Fetal Radiation Shield

Limiting dosage of high-energy radiation to the developing fetus

Final Report
BME 400: Senior Capstone Design Course in Biomedical Engineering
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Abstract

Radiation can be extremely dangerous to a developing fetus, with risks including birth defects and increased likelihood of childhood cancer. Pregnant patients undergoing radiation therapy, therefore, require modification of treatment plans in order to reduce the fetal radiation dose. Currently, there exists no universal product to physically shield the fetus from oncoming radiation. Existing apparatuses for this purpose are either unsafe or cost-prohibitive for most institutions. The Department of Human Oncology at University Hospital requests that a shield be designed specifically to protect the fetus from leakage from the head of the radiation machine and scatter off of the patient. This will be accomplished with a lead shield that is five centimeters thick and: safe for the patient and medical personnel, mobile for storage outside the treatment room, capable of raising and lowering to accommodate different treatment plans, and shields 50% of stray radiation capable of reaching the fetus. Throughout the last semester, the team developed a transportation system, refined the shape of the shield, and added further detail to te lifting/ support mechanism. The team now has a full model of the shield design with its various components. Implementation of the apparatus in University Hospital will provide more treatment options for pregnant patients throughout the state of Wisconsin.

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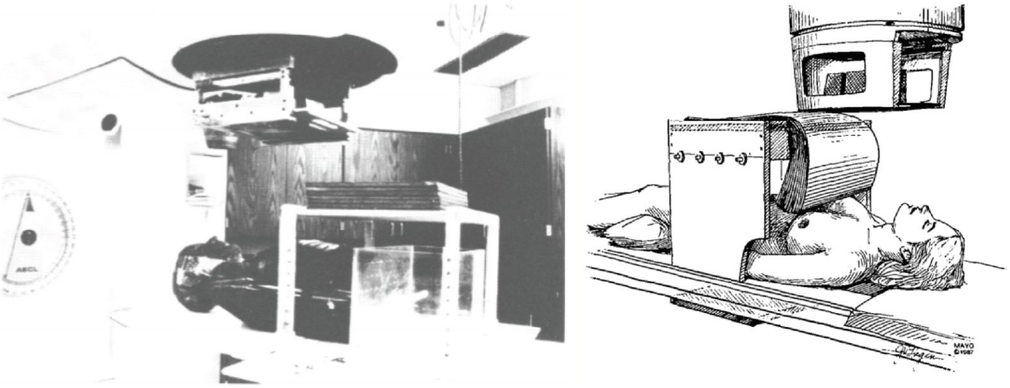
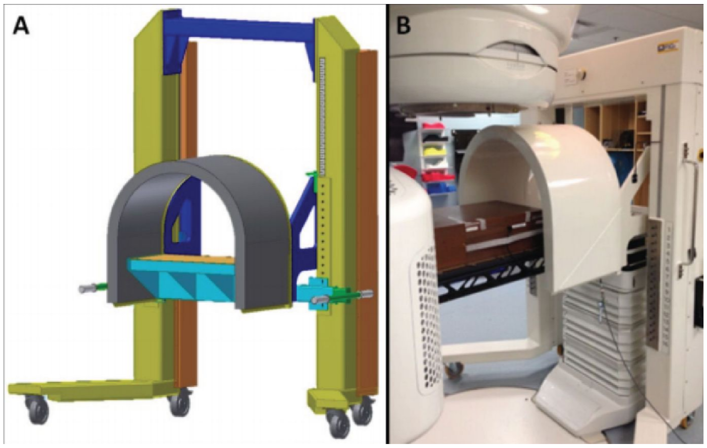
I. Introduction

Each year, nearly 4,000 pregnant women are treated with radiation therapy within the United States [1]. This number is increasing yearly due to more incidental cancer diagnoses and an increase in the average childbearing age [2]. Radiation therapy is most often considered when treatment cannot be delayed until after childbirth. The majority of patients are young women with either brain or breast cancer [1]. In these cases, the primary goal of the treatment plan is to treat the tumor while minimizing the amount of stray radiation reaching the fetus. Biological consequences of fetal absorption of over 0.05 joules of radiation energy per kilogram (0.05 Gray) include increased risk of fetal death, malformation, mental and growth impairment, gene mutations, and childhood cancers, depending on the point in development at which treatment occurs [3][4]. Current efforts to reduce fetal dose [Figure 1] are limited to altering the treatment parameters such as angle and direction of the beam [3]. These techniques can be further supplemented by using a fetal radiation shield in order to ensure even more protection from stray radiation.



[Figure 1] Examples of previously-devised methods of shielding pregnant patients, named the bridge over patient and table over treatment couch, respectively [1].

Lead shields utilized for these purposes through the 1990's include a bridge or table placed over the treatment couch. Both methods required manual stacking of lead bricks or sheets over the patient, a practice that has since been discontinued due to the safety risk posed to the patient and medical personnel [1]. Another proposed solution involved placing a Cerrobend brick against the head of the treatment machine to block radiation leakage to the fetus at the source of the radiation. This was also discontinued due to safety concerns and inefficiency [5]. In 2010, the University of Michigan's Medical Innovation Center developed a mobile, U-shaped shield which included a sophisticated locking system and hydraulic motors [Figure 2]. Although the shield was effective at blocking 50% of the peripheral dose (PD) to the fetus, the design proved far too expensive and led to the bankruptcy of the manufacturing company [3][6]. Due to the prohibitive cost of manufacturing such barriers, there currently exists no safe, commercially-available product that limits fetal radiation dose. In the absence of a shield, many oncology departments instead rely on simply positioning the treatment table such that the fetus is as far away from the head of the machine as possible.



[Figure 2] The Michigan Shield Design. Images from Owrangi et al. depicting the University of Michigan's U-shaped shield, including a CAD model and photo of the final product [2].

This project will focus on creating a fetal radiation shield that is effective at blocking 50% of fetal radiation, economical, can be moved between treatment room and storage place, raised and lowered, and above all, is safe for the patient and all medical personnel involved.

II. Background

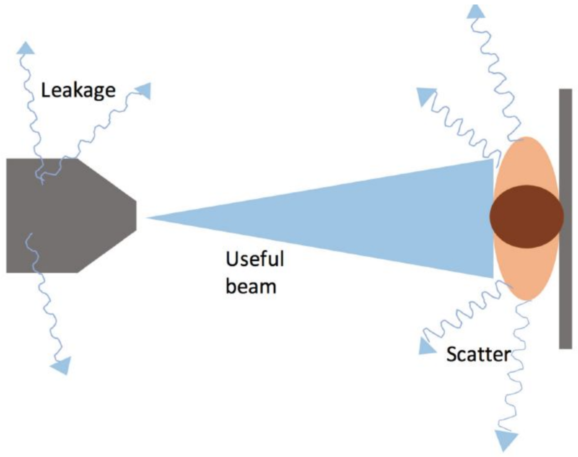
2.1: Cancer Treatment

The most common cancers with which pregnant patients present include breast cancer, brain cancer, cervical cancer, lymphoma, and melanoma [4]. Most of these patients will not require immediate radiation therapy during their pregnancy and will chose to delay treatment. However, in some cases, the risk of the cancer to the patient will outweigh the potential risk of radiation exposure to the fetus. In these limited cases, a shield will aid in treatment if the patient presents with cancer in the upper portion of the body, such as brain or breast cancer.

Radiation therapy is often used in combination with surgery and chemotherapy to attack cancer cells in body by creating free radicals within the cell and damaging the DNA. While there are many types of radiation, such as the low doses of radiation that are used in x-rays, the radiation that is used to treat cancer delivers extremely localized, high energy beams of ionizing radiation to a specific point in the body. This radiation is powerful enough to damage the DNA of cancer cells. Once the DNA has been corrupted in the cancer cells, those cells can no longer replicate and thus, die. However, while this is very effective at treating cancer, the ionizing radiation can just as easily damage normal, healthy cells, including the cells and tissues that are in a developing fetus [14]. Primary risks to the fetus resulting from radiation exposure include death, malformation, and increased childhood cancer rate. Without a shield, this risk is already quite low at approximately 0.5% chance [2].

When considering the effects of radiation, pregnancy can be split into three different periods. The first period is the week directly after implantation of the embryo in the uterus (Week 1). The second period is known as organogenesis (Weeks 2-7) [4]. The third period is called the fetal period (Weeks 8-40). While the risk to the fetus is relatively constant throughout the pregnancy, the risks change throughout development. During the first period after implantation, radiation effects can be lethal. During the second period, the main risks to the fetus are growth retardation and malformation [7]. Once the pregnancy is in the final period, the primary concern becomes increased risk of childhood cancer and microcephaly.

When evaluating the amount of radiation that reaches the fetus [Figure 3], the main source is photon leakage through the head of the machine, radiation scatter from the collimators, and radiation scattered within the patient from the treatment beams [4].



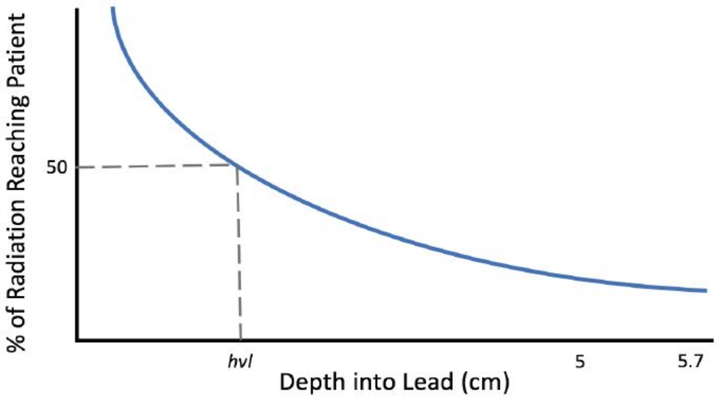
[Figure 3] Fetal Dose explained: a schematic of the leakage and scatter off the patient, which together constitute the radiation of concern to the fetus. Image derived from [8].

2.2: Electron and Photon Testing

It will be important to test the levels of radiation that the shield prevents from hitting the fetus. One possible testing would be dosimetry, which is a method that studies the absorbed dose in external photon and electron beams hitting the object [9]. However, the dosimetry protocols do not measure depth-dose curves required for beam quality specifications, as it only measures the absorbed dose [9]. A dosimetry test would be completed with the final design to measure the photon and electrons that get through the shield. An option within dosimetry testing is Monte Carlo simulation for electron and photon transport. This is a computer simulation of electron and photons transport through a system [10]. When all the interactions experienced by a particle is exact, it yields precise results of the amount of electrons and photons that are expected the hit the system [10]. However, in practice, detailed simulation is only feasible when the average number of collisions are less than 300 [10]. With increasing complexity of a system, this increases the length of time needed to complete this computer simulation [10].

2.3: Design Specifications

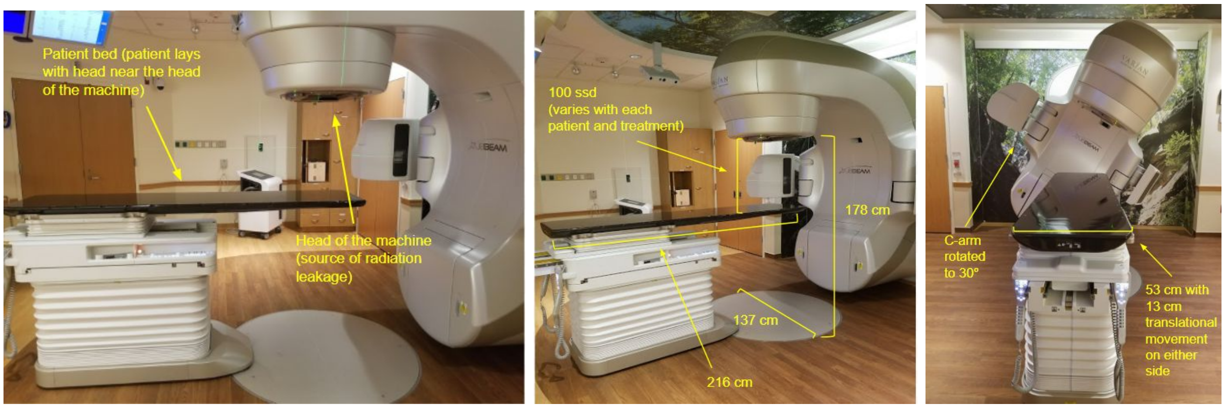
Lead is the industry standard for blocking radiation due to its effectiveness relative to its volume and weight [1]. When deciding on the thickness of lead for the shield, the team looked into the tenth value layer (TVL) of pure lead. This was found to be 5.7 cm [11]. The TVL indicates the thickness of lead required to block 90% of the incoming radiation. The reported half value layer (HVL) value of lead lies between 2-3 cm and is the thickness required to block 50% of the radiation. A width of 5 cm was decided on, to increase the likelihood of meeting the 50% attenuation requirement [Figure 4].



[Figure 4] Lead Thickness Diagram for Blocking Radiation

The radiation that scatters throughout the patient is impossible to physically block, thus our device will focus on radiation leakage and scatter. The shield should have sufficient coverage on the sides of the treatment table to block lower-energy scattered electrons and provide proper protection over the abdomen and towards the chest to prevent contact with the head leakage. Throughout this project, it will be essential to use the industry standard thickness of lead to block radiation as well as optimize the coverage of the patient.

The client for this project is Dr. Zac Labby, a radiation physicist at University Hospital in the Department of Human Oncology. When confronted with his first pregnant patient at UW, Dr. Labby devised a protocol describing how the hospital should go about treating pregnant patients. He is hoping to expand the protocol to include an effective method of blocking radiation from reaching the fetus to better accommodate these patients and requested the team to design an apparatus to accomplish this. The main requirement for the project was that the shield must not pose a larger risk to the patient than the radiation itself, which is only a moderate risk. The other requirements are that it must block at least 50% of the radiation capable of reaching the fetus, accommodate women of all shapes and at different stages of pregnancy, and must be able to move and be stored easily. The design must be compatible with the treatment room specifications [Figures 5]. The budget is $10,000 total for the final product.



[Figure 5] Diagram of the treatment room showing treatment directionality (left); dimensions of University Hospital radiation therapy treatment suite (middle and right).

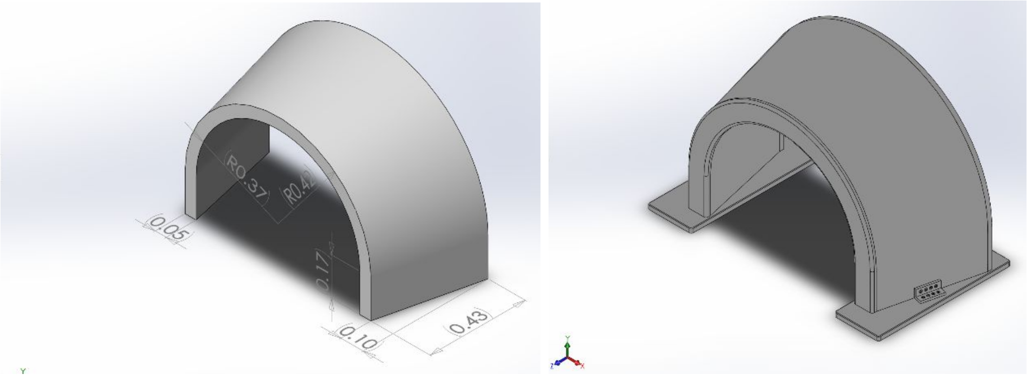
Compatibility with the radiation therapy treatment rooms is important for the design. There are several critical dimensions that were considered. These include the 122 cm-wide doorway, the 137 cm-diameter force plate, the 53 cm-wide treatment table, and the 13 cm translational movement of the treatment table. The shield must fit through the door into the treatment rooms in order for it to be an effective apparatus, measuring 1.2 meters in width. The rotational mechanics are housed underneath the force plate in a honeycomb aluminum structure that is not strong enough to support a significant force. For this reason, the design must accommodate for this with legs that extend past it. The lifting/ support mechanism needs to be able to support the weight of the field with up to three times the factor of safety for an increased protection of the patient. The transportation will also need to support the weight the of whole system and be transported between treatment rooms and storage in an adjoining hallway with minimal safety concerns for hospital personnel.

To ensure adequate protection for the fetus, it is vital that the lip of the shield fits snugly around the patient's chest when lowered and that the dimensions cover the fetus from both the leakage from the head of the machine and the scatter created when the photons reflect off the patient's body. To allow for the shield to be used with a wide variety of patients, the inner dimensions of the shield will be based on anthropometry measurements from the 95th percentile of pregnant US women in the ninth month of pregnancy. The shield must fit a woman with an abdominal width of at 21" (53.3 cm) and chest width of 12" (30.5 cm) as measured in the coronal plane and an abdominal depth of 17" (43.2 cm) and chest depth of 14" (35.6 cm) as measured in the sagittal plane [12][13][15].

III. Previous Work

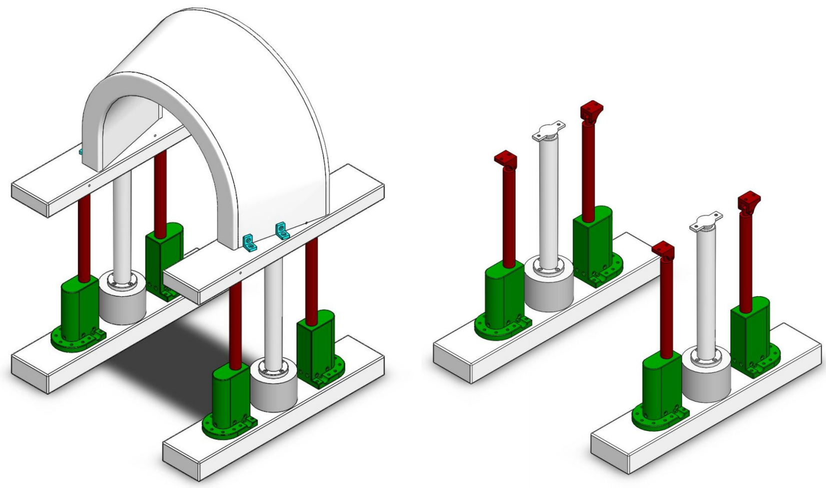
The problem was originally divided into five parts: the lead shield, the lifting and support mechanism, the transportation system, the automation component, and the safety features. Previous teams tackled the lead shield and the lifting mechanism, which the transportation system will be centered around.

When designing the shield, it was important to create a barrier that provided as much coverage as possible to a variety of patients, while also being conscious of the weight and physical constraints of the room. The idea was to mobilize the shield in the vertical dimension, facilitating its ability to be placed as close to the abdomen as possible. In doing so, the team first considered a "U" shape similar to the University of Michigan design. The team felt that this shield lacked optimal coverage. Aiming to address this, the team ultimately decided on a design that contoured the shape of the patient's abdomen, deemed the "high-waisted skirt" design [Figure 6]. This high-waisted skirt shape allows the greater coverage of the abdomen from leakage and scatter at the head of the machine than the U-shape. It also consciously limits the weight of the lead by not extending the full length of the abdomen. The sides of the high-waisted skirt extend past the table towards the ground to block lateral radiation. Dimensions of this design were determined by anatomical patient size throughout pregnancy with the idea that it could be raised and lowered over the patient as necessary. The team also considered the physical constraints of the treatment room including the couch, linear accelerator, and width of the door.



[Figure 6] SolidWorks model of previously designed lead shield (Left) and its steel casing (Right). All dimensions are in meters.

When designing the lifting and support mechanism, it was vital that it be able to support the entire weight of the lead shield and its casing, which was estimated to weigh roughly 1000 lbs. To ensure the safety of the both the patient and the medical team, the team designed a dual lifting system that is mechanical in nature and relies on electric power [Figure 7]. The primary lift system uses four linear actuators, designed by Progressive Automations, Inc., which will be placed in each corner, directly under the lead. The backup system will employ two power screws, one situated in the middle of each side of the shield, that behave in a manner similar to the screw jacks used to lift the foundations of buildings. These would be custom made with a motor to control the speeds at which the power screws rise, and the motor and power screws will be linked with bevel gears. Both systems operate independently of each other, and the systems are capable of independently supporting the entire load. The idea behind this is to ensure that, should one system fail due to unforeseen circumstances, the other system acts as a fail-safe to prevent the supports from buckling and collapsing on the patient. The lifting systems connect to the shield via two casing mounts and are supported by a bottom frame, to which the transportation system would be mounted.



[Figure 7] The entire shield, shield casing, and lifting mechanism that was created in last semester (Left) and the lifting mechanism with the six supports and bottom frame (Right).

Initial static load testing on the device done in SolidWorks was promising, but later analysis revealed that several calculations were done improperly. While some of the results remain unchanged, others were affected by the calculations, which lead to inconclusive results. The team was confident that the steel casing is strong enough to support the weight of the lead and that the four linear actuators can lift the entire shield, but for future work, the team wanted to focus on incorporating the transportation system into the static loading simulations, as well as simulations to describe the dynamic loading and fatigue failure of the entire device.

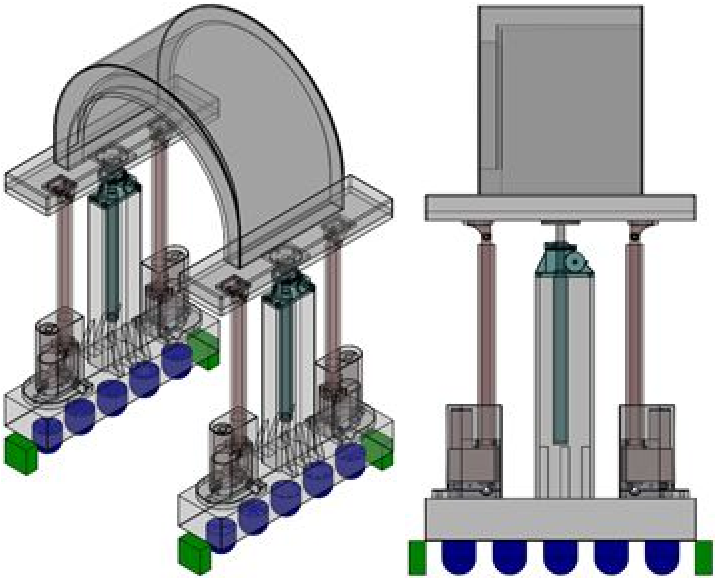
The focus of this semester was developing a transportation mechanism and further modifications to the shield and the lifting system. At the beginning of this semester, a system to move the shield assembly from where it would be stored, to the treatment room had not been devised. In addition, the team had not determined the specifics of the backup power screws, an idea upon which needed to be expanded. Finally, the team had to completely redesign the shape of the shield to drastically reduce the cost from the original $20,000 estimate.

IV. Preliminary Designs

4.1: Transportation System

Four preliminary transportation designs were formulated for designing the transportation system of the entire shield assembly, each with an unique combination of wheels and braking components.

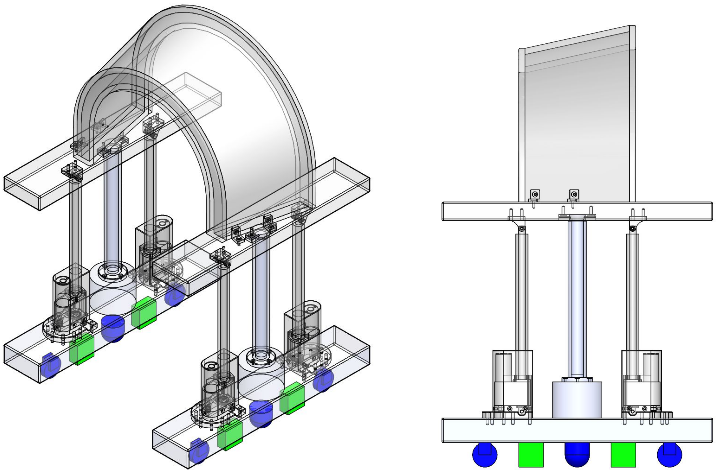
4.1.1: The Rollerblade



[Figure 8] SolidWorks view of the "Rollerblade" transportation system. The wheels are circled in blue and the braking system is highlighted in green.

The first design that was formulated has been termed the "Rollerblade" [Figure 8]. Similar to actual rollerblades, there will be five to seven caster wheels on each side of the support base for the shield. This allows for more even weight distribution over more points of contact with the ground, increasing the mechanical stability of the system. The wheels will be able to rotate 360 degrees and allow sideways movement of the shield assembly, which is necessary considering the size limitations posed by the doors in the radiation therapy wing of the hospital. The wheels will be attached to metal bars, which will then be attached to the support base of the shield assembly, thus preventing excessive holes from having to be drilled into the base and the subsequent reduction of mechanical stability. The braking system will consist of four foot controlled brakes that will be positioned on the superior and inferior positions of the shield system. The four brakes will secure the shield assembly in place when it is positioned over the patient.

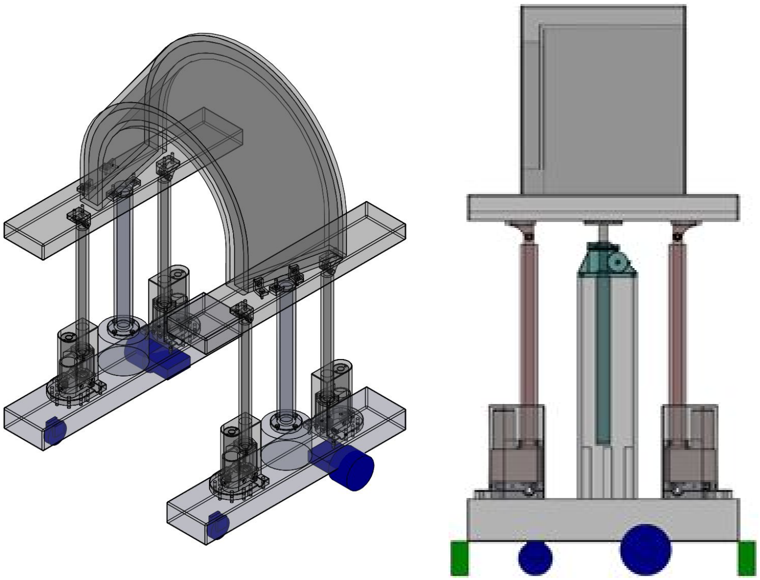
4.1.2: The Semi



[Figure 9] SolidWorks depiction of the "Semi" transportation system design. The wheels are colored in blue and the brakes are colored in green.

The second design was termed the "Semi" for the resemblance of its braking system and wheels to those of a semi-truck [Figure 9]. The design includes four wheels at the front and back corners of the shield support base in addition to two ball transfer units at the center of each support bar. Although the smaller number of wheels reduces the number of points of contact in comparison to the "Rollerblade", the wheels will still be able to rotate 360 degrees, allowing for sideways movement of the shield assembly. As in the "Rollerblade" design, the wheels will be attached to metal bars and the metal bars to the support base of the shield. The braking system of the "Semi" design is very similar to that of a semi, with four step down brakes each positioned between a caster wheel and the centered ball caster. The brakes are employed using the user's foot, reducing pinching hazards and keeping the shield assembly in place during treatment.

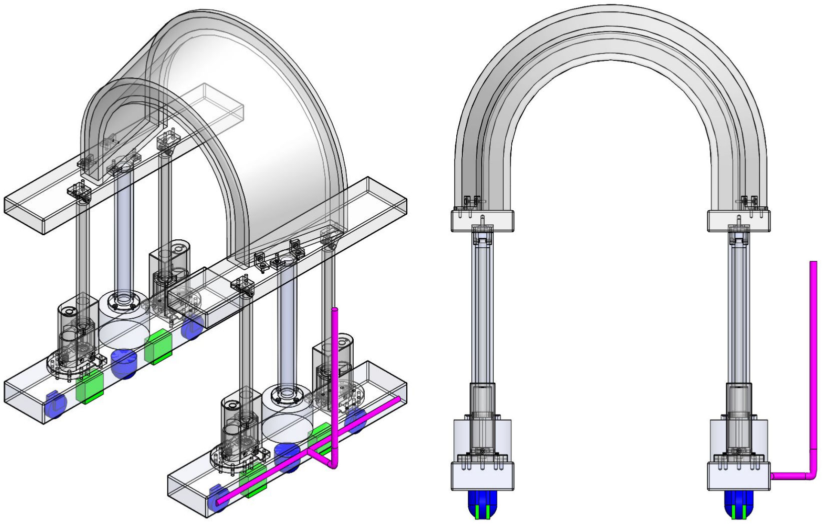
4.1.3: The Trolley



[Figure 10] SolidWorks depiction of the "Trolley" transportation system design. The wheels are colored blue and the braking system is colored green.

The "Trolley" design was based on a method currently used to move large portable x-ray machines in the hospital [Figure 10]. Since the center of mass of the shield is toward the back of the assembly, adding larger wheels at the back would provide greater stability than a pair of smaller wheels. In the portable x-ray machines, the back wheels are larger than the front wheels and fixed while the smaller front wheels can rotate 360 degrees. The braking system would rely on the placement of wedges under each wheel to prevent movement while the shield assembly is positioned over the patient. While utilizing these simple wedges for the braking system makes removal straightforward and intuitive, it also poses a significant pinching risk. The biggest drawback of this design is that because the back wheels are fixed; wheels cannot rotate 360 degrees, preventing the sideways movement required to clear the door to the treatment room.

4.1.4: The Control Enthusiast

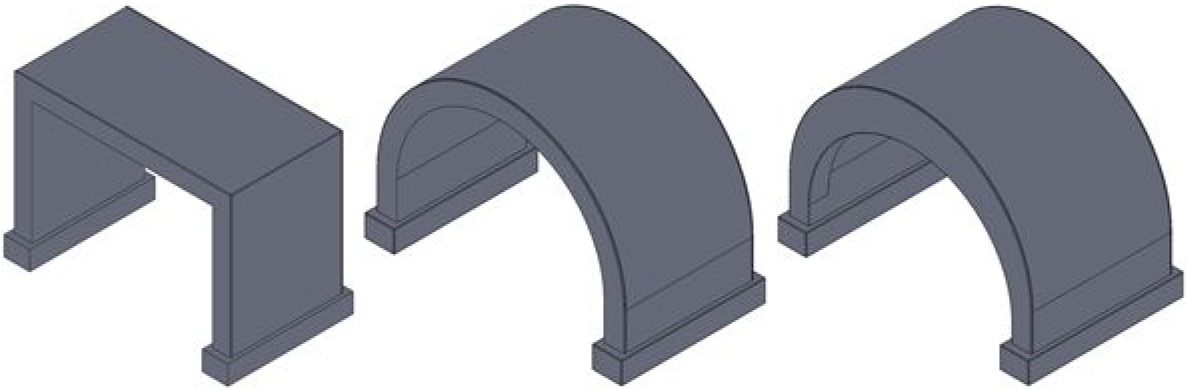


[Figure 11] SolidWorks depiction of the "Control Enthusiast" transportation system design. The wheels are colored blue, steering system colored purple, and the braking system colored green.

The "Control Enthusiast" design is essentially an extension of the "Semi" design. It will have four 360 degree rotating caster wheels, two at the front and two at the back, and two ball caster wheels in the middle [Figure 11]. In order to stabilize the system, four step-down brakes will be positioned between the center ball casters and rotating casters, two on each side of the shield. To provide better steering and shield handling, the wheels on one side of the shield will be coupled and will be able to rotate via a steering lever. The steering lever will direct the angle of the wheels, so they can be rotated sideways, allowing for sideways movement of the shield. This steering mechanism is similar to a car steering mechanism but it is not motorized. The axle would then bear most of the weight on the side of the assembly but would then allow for the wheels to be rotated more easily. Advantages to this design is that there is more control over the steering while still maintaining safe and intuitive braking mechanism. However, the steering axle will add expense and complexity to the design.

4.2: Shield Redesign

To keep the total cost within the $10,000 budget, the team had to redesign the shape of the shield. During discussions with Vulcan Manufacturing, the company that the team wants to assemble the shield, the main problem that arose when creating the high-waisted skirt was the funnel shape. Since the shield flared out, Vulcan Manufacturing raised some concerns about the difficulty of machining that particular shape and how it would significantly increase the price of the shield. This semester, the team came up with three alternatives to the high-waisted skirt that would reduce machining difficulty and thus reduce overall cost [Figure 12].



[Figure 12] The box shield shape (Left), the cylinder shield shape (Middle), and the lipped cylinder shield shape (Right) that were considered as alternative shield designs for the high-waisted skirt.

The first shape redesign that was considered was converting back to the cylinder shape that had originally been considered at the start of the project. In order to compensate for the loss of the flared shape that was designed to contoured the shape of the patient’s abdomen, this shield was designed with a lip on the front. This would essentially replace the flared geometry of the “High-Waisted Skirt”, while still providing the extra protection from radiation scatter. The second design we considered was simply a cylinder without the lip. The team wanted to see what kind of cost reduction could be obtained without the lip in case the lipped design was over budget. Finally, the team considered an even simpler design of a box shape. The design was really only created as a last resort option if the other two were still over the teams allotted budget.

V. Preliminary Design Evaluation

5.1: Design Matrix and Evaluation

5.1.1: Design Criteria

Safety primarily to the patient, but also to the medical personnel involved in operating the shield assembly, was the highest priority in designing the shield assembly and transportation system. The objective of the radiation shield is to enhance safety of the mother and fetus by reducing fetal radiation dose, therefore a shield assembly that introduces another significant risk to their safety would defeat the purpose of the project. With the safety category, we were chiefly concerned with the worst-case-scenario: shield collapse by or on the patient.

The degree to which the transportation system created or reduced a bending moment about the assembly supports was used to assess the risk of collapse.

The transportation system designs were rated for the intuitive design category based on the quickness and ease with which an individual operating the shield assembly would be able to understand the function of its components. The client was concerned with how quickly one would be able to move the shield assembly if a patient were to get sick and/or need to get off the treatment bed as soon as possible without forgoing important safety precautions. The pressure to forego safety precautions, therefore, should be minimized to reduce the incident of shield misuse and safety hazards to the patient by making the transportation design, particularly the brake system, as straightforward and intuitive as possible. The intuitive design category was weighted second highest after safety due to how related it is to the safety of the patient and medical personnel.

The durability criterion was concerned with how often the transportation system components would require maintenance or replacement to ensure safe and proper function of the shield assembly. According to the client, the shield likely be used no more frequently than once a year. Hence, the components would be made from high-quality, durable materials and preferably not require replacement during the lifetime of the shield. Repairing or replacing components of the shield assembly, even if it is a single broken wheel, would be challenging and likely expensive due to the massive weight of the lead shield. Furthermore, failure of any transportation or support components during operation of the shield could be catastrophic, therefore durability was weighted the third highest of the design criteria.

Maneuverability, the fourth criterion, refers to the ease and safety with which the user could push, steer and employ the brake system during transportation of the shield assembly. It additionally includes how well the transportation system facilitates positioning of the shield over the patient on the treatment table in various treatment configurations. The client emphasized during discussion of design criteria that maneuverability of the shield assembly is a relatively low priority; because the shield will be rarely used, it is not an issue if multiple people and labor-intensive, complex maneuvers are required to transport the shield assembly. Nevertheless, safety risks to the staff involved in transportation of the shield are still a priority, so this category is weighted the fourth highest.

Two considerations were made when rating the transportation system for feasibility: (1) The comparative simplicity or complexity of the transportation mechanism and (2) the compatibility of the transportation mechanism with the current shield assembly design. For this category, we were most concerned about whether the transportation system would interfere with or weaken the support system and thus increase safety risks to the patient and medical personnel. The simplicity or complexity of the design is intertwined with the concept of intuitive design; for our purposes, the simpler the design, the better.

Although it was not emphasized much by the client, the transportation design should be as cost-effective as possible as the fabrication of the lead shield will take up most of the $10,000 budget.

When evaluating the alternative shield shapes, the team was primarily concerned with three criteria: cost, safety, and compatibility with treatment options. Since these new shield shapes were simply modified versions of the shield chosen during the first semester of the project, the deciding factor for the designs were the cost estimates from Vulcan Manufacturing.

5.1.2: Evaluation

Design Criteria	Designs			
	"The Trolley"	**"The Semi"**	**"The Rollerblade"**	**"The Control Enthusiast"**
Safety (30)	12 (2/5)	18 (3/5)	21 (3.5/5)	18 (3/5)
Intuitive Design (25)	10 (2/5)	15 (3/5)	15 (3/5)	15 (3/5)
Durability (20)	4 (1/5)	18 (4.5/5)	8 (2/5)	14 (3.5/5)
Maneuverability (10)	2 (1/5)	8 (4/5)	6 (3/5)	10 (5/5)
Feasibility (10)	4 (2/5)	8 (4/5)	8 (4/5)	6 (3/5)
Cost (5)	3 (3/5)	4 (4/5)	3 (3/5)	3 (3/5)
Total	**35**	**71**	**61**	**66**

[Table 1] Design Matrix with the four transportation system designs and six criteria the designs were evaluated on.

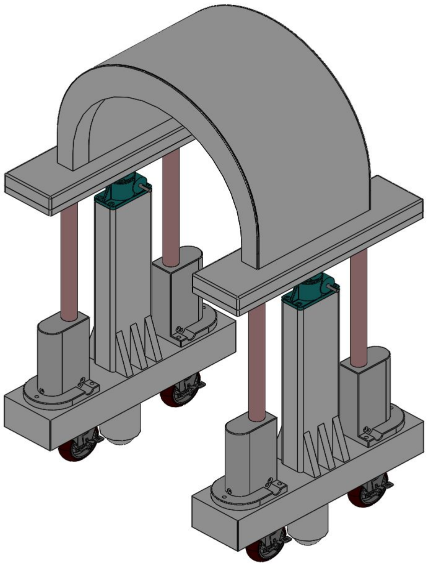
Although the "Trolley" design was initially very promising due to its widespread use in the clinical setting for transporting x-ray machines, the size constraints posed by the force plate and the door to the treatment suite prevent it from being a viable option for transporting the shield assembly. As previously mentioned, the diameter of the force plate is greater than the width of the treatment suite door, requiring that the shield assembly be rotated 90 degrees in order to clear the door while still being wide enough to both straddle the treatment table and avoid putting weight on the force plate. The larger rear wheels of the "Trolley" design are attached at the side of the shield assembly supports as opposed to below the supports, preventing this 90-degree rotation and additionally creating a bending moment about the axis perpendicular to the supports. Resultantly, the “Trolley” received the lowest scores in the maneuverability, feasibility (rotation), durability and safety (additional bending moment) categories. The design received a cumulative rating of 35/100, eliminating it as an option for the shield assembly transportation system.

The “Rollerblade” transportation design was rated the highest in safety due to the more even distribution of weight over 5 to 7 wheels on each side as opposed to only two wheels on each side. The more evenly distributed the weight, the smaller the bending moment about the power screws and actuators supporting the shield, and thus the smaller the risk of the shield assembly collapsing during use. Despite its relatively high safety rating, the “Rollerblade” design scored relatively low in the durability category because the smaller wheels cannot bear as high of loads as the larger wheels in the three other designs, and would consequently be more susceptible to failure. Additionally, moving several small, independently-rotating wheels in unison would be challenging, resulting in a lower rating for maneuverability for the “Rollerblade” design. The “Rollerblade” design was rated third highest of the designs, however, it is important to consider that safety of the design is a higher priority than durability or maneuverability. Hence, we will likely revisit the “Rollerblade” and incorporate the elements that distinguish it in terms of safety into the final design.

The “Semi” and “Control Enthusiast” designs were essentially the same with the latter distinguished solely by its more sophisticated steering mechanism in which the wheels on one side of the shield system are coupled, thus allowing for enhanced maneuverability. The two designs were rated similarly in the categories of safety and intuitive design, with the larger bending moments created about the supports at the corners of the shield assembly being the chief safety concern. The foot controls used to employ the brake systems in both designs are straightforward, safe and commonly used in the clinical setting with patient beds, for example, adding to the intuitiveness of the design. The “Semi” design scored higher than the “Control Enthusiast” during evaluation of durability, feasibility and cost because it has the simplest design with the fewest parts that could fail and/or require repair, making it easier and cheaper to incorporate into the current shield assembly. The coupling of the wheels and steering mechanism in the “Control Enthusiast” significantly increase the cost and complexity of the design and the number of parts that could potentially fail. Although the improved steering function of the “Control Enthusiast” design would ease transportation of the shield assembly, the importance of durability, feasibility and cost collectively outweighed the importance of maneuverability. Overall, the “Semi” marginally outperformed the “Control Enthusiast” during design evaluation, making it the first draft of our final design.

The modified shield designs were all based off of the high-waisted skirt design, using the same physical constraints as the original shield shape. Both the cylinder and lipped cylinder still allowed for the treatment apparatus to move from side to side, and lipped cylinder provided additional protection for the fetus by helping to block the radiation scatter that would come from the patient’s body. The team’s preferred shape was the lipped cylinder since it provided the most coverage, and the cylinder was the second choice since, while it allowed for movement of the treatment apparatus, it did not have the additional protection from scatter that the lipped cylinder did. The team decided that the box shape would serve only as a last resort if the cost of manufacturing both the cylinder and lipped cylinder was too high. After consulting with Vulcan Manufacturing for creating the lipped cylinder, the team received a cost estimate of $7,328.98. This allowed the team to keep the cost within the budget constraints, so the lipped cylinder was chosen.

5.2: Proposed Final Design



[Figure 13] SolidWorks view of the assembled final design. This includes the lipped cylinder shield, linear actuators, power jacks, and transportation system.

The final design [Figure 13] has three main features: the new redesigned shield, the lifting mechanism, and the transportation system. The shield design the team chose to continue with is the lipped cylinder shape. The quote received from Vulcan Manufacturing put the new shield cost at $7,328.98 which was significantly reduced from the original quote of almost $20,000 for the “High-Waisted Skirt”.

The lifting mechanism did not change significantly from previous designs, however, the team was able to find individual power jacks that could be purchased (Joyce/Dayton Co., Dayton, OH) instead of having to design and create them from scratch. The jacks from Joyce/Dayton each have a capacity of 2 tons and thus a system of two can adequately support the shield. The linear actuators previously chosen from Progressive Automations were not changed and thus can still support the weight of the shield when stationary.

Finally, the team initially chose to move forward with “The Semi” transportation system. However, after further research, the team was able to find caster wheels that had brakes built into the wheels. As a result, the step down locks were not pursued. The team found four 6 x 2 inch swivel casters made of polyurethane coated iron wheels. Each caster has a weight capacity of 1200 pounds and thus a system of four is more than capable of supporting the shield. In addition, the team plans to move forward with implementing the ball caster wheels into the final design. They will provide more support for the system and assist in moving the entire shield from room to room.

Key features to be incorporated into the shield and lift system include safeguards. The weight of the shield clearly presents a safety hazard to the patient and technicians operating the system, yet it cannot be completely eliminated. Therefore, reduction of the risk posed by the weight of the shield will primarily depend on the ability of the lift and transportation systems to function reliably and safely. According to the Occupational Safety and Health Administration (OSHA), critical features of a safeguard include preventing contact between moving parts and the clothing or body of the technician, being securely attached to the machine, preventing objects from falling into moving parts, not introducing new hazards or interfering with the machine function, and allowing for safe maintenance of the machine. Hazardous machine components of the shield's apparatus would be any rotating parts, reciprocating parts, transversing parts, and any pinch points [16]. Possible safety features that the team will consider adding include force, displacement, and speed sensors to alert the technicians operating the device if operating past the recommended values. All machine parts will be covered to prevent accidental entanglement.

VI. Fabrication & Development

6.1: Materials

6.1.1: Shield and Shield Casing

Pure lead is the most suitable material to stop the high energy photons from radiation therapy. The lead itself will be sealed in a casing to protect everybody involved from potential lead exposure and to protect the shield itself from scratching and denting. Creating the lead shield will likely be the most costly aspect on the design, and since lead is very soft, it is important for the lead to be protected from any unintentional scratches or bumps. The underside of the steel casing will also act as a secondary support, preventing the lead from caving in on itself. For these reasons, the casing will be made from A36 steel, a common and cheap carbon steel, with properties in accordance with ASTM standards. To prevent corrosion, the steel will have a protective coating over it. The bottom casing will be welded to the casing mounts, and the top casing will be connected by bolts to the casing mounts.

6.1.2: Lifting Mechanism and Frame

The lifting mechanism and frame are vital for supporting the lead shield, which weighs 957 lbs. To reduce manufacturing error and testing costs, several parts will be purchased from third parties that have done their own extensive analysis. The four primary linear actuators will be the PA-17 Heavy Duty Linear Actuators from Progressive Automations, Inc. with a maximum stroke of 20”, a load limit of 2000 lbs, and a stroke speed of 0.33 $\frac{in}{sec}$. Each linear actuator will be connected via a Heavy Duty Mounting Bracket, also from Progressive Automations, to the casing mounts. To connect the linear actuators to the frame at the bottom, the team will create a base that fits under the linear actuator as well as a top part that covers the motor and the entire bottom part of the subassembly will be connected via a custom-made mounting rod. The top part of the linear actuator cover will be anchored at the base to the bottom casing mount.

For the backup lifting system, the team will purchase two 2-ton machine screw jacks from Joyce/Dayton. The specific model number is WJT62U2S-20.00-STDX-STDX-A95BM3ST0ENCA. The translating screw jacks will be upright with a load pad to help distribute the weight evenly. Only one input shaft is needed for the motor, and since it is critical for the positioning to be accurate, the jacks will contain internal anti-backlash devices to reduce the amount of additional movement between the lifting screw and the nut. A protective boot will encase the lifting screw and serve as additional protection for both the screw jack and the team operating the shield. While the team plans to program a maximum lifting height when creating the electrical components, an additional extending screw stop will be built into the screw jack to act as a fail-safe should the operator raise the shield too high. The inner input shaft of the screw jacks will contain an encoder to monitor the screw jack's position and create a feedback loop for automating the raising and lowering of the shield. The outer input shaft will be connected to a gear reducer and motor that is controlled by the medical team. To hold the two screw jacks, a screw jack support will be created, which stabilize the screw jacks while they are raising and lowering the shield.

The rest of the device will be custom made from the same A36 steel that the shield casing is made out of. The purchased parts will be connected to the frame via bolts and nuts, and the screw jack support will be welded to the bottom frame.

The main components of the lift and electrical components that control it will be surrounded by an enclosure so as to not be intimidating to the patients and the staff, likely mimicking other aesthetically pleasing machinery in the hospital. However, the lift should be easily accessible should regular maintenance, such as keeping the parts well-oiled, need to be performed, which means that the cover should be removable. Due to the weight of the shield and the potential hazard created by the moving parts, warning labels will be needed inside the enclosure to mitigate any accidents.

6.1.3: Transportation System

The transportation system will utilize four caster wheels, one positioned underneath each linear actuator. The wheels will be coated with a material that has a low coefficient of friction to improve the mobility of the shield while preventing any damage to the hospital floor. To provide additional stability, two ball transfer units will be placed under each screw jack. The six wheels will be attached to the bottom frame via bolts and nuts.

6.2: Methods

6.2.1: Computer Modeling

The modeling of final prototype and subsequent computer simulations were all done with SOLIDWORKS® 2018 Education Edition, which is purchased through the College of Engineering at the University of Wisconsin-Madison. The software is the property of the SolidWorks Corporation, which is headquartered in Waltham, MA, and it is published through the French-based Dassault Systèmes. SOLIDWORKS® Student Premium was used to create a 3D model of the design while SOLIDWORKS® Simulation Premium allowed us to run various tests on the final model.

The entire device was modeled in a top-down assembly design, starting with the shield and its casing before fitting it with the supports. Individual subassemblies were created for the shield and its casing, the linear actuators, and the backup screw jack mechanism respectively, while the bottom frame that supports the entire system was created as its own part before adding it to the assembly. Since all parts and materials would be purchased/manufactured by US-based companies, the SolidWorks templates for the parts, assemblies, and drawings utilized the IPS (inch, pound, second) unit system, with all the decimals customized to the ten thousandths place. Since every component has yet to be manufactured, the materials that were applied to individual parts were based on the proposed materials [Table 2]. For all parts that would be custom made, the materials were customized using the properties provided by the manufacturer or, if the manufacturer's material properties were not available, using the preprogrammed properties from the SolidWorks library of materials. [Appendix, Section 11.2.1: Material Properties]

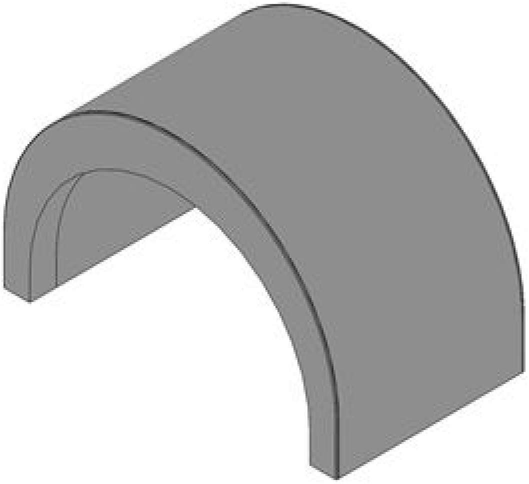
SolidWorks Parts

Section	*Part Name*	*Number*	*Material*	*Source*
Shield	Lead Shield	1	Lead	Custom
	Shield Bottom Casing	1	A36 Steel	
	Shield Top Casing	1		
Linear Actuator	Inner Linear Actuator	4	***	Progressive Automations
	Outer Linear Actuator	4		
	Mounting Bracket	4		
	Linear Actuator Cover	4	A36 Steel	Custom
	Linear Actuator Base	4		
	Mounting Rod	4		
Mechanical Screw Jack	Jack Housing	2	***	Joyce/Dayton
	Screw	2		
	Bearing Cap	4		
	Screw Jack Support	2	A36 Steel	Custom
Shield Frame	Top Casing Mount	2	A36 Steel	Custom
	Top Casing Mount (Underside)	2		
	Bottom Casing Mount	2		

***Indicates that part is purchased from an outside party and materials used can be found on the sources' websites.

[Table 2] A table of the individual SolidWorks parts created for the full shield assembly, their materials, and the source of those materials

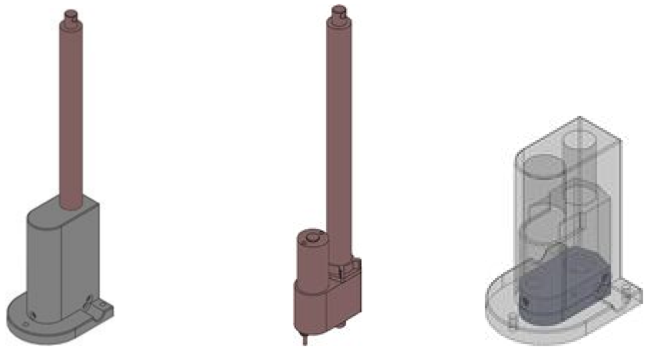
Section: Shield



[Figure 13] The shield, bottom casing, and top casing the is used in the final shield assembly.

The main body of the shield is in the shape of a half cylinder [Figure 13]. Since the lead shield must fit over a treatment table with a width of 21” (53.34 cm) and a translational movement of up to 5” (12.7 cm), the inner width of the steel casing was set to be 28” (71.12 cm). This allows the lead shield and its steel casing to fit over the treatment table with an additional cushion of 1” (2.54 cm) on either side. The most important constraint that the team worked with was that the lead shield must be at least 5 cm thick in all places. However, since the parts that the team planned on purchasing would be based on the Imperial system, this lead thickness was rounded up to 2” (5.08 cm). An additional lip was added to the front of the shield to provide additional protection from radiation scatter originating from patient’s body.

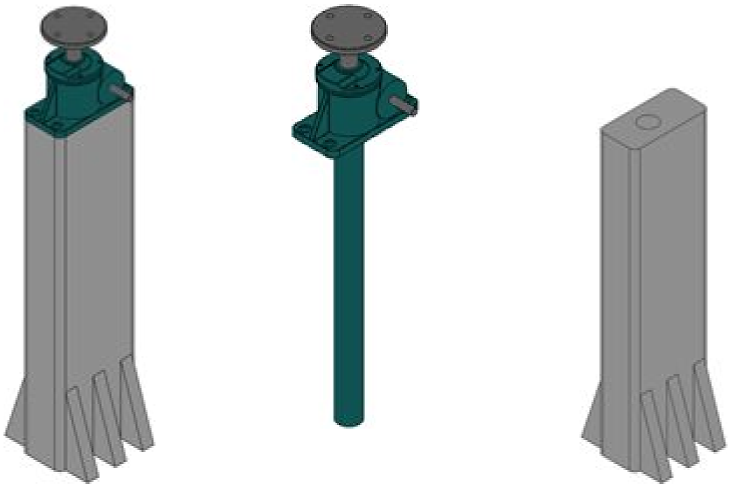
Section: Linear Actuator



[Figure 14] The whole subassembly of the linear actuators (Left), the PA-17 model that will be purchased from Progressive Automations (Middle), and the top cover and base that will cover the motors (Right). There will be four of these in the full shield assembly, one on each corner.

The SolidWorks files of the linear actuators and the associated mounting brackets were uploaded into SolidWorks via Progressive Automations [Figure 14]. For the simulations, the inner cylinder was separated from the rest of the linear actuator and added to the device assembly as an independent part. A bottom anchor was made to snugly fit around the ends of the linear actuators, with dimensions rounded to easy-to-work with values, such as whole numbers. The top cover was also made to closely fit to the motor and base of the linear actuator, with numerous bolt holes added to anchor it to both the bottom anchor and the bottom frame. To ensure that the top cover would be capable of easily sliding over the linear actuator, the series of holes (starting from the top) were extended all the way to the bottom of the cover or extended until they reached an outer face of the linear actuator. This ensured that when the cover is placed over the actuator, there are no ends sticking out that would prevent the cover from fully covering the actuator. The linear actuator was connected to the base and top cover via a mounting rod. For animation purposes, the inner cylinder and the rest of the linear actuator were split into two SolidWorks parts that would be mated together in the full assembly.

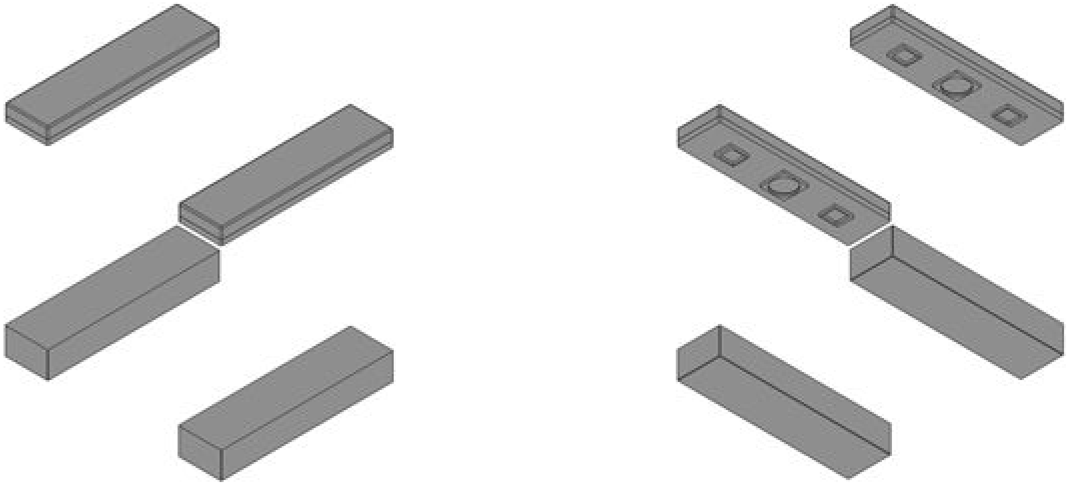
Section: Mechanical Screw Jack



[Figure 15] The mechanical screw jack subassembly (Left), the mechanical screw jack that will be purchased from Joyce/Dayton (Middle), and the screw jack support (Right). There will be two of these in the full shield assembly, one placed in the middle of each bottom casing.

The SolidWorks file of the mechanical screw jack that will be purchased from Joyce/Dayton was downloaded from Dassault Systemes 3DContentCentral website [Figure 15]. The configuration of the 2 Ton Machine Screw Jack from Joyce/Dayton was a 6-to-1 worm gear ratio, upright configuration, translating design, type 2 (load pad) end condition, reverse base base type, single lead type, standard shaft input for both the left and right shaft, an A95 design anti-backlash, a bellows boot, and a rise of 20.00 inches. The screw jack support was modeled in SolidWorks to contain the entirety of the protection tube while still connecting it to the bottom casing mount. For animation purposes, the bearing cap was not inserted into the full SolidWorks assembly, and the input shaft was separated from the jack housing and created as a separate SolidWorks part.

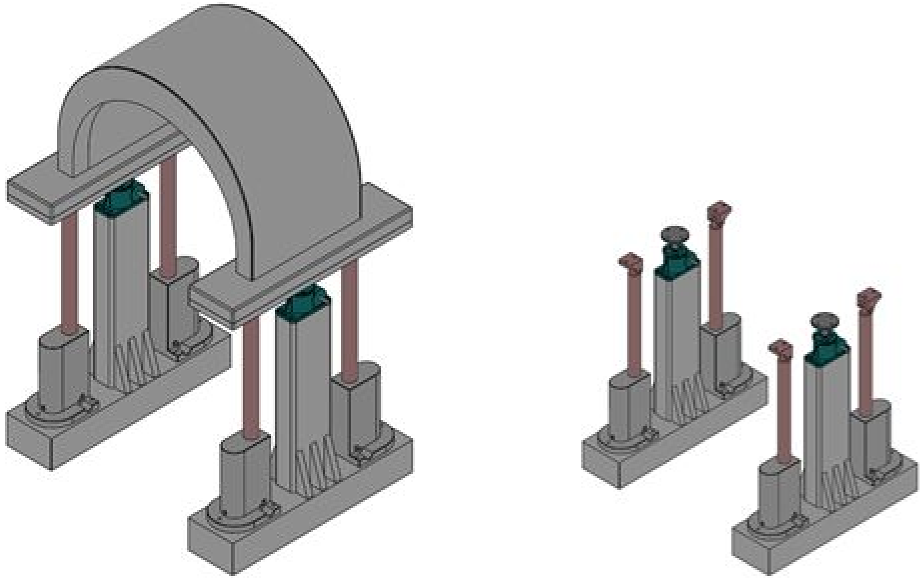
Section: Shield Frame



[Figure 16] The frame of the shield assembly that consists of the top casing mounts and bottom casing mounts. Views shown are top isometric view (Left) and bottom isometric view (Right).

The frame consisted of top and bottom casing mounts that would connect the shield to the lifting system and the lifting system to the wheels attached to the bottom casing mount [Figure 16]. The top casing mount was split into two sections that would be welded together.

Fetal Radiation Shield Assembly



[Figure 17] Going from left to right: the entire assembly of the radiation shield, the entire assembly with covers shown as transparent, and the dual lift system. The proposed final design includes two linear actuators and one screw jack on either side of the shield supporting a platform that the shield rests on.

To create the full assembly, all the individual SolidWorks parts were inserted such that no interferences occured [Figure 17]. Since the team did not do any dynamic testing this semester, there were no subassemblies inserted into the final assembly. Each part was inserted individually.

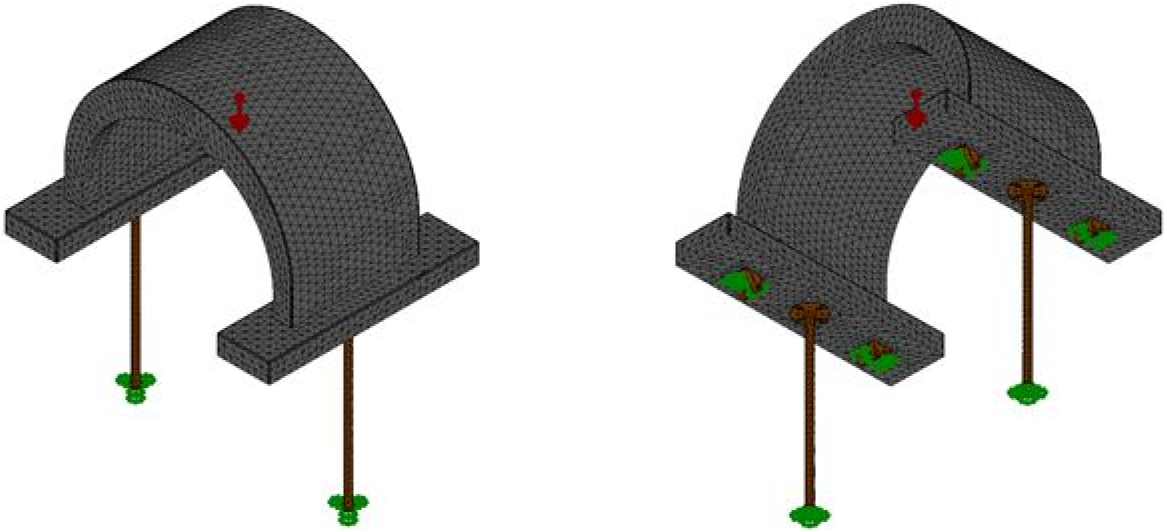
For animation purposes, several mates were introduced to the assembly. To ensure the shield and its casing moved as one unit, the bottom casing, the top casing mounts, the underside of the top casing mounts, the lead shield, and the top casing were locked relative to one another. Positioning lock mates were also introduced to each inner part of the linear actuators and their respective mounting brackets. Since the inner and outer parts of the linear actuators would move relative to each other, those two parts were mated concentrically. This ensured that once the outer part of the linear actuator was fixed, the inner linear actuator could only move a specified distance along their shared axis. To keep the mounting brackets attached to shield casing, a shared vertex on both the mounting bracket and underside of the top casing mount were mated coincidentally. The concentric and coincident mates were also applied to the screw and jack housing of the machine screw jack. To animate the turning of the input shaft on the machine screw jack, a rack and pinion mate was used. The rack was chosen to be the cylindrical face of the screw while the pinion was specified as the cylindrical face of the worm shaft. To get the 6-to-1 worm gear ratio, the ratio was set as 1” of travel by the rack to 6 revolutions of the pinion.

6.2.2: Shield Fabrication

Fabrication of the shield will have to be outsourced to a company specializing in casting lead. The team has consulted Vulcan Global Manufacturing Solutions out of Milwaukee, WI [17]. This company specializes in radiation shielding for a variety of applications. They also offer an engineering resource for the integration of the shield with the lifting and support mechanism. The bottom casing and casing mounts will be manufactured first, and then lead sheets will be laid on top of the casing and welded together to create the necessary thickness. The top casing will be placed over it and bolted to the casing mounts as well. After the shield and its casing have been assembled, it will be connected to the support system.

6.3: Testing

6.3.1: Computer Simulations



[Figure 18] The shield assembly the was subjected to the static load testing. Intersecting lines represent nodes, the areas created by those lines represent the elements, the red arrow represents the direction of gravity, the gray parts represent the parts included in the analysis, the brown parts indicate the parts made rigid, and the green arrows point to the faces that were kept fixed.

Static load testing of the shield and its casing was completed in SolidWorks to determine the effect that the weight of the lead had the casing and the distribution of the weight among the six supports [Figure 18]. Due to the heaviness of the lead, it was critical that the steel casing be able to support the weight of the lead and not exceed its yield strength. This would ensure that the shield would not collapse on the patient. The stresses and reaction forces that were induced as a result of the weight of the shield casing being distributed among the six supports would give an accurate representation of how much of the load each support bore.

Since SolidWorks was limited by the computer's memory and capabilities, the fetal radiation shield assembly had to be simplified before simulations could be run on it. All mates used in the animation were suppressed and each individual part was set to float. This ensured that the measured stresses would come from surface-to-surface contact and closely resemble how the parts would act in the physical world. Since the team was mainly interested in the results from the steel casing, all parts that were not in direct contact with the steel casing were suppressed, which left the machine screw, the mounting brackets, and the lead shield. Since the mounting brackets and machine screw have already been subjected to rigorous testing by their respective companies, those parts were made rigid in the analysis. The bottom casing and lead shield were bonded to the top casing mounts and underside of the top casing mounts to accurately simulate the effect of welding. The only other component contact applied to the model was global contact that was set as no penetration.

The bottomost flat faces of the machine screws and mounting brackets were fixed in space to accurately represent the summation of weight on the parts closer to the ground. Mesh was applied to each part individually and the SolidWorks default mesh was used, which created an element size of 1.0575 in and a ratio of 1.5 on all parts involved in the simulation. Gravity was applied as -32.19 $\frac{ft}{s^2}$ in the downwards direction.

6.3.2: Statistical Methods

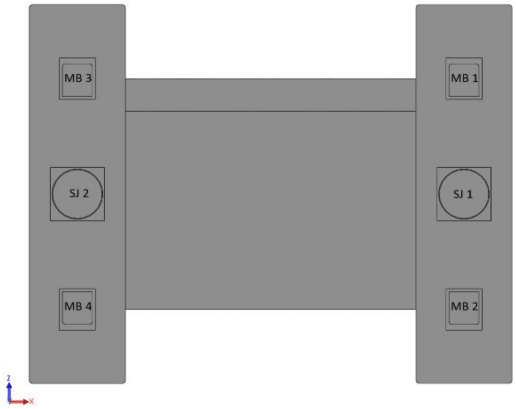
After running the simulation, the von Mises stresses on each node of the steel casing were compared to yield strength of A36 steel, which is accepted to be 200 GPa. If the maximum von Mises stress exceeded the yield strength, then failure due to static loading would occur, and if the maximum von Mises stress was below the yield strength, then the design factor of safety would be acquired. To determine the resultant forces of the support system on the casing mounts, the free body forces of all faces on the underside of the top casing mounts for each mounting bracket and machine screw were determined.

Summary statistics were calculated for the data collected through gravity simulation and weight distribution tests performed in SolidWorks using Matlab R2016b. From weight distribution analysis, the mean, maximum and standard deviation for the stress and strain in each member of the support assembly was determined. Gravity simulation data analysis was performed to determine the mean, maximum and standard deviation for the stress and strain at the contact faces of each component of the shield and steel encasement assembly. Lastly, the mean and standard deviation of the highest 10% of stress values recorded at the nodes during weight distribution testing in SolidWorks were calculated for each support assembly member to assess if yield stress was exceeded.

VII. Results

7.1: Static Load Testing Results

The weight of the lead shield was found be 958.99 lbs and the steel casing 550.09 lbs, for a total of 1509.08 lbs. The primary aim of the weight distribution testing was to determine the load each support system component would have to bear.

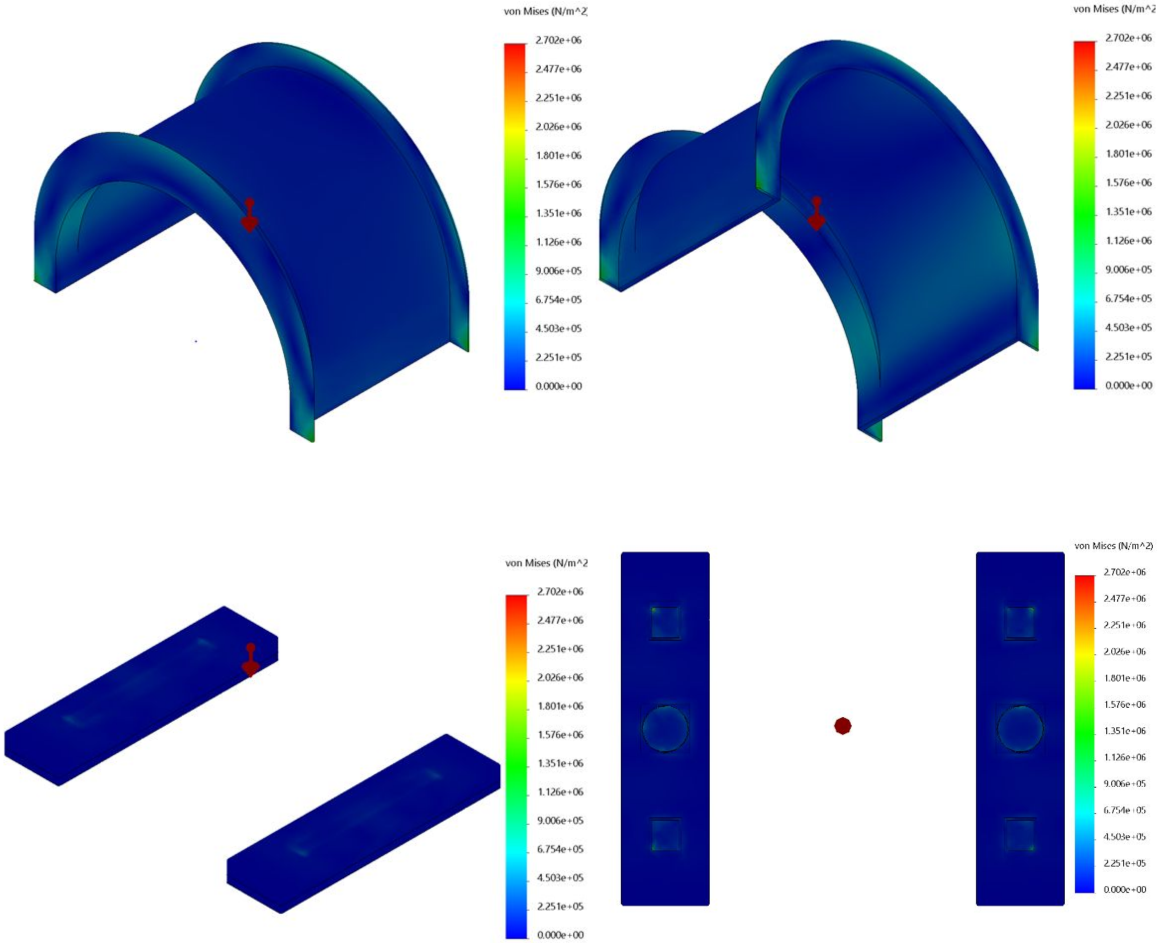


[Figure 19]. Bottom view of shield casing showing where the linear actuators (four corners) and power screws meet the mounting brackets. Referenced in [Table 3].

Part	Unit	Resultant Force (lbs)
Power Jackscrew	1	319.32
	2	319.46
	Average ± Std.	319.39± 0.10
Linear Actuator	1	231.58
	2	211.95
	3	230.77
	4	212.70
	Average ± Std.	221.75 ± 10.89
Total		1525.76

[Table 3]. Values for the distribution of the weight of the lead shield over where the support components meet the steel bottom casing.

The largest portion of the shield weight was collectively over the linear actuators, whereas the highest individual loads were supported by the power screws. The four linear actuators altogether support 547.37 lbs (2,434.8 N), while the power screws support 532.31 lbs (2,367.8 N) [Figure 19]. The mounting brackets directly below the shield lip bear a marginally larger load than in the back.



[Figure 20] The stress on the bottom casing in the top front isometric view (Upper Left), the stress on the bottom casing in the bottom back isometric view (Upper Right), the stress on the casing mounts in the top isometric view (Lower Left), and the stress on the casing mounts in the bottom view (Lower Right). Scales in each picture are relative to maximum stress felt and not indicative of a certain value.

The highest areas of stress on the bottom casing are located at the edges closest to the casing mounts [Figure 20]. The top arch of the shield, which is the part located directly over the patient, does not appear to exceed 100 kPa. There are no significant stress concentrations on the casing mounts, and the areas with the highest stress occur on the edges of the recesses that accomodate the mounting brackets and screw jack load pads. All other areas appear to have negligible stress.

7.2: Animation Results

[Figure 21] The animation of the shield as is fully retracted (Left) to when it is fully extended above the patient (Right).

The animation results of the shield raising and lowering allowed us to see how stable the shield would be once fully extended [Figure 21]. As the shield is raised and lowered, the maximum distance the shield can travel upwards is 20” (50.8 cm). The minimum height from the bottom of the bottom frame to the bottom of the shield is 40.778” (103.58 cm) plus the height of the wheels, which gives an additional 8” (20.32 cm) while the same measurement when the shield is extended is 60.778” (154.38 cm). The location of the center of mass increases from 50.796” to 87.225” in the y direction as it is extending. The x components and z components stay the same at 0” and 0.21142” respectively.

VIII. Discussion

8.1: Implications

The yield stress of the A36 steel that constitutes the bottom casing supporting the lead shield is 29.01 Mpsi (200 GPa), while the maximum stress at a specific node due to gravity recorded was 11.20 psi (77.25 kPa). The maximum stress felt on the steel casing is significantly lower than the yield strength, so therefore the steel bottom casing would more than sufficiently support the lead shield. The highest stress values were observed where the support components join the casing mounts, which is ideal because the shield casing is not most likely to fail directly above the patient. Furthermore, each linear actuator and power screw can individually support up to 2,000 lbs and 4,000 lbs, respectively, for a total loading-bearing capacity of 8 tons. As mentioned previously, the powers screws act as a failsafe should the linear actuators fail and vice versa, so the factors of safety for the linear actuators and power screws are roughly 3 and 4, respectively. Therefore, the support system could safely and comfortably support the weight of the lead shield and steel casing.

However, dynamic loading simulations will also be critical to determining the robustness of the support system because of the additional forces resulting from acceleration of the shield during raising and lowering. The speed at which the height of the shield is adjusted will be very low to reduce these forces.

8.2: Ethical Considerations

Regarding ethical considerations, the conduct of future research presents many challenges. As described above, the work this semester will involve rigorous modeling in SolidWorks to ensure safety of the device, followed by additional efficacy testing using a phantom at the University Hospital. As such, testing itself will not involve any risk to the patient. Concerning the ethical nature of the design and its ultimate use, there is little controversy. It is well-known that there exist few options for safe, effective blocking of fetal radiation dose, and most would agree that providing something for these patients would be beneficial. The team believes that they have designed a shield that will accommodate as many patients as possible regardless of age, size, and stage of pregnancy, encouraging various patients to pursue treatment who man have initially shied away from radiation therapy due to fetal risk. The main ethical dilemma comes in balancing the trade-off of incurred risk to the mother and child due to potential mechanical failure of the shield-support system with the efficiency of blocking. The shield must not incur more potential risk to the patient than the minimal risk of malformation (0.5%) [1]. In order to be worth the added risk, the shield must block at least 50% of all radiation capable of reaching the fetus, as assessed by Dr. Labby. Thorough SolidWorks modeling, factor of safety considerations and further design modifications will thus be required to meet this criterion and minimize risk to the patient and fetus.

8.3: Sources of Error

Since all testing was done in SolidWorks, all parts that were tested so far were assumed to be solid and uniform throughout. This is simplified form of the physical materials. Since the team was limited in terms of RAM and the graphics card, both of which are required to be very good for any computer to run SolidWorks, we needed to simplify the simulations performed. This included suppressed parts that did not contribute to a significant portion of the results and treating subassemblies as a single unit. In addition, there is no geometry that is truly fixed in the real world, and all parts will undergo some degree of stress when in contact with another part. This leaves the results from the simulations prone to error. It is also worth noting that since SolidWorks requires some part of an assembly to be fixed in space, this contributes to the error.

To run more accurate simulations, SolidWorks would have to do analysis from a computer with larger RAM and either a NVIDIA Quadro, AMD FirePro, or AMD Radeon Pro WX graphics card to allow us to run larger, more complex simulations such as motion analysis. However, real-world testing is the only way to entirely eliminate the errors that accompany computer simulations.

During the weight distribution simulation, the stress that was calculated included both the axial stress and the stress due to the bending moments. This increased the load felt on each support, and although it suggests that the supports can bear more than the shield's weight, is not accurate of the percentage of weight the supports bear. To determine that, new simulations are needed to focus on calculating the stress in only the Y direction.

IX. Conclusions

9.1: Summary of Findings

The overarching purpose of this project is to create a fetal radiation shield that effectively blocks 50% of radiation leakage and scatter emanating from the accelerator head and collimators, respectively. Although relatively few pregnant women are treated with radiation therapy, about 4,000 annually within the United States, the deleterious risks posed by radiation exposure to the fetus at varying stages of gestation make the design and fabrication of a fetal radiation shield pertinent. The shield must transported between treatment rooms, and raised and lowered to position the shield over the abdomen of the pregnant woman. The budget allotted for the shield, and the lift and transportation mechanisms is $10,000, with fabrication of the components likely to be outsourced. Lastly, it is critical that the shield and its lift and transportation systems not be unjustifiably hazardous for the patient and medical personnel involved.

This semester, the team primarily focused on the transportation system with refining the designs for both the shield shape and the power screw design. In designing this, physical and practical design constraints were considered. The design process included common transportation mechanisms in industry. Ultimately, the team decided on utilizing four swivel caster caster wheels with brakes attached and two ball transfer units. The swivel caster wheels will be industrial iron wheels with a polyurethane coating to protect the floor from scratches. Each of the swivel caster wheels can support up to 1,200 pounds. In addition to the transportation system, the shape of the shield was redesigned to help to lower the cost. The new shield has a half-cylinder shape with a front lip to assist in reducing the levels of radiation that the fetus receives. Additionally, the team has made progress in its efforts to create a fabrication plan with Vulcan Global Manufacturing Solutions (Milwaukee, WI). With respects to the lifting/ support mechanism, the team has decided to go with a power jack screw from Joyce/Dayton instead of having this be costume made for this device. One of the large goals of the semester was to significantly reduce the price, which was accomplished. The total cost was reduced by half, but it is still over budget; this means that more work will need to be done to reduce the costs to have it be under budget.

9.2: Future Work

First, the team wants to complete further testing in SolidWorks to ensure safety for the patients. Stress testing of shield on all supports, dynamic testing, and fatigue testing and some of the SolidWork tests that will need to me completed. Once those have been done, a third party mechanical testing facility will look the system to ensure a safe design. In addition, the electronic component of the lifting mechanism will need to be put in place. This will be important to integrate the power and controls for lifting, as this system is extremely heavy.

As the system is still over budget, it will be necessary to find areas where the cost can be reduced. One item that will be considered is reducing the price of the power jack screws by either finding a new company or working with Joyce Dayton to reduce the cost. The reason why it is essential to reduce the price is so there is room in the budget for physical prototyping to ensure the design is compatible with the treatment room before manufacturing the final product.

In terms of manufacturing and assembly, once the shield shape, support, and mobility systems are fully defined and approved, the shield will be manufactured by Vulcan Global Manufacturing Solutions (Milwaukee, WI) as discussed previously. The electric components of the lifting mechanism, including linear actuators and motors, will be ordered from Progressive Automations (Blaine, WA). Final assembly of the shield will occur at Vulcan Global Manufacturing and the shield will then be transported to UW Hospital by methods still to be determined.

Extensive testing will be conducted on the final prototype. Actuators and screw jacks will be tested individually to ensure their ability to support the shield on their own. The not-yet-designed mobility system will be tested on the various flooring types in the hospital. The efficacy of the shield in blocking fetal dose will be tested using a phantom at Dr. Wesley Culberson's lab, at which time the shield will be placed over the phantom for multiple treatment plans. The capacity of the shield to attenuate fetal radiation dose will be measured by comparing the percentage of radiation reaching the abdomen of the phantom when the shield is in place compared to when no shield is used.

Finally, the shield will need to be incorporated into a general treatment protocol for use by University Hospital. Workflow will need to be assessed and medical staff trained on how to use the shield. Phantom testing will also be used to inform the appropriate placement of the shield for the different treatment options. This will likely be conducted over the course of several months after final fabrication and involve coordination between staff and other users as well as the design team.

In the past three months, this design has been greatly extended. Now, with an overall design for the whole system, the team is well on its way to completing a safe and effective shield to provide peace of mind for pregnant patients considering undergoing radiation therapy.

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XI. Appendix

11.1: Product Design Specification

Product Design Specification: Fetal Radiation Shield

Client: Dr. Zac Labby

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Date: September 7th, 2018

Function:

Approximately 4000 women per year require radiation therapy for brain and breast cancer during pregnancy in the United States. The deleterious effects of ionizing radiation on the fetus can generally be reduced with a lower fetal dose. The shield used to protect the fetus during standard radiation would include about half a ton of lead held safely over the fetus during treatment. The Department of Human Oncology at UW Hospital is seeking a safe and effective shield for to mitigate the potential effects of ionizing radiation on the fetus during treatment. The shield must be mobile, compatible with a variety of treatment delivery machines and techniques and be safe to use for all involved, particularly the patient. Our team will design, fabricate, and test the shield with clinical treatment delivery system over the course of the next two semester, while focusing on designing a transportation mechanism for the shield and its support system this semester.

Client Requirements:

- Must physically block radiation leakage from the head of the instrument and scattered photons from the collimators from reaching the fetus
- Must not increase health risks to mother or fetus
- The shield must be at least 5 cm thick to reduce the fetal dose by at least 50%
- The shield must be transportable between treatment suites in the hospital

Design Requirements:

- Must be mobile enough to easily move between patient treatment rooms and storage
- Must reduce the fetal dose by 50%
- Must be compatible with women of all sizes and varying stages of pregnancy
- Must be compatible with current treatment room equipment, specifically the treatment table and linear accelerator, and their respective ranges of motion

1. Physical and Operational Characteristics
    a. *Performance Requirements:* In addition to blocking 50% of radiation from reaching the fetus, the shield must be able to be moved around the hospital between treatment rooms and storage. Primary and scattered radiation approach the patient from a variety of angles depending on treatment plan and treatment site, therefore the shield should fully cover the abdomen. The shield must be capable of moving vertically in order to accommodate different table heights. It is possible that the shield will also have to move laterally when the head is rotated such that it is at adjacent to the treatment table.
    b. *Safety:* Safety is the highest priority for this design. In order to be used with a patient, the risk of collapse and resultantly injury of the patient, which could be fatal to the mother and/or fetus, must be less than the benefit of reduced fetal dose. A primary risk of safety will involve transporting the shield by technologists, and physicians around patients. Safety standards for this type a medical device are challenging to find due to the lack of a regulatory specific to this engineering application, but nevertheless must be rigorous. Any patient-to-lead contact, which could lead to lead poisoning, must be prevented. Additionally, the apparatus must capable of being wiped down with cleaning reagents used in a clinical environment (ex: Cavi-Wipes) before and after each use.
    c. *Accuracy and Reliability:* The apparatus must shield the fetus from 50% of incoming radiation. The support and transportation systems must be of materials that can withstand stress about three times the yield stress and have a high fatigue limit.
    d. *Life in Service:* The design will go through periodic cycles of use, depending on whether patients being treated require the shield. It will not be used frequently, according to the client; about one patient per year will require radiation therapy while pregnant. The apparatus will remain at the hospital permanently. When not in use, the apparatus will be stored away. Due to the massive weight of the shield and support system, it is preferable that parts in the shield-support assembly and transportation system will not have to be replaced.
    e. *Shelf Life:* This is intended to be kept in the Department of Human Oncology to be used to aid in the treatment of pregnant patients. Lead, the primary material that will be

incorporated into the design, is highly corrosion-resistant and dense. The entire device should be designed to last indefinitely.

f. *Operating Environment:* The apparatus will be utilized in radiation treatment rooms while patients undergo therapy. The rooms are surrounded by 8 foot thick concrete walls that house a linear accelerator, the head which rotates about 270 degrees on a gantry, a translating patient bed and various medical instruments. The shield transportation and support system must avoid a circular force plate, about 4 ½ ft in diameter, beneath the treatment table and allow for full rotation of radiation machinery to achieve all desired angles the physicians might need.

g. *Ergonomics:* ALthough patient safety is the top priority, safety of the medical personnel transporting and operating the shield assembly is also important. The transportation mechanism should not require an unreasonable amount of force exerted on the assembly to maneuver it and ideally not cause staff to strain their backs and knees. Similarly, the support system should need only minimal effort to operate and avoid strain and injury to the staff using it. The shield itself must fit comfortably across the patient's abdomen and take into account potential different sizes of pregnancy (from single to triplets) and variability in the patient size themselves. Additionally, the apparatus must allow the patient to lay comfortably on their back during treatment sessions.

h. *Size:* The size of the apparatus must be compatible with the current treatment room set-up. The dimensions of the apparatus must be able to fit a patient up to 300 lbs. The hallways through which the shield-support assembly will be transports are over 7 ft wide, however, the door to the treatment room is about 51 in--4 ¼ ft. This poses a considerable challenge to designing the support and transportation systems as the diameter of the force plate in the treatment room that must be avoided, about 4 ½ ft, is wider than the door.

i. *Weight:* The maximum load to be supported by the transportation system will be roughly 1500 lbs, with the center of mass (COM) closer to the rear of the shield and support system due to the shape of of the "Highwaisted Skirt" shield design. It is critical that the intrinsic instability of the shield due to its eccentric COM is accounted for in the transportation system design. The highest stress exerted by the shield-support assembly will be where the linear actuators interface with the transportation system toward the middle on each side. There are no industry-specific standards for the factor of safety (FoS) for hospital equipment; however, because the weight of the shield-support assembly and the expected frequency of interactions between medical personnel, patients and the equipment, and the potential for workarounds by busy hospital staff, we believe that the FoS should be between 3 and 4. Therefore, the total load that the transportation system should be able to support is 4500 to 6000 lbs.

j. *Materials:* The shield will be fabricated from lead and encased in steel, and the support system from aluminum, steel and various plastics. If wheels, particularly the caster variety, are used to transport the shield-support assembly, they must avoid scuffing and scratching the linoleum or laminate floors of the hospital and thus be made from polymers like nylon and polyurethane. However, there must also be a low coefficient of friction (stationary and kinetic) between the wheels and the floor to facilitate easy maneuvering of the assembly by hospital staff. Additionally, transport of the assembly should create as little noise as possible. The wheel mounting material should be compatible with the materials used in the support system and have high compressive strength and durability.

k. *Aesthetics, Appearance, and Finish:* The shield-support assembly and transportation mechanism should be aesthetically appealing and instill trust to the patient and medical personnel who interact with them. The shield finish and any components/moving parts in the support and transportation assemblies must safely permit cleaning per clinical standards Components of the support and transportation systems should operate smoothly and create as little noise possible during use

2. Production Characteristics

   a. *Quantity*: Only one (1) apparatus will be fabricated. At least four wheels will be required to transport the shield-support assembly.

   b. *Target Product Cost*: The total cost of the project (prototyping, testing and fabrication) for the final product (shield, support and transportation systems, electrical components) must not exceed $10,000.

3. Miscellaneous

   a. *Standards and Specifications:* All medical devices are classified by FDA standards into Classes I, II, or III. Each class has certain standards that must be met before the product can be used. Most Class I medical devices are exempt from Premarket Notification 510(k), while most Class II medical devices require Premarket Notification 510(k). A Premarket Notification 510(k) must show that the device is substantially equivalent to one commercially used in the USA before it can be distributed. Class III medical devices require Premarket Approval (PMA). A PMA is a more inclusive test than the 510(k) for devices which pose a significant threat to injury or illness. Additionally, a clinical study is required to support a Premarket Notification 510(k) or PMA submission to the FDA. It will be necessary to follow the American Standards of Mechanical Engineers when designing the various aspects of this device. In addition, a safety engineer will have to review the design to ensure the is minimal risk of failure, which could result to harm of the patient.

   b. *Customer:* Our client, Dr. Zac Labby, is associated with the Department of Human Oncology and has indicated that the shield apparatus we design and fabricate will likely not be marketed and used solely in the UW Hospital. Therefore, our goal is to design a shield that meets our client's specifications and achieves its intended purpose of reducing fetal dose by at least 50% during radiation therapy. Marketing the shield apparatus is currently not a priority.

c. *Patient-Related Concerns*: The chief concerns for a patient undergoing radiation therapy while pregnant is the risk of disrupting fetal development and the increased likelihood of childhood cancer. While these risks are generally low, the possibility of devastating effects on fetus due to radiation exposure warrant a solution. The shield should reduce this possibility without incurring additional risks to the mother and fetus. This device will also be placed over the patient during the radiation, so it is important to ensure there is no risk of the device collapsing on the patient.

d. *Competition:* Currently, no products of this nature are commercially available. Previously, clinics utilized table-like supports with lead draped or placed on top. This is now forbidden in clinic due to safety concerns and no way to ensure that the dense lead is adequately supported. According to the client, pregnant patients seeking radiation therapy at UW Hospital are usually referred to the Mayo Clinic, which uses a wooden bridge stacked with lead bricks to shield the fetus from radiation leakage and scattering. The University of Michigan developed a custom fetal lead shield that was highly effective in reducing radiation, but not economically feasible. The company behind the development of the shield went bankrupt.

11.2: SolidWorks Modeling

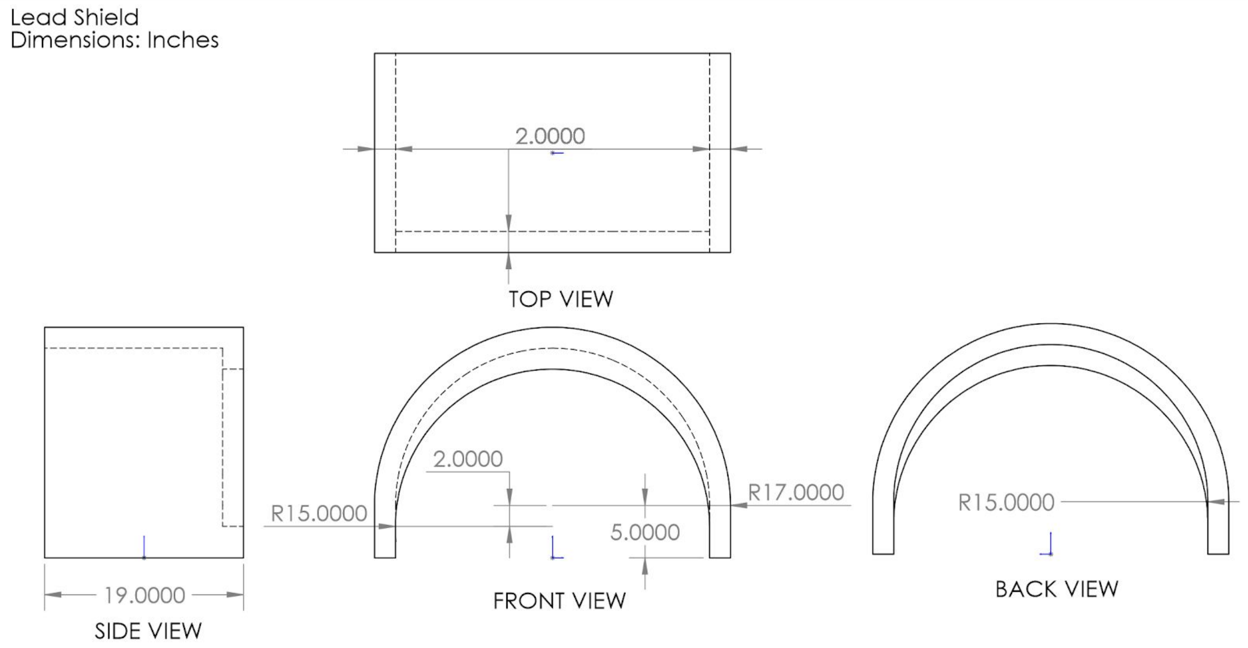
11.2.1: Material Properties

Material: Lead	
Parts/Assemblies	Shield
Source of Properties	SolidWorks Library
Material Properties	
Elastic Modulus	14 GPa
Poisson’s Ratio	0.4
Shear Modulus	49 GPa
Mass Density	11000 $\frac{kg}{m^3}$
Tensile Strength	14.5 MPa
Yield Strength	12 MPa
Thermal Expansion Coefficient	5.3×10^{-5} $\frac{1}{K}$
Thermal Conductivity	35 $\frac{W}{m*K}$
Specific Heat	130 $\frac{J}{kg*K}$

Material: A36 Steel	
Parts/Assemblies	Bottom Casing Top Casing Top Casing Mounts (Top and Underside) Bottom Casing Mounts Linear Actuator Base Linear Actuator Cover Mounting Rod Screw Jack Support
Source of Properties	SolidWorks Library
Material Properties	
Elastic Modulus	200 GPa
Poisson’s Ratio	0.26
Shear Modulus	79.3 GPa
Mass Density	7850 $\frac{kg}{m^3}$
Tensile Strength	400 MPa
Yield Strength	250 MPa

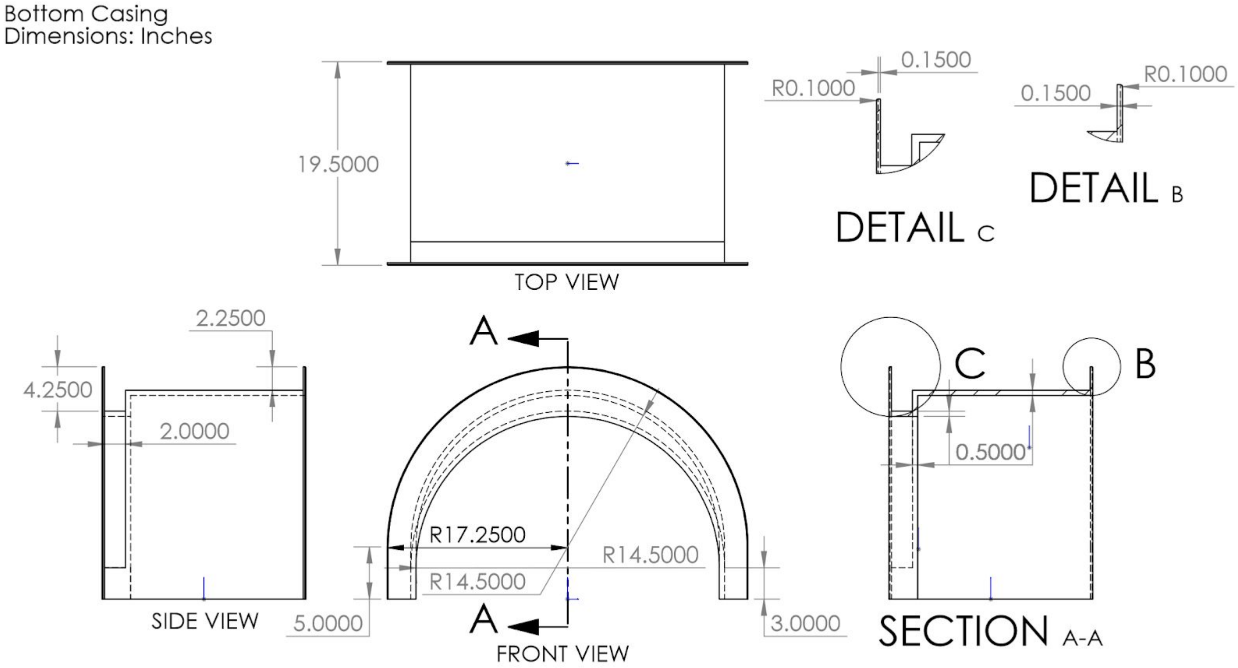
11.2.2: Part Dimensions

SolidWorks Part: Shield



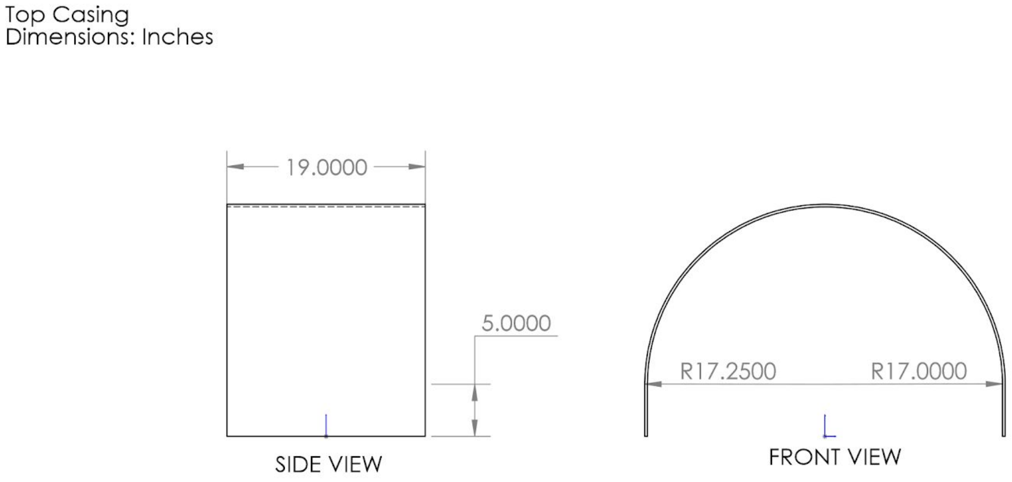
[SolidWorks Drawing] The lead shield that will be placed over the woman to protect the fetus from ionizing radiation. The material will need to be pure lead, and it is expected to weigh roughly ½ ton.

<u>SolidWorks Part: Bottom Casing</u>



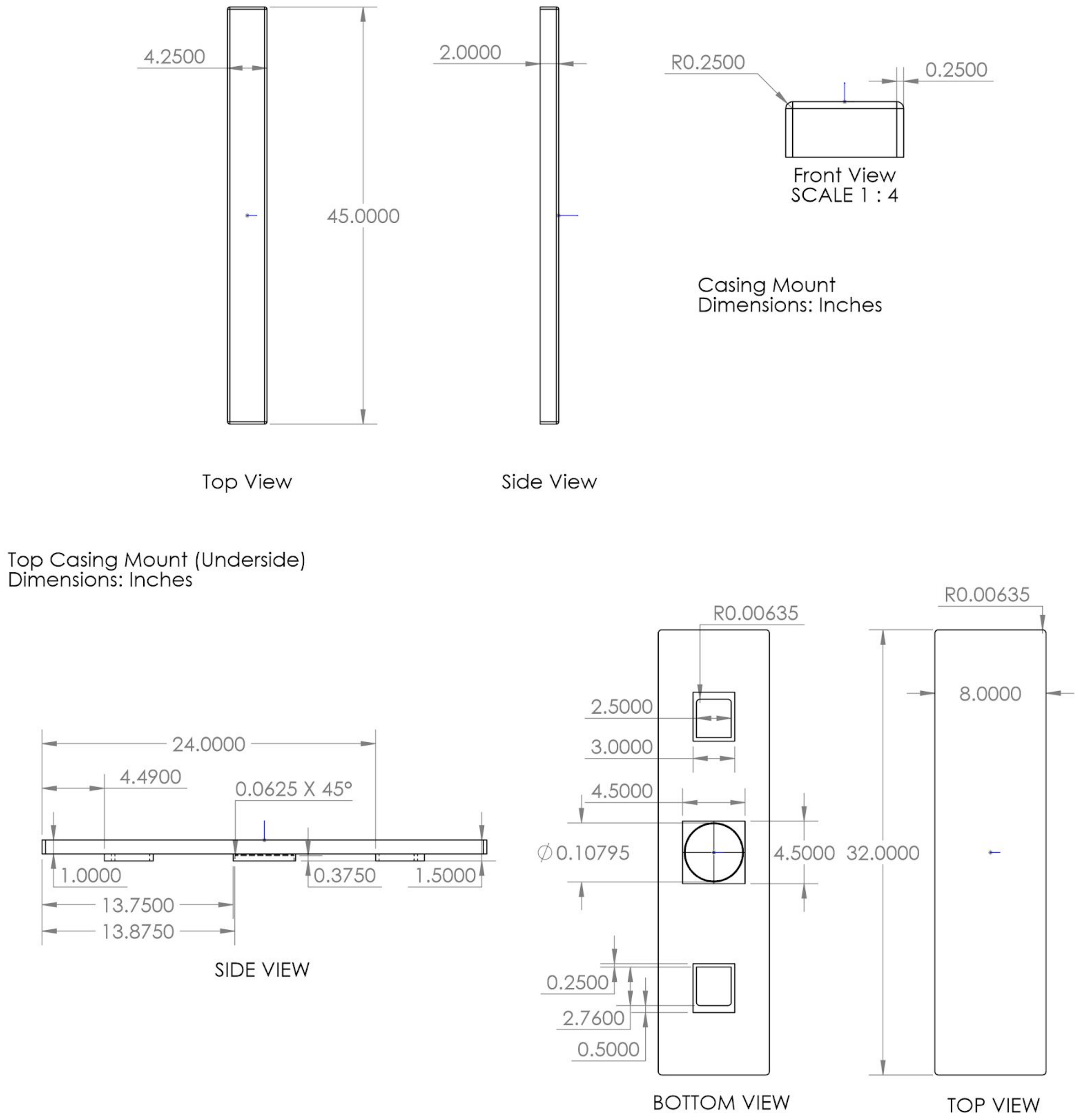
[SolidWorks Drawing] The bottom casing of the shield. It will be welded to the two casing mounts and will bear the brunt of the shield's weight.

SolidWorks Part: Top Casing



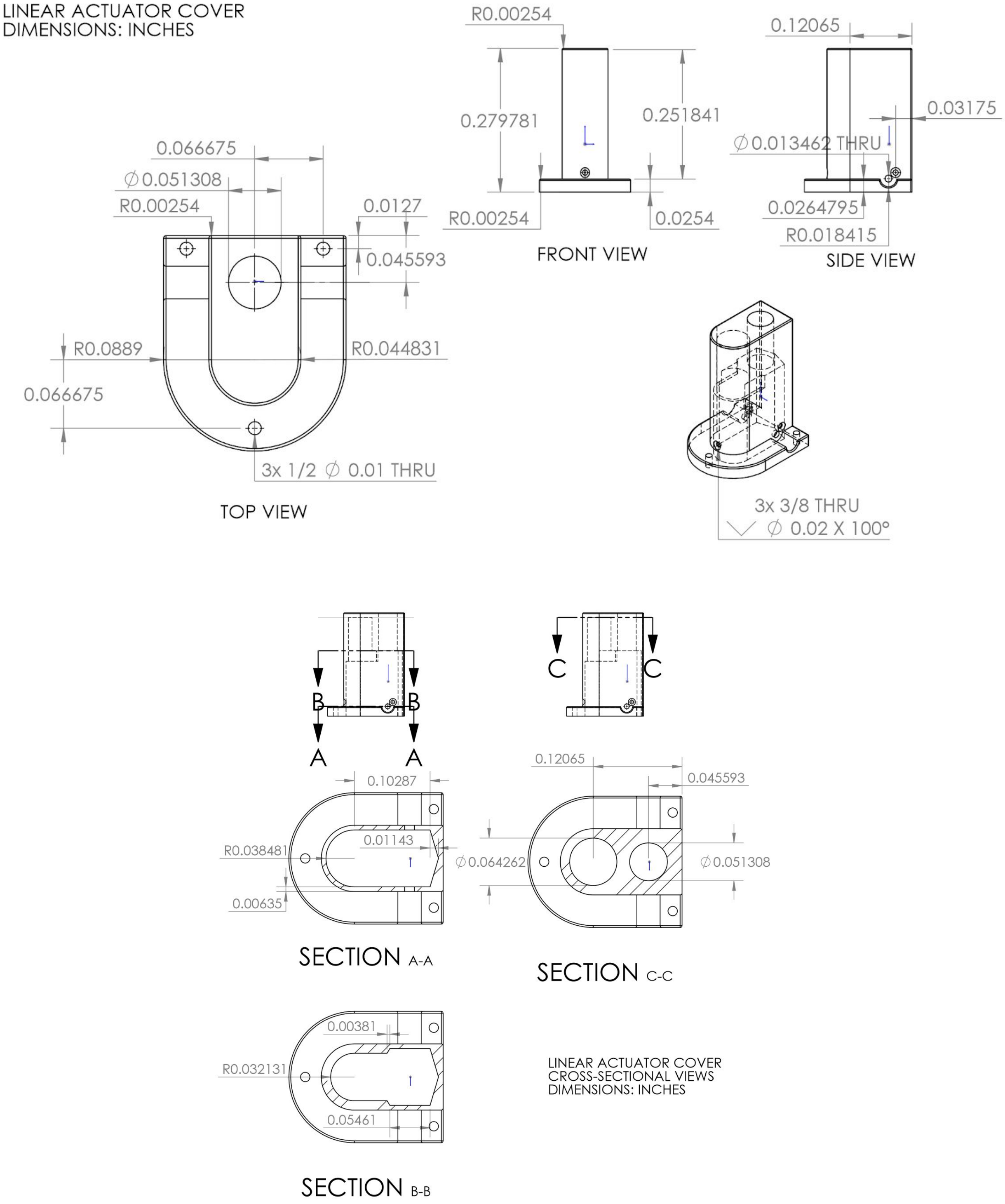
[SolidWorks Drawing] The top shield casing. Its main job is to prevent the lead shield from any accidents that would result in deformation. It will be bolted to the casing mounts via the flange mounts and will rest over the top of the lead shield.

SolidWorks Part: Casing Mounts



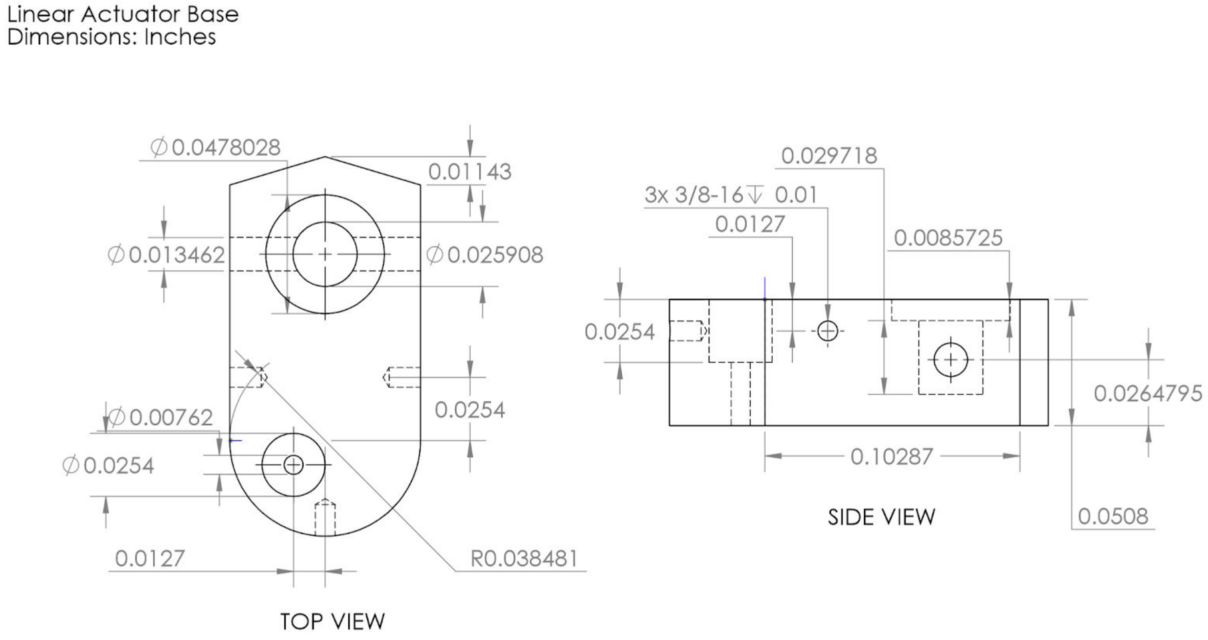
[SolidWorks Drawing] The shield casing mounts that will serve as the connection point between the shield and the lifting mechanism. While there are two, they share the same dimensions because the casing mounts are mirror images of each other.

<u>SolidWorks Part: Linear Actuator Top Cover</u>



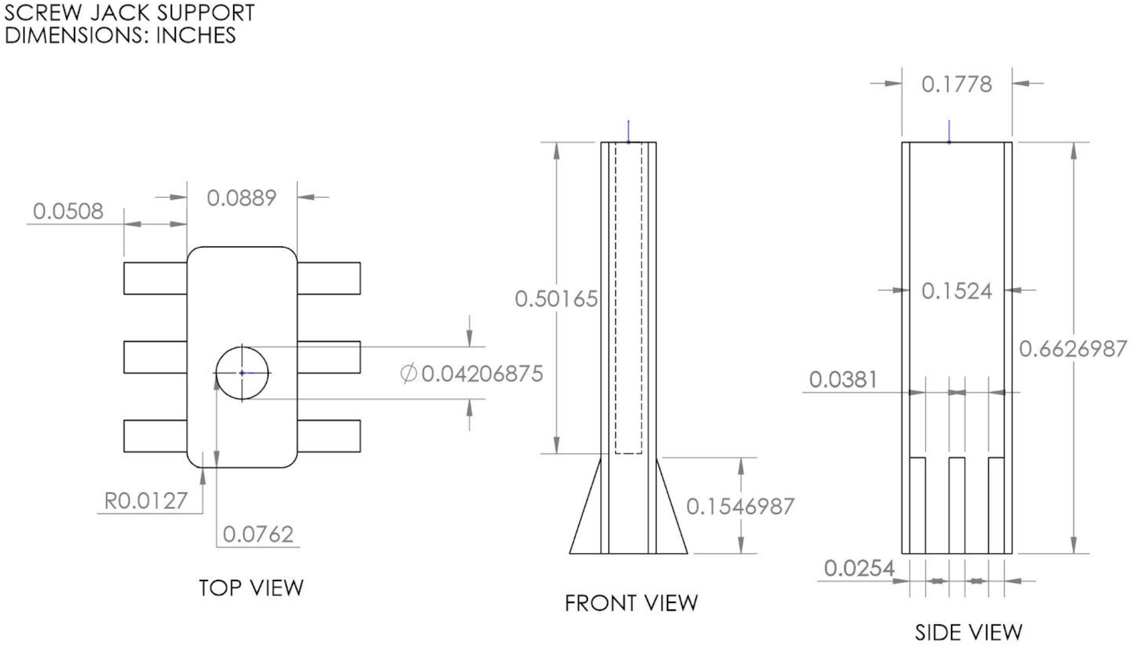
[SolidWorks Drawing] The linear actuator cover that will encase the bottom, bulkier part of the linear actuator.

SolidWorks Part: Linear Actuator Bottom Cover



[SolidWorks Drawing] The bottom part of the linear actuator cover that will bear the brunt of the weight and will serve as a connector to anchor the linear actuator to the bottom frame.

SolidWorks Part: Screw Jack Support



[SolidWorks Drawing] The screw jack support for the mechanical screw jack..