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Larger breast implants warranted for post-mastectomy reconstruction

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ABSTRACT

Aim: Our goal was to ascertain if there was a role for larger breast implants in breast reconstruction. **Methods:** Patients that underwent mastectomy and implant-based breast reconstruction were identified and reviewed. **Results:** Of the total specimens, 92 (14.7%) weighed more than 800 g with a mean weight of 1140 g (range 803 to 2177 g). Of the patients with these larger specimens, 45 (48.9%) selected the largest available implants (800 mL implants) for their reconstruction. **Conclusion:** There are patients undergoing mastectomy and implant-based breast reconstruction who are unable to have reconstruction to their native breast volume because of the current implant-volume restrictions.

INTRODUCTION

The mastectomy rate in the United States has been steadily increasing, including the rate for contralateral prophylactic mastectomy and elective mastectomy[1-5]. Mastectomies permanently alter a patient's body image and thereby impact self-esteem[6]. Patients who undergo breast reconstruction after mastectomy are more satisfied than those who undergo mastectomy without reconstruction[7-9]. However, the reconstructed breast can leave a patient feeling incompletely restored when the native breast size was larger than reconstructed breast volume[10]. Limited data exists that links patient satisfaction to the size of a reconstructed breast[10], especially for patients who have native breast volumes larger than 800 mL. These women are not able to match their native breast size with implant alone based reconstruction with the current implant-size limitations imposed by the US Food and Drug Administration (FDA) (maximum volume, 800 mL, Table 1). Of note, the FDA has recently approved human trials of larger breast implants (volumes to 1445 mL)[11,12]. We designed a retrospective study to determine how native breast volumes related to reconstructive implant volumes for patients who underwent mastectomy followed by

Table 1: FDA-approved breast implants (January 1, 2016)

Breast implants	Volume range (mL)
Saline-filled	
Ideal Implant Saline-Filled Breast Implant (Ideal Implant Inc.)	210-755
Allergan Medical RTV Saline-Filled Breast Implant (Allergan, Inc.)	120-800
Mentor and Spectrum (Mentor Worldwide)	125-700
Silicone Gel-filled	
Allergan Natrelle (Allergan, Inc.)	80-800
Allergan Natrelle 410 (Allergan, Inc.)	140-740
Mentor MemoryGel (Mentor Worldwide)	100-800
Mentor MemoryShape (Mentor Worldwide)	120-775
Sientra (Silimed Indústria de Implantes Ltda)	80-700

FDA: US Food and Drug Administration. Data from FDA. Silicone gel-filled breast implants [Internet]. 20 Sep 2013 [cited 24 Mar 2016]. Available from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants

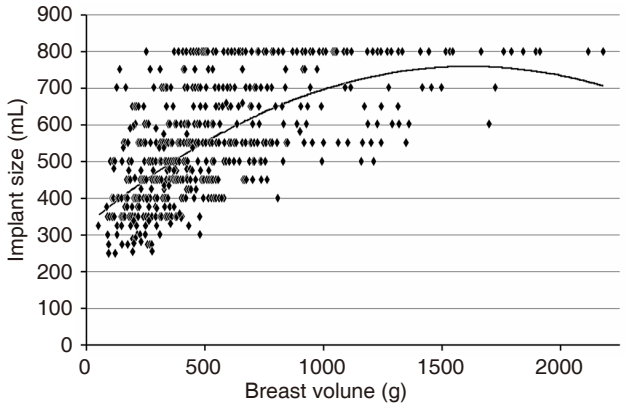

Figure 1: Relationship of breast volume to implant size, with curve of best fit showing a high positive correlation between native breast volume and the implant size used for reconstruction

reconstruction with a silicone gel-filled implant.

METHODS

This retrospective study was conducted at 2 tertiary care centers after institutional review board approval at both locations. We reviewed electronic health records of patients who underwent mastectomy followed by reconstruction with silicone-gel breast implants during a 5-year period from January 2009 to December 2014. All patients included in the study underwent mastectomy either for a diagnosis of breast cancer or a desire for prophylactic mastectomy. All patients had reconstruction with breast implants either at the time of mastectomy or by tissue expansion and subsequent implant reconstruction. Each patient had only one implant per reconstructed breast, no implant stacking was utilized. We collected data regarding mastectomy specimen weights and final implant volumes used in the breast reconstructions. The patients' native breast volume was extrapolated from the recorded mastectomy specimen mass. Each breast was considered separately (a patient with a bilateral mastectomy and bilateral implant reconstruction was entered in the data twice, with unique data for each breast). Patients who underwent any form of autologous tissue reconstruction or had saline implants were excluded.

RESULTS

Weights were available for 627 mastectomy specimens for patients who underwent mastectomy and implant-based reconstruction during the 5-year period. The mean gross mastectomy specimen weight was 501.2 g (range 51 to 2177 g). The mean implant size used in the reconstructions was 533.9 mL. The mean patient body mass index (BMI) was 26.9 (range 16.6 to 52). Of the total specimens, 92 (14.7%) weighed more than 800 g (mean 1140 g and range 803 to 2177 g) and these patients had a mean BMI of 34.0 (21.3 to 52). Forty-five (48.9%) of the patients with these larger specimens selected 800 mL implants for their reconstructions. From our total patient population, 80 patients (12.7%) chose 800 mL implants for their reconstructions. The mean specimen weight for this group was 933 g (252 to 2177 g) and the mean BMI was 34.6 (20.3 to 49.5). The Figure 1 shows the trend for native breast mass (as a proxy for volume) *vs.* reconstruction implant size.

DISCUSSION

Patients' desires ultimately determine the goal of post-mastectomy breast reconstruction. Not all patients with large native breasts (mastectomy specimens > 800 g) selected 800 mL implants for their reconstruction. Alternatively, some women with smaller breasts (mastectomy specimens < 800 g) chose to increase the size of their breasts at the time of implant-based reconstruction by selecting 800 mL implants. Thus, at the time of breast reconstruction, some patients with large breasts wanted to have smaller reconstructed breasts, some with smaller breasts wanted larger

reconstructed breasts, and many elected to maintain a similar breast volume following their mastectomy. Other factors to be considered in the decision regarding the size of implant used in reconstruction may include history of radiation or other comorbid conditions such as current smoking status and diabetes. Native breast shape and degree of ptosis must also be considered. These are especially important when trying to achieve symmetry in unilateral breast reconstruction. There are many reconstructive options available to patients, thus surgeons must aid patients in this decision making process.

A study by Huber *et al.*[10] reported that women who augmented their native breast volume at the time of reconstruction were more satisfied with their overall reconstructive outcome than those who did not, and no increase in complication rate occurred in those who augmented their breast volume. For woman with large breasts, low patient satisfaction may be related to the inability to match native breast volume with a similarly sized implant at reconstruction because of current implant-volume restrictions. Patient-reported outcomes would provide more insight as to what influences patients' initial decisions, if they remain satisfied long-term with their choice, and if they would have chosen differently had a larger implant been available at the time of their reconstruction.

Women may have asymmetry between native breast volumes. Those who underwent unilateral mastectomy with implant based reconstruction likely desired their reconstructed breast to appear similar in size and volume to their native breast. This would affect their choice in implant size.

Our study is limited by the lack of patient-satisfaction data for our patient population. However, it was not designed to evaluate this aspect of breast reconstruction. To investigate this further, we would use an outcome measurement tool, such as the BREAST-Q questionnaire (Memorial Sloan Kettering Cancer Center). Future studies could investigate the relationship between patients' preoperative decisions and postoperative satisfaction scores. For example, how many patients would have selected an implant with a volume > 800 mL if they had that option available to them at the time of their reconstruction? This will be especially informative when patients have the option to match their native breast volume to breast implant volumes as large as 1445 mL.

In addition to satisfaction data, future studies will investigate complication rates to ensure that larger implants are as safe and effective as those currently approved for use in reconstruction. Larger implants will have their own unique risks. Known complications that may be associated with breast implants include, but are not limited to, asymmetry, tissue atrophy/skin necrosis, extrusion, infection, hematoma, ptosis, and pain. The specific incidence of these, and other, complications associated with large volume implant use will need to be determined.

Furthermore, patients with class II or III obesity have an increased risk of surgical morbidity following breast reconstruction of any modality[13]. The risks of larger implant use in this population should be carefully considered. In our study, women with breast volumes greater than 800 g had a mean BMI of 34.0. BMIs of 30-34.99 are classified by the World Health Organization as obesity class I[14]. This patient cohort is not at increased risk of surgical morbidity following breast reconstruction[13].

There may be a role for implants larger than 800 mL for patients undergoing post-mastectomy breast reconstruction in the United States. The FDA has recently approved ATHENA, a clinical trial that will allow patients to select breast implants with larger volumes ranging from 800 to 1445 mL for breast reconstruction. Patient preferences and outcome goals will continue to guide reconstructive efforts. Future studies on satisfaction and complication rates will allow us to better counsel our patients and assist them in their decision making.

DECLARATIONS

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Authors' contributions

Abstract and manuscript author, data collection: A.L. Howarth

Substantial data collection, manuscript review: A.M. Rodriguez

Abstract writing and data collection, manuscript review: V. Gargya

Substantial data collection, manuscript review: H.D. Lucas

Primary investigator, original idea, manuscript review: R.C. Mahabir

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Conflicts of interest
Dr. Mahabir serves on the Mentor Advisory Board.

Patient consent
Institutional review board approval was obtained at both locations of data collection prior to beginning this retrospective study.

Ethics approval
Institutional review board approval was obtained at both locations of data collection prior to beginning this study.

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