An MRI-Compatible Leg Exercise Device for Assessing Cerebral Blood Flow Responses to Exercise

Mid-Semester Report

March 9, 2011

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Client

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Advisor

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Abstract

Our client, Dr. William Schrage, is an Assistant Professor of Kinesiology for the University of Wisconsin – Madison and a part of the Cardiovascular Research Center as a specialist in vascular biology. He has proposed a study that examines changes in cranial blood flow during patient exercise. This study incorporates the utilization of a Magnetic Resonance Imaging (MRI) device in order to view cranial blood flow and blood vessel diameters. Our clients have proposed that we develop a non-ferromagnetic exercise device that will allow a patient to exercise while undergoing a MRI scan. After testing past designs, we determined a pulley device was the best and begun prototyping the design. Throughout the remainder of the semester we hope to continue refining the prototype and finally build a non-ferromagnetic finished product.

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Background

Client Description

Dr. William Schrage is an Assistant Professor of Kinesiology for the School of Education at the University of Wisconsin – Madison[1]. His research focuses on how muscle blood flow is controlled during exercise. He is also investigating how cardiovascular conditions caused by aging or high blood pressure can change or impair blood flow. Our client is interested in determining if regular physical activity improves blood flow and blood vessel function and uses both human and animal models. Dr. Schrage is also affiliated with the Cardiovascular Research Center at the University of Wisconsin – Madison, where he focuses on vascular biology.

Throughout Dr. Schrage's career he has published work in numerous peer-reviewed journals and is currently interested in studying how cranial blood flow changes during exercise. As cranial blood flow is best observed with a magnetic resonance imaging (MRI) device, any exercise device used must be MRI-compatible. A wide range of patients are to use this device and so it must fit a range of heights and fitness levels. Consequently, our client has proposed that we design an exercise device that increases the heart rate to 120-130 beats per minute (bpm), the typical working heart rate, while a patient is within an MRI.

Current Devices

Marketed Devices

The MRI compatible exercise devices produced by Lode BV are the main competition to our device. The Lode Ergometer products are utilized by many studies but each product has several shortcomings[6,7]. GE scanners have smaller bore sizes than Phillips and Siemens brand scanners, and so the cycling ergometer is not compatible with GE scanners and the MRI

Ergometer Push/Pull is not compatible with the newest GE scanners. Additionally, Lode Ergometers are priced near $50,000, limiting availability to researchers[3].

Past Prototypes

Three MRI compatible exercise devices have been created. The first, built by a BME Design group in Fall 2009, utilized a cycling motion to create the resistance necessary to elevate heart rate and is shown in Figure 1. This prototype was designed to be used while a patient was receiving a chest MRI, which severely limited the range of motion within which a patient could exercise. The range of motion was so impeded that most patients were unable to exercise within the MRI bore using the cycling device, rendering the device useless for chest imaging during exercise.

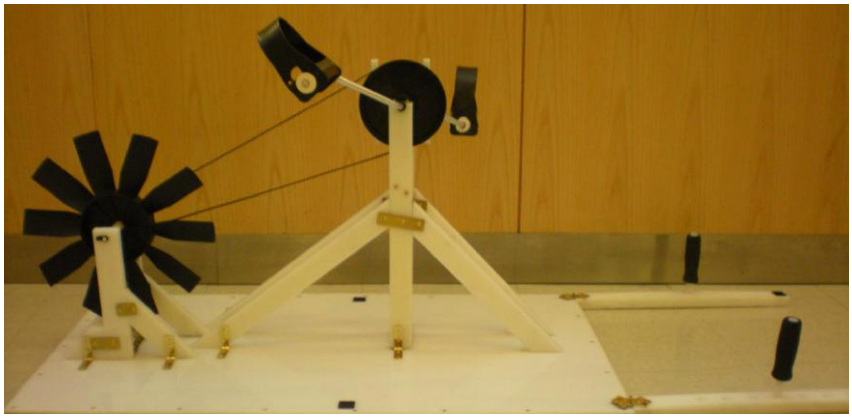

Figure 1: Picture of Fall 2009 Design

The user's feet are affixed to pedals and rotate in a cyclic motion similar to the motion of riding a bike. Handholds, shown on the right, can be used by the patient for increased stability and comfort.

The BME design team altered the design for Spring 2010 and developed a stepping exercise device, shown in Figure 2, that could be used while performing a chest MRI scan. Resistance bands attached to pedals were used to increase the heart rate of a patient and two hand grips were included to assist in patient stability and improve patient

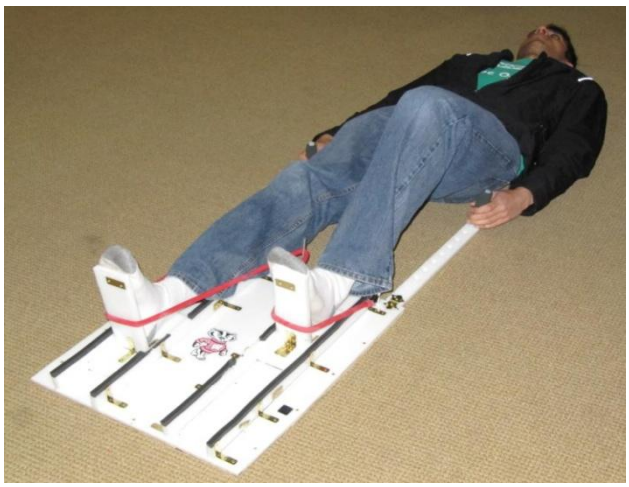

Figure 2: Picture of the Spring 2010 Design

The user exerts force downward against foot braces to work muscles and increase the heart rate. The foot braces are attached to tracks to ensure controlled movement.

comfort. This design required a minimal range of motion within the MRI but did not utilize the principles of dynamic exercise or create a natural-feeling movement. Additionally, significant forces were exerted along the anteroposterior body axis so if utilized, this device could create enough artifact in MRI images so that the images are rendered unusable.

The Fall 2010 BME design team created an exercise device that allowed patients to exercise while receiving a head MRI. The head MRI scan leaves the legs of most patients outside of the MRI bore, thus increasing the range of potential exercise movements.

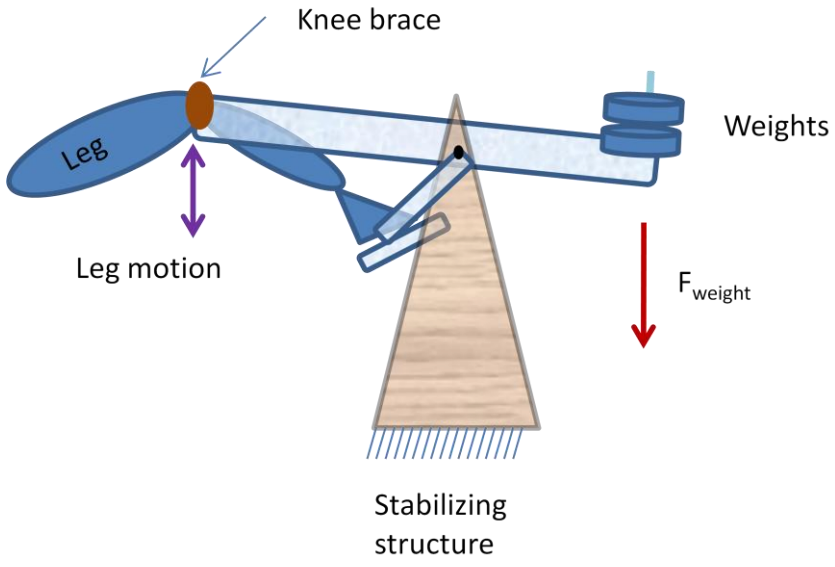

Figure 3: Diagram of the Fall 2010 Design

The knee is attached to a large lever with weights at the opposite end. Each foot is supported at a platform that stabilizes the leg while in motion.

This design consisted of two pivoting levers with weights attached at one end, as shown in the schematic in Figure 3. The lever design used the principles of dynamic exercise and minimized forces applied along the anteroposterior body axis in order to minimize head movement and MRI artifact. However, this design did not allow a patient to exercise with a natural feeling motion. Upon analysis, this device was found to create the greatest acceleration when the knee is at the highest and lowest points during exercise. To counter this acceleration and prevent knee hyperextension, patients were forced to generate the greatest amounts of force at the highest and lowest point of the motion, which correspond to areas where the major leg muscles are highly contracted or extended. Highly extended or

contracted muscles produce relatively small amounts of force, and so during exercise patients were unable to exercise efficiently and increase their heart rate to 120-130 bpm[2].

Problem Motivation

Magnetic Resonance Imaging (MRI) is a crucial component of the medical field; it provides a deeper insight into the workings of the human body and allows researchers to observe blood flow and other bodily processes in greater detail than alternative methods would allow. Exercise-induced increased cerebral blood flow can be analyzed to determine if cerebral blood flow patterns differ in patients suffering from obesity or pre-diabetes. MRI can then be used to study global cerebral blood flow patterns and blood vessel diameter[6]. Currently, one MRI compatible exercise device is marketed but its high cost limits availability to researchers and the device does not allow the user to exercise while inside the MRI machine. Instead, the device is used to elevate the heart rate prior to scanning; the patient is quickly pushed into the MRI and scanned after exercise ends. This method is not optimal, as the heart rate returns to its original pace within a period of minutes, and MRI scans are typically ten to fifteen minutes in length. Our client would like to be able to measure the effects of exercise on blood flow during patient exercise, so the final device must be non-ferrous, MRI compatible, portable, and cost-effective. Our client has reported many researchers wish to perform MRI scans on patients with elevated heart rates, so the device must also be marketable and patentable in order to make it available to a wide range of researchers.

Design Requirements

The design requirements outlined in the Project Design Specifications in the Appendix and are explained in detail here. The device must not cause muscle strain or damage, as it will be used by patients to exercise with for extended periods of time while within the MRI. All

materials must be non-ferromagnetic to be compatible with the MRI and comply with the standards of the Food and Drug Administration.

In addition to essential safety requirements, the design must also meet a set of performance standards set forth by our client. The final design of our device should have a life in service of the duration of the study, which is approximately three years. The device must be easily disinfected and usable by patients 5’4” to 6’4” tall. The flywheel resistance must be adaptable to different fitness levels in order to raise the heart rate to 120-130bpm in all patients. Forces along the anteroposterior body axis must be minimized in order to decrease movement artifact in MRI images and the device must produce a natural feeling exercise motion in order to maximize patient comfort.

The product must be as lightweight as possible without impeding functionality or usability as it is to be positioned on the MRI bed with the patient. If the final product is too heavy, the upper weight limit of the MRI bed could limit device users to patients under a certain maximum weight. The device must fit securely onto the MRI bed, which is 25.5 inches in width and 64 inches in length. While exercising, the patient must not come into contact with the MRI bore, as this could cause discomfort to the patient or damage to the MRI or the exercise device.

Patient comfort is a major factor regulating the usability of our device. A large portion of patients become claustrophobic while undergoing a MRI scan, and patients under the additional stress of exercise may become claustrophobic faster than an average patient. The device should therefore limit straps or other restrictive devices in order to lessen patient duress during the MRI scan. In order to create a more natural feeling method of exercise, acceleration should be minimized when the leg muscles are most extended or contracted. This will allow patients to exercise with the greatest amount of force when leg muscles are of medium length and able to

generate the greatest amount of force, and will address the non-natural feeling motion of the previous design.

Design Alternatives

Prior to building and testing a chosen design, three potential product designs were created and evaluated. Each design utilized dynamic exercise and attempted to minimize forces along the anteroposterior body axis.

Beam Design

The beam system design, shown in Figure 4, uses several non-ferromagnetic metal beams that are linked in such a way so patients would be able to exercise by extending and contracting the legs. Resistance would be provided by concrete-based or sand-based weights attached to the

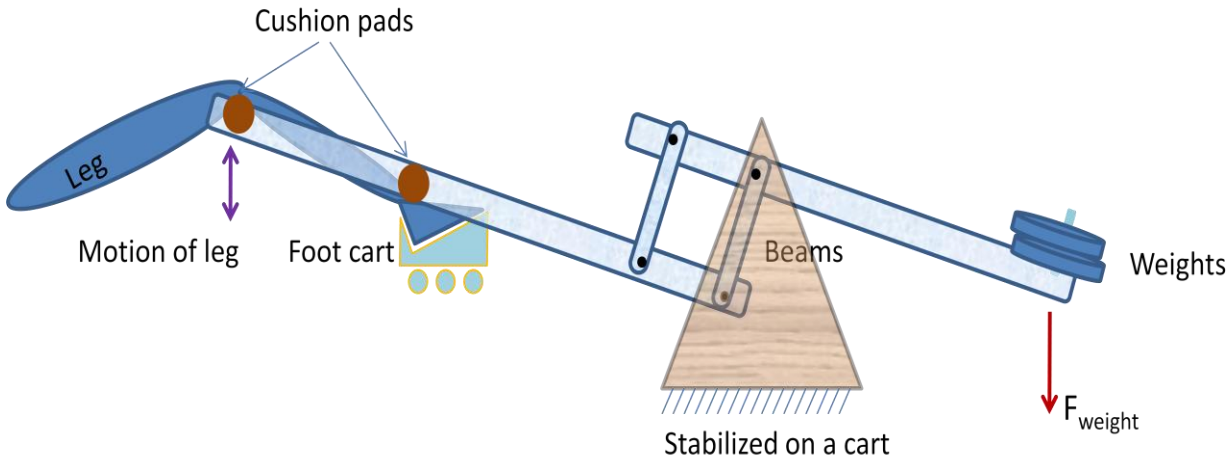

Figure 4: Beam System Diagram
The system consists of beams, a stabilizing structure, and foot cart. The beam structure transmits gravitational force generated by the weights to the knees of the patient. The foot cart eliminates friction force acting on the horizontal direction.

end of the main beams. The weights could be easily changed, providing different levels of resistance to patients with different fitness levels. The main beam would be attached to the leg at the knee, so patients would be able to utilize the quadriceps and hamstrings to work against the weights. The beam structure would transmit gravitational force generated by the weights to the

knees of the patient. A foot cart would eliminate friction force acting on the horizontal direction and ensures forces are limited to the vertical direction. The stabilizing structure would be assembled on a portable cart that could slide onto the MRI bed.

Pulley Design

The pulley system utilizes pulleys, a connection mechanism, and a fly-wheel that generates resistance to allow patients to exercise. This design also contains a rail track system that eliminates frictions on patients' feet while their legs are exercising. The design is shown in Figure 5. The pulleys transform the vertical motion generated by patients' legs into circular motion in the flywheel. The use of a flywheel will allow the legs to move in a sinusoidal rhythm and mimic the natural-feeling motion produced by an exercise bike. This will also allow the user to adjust the device to an individual rate of exercise, which will improve patient comfort and mimic other commonly used exercise devices. Inertia generated by the flywheel will cause the device to move whether the patient is exerting a vertical force or not; this will provide the user with a smoother exercise experience. A rubber break or resistance band on the fly-wheel system will generate resistance and allow researchers to adjust the work load on patients.

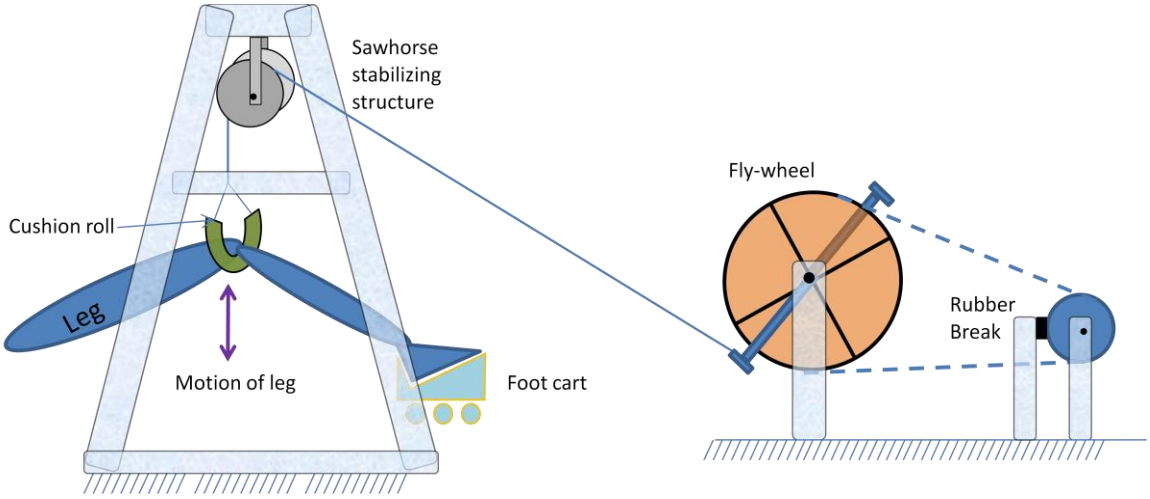

Figure 5: Pulley System Diagram

The system consists of pulley, a stabilizing structure, a fly-wheel system and foot cart.

Spring Design

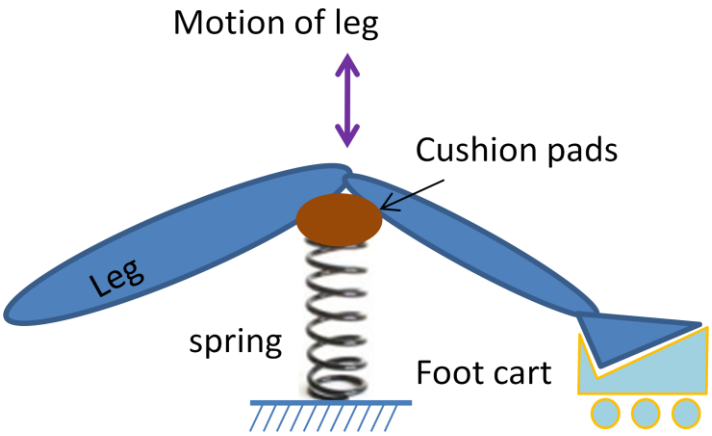

Figure 6: Pulley System Diagram

The system consists of two springs attached to a baseboard and a foot cart. Cushioned pads or braces are attached to each spring, allowing the patient to depress the spring to perform exercise.

The spring system uses springs located under the knees of the patients. Cushion pads or individual knee braces are placed on the top of the two springs ensure a soft and comfortable contact of the patients' knees and the springs. This design is shown in Figure 6. This is a relatively simple design that only consists two springs, one for each leg, and two foot carts, one for each foot. Springs could be adjusted in order to control the work-load of the patient. The springs would provide a resistance load similar to resistance bands used in other forms of exercise.

Design Matrix

Each preliminary design had its own strengths and weaknesses in comparison to the others. To effectively evaluate the individual points of each design, a design matrix was constructed and used to analyze each preliminary design.

The three leg exercising mechanisms were rated on a variety of design criteria. These aspects were selected because of their importance in an effective design. It was determined that certain criteria, such as effectiveness, safety, and patient comfort, were more significant, and therefore were weighed more heavily. The scores for each design in each category were added up to give a total score out of 100, which is shown in Table 1. Based on the point breakdown

shown below, the pulley design received the largest allotment of points and we have chosen to pursue prototyping and developing the pulley design.

Table 1: Design Matrix

The maximum point values are indicated in parentheses in the row headings. The point allotment will be discussed in the proceeding analysis.

Weight	Criteria	Beam system	Pulley system	Spring system
25	Effectiveness	22	23	18
20	Safety	15	18	13
20	Patient comfort	15	17	10
15	Portability	12	10	14
10	Cost	8	8	10
10	Durability	6	6	8
100	**Total**	**78**	**82**	**73**

Effectiveness

Effectiveness is defined as the ability of the exercising devise to give a constant resistance to patients and allow patients to elevate their heart rate around 120 beats per minute through exercise. This criterion is also defined as the adjustability of the design. It was given a weight of 25 points in the matrix, designating it as the most important category, because it determines the ultimate performance of the exercising devises. The pulley system design scored highest and received 23 points while the beam system second-highest with 22 points. The pulley system was allotted an additional point as the inertia generated by the flywheel will improve the overall smooth motion of the pulley system and allow patients to exercise in a more dynamic manner. The spring system was given the fewest points it would be more difficult to adjust the

resistance provided by the spring system than to adjust the resistance provided by the pulley system or beam system.

Safety

The final design of the device must also take safety into account. As a result of involvement of MRI scanning, the design must be safe to be used near MRI. Safety was allotted 20 points in the matrix, as a design that injures the patient or could cause damage to the MRI machine must be avoided. A safe design requires that all of the components are fabricated of non-ferromagnetic materials and that the design provides natural feeling motion to patients. The pulley system design scored highest, receiving 18 points, as the sinusoidal motion produced during exercise will feel natural to the patient. Additionally, the inertia generated by the flywheel will maintain a level of motion that will eliminate the sub-optimal contractions caused by the Fall 2010 design. The beam design received a lower score of 15 points, as the long beams required to clear the MRI bed would provide a hazard to MRI operators while the exercise device is in motion and because the device could cause muscle damage over long periods of time in a similar fashion to the Fall 2010 design. As it would be difficult to fabricate the spring system design out of non-ferromagnetic materials, the spring system received the lowest score of 13 points.

Patient Comfort

Patient comfort is an additional concern when designing different prototypes and as such was given 20 total points. It was determined to be as significant as safety, and was thus weighted the same. Many patients experience claustrophobia and an increased heart rate while within an MRI scan and an exercise-induced increased heart rate could cause increased patient discomfort and mental duress. Thus, it is imperative to design a device that will maximize patient comfort

by utilizing a natural feeling motion, rather than solely concentrating on what will raise the heart rate in the most efficient manner. The pulley system received a score of 17 in this category, as it will provide patients with a comfortable sinusoidal motion similar to the motion produced when riding a bike. The beam system received the slightly lower score of 15, as patients would experience more discomfort where the knee attaches to the beam and because the beam requires patients to exercise with an unfamiliar motion. The spring design received the lowest score of 10 points in this category, as patients will experience a large amount of force over a small area of the knee, thus likely leading to discomfort at the knee after long periods of exercise.

Portability

In conjunction with the request of our client, another component of the design matrix is portability. The final design cannot be stored within the MRI room and no modifications can be made to the MRI room itself, so each time a researcher utilizes the device it must be transported from a storage facility to the MRI suite. The MRI machine is often fully booked on any given day so device setup must be minimal in order to provide researchers with the maximum amount of scanning time. Portability was given 15 total points, as it is important to our client but not the most important category. The spring system was given the fourteen points for portability, as it was concluded that the device would not consist of much more than two springs attached to a rolling bed and two foot carts and one researcher would be able to transport the spring system with ease. The beam system would be large but consist of one apparatus and be simple for two researchers to transport and set up, so it was allotted 12 points. The pulley system would consist of two separate apparatuses, the actual stabilizing structure and the flywheel, and so would require two researchers or a cart to transport the device. For this reason the pulley system was allotted only 10 points.

Cost

In order to make the device marketable and available to a wide variety of researchers, it must be cost effective. This design should have a low cost but use strong and durable materials. As any device developed is likely to be well under the price of the currently marketed device, cost is less important and was given 10 points. As the pulley system and beam system both contain a greater number of components, they were each given eight points. The spring system consists of few components and so is thought to be the most cost-effective, so we gave it a perfect 10 points.

Durability

As previously stated and requested by our client, the final device must be usable for the duration of the study, at least three years. Thus, durability must be included in the design matrix, but as parts are replaceable is not a significant contributor. The use of any machine over an extended period of time causes expected wear on individual parts, but the chosen device must minimize wear to every component. Durability was given 10 points in the design matrix, as it should be considered but should not be a major factor of the design. Each design alternative has different points at which expected wear will occur; the spring design has the fewest components and so has the fewest possible points of failure and was thus awarded eight points. Both the pulley design and the beam design have several points where the design requires a repetitive motion that will cause wear to the design, and were thus each allotted six points. The pulley design would likely have a failure of the inextensible cord or the pulley, while the beam design would likely have a failure at the center joints where the greatest amount of metal to metal contact occurs.

Future Work

Testing

In order to maximize our efficiency in designing a new alternative to the given problem, we found it necessary to perform preliminary testing on the prototype that was designed in Fall 2010. Table 2, Table 3, and Table contain this data. As is shown in the tables, only the first female patient was able to elevate her heart rate to 120 bpm, while the second male patient was not. It is apparent however that the ability to increase heart rate was increased with the amount of weight placed on both legs. During testing, we found this to greatly decrease the stability of the device to the point that components were actually falling off the prototype. As this is a safety hazard to researchers and patients, a safer, more stable device that can effectively raise the heart rate is required.

Time elapsed (min)	Heart rate (bpm)
0	93
2:00	103
3:10	111
4:30	110
5:30	118
6:00	115
6:30	115
7:30	120
8:30	115
9:00	116
10:00	119

Table 2: Patient 1. Female. Height: 5'5" 11lbs on each leg

.Patient exercised for ten minutes and was able to successfully raise heartbeat to 120 bpm

Time elapsed (min)	Heart rate (bpm)
0	83
1:10	98
3:15	100
4:14	98
5:00	97
5:30	101

Table 3: Patient 2. Male, Height: 6'0" 11 lbs on each leg.

Patient exercised for five minutes and was unable to successfully raise heart rate to 120 bpm.

Time elapsed (min)	Heart rate (bpm)
0	89
1:00	100
1:30	106
3:30	100
5:00	105
5:30	106

Table 4: Table 3: Patient 2. Male, 6'0" 15 lbs on each leg

Patient exercised for over five minutes and was unable to successfully raise heart rate to 120 bpm. Device failure occurred while testing.

Future testing of the fully constructed prototype will be performed in a similar manner to the testing described above. A heart rate monitor will be worn around the chest, and a digital watch will be used to record the heart rate at any given time. A test subject will then proceed to use the prototype for a duration of 10 minutes, and the heart rate will be checked and recorded once every minute. If the prototype is unable to raise the heart rate as desired, modifications will be made to improve the effectiveness of the device. Testing a wide range of users will better simulate research conditions; subjects must be chosen based on age, gender, height, and fitness levels to accurately portray the range of patients who will use this device. After the device has been established as non-ferromagnetic, the device will be tested during a MRI scan to ensure it will allow researchers to capture clear images. MRI scans are prohibitively expensive and therefore this type of testing must be performed only after a final prototype is completed.

Projected Costs

We are planning on creating and testing a pulley system with the assistance of Dr. Kreg Gruben, an Associate Professor of Kinesioligy at the University of Wisconsin – Madison. Parts cost is expected to be under $500, as the individual supplies are inexpensive and many can be purchased at local hardware stores. One primary cost will be the High Density Polyethylene used for the stabilizing structure, which is priced $\$238.97/m^2$ ($\$22.20/ft^2$). Dr. Gruben has donated many supplies to us, which may alter the final cost of the project.

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An MRI-compatible leg exercise device for assessing cerebral blood flow responses to exercise (Leg Exercise)

Project Design Specifications
03/09/2011

Group Members: Katherine Lake, Henry Hu, Kelsi Bjorklund, Jacob Stangl

Advisor: Michael Toepke, PhD

Function:

Traditionally, transcranial Doppler ultrasound can be used to measure human cerebral blood flow in response to environmental stress or exercise. Exercise-induced increased cerebral blood flow can then be analyzed to determine if cerebral blood flow patterns differ in patients suffering from obesity or pre-diabetes. Transcranial Doppler ultrasound is limited in that it only measures middle cerebral artery velocity. Magnetic Resonance Imaging (MRI) can be used to also study global cerebral blood flow patterns and blood vessel diameter, but any exercise device used in an MRI must be non-ferromagnetic. We aspire to design and test a durable, non-ferrous exercise device that utilizes dynamic exercise and that is able to raise the average patient's heart rate to 120-130bpm for a minimum of eight minutes.

Client Requirements:

- Must be non-ferromagnetic and fit on a standard MRI bed
- Must increase heart rate to 120-130bpm for a minimum of eight minutes
- Must minimize head and chest movement

1. Physical and Operational Characteristics

A. **Performance requirements**: The product must increase the heart rate of the user to 120-130bpm for a minimum of eight minutes but not allow significant movement along the anteroposterior axis.
B. **Safety**: The product must be non-ferromagnetic, stable, and safe to use in an MRI machine. The product cannot cause muscle injury in patients.
C. **Accuracy and Reliability**: The product must allow researchers to take precise and accurate images of blood vessel diameter and measure middle cerebral artery velocity.
D. **Life in Service**: The product must be usable for three years while undergoing frequent use.
E. **Operating Environment**: As the device is to be used while an MRI is in progress, no ferromagnetic materials may be used in construction.
F. **Ergonomics**: As this device will be used by a range of patients at varying heights and fitness levels, ergonomics is extremely important. The final product must allow patients to exercise using a "natural-feeling" motion. The product must also adjust to fit male and female patients of average heights, from 5'4" to 6'4". The device must

also have minimal set-up and be portable and simple for technicians and patients to operate.

G. **Size**: The product must be small enough to fit onto the standard MRI bed and should be positioned to ensure that a patient's movement during exercise is not restricted by the MRI bore.
H. **Weight**: The product should be as lightweight as possible without impeding functionality or usability as it is to be positioned on the MRI bed with the patient. A heavy product may limit the weight of potential research subjects or be difficult to transport and set up.
I. **Materials**: No ferrous materials can be used in the final product, as this device is to be used within 30 ft of a MRI. The materials that contact patients must be easily sterilized with alcohol to ensure cleanliness and allow the device to be used by multiple subjects.
J. **Aesthetics, Appearance, and Finish**: The product should be simple for both patients and researchers to use. The device should look professional and if possible, match the appearance of the MRI.

2. Production Characteristics

A. **Quantity**: One device should be constructed.
B. **Target Product Cost:** A similar prototype cost $275.50 so a new device should be under a budget of $1,000.

3. Miscellaneous

A. **Standards and Specifications:** If marketed, the final product will require the approval of the Food and Drug Administration.
B. **Customer:** The intended user is an exercise research study patient and will vary in fitness level and height. Thus, the product must be compatible with many different body types, be simple to operate, comfortable for the user and provide researchers with a way to adjust the resistance and applied workload. The product should also ensure head and neck stability in order to minimize any artifact in images captured by the MRI. Each of these requirements must be considered in designing a final product.
C. **Patient-related Concerns:** In order to be useful to researchers, the product must meet the terms of all and any Food and Drug Administration provisions relating to its design and use. It must not be harmful to the user in any way and it must allow a patient to exercise in a 'natural' motion. As multiple users are to exercise with the same device, it should be easily disinfected to prevent cross-contamination.
D. **Competition:** Similar products currently on the market do not allow a patient to exercise while being scanned and can cost upwards of $50,000, making these products ill-suited for many researchers. This device will allow researchers to observe cerebral blood flow during exercise and thus could become a competitor to these other products.