



# Evaluation of the reliability of a new simple device for standardized breast volume measurements

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## Abstract

**Background** Despite the breast volume being an essential metric component of any aesthetic or reconstructive breast surgery, up to date, there has been no accepted measurement technique that is globally accepted by breast surgeons. Appropriate measurement might lead to decrease of the reoperation rates. We introduced a novel technique that provides simply accurate volume measurement.

**Methods** Thirty patients with breast cancer who were scheduled for modified radical mastectomy were included in the study. Preoperative breast volume measurement using the novel device and breast MRI studies was done for all patients; meanwhile, the gold standard technique (direct water displacement measurement of mastectomy specimen) was used to measure the volume of breast specimen following mastectomy.

**Results** There were strongly positive correlations between the device and gold standard technique ( $r = 0.957$ ) in 23 patients, and ( $r = 0.997$ ) in 30 patients when MRI was compared to gold standard measurements. In group 1 (breast volume < 500), there is a strong correlation between the device and gold standard ( $r = 0.914$ ) and for the MRI and gold standard ( $r = 0.965$ ). In group 2 (500–1000), there was also a strong correlation between the device and gold standard ( $r = 0.986$ ) and for the MRI and gold standard ( $r = 0.989$ ) as well.

**Conclusions** The novel device had been proven to be cost-efficient, simple, reproducible technique with minimal learning curve. It provides reliably comparable results to gold standard techniques and MRI measurement in breast volumes up to 1000 cc. It utilized simple material and basic principles that can be easily used in most settings.

Level of evidence: Level IV, diagnostic study.

**Keywords** Breast volume · Modified radical mastectomy · Water displacement techniques

## Introduction

Breast volume is a key metric in breast surgery, whether aesthetic or reconstructive procedures [1]. The assessment and measurement of the volume of the breast conus would be of a great value in preoperative evaluation and planning in patients with in-patient schedule for post oncological breast reconstruction, whether autologous or implant-based reconstruction, aimed at achieving symmetrical breasts [2, 3]

Breast volume measurement had been always a point of controversy in literature, with no standard technique available.

Despite the description of multiple techniques by a number of authors for accurate breast volume measurement, up to current date, there has been no globally accepted or routinely performed technique among surgeons. This is due to the lack of clear information regarding reliability and accuracy of these techniques in clinical practice [4]. Additionally, the difficulty and discomfort that can be afforded to the patient while using the Archimedes method or casting has limited their use [4–6].

The main difficulty during accurate measurement of the breast volume lies in the fact that the breast is a three-dimensional structure that is hanging from a curved chest wall, adding to that are the variations in breast shapes, sizes, and positional change [2, 7], and difficulty in identifying the breast boundary particularly in obese patients [8]. All these factors cause significant variability in volume measurement.

In this study, a novel technique had been introduced for breast volume measurement that could be easily integrated in

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every breast surgeon's daily practice, with high level of accuracy, while affording minimal patient discomfort. In order to verify the accuracy and reliability of the novel device, we compared the measurements obtained to both the gold standard technique (direct water displacement measurement of mastectomy specimen) and the MRI breast volumetric measurements in each individual case.

## Material and methods

Following obtaining ethical committee approval, written informed consents were obtained; patients suffering from breast masses and those who were scheduled for a modified radical mastectomy (MRM) procedure were included in our study.

For all patients, preoperative breast volume measurement was done using the newly introduced device and breast MRI studies, which is a routine practice in this group of patients; meanwhile, the gold standard technique was used to assess the volume of breast specimen following MRM. For the sake of abolishing bias due to major volume discrepancy, patient who underwent skin sparing mastectomies were excluded, since the remaining envelopes could not be measured using the gold standard technique. Also, patients with breast cancer stage IV, patients with fungation or ulceration on the breast surface, pregnant patients, and patients who were not candidates for MRI studies were excluded.

For the sake of proper evaluation of the device, we divided the patients into 2 groups according to their breast volume; patients with breast volume less than 500 cc, patients with breast volume between 500 and 1000 cc, patients with breast volume more than 1000 cc were excluded from this study, since the plastic cup used in this study was manufactured to accommodate breast volumes up to 1000 cc only.

### Breast volume measurement using the novel device

An appropriately sized, pre-calibrated, specially manufactured plastic breast cup with four openings (two on each size, which enable the same cup to be used for both right and left sides), where two of the openings were sealed during measurement, depending on the breast side being measured (Fig. 1), while one of the two other openings was connected to a reversely calibrated cylindrical jar by a rubber tube, was used. The remaining opening helped in allowing air displacement as the cup is filled with water during measurement.

The plastic breast cup was applied to the breast while the patient was lying supine; this insured a water-tight seal; a transparent film dressing was used to ensure proper sealing, thus avoiding any fluid leakage.

Following proper positioning and sealing, water at body temperature was added to the cylindrical jar. By simple gravity, the water moved from the jar filling the plastic breast cup



**Fig. 1** A picture of the novel device that we used in this study. It consists of a pre-calibrated plastic breast cup which is connected to a reversely calibrated cylindrical jar by a rubber tube

and displacing the air outside. Once the water level is stabilized in the jar, ensuring complete fill of the remaining space within the breast cup, the breast volume measurement could be easily obtained from the reversely calibrated jar according to the fluid level (Fig. 2).

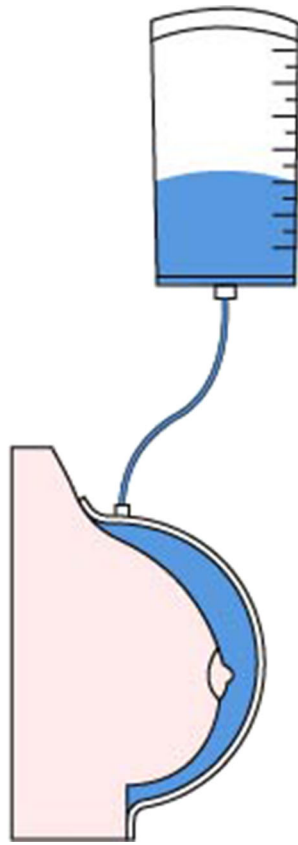
### Breast volume measurement using breast MRI

Breast volume measurements were made using a 1.5-T MRI machine, using dedicated double breast coil with eight channels.

On the sagittal cuts, the breast regions were drawn and the tissue volumes were estimated in cubic centimeters for each slice individually; then, the total breast volume was calculated as the sum of all individual slice volumes as described by Bulstrode et al. [5]. All measurements were made by the same radiologist to ensure uniformity of the method.

### The gold standard technique

Mastectomy specimens, before being fixed and after separation of the axillary component, were directly merged in saline-filled calibrated jar. The breast volume was determined by calculating the amount of displaced water. This was repeated three times to get an average volume for each breast.



**Fig. 2** An illustration showing the application of the device to the patient. Following proper positioning on the chest wall and sealing, water at body temperature was added to the cylindrical jar. By simple gravity, the water moved from the jar filling the plastic breast cup, and the breast volume is then obtained

### Statistical analysis

Data was statistically described in terms of mean  $\pm$  standard deviation ( $\pm$  SD), or frequencies (number of cases) and percentages when appropriate. Numerical data were tested for the normal assumption using the Kolmogorov-Smirnov test. Comparison of numerical variables between each of the three methods, (a) device measurements, (b) MRI results, and (c) the gold standard results, was performed using paired *t* test. For comparing categorical data, chi-square ( $\chi^2$ ) test was performed. Exact test was used instead when the expected frequency is less than 5. Two-sided *p* values less than 0.05 was considered statistically significant. All statistical calculations were done using computer program IBM SPSS (Statistical Package for the Social Science; IBM Corp., Armonk, NY, USA) release 22 for Microsoft Windows.

### Results

Between January 2017 and October 2019, a total of 30 breasts were included in the current study, with a mean age of  $32.1 \pm$

13.43 years (range, 18–57 years). Patients' mean BMI was  $28.33 \pm 4.49$  (ranging from 20 to 37) (Table 1). All patients had been measured using the three modalities. However, it is important to mention that 8 patients presenting were excluded, as the current manufactured cup volume was insufficiently small, therefore hindering a proper complete fit for the breast conus and volume measurement.

In group 1 (breast volume  $< 500$ ), there were 11 patients and the mean breast volume in gold standard technique was  $339.09 \pm 101.623$ ; for the device, it was  $341.82 \pm 91.084$ ; and for the MRI, it was  $376.82 \pm 100.256$ . The mean difference between the device and gold standard for this group was  $-2.81 \pm 13.279$ , while the mean difference between MRI and gold standard was  $12.38 \pm 11.744$ . Paired sample correlation between the device and gold standard was 0.914; and for the MRI and gold standard, it was 0.965; both of them were highly statistically significant (Table 2).

In group 2 (breast volume between 500 and 1000), there were also 11 patients and the mean breast volume in gold standard technique was  $733.63 \pm 139.662$ ; for the device, it was  $765.45 \pm 136.775$ ; and for the MRI, it was  $747.27 \pm 152.338$ . The mean difference between the device and gold standard for this group was  $-4.61 \pm 3.213$  while the mean difference between MRI and gold standard was  $1.67 \pm 3506$ . Paired sample correlation between the device and gold standard was 0.986, and for the MRI and gold standard, it was 0.989; both of them were highly statistically significant (Table 3).

When we compared the results of the device as opposed to the MRI measurements, there was a strong correlation ( $r = 0.954$ ) which showed high statistical significance.

### Discussion

Despite breast volume measurement being an essential requirement for achieving aesthetically pleasant symmetrical breasts in patients undergoing reconstructive or aesthetic breast procedures, the amount of tissues to be removed or added during aesthetic and reconstructive procedures is estimated essentially using simple anthropometric measurements preoperatively, and mainly depends on the surgeon's own experience as the sole guarantee for accurate estimation. Direct measurement of the breast volume by the gold standard technique provides an accurate estimation of the volume of removed tissue in oncological mastectomies intraoperatively; this scenario is however unavailable in other cases and cannot be used for preoperative volume measurement [3, 9–11].

Despite several techniques had been proposed for accurate breast volume measurement through the use of water displacement techniques (Archimedes) [12–14], breast casts [15, 16], medical imaging technology [17], and devices based on geometric measurement [18], up to date, there have been no clinically relevant objective breast volume measurement

**Table 1** Demographic distribution of patients according to each group with the percentage of difference between MRI and gold standard measurement as well as the device and gold standard measurement

Group	Number		Age	BMI	MRI	Device	Gold d standard	MRI % diff	Device % diff
< 500	11	Mean	31.00	24.82	376.82	341.82	339.09	12.38	– 2.81
		Std. deviation	14.128	4.309	100.256	91.084	101.632	11.744	13.279
500–1000	11	Mean	29.64	29.00	747.27	765.45	733.64	1.67	– 4.61
		Std. deviation	14.193	2.569	152.338	136.775	139.662	3.506	3.213
> 1000	8	Mean	37.00	32.25	1656.88	1000.00	1640.00	0.70	25.93
		Std. deviation	11.637	3.151	328.839	-	282.084	3.763	-
Total	30	Mean	32.10	28.33	854.00	573.04	830.67	5.34	– 2.42
		Std. deviation	13.430	4.490	553.248	256.523	552.648	9.222	11.128

techniques or devices that can be routinely used for simple preoperative quantitative volumetric measurements of the breasts [4].

The purpose of this study was to provide a clinically reliable device for accurate breast volume measurement that would serve as a base for further studies and future modifications. Since the gold standard technique provided highly accurate measurements, we compared the measurements obtained by the newly designed device to those measurements obtained by the gold standard technique following MRM of the same patient. We also compared the obtained results to the MRI measurements.

The selection of patients undergoing MRM comes from the fact that the range of errors during the gold standard measurement in those patients is limited, since a small part of the breast envelop is kept, which serves in reducing the margin of error. Unlike the skin sparing technique, most of the breast envelop is preserved, therefore leading to an underestimation of the volume.

Since the conservative breast surgeries had become the trend in the treatment of breast cancer nowadays, the clinical spectrum for application of MRM becomes restricted to patients with advanced or aggressive breast cancer. According to Radecka and Litwiniuk, the growing number of young patients diagnosed in more advanced stages is due to the lack of screening and preventive measures in that age group [19, 20]; thus, a more aggressive disease course usually requires a more aggressive form of treatment [21]. According to Schlichting et al., the incidence of breast cancer in young patients in Egyptian

women was 3-fold of the US women. Those authors had contributed this difference to many factors; however, the age differences in the population structure of the two countries had been the most important factor in their conclusion [22]. We attributed our younger study population mainly to those two factors. However, another important consideration was noticed in our population that the older patients had showed disinterest regarding breast reconstruction following MRM, unlike the younger patients.

In the current study, single density value was used based on the work of Yip et al. [2] who stated that single value could be used effectively for multiple patients. Literature review revealed that accepted value should be between 0.92 and 1.00 g/cm<sup>3</sup> [4]. However, Parmar et al. [23] reported an average density of 1.07 g/cm<sup>3</sup> when they compared weight and volume of 69 breast specimens. We attribute this difference between both values reported in literature and Parmar et al.; as the majority of Parmar et al., specimens were breast that contained a cancer mass. Since the density of the tumor itself is higher than normal fat density, this could explain their finding. In our study, we used a value equal to 1.00g/cm<sup>3</sup> which is the average value between both values; adding to that, we excluded patients with large or fungating mass in order to avoid large masses which in turn will increase the density of the whole specimen.

The results obtained in the current study showed a strong correlation between the measurement of the device and the measurements obtained by the MRI as opposed to the measurements of the gold standard technique, which proved

**Table 2** Paired samples correlations between the device and gold standard (pair 1) and MRI and gold standard (pair 2) in patients with breast volume < 500 cc

		N	Correlation	p value
Pair 1	Device and gold standard	11	0.914	0.000
Pair 2	MRI and gold standard	11	0.965	0.000

**Table 3** Paired samples correlations between the device and gold standard (pair 1) and MRI and gold standard (pair 2) in patients with breast volume 500–1000 cc

		N	Correlation	p value
Pair 1	Device and gold standard	11	0.986	0.000
Pair 2	MRI and gold standard	11	0.989	0.000

highly statistically significant results. Nevertheless, the MRI showed slightly higher correlation, when compared to the results obtained by the novel device. This led to the conclusion that both the device and MRI can be used with high level of confidence preoperatively and for obtaining accurate breast volume measurements.

In order to assess the significance of volume difference between both MRI and device when compared to gold standard technique, there was no statistically significant difference between the device and gold standard technique; meanwhile, there was statistically significant difference between the MRI and gold standard. These results give the device a clinical privilege over the MRI when compared.

Despite the MRI showing a stronger correlation with the gold standard technique, there were multiple drawbacks for its routine use on larger scales. In this study, all patients were breast cancer patients, so MRI scanning was an integral part of their preoperative evaluation. However, the use of MRI preoperatively in aesthetic breast surgeries will significantly add to the cost and can be considered unwarranted overuse of the investigation; this is considered in the light of the cost benefit given that the only significant data that will be obtained is a volumetric measurement that can otherwise be obtained with much simpler technique. Not to forget patients suffering from claustrophobia as well as those with contraindications for MRI such as pacemakers [5]. Accordingly, the novel device can fit to provide a simpler modality applicable to all patients with great practicality, and with high level of confidence near or equal to MRI measurement. The device seemed to be tolerated well by all patients with no contraindications or side effects to its use [24].

The limitation of measurement of large breast volumes > 1000 cc in this current study was due to the fact that the plastic cup size used in this study was manufactured to fit sizes up to 1000 cc only. Our main concern during the preparation of this study was that increasing the cup size and diameter might hinder readings among smaller busted patients as it may affect the seal and lead to water leakage; thus, we preferred to use our device only in patients with breast volumes up to 1000 cc only. However, with alternatively differently sized cups accommodating larger breast volumes, this device can be used easily in those patients. A more detailed study will be needed then to evaluate the accuracy of the device in patients with breast volumes more than 1000 cc.

Despite large volume errors negatively impacting a surgeon's ability to make an appropriate decision, for example, the volume need for aesthetic breast reconstruction, literature review revealed a great diversity of accepted error of measurements, with the highest accepted errors had been reported by Losken et al. [25] who suggested a volume error as high as 10% of breast volume. Other reports stated that a 5 to 10% appears to be acceptable in clinical practice [24, 26–28]. MRI consistently demonstrated the highest accuracy, and many

authors had reported measurement errors less than 10% for different breast sizes [28].

In this study, the main concern was the breast volume estimation for each breast, independent of all the other estimates that are of great value during breast aesthetic or reconstructive procedures. One must put in mind that the breast conus volume is a single variable out of many other important parameters that also play a great role in decision-making, such as anthropometric measures of the breast, skin quality, the degree of breast ptosis, skin incision patterns, technique used for ipsilateral breast reconstruction, and technique used for breast reshaping on the contralateral side. Lastly, because this study was conducted in a single academic center, the sample size was relatively small; thus, we recommended a study on a bigger scale as well as including patients with large breast volume to prove the high efficacy of this device.

## Conclusions

The novel device had been proven to be a cost-efficient, simple, reproducible technique with minimal learning curve. It provides reliable comparable results to gold standard techniques and MRI measurement in breast volumes up to 1000 cc. Although a wider range of cup sizes should be developed to be easily applicable for different breast sizes, a fact that a modification to the device making it into a closed system can add to both the accuracy and simplicity of the device.

## Declarations

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The Ethics Committee of Cairo University approved this study.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

**Patient consent** Patients signed informed consent regarding publishing their data.

**Conflict of interest** Rasha Abdelkader, Tarek Mahboub Ahmed, Walaa Anis Mansour, Sahar A. Abdalbary, Mohammed Ahmed Hussein declare no conflict of interest.

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