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Portable Device for Breast Volume Measurement

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Abstract

A device for the measurement of breast volume is proposed. A surgeon, Dr. Ramzi Shehadi, who wants the volume of a normal breast for reconstructive surgery following a mastectomy, is the inspiration for this device. This device would improve the symmetry of the breasts following reconstructive surgery and would benefit a wide range of surgeons—especially those lacking in experience. Background information, three possible designs alternatives, and a design matrix are presented. This report summarizes the design process taken by a group of undergraduate biomedical engineers and concludes with the final design and future work for this project.

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1.0 Introduction

1.1 Problem Statement

Estimating breast volume is a challenge for any plastic surgeon performing breast reconstruction following mastectomy for cancer. Matching the volume and shape of the contralateral breast intraoperatively as is the standard at present is complicated by the swelling induced by the surgery itself. A preoperative accurate assessment of the volume would help the reconstructive surgeon in achieving better symmetry more consistently. A portable device that could take this assessment simply and quickly would be ideal. The device would also be used to estimate the volumes of flaps such as a TRAM flap also to achieve better symmetry.

1.2 Background Information

Breast cancer is an extremely widespread disease. In the United States, is estimated that there will be 288, 130 new cases of breast cancer (both invasive and non-invasive) in 2011 alone, claiming the lives of almost 40,000 women [1]. Treatment options for breast cancer include chemotherapy, radiation therapy, lumpectomy, and mastectomy. In 2004, 69.8 percent of procedures to remove breast cancer were mastectomies [2], with many women pursuing breast reconstruction afterwards. Breast reconstruction is done to permanently regain breast shape, to make the breasts look balanced when wearing a bra, and to avoid the use of external prosthesis [3]. These procedures have a significant impact on not only the health of women with breast cancer, but on their quality of life afterwards.

Breast reconstruction surgery can be performed either immediately after the mastectomy or delayed to a later date; however, to reduce the number of surgeries, it is often recommended that the surgery be done immediately after the mastectomy [3]. There are three different types of procedures currently used to reconstruct the breast that is removed. Surgeons and patients may choose between implants, tissue flap procedures, or recently developed artificial tissue support material [3]. The most common of the aforementioned procedures, and the one used by the client in this project, is the TRAM flap procedure (a type of tissue flap procedure). The TRAM (transverse rectus abdominis myocutaneous) flap is a procedure that uses muscle, skin, and fat from the abdomen to reconstruct the breast vacancy. Currently, the TRAM flap is the most common form of living tissue used for reconstruction [4]. Figure 1 displays an artist's representation of the different steps in the procedure.

There are two types of TRAM flaps that can be used for the breast reconstruction: pedicle flap or free flap [3]. The pedicle flap leaves the muscle attached to the original muscle supply and, in the procedure, the flap is passed under the skin to the point of attachment. Alternatively, the free flap disconnects the muscle from the original blood supply, requiring the surgeon to reattach all capillaries and veins at the new site. The tissue taken in this surgery is very similar to the tissue removed in an abdominoplasty—or ‘tummy tuck’—and is another reason for the popularity of this technique.

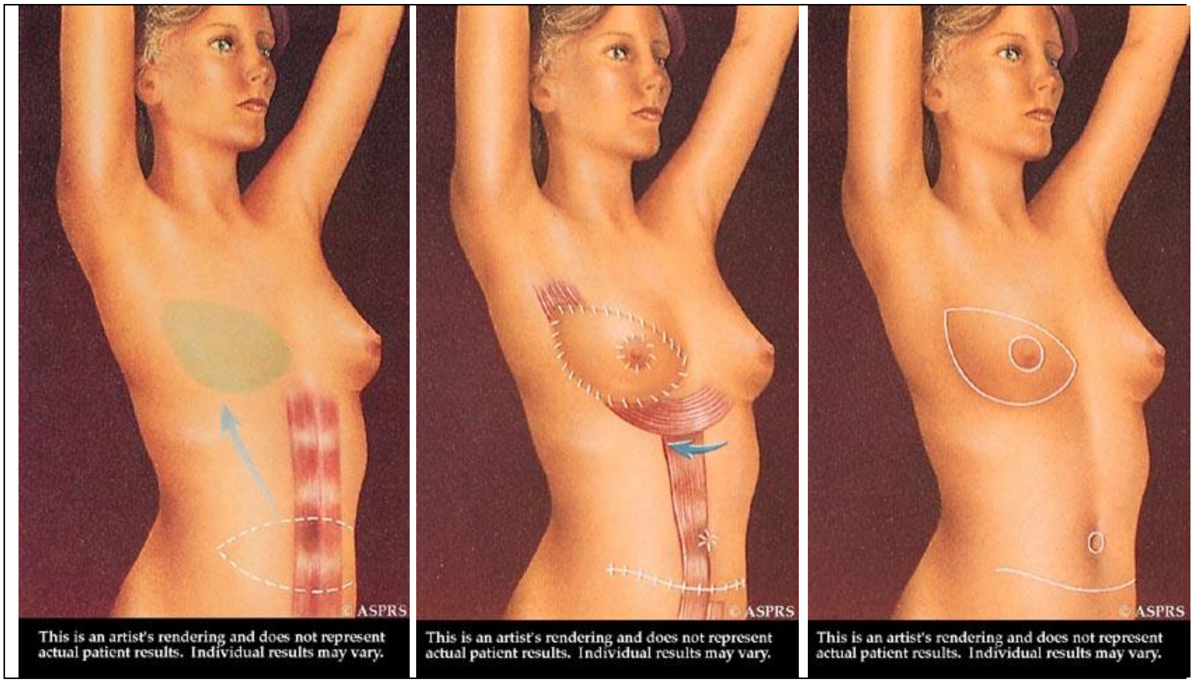

Figure 1: Representation of the TRAM flap procedure.

To improve the symmetry of the reconstructed breast, our client wishes to have a device that estimates the volume of the healthy breast before surgery. This estimate will give the surgeon an idea as to how much TRAM flap tissue to remove. Currently, our client does not use any tools to take this estimate and uses his own judgment and experience to estimate the amount of tissue to remove. This technique is limited to surgeons who have this experience; therefore this device would be tailored to inexperienced surgeons.

1.3 Motivation

A device for accurately measuring volume of a breast would save both time, money, and work for the surgeon as well as the patient. The current techniques that are available for measuring breast volume pre-surgery are either very expensive or inaccurate. 3-D imaging devices that are currently on the market that are able to calculate volume accurately can be priced as high as $30,000. This is much too high for most hospitals and the goal of this project is create a device that is under $500. This way it will be marketable to all hospitals small or large. Other methods include the comparison of the breast to prosthetics of a known volume. This method is inaccurate because it does not account for the individuality of the various breasts that it will have to measure. This method also leads to variability between surgeons who may choose one prosthetic over another. A surgeon who is more experienced at the TRAM flap procedure will be able to make a much more accurate assessment of the breast which leads to steep learning curve for the inexperienced surgeons. A cheap and accurate device will lead to more efficient surgeries and therefore a lower cost for both surgeon and patient

2.0 Design Specifications

The device must be able to determine the volume of a breast with little work done by the surgeon. A simple and portable device is the most convenient and effective approach to take to designing this type of device. Portability is an important trait of the device due to the need that it must be able to be used in a clinic setting. This means that it must have the ability to perform its task in a relatively small room and be able to easily be transported into a similar room to accomplish the same task. Along with this, the device must take up a small amount of space when stored. The device must be easy to use in the sense that a surgeon who has little to no knowledge in the engineering or computer science fields will be able to learn how to use it very quickly. The accuracy of the device is also a necessity. The volume that is determined by the device will be of little importance unless it is within a reasonable degree of accuracy for any type of breast. Breasts that are large, small, saggy, uneven, or contain any other complication will have to be taken into account in order for the device to be useful. The cost of this device is also of much importance. There are devices available that can determine the volume of abnormal objects such as breasts, but these are much too expensive. The device should be under a $500 budget so that it is affordable to all types of clinical setting. A safe device is always important when it is going to be used on patients. This entails that the device must be sterilizable or covered with a sterile material without losing its ability to perform its function.

3.0 Design Alternatives

In order to perform most efficiently in breast reconstruction surgery, the surgeon must have an idea of the volume that the breast needs to be. This is difficult to determine without a device. In order determine a solution for the problem along with meeting the design specifications mentioned in the previous section, three design alternatives were considered. One of the design alternatives used volume displacement while the other two used laser technology and 3-D sensing technology in order to determine the volume. The designs are described below.

3.1 Lasers

The first design utilizes laser technology that is able to calculate and store the distance between the origin of the laser and the first solid material that the laser comes in contact with. The general design behind this idea consists of an adjustable stand and a certain number of lasers that are supported at the top of this stand (Fig. 2). The lasers at the top of this stand would have to be adjustable in order to compensate for breasts of different width. It was determined that in order to accurately measure the volume of a breast, at least three measurements would have to be taken. The three measurements would be at the crown of the breast and slightly to the right and left of this measurement. These measurements could be taken most efficiently with the use of two lasers. The third measurement would simply be taken by the same laser that took the measurement of the crown of the breast after adjustment to the right or left. These distances that are recorded by the lasers would have to be subtracted from the known distance of the lasers from the sternum of the female in order to get the height of the breast at that particular point. These heights would then be used with the known lengths between the measurements taken in order to from a rough curve that would fit the curvature of the breast. Assuming symmetry of the top and bottom of the breast, the curve could then be rotated about an axis and the volume of the breast could be estimated. The mathematics involved in this design would be done by a computer program, but the values of the heights and lengths that must be recorded for this calculation must be typed into this computer program by the person operating the device. This involves much more human interaction than is desired by the client and therefore is not as easy to use as would be preferred. This technique is also rather inaccurate for breasts that are abnormally sized and could not be optimized as a symmetrical mound. This design would be rather portable and would also be safe and sterilizable.

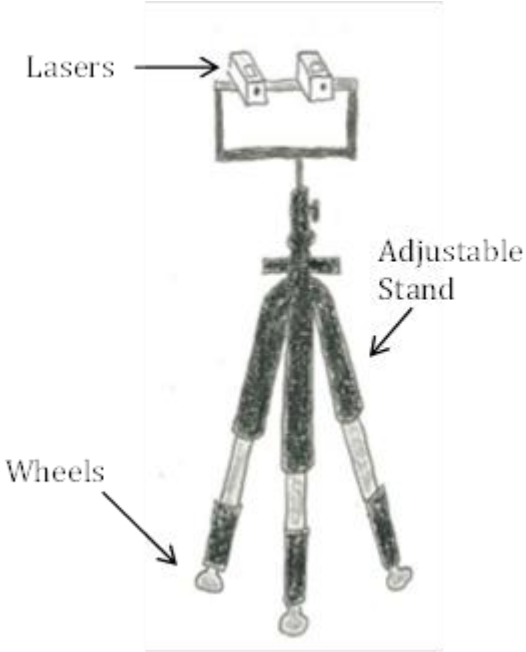

Figure 2: Lasers slide along horizontal while the stand adjusts device vertically.

3.2 3D Imaging

The second design alternative involves using preexisting technology. In 2010, Microsoft released Xbox Kinect, a motion sensing input device that is capable of creating a 3D image (Fig. 3). The 3D sensing technology used in Kinect comes from the company Primesense and consists of 3 parts: a chip (PrimeSense PS1080 SoC), depth sensors (IR light source and CMOS image sensor), and a RGB color camera. The Kinect works by first allowing the chip to acquire a depth image by infrared lights. Then, in a stage called light coding, the CMOS image sensor reads the coded light back from the scene. After light coding, the chip uses an algorithm to process data from the CMOS image sensor and creates a 3D image of the scene [5]. The second part of the design would involve writing a computer program that would use the raw data obtained from the Kinect to calculate the volume of a breast. Essentially, the Xbox Kinect would be on an adjustable stand and a woman would stand in front of the stand such that her breast aligns with the Kinect. A 3D image of her breast would be produced and the data from the Kinect would be transferred to a computer, via a USB cable, and the computer program would be used to process the data and calculate the volume of the breast.

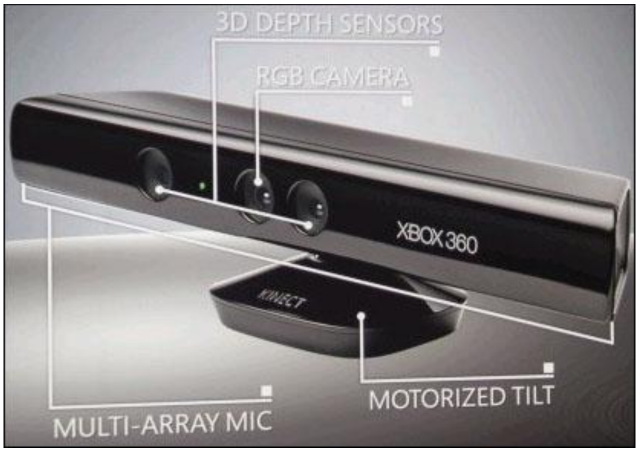

Figure 3: The 3D depth sensors and RGB camera on the Xbox Kinect help create a 3D image of a scene. [6]

3.3 Volume Displacement

The final design alternative would use Archimedes' Principle (or volume displacement) in order to determine breast volume. The design would include different sizes of primary containers, external container, and valve (Fig. 4). The primary containers would have a plastic membrane sealed onto the rim so that it fits loosely into the container and creates a "pouch". The breast would be inserted into this pouch, not necessarily stretching or filling the pouch. The potential extra room in the pouch is eliminated as the known volume in the external container is allowed to flow through the valve into the primary container. The volume continues to flow until all of the empty space in the primary container is filled, and the membrane is tight against the breast. The volume of the breast is determined by subtracting the change in volume of the external container from the known volume of the primary container. With this design, some complications arise with reusability and creating a water-tight system. The design would have to be reset, so that no volume is in the primary container and the external container has its starting amount of volume. Also, the seal of the membrane to the primary container could be one area with a high potential of allowing volume to escape.

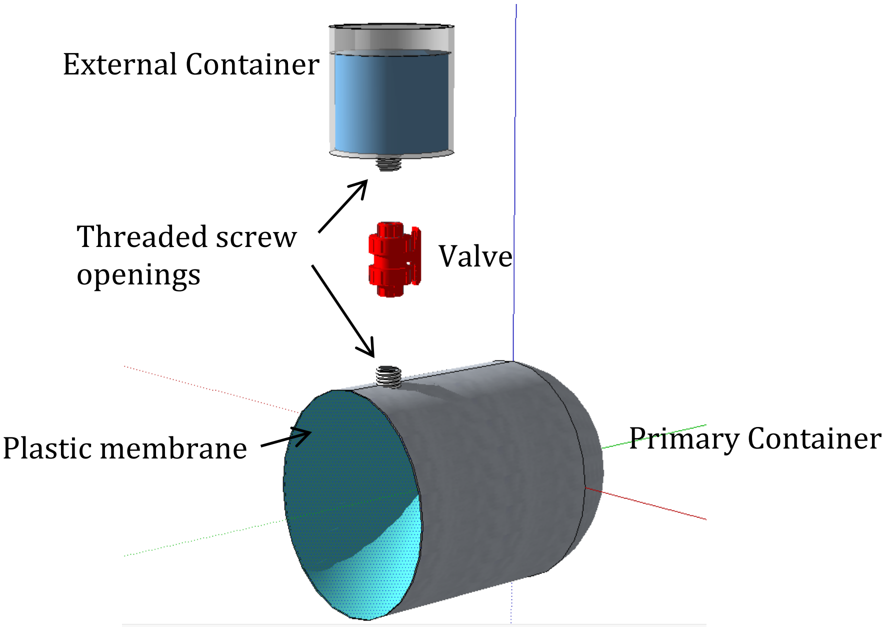

Figure 4: External and different sized primary containers screw into valve.

4.0 Design Matrix

In order to choose a final design, a design matrix was created (Fig. 5). The following categories were chosen for the design matrix (in order from most important to least important): Cost, accuracy, portability, ease of use, maintenance, speed, patient comfort, and safety. Cost was determined to be the most important part of the design. This was due to the availability of current devices that can measure the volume of a breast; however, these devices are expensive. The water displacement design received the highest point value in the cost category because the cost to manufacture the design will be under our budget of $500. The laser and 3D imaging design were given lower point values in the category of cost because they will likely exceed our $500 budget.

Accuracy and portability were the next two most important categories. Our client would like the volume of the breast to be accurate in order to know how much muscle, skin, and fat from the abdomen must be used during the TRAM flap procedure. The integration programs that would be used to calculate the volume of a breast in the laser and 3D imaging designs assume symmetry of the breast which would lead to a less accurate volume of a breast. Therefore, the water displacement design would give the most accurate volume of a breast since it uses Archimedes' Principle to determine the volume. Our client would also like the device to be portable so it can be carried to different rooms. Because both the laser and the 3D imaging design would require stands, they would be less portable than the water displacement design.

Ease of use and maintenance of the device were the next most important categories. The device should be simple enough to use such that a person with little training on the device would be able to accurately determine the volume of a breast. The device will be used in a hospital setting so it must be easy to clean and sterilize. Since the laser and 3D imagining design don't actually touch the patient, they would be easier to clean than the water displacement design.

The final two categories were safety and patient comfort, both of equal importance. The design must be safe to use and must not harm the patient. The patient should feel comfortable while the device is measuring the volume a breast. Because both the 3D imaging design and the laser design don't physically touch the patient, they were given a higher point value in the category of patient comfort.

Category	Lasers	Water Displacement	3D Imaging
Cost (25)	10	25	15
Accuracy (20)	5	15	10
Portability (15)	7	12	7
Ease of Use (15)	5	12	14
Maintenance (10)	9	5	9
Speed (5)	1	4	4
Patient Comfort (5)	5	3	5
Safety (5)	5	5	5
Total (100)	47	81	69

Figure 5: Design matrix for the different designs to measure breast volume.

5.0 Final Design

The design that was chosen to pursue further was the Volume Displacement design. This design scored the highest in the design matrix with a total score of 81 out of 100 (Fig. 5). This was because of the design's high portability, low cost, and high relative accuracy compared to the other design alternatives. The Laser design was dismissed from final design consideration, as it received a low score of 47. This was because of a high cost, low ease of use, and relatively low accuracy. The 3D imaging design was also dismissed, receiving a score of 69. This was due to its low portability and insufficient accuracy.

The design team concluded that the Volume Displacement design was indeed the best alternative of the three. The cost is under budget, it is highly portable, and maintains a consistently high accuracy. The team will move forward with this design with confidence.

6.0 Future Work

The first goal of the team for future work is to research materials for the final design. This includes possible materials for the primary containers, external container, valve, membranes, and the seal on the rim of the primary container. Preferably, the primary containers and external container would all attach to the valve directly, possibly with male-threaded screw openings on the containers and a valve with female-threaded ends. Both containers would be made from hard, light-weight plastic. The external container would be labeled to accurately determine the current volume inside of it. The primary container would have a known volume to simplify the breast volume calculation. The membranes need to be stretchable and attachable to the rim of the primary container. The seal between the primary container and the membrane also needs to be water-tight. Possible ideas for the seal are various adhesives, screws, or a combination of both.

The valve could be a plastic ball valve with female-threaded ends as mentioned before. After these materials are determined, they will be purchased and assembled.

After the device has been built, testing will need to be done before it can be delivered to the client. Numerous tests will be performed to determine the effectiveness of the prototype in a variety of categories including accuracy, reusability, ease of use, maintenance, and other factors that are important to the client. Depending on the results of these tests, the design may be altered in order to improve the prototypes effectiveness. Once these changes are made, and the device is working properly, it will be delivered to the client for review. Hopefully, the device will be deemed effective enough to be implemented into the client's hospital. From there, the team and client may come to the decision that the design is marketable and may move to try to patent and/or mass-produce the device. There are many inexperienced reconstructive surgeons around the United States that could benefit and be interested in such a device.

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