University of Wisconsin - Madison Department of Biomedical Engineering

MRI-Compatible Cardiac Exercise Device

Mid-semester Report

Nick Thate – Communicator Evan Flink - BSAC Tongkeun Lee - BWIG Andrew Hanske - Leader

Client: Professor Naomi Chesler, Department of Biomedical Engineering Advisor: Professor Willis Tompkins, Department of Biomedical Engineering

October 26, 2011

Table of Contents

| I. | Abstract | 3 |
|-------|---|----|
| II. | Problem Statement and Design Specifications | 3 |
| III. | Background Information | 4 |
| | Pulmonary Hypertension | 4 |
| | Competition and Past BME Designs | 5 |
| IV. | Previous Prototype | 7 |
| | Design | 7 |
| | Testing | 8 |
| | Problems | 9 |
| V. | Lateral Arm Stability Designs | 10 |
| | Track-Guided | 10 |
| | Block | 10 |
| | Arc-Support | 11 |
| | Design Evaluation | 12 |
| VI. | Securing Patient to Device Designs | 13 |
| | Extended Base | 13 |
| | Backpack Straps | 14 |
| | Velcro Yoga Mat | 15 |
| | Design Evaluation | 15 |
| VII. | Additional Design Improvements | 16 |
| VIII. | Future Work | 18 |
| IX. | References | 19 |
| X. | Appendix A: Product Design Specifications | 20 |

I. Abstract

The goal of this project is to develop an exercise device that can be used by patients in a magnetic resonance imaging (MRI) scanner in order to better understand and assess pulmonary hypertension. Currently, there is no device on the market that allows a patient to exercise during a cardiac MRI scan. In the previous semester, a design was created which utilized a stepping motion with adjustable weight resistance, and allowed for patients to exercise inside the MRI bore. Test subjects obtained an average exercising heart rate of approximately 130 beats/min, 65% of their maximum heart rates, when using the device in a mock bore. There were several problems with this device that require improvement and redesigning. The major areas include lateral lever arm stability and securing the patient to the device. Three design alternatives were proposed for each, and ultimately the block and backpack straps designs were chosen. A range of other modifications, including base tracking and a stopping mechanism for the lever arms, will also be implemented. Some of the work that still must be done includes finalizing dimensions, salvaging and ordering materials, and construction of a new prototype. In addition, testing of the new prototype for both effectiveness and MRI use is planned.

II. Problem Statement and Design Specifications

In order to better understand the effect of exercise on patients with pulmonary hypertension, Professor Naomi Chesler would like to use magnetic resonance imaging (MRI) to accurately measure changes in blood pressure and flow of the pulmonary arteries during exercise. Our task is to develop an MRI-compatible exercise device for patients undergoing cardiac MRI scans. It should allow the patient to exercise while lying within the MRI bore and have adjustable workloads so patients of varying fitness levels can generate a sufficient increase in cardiac output and heart rate.

There are several design requirements that the device must meet in order to be used effectively in a clinical setting. First and foremost, all materials should be MRIcompatible. This means that no ferrous metals, such as steel or iron, can be used. In addition, the device must be reasonably sized to allow for easy transportation and storage, and have a weight that, when combined with patient weight, is less than the MRI scanner weight limit of 150 kg. Of all major MRI models currently on the market, the smallest distance from the bed to the top of the bore is 42 cm [1]. However, the bore of the scanner at UW Hospital, which will be used, has a height of 50 cm. The device will be designed to meet the specifications of both MRI scanners.

Another critical design specification is for the device to have an adjustable workload. Since the study will involve patients of a wide variety of fitness levels, the resistance level should be both measurable and variable for each patient. Moreover, the resistance should be sufficient to allow patients to reach the target heart rate zone, which is 70-80% of their maximum heart rate (220 beats/min – age). The exercise motion should be natural and fluid, with no risk for patient injury. Additionally, since the patient's torso will be scanned by the MRI machine, movement of the upper-body should be minimized. For additional details on product specifications, see **Appendix A**.

III. Background Information

Pulmonary Hypertension

Pulmonary hypertension is a cardiovascular disease characterized by increased blood pressure due to narrowing in the pulmonary arteries. This will lead to overworking and enlargement of the right side of heart (seen in **Figure 1**), as well as lowered systemic blood oxygen concentration. Some potential causes of pulmonary hypertension are HIV infection, lung or heart valve disease, certain diet medications, and any condition that causes chronic low oxygen levels in the blood, among others [2]. Major symptoms of pulmonary hypertension include shortness of breath and lightheadedness during activity, fast heart rate, swelling of the lower extremities, bluish color of the lips or skin, chest pain or pressure, dizziness, fainting, weakness, and fatigue [2]. To diagnose pulmonary hypertension, ECG, CT scans of the chest, and nuclear lung scans, as well as physical examinations, are performed [2].



Figure 1 : The effects of pulmonary hypertension effects on the heart and pulmonary arteries [2]

Image courtesy of PubMed Health: http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHoo 01171/

Currently, there is no specific treatment for pulmonary hypertension. Rather, the major goal of treatment is focused on controlling the symptoms of the disease. Professor Chesler is interested in determining how exercise affects the pulmonary blood pressure and cardiac output of pulmonary hypertension patients, in order to better understand the disease as well as assess the severity in each patient. A common way to execute this study is to have patients exercise outside of the MRI bore and then quickly perform the scan. However, this method is flawed because the time difference allows the patient's heart rate and blood pressure to recover from the effects of exercise. Her study will use MRI scanning to test the pulmonary blood pressure before, during, and after specific

exercise. Therefore, she requires an MRI-compatible exercise device that can be used within the bore while a patient is being scanned.

Competition and Past BME Designs

Several exercise devices have been designed for use with an MRI scanner. Lode B.V. provides several MRI-compatible devices that allow patients to exercise prior to MRI scans. These machines use a variety of exercise options, including cycling, ankle flexion, push/pull (seen in **Figure 2**), and up/down motions [3]. However, the major problem with these devices is that they are much too expensive; the lowest price found was \$28,000 [4]. In addition, most cannot be used during a cardiac MRI scan because the patient is too far into the bore, limiting their range of motion.

Another current product, the MRI-compatible treadmill, was designed by a team at Ohio State University. It is essentially a separate treadmill outside of the scanner that has been completely modified to be compatible with the MRI environment [5]. This device can be seen in **Figure 3**. However, since exercise does not occur within the bore, this device has the problem of patient recovery between exercising and scanning, as mentioned above. Therefore, this device gives less accurate results than Professor Chesler desires.



Figure 2: The Push/Pull version of the Lode B.V. MRI Ergometer [3]

Image courtesy of Lode B.V.



Figure 3: The MRI-compatible treadmill, designed by a team at Ohio State [6]

Several UW-Madison Biomedical Engineering design teams have attempted similar projects in the past. One team spent two semesters (Fall 2009 and Spring 2010) working on a project with the same purpose and developed two prototypes. The first prototype was a cycling device, shown in **Figure 4**. The design team made a critical error by not designing the bike to fit the dimensions of the MRI bore. Therefore, when

Image courtesy of MedCity: http://www.medcitynews.com/2009/05/comm ercialization-ramps-up-on-ohio-stateuniversity-treadmill-used-for-mri-heart-tests/

they attempted to test their prototype, the user's knees hit the edge of the bore which prevented them from completing the cycling motion. This resulted in the ultimate failure of their cycling design idea. Because of this, the team had to design a completely new prototype.

Their second prototype was a stepping motion device that used two sliding foot pedals with fitness gear adjustable resistance tubes for the resistance (Figure 5). The stepping motion of the device could be successfully completed while the user was in the MRI scanner; however, this prototype had several flaws. A major problem with the prototype was the lack of support for the foot pedals. The foot pedals were held up by a thin brass facet and the resistance bands. This proved to be insufficient to withstand the force generated by the user. During testing and use following prototype completion, both pedals were broken. This shows that this prototype would have never withstood multiple patient trials. Another problem with the prototype was the large amount of friction generated between the foot pedals and the track. The design team did not mitigate this friction, leaving the two polyethylene surfaces to rub against each other during the motion. This decreased the smoothness of the stepping motion and reduced user comfort. In addition to these structural defects, the prototype failed to generate sufficient resistance to allow the user to reach the target heart rate during exercise. According to the previous group's tests, the three subjects reached maximum heart rates of 88, 91, and 86 bpm [8]. That is only about 43-45% of their maximum heart rates, significantly less than the desired value. Due to these shortcomings, a more effective prototype is still needed.



Figure 4: The cycling device developed by a UW-Madison biomedical engineering design team in Fall 2009 [7]

Image courtesy of UW-Madison BME Design: http://bmedesign.engr.wisc.edu/websites/project.php?id=29



Figure 5: The stepper design, developed by the same group as the design in Figure 4 [8]

Image courtesy of UW-Madison BME Design: http://bmedesign.engr.wisc.edu/websites/project.php?id=295

In the fall of 2010, a separate BME design team developed another MRI compatible exercise device (**Figure 6**). This team designed their prototype for patients that would be subjected to MRI scans of the brain [9]. The nature of these brain scans allows for more of the patient's body to be out of the MRI bore. Therefore, this prototype

would not work for the reduced space restraints of a cardiac MRI scan without modification. In addition, this device has several other flaws. It is quite bulky, which makes transportation and storage exceedingly difficult and may intimidate patients. In addition, this device features an unnatural loading mechanism, where the resistance pulls up on the user's knees. This strange method of loading would lead to increased patient discomfort. Given these reasons, a modification of this design was not pursued.



Figure 6: The device designed by a Fall 2010 UW-Madison biomedical engineering design team [9]

IV. Previous Prototype

<u>Design</u>

In addition to the two design teams mentioned, our team worked on this same project during the previous semester (Spring 2011). The final prototype that we constructed can be seen in **Figure 7**. It is composed mostly of 1.27 cm (1/2") thick highdensity polyethylene (HDPE) assembled with brass screws and fasteners, to ensure MRI compatibility. The user lies on the attached yoga mat and performs an alternating stepping motion to raise the plastic, sand-filled weights on the L-shaped lever arms. The vertical supports and the lever arms are constructed as I-beams in order to add structural integrity and strength. The lever arms rotate around an aluminum rod on acetal and glass bearings. Finally, two nylon straps were attached to the base of the device for the patient to grip during exercise. These straps and the yoga mat were meant to hold the patient to the device. Professor Chesler approved of the stepper design and was happy with the progress made on the project, so this design will be used as a platform for the new design.

Image courtesy of UW-Madison BME Design: http://bmedesign.engr.wisc.edu/websites/project.php?id=332



Figure 7: The prototype developed during the Spring 2011 semester

Testing

The past semester's design was tested in a mock MRI bore (Figure 8). This was constructed based on the dimensions of the MRI scanner located at the Wisconsin Institutes for Medical Research (WIMR). This scanner has only a 42 cm bore height, which is smaller than the new scanner recently acquired by the UW Hospital. A mass of 6.77 kg (14.9 lbs) was placed on each lever arm, and the subject exercised at a stepping cadence of about 130 steps/minute for ten minutes. This is equivalent to the production of about 62 Watts of power [10]. A pulse oximeter was used to continuously measure their heart rates during exercise. The results of this exercise testing can be seen in **Table 1.** The subjects were able to raise their heart rate to an average of about 130 beats/minute. This is about 65 % of their maximum heart rate. This is close to the 70-80% desired by Professor Chesler, but ideally it would be a bit higher.

In addition to the mock MRI exercise testing, the physical compatibility of the prototype was tested in the WIMR MRI scanner (**Figure 9**). Although at least two people were required to secure the device during exercise, subjects from 172 cm (5'8") to 191 cm (6'3") were able to use the device while within the bore. They reported no problems relative to comfort of motion or safety issues. Professor Chesler took MR images while using the device in the summer of 2011. She was able to retrieve some data from the imaging, but she encountered several problems that will need to be addressed.



Figure 8: The test setup used during Spring 2011 exercise testing

Table 1: Resting, exercising, and % of maximum heartrates for four subjects using the test set-up above

| Subject | Resting HR (bpm) | Exercising HR (bpm) | % Max. HR |
|---------|------------------|---------------------|-----------|
| 1 | 65 | 130 | 65.33 |
| 2 | 62 | 128 | 64.32 |
| 3 | 62 | 118 | 59.30 |
| 4 | 58 | 146 | 73.37 |
| Average | 61.75 | 130.50 | 65.58 |



Figure 9: Testing of the previous prototype within the WIMR MRI bore

Problems

Though the previous prototype was fairly effective, there are areas in which the device requires improvement. These will be some of the major focus areas of the proposed design modifications. One of largest issues with the previous prototype was the poor lateral stability of its L-shaped lever arms. When the device was tested, the subject's feet had a tendency to move laterally on the foot pedal as a natural effect of exercise. Due to a lack of restriction, this movement caused the lever arm to sway and sometimes fall off of the acetal/glass bearings. This resulted in an even more unstable motion and poses a durability problem that will need to be addressed. This unstable motion causes the patient to focus on stabilizing their movement instead of exercising to their fullest potential.

Another major problem was the fact that the patient would move away from the device during testing. This occurred because the force of the weights pushing back on the subjects was greater than the forces holding them in place. When Professor Chesler tested the prototype, she took an image of the pulmonary arteries prior to beginning

testing. Her final images ended up being almost 6" away from this initial image due to this movement. This severely hindered the ability to acquire and compare images for analysis. In addition, sliding away from the device takes the subject out of their optimal range of motion, reducing their ability to reach the highest possible cardiac output.

A few additional problems made the prototype cumbersome to use and adjust. It did not rest entirely on the sliding portion of the couch, so it required two people to lift and adjust its position whenever the patient was moved. Also, when the patient used the device, the weights would slide back and forth on their fixtures because the diameter of the aluminum rods were thinner than the holes in the weights. Lastly, the overall size of the device made it difficult to move and transport.

V. Lateral Lever Arm Stability Designs

Track-Guided

In order to improve the major problem of lateral lever arm stability, three design alternatives were developed. The first is called the track-guided design (Figure 10). This design utilizes a semicircular piece of material under the existing lever arms that slides through a block of HDPE, creating a track for the lever arm to rotate through. By using a track to guide the lever arms, their movement would ideally be limited to a single plane. The track-guided design would be cost effective because the original prototype could be used and only materials for the tracks would need to be purchased. However, there are some drawbacks to this design. The constant friction of the semicircular piece sliding through the HDPE block would wear down the surfaces and could cause durability problems. Additionally, this design is only an indirect solution to the problem of lever arm stability. Since the original lever arms would still be used, they could still fall off of the bearings if lateral movement is not completely eliminated.



Figure 10: The track-guided design for lateral lever arm stability

<u>Block</u>

The second design to limit lateral movement of the lever arms is called the block design **(Figure 11).** This design utilizes lever arms of the same dimensions as the past

prototype, but there is not just one point of articulation with the aluminum rod. Two blocks of 1.905 cm ($^{3}4$ ") thick HDPE would be placed on each side of the vertical member of the I-beam, filling the entire area within the I-beam at the interface with the aluminum rod. Each block would have a space drilled into them on the outer surface just big enough to fit a glass/acetal bearing. Then, 1.27 cm ($^{1}2$ ") thick HDPE pieces would be put over the outer surfaces of the blocks to cap the entire structure and hold the two bearings in place. By using two bearings, there are two points of articulation with the aluminum rod that provide even support. Since the bearings are approximately two inches apart, the moment arms of the reaction forces on the rod are increased, thereby better counteracting the moments generated by lateral movement. Also, the use of bearings will reduce the friction and wear on the interface between the lever arm and aluminum rod.



Figure 11: The block design for lateral lever arm stability

Arc-Support

The third alternative to fix the stability issues with the lever arms is the arcsupport design (Figure 12). This idea utilizes two arcing supports beginning at the vertical member of the I-beam and extending to the aluminum rod, providing an additional two points of articulation with the aluminum rod. The two additional supports create greater reaction moments that limit the lateral motion of the lever arms. This design would also be a cost effective choice because the original prototype could be used and only materials for the arcs would need to be purchased. However, this design would produce a lot of friction between the arc supports and aluminum rod because bearings could not be incorporated without encountering the same problem occurring in the current prototype. Also, if the patient does try to move their feet laterally, the forces on the arcs could cause them to break, depending on their thickness.



Figure 12: The arc-support design for lateral arm stability

Design Evaluation

Using a design matrix, the previous three designs were evaluated on the following four criteria: effectiveness, durability, ease of assembly, and cost (Table 2). Each criterion was weighted with a certain percentage out of 100% based on relative importance, and each design was given a score out of 10 for each individual criteria. These scores were then multiplied by the weight of each category and then added to get the final score of each design. The track-guided design was given lower scores on effectiveness and durability because the track may not completely limit the lateral movement of the lever arms and may wear down due to friction over time, however it received a higher score for cost and ease of assembly due to the little amount of material that needs to be purchased and fabricated. It received a final score of 5.1 out of 10. The block design received higher scores for durability, effectiveness, and ease of assembly because this design limits the lateral lever arm movement, lowers the amount of friction on the interface between the lever arms and aluminum rod, and utilizes simple shapes which would make fabrication easier. However the block design scored lower in the cost category because this design requires the most new materials. It received an overall score of 8.2 out of 10. The arc-support design received high scores in the effectiveness and cost categories because the arcs would effectively limit lateral motion and new materials would only need to be purchased for the arcs. It scored lower however in the durability and ease of assembly categories because the arc supports have the potential to break and fabricating the arcs would be difficult. The arc supports design received an

overall score of 7.4 out of 10. Therefore, the block design alternative is the design that will be pursued.

Table 2: Design matrix comparing the lateral arm stability designs. Criteria were weighted out of 100% based on relative importance; each design was given a score out of 10 for each criteria. Scores were multiplied by weight and added to get the final score of each design.

| Weight | Criteria | Track-Guided | Block | Arc-Support |
|--------|------------------|--------------|-------|-------------|
| 0.4 | Effectiveness | 4 | 8 | 9 |
| 0.4 | Durability | 5 | 9 | 6 |
| 0.1 | Ease of Assembly | 7 | 8 | 6 |
| 0.1 | Cost | 8 | 6 | 8 |
| | Weighted Total: | 5.1 | 8.2 | 7.4 |

VI. Securing Patient to Device Designs

Extended Base

The second major area for improvement that was focused on was securing the patient to the device. The extended base design addresses this issue by lengthening the HDPE base so that the patient's whole body rests on top of it (**Figure 13**). The user will be held in place by two shoulder pads. The base of the shoulder pads will have four pegs that fit into holes on the HDPE base. This will allow the shoulder pads to be adjustable and accommodate for users of varying heights. This design would be very effective at securing the patient in place relative to the device. It would also be very easy for the patient to exit the device quickly in an emergency situation. One downfall for this design is the fact that extending the base would almost double the size of the device, making transportation and use more difficult. The cost of the HDPE needed to construct the base would also make this a relatively expensive design.



Figure 13: The extended base design for securing the patient to the device

Backpack Straps

This design utilizes straps, similar to those found on a backpack, to hold the patient to the device (**Figure 14**). The connecting straps would be adjustable so that users of various heights can be held at the appropriate distance from the device. In comparison with the extended base design, this solution would be lightweight and allow for easier transportation. Additionally, with the appropriate choice of backpack straps, this design would be very comfortable for the patient and relatively affordable. However, the straps may prove to be slightly restrictive if the patient needs to be removed quickly from the device.





Velcro Yoga Mat

The Velcro yoga mat design incorporates the yoga mat of the previous prototype with a Velcro interface to better secure the patient to the device (**Figure 15**). In the previous prototype, the patient's weight alone was not sufficient to generate the friction needed to hold the user to the device. Another problem encountered with the yoga mat in the previous prototype was that the epoxy used to attach the mat to the base wore out over time. This could be overcome by screwing the yoga mat to the base. In the improved design the patient would wear a large belt with a Velcro patch that matched a complimentary Velcro surface on the yoga mat. This would effectively hold the patient to the device. Additionally this design is light weight, permitting for easy storage and transportation. Despite these benefits, this may be a fairly uncomfortable set up for the patient and the Velcro interface might wear out over time.



Figure 15: The Velcro yoga mat design for securing the patient to the device

Design Evaluation

A design matrix comparing the three previously mentioned designs was created in order to determine the best solution to the problem of securing the patient to the device (**Table 3**). The three designs were evaluated based on a range of criteria including: effectiveness, patient comfort, size/weight, durability, safety, and cost. These six criteria were then given a weight based on their importance. Patient comfort and effectiveness were given the highest weight because they are the most critical to the success of the prototype. Patient comfort is extremely important for this device because there is already some level of discomfort involved with being inside of the potentially claustrophobic MRI bore. Therefore, the exercise device should not add to that by being uncomfortable or strenuous to use. If the design is not effective at attaching the patient to the device the patient will move away from the device during use. This will take the patient out of the optimal range of leg movement, in turn making it more difficult for the patient to increase their heart rate. Additionally, if the patient's body moves during the scanning, the images taken will not correspond to the same spot in the body. Finally, safety is the top priority for our design team; however, it was given an average rating because all of the designs are considered to be relatively safe.

| Weight | Criteria | Extended Base | Backpack Straps | Velcro Yoga Mat |
|--------|-----------------|---------------|--------------------|-----------------|
| 0.25 | Effectiveness | 9 | 9 | 6 |
| 0.2 | Patient Comfort | 7 | 8 | 6 |
| 0.15 | Size/Weight | 3 | 9 | 8 |
| 0.15 | Durability | 7 | 7 | 5 |
| 0.15 | Safety | 10 | 8 | 7 |
| 0.1 | Cost | 5 | 7 | 6 |
| | Weighted Total: | 7.15 | 8.15 | 6.3 |

Table 3: Design matrix comparing the designs for securing the patient to the device. Criteria were weighted out of100% based on relative importance; each design was given a score out of 10 for each criteria. Scores were multipliedby weight and added to get the final score of each design.

As seen in the design matrix above, the backpack straps design scored the highest, with a score of 8.15/10. It was followed by the extended base (7.15/10) and the Velcro yoga mat (7.05/10). It managed relatively high scores in almost every category and therefore will be pursued in the fabrication of our new prototype.

VII. Additional Design Improvements

The major modifications previously mentioned will be effective at addressing some of the main shortcomings of the previous prototype. However, there are several other improvements that can be made to correct the rest of the problems. First, a stopping mechanism will be implemented to hold the lever arms when not in use **(Figure 16).** By stopping the lever arms, it will be easier for the patient to enter and exit the device. This design requires a hole on each vertical I-beam support to hold an aluminum pin that will slide in and block the motion of the lever arms. The contact area of the pin will be directly below the foot pedal.



Figure 16: The aluminum pin stopping mechanism for the lever arms

Additionally, a tracking structure will be added at the bottom of the base plate to improve compatibility with the sliding MRI couch (Figure 17). This will concentrate the weight of the device onto the sliding portion of the couch, allowing it to move with the patient. The tracks will be composed of HDPE with rubber padding that will form fit with the curvature of the couch.



Figure 17: Tracking structure to improve compatibility with sliding MRI couch

In order to better prevent lateral movement of components on the aluminum bar, the ends of the rod will be threaded and tightened with two 1.27 cm (½") brass nuts. Another modification to the device will be the reduction of lever arm length on the weight bearing side. The previous prototype has a 1:2 ratio between the foot pedal and weight loading side lengths. This will be changed to a 1:1.5 ratio in order to decrease the overall size of the prototype while still providing a mechanical advantage. Additionally, the weight loading interface will be improved by increasing the diameter of the aluminum fixture to better fit the weights. Finally, more comfortable D-shaped hand straps will be added along with adjustable nylon foot straps in order to help secure the

patient while maintaining comfort during exercise. Only the distal part of the foot will be secured, allowing for the possibility of heel separation from the pedals during leg extension.

VIII. Future Work

Now that the specific modifications have been determined, the proper steps need to be taken in order to implement these designs. Some of the specific dimensions, such as those needed for the base tracking, must still be determined. Many of the parts from the previous prototype can be recycled and reused, including many of the HDPE components and the aluminum bar. A list of new materials must be compiled, finalized, and ordered. After these materials arrive, construction of the new prototype will be completed.

Once the device is made, it will undergo several stages of testing. First, its overall effectiveness at increasing the heart rate to the target zone will be tested. MRI scans will then be performed on the team members before, during, and after exercise with the device. Provided that the initial scans are successful and IRB approval has been attained, the device will be used in human studies with various subject demographics.

X. References

- [1] Price, D., et. al. 2009. *MRI scanners: a buyer's guide*. European Respiratory Society. http://dev.ersnet.org/uploads/Document/8d/WEB_CHEMIN_2563_1194523150.pdf
- [2] Blaivas, A.J. 2010, Apr. 27. *Pulmonary hypertension*. PubMed Health.http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001171/
- [3] Lode B.V. 2008. *MRI ergometer*. Lode: the Standard in Ergometry. http://www.lode.nl/en/products/mri_ergometer
- [4] *MRI Ergometry*. 2008, Nov. 26. Vacumed. http://www.vacumed.com/zcom/product/Product.do?compid=27&prodid=7787
- [5] Murray, A. 2009, May 14. Ohio state team creates new company based on university invention. The Ohio State University – News Room. http://www.osu.edu/news/newsitem2425
- [6] Seper, C. 2009, May 14. Commercialization ramps up on Ohio State University treadmill used for MRI heart tests. MedCity News. http://www.medcitynews.com/2009/05/commercialization-ramps-up-on-ohio- stateuniversity-treadmill-used-for-mri-heart-tests/
- [7] Yagow, D., et. al. 2009, December 9. MRI-compatible lower leg exerciser. BME Design, UW-Madison College of Engineering. http://bmedesign.engr.wisc.edu/websites/project.php?id=29
- [8] Yagow, D., et. al. 2010, May 5. An MRI-compatible lower-leg exercising device for assessing pulmonary arterial pressure. BME Design, UW- Madison College of Engineering. http://bmedesign.engr.wisc.edu/websites/project.php?id=295
- [9] McGuire, J., et. al. 2010, December 7. MRI exercise device. BME Design, UW-Madison College of Engineering. http://bmedesign.engr.wisc.edu/websites/project.php?id=332
- [10] Thate, N., Flink, E., Lee, T., Hanske, A. 2011, May 4. MRI-compatible cardiac exercise device. BME Design, UW-Madison College of Engineering. http://bmedesign.engr.wisc.edu/websites/project.php?id=380

XI. Appendix A: Product Design Specifications

Problem Statement

In order to better understand the effect of exercise on patients with pulmonary hypertension, Professor Naomi Chesler would like to use magnetic resonance imaging (MRI) to accurately measure changes in blood pressure and flow of the pulmonary arteries during exercise. Our task is to develop an improved MRI-compatible exercise device for patients undergoing cardiac MRI scans. It should allow the patient to exercise while lying within the MRI bore and have adjustable workloads so patients of varying fitness levels can generate a sufficient cardiac output and heart rate.

Client Requirements

- MRI-compatible, in both materials and dimensions
- Comfortable exercise motion in supine position
- Sufficient resistance to increase heart rate and cardiac output
- Adjustable workload

Design Requirements

- 1. Physical and Operational Characteristics
 - a. *Performance requirements:* The device should provide a natural exercise motion that can be performed while the patient is within the MRI bore. The workload provided must increase the patient's heart rate to >70-80% of their maximum predicted heart rate, which is equal to 220 beats/min minus the patient's age. It needs to be adjustable for various patient fitness levels and heights (155-195 cm). Additionally, only one assistant should be required during set up and testing.
 - b. *Safety:* All materials must be MRI-compatible (non-magnetic) for the safety of the patient, scanner, and medical staff. The exercise motion cannot put the patient at risk for injury during use.
 - c. *Accuracy and reliability:* The design should provide consistent workload settings from patient-to-patient. All patients should be able to reach the target heart rate.
 - d. *Life in service:* The device must be able to withstand clinical use for three years with minor maintenance.
 - e. Shelf life: N/A
 - f. *Operating environment*: The design will be used in clinical or research settings in the presence of an MRI scanner and ECG leads.
 - g. *Ergonomics:* The motion should be natural, fluid, and controlled without any undesirable friction.

- h. *Size:* The device must allow for exercise within the bore of any MRI scanner. The standard measurements of the bore are 42 cm from the couch to the top and 60 cm in width.
- i. *Weight:* The weight on the couch cannot be greater than 150 kg, so the device will not exceed 25 kg. Individual components should not weigh more than 15 kg to ensure portability.
- j. *Materials:* All components must be durable and made of non-ferrous materials.
- *k. Aesthetics, appearance, and finish:* The device should be quiet and not intimidating to the user.
- 2. Product Characteristics
 - a. *Quantity:* One working prototype
 - b. *Target product cost:* \$200.00
- 3. Miscellaneous
 - a. *Standards and specifications:* Must pass inspection for use in MRI and eventually be IRB approved for human trials
 - b. *Customer:* Hospitals, clinics, and research labs
 - c. *Patient-related concerns:* Comfortable, safe, and durable

Competition: Lode B.V. MRI Ergometer, prototypes from other universities, and past UW BME design projects