Original Research

Restoring Breast Volume in High BMI Patients: A Single-Center Review of Breast Reconstruction Using Hyperinflated Saline Implants

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Abstract

Background. Breast reconstruction in the obese patient is often fraught with poor patient satisfaction due to inadequate volume restoration. The off-label hyperinflation of saline implants is a direct yet controversial solution to this problem, with limited studies in the literature. This study sought to determine the safety and efficacy of this technique for breast reconstruction.

Methods. A retrospective chart review was performed to identify all patients with a body mass index (BMI) greater than or equal to 30 kg/m2 who underwent breast reconstruction between the years 2013 to 2020 with saline implants filled beyond the manufacturer's maximum recommended volume.

Results. The 21 patients identified had an average age of 49 years. The mean BMI was 39.5 kg/m2. A total of 42 implants were placed; 34 were 800 mL, 4 were 750 mL, and 4 were 700 mL. The average overfill volume was 302 mL (138%). Mean follow-up was 65.0 months. Of these, 1 (4.8%) patient with a history of chest wall radiotherapy underwent reoperation for unilateral implant exposure 27 days after the index procedure, no patient sustained spontaneous leak or rupture, and 1 patient had unilateral deflation following emergent central line and pacemaker placement 2 years after the implant was placed for an unrelated cardiovascular event.

Conclusions. Hyperinflation of saline implants beyond the maximum recommended volume may be considered for volume replacement in obese patients undergoing implant-based breast reconstruction. This practice is well tolerated, has a complication rate comparable to using implants filled to the recommended volume, and has the potential to restore lost breast volume in the obese patient post mastectomy.

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Keywords: implant based; hyperinflation; breast reconstruction; saline implant; obesity; volume; plastic surgery; reconstructive surgery

Introduction

Our society is in the midst of an obesity epidemic, with over 93 million adults affected.[1] With an increasing percentage of obese patients, there is a concurrent rise in the number of breast cancer diagnoses. In 2021, an estimated 281,550 female patients will be diagnosed with breast cancer in the United States alone.[2] This is in part due to the increased risk of breast cancer seen in patients with higher body mass index (BMI).[3] Mastectomy remains a popular treatment and is the standard of care in certain circumstances.[4] The reconstructive options following mastectomy continue to evolve; yet despite advancement in surgical techniques, restoration of breast volume in the obese patient remains a significant challenge to plastic surgeons.[5]

Obese patients experience lower rates of satisfaction with reconstructive cosmesis.[6] The replacement of the sizable amount of native breast tissue extirpated with mastectomy represents a formidable challenge given the largest available implant has a

volume of 800 mL with a recommended maximum fill value of 960 mL in the United States.[7] Due to this constraint on implant size, methods to restore volume include autologous reconstruction with or without implant placement; however, this can expose the patient to increased operative time and increased incisions, both of which are inherently riskier in obese patients.[8]

A more elegant solution for attempting restoration of native breast volume in obese patients is to hyperinflate saline implants beyond the manufacturer's recommended value. Greenwald et al studied the mechanical properties of saline implants and concluded no significant differences existed in strength, elasticity, and toughness of the implant shell in overfilled implants as compared with those filled to the recommended maximum volume.[9] Similarly, Hallock studied the mechanical properties of tissue expanders and found overexpansion to 15 times the stated maximum volume was safe without risk of implant failure.[10] In the setting of breast augmentation, overfilling beyond the recommended maximum fill volume has been associated with increased implant longevity and higher patient satisfaction.[11,12]

The proven efficacy of overfilled implants regarding patient satisfaction and mechanical properties has been well documented. Prior studies have demonstrated this benefit in cosmetic patients. There is a paucity of literature, however, evaluating the use of hyperinflated saline implants in the setting of implant-based breast reconstruction. This study sought to determine the outcomes of hyperinflating saline implants in obese patients following mastectomy for the treatment of breast cancer and hypothesizes that this method is safe and effective.

Methods and Materials

Design and Study Population

A single-center, retrospective chart review, approved by the University of Louisville Hospital Institutional Review Board (protocol # 17.0522), was performed to identify all patients who underwent hyperinflation of saline implant-based breast reconstruction between 2013 and 2020 by the senior surgeon (BJW). Inclusion criteria were as follows: BMI greater than or equal to 30 kg/m^2 and implant sizes of 700 mL, 750 mL, or 800 mL expanded beyond the manufacturer's maximum recommended inflation. Exclusion criteria included BMI less than 30 kg/m^2, non–implant-based breast reconstruction, and patients with incomplete data.

Data Source, Covariates, and Outcomes

Patient demographics as well as clinical and operative variables were extracted through review of the electronic medical record. Variables extracted included the following: age, race, ethnicity, BMI, smoking status, history of diabetes, deep vein thrombosis, pulmonary embolus, peripheral vascular disease, hypertension, immunocompromised status, adjuvant radiotherapy, BRCA status, bra size, and implant size. Outcomes included postoperative complications such as surgical site infection (SSI), hematoma, seroma, length of stay, implant infection, displaced implant, readmission, reoperation, fat necrosis, dehiscence, and implant rupture/deflation.

Operative Technique

Hyperinflation is defined as expansion of saline implants beyond the manufacturer's maximum fill volume. Overinflation is defined as expansion beyond the stated implant size, but within the manufacturer's recommended maximum fill volume. A comprehensive discussion of all the risks and benefits was held with each patient prior to surgery. This included emphasizing that the hyperinflation of implants was an off-label use and thus may carry additional risks and would void any implant-specific warranty. Following this, all patients consented to undergo reconstruction with hyperinflated implants. MENTOR smooth round moderate profile plus implants (Mentor Worldwide, LLC) were used in all cases and placed sub-pectorally. The implants were hyperexpanded beyond the maximum fill volume of 960 mL, 900 mL, and 840 mL as specified by the manufacturer for 800 mL, 750 mL, and 700 mL implants, respectively.[7] The final fill volumes were ultimately determined intraoperatively, with an attempt to restore patients' breasts based on the mastectomy weights and premastectomy photographs. However, this was done cautiously to ensure a healthy skin flap, good capillary refill, and a tension-free closure.

Statistical Analysis

Descriptive statistics were used to report counts and frequencies for categorical data and medians and interquartile range (IQR) for non–normally distributed continuous data. Data storage and analysis was performed using Microsoft Excel (version 16.40, 2020).

Results

A total of 21 patients met inclusion criteria, all of whom had an immediate staged breast reconstruction with a tissue expander prior to final implant. Demographics can be seen in **Table 1**. The median age was 49 years (IQR ± 21). The mean BMI was 39.5 kg/m^2 and ranged from 30.3 kg/m^2 to 62.4 kg/m^2. The majority of patients were Caucasian (61.9%), non-Hispanic (81%), and non-smokers (71.4%). Positive BRCA status was seen in 2 patients (9.5%), and 2 patients (9.5%) had undergone neoadjuvant radiotherapy. A total of 42 implants were placed: 34 were 800 mL, 4 were 750 mL, and 4 were 700 mL. Implants were hyperinflated 50 mL to 340 mL beyond the maximum volume, which was between 200 mL to 500 mL beyond the stated shell size **(Figure 1)**. The mean hyperinflation volume was 145 mL (115%) beyond the manufacturer's recommended maximum fill volume and on average 302 mL (138%) beyond the stated implant shell sizes. There were 10 patients (47.6%)

Table 1. Patient Demographics and Comorbidities

	All patients (N=21)
Characteristic	**No. (%)**
Age, years	49 ± 21
BMI, kg/m²	39.5 (30.3-62.4)
Ethnicity	
Non-Hispanic	17 (81)
Hispanic	4 (19.1)
Race	
African American	4 (19.1)
Caucasian	13 (61.9)
Unknown	4 (19.1)
DM	8 (38.1)
History of DVT/PE	1 (4.8)
Hypertension	7 (33.3)
Immunocompromised	1 (4.8)
PVD	0 (0)
Smoking status	
Never	15 (71.4)
Current	7 (33.3)
Former	1 (4.8)
BRCA	4 (9.5)
Neoadjuvant radiation	2 (9.5)
Bra size	
B	2 (9.5)
D	6 (28.6)
DD	6 (28.6)
DDD	5 (23.8)
G	1 (4.8)
Implant size	
800 mL	34 (82.9)
750 mL	4 (9.5)
700 mL	4 (9.5)

DM, diabetes; PVD, peripheral vascular disease; DVT, deep venous thrombus; PE, pulmonary embolus.

who underwent simultaneous fat grafting to the breasts with volumes ranging from 100 mL to 250 mL. All fat grafting was performed prior to definitive implant insertion.

The average follow-up time was 65.0 months (range 21.2-97.7). The mean length of stay was 1 ± 1 day. The most common complications were fat necrosis (9.5%) and dehiscence (9.5%). The remaining outcomes were seen in 4.8% of the cohort and

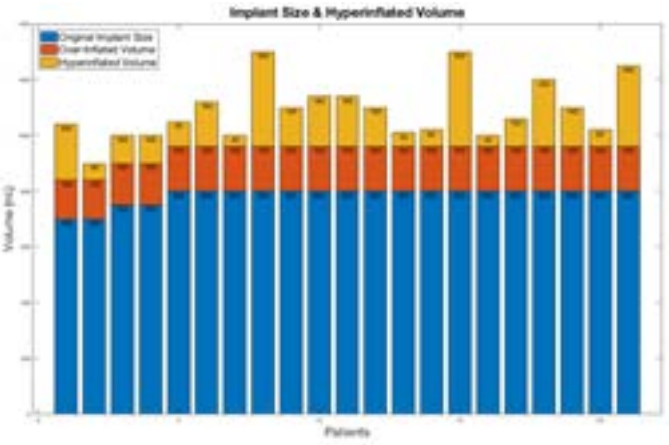

FIGURE 1. The x-axis represents each patient within this study. The y-axis is defined by implant volume as measured in mL. The blue depicts the original implant volume, red the over-inflated volume to the recommended maximum fill volume, and yellow the hyperinflated volume.

Table 2. Postoperative Outcomes

	All patients (N=21)
Characteristic	**No. (%)**
Spontaneous implant rupture 0	0
Wound complication:	
SSI	0
Hematoma	0
Seroma	1 (4.8)
LOS (median, IQR)	1 ± 1
Implant infection	1 (4.8)
Displaced implant	1 (4.8)
Readmissions	1 (4.8)
Re-operations	1 (4.8)
Fat necrosis	2 (9.5)
Dehiscence	2 (9.5)

DM, diabetes; PVD, peripheral vascular disease; DVT, deep venous thrombus; PE, pulmonary embolus.

included seroma, implant infection, displaced implant, and readmission **(Table 2)**. There were no documented surgical site infections requiring debridement or antibiotics. Reoperation was required in 1 patient (4.8%). This patient had bilateral implants and underwent removal of 1 implant 27 days postoperatively due to implant exposure on the previously radiated side. No patients experienced spontaneous implant rupture or deflation. Deflation occurred in 1 patient and was associated with emergent pacemaker and central line placement for an unrelated cardiovascular event 2 years after the index procedure.

The largest hyperexpansion occurred in 2 patients who had

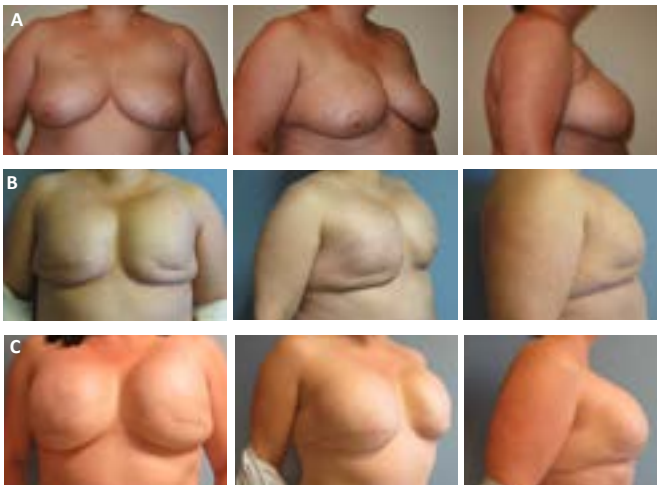

FIGURE 2. (A) Preoperative/premastectomy. (B) Postmastectomy with 800 mL gel implants. (C) Postoperative with hyperexpanded saline implants to 1020 mL.

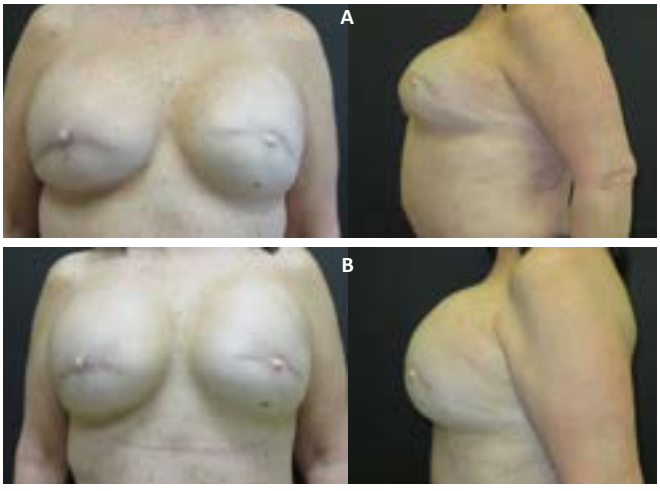

FIGURE 3. (A) Preoperative with 800 mL gel implants. (B) Postoperative with hyperexpanded saline implants to 1000 mL.

800 mL implants filled to 1300 mL, which is 340 mL beyond the recommended maximum overfill. Initial gel implants were present in 3 patients (14.3%), which were replaced with hyperexpanded saline implants per the patients' request because they were dissatisfied with the limited volume of the gel implants. Pre- and postoperative photos are seen in **Figure 2** and **Figure 3**, demonstrating satisfactory outcomes. Patients were subjectively satisfied with the reconstructive cosmesis, and there were no instances in which an implant downsize was requested nor spontaneous leakage resulted.

Discussion

Breast reconstruction in the obese patient is a formidable challenge to even the most skilled plastic surgeon. These patients experience higher rates of complications and lower rates of satisfaction due to volume and shape, especially with implant reconstruction.[6,13] Given that nearly 40% of the adult population is classified as obese (BMI > 30kg/m^2) with an expected increase in prevalence, it can be inferred that a substantial portion of breast reconstruction patients will also be obese.[14,15] Therefore, it becomes critical that efficacious therapeutic options are available for this population.

Although flap-based breast reconstruction is purported to be advantageous amongst obese patients, implant-based reconstruction remains by far the most common method,[13,16] likely due to the risks to using a flap in obese population. Obesity has been identified as an independent risk factor for major surgical, wound, and medical complications, as well as return to the operating room in women undergoing breast reconstruction.[13] A recent meta-analysis of free autologous breast reconstruction found significantly higher prevalence of overall complications and flap failure in obese (BMI ≥ 30 kg/m^2) compared with nonobese (BMI < 30 kg/m^2) patients.[17] Hyperinflation of the largest available saline implant is a simple solution to adequately reconstruct large amounts of breast volume in obese patients. This study sought to determine whether the hyperinflation of saline implants is an efficacious option to restore breast volume in the obese patient postmastectomy.

The need for larger breast implants in certain patient populations undergoing postmastectomy reconstruction has been identified in the literature. Howarth et al noted that there was a high correlation between native breast mass and implant volume while reporting nearly 15% of mastectomy specimens were over 800 grams.[18] The average weight of mastectomies in our study was over 1000 grams, demonstrating a need for additional volumetric replacement in the obese patient.

Recently, the FDA initiated the ATHENA trial, which aims to evaluate the safety and efficacy of implants up to 1445 mL.[19] Yet, the largest implant currently available remains 800 mL with a maximum fill of 960 mL.[7] This poses a challenge to adequately replace the native breast tissue lost postmastectomy in some women.[18] The use of hyperinflated implants in this study allowed for a more complete restoration of breast volume amongst obese patients.

Although a straightforward solution for the restoration of breast volume, there are inherent concerns with expanding implants beyond the manufacturer's recommendation, namely regarding spontaneous rupture or deflation due to compromising the integrity of the implant shell or valve. Yet, among this study's patient population, no cases of spontaneous implant rupture or deflation were encountered. This remained true even when implants were filled to 135% of the recommended maximum volume. Although no prior studies have measured the use of hyperinflated implants in the setting of breast reconstruction, the safety of this practice is supported within the literature in

other settings.

Overfilling of implants by more than 25 mL beyond the recommended volume was reported to have no significant differences in the rate of rupture and even demonstrated a significant advantage in 10-year implant survival in augmentation mammoplasty.[11] Becker et al studied the effects of hyperinflating implants ranging from 175 mL to 575 mL and concluded that this led to a more optimal usage of implants in breast augmentation, improving patient satisfaction by decreasing apparent rippling without increased rates of implant leakage or rupture.[12] Furthermore, the mechanical integrity of the implant shell has been assessed ex vivo with values up to 500% of the fill recommendation in a 275-mL implant and found to have no significant differences in terms of strength, toughness, or elasticity compared with the recommended level of inflation.[9] This study's lack of spontaneous implant rupture and deflation is well supported in the literature and is in concordance with the mechanical properties of the implant shells.

Obesity is known to increase the risk of complications following surgery, including implant-based reconstruction.[20] The reoperation rate amongst obese patients undergoing breast reconstruction has been reported at 9.9% within 30 days of surgery.[13] Amongst all saline implants, a reoperation rate of 20.6% over a mean follow-up of 6 years has been noted. Commonly cited reasons for reoperation include asymmetry, wound repair, implant replacement or removal, and capsular contracture.[19] The rate of significant contracture has been cited in the literature ranging as high as 16.6% to 20.4%.[18,20] A deflation rate of 5.5% has been reported in a 6-year period.[21] Amongst other complications, a 0.1% rate of seroma formation, 0.2% rate of wound infection, 0.3% rate of wound dehiscence, and 1.6% rate of hematoma formation has been reported.[21] The present study demonstrated a comparably lower reoperation rate of 4.8% across a mean follow-up period of 5.4 years. Given the well-known deleterious effects of radiation, a prior history of chest wall radiotherapy may have contributed to the unilateral implant exposure in the single patient that required reoperation in our series.

Limitations

There are inherent limitations as this is a retrospective chart review with a relatively small sample size. The breadth of BMI (30.3-62.0 kg/m^2) and age range (31-72 years) do, however, add diversity to the study population and the generalizability of its results. Further, the senior surgeon provided free clinic visits to this cohort of patients after the 90-day global period in an effort to follow more closely for any potential complications. Additionally, the lack of a control group limits any objective discussion of the superiority/inferiority of this method to alternative techniques.

Conclusions

The hyperexpansion of saline implants is a simple and effective method to restore breast volume in the obese patient undergoing postmastectomy reconstruction. The patients in this study were satisfied with the cosmesis and volume restoration, with no patients experiencing spontaneous implant rupture or leak. Continued follow-up and comparison to alternative breast reconstruction methods are needed to further elucidate long-term patient and implant outcomes.

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Ethics: Written informed consent was obtained from the patients for publication of this manuscript and accompanying images. This study was approved by the University of Louisville Hospital Institutional Review Board (protocol # 17.0522).

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