



Fasciotens[®] Abdomen ICU: Novel Device Prevents Abdominal Wall Retraction and Facilitates Early Abdominal Wall Closure of Septic Open Abdomen

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Abstract

One of the major challenges in the management of patients with open abdomen (OA) due to septic peritonitis (SP) or abdominal compartment syndrome (ACS) is to control abdominal wall retraction. We herein present a novel device which was successfully implemented on a 49 years old patient with OA caused by necrotizing pancreatitis. Based on a dynamic Fascia-Mesh-Thread-Tensioning System (FMTTS), this device named Fasciotens[®] Abdomen ICU prevented abdominal wall retraction and even displayed abdominal wall extension. Fasciotens[®] Abdomen ICU has been successfully implemented in preclinical studies of animal models and was approved for CE-1 certification.

Keywords: Fasciotens[®] Abdomen ICU; prevention of fascia retraction, open abdomen

Abbreviations: CECT: Contrast-Enhanced Computed Tomography; OA: Open Abdomen; FMTTS: Fascia-Mesh-Thread-Tensioning System; NPWT: Negative Pressure Wound Therapy; VACM: Vacuum and Mesh Mediated Fascial Traction

Introduction

Open abdomen (OA) therapy is often indispensable and life-saving in patients with septic peritonitis, abdominal compartment syndrome, or at damage control surgery after trauma [1]. Patients with OA have a high risk of major complications such as multiple organ failure (30%-40%) [2,3], intraabdominal abscess formation (83%), abdominal wall hernia (25%) [4], and enterocutaneous fistula formation (2%-25%) [5,6]. Mortality of OA has been reported with rates up to 40% and it is associated with increased rates in cases with infection [1]. In a recent study, a significant increase of complication rates after 8 days of OA therapy was reported [7]. Therefore, early closure of OA should be one of the major goals.

One of the major challenges for treatment of patients with OA is primarily to control sepsis and prevent multiple organ failure and secondly, to prevent fascia retraction of temporary closed abdominal wall for delayed primary closure. Previously, various temporary abdominal closure techniques of OA have been proposed [2,8-10]. All of these methods insufficiently counteracted fascia retraction and displayed only, if performed, higher traction on the

fascia by stepwise closing of the fascia during repeated abdominal exploration [11]. Hence, many OA patients frequently develop large ventral hernias of the abdominal wall, that require complex repair surgery at a later stage [4]. Fasciotens[®] Abdomen ICU (Essen, Germany) is a novel device based on dynamic Fascia-Mesh-Thread-Tensioning System (FMTTS). This device allows decompression of increased abdominal pressure, prevents fascial retraction and facilitates early abdominal wall closure in patients with OA. Fasciotens[®] Abdomen ICU has been successfully implemented in preclinical studies of porcine animal model [12]. In the present case, we report the use of Fasciotens[®] Abdomen ICU in an OA patient with generalized sepsis due to necrotizing pancreatitis.

Case Report

A 49 years old patient with a history of alcohol induced necrotizing pancreatitis previously diagnosed with Contrast-enhanced Computed Tomography (CECT) scan and treated conservatively at the department of internal medicine of an associated teaching hospital of our university clinic was relocated

due to generalized sepsis in December 2018 for further treatment in the ICU of our surgical department. On admission, the patient was on mechanical ventilation and hemodynamic unstable. Blood chemistry on admission showed increased levels of leucocytes ($25.5 \times 1000/\mu\text{l}$), C-reactive protein (20.2 mg/dl) and serum amylase (629 U/L). Despite conservative therapy with calculated antibiotics, analgesia and intravenous fluid substitution, the patient's clinical condition progressively worsened. CECT-scan four days after admission showed a progression of the necrotizing pancreatitis with peripancreatic fluid collection as well as ascites. Because of the high risk of bowel perforation, image-guided percutaneous catheter drainage of the necrotic peripancreatic fluid collection, was not performed. On the fifth day of clinical course, the patient developed ACS. After emergency decompressive laparotomy, necrosectomy and abdominal lavage, the abdominal cavity was sealed temporary with a Bogotá bag. On a period of two weeks, daily abdominal lavage with necrosectomy of the pancreatic necrosis was performed. Here, temporary closure of the abdominal cavity was carried out with a vicryl mesh. Three weeks after pulmonary and hemodynamic stabilization, Fasciotens® Abdomen ICU was applied.

Despite the unfavourable Björck grade 3 [12] (Figure 1) classification of the patients OA and initially retracted fascia, Fasciotens® Abdomen ICU was implemented. Prior to application,

the patient was intraoperative fully relaxed using a muscle relaxant agent (Esmeron®), before the gap between both fascial margins was measured (15 cm)(Figure 2). After abdominal lavage and surgical debridement of the fascia to create clean mobile fascia margins, a doubled vicryl mesh (maximum. width: 2-3cm) was sewed at both fascial margins. Hereafter, twelve commercial surgical threads, with six attached at each side to defined areas on both meshes (Figure 2) were then crossly tensed on the Fasciotens® Abdomen ICU clamping system (Figures 3&4). The abdominal cavity was temporary sealed with a Bogotá bag and abdominal cloths (Figures 2&4). During repeated abdominal exploration 48 hours after Fasciotens® Abdomen ICU implementation, a significant gap reduction of 5 cm between both fascial margins was evident (initially 15 cm). Further abdominal exploration on-demand using the dynamic tension of Fasciotens® Abdomen ICU also proved abdominal wall extension. Two weeks after the device application, the abdominal wall was successfully closed (Figure 5). Four days prior to abdominal wall closure, the patient was extubated and the extended abdominal wall temporary closed with a vicryl mesh to facilitate surgery for repeated lavage. A postoperative subcutaneous wound healing disturbance (Figure 5) which occurred after abdominal wall closure was successfully treated one week later at our outpatient clinic.



Figure 1: Patient's Björck grade 3 OA with retracted fascial margins.



Figure 2: After abdominal lavage and debridement of the fascia, a double vicryl mesh was attached on both fascial margins and 6 commercial surgical threads were sewed on each side of the vicryl mesh. The abdomen was temporary sealed with a Bogotá bag. The gap between both fascial margins was measured.



Figure 3: Surgical cloths placed on the Bogotá bag. The surgical threads are crossly tensed on the common suspension of Fasciotens® Abdomen ICU.

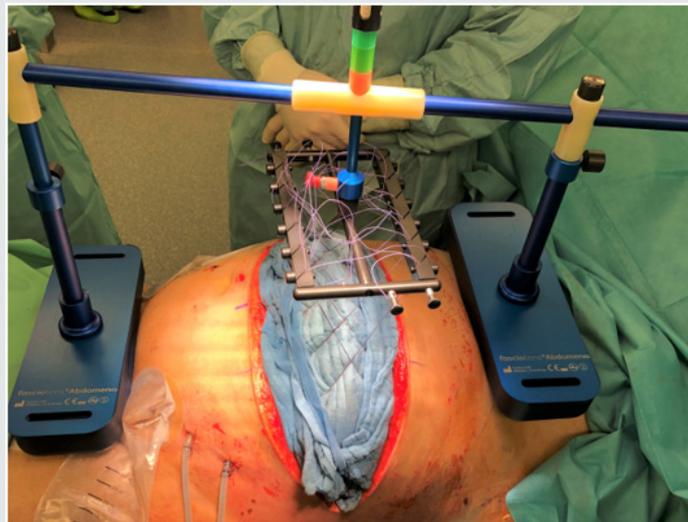


Figure 4: Position of the complete mounted Fasciotens® Abdomen ICU on the OA patient.



Figure 5: Subcutaneous wound healing disturbance after abdominal wall closure.

Device description

The main principle of the device is the application of ventrally-directed traction along both fascial margins over a clamping system (Figure 4). It consists of a beam with two buttresses applied to the thorax and anterior pelvic ring. After midline or transverse laparotomy, a doubled vicryl mesh sewed at both fascial margins and looped using commercial sutures distributes traction force along the entire length of the fascial edges. Six sutures on the mesh of each fascial margin carried through eyelets are fastened on a common suspension. The eyelet suspension is attached to the longitudinal beam with a height-adjustable connection. Using this dynamic connection, the fascial traction can be increased or decreased as needed. In this case, we adjusted the fascial traction to the dark green field of the longitudinal beam. This field corresponds to a traction force of 80 Newton according to the manufacturer's specifications. Once suspended and tensed on the adjustable longitudinal beam, the fascial margins are pulled anteriorly relative to the thorax and pelvis. This prevents the natural muscle traction and the resulting fascial retraction and also promotes anterior extensive tissue development. Simultaneously, the open abdomen allows pressure release.

Discussion

In this case report, a novel device which prevents fascial retraction and facilitates early abdominal wall closure was successfully implemented for the first time on a patient with open abdomen (OA). Despite OA for three weeks prior to Fasciotens® Abdomen ICU application, closure of the patient's septic abdomen was achieved in two weeks. However success rate of abdominal closure depends on the etiology [13]. Patients with septic abdomen or higher Björn grade (grade 2B-4) have lower chance of fascial closure compared to non-septic or lower Björn grade (1A-2A) [2,10]. Up to date, treatment of the OA underlies a negative pressure wound therapy (NPWT). Although NPWT has been reported to have the best closure results, NPWT is also associated with a high rate of incisional hernias [15]. Recently, various closure methods for OA have been proposed. In the study of Acosta et al. [10] high rates (>90%) of primary delayed fascial closure were achieved with vacuum and mesh mediated fascial traction (VACM) after aortic repair. Here, the median duration of OA was 11 days. However, this high rates of fascial closure were observed in patients with non-septic abdomen (Björn grade 1A). In contrast, in the study of Verdam FJ al [2] primary abdominal closure rate of 88 % of patients with septic open abdomen was achieved using an Abdominal Re-approximation Anchor System (ABRA®). Here, primary abdominal closure of the midline was accomplished in 15 days (range: 7-30 days). Supported with NPWT, the ABRA® system approximates the wound margins through dynamic traction exerted by transfascial elastomers. Despite primary midline closure with ABRA®, high rates of pressure sores of the skin and dermis as well as ventral hernias were observed. In this case, Fasciotens® Abdomen ICU was applied on a patient with OA under general anesthesia. 48 hours after Fasciotens® Abdomen ICU application and during further repeated abdominal exploration, we observed a significant reduction of the gap between both fascial margins. Fascia traction und fascia

extension leading to delayed primary closure was achieved with the dynamic tension of this device. Application of NPWT was not performed due to frequent lavage. As reported on the preclinical porcine model of Eickhoff et al. [12], the exerting pressure of this device on the thorax did not affect the breathing and vital signs of our patient. Furthermore, we observed no pressure sores of the skin despite pressure exerted by the buttresses on the thorax and the anterior pelvic ring. However, repositioning of the buttresses and readjustment of the longitudinal beam was frequently undertaken after positioning of the patient, in order to maintain tension on the fascia.

Conclusion

In conclusion, the implementation of Fasciotens® Abdomen ICU prevented in this case further fascia retraction and also enhanced abdominal wall extension. This could reduce the necessity of complex abdominal wall reconstructions as well as the rate of mesh graft transplantation. Moreover, this could be of socio-economic importance due to reduction of the length of hospitalisation. However, a prospective study with a large number of patients is needed to investigate feasibility and efficacy regarding fascial conditioning.

Conflicts of interest

There are no conflicts of interest

Funding

Fasciotens GmbH (Essen, Germany) provided the device. They were not involved in analysis, interpretation of data and in writing the manuscript.

Ethical Approval

The Ethics Committee of the Heinrich Heine University Düsseldorf and University Hospitals Düsseldorf confirms that this Case report does not require the formal vote of its Ethics Committee based on the current laws.

Consent

An informed consent was obtained from the patient. All the patient related data and pictures were anonymised.

Author Contribution

Fung SN designed, wrote the report, analyzed and interpreted the data; Vaghiri S and Rehders A were attending doctors of the patient; Kröpil F, Fung SN and Vaghiri S performed the operation; Ashmawy H, Rehders A. and Knoefel WT critically revised the report and gave important intellectual input

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none

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