EAST MCT PROPOSAL

Study Title: Evaluation of Triclosan-Coated Barbed Suture Following Emergency Laparotomy: A Multicenter Retrospective and Prospective Cohort Study

Outline the burden of the problem:

Emergency exploratory laparotomy carries high risk of morbidity and mortality, primarily due to early complications such as fascial dehiscence and surgical site infection (SSI). Reported rates of fascial dehiscence and surgical site infections (SSI) following emergency laparotomy vary widely, with most studies indicating rates between 10–15%, and some with documented rates as high as 45%, particularly in high-risk populations. These early complications can lead to longer-term issues, including incisional hernia, prolonged hospital length of stay, readmission, increased healthcare cost, and mortality. Thus, prevention of dehiscence and local infectious complications following emergency laparotomy remains a topic of academic and clinical importance. In efforts to mitigate these risks, recent academic interest has focused on the suture type and technique use in fascial closure. The majority of published data on laparotomy closure techniques is derived from the elective surgical environment, as such these findings do not fully translate to the unique challenges of emergency laparotomy. Elective procedures benefit from comprehensive preoperative planning, patient optimization, and controlled operative environments—factors that are often absent in the emergency setting. Emergency laparotomy is typically performed under time-sensitive, high-stress conditions with patients who may be hemodynamically unstable, coagulopathic, hypothermic, or suffering from intra-abdominal contamination. These factors contribute to the significantly higher risk of postoperative complications. Fascial closure using triclosan-coated barbed (TCB) suture has shown a reduction of local complications following elective laparotomy, but evidence in emergency laparotomy remains sparse. This study aims to determine the benefit of fascial closure with triclosan-coated barbed sutures in emergency laparotomy through a robust multicenter analysis.

Review what major published studies exist on the topic of the proposed project:

Data from elective case literature consistently demonstrates that optimal fascial closure techniques can mitigate the risk of wound complications. Specifically, the use of slowly absorbable monofilament sutures applied in a continuous fashion with a 4:1 suture-to-wound length ratio has been shown to reduce the incidence of incisional hernias, dehiscence, and SSIs. The rationale being distributing tension evenly along the fascial closure line minimizes localized

stress points that predispose to mechanical failure. Although initial data from non-trauma emergency laparotomies suggest that these principles may also apply in urgent/emergent settings, the generalizability of elective data to emergency and trauma populations remains uncertain due to differences in patient physiology, operative conditions, and tissue integrity.

Beyond technique, the choice of suture material itself may significantly influence outcomes. Triclosan-coated barbed (TCB) sutures have emerged as a promising alternative to conventional smooth monofilament sutures. The barbed design allows for even tension distribution without the need for knots, which can be potential sites of infection and mechanical weakness. Additionally, the triclosan coating provides antimicrobial properties aimed at reducing bacterial colonization along the suture line, thereby decreasing the risk of SSIs. In a prospective, randomized multicenter trial, Ruiz-Tovar et al. evaluated the efficacy of TCB sutures in emergency non-trauma laparotomy patients. Their findings demonstrated a significant reduction in SSIs and acute evisceration when compared to standard fascial closure techniques using triclosan-coated polydioxanone (PDS) looped sutures and non-coated PDS looped sutures. These results suggest that TCB sutures may offer both mechanical and antimicrobial advantages in the context of contaminated or high-risk abdominal closures.

The existing literature has notable limitations. Many studies are restricted by small sample size, limited follow-up periods, and a focus on non-emergency patients, which makes it challenging to extrapolate these findings to the breadth of acute care surgery populations. Acute care surgery patients often present with additional risk factors, such as coagulopathy, hypoperfusion, and complex injury patterns, which may influence wound healing dynamics and the performance of different suture materials. Furthermore, emergency general surgery and trauma cases frequently involve contaminated or open abdomens, conditions not adequately represented in existing trials.

The only study to date that has specifically evaluated the use of TCB sutures in both emergency general surgery and trauma laparotomy was a single-institution retrospective analysis. This study reported decreased incidence of fascial dehiscence and overall incision-related complications in patients whose fascial closures utilized TCB sutures compared to those closed with traditional PDS sutures. While these results are encouraging, the study's single-center design, potential for selection bias, and retrospective methodology limit the strength of its conclusions. Larger, multicenter studies are needed to validate these findings, assess the long-term impact on outcomes such as incisional hernia rates, and determine whether the benefits of TCB sutures extend across diverse patient populations and clinical settings.

Outline how this idea is innovative and it's anticipated impact:

Given the significant burden of postoperative complications following emergency laparotomy—including the long-term consequence of incisional hernia, which affects up to 500,000 patients annually in the U.S.—identifying optimal strategies for fascial closure is of paramount importance. A comprehensive evaluation of both suture technique and material, particularly in high-risk populations such as trauma and emergency general surgery patients, is critical for improving patient outcomes, reducing healthcare costs, and informing best practices in surgical care.

Describe what and how the MCT will add to the existing body of literature

There is currently a paucity of literature regarding the full breadth of the best technique to use when closing a laparotomy performed for emergency general surgery or trauma. While there have been studies describing the suture technique, the ideal suture has yet to be determined. Because TCB has shown promise in previous non-trauma studies, larger studies inclusive of the trauma and emergency general surgery populations are indicated to determine the true benefit. We aim to address this knowledge gap.

Specific Aims & Hypotheses

1. Aim: Compare the incidence of short-term incisional outcomes of emergency laparotomy facial closure with TCB vs conventional non-barbed sutures.

Primary outcome: Fascial dehiscence at within 30 days postoperatively.
Secondary outcomes: SSI and evisceration within 30 days postoperatively.

Hypothesis: The use of TCB suture will result in lower rates of fascial dehiscence, evisceration, SSI, compared to conventional non-barbed sutures.

2. Aim: Compare the incidence of long-term incisional outcomes of emergency laparotomy facial closure with TCB vs conventional non-barbed sutures.

Primary outcome: Incisional hernia within 12 months postoperatively.

Hypothesis: The use of TCB sutures will result in lower rates of incisional hernia compared to conventional non-barbed sutures.

Methods

This study will be a prospectively collected observational study with a retrospective arm performed on patients undergoing emergent laparotomy for trauma and emergency general surgery. The retrospective arm will include patients collected over three years (2021-2024) utilizing the appropriate STROBE guidelines for observational studies. Patients will be identified from each participating center's registry and/or electronic health record. The prospective observational arm will enroll patients over 6 months (July 2025 -December 2025) and will observe patients for 12 months after fascial closure using the appropriate STROBE guidelines for observational studies. Patients in the prospective arm will be identified by each participating center at the time of initial laparotomy fascial closure starting from the time the center is officially enrolled in the study. The study cohorts will be established based on the management of the initial fascial closure. Patients who were closed with TCB sutures will be compared to those patients whose fascia was closed with non-barbed sutures. Participating centers can include patients in the retrospective arm, enroll patients in the prospective arm, or both.

Study Design:
Retrospective Component: Observational cohort study from 2021-2024 using data from trauma registries and electronic medical records.

Prospective Component: A cohort of patients undergoing emergency laparotomy will be identified and followed for 1 year to assess long-term outcomes.

Inclusion Criteria:
- Patients $\geq$18 years undergoing emergent midline laparotomy for trauma or emergency general surgery with primary fascial closure during the same hospital admission

Exclusion Criteria:
- Age <18, pregnant, incarcerated, patients whose index operation or fascial closure was performed at an outside institution and transferred to the enrolling site, patients who were transferred to an outside hospital after their index operation and/or fascial closure was performed at the enrolling site, fascial closure with permanent or braided suture, or death within 30 days post-laparotomy.

How will the project be conducted:

Each participating center will obtain individual IRB approval to access the electronic medical record of each patient who meets inclusion criteria from their respective registry. Data will be collected according to a data collection tool provided by the coordinating institution. Each center will upload de-identified data to a centralized REDCap database supported by the Medical College of Wisconsin. Data use agreements will be obtained should a participating institution require a DUA to share de-identified data. Data will then be collated for analysis. As this is an observational study, no specific interventions are required, and patients will have been managed at the surgeon's discretion. There will be no payments or cost to the subjects for participating in this study as it is an observational review. Given the minimal risks of this study, a waiver of consent will be requested.

Aim 1: Compare the incidence of short-term incisional outcomes of emergency laparotomy facial closure with TCB vs slowly absorbable monofilament non-barbed sutures.

Primary outcome (retrospective and prospective arm)- The primary outcome will be fascial dehiscence measured within the first 30 days after abdominal fascial closure following emergency laparotomy. Fascial dehiscence will be defined as the separation of the previously approximated abdominal fascial diagnosed clinically or radiographically. Outcomes will be measured at the time of discharge and at 30 days postoperatively after abdominal closure if the patient remains hospitalized or at the time of first postoperative visit, whichever occurs first.

Secondary outcomes (retrospective and prospective arms)- The secondary outcomes will be SSI and evisceration measured within the first 30 days after abdominal fascial closure following emergency laparotomy. SSI will be defined according to the CDC definition of SSI. Evisceration will be the protrusion of abdominal contents/viscera outside the wound with exposure to the atmosphere. This will be diagnosed clinically. Outcomes will be measured at the time of discharge and at 30 days postoperatively after abdominal closure if the patient remains hospitalized or at the time of first postoperative visit, whichever occurs first.

Aim 2: Compare the incidence of long-term incisional outcomes of emergency laparotomy facial closure with TCB vs slowly absorbable monofilament non-barbed sutures.

Primary outcome (prospective arm only)- The primary outcome will be incisional hernia within 12 months after abdominal fascial closure following emergency laparotomy. Incisional hernia will be defined as the fascial defect along the incision with or without the protrusion of abdominal contents noted clinically or radiographically following discharge from the hospital. Outcomes will be measured using the EHR up to 12 months postoperatively. If a 12-month

follow-up visit was not completed by the enrolling institution, a phone call will be made by that institution to the patient to ascertain symptomatic hernia occurrence.

Variables to be collected:
Checked boxes: Baseline participating institution information, demographics, baseline clinical characteristics, hospital course, treatments and interventions, outcomes of interest

Additional variables: Patients will be evaluated based on the type of suture used at the initial fascial closure. Extracted clinical variables will include demographic data (age, sex, BMI, comorbidities, smoking status, preoperative steroid use, preoperative immunosuppression medications, prior laparotomy, prior abdominal mesh placement, preoperative diagnosis, mechanism of injury, injury severity score [ISS], emergency surgery score [ESS], abdominal AIS, and ASA), procedural data (operative procedures performed, presence of associated injuries, wound class, degree of contamination, blood product utilization before fascial closure, blood product utilization after fascial closure, damage control laparotomy, temporary abdominal closure, number of operations before fascial closure, suture size, number of sutures used, interrupted vs. continuous bites, suture:wound ratio, presence of fascial closure device, presence and type of mesh, use of direct peritoneal resuscitation, presence of skin closure, use of fascial ICG, presence of wound vacuum device, presence of incisional vacuum device, and timing of facial closure [if not performed during index laparotomy]) and postoperative occurrences (superficial surgical site infection [SSI], deep SSI, organ site infection, dehiscence, evisceration, fascial necrosis, hernia, need for unplanned abdominal reoperation, need for negative pressure wound therapy (if not already placed), bacteremia, sepsis, presence of postoperative steroids, need for prolonged [>7 days] postoperative antibiotics, and length of stay [LOS]),

Data Collection

Outline the data collection tool/plan succinctly

Participating institutions will utilize their registries, EHR, and/or operative case reports to identify patients meeting the inclusion criteria described above. Each patient's medical record number will then be used to access the electronic medical record. Data collection will then be performed based on the data collection tool provided. Data will be collected via local participant registries, clinic visits, and electronic health records. Each participating institution will then upload each patient's data onto a REDCap database once a DUA has been obtained.

Each patient will be de-identified and will be given a unique ID number within the study to limit the risk of loss of confidentiality. The REDCap database will be password protected and access will only be given to key personnel on each institution's research team. Once the REDCap database is complete, the PI and Co-PI at the host institution will download and collate the data on password-protected computers. Data sharing will only take place between approved research team members through HIPAA-compliant email

Has IRB approval been obtained at the primary site: Yes

Is DUA required for participation in this study: Not from the primary site

List the primary contact (name/email) to contact to initiate the DUA: Madison Rundell; mrundell@mcw.edu

Identify the individuals that will primarily be responsible for the data collection process: At our institution the PI will primarily be responsible for the data collection process. Designated surgical critical care fellows, residents, or medical students may also assist with the data collection process at the discretion and under the direction of site PI. Each participating institution will identify a site PI and one additional study member as Co-PI to collect data.

Include detailed description of data analysis plan:
Standardized data will be collected for each patient via the data collection tool provided. Retrospective data will be collected from January 1, 2021 through December 31, 2024. Prospective data will be collected from July 1, 2025 through December 2026. De-identified patient data will be entered into the REDCap database. Descriptive statistics for baseline characteristics will be compared using Chi-square/Fisher's exact test (categorical variables) and Mann-Whitney U test (continuous variables). Descriptive statistics will be reported as the mean +/- standard deviation for continuous normally distributed data, skewed data will be reported using median [IQR], and as frequencies for categorical variables. Univariate logistic regression will be used to evaluate the effect of candidate variables and type of suture on patient outcomes. Potential confounding variables will be adjusted for and controlled for using a multivariate regression model. The dependent outcome variables will be dehiscence (short-term aim) and hernia (long-term aim). Kaplan-Meier survival analysis for time-to-event data (hernia occurrence, reoperation). Statistical significance will be set at $p<0.05$.

Subanalysis, similar to above, will be performed on operations performed for trauma and EGS. Additional subanalysis will be performed on patients who underwent damage control laparotomy and had fascial closure performed on a date after the index operation.

Include power analysis:

A previous single center retrospective study demonstrated a fascial dehiscence rate of 4.1 % in the TCB group and a fascial dehiscence rate of 13.5% in the PDS group. Using this data and an intraclass correlation coefficient assuming 8 centers, the proposed study will require a total sample size of 384 patients (192 in each cohort) to achieve an alpha of 0.05 and 80% power.

What does the enrollment procedure for this study entail:

Patients will be identified at each institution as meeting inclusion criteria through the site patient registry, EHR, and/or resultant operative reports. De-identified data will then be abstracted from the medical record and uploaded to a REDCap database once a data use agreement has been obtained. As this is a observational chart review, patients will not be paid to participate, nor will there be any costs accrued as a result of being a part of this study. While there are no direct benefits to the participants, the knowledge gained from this study may benefit trauma and emergency general surgery patients in the future.

Outline the consent process here, if applicable:

As this is an observational study with minimal risk to each participant, a waiver of consent is requested. All collected data is pre-existing in the patient's medical record at the time of collection and thus will not impact their future care. Data that is collected will be recorded on a data collection sheet and will then be transferred to a secure REDCap database with no patient identifiers.

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References

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Project Title: Evaluation of Triclosan-Coated Barbed Suture Following Emergency Laparotomy: A Multicenter Retrospective and Prospective Cohort Study

Introduction:

Emergency laparotomy carries high morbidity and mortality risks, with fascial dehiscence and SSI rates from 10–45% in high-risk patients. While elective surgery studies support optimal closure techniques using slowly absorbable monofilament sutures, these findings have not been meticulously validated in emergency settings, where factors like patient instability and contamination are common. The ideal suture choice has not been extensively studied in fascial closure following laparotomy for trauma and emergency general surgery. A single-center retrospective study indicated that triclosan-coated barbed (TCB) sutures may reduce complications compared to traditional slowly absorbable monofilament sutures, but its short-term outcomes and limitations restrict broader applicability. This study aims to address the knowledge gap by validating TCB efficacy in emergency laparotomy and evaluating long-term outcomes such as incisional hernia rates through a robust multicenter analysis. We hypothesize that using TCB sutures for abdominal fascial closure following emergency laparotomy will result in lower rates of fascial dehiscence, SSI, and long-term incisional hernias compared to conventional non-barbed sutures.

There are two specific aims of this proposed trial:

1) **Understand the effect on short-term local outcomes of abdominal fascial closure using TCB sutures following emergency laparotomy.** The first objective of this study is to assess the effects of TCB suture fascial closure on local incisional short-term outcomes after emergency laparotomy. Through both retrospective and prospective observational study design, preoperative and short-term incisional outcomes data will be collected on patients undergoing emergency laparotomy. Retrospective data will be collected from 2021-2024, and prospective data will be collected starting at the official site enrollment. Local wound complications, including dehiscence, evisceration, and SSI, will be collected and evaluated using the electronic health records. We hypothesize that short-term dehiscence, evisceration, and SSI rates will be lower in patients whose fascial was closed with TCB sutures compared to conventional non-barbed sutures.
2) **Understand the effect on long-term local outcomes of abdominal fascial closure using TCB sutures following emergency laparotomy.** The second objective of this study is to assess the effects of TCB suture fascial closure on local incisional long-term outcomes after emergency laparotomy. Through prospective observational design, patients undergoing emergency laparotomy will be followed for 12 postoperative months. Local wound complications, including dehiscence and hernia, will be prospectively collected and evaluated using the electronic health records. We hypothesize that long-term dehiscence and hernia rates will be lower in patients whose fascia was closed with TCB sutures compared to conventional non-barbed sutures.

Conclusion: Emergency laparotomy carries the inherent risk of short and long-term incisional morbidity. The ideal fascial closure strategy has yet to be robustly studied and identified in the acute care population, including both emergency general surgery and trauma patients. This will be the first study to prospectively evaluate the use of TCB in emergency general surgery using a large patient cohort. The results from this study will better delineate the ideal strategy for fascial closure following laparotomy in acute care surgery patients.

Specific Aims & Hypotheses

1. **Aim**: Compare the incidence of short-term incisional outcomes of emergency laparotomy facial closure with TCB vs slowly absorbable monofilament non-barbed sutures.
   Primary outcome: Fascial dehiscence at within 30 days postoperatively.
   Secondary outcomes: SSI and evisceration within 30 days postoperatively.
   Hypothesis: The use of TCB suture will result in lower rates of fascial dehiscence, evisceration, SSI, compared to slowly absorbable monofilament non-barbed sutures.

2. **Aim**: Compare the incidence of long-term incisional outcomes of emergency laparotomy facial closure with TCB vs slowly absorbable monofilament non-barbed sutures.
   Primary outcome: Incisional hernia within 12 months postoperatively.
   Hypothesis: The use of TCB sutures will result in lower rates of incisional hernia compared to slowly absorbable monofilament non-barbed sutures.

Inclusion Criteria
Patients ≥18 years undergoing emergent midline laparotomy for trauma or emergency general surgery with primary fascial closure during the same hospital admission.

Exclusion Criteria
Age <18, pregnant, incarcerated, patients whose index operation or fascial closure was performed at an outside institution and transferred to the enrolling site, patients who were transferred to an outside hospital after their index operation and/or fascial closure was performed at the enrolling site, fascial closure with permanent or braided suture, or death within 30 days post-laparotomy.

Consent
As this is an observational study, no specific interventions are required, and patients will have been managed at the surgeon's discretion. There will be no payments or cost to the subjects for participating in this study as it is an observational review. Given the minimal risks of this study, a waiver of consent will be requested.

Variables
See table below

Statistical Analysis Plan

a. Statistical tests that will be used to evaluate the hypotheses:
Descriptive statistics for baseline characteristics will be compared using Chi-square/Fisher's exact test (categorical variables) and the Mann-Whitney U test (continuous variables). Descriptive statistics will be reported as the mean +/- standard deviation for continuous normally distributed data; skewed data will be reported using median [IQR] and as frequencies for categorical variables. Univariate logistic regression will be used to evaluate the effect of candidate variables and type of suture on patient

outcomes. Kaplan-Meier survival analysis for time-to-event data will be performed (hernia occurrence, reoperation). Statistical significance will be set at $p<0.05$.

b. Sample size justification and power analysis, including:

A previous single center retrospective study demonstrated a fascial dehiscence rate of 4.1 % in the TCB group and a fascial dehiscence rate of 13.5% in the PDS group. Using this data and an intraclass correlation coefficient assuming eight centers, the proposed study will require a total sample size of 384 patients (192 in each cohort) to achieve an alpha of 0.05 and 80% power.

c. Handling of missing data:

Patients with missing data on outcomes will be not be involved in the outcomes analysis. Patients with missing data on key preoperative and operative factors will not be included in the analysis.

d. Confounding and bias control, including:

Potential confounding variables will be adjusted for and controlled for using a binomial multivariate regression model. Key preoperative and operative factors such as sex, wound class, ASA will be used in the overall regression models. Statistical significance will be set at $p<0.05$.

e. Planned subgroup analyses and sensitivity analyses:

Subanalysis, similar to above, will be performed on operations performed for trauma and EGS. The multivariate regression model for trauma patients will include sex, blood product use, and ISS score. The multivariate regression model for EGS patients will include sex, wound class, and ESS score. The dependent outcome variables will be dehiscence (short-term aim) and hernia (long-term aim).

Additional subanalysis will be performed on patients who underwent damage control laparotomy and had fascial closure performed on a date after the index operation.

f. Software to be used:

REDCap will be used for data collection. SPSS will be used for statistical analysis.

Table 1. Variables

Demographic	Definition	Comments
Age		
Sex		
BMI		
Comorbidities		
Preoperative diagnosis	Diagnosis based on reason for operation	
Mechanism of injury		Trauma patients only
ISS		Trauma patients only
ASA score		
Abdominal AIS		Trauma patients only
Emergency Surgery Score (ESS)		EGS patient only
Procedural Data		
Associated Injuries	Additional organs injured	Trauma patients only
Operative procedures performed		
Blood product utilization before fascial closure		
Blood product utilization after fascial closure		
Damage control laparotomy		
Temporary abdominal closure		
Number of abdominal operations before fascial closure		
Suture type		
Suture size		
Number of sutures used		
Continuous suture	Fascia closed with continuous bites	
Interrupted suture	Fascia closed with interrupted bites	

Suture:wound length ratio		
Presence of fascial closure device	Whitman patch, AbClo, fascial traction, etc…	
Presence and type of mesh		
Use of direct peritoneal resuscitation	Use and days used	
Skin closure at time of fascial closure		
Use of ICG for fascial integrity determination		
Presence of wound vacuum device	Including length of therapy	
Presence of incisional vacuum device	Including length of therapy	
Timing of fascial closure		If not performed at the index operation
Postoperative Occurrences		
SSI	per CDC definition	
deep surgical site infection	per CDC definition	
organ site infection	per CDC definition	
Dehiscence		
Evisceration		
Fascial necrosis		
Unplanned abdominal operation		
Need for new negative pressure wound therapy		
Bacteremia		
Sepsis		
Postoperative steroids		
Prolonged antibiotics	>7days	
Length of stay		