MAMMOGRAM MORE LIKE MAMMOGREAT

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i. Abstract

Studying engineering has allowed me to develop a unique perspective on the technology used every day. My goal for this research project is to take the knowledge acquired through my studies of engineering and apply it to improving the mammogram machine. Viewing my mother's struggles with breast cancer and witnessing the difficulties of receiving a mammogram have inspired my interests in this research. In this paper I will use, my mother's personal experience along with scientific journals, and research studies. Through this I will gain background knowledge on how the design of the machine intimidates patients. Along with, how the procedure can cause anxiety and how that's anxiety affects the people receiving these exams. I will further learn about recent improvements in the testing procedure and the design of the machine. Based on this knowledge I will offer an improved design and a new method for running the exams.

Key Words: mammography, mammogram redesign, breast cancer, breast imaging

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i. Introduction

Studying engineering has allowed me to develop a unique perspective on the technology used in life. In January 2020, my mother, Jill Einsmann, was diagnosed with aggressive stage one breast cancer. When first faced with the mammogram machine, it was intimidating and looked painful to use. The machine is large with two paddles, one the breast is placed upon, and the other moves down and compresses the breast. During the diagnostic process she was required to receive several mammograms. After speaking with her about these experiences she spoke on how uncomfortable the experience was. The patient is positioned awkwardly and then must completely expose their breasts. Furthermore, each breast is placed in three to four different positions during each appointment. Jill recounted her experience,

"I went in, I had to put on a dressing gown, they give you an alcohol wipe to wipe under your arms and around your breast. Then you follow the nurse into the room, in the room is the machine, and the technician. You then have to undo the gown and expose one breast. The nurse then manipulates your breast and lifts it up and puts it on one of the paddles. From there they push on your shoulders and butt. They then move the upper paddle close to your breast. The nurse then moves behind the screen. As your breast is compressed, they instruct you on when to breathe and when to hold your breath. Then they take the picture, if the picture is correct, they then move on to flattening the breast vertically. They change the position of the machine and then repeat the process of the nurse manipulating you and moving you to stand in just the correct spot. If the image is not what they want they will repeat the horizontal process until they achieve the desired image. This process is then repeated on the other side."

A breast consists of mostly tissue, fat cells, nerves and are very sensitive. Breasts are especially sensitive when they contain cancer cells. Position of the breast can create inaccurate

images. This causes issues when it comes to surgery and necessary medical decisions made by the patients. For example, the first mammogram Jill received had only shown only one lump. During the surgery that followed the doctors discovered a second lump, causing the surgery to be longer than expected, along with creating changes to the treatment plan that followed the surgery. Overall, this machine is outdated. The mammogram machine must be updated to provide a better more comfortable experience, as well as, creating clearer images.

ii. History of Mammography

A mammogram is the use of a low-energy x-ray used to examine the human breast. Typically, mammograms are conducted by taking the breast and compressing, using twenty pounds of pressure, the mammogram can require the breast to be positioned in several different ways. A diagram on how a mammogram is preformed is shown in figure 1. The mammogram was first developed in 1949 by Raul Leborgne in Uruguay (The). In the late 1950s, a new fine grain intensity was developed which allowed for better images to be produced. The fine grain intensity allows for the radiation to move perpendicularly to the direction of the motion of the wave, this allows for higher quality images. Twenty years after the first development, the mammogram became available all over the world. In 2000, the FDA approved mammography for digital imaging (The). An example of this imaging can be seen in figure 2.

The mammogram admits a low level of radiation thus making it safer than other forms of x-ray imaging. This low level of radiation causes the x-ray to not move through the tissue as easily, thus creating the need for both plates and compression (What). However, the low level of radiation is important because these exams occur annually and occur multiple times for women with breast cancer. In the past, mammogram images were printed on large sheets of film however today digital mammograms are more common. Other than the digital 2D mammogram

there is a new 3D mammogram called “digital breast tomosynthesis (DBT)” (What). These 3D mammograms occur the with the same procedure as a 2D mammogram however, unlike the 2D mammograms the breast is compressed once and the computer creates the 3D image. The 3D mammogram allows for better visibility of the tissues. These forms of mammograms are not customary. The development of the mammogram lowered the mortality rate for breast cancer by 20 percent (Claire Goodliffe). This exam is vital to discovering breast cancer early in patients. The earlier the cancer is located the higher the likelihood of survival. However, many women tend to skip going to these exams.

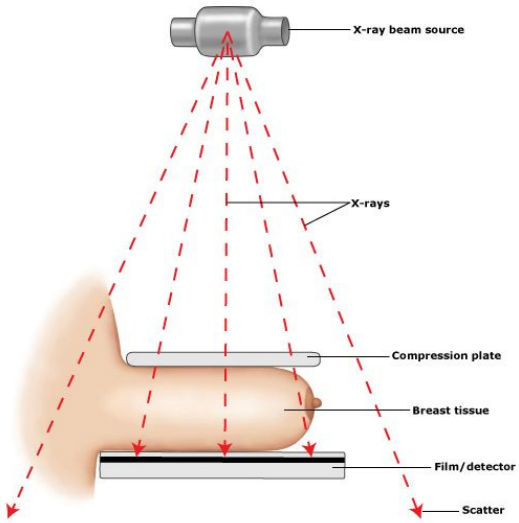

Figure 1: Figure 1 displays how the test would occur

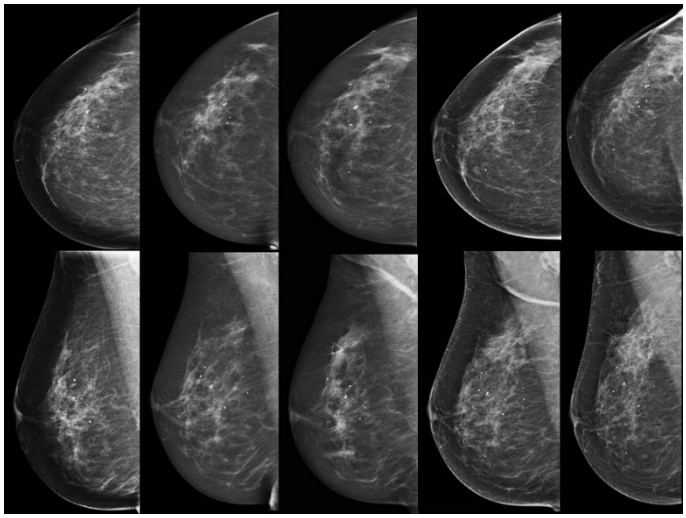

Figure 2: An image of what a 2D mammogram result would look like.

iii. Traditional Design

The original design of the mammogram machine can be shown in Figure three. The machine is bulky and tall. The x-ray tube is coated in molybdenum; it's a metal commonly found in Earth's crust. This metal filters the photon energy to help create clear images (Sprawls).

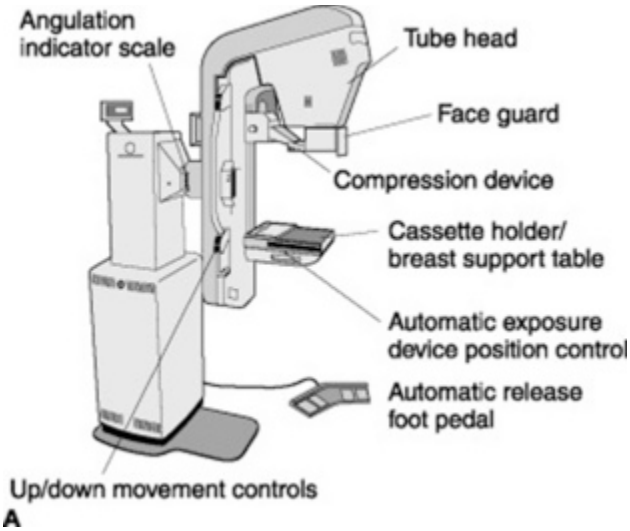

Figure 3: Diagram of Mammography Machine

It can be adjusted for different people's heights. The motor controls are on the left side of the machine. These controls will move the breast support plate to a more comfortable position. The

breast support plate however is rather thick and the face shield is perpendicular to the edge of the breast support table. There are no handles on the machine, there are bars that can work as handles but they are high up on the tube head. The automatic release foot pedal is used to start and terminate the compression.

iv. Indications for Testing and Attitudes

Forty percent of women in Europe and thirty percent of women in the USA will skip screening (Kellner). Women are afraid of the discomfort caused by these exams, as well as the results of them, no one wants to hear they have cancer (Kellner). Ages for women that require mammograms varies from twenty-five and older. Typically, women at 45 will begin screening and receive a mammogram every year, at 55 screening switches to every two years (cancer.org). The amount of screening required goes down at the age of fifty-five due to menopause (webmd). Twenty-five is the youngest that a mammogram will occur; typically, the women receiving mammograms at this age have had genetic testing done to show they are genetically predisposition to develop breast cancer. These genetic tests are vital for women whose mothers possess the broken BRACA1 and BRACA2 genes. This test is important for several reasons, in order to start undergoing mammograms at the twenty-five one must have proof it is medically necessary for the insurance company. The test itself is simple, however the person needs to schedule an appointment with a genetic counselor and then have a blood test. The appointment with the genetic counselor is extremely overwhelming, the counselor wants to know the persons family history of cancer, and talk about the effects of learning that the patient has this gene as well as the effect it has on insurance. The genetic counselor will ask you to think about how this knowledge will affect your mental state and if you want to wait until just before you turn 25. These tests are recommended, for those who have the broken gene in their family to acquire

them before the age of 25. They also mention that if you are unfortunate enough to possess the broken gene, your partner should also be tested for the gene because if the gene is passed from both your partner and yourself it can cause serious problems for your unborn child's health. The meeting with the genetic counselor is mandatory to receive the testing.

Dread over the results of the blood test can cause women to either never receive a blood test or skip the actual mammogram all together. The fear of the physical mammogram as well as the discomfort can cause errors in the test due to women becoming fidgety creating blurs on the image. Many hospitals will claim only twenty pounds of pressure is used, however depending on breast size and density more or less pressure may be used. Twenty pounds of pressure is a lot of weight to be compressing any part of the body. It takes eight pounds of pressure to break the average person's collar bone, 15 pounds of pressure to break someone's knee and yet in a normalized examination 20 pounds of pressure is the "typical" amount. For Jill, forty-two pounds of pressure was used for each image taken. She recounts,

"The entire time of this process someone is molesting your breast until the machine is in the correct position with the correct pressure. The pressure hurts, on a scale of 1-10, it was a 7 or an 8 and I have a high pain tolerance. After leaving the exam I felt sore, relieved it was over and moderately anxious. The very first time I had a mammogram I wasn't scared of the results but that is how I am. When I got the results back, they told me I had to go for a more aggressive mammogram (DBT)."

v. Densities and Different Demographics

Almost fifty percent of women in the US aged 40 to 74 have dense breasts, this is approximately 276 million women (Kerlikowsek). This amount does not include younger women, a woman at any age can have dense breasts. There are four categories for breast density: entirely

fatty, scattered areas of fibro-glandular density, heterogeneously dense, or extremely dense, an example of each is shown in 4. Breast density is included in the risk assessment for breast cancer. Twenty-four percent of women with dense breasts, with a higher-than-average risk factor, are at a high risk for interval cancer (Kerlikowsek). Dense breast tissue can obscure lumps from being detected, for my mother this occurred in a regular 2D mammogram as well as the 3D mammogram. Judy Dean M.D., a lead radiologist who specializes in breast imaging says, "Mammography is adequate for women without dense breast tissue, but for women with very dense breast there is an 18 times higher risk for having cancer missed by mammography" (Jacobson).

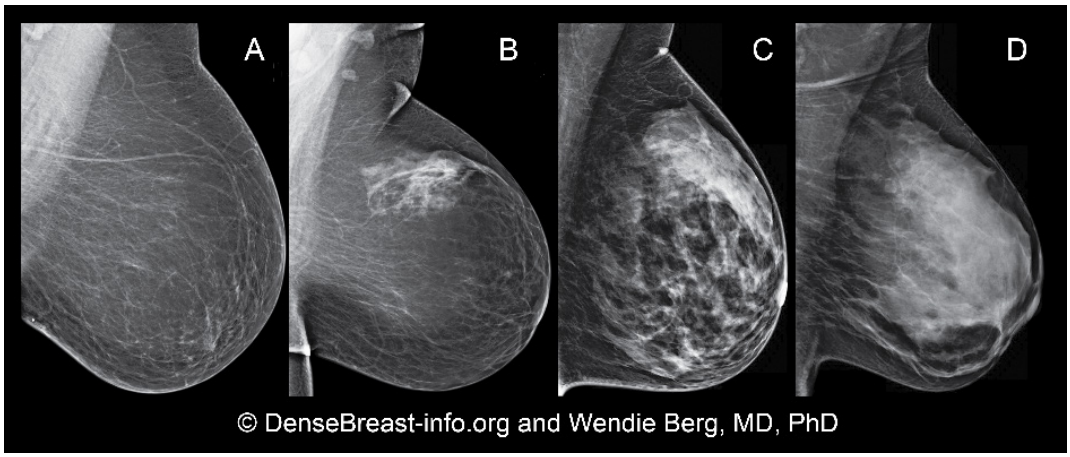

Figure 4: A: entirely fatty B: fibroglandular density C: heterogeneously dense D: extremely dense

Breast density depends on a person's genes as well as their race. Typically, breast density is higher in Asian women, middle of the spectrum in white women, and least dense in African American women (del). The study done took into consideration age, body mass, and breast size, data was collected from 15,292 women. The compression done in the mammogram will make the tissue appear denser, even though the compression is used as a way to increase the likelihood that the x-ray moves through the entire breast. Due to an x-ray's transmissive nature, it moves

through the tissue once, if the tissue is too thick it will obscure any tumors in the image thus resulting in a tumor being missed.

vi. Men

Breast cancer is typically thought of in women, however, it can affect men. In fact, breast cancer appears in 1 out of 833 men (Breast). While rare it does happen, the men affected are at a high risk for breast cancer and receive a mammogram. It is not recommended for men to receive regular mammograms. Most men diagnosed are sixty-five and over. For most men needing a mammogram can be difficult to understand due to the stigma of only women being diagnosed with breast cancer. This leads to anxiety which can cause men to go without being tested. While this discomfort and anxiety cannot be fixed without changing society, the physical discomfort and awkwardness of the test itself can be changed. A mammogram performed on a man is the same as a mammogram performed on a woman (Mammography). Knowing this it is safe to assume that due to men typically having smaller breasts than women, these exams are difficult to obtain. However, for men the images are clearer because they have less dense breasts.

vii. Challenges with the Mechanics of the Exam

There are several challenges with the current mechanics of the design. For one, there is no handles for the patient to hold on to when receiving the exam. These handles would allow the patient to be able to position themselves more comfortably and easily hold themselves closer to the machine allowing for better images to be produced. The start and release for the compression are controlled by a foot pedal placed near the patient however they are not allowed to control it. This means the patient must be compressed before, during and after until the administrator is able to get up and walk around to this pedal. Furthermore, the patient must be manhandled every

time the position is changed for the image. This occurs because any excess skin, fat or roll of any kind can causes the image to be distorted. The area around a women's breast, especially when her breasts are large can have a lot of fat and the skin can roll and move in ways that cause distortion to these images. For women with little breast this exam is extremely challenging due to there not being much there to compress. The three main issues with this machine are, it is not designed for the needs of a women's body, it is not designed to fit all body types and lastly its imaging ability is subpar.

viii. Design Opportunities

The medical industry currently is working on improving some aspects of the mammogram machine. The industry has designed curved paddles and are testing a system where the patient controls the amount of pressure used to compress their breasts during the exam. The studies done where the women control the amount of force used, show that the women tend to apply more pressure that the techs would. The women typically feel as though they are more in control which helps lesson the anxiety of the test allowing for more pressure to be applied. The curved paddles, show in in figure 5, while revolutionary is not a fix for everyone. These paddles cannot be used for people with very large or very small breasts; nor can they be used on people with certain types of implants (Bartosch). However, for those these paddles do work for it allows for a more comfortable experience and creates better quality images.

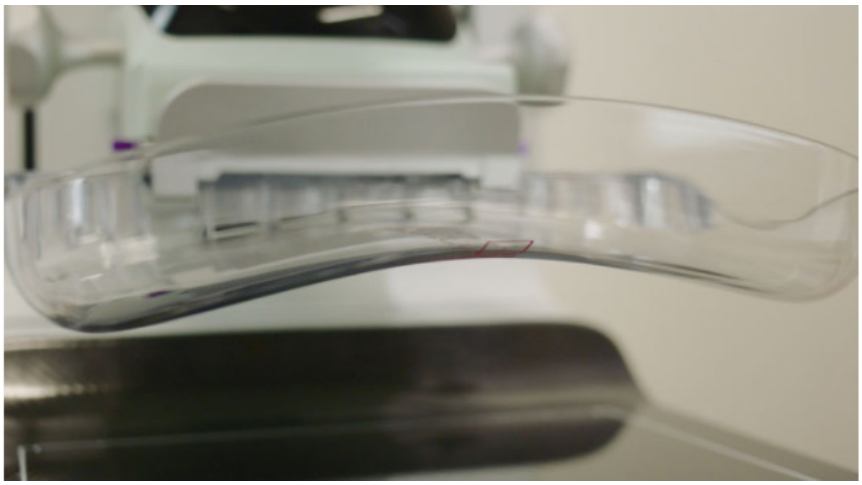

Figure 5: SmartCurve breast-shaped paddles make mammograms more comfortable.

Overall, only the paddles and the pressure delivery system have been altered, the overall machine design has not been changed. These new design features are in the process of becoming more common place. Furthermore, there are several other ways for breast imaging such as a breast MRI, or CT. These tests are more expensive, the CT usually occurs before the MRI. The MRI is used to help identify less invasive and aggressive tumors. When the CT is conducted a woman is laid flat on a table and places her breast in a large hole, where the imaging technology spins 360 degrees around the breast. This process provides a clearer image of what is occurring in the whole breast without the need for compression. The CT however cost 270 dollars with insurance and 5,000 dollars without insurance. The mammogram without insurance costs 250 dollars if your over 40 or have significant risk factors (Stephan). When conducting a general cost analysis, the figures below are my best guess at how the money would be distributed its not possible to find actual information on this:

Item	Details	Cost
Machine Run Time	Amount of time, how many pictures need to be taken	100
Operator/ Hospital staff	Contributing to salary	40
Appointment Time	Holding the appointment	20
Cleaning Time	Contributing to salary	40
Radiologist	Contributing to salary	40
Additional fee	In-case of missing contributing factor	10
Total Cost:		$250

Table 1: Cost Analysis

The best way to lower the price of this exam would be to make the run time shorter and make the images easier to read.

ix. J1 Mammogram Design

In the previous section's factors such as, breast density, user comfort, different demographics and genders, as well as challenges with the current design have been researched, this research has led to the development of requirements for a new, improved and ultimately better deign. The J1 design stands at 7 feet 2 inches tall from the floor to the top. Furthermore, light blue, was added to the color scheme of the machine to make the machine appear less threatening. Blue is a color associated with calm and health thus allowing the patient to subconsciously relax more during the exam. The more relaxed the patient is the better quality the images will be and the more efficient the exam is. Here is the J1 Design:

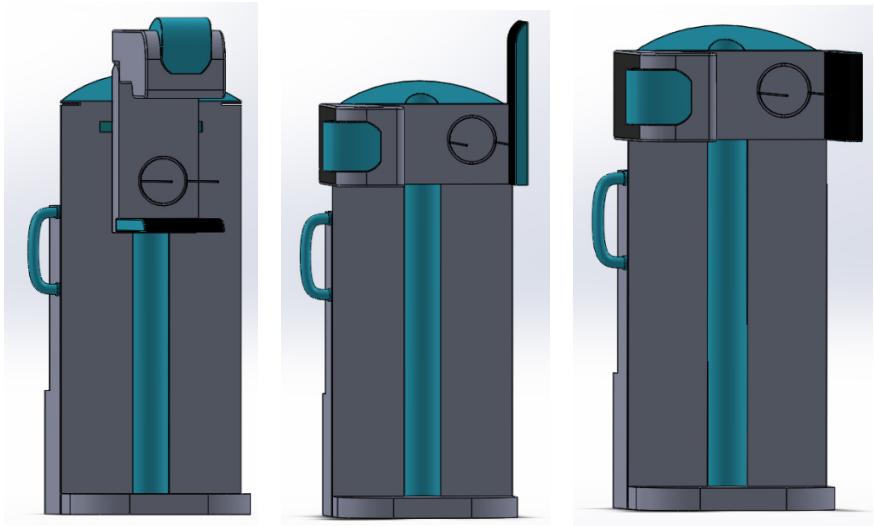

Figure 6: Full J1 assembly and motion.

The nurse will help the patient into the breast plates and then will explain the patient how and where to attach themselves to the connecting rods. The nurse will then turn on the suction and being the imaging. After the first image is taken, the nurse will turn off the suction and the patient will be able to remove themselves, step back while the machine rotates as shown in figure 6 and then the patient can reattach to the connecting rods to repeat the process. The purpose of this design is to allow of the nurse and patient to have minimal contact creating a more comfortable environment for both parties.

The J1 design will have three simultaneously rotating sections, the entire imaging head, the connecting rods, and the film plate. There are only two types of motion in this system the imaging head and connecting rods move with the same axis of motion whereas the film plate moves on a different axis of motion, a diagram of this is shown below.

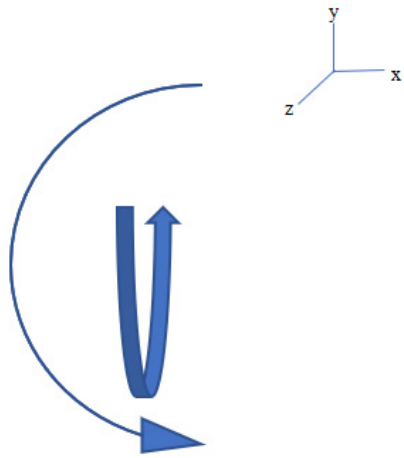

Figure 7: Axis of motion.

This is achieved using a planetary gear combined with a bevel gear. A planetary gear can support the most weight and torque of the gear types without failing, thus making it the optimal choice for the motion of the imaging head due to the size and weight. Combining the bevel gear with the planetary gear will allow for only one motor to be used to control two sets of motion creating simultaneous movement.

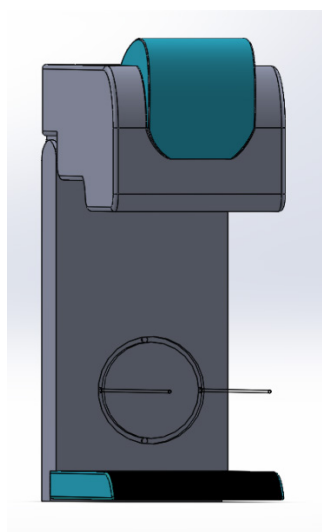

Figure 7: J1 Imaging head

The connecting rods are made out of a clear, hard plastic and are hollow. The breast plates clip onto these rods and suction is pulled through these rods into the breast plates, the breast plates are shown below. The suction is used by a piston system. The suction will pull the breast and skin away from the body while compressing it slightly. The rods rotate and lock into place using a locking pin so that they do not move.

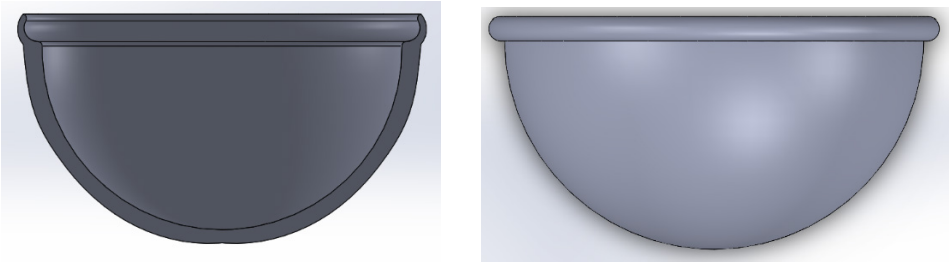

Figure 8: J1 Outside breast plate design

Above are the J1 breast plate design, these will be made out of a hard, clear, plastic so they do not interfere with the imaging. The plates will clip together with a small latch not shown in the images above. Each plate will have a top and a bottom plate. There was a study done by the University of California to measure women's breast diameters based on bra sizes ranging from AA to DD, from this study I was able to create breast plate with an inner ID according to this study:

Bra Size	Plate ID (cm)
AA	11.1
A	11.4
B	13
C	13,5
D/DD	13.7

Table 2: Breast plate inner diameter sizes in centimeters

The goal for the J1 design is to be able to accommodate women with bra sizes up to F, therefore future research will be needed to be conducted. The breast plates will be stored in a cabinet attached to the back of the J1 machine.

The requirements set for this design can be found in the tables 2-6 below.

Requirement	Type	Description
1.1	Functional	The system shall accommodate a wide range of patient heights
1.2	Functional	The system shall minimally compress or pull at the breast
1.3	Functional	The system shall accommodate a wide range of breast sizes

Table 3: Functional Requirements

It is important that this machine be able to accommodate multiple height because many people have heath conditions causing them to be shorter or taller than the average person thus creating a machine that can accommodate for very tall or very short individuals is important. The goal is that this machine will be able to accommodate people approximately from 7 feet 4 inches tall to 4 feet zero inches. Furthermore, not everyone who requires a mammogram is a woman or was assigned woman at birth. As well as this many women have implants, with current technology, this includes the improvements of the curved paddles, it is imperative that only slight compression is applied. The compression will come from the breast being encased in a cup that fits the patients breast size, from there the machine will pull slightly to move the breast away from the body allowing for no rolls or bumps in the skin. This will alleviate the issues stated in section “Challenges with the Mechanics of the Exam”.

Requirement	Type	Description
2.1	Performance	The system shall take clear images
2.2	Performance	The imaging system shall be able to rotate

Table 4: Performance Requirements

Requirement	Type	Description
3.1	Environmental	The system shall not increase anxiety in user
3.2	Environmental	The user shall not be placed in any awkward positions

Table 5: Environmental Requirements

Requirement	Type	Description
4.1	Safety	The system shall be stable
4.2	Safety	There shall be handles on the sides of the machine for the user to hold
4.3	Safety	The system shall not tear, bruise or damage the skin or tissue of the user

Table 6: Safety Requirements

Requirement	Type	Description
5.1	Physical	The system shall use the in-place mammography imagining technology or a similar type
5.2	Physical	The system shall not create tissue rolls or other issues that can interfere with imaging

Table 7: Environmental Requirements

Below is a test matrix displaying the three major design considerations: comfort, efficiency, and quality. The sections: importance, and achieved are ranked zero being the lowest possible score and five being the best possible score. To achieve the total value the value for the importance column and the achieved column are multiplied together. The total achieved is the total value per each row added together and then divided by the maximum amount possible in order to achieved the percentage.

Current Mammogram Design:	Importance (0-5)	Achieved (0-5)	Total
Comfort	5	1	5
Efficiency	5	2	10
Quality	5	3	15
			Total Achieved (30/75) = 40%

Table 8: Test Matrix for Current Mammogram Design

These values were found by speaking with Jill about her experience during her mammogram and having her rate it out of five.

J1 Mammogram Design:	Importance (0-5)	Achieved (0-5)	Total
Comfort	5	4	20
Efficiency	5	4	20
Quality	5	3	17
			Total Achieved (57/75) = 76.6%

Table 9: Test Matrix for J1 Design

These values were determined based on data from the smart-curve paddles as well as inferences based on improving the overall designs of the machine. After looking at the data from the trade of matrix I calculated that there is a 90% increase with the J1 Mammogram Design. This design takes into account current research and accounts of a person who has experience this examination.

x. Conclusion

In conclusion it is important to take into consideration that the J1 design still requires testing to be conducted. The next steps for the process are to meet with an x-ray specialist to iterate and validate the design to ensure the clarity of the image will not be impacted by the change in the compression. Furthermore, building a prototype and conducting testing of the machine and the breast plates to ensure the machine and breast plates increases the comfortability of the patient, increase the efficiency of the exam and do not affect the quality of the image. From the research

conducted, the design should not affect the quality of the image, the only item that may cause an issue is the minimal compression due to the type of x-ray being used, however, that is outside my knowledge base thus needing to consult with an x-ray expert.

The J1 design overall will improve the experience of the patient, accommodate people of all breast sizes, densities and heights, along with not causing damage to breast implants. The improvements made by changing the compression system and paddles has allowed for all of the desired improvements to be met.

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