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A Prospective Study Assessing Complication Rates and Patient-Reported Outcomes in Breast Reconstructions Using a Novel, Deep Dermal Human Acellular Dermal Matrix

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Background: The value proposition of an acellular dermal matrix (ADM) taken from the deep dermis is that the allograft may be more porous, allowing for enhanced integration and revascularization. In turn, this characteristic may attenuate complications related to foreign body reactions, seromas, and infection. However, this is juxtaposed against the potential loss of allograft structural integrity, with subsequent risk of malposition and extrusion. Despite the active use of novel, deep dermal ADMs, the clinical outcomes of this new technology has not been well studied.

Methods: This is a prospective study to evaluate surgical and patient-reported outcomes using a deep dermal ADM, FlexHD Pliable. Surgical outcomes and BREAST-Q patient-reported outcomes were evaluated postoperatively at 2- and 6-month time points.

Results: Seventy-two breasts (41 patients) underwent reconstruction. Complication rate was 12.5%, including 2 hematomas and 7 flap necroses. One case of flap necrosis led to reconstructive failure. Notably, there were no cases of infection, seroma, or implant extrusion or malposition. Average BREAST-Q scores were satisfaction with outcome (70.13±23.87), satisfaction with breasts (58.53±20.00), psychosocial well being (67.97±20.93), sexual well being (54.11±27.72), and physical well being (70.45±15.44). Two-month postoperative BREAST-Q scores decreased compared with baseline and returned to baseline by 6 months. Postoperative radiation therapy had a negative effect on satisfaction with breasts ($P = 0.004$) and sexual well being ($P = 0.006$).

Conclusions: Deep dermal ADM is a novel modification of traditional allograft technology. Use of the deep dermal ADM yielded acceptably low complication rates and satisfactory patient-reported outcomes. *(Plast Reconstr Surg Glob Open 2015;3:e585; doi: 10.1097/GOX.0000000000000574; Published online 18 December 2015.)*

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Biologic meshes are increasingly popular adjuncts for prosthetic breast reconstruction, assisting about 67% of these operations.[1]

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Today, a litany of acellular dermal matrix (ADM) products are available for use in breast reconstruction, including AlloDerm (LifeCell Corp., Bridgewater, N.J.), Strattice (LifeCell Corp.), and FlexHD Structural (Musculoskeletal Transplant Foundation, Edison, N.J.). Potential advantages conferred by ADM include greater lower pole expansion and coverage, reduced capsular contracture, and more precise control of the inframammary fold and implant position.[2–4] However, ADM has also been subject to criticism for its high costs and potentially increased complication rates such as infection and seroma.[5–10] Given the rising popularity of ADM use in breast reconstruction, new products continue to be developed with modifications and enhancements meant to improve these reconstruction endpoints.

One intriguing avenue for improving ADM is taking a deeper cut of dermal tissue, where the collagen matrix is less dense and more porous relative to the majority of the dermis.[11] FlexHD Pliable (Musculoskeletal Transplant Foundation) is a new generation of human ADM that is designed with this deep dermal modification.[12] Density analysis and microhistological and ultrahistological studies have shown that this allograft is more porous compared with traditional ADM; the material also demonstrates increased cellular ingrowth and elasticity.[13] Porosity is known to be a critical factor influencing integration and revascularization of grafts. Both in vitro and in vivo research have demonstrated that grafts with larger pores are more amenable to cellular attachment,[11,14] and that fibrovascular ingrowth and revascularization is superior in grafts with greater porosity.[15–18] Furthermore, swifter revascularization may reduce the extent of the foreign body reaction inherent to allograft use, which, in turn, may diminish the incidence of seroma and subsequent secondary infection.[9,16] On the other hand, reducing the density of the acellular dermal matrix has a corollary concern that it may become excessively malleable and insufficiently durable, which could lead to implant malposition and extrusion. With these competing concerns, we endeavored to conduct the first prospective study to assess the complication profile associated with this new, deep dermal ADM.

Along with traditional tracking of surgical complications as outcomes markers for breast reconstruction, patient-reported outcomes have also received more intense investigation in recent years.[19–25] These subjective outcomes are positively associated with objective outcomes like clinical effectiveness and patient safety.[26,27] BREAST-Q (Memorial Sloan-Kettering Cancer Center, New York, N.Y.) is a validated survey instrument designed to quantify patient-reported outcomes in breast surgery[28,29] and has been successfully employed to understand how key perioperative variables impact the patient experience. For example, patients undergoing perioperative radiation therapy scored lower on all scales of the BREAST-Q©.[19,30] Although investigators are increasingly interested in patient-reported outcomes, there remain few studies examining the relationship between these outcomes and ADM use specifically. We sought to further examine these patient-reported outcomes in breast constructions using deep dermal ADM. We hypothesized that if more porous ADM leads to faster integration and reductions in complications, patients may also express correspondingly high levels of satisfaction.

Thus, to address these gaps in current knowledge, the present study prospectively examined immediate, 2-stage breast reconstructions assisted by a deep dermal ADM. We aimed to characterize both the complication profile and the patient-reported outcomes in the reconstructions performed with this more porous and pliable allograft. Our secondary objective was to identify key trends and associations in the patient-reported outcomes of ADM-assisted breast reconstruction.

METHODS

Patient Selection

This is a prospective observational cohort study approved by the Northwestern University Institutional Review Board. All patients provided a written and signed informed consent. Between July 2013 and July 2014, we consecutively enrolled patients undergoing immediate 2-stage prosthetic reconstruction after mastectomy. Patients were included if they had single or bilateral postmastectomy tissue-expander reconstruction, were at least 18 years of age, and were able to sign a written informed consent. Patients were excluded if they underwent breast reconstruction after complications from breast augmentation, mastopexy, breast reduction, or breast conservation; had a previously failed reconstruction; underwent autologous breast reconstruction with a tissue expander (ie, latissimus dorsi flap technique); had body mass index greater than 40; or had previous radiation treatment.

Surgical Technique

The reconstructions for all study patients were performed by the senior author (J.Y.S.K.) at Northwestern Memorial Hospital. After tumescent-technique mastectomy by general surgery, the reconstruction team began antibiotic irrigation and hemostasis. The pectoralis muscle was incised along the lower border

and elevated using monopolar electrocautery. After a submuscular space was dissected, a 6×16 cm piece of deep dermal ADM, FlexHD Pliable, was soaked in antibiotic solution and contoured to fit the lower pole defect. It was then secured to the lower chest-wall/mastectomy flap cusp using 2.0 polydioxanone suture in running fashion. An expander was sized and introduced through the pectoralis–ADM interface and secured in the submuscular, subgraft position using 2.0 polydioxanone suture. Minimal touch technique was used when handling both ADM and expander. The pectoralis–ADM interface was then closed and judicious expansion (generally less than 50% of final volume) was performed; 2.0 10-mm clot-stop drains were placed through axilla and the incision closed. Generally, expansion was started at postoperative week 2 and exchange performed 4 weeks after the last expansion.

Data Acquisition

Objective data and patient-reported subjective data were collected prospectively. Objective data were gathered from patient records and recorded on standardized forms. These data consisted of preoperative demographic data, preoperative clinical data, and clinical data taken at 2 and 6 months postoperatively. Subjective data were gathered using the BREAST-Q questionnaire, delivered in office and, when necessary, by mail with self-addressed, postage-paid envelopes included. BREAST-Q is a validated patient questionnaire that is used to gauge patients' perspectives for various breast surgeries, including reconstruction.[29] Surveys were given preoperatively, 2 months postoperatively and 6 months postoperatively. Preoperative and postoperative time points were defined relative to the initial tissue expander placement operation. The preoperative questionnaire contained 42 questions and the postoperative questionnaires contained 103 questions. The preoperative BREAST-Q survey assesses patients' satisfaction with breasts, psychosocial wellbeing, sexual wellbeing, and physical wellbeing; in addition to those dimensions, the 2 and 6 months postoperative surveys also collect information to assess patients' satisfaction with outcome, information, surgeon, medical team, and office staff. Table 1 illustrates representative questions that belong to each scale.

Variables and Statistical Analysis

The 2 principle outcomes of interest were surgical complications and patient-reported outcomes evaluated by the BREAST-Q. The surgical complications evaluated were hematoma, seroma, infection, flap necrosis, and reconstruction failure. For patient-reported outcomes, raw BREAST-Q survey results were computed into the 6 composite BREAST-Q scores using Q-Score, the standardized scoring program. For each scale, Q-score outputs a score from 0 to 100 and does not require that every question in the survey be answered. Trends in BREAST-Q scales over the 3 time periods were assessed by fitting data to linear mixed-effects models. Correlations between physical well being and the other BREAST-Q scales were assessed using Spearman's ρ. Finally, the effect of postoperative radiation therapy (XRT) on the BREAST-Q scales was assessed using unpaired, 2-tailed Student *t* test. For all statistical analyses, *P* values of 0.05 or less were considered significant. All statistical analyses were performed using IBM Statistics version 22.

Table 1. Representative Questions from Each BREAST-Q Dimension

Dimension	Representative Questions
Satisfaction with breasts	How satisfied are you with the softness of your reconstructed breast?
Satisfaction with outcome	How much do you agree with the following statement? "The outcome perfectly matched my expectations."
Satisfaction with information	How satisfied were you with the information you received from your plastic surgeon about healing and recovery time?
Satisfaction with surgeon	Did you feel your plastic surgeon was competent?
Satisfaction with medical staff	Did you feel the members of the medical team other than the surgeon treated you with respect?
Satisfaction with office staff	Did you feel members of the office staff were professional?
Psychosocial well being	How often do you feel confident in a social setting?
Sexual well being	How often do you feel confident sexually?
Physical well being	How often do you have pain in your chest muscles?

Ethical Approval

This study was approved by the Northwestern University Institutional Review Board.

RESULTS

Patient Demographics and Perioperative Characteristics

Seventy-two breasts (41 patients) were enrolled and completed the study. Patient demographics are summarized in Table 2. The average age and body mass index of our cohort were 46 years and 26, respectively. Twenty-eight of the 72 (38.9%) breasts underwent nipple-sparing mastectomy, with the remaining having a simple or modified radical approach. Indica-

Table 2. Patient Demographics

Patients, n	41
Breasts, n	72
Age (yr), mean ± SD	45.66±10.19
BMI, mean ± SD	26.49±5.23
Smokers, n (%)	
Currently	1 (2.4)
In the past	9 (22.0)
Unilateral reconstruction, n (%)	32 (78.0)
Radiation therapy, n (%)	
Preoperative	0 (0)
Postoperative	10 (24.4)
Chemotherapy, n (%)	
Preoperative	6 (14.6)
Postoperative	16 (39.0)
Mastectomy method (breasts), n (%)	
Simple/modified radical	44 (61.1)
Nipple sparing	28 (38.9)
Pathology (breasts), n (%)	
Prophylactic	42 (58.3)
In situ	4 (5.6)
Invasive	26 (36.1)

BMI, body mass index.

tions for 42 of the mastectomies were prophylactic, and the remaining being therapeutic for 4 cases of in situ cancerous and 26 cases of invasive pathology. Ten patients received postoperative XRT. One patient was currently smoking, with an additional 9 reporting that they had smoked in the past.

Complications

No medical complications (myocardial infarction, deep vein thrombosis, or pulmonary embolism) occurred during the study period. Surgical complication rates encountered during the study are summarized in Table 3. Table 4 provides further characteristics of the patients who suffered complications. Of the 72 study breasts, 9 breasts suffered a surgical complication, giving the cohort an overall complication rate of 12.5%. These 9 complications occurred in 7 patients.

Hematoma occurred in 2 breasts, both requiring reoperation to evacuate them and to replace the tissue expander. Both hematomas resolved without further complication. The remaining 7 complications were breasts that developed skin flap necrosis, necessitating surgical debridement, and/or tissue-expander replacement. Six of these flap necroses resolved without further complication. One breast with flap necrosis ultimately failed reconstruction. This breast belonged to a 44-year-old prior smoker who had bilateral mastectomy and reconstruction and was the only complicated breast to have received postoperative XRT (Table 4). Notably, there were no infections or seromas throughout the study period. Additionally, implant malpositions (ie, lateral displacement, bottoming out) and extrusions did not occur.

Patient-Reported Outcomes

Of the 123 surveys delivered, 120 (97.6%) received a response. Table 5 shows average BREAST-Q© scores at 6 months postoperatively. Relative to preoperative scores, 2-month postoperative satisfaction with breasts, psychosocial well being, physical well being, and sexual well being were significantly decreased ($P = 0.018$, $P = 0.003$, $P < 0.001$, $P = 0.005$, respectively; Fig. 1). At 6 months, satisfaction with breasts and psychosocial and sexual well being had returned to preoperative values ($P = 0.903$, $P = 0.321$, $P = 0.479$, respectively). Physical well being at 6 months had improved but remained significantly decreased from baseline ($P < 0.001$, Fig. 1C). Six-month physical well being was correlated with six-month overall satisfaction with surgical outcome ($\rho = 0.373$, $P = 0.021$), as well as six-month baseline-adjusted psychosocial well being ($\rho = 0.462$, $P = 0.003$) and sexual well being ($\rho = 0.353$, $P = 0.032$; Fig. 2). Patients who had postoperative XRT (Table 6) were also significantly less satisfied with their breasts by an average of 20.53 points ($P = 0.004$) and had lower reported sexual well being by an average of 27.28 points ($P = 0.006$).

DISCUSSION

With so many ADM options available, it is crucial for surgeons to have access to evidence-based assessments of the materials' effectiveness. Like other ADM, FlexHD Pliable is a matrix of human allograft skin that has been stripped of dermal cells.[35]

Table 3. Surgical Complications and Comparison to Selected Literature Values of ADM Reconstructions

	Present Study	2012 Meta-analysis[7] (%)	2010, n = 15,3 Sloan-Kettering Cohort[31] (%)	2012, n = 428, Georgetown Cohort[32]	2012, n = 548, MD Anderson Cohort,[33]*	2015, n = 199, BREASTrial[34]
Total complications, n breasts (%)	9 (12.5%)	15.4	23.6	N/A	15.6%, 43.3%	36.2%
Reconstructive failure	1 (1.4%)	3.8	5.9	3.2%	N/A	N/A
Infection	0	5.3	3.3	5.4%	6.2%, 13.3%	15.1%
Seroma	0	4.8	7.2	3.5%	5.0%, 13.3%	4.5%
Hematomas	2 (2.8%)	1.0	2.0	1.2%	0.7%, 0%	1.0%
Flap necrosis	7 (9.7%)	6.9	4.6	3.5%	7.5%, 26.7%	19.6%

*Nonirradiated breasts, irradiated breasts.

Table 4. Characteristics of Patients Suffering Complications

Patient	Complication	Age	BMI	Prior Smoker	Breast Pathology	Bilateral Reconstruction	Postoperative XRT
Patient 1	Hematoma	33	21	Yes	Prophylactic	Yes	No
Patient 2	Hematoma	56	24.5	No	Prophylactic	Yes	No
Patient 3*	Flap necrosis	47	26.2	No	Prophylactic	Yes	No
	Flap necrosis	47	26.2	No	In situ	Yes	No
Patient 4*	Flap necrosis	40	24.3	No	Prophylactic	Yes	No
	Flap necrosis	40	24.3	No	Prophylactic	Yes	No
Patient 5	Flap necrosis	51	20.9	Yes	Invasive	No	No
Patient 6	Flap necrosis	39	34.1	Yes	Invasive	No	No
Patient 7	Recon failure due to flap necrosis	44	29.9	Yes	Prophylactic	Yes	No

*These bilateral reconstruction patients suffered complications to both breasts.

However, it is unique in being taken from a deeper layer of the dermis, which presents a more open collagen matrix.[12,13] Prior density analysis and histological studies with light and electron microscopy have shown that the matrix of this acellular dermis is more porous and open compared with other similar allografts and also demonstrates better cellular ingrowth and tissue integration.[13] Indeed, this relationship between pore size and cellular ingrowth behavior has been noted before in studies of other grafts and implants.[11,14] Previous research suggests that porosity hastens revascularization and integration,[15–18] reducing the amount of time that the foreign body incites the usual inflammatory reaction. Consequently, complications provoked by the foreign body reaction, especially seroma and infection, may be attenuated.[9,16] In contrast, there is also the possibility that the more pliable nature of the deep dermal ADM could lead to implant malposition or extrusion because of weak reconstruction pockets. Therefore, it is necessary to determine if there is any clinical evidence for reduced structural integrity of these modified allografts. Thus far, no prospective studies have characterized the implications of this more porous deep dermal ADM, prompting us to evaluate the clinical outcomes associated with its use. Based on the above reasoning, we hypothesized that using this material would translate into low surgical complication rates, particularly for seroma and infection.

Table 5. Average BREAST-Q Scores at 6 Months (Mean ± SD)

Satisfaction with	
Outcome	70.13 ± 23.87
Breasts	58.53 ± 20.00
Information	71.87 ± 18.41
Satisfaction with	
Surgeon	87.18 ± 16.98
Medical team	88.61 ± 21.19
Office staff	95.97 ± 11.62
Well being	
Psychosocial	67.97 ± 20.93
Sexual	54.11 ± 27.72
Physical	70.45 ± 15.44

Indeed, in this study, we found the material yielded an acceptably low complication profile compared with many previous literature-reported values for other ADM products (Table 2), with an overall complication rate of 12.5% over the 72 breasts tracked. Most of our complications were flap necroses. Notably, there were no infections or seromas. The reported rates of complication vary widely in the literature for breast reconstruction with ADM. A meta-analysis of the breast reconstruction literature determined the mean reported complication rate to be 15.4%, with the most common causes being flap necrosis, followed by infection, seroma, and reconstructive failure.[7] Contrastingly, the randomized, controlled BREASTrial reported much higher complication rates compared with most other authors, documenting an overall complication rate of 36.2%.[34] Most of their complications were flap necroses, followed closely by infections. The BREASTrial authors postulated that previous chart reviews had underreported true complication rates by nature of their retrospective design. The prospective nature of this present study helped to mitigate reporting bias that may have confounded previous retrospective studies' assessments of complication rates.

Potentially heightened complication rates have been a serious concern for ADM use in breast reconstruction.[5–10] Complications threaten reconstructive outcomes and introduce extra costs associated with their management. Our study's overall complication rate sits at or below most other literature-reported values, suggesting that deep dermal ADM technology may offer a significant step toward improving these traditionally poor complication profiles. The lack of seromas and infections is particularly significant result given that other researchers have shown seroma and infection to be some of the most common complications.[31,36] Furthermore, de Blacam

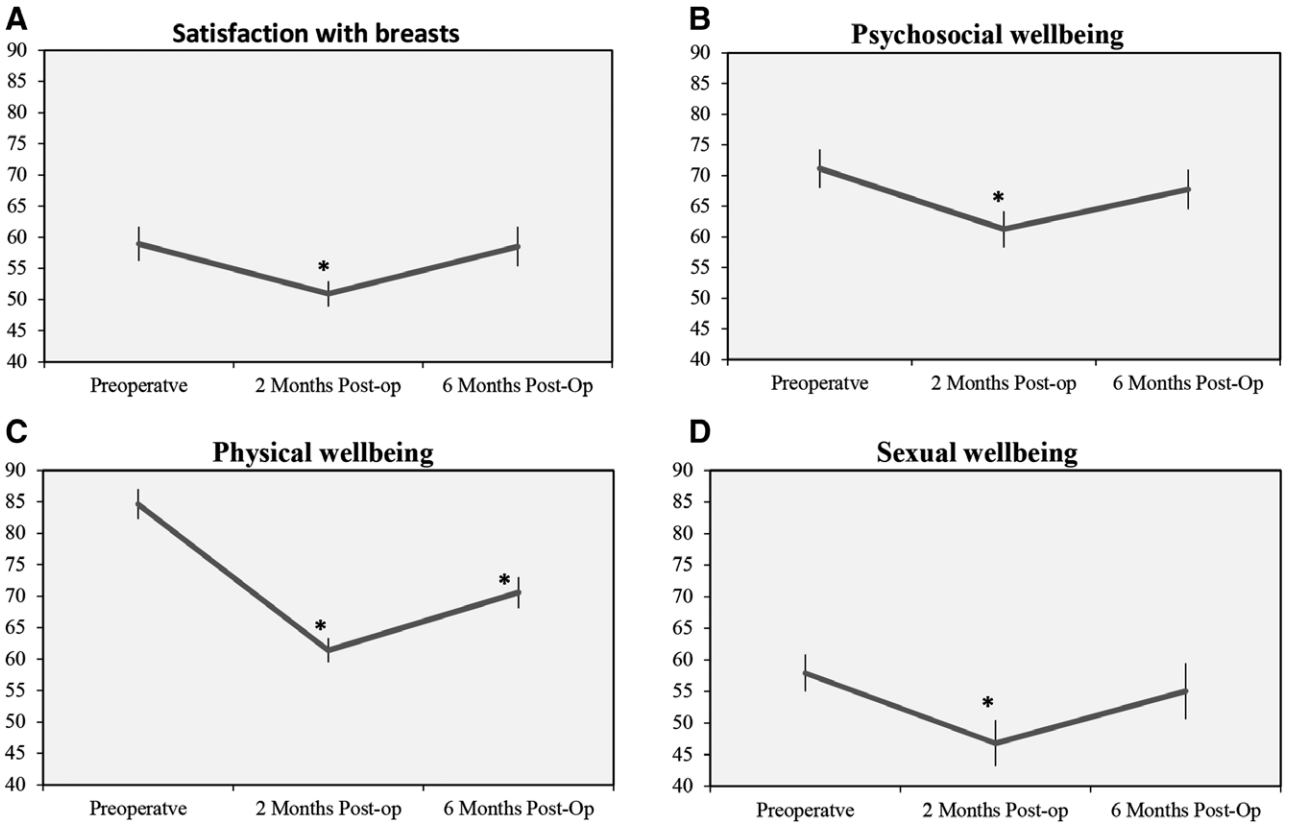

Fig. 1. Mean BREAST-Q scores over time analyzed for significant trends using mixed linear modeling. A, satisfaction with breasts; B, psychosocial well being. C, physical well being; D, sexual well being. Error bars represent standard error from the mean. *$P < 0.05$ compared with preoperative value.

et al[10] reported that infections requiring admission for intravenous antibiotics are the most costly complications to manage. Although formal cost-analysis must be conducted to thoroughly explore the economic implications of deep dermal ADM use, these preliminary results are encouraging for those concerned about the costs of ADM.

Despite the theoretical possibility of weakened structural integrity in deep dermal ADM, here, we did not observe any cases of implant malposition or extrusion. Malposition can cause lateral displacement or bottoming out and often requires revision to redefine the implant pocket. It is, therefore, critical that allografts be strong enough to maintain the implant in the desired position. Previous mechanical analysis of this allograft material found it to have at least equivalent tensile strength and elasticity as traditional ADM,[13] but our study provides clinical evidence that ADM can be designed with lower density and higher porosity without sacrificing necessary durability. Our cohort did encounter a rate of flap necrosis higher than many reported values; we attributed this, in part, to the use of tumescent mastectomy technique, a method that is not often used at other institutions. This technique may reduce bleeding and postoperative pain but has been shown to potentially increase the risk of flap necrosis because of the vasoconstricting effect of epinephrine.[37,38]

This study also assessed patient-reported outcomes of reconstructions using deep dermal ADM, outcomes which presently have very limited data with respect to ADM use. Although objective measures have been the traditional standard for assessing outcomes, researchers are now increasingly accounting for patient-reported outcomes when considering the overall success of surgery. However, there is still a paucity of literature investigating BREAST-Q scores specifically for ADM-assisted prosthetic reconstructions. Wu et al[39] some of the few authors to do so, administered BREAST-Q to their cohort of 31 patients receiving AlloDerm. Their average scores 1 year postoperatively were 63, 64, 60, 69, and 67 for satisfaction with outcome, breasts, information, psychosocial well being, and physical well being, respectively.[39] Taking into account minimal important differences for BREAST-Q scores as reported by the tool's creators,[40] the average differences between our and Wu et al[39] results are not clinically significant, suggesting preliminarily that allograft porosity and

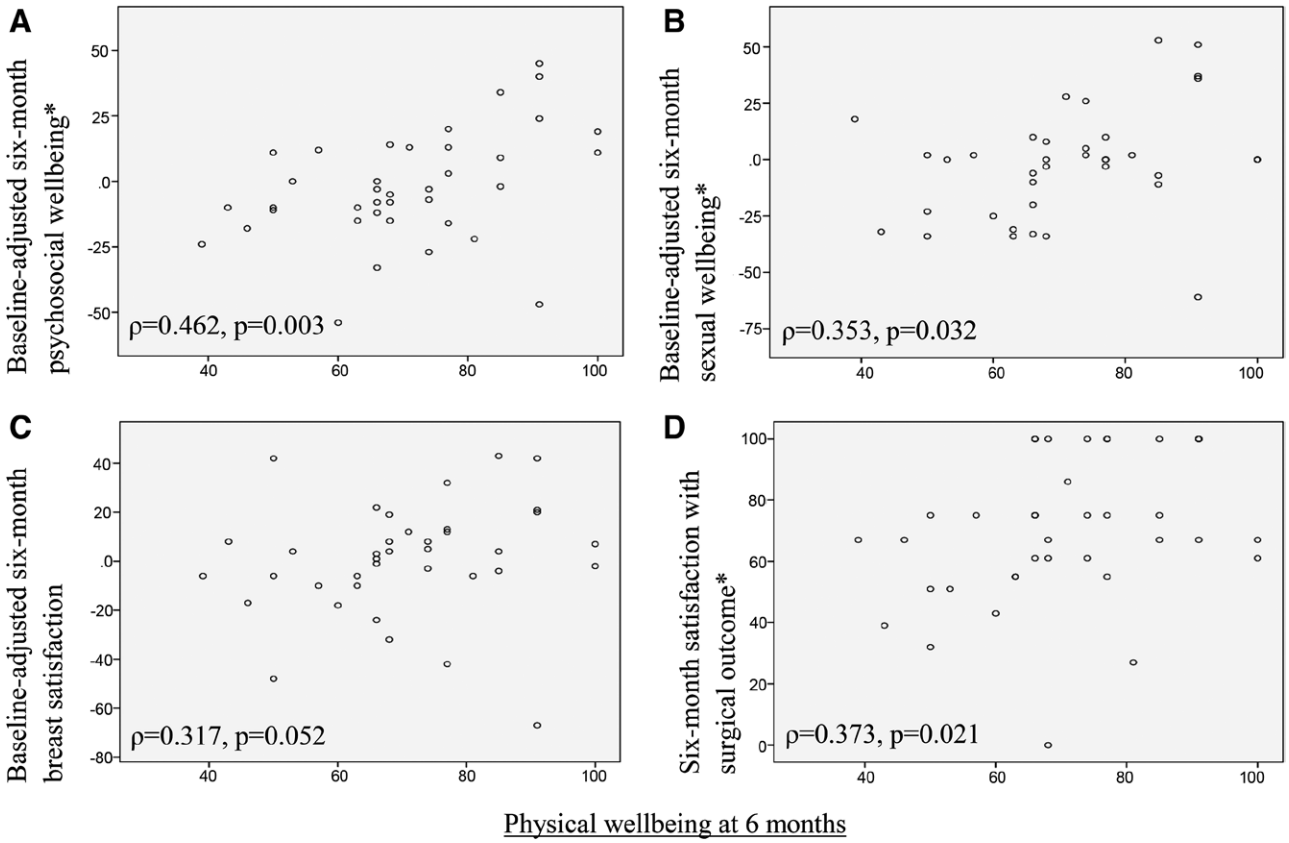

Fig. 2. Physical well being at 6 months versus various 6-month BREAST-Q scores. A, Baseline-adjusted psychosocial well being; B, baseline-adjusted sexual well being; C, baseline-adjusted breast satisfaction; D, satisfaction with outcome at 6 months. ρ = Spearman's rho. *Significance, $P < 0.05$.

pliability may not directly impact patients' reported satisfaction with their reconstructions.

Our secondary goal was to further elucidate broader patterns in patient-reported outcomes for breast reconstructions using ADM. Sugrue et al[41] reported that preoperative and postoperative BREAST-Q scores do not differ significantly, but they did not precisely define their survey timing. On the other hand, recent data published by Weichman et al[24] showed that by 3 months postoperatively, patients' BREAST-Q scores had not returned to baseline. Our present study, which recorded BREAST-Q data at both 2 and 6 months postoperatively, extends and links these prior findings. Here, patient-reported outcomes 2 months postoperatively had decreased from preoperative baseline, implying that patients may still be recovering from the burdens of surgery. Most BREAST-Q scales returned to preoperative levels by 6 months (Fig. 1). Understanding the typical time-course of patient-reported outcomes can help clinicians counsel patients about postoperative expectations and ease them through their recovery periods. For example, patients may have to be warned that even at 6 months, some physical pain and discomfort may persist (Fig. 1).

Table 6. Effect of XRT on Patient-Reported Outcomes

		Mean Score (SD)	*P*
Satisfaction with breasts*	No XRT	63.93 (17.05)	0.004
	XRT	43.40 (20.69)	
Satisfaction with outcome	No XRT	74.04 (20.14)	0.092
	XRT	59.20 (30.77)	
Psychosocial well being	No XRT	71.18 (20.18)	0.115
	XRT	59.00 (21.42)	
Sexual well being*	No XRT	61.48 (24.28)	0.006
	XRT	34.20 (27.69)	
Physical well being	No XRT	72.43 (16.51)	0.189
	XRT	64.90 (10.74)	

* indicates $P < 0.05$.

We also found a positive relationship between physical well being and many other BREAST-Q scales such as overall satisfaction with the surgery (Fig. 2). Intuitively, a patient experiencing physical discomfort may also have reduced social confidence, self-esteem, and overall satisfaction. This emphasizes the importance of selecting strategies that maximize patients' physical well being after the reconstruction. It is important to note that inverse-causality may have played a role in this relationship; for example, less

satisfied patients may have been biased to report higher levels of pain. In contrast, postoperative XRT had a negative effect on satisfaction with breasts and sexual well being (Table 6), a finding that supports prior BREAST-Q analyses by Ho et al[21] and McCarthy et al.[23] This decrease in sexual well being may ultimately be linked to poor satisfaction with their breast cosmesis, as XRT causes chest-wall distortion and capsular contractures that can introduce asymmetry and compromise aesthetics.[42]

Despite providing important insights about breast reconstruction using higher porosity, deep dermal ADM, this study is a preliminary investigation that should motivate further inquiry into this new direction for allografts. With our present cohort of 72 breasts and the paucity of other literature discussing ADM or patient reported outcomes in ADM-assisted breast reconstructions, more studies of greater sample sizes and longer follow-up times are warranted to further support our findings. It is important to note that malposition complications such as bottoming out sometimes occur later than 6 months postoperatively, making it possible that some of these long-term complications may not have been captured in our study's timeframe. Additional studies can also capture results from different surgeons; although a single-surgeon study is able to control for intersurgeon technical variability, an inherent limitation is the inability to represent the entire spectrum of surgical practices. Finally, randomized control trials comparing deep dermal ADM with traditional ADM are needed to rigorously evaluate the performance of this new allograft technology.

CONCLUSIONS

This prospective study shows the utility of deep dermal ADM in 2-stage prosthetic breast reconstruction. Complication rates were acceptably low, with no infections or seromas. Increased porosity did not compromise structural integrity, as evidenced by the lack of implant malpositions or extrusions. Patient-reported outcomes reflected good patient experiences during the postoperative period. As prosthetic breast reconstruction continues to evolve and improve, ADM modifications such as heightened porosity may enhance both objective and subjective patient outcomes.

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