HHS Public Access

Author manuscript

Am Surg. Author manuscript; available in PMC 2015 August 01.

Published in final edited form as:

Am Surg. 2014 August ; 80(8): 725–731.

Component Separation with Porcine Acellular Dermal Reinforcement Is Superior to Traditional Bridged Mesh Repairs in the Open Repair of Significant Midline Ventral Hernia Defects

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Abstract

The optimal technique for complex ventral hernia repair (VHR) remains controversial. Component separation (CS) reinforced with porcine acellular dermal matrix (PADM) has shown favorable results compared with series of conventional bridged VHR, but few comparative studies exist. We conducted a retrospective cohort study comparing 40 randomly selected patients who underwent CS/PADM reinforcement against an identical number of patients who underwent conventional open VHR with mesh at our institution. Patient characteristics, operative findings, outcomes, complications, reoperations, and recurrences were obtained by chart review. Fisher's exact/*t* test compared outcomes between the two cohorts. Statistical significance was set as $P < 0.05$. Mean follow-up was 33.1 months. Patient groups did not differ significantly in race ($P = 1.00$), age ($P = 0.82$), body mass index ($P = 0.14$), or comorbid conditions (smoking, chronic obstructive pulmonary disease, obesity, steroid use; *P* values 0.60, 0.29, 0.08, and 0.56, respectively). Defect size was greater in the CS/PADM group (mean, 372.5 *vs* 283.7 cm^2, $P = 0.01$) as was the percentage Ventral Hernia Working Group Grade III/IV hernias (65.0 *vs* 30.0%, $P = 0.03$). Recurrences were lower in the CS/PADM group (13.2 *vs* 37.5%, $P = 0.02$). Mesh infection was lower in the CS/PADM group (0 *vs* 23% in the bridged group, $P = 0.002$), all of which occurred with synthetic mesh. Indications for reoperation (recurrence or complications requiring reoperation) were also lower in the CS/PADM group (17.5 *vs* 52.5%, $P = 0.002$). Superior results are achieved with CS/PADM reinforcement over traditional bridged VHR. This is evidenced by lower recurrence rates and overall complications requiring reoperation, particularly mesh infection. This is despite the greater use of CS in larger defects and contaminated hernias (VHWG Grade III and IV). CS/PADM reinforcement should be strongly considered for the repair of significant midline ventral hernia defects.

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Presented at the Annual Scientific Meeting and Postgraduate Course Program, Southeastern Surgical Congress, Savannah, GA, February 22–25, 2014.

Ventral hernia repair (VHR) represents a major clinical challenge to practicing surgeons with approximately 350,000 repairs performed yearly in the United States.[1] Debate continues within the surgical community as to the optimum technique for repair and the best choice of material—biologic or synthetic—for reinforcement of the repair.[2–4] Despite the widespread nature of the problem and the controversies surrounding it, the literature has ultimately failed to definitively answer these key questions. The available published data tend to favor the use of component separation with primary fascial reapproximation and mesh reinforcement of the repair as the repair of choice.[2, 3, 5–8] However, the majority of published case studies are retrospective, single-institutional case series involving an analysis of results using a specific technique or mesh product.[2, 3, 6] Few studies exist, however, that provide a head-to-head comparison of the results of the different available repairs and meshes.

The following study involves a single-institutional experience comparing the results of two commonly used techniques of VHR: that of component separation reinforced with noncrosslinked porcine acellular dermal matrix (PADM) *versus* a similar cohort who underwent repair through a traditional bridged technique using either synthetic or biologic mesh.

Methods

This was a retrospective analysis of two patient populations aged 18 years or older who underwent VHR at Charleston Area Medical Center (CAMC) between January 1, 2006, to December 31, 2012, through either 1) conventional bridged VHR using synthetic or biological mesh; or 2) component separation (CS) with noncrosslinked PADM (Strattice™; Lifecell™, Branchburg, NJ) reinforcement (CS/PADM). All aspects of the study were reviewed and approved by the CAMC/West Virginia University, Charleston Division Institutional Review Board.

Patients for the study were identified by *Current Procedural Terminology (CPT)* codes. For the conventional VHR cohort, patients were identified using *CPT* codes of primary ventral hernia (49560), strangulated ventral hernia (49561), and recurrent ventral hernia (49565) combined with the implantation of mesh (49568). For the CS group, these codes were used as was the additional code 15734 for trunk, open-component separation repair. Patients who underwent laparoscopic VHR, nonmidline VHR, or umbilical or inguinal hernia repair were excluded. We identified 40 patients who received CS/PADM in the time period who met the inclusion criteria. An equal number of patients who received conventional bridged VHR during the study period were randomly selected using the random sample generator capability of the statistical program, IBM-SPSS, Version 19. Patients were not matched because we intended to examine differences in patient and hernia characteristics between the two treatment cohorts.

The operative technique for the CS group involved the development of subcutaneous flaps and the performance of an anterior external oblique release as described by Ramirez et al.[9] After the release was performed, a piece of PADM was placed intra-abdominally as an underlay with a minimum fascial overlap of 5 cm and secured with nonabsorbable mattress

sutures placed 2 cm apart. The fascia was then approximated in the midline using a running nonabsorbable suture, drains were placed, and the skin edges were trimmed 3 to 5 cm and closed. Drains were maintained until the daily output was less than 30 mL. Of note, specific perforator-sparing techniques (such as endoscopic CS or periumbilical-sparing techniques) were not used in our practice during the study period, but have since been adopted at our institution as a result of their lower incidence of wound-related complications.[10–12]

For the conventional bridged VHR group, all patients underwent placement of an intra-abdominal underlay with a minimum fascial overlap of 5 cm. The prosthesis, the choice of which was left to the operating surgeon, was secured with circumferential nonabsorbable mattress sutures placed 2 cm apart. The fascia was not reapproximated over the mesh. Drains were placed and maintained until the daily output was less than 30 mL.

Information on patient characteristics (age, race), pre-existing comorbidities (chronic obstructive pulmonary disease [COPD], steroid use, obesity, current smoking), operative technique, mesh type, defect size, Ventral Hernia Working Group grade,[13] previous abdominal surgeries including previous VHRs, and any concomitant procedures (for example, bowel resection, ostomy takedown, or mesh explantation) were obtained by review of hospital and physician office medical records.

Defect size was determined based on the intraoperative measurement of the defect after operative exposure of its full extent and was calculated in square centimeters using standard geometric formulas based on the width, length, and shape of the defect. Obesity severity was classified based on patients' body mass index (BMI) as follows: nonobese (BMI less than 30.0 kg/m^2), Class I obesity (BMI 30.00 to 34.99 kg/m^2), Class II obesity (BMI 35.00 to 39.99 kg/m^2), Class III obesity (BMI 40.00 kg/m^2 or greater).

Our primary outcomes of interest were VHR failure, defined by both ventral hernia recurrence and subsequent need for reoperation (subsequent surgical rerepair, extensive wound débridement, or mesh explantation). Recurrence was diagnosed based on the impression of the clinician's most recent physical examination or by imaging evidence (computed tomography scan) if available. Other endpoints included the incidence of any postoperative complications, including enterocutaneous fistula development, surgical site occurrences (SSOs), including surgical site infection (SSI, including mesh infection), and noninfectious SSO such as seroma, hematoma, or wound dehiscence/necrosis in the perioperative period. For purposes of standardization, the Ventral Hernia Working Group definitions of SSO/SSI were used to determine the incidence of these complications in the perioperative period.[13] Mesh infection, however, was considered a manifestation of SSI regardless of when it occurred.

Data Analysis

Continuous variables were summarized using means and standard deviations, and categorical variables were summarized with frequencies and percentages. Fisher's exact and *t* test analyses were used to compare patient characteristics and outcomes between the two cohorts. Statistical significance was set as $P < 0.05$ and the analysis was performed using IBM-SPSS™, Version 19.

Results

Of the 40 CS/PADM repairs, complete reapproximation of the midline fascia was accomplished in 35 patients, whereas five repairs required partial bridging of a residual defect after partial fascial closure. Strattice™ was used exclusively in this group.

In the conventional bridged VHR group, 26 patients received synthetic mesh and 14 patients received biological mesh. Of the 26 patients in the bridged group who received synthetic mesh, 14 underwent implantation of Proceed™ (Ethicon, Cincinnati, OH), four received Sepramesh™ (Davol™, Warwick, RI), five received Composix™ (Davol™), and three received Ventralight™ (Davol™). Of the 14 patients in the conventional bridged VHR group who received biologic mesh, eight received Strattice™, four received Collamend™ (Davol™), and two received Alloderm™ (Lifecell™).

The two VHR cohorts did not differ in age ($P = 0.09$) or race ($P = 1.00$) (Table 1). The prevalence of comorbidities (current smoking, COPD, and steroid use) were not significantly different between the two groups ($P = 0.64$, 1.000, and 1.00, respectively). Patient distribution of obesity severity also did not differ between the two cohorts ($P = 0.13$).

Overall, the CS/PADM cohort had more complicated ventral hernia defects as evident by a greater percentage of patients having contaminated or potentially contaminated hernias (VHWG Grade 3 or 4, $P = 0.003$). Patients in the CS/PADM group were also more likely to have had at least one previous VHR when compared with the conventional bridged group (62.5% CS/PADM *vs* 32.5% bridged VHR, $P = 0.01$). The defect size was significantly larger in the patients receiving CS/PADM repair (372.5 ± 92.9 cm^2; range, 160 to 720 cm^2) when compared with the conventional VHR group (283.7 ± 185.8 cm^2; range, 36 to 780 cm^2) ($P = 0.01$) (Table 1). In addition, 82.5 per cent of the patients in the CS/PADM group underwent a concomitant procedure performed at the time of VHR *versus* 32.5 per cent of patients in the bridged VHR group ($P < 0.001$) (Table 2).

Overall rates of postsurgical wound complications (SSO and SSI) did not differ between the conventional and CS/PADM groups (Table 3). Noninfectious SSOs (hematoma, seroma, and wound necrosis/dehiscence) were more common in the CS group, but this failed to reach statistical significance ($P = 0.10$). However, mesh infections were significantly less frequent in the CS/PADM group (0 *vs* 11.5% in the conventional VHR group, $P = 0.002$) with eight of the nine infections in the conventional VHR group occurring in patients who received synthetic mesh (four Composix™, three Proceed™, one Ventralight™). All eight of the synthetic mesh infections required explantation of the prosthesis. The ninth patient with mesh infection in the conventional VHR group had undergone placement of Alloderm™, which was able to be salvaged without explantation. Again, no mesh infections occurred in the CS/PADM group.

The median patient follow-up time was 33.1 months (range, 5 to 88 months). The CS/PADM group had significantly lower rates of VHR failure, defined as hernia recurrence or complications requiring rerepair, than the conventional bridged VHR patients (17.5 *vs* 52.5%, $P < 0.01$). Ten patients had complications attributed to VHR that required surgical

repair, two in the CS/PADM cohort and eight patients in conventional VHR ($P = 0.10$). All eight repairs for conventionally treatments patients involved explantation of infected meshes that occurred anywhere from two weeks to three years post-VHR. In the CS/PADM cohort, one reoperation was the result of the acute development of abdominal compartment syndrome in the perioperative period, and the other involved reoperation for repair of a missed enterotomy. In both patients, the reoperation occurred during the index admission and involved converting the original CS to a conventional bridged VHR. Therefore, although these complications were included in the data analysis, these two patients were not included in the long-term follow-up of the CS/PADM cohort because they were in fact discharged from the hospital with a conventional VHR. Therefore, 78 patients were available for long-term follow-up. Of the 78 patients available, 20 patients had recurrence of ventral hernia, the incidence of which was significantly higher in the conventional VHR group (37.5%) when compared with the CS/PADM group (13.2%, $P = 0.02$) (Table 4).

Discussion

Ventral hernia repair remains a major challenge for surgeons in practice today. It is estimated that 10 to 20 per cent of laparotomies result in a midline ventral hernia, which subsequently result in approximately 350,000 ventral hernia repairs performed annually in the United States,[1] thereby creating a substantial burden on the healthcare system. Ventral hernia repair historically has been plagued by high recurrence rates and significant complication rates. A variety of repair techniques and types of mesh used for hernia reinforcement have evolved over the past three decades; however, no clear consensus exists among surgeons as to the best approach for repair of midline ventral hernia and as to which mesh for reinforcement is most appropriate in a given circumstance.[2–8, 13, 14]

In 2000, the results of a randomized, prospective trial were published in which patients were randomized to either undergo primary suture repair of their ventral hernia defect or to undergo a repair using a synthetic polypropylene mesh placed as an intra-abdominal underlay in a bridged fashion. The results were strongly in favor of the use of synthetic mesh with a 24 per cent recurrence rate at three years *versus* a 43 per cent recurrence in the primary suture repair group.[15] Although this study did make a strong case for the use of mesh, the recurrence rate was still quite high, a finding made even more impressive by the fact that the study was composed of largely healthy patients with a maximum defect size of 6 cm and an average defect area of 30 cm.[2, 15] Furthermore, the use of intraperitoneal uncoated synthetic mesh has been linked to significant complications, including infection, obstruction, and enterocutaneous fistula formation.[16] As a result of these complications, polypropylene composite meshes were developed that used a posterior layer of expanded polytetrafluoroethylene or similar material to serve as a barrier between the anterior layer of polypropylene and the underlying viscera. These composite meshes, however, were plagued by higher rates of mesh infection[17] and have largely fallen out of favor. Our results are supportive of this, because eight of the nine mesh infections (11.5% of all synthetic meshes placed in the series of bridged repairs) occurred in patients who received a composite synthetic mesh, all of which required mesh explantation.

The high incidence of mesh-related complications and the high recurrence rates with bridged synthetic mesh led to a resurgence of interest in autologous tissue repair. Component separation, originally described by Ramirez et al.[9] in 1990, involves the creation of subcutaneous flaps to allow division of the external oblique tendon bilaterally and thereby permitting the fascia to be reapproximated in the midline. Recent series involving reinforcement of the component separation repair with either synthetic or biologic mesh have demonstrated improvement in recurrence rates over previously published series of unreinforced repairs[2, 3, 5–8, 10] and with overall recurrence rates that are improved over historical series with bridged repairs.[5] Our data are supportive of this approach with statistically lower recurrence rates in the CS/PADM group compared with that in the bridged VHR group (13.2 *vs* 37.5%, $P = 0.02$). This was despite the presence of larger defects, more contaminated/potentially contaminated defects (VHWG 3 and 4), concomitant procedures at the time of repair, and a higher likelihood of at least one previous hernia repair. This is exceptionally relevant, because all of these factors have been shown to predict a higher likelihood of complications and hernia recurrence.[3, 18–20]

Although the reinforcement of CS is fairly well accepted as a standard practice among expert hernia surgeons, the choice of mesh and the location of the mesh placement remain controversial. Several authors have advocated the use of lightweight macroporous polypropylene mesh, particularly in the retrorectus position.[2, 21] They cite the lower cost of synthetic mesh when compared with biologics, acceptable recurrence rates, and recent evidence suggesting that the resistance of lightweight macroporous polypropylene meshes to infection is substantially better than that of its heavyweight predecessors.[21] This is felt to be a factor not only of the properties of the lightweight mesh itself, but also the placement of the mesh between two well-vascularized planes of tissue, specifically the retrorectus space.[2, 21] It is noteworthy, however, that patients required mesh explantation in both of these series as a result of infectious complications.[2, 21] Two of 88 VHWG Grade 2 patients in a series by Krpata et al.[2] required mesh explantation and a third developed a chronic draining sinus. Similar results were reported in a series by Carbonell et al.[21] of 100 VHWG Grade 3 and 4 patients treated with lightweight retrorectus synthetic mesh. In their series, four patients required explantation and one developed an enterocutaneous fistula.

Opponents of synthetic mesh cite a high likelihood of selection bias in the published series, possibility of mechanical mesh failure,[22] and the potential cost of downstream synthetic mesh-related complications,[23] because the follow-up in these series is comparatively short.[2, 21] We are unable to draw any conclusions regarding this controversy from our data, because all of our repairs were performed using medium-weight composite meshes in an intraperitoneal position. However, the morbidity related to synthetic mesh use was substantial in our series with a 23 per cent overall infection rate in all synthetic meshes that were implanted. One criticism of CS is a higher reported incidence of SSO, typically related to seroma/hematoma formation or wound dehiscence/necrosis related to the development of extensive subcutaneous flaps.[11, 12] Our results indicated a trend toward higher seroma/hematoma and wound dehiscence/necrosis in the CS group, but these results did not reach statistical significance ($P = 0.10$). Only mesh infection as a manifestation of SSO emerged as a significant difference in wound-related morbidity between the two cohorts, leading us

once again to take a very conservative position in our practice with respect to the use of synthetic mesh in high-risk situations.

Advocates of noncrosslinked PADM (Strattice™) cite its resistance to infection, decreased adhesion formation, and its ability to act as a scaffold for revascularization and regeneration as well as decreased adhesion formation. Indeed, the use of biologics, specifically noncrosslinked PADM, as a reinforcing material has a well-established track record of safety.[24, 25] Recurrence rates have been variable, however, ranging from 0 to 31.3 per cent with the highest recurrence rates being observed in infected and contaminated fields (VHWG Grade 3 or 4).[3, 5, 6, 8, 11, 18, 20, 26] Based the variability of these reported recurrence rates, the durability of biologic mesh-based repairs has become an area of controversy in the ventral hernia literature. Rosen et al. reported a recurrence rate of 31.1 per cent in a series of 128 patients who underwent a single-stage repair of contaminated ventral hernia using CS/PADM.[20] However, only seven of the 128 patients in the series required reoperation for recurrence in this extremely complicated patient group,[20] which calls into question the clinical significance of the observed recurrences. In our series, 65 per cent of cases were contaminated or potentially contaminated (VHWG Grade 3 or 4), yet our cumulative recurrence rate was 13.2 per cent with no mesh infections. When the recurrence rates of the two cohorts were combined with complications requiring reoperation (such as mesh explantation)—an occurrence we termed “ventral hernia failure”—the results were even more impressive with a 17.5 per cent incidence of failure in the CS/PADM group compared with a 52.5 per cent incidence in the conventional bridged VHR group ($P = 0.002$).

Limitations of this study include its relatively small sample size and its retrospective design. Also, there is a possibility that selection bias may have affected the results. This is unlikely, however, because the CS/PADM cohort had both the best results and the most complicated patients/hernia defects when compared with the traditional bridged VHR group.

Conclusions

The best technique for the repair of midline ventral hernia remains controversial. It appears that CS is superior to bridged repairs, and the use of a reinforcing mesh to buttress the repair is beneficial. Although this series lends credibility to the argument that CS/PADM performs well in the repair of challenging hernias, we acknowledge the need for randomized controlled trials designed to determine the best type of mesh (synthetic *vs* biologic) and location for mesh placement (onlay *vs* retrorectus *vs* underlay) for each specific grade of hernia encountered.

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Table 1

Patient Characteristics

	CS/PADM (n = 40)	Traditional VHR (n = 40)	*P* Value
Demographic data			
Age (years)	59.0 ± 10.7	54.8 ± 11.6	0.09
Race (white)	39 (98%)	38 (95%)	1.00
Comorbidities			
Current smoker	15 (38%)	12 (30%)	0.64
Chronic obstructive pulmonary disease	13 (33%)	12 (30%)	1.00
Steroid use	2 (5%)	1 (3%)	1.00
Obesity classification (kg/m^2)			
Not obese (BMI < 30)	19 (48%)	10 (25%)	0.13
Moderately obese (BMI 30–35)	11 (28%)	11 (28%)	
Severely obese (BMI 35–40)	6 (15%)	11 (28%)	
Morbidly obese (BMI > 40)	4 (10%)	8 (20%)	
Hernia characteristics			
VHWG Hernia Grade 3 or 4	26 (65%)	12 (30%)	0.003
Number of previous abdominal surgeries	3.3 ± 1.8	2.8 ± 1.4	0.25
One or more previous VHR	25 (63%)	13 (33%)	0.01
One or more concomitant procedures	33 (82.5%)	13 (32.5%)	<0.001
Hernia defect size (cm^2)	372.5 ± 92.9	283.7 ± 185.8	0.01

CS, component separation; PADM, porcine acellular dermal matrix; VHR, ventral hernia repair; VHWG, Ventral Hernia Working Group; BMI, body mass index.

Table 2

Concomitant Procedures Performed*

	CS/PADM (n = 40)	Traditional VHR (n = 40)	*P* Value
At least one concomitant procedure performed with VHR	33	13	<0.001
Procedure type			
Explant of old mesh	21 (52.5%)	6 (15.0%)	0.001
Bowel resection	13 (32.5%)	5 (12.5%)	0.06
Parastomal hernia repair	3 (7.5%)	1 (2.5%)	0.62
Colostomy reversal	5 (12.5%)	1 (2.5%)	0.20
Fistula takedown	2 (5.0%)	1 (2.5%)	1.00
Other	8 (20.0%)	4 (10.0%)	0.35

*Other procedures included two cholecystectomies, two enterotomy repairs, gastric stimulator placement, irrigation of an infected aortic graft, inguinal hernia repair and enterotomy repair in the CS/PADM cohort, and salpingo-oophorectomy, two enterotomy repairs, and drainage of intra-abdominal abscess in the traditional VHR cohort.

CS, component separation; PADM, porcine acellular dermal matrix; VHR, ventral hernia repair.

Table 3

Postoperative Wound Complications

Postoperative Wound Complications (SSI/SSO)	CS/PADM (n = 40)	Traditional VHR (n = 40)	*P* Value
Fistula	1 (3%)	1 (3%)	1.00
Wound dehiscence/necrosis, seroma, or hematoma	12 (30%)	5 (13%)	0.10
Surgical site infection	7 (18%)	6 (15%)	1.00
Mesh infection	0 (0%)	9 (23%)	0.002

SSI, surgical site infection; SSO, surgical site occurrence; CS, component separation; PADM, porcine acellular dermal matrix; VHR, ventral hernia repair.

Table 4

Hernia Failure/Recurrence Rates

	CS/PADM (n = 40)	Traditional VHR (n = 40)	*P* Value
VHR failure: recurrence or complication requiring reoperation	7 (17.5%)	21 (52.5%)	0.002
	CS/PADM (n = 38)	Traditional VHR (n = 40)	*P* Value
Hernia recurrence	5 (13.2%)	15 (37.5%)	0.02

CS, component separation; PADM, porcine acellular dermal matrix; VHR, ventral hernia repair.