Fetal Radiation Shield

Limiting dosage of high-energy radiation to the developing fetus

Preliminary Report

BME 301: Biomedical Engineering Design 301

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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. The team has a SolidWorks model of the final shield shape and is in the process of refining a scissor lift mechanism to raise and lower the shield that is compatible with the treatment rooms and is also exploring mobility and testing options. 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 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.

Lead shields utilized for these purposes through the 1990's include a bridge or table placed over the treatment couch [1]. 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 [5]. 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. Although the shield was effective at blocking 50% of the peripheral dose (PD) to the fetus [3], 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.

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: Physiology

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.

2.2: Radiation

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 (week 2-7) [4]. The third period is called the fetal period (week 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 [4].

When evaluating the amount of radiation that reaches the fetus, 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].

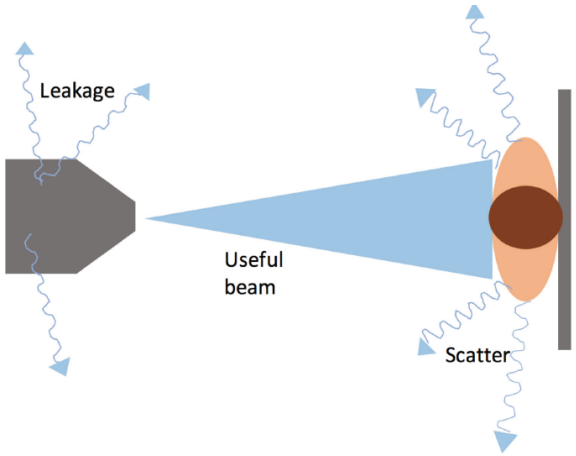


Figure 1: Radiation scatter explained [8]

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 [9]. 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 2).

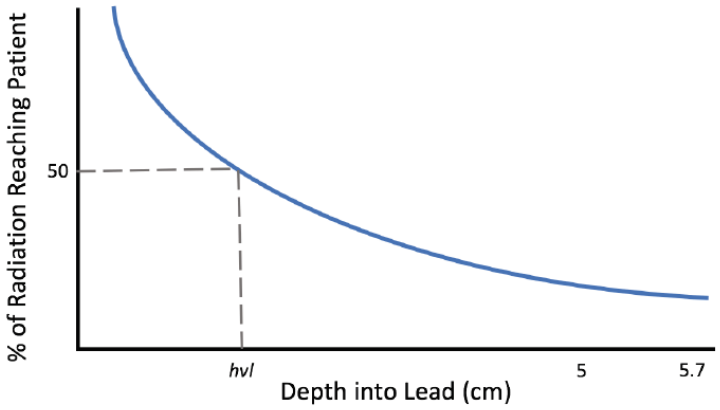
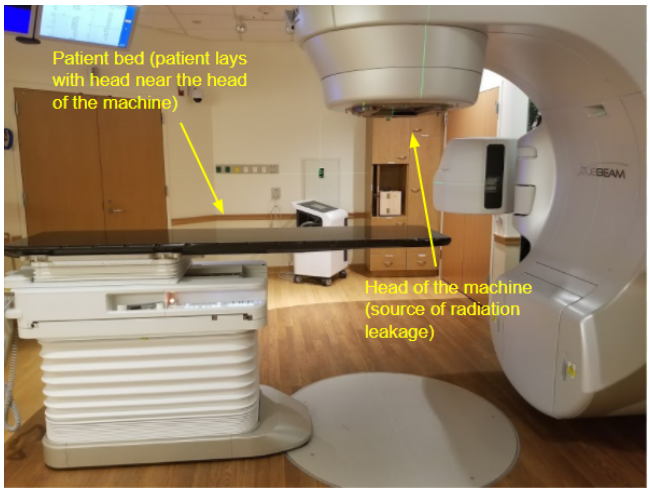
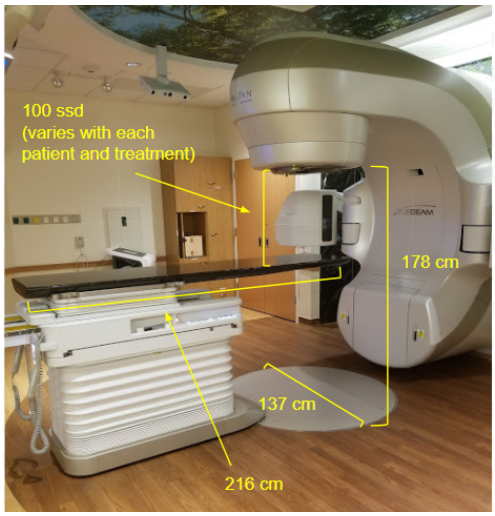


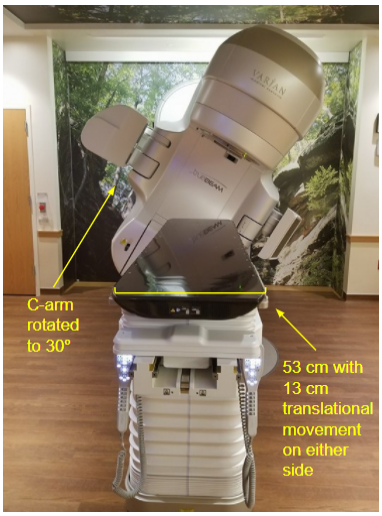
Figure 2: Lead Thickness Diagram for Blocking Radiation

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 (See Figures 3-5). The budget is $10,000 total for the final product.







Figures 3 (Top), 4 (Bottom Left), & 5 (Bottom Right): Diagram of the treatment room showing treatment directionality (Figure 3); University Hospital radiation therapy treatment suite (Figures 4 & 5).

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 (See Figures 3-5).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 apparatus also needs to be

safe for hospital personnel to transport between treatment rooms and storage in an adjoining hallway.

III. Previous Work

3.1: Shield

Last semester, the team decided to tackle this project by focusing on one component at a time. First, the team focused on designing the lead portion of the shield. The team wanted to provide 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.

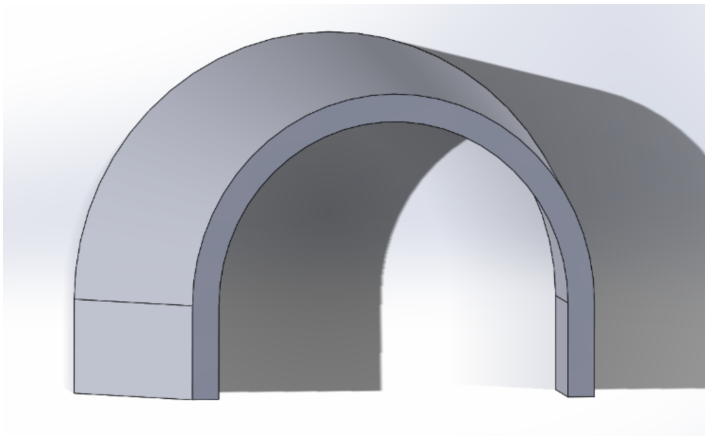


Figure 6: SolidWorks model of previously designed lead shield.

Using this shield shape, the team was able to perform stress testing in Solidworks, ensuring no points of weakness. Stress testing would become more important once integrated with the support system. The SolidWorks model also estimated the weight of the shield to be 381 kg. Lastly, this model was able to estimate the square area of the shield, shielding 5963.8 cm^2. Additionally, the team fabricated a paper mache prototype to confirm that the dimensions established were reasonable. With confidence in the shield shape from last semester, the focus has now shifted to the support mechanisms.

3.2: Current Focus

This semester, the team plans to focus on the second component of the apparatus: support of this shield. The support will have to confidently secure the lead over a patient, while also integrating movement mechanisms. It needs to move in the vertical direction over the patient to optimize photon blockage personal to the patient size. It also needs to be mobile horizontally for positioning over the patient and moving in and out of various treatment rooms.

In addition to developing mobility for the shield, the team will revisit a rotational mechanism for the shield in order to better personalize the blockage to the patient's contours. This rotation would occur in the cranio-caudal direction over the patient. Both the lifting and the rotation mechanisms will be evaluated using a design matrix. They will also both be simulation in SolidWorks. The overall efficacy of the shield will be tested using a Monte Carlo simulation

package, where the fetal dose can be estimated. Lastly, the team will put together a plan for fabricating the entire apparatus.

IV. Preliminary Designs

4.1: Scissor Lift

The first design the team came up with for lifting in the z-direction was a scissor lift, as is commonly seen in many automotive and construction settings. The basic functionality of a scissor lift is derived from translating a horizontal force to produce a vertical displacement (Figure 7). Briefly, bars of the same length are pinned at their centers to form an "X". These "X's" are then joined to one another by pins at their ends. Application of a horizontal force at either at the bottom of the lift or the center pin decreases the Y-labeled angles while simultaneously increasing the X-labeled angles. This change in geometry results in the raising of lift. Thus, the team envisioned one scissor lift on either side of the shield, both connecting to a platform at the top upon which the shield is secured. This horizontal force can be applied in one of two ways (Figure 8) and would be derived from either a pneumatic or hydraulic cylinder, or a linear actuator. Benefits of the scissor lift include the abundant resources regarding their construction and the potential to use pre-fabricated parts. To limit the number of moving parts and the potential for failure, the proposed design would only include one "X," as in Figure 8.

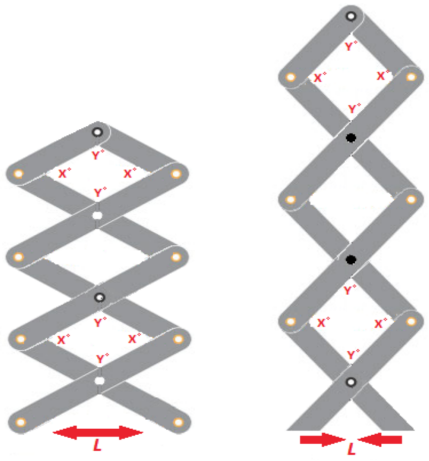


Figure 7: Schematic of scissor lift geometry before (left) and after (right) application of the horizontal force [10].

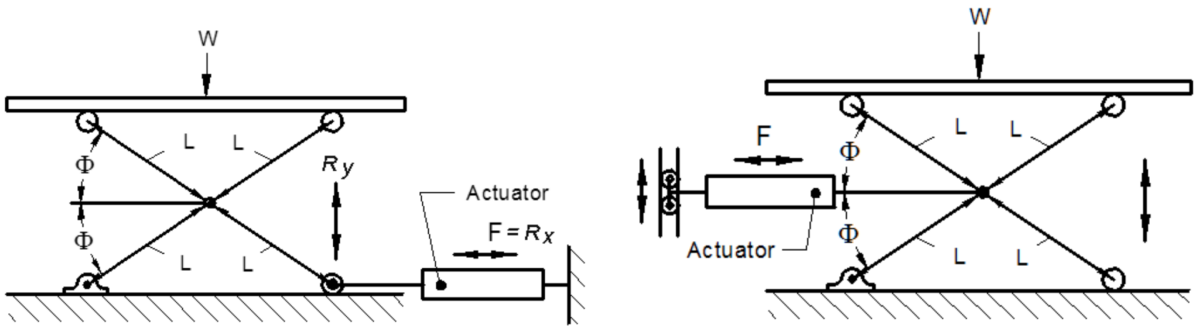


Figure 8: Schematic of scissor lift with horizontal force applied at bottom (left) and center pin (right) [10].

4.2: Dentist Chair

The second design the team chose to include for further consideration was based off a patent for a dentist chair (Figure 9). Like the scissor lift, the dentist chair utilizes a horizontal force to produce a vertical displacement. However, it does so in a different manner than the scissor lift. Instead of an "X" shape, the dentist chair appears to be an upside-down "V": two bars are joined by a pin that is also attached to a platform at the top. One arm has a fixed position but lengthens in the vertical direction, while the other lies on rollers and has fixed length. When the rolling arm is subjected to a horizontal force directed towards the fixed arm, it results in a raising of the platform and a lengthening of the fixed arm. A schematic of this can be seen in Figure 10. As with the scissor lift, there would have to be a mechanism on each side of the shield.

Additionally, the horizontal force would again be derived from either a pneumatic or hydraulic cylinder, or a linear actuator.

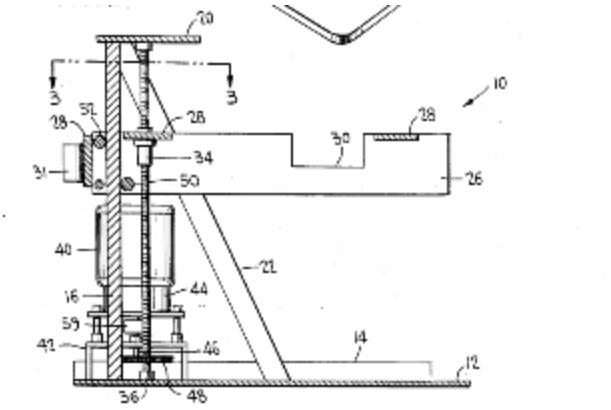


Figure 9: Schematic from [11] depicting the specific components of the lifting mechanism.

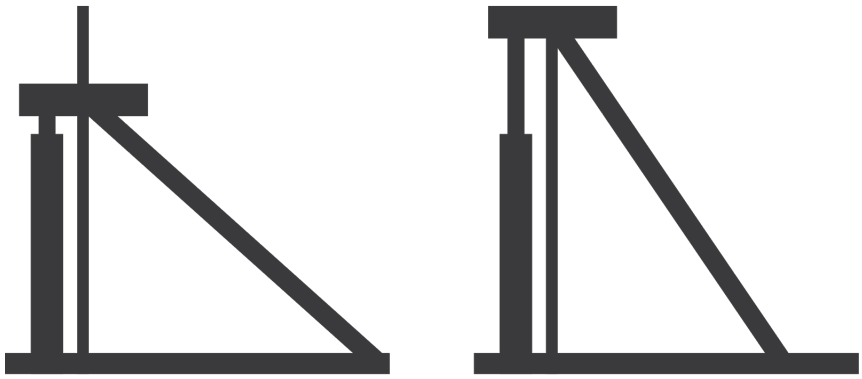


Figure 10: Schematic of dentist chair geometry before (left) and after (right) application of the horizontal force.

4.3: Suspension

One of the responses the team received throughout the semester included the idea of suspending the shield, an idea that was also considered last semester. Despite initially dismissing the idea, the team revisited the option. The suspension mechanism would be based on a Hoyer lift (Figure 11). Because Hoyer lifts are designed to support 450 lbs [12], further design would be necessary; using a standard Hoyer lift would not be able to support the near-500 lbs of the shield. Benefits of the suspended design over the two previously-described anchored ones include the

reduced footprint and the familiarity of hospital staff with its use. Concerns include the potential for swinging and the requirement for staff to guide the shield into place.

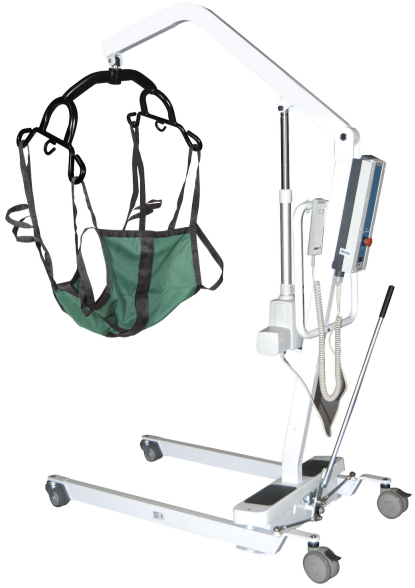


Figure 11: Example of a standard hydraulically-powered Hoyer lift utilized to assist with lifting and lowering patients in the medical field [12].

V. Preliminary Design Evaluation

5.1: Design Matrix and Evaluation

The three preliminary lifting designs were compared to one another based on the following five categories: cost, fabrication, implementation, user operation, and safety. The most heavily weighted category was safety. Assigned a value of 40, as this category considers not only the patient, but also all medical staff involved in the placement and use of the device. The two categories assigned the next-highest weights were fabrication and implementation. The former includes the ease with which the mechanism can be fabricated, based mostly on whether or not custom parts were required and the different machining equipment necessary. Implementation is used as a judgment for how well the mechanism can function in the treatment suite with the

physical constraints including treatment couch, linear accelerator, and door width. The next-highest ranked category was user operation, which considers the extent that the medical staff need to properly position it in the treatment suite. Finally, cost was also included to account for the budget of $10,000.

Table 1: Preliminary Design Matrix for Lifting Mechanisms.

	Scissor Lift	Dentist Chair	Suspension
Cost (5)	4/5 = 4	3/5 = 3	2/5 = 2
Fabrication (20)	3/5 = 12	2/5 = 8	2/5 = 8
Implementation (20)	3/5 = 6	3/5 = 6	5/5 = 20
User Operation (15)	4/5 = 12	4/5 = 12	1/5 = 3
Safety (40)	5/5 = 40	5/5 = 40	1/5 = 8
TOTAL (100)	72	69	41

The two safest options were the scissor lift and the dentist chair because they provide a physical support of the shield in the direction of most critical consideration: downward. In addition to allowing a bottom-up support, these two anchored designs allow for the addition of many fail-safe mechanisms between the shield and the ground, a significant benefit over the suspension design. The scissor lift was also ranked the easiest to manufacture due to its well-established mechanism and the various resources available for manufacturing [13]. Importantly, the suspension design outperformed both anchored designs in the category of implementation. It has smaller footprint and cantilevered mechanism allow for significant available space in the treatment suite. Both anchored designs were ranked equally easy to operate because medical staff would use a button to operate either lifting mechanism. The suspension mechanism, alternatively, would require manual guidance over the patient to properly place it. In terms of cost, the scissor lift was given the highest score because it requires parts that are relatively simple and commonly available in kits or for retail. It was followed by the dentist

chair, which includes less readily-available parts such as the worm gear and would need to be adapted to support a greater weight than the initial patent use, as described above. For similar reasons, the suspension mechanism was ranked last, as Hoyer lifts are typically designed to support no more than 450 lbs [12] and the team would not be able to make use of existing commercially available products.

5.2: Proposed Final Design

5.2.1: Lifting Mechanism

Due to its stability and ease of manufacturing, the scissor lift will be used to raise and lower the radiation shield. Since the shield does not have to be lifted up very high, there is no need to have more than one centralized pivot hinge on each side. To ensure that the beams do not fail, there are two options: reinforcement of each pivot hinge with additional beams or addition of non-load-bearing beams. These options will be discussed further and evaluated on both cost and safety. The component that applies the force needed to raise the platform will be single-acting hydraulic cylinders rather than any mechanical, manually controlled devices. While it will cost more to produce, the reliability of hydraulic cylinders outweighed the cost. Since it is critical that all the cylinders extend and contract uniformly, everything will be operated via automatic controls.

5.2.2: Additional Features

The team has looked into adding a rotating element to the shield to allow for a greater degree of freedom when positioning the shield over the patient. The mechanism currently being considered would employ a scissors-jack, similar to the manual car jacks that are used to lift a car when changing a tire. There would be four jacks (two on either side of the patient's head and two on either side of the patient's feet) that the shield would be resting on, and to rotate the shield, the medical team would rotate the jack near the head. All the jacks would be coupled so that when the jacks near the head lower their portion of the shield, the jacks by the feet would

raise the other side of the shield, and vice versa. This will allow the medical team an additional degree of freedom when positioning the patient.

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 system 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 [14]. Hazardous machine components of a shield lift system would be any rotating parts, reciprocating parts, transversing parts, and any pinch points [14]. The final design incorporates a scissor lift which poses three ostensible hazards: the pinch points created at the fulcrums during lowering, the risk of complete support failure at any point during operation and the rotational screw motion that causes the shield to be lifted or lowered.

Ways in which safeguards could be incorporated into the final design include covering the scissor-jack parts with a removable or adjustable (to allow for easy maintenance) barrier, foot controls to reduce hands-on operation, an auto-locking mechanism to prevent complete collapse of the scissor-jacks supporting the shield should they fail and hazard indicator lights to warn technicians if system components are in need of repair. A pneumatic- or hydraulic-powered scissor lift would ideally reduce hazardous machine-technician interactions [14].

VI. Fabrication and Development

6.1: Materials

6.1.1: Shield

Pure lead is the most suitable material to stop the high energy photons from radiation therapy. This lead will likely be coated with a paint or powder coating to prevent any contact directly with the lead which would be a toxic hazard.

6.1.2: Lifting Mechanism and Frame

The lifting mechanism and frame are vital for supporting the lead, which will be 840 lbs (381 kg). It will be made of a sturdy material resistant to fatigue. Most likely, this will be steel. The main components of the lift will be surrounded by an enclosure, so it need not be aesthetically pleasing. Structural steels either iron-based or carbon-based will be considered. The visible part of the shield must not be intimidating to the patients and the staff, likely mimicking other aesthetically pleasing machinery in the hospital, such as stainless steel. Compared to the iron-based steel, stainless steels are less tough, but properties are within the required limits.

6.1.3: Additional Features

If the team were to incorporate the rotating component, it would most likely be made out of steel or similar alloy. The rotating mechanism would be smaller, and it would be an option to use a higher quality metal than the frame since the amount of raw material we would purchase for the rotating element would be smaller. Regardless, whichever grade of steel we use for the rotating element would likely be in the same class of steel as the scissor lift and frame.

6.2: 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 [15]. 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. Likely, a permanent mold will be machined and then molten lead cast into it. The final lead shield will be coated with a powder or paint coating.

6.3: Testing

6.3.1: Monte Carlo

In order to establish the efficacy of the high-waisted skirt radiation shield, the absorbed dose to the fetus must first be calculated by simulating radiation leakage and scatter from the accelerator head in a computational environment. Estimating the absorbed dose of the fetus at differents points during gestation has often relied on simplistic phantoms models for both mother and fetus with little data (from computational tomography) to approximate the anatomy of the pregnant woman [16]. Xu et al. describes a more accurate model for estimating absorbed dose to 35 organs of both the mother and the fetus from radiation leakage and scatter at 3, 6 and 9 months gestation using the RPI-3, RPI-6 and RPI-9 phantoms, respectively [16]. The Monte Carlo code package MCNPX was used to model radiation leakage and scatter from the accelerator head during treatment with a 6-MV photon beam [16][17]. The RPI models and MCNPX package were then utilized to estimate absorbed dose to the fetus at each of the 3 stages of gestation. Although the treatment setup used to simulate radiation therapy in Monte Carlo would have to be altered with the addition of the high-waisted skirt shield, the method described by Bednarez and Xu et al. could be a viable testing method to determine the efficacy of the shield [16][17].

In addition to virtual testing, measurement of peripheral dose to physical anthropomorphic phantoms and Solid Water®, as described in Owrangi et al. 2016 and used to

test the efficacy of the shield developed by the University of Michigan, could also be performed [2]. Given the current access to resources, however, virtual testing remains the most realistic option.

6.3.2: SolidWorks

Initial testing for failure and stress will be performed in SolidWorks. The individual components will be tested to failure separately first and compared to the total load. If each component separately can support the weight of the shield, then the combined sturdiness will be a high factor of safety. If a component cannot support the weight of the shield alone, additional support will be added to that area. After the individual tests, the team will move onto assembly simulations and analyze the critical stresses using a factor of safety greater than four, adding additional supports as needed. That analysis can be evaluated at different configurations (i.e: different heights and positions of the shield).

Motion studies will also be performed using SolidWorks. Basic Motion will be the first test run since it is rather simple and can give us a general idea of how the device will move. After the Stress Analysis has been completed, those values will then be used for Motion Analysis, which will be critical when assessing the dynamic performance of the entire device. Like the simulations to test for failure, the Motion Analysis can also be performed on subassemblies and individual parts.

6.3.3: Physical Testing

While the lead shield and the hydraulics are too expensive to create several duplicates for the purpose of compression and tension tests, the parts that are mechanically based (such as the rotating element) are relatively cheap. This will allow us to make several copies to test using an MTS machine, which will give us the best overall picture of how our support mechanism would fare in the real world. If these values differ significantly than the values produced from SolidWorks simulations, the SolidWorks simulations can be rerun using the values from the MTS testing.

VII. Discussion

7.1: Summary

The scissor-jack lift design was ultimately found to be superior to the dentist chair and suspension lift designs in terms of cost, ease of fabrication, ease of user operation and overall safety. It was decided that bottom-up lift systems would provide greater stability and support to shield, especially during transportation, due to their lower centers of gravity. Compatibility between the high-waisted skirt shield and the lift system will be critical to the fabrication process and was taken into account during evaluation of the lift designs. The simplicity of the scissor-jack lift and its widespread use in industrial settings to lift heavy loads on the order of tons also distinguished it from the other designs. Although the focus of the project this semester is chiefly the lift system, the ability to incorporate methods for transporting the shield-lift system between storage and treatment rooms was additionally considered. Testing will ultimately determine whether the scissor lift system adequately supports, lifts and lowers the fetal radiation shield.

The scissor lift design must be developed further along with detailed SolidWorks sketches for stress testing, and the way in which the lift system will be incorporated into the shield design or vise versa must be determined. The degrees of freedom of the lift system for orientating the shield over the patient during treatment, or whether to permit rotational motion in addition to just up-and-down motion, additionally remain to be determined. Incorporating rotational motion into the lift system would increase the complexity of the design and present additional safety hazards, therefore the risk-to-benefit ratio of these features must be carefully considered.

Future work for the project this semester will include revisiting the high-waisted skirt shield design developed last semester. The Monte Carlo environment along with the MCNPX coding package will be used to evaluate the efficacy of the shield in reducing absorbed dose for the fetus resulting radiation leakage and scattering. Previously, computationally modeling

radiation leakage and scattering from the accelerator head and collimators, respectively, has proven challenging. However, the methods described in Bednarez and Xu et al. 2008 and likely guidance from experts in the UW Department of Medical Physics will allow us to quantitatively assess the performance of the high-waisted skirt design.

7.2: 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 exists 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. 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.

VIII. Conclusions

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 makes 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.

Development of a support system that enables the safe lifting and lowering of the fetal radiation shield has been the focus for this semester. Of the three preliminary designs, the scissor lift support system outranked the dentist chair and suspension support system designs in terms of cost, ease of fabrication, ease of user operation and safety. However, elements from the other two designs will likely be incorporated into the final scissor lift support system design. Furthermore, many details of how the scissor lift design and how it will work need to be specified. The remainder of the semester therefore will be dedicated to improving the scissor lift design, notably by incorporating safeguards, developing SolidWorks sketches for the design, and conducting SolidWorks and Monte Carlo simulations to test the efficacy of the scissor lift and shield, respectively.

Beyond developing and testing designs for the fetal radiation shield and its support system, the method by which the apparatus will be transported between treatment rooms and storage must also be addressed. Given the challenge of devising a support system to securely lift and lower a 381 kg lead shield over a pregnant patient, final design elements like transportation mechanisms may best be left for another semester.

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X. Appendix

10.1 Product Design Specification (PDS)

Product Design Specification: Fetal Radiation Shield

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Date: February 7th, 2018

Function:

Approximately 4000 women per year will require radiation therapy treatments during pregnancy in the United States. Negative effects of ionizing radiation on the fetus are moderately understood, and are generally reduced with lower fetal dose. Appropriate shielding for standard radiation would include several hundred pounds of lead held safely over the fetus during radiation therapy for brain and breast cancer. The Department of Human Oncology at UW Hospital is seeking a safe and effective shield for these purposes. The shield will need to be mobile, adaptable to a variety of treatment delivery machines and techniques, and be safe to use for all involved. This team will design, fabricate, and test the shield with clinical treatment delivery systems throughout this semester.

Client Requirements:

- Must provide physical blockade of the fetus from radiation leakage from the head of the instrument and scattered photons from the collimators
- Must not pose greater risk of safety to mother or fetus than radiation itself

Design Requirements:

- Must be mobile: easily moved between patient treatment rooms and stored when not in use
- Must reduce the fetal dose by 50%
- Must be compatible with women of all sizes and varying stages of pregnancy
- Must be usable 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:* Aside from the shield blocking 50% of the radiation reaching the fetus, it must have the ability to be moved around the hospital to different treatment rooms. Primary and scattered radiation can approach the patient from from a variety of angles depending on treatment plans and location of treatment site, thus the shield should cover the majority of the abdomen. The shield must possess the capability to move in the vertical direction in order to accommodate different table heights.

    b. *Safety:* This is the most important aspect of this design. In order to be used with a patient, the risk of it falling and injuring the patient must be less than the benefit that the patient may receive from the shield. A primary risk of safety will involve the mobility of the shield for patients, technologists, and physicians. Safety standards for a medical apparatus similar to this are highly regulated by medical professionals and government agencies. The apparatus must prevent any patient-to-lead contact, which could lead to lead poisoning. Additionally, the apparatus must capable of being wiped down with common clinical cleaning reagents (ex: Cavi-Wipes) before and after each use.

    c. *Accuracy and Reliability:* The apparatus must shield the fetus from 50% of incoming radiation, assessed during each treatment session. This support mechanisms of this device must stay below the yield stress of the chosen material 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. However, the apparatus will remain at the hospital permanently. Frequency and length of treatments vary greatly, ranging between 1-45 fractions, with each fraction lasting 15-30 minutes. When not in use, the apparatus will be stored away.

    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.

    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 and rotating patient bed, along with various medical instruments that assist with treatment.

g. *Ergonomics:* The shield must fit comfortably across the patient's abdomen and take into account potential different positions of the fetus and variability in patient physiology. 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. Additional measurements of the room are to be determined.

i. *Weight:* The treatment couch has a weight limit of 440 pounds, which includes the patient's weight. If the apparatus is attached to the bed or rests on the bed in any way, the weight of the apparatus must account for this as well.Additionally, the covering on the floor beneath the treatment table covers the rotating machinery- the heavy apparatus cannot stand on this cover and must be moved carefully around this location.

j. *Materials:* Lead will comprise the body of the shield of the apparatus; other materials required for support and safety will consist of aluminum, steel, and various plastics to be determined by the final design.

k. *Aesthetics, Appearance, and Finish:* This apparatus must comply with the safety standards for approval in clinical use. It must be aesthetically appealing and non-threatening to the patient and physicians in the room. The finish on this device must also be able to be wiped down per clinical standards.

2. Production Characteristics

a. *Quantity*: Only one (1) apparatus will be fabricated.

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

3. Miscellaneous

a. *Standards and Specifications:* All medical devices are classified into Class I, II, or III. Each classification 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.

b. *Customer:* This device will be in a relatively clean environment that can also be a very uncomfortable setting for patients. As a result, the apparatus must not appear threatening.

c. *Patient-Related Concerns*: Some of the greatest patient concerns of undergoing radiation therapy while pregnant are the associated risks of disrupted fetal development and later childhood cancer. While these risks are generally relatively low, the shield should reduce this risk without incurring another immediate risk to the fetus.

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 support of the heavy, dense lead. According to the client, pregnant patients seeking radiation therapy at UW Hospital are most likely referred to the Mayo Clinic, which uses a wooden bridge supporting lead bricks to shield leaked radiation. Aiming to provide a safer option, The University of Michigan developed a custom fetal lead shield. The shield was highly effective in reducing radiation, but not economically feasible. The company responsible for development went bankrupt and could not support further development.