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Management of the open abdomen with the Abdominal Reapproximation Anchor dynamic fascial closure system

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Abstract

BACKGROUND: With the increased use of damage control surgery and open abdomens, there are growing challenges in achieving primary fascial closure. The purpose of this study was to retrospectively review our experience using the Abdominal Reapproximation Anchor (ABRA; Canica Design Inc, Almonte, Ontario, Canada), a dynamic fascial closure system, to gain fascial apposition in complex abdominal surgical patients.

METHODS: A retrospective review of patients who underwent placement of the ABRA device to aid in abdominal closure was undertaken. Details including age, sex, the reason for an open abdomen, the number of operations, the time to primary closure, the success rate of primary closure, and complications related to the use of the ABRA were analyzed.

RESULTS: Between January 2006 and July 2011, 36 patient charts were identified. The average Acute Physiology and Chronic Health Evaluation II score was 21.9 ± 6.9. There was a mean of 3.1 ± 1.8 laparotomies before ABRA placement for each patient, and the duration of ABRA placement until removal was 10.4 ± 6.1 days. Complete fascial apposition was achieved in 83% of the patients across the entire study and in 91% of the patients in the final 2 years. Component separation was used in 17% of cases. The incisional hernia rate was 13% at 6 months and 11% at 12 months.

CONCLUSIONS: Our use of the ABRA system resulted in an 83% fascial apposition rate, which further improved when experience was taken into account. The incisional hernia rate was acceptable in this complicated patient group. This technique is an excellent addition to a surgeon's armamentarium for complicated abdominal cases that require an open abdomen. Further prospective studies are planned to identify ideal candidates for this technique.

Over the last couple of decades, there has been an increasing rate of damage control surgery used in abdominal trauma, complex abdominal sepsis, and abdominal compartment syndrome. The immediate goal in these cases is to avoid intraoperative coagulopathy, hypothermia, and acidosis—the triad of death.[1,2] Patients now surviving such significant injuries and illnesses are left with an open abdomen and are bound for multiple visits to the operating room with the plan of eventual definitive abdominal closure.

Historically, closure of the open abdomen has posed a major challenge for the surgeon, in particular when and how to achieve closure. It is generally accepted that the traditional approach to an open abdomen with planned ventral hernia and delayed abdominal wall reconstruction is a significant source of morbidity for the patient.[3–5]

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Contrary to the work of others, Cheatham et al's review[4] of the effect of delayed abdominal closure on quality of life argued that although morbidity exists, it may not be severely functionally limiting.

There are a variety of techniques and some commercially available products on the market to help facilitate primary fascial approximation. Examples include static traction devices like the Wittmann Patch (Star Surgical Inc, Burlington, WI) with it's Velco-like (Velcro Industries B.V., Manchester, NH) mesh, zipper patches and older techniques such as towel clip closure, Bogota bag and the silo.[1,6,7] The only dynamic fascial traction device on the market is the Abdominal Reapproximation Anchor (ABRA; Canica Design Inc, Almonte, Ontario, Canada).

The ABRA is a commercially available product with several well-designed and easy-to-use components. When the abdomen is ready for the closure process to begin, the surgical team maps out a perimeter of 5 cm from the wound edge around the entire wound circumference. A modifiable 43 cm $\times$ 30 cm $\times$ 1 mm perforated silicone sheet is placed over the viscera. Graduated silicone elastomers (elastic bands) are passed through all layers of the abdominal wall with a cannulation instrument along the premarked line 5 cm from the wound edge. The elastomers are anchored to the abdominal wall with plastic "button anchors," which adhere to the abdominal skin with a self-adhesive spongy backing. Mirror image elastomer anchor placement is achieved on the contralateral abdominal wall pulling the elastomer through the center of the wound to the opposing skin surface. Elastomer alignment is maintained in the center of the wound with a tubular silicone retainer, which has slits to secure the elastomers in place as they are stretched between opposing wound edges. Once all elastomers and anchor buttons are in place, they are tightened such that the black calibration markers on the elastomers are stretched to roughly 2 times their original length. A negative pressure wound therapy device is then placed over the apparatus in the wound between the free skin edges. The wound edges are steadily brought into apposition by adjusting the elastomers regularly such that the graduated markings continue to be stretched to twice their original length. The great benefit of the ABRA over other techniques is that these approximating moves can be made outside of the operating room without deconstructing the device itself. This is done at the bedside in the intensive care unit with the assistance of a nurse such that the surgeon need only be present for the tightening, which takes less than 5 minutes. The negative pressure wound therapy device is removed, and the elastomers are tightened, after which the Vacuum Assisted Closure (VAC; KCI, San Antonio, TX) is replaced. The viscera remain completely protected by the silicone sheet. Once the ABRA is applied initially, the patient has no need to return to the operating until final closure unless there are unforeseen reasons to do so.

There is currently no consensus as to what constitutes optimal management of the open abdomen.[8,9] Limited outcomes research on the ABRA prompted this retrospective study to review our experience with the device in combination with the wound VAC in complex open abdominal management.[10–12] Our primary research question was to determine the rate of primary fascial closure achieved by the ABRA when combined with the VAC in patients managed with an open abdomen. The secondary question involved identifying the frequencies of component separation, skin grafts, and reherniation among patients managed with this technique.

Methods

This retrospective observational study was based out of Royal Columbian Hospital, New Westminster, British Columbia, Canada. After approval from the Fraser Health Research Ethics Board, chart reviews were performed to identify patients who met the following inclusion criteria: a minimum age of 19 years, laparotomy with staged surgical closure using the ABRA in conjunction with the VAC, and surgery between January 2006 and July 2011 by a group of 6 surgeons. The sole exclusion criterion was death before definitive fascial closure. Detailed demographic and clinical data were collected for each patient.

Given the descriptive rather than inferential nature of the primary research question, a statistically based power calculation was not necessary. The analysis of demographic and clinical data consisted of univariate descriptive statistics for all measures including summary statistics such as means, medians, and proportions for continuous, ordinal, and categoric data. Exploratory cross-tabulation of the proportion of patients having complete fascial apposition with skin grafts and reherniation was also performed. Chi-square tests were performed to identify statistically significant differences in proportion. Bivariate analysis using the chi-square test for categoric variables and the Mann-Whitney U test for continuous variables were conducted to identify demographic and clinical characteristics that may be associated with successful fascial closure. A P value of .05 was considered significant.

Results

A study population of 36 patients was established through chart reviews. One participant died after primary closure and was therefore included in the study. Demographic and clinical characteristics of the population are presented in Table 1, which shows a predominance of male (81%) and obese patients (body mass index [BMI] $\geq 25 = 73$) with high Acute Physiology and Chronic Health Evaluation II (APACHE II) scores. Table 2 presents the pathologic categorization and corresponding rate of fascial apposition within each group. This table shows a clear trend toward more successful fascial apposition rates in trauma patients (100%) and 2 other subsets of pathology. However, these subgroups were small, with only 9 trauma patients. Table 3 reveals proportions of secondary outcomes and their relationship with

Table 1 Subject characteristics

Characteristic	
N	36
Demographic characteristics	
Age, y (mean ± SD)	58.5 ± 15.8
Sex	
Males, n (%)	29 (81%)
Females, n (%)	7 (19%)
Weight, kg (mean ± SD)	82.1 ± 17.0
Height, m (mean ± SD)	1.7 ± .08
BMI	
Normal (<25), n (%)	8* (27%)
Overweight/obese (≥25), n (%)	22* (73%)
Missing, n	6
Trauma, n (%)	9 (25%)
Surgical/clinical characteristics	
APACHE II score (mean ± SD)	21.9 ± 6.9
Number of laparatomies to ABRA placement (mean ± SD)	3.1 ± 1.8
Time from first laparatomy to ABRA placement, days (mean ± SD)	11.9 ± 10.0
Time from placement to ABRA removal, days (mean ± SD)	10.4 ± 6.1

SD = standard deviation.
*Relative percentages given missing data for 6 patients.

complete fascial apposition. Rates of component separation and skin grafts were 17% and 8%, respectively. In this category, incisional hernia rates were 13% at 6 months and 11% at 12 months of 23 and 18 patients, respectively, seen at the follow-up. The only statistically significant relationships were those of component separation ($P < .01$) and the presence of a residual wound ($P < .05$) being associated with a lack of primary fascial closure. There were only 2 instances of documented superficial skin breakdown associated with the button anchors.

The bivariate analysis displayed in Table 4 reveals the association between patient and clinical characteristics with fascial closure. The only statistically significant parameter was a shorter average time period from the placement to the removal of the ABRA ($P < .001$). Finally, Table 5 shows primary abdominal closure rates across the duration of the entire study versus those in the final 2 years, with a trend toward better outcomes in the later years.

Table 2 Pathologic classification and respective rate of fascial apposition

Reason for open abdomen	n	Fascial apposition	%
Trauma	9	9	100
General abdominal pathology	6	6	100
Pancreatobiliary pathology	4	4	100
Large bowel pathology	6	5	83
Small bowel pathology	4	3	75
Other	2	1	50
Vascular	5	2	40
Total	36	30	83

Comments

When faced with the dilemma of an open abdomen, primary fascial closure is preferable to planned ventral hernia because the former results in fewer complications for patients.[13] Our study represents the largest case series on complex open abdominal management using the ABRA reported in the literature to date. Primary fascial apposition was achieved in 83% of patients.[11,12] In this respect, our efforts to gain primary fascial approximation with the ABRA plus the VAC are consistent with other research on this subject.[11,12]

Definitive fascial closure rates of 61% and 88% were reported in the only existent ABRA-specific case series in the current literature. These were slightly smaller studies of 23 and 18 patients, respectively.[11,12] In comparison, primary closure rates of 55% to 100% have been reported with a variety of other techniques including the modified VAC and the Wittmann patch.[6,7,14]

Other authors have also explored specific patient and clinical factors associated with successful and expedited primary fascial approximation including exposure to neuromuscular blocking agents, the use of negative pressure wound therapy, and direct peritoneal resuscitation.[15–18] We found a significant association between primary fascial approximation and a shorter duration of ABRA placement to removal. The median duration of application was 7 days in those who were primarily closed versus 17 days in those lacking primary fascial apposition ($P < .001$). Similarly, the 100% primary fascial closure rate reported in the study by Cothren et al[14] was associated with an average time to closure of 7½ days. For these reasons, we recommend aggressive tightening of the elastomers to obtain closure as soon as possible.

In our series, an increased closure rate was also observed in certain subsets of pathology. One hundred percent fascial apposition was achieved in a group of 9 trauma patients, comprising one quarter of our study population. Similarly, Mentula[9] described that nontraumatic etiologies of open abdomens are associated with a lower likelihood of primary fascial closure and higher complication rates.

Another patient characteristic that often plays into operative strategy is BMI. This parameter was missing for 6 of our patients. All remaining patients with a normal BMI had primary closure, whereas only 68% of overweight or obese patients had primary closure. This finding was not significant in bivariate analysis. We found no absolute BMI cutoff above which the ABRA could not achieve primary fascial apposition. In fact, the patient with the greatest BMI (36 kg/m^2) in our series was closed primarily. Only more experience with the ABRA will answer questions on the relevance of BMI to primary closure.

There was a trend toward higher APACHE II scores in those who were primarily approximated although this trend was not statistically significant. This cannot be explained

Table 3 Cross-tabulations of complete fascial apposition with secondary outcomes

Secondary outcomes	Fascial apposition (n = 30)	No fascial apposition (n = 6)	*P* value
Component separation, %	0	6 (100)	<.01
No component separation, %	30 (100)	0	
Residual wound, %	3 (10)	3 (50)	.045
No residual wound, %	27 (90)	3 (50)	
Skin graft, %	2 (7)	1 (17)	.43
No skin graft, %	28 (93)	5 (83)	
Incisional hernia at 6 months, %	3 (16)	0	1.00
No incisional hernia at 6 months, %	16 (84)	4 (100)	
Incisional hernia at 12 months, %	2 (13)	0	1.00
No incisional hernia at 12 months, %	14 (88)	2 (100)	

solely by the fact that several of the trauma patients had high scores. Many patients with nontraumatic etiologies of abdominal pathology also had APACHE II scores in the 30s. At this stage, there is no clear explanation for this trend.

Interestingly, those who received primary closure also had a longer median time from the first laparotomy to the placement of the ABRA. It is possible that in these very sick patients the surgical team was even more judicious in clearing abdominal contamination before beginning the closure process with the ABRA.

Patient characteristics are important variables; however, surgeon experience also affects outcomes. In the final 2 years of the study, a pattern emerged of an increased rate of primary abdominal wall closure (91%) compared with the average rate across all 4½ years (83%). This trend was believed to be caused by a number of factors. In our early experience with the ABRA, there was no established recommended positioning for button anchor–elastomer complexes with respect to the distance from the wound edge and the proximity of 1 complex to the next. After trial and error, the optimal position from the wound margin seemed to be 5 cm, which left adequate room for VAC application. We also established that an interanchor distance of 3 cm was consistently effective. With this elastomer configuration away from the wound edge, fascial health and integrity are preserved, avoiding traumatization in the region of ultimate closure. This may, in part, have contributed to our improved success with ABRA over time.

One great benefit of the ABRA is the reduced operating room time and associated costs given the capacity to adjust the device on the floor, drawing the fascial edges into gradual approximation. At the inception of ABRA use at the Royal Columbian Hospital, the surgical team waited 72 hours between elastomer tightenings. Although no strict protocol was developed, the adjustment interval was hastened every 24 to 48 hours as the team gained confidence in this dynamic system's capabilities over time. Additionally, in earlier years, the patients were frequently extubated before definitive closure. We now advocate for patients to remain intubated to facilitate closure when it is reasonable to do so.

Table 4 Bivariate analyses of demographic and clinical factors associated with fascial apposition

	Fascial apposition (n = 30)	No fascial apposition (n = 6)	*P* value*
Categoric variables			
Sex, n (%)			
Females	6 (20)	1 (17)	1.00
Males	24 (80)	5 (83)	
BMI			
Normal (<25), n (%)	8 (32)	0	.29
Overweight/obese (≥25), n (%)	17 (68)	5 (100)	
Continuous variables			
Age (median)	56.5	70	.11
APACHE II score (median)	21.5	17.0	.09
Number of laparatomies to ABRA placement (median)	3.0	2.5	.52
Time from first laparatomy to ABRA placement, d (median)	10.0	7.0	.69
Time from placement to ABRA removal, d (median)	7.0	17.0	<.001

**P* value for chi-square tests for categoric variables and the Mann-Whitney *U* tests for continuous variables.

Table 5 Overall outcomes compared with outcomes in the latter 2 years of the study

Outcomes	January 2006–July 2011 n = 36	January 2009–July 2011 n = 21
Complete fascial apposition, n (%)	30 (83)	19 (91)
Component separation, n (%)	6 (17)	2 (10)
Residual wound, n (%)	6 (17)	3 (14)
Skin graft, n (%)	3 (8)	2 (10)
Incisional hernia, n (%)		
At 6 months	3 (13)	1 (6)
Number of patients seen at the follow-up	23	16
At 12 months	2 (11)	1 (7)
Number of patients seen at the follow-up	18	14

Management of the complex open abdomen is fraught with complications, but expedited fascial approximation reduces this burden.[13] One research group identified specifically that the number of complications increased if the abdomen had not been closed by day 8 after the original laparotomy.[13] Other work has shown increased abdominal wall herniation and intestinal obstruction associated with a longer median time to closure.[19]

Previous reviews of ABRA use found complications in the way of enterocutaneous fistulae in 9% to 21% and ventral hernias in 26% to 29% of patients.[11,12] There were no enterocutaneous fistulae in our series; however, we did find an incisional hernia rate of 13% and 11% at 6 and 12 months, respectively. Two patients who presented with hernias at follow-up did have wound residuals noted in their charts at the time of closure despite fascial approximation.

Some complications had a significant association with failure to achieve primary closure including the presence of a residual wound ($P = .045$) and the use of component separation ($P < .01$). Component separation was necessary in 17% of patients. Complete primary fascial apposition was not achieved in these cases. Prosthetic mesh was used in 2 of the 6 patients with component separation. This is comparable with Verdam et al's experience with the ABRA in which 2 of 16 patients were treated in a similar fashion with component separation.[12]

Skin pathology is yet another concern in dealing with complex open abdominal wounds. A small number of patients (8%) in our study received split-thickness skin grafting. Two of the 3 skin-grafted patients required grafting despite having complete fascial apposition. The unpublished work of 1 team revealed a decrease in the number of skin grafts in their ABRA group compared with a similar population managed without the ABRA.[20] Skin breakdown and ulceration have also been reported at anchor sites with the ABRA; however, we found only superficial wounds developed occasionally and healed easily without complications.[12] In some instances, bleeding was encountered as the abdominal wall was penetrated during elastomer placement, but this ceased once the device was in place and under tension.

We acknowledge the retrospective nature of our small case series with its inherent bias. Our data are generated from the experience of a single center and only begin to explore the question about ideal candidates for the use of the ABRA. The finding of improved success with experience was a post hoc realization not considered before data analysis. Because of the nature of our ethics approval, we were unable to contact patients if they did not voluntarily attend our clinics for follow-up, which potentially limited hernia detection. Despite these concerns, this study remains the largest case series in the literature to date evaluating ABRA's usefulness.

We are prepared to launch a prospective study to better delineate patient characteristics associated with improved outcomes with the ABRA through the development of a database. Our aim is to establish a more definitive protocol for an aggressive fascial closure schedule involving close coordination with the critical care team. In the meantime, we have found that the ABRA is an excellent tool in the armamentarium of the surgeon managing the open abdomen.

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Discussion

Karen Kwong, M.D. (Portland, OR): There are a plethora of products used to manage open abdomens. As the authors nicely review, there are studies with similar success rates including the dynamic closure Trans Abdominal Wall Traction Wittmann Patch, the Wound VAC alone (which is perhaps the cheapest method), and the ABThera system (KCI, Inc). When there are many products out there, it means that no one has found the best way to address the problem. What factors contributed to your group's use of the ABRA system? Of all the methods and types, what are some hospital and surgeon considerations in choosing one over the other? How does the ABRA system compare in cost or advantages of use? What method had you used before? If one has a good success rate with one of the other methods, should they switch to the ABRA? Table 5 shows an improvement with a learning curve. Were there many different surgeons using the system or was this a single-surgeon experience? What are some of the important factors in placing the system that might have contributed to this? Was there a general protocol for when and how much the surgeons did the tightening of the device, and how does that relate, if at all, to the timing of extubation? How many times, if at all, did patients have to return to the operating room with the ABRA in place before final closure? How is the device tolerated? Were there any skin problems from the anchors? Are there any pitfalls in terms of how you place the tensile materials through the abdominal wall? What considerations would you make or change in techniques if a patient has an ostomy? Although statistically nonsignificant, it is interesting that those who had successful fascial closure on average had higher APACHE II scores, more operations, and longer time until placement of the ABRA. What factors might have contributed to that? Was there a difference between trauma and nontrauma patients or BMI? In your retrospective review, could you see any cutoff of BMI that correlated with an inability to close because all patients with normal BMIs were able to be closed?