

1 Intraoperative Fascia Tension as an Alternative to Component Separation. A Prospective Observational Study ¹

This prospective trial was carried out in 7 hospitals specialized in hernia surgery between November 2019 and August 2020. In this study, the fasciotens®Abdomen device was used for the same indication as fasciotens®Hernia. The patient characteristics can be found in Table 1. Inclusion criteria were a ventral hernia with a transverse diameter of 8 cm or above (W2 or higher according to EHS classification). Maximum traction forces of 10kg were applied and mean traction time was 32.5 ± 3.4 (mean and Standard Deviation (SD)). 19 patients received mesh augmentation in Sublay position, and two patients were treated with an intraperitoneal Onlay mesh (IPOM). Despite one patient, all cases had a closure of the anterior rectus sheet with moderate tension. One patient needed an additional anterior component separation.

Table 1 Patient characteristics (according to Niebuhr et al., 2021¹)

Gender (male/female) – N = 21	15/6
Age [years] – N = 21, mean \pm standard deviation (range)	58.2 ± 12.2 (33–77)
BMI [kg/m²] – N = 20, mean \pm standard deviation (range)	32.5 ± 7.8 (20.3–51.6)
ASA – N = 21	
I	0
II	7
III	14
IV	0

Thirteen (13/21) patients were treated with BTA preoperatively. No significant difference regarding outcome was found between the two groups. The mean preoperative fascial distance measured either on CT scan or MRI was 15.2 ± 8.8 (mean and SD). The intraoperative measured fascial distance before traction and under full relaxation was 17.3 ± 8.6 (mean and SD). After fascial traction, the distance was 7.5 ± 5.7 (mean and SD) with a significant reduction in fascial distance of 9.8 ± 5.7 (mean and SD) ($p < 0.001$). No device-related events were reported. One patient required VAC treatment due to surgical site infection and was reoperated on day 14 postoperatively having a 5 cm fascial dehiscence. Three other patients suffered from subcutaneous wound healing disorder and were treated with negative pressure wound therapy (NPWT). In total 4 cases had a Surgical Site Occurrence (SSO) (4/21, 19%). Five other patients had postoperative complications during hospital stay (5/21, 23.8%).

2 Intraoperative fascial traction (IFT) for treatment of large ventral hernias: A retrospective analysis of 50 cases ²

This retrospective analysis was carried out after treating 50 patients with fasciotens®Hernia in 11 different hospitals specialised in hernia surgery. The patients were treated between November 2019 and April 2021. In this paper either fasciotens®Abdomen or fasciotens®Hernia in combination with fasciotens®Carrier was used in all cases. Patient characteristics can be found in Table 2

Table 2 Patient characteristics (according to Niebuhr et al., 2022²)

Gender (male/female) – N = 50	20/30
Age [years] – N = 49 mean \pm standard deviation (range)	60.4 ± 2.1 (33–89)
BMI [kg/m²] – N = 50, mean \pm standard deviation (range)	30.5 ± 0.9 (20.3–49.1)

ASA – N = 50	
I	1
II	29
III	20
IV	0

Inclusion criteria were a ventral hernia with an intraoperatively measured transverse diameter of 8 cm or above (W2 or higher according to EHS classification). The diameter ranged from 8 to 44 cm with 94% of patients having a hernia gap above 10 cm (W2 or higher according to EHS classification). Mean defect size intraoperatively measured with patient being under full relaxation before IFT was carried out was 16.1 ± 0.8 (mean and SD). The Fascial distance after IFT was 5.8 ± 0.7 (mean and SD). The reduction was therefore 10.2 ± 0.7 which was significant ($p < 0.0001$). The direct closure rate of the anterior rectus sheets was 90% (45/50). All patients received a mesh augmentation in Sublay position. Postoperative complications occurred in 6 patients (12%) with 3 patients requiring a re-operation due to subcutaneous healing disorders. Three patients had either seroma or hematoseroma and were treated conservatively. No other complications and no device-related adverse events were reported in this trial.

3 Assessment of myofascial medialization following intraoperative fascial traction (IFT) in a cadaveric model ³

This study aimed to assess the impact of IFT on the extent of myofascial advancement using a cadaveric model. 4 fresh-frozen specimens were used and retromuscular dissection (Rives-Stoppa) was carried out, followed by 30 minutes of fascial traction using fasciotens®Hernia. Medial advancement after 15 and 30 minutes was measured. Furthermore, traction forces were also recorded. After 30 minutes a total medialisation of 10.5 cm (mean) was achieved and a mean traction force of 16.28 kg was applied. Table 3 shows the myofascial advancement per side and in total.

Table 3 Mean values for medialization of the anterior rectus sheets

	Left [cm]	Right [cm]	Both sides [cm]
Myofascial advancement (mean cumulative)	5.5	5	10.5
Myofascial advancement (mean cumulative)	3	4	7
Myofascial advancement (mean cumulative)	2.5	1	3.5

Noteworthy, the myofascial advancement was significantly higher after the first 15 minutes of IFT. The results align with intraoperative findings for IFT, especially regarding medialisation of the abdominal wall. The data are comparable to results from cadaver studies for component separation.

4 Preoperative Botulinum toxin A (BTA) and intraoperative fascial traction (IFT) in the management of complex abdominal wall hernias ⁴

The retrospective single-center analysis was carried out by Prof. Niebuhr and colleagues from the Hamburg Hernia Center. 143 patients with complex abdominal wall hernias treated with preoperative Botulinum Toxin A (BTA) administration to the lateral abdominal wall and intraoperative fascial traction (IFT) were included. Cases from August 2019 to December 2023 were identified in the prospectively maintained database and reviewed retrospectively. Metrics included intraoperative findings and short-term (30 days) postoperative outcomes. Main characteristics are shown in Table 4. The mean intraoperative reduction of fascia-to-fascia after BTA and IFT was 9.81 cm. 14 patients either

had a lateral defect or a combination of a midline and lateral hernia. An additional uni- or bilateral transverse abdominis release (TAR) was necessary in 43 cases (30.1 %). The overall surgical postoperative complication rate was 30.1 % of which 13.8 % were surgical site infections (SSI). Re-operation and complication rates were significantly higher if an additional TAR was performed (both $p=0.001$; $\alpha=0.05$). It can be concluded that IFT, especially in combination with BTA is a transformative and clinically proven tool in the surgeons' toolbox.

Table 4 Patient and surgery related parameters

Age [years] – mean and standard error of the mean	58.9 ± 1.2
BMI [kg/m²] – mean and standard error of the mean	32.4 ± 0.9
Defect width before IFT [cm] – mean and standard error of the mean	16.9 ± 0.4
Defect width after IFT [cm] – mean and standard error of the mean	4.7 ± 0.3
Additional TAR required [%]	30.1
Length of Stay [days] - mean and standard error of the mean	7.67 ± 0.5

Based on the positive results of IFT to date, an algorithm (Hamburg algorithm) for the surgical treatment of complex abdominal wall/incisional hernias was developed.

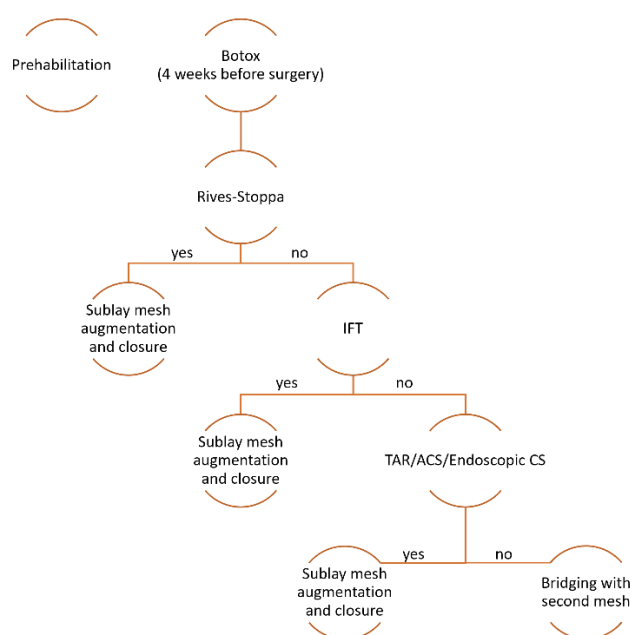


Figure 1 Algorithm for complex ventral and lateral abdominal wall hernias

5 Case Report: Intraoperative Fascial Traction in Robotic Abdominal Wall Surgery; An Early Experience ⁵

This is the first report on fasciotens being used in robotic abdominal wall surgery. The cases were selected due to the expectation of difficult midline closures because of high BMI. The first patient had an incisional hernia following an emergency laparotomy. The second and third cases presented recurrent midline hernias. The last case had mesh in situ from a previous hernia repair. In all three cases, midline closure was achieved using fasciotens. The Midline closure was carried out without any tension during suturing. The added time of the fasciotens technique decreased over the three cases and was approximately one hour in the third case compared to a standard robotic TARUP. In

conclusion, the use of IFT is feasible in robotic abdominal repair. Summarized results are shown in Table 5

Table 5 Patient characteristics and operative results

Age	Length [cm]/weight [kg]/BMI [kg/m ²]	Hernia width [cm]	Operative time [min]	Length of stay [days]
65	186/114/33.0	10	255	2
47	172/110/37.1	7	171	3
48	202/169/41.2	7	186	2

6 Follow-up of Complex Hernia Repair with Intraoperative Fascial Traction

This trial was conducted by five hospitals in Germany specialized in abdominal wall surgery. The presented data are collected from the evaluation of 100 patients who underwent complex ventral hernia repair and were invited for a planned follow-up. A clinical examination and standardized ultrasound were conducted. Furthermore, the patients answered the HerQles questionnaire to determine postoperative Quality of Life. The following Table 6 shows patient and surgery related outcome.

Table 6 Patient and surgery related parameters

Age [years] – mean and standard error of the mean	60.7 ± 14.3
BMI [kg/m ²] – mean and standard error of the mean	31.3 ± 6.7
Defect width – mean and standard error of the mean	15.8 ± 5.2
BTA pretreatment [%]	87
Additional TAR required [%]	28
Bridging of the anterior rectus sheet (w/o TAR) [%]	6
Length of Stay [days] - mean and standard error of the mean	8.8 ± 11.8
Follow-up time [month] – mean and standard error of the mean	19,6 ± 10,7

All patients in this cohort had a W3 hernia according to EHS classification. Postoperative Surgical Site occurrences (SSO) were seen in 33% of all patients whereby Surgical Site Infections (SSI) occurred in only 9 patients (9%). The rate of SSIs and SSOs differed between the patients who only had IFT and patients who were treated with IFT and TAR (10,7% vs. 8,3% and 50% vs. 26,4 % respectively). Interestingly, the occurrence of a postoperative SSO was significantly higher if an additional TAR was performed ($p=0.024$, $\alpha=0.05$) as well as the development of a seroma ($p=0.008$, $\alpha=0.05$).

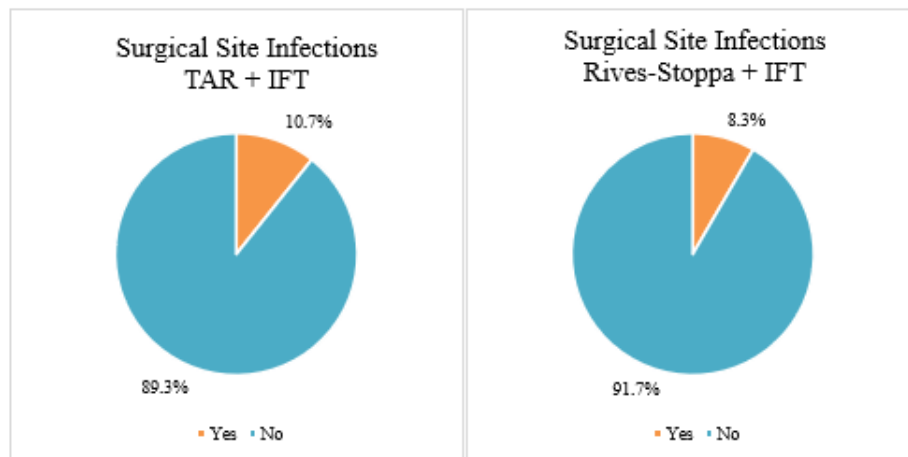


Figure 2 SSIs for patients treated with transverse abdominis release (TAR) and intraoperative fascial traction (IFT) as well as patients treated only with Rives-Stoppa and IFT

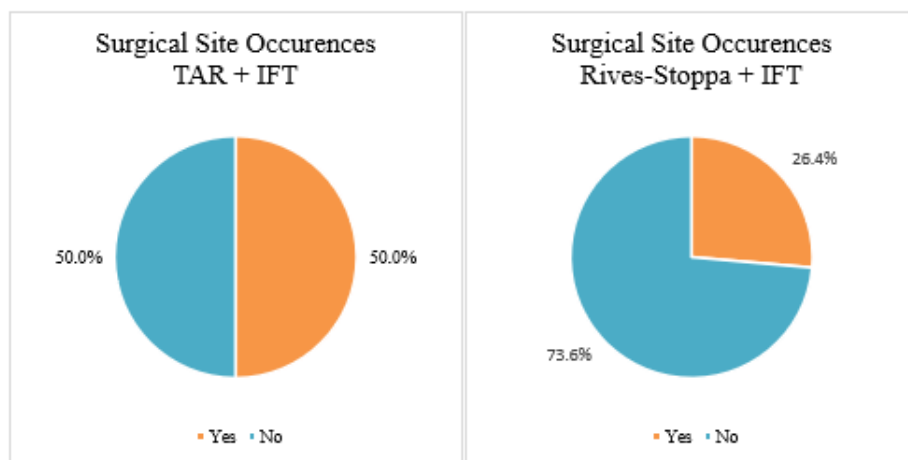


Figure 3: SSOs for patients treated with transverse abdominis release (TAR) and intraoperative fascial traction (IFT) as well as patients treated only with Rives-Stoppa and IFT.

Surgical revision was necessary in sixteen cases (16%). Interestingly, the number of cases in need for a revision was higher if an additional TAR was performed. However, the need for revision due to SSO wasn't significantly higher in the TAR group ($p=0.126$, $\alpha=0.05$). The reasons for revision were mainly seroma or hematoma.

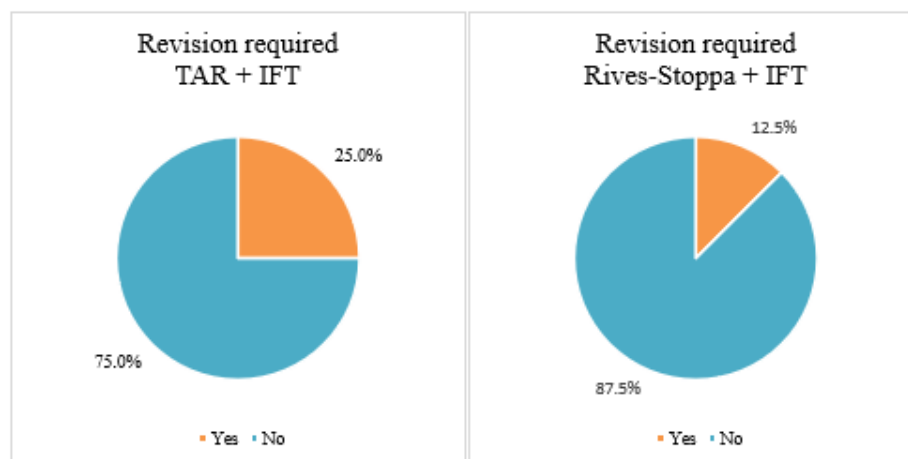


Figure 4 Percentage of patients with SSO who required revision treated with transverse abdominis release (TAR) and intraoperative fascial traction (IFT) as well as patients treated only with Rives-Stoppa and IFT

No device-related complications have been reported or led to a surgical revision. The Mortality rate was 0%. The Mean follow-up time was 19.6 ± 10.7 (Mean and SD) months. Two recurrences have been found during clinical examination or standardized ultrasound. Both patients with recurrence developed them 6 months after primary surgery and had to undergo a re-operation. The mean HerQles summary score in this cohort was 68.5.

In summary, this study is the first to present long-term follow-up data on complex hernia repair with IFT. Complication and re-Operation rates are comparable to other advanced techniques like TAR or ACS. No device-related complications were reported. Recurrences were only seen in 2 cases showing the high potential of IFT.

7 Case Reports and Summaries (not summarised)

Romain et al. 2022 - A complex incisional hernia repair with Intraoperative Fascial Traction device (with video) ⁶

Gorjanc et al. 2023 - The use of intraoperative fascial traction in W3-incisional hernia repair: A revolution or an emergency exit (two case reports) ⁷

Eucker and Rosenberg 2023 - „Loss of domain“ und Verringerung der medianen Nahtspannung ⁸

De Matteis et al. 2023 - From damage control surgery to complex abdominal wall reconstruction It is possible even in the elderly in a Spoke Center? ⁹

Gök 2025 - Case Report: Intraoperative Fascial Traction for Increasing Intra-Abdominal Volume in Loss-of-Domain Incisional Hernias: A Report of Two Cases ¹⁰

Groß et al. 2025 - Osterix im Land der Hernien (Osterix in the Land of Hernias) ¹¹

Balachandran et al. 2025 - Botulinum toxin and fasciotens in the management of complex ventral hernia: a case report ¹²

Published summarised data fasciotens®Abdomen

1 Vertical traction device prevents abdominal wall retraction and facilitates early primary fascial closure of septic and non-septic open abdomen ¹³

In this retrospective multicentre study, researchers evaluated fasciotens®Abdomen for managing patients with open abdomen (OA). The aim of the study was to evaluate whether fasciotens®Abdomen can control abdominal wall retraction and improve primary fascial closure (PFC). The study included 20 patients treated with OA. Causes of septic OA were gastrointestinal perforation (n=10) and necrotizing, infected pancreatitis (n=2). Non-septic OA resulted in ACS after aortic rupture and repair (n=4), intestinal ischemia (n=2), and mechanical ileus (n=2).

Table 7: Patient characteristics

Gender (male/female) – N = 20	16/4
Age [years] – mean (range)	60 (36-80)
APACHE II score – mean (range)	20 (15-28)
Björck classification of OA	
1A	4 (20%)
1B	4 (20%)
2B	12 (60%)

The abdomen was initially stabilized using laparostomy and sealed with either a Bogotá bag or negative pressure wound therapy (NPWT). The mean duration of OA before applying fasciotens®Abdomen was 3 days and the mean fascia-to-fascia distance (FTF) was 15 cm. After implementation of fasciotens®Abdomen, the mean FTF decreased significantly to 10 cm ($p = 0.0081$) after 48 hours. Definitive fascial closure was achieved in all cases after a mean period of 7 days. This study was the first evaluation of fasciotens®Abdomen in a patient collective. No device-related adverse events were reported in this trial. The study showed that vertical mesh-mediated fascial traction can facilitate definitive fascial closure in open abdomen treatment and is a feasible and innovative method.

2 Vertical Mesh-Mediated Fascial Traction and Negative Pressure Wound Therapy: A Case Series of Nine Patients in General and Vascular Surgery ¹⁴

The publication examined the application of vertical mesh-mediated fascial traction (VMMFT) using fasciotens®Abdomen in combination with abdominal negative pressure wound therapy (NPWT) for the treatment of open abdomen (OA). A total of nine patients (two in vascular surgery, and seven in abdominal surgery) were treated between 2019 and 2023. A complete fascial closure was achieved in seven out of nine cases and the average duration of the open abdomen was 9.6 days. The initial fascial dehiscence before applying fasciotens®Abdomen averaged 14.2 cm. The time to fascial closure after starting with fasciotens®Abdomen was 6.2 days. No treatment-related complications were reported. Based on the results, a treatment algorithm, modelled after the Koblenz Algorithm, was developed and presented for the first time for the treatment of open abdomen cases with abdominal NPWT and fasciotens®Abdomen.

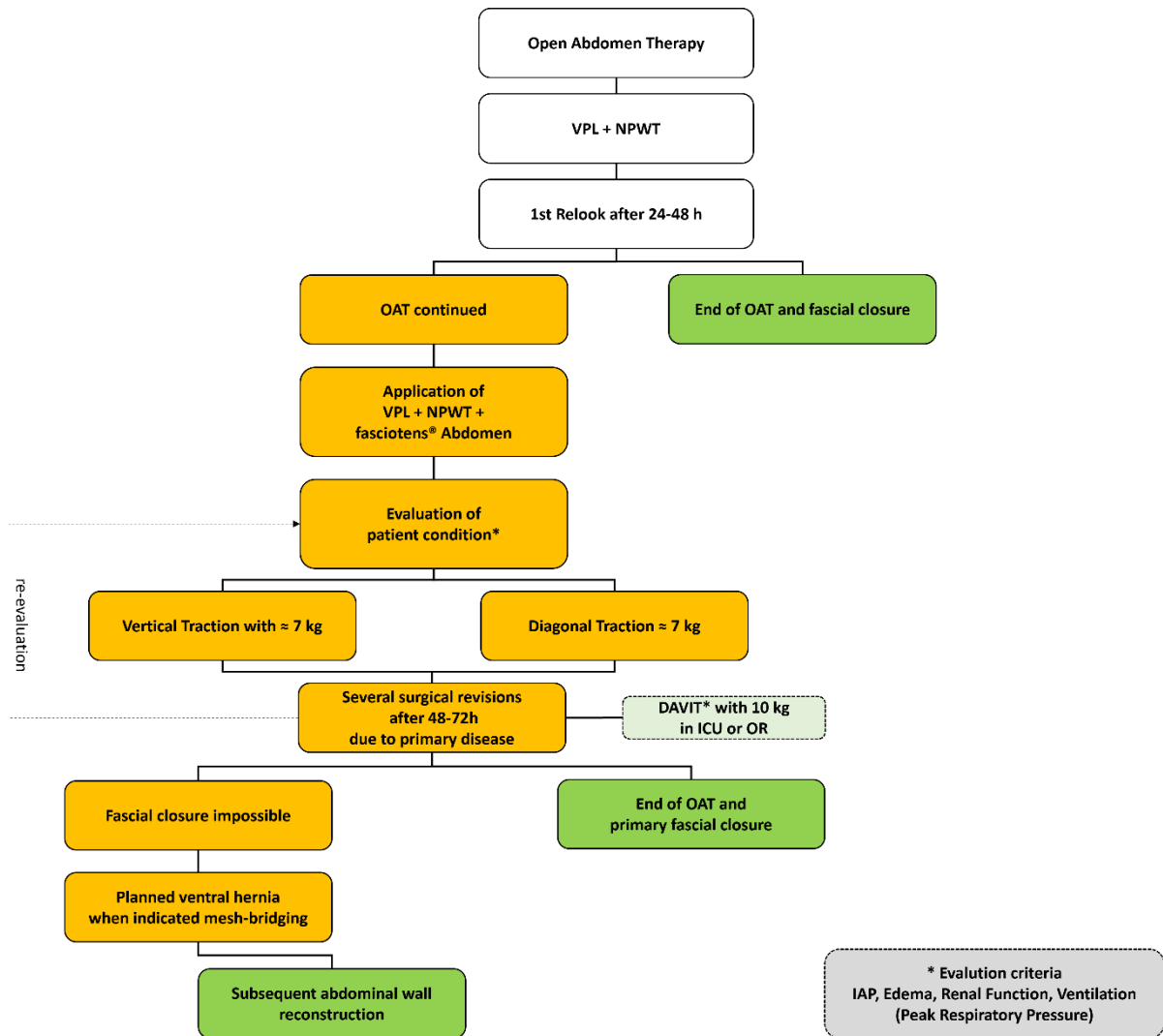


Figure 5 Algorithm for VMMFT using a device to apply controlled and reproducible traction to abdominal wall

Additionally, this publication details and illustrates the application of fasciotens®Abdomen and abdominal NPWT.

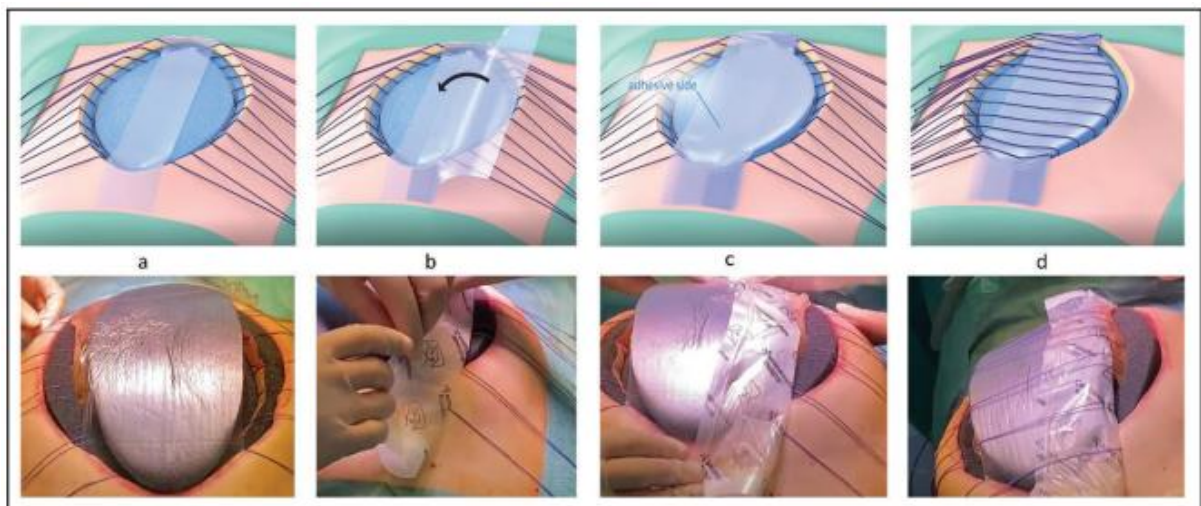


Figure 6 Airtight sealing for NPWT Part 1

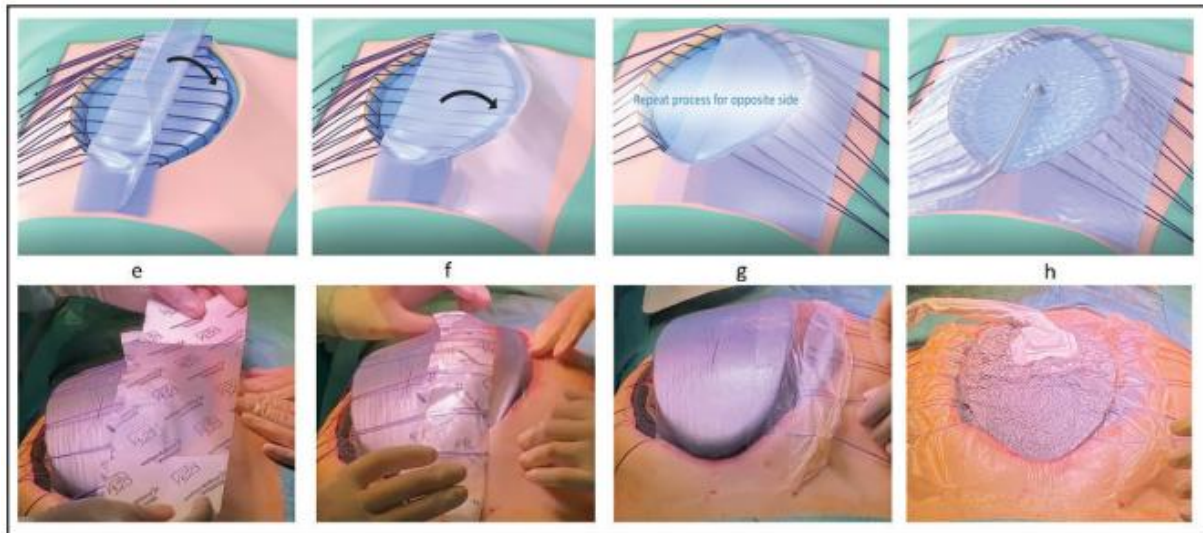


Figure 7 Airtight sealing for NPWT Part 2

3 Case Report: Fasciotens® Abdomen System Application for Delayed Primary Fascial Closure and Observed Physiological Improvement of the Patient ¹⁵

The publication examined the use of fasciotens®Abdomen in a middle-aged patient with severe peritonitis following small intestine perforation. Within a few hours after the installation of the device, a significant improvement in organ function was achieved. This was evidenced by increased urine output, increased stoma output (intestinal transport), stabilization of hemodynamic status and ventilation. These physiological improvements indicate a profound impact on the overall stabilization of the patient. Successful fascial closure was achieved after 6 days using the device. The case report on one patient suggests a stabilizing effect of fasciotens®Abdomen on hemodynamic as well as excretion and lung function in the treatment of open abdomen.

4 Evaluating a novel vertical traction device for early closure in open abdomen management: a consecutive case series ¹⁶

This study is a retrospective analysis of nine patients in need of an open abdomen (OA) treated at the University Hospital of Bonn, Germany between 2019 and 2020. Six patients achieved early definitive fascial closure (DFC). Three patients died of organ failure during OA treatment unrelated to the application of the device. Fasciotens®Abdomen was used in combination with negative pressure wound therapy (NPWT). The mean time to DFC was 9 ± 3 days, and patients required an average of 3 ± 1 surgical procedures after establishing OA. The use of fasciotens®Abdomen resulted in a reduction in the fascia-to-fascia distance by 76% until DFC was achieved. Additionally, intra-abdominal pressure (IAP) was reduced from 31 ± 8 mmHg before OA to 8.5 ± 2 mmHg after applying the device. The application did not adversely affect ventilation parameters or the Simplified Acute Physiology Score II (SAPS II), indicating that the device is safe for use in critically ill patients. The primary complication observed was skin irritation, with three patients developing skin blisters. No other significant complications were reported.

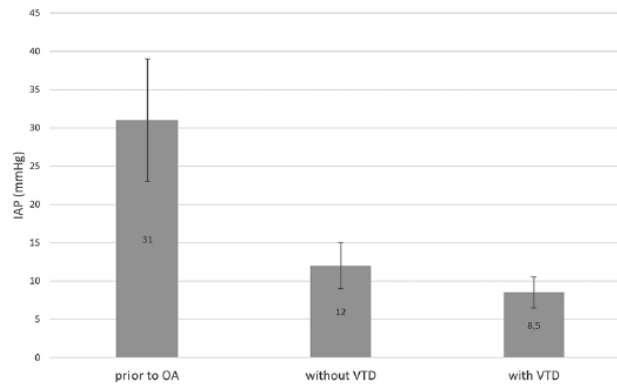


Figure 8 Intra-abdominal pressure (IAP) was measured in mmHg at various timepoints: Prior to laparotomy for Abdominal Compartment Syndrome (ACS), after pressure relief without fasciotens®Abdomen and after pressure relief and application of fasciotens®Abdomen. Results represent mean values and standard deviations ¹⁶

The study concludes that fasciotens®Abdomen is a safe and feasible option for managing OA cases. By promoting early DFC, fasciotens®Abdomen may help reduce complications associated with OA, such as abdominal infections, entero-atmospheric fistula (EAF), and abdominal wall hernia formation.

5 Case Reports (not summarised)

Eickhoff et al. 2019 - A new device to prevent fascial retraction in the open abdomen – proof of concept in vivo ¹⁷

Fung et al. 2019 - Fasciotens© Abdomen ICU Novel Device Prevents Abdominal Wall Retraction and Facilitates Early Abdominal Wall Closure of Septic Open Abdomen ¹⁸

Halama et al. 2020 - Chirurgische Allgemeine - Fasziendehnung zum Bauchverschluss nach perforiertem Bauchaaortenaneurysma

Hees and Willeke 2020 - Case report - prevention of facial retraction in the open abdomen with a new device ¹⁹

Ramana and Nguyen 2024 - AbThera, Botox, and Fasciotens: A Trifecta in Open Abdomen Management ²⁰

Published summarised data fasciotens®Pediatric

1 Use of a new vertical traction device for early traction-assisted staged closure of congenital abdominal wall defects: a prospective series of 16 patients ²¹

In this multicentre prospective feasibility study, four different university hospitals in Germany collected clinical data on the application of standardized vertical traction to the abdominal wall using fasciotens®Pediatric in newborns with Gastroschisis (GS) and Giant omphalocele (GOC). 16 patients were included. The following variables were collected during this study: age, sex, body weight, diagnosis, defect type, force and duration of traction, surgical or mechanical complications during and after the traction treatment (surgical site occurrence (SSO) and surgical site infections (SSI)), duration of mechanical ventilation, duration of intensive care admission, duration of hospital stay. Patients with OC and GS were included in the case of a viscerio-abdominal disproportion with the need for a staged closure approach. Patients with abdominal wall aplasia, coagulation disorders, and cardiorespiratory instability including pulmonary hypertension, pulmonary hypoplasia, and severe cardiac defects were excluded. The results are summarized in Table 8

Table 8 Overview of patient and outcome data in patients treated with fasciotens®Pediatric for giant omphalocele and gastroschisis

	Giant omphalocele	Gastroschisis
Number of cases	10	6
Median age at birth (range)	37+5 (34+5 to 39+1)	35+6 (32+2 to 38+2)
Median birth weight in gram (range)	3,185 (2,070-3,740)	2,525 (1,500-3,500)
Median traction force in gram (range)	1,000 (500-1,000)	1,000 (500-1,000)
Median ration of traction force to body weight in % (range)	29 (16-35)	33 (26-45)
Median days of traction (range)	7 (4-22)	5 (2-11)
Median days of ventilation (range)	12 (0-46)	7 (2-27)
Median days of NICU admission (range)	28 (10-137)	28 (16-37)
Median days of hospital stay (range)	31 (17-137)	32 (26-62)

In two GOC cases, a SSO (tear out of the Gore-Tex® patch, tear out of traction sutures) was documented during the traction treatment. In one GS case, a SSO (skin suture line dehiscence) was documented. There was no case of SSI during or after the traction procedure and no compartment syndrome was seen. Also, no device-related adverse events could be observed. The median follow-up time was 12 months (range 4 to 22 months). During this time, no hernia formation was found in any of the cases. None of the patients died during the treatment or in the course of the follow-up. In conclusion, the feasibility and safety of the device was confirmed. The quantification and reproducibility of the procedure were seen as an advantage compared to previous therapies. . A 2-step procedure could be a great advantage for the treated newborns, as a definitive closure is achieved, and future operations can be prevented for these patients.

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