Original Article

Effect of acellular dermal matrix thickness and surface area on direct-to-implant breast reconstruction

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Background: The use of an acellular dermal matrix is advantageous for direct-to-implant breast reconstruction after skin-preserving mastectomy, but is associated with postoperative complications, especially increased seroma. Therefore, this study aimed to determine whether acellular dermal matrix surface area and thickness are associated with an increased risk of seroma.

Methods: This retrospective chart review was based on the medical records of patients who underwent submuscular direct-to-implant breast reconstruction from January 2011 to June 2018 by a single surgeon. The acellular dermal matrices were divided into groups according to surface area and thickness (group I, thin and small; group II, thin and large; group III, thick and small; and group IV, thick and large). The drainage volume and period were analyzed between the groups using an analysis of variance. The factors influencing drainage were analyzed using Pearson correlation coefficients.

Results: Of the 219 cases of direct-to-implant breast reconstruction (217 patients), 77, 63, 42, and 37 were in groups I, II, III, and IV, respectively. A large acellular dermal matrix resulted in a larger drainage volume, longer drainage period, and more complications. The drainage volume increased as the body mass index ($r=0.217$; $P<0.01$), mastectomy volume ($r=0.358$; $P<0.01$), and implant volume ($r=0.385$; $P<0.01$) increased. There was no difference in drainage volume, drainage period, and complications depending on the thickness and manufacturer of the acellular dermal matrix.

Conclusions: In direct-to-implant breast reconstruction, the use of a larger acellular dermal matrix, not a thicker acellular dermal matrix, increases the drainage volume and period, thereby resulting in a greater risk of seroma or infection.

Keywords: Acellular dermal matrix (ADM); breast implant; seroma; breast reconstruction

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Introduction

Breast reconstruction using an implant is commonly performed after skin-sparing mastectomy (1). In immediate single-stage implant-based breast reconstruction, the state of the breast skin envelope supporting or covering the implant is an important factor impacting the surgical outcome. Breast reconstruction using only an implant is limited; as tension is generated by the insertion of the implant, additional trauma is caused to the breast skin envelope (2). Thus, to reinforce the breast skin envelope, additional procedures, such as muscle flap reconstruction, are often performed. In 2005, Breuing *et al.* first started to cover or support implants using an acellular dermal matrix (ADM) and Zienowicz *et al.* demonstrated advantages in structural strength and natural appearance (3,4). Additionally, the use of an ADM has been reported to

Table 1 Classification by acellular dermal matrix size and thickness

Size	Thin (<2.5 mm)	Thick (≥2.5 mm)
Small (≤64 cm²)	Group I	Group III
Large (>64 cm²)	Group II	Group IV

reduce the incidence of capsular contracture (5). Therefore, in implant-based breast reconstruction, an ADM is the main option as it covers a wide area during the initial stage of breast reconstruction.

As the use of an ADM in implant-based breast reconstruction increases, many studies on ADM-related complications have also been reported (6-8). Whether using an ADM increases the incidence of infection or flap necrosis remains controversial. However, it has been reported to increase the incidence of seroma (9).

ADMs are marketed by several manufacturers in various sizes and thicknesses. Recently, there have been studies on the relationship between ADM size and the incidence of seroma, but there are not enough studies yet to draw a firm conclusion. There are no studies on the correlation between ADM thickness and the incidence of seroma in implant-based breast reconstruction. Therefore, this study aimed to determine whether the ADM surface area and thickness are associated with an increased risk of seroma. We hypothesized that a high drainage volume and a long drainage period would increase the incidence of seroma. This study aimed to investigate the drainage volume and drainage period according to the type of ADM used in implant-based breast reconstruction. We present the following article in accordance with the STROBE reporting checklist (available at https://gs.amegroups.com/article/view/10.21037/gs-22-175/rc).

Methods

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Review Board of Yeungnam University Hospital (No. 2020-12-047-002), and individual consent for this retrospective analysis was waived. A retrospective chart review was conducted based on the medical records of patients who underwent submuscular direct-to-implant breast reconstruction from January 2011 to June 2018 by a single surgeon (JHL) at our institution. Only cases of dual-plane ADM reconstruction with unilateral or bilateral direct-to-implant were included. Exclusion criteria were as follows: patients who had undergone a prophylactic mastectomy, patients in whom a tissue expander has been used, patients who had undergone autologous reconstruction at the same time, a history of breast conservative surgery, a history of radiation therapy, a history of significant comorbidities that might affect wound healing, a follow-up period less than 6 months, incomplete data, and having undergone reoperation, which is classified as a major complication. The cases of reoperation were excluded as external factors since the open wound greatly influences the change in drainage volume.

Complications included infection, flap necrosis, seroma, and hematoma. Cases in which wound healing was delayed due to an antibiotic-controlled infection, focal flap necrosis, or dehiscence were classified as having minor complications. Infection was defined as any erythematous changes in the affected breast with general symptoms of infection, including a sensation of heat on the breast, a generalized febrile sensation, and fever. Any infectious complications encountered during the follow-up period were regarded as clinically significant. Flap necrosis was defined as skin necrosis only along the incision line without any erythematous changes in the breast. Seroma was defined as a fluid collection in the affected breast that required ultrasound-guided aspiration after removing both drains. The drains were removed when the drainage volume was less than 20 mL/day for two consecutive days.

Breast implants and ADM

Allergan (Allergan, Inc., Dublin, Ireland), Mentor (Mentor Corp., Santa Barbara, CA, USA), or BellaGel textured-type implants (Hans Biomed, Seoul, Korea) were used. In all cases, only a single AlloDerm (LifeCell Corp., Branchburg, NJ, USA), MegaDerm (L&C Bio Corp., Seoul, Korea), or CGCryoDerm (Daewoong Bio Inc., Seoul, Korea) ADM allograft was used. The ADMs were divided into groups according to their surface area and thickness: group I, thin and small with a median thickness <2.5 mm and a surface area ≤64 cm^2; group II, thin and large with a median thickness <2.5 mm and a surface area >64 cm^2; group III, thick and small with a median thickness ≥2.5 mm and a surface area ≤64 cm^2; and group IV, thick and large with a median thickness ≥2.5 mm and a surface area >64 cm^2 (*Table 1*). The classification criteria for surface area and thickness were set as the average value for adequate classification of the number of patients in our data (*Tables 2,3*).

Table 2 Criteria of acellular dermal matrix thickness

ADM type	Thin (<2.5 mm)	Thick (≥2.5 mm)
AlloDerm	1.66	2.8
MegaDerm	1.25, 1.9	2.65
CGCryoDerm	1.5, 1.62, 1.66	2.5, 2.65

The thickness is the average value provided by the manufacturer (e.g., 1–2 mm is calculated as 1.5-mm thickness). ADM, acellular dermal matrix.

Table 3 Criteria of acellular dermal matrix surface area

ADM type	Small (≤64 cm²)	Large (>64 cm²)
AlloDerm	48, 60, 64	96
MegaDerm	48, 64	96, 126
CGCryoDerm	40, 48, 52, 55, 56, 60, 64	70, 75, 80, 90, 96, 112, 114, 120, 144

ADM, acellular dermal matrix.

Operative technique and postoperative management

A single surgeon (JHL) performed all the breast reconstructions using the same surgical protocol. After skin-sparing mastectomy, a subpectoral pocket was created by dividing the pectoralis major muscle from the chest wall to place the implant. The ADM was fixed along the inferior border of the pectoralis muscle superiorly, inframammary fold inferiorly, and serratus anterior fascia laterally to create a structurally robust and natural ADM sling. Two closed-suction drains were placed in the supramuscular plane (between the pectoralis major muscle and the skin) and the submuscular plane (between the implant and the pectoralis major muscle). ADM size was determined in consideration of implant size, subpectoral pocket size, the degree of ptosis, and chest wall size. ADM thickness was used randomly without indication. Fenestrated ADM was not used, and no additional procedure was performed to stick the ADM into the mastectomy flap.

Second-generation cephalosporin intravenous antibiotics were administered for 10 days prophylactically, and dressing changes were performed daily. To reduce dead space, the breast was compressed using an elastic band. The drains were removed based on the drainage volume recorded by the patient (less than 20 mL/day for two consecutive days). Patients with increased drainage volume were also removed with the same protocol. Instead, because the drain maintenance period was long, it was removed from the outpatient department after discharge. After discharge, the patient measured and recorded the drainage volume by herself at a certain time every day, and visited the hospital twice a week for drain site dressing.

Statistical analysis

The drainage volume and period were analyzed between the groups using analysis of variance (ANOVA) and Chi-square tests. The factors influencing drainage were analyzed using Pearson correlation coefficients. An analysis of covariance (ANCOVA) was used to correct the group distribution among the manufacturers. IBM SPSS version 21.0 for Windows (IBM Corp., Armonk, NY, USA) was used for statistical analyses, and a value of $P<0.05$ was considered significant.

Results

Among the 319 cases of submuscular direct-to-implant breast reconstruction (303 patients), 219 (217 patients) were included. There were 77 cases in group I, 63 in group II, 42 in group III, and 37 in group IV. The groups had similar characteristics without significant differences in terms of body mass index (BMI), diabetes, hypertension, mastectomy volume, chemotherapy, and nipple-areolar sparing. Patient age was higher in group IV (50.05±8.37 years) than in groups I (45.18±7.12 years) and III (43.88±6.57 years) ($P<0.001$) (*Table 4*). There was no significant difference in the drainage volume of the supramuscular drain between the groups. However, the drainage volume of the submuscular drain was significantly larger in groups II (614.38±287.40 mL) and IV (574.38±346.74 mL) than in groups I (430.82±186.46 mL) and III (360.86±176.2 mL); there were no significant differences between groups I and III and between groups II and IV. The total drainage volume of the supramuscular and submuscular drains combined was larger in groups II (780.03±336.98 mL) and IV (704.46±351.85 mL) than in groups I and III. However, the difference was only significant between groups II and III (547.64±223.98 mL) (*Table 5*, *Figure 1*). There was no significant difference in the timing of supramuscular drain removal ($P=0.069$). The submuscular drain lasted significantly longer in groups II (17.79±7.18 days) and IV (16.92±6.87 days) than in groups I (13.26±4.42 days) and III (10.52±3.81 days); however, there were no significant differences between groups I and III and between groups II and IV (*Figure 2*). Overall, infection and seroma occurred

Table 4 Patients' demographics by groups

Characteristic	Group I (n=77)	Group II (n=63)	Group III (n=42)	Group IV (n=37)	P value
Mean age ± SD, years	45.18±7.12	47.25±6.46	43.88±6.57	50.05±8.37	<0.001
Mean BMI ± SD, kg/m^2	22.29±2.26	22.47±2.87	22.43±2.79	21.99±2.55	0.829
Comorbid conditions, n (%)					
Diabetes	1 (1.3)	3 (4.8)	1 (2.4)	1 (2.7)	0.630
Hypertension	2 (2.6)	2 (3.2)	1 (2.4)	1 (2.7)	1.000
Mean mastectomy volume ± SD, cc	225.73±115.59	263.87±118.97	248.81±129.44	242.14±109.7	0.300
Adjuvant chemotherapy, n (%)	30 (39.0)	30 (47.6)	17 (40.5)	17 (45.9)	0.729
Mean implant volume ± SD, cc	202.57±72.4	237.86±76.25	225.76±83.6	229.32±82.25	0.051
NSM, n (%)	36 (46.8)	36 (57.1)	22 (52.4)	21 (56.8)	0.608

SD, standard deviation; BMI, body mass index; NSM, nipple-sparing mastectomy.

Table 5 Comparison of drain volume and period by groups

Characteristic	Group I (n=77)	Group II (n=63)	Group III (n=42)	Group IV (n=37)	P value
Drain volume, mL					
Mean supramuscular drain ± SD	191.13±133.03	165.65±137.73	186.79±118.71	130.08±109.55	0.098
Mean submuscular drain ± SD	430.82±186.46^a	614.38±287.4^b	360.86±176.2^a	574.38±346.74^b	<0.001
Mean total drain ± SD	621.95±243.77^{ab}	780.03±336.98^b	547.64±223.98^a	704.46±351.85^{ab}	<0.001
Drain period, days					
Mean supramuscular drain ± SD	7.61±3.03	7.19±2.81	7.60±2.47	6.19±2.71	0.069
Mean submuscular drain ± SD	13.26±4.42^a	17.79±7.18^b	10.52±3.81^a	16.92±6.87^b	<0.001

^{a,b}, Scheffe's multiple comparison. Means followed by the same letter in a column are not significantly different. SD, standard deviation.

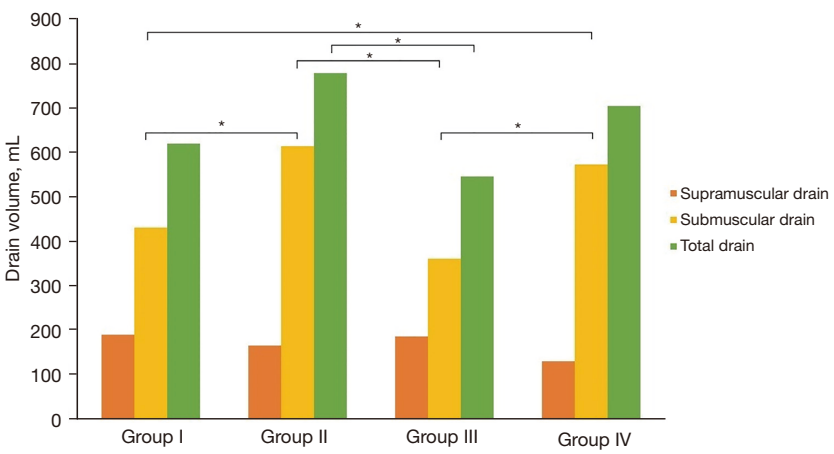

Figure 1 Supramuscular, submuscular, and total drainage volume (mL) by groups. *, P<0.01.

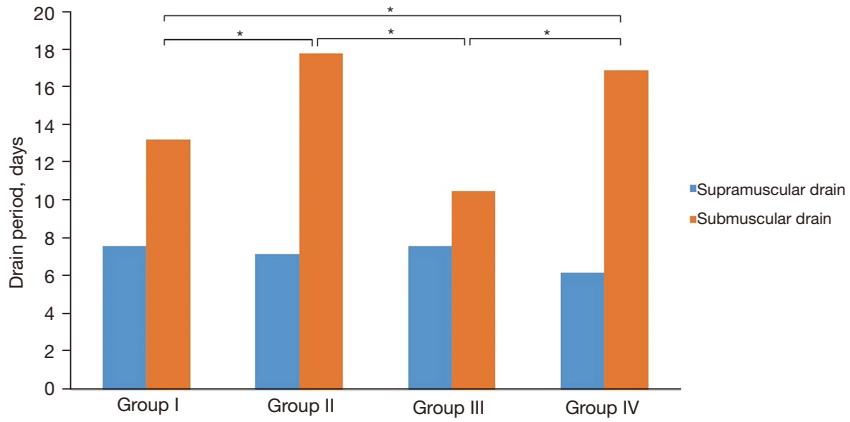

Figure 2 Supramuscular and submuscular drainage period (days) by groups. *, P<0.01.

Table 6 Postoperative minor complications by groups

Complication	Group I (n=77), n (%)	Group II (n=63), n (%)	Group III (n=42), n (%)	Group IV (n=37), n (%)	All patients (n=219), n (%)	P value
Infection	2 (2.6)	10 (15.9)	0 (0.0)	5 (13.5)	17 (7.8)	0.002
Delayed wound healing	4 (5.2)	2 (3.2)	1 (2.4)	1 (2.7)	8 (3.7)	0.921
Seroma	1 (1.3)	11 (17.5)	0 (0.0)	7 (18.9)	19 (8.7)	<0.001

in 17 (7.8%) and 19 cases (8.7%), respectively. Among the groups, the incidence of infection and seroma was significantly higher in groups II and IV than in groups I and III (*Table 6*).

In analyzing the correlation of total drainage volume with age, BMI, mastectomy volume, and implant volume, a correlation was identified for all the variables (age: 0.137, BMI: 0.217, mastectomy volume: 0.358, implant volume: 0.385) (*Figure 3*). While similar characteristics were observed among the ADM manufacturers, there was a difference in the group distribution. ANCOVA results revealed no significant difference in the total drainage volume of ADMs among the manufacturers (P=0.136).

Discussion

This study revealed that the use of a larger ADM resulted in a larger drainage volume, longer drainage period, and more complications. However, there was no difference in the drainage volume, drainage period, and complications based on the thickness and the manufacturer of the ADM. In addition, as the mastectomy volume increased, the amount of drainage also increased, but there was no difference in the amount of drainage or complications between ADM manufacturers.

Several clinical studies have demonstrated that ADM use increased the seroma rate. Chun *et al.* reported a 4.24-fold difference in the incidence of seroma when using an ADM (10). Ho *et al.* analyzed four studies and reported a pooled odds ratio of 3.89 (11). Similarly, in 2017, Mangialardi *et al.* reported a pooled risk ratio of 2.73 for seromas after ADM use in a meta-analysis of six studies (8). In 2013, Cayci *et al.* studied the association between ADM size and complications (12). However, there are limited studies on the size of an ADM.

In this study, drain volume and period were analyzed to predict the incidence of seroma according to the ADM type. One drain was inserted into the supramuscular area and another into the submuscular area (based on the pectoralis major muscle). The drainage volume and drainage period were higher for the submuscular drain than the supramuscular drain. This may have been due to faster integration between the breast skin tissue and the ADM than between the ADM and the implant. The drainage volume of the submuscular drain was larger in group II than in group I and in group IV than in group III.

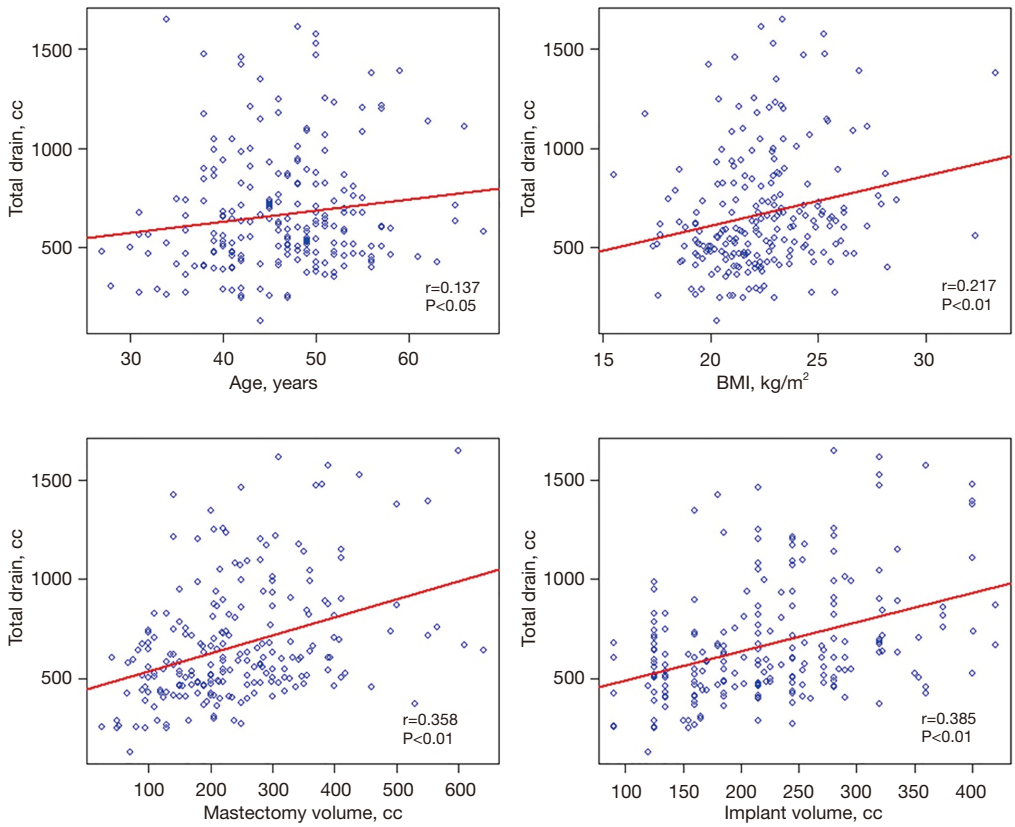

Figure 3 Pearson correlation coefficient of total drain volume and characteristics.

However, there was no difference between groups I and III and between groups II and IV. In other words, the drainage volume was larger in cases using a large ADM with similar thickness. Meanwhile, there was no difference in the drainage volume in cases with a similar ADM size but varied thickness. Although the significance of the total drainage volume decreased, similar results were observed with submuscular drainage volume. The timing of drain removal demonstrated the same trend as the results of the drainage volume, likely because the standard for removing the drain was set to less than 20 mL/day for two consecutive days.

The incidences of infection and seroma without reoperation were high in groups II and IV, and this trend was the same for the drainage volume and drainage period. This suggests that the risk of infection or seroma increases after removing the drain when the drainage volume is large or if the drain is maintained for a long period. Alternatively, an incident of breast implant infection may have resulted in an increase in drainage volume, drainage period, and seroma incidence (13). The sequential relation is not clearly demonstrated in this study, but a close relation of the drain with the incidences of infection and seroma was identified.

When the mastectomy volume is large, the damaged tissue size is large, with a high possibility of dead space between the ADM and the overlying breast tissue. Therefore, it is highly likely that the drainage volume will increase due to poor incorporation; in fact, a positive correlation was confirmed in our study. It can be interpreted that the implant volume required increases in proportion to the mastectomy volume. As patients with a high BMI tend to have pendulous breast skin, the drainage volume appears to increase for the same reason as the mastectomy volume. Further, Mendenhall *et al.* reported that obesity increases the drainage removal period by 21.5% (P=0.009) (14).

No consensus has been reached regarding the difference in the incidence of seroma according to the ADM type and processing. Butterfield *et al.* reported that replacing the aseptic human cadaveric ADM, AlloDerm, with a xenogeneic ADM, SurgiMend (TEI Biosciences, Inc., Waltham, MA, USA), decreased the incidence of seroma from 15.7% to 8.6% (P=0.044) (15). Brooke *et al.* compared AlloDerm, DermaMatrix, and FlexHD and reported seroma

rates of 4.0%, 5.4%, and 14.8%, respectively (16). In this study, there was no difference in the drainage volume or complication rate between the manufacturers of the ADMs. This result was in line with that of our previous studies in which there was no difference in the complication rate between aseptic or sterile ADMs (17,18).

A single surgeon performed the surgery using the same surgical protocol. Nevertheless, ADMs of different sizes were used as the ADM size was adjusted according to the implant size, subpectoral pocket size, the degree of ptosis or chest wall size.

There are some limitations to this study. First, this study did not have a prospective design; thus, selection bias may have occurred. Second, there was a difference in the breast skin thickness of each patient, but this could not be distinguished by quantitative measurement. Third, the relatively small sample size limits the power of our study in detecting significant differences. Nevertheless, the strength of this study is that this is the first study regarding the clinical outcome of ADM thickness and surface area on submuscular direct-to-implant breast reconstruction.

Conclusions

In direct-to-implant breast reconstruction, using a larger ADM, not a thicker ADM increases the drainage volume, resulting in a greater risk of seroma or infection. ADM use is expected to increase in the future, and prospective studies should be conducted on more patients to ensure the safe and effective use of ADMs.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://gs.amegroups.com/article/view/10.21037/gs-22-175/rc

Data Sharing Statement: Available at https://gs.amegroups.com/article/view/10.21037/gs-22-175/dss

Peer Review File: Available at https://gs.amegroups.com/article/view/10.21037/gs-22-175/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://gs.amegroups.com/article/view/10.21037/gs-22-175/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Review Board of Yeungnam University Hospital (No. 2020-12-047-002), and individual consent for this retrospective analysis was waived.

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