

One-Year Follow-up After Open Abdomen Therapy With Vacuum-Assisted Wound Closure and Mesh-Mediated Fascial Traction

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Abstract

Background Open abdomen (OA) therapy frequently results in a giant planned ventral hernia. Vacuum-assisted wound closure and mesh-mediated fascial traction (VAWCM) enables delayed primary fascial closure in most patients, even after prolonged OA treatment. Our aim was to study the incidence of hernia and abdominal wall discomfort 1 year after abdominal closure.

Methods A prospective multicenter cohort study of 111 patients undergoing OA/VAWCM was performed during 2006–2009. Surviving patients underwent clinical examination, computed tomography (CT), and chart review at

http://www.clinicaltrials.gov (Registration number: NCT00494793)

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A. Wanhainen · M. Björck Department of Surgical Sciences, Vascular Surgery, Uppsala University, Uppsala, Sweden 1 year. Incisional and parastomal hernias and abdominal wall symptoms were noted.

Results The median age for the 70 surviving patients was 68 years, 77 % of whom were male. Indications for OA were visceral pathology (n = 40), vascular pathology (n = 22), or trauma (n = 8). Median length of OA therapy was 14 days. Among 64 survivors who had delayed primary fascial closure, 23 (36 %) had a clinically detectable hernia and another 19 (30 %) had hernias that were detected on CT (n = 18) or at laparotomy (n = 1). Symptomatic hernias were found in 14 (22 %), 7 of them underwent repair. The median hernia widths in symptomatic and asymptomatic patients were 7.3 and 4.8 cm, respectively (p = 0.031) with median areas of 81.0 and 42.9 cm², respectively (p = 0.025). Of 31 patients with a stoma, 18 (58 %) had a parastomal hernia. Parastomal hernia (odds ratio 8.9; 95 % confidence interval 1.2-68.8) was the only independent factor associated with an incisional hernia.

Conclusions Incisional hernia incidence 1 year after OA therapy with VAWCM was high. Most hernias were small and asymptomatic, unlike the giant planned ventral hernias of the past.

Introduction

Open abdomen (OA) therapy was initially described as a means of drainage for severe peritonitis [1, 2]. With the introduction of damage control surgery and increased awareness of abdominal compartment syndrome and its detrimental effects, OA therapy has become common practice and has been shown to contribute to increased patient survival in acute surgical situations [3]. To protect the abdominal contents and prevent loss of domain, temporary abdominal closure (TAC) is necessary during OA therapy. Many TAC methods have been described, such as the originally used gauze dressings [1, 4], plastic silo (Bogotá bag) [5], artificial burr (Wittman patch) [6], vacuum pack [7], and elaborate vacuum dressing systems [8, 9]. Fascial closure rates after OA therapy have generally been low [10, 11], especially for nontrauma patients, leaving many patients with a giant planned hernia that requires skin grafting and subsequent extensive reconstructive surgery. Recently, modified TAC methods combining vacuum dressings and sequential fascial suturing [12, 13] or moderate fascial traction [9, 14–16] have emerged, with high fascial closure rates reported, even after prolonged OA treatment in nontrauma patients. A literature search revealed few studies that address longterm results after OA therapy and none with a primary focus on hernia development after successful delayed primary fascial closure. We recently described the early outcomes of a prospective, multicenter cohort study that evaluated the vacuum-assisted wound closure and meshmediated fascial traction (VAWCM) technique in 111 consecutive patients [16]. The aim of the present study was to report the incidence of incisional and parastomal hernias, abdominal wall complaints, and surgical interventions during the first year after abdominal closure in the same cohort.

Materials and methods

The ethics committee of Lund University approved the study, which was registered at http://www.clinicaltrials.gov (registration number: NCT00494793).

Study population

A multicenter, prospective cohort study was conducted in four Swedish hospitals between 2006 and 2009 [16]. Patients who were alive 1 year after abdominal closure were included in the current study. Data was retrieved from Malmö and Uppsala University Hospitals and from the Falun and Gävle County Hospitals. Primary delayed fascial closure was achieved in 85 patients and definitive fascial closure with mesh reinforcement in 8 (in 4 cases due to previous fascial dehiscence and in the other 4 due to remaining fascial diastasis). In two patients, complete fascial closure was not possible due to heterotopic ossification in the wound. Overall, 41 of the 111 patients (37 %) from the multicenter study died before the 1-year followup. Among them, 16 died with an open abdomen and, further 17 after abdominal closure but before hospital discharge, mostly due to multiple organ dysfunction, sepsis, or cardiac events. Of the 78 patients who were discharged from the hospital, 8 (10 %) died during the first year: one due to short bowel syndrome with chronic sepsis. The other deaths were unrelated to the reason for OA treatment. Mortality and fascial closure rates are summarized in Fig. 1 The remaining 70 patients constitute the study population of this investigation. No hernias had been diagnosed in patients who died before the 1-year follow-up.

Vacuum-assisted wound closure and mesh-mediated fascial traction

The technique of combining VAWCM has already been described in detail [9, 16]. Briefly, the visceral protective layer of the V.A.C. system (KCI, San Antonio, TX, USA) is placed intraabdominally. The abdomen is then temporarily closed with a large polypropylene mesh that is sutured with a running polypropylene suture to the fascial edge on each side. Polyurethane sponges are placed above the mesh between the wound edges, and the wound is covered with air-tight drapes and connected to the negative pressure unit. Every 2-3 days the mesh is opened in the midline, and the dressing is changed. As the intraabdominal swelling decreases, the mesh can be tightened with each dressing change, gradually bringing the fascial edges toward the midline. The mesh is removed as soon as possible, and the fascia is closed with a running polydiaxanone (PDS) suture, aiming for a suture length/wound length ratio of >4:1. When primary fascial closure was not possible or when the fascia was of poor quality, an option was to use polypropylene mesh for permanent closure, thereby avoiding an otherwise planned ventral hernia.

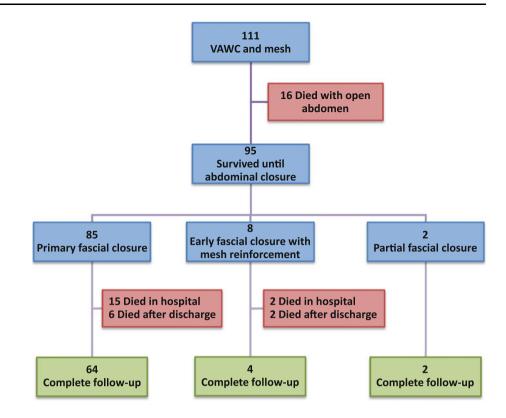
Follow-up protocol and definitions

Information on events occurring before the follow-up visit was retrieved from medical records. Patients diagnosed with a hernia earlier than the scheduled follow-up were identified. In case the patient had been operated on without a previous CT scan, the laparotomy findings were registered. Otherwise, patients were offered a clinical examination and a CT scan of the abdominal wall 1 year after fascial closure. The follow-up interval was measured from the date of abdominal wall closure to the earliest examination at which a hernia was diagnosed or to the last examination performed in cases in which no hernia was present.

A senior surgeon performed the *clinical examination*. The occurrence of a midline incisional hernia and, if relevant, a parastomal hernia was investigated. Patients were asked about any pain or discomfort from the postoperative scar and, if appropriate, the area of the stoma.

Computed tomography scans were performed with the patient in the supine position without a Valsalva maneuver.

Fig. 1 Fascial closure and mortality from enrollment to the 1-year follow-up. VAWC vacuum-assisted wound closure



The CT scans were evaluated with regard to incisional and parastomal hernias. In patients without an incisional hernia, the maximum distance between the medial edges of the rectus muscles (fascial diastasis) was measured. One radiologist and three surgeons performed this evaluation independently. In case of discrepancy, consensus was reached.

Incisional hernia was defined as proposed by Korenkov et al. [17] and the European Hernia Society: "Any abdominal wall gap with or without a bulge in the area of a postoperative scar, palpable or perceptible by clinical examination or imaging". The width and length of the incisional hernia defect(s) seen on the CT scans was measured according to the European Hernia Society proposal [18]. Defects ≥ 1 cm were included. The hernia area was defined as a rectangle (length \times width of hernia area).

Parastomal hernia was defined as proposed by Moreno-Matias et al. [19]. With type I, the hernia sac contained only the bowel forming the stoma. This type was further divided into type Ia (sac diameter <5 cm) and type Ib (sac diameter ≥ 5 cm). With type II, the hernia sac contained omentum. With type III, the sac contained other bowel loops, as seen on a CT scan.

Statistical analysis

Data management and statistical analysis was performed using SPSS 19.0 software (SPSS, Chicago, IL, USA).

Differences in proportions were evaluated in a using the χ^2 test or Fisher's exact test. Continuous variables were expressed as the median and range. Comparisons between two groups were made with a Mann–Whitney U-test. A value of p < 0.05 indicated statistical significance. Variables indicating a trend toward an association (p < 0.10) with the development of an incisional hernia at 1 year according to the univariate analysis were tested in a multivariate binary logistic regression analysis. Significant associations were expressed in terms of the odds ratio (OR) with a 95 % confidence interval (CI).

Results

Patient characteristics

Deaths occurring before the 1-year follow-up were described earlier and are summarized in Fig. 1. Among the 70 patients alive at 1 year, 64 had undergone delayed primary fascial closure according to the technique protocol, 4 had undergone fascial closure with a permanent mesh, and 2 had undergone subtotal fascial closure (with complete skin closure)—in both cases due to heterotopic ossification that prevented complete fascial closure. No surviving patient was lost to follow-up. In this group, the median age was 68 years, and 77 % were male. The indication for OA treatment was visceral (57.0 %), vascular

(31.5 %), or trauma (11.5 %). The median OA treatment time was 14 days (range 4–61 days).

Patients closed with mesh reinforcement or subtotal fascial closure

In all four surviving patients who had early definitive facial closure with permanent mesh reinforcement, CT scans showed an intact abdominal wall with no signs of a hernia or mesh displacement. In two patients, the wound was not completely healed at the time of follow-up despite skin grafting in one. Both of these patients had smaller parts of the mesh excised during wound revisions, but no patient required total mesh removal. The other two patients were asymptomatic. One patient had a colostomy with no sign of a parastomal hernia.

In two patients, complete fascial closure was not possible because of ossification in the wound. Both patients were alive at the time of follow-up. One patient had a large (10 cm) defect that was later repaired with a sublay polypropylene mesh reconstruction. The other patient had a small defect that was not clinically detectable, and surgical repair was not scheduled. Neither patient had a stoma.

Patients with delayed primary fascial closure

Details of the patients who had delayed primary fascial closure are shown in Table 1. The median suture length/ wound length ratio at fascial closure was 5.3 (range 3.6–17.1) among the 46 patients in whom this ratio was registered.

Follow-up time and performed examinations

The interval from abdominal closure to follow-up examination was a median of 374 days (range 127–1,683 days). Short follow-up intervals were due to early hernia diagnoses. The longest interval was attributable to a patient who was lost to follow-up but turned up later and was found not to have a hernia on clinical examination. Clinical examination and a CT scan of the abdominal wall was performed in 56 patients. The remaining 8 patients were diagnosed with clinical examination and relaparotomy without a preoperative CT scan (n = 7) or with a clinical examination only (n = 1).

Incisional hernia, abdominal wall symptoms, fascial diastasis

Of the 64 surviving patients, 42 (66 %) were found to have an incisional hernia on either CT (n = 35), clinical examination with negative CT (n = 3), or clinical examination and relaparotomy without preoperative CT (n = 4). In the three above-mentioned patients in whom a hernia was diagnosed clinically but not on a CT scan, a thin but uninterrupted fascial cover was seen on the CT scan. Thus, according to the diagnostic criteria, the defect represented a fascial diastasis rather than a hernia. Of the 64 patients, 23 (37 %) had a clinically detectable hernia, and 12 (19 %) had a symptomatic, clinically detectable hernia. The sensitivity and specificity of clinical examination, compared to CT, for the diagnosis of incisional hernia were 49 % (17/35) and 86 % (18/21), respectively, among the 56 patients who had undergone both CT and clinical examination. Of the 35 patients with CT-verified hernia, the hernia was situated above the umbilicus in 18 (51 %), below in 6 (17%), and paraumbilically in 11 (31%) patients. In 23 patients (66 %), the hernia area consisted of multiple defects.

In a univariate analysis (Table 2), only the presence of a parastomal hernia at 1 year was significantly associated with an incisional hernia at 1 year (p = 0.018). Parastomal hernia at 1 year, obesity, and renal replacement therapy during the OA phase were entered into a multivariate analysis. The presence of a parastomal hernia at 1 year was independently associated with the presence of a midline incisional hernia (OR 8.9, 95 % CI 1.2–68.8; p = 0.035).

The widths and sizes of the hernia areas according to the EHS definition [18] are shown in Table 1. When 11 symptomatic and 24 asymptomatic patients were compared, it was found that the hernia width (p = 0.031) and area (p = 0.025) were significantly larger for symptomatic than for asymptomatic patients.

Fascial diastasis was measured in the remaining 22 patients who did not have a hernia. Among them, CT scans were available for 18. The results are shown in Table 1. All but one had a diastasis >25 mm.

Ossification in the midline postoperative scar was seen in 16 of the 56 patients undergoing a CT scan and in 3 of the 8 patients examined clinically, resulting in a total of 19 patients (30 %). In 15 of the 19 cases, ossification was present in the vicinity of the xiphoid process. None had ossification near the pubic symphysis. In all, 13 patients had ossification in multiple parts of the wound.

Operations after abdominal wall closure during the first year

Ten of the 64 surviving patients with primary fascial closure underwent relaparotomy before the 1-year follow-up for the following indications: stoma takedown (n = 4), repair of an incisional hernia (n = 2), stoma takedown with concomitant hernia repair (n = 2), and bowel resection with a concomitant hernia repair (n = 2). In addition, a

Table 1 Hernia status at 1-year follow-up after successful primary delayed fascial closure in patients treated with OA using VAWCM

Parameter	All eligible patients	Symptomatic patients	Asymptomatic patients	p^*
Incisional hernia				
All (/64 patients)	42 (66 %)	14	28	
Clinically detectable	23 (36 %)	12	11	0.004
Not clinically detectable	19 (30 %)	2	17	
Detected on CT only	18 (28 %)	2	16	
Detected at relaparotomy	1 (2 %)	0	1	
Hernia size according to CT				
Width <2 cm	7	1	6	
Width ≥ 2 to ≤ 4 cm	4	1	3	
Width >4 cm	24	9	15	
Width (cm)	5.0 (1.0-20)	7.3 (1.0–20)	4.8 (1.0–11.7)	0.031
Area in (cm ²)	61.2 (0.5-516)	81.0 (0.5-516)	42.9 (0.7–140.4)	0.025
No incisional hernia				
All (/64 patients)	22 (34 %)	1	21	
Fascial diastasis (mm) ($n = 18$)	4.8 (1.0-7.9)			
Parastomal hernia				
All (/31 patients)	18 (58 %)	9	9	
Clinically detectable	15	9	6	0.21
Detected on CT only	3	0	3	
Concomitant incisional hernia	15	9	6	0.21
No concomitant incisional hernia	3	0	3	
CT classification (/15 patients)				
Type Ib	8	2	6	
Туре ІІ	2	1	1	
Type III	5	4	1	

Results are the number of patients or the median and range unless otherwise stated

* Comparisons of symptomatic and asymptomatic patients

small, preoperatively undiagnosed incisional hernia was noted in one of the patients operated on for a stoma takedown, resulting in a total of seven hernia repair operations (11 %).

Parastomal hernia

A total of 31 (48 %) of the 64 patients with primary fascial closure had undergone an acute ileostomy (n = 6), colostomy (n = 20), or both (n = 5) at the start of OA therapy. Among them, 18 (58 %) were found to have a parastomal hernia at 1 year that was detected on CT (n = 15), clinically (two patients who were operated on without previous CT and one patient who's CT did not include the stomal area), or both (Table 1). Three of the parastomal hernia patients were operated on during the follow-up interval, all with a stomal takedown and closure of the hernial defect. Concomitant incisional hernia was present in 15 (83 %) of the patients with a parastomal hernia (Table 2).

Discussion

Delayed primary fascial closure after OA therapy used to be achieved in a small number of patients, most often when the treatment could be ended and the abdomen closed within a few days. With longer OA duration, adhesions usually resulted in a "frozen abdomen," making fascial closure impossible and a large hernia inevitable. Improved TAC methods, such as vacuum dressings or Wittmann patches, improved the chances of fascial closure, especially in trauma situations [10, 11]. Recently, methods combining VAWC with moderate tension on the fascia have resulted in high fascial closure rates, even in nontrauma patients needing long OA therapy, practically eliminating the need for planned ventral hernias [9, 12–16]. Consequently, it has become clinically relevant to study hernia development after successful delayed primary fascial closure. Long-term results after OA therapy are sparsely described in the literature. We found no other study that systematically described hernia incidence after OA therapy. This is the

Variable	No. of eligible patients	Midline incisional hernia at 1 year	Univariate analysis (p)
Total patients	64	42 (66 %)	
Background data			
Age \geq 75 years	12 (19 %)	7/12 (58 %)	0.56
Sex			
Male	50 (78 %)	33/50 (66 %)	0.90
Female	14 (22 %)	9/14 (64 %)	
Obesity (BMI \geq 30 kg/m ²)	10/45 (22 %)	9/10 (90 %)	0.076
Repair of AAA	16 (25 %)	9/16 (56 %)	0.36
Abdominal infection	27 (42 %)	17/27 (63 %)	0.70
Trauma	5 (8 %)	2/5 (40 %)	0.33
Prior to open abdomen treatment			
SOFA score ≥ 12	10/42 (24 %)	6/10 (60 %)	0.48
Fluid overload ≥10 kg	27/54 (50 %)	16/27 (59 %)	0.57
ACS	10/24 (42 %)	8/10 (80 %)	0.40
After initiation of open abdomen treatment			
IAP decreased $\geq 10 \text{ mmHg}$	11/23 (48 %)	8/11 (73 %)	0.75
V.A.C. treatment \geq 21 days	19 (30 %)	10/19 (53 %)	0.16
Ventilator-assisted respiration \geq 14 days	19/60 (32 %)	12/19 (63 %)	0.84
Renal replacement therapy	15/63 (24 %)	13/15 (87 %)	0.060
Maximum weight ≥100 kg	19/55 (35 %)	15/19 (79 %)	0.086
ICU stay ≥ 21 days	23/61 (38 %)	14/23 (61 %)	0.55
Intestinal changes			
Bowel resection	24 (38 %)	17/24 (71 %)	0.50
Bowel anastomosis	16 (25 %)	12/16 (75 %)	0.36
Ileostomy	11 (17 %)	6/11 (60 %)	0.68
Colostomy	25 (39 %)	15/25 (60 %)	0.45
Any stoma	31 (48 %)	19/31 (63 %)	0.72
Abdominal wound specifics			
Max. fascial diastasis ≥20 cm	24/61 (39 %)	16/24 (67 %)	0.88
OA grade >1A, anytime during OA	30/64 (47 %)	17/30 (59 %)	0.16
Mesh-tightening procedures ≥ 6	14/63 (22 %)	8/14 (57 %)	0.39
Suture/wound length <4	5/46 (11 %)	4/5 (80 %)	1.0
Superficial SSI	9 (14 %)	6/9 (67 %)	0.94
Follow-up at 1 year			
Parastomal hernia (31 with stoma)	18/31 (58 %)	15/18 (83 %)	0.018
Obesity at 1 year (BMI \ge 30 kg/m ²)	11/57 (19 %)	9/11 (82 %)	0.23

 Table 2
 Factors associated with midline incisional hernia at 1-year after successful primary delayed fascial closure in patients treated with OA using VAWCM

BMI body mass index, AAA abdominal aortic aneurysm, SOFA sequential organ failure assessment, ACS acute coronary syndrome, IAP intraabdominal pressure, ICU intensive care unit, Max. maximum, OA open abdomen, SSI surgical-site infection

first detailed follow-up after OA therapy, describing all surviving patients 1 year after OA therapy using VAWCM.

In-hospital mortality was high, with more than onethird of all included patients dying before the 1-year follow-up, which demonstrates the severity of the underlying conditions as well as co-morbidities in these elderly patients. Several in-hospital deaths occurred after abdominal closure because of multiple organ dysfunction and sepsis. In other words, life-threatening conditions persisted after the underlying abdominal catastrophe had been treated.

The incidence of incisional hernias was 66 %, which is considerably higher than after elective laparotomy, which has been reported at 0-21 % by clinical examination [20]. The comparison between OA therapy and elective laparotomy is, of course, not entirely fair. Frequent dressing changes, often in a contaminated environment, together with sutures and traction on the fascial edges might interfere with the healing process and thus increase the risk of subsequent incisional hernia. In addition, underlying conditions such as sepsis or multiple organ dysfunction frequently cause an intense catabolic state with further impairment of wound healing. During the early stages of planning the study, a control group was selected, consisting of patients undergoing elective midline laparotomy for aortic aneurysm repair or colorectal surgery. This study design was, however, abandoned because it became apparent that such a comparison would not be realistic.

In reality, the difference in hernia incidence between OA and non-OA situations might be less extreme than the incidence figures indicate. The prospective design of this study, including both clinical and CT scan examinations, allows detection of even the smallest of hernias in all surviving patients, which undoubtedly results in a higher hernia incidence. Similarly, if patients after non-OA laparotomy were examined with CT, the incidence might be considerably higher, as seen in one study showing a 60 % hernia incidence after vascular surgery [21]. As a comparison, the hernia incidence in the current study based only on clinical examination was 36 %. Had only symptomatic patients been examined clinically, as is the case in some studies, the incidence would have been 19 %. Based on the number of patients who underwent hernia repair, the incidence would be 11 %. It can be debated whether small, asymptomatic hernias that are not detectable on clinical examination are of any clinical significance. In practice, only a small fraction of the symptomatic, palpable hernias were repaired, and by that definition most of the hernias diagnosed in this study were insignificant. A 5-year followup is pending, which may reveal further information on the clinical course in these patients.

Abdominal wall symptoms were present in 33 % of the patients with an incisional hernia but only in one (5 %) of the patients who did not have a hernia. In other words, symptoms seemed to be related to the hernia itself, not the surgical scar. Although large hernias were more likely to be symptomatic than small ones, it was apparent that many large hernias were asymptomatic. Of the asymptomatic patients, 63 % had a hernia >4 cm in width.

Several potential risk factors were tested for an association with incisional hernia at 1 year. Only the presence of a parastomal hernia was found to be independently associated with the presence of an incisional hernia (discussed below). The fact that known risk factors, such as obesity, did not show a statistically significant association could be an indication of a type II statistical error.

In three patients, a hernia was found on clinical examination but not on a CT scan. In these cases, the CT did not show a fascial defect but, rather, a diastasis covered with a thin fascial layer. Thus, the diagnostic criteria were not met. Perhaps the definition of incisional hernia [17] should be modified to incorporate clinically relevant fascial diastasis.

Fascial diastasis for the patients who did not have a hernia was a median of 5.1 cm. Burger et al. [22] demonstrated that fascial diastasis of >2.5 cm within the first month after laparotomy predicted an increased risk of developing a hernia. Subsequent development of incisional hernias in this group of patients will be analyzed in a 5-year follow-up study.

Areas of heterotopic ossification were frequently seen on CT scans. Massive ossification precluded complete fascial closure in two patients. Heterotopic ossification is a well-known complication in diverse situations, such as hip replacement surgery, spinal cord injuries, traumatic amputations, and burn injuries. Previously considered rare in midline laparotomy wounds, heterotopic ossification has recently been shown to occur in up to 25 % of cases [23, 24]. Although recognized clinically, reports on the association with OA therapy are scarce in the literature. Seeding of osteoblast or chondroblasts from incisions in the vicinity of the xiphoid process or pubic symphysis has been suggested as a possible cause, which is supported by the results of the current study, with ossification near the xiphoid process in three of four cases. On the other hand, heterotopic ossification in locations not involving the xiphoid process and the absence of ossification in most sternotomy patients indicates that other mechanisms must be involved as well [24]. Whether VAWC therapy is involved in the ossification process is unclear. It was not found reported in the literature. It is plausible that the mechanisms that induce granulation tissue formation [25] also affect bone and cartilage. In addition, dispersion of fluid through the wound bed could help spread bone and cartilage forming cells.

Recent studies indicate that the incidence of parastomal hernia might be higher than previously reported. In a study by Moreno-Matias et al. [19], where patients were examined clinically and with a CT scan, the overall hernia incidence was 60 %. In another study by the same authors, the incidence was 41 % on clinical examination and 52 % according to CT scans [26]. Jänes et al. [27] used clinical examination during a Valsalva maneuver and found an incidence of 50 % after 1 year and 81 % after 5 years. The incidence of parastomal hernia in our study (60 %) is comparable to these figures, suggesting that OA therapy might not increase the risk of parastomal hernia. The results also indicate that parastomal hernias of higher classification types seem to have more symptoms. An association between incisional and parastomal hernia was observed, with 83 % of patients with a parastomal hernia having a concomitant incisional hernia. A literature search revealed no reports on such association. It seems logical, however, that if a risk factor for hernia development is

present it should affect all types of hernias. In other words, there might be a common risk factor rather than a causal relation.

Conclusions

The incidence of incisional hernia 1 year after OA and VAWCM therapy was high. However, most of the hernias were small and asymptomatic, with few requiring surgical repair, unlike the giant planned ventral hernias of the past.

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Conflict of interest The authors declare no conflict of interests.

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