Prospective Evaluation of Vacuum-Assisted Closure in Abdominal Compartment Syndrome and Severe Abdominal Sepsis

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BACKGROUND: Open abdomen treatment because of severe abdominal sepsis and abdominal compartment syndrome remains a difficult task. Different surgical techniques are available and are often used according to the surgeon's personal experience. Recently, the abdominal vacuum-assisted closure (VAC) system has been introduced, providing a new possibility to treat an open abdomen. In this study, we evaluate the role of this treatment option.

STUDY DESIGN: This prospective observational cohort study includes 37 consecutive patients who were temporarily treated with VAC for severe abdominal sepsis or abdominal compartment syndrome, or both. Patients with abdominal trauma were excluded from the study. Thirty-seven patients undergoing major elective laparotomy and primary abdominal closure served as control group. Primary end points were fascial closure rate, physicoemotional recovery, and appearance outcomes 1 year after closure. Secondary end points included mortality, duration of open abdomen, length of ICU stay, and hospitalization time.

RESULTS: Abdomens were left open for 23 days (range 3 to 122 days) with 3.8 dressing changes (range 1 to 22) per patient. Abdominal closure was achieved in 70% ($n = 26$), with no marked relation to duration of open abdomen treatment ($p > 0.05$). After 3 months, patients with VAC treatment recovered to a physical and mental health status similar to patients in the control group ($p > 0.05$). This status remained stable until the end of the study. Aesthetic outcomes (according to the Vancouver Scar Scale) were considerably poorer in the VAC group compared with controls ($p < 0.01$).

CONCLUSIONS: Treatment of laparostomy with VAC for abdominal sepsis and abdominal compartment syndrome results in a high rate of successful abdominal closure. In addition, patients recover more rapidly, although hypertrophic scars might interfere with body perception. We recommend abdominal VAC system as first option if open abdomen treatment is indicated. (J Am Coll Surg 2007;205:586–592. © 2007 by the American College of Surgeons)

Closing an abdomen in the presence of abdominal compartment syndrome and severe abdominal sepsis remains the subject of many controversies. Although there are currently no standard approaches, few principles are universally accepted, with the common aims to ease and reduce need for staged relaparotomy and enhance wound healing. The most widely used techniques include implantation of a mesh, a saline-soaked towel packing, the "Bogotá bag," or a synthetic patch sutured to the fascial edges.[1-4] Each of these techniques is associated with major shortcomings, including bowel fistula formation, retraction of the abdominal fascia, and intestinal adherence to the prosthesis.[1,5,6] In addition, lack of hermetic closure and effective drainage frequently causes profuse seeding of ascites, requiring unpleasant nursing care and complex fluid management.[7]

An emerging alternative, introduced about a decade ago for patients after damage-control operation, is the abdominal vacuum-assisted closure system (VAC).[8] This modality was claimed to provide a number of advantages related mostly to availability of hermetic closure and to ease repeated laparotomy. The system consists of a nonadherent

Competing Interests Declared: None.

Received February 19, 2007; Accepted May 15, 2007.

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ISSN 1072-7515/07/$32.00
doi:10.1016/j.jamcollsurg.2007.05.015

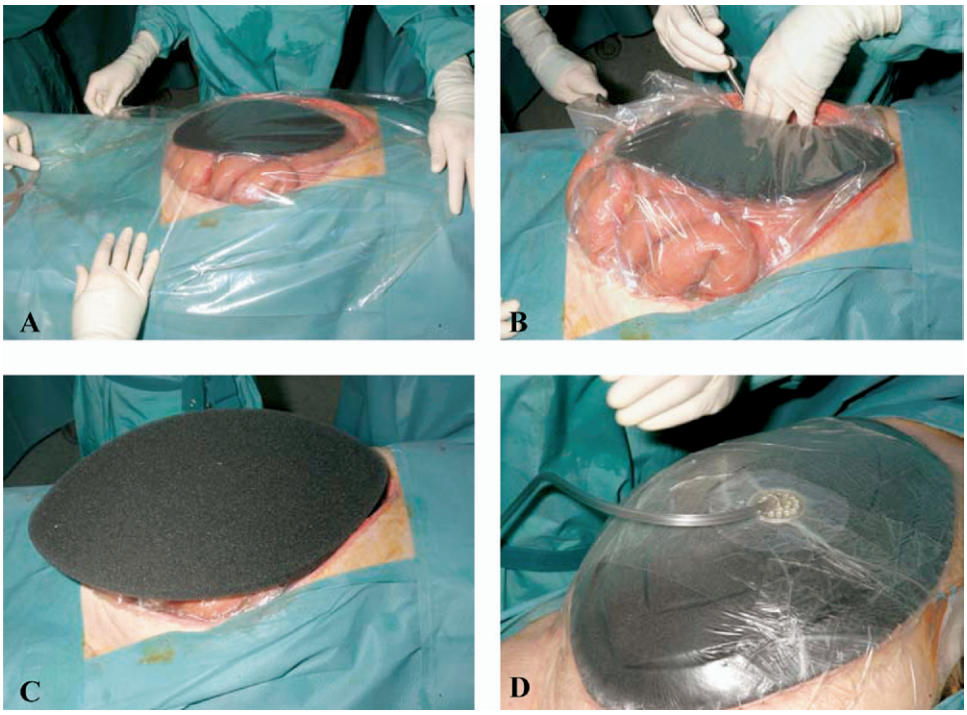

Figure 1. Application of the abdominal vacuum-assisted closure system. (A) Perforated nonadherent plastic sheet with a small sponge is placed directly over the viscera. (B) Plastic barrier is extended laterally under the anterior abdominal wall. (C) This first layer is covered with a large polyurethane sponge. (D) Dressing is sealed with an airtight plastic sheet and an aspiration system is placed with a suction ranging between 75 and 150 mmHg.

perforated plastic barrier placed over the viscera and extended laterally under the anterior abdominal wall (Fig. 1A-1D).[5] This first permeable layer is then covered with a polyurethane sponge and sealed with an airtight plastic sheet. An aspiration system is placed with a suction ranging between 50 and 150 mmHg.

A number of recent studies have shown that VAC effectively reduces intraabdominal pressure after abdominal compartment syndrome.[9] It enables visualization and quantification of postoperative amounts of ascites. In addition, the wound is preconditioned for delayed closure. VAC eases nursing care with safe patient transport, and might even allow patients to sit or walk.[8,9] Because of these apparent advantages, VAC is used increasingly in a number of institutions for a variety of indications. We routinely used the VAC in all of our patients with an open abdomen treatment, and designed a prospective database to measure outcomes. Here we report our results with a focus on fascial closure, patient's physicoemotional recovery, and aesthetic outcomes after abdominal reconstruction.

METHODS

From April 2004 to December 2005, all patients undergoing open abdomen management after operation for severe abdominal sepsis (Mannheimer Peritonitis Score $\geq$ 29) or abdominal compartment syndrome (bladder pressure $>$ 25 mmHg, or both) were prospectively included in the study.[10] Indications for open abdomen treatment with VAC were high tension on the fascia, persistent bacterial contamination of the abdominal cavity, and massive bowel edema. We analyzed patients, as a control group, after major elective abdominal operation with primary abdominal closure during the same study period. Inclusion criteria for the control patients were standard median or transverse laparotomy with total operation duration (skin incision to skin closure) of 3 hours or more. None of them had abdominal compartment syndrome. We included this control group with the understanding of substantial differences between both groups; this group was a somewhat "negative" control cohort. Health status on admission was recorded in both groups by means of sequential organ failure assessment (SOFA).[11] Data were collected prospectively in both groups during the year after initial operation. Patients were treated according to protocol presented in Figure 2. To obtain a homogenous cohort, patients suffering from abdominal trauma were excluded from the study.

Primary end points in the study were fascial closure rate, physical and emotional recovery, and appearance outcomes

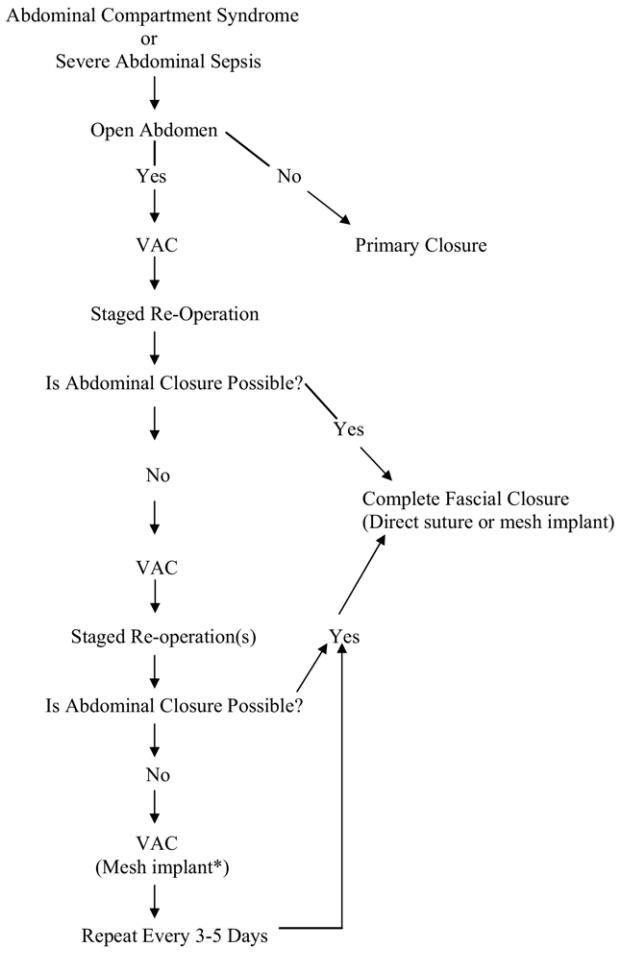

Figure 2. Treatment algorithm for patients with an open abdomen. *In case of partial closure, a composite mesh is implanted directly on the granulated bowel and covered with a split skin graft. VAC, vacuum-assisted closure.

1 year after abdominal closure. Secondary end points included mortality, duration of open abdomen, and lengths of ICU and hospital stay. Physical and emotional recovery was assessed by means of the medical outcomes study 36-item short-form health survey, which is the most frequently used instrument to investigate mental and physical health status in terms of quality of life, and has been validated previously for ICU patients.[12,13] We evaluated the physical and mental impairment in VAC and control groups at three time points: within the first 3 days after extubation, 3 months, and 1 year after definitive abdominal closure.

Patient's aesthetic satisfaction with the final abdominal reconstruction was assessed using the visual analogue score and validated Vancouver Scar Scale 3 months and 1 year postoperatively (Table 1).[14,15] Followup was performed by independent observers (DP, MB, and CK) in our outpatient clinic. The study was approved by the ethic committee of the University of Zurich and written informed consent was available for all patients.

Table 1. Aesthetic Appearance Assessment[15,33]

	Points
Objective measurement (Vancouver Scar Scale)	
Consistency	0–3
Tissue hypertrophy	1–3
Irritation	0–3
Pigmentation	0–3
Patient satisfaction (visual analogue scale)	
Very poor	1–2
Poor	3–4
Acceptable	5–6
Good	7–8
Very good	9–10

Statistical analysis

Values are presented as median with the corresponding interquartile range or as mean ± SD. Mann-Whitney U test and two-tailed asymptotic Wilcoxon signed rank test were used to determine statistical significance ($p < 0.05$). Marginal homogeneity test was used to test whether dependent categorical data of two groups differed. Statistical analysis was performed with the SPSS 11.0 data analysis program (SPSS Inc).

RESULTS

Which patients required open abdomen management with VAC?

Thirty-seven consecutive patients with an open abdomen and a VAC were analyzed. All VAC patients presented with advanced abdominal pathology, including 16 (43%) patients with abdominal compartment syndrome and 21 (57%) patients with severe abdominal sepsis. Patient characteristics are summarized in Table 2. All VAC patients were in critical general condition as reflected by an overall mortality of 65% (n = 24), which occurred either during use of VAC (n = 14) or within 3 months after abdominal closure (n = 10). Median stay in the ICU was 20.4 days (12.3 to 35.2 days), with a need for assisted mechanical ventilation of 18.9 days (12.6 to 29.9 days.). Initial SOFA score of 8.7 (7.2 to 11.5) underlined the critical health conditions. Three months after abdominal closure, 13 patients (35%) were still alive and available for complete followup, up to 1 year.

The control group consisted of 35 patients in considerably better health condition (SOFA 3.8; range 3.3 to 5.2) compared with VAC patients (Table 2). Mortality rate in this population was 9% (n = 3) in the initial 3

Table 2. Demographic and Clinical Characteristics

Patient characteristic	VAC	Control*
Patients	37	35
Men	18	19
Women	19	16
Age, y (range)	58 (34–86)	63 (38–91)
Followup, d (range)	324 (70–445)	354 (81–467)
In-hospital mortality (%)	38 (n = 14)	9 (n = 3)
ICU, d (range)	20.4 (12–35)	3.1 (2–4)
SOFA score, points (range)	8.7 (7.2–11.5)	3.8 (3.3–5.2)
Diagnosis		
Cancer		
Colon	2	11
Stomach	5	2
Pancreas	2	5
Gallbladder	1	1
GIST	2	0
Diverticulitis	10	9
Bowel obstruction	10	3
Mesenteric ischemia	0	3
Pancreatitis	3	0
Ulcer	2	1

*Patients after uncomplicated laparotomy.
GIST, gastrointestinal stromal tumors; SOFA, Sequential Organ Failure Assessment[13]; VAC, vacuum-assisted closure.

postoperative months, ICU stay was 3.9 days (3.0 to 4.3), with a need for mechanical ventilation of 3.1 days (2.5 to 4.1).

What was the rate of successful fascial closure after open abdomen treatment with VAC?

Median duration of open abdomen treatment was 22.7 days (3 to 122 days) with 3.8 dressing changes per patient (1 to 22 changes). Complete fascia closure was achieved in 26 patients (70%). Of these, 13 (35%) patients had direct fascia suture and 13 patients (35%) had complete fascial restoration with a composite mesh implant, because of poor tissue quality. In three patients (8%), abdominal fascia could not be closed and was covered by a mesh placed directly on the bowel, followed by split skin grafting. A high-output enterocutaneous fistula that developed in one of these three patients was first treated surgically, but recurred 9 days later. Seven patients (19%) suffered from severe systemic complications (four with multiorgan failure and three with lung embolism) during open abdomen treatment and died before abdominal closure was possible. The technique that was chosen to finally close the abdomen, ie, direct fascial closure (n = 13), reinforcing mesh with fascial closure (n = 13), and persisting ventral herniation (n = 4), did not correlate with duration of open abdominal treatment ($p > 0.05$).

To what extent did critically ill patients with an open abdomen recover?

After salvage operation and prolonged ICU stay, physical and mental health become key outcome parameters. In the first assessment after extubation, the VAC group showed considerably worse results in three subcategories (mental health, pain, and vitality; $p < 0.05$), and a tendency for lower scores in the remaining five domains (physical and social functioning, physical and emotional role and general health; $p = 0.05$ to 0.09). Median physical score in the VAC group was 27.4 (25.8 to 28.8) points, compared with 43.5 (39.4 to 48.2) points in the control group, indicating severe impairment of the VAC patients. Similarly, emotional parameters in the control group were substantially higher compared with the VAC group (27.5 [21.3 to 29.1] versus 45.2 [42.1 to 49.9] points).

After 3 months, VAC patients had recovered progressively and presented with statistically similar scores in all eight domains of the medical outcome study 36-item short-form health survey compared with the control group ($p > 0.05$ in all domains). At the final examination, 12 months after VAC closure, physical and mental health levels remained stable in the VAC population. A tendency for improvement was observed for vitality and mental health during the last 9 study months ($p = 0.08$ to 0.09). One patient in the VAC group died 8 months postoperatively from myocardial infarction. The exact values and standard deviations for all three study time points are outlined in Figure 3A for the VAC patients and Figure 3B for the control group.

Is appearance after abdominal closure acceptable?

Because abdominal wall reconstruction might be challenging, we sought to investigate outcomes 3 and 12 months after abdominal closure. The objectively rated appearance of the scar assessed by means of the Vancouver Scar Scale revealed poor outcomes in the VAC group (3.4 [2.7 to 4.1] points) at 3 months. During the next 9 months, the aesthetic appearance of the scar improved only minimally (3.7 [2.7 to 4.4] points), related mainly to large and stiff scars at the site of the former laparostomy (Fig. 4). In contrast, the control laparotomy group had small and smooth scar formation at first and second examination (8.7 [8.2 to 9.3] points) and 9.1 [8.6 to 9.7] points). Interestingly, these findings were in contrast to the patient's individual perception (visual analogue scale) of the wound, because the VAC group (4.5 [4.3 to 4.9] points) and standard group (5.1

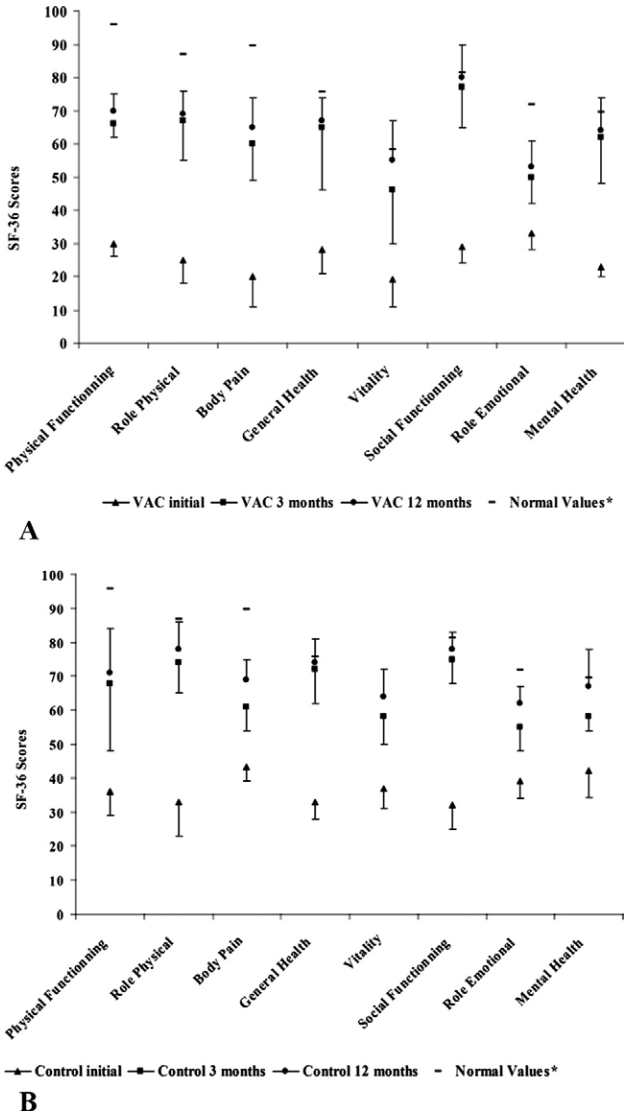

Figure 3. (A) Physical and mental health scores of the vacuum-assisted closure (VAC) patients at the initial, the 3-month and 23-month followup examinations. (B) Physical and mental health scores of the control patients at the initial, 3-month, and 23-month followup examinations. *Normal values in a healthy cohort.[32] Error bars indicate ± SD.

[4.7 to 5.5] points) were similarly satisfied with the final results ($p = 0.48$).

DISCUSSION

Management of abdominal catastrophes resulting from abdominal compartment syndrome or sepsis remains a major challenge and the source of extraordinary costs. The paucity of convincing data on the optimal treatment of such severely ill patients is surprising. We found very few studies reporting clinical results with a variety of temporary closure techniques.[1,4,5,8,16-19] In this series, 70% of the patients had a complete delayed fascial closure, compared with complete fascial closure rates of 47% to 50% with absorbable mesh or polytetrafluoroethylene patches in previously published studies.[1,17,19,20] In addition, a considerably higher risk for abscesses and enterocutaneous fistulas has been reported in some of these studies.[1,4] This might be a result not only of the covering technique, but also of underlying diseases. Trauma patients are more likely to have complete abdominal reconstruction, compared with patients with gastrointestinal sepsis and pancreatitis.[21] Recently, Cothren and colleagues[22] described a 100% fascial closure rate using the VAC device in patients after damage-control operation and abdominal trauma. In this study, the cohort consisted of nontrauma patients with predominantly gastrointestinal malignancies, inflammatory and septic bowel diseases, and gastrointestinal bleeding.

Several previous studies have shown that the reduction of time until definitive abdomen closure is important because open abdomen treatment is associated with increased morbidity and mortality.[1,9,23-25] In accordance with data reported by Barker and colleagues[8] in trauma patients, we also documented enhanced fascial closure compared with conventional approaches.[1,4,19,26] Surprisingly, the duration of VAC treatment in our study had no influence on the technique required for definitive abdominal closure. This might be related to two factors: permanent negative pressure in the abdominal cavity and the anterior abdominal wall can reduce tissue retraction, and fascial edges are well-preconditioned and stay viable to resist mechanical forces after closure.

A number of studies analyzing abdominal VAC treatment revealed similar pitfalls with the device.[5,8,9,18,27-29] For example, some authors expressed concern about risk of enteric fistula formation under constant negative intraabdominal pressure. When comparing the data in our series with the available reports of conventional devices, we noted similar rates of bowel fistulas with the VAC treatment (3%) and polytetrafluoroethylene patch (4%).[4,19] Fistulas appear considerably more frequently when the abdomen was covered with a prosthetic mesh (23%).[1] If chronic bowel fistulas occur, continuous negative pressure drainage can even improve healing processes.[30] To clarify more precisely the impact of negative pressure on the bowel fistulas, more studies are needed.

Concerning clinical recovery, survivors experienced a dramatic improvement of somatic and emotional well-being in the first months after abdominal closure. All patients with VAC treatment were initially in very poor general condition, as demonstrated by SOFA results, long ICU stay, and high in-hospital mortality. Despite the severe un-

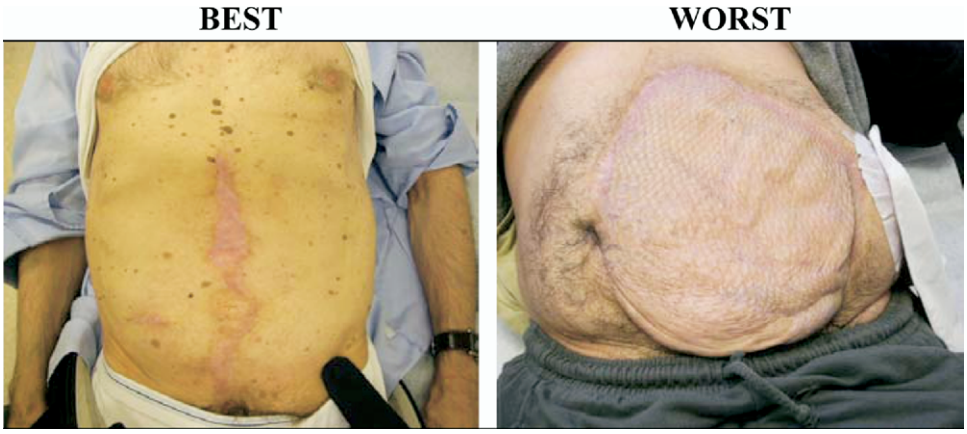

Figure 4. Aesthetic outcomes after open abdomen.

derlying conditions, VAC patients recovered during the first 3 months in the same time range as those patients in the control group and remained at a stable level until the end of the study. This observation might be explained by a reduction of time needed for abdominal closure, resulting in shorter duration of the disease. In addition, VAC treatment provided a convenient method to stabilize the abdominal wall and to remove intraabdominal fluids, allowing the patients to sit in the bed or even ambulate. In our experience, optimal fluid monitoring and nursing with the VAC often resulted in earlier discharge from the ICU compared with former dressing systems. Reducing ICU stay might additionally improve patient's recovery, because it is well-known that a long ICU treatment represents a major perioperative stress factor and risk for future physical and mental disorders.[31]

The observed aesthetic results after VAC were rather poor. Scars were often found to be large and stiff. Some were still heavily irritated 3 months after abdominal closure and formed large plaques on the abdominal wall (Fig. 4). Patients with large ventral hernias presented with unstable and hypertrophic scars. Despite these findings, the patients appeared surprisingly satisfied with the aesthetic results. Degree of satisfaction was comparable with that observed in the control group. This discrepancy between objective and subjective results might be explained by the fact that severely ill patients are grateful to survive, and do not expect optimal aesthetic results. At present, considerable research efforts are being undertaken to understand the molecular and physiologic mechanisms of wound healing under negative pressure. Future studies might elucidate additional factors modulating wound granulation and scar formation.

We conclude that the VAC system is a helpful tool in severely ill patients who have large abdominal wounds and suffer from complicated postoperative followup. Fascial closure rate after prolonged open abdomen treatment with the VAC system is high, and duration of disease can be reduced. Despite initially poor health conditions, patients after VAC treatment recover to normal daily activity, similar to patients after uncomplicated laparotomy. Because the VAC caused hypertrophic and large scars in our series, future investigations should focus on the molecular mechanisms of scar formation under negative pressure atmosphere.

Author Contributions

Study conception and design: Perez, Demartines, Clavien
Acquisition of data: Perez, Bramkamp
Analysis and interpretation of data: Perez, Wildi, Demartines, Koehler, Clavien
Drafting of manuscript: Perez, Wildi, Demartines, Clavien
Critical revision: Clavien

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