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Authors
Sujatha-Bhaskar, Sarath
Jafari, Mehraneh D
Hanna, Mark
et al.

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An endoscopic mucosal grading system is predictive of leak in stapled rectal anastomoses

Sarath Sujatha-Bhaskar1 • Mehraneh D. Jafari1 • Mark Hanna1 • Christina Y. Koh1 • Colette S. Inaba1 • Steven D. Mills1 • Joseph C. Carmichael1 • Ninh T. Nguyen1 • Michael J. Stamos1 • Alessio Pigazzi1

Abstract

Background Anastomotic leak is a devastating postoperative complication following rectal anastomoses associated with significant clinical and oncological implications. As a result, there is a need for novel intraoperative methods that will help predict anastomotic leak.

Methods From 2011 to 2014, patient undergoing rectal anastomoses by colorectal surgeons at our institution underwent prospective application of intraoperative flexible endoscopy with mucosal grading. Retrospective review of patient medical records was performed. After creation of the colorectal anastomosis, application of a three-tier endoscopic mucosal grading system occurred. Grade 1 was defined as circumferentially normal appearing peri-anastomotic mucosa. Grade 2 was defined as ischemia or congestion involving\30% of either the colon or rectal mucosa. Grade 3 was defined as ischemia or congestion involving [30% of the colon or rectal mucosa or ischemia/congestion involving both sides of the staple line.

Results From 2011 to 2014, a total of 106 patients were reviewed. Grade 1 anastomoses were created in 92 (86.7%) patients and Grade 2 anastomoses were created in 10 (9.4%) patients. All 4 (3.8%) Grade 3 patients underwent immediate intraoperative anastomosis takedown and re-creation, with subsequent re-classification as Grade 1. Demographic and comorbidity data were similar between Grade 1 and Grade 2 patients. Anastomotic leak rate for the entire cohort was 12.2%. Grade 1 patients demonstrated a leak rate of 9.4% (9/ 96) and Grade 2 patients demonstrated a leak rate of 40% (4/ 10). Multivariate logistic regression associated Grade 2 classification with an increased risk of anastomotic leak (OR 4.09, 95% CI 1.21–13.63, P = 0.023).

Conclusion Endoscopic mucosal grading is a feasible intraoperative technique that has a role following creation of a rectal anastomosis. Identification of a Grade 2 or Grade 3 anastomosis should provoke strong consideration for immediate intraoperative revision.

Keywords Colorectal • Anastomotic leak • Endoscopy • Mucosal grading

Anastomotic leak following rectal anastomosis is a significant health care burden associated with increased postoperative morbidity rates, longer length of stay, greater hospital cost, and reduction in cancer-free survival [1–3]. Recent large randomized control trials report anastomotic leak rates following open and laparoscopic proctectomy to be approximately 10–13% [4].

Despite a variety of intraoperative methods currently available to assist in detection of anastomotic leak, no single approach has consistently demonstrated both feasibility and reliability. In the absence of any intraoperative evaluation method, operating surgeons' global clinical risk assessment of anastomotic leak has been found to have a poor predictive value, emphasizing the need for supplemental methods of evaluation [5]. Moreover, mechanical air leak testing while standardly employed has yielded no significant impact on clinical anastomotic leak rates [6].

To account for this, we devised an intraoperative method to assist in predicting anastomotic leak. In this study, we examined the application of a novel, three-tiered anastomotic grading system using white light flexible endoscopy. Furthermore, we determined the predictive capability of this method in determining anastomotic leak.

Methods

From 2011 to 2014, colorectal surgeons at the University of California, Irvine Medical Center instituted intraoperative flexible endoscopy after creation of stapled colorectal anastomoses. Athree-tiered grading system was devised based on the degree of mucosal ischemia or venous congestion in the rectal anastomosis (Fig. 1). The score is applicable assuming a negative air leak test and no stapler failures. Grade 1 was defined as circumferentially normal appearing mucosa. Grade 2 was defined as ischemia or congestion at the staple line involving\30% of either the colonic mucosa or rectal mucosa. Grade 3 was defined as ischemia or congestion at the staple line involving[30% of either the colonic mucosa or rectal mucosa or ischemia/congestion involving both sides of the anastomosis. All colorectal surgeons in our institution were involved in the designations of this anastomotic grading scale. Both ischemia and venous congestion were equivalently appreciated as markers of poor perfusion.

Colorectal surgeons in our institution employed similar operative approaches for low anterior resection and sigmoidectomy. High ligation of the inferior mesenteric artery was performed with medial to lateral dissection of the mesocolon and splenic flexure mobilization. Inferior mesenteric vein ligation was performed adjacent to the ligament of Trietz at the inferior edge of the pancreas. Initial visual assessment of the proximal colon serosal surface was performed in all cases to determine an appropriate point for proximal transection. Furthermore, in all cases, the cut mucosal edge of the proximal colon demonstrated adequate perfusion prior to anastomosis creation. As prior visual assessments relayed no significant concerns, no other standardized measures were employed by our surgeons for specific perfusion assessment in this population set and protocol.

After completion of the anastomosis, high-resolution white light flexible video endoscopy with examination of the peri-anastomotic colon and rectal mucosa was performed with immediate grading. The appointed grade for each anastomosis was agreed upon by all surgeons in the operating room. As all our colorectal surgeons were involved in the construction of the grading system, they were all equally adept at anastomosis stratification. The integrity of the staple line was also evaluated by mechanical leak testing. Based on endoscopic findings or the result of mechanical leak testing, the decision to perform immediate intraoperative modification of the anastomosis was left to the judgment of the surgeon.

Patient clinical data from 2011 to 2014 were retrospectively reviewed from the day of the operation with 60-day postoperative follow-up. Inclusion criteria consisted of patients over the age of 18 undergoing stapled colorectal anastomosis with concomitant flexible endoscopy and mucosal grading. Patient under the age of 18 or those with incomplete chart data during review were excluded from the study. Approval for this study was acquired through the institutional review board at the University of California, Irvine Medical Center.

Patients were stratified on the basis of endoscopic grade. Demographic and comorbidity data were analyzed among endoscopic grades through univariate analysis with Pearson Chi-Square testing, Fisher's exact test, and unpaired Student's t-testing. Additional univariate examination of operation type, approach, surgical indication, and key intraoperative outcomes was performed as well. Multivariate logistic regression adjusted to anastomotic level was used to examine postoperative outcomes. Analyses were carried out in the R language and environment for statistical computing (R Foundation for Statistical Computing, Vienna, Austria 2016).

Anastomotic leak was defined as radiological or endoscopic evidence of a disruption in the staple line with or without intervention. Symptomatic leak was defined as anastomotic leak with physical symptoms or radiological/ endoscopic evidence of anastomotic leak sequelae such as abscess formation. Intervention was defined as endoscopic, percutaneous, or operative intervention in the management of an anastomotic leak.

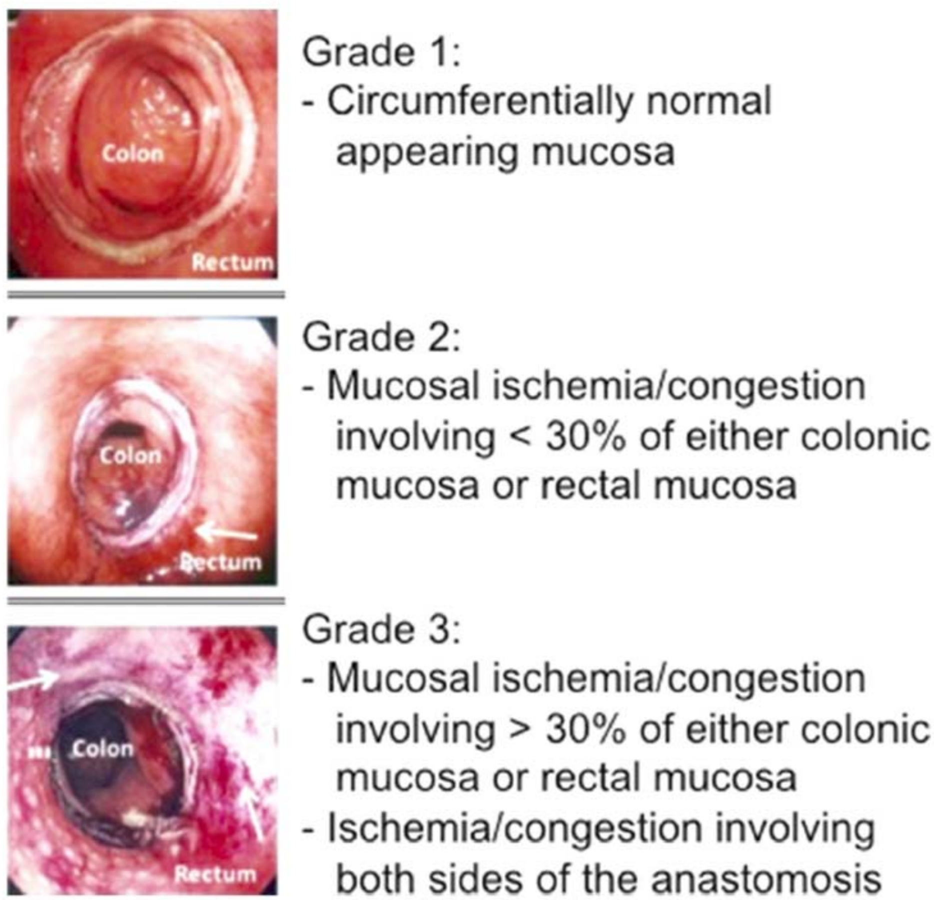

Fig. 1 A 3-tiered mucosal grading system was created based on the degree of tissue ischemia and venous congestion involving the colon and rectal mucosa. *White arrows* point to the location of mucosal irregularities in *Grade 2* and *Grade 3* anastomoses

Results

From 2011 to 2014, 106 patients underwent stapled colorectal anastomoses with intraoperative flexible endoscopy and mucosal grading. Of this cohort, 92 (86.7%) were identified as Grade 1, 10 (9.4%) were identified as Grade 2, and 4 (3.7%) were identified as

Grade 3. Given the substantial anastomotic compromise suspected with identification of a Grade 3, all patients in this stratification underwent immediate intraoperative anastomosis takedown and re-creation. They were re-classified as Grade 1. Patient demographic and comorbidity data demonstrated no significant differences (Table 1). Mean age was 57 ± 12 for Grade 1 patients and 56 ± 12 for Grade 2 patients with similar body mass index (Grade 1: 27.3 ± 5.9, Grade 2: 30.1 ± 8.2). Distribution of comorbidities including diabetes mellitus, hypertension, tobacco use, and cardiovascular disease was principally equivalent between both grades. Rates of ASA score[2 were similar in both grades, 57.2% in Grade 1 and 50% in Grade 2. Rectal cancer was the most common diagnosis in both grades with diverticulitis as the second most common. Of patients with rectal cancer, preoperative neoadjuvant radiation was utilized in 42% (25/59) of Grade 1 patients and 57.1% (4/7) of Grade 2 patients (P = 0.79). With respect to operative approach, a minimally invasive (laparoscopic/robotic) approach was most commonly utilized in both grades, 84/96 (87.5%) of Grade 1 patients and 9/10 (90%) of Grade 2 patients. Low anterior resection and sigmoidectomy were the two most common operations in both grades.

Table 1 Patient demographics, comorbidities, and operative type

	Grade I $N = 96$	Grade II $N = 10$	P value
Mean age, years	57 ± 12	56 ± 12	0.82
Body mass index	27.3 ± 5.9	30.1 ± 8.2	0.18
Male	52 (54%)	8 (80%)	0.12
Female	44 (46%)	2 (20%)	0.12
ASA class >2	55 (57.2%)	5 (50%)	0.66
Diabetes mellitus	13 (13.68%)	0 (0%)	0.61
Hypertension	32 (33.68%)	5 (50%)	0.29
Tobacco use	19 (20%)	4 (40%)	0.47
Cardiovascular disease	19 (20%)	1 (10%)	0.45
Top diagnoses			
Rectal cancer	59 (61.5%)	7 (70%)	0.74
Neoadjuvant radiation	25/59 (42%)	4/7 (57.1%)	0.79
Diverticulitis	22 (22.9%)	3 (30%)	0.7
Operative approach			
Laparoscopic/robotic	84 (87.5%)	9 (90%)	0.82
Open	12 (12.5%)	1 (10%)	0.82
Operation			
Low anterior resection	55 (57.3%)	7 (70%)	0.3
Sigmoidectomy	36 (37.5%)	2 (20%)	0.3
Colostomy takedown	4 (4.2%)	1 (10%)	0.4

ASA American Society of Anesthesiologists

With respect to intraoperative outcomes, statistically similar operative duration and estimated blood loss were demonstrated in both grades (Table 2). Although statistically insignificant, diverting ileostomy creation more frequently occurred with Grade 2 patients (60%) than Grade 1 patients (38.5%), (P = 0.31). The decision to perform fecal diversion during the index operation was left to the preference and judgement of the operating surgeon; contributing variables for this decision included patient risk factors, comorbidities, degree of case difficulty, level of anastomosis, and prior radiation. Anastomosis level at < 5 m from the anal verge was performed in 40% (N = 4) of Grade 2 patients compared to 25% (N = 24) of Grade 1 patients, (P = 0.09). Examination of Grade 3 patients revealed a principally similar demographic and comorbidity profile with a minimally invasive approach for rectal cancer most commonly employed. Of Grade 3 patients, (3/ 4) 75% underwent a low pelvic (<5 cm) anastomosis, while (1/4) 25% underwent a high pelvic (>10 cm) anastomosis (Table 3). In patients with a Grade 3 anastomosis, there was no external visual evidence of ischemia or malperfusion in the proximal colon. No evidence of difference in operative technique was present for patients found to have a Grade 3 anastomosis.

Table 2 Intraoperative outcomes

	Grade I $N = 96$	Grade II $N = 10$	*P* value
Mean operative length (min)	262 ± 119.4	309.7 ± 106.2	0.24
Mean EBL (min)	158.5 + 268.9	81.0 ± 57.4	0.37
Drain use	73 (76%)	8 (80%)	0.78
Diverting ileostomy	37 (38.5%)	6 (60%)	0.31
Anastomotic level			
<5 cm	24 (25%)	4 (40%)	0.09
5–10 cm	25 (26%)	1 (10%)	0.26
>10 cm	47 (49%)	5 (50%)	0.59

EBL estimated blood loss

Of the 96 patients with a Grade 1 anastomosis, 7 (7.3%) patients underwent intraoperative anastomosis re-creation or revision (Table 4). None of these patients developed a leak. Of these, 4 (4.2%) were patients initially found to have a Grade 3 anastomosis that underwent complete anastomosis takedown and re-creation. The remaining 3 (3.1%) patients underwent intraoperative revision due to positive mechanical leak testing or the judgment of the operating surgeon. Of these three patients, two underwent suture reinforcement of the anastomosis due to a positive air leak test. The third patient was noted to have an incomplete anastomotic rectal doughnut that prompted complete anastomosis re-creation. Of the 10 patients with a Grade 2 anastomosis, 2 (20%) underwent immediate revision with suture reinforcement of the anastomotic line. Neither of these patients developed leak.

The anastomotic leak rate of the entire cohort was 12.2% (13/106). Of patients classified with a Grade 1 anastomosis, incidence of leak was 9.4% (9/96). Those patients classified with a Grade 2 anastomosis demonstrated an anastomotic leak rate of 40% (4/10). Using multivariate logistic regression, mucosal classification as Grade 2 was associated with an increase in anastomotic leak compared to Grade 1 classification (OR 4.09, 95% CI 1.21–13.63, P = 0.023).

Table 3 Demographic, diagnosis, and operative approach for Grade 3 patients

	Grade 3 $N = 4$
Mean age	60 ± 3.1
Body mass index	29.1 ± 6.32
Male	2 (50%)
Female	2 (50%)
Laparoscopic/robotic	4 (100%)
Top diagnoses	
Diverticulitis	1 (25%)
Rectal cancer	3 (75%)
Operative approach	
Sigmoidectomy	1 (25%)
Low anterior resection	3 (75%)
Low pelvic anastomosis (<5 cm)	3 (75%)
Diversion	3 (75%)
Drain placement	4 (100%)

With respect to the Grade 1 and Grade 2 patients with anastomotic leak, incidence of other leak risk factors was similar between both groups (Table 4). A low pelvic anastomosis at \5 cm occurred in 55.5% of Grade 1 patients with leak and 75% of Grade 2 patients with leak (P = 0.61). Neoadjuvant radiation was utilized in 88% of Grade 1 patients with leak and 50% of Grade 2 patients with leak (P = 0.20). With respect to gender, 66.7% of Grade 1 patients with leak were male, while 75% of Grade 2 patients with leak were male (P = 0.64). Of the 9 patients with a Grade 1 classification who developed anastomotic leak, five demonstrated symptomatic leak requiring intervention. One patient required a returned to the OR on postoperative day 4 for ileostomy creation and drain placement. Two patients were managed with percutaneous drainage catheters placed by interventional radiology with no further intervention. The remaining two patients had transanal drainage catheter placement. The remaining four Grade 1 patients with asymptomatic anastomotic leak had uneventful observation with resolution of leak on subsequent endoscopy and contrast studies.

Table 4 Key perioperative outcomes and anastomotic leak risk factors in Grade 1 and Grade 2 patients

Overall cohort	Grade I $N = 96$	Grade II $N = 10$	OR	95% CI	*P* value
Intraoperative anastomosis re-creation or revision	7 (7.3%)	2 (20%)	2.45	0.41–14.69	0.32
Anastomotic leak	9 (9.78%)	4 (40%)	4.09	1.21–13.63	0.023

Patients with anastomotic leak	Grade I $N = 9$	Grade II $N = 4$	OR	95% CI	*P* value
Symptomatic leak	5 (55.6%)	2 (50%)	0.8	0.29–2.86	0.65
Intervention	5 (55.6%)	2 (50%)	0.8	0.29–2.86	0.65
Diverting ileostomy	6 (66.7%)	3 (75%)	1.12	0.54–2.38	0.64
Low pelvic anastomosis (<5 cm)	5 (55.5%)	3 (75%)	1.35	0.59–3.03	0.61
Male	6 (66.7%)	3 (75%)	1.12	0.54–2.38	0.64
Preoperative radiation	8 (88%)	2 (50%)	0.56	0.21–1.56	0.2

Of the four patients with a Grade 2 classification who had an anastomotic leak, two patients demonstrated symptomatic leak requiring intervention. One patient required placement of a transrectal drainage catheter, while the other symptomatic leak patient required return to the operating room for creation of a diverting ileostomy. In patients with anastomotic leak, the decision for stoma placement versus conservative management was ultimately predicated on the clinical severity of symptoms in patients. In cases of leak with minimal symptoms, percutaneous drainage was found to be sufficient, whereas in more severe cases with substantial leak and significant intraperitoneal contamination, diversion with operative drainage was necessitated.

With regard to the two Grade 2 patients with asymptomatic anastomotic leak, one was found to have physical evidence of a 10–20% anastomotic line disruption on digital rectal exam confirmed with flexible sigmoidoscopy at the time of ileostomy reversal. No additional intervention was required. For the other Grade 2 asymptomatic anastomotic leak patient, identification of the anastomotic line disruption was similarly noted on postoperative flexible sigmoidoscopy and was conservatively managed.

Discussion

Our study consists of a retrospective examination of the novel application of endoscopic mucosal grading with stapled rectal anastomoses. Through our cohort, 100% feasibility was demonstrated, as intraoperative endoscopy of a newly created rectal anastomosis was well tolerated by all patients. Multivariate analysis significantly correlated Grade 2 classification with anastomotic leak. Thus, it is our recommendation that peri-anastomotic mucosal classification of either Grade 2 or Grade 3 should provoke consideration for immediate anastomotic revision or takedown and re-creation.

To date, existing methods of intraoperative leak identification have largely produced statistically insignificant results. In a large systematic review by Schiff et al., although a trend towards lower postoperative leak rates was demonstrated in cohorts that underwent mechanical leak testing, this relationship ultimately was statistically insignificant (air leak testing leak rate 4.3%, no testing 6.8%, P = 0.051) [7]. Similarly, in a systematic review by Wu et al., air leak testing did not appreciably impact clinical leak rates in the tested population (OR 0.61, 95% CI 0.32–1.18, P = 0.15) [6]. Techniques such as Doppler flowmetry, tonometry, and visible/infrared spectroscopy that potentially permit identification of anastomotic malperfusion have yet to consistently demonstrate ease of use, reproducibility, and reliability [8, 9].

Application of intraoperative endoscopy has previously been examined in multiple studies. However, no clear consensus regarding the benefit of this method has been established. In a retrospective study by Shamiyeh et al. from May 1999 to July 2007, impact of intraoperative endoscopy after creation of circular-stapled anastomoses was examined in a cohort of 253 patients. Endoscopic examination allowed intraoperative identification of anastomosis line disruption in 2.4% of patients allowing immediate revision. Nonetheless, no statistically significant reduction in leak rate was appreciated in the endoscopic subset [10]. In a 2009 retrospective chart review by Li et al., although routine intraoperative endoscopy trended towards lower anastomotic complication rates than selective utilization (0.9 vs. 5.1%) as well as the benefit of immediate laparoscopic revision, this relationship failed to be statistically significant, likely due to small sample size [11]. Additional non-randomized controlled trials by Lieto et al., Lanthaler et al., Schmidt et al., and Saknoue et al. featuring application of intraoperative endoscopy were included in a meta-analysis by Nachiappan and colleagues [12–15]. Of the 950 patients included in this meta-analysis,intraoperative endoscopy permitted detection and immediate repair of anastomotic disruption in 13.8% of the endoscopy subset. Despite this effect, no significant differences in postoperative leak rates was established between test and control subsets, P = 0.30 [9].

Compared to prior literature, our study has elucidated a clear benefit to intraoperative mucosal grading, significantly correlating intraoperative endoscopy with clinical anastomotic leak rates. Moreover, our method allows objective quantification of the degree of anastomotic vascular compromise. Given the implicit importance of an intact vascular supply for anastomotic healing, stratification of our grading scale on the basis of mucosal ischemia and venous congestion acknowledges our current understanding of the pathophysiology of anastomotic leak.

Endoscopic mucosal assessment uncovered evidence of malperfusion despite adequate external visual assessment at the time of proximal colon transection. The absence of any visual evidence of malperfusion on the colonic serosal surface for our Grade 3 anastomoses highlights the inadequacy of visual assessment alone and the need for adjunctive measures such as endoscopic grading. Following a minimally invasive resection, intraoperative identification of either a Grade 2 or Grade 3 anastomosis additionally allows the benefit of immediate laparoscopic revision. (Video Clip 1 link). Postoperative identification of leak often may mandate more extensive open resections or diversion procedures due to tissue friability and patient instability. Moreover, given the confinement of mucosal irregularity to\30% of one side of the anastomosis in the Grade 2 classification, anastomotic repair by means of suture reinforcement accompanied with diversion may be adequate under certain circumstances.

Currently, innovative technologies such as indocyanine green fluorescent angiography have been introduced; fluorescent angiographic methods permit high-detail assessment of tissue perfusion [16]. Nonetheless, these methods bear increased cost, require access to near-infrared imaging devices, and require some technical experience. Moreover, intraluminal examination by fluorescent angiography is currently limited and may not offer a precise examination of the anastomosis such as with white light endoscopy. We support the routine application of intraoperative flexible endoscopy with mucosal grading alongside other methods given the widespread availability, ease of use, minimal expense, and strong correlation with leak.

There were some limitations with our study. Inherent biases were present in our retrospective study design. Relatively small sample size may have impacted overall power and the ability to discern effect on other key endpoints. Despite an objective grading scale, subjectivity may be still present between different surgeons with respect to endoscopic grading. Despite Grade 1 classification, a 9.78% leak rate was still noted. While this falls below cited leak rates in colorectal literature, it does suggest that other factors such as tension, stapler techniques, and bacterial presence may influence anastomotic leak rates [17]. Nonetheless, these findings do indicate that when perfusion abnormalities are identified, anastomotic leak rates are prohibitively high. Future prospective studies with a larger population size are warranted. This includes studies that focus on the role of specified intraoperative repair methods such as suture reinforcement in the management of Grade 2 anastomoses.

Conclusion

In conclusion, our study illustrates that flexible endoscopy with implementation of a mucosal grading system is a feasible and valuable intraoperative tool that could be employed by general and colorectal surgeons. Identification of Grade 2 and Grade 3 anastomoses strongly correlates with risk of postoperative anastomotic leak and should elicit consideration for immediate anastomotic revision. Grade 2 classification may be safely managed by suture reinforcement and diversion; however, future studies focused on intraoperative repair techniques in Grade 2 anastomoses will be needed. Grade 3 classification, however, appears consistent with serious vascular compromise and should be managed with takedown and anastomosis recreation.

Compliance with ethical standards

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Alessio Pigazzi
apigazzi@uci.edu

1 Department of Surgery, University of California, Irvine, 333 City Blvd W. Suite 850, Orange, CA 92868, USA