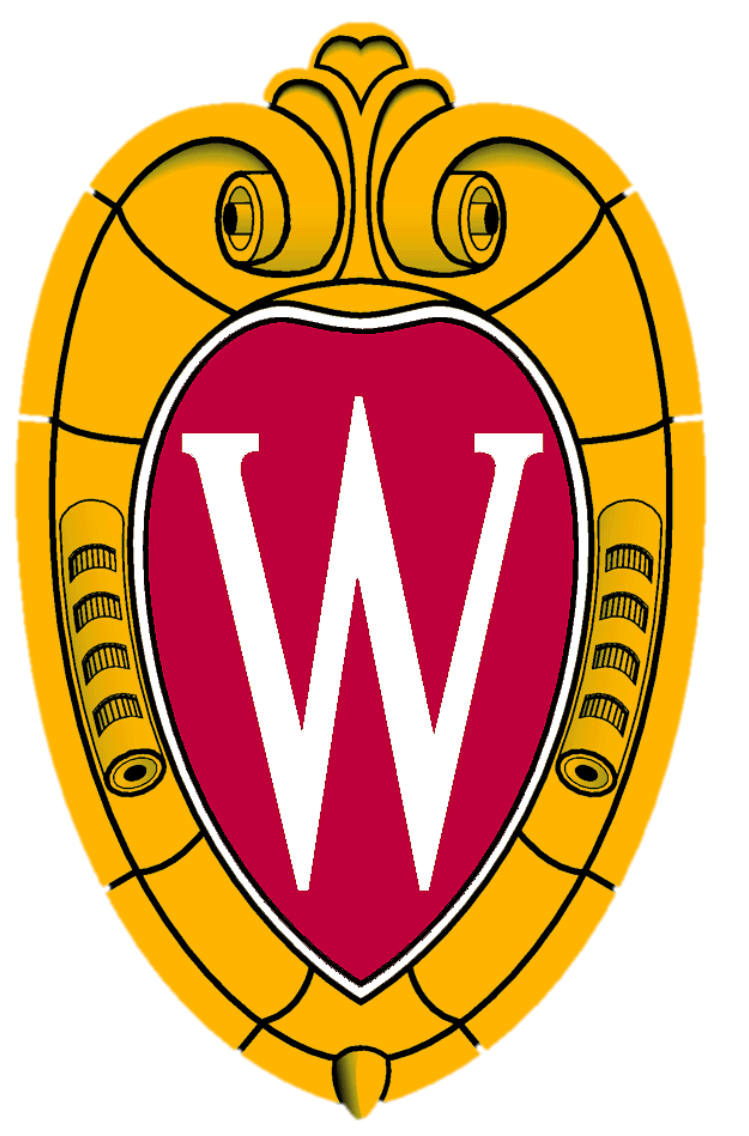


PORTABLE DEVICE FOR BREAST VOLUME MEASUREMENT

Aaron Dederich, Joseph Henningsen, Brett Napiwocki, Ben Smith

Client: Dr. Ramzi Shehadi

Advisor: Dr. Tracy Puccinelli



ABSTRACT

Our client, Dr. Ramzi Shehadi is a reconstructive surgeon interested in developing a device to pre-operatively measure the volume of a patient's healthy breast in order to more accurately perform the Transverse Rectus Abdominus Myocutaneous (TRAM) Flap procedure on the breast that underwent a mastectomy. The device would improve the rate of success of the procedure and the symmetry of the breasts – especially for surgeons lacking significant experience with the procedure. Our final design uses volume displacement principles and incorporates two containers, a valve, and a sliding scale to measure the breast volume. The device was designed to accurately measure breast sizes up to 600 cm³ for the small version, and 1300 cm³ for the large version. This encompassed a small to medium breast size range. It was demonstrated through testing that the device was able to determine volume precisely and with the desired accuracy.

INTRODUCTION

- Problem Statement:** A simple, cheap, portable device is needed in order to pre-operatively determine the volume of a breast
- Mastectomies are the most common treatment for breast cancer^[1]
- TRAM flap procedure is performed after mastectomy^[2]
- Knowing the volume of the healthy breast pre-surgery would allow surgeons to determine the amount of tissue to take during the procedure

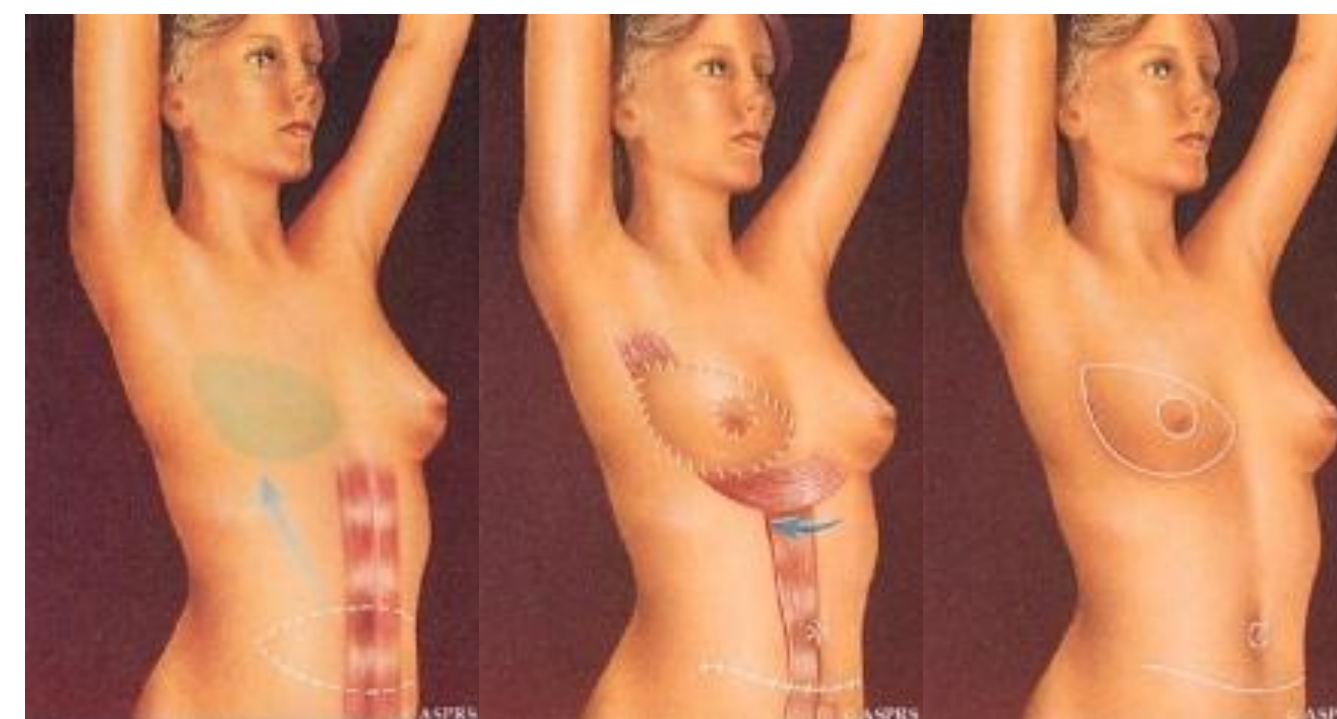


Figure 1: TRAM flap procedure illustration with tissue taken from the abdomen and transferred to the breast.^[1]

CURRENT METHODS

- Comparison to prosthetics
- Estimation by using touch and sight
- 3D Imaging devices
- MRI scan
- Cast molds
- Grossman-Roudner device^[3]



Figure 2: HandyScan 3D, a portable laser device able to produce an accurate 3-D image from which a volume could easily be determined^[4]

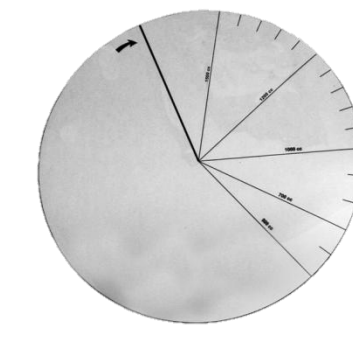


Figure 3: Grossman-Roudner device measures volume using cone geometry^[3]

DESIGN SPECIFICATIONS

- Quick determination of breast size
- Accurate within 10% of the actual breast volume
- Simple enough for any one person to use
- Portable in a clinical setting
- No more than 10lbs
- \$500 preliminary budget

Table 1: Design matrix describing the justification for the final design choice

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

FINAL DESIGN

Components:

- External container: Acrylic cylinder, acrylic cap, and aluminum bottom that holds water that flows into primary container
- Primary container: PVC cylinder in which the breast is inserted and water flows into
- Valve: Starts and stops flow between external and primary container
- Membrane: LDPE film attached to the rim of the primary container, forming a water-tight seal between the breast and the primary container
- Membrane seal: Steel hose clamp attaches membrane to primary container
- Scale: ABS component allowed to be adjusted up and down the external container; and calibrated to show the volume of the breast as a function of the water remaining in the external container

Process:

- Breast is inserted into primary container in loose fitting membrane
- Top of scale is positioned at water level of external container
- Valve is opened, water fills primary container around breast
- Remaining water level in external container is measured by the scale, determining breast volume

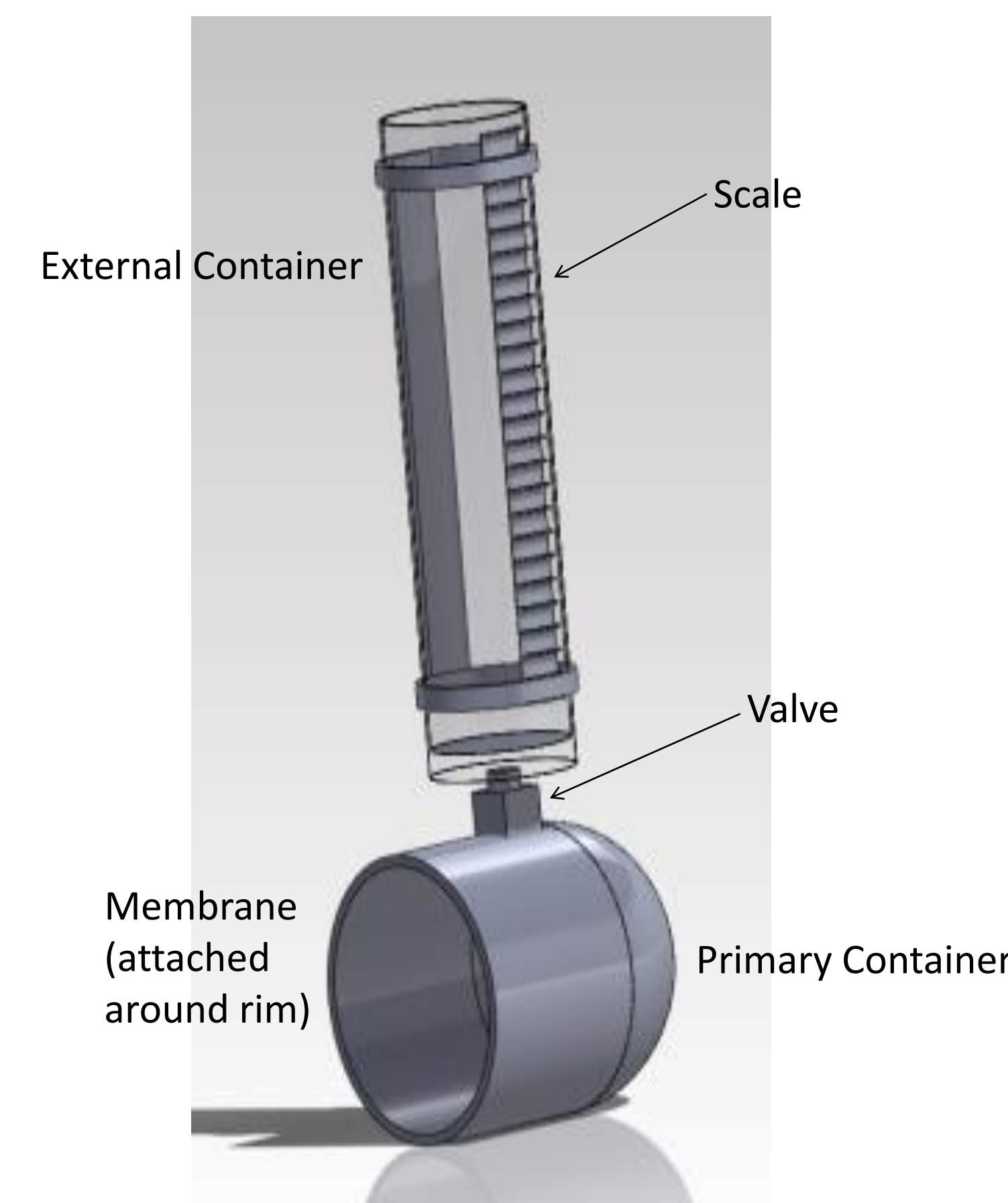


Figure 4: Final design SolidWorks model



Figure 5: Final larger-sized prototype

Cost Analysis:

Table 2: Cost Analysis of small version of device

Part of Design	Specific Material	Cost
Primary Container	4½ inch diameter PVC Slip Cap	\$7.71
Membrane	Dual-layered LDPE Sheet	\$2.40
Membrane Attachment	4½ - 7 inch Steel Hose Clamp	\$1.72
Membrane Attachment Cover	12 x 12 inch, 1/32 inch thick, Nitrile	\$10.36
Valve	¼ inch end, Male x Female threaded, Chrome-plated, Brass Ball Valve	\$7.90
External Container (Bottom)	1 inch thick, 3½ inch diameter, High-strength, Aluminum disk	\$19.71
External Container (Sides)	12 inch long, 3 inch inside diameter, ½ inch thick wall, Acrylic cylinder	\$22.03
External Container (Top)	¼ inch thick, 3 inch diameter Acrylic disk	\$6.64
Scale	ABS (Rapid Prototyped)	\$57.04
	Total Cost = \$135.51	

RESULTS

Table 3: The mean was found from 5 measurements of each object

Object Number	Accepted Volume	Mean	Standard Deviation
1	260 mL	280 mL	11.18 mL
2	150 mL	180 mL	20.92 mL
3	125 mL	160 mL	13.69 mL

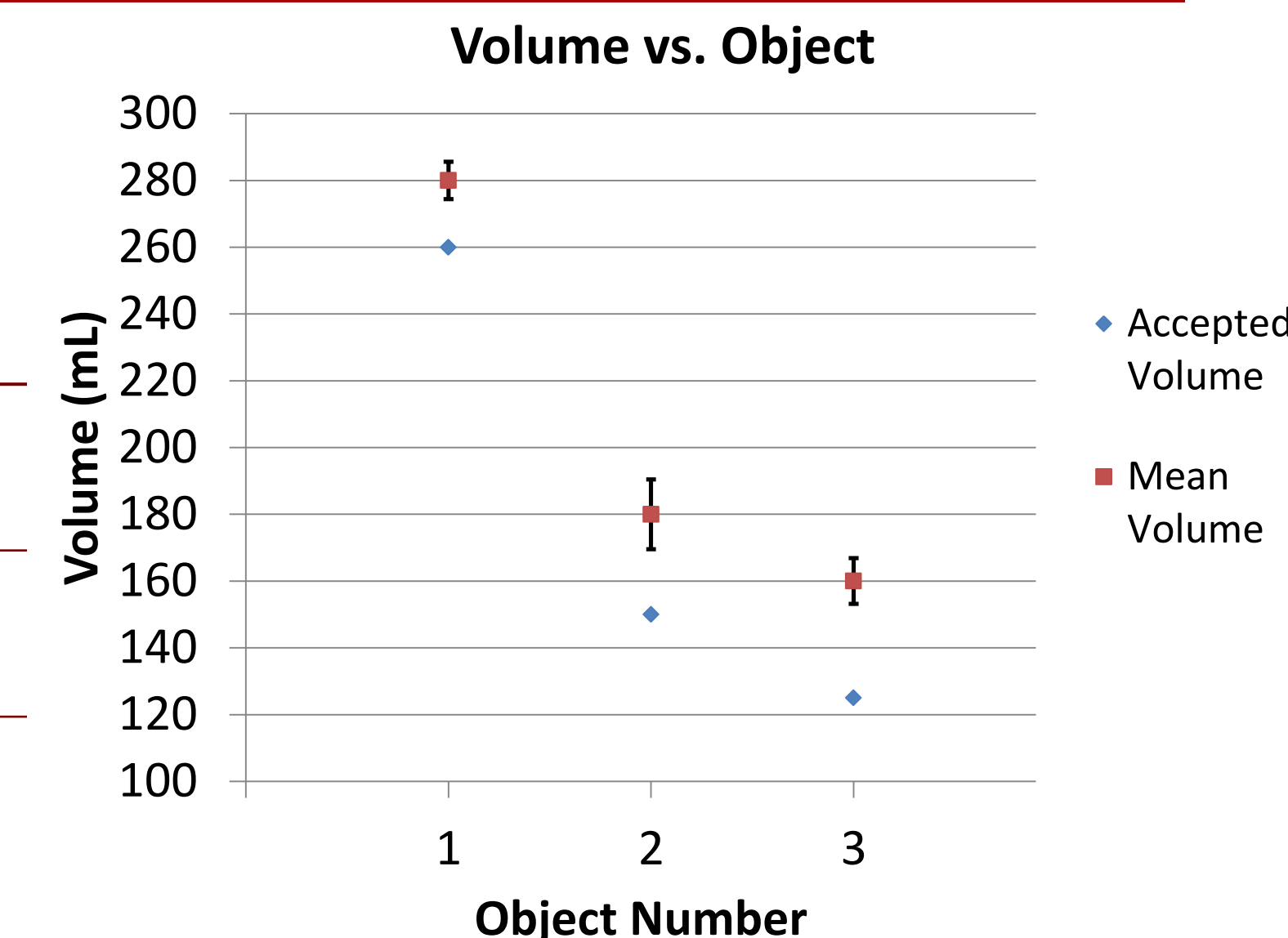


Figure 6: Error bars were one standard deviation of data set

DISCUSSION

- Testing shows repeatability
- Reasonably accurate – gives an approximate volume
- Slightly difficult to use
- Measurement was more accurate for uniform objects
- Device determined volume quickly
- Inversion of device was efficient
- Easy to switch primary container sizes

FUTURE WORK

- Improve ease of use
- Wider range of sizes
- Test the device on prosthetics and human breasts
- Change external container to a more compact size
- Add transducer that outputs the volume based on measured pressure
- Coverable or sterilizable
- Increase durability of device
- Develop better seals between containers, membrane, and valve
- Increase denominations on scale

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