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Breast

Comparing Polyurethane and Acellular Dermal Matrix Implant Cover in Prepectoral Breast Reconstruction: Short-term Complications

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Background: Implant covering with an interface material is the standard in prepectoral breast reconstruction. Acellular dermal matrix (ADM) is frequently used, but it is expensive and associated with complications. Alternatively, we have been using integrated devices consisting of a silicone implant coated with polyurethane (PU) foam. We aimed to compare both techniques in terms of acute complications.

Methods: The authors retrospectively reviewed patients undergoing prepectoral direct-to-implant reconstruction from June 2018 to January 2022. Two cohorts were defined based on the interface material used: ADM versus PU. Total drainage volume, time to drain removal, and acute complications (hematoma, seroma, infection, and explantation) were analyzed.

Results: Forty-four breast reconstructions were performed in 35 patients (10 bilateral); implants were covered with ADM in 23 cases and with PU foam in 21. Median total drainage volume (500 versus 515 cc for ADM and PU, respectively) and time to drain removal (9 versus 8 days) were not affected by the interface material used, but seromas and infections occurred exclusively in the ADM cohort (seromas in four of 23 of cases, $P = 0.109$; infections in three of 23 cases, $P = 0.234$). Overall complications occurred more often in cases reconstructed with ADM, but the difference was nonsignificant ($P = 0.245$).

Conclusions: The use of interface materials is generally considered a prerequisite for state-of-the-art prepectoral breast reconstruction for a variety of reasons, including the prevention of capsular contracture. In this study, PU coating tended to be associated with fewer short-term complications than ADM, including seroma and infection. *(Plast Reconstr Surg Glob Open 2023; 11:e4798; doi: 10.1097/GOX.0000000000004798; Published online 2 February 2023.)*

INTRODUCTION

In the early days, breast cancer surgery was essentially limited to radical mastectomy. These procedures invariably resulted in a thin and tight skin envelope that could not accommodate an implant placed directly in the subcutaneous plane. Currently, mastectomies are more anatomically driven, and so the implant can directly fit in the space where the gland is removed from. Although the implant no longer needs to be placed behind the pectoralis muscle, most surgeons believe it still needs to be covered with some kind of interface material. Acellular dermal matrix (ADM) is often used as this interface between the implant and the mastectomy flaps to help support, protect, position, and camouflage the prosthesis, and, most importantly, to prevent capsular contracture. However, placing this additional layer has been associated with increased postoperative drainage and higher rates of seroma and infection.[1,2] Furthermore, there is substantial increase in cost associated with the use of this material. Finally, it should be noted that its uniform effectiveness against capsular contracture has been questioned in a recent report.[3]

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Polyurethane (PU) implants are regular silicone implants coated with an integrated layer of polyurethane foam. This additional layer confers a protective effect against capsular contracture that has withstood the test of time.[4–6] These implants are also well known for rapidly adhering to breast tissue through a velcro-like effect which, in addition to stabilizing the implant, leaves virtually no dead space for fluid to accumulate. The authors have been using these integrated devices for direct-to-implant (DTI) prepectoral breast reconstruction after conservative mastectomies as a convenient alternative to regular silicone implants with ADM coverage. In this study, we sought to compare both techniques regarding postoperative drainage and risk of acute complications, including seroma and infection.

Takeaways

Question: ADM-assisted prepectoral breast reconstruction is currently considered the standard of care. The alternative use of polyurethane (PU)-coated implants has grown in popularity in some European countries because of cost, convenience, and most importantly, the clinical impression of fewer short-term complications associated with this technique.

Findings: In this retrospective cohort study comparing both techniques, prepectoral breast reconstructions with PU-coated implants tended to be associated with fewer short-term complications, including seroma and infection, than ADM-assisted reconstructions.

Meaning: When used for prepectoral breast reconstruction, PU coating may share many of the advantages of ADM, while circumventing some of its shortcomings.

PATIENTS AND METHODS

Study Design

A retrospective review was performed of consecutive patients undergoing immediate implant-based breast reconstruction after conservative mastectomy at a single institution between June 2018 and February 2021. Only patients undergoing prepectoral DTI reconstruction were analyzed. In addition to nipple-sparing (NSM) and skin-sparing mastectomy (SSM), patients who underwent skin-reducing mastectomy (SRM) and reconstruction were eligible. Reconstructions after prophylactic mastectomies performed concomitantly with a therapeutic procedure were also included. Patients with a history of prior radiation therapy were excluded because it is a known confounder and stratification was impossible as none of the patients in the PU group were irradiated. Other known risk factors for complications [ie, obesity, active smoking, diabetes mellitus (DM)] were not considered exclusion criteria. Cases are defined per breast.

Implants used in this series were either anteriorly covered with ADM or entirely coated with PU foam as an integrated device, and two separate cohorts were defined accordingly (ADM group and PU group). In no instance did the reconstructive surgeon attempt to use bare regular implants or combine a PU-coated implant with an ADM cover. We primarily aimed to compare the time to drain removal, total drainage volume, and seroma rates between groups. Secondary outcomes included other short-term complications occurring within three months after surgery (infection, hematoma, mastectomy flap or nipple partial or full-thickness necrosis, explantation, any complication). Data on patient-related variables [age, body mass index (BMI), smoking status, DM, hypertension, previous breast surgery] and oncologic and surgical details [laterality, tumor stage, type of mastectomy (SSM, NSM, SRM; prophylactic/therapeutic), weight of mastectomy, implant volume, postmastectomy radiation therapy, neo- or adjuvant chemotherapy] were collected.

Surgical Technique

Mastectomies were performed by one of three experienced breast surgeons. Reconstructions were undertaken by two of the authors. The first reconstructive surgeon performed ADM-based reconstruction using microtextured anatomical implants manufactured by Polytech (Replicon Mesmo—Polytech Health & Aesthetics; Dieburg, Germany) or Mentor (Mentor CPG—Mentor Corporation; Santa Barbara, Calif.). The second surgeon exclusively used PU-coated anatomical implants from Polytech (Replicon Microthane) since 2018 but changed to ADM-based reconstruction in selected cases by the end of 2021 because of concerns of increased rippling noted with PU implants and limited PU implant availability in our institution. Otherwise, the technique of both surgeons did not differ significantly.

After the mastectomy, suitability to DTI reconstruction was evaluated clinically and confirmed through indocyanine green (ICG) angiography, with a sizer in place. In the event of hypoperfusion, debridement of limited areas followed by tissue expander introduction was undertaken if adequate, or the reconstruction was delayed. The mastectomy flap condition never influenced the choice between ADM-covered or PU-coated implants as this was predetermined by the surgeon. Breast landmarks were reconstituted with sutures as needed regardless of whether PU-coated or ADM-covered implants were selected.

If ADM-based reconstruction was elected, a sheet of fenestrated Surgimend PRS (Integra LifeSciences; Princeton, N.J.) of 1 mm thickness and varying size from 10×15 cm to 10×20 cm was used. Anterior only implant coverage was performed according to the "in vivo" technique previously published.[7] In some cases, two sheets of ADM were used to fully cover the anterior implant surface. In NSMs and SSMs, the matrix was invariably anchored to the inframammary fold and lateral breast border but not always to the upper limit of the pocket. In reconstructions after SRM, the ADM was used either in the same way or as an elongation of an inferior dermoadiposal flap with fixation to it and to the upper limit of the pocket. PU implants were introduced directly into the pocket without further coverage except for the inferior dermoadiposal flap in SRM patients. When managing these implants, particular attention was paid to pocket tailoring and implant

positioning because initial dystopia usually becomes permanent.

Preoperative prophylactic antibiotic coverage with cefazolin or clindamycin was administered and continued for 24–48 hours. Sterile measures and triple antibiotic irrigation of the pocket (betadine, cefazolin, gentamycin) were adopted in all cases. One or two Jackson Pratt drains nr 14 were inserted with one of them being invariably placed along the inframammary fold. Drains were kept until the output was less than 20–30 cc/day (as registered daily by the patient). In some cases of PU-based reconstruction, a Tegaderm (3M; Saint Paul, Minn.) "bra" was applied instead of the usual surgical bra for 2–3 days to avoid early implant malposition. A soft surgical bra was otherwise recommended for 4 weeks.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics Version 28.0.1. Continuous variables were assessed for normality and described using mean and standard deviation or median and interquartile range, accordingly. Categorical variables were described using absolute and relative frequencies. Normally distributed continuous variables were compared between the two groups using Student *t* test for independent samples. Other continuous variables were compared using the Mann–Whitney U test. Categorical variables were compared using the Pearson chi-square test or Fisher exact test, depending on expected counts. A significance cutoff value of 0.05 was used.

RESULTS

During the 2.5-year period, a total of 44 breast reconstructions were performed in 35 patients (10 bilateral), of which 23 (53%) used ADM-covered implants and 21 (48%) used PU-coated silicone gel implants. Patient-related oncological and surgical variables were generally comparable between groups (Tables 1 and 2). Average age was 51.3 ± 7.4 and 54.3 ± 8.0 years and BMI was 24.8 ± 3.1 and 24.7 ± 3.4 kg/m² in the ADM- and PU-based reconstruction cohorts, respectively. Comorbidities also did not display statistically significant differences between groups, but more cases had undergone previous breast surgery in the PU group (3/21 cases). Tumor type and stage showed similar distributions between groups. None of the cases in the PU group required postmastectomy radiation therapy (PMRT), compared to three of 23 cases in the ADM group. A similar number of cases required neo- or adjuvant chemotherapy in both groups. Most cases were therapeutic NSM mastectomies in either group, with the vast majority of patients undergoing sentinel lymph node biopsy. Median mastectomy weight was similar in both groups (298 g in the ADM group versus 314 g in the PU group), but median implant volume was higher in the ADM-based reconstruction cohort (495 versus 350 cc).

The rate of overall acute complications was higher in the ADM group, even though this was not statistically significant (6/23 [26.0%] versus 2/21 [9.5%], $P = 0.245$) (Table 3). ADM use was not associated with an increase in median total drainage volume (500 mL, IQR 430–620 in the ADM group versus 515 mL, IQR 387–730 in the PU group, $P = 0.851$), nor did it significantly extend the median period of drainage (9 days IQR 7–10 in the ADM group versus 8 days IQR 6.5–12.5 in the PU group, $P = 0.371$). Seroma was the most common complication in the ADM group (4/23, 17.4%). These were clinically significant seromas requiring aspiration. In contrast, this complication was never observed in the PU group. The reported difference did not narrowly reach significance ($P = 0.109$). Similarly, surgical-site infections occurred exclusively in the ADM cohort (3/23, 13%) ($P = 0.234$). A hematoma occurred in a single patient who had undergone

TABLE 1. Patient and Oncologic Variables

	ADM	PU	*P*
Breast	23	21	—
Laterality			—
Right	12	8	
Left	10	13	
Age (y)*	51.3 ± 7.4	54.3 ± 8.0	0.199
BMI (kg/m²)*	24.8 ± 3.2	24.7 ± 3.4	0.911
DM	0	0	-
Hypertension	7 (30.4%)	9 (42.9%)	0.392
Active tobacco use	3 (13.0%)	5 (23.8%)	0.448
Previous breast surgery	0	3 (14.3%)	0.100
PMRT	3 (13.0%)	0	0.234
Chemotherapy	9 (39.1%)	7 (33.3%)	0.690
Tumor stage			-
0	4 (22.2%)	4 (23.5%)	
I	11 (61.1%)	10 (58.8%)	
II	3 (16.7%)	2 (11.8%)	
III/IV	0	0	
Tumor type			0.558
DCIS	4 (22.2%)	2 (12.5%)	
LCIS	0	2 (12.5%)	
Ductal carcinoma	9 (50.0%)	7 (43.8%)	
Lobular carcinoma	5 (27.8%)	5 (31.3%)	

*Mean ± standard deviation.
DCIS, ductal carcinoma in situ; LCIS, lobular carcinoma in situ.

Table 2. Surgery-related Variables

	ADM	PU	*P*
Mastectomy type			0.492
NSM	18 (78.3%)	14 (66.7%)	
SSM	0	2 (9.5%)	
SRM	5 (21.7%)	5 (23.8%)	
Mastectomy intent			1.000
Therapeutic	18 (78.3%)	17 (81.0%)	
Prophylactic	5 (21.7%)	4 (19.0%)	
SLNB	18 (78.3%)	16 (76.2%)	0.854
Mastectomy weight (g)*	298 (202–420)	314 (266–504)	0.605
Implant volume (mL)	495 (350–550)	350 (315–395)	0.001

*Median (interquartile range).
SLNB, sentinel lymph node biopsy.

Table 3. Comparison of Short-term Outcomes

	ADM	PU	*P*
Total drainage volume (cc)*	500 (430–620)	515 (387–730)	0.851
Time to drain removal (d)	9 (7.0–10.0)	8 (6.5–12.5)	0.371
Seroma	4 (17.4%)	0	0.109
Infection	3 (13.0%)	0	0.234
Hematoma	0	1 (4.8%)	0.477
Ischemic complications	4 (17.4%)	1 (4.8%)	0.348
Explantation	2 (8.7%)	0	0.489
Any complication	5 (21.7%)	2 (9.5%)	0.416

*Median (interquartile range).

reconstruction with PU implants (P = 0.477). Overall ischemic complications including mastectomy flap and nipple partial or full-thickness necrosis were registered in four of 23 (17.4%) and one of 21 (4.8%) in the ADM and PU groups, respectively (P = 0.348). Explantation was required in two patients reconstructed with ADM-covered implants (8.7%) with no lost implants in the PU group (P = 0.489). Both explantations observed in the ADM group occurred in patients with a history of infected seroma, as discussed below. Again, neither of the observed differences reached significance.

DISCUSSION

Most surgeons believe that if one embarks in prepectoral breast reconstruction, placing some kind of interposition material between the silicone implant and the mastectomy flaps is a *sine qua non*. ADM has been the mainstay, but recent studies have reported equivalent outcomes with the use of synthetic meshes.[8]The 1- to 2-mm-thick PU foam layer coating PU implants available in some European and South American countries could provide the same benefits of these other interface materials, offering the additional advantages of a cheaper ready-to-use integrated device.[9]

The reasons for using an adjunctive interface material covering a silicone gel implant are manifold. The first goal is to support the implant, thereby reducing pressure on the mastectomy flaps. PU implants adhere tightly to the pectoralis muscle after hours to a few days, which could also theoretically unload tension exerted on the breast envelope. Some argue that ADM could protect the implant in the event of mastectomy flap necrosis or dehiscence, but we disregard this idea. In our opinion, only vascularized pectoralis muscle could protect the implant in such an instance. This may well be the main downside of prepectoral reconstruction. Both ADM and meshes add in precise pocket control initially, although some argue that ADM is not as effective at holding implant position, as it stretches over time. PU implants are remarkable for keeping its initial position on the chest wall. This is actually why strict pocket control (ie, tailoring with sutures) and early postoperative care (eg, applying a Tegaderm "bra" instead of a surgical compressive bra) is paramount to prevent permanent implant malposition. Another purported advantage of ADM or meshes is the ability to camouflage the implant, reducing rippling and implant edge visibility, but this remains to be proven. We do feel that PU implants can be more visible and cause more rippling, perhaps because they so intimately adhere to the breast envelope. This is circumvented by fat grafting either immediately or at a second stage. The most frequently cited rationale for using an ADM or mesh interface is the prevention of capsular contracture, and this is ultimately the most significant. Even though low rates of capsular contracture have been consistently reported with the use of ADM,[10] a recent publication has described the "phenomenon of ADM-associated contracture" in 19 of 92 breasts (21%) reconstructed with this material.[3] Comparative data are lacking, but PU implant coating seems to be at least as effective as ADM in preventing capsular contracture in aesthetic and reconstructive breast surgery.[4,5,9,11,12]

The purpose of the present study was to compare short-term complications associated with the use of either interface material. These were defined as occurrences within the first 3 months after surgery in line with a recent publication concluding that infections more frequently occur after the first month.[12] Long-term outcomes, including capsular contracture rates and aesthetic outcomes, are beyond the scope of this publication and will be addressed in the future. Seroma formation is consistently reported as one of the most frequent complications after implant-based breast reconstruction. It frequently heralds infection and reconstructive failure, even if properly managed. It has been hypothesized that ADM acts as an additional foreign body contributing to the inflammatory response after surgery, potentially leading to increased drainage, seroma, and infection. Even though early literature on the use of ADM for dual-plane reconstruction[1,2] seemed to support this theory, more recent studies comparing prepectoral reconstruction with and without ADM support are still not conclusive.[13,14] The literature is scarce on the use of PU implants, but, still, it points to an exceedingly low rate of seromas when these devices are applied for prepectoral reconstruction.[9,11] This is readily explained by the adhesive properties of the PU foam coating which result in rapid obliteration of periprosthetic dead space. In the present study, we were not able to demonstrate any significant difference in initial drainage (ie, total drainage volume and time do drain removal) between both arms. By contrast, although seromas were essentially not seen with PU implants, they were a common complication in the ADM cohort occurring in four of 23 (17.4%) patients. One can speculate that PU implants take a few days to adhere to the surrounding breast envelope, behaving no differently from the ADM-covered implants during this period. However, once this is accomplished, fluid accumulation is more effectively prevented. It should be noted that even after successful incorporation of ADM into surrounding tissue, there is always a gliding plane between the ADM and the implant. This is not the case in integrated PU devices. In accordance with the literature, we suppose that the observed differences in seroma rates between the groups are due to a protective effect of PU coating rather than a deleterious effect of ADM cover.

Although surgical-site infection is usually multifactorial in prosthetic breast reconstruction, postoperative seroma has proven to be a strong risk factor.[15] As with seroma, some studies link ADM use to an increased risk of infection, but data are even more conflicting. In this series, infections occurred in three of 23 (13%) cases reconstructed with ADM. All of them were infected seromas, although delayed wound healing could have contributed in two cases. Two of these patients eventually required explantation. One patient developed an infected seroma and was treated with aspiration and antibiotic therapy with initial improvement but eventually required explantation after initiating PMRT. No

infections were detected in the PU group. By avoiding the accumulation of periprosthetic fluid, PU implants could not only protect from seroma but also from infection. This might ultimately mitigate the risk of reconstructive failure.

Red breast syndrome refers to an erythematous rash that has been described after prepectoral breast reconstruction with both ADM-covered[16] and PU-coated implants.[9] It can closely mimic infection both in time to onset and clinical characteristics. An inflamed breast should always raise suspicion for infection, and treatment must be instituted accordingly. If the rash neither responds to antibiotic therapy nor does it progress, red breast syndrome can be assumed.[16] In our series, two patients presented with such a clinical picture, one in each group. These were not considered infections and therefore were not included in the analysis. Further studies are needed to better define this puzzling entity.

Ischemic complications mainly consisted of minor superficial blistering of the nipple areolar complex (NAC) or the mastectomy flaps, except for one case in the ADM group which went on to develop full-thickness necrosis and dehiscence after initiating PMRT. This patient had been treated with aspiration and antibiotics for an infected seroma and finally required explantation, as previously mentioned. Hematomas were rare in either group. The higher likelihood of overall complications seen in the ADM group was mainly driven by the higher rate of infected seromas.

This study is intrinsically limited by its retrospective nature. Despite the clinical relevance of the observations made, the relatively small sample size should be taken into consideration when interpreting these results. Because some kind of adjunctive material was used in all cases in this series, it is not possible to ascertain whether the observed differences were due to a detrimental effect of ADM or a favorable consequence of PU implant use. The two cohorts differed slightly, as more patients in the PU group had history of previous breast surgery and PMRT was more frequently administered to cases in the ADM arm. It is unlikely that the outcomes have been affected by these differences. Implant volume was significantly larger in the ADM cohort. This could have been related to a sense of increased support with ADM use or a tendency of the first surgeon to select slightly larger implants. These differences could have impacted complication rates, mainly ischemic complications. Reconstructions with PU and ADM were for the most part performed by different surgeons but with very similar techniques. Most importantly, the choice between ADM or PU was not influenced in any way by mastectomy flap quality. Meshes are another option for prepectoral breast reconstruction, and these were not analyzed herein. The use of an ADM wrap concomitantly with PU-coated implants has recently been reported,[17] as has the use of implants without any further coverage.[14] A head-to-head comparison between these many interface materials and the use of implants alone is warranted to clarify the true short and long-term benefits of each. Finally, despite being aware that PU devices are currently unavailable in the United States, we are confident that this article may lead to interesting discussion amongst international readership.

CONCLUSIONS

Prepectoral reconstruction with implants and ADM support has become the standard method of prosthetic breast reconstruction in many parts of the developed world. The use of PU implants has emerged as a less expensive and more convenient alternative in certain European countries. We aimed to directly compare short-term outcomes between both techniques. In this series, PU implants tended to be associated with fewer short-term complications and reconstructive failure than ADM-covered implants. Larger studies addressing longer-term outcomes are needed to better guide surgeons caring for the growing population of women willing to undergo immediate implant-based breast reconstruction after SSM and NSM.

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