresses from the amplified force and weight. The density of carbon fiber ranges from 1.75 to 1.95 g/cm³, offering a specific tensile strength of about 2500 MPa · cm^3/g indicating a high strength to weight ratio that in turn satisfies the PDS criteria of each component of the design being under 50 lbs. Given a carbon fiber shaft, the safety factor relative to the critical bending stress is shown below:

Equation 4. Max bending stress equation where M is the maximum bending moment generated, y is the distance to the neutral axis, and I is the moment of inertia. Solving this equation for weight yields the value displayed below when considering a Safety Factor of 3.

$$\sigma_{max} = -My/I$$

$$w = 2449 \text{ N}, \textit{Safety Factor} = 3$$

Lastly, nylon threaded fasteners and plastic frame glass ball bearings were selected due to accessibility as non-ferrous alternatives with deliveries within 1 week from vendors including McMaster Carr and Grainger.

Fabrication Process

Once materials had been carefully considered, the next step forward was to begin fabrication. This encompassed a base sheet and side posts for the weight stack and the entire slider portion of the design. To do so appropriate measurements were taken as referenced in the procedures (Appendix B).

The first piece that was fabricated was the slider portion of the design. Once the proper materials were gathered, the team utilized fabrication resources including a bandsaw in the

TEAMLab in order to cut the side rails down to size. Next, a drill press was utilized to remove material from the side rails to allow for placement of a stopper. Once these pieces were completed, holes were threaded and tapped that allowed for the side rails to be screwed onto the pre-cut base of the slider assembly. The one challenge faced in the portion of fabrication was to determine how best to connect the side rails. Originally, the plan was to use epoxy. However, using a similar product, it was determined that it did not adhere strongly enough to the material for this particular application. Finally, a piece was 3-D printed which the Dyneema cable was tied to in order to actually operate the device.

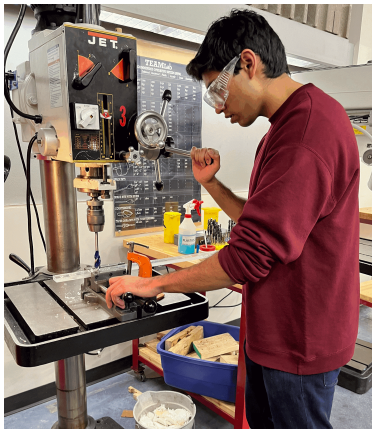


Figure 24. Use of a drill press in UW-Madison's TEAMLab to bore limiting holes for the slider side walls.

Now that the slider portion of the design was completed, it was now time to move onwards to the weight stack portion of the design. The first step was to drill the holes in the side posts in which the bearings would be set. To do so, a hole saw was used that cut a 1 ⅝ inch hole in which the bearing fit. However, initially it did not provide a compressive fit, and allowed the bearing to fall out. So, improvisation was needed, which resulted in 3D printed pieces that fit on both sides of the hole, and held the bearing in place. Then, the side posts needed to be cut down to the correct size, so as to allow the force generated by the pulley to run in a straight line "out of the foot". This provided insurance that the force recorded by researchers was correct.

Finally, was fabrication of the base of the design which included providing sufficient support for the side posts. First, a jigsaw was utilized to cut holes in the base that the side posts would be able to fit within. This process was relatively time consuming as the material for the base was extremely thick, and precise cuts were necessary. Following this, supports were cut out

of a thick piece of HDPE. Then several holes through which screws were to pass through were drilled and threaded in both the base sheet and the triangle supports. Once these were secured, the side posts were inserted to determine the amount of support provided by the initial solution.

Figure 25. Base plate screw alignment being validated

Besides the challenges aforementioned in other sections of fabrication, there were several faced in the fabrication of the base sheet. One that presented major issues, and is discussed below in further detail, was the shearing of the nylon screws in the support material. While they were able to support the weight of the posts, even a relatively small amount of force positioned just right was enough to cause shearing.

Despite the challenges faced during fabrication, a cohesive final prototype that meets a majority of the criteria asked for by the client was put together, as discussed in Testing and Results.

Testing and Results

Considerations of the design which were important to be tested were directly related to client requirements, Product Design Specifications criteria, and overall device functioning. As the Design Criteria section outlines, the device's ability to apply a constant resistance to the subject is imperative. Therefore, this was a focus of testing, along with verification of proper pulley force amplification. In order to collect quantitative data for this purpose, a spring force gauge (exemplified below in Figure 26) and standard exercise weights of 5, 10, and 15 lbs. were used.

Figure 26. Example of a spring force gauge similar to what was used for force measurement in device testing [35].

As the Final Design section describes, the amplification of the step pulley due to the difference in its radii is intended to be a factor of 2.0. Since the resistance that the device provides is equal to this amplification factor multiplied by the known standard weight, it is important that this factor is experimentally determined and is 2.0.

Using the spring force gauge represented in Figure 26 on one side of the pulley and a set of three available known weights on the other end of the pulley, this factor could be easily observed. For a detailed testing protocol, see Appendix C. At each of the three weights, force gauge readings were recorded, and the force reading was plotted against the known weight value on the other side of the pulley, resulting in Figure 27 as shown below.

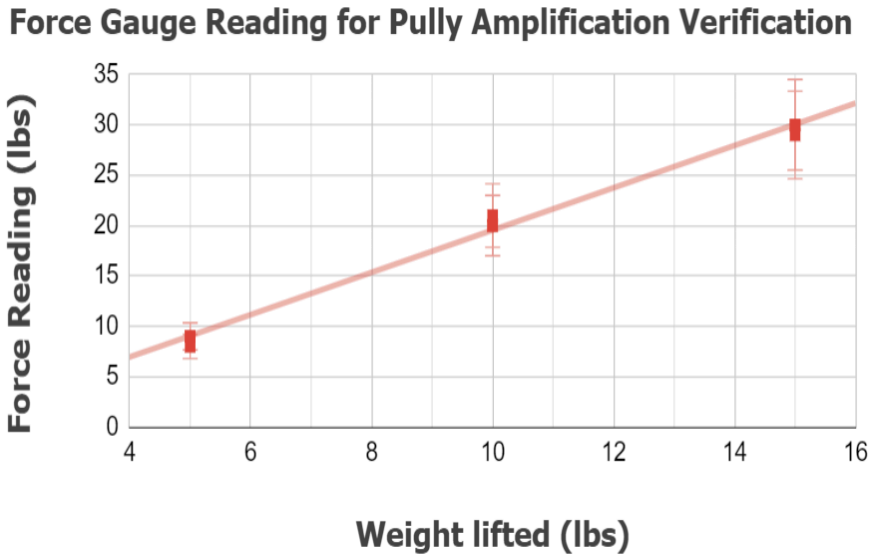


Figure 27. Google Sheets plot showing the force reading of the weight on one side of the pulley compared to the set of known weights on the other side.

Using the built in trendline function in Google Sheets which uses linear least squares regression, the statistical relationship between force reading and weight lifted could be quantitatively determined. As a result of this statistical analysis, the pulley amplification—represented as the trendline slope—was determined to be equal to 2.1 experimentally. The R^2 value, which is a measure of accuracy between the model and data, was 0.993, indicating this experimental slope fits the data very well. There is no available statistical method capable of comparing 2.1 to the intended 2.0, however a pulley amplification of 2.1 is satisfactory and very close to 2.0. The client can account for any slight discrepancy with their calculations, determining the resistance by multiplying the weight by 2.1. This is the case as long as the resistance value is constant.

Therefore, ensuring that the device provides constant resistance to the subject is not only a client requirement, but critical to the accuracy of the device and the research which it facilitates. The experimental setup for the constant tension testing was similar to that of the pulley verification testing, again using the spring force gauge on one side of the pulley and the set of weights on the other end. In order to measure the force at various points throughout the heel slide cycle, force readings were taken at three horizontal positions on the slider. The three positions were equally spaced along the slider at 0 inches, 15 inches, and 30 inches, indicated as 1, 2, and 3 respectively in Figure 28 below.

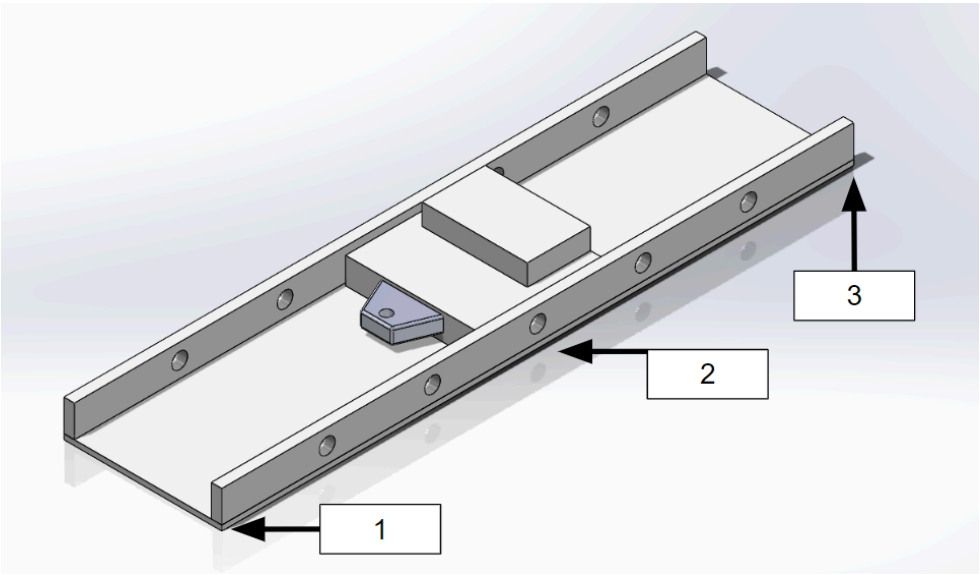


Figure 28. SOLIDWORKS sketch illustrating the slider, labeled with each of the three positions where force readings were taken in the constant tension testing.

At these three positions as shown in Figure 28 above, force readings from the spring gauge were recorded for each of the three standard weights. This force data for each weight was plotted against the position from where the measurement was taken, yielding Figure 29 below.

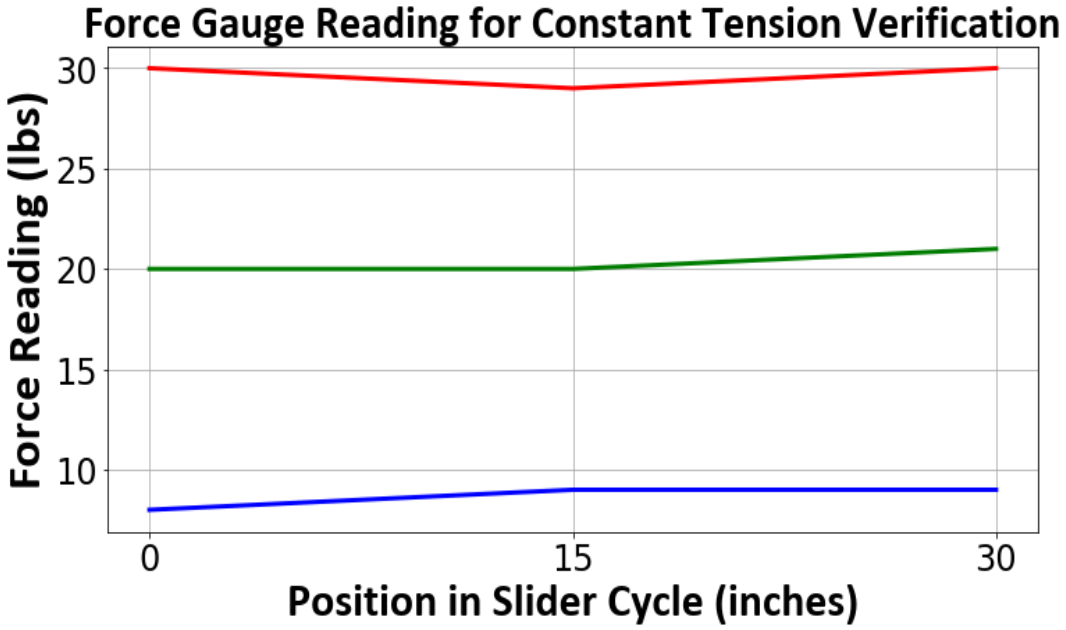


Figure 29. Python matplot library graph showing the force reading in pounds at each of the three experimental position groups for each standard weight.

Python's matplot library was used for graphing this data due to its flexibility in handling multiple groups of data, such as the three different weight values. For the purpose of statistical analysis, however, the position on the slider was considered the independent variable. In MATLAB, the data was processed and statistical analysis was performed, with the full code in Appendix D. In order to perform meaningful and accurate statistical analysis, a sample size of n=30 is typically required. For each position group, the initial data had a sample size of only n=9 (3 measurements for each weight). As a result, it was necessary to perform a bootstrap. A bootstrap is a resampling method which uses random sampling with replacement of the original data. Bootstrapping uses this to expand sample sizes, ensuring that all additional points which were generated follow the sample distributions and key aspects of the original data set. Using these additional samples, the sample size is adequate to support various statistical calculations. For this testing, the bootstrap created sample sizes of n=100 for each position group, thus allowing for accurate statistical analysis.

The optimal statistical analysis for the constant tension testing is ANOVA, which is similar to a two sided t-test in that it compares groups for statistically significant differences, but for multiple groups. Like a t-test, ANOVA produces a p-value. For the constant tension testing, the α value is 0.05 and the null hypothesis is that there is no significant difference between any of the three position groups, indicating that there is constant tension throughout the heel slide motion. The alternative hypothesis would then be that there is a significant difference in two or all of the groups. Using MATLAB code for an ANOVA test (see Appendix D), the p-value was determined to be 0.966. This p-value is high and much greater than the α value is 0.05. Therefore, the null hypothesis is upheld, indicating that the constant tension testing conclusively demonstrates that the device is capable of providing a constant resistance throughout the heel slide motion.

Lastly, it is imperative that the design has no ferrous materials which interact with the MRI machine, as well as no moving metal components which would cause artifact. This is not a concern, since the materials used include HDPE and various plastics, PLA, nylon, Dyneema, and glass. All of these materials are known to be non-ferrous and non-metallic and are from reputable vendors. However, before the device's use in the MR setting, it is required that an MRI caliper hand magnet is used to screen all materials. This has been arranged with Dr. Block of the University of Wisconsin-Madison Biomedical Engineering department and will be completed prior to use.

Discussion

The lower extremity loading device is designed for MRI compatibility and aims at providing better accuracy in the functionality of carrying out effective f-MRI testing for isolated hamstring activation. It improves existing device functionality by the way of accurate muscle activation control with precise tension. This design improvement is backed through comparison analysis with similar studies from institutions like Emory University, which, though very successful in activation of the hamstrings, failed to keep constant tension [6]. One of the high points of the device is its ability to keep constant tension throughout eccentric and concentric movements while isolating the activation of the hamstring. The device's performance was assessed through isolated position based testing, which yielded a p-value of 0.966. This value

exceeds the threshold of 0.05, thereby upholding the null hypothesis and demonstrating consistent tension maintenance throughout eccentric, concentric, and isometric motion.

Most of the devices of today have been designed such that the resistance is variable across movement, but very few to optimize MRI compatibility. This makes the frictionless slider system unique in allowing for constant tension for a given attached weight, which helps in real-time f-MRI analysis within the clients' research.

Ethical considerations have been an important aspect in the development of the device for the safety of the users and reliability of the device. Design choices were made with the idea of minimizing user risk and discomfort, particularly since patients actions will directly affect research data. Enhancements like removing sharp edges and allowing for the integration of ankle wraps or boots not only addresses subject comfort, but also allows for the adjustment needed. In terms of reliability of the device we designed this as if the weight being used would be a maximum. This ensures that the device has been fabricated for reliability and repeatability.

Material selection was crucial due to the necessity of MRI compatibility. High-density polyethylene (HDPE) was chosen for the structural components of the slider and weight stack design. In conjunction with HDPE, 3D printed polylactic acid (PLA) parts were used for the bearing fittings and pulley. The pulley was supported by a carbon fiber rod, and assembly utilized nylon fasteners. These materials were selected based on criteria outlined in the Product Design Specification (PDS), considering factors such as strength, MRI compatibility, and cost.

Another important criterion addressed in the PDS was the ability to withstand a 25 lbs. alternating load with a factor of safety of 3. Given direct subject interaction with the device, ensuring a factor of safety was paramount. This was achieved by calculating the strength of the rod required to support the pulley and determining the strength of the rope to provide a factor of safety of 3 for the alternating load of 25 lbs.

Preliminary testing had indicated weaknesses in the strength of vertical support side joints and the durability of non-ferrous nylon fasteners. These could eventually lead to mechanical breakdowns or reduce the reliability level of the device under its stipulated conditions if not addressed.

Conclusion

The main goal of the project was to design and construct a lower extremity loading device for the hamstring compatible with MRI environments, aimed at advancing research in retrieving f-MRI signals during hamstring activation. The final prototype was composed of a frictionless slider system, where an individual lying supine pulls a slider towards their glutes, thereby performing knee flexion and activating their hamstring. The load is supplied by a pulley weight stack system that amplifies an attached weight and transmits it through a cable.

Through iterative testing the design was successfully verified to show no statistically significant difference in cable tension throughout slider movement. All materials/components including HDPE sheets, nylon sheets, and the PLA step pulley were selected for their MRI compatibility. And notably the pulley weight stack integrating a carbon fiber shaft can support a 550 lb amplified force with a safety factor of 3.

Future improvements will focus on strengthening the structural supports by integrating more durable fasteners for the base sheet and vertical supports of the pulley in order to enhance the device's efficacy and reliability in clinical applications.

As a whole, the frictionless slider and pulley weight stack system successfully aligns with the principle criteria and specifications of the client. Major steps forward will require the IRB testing of the biomedical device for its implementation in the client’s ongoing research study with the broader implication of investigating the underlying neuromuscular differences of individuals with hamstring strain injuries.

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Appendix A - Materials List

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total
HDPE 12 x 48 x 1	Moisture-Resistant HDPE Sheet	King Plastic Corporation	King KPC HDPE	McMaster-Carr	8619K493	4/13	2	$91.54	$183.08
HDPE 24x24x1	Moisture-Resistant HDPE Sheet	King Plastic Corporation	King KPC HDPE	McMaster-Carr	8619K494	4/13	1	$91.54	$91.54
Plastic Glass Ball Bearings	Plastic Ball Bearing with Glass Ball, Trade No. R12, for 3/4" Shaft Diameter	N/A	6455K12	McMaster-Carr	6455K12	4/13	2	$21.72	$43.44
Nylon Screws	Nylon Socket Head Screws	N/A	95858A744	McMaster-Carr	95858A744	4/13	1	$13.84	$13.84
HDPE Rod	Plastic Rod: 4 ft Plastic Lg, Off-White, Opaque, 4,500 psi Tensile Strength, 2.75 ft-lb/in	Grainger	22JL44	McMaster-Carr	22JL44	4/13	1	$24.74	$24.74
Synthetic Winch Line	Nylon Rope,100 Feet White Nylon Rope,1/4 Inch Solid Braided Rope	JIJIA	JS-Z08021-F1	Amazon	B07V1TN41Q	4/14	1	$9.99	$9.99
Carbon Fiber Rod	Black Carbon Fiber Rod Stock 1 ft. L, 3/4" Dia.	Zoro Select	BULK-CR-CF-9	Zoro	G7285584	4/17	1	$46.99	$46.99
								TOTAL:	**$414**

Appendix B - Fabrication Procedures

Procedure for Cutting Parts of Slider Design

Name of fabrication step/portion of prototype: Cutting the Parts of the Slider Design
Date to be completed: 04/19/2024
Team member(s) fabricating: Micah Schoff, Nikhil Chandra, Ethan Rao, Caelen Nickel
Detailed sketch of portion of prototype being fabricated:

List of Materials Needed:

- Material 1: Sheet of High Density Polyethylene (HDPE)
    - Quantity: 2
    - Dimensions: 48 in. long by 12 in. wide
    - Manufacturer/Part Number: Zoro (PN:1ZAX7)
    - Purpose: The purpose of this material in the protocol is to provide the material with which this section of the device is to be fabricated
- Material 2: Wool Felt Strip with Acrylic Adhesive
    - Quantity: 1
    - Dimensions: 12 in. length by 1 in. width
    - Manufacturer/Part Number: Zoro (PN: 2FGZ7)
    - Purpose: The purpose of the felt is to create as close to a frictionless surface as possible for the slider to move across.
- Material 3: Bandsaw
    - Quantity: 1
    - Manufacturer: Global Industrial (PN:28-400) or any found in TEAM Lab [1]
    - Purpose: The purpose of the bandsaw is to cut the HDPE into the correct dimensions as specified by the drawing created.
- Material 4: Scissors
    - Quantity: 1
    - Manufacturer: Clauss (PN: 22UM87) or any other handheld scissors that will cut felt [2]
    - Purpose: The purpose of the scissors is to cut the felt to the dimensions specified by the drawing created

Detailed bulleted steps of fabrication:

1. Following the dimensions on SolidWorks drawing (see "Detailed Sketch" above) mark cuts on a 48 in. x 12in. sheet of HDPE using a marker
    a. Part 1: 1 base sheet of HDPE (30 in. long by 7.5 in. wide by 0.5 in. height)
    b. Part 2 and 3: 2 side runners of HDPE (30 in. long by 0.5 in. wide by 1.5 in. height)
    c. Part 4 and 5: 2 vertical limits of HDPE (30 in. long by 1 in. wide by 0.25 in. height)
    d. Part 6 and 7: 2 slider of HDPE (6 in. long by 6.25 in. wide by 0.5 in. thick)
    e. Part 8 and 9: 2 foot mounts of HDPE (3 in. long by 5 in. wide by 0.5 in. thick)
2. Place each respective piece of HDPE on the bandsaw
3. Set the bandsaw to the appropriate speed (~1000 ft/min.) [3]
4. Turn on the bandsaw
5. Move the piece of HDPE slowly through the bandsaw following each mark of the cut
6. Turn off the bandsaw
7. Remove newly cut piece from the bandsaw
8. Sand newly cut piece if necessary to remove unnecessary material
9. Repeat Steps 2-8 for each Part referenced in Step 1
10. Mark cut for felt lining on a piece of felt (3.7 in. wide and 3 in. long)
11. Cut one piece of felt using scissors
12. Utilize these now cut pieces for assembly (Refer to Assembly for Slider Design Protocol)

Procedure for Fabrication of Side Posts

Name of fabrication step/portion of prototype: Side Posts/Supports
Date to be completed: 04/19/2024
Team member(s) fabricating: Micah Schoff, Nikhil Chandra, Ethan Rao, Caelen Nickel

List of Materials Needed:

- Material 1: Sheet of High Density Polyethylene (HDPE)
    - Quantity: 2
    - Dimensions: 48 in. long by 12 in. wide
    - Manufacturer/Part Number: Zoro (PN:1ZAX7)
    - Purpose: The purpose of this material in the protocol is to provide the material with which the side posts/supports for the pulley system will be created
- Material 2: Drill Press
    - Quantity: 1
    - Dimensions: Not applicable

        - Manufacturer/Part Number: Grainger (PN: 36VE10) or any found in TEAM Lab
        - Purpose: The purpose of this drill press is to attach to the hole saw in order to cut the holes necessary for the rod in the pulley system to pass through
    - Material 3: Hole Saw
        - Quantity: 1
        - Dimensions: 1 and 5/8' diameter
        - Manufacturer/Part Number: Zoro (PN: 49-56-9119)
        - Purpose: To drill the hole through which the rod will pass
    - Material 4: 3D Printed Pieces
        - Quantity: 2
        - Dimensions: As specified within the SolidWorks File
        - Manufacturer/Part Number: N/A
        - Purpose: To ensure a compressive fit for the bearings to be inserted within the holes created using the hole saw
    - Material 5: Bearings
        - Quantity: 2
        - Dimensions: 1 and 5/8 " outer diameter and 5/8 " inner diameter
        - Manufacturer/Part Number: McMaster Carr (PN: 5951N129)
        - Purpose: To give the rod and pulley rotation within the system
    - Material 6: Plastic Screws
        - Quantity: 8
        - Dimensions 1" long and 3/8" diameter
        - Manufacturer/Part Number: TEAM Lab
        - Purpose: To fasten the 3D printed pieces to the side posts

Detailed bulleted steps of fabrication:

1. Acquire the appropriate materials utilizing the stated websites
2. Measure out the correct dimensions (5.1875 inches from the side of the post and 2 inches from the top of the post)
3. Use a marker in order to trace the bearing at the location specified by the measurements in Step 2
4. Attach the hole saw to the drill press
5. Set the speed on the drill press to between 250-350 RPM (relatively slow speed)
6. Place sheet of HDPE on the drill press and clamp down, using the provided clamps in the TEAM Lab
7. Turn the drill press on
8. Bring the drill press down slowly using the peck drilling technique to reasonably slowly to remove the material necessary

9. Place the 3D printed material on top of the post and align hole with the hole made using the hole saw
10. Use the drill press to make 4 identical holes in the four corners of both 3-D printed pieces
11. Use tools found in the TEAM lab to countersink and tap the holes in order to insert screws
12. Insert bearing
13. Insert 3-D printed pieces and screws through the holes that have been drilled in all three materials
14. Tighten all screws
15. Repeat for Post 2
16. Add to Final Assembly

Procedure for Fabrication of the Base

Name of fabrication step/portion of prototype: Base
Date to be completed: 04/23/2024
Team member(s) fabricating: Micah Schoff, Nikhil Chandra, Ethan Rao, Caelen Nickel

List of Materials Needed:

- Material 1: Sheet of High Density Polyethylene (HDPE)
    - Quantity: 1
    - Dimensions: 24 in. long by 24 in. wide
    - Manufacturer/Part Number: Grainger (PN: 1ZAN3)
    - Purpose: The purpose of this material in the protocol is to provide the base for the overall project
- Material 2: Hand Drill
    - Quantity: 1
    - Dimensions: 1/4 20 Drill Bit
    - Manufacturer/Part Number: TEAM Lab
    - Purpose: The purpose of the hand drill is to drill the holes through which the screws will secure the triangle supports to the base
- Material 3: Jig Saw
    - Quantity: 1
    - Dimensions: N/A
    - Manufacturer/Part Number: TEAM Lab

        - Purpose: The purpose of the jigsaw is to cut the holes through the base that are necessary in order to place the side posts in position
    - Material 4: Plastic Screws
        - Quantity: 10
        - Dimensions: 3/8 inch screws
        - Manufacturer/Part Number: TEAM Lab
        - Purpose: The purpose of the plastic screws is to properly attach the triangular supports to the base
    - Material 5: HDPE Sheet
        - Quantity: 1
        - Dimensions:
        - Manufacturer/Part Number: 18 inches long by 9 inches wide by 2 inches thick
        - Purpose: To provide support for the side posts

Detailed bulleted steps of fabrication:

1. Acquire the appropriate materials utilizing the stated websites and the TEAM Lab
2. Measure out two 12 inch long 1 inch wide holes approximately 6 inches from one side and 3 inches from the other on the 24 X 24 sheet of HDPE
3. Choose an appropriate blade size for the jigsaw as consulted by the TEAM Lab
4. Turn the jigsaw on
5. Follow the marks made with the jigsaw as best as possible and remove the material from the 24 X 24 sheet
6. Measure out as many 2.5 inch wide and 8 inch tall triangles from the thick sheet of HDPE as possible to provide ample support
7. Use the jig saw (or alternatively the band saw) to follow each line in order to cut out the triangle supports
8. Place the triangles at appropriate positions (at user discretion) in order to best support the side posts
9. Trace the form of the triangles with a marker in order to prepare for drilling
10. Measure approximately the center of each tracing of the triangle support on the base
11. Attach the appropriate drill bit (reference materials) to the hand drill

12. Utilize the hand drill to make all holes through the base and triangle supports
13. For all drilled holes, countersink and thread appropriately using tools found within the TEAM Lab
    1. NOTE: When threading, make sure to go slowly and use the 3 turns clockwise, 1 turn counterclockwise rule
14. Attach all screws, securing the triangle supports to the base plate

Appendix C—Testing Procedures

Procedure for General Mechanical Testing

Name of Test: Testing of the Pulley/Constant Tension
Date to be completed: 04/24/2024
Team member(s) testing: Micah Schoff, Nikhil Chandra, Ethan Rao, Caelen Nickel

List of Materials Needed:

- Material 1: Prototype
  - Quantity: 1
  - Dimensions: Refer to the dimensions for each part in Solidworks
  - Manufacturer/Part Number: MR Leg Loader Team
  - Purpose: The purpose of this material is for it to be tested to judge its efficacy in two major categories
- Material 2: Spring Gauge
  - Quantity: 1
  - Dimensions: N/A
  - Manufacturer/Part Number: Grainger (45AE70) or any that are readily available
  - Purpose: The purpose of the spring gauge is to be able to assess the weight at different points in the hamstring activation to ensure both constant tension and that the weight is being amplified
- Material 3: Weight
  - Quantity: 3
  - Dimensions: N/A
  - Manufacturer/Part Number: Any that are readily available (can use dumbbells or plates for testing)
  - Purpose: The purpose of the weight is to provide the tension that will be acting upon the device

Detailed bulleted steps of fabrication:

1. Acquire the appropriate materials utilizing the stated websites
2. Set up the prototype as referenced in assembly
3. Tie the weight onto the end of the pulley
4. Attach the other end to the spring gauge
5. Complete testing
    1. One person support the weight stack portion of the device and prevent damage and any unforeseen issues with the device during testing
    2. One person pull on the spring gauge

        1. Stop at 3 distinct positions in the slider portion of the design (We chose beginning, middle and end but these can be variable)
6. Take a video of the spring gauge as it moves in order to retrieve close to analog data
    1. Pictures are an alternative at the three points if necessary
7. Slowly allow the weight to move back towards the ground
8. Release the spring gauge once the weight has moved fully back to the ground
9. Utilize said data for graphs as well as statistical analysis of the device

Constant Tension Testing Procedure

Name of Test: Constant Tension Test
Date to be completed: 04/24/2024
Team member(s) testing: Micah Schoff, Nikhil Chandra, Ethan Rao, Caelen Nickel

List of Materials Needed:

- Material 1: Prototype
    - Quantity: 1
    - Dimensions: Refer to the dimensions for each part in Solidworks
    - Manufacturer/Part Number: MR Leg Loader Team
    - Purpose: The purpose of this material is for it to be tested to judge its efficacy in two major categories
- Material 2: Spring Gauge
    - Quantity: 1
    - Dimensions: N/A
    - Manufacturer/Part Number: Grainger (45AE70) or any that are readily available
    - Purpose: The purpose of the spring gauge is to be able to assess the weight at different points in the hamstring activation to ensure both constant tension and that the weight is being amplified
- Material 3: Weight
    - Quantity: 3
    - Dimensions: N/A
    - Manufacturer/Part Number: Any that are readily available (can use dumbbells or plates for testing)
    - Purpose: The purpose of the weight is to provide the tension that will be acting upon the device

Detailed bulleted steps of fabrication:

1. Acquire the appropriate materials utilizing the stated websites

2. Set up the prototype as referenced in assembly
3. Tie the weight, starting with 5 lbs onto the end of the pulley
4. Attach the other end to the spring gauge
5. Complete testing
    a. One person support the weight stack portion of the device and prevent damage and any unforeseen issues with the device during testing
    b. One person pull on the spring gauge
        i. Hold the spring gauge at position 1, which is the beginning of the slider and standardized to be 0 inches.
        ii. Collect a force reading from the spring force gauge
        iii. Move the spring gauge to position 2, which is the middle of the slider and standardized to be 15 inches, and hold.
        iv. Collect a force reading from the spring force gauge
        v. Move the spring gauge to position 3, which is the end of the slider and standardized to be 30 inches, and hold.
        vi. Collect a force reading from the spring force gauge
        vii. Slowly allow the weight to move back towards the ground
        viii. Release the spring gauge once the weight has moved fully back to the ground
        ix. Repeat this testing 3 times to construct a sample data with multiple trials
6. Untie and remove the weight from the end of the pulley
7. Tie the 10 lbs weight now onto the end of the pulley
8. Repeat testing as described in step 5
9. Repeat steps 6 and 7, this time tying the 15 lbs weight
10. Repeat testing as described in step 5
11. Using the 3 trials for each of the 3 standard weights, complete data analysis and visualization to determine whether there is statistically significant constant tension

Pulley Verification Testing Procedure

Name of Test: Pulley Verification Test
Date to be completed: 04/24/2024
Team member(s) testing: Micah Schoff, Nikhil Chandra, Ethan Rao, Caelen Nickel

List of Materials Needed:

- Material 1: Prototype
    - Quantity: 1
    - Dimensions: Refer to the dimensions for each part in Solidworks

        - Manufacturer/Part Number: MR Leg Loader Team
        - Purpose: The purpose of this material is for it to be tested to judge its efficacy in two major categories
    - Material 2: Spring Gauge
        - Quantity: 1
        - Dimensions: N/A
        - Manufacturer/Part Number: Grainger (45AE70) or any that are readily available
        - Purpose: The purpose of the spring gauge is to be able to assess the weight at different points in the hamstring activation to ensure both constant tension and that the weight is being amplified
    - Material 3: Weight
        - Quantity: 3
        - Dimensions: N/A
        - Manufacturer/Part Number: Any that are readily available (can use dumbbells or plates for testing)
        - Purpose: The purpose of the weight is to provide the tension that will be acting upon the device

Detailed bulleted steps of fabrication:

1. Acquire the appropriate materials utilizing the stated websites
2. Set up the prototype as referenced in assembly
3. Tie the weight onto the end of the pulley
4. Attach the other end to the spring gauge
5. Complete testing
    a. One person support the weight stack portion of the device and prevent damage and any unforeseen issues with the device during testing
    b. One person pull on the spring gauge
        i. Hold the spring gauge at a constant position
        ii. Collect a force reading from the spring force gauge
        iii. Slowly allow the weight to move back towards the ground
        iv. Release the spring gauge once the weight has moved fully back to the ground
        v. Repeat this testing 3 times to construct a sample data with multiple trials
6. Untie and remove the weight from the end of the pulley
7. Tie the 10 lbs weight now onto the end of the pulley
8. Repeat testing as described in step 5
9. Repeat steps 6 and 7, this time tying the 15 lbs weight
10. Repeat testing as described in step 5
11. Using the 3 trials for each of the 3 standard weights, complete data analysis and visualization to determine whether there is proper pulley amplification.

Appendix D—MATLAB Code

```
data1 = [8, 20, 30];

data2 = [9, 20, 29];

data3 = [9, 21, 30];

% Number of values to generate using bootstrap

numValues = 100;

% Perform bootstrap resampling

bootstrapData1 = zeros(1, numValues);  % Initialize array to store bootstrap samples

for i = 1:numValues

    % Resample with replacement from the original dataset

    bootstrapSample1 = datasample(data1, 3, 'Replace', true);



    % Calculate statistic of interest (e.g., mean, median, etc.)

    % Here, we'll just use the first value of the bootstrap sample

    bootstrapData1(i) = bootstrapSample1(1);

end

bootstrapData2 = zeros(1, numValues);  % Initialize array to store bootstrap samples

for i = 1:numValues

    % Resample with replacement from the original dataset
```

```
    bootstrapSample2 = datasample(data2, 3, 'Replace', true);


    % Calculate statistic of interest (e.g., mean, median, etc.)
    % Here, we'll just use the first value of the bootstrap sample
    bootstrapData2(i) = bootstrapSample2(1);
end
bootstrapData3 = zeros(1, numValues);  % Initialize array to store bootstrap samples
for i = 1:numValues
    % Resample with replacement from the original dataset
    bootstrapSample3 = datasample(data3, 3, 'Replace', true);


    % Calculate statistic of interest (e.g., mean, median, etc.)
    % Here, we'll just use the first value of the bootstrap sample
    bootstrapData3(i) = bootstrapSample3(1);
end
% Combine data into a single vector
data = [bootstrapData1, bootstrapData2, bootstrapData3];
% Create grouping variable
```

```
groups = [ones(1, numel(bootstrapData1)), 2*ones(1, numel(bootstrapData2)), 3*ones(1,
numel(bootstrapData3))];

% Perform one-way ANOVA

[p, tbl, stats] = anova1(data, groups);

% Display ANOVA table

disp(tbl);

% Check significance

if p < 0.05

   disp('ANOVA result: There is a significant difference between groups.');

else

   disp('ANOVA result: There is no significant difference between groups.');

   disp(p)

end
```

Appendix E—PDS

Function:

Hamstring strain injuries (HSIs) are the most common musculoskeletal injuries experienced in many sports and recreational activities [1]. Prior HSIs have been shown to significantly increase patients' risk for additional injury, due in part to neuromuscular alterations [1]. In order to research this phenomena and supplement the current rehabilitation process for HSIs to mitigate reinjury risk, a biomedical device is required. This device must be compatible with magnetic resonance imaging (MRI) and mechanically induce hamstring activation on a patient in the supine position in the MRI machine. The device will then collect knee flexion and resistance data. In parallel to the device, an fMRI machine will be taking images of the blood flow in the brain due to brain activity. When paired with these images, the data the device will collect will allow for researchers to better understand the correlation between knee flexion/resistance and the stimulation of the brain during hamstring loading. Furthermore, this will allow for researchers to determine what conditions (i.e prior hamstring injury at a certain angle) will result in the neuromuscular alterations that increase the risk of additional injury.

Client Requirements:

1. The device must be compatible with the client's experimental setup involving function MRI (fMRI) of the head.
    a. Since the device will be used in conjunction with MRI, it is imperative that the design does not incorporate ferrous materials or affect the machine and its imaging in any way.
    b. The biomechanical functioning of the device should be applicable to a patient lying supine in the MRI machine.
2. For the experimentation, the device is required to cause activation of the patient's hamstring, specifically the biceps femoris long head.
    a. It is vital that the force(s) applied to the hamstring are a result of constant tension, rather than variable tension.
    b. The hamstring loading should be cyclic, with a consistent frequency between 0.5 Hz to 0.75 Hz.

c. The load applied to the hamstring should elicit approximately 20% to 30% of maximum effort for the patient.

3. The device should return reliable, accurate data on the knee flexion angle and resistance force applied to the patient's lower leg. In order to compare these values to the fMRI head scans, the data should be in respect to time.
    a. The client would also find EMG data relative to time useful, so MR compatible EMG electrodes and corresponding circuitry should be incorporated into the design.

Design Requirements:

1. Physical and Operational Characteristics:

a. Performance Requirements:

- The biomedical device will induce hamstring activation in a cyclic manner. As a result, the device must be able to withstand high volumes of loading and unloading by the patient during its use. For a single trial of data collection, the device will be loaded every 1.5 seconds (0.66 Hz) for approximately 5 minutes.
- During this hamstring activation, the device or separate components that are used in conjunction with the device will measure knee flexion angle in degrees, as well as force applied to/by the leg in Newtons.
- The device should be reusable, both allowing for multiple trials to be conducted on the same patient and be usable on all possible patients/test subjects.
    - As a result, the fabrication of the device should allow for such repetitive use.
    - In addition, all potential users should be able to use the device. This means that variable patient heights, weights, foot sizes, and strengths must be accounted for
        - The approximate variability in weight that can be placed on the device will be between 2.27 and 15.88 kg to account for a wide range of strengths

        - The approximate length of the sliding portion of the device will be 36 inches with stops to account for different leg lengths/heights
- To induce sufficient hamstring activation, the device must withstand 20% to 30% of the force the patients' hamstrings can generate. This value varies substantially across patients due to disparities in strength and hamstring health, but will average 110.55 N.

b. Safety:

- To avoid the device being forcefully attracted to the MRI machine, it is necessary to fabricate the device without ferrous metals, including but not limited to iron alloys, nickel, magnesium, lithium, and cobalt. This is essential in preventing patient and/or operator injury, as well as avoiding damage to the device and MRI.
- Because the device is to be utilized within an MR room (see *Operating Environment*), the device as well as the personnel operating it must adhere to MR Zone IV safety requirements [2]. This includes constant supervision by trained MR personnel, only MR compatible equipment within the room, and the operator having a clear view of entrances to the room [3].

c. Accuracy and Reliability:

- The device should be able to maintain constant tension, fluctuating less than 5% in force applied while the subject performs isometric, eccentric and concentric contractions of the hamstring muscle.
- The device should be able to take the kinematic measurements of knee flexion within 2.0° as well as measure the forces exerted by the hamstring on the device within 1.0-3.0 N.

d. Life in Service:

- Ideally, the device should be able to withstand 5 years of usage without replacement of constituent components of the device. Once replacement begins, the device should be able to operate another 5-10 years of usage.
- During usage, the device must be designed to log 2 hours of total use per month.

e. Shelf Life:

- The device will be stored within a storage closet in the research facility or hospital that will be maintained at a temperature of 20°C to 22.8°C when not in use [4]. The device may also be subject to dust and other debris when in the storage closet.

f. Operating Environment:

- The device will be used by researchers and MR personnel within the MR room at the Waisman Center. This indicates that the device will be operating in the presence of the magnetic fields generated by the 3 Tesla GE MAGNUS Scanner (static, radiofrequency, and gradient fields) and must be unaffected by said fields [5] [2].
- The device will otherwise be exposed to normal indoor, climate controlled conditions. Standard room temperature of 20°C to 22.8°C and humidity of 40% will be expected and are factors to be incorporated into the design/fabrication.

g. Ergonomics:

- As mentioned in *Performance Requirements*, the device must be able to regularly withstand 20% to 30% of the maximum force exerted by the hamstring when activated, equating to 110.55 N, but this is dependent on patient strength [6].
- The device may have to angle upwards at around 30° in order to account for the height of subjects taller than 2 meters [7].
- Finally, the device must be constructed so as to allow the heel to contact to better isolate the hamstrings [1]. The mechanism securing the patient's heel to the device must be secure and not impair the testing motion.

h. Size:

- The size of the device will need to fit the MRI table dimensions (≈ 31 ⅞ inches wide) and allow for adjustment based on the subject's physical features, including height, leg thickness, and foot size [8].

- The size must also allow the device to be transportable through standard doorways and elevators. This equates to a maximum width of 36 inches in order to ensure easy transport [9]

i. Weight:

- The weight of the device must allow researchers to transport and easily lift it. This being said, the device should not weigh more than 50 pounds in order to protect the operator when transporting the device [10].
- Since this device will be used to provide resistance at 20-30% of maximum loading capability by the patient's hamstring, this may affect the weight of the device depending on how resistance is implemented (weights, resistance bands, pneumatics).

k. Materials:

- The materials used to build the device and add variable resistance to the hamstring loading must be MRI compatible. This means that no ferrous materials can be used [11].
- Materials to be used include high density polyethylene to craft the main body of the device, felt to allow for a frictionless slide, and a synthetic non-ferrous material for the cables/wires that make up the pulley system
- Additionally, epoxy will be used to connect the distinct portions of the device

l. Aesthetics, Appearance, and Finish:

- The aesthetics and appearance of this device need to be safe and medical as to show that the device does not impose any danger to the user. The finish of this device needs to hold up to medical grade sanitation as it will be used by multiple subjects.

2. Production Characteristics:

a. Quantity:

- There needs to be one device created along with the necessary materials/parts to fix and maintain the device.

b. Target Product Cost:

- As this is primarily a research device, the budget is limited. The cost of this device should roughly be below $300. This includes prototype materials and final fabrication costs.

3. Miscellaneous:

a. Standards and Specifications :

- There are several relevant standards and specifications to consider in the safe and reliable development of an MRI-compatible hamstring lower extremity loading device that will be used by researchers and patients with hamstring strain injuries.
    - ASTM International F2503 and IEC 60601-1-2 are standards for fabricating devices that are safe and compatible in magnetic resonance environments or more broadly in the emission of electromagnetic disturbances [13][14].
    - ASTM F2503 categorizes devices into MR Safe, MR Conditional, MR Unsafe and when developing the hamstring loading device, it will be essential for us to refer to the set of guidelines for this categorization to ensure the device does not negatively interfere with the MRI readings or the patient's safety.
- In addition, ISO 10993 is a series of standards that help ensure the biocompatibility of medical devices both internal, external and direct and indirect contact devices which is critical for the hamstring loading device where a patient will be in direct external contact with the device while maintaining a supine position [15].
    - These standards will help guide product development as we aim to ensure the device is biocompatible and has limited risk given the underlying physiology

of the sensitive recovery process of patients with HSIs. For example, we may need to consider creating a loading device where a patient's lower extremities are not strapped to the device and they can easily release the load at any given moment.

- Another standard that further may guide development given this constraint is IEC 62366-1, which is focused on usability and human factor engineering ensuring that medical devices specifically effectively consider user needs and limitations [16]. The standard outlines a process by which engineers can assess and mitigate risks in creating user-centered designs.

b. Customer:

- The target customers for this product are the clients and their laboratory staff. However, this device could be useful to other exercise physiology or kinesiology research labs, as well as orthopedists, athletic trainers, and physical therapists.
- In addition to the major customer/client constraints and preferences that the device be MRI compatible for patients in a supine position and that the device must deliver a constant selectable load, other preferences include that the individual's heels are elevated as that may allow for more effective hamstring activation.

c. Patient-Related Concerns:

- The MRI-compatible loading device will be used by patients with HSIs and as previously mentioned, the device will have to be designed to mitigate the risk of further injury in hamstring activation.
- As the device will make external contact with the patient, it will be sterilized between uses.
- The device will have an adaptable loading mechanism, where the researchers can easily switch out larger or smaller loads to accommodate for the specific patient's strength and injury sensitivity. The alteration of resistance can be due to changing the exercise bands or weight.

- In addition, in regards to data collection, patient specific kinematic data on knee flexion and flexion rates, will be handled by the client as a part of the application of the loading device within a broader research study into neuromuscular control.

d. Competition:

- There are no known commercially available MRI-compatible hamstring loading devices for users laying in the supine or prone position.
- In literature, there is one major non-patented prototype developed by Amy Slider, Christopher Westphal, and Darry Thelen from the Department of Biomedical Engineering at UW Madison [17]. They developed a prototype for a hamstring specific loading device compatible with magnetic resonance machines.
    - The machine is strapped to a patient's ankle and allows them to perform isolated eccentric and concentric knee flexion and extension in the prone position with an average of 30 degree knee flexion motion amongst patients [17].
    - The major drawback of the prototype is that the loading device is designed for patients in a prone position as opposed to the client's principle constraint that the individual should be lying supine in an MRI machine.
- Furthermore, although not MRI-compatible, there are several relevant and common hamstring loading machines of which we can extract design strategies from. The Lying Leg Curl, Seated Leg Curl, Standing Leg Curl, Smith Machine Stiff-leg Deadlift, Smith Machine Romanian Deadlift, and the Leg Press machines are amongst the most common gym machines that can effectively target the major hamstring muscles Semitendinosus, Semimembranosus, and Biceps femoris [18].
    - They function for patients in various positions (prone, supine, sitting, standing) by applying a loading force mainly on the heels and ankles which reasonably generates a larger moment arm relative to the knee and hip and these forces allow a user to do mechanical work as they perform biomechanical movements mainly knee flexion, hip extension, and hip adduction and abduction [18].

    - Extracting machine element design considerations including the use of pulleys, belt drives, lever mechanisms, amongst more will be useful when designing an MRI-compatible loading device.
- Amongst the broader set of common hamstring targeted weight machines, there are two notable patented inventions. First, one by Carlstrom (Patent #5634873) features a simple pulley anchor system that uses a resistance band for an individual to stretch their hamstrings while in a supine position [19].
    - The design is especially interesting as it allows for a versatile range of movements from knee flexion to hip extension, along with potentially hip adduction, and abduction (less range of motion) all of which target different hamstring muscle groups.
    - The design deviates from client requirements in that the loading device needs to apply a constant load and resistance bands inherently increase in tension as they stretch.
- The other device is the CrossFire Contralateral Hamstring Device by Exerbotics that allows for isolated hamstring movements in a standing position, and although not MRI compatible or for supine positions, the device notably allows for electronically dynamic and constant resistance and can also map out knee flexion movements [20].

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