



Novel method for delayed primary closure and incisional hernia prevention in open abdomen: COMbined and MODified Definitive Abdominal wall closure (COMODA)

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Abstract

Background Intended open abdomen is an option in cases of trauma and non-trauma patients. Nevertheless, after primary closure, incisional hernia rate is high. We describe a novel method, called COMbined and MODified Definitive Abdominal closure (COMODA), a delayed primary closure which prevents incisional hernia.

Methods A negative pressure wound therapy system is combined with a condensed polytetrafluoroethylene (cPTFE) mesh. Trial registration: ISRCTN72678033.

Results Ten male patients with a median age of 68.8 (43–87) years were included. Primary closure rate was 100% per protocol. The median number of procedures per patient was 5.7 (5–9). Primary closure was obtained in 20.8 (10–32) days and median hospital stay was 36.3 (18–52) days. Only one patient developed incisional hernia during a median follow-up of 27 (8–60) months.

Conclusion COMODA method allows for a high rate of delayed primary closure. It is safe and decreases the risk for developing an incisional hernia. However, a large number of patients are needed to support this conclusion.

Keywords Open abdomen · Incisional hernia · Primary closure · Intra-abdominal pressure

Introduction

Open Abdomen (OA) can be defined as a condition in which the fascial edges are intentionally left open exposing the intra-abdominal contents. It is a surgical strategy caused by a specific underlying condition in the patient such as an increase in intra-abdominal pressure due to the development of significant intestinal edema following massive resuscitation for hypovolemic shock. It can also be caused by a rupture in an abdominal aortic aneurysm where it is not possible to close the abdominal wall, because we want to prevent compartment syndrome due to intra-abdominal hypertension. Other unexpected situations could be eviscerated patients in poor general condition who would not be able to withstand the lengthy surgical procedure of abdominal wall reconstruction, or to allow easy and repeated access to the abdominal cavity in patients expected to require frequent re-interventions, such as those with severe peritonitis caused by diverse etiologies [1], thereby also avoiding repeated injury to the structures of the abdominal wall. Therefore, open abdomen

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management plays an important role in damage control surgery for both trauma and non-trauma patients [2, 3].

It has been associated with a mortality rate of up to 40% [4, 5], but, in recent years, its management has undergone substantial changes that have led to a significant reduction in mortality [6]. Complications such as enteroatmospheric fistulae [7], infections, or significant retraction of the abdominal wall may increase morbidity and mortality, especially in septic patients [8, 9]. All of this has led to the development of new surgical techniques that can minimize or avoid these complications [10]. Taking the aim of delayed primary closure of the open abdomen as well as that of reducing the incidence of incisional hernias into consideration, a novel technique that combines negative pressure wound therapy (NPWT) with the placement of an intra-peritoneal mesh that overlaps the fascial edges by up to 5 cm, used as a bridge and allowed to be in contact with the viscera, is described below.

Materials and methods

A well-designed observational prospective clinical trial in a single center was developed to test the safety and the efficacy of a new method to close an Open Abdomen. Inclusion criteria for candidates to undergo this method were patients whose condition was of non-traumatic origin, whether inflicted to manage severe sepsis, abdominal aortic aneurysm (AAA), intestinal ischemia, or acute fascial dehiscence (burst abdomen) and who had Open Abdomen types 1 and 2 [11]. Trauma patients were excluded, since abdominal wall closure is performed up to 48–72 h after having left an open abdomen to avoid abdominal compartment syndrome, as our method is an option only for delayed primary closure. Patients included in this study underwent an open abdomen, because their severe conditions involved 3 or more revisions in the operating room, whether for peritoneal “washing”, re-anastomosis, conditions that promote an intra-abdominal hypertension or inability to close the abdominal wall.

The presence of intra-abdominal hypertension and/or abdominal compartment syndrome was defined according to the guidelines of the World Society of the Abdominal Compartment Syndrome (WSACS) [12]. Patient with severe sepsis were defined as a syndrome of infection complicated by acute organ dysfunction.

Analysis was performed of demographic variables, comorbidities, type of patient, intra-abdominal pressure (IAP) measurements, time from open abdomen initiation until complete closure, and clinical follow-up. The outcomes were expressed in median and range. An abdominal CT scan was done at 6 months to check for the presence of an incisional hernia.

This study was approved previously by the Clinical Ethic Committee of our hospital. Trial registration: ISRCTN72678033.

We developed the COMbined and MODified Definitive Abdominal closure of the open abdomen: (COMODA method) for a delayed primary closure. With this method, we achieve tension-free closure of the defect in the abdominal wall by leaving in place a mesh for posterior reinforcement. It combines negative pressure wound therapy (Renasys F/AB™ Smith & Nephew Medical Limited Hull, England, UK) with the use of a 26×36 cm condensed polytetrafluoroethylene (cPTFE) mesh (Omyra® Mesh, B. BRAUN Surgical S.A., Rubí, Barcelona, Spain) during the procedure of closing the abdominal wall. The suitability of using a cPTFE mesh lies in its non-adhesion to the viscera features and its macro-porosity, which makes it possible to avoid using the intra-abdominal polyethylene film commonly used in negative pressure wound therapy (NPWT). In addition, its structure prevents biofilm formation, thus making it resistant to infection.

The procedure of closing the abdominal wall using this method has been divided into three stages related to the degree of compromise of the patient's physiologic reserve:

Stage 1: Uncontrolled scenario: Patient in critical and unstable condition makes it necessary to leave the abdomen open. The components for the NPWT kit will need replacement on demand or every 3–4 days, with 100 mmHg of negative pressure. The dressings and components will be changed until the patient becomes stable.

Stage 2: Controlled scenario: Patient that has improved the hemodynamic and metabolic parameters. In this second stage, a cPTFE mesh that prevents gradual contraction by the lateral abdominal muscles is used. Using slow-absorbable or non-absorbable monofilament suture size 1, the mesh is secured at about 1 cm from its edge with full-thickness “U” stitches that are placed 5 cm from the dissected edges, totally covering the exposed viscera. Foam dressing is then placed over it, which is a kit without the polyethylene film (Figs. 1, 2a). After 3–4 days, the NPWT is removed and the mesh is cut along the middle lengthwise, so that there is a flap on either side. Afterwards, at about 3 cm from the cut edges of the mesh, “U” stitches are placed from one side to the other every 3–4 cm. Knot tying begins and it is recommended to start from both ends and work towards the middle with the aim of reducing the tension in the knots. With this procedure, the fascial edges are pulled closer together. The excess mesh is cut away and the NPWT kit is placed. These steps are performed as many times as necessary until a transverse defect of approximately 5–6 cm is obtained, at which point we will proceed to the third stage. (Figure 2b).

An important step of this method is to measure the intra-abdominal pressure (IAP) to keep it under control at all times during surgery to prevent inadvertent

Fig. 1 COMODA method diagram

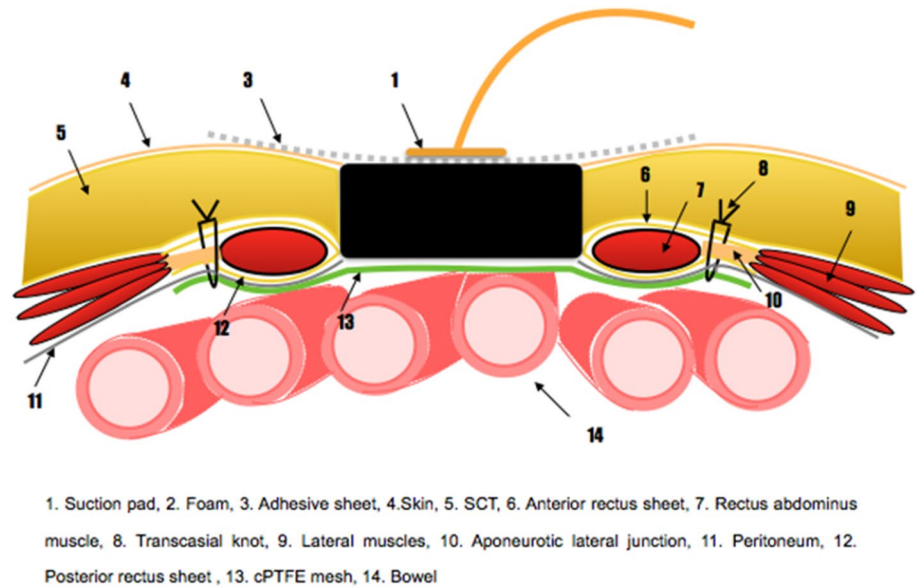
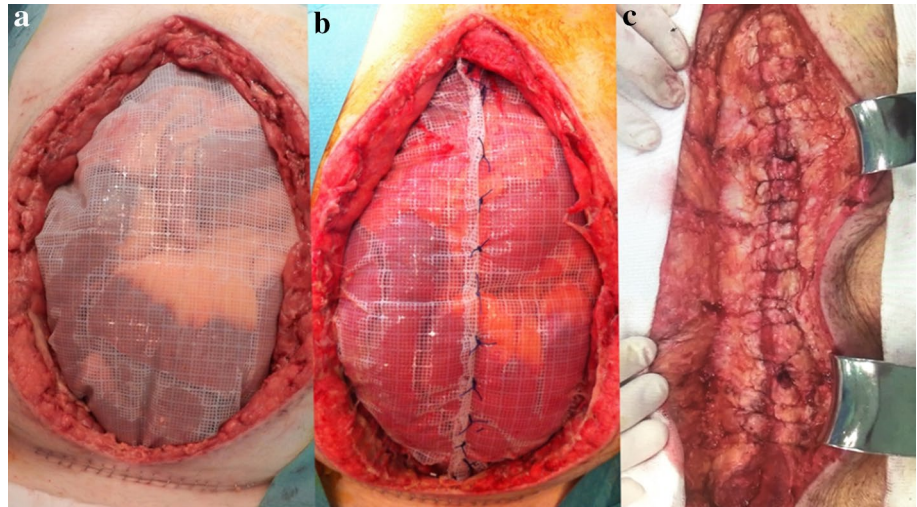


Fig. 2 **a** Stage 2: abdominal wall closure. **b** Stage 2: the cPTFE mesh is applied. The mesh is cut along the middle lengthwise, so that there is 1 flap on either side. **c** Stage 3: definitive closure



intra-abdominal hypertension (IAH) from developing due to the procedures of medial approximation of the mesh.

Stage 3: Definitive closure of the abdominal wall: All of the subcutaneous tissue (SCT) is dissected to obtain a 5 cm margin at the edges. The knots are removed from the cut mesh and new “U” stitches are placed from one side to the other at the fascial edges using monofilament suture size 0 or 1. Following this procedure, approximation of the fascial edges is virtually achieved, with 5 cm of intra-peritoneal mesh on either side. The fascia is then sutured continuously using slow-absorbing monofilament suture size 1 with a conventional ratio of $\geq 4:1$ and gripping the midline of the sutured mesh to achieve complete closure (Fig. 2c). With this method, fascial closure in healthy tissue and intra-peritoneal reinforcement with a “prophylactic” mesh for incisional hernia prevention extending

5 cm on either side is achieved. Moreover, skin remains undamaged.

All patients were admitted at the ICU after surgery during the first and second stages.

Results

A total of ten patients were operated on using this method between January 2015 and June 2016; all were male, median age was 68.8 (43–87) years, and median BMI was 28.09 (24–32). Co-morbidities are described in Table 1. The median number of procedures until definitive closure of the abdominal wall was 5.7 (5–9) being the maximum in the case of a patient with severe sepsis after intestinal suture failure. The median time of definitive closure was 20.8 days

Table 1 Patient characteristics and comorbidity

Age; median (range)	68.8 years (43–87)
Male (%)	10 (100%)
BMI; median (range) ^a	28.1 (24.8–32)
Diabetes [N (%)]	0 (0)
Smokers [N (%)]	5 (50)
COPD [N (%)] ^b	4 (40)
Corticosteroids treatment [N (%)]	2 (20)
Malnutrition [N (%)]	10 (100)
Obesity [N (%)]	3 (10)

^aBMI Body mass index^bCOPD Chronic obstructive pulmonary disease

(10–32). The rate of definitive closure of the abdominal wall was 80% (intention-to-treat) and 100% (per protocol, that is, without taking into account the two patients who died in stage 2 as they were unable to recover from severe sepsis). The median hospital stay was 36.3 (18–52) days. Diagnoses, time to definitive closure, separation of fascial edges, and IAP after closure and others pre- and intra-operative findings are presented in Table 2. In all 6 cases of severe sepsis, the basic cause was an intestinal anastomosis dehiscence.

With regard to early complications related to the procedure, in the eight patients in whom definitive closure of the abdominal wall was achieved, only 1 (14.2%) developed an intestinal fistula because of partial anastomotic dehiscence in the course of a cytomegalovirus (CMV) infection. The other seven patients did not present with any type of wound complications.

Clinical and radiological follow-up with an abdominal CT scan (at 6 months after closure of the abdominal wall) was subsequently performed to assess for the presence of incisional hernia. Only one case develops an incisional hernia during a follow-up of 27 (8–60) months. This patient had previously an incisional hernia as a consequence of a colon

cancer surgery with colostomy. Of the two deceased patients, the first case died due to respiratory failure caused by poor lung capacity as he had a history of right pneumonectomy. In the second case, death was due of a secondary complication due to a ruptured abdominal aneurysm. Both patients died during the second stage (Table 3).

Discussion

In this study, a new method for a delayed primary closure of open abdomen in non-trauma patients, mainly with septic infection, has been applied with a 100% rate of success per protocol within the first 30 days. Studies in which delayed primary closure has been attempted in septic patients have had a success rate of up to 66% [13, 14], although a recent systematic review by Atema et al. [15] describes six series (463 patients) with a global 73.1% rate of success.

Open abdomen plays an important role in the initial control of a focus of infection (damage control) by facilitating repeated examination of the abdominal cavity, preventing compartment syndrome [16]. Nevertheless, Open Abdomen may present with serious complications [17]. To avoid these complications, it is necessary to close the abdomen as soon as possible.

Various techniques for the temporary closure of the abdomen have been described [18], the Bogotá bag, the Wittmann Patch (velcro) [19], and the Brock and Barker methods (vacuum pack) [20–25]. The highest rates of successful primary closure have been observed when NPWT is associated to either of these two methods: in the first case, it is combined with a polypropylene mesh sutured to the fascial edges to carry out medial traction, and the second case, a dynamic closure is used.

The technique which we describe is a modification of the one described by Petersson and Acosta in 2007 [6, 26], in which NPWT was used with gradual medial traction of the

Table 2 Pre- and intra-operative findings

Diagnosis	
Sepsis [N (%)]	6 (60)
Evisceration [N (%)]	2 (20)
AAA; (%) ^a	2 (20)
Surgical features	
Surgical procedures; median (range)	5.7 (4–9)
IAP after closure; median (range)	11.26 mmHg (9.1–13.2)
Separation aponeurotic edges; median (range)	19.98 cm (16.5–24.2)
Time of definitive closure; median (range)	20.8 days (10–32)
Definitive closure [N (%)]	8 (80)

^aAAA Aortic abdominal aneurysm**Table 3** Postoperative findings

Complications	
Wound infection [N (%)]	0(0)
Intestinal fistula after NPWT [N (%)] ^a	1(10)
Incisional hernia [N (%)]	1(10)
Non-surgical variables	
ICU stay; median (range) ^b	12.3 days (6–21)
Hospital stay; median (range)	36.3 days (18–52)
Follow-up; mean (range)	27 months (8–60)
Mortality [N (%)]	2(20)

^aNPWT negative pressure wound therapy^bICU intensive-care unit

abdominal wall by means of a polypropylene mesh fixed to the fascial edge of the defect to achieve primary closure.

Different techniques have been described recently with the objective to preserve the fascial edges [27, 28]. Despite the good results, there are great concerns regarding the severe damage of the fascial edges and the risk of subsequently developing an incisional hernia [29–31]. In patients treated for secondary peritonitis with open abdomen, the incidence of incisional hernia was from 25% up to 50% [32, 33]. The other technique reported primary closure of the open abdomen in septic patients, which consists of a dynamic closure system known commercially as the ABRA (Abdominal Reapproximation Anchor) system [32]. Use of this technique leaves the fascial edges undamaged; however, the abdominal wall and the skin at the site where the elastic bands are inserted are frequently damaged, and, on occasions, can cause ulcerated wounds. More than 30% of patients who only received NPWT and had primary closure developed an incisional hernia [34] whereas among those on whom NPWT + mesh was used only 21% did [29]. Reimer et al. [35] reported a 26% incidence of incisional hernias when this dynamic closure system was used. Montori et al. [36] reported good results using a biological mesh (swine dermal non cross-linked mesh) to reinforce an abdominal wall closure after an open abdomen with only 1 incisional hernia in 9 (53%) cases of total fascia closure. Our group does not have experience using these kinds of meshes.

We have described three stages for the specific treatment with this method that differs from the one published by Cocolini et al. in which four stages were described [37]. We have considered this as three stages referring to the surgical technique but not to the schematic flow-chart for the treatment of the open abdomen described by Cocolini et al.

The COMODA method of the open abdomen that we describe leaves the fascial edges undamaged until the time of definitive closure, a condition that is not considered in other combined traction techniques using meshes where they are sutured to the fascial edge. Our technique also preserves part of the mesh, so that it serves as intra-peritoneal reinforcement, which may contribute to a reduction in the incidence of incisional hernias. In addition, using the cPTFE mesh, there is no need to use the polyethylene film, because the features of this mesh allow contact with the viscera, thereby reducing costs. This is unprecedented, so the application of this method is a novelty. It must be noted that the use of this method is only indicated for patients that are grade 1 and 2 in the classification of the Open Abdomen according to Björck et al. [11].

Another important aspect to consider is the resistance of the mesh used to infection; it is important to take note of this fact because of the fear of leaving in a mesh that has come into contact with a contaminated environment,

as the development of biofilms may perpetuate the infection. This problem did not occur with the mesh that was used. The experimental studies in which this mesh was used showed it to have high resistance to infection due to its structural features (monolayer, uniform, resistant, hydrophobic, macro-porosity, wet-ability, and non-fibrillar structure) and also determined a better inflammatory and wound healing response [38, 39], so we felt that preserving the 5 cm overlap of the mesh on either side and including it in the continuous suture during the definitive closure of the abdominal wall would not entail an added risk, but, instead, would provide a benefit in reinforcing the abdominal wall and reducing the risk for development of an incisional hernia. We had one patient with an incisional hernia in the follow-up. This patient was a particular case, because he had a previous medial incisional hernia, complicated by a small bowel perforation, and so, the fascial edges were not comparable with the other cases. Some studies about the permanence of extended PTFE in inlay or underlay position described the safety when it is used in ventral/incisional hernia repair [40], but they did not demonstrate a beneficial effect of the ePTFE as an adhesive barrier with respect to the occurrence of enterotomy or unplanned bowel resection. In our study, we used a condensed PTFE because of its effectively and durably for the treatment in contaminated and clean-contaminated scenarios described by Cheesborough et al. [41].

In this study, we applied a negative pressure of 100 mmHg and did not have complications, but some authors only use up to 75 mmHg, since an increase of anastomotic leaks and fistulae formation can occur. Therefore, it is very important not to expose the anastomosis directly below the foam sponge to avoid these complications.

The decision to leave an abdomen open must be taken after a thorough assessment of the patient, because the benefit that is sought may turn into an unnecessary risk due to the serious complications that can arise. The duty of the multidisciplinary surgical–medical team is to strictly control the patient's course, so the abdominal wall can be closed as soon as the patient has been stabilized and the initial problem is under control, which, in the case of sepsis, is the site of the infection. Our method would allow a high rate of definitive closure of the abdominal wall and, as an additional measure, would prevent the development of incisional hernias as the abdominal wall is reinforced, but it has some limitations as the small number of cases presented, the absence of a control group with standard medial mesh traction plus NPWT technique, so it will be necessary to conduct studies with larger patient populations, preferably multi-center studies with long-term follow-up, to reach definitive conclusions.

Compliance with ethical standards

Conflict of interest The authors of this manuscript have no conflicts of interest to disclose. RV declares no conflict of interest. YM declares no conflict of interest. MM declares no conflict of interest. CG declares no conflict of interest. GP declares no conflict of interest. AE declares no conflict of interest. JO declares no conflict of interest.

Ethical statement All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Statements of human and animal rights This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

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