



# Complex ventral hernia repair with a human acellular dermal matrix and component separation: A case series



Alvaro Garcia\*, Anthony Baldoni

General Surgery and Abdominal Wall Reconstruction Center of South Florida, 17900 NW 5th St., Suite 201, Pembroke Pines, FL 33029, USA

## HIGHLIGHTS

- Intraoperative placement of acellular dermal matrix using component separation.
- Acceptable recurrence rates of 16% at 2 years of follow up.
- Correlation in age and complication chances.
- Retrorectus technique possibly the best surgical technique for hernia repair.

## ARTICLE INFO

### Article history:

Received 4 December 2014  
Received in revised form  
30 June 2015  
Accepted 6 July 2015

### Keywords:

Ventral hernia repair  
Allograft  
Biologic mesh  
FlexHD acellular dermis  
Human acellular dermis  
Abdominal wall reconstruction

## ABSTRACT

We present a case series of 19 patients requiring complex abdominal hernia repairs. Patients presented with challenging clinical histories with 95% having multiple significant comorbidities including overweight or obesity (84%), hypertension (53%), diabetes (42%), cancer (26%), and pulmonary disease (16%). The majority of patients (68%) had prior abdominal infections and 53% had at least one failed prior hernia repair. Upon examination, fascial defects averaged 282 cm<sup>2</sup>. Anterior and posterior component separation was performed with placement of a human acellular dermal mesh. Midline abdominal closure under minimal tension was achieved primarily in all cases. Post-operative complications included 2 adverse events (11%) – one pulmonary embolism and one post-operative hemorrhage requiring transfusion; 6 wound-related complications (32%), 1 seroma (5%) and 1 patient with post-operative ileus (5%). Operative intervention was not required in any of the cases and most patients made an uneventful recovery. Increased patient age and longer OR time were independently predictive of early post-operative complications. At a median 2-year follow-up, three patients had a documented hernia recurrence (16%) and one patient was deceased due to unrelated causes.

**Conclusion:** Patients at high risk for post-operative events due to comorbidities, prior abdominal infection and failed mesh repairs do well following component separation reinforced with a human bioprosthetic mesh. Anticipated post-operative complications were managed conservatively and at a median 2-year follow-up, a low rate of hernia recurrence was observed with this approach.

© 2015 The Authors. Published by Elsevier Ltd on behalf of IJS Publishing Group Limited. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

## 1. Background

Patients with complex hernias present surgeons with significant technical challenges. Over the past decade, a better understanding of abdominal wall anatomy, physiology and pathophysiology of hernia formation has resulted in the development of new surgical

approaches focused on restoration of the midline and abdominal wall functionality, protection of intra-abdominal viscera, and the prevention of hernia or bulge formation post-operatively [1].

First introduced 25 years ago by Ramirez [2], over the past decade the technique of component separation has come to the forefront with clinicians presenting the approach as a means to achieve primary abdominal closure under minimal abdominal tension in difficult cases. The addition of mesh to reinforce the repair has been shown to decrease hernia recurrence rates [3–5].

In recent years, a number of new prosthetic materials and surgical techniques have been introduced to address challenging hernias and most publications report series with variable

\* Corresponding author.

E-mail addresses: [alvarogarciamd@gmail.com](mailto:alvarogarciamd@gmail.com) (A. Garcia), [baldoni.anthony@gmail.com](mailto:baldoni.anthony@gmail.com) (A. Baldoni).

URL: <http://www.alvarogarciamd.com>

approaches and mesh materials.

Early literature suggests that the placement of synthetic mesh runs a high risk of infection requiring subsequent removal and/or hernia recurrence [6,7]. Biologic mesh, suggested as an alternative for use in infected fields, has been associated with a high rate of long-term laxity and recurrence [8–16].

With no randomized prospective trials reported, the heterogeneous nature of existing studies, specifically differences in patient characteristics, mesh selection and surgical approach, appears to contribute significantly to the wide range of post-operative outcomes [17]. Surgeons are left struggling to draw conclusions related to optimal surgical technique and mesh selection.

Over the past several years, the authors have selected open component separation reinforced with a human acellular dermal mesh (Flex HD Musculoskeletal Transplant Foundation, Edison, NJ) to treat patients with complex abdominal wall defects. To assess the validity of our preferred approach, we prospectively studied a cohort of high-risk patients from our practice, treated in the same facility by a single surgeon.

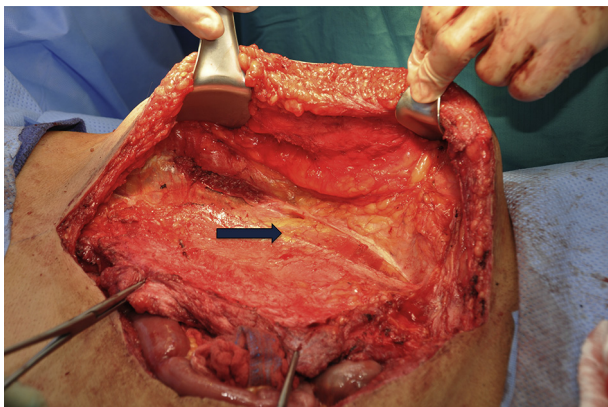
## 2. Methods

This is a prospective review of 19 consecutive high-risk patients, 8 males and 11 females, with large hernias repaired between July 2011 and July 2013. Prior to surgery, a detailed clinical assessment including a CT scan and cardiopulmonary evaluation was performed.

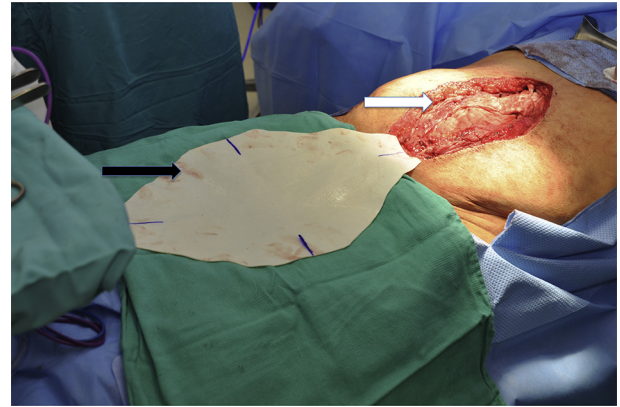
### 2.1. Surgical technique

Abdominal wall reconstruction was performed, decreasing tension across the midline using anterior and posterior component separation, and achieving primary closure in all cases. Depending on patient anatomy and risk profile, a selective periumbilical perforator sparing technique was used, particularly when the likelihood of skin necrosis was high.

Bilateral anterior component separation (Fig. 1) with intraperitoneal placement of a non-crosslinked human acellular dermal biologic mesh (FlexHD, Musculoskeletal Transplant Foundation, Edison, NJ) and midline closure was performed in the first 15 cases. The mesh, placed as an intraperitoneal underlay was prepared by delineating the four quadrants prior to implantation (Fig. 2). Using 1.0 PDS suture (Ethicon, Somerville, NJ), the mesh was secured to the anterior abdominal wall with interrupted vertical mattress stitches



**Fig. 1. Anterior component separation technique:** the aponeurosis of the external oblique muscle is incised to 1–2 cm lateral to the lateral border of the rectus abdominus muscle as indicated by the arrow. The anterior component separation is performed bilaterally to decrease abdominal wall tension during subsequent midline closure.



**Fig. 2. Preparation of the mesh:** to ensure proper size and placement, the mesh is measured and each of the quadrants marked prior to its introduction into the abdominal cavity (white arrow). In this figure we show the new diamond shape mesh (FlexHD® Diamond™).

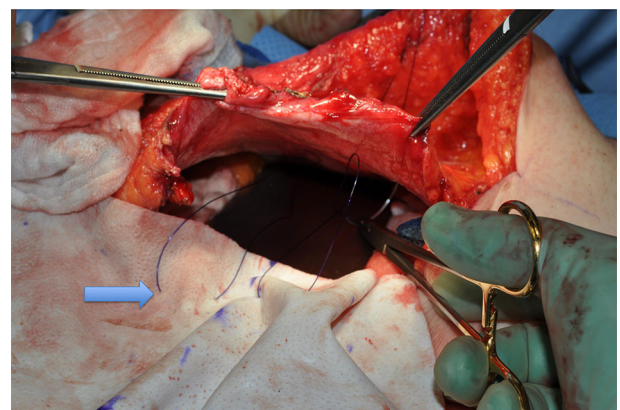
placed circumferentially to provide support and prevent small bowel entrapment (Fig. 3).

In the more recent 4 cases, posterior component separation (Fig. 4), involving release of the posterior sheet of the rectus muscle and preserving the abdominal wall innervation and epigastric circulation, was performed as described by Pauli and Rosen [18]. In these cases, the biologic mesh was placed within the retrorectus space with overlap of at least 10 cm on each side of the midline and fixed in position with transfascial sutures (Fig. 5).

Following evaluation of mesh placement, midline approximation and debridement of the midline fascia was performed to obtain a well vascularized linea-alba. The midline was closed with running double loop 1.0 PDS suture. When posterior component separation was performed, the posterior fascia was closed using interrupted figure 8 1.0 vicryl sutures (Ethicon, Somerville, NJ) and the anterior fascia closed as described above.

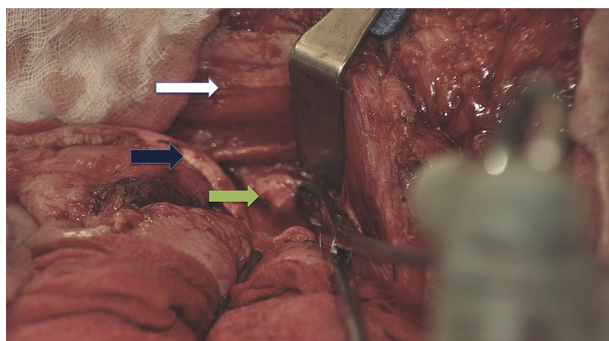
During the course of this series, a newly shaped mesh, FlexHD® Diamond™ was introduced. This shape was used in last 7 cases of our series. With a larger surface area due to its rhomboid shape, the surgeons found that it offered enhanced abdominal wall coverage and reduced operative time as no intraoperative shaping was required prior to use.

To minimize the risk of seroma and bleeding, meticulous hemostasis was performed and Evice!® fibrin sealant (Ethicon, Somerville, NJ) and five grams of Arista®AH, a sterile, absorbable

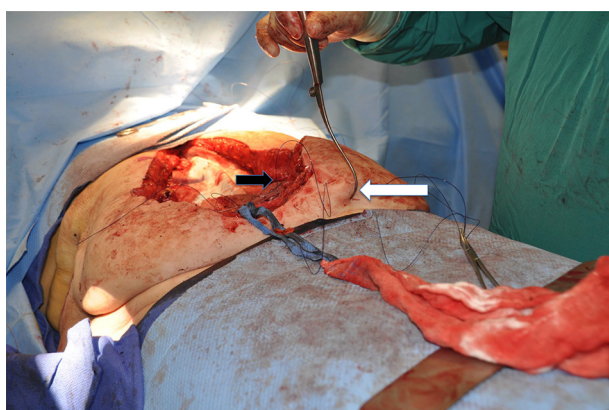


**Fig. 3. Intraperitoneal placement of human acellular dermal matrix:** this figure shows the U-stitch that is placed through the abdominal wall to the mesh and back to the abdominal wall (see arrow).





**Fig. 4. Posterior component separation:** in this figure the right angle retractor is placed in the internal oblique aponeurosis while it is divided (green arrow). The blue arrow represents the posterior rectus sheet together with the transverse abdominis muscle. The white arrow indicates the rectus muscle seen inferiorly.



**Fig. 5. Mesh fixation:** the fixation of the mesh transfacially is accomplished by inserting the Reverdin needle (white arrow) percutaneously through the skin, subcutaneous tissue and anterior fascia and picking the stitches previously placed in the mesh in a U fashion (black arrow).

hemostatic powder (*Medafor, Inc. Minneapolis MN*) was administered. Two No. 19 closed-suction round drains were placed percutaneously and secured to the skin with 3.0 Nylon sutures (*Ethicon, Somerville, NJ*). A subcuticular closure was performed with Quill 3.0 Monoderm (*Angiotech Pharmaceuticals, Inc. Vancouver, BC Canada*). Drains were removed after 7–10 days and/or when the output was less than 20 cc daily.

Post-operative follow-up was scheduled at 2 weeks and subsequent 6 month intervals. The abdominal wall was assessed clinically and if there was any sign of hernia recurrence, a CT scan of the abdomen was performed.

## 2.2. Statistical analysis

Patient demographics, pre-existing medical comorbidities and surgical histories were collected prior to surgery. Following hernia repair, intraoperative characteristics, surgical techniques, short and longer-term outcomes, and reported complications were assessed. Data were summarized using descriptive statistics (means and standard deviation for continuous variables; count and frequency for categorical variables). Patient demographics and preoperative and intraoperative characteristics associated with increased post-operative complication risk were analyzed using the Mann–Whitney U test (for continuous variables) or Fisher exact test (for categorical data). Logistic regressions were conducted to identify preoperative and intraoperative variables predictive of major and

minor complications. Because of the small sample size, Firth's penalized likelihood method was used to reduce sample bias in maximum likelihood estimation [19]. The results of the univariate analysis were used to identify candidate variables for multivariate modeling. Because of the relatively small cohort of patients ( $n = 19$ ), the multivariate analysis was limited to only include variables with  $p < 0.1$  in the univariate analysis. Based on the results of the univariate analysis, only one multivariate model with two independent variables (age and OR time) was performed for the minor complication outcome. Our post-hoc power analysis indicated that our sample size will yield an  $R^2$  of 0.32 in the univariate regression model and an  $R^2$  of 0.38 with two independent variables in multivariate analysis with 80% power. All statistical analyses were performed using SAS 9.4 statistical software (*SAS Inc., Cary, NC*).

## 3. Results

### 3.1. Patient demographics

Nineteen consecutive patients, detailed in Table 1, underwent hernia repair with bilateral component separation and intraperitoneal and retrorectal placement of FlexHD® or FlexHD® Diamond™, human acellular dermal matrix mesh using an open abdominal approach. The cohort included 11 females and 8 males with mean patient age of 54.9 (range 41–76 yrs) and mean body mass index (BMI) of 29 kg/m<sup>2</sup> (range 21.0–37.9). Besides large clinically significant abdominal wall hernias, patient histories included an array of chronic health conditions listed in Table 2. All patients had at least one pre-existing comorbidity, with 95% having two or more. The most common comorbidities included BMI >25 (84%), hypertension (53%), and diabetes mellitus (42%).

### 3.2. Clinical presentation

Ten patients (52%) had failed prior hernia repair, six of whom had two prior recurrences. Thirteen patients (68%) had prior infections with 42% having a history of perforated bowel. Four patients (21%) presented with stomas. Patients were categorized using the Ventral Hernia Working Group classification system which is based upon risk factors for surgical site occurrences [17]. The majority of patients in our series, 42%, were Grade 3 with 36% categorized as Grade 2 and 21% Grade 4. Baseline characteristics of the cohort are detailed in Table 2.

### 3.3. Operative course

Upon entry into the abdomen, lysis of adhesions and removal of prior mesh implants was carried out as necessary. Upon inspection, the mean fascial defect to be repaired was  $282 \pm 70.5$  cm<sup>2</sup> (range 150–450) and the associated mean surface area of the biologic mesh we used to reinforce the repair was  $454.3 \pm 101.1$  cm<sup>2</sup> (range 160–521 cm<sup>2</sup>). Additionally, in two cases, concomitant small bowel resection was required. Mean operative time was  $194 \pm 63$  min (range 127–360 min). Patients generally tolerated the procedure well and returned home after an average length inpatient stay of  $4.6 \pm 1.3$  days (range 2–6). Table 3 summarizes the intraoperative characteristics in the group.

### 3.4. Peri-operative outcomes

The majority (58%) of patients in our cohort had an uneventful recuperative course with no peri-operative complications (within 30 days).

The most frequent peri-operative events, which we consider minor complications, were superficial wound infections in six

**Table 1**  
Detailed demographics, characteristics and outcomes of each individual patients.

Patient#	Demographics					Post operative complication						
	Age (yr)	Sex	BMI (kg/m <sup>2</sup> )	# of comorbidity	Follow-up (month)	Recurrence	Wound infection	Bleeding	Seroma	Ileous	PE	Decease
1	45	F	27.0	1	42	No	No	No	No	No	No	No
2	41	M	34.0	2	24	No	No	No	No	No	No	No
3	45	M	27.0	2	43	No	Yes	No	No	No	No	No
4	76	M	23.0	6	41	No	No	Yes	No	No	No	No
5	75	F	28.0	4	17	No	Yes	No	No	No	No	No
6	49	M	28.5	2	12	Yes	No	No	No	No	No	No
7	45	M	27.5	3	32	No	Yes	No	Yes	Yes	No	No
8	49	F	28.0	4	25	No	No	No	No	No	Yes	No
9	70	M	27.0	5	9	Yes	Yes	No	No	No	No	No
10	43	M	37.9	3	35	Yes	No	No	No	No	No	No
11	51	F	22.2	2	30	No	No	No	No	No	No	No
12	52	F	28.3	2	6	No	No	No	No	No	No	No
13	59	F	33.4	4	12	No	No	No	No	No	No	No
14	40	F	30.0	5	30	No	No	No	No	No	No	No
15	59	F	21.0	3	12	No	No	No	No	No	No	Yes <sup>a</sup>
16	51	M	36.0	2	24	No	No	No	No	No	No	No
17	59	F	35.0	2	25	No	No	No	No	No	No	No
18	80	F	28.0	2	23	No	Yes	No	No	No	No	No
19	55	F	41.0	3	11	No	Yes	No	No	No	No	No

<sup>a</sup> Patient died of pulmonary fibrosis unrelated to the surgery.

**Table 2**  
Baseline characteristics of the 19 patients in the series.

Characteristics	N	%
<b>Demographics</b>		
Age (yr), [mean ± sd]	54.9 ± 12.3	
BMI (kg/m <sup>2</sup> ), [mean ± sd]	29.6 ± 5.3	
Gender (female), %	11	57.9
<b>Comorbidity</b>		
Any pre-existing comorbidity	19	100.0
- with 1 pre-existing comorbidity	1	5.3
- with 2 or more pre-existing comorbidity	18	94.7
Smoking	1	5.3
Overweight or obese (BMI ≥ 25 kg/m <sup>2</sup> )	16	84.2
Diabetes	8	42.1
HTN	10	52.6
CAD	1	5.3
History of cancer	5	26.3
COPD	3	15.8
On steroid	2	10.5
Renal failure	1	5.3
Rheumatoid arthritis	1	5.3
GERD	1	5.3
Hypothyroidism	1	5.3
<b>Clinical characteristics</b>		
Previous recurrence	10	52.6
- with one previous recurrence	4	21.1
- with two previous recurrence	6	31.6
Previous infection	13	68.4
Hernia grade ≥ 3	12	63.2
1	0	0.0
2	7	36.8
3	8	42.1
4	4	21.1

patients (32%). Additionally one seroma and one post-operative ileus, both occurring in a patient with a wound infection, were noted. Of the six wound infections, three were resolved with a course of oral antibiotics and the other 3 were treated in the office with incision and drainage of the wound. The one instance of seroma formation occurred several weeks after surgery. The seroma was drained under ultrasound at an office follow-up visit with complete resolution. Two patients experienced major complications; one developing a pulmonary embolism who was placed on six months of anti-coagulant therapy and the other with a hemorrhage requiring transfusion. Both patients recovered without further incident. Patient outcomes are summarized in [Table 4](#).

**Table 3**  
Intra-operative patient characteristics.

Characteristics	N	%
Mesh removed	6	31.6
Ostomy present	4	21.1
H/O perforated bowel	8	42.1
Size of defect (cm <sup>2</sup> ), [mean ± sd]	282 ± 79	
Defect ≥ 300 cm <sup>2</sup>	8	42.1
<b>Surgical techniques</b>		
Underlay	7	36.8
Underlay/Overlay	4	21.1
Diamond underlay	4	21.1
Retrorectus	4	21.1
Mesh area (cm <sup>2</sup> ), [mean ± sd]	454 ± 95	
Area ≥ 500 cm <sup>2</sup>	12	63.2
Perforator sparing	7	36.8
OR time (min), [mean ± sd]	194 ± 63	
Length of stay (day), [mean ± sd]	5.3 ± 3.2	

Our series included highly complex cases. As an example, late in the series, an obese 80 year old female with 20 year history of recurrent hernia, presented with an enterocutaneous fistula, stoma and loss of abdominal domain ([Figs. 6 and 7](#)). Component separation using a retrorectus approach was performed. The patient experienced post-operative wound infection but the biologic mesh remained intact. At 18 months follow-up, a CT scan demonstrated an intact abdominal cavity with no evidence of hernia (Also see [Videos 1 and 2](#)).

The patient has fully recovered and a subsequent abdominal CT scan, performed relative to other medical conditions, revealed no evidence of recurrence.

Supplementary video related to this article can be found at <http://dx.doi.org/10.1016/j.amsu.2015.07.002>.

Video 1 and Video 2: Video 1 shows the pre-operative CT scan. Video 2 shows the 18 month follow up CT scan of the reconstruction of the abdominal wall with retrorectus repair and intermuscular mesh placement.

### 3.5. Post-operative follow-up

Nearly half (47%) of our patients are >2 years post-treatment with patients followed for a median of 24 months post-repair (range 6–43 months). One patient expired one year after surgery as

**Table 4**  
Postoperative follow-up details.

Complications	N	%
<b>Median follow-up time (month)</b>	24 month	
< 1 yr	3	15.8
1–2 yr	7	36.8
2–3 yr	6	31.6
3–4 yr	3	15.8
<b>Post-operative complications</b>		
Superficial wound infection	6	31.6
- Wound infection needing ID	3	15.8
Seroma requiring drainage	1	5.3
Post-operative ileus	1	5.3
Post-operative flap bleeding requiring transfusion	1	5.3
Pulmonary embolism	1	5.3
Recurrence	3	15.8
Death <sup>a</sup>	1	5.3
<i>Patient with no complications</i>	11	57.9

<sup>a</sup> 1 patient died of pulmonary fibrosis unrelated to surgery.



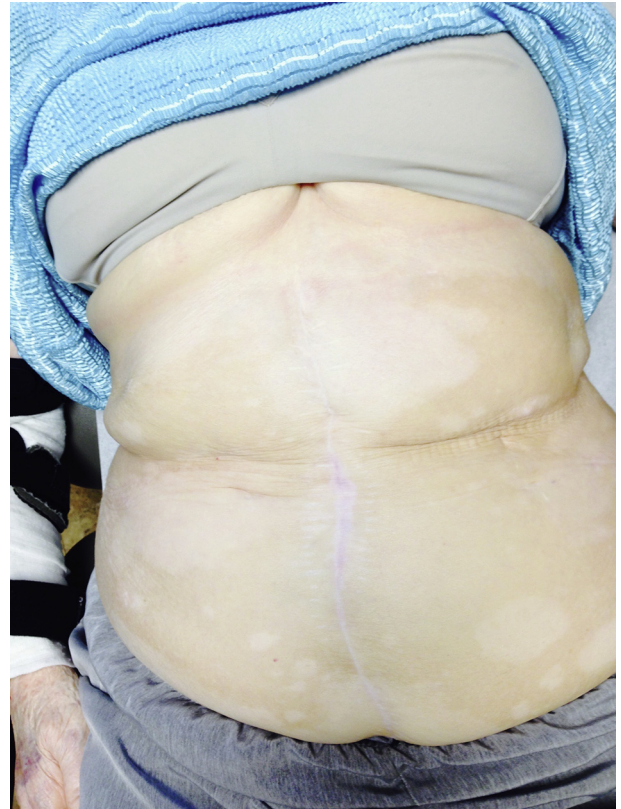
**Fig. 6.** 80 yo female with a 20 year history of recurrent hernia presenting with an enterocutaneous fistula, stoma and loss of abdominal domain.

a result of pulmonary fibrosis unrelated to her hernia repair. Three recurrences (17%) were confirmed among the remaining 18 patients.

The first recurrence occurred in a 70 year old male who had a lengthy operation with removal of prior synthetic mesh implant. A peri-operative MRSA infection was cultured from one of his drains which responded well to local incision and drainage followed by antibiotic therapy. At 9 months following his repair, he developed bulging and an asymptomatic defect in the upper part of his abdomen. Of note was his clinical history of a severe MRSA infection and septic shock occurring after a previous hernia repair. For health reasons, the patient was advised to undergo no further procedures unless medically necessary.

The second recurrence was seen 12 months post-procedure in a very active 49 year old male who routinely plays basketball. Similar in nature to the first recurrence, an asymptomatic bulge was appreciated in his upper abdomen. The patient declined a repeat hernia repair and is being followed clinically.

The third recurrence was observed at 35 months follow-up. In this patient, the recurrence was noted in the inferior aspect of the wound. He returned for repeat surgery and a retrorectus repair was performed without any subsequent complications. Upon return to the OR, we found some of the original mesh, which was placed intraperitoneally, was loose within the peritoneal cavity. From observation, it appears that poor mesh integration inferiorly may have been a contributing factor to this recurrence.



**Fig. 7.** Follow-up at 18 months after posterior component separation reinforced with ADM in the retrorectus space.

### 3.6. Regression analysis

To assess potential predictors of complication outcomes, we have grouped patient complications into major complications (including bleeding requiring transfusion and pulmonary embolism) and minor complications (including superficial wound infection, seroma requiring drainage and ileus). [Table 5](#) summarizes the results of univariate logistic regression analysis. Older age (OR = 1.07, 95% CI 1.02–1.17,  $p = 0.0483$ ) and longer OR time (OR = 1.02, 95% CI 0.99–1.04,  $p = 0.0945$ ) were associated with higher risk of minor complications at  $p < 0.1$ . In the subsequent multivariate analysis including only age and OR time, however, only age remained a significant predictor of post-operative complications (OR = 1.12, 95% CI 1.06–1.32,  $p = 0.0324$ ). No other variables were found to be predictive of recurrence or postoperative complications.

## 4. Discussion

Understanding the underlying causes and variables associated with negative outcomes is critical so that efforts can be made to avoid landmines when a complicated operative path lies ahead. Since the early 1960s, the surgical community has sought to perfect hernia repair, and has been particularly challenged by complex cases when infection was present or anticipated.

Over time, studies have demonstrated mesh reinforced repairs offer superior outcomes versus primary repair [20]. However, synthetic meshes can have significant complications and negative outcomes. An alternative was sought with desirable material characteristics including biocompatible, soft and flexible when implanted, infection resistant, and strong enough to withstand



**Table 5**  
Univariate logistic regression for post-operative complication and recurrence.

Predictor	Recurrence		Major complication		Minor complication	
	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value
<b>Demographics</b>						
Age	0.99 (0.89–1.10)	0.8813	1.05 (0.94–1.18)	0.3668	1.07 (1.02–1.17)	<b>0.0483</b>
BMI	1.07 (0.85–1.35)	0.5856	0.79 (0.52–1.19)	0.2595	1.01 (0.84–1.21)	0.9413
Gender (female)	0.07 (0.01–1.82)	0.1089	0.70 (0.04–13.2)	0.8117	0.63 (0.09–4.40)	0.6369
<b>Comorbidity (%)</b>						
Number of comorbidity	1.25 (0.50–3.09)	0.6309	4.56 (0.77–27.1)	0.0956	1.15 (0.55–2.40)	0.7047
Overweight or obese	1.81 (0.05–8.39)	0.7477	1.82 (0.34–13.4)	0.2186	4.33 (0.12–15.3)	0.4204
Smoking	1.53 (0.02–15.8)	0.8588	25.1 (0.28–68.2)	0.1499	0.62 (0.01–6.59)	0.8407
Diabetes	3.48 (0.32–37.8)	0.3050	1.77 (0.13–23.7)	0.6666	0.32 (0.03–2.89)	0.3066
HTN	4.63 (0.41–32.9)	0.2151	14.8 (0.52–43.6)	0.1155	1.17 (0.15–8.98)	0.8781
CAD	1.53 (0.02–15.8)	0.8588	25.1 (0.28–68.2)	0.1499	0.62 (0.01–65.9)	0.8407
History of cancer	3.30 (0.23–8.99)	0.4867	20.7 (0.68–63.1)	0.1821	0.58 (0.06–5.72)	0.6376
COPD	0.83 (0.02–41.3)	0.9248	1.24 (0.02–65.4)	0.9154	2.27 (0.12–43.7)	0.5865
On steroid	0.83 (0.02–41.3)	0.9248	1.24 (0.02–65.4)	0.9154	2.27 (0.12–43.7)	0.5865
Renal failure	1.53 (0.02–15.8)	0.8588	25.1 (0.28–68.2)	0.1499	0.62 (0.01–65.9)	0.8407
Rheumatoid arthritis	1.53 (0.02–15.8)	0.8588	2.27 (0.02–24.8)	0.7319	7.26 (0.07–74.3)	0.4007
GERD	19.6 (0.18–72.1)	0.2163	2.27 (0.02–24.8)	0.7319	7.26 (0.07–74.3)	0.4007
Hypothyroidism	19.6 (0.18–72.1)	0.2163	2.27 (0.02–24.8)	0.7319	7.26 (0.07–74.3)	0.4007
<b>Pre-operative</b>						
Previous infection	0.80 (0.07–8.89)	0.8539	0.07 (0.01–1.94)	0.1155	11.3 (0.42–30.3)	0.1494
Previous recurrence	0.48 (0.05–4.98)	0.5338	0.14 (0.01–4.02)	0.2529	5.67 (0.62–51.7)	0.1240
<b>Intra-operative</b>						
Mesh removed	1.25 (0.11–13.9)	0.8539	0.35 (0.01–10.8)	0.5510	8.27 (0.93–74.1)	0.1587
Ostomy present	0.40 (0.01–12.9)	0.6035	0.60 (0.02–20.9)	0.7780	2.56 (0.27–24.5)	0.4160
H/O perforated bowel	0.76 (0.07–8.06)	0.8196	0.22 (0.01–6.42)	0.3817	1.55 (0.23–10.6)	0.6579
Hernia grade $\geq 3$	0.55 (0.01–8.39)	0.1779	0.57 (0.04–7.58)	0.6666	1.17 (0.16–8.54)	0.8808
Defect $\geq 300$ cm <sup>2</sup>	2.69 (0.25–28.6)	0.4115	1.40 (0.11–18.5)	0.7982	3.80 (0.51–28.3)	0.1929
<b>Surgical techniques</b>						
Diamond vs. underlay	4.33 (0.28–66.3)	0.2922	6.42 (0.15–26.8)	0.3286	0.94 (0.07–13.6)	0.9656
Underlay/Overlay vs. underlay	0.48 (0.01–21.1)	0.7046	6.42 (0.15–26.8)	0.3286	0.94 (0.07–13.6)	0.9656
Retro vs. underlay	0.48 (0.01–21.1)	0.7046	1.67 (0.02–14.6)	0.8230	2.20 (0.18–27.6)	0.5413
Mesh area $\geq 500$ cm <sup>2</sup>	5.53 (0.20–15.2)	0.3122	3.57 (0.12–14.8)	0.4604	1.17 (0.16–8.54)	0.8808
<b>Perforator sparing</b>						
OR time	0.99 (0.96–1.02)	0.3698	0.99 (0.98–1.02)	0.9466	1.02 (0.99–1.04)	<b>0.0945</b>
Length of stay	0.54 (0.19–1.54)	0.2458	1.02 (0.66–1.58)	0.9307	1.73 (0.82–3.64)	0.1498

Major complication: bleeding requiring transfusion and pulmonary embolism.

Minor complication: superficial wound infection, Seroma requiring drainage, and ileus.

OR = odds ratio; CI = confidence interval.

intra-abdominal pressures allowing patients an active lifestyle without hernia recurrence. When biologic mesh was introduced over a decade ago the hope was that it was the answer to all of these needs. Early experience, primarily cases in which the first allograft dermal matrix (ADM) available was placed as a bridge across large abdominal defects, reported significant recurrent bulging at follow-up [12,13]. Many biologic mesh products have followed including other allografts and a range of xenograft derived materials. Each is manufactured using different processing techniques. Recent literature suggests that ADM biologic mesh should be the material of choice when encountering wound infections and contamination [21].

In addition to a plethora of new mesh options, new surgical techniques for abdominal wall reconstruction have emerged. Few studies exist evaluating these advances in controlled settings and recently some have suggested that operative technique may have more influence on outcomes than mesh selection, but that has not been demonstrated in a systematic manner [22]. Thus, surgical approach and mesh selection remain a matter of surgeon preference with no definitive data to conclusively support one over another. After reviewing the literature along with personal surgical outcomes, the authors now choose to repair complex hernias using an open abdominal component separation reinforced with a non-crosslinked human acellular dermal mesh, FlexHD. While we have used the rectangular shape in some cases, when available, we prefer to use the diamond shape which allows

for wider anatomic coverage. As has been reported, we believe tension-free closure of the midline is critical to achieve positive surgical outcomes [23].

While surgeons have control over their operative approach and mesh selection, there are variables which affect outcomes that are beyond a surgeons' scope. It is important, however, for surgeons to understand and recognize these variables and take steps to mitigate their influence over outcomes whenever possible. A number of studies have described an increased risk, reported up to 4× greater, of infection related to individual comorbidities. Analyses have suggested older age, obesity, smoking, coronary artery disease, corticosteroid use, prolonged operative time and pulmonary disease as several independent predictors for infections [24]. Even in our small series, increased age and OR time were found to be statistically independent predictors of minor complications, the majority of which were wound infections.

We saw a low rate of seroma formation (n = 1, 5%), that we speculate is attributed to our surgical protocol which includes use of Evicel fibrin glue, active prophylaxis regimen and the use of large bore drains. Köhler et al. also reported a reduction of seroma formation when Evicel was used. In their series of 60 patients who underwent open ventral hernia repair, half were treated with fibrin glue and the other half served as controls treated without fibrin glue. In addition to a significant reduction in seroma formation, the authors noted a related shorter length of stay in the treatment group [25].

In a review of ventral hernia recurrence, Awad et al. estimated that greater than 75% of all recurrence is due to infection and inadequate repair material fixation and/or overlap [26]. Similarly, in our series, 68% of our recurrences (2 of 3) were patients who experienced a post-operative wound infection. During reoperation for the third recurrence, upon inspection, the authors observed poor biologic integration resulting from suboptimal mesh positioning. Therefore it was our technique, as opposed to the inherent properties of the bioprosthetic, which likely contributed to this negative outcome. During the course of this series, the authors modified our approach and performed a posterior component separation on the final four cases. We placed the FlexHD Diamond mesh in the retrorectus space and to date with 15–25 month follow-up, no recurrences have been seen in these cases.

We believe that our findings are a promising indicator that disproves the perception that all human acellular dermal meshes are an unacceptable choice for complex hernia repair due to a propensity for long-term bulging. Existing literature reviews include a heterogeneous mix of patient sets, biologic mesh materials and surgical techniques [13]. The current study, comprised of complex patients with large hernia repairs reinforced exclusively with FlexHD, showed a clinically acceptable recurrence rate of 16% at a median 2-years follow-up, comparing favorably to similar reports of other biologic and synthetic mesh materials [9,11,26–31]. We are encouraged by this outcome, as the majority of our patients had experienced prior hernia recurrence, putting them at greater risk for future recurrence.

With the population aging and more baby boomers entering their senior years, it is important to consider the inherent risks associated with older patients. We feel age may be an indication for the utilization of a biologic mesh as older patients are inherently prone to higher risk of infection. As identified in our analyses, older age was predictive of minor complications, yet in all cases, these events were resolved without costly operative intervention, extended in-patient care or long term clinical sequelae. We consider these results as suggestive that use of a biologic mesh may reduce the overall cost of care of complex hernias particularly in high-risk older patients. We theorize that long-term savings from the use of biologic mesh may far outweigh their upfront costs in this patient subset. This assumption, of course, must be demonstrated across a larger patient cohort in a well-designed controlled clinical trial.

## 5. Conclusions

There is no clear-cut standard protocol to treat patients who present with complex abdominal wall defects. Surgeons need to evaluate individual patient characteristics and have an understanding of anatomy and various mesh materials in order to select the most appropriate operative course.

Our series demonstrates that an open component separation reinforced with a human biologic mesh, FlexHD, and complete midline closure is a safe, viable approach that achieves desirable short and mid-term outcomes. Patients in our series were at high risk for post-operative infection due to comorbidities or prior infection and did quite well with follow-up beyond 2 years.

Continued long-term assessment of this cohort is planned and a controlled prospective trial directly comparing our current technique and the Rives Stoppa technique with different mesh materials is being considered.

## 6. Limitations

We recognize the limitations of our series, specifically, the small number of cases, non-randomization and lack of a control group.

While the technique described here produced outcomes which are comparable or better than other experiences reported in the literature, controlled studies to compare specific surgical approaches and mesh materials and assess clinical outcomes are needed and would further contribute to the existing body of knowledge on use of reinforcing matrices in complex hernia repair.

## Ethical approval

No ethical approval was required for this case series.

## Funding

Some funding was provided for the statistical analysis of the data from the Musculoskeletal Transplant Foundation.

## Author contribution

Both authors have contributed in the design, data collection, as well as writing and editing the paper.

## Conflict of interest statement

Dr. Alvaro Garcia works as a consultant and lectures on behalf of MTF (Musculoskeletal Transplant Foundation) the tissue bank which processes FlexHD, and is also participating in a multicenter prospective trial sponsored by MTF ([www.mtf.org](http://www.mtf.org)). Dr. Anthony Baldoni has no conflict of interest.

## Guarantor

Alvaro Garcia, MD.

## Acknowledgments

The authors recognize and thank Edward Wang, PhD who reviewed our data and performed all statistical analyses. Dr. Wang's insights and assistance in the preparation of this paper are greatly appreciated.

## References

- [1] J.M. Sacks, J.M. Broyles, D.P. Baumann, Considerations in abdominal wall reconstruction, *Semin. Plast. Surg.* 26 (1) (2012) 5–7.
- [2] O.M. Ramirez, E. Ruas, A.L. Dellon, Components separation method for closure of abdominal-wall defects: an anatomic and clinical study, *Plast. Reconstr. Surg.* 86 (1990) 519–526.
- [3] T.S. de Vries Reilingh, H van Goor, C. Rosman, et al., Components separation technique for the repair of large abdominal wall hernias, *J. Am. Coll. Surg.* 196 (1) (2003) 32–37.
- [4] J.H. Ko, E.C. Wang, D.M. Salvay, B.C. Paul, G.A. Dumanian, Abdominal wall reconstruction: lessons learned from 200 “components separation” procedures, *Arch. Surg.* 144 (11) (2009) 1047–1055.
- [5] T.S. Satterwhite, S. Miri, C. Chung, D. Spain, H.P. Lorenz, G.K. Lee, Outcomes of complex abdominal herniorrhaphy: experience with 106 cases, *Ann. Plast. Surg.* 68 (4) (2012) 382–388.
- [6] D. Maman, D. Greenwald, J. Kreniske, A. Royston, S. Powers, J. Bauer, Modified Rives-Stoppa technique for repair of complex incisional hernias in 59 patients, *Ann. Plast. Surg.* 68 (2012) 190–193.
- [7] E.T. Alicuben, S.R. Demeester, Onlay ventral hernia repairs using porcine non-cross-linked dermal biologic mesh, *Hernia* (2013), <http://dx.doi.org/10.1007/s10029-013-1054-2>.
- [8] V. Shankaran, D.J. Weber, R.L. Reed, F.A. Luchette, A review of available prosthetics for ventral hernia, *Ann. Surg.* 253 (1) (2011) 16–26.
- [9] N.J. Slater, M. van der Kolk, T. Hendriks, H. va Goor, R.P. Bleichrodt, Biologic grafts for ventral hernia repair: a systematic review, *Am. J. Surg.* 205 (2013) 220–230.
- [10] J.M. Souza, G.A. Dumanian, Routine use of a bioprosthetic mesh is not necessary: a retrospective review of 100 consecutive cases of intra-abdominal midweight polypropylene mesh for ventral hernia repair, *Surgery* 153 (3) (2013) 393–399.
- [11] H. Nasajpour, K.A. LeBlanc, M.H. Steele, Complex hernia repair using

- component separation technique paired with intraperitoneal acellular porcine dermis and synthetic mesh overlay, *Ann. Plast. Surg.* 66 (3) (2011) 280–284.
- [12] R. Schuster, J. Singh, B.Y. Safadi, S.M. Wren, The use of acellular dermal matrix for contaminated abdominal wall defects: wound status predicts success, *Am. J. Surg.* 192 (5) (2006), 594–597.
- [13] S.B. Glasberg, R.A. D'Amico, Use of regenerative human acellular tissue (AlloDerm) to reconstruct the abdominal wall following pedicle TRAM flap breast reconstruction surgery, *Plast. Reconstr. Surg.* 118 (1) (Jul 2006) 8–15.
- [14] N.J. Slater, M. van der Kolk, T. Hendriks, H. va Goor, R.P. Bleichrodt, Biologic grafts for ventral hernia repair: a systematic review, *Am. J. Surg.* 205 (2013) 220–230.
- [15] J.E. Janis, A.C. O'Neill, J. Ahmad, T. Zhong, S.O. Hofer, Acellular dermal matrices in abdominal wall reconstruction: a systematic review of the current evidence, *Plast. Reconstr. Surg.* 130 (5 Suppl. 2) (2012) 183S–193S (abstract).
- [16] N.A. Kissane, K.M. Itani, A decade of ventral incisional hernia repairs with biologic acellular dermal matrix: what have we learned? *Plast. Reconstr. Surg.* 130 (5 Suppl. 2) (2012) 194S–202S (abstract).
- [17] M. Cevasco, K.M. Itani, Ventral hernia repair with synthetic, composite, and biologic mesh: characteristics, indications, and infection profile, *Surg. Infect. Larchmt* 13 (4) (Aug 2012) 209–215.
- [18] E.M. Pauli, M.J. Rosen, Open ventral hernia repair with component separation, *Surg. Clin. North Am.* 93 (5) (2013) 1111–1133, <http://dx.doi.org/10.1016/j.suc.2013.06.010> (epub 2013 Jul 25).
- [19] G. King, L. Zeng, Logistic regression in rare events data, *Polit. Anal.* 9 (2001) 137–163.
- [20] Ventral Hernia Working Group, K. Brueing, et al., Incisional ventral hernias: review of the literature and recommendations regarding the grading and technique of repair, *Surgery* 148 (3) (2010) 544–558.
- [21] P.B. Garvey, R.A. Martinez, D.P. Baumann, J. Liu, C.E. Butler, Outcomes of abdominal wall reconstruction with acellular dermal matrix are not affected by wound contamination, *J. Am. Coll. Surg.* 219 (5) (2014) 853–864.
- [22] J. Jin, M.J. Rosen, J. Blatnik, M.F. McGee, C.P. Williams, J. Marks, J. Ponsky, Use of acellular dermal matrix for complicated ventral hernia repair: does technique affect outcomes? *J. Am. Coll. Surg.* 205 (5) (2007) 654–660.
- [23] M.N. Basta, J.P. Fischer, S.J. Kovach, Assessing complications and cost-utilization in ventral hernia repair utilizing biologic mesh in a bridged underlay technique, *Am. J. Surg.* 209 (4) (2015) 695–702 (epub 2014 Jul 11).
- [24] K.R. Finan, C.C. Vick, C.I. Kiefe, L. Neumayer, M.T. Hawn, Predictors of wound infection in ventral hernia repair, *Am. J. Surg.* 190 (2005) 676–681.
- [25] G. Köhler, O.O. Koch, S.A. Antoniou, M. Lechner, F. Mayer, K. Emmanuel, Prevention of subcutaneous seroma formation in open ventral hernia repair using a new low-thrombin fibrin sealant, *World J. Surg.* 38 (11) (2014) 2797–2803.
- [26] Z.T. Awad, V. Puri, K. LeBlanc, et al., Mechanisms of ventral hernia recurrence after mesh repair and a new proposed classification, *J. Am. Coll. Surg.* 201 (2005) 132–140.
- [27] L. Heller, C. Chike-Obi, A.S. Xue, Abdominal wall reconstruction with mesh and components separation, *Semin. Plast. Surg.* 26 (1) (2012) 29–35.
- [28] W.H. Hope, D. Griner, A. Adams, W. Borden Hooks, T.V. Clancy, Use and indications of human acellular dermis in ventral hernia repair at a community hospital, *Plast. Surg. Int.* (2012), <http://dx.doi.org/10.1155/2012/918345>.
- [29] J.J. Diaz Jr., A.M. Conquest, S.J. Ferzoco, D. Vargo, P. Miller, Y.C. Wu, R. Donahue, Multi-institutional experience using human acellular dermal matrix for ventral hernia repair in a compromised surgical field, *Arch. Surg.* 144 (3) (2009) 209–215.
- [30] K. Hood, K. Millikan, T. Pittman, M. Zelhart, B. Secermisky, M. Rajan, J. Meyers, M. Luu, Abdominal wall reconstruction: a case series of ventral hernia repair using the component separation technique with biologic mesh, *Am. J. Surg.* 205 (2013) 322–328.
- [31] R. Candage, K. Jones, F.A. Luchette, J.M. Sinacore, D. Vandevender, R.L. Reed 2nd, Use of human acellular dermal matrix for hernia repair: friend or foe? *Surgery* 144 (4) (2008) 703–709.