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Abdominal Wall Expanding System. Intraoperative Abdominal Wall Expansion as a Technique to Repair Giant Incisional Hernia and Laparostoma. New and Long-Term Results From a Three-Center Feasibility Study

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Abstract

Background: The abdominal wall expanding system (AWEX) was first applied in 2012 and published in 2017. This novel technique was developed to reconstruct complex incisional hernias and residual skin-grafted laparostoma after treatment of an open abdomen, when primary midline closure was impossible. The main aim was the anatomical reconstruction of the abdominal wall and the avoidance of dissecting techniques (component separation).

Methods: Between 2012 and 2019, 33 patients underwent AWEX hernia repair in three certified hernia centers. The retracted abdominal wall was stretched with the AWEX system intraoperatively for approximately 30 min. Hernia size was measured preoperatively, on CT, and intraoperatively. The gain in length on the lateral abdominal wall (decrease in width of the defect) after stretching and any residual midline gap were determined in the OR.

Results: 33 patients underwent AWEX procedures. Six cases were evaluated separately because of additional procedures (TAR, four cases) and preoperative application of botulinum toxin (two cases). The median (95% confidence interval) measured width of hernia defects was 13 (12–16) cm, the median gain in length on the lateral abdominal wall was 12 (10–15) cm. After median follow-up of 29 (12–54) months, one recurrence from the broken mesh was observed. No method-related complications occurred.

Conclusion: Based on the 2017 and current results, the AWEX system represents an alternative or supplemental procedure to current techniques for complex abdominal wall reconstruction. The system proved again to be time-saving, safe, effective, and easy to learn. Further studies with enhanced technology are in progress.

Keywords

hernia, abdominal wall reconstruction, incisional hernia, laparostoma, lateral release, botulinum toxin, colorectal surgery, evidence-based medicine, AWEX, fasciotens

Background

Intraoperative abdominal wall expansion with AWEX (abdominal wall expanding system) for the reconstruction of skin-grafted laparostoma and giant incisional hernia was first published in 2017 by Eucker/Steinemann/Zerz.[1] After various congresses and presentations of the case series, the simple and effective technique was adopted and immediately implemented by two German-certified hernia centers. This collaboration has now enabled presentation of more data.

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Principles

One of the biggest challenges in abdominal wall reconstruction is a giant midline hernia or skin-grafted laparostoma remaining after treatment of open abdomen. Unless loss of abdominal wall tissue has also occurred, bilateral muscle shortening is the crucial issue. The lack of abutment leads to retraction and shortening of the abdominal wall muscles within a short time, with the lateral muscles particularly affected. Experience treating the open abdomen indicates that this effect is pronounced after mere hours and becomes more difficult to reverse over time.[2] Extreme cases, with quantitative herniation of intra-abdominal viscera from the abdominal cavity are described as "loss of domain."[3] As a result, the trunk muscles lose their stabilizing ventral pillar. Changes in the resting body state and limitations in physical performance lead to health problems.[4,5] An intact abdominal wall is important for proper digestive function, and contraction during defecation or coughing can be greatly impaired. The quality of life for affected patients is, thus, significantly reduced. Therefore, reconstruction, preferably physiological, is indicated even for complicated cases despite the inherent risks.

The goal of abdominal wall reconstruction is to restore the ventral wall as anatomically or at least physiologically as possible. In general, such reconstruction is performed with mesh augmentation[6] (e.g., retromuscular sublay mesh and intraperitoneal onlay mesh). Various surgical techniques and treatments deal with midline abdominal wall gaps and the inability to approximate the fascial edges. Shortening of the lateral abdominal muscles has been identified as a major problem. Lateral release techniques (e.g., the Ramirez component separation technique[7,8] and transversus abdominis release[9,10]) were developed to increase the length of the lateral abdominal wall. Increased length can be achieved by dissecting the lateral muscle layers and creating an intermuscular shift toward midline closure. The comorbidity associated with this dissection is accepted in return.[11–13] Progressive pneumoperitoneum has also been used for gradual stretching of the abdominal wall muscles.[14-21] After inserting a peritoneal catheter, air is insufflated into the abdominal cavity under low pressure for up to 14 days to stretch the contracted muscles. The limited efficiency of this method has precluded widespread use although it has been reported for decades. In recent years, chemical component separation has proven much more efficient.[22–24] Botulinum toxin is injected into the lateral abdominal wall muscle area approximately 4 weeks before planned reconstruction, resulting in relaxation and passive muscle stretching with preoperative length gain.

Most similar to the intraoperative abdominal wall expanding system (AWEX) are traction approaches used for the open abdomen. One example is the ABRA system.[25–27] The fasciotens system[28–30] was also initially intended for this use. These systems apply continuous traction to the abdominal wall over days to weeks, leading to successive increases in length. Application to the open abdomen in intensive care environments remains plausible. Traction over several days for elective repair of incisional hernias seems feasible but intraoperative traction can shorten the procedure from days to 30 min as shown in the previous AWEX-study.

In 2012, at the Kantonsspital Baselland, Switzerland, the abdominal wall expanding system (AWEX) was initially used intraoperatively to replace dissection techniques as much as possible during abdominal wall reconstructions and reduce comorbidity. It was planned as a one-time intraoperative application, and thus, also appropriate for elective incisional hernia repair. The results of a small patient series, published in 2017,[1] far exceeded expectations regarding efficacy and complication rates. Other certified hernia centers began adopting the straightforward technique in 2018. The hernia center at Kantonsspital Baselland has worked since then in cooperation with the Asklepios-Klinikum Hamburg Wandsbek and the Westpfalz-Klinikum Kusel hernia centers. By the end of 2019, additional cases of very large incisional hernias and skin-grafted laparostomas were successfully reconstructed.

Methods

The case series included patients with large incisional hernias or laparostoma where primary midline closure was not possible. Patients in the laparostoma group had undergone open abdomen treatment for different reasons (e.g., abdominal compartment syndrome for necrotizing pancreatitis and rupture of aortic aneurysm), resulting in skin-grafted large fascial defects. Both, large incisional hernia and remaining laparostoma, show similar pathophysiology of the abdominal wall, resulting in relevant retraction, shortening, and fibrosis. Also, there are no major technical differences in reconstruction, which is why the two groups are not evaluated separately. 33 patients were treated with the AWEX system from May 2012 until December 2019.

Of these, six patients were excluded and assessed separately: in four patients who underwent supplemental transversus abdominis muscle release, the decision to perform the supplemental dissection technique had to be taken intraoperatively and data from length gain on lateral abdominal wall had not been separately obtained for the traction and the dissecting part of the operation. So, proper analysis of effectiveness of traction was not possible. In two patients, botulinum toxin was administered preoperatively. Therefore, the feasibility of the combination of AWEX and chemical component separation was

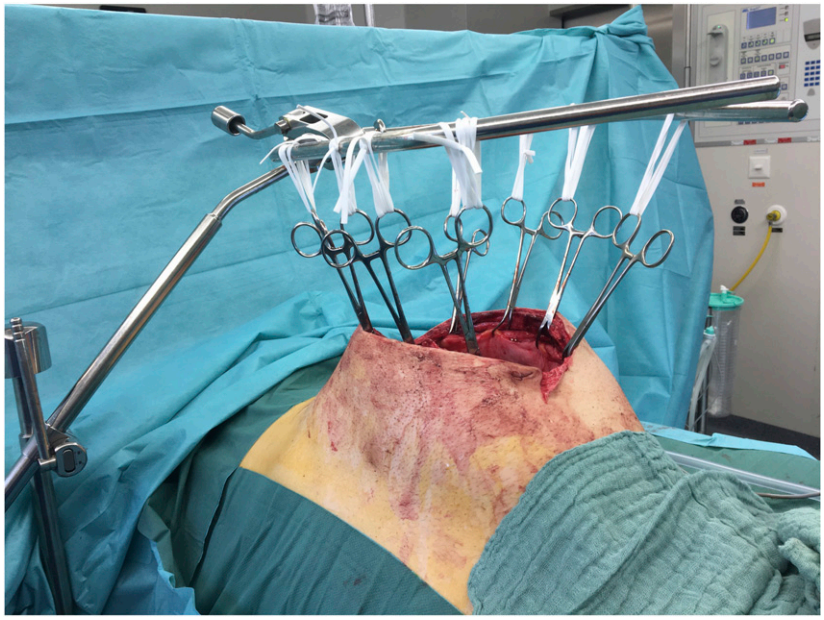

Figure 1. Intraoperative setting.

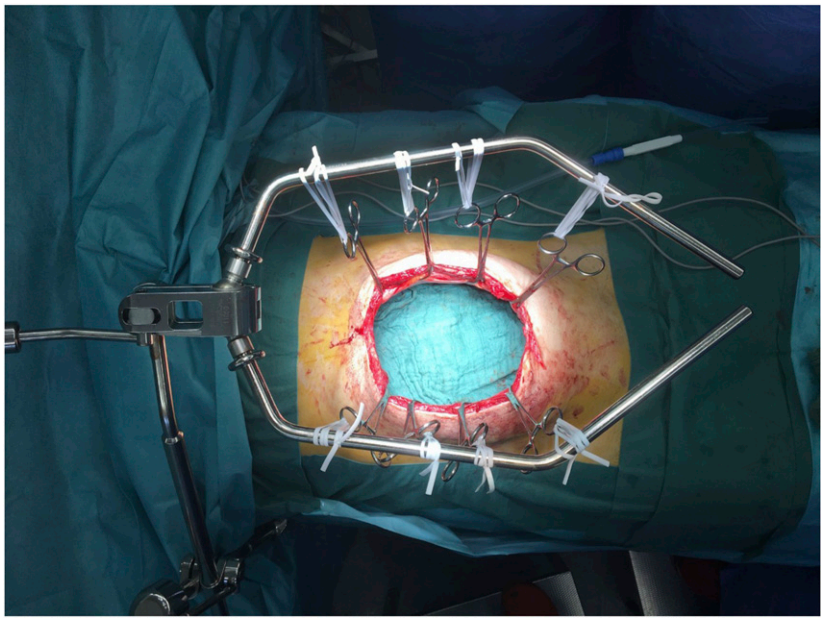

Figure 2. Intraoperative setting.

shown, but the effect of both measures could not be evaluated separately.

Patient data were analyzed retrospectively. The decision to use AWEX was made either preoperatively or intraoperatively if the edges of the fascia could not be approximated after adhesiolysis. Only midline abdominal wall defects were treated.

Setup and Surgical Technique

Preoperative abdominal CT scans were generally performed including Valsalva's maneuver. The abdominal wall defect was thus determined and the maximum distance between facial edges measured. Further measurements were carried out in the OR after adhesiolysis and

Table 1. Patients' Demographic and Characteristics.

Sex	
Male, n (%)	20 (74.1)
Female, n (%)	7 (25.9)
Age, years, median (95% CI)	69 (61–74)
BMI, kg/m2 (95% CI)	28.3 (23.7–30.2)
ASA score	
Grade I, n (%)	0 (0)
Grade II, n (%)	3 (11.1)
Grade III, n (%)	23 (85.2)
Grade IV, n (%)	1 (3.7)
Type of hernia	
Laparostoma, n (%)	8 (29.6)
Incisional hernia, n (%)	14 (51.8)
Recurrent incisional hernia, n (%)	5 (18.5)
Size of hernia	
Median width (cm, 95% CI)	13 (12–16)
Median length (cm, 95% CI)	20 (18–22)

Abbreviations: CI, confidence interval; BMI, body mass index; ASA, American Society of Anesthesiologists.

Table 2. Procedure Characteristics.

Operative time, minutes, median (95% CI)	253 (192–312)
Additional procedures	
Adhesiolysis, n	22
Restoration of bowel continuity, n	3
Cholecystectomy, n	3
Appendectomy, n	2
Re-reconstruction of Billroth-II, n	1
Segmental ileal resection, n	1
Transposition urostomy, n	1
Correction transversostomy, n	1
Subcutaneous V.A.C., n	1
None, n	3
Mesh location	
Sublay, n (%)	17 (63)
IPOM, n (%)	6 (22.2)
IPOM/Sublay, n (%)	1 (3.7)
MILOS, n (%)	1 (3.7)
None (suture), n (%)	2 (7.4)
Mesh type	
Ultrapro, n (%)	7 (26)
Parietene lightweight, n (%)	6 (22.2)
Strattice/Ultrapro, n (%)	5 (18.5)
Dynamesh cicat, n (%)	4 (14.8)
Strattice/Symbotex, n (%)	1 (3.7)
Strattice, n (%)	1 (3.7)
Dynamesh cicat/Phasix ST, n (%)	1 (3.7)
None (suture), n (%)	2 (7.4)
Mesh size (n = 25)	
Median Length, cm	30
Length 20–29 cm, n (%)	5 (20)
Length 30–39 cm, n (%)	15 (60)
Length 40–42 cm, n (%)	5 (20)
Median Width, cm	20
Width 15–19 cm, n (%)	6 (24)
Width 20–24 cm, n (%)	13 (52)
Width 25–30 cm, n (%)	6 (24)

Abbreviations: CI, confidence interval; V.A.C., vacuum-assisted closure; IPOM, intraperitoneal onlay mesh; MILOS, mini- or less-open sublay.

before traction application. The midline gap between the stretched fascial edges, approximated with slight traction, was collected, and the length and width of the hernial defect were measured to quantify defect size. The intraoperative data were used for statistical calculations. The retractor system was then applied. For this, maximum muscle relaxation was required. Coincidentally, the Omni-Flex retractor (Omni-Flex, Integra LifeSciences, Plainsboro, NJ) was used at all three hernia centers. This proved to be well-suited with regard to stability and flexibility. The two height-adjustable arms were positioned approximately 20 cm above the operative field. Four to five Backhaus towel clamps per side were anchored into the fascial edges and connected to the arms with large vessel loops, applying continuous tension to the abdominal wall, as shown in Figures 1 and 2. For approximately 30 min, the vessel loops were continuously re-tensioned, indicating increases in abdominal wall length and muscle stretching.

Length gains on the lateral abdominal wall tended to stabilize after approximately 30 min of continuous traction. Thus, the system was dismantled, and the abdominal wall reconstructed as required with an appropriate implant. Length-gain values (= decrease of fascial defect width) were obtained by documenting fascial closure or remaining defect measurements and subtraction from initial defects. In individual cases, the remaining midline gaps reconstructed by bridging were also recorded. The reconstruction, implant, use of drains, fascial closure, and dressing techniques were implemented based on technical requirements and each hernia center's practices. So, reconstruction techniques evolved over time and varied by center. In some earlier cases (2012–2015), reconstruction was carried out by using biological meshes in intraperitoneal position (7 cases, Kantonsspital Baselland); in 6 cases, the biological implant was augmented by a non-resorbable lightweight mesh because of our early doubts regarding reliability of biomeshes. The appreciation of biomeshes has fundamentally changed since then. In later cases when intraperitoneal implants were needed, coated polyethylene meshes were used (Symbotex, Medtronic Meerbusch Germany). PVDS und polypropylene meshes were used in the sublay mesh repair technique (Ultra Pro, Ultra Pro advanced, Ethicon/Johnson&Johnson Georgia United States; Dynamesh cicat, FEG Textiltechnik Aachen Germany; Parietene

lightweight, Medtronic Meerbusch Germany). Midline closure was carried out using the small-step-small-bite technique,[31] using long-term resorbable monofilament sutures (Monomax, B. Braun Tuttlingen Germany). Fixation of sublay meshes was carried out with non-resorbable monofilament single sutures (Prolene, Ethicon/Johnson&Johnson Georgia United States), fixation of intraperitoneal meshes either in the same manner or by tacking (Secure Strap, Ethicon/Johnson&Johnson Georgia United States). In one case (Westpfalz Klinikum), even reconstruction with the MILOS-technique (Mini or Less Open Sublay)[32] was carried out, suggesting the possibility of combining AWEX with various reconstruction methods.

Table 3. Postoperative Outcomes.

Length of hospital stay, days, median (95% CI)	12 (10–16)
Postoperative morbidity, n (%)	15 (55.5)
Clavien–Dindo grade I–IIIa	7 (25.9)
Clavien–Dindo grade IIIb–V	8 (29.6)
Postoperative complications	
Seroma, n	6
Impaired wound healing, n	5
Postoperative delirium, n	3
Cardiac decompensation	3
Respiratory decompensation, n	1
Pneumonia, n	2
Pulmonary embolism, n	1
Artrial fibrillation, n	1
Urinary tract infection, n	1
Bile leakage, n	1
None, n	12
Overall perioperative mortality, n (%)	1 (3.7)

Abbreviations: CI, confidence interval.

Evaluation

All patients underwent procedures in certified hernia surgery centers by verified specialists, and all relevant patient data were entered into the Herniamed database.[33] Patient demographics such as age, sex, height and weight, EHS (European Hernia Society) classification,[34] ASA (American Society of Anesthesiologists) classification, and previous procedures were recorded preoperatively. The length and width of the abdominal wall defects were measured intraoperatively with a ruler under sufficient muscle relaxation. Surgical duration, intraoperative complications, postoperative morbidity, [35] and length of hospital stay were recorded, along with residual defects (when applicable), type and size of the mesh used for reinforcement, and the reconstructive technique. Variations in the use of AWEX (e.g., crossed vs. vertical traction) were also recorded. The patients were examined postoperatively during office hours of the treating surgeons. Follow-up evaluations were

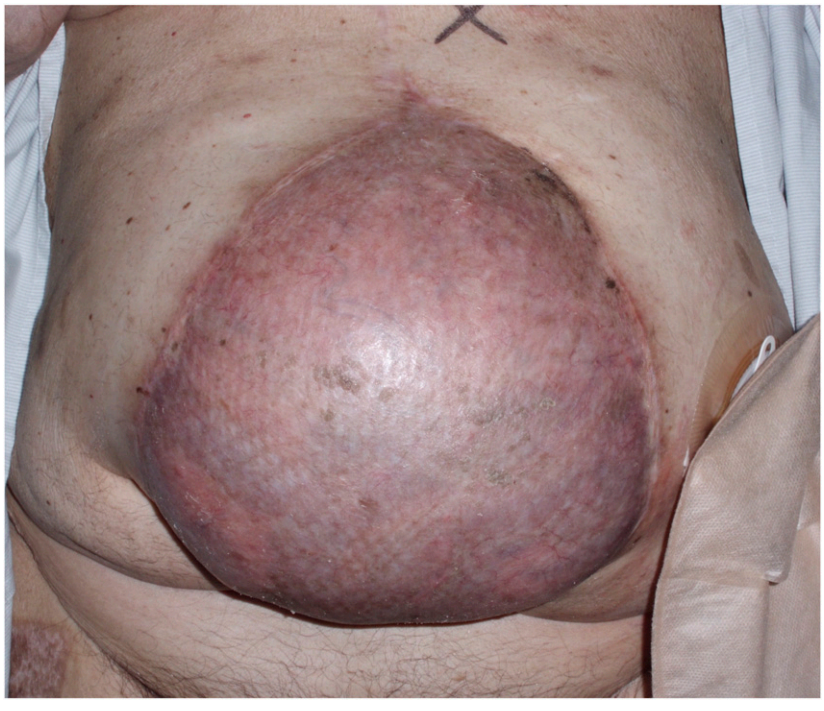

Figure 3. Patient 3 preoperatively.

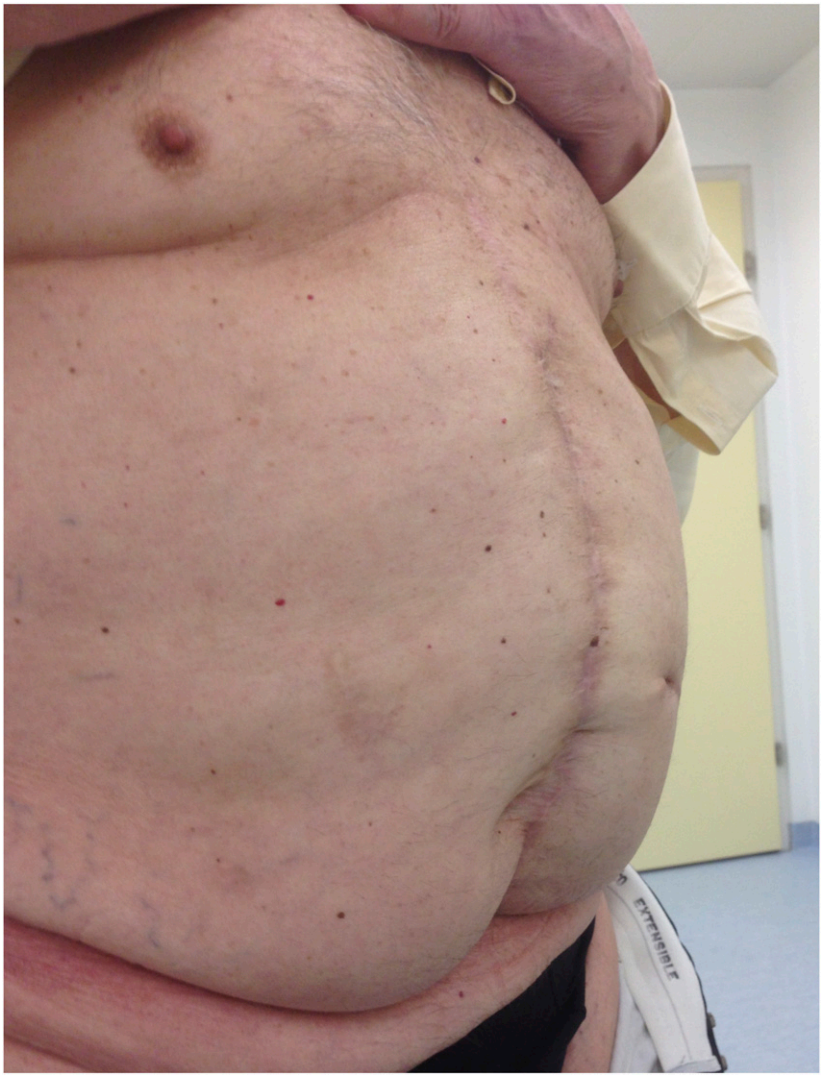

Figure 4. Patient 3, 18 months after abdominal wall reconstruction using the abdominal wall expanding system.

carried out after 4 weeks, 3 months, 6 months, and 12 months, followed by annual re-evaluation if possible. The abdominal wall was assessed clinically and by use of ultrasound for implant position, hernia recurrence, seroma development, and stability performing the Valsalva maneuver. Long-term follow-up, sometimes over several years, was possible in some patients (longest current follow-up: 8 years). All patients received follow-up within the framework of the Herniamed database.[33]

Statistics

Descriptive statistics were used, including medians and 95% confidence intervals for continuous variables and frequencies and percentages for categorical variables. Fisher's exact test was used for categorical variables and a two-tailed Mann–Whitney U test for continuous variables to compare groups. A p-value < .05 was considered significant. Statistical analyses were performed using GraphPad Prism version 8.4.2 for macOS (GraphPad Software, La Jolla California United States).

Results

Patient Characteristics

Twenty seven patients underwent abdominal wall reconstruction with AWEX between May 2012 and September 2019. Another four patients had supplemental partial or complete transversus abdominis release, and two received botulinum toxin injections. These six were excluded from the study. Demographic and preoperative patient variables are listed in Table 1, which shows

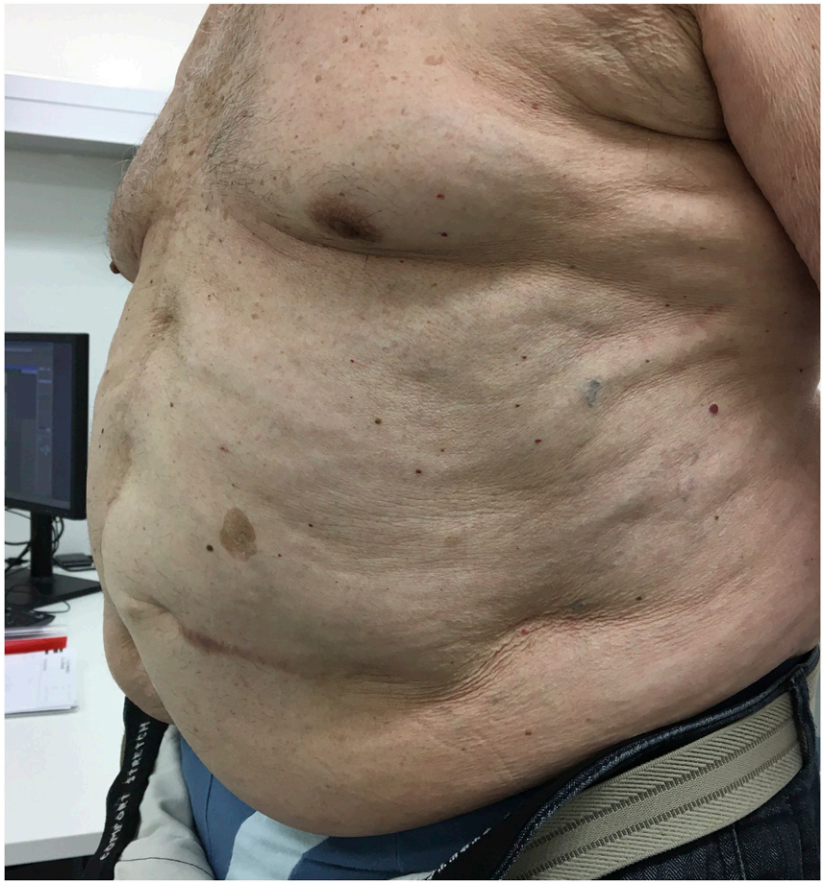

Figure 5. Patient 3, 48 months after abdominal wall reconstruction using the abdominal wall expanding system.

a predominance of male (74.1%) and obese patients (median BMI 28.3 (23.7–30.2) kg/m2). Nearly one-third of the patients had skin-grafted laparostoma, and the others were treated for incisional or recurrent incisional hernias. The initial surgeries varied considerably and included oncological procedures, treatment of burst abdomen, and aortic surgeries.

Procedure Characteristics

The median duration of surgery was 253 (192–312) minutes. Most cases required extensive adhesiolysis and additional procedures such as bowel reconstruction, cholecystectomy, etc. were performed in 8 cases. Table 2 offers further details about the supplemental interventions and reinforcement mesh specifications. Two cases were treated without mesh. In the initial phase of AWEX implementation, the direction of fascial traction was to the contralateral side ($n = 7$), but it progressed to vertical ($n = 20$).

Complete rectus sheath closure was possible in 20 patients after AWEX. Defects remained in seven patients with a median width of 4 cm (3–8). The 2017 publication reported a significant correlation between hernial width and the need for bridging. The current study found no significant variation (median width without bridging 12.5 (12–16) cm, with bridging 14 (11–22) cm, $p = .48$). The median length gain on the lateral abdominal wall (decrease in defect width) after 30 min of fascial stretching was 12 (10–15) cm.

Intraoperative complications, particularly enterotomy during adhesiolysis, occurred three times, and no other complications were reported. All postoperative complications are given in Table 3. Major complications (≥ IIIb, Clavien–Dindo[35]) occurred in 29.6% of patients, minor complications in 25.9% (7 patients), and no complications in 44.5% of patients. None of the complications were method related. The median postoperative hospital stay was 12 (10–16) days.

Follow-Up

There was one hernia recurrence over a median follow-up of 29 (12–54) months (Figures 3–8). A lightweight,

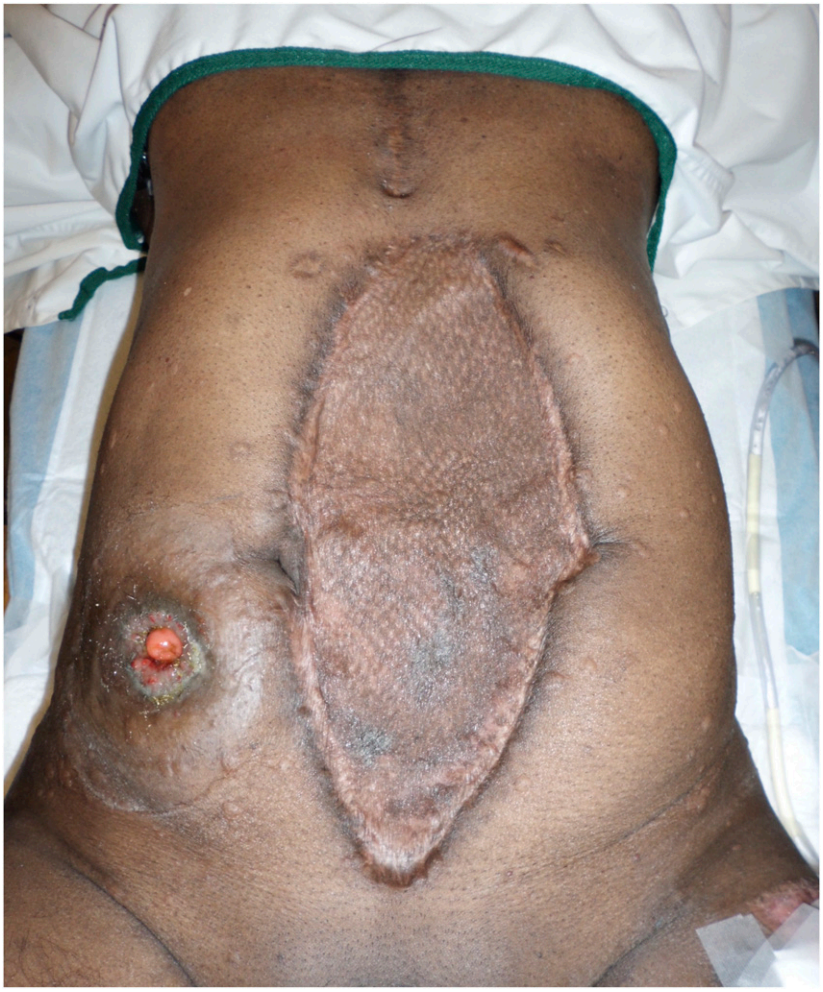

Figure 6. Patient 9, preoperatively.

sublay mesh ruptured in an obese male patient 7 years after reconstruction and was treated with an open intraperitoneal onlay mesh repair. One patient died from other causes during the first postoperative year.

Excluded Patients

The six patients receiving transversus abdominis release or botulinum toxin injections in addition to the AWEX procedure were analyzed separately. The median width of these hernias was significantly wider than those without supplemental procedures (18 (15–19.5) cm vs. 13 (12–16), $p = .02$). The median length gain was 16 (13.5–18) cm. Midline closure was not possible in one patient, and a 6-cm defect remained. No major complications occurred in this group, and three patients had no complications at all. Over follow-up, there was one recurrent hernia, and one patient died of old age and multimorbidity.

Discussion

As expected, patient characteristics in our case series were varied and complex. At the same time, the intraoperative abdominal wall expanding system offered an effective and safe tool to experienced hernia surgeons at qualified centers. The 12-cm (6 cm per side) average gain in length exceeded expectations. It remains to be seen whether equally optimistic values can be achieved in future series.

Even for the challenging subxiphoidal area (EHS M1-hernias), successful fascial closure rates were not lower than in other hernias. This special area is characterized by retraction of the transversus abdominis muscle behind the ribs and traction also resulted in significant decrease of the defect.

Another encouraging observation is that the surgical technique has not yet produced any method-related complications.

Damage to the muscular abdominal wall, a feared potential complication, has not yet appeared in any cases.

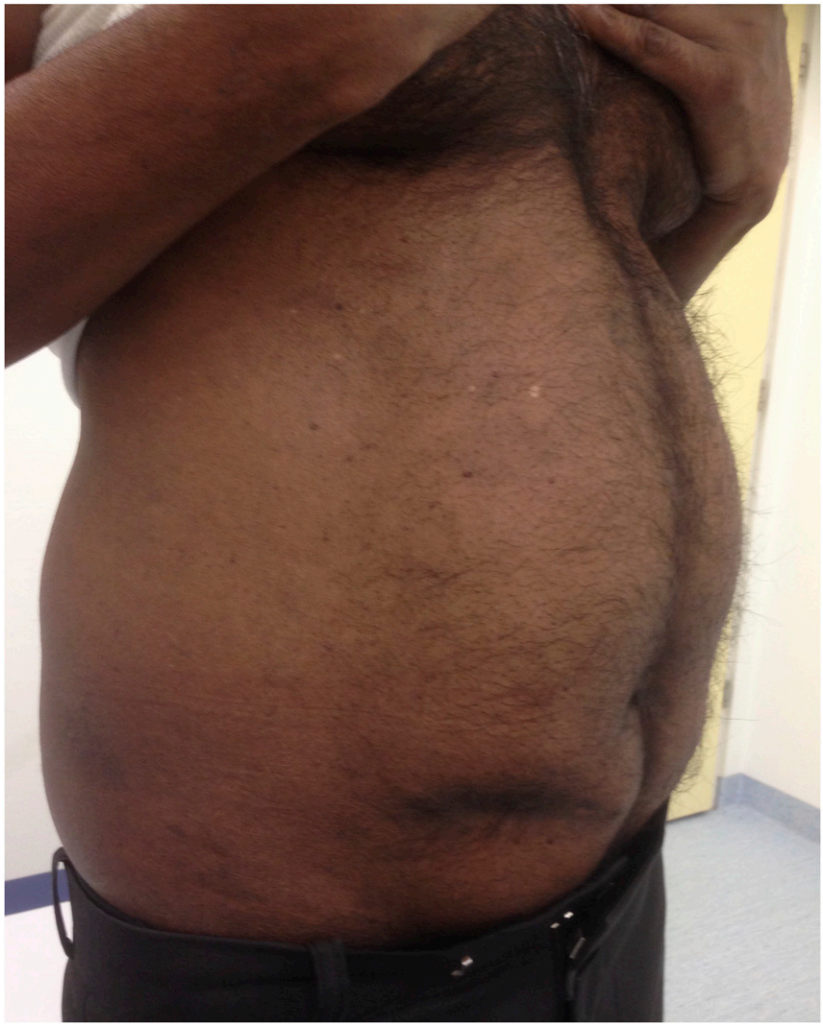

Figure 7. Patient 9, 24 months after abdominal wall reconstruction using the abdominal wall expanding system.

Long-term observations have given no indications of method-specific problems. All patients in our long-term follow-up experienced subjectively improved quality of life compared to the preoperative state.

Another positive is that the surgical technique is quickly learned. The experienced hernia surgeon can easily apply the technique to patients based on images and descriptions. However, it should not be forgotten that this complex patient population with large incisional hernia and laparostoma still requires appropriate reconstruction after intraoperative abdominal wall expansion. A specialized team should manage these cases.

Using our simple construction model, which can be followed with "ordinary equipment," the intraoperative abdominal wall expanding system can be applied with efficient results. As early as 2014, we tried to develop and patent a refined mechanical system to measure force and length and enable better quantification. Unfortunately, this patent has expired because of a lack of investors. However, the fasciotens system,[28–30] designed initially for use in the open abdomen, has since been found suitable for intraoperative abdominal wall expansion. Thus, a certified extension device with integrated length and force measurement is already available for further standardized quantification and first patient series are published[36] (Figures 9 and 10). The combination of these procedures offers more tools for future abdominal wall reconstructions. Evaluation of combined use with the preoperative botulinum toxin injections is also currently in preparation.

We do not consider the cases where a bridging technique or an additional transversus abdominis release is required as a failure of the abdominal wall expansion technique. The efficacy of the technique was successfully shown in each case we treated. The concept of closing defects of all sizes by applying only one single technique

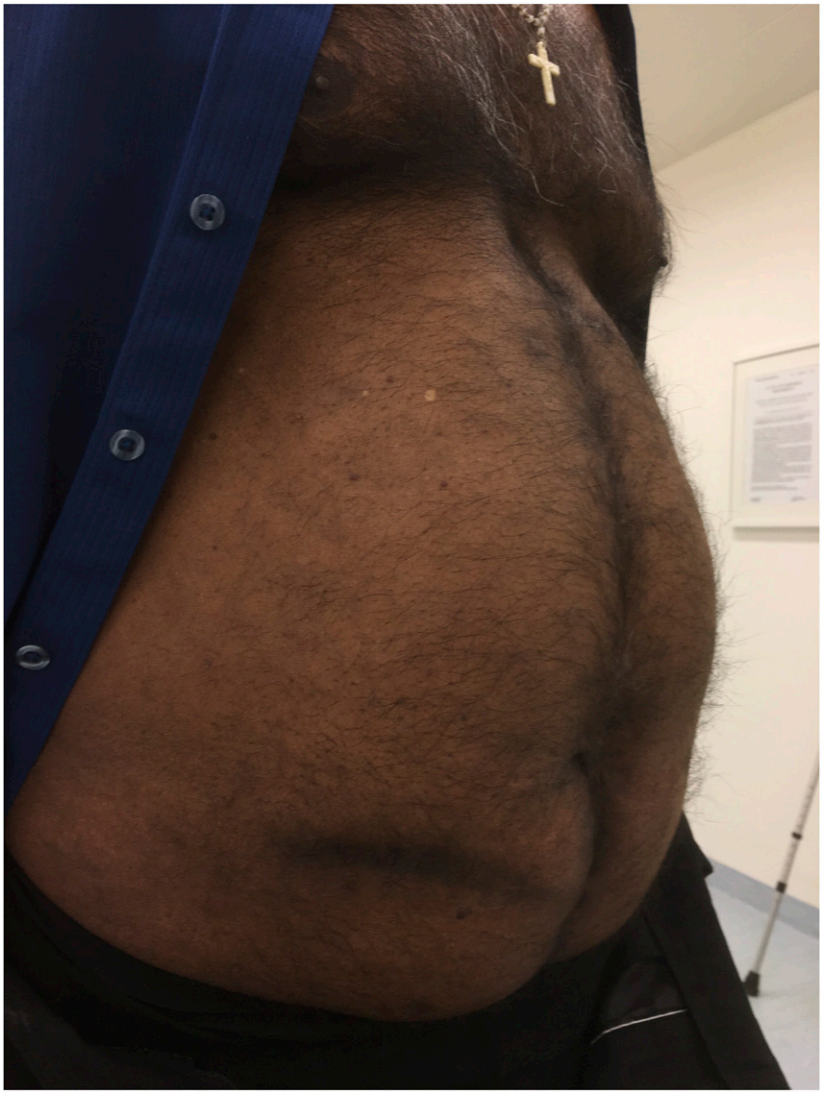

Figure 8. Patient 9, 32 months after abdominal wall reconstruction using the abdominal wall expanding system.

certainly appears unrealistic to us. AWEX proved to significantly reduce the need for dissection techniques. However, AWEX does not enter into direct competition with other reconstruction techniques including Botox, pneumoperitoneum, or TAR, as these techniques rely on different approaches that do not compete with one another. It may well be the combination of these techniques that will reveal the full potential of the "toolbox of abdominal wall reconstruction." It is already evident from the current study that the technique can be combined with Botox and the transversus abdominis release or less/minimal invasive techniques as MILOS.

We operated our first cases applying AWEX in 2012. The first experience with TAR was also published in 2012, hence TAR was not yet implemented in the routine procedures of abdominal wall surgeons, even in centers like ours. We applied bridging and intraperitoneal onlay meshes as state-of-the-art techniques. We still consider leaving a small bridging gap after reconstruction of a large incisional hernia as a more than acceptable technique, which results in excellent functional outcomes as shown based on our long-term follow-up results. Moreover, bridging shows less surgical complications than open anterior component separation.

Besides the intraoperative abdominal wall expansion being an effective, simple technique, a number of questions remain to be addressed in future series:

The optimal traction force has not yet been determined. We put about 6 kg of traction on each rein, which corresponds to a maximally tensioned vessel loop folded four times. The use of six to eight reins probably exceeds the

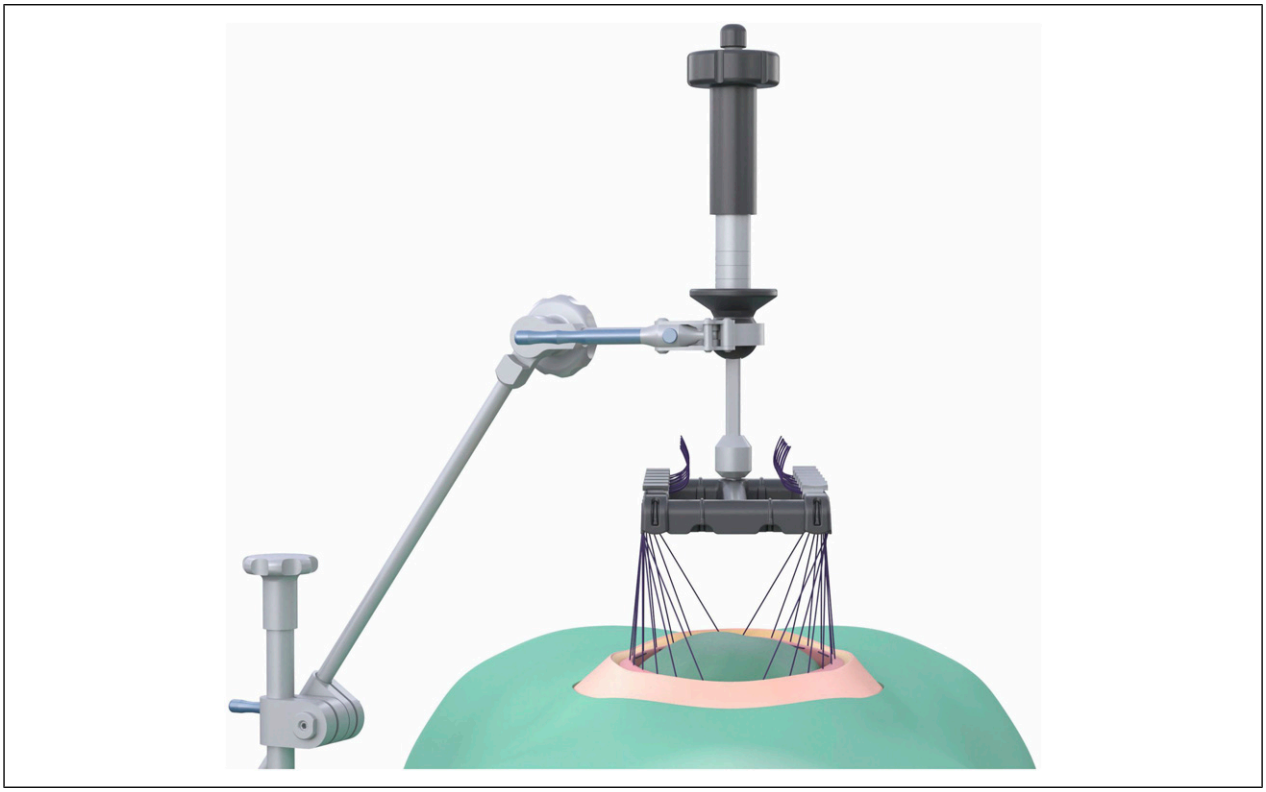

Figure 9. fasciotens device (courtesy of fasciotens®).

required traction force but did not cause any harm to the abdominal wall.

Changing the vector of traction from vertical to cross-wound did not improve length gain. In our opinion, vertical traction is more effective for the laterodorsal wall muscles and avoids visceral compression.

One weakness of the current study was that time of tension was not precisely recorded. In practice, the loops were re-tensioned until length gain abated. This usually occurred approximately 30 min after tensioning was initiated. In this way, operative time was kept within reasonable limits, and there were no signs of muscular ischemia or tearing. It is conceivable that intermittent traction could enable optimization of atraumatic length gain. Does myofibrillary relaxation play a role? Under complete paralysis?

Considering the above, should a two-step procedure be considered? It might be worthwhile to take difficult cases to the OR more than once before definitive reconstruction. Abdominal wall traction can also be applied outside the OR, even in conscious patients.[30]

What do we know about the state of the retracted lateral abdominal wall muscles? Is there relevant fibrosis as shown in 2007 in the rat model by Dubay et al,[37] where disuse atrophy, shortening, myofibrillar changes, and increased extracellular collagen deposition are described? How does time in the retracted state affect muscle histology and, later, function? There certainly is a (reduced) residual muscle function, even after reconstruction. Should we take biopsies before and after surgery?

Giant hernia and laparostoma are commonly treated with open surgery. Recently, cases of combination of abdominal wall expansion with minimal invasive techniques have been shown as well as tensioning reins being applied transcutaneously, without laparotomy, reconstruction performed laparoscopically. A robotic approach will certainly follow. Cases and series will be published soon.

Outlook

We believe that the intraoperative abdominal wall expanding system will disperse worldwide because it is a straightforward technique that greatly simplifies a complex procedure. In the fields of abdominal traumatology and possibly war surgery, an appropriately simple, safe, and effective system like this is undoubtedly an asset. Thus, we expect global use of the intraoperative abdominal wall expanding system in the medium-term future. We are very excited about further investigations with more patient series and other hernia centers.

The newly certified devices like the fasciotens system[28–30] will enable future investigators and users to

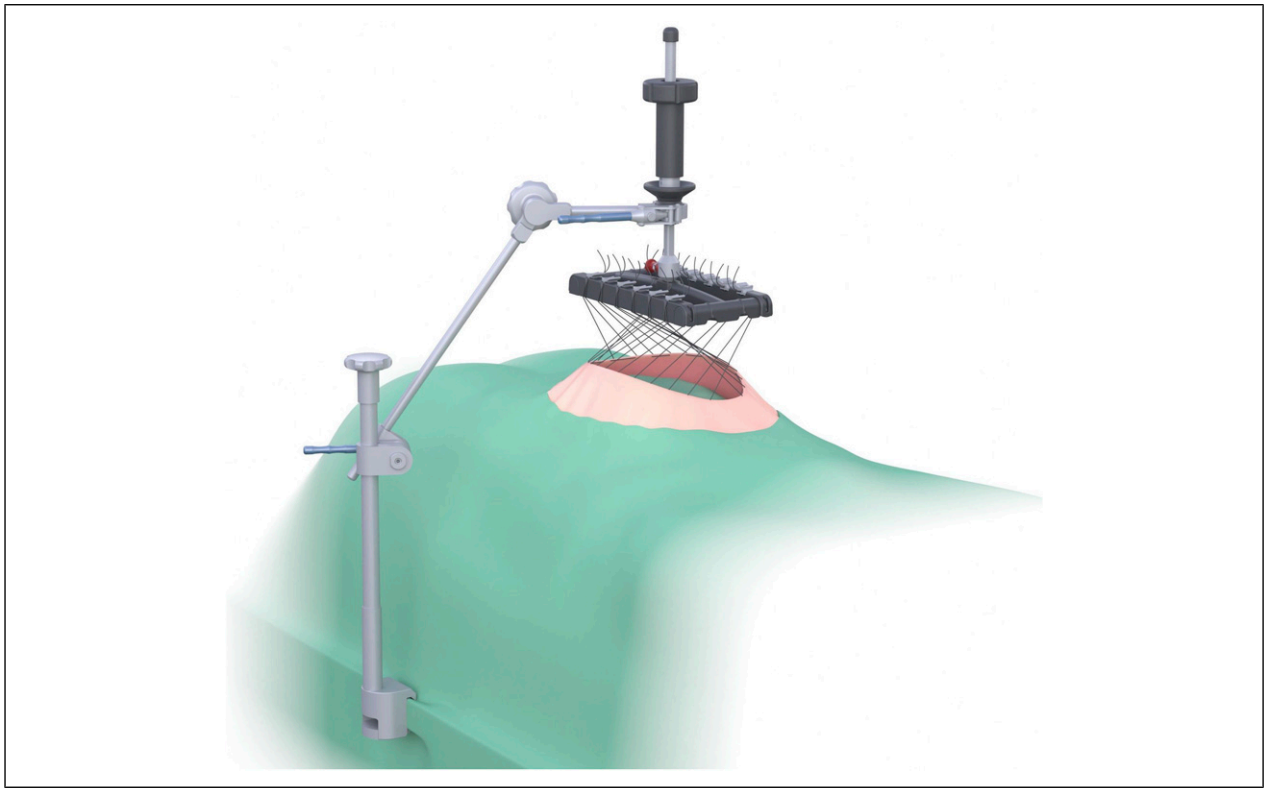

Figure 10. fasciotens device (courtesy of fasciotens®).

obtain data and perform intraoperative traction in a less experimental, that is, more standardized manner.

Furthermore, we are convinced that the combination of the several techniques available for complex abdominal wall reconstruction will allow the implementation of surgical algorithms that might include preoperative Botox treatment, eventually preoperative pneumoperitoneum, and intraoperative traction on the abdominal wall. Depending on the success of these measures the application of dissection techniques and, in extreme cases, the acceptance of a remaining defect covered by bridging, might be considered.

Conclusion

The intraoperative abdominal wall expanding system (AWEX) has proven safe and effective, even in an extended patient cohort and implemented at three hernia centers. Ease of learning, preservation of abdominal wall integrity, short intraoperative application time, and absence of method-related morbidity are all positive factors that should be emphasized. The system can and should in the future be combined with other reconstructive techniques. Thus, it is a valuable addition to the technical toolbox for complex abdominal wall reconstruction.

The design requires further development and refinement. In the future, it should be used with an approved extension device and integrated measuring functions. Further studies with larger case numbers and prospective study design are desirable.

The authors are convinced that the abdominal wall expanding system technique will spread rapidly due to its simplicity, safety, and effectiveness. Nevertheless, the complex reconstruction of abdominal wall defects belongs in the hands of specialists.

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Author Contributions

Study concept and design: Dietmar Eucker
Acquisition of data: Dietmar Eucker, Clinton Luedtke, Oliver Stern, Henning Niebuhr, and Andreas Zerz
Analysis and interpretation: Dietmar Eucker and Nadine Rüedi
Study supervision: Dietmar Eucker and Robert Rosenberg

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Informed consent

All procedures followed the ethical standards of the committee responsible for human experimentation (institutional and national) and the Helsinki Declaration of 1964 and its later amendments. Written informed consent for patient information and images to be published was provided by the patients.

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