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A direct comparison of porcine (Strattice™) and bovine (Surgimend™) acellular dermal matrices in implant-based immediate breast reconstruction☆

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Summary *Introduction:* Acellular dermal matrix (ADM) assisted implant-based breast reconstruction (IBBR) has grown in popularity over traditional submuscular techniques. Numerous human, bovine or porcine derived ADMs are available with the type used varying considerably worldwide. Yet, comparative evidence for the efficacy of different ADMs particularly xenogenic is limited. This study directly compares early outcomes of porcine (Strattice™) and bovine (Surgimend™) ADMs in IBBR.

Method: Retrospective study of sequential experience of immediate IBBR using Strattice or Surgimend ADM. Data was collected for patients undergoing ADM assisted IBBR after prophylactic or therapeutic mastectomy in Cambridge (October 2011–March 2016). Patient demographics, adjuvant and neoadjuvant therapies, operative details, postoperative management and outcomes were analysed.

Key results: Total of 81 patients underwent IBBR with ADM; 38 bilateral and 43 unilateral (n = 119 breasts). Strattice was used in 30 breasts (25%) and Surgimend in 89 (75%). Analysis of patient specific variables showed statistical significance only for higher mastectomy weight in the Strattice group (367.1 ± 159.3 g versus 296.3 ± 133.4 g; $P = 0.0379$). Strattice was

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associated with higher rates of skin erythema post-operatively (16.7% versus 4.5%; $P = 0.044$). Analysed per woman or per breast, there was no statistically significant difference in rates of haematoma, infection, wound dehiscence, skin necrosis or seroma, although there was a trend towards more complications with Strattice.

Conclusion: This study found significantly higher rates of skin erythema and a trend towards higher complication rates with Strattice in IBBR. Randomised controlled trials comparing different ADM outcomes are needed to inform best practice.

Introduction

Immediate breast reconstruction with fixed volume or tissue expander implants has become increasingly popular, so much so that in many countries including the UK, it is the most common reconstructive technique post-mastectomy.[1] Incorporating the use of an acellular dermal matrix (ADM) with this technique has become favourable with a number of reported benefits. ADM provides coverage of the implant inferiorly giving an additional layer over the lower pole in patients with little or poor soft tissue. It enhances lower pole expansion facilitating single-stage surgery, greater initial expander implant fill volumes and allowing for reconstruction in patients with larger breasts thus widening the pool of patients who are suitable for implant-based breast reconstruction (IBBR). Aesthetically, ADM-assisted breast reconstruction has been reported to give superior outcomes in comparison with traditional subpectoral implant placement by improving the contour of the lower pole and inframammary fold definition.[2] In comparison with flap based reconstruction, IBBR with ADM has a shorter operative and recovery time, and lower morbidity by eliminating the need for a donor site and attendant scars.[3]

ADMs however have drawbacks: they are expensive and there is controversy with reports of associated increased risk of complications including surgical site infection, skin flap necrosis, seroma formation and reconstructive failure.[4–6] A frequent complication termed 'red breast syndrome' is thought to be a delayed hypersensitivity reaction of the skin overlying the ADM (to the ADM or its preservative) that mimics a post-operative cellulitis. ADMs are not a panacea and patient selection is very important as demonstrated by reports of higher complication rates associated with mastectomy weights of >600 g (large breasts), BMI >30 (clinical obesity), smoking and simultaneous axillary clearance.[4,7–9]

There are an increasing number of ADMs available on the market today and selecting the optimum matrix remains difficult. There is great variation in the components, decellularisation and sterilisation processes that impact on matrix properties and host-implant response characteristics.[10] Additionally, storage requirements, preparation and cost vary significantly. Perhaps, as human derived ADM has been shown to be inferior in hernia repair due to comparatively higher rate of unfavourable outcomes,[11] it may be illogical to expect in breast reconstruction that all ADMs are equal. Appraising the literature, the most extensively investigated ADM in breast reconstruction is the human derived AlloDerm® (Acelity™ San Antonio, Texas, United States (US)) that is commonly used in the US but has not yet received a CE mark for use in Europe. Subsequently, there is a lack of data comparing outcomes and safety with the use of other ADMs particularly xenogeneic.

Strattice™ (Lifecell, Branchburg, NJ, US) and Surgimend™ (TEI Biosciences; Boston, MA, US) are xenogeneic ADMs, derived from porcine and bovine foetal or neonatal dermis respectively. Both non-cross linked matrices reinforce soft tissue and are a framework for cellular re-population and neovascularisation. Strattice became commercially available in the EU and US in 2008 and has been widely used in breast reconstruction and abdominal wall repair. It is terminally sterilised by electron beam irradiation and decellularized to remove precipitants thought to trigger a xenogeneic rejection response.[12] It is preserved in a phosphate buffered aqueous solution containing matrix stabilisers and in accordance with manufacturer's instructions can be stored at room temperature. Prior to use it requires washing in saline at room temperature for at least 2 minutes[13] but in our practice this was done for longer.

Surgimend has been widely used in hernia repair, muscle flap reinforcement, plastic and reconstructive surgery. It is a non-cross linked matrix of type I and II collagen terminally sterilised with ethylene oxide and free from preservatives including polysorbate 20, thought to be a possible irritant or allergen in some patients. The manufacturer instructs that it can be stored at room temperature and requires rehydration for 1–2 minutes prior to use[14] but again in our practice this was done for longer.

A study by Adelman et al. compared the mechanical properties of both ADMs using a series of in vitro pre-implantation biomechanical tests. They found Surgimend had increased mechanical strength compared with Strattice of equal thickness but further studies are needed to investigate how this transpires in vivo and into clinical outcome.[15]

The aim of this study was to undertake a direct comparison of the sequential use of Strattice and Surgimend ADM in IBBR focussing on short-term outcomes.

Methods

A retrospective analysis of consecutive cases of ADM-assisted immediate IBBR performed in Cambridge