European Journal of Trauma and Emergency Surgery (2022) 48:2107–2116
https://doi.org/10.1007/s00068-021-01814-w

ORIGINAL ARTICLE

# Time is domain: factors affecting primary fascial closure after trauma and non-trauma damage control laparotomy (data from the EAST SLEEP-TIME multicenter registry)

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Received: 15 July 2021 / Accepted: 25 October 2021 / Published online: 29 November 2021


**Abstract**

**Purpose** Damage control laparotomy (DCL) is used for both traumatic and non-traumatic indications. Failure to achieve primary fascial closure (PFC) in a timely fashion has been associated with complications including sepsis, fistula, and mortality. We sought to identify factors associated with time to PFC in a multicenter retrospective cohort.

**Methods** We reviewed retrospective data from 15 centers in the EAST SLEEP-TIME registry, including age, comorbidities (Charlson Comorbidity Index [CCI]), small and large bowel resection, bowel discontinuity, vascular procedures, retained packs, number of re-laparotomies, net fluid balance after 24 h, trauma, and time to first takeback in 12-h increments to identify key factors associated with time to PFC.

**Results** In total, 368 patients (71.2% trauma, of which 50.6% were penetrating, median ISS 25 [16, 34], with median Apache II score 15 [11, 22] in non-trauma) were in the cohort. Of these, 92.9% of patients achieved PFC at 60.8 ± 72.0 h after 1.6 ± 1.2 re-laparotomies. Each additional re-laparotomy reduced the odds of PFC by 91.5% (95%CI 88.2–93.9%, $p < 0.001$). Time to first re-laparotomy was highly significant ($p < 0.001$) in terms of odds of achieving PFC, with no difference between 12 and 24 h to first re-laparotomy (ref), and decreases in odds of PFC of 78.4% (65.8–86.4%, $p < 0.001$) for first re-laparotomy after 24.1–36 h, 90.8% (84.7–94.4%, $p < 0.001$) for 36.1–48 h, and 98.1% (96.4–99.0%, $p < 0.001$) for > 48 h. Trauma patients had increased likelihood of PFC in two separate analyses ($p = 0.022$ and 0.002).

**Conclusion** Time to re-laparotomy ≤ 24 h and minimizing number of re-laparotomies are highly predictive of rapid achievement of PFC in patients after trauma- and non-trauma DCL.

**Level of evidence** 2B.

**Keywords** Trauma · Non-trauma · Damage control laparotomy · Primary fascial closure

## Background

Damage control laparotomy (DCL) was initially developed to treat critically ill trauma patients. The technique involves performing an abbreviated laparotomy with temporary abdominal closure to control acute hemorrhage and limit peritoneal contamination [1–3]. The patient is then transferred to an intensive care unit (ICU) for resuscitation and continued correction of acidosis, coagulopathy and hypothermia prior to definitive repair and closure in the operating room [4–6].

Gradually, surgeons have begun to apply DCL principles to critically ill emergency general surgery patients; acute mesenteric ischemia, postoperative peritonitis, and bowel perforation are just a few of the diagnoses resulting in the use of DCL in recent literature. Utilization of

List of meetings presented: 5th World Trauma Congress, February 2021.

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DCL in critically ill trauma patients has been associated with improved outcomes and decreased mortality [5]. DCL has gradually become an accepted strategy for non-trauma abdominal emergencies such as acute mesenteric ischemia and bowel perforation [7–18]. DCL has been associated with increased hospital length of stay (LOS)and resource utilization, although these findings may actually represent survival or selection bias as there are no randomized controlled trials in this area [19, 20]. In the trauma population, DCL-associated complications include wound infections, enterocutaneous or entero-atmospheric fistula (ECF/EAF), intra-abdominal sepsis (IAS), and mortality [18, 19, 21]. ECF are associated with increased morbidity and mortality, as they can lead to many complications, including fluid loss, electrolyte abnormalities, complex wound care issues, malnutrition, and increased ICU and hospital LOS [22]. Large bowel resection, large-volume fluid resuscitation, and increased number of re-laparotomies were statistically significant predictors of ECF, EAF, or IAS in trauma patients who underwent DCL [18]. Some data suggest that early fascial closure is associated with reduced complications in patients who undergo DCL [23].

Bradley previously reported that time to the first re-laparotomy was a key predictor of time to PFC, particularly with time intervals less than 24 h; however, this work did not further subdivide the first 24 h, nor did it include non-trauma patients [18]. We therefore sought to elucidate factors associated with time to PFC in both trauma and non-trauma patients.

Although there is an increasing number of studies related to the use of DCL in non-trauma patients, there is a paucity of data on identifying factors associated with time to PFC in this patient population [7–9, 11–15]. The authors of this study reviewed retrospective data from 15 centers over a 2-year period as part of the Eastern Association for the Surgery of Trauma multicenter trial entitled "Sedation Level after Emergency Exlap with Packing—TIME to Primary Fascial Closure (SLEEP-TIME)" to identify factors associated with time to PFC in both trauma and non-trauma populations.

## Methods

### Inclusion and exclusion criteria

We reviewed retrospective data from January 1, 2017 to December 31, 2018 from 15 centers in the EAST SLEEP-TIME trial. This study was evaluated by the Institutional Review Board at the Loma Linda University Medical Center and judged to be exempt from IRB review. The EAST SLEEP-TIME trial included all adult patients undergoing DCL, regardless of diagnosis, with at least daily recordings of Richmond Agitation Sedation Score (RASS) and/or Confusion Assessment Method-ICU (CAM-ICU) admitted during the previously mentioned dates. In this pre-planned study of existing data from the SLEEP-TIME trial, we included all adults undergoing DCL regardless of diagnosis. Patients younger than 18 years, pregnant women, prisoners, and patients who died before the first takeback were excluded. Of note, the criteria for which DCL were selected as an operative technique could not be standardized in this retrospective analysis.

### Data collection and analysis

Each center coordinated with the primary site in obtaining appropriate local IRB approvals and in signing standard data use agreements. Then, each center uploaded de-identified patient data to a previously created database in RedCap (developed at Vanderbilt University, Nashville, TN). This data included age, gender, injury severity score (ISS) for trauma patients, Acute Physiology and Chronic Health Evaluation (APACHE) II score for non-trauma patients, Charlson Comorbidity Index (CCI), diagnosis, operative interventions performed including small and large bowel resection, use of bowel discontinuity, vascular procedures, use of retained packs, number of re-laparotomies, net fluid balance after 24 h, trauma or non-trauma status, and time to first re-laparotomy in 12-h increments. Standard parametric statistics were used for statistical analysis. Data were imported from RedCap into SPSS version 25.0 (IBM Inc, Armonk NY).

The primary endpoint was the likelihood of achieving PFC at a given time interval as determined through two separate multivariate Cox regression analyses focusing on surgical and ICU factors. Variables included in the regression model on surgical factors included small bowel resection, large bowel resection, the presence of bowel discontinuity, the performance of an abdominal vascular procedure, the use of retained packs, the number of takebacks, age, CCI, fluid balance for the first 24 h, trauma status, and time to first re-laparotomy in 12-h increments. Variables included in the regression model on ICU factors included age, CCI, fluid balance for the first 24 h, trauma status, and exposure to opioid, benzodiazepine, propofol, dexmedetomidine, and paralytic infusions in days.

## Results

Three hundred and sixty-eight patients underwent DCL in the 2-year period (Table 1). Of these, 71.2% underwent DCL for trauma, of which 50.6% were for penetrating trauma, with median ISS 25 [16, 34]. The remaining 28.8% of the patients underwent DCL for non-trauma with median Apache II score 15 [11, 22]. The proportion of female patients was 30.4% and mean patient age was 43.9 ± 18.4 years. Mean CCI was 2.0 ± 2.9. At initial DCL, 37.5% of patients had a small

**Table 1** General data

| Variable | %(*N*) or Mean ± SD or Median [IQR] |
|---|---|
| Total number of patients | 368 |
| Male | 69.6% (256/368) |
| Age | 43.9 ± 18.4 |
| CCI | 2.0 ± 2.9 |
| Trauma | 71.2% (262/368) |
| ISS | 25 [16, 34] |
| Penetrating trauma | 50.6% (133/262) |
| APACHE II (Non-trauma) | 15 [11, 22] |

**Table 2** Operative data

| Variable | %(*N*) or Mean ± SD |
|---|---|
| Small bowel resection | 37.5% (136/368) |
| Colon resection | 30.7% (113/368) |
| Bowel discontinuity | 38.3% (141/368) |
| Duration (h) | 42.4 ± 29.2 |
| Abdominal vascular procedure | 17.9% (66/368) |
| PFC achieved | 92.9% (342/368) |
| Time to PFC (h) | 60.8 ± 72.0 |
| Number of takebacks | 1.6 ± 1.2 |

bowel resection and 30.7% had a large bowel resection, with 17.9% of patients having a vascular procedure and 38.3% were left in bowel discontinuity. (Table 2) Bowel continuity was achieved at 42.4 ± 29.2 h. 92.9% of patients achieved PFC at 60.8 ± 72.0 h after 1.6 ± 1.2 re-laparotomies.

Overall fluid balance was noted to be more positive in the trauma cohort after DCL (Day 1: 9.50 ± 10.3 L vs. 6.02 ± 6.38 L, $p < 0.001$; Day 2: 9.01 ± 7.93 L vs. 7.29 ± 6.19 L, $p = 0.008$). Total amount of blood products transfused was also increased in the trauma cohort after DCL (Day 1: 6.01 ± 8.38 L vs. 2.25 ± 5.19 L, $p < 0.001$). This is illustrated diagrammatically in Fig. 1.

In our Cox regression analysis of surgical factors associated with likelihood of achieving PFC (Table 3), time to first re-laparotomy was highly significant ($p < 0.001$) in terms of odds of achieving PFC with no difference between 12 and 24 h to first re-laparotomy and decreases in odds of PFC of 78.4% (65.8–86.4%, $p < 0.001$) for first re-laparotomy after 24.1–36 h, 90.8% (84.7–94.4%, $p < 0.001$) for 36.1–48 h, and 98.1% (96.4–99.0%, $p < 0.001$) for > 48 h (Fig. 2). Each additional re-laparotomy reduced the odds of PFC by 91.5% (95%CI 88.2–93.9%, $p < 0.001$, Fig. 3). Trauma patients had increased likelihood of achieving PFC, despite the positive fluid balance data illustrated above (OR 1.66 [1.22, 2.28, $p = 0.002$]).

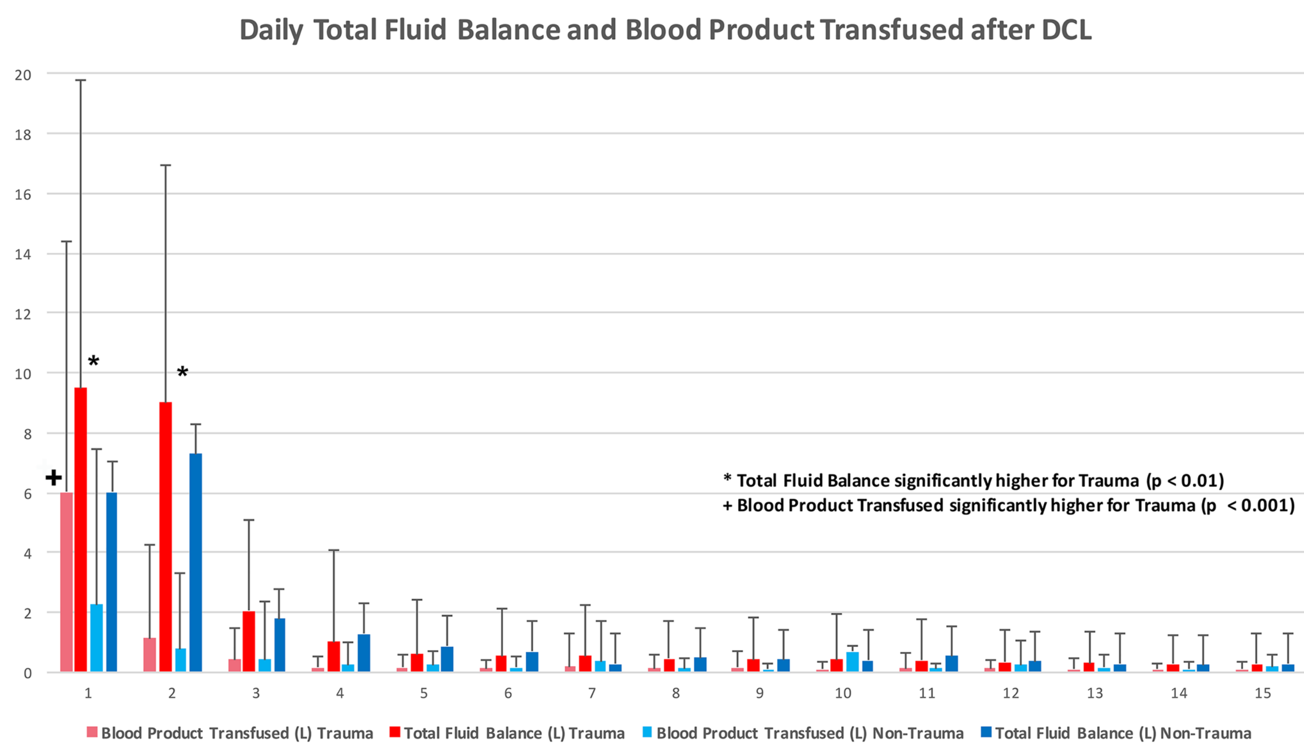


**Fig. 1** Net fluid balance is more positive in the trauma cohort on days 1 and 2 after DCL ($p < 0.01$ in both cases), while blood product transfusion is higher in the trauma cohort on day 1 after DCL ($p < 0.001$)

In our Cox regression analysis of ICU factors associated with likelihood of achieving PFC (Table 4), trauma patients were again associated with increased likelihood of achieving PFC (OR 1.49 [1.06, 2.10, $p = 0.022$]). This data are also indicated diagrammatically in Fig. 4. Finally, we noted that the use of opioid infusions was associated with decreased likelihood of achieving PFC (OR 0.938 [0.911, 0.967, $p < 0.001$]). This data are also indicated diagrammatically in Fig. 5. Of note, the use of propofol, dexmedetomidine, benzodiazepine, or paralytic infusions was not associated with achieving PFC.

**Table 3** Results of multivariable Cox regression for surgical factors associated with likelihood of achieving PFC

| Variable | Odds ratio [95%CI] | *p* value |
|---|---|---|
| Age (years) | 1.00 [0.99, 1.01] | 0.954 |
| Charlson Comorbidity Index | 1.03 [0.98, 1.09] | 0.232 |
| Trauma | 1.66 [1.21, 2.28] | 0.002 |
| Small bowel resection | 1.09 [0.82, 1.46] | 0.551 |
| Large bowel resection | 1.26 [0.92, 1.72] | 0.154 |
| Bowel left in discontinuity | 0.75 [0.52, 1.08] | 0.119 |
| Retained packs | 1.14 [0.88, 1.46] | 0.326 |
| Abdominal vascular procedure | 1.06 [0.78, 1.44] | 0.696 |
| Resuscitation in first 24 hours (L) | 1.00 [1.00, 1.00] | 0.977 |
| Time to first re-laparotomy (h) | | < 0.001 overall |
| 0–12 | Ref | |
| 12.1–24 | 1.01 [0.65, 1.55] | 0.978 |
| 24.1–36 | 0.216 [0.136, 0.342] | < 0.001 |
| 36.1–48 | 0.092 [0.056, 0.153] | < 0.001 |
| > 48 | 0.019 [0.010, 0.036] | < 0.001 |
| Number of re-laparotomies | 0.085 [0.061, 0.118] | < 0.001 |

## Discussion

DCL was originally introduced for critically ill trauma patients with associated improved outcomes. This strategy has been gradually implemented for a broad range of intra-abdominal emergencies, but the evidence supporting its use continues to evolve. Our previous study indicated that our cohort was 25.8% non-trauma patients, with the most common diagnoses in the non-trauma cohort being bowel ischemia (28.1%), end-stage liver disease (13.7%), bowel perforation (12.2%), small bowel obstruction (8.6%), and abdominal compartment syndrome (6.5%). We also found that trauma patients had a higher incidence of delirium, likely attributable to the high incidence of traumatic brain injury in our cohort [24]. This manuscript was intended

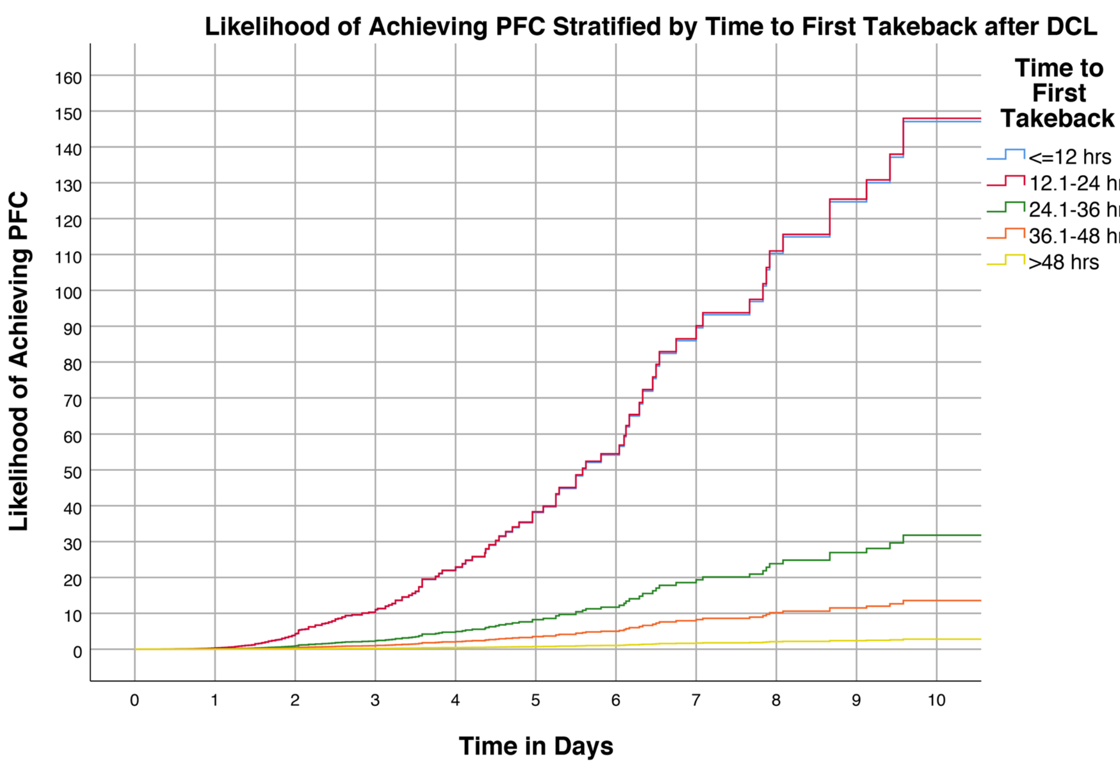


**Fig. 2** Waiting longer than 24 h for the first re-laparotomy after DCL is associated with a significantly reduced rate of achieving PFC ($p < 0.001$), although there is no difference between re-laparotomy within 12 and 24 h

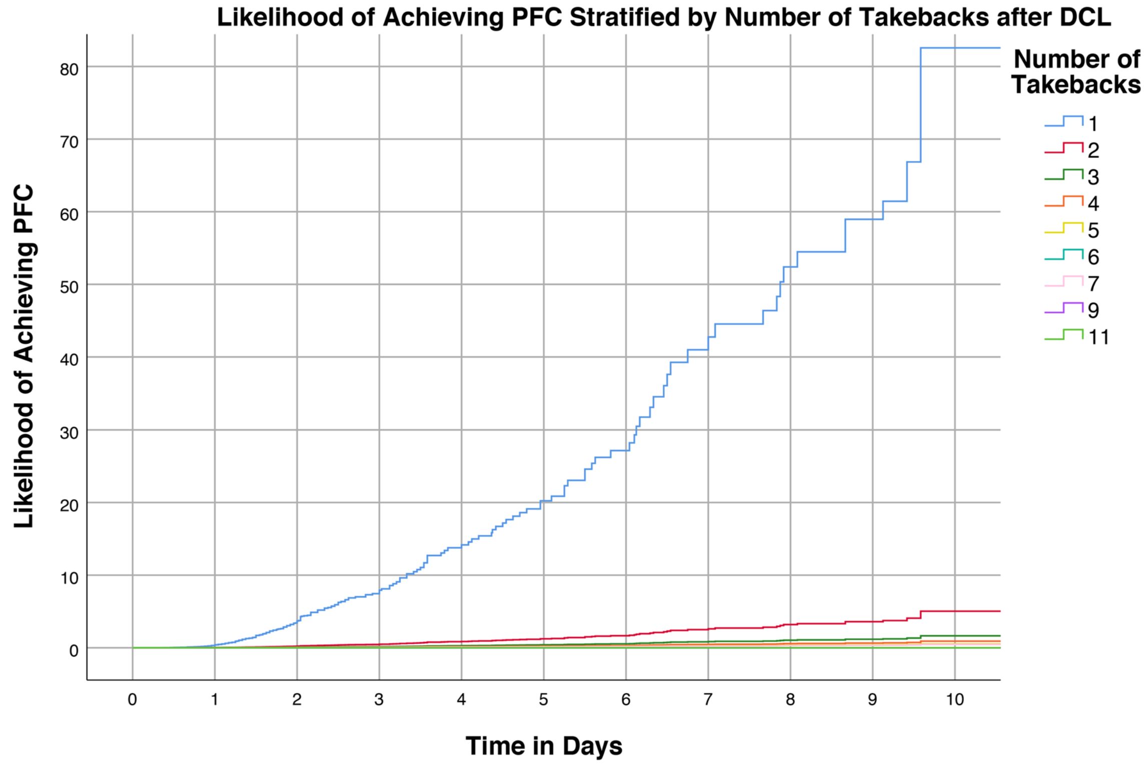


**Fig. 3** There is a dramatic decrease in the rate of achieving PFC associated with each additional re-laparotomy after DCL ($p<0.001$)

**Table 4** Results of multivariable Cox regression for ICU factors associated with likelihood of achieving PFC

| Variable | Odds ratio [95%CI] | *p* value |
|---|---|---|
| Age (years) | 1.00 [1.00, 1.00] | 0.731 |
| Charlson Comorbidity Index | 1.03 [0.97, 1.09] | 0.336 |
| Trauma | 1.49 [1.06, 2.10] | 0.022 |
| Resuscitation in first 24 hours (L) | 1.00 [1.00, 1.00] | 0.924 |
| Opioid infusion (days) | 0.938 [0.911, 0.967] | < 0.001 |
| Benzodiazepine infusion (days) | 1.00 [0.913, 1.09] | 0.982 |
| Propofol infusion (days) | 0.975 [0.919, 1.03] | 0.389 |
| Dexmedetomidine infusion (days) | 0.937 [0.868, 1.01] | 0.098 |
| Paralytic infusion (days) | 0.927 [0.764, 1.13] | 0.447 |

as a pre-planned follow-up analysis to address the factors associated with PFC. The most important finding of this retrospective, multicenter study is that achievement of PFC after trauma and non-trauma DCL is associated with time to first re-laparotomy and the number of re-laparotomies, even after adjusting for age, comorbidities, trauma status, fluid administration in the first 24 h, and the types of surgical interventions performed.

There is increasing data on DCL-associated complications such as ECF and IAS, along with studies focusing on risk factors for complications, to assist with prevention and management. ECF can lead to many complications including fluid loss, electrolyte abnormalities, complex wound care, malnutrition, and increased ICU and hospital LOS, and is associated with increased morbidity and mortality. In the prospective observational multicenter American Association for the Surgery of Trauma (AAST) Open Abdomen Study, Bradley previously reported that predictors of ECF and IAS after DCL were increasing number of re-laparotomies along with large bowel resection and large volume fluid resuscitation; those who developed ECF and IAS underwent double the number of abdominal re-laparotomies than those who did not. Dubose, a co-investigator in the AAST Open Abdomen group, reported risk factors for failure to achieve PFC, including the number of re-laparotomies, development of intra-abdominal abscess/sepsis, and enteric fistulas. Our study supports these results from the AAST Open Abdomen Study Group, which analyzed only trauma patients. However, our study also included non-trauma patients. Therefore, the conclusions made in the AAST Open Abdomen Study may also be valid for non-trauma patients. Additional predictors of ECF and IAS will be studied as part of the follow-up work in this study.

Bradley previously reported that time to the first re-laparotomy was a key predictor of time to PFC, particularly

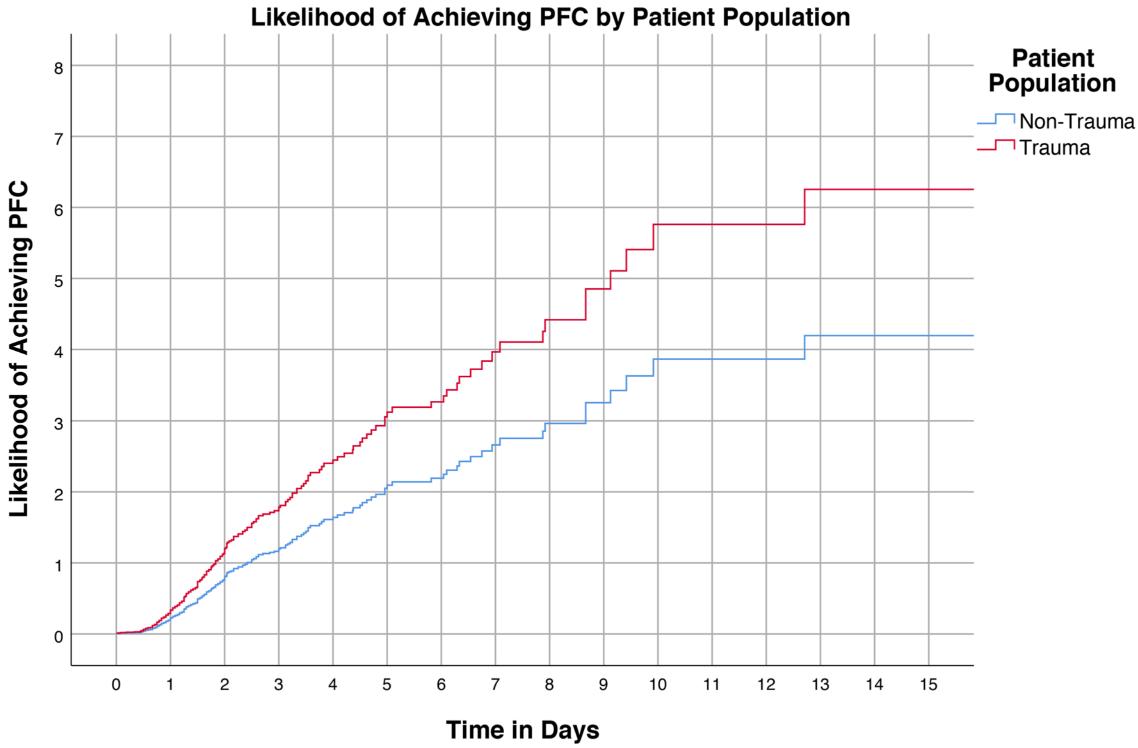


**Fig. 4** Trauma patients are more likely to achieve PFC than non-trauma patients ($p=0.022$ and $p=0.002$ in two separate Cox regression analyses)

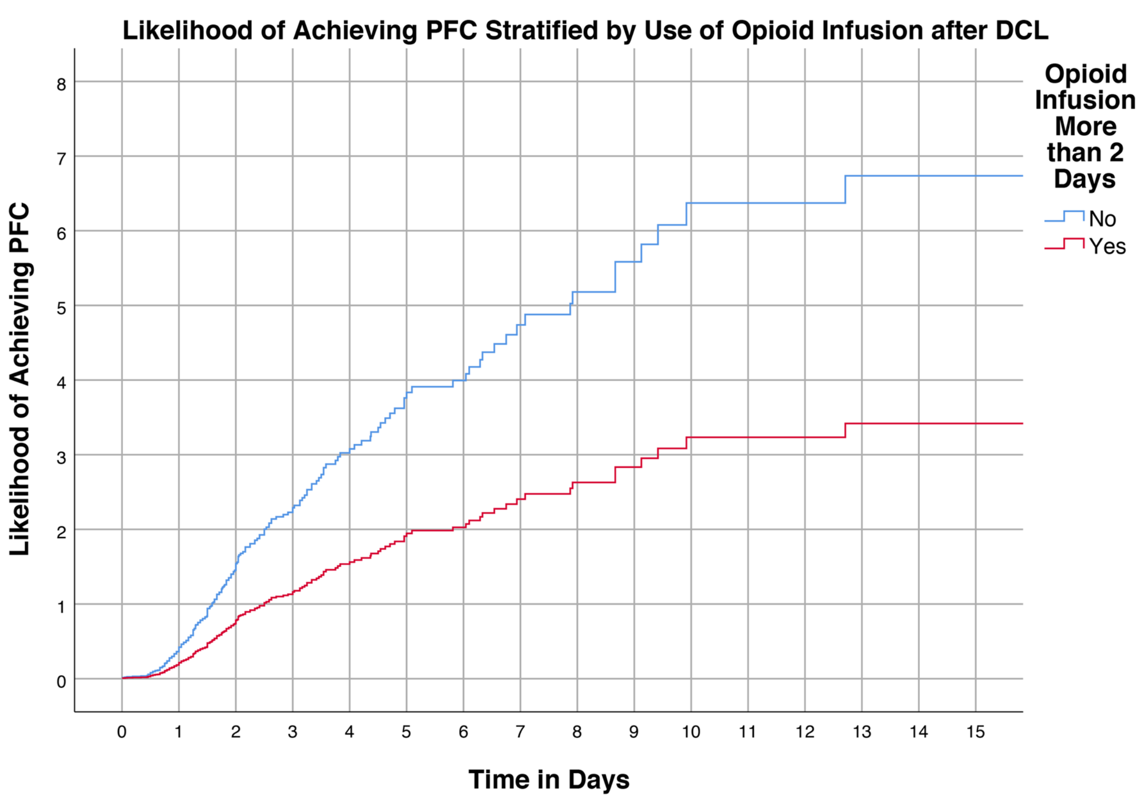


**Fig. 5** There is a significant decrease in the likelihood of achieving PFC associated with the increased use of opioid infusions ($p<0.001$)

with time intervals less than 24 h; however, this work did not further subdivide the first 24 h, nor did it include non-trauma patients. Pommerening reported decreased odds of achieving PFC after 24 h, with increased risk of intra-abdominal complications after 48 h. Our study subdivided the time to first re-laparotomy further into 12-h increments. We found no difference in PFC with first re-laparotomy within 12 h compared to 24 h but found a dramatic decrease in the rate of achieving PFC with delay beyond 24 h that continued to worsen with more prolonged delay. Boolaky et al. [25] identified other risk factors for delay in PFC, including hypoalbuminemia, anastomotic leak, ventilator-associated pneumonia, age, intra-abdominal abscess or deep surgical site infection, abdominal compartment syndrome, or multi-organ failure. Although we did not have all the data required to verify Dr. Boolaky's results in our study, there is ample room for further investigation in these areas.

The other key finding that bears discussion is that trauma patients had a more rapid rate of achieving PFC than non-trauma patients. Moreover, this difference is independent of age, comorbidities, surgical interventions performed, bowel discontinuity, and fluid balance in the first 24 h. This speaks to the different disease processes at work between traumatic injury and abdominal sepsis, and is an interesting difference that could be the subject of future work in this area. In addition, our data call into question some of the previous thinking in this area regarding the importance of fluid balance [26]. In neither of our regression analyses was fluid balance in the first 24 h after DCL significantly associated with likelihood of achieving PFC. Furthermore, trauma patients were more likely to achieve PFC even though their fluid balance and amount of transfusion were far in excess of that for non-trauma patients. This correlates with some other work in the field, which has found that artificially removing fluid via furosemide infusions also does not decrease time to achieving PFC [27].

The findings concerning sedative agents and opioid infusions were, quite frankly, unexpected. Much has been made of the use of neuromuscular blockade to facilitate more rapid achievement of PFC, although the most recent data do not support this assertion [28]. We previously published single-center data indicating that shorter duration of sedation infusions was associated with reduced time to PFC in trauma patients [29]. In this larger multicenter study of both trauma and non-trauma patients, we did not find that the duration of benzodiazepine, propofol, dexmedetomidine, or paralytic infusions was associated with the likelihood of achieving PFC. However, we did find that the duration of opioid infusion was associated with decreased likelihood of PFC. This is the first finding of its type in the literature, although the association of opioids with delayed return of bowel function is not new. Utilization of other pain management strategies such as locoregional anesthesia and narcotic-sparing pain management regimens has averted some of these effects [30]. Ketamine infusion may also be an alternative in selected patients [31, 32]. Certainly, more study is needed to study these observations.

This study has limitations. This was a retrospective study, and data points were missing in some patients and intentional choices were made about variables to examine (i.e., the use of ISS as an injury severity stratification); furthermore the investigators were dependent on the patients included by the referring center without independent verification. As a multi-center study, variability in practice patterns or protocols among the difference centers may contribute to confounding factors. One center, for example, conducted a higher than average number of liver transplants employing DCL technique. Another potential limitation is that this study combined analysis with trauma and non-trauma patients, who have different primary diagnoses at baseline. We did not collect universal data on all intra-abdominal injury patterns; for example while we did collect data on intra-abdominal vascular injuries, these were not specified by vessel. Retroperitoneal injuries were also not included and we did not have data on the physiology of the patients at the end of the index laparotomy. We did collect data on fluid balance daily, but not specific items such as drainage from the temporary abdominal closure device or the use of vasopressors or other adjuncts such as hypertonic saline. As the study was retrospective, it was not possible to specifically abstract data on the reasons why damage control laparotomy was performed in each case.

There was a higher percentage of trauma patients undergoing DCL compared to non-trauma patients in our study. A key difference between the two groups is the type of shock they experience; in the trauma population, shock is often hemorrhagic compared to the non-trauma population in which it is often due to sepsis. However, there is evidence of equivalent rates of septic complications and PFC rates regardless of cause for DCL [33]. This is consistent with our own analysis; there is no significant different in the time to achieve PFC or the percent of patients achieving PFC between the trauma and non-trauma patients.

In conclusion, achieving primary fascial closure is essential in open abdomen management after DCL to minimize risk of complications. Our study demonstrates that rapid achievement of PFC in patients after trauma and non-trauma DCL is highly predicted by time to first re-laparotomy and number of re-laparotomies. To minimize complications, greater emphasis should be placed on returning to the operating room as early as possible, ideally within 24 h, and minimizing the number of re-laparotomies. It is also possible that the ICU management can play a significant role in accelerating the achievement of PFC through the avoidance or minimization of opioid infusions.

**Author contributions** EK: data collection, analysis of data, generation of figures, writing of manuscript, presenting author. CK, KMcA, XLO: data collection, analysis of data, critical review of manuscript. MCY, LS, SB, DT,CK, AG, JN, AB, AG, AL, MK, MNF, NG, ST, EL, SRL, ODG, JMB, CD, SMW, KL, NTD, JN, SM, JP, LN, HK, HRK, MJL, AD, GC, ZN: critical editing of manuscript and approval of final manuscript. KM: principal investigator, statistical analysis, editing and detailed revision of manuscript.

**Funding** *JMB* Research reported in this publication was supported by the National Institute of General Medical Sciences of the National Institutes of Health under Award Number 5U54GM104942-04. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

**Availability of data and material** All data generated or analyzed during this study are included in this published article.

## Declarations

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethics approval** This study was evaluated by the Institutional Review Board at the Loma Linda University Medical Center and judged to be exempt from IRB review.

**Consent to participate** Consent to participate was not applicable as this was a retrospective study.

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