Fetal Radiation Shield:

Limiting dosage of high-energy radiation to the developing fetus

Final Report

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Abstract

Every year, one in 1500 pregnancies in the United States is complicated by cancer that necessitates the use of radiation therapy before the end of the pregnancy. Treatment of the affected patients must be adjusted in order to reduce the fetal radiation dose, as it is associated with a variety of birth defects and childhood cancer. Currently, there is no way to physically shield the fetus as existing apparatuses for this purpose were either be unsafe or too expensive and impractical. The Department of Human Oncology at University Hospital has requested that a shield be designed to block leakage from the head of the radiation machine and scatter off of the patient. This will be accomplished with a shield that is five centimeters thick, safe for the patient and medical personnel, mobile, and able to shield 50% of stray radiation. The team created a SolidWorks model and a to-scale physical model of the final design. The SolidWorks model was used to do static linear testing, which determined the location of the points of maximum stress. Surface area was also calculated from this model to estimate coverage against radiation leakage and scatter. A preliminary support system that is compatible with the treatment rooms is being developed that will allow for vertical motion of the shield and mobility. Implementation of the apparatus in University Hospital will provide more treatment options for pregnant patients throughout the state of Wisconsin.

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Introduction

Every year, nearly 4000 pregnant women are treated for cancer within the United States[1]. Radiation therapy is often considered for pregnant patients when treatment cannot be delayed until after childbirth. Of the pregnant women treated across the U.S., the majority 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 [2][3]. Current efforts to reduce fetal dose are limited to altering the treatment parameters such as angle and direction of the beam [2]. 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 [4]. This was also discontinued due to safety concerns and inefficiency [4]. 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 [2], the design proved far too expensive and led to the bankruptcy of the manufacturing company [2][5]. Due to the current safety and cost barriers, there are currently no commercially-available products that limit 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, mobile, and above all, safe for the patient and medical personnel involved. See Appendix A for the Problem Statement and Appendix B for the Product Design Specifications (PDS).

Background

The most common cancers with which pregnant patients present include breast cancer, brain cancer, cervical cancer, lymphoma, and melanoma [3]. 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.

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 [6]. When considering the effects of radiation, pregnancy can be split into three different periods. The first period is the week directly after implantation (week 1). The second period is known as organogenesis (week 2-7) [3]. 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 [3].

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 [3].

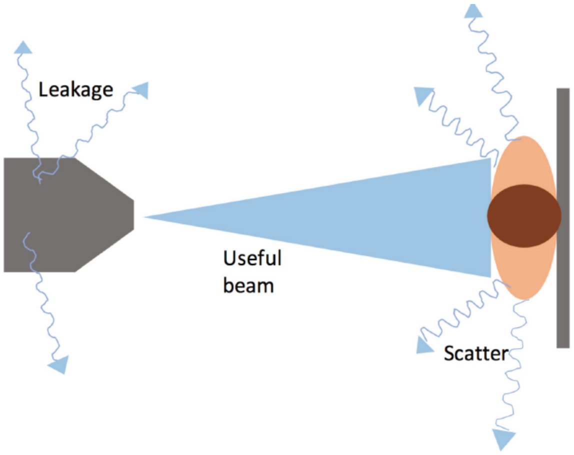


Figure 1: Radiation scatter explained [8]

Lead is the industry standard for blocking radiation due to its effectiveness relative to its volume and weight [1]. Alternatives to lead include an alloy called Cerrobend. It is a mixture of metals including lead and cadmium that has proven effective at blocking radiation and is often used to make smaller shields to block specific body parts [4].

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. After discussion with the client, the team decided on a width of 5 cm, a width greater than the HVL of lead in order to increase the likelihood of meeting the 50% attenuation requirement stated by the client (Figure 2).

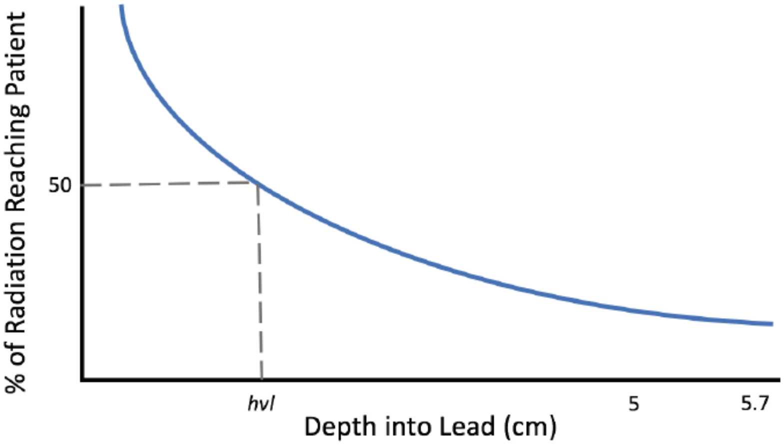


Figure 2: Lead Thickness Diagram for Blocking Radiation

The radiation that scatters throughout the patient is nearly impossible to stop, thus the device will focus on radiation leakage from the machine head and scatter. Additionally, 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. Zacariah 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. 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. More information can be found in the Product Design Specifications, or PDS, found in Appendix B.

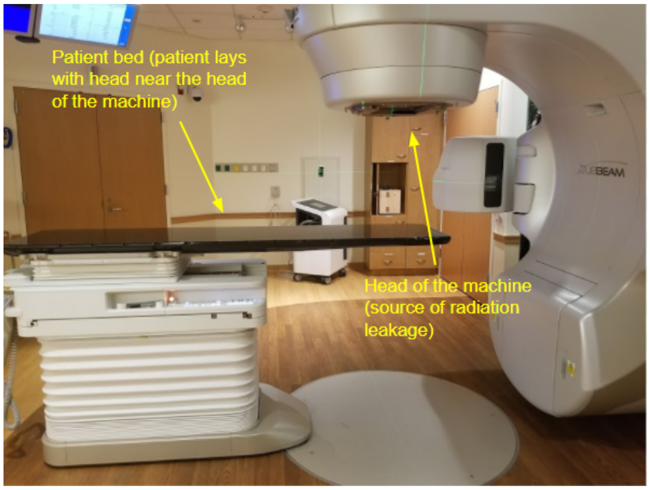
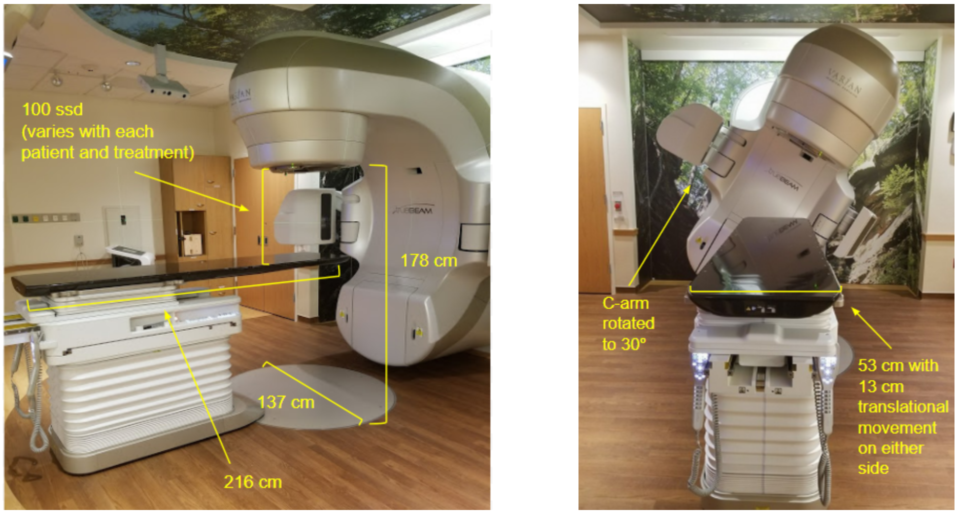


Figure 3: Diagram of the treatment room showing treatment directionality.



Figures 4 & 5: University Hospital radiation therapy treatment suite.

Compatibility with the radiation therapy treatment rooms is of the utmost importance 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. 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, making sure that it is not excessively cumbersome. This is also important for storage as it will be stored in the hallway that leads to the morgue of the hospital. There is a reasonable amount of room in this location, but it cannot hinder movement through the hallway.

Preliminary Designs

The team agreed that the best way to tackle this project was one component at a time. Initially, the team focused on the structure of the shield as this was paramount to the overall design. Secondly, the team determined an appropriate material. Lastly, the team designed a support mechanism and established mobility for the shield, designed around the shape chosen for the shield. This shield has to be effective, adaptable to a variety of patient sizes, and safe for all parties involved. After evaluating previous designs for the shield such as the University of Michigan design, one vital component the team found lacking was extended coverage of the inferior and superior sides of the patient's abdomen [2]. The team decided the shield should provide more complete shielding from various treatment angles, allowing the physician to devise a treatment plan less limited by the fear of radiation reaching the fetus.

Initial shield designs considered patients of all sizes and at various stages in their pregnancies. This was pertinent in evaluating the dimensions of the design. It must be mobile to be stored in a back hallway and moved into various radiation suites in between treatments. Both the shield and support components will be vital to the implementation of this radiation shield.

Shield Design

Modified U

This U-shaped design provides simplicity and basic shielding coverage in the pathway of the radiation scatter and leakage from the head of the radiation machine. Of note is the extended coverage on the superior side of the shield, adding curvature to the overall U design. The sides of the shield extend laterally to the treatment couch and are equivalent thickness to the rest of the shield, to provide coverage on the sides of the patient. This shield is mobile in the vertical direction for adjustments of the treatment table.

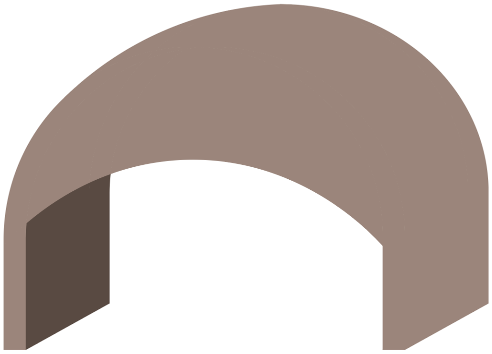


Figure 6: Modified U shape shield. Extruded on the superior side to extend coverage.

Wall

The wall design provides the most simple solution to the leaked radiation. It is a solid vertical block extending from the superior of the patient's abdomen towards the ceiling, level with the height of the radiation machine head. Since the primary radiation leakage is at the head of the machine, a solid wall would focus on complete blockage from this radiation. This design would also be mobile in the vertical direction. Concerns with this design would be the instability of the heavy shield and high center of mass.

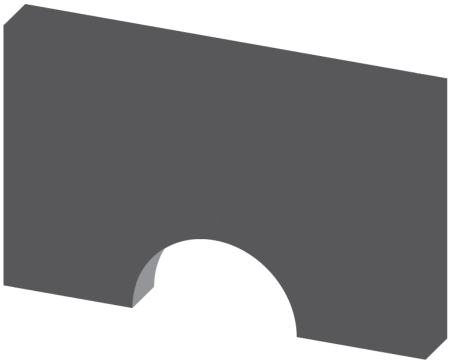


Figure 7: Wall shape shield. Tall to provide more blockage from the machine head.

Helmet

The helmet design is the most sophisticated, adding the additional benefit of rotation. This shield has a pivot joint, allowing rotation around a singular point. This rotation provides customizable protection to the fetus in unison with various treatment angles and couch positions. This will allow for more options in the angles and locations for the therapy regimen. This shield has a consistent thickness throughout, even on the sides down to the pivot joint to deflect scatter at these different angles. This design will allow for greater accommodation of women of all shapes, sizes, and stages of pregnancy. Adding this aspect of rotation will present additional safety concerns as with any moving part. The support system is vital to ensuring the safety of the patient, specifically with the helmet design.

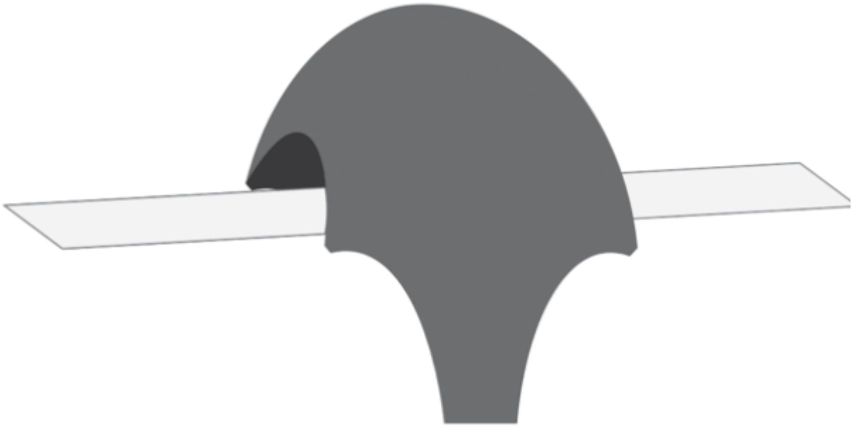


Figure 8: Helmet shape shield shown relative to the operating table.

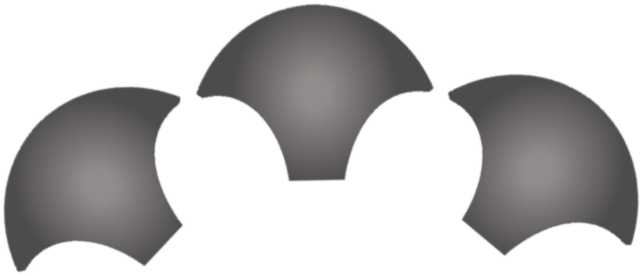


Figure 9: Pivoting motion of the helmet design from a profile view

Materials/Specifications

All shield designs must be able to accommodate all sized patients at various stages in their pregnancies. The shield will be 5-6 cm thick, variable to the material chosen [10]. As mentioned above, collateral components of the design may be thinner if shielding is not vital, though some protection is necessary. Most important for the material choice is its efficacy in shielding such high energy radiation. Both materials considered below are proven extremely effective in radiation therapy shielding in a clinical application and industry standard materials for this purpose.

Lead

Lead is a well documented material in stopping radiation that has been implemented effectively in various clinics [11]. It stops radiation because of its high molecular density [1]. With an atomic mass of 11.34 g/mol, a lead shield would be heavy and require various safety components to be incorporated. Other benefits to using lead is its vast availability, ease of fabrication, and affordable costs [9]. Lead would cost approximately \$0.03/cm^3, though fabrication of this lead could potentially result in other expenses and would have to be done by an external company.

Cerrobend

Cerrobend is a modern composite for radiation shielding made of 50% bismuth, 26.7% lead, 13.3% tin, and 10% cadmium by weight [4]. A desirable characteristic of this shield is its melting point, 70 °C, making fabrication and molding of a Cerrobend shield straightforward and within the abilities of the design team without external aid. Currently used in the Department of Human Oncology for other applications, this material would be familiar to other oncologists and is proven to be effective in shielding radiation (See Appendix C). 6 cm of Cerrobend (9.38 g/cm^3) would be equivalent to the 5 cm of lead (11.34 g/cm^3) that we had calculated. Cerrobend would also be more expensive, near $12.50 per pound [11]. Overall, Cerrobend would be desirable for its ease of fabrication, as it is molded in house, but is more expensive than traditional lead.

Support

Support and mobility of this shield design is vital to the clinical setting it will be used in. It was understood that this shield, regardless of the shape design, needs to be supported and mobile in the x,y, and z directions.

First, the team considered the support. This shield could be suspended in the air, similarly to a hoyer lift, or anchored to the ground. With this much weight, the anchored support was more straightforward and safe. The team also considered a combination of suspended and anchored support. The frame chosen will be based off of the final shield shape.

The shield must move between treatment rooms, so wheels were the obvious choice. These wheels must be able to support approximately 381 kg of lead. They must safely move the shield through patient areas in the hospital with expected bumps and turns of the hospital. These wheels also must have locking capability for the insurance of stability during therapy.

Once in the patient room, the shield has to be positioned over the patient, safely locked, and then adjusted to various heights as the therapy couch is set. This lifting and lowering of the shield will likely be accomplished by a hydraulic system, utilizing fluid pressure to adjust heavy components. Hydraulics will likely provide the largest assurance of safety for the patient and staff involved in therapy.

Preliminary Design Evaluation

Shield

After deciding upon the anchored support system, the team focused on determining which of the preliminary shield designs to pursue. A design matrix (Table 1) below, was created.

Table 1: Design matrix evaluating the three design alternatives for the shield shape.

	Modified U	Helmet	Wall
Cost - 5	(4/5) | 4	(4/5) | 4	(5/5) | 5
Safety - 30	(5/5) | 30	(4/5) | 24	(4/5) | 24
Ease of Use - 15	(5/5) | 15	(4/5) | 12	(5/5) | 15
Weight - 15	(3/5) | 9	(5/5) | 15	(1/5) | 3
Shielding - 25	(3/5) | 15	(5/5) | 25	(3/5) | 15
Cleanliness - 10	(5/5) | 10	(4/5) | 8	(5/5) | 10
TOTAL	83	88	72

Six criteria were utilized to compare and rank the three preliminary shield designs. The first was safety. As with any biomedical device, safety is always of the utmost concern. For this particular design, it becomes even more relevant; because the risk to the fetus is already so low, the shield must be designed in such a way to minimize any added risks. Additionally, safety for technicians involved in setup and movement of the shield was also considered. Because of this importance, this category was given a weight of 30. The next-highest ranked category was shielding efficacy. Because positioning over 800 pounds above a pregnant woman inherently incurs a safety risk, the shield must block sufficient radiation from reaching the fetus. The client has deemed this proportion as 50%, as stated in the PDS (See Appendix B) and the category was assigned a weight of 25. Overall, designs with greater coverage from various potential beam angles were ranked higher. The next two categories were ease of use and weight, each assigned a weight of 15. These two categories were considered to account for the need for the shield to be set up, moved and stored by technicians. The shield needs to be easily cleaned by standard clinical-grade cleaners such as Cavi-Wipes, so this was also considered and assigned a weight of 10. Finally, the design should cost no more than $10,000. Cost was considered by examining ease of fabrication and anticipated volume of lead. Thus, it was assigned the lowest weight of 5.

The wall design ranked highest in the cost category, as it would likely be the easiest to manufacture due to its simple shape: a thick sheet of lead and a semi-circular cut-out. The modified U design won out for safety against the other two designs, as it has the largest amount of area available upon which to support the large amount of weight. The modified U and wall designs each were ranked highest for cleanliness and ease of use, as they are streamlined and do not have the rotational aspect of the helmet design. The helmet design outperformed the wall and modified U designs in the weight and efficacy of shielding categories. The shield is slimmer on the sides, and thus lighter. Additionally, the rotational aspect of the design allows for a closer fit to the body to protect the abdomen from radiation from behind the patient at an angle, an aspect against which the other designs do not protect .

Material

In addition to picking a shield shape, the team had to determine the best material from which to create the shield. Because all previous literature had focused on lead-based shields [2][1], the team initially decided to pursue a lead-based shield. However, after a discussion with the client regarding Cerrobend-based plates, which are cast in-house on a case-by-case basis to block specific areas of the body from radiation, the team decided to also consider creating a shield out of Cerrobend. To make a decision more objectively, the team created a design matrix for the material, shown below (Table 2).

Table 2: Matrix evaluating lead and Cerrobend as potential shield materials.

	Lead	Cerrobend
Thickness - 25	5/5 | 25	4/5 | 20
Weight - 25	5/5 | 25	5/5 | 25
Cost - 5	5/5 | 5	3/5 | 3
Ease of Manufacturing - 15	3/5 | 9	5/5 | 15
Safety - 30	5/5 | 30	3/5 | 18
TOTAL	94	81

There were five categories considered when ranking the materials options. As with the shield, safety was considered the top category, with a weight of 30. It was closely followed by thickness, as a relative equivalent to the industry standard of 5 cm lead, and weight. Ease of manufacturing and the potential to expand the design to other hospitals was also considered, as there is no universal standard of treatment for pregnant women undergoing radiation therapy. Cost was also considered, but not given as high a weight as the other categories.

With respect to safety, lead won out due to the lack of hazardous cadmium compounds found within Cerrobend. In addition to the potential for lead poisoning for the patient and fetus, there would be an added harm to all users, including technicians, if Cerrobend were used. With respect to thickness, Dr. Labby calculated that 5 cm of lead would be roughly equivalent to 6 cm of Cerrobend (See Appendix C). While not a substantial amount, the added thickness of using Cerrobend over lead would make it difficult to shield the fetus when the patient is undergoing breast surgery, as the abdomen changes shape throughout pregnancy [1]. Thus, Cerrobend was given a lower score. With respect to weight, Dr. Labby's calculations indicate that the density, when scaled by the extra 1 cm of thickness required for Cerrobend, would be roughly equivalent between lead and Cerrobend shields. Due to its low melting point, a Cerrobend-based shield could potentially be cast in-house at the University Hospital, making manufacturing much easier than having to contract the job out and motivating the higher rank for Cerrobend in this category. Ultimately, based on Dr. Labby's calculations (Appendix C), the cost of Cerrobend is much higher than that of lead, meaning lead is the stronger alternative in terms of a financial standpoint.

Ultimately, lead out-scored the Cerrobend option and the team decided to pursue the helmet design fabricated with lead.

Support Mechanism

As discussed previously, many potential options for supporting the shield were assessed by the team, including suspending the shield using a Hoyer lift or similar device, and anchoring the device to the ground. Almost immediately after considering the preliminary designs for the shield and estimating the weight, the team agreed to pursue an anchored support mechanism as opposed to a suspended one to avoid the risk of the shield dropping or injuring someone.The biggest concern is the tremendous weight of the shield itself. As requested by the client and outlined in the PDS (see Appendix B), the shield must be able to move vertically to accommodate different couch heights possible for various treatment plans. This will likely be achieved via a hydraulic lift system.

Final Design

Shield

Originally, the team had planned to pursue the helmet design, but subsequently realized that having a rotational shield was not plausible due to fabrication, safety, and cost concerns. In order to have a design that maximized coverage and safety, the team revisited one of the earliest designs, dubbed the “High-Waisted Skirt”. This design moves only in the vertical direction, in terms of the shield itself, similar to the “Modified U”. This shield will have uniform thickness and easily maintained cleanliness. It will also accommodate women of all shapes and sizes. The dimensions and flared shape towards the patient’s feet and over the abdomen of the patient will allow for this. Lowering the shield so that the smaller arc rests close to the abdomen will provide greater coverage of the cranial side of the patient. With a design that incorporates one solid piece of lead, this design also greatly simplifies fabrication (Figure 10).

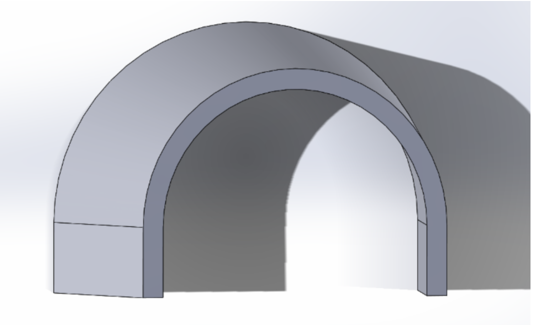


Figure 10: View of the Final Design

Support Mechanism

The team felt it most appropriate to design a support system around the shield shape chosen. This seemed to be the most effective way to ensure a high factor of safety for this apparatus. Although some consideration was given to the support based on the helmet design, most of the development of this component came after the team chose to pursue the high-waisted skirt design.

As mentioned in the previous section, the shape of the shield flares out towards the patient’s feet. There will be two identical frames on either side of the shield, 150 cm apart, to accommodate for the 137 cm diameter force plate in the treatment room, to which no force can be applied. Since this 150 cm is far wider than the 76 cm and 96 cm diameters of the shield base, two identical trapezoidal platforms must extend inwards for the shield to rest on (Figures 11, 15). As placing the shield on the end of these platforms will induce a lot of stress on the adjacent corners, a truss system is implemented to provide the joints with more support and prevent it from caving in.

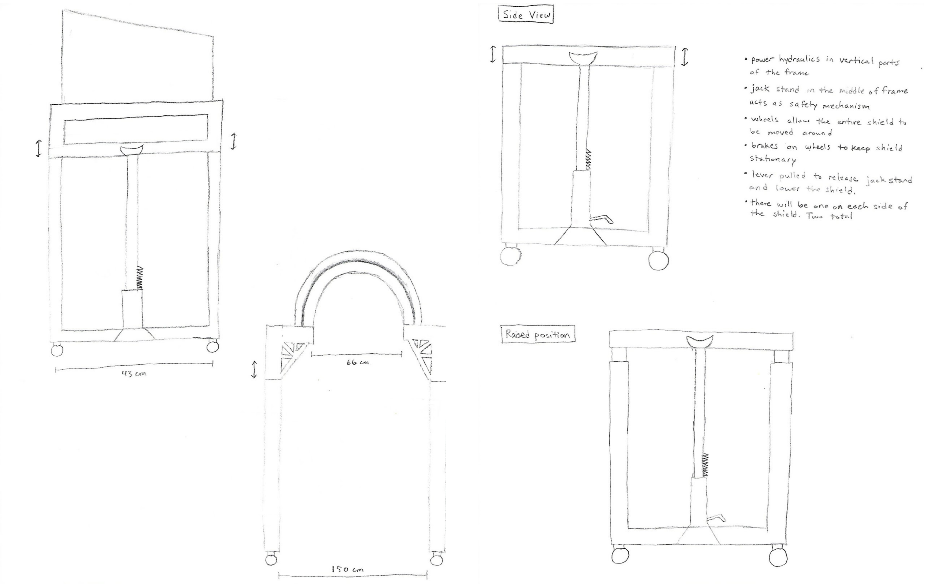


Figure 11: Preliminary sketches of support mechanism. Top left: profile view of entire support system with shield resting on top. Bottom left: frontal view of the entire support system. Top and bottom right: focused profile view of the jack stand safety mechanism in the lowered and raised positions, respectively.

The frames of the support system will include hydraulics to lift and lower the shield before, during, and after treatment. Of course, machinery like this is never failsafe, so a jack stand will be implemented for added safety (Figure 11). As the shield is raised by the hydraulics, the notches on the rod will catch into ratchets on the jack stand. The shape of these notches will allow for the shield to continue to move upwards, but will not allow the shield to fall, in the worst case scenario that the hydraulics fail.

The entire support system will need omnidirectional wheels, to be able to turn and swivel easily, and to be able to move from storage to treatment room and from treatment room to treatment room. The wheels will also include brakes to provide that the entire apparatus is stationary and stable during treatment.

Fabrication and Development Process

In the fabrication of this elaborate and multi-component design, two aspects were finalized this semester: a Solidworks model and a physical, non-functional prototype. Final fabrication will occur in the future after multiple design iterations. With an elaborate and costly design, it would be highly beneficial to ensure efficacy before final fabrication. However, due to a lack of technology for modelling radiation, this will likely not be possible for this design. The majority of testing will be conducted through modelling and following fabrication.

Development

Design Dimensions and Weight

The weight of the shield will be 381 kg. The proximal end of the shield will have a radius of 33 cm. The distal end of the shield will have a radius of 43 cm. The total length of the shield is 43 cm. The thickness of the shield is 5 cm throughout [9].

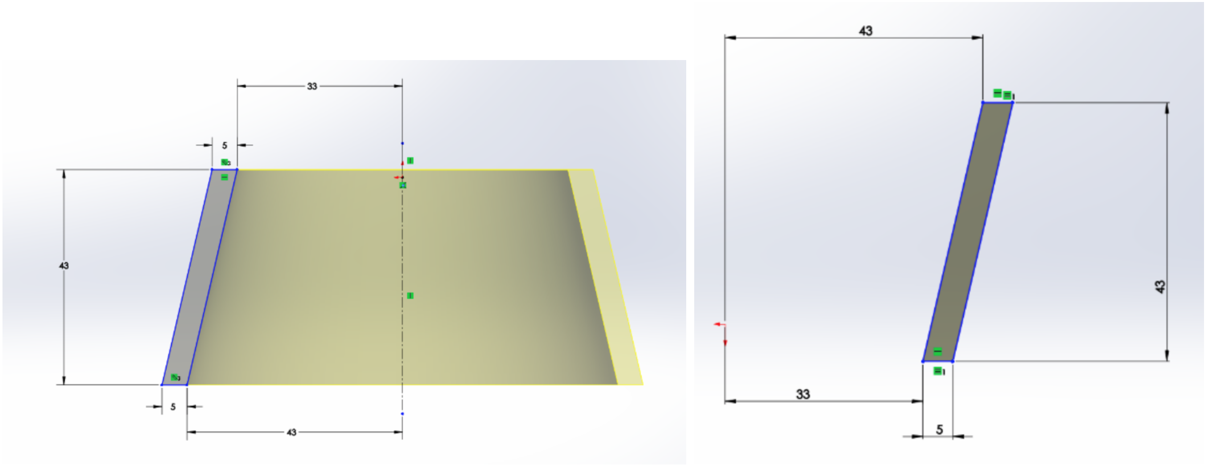


Figure 12 and 13: Dimensions of the shield

Fabrication

Solidworks Model

One of the two deliverables this semester is a Solidworks model, serving as a visual representation of the shield and structural apparatus. In order to construct the design, a base parallelogram was formed (5 cm thick). This shape was then rotated about the y-axis in order to achieve the desired radii for the two semi-circular arcs, set using the “Smart Dimension” tool (Figure 12 and 13). The extended sides of the shield were created from the same base shape, but instead extruded to 17 cm. Both components were set to lead material and then joined to be an assembly between the rotated part and two extruded sides (Figure 14). The support mechanism was also modelled in Solidworks. A frame was constructed to represent the platform and truss system, parallelling the dimensions of the shield. Using GrabCAD.com, rotating wheels with a locking mechanism were found and incorporated into the support design. Lastly, a final assembly was constructed, combining the shield, support, and four wheels, giving the final Solidworks model (Figure 15).

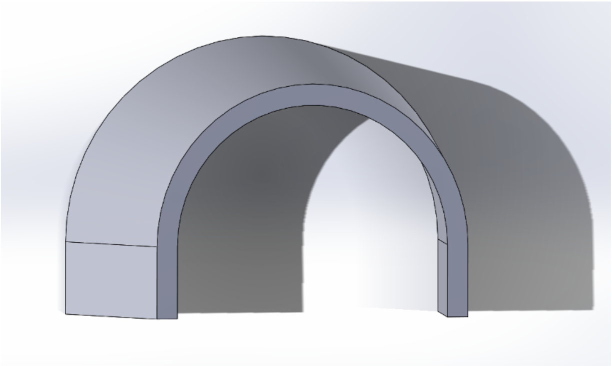


Figure 14: Full View of the Shield. Isometric depiction of the shield, showing flare outward to the sides and upwards.

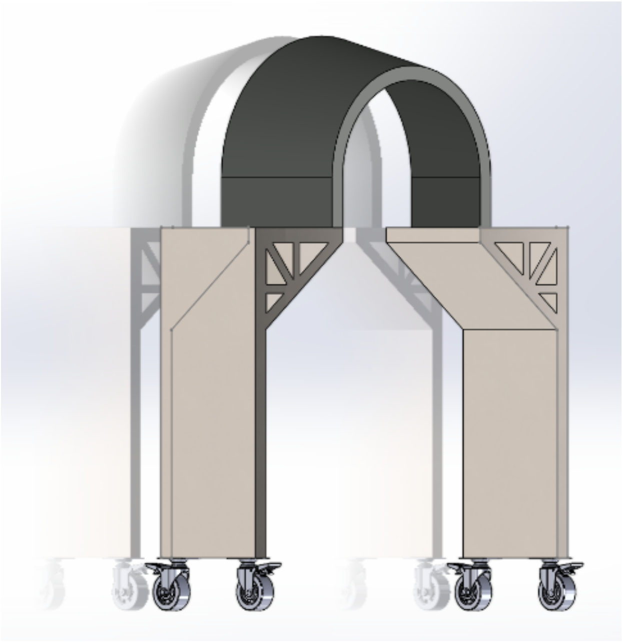


Figure 15: Full view of device with support system, not including jack stands.

Physical Prototype

For dimensional analysis, a physical model was constructed. Although several different materials and techniques were considered for the shield model, paper mache over a constructed frame was selected due to its ease of use and low cost. While the technique proved time intensive when drying time was taken into account, paper mache ultimately provided the ideal means to construct the curved lines of the shield and was reliable in holding its shape. The to-scale model of the shield was essential to the spatial understanding of the shield shape.

Using chicken wire, 1 cm diameter garden stakes, cardboard, elmer's glue, and newspaper, the team built a paper mache model of the apparatus (see Appendix D). The frame of the model was developed through shaping chicken wire into a properly sized arch and supporting it with cardboard and garden stakes (Figure 16). Paper mache techniques were then used to cover the entirety of the structure (Figure 18). Over the course of several days additional layers of newspaper were added to further fortify the structure. A layer of brown paper towelling served as the final layer to ensure that none of the newspaper's text would show through once the shield was painted (Figure 19). Through utilizing the UW-Madison Makerspace's paint room, two coats of grey spray paint were added to both sides of the shield (Figure 20).

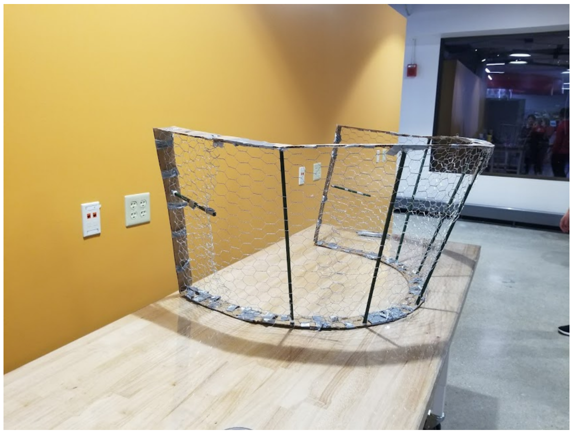


Figure 16: Frame of the model radiation shield constructed from chicken wire, garden stakes, and cardboard.

Figure 17: Depiction of how the shield is oriented with respect to the patient, the smaller arch is on the side nearest to the patient's head.

Figure 18: Process of applying paper mache to the outside of the model.

Figures 19 and 20: Model before and after spray painting.

Final Fabrication Plan

Currently, the team is talking to a manufacturing company, Swift Engineering and Manufacturing. The manufacturing company is currently working on a quote using 99.99% pure lead and the Solidworks file that was created to model the design. The next steps for subsequent semesters will be to manufacture the shield and use it to test radiation blockage with a RANDO® phantom. Before this testing can be conducted, the support design will need to be finalized, tested to ensure it will be able to support 381 kgs, and manufactured. It is currently unknown as to whether future teams will need to find a new company to manufacture the support as Swift was unsure if their facilities could handle that work. Following manufacturing of both components, the entire apparatus will need to be assembled, which will likely be done in-house by the team or the manufacturing company..

Testing

From the beginning, the team anticipated complications in the testing of the shield. In order to understand the efficacy of the device, the team would have to prove that 50% of the radiation directed towards the fetus is blocked. In the scope of this semester, the team agreed that a reasonable goal was to have a CAD model of the design, not a full lead prototype. The only way to truly test for radiation blockage is to measure the radiation at different spots on a phantom in an actual treatment room. These tests would be conducted with and without the shield for comparison. There is no CAD model that is able to simulate the leakage and scatter. The team believes that by using a shield design optimized for coverage and industry-standard lead thickness, the apparatus will effectively shield enough radiation to meet the goal of 50%.

Solidworks

A. Stress Testing

Stress testing of the Solidworks design provided an estimate to the material safety and areas of likely failure within the design. The design underwent mechanical testing within the software to determine the mechanical properties of the design, specifically where the supports could fail based on the internal and external forces. Static linear testing to model the effect of gravity and the support attachment was modelled to find the deformation and stress points.

B. Surface Area

Another estimation of the efficacy of the shield can be extrapolated from the amount of surface area that the shield is providing coverage for. By estimating how much surface area the shield covers, the team can optimize the design further to maximize this.

Future Device Testing

In the future, it will be necessary to test the efficacy of the final apparatus directly. To do this, the Department of Human Oncology has a phantom that replicates the density of a body, and can be tagged with radiation markers. These radiation markers will be placed on the model specific to critical structures on the patient and fetus. With the shield in place, the model will undergo therapy, and fetal dose will be calculated both with and without the shield.

Figure 21: Model used to simulate patient undergoing radiation therapy.

Results

Prototype

The to-scale paper mache model of the radiation shield essentially served to achieve a more comprehensive spatial awareness of the exact shape of the shield. The model allowed both the team and client a clearer picture of the design and helped provide necessary specifications for the support structure. It provided a confirmation that the team's chosen dimensions were feasible.

Solidworks Model

The Solidworks model created was a preliminary step to fabricating the shield design, an achievable goal for this single semester project. The CAD model served multiple purposes this semester. Importantly, it was to-scale and accurate for visualizing the apparatus. This model was vital to the portrayal of the shield to our client and audience going forward, including estimations of weight and surface area, two important characteristics of this project. The model served for basic stress testing as well as submitted for a fabrication estimate on the project. This Solidworks model was successfully created and utilized for quantitative analysis.

Solidworks Testing

Stress Testing

Static linear testing (Figure 22) was used to quantify gravity on the shield, ultimately finding the deformation and maximum stress points. It was determined that a very small deformation would occur (2.99855E-5 m). This was small and similar to what was expected using such a dense lead material. The points of maximum stress were localized at the posterior corners of the design (Figure 23). As this is the broadest section of the shield, this area supports the most weight, which explains this finding. Further customization of the support mechanism will be utilized in order to account for these potential points of failure. Though this area is most likely to fail, the vonMises force is 3.717 • 10^5 N/m^2. Upon evaluation, this very small value indicated that material failure is highly unlikely.

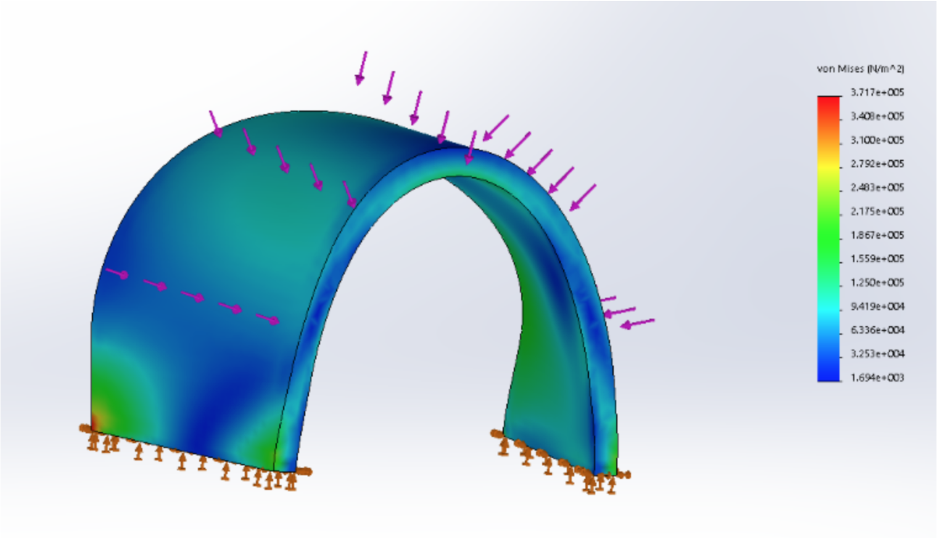


Figure 22: Solidworks stress testing results

Surface Area

Using Solidworks, surface area was calculated to shield 5963.8 cm^2 (Figure 23). This is directly correlated to the amount of radiation that is being shielded from the patient and can be used as an estimate to the efficacy of the shield.

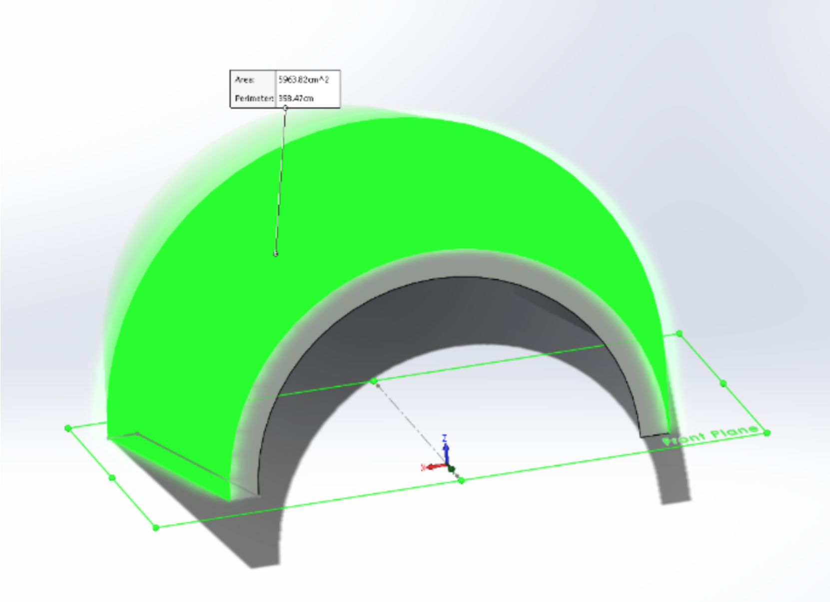


Figure 23: Solidworks surface area estimate

Discussion

There exists no relevant data useful for comparing the stress testing conducted in SolidWorks on the proposed shield design. While Owrangi et al. describe evaluating treatment techniques using a custom shield, little background on the design process of this shield is included, as the authors instead focused on the efficacy testing of the apparatus once complete using a phantom, as described above [2]. Once again, this testing will only be possible after fabrication and assembly of the shield and support system. Regarding the stress testing, however, for internal purposes, there is little need to make comparisons. Initial data revealed a very small deformation, as well as the locations of maximum stress. Future SolidWorks modeling will aim to determine this same information with the addition of the support system, as well as any modifications necessary to ensure an appropriate factor of safety for all potential failures, including but not limited to: buckling of support system under the weight, tipping of shield due to high center of mass, and shearing of the wheels. With any modifications to the shield, surface area calculations, as used in preliminary testing, will again offer a rough estimate of relative coverage and give insight into potential ways to maximize it. However, the geometry of the shield, as well as specific properties of the treatment set-up, including variation between linear accelerators, collimator setup, location of useful beam and positioning of the shield will all play a role in the true efficacy of the design [2]. Again, due to the difficulties in modeling head leakage and scatter, designing a system that will not fail is of the utmost importance [2].

Regarding ethical considerations, the conduct of future research presents many challenges. As described above, future work will involve rigorous modeling in SolidWorks to ensure the safety of the device, followed by additional efficacy testing using a phantom at 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 very few options for safe, effective blocking of fetal radiation dose [1][2], and most would agree that providing something for these pregnant patients would be beneficial. The team believes 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 may have initially shied away from it due to the potential damaging effects to the fetus. 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. As Dr. Labby indicated in the first client meeting, the design must not incur more of potential risk to the patient and fetus than the true risk of malformation, which is 0.5%, as discussed above. He has suggested that, in order to be worth any 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 patient and fetus.

While there are no explicit sources of error, the data analysis requires appropriate acknowledgment the limitations of the SolidWorks testing. Again, the surface area, while helpful in giving an indication of the coverage potential of the shield, does not perfectly represent the efficacy of shielding. Additionally, stress testing was conducted on the shield alone and does not include contributions from the support system, as a material for the support has not yet been chosen. These limitations exist, and further testing as described above will be required to corroborate and expand upon the initial findings.

Conclusions

One in 1500 pregnancies in the United States are complicated by cancer each year [1]. At present, there is no device that can protect developing fetuses from radiation therapy received by pregnant patients. Currently, these patients either pursue other forms of treatment or rely on hospital staff to modify the treatment plan to limit fetal dose, often achieved by positioning the fetus as far away from the head of the machine as possible. The team was tasked with designing a lead shield that can protect the developing fetus while keeping both patient and staff safe.

The team ultimately chose to pursue a shield shape dubbed the "High-Waisted Skirt," a shape initially suggested during a brainstorming session. The team decided to move away from the initially-chosen Helmet design due to complications of implementing a rotation mechanism, difficulty casting, and decreased opportunity for safety precautions. Advantages of the High-Waisted Skirt design over the Helmet design include significant coverage of the cranial half of the abdomen, even without rotation. As stated above, the raising and lowering mechanism, along with the up and outward flares allows for the shield to accommodate a wide variety of patients throughout their pregnancies, something the team initially thought only available via rotation. This design was not part of the original design matrix, but the decision to move forward with this design was made after researching fabrication costs of a more complex design. A simple design is more practical and cost effective. The team believes that this is the most practical design for its use and it will be the most cost effective.

Throughout the design process, there was much deliberation on what would be most effective. The team originally planned to use pure lead as it was thought to be cheapest and most effective material, and after more research was done, this was proven true. Cerrobend was the only other material that was considered but it was far too expensive for its benefits [11]. Another idea that the team explored was a rotating mechanism in addition to a vertical lifting component. This idea seemed ideal in theory and it would provide extra coverage for the patient. However, once the team began to research support designs, creating a support system that could safely support motion in multiple directions was deemed implausible. The design itself did not offer enough extra protection from radiation to justify the risk of falling or collapsing, so it was not worth pursuing.

The team spent most of the time this semester perfecting a design that was simple enough to manufacture, while also adhering to the design requirements presented by the client. As such, the support mechanism is still in the early stages of development because the main focus of the semester was the shield itself. Given the demands of each component, it was determined that this was the most effective use of time and resources. The preliminary support designs will need to be fine-tuned by subsequent design teams.

The team has been in contact with Swift Manufacturing and Engineering regarding fabrication of the lead shield. They are currently in the process of providing a quote for the estimated cost of the mold and material. The support mechanism, however, may need to be manufactured by a different company, as Swift is unsure whether or not they have the proper machinery to construct it. Extensive testing will be required to ensure that the apparatus can safely support the weight of the shield. The entire apparatus will need to be assembled and tested with the radiation equipment on a phantom before being integrated into University Hospital.

This apparatus could improve the treatment options available for pregnant patients across the state of Wisconsin. Currently, patients must choose between potential risks to their unborn child due to radiation exposure and the risk to themselves of delaying treatment. The ultimate goal of this project is to provide a safe alternative that mitigates these risks.

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Appendix

A. Problem Statement

Approximately 4000 women per year will require radiation therapy treatments during their pregnancies. Negative effects of ionizing radiation on the fetus are moderately understood; it is generally accepted that they are reduced with lower fetal dose. Appropriate shielding for standard radiation would include several hundred pounds of lead held safely over the fetus. The Department of Human Oncology is seeking a safe and effective shielding device for use in the Radiation Therapy department of University Hospital. 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.

B. Product Design Specifications

Client requirements

- Must shield the fetus from radiation leakage from the head of the instrument and scattered lower frequency photons
- Must not pose greater risk to mother or fetus than radiation itself

Design requirements

- Must be mobile enough to be moved between patient treatment rooms and storage
- Must shield fetus from 50% of incoming radiation
- Must be compatible with women of all sizes and varying stages of pregnancy
- Must be compatible with treatment room equipment, specifically the treatment table and linear accelerator
- Must be able to move vertically to accommodate varying heights of the table

1. Physical and Operational Characteristics
    a. *Performance requirements:* Aside from the shield blocking about 50% of the radiation, 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 fetal 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.
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 and thus cannot fully be anticipated. When not in use, the apparatus will be stored away.
e. *Shelf life:* This is intended to be a permanent fixture 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 a highly corrosion-resistant and dense material [1].
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 [3]. 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. However, the apparatus does not necessarily have to be connected to the table and it will not be connected to the table.
j. *Materials:* Lead or a lead-based composite 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.
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 [4].
    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 [3]. This is now forbidden in clinic due to safety concerns and no way to ensure support of the heavy, dense lead. 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 [2]. The company responsible for development went bankrupt and could not support further development.

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C. Client Correspondence

From: Zac Labby <zelabby@humonc.wisc.edu>
Sent: Thursday, September 21, 2017 1:12 PM
To: Maura McDonagh
CC: Edward T Bersu; Emily Knott; Julia Mauser; Julia Garofalo; Elizabeth A Schmida; Ethan S Wen
Subject: Re: BME 200/300: Fetal Radiation Shield

Hi Maura -

I just thought I’d throw out a comment on one of the line items I saw in the report, in case it can help you make progress in the interim before our next meeting. I see the line for “look into possible alternative materials to lead.” I thought I’d offer up that, from a radiation shielding perspective, common materials are, in order of density and usefulness: dirt, concrete, steel, lead, and tungsten. If you want to replace 5cm of lead with steel, you’ll need about 9-10cm of steel for the equivalent attenuation, and the required volume of steel will actually weigh more for the same attenuation. This is due to the lower average atomic number of steel, compared with lead. Going between tungsten and lead, you’d scale the thickness by the ratio of densities, so you’d only need about (11.35/19.3 = 59%) the thickness of tungsten for the same shielding, but that would work out to be the same weight. Lead is used commonly for this type of thing because it achieves a thinner shield than concrete, as cheaply and as lightly as possible.

Hopefully that's useful information!
Zac Labby

From: Zac Labby <zelabby@humonc.wisc.edu>
Sent: Friday, September 22, 2017 12:42 PM
To: Maura McDonagh
CC: Edward T Bersu; Emily Knott; Julia Mauser; Julia Garofalo; Elizabeth A Schmida; Ethan S Wen
Subject: Re: BME 200/300: Fetal Radiation Shield - PDS

Hi Maura -

Thanks for this! I think you've identified the major design specifications for this project. I especially appreciate that you've identified the necessity to clean the device to clinical standards. While the device will not require sterilization (and our treatment rooms definitely aren't sterile), it will need to be cleaned with common cleaning agents in clinical use ("cavi-wipes," etc.). You probably already were considering this too, but the device shouldn't have any lead that would make contact with the patient. Workers can always handle lead by hand, if necessary, using gloves, but we need to avoid even the remotest concerns re: fetal lead poisoning by making sure that exposed lead won't come in contact with the patient.

Thanks for this! Can't wait to see what you guys come up with!
Zac

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Work: (608) 263-5103
zelabby@humonc.wisc.edu

From: Zac Labby <zelabby@humonc.wisc.edu>
Sent: Friday, September 29, 2017 5:32 PM
To: Julia Mauser
Subject: project notes

Next Tuesday, October 3, the treatment machines finish around 6:15pm here on campus. That's probably the best we'll get that week. If you guys (1) have a car and (2) want to drive to our East Clinic location, we could access a machine at 4:30pm on Monday or 4:00pm on Tuesday instead of 6:15pm. If that doesn't work for you, no sweat.

In terms of low-melting-point alloys, the thickness ratios required for shielding are approximately equal to the ratio of densities. Cerrobend is 9.4 g/mL, so the thickness ratio is 11.35/9.4 = 1.21…a 5cm lead shield would be about 6cm of cerrobend, with an equal weight. (for materials of similar atomic number, equal weight per area will give equal shielding). This could really be a boon for the fabrication ease of the shield itself.

Cerrobend has the added toxicity of cadmium, so it really can't be handled in the "raw" state, or shouldn't, so it would need to be well-covered or encapsulated. http://www.bendalloy.co.uk/Cerrobend.pdf However, it seems more expensive than I realized: http://www.purityalloys.com/Low_Melting_Point_Alloys.html $12.50/lb is the cheapest I could quickly find. While lead would be harder to cast, it's way cheaper…even the pure stuff is $3/lb or less. If you buy a lot it's cheaper (https://www.rotometals.com/bullet-casting-alloys/ $1.39/lb or so) but then you'd have to identify how to cast.

I know we discussed that the shield itself may not be finished as part of this semester, but it would be cool to have a gameplan on how it would be finished, including gameplans for materials and fabrication.

Anyway, there's some thoughts. Have a good weekend, and let me know about next week.

Zac

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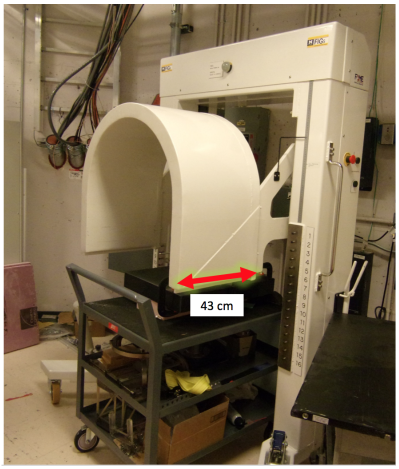
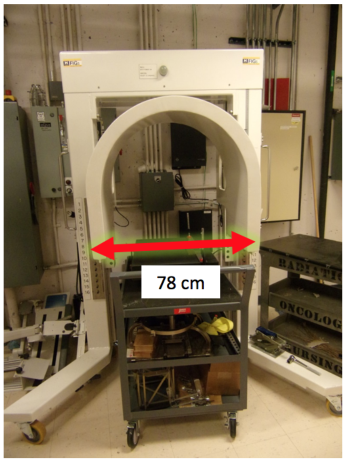
From: Zac Labby
Sent: Thursday, November 2, 2017 4:59:52 PM
To: Emily Knott
Cc: Julia Garofalo; Julia Mauser; ETHAN S WEN; Maura McDonagh; ELIZABETH A SCHMIDA
Subject: Re: BME 200/300: Fetal Radiation Shield

Here they are! These seem reasonable to me. The width, especially…you can't make it super wide or it will just be impractical. Like I mentioned before, most of our patients don't extend past the table itself. What was the table width you measured?
Zac





D. Radiation Shield Model Construction

The first stages of building the frame required two cardboard arches, 5 cm in width, matching the dimensions of the SolidWorks model. Chicken wire was then formed to follow the shape of the larger arch, and cut to extend no more than 43 cm outward. Garden stakes of 1 cm in diameter, which had been cut in half to also be 43 cm were woven through the chicken wire and attached to the larger of the two arches using hot glue and duct tape. After a moment to dry, the unattached side of the chicken wire was connected to the smaller arch by cutting four slits in the chicken wire between the garden stakes. The slits allowed the chicken wire to overlap and converge inward and attached smoothly to the cardboard. Two rectangular cardboard strips that were 5 cm x 43 cm were also attached to the ends of the arches, connecting them together.

The paper mache coverage of the frame was completed over the course of 3 days. On the first day, two layers of newspaper were added, using a 1:1 ratio of glue to water, the strips of newspaper were dipped in the mixture and then applied to the shield. It was agreed to only paper mache the outside of the shield in order to reduce the necessary drying time. Day two was allocated as a day for the layers to dry and harden. On the third day, another layer of newspaper was added followed by a layer of brown paper toweling to cover the newspaper's text. The brown paper toweling ensured that no text would be seen through the paint that was applied.

Once the shield had fully dried, a layer of grey spray paint was applied to both its interior and exterior. A day later an additional coat was applied to complete the process.