



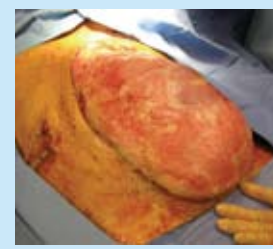
# Early Primary Closure of Open Abdominal Wounds Using the Abdominal Reapproximation Anchor (ABRA) System<sup>®</sup>



Scott M Cinelli DO, Michael J Casey MD, Deborah A Kuhls MD, Timothy D Browder MD, Jay E Coates DO, John J Fildes MD  
University of Nevada School of Medicine, Division of Trauma and Critical Care, University Medical Center of Southern Nevada

### Background

- The Abdomen That Will Not Close
  - Increased hospital resource utilization<sup>1,2</sup>
    - Intensive Care Unit (ICU) & Hospital Stay
    - Operative procedures
    - Disability/Rehabilitation
  - Increased complications<sup>3,4</sup>
    - Hernia: intentional/unintentional<sup>5,6,7</sup>
    - Fistula<sup>3,4,6</sup>
- Techniques of Closure (success)
  - Aggressive fascial closure
    - Primary closure (68% -100%)<sup>8</sup>
    - Serial Abdominal Closure (40-100%)<sup>9</sup>
    - Adhesion barriers (98%)<sup>10</sup>
    - Biologics: Alloderm/Surgisis<sup>11,12</sup>
  - Intentional hernia<sup>3,4,5</sup>
    - Chronic granulation +/- skin graft
    - Skin flap closure +/- mesh<sup>13</sup>
    - Late hernia repair
      - up to 45% wound complications<sup>6</sup>
      - up to 23% recurrence at 13 years<sup>7</sup>
  - Dynamic wound closure (success)
    - Vacuum-Assisted Closure (VAC)<sup>7,8,9</sup>
    - Sequential Closure<sup>2</sup> (100%)
    - Whitman Patch<sup>®</sup> (78%)<sup>14</sup>
- Abdominal Reapproximation Anchor System<sup>®</sup> (ABRA)
  - Urbanik et al. Ann Plast Surg; 2006 (case report)<sup>15</sup>
  - Reimer et al. Can J Surg; 2008<sup>16</sup>
    - Widely varied techniques in 23 patients
    - 61% delayed primary closure
    - 6 Hernias/2 fistulae



### Hypothesis

Use of the ABRA<sup>®</sup> system in open abdominal wounds results in higher primary closure rates and decreased wound-associated complications when compared to a variety of tradition methods of wound closure.

### Methods

- Retrospective review from July 2006 to June 2008
- Two treatment groups:
  - ABRA<sup>®</sup> w/ VAC
  - Comparison group: multiple techniques without ABRA<sup>®</sup>
- Patient data/resource utilization
  - Demographics
  - Number of abdominal operations
  - Injury severity
  - Length of stay
  - Complications (ICD-9)
  - Ventilator days
  - Operative costs based on OR billing
- End-points
  - Primary closure
  - Skin closure with hernia +/- mesh
  - Chronic open wound +/- skin graft
  - Late hernias
- Criteria for ABRA<sup>®</sup>:
  - Fascia cannot be closed after several attempts
  - Earlier if the fascia will clearly not close
  - Surgeon is willing to use the device
- Contraindications:
  - Ongoing intra-abdominal sepsis
  - Ongoing hemodynamic instability
- Statistics
  - Standard T-test for means
  - Comparisons made using two-by-two table analysis
  - Fischer Exact test where appropriate
  - A p value of 0.05 was considered significant

### Key Components of the Abdominal Reapproximation Anchor (ABRA) System<sup>®17</sup>

**Button Anchor, Button Tail and Skin Pad:** enables tension adjustments while distributing force over a wider area and protecting skin from breakdown.

**Silicone Elastomere:** provides the dynamic force that closes the wound. Tension is measured by the indication marks.

**CANICA<sup>®</sup>**

### How it Works<sup>17</sup>

**System Applied: The ABRA<sup>®</sup> Abdominal Wall Closure System** restores the primary closure option for full thickness, retracted midline abdominal defects.

**Post-Op Inflammatory Response Period:** System expands to control wound edges.

**Closure Period: Dynamic re-approximation of muscle/fascia with daily bedside adjustments ("The Move") and reassessment in OR every 2-3 days**

**Fascia Re-approximated:** Over time, the system pulls the muscle planes together under tolerable tension while leaving fascial margins intact and ready to suture for a sound primary closure

**Closure: The ABRA System eliminates the hernia without the need for mesh and re-approximates the skin margins, eliminating the need to graft.**

Urbanik et al. Ann Plast Surg; 2006

### Results

- 67 trauma + 11 general surgery patients
  - 41 pts: early primary fascial closure (closed in 0 - 9 days)
  - 6 died prior to attempted closure
  - 4 complex abdominal wall wounds not amenable to any closure
  - 27 patients uncloseable = Study Cohort
- Two Groups
  - ABRA<sup>®</sup> with VAC Group: 13 pts (11 w/ acute trauma)
  - Comparison Group: 14 pts (13 w/ acute trauma)
    - 11 frozen abdomens (four w/ ECF) - VAC
    - 2 with skin closure over mesh
    - 1 with skin closure over a fascial defect
    - 1 with delayed ABRA closure

Patient Demographics			
Datum	ABRA (n = 13)	Comparison (n = 14)	p-value
Age	47.7	34.1	0.0704
Male	11	13	0.3733
NISS	38.9	37.8	0.8121
ISS	30	27.8	0.6428
RTS	9.8	10.5	0.4340
Abdominal AIS	3.3	3.57	0.5809
APACHE II	20.3 (3 pts)	19 (1 pt)	NA
Crossed Groups	1	1	0.5185

Resource Utilization			
Benchmark	ABRA (n=13)	Comparison (n=14)	p value
Death	1	1	0.5185
Hospital LOS	58.7	68	0.5473
ICU LOS	34.8	33.5	0.8079
Ventilator Days	33.7	27.8	0.3291
Total Complications	100	101	
Mean Complications	7.5	7.1	0.7299

No significant differences in individual ICU complication rates between groups

Patient Outcomes			
Outcome	ABRA (n=13)	Comparison (n=14)	p value
Abd Procedures (before device)	6.8	13.74	0.0376
(after device)	3.4	NA	NA
Days to Any Closure (before device)	3.4	NA	NA
(after device)	15.8	50.1	0.0089
Primary Closure (after device)	8.8	NA	NA
Fistula	7	NA	NA
Skin Graft	12	5	0.0031
Hernia at Follow-up	1	4	0.1611
	0	6	0.0101
	2	8	0.0278

- Single device failure in the ABRA<sup>®</sup> group
  - Blunt abdominal trauma with ISS of 25
  - Hemodynamic instability with myocardial infarction
  - Initially closed with ABRA<sup>®</sup> then reopened
  - Intentional hernia with fistula
  - Closed by granulation and skin graft

- Follow-up was documented in 60% of patients
  - 3 to 24 months
  - 1 ABRA<sup>®</sup> group patient with late ventral hernia underwent repair
  - 2 comparison group patients underwent later hernia repair

- Average operative costs for abdominal wound
  - Total ABRA<sup>®</sup> device cost per patient = \$4,980
  - (average # of procedures x cost range) + device cost
  - ABRA<sup>®</sup> group: (6.8 x (\$2500 to \$7500)) + \$4,980 = \$21,980 to \$55,980
  - Comparison: (13.74 x (\$2500 to \$7500)) + \$0 = \$34,350 to \$103,050

### Conclusions

- ABRA<sup>®</sup> System with Vacuum-Assisted closure:
  - Significant decrease abdominal procedures
  - Significant decrease in days to abdominal closure
  - Significantly higher rates of primary closure
  - Significantly fewer skin grafts
  - Significantly fewer hernias at follow-up
- Other benefits
  - Lower fistula rates
  - Cost of device versus fewer operations
    - Reduced operative costs due to wound
    - Estimated cost reduction of \$12,370 to \$47,070 per patient
- Study Limitations:
  - Selection bias
  - Retrospective design

### Future Directions

- Prospective/Randomized comparisons:
  - Earlier versus later application
  - Recovery and Rehabilitation
  - Late follow-up (hernia, cosmesis)
  - Cost analysis

### References

- Ivatury RR, Nallathambi M, Rohman M, Stahl WM. Open management of the posttraumatic septic abdomen. Am Surg. 1990 Sep;56(9):548-52.
- Cothren CC, Moore EE, Johnson JL, Moore JB, Burch JM. One hundred percent fascial approximation with sequential abdominal closure of the open abdomen. Am J Surg. 2006 Aug;192(2):238-42.
- Miller PR, Thompson JT, Faler BJ, Meredith JW, Chang MC. Late fascial closure in lieu of ventral hernia: the next step in open abdomen management. J Trauma. 2002 Nov;53(5):843-9.
- Miller RS, Morris JA Jr, Diaz JJ Jr, Herring MB, May AK. Complications after 344 damage-control open celiotomies. J Trauma. 2005 Dec;59(6):1365-71.
- Ekeh AP, McCarthy MC, Woods RJ, Walusimbi M, Saxe JM, Patterson LA. Delayed closure of ventral abdominal hernias after severe trauma. Am J Surg. 2006 Mar;191(3):391-5.
- Jernigan TW, Fabian TC, Croce MA, Moore N, Pritchard FE, Minard G, Bee TK. Staged management of giant abdominal wall defects: acute and long-term results. Ann Surg. 2003 Sep;238(3):349-55; discussion 355-7.
- Flum DR, Horvath K, Koepsell TH. Have outcomes of incisional hernia repair improved over time: a population-based analysis. Ann Surg. 2003;237:129-35.
- Barker DE, Green JM, Maxwell RA, Smith PW, Mejia VA, Dart BW, Cofer JB, Roe SM, Burns RP. Experience with vacuum-pack temporary abdominal wound closure in 258 trauma and general and vascular surgical patients. J Am Coll Surg. 2007 May;204(5):784-92.
- Garner GB, Ware DN, Cocanour CS, Duke JH, McKinley BA, Kozar RA, Moore FA. Vacuum-assisted wound closure provides early fascial reapproximation in trauma patients with open abdomens. Am J Surg. 2001 Dec;182(6):630-8.
- Howdieshell TR, Proctor CD, Sternberg E, Cué JI, Mondy JS, Hawkins ML. Temporary abdominal closure followed by definitive abdominal wall reconstruction of the open abdomen. Am J Surg. 2004 Sep;188(3):301-6.
- Scott BG, Welsh FJ, Pham HQ, Carrick MM, Liscum KR, Granchi TS, Wall MJ Jr, Mattox KL, Hirschberg A. Early aggressive closure of the open abdomen. J Trauma. 2006 Jan;60(1):17-22.
- Johnson EK, Paquette EL. Use of surgisis for abdominal wall reconstruction/closure in battlefield casualties during Operation Iraqi Freedom. Mil Med. 2007 Oct;172(10):1119-24.
- Fansler RF, Taheri P, Cullinane C, Sabates B, Flint LM. Polypropylene mesh closure of the complicated abdominal wound. Am J Surg. 1995 Jul;170(1):15-8.
- Weinberg JA, George RL, Griffin RL, Stewart AH, Reiff DA, Kerby JD, Melton SM, Rue LW 3rd. Closing the open abdomen: improved success with Wittmann Patch staged abdominal closure. J Trauma. 2008 Aug;65(2):345-8.
- Urbanik RM, Khuthaila DK, Khalil AJ, Hammond DC. Closure of massive abdominal wall defects: a case report using the abdominal reapproximation anchor (ABRA) system. Ann Plast Surg. 2006 Nov;57(5):573-7.
- Reimer MW, Yelle JD, Reitsma B, Doumit G, Allen MA, Bell MS. Management of open abdominal wounds with a dynamic fascial closure system. Can J Surg. 2008 Jun;51(3):209-14.
- http://www.canica.com/

\* For additional information, please contact Scott Cinelli, DO at scottcinelli@yahoo.com