



## Volume Change after Primary Breast Augmentation: Predicting and Defining a Significant Cause for Re-Operation

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### Abstract

**Introduction:** Accepted re-operation rates after primary breast augmentation range between 20% to 30% with requests for volume change as a leading cause. This is the first report to characterize this patient population and define actual volume changes.

**Methods:** We conducted a retrospective review of 812 patients that underwent primary augmentation mammoplasty at the authors' previous surgery center over a fifteen year period. On average, patients were white females, 36 years old and with a BMI of 21.0 kg/m<sup>2</sup>. They were augmented primarily with Mentor Moderate Profile implants (average 318 cc) in the sub-muscular plane (51.9%). Charts were queried for patient demographics and implant characteristics. A Chi square test was used to compare binary data and a Student's t-test and correlation coefficients were used to compare ordinal data.

**Results:** Our mean follow-up was 2.2 years (range 0 to 13 years) with a rate at six years of 31.5%. The re-operation rate was 20.1% at three years and 5.7% of patients underwent volume change. Women requesting a volume change were four times more likely to have saline implants ( $p=0.001$ ), thinner, and have larger implants placed at initial operation ( $p=0.012$ ). Examining the 46 patients revised for volume dissatisfaction, the average change was 10.2% larger (35.0 cc, range: -235 cc to 170 cc). Women requesting larger implants had significantly more augmentations in the sub-muscular plane and those requesting smaller implants had significantly more augmentations in the sub-glandular plane ( $p=0.022$ ). Time to re-operation, age, BMI, and type of fill material did not significantly influence a woman's desire to be larger or smaller.

**Discussion:** A majority of women re-operated on for volume discrepancy wished to be larger (66.0%). Patients dissatisfied with their volume had significantly more saline devices and larger implants at initial operation. Pocket location also significantly influences a patient's perception of breast size.

**Keywords:** Size; Volume; Change; Augmentation; Breast

### Introduction

Over four million women worldwide have prosthetic breast implants for aesthetic and reconstructive purposes. In 2015, roughly 279,000 women received breast implants in the United States alone [1]. Although this is a decrease of 12% from the prior year, augmentation mammoplasty remains the number one cosmetic surgical procedure. Patients and surgeons today have multiple options of implant fill, surface texture, shape, projection and pocket location to tailor an implant to both the patient's body and her wishes. Despite this, patient dissatisfaction with size remains a significant cause for revision surgery [2].

Implants are widely considered safe; however, they are not without local complications such as hematoma, infection, and malposition and systemic complications of capsular contracture and patient dissatisfaction. Most large series quote a re-operation rate at three years for augmentation patients of approximately 20% to 30% [3,4]. Capsular contracture and volume dissatisfaction account for a majority of these cases [5]. One positive from the FDA imposed moratorium on silicone breast implants is the wealth of data from the pre-market approval studies (PMA) performed by Allergan and Mentor Corporations. With a 61% six year follow-up, the Mentor study found a 19.4% re-operation rate, a contracture rate of 9.8%, and a replacement rate for size discrepancy of 3.9% [3].

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The Allergan study had an 81% follow-up at six years and a revision rate of 28.0% [4]. Almost 15% noted significant capsular contracture and 10% of patients were revised for volume dissatisfaction. Of these, two thirds requested larger implants although the actual volume changes are not published.

Patient expectation and ultimate satisfaction with the volume, feel, and look of their breasts is subjective. The ultimate decision on implant volume is made in the operating room based on patient input and surgeon experience. Complicating the design is the fact that well over 80% of women do not wear the correct bra size; thus, quoting cup size is an inexact science [6,7]. Previous reports have focused on anatomic measurements, pre-operative bra fillers and computer simulations to improve patient satisfaction [8-14]; however, volume dissatisfaction remains a significant cause for re-operation.

The purpose of this study is to review our experience with revision breast augmentation surgery and to both define the volume changes and describe the patient population. Our fundamental questions were: (i) what percentage of patients that we see in follow-up request an implant size change, (ii) can we predict those patients that will be unhappy with their implant volume, and (iii) whom are the patients wanting to be smaller or larger?

## Methods

A medical record search was conducted at Paces Plastic Surgery in Atlanta, Georgia to review patients that underwent primary breast augmentation. Data was taken from pre-operative consultations, operative reports, implant identification cards, and follow-up notes. When applicable, pre-operative and post-operative photographs were taken. Between 1994 and 2005, women received only saline filled breast implants due to the FDA imposed moratorium on silicone gel devices. Thereafter, both silicone and saline devices were implanted.

Pre-operative assessment was performed via the high-five measurement technique, and taking account of the patient's subjective desires. The authors used the axiom that a skin pinch of less than 2 cm obligated placing the implant in the sub-muscular plane. Nipple to notch, nipple to inframammary fold, and base width measurements were also variably used to guide implant volume.

All patients were given pre-operative antibiotics, most often cefazolin, and drains were not used. Incisions were made in the axilla, inframammary fold or around the areola. Both sub-muscular and sub-glandular pockets were created based on the patient's overlying tissue envelope and the surgeon's preference. Strict hemostasis was ensured in all cases and pockets were universally irrigated with either saline or a triple antibiotic irrigant. Post-operative care included wearing a supportive bra for two weeks, avoiding excessive lifting or exercise for three weeks, and breast massage starting two weeks after surgery. Patients were offered free revision surgery up to one year after the original operation and a discounted rate thereafter.

Statistics and graphs were analyzed using StatPlus (AnalystSoft, Vancouver, BC). Two-sample T-tests and chi-square tests of association were conducted to determine significance of the continuous and categorical covariates, respectively. In addition, simple logistic regression was used, with dichotomous outcome direction of desired change, to assess the significance of each covariate individually. Unadjusted odds ratios and corresponding 95 percent Wald confidence intervals were calculated for each covariate.

**Table 1:** Cohort demographics.

	Non Revised (n=766)	Revised Patients (n=46)	p-value
Age	36.0	34.5	0.29
BMI	21.0	20.5	<b>0.017</b>
Initial Volume	316.6	340.2	<b>0.006</b>
Saline (%)	59.4%	80.4%	<b>0.003</b>
Sub-muscular (%)	51.9%	54.3%	0.73

**Table 2:** Revised patient demographics.

	Down-sized (n=16)	Up-sized (n=30)	p-value
Age	37.4	32.9	0.095
BMI	20.5	20.4	0.86
Initial Volume	328.8	346.3	0.30
Time to re-op (months)	32	23	0.29
Saline (%)	75.0%	83.3%	0.69
Sub-muscular (%)	31.3%	66.7%	<b>0.022</b>

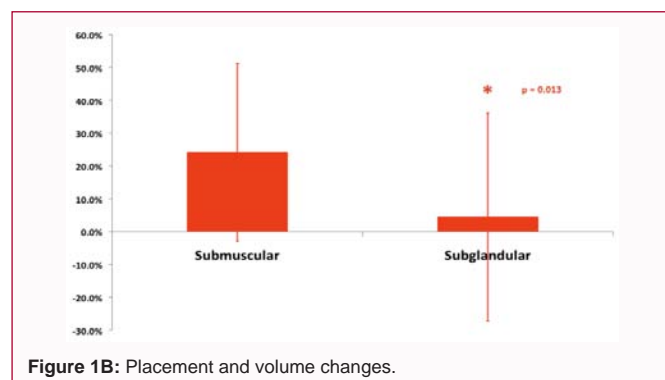
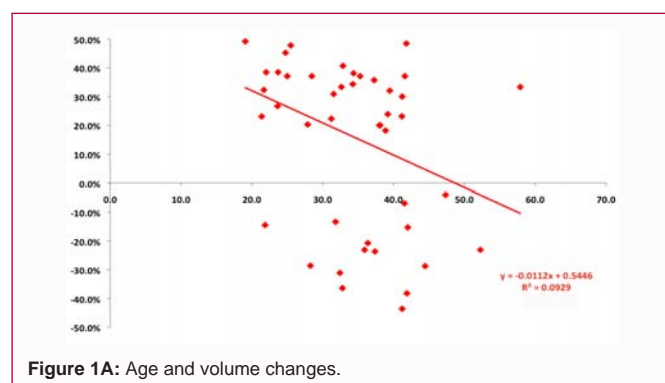
## Results

Eight hundred and twelve patients (1,624 implants) had sufficient data to be included in this study. The patients were all female, predominantly Caucasian, 36 years of age (range 16-72), and with a body mass index (BMI) of 21.0 (range 15.3-40.7). Mentor implants (Mentor Corporation, Santa Barbara, CA) were exclusively used in this cohort. Patients were augmented predominantly with a Moderate Profile implant averaging 318 cubic centimeters (range 125 cc to 650 cc). Saline-filled implants were used in 59.4% of patients. There was an even distribution between sub-muscular placement (51.9%) and sub-glandular placement (Table 1). The mean follow-up time was 2.2 years (range 0 to 14.5 years) with a six year follow up of 31.5%. The mean follow-up time for silicone implants was shorter than saline due to the moratorium on silicone implants by the FDA (1.3 years vs. 2.8 years).

Forty-six patients (5.7%) were later revised for volume dissatisfaction at a mean of 22 months post-augmentation (range 0 to 119 months). These women were on average 34.5 years old (range 19 to 58) and with a BMI of 20.5 (range 17.7-23.9). The revised patients had larger implants placed originally (340.2 cc), but with a similar percentage of implants in the sub-muscular plane (57%). Considerably more patients revised for volume dissatisfaction had saline devices place on initial operation (80.4%). No statistical difference existed between the revised and non-revised patients in regard to age, BMI, and pocket location (Table 1).

In total, women undergoing revision were up-sized on average 10.2% (34.9 cc) with a range of -235 cc to 170 cc. One-third of patients requested and received smaller implants at an average of a 92 cc decrease while two-thirds of patients received larger implants at an average of a 103 cc increase. Sixty-five percent of women with saline implants received saline implants at re-operation while thirty-five percent switched to silicone. A majority of those switched from saline to silicone after the FDA moratorium was lifted in 2005. No patients were converted from a sub-glandular to a sub-muscular pocket, but 21.5% of sub-muscular implants were changed to sub-glandular (Figure 1A and 1B).

The average time to re-operation for the 46 women was 26 months. Those women requesting smaller implants were re-operated on at 32 months and those requesting larger implants at 23 months



( $p=0.29$ ). There was no difference in BMI for patients receiving larger versus smaller implants (average BMI=20.5 for both groups,  $p=0.86$ ). The original implants in the population down-sized were smaller when compared to the patients up-sized (329 cc and 346 cc, respectively), however, this was not statistically significant ( $p=0.30$ ). Patients augmented with saline implants were re-augmented with a 40 cc increase compared to a 14 cc increase for silicone implants ( $p=0.38$ ). The average age of women requesting smaller implants was 37.4 years vs. 32.9 years for women wanting larger devices, a trend that was close to significance ( $p=0.095$ ).

Sub-muscular placements were significantly associated with patients requesting larger implants both on uni-variate and multi-variate analysis. Women augmented in the sub-muscular plane received larger implants initially (342 cc vs. 331 cc for sub-glandular); however, they requested and were augmented with significantly larger implants at re-operation (15.8% increase vs. a 1.0% increase,  $p=0.022$ ). Significant results are displayed in Table 1 and 2.

## Discussion

Roughly one in four women will undergo re-operation after breast augmentation due to local and systemic complications [15]. Volume dissatisfaction ranks as one of the leading causes; however, there is a dearth of information in the literature defining volume discrepancies. Previous reports have focused on pre-operative bra fillers and anatomical measurements to improve patient satisfaction. These methods are a great adjunct as they focus on prevention; unfortunately they cannot simulate the feel, weight and look of breast implants. To date, only pre-operative ptosis and concomitant mastopexy are shown to predict the need for re-operation in augmentation patients [16]. Therefore, we wanted to review our experience to determine if patient and surgical factors could predict those patients likely to be unhappy with their augmented breast volume.

Women that return to clinic dissatisfied with their augmented breast volume may be a unique population. A large majority of these patients requested and received larger implants at re-operation. Originally, we speculated that women requesting larger implants would be younger, heavier, have smaller implants placed initially, and implants in the sub-muscular plane. This was not evident in this series nor our previous experience [17], and it is likely attributable to several factors.

## BMI

Our population of primary breast augmentation patients represents a regional sample of young, thin, healthy women. As a result, the standard deviation of BMI in the overall cohort was only 2.45 points, and thus the difference between a “heavy” and “thin” patient is minimal. The population of women, we re-operated on for volume discrepancy had a statistically significant lower BMI; however, the difference was less than a point and we feel is not clinically relevant despite previous anecdotal reports [18]. To support this, no BMI differences were seen between women wanting larger versus smaller implants.

## Age

Women seen in follow-up requesting a volume change were relatively the same age at primary surgery as the cohort. A trend was evident that younger women were more likely to request larger implants; however, the numbers were not large enough to reach statistical significance. This is partially due to the relative homogeneity of our patients. The ideals, perceptions and body image of a 33-year-old female are not likely to be vastly different from that of a 37-year-old woman.

## Implant fill

We did see more women with saline devices return unhappy with their volume; however, both the FDA moratorium and the longer follow-up with our saline devices are confounders. Most women re-operated on after the moratorium was lifted changed from a saline device to a silicone implant. We cannot fully determine if these patients were solely unhappy with their volume or if they had extra motivation to seek consultation due to a desire to switch implant fill. Furthermore, the overall follow-up for our saline cohort is twice that of the silicone population; therefore, we may expect to see more silicone patients requesting size change as time goes on.

## Initial volume

Women returning for volume revision had significantly, both statistically and clinically, larger implants placed at initial operation. More profound, those that desired volume had even larger implants in place. One explanation is larger and potentially firmer breast implants are more explicit and by nature subject to more scrutiny. Another possibility is that the patients we see for revisional surgery requesting larger implants are those women that desire the “augmented” look of larger, pronounced devices. In support of this are four women whom returned for tertiary volume change, three of which requested and received even larger implants.

## Pocket location

Overall, the returning patients had a similar percentage of sub-muscular and sub-glandular devices as the overall cohort; however, pocket location appears to influence volume perception when directly comparing the smaller cohort of women requesting smaller implants versus those requesting larger implants. The odd is that a woman will

request larger implants with sub-muscular devices are 4.4 times that of a woman with implants in the sub-glandular plane. It is clinically evident that sub-muscular implants have less upper pole fullness and less projection while sub-glandular have a more pronounced upper pole shoulder and medial fullness. It appears that women are seeking a compromise between the flat but more natural upper pole of a sub-muscular implant and the medial cleavage and show of a sub-glandular implant. These two competing elements, the augmented cleavage and the natural upper pole slope, appear to significantly motivate a woman to seek volume change. Of note, no patients underwent a pocket change from sub-glandular to sub-muscular, but 21% changed from sub-muscular to sub-glandular. Unlike Lesavoy et al. [19] description of their experience with site change from sub-muscular to sub-glandular formal-position and hyper-animation, all our patients presented to clinic with a primary complaint of size dissatisfaction. They describe an average decrease of 27 cc in 36 patients when changing pocket which partially accounts for the increased prominence expected with sub-glandular augmentation.

A woman's perception and overall happiness with her breast augmentation is dynamic and multi-factorial. The final breast is a combination of width, height, projection, and feel coupled with pre-operative expectations and sense of self. Both implant location and initial volume play integral roles in the feel of the breast as well as the inner and upper pole fullness. Most women desiring to have larger implants after augmentation are larger to begin with and have sub-muscular implants. Thus, it is possible that surgeons are underestimating the influence of cleavage and upper pole show in this patient population.

The greatest limitations of this study are its retrospective nature and the low rate of follow-up. An initial strength of our review was the rather large patient sample, however, because our follow-up rate was only 31% and the volume revision rate only 5.7% we have a small cohort of women returning for volume discontent. This is compounded when comparing the populations requesting larger versus smaller implants. Thus, differences may exist that we cannot detect from this study. We are sure that some patients may be unhappy with their implant volume but not to the degree that warrants a follow-up consultation. Furthermore, other patients likely seek another surgeon for potential revision surgery. Therefore, we feel that our revision rate and dissatisfaction rate are underestimations.

## Conclusion

In our experience, 20% of patients undergoing breast augmentation returned for additional surgery. If a patient returns to clinic complaining of volume dissatisfaction, she most often wishes to be larger. These women are more likely to have larger than average implants and implants placed in the sub-muscular plane.

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