# Product Design Specifications: Lower Extremity Loading Device During Magnetic Resonance Imaging

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*BME 301: Lab Section 302*

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## Table of Contents:

**Function:** 3
**Client Requirements:** 3
**Design Requirements:** 4
- **1. Physical and Operational Characteristics:** 4
  - a. Performance Requirements: 4
  - b. Safety: 4
  - c. Accuracy and Reliability: 5
  - d. Life in Service: 5
  - e. Shelf Life: 5
  - f. Operating Environment: 5
  - g. Ergonomics: 5
  - h. Size: 6
  - i. Weight: 6
  - k. Materials: 6
  - l. Aesthetics, Appearance, and Finish: 6
- **2. Production Characteristics:** 7
  - a. Quantity: 7
  - b. Target Product Cost: 7
- **3. Miscellaneous:** 7
  - a. Standards and Specifications : 7
  - b. Customer: 8
  - c. Patient-Related Concerns: 8
  - d. Competition: 8

**References** 11

## 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 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.

## 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.
- 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 5.0 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]. Some potential materials would be polyethylene for structure and use of ceramic weights or elastic resistance bands [12].

*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 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].

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