

A novel dynamic abdominal wall traction system for open abdomen: preclinical evaluation

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ABSTRACT

Aim: This study evaluates the efficacy and safety of Dynatract®, a novel device designed to facilitate early primary closure and prevent aponeurotic retraction in patients with an open abdomen (OA).

Method: A preclinical trial was conducted using a porcine model, comparing two groups: one treated solely with AbThera™ Negative Pressure Wound Therapy (NPWT), and another combining AbThera™ NPWT with Dynatract®. The primary endpoint was to evaluate the distance between fascial edges, with secondary measures including the force required to achieve abdominal closure and overall closure success.

Results: The Dynatract® group showed a progressive reduction in fascial edge distance over time compared to the control group, with statistically significant differences observed at the caudal and midpoint positions (but not at the cranial position), as well as in the force required to achieve closure after 36 h. Complete fascial closure was achieved in all animals in both groups.

Introduction

Open abdomen (OA) is a surgical procedure where the fascial edges of the abdomen remain unapproximated after a laparotomy [1]. It is one of the most challenging wounds that a surgeon faces, because of the metabolic, physiological, and dynamic implications that this condition entails [2]. This approach is primarily utilized in damage control surgery (DC) and the management of conditions such as abdominal compartment syndrome (ACS), severe intra-abdominal infections, and bowel ischemia [2–4]. The decision to maintain an OA is multifactorial and depends on the need for ongoing resuscitation, staged surgical interventions, and prevention of complications associated with elevated intra-abdominal pressure [5,6].

OA is indicated in both trauma and non-trauma settings. In trauma patients, it is commonly employed as part of DC to control severe hemorrhage and contamination while preventing the progression to ACS [7]. In non-trauma patients, OA is used for conditions such as severe acute pancreatitis, mesenteric ischemia, septic peritonitis, and post-operative complications requiring repeated abdominal exploration [8,

9]. The use of OA must be carefully balanced against its risks, including fluid loss, infection, and delayed fascial closure, which can lead to long-term morbidity such as large ventral hernias [10].

Temporary abdominal closure (TAC) techniques are essential in OA management to protect viscera, prevent fluid loss, and facilitate reinterventions [11]. While TAC plays a role in optimizing conditions for eventual closure, overall patients survival depends on multiple factors, including timely hemorrhage control, infection management, resuscitation strategies, and early definitive closure when feasible [12]. Among TAC techniques, Negative Pressure Wound Therapy (NPWT) has emerged as a widely used approach due to its ability to reduce lateral fascial retraction, promote granulation tissue formation, and facilitate delayed primary closure [13,14]. However, despite its advantages, NPWT alone does not prevent progressive fascial retraction, which can make definitive closure increasingly difficult over time [15].

Several adjunctive techniques have been developed to enhance the likelihood of successful primary closure. These approaches aim to counteract lateralization of the abdominal wall and maintain fascial integrity throughout OA management [16,17]. However, abdominal

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wall traction techniques are challenging to combine with NPWT systems while effectively counteracting lateral abdominal wall retraction [18]. The ensuing incisional hernias result in a significant surgical challenge affecting both the physical and mental health of the patient [17]. Patients requiring OA have lengthy hospital stays, with existing literature consistently reporting morbidity rates of >30 % [18,19]. Although many techniques to achieve temporary abdominal closure exist, their complexity is still a challenge in surgical interventions [20–22].

Here we present a new dynamic wall traction device (*Dynatract*®) that prevents aponeurosis retraction from the beginning of OA management and facilitates a safe correction of the abdominal defect at the end of the NPWT. The device allows for earlier primary closure using NPWT without damaging the aponeurotic border. A preclinical trial using a porcine animal model was conducted to gather initial data on effectiveness and safety.

Materials and methods

System description

The medical device (*Dynatract*®) [23] relates to a dynamic wall traction system for OA wounds, which can be temporarily applied to an OA wound for gradual and controlled closure of the abdominal wall. The device is essentially composed of five parts. The first three components are responsible for retaining the rings in the abdominal wall: the elastomeric ring itself, a retainer, and a suture thread (Fig. 1). After the opening of the abdomen through a laparotomy, the retaining elements are attached to the internal or parietal peritoneum surface of the abdominal wall without suture (Figs. 1, 2). The suture thread is first tied to the retainers, and then passed through the abdominal wall using a passer. It pierces the fascia, muscular layers, and subcutaneous tissue as close as possible to the aponeurotic edge, and exits through the outer surface of the abdominal wall, where it is then tied to the elastomeric ring at the opposite end. This technique ensures that the retainer is positioned within the abdominal wall without being directly attached to it. In this way, the elastomeric rings are not directly linked to the fascial edge but to the retaining elements (Figs. 1, 3). This is the system's main advantage since a tangential traction of the aponeurosis is performed. The fourth component, the tensile threads, which pass through the rings and intertwine in a zigzag fashion, exert a variable traction force through the fifth component, the tensile element, bringing the sides of the OA closer and achieving its progressive closure (Fig. 4). The tangential traction applies to both the aponeurosis and the fascia, ensuring a uniform and controlled tension distribution to facilitate optimal closure.

In our system, the traction or fixation point is positioned at the



Fig. 2. Representation of the positioning of the retainer in the Open Abdomen.

parietal peritoneum surface, in contrast to other systems (e.g. [24–26]), where the fixation point is external to the abdominal wall. In these systems, the closure force originates externally and must traverse the entire thickness of the abdominal wall before acting on the fascia.

In contrast, the *Dynatract*® system applies traction from within the abdominal cavity, directly acting on the myofascial layer without crossing the full thickness of the abdominal wall.

Additionally, each elastomeric ring in *Dynatract*® is traversed by a tensile thread, generating two traction forces (Fig. 5). This configuration enables automatic adjustment of the traction direction as the tensile threads, which pass through the elastomeric rings in a zigzag pattern, dynamically align in response to the applied traction force. As tension is applied, the direction of the force naturally adjusts to the most efficient path between the fascial edges, allowing the system to maintain uniform traction and optimal approximation, regardless of minor asymmetries or

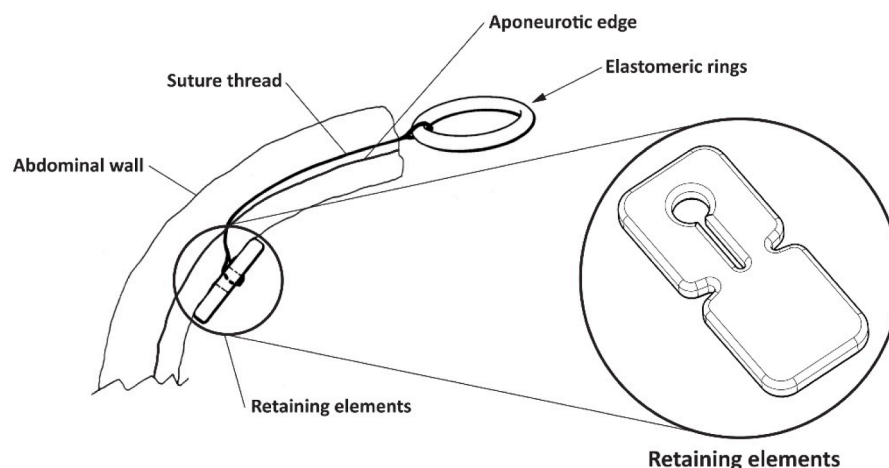


Fig. 1. Illustration of *Dynatract*® components and their arrangement along the abdominal wall.

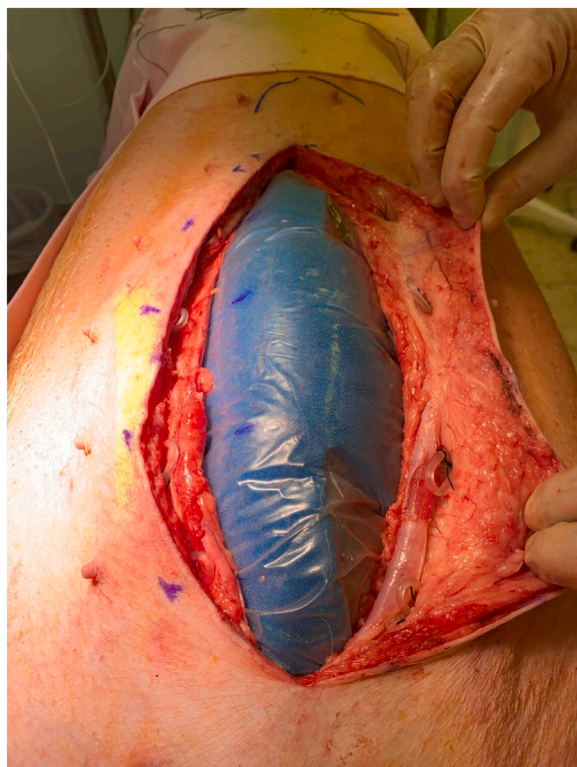


Fig. 3. Representation of the positioning of elastomeric rings within the Open Abdomen.



Fig. 5. Illustration of the Dynatract® positioning in the Open Abdomen prior to the placement of Negative Pressure Wound Therapy. Arrows indicate the two traction vectors generated at the elastomeric ring.

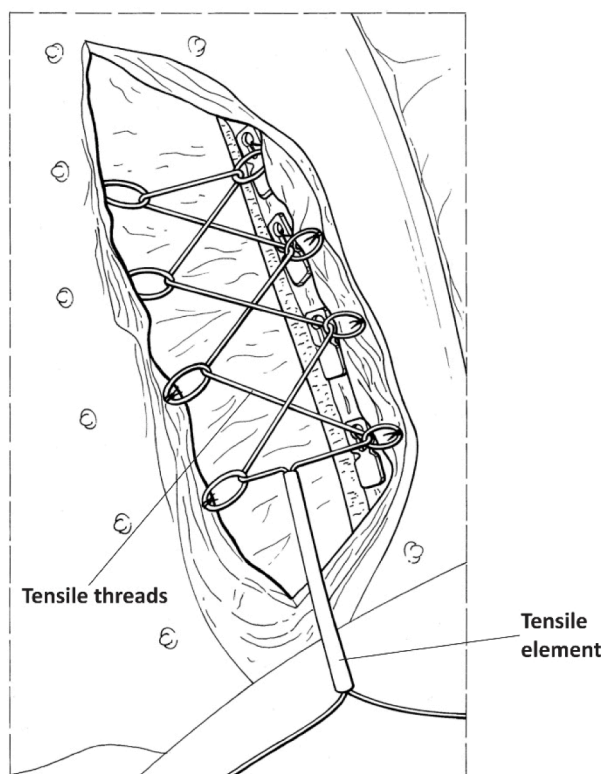


Fig. 4. Illustration of Dynatract® positioned on the Open Abdomen.

tissue shifts during the closure process. In contrast, other systems (e.g., [24]), generally apply force in a single direction, resulting in a fixed and non-adjustable traction vector.

All components of the system comply with the required standards for medical device development, specifically UNE-EN ISO 10,993. This standard evaluates the biological safety of materials used in medical applications and differentiates between the nature of body contact and the duration of exposure.

For the elastomeric rings, a medical-grade thermoplastic material was chosen to provide the necessary flexibility and biocompatibility. The retainers were made from a modified styrene-acrylic copolymer (MBS), ensuring durability while minimizing the risk of tissue trauma.

Dynatract® is designed for use in conjunction with NPWT. After placing the protective dressing for the abdominal viscera, the system is positioned, with the tensile threads situated between the protective layer and the polyurethane foam, which is then covered with an adhesive drape to create the seal (Figs. 5, 6).

After transferring the patient to the intensive care unit, the surgeon or trained personnel will adjust the device by applying or releasing tension over a recommended period. This process ensures that the abdominal wall retains its flexibility. The controlled traction gradually draws the fascial edges closer to the midline. When the fascial edges are within approximately 3–7 cm of each other and the abdominal compartment syndrome (ACS) has resolved, definitive closure can be attempted.

Dynatract® provides effective access to the abdominal cavity for surgical re-interventions in OA management while allowing concurrent use with NPWT. Reinterventions can be performed by simply removing the tensile cord, while the retention elements and elastomeric rings remain in place, ensuring the system's integrity until final abdominal wall closure. It enables easy dressing changes and prevents damage to the aponeurotic border since the elastomeric rings and retaining elements are only individually attached to the abdominal wall. Additionally, it prevents wall retraction, reducing the likelihood of ventral hernias and fistulas after the final closure of the OA.

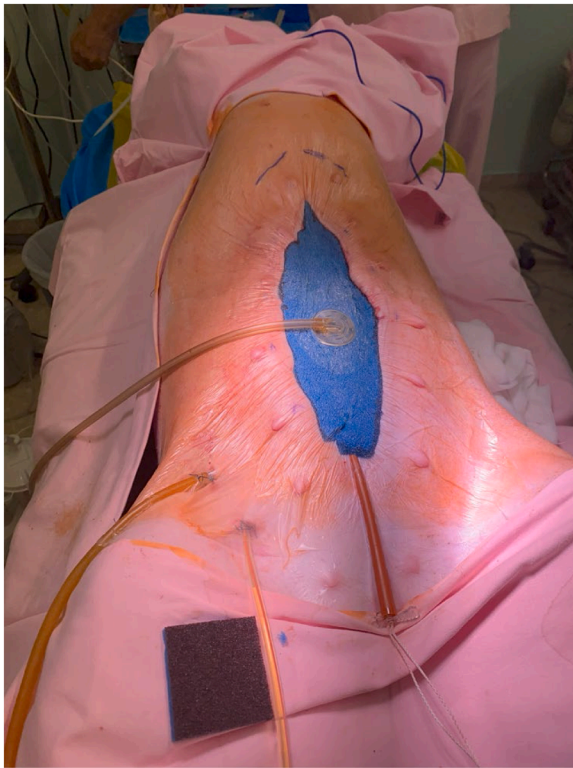


Fig. 6. Final illustration of Dynatract® plus the Negative Pressure Wound Therapy system positioned in the Open Abdomen.

Animal test protocol

All experiments were in accordance with Spanish legislation governing animal studies (RD 53/2013, Animal experimentation) and the ARRIVE guidelines (Animals in Research: Reporting In Vivo Experiments) [25], which established the basic standards applicable for protecting animals used in experimentation and other scientific purposes. The preclinical study project has been evaluated by an authorized ethics and animal welfare committee. Twelve female pigs of 57–66 Kg were randomly assigned into two groups (control group I and experimental group II). Allocation concealment was maintained by assigning animals immediately before surgery. The surgeon performing the surgical procedure and subsequent assessments was blinded to the group assignments to further reduce bias.

The inclusion criteria included general good health, absence of prior abdominal surgeries, and no signs of disease or abnormalities during the baseline medical examination. Female pigs were chosen as their abdominal anatomy more closely resembles that of humans, and the specified weight range was selected to minimize the need for extensive trimming of the visceral protective layer during Negative Pressure Wound Therapy (NPWT). Pigs were sourced from an authorized farm certified by the regulatory authority.

A superiority trial design was implemented. Considering the variable to be measured, which is the distance between aponeurotic edges (10 mm less in group II than in group I), 12 animals were required to achieve a 90 % chance of detecting, as significant at the 5 % level, a decrease in the primary outcome measure from 20 mm in the control group (group I) to 10 mm in the experimental group (group II), with a standard deviation of 6 mm, a two-sided alpha of 0.05, and 90 % power. The animal experimental surgeries were conducted over four different days. All pigs were housed in groups of 3 in Valdecilla Virtual Hospital for a minimum of 1–3 days before the first treatment for acclimatization after a medical baseline examination. Animals were kept under standardized and hygienic optimized conditions on litter: temperature between 21 °C and 23

°C; relative humidity 50–70 %; and 12h/12 h of light/dark cycle. They got free access to water and food. Before starting surgery, the animals were put to sleep, and intubation was performed. The experiment duration was 36 h after initiating anesthesia in the operating room without awakening afterward. The primary endpoint was the achievement of a shorter distance between fascial edges before closure. The final endpoint was the closing force at 36 h and the closure of the OA.

Surgical procedure

Two groups were randomly created. Randomization was carried out using a simple draw method to ensure unbiased group allocation. Twelve papers—six labeled "Group I" and six labeled "Group II"—were placed into a bag. For each animal, a paper was randomly drawn, determining the assigned group. This approach guaranteed an equal probability of selection for each condition, minimizing selection bias. Group I was treated only with AbThera™ NPWT, while Group II received AbThera™ NPWT combined with Dynatract®. For AbThera™ NPWT, 3M™ V.A.C.® Ulta Therapy Unit was employed.

The animals were anesthetized with intramuscular Xylazine (30 mg) and a combination of Tiletamine and Zolazepam (125 mg). Pre-oxygenation was followed by the intravenous administration of 2–3 ml boluses of propofol. A 20 G catheter was inserted into an auricular vein, and intubation was performed using an endotracheal tube with an internal diameter of 6–7 mm. Mechanical ventilation was provided by a servo-ventilator (*paraPAC plus 310, PneuPac™*). Anesthesia and muscle paralysis were maintained through continuous intravenous infusions of propofol (0.25–1 mg/kg/hour), fentanyl (0.1–0.2 mg/kg/hour), and an additional agent at 0.1–0.2 mg/kg/hour. A bolus of cisatracurium was administered during the initial surgery. An infusion pump (*B Braun Infusomat® Space*) was utilized. The animals were continuously monitored with the *iM8 VET Series monitor*, which tracked respiration, capnography, temperature, and blood pressure throughout the procedure.

Both groups underwent a midline laparotomy with a 30 cm incision centered between the symphysis and xiphoid. To simulate an open abdomen (OA) with intra-abdominal hypertension, a simple custom-made model consisting of a transparent, air-filled plastic bag connected to a manometer was used to mimic intestinal swelling. Air was pumped into the bag to maintain an intra-abdominal pressure (IAP) of ≤ 10 mmHg. This model was positioned within the abdominal cavity and remained in place throughout the entire 36-hour study period. The silicone model was carefully placed beneath the protective dressing of the AbThera system while ensuring it did not interfere with the functionality of the negative pressure wound therapy (NPWT). The design of the model allowed for adequate fluid drainage and uniform pressure distribution, maintaining the intended effects of NPWT. This approach provided a controlled setting to assess the mechanical behavior of the abdominal wall and the effectiveness of the fascial traction system under conditions that closely approximate clinical scenarios of OA management.

For Group I, a layer of AbThera™ Dressing system was placed, a visceral protective layer, then perforated foam within the margins of the elliptical opening. AbThera drape was then arranged and covered to create a seal. Negative pressure at -125 mmHg was maintained for 36 h with the 3M™ V.A.C.® Ulta Therapy Unit.

For Group II, a layer of AbThera SensaT.R.A.C Dressing from the AbThera Dressing system was placed within the margins of the elliptical opening. Dynatract® was then applied in the OA. Retainers were positioned on the parietal peritoneum surface of the abdominal wall, 4 cm laterally from the incision, and secured with suture thread to the elastomeric rings along the upper edge of the aponeurosis. A polyurethane cord was threaded through the elastomeric rings and introduced into the traction element to enable dynamic traction of the abdominal wall (Figs. 3, 4). AbThera vacuum polyurethane foam was then arranged and covered with an adhesive drape to create a seal. Negative pressure at -125 mmHg was maintained for 36 h with the 3M™ V.A.C.® Ulta

Therapy Unit. Dynatract® was tensioned every 6 h, maintained for 15 min, and then released.

Hemodynamic variables were monitored during the whole procedure and measured every 6 h until the end of the test. The variables measured were heart rate, electrocardiogram (ECG), oxygen saturation, CO₂ level, temperature, and diuresis.

The distance between the approximated fascial edges at the center of the laparotomy incision and 5 cm cranially and caudally was measured and repeated three times at each point. Average values were used for further calculations. These measurements were taken immediately after initiating NPWT (with or without Dynatract®), once negative pressure was established (t0, 0h), and subsequently at t1(12h), t2 (24h), and t3 (36h). Thus, t0 does not represent a pre-treatment baseline, but the very early physiological response to the intervention. Intra-abdominal pressure (IAP) and diuresis measurements were also recorded as controls.

In the last nine animals, and additional procedure was implemented to measure the force required to close the open abdomen. A suture was placed at the midpoint of the laparotomy on both aponeurotic edges, a dynamometer (Pesola®, Macro-Line Series, 200 Newtons) was attached to the suture to measure the upward force required to bring the aponeurotic edges together (Fig. 7). All pigs were euthanized after 36 hours with an overdose of pentobarbital (160 mg/kg BW).

Statistical analysis

All statistical analyses were performed using R Statistical Software for Windows (v4.4.1; R Core Team).

The test was designed to evaluate the hypothesis that the distance between the aponeurotic edges or fascial margins of the OA would be shorter in the group using Dynatract® compared to the control group. Additionally, it was hypothesized that the retraction of the aponeurotic edges would be reduced in the same group.

Differences in medians between groups based on weight, size, and abdominal perimeter were assessed using a non-parametric Mann-Whitney U test. Changes in fascial margin distances over time for each group were analyzed independently using the Friedman test, when



Fig. 7. Illustration depicting the force measurement procedure.

relevant, pairwise Wilcoxon signed-rank tests were used to explore time-point differences.

Given the limited number of pre-specified endpoints and comparisons, and the absence of exploratory data dredging, no multiplicity adjustment was applied. Exact two-sided p-values are reported.

The Mann-Whitney U test was also used to compare fascial margin distances measured at various time points within each group and the differences in the force required to bring both aponeurotic edges to the center and upwards.

IAP and diuresis were measured as control variables, and the differences between the two groups were analyzed using a Mann-Whitney U test.

P-values smaller than 0.05 were considered to be statistically significant.

Results

One pig in the control group died 18 h after laparotomy. However, all available data up to the time of death were included in the mean comparison analysis. Thus, a total of 11 pigs (Group I = 5, Group II = 6) were observed over 36 h.

Measurements are reported at t0 (0 h, post-initiation), t1(12 h), t2 (24 h), t3 (36 h). Because t0 reflects an early post-treatment state, between-group comparisons at later time points (t1-t3) were interpreted as evolution from an already treated condition, and within-group changes were analyzed over time accordingly.

Baseline characteristics

There were no significant differences between the two groups in terms of weight, body size, abdominal length (xiphoid to pubis), or abdominal perimeter.

Primary endpoint: fascial edge approximation

We first conducted a within-group analysis to evaluate the temporal evolution of fascial edge distances. At the midpoint, the time effect was statistically significant in both groups (Group I: $p = 0.018$; Group II: $p = 0.026$; (Fig. 8)).

When comparing the two groups, statistically significant differences favoring the Dynatract® group (Group II) were observed at the midpoint and caudal positions (Table 1; Fig. 9). At the cranial position, no statistically significant differences were observed at any time point; median values in Group II were nevertheless consistently lower across all intervals (Fig. 9).

Secondary endpoint: force required for closure

After 36 h, the force required to bring the fascial edges together was significantly lower in the Dynatract® group (2.5 N) compared to the control group (7 N, $p = 0.026$) (Table 2). This measurement was performed after removal of both devices, ensuring that the recorded values reflected the residual biomechanical condition of the abdominal wall rather than any direct device traction.

Final endpoint: complete closure of the open abdomen

At the conclusion of the study, all animals in both groups achieved complete closure of the open abdomen without complications.

Physiological parameters

Over the 36-hour observation period, there were no significant differences between the groups in heart rate, temperature, CO₂ saturation, intra-abdominal pressure, and diuresis.

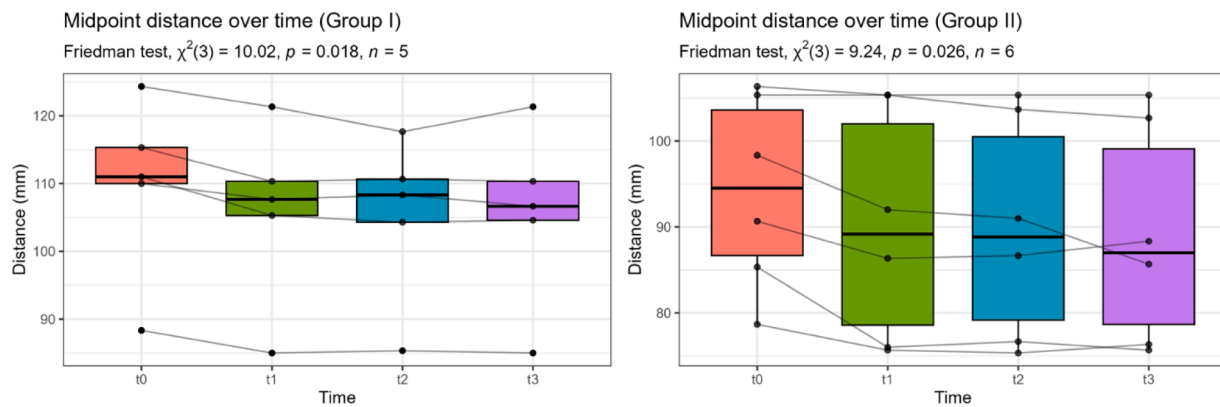


Fig. 8. Friedman test for midpoint measurements over time (t0, t1, t2, and t3) within each group. Thin lines connect repeated measurements from the same pig; dots show individual observations; boxes indicate medians and interquartile ranges (IQR). Reported p-values correspond to the overall time effect (Group I: $p = 0.018$; Group II: $p = 0.026$). t0 = 0 h, t1 = 12 h, t2 = 24 h, t3 = 36 h. $n = 6$ in the Dynatract® group; $n = 5$ in control group from t1 onwards due to one death.

Discussion

Fascial apposition without concerns for ACS is the ultimate goal of OA management. The World Society of Emergency Surgery recommends NPWT combined with continuous fascial traction (CFT) as the primary technique for TAC [9]. While current methods such as NPWT are effective in achieving early closure and controlling intra-abdominal pressure, they often fail to prevent abdominal wall retraction and mitigate the risk of complications, such as incisional hernias. A meta-analysis conducted by [20] demonstrated that dynamic traction yielded superior outcomes compared to static traction across all evaluated endpoints. However, the authors noted potential limitations due to data heterogeneity and emphasized the need for further research to determine the OA management technique for trauma patients.

Several commercial devices (some of which may be considered invasive due to the surgical manipulation of abdominal wall structures) are available for TAC in open OA management, including the Wittmann Patch (WP), mesh-mediated fascial traction (MMFT), Fasciotens, and the ABRA System.

These devices can be differentiated based on their method of anchoring to the abdominal wall. The WP, MMFT, and Fasciotens are anchored at the aponeurotic edge. Due to their laminar textile structure, both WP and MMFT may interfere with NPWT, particularly in cases involving complex abdominal exudate drainage. In such situations, approximation of the abdominal wall is often limited to intraoperative settings. Fasciotens, because of its external configuration and structural weight, presents additional challenges when combined with NPWT. In critically ill patients, it may increase the risk of ventilatory compromise or elevated intra-abdominal pressure, especially in the lower abdomen.

The ABRA system, owing to its numerous elastomers and retention elements, can further complicate the surgical procedure. Traction is applied linearly, beginning at the retention element on the skin, traversing the abdominal wall, and exiting through the parietal peritoneum. In the event of reintervention, the device's integrated protective layer can significantly hinder the effective transmission of negative pressure to the abdominal cavity.

Although a direct comparison with Dynatract® falls outside the scope of this study, our findings support its feasibility for use alongside NPWT. Dynatract® does not interfere with the negative pressure system, allows continuous access to the abdominal cavity, and does not require dressing removal to adjust traction (key considerations for surgical reinterventions). Additionally, Dynatract® helps preserve the integrity of the aponeurotic edge by avoiding direct suture fixation and instead applying tangential traction forces. The system allows for externally controlled, progressive traction of the musculoaponeurotic structures: initially to prevent wall retraction in the early, more critical phase, and subsequently to facilitate controlled closure as the patient stabilizes.

These features may offer clinical advantages in preserving fascial continuity. Further comparative research is needed to determine how these technical characteristics translate into clinical outcomes relative to existing technologies.

Primary endpoint: reduction in fascial edges distance

The primary endpoint of this study was to assess the effectiveness of Dynatract® in reducing the distance between the fascial edges. Over the 36-hour observation period, pigs treated with the combination of NPWT and Dynatract® showed a consistent reduction in fascial margin distances compared to those treated with NPWT alone. Statistical significance was achieved at the midpoint and 5 cm caudally of the laparotomy incision (see Table 3 for p-values), indicating that the system effectively brought the aponeurotic edges closer at these locations.

Though measurements taken cranially approached but did not reach statistical significance, the consistently lower median values in the Dynatract® group suggest a trend toward reduced fascial separation across the entire incision. This finding is crucial, as reduced fascial edge retraction directly impacts the likelihood of achieving primary closure and possibly minimizing complications like incisional hernias.

Secondary endpoint: force for closure

In this study, we measured the force required to approximate the fascial edges to the midline at 36 h, as an indicator of the tension necessary for closure. While this measurement provides a useful approximation, it is important to acknowledge that it may not fully represent the total force required for definitive closure. True closure involves additional factors beyond the initial fascial traction, such as tissue elasticity, intra-abdominal pressure variations, and the mechanical behavior of the abdominal wall over time. However, this approximation remains relevant as it allows for a standardized comparison of the mechanical forces involved in fascial reapproximation, offering valuable insights into the biomechanical feasibility of different closure techniques.

Importantly, the measurement of closure force was performed after removal of both NPWT and Dynatract® systems, ensuring that the observed differences reflected residual biomechanical properties of the abdominal wall rather than any ongoing mechanical support.

The significantly lower force needed to reapproximate the fascia in the Dynatract® group (2.5 N) compared to the control group (7 N) highlights the system's ability to facilitate abdominal wall closure with less strain on the aponeurotic edges. This is particularly important in reducing tension on the tissues, which may help prevent long-term complications such as abdominal wall dehiscence and hernia formation.

Table 1
Distance between the fascial margins in mm for both groups at cranial (Cr), midpoint (Mid), and caudal (Ca) positions across all time points. Median and interquartile range (Q1–Q3) shown in brackets. Mann–Whitney U test used for between-group comparisons. $n = 6$ in Dynatract® group; $n = 5$ in control group from 12 h onwards due to one death.

	0h		12h		24h		36h	
	NPWT	Dynatract	p	NPWT	Dynatract	p	NPWT	Dynatract
Cr	94.5 (89.7–99.3)	87.5(84.1–90.8)	0.287	88.8(83.1–94.5)	76.2(65.9–86.5)	0.09	92.3(83.0–101.6)	78.3(67.1–89.5)
Mid	113(108.5–117.5)	94.5(86.05–103.4)	0.013	109(103.1–114.8)	89.2(77.5–100.8)	0.032	107(104.1–109.9)	87(76.8–97.4)
Ca	97.3 (93.7–100.9)	82.5(77.8–87.2)	0.046	96.5(93.7–99.3)	76.8(71.1–82.6)	0.020	94(93.0–95.0)	76(69.9–82.1)
								0.041

Complications and monitoring

There were no significant complications related to the device during the study. Hemodynamic variables such as heart rate, temperature, CO₂ saturation, intra-abdominal pressure, and diuresis were closely monitored throughout the experiment, with no significant differences observed between the two groups. This suggests that adding Dynatract® to NPWT does not adversely impact systemic physiological parameters, supporting its safety profile.

Clinical implications

The findings from this preclinical trial are promising and suggest that Dynatract® offers a new avenue for managing the challenges associated with OA. Its ability to gradually bring the fascial edges closer together could lead to better outcomes in terms of early closure and reduced postoperative complications like hernias. By facilitating the earlier approximation of the fascial edges, Dynatract® may also reduce the duration of OA management, shortening hospital stays and improving patient recovery times. Dynatract® facilitates a progressive closure, with less force required to approximate the edges, which could reduce the incidence of ventral hernias, a complication that has been reported in up to 30 % of cases [26].

The management of OA is multifaceted and extends beyond the prevention of abdominal wall retraction. Several critical factors influence the feasibility of primary closure, including the number of take-backs, time to takeback, obesity, the presence of stomas, enteroatmospheric fistulas, and fluid overload [27]. These factors often contribute to delayed or failed closure, increasing the risk of complications such as ventral hernias and enterocutaneous fistulas.

In this study, we utilized a preclinical experimental model of abdominal compartment syndrome (ACS) because it represents one of the most severe clinical scenarios in which an OA occurs. ACS presents significant challenges for closure, as the aponeurotic edges are more widely separated, and the patient is physiologically more compromised.

The progressive traction applied by Dynatract® could be particularly beneficial in cases where early closure is not possible due to bowel edema or excessive visceral volume. However, future clinical studies should explore its efficacy in patients with diverse indications for OA.

Another important factor is the device's compatibility with NPWT systems, particularly the AbThera dressing used in this study. NPWT has long been a cornerstone in managing OA, and combining it with a device that enhances abdominal wall traction without compromising visceral protection or increasing intra-abdominal pressure could represent a significant step forward in the field.

Another advantage of Dynatract® is its ability to facilitate the management of OA in patients requiring multiple surgical re-interventions. Adequate access to the abdomen during these re-interventions is crucial, and traditional dynamic closure or negative pressure systems can make this process difficult. In our study, Dynatract® allowed dressing changes to be performed quickly and without causing additional damage to the fascial edges. This suggested that this system could simplify OA management in the clinical setting, thereby improving both the surgeon's and patient's experience.

Study limitations and future directions

While this study provides strong preliminary data, several limitations must be acknowledged. First, the sample size was relatively small, and the preclinical nature of the study means that further validation in human clinical trials is necessary. Additionally, while the female porcine model was chosen for its anatomical similarity to the human abdomen, there may be differences in tissue healing and inflammation that need to be explored in human subjects. Moreover, the simulation involved conditions that may not fully replicate real-life scenarios. The complexity of simulating an OA and the subsequent treatment differs

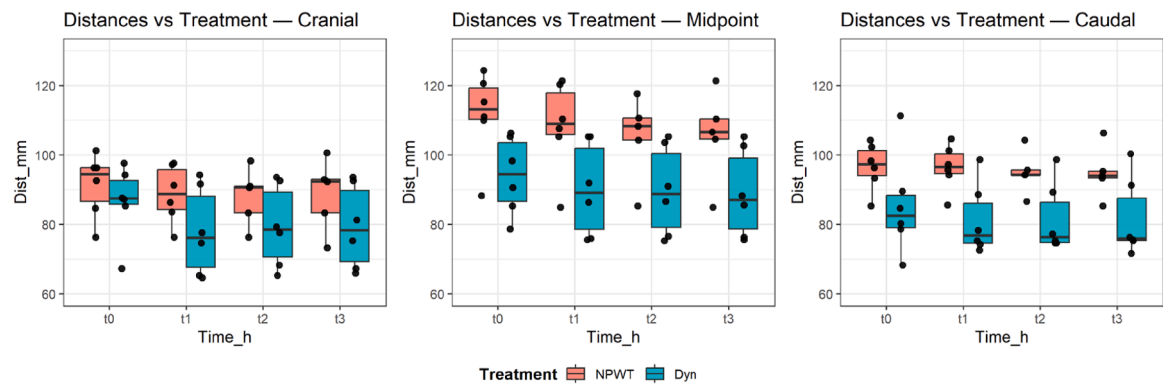


Fig. 9. Comparison of the distances of the different measurements (cranial, midpoint, and caudal) over time (t0, t1, t2, and t3) between the two groups. Dots show all individual pigs; boxplots display medians and interquartile ranges (IQR). Mann–Whitney U tests were applied for each time point. t0 = 0 h, t1 = 12 h, t2 = 24 h, t3 = 36 h. *n* = 6 in the Dynatract® group; *n* = 5 in control group from t1 onwards due to one death.

Table 2
Closing Forces (in Newtons). Median and interquartile range (Q1–Q3) shown in brackets. P-values are indicated for group comparison. Mann–Whitney U test used for between-group comparisons. *n* = 6 in Dynatract® group; *n* = 5 in control group from 12 h onwards due to one death.

	36h		<i>p</i> -value
	NPWT	Dynatract	
Upwards	7 (6.63–7.38)	2.5(2.44–2.56)	0.026

Table 3
Heart rate, temperature, CO₂ saturation, intra-abdominal pressure, and diuresis measurements at 36 h. Median and interquartile range (Q1–Q3) shown in brackets. P-values are indicated for group comparison. Mann–Whitney U test used for between-group comparisons. *n* = 6 in Dynatract® group; *n* = 5 in control group from 12 h onwards due to one death.

	36 h		
	NPWT	NPWT + Dynatract	<i>p</i> -value
Heart rate (bpm)	70 (59.0–85.0)	95.5 (78.2–98.5)	0.121
Temperature (°C)	38.9 (38.9–39.2)	38.4 (37.9–39.5)	0.647
CO ₂ saturation (ppm)	97 (96.0–98.0)	98.5 (98.0–99.8)	0.074
IAP (mmHg)	8.09 (6.98–8.15)	7.09 (6.93–7.87)	0.583
Diuresis (ml)	230 (200–300)	225 (145–282.5)	0.853

from the actual conditions encountered in intensive care units.

This preclinical study was designed as a superiority trial with a limited sample size (*n* = 12), determined by ethical and logistical constraints in accordance with current animal experimentation regulations. The sample size calculation was based on detecting a clinically relevant reduction of 10 mm in fascial separation (from 20 mm to 10 mm), assuming a standard deviation of 6 mm, 90 % power, and a two-sided alpha of 0.05. Although the sample size calculation relied on parametric assumptions, the final analysis used non-parametric tests (Friedman, Wilcoxon, and Mann–Whitney U) due to deviations from normality in the observed data.

The primary endpoint (fascial edge distance at three anatomical locations) was analyzed by comparing groups at each time point. Statistically significant differences favoring the Dynatract® group were found at the midpoint and caudal positions, whereas the cranial position did not reach statistical significance at any point (Table 1; Fig. 10).

Within-group analyses using the Friedman test showed a significant time effect at the midpoint in both groups over 36 h (Control *p* = 0.018; Dynatract® *p* = 0.026) (Fig. 8). Pairwise comparisons were considered exploratory and are not the focus of the present analysis. The direction and consistency of the medians across all time points further support the mechanical effect of the Dynatract® system.

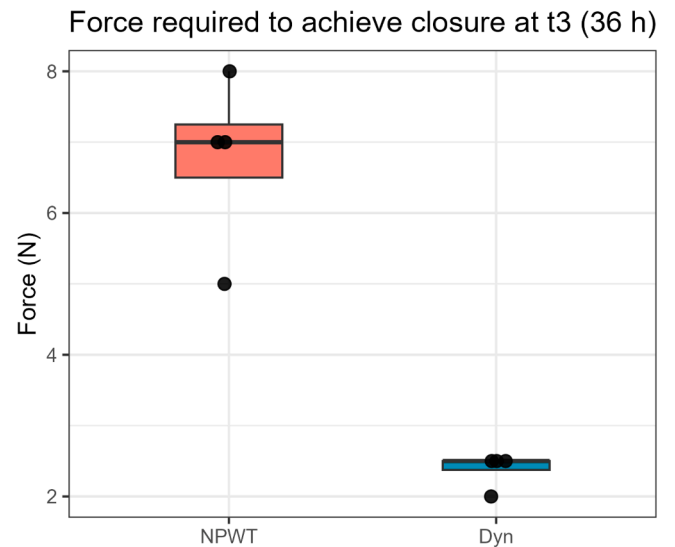


Fig. 10. Force required to achieve abdominal closure at t3 (36 h) in both groups. Dots show all individual pigs; boxplots display medians and interquartile ranges (IQR). Measurement was performed after removal of both devices. *n* = 4 per group (force measured in 8 pigs; one control animal died before t3).

This trend was also observed in secondary outcomes, such as the force required for fascial closure after 36 h, which was significantly lower in the Dynatract® group, and in the successful achievement of complete fascial closure in all animals from both groups.

Although non-parametric methods are known to require larger samples to achieve the same statistical power as parametric tests, the consistency of the findings provides a robust signal supporting the hypothesis of reduced fascial retraction with Dynatract®. These results offer a compelling rationale for further validation in larger, confirmatory studies.

Future studies should focus on longer-term outcomes, including the potential for reducing incisional hernia rates and other late-stage complications. Additionally, it would be beneficial to assess the device's efficacy in more complex OA cases, such as those with higher intra-abdominal pressures or larger defects. Furthermore, while no significant complications related to fascial integrity were observed in our study, future research should also investigate potential long-term effects on the myofascial layers, particularly regarding prolonged traction and tissue response over extended periods. In this regard, attention should also be given to any potential mechanical impact, friction, or pressure-related effects resulting from the positioning of the retaining elements

in contact with the inner surface of the parietal peritoneum of the abdominal wall.

To translate these findings into clinical practice, a well-designed clinical trial will be conducted to generate high-quality evidence on *Dynatract*®'s role in optimizing OA management and improving surgical outcomes. This validation will be crucial for its clinical integration and for enhancing patient prognosis in this complex setting. Based on prior research and using the ABRA® clinical trial [28] as a reference, a sample size of 14 patients is expected to provide sufficient statistical power. Given the high incidence of incisional hernias associated with standard NPWT [29,30], the study will incorporate long-term follow-up. One of the expected advantages of *Dynatract*® is its ability to prevent abdominal wall and fascial retraction, potentially reducing the risk of ventral hernias and fistulas following definitive closure. This could represent a significant improvement over existing NPWT-based strategies.

Conclusion

The promising results from our preclinical study in a porcine model suggest that *Dynatract*® may facilitate early primary closure in open abdomen (OA) management by reducing fascial retraction and lowering the force required for closure. However, to validate these findings in clinical practice, a well-designed clinical trial is essential to thoroughly evaluate its safety and efficacy in human patients. A randomized controlled trial (RCT) with a rigorous methodology should be conducted to compare *Dynatract*® in combination with Negative Pressure Wound Therapy (NPWT) versus NPWT alone. Key clinical outcomes should include primary closure rates, incidence of ventral hernias, hospital length of stay, and associated complications.

Ethics statement

The study does not involve patients. All experiments were in accordance with Spanish legislation governing animal studies (RD 53/2013, Animal experimentation) which established the basic standards applicable for protecting animals used in experimentation and other scientific purposes. The preclinical study project has been assessed by the Ethics and Animal Welfare Committee of the Valdecilla Virtual Hospital (Santander, Spain) in the capacity of Authorized Body by RD 53/2013, (reference number: 19/2024).

CRediT authorship contribution statement

Patricia Zorrilla de la Fuente: Writing – original draft, Validation, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Federico Castillo Suescún:** Writing – review & editing, Supervision, Resources, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Rodrigo González Larrán:** Validation, Methodology. **Ramón Sancibrian Herrera:** Writing – review & editing, Validation, Supervision, Methodology. **Galo Peralta Fernández:** Writing – review & editing, Validation, Supervision, Resources, Methodology, Funding acquisition.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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