SurgiMend®
Collagen Matrix for Soft Tissue Reconstruction
Strong to Last Long

INTEGRA®
LIMIT UNCERTAINTY

CLINICAL EVIDENCE SUMMARY

OVERVIEW

SurgiMend® is a unique bovine dermal matrix that provides a durable, long-lasting hernia repair. SurgiMend not only provides a low (4-8%) recurrence rate for complex hernia repairs+^, but also demonstrates key advantages over other biologic acellular dermal matrices (ADMs). SurgiMend has a long history of clinical efficacy, as evidenced by the following key clinical studies.

TABLE OF CONTENTS

+ Based on data from: Giordano SA, et al. [N=223; RR=6.2%, excluding bridging; AFU=30.5; ADMP=underlay with ACS]; Garvey PB, et al. [N=60; RR=6.4% (3 yr) & 8.3% (5 yr), excluding bridging; AFU=52.9; ADMP=underlay with ACS]; Soares KC, et al. [N=67; RR=3.5%; AFU=8.7; ADMP=sandwich technique or onlay]; Garvey PB, et al. [N=135; RR=6.4%, excluding bridging; AFU=28.1; ADMP=underlay with ACS]; Clemens M, et al. [N=51; RR=3.9%; AFU=18.1; ADMP=underlay with ACS]; Lineaweaver W, et al. [N=15; RR=7.0%, excluding bridging; AFU=18.0; ADMP=onlay with ACS].[4,1,^,7,2,6]

ACS= Anterior Component Separation; ADMP=acellular dermal matrix placement; AFU=average follow-up (months); RR=recurrence rate.

^ Soares KC, Baltodano P a., Hicks CW, et al. Novel wound management system reduces surgical site morbidity after ventral hernia repairs: a critical analysis. Am J Surg. August 2014. doi:10.1016/j.amjsurg.2014.06.022.

Long-term Outcomes after AWR with ADM[1] *Garvey et al. 2016*

OBJECTIVE

Little published data successfully tracks the long-term results of hernia repairs or more complex abdominal wall reconstructions. The objective of this study was to investigate the long-term outcomes data, particularly hernia recurrence for AWR with ADM.

STUDY DESIGN

Retrospective, longitudinal study of patients across VHWG grades with more than 3 years follow-up.

SUMMARY

This large, retrospective study of 191 patients undergoing large complex AWR with biologic mesh (SurgiMend and Strattice) had durable repairs with low, long-term hernia recurrence rates (8.3% at 5 years) and wound complications did not progress to more serious complications like mesh removal.

DETAILS

REPAIR TYPE

Intraperitoneal underlay with component separation

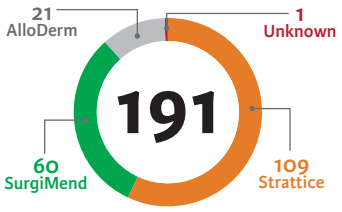
HERNIA GRADE

I, II, III, IV

MEAN FOLLOW-UP

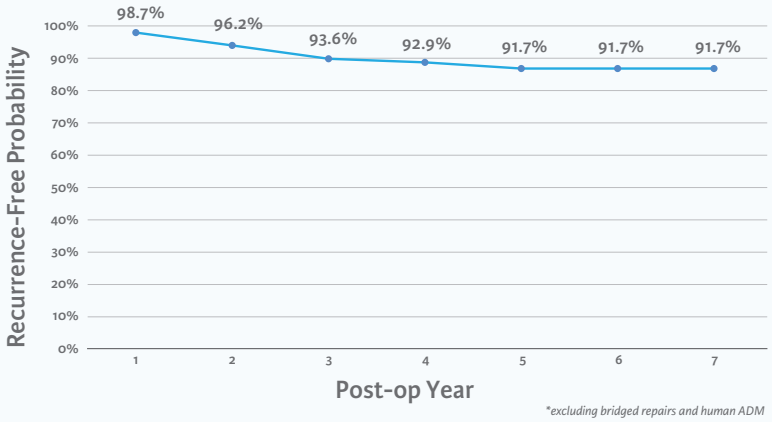
4.4 years

 # OF PATIENTS



RESULTS

RECURRENCE-FREE PROBABILITY BY POST-OP YEAR*



*excluding bridged repairs and human ADM

In this study, long-term hernia recurrence rates with biologic mesh were low (8.3%) and improved when bridging and human ADM were avoided.

CONCLUSION

Avoiding bridged repairs and human cadaveric ADM can improve long-term AWR outcomes using ADM.

These data demonstrate that hernia recurrence rates can even be improved when a bridged repair is avoided and xenograft rather than human allograft ADM is used.

ADMs appear to result in lower rates of infections, extrusion, erosion, and adhesion formation compared with synthetic meshes.

1. Garvey PB, Giordano SA, Baumann DP, Liu J, Butler CE. Long-term outcomes after abdominal wall reconstruction with acellular dermal matrix. J Am Coll Surg. 2016;224(3):341-350.

Bovine versus Porcine ADM for Complex AWR[2] *Clemens et al. 2013*

OBJECTIVE

To directly compare clinical outcomes and complication rates for commonly used biologic meshes in AWR.

STUDY DESIGN

Retrospective, comparative study, excluding bridging repairs.

SUMMARY

A total of 120 subjects underwent AWR for ventral hernia or musculofascial resection defects with underlay biologic mesh with a majority requiring anterior component separation to achieve midline closure and excluded anyone with a bridged repair.

Overall, low recurrence rates were reported with both SurgiMend (3.9%) and Strattice (2.9%). A total of 7 (10.1%) intraoperative complications were reported, all concerning the use of Strattice: 1 mesh was of uneven thickness and required replacement and in 6 cases, the mesh tore and required repair or replacement. No intraoperative complications or bulges (0%) were reported with SurgiMend however, 5 bulges (7.2%) were observed with Strattice.

DETAILS

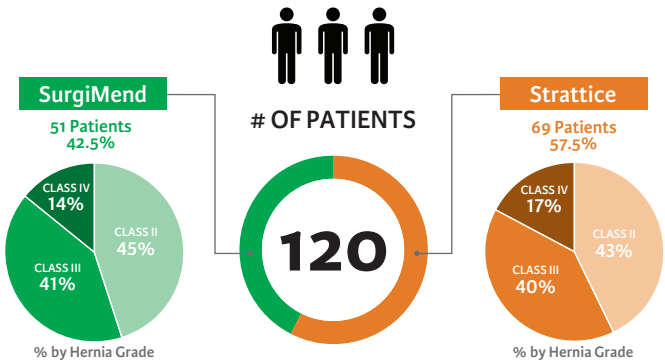
REPAIR TYPE

Underlay with Anterior Component Separation

MEAN FOLLOW-UP

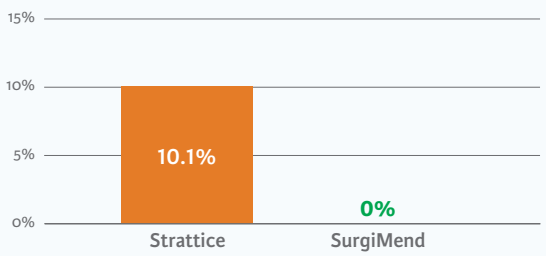
21 months

 # OF PATIENTS

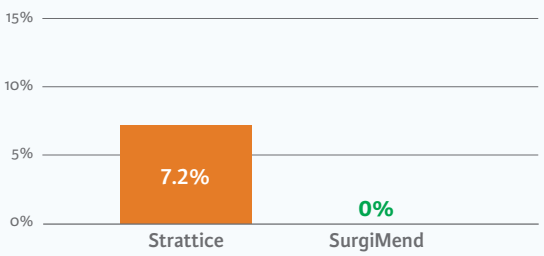


RESULTS

INTRAOPERATIVE MESH DEVICE FAILURE RATE
(TEAR, SUTURE PULL-THROUGH)



BULGE RATE
(AT 21 MONTH FOLLOW-UP)



CONCLUSION

Patients who undergo AWR with porcine matrix may experience a higher rate of device failure than those who do so with bovine matrix, and this requires more extensive evaluation.

Bovine matrix [SurgiMend] may be preferred over porcine matrix [Strattice] when AWR is performed with ADM placed under tension during closure.

2. Clemens MW, Selber JC, Liu J, et al. Bovine versus porcine acellular dermal matrix for complex abdominal wall reconstruction. Plast Reconstr Surg. 2013;131(1):71-79. doi:10.1097/PRS.0b013e3182729e58.

Primary Fascial Closure with Mesh Reinforcement is Superior to Bridged Mesh Repair for AWR[3] *Booth et al. 2013*

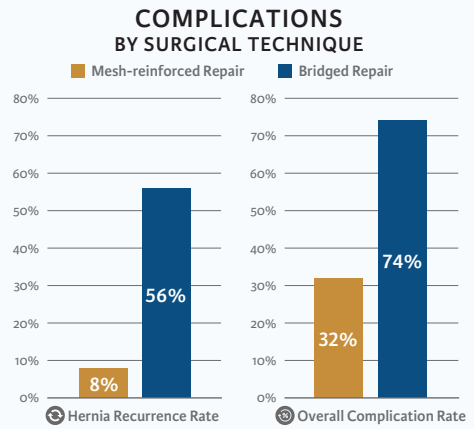
OBJECTIVE

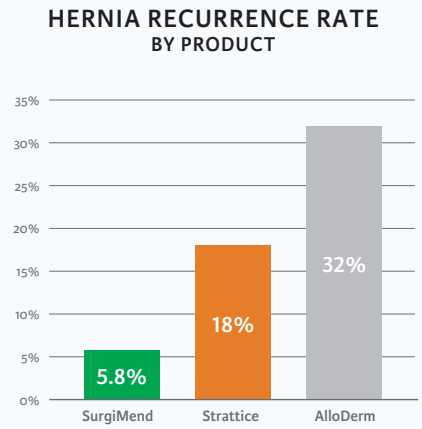
To investigate complication rates including hernia recurrence in bridging repair compared to primary fascial reinforcement with commonly used biologics.

SUMMARY

222 patients (195 mesh-reinforced and 27 bridged repairs) with a mean follow-up of 31.1 months found a significantly higher risk of hernia recurrence and complication rates with bridged repair.

RESULTS





CONCLUSION

Patients who underwent AWR with mesh-reinforced, primary fascial coaptation experienced fewer hernia recurrences and complications than those who underwent bridged repair.

3. Booth JH, Garvey PB, Baumann DP, et al. Primary Fascial Closure with Mesh Reinforcement Is Superior to Bridged Mesh Repair for Abdominal Wall Reconstruction. J Am Coll Surg. 2013;217(6):999–1009. doi:10.1016/j.jamcollsurg.2013.08.015.

Primary Fascial Closure with Biologic Mesh Reinforcement Results in Lesser Complication and Recurrence Rates than Bridged Biologic Mesh Repair for AWR: A Propensity Score Analysis[4] *Giordano et al. 2017*

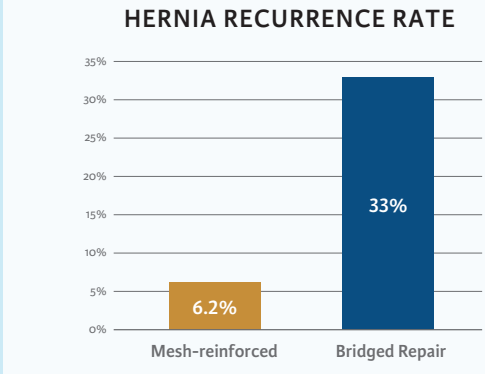
OBJECTIVE & HYPOTHESIS

Comparison of long-term results of bridged and mesh-reinforced AWR groups using propensity score analysis. The researchers hypothesized that primary facial closure with underlay mesh placement decreases hernia recurrence rates in comparison to bridged fascial repairs.

SUMMARY

More than 500 patients were reviewed over a 10 year period. Increased hernia recurrence rates were found with bridged repairs. Low recurrence rates (6.2%) were reported for fascial closure reinforced with xenograft mesh, including more than 200 SurgiMend patients.

RESULTS



CONCLUSION

The hernia recurrence rate in propensity matched, bridged repair patients was higher than reinforced primary fascial closure.

The study demonstrated that **using a xenograft mesh in underlay reinforcement** of primary facial closure of complex AWRs **results in a low, 6.2% hernia recurrence rate at an average of more than 2.5 years follow-up**.

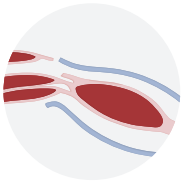
> *[Previous] studies often detail the experiences of surgeons who employ ADM selectively for only the most challenging cases... less complex hernia patients receive synthetic mesh and thus, not surprisingly, may experience better outcomes... our data represent a more accurate appraisal of the performance of ADM in complex AWR.*

4. Giordano S, Garvey PB, Baumann DP, Liu J, Butler CE. Primary fascial closure with biologic mesh reinforcement results in lesser complication and recurrence rates than bridged biologic mesh repair for abdominal wall reconstruction: A propensity score analysis. Surg (United States). 2017;161(2):499–508. doi:10.1016/j.surg.2016.08.009.

Long-term Outcomes of Sandwich Ventral Hernia Repair (SVHR) Paired with Hybrid Vacuum-Assisted Closure (HVAC)[5]

Hicks et al. 2016

SUMMARY



SANDWICH
(SurgiMend underlay; polypropylene onlay)

This retrospective study reported a subset of a prospectively maintained database of large complex abdominal wall defects with bridging repairs utilizing a sandwich technique (SurgiMend as an underlay & light weight polypropylene mesh as an onlay) paired with HVAC therapy. Despite very complex patients in bridging repairs, they report a **comparatively low (13%) hernia recurrence rate,** and a low surgical site occurrence rate (21.7%) at an average follow-up of almost 2 years.

PATIENT DEMOGRAPHICS (N=60)

- **Average BMI** 35.9
- **Modified VHWG Grade 2/3 (Kanters scale)** 93.3%
- **ASA Physical Status (PS)** PS 3: 75%
- **Bridged Repair** 100%

CONCLUSION

Comorbid patients with excessively large (~300cm²) hernia defects underwent bridging repairs using a sandwich ventral hernia repair technique with incisional negative pressure wound therapy resulting in low SSOs and hernia recurrence rates through 1 year follow-up.

This technique combines the benefits of the biologic repair (including its ability to resist infection and less bowel complications) with those of synthetic mesh utilization.

5. Hicks CW, Poruk KE, Baltodano PA, et al. Long-term outcomes of sandwich ventral hernia repair paired with hybrid vacuum-assisted closure. J Surg Res. 2016;204(2):282-287. doi:10.1016/j.jss.2016.04.072.

Improvement of Success Rates for Abdominal Component Reconstructions Using Bovine Fetal Collagen [SurgiMend][6]

Lineaweaver 2012

SUMMARY

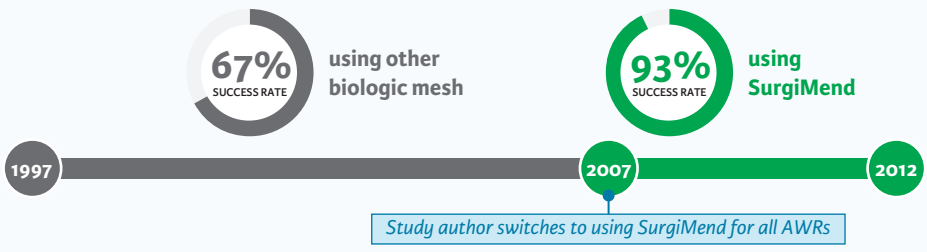
ONLAY

This study evaluated outcomes of standard component separation repairs reinforced with SurgiMend compared to the author's earlier published analysis. Of 15 repairs, 14 (93%) were intact at an average follow-up of 18 months. This study demonstrated decreased hernia recurrence with SurgiMend compared to previously published experience with other materials in onlay reinforcement of component separation.

The substantial initial tensile strength of this material, as well as its rapid assimilation into tissue, may mean that it provides strong initial reinforcement, and its rapid cellular repopulation and neovascularization allows it to resist failures related to superficial wound complications.

RESULTS

AUTHOR'S SUCCESS RATE*



*Success, in the context of this study, was defined as lack of a hernia recurrence at an average post-op follow-up of 18 months

This positive finding will be the basis for continuing the author's use of [SurgiMend] while treating new patients and following these accomplished cases.

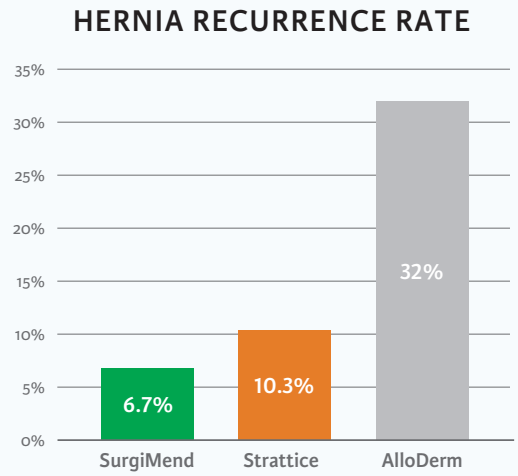
6. Lineaweaver W. Improvement of success rates for abdominal component reconstructions using bovine fetal collagen. Ann Plast Surg. 2012;68(5):438-441. doi:10.1097/SAP.0b013e31824bd75c.

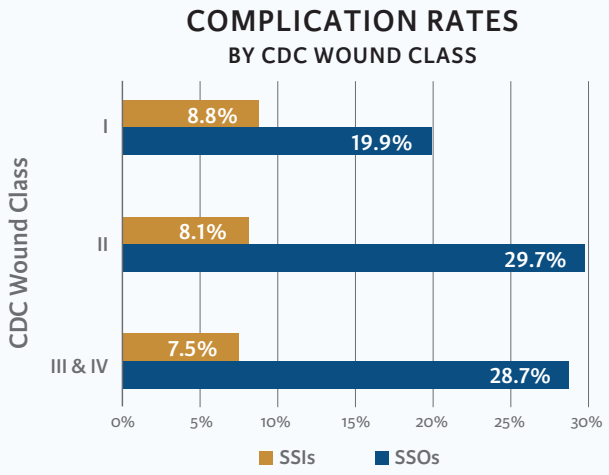
Outcomes of AWR with ADM are not Affected by Wound Contamination[7] *Garvey et al. 2014*

SUMMARY

This large, retrospective study of 359 patients found a low (1%) explantation rate and no increase in complications with increasing CDC wound classification with biologic mesh. This contrasts with reports of synthetic mesh showing progressively higher complications with increasing CDC class.

RESULTS



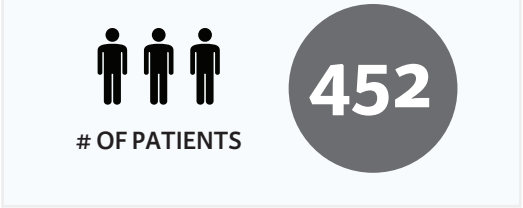


7. Garvey PB, Martinez R a., Baumann DP, Liu J, Butler CE. Outcomes of Abdominal Wall Reconstruction with Acellular Dermal Matrix Are Not Affected by Wound Contamination. J Am Coll Surg. 2014;219(5):853-864. doi:10.1016/j.jamcollsurg.2014.06.021.

Hospital Readmission Following Open, Single-Stage, Elective AWR Using ADM Affects Long-term Hernia Recurrence Rate[8] *Giordano et al. 2018*

SUMMARY

This large, retrospective study of more than 450 patients (187 SurgiMend patients) who underwent large complex AWR with biologic mesh (SurgiMend and Strattice) found that the 30 day readmission rate, although low overall (6.4%), was correlated with increased hernia recurrence with long-term follow-up. Surgical site occurrence (SSO) is the most common cause for readmission.



Post-Op Outcomes For AWRs Using ADMs

Patient Readmission Status	Hernia Recurrence Rate
Non-Readmitted	9.9%
Readmitted	17.2%

The use of biologic mesh rather than synthetic mesh reduce complications and hernia recurrence rates after AWR, particularly in complex and contaminated cases.

8. Giordano SA, Garvey PB, Baumann DP, Liu J, Butler CE. Hospital readmission following open, single-stage, elective abdominal wall reconstructions using acellular dermal matrix affects long-term hernia recurrence rate. Am J Surg. 2018. doi:10.1016/j.amjsurg.2018.01.072.

SurgiMend for AWR: Key Published Clinical Data at a Glance

STUDY TITLE	AUTHOR(S)	YEAR OF PUB.	REPAIR TECHNIQUE	VHWG*/ MODIFIED VHWG GRADE	HERNIA RECURRENCE RATE	FOLLOW-UP	# PATIENTS	# SURGIMEND PATIENTS	OTHER ADMs USED	PAGE #
Hospital Readmission Following Open, Single-Stage, Elective AWR Using ADM Affects Long-term Hernia Recurrence Rate[8]	**Giordano et al.**	2018	Underlay with Anterior Component Separation (ACS)	I, II, III, IV / 1, 2, 3	10.2% including bridged and human ADM	35 months	452	187	Strattice, AlloDerm	7
Primary Fascial Closure with Biologic Mesh Reinforcement Results in Lesser Complication and Recurrence Rates than Bridged Biologic Mesh Repair for AWR: A Propensity Score Analysis[4]	**Giordano et al.**	2017	Underlay with ACS	II, III, IV / 2, 3	6.2% excluding bridged repairs	30.5 +/- 22.3 months	535	223	Strattice, AlloDerm	5
Long-term Outcomes after AWR with ADM[1]	**Garvey et al.**	2016	Intraperitoneal underlay with component separation	II, III, IV / 2, 3	6.4% at 3 years, and 8.3% at 5 years (excluding bridged and human ADM)	4.4 years	191	60	Strattice, AlloDerm	3
Long-term Outcomes of Sandwich Ventral Hernia Repair (SVHR) Paired with Hybrid Vacuum-Assisted Closure (HVAC)[5]	**Hicks et al.**	2016	Sandwich Technique for bridged repair: SurgiMend underlay; polypropylene onlay	II, III, IV / 2, 3 (93.4%)	13.3%	12 months	60	60	polypropylene (permanent synthetic)	6
Outcomes of AWR with ADM are not Affected by Wound Contamination[7]	**Garvey et al.**	2014	Underlay with ACS	I, II, III, IV / 1, 2, 3	6.2-6.5% excluding bridged repairs	28.1 +/- 19.1 months	359	135	Strattice, AlloDerm	7
Bovine versus Porcine ADM for Complex AWR[2]	**Clemens et al.**	2013	Underlay with ACS	II, III, IV / 2, 3	3.9%	21 months	120	51	Strattice	4
Primary Fascial Closure with Mesh Reinforcement is Superior to Bridged Mesh Repair for AWR[3]	**Booth et al.**	2013	Underlay with ACS	II, III, IV / 2, 3	56% bridged, 8% primary fascial closure (18% Strattice, 32% AlloDerm, 5.8% SurgiMend)	31 months	222	69	Strattice, AlloDerm	5
Improvement of Success Rates for Abdominal Component Reconstructions Using Bovine Fetal Collagen [Surgimend][6]	**Lineaweaver**	2012	ACS	Not specified	7%	18 months	15	15	None	6
								Total Number of SurgiMend Patients	**800**	

*Ventral Hernia Working Group

Indications: SurgiMend is intended for implantation to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. SurgiMend is specifically indicated for: 1. Plastic and reconstructive surgery, 2. Muscle flap reinforcement, and 3. Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias

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United States, Canada, Asia, Pacific, Latin America
USA 877-444-1122 ▪ 866-800-7742 fax
International +1 617-268-1616 ▪ +1 617-268-3282 fax
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