Clinical experience with Surgimend in breast reconstruction: an overview

Abstract

In the field of breast reconstruction, products and techniques are continuing to evolve to ensure good clinical and quality outcomes. This article reviews the published literature regarding the use of fetal bovine-derived acellular dermal matrix (SurgiMend, SurgiMend PRS and SurgiMend PRS meshed), focusing on safety, clinical outcomes and surgical techniques.

F Bassetto[1]

L Pandis[1]

Author details can be found at the end of this article

Correspondence to:
L Pandis; laura.pandis@gmail.com

Introduction

Acellular and immunologically inert dermal replacements can be obtained from cadavers or xenografts (Marler and Upton, 2006). These materials act like a biological scaffold, intended to be integrated into the host's tissue through neovascularisation and fibroblast infiltration (Middelkoop et al, 1995; Wainwright, 1995), and so reinforcing the tissue after surgery.

Production processes and product features differ for decellularised dermal matrices, and lead to variations in histological and clinical behaviour, outcomes and cost (Jansen et al, 2013).

SurgiMend (TEI, Biosciences, Inc., Boston, MA, USA) is an acellular dermal matrix derived from neonatal or fetal bovine dermal collagen. It is rich in type III collagen, which is prominent in embryological development and wound healing. The material is treated with chemicals to remove cellular components from the dermis, reducing the foreign body reaction and inflammatory processes. It is terminally sterilised through ethylene oxide. The preservation process allows the material to be stored at room temperature and then hydrated intraoperatively in room temperature saline for around 60 seconds (Ohkuma et al, 2013).

SurgiMend was introduced to the market in 2009 for abdominal wall repair, and it was then used for breast reconstruction (Maxwell and Gabriel, 2009). Breast surgeons were looking for a more pliable and soft acellular dermal matrix, without the high mechanical strength required for hernia repair. SurgiMend PRS was subsequently developed and remains one of the few biological matrices with fenestration, theoretically allowing fluid which might gather around the implant to drain into the surrounding tissue (Dieterich and Faridi, 2013). After a positive clinical experience in the subpectoral position, a new meshed SurgiMend PRS was introduced in September 2017, proposed for prepectoral reconstruction (Wazir and Mokbel, 2018; Gui and Tsang, 2019).

Histological examination showed a decreased inflammatory response compared to other bovine-derived matrices and in contrast to human-derived biologic matrices (Hwang et al, 2007). In a histology study conducted 4 months after SurgiMend PRS implantation, adequate vascularisation with CD31 positive cells was observed, demonstrating quick tissue integration (Craft and May, 2011).

The original concept of meshed tissue, first described in plastic surgery for partial thickness skin grafts, was taken further and applied experimentally with meshed SurgiMend PRS by Lotan et al (2018). This study hypothesised that meshing might reduce the overall bioburden (the mass of added acellular dermal matrix at the implantation site) and increase the surface area of the matrix, meaning that more host connective tissue and cells are in contact with more reactive matrix margins, potentially leading to faster integration processes, reducing processes such as inflammation, fibroplasia and scar tissue formation. This was demonstrated with antibovine collagen type I staining on SurgiMend samples in a porcine model: the meshed matrix showed more cellularity with better penetration evidenced by nuclei staining and less bovine collagen staining, presumably as it had been replaced by host porcine collagen. Thus, the expanded surface area of meshed acellular dermal matrix may promote better cellular penetration and hence faster replacement and integration by

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the host. Based on the histopathological results of this study, as well as preliminary efficacy and safety data from clinical studies of meshed acellular dermal matrix (Martin et al, 2014; Hagarty et al, 2015; Palaia et al, 2015), the authors initiated a clinical study of acellular dermal matrix meshed at a 1:2 ratio in immediate, implant-based breast reconstruction.

Literature review

Aim

This article reviews the literature regarding the use of bovine-derived acellular dermal matrix such as SurgiMend, SurgiMend PRS and SurgiMend PRS meshed. This provides an overview of the published experience with this acellular dermal matrix, focusing on safety, clinical outcomes and surgical techniques.

Materials, patients and methods

Inclusion criteria were articles available in English about the use of SurgiMend in breast reconstruction. Articles relating to other areas of application (abdomen, head and neck, extremities, trunk, pelvis) and articles on basic science were excluded. A computer-based search of the following electronic databases was performed on 15 July 2019: OVID MEDLINE, Cochrane Database of Systematic Reviews, Scopus. The search was performed using the search terms and Boolean operators 'SurgiMend'.

Results

The literature search resulted in the identification of 132 publications. Thirty duplicates were removed, and after application of the exclusion criteria 33 articles remained. A manual search of the literature identified six additional articles. Articles were identified which focused on safety, outcomes and surgical techniques, thus the final review included 26 articles.

Surgical techniques

Several articles describe surgical techniques, ranging from a subpectoral approach to a prepectoral approach, through use in revision surgery.

In 2009 Maxwell and Gabriel first described the use of SurgiMend for revisionary aesthetic breast surgery. The use of acellular dermal matrix was presented as a way of preventing uncontrolled evolution of the capsule and assessing problems of tissue thinning and implant malposition. The author explained how acellular dermal matrix can counteract the inflammatory process, by making more regenerative tissue available to help control the interface of the implant pocket. The clinical evidence was the reported successful treatment of 56 patients with Baker grade III and IV capsular contracture. They found that the use of acellular dermal matrix enhanced soft tissue thickness or cushioning, decreasing or eliminating the visibility of implants. Moreover, the use of these products increased the ability to successfully manage original or recurrent implant displacement. Lower pole thickness was improved in patients with either dual plane or neopectoral pocket conversions, in particular for patients undergoing concurrent mastopexy, by interposing regenerative tissue between skin closure and implant (Figure 1).

In 2011, Craft and May described a two-stage nipple reconstruction with SurgiMend in a patient requiring bilateral breast reconstruction. After complete expansion, at the time of expander exchange, and after implant placement a 5 cm circular pocket was undermined in a position above the capsule and below the dermis, at the site of planned nipple reconstruction. A 5 cm disk of 2 mm thick SurgiMend was placed into this pocket, without needing sutures for fixation. When the patient returned for nipple reconstruction 4 months later, a skate flap was designed where the SurgiMend disk had been placed. The flap was performed, including adding SurgiMend to the dermis and subcutaneous tissue. The SurgiMend disk was noted to be well vascularised. A piece of SurgiMend was sent for histological evaluation, and showed a well-vascularised matrix with positive CD31 staining. The nipple projection was evaluated at 8 mm in height, which was maintained at 7 mm at 4-month follow up and 6 mm at 7-month follow up.

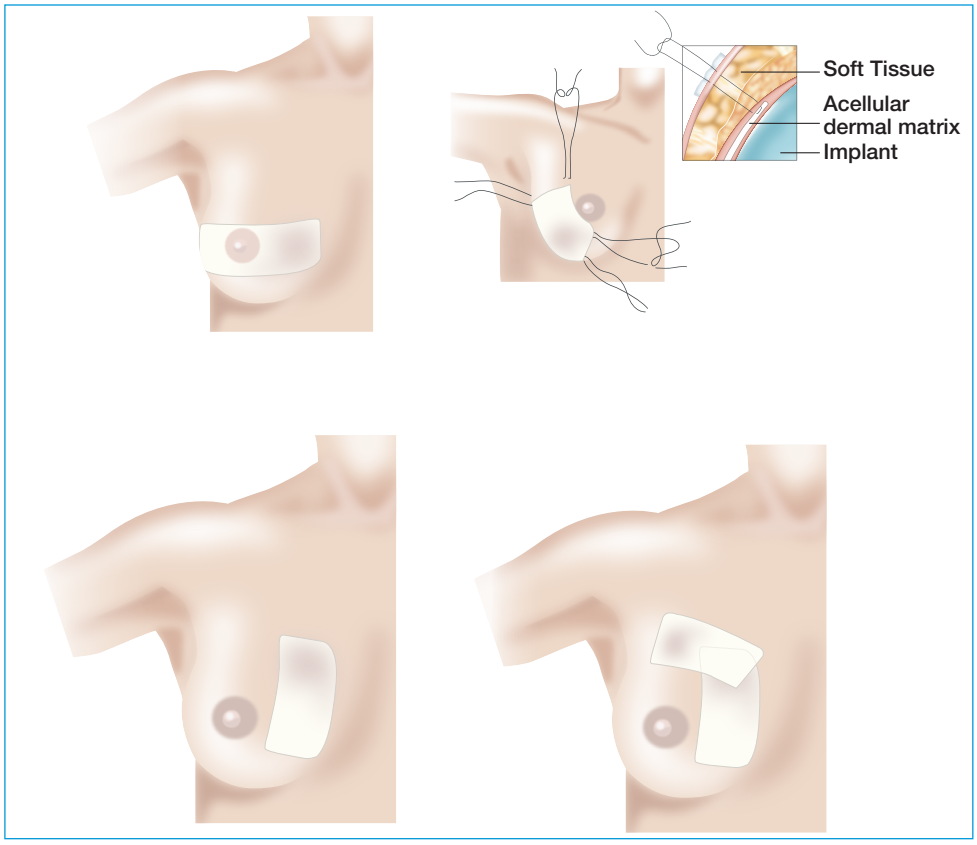

Figure 1. Different placement of the acellular dermal matrix: (a) centre, (b) lower lateral, (c) medial and (d) upper medial areas.

SurgiMend was mentioned in many reviews as a product suitable for breast reconstruction. In one of these Salzberg (2012) proposed an algorithm for immediate reconstruction (**Figure 2**).

Another review (Macadam and Lennox, 2012) summarised all surgical applications known to date. To favour expansion of the submuscular pocket for direct-to-implant breast reconstruction and two-stage breast reconstruction the acellular dermal matrix was used as a sling, which was interposed between the lateral pectoral edge and the thoracic wall. The acellular dermal matrix was also used to correct symmastia, to camouflage surface irregularities, to mask rippling of the upper pole, and to correct the inframammary fold malposition or bottoming out. After capsular elevation, the acellular dermal matrix was placed in between tissues and frequently fixed with marionettes sutures. The use of acellular dermal matrix was also quoted to provide an additional interface after contracture-releasing capsulotomies (**Figures 3–5**).

From 2012 onwards, many articles described placement of a sling of SurgiMend in the subpectoral position, between the lateral and inferior borders of the pectoralis major and the chest wall, to complete the inferior lateral part of the implant pocket, with either a tissue expander or a permanent breast implant. Few technical differences were found in the articles, i.e. in the timing of upper border suture, the type of surgical suture used for the chest wall (PDS or Vicryl/VicrylPlus), or the management of drains. Irrigation of the surgical field with different antibiotics or antiseptics is frequently described in the surgical technique, as well as the need for changes of gloves and instruments, and to repeat breast skin cleansing with antiseptics (Ohkuma et al, 2013). The need to ensure that the closed mastectomy incision lies over the muscle and not over the acellular dermal matrix–implant surface, and the need for meticulous assessment of mastectomy flap viability and final excision of poorly perfused skin flaps are constantly highlighted. These technical points reflect the need to prevent the most frequent complications (necrosis, seroma and infection) summarised in **Table 1** online.

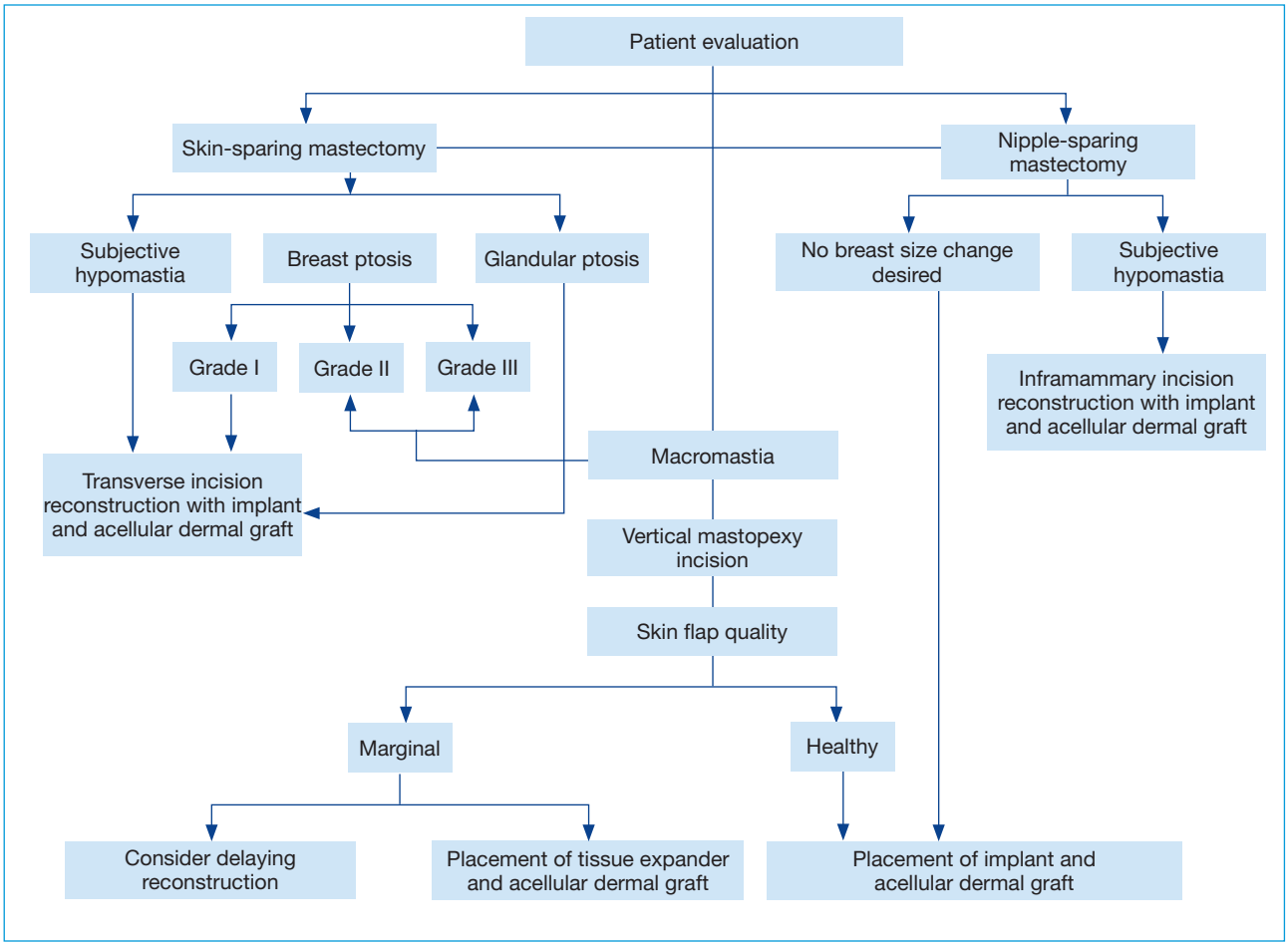

Figure 2. Algorithm to guide clinical decision making in single-stage breast reconstruction with acellular dermal matrices. From Salzberg (2012).

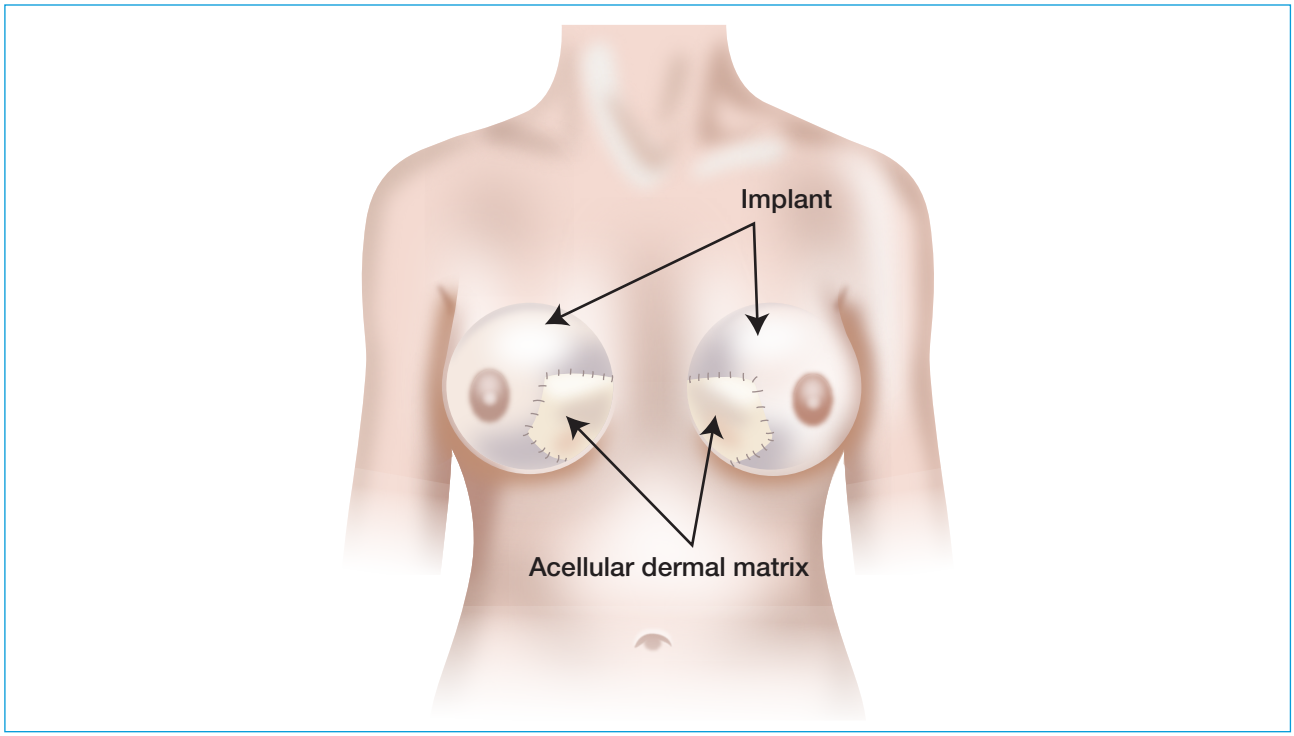

Figure 3. Medial placement of acellular dermal matrix to correct symmastia.

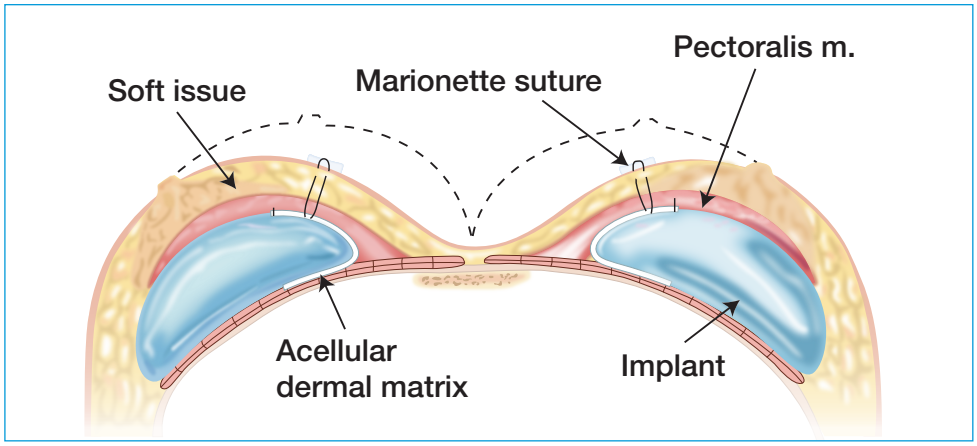

Figure 4. Placement of acellular dermal matrix to correct symmastia.

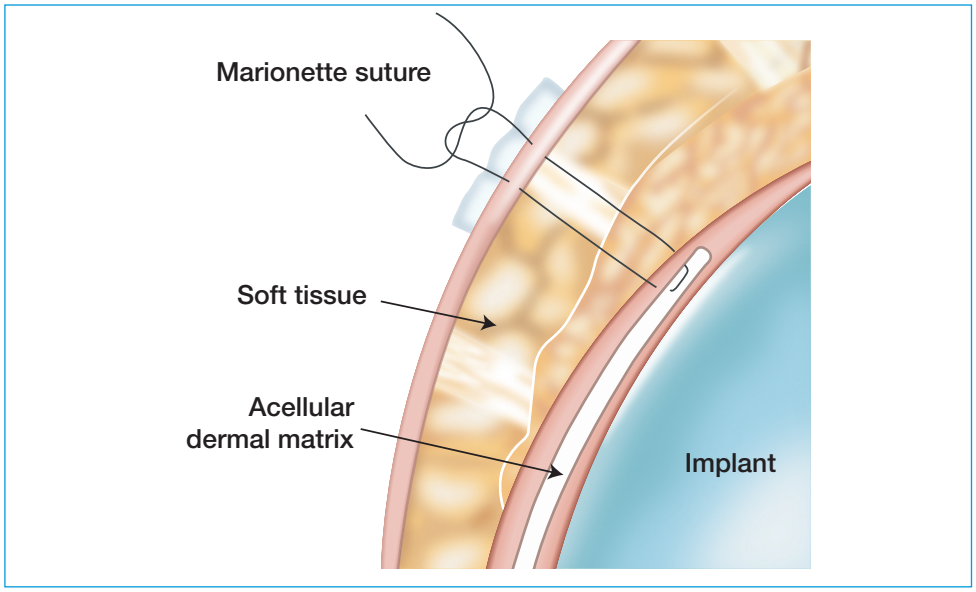

Figure 5. Placement of acellular dermal matrix to correct rippling.

In his review Zenn (2018) remarked that a well-performed nipple-sparing or skin-sparing mastectomy is the foundation of successful reconstruction, while the standard use of the pectoralis muscle and tissue expanders should be debated (because of the prepectoral reconstruction technique) and that acellular dermal matrix is both useful and cost-effective in performing immediate one-stage breast reconstruction. According to these principles he described the 'Zenn delay' for high-risk patients (Table 2) and for those in need of improved vascularity, based on technical or clinical judgment at surgery. Staged immediate breast reconstruction, known as the Zenn delay, was created to improve vascularisation in mastectomy flaps, so that immediate reconstructions can still be performed and tissue expanders can be avoided. If a patient is considered high risk, or if the patient experiences ischaemia intraoperatively, the Zenn delay dictates that nothing further should be done at the initial setting. Backing out of the mastectomy gives the best chance of allowing skin survival, taking advantage of surgical delay to improve and secure the best possible vascularisation for reconstruction. Two weeks after mastectomy, a direct-to-implant reconstruction can be safely performed with excellent cosmetic results, because scar tissue has not yet formed and the natural skin envelope can be used.

The use of SurgiMend was also described after skin-reducing mastectomy in patients needing a very large implant, for which dermal and anterior serratus flaps were inadequate

Table 2. High-risk patients for immediate reconstruction with nipple-sparing mastectomy
Large breast size (D cup or larger)
Significant breast ptosis (grade 3)
Previous lumpectomy and breast irradiation
Previous breast reduction or mastopexy
Previous breast augmentation
Inexperienced surgical oncologist
Active smoker

(De Vita et al, 2015). Generally, the use of acellular dermal matrix had been reserved for patients who have undergone previous breast surgery such as quadrantectomy, for patients with extremely high insertions of their pectoralis muscle, and for patients needing a large breast implant or large pouch. Acellular dermal matrix was placed on the lateral side of the pocket, with the aim of avoiding the need to detach the serratus muscle. In 2018 Kankam et al also described the use of acellular dermal matrix (SurgiMend, Strattice, Braxon) in skin-reducing mastectomy in five patients. The inferior dermal sling was secured to the pectoralis major with 2/0 PDS sutures, covering the acellular dermal matrix. The authors concluded that acellular dermal matrix can be successfully combined with a de-epithelialised dermal sling to buttress the T-junction, protecting the underlying implant and improving the reliability of the reconstruction.

As well as the subpectoral approach, a novel technique sparing the pectoralis muscle started to be reported. In 2018 Wazir and Mokbel described the prepectoral acellular dermal matrix-assisted approach in implant-based immediate breast reconstruction following conservative mastectomy with the used of SurgiMend PRS meshed. In this case report the patient was highly satisfied with the outcome of surgery. The authors suggested that an acellular dermal matrix-based prepectoral approach could result in improved aesthetic results by facilitating the surgeon's ability to fully control the definition of the implant pocket. However, the muscle-sparing approach may lead to an increased incidence of rippling, and palpability and visibility of the implant in the upper pole of the reconstructed breast. Furthermore, this technique is not ideal for deeply located tumours that may extend to the deep margin. The number of subsequent procedures which is required to optimise the reconstruction, such as fat transfer to reduce postoperative rippling, should be also considered when assessing the cost effectiveness of this technique.

Gui and Tsang (2019) also described how to manage the prepectoral technique to control the level of ptosis, looking at one-stage immediate breast prepectoral reconstruction with the use of meshed SurgiMend PRS with two different techniques for varying ptosis: 'enhanced hammock' and 'tent' (**Figure 6**). The tent technique is used when a youthful appearance is desired. Interrupted 3/0 PDS sutures can be placed around the periphery of each of the edges (superior, lateral, medial and inferior), suturing the acellular dermal matrix to the pectoralis fascia along the original mastectomy footprint. The sutures can be placed through the fenestrations in the acellular dermal matrix or through the acellular dermal matrix substance itself, taking care to leave the knots facing downwards, thus being covered by the acellular dermal matrix. At the inferior edge, the fascial layer can be used to either reinforce or repair the inframammary crease, to prevent displacement in the caudal direction. The enhanced hammock technique can be used to recreate ptosis. In this case, the surface markings of the implant footprint must be placed lower on the chest wall. Once the implant is introduced into the pocket, the patient is positioned in a sitting position on the operating table to recreate the natural ptosis, and the skin envelope can be draped over the implant to match the contralateral side. The lower boundary of the implant is intended to lie below the inframammary crease in this position.

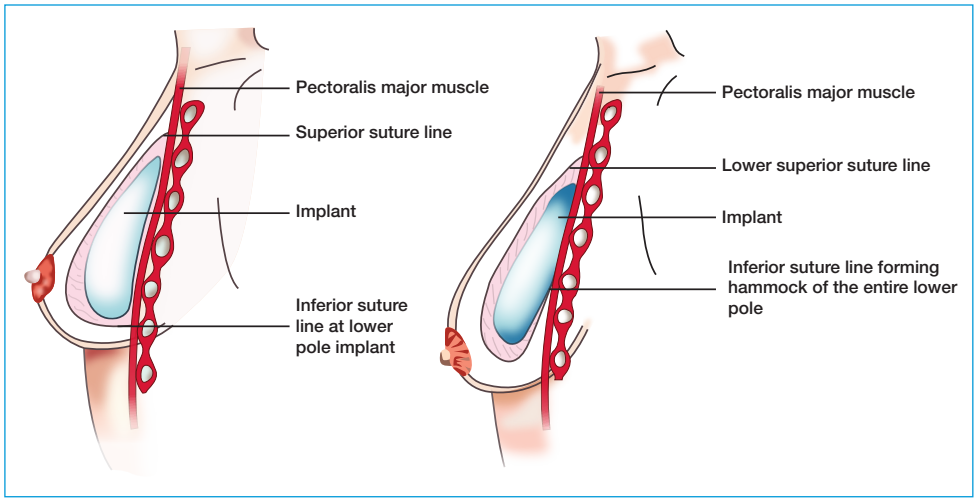

Figure 6. Prepectoral placement of acellular dermal matrix. a. Tent technique. b. Enhanced hammock technique.

Safety and performance outcomes of SurgiMend

Twenty papers referred to SurgiMend in breast reconstruction, focusing on clinical outcomes and safety data, including two prospective studies, seventeen retrospective studies and one case report, with no randomised studies.

Six studies reviewed the use of SurgiMend in breast reconstruction without a control group (including one case report), one study compared the use of SurgiMend in breast reconstruction with no use of acellular dermal matrix, one study reviewed the use of acellular dermal matrix (SurgiMend or AlloDerm) *vs* no acellular dermal matrix, one study compared the use of SurgiMend *vs* the latissimus dorsi flap, one study compared the use of SurgiMend *vs* EpiFlex, three studies compared the use of SurgiMend *vs* AlloDerm, one study compared the use of SurgiMend *vs* Tutomesh, and two studies compared the use of SurgiMend *vs* Strattice.

In one study the use of SurgiMend was analysed together with no use of acellular dermal matrix and the use of the serratus muscle flap; in two studies SurgiMend was analysed together with AlloDerm, Neoform, DermaMatrix, FlexHD and Strattice and in another study, SurgiMend was compared to AlloDerm. One meta-analysis compared the results of twenty-one studies of breast reconstruction with SurgiMend, AlloDerm and Strattice.

The publications reviewed the use of SurgiMend in breast reconstruction in terms of histological properties, aesthetic outcomes, patient satisfaction, initial and final tissue expander fill volumes, and number of revision surgeries. The results are summarised in Table 3 online and show a higher performance of acellular dermal matrices *vs* traditional surgery. Histology shows a relatively low level of inflammatory response and degradation, while cellular infiltration and neovascularisation correlated to thickness and quality of the overlying host tissue. These laboratory findings suggest that acellular dermal matrix protects the implant from capsular contracture. In this regard the meta-analysis from Loo et al (2018) highlighted a zero capsular contracture rate. The overall aesthetic outcome was better with the use of acellular dermal matrix than traditional surgery or autologous tissue (latissimus dorsi flap). The initial fill volume was higher in patients who had been treated with acellular dermal matrix, allowing a quicker expansion time and keeping an anatomical shape, resulting in a more natural final appearance.

Safety was reviewed in terms of reported complications that might be associated with the use of the product. Results are summarised in Table 4 online. Four studies reported a significant difference in complication rate between the study group treated with SurgiMend and the control group. Eichler et al (2015) reported a significantly higher incidence of infection requiring intravascular antibiotics and overall complication rate in the group treated with Epiflex *vs* SurgiMend. In the study by Butterfield (2013) a

Key points

- The fetal bovine-derived acellular dermal matrix SurgiMend was initially proposed for abdominal wall repair, and then was quickly used for breast reconstruction in the form of SurgiMend PRS and later SurgiMend PRS meshed.
- SurgiMend has been used since 2009 for revisionary aesthetic breast surgery and since 2012 sutured to the lateral and inferior borders of the pectoralis major and the chest wall to complete the inferior lateral part of implant pouch in breast reconstruction. SurgiMend PRS and SurgiMend PRS meshed have been used since 2016 for prepectoral breast reconstruction.
- Safety data analysis reported mostly statistically non-significant differences in rates of complication compared to other acellular dermal matrices, but reviewed studies concluded that appropriately powered randomized trials are needed to provide further information.

statistically significant higher number of subjects treated with AlloDerm suffered from seroma ($P<0.05$), while subjects treated with SurgiMend showed a higher rate of minor necrosis ($P<0.05$). No difference was found in the overall complication rate between these groups.

The second study investigating the use of SurgiMend *vs* AlloDerm did not report any significant difference in the rate of seroma and necrosis between the two groups (Selber et al, 2015), nor any difference in complication rate between the use of SurgiMend and no use of acellular dermal matrix. Ricci et al (2016) described similar rates of major complications for AlloDerm and Surgimend when used in immediate implant-based breast reconstruction, and a difference in the rate of skin necrosis requiring debridement between the groups (SurgiMend 2.9%; AlloDerm 6.6%; $P=0.01$). Mazari et al (2018) found a significantly higher re-operation rate in the Strattice group (17.3% *vs* 3.7%). The incidence of red breast syndrome was significantly higher in the SurgiMend group (9.2% *vs* 3.6%). Seroma, wound problems and infection rates were similar. More recent studies are focusing on complication rate and cost, rather than quality performance of the product, bringing to attention the emerging synthetic materials and cheaper acellular dermal matrices (Loo, 2017).

The study of Ben-David et al (2016) is not included in Table 4, as it did not describe complication rates, but it remains of interest in showing product safety in term of radiotherapy administration. It concluded that postmastectomy radiation therapy could be delivered effectively and safely after immediate implant-based breast reconstruction, even for patients who require internal mammary chain radiation.

Conclusions

Twenty-six papers were reviewed referring to SurgiMend in breast reconstruction, focusing on safety, clinical outcomes and surgical techniques. Analysis of safety data reported mostly non-significantly statistical different rates of complication compared to other acellular dermal matrices. SurgiMend performs better than or as well as the alternatives, including similar devices, no use of acellular dermal matrix, or the use of autologous tissue transfer. However, there were some limitations in this work. The main weakness is the low level of evidence in the mentioned studies, which were mostly prospective cohort or observational studies. Further randomised trials are needed to prove definitively findings of simpler studies and provide further information.

Conflicts of interest

The authors have no conflicts of interest to declare.

Author details

[1]Plastic Surgery Department, Padova University, Italy

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Table 1. Surgical techniques in studies referring to SurgiMend

Reference	Product	Field	Technique
Maxwell and Gabriel (2009)	AlloDerm, Neoform, Derma Matrix, Flex HD, SurgiMend, Strattice	Revisionary aesthetic breast surgery	■ Lamellar interpositioning (site change to a subpectoral plane or neopectoral pocket with the addition of an acellular dermal matrix) ■ Subfascial pocket with an acellular dermal matrix sling use after capsular elevation
Craft and May (2011)	SurgiMend	Staged subpectoral breast reconstruction	■ Staged nipple reconstruction with vascularised SurgiMend acellular dermal matrix
Macadam and Lennox (2012)	AlloDerm, Flex HD, DermaMatrix, AlloMax, SurgiMend, TiMesh TIGR	Reconstructive and aesthetic breast surgery	■ Lamellar interpositioning for direct-to-implant breast reconstruction or two-stage breast reconstruction ■ Correction of symmastia ■ Correction into the upper pole to camouflage surface irregularities and rippling ■ Correction of inframammary fold malposition and 'bottoming out' ■ Provision of an interface when performing capsulotomies or capsulectomy for recurrent capsular contracture

Reference	Product	Field	Technique	Drains	Acellular dermal matrix suture
Ohkuma et al (2013)	SurgiMend	Staged subpectoral	Sling interposed between PM and IMF	Blake 19 drains Threshold of 30 ml/24 h	First lower border: IMF After upper border: PM 3-0 Vicryl sutures
Butterfield (2013)	SurgiMend, Alloderm	Breast reconstruction	Sling interposed between PM and IMF	1 or 2 drains	Interrupted 3-0 Vicryl sutures
Gaster et al (2013)	SurgiMend	Staged and immediate subpectoral breast reconstruction	Sling interposed between PM and IMF	Jackson-Pratt	First upper border: PM with 3-0 Monocryl After lower border: IMF border of SurgiMend with 2-0 PDS
Endress et al (2012)	SurgiMend	Staged subpectoral breast reconstruction	Sling interposed between PM and IMF	Suction drains over the acellular dermal matrix, threshold of 30 ml/24 hours for two consecutive days	First upper border: PM with 3-0 Monocryl After lower border: IMF border of SurgiMend with 2-0 PDS
Eichler et al (2017)	SurgiMend, Tutomesh	Staged subpectoral breast reconstruction	Sling interposed between PM and IMF	Threshold of 330 ml/24 hours	N/A

Table 1 (Continued)

Mazari et al (2018)	SurgiMend, Strattice	Immediate subpectoral breast reconstruction	Sling interposed between PM and IMF	Threshold of 50 ml for two consecutive days	N/A
Scheflan et al (2018)	SurgiMend PRS	Immediate subpectoral breast reconstruction	Sling interposed between PM and IMF	Before discharge from the hospital, threshold of 30 ml/24 hours	Vicryl plus suture
Ball et al (2017)	SurgiMend, Strattice	Staged and immediate subpectoral breast reconstruction	Sling interposed between PM and IMF	Threshold of 30 ml/24 hours always before discharge	First lower border: IMF After upper border: PM with an absorbable suture
Ricci et al (2016)	SurgiMend, Alloderm	Immediate subpectoral breast reconstruction	Sling interposed between PM and IMF	Under the acellular dermal matrix, threshold of 30 ml/24 hours	First lower border: IMF After upper border: PM
De Vita et al (2015)	SurgiMend	Staged and immediate subpectoral breast reconstruction	Use of acellular dermal matrix (SurgiMend) in skin-reducing mastectomy		
Kankam et al (2018)	SurgiMend, Strattice, Braxon	Immediate submuscular reconstruction	Use of acellular dermal matrix (SurgiMend, Strattice, Braxon) in skin-reducing mastectomy		
Zenn (2017)	AlloDerm, Flex HD, DermaMatrix, AlloMax, SurgiMend	Immediate submuscular reconstruction staged and immediate subpectoral and prepectoral breast reconstruction	'Zenn delay'		
Wazir and Mokbel (2018)	SurgiMend PRS meshed	Immediate prepectoral reconstruction	Acellular dermal matrix placement with tent technique in immediate implant-based breast reconstruction with prepectoral placement of the implant		
Gui and Tsang (2019)	SurgiMend PRS meshed	Immediate prepectoral reconstruction	■ 'Enhanced hammock' technique ■ 'Tent' technique		

IMF = inframammary fold; PM = pectoralis major

Table 3. Performance outcomes of studies referring to SurgiMend

Reference	Study design	Product #1 (total # breasts)	Product #2 (total # breasts)	Performance outcomes
Gaster et al (2013)	Prospective, single-surgeon	SurgiMend (17)	N/A	■ Relatively low level of inflammatory response and degradation ■ Cellular infiltration and neovascularisation correlated to thickness and quality of the overlying host tissue ■ Initial fill volume = 65±100 ml ■ Final fill volume = 470±129 ml
Ohkuma et al (2013)	Retrospective, single-surgeon	SurgiMend (95)	N/A	Two re-operations required, both resulting in successful reconstruction
Endress et al (2012)	Retrospective, single-surgeon, non-randomised	SurgiMend (49)	No acellular dermal matrix (123)	■ Initial fill volume SurgiMend = 181.2±148.3 ml ■ Initial fill volume non-acellular dermal matrix = 117.7±66.3 ml (P<0.001)
Ibrahim et al (2015)	Single-centre, non-randomised	SurgiMend (3)	AlloDerm (15) No acellular dermal matrix (20)	■ Overall aesthetic outcomes significantly improved with the use of acellular dermal matrix (12.1%, P=0.022) ■ Subscales contour and implant placement mainly contributed to positive aesthetic outcomes (P=0.003 and P=0.021 respectively)
Lee and Bae (2015)	Retrospective, non-randomised	SurgiMend (28)	Latissimus dorsi (32)	■ Overall aesthetic outcomes (breast softness, tension with movement, patient satisfaction) did not significantly differ between the two groups ■ Subscales breast symmetry and breast shape scored significantly higher in the latissimus dorsi group (P<0.0001 and P=0.0008 respectively)
Eichler et al (2015)	Retrospective, single-surgeon, non-randomised	SurgiMend (63)	Epiflex (64)	■ 3 (4.8%) revision surgeries required for SurgiMend ■ 8 (12.5%) revision surgeries required for Epiflex (P=0.21)
Selber et al (2015)	Retrospective, single-centre, non-randomised	SurgiMend (137)	AlloDerm (487)	■ Initial fill volume SurgiMend + AlloDerm = 258±156.3 ml
Butterfield (2013)	Retrospective, multi-centre, single-surgeon, non-randomised	SurgiMend (351)	AlloDerm (89)	SurgiMend was approximately 1000 US dollars less expensive than AlloDerm
De Vita et al (2015)	Retrospective, single-centre, non-randomised	SurgiMend (14), serratus muscle flap (18), no acellular dermal matrix (56)	N/A	■ Photographic review of the aesthetic outcomes of the mastectomies by external surgeons indicated excellent results for 39 subjects, good for 27 subjects and poor for 8 subjects (no differentiation made between acellular dermal matrix and no-acellular dermal matrix use) ■ Patient satisfaction indicated high satisfaction for 32 subjects, moderate satisfaction for 34 subjects and no satisfaction for 8 subjects (no differentiation made between acellular dermal matrix and no-acellular dermal matrix use)

Table 3 (Continued)

Maxwell and Gabriel (2009)	Retrospective, non-randomised	SurgiMend, AlloDerm, Neoform, DermaMatrix, FlexHD, Strattice (total 78)	N/A	N/A
Maxwell and Gabriel (2013)	Retrospective, non-randomised	SurgiMend (8)	AlloDerm (57), Neoform (4), DermaMatrix (2), FlexHD (19), Strattice (96)	N/A
Fox and Lee (2012)	Single case report	SurgiMend (1)	N/A	N/A
Headon et al (2016)	Prospective single institution	SurgiMend	N/A	At a mean follow up of 21 months, patient satisfaction with the procedure was found to be very high. The mean Breast Q score was 85 and the mean overall patient satisfaction rating was 9 out of a possible 10. The mean objective assessment score was 8.9 out of a possible 10 and the mean subjective capsular contracture severity score was 2.9 out of 10

Table 4. Safety outcomes of studies referring to SurgiMend

Reference	Study design	Product #1 (total # breasts)	Safety outcomes	Incidence # (%)	Product #2 (total # breasts)	Safety outcomes	Incidence # (%)
Gaster et al (2013)	Prospective, single surgeon	SurgiMend (17)	Infection requiring expander removal	1 (8.3)	N/A	N/A	N/A
Ohkuma et al (2013)	Retrospective, single surgeon	SurgiMend (95)	Haematoma	3 (3.2)	N/A	N/A	N/A
			Seroma	2 (2.1)			
			Infection required reoperation	2 (2.1)			
			Infection requiring intravenous antibiotics only	1 (1.1)			
				13 (13.8)			
			Infection requiring oral antibiotics	0			
			Wound dehiscence	21 (22.1)			
			Total # of complications				
Endress et al (2012)	Retrospective, single surgeon, non-randomised	SurgiMend (49)	Haematoma	3 (5.7)	No acellular dermal matrix (123)	Haematoma	2 (1.6)
			Seroma	0		Seroma	1 (0.8)
			Flap necrosis	3 (5.7)		Flap necrosis	2 (1.6)
			Infection requiring explantation	1 (1.9)		Infection requiring explantation	8 (6.5)
			Infection requiring antibiotics	1 (1.9)		Infection requiring antibiotics	1 (0.8)
			Deflation	2 (3.8)		Deflation	0
			Wounds requiring explantation	1 (1.9)		Wounds requiring explantation	2 (1.6)
			Total # of complications	11 (20.8)		Total # of complications	16 (13.0)
Ibrahim et al (2015)	Single centre, non-randomised	SurgiMend (3) AlloDerm (15)	Seroma	1 (5.5)	No acellular dermal matrix (20)	Seroma	2*
			Infection	1 (5.5)		Infection	2*
			Implant rippling	2 (11.1)		Implant rippling	0*
			Implant extrusion	1 (5.5)		Implant extrusion	0*
			Capsular contracture	4 (22.2)		Capsular contracture	1 (5)
			Total # of complications	9 (50)		Total # of complications	6 (30)
Lee and Bae (2015)	Retrospective, non-randomised	SurgiMend (28)	Seroma in cavity	1 (3.6)	Latissimus dorsi (32)	Seroma in cavity	1 (3.1)
			Severe infection of covering material	1 (3.6)		Severe infection of covering material	0
			Inflammation in cavity	1 (3.6)		Inflammation in cavity	0
			Capsular contracture (grade II)	1 (3.6)		Capsular contracture (grade II)	0
			Total # of complications	4 (14.3)		Total # of complications	1 (3.1)

Table 4 (Continued)

Reference	Study design	Product #1 (total # breasts)	Safety outcomes	Incidence # (%)	Product #2 (total # breasts)	Safety outcomes	Incidence # (%)
Eichler et al (2015)	Retrospective, single surgeon	SurgiMend (63)	Seroma requiring aspiration	1 (1.6)	Epiflex (64)	Seroma requiring aspiration	3 (4.7)
			Infection requiring intravenous antibiotics	**0**		**Infection requiring intravenous antibiotics**	**6 (9.4)**
			Red breast syndrome	3 (4.8)		Red breast syndrome	9 (14.1)
			Revision surgery	3 (4.8)		Revision surgery	8 (12.5)
			Total # of complications	**7 (11.1)**		**Total # of complications**	**26 (40.6)**
Selber et al (2015)	Retrospective, single centre, non-randomised	SurgiMend (137)	Seroma	15 (11.4)	AlloDerm (487)	Seroma	50 (11.8)
			Necrosis	28 (21.2)		Necrosis	115 (26.9)
			Infection	18 (13.5)		Infection	51 (12.1)
			Explantation	14 (10.2)		Explantation	37 (8.6)
			Total # of complications	65 (47.7)		Total # of complications	184 (44.6)
Butterfield (2013)	Retrospective, multi-centre, single surgeon, non-randomised	SurgiMend (351)	Haematoma	4 (1.1)	AlloDerm (89)	Haematoma	0
			Seroma	**30 (8.6)**		**Seroma**	**14 (15.7)**
			Necrosis	**39 (11.1)**		**Necrosis**	**3 (3.4)**
			Infection	17 (4.8)		Infection	6 (6.7)
			Expander / implant loss	29 (8.3)		Expander / implant loss	10 (11.2)
			Total # of patients with complications	79 (22.5)		Total # of patients with complications	22 (24.7)
De Vita et al (2015)	Retrospective, single centre, non-randomised	SurgiMend (14)	Seroma	5	N/A	N/A	N/A
		Serratus muscle flap (18)	Infection	3			
		No acellular dermal matrix (56)	Cutaneous epidermolysis/ necrosis-- Wound dehiscence	3			
				4			
			Prosthetic exposure	2			
			Nipple areola complex necrosis	5			
			Total # of complications	22			
Maxwell and Gabriel (2009)	Retrospective, non-randomised	SurgiMend	Haematoma	1 (1.3)			
		AlloDerm	Seroma	2 (2.6)			
		Neoform	Implant malposition	1 (1.3)			
		DermaMatrix	Implant rupture	0			
		FlexHD	Infection	0			
		Strattice	Total # of complications	4 (5.1)			

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Table 4 (Continued)

Reference	Study design	Product #1 (total # breasts)	Safety outcomes	Incidence # (%)	Product #2 (total # breasts)	Safety outcomes	Incidence # (%)
Maxwell and Gabriel (2013)	Retrospective, non-randomised	SurgiMend (8)	Haematoma	0	AlloDerm (57)	Haematoma	1 (0.5)
			Seroma	0	Neoform(4)	Seroma	1 (0.5)
			Implant malposition	0	DermaMatrix (2)	Implant malposition	1 (0.5)
			Infection	0	FlexHD (19)	Infection	3 (1.7)
			Capsular contracture	2 (25)	Strattice (96)	Capsular contracture	1 (0.5)
			Total # of complications	2 (25)		Total # of complications	7 (3.9)
Fox et al (2013)	Single case report	SurgiMend	Tissue expander infection	1	N/A	N/A	N/A
Ball et al (2017)	Retrospective, non-randomised	SurgiMend (89)	Haematoma	1 (1.1)	Strattice (30)	Haematoma	2 (6.7)
			Major infection	5 (5.6)		Major infection	1 (3.3)
			Minor infection	4 (4.5)		Minor infection	2 (6.7)
			Wound dehiscence	2 (2.2)		Wound dehiscence	1 (3.3)
			Skin necrosis	3 (4.8)		Skin necrosis	1 (3.3)
			Seroma	4 (6.5)		Seroma	3 (10)
			Skin erythema	4 (4.5)		Skin erythema	5 (16.7)
			Total # of complications	25 (28)		Total # of complications	12 (40)
Headon et al (2016)	Prospective, single institution	SurgiMend (164)	Seroma/explantation	2 (1.2)	N/A	N/A	N/A
			Seroma	1 (0.6)			
			Haematoma	2 (1.2)			
			Wound dehiscence	1 (0.6)			
			Total # of complications	6 (4)			
Ricci et al (2016)	Retrospective Non-randomised	SurgiMend (374)	Haematoma	5 (1.3)	AlloDerm (578)	Haematoma	6 (1)
			Seroma	7 (1.8)		Seroma	13 (2.5)
			Skin necrosis	**11 (2.9)**		**Skin necrosis**	**38 (6.6)**
			Infection	12 (3.2)		Infection	22 (3.8)
			Reoperation	23 (5.9)		Reoperation	48 (8.3)
			Explantation	10 (2.6)		Explantation	17 (2.9)
			Total # of complications				
Eichler et al (2017)	Retrospective Non-randomised	SurgiMend PRS (18)	Postoperative redness	3 (16.7)	Tutomesh (27)	Postoperative redness	10 (27)
			Red breast syndrome	3 (16.7)		Red breast syndrome	4 (14.8)
			Seroma requiring aspiration	0 (0)		Seroma requiring aspiration	0 (0)
			Infection requiring i.v. antibiotics	1 (5.6)		Infection requiring i.v. antibiotics	5 (18.5)
			Haematoma	1 (5.6)		Haematoma	0 (0)
			Immediate revision surgery	0 (0)		Immediate revision surgery	1 (3.7)
			Subsequent revision surgery	4 (22.2)		Subsequent revision surgery	6 (22.5)
			Total # of complications	5 (27.8)		Total # of complications	10 (37.0)

Table 4 (Continued)

Reference	Study design	Product #1 (total # breasts)	Safety outcomes	Incidence # (%)	Product #2 (total # breasts)	Safety outcomes	Incidence # (%)
Scheflan et al (2017)	Retrospective single centre observational	Surgimend PRS (147)	Haematoma	7 (4.8)	N/A	N/A	N/A
			Seroma	20 (13.6)			
			Necrosis	22 (15)			
			Infection	35 (23.8)			
Mazari et al (2018)	Retrospective multicentre observational	Surgimend (37)	**Reoperation**	**3 (7)**	Strattice (45)	**Reoperation**	**18 (33.3)**
			Explantation	3 (7)		Explantation	10 (18.5)
			Red breast syndrome	**9 (20)**		**Red breast syndrome**	**3 (5.6)**
			Seroma requiring aspiration	5 (11.6)		Seroma requiring aspiration	17 (31.5)
			Infection requiring i.v. antibiotics	12 (27.9)		Infection requiring i.v. antibiotics	15 (27.8)
			Haematoma	1 (2,3)		Haematoma	5 (9.3)
			Necrosis	10 (23.3)		Necrosis	15 (27.8)
Craig et al (2019)	Retrospective cohort single centre study	Surgimend Alloderm	Deihescence	30 (6.2)	Surgimend Alloderm + postmastectomy radiation therapy	Dehiscence	5 (5.7)
			Haematoma	7 (1.4)		Haematoma	3 (3.7)
			Infection	56 (11.5)		Infection	14 (15.9)
			Necrosis	124 (25.5)		Necrosis	21 (23.9)
			Seroma	53 (10.9)		Seroma	12 (13.9)
			Explantation	46 (9.5)		Explantation	10 (11.9)
			Total # of complications	182 (37.4)		Total # of complications	42 (47.7)
Loo et al (2018)	Literature meta-analysis	Surgimend (912)	Major (%)	3 (51)	Alloderm	Major (%)	3 (8)
			Minor (%)	4 (17)		Minor (%)	3 (44)
			Seroma (%)	4 (61)		Seroma (%)	3 (07)
			Haematoma (%)	1 (21)		Haematoma (%)	2 (11)
			Explantation (%)	4 (5)		Explantation (%)	2 (59)
			Capsular (%)	0 (0)		Capsular (%)	1 (21)
			Total # of complications (%)	17 (98)		Total # of complications (%)	16 (21)
					Strattice	Major (%)	2 (10)
						Minor (%)	4 (6)
						Seroma (%)	8 (61)
						Haematoma (%)	2 (10)
						Explantation (%)	5 (61)
						Capsular (%)	0 (80)
						Total # of complications (%)	23 (82)

Significant differences are marked in bold.