Interrupted versus continuous fascial closure in patients undergoing emergent laparotomy: A randomized controlled trial

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BACKGROUND: The optimal method of fascial closure, interrupted fascial closure (IFC) versus continuous fascial closure (CFC) has never been studied exclusively in the setting of emergency surgery. We hypothesized that IFC decreases postoperative incisional hernia development following emergent laparotomies.

METHODS: Between August 2008 and September 2015, patients undergoing emergent laparotomies were consented and randomly assigned to either IFC or CFC. Patients were followed up postoperatively for at least 3 months and assessed for incisional hernia, dehiscence, or wound infection. We excluded those with trauma, elective surgery, mesh in place, primary ventral hernia, previous abdominal surgery within 30 days, or those not expected to survive for more than 48 hours. Our primary endpoint was the incidence of postoperative incisional hernias.

RESULTS: One hundred thirty-six patients were randomly assigned to IFC (n = 67) or CFC (n = 69). Baseline characteristics were similar between the groups. No difference was noted in the length of the abdominal incision, or the peak inspiratory pressure after the closure. The median time needed for closure was significantly longer in the IFC group (22 minutes vs. 13 minutes, $p < 0.001$). Thirty-seven (55.2%) IFC and 41 (59.4%) CFC patients completed their follow-up visits. There was no statistically significant difference in baseline and intraoperative characteristics between those who completed follow-ups and those who did not. The median time from the day of surgery to the day of the last follow-up was similar between IFC and CFC (233 days vs. 216 days, $p = 0.67$), as were the rates of incisional hernia (13.5% versus 22.0%, $p = 0.25$), dehiscence (2.7% vs. 2.4%, $p = 1.0$), and surgical site infection (16.2% vs. 12.2%, $p = 0.75$).

CONCLUSION: There was no statistically detectable difference in postoperative hernia development between those undergoing IFC versus CFC after emergent laparotomies. However, this may be due to the relatively low sample size. (*J Trauma Acute Care Surg.* 2018;85: 459–465. Copyright © 2018 American Association for the Surgery of Trauma. All rights reserved.)

LEVEL OF EVIDENCE: Therapeutic/Care Management Study, level III.

KEY WORDS: Fascial closure; emergency surgery; acute care surgery; laparotomy.

The optimal method of fascial closure after laparotomy is unclear. In fact, the first studies that compared interrupted versus continuous techniques of fascial closure appeared in the literature more than three decades ago.[1–6] These studies had concluded that the two methods were equivalent in terms of postoperative wound complications, including dehiscence, wound infections, and incisional hernia development. The early findings were largely supported by subsequent randomized controlled trials.[7–11] However, even though interrupted closure had not been found to be inferior, many authors were advocating against it, given the fact that continuous closure could be performed significantly faster hence less time was spent in the operating room. In addition, more recent studies have shown that continuous closure is actually associated with better outcomes after elective surgery.[12] As a result, according to the recently published guidelines by the European Hernia Society, fascia should be closed using a continuous suturing technique, based on the decreased rates of incisional hernias after elective laparotomy.[13]

Despite the extensive literature on elective operations, none of the previously published studies had examined the two methods of fascial closure exclusively in the emergency surgery setting. Only a recently published study reported the rates of wound dehiscence after implementation of a standardized method of continuous fascial closure following emergent midline laparotomy.[14] The authors concluded that continuous closure with slowly absorbable suture reduced the occurrence of dehiscence, but emphasized that further research is necessary to evaluate other outcomes, including incisional hernias.

In this study, we sought to examine both methods of fascial closure after emergent laparotomy. We hypothesized that interrupted fascial closure would be associated with a decrease in postoperative incisional hernias.

METHODS

We designed a randomized controlled trial, which took place in the division of emergency surgery at Massachusetts General Hospital between August 2008 and September 2015. The study was registered in ClinicalTrials.gov (identifier: NCT02145052). Adult patients undergoing midline laparotomy for gastrointestinal emergencies were considered eligible for inclusion. We excluded patients who underwent elective operations, laparotomies due to trauma, were pregnant, did not have their fascia closed, were not expected to survive for more than 2 days given their baseline comorbid status, had a primary ventral hernia with or without mesh in place, had undergone any abdominal operation within the last 30 days, or were unable to communicate in English.

Patients were randomly assigned in a one-to-one fashion with a simple randomization method, using opaque sealed envelopes, into two groups, continuous versus interrupted fascial closure. Patients in the continuous group had their fascia closed with no. 0 nonlooped, slowly absorbable polydioxanone sutures (Ethicon, Inc, Somerville, NJ). The ratio of suture length to incision length was kept at 4:1. A tapered needle was used, and the fascia was closed from both the superior and inferior edge of the wound simultaneously, with the sutures being placed at approximately 10 mm from the fascial edge and 10 mm advancement. The fascia was eventually closed in the middle of the incision, where the two sutures were knotted together with at least four square knots or eight throws. Interrupted closure was also performed with no. 0 nonlooped, slowly absorbable polydioxanone

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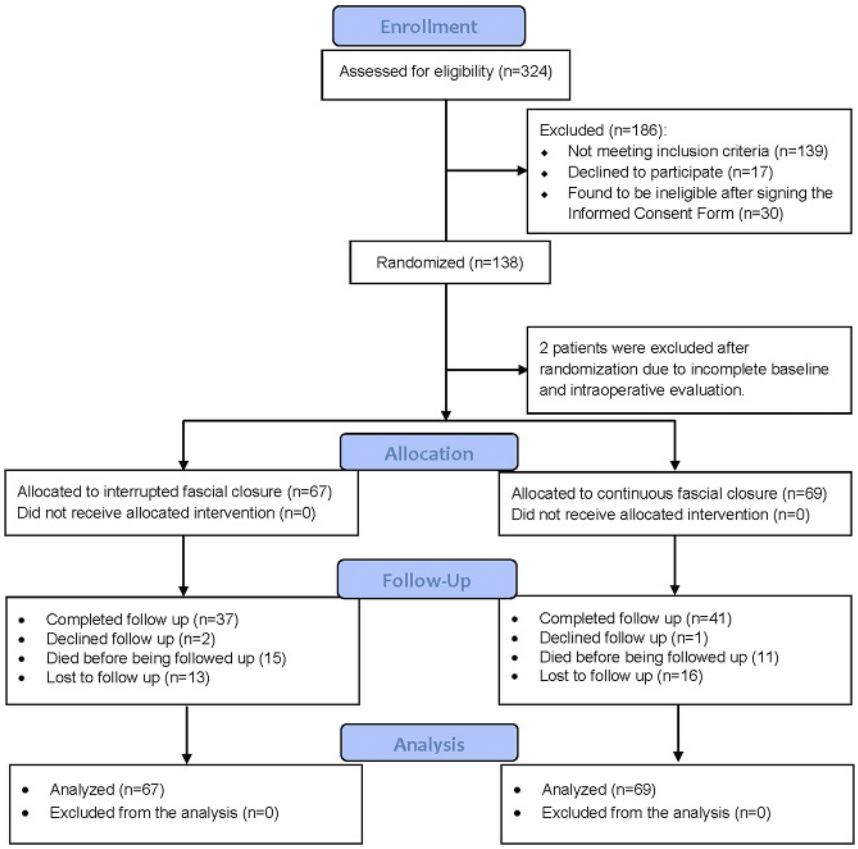

Figure 1. Consort diagram.

sutures in a simple interrupted fashion. Again, sutures were placed at 10 mm from the fascial edge after advancing 10 mm. Patients were enrolled and operations were performed by experienced acute care surgeons, who were instructed beforehand about the techniques of the study in detail. The attendings either closed the fascia or provided close direct supervision if residents were placing stitches. We captured baseline (e.g., age, sex, body mass index [BMI], and American Society of Anesthesiologists [ASA] class), intraoperative (e.g., wound classification, length of the incision, peak inspiratory pressure before and after the closure, duration of closure, number of stitches [in interrupted closure], and length of the suture [in continuous closure]), and postoperative variables (e.g., incisional hernia, surgical site infection, dehiscence, and 30-day mortality).

Our primary endpoint was postoperative incisional hernia formation. Our secondary endpoints comprised dehiscence, wound infection, and 30-day mortality rates. Patients were assessed clinically (without ultrasound or computed tomography scan) both during hospitalization and in the clinic, at least 3 months following discharge. Both patients and assessors of clinical outcomes were blinded to the treatment arm. We evaluated patients for dehiscence and wound infections during the index hospitalization and subsequent follow up. Dehiscence was defined as a defect in the fascia larger than 1 cm. Wound infections were considered positive if: (1) only the skin or subcutaneous tissues were involved; (2) there was purulent drainage from the wound or organisms were isolated in wound cultures; and (3) pain/tenderness, localized edema, or erythema were present. Our intent was a 5-year follow up.

Statistical analysis was performed using the STATA software (version 13.1). Numerical variables are reported as medians with interquartile ranges (25th to 75th percentile), and categorical ones as frequencies and percentages. We used the Mann-Whitney *U* nonparametric test to compare numerical variables and the χ^2 or the Fisher's exact test to compare categorical variables as appropriate. We were unable to perform multivariable logistic regression analyses to identify independent predictors of incisional hernia development given the relative rarity of this outcome in our patient population. We defined a p value less than 0.05 as the level of statistical significance. The goal was to recruit 388 patients (194 in each group). This would have given us the ability to detect a decrease in incisional hernias from 20% after continuous to 10% after interrupted closure with power of 80% and alpha < 0.05, using one-sided testing. Due to the slow recruitment, we opted to end the study prior to enrolling 388 patients. The study was approved by the institutional review board, and an informed consent form was obtained from all patients.

RESULTS

The CONSORT style diagram in Figure 1 describes the flow of patients in the study. Of the 370 patients who underwent an emergent laparotomy during the study period, 324 were assessed for eligibility. Of those, 139 were excluded due to various exclusion

TABLE 1. Baseline and Intraoperative Characteristics of the Patients Who Underwent Continuous Versus Interrupted Fascial Closure

Variables	Continuous (n = 69)	Interrupted (n = 67)
Age: median (Q1–Q3), y	74 (58–82)	66 (54–77)
Male sex, n (%)	37 (53.6)	35 (52.2)
BMI, median (Q1–Q3)	25.8 (22.7–28.5)	25.4 (20.7–26.9)
Wound classification*		
Clean, n (%)	15 (22.1)	10 (14.9)
Clean/contaminated, n (%)	42 (61.8)	47 (70.1)
Contaminated, n (%)	6 (8.8)	6 (9.0)
Dirty/infected, n (%)	5 (7.3)	4 (6.0)
ASA class*:		
1, n (%)	3 (4.5)	4 (6.3)
2, n (%)	19 (28.3)	26 (41.3)
3, n (%)	28 (41.8)	23 (36.5)
4, n (%)	17 (25.4)	10 (15.9)
Incision length: median (Q1–Q3), cm	20 (16–25)	20 (15–23)
Closure duration: median (Q1–Q3), min	13 (11–17)	22 (17–25)
Peak inspiratory pressure before closure: median (Q1–Q3), mm Hg	20 (17–24)	19 (16–24)
Peak inspiratory pressure after closure: median (Q1–Q3), mm Hg	22 (19–26)	22 (18–25)
Suture length: median (Q1–Q3), cm**	80 (63–112)	155 (90–260)
Suture length/incision length: median (Q1–Q3)	4.3 (3.5–5.5)	n/a
No. stitches used: median (Q1–Q3)	n/a	18 (16–23)

* ASA missing for 6 patients. Wound classification missing for 1 patient.
**In interrupted closure the number represents the length per suture.
Q1, 25th percentile; Q3, 75th percentile.

criteria and 17 declined to participate. Additionally, 30 were found to have one of the exclusion criteria after signing the informed consent form (but before randomization) thus were excluded as well. One hundred thirty-eight patients were eventually randomized, of whom two were excluded postrandomization due to incomplete baseline and intraoperative data. We analyzed a total of 136 patients of whom 67 underwent interrupted and 69 continuous fascial closure. The most common indications for surgery were small bowel obstruction (27.2%), colonic perforation (17.0%), and *Clostridium difficile* colitis (11.0%). Of the interrupted closure patients, 15 (22.4%) died before completing their follow-up

TABLE 2. Comparison of the Outcomes of the Two Groups, Including Only the Patients Who Completed a Follow-up Appointment at Least 3 Months After Surgery

Variables	Continuous (n = 41)	Interrupted (n = 37)	*p*
Time from surgery to last follow-up: median (Q1–Q3), d	216 (131–688)	233 (112–307)	0.674
Dehiscence, n (%)	1 (2.4)	1 (2.7)	1.0
Surgical site infection, n (%)	5 (12.2)	6 (16.2)	0.748
Incisional hernia, n (%)	9 (22.0)	5 (13.5)	0.251
30-d Mortality, n (%)	7 (10.1)	7 (10.5)	1.0

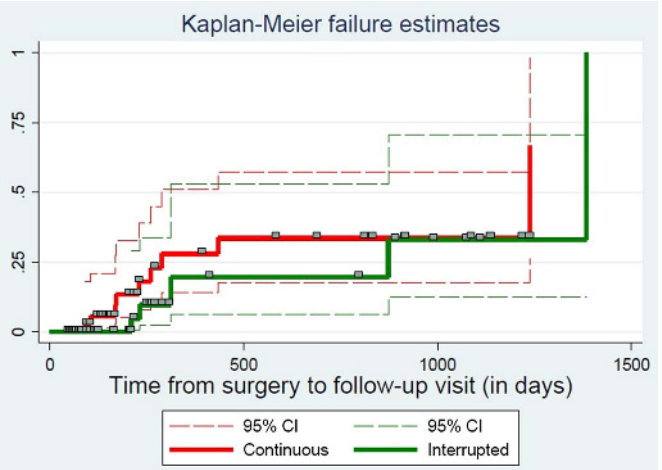

Figure 2. Kaplan-Meier analysis. (*red line*) Continuous running closure group; (*green line*) interrupted suture closure group; *y*-axis is incidence of hernia formation.

appointment in the clinic, 2 (3.0%) declined follow-up, and 13 (19.4%) were lost to follow-up. These numbers were similar to those observed in the continuous fascial closure group ($p = 0.95$). In the latter, 11 (15.9%) died before completing their follow-up visit, 1 (1.5%) declined to return to the clinic, and 16 (23.2%) were lost to follow-up. When we compared those who were lost to follow-up with those completing the follow-up appointments, we found no differences in baseline or intraoperative characteristics. Thirty-seven (55.2%) of the interrupted closure and 41 (59.4%) of the continuous closure patients completed their follow-up visits and were fully assessed for postoperative outcomes.

Table 1 shows the baseline and intraoperative characteristics of randomized patients. Age, sex, BMI, ASA class, and wound classification did not differ between the two groups. Additionally, the length of the incision was similar (median, 20 cm for both groups, $p = 0.661$), as was the peak inspiratory pressure before and after the closure (median, 20 mm Hg before and 22 mm Hg after for continuous closure versus 19 mm Hg before and 22 mm Hg after for interrupted closure, $p = 0.317$ and $p = 0.325$, respectively). The time required to close the fascia was longer in interrupted closure (median, 22 minutes vs. 13 minutes, $p < 0.001$).

Table 2 describes postoperative outcomes of patients who attended their follow-up appointments. The median time from the operation to the study follow-up clinic visit was approximately 7 months and was similar between the two groups (216 days in continuous and 233 days in interrupted closure, $p = 0.674$). We observed similar dehiscence and surgical site infection rates, with only one patient in each group dehiscing ($p = 1.0$) and 12.2% of the continuous versus 16.2% of the interrupted closure patients developing wound infections ($p = 0.748$). Nine (22.0%) of the patients undergoing continuous closure developed an incisional hernia compared with five (13.5%) of those undergoing interrupted closure; however, the difference was not statistically significant ($p = 0.251$). Figure 2 shows the Kaplan-Meier failure estimates over time, with failure being defined as incisional hernia development (log rank test $p = 0.469$). Finally, the 30-day mortality rates did not differ between the two groups.

DISCUSSION

This is the first randomized controlled trial that evaluates the two methods of fascial closure in terms of incisional hernia occurrence following emergent laparotomy. We hypothesized that patients undergoing interrupted closure would develop incisional hernias less frequently; however, we were unable to detect a statistically significant difference between the two techniques.

In the study by Tolstrup and colleagues,[14] a standardized method of continuous fascial closure was evaluated exclusively in emergent midline laparotomies. The incisions were closed with a slowly absorbable suture (no. 2-0 polydioxanone) in a continuous fashion, with the ratio of the suture length to incision length being at least 4:1. They enrolled 494 patients who received this standardized closure and were subsequently compared with historical controls. They reported that the rate of postoperative dehiscence decreased from 6.6% to 3.8% by using this method. However, they did not comment on the rate of incisional hernia development in their patient population and highlighted the absence of relevant literature.

The only studies that have looked specifically into the occurrence of incisional hernias have been done in elective surgery. Seiler and colleagues[15] performed a multicenter randomized controlled trial and concluded that the rate of incisional hernias remains the same irrespective of the technique of closure, with the authors admitting that the rates of incisional hernias were overall higher than what they were expecting, ranging from 8.4% to 15.9% among the studied groups. A meta-analysis by van't Riet and colleagues[16] reported that the two methods are similar in terms of postoperative incisional hernia occurrence, but pointed out that continuous closure requires less time than interrupted thus concluded that it might be a better choice. Another meta-analysis also showed that the two methods have similar rates of incisional hernias, even though interrupted closure is associated with a lower risk of dehiscence.[17] However, the most recent meta-analysis by Diener and colleagues[12] advocated against interrupted closure after elective midline laparotomies. The authors found a lower hernia rate with continuous closure, but again underlined the lack of relevant data to draw appropriate conclusions in the emergency setting.

It has been repeatedly shown in the literature that emergency surgery is an independent predictor of poor postoperative outcomes.[18] This is usually attributed to the prominent metabolic derangement and various comorbidities that are not dealt with because they would have been in elective scenarios. One could safely assume that incisional hernias also occur more frequently after emergent operations. Indeed, our study reports a relatively high rate of incisional hernias in both groups. Given the fact that the technique of fascial closure does affect the rate of incisional hernias after elective operations, it could also be a crucial factor after emergent laparotomies. To our knowledge, this is the first study that looks into this very issue exclusively in the higher risk group of patients undergoing emergency abdominal surgery. The difference of 8.5% in favor of the interrupted closure was not statistically significant. However, this result should be evaluated with caution given the possibility of a Type II error given the sample size did not meet our initial goals.

Finally, previous studies have described a variety of independent predictors for incisional hernia development after abdominal surgery. These include surgical site infections, high BMI, female sex, wound Class III and IV, and midline abdominal incision.[19,20] Even though we were unable to perform multivariable regression analysis, sex, BMI, wound classification, and surgical site infections did not differ between those who developed hernias and those who did not in the univariate analysis.

Our study carries a number of limitations that need to be acknowledged. First and foremost, there is a substantial possibility of a Type II error due to the relatively small sample size. Second, approximately one third of the patients in each group were not assessed beyond hospitalization. However, we did compare the baseline and intraoperative characteristics of those who were lost to follow-up with those who were eventually evaluated and found no differences between the groups. Third, this is a single-center study and all operations were performed by experienced acute care surgeons, who were thoroughly instructed about the two methods of fascial closure thus the results may not be generalizable to other institutions.

CONCLUSION

There was no statistically detectable difference in postoperative hernia development between those undergoing interrupted versus those undergoing continuous fascial closure after emergent laparotomies. This may be due to the relatively low sample size, therefore, a multicenter randomized-controlled trial with a larger sample size might be more appropriate to identify a significant difference.

AUTHORSHIP

T.P. participated in the literature search, data collection, data analysis, data interpretation, writing, critical revision. J.D.B. participated in the data collection, data interpretation, critical revision. S.M. participated in the data collection, data interpretation, critical revision. E.F. participated in the data collection, data interpretation, critical revision. G.M.vdW. participated in the data collection, data interpretation, critical revision. A.M. participated in the data collection, data interpretation, critical revision. H.A. participated in the study design, data collection, data interpretation, critical revision. H.M.A.K. participated in the data collection, data interpretation, critical revision. P.J.F. participated in the data collection, data interpretation, critical revision. D.R.K. participated in the data collection, data interpretation, critical revision. D.D.Y. participated in the data collection, data interpretation, critical revision. G.C.V. participated in the study design, data collection, data interpretation, critical revision. M.A.dM. participated in the study design, data collection, data interpretation, critical revision.

DISCLOSURE

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DISCUSSION

Dr. Brandon Bruns (Baltimore, Maryland): Thank you. I would like to thank the Program Committee and the AAST for the opportunity to discuss this clinically-important study.

First and foremost, I would like to sincerely commend the authors in their efforts to attempt to address a clinically-important emergency general surgery topic, whether continuous or interrupted fascial closure in emergent, non-trauma abdominal operations is superior as it relates to incisional hernia formation, dehiscence, wound infection, and 30-day mortality rates.

The manuscript is well-written and was provided with ample time for review.

In an ambitious fashion, the authors conducted a randomized, controlled trial over a seven-year period. Specifically, the authors studied Number Zero, non-looped, PDS suture on a tapered needle in a continuous fashion, running approximately 10 millimeters from the fascial edge, and with 10 millimeters of advancement versus the same suture type in a simple interrupted fashion, again, approximately 10 millimeters from the fascial edge with 10 millimeters of advancement.

An enrollment goal of 194 patients in each group would have given the authors the ability to detect a decrease in incisional hernia formation from 20 percent with continuous to 10 percent with interrupted, with a power of 80 percent.

However, instead of 194 patients in each group, the authors enrolled 67 in the interrupted group, 37 of whom completed follow-up, and 69 in the continuous group, 41 of whom completed follow-up.

The authors found no difference in fascial dehiscence, surgical site infection, incisional hernia, or 30-day mortality between the two groups.

I am the first to admit that I am not a master statistician, but I find the total enrollment numbers to be troublesome and leads me to ask what I can actually conclude from this study.

Besides the obvious statistical "elephant in the room," I have some more clinically-relevant questions that I'd love for you to address.

Number 1. The authors state that "adult patients undergoing midline laparotomy for GI emergencies were considered eligible;" however, the results do not address the types of operations that were actually performed.

I am curious if the authors have any indication as to what operations were performed. Specifically, I am curious about operations performed for colonic ischemia, necrosis, and perforation.

In reading the manuscript I am left to assume the skin was closed in all the cases, though this is not specifically addressed. How do you manage the skin in patients with these colonic pathologies? And were they included in the results?

In consideration of some recent data suggesting incisional vacs may help with wound healing and infection, did any of these patients have incisional vacs placed?

If not, how were the wounds managed and dressed? Was there a standardized protocol for midline dressing or was it left to the discretion of the surgeon?

You also state that operations were performed by "experienced acute care surgeons;" however, you do not specifically state who closed the fascia. Did you allow residents to close the fascia on study patients? And were they supervised if they did?

The median time to follow-up clinic visit was seven months. Do you guys just have an insanely busy clinic or were the lengths of stay protracted?

There are no data related to hospital length of stay or other seemingly important clinical outcomes, such as need for additional operations, need for opening of the surgical wound, fistula formation, et cetera.

I am also led to assume that patients managed with an open abdomen who underwent eventual fascial closure were not included in this analysis. Am I correct in making this assumption?

And, finally, back to the elephant, your Consort diagram shows that only 324 patients were assessed for eligibility over this seven-year study period.

As a clinical researcher who has not yet taken the initiative of this group and actually attempted a randomized controlled trial, did you learn any lessons or additional lessons that you could pass on regarding enrollment because I have to assume that you have sufficient clinical volume?

Additionally, your primary outcome of clinical incisional hernia, though not "statistically significant," is clinically significant, in my book, 22 percent incisional hernia rate in continuous and 13.5 percent in the interrupted, which, coincidentally, supports my bias.

However, as I mentioned, I am not a master statistician but, as your manuscript states, the study "only had 17 percent power to detect an 8.5 percent difference."

How can I interpret these data, or is this a hypothesis-generating study for future multi-center trials, as you suggest in the manuscript?

Again, I truly applaud the authors for their undertaking a seven-year randomized controlled trial looking at a clinically important emergency general surgery topic. And I very much look forward to their responses.

Dr. Joseph P. Minei (Dallas, Texas): Marc, very nice. A quick question all about methodology. When I have done this with my own residents; small bite, small travel, I actually get a ruler out and show them - look how small half-a-centimeter to a centimeter actually is. So my question is, what quality control did you use during the closure?

Dr. H. Gill Cryer (Los Angeles, California): I enjoyed the study. The question I have regards the size of the hernia.

So one advantage of an interrupted technique is that if you do have a disruption of the suture line it's small. It might be only one of the knots; whereas, if you, in a running you might lose the whole thing. So was there a difference in the size of the ventral hernias in the two groups?

Dr. Robert D. Winfield (Kansas City, Kansas): Similar question to Dr. Minei's, I am curious as to why the travel was allowed to be one centimeter and the bite allowed to be one centimeter in light of the data that suggests that small bites lead to reduced incisional hernia rates.

Dr. Stephen M. Cohn (Staten Island, New York): Marc, enjoyed that. Have you considered using on-lay mesh?

There is quite a bit of data now on the value in a randomized trial in AAA patients, elective patients, lowered the ventral hernia rate in two years from 28 percent to zero so maybe there is a better way to manage these patients besides or in addition to primary fascial closure. Thanks.

Dr. Weidun Alan Guo (Buffalo, New York): Marc, congratulations. Excellent work. I have a quick question for you.

You said there is no difference between continuous and interrupted suture. But I want to know if there is a difference in these two groups in terms of the comorbidity, like APACHE II physiologic score.

Did one group have more patients who were on steroid use or have a history of a kidney transplant, something like that?

Dr. Marc A Demoya (Milwaukee, Wisconsin): I would like to thank you for all your questions. Just to kind of get through them, we did not use mesh, Dr. Cohn.

The size of the hernia, I would imagine, probably did change over time, Dr. Cryer.We considered them to be hernias if they were at least one centimeter or if we could palpate the hernia. But I'm sure that there may be more of a difference over a longer period of time.

Dr. Minei and Dr. Bruns, the attending staff was there for the entire closure and we were watching very closely. And I have to say that there were times when I certainly would take out the ruler and show them exactly how to stick to the outlined technique.

The stitch trial wasn't done when this trial was started so we kept it out. That wasn't part of the algorithm at that time. At this point I think it is reasonable to follow the stitch trial recommendations.

We did not include open abdomen. Dr. Bruns, that's correct. The follow-up time mentioned at seven-months was actually the last follow-up. It wasn't the first follow-up. If a patient developed a hernia they were considered completed in the study.

In terms of the types of cases, 30 percent of the cases were perforated colons. I think I've hit on pretty much them all. And I have no more time left. Thank you.

