.decimal Proton Therapy Device Manager

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Contents

Table of Figures

Table of Tables

Abstract

.decimal has tasked this senior design team with developing a robotic system to load apertures into the Mevion S250 proton therapy machine. Currently, this process is carried out by a technician; extending treatment times unnecessarily due to the time consuming nature of the process. The proposed design utilizes a platform mechanism which docks up against the nozzle of the Mevion S250 to load and unload the apertures. A linear rail system controls the motion of the system to allow for indexing of the apertures within the nozzle. An Arduino Mega will be used to control the entire system and the user will be able to operate the system remotely. .decimal is pleased with the team's design and excited to see the project's development. Assembly of the system is expected to occur early in the spring semester, leaving ample time for troubleshooting.

1 Introduction

Proton therapy is currently being used as a cancer treatment when traditional radiation methods would cause too much damage. Proton therapy relies on a large cyclotron to accelerate protons to a desired speed, a 'snout' then directs those protons towards the patient's tumor. However, this beam of protons still has the potential to radiate a large region surrounding the tumor. To remedy this, .decimal manufactures brass apertures to focus and shape the proton beam in three dimensions. The current setup relies on a nurse to navigate through a maze of radiation shielding walls and exchange the final brass aperture which shapes the proton beam’s cross section. These pieces weigh around 30 lbs and need to be changed five times per patient, for each position of the snout. This process increases strain on the technician and the patient as treatment time is delayed; as a result, the chance of patient movement increases which greatly affects the accuracy and effectiveness of the treatment. The goal for .decimal, and this senior design team, is to reduce treatment time and improve the accuracy of proton therapy treatment by creating an automated system to load and unload the apertures in the snout of the cyclotron.

2 Project Definition

2.1 Background

Proton therapy is a form of radiation treatment that allows physicians to precisely deliver a high dose of radiation to target specific tumors. If enough radiation is delivered to the tumor, all the cancer cells will die, inhibiting their ability to heal and propagate. Proton therapy can deliver higher doses of radiation with far more accuracy and controls cancer with fewer treatments than conventional photon treatment (x-ray). As a result, patients experience a higher post-treatment quality of life as compared to conventional methods. Currently there are 14 proton therapy centers operating in the U.S. and 12 more in development (http://proton-therapy.org/dotmed_progress_sept_2014.html).[2] Of the 12 centers in development, 6 will be equipped with proton therapy systems developed by Mevion Medical Systems, Inc. Mevion Medical Systems, Inc. is a Massachusetts based radiation therapy company. They are the developer and manufacturer of their flagship product, the Mevion S250 Proton Therapy System. The Mevion S250 is the world's smallest single room proton therapy system, Figure 1. The Mevion S250 Proton Therapy System is USFDA 510(k) cleared and complies withMDD/CE requirements. With a price tag of $25M, the device is one quarter the cost of previously available systems. The system is built around the world's first superconducting synchrocyclotron accelerator, allowing the device to deliver 250 MeV high energy protons to localized tumors while sparing surrounding healthy tissues. This precise form of radiation is due to custom machined brass apertures that snugly fit on the nozzle of the S250. The apertures are designed to guide the radiation to affected area while blocking radiation from hitting healthy tissue.

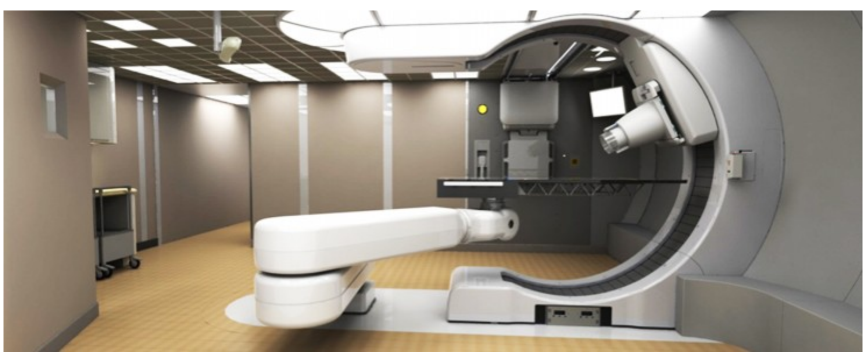

Figure 1 The Mevion S250 Proton Therapy System

Dot Decimal, a Florida based radiation therapy company, is the manufacturer of these patient specific apertures. The brass aperture cutouts are designed according to the Treatment Plan parameters designated by hospital personnel and then transmitted to Dot Decimal machining centers for custom manufacture and delivery back to the hospital (http://www.accessdata.fda.gov/cdrh_docs/pdf12/K123893.pdf).[3] Each aperture can weigh up to 30 lbs. due to the high lead content in the brass. Currently, technicians are manually lifting, inserting, and removing these heavy apertures into the correct position on the beam's nozzle. The process is physically strenuous and, more importantly, time consuming. More patients can be treated each year if this time consuming process can be eliminated from each therapy session.

Additionally, speeding up the process will be a selling point for proton therapy treatments. All companies involved with proton radiation therapy will make more money if the technology is easier to sell.

2.2 Need Statement

The sponsor for this project is Dot Decimal. Dot Decimal is a medical device manufacturing company in North Orlando. They manufacture patient specific devices for various types of cancer treatments including proton, photon, and electron beam treatment. The need that they have expressed to the senior design team has been that the apertures, or patient specific devices, take too long to load into a Mevion S250 Proton Therapy System. For the technician to come into the room, the machine must be off and then they have to navigate through a long hallway before getting to the treatment room. Also the apertures can be up to 25 pounds and the technicians have complained about having to lift the heavy apertures repeatedly throughout the therapy session.

It takes too long and too much effort for a technician to load and unload apertures during a patient's treatment.

2.3 Goal Statement & Objectives

Goal Statement: Provide proof of concept by developing a functioning 1:4 scaled model of an automation device that will load and unload Dot Decimal's apertures and range compensator into the snout of the Mevion S250.

Objectives:

- Decrease the time a patient is in the treatment room
- Eliminate manual process for technician

2.4 Constraints

- Automation device must lift up to 25 lbs.
- Automation device must not interfere with proton beam or the patient couch
- Automation device must scan apertures to identify patient specific aperture
- Automation device must be installed in the same room as the Mevion S250
- Automation device must load apertures and range compensator
- Automation device must unload apertures and range compensator

3 Project Management

The team has created a few initial prototypes and is now in the process of finalizing the details of the design and then plans to begin purchasing and assembling the final pieces, as well as programming the system to run autonomously.

3.1 Risk Analysis and Reliability

3.1.1 Human Risk

The most important aspect of any project is ensuring human safety. Due to the nature of proton therapy treatments with the Mevion S250, the potential for harmful accidents is present. The heavy brass apertures can be directly positioned above the patients during treatment, and if the aperture is not locked in place it has the potential to fall on the patient. Additionally, during the loading/unloading process and indexing, the aperture will be moved around and must avoid the patient. If the gripper were to fail to secure the aperture during movement or loading/unloading, the aperture could fall and seriously injure the patient.

Risk also comes into play during the construction of the prototypes. The team must be careful when machining any necessary parts and when using the tools to complete the assembly. Also when the system is built, it will be lifting heaving objects, rotating and moving vertically. These motions could lead to a pinching/crushing injury if a human is in the way of the system.

3.1.2 System Risk

This device must be integrated with the Mevion S250 system, a $60 million setup. The device will interface with the Mevion S250 and has the potential to damage it. Additionally, the device cannot come in contact with the machine, other than at the nozzle. The proton therapy machine gives off high levels of radiation so the device manager could be damaged by these particles, thus making it unusable. The machine that controls the couch that the patient lays on takes about a week to calibrate, and the system itself takes up to two months to calibrate. If the device manager jeopardized this, the customer would be very displeased.

3.1.3 Environmental Effects and Safety Concerns

This project does not really effect the environment, as it is a robotic system located within a hospital. It does consume energy though, and so the team plans to design a system with a low power requirement, but the team also realizes that lifting the heavy apertures requires a relatively large amount of power.

When it comes to safety of the design team, considerations for electrical components and sharp points will need to be handled with precaution during the assembly phase. Also the team must be cognizant of the patient's safety. Where this is relevant is when the apertures are being loaded and it needs to be ensured that the correct aperture is being loaded for the right treatment session, and then the system also needs to be strong enough to carry the aperture and make sure it does not drop it on the patient.

3.2 Schedule and Work Breakdown

We have built our initial cardboard prototypes and have now settled upon a final design. This will allow the team to utilize the spring semester to refine the design and take the necessary measures to correct the design to make it the best it can be. Our schedule can be seen in the Gantt Chart in Figure 1. The work breakdown structure is in Table 2. The team is aware that we are slightly behind schedule when it comes to our previously planned Gantt chart. When the team meets over the holiday break and at the beginning of the spring semester, we will create an updated version that will account for more future plans. The team will be referring to our defined roles when delegating who will do the tasks. Since the team is small, most aspects will be completed together.

Table 1 Work Breakdown Structure for Fall 2015

Task Name	Duration	Start	Finish
Brainstorming	**12 days**	**Sun 9/20/15**	**Sat 10/3/15**
Create many ideas	6 days	Sun 9/20/15	Fri 9/25/15
Narrow it down to 3	0 days	Fri 9/25/15	Fri 9/25/15
Select Initial idea to begin designing	2 days	Mon 9/28/15	Tue 9/29/15
Initial Prototype	**11 days**	**Wed 9/30/15**	**Wed 10/14/15**
Buy cheap supplies	3 days	Wed 9/30/15	Fri 10/2/15
Build very basic and cheap prototype	3 days	Mon 10/5/15	Wed 10/7/15
Evaluate if chosen design is a good concept	3 days	Thu 10/8/15	Mon 10/12/15
Design 2nd Prototype	**6 days**	**Thu 10/15/15**	**Thu 10/22/15**
Create CAD Files	3 days	Thu 10/15/15	Mon 10/19/15
Reasearch Parts for purchase	3 days	Tue 10/20/15	Thu 10/22/15
Build 2nd prototype	**29 days**	**Thu 10/22/15**	**Tue 12/1/15**
Order parts needed	4 days	Thu 10/22/15	Tue 10/27/15
Create Software to operate device manager	16 days	Mon 10/26/15	Mon 11/16/15
Assembly Prototype as parts are delivered	20 days	Mon 11/2/15	Fri 11/27/15
Evaluate quality of design and prototype	3 days	Fri 11/27/15	Tue 12/1/15

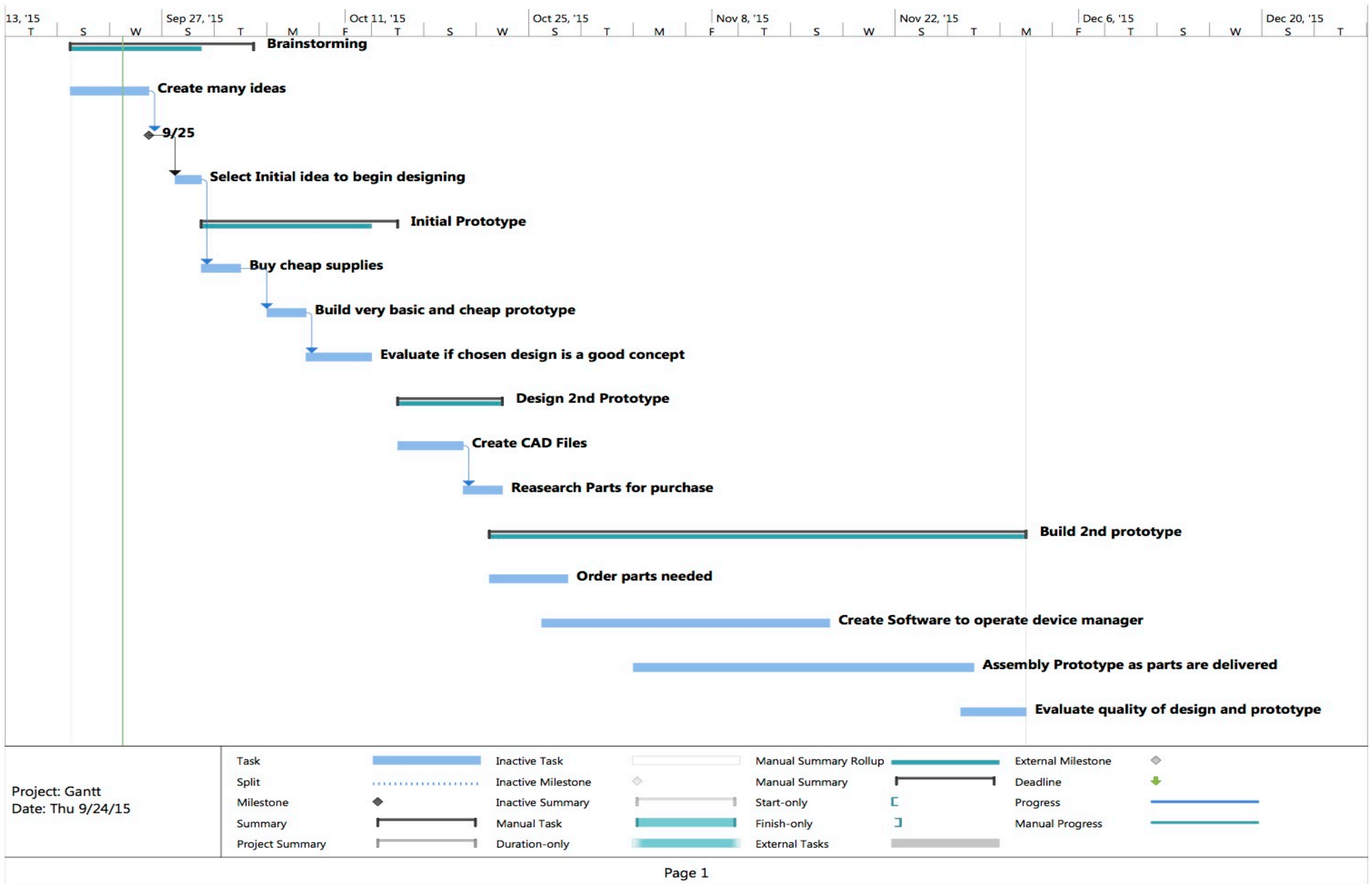

Figure 2 Gantt Chart for Fall 2015

3.3 Product Specifications

3.3.1 Design Specifications

The design must be fully automated and fit inside the proton therapy room. It must not interfere with the 6 degree of freedom robotic couch, which positions the patient for treatment. The automation device must not interfere with the movement of the electron therapy system's nozzle. The device must repeatedly and reliably be able to identify, pick up, and load an aperture. The design must incorporate a device that releases a spring-loaded safety latch. The purpose of this is to enable the aperture to be unloaded from the nozzle of the Mevion S250. Preliminary discussion with Dot Decimal has established that a secondary device can be designed to perform this operation. An integrated safety system for identifying the order of each aperture should be created. The system must return to its original position after a full cycle of loading and unloading has occurred. After unloading, the cycle must repeat. . A life cycle will need to be developed to ensure a re-design is in line with the latest market requirements of the Mevion S250. Design for manufacturability must be considered. One Mevion S250 Proton Therapy System is clinically active and 6 are under installation and architectural planning in the United States.

3.3.2 Performance Specifications

The system must perform the loading and unloading process faster than a human technician. The goal for operation time of one complete cycle (unloading and loading) is under one minute. Patient safety is of utmost importance. The apertures must be rigidly secured to the automation device during loading and unloading. The system should be able to lift up to 25 lbs. The device's deflection under load must be minimized and accounted for to ensure the aperture is able to be secured in the nozzle. Failure mode analysis must be performed on all components of the system in order to identify any safety concerns. Safety factors should be considered to ensure failure does not occur during operation. Additionally, the automation device must be manufactured from materials that are anticorrosive. Additionally, the cycle progress and state will be continuously monitored and outputted to the technician. Data transmission will be wired and should not affect the room.

4 Design and Analysis

4.1 Design Concept

Team 14 is required by Dot Decimal to create an automated system that can load and unload 4 different proton therapy products: 25 cm aperture, 25 cm range compensator, 18 cm aperture, and 18 cm range compensator. The 25 cm aperture can weigh up to 16 kg. The design must accommodate for the varying thicknesses of each product. The final system will be installed in the hospital's therapy room. Therefore, it must not interfere with Mevion's current proton therapy system. An ideal system will take less than 20 minutes to load and unload all products during one patient's proton therapy session.

Figure 3 depicts the current design for the automation device. The machine is composed of two main systems: a loading system and guiding system. The loading system contains 3 key parts: platform, loading arm, and a tool. The guiding system contains two linear rails systems: y-direction linear rail and z-direction linear rail.

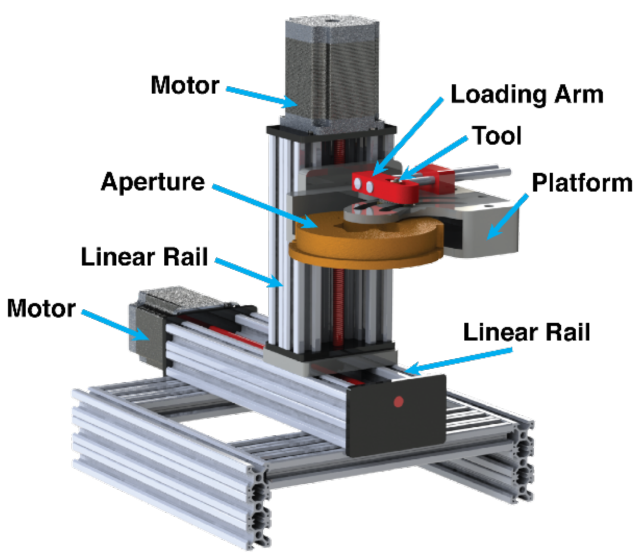

Figure 3 Current design for the proton therapy device manager.

Team 14 has modified the design of Dot Decimal's aperture design by adding two alignment notches to the top surface of the aperture, Figure 4.

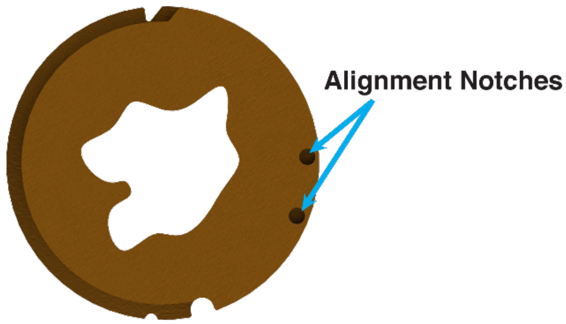

Figure 4 Team 14’s design for a 25 cm brass aperture with alignment notches.

The tool, Figure 5, contains two cylindrical stems that will be inserted 5 mm into the alignment notches on the surface of the aperture, as seen in Figure 6. A platform will support the bottom of the aperture. A motor will activate the y-direction linear rail system in order to dock the platform next to the applicator. The loading system utilizes a functional slot mechanism located on the top of the platform that guides the tool, Figure 7.

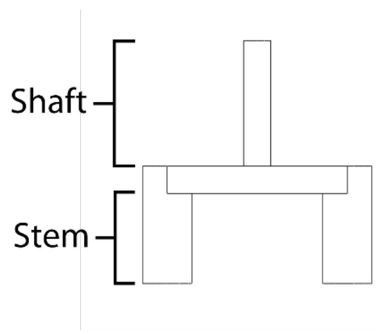

Figure 5 Illustration of the proton therapy tool.

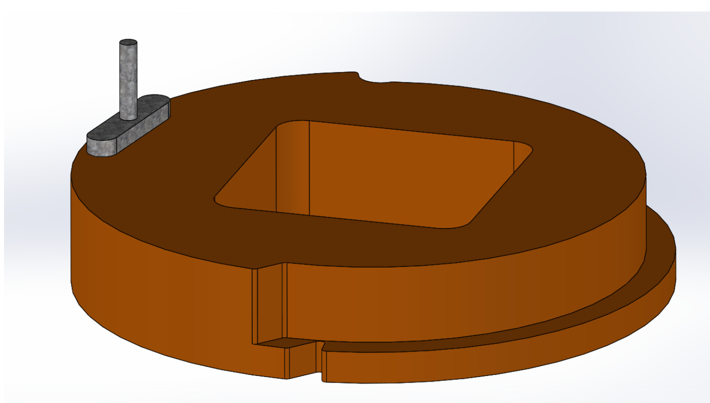

Figure 6 Assembly depicting the tool loaded into the brass aperture.

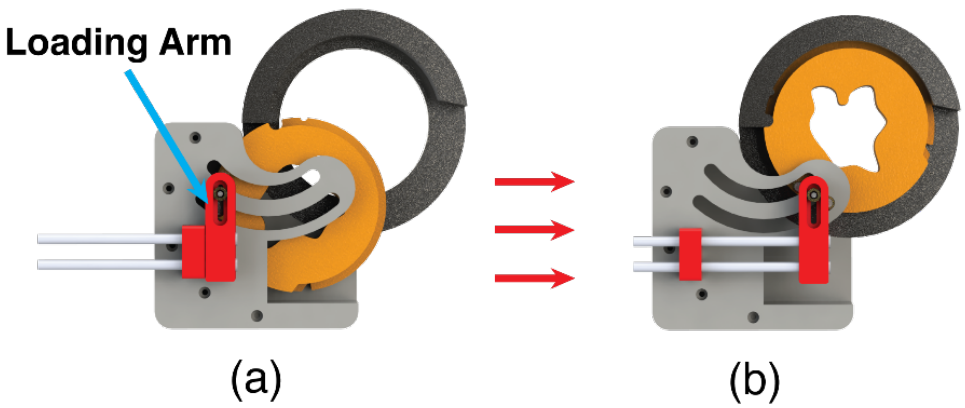

Figure 7 Loading procedure for a 25 cm brass aperture.

The tool will ensure the aperture is precisely loaded into the applicator as seen in Figure 8. Up to 4 apertures per treatment will be loaded into this applicator. The 15 mm tool shaft will be subjected to transverse loading throughout its lifetime, making it a point of failure for the automation system, as seen in Figure 9. Additionally, the platform will be subjected to bending forces due to the weight of the aperture. The tool and platform were analyzed using the finite element method and can be seen below.

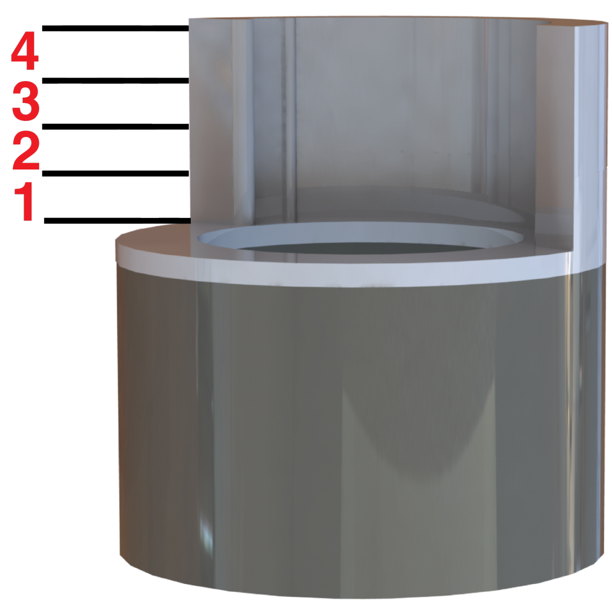

Figure 8 Mevion S250 Snout

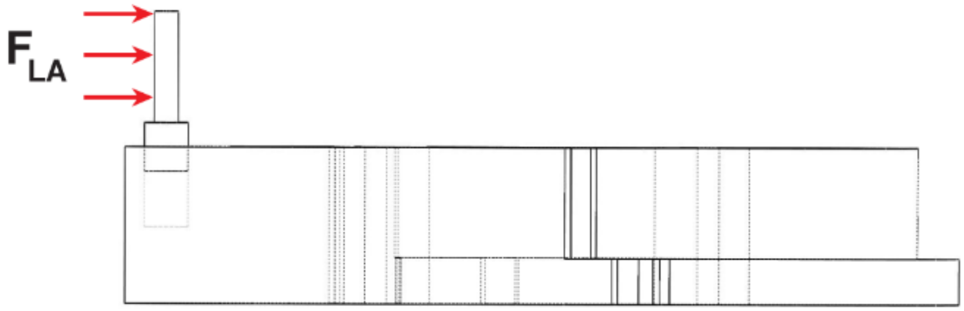

Figure 9 Force of the loading arm acting on the shaft of the tool.

4.2 System Control

The full system will consist of two linear rail systems actuated by two NEMA 23 stepper motors, two smaller steppers on the platform controlling the loading and loading security of the apertures, one stepper controlling the rotation of the mechanism, and one camera for barcode scanning. These five motors will be controlled by an Arduino Mega 2560 and three separate motor drivers. A 12 – 24 V power supply will be used to power the system.

The Mega will programmed to allow full automation upon remote user control. The user will select the desired aperture and the system will scan the apertures to ensure the correct one is loaded. The loading/unloading penis will be fully stroked and completely automated.

4.3 Finite Element Analysis of the Tool

When the motor is activated the loading arm that will exert a uniformly distributed load on the tool shaft when as the aperture is guided into the applicator. The force must be large enough to move the 16 kg aperture from the resting position. A free body diagram was made to determine the force of the loading arm F_{LA} acting on the aperture, Figure 10. A force of 160 N is needed to overcome the force of static friction F_{fr}.

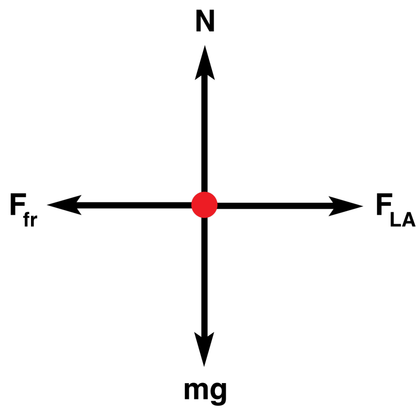

Figure 10 Free body diagram of the forces acting on the aperture.

The load exerted on the tool will be uniformly distributed, in the transverse direction, over a 10 mm section of the tool. The thickness of the loading arm will determine how the load is distributed over the surface of the tool. The system can be modeled as a cantilever beam, as seen in Figure 11.

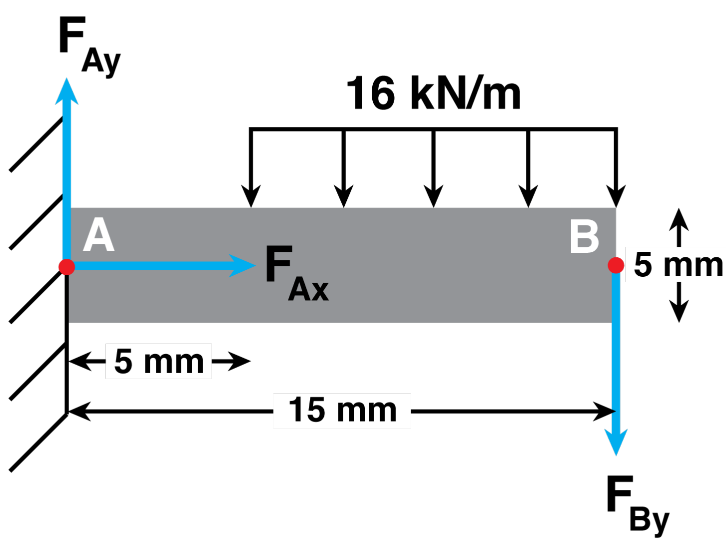

Figure 11 Free body diagram of the tool shaft modeled as a cantilever beam.

The tool must be designed to withstand the maximum stresses induced by loads, which the, requires determination of the maximum shear *V*. The governing equation for shear stress is defined as

$$\tau = \frac{F_{Ay}}{A_c} \tag{1}$$

where A_c is the cross-sectional area of the tool shaft and F_{Ay} is the shear force acting in the y-direction at point A, as seen in Figure 8. A maximum shear stress of approximately 13.6 MPa is exerted at point A. The yield strength for AISI 4130 steel is 435 MPa and Young's modulus is 205 GPA (ASM.com).

The deflection of the tool shaft must be limited in order to provide stability and integrity of the loading mechanism. To secure the aperture safely, the tool must not deflect severely. The maximum displacement will occur at point B, when x=0. The governing equation for maximum displacement *v* is defined as (Hibbeler, 2014)

$$v = -\frac{F_{By}L^3}{3EI} \tag{2}$$

where *L* is the length of the beam, *E* is the elastic modulus for the material, and *I* is the moment of inertia about the neutral axis. The moment of inertial about the neutral axis for a thin rod is defined as

$$I = \frac{mr^2}{2} \tag{3}$$

where *m* is the mass of the rod, and *r* is the radius. The maximum deflection for the tool shaft is 1.22×10^{-7} m in the negative y-direction.

A finite element model was created in order to verify the theoretical model. It is assumed that the system can be modeled using the Euler-Bernoulli beam theory. The thickness of the rod is relatively small compared to the overall length. There are no loading forces about the neutral axis, and the body of the rod does not vary in thickness. The rod is made of a linearly elastic material, steel. Solutions were created with this model using two nodes over one element as 160 N is applied as a concentrated point load at node 2.

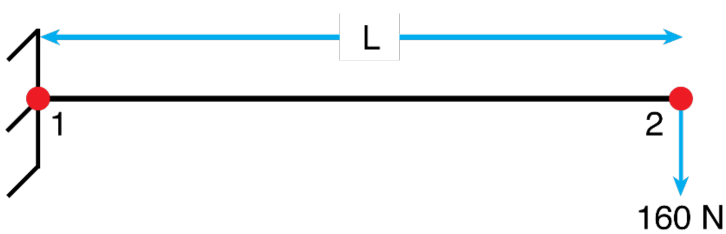

Figure 12 Beam modeled as one element in Abaqus.

In this theory, bending moment M and transverse deflection w in a beam are related by

$$-EI\frac{d^2w}{dx^2} = M(x) \tag{4}$$

where *M(x)* is a known function of *x* (Reddy, 2006). The maximum deflection can be determined by using the finite element model. The FEM is given by

$$[K^e]\{w^e\} = \{f^e\} + \{Q^e\} \tag{5}$$

Abaqus approximated the maximum displacement at node 2 to be 0.0022 mm, Figure 12. The displacement for the theoretical model was 0.0001 mm. A uniformly distributed load was analyzed in the theoretical model, and a concentrated point load was modeled in the FEM model and approximated in Abaqus. Analysis for the different type loads may have resulted in the variance in displacement. The displacement for the theoretical model and the finite element model was extremely small, as seen in Figure 13. The 5mm diameter steel tool shaft will remain rigid enough to safely and securely guide the aperture into the applicator. Further analysis of the system would include lifecycle calculations to determine when the tool will require maintenance or replacement.

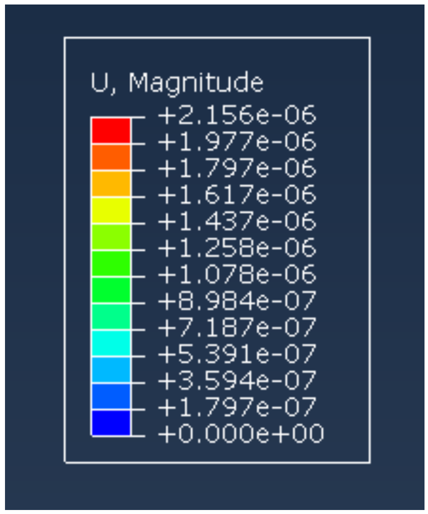

Figure 13 Maximum deflection for 1 element model

4.4 Finite Element Analysis of the Platform

Dot decimal has tasked our senior design team with designing a loading/unloading mechanism for brass apertures used in proton therapy treatments. The solution that our team has designed involves the use of a platform to support the large mass of these brass apertures as they are being exchanged from the machine. Preliminary modeling uses a critical cross-section of this platform to model bending, as seen in Figure 14. The dimensions are explained in Table 2. The material properties of A36 Steel, which is the material being used in this model, is given in Table 3. This cross-section is taken where the platform supports the aperture at the greatest distance from its anchoring point, where the largest moment will occur.

Modeling of this system is done using Euler-Bernoulli beam theory where vertical displacement is a function of horizontal displacement over the platform's length, given by equation 1.

$$\frac{d^2}{dx^2}\left(EI\frac{d^2w}{dx^2}\right) = q(x) \qquad \text{for } 0 < x < L \qquad (6)$$

Where E is elastic modulus, I is the moment of inertia, w is displacement, and q is the distributed load along the section. Steel is chosen as the material for preliminary modeling.

The supporting wall is the location where the platform will be fixed to the rest of the system, thus it is given a constraint of zero displacement. The load, q, is 0 from 0 < x < 1cm. The load from 1 cm < x < L is taken to be the weight of the plate equally distributed along the beam's length. The end of the beam is left free.

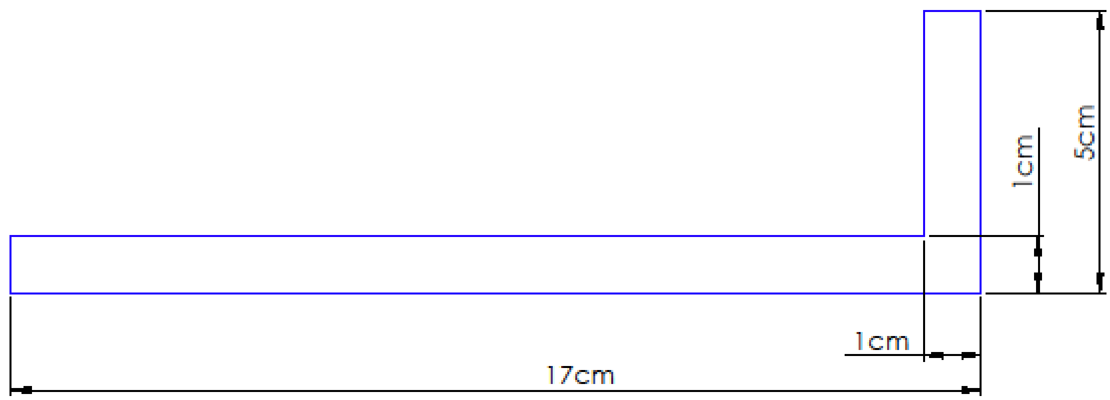

Figure 14. Critical cross-section of platform

Table 2. Device Dimensions

Aperture	Mass	15 kg
Platform	Length	17 cm
	Thickness	1 cm
	Wall length	1 cm
	Wall height	5 cm
	Support area	164.5 cm^2

Table 3. Material Properties of A36 Steel

Density	7850 kg/m^3
Elastic Modulus	200e9 Pa
Poisson's Ratio	0.33

For ease of calculation and validation, the critical cross-section used for this analysis will be given a thickness and width of 1 cm. Additionally, the curve of the wall will be assumed to be linear to simplify the problem even further.

The deflection at the end of the platform can be easily calculated using theory. To further simplify the calculations, both sides of the wall are assumed to have a deflection of 0 cm. With this, the deflection at the end of the platform can be modeled by.

$$\delta = \frac{Fl^3}{8EI} \tag{7}$$

Where F is the load acting on cross-sectioned platform of width = 1cm, l is the length of the platform's base, E is the elastic modulus, and I is the section moment of inertia given by

$$I = \frac{wh^3}{12} \tag{8}$$

Assuming that the weight of the plate is evenly distributed across the platform's area, the force, F, acting on the modeled section is calculated by multiplying the aperture's weight by the fraction of area the model occupies on the entire platform. It follows that

$$F = (15kg)\left(9.81\ \frac{m}{s^2}\right)\left(\frac{(16cm)(1cm)}{164.5\ cm^2}\right) = 14.31\ N \tag{9}$$

$$I = \frac{(1cm)(1cm)^3}{12} = 0.0833\ cm^4 \tag{10}$$

$$\delta = \frac{(14.31\ N)(16\ cm)^3}{8(200e9\ Pa)(0.0833\ cm^4)} = 4.4e-3\ cm \tag{11}$$

In order to more accurately model this system, the platform's entire geometry was looked at in 3 dimensions. The assumption was made that the weight of the aperture was distributed equally along the platform's surface as a total force. This is not what actually happens in due to the aperture only being supported along a portion of its surface; however, the approximation is sufficient for this analysis. Additionally, the platform is fixed at its mounting surface along the back wall of the aperture. The mounting surface can be seen at the far end of the x-axis contacting the y-z plane's grid in Figure 15.

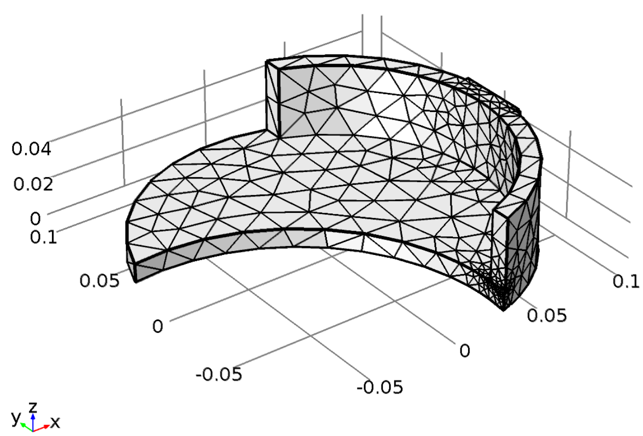

Figure 15 Platform Model Mesh

The developed stresses in the platform are shown in figure xx. Due to the platform's design, largest stresses occur on the mounting side of the device (seen contacting the y-z grid in figure xx) where the mounting surface meets with the platform's wall. This is expected as the geometry in this area hinders bending, forcing the area to support the load under minimum strain. These max stresses are under 10 MPa, well below the steel's yield strength of 250 MPa.

Maximum displacement of this device is 3.03e-3 cm occurring at the smallest x value. This solution is 31% smaller than the theoretical solution. This is due to the geometry of the platform, which includes the curved wall, developing larger stresses and hindering platform bending.

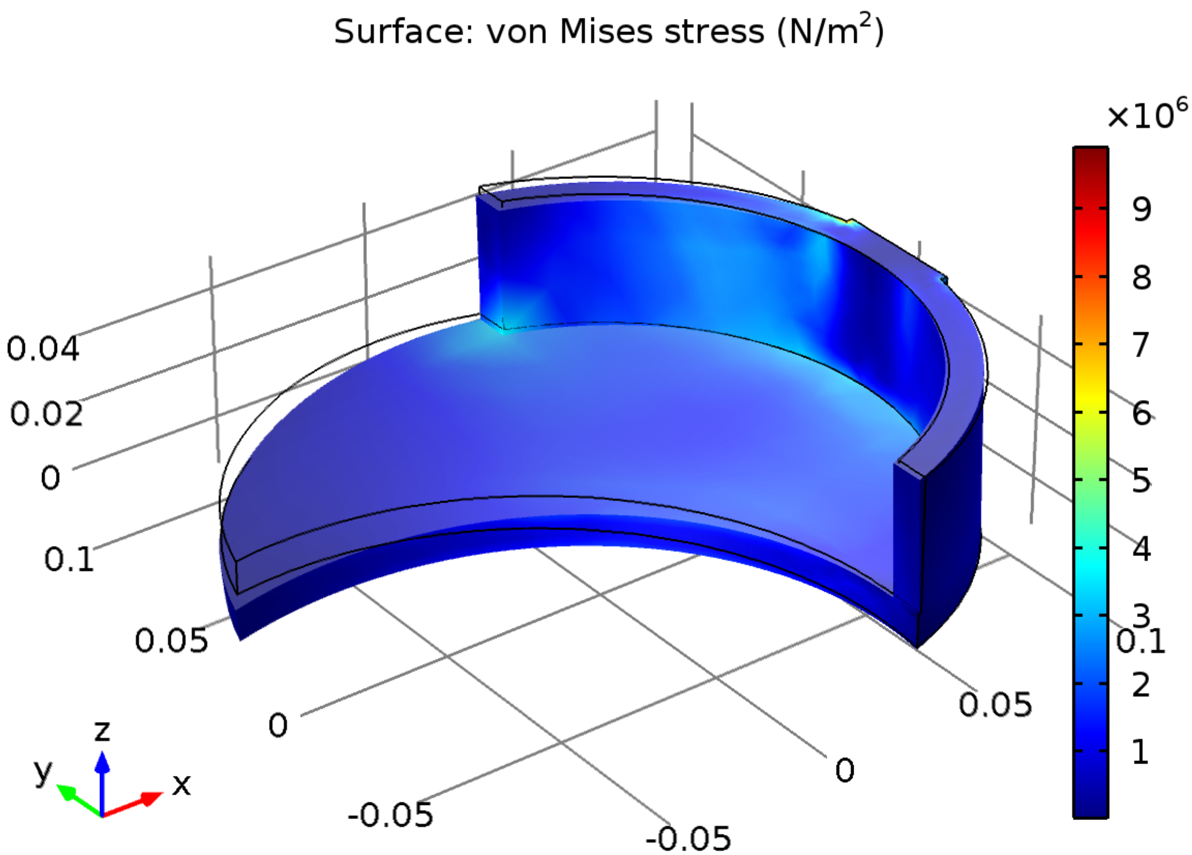

Figure 16. Von Mises Stresses

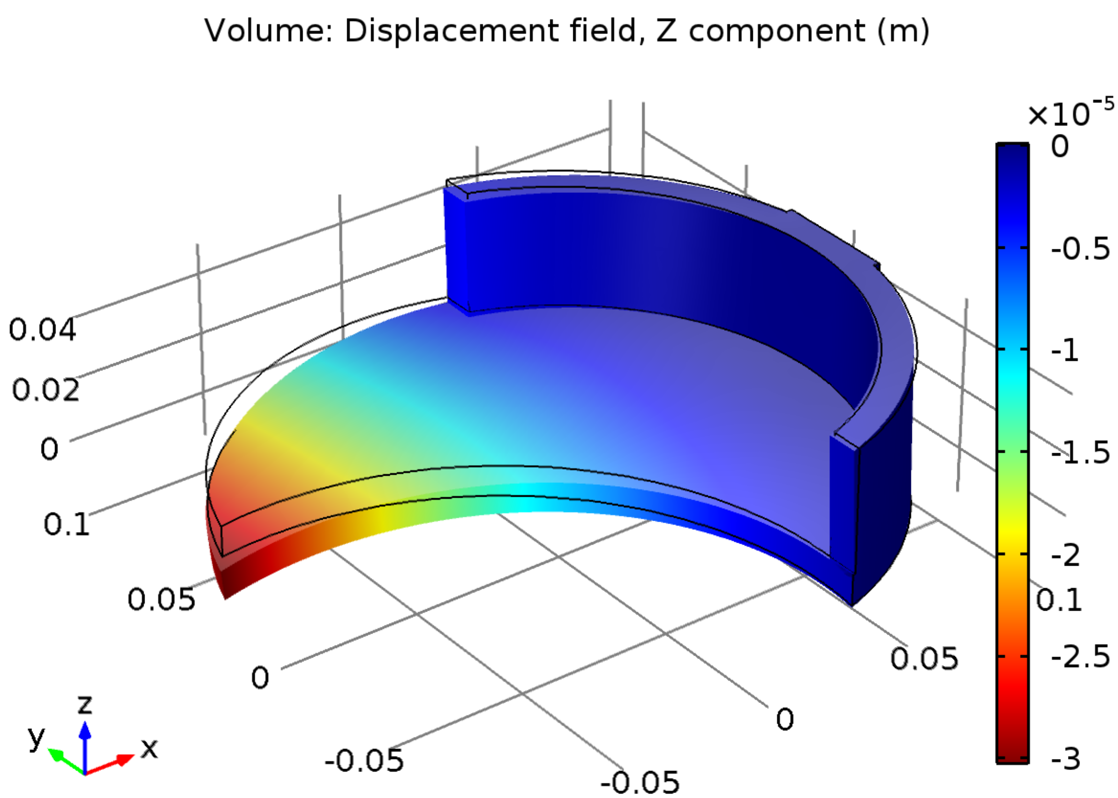

Figure 17. Displacement in Z direction

The mesh in this model was refined further to verify that the solution converges. The max displacement value for this model did not change.

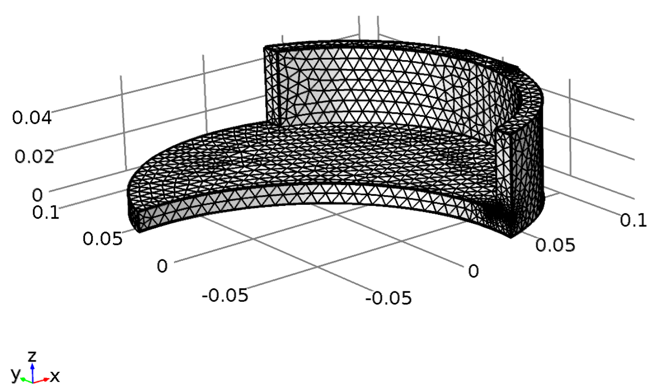

Figure 18. Refined Mesh

The results are as expected. The load from the aperture causes little displacement along the length of the 1 cm thick steel platform. The 3D analysis is verified with mesh refinement and by comparing the value of interest, displacement with the theoretical model. Deformation in the 3D finite element model is about 30% smaller than what is seen in the theoretical; this is more than likely accurate due to the geometry of the platform increasing its resistance to bending. Additionally, the preliminary model approximates the complex platform geometry as a cantilever beam, which opens up the solution for error.

This analysis will be used to optimize the platform's geometry (mainly thickness) to reduce the mass of the platform while maintaining sufficient rigidity.

5 Conclusion

The team is off to a good start and we are excited about the coming weeks in our project. The team has accomplished many of the goals set forth in the schedule, and have maintained a positive and productive group dynamic. The schedule will have to be revisited at the beginning of the spring semester as we have fallen slightly behind with the initial plan and the project scope has been reduced. A prototype for the loading/unloading mechanism has been made and a design for the full system has been selected. The linear rail systems, stepper motors, Arduino Mega microcontroller, motor drivers, and camera will be ordered prior to the break to allow this project to progress away from school. The system will be assembled upon return from break and the troubleshooting process will begin. We will be restricting our focus to the loading/unloading of the aperture. If time permits, we will explore designs for the storage and indexing of the apertures within the treatment room. We have been in contact with our sponsor, Kevin Erhart, and will be maintaining contact throughout the coming months. We have also been maintaining regular meetings with our advisor, Dr. Clark.

6 Acknowledgement

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