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Intraoperative fascial traction (IFT) for the treatment of large ventral hernias

A retrospective analysis of 50 cases

Note:
This article has been translated from German to Englisch language by a certified translation agency.

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Summary

Objective: The aim was to evaluate the effectiveness, clinical practicability, and complication rate of the intraoperative fascial traction (IFT) procedure for the treatment of large ventral hernias.
Method: This study evaluated 50 patients from 11 specialised centres with an intraoperatively measured fascial distance of more than 8 cm, who were treated by IFT (traction time 30–35 min) using the hernia traction procedure (fasciotens GmbH, Essen, Germany).
Results: Fascial distances measured preoperatively ranged from 8 cm to 44 cm, with most patients (94%) having a fascial distance greater than 10 cm (W3 according to the European Hernia Society classification). The mean fascial distance was reduced from 16.1 ± 0.8 cm to 5.8 ± 0.7 cm (stretch gain 10.2 ± 0.7 cm, $p < 0.0001$, Wilcoxon matched-pairs signed-ranks test). A reduction in fascial distance of at least 50% was achieved in three quarters of the patients and in half of the treated patients the reduction in fascial distance amounted to even more than 70%. The closure rate achieved by IFT after a mean surgical duration of 207.3 ± 11.0 min was 90% (45/50). Hernia closure was performed in all cases with a mesh augmentation in a sublay position. Postoperative complications occurred in 6 patients (12%). A reoperation was required in 3 patients (6%).
Conclusion: The described IFT method is a new procedure for abdominal wall closure in large ventral hernias. The presented results demonstrate a high effectiveness, a good clinical practicability and a low complication rate for IFT.

Keywords
Abdominal wall hernia · Incisional hernia · Component separation · Fascial distance · W3 hernias

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Abdominal wall hernias are among the most common conditions that require (visceral) surgery. The incidence one year after laparotomy is approx. 8-16 % [1, 29].

Large incisional hernias are a growing problem for abdominal wall surgeons, who face a growing number of operations being performed on increasingly older and increasingly obese patients. Hernia sizes of 10-25 cm transverse extension and up to 30 cm longitudinal extension are not uncommon [21–23]. The consequences are limitations in physical resilience, intestine and organ functions, pain and cosmetic impairments [21]. Effective surgical care is therefore necessary for improving patients' quality of life [4]. Looking at the follow-up costs also indicates a considerable socio-economic significance.

To restore the integrity of the abdominal wall, different surgical procedures are used depending on the aetiology, the extent of the abdominal wall defect and the individual patient's profile [14, 15].

There is a high risk of wound healing disorders, haematoma and seroma [16, 17] with the Ramirez open component separation technique [2, 25, 27]. With endoscopically assisted component separation [3, 17, 24, 28], wound healing disorders and infections occur less frequently because the vessels of the ventral abdominal wall skin are spared. Posterior component separation [2] or transversus abdominis muscle release (TAR) is one way to avoid the wide subcutaneous epifascial mobilisation.

In 2017, Eucker et al. [7] described an innovative procedure for the treatment of large abdominal wall hernias. The procedure has been termed the 'abdominal wall expander system' (AWEX) and uses ventrally directed traction to stretch the abdominal wall in such a way as to allow direct fascial closure. Eickhoff et al. [5] showed in a porcine in vivo model that ventrally directed traction can stretch the abdominal wall with an existing laparostoma to such an extent that there is a significant reduction in the necessary closing force of the abdomen. This procedure offers a potentially gentler alternative to the methods used to date.

Following animal studies [5], case studies [8–11] and a smaller observational study [23], this study aims to investigate the effectiveness, clinical practicability and complication rate of intraoperative fascial traction (IFT) in the treatment of large ventral hernias in a larger patient population.

Methods

Patient selection

To avoid selection bias, all patients with complex abdominal wall hernias during the survey period were offered IFT. Detailed information was provided on this procedure and on alternative procedures such as component separation. All patients who consented to IFT were treated with this procedure.

Tension-free direct closure was attempted first in all patients. Patients where direct closure was possible without specific surgical intervention were not included. If direct closure was not possible, IFT was used.

The data of 50 consecutive patients treated with IFT were included in the evaluation. Patients from 11 specialised centres between November 2019 and April 2021 were analysed. The patient data were taken from the Herniamed registry [12] and then analysed anonymously. Patients gave their consent for the data analysis.

Surgical procedure

All diagnostic and therapeutic measures were carried out within the framework of the clinical standard of care. Data documentation and storage followed the rules of national and international data protection regulations. The medical devices used (fasciotens® Hernia/Abdomen, fasciotens GmbH, Essen, Germany) are approved for the indication (fasciotens®Hernia, Z/19/0457E risk class I).

Fasciotens®Hernia/Abdomen is used to stretch the abdominal wall for primary tension-free abdominal wall closure. To do this, a ventrally directed traction is applied to the abdominal wall structures via an external device (**Fig. 1**). Commercially available surgical sutures are applied longitudinally into the fascia at an even distance of approx. 2 cm and 1 cm from the medial fascial edge with a stitch length of 2 cm. The suture material is then attached to a specially designed suture retainer on the frame so that the sutures can be individually retightened and the cumulative applied tensile force can be read. The abdominal wall is pulled ventrally with quantifiable tensile force, thus exerting continuous traction on the abdominal wall. The traction on the abdominal wall or fascia can be maintained until a sufficient length of the abdominal wall or a sufficient increase in volume of the abdominal cavity is achieved for closure of the fascia. The tension can be aligned either vertically or diagonally-ventrally. In the present study, all patients were treated with a diagonal-vertical traction of approx. 12 kg for a duration of 30-35 min. While the traction was applied, the sutures were retightened every 2 min.

Total relaxation was performed as guided by and at the discretion of the anaesthetist. The patient underwent muscle relaxation once more just before the pretraction hernia width was measured.

In 7 cases with traction threads inserted partially transcutaneously, the preparation of the retromuscular space had been done transhernially with opening of the posterior blades of the rectus sheaths in a mini/less-open-sublay (MILOS) technique. The skin incision required for this was no longer than the diameter of the hernia ring. To perform percutaneous traction suture placement in the anterior blades of the rectus sheaths, it was necessary to perform the subcutaneous dissection sparingly. This manoeuvre makes it possible to manage with a relatively small skin incision, even in large W3 hernia gaps. In all cases, a mesh measuring at least 20 × 30 cm was inserted in sublay position in both the 'wide open' and the partially transcutaneous procedures. A total of 42 patients underwent mesh augmentation with a Cicat/Dynamesh (Dahlhausen GmbH Siegburg, Germany), 3 patients with Softmesh/Ethicon (Ethicon J&J Medical Devices, Norderstedt, Germany), 3 patients with Softmesh/BD (BD GmbH, Heidelberg, Germany) and 2 patients with Optilene Elastic/B.Braun (B.Braun SE, Melsungen, Germany), each in sublay position.

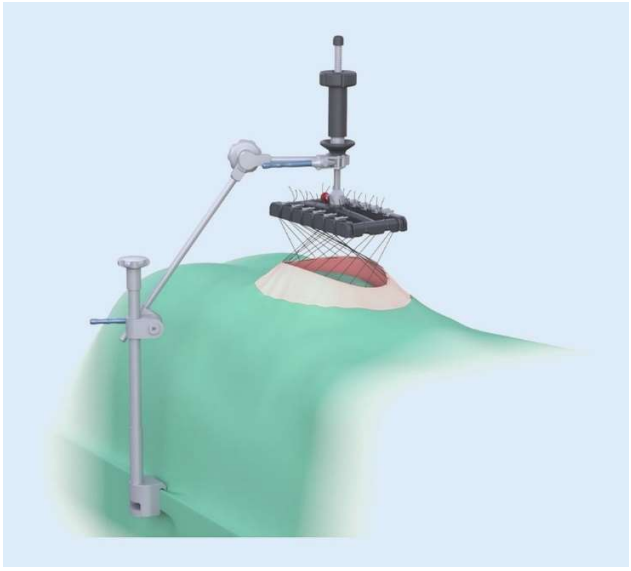

Fig. 1 Functional principle of fasciotens®Hernia (fasciotens GmbH, Essen, Germany)

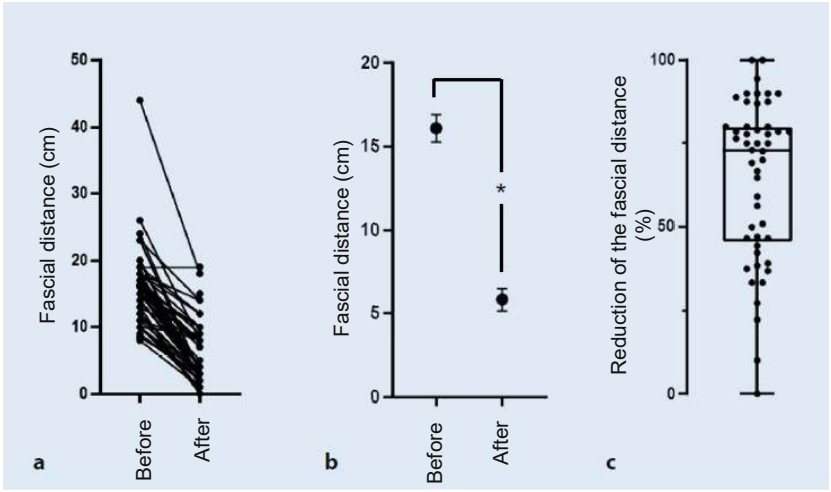

Fig. 2 Fascial distance (cm) before and after intraoperative fascial traction. Individual values (**a**) and the mean values ±SEM (standard error of the mean) of $n = 50$ patients (**b**) are shown. (* $p < 0.0001$, Wilcoxon matched-pairs signed-ranks test). **c** shows the reduction of the fascial distance (%) after intraoperative fascial traction as a single measured value. (The box corresponds to the lower and upper quartiles, the 'whiskers' correspond to the range).

Of the 45 patients in whom direct closure was possible after IFT, 41 patients were treated with a mesh inserted in the retromuscular sublay position in the rectus space. An additional transversus abdominis muscle release (TAR) was performed due to additional pathologies (e.g. additional hernia at the former stoma) in 4 other patients where direct closure was possible.

TAR was also performed in the 5 patients in whom direct closure after IFT was not possible. Direct closure was then possible in 3 patients.

Patients where direct closure was possible following IFT and TAR ($n = 7$) received mesh augmentation in sublay position both in the rectus spaces and on the respective transversalis fascia behind the transversalis muscle.

Of the two extreme cases with defect widths of 35 and 44 cm, one is described separately here as an example: The patient with the defect width of 35 cm was found to have a large scarified area of bone. In this case, after resection of the scarified bone, the remaining peritoneal defect was closed with an openly sewn-in 12 cm IPOM (intraperitoneal onlay mesh technique) mesh. The mesh placed above it in sublay position measured 30 × 25 cm. The remaining gap between the two anterior blades of the rectus sheaths was 19 cm after IFT and 12 cm after additional TAR and was closed by a bridging mesh of 15 × 22 cm (triple sandwich).

The second case with a defect width of 44 cm was treated similarly – with the exception of the IPOM mesh, which was not necessary in this patient.

Statistics

The data were presented as individual values, mean values ±SEM (standard error of the mean) and medians (range). The Wilcoxon matched-pairs signed-ranks test was carried out (GraphPad InStat, San Diego, USA). A $p < 0.05$ was evaluated as statistically significant.

Results

Patient characteristics

The average age of the patients was 60.4 ± 2.1 years. Most of the patients were overweight with an average body mass index of 30.5 ± 0.9 kg/m2 . The patients had an ASA (American Society of Anaesthesiologists) score of II-III, except for one patient with an ASA score of I.

The patient characteristics are summarised in **Tab. 1**.

Among the hernias treated, there were 48 incisional hernias and 2 primary epigastric hernias. In 46 cases the hernia had developed after a median laparotomy, in 2 cases after a transverse laparotomy.

Fascial measurements

IFT using the fasciotens®Hernia/Abdomen procedure was carried out in 11 different centres and proved to be practicable.

Tab. 1 Patient characteristics, fascial measurements and surgical outcomes of intraoperative fascial traction in complex hernias, *n* =50

1. Patient characteristics	
Sex (male, female)	20/30
Age (years)	
Mean ±SEM	60.4 ± 2.1 (*n* = 49)
Median, range	59 (33–89)
Body mass index (kg/m2)	
Mean ±SEM	30.5 ± 0.9
Median, range	30.4 (20.3–49.1)
ASA	
I	1
II	29
III	20
IV	0
2. Fascial measurements	
Fascial distance before IFT (cm)	
Mean ±SEM	16.1 ± 0.8
Median, range	15 (8–44)
Fascial distance after IFT (cm)	
Mean ±SEM	5.8 ± 0.7
Median, range	3.5 (0–19)
Reduction of the fascial distance (cm)	
Mean ±SEM	10.2 ± 0.7
Median, range	9 (0–26)
3. Surgical results	
Closure rate	45/50 (90%)
Duration of operation (min)	
Mean ±SEM	207.3 ± 11.0
Median, range	182.5 (95–390)
Postoperative complications	6/50 (12%)
Reoperations	3/50 (6%)
Time spent in hospital (days)	
Mean ±SEM	8.8 ± 1.4
Median, range	6 (2–73)

IFT intraoperative fascial traction, *SEM* standard error of the mean, *ASA* American Society of Anaesthesiologists physical status classification system

Fascial distances measured preoperatively ranged from 8 cm to 44 cm, with most patients (94%) having a fascial distance greater than 10 cm (W3 according to the European Hernia Society). With one exception, IFT was able to significantly reduce the fascial distance in all patients (**Fig. 2a**). The mean fascial distance was significantly reduced from 16.1 ± 0.8 cm to 5.8 ± 0.7 cm ($p < 0.0001$, **Fig. 2b**). The mean reduction in fascial distance achieved was considerable, averaging 10.2 ± 0.7 cm. A reduction in fascial distance of at least 50% was achieved in three quarters of the patients, and in half of the treated patients the reduction in fascial distance amounted to even more than 70% (**Fig. 2c and 3**). The distance reduction was less than 25% in only 3 out of 50 patients. The fascial measurements are summarised in **Tab. 1**.

Surgical results

The closure rate achieved by IFT after a mean surgical duration of 207.3 ± 11.0 min was high at 90% (45/50). Postoperative complications occurred in 6 patients (12%). A reoperation was required in 3 patients (6%). Of the 6 cases with complications, 2 patients showed a subcutaneous seroma confirmed on ultrasound that did not require puncture and clearly regressed in a repeat ultrasound examination after 3 months in each case. In 1 case we saw an organised subcutaneous haematoma, which was also treated conservatively and after 3 months appeared much smaller on ultrasound.

In the 3 cases requiring treatment, negative pressure therapy (VAC) had to be initiated in 2 cases due to a subcutaneous wound healing disorder (infected haematoseroma). In one case, 11 VAC changes were necessary until secondary closure of skin and subcutaneous tissue was achieved. In the second case, 1 VAC change sufficed. In one case, a 2 × 3 cm area of skin necrosis was excised. This was followed by direct skin closure. The actual reconstruction of the deep abdominal wall layers including the meshes inserted in sublay position was not affected in any case and did not have to be dissolved in any case.

In 49 cases, primary closure was by skin suture or staples. In 1 case, a subcutaneous epifascial VAC was applied postoperatively. All patients received a drain in the mesh bed, in some patients an additional subcutaneous drain was applied.

The average length of hospital stay was low at 8.8 ± 1.4 days (2-73). The results are summarised in **Tab. 1**.

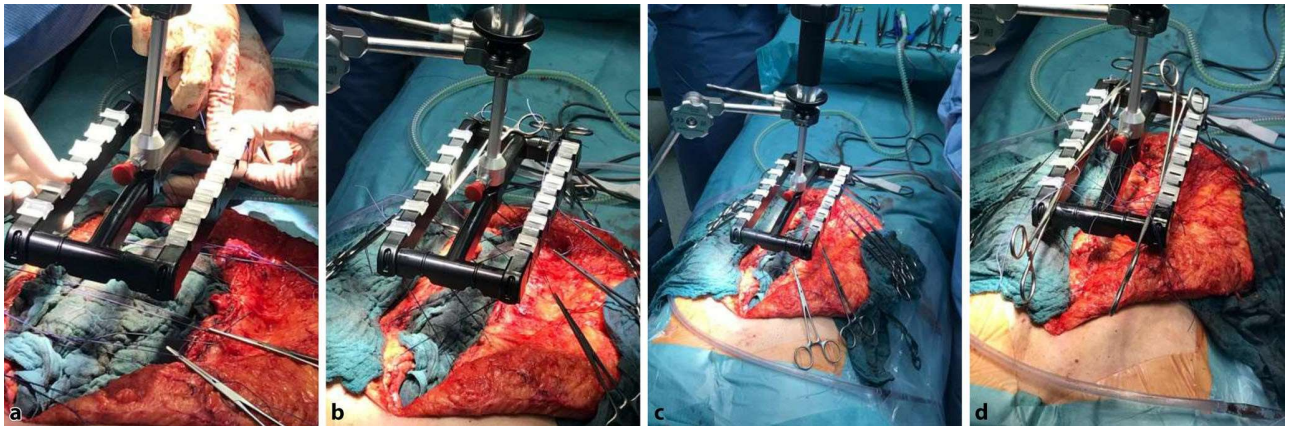

Fig. 3 Fascial distance at the start (**a**), after 10 min (**b**), after 15 min (**c**) and after 25 min (**d**) of intraoperative fascial traction

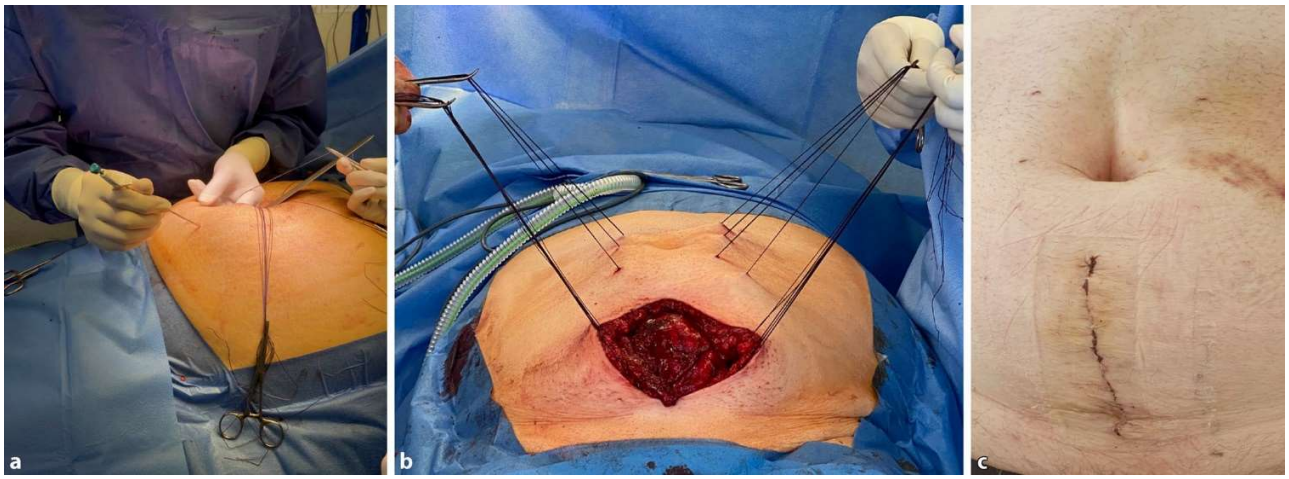

Fig. 4 Partially open, partially transcutaneous retention thread placement (**a**, **b**) and postoperative result (**c**)

Discussion

This study confirms and expands upon the previous individual case reports [8–10, 23] and demonstrates a high effectiveness, a good clinical practicability and a low complication rate for IFT.

The measurability of the tensile forces represents a decisive further development of the traction method introduced by Eucker et al. [7] and enables the application of a standardised tensile force to the fasciae. This ensures sufficient tensile force and prevents excessive pulling. With an achieved closure rate of 90% in large (mean hernia diameter 16.1 cm) hernias, the effectiveness of intraoperative fascial traction was high. The method proved to be feasible, the average operation time was less than 4 hours and thus is comparable to component separation procedures. The 30-35 minutes IFT procedure therefore did not lead to an increase in the operation time.

The IFT resulted in a reduction of the fascial distances that varied on an individual basis. Although a statistical subgroup analysis could not be performed due to the relatively low number of cases, the clinical impression was that the best effects in terms of reducing the fascial distance were in women in the lower and middle abdomen. It can be assumed that in strong, muscular men, the reduction of fascial distance by IFT may be lower than in women. The lower effects in the epigastrium could be attributed to the shorter abdominal wall to be stretched in the area of the ribs.

In the various component separation procedures [6, 16–18, 24], the integrity of the lateral abdominal wall is not maintained, which can lead to circulatory disorders due to severing of the perforator vessels [24]. Due to the invasiveness of these procedures, complications (seromas, infections, haematomas, abdominal wall necrosis, sensory disturbances) are not uncommon [16, 17].

By only stretching the abdominal wall during IFT, the lateral abdominal wall remains intact and there is no localised weakening of the fasciae. In terms of the mechanics, it can be assumed that the contracted lateral abdominal wall musculature has been at least partially reconstituted as part of the chronic loss of continuity of the abdominal muscle loop. Only a sparing dissection of the fascia and the subcutaneous tissue is necessary to place the traction threads, meaning that the subcutaneous wound area is

significantly smaller, at least in comparison to the Ramirez technique. Partly open, partly transcutaneous suture placement is possible, so that intraoperative fascial traction can also be combined with the principles of the MILOS technique (**Fig. 4**).

Maloney et al. [19] reported a complication rate of 43% after anterior component separation and 31% after posterior component separation. In a meta-analysis based on 63 studies, Switzer et al. [30] calculated a total wound infection rate of 21% for minimally invasive or endoscopic component separations and of 35% for open component separations. Similar results were also published in the meta-analysis based on 7 studies by Hodgkinson et al. [13]. A retrospective cohort study by Parent et al. [26] showed a reoperation rate of 19% after minimally invasive anterior component separation and 12% after TAR.

In the cases presented here, there were no intra-abdominal complications after IFT. The overall complication rate of 12%, and of this a reoperation rate of 6%, appear low compared to component separation techniques and can most likely be attributed to the lower invasiveness of IFT. The overall complication rate of IFT observed in our study is comparable to the complication rate of retromuscular mesh procedures with fascial defects larger than 100 cm^2, which was 16% [20].

The reconstruction of complex hernias requires increasing the length of the fascia for anatomical closure of the abdominal wall. Without a sufficient stretch gain, forced abdominal wall closure often results in an increase in intra-abdominal pressure with the possible consequence of abdominal compartment syndrome, if abdominal wall closure is successful at all without additional procedures. As in the previous study [23], there were no cases of postoperative abdominal compartment syndrome in this study after IFT.

The data demonstrate a high effectiveness for IFT with good clinical practicability and a low complication rate.

Limitations

The following limitations should be considered:

- This is an uncontrolled, non-randomised and non-blinded retrospective study in an unselected population. The resulting methodological issues limit the significance. Due to the involvement of several centres, there are site-specific characteristics in pre- and postoperative care as well as in surgical techniques.
- No results are yet available on possible long-term complications and recurrence.
- A comparative study regarding the effectiveness and complication rate of IFT compared to component separation will allow for a more accurate evaluation of the procedure.

Significance in practice

- **The described intraoperative fascial traction (IFT) is a new procedure for stretching the abdominal wall with an open abdomen and for large incisional hernias.**
- **The medical device (fasciotens®Hernia) is approved for this indication (no off-label use).**
- **The presented study demonstrates a high effectiveness for IFT with good clinical practicability and low complication rate.**

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Compliance with ethical guidelines

Conflict of interest. H. Niebuhr, Z.O. Malaibari, F. Köckerling, W. Reinpold, H. Dag, D. Eucker, P. Fikatas, R.H. Fortelny, J. Kukleta, H. Meier, C. Flamm, G. Baschleben and M. Helmedag state that there is no conflict of interest. T. Aufenberg has been employed as a surgeon by fasciotens GmbH since 1 January 2021 and left St. Elisabeth Hospital in January 2021.

No studies on humans or animals were conducted by the authors for this article. The ethical guidelines of the studies listed are described in those studies.

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Abstract

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Objective: The aim was to evaluate the effectiveness, clinical practicability, and complication rate of the intraoperative fascial traction (IFT) procedure for the treatment of large ventral hernias.
Method: This study evaluated 50 patients from 11 specialized centres with an intraoperatively measured fascial distance of more than 8 cm, who were treated by IFT (traction time 30–35 min) using the fasciotens®Hernia traction procedure.
Results: Fascial gaps measured preoperatively ranged from 8 cm to 44 cm, with most patients (94%) having a fascial gap above 10 cm (W3 according to the European Hernia Society classification). The mean fascial distance was reduced from 16.1 ± 0.8 cm to 5.8 ± 0.7 cm (stretch gain 10.2 ± 0.7 cm, $p < 0.0001$, Wilcoxon matched-pairs signed ranks test). A reduction in fascial distance of at least 50% was achieved in three quarters of the patients, and in half of the treated patients the reduction in fascial distance amounted to even more than 70%. The closure rate achieved by IFT after a mean surgical duration of 207.3 ± 11.0 min was 90% (45/50). Hernia closure was performed in all cases with a mesh augmentation in a sublay position. Postoperative complications occurred in 6 patients (12%). A reoperation was required in 3 patients (6%).
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Keywords
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