

ABRA[®] Literature Compendium

Use of ABRA Abdominal, ABRA Surgical, and ABRA Adhesive in Clinical Practice



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The ABRA systems are characterized by their core Dynamic Tissue Systems technology: a proprietary, stretchable, silicone elastomer that leverages the skin's natural physiological processes to facilitate wound closure. By locking into anchors on either side of the wound, these silicone elastomers exert a dynamic appositional force to counteract the wounds' own retracting forces and medialize wound edges.

This dynamic appositional force has been found to facilitate re-approximation and primary closure in a variety of wounds including fixed or frozen wounds and wounds along the midline of the abdomen.

There has been a wealth of clinical research supporting the use of the ABRA systems for controlling, reducing, and closing retracted soft tissue defects. The extensive body of research includes more than 30 clinical, peer-reviewed articles on the various ABRA devices and more than 50 clinical peer-reviewed articles on the use of dynamic force in managing retracted wounds. Some of the most relevant publications regarding the ABRA systems have been summarized in this compendium.

The publications presented in this compendium contain the opinions of and personal techniques practiced by the treating physician(s). The techniques presented herein are for informational purposes only. The decision of which techniques to use in a particular clinical application lies with the treating physician(s) based on patient profile, particular circumstances surrounding the procedure, and previous clinical experiences.

Cases presented involving Veterans Administration facilities or physicians do not reflect the opinion of the United States military or Veterans Affairs office.

The authors of certain publications presented in this compendium may make claims that are not made by ACell or its representatives. In these publications, the underlying use of the ACell surgical devices falls within the current indications for use of these devices, and therefore these publications are summarized within this compendium.

Some articles reference Negative Pressure Wound Therapy (NPWT). ABRA Abdominal is not specifically cleared for concomitant use with NPWT. NPWT is used with ABRA Abdominal only if clinician independently decides to utilize it. Follow NPWT manufacturer's instructions for use for vacuum application, draw-down, and maintenance.

† Consultant

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Management of the Open Abdomen with Abdominal: Reapproximation Anchor Dynamic Fascial Closure System. Haddock, C, Konkin DE, Blair, NP. *American Journal of Surgery*. 2013 May;205(5):528-33; discussion 533. doi: 10.1016/j.amjsurg.2013.01.028.

In this retrospective case series, the authors presented 36 patients who had open abdomens as a result of damage control surgery and were then treated with ABRA Abdominal. Patients had an average Acute Physiology and Chronic Health Evaluation II (APACHE II) score of 21.9 +/- 6.9, and had an average of 3.1 +/- 1.8 laparotomies performed before the ABRA system was placed.

With increased experience over the 4.5-year study, complete **fascial apposition** was achieved in **91% of the patients** in the final two years.

Complete fascial apposition was achieved in 83% of patients across the entire study. The author noted that the number rose to 91% for cases conducted in the final two years of the study, which he attributed to increased experience with the ABRA device. In the remaining 17% of cases component separation was used to provide complete fascial closure. The average duration of ABRA Abdominal installation was 10.4 +/- 6.1 days, and the incisional hernia rate was 13% following six months and 11% at twelve months.

At the end of this study, the author noted that the ABRA Abdominal system was, "an excellent addition to a surgeon's armamentarium," citing its high fascial apposition rate and low incisional hernia rate.

Delayed Primary Closure of the Septic Open Abdomen with a Dynamic Closure System.

Verdam FJ, Dolmans DE, Loos MJ, Raber MH, Wit RJ, Charbon JA, Vroemen JP. *World Journal of Surgery*. 2011 Oct;35(10):2348-55. doi: 10.1007/s00268-011-1210-8.

This retrospective case study presents the results of 18 open abdomen patients from three non-academic surgical centers who were all treated with the ABRA Abdominal system. The mean age of the patient population was 66 (50-90), the average width of the defect was 21 cm, and the open abdomen scores, according to Björck, et al¹, were grade 2B (5/18), grade 3 (2/18), and grade 4 (11/18). Two of the 18 patients died as a result of non-ABRA related complications before primary closure could be achieved.

The ABRA device was applied, on average, 12 days (2-39 days) after the initial laparotomy. Fourteen of the remaining 16 patients (88%) achieved primary fascial closure in an average of 15 days from application. The other two patients were closed following a component separation technique; however, secondary wound dehiscence was reported in both of those patients. The author noted that in both of these cases the ABRA system was applied relatively late, 22 and 39 days after initial laparotomy, and suggested a possible correlation. This study noted superficial pressure sores in nearly two thirds of the original 18 patients, but all healed without further complications*.

The author compared the relatively high rate of primary fascial closure with ABRA Abdominal to the results seen in a previous study featuring the Velcro[®]-sided Wittmann Patch, where primary closure was achieved in 80% of patients². However, the author noted that in the Wittmann Patch study, 90% of the patient population were classified as either Björck grade 1A or 1B, as opposed to this retrospective review where 61% of the population had Grade 4 open abdomens.

	ABRA	Wittmann Patch
Björck Grade	Grade 2B or 3 (31%) and Grade 4 (61%)	Grades 1A or 1B (90%)
Fascial Closure Rate	88%	80%
Days to Closure	15 days	18 days

In conclusion, the author recommends considering ABRA Abdominal when treating an open abdomen patient, citing its high rate of closure in this very complex population base. "Our results advocate the abdominal re-approximation system as a useful aid in the management of the infected open abdomen."

1. Björck M, Bruhin A, Cheatham M, Hinck D, Kaplan M, Manca G, Wild T, Windsor A. Classification - important step to improve management of patients with an open abdomen. *World Journal of Surgery*. 2009 Jun;33(6):1154-7. doi: 10.1007/s00268-009-9996-3.
2. Acosta S, Bjarnason T, Petersson U. Multicentre prospective study of fascial closure rate after open abdomen with vacuum and mesh mediated fascial traction. *The British Journal of Surgery*. 2011 May; 98(5):735-43. doi: 10.1002/bjs.7383.

* The device used in this study is an older generation of the product. The current ABRA Abdominal system is designed to mitigate pressure ulcer complications.

ABRA Abdominal

Successful Abdominal Closure Utilizing Novel Technique Combining Mechanical Closure with Biologic Xenograft that Accelerates Wound Healing. Puckett YG, Estrada M, Ronaghan C†. Texas Tech University Health Sciences Center. Poster presented at: World Congress of the Abdominal Compartment Society; June 15-17, 2017; Alberta, Canada.

In this case series the authors present a novel method for closing complex abdominal wounds using ABRA Abdominal for mechanical traction and MatriStem UBM™ (Urinary Bladder Matrix) to accelerate wound healing.

The study presents twelve patients that underwent open abdominal wound closure utilizing the above devices. The patients' average age was 48.1 (SD 10.0), their average BMI was 40.5 (SD 9.8), and the average length, width, and extrusion height was 26.5 cm (SD 10.1), 18.0 cm (SD 6.0), and 6.8 cm (SD 1.6) respectively. On average, ABRA Abdominal was installed eight days following the initial laparotomy and a delayed primary fascial closure was achieved in all twelve patients. The average length of ABRA installation was 9.4 days (SD 4.2) before fascial closure was achieved and the MatriStem UBM material was applied to the exposed subcutaneous tissues. Closure by secondary intention was then achieved by all twelve patients.

The author concludes this study by offering up this method as an effective option for definitive fascial closure and accelerated wound healing for a difficult patient population.

	Mean	Standard Deviation
Age	48.1	10.0
BMI	40.5	9.8
Visceral Extrusion (Centimeters)	6.8	1.6
Incision Length (Centimeters)	26.6	10.1
Adjustments of ABRA Prior to Closure (Days)	1.8	1.0
Days Abdomen Open Before ABRA Application	8.0	9.0
Myofascial Gap Before ABRA Application	18.0	6.0
Myofascial Gap After ABRA Application	9.1	2.0
Days to Closure of Fascia	9.4	4.2

Early Primary Closure of Open Abdominal Wall Using the Abdominal Reapproximation Anchor (ABRA) System. Cinelli S, Casey M, Kuhls D. University of Nevada School of Medicine. Poster presented at: Southwestern Surgical Congress; March 22-25, 2009; Coronado, CA.

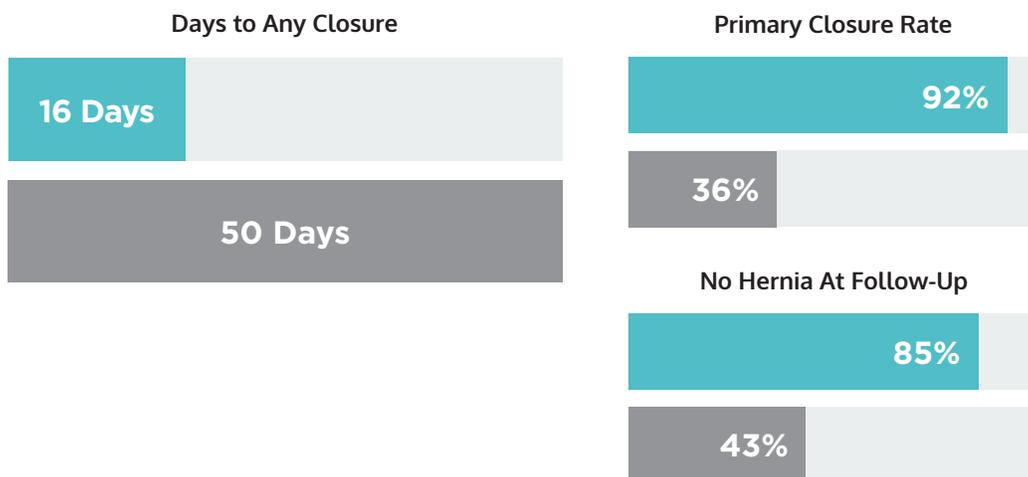
This retrospective study featured 27 patients who had open abdomens as a result of damage control surgery and were deemed unable to be closed as a result of muscle fixation. Thirteen of the patients were treated with ABRA Abdominal and Negative Pressure Wound Therapy (NPWT), and the remaining 14 patients were treated with NPWT and several other modalities according to clinician discretion. The criteria for ABRA Abdominal usage was based on whether the patient’s fascia could not be closed after several attempts and the patient was no longer experiencing intra-abdominal sepsis or hemodynamic instability.

Authors noted that ABRA could result in an estimated **cost reduction** to the hospital of **\$12,370 to \$47,070**.

The author reported that the patient group treated with ABRA Abdominal saw full-thickness primary closure in 92% of their population, while only 36% of the control group saw fascial closure. Patients in the ABRA Abdominal treatment group also saw a reduced number of abdominal procedures and an improved rate of closure. On average, patients treated with ABRA had 6.8 abdominal procedures (3.4 before device, 3.4 after device) and took 15.8 days to close (8.8 before device, 7.0 after device), while the comparison group had 13.7 abdominal procedures and took 50.1 days to close. Follow-up was documented in 60% of patients out to 24 months. Two patients from the ABRA group and eight patients from the comparison group presented with a hernia during the follow-up period.

The author concluded their presentation of this retrospective study by noting significantly higher rates of primary closure in the ABRA Abdominal group, a significant decrease in the days to abdominal closure in the abdominal group, and noting an average cost reduction to the hospital of \$12,370 to \$47,070 per patient when treated with ABRA Abdominal. The author then recommended future studies comparing the treatment of frozen abdominal walls with ABRA Abdominal to standard methods of closure, using a prospective model if possible.

ABRA (n=13) Comparison (n=14)



Management of the Open Abdomen Using Combination Therapy with ABRA and ABThera Systems. Mukhi AN, Minor S. *Canadian Journal of Surgery*. 2014 Oct;57(5):314-9.

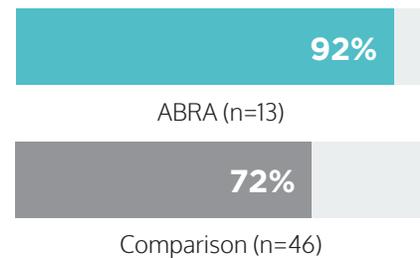
This retrospective study reviews 78 open abdomen patients from a single surgical center between the years of 2007 and 2012. Sixteen patients were treated with the ABRA Abdominal system in conjunction with a negative pressure wound therapy system (ABThera™), with the use of ABRA left to the surgeon's discretion. The author reported that typically surgeons chose to use the ABRA Abdominal system when significant fascial retraction was observed, or when the fascia was failing to medialize over time.

Out of the 16 patients who received treatment with the ABRA Abdominal system, three died prior to primary closure as a result of multisystem organ failure and sepsis. In the remaining 13 patients, twelve achieved primary fascial closure with a median installation time of 17 days. The remaining patient was closed after the surgeon elected to remove the ABRA system and bridge the fascial gap with a vicryl mesh after 31 days with an open abdomen. The author noted that primary closure could have been possible with extended ABRA therapy. Patients in this study ranged from ages 33-66, had an average Simplified Acute Physiology II Score (SAPS II) of 54 (41-97), and eleven out of the 16 patients possessing either an anastomosis or an ostomy. However, none of these patients reported any complications as a result of their treatment with ABRA Abdominal.

The author compared patient outcomes in the ABRA group to the 62 other open abdomen patients treated during this time period. After removing the 16 patients in the comparison group who died prior to closure, 72% achieved primary fascial closure compared to 92% with ABRA.

Following this retrospective review, the author noted that the higher primary fascial closure rate seen in the ABRA group corroborated the results of similar studies measuring the ability of mechanical traction to medialize retracting abdominal forces. The author concluded the study by noting that ABRA Abdominal should be considered when treating patients with a high risk for failure to achieve primary fascial closure.

Primary Closure Rate (Surviving Patients)



“... surgeons typically choose to use the ABRA in patients in whom they feel the fascia is unlikely to close with the ABThera alone.”

Complicated Abdominal Wall Closure: New Technique. Schlaefer J, Dries D, Engwall S, Lindvall K, Obst MA. Regions Hospital. Poster presented at: The Abdominal Wall Reconstruction Conference; June, 2017; Washington, DC.

This poster presentation details Regions Hospital's initial experiences with the ABRA Abdominal system and compares them to their standard open abdomen treatment techniques.

Over the course of the study, five patients ages 26-74 required an open abdomen after presenting with either trauma-related injuries or complications after abdominal aortic aneurysm repairs. Initial fascial defect sizes varied from 17-25 cm wide. After the presenting insults stabilized, the ABRA Abdominal system was installed in all five patients. Within 7-12 days, all patients achieved progressive closure and had no device-derived complications, including pressure wounds or incisional hernias. Case photos illustrate four patients' treatment progressions with ABRA, from pre-installation to fascial closure, including measurements of post-installation defect reductions.

Authors also include case photos and information for one patient outside of the case series who received temporary closure with a skin grafting technique. At 30 months post-skin graft, the patient was still awaiting definitive repair and had a greatly inferior cosmetic and clinical outcome, compared to patients treated with ABRA.

The authors conclude that the use of ABRA Abdominal resulted in a successful fascial closure for all five patients without any skin-related pressure wounds or early incisional hernias.

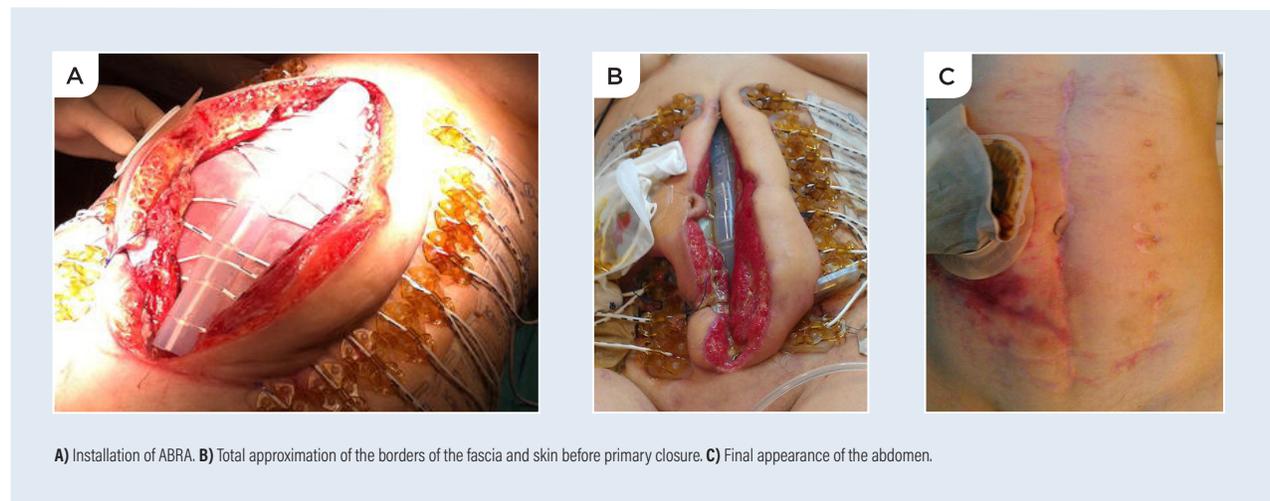
ABRA Abdominal

Delayed Primary Closure in Open Abdomen with Stoma using Dynamic Closure System. Suarez-Grau JM, Jurado J, Menchero J, Luque J. *SpringerPlus*. 2015; 4: 519. doi: 10.1186/s40064-015-1316-9.

Here the author presents a case where an open abdomen patient with a stoma is successfully closed with ABRA Abdominal.

The patient is a 50-year-old who became septic following surgery to remove an intestinal obstruction. The patient had a Bogota bag laparotomy to address their abdominal compartment syndrome. An ostomy was also deemed necessary. Following six days in the ICU, the patient was deemed stable enough to remove the bag, and in the same procedure ABRA Abdominal was installed. The authors were able to use a staggered anchor approach, where ABRA Abdominal could accommodate the ostomy without a loss in efficacy. At the time of ABRA Abdominal installation, the abdominal defect was 15 cm wide by 27 cm long. Sixteen days after ABRA Abdominal was installed, the patient was successfully closed. Follow-up with the patient was continued until 36 months, with no evidence of hernia formation.

The case report concludes with the author noting the successful primary fascial closure of this patient with the ABRA Abdominal system, despite a frozen abdomen and ostomy.



Images reprinted with permissions from Springer Nature.

Closure of Massive Abdominal Wall Defects: A Case Report Using the Abdominal Reapproximation Anchor (ABRA) System. Urbaniak R, Khuthaila DK, Khalil A, Hammond DC. *Annals of Plastic Surgery*. 2006 Nov;57(5):573-7.

In this case report, a complex open abdomen and its treatment methods are presented, including the use of ABRA Abdominal ultimately facilitating a primary fascial closure.

A 33-year-old civilian contractor working in Iraq was involved in an incendiary explosive device's detonation, suffering severe internal damage requiring an exploratory laparotomy. The abdominal wound was left open to

facilitate easy access for re-exploration and treatment for three weeks before the patient was deemed stable enough to close. At the time, the wound measured 35 cm X 25 cm, involving all layers of the abdominal wall, and both the large and small intestine protruded through the defect for a significant loss of domain.

ABRA Abdominal was installed three weeks post-original laparotomy and was left installed for a total of 21 days before removal and primary fascial closure. The author noted that the wound was approximated at day 17, with definitive closure delayed secondary to concerns about continued fevers with leukocytosis. The author noted at that at the time of primary closure, there was no difficulty closing the midline muscle and fascia and that the previously frozen tissue was very pliable.

This case report concludes with the author noting that initially he was very concerned with the size of the abdominal defect and the extensive loss of domain, however the ABRA system was able to effectively medialize the wound margins. "The ease of application and the effectiveness of the technique make it an attractive option for the restoration of abdominal wall integrity."

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ABRA Abdominal

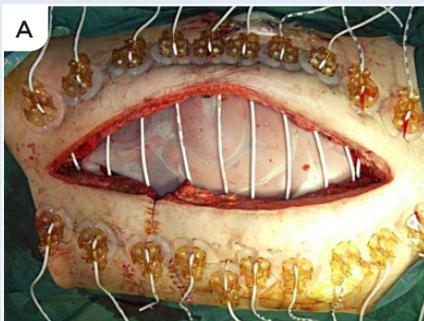
Delayed Dynamic Abdominal Wall Closure Following Multi-visceral Transplantation. Iype S, Butler A, Jamieson N, Middleton S, Jah A. *International Journal of Surgery Case Reports*. 2014; 5(12): 988–991.

This article discusses a case report involving a midline abdominal defect, its closure with ABRA Abdominal, and the opportunities a delayed closure of a laparotomy offers for treating patients.

A 38-year-old woman presented with a large abdominal defect through the full-thickness of the abdominal wall, following complications from a multi-visceral transplantation procedure. Following numerous laparotomies to control abdominal compartment syndrome, the patient was left with a right-sided T-shaped abdominal defect with loss of domain. Approximately one week after the first laparotomy was performed, the right-sided defect was closed primarily and ABRA Abdominal was installed along the midline. Following installation of ABRA Abdominal, the width of the defect was approximately 12 cm, and over the course of 16 days, the system was adjusted manually until the defect margins were approximated. Complete fascial approximation was achieved in approximately three weeks.

In their discussion, the authors note the benefits of delayed abdominal closure using dynamic continuous tension. These benefits include the ability to maintain the abdominal domain while the abdomen is left open for prevention of abdominal compartment syndrome, as well as not requiring the use of any prosthetic material for fascial closure. The author also noted that, to the best of their knowledge, this was the first report of delayed abdominal closure with dynamic tension following intestinal transplantation. They concluded by saying, “the use of dynamic abdominal wall closure is a safe technique for use post-transplant and leads to primary fascial and skin closure with excellent long-term outcomes.”

“The use of the dynamic abdominal wall closure is a safe technique for use post-transplant and leads to primary fascial and skin closure with excellent long-term outcomes.”



A) ABRA application at day 5. **B)** ABRA application at day 16. **C)** Laparotomy scar 6 months after ABRA application.

Images reprinted with permissions from Elsevier.

ABRA Surgical & Adhesive

Dynamic Wound Closure for Decompressive Leg Fasciotomy Wounds. Singh N, Bluman E, Starnes B, Andersen C. *The American Surgeon*. March 2008; Vol. (74) 217-220.

This case series features eleven patients at the 28th Combat Support Hospital in Baghdad, Iraq that were diagnosed with compartment syndrome of the leg, received fasciotomies, and were then treated with ABRA Surgical.

Five patients underwent a vascular repair and six patients had orthopedic injuries, including three tibial fractures, two fibula fractures, and one closed pilon fracture. Following washout and wound inspection, the medial incision was closed and the ABRA Surgical device was placed on the lateral incision.

The mean initial and post-placement wound sizes were 8.1 cm and 2.7 cm wide, respectfully. Successful, delayed primary closure of the fasciotomy wounds were achieved in 91% (10/11) of patients, in an average of 2.6 days. One patient failed due to the onset of heparin-induced thrombocytopenia, which required bilateral, above-the-knee amputations.

The author concludes by discussing the advantages and disadvantages of alternative treatment options, compared to ABRA Surgical. Ultimately, the author found the ABRA Surgical device to be an effective way to treat patients with fasciotomies, while avoiding the need to create additional wounds in patients subject to multiple injuries.

Early Results Using a Dynamic Method for Delayed Primary Closure of Fasciotomy Wounds.

Taylor R, Reitsma B, Sarazin S, Bell M†. *The American College of Surgeons*. November 2003, Vol. 197, 5: 872-878.

This case series reviews five patients, with six incisional fasciotomies, that were treated with the ABRA Surgical device at the same facility.

The initial incisional wounds averaged 28.0 cm long by 8.5 cm wide and were located in both upper and lower extremities.

On average, application of ABRA Surgical occurred 9.8 days (6-21 days) from the initial incision. All five patients were able to be closed successfully, including two patients who had previously failed to achieve closure with pre-positioned sutures. While faster closure rates were associated with early device application, on average, full wound closure was achieved 11.5 days from application, with an approximate 1.0 cm reduction in wound size per day. Patients were able to maintain full range of motion in their involved limbs throughout treatment and they all reported a satisfactory cosmetic result.

“Advantages over other currently available wound closure methods include versatile and straightforward bedside application; the ability to close large skin defects or defects that exhibit excessive tension; and adequate and customized tensile strength, elasticity, and durability over a full range of motion.”

The authors concluded by discussing the advantages of ABRA Surgical over other skin closure devices. They noted that ABRA seems to make use of the innate biomechanical and physiological properties of skin, conforming to bodily movements, and enabling new tissue growth, while also facilitating regular dressing changes and bedside adjustments for tension. Overall, authors described ABRA as an effective method for ensuring a delayed primary closure in a timely manner.

Elastic Device Facilitating Delayed Primary Closure of Sternal Wound Infection. Price J, Rubens F, Bell M†. *The Annals of Thoracic Surgery*. 2007: (83) 1162-1165.

This retrospective study evaluates three cases of obese, diabetic patients ranging from 49-73 years old who developed sternal wound infections after cardiac surgery. The ABRA Adhesive device was used in place of tissue flaps to facilitate primary closure of the wound, following surgical debridement.

The ABRA Adhesive devices were installed 2-13 days after debridement and wound margins were re-approximated in all patients after an average of 29 days.

The author describes the complexities of managing a sternal wound infection and the difficulties for wound closure after surgical debridement. Comparing the ABRA Adhesive device to the more traditional sternal wound infection treatment methods (pectoral flap or wound VAC), the author finds ABRA Adhesive to be less invasive, more cosmetically appealing, and more effective with significantly higher rates of delayed primary closure. The author further describes the device as convenient, citing how patients were discharged after device installation and how homecare nurses can make adjustments until closure is achieved.

Indications for Use

ABRA® Abdominal is indicated for use in controlling, reducing or closing retracted soft tissue wounds.

ABRA® Surgical and **Adhesive** are indicated for use in controlling, reducing or closing retracted soft tissue defects.



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