

Stapled vs Handsewn : A Prospective Emergency Surgery Study (SHAPES)

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Background and Significance

The trauma literature has explored the relationship between handsewn and stapled anastomoses and anastomotic complications, with varying conclusions. In a retrospective analysis, Brundage and colleagues, working with the Western Trauma Association Multi-institutional Study Group, found that stapled anastomoses appeared to have higher leak and abscess rates when compared to handsewn. However, in a prospective analysis sponsored by the AAST, Demetriades, *et al.*, found no difference in leak rates or abscess formation between the two techniques after penetrating injury to the colon.

In a 2011 Cochrane review, Neutzling and colleagues examined this question in elective colorectal surgery and identified nine trials consisting of 1233 patients (622 stapled / 611 handsewn). They found the evidence was insufficient to demonstrate any superiority of stapled over handsewn anastomotic techniques in elective surgery. However, they did conclude the following: “in risk situations, such as emergency surgery, trauma and inflammatory bowel disease, new clinical trials are needed.”

Few and varying reports have been published regarding handsewn versus stapled anastomotic techniques in the emergency general surgery setting. Catena and colleagues found no difference in leak rate or mortality between stapled and handsewn anastomoses in a series of 201 patients undergoing emergency intestinal operations. However, they did note an increase in operation times for those in the handsewn group. Beuran, *et al.*, retrospectively examined 72 patients undergoing emergency surgery secondary to colorectal surgical complications and found an increased morbidity rate and mortality rate in those undergoing stapled anastomosis and a longer operating time in the handsewn group. Farrah and colleagues have recently published their retrospective experience with 233 emergency surgery patients. They found handsewn anastomotic techniques to have a lower leak rate than stapled (15% vs. 6.1%, $p=0.003$) and shorter operative times for stapled techniques versus handsewn (193 min vs. 205 min, $p=0.02$).

Similarly, contradictory results have been reported in the setting of damage control surgery resection and anastomosis. In 2007, Miller, *et al.*, compared delayed and immediate anastomosis in a population of damage control laparotomy patients for traumatic injury. They found similar rates of anastomotic leak, abscess, and colon related death. Ott and colleagues examined trauma patients undergoing colonic resection with anastomosis after damage control laparotomy and found a 27% leak rate in patients undergoing colonic anastomosis who were managed with open abdomen.

Lessons learned from trauma surgery may not be applicable in the emergency surgery patient given the potential for generalized peritonitis and bowel wall edema. We hypothesize that in the emergency surgery patient, a handsewn anastomosis will have a lower leak rate than those performed with the stapler. Additionally, we hypothesize that the rate of anastomotic complications in the emergency

surgery patient managed with an open abdomen and staged gastrointestinal reconstruction will have higher anastomotic complications than those performed at the initial operation and higher complication rates than patients managed without damage control surgery.

Primary Aim:

- To define the overall rate of anastomotic complications after intestinal resection performed in the urgent / emergent setting by acute care surgical teams
- To compare the rates of anastomotic complications (leak / intra-abdominal abscess) between stapled and handsewn anastomoses in urgent / emergent intestinal resection

Secondary Aims:

- To compare the rates of anastomotic leak and intra-abdominal abscess between stapled and handsewn anastomoses performed in the context of damage control techniques managed with an open abdomen
- To compare the rates of enter-cutaneous/atmospheric fistula formation between stapled and handsewn anastomoses in urgent / emergent intestinal resection and after damage control techniques
- To compare the rates of fascial complications between stapled and handsewn anastomoses in urgent / emergent intestinal resection and define overall incidence

Inclusion Criteria:

- Intestinal resection with anastomosis performed by acute care surgeons in an urgent / emergent setting (*urgent / emergent operations are defined as those performed in a non-elective setting and performed within 24 hours of consultation or within 24 hours after the decision was made to pursue operative intervention*)
- Intestinal resection with anastomosis performed by acute care surgeons in any patient managed with damage control techniques / open abdomen

Exclusion Criteria:

- Proximal diverting ostomy creation at the time of intestinal resection and anastomosis
- Duodenal resection / anastomosis
- Elective operations performed by acute care surgeons within 24 hours of the decision to operate (scheduled resection of non-obstructed, non-perforated malignancy)
- Patients less than 18 years of age

- Prisoners
- Pregnancy

Therapeutic Intervention:

- This is a prospective observational study, therefore patient management decisions are the sole responsibility of the managing surgeon

Outcomes Measured:

1. Primary outcome – intra-abdominal postoperative complication after urgent / emergent intestinal resection (*patients allowed one complication per anastomosis, if dehiscence / leak verified, intra-abdominal abscess will not also be included*)
 - a. Anastomotic dehiscence / leak – verified by reoperation and visualization or contrast enhanced study showing extravasation
 - b. Intra-abdominal abscess – identified at reoperation or radiographically
2. Secondary outcomes
 - a. Intra-abdominal postoperative complication in intestinal resection performed as part of damage control techniques
 - i. Anastomotic dehiscence / leak – verified by reoperation and visualization or contrast enhanced study showing extravasation
 - ii. Intra-abdominal abscess – identified at reoperation or radiographically
 - b. Entero-cutaneous/atmospheric fistula – documented in the medical record as a clinical finding
 - c. Operating time (minutes)
 - d. Intra-operative blood loss (mL)
 - e. Intra-operative transfusion
 - i. Number of units PRBCs
 - ii. Number of units FFP
 - f. Surgical site infection
 - g. Fascial dehiscence
 - h. In-hospital mortality
 - i. ICU and hospital length of stay (days)

Measured Variables:

1. Demographics

- a. Age
 - b. Gender
 - c. Weight (kg)
 - d. Height (m)
 - e. Lab values – *most immediate pre-operative lab available*
 - i. Hemoglobin (g/dl)
 - ii. WBC count ($\times 10^3 \mu\text{l}$)
 - iii. Albumin (g/dl)
 - f. Hemodynamic instability
 - i. Required pre-operative vasopressor therapy (*yes or no*)
2. Management variables
- a. Operating time (min)
 - b. EBL (mL)
 - c. Intra-operative transfusion requirement
 - d. Technique and number of anastomoses
 - i. Stapled
 - 1. Circular versus linear
 - ii. Handsewn
 - 1. Single versus two layer
 - iii. Stapled and Handsewn (combined technique)
 - e. Damage control / open abdomen
 - i. Indication for damage control
 - 1. Hemorrhage / Contamination Burden / Shock / Abdominal Compartment Syndrome / Ischemia Requiring Second Look
 - ii. Day of anastomosis after initial operation left the patient with an open abdomen
 - iii. Type and technique of anastomosis
 - 1. Stapled
 - a. Circular versus linear
 - 2. Handsewn
 - a. Single versus two layer
 - 3. Stapled and Handsewn (combined technique)
 - f. Location of anastomosis
 - i. Jejunal

- ii. Ileal
 - iii. Ileo-colonic
 - iv. Colonic
 - v. Colorectal
 - vi. Other
3. Post-operative variables
- a. Anastomotic complication
 - i. Leak / dehiscence
 - ii. Intra-abdominal abscess
 - b. Entero-cutaneous/atmospheric fistula – clinical documentation of presence
 - c. Surgical site infection (see appendix)
 - d. Fascial dehiscence – evidence of fascial separation diagnosed clinically or radiographically
 - e. Mortality
 - f. ICU LOS
 - g. Hospital LOS

Data Collection and Statistical Analysis:

Standardized data will be collected for each patient. Risk factors for anastomotic complications will be assessed using univariate and multivariate analysis. Continuous variables will be compared using Student's t-test for normally distributed variables and the Mann Whitney U test for non-parametrically distributed variables. All tests will be two-tailed. Chi-squared and Fisher's exact tests will be used to compare categorical variables. A logistic regression model will be constructed using stepwise selection of variables. Variables will be selected for inclusion in the model based on Akaike's Information Criteria (AIC). Data will be reported as adjusted odds ratios with 95 % confidence intervals. A P values < 0.05 will be considered statistically significant.

Utilizing data from Farrah and colleagues, we assume a 10% difference in anastomotic complications between stapled and handsewn anastomotic techniques. With an alpha of 0.05 and a power of 90%, we project needing 224 patients in each group (448 total patients).

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Appendix

Skin and Soft Tissue Infection (SSI):

1. Superficial Incisional SSI must meet one of the following:

Infection occurs within 30 days after the operative procedure

And

Involves only skin and subcutaneous tissue of the incision

And

Patient has at least one of the following:

- a. Purulent drainage from superficial incision
- b. Organisms isolated from an aseptically obtained culture
- c. At least one of the following: pain or tenderness, localized swelling, redness, or heat and superficial incision is opened by surgeon
- d. Diagnosis of superficial incision by surgeon

2. Deep Incisional SSI must meet one of the following:

Infection occurs within 30 days after the operative procedure

And

Involves deep soft tissues (fascia and muscle) of the incision

And

Patient has at least one of the following:

- a. Purulent drainage from the deep incision but not from the organ/space component of the surgical site
- b. A deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured
- c. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, by histopathology or radiology
- d. Diagnosis by the surgeon

3. Organ/Space SSI must meet one of the following:

Occurs within 30 days

And

Involves any part of body, excluding the skin incision, fascia, or muscle layers, that is opened during initial operation

And

Patient has at least one of the following:

- a. Purulent drainage from a drain that is placed through a stab wound into the organ/space
- b. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space
- c. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathology or radiology
- d. Diagnosis by the surgeon