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Breast

A Second Drain Decreases Seroma Formation in Prepectoral Immediate Breast Reconstruction with an Acellular Dermal Matrix

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Background: Seroma formation is the most common complication after mastectomy. While the exact pathophysiology behind seroma development has not been entirely elucidated, seromas are associated with negative outcomes in breast reconstruction. The utilization of drains is one method to combat seroma. However, the current state of plastic surgery is divided as to whether one drain or two drains is optimal in reducing seroma formation. We hypothesized that using two drains instead of one drain would reduce the risk of seroma more so than one drain.

Methods: This was a retrospective cohort study of patients who underwent prepectoral direct to implant reconstruction at a single institution by a single surgeon. Each patient underwent reconstruction with either one or two drains. Patients were followed postoperatively for rates of seroma formation. Seroma were classified as either minor or major. Secondary variables including drain duration, infection, and necrosis were also analyzed.

Results: A total of 99 breasts and 71 patients experienced breast reconstruction with two drains, and 163 breasts corresponding to 135 patients received reconstruction with one drain. In the two drain cohort, 14 (14.1%) developed a seroma, with 11 (11.1%) being minor seromas and three (3.03%) being major seromas. In comparison, out of the one drain cohort, 41 (25.2%) developed a seroma, with 35 (21.5%) being a minor seroma and six (3.68%) being classified as major.

Conclusion: This study suggests that two drains decreases the rate and risk of seroma formation compared to one drain in prepectoral breast reconstruction with an acellular dermal matrix. *(Plast Reconstr Surg Glob Open 2022; 10:e4667; doi: 10.1097/GOX.0000000000004667; Published online 12 December 2022.)*

INTRODUCTION

Breast reconstruction after mastectomy has been shown to improve patients' psychological health and well-being while also decreasing rates of depression. The demand for breast reconstruction has increased in recent years. The American Society of Plastic Surgeons reported continued growth in such reconstruction, noting a 75% increase in volume since 2000 and 1% increase from 2019 to 2020.[1] Postmastectomy breast reconstruction has proven psychosocial benefits to patients.[2] However, as with all surgical procedures, breast reconstruction is not without potential complications and risks. One such risk is seroma formation. A seroma is a collection of serous fluid that occupies dead space and is the most common complication after mastectomy.[3] It is contentious as to whether the composition of a seroma is more similar to that of lymph or exudate.[4–9] Although the pathophysiology of seroma formation is not entirely elucidated, it has been associated with various complications after reconstruction. A review by Kim et al in 2015, through a series of 1604 alloplastic breast reconstructions, demonstrated that the most significant complication associated with seroma formation is infection. This review found that patients with seroma were four times as likely to experience major infection and almost seven times as likely to undergo expander loss.[10] However, as the authors mention, it is currently unclear as to whether or not seromas

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cause these negative outcomes, or merely indicate poor wound healing.

A multitude of risk factors for seroma formation after breast reconstruction have been identified. One such factor is obesity. For each unit increase in body mass index, there is a 7%–14% increase in the risk of seroma formation.[10,11] In addition, obesity has been associated with an increase of 21.5% for time until drain removal.[12] Mastectomy weight has also been shown to have a positive association with the risk of seroma.[13] These associations between obesity and mastectomy weights with regard to seroma risk may be due to increased postoperative dead space. Another potential risk factor is the use of acellular dermal matrix during reconstruction. There is varying evidence regarding the impact of acellular dermal matrix. A 2011 study by Sbitany and Serletti concluded that there was a significantly higher incidence of seroma in the submuscular group that utilized an acellular dermal matrix (8.4%) versus the submuscular group that did not use an acellular dermal matrix (4.3%) ($P = 0.03$).[14] In contrast, the aforementioned study by Jordan et al[10] in 2016 found a seroma incidence rate of 3.1% with the use of an acellular dermal matrix and 2.9% without (n = 1605, $P = 0.882$). Differences in seroma formation may also be affected by the type of acellular dermal matrix used. Glasberg and Light[15] reported a rate of seroma formation of 12.9% with AlloDerm (LifeCell Corp, Branchburg, N.J.), versus the 1.4% chance of seroma formation when Strattice (LifeCell) was used. It is theorized that the acellular dermal matrix acts in a way that resembles a foreign body; this results in increased inflammation and subsequently serous fluid.

The prepectoral approach to reconstruction has been proven to be safe, with comparable rates of seroma formation to the subpectoral approach. A 2019 meta-analysis by Li et al found there to be no significant differences in seroma formation between the prepectoral and subpectoral techniques across 16 comparative studies. Notably, 15 of 16 studies that this meta-analysis investigated used acellular dermal matrix in both the prepectoral and subpectoral groups.[16] Data comparing prepectoral reconstruction with acellular dermal matrix and subpectoral reconstruction without acellular dermal matrix is lacking. Additionally, universal risk factors such as diabetes, age, and smoking increase the risk of morbidity.[17]

Current guidelines regarding clinically evident seroma management initially include needle aspiration with or without ultrasound visualization. Some surgeons opt to expand the tissue expander if aspiration is required to reduce the dead space present.[10,14,18] Other variable practices in initial management of seroma include prophylactic antibiotics, drain placement/replacement, and fluid culture. In patients who do not respond to repeated aspiration, operative washout may be required. Finally, in patients with capsular infection that is resistant to IV antibiotics, surgical inspection and replacement or removal of the device may be indicated.[19]

There are various methods intended to decrease seroma formation in breast reconstruction. A recent review in 2017 reports that flap fixation, either with sutures or glue, has positive effects in decreasing seroma formation.[20] The use of drains is another common method employed to prevent seroma formation. However, the ideal number of drains, either one or two drains, is a topic of current research. Phillips et al[21] surveyed members of the American Society of Plastic Surgeons and the Canadian Society of Plastic Surgeons and "were unable to determine a consensus regarding number of drains…" with 52.9% of surgeons using one drain, 45.5% using two drains, and 1.55% using more than two drains in the setting of prosthetic breast reconstruction. Since this survey, there has been further research regarding the number of drains used in breast reconstruction and seroma formation. A recent systematic review conducted in 2019 examining surgical site drains in breast reconstruction identified 2252 studies and included 21 studies.[22] Of the studies they analyzed, only two were implant based reconstructions. Moreover, one study included direct-to-implant postmastectomy reconstructions, and it is unclear if the other was immediate or delayed based reconstructions. In addition, both of these studies included patients with implant-based reconstructions utilizing the submuscular pocket. As noted by Afifi et al, the current literature would benefit by the addition of studies investigating drain placement in the prepectoral plane.[23] Our study sought to investigate the ideal number of drains in prepectoral direct to implant breast reconstructions, with the hypothesis that two drains would decrease the rate of seroma formation in comparison to one drain.

Takeaways

Question Does a second drain decrease the rate of seroma formation in immediate prepectoral breast reconstruction?

Findings: A second drain does decrease the rate and risk of seroma formation in immediate prepectoral breast reconstruction.

Meaning: Two drains may improve seroma management in immediate prepectoral breast reconstruction.

METHODS

Study Design/Sample

Institutional review board approval was obtained before this study was conducted, and we report compliance with the Helsinki Declaration. This single-institution, retrospective study included two different arms—those who underwent reconstruction with one drain and those who underwent reconstruction with two drains. Data from 163 breasts and 135 patients who underwent surgery with one drain over a 24-month period between 2015 and 2017 were compared to data from 99 breasts and 71 patients whose surgery incorporated two drains between October 2018 to March 2021. After mastectomy, each patient underwent a single-stage prepectoral reconstruction performed by the senior author. Surgical technique was identical other than the number of drains used at the end of the procedure. Once mastectomy was completed, the mastectomy

skin was reprepared with Chloraprep, followed by fresh sterile drapes. Skin flap quality and hemostasis were then verified. The mastectomy weight and patient's preferences for final bra cup size were taken into consideration, and a temporary sterile implant sizer was placed with temporary staple closure. Mastectomy skin flap viability with a given sizer volume was then examined based on ICG angiography and clinical examination. If the sizer appeared to be appropriate, the sizer was removed and the mastectomy pocket was lavaged first with a solution of 50% betadine followed by triple antibiotic solution consisting of 1 L of Ringer's lactate with 1 g cefazolin, 80 mg gentamicin, and 50,000 units of bacitracin. The acellular dermal matrix (AlloDerm, ready to use; LifeCell, Inc.) was washed for at least 10 minutes with sterile saline. The sheet was perforated repeatedly with a 3-mm dermatologic punch to improve fluid drainage. The acellular dermal matrix was then trimmed such that its tapering profile mirrored that of the underlying implant's base contour. The dermal matrix was then subsequently sutured to the anterior surface of the pectoralis major muscle with running 2-0 polydioxanone sutures. Following this, the pocket was again lavaged as it was before and the attending surgeon changed gloves before then using a Keller funnel (Keller Medical, Inc., Stuart, Fla.) to insert the implant into the pocket. The Keller funnel prevented any contact between the skin and the implant. Implants consisted of anatomic cohesive gel full height, full or extra full profile textured surface implants (Allergan, Inc.) which were placed with complete anterior coverage with acellular dermal matrix by tightly tying down the matrix using 2-0 polydioxanone suture. The tension applied by the acellular dermal matrix over the implant reduces risk of rotation and movement of the implant.[24] Then, either one or two, depending on study arm, 15 French, fully fluted, hubless drains were placed subcutaneously in all patients. Closure was achieved with two layers of 3-0 Monocryl (Ethicon, Somerville, N.J.) and patients were given oral antibiotics for a course of 5 days after surgery.

Patients were then followed postoperatively in clinic by both the senior author and the breast surgeons. Patients were monitored for any signs of seroma for at least four months postoperatively. Any patient who had less follow-up than this was excluded from the study. Seromas were classified as either major seromas or minor seromas. Major seromas were defined as those that necessitated multiple aspiration and drain reinsertion with interventional radiology. Minor seromas were those that were managed with office aspiration after drain removal. Drains were removed when there was less than 30 mL of output over a 24-hour period for two consecutive days.

Study Variables/Outcomes

The primary outcome of interest was the rate of major and minor seroma formation after direct-to-implant prepectoral alloplastic breast reconstruction when either one or two drains were used intraoperatively. Other variables collected included patient age, duration of drain placement (defined as time until breasts were free of drains), BMI, nicotine use within 8 weeks of surgery, premastectomy radiation, implant size, mastectomy weight, and presence of postoperative infection, necrosis, or device explantation.

Statistical Analysis

Univariate analysis was performed. G*Power (Kiel, Germany) was utilized to perform sample size calculations with an alpha level of 0.05 and a power of 0.8 which yielded a requirement of at least 64 breasts in each arm. Rates of major and minor seroma formation were abstracted and compared between the one drain and two drain cohorts. Surgical methods used in this study were identical among cohorts except for the varying number of drains placed postoperatively. In addition, the duration of drain placement (time until all drains removed) was also recorded and averaged. To ensure that seroma formation was not influenced by our cohort's demographics, Student *t* test (two-tailed) was used to compare age, BMI, drain duration, mastectomy weight, and implant volume between the two groups. The relative risk of seroma, infection, necrosis, return to OR, and device explantation was calculated between cohorts. Relative risk reduction, absolute risk reduction, and number needed to treat (NNT) was calculated for any statistically significant difference in relative risk between dependent variables. Furthermore, Chi-squared testing of independence was used to compare nicotine use and prior radiation. An alpha level of 0.05 was used to define statistical significance.

RESULTS

This study consisted of 71 patients and 99 breasts that underwent prepectoral direct-to-implant reconstruction with two drains and 135 patients corresponding to 163 breasts with one drain—both cohorts utilized an acellular dermal matrix. Among the single drain cohort, the average patient age was 48.0 (11.6) and the average BMI was 27.1 (5.74). Ten (6.13%) breasts that underwent reconstruction with one drain were exposed to nicotine and five (3.07%) were exposed to radiation preoperatively. In this cohort, the average implant size was 510.0 cm^3 (158.0) and the average mastectomy weight was 508.1 g (243.7). The average drain duration in this group was 15.4 (7.10) days. Of breasts that were reconstructed with one drain, 41 (25.2%) developed a seroma, with 35 (21.5%) being a minor seroma and six (3.68%) being classified as major. Postoperatively, 11 (6.75%) breasts were subject to an infection requiring antibiotics, six (3.68%) experienced necrosis that required debridement, 10 (6.14%) breasts required a return to the operating room, and finally, 10 (6.14%) devices required explantation.

Regarding breasts that pertained to the two-drain cohort, the average age was 49.6 (10.8) and the average BMI was 29.0 (6.20). In addition, 11 (11.1%) breasts in the cohort were exposed to nicotine within 8 weeks of their operation. Moreover, four (4.04%) breasts were exposed to radiation before surgery. The average implant size was found to be 532.2 cm^3 (143.0) with an average mastectomy weight of 601.5 g (305.0) (Table 1). Of the 99 breasts included in the two drain cohort, 14 developed a seroma

Table 1. Demographics

Characteristic	One Drain	Two Drain	*P*
Patients	135	71	
Breasts	163	99	
Age (y)	48.0 (11.6)	49.6 (10.8)	0.260
BMI (kg/m^2)	27.1 (5.74)	29.0 (6.20)	**0.015**
Prior radiation	5 (3.07%)	4 (4.04%)	0.675
Prior nicotine	10 (6.13%)	11 (11.1%)	0.150
Mastectomy weight	508.1 (243.7)	601.5 (305.0)	**0.0069**
Implant volume	510.0 (158.0)	532.2 (143.0)	0.261

Bold values signify statistical significance.

(14.1%). Of these, 11 (11.1%) were minor seromas and three (3.03%) were major seromas. Regarding other complications, six breasts (6.06%) developed a surgical site infection requiring antibiotics, two (2.02%) experienced necrosis requiring debridement, eight (8.08%) returned to the operating room (OR), and seven (7.07%) devices had to be explanted.

The relative risk of developing any seroma when prepectoral reconstruction was completed with two drains compared to one was 0.5622 [95% confidence interval (CI) 0.323–0.977; $P = 0.0412$]. The relative risk reduction with respect to any seroma when two drains were used was 43.8%, with an absolute risk reduction of 11.0%, and an associated NNT of 9.08. The relative risk of a minor seroma was 0.514 (95% CI 0.274–0.963; $P = 0.0378$). The relative risk reduction with regard to minor seroma when two drains were used was 48.3%, with an absolute risk reduction of 10.8%, and a concomitant NNT of 9.23. The relative risk of a major seroma was 0.727 (95% CI 0.187–2.831; $P = 0.646$). The relative risk of infection was 0.898 (95% CI 0.343–2.352; $P = 0.827$), the relative risk of necrosis requiring debridement was 0.549 (95% CI 0.113–2.666; $P = 0.457$), the relative risk of returning to the operating room was 1.317 (95% CI 0.538–3.225; $P = 0.547$), and the relative risk of device explantation was 1.153 (95% CI 0.453–2.930; $P = 0.766$) (Table 2).

DISCUSSION

Interestingly, in this retrospective cohort study the results demonstrate that two drains decrease the rate (14.1% versus 25.2%) and risk [relative risk (RR) = 0.562, relative risk reduction (RRR) = 43.8%, and absolute risk reduction (ARR) = 11.0%] of seroma in patients undergoing immediate prepectoral breast reconstruction with an acellularized dermal matrix. Moreover, when seroma formation was stratified into major and minor seroma, the use of two drains decreased the rate (11.1% versus 21.5%) and risk (RR = 0.514, RRR = 48.3%, and ARR = 10.8%) of minor seroma development to a statistically significant degree, but not that of major seroma. The data suggest that approximately nine patients need to be treated with a second drain to reduce one additional seroma in comparison to patients treated with one drain. In our study, we abstracted variables that reflect the potential clinical implications of seroma. Notably, the relative risks of postoperative infection, necrosis, return to the operating room, or device explantation were all not statistically significant between the two cohorts. The reason for this may be due to insufficient power to distinguish this difference in accordance to a type 2 error. Such an error may also caused an inability to calculate a statistically significant difference in major seroma formation between the two arms.

When comparing demographic data, there was no statistically significant difference between the two groups in terms of age, nicotine, prior radiation, or implant size. However, there was a statistically significant difference with respect to mastectomy weight and BMI with the two drain cohort including patients of both greater BMI and mastectomy weight. As mentioned in the introduction, both variables have been found to be associated with postoperative seroma formation. Therefore, it is possible that the degree to which a second drain decreases seroma formation in prepectoral breast reconstruction with an acellular dermal matrix is actually greater than the results of this study suggest.

The patients who received one drain during reconstruction did have a statistically significant decrease in time until all drains were removed. On average, patients in the one-drain cohort were drain free approximately five days sooner than those who had two drains incorporated in the reconstruction—a difference between 15.4 (7.10) days versus 20.2 (11.2) days. This is somewhat intuitive, as when there are twice the amount of drains it seems logical that it may take longer for all drains to be removed with the requirement of less than 30 cm^3 of output over a 24-hour period for two consecutive days. This does bring up the possibility that perhaps drains are removed too early using this classic threshold for drain removal and that complications could be decreased if a more conservative removal requirement were used. However, further research is required to explore this concept and determine if it has any merit. The findings in this study surprisingly differ from those of Poore et al who showed that in patients undergoing submuscular tissue expander placement for breast reconstruction, including a subcutaneous

Table 2. Results

Variable	One Drain	Two Drain	RR	*P*	RRR (%)	ARR (%)	NNT
Seroma	41 (25.2%)	14 (14.1%)	0.562 (0.323–0.977)	**0.041**	43.8	11.0	9.08
Minor	35 (21.5%)	11 (11.1%)	0.514 (0.274–0.963)	**0.038**	48.3	10.8	9.23
Major	6 (3.68%)	2 (2.41%)	0.727 (0.187–2.83)	0.646			
Infection	11 (6.75%)	6 (6.06%)	0.898 (0.343–2.35)	0.827			
Necrosis	6 (3.68%)	2 (2.02%)	0.549 (0.113–2.67)	0.457			
Return to OR	10 (6.14%)	8 (8.08%)	1.317 (0.538–3.23)	0.547			
Explantation	10 (6.14%)	7 (7.07%)	1.153 (0.453–2.93)	0.766			
Drain duration	15.4 (7.10)	20.2 (11.2)		**0.0002**			

Bold values signify statistical significance.

drain and a submuscular drain compared to one subcutaneous drain did not decrease rates of seroma or infection.[25] The reason for this difference may be attributed to the use of an acellular dermal matrix in our cohorts, which has been shown to be serogenic and was not used in the patients examined in the study by Poore et al.

This study is not without limitations. The primary limitation is that this investigation was retrospective in nature as opposed to prospective. This is an intrinsic limitation in this study design, but our conclusion would be strengthened if we were able to be randomized in a prospective fashion to either one or two drains. In addition, our data stems from one plastic surgeon from one institution. While this is beneficial with respect to serving as a control factor, it does potentially decrease the degree to which our results our generalizable. Another point is that while the technique remained constant, increased familiarity over time with the use of acellular dermal matrix and immediate prepectoral reconstruction may have improved outcomes in the latter cohort. Future studies may find it useful to pool data between various surgeons who either have in the past, or currently use, one drain versus surgeons who use two. Although this method reduces the theoretical internal validity, it would possibly lead to more generalizable results. Additional future studies could potentially randomize patients in a prospective fashion.

CONCLUSIONS

In conclusion, this retrospective cohort study demonstrated that the inclusion of a second drain in patients undergoing immediate prepectoral breast reconstruction with use of an acellular dermal matrix decreased the rate and risk of seroma formation. However, future studies must be conducted to determine the degree to which this affects the potential incidence of the sequelae associated with seroma (eg, infection, necrosis, secondary operations, or device explantation).

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