Review Article

Complications associated with acellular dermal matrix use in implant-based breast reconstruction

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Abstract: Acellular dermal matrix (ADM) has become an established adjunct in implant-based breast reconstruction, improving implant coverage, pocket control, and soft-tissue support and hastening the adoption of prepectoral techniques. Notwithstanding its more than two decades of use in breast reconstruction, breast reconstruction remains an off-label indication for ADM use in the US. Human, porcine, and bovine sources have all been used to provide ADMs. They undergo distinct processing and sterilization methods that may affect matrix architecture, host integration, and clinical performance. Following implantation, ADM serves as a biologic scaffold for cellular infiltration and neovascularization. However, its use remains associated with important complications, including seroma, infection, red breast syndrome (RBS), mastectomy skin flap necrosis (MSFN), implant exposure, and reconstructive failure. Reported outcomes vary widely across the literature, likely due to differences in reconstructive technique, mastectomy flap perfusion, ADM characteristics, perioperative management, and patient risk factors. Elevated body mass index (BMI), smoking, diabetes, prior radiation, larger ADM burden, and compromised skin flap vascularity consistently emerge as contributors to adverse outcomes. From a clinical standpoint, successful ADM use depends on judicious application, meticulous technique, and early recognition of evolving complications. Despite its off-label status, ADM use in breast reconstruction remains widespread and an important tool for plastic surgeons.

Keywords: Acellular dermal matrix (ADM); breast reconstruction; mastectomy; complications

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Introduction

Over the past two decades, acellular dermal matrix (ADM) has emerged as a foundational tool in implant-based breast reconstruction. By providing an internal scaffold for tissue support and implant coverage, ADM facilitates a more natural breast contour and enables a range of reconstructive techniques (1-3). Its use has expanded across both direct-to-implant (DTI) and two-stage implant-based reconstructions, and it has played a pivotal role in the growing popularity of prepectoral approaches (3,4).

ADMs were first applied clinically in the 1990s for burn reconstruction, with subsequent applications in head and neck reconstruction, abdominal wall repair, rhinoplasty, dural repair, and more (5-13). The use of ADMs in breast surgery was first reported in 2001 by Duncan, who described their application in revisionary procedures to

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correct implant rippling (14). Shortly thereafter, ADM use expanded into breast reconstruction and was first described by Breuing and Warren in 2005 and Salzberg in 2006, who pioneered its application in DTI reconstruction (15,16).

Despite the widespread adoption of ADMs in breast reconstruction, it is important to note that ADMs have not been specifically approved by the U.S. Food and Drug Administration (FDA) for this indication. While approved for other applications, ADM use in reconstructive and aesthetic breast surgery is considered off-label (17,18). In 2019, the FDA released updated guidance outlining the evidentiary requirements for premarket approval of ADMs and synthetic meshes in breast reconstruction (19). This was followed in 2021 by a formal safety communication addressing variability in complication rates released (20). Notably, the FDA denied a premarket approval application for one ADM product (SurgiMend®) in the same year (21).

Nevertheless, the use of ADMs has become increasingly prevalent in current practice. Recent studies have shown a steady increase in ADM utilization over the past decade (22,23). This widespread adoption reflects the potential benefits of ADMs, including improved implant positioning, enhanced aesthetic outcomes, reduced capsular contracture rates, and the facilitation of prepectoral breast reconstruction techniques (24-28).

While ADMs offer numerous potential advantages, their use is not without complications. Understanding the nature, incidence, and management of these complications is essential for optimizing patient outcomes. While various studies have evaluated ADM-associated complications, reported outcomes vary widely across the literature. This variability is likely multifactorial and influenced by differences in surgical plane (prepectoral *vs.* subpectoral), ADM processing (aseptic *vs.* terminally sterilized), and mastectomy flap perfusion. This review aims to comprehensively examine the major complications associated with ADM use in breast reconstruction, including seroma formation, infection, RBS, mastectomy skin flap necrosis (MSFN), implant exposure, and reconstructive failure, while also exploring preventative strategies and management options.

Basic science of ADM

ADMs used in breast reconstruction are typically derived from three primary sources: human (allograft), porcine (xenograft), and bovine (xenograft) tissues. Human-derived ADMs, such as AlloDerm® (Allergan) and FlexHD® (MTF Biologics), are processed from cadaveric dermis and are the most widely used category of ADM in the US (29). Porcine-derived products, including Strattice™ (Allergan) and Braxon® (Decomed S.r.l.), are more commonly employed in European markets and tend to exhibit greater tensile strength due to their thicker dermal composition (29). Bovine-derived ADMs such as SurgiMend® (Integra Life Sciences) and Veritas® (Synovis) are sourced from fetal bovine dermis or pericardium, offering unique mechanical properties such as increased pliability or enhanced collagen organization (30-32). Each of these sources present distinct characteristics that can influence the matrix's handling properties and performance.

Regardless of tissue origin, all ADMs undergo rigorous processing to remove immunogenic components while preserving the structural integrity of the extracellular matrix (ECM). However, the specifics of these processing methods can vary significantly between products and consequently affect the final matrix properties (33). Decellularization methods may include detergent washes, enzymatic digestion, or physical agitation, each varying in their efficacy and impact on matrix integrity (34). Another important variable in ADM processing is sterilization. Aseptic processing refers to tightly controlled techniques used throughout the manufacturing process to minimize contamination. In contrast, terminal sterilization involves subjecting the fully processed and packaged ADM to an additional sterilization step—typically using gamma irradiation, electron-beam irradiation, or ethylene oxide (35). While terminal sterilization achieves a defined sterility assurance level, it has been shown to compromise the structural and biomechanical properties of the matrix by disrupting collagen architecture, leading to reduced tensile strength and altered host integration (36).

The end result of this extensive processing is a three-dimensional scaffold that, while devoid of cells, retains the complex architecture and biological cues of the ECM. Once implanted, ADMs elicit a host response that closely resembles the physiologic cascade of wound healing. In the initial days following implantation, an acute inflammatory response occurs, marked by infiltration of macrophages and monocytes and the release of signaling molecules such as cytokines and growth factors (37-40). This initial cellular invasion of the ADM promotes further cellular recruitment and host cell proliferation within the matrix (38-41). Concurrently, angiogenesis is initiated, with functional neovascularization typically observed within one month of implantation (39,40,42).

Importantly, ADMs do not appear to induce a chronic inflammatory response, distinguishing ADMs from synthetic materials that may provoke prolonged foreign body reactions. Instead, ADMs continue to remodel and integrate with host tissue over time (43). In a cohort of 145 patients, Lee *et al.* found that ADM became thinner over five years, with a progressive decline in ECM components and an increase in fibroblasts, neovascularization, and immune cell infiltration (43). Moreover, a 12-year histologic sample of ADM demonstrated preserved structure, vascularization, and an absence of capsular formation, further supporting the long-term biocompatibility of ADM (44). While differences in cellular and vascular ingrowth may exist between human- and xenograft-derived products, both have demonstrated favorable integration and low complication rates in long-term use (45,46).

Review of major complications of ADM

Although ADM has revolutionized implant-based breast reconstruction, its use has been associated with a variety of complications. These include seroma formation, infection, tissue expander or implant exposure, and MSFN, all of which may necessitate revision procedures or explantation (47). Understanding the pathophysiology and management of these complications is essential for optimizing patient outcomes.

Seroma formation

Seroma, the accumulation of fluid between the ADM and underlying soft tissue, is one of the most frequently reported complications, with incidence rates ranging from 7.1% to 20% (48,49). Historically, clinical evidence has suggested a higher incidence of seromas in breast reconstructions involving ADMs compared to non-ADM techniques. However, more recent studies have challenged this notion, reporting no significant difference in seroma rates between the two approaches (50).

The precise mechanism behind seroma formation in ADM-supported breast reconstruction remains unclear; however, several theories on its pathophysiology have been proposed in the literature. The leading theory suggests that prior to revascularization, ADM provokes a foreign body response, stimulating local inflammation and enhancing capillary permeability. This response hinders the integration of the ADM into the surrounding soft tissues, creating dead space that allows for further fluid accumulation (51). Additionally, sentinel or axillary lymphadenectomy at time of ADM placement may interfere with the clearance of interstitial fluid, further increasing risk of seroma formation (52). Lastly, ADM properties such as surface area, fenestration and composition may play a role, with less porous materials being associated with higher rates of seroma formation (53). Additional risk factors associated with seroma formation in the context of ADM use include advanced age, higher body mass index (BMI), larger breast size, and greater ADM area, with elevated BMI serving as the most significant predictor (54,55).

Seromas typically develop within the first four weeks postoperatively. Patients may present with localized swelling, firmness and discomfort in the reconstructed breast. If left untreated, persistent seromas can lead to more severe complications such as infection, MSFN or failed reconstruction. Postoperative seromas are most often diagnosed clinically; however, ultrasound imaging can be utilized to confirm the diagnosis, assess the volume of fluid accumulation, and rule out concomitant infection.

Various preventative strategies have been proposed to minimize seroma formation. From a technical perspective, ensuring that the ADM is smoothly adhered to the soft tissue without folds is crucial in minimizing dead space. Closed-suction drains should be placed at the time of reconstruction and remain in place until outputs are minimal. The number of drains used remains a contentious discussion among surgeons, with a recent study demonstrating that the placement of two drains may decreases the rate and risk of seroma formation (56). Additionally, a recent randomized controlled trial found that tranexamic acid (TXA) may reduce drain output (57). Finally, patient compliance with postoperative activity restrictions may further reduce the risk of seroma formation.

The management of post-operative seroma depends on the severity and persistence of symptoms. Small symptomatic seromas can be managed conservatively with aspiration, while larger, persistent or recurrent seromas may necessitate image-guided drain placement. Fluid sampling at time of drain placement allows for the assessment of concurrent infection. In cases of infection or mastectomy skin flap compromise, surgical intervention, including removal of ADM, may be required. Additionally, if infection is a concern, antibiotic prophylaxis should be considered.

Infection

Infection is one of the most concerning complications

associated with ADM use in breast reconstruction, and if not promptly identified and managed, it can significantly impact surgical outcomes and increase the risk of reconstructive failure. The reported incidence of infection after ADM-assisted breast reconstruction ranges from 5% to 31% (15,58,59).

The pathophysiology of infection in the setting of ADM use is multifactorial. Surgical site contamination, suboptimal handling and sterility techniques, the need for prolonged drain placement associated with ADM use, and ischemic mastectomy skin flaps can create an environment conducive to bacterial proliferation (12). Importantly, ADMs are terminally sterilized prior to clinical use and are unlikely to represent a primary source of infection. Instead, infections associated with ADM-assisted reconstruction are typically secondary to persistent seromas, non-incorporated ADM, or compromised mastectomy skin flaps. Additionally, patient-related risk factors such as advanced age, medical comorbidities (i.e., diabetes), smoking, elevated BMI and history of chemoradiation further increase the likelihood of infection (60).

Infections can be categorized based on their severity and depth of involvement. Superficial infections often present as cellulitis, characterized by localized erythema, warmth, and tenderness. More severe infections may involve the implant pocket, leading to purulent drainage, systemic symptoms, leukocytosis, and, in some cases, progressive tissue compromise. If left untreated, these infections can result in implant exposure, necessitating explant of the implant and ADM construct.

Preoperatively, comorbid conditions should be optimized, and smoking cessation encouraged to reduce risk of infection. Intra-operatively, minimize handling of ADM. Several studies suggest that certain processing techniques, such as terminal sterilization or antibiotic impregnation, may reduce rates of infection (61). Post-operatively, the role of prophylactic antibiotics remains controversial, with several studies showing no significant difference in infection rates between various regimens in ADM-assisted breast reconstruction. Lastly, early drain removal is recommended to reduce infection risk; however, this must be carefully balanced against the risk of seroma.

RBS

RBS, or idiopathic postoperative erythema, is a non-infectious inflammatory response that mimics cellulitis but does not respond to antibiotics. The reported incidence of RBS varies, ranging from 5.8% to 27% in the literature (62,63). The wide range of reported RBS incidence likely reflects differences in ADM processing, patient selection, and surgical technique across studies. Variations in sterility assurance level, residual biologic material, and host immune response may all contribute to this heterogeneity.

Several etiologies have been proposed for RBS in the setting of ADM, with the most widely accepted being a delayed, type IV, T-cell mediated, hypersensitivity reaction. This response may be triggered by the presence of residual DNA or endotoxins from gram-negative bacteria within the ADM complex (64,65). Subclinical mycobacterial infection and lymphatic disruption have also been suggested as other potential causes (66). Identified risk factors for ADM include history of radiation therapy and use of porcine-derived ADM.

RBS is a clinical diagnosis characterized by blanching erythema overlying the area of the breast where the ADM was placed or, in some cases, the entire reconstructed breast. The affected area may feel warm to the touch but is typically non-tender and without induration or palpable fluctuance. Patients are generally afebrile, with stable vital signs and normal or non-specific laboratory findings (67,68).

Ultrasound imaging often reveals non-specific findings, such as small, thin fluid collections surrounding the implant, which are often not amenable to drainage. Due to the overlap in clinical presentation with cellulitis, patients are frequently started on prophylactic antibiotics; however, RBS is refractory to antibiotic treatment. While some reports suggest that RBS may be self-limiting, resolving within weeks to months without intervention, others indicate that symptom resolution may not occur unless washout occurs and the ADM is removed (66).

Systemic corticosteroids have demonstrated efficacy in managing symptoms. A 2014 study by Ganske *et al.* reported that 75% of patients experienced symptom improvement following steroid treatment (64).

MSFN & exposure

MSFN is a challenging complication that can lead to reconstructive failure. The incidence of MSFN in breast reconstruction varies widely, with some studies suggesting rates as high as 10–30% (69,70). MSFN is a multifactorial complication primarily driven by compromised tissue perfusion. The association between ADM use and MSFN remains controversial; however, its use in the setting of hypovascular mastectomy flaps has been associated with

worsened perioperative outcomes. ADM itself is not an intrinsic cause of MSFN; rather, its use in the setting of poorly vascularized mastectomy flaps may exacerbate complications due to impaired incorporation. In this context, ADM should be viewed as a passive scaffold where integration depends on adequate tissue perfusion rather than a causative factor in ischemia. A 2017 retrospective cohort study found that when ADM was used under hypovascular mastectomy flaps, complication rates (infection and expander loss) were higher compared to cases of MSFN alone (71).

MSFN is often the result of an aggressive mastectomy approach that damages the sub-dermal plexus, which limits perfusion to the skin flaps. Additionally, excessive tension or overfilling of the tissue expander at time of immediate reconstruction can further inhibit vascularity. Patient risk factors such as prior radiation therapy, comorbidities (i.e., diabetes, obesity) and smoking history also play a role in flap viability.

Intraoperatively, skin flap necrosis may manifest as dusky or pale discoloration with delayed capillary refill, which may continue to progress over time. As necrosis progresses, affected areas become darker, and eventually form an eschar. If left untreated, full-thickness necrosis may lead to wound dehiscence and subsequent implant or ADM exposure, which prompts early surgical intervention. Treatment options for ADM exposure, include debridement and local flap advancement, or in severe cases, implant removal and delayed reconstruction. The decision to salvage reconstruction depends on infection status, tissue viability and patient-specific risk factors.

Reoperation & implant removal

Reoperation and implant removal rates in ADM-assisted breast reconstruction vary across studies. A 2022 analysis of nearly 50,000 TE-based breast reconstructive cases reported a 7.4% reoperation rate in ADM-assisted tissue expander-based reconstructions, compared to 6.0% in non-ADM cases (22). Another study by Govshievich observed a reoperation rate of 9.7% in ADM-assisted DTI reconstruction (72). Regarding implant loss, the literature suggests rates ranging from 6.8% to 12.5% in ADM-assisted reconstruction (73).

Comparative analysis of ADM types

ADMs used in breast reconstruction are derived from three main sources: human (allograft), porcine, and bovine (xenografts). Each type presents distinct mechanical and biological characteristics that can influence outcomes and complication profiles.

Human-derived ADMs (e.g., AlloDerm®, FlexHD®, DermaMatrix®) are commonly used in the US. They mainly differ in processing requirements: AlloDerm requires refrigeration and a 30-minute rehydration, while DermaMatrix and FlexHD are shelf-stable and require minimal to no hydration. Despite minor product handling differences, multiple retrospective studies have shown no statistically significant differences in major complication rates among human ADM types. In one such study, infection rates were identical at 10% for AlloDerm, FlexHD, and DermaMatrix (74).

Porcine-derived ADMs, such as Strattice™ and Braxon®, are more commonly used in European settings and offer greater tensile strength due to thicker dermal composition. Bovine-derived ADMs (e.g., SurgiMend®, Veritas®) provide pliability and may show enhanced collagen architecture (75). However, differences in host integration and immunogenic response are still under investigation, with some studies noting higher RBS incidence in porcine products (29).

Fenestrated *vs.* non-fenestrated ADMs also differ in their complication profiles. Fenestration is thought to facilitate the egress of interstitial fluid from surrounding tissue planes through the ADM, thereby reducing the risk of fluid accumulation within the implant pocket (49).

Ultimately, no single ADM type has demonstrated clear superiority in reducing all complications. Selection should be individualized, considering handling characteristics, surgical setting, and patient-specific risk factors such as BMI, radiation history, and skin flap thickness.

Conclusions

ADMs have revolutionized implant-based breast reconstruction, enabling improved aesthetic outcomes, reduced capsular contracture rates, and the widespread adoption of prepectoral techniques. However, their use is associated with potential complications including seroma, infection, RBS, MSFN and implant exposure. Minimizing these complications relies on meticulous patient selection, optimization of modifiable risk factors, careful surgical technique, and close postoperative monitoring.

Ongoing research into novel ADM technologies aims to further improve outcomes and mitigate complications. For example, antibiotic-impregnated ADMs have shown promise

in reducing biofilm formation and infection risk (76). Moreover, a recent randomized trial of an ADM without a basement membrane demonstrated lower seroma rates and improved biomechanical properties compared to traditional ADMs (77). Future studies should also incorporate cost-effectiveness analyses to guide product selection and clinical decision-making.

Ultimately, the successful use of ADMs in breast reconstruction depends on a commitment to evidence-based best practices. Key recommendations include careful patient selection based on risk factors like obesity and smoking status, optimization of preoperative comorbidities, use of sound technical principles to minimize dead space and ensure vascularity of mastectomy skin flaps, and vigilant monitoring for signs of complications coupled with prompt intervention when issues arise. With ongoing research and a dedication to continuous improvement, ADMs will undoubtedly remain an invaluable tool in breast reconstruction.

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Footnote

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