Preliminary Report: Lower Extremity Loading Device During Magnetic Resonance Imaging

BME 301: Section 302

Date: 03/06/2024

Clients: Dr. Scott Crawford, Dr. Beth Meyerand

Advisor: Dr. John Puccinelli

Team Members:

Team Leader: Nikhil Chandra

Communicator: Caelen Nickel

BWIG: Ethan Rao

BPAG & BSAC: Micah Schoff

Abstract:

Hamstring strains injuries (HSIs) are one of the most common injuries in sports, exercise, and recreational activities. Our 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.

Table of Contents:

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 this reinjury phenomenon until now has majorly 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.

Our 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 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].

Figure 1. Emory University illustration depicting their bilateral hamstring activation device and overall experimental setup with fMRI [6].

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. 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, it is apparent in Figure 1 that there was an element of the design necessary to secure the upper body and stabilize 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 Background section [6][7].

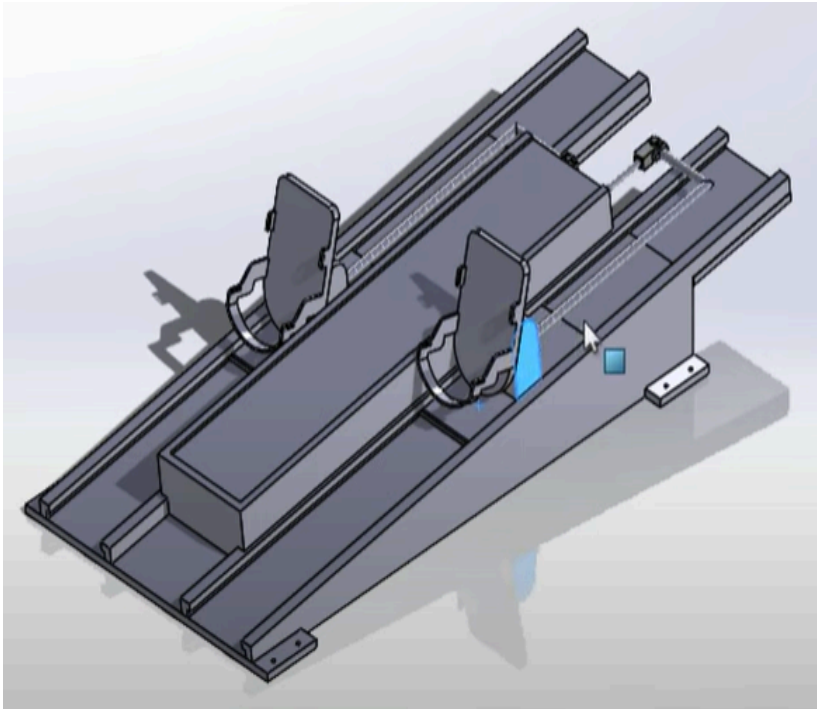


Figure 2. SOLIDWORKS schematic of the hamstring activation device used in the Emory study [6].

In order to induce hamstring activation for their study, Emory used the device as depicted in the SOLIDWORKS schematic in Figure 2. 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 this design used by Emory University

differs from our design and experimental setup is that this design uses elastic bands to apply resistance to the hamstring, where our client requires a constant tension be applied.

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, where the design envelops the patient's heel and there appears to be a loop on each side of the upper foot for a strap to secure 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].

A current commercially available product that is used in providing constant, measurable resistance to a muscle is the Marsh-Bellofram Rolling Diaphragm as modeled in Figure 3 [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, and this 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.

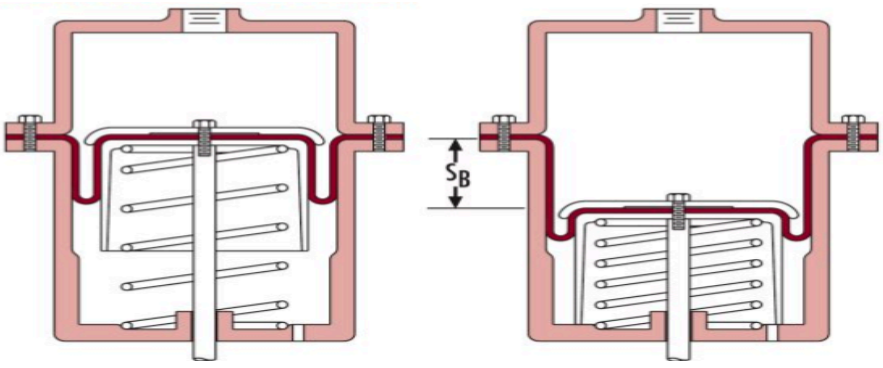


Figure 3. Marsh-Bellofram Rolling Diaphragm pneumatic pressure vessel design with the piston compressed (left) and decompressed (right) [8].

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:

Biology and Physiology

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.

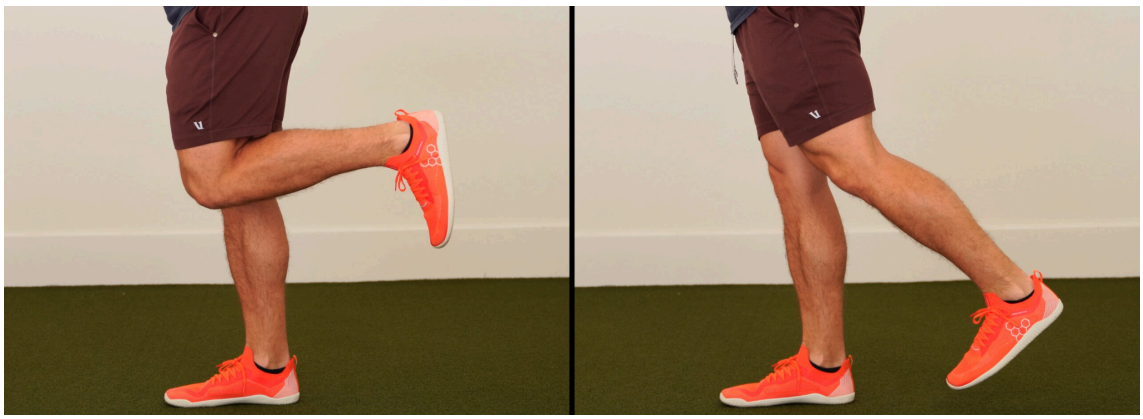


Figure 4. Demonstration of knee flexion (left) and hip extension (right) by the subjects left leg in the foreground [11].

The hamstring is commonly thought of as a singular muscle; however, it is comprised of three distinct anatomical muscles which are the biceps femoris, semitendinosus, and semimembranosus. 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 pages 13 and 16 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.

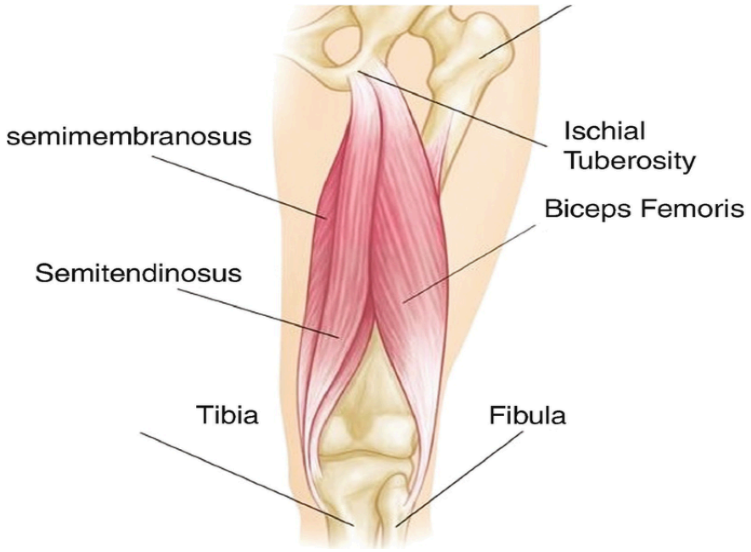


Figure 5. Diagram of the hamstring anatomy highlighting the three distinct muscles and their origin/insertion [12].

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 two parts, a long head and a short head. For kinesiology and exercise physiology purposes, our 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 2 in. from the axis of rotation of the knee. This value was determined on a 72 in. tall male, and likely varies across populations.

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 concentric, eccentric, 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.

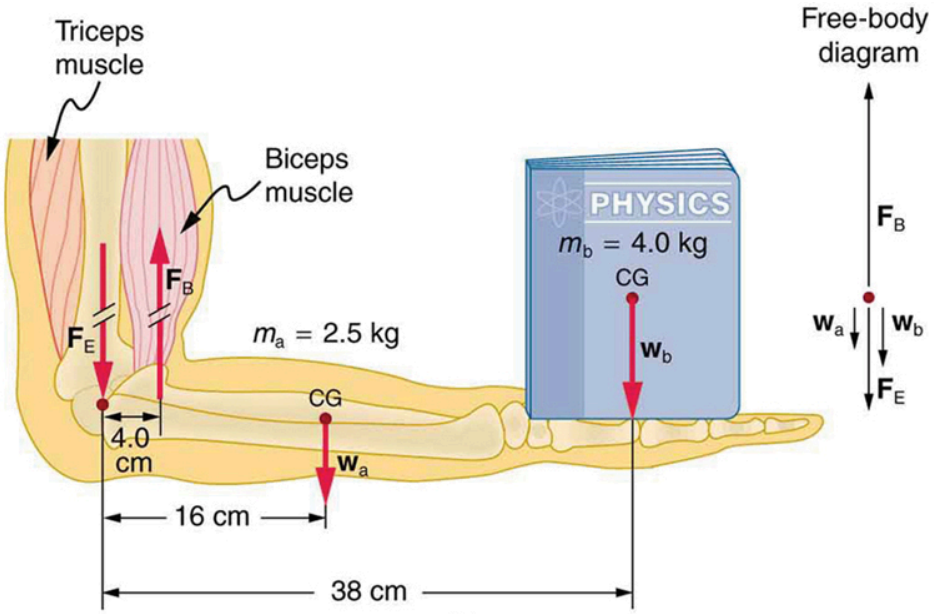


Figure 6. Free body diagram of the force considerations of a distally applied force, weight of the body segment, and force generated by the muscle [15].

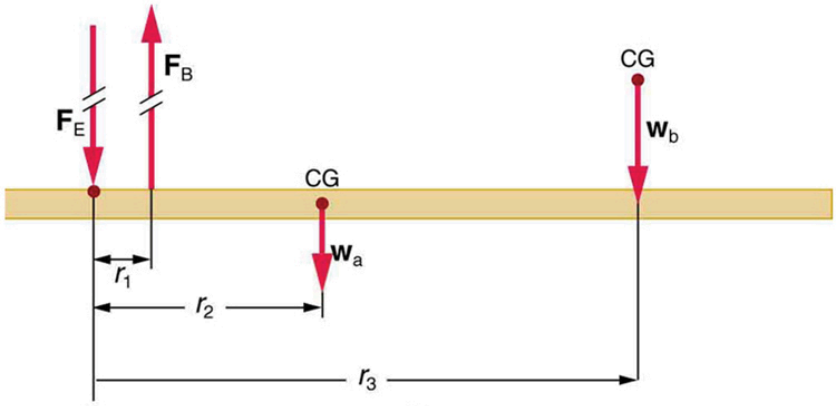


Figure 7. Simplified free body diagram from Figure 6 highlighting the moments applied about the axis of rotation [15].

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

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.

Muscles are able to generate force in this manner through what can be modeled as a sum of moments diagram as exemplified in Equation 2 and Equation 3. 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 6 and 7) also applies a moment about the axis of rotation. 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 based on Equation 1.

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

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.

Muscles are able to generate the force required to produce a moment about the proximal joint 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 [16]. 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 [17]. 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 [17]. 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.

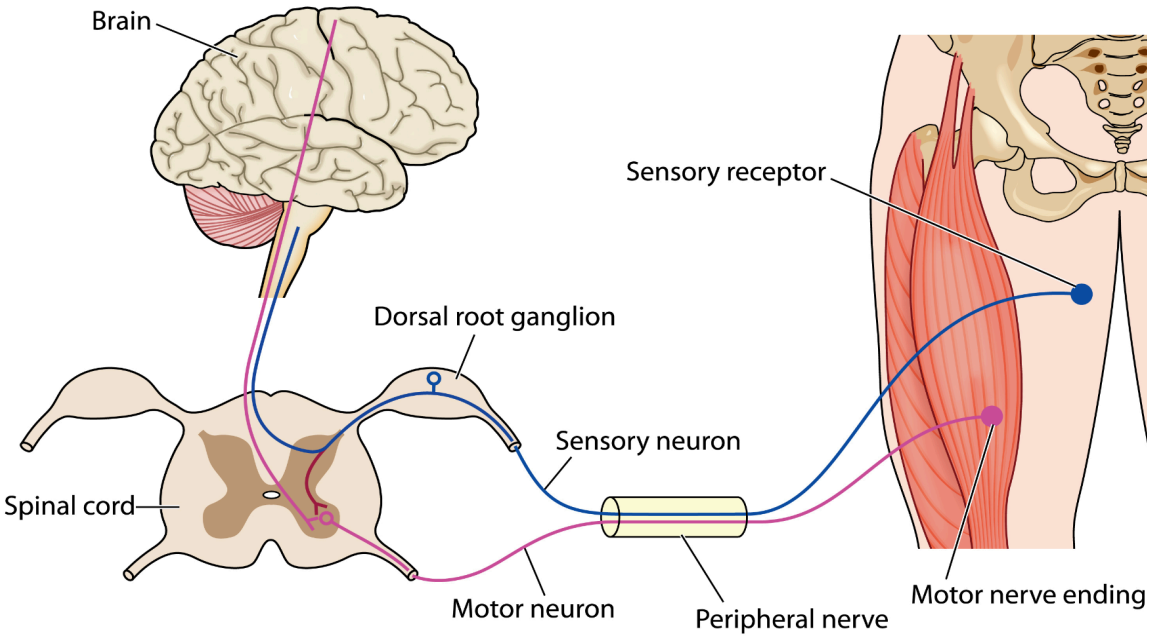


Figure 8. Diagram of how the nervous system propagates a signal to activate skeletal muscle [18].

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 8, through the central nervous system. Motor neurons exit the spinal cord where they become part of the peripheral nervous system and end within their affiliated muscle [18]. 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.

Figure 9. Image of an fMRI machine for brain 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 activate 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 [below]. The imaging results are exemplified by Figure 10, where hotspots of activity appear.

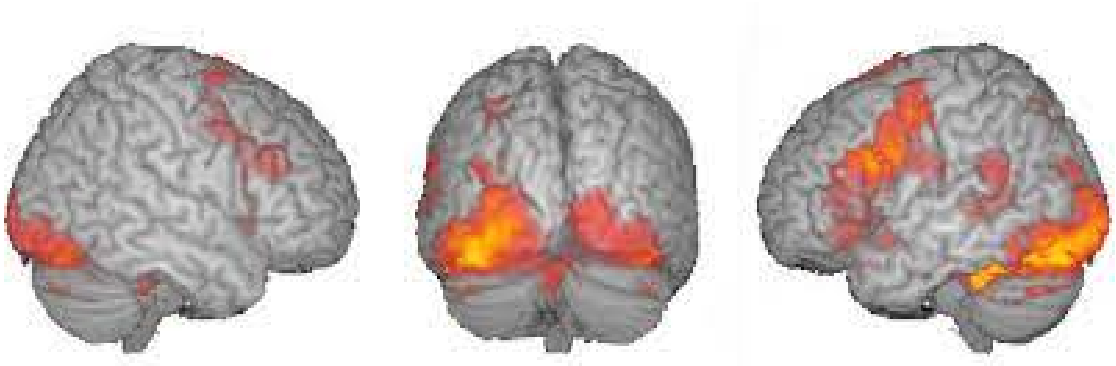


Figure 10. Brain fMRI showing neuronal activation [7].

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 [19]. 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.

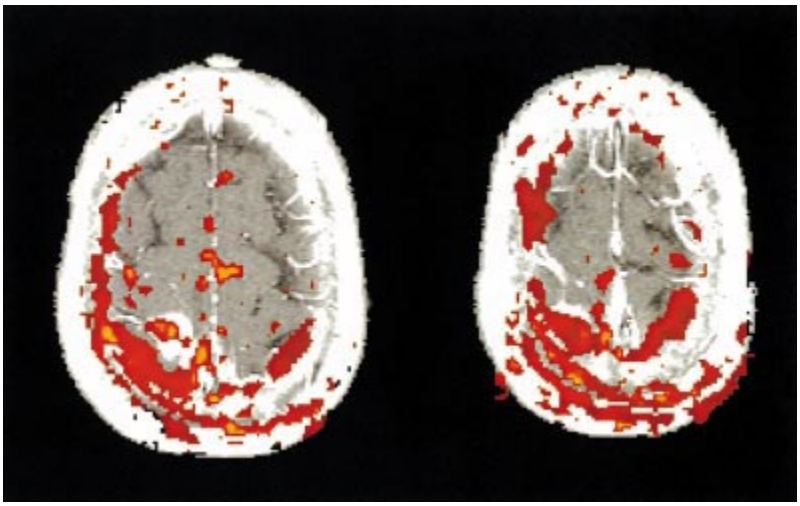


Figure 11. Severe motion artifact from patient movement during an fMRI [19].

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 [20][21]. 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 our 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 [22]. Certain materials have been observed to heat as a result of interaction with the magnetic and radiofrequency fields from the magnet used in MRI [23].

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 [24]. 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 [25].

Design Specifications:

Preliminary Design Specifications (Appendix C) 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 [26]. 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 [27]. This indicates that no part of the device can be made of ferrous metals or other non-compatible materials [28]. 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) [29].

Resistance Preliminary Designs:

Resistance Design 1: Cable Stack

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 [30].

The first design that was developed is a design representative of cable systems within gym machines. This design is to 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.

Resistance Design 2: Friction

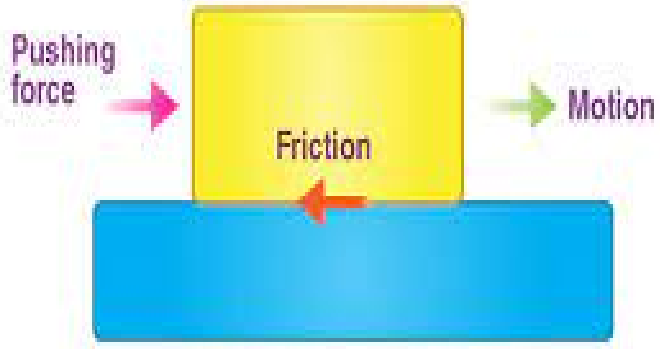


Figure 13. Representation of the friction design as a method of motion resistance [31].

The second design 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.

Resistance 3: Elastic Bands

Figure 13. Representation of the elastic band design. Important features of this design include the handles which will attach the band to the device [32].

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.

Resistance Design Evaluation:

Design Category Descriptions

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

Hamstring Activation:

The hamstring activation criteria for evaluating the preliminary designs is targeted at assessing the designs' ability to address the crucial client requirements around hamstring activation and resistance. For the Mechanism Design Matrix (Table 1), 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. For the Resistance Design Matrix (Table 2), 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 Mechanism Design Matrix (Table 1), 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. For the Resistance Design Matrix (Table 2), 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, both the Mechanism Designs and Resistance Designs, shown in Table 1 and Table 2 respectively, 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 doesn't 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 be 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

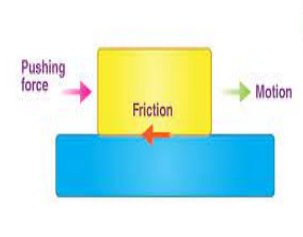
materials as mentioned. A unique consideration for ease of fabrication and materials is the ability to use all non ferrous components in the design. This is equally applicable to both the Mechanism Designs and Resistance Designs, shown in Table 1 and Table 2 respectively. Since these designs are intended 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 both the Mechanism Designs and Resistance Designs, shown in Table 1 and Table 2 respectively, 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

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 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 the team to make accurate calculations 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 inherently. 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. In specific, there would be more steps of use, as the machine would have to be set up in a specific way, which could potentially prove more complex.

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:

Mechanical Design 1: Slider

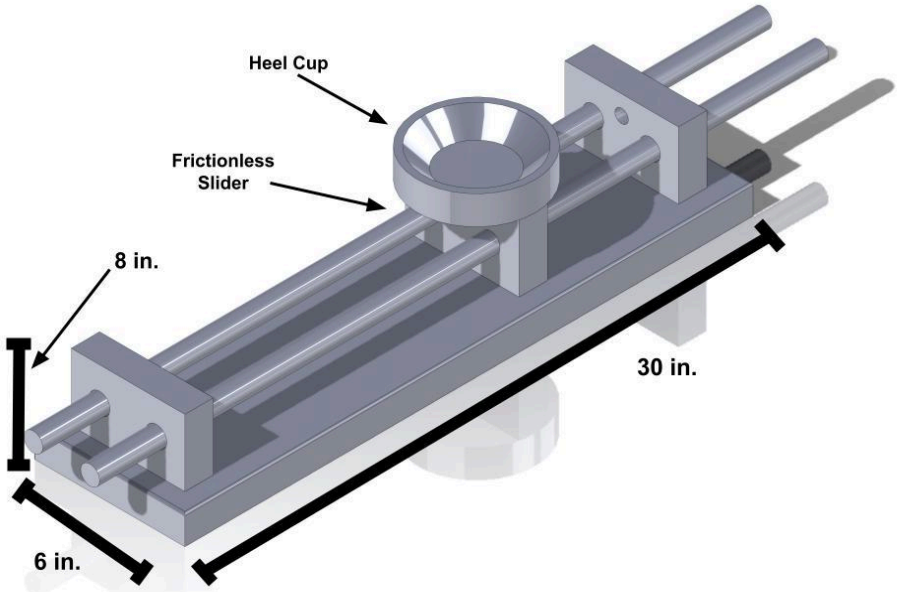


Figure 14. Slider Design. Important features of this design include the heel cup where the foot will be placed as well as the tract that this heel cup will move along during usage.

The slider design 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 to generate an opposing moment of knee flexion and hip flexion. Through the design given 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.

Mechanical Design 2: Bike Pedal

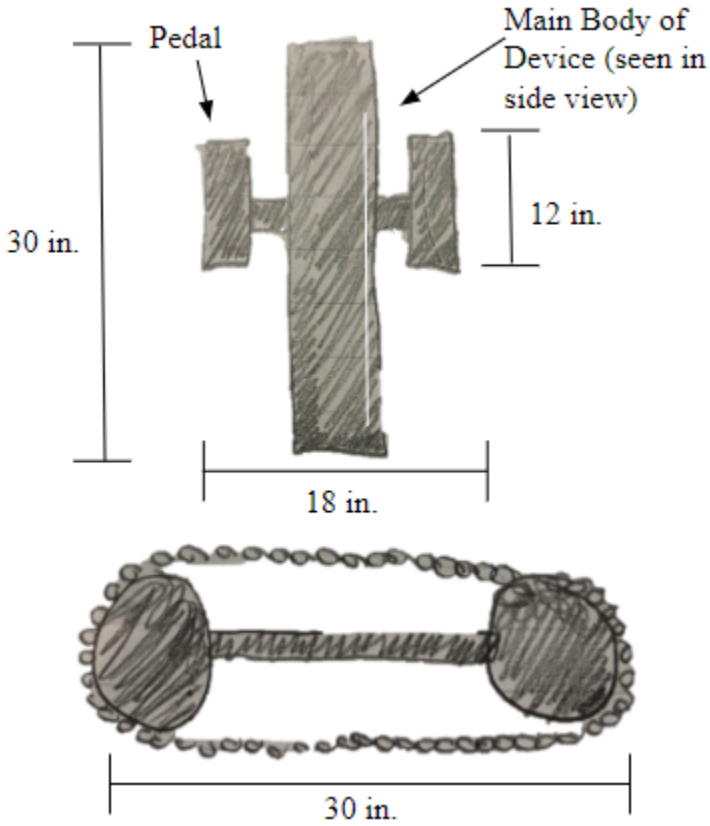


Figure 15. The bike pedal design. Important features of this design include the pedals and the system (similar to a bicycle) that allows for a cyclical motion.

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 slightly has to 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 and in turn 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 active opposing moment of knee flexion activating 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.

Mechanical Design 3: Leg Support

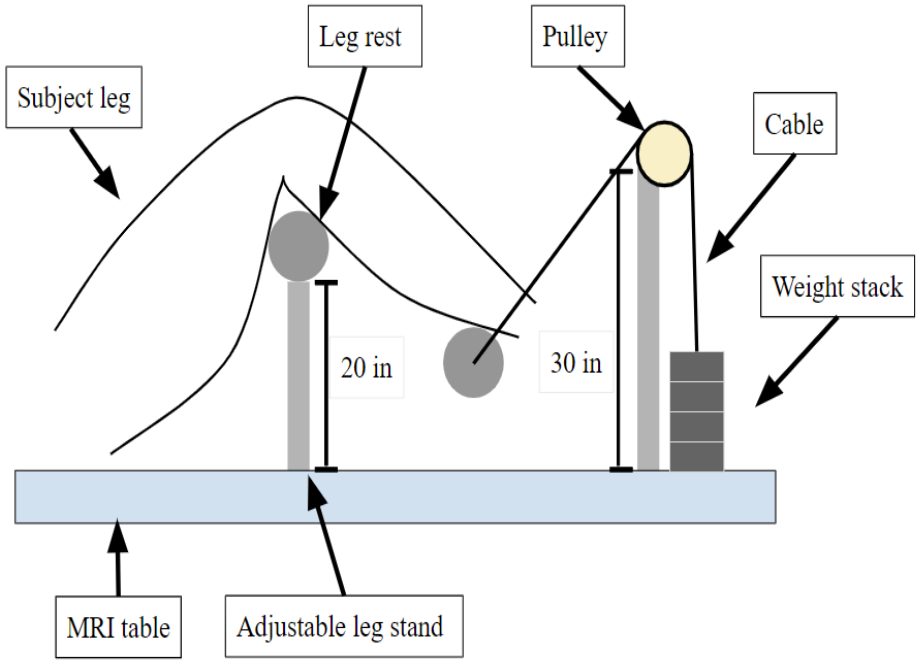


Figure 16. Leg Support Design. Important features of this design include the pulley system distributing forces and the ankle roller that allows for activation of the hamstring

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, where the 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.

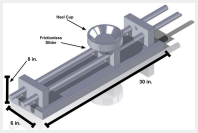
Mechanical Design Evaluation:

Design Category Descriptions

The design categories are identical for both the resistance and mechanical design matrices. However, there are varieties in the specific meaning and context of some criteria, as is explained in the Resistance Design Evaluation above the resistance design matrix.

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 Matrix Discussion

The mechanical design that performed the best given our mechanical 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 with a minor drawback of 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 encompasses 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 where it may be especially difficult to purchase or develop durable and reliable non-ferrous iterations of. When it comes to ease of use and size, the slider design performs best as although it encompasses 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. And 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. For the slider design it will be created with a MR-compatible material (non-ferrous), HDPE (High Density Polyethylene), which will be the structural material. This slider design will be in combination with the cable stack design. This resistance design will implement ceramic weights, non-ferrous pulleys made of HDPE, and a Dyneema cable.

Proposed Fabrication and Testing:

Materials:

The primary structural components of the slider and cable stack, responsible for supporting the leg extension mechanism and cable stack, will be constructed using High-Density Polyethylene (HDPE). This choice is rooted in the material's robust mechanical properties, including high strength and impact resistance, ensuring the structural integrity of the device during leg extension movements [33]. The slider's rails, crucial for smooth leg extension, again will be crafted from High-Density Polyethylene (HDPE). This will provide a low friction material in which the user can extend and contract their leg.

The cable stack mechanism in our design will incorporate ceramic weights to optimize performance and ensure Magnetic Resonance Imaging (MRI) compatibility. The use of ceramics combines durability with the essential quality of being non-ferrous, aligning with the requirement of being MR-Compatible. The chosen cable material, Dyneema, is made of ultra-high-molecular-weight polyethylene (UHMWPE) fiber, ensuring resilience and smooth operation while avoiding any magnetic interference with MRI equipment [34]. High-Density Polyethylene (HDPE) will be employed for the pulleys, leveraging its robust mechanical properties to ensure durability and smooth operation in the slider mechanism [35]. To provide resistance we will use Ceramic weights in increments of 5 lbs. These weights are non-ferrous allowing for MR-Compatibility as well as easy adjustability.

Methods:

To fabricate the slider design we will be utilizing the team lab machines to cut our HDPE. The main machines we will use will be the band saw, drill press, and hand tools. We will assemble the structure using non-ferrous screws and epoxy. This will be the same process for the structural components of the cable stack/pulley system. For the pulleys we will create using the 3D printers in order to achieve accuracy as they have more complex geometry.

Testing:

Load testing will be a crucial aspect, involving subjecting the device to varying weights and stress levels to assess its structural integrity and weight-bearing capacity. Additionally, SolidWorks simulations will be employed to virtually analyze the mechanical behavior of the components, predicting stress points and potential areas of improvement. These simulations will offer valuable insights into the device's performance under different conditions before physical testing begins. Practical testing will involve real-time assessments with subjects engaging in leg extension exercises to evaluate the device's functionality, comfort, and the consistency of hamstring activation. Feedback will be collected to address any ergonomic concerns. Moreover, durability tests, including repetitive motion and environmental stress, will be conducted to ensure the longevity of the device.We will also put the device through MRI-Compatibility testing using a hand magnet to ensure the device will be safe in the MRI machine.

Discussion:

The primary implication of the results is a determination of if a previous hamstring injury affects brain activity during stimulus of the hamstring in a loading scenario. There are several studies that have looked into the effect on the hamstring itself but not on brain activity. Additionally, much of the literature found was not conducted in an MR environment. However, as stated in the Background section of the report, a study at Emory was conducted in a very similar manner, other than the fact that this study was not conducted under constant tension. Therefore, the device to be fabricated will improve upon this experimental design as it will examine the effects under this novel constraint.

In order to ensure the universality of the design, there were several considerations made. The first was making the mount of support for the knee adjustable, as this will account for individuals who may have suffered a lower extremity injury and need more support when conducting the movements in the study. Additionally, the adjustability in the amount of weight is extremely important as it allows for the device to be adjusted to meet the 20 % of maximal hamstring activation in a large population.

Based on the team’s evaluation of the design once fabricated, changes will be made as necessary to the design. For example, should a material not pass the MRI test, this material will have to be replaced as it will represent a major safety hazard within the context of the MR room.

Additionally, should any of the major portions of the design fail, either in terms of resistance or mechanical factors, that part of the design must be reworked to some extent.

The main source of error that could affect the device are the calculations done prior to the fabrication and determination of materials as a result of this. This is because should the free body diagram, or the forces calculated from that be wrong, it will affect how well the design will be able to meet the criteria set forth by the client at the beginning of the project. Something that may affect this is if the slider does not run on a fully frictionless track, as this will change the calculations and potentially affect the resistance needed.

Conclusion:

In order to measure f-MRI results during the activation of injured or previously injured hamstrings, we are creating a slider design to provide resistance allowing for isolated hamstring activation. This design allows for a heel slide motion under a 20-30% load via a cable weight stack that is capable of being in a MR environment. We concluded that this slider design and resistance design would be the most effective combination allowing us to reach all client requirements and allow us the ability to fabricate a fully working prototype within the semester. In terms of future work on the project we need to first finalize the prototype within SolidWorks and confirm our design will work within the context of the GE Magnus MRI scanner. This will be coincided by material selection/ordering then fabrication. Following the fabrication of both the slider and the cable stack system we will move into functionality testing, load testing, and implement any changes required.

References:

[1] C. R. Criss, J. A. Onate, and D. R. Grooms, “Neural activity for hip-knee control in those with anterior cruciate ligament reconstruction: A task-based functional connectivity analysis,” Neuroscience Letters, vol. 730, p. 134985, Jun. 2020, doi: 10.1016/j.neulet.2020.134985

[2] M. A. Sherry, T. S. Johnston, and B. C. Heiderscheit, “Rehabilitation of acute hamstring strain injuries,” Clin Sports Med, vol. 34, no. 2, pp. 263–284, Apr. 2015, doi: 10.1016/j.csm.2014.12.009.

[3] G. Tokutake, R. Kuramochi, Y. Murata, S. Enoki, Y. Koto, and T. Shimizu, “The Risk Factors of Hamstring Strain Injury Induced by High-Speed Running,” Journal of Sports Science & Medicine, vol. 17, no. 4, p. 650, Dec. 2018.

[4] J. DeWitt and T. Vidale, “RECURRENT HAMSTRING INJURY: CONSIDERATION FOLLOWING OPERATIVE AND NON‐OPERATIVE MANAGEMENT,” International Journal of Sports Physical Therapy, vol. 9, no. 6, p. 798, Nov. 2014.

[5] M. Torres-Velázquez, C. M. Wille, S. A. Hurley, R. Kijowski, B. C. Heiderscheit, and A. B. McMillan, “MRI radiomics for hamstring strain injury identification and return to sport classification: a pilot study,” Skeletal Radiol, vol. 53, no. 4, pp. 637–648, Apr. 2024, doi: 10.1007/s00256-023-04449-7.

[6]“Neuroscience Research | Emory School of Medicine.” Accessed: Feb. 29, 2024. [Online]. Available:https://med.emory.edu/departments/orthopaedics/research/sparc/imaging-research.html

[7]“Functional Magnetic Resonance Imaging (fMRI),” Thesen Lab. Accessed: Feb. 29, 2024. [Online].Available:https://med.nyu.edu/thesenlab/research-0/research-functional-magnetic-resonance-imaging-fmri/

[8] “Marsh Bellofram - Bellofram Rolling Diaphragm Design Manual - Marsh Bellofram - Page - PDF Catalogs | Technical Documentation | Brochure.” Accessed: Feb. 29, 2024. [Online]. Available: https://pdf.directindustry.com/pdf/marsh-bellofram/marsh-bellofram-bellofram-rolling-diaphragm-design- manual/11788-27709-_5.html

[9] “Impact of exercise selection on hamstring muscle activation”, Accessed: Jan. 31, 2024. [Online]. Available: https://core.ac.uk/reader/159507467?utm_source=linkout

[10] “Hamstring injury - Symptoms and causes,” Mayo Clinic. Accessed: Mar. 07, 2024. [Online].Available:https://www.mayoclinic.org/diseases-conditions/hamstring-injury/symptoms-causes/syc-20372985

[11] M. Surdyka, “How to Perform Nordic Hamstring Curls,” E3 Rehab. Accessed: Mar. 07, 2024. [Online]. Available: https://e3rehab.com/how-to-perform-nordic-hamstring-curls/

[12] Bisciotti, Gian Nicola, et al. “Return to Training and Return to Play Following Hamstring Injury.” Return-to-Play after Lower Limb Muscle Injury in Football: The Italian Consensus Conference Guidelines, edited by Gian Nicola Bisciotti et al., Springer International Publishing, 2022, pp. 55–59, https://doi.org/10.1007/978-3-030-84950-4_9.

[13] “Biceps Femoris,” Physiopedia. Accessed: Mar. 07, 2024. [Online]. Available: https://www.physio-pedia.com/Biceps_Femoris

[14] “Tendon Biomechanics,” Physiopedia. Accessed: Mar. 07, 2024. [Online]. Available: https://www.physio-pedia.com/Tendon_Biomechanics

[15] “Forces and Torques in Muscles and Joints | Physics.” Accessed: Mar. 07, 2024. [Online]. Available:https://courses.lumenlearning.com/suny-physics/chapter/9-6-forces-and-torques-in-muscles-and-joints/

[16] H. D. Dave, M. Shook, and M. Varacallo, “Anatomy, Skeletal Muscle,” in StatPearls, Treasure Island (FL): StatPearls Publishing, 2024. Accessed: Mar. 07, 2024. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK537236/

[17] S. Y. Bershitsky et al., “Muscle force is generated by myosin heads stereospecifically attached to actin,” Nature, vol. 388, no. 6638, pp. 186–190, Jul. 1997, doi: 10.1038/40651.

[18] “The Central Nervous System – Scottish Acquired Brain Injury Network.” Accessed: Feb. 29, 2024.[Online]. Available:https ://www.acquiredbraininjury-education.scot.nhs.uk/impact-of-abi/physical-impairments-related-to-movement/normal-movement-and-movement-following-acquired-brain-injury/the-central-nervous-system/

[19]“Movement related artifacts" ResearchGate. Accessed: Mar. 07, 2024. [Online]. Available: https://www.researchgate.net/figure/Movement-related-artefacts-This-figure-shows-the-typical-motion-artefact-present-during_fig1_11954127

[20] Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. https://www.astm.org/f2503-20.html. Accessed 8 Feb. 2024.

[21] IEC 60601-1-2:2014 | IEC Webstore | Electromagnetic Compatibility, EMC, Smart City. https://webstore.iec.ch/publication/2590. Accessed 8 Feb. 2024.

[22]“1910.304 - Wiring design and protection. | Occupational Safety and Health Administration,” www.osha.gov. https://www.osha. gov/laws-regs/regu lations/standardnumber/1910/1910.304

[23] P. A. Bottomley, “Turning Up the Heat on MRI,” J Am Coll Radiol, vol. 5, no. 7, pp. 853–855, Jul. 2008, doi: 10.1016/j.jacr.2008.04.003.

[24] “Crawford, Scott,” Kinesiology. Accessed: Feb. 29, 2024. [Online]. Available:https://kinesiology.education.wisc.edu/fac-sta ff/crawford-scott/

[25] “Meyerand, PhD, Beth,” McPherson Eye Research Institute. Accessed: Feb. 29, 2024. [Online]. Available: https://vision.wisc.edu/staff/beth_meyerand/

[26] Giakoumis, Michael, et al. “Eccentric Hamstring Strength in Elite Track and Field Athletes on the British Athletics World Class Performance Program.” Physical Therapy in Sport, vol. 43, May 2020, pp. 217–23, https://doi.org/10.1016/j.ptsp.2020.03.008.

[27] Sammet, Steffen. “Magnetic Resonance Safety.” Abdominal Radiology (New York), vol. 41, no. 3, Mar. 2016, pp. 444–51, https://doi.org/10.1007/s00261-016-0680-4

[28] “Slice Blog,” blog.sliceproducts.com. https://blog.sliceproducts.com/blog/mri-compatib le#:~:text=Some%20common%20materials%20that%20are%20MRI (accessed Feb. 07, 2024).

[29] G. Crowley, “Control-X – Phoenix – Elevating Radiographic Table,” Advanced Medical X-ray, Mar. 24, 2016. https://cr-pacs.com/phoenix-elevating-radiographic-table/ (accessed Feb. 08, 2024).

[30] “Wall Mounted Cable Column | Strength Training | BLK BOX.” Accessed: Feb. 29, 2024. [Online]. Available: https://www.blkbo xfitness.com/products/bl k-box-wall-mo unted-cable-colu mn

[31] “Coefficient Of Static Friction - Definition, formula, S.I Unit, Explanation,” BYJUS. Accessed: Feb. 29, 2024. [Online]. Available: https://byjus.com /physics/coefficie nt-of-static-friction/

[32]“Amazon.com: THERABAND Resistance Band 50 Yard Roll, Medium Red Non-Latex Professional Elastic Bands For Upper & Lower Body Exercise, Physical Therapy, Pilates, & Rehab, Dispenser Box, Beginner Level 3 : Sports & Outdoors.” Accessed: Feb. 29, 2024. [Online]. Available: https://www.ama zon.com/THERABAND- Resistance-Non-Latex-Prof essional-Dispenser/dp/B00EAR6 Q02/ref=asc_df _B00EAR6Q02 /?tag=hyprod-20 &linkC ode=df0&hv

[33] ACME Plastics, “What is High Density Polyethylene (HDPE)? | Acme Plastics,” Acmepla stics.com, 2020. https://www.acmeplastics.com/what-is-hdpe

[34] “Dyneema® Fiber | Pelican Rope,” pelicanrope.com. https://pelican rope.com/rope-by-fib er/dyneema/ (accessed Mar. 06, 2024).

[35] ACME Plastics, “What is High Density Polyethylene (HDPE)? | Acme Plastics,” Acmepla stics.com, 2020. https://www.acmeplastics.com/what-is-hdpe

Appendix A - Materials List

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Heel Slider										
HDPE	Plastic Sheet: 0.5 in Thick, 12 in W x 48 in L, Black, Opaque, 4,600 psi Tensile Strength	Zoro	1ZAX7	Grainger	1ZAX7	N/A	2	$49.38	$98.76	Grainger
Epoxy	J-B WELD Epoxy Adhesive: KwikWeld, Ambient Cured, 10 fl oz, Tube, Dark Gray, Paste	J-B WELD	8271	Grainger	14G802	N/A	1	$23.17	$23.17	Grainger
PLA	PLA is a 3D printable material measured in grams	N/A	N/A	Makerspace	N/A	N/A	50	$0.08	$4.00	Makerspace
Felt	Wool felt strip with acrylic adheseive	Zoro	2FGZ7	Grainger	2FGZ7	N/A	1	$0.14	$0.14	Grainger
HDPE Rod	Plastic Rod: 8 ft Plastic Lg, Off-White, Opaque, 4,500 psi Tensile Strength, 2.75 ft-lb/in	Grainger	22JL41	Grainger	22JL41	N/A	1	$19.00	$19.00	Grainger
Synthetic Winch Line	Synthetic line with tensile stregth of 10,000 lbs. Used for cable. 50 ft	Ucreative	Mfr	Amazon	Mfr	N/A	1	$19.99	$19.99	Amazon
								TOTAL:	**$165.06**	

Appendix B - General Fabrication Procedure

1. Slider Design
    a. Order materials from respective vendors
    b. Using SolidWorks, create part drawings
    c. Following dimensions on SolidWorks drawing mark cuts
        i. Use of bandsaw to make cuts
    d. Mark all screw and assembly holes
        i. Use of drill press
    e. Organize parts for assembly
        i. Use epoxy to assemble
2. Cable Stack and Pulley
    a. Using SolidWorks mark dimensions on HDPE
        i. Use of bandsaw to make all cuts
    b. Mark all screw and assembly holes
        i. Use of drill press
    c. Organize parts for assembly
        i. Use of epoxy to assemble
3. Final Assembly
    a. Join the slider design and cable stack together for functionality testing
    b. Make sure all fasteners line up with GE MAGNUS MR Table

Appendix C- 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 the team decides to implement resistance (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 our 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 our 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 our 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].

References

[1] C. R. Criss, J. A. Onate, and D. R. Grooms, "Neural activity for hip-knee control in those with anterior cruciate ligament reconstruction: A task-based functional connectivity analysis," Neuroscience Letters, vol. 730, p. 134985, Jun. 2020, doi: 10.1016/j.neulet.2020.134985

[2] Sammet, Steffen. "Magnetic Resonance Safety." Abdominal Radiology (New York), vol. 41, no. 3, Mar. 2016, pp. 444–51, https://doi.org/10.1007/s00261-016-0680-4

[3] "Access Restriction." *UCSF Radiology*, 20 Jan. 2016, https://radiology.ucsf.edu/patient-care/patient-safety/mri/access-restriction.

[4] What's the Ideal Temperature in a Hospital? Automatic Controls.https://automaticcontrols.net/whats-the-ideal-temperature-in-a-hospital/. Accessed 6 Feb. 2024.

[5] "MRI." Waisman Center, https://www.waisman.wisc.edu/brain-imaging/mri/. Accessed 8 Feb. 2024.

[6] Giakoumis, Michael, et al. "Eccentric Hamstring Strength in Elite Track and Field Athletes on the British Athletics World Class Performance Program." Physical Therapy in Sport, vol. 43, May 2020, pp. 217–23, https://doi.org/10.1016/j.ptsp.2020.03.008.

[7] Neuroscience Research | Emory School of Medicine. https://med.emory.edu/departments/orthopedics/research/sparc/imaging-research.html. Accessed 6 Feb. 2024.

[8] G. Crowley, “Control-X – Phoenix – Elevating Radiographic Table,” Advanced Medical X-ray, Mar. 24, 2016. https://cr-pacs.com/phoenix-elevating-radiographic-table/ (accessed Feb. 08, 2024).

[9] “What is the standard interior door size? Nominal and Actual sizes at Door Design Lab,” Door Design Lab. Accessed: Feb. 08, 2024. [Online]. Available: https://doordesignlab.com/door-sizes

[10] “OSHA procedures for safe weight limits when manually lifting | Occupational Safety and Health Administration,” www.osha.gov. https://www.osha.gov/laws-regs/standardinterpretations/2013-06-04-0

[11] “Slice Blog,” blog.sliceproducts.com. https://blog.sliceproducts.com/blog/mri-compatible#:~:text=Some%20common%20materials%20that%20are%20MRI (accessed Feb. 07, 2024).

[12] A. Silder, C. J. Westphal, and D. G. Thelen, “A Magnetic Resonance-Compatible Loading Device for Dynamically Imaging Shortening and Lengthening Muscle Contraction Mechanics,” Journal of Medical Devices, vol. 3, no. 3, Sep. 2009, doi: https://doi.org/10.1115/1.3212559.

[13] *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*. https://www.astm.org/f2503-20.html. Accessed 8 Feb. 2024.

[14] *IEC 60601-1-2:2014 | IEC Webstore | Electromagnetic Compatibility, EMC, Smart City*. https://webstore.iec.ch/publication/2590. Accessed 8 Feb. 2024.

[15] 14:00-17:00. “ISO 10993-1:2018.” *ISO*, https://www.iso.org/standard/68936.html. Accessed 8 Feb. 2024.

[16] 14:00-17:00. “IEC 62366-1:2015.” *ISO*, https://www.iso.org/standard/63179.html. Accessed 8 Feb. 2024.

[17] Silder, Amy, et al. “A Magnetic Resonance-Compatible Loading Device for Dynamically Imaging Shortening and Lengthening Muscle Contraction Mechanics.” *Journal of Medical Devices*, vol. 3, no. 3, Sept. 2009, p. 10.1115/1.3212559, https://doi.org/10.1115/1.3212559.

[18] Bajaj, Aryan. *6 Best Gym Machine Exercises For Hamstrings*. 28 Aug. 2022, https://www.sportskeeda.com/health-and-fitness/6-best-gym-machine-exercises-for-stronger-hamstrings.

[19] USPTO.report. “Hamstring Stretching Device and Method.” *USPTO.Report*, https://usptoreport/patent/grant/5,634,873. Accessed 8 Feb. 2024.

[20] *CrossFire Contralateral Hamstring Device* |. https://exerbotics.com/crossfire-hamstring/. Accessed 8 Feb. 2024.