Fetal Radiation Shield

Limiting dosage of high-energy radiation to the developing fetus

Preliminary Report

Biomedical Engineering Design 200/300
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Abstract

One in every 1500 pregnancies in the United States are complicated by radiation therapy. Therapy of the affected patients must be adjusted in order to reduce the fetal radiation dose. Typically the angle of treatment is altered to accomplish this as there is currently no protocol to physically shield the fetus. The Department of Human Oncology at University Hospital has requested that a shield be designed that will block leakage from the head of the radiation machine as well as radiation scatter to the sides of the abdomen. Although several shield designs have been developed, they were discontinued due to safety and costs concerns. A shield that is 5-6 cm in width will be fabricated that is safe for the patient and medical personnel, mobile, and able to shield 50% of radiation leakage and scattering. In order to construct this device, a SolidWorks model and non-functional prototype will be created to evaluate the design before final fabrication will be completed, likely by a third-party source. Mechanical and clinical testing will also be necessary to evaluate the safety and effectiveness of the device.

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Introduction

Each 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 in radiology and oncology departments across the U.S., the majority are young women with brain or breast cancer [1]. In these cases, the primary goal of the developed treatment plan is to regulate the growth of the tumor while minimizing the amount of radiation absorbed by the fetus. Biological consequences of fetal absorption of over 0.05 joules of radiation energy per kilogram (0.05 Gray) include increased risks of malformation, mental and growth impairment, gene mutations, and childhood cancers [2][3]. While there are several radiation treatment precautions implemented to reduce fetal dose, these techniques can be further supplemented by using a fetal radiation shield.

Lead shields utilized through the 1990s included the bridge over patient and table over treatment couch apparatuses, both of which required the manual stacking of lead bricks or sheets over the patient [1]. Both of these designs have since been discontinued due to the safety risk they posed to the patient and medical personnel. An additional design that was also discontinued due to safety concerns involved placing a Cerrobend brick against the head of the treatment machine to block radiation leakage to the fetus [4]. After 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, 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 fetal radiation shields on the market or available in most hospitals. Thus, many radiology departments have opted to use no shield and position the treatment machine head as far from the patient as possible until a design that is safe, economical, and mobile is developed.

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 occurring during pregnancy include breast cancer, brain cancer, cervical cancer, lymphoma, and melanoma [3]. Most patients will not require radiation therapy during their pregnancy. However, in some cases, the risk of the cancer to the mother will outweigh the potential risk of radiation exposure to the fetus and decisions will need to be made about the treatment plan.

The risk of the child developing a malformation or possible cancer later in life is the main concern when treating these patients. Without a shield, this risk is already quite low at approximately 0.5% chance [6]. When considering these effects, the 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). The risk to the child is greatest during the first week, during which time radiation effects can be lethal. During the second period, the main risks to the fetus are growth retardation, malformation, or death [7]. Once the pregnancy is in the final period, the major concerns are increased risk of childhood cancer. The previous risks still play a factor at this stage, but they are less likely aside from microcephaly [3].

During the initial stages of research, the team was hoping to potentially use an alternative to lead due to its heavy weight. The most notable of the other materials researched was Cerrobend, a mixture of metals including lead which has been shown to be effective at blocking radiation [4]. The material that was ultimately decided on was lead, the reasoning for which is outlined in the Preliminary Design Evaluation section of the report.

The main sources of radiation that can interact with the fetus include photon leakage through the head of the machine, radiation scatter from the collimators, and radiation scattered within the patient from the treatment beams [3].

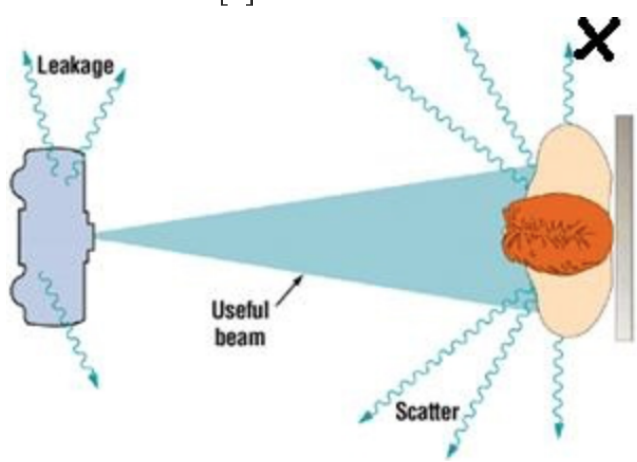


Figure 1: Radiation scatter explained [8]

There are a few equations used to measure the barriers needed for scatter and leakage of radiation throughout the patient's body. The equation used to find the barrier needed for scatter is modeled by:

$$B_s = \frac{P}{aWT} d_{sec}^2 d_{sca}^2 \frac{400}{F}$$

where a is the scatter fraction for the particular angle and incoming beam energy, d_{sec} is the distance of the scatter to the point of measurement, and d_{sca} is the distance from the scatter to the target, and F is the area of the beam [10]. The equation to model the barrier needed for leakage is:

$$B_l = \frac{1000 * P d_l^2}{WT}$$

where d_l is the distance from the target to the point of measurement. The factor of 1000 stems from the fact that regulations require the leakage radiation at 1 m not exceed 0.1% of the primary beam at isocenter [10]. The numbers obtained from these equations are then manipulated to give an equation for the barrier thickness:

$$T = -TVL * log_{10}(B)$$

where TVL is the tenth value layer for the material under consideration. For lead, since the density is high, the TVL is relatively low [9]. After the equations are worked out, the thickness required for lead is at minimum 5 cm. This is how the team acquired the necessary thickness ratio. The radiation that scatters throughout the patient is nearly impossible to stop so the device will focus on radiation scatter and leakage from the machine head (See Figure 2). 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.

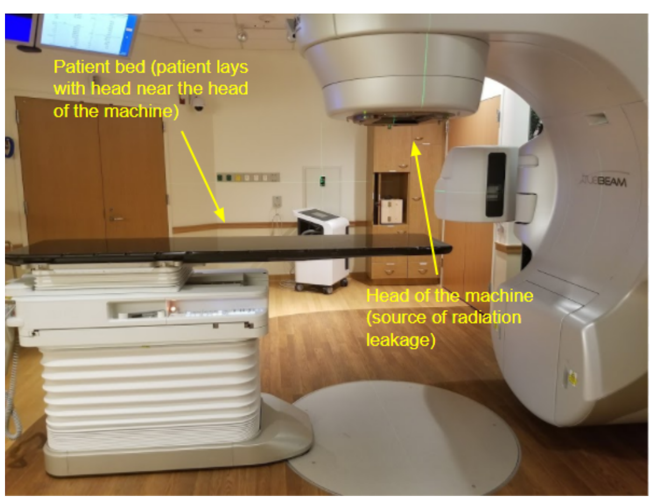
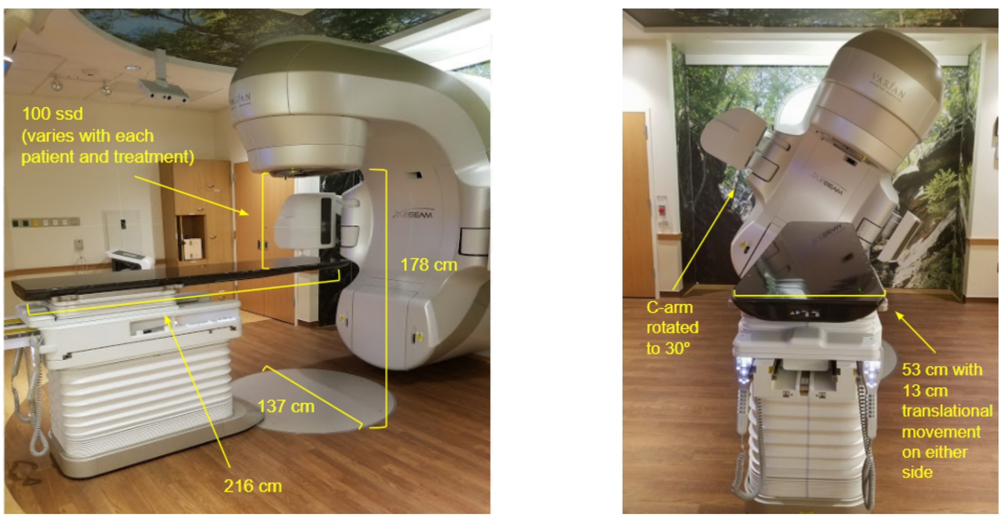


Figure 2: Diagram of the treatment room showing treatment directionality.

The client for this project is Dr. Zacariah Labby, a radiation physicist at UW 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. His 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 be stored and moved easily. The design must be compatible with the treatment room specifications (See Figures 3 and 4). 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.



Figures 3 & 4: University Hospital radiation therapy treatment suite.

Preliminary Designs

The team agreed to focus initially on the structure of the shield as this was paramount to the overall design. Secondly, the team determined an appropriate material. Lastly, design a support mechanism and establish 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 designed 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. This primarily involved the superior shield component.

Shield designs must be able to accommodate patients of all sizes and at various stages in their pregnancies. This will be pertinent in evaluating the dimensions of the design. Each shield will need to provide the same shielding as would 5 cm of lead.

Secondary design components will be added support and mobility of the shield. As mentioned previously, this shield must be adaptable to a variety of patient sizes and treatment regimens. Additionally, 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.

<u>Shield Design</u>

I. 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.

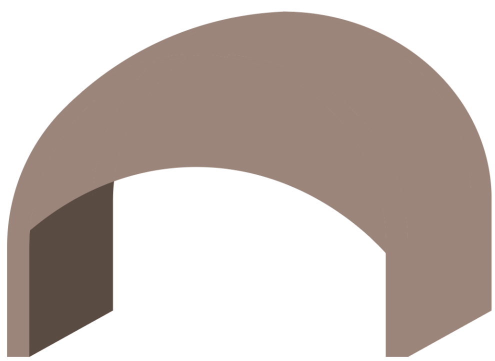


Figure 3: Modified U shape shield. Extruded on the superior side to extend coverage.

II. 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.

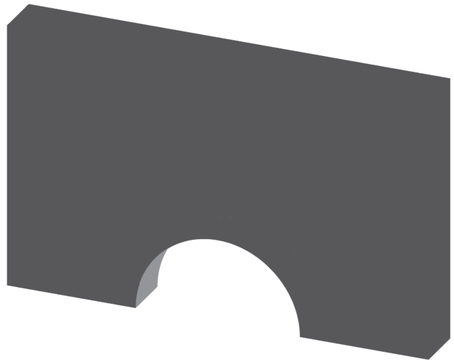


Figure 4: Wall shape shield. Tall to provide more blockage from the machine head.

III. 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 and mobility of this shield is vital to the ensurance of safety for this patient, specifically with the helmet design.

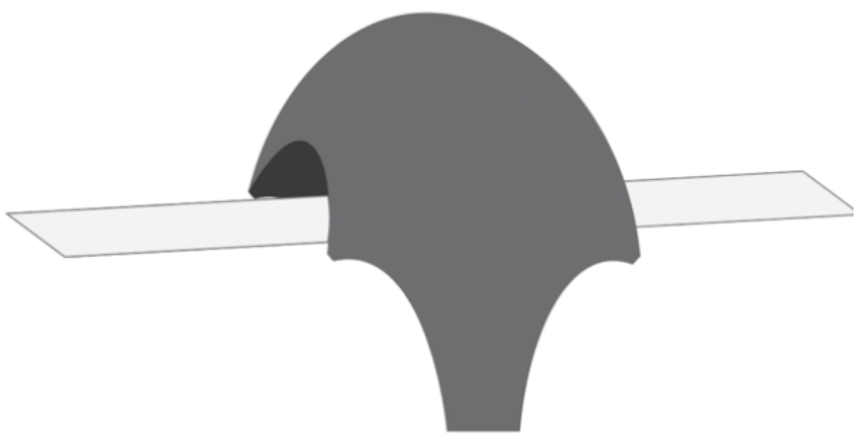


Figure 5: Helmet shape shield shown relative to the operating table.

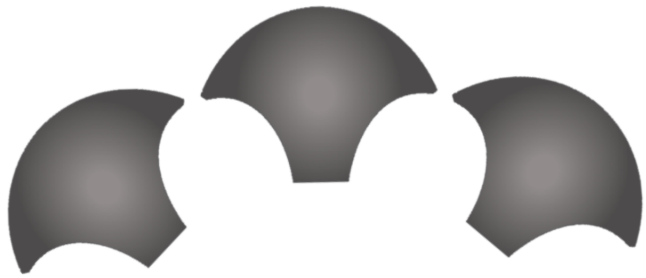


Figure 6: Pivoting motion of the helmet design from a profile view

<u>Materials/Specifications</u>

All shield designs must be able to accommodate all sized patients at various stages in their pregnancies. This will be pertinent in evaluating the dimensions of the design. Based on popular literature the average zone of coverage necessary is. Each shield will be 5-6 cm thick [10]. This is variable based on the material chosen. As mentioned above, collateral components of the design may be thinner if shielding is not vital, though some protection is necessary. Most important in our choice of material 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.

Lead:

Lead is the first proven material in stopping radiation and implemented in most radiation settings today. It stops radiation because of its high molecular density. 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. It is a metal composite 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 would be equivalent to the 5 cm of lead that we had calculated. Cerrobend would also be more expensive, near $12.50 per pound. Overall, Cerrobend would be desirable for its ease of fabrication, only more expensive than the lead alternative.

Support/Mobility

Support and mobility of this shield design is vital to implementing it in a clinical setting. 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.

Mobility is another component of this shield. It must be mobile to move between treatment rooms, so wheels were the obvious choice. These wheels must be able to support approximately 181 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 and then adjustable 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, of course, 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 400 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 client also desires for the shield 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, so cost was considered, mostly via ease of fabrication and anticipated volume of lead and thus 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 . Ultimately, the helmet design ranked highest overall in the design matrix due to its performance in the weight and efficacy categories and the fact that it was a close second for all other categories.

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. While this is not the whole cost and fabrication must also be considered, the team decided that cost of raw material would suffice as an estimate and thus ranked lead higher than Cerrobend in that category.

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

Mobility

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, as well as 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 with its swinging motion. The team is currently assessing the options for supporting a lead shield with a helmet shape.

Ultimately, the team decided to move forward with the helmet design and determine a support system for it that would be anchored to the ground.

Fabrication and Development

The next step in the development of the radiation shield is the design of the support system. This will involve materials, structure, and incorporation of mobility. In the fabrication of this elaborate and multi-component design, two aspects will be 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 is important to ensure efficacy before final fabrication. Using the two models this semester, the team hopes to understand the mechanics and dimensional components of the design through preliminary testing.

Development

Design Dimensions and Weight

Currently, the design ideas do not have dimensions or a calculated weight. The team can only estimate the dimensions and weight based on the measurements taken from the radiation suite at UW Health. Once more research is done and a working SolidWorks model is generated, the team will be able to derive more exact calculations of the dimensions and weight of the shield.

Support System Design

Now that the a shield shape and material have been chosen, the team must focus on designing the support system. The biggest concern is the tremendous weight of the shield itself. Current options for supporting the helmet include main supports at the pivot locations, as well as secondary supports that would be attached to the shield and rotate with it. 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. The rotation of the shield poses a significant challenge, specifically, ensuring that the shield rotates evenly on both sides of the support will be critical. The team is considering utilizing a double winch system to do so.

Fabrication

Solidworks Model of Shield

One of the two deliverables this semester is a Solidworks model, serving as a visual representation of the shield and structural apparatus. Through this model, materials and dimensions will be optimized. There will also be mechanical testing of internal and external forces on the shield.

Physical Prototype

For dimensional analysis, a physical model will also be constructed. This will be a low cost model in order to test dimensions, rotation, and position of the shield for treatment. Importantly, this model will give the team spatial understanding of the shield shape. In order to construct this, a base form will hold layers of paper and glue, in the desired helmet shield shape.

Final Fabrication Plan

At the request of the client, the team will put a tentative fabrication plan into place. This will involve the exact materials and items necessary for future fabrication of the entire design, from the Solidworks model. The fabrication plan will serve as a guide to future design teams to put into motion the work that was done this semester.

Testing

Solidworks

The SolidWorks model of the design will undergo mechanical testing within the software to determine the mechanical properties of the design, specifically where the supports could potentially fail based on the internal and external forces. From this testing further customization of the support mechanisms will be completed in order to optimize the safety of the design.

Physical Prototype

The physical prototype will be tested in a treatment room, where the size and shape will be assessed. Though only qualitative, interference with the radiation machine, mobility with couch rotation, and overall coherence with the radiation therapy will be noted. During this testing, optimization of the support structure will also be assessed with the positioning in relation to the floor cover.

Final Device Testing

In a future semester, it will be necessary to test the efficacy of the final product/lead device. To do this, the Department of Human Oncology has a model 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 7: Model used to simulate patient undergoing radiation therapy.

Conclusions

Pregnant patients undergoing radiation therapy are faced with concerns of fetal radiation and negatively associated effects. Two sources of fetal radiation are leakage from the head of the C-arm machine and scattering of photons. Currently, minimal solutions exist for these purposes, primarily just altering treatment regimens to try and avoid stray radiation in the fetal area. To remedy this issue, the design team is developing a radiation shield to physically block radiation from reaching the fetus. This will shield the fetus during therapy and reduce the fetal dose by 50%. The team chose a helmet shaped lead shield supported by a metal frame. The frame support system will include locking wheels, hydraulics, and a pivoting mechanism to provide the whole device more dexterity. This project will require more than a semester to complete, but current goals include a CAD model, physical structural model, and detailed fabrication plan. This semester, the team will optimize a design to tackle the unmet need for a pregnant patients undergoing radiation therapy.

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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.
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.

PDS References

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[2] A. M. Owrangi, D. A. Roberts, E. L. Covington, J. A. Hayman, K. M. Masi, C. Lee, J. M. Moran, and J. I. Prisciandaro, “Revisiting fetal dose during radiation therapy: evaluating treatment techniques and a custom shield,” *Journal of Applied Clinical Medical Physics*, vol. 17, no. 5, Oct. 2016.

[3]M. Stovall, C. Blackwell, J. Cundiff, D. Novack, J. Palta, L. Wagner, E. Webster and R. Shalek, "Fetal dose from radiotherapy with photon beams: Report of AAPM Radiation Therapy Committee Task Group No. 36", *Medical Physics*, vol. 22, no. 1, pp. 63-82, 1995.

[4] "Overview of Device Regulation," in *U.S. Food & Drug Administration*, U.S. Department of Health and Human Services, 2015. [Online]. Available: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/.

C: Client Emails

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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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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