

Current opinions on indications and algorithms for acellular dermal matrix use in primary prosthetic breast reconstruction

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Abstract: Acellular dermal matrix (ADM) is widely used in primary prosthetic breast reconstruction. Many indications and contraindications to use ADM have been reported in the literature, and their use varies by institution and surgeon. Developing rational, tested algorithms to determine when ADM is appropriate can significantly improve surgical outcomes and reduce costs associated with ADM use. We review the important indications and contraindications, and discuss the algorithms that have been put forth so far. Further research into algorithmic decision-making for ADM use will allow optimized balancing of cost with risk and benefit.

Keywords: Breast reconstruction; acellular dermal matrix (ADM); algorithm

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Introduction

Since Salzberg's first description (1) and Breuing's subsequent publication (2) of the use of human acellular dermis as an adjunct to traditional prosthetic breast reconstruction, there has been a surge of interest in this technique. Today, acellular dermal matrix (ADM) is used in nearly 60 percent of the 50,000 prosthetic-based breast reconstructions that are performed annually (3). Users have cited numerous benefits of ADM in prosthetic breast reconstruction, ranging from better control of anatomic placement (1,4-10) increased definition of the inframammary fold (1,4-10) reduced capsular contracture (5,7-17) faster and fewer expansions especially of the lower pole (1,4,7-10,12,14,16-22) and overall improved aesthetic outcomes (6,23-26).

Nonetheless, important concerns have arisen surrounding ADM use, most notably including increased cost and heightened complication rates (3,8,9,27-31). Among the literature there is a very high variation in many of the reported outcomes for ADM compared to traditional non-ADM techniques (32,33). A literature review by Kim *et al.* revealed reported complication rates from ADM-assisted reconstruction ranging from as low as 8.6% to as high as 19.5% (28). In that study, the complication rate

with ADM use had a pooled average of 15.4%, slightly but statistically significantly higher than the non-ADM pooled average of 14.0%. Certainly, rigorous randomized controlled trials (RCTs) investigating complication rates would be enlightening, but unfortunately only one has been completed to our knowledge; it showed equal outcomes between ADM use and traditional, no-ADM breast reconstruction (30), although the conclusions of this study may be limited by its use of an older, now-disfavored size of ADM sheet (34). The Multi Center Canadian Acellular Dermal Matrix Trial (MCCAT) promises to provide further RCT data to answer this question (35), which is reassuring because clearly, more data from RCTs can help to sharpen our understanding of ADM's effects on surgical outcomes.

Even so, some have posited that at least some of the disparity in reported complication rates with and without ADM is actually due to the lack of clear indications and contraindications to use (36). The disparate complication rates we are seeing in the literature may be caused by implicit variations in patient selection. Careful and rational patient selection is critical to maximize reconstructive outcomes (9). The literature is rife with associations between certain patient parameters and better or worse outcomes (*Table 1*). For example, a recent publication by

Table 1 Various literature-reported indications and contraindications for acellular dermal matrix use in primary breast reconstruction

Indications	Contraindications
Nipple-sparing or direct to implant procedure (37-41)	Obese (42-45)
Large breasts (46,47)	Large breasts (43,48,49)
Anticipated post-operative radiation (43,50,51)	Pre-operative radiation (39,42,43,48,52)
Non-ptotic breasts (46)	Smoker (43,44)
Compromised or small pectoralis major (31,43,53-55)	Thin skin flaps (43)
Skin excess (56)	Poor flap vascularity (36,39,43,57)

Mendenhall *et al.* (42) studying the difference between two different ADMs notably found that radiation therapy, larger tissue expander size, and obesity were all predictors of a longer time spent with drains, which itself was associated with a greater number of complications.

When surgical decision-making relies on many factors, it is common and helpful to develop rational algorithms to help guide decisions. For example, the decision to choose a particular breast reconstruction modality, i.e., prosthetic versus autologous reconstruction, has enjoyed significant discourse that explores rational algorithms (37). Yet until very recently, there has been a paucity of literature on whether selective use of ADM is even possible, let alone specific proposals for algorithms governing ADM use. We believe that the body of literature surrounding ADM indications and contraindications in primary prosthetic breast reconstruction has matured sufficiently to where a discussion of selective ADM algorithms is both now possible and necessary. Therefore, we wish to review the literature's current opinion on those various indications and contraindications, and discuss the few algorithms that have thus far been proposed.

Pre-operative indications and contraindications

Surgical technique: direct-to-implant and nipple-sparing surgical techniques

The advent of ADM has made major impacts on breast reconstruction, one of the most notable of these being the expanded use of the direct-to-implant reconstructive

modality (37,38). These single-stage techniques avoid the need for the expansion visits necessary for tissue expander reconstructions. Because there is no planned expansion of the skin envelope, maximal placement of volume must be achieved at the time of prosthesis insertion. However, the patient's pectoralis major muscle will likely be insufficient to accommodate the prosthesis, so ADM emerges as an obvious choice to allow the release and augmentation of the existing pectoralis (39).

A similar situation arises in the setting of a nipple-sparing mastectomy (NSM) and total-skin-sparing mastectomy (TSSM). In these cases, there will be maximal skin remaining since the surgeon has taken none; hence the discordance between the inner pectoralis lamellae and the outer lamellae of the skin envelope will be high. Proper alignment between these two lamellae improves the overall outcome and aesthetics of the reconstruction (36) (*Figure 1*). Like in the case of direct-to-implant reconstructions, NSM and TSSM techniques may benefit from releasing the pectoralis muscle and using ADM as a sling augmenting the inner tissue plane (40,41).

Body mass index and breast size

The relationship between body mass index and breast size can affect the concordance between the reconstructive outer lamella and the reconstructive inner lamella. When patients with high body mass index also have large, ptotic breasts, the available pectoralis major muscle may not accommodate the redundant skin hosted by the outer lamella. Therefore, in these patients ADM can be useful in providing the needed inner lamellar surface area, resulting in better contact between the skin flap and the underlying pectoralis muscle layer and ultimately reduced dead space (*Figure 1*). The ability to manipulate the ADM also confers control over the projection vector of the lower so that it better replicates the shape of the pre-mastectomy breast (46,47). ADM may also be used advantageously in high body mass patients to reduce the risk of seroma and other complications when it is employed as a tool to define the lateral and inferior edges of the prosthetic pocket (36).

On the other hand, it has also been noted that patients with high body mass index and large breasts may be at increased risk of poor wound healing due to the long flaps of skin which become prone to ischemia (43). Some studies have identified obesity as a risk factor for breast reconstruction using ADM (48,49). This conflict in the literature is reflected in *Table 1*. Therefore, while the use of ADM may help protect the reconstruction in the case of an

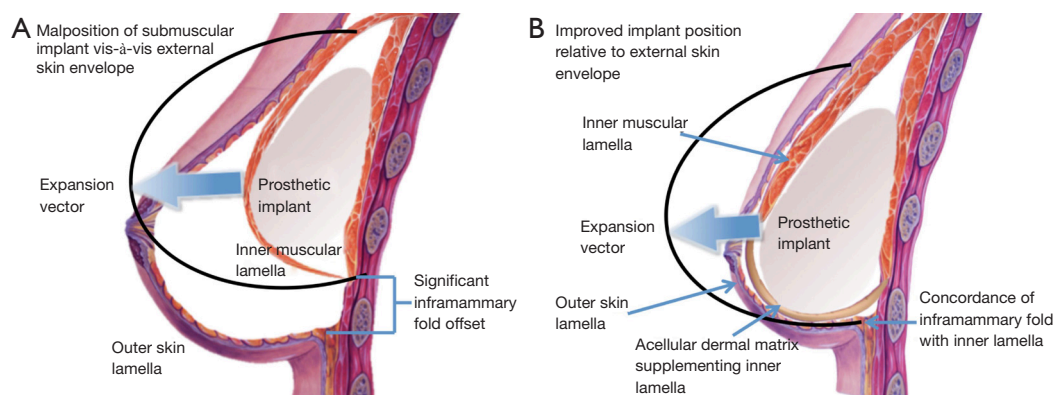


Figure 1 The relationship between the outer lamella, or skin envelope, and the inner lamella, or pectoralis-acellular dermal matrix plane. (A) A discordant alignment between the inframammary fold and the inferior border of the pectoralis major produces a vertical offset that causes unwanted ptosis; (B) the inner layer is augmented with acellular dermal matrix to resolve the disparity between the pectoralis and the outer skin flap, improving the expansion vector of the lower pole.

ischemic complication, a surgeon will likely have to weigh the option of a delayed reconstruction in high body mass index patients with large breasts.

Pre-operative radiation therapy and expectation of post-operative radiation

Pre-operative radiation exposure has been tenuously linked to poor outcomes, most likely due to the observation that irradiation compromises tissue microvasculature by provoking fibrosis (43,58-60). Additionally, fibroblast infiltration into the ADM disrupts its usual incorporation into surrounding tissue. Consequently, the integration of the ADM is threatened by serious complications such as infection, seroma, infection, explantation, and poor aesthetic outcomes because it begins to act as a foreign body (60-62).

But while pre-operative radiation contraindicates the use of ADM, preliminary evidence in conjunction with our own clinical experience suggest that ADM can accelerate expansion of the prosthetic pocket before the start of post-operative radiotherapy and provide protection against the risk of skin flap necrosis induced by post-operative radiation (50). Moreover, when the inferior border of the pectoralis major is released during the course of breast reconstruction with ADM, pectoralis tightness due to post-operative radiation-induced fibrosis is alleviated. For example, post-operatively irradiation was shown to reduce rates of explantation in a study of 428 breasts undergoing two-stage prosthetic breast reconstruction using ADM, compared to historically reported values (62). Likewise, another study reported that

postmastectomy radiation therapy without the use of ADM during reconstruction resulted in a 2.63-fold increase in complications, compared to a similar cohort who received ADM during reconstruction (63). In contrast, ADM has not demonstrated any benefits when used on breasts that have undergone pre-operative radiotherapy (39,43,64,65). Therefore, when post-operative radiotherapy is expected, the surgeon should consider using ADM during the breast reconstruction.

Intra-operative indications and contraindications

Pectoralis major anatomy

Surgeons conducting breast reconstruction must continuously assess the integrity and tautness of the pectoralis major as it is being manipulated. During the operation, the pectoralis, serratus fascia, or rectus fascia may be subject to iatrogenic damage that compromises their ability to house the reconstructive pocket. In these cases, ADM is used as an interpositional graft (31,43,47,53,54). On a similar note, expansion of the inferior pole is restricted when the pectoralis muscle is too tight, a situation that can arise when the muscle is too narrow or sits high on the chest wall; therefore, in these cases the pectoralis is released inferiorly and its coverage augmented with ADM in order to close the gap between the inframammary fold and the inferior border of the muscle. Indeed, Madsen *et al.* reported that 72 percent of patients have pectoralis that is either too high or too narrow (55).

While it is true that these cases may be handled simply

with elevation of the serratus and rectus fascial flaps, use of ADM often provides more powerful control over the breast mound. It permits full expansion of the lower pole and limits iatrogenic damage to the serratus anterior and rectus abdominus fascia that would otherwise endanger the definition of the inframammary fold.

Flap vascularity and skin excess

Flap vascularity is a critical prerequisite for expedient wound healing. In the face of numerous, often-conflicting indications and contraindications (*Table 1*), flap vascularity is in general the most important factor and ought to take precedence in the event of a conflict between different decision-points (36). Skin flaps are inherently hypovascular, which renders them vulnerable to incisional breakdown and prosthetic exposure if they are not managed properly (57). A number of patient comorbidities, notably smoking, peripheral vascular disease, and hypertension have been shown to compromise flap vascularity (57,66,67). The surgeon must observe flap vascularity intra-operatively to assess the degree of perfusion that the flap will be capable of providing. Compromised skin edges must be trimmed for optimal healing. If the flap is significantly devascularized, the subdermal vascular plexus damaged, or the flap itself is too thin, use of ADM is contraindicated due to the probability that it will not integrate (39,43).

If vascularity is deemed sufficient, the decision to use ADM rests on an intra-operative determination of relative skin excess. The goal of the operation is to match the length of the outer skin to the length of the muscle layer underneath, maximizing contact between the two layers. If the pectoralis muscle and the outer skin flap are mismatched, the skin flap may experience tension that can harm the natural aesthetic of the breast as well as disrupt perfusion to the nipple, causing nipple necrosis (56).

Sentinel-node status

As mentioned previously, the expectation of post-operative radiation is a good indicator for ADM use in breast reconstruction because of its beneficial effects on capsular constriction elicited by radiation. From an intra-operative finding of positive lymph node status, the surgeon can infer that the patient will likely undergo post-operative radiation therapy. Therefore such a finding is also a good indicator for the surgeon to use ADM (36).

Previously proposed algorithms

Presently, algorithms that assist surgeons to decide whether ADM is appropriate have not been well investigated, and specific proposals of such algorithms in the literature are sparse. Most such algorithms proposed so far have been one- or two-factor decision tools. For example, Colwell *et al.* suggested using a focused algorithm for ADM use that centered on the evaluation of skin flap vascularity (39). According to this algorithm, patients with thin or devascularized skin flaps would be reconstructed using total muscular coverage while thick and well-vascularized skin flaps would be reconstructed with ADM using a direct-to-implant technique.

Dupin *et al.* has also formulated a strategy that helps to identify scenarios where ADM is appropriate (68). In their algorithm, reconstruction assisted by ADM is favored for patients who have small breasts. Patients with large breasts, or those who smoke or are obese, may still be reconstructed with ADM at the surgeon's discretion, but the algorithm recommends against it if the mastectomy is associated with radiation.

Peled *et al.* (50) went further by formally assessing their simple algorithm, which selected the use of ADM for patients undergoing total skin-sparing mastectomies whose skin flaps weren't substantial enough to adequately fill tissue-expanders. Compared to not using ADM at all, which had an infection rate of 27.8%, and compared to indiscriminant ADM use, which had an infection rate of 20%, implementation of their selection algorithm significantly reduced infection rates to 15.8%.

Finally, we have previously published our own algorithm (36) designed to account for a multitude of patient factors and help generate a decision about whether reconstruction should be assisted by ADM. Our algorithm considered patient body mass index, pectoralis anatomy, flap vascularity, skin excess, and pre- and post-operative radiation therapy including sentinel-node status as a predictor of radiation. By deploying the algorithm for consistent use in our practice, we demonstrated a reduction in ADM usage without compromising safety or aesthetic outcomes.

The promises of well-designed algorithms to help ADM decision-making

Cost reductions

Rapidly mounting costs of health care alongside changes brought by the Affordable Care Act are forcing physicians

to reevaluate cost-benefit analysis of many procedures, as even the smallest inefficiencies will likely come under close scrutiny. Surgical decision-making should not only include consideration of utility and complications, but must also be sensitive to the economic consequences of the decisions. The economics of ADM use have been hotly debated in the literature, yielding various viewpoints and conclusions. Besides improving outcomes, one benefit of introducing algorithms for ADM use to surgical practice may be a reduction in healthcare costs as a direct result of more selective and therefore less frequent ADM use. Because ADM is instrumental in direct to implant reconstructions, which obviate the second operation of a two-stage reconstruction, ADM makes available a significantly cost-saving option (39,69-72). Even when patients elect to perform further aesthetic procedures after a direct to implant ADM-assisted breast reconstruction, the total cost may still lie below that of traditional non-ADM two-stage techniques (71). de Blacam *et al.* (69) published a cost-minimization analysis in the United States healthcare setting that estimated the cost of direct to implant reconstruction with ADM to be \$5,423.02 versus \$10,934 for the traditional non-ADM two-stage technique. This finding makes suggests that algorithms should include surgical technique, such as direct-to-implant, as a relevant factor in deciding ADM appropriateness.

Of course, not every patient is a candidate for a single-stage breast reconstruction, and the more challenging question is whether ADM use in two-stage techniques is still economically sound compared to similar non-ADM two-stage techniques. As an example of the divergent views in the existing literature, de Blacam *et al.*'s analysis (69) reported that ADM use in two-stage reconstructions cost \$11,255, compared to \$10,934 for a similar non-ADM option; Krishnan *et al.* arrived at a similar result, estimating a \$362 cost increase when ADM is used. Both of these reported price differences could be described as negligible. In contrast, Bank *et al.* (73) found a \$3,047 increase when ADM was used in two-stage reconstruction, nearly ten times greater than de Blacam's or Krishnan's estimation. Some authors have also argued that alternatives to ADM such as dermal allografts provide the same benefits at a reduced price (74-76).

There are many variables that may help or harm the cost-effectiveness of ADM in two-stage reconstruction. ADM use in tissue-expander surgery can cut the number of post-operative expansion visits required because larger intraoperative fill volumes can be attained; in that respect,

they have a cost-saving advantage versus a similar non-ADM-assisted technique (71-73). Specifically Bank *et al.* (73) argued that the cost of breast reconstruction rises in part due to the number of expansion visits needed, and that ADM use in large breasts (over 500 mL) was particularly effective at reducing costs. This analysis seems to support the inclusion of breast size in an ADM-use algorithm, as previously discussed, large breasts also come with countervailing effects that may warrant a delayed reconstruction in such breasts instead (*Table 1*). But likely the source of uncertainty in the costs of ADM use is driven by its aforementioned variance in reported complication rates (69,77). If ADM's complication rates are and severities are truly high, the overall cost of using them will obviously increase. Thus, an algorithm whose rational selection of ADM use can successfully reduce complication rates will likely improve the cost-effectiveness of ADM.

Despite these differences and uncertainties, Bank *et al.* and Krishnan *et al.* both have suggested that in reality, material costs are the largest factor driving ADM cost-utility analyses (73,75). Presently the market price of a 6 cm × 16 cm sheet of ADM is approximately \$3,100. With these assumptions, we reported that our algorithm could save on material costs by \$150,000 over a year of 100 prosthetic breast reconstructions, given that our algorithm reduced ADM use from 84% to 36% (36). If material costs truly represent the majority of the economic burden of ADM-use in breast reconstruction, an algorithm that can be more selective in choosing patients for whom to use ADM would represent a substantial improvement in cost-effective surgical practice.

Aesthetic outcomes and complication rates

ADM used in breast reconstruction effectively acts as a supporting hammock for the prosthetic in order to recreate natural breast morphology (47), and many authors have supported claims that it produces better aesthetic outcomes. Vardanian *et al.* (11) showed ADM can improve the surgeon's control over and definition of the inframammary fold, boosting aesthetic outcomes. Nguyen *et al.* (78) comparably demonstrated improved breast mound volume, breast mound placement, and inframammary fold definition with the use of ADM compared to non-ADM-assisted reconstructions. More recently, Forsberg *et al.* (26) found that ADM resulted in better aesthetic scores in the naturalness of the contour, the symmetry of shape and size, the position on the chest wall, and the overall aesthetic of the reconstructed breast. With all of the positive reports,

it is natural to suppose that a mature, honed algorithm can improve reconstruction aesthetic outcomes if it is able to accurately select patients that will benefit most from ADM.

Likewise, such an algorithm can reduce complication rates by allowing surgeons to judiciously decide whether ADM is appropriate given a particular patient's individual factors. Peled *et al.* was able to lower complication rates using their basic ADM algorithm for TSSM reconstructions (50), which is an encouraging finding for those interested in further developing more complex algorithms.

The challenge, of course, is developing and refining the right algorithm. For any of these promises to be realized, much greater effort must be applied toward the development and assessment of sophisticated algorithms—ones that account for the many factors the field has identified as indications and contraindications. Furthermore, long-term outcomes such as capsular contracture, as well as detailed aesthetic outcomes, have been insufficiently assessed in ADM algorithms including our own. In order to discover what parameters the surgeon can leverage to make good ADM decisions, researchers must be prepared to conduct long-term studies to assess complications, as well as test for aesthetic end-points in sophisticated manners.

Finally, we wish to stress that it is not our intention to lock surgical decision-making into a rigid decision-making protocol. Obviously, the clinical experiences of different surgical practices may conflict with our algorithm. Furthermore, many situations cannot be perfectly captured by an uncompromising decision algorithm; additional judgment extending past our simple algorithm must also contribute to the decisions in such cases. Rather, the purpose of this algorithm is to stimulate a shift away from the previously indiscriminate use of ADM in breast reconstruction, and encourage discussion about rational selection criteria for patients who would most benefit from ADM.

Conclusions

Surgical decision-making with ADM in primary prosthetic breast reconstruction continues to evolve. We have reviewed some important indications and contraindications for the use of ADM, as well as the few algorithms that have been thus far proposed to assist in the decision of whether ADM is appropriate. This approach can reduce costs and improve aesthetic outcomes and complication rates. We encourage plastics practices to further develop and evaluate their own decision-making tools for ADM use.

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