

# New Deep Dermal ADM Incorporates Well in Case Series of Complex Breast Reconstruction Patients

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**Abstract:** Breast cancer patients with significant comorbidities present reconstructive challenges due to a predictably high complication rate. During expander-based breast reconstruction, human acellular dermal matrix (ADM) is often used to prevent pectoralis muscle retraction, facilitate early expansion, and improve cosmetic outcome. Device infection and chronic seroma have been correlated to the addition of the graft by some large database reports but not others. This study describes the first reported experience with a new deep dermal ADM, FlexHD<sup>®</sup> Pliable<sup>™</sup> (MTF, Edison, NJ).

Sixteen breasts in 10 consecutive patients identified retrospectively and followed prospectively had immediate expander-based breast reconstruction utilizing the new ADM. Patient comorbidities were catalogued, complications were recorded, and overall reconstructive success was assessed. At implant exchange, the ADM was examined for tissue ingrowth and biopsied for histologic examination.

All 16 breasts had successful reconstructions. Two breasts (12.5%) developed device infection, requiring removal and later replacement of the expander. One breast (6.7%) developed chronic seroma, also requiring expander removal and later replacement. All the complicated patients had significant comorbidities, including obesity in all 3. At expander removal, the FlexHD Pliable showed near-complete visual tissue incorporation in 14 of 16 breasts (88%).

This case series demonstrates significant reconstructive success in challenging patients utilizing a novel ADM. Visual and histologic assessment of tissue ingrowth into the graft suggests the high rate of complication may be due to patient comorbidities rather than addition of ADM. Additional experience is needed to confirm and the study is ongoing.

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**Abbreviations:** ADM = acellular dermal matrix, BMI = body mass index, DCIS = ductal carcinoma in situ, IDC = intraductal carcinoma, L = left, MTF = Musculoskeletal Transplant Foundation, R = right, TOPS = Tracking Operations in Plastic Surgery.

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## INTRODUCTION

Tissue expander and implant reconstruction comprise the majority of postmastectomy breast reconstructions in the United States today.<sup>1–3</sup> Such reconstructions require the creation of a submuscular pocket to cover the implant. This may be difficult to achieve because of the surgical loss of local breast tissue following mastectomy and in patients with insufficient local tissue availability. Allograft techniques have been developed to form an inferolateral “sling” covering the implant<sup>4</sup> to prevent visible implant contours and avoid pectoralis muscle “window-shading” following its partial release.<sup>5</sup> The use of allograft appears to facilitate improved control over the mastectomy space and the precise location of prosthetic device. In 2-stage reconstruction of the breast following mastectomy, a tissue expander is used beneath the pectoralis muscle, which is coupled with the acellular dermal matrix (ADM) to completely cover the expander beneath the mastectomy skin flaps. The expander is serially increased in fluid volume to stretch the breast pocket and eventually is exchanged for a permanent implant.<sup>6</sup> Such use of acellular dermis results in good clinical and aesthetic outcomes for those patients electing 2-stage breast reconstruction.<sup>1,7</sup> A recent outcomes article analyzing the Tracking Operations and Outcomes for Plastic Surgeons (TOPS) database indicated that 35% of the expander-based reconstructions utilized such a technique.<sup>8</sup> Furthermore, use of the technique appears to be increasing, with 1 recent market analysis reporting growth of 9.4% in sales of biologic matrices for the breast compared with the same period 1 year previously.<sup>9</sup>

Human ADM is the most commonly used allograft in breast reconstruction today. The first human ADM widely used in breast reconstruction was AlloDerm<sup>®</sup>. Other manufacturers have since marketed similar products. These ADM grafts are all derived from a common source, human tissue donors. The grafts are processed in varying techniques and include unique, proprietary washes as well as in-package irradiation. Previous human ADMs used in breast reconstruction were all marketed as having multiple applications in surgical reconstructions at varying locations in the body. In some of these applications, for example, abdominal wall, higher value would be placed on having a graft with higher tensile strength, more tightly woven collagen and, perhaps, less elasticity as well.

The human ADM graft studied in this case series, FlexHD Pliable (Musculoskeletal Transplant Foundation, Edison, NJ), undergoes a unique mechanical preparation different from other ADMs. The source tissue is cut in such a way that removes not only the epidermal surface but also the more superficial dermis. Only the deeper part of the dermis is utilized as a graft. This part of the dermis has more loosely packed collagen bundles with greater elasticity, and somewhat lower overall lower tensile strength when compared with other ADMs on the market. We believe these qualities that are unique to the deep part of the dermis may make FlexHD Pliable more specific as a graft for the reconstruction of the lower pole of the breast. This investigation represents

the first report of the use of the FlexHD Pliable specifically for breast reconstruction

## PATIENTS AND METHODS

The institutional review board of our hospital (Centra Health, Inc.) approved the study, and informed consent was obtained from all patients. We performed retrospective review that identified 10 consecutive patients between October 2012 and February 2013 representing 16 breast reconstructions utilizing FlexHD Pliable. The same breast removal surgeon performed all mastectomies with the exception of 2. A single plastic surgeon performed the breast reconstructions. All patients underwent immediate reconstruction with expanders and allograft following breast removal. After tissue expansion generated adequate breast volume, the expanders were replaced by permanent implants in the second stage. Table 1 summarizes the patients and the overall results.

Six of the 10 cases were bilateral and four were unilateral mastectomies. Of the 16 breasts, 7 were removed for prophylactic reasons. Five of the women were diagnosed with invasive ductal carcinoma (IDC), 2 with ductal carcinoma in situ (DCIS), 1 with multifocal IDC, and 1 with both IDC and DCIS. One patient had a strong family history of breast cancer with a personal history of multiple benign biopsies; she underwent bilateral prophylactic mastectomies. The age range was 37 to 59 years (mean 47) and BMI range was 23.7 to 42.1. The mean BMI was 30.4 indicative of a preponderance of obese subjects. Other comorbidities were also quite prevalent in this population (Table 1).

## Surgical Technique

Following consultation with the general surgeon, a variety of incision patterns were used depending on the size of the breast (breast tissue removal range was 155–1209 g, mean weight, 526.8 g) and the existence of previous scars. There were 8 oblique, 4 periareolar nipple sparing, 3 Wise-pattern, and 1 inframammary nipple-sparing incisions, all of which were designed by the plastic surgeon preoperatively for the breast surgeon. Following mastectomy, clinical skin flap evaluation was performed, with selective use of intraoperative indocyanine green angiography system to quantify skin flap perfusion (Spy Elite; Novadaq, Bonita Springs, FL). This was used in all 3 nipple-sparing mastectomy patients and in 1 patient with prior bilateral lumpectomy with radiation. In all cases, the subpectoral plane was developed and a portion of the inferomedial pectoralis was divided and released. Expanders used were Mentor (Santa Barbara, CA) or Sientra (Santa Barbara, CA) and were selected for ultimate volume expansion based on expected size and contour of the fully reconstructed breast. The expander footprint was marked on the chest wall and the inframammary fold was transposed to the chest wall and marked with methylene blue. The chest wall was measured in each case for width and height of that part of the expander not covered by the pectoralis major; the size of the allograft was selected according to these measurements. A 6 cm × 16 cm (11 breasts) or an 8 cm × 16 cm (5 breasts) FlexHD Pliable allograft was rinsed in saline for 3 minutes (per MTF product instructions) and carefully trimmed to the exact size needed. It was then used to define the inferolateral extent of the breast pocket in each case before the placement of the expander.

**TABLE 1.** Patient Overview and Results Summary

	Age	Breasts Treated	Comorbidities	Surgical Complications	Degree of ADM Incorporation (%)	Successfully Reconstructed Breasts
Patient 1	59	1	Obesity 2 (BMI 36), previous radiation therapy following lumpectomy	None	50	1
Patient 2	45	1	Morbid obesity 3 (BMI 42)	None	100	1
Patient 3	41	2	Overweight (BMI 28), cerebrovascular insufficiency with cerebrovascular accident and mild partial paralysis	Infected left expander (removed)	100, R	2
Patient 4	50	1	Obesity 1 (BMI 34), hypertension, diabetes, nicotine use	Chronic seroma (expander removed)	80, L 100	1
Patient 5	44	1	Obesity 1 (BMI 31), postop radiation therapy	None	100	1
Patient 6	37	2	Overweight (BMI 26.2), nicotine use, postop radiation therapy	None	100, R	2
Patient 7	42	2	None	None	100, L 100, R	2
Patient 8	52	2	None	None	100, L 100, R	2
Patient 9	59	2	Obesity 2 (BMI 37), hypertension	Infected left expander (removed)	100, R	2
Patient 10	45	2	None	None	90, L 100, R 100, L	2

ADM = acellular dermal matrix, BMI = body mass index, L = left, R = right.

Beginning with case six, the allografts were perforated at 2-cm intervals prior to use with either a 15 blade or 2-mm dermal punch to increase drainage efficiency during the stage 1 postoperative period. In all cases, the allograft was trimmed to fit (and perforated, if applicable) before implantation. Irrigation of the breast pocket and cleansing of the skin with a triple antibiotic solution (cefazolin, bacitracin, and gentamycin) was performed before sewing in the graft. The FlexHD Pliable was sewn in place using interrupted sutures at the transposed inframammary folds. The expander, evacuated of air and filled with 50 cc of sterile saline, was then placed on the chest wall and situated at its marked footprint and then sutured in place using the suture tabs provided. The pectoralis major was then approximated to the allograft with running 2-0 absorbable suture and additional fluid was placed in the expander until the expander had a snug fit within the cavity. Initial expansion fluid volumes ranged from 50 to 500 mL with an average of 266 mL. Two 7 mm drains, 1 in the sub-pectoral plane and 1 in the subcutaneous plane, were used on each reconstructed breast. The skin was then closed in layers with absorbable suture. Incisions were covered with a clear barrier dressing and each drain site was fitted with a Biopatch (Ethicon, Somerville, NJ) and clear barrier dressing. The surgeries took an average of 1 hour, 31 minutes per breast with a range of 1 hour, 0 minutes to 1 hour, 59 minutes per breast.

### Postoperative Care

Length of hospital stay was between 1 and 3 days, with the majority (5 women) remaining in house for 2 days. A postoperative prophylactic regimen was prescribed for 7 days and followed in all. Patients wore surgical bras for support and were permitted to shower on postoperative day 2. Postoperative visits were performed in office with the subcutaneous drain removal by 7 days in all cases. Secondary drains were removed between 13 and 34 days (mean removal at 22 days) after surgery. The criterion for drain removal was an output of 30 cc or less daily. The number of in-office expansions ranged from 2 to 5 with the majority of expansions completed in two office visits. Range for total expansion was 200 to 625 mL with a mean final expansion of 329 mL. Final fill volumes were between 400 and 925 mL, with an average of 594 mL. Second-stage surgeries were performed between 1.5 and 12.5 months after the first stage with an average time of 5.1 months. Mentor smooth, round implants, or Sientra-shaped, textured implants were used, with size and profile depending upon individual reconstruction plans. Two patients had postmastectomy radiation and six had chemotherapy coincident with their reconstructions. One patient had a history of prior lumpectomy, radiation, and chemotherapy before mastectomy and subsequent reconstruction. Three women returned for delayed expander replacement due to complications following stage 1 that led to expander removal.

The patients were followed continuously at regular intervals. At 6 months following their last procedure, a third party administered the postoperative reconstructive module of the BREAST-Q™ questionnaire<sup>10</sup> to each patient.

### RESULTS

All patients experienced successful reconstructions; 3 were selected to depict the variety of patients represented in the series. Figures 1–4 show a patient whose management was complicated by seroma, while Figures 5–8 display a patient who had nipple-sparing prophylactic mastectomies. Figures 9–12 show a patient with bilateral reconstructions who received postoperative radiation to 1 breast but not the



**FIGURE 1.** Preoperative photograph of patient 4. This patient had a chronic seroma after left breast reconstruction leading to expander removal due to suspicion of infection.

other. In every patient except 1 (see later), the graft was found to be supple and well-incorporated on both visual and microscopic examination (Figures 3, 4, 7, 8, 11, and 12).

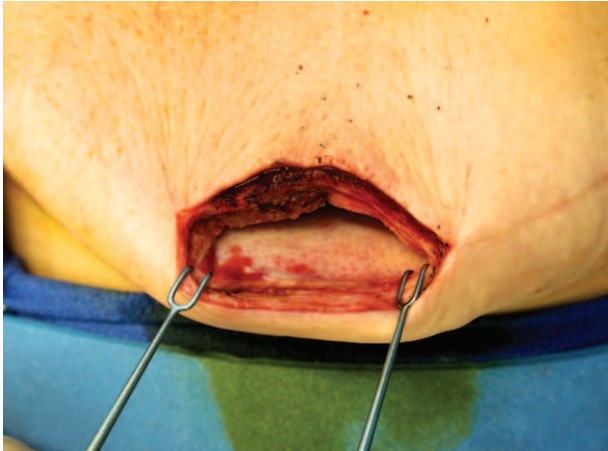
Satisfaction with reconstruction was measured with the administration of the postoperative BREAST-Q reconstruction module, which 9 of the 10 (90%) patients completed (including 2 of the 3 patients who had major complications). The BREAST-Q scoring resulted in a mean Q-Score of 81 (on a 100-point scale) for “Satisfaction with Breasts,” a measurement of a woman’s body image as it relates to her breast. The Q-Score for Physical Well-Being: Chest and Upper Body averaged 85 (out of 100) for the case series; this indicates minimal postsurgical pain, limitations in range of motion, or tenderness. Finally, a woman’s overall assessment of the outcome of her reconstruction is measured by the “Satisfaction with Outcome” Q-Score, which for these patients averaged 92 out of 100.

Two patients with breast reconstructions (12.5%) experienced infections and had expanders removed. Another experienced chronic seroma (all cultures negative including those



**FIGURE 2.** Postoperative photograph of patient 4, following repeat left expander reconstruction, exchange of expander to permanent gel implant, nipple/areola reconstruction and tattoo, and right breast reduction.





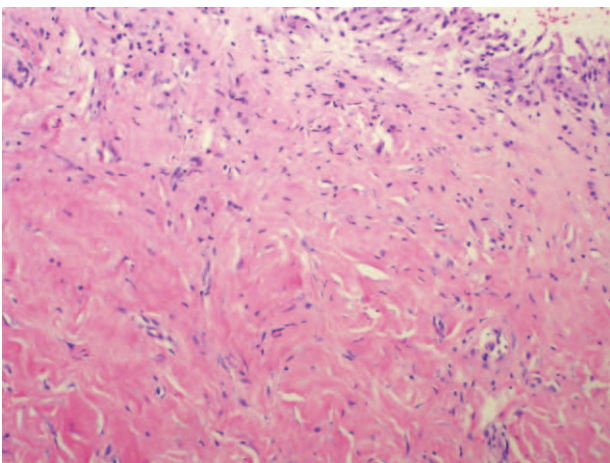
**FIGURE 3.** Well-incorporated FlexHD Pliable was noted at the time of expander removal due to seroma.

before antibiotic use) and required removal (Figures 1–4). In all 3 of these patients, the allograft had incorporated well despite the presence of infection or seroma; unincorporated allograft tissue was removed in each case. Following a 3-month delay, successful replacement of the expander in each of these 3 cases was accomplished without adding additional graft. Successful second-stage expander-to-implant exchanges for all 16 breasts in all 10 patients were performed with no complications. Only 1 patient had limited incorporation of the graft at the time of exchange. This patient had a history of lumpectomy and radiation in the affected breast several years previously. Eight patients (13 breasts) have completed nipple reconstruction. One patient still awaits nipple reconstruction on 2 breasts and another patient has elected not to have the procedure performed on her treated breast.

Two patients who underwent radiation treatment after expander placement not only had successful reconstruction but were also noted to have softer-than expected reconstructions following radiation (Figures 9–12).

## DISCUSSION

Two-stage prosthetic breast reconstruction using an expander and implant is the most common reconstructive breast



**FIGURE 4.** Photomicrograph of well-incorporated FlexHD Pliable at the time of expander removal due to seroma.

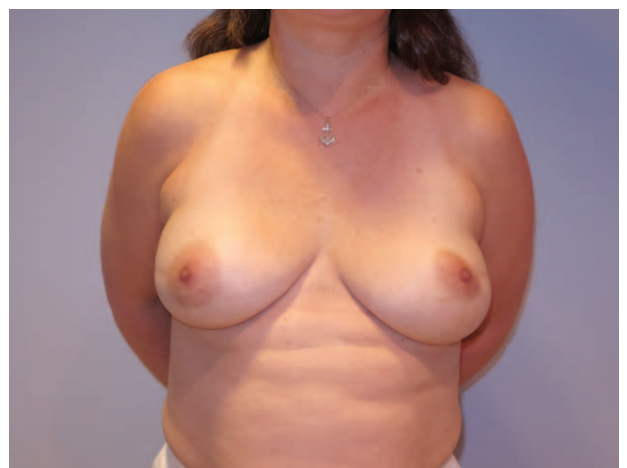


**FIGURE 5.** Preoperative photograph of patient 10. This patient underwent bilateral nipple-sparing mastectomy with immediate expander reconstruction.

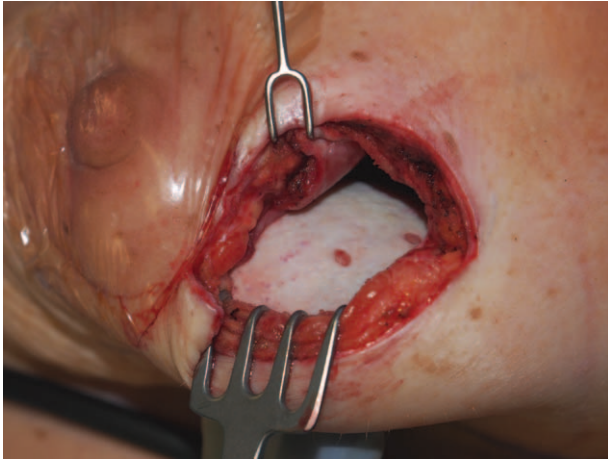
procedure performed in the United States today, with 69,608 performed in 2013.<sup>1</sup> A recent article identified approximately 35% of expander-based reconstructions being performed with the use of ADMs, although that number is based on analysis of the TOPS (Tracking Operations in Plastic Surgery) Database, in which only 6.5% of American plastic surgeons participate. More accurate numbers are difficult to obtain, though it is at least clear that a large number of breast reconstructions are performed using ADMs, and that number may be increasing as younger surgeons familiar with the technique continue to replace older retiring surgeons who are reluctant to try it.

Although ADMs have been used in the breast for over 10 years, the grafts themselves have changed little, differing only in the types of preparatory treatments and the use or nonuse of radiation during packaging. Many practitioners believe that it does not matter which one is used, and even speakers at national meetings admit to “package syndrome” – considering all of the grafts to be the same with the exception of their packaging.

Using an ADM to reconstruct the lower pole of the breast over a tissue expander, however, presents some unique



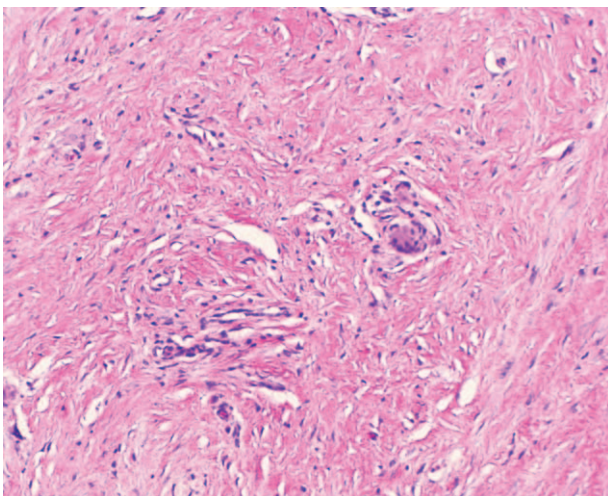
**FIGURE 6.** Postoperative photograph of patient 10, following bilateral exchange of expanders to permanent saline implants (480 cc right, 400 cc left).



**FIGURE 7.** Well-incorporated FlexHD Pliable was noted at the time of expander exchange.

challenges that warrant consideration when selecting a graft. As reconstructive surgeons, we are expecting the graft to incorporate quickly and stretch with the tissue expander's gradual increase in size. We are also expecting the graft to perform well in a surgical field contaminated by extensive extirpative surgery. As in this study, our patients are often overweight and present a multitude of morbid conditions. The urgency of the cancer removal prevents addressing these comorbidities preoperatively. In addition, an increasing rate of bilateral mastectomies,<sup>11</sup> with reconstruction, and their associated prolonged operating room time and we have a potent culture media for seroma and/or infection.

The patients in this case series are admittedly a challenging population to reconstruct. Six out of 10 are obese, which confers an increased relative risk of implant loss of 1.9 for BMI 30 to 40 and 4.2 for BMI >40.<sup>6</sup> Obesity has also been linked to increased rates of seroma,<sup>12</sup> which probably contributed to drainage volumes persistently >30 cc daily, as evidenced by the average second drain duration of 22 days. Additional challenges were 20% smokers and 30% radiated. Not surprisingly, there were some complications, notably infection in 2 breasts and chronic



**FIGURE 8.** Photomicrograph of well-incorporated FlexHD Pliable at the time of expander exchange.



**FIGURE 9.** Preoperative photograph of patient 6. This patient underwent right therapeutic mastectomy with immediate expander reconstruction followed by radiation. She later underwent left prophylactic mastectomy with expander reconstruction.

seroma in 1. Nevertheless, patient satisfaction, as measured by the BREAST-Q survey Q-Scores in several areas, appears to be high. (Validated norms for the Q-Score are not yet available, but the results for these patients compare very favorably with those in previously published studies<sup>13,14</sup> and suggest a high degree of patient satisfaction.)

The use of ADMs in breast reconstruction has its critics, largely centered on suspicions of higher complication rates such as seroma or infection leading to reconstructive failure.<sup>4,5</sup> Poorly incorporated graft is often noted when such complications occur. A human ADM specifically prepared for use in the breast therefore holds promise if it has the potential to decrease these complications or is found to perform better in the breast in some other fashion. Although there is now a significant and growing number of publications on allografts in general and FlexHD in particular, this case series is the first report of FlexHD Pliable in the literature.

It was remarkable to us that the grafts had ingrowth of tissue even in the patients who were reoperated for complications. In addition, the graft had extensive incorporation in the 2 patients who had radiation therapy following expander/ADM



**FIGURE 10.** Postoperative photograph of patient 6, following bilateral exchange of expanders to permanent gel implants (600 cc right, 550 cc left).





**FIGURE 11.** Well-incorporated FlexHD Pliable at the time of expander exchange on the left (nonradiated) breast.

reconstruction. Not only was the graft well incorporated at the time of exchange both macro- and microscopically, there was a relatively small degree of capsular contracture in those reconstructed breasts (Baker II in each case). One patient who had had *previous* radiation therapy (for breast cancer 11 years prior treated with breast conservation) was the only patient with a substantial amount of unincorporated graft (about 50%) at the time of implant exchange. This patient was also obese, with a BMI of 35.5.

Until recently, the only quantification of the grafts was their thickness: thin, thick, and extra-thick by the company



**FIGURE 12.** Well-incorporated FlexHD Pliable at the time of expander exchange on the right (radiated) breast.

supplying them. The implanting surgeon was encouraged to pay particular attention to the orientation of the graft and to be sure that the dermal (as opposed to the epidermal) side was oriented toward the vascularized skin flap, lest the graft fail to incorporate.<sup>15</sup> Since the *superficial* side of FlexHD Pliable is itself relatively deep in the dermis, with looser collagen architecture, such orientation is probably less important. In addition, the increased elasticity may enhance its ability to conform to the tissue expander's curve in the lower pole of breast, potentially improving the cosmetic results of reconstruction. The looser collagen architecture and increased elasticity of FlexHD Pliable is unique among ADMs currently on the market, and may be an advantage in the role of lower pole breast reconstruction.

The small size of the case series here necessarily limits any significant conclusions that can be drawn, but it does point to some noteworthy observations and suggestions for future study. The unfortunate need to operate on patients for complications affords the opportunity to view a graft's performance in a hostile environment. In the cases reported here that had complications, the graft's performance, as measured by its degree of incorporation in the face of infection or seroma, was notable, and to the author raises the question of whether the unique qualities of the graft enhances its ability to be incorporated into the patient or the speed with which this occurs.

Despite the morbidities present in this patient population, the author is concerned with the relatively high rate of expander removal in 3 out of 16 (19%) patients due to infection or seroma. A new technique utilizing concepts of "no-touch" principles<sup>16–18</sup> is currently being developed to potentially address these issues. Further technique refinements include the use of a single drain rather than 2 to decrease the risk of contamination from colonized drain fluid or drain tube "pistoning" at the skin exit site. It is felt that the use of perforations in the graft may facilitate fluid communication between the subcutaneous plane and the submuscular plane (where the expander is located), thus decreasing the need for separate drains in each space.

## CONCLUSIONS

At this early stage, the most that can be concluded is that this novel graft is capable of successful, and cosmetically appealing, breast reconstruction in a population of subjects that would predict multiple postoperative complications. More experience with it in larger numbers of patients will hopefully elucidate whether its unique mechanical preparation affords advantages of faster incorporation, fewer complications, or superior cosmetic reconstructions.

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