A Limited Submuscular Direct-to-Implant Technique Utilizing AlloMax

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Background: This study evaluates a novel limited submuscular direct-to-implant technique utilizing AlloMax where only the upper few centimeters of the implant is covered by the pectoralis, whereas the majority of the implant including the middle and lower poles are covered by acellular dermal matrix.

Methods: The pectoralis muscle is released off its inferior and inferior-medial origins and allowed to retract superiorly. Two sheets of AlloMax (6×16 cm) are sutured together and secured to the inframammary fold, serratus fascia, and the superiorly retracted pectoralis. Thirty-seven breasts in 19 consecutive patients with follow-up at 6 months were reviewed.

Results: Nineteen consecutive patients with 37 reconstructed breasts were studied. Average age was 50 years, average BMI was 24.3. Ptsis ranged from grade 0–III, and average cup size was B (range, A–DDD). Early minor complications included 1 seroma, 3 minor postoperative hematomas managed conservatively, and 3 minor wound healing problems. Three breasts experienced mastectomy skin flap necrosis and were managed with local excision. There were no cases of postoperative infection, red breast, grade III/IV capsular contractures, or implant loss. A single patient complained of animation postoperatively. One patient desired fat grafting for rippling.

Conclusions: The limited submuscular direct-to-implant technique utilizing AlloMax appears to be safe with a low complication rate at 6 months. This technique minimizes the action of the pectoralis on the implant, reducing animation deformities but still providing muscle coverage of the upper limit of the implant. Visible rippling is reduced, and a vascularized bed remains for fat grafting of the upper pole if required.

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INTRODUCTION

Single-stage retropectoral direct-to-implant techniques with partial implant coverage utilizing a single sheet of acellular dermal matrix (ADM) have been well described. In the retropectoral technique, the pectoralis covers the majority of the implant, which may result in reduced projection and implant animation (Fig. 1A). In contrast, the subcutaneous technique offers a much lower incidence of animation but results in more implant visibility, increased rates of rippling, and higher rates of implant loss.

Reported complication rates for single-stage immediate direct-to-implant breast reconstruction with ADM vary widely in the literature. Complication rates from as low as 3.9% to as high as 78.4% have been described. The most commonly reported complications include capsular contracture, infection, seroma, mastectomy skin flap necrosis, and implant loss.

We describe a limited submuscular direct-to-implant technique utilizing 2 sheets of ADM per breast where only the upper few centimeters of the implant is covered by the pectoralis, whereas the majority of the implant including the middle and lower poles are covered by ADM. We describe the details of this novel technique and evaluate its effectiveness by focusing on complications and revisions required in the first 6 months following surgery.

MATERIALS AND METHODS

Patients
All patients undergoing direct-to-implant breast reconstruction cases using AlloMax (Bard Davol Inc., Warwick, R.I.) by the senior author were studied. All patients were

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followed up to 6 months postoperatively. Patients were not excluded based on factors such as age, body mass index (BMI), tobacco use, preoperative bra size, ptosis grade, or pre/postoperative radiotherapy.

ADM

The senior author began to utilize Allomax in July 2013 and has used this particular ADM exclusively in all cases where use of ADM is indicated.
Surgical Technique

Skin or nipple-sparing mastectomy is first carried out by the general surgeon in the standard fashion. A circum-areolar incision is utilized for skin-sparing mastectomy. In nipple-sparing mastectomy, we utilize an inframammary fold (IMF) incision in smaller breasts with minimal ptosis (grade I to II) and a vertical incision from the bottom of the areola to the IMF in larger breasts with greater degrees of ptosis.

Skin flap thickness varied from 0.5 to 1 cm depending on the mastectomy surgeon, the side, the proximity of the cancer to the skin, the depth of the subcutaneous fat and breast gland interface, and the patient’s BMI.

The pectoralis muscle is then released off its inferior and inferior-medial origins. The deeper fibers of the inferior-medial pectoralis major are transected over approximately 1–3 cm so that the inferior margin of the pectoralis becomes pliable, and the middle and lateral thirds can retract superiorly. Only the inferior medial perforators are sacrificed. The breast pocket is irrigated with antibiotic solution, surgical gloves are exchanged, and implants are placed bilaterally in a submuscular position utilizing a Keller funnel. Ideally, implants at least 10% larger than the mastectomy weight are used to accommodate the obligatory skin redundancy that occurs after mastectomy. Two 6×16 cm sheets of AlloMax (Bard Davol Inc.) are sutured together on the back table using vicryl and then secured to the IMF, serratus fascia, and the superiorly retracted pectoralis (Fig. 1B). This provides coverage of the lower two-thirds and lateral aspects of the implant (Fig. 2). The sutures joining the ADM sheets are not palpable beneath the skin. Alternatively, a larger Allomax sheet could be utilized; however, this is not available at our institution.

A Jackson-Pratt drain is placed laterally in a subcutaneous position and tunneled 5 cm below the IMF to eliminate communication between the implant and the external environment when removed. In previously irradiated patients, the drain is brought out beyond the grid of radiation skin changes. Drains are removed when output is less than 30 cc per day for 2 consecutive days. Figure 3 shows the inset ADM together with the position of the postoperative drain.

Provided mastectomy skin flaps appeared viable, they were closed with a modified purse-string suture to reduce the length of horizontal scar on the breast. Figure 4 shows a typical patient following skin-sparing mastectomy with a modified purse-string closure, preoperatively and postoperatively. Mastectomy skin flap viability was clinically assessed intraoperatively by the senior author, and no intraoperative imaging was performed. Topical nitroglycerin paste was applied to any clinically determined areas of questionable viability.

Initially smooth, round, moderate profile Mentor implants were utilized. However, we felt rippling may have been related to lower implant fill volume, so we subsequently switched to using moderate-profile plus implants. All patients were given a minimum of 7 days of a first-generation cephalosporin, provided they had no allergy. If an implant was found to be riding high in the immediate postoperative period, a bandeau was utilized for 4–6 weeks until the implant settled into normal position. Any suspicion of full thickness skin loss was immediately revised under local anesthetic.

A typical result following nipple-sparing mastectomy is shown in Figure 5. A typical result following skin-sparing mastectomy is demonstrated in Figure 6, with the same patient shown 1-year postoperatively demonstrating no animation.

RESULTS

Thirty-five breasts in 19 consecutive patients were reviewed at 6 months postoperatively. Table 1 provides a summary of patient demographics. Average age was 50 years (range, 29–72), and average BMI 24.3 (range, 18.1–44.6). The majority of patients had no comorbidities (17 of 19; 90%). Most patients had never used tobacco products (13 of 19; 68%), whereas the remainder used them previously (6 of 19; 32%). Of these 6 patients, 1 had quit less than 6 months prior, whereas the remaining 5 had quit more
than 5 months prior. Bra size preoperatively varied from A to larger than D, with size B being most common (8 of 19; 42%). Ptosis grade preoperatively varied from none to grade III, with a fairly even distribution between groups.

Table 2 details the patient’s breast cancer and related interventions. Five patients (5 of 19; 26%) were undergoing prophylactic mastectomies due to positive BRCA mutation status. Of patients with breast cancer, the majority had unilateral breast cancer (13 of 14; 93%). Stage ranged from 0 to IV, with stage I and II being most common (12 of 14; 86%). The majority of patients had ductal cancer (13 of 14; 93%) and also invasive cancer (13 of 14; 93%). Five of 19 patients had previous radiotherapy, whereas 2 of 19 required it postoperatively. Five of 19 patients had previous chemotherapy, whereas 4 of 19 required it postoperatively. One patient in the prophylactic mastectomy group was previously affected by a breast cancer requiring radiotherapy and chemotherapy. This patient subsequently

Fig. 4. Typical patient following skin-sparing mastectomy, preoperatively (A) and 3 weeks postoperatively (B).

Fig. 5. Typical patient following nipple-sparing mastectomy through an IMF approach, preoperatively (A) and 7 weeks postoperatively (B).
discovered her BRCA status and elected to proceed with prophylactic mastectomy.

Table 3 details previous breast surgeries in our cohort. The most common procedure performed was core biopsy (15 of 19; 79%). Two women previously had bilateral breast reduction (2 of 19; 11%), and 2 others bilateral breast augmentation (2 of 19; 11%).

Table 4 provides details related to mastectomy and reconstruction. Eight of 19 (42%) patients did not require or receive nodal dissection at the time of reconstruction,
11 of 19 (58%) required a sentinel node biopsy, whereas 1 of 19 (5%) required conversion to full axillary dissection. The majority of patients had circumpolar skin-sparing mastectomy (18 of 19; 95%), whereas the remaining patient received nipple-sparing mastectomy using an IMF incision. The majority of reconstructions performed were bilateral (16 of 19; 84%). Most often 2 sheets of ADM were used per breast (17 of 19; 90%); however, due to patient size, slightly more or less was required in 1 case each. The majority of patients received Mentor, smooth, round, moderate profile implants (11 of 19; 58%). Cephalexin was most commonly utilized for postoperative prophylaxis (18/19; 95%), and duration of antibiotic use ranged from 5 to 21 days. Drains were left in postoperatively an average of 8.1 days (range, 4–15).

Table 5 details complications and revisions required in the first 6 months following surgery. One patient was found to have mild animation bilaterally, which was not bothersome to her. This patient is a massage therapist and noticed some animation while working. Three patients experienced unilateral hematoma, which was managed conservatively or with aspiration. Two patients had unilateral implant malposition. Three patients had unilateral mastectomy skin flap necrosis, which was managed conservatively or under local anaesthetic. Five patients had unilateral palpable ADM irregularity. Four patients had rippling, with only 1 case being bilateral. One patient had a seroma bilaterally. Three patients experienced minor wound healing complications unilaterally without implant exposure. There were no cases of grade III/IV capsular contracture, major hematoma, or mastectomy skin flap necrosis requiring management in the operating room (OR), red breast syndrome, or major wound healing problems with implant exposure or loss. One patient desired fat grafting unilaterally due to rippling. This same patient also underwent implant exchange from a moderate profile to a moderate profile plus implant unilaterally due to rippling (Fig. 7).
Table 4. Mastectomy and Breast Reconstruction Details

| Variable                                      | n (%) |
|-----------------------------------------------|-------|
| Node dissection (at the time of reconstruction) |       |
| N/A                                                                                          | 7/19 (37) |
| No                                                                                           | 1/19 (5) |
| Sentinel node                                                                               | 10/19 (53) |
| Axillary dissection                                                                         | 1/19 (5) |
| Type of mastectomy                                                                          |       |
| Nipple-sparing (IMF incision)                                                                | 1/19 (5) |
| Skin-sparing (circumareolar incision)                                                        | 18/19 (95) |
| Side of reconstruction                                                                      |       |
| Unilateral                                                                                   | 3/19 (16) |
| Bilateral                                                                                   | 16/19 (84) |
| Number of sheets of ADM used per breast                                                      |       |
| 1.5                                                                                          | 1/19 (5) |
| 2                                                                                             | 17/19 (90) |
| 2.5                                                                                          | 1/19 (5) |
| Implant type                                                                                 |       |
| Mentor, smooth, round, moderate profile                                                      | 11/19 (58) |
| Mentor, smooth, round, moderate profile plus                                                 | 7/19 (37) |
| Mentor, smooth, round, high profile†                                                        | 1/19 (5) |
| Postoperative antibiotic utilized                                                             |       |
| Cephalexin                                                                                   | 18/19 (95) |
| Clindamycin                                                                                  | 1/19 (5) |
| Duration of postoperative antibiotic use (d)†                                                 |       |
| 5                                                                                             | 1/19 (5) |
| 7                                                                                             | 5/19 (26) |
| 10                                                                                            | 3/19 (16) |
| 14                                                                                            | 6/19 (32) |
| 21                                                                                            | 4/19 (21) |
| Duration drains left in days                                                                 |       |
| Average                                                                                      | 8.1 |
| Range                                                                                       | 4–15 |

*Includes prophylactic mastectomies in BRCA-positive patients and those cases not requiring a nodal procedure at the time of reconstruction.
†Utilized in a patient with previous bilateral breast augmentation.
‡Duration of antibiotic use was based on resident’s choice at discharge; however, in some cases, it was extended by the senior author at follow-up.

DISCUSSION

Reports of complication rates in single-stage immediate direct-to-implant breast reconstruction with ADM are quite varied in the literature.\(^1,3,8,10–15\) Comparing complication rates between studies is difficult as different studies focus on different complications. Furthermore, large variability in complication rates exists among different studies even when utilizing the same ADM.\(^10,11,16\) This suggests that technical differences likely play a significant role in achieved outcomes.

We demonstrated a low incidence of complications in the limited submuscular direct-to-implant technique utilizing AlloMax. We focused on the 6-month postoperative period in this study, as this has been previously utilized as an acceptable duration for determining failure in direct-to-implant breast reconstruction with ADM.\(^11\)

Grade III/IV capsular contracture has been reported in up to 11% of cases.\(^1\) We had no cases of capsular contracture and did not demonstrate an increased rate compared with other techniques or utilizing other ADMs.\(^3,11,13,15\)

Mastectomy skin flap necrosis has been reported in 20% of breasts by Dikmans et al.\(^6\) and in 29% of cases by Gdlevitch et al.\(^4\) Implant loss was reported in 11.8% of breasts by Dikmans et al.\(^6\) and in 14% by Lardi et al.\(^15\) Our incidence of mastectomy skin flap necrosis was low, and all cases were minor. We had no cases of implant loss and a 100% implant retention at 6 months. This may be due to selection bias rather than due to our technique itself. In close consultation with our oncologic surgeons, we defer to completely autogenous reconstruction or add the latissimus dorsi in patients we feel are high-risk for mastectomy skin loss.

In general, a predicted high-risk of mastectomy skin necrosis is our only selection bias. Patients were not excluded based on factors such as age, BMI, tobacco use, preoperative bra size, or ptosis grade; the broad range of these variables is reflected in Table 1. Either preoperative and postoperative radiotherapy or chemotherapy were likewise not excluding factors, as demonstrated in Table 2. Patients had a broad range of previous breast surgeries including both breast reduction and augmentation (Table 3).

Infection requiring intravenous antibiotics has been reported in up to 9.4% of cases and red breast syndrome in up to 14.1%.\(^14\) We saw no cases of either minor or major infection requiring further use of either oral or intravenous antibiotics and no cases of red breast syndrome. All patients were given a minimum of 7 days of prophylactic antibiotic therapy. Duration of antibiotic use varied substantially as the resident discharging the patient would use their judgment when writing the discharge prescription. In some instances, the duration of antibiotic use was extended by the senior author on follow-up in clinic from that written by the resident out of caution. Including this addition of antibiotic use, the longest duration of antibiotic use was 21 days.

Table 5. Complications and Revisions following Reconstruction

| Complications                                      | Patients, n (%) | Breasts, n (%) |
|---------------------------------------------------|-----------------|---------------|
| Animation                                         | 1/19 (5)        | 2/35 (6)      |
| Capsular contracture (grade III/IV)               | 0               | 0             |
| Hematoma                                          | 3/19 (16)       | 3/35 (9)      |
| Minor (managed conservatively or under local)     | 0               | 0             |
| Major (requiring management in OR)                | 0               | 0             |
| Implant malposition*                              | 2/19 (11)       | 2/35 (6)      |
| Infection                                         | 0               | 0             |
| Minor (treated with oral antibiotics)             | 0               | 0             |
| Major (treated with intravenous antibiotics)      | 0               | 0             |
| Mastectomy skin flap necrosis                     | 3/19 (16)       | 3/35 (9)      |
| Minor (managed conservatively or under local)     | 0               | 0             |
| Major (requiring management in OR)                | 0               | 0             |
| Palpable ADM irregularity                         | 5/19 (26)       | 5/35 (14)     |
| Red breast syndrome                               | 0               | 0             |
| Rippling                                          | 4/19 (21)       | 5/35 (14)     |
| Seroma                                            | 1/19 (5)        | 2/35 (6)      |
| Wound healing problems                           | 3/19 (16)       | 3/35 (9)      |
| Minor (without exposure of implant)               | 0               | 0             |
| Major (with exposure of implant)                  | 0               | 0             |

| Required revisions                                 | Patients, n (%) | Breasts, n (%) |
|---------------------------------------------------|-----------------|---------------|
| Capsulorrhaphy†                                    | 1/19 (5)        | 1/35 (3)      |
| Fat grafting‡                                      | 1/19 (5)        | 1/35 (3)      |
| Implant removal with replacement§                 | 1/19 (5)        | 1/35 (3)      |

*One of 35 with lateral malposition, and 1 of 35 with superior malposition requiring use of bandeau.
†Required in patient with lateral displacement with BMI 44.6.
‡Due to rippling in patient with moderate profile implant.
§Exchange from moderate profile to moderate profile plus implant due to rippling.
We feel the low incidence of these is likely multifactorial and may involve tunneling of drains, early revision of any full-thickness skin loss, decreased seroma rates, or the use of AlloMax. Subcutaneous tunneling of drains prevents a portal to the external environment directly over the implant or ADM when they are removed. AlloMax is prepared by the Tutoplast process, which involves decellularization, sterilization, and viral inactivation. Unlike many other ADM products, AlloMax is terminally sterile.

Seroma has been reported in up to 20.9% of breasts by Dikmans et al. and in up to 14% of cases by Chun et al. Hematoma has been reported in up to 5% of cases. In our series, only 1 patient experienced a bilateral seroma, the more significant of which occurred in a previously radiated breast but which was still managed conservatively. When using 1 sheet of ADM, we feel the hammock supporting the implant is too tight and pulls the implant upward. In contrast, using 2 sheets of ADM (or 1 larger sheet) allows the implant to sit lower and better fills out the lower pole of the breast. This eliminates dead space in the area where collections most commonly occur.

Implant malposition has been reported in up to 11% of cases. We demonstrated 2 cases; however, we feel these were likely due to patient factors. One case of lateral displacement occurred unilaterally in a patient undergoing bilateral reconstruction with BMI 44.6, DD bra size, and grade III ptosis. One case of a high riding implant occurred in a previously radiated lumpectomy patient undergoing completion mastectomy. The lower pole skin was initially tight forcing the implant upward; however, this eventually relaxed with the use of a bandeau.

Rates of animation following direct-to-implant reconstruction utilizing ADM are not well described. We saw animation in only 1 patient, and in that case it was minor and the patient desired no correction. At this time, we have not had any patients complain of animation deformity beyond 6 months postoperatively, which was not previously detected. We feel that a similar principle applies in this case. When the implant sits lower, less of it is covered by the pectoralis major muscle. The benefit of this is 2-fold: the action of the pectoralis on the implant is decreased, and there is less of the implant located underneath the pectoralis, which can be caught and pulled upward.

Rates of rippling in these cases are likewise not well described. Using a subcutaneous direct-to-implant technique, Downs and Hedges reported rippling in 35.4% of patients, with 70% of these requiring fat grafting to correct the rippling. In our series, we felt that the cause of rippling was related to the fill volume of the implant. We subsequently switched from using smooth, round, moderate profile Mentor implants to using moderate profile plus implants. This was done as it was felt to reduce the incidence of visible postoperative rippling. Although this has not completely eliminated rippling, we felt it has decreased its incidence. At this time, we do not have adequate patient numbers in both groups to perform a meaningful subgroup analysis to confirm these findings.Implant removal and replacement was performed in only 1 patient, and this was done to exchange from a moderate profile to a moderate profile plus implant to reduce rippling. This was done concurrently with fat grafting.

Rates of palpable ADM have likewise not been well described in the literature. In certain cases, ADM was palpable but not visible in reconstructed breasts. All patients in which this occurred were imaged, and these studies were negative for concerns of recurrence. We feel that this may occur in areas where a small amount of excess ADM was sutured, areas where sutures released and ADM became rolled up, or areas of unincorporated ADM.

We feel that the limited submuscular direct-to-implant technique utilizing AlloMax offers distinct advantages over other techniques. The lower position of the implant reduces dead space and results in low seroma and hematoma rates. This lower position likewise minimizes the action of the pectoralis on the implant, reducing animation rates.

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**Fig. 7.** Patient following skin-sparing mastectomy: preoperatively (A), 5 months postoperatively demonstrating rippling (B), and 1 year following implant exchange to moderate plus profile and fat grafting to the right breast (C).
Animation is possible even in the subcutaneous technique as the implant sits directly on the pectoralis major and may become adherent to it when a capsule forms. In this technique, the implant sits on static chest wall structures (ribs and intercostal) and is less susceptible to this issue. This technique still covers the upper pole of the implant where rippling is most likely to occur and provides a stable bed for fat grafting if it is required. Although it can be argued that a stable bed for fat grafting can likewise be obtained by placing ADM in this area and developing a plane between the incorporated ADM and the skin, this results in an additional cost which is otherwise avoided by our technique.

In our experience, the use of AlloMax appears to be associated with low complications when utilized in our limited submuscular technique. The use of 2 sheets of ADM allows the implant to sit in a more inferior position than would be allowed by a single sheet. Although this results in an increased cost of performing the procedure, the benefits include decreased complications and decreased need for revisions. This allows women to return to their baseline function more rapidly and better restores their quality of life. It is difficult to quantify the cost benefit of these factors to individual women and to society as a whole.

CONCLUSIONS

For immediate direct-to-implant breast reconstruction with ADM, the limited submuscular technique utilizing AlloMax appears to be both safe and effective with low complication rates seen in the first 6 months following surgery. Our decreased complication rate may partially be due to the processing of AlloMax, due to proper patient selection, or due to our technique. Allowing the implant to sit in a lower position results in low seroma and hematoma rates and decreases animation by minimizing the action of the pectoralis on the implant. Coverage of the upper pole where rippling is most likely to occur is maintained, and this also provides a stable bed for fat grafting if it is required. Lower complication rates translate into lower revision rates, which are beneficial to the quality of life of women and may offset the cost of additional ADM in this technique.

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