“Genuine” Damage Control Laparotomy in Peritonitis: A Twenty-Year Review

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Background

The term “damage control laparotomy” was first coined by Rotondo et al. in 1993. However, this approach was described more than 10 years earlier as an alternative surgical strategy in the management of severe liver injuries [1-3]. Rather than pursuing prolonged attempts at definitive management of major vascular, solid organ, or visceral injury in the setting of hypotension, acidemia, hypothermia, and multisystem trauma, those surgeons performed an abbreviated laparotomy with a view to controlling hemorrhage and preventing further intestinal contamination of the peritoneum. This strategy was expected to prevent patients from entering a downward spiral into the lethal triad of hypothermia, hypotension, and coagulopathy. In their case control study, Rotondo et al. reported survival rate of 77% in the damage control surgery group compared to 11% in the definitive laparotomy group [2]. That initial report spawned literally hundreds of subsequent publications extolling the virtues of this approach in practically every region of the body such that damage control has now become an integral part of modern trauma care [4-9].

Given the favorable results of damage control strategy in trauma, similar approach has been adopted in the surgical treatment of severe abdominal sepsis. However, there is much confusion in the terminology and the use of damage control strategy in this setting. At the outset, the terms, “open abdomen”, abbreviated laparotomy, “peritoneal toilet”, second look operation, planned and on-demand laparotomy have recently been labeled damage control surgery in several publications pertaining to abdominal sepsis [10-15]. However, these surgical strategies encompass only certain aspects of damage control strategy. Moreover, the situations that would trigger the application of damage control principles in the setting of severe peritonitis and acute care surgery in general, are for the most part, different from those in the trauma setting [16-21].

To address the aforementioned issues, we performed a systematic review of studies that describe the use of damage control surgery in the non-trauma setting focusing on patients with peritonitis.

Methods

All studies included in our literature review were obtained using an electronic search of the National Library of Medicine MEDLINE (PubMed Entrez) and EMBASE databases. The citations in English were identified during the period of January 1997 through September 2017. The search pertained to the following specific topics:

- Open abdomens, damage control surgery, and damage control laparotomy in non-trauma patients.
- Intra-abdominal infections, sepsis, and peritonitis.

The search excluded case reports, letters to the editor, experimental studies, pediatric patient population, cases not related to acute care general surgery, and duplicates. Of the 141 articles captured in the search, 91 did not relate to damage control in the setting of peritonitis and abdominal sepsis, and hence were not included in the study. The remaining 50 articles were reviewed by the authors.

Principles of Damage Control Surgery in Trauma

The main principles underlying “damage control” approach in trauma surgery are:

1. Initial laparotomy focusing on control of major bleeding and source of contamination.
2. Temporary Abdominal Closure (TAC)
3. Correction of abnormal physiological parameters, a process that usually takes place in the Intensive Care Unit (ICU) setting.
5. Definitive abdominal wall closure.

These five principles of damage control surgery are managed in a sequential staged manner:

Stage one focuses on gaining control of a complex situation in an unstable patient. In abdominal trauma, the primary objective is to control blood loss. This is achieved through:

- ligation of obvious bleeding vessels
- repairing or shunting of vessels not amenable to ligation
- packing of hemorrhage in vital organs amenable to tamponade
- packing of non-surgical sources of bleeding.

Control of ongoing peritoneal contamination is achieved by over sewing or stapling holes in the GI tract, by resecting any dead or devascularized bowel, and by leaving behind “blind loops” of the bowel without anastomosis or stomas. At this stage, removal of unsalvageable non-vital organs may be performed. Subsequently temporary abdominal wall closure is performed with the intent of reoperative surgery for definitive management. Total operative time should be less than 90 minutes in this phase [22].

Stage two centers on stabilizing the patient in the ICU. The initial phase of this process takes in average 24 to 72h. It includes rewarming, improving hemodynamics to restore tissue perfusion, addressing acid-base imbalance, and normalizing coagulation parameters. Finally, in stage three, the patient is returned to the operating room for definitive repair of vascular injuries, removal of pack sponges, and definitive management of the injuries. This may involve primary anastomosis or stoma formation depending on local and systemic findings. If possible, primary abdominal wall closure is performed at this point. However, patients often require multiple surgical interventions before final closure of the abdominal wall is achieved. The notion that damage control surgery might be applicable to non-trauma/acute care surgery patients presenting with an abdominal catastrophe is perfectly suitable and would, in general terms, follow the same staged approach. Specifically, initial care aimed at establishing control of hemorrhage and/or intra-abdominal infection would be followed by a period in the intensive care unit for stabilization, in preparation for a return to the operating room for definitive management and potential closure of the abdominal wall. However, in the context of peritonitis, it is important to distinguish this approach from two surgical strategies that frequently go under the misnomer of damage control.

The first is the use of scheduled repeat laparotomy/staged abdominal reconstruction aimed at preventing residual or recurrent infection in patients with severe intra-abdominal sepsis. This strategy is based on the logistical advantage of leaving the abdomen open with Temporary Abdominal Coverage (TAC) to facilitate multiple interventions to achieve complete source control [23-26]. Despite the advantages of scheduled repeat laparotomy/ Staged Abdominal Reconstruction (STAR) this strategy, if not appropriately indicated, could expose patients to the risks of leaving the abdomen open unnecessarily [12,13,14,27]. Accordingly, in prospective randomized clinical trial 40 patients with severe secondary peritonitis were randomly allocated to two groups after the initial laparotomy; group “A” open abdomen and group “B” closed abdomen [28]. Even though the difference in mortality between groups A and B did not reach statistical significance (respectively, 55% vs. 30%), the relative risk and the odds ratio for death were 1.83 and 2.85 times higher for group A compared to group B. Thus, the study was prematurely interrupted after the first interim analysis. In spite of that, a prospective nonrandomized trial involving a total of 239 patients with severe peritonitis showed no significant difference in mortality between patients managed with an open abdomen (44% mortality) compared to those managed with closed abdomen after the initial operation (31% mortality) [29].

In a larger study, a meta-analysis of planned relaparotomy and on-demand laparotomy looking at in-hospital mortality as the main outcome captured a total of 1266 patient; respectively 298 planned relaparotomy and 980 on-demand cases. The overall evidence of this study was inconclusive and showed no statistically significant difference in mortality between the groups [30]. This notion was substantiated in a randomized trial that showed no difference in mortality and morbidity between scheduled repeat laparotomy (leaving the abdomen open) and on-demand laparotomy (preemptively closing the abdomen), based on clinical and radiological parameters [31]. However, patients managed with on-demand laparotomy had shorter intensive care unit stays, shorter hospital stays, and lower direct medical costs compared to scheduled relaparotomy group [31]. The key feature of this study was that surgeons felt that definitive surgical treatment could be performed at the initial operation challenging the need for scheduled relaparotomy, hence leaving the abdomen open [31]. Furthermore, in another study published by the same group it was shown that the cause of peritonitis and the operative findings during the initial operation were poor indicators for relaparotomy [32]. In that study, the best indicators for a relaparotomy were markers of progressive or persistent organ failure in the early postoperative period [32].

Timing of abdominal re-exploration is also critical in patients with peritonitis. Previous research showed that patients with peritonitis managed with on-demand laparotomy who underwent re-exploration more than 48h after the initial operation had significantly higher mortality rate than those re-explored within the first 48h; respectively 76.5% vs. 28% (p = 0.0001) [33]. This finding demonstrates that timely re-exploration is important, whereas procrastination can lead to persistent septic insult with
serious complications [11, 34-41]. The second surgical strategy that is distinct from actual damage control surgery is referred to as “second look” laparotomy. This approach is used when there is concern about the viability of the bowel during the initial operation. One of the main advantages of a “second look” laparotomy is to provide means to reassess the vascular viability of the bowel, preventing unnecessary resection of healthy segments. “Second look” laparotomies are also used in intra-abdominal vascular emergencies [42]. Appropriate application of damage control principles in peritonitis, in contrast to “second look” laparotomies and STAR/re-laparotomy as previously described, involve postponing definitive surgical treatment based on hemodynamic instability and poor tissue perfusion. These findings along with profound metabolic acidosis, elevated lactate levels, severe sepsis, coagulopathy, and septic shock result in overwhelming Systemic Inflammatory Response Syndrome (SIRS). The damage control approach in these conditions calls for source control, hemorrhage control, and interruption of the operation in lieu of a standard procedure. Our review showed that the literature pertaining to damage control laparotomy in peritonitis used under the aforementioned scope is limited in quantity and quality, and the term damage control surgery is often used interchangeably with the open abdomen, “second look” laparotomies, planned and on-demand laparotomy [43-49].

**Use of Damage Control Surgery in The Setting of Peritonitis**

One of the few studies in which actual damage control was employed in the setting of peritonitis involved 67 patients with complicated acute colonic diverticulitis (Hinchey III/IV) and 2 cases of severe bleeding. Damage control approach defined by source control, leaving the colon in discontinuity, and patient transfer to intensive care unit for stabilization, was only used in 4% of the cases. Whereas 45% underwent one stage management (resection and primary colonic anastomosis) [50]. Similarly, in a cohort of 835 patients who underwent elective pancreatic surgery only eight required actual damage control surgery [51]. In only two of those patients the indication for classic damage control was intra-abdominal sepsis [51-53]. Our review disclosed only 12 additional studies that specifically described the use of damage control strategy in the setting of profound abdominal sepsis, bleeding, ischemic bowel, or necrotizing pancreatitis in emergency general surgery (Table 1).

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Study type</th>
<th>No of Cases</th>
<th>Indications for Damage Control Surgery</th>
<th>Damage Control Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filicori et al.</td>
<td>2010</td>
<td>Retrospective</td>
<td>8</td>
<td>Hemorrhage</td>
<td>Packing; Hartmann’s procedure (1)</td>
</tr>
<tr>
<td>Finlay et al.</td>
<td>2004</td>
<td>Prospective</td>
<td>14</td>
<td>Peritonitis (9) Hemorrhage (5)</td>
<td>Bowel in discontinuity (8) Hartman’s procedure (1) Packing (5)</td>
</tr>
<tr>
<td>Goussous et al.</td>
<td>2013</td>
<td>Retrospective</td>
<td>111</td>
<td>Peritonitis/Sepsis (79) Hemorrhage (32)</td>
<td>Not specified</td>
</tr>
<tr>
<td>Kafka-Ritsch et al.</td>
<td>2012</td>
<td>Prospective</td>
<td>51</td>
<td>Peritonitis (51)</td>
<td>Colon resection w/ blind loops (45) Interrupted suture of the perforation (6)</td>
</tr>
<tr>
<td>Khan et al.</td>
<td>2013</td>
<td>Retrospective</td>
<td>42</td>
<td>Peritonitis (10) Hemorrhage (13) Bowel ischemia (13) Physiological reason (6)</td>
<td>Not specified</td>
</tr>
<tr>
<td>Morgan et al.</td>
<td>2010</td>
<td>Retrospective</td>
<td>8</td>
<td>Peritonitis/sepsis (2) Hemorrhage (6)</td>
<td>Bowel in discontinuity (1); drainage (2) Packing (6); drainage (3); bowel in discontinuity (3)</td>
</tr>
<tr>
<td>Becher et al.</td>
<td>2016</td>
<td>Retrospective</td>
<td>53</td>
<td>Peritonitis/sepsis (53)</td>
<td>Rapid source control (53)</td>
</tr>
<tr>
<td>Ordóñez et al.</td>
<td>2010</td>
<td>Retrospective</td>
<td>30</td>
<td>Peritonitis (30)</td>
<td>Bowel in discontinuity (30)</td>
</tr>
<tr>
<td>Person et al.</td>
<td>2009</td>
<td>Retrospective</td>
<td>31</td>
<td>Peritonitis (15) Bowel ischemia (10) Bowel obstruction (2) Bleeding (3), other (1)</td>
<td>Not specified</td>
</tr>
<tr>
<td>Perathoner et al.</td>
<td>2010</td>
<td>Prospective</td>
<td>15</td>
<td>Peritonitis/sepsis (15)</td>
<td>Bowel in discontinuity; lavage; VAC (15)</td>
</tr>
</tbody>
</table>
were previously left stapled-off in the abdominal cavity; the patients underwent anastomosis of the ends of the bowel that had been resected. At the second operation, six of those patients underwent bowel resection at the initial procedure without anastomosis or stoma formation [52].

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In this study, the mortality rate of patients who underwent re-exploration was 43 percent. This was lower than the predicted mortality as per the Portsmouth predictor equation (P-POSSUM) [52]. These studies underscore the benefits of the appropriate use of damage control surgery in the setting of peritonitis. Moreover, they also show that primary anastomosis of the discontinuous gastrointestinal tract can be safely performed at repeat surgery in patients with intra-abdominal sepsis who had resection without anastomosis at the initial operation, so-called definitive Deferred Primary Anastomosis (DPA).

In a study involving 16 patients who met the criteria for damage control surgery, namely hypothermia, coagulopathy and acidosis, the average number of surgical re-interventions in the abdomen after the initial operation for peritonitis was 2.44 (range 1-4) [53]. In this study, the mortality rate of patients who underwent damage control surgery was 43 percent. This was lower than the predicted mortalities of 60 percent and 75 percent based on the APACHE II and POSSUM scores respectively [53]. Similarly, a report on 8 patients who underwent a damage control surgery for peritonitis and sepsis related to GI perforation showed that all patients underwent bowel resection at the initial procedure without anastomosis or stoma formation [52]. At the second operation, six of those patients underwent anastomosis of the ends of the bowel that were previously left stapled-off in the abdominal cavity; the remaining two patients were ostomized [52]. The overall patient mortality rate was 7 percent, which was considerably less than the 64.5% predicted mortality using the POSSUM score and the 49.6% predicted mortality as per the Portsmouth predictor equation (P-POSSUM) [52]. These studies underscore the benefits of the appropriate use of damage control surgery in the setting of peritonitis. Moreover, they also show that primary anastomosis of the discontinuous gastrointestinal tract can be safely performed at repeat surgery in patients with intra-abdominal sepsis who had resection without anastomosis at the initial operation, so-called definitive Deferred Primary Anastomosis (DPA).

This strategy was validated in a study that reported a treatment algorithm that included 15 patients with Hinchey III/IV perforated diverticulitis on inotropic support, profound edema of peritoneal tissues, and generalized peritonitis [56]. The surgical treatment in these patients consisted of abdominal washout (source control), limited resection of the affected colonic segment, and stapled-off ends of the remaining colon left in discontinuity in the abdomen. Temporary abdominal closure was performed with a vacuum-assisted closure device [56]. Following stabilization, patients returned to the operating room. In 9 patients, local conditions and the systemic state were considered adequate to perform primary anastomosis. The remaining 6 underwent a Hartmann’s procedure. In the anastomosis group, there was 1 anastomotic leak which resulted in death. In the Hartmann’s procedure group, two of the patients subsequently died with sepsis. Importantly, primary closure of the abdominal wall was achieved in all 15 patients. In this study, the overall mortality was 26 percent and the mortality directly linked to the perforation of the colon was 15 percent. Furthermore, 52% percent of the patients underwent primary anastomosis, and survived without a stoma [56].

Deferred Primary Anastomosis (DPA) was also investigated in the setting of secondary peritonitis caused by various intraabdominal infections. The table below summarizes the results of various studies involving the use of damage control surgery in the setting of intra-abdominal infections.

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Design</th>
<th>Patients</th>
<th>Cause of Sepsis</th>
<th>Treatment</th>
<th>Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stawicki et al.</td>
<td>2008</td>
<td>Retrospective</td>
<td>16</td>
<td>Peritonitis/sepsis (6) Bleeding/Intra-op. (5) Bowel ischemia (3) Pancreatitis (2)</td>
<td>Not specified</td>
<td></td>
</tr>
<tr>
<td>Subramanian et al.</td>
<td>2010</td>
<td>Retrospective</td>
<td>64*</td>
<td>Peritonitis/sepsis (30) Ischemia/obstruction (21) Pancreatitis (11) Hemorrhage (2)</td>
<td>Not specified</td>
<td></td>
</tr>
<tr>
<td>Tamijmarane et al.</td>
<td>2006</td>
<td>Retrospective</td>
<td>25</td>
<td>Pancreatic leak/bleeding (20) Bleeding (5)</td>
<td>Completion pancreatectomy (25); Not specified (packing, splenectomy, angiographic embolization)</td>
<td></td>
</tr>
<tr>
<td>Girard et al.</td>
<td>2017</td>
<td>Prospective</td>
<td>164</td>
<td>Peritonitis (23) Bleeding (14)</td>
<td>Not specified</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Publications pertaining to actual use of damage control surgery in the setting of intra-abdominal infections.
conditions [57]. The authors retrospectively investigated septic patients with peritonitis and hemodynamic instability who required bowel resection and were subjected to a second laparotomy as part of damage control procedure [57]. The outcomes of patients who underwent bowel resection followed by an ostomy were compared to those of patients who underwent deferred primary anastomosis. In both groups the abdomens were left open after the first laparotomy and definitive closure was performed when septic sources were controlled, and abdominal closure considered appropriate [57]. The decision regarding treatment arm was made by the operating surgeon with no effort towards randomization. Interestingly, the trauma surgeons at the institution tended to use the deferred primary anastomosis approach, while the non-trauma surgeons (at the same hospital) uniformly performed resection with diversion [57]. A total of 112 patients were considered eligible for analysis with the ratio of DPA to stoma of approximately 30:70. However, 23 patients sustained trauma, thus only 89 patients had non-traumatic cause of peritonitis [57]. The two groups were comparable in their demographics including age, gender, APACHE II and source of peritonitis. In the DPA group, the surgeons were able to successfully perform an anastomosis in more than 80% of the patients and failure to do so was related to technical reasons. The rate of anastomosis did not differ whether the colon or the small bowel were considered. The overall outcome between the two approaches was remarkably similar. The rates of fistulas and leaks were also similar between the groups, 8.8% in the DPA group and 5.1% in the stoma group. In the latter group, the majority (3/4) of the events were due to leakage related to the stoma [57]. This particular complication in the stoma groups underscores the challenges involved in creating stomas in these patients, including considerable abdominal wall thickness due to obesity, intestinal edema and mesenteric shortening, all of which make it difficult to easily exteriorize the intestinal ends in this setting. This study also did not report on long-term outcomes related to re-establishment of intestinal continuity in those patients, which must be factored into the overall decision making regarding this approach. Obviously, the paper is methodologically weak, but it supports the findings from several reports demonstrating that primary anastomosis is a treatment option after adequate indications of damage control strategy [57]. One of the few prospective studies in our review described damage surgery in patients with peritonitis caused by diverticulitis (Hinchey III and IV) [58]. Results of this study showed that 76% of the patients underwent a successful colonic anastomosis before discharge. Interestingly, primary fascial closure was performed in all patients [58].

A study by Person et al. set out to evaluate abbreviated laparotomy (damage control surgery) versus Definitive Laparotomy (DL) in the non-trauma setting [59]. Unfortunately, the procedures performed in the abbreviated laparotomy group were not described. Thus, the application of actual damage control strategy is unknown. This retrospective analysis included 291 patients.

Abbreviated laparotomy (AL) was used in 10.7% of patients, and Definitive Laparotomy (DL) in the remainder. In this report, the criteria guiding the decision to treat a patient using AL were not well defined. The only listed difference between the two groups was that all patients in the DL group were stable at admission, whereas 29% of patients in the AL group were hemodynamically unstable at admission [59]. Peritonitis and mesenteric ischemia were significantly more common indications in patients in the AL group than in the DL group (48.4% vs. 30.4% and 32.3% vs. 3.5% respectively). Moreover, 9.7% of patients with AL displayed profound gastrointestinal bleeding compared to 3.1% of patients in the DL group. However, this difference was not statistically significant. Patients in the AL group were significantly more likely to develop sepsis, multi-organ failure, and wound infection. The AL group displayed a mortality of 54.8%, which was significantly higher than the 16.5% mortality in the DL group. The mortality in both groups occurred predominately due to sepsis [59]. At face value, these outcomes would argue in favor of definitive laparotomy as being the preferred approach. However, the nature of patient selection preferentially allocated sicker patients to the AL arm and therefore, the poorer outcome was predictable. The authors did not study outcome relative to defined stratification systems such as APACHE II or POSSUM scores [59].

A retrospective study reviewed the indications for damage control laparotomy in the non-trauma setting in 42 patients during a three-year period [60]. The authors reported that peritonitis was the third most common reason for a damage control procedure; ischemic bowel and bleeding were respectively the first and second causes [60]. As previously mentioned herein, the strategy used in ischemic bowel cases was actually a second look operation, not damage control surgery.

**Management of The Open Abdomen in The Setting of Peritonitis**

Management of the open abdomen is an integral part of damage control surgery in both trauma and acute care surgery settings. The ultimate goal is to achieve definitive abdominal wall closure. A prospective multi-center study on open abdomens showed that delays in returning to the operating room beyond 24 hours after the initial damage control procedure, were associated with a 1.1% hourly decrease in the likelihood of successful primary fascial closure in trauma patients [61]. This study also showed that primary fascial closure at the first take back significantly reduced the incidence of intra-abdominal complications [61]. Management of the open abdomen in acute care surgery is, for the most part, even more challenging than in the context of trauma. Particularly when the primary indication for the open abdomen occurs in the setting of peritonitis and intra-abdominal sepsis [62-65]. Closure of the abdominal wall with synthetic mesh under these conditions is associated with high incidence of infection and fistula formation [66-
Moreover, it is ill advised to perform extensive undermining of the subcutaneous tissue or component separation to achieve primary fascial closure before resolution of the intra-abdominal infection and tissue edema. These maneuvers facilitate the propagation of the infectious process through the undermined tissue and cause serious systemic and local infectious complications. Previous studies showed that performing abdominal wall reconstruction and component separation in the setting of peritoneal infection resulted in overall complication rates as high as 60% [72,73]. Furthermore, successful primary fascial closure rate was lower in patients who underwent Staged Abdominal Reconstruction (STAR) for peritonitis compared to patients who underwent the same procedure for reasons different than peritonitis [74-76].

Direct comparison of closure of the open abdomen in the settings of trauma, gastrointestinal sepsis, and pancreatitis were investigated in another study [77]. Results showed that the need for mesh was more common in patients with gastrointestinal sepsis and that inability to close was more frequent in pancreatitis. Successful primary fascial closures were more likely in trauma patients who underwent damage control surgery. Moreover, patients with open abdomens in the setting of pancreatitis required more reinterventions than those in the other two groups. Interestingly, definitive fascial closure in this study was achieved in only 29% of the patients [77]. Closure rates based on the etiology of the open abdomen was also investigated in a systematic review. This study showed a 65% fascial closure rate in series that included only trauma cases and 50% closure rate in peritonitis-only series [78]. Similarly, a more recent systematic review and meta-analysis of the “open abdomen” and temporary abdominal closure techniques involving more than 3400 patients with peritonitis showed an overall weighted rate of delayed fascial closure of 50.2% [43]. These findings were also confirmed in a retrospective review of 42 non-trauma patients who underwent damage control laparotomies [60]. The overall primary fascial closure rate in this study was 57%. However, significantly lower rates were observed when the indication for damage control surgery involved peritonitis. The authors also showed that delayed abdominal closure (> 7 days) was associated with higher rates of septic complications and residual intra-abdominal abscesses [60]. Interestingly, these complications were more common among the patients than respiratory failure. Several other studies underscored the significant challenges involved in the managing the open abdomen in peritonitis [79-81]. The most important contributors to this problem were residual intra-abdominal abscesses, enterocutaneous fistulae, prolonged duration the open abdomen, and the need for multiple abdominal explorations [82-97].

**Summary**

In summary, damage control surgery in the non-trauma setting appears to be feasible, but its effectiveness has not been clearly established in the literature. Our review showed that the use of damage control procedures for the treatment of severe intra-abdominal infections is uncommon. Moreover, procedures referred to as damage control are actually staged laparotomy for control of residual intraabdominal infection and the second look operation in the setting of ischemic GI tract. Nonetheless, damage control surgery for the treatment of profound intraabdominal infection with associated hemodynamic and metabolic instability may improve mortality. This conclusion is based primarily on outcome comparison to patient stratification themes. However, patients with intra-abdominal sepsis who undergo damage control surgery have high morbidity both prior to definitive repair as well as after abdominal closure. Therefore, indications for this procedure in the setting of severe intraabdominal sepsis need to be better defined. The studies do raise the intriguing possibility that, with the use of a damage control approach, patients might be spared of stomas by virtue of being able to have a definitive GI anastomosis. Clearly, further clinical studies are warranted to investigate this possibility.

**References**