A Direct Comparison of Porcine (*Strattice*™) and Bovine (*Surgimend*™) Acellular Dermal Matrices in Implant-Based Immediate Breast Reconstruction

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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 (StratticeTM) and bovine (SurgimendTM) 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 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 grams versus 296.3 ± 133.4 grams; *p =* 0.0379). Strattice was 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.

***Key words*** Acellular dermal matrix; Strattice; Surgimend; Implant; Breast reconstruction

***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]](#endnote-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]](#endnote-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]](#endnote-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]](#endnote-4),[[5]](#endnote-5),[[6]](#endnote-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 > 600g (large breasts), BMI >30 (clinical obesity), smoking and simultaneous axillary clearance3,[[7]](#endnote-7),[[8]](#endnote-8),[[9]](#endnote-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, de-cellularisation and sterilisation processes that impact on matrix properties and host-implant response characteristics[[10]](#endnote-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]](#endnote-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® (AcelityTM San Antonio, Texas, United States (US)) that is commonly used in the US but does not have CE marking for use in Europe. Subsequently, there is a lack of data comparing outcomes and safety with the use of other ADMs particularly xenogeneic.

StratticeTM (Lifecell, Branchburg, NJ, US) and SurgimendTM (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 decellularised to remove precipitants thought to trigger a xenogeneic rejection response[[12]](#endnote-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]](#endnote-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]](#endnote-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]](#endnote-15).

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

***Methods***

A retrospective analysis of consecutive cases of ADM-assisted immediate IBBR performed in Cambridge between October 2011 and March 2016 was undertaken. Strattice was used in all cases until October 2014 when due to anecdotal concerns about outcomes there was a wholesale departmental move to using Surgimend.

*Patient selection:*

Patients who underwent immediate IBBR by one of the three plastic surgeons in the group following oncological or prophylactic mastectomy were identified using hospital operative logbooks, implant diaries and patient clinical records. Patient demographics were collected including age at the time of surgery, body mass index, smoking status, co-morbidities (ASA grade), neo adjuvant/adjuvant chemotherapy and radiotherapy. Smokers were classified as those who were currently or had been smoking up to 3 months prior to surgery. For data analysis, each breast was recorded as a separate procedure in patients who had undergone bilateral reconstruction.

*Endpoints:*

A minimum of 3 months’ follow up from the date of surgery was attained for each patient. Clinical records were reviewed and data collected on rates of erythema or ‘red breast syndrome’, skin necrosis, infection, seroma formation, haematoma and return to theatre for revision surgery. In the latter, it was specified whether the implant was removed and if replaced at the time of that surgery.

There was overlap in the clinical picture between skin erythema or ‘red breast syndrome’ and infection. Those with skin erythema were often given a course of oral antibiotics due to patient and surgeon anxiety regarding infection near the underlying implant. However, from the clinical course we could determine those who had simple skin erythema.

Breast and axillary seromas were differentiated; the latter were not included as they were considered to be secondary to any axillary surgery rather than the breast reconstruction.

*Surgery:*

Mastectomies were performed by an oncological breast surgeon and then immediate reconstruction by one of three breast reconstructive plastic surgeons. A standard surgical technique was followed where pectoralis major is mobilised or freed inferomedially. The implant is washed with aqueous iodine solution. Following preparation, the ADM is sutured along the inframammary fold and secured to the infero-lateral free border of the pectoralis major with an absorbable suture.

Each reconstructed breast has two suction drains inserted (subcutaneously and subpectorally). These are removed when the output is less than 30-40mls over 24 hours and always prior to discharge from hospital. Patients receive antibiotic (co-amoxiclav unless penicillin allergy) intravenously until at least 48 hours after all drains are removed.

***Results***

*Patient demographics:*

Of 81 women included in this study, 38 had bilateral reconstruction and 43 had unilateral (119 reconstructed breasts). Strattice was used in 19 women (25%, 30 breasts) and Surgimend in 62 women (75%, 89 breasts). Strattice was initially used for one patient in October 2011, then in 18 women from April 2013 to April 2014. A business case was accepted by out NHS trust in 2013 which enabled ADM reconstructions to be offered as our routine practice. Surgimend was used from March 2014 to date, but data collection was performed up to February 2016. Follow up duration was calculated from surgery to the last clinical encounter and was obtained in 61 women (75%). The mean follow up was 432 days (range 83 to 945 days). Calculated by group this was 701 days for Strattice and 380 days for Surgimend.

A summary of the data of patient specific variables is displayed in **Table 1.** The mean age of women in this study was 45 years and there was no statistical difference between age in the Strattice group (range 26 to 67 years; 44 ± 11.3 years) versus the Surgimend group (range 24 to 70 years; 46.9 ±11.2 years) (*P* 0.326). Analysis of BMI, mastectomy (breast) weight, smoking status, ASA grade, and oncological treatment with chemotherapy and/or radiotherapy demonstrated only significantly significant difference for higher mastectomy breast weight in the Strattice group. This was 367.1 ± 159.3 grams and in the Surgimend group 296.3 ± 133.4 grams (*P* 0.0379).

*Indication and Surgery:*

Oncological treatment was the most common indication in both groups accounting for surgery in 68 women (85%); 13 in the Strattice group (68%) and 55 in the Surgimend group (89%) (*P* 0.067). Of these 68 women, 13 had a risk reducing contralateral mastectomy for BRCA 1 or BRCA 2 gene positivity or high risk of contralateral disease. The remaining 13 women had prophylactic bilateral mastectomies; 12 for BRCA 1 or BRCA 2 gene positivity and one for a strong oncological family history.

Axillary surgery with either sentinel lymph node biopsy or axillary node clearance was performed at the time of mastectomy in 58 women; 13 women (68.4%) in the Strattice group and 44 women (71%) in the Surgimend group (*P* 1.0).

*Post-operative outcomes:*

Complications are classified into immediate prior to discharge and late after discharge, necessitating readmission to hospital and those requiring return to theatre. There was one inpatient complication of a breast haematoma that required a return to theatre 2 days after reconstruction. There were 13 hospital readmissions for treatment of a complication (10.9%), including one patient who required two readmissions. Of these three breasts were reconstructions with Strattice (10%) and ten were with Surgimend (11%). There were eight breast complications that required a return to theatre for revisional surgery (6.7%); two were reconstructions with Strattice (6.7%) and six with Surgimend (6.7%). Of these, in two breasts the implant was removed without replacement at that time (1.7%), both were reconstructions with Surgimend.

There were 12 breast infections (10%) of which three were reconstructions with Strattice and nine with Surgimend. Of these, six had minor infection successfully treated with oral antibiotics as outpatients and six required admission for intravenous antibiotic therapy. Only one patient, who presented with a delayed infection 3 months after reconstruction with Surgimend, required return to theatre. The implant in the reconstructed breast and an augmentation implant in the other breast were removed and at a subsequently date salvage late reconstruction and balancing surgery with a deep inferior epigastric perforator (DIEP) flap was performed.

There were three breast haematomas (2.5%); two in breasts reconstructed with Strattice and one with Surgimend. One case was an inpatient and two required re-admission. All necessitated return to theatre for evacuation of haematoma and the implant was salvaged.

There were four cases of breast skin necrosis (3.4%) of which two were minor and successfully managed conservatively, and two required hospital admission for revisional surgery. One patient who had undergone a prophylactic nipple sparing mastectomy with Surgimend reconstruction, developed breast flap necrosis requiring return to theatre 19 days after the initial reconstruction for debridement to prevent implant loss. The other patient who had undergone a completion mastectomy with periareolar incision and reconstruction with Surgimend, was a previous smoker noted to have poor skin quality. They developed protrusion of the implant through thin mastectomy flap causing skin compromise and required revisional surgery 13 months after reconstruction for debridement and removal of the implant without replacement.

Dehiscence of the wound occurred in three breasts (2.5%), of which two were reconstruction with Surgimend and one with Strattice. The latter was minor dehiscence that was managed conservatively. Of the other two cases, one required admission 2 months after reconstruction for debridement in theatre and treatment with a gentamicin irrigation system. The remaining patient was admitted 5 weeks’ post reconstruction and returned to theatre for debridement with removal of the implant and simultaneous replacement.

Seven women (8.6%) developed a clinically detectable breast seroma of which five required one or more aspiration as outpatients. Eight (9.9%) women had breast skin erythema thought to be ADM related. Three were given prophylactic oral antibiotic cover due to anxiety in the context of an underlying implant. All were treated conservatively not requiring any other intervention.

The only statistically significant difference in post-operative complications between the Strattice and Surgimend groups was breast skin erythema (16.7% versus 4.5% respectively) when analysed per breast (*P* 0.044). There was no statistical difference between the rates of haematoma, wound infection, skin necrosis, wound dehiscence and seroma formation either when analysed per woman or per breast. See **Table 2** for comparison of outcomes.

***Discussion***

This study has sought to directly examine the early postoperative outcomes of porcine (Strattice) versus bovine (Surgimend) ADMs in IBBR to expand upon the comparative evidence in the literature for different ADMs, particularly xenogeneic. With the widespread use of ADMs, this is important to inform the surgeon in choosing the appropriate ADM for their patient by evolving our understanding of the product characteristics and safety profile.

This study comprised of 81 women (119 breasts) who had immediate IBBR with ADM. Analysis of patient specific variables showed no statistically significant difference between the two ADM groups, except for increased mean mastectomy weight in the Strattice group (367.1 ± 159.3 versus 296.3 ± 133.4 grams; p=0.0379). Mastectomy weight of 600g or more is a known risk factor for complications. Despite the increased mean breast weight in the Strattice group, of 30 breasts only two mastectomies were over 600g (601g and 779 g). There was no statistically significant difference in age, BMI, smoking status and neoadjuvant or adjuvant treatment with chemotherapy or radiotherapy between the two ADM groups.

There has been no other head to head study of Strattice versus Surgimend in the literature to compare our findings with, only reports of experience with one ADM or as a comparison with the human derived ADMs AlloDerm and Epiflex (Deutsches Institut fur Zell- und Gewebeersatz gGmdH, Berlin, Germany)16,17,18,19,20. In our study postoperative outcomes of haematoma, infection, soft tissue breakdown, seroma and skin erythema have been reported per women and breast to facilitate comparison with this literature. Yet recognisably, in cases of bilateral reconstruction, each breast was subject to the same patient specific conditions and thus were not independent entities.

As anticipated, mean length of follow up in the Strattice group was longer than in the Surgimend group (701 days versus 380 days) because our use of Strattice pre-dated Surgimend (Strattice; October 2011 to April 2014, Surgimend; March 2014 to February 2016). Despite this, the length of follow up for both groups is ample to capture the important early postoperative complications in question and thus we are confident it has not influenced outcome figures.

Of the outcomes analysed statistical significance was demonstrated for increased skin erythema in the Strattice group when analysed per breast (16.7% versus 4.5%). Dikmans et al in a study of 110 breasts reconstructed with Strattice reported comparable skin erythema rates of 14.5%16. Skin erythema or ‘red breast syndrome’ is well reported with ADM use and although the exact aetiology is uncertain, a delayed hypersensitivity reaction overlying the ADM has been postulated. Although self-limiting and requiring only conservative management, it is a significant complication nonetheless that can cause anxiety both for the patient and clinician concerning infection and as in our cohort, can result in cautious management with prophylactic antibiotics.

A higher seroma rate was observed in our Strattice group (10% versus 4.5%) although not statistically significant. Dikmans et al found seroma was the commonest complication associated with reconstruction with Strattice and reported an even higher rate of 20.9% but other studies have reported lower rates of 1.4% -1.9% with Strattice use[[16]](#endnote-16),[[17]](#endnote-17),[[18]](#endnote-18). For Surgimend Eichler demonstrated seroma in 1.6% in a comparative study with Epiflex ADM but Ohkuma et al found a higher rate of 7.5% in a 65-patient study with Surgimend showing variability within the literature[[19]](#endnote-19),[[20]](#endnote-20). In our study, of the three women in the Strattice group who experienced a seroma we observed particularly large volumes and all required intervention with one or more aspiration, a procedure that poses risk of introducing infection and can be distressing for patients.

We observed higher rates of postoperative haematoma in the Strattice group (6.7% versus 1.1%) and higher than reported in the literature (2.7%)16 however this difference is exaggerated by the small number of cases (two cases versus one case) and is not statistically significant.

Overall rates of return to theatre for revisional surgery were comparable in the Strattice (6.7%) and Surgimend (6.7%) groups. Interestingly though, for implant removal without concurrent replacement which can signify failure of the reconstruction, there were two cases in the Surgimend group and non in the Strattice group. Recognisably though these are small case numbers. Glasberg et al similarly reported low explant rates in Strattice of 1.4% but this is not consistent across the literature and rates of 11% and 15.5% have also been reported17,[[21]](#endnote-21). Eichler et al had revision surgery rates of 4.8% for Surgimend but did not report whether the implant was salvaged in these cases19.

We recognise there are some limitations of our study. The total patient number in each group is skewed towards Surgimend as our department moved away from the use of Strattice early. There was a statistically significant higher mastectomy breast weight in the Strattice group, a recognised risk factor for higher complication rates. Operations were performed by three plastic surgeons with a subspecialist interest in breast reconstruction working closely and with similar surgical technique, however minor variation in the time of drain removal and duration of postoperative antibiotic regimens may have existed. It was beyond the scope of this paper to assess the long term and cosmetic outcomes, but this would be of interest in future studies.

Considering the body of literature on ADMs there are significant limitations. We found only a few head to head comparative ADM studies, of which most were retrospective with small sample sizes and often from a single centre. Furthermore, a preponderance of these focused on human derived ADMs notably AlloDerm. Cross analysis of existing studies is problematic as there is considerable variability and a lack of standardisation in the reporting and classification of outcomes. For instance, infection rates have been reported as major or minor, using standard surgical site infection grading scales or only if requiring admission or causing implant loss.

We hope this study will add to the literature and pre-empt further well designed comparative ADM studies, preferably randomised control trials in this area and we await the iBRA study findings to further inform the breast reconstructive surgeon in selecting the best ADMs for each patient[[22]](#endnote-22).

***Conclusion***

This study suggests an increased rate of breast skin erythema with use of porcine (Strattice) compared to bovine (Surgimend) ADM. We found no other statistically significant differences in post-operative complications. With the expanding use of ADMs there is a current need for larger, multicentre, randomised studies, particularly comparing xenogeneic ADMs in IBBR to direct best practice.

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    ***Table 1.*** Summary of patient specific variables for reconstruction with Strattice or Surgimend

    |  |  |  |  |  |
    | --- | --- | --- | --- | --- |
    | **Variables** | **Group total** | **Strattice** | **Surgimend** | ***P* value** |
    | **Number of women** | 81 | 19 | 62 | - |
    | **Number of breasts** | 119 | 30 | 89 | - |
    | **Mean age** | 45 | 44 | 46.9 | 0.326 |
    | **Mean BMI *ɸ*** | 23.3 | 23 | 23.4 | 0.3 |
    | **Mastectomy weight** |  | 367.1 ± 159.3 | 296.3 ±133.4 | 0.037\* |
    | **Smoking** | 17 (21%) | 3 (15.8%) | 14 (22.6%) | 1 |
    | **ASA grade 2*ɸ*** | 43 | 5 | 38 | - |
    | **ASA grade 3*ɸ*** | 3 | 0 | 3 | - |
    | **Chemotherapy:** |  |  |  |  |
    | **Preoperative** | 25 | 7 | 18 | 0.58 |
    | **Postoperative** | 9 | 0 | 9 | 0.11 |
    | **Radiotherapy:** |  |  |  |  |
    | **Previous  *ɸ*** | 5 | 1 | 4 | 1 |
    | **Postoperative** | 20 | 7 | 13 | 0.22 |

    \*Statistically significant *P* value <0.05

    *P* values obtained using T test and Fisher exact test. (T test for age, breast weight, BMI)

    *ɸ* Data absent for: previous radiotherapy status in 2 patients, ASA in 22 patients, BMI in 5 patients

    *Table 2*. Summary of postoperative outcome results for reconstruction with Strattice or Surgimend calculated per women and breast

    |  |  |  |  |  |  |  |  |
    | --- | --- | --- | --- | --- | --- | --- | --- |
    | **Outcome measure** | **Total breasts**  **n=119**  **(%)** | **Per woman** | | | **Per breast** | | |
    | **Strattice**  **n=19**  **(%)** | **Surgimend**  **n=62**  **(%)** | ***P* value** | **Strattice**  **n=30**  **(%)** | **Surgimend**  **n=89**  **(%)** | ***P* value** |
    | **Haematoma**  *Return to theatre* | 3 (2.5)  3 (2.5) | 2 (10.5)  2 (10.5) | 1 (1.6)  1 (1.6) | 0.136  - | 2 (6.7)  2 (6.7) | 1 (1.1)  1 (1.1) | 0.156  - |
    | **Major infection**  *Return to theatre* | 6 (5)  1 (0.8) | 1 (5.3)  0 | 5 (8.1)  1 (1.6) | 1  - | 1 (3.3)  0 | 5 (5.6)  1 (1.1) | 1  - |
    | **Minor infection** | 6 (5) | 2 (10.5) | 4 (6.5) | 0.621 | 2 (6.7) | 4 (4.5) | 0.641 |
    | **Wound dehiscence**  *Return to theatre* | 3 (2.5)  2 (1.7) | 1(5.3)  0 | 2 (3.2)  2 (3.2) | 1  - | 1 (3.3)  0 | 2 (2.2)  2 (2.2) | 0.557  - |
    | **Skin necrosis**  *Return to theatre* | 4 (3.4)  2 (1.7) | 1 (5.3)  0 | 3 (4.8)  2 (3.2) | 1  - | 1 (3.3)  0 | 3 (3.4)  2 (2.2) | 1  - |
    | **Seroma**  *Aspirated* | 7 (5.9)  5 (4.2) | 3 (15.8)  3 (15.8) | 4 (6.5)  2 (3.2) | 0.346  - | 3 (10)  3 (10) | 4 (4.5)  2 (2.2) | 0.366  - |
    | **Skin erythema** | 8 (6.7) | 4 (21.1) | 4 (6.5) | 0.083 | 5 (16.7) | 4 (4.5) | 0.044\* |

    \*Statistically significant *P* value <0.05

    *P* values obtained using Fisher exact test [↑](#endnote-ref-22)