MRI-Compatible Lower Leg Exerciser

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Abstract

Magnetic resonance imaging can be used to study pulmonary blood flow in hypertensive patients before and after exercise. The goal of this project is to create a device which will be used to exercise subjects to 40% of a predetermined maximal workload in both healthy subjects and patients with hypertension. A preliminary cycling device was constructed and tested via Doppler Ultrasound and found to increase the pulmonary systolic pressure an average of 5.54 mmHg. This pressure increase was determined using the modified Bernoulli equation with the tricuspid regurgitant velocity.

Problem Statement

The goal of this project is to design and construct a lower leg exerciser that is compatible with MR imaging and Doppler Ultrasound to be used during cardiopulmonary research studies on pulmonary hypertension patients and healthy volunteers. The device must have repeatable loads that can be measured and relayed to the patient via biofeedback.

Background and Device Necessity

Pulmonary Hypertension (PH) is a condition in which the blood vessels of the lungs constrict, thickening the walls and leading to increased pressure in the pulmonary arteries. The pulmonary pressure cannot be measured with a pressure cuff like systemic pressure, and therefore must be estimated using the tricuspid regurgitant jet velocity. The tricuspid regurgitant jet is formed from an insufficiency of the tricuspid valve separating the right atrium and right ventricle of the heart. As the ventricle contracts, a stream of blood leaks back through the valve into the atrium and the velocity of this jet can be used with the modified Bernoulli equation to find the blood pressure Hypertension can be of unknown cause, primary PH, but is more commonly a result of emphysema, COPD, HIV, heart defects, or only appears with exercise (Primary Pulmonary Hypertension News, 2009). Patients are often physically limited by PH and therefore the focus of research here is, “Does moderate exercise affect the stiffness of the patient’s pulmonary artery or their blood pressure?”

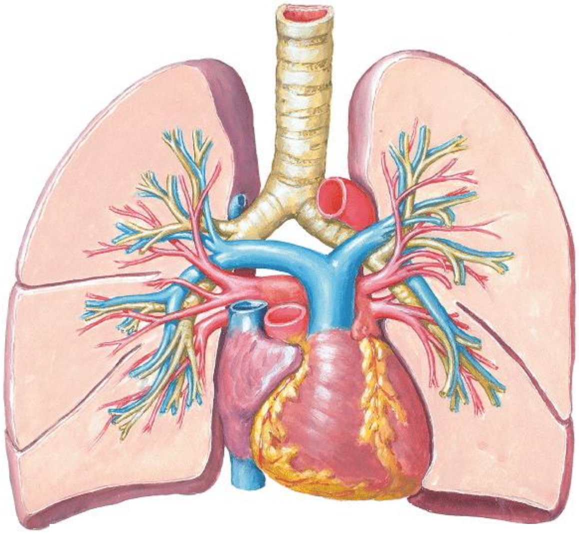

Figure 1: Pulmonary blood flow to heart (pulmonary artery/branches in blue) (CIC, 2005).

The research is being conducted at the Vascular Tissue Biomechanics Laboratory in the Biomedical Engineering Department of the University of Wisconsin-Madison by Dr. Naomi Chesler and Alejandro Roldán-Alzate. The study uses MR imaging to scan the activity of the heart in both PH patients and healthy subjects prior to and following exercise. Patients will be injected with contrast dye via catheterization in order to produce a better signal in the pulmonary arteries during scanning. The subject will then exercise for a predetermined time period to raise the pulmonary blood pressure while non-ferrous EKG leads monitor the heart’s vital signs. After the completion of exercise, the subject will be scanned again in order to detect any changes in the pulmonary blood pressure via the tricuspid regurgitant jet. Doppler Ultrasound imaging studies of the heart may be carried out as well. Although PH severity varies on a patient-to-patient basis, the goal of this research is to find an ideal level of exercise that is of more benefit than harm to a majority of PH patients.

Similar research studies have been done in the past and have set a precedent protocol for exercise involving subjects with PH. One recent case done by Holverda et al. (2009) had the workload at which the PH patient exercised increased to 40% of a predicted maximal workload in the first minute while healthy subjects were started at the 40% of the maximum workload for the gender and specific anthropometric measurements.

Research and Competition

A number of other products and projects have been designed to fill the need for an MRI compatible exerciser. A Norwegian ergometer company, Lode B.V., provides a number of machines to accomplish exercising while in an MR scanner. The machines offered through this company include a pedal system (Figure 2), dorsal ankle flexion, and both push/pull and up/down motions. The products that are offered through the company may fit the exercise need but are more complicated and expensive than is necessary for this design project. The machines include special electronic braking, torque measurements, and the ability to program up to 24 protocols. These features add a significant amount to the cost, quoted from Lode representative Dana Burger-Dipzinski as $58,000 with shipping and handling, and can be alternatively designed for this project.

Figure 2: Lode Ergometer (2009)

Another competitive device was designed by a team out of Northeastern University and is an fMRI compatible mechatronic ankle device. This device allows for both isometric and dynamic positioning of the ankle in order to provide imaging of the cortical response. This device is constructed from polymers and has a sliding bar which allows for a 40° plantar flexion and 10° dorsiflexion range. There is also the option for a pin setting which gives an isometric position. While this device allows for movement with the lower extremity via ankle flexion, it is not designed to exercise the patient to any specific workload. This device is more used in for imaging the brain during ankle movement than as a means to imaging the heart with exercise. Another problem is that since this was a design project of a university it is not commercially available for purchase.

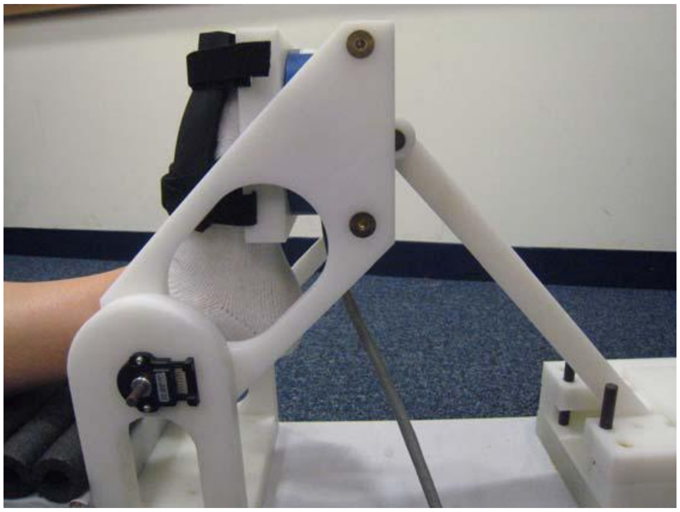

Figure 3: fMRI Compatible Ankle Device (Doane, 2007, p.102)

Client Requirements

The client has stipulated certain requirements for the design project in order to fit the needs of the research. The target overall cost for the device is $150. The device must be created completely out of MRI-compatible materials, which excludes any ferrous metals. It should be adjustable to interface sturdily with multiple MRI scanner beds and to accommodate many subjects of differing heights and exercise intensity levels. All subjects should achieve an increase in pulmonary systolic blood pressure within the range of 7-8 mmHg during exercise in the scanner, be able to reach maximum workload and incremental percentages of that value, and be aware of their exercise level through the use of a metronome which will be set between 1.167-1.667 Hz, which corresponds to cycling between 70-100 revolutions per minute (rpm). Finally, all human subject testing protocols must be IRB approved. These protocols must repeatable to achieve consistency between subjects throughout the entirety of the research study. The requirements of design are laid out quantitatively in the Product Design Specifications seen in Appendix D.

Ergonomics

In order to ensure that this product is effective with a variety of patients, it is important to consider the ergonomics of the design. The first aspect to consider would be the flexibility of use. This means that the design would have to accommodate a wide range of patients with a range of size and abilities. This testing will be done on both healthy subjects and patients with PH and therefore the device will need to exercise both groups to 40% of the predicted maximum in order to fit with the previous research already done with ultrasound. The comfort level of these different groups will vary and must be accommodated for in the design. Exercising while lying down can put extra stress on certain parts of the body, such as the back or hips. There would need to be additional features like handle grips to stabilize and a support wedge to increase comfort. This diversity of patients also means that there must be an adjustability factor to allow the difficulty of exercising to be altered to the physical ability of the current subject. The device must be able to increase the tricuspid regurgitant jet velocity of both healthy individuals and patients with hypertension.

Figure 4: Self-generated photo of PH patient in scanner during research study

Another important aspect of this design is the biofeedback. The patients must be able to recognize their level of exercise and adjust accordingly, making perceptible information extremely important. The information must be communicated to both the patient and physician effectively and use various modes of information to accommodate different preferences and abilities. If only visual feedback were given it would hinder the ability of the visually impaired or may be difficult to follow during exercise. By adding multiple forms of feedback, such as auditory, it would increase the level of communication the physician has with the patient during scanning and reinforces the feedback given to the subject.

Design Options

Three design options emerged from brainstorming and are categorized according to the exercise motion involved: Cycle, Leg Press, and Flexion with Resistance Bands. For the first design, the cycle seen in Figure 5 will recruit multiple muscle groups such as the quadriceps and gastrocnemius, providing an increased cardiovascular workout in a simple motion. It will also have very repeatable, incrementable resistance levels, but will involve more complicated construction due to the necessity of gears and belts composed of non-ferrous materials.

The second option is the Leg Press. This push/pull motion has a number of possibilities for construction, including springs, dashpots, multiple resistance bands, or a combination. This is a simple motion for patients to quickly understand and involves a larger range of motion.

Finally, the third design option is for the patient to perform plantar and dorsiflexion against resistance bands of varying elasticities. This will be easiest exercise for the patients with the most severe PH, but simply will not exercise the healthy subjects to an adequate level. Resistance bands also do not allow for easy quantification of the actual work the subject performed. This would be the easiest of the three devices to construct.

Design Matrix

To assist in selecting the final design, a matrix was constructed and relevant categories were evaluated to quantitatively compare the three design options. As seen below in Table 1, the Cycle option scored the highest at 87 and was the chosen design to move forward with the project.

The main category where the Cycle excelled was in effectiveness, due to its increased cardiovascular workout resulting from recruitment of anterior and posterior thigh and shank muscle groups. It is also highly repeatable as loads can be adjusted by the clinician, and the patient is constricted by the pedals to a strict plane of motion.

All three design options achieved full marks in the safety category, as it is absolutely essential that the device is MRI-compatible and will not harm either healthy subjects or patients. Areas where the Leg Press and Flexion options were inferior in

Figure 5: Self generated images of three design options. Top to bottom: Cycle, Leg Press, and Flexion.

durability and repeatability. The elastic properties of the exercise bands will likely change over time, and the exercise motion against them is difficult to repeat and quantify. Also, these two options also may not offer enough resistance to challenge a healthy subject in a reasonable duration of time.

Category	Weight of Category	Cycle	Leg Press	Flexion
Safety	20	20	20	20
Adjustability	15	10	12	13
Client Preference	10	8	8	10
Effectiveness	20	20	15	10
Price	5	3	4	5
Durability	10	8	8	5
Repeatability	15	14	12	10
Ease of Manufacturing	5	4	4	5
Total	100	**87**	83	78

Table 1: Design Matrix

Final Device

The final prototype was constructed for the patient to exercise with a cycling motion. Accommodating the constraints set forth in the client's design criteria, a picture of the final device is seen in Figure 6. The top layer of the base and all supports were fashioned out of a sheet of High Density Polyethylene (HDPE). The bottom layer of the base is wood for added stability and weight. The pedaling mechanism consists of a Kevlar-reinforced timing belt and two timing gears with 1 in diameter at the fan end and 5 in diameter at the pedals. The crank arm is a 3/8 in bent aluminum rod, which is a non-ferrous metal, with plastic pedals that slide on the ends and are held on by rubber stoppers. The device at its tallest height is 21 in with one pedal at its highest. The resistance at the front end is supplied by a 12 in diameter plastic fan which is secured to the smaller gear. All brackets and bolts are brass, another non-ferrous metal. Total weight of the device is 18 lbs (8.165 kg).

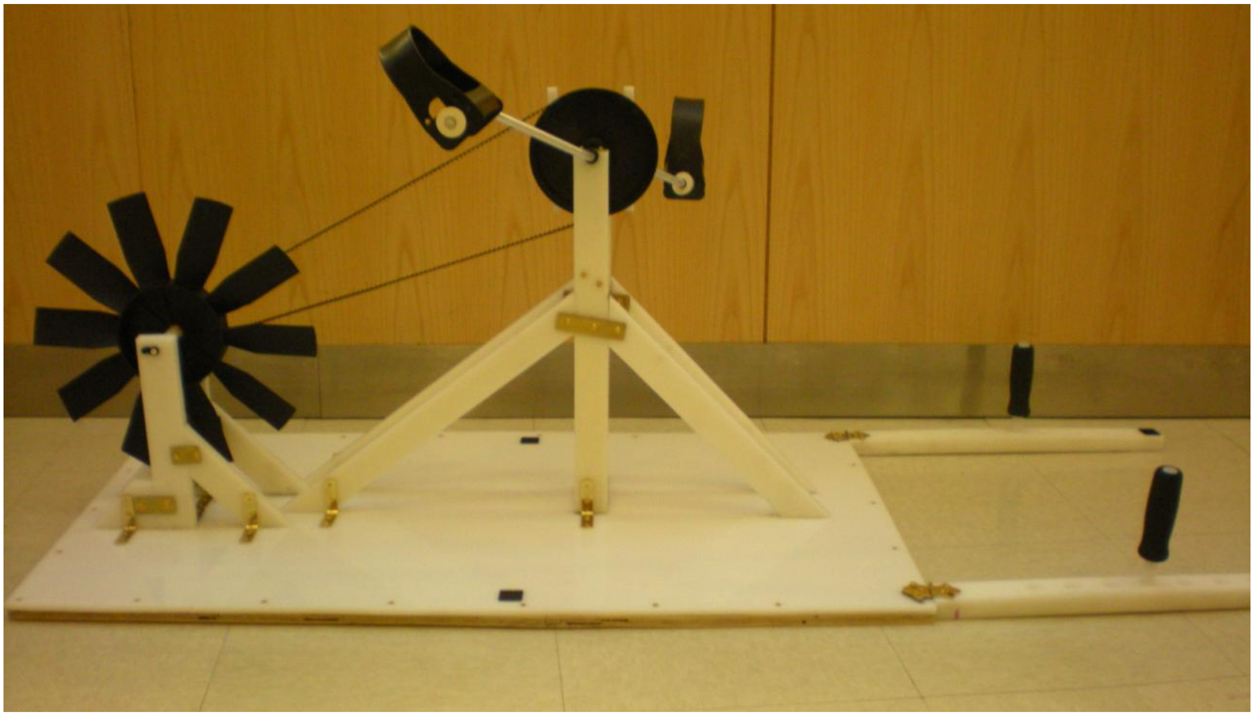

Figure 6: Final prototype design (seen from left side)

For adjustability, the base is 19 in wide and 34.875 in long to fit onto a few models of MRI scanning beds that are at least 18.79 in wide. To allow patients of any height to exercise, handles were made that can be incrementally moved axially along eight holes spaced one inch apart, depending on how close the subject must be oriented to the device for their legs to pedal comfortably. These isometric handgrips also help recruit the subject's arm muscles and contribute to raising systemic blood pressure. To adjust the tension of the belt, the aluminum axle of the fan can move laterally between three slots, the closest of which creates the least tension (Fig. 7). Small plastic spacers are then inserted into the unused spaces of the slot in order to secure the axle. The final SolidWorks schematic of the device can be seen in Figure 8.

Figure 7: Magnification of horizontal slot to tension belt at three adjustable axle positions.

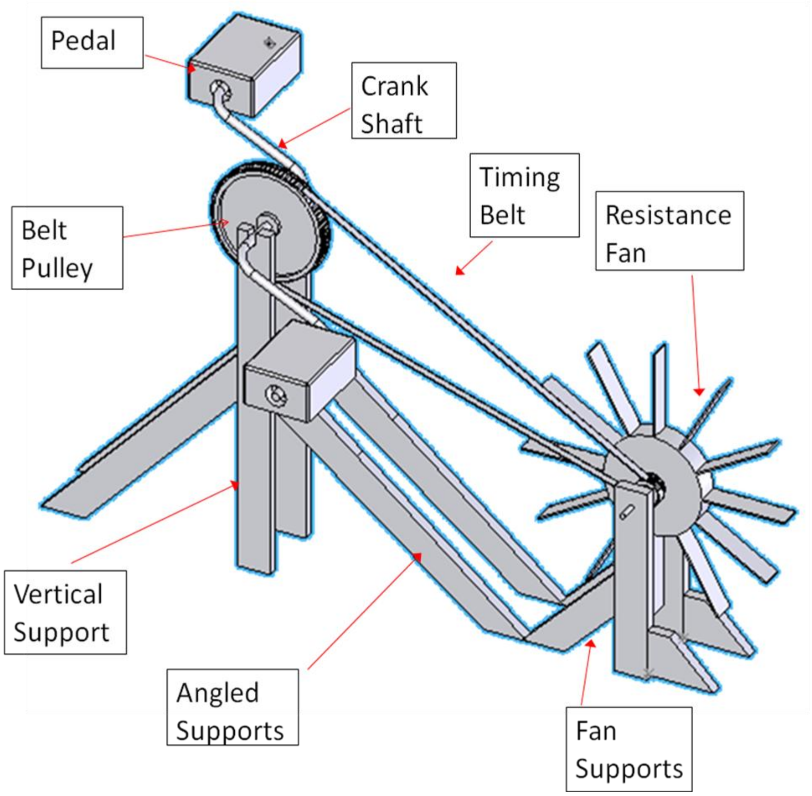

Figure 8: SolidWorks schematic of final design. (Note: base, handles, and tensioning slot not pictured).

In order to analyze the system which has been constructed, the maximum horsepower of the fan must be determined. Using known values from the manufacturer for cubic feet per minute (cfm) and static pressure (inches of water) of the fan, below is the calculation of the maximum power of the fan:

Fan power(hp)=airflow(cfm)*static pressure(inches of water)/3814

Max hp in our fan=(1100cfm*0.02)/3814= 0.0058 hp

Conversion to Watts: 0.0058 hp*[(550ft*lb/s)/1hp]*[1.356Watts/(1ft*lb/s)]= 4.302 Watts

From this value, 4.302 Watts, and knowing the rpm the subject was cycling at, the torque the patient must perform on the pedals is found with the following methodology, where ω is the angular velocity, V is the translational velocity, r is the gear radius, and T is the torque around gear axle. A free body diagram of the system is shown in Figure 9. For example, if the subject cycled at 80 rpm, the axle angular velocity is about 8.37 rad/s, giving a torque of 0.4817 Nm.

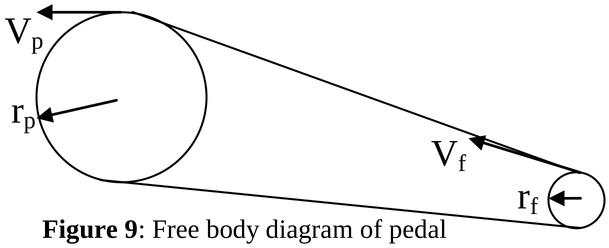

Figure 9: Free body diagram of pedal (V_p, r_p) and fan (V_f , r_f) gear system.

Power (in Watts) = torque*angular velocity

$$v_p = \omega_p r_p \qquad v_f = \omega_f r_f$$

$$\omega_p r_p = \omega_f r_f$$

Angular velocity scale factor (our gear ratio is 5:1, pedal:fan)

$$\frac{\omega_p}{\omega_f} = \frac{r_f}{r_p}$$

$$T_p = T_f$$

As the device was built, the exercise protocol was developed to utilize the device in a way that provides the subject the required exercise levels. This protocol was preliminarily discussed with Dr. Bill Schrage from the UW-Madison Department of Kinesiology who has performed multiple exercise physiology research studies. He said that there exists a nearly linear relationship between workload and heart rate during cycling. He suggested it as an option when carrying out the maximum workload test with subjects prior to entering the scanner. Exercise and testing protocols can be viewed in Appendix C.

Testing

Preliminary testing was done prior to construction on the different exercise methods discussed above in our Design Options section, as well as a few other variations of the basic movements. Figure 10 below shows the results of this testing.

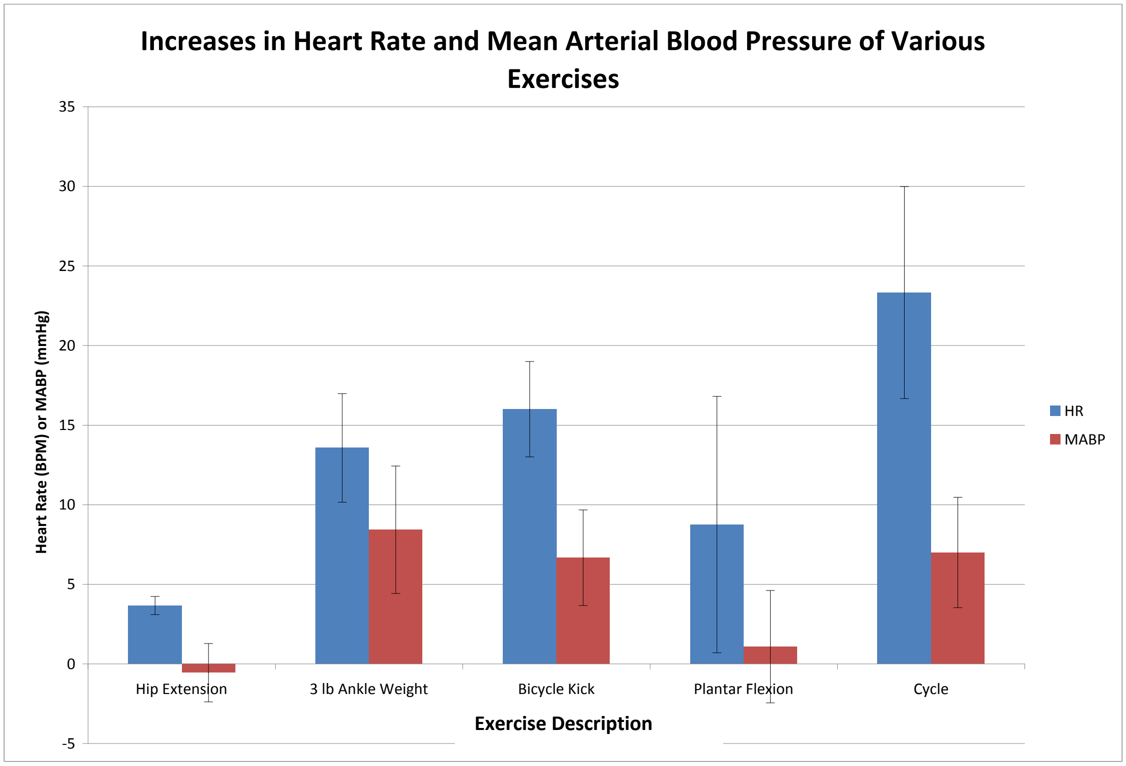

Figure 10: Increases in HR and MABP of various exercises (Note: MABP is calculated by diastolic pressure + 1/3 (systolic pressure – diastolic). Heart rate and MABP were used because calculating pulmonary pressure was not available at the time of testing.

Cycling caused the heart rate to increase 23 beats per minute (BPM) on average while the mean arterial blood pressure (MABP) increased by 7 mmHg. While the bicycle kick and the 3 lb ankle weight (lifting one leg 30 degrees in the air to the horizontal while a 3 lb weight was strapped to the ankle) did show potential for increasing the subject's vitals, we determined that those motions required too much abdominal and core muscle strength, which something that the PH patients may not have. These factors, combined with the fact that most people are familiar with a cycling motion, led us to definitively select the cycling mechanism.

The next step in testing was determining the effect the cycling exercise had on a patient's pulmonary systolic pressure. Before this could be determined, preliminary testing had to be done to evaluate which members of the team had the tricuspid regurgitant (TR) jet. With the help of Claudia Korcarz, a sonographer at the UW-Hospital, it was determined using ultrasound that two members of the design group (Val Maharaj and Deborah Yagow) have a tricuspid regurgitant jet. Between 80-90% of the population have the tricuspid regurgitant jet while having no other apparent heart problems (Korcarz, 11/23/09).

Due to the time constraints with our sonographer and our team schedule, only two ultrasound scans were completed this semester. A picture of this testing is seen in Figure 11. Furthermore, the duration of each exercise test was only 6-7 min because of the difficulty of locating the tricuspid regurgitant jet. Previous studies have used a six minute walk to exercise hypertensive patients (Mereles et al, 2006), but future scans will involve a similar cycling protocol that the client has previously used.

Korcarz stated that it is more difficult to image the tricuspid regurgitant jet while subjects are lying down on their backs compared to laying down on their side. While it is plausible to first image the patient while on their side, exercise, and then re-image as the patient returns to their side, we wanted data every two minutes, even while exercising. However, this situation will not be a problem when imaging in an MR scanner because patients are already lying on their backs for normal scanning.

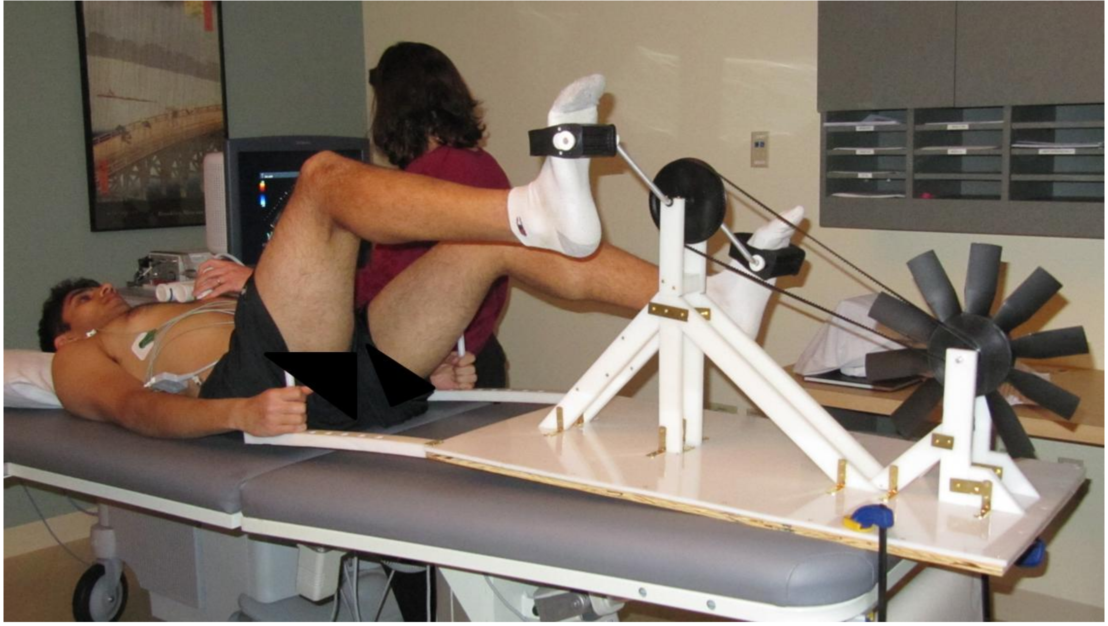

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Figure 11: Team member, Val Maharaj, exercising on the cycle with Claudia Korcarz administering ultrasound scan. Notice the handles help provide stability for the patient's torso and brace the device from moving away.

Figure 12 shows images of the subject's heart acquired during ultrasound testing. Using ShowCase, a medical image viewing program, the sonographer can read the magnitude of the TR jet and image the opened tricuspid valve.

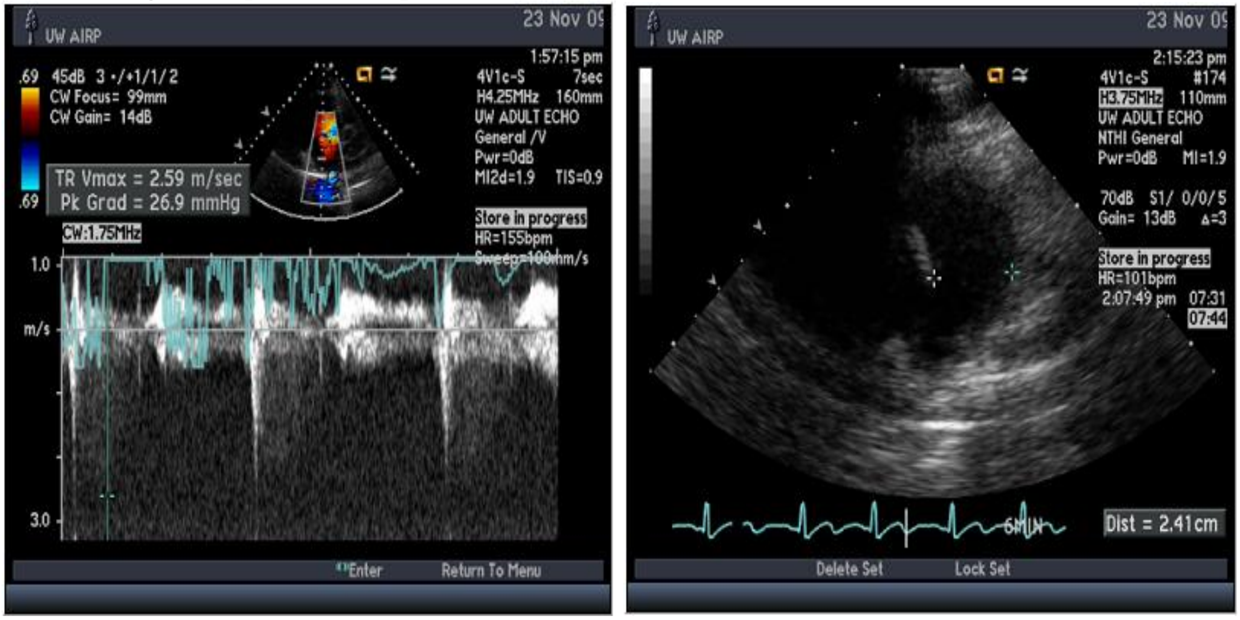

Figure 12: Left: Tricuspid jet velocity displayed with each heart beat. Maximum value shown is 2.6 m/s.
Right: Tricuspid valve, shown in systole.

A modified Bernoulli's equation is used to calculate the increase in pulmonary systolic pressure:

$$\Delta P = 4(\Delta v)^2$$

where ΔP is the increase in pulmonary systolic pressure (mmHg), and Δv is the increase in the tricuspid regurgitant jet velocity (m/s). Measurements of the TR velocity and pulmonary artery (PA) diameter were made at two minute time intervals over the course of the six minute scan. Figure 13 shows the compilation of this testing data and indicate the changes in pulmonary pressure throughout exercising.

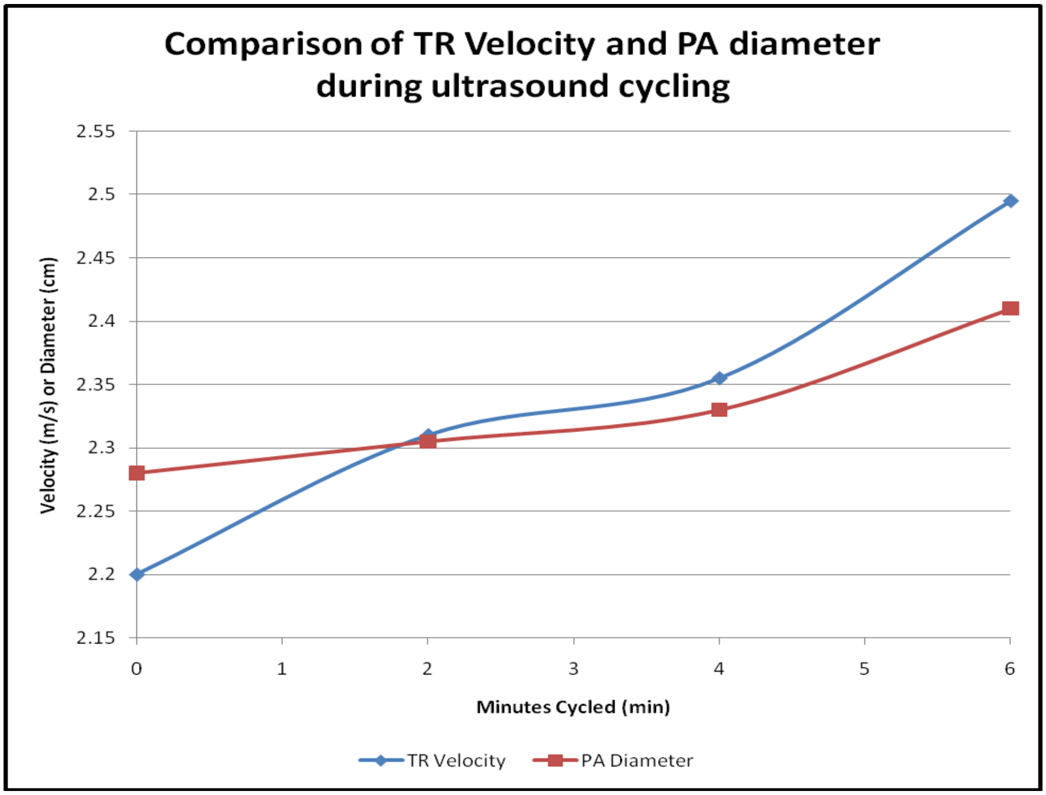

Figure 13: TR jet velocity and pulmonary artery diameter measured over the duration of cycling. Measurements were taken every two minutes for six minutes.

The TR jet velocity values from the ultrasound were plugged into Bernoulli's equation and the average increase in pulmonary systolic pressure between the two scans was found to be 5.54 mmHg. This is slightly less than the desired increase of our client. The first scan saw an increase in pressure of about 7 mmHg, a value our client was very pleased with, however, the second scan saw an increase in pressure of only 3.5 mmHg. Maintaining consistency between scans and patients will be an important part of the future work of this project. Experimental error could have been introduced in a number of ways. There are a lot of variables that can affect the change in pulmonary blood pressure aside from exercise, such as sleep, caffeine, dehydration, and inconsistent cycling rate. The differing results between scans could be attributed to one of these other factors; therefore, more trials will need to be done to determine the effect of cycling alone.

Finite Element Analysis/ Strength Testing

A finite element analysis was performed on our device using SolidWorks to assess the strength of the high density polyethylene (HDPE) when subjected to cycling loads. To perform the analysis, the front brace that supports the crank arm was modeled using a moderately fine element mesh. All materials were assigned as HDPE in the model. The front support was modeled as an assembly where the mates between separate parts are assumed to be rigid. The base at each of six supports was fixed on the bottom horizontal plane which is in contact with the base of the device in the model. Then two point loads were applied to the model where the relative location at the center point of each pedal. The forces at the pedal were averages which considered multiple parameters (density of air, mass of rider, zero grade, and power output equal to 2000 W) based on the use of a cycling ergometer. The case was taken as the extreme of what the pedal would experience in nominal operation. Using a program called Engineering Equation Solver (EES), an average pedal force was calculated using an equation for average force:

$$F_{avg} = \frac{4P}{\frac{d}{2} * \omega}$$

Using the above equation, power (P in Watts), diameter of rotation (d in m), and radians per second (ω) were defined to those of average ergometer values and an average force on the upstroke of cycling was found to be approximately 40 N. In SolidWorks, one pedal force was equivalent to this calculated force. The second force was applied at 10 N, simulating the backstroke of pedaling. Deformation and stress calculations were then performed in SolidWorks on the front support. The frontal plane diagram below (Figure 14) displays maximum deformation of 1.77 mm at the upper corner of the support. Notice the rotation observed due to the torque being applied by the upstroke pedaling force on the angled braces as well. Also note that SolidWorks exaggerates the results in the image, so actual results would not appear as such (refer to the scale on the right). Figure 14 shows a side view, also of deformation, where the location of the forces being applied to the curved slot that support the crank arm can better be observed.

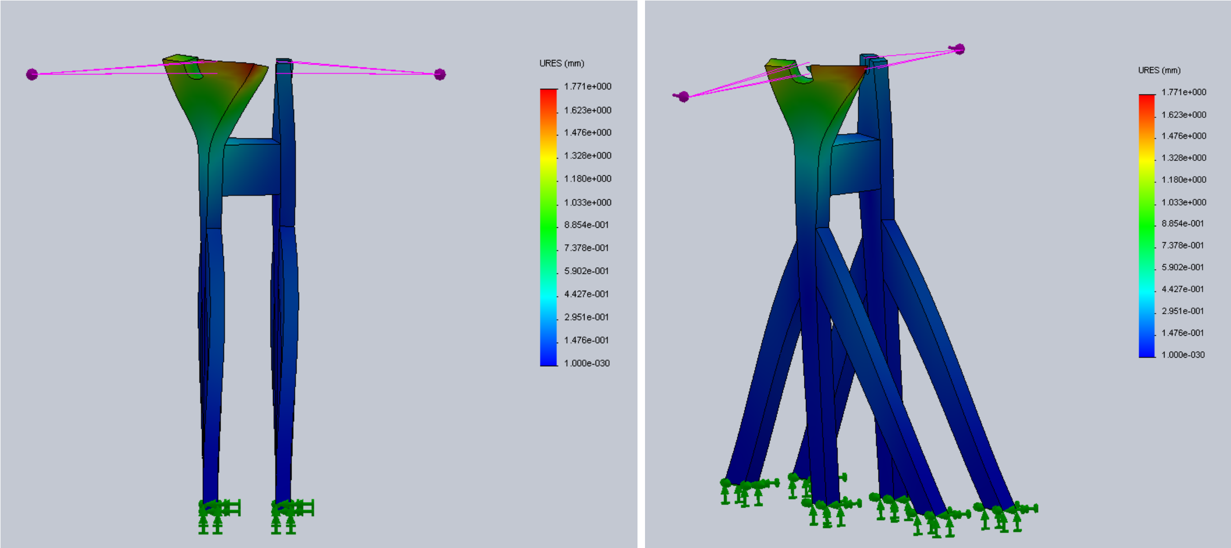

Figure 14: Left: Front view of front support showing maximum deformation
Right: Side view of front support showing deformation and location of load being applied to support.

Lastly, stress analyses were also performed in SolidWorks and can be seen in Figure 15. Observations seen here are the stress concentration located on the inside of the slot for the crank arm on the support. Due to the pedal force being applied, the part will most likely fail due to torsion and shear being applied to this small cross-sectional area which supports the weight and force of the crank arm.

Based on the observations made by the finite element analysis, improvements can be made to the geometry of the support to minimize deformation and to increase strengths, which will be further discussed in future work.

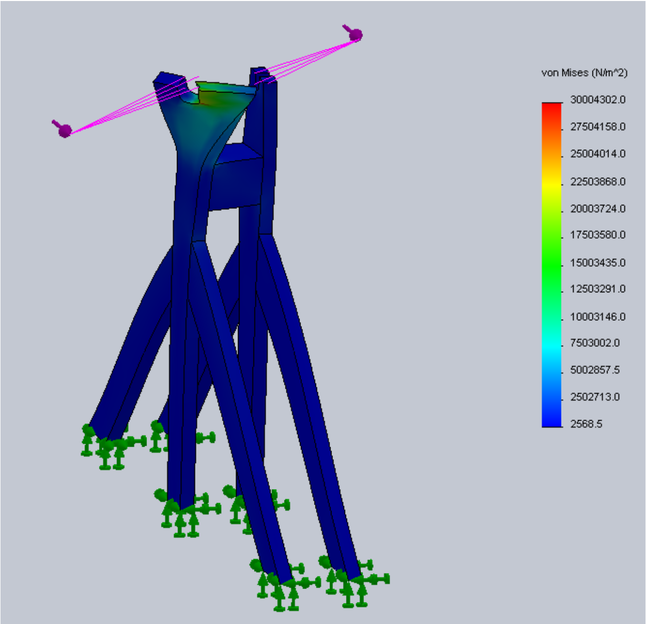

Figure 15: Side view of front support showing stress concentrations in yellow and green.

Future Work

Although a successful device was constructed this semester, there are a number of ways in which the design could be improved. In an effort to save time and money on the preliminary prototype, smaller scraps of HDPE were bracketed together to form the supports of the cycle. Based on the finite element analysis above, solid supports would make a more stable base and eliminate the need for many of the brass brackets and screws. The new supports would require a sheet of HDPE which would be milled out to form the solid brace. Purchasing solid sheets of HDPE, however, are more costly than individual pieces and this will adjust our future total cost (see Appendix B for expected cost analysis). This modified design would also eliminate the bracket connections which would allow various base structures could be modeled in SolidWorks in order to determine the strongest support shape. By modeling the structure first, it would determine the design with the smallest strain deformations and stress concentrations.

Another important improvement which will need to be made is a way to increase the resistance of the cycle. As it currently is designed, the fan blades in addition to the tension of the belt provide very limited resistance for the user. As previously discussed, it is very important for the final device to be adjustable among both pulmonary hypertension patients and healthy subjects. Such a low resistance of the system does not allow for a device which is as effective as possible for healthy patients. Through the testing of the current device, it took approximately 6 minutes to obtain acceptable increases in both tricuspid regurgitant jet velocity and pulmonary artery diameter for a healthy subject. This exercise time could be decreased through an increase in resistance, and would therefore limit the amount of time the subject had to remain in the scanner bore. There are a few possibilities in order to accomplish this increase in resistance. First, an extension could be put onto the back axle so that additional fans could be slid on and secured to create additional air resistance. Or a fan with adjustable pitch fan blades could be used If the fans are no longer used, disk brakes could be used on the gears or an adjustable height roller could be used to increase tension in the belt.

While conducting the preliminary testing on the existing device, there were some ergonomic issues with the pedals. They did not offer much comfort to the subject because the lack of support led to a tendency of the foot to "curl" around the edge of the pedal to keep the foot stable. This resulted in muscle cramping and improper form. Redesigning the pedals or an addition of toe clamps/heel straps will need to be addressed in order to maximize the comfort and exercise potential of the subject. Also during testing it was determined that the pedals are set too wide for the position of the subject and cause a bowing in at the knees. To prevent injury and ensure comfort, the crank arm will need to be redesigned and refabricated.

Once the new device is fabricated, it will be important to ensure proper securing to the MRI scanner bed during exercise. Various models of scanners differ slightly in the shape and size of the bed and the securing device must therefore be able to accommodate a range of sizes. An extension can be made from the platform of the cycle back to the patient and lie under the back of the subject to provide an initial form of anchoring. Other adjustable straps or supports will have to be built to prevent the platform of the device from rocking or sliding on the scanner couch as the subject cycles. This support system should also help prevent damage to the scanner throughout the duration of the testing.

Preliminary testing was done this semester via Doppler Ultrasound on our existing device. The next step of testing will involve an MRI scan with the cycle. Based on the results of this scan, it will be known the degree to which we need to increase the resistance. This scan may also indicate other weak points of the current design which have not yet been discovered. As construction begins on a second prototype, the ultrasound testing will have to be repeated and an updated exercise protocol determined.

There are a few other minor details which can be dealt with in the upcoming semester. The entire device was found to weigh 18 lbs; and while this is not excessive, the platform is bulky and difficult to carry. Wheels and a handle could be added to the base of the device to allow for easy transport between scans. One last idea that surfaced following the interview with Dr. Schrage involved constructing a "pseudo-bore" for use during the maximal workload testing to familiarize the subject with the claustrophobic environment of the MRI to prevent a stress response from affecting their cardiovascular system. This may or may not be something pursued, depending on time available after construction and testing.

Ethics

Any time that human subjects are being used in research, many ethical concerns must be considered. This particular research involves the exercising of patients with pulmonary hypertension, which could potentially be dangerous if not properly monitored. An understanding of the limitations of such patients will help to establish a biomarker which determines the safe limit of such exercise. The researcher, Alejandro Roldán, has already received IRB approval to do such research and therefore the device will be covered under his research. Under that approval, a consent form exists to address any risks with testing and inform the subject as such.

The testing of the device, however, had to be examined before determining if additional approval was required. The results of the ultrasound testing were being used solely within the scope of the academic project and not, at this point, as a study of blood flow. Due to this and the fact that the testing was done only on the members of the design group, no additional IRB approval was needed. Also, there was no requirement of the team members to participate in testing. Although the ultrasound to determine the presence of the tricuspid regurgitant jet is considered noninvasive, there was still a risk of finding a pre-existing condition or problem with a team member's heart, and therefore participation was purely voluntary. The absence of a TR jet eliminated a teammate from being tested on due to the inability to estimate pulmonary blood pressure. For further testing on more healthy subjects outside of the group, drafting an IRB protocol to test the prototype using Doppler Ultrasound may be necessary

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Appendices

Appendix A: Current patents

US Patent 6,358,208: Assessment of cardiovascular performance using ultrasound methods and devices that interrogate interstitial fluid. March 19, 2002

The present invention provides for methods and devices for monitoring cardiovascular performance. The invention also includes methods of measuring capillary related interstitial fluid, as well as cardiac and vascular function. Specific devices, particularly probes, are provided for such methods.

US Patent 4,265,591: Adjustable Pitch Fan. December 12, 1978

Apparatus having radially disposed adjustable pitch fan blades embodies a split hub that is adapted to retain the blades in the plane of the hub. One portion of the hub includes an annular base with concentric upstanding inner and outer walls that define a channel. The outer wall includes a plurality of openings in which the blades are rotatably journalled with a cam portion of each blade extending into the channel. Cam follower means are slidably disposed in the channel and interlink adjacent cam portions so that rotation of any one blade will correspondingly adjust the pitch of each of the other blades. The blades are locked to a predetermined pitch setting by fastening the hub portions together. Another embodiment includes the fan blades and split hub which is bushed and secured to a shaft of a reversible drive motor. The fan and motor are mounted in a housing having open ends, an inlet end including air straightening means to improve air coupling with the fan blades and being adapted to fit a grain drying bin. The other end includes a shutter that is normally closed but which opens under air pressure to exhaust the air from the bin when the apparatus operates. Means are provided to hold open the shutter so that when the motor rotation is reversed, air may be blown into the bin.

Appendix B: Final Prototype Total and Future Device Total

Item	**Part #**	**Qty.**	**Cost**	**S/H**	**Tax**	**Total**	**Date**	**Vendor**
Timing Pulley	A 6L 3-78SF03712	1	$10.20	$11.29	$0.00	$21.49	11/6/2009	Stock Drive Products
Timing Belt	A 6B 3-240037	1	$12.70	$2.26	$0.00	$14.96	11/6/2009	Stock Drive Products
Timing Pulley	A 6L 3-16DF03708	1	$4.03	$2.26	$0.00	$6.29	11/6/2009	Stock Drive Products
Replacement Fan Blade	FLX-30132K	1	$21.95	$4.95	$0.00	$26.90	11/13/2009	Summit Racing Equipment (Flex-a-lite)
Aluminum Round Rod (3/8", 4' long)	5117874	1	$8.99	$0.00	$0.49	$9.48	11/16/2009	ACE Hardware
Gorilla Glue Epoxy 25 ml	011041	1	$5.49	$0.00	$0.30	$5.79	11/16/2009	ACE Hardware
Brass Corner Brackets	44074429954	4	$2.97	$0.00	$0.65	$12.53	11/17/2009	The Home Depot
Brass Strips	690636	3	$2.59	$0.00	$0.43	$8.20	11/17/2009	Dorn True Value
Brass Screws	030699293117	3	$0.98	$0.00	$0.16	$3.10	11/17/2009	The Home Depot
Brass Nuts	030699186013	2	$0.98	$0.00	$0.11	$2.07	11/17/2009	The Home Depot
Aluminum Round Rod	622397	1	$3.29	$0.00	$0.18	$3.47	11/17/2009	Dorn True Value
Screw Bumpers	039003091319	1	$1.95	$0.00	$0.11	$2.06	11/17/2009	The Home Depot
Brass Phillips Flathead Wood Screws	H385620	1	$6.49	$0.00	$0.36	$6.85	11/21/2009	ACE Hardware
Brass Narrow Hinge	5299730	1	$4.49	$9.00	$0.25	$13.74	11/22/2009	ACE Hardware
White Lith Grease 1.25 oz	87211	1	$3.29	$9.00	$0.18	$12.47	11/22/2009	ACE Hardware
Chairleg Axle Spacers 3/8"	52504	1	$1.79	$0.00	$0.10	$1.89	11/22/2009	ACE Hardware
Orings Large	16	1	$0.40	$0.00	$0.02	$0.42	11/22/2009	ACE Hardware
Orings Medium	16	4	$0.25	$0.00	$0.06	$1.06	11/22/2009	ACE Hardware
Orings Small	16	4	$0.25	$0.00	$0.06	$1.06	11/22/2009	ACE Hardware
Spacers	16	6	$0.30	$0.00	$0.10	$1.90	11/22/2009	ACE Hardware
Toe Clips	-	1	$9.99	$0.00	$0.65	$10.64	11/27/2009	Erik's Bike Shop
Decorative Hinge	283413	1	$3.79	$0.00	$0.21	$4.00	12/6/2009	Dorn True Value
Bulk Strap Clips	-	2	$2.99	$0.00	$0.33	$6.31	12/8/2009	Dorn True Value
Bulk Straps	856013	12	$0.45	$0.00	$0.30	$5.70	12/8/2009	Dorn True Value
Brass Screws	-	13	$0.17	$0.00	$0.12	$2.33	12/8/2009	Dorn True Value
Prototype Total	**$184.69**							

Item	**Part #**	**Qty.**	**Cost**	**S/H**	**Tax**	**Total**	**Vendor**
Timing Pulley	A 6L 3-78SF03712	1	$10.20	$11.29	$0.00	$21.49	Stock Drive Products
Timing Belt	A 6B 3-240037	1	$12.70	$2.26	$0.00	$14.96	Stock Drive Products
Timing Pulley	A 6L 3-16DF03708	1	$4.03	$2.26	$0.00	$6.29	Stock Drive Products
Replacement Fan Blade	FLX-30132K	1	$21.95	$4.95	$0.00	$26.90	Summit Racing Equipment (Flexalite)
Aluminum Round Rod (3/8", 4' long)	5117874	1	$8.99	$0.00	$0.49	$9.48	ACE Hardware
Aluminum Round Rod	622397	1	$3.29	$0.00	$0.18	$3.47	Dorn True Value
Screw Bumpers	039003091319	1	$1.95	$0.00	$0.11	$2.06	The Home Depot
White Lith Grease 1.25 oz	87211	1	$3.29	$9.00	$0.18	$12.47	ACE Hardware
Chairleg Axle Spacers 3/8"	52504	1	$1.79	$0.00	$0.10	$1.89	ACE Hardware
Orings Large	16	1	$0.40	$0.00	$0.02	$0.42	ACE Hardware
Orings Medium	16	4	$0.25	$0.00	$0.06	$1.06	ACE Hardware
Orings Small	16	4	$0.25	$0.00	$0.06	$1.06	ACE Hardware
Spacers	16	6	$0.30	$0.00	$0.10	$1.90	ACE Hardware
Toe Clips	-	1	$9.99	$0.00	$0.65	$10.64	Erik's Bike Shop
Decorative Hinge	283413	1	$3.79	$0.00	$0.21	$4.00	Dorn True Value
Bulk Strap Clips	-	2	$2.99	$0.00	$0.33	$6.31	Dorn True Value
Bulk Straps	856013	12	$0.45	$0.00	$0.30	$5.70	Dorn True Value
Brass Screws	-	13	$0.17	$0.00	$0.12	$2.33	Dorn True Value
HDPE Sheet (.5" thick, 2'x2')	8619K474	2	$37.74	$5.00	$0.00	$80.48	McMaster
Plywood Board	-	1	$5.00	$0.28	$0.00	$5.28	Home Depot
HDPE Sheet (.25" thick, 2'x3')	8619K466	1	$28.76	$5.00	$0.00	$33.76	McMaster
Future Device Total	**$251.93**						

Note: This is an overestimate since a lot of these supplies are purchased and it's unnecessary to buy more. This is simply showing what it would cost to purchase everything to build the future device from scratch.

Appendix C: Exercise and Testing Protocols

Testing methods: For preliminary exercise testing shown in Figure 10, a Welch-Allyn Electronic Blood Pressure/Pulse Monitor, Therabands, and a Velcro ankle strap weight were used.

Ultrasound Testing:

- Have patient lie down on bed for measuring baseline vitals: systolic blood pressure, heart rate, TR jet velocity, pulmonary artery (PA) diameter.
- Once technician has found correct Doppler Ultrasound measuring angle, start timer and have patient begin cycling
- Measure all four vitals at two minute increments until six minutes, increasing rpm at each two minute interval
- Burn data onto CD for analysis

Exercise Protocol

- Ultrasound test first to get PA systolic pressure at various rpm (cycling to metronome)
- Transport device to MR scanner
- Send patient into bore, give headphones
- Clamp device onto table
- Baseline scan
- Start six minute cycling, increase metronome Hertz at two min intervals
- Arbitrary cycling during post-exercise scan

Appendix D: Product Design Specifications

Product Design Specification for BME 400-Group 12: MRI-Compatible Lower Leg Exerciser

December 9, 2009
Group Members: Amy Lenz, Colleen Farrell, Val Maharaj, Deborah Yagow

***Problem Statement*:**

The goal of this project is to design and construct a lower leg exerciser that is compatible with MR imaging and Doppler Ultrasound to be used during cardiopulmonary research studies on pulmonary hypertension patients and healthy volunteers. The device must have repeatable loads that can be measured and relayed to the patient via biofeedback.

***Client Requirements*:**

1. Design Requirements

The device must meet all of the client requirements.

a. *Performance requirements:* To exercise the patient with a device supplying variable loads to reach maximum workload and a specified percentage of that, usually 40%, and also raise pulmonary systolic blood pressure by 7-8 mmHg. Device must accommodate different patient sizes and capabilities and provide suitable biofeedback for them to continue exercise at the desired level. Device must not damage the scanner bed in any way.

b. *Safety:* The exercise device must cause no harm to the patient while in use or during scanning. The biofeedback must not damage any patient senses (visual or audio). All materials must be MRI-compatible for the safety of the magnet and medical personnel.

c. *Accuracy and Reliability*: Maintain consistent loading from patient to patient. Biofeedback must accurately display measurement within 5% of actual value.

d. *Life in Service*: 5 years

e. *Shelf Life*: 5 years

f. *Operating Environment*: Hospital and research lab in presence of EKG leads, MRI scanner and ultrasound devices.

g. *Ergonomics*: Device must be comfortable for the patient while exercising and during scanning, while lying in the MRI tube for up to two hours.

h. *Size*: Must be compatible with dimensions of scanner bore: 11.83” radius, 21.875” table width, 4.50” height from table to center of bore, and 18.79”scanner bed width.

i. *Weight*: Less than 30 lbs; able to be transported by hand.

j. *Materials*: All materials must be non-ferrous and durable.

k. *Aesthetics, Appearance, and Finish*: Device shouldn't squeak excessively during use or contain sharp corners or edges.

2. Product Characteristics

a. *Quantity*: One working prototype with goal of creating more devices to be used in other research studies.

b. *Target Product Cost*: $150

3. Miscellaneous

a. *Standards and Specifications*: IRB approved for use on human test subjects.

b. *Customer*: Researchers in cardiovascular physiology medicine

c. *Patient Related Concerns*: Comfort and multiple options for biofeedback to notify patients with possible disabilities.

d. *Competition*: Other labs and design groups with similar interest from competing universities, and commercially, Lode Ergometry.