# Poly-4-Hydroxybutyric Acid Mesh Compares Favorably With Acellular Dermal Matrix in Tissue Expander–Based Breast Reconstruction

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**Background:** Acellular dermal matrix (ADM) is commonly used during immediate expander-based breast reconstruction, with potential advantages of greater intraoperative expansion, decreased time to complete expansion, and decreased rates of capsular contracture. However, ADM is associated with increased infection rate, seroma, and subsequent reconstructive failure. Poly-4-hydroxybutyric acid (P4HB) mesh is a large pore, biosynthetic scaffold shown to fully resorb and incorporate host tissues within 18 months. We sought to compare outcomes between the use of P4HB and ADM in immediate retropectoral expander-based reconstruction.

**Methods:** One hundred ninety-two consecutive cases (107 patients) of breast reconstruction using ADM were compared with a subsequent cohort of 112 cases (62 patients) using P4HB mesh. In all patients, reconstruction was performed immediately after mastectomy by a single surgeon, and outcomes were compared between groups.

**Results:** Baseline characteristics were similar between the P4HB and ADM groups. Overall infection rates were lower, but not significantly with P4HB (11% vs 17%, $P = 0.18$). Time to drain removal was significantly lower with P4HB (15 vs 18 days, $P = 0.008$), although there was no difference in rates of seroma (0.9% vs 3%, $P = 0.43$). Similar numbers of patients underwent external beam radiation (22% vs 24%) and received chemotherapy in each group (48% vs 45%). By univariate analysis, all odds ratios were decreased with use of P4HB, including risk of major complications (0.55), seroma (0.17), infection (0.59), need for reoperation (0.78), and skin necrosis (0.77).

**Conclusions:** Initial findings suggest P4HB mesh to be a safe alternative to ADM in expander-based breast reconstruction, with trends toward decreased rates of infection, seroma, and need for device removal using P4HB mesh. Although our results are limited to a small series of initial patients, P4HB mesh may be a promising novel technique to decrease complications inherent to use of ADM at a reduced material cost.

**Key Words:** breast reconstruction, mastectomy, tissue expander, implant-based reconstruction, outcomes, ADM, acellular dermal matrix, P4HB, Phasix

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After skin cancer, breast cancer is the second most common type of cancer in women. In 2019 alone, it is estimated that more than 250,000 cases of invasive breast cancer will be diagnosed in the United States.[1] Many of these women will require a mastectomy as part of their treatment plan, and breast reconstruction is a critical step in the road to recovery as it has the ability to improve body image, psychological health, sexuality, and quality of life. The number of women opting for immediate reconstruction continues to grow, with almost 40% of women currently choosing this option, of which nearly two-thirds undergo implant-based reconstruction.[2,3]

Acellular dermal matrix (ADM) is commonly used during immediate tissue expander (TE)–based breast reconstruction, as it allows the plastic surgeon to extend the soft tissue coverage over the TE beyond the patients' pectoralis muscle.[4] The utilization of ADM in TE-based reconstruction provides other benefits; namely, it allows the surgeon to achieve greater intraoperative fill of the expander and decreases the time to complete expansion and subsequently time to permanent implant placement. The use of ADM may decrease the rate of capsular contracture and may improve the overall aesthetic outcome.[5,6] Despite the benefits of ADM, disadvantages of its use include high cost, and increased infection and seroma rates, leading to additional surgeries and subsequent reconstructive failure.[5–8] Acellular dermal matrix can also be inconsistent, as it is a biologic graft that comes from human or other animal tissue, and therefore, each piece is inherently unique. An assortment of available ADM products from different manufacturers can have varying properties based on proprietary decellularization or sterilization techniques, further contributing to product variability.[9] For these reasons, there is keen interest in seeking an alternative material to ADM to be used in TE-based breast reconstructions that parallels the benefits, while minimizing the complication rate and other shortcomings of ADM use.

A biosynthetic mesh may be one such alternative that has the potential to minimize the disadvantages of biologic materials, while still serving a similar coverage and reconstructive purpose.[10] Poly-4-hydroxybutyrate (P4HB; GalaFLEX scaffold; Galatea Surgical, Inc, Lexington, Massachusetts) is a biosynthetic mesh that is categorized as a polyhydroxyalkanoate, a group of natural biopolymers that can be woven into a resorbable material. The Food and Drug Administration first approved its use in 2007 for manufacturing resorbable sutures. By the end of 2015, it was approved for use in the creation of a large-pore, biosynthetic sheet mesh that is strong, flexible, and biocompatible to aid in the reinforcement of soft tissue defects. Its use is becoming increasingly appealing given its ability to provide strength to the repair, not only immediately during the healing phase but also over an extended period. In fact, Deeken and Matthews[11] showed that it maintains its original strength for at least 52 weeks in a ventral hernia model. In addition, its unique balance of elastomeric and strength properties allows for P4HB to be manufactured as a monofilament. This is preferable over the other commonly used multifilament polymers, given that a smooth surface has fewer places for bacteria to grow and theoretically leads to decreased infection rates, which is of particular concern in device-based breast reconstruction.

Given the appealing mix of synthetic and biologic properties of P4HB, it is a seemingly ideal candidate to be used in place of ADM as support and coverage during immediate TE-based breast reconstruction. We hypothesized that P4HB could serve a similar utility to ADM in immediate implant-based reconstruction, while avoiding the complications

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**TABLE 1.** Patient Demographics Comparing Groups of Patients Receiving ADM or P4HB Mesh

| | ADM | | | P4HB | | |
|---|---|---|---|---|---|---|
| **Factor** | **n** | **%** | **SD** | **n** | **%** | **SD** |
| No. patients | 112 | | | 62 | | |
| No. breasts | 192 | | | 107 | | |
| Age, y | 46.8 | | 11.49 | 49.73 | | 10.97 |
| Unilateral | 32 | 0.17 | | 17 | 0.16 | |
| Bilateral | 160 | 0.83 | | 90 | 0.84 | |
| Right | 100 | 0.52 | | 50 | 0.47 | |
| Left | 92 | 0.48 | | 57 | 0.53 | |
| Prophylactic | 92 | 0.48 | | 47 | 0.44 | |
| Cancer | 100 | 0.52 | | 59 | 0.55 | |
| ALND | 30 | 0.16 | | 15 | 0.14 | |
| SLND | 150 | 0.78 | | 84 | 0.79 | |
| XRT | 46 | 0.24 | | 24 | 0.22 | |
| Pre-XRT | 8 | 0.04 | | 3 | 0.03 | |
| Post-XRT | 38 | 0.20 | | 19 | 0.18 | |
| Chemo | 87 | 0.45 | | 51 | 0.48 | |
| Prechemo | 40 | 0.21 | | 19 | 0.18 | |
| Postchemo | 56 | 0.29 | | 34 | 0.32 | |
| Prior surgery | 42 | 0.22 | | 29 | 0.27 | |
| BMI, kg/m$^2$ | 24.1 | | 4.31 | 24.5758 | | 3.9669 |
| Smoker, % cases | 30 | 0.16 | | 21 | 0.20 | |
| Current smoker, % of cases | 4 | 0.02 | | 2 | 0.02 | |
| Former smoker, % of cases | 26 | 0.14 | | 19 | 0.18 | |

ALND, axillary lymph node dissection; SLND, sentinel lymph node dissection.

associated with using a biologic material. Herein we review our experience and compare clinical outcomes using P4HB and ADM in immediate device-based breast reconstruction after mastectomy.

## METHODS

Charts of 174 consecutive patients (299 breasts) undergoing immediate TE-based breast reconstruction by a single plastic surgeon (D.M.O.) were reviewed. Acellular dermal matrix (AlloMax; Bard-Davol, Warwick, Rhode Island) was used in the first 112 consecutive patients (193 breasts) from November 2011 to October 2014, followed by P4HB for the subsequent 62 patients (107 breasts) between October 2014 and June 2016. All cases of reconstruction were undertaken immediately after extirpative surgery for confirmed breast cancer or prophylaxis in high-risk patients by 1 of 3 breast surgeons. Patients underwent either nipple-sparing or skin-sparing mastectomy based on joint decision between the plastic and breast surgeons, with regard for both patient-specific and oncologic factors. All cases were performed at NewYork-Presbyterian Hospital/Weill Cornell Medical Center. Institutional review board approval (Protocol 1604017199R001) was obtained for purposes of this study to retrospectively review patient charts for data, including age, comorbidities, body mass index (BMI), relevant oncologic treatment details, operative details, and postoperative outcomes, including complications. Outcomes were compared between P4HB and ADM, with primary outcomes being rates of infection, seroma, skin necrosis, device explantation, or need for reoperation. Other outcomes of interest included wound healing complications, time to drain removal, chemotherapy or radiation impact, and differences in material cost. Each breast was counted independently for analysis.

Complications were defined as major or minor, with major complications requiring operative or procedural intervention, hospital admission, or intravenous antibiotics. Minor complications were treated on an outpatient basis with oral antibiotics, office-based interventions (eg, seroma aspiration) or local wound care. Seroma was diagnosed by simple fluid collection seen on imaging or clinically evident fluid collection without evidence of infection or positive culture results. Cellulitis was defined as breast erythema, with or without leukocytosis or fever, which responded to oral antibiotics within 10 days. Red breast syndrome (RBS) was defined as noninfectious erythema associated with the use of ADM or P4HB mesh and without additional signs of clinical infection. Surgical site infection was defined as any breast erythema with

**TABLE 2.** Outcomes of Immediate TE*Based Breast Reconstruction

| | ADM | | | P4HB | | | |
|---|---|---|---|---|---|---|---|
| **Factor** | **n** | **%** | **SD** | **n** | **%** | **SD** | ***P*** |
| Major complication, per pt | 27 | 24.11 | | 9 | 14.52 | | 0.17 |
| Minor complication, per pt | 11 | 9.82 | | 7 | 11.29 | | 0.80 |
| Infection per breast | 34 | 17.71 | | 12 | 11.21 | | 0.18 |
| Admitted per pt | 14 | 12.50 | | 6 | 9.68 | | 0.63 |
| Days admitted | 3.07 | | 1.69 | 3.4 | | 2.19 | 0.27 |
| Antibiotics, per pt | 26 | 23.21 | | 14 | 22.58 | | 1.00 |
| Necrosis | 17 | 8.85 | | 10 | 9.35 | | 1.00 |
| Seroma | 6 | 3.13 | | 1 | 0.93 | | 0.43 |
| Time to drain removal, d | 18.32 | | 7.80 | 15.22 | | 6.29 | 0.0080 |
| Treated seroma | 2 | 1.79 | | 0 | 0.00 | | 0.54 |
| Red breast | 5 | 2.60 | | 1 | 0.93 | | 0.43 |
| Reop (any) | 31 | 16.15 | | 14 | 13.08 | | 0.51 |
| Avg time to reop, d | 53.21 | | 48.00 | 27 | | 15.24 | <0.0001 |
| Salvage | 12 | 6.32 | | 5 | 4.67 | | 0.80 |
| Explant | 19 | 10.00 | | 12 | 11.21 | | 0.70 |
| Days to explant | 62.84 | | 46.64 | 31 | | 12.41 | <0.0001 |
| f/u months | 26 | | 15.07 | 15.31 | | 8.309 | <0.0001 |
| Time to implant, mo | 6.96 | | 7.84 | 5.47 | | 5.66 | 0.0847 |

Avg, average; f/u, follow-up; pt, patient; reop, reoperation.

**TABLE 3.** Univariate Regression for Associated Complications

| | | | Confidence Interval | |
|---|---|---|---|---|
| **Factor** | **OR** | ***P*** | **Lower** | **Upper** |
| Major complication | 0.55 | 0.14 | 0.25 | 1.22 |
| Minor complication | 1.11 | 0.83 | 0.42 | 2.97 |
| Infection | 0.59 | 0.15 | 0.29 | 1.2 |
| Necrosis | 0.77 | 0.54 | 0.34 | 1.76 |
| Seroma | 0.17 | 0.11 | 0.02 | 1.46 |
| Red breast | 0.18 | 0.12 | 0.02 | 1.54 |
| Reoperation (any) | 0.78 | 0.48 | 0.39 | 1.54 |

purulence, suspicious fluid collection on imaging, purulent fluid on surgical exploration, simple fluid associated with positive culture result, or cellulitis that did not respond to a course of oral antibiotics. Wound healing complications ranged from superficial epidermolysis to full-thickness mastectomy skin flap necrosis. In cases of impending device exposure from skin necrosis, patients were taken to the operating room for sharp debridement of nonviable tissue, antibiotic irrigation, and device removal, with device replacement if no gross contamination was encountered. In cases of skin necrosis with no device exposure, the device was partially deflated to facilitate skin closure after sharp debridement, with subsequent resumption of expansion when clinically appropriate.

## Operative Technique

All patients received a dose of perioperative antibiotics and no routine postoperative doses. After completion of the oncologic portion of the case by the breast surgeon, the field was reprepped in sterile fashion. The pectoralis major muscle was released from its inferior and inferomedial attachments to create a submuscular pocket. The pocket was washed with betadine, then thoroughly irrigated with antibiotic containing normal saline (ancef 1 g/L+ gentamicin 80 mg/L; antibiotics excluded if documented allergy). Acellular dermal matrix was fenestrated using a No. 15 scalpel blade. Acellular dermal matrix or P4HB was briefly soaked in antibiotic containing saline solution for 60 seconds before fixation to the inframammary fold and lateral chest wall using 2–0 Vicyl sutures (Ethicon, Inc, Somerville, New Jersey). The TE was rinsed in antibiotic containing solution before placement within the pocket. Next, the cephalad portion of the ADM or P4HB mesh was trimmed to appropriate size so that it just approximated the detached caudal border of the pectoralis muscle and secured in place with 2–0 Vicryl sutures. The TEs were filled with the minimal amount of saline to allow for unfolding of the device, with no pressure on overlying skin. Two No. 15F Blake drains were placed through separate stab incisions lateral to the inframammary fold, with one drain within the pocket and the other in a subcutaneous location. Skin was closed in layers using 3–0 monocryl interrupted deep dermal sutures and a running subcuticular 3–0 V-loc (Covidien, Minneapolis, Minnesota). Tissue adhesive and steri-strips were placed along with padded dressings. Patients were admitted to the hospital ward overnight or until postoperative day 2 as the clinical situation dictated. Drain output by bulb suction was recorded daily, and drains were removed when output remained <30 cc/d for 2 consecutive days.

## Statistical Analysis

Both patients and individual breasts were included for data analysis. Categorical values were counted by frequency and percentage and compared between the ADM and P4HB groups by 2-tailed $\chi^2$ test. Continuous variables were analyzed by calculating means and SDs, and compared by Fisher exact test. Univariate logistical regressions were performed to calculate odds ratios (ORs). A $P$ value <0.05 was considered significant in all cases. All statistics were performed using Prism and STATA software.

# RESULTS

From November 2011 to June 2016, 299 cases of immediate device-based breast reconstruction were identified, of which 192 cases used ADM followed by 107 cases of P4HB. Patients were followed up to 55 months. Clinical and demographic features of these cohorts were compared, with baseline characteristics largely similar between groups (Table 1). There were no significant differences found between P4HB and ADM in regard to patient age (50 vs 47 years, $P = 0.09$), BMI (25 vs 24 kg/m$^2$, $P = 0.49$), smoking status (any tobacco exposure: 20% vs 16%, $P = 0.27$; current smoker: 2% vs 2%, $P = 0.9$; former smoker: 18% vs 14%, $P = 0.37$), or prior breast surgery (27% vs 22%, $P = 0.37$). Groups were similar in ratio between unilateral (16% vs 17%) and bilateral (84% vs 83%) cases, and there were no differences in laterality (52% vs 47%, $P = 0.57$). Rates of mastectomy for cancer (55% vs 52%, $P = 0.61$) and prophylaxis in high-risk patients (44% vs 48%, $P = 0.61$) were also similar, as well as frequency of sentinel (79% vs 78%, $P = 0.96$) or axillary lymph node dissection (14% vs

**TABLE 4.** Chemotherapy Effects

| | ADM | | | P4HB | | | |
|---|---|---|---|---|---|---|---|
| **Factor** | **n** | **%** | **SD** | **n** | **%** | **SD** | ***P*** |
| No. breasts | 87 | | | 51 | | | |
| Time to drain removal, d | 19.37 | | 7.26 | 13.80 | | 5.06 | <0.0001 |
| Neoadjuvant only, d | 19.30 (n = 41) | | 7.00 | 14.6 (n = 19) | | 3.90 | 0.01 |
| Infection, n | 17 | 19.54 | | 5 | 9.80 | | 0.1544 |
| Major complication | 14 | 16.09 | | 4 | 7.84 | | 0.1984 |
| Patients readmitted, n | 7 | 13.46 | | 3 | 10.34 | | 1 |
| Red breast | 3 | 3.45 | | 1 | 1.96 | | 1 |
| Skin necrosis | 7 | 8.05 | | 3 | 5.88 | | 0.7447 |
| Seroma | 3 | 3.45 | | 1 | 1.96 | | 1 |
| Reoperation | 13 | 14.94 | | 0 | 0.00 | | 0.0021 |
| Explant | 11 | 12.64 | | 5 | 9.80 | | 0.7848 |
| Salvage | 4 | 4.60 | | 2 | 3.92 | | 1 |

**TABLE 5.** Outcomes of Radiated Breasts

| | ADM | | | P4HB | | | |
|---|---|---|---|---|---|---|---|
| **Factor** | **n** | **%** | **SD** | **n** | **%** | **SD** | ***P*** |
| No. breasts | 46 | | | 24 | | | |
| Time to drain removal, d | 18.79 | | 7.60 | 16.24 | | 7.96 | 0.19 |
| Infection, n | 9 | 19.57 | | 1 | 4.17 | | 0.1476 |
| Major complication | 10 | 21.74 | | 2 | 8.33 | | 0.1974 |
| Patients admitted, n | 5 | 10.87 | | 2 | 8.33 | | 1 |
| Red breast | 2 | 4.35 | | 0 | 0.00 | | 0.5429 |
| Skin necrosis | 6 | 13.04 | | 1 | 4.17 | | 0.4089 |
| Seroma | 1 | 2.17 | | 0 | 0.00 | | 1 |
| Reoperation | 12 | 26.09 | | 2 | 8.33 | | 0.1162 |
| Explant | 8 | 17.39 | | 2 | 8.33 | | 0.476 |
| Salvage | 4 | 8.70 | | 0 | 0.00 | | 0.2911 |

16%, $P = 0.85$). Rates of neoadjuvant and adjuvant chemotherapy and radiation were also found to be similar.

Major complications were found in 14.5% of patients with P4HB and 24.1% with ADM ($P = 0.17$; Table 2). Interestingly, time to drain removal was significantly lower in the P4HB cohort (15 vs 18 days, $P = 0.008$), including the portion of patients who received any chemotherapy (19 vs 14 days, $P < 0.001$). Seroma rates were low overall (0.9% vs 3.1%, $P = 0.43$). Two of the patients with ADM who developed seroma required intervention; one patient for image guided drainage and intravenous antibiotics and a second patient required eventual explantation for an infected seroma. No patient in the P4HB group required operative intervention for seroma. Infection rates were lower, though not significantly, with P4HB (11.2% vs 17.7%, $P = 0.18$). Courses of outpatient oral antibiotics were given in 23% of patients with both P4HB ADM for suspected infection, clinically evident cellulitis ($P = 0.75$), or selected cases of skin necrosis. There was no difference in numbers of patients who required reoperation for any reason (13% vs 16%, $P = 0.51$), including elective device removal. However, of the subset that received chemotherapy, we did observe a significant increase in reoperation rates with ADM (15% vs 0%, $P = 0.002$). Two patients in each cohort required reoperation for hematoma ($P = 0.62$). Of those with threatened devices, there were no differences in rates of salvage (4.7% vs 6.3%, $P = 0.8$) or rates of explantation (11% vs 10%, $P = 0.7$). There was a difference in time to explantation between groups, with P4HB being nearly 30 days earlier on average (31 vs 63 days, $P < 0.001$). At the time of TE explantation, exchange, or any return to the operating room, any nonincorporated ADM or P4HB scaffold was debrided, although in all cases P4HB seemed to be well integrated after 4 weeks. There was no difference in rates of skin flap necrosis (9.3% vs 8.9%, $P = 0.99$) between cohorts, with flap ischemia thought to be largely determined by quality of mastectomy with an unclear impact of device placement or choice of ADM versus P4HB.

Overall follow-up times were longer in the ADM group (15.3 vs 26 months, $P < 0.001$) because of sequential cohorts with ADM before use of P4HB. With regard to time from TE placement to exchange for permanent implant, there was a trend toward faster time to exchange in the P4HB group (5.5 vs 7 months, $P = 0.08$). Overall material cost was found to be 44% less for P4HB mesh than for ADM ($\$14/cm^2$ vs $\$25/cm^2$) at our institution.

Odd ratios calculated by univariate analysis were found to be lower for P4HB in all circumstances (Table 3), including major complications (0.55), seroma (0.17), infection (0.59), skin necrosis (0.77), or need for reoperation (0.78). No ORs were found to have significant *P* value, likely due to sample size, but can be considered clinically significant. Further subset analysis examined the effects of adjuvant therapy for those patients who received chemotherapy, external beam radiation (XRT), and no XRT (Tables 4–8). Time to drain removal remained significantly different in patients who received any chemotherapy (14 vs 19 days, $P < 0.001$), neoadjuvant chemotherapy (15 vs 19 days, $P = 0.01$), and nonradiated patients (15 vs 18 days, $P = 0.001$).

**TABLE 6.** Outcomes of Nonradiated Breasts

| | ADM | | | P4HB | | | |
|---|---|---|---|---|---|---|---|
| **Factor** | **n** | **%** | **SD** | **n** | **%** | **SD** | ***P*** |
| No. breasts | 146 | | | 79 | | | |
| Time to drain removal, d | 18.17 | | 7.86 | 14.86 | | 5.80 | 0.0012 |
| Infection, n | 25 | 17.12 | | 9 | 11.39 | | 0.2519 |
| Major complication | 17 | 11.64 | | 7 | 8.86 | | 0.6526 |
| Patients admitted, n | 9 | 6.16 | | 4 | 5.06 | | 1.0000 |
| Red breast | 3 | 2.05 | | 1 | 1.27 | | 1.0000 |
| Skin necrosis | 11 | 7.53 | | 9 | 11.39 | | 0.3367 |
| Seroma | 5 | 3.42 | | 1 | 1.27 | | 0.6679 |
| Reoperation | 19 | 13.01 | | 12 | 15.19 | | 0.6876 |
| Explant | 11 | 7.53 | | 10 | 12.66 | | 0.2338 |
| Salvage | 8 | 5.48 | | 5 | 6.33 | | 0.7728 |

**TABLE 7.** Outcomes of Patients Not Receiving Chemotherapy

| | ADM | | | P4HB | | | |
|---|---|---|---|---|---|---|---|
| **Factor** | **n** | **%** | **SD** | **n** | **%** | **SD** | ***P*** |
| No. breasts | 105 | | | 56 | | | |
| Time to drain removal, d | 17.36 | | 8.16 | 16.53 | | 6.99 | 0.52 |
| Infection, n | 17 | 16.19 | | 5 | 8.93 | | 0.214 |
| Major complication | 13 | 12.38 | | 5 | 8.93 | | 0.6062 |
| Patients admitted, n | 7 | 6.67 | | 3 | 5.36 | | 1 |
| Red breast | 2 | 1.90 | | 0 | 0.00 | | 0.5435 |
| Skin necrosis | 10 | 9.52 | | 7 | 12.50 | | 0.5957 |
| Seroma | 3 | 2.86 | | 0 | 0.00 | | 0.5521 |
| Reoperation | 18 | 17.14 | | 8 | 14.29 | | 0.8225 |
| Explant | 10 | 9.52 | | 7 | 12.50 | | 0.5957 |
| Salvage | 6 | 5.71 | | 1 | 1.79 | | 0.4231 |

**TABLE 8.** Outcomes After Neoadjuvant Chemotherapy and Adjuvant Radiation

| | ADM | | | P4HB | | | |
|---|---|---|---|---|---|---|---|
| **Factor** | **n** | **%** | **SD** | **n** | **%** | **SD** | ***P*** |
| No. breasts | 23 | | | 8 | | | |
| Time to drain removal, d | 20.40 | | 7.60 | 15.50 | | 3.70 | 0.09 |
| Infection, n | 6 | 26.09 | | 0 | 0.00 | | 0.3 |
| Major complication | 5 | 21.74 | | 1 | 12.50 | | >0.99 |
| Patients admitted, n | 4 | 17.39 | | 1 | 12.50 | | >0.99 |
| Red breast | 2 | 8.70 | | 0 | 0.00 | | >0.99 |
| Skin necrosis | 2 | 8.70 | | 1 | 12.50 | | >0.99 |
| Seroma | 0 | 0.00 | | 0 | 0.00 | | >0.99 |
| Reoperation | 6 | 26.09 | | 1 | 12.50 | | 0.64 |
| Explant | 5 | 21.74 | | 1 | 12.50 | | >0.99 |
| Salvage | 1 | 4.35 | | 0 | 0.00 | | >0.99 |

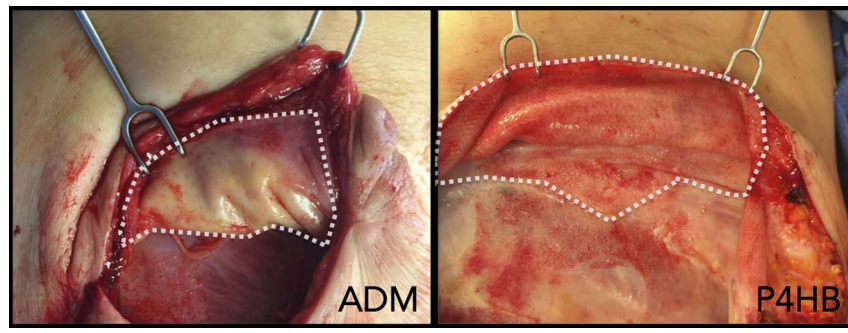


**FIGURE 1.** Acellular dermal matrix and P4HB mesh (within dotted lines) shown at the time of implant exchange after device removal. In all cases, P4HB was fully incorporated, whereas ADM often required debridement of nonadherent segments. full color online

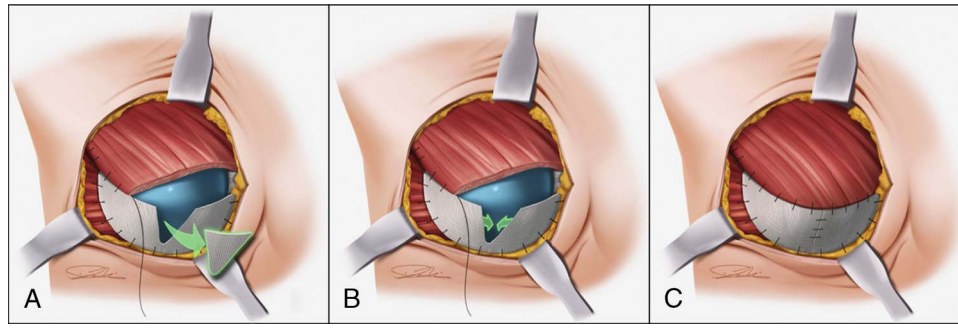


**FIGURE 2.** A, Operative technique. P4HB mesh is inset along the inframammary fold before implant placement. B, With the implant temporarily inflated with air, a triangle is removed to allow for improved contouring of the material into a more conical shape. C, The seam is then closed with a running suture, and the superior portion of the mesh can be affixed to the muscle. full color online

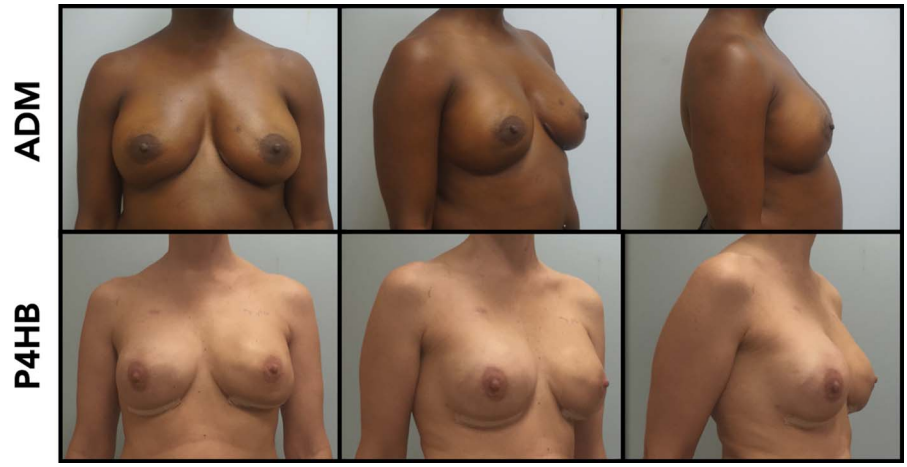


**FIGURE 3.** Two patient examples showing similar results using either ADM (top) or P4HB (bottom) materials at the time of TE placement. Images shown are after final implant exchange. full color online

Interestingly, no difference was seen in time to drain removal in patients who received radiation therapy (16 vs 18 days, $P = 0.22$). There were inadequate patient numbers to further delineate the effect of neoadjuvant or adjuvant therapies. Finally, there was no observed difference in patients with RBS (0.9% vs 2.6%, $P = 0.43$).

## DISCUSSION

Although there are numerous options for mesh or ADM support during device-based breast reconstruction, this is the first study to the author's knowledge using a biosynthetic, absorbable mesh in 2-stage TE-based reconstruction. In comparison to ADM, purported advantages include decreased seroma formation, less immunogenicity (eg, RBS), consistency of product, resistance to infection, avoidance of religious/ethical conflicts associated with cadaver or animal products, and decreased material cost. By comparing 2 consecutive cohorts of patients undergoing immediate breast reconstruction at a single institution by a single surgeon, we found evidence for several of these important differences.

We found significantly decreased time to drain removal in patients with P4HB mesh by an average of 3 days, possibly indicating less seroma potential, a well-known complication of ADM. We show low overall rates of seroma with ADM in this series (3.1%), with prior studies finding higher rates between 4% and 14.7%.[12,13] In contrast, we found only 1 (0.9%) case of seroma associated with P4HB in more than 100 cases, which is similar to published rates without ADM.[12] This particular patient had undergone neoadjuvant chemotherapy and later developed infection of the seroma requiring device removal. The macroporous architecture of this material may in part explain our findings of lower seroma and faster time to drain removal.

Although there seemed to be a trend toward decreasing infection rates in patients with P4HB (11.2%) compared with ADM (17.7%), this did not reach statistical significance. In those who developed an infection requiring explantation, we noted a prolonged time to explantation in the ADM group (63 vs 31 days) possibly explained by nonincorporation of the ADM leading to persistent or late infection. By contrast, there was only one patient in the P4HB group who developed an infection after 1 month, supporting the clinical observation that at the time of reoperation for implant exchange, all P4HB mesh was well incorporated (Fig. 1). No patient in the P4HB group required mesh explantation after 30 days, whereas several patients in the ADM cohort had debridement of nonincorporated material at the time of exchange or explantation in the case of infection.

Prior studies have observed incidences of RBS in 0% to 13% of patients undergoing reconstruction with ADM, although this may vary based on specific product and processing methods.[5,14] In our series, we observed 5 (2.6%) cases with evidence of RBS with ADM and only 1 case (1.6%) with persistent mild erythema that did not respond to antibiotics in a patient with P4HB. Although generally considered a benign entity, RBS can lead to unnecessary antibiotic use with important consequences such as unnecessary device removal.[14] In addition, we found a decrease in material cost of P4HB compared with ADM of greater than 40%. A cost analysis performed with use of P4HB in abdominal wall reconstruction similarly showed a large financial advantage over porcine mesh.[15]

In comparison to ADM, P4HB mesh is more rigid and has minimal ability to stretch. Consequently, small folds in the material may be noticeable to the patient and requires more precise contouring to avoid possible long-term concerns with "ridging" or palpable areas of the mesh folded on its self (Fig. 2). However, the addition of the P4HB similarly allows for an increase in initial fill volume and subsequent rapid expansion of the TE and lower breast pole compared with a total submuscular approach. Compared with ADM, we found a trend toward faster time to implant exchange that was not significant ($P = 0.14$; nonradiated patients, $P = 0.84$). We found that at the time of exchange, P4HB was usually well integrated into a neocapsule, whereas ADM was often not integrated and required partial excision. At the time of exchange, neocapsules from P4HB were typically soft, pliable, and handled similar to those formed by ADM.

At this time, it is unclear how the choice of mesh material affects long-term aesthetic or patient reported outcomes. Although we did not observe increased rates of revisional surgery or capsular contracture in either group, it is yet to be seen how this new material choice will affect the implant pocket over time. At this time, the earliest patients undergoing P4HB mesh reinforcement have 48 months of follow-up, and the authors have not noted a clinical difference in outcomes (Fig. 3). Further limitations of this initial experience are that it is a retrospective cohort study performed by a single surgeon. Also, with the increasing popularity of prepectoral breast reconstruction and common use of ADM, closer examination of alternative materials such as P4HB is warranted.

## CONCLUSIONS

We find that use of P4HB mesh during immediate breast reconstruction is safe and may have some benefits compared with ADM, with trends toward decreased seroma formation, RBS, and material cost. Based on these findings, P4HB mesh material may serve as a good alternative to ADM in subpectoral breast reconstruction.

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