OPEN

ORIGINAL ARTICLE
Breast

A Head-to-head Comparison between SurgiMend and Epiflex in 127 Breast Reconstructions

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Background: The use of acellular dermal matrices (ADM) has become a widely used option in breast reconstruction. A great deal of literature is available, totaling over 2400 ADM reconstructions. Nonetheless, head-to-head comparisons between SurgiMend and Epiflex are not yet reported. In fact, this is the first clinical data report on the use of Epiflex. This work will, therefore, compare postoperative complication rates and costs for these ADMs.
Methods: This analysis is a retrospective review of a single surgeon's 6-year experience with both SurgiMend—an acellular bovine dermal collagen matrix for soft-tissue reconstruction and Epiflex—a decellularized human skin tissue from 2008 to 2013.
Results: One hundred patients had a total of 127 implant-based reconstructions using SurgiMend (64 cases; 50.4%) or Epiflex (63 cases; 49.6%). Gross complication rates were 11.1% for SurgiMend and 40.6% for Epiflex including hematoma, postoperative skin irritation, infection, necrosis, and revision surgery. The most common complication was postoperative red breast syndrome. Severe complications requiring revision surgery were significantly increased in patients treated with Epiflex (12.5%) compared with SurgiMend (4.8%).
Conclusions: This retrospective analysis favors the use of SurgiMend over Epiflex because of significantly lower gross complication rates. Severe complication rates are comparable with those reported in literature for both products. Although results promote the use of SurgiMend, the single surgeon retrospective nature of this work limits its clinical impact. *(Plast Reconstr Surg Glob Open 2015;3:e439; doi: 10.1097/GOX.0000000000000409; Published online 25 June 2015.)*

Breast reconstruction in a postoncological intervention scenario may either be performed via an autologous or implant-based approach. For skin sparing mastectomies (SSM)/nipple sparing mastectomies, literature states a shift from autologous breast reconstruction toward implant-based reconstruction. Recent data from the United States demonstrated that implant-based breast reconstruction is used in 37% of breast cancer patients.[1,2] Comparability between Germany and the United States may be limited because of a different reimbursement system in the public health sector and the availability of other types of implants. The limited reimbursement envelope is based on the German Diagnosis Related Groups system. Here, additional costs are covered by the hospital. Regardless of the healthcare system, literature shows that acellular dermal matrix (ADM)-supported reconstruction should be carefully considered because of a limited long-term financial benefit.[3] Some published head-to-head analyses of available biological products may be used as a decision-making tool to determine which cost

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Received for publication December 20, 2014; accepted May 4, 2013.

DOI: 10.1097/GOX.0000000000000409

intensive reconstructive option should be used.[4] However, performing implant-based reconstructions, even if ADMs are required, has a variety of advantages. Most importantly, overall patient morbidity is decreased because of the fact that implant-based reconstruction is a far less invasive procedure. Additionally, factors such as a decrease in the donor site morbidity, more cost effective surgical procedures, and improved implant materials play an important role in a general shift toward implant-based reconstruction.[5–7]

Implant-based reconstruction of SSM procedures may, however, present its own problems. Some may be solved using an ADM. Their use has become an attractive option in implant-based breast reconstruction, and an increasing number of publications is becoming available, currently including over 2400 ADM reconstructions (both synthetic and biological). Promising results were shown when ADMs were used in soft-tissue replacement, additional implant coverage, and fixation of the pectoralis major muscle. Furthermore, increased implant stability may be achieved by introducing a lower pole ADM hammock type situation. The main goal of ADM-assisted implant-based breast reconstruction is improving coverage of the implant, implant site stability, and fixation of the pectoralis muscle (Fig. 1). Therefore, there is a need to evaluate the clinical benefit of the use of ADMs. Although there seems to be some literature evidence of differing complication rates because of different ADMs, no direct comparison of the fetal bovine ADM—SurgiMend[8,9] and the decellularized human skin tissue product—Epiflex[2,10] has been published so far.

PATIENTS AND METHODS

This analysis is a retrospective review of a single surgeon's 6-year experience, 2008–2013, with both SurgiMend—an acellular bovine dermal collagen matrix for soft-tissue reconstruction and Epiflex—a decellularized human skin tissue. Surgical interventions included both oncological and plastic reconstructive patients. One hundred patients had a total of 127 implant-based reconstructions. In the case of a bilateral intervention, each side was counted separately. This resulted in 127 ADM-supported procedures. It should be noted that before and after this consecutively recruited trial, a more cost effective titanium-coated mesh such as TiLoop (pfm medical ag, Koeln, Germany) was used.[11–13] Choice of ADM was based on availability. Due to a price difference, not all health insurance companies will compensate the additional ADM cost. If this is the case, we generally fall back on titanium-coated mesh.

Disclosure: *The authors have no financial interest to declare in relation to the content of this article. The Article Processing Charge was paid for by POLYTECH Health & Aesthetics GmbH.*

Endpoints

The retrospective points of interest were postintervention complication rates. These included postsurgical red breast syndrome (RBS—redness exceeding normal postoperative redness; Fig. 2), seroma requiring aspiration, infection requiring intravenous (i.v.) antibiotics, and revision surgery. RBS was considered a mild, transient complication, which, although clinically apparent, was of little clinical relevance. Unlike cellulitis or infection, a common differential diagnosis, it should not be treated with antibiotics as this hypersensitivity better responds to corticosteroids.[14] It may also simply resolve itself, without additional intervention.

More severe complications included seroma requiring aspiration and infection requiring i.v. antibiotic treatment because of the fact that they required rehospitalization. Lastly, revision surgery (because of wound dehiscence, hematoma, antibiotic resistant infection, etc.) was considered a severe complication.

SurgiMend

SurgiMend PRS (TEI, Biosciences, Inc., Boston, Mass.) is derived from fetal bovine dermal collagen (Fig. 3). Apart from advantageous mechanical properties,[15] the manufacturer states it to be rich in type III collagen, which may mediate tissue healing while inhibiting scarring.[16] It may also not elicit an acute or chronic foreign body inflammatory response thus eliminating degeneration of the implant site. Furthermore, its microporous matrix is rapidly revascularized, which, in turn, may support tissue building and healing for prolonged reinforcement.[17] It is the only biological mesh with fenestration, theoretically allowing fluid accumulations around the implant to drain into the surrounding tissue.[2] A PubMed search currently (October 2014) lists 8 publications regarding the SurgiMend ADM. Ohkuma et al[8] (65 patients, retrospective) and Butterfield et al[4] (222 patients) are two retrospective analyses available in breast reconstruction to date.

Epiflex

Epiflex (Deutsches Institut für Zell- und Gewebeersatz gGmbH, Berlin, Germany)[18] is derived from human skin and undergoes a complex decellularization process, leaving behind a collagen matrix with low residual levels of genomic material insufficient to provoke an immune reaction[2] (Fig. 4). A PubMed search shows 5 publications, none of which report clinical data. This work will be the first to report clinical data on the Epiflex system.

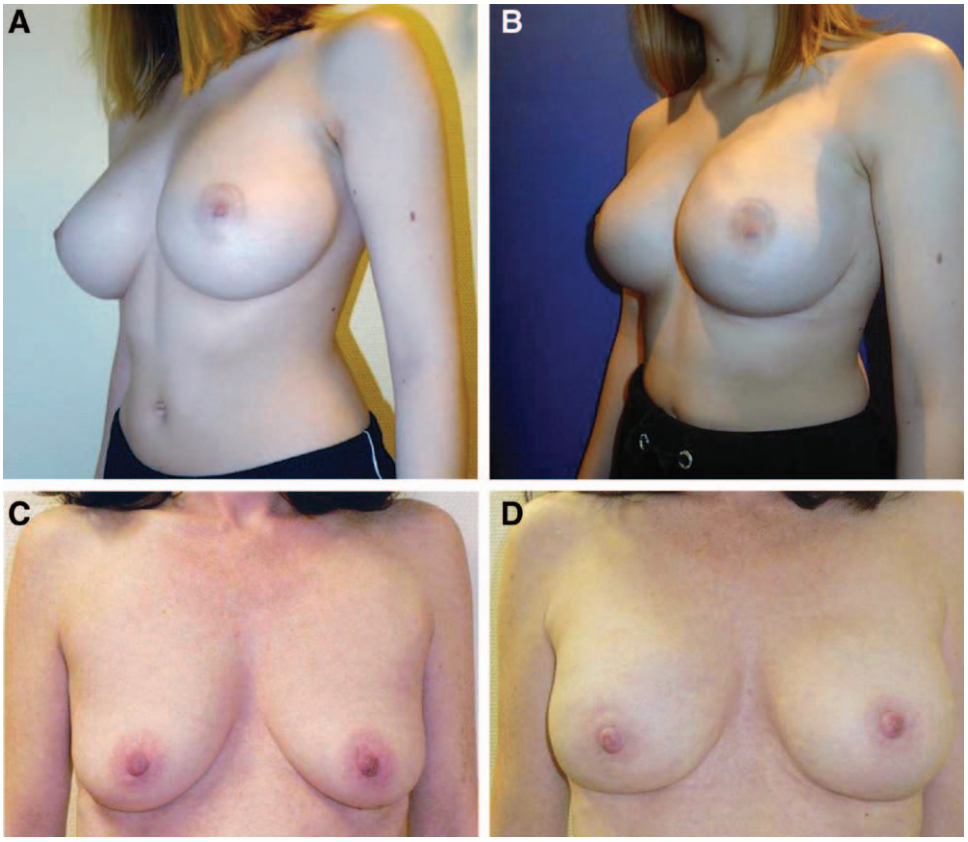

Fig. 1. A, Presurgical image. The patient had received nipple sparing, bilateral subcutaneous mastectomies with immediate implant-based reconstruction. The esthetic thoracic wall/breast transition was insufficient, and revision was desired. B, Six-month postsurgical image shows this prepectoral reconstruction where SurgiMend was used in the upper quadrant to optimize esthetic thoracic wall/breast transition. Adequate, complication-free surgical outcome was achieved. C, Presurgical image before a nipple sparing, bilateral subcutaneous mastectomy. D, Six-month postsurgical image for a subpectoral Epiflex assisted reconstruction where the ADM has been used to cover the implant in the lower breast pole in a hammock-type situation. Adequate, complication-free surgical outcome was achieved.

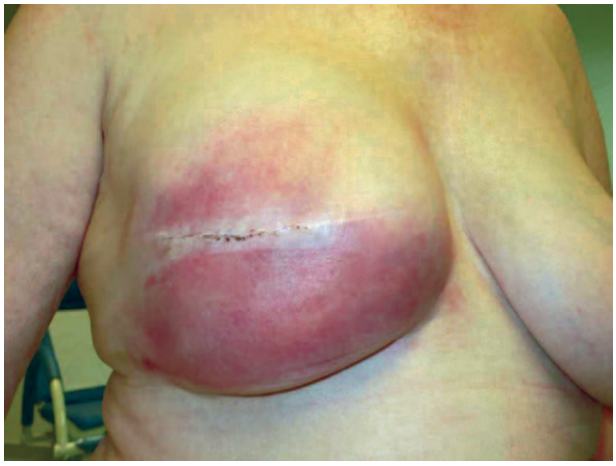

Fig. 2. Immediate postoperative RBS after a subcutaneous mastectomy using implant-based reconstruction and Epiflex—decellularized human skin tissue.

Surgical Technique

Surgery was performed according to the gold standard for SSM/nipple sparing mastectomies implant-based reconstruction. All materials were handled according to the manufacturer specifications. Antibiotics were administered during surgery and continued until drain removal. In most cases, cefazolin, a first-generation cephalosporin, was used. Drains were not removed within the first 24 hours postsurgical period. Thereafter, a threshold of 50 mL per 24 hours was used as a cutoff for maintaining drainage. Surgical compression bras were applied immediately after surgery and worn by the patient for at least a 4-week period.

Patients Satisfaction

No patients were lost because of unsatisfactory results. In the event of a revision surgery, it was

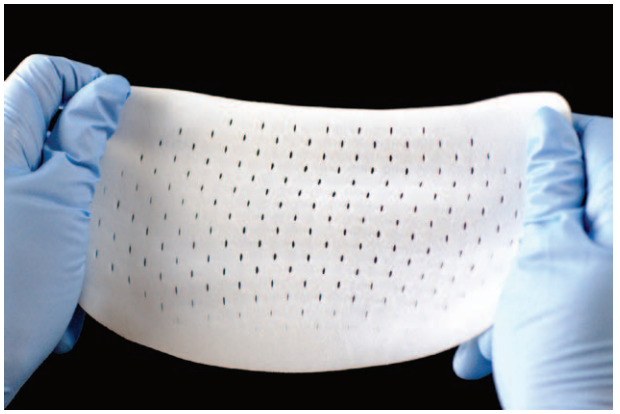

Fig. 3. SurgiMend PRS is derived from fetal bovine dermal collagen. This image shows a fenestrated 10 × 15 cm ADM.

Fig. 4. Epiflex—decellularized human skin tissue.

performed by the reporting physician. Patient satisfaction was, therefore, assumed to be adequate, and it has, however, not been separately quantified.

Statistics

Statistical analysis was performed using the VassarStats (Vassar College, Poughkeepsie, N.Y.) statistics program. Pearson's χ^2 tests, *t* tests and Mann–Whitney tests were used to evaluate significances when appropriate.

RESULTS

One hundred twenty-seven reconstructions were divided up as follows: 63 surgical sites received the SurgiMend and 64 sites were reconstructed with Epiflex. A summary of all data may be found in Table 1. In the SurgiMend group, 57 (90.5%) surgeries were oncological interventions and 6 (9.5%) were aesthetic procedures. The Epiflex group consisted of 54 (84.4%) oncological interventions and 10 (15.6%) aesthetic interventions ($P = 0.44$). Both groups contained approximately 14% smokers. Twenty-four percent (SurgiMend) and 22% (Epiflex) of the patients had received prior chemotherapy, and approximately 14% (SurgiMend) and 20% (Epiflex) had received radiation treatment. Intergroup homogeneity is given for all subgroups ($P > 0.05$). The median age for the SurgiMend group was 54 years (range = 55), and the median age for the Epiflex group was 55 years (range = 56; Mann–Whitney $P = 0.5222$). The median body mass index (BMI) for SurgiMend group was 22 (range = 14) and 21 (range = 16) for the Epiflex group (Mann–Whitney $P = 0.6527$). Gross complication rates include postoperative RBS, seroma-requiring aspiration, infection requiring i.v. antibiotic treatments, and revision surgery.

Gross complication rates showed that 7 (11.1%) of the 63 SurgiMend patients experienced some form of postsurgery complication compared with 26 (40.6%) of 64 Epiflex patients. The difference is statistically significant ($P = 0.003$). The SurgiMend group included 3 patients with increased postoperative RBS, 1 patient requiring seroma aspiration, and 3 patients requiring revision surgery. The Epiflex group included 9 patients with RBS, 3 patients requiring seroma aspiration, 6 patients requiring rehospitalization because of i.v. antibiotic treatment, and 8 requiring revision surgery. RBS and required i.v. antibiotic treatment differed significantly. Required seroma aspiration and the amount of revision surgery did not differ significantly, although a strong trend is apparent in favor of SurgiMend.

DISCUSSION

Literature shows a growing body of available data regarding biological matrices and synthetic meshes in breast reconstructive surgery. Although their role in implant-based breast reconstruction is increasing, prospective randomized trials are still not available for all matrices currently on the market. In addition, high product costs combined with uncertain reimbursement of additional ADM implementation make it difficult to choose an appropriate biological/synthetic matrix. In a recent review, Dieterich and Faridi[2] summarized the role of either synthetic or biological options. The authors conclude that biological matrices are preferred over synthetic material. Because there are no prospective randomized trial data available, these evaluations are largely based on single surgeon experiences. This study presents data from a single surgeon retrospective analysis in comparison with 2 available SurgiMend studies.[8,9] Unfortunately, a cross comparison with Epiflex data is not possible because no published data are available.

Table 1. Data Summary for SurgiMend—Fetal Bovine ADM versus Epiflex—Decellularized Human Skin Tissue for 127 Cases

	SurgiMend (Bovine ADM)		Epiflex (Human ADM)		
		%		%	*P* *
Patients	63		64		
Oncological intervention	57	90.5	54	84.4	0.44
Aesthetic surgery	6	9.5	10	15.6	
Smoking	9	14.3	9	14.1	0.82
Chemotherapy	15	23.8	14	21.9	0.79
Radiation	9	14.3	13	20.3	0.36
Average age	55.4±21.8		53.8±13.4		0.50
Range	23–79		23–78		
Average BMI	21.8±2.6		21.8±3.3		0.35
Range	17–31		16–32		
Complications	7	11.1	26	40.6	0.003
RBS	3	4.8	9	14.1	0.07
Seroma requiring aspiration	1	1.6	3	4.7	0.61
Infection requiring i.v. antibiotics	0	N/A	6	9.4	0.03
Revision surgery†	3	4.8	8	12.5	0.21
Cost by size					
List price	$2485		$2230		

*Pearson χ^2 test, Fisher's exact probability test, or *t* test (two-tailed) whenever appropriate.
†Revision surgery because of wound dehiscence, hematoma, etc.
N/A, not applicable.

Our analysis of 127 cases of ADM-supported implant-based breast reconstruction resulted in 2 homogeneous groups with adequate intergroup comparability. There was no significant difference in smoking habits, prior chemotherapy, or prior radiation treatment. Average patient age and average patient BMI did not differ significantly. These factors had to be considered because smoking, chemotherapy, radiation treatment, and average BMI constitute known risk factors for postoperative complications, such as seroma formation, postsurgical infections, and required revision surgery.[19–21]

The gross complication rates of 11.1% SurgiMend and 40.6% Epiflex differ significantly. In contrast to some other studies, we included skin irritation as a minor complication as it may often lead to premature antibiotic treatment and/or corticosteroid application. We could show that postsurgical RBS is higher in the Epiflex group and should be carefully observed in further studies. Although a slight trend in favor of the SurgiMend group is apparent, no statistical significance was achieved. Ohkuma et al[8] found, in their 65-patient analysis with SurgiMend, an overall hematoma rate of 3.2% and an overall seroma formation rate of 7.5%. Our analysis yielded similar results with a seroma rate of 1.6% (SurgiMend) and 4.7% (Epiflex). Interestingly, a larger retrospective analysis by Butterfield et al[4] listed a seroma rate of 15.7% for AlloDerm (AlloDerm-LifeCell Corp., Branchburg, N.J.), which was significantly higher than that of 8.3% for SurgiMend; AlloDerm being a product very similar to Epiflex. Thus seroma formation was less than that reported in literature for both products evaluated in our study.Revision surgery (including hematoma drainage) had to be performed in 4.8% (SurgiMend) and 12.5% (Epiflex). Ohkuma et al[8] had a SurgiMend reoperation rate of 2.1% excluding hematoma evacuation. During revision surgery, we had the opportunity to evaluate ADM revascularization and acceptance by the surrounding tissue. Though sample numbers are very small, we feel the need to report that insufficient revascularization and failure of ADM inclusion into the surrounding tissue was present in all revisions. The causality chain, however, needs to be further evaluated.This retrospective analysis shows that gross complication rates differ significantly in favor of a SurgiMend ADM in direct head-to-head comparison with an Epiflex ADM. Revision surgery was required in approximately 5% and 13%, respectively. This included hematoma drainage and is slightly higher than the revision rates reported in literature. Despite a trend toward the SurgiMend ADM, results do not differ significantly ($P = 0.21$). Our findings reflect the limited retrospective data reported in literature. Clinically speaking, this work indicates that SurgiMend should be favored.Finally, cost factors have to be evaluated. The bovine ADM SurgiMend tends to be similarly cost effective compared with the Epiflex human ADM counterpart. Online price listings adjusted for dollar pricing, thickness, and size show a similar price. Individual pricing is of course subject to negotiation for both manufacturers and may, therefore, favor either ADM. The current status of our analysis favored the SurgiMend ADM.

This study is limited by a fairly small sample size, and data overinterpretation should be avoided. Nonetheless, interstudy comparability and a solid statistical difference in gross complication rates support the overall trend in favor of SurgiMend.

CONCLUSIONS

This head-to-head analysis between SurgiMend and Epiflex in an implant-based ADM-supported breast reconstruction shows SurgiMend to perform better in terms of gross complication rates, that is, postoperative red breast syndrome, seroma formation, infection requiring i.v. antibiotics, and revision surgery.

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PATIENT CONSENT

Written informed consent was obtained from all patients. This study was conducted in accordance with institutional review board standard operating procedures.

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