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Early placement of a non-invasive, pressure-regulated, fascial reapproximation device improves reduction of the fascial gap in open abdomens: a retrospective cohort study

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ABSTRACT

Background Since current fascial traction methods involve invasive procedures, they are generally employed late in the management of the open abdomen (OA). This study aimed to evaluate early versus late placement of a non-invasive, pressure-regulated device for fascial reapproximation and gap reduction in OA patients.

Methods The study included all patients who had the abdominal fascia intentionally left open after damage control operation for trauma and emergency general surgery and were managed with the device in an academic hospital between January 1, 2020, and December 31, 2023. Time of device placement in relation to the end of index laparotomy was defined as early (≤24 hours) versus late (>24 hours). Time-related mid-incisional width reduction of the fascial gap and fascial closure were assessed using descriptive and linear regression analysis.

Results There was a significantly higher percent reduction in the fascial gap at the midpoint of the laparotomies in the early (≤24 hours) AbClo placement group compared with the late (>24 hours) AbClo placement group, respectively, median 76% versus 43%, p<0.001. Linear regression adjusting for body mass index and the number of takebacks indicated that fascial approximation was 22% higher for early placement (β=0.22; CI 0.12, 0.33, p<0.001). Primary myofascial closure rate with early (≤24 hours) application of the device was 98% versus 85% with late application.

Conclusion Early non-invasive application of the device (≤24 hours) after the initial laparotomy resulted in greater reduction of the fascial gap and higher primary fascial closure rate compared with late placement (>24 hours). Early non-invasive intervention could prevent abdominal wall myofascial retraction in OA patients.

Level of evidence IV.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Current fascial traction systems are invasive and therefore infrequently used early in open abdomens engendering lateral retraction of the abdominal wall.

WHAT THIS STUDY ADDS

⇒ Early application of a non-invasive fascial device helps reduce the fascial gap and promote fascial closure.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Change the care path in open abdomens from reactive to preventive reducing lateral retraction of the abdominal wall and facilitating primary fascial closure.

INTRODUCTION

Intentionally leaving the abdominal fascia open at the end of a laparotomy entails significant complications in both trauma and emergency general surgery (EGS).[1–7] Timely primary fascial closure and fewer takebacks are conceivably the most effective approach to reduce the complications related to open abdomens (OA).[2 8–12] However, loss of the midline attachment of the abdominal wall fascia results in muscle unloading and time-dependent muscle contracture hindering myofascial closure in OA.[13 14] Higher rates of fascial closure have been achieved when temporary abdominal coverage methods are used in conjunction with fascial traction systems, in particular, continuous traction with retention sutures and synthetic polymer sheets, mesh-mediated traction, and elastomers transpierced through the abdominal wall.[6 10 11 15–24] Although those technologies provide gradual traction of the fascia, they require invasive surgical procedures under general anesthesia, and may cause fascial damage, adding to the complications of the OA.[11 14 25–27] Therefore, they are infrequently used early in the management of the OA engendering lateral retraction of the abdominal wall and increase of the fascial gap. A recently developed non-invasive, pressure-mediated device (AbClo, InventoRR MD Inc., Markham, ON, Canada) has been used to mitigate lateral retraction of the abdominal wall fascia and provide gradual myofascial medialization to facilitate ultimate primary fascial closure of the OA.[28] The biomechanical principle of the device is based on non-invasive propagation of force vectors from the skin to deeper myofascial layers.[29–32]

The primary objective of this study was to compare time-related reduction of the width of the fascial gap in response to the early placement (≤24 hours after the initial laparotomy) versus late

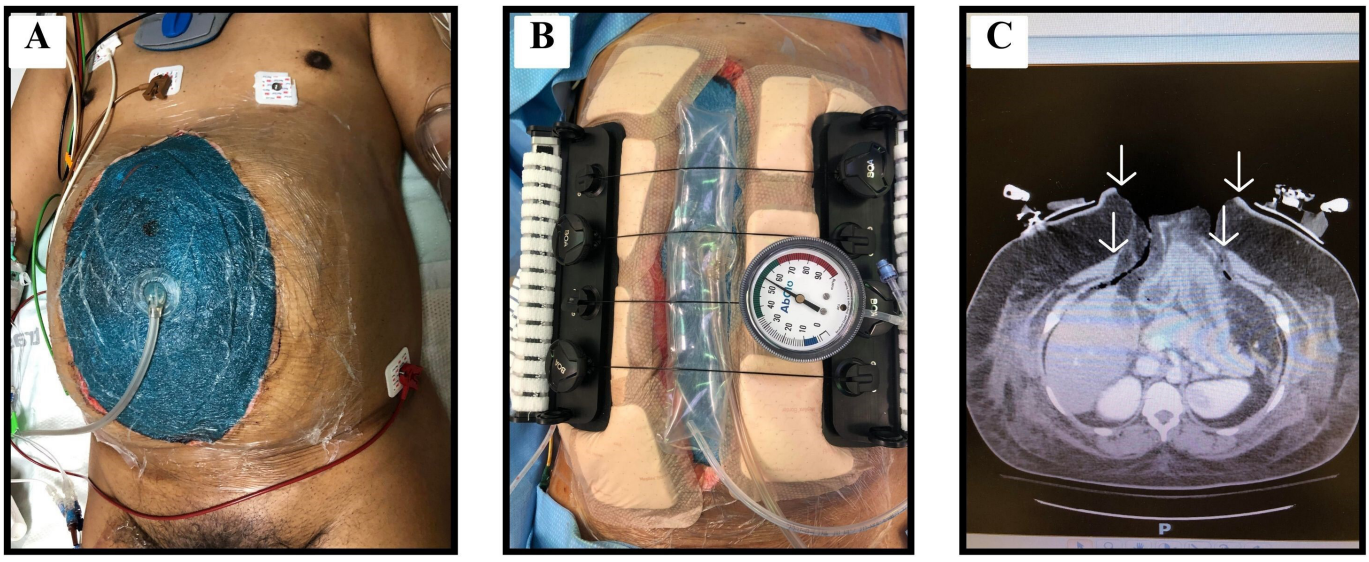

Figure 1 Photograph of the initial fascial gap on an open abdomen covered with a negative pressure wound dressing prior to device placement (A). Reduction of the fascial gap after non-invasive placement of the AbClo device in the same patient (B). Primary fascial closure was achieved after 9 days of open abdomen and two takebacks. Photograph of a CT scan axial view of a different patient showing the rectus muscle splint medialization of all layers of the abdominal wall, from skin to fascia (arrows). Primary fascial closure was achieved despite 19 days of open abdomen and five takebacks; body mass index 50 kg/m^2 (C).

placement (>24 hours after laparotomy) of the AbClo device in OA patients for trauma and EGS. The study also aimed to assess the overall effectiveness of the device in facilitating myofascial closure.

METHODS

Study design

This study included all patients 18 years or older who had the abdominal wall fascia intentionally left open after a damage control for trauma and EGS and were managed with the AbClo device between January 1, 2020, and December 31, 2023. The decision to leave the fascia open at the index laparotomy and at takebacks was at the clinical discretion of the surgeon. The device is standard of care for management of the OA at our institution and utilization was determined by provider clinical decision. Exclusion criteria encompassed patients not managed with the AbClo device.

Device components and method of use

The AbClo device (AbClo, InventoRR MD Inc.) is a trademarked product approved by the US Food and Drug Administration. The device is applied externally on the abdominal wall over a temporary abdominal coverage dressing and consists of four components: a pair of rigid polyethylene rectus abdominis muscle splints (24.5 cm×8 cm×1.5 cm), a circumferential elastic binder (130 cm×20 cm), and a diaphragm-type pressure gauge connected to a cylindrical polyethylene balloon (25 cm×6 cm) (figure 1). Training is provided by a clinical specialist. It encompasses a 15-minute hands-on demonstration with emphasis on the correct position of the rectus muscle splints (at least 5 cm lateral to the edge of the OA), skin protection, and appropriate tightening technique. The device is supported on the abdominal wall only by the tension generated between the two rectus abdominis muscle splints and the circumferential elastic binder around the patient's back (figure 1). The undersurface of the rectus abdominis muscle splint is concave to conform to the lateral edge of rectus abdominis muscles and padded with silicone. The splints have a crossbar with a locking mechanism to secure the binder. Each splint has a pair of reel dials with stainless steel cables wrapped in nylon (Boa Technology Inc., Denver, CO) and cable anchoring cleats. The reel dials have a lock and release mechanism to regulate the tension of the cables. The gauge has four colored ranges of tension to facilitate monitoring of the safe tension zone, 35–65 mm Hg (green zone) (figure 1). The device was tightened daily by the surgeon, tension was kept between 35 and 65 mm Hg. The nursing team assessed the pressure and the position of the device every 6 hours. Among the contraindications for AbClo use are conditions that could prevent the device from being positioned on the abdominal wall or could be exacerbated by its application, that is, abdominal wall necrosis, major burns. Intestinal stomas and abdominal compartment syndrome are not considered a contraindication for AbClo. Accordingly, in those cases, the rectus muscle splints can be placed laterally to the stoma site, and the pressure gauge allows the tension to be adjusted in real time.

Data collection

Data were collected from electronic medical records, including demographics, body mass index (BMI), type of surgery, time of device placement after the initial laparotomy, device tension, takebacks to the operating room, fluid status, and primary myofascial closure rate.

Additionally, the length and the width of the fascial defects were measured at the end of the first laparotomy before AbClo placement, at 8 hours after AbClo placement, and daily thereafter using a measuring paper tape (Graham-Field, Atlanta, GA). The measurements of the fascial gap were taken at the skin edge 5 cm below the xyphoid, at the midpoint of the laparotomy incision, and 5 cm above the pubic symphysis.

Patients were divided into two groups based on the time of the placement of the device in relation to the initial laparotomy: early placement (≤24 hours after initial laparotomy) and late placement (>24 hours after initial laparotomy). All trauma and acute care staff surgeons, general surgery residents, and trauma

fellows were trained to apply the device. Allocation time was at the clinical discretion of the surgical team based on the availability of the surgeon to place the device on the patient. Allocation time was calculated by subtracting the time of AbClo placement from that of the end of the laparotomy in which the abdomen was intentionally left open. The primary outcome of interest was time-related percentage width decrease assessed at the midpoint of the fascial gap, calculated using the formula:

$$Percentage\ Width\ Reduction = (Original\ Width - New\ Width) / Original\ Width \times 100$$

Statistical analysis

Descriptive statistics were used to summarize demographic and clinical characteristics. The preferred measure of central tendency used to report continuous data was medians and IQRs, whereas categorical data were represented using numbers and percentages. The differences between groups were assessed using Pearson's χ^2 test for categorical variables, Wilcoxon rank-sum test for skewed continuous variables, and Fisher's exact test when appropriate. A p value <0.05 was considered statistically significant.

A linear regression analysis was done to determine the relationship between early placement and percentage closure while adjusting for confounders. The model was validated using a Q-Q plot, Durbin-Watson test, scale-location plot and observed versus predicted values plot. All analyses were performed using statistical software R V.4.2.3 (R. Foundation for Statistical Computing, Vienna, Austria) and Python V.3.11.0 (Python Software Foundation, Beaverton, OR).

RESULTS

Demographics

The study included 75 patients who had the abdominal wall fascia intentionally left open for trauma and EGS managed with the AbClo device. 47 patients underwent an early placement of AbClo (≤24 hours from the initial laparotomy), while 28 patients underwent a late placement of the device (>24 hours from the initial laparotomy) (table 1). More granular data related to the time of AbClo application showed that 72.3% of the patients in the early placement group had the device applied to the abdominal wall within 6 hours of the index laparotomy and 27.7% had it applied between 6 and 24 hours. In the late placement group, 57.1% had the device applied after 48 hours of the index laparotomy. Age, gender, and BMI were similar between the groups (table 1). The most common indication to leave the abdomen open was a combination of logistical (anticipated abdominal reintervention) and physiological reasons (severe acidosis, coagulopathy, high doses of vasopressors), that is, 56% in the early AbClo placement group and 46% in the late placement group (p=0.8).

Table 1 Demographics and descriptive analysis of early vs. late AbClo placement

Characteristic	Overall, n=75*	Early (<24 h), n=47*	Late (>24 h), n=28*	P value†
Sex (male)	55 (73%)	32 (68%)	23 (82%)	0.2
Age	51 (34, 68)	49 (37, 68)	55 (28, 70)	0.7
BMI (kg/m²)	32 (27, 37)	33 (28, 38)	29 (26, 35)	0.054
NA	1	0	1	
Classification				0.8
EGS	31 (41%)	20 (43%)	11 (39%)	
Trauma	44 (59%)	27 (57%)	17 (61%)	
Bridging mesh only	4 (5.5%)	1 (2.2%)	3 (11%)	0.2
NA	2	2	0	
NA	1	1	0	
MHP	44 (59%)	28 (60%)	16 (57%)	0.8
ISS (trauma)	34 (24, 34)	34 (25, 41)	34 (20, 34)	0.5

*n (%); median (IQR).
†Pearson's χ^2 test; Wilcoxon rank-sum test; Fisher's exact test.
BMI, body mass index; EGS, emergency general surgery; ISS, Injury Severity Score; MHP, massive hemorrhage protocol; NA, not available.

Patient management and OA characteristics

A negative pressure wound therapy (NPWT) system (3M ABThera, St. Paul, MN) was used in conjunction with AbClo in 68 patients (91%); 45 (96%) in the early group and 23 (82%) in the late group, p=0.095. The remaining were managed with skin closure and open fascia underneath and AbClo was applied on top of the skin. The median duration of OA was significantly different between the two groups, 4.0 days (3.0, 5.0) in the early placement group and 6.0 days (5.0, 8.0), p<0.001, in the late placement group. EGS patients had a duration of OA of 4 days (3, 6) compared with 5 days (3, 7) in trauma patients (p=0.3).

The number of takebacks to the operating room after the initial OA ranged from 1 to 8 (table 2). Single takebacks were more common in the early AbClo placement group than in the late placement group, respectively, 28 (61%) versus 6 (21%) (p=0.003). The necessity for two or more takebacks was similar between EGS patients and trauma patients, respectively, 18 (58%) versus 22 (51%) (p=0.2). Similarly, the overall primary fascial closure rate between EGS and trauma patients was comparable (EGS 27/29, trauma 38/41) (p=0.9). The number of patients who underwent late device placement and required two or more takebacks was also similar in EGS and trauma laparotomies, respectively, (81%, 9/11) versus (76.5%, 13/17) (p=0.73).

Patient fluid status from the index laparotomy, assessed at the time of AbClo placement and at the time of device removal (definitive closure), was similar between early and late placement groups (table 2). The initial fluid volume of patients with OA due to a trauma was positive 9.8 L (5.2, 13.1) and positive 8.0 L (5.1, 11.2) in EGS patients (p=0.3). Similar volumes were seen at the time of closure; positive 8.5 L (5.3, 11.3) in trauma patients versus positive 8.2 L (6.2, 9.9) in EGS patients (p=0.7).

The tension generated on the abdominal wall was assessed through the air-filled balloon. The device was tightened daily by the surgeon and was assessed every 6 hours by the nursing team. The final tension of the device was similar between the groups, 40 mm Hg (37, 45) in the early AbClo group versus 46 mm Hg (40, 48) in the late group (p=0.2), both were within predefined safe tension zones (green range) on the gauge.

Placement of the device did not result in a statistically significant increase in peak airway pressure, 29.5 mbar (6.6) prior to AbClo placement versus 29.8 mbar (6.6) with AbClo (p=0.15). Moreover, no significant changes in peak airway pressure were shown at the end of the last takeback after device removal compared with previous assessment, 29.8 mbar (6.6) with AbClo versus 30.7 mbar (5.7) after removal. Those findings persisted regardless of early or late device placement, respectively, 30 mbar (27.5, 33.0) versus 32.5 mbar (30.2, 34.8) (p=0.2).

Outcomes

The median initial widths of the fascial gaps at the midpoint of the laparotomy taken before placing the AbClo device were equivalent between the early and late AbClo groups, respectively,

Table 2 Patient management and open abdomen characteristics

Characteristic	Overall, n=75*	Early (<24 h), n=47*	Late (>24 h), n=28*	P value†
Total days of open abdomen	4.5 (3.0, 7.0)	4.0 (3.0, 5.0)	6.0 (5.0, 8.0)	<0.001
Number of takebacks				0.003
1	34 (46%)	28 (61%)	6 (21%)	
2	21 (28%)	12 (26%)	9 (32%)	
3	11 (15%)	3 (6.5%)	8 (29%)	
4	5 (6.8%)	2 (4.3%)	3 (11%)	
5	2 (2.7%)	1 (2.2%)	1 (3.6%)	
NA	1	1	0	
Initial fluid status before AbClo placement (liters positive)	8.0 (5.2, 12.8)	8.7 (5.3, 12.8)	8.0 (5.2, 12.2)	0.7
NA	6	2	4	
Final fluid status after AbClo removed (liters positive)	8.3 (5.6, 10.1)	8.5 (6.1, 11.3)	7.2 (4.5, 10.0)	0.2
NA	7	4	3	
Time AbClo placed after OA	7 (0, 44)	0 (0, 6)	52 (40, 78)	<0.001
Duration of AbClo (h)	70 (48, 109)	70 (52, 100)	68 (36, 119)	0.9
NA	1	1	0	
Length of laparotomy (cm)	30.0 (25.8, 32.0)	30.0 (27.2, 32.0)	28.5 (25.0, 31.2)	0.13

*n (%); median (IQR).
†Pearson's χ^2 test; Wilcoxon rank-sum test; Fisher's exact test.
NA, not available; OA, open abdomen.

15.0 cm (12.1, 18.0) and 15.0 cm (12.0, 17.2) (p=0.8). Similar findings were shown in the measurements taken at the top and at the bottom of the fascial gaps (table 3). In contrast, medians of the final widths of the fascial gaps reduced significantly more in the early AbClo placement group compared with the late placement group in all three sites, respectively: top (3 cm vs. 4 cm), midpoint (3 cm vs. 8 cm), bottom (3 cm vs. 4 cm), p<0.05 (table 3).

There was a significantly higher percent reduction in the fascial gaps at the midpoint of the laparotomies in the early AbClo placement group compared with the late AbClo placement group, respectively, median 76% versus 43%, p<0.001 (figure 2). Moreover, our findings showed a linear relationship between the extent of the fascial gap decrease and the timing of the end of the index laparotomy. Furthermore, most of the reduction and reapproximation of the fascial gap occurred within the first 8–24 hours after the placement of the device (figure 3). Specifically, early AbClo placement resulted in an average decrease of 50% of the width of the fascial gap at the midpoint at 8 hours and a 74.5% decrease at 24 hours, whereas late AbClo placement resulted in an average decrease of 24% of the width at the midpoint at 8 hours and 44% at 24 hours (figure 3). The differences between mid-incisional width reductions at 8 and 24 hours between early and late AbClo placement were statistically significant (p=0.04). However, subsequent gains in fascial reapproximation and gap reduction were much less pronounced with an additional 2.5% reduction in the early placement group and a 1.5% reduction in the late placement group at 48 hours (p=0.03).

As the chances of primary fascial closure are higher on the first return to the operating room, we reran our analysis after excluding all patients who were closed at the first takeback to

Table 3 Patient outcomes

Characteristic	Overall, n=75*	Early (<24 h), n=47*	Late (>24 h), n=28*	P value†
Primary closure	65 (93%)	42 (98%)	23 (85%)	0.069
NA	5	4	1	
Top incisional width pre-AbClo (cm)	9.00 (7.00, 10.00)	9.00 (7.00, 10.00)	7.50 (6.00, 10.25)	0.2
Midpoint incisional width pre-AbClo (cm)	15.0 (12.0, 18.0)	15.0 (12.1, 18.0)	15.0 (12.0, 17.2)	0.8
Bottom incisional width pre-AbClo (cm)	8.50 (7.00, 10.00)	9.00 (7.25, 10.00)	8.00 (5.75, 10.25)	0.4
Final top incisional width post-AbClo (cm)	3.00 (2.00, 4.25)	3.00 (2.00, 3.00)	4.00 (2.75, 6.62)	0.008
NA	3	3	0	
Final midpoint incisional width post-AbClo	4.00 (2.95, 8.00)	3.00 (2.00, 5.00)	8.00 (4.00, 10.25)	<0.001
NA	3	3	0	
Final bottom incisional width post-AbClo	3.00 (2.00, 4.00)	3.00 (2.00, 3.00)	4.00 (2.88, 6.25)	0.003
NA	3	3	0	
Middle width percent reduction post-AbClo	0.71 (0.48, 0.80)	0.76 (0.67, 0.83)	0.43 (0.27, 0.65)	<0.001

*n (%); median (IQR).
†Pearson's χ^2 test; Wilcoxon rank-sum test; Fisher's exact test.
NA, not available.

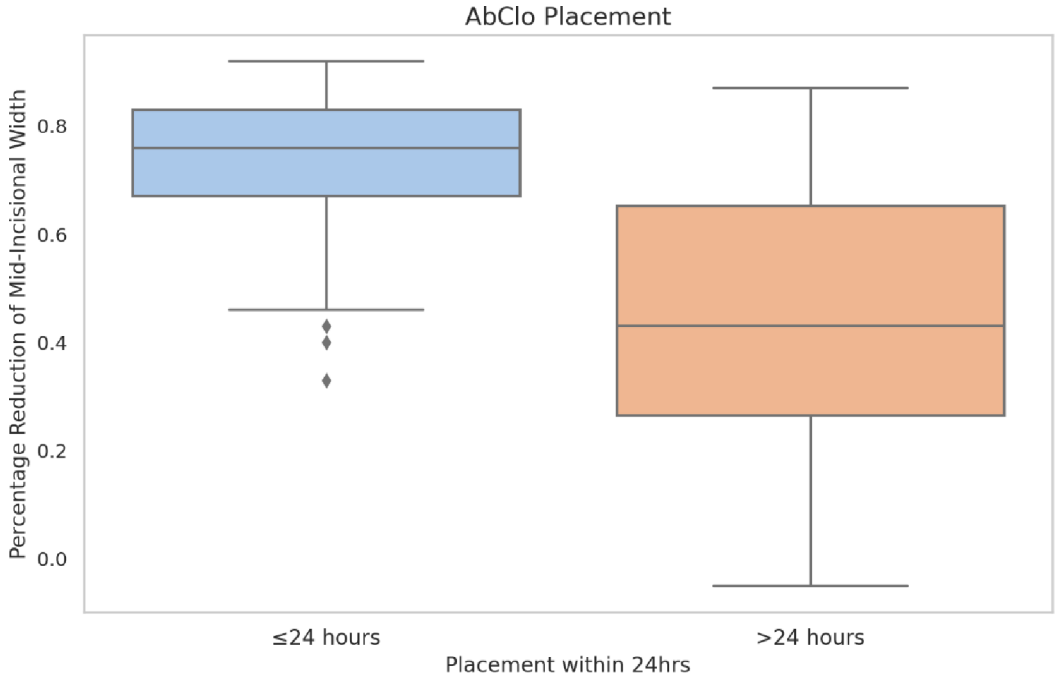

Figure 2 Percent reduction of the of mid-incisional width of the fascial gap in early device placement (≤24 hours) versus late placement (>24 hours) after index laparotomy.

validate the importance of early placement of the device. That analysis still showed a significantly greater percent reduction of the fascial gap at the midpoint of the laparotomy in the early AbClo placement group compared with the late placement group, respectively, 75% versus 43% (p<0.001). That same analysis also showed that the median final width of the fascial gap at the midpoint of the laparotomy was significantly shorter in the early AbClo placement group compared with the late placement group, respectively; 3 cm (2.8, 4.5) versus 8.2 cm (4.5, 10.8), p=0.002.

Primary closure of the abdominal wall fascia was successfully achieved in 98% of the patients in the early AbClo group compared with 85% of the patients in the late AbClo group (p=0.069). Overall, 93% of patients achieved primary myofascial closure (table 3). Our results also showed that despite the exclusion of patients who were closed at the first takeback, the primary fascial closure rate in the early AbClo placement group was 94% compared with 82% in the late placement group (p=0.4).

The complications related to the use of the AbClo device were stage 2 pressure ulcers characterized as small open bullae at the site of the rectus muscle splints in five patients (11%) in the early placement group and two patients (7.4%) in the late AbClo group (p=0.9). Incisional hernias were detected in five out of 35 patients (14.3%) at 3-month follow-up. Overall, 17 of 75 patients died during hospital stay, none of the deaths were related to the use of the device or abdominal wall closure.

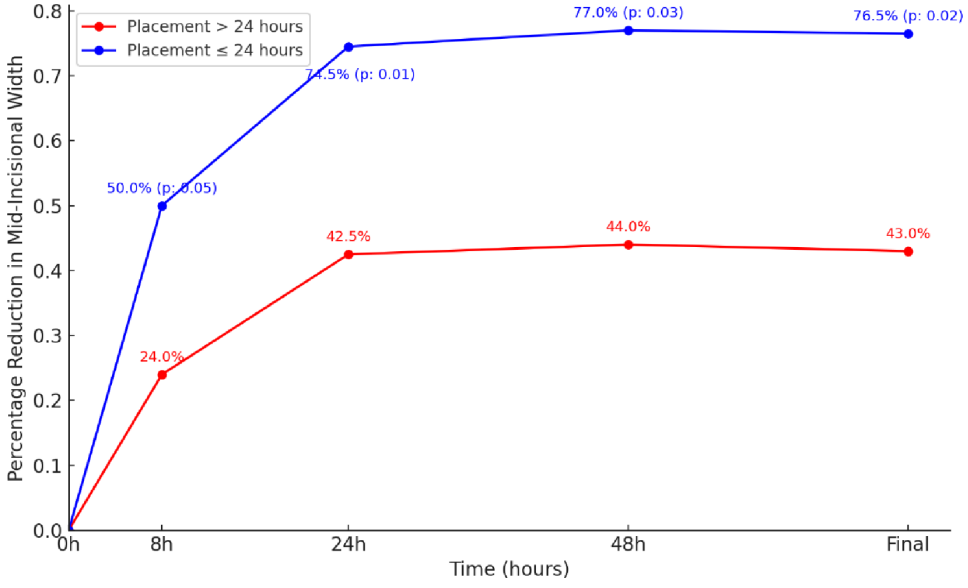

Figure 3 Temporal percent reduction of mid-incisional width of the fascial gap in early device placement (≤24 hours) versus late placement (>24 hours) after the end of the index laparotomy.

Regression model

The linear regression model analysis indicated a significant positive association between early AbClo placement (β=0.22; CI 0.12, 0.33, p<0.001) and a reduction of the width of the fascial gap at the midpoint of the laparotomy when adjusting for BMI and the number of takebacks. Specifically, the average fascial gap reduction and fascial reapproximation was 22% higher for early AbClo placement (≤24 hours) compared with late placement of the device (>24 hours). The model diagnostics indicated that all assumptions were adequately met, suggesting that the model is robust, and the results are reliable.

DISCUSSION

In this study, we investigated the time-related effects of the AbClo device on patients who had the abdominal wall fascia intentionally left open at the end of a laparotomy for trauma and EGS. Our findings showed that 8 hours after the index laparotomy, the percent decrease in the maximum width of the fascial defect was two times greater with early placement of the device (≤24 hours after the index laparotomy) compared with late placement (>24 hours after the index laparotomy). Moreover, a 74.5% decrease in the width of the fascial gap was achieved 24 hours after the index laparotomy, indicating a gap reduction 1.7 times greater with early placement versus late placement of the device. Myofascial reapproximation with this non-invasive approach tended to plateau at approximately 48 hours after device placement. Nevertheless, the fascial gap reduction in the early placement group was significantly better than late placement. Those findings underscore the potential advantages of a preventative approach to the lateralization of the abdominal wall in the OA. They also support the notion that cutting the *linea alba* disrupts the midline attachments of the fascia, resulting in rapid lateral retraction of the myofascial layers.[15 33]

The disruption of the *linea alba* causes shortening of the muscles and a reduction in elasticity which increases the fascial gap and interferes with efforts to medialize the muscles.[15 33] Unloading of the abdominal wall muscles results in muscle atrophy with reduction in fiber diameter in as early as 3–5 days.[34 35] Those findings are linked to the predominance of slow twitch fibers in abdominal muscles which are more susceptible to atrophy than fast twitch muscles.[34 35]

Primary myofascial closure rate was 98% with early placement of AbClo, and 85% with late device placement. Overall primary myofascial closure rate was 93%, similar to current closure rates for invasive fascial traction systems.[6 7 10 11 14 15 21 23 27 36 37] Interestingly, an 85% rate of primary closure with late placement of AbClo reproduced the results of our group's previous pilot study in which the device was initially placed 48 hours after the index laparotomy.[28] This finding validates that the preventive care path of this technology relies on applying it before myofascial contraction and lateral retraction of the abdominal wall become too difficult to overcome non-invasively. Accordingly, recent studies showed that incorporating a gradual fascial traction strategy, as soon as possible, after the index laparotomy significantly increases the rate of primary fascial closure in OA.[10 11 14 15 22 23 25 38] Delaying the application of a fascial traction method reduced fascial closure rate by 30–60%.[10 11 14 15 28 38] One study also showed that approximately 80% of patients who did not achieve fascia closure experienced a delay of three or more days to undergo the application of a fascial traction method.[15]

Nearly all fascial traction strategies currently used for OA are invasive requiring surgical procedures to fasten retention sutures, mesh, and elastic material to the abdominal wall fascia.[6 10 11 15–24 36 38] Consequently, usage of those strategies immediately after the index laparotomy can be curbed by coagulopathy, takebacks, recent gastrointestinal anastomosis, risk of abdominal compartment syndrome, fluid overload, bowel edema, injury burden, and surgical site infection.[10 12 15 36–38] Invasive fascial traction in the presence of those conditions could contribute to early complications in OA.[15 36–38] In contrast, a non-invasive approach that avoids direct surgical manipulation of the myofascial layers could be more suitable for early application in the OA. Accordingly, the main advantages of the AbClo device include preservation of the fascia and rapid non-invasive bedside placement, adjustment, and removal. Moreover, the pressure gauge with preset safety tension zone helps avoid abdominal compartment syndrome.

The biomechanical principles of the device hinge on the compression and shear forces generated by the rectus abdominal muscle rigid splints and the elastic binder. The resultant vector from those forces produces 44.12 pound-force (lbf) distributed tangentially over the *recti abdominis* pushing the myofascial layers toward the midline.[28] Load response deformation of the abdominal wall is subject to mechanical laws that include the coefficients of elasticity (Young's modulus) and of stiffness (shear modulus).[39–42] At the skin level, the biomechanics of load propagation is primarily determined by collagen and elastic fibers arranged according to Langer's lines.[32 41 43 44] Previous experiments showed that skin collagen bundles realign, increase rigidity, and undergo morphological changes in the direction of external forces in 30 minutes.[45] This notion supports the non-invasive midline transfer of resultant force vector generated by the rectus muscle splints and the circumferential dynamic binder of the AbClo device.[28 29 32] Moreover, myofascial medialization is enhanced by the concave undersurface of the splints.[28]

Force transmission across the subcutaneous adipose tissue is also determined by mechanical laws that include the coefficients of elasticity and stiffness.[29 46] Magnetic resonance elastography showed that compression and shear strains applied to the subcutaneous adipose tissue induced more stiffness than when applied to muscles.[29 46] Those findings corroborate the process of non-invasive propagation of the resultant force vector across all layers of the abdominal wall and the retention of those layers by the AbClo device.

Several studies have shown a decreased likelihood of primary fascial closure with higher number of takebacks.[9–11 47] Recent data showed that each additional takeback reduced the odds of primary fascial closure by approximately 90%.[10] Furthermore, a delay to first takeback beyond 24 hours after the index laparotomy was also linked to decreased odds of primary fascial closure, with approximately 80% decrease in delays between 24.1 and 36 hours up to 98% with delays longer than 48 hours.[10 12] Our findings showed that a single takeback was three times more common in the early placement group than in the late group. Considering the favorable effect of a single takeback on fascial closure, we also reassessed our data after excluding all patients that were closed on the first takeback. Despite the exclusion of those patients, our findings still showed a higher percent reduction in the fascial gap and primary fascial closure with the placement of the device compared with late placement.

Previous studies showed a higher prospect of primary fascial closure in patients who had OA for trauma than EGS.[6–8 10 11 14 14 21 28 37] This is most likely due to fewer comorbidities, new adjuncts to resuscitation, and more judicious use of crystalloids in trauma, and fewer takebacks.[6–8 10 11 14 14 21 28 37] However, in our study, primary fascial closure and the need for two or more takebacks were similar in EGS and trauma patients.

In addition, patients' median fluid volume status was consistently above 8 L, but fascial closure did not seem to be impacted. Those findings suggest that early application of the device could have a favorable impact in the number of takebacks and primary fascial closure regardless of the reason for the OA. That notion is supported by the capability of uncomplicated pressure-regulated fascial reapproximation at the bedside avoiding unnecessary changes of in the operating room with an estimated cost of US$5600 per device. Moreover, the same device can be reused on the same patient after each takeback. Accordingly, in a recently published cost-minimization analysis, the use of AbClo was associated with lower incremental costs of −$6012 (95% CI −19 499 to 1996) compared with NPWT alone including operating room costs.[48] The mean cumulative costs per patient were $76 582 for those treated with NPWT alone versus $70 582 for those treated with the AbClo device.[48]

Studies showed that a BMI≥30 kg/m^2 could have a negative impact on the success and timing of primary fascial closure in OA patients.[47 49 50] Therefore, we specifically assessed the impact of patients' BMI on non-invasive approach for myofascial mobilization. Our findings showed that the BMI was similar between the groups with an overall median BMI>30 kg/m^2. Moreover, after adjusting for BMI and number of takebacks, our findings still showed an average fascial gap reduction and fascial reapproximation 22% higher with early AbClo placement (≤24 hours) compared with late placement. Those findings corroborate mechanical load transmission generated by the device through the subcutaneous adipose tissue.[29 46]

Considering the complications specifically related to the use of the AbClo device, our results showed only minor (stage 2) pressure ulcers of the skin which were treated conservatively with saline and dressings. Those ulcers were unrelated to early or late application of the device and were undoubtedly less severe than the complications reported with current surgical methods of fascial traction.[1–7] A particularly important finding was the absence of abdominal compartment syndrome and elevated peak pressures, indicating the safety of the device's safe tension zone monitoring feature (35–65 mm Hg). Moreover, there were no cases of acute fascial dehiscence, and enterocutaneous fistula related to the use of the device. The postoperative hernia rate of the patients who underwent primary fascial closure was 14.3% at 3-month follow-up.

This study has several limitations. In addition to its small sample size and non-randomized management, we did not compare the reduction in fascial gap and primary closure rates achieved with the AbClo device to that of other methods including invasive fascial traction systems. This was due to two factors: first, the non-invasive approach of the AbClo is fundamentally different from surgical procedures for fascial traction, and second, we have not used invasive fascial traction techniques in our center. Moreover, we did not specify the time to first takeback and the indications for the OA based on specific surgical findings during the index damage control laparotomy. Comorbidities and prognostic scores were not assessed for EGS patients. Furthermore, time to follow-up was very limited to provide meaningful data related to postoperative hernia formation after primary fascial closure. Finally, we did not directly assess additional factors that have been shown to promote fascial closure in OA patients including direct peritoneal resuscitation, botulin toxin injection, damage control resuscitation, and whole blood transfusion.

CONCLUSION

Early application of the AbClo device, ≤24 hours after the initial laparotomy, was associated with a significantly greater reduction of the abdominal wall fascial gap in the OA. Moreover, early application of the device resulted in a primary myofascial closure rate of 98% (online supplemental file 1). Our findings suggest that a non-invasive, pre-emptive approach to fascial reapproximation could have a positive impact in preventing lateralization and contraction of the abdominal wall in OA patients. New research is needed to explore potential long-term effects of early AbClo placement compared with other methods.

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Competing interests JBR-N is the inventor of the AbClo device and holds a patent on the device (PCT/CA2016/050125) and is co-founder of InventoRR MD Inc. MB is the principal investigator of an ongoing clinical trial (Assessment of a non-invasive device AbClo in the management of open abdomen. This trial is funded by InventoRR MD Inc., NTC 06242925).

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