Review Article

Acellular dermal matrices in breast reconstruction: a narrative review and institutional perspective

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Abstract: Breast reconstruction after mastectomy is commonly undertaken in patients inappropriate for breast conserving surgery, women who are at high genetic risk for breast cancer or otherwise based on patient preference. Current breast reconstruction techniques are diverse and may involve the use of an autologous tissue flap, tissue expanders or definitive implants. Regardless of the technique used, the use of acellular dermal matrices (ADMs) has become increasingly prevalent. The increased uptake of ADMs has led to a paradigm shift in breast reconstruction. This has led to a proliferation of new products and materially contributed to increased rates of pre-pectoral reconstruction. Single-stage and two-stage breast reconstruction remain a contentious issue with increasing evidence justifying direct-to-implant reconstruction in well selected patients with ADMs. ADMs are able to provide solutions to a multitude of issues surrounding inadequate tissue coverage and support, such as implant rippling, implant migration and capsular contracture. This review outlines an overview of the history of ADMs, commonly used ADMs and addresses the evidence with respect to known complications of ADMs. A number of product alternatives to ADMs are explored and an analysis of materials and characteristics are also provided. Notwithstanding cheaper costs of manufacturing these products may offer comparable outcomes. Ultimately this narrative review provides an institutional insight into breast reconstruction in a high volume Australian centre routinely employing ADMs. Important adjuncts such as indocyanine green angiography (ICGA) and negative pressure wound therapy (NPWT) have enhanced outcomes in our practice facilitating the identification of patients likely to benefit from staged expander based reconstruction.

Keywords: Acellular dermal matrices (ADMs); breast reconstruction; indocyanine green (ICG); negative pressure wound therapy (NPWT)

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Introduction

Acellular dermal matrices (ADMs) are now a cornerstone in breast reconstructive surgery with increasing uptake in the last 2 decades. First used in 1995 for the management of full thickness burns (1), they are now used for a myriad of soft tissue reconstructive purposes including abdominal hernia repair, rhinoplasty, dural repair, lip augmentation and oculofacial procedures (2). Anecdotally ADMs were first used in breast reconstruction by Salzberg *et al*. in 2001 with the first published use in 2005, by Breuing and Warren (3). These initial techniques involved creation of an inferolateral sling anchoring the pectoralis major muscle to the rectus abdominis fascia inferiorly and serratus anterior

fascia laterally. The ensuing ADM hammock provided lower pole support, allowed precise control of lower pole fullness and minimized the need for expansion of the submuscular pocket.

Prior to the use of ADMs, breast reconstruction necessitated the creation of a submuscular pocket that provided complete muscular coverage for a tissue expander. The subsequent expansion and exchange to a definitive implant then carried disadvantages of animation deformity, multiple operations, patient discomfort and infection risk. The advent of ADMs however, have allowed for a return to pre-pectoral reconstruction, initially popularized in the 1970s. This narrative review therein explores the role of ADMs generally with a focus on its usage in pre-pectoral reconstruction at one institution.

The additional tissue support from ADM minimizes prosthesis migration and precise fashioning allows for an individually tailored pre-pectoral pocket. The putative benefits of ADMs include increased definition of the infra-mammary fold, decreased post-operative pain, reduced capsular contracture, improved cosmesis, improved lower pole expansion and a scope for faster and fewer expansions (4-7). It does however remain unclear how particular ADMs offer the greatest benefit with respect to the aforementioned domains. This review explores this question with reference to individual ADM characteristics. We present the following article in accordance with the Narrative Review reporting checklist (available at http://dx.doi.org/10.21037/abs-20-68).

In the setting of their known advantages, ADMs are now incorporated in up to 60% of all alloplastic reconstructions in the United States (2) and 75% of implant based reconstructions in the UK (8).

Types & composition of ADM

ADMs are decellularized extracellular dermal matrices derived from human, bovine or porcine tissues. They are comprised of collagen, elastin, hyaluronic acid and proteoglycans which form a scaffold for a process of re-integration involving fibroblast proliferation, neovascularization and repopulation by host cells. ADMs are devoid of antigenic epitopes that would otherwise stimulate a host mediated inflammatory response or rejection and form an ideal medium for soft tissue reinforcement.

Matrices vary in both design and commercial preparation and are generally available in pre-formed sheets. Methods of storage vary between pre-wetted, freeze dried or 'ready to use' however are not known to have an impact on complication rates (9). Overall, the increased utilization of ADMs has fostered the development of multiple products of which we will review the most common.

Veritas

Veritas (Synovis Life Technologies, Inc., St. Paul, MN) is a collagen matrix xenograft derived from the bovine pericardium of cattle less than 30 months of age. It is manufactured by a proprietary chemical process that involves decellularization and exposure to sodium hydroxide solution to eliminate bovine spongiform encephalopathy transmission. The subsequent step comprises treatment with polypropylene oxide that caps free amine groups resulting in immunological stability of tissues (10). Finally Veritas is terminally sterilised by electron beam irradiation.

Veritas does not require rehydration before use and has a reported tensile strength per unit time in Yucatan minipigs during uniaxial testing of 29.9 N/cm with a maximum load sustained at 89.6 N and a stiffness of 10.0 N/mm (11). It is a thinner product compared to the majority of ADMs with histological studies demonstrating a superior capacity for host revascularization at 1, 6 and 12 months (12). It has a lower reported elastin content (2.98%) compared to most ADMs (5–7%) and therefore exhibits less stiffness and undergoes less deformation over time (13). These properties make Veritas ideally suited to prevent window shading of pectoralis major during expansion when used as a dermal sling.

FlexHD

FlexHD (MTF/Ethicon, Inc., Somerville, NJ) is an acellular hydrated dermis derived from cadaveric human allograft skin. The tissue is minimally processed to remove epidermis and dermis while maintaining the extra-cellular matrix. This involves a 2-step decellularization initially utilizing hypertonic saline with the ensuing plasmolysis facilitating disruption of cells and DNA. The second stage employs Triton X-100, a non-ionic surfactant, comprising a hydrophilic polyethylene oxide chain that further disrupts cell membranes and reduces cellular debris. The subsequent sterilization of the product involves treatment with peracetic acid which oxidizes and eliminates microbial contaminants. An aseptic packaging process is employed involving treatment with 70% ethanol, with the final product delivered pre-hydrated in a ready to use fashion

without the need for refrigeration.

FlexHD displays remarkable tensile strength (15.7 Mpa) making it suitable for hernia repair as well as breast reconstruction (14). Orenstein *et al.* demonstrated that FlexHD induced a greater activation of monocytes and macrophages *in vitro*, compared to AlloDerm and that it also induced significantly more interleukin-1 beta. The implication therefore was that FlexHD may induce greater inflammation (15). However Sobti *et al*. in a subsequent review of 233 patients undergoing matrix-based reconstruction, demonstrated no statistically significant differences in all endpoints comparing FlexHD to Alloderm in domains of seroma, haematoma, explantation and delayed wound healing (16).

Uniquely 'FlexHD Pliable' yields no sidedness. This ADM, derived from a deeper cut in the reticular dermis has similar porosity for tissue ingrowth on either side of the matrix. Critically this minimizes any error in orientation of the ADM.

Our practice has been to fashion a single FlexHD sheet or suture two sheets together with V-Loc^{TM}, a barbed unidirectional absorbable suture. The technique of the senior author has been to secure the lower medial corner of the ADM at the level of the inframammary fold with V-Loc^{TM}, suturing the medial aspect, superior aspect and lateral aspect of the ADM sequentially. This allows for both excess ADM to be trimmed away laterally as well as accurate control of the lateral pocket along the lateral border of pectoralis major. An appropriately sized tissue expander can then be inserted inferiorly with a second v-loc suture utilized to secure the inferior aspect of the ADM. The sizes of flexHD we commonly utilize include 6×12 cm, 8×16 cm and 16×20 cm. A tailored approach to the amount of flexHD used, ensures preservation of arc length in addition to pocket width and height in the pre-pectoral plane. Furthermore by tucking excess ADM under the expander device, the 'bottoming out' phenomenon can be mitigated. Commonly the senior author will employ an internal bra stitch utilizing V-Loc^{TM} to further prevent the descent of the infra-mammary fold. Finally an infra-mammary hitching stitch utilizing 3-0 PDS is employed to further elucidate the infra-mammary fold, after the ADM is secured.

Strattice

Strattice Reconstructive Tissue Matrix (LifeCell Corp., Branchburg, NJ) is a sheet of sterile tissue derived from porcine dermis denuded of antigenic cells. Preparation involves removal of the epidermis with sodium chloride and Triton X-100, decellularization with sodium deoxycholate and enzymatic degradation of deoxyribonucleic acid (DNA). The proprietary process causes a marked reduction in 1,3-alpha-galactose epitope, a major component of the xenogenic rejection response. It does not require rehydration and during uniaxial testing of tensile strength in Yucatan minipigs, Strattice demonstrates a strength of 128.4 N/cm and sustained a maximum load of 385.1 N. Strattice being a thick and strong xenograft material, is also available in large sheets potentially minimizing wound dehiscence complications (17,18).

Alloderm

Alloderm Regenerative Tissue Matrix (LifeCell Corp., Branchburg, NJ) is produced by a multi-step proprietary process that removes the epidermis from human cadaveric skin. Decellularization is achieved via treatment with both sodium hydroxide and sodium deoxycholate prior to freeze drying. The resultant acellular matrix has reduced antigenicity, however does require a process of rehydration for a minimum of five minutes in warm saline or lactated ringer solution.

Alloderm during uniaxial testing of tensile strength in Yucatan minipigs, demonstrates a strength of 84.3 N/cm with a maximum load of 253.0 N. As one of the pioneering ADMs in breast reconstruction, there is a significant body of evidence supporting its use. In a systematic review, Jansen *et al.* outlined key benefits including shorter operative times, improved inframammary fold definition and decreased post-operative pain (19). Alloderm is not terminally sterile and considered aseptic. A sterile version Alloderm RTU (Ready To Use) was released in 2011 but is less well studied. Jones *et al.* in a series of 73, described a 98% success rate at 8 weeks for pre-pectoral direct to implant reconstruction using Alloderm.

ADM complications

Despite increasing traction as a useful adjunct in breast reconstruction, concerns still exist regarding the potentially increased risk of complications associated with ADM use. In 2012, two systematic reviews identified that ADM-assisted breast reconstructions were associated with increased skin flap necrosis, seroma formation, infection and reconstructive failure (20,21). Other reviews have

reported no increased risk of complications associated with ADMs (22-24). Disparate results have been attributed to heterogeneous patient characteristics with considerable differences in comorbidities, breast size and BMI between ADM and non-ADM groups in prior studies, despite large study populations.

Ibrahim *et al.* performed the largest multi-institutional database review in 2013 analyzing 19,100 reconstructive cases from the National Surgical Quality Improvement Program (NSQIP) database, comparing ADM and non-ADM reconstruction. There was no statistically significant difference in the rate of overall complications between the groups (ADM: 5.3%, non-ADM: 4.9%, P=0.396) with no statistically significant difference in baseline comorbidities between the groups (25).

Red breast syndrome (RBS) is a rare but notable complication associated with ADM. The incidence varies between 0% and 10% (26). RBS presents with breast erythema without systemic features of infection such as fever or leukocytosis. Although the exact aetiology remains elusive, proposed mechanisms include a type IV delayed hypersensitivity reaction, foreign body reaction, lymphatic obstruction and hyperaemia secondary to neovascularization (27).

Capsular contracture is a known complication of reconstructive breast surgery associated with subjective pain and firmness of the implant capsule. Multiple studies now demonstrate that the rate of capsular contracture in patients receiving post mastectomy radiotherapy, is superior in those reconstructions involving ADMs (28,29). ADMs lack live connective tissue components including fibroblasts. As a result capsular fibroproliferative disorder associated with radiation induced capsular contracture may be less prominent.

Biologic *vs.* synthetic meshes

There is currently no consensus on whether synthetic meshes or biologic matrices afford the best outcomes in breast reconstruction. The majority of the literature has focused on ADM based reconstruction with recent studies now investigating the use of low cost synthetic meshes. These include vicryl mesh, long term absorbable meshes such as TIGR® and non-absorbable meshes such as the titanium coated polypropylene mesh TiLOOP®.

Vicryl meshes are widely available and resistant to bacterial biofilm formation, however are rapidly reabsorbed, limiting their structural advantage in the long term. TIGR® matrix is a completely synthetic mesh comprised of two fibres with different degradation characteristics. This allows it to become increasingly mechanically compliant over its integration phase (30). TiLOOP® mesh in contrast is a non-absorbable lightweight polypropylene mesh with a monofilament structure. Titanium covalently bonded to the plastic's surface facilitates lower inflammation, less scarring and less shrinkage of mesh over time. This mesh has the advantage of distribution in preformed pockets designed for use in the pre-pectoral plane without the need for intra-operative adaption of the mesh.

The aforementioned characteristics of synthetic meshes may confer unique advantages aside from being cost effective. Importantly however, there are no well conducted randomized trials comparing synthetic and biologic meshes with true differences in key domains such as infection, seroma, flap necrosis and implant loss not being known.

Indocyanine green technology

Mastectomy skin flap ischemia and necrosis is a serious consequence of breast reconstruction with a reported incidence of 5% to 30% in the literature (31). A key element to achieving a successful pre-pectoral reconstruction is adequacy of mastectomy flap perfusion. Operatively this is preserved by careful adherence to the plane of dissection in order to maximise the subdermal fat and its associated vasculature on the mastectomy flap. Flap thickness however varies between patients based on age, racial background and other variables. Traditionally intra-operative assessment of perfusion has been reliant on clinical appraisal of temperature, colour, capillary refill, turgor and bleeding. Clinical assessment however, lacks sensitivity and specificity for flap necrosis. The authors therein advocate the use of SPY Elite technology (SPY Elite system, Novadaq Technologies, Kalamazoo, Mich.) utilizing indocyanine green (ICG) angiography as a method of intra-operative tissue perfusion assessment. The ICG dye is a safe fluorescent agent that binds strongly to plasma proteins and when excited by an 805 nm laser, emits fluorescence which is captured by a near infra-red camera to provide a real time assessment of skin perfusion. This method of laser assisted fluorescence angiography minimizes perfusion related complications including skin necrosis, delayed wound healing, wound dehiscence, infection and implant extrusion.

The senior author pioneered the use of SPY technology in breast reconstruction in Australia. It is employed as a matter of course for all skin and nipple sparing

mastectomies whereby a staged reconstruction is performed in 1 week if perfusion is significantly compromised. This allows time for the skin flaps to develop robust perfusion which is re-assessed prior to expander insertion. In a recent series, the authors have demonstrated that the ADM being a biologic is reliant on re-integration into the skin flap which is a function of blood supply. It is for this reason SPY technology is highly complementary in ADM assisted breast reconstruction (*Video 1*).

Negative pressure wound therapy (NPWT)

The use of NPWT on a variety of wounds has been broadly increasing over the last 3 decades. Webster demonstrated that NPWT compared to conventional dressings reduces surgical site infection (SSI) (RR 0.67; 95% CI, 0.53 to 0.85) but did not reach statistical significance with respect to seroma, haematoma and wound dehiscence rates (32). Broadly speaking, the available randomized trials exhibit significant heterogeneity with respect to types of wounds as well as primary endpoints making results difficult to generalize.

Conceptually the generation of negative pressure leads to excess fluid removal, oedema reduction, increased dermal perfusion and reduced bacterial contamination (33). It is in this context that the authors advocate the use of PICO (Smith and Nephew Healthcare, Hull, United Kingdom) single use NPWT. Strugala demonstrated a reduction in SSI (RR 0.43; 95% CI, 0.32–0.57; P<0.0001 with NPWT) and wound dehiscence (RR 0.71; 95% CI, 0.54–0.92; P<0.01) with the use of PICO. The experience of the unit has been to have good outcomes when used in concert with rigorous patient education around the product with a breast care nurse.

Single- versus two-stage reconstruction

Immediate post mastectomy reconstruction can either be performed in a direct-to-implant or expander-based fashion. The authors prefer the latter approach with a second stage expander to implant exchange performed following completion of adjuvant therapies. The key advantages include the opportunity to revise the position of the infra-mammary and lateral mammary fold, perform a capsulorrhaphy, select an optimal implant, perform contralateral symmetrization post radiotherapy and have the assurance of clear margins prior to definitive reconstruction. The second stage also avails the opportunity to perform lipofilling with tissue expander *in situ* prior to implant exchange.

Importantly, from the patient viewpoint, studies of single stage versus two stage ADM based breast reconstruction have yielded no difference in domains of physical wellbeing, psychosocial wellbeing, sexual wellbeing and outcome satisfaction (34).

Lee *et al.* demonstrated a significantly higher risk for reconstruction failure (RR 1.54, 95% CI, 1.08 to 2.19) and overall complications in the single-stage versus the two-stage group (35).

Direct to implant reconstruction has however been gaining traction recently due to improved techniques, ADM use and improved patient selection. Importantly these recent series have not integrated objective flap perfusion assessment such as SPY which underpins our ability to estimate ADM reintegration and success of reconstruction.

Conclusion & future directions

The evidence base for ADMs lies mostly in retrospective case series and non-randomized studies with a small preponderance of randomized trials. Although copious data exists to support the use of ADMs, recent reviews suggest a need for additional level 1 evidence to establish the merits of one ADM compared to another. Despite this, the senior author's experience with the combination of SPY technology to evaluate flap perfusion, NPWT and the two-stage reconstructive approach with ADM has yielded sustained reliable results over many years.

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