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Clinical Abstract

Use of BloodSTOP iX Hemostat for Life-threatening Hemorrhage in Intra-abdominal Damage Control Surgery

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Background: BloodSTOP iX, is an etherified, sodium carboxymethyl cellulose matrix which achieves hemostasis by activating the intrinsic coagulation pathway, accelerating thrombin formation, and assisting with aggregation of platelet deposition. It has been used in several hemorrhage control scenarios with great utility. Its efficacy is well established in treatment of severe burns during excessive hemorrhage from debridement and grafting, with an excellent safety profile. While some animal data exists, there is a paucity of data evaluating its benefit when used in damage control surgeries and exploratory laparotomies in human subjects. This retrospective review evaluates the benefit of BloodSTOP iX in damage control surgery/exploratory laparotomies in trauma.

Methods/study design: This retrospective study analyzed twenty-three patients undergoing a collective total of forty-eight damage control exploratory laparotomies. Each case was analyzed with respect to blood utilization, operative time for damage control surgery, and lack of complications post op, along with safe return to operative theater with evaluation of hemorrhage control. The use of packed red blood cells prior to, during, and after surgery for a period of twenty-four hours was also examined. Lastly, each case was reviewed for development of an intra-abdominal abscess for a period of thirty days after abdominal closure.

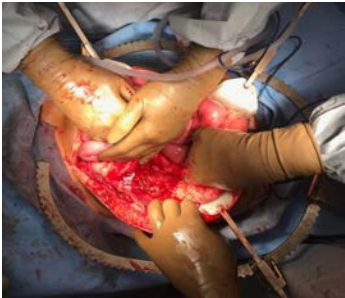
Results: A total of 51 exploratory laparotomies from 2019 through June 2021 were studied. Of these cases, three were excluded for lack of life threatening intra-abdominal hemorrhage during operation. Hemorrhage control was achieved with BloodSTOP iX in all of the 48 cases; 16 cases had a second look laparotomy with abdominal closure, and the other 32 cases required no further operative intervention. In the 16 cases with second look laparotomy/operation, there was no evidence of retained BloodSTOP iX, and there was no evidence of any further hemorrhage, and all abdomens were able to be closed on second look laparotomy. Post operatively, in all cases, blood transfusion was reduced. Overwhelmingly, BloodSTOP iX reduced the amount of PRBC transfusions: an average of 1.25 units of PRBC was transfused in cases where damage control surgery was followed by immediate abdominal closure, whereas an average of 6.75 units of PRBC's was transfused in cases requiring second look laparotomies. Upon review of all cases, only three intra-abdominal abscesses were reported; all three were attributable to distal pancreatectomy with resultant pancreatic leak.

Conclusions: This study demonstrated a measurable reduction in the use of blood products, operative time, and need for re-operation due to superior hemorrhage control in patients undergoing damage control exploratory laparotomy where BloodSTOP iX was used. In this retrospective review, BloodSTOP iX demonstrates an extreme safety profile, identified by lack of post-operative death and lack of post-operative intra-abdominal infection. Further studies, in a prospective, multi-institutional format are needed to determine whether BloodSTOP iX could be indicated for use as a standardized hemostatic agent in intra-abdominal surgery.

Disclosure: The author(s) received no financial support for the research, authorship, and/or publication of this article. The author/principal investigator is the sole researcher of this clinical abstract and further on-going research are in progress with a multi-center collaboration pending.

Disclaimer: BloodSTOP iX products are US FDA 510(k) cleared for external temporary control of minor to moderate bleeding of traumatic wounds. This study abstract concerns absorbable use, which has not been approved by US FDA.

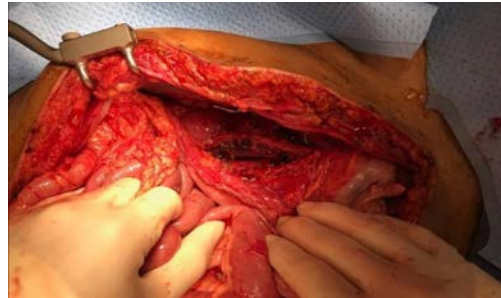
Blunt Abdominal Trauma Injury



Retroperitoneal bleeding

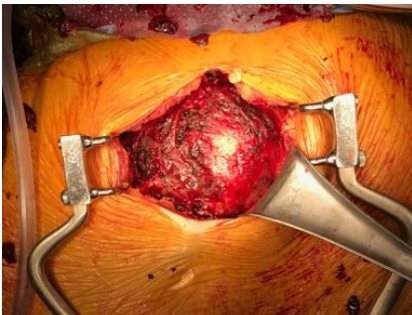


BloodSTOP iX Trauma Matrix applied

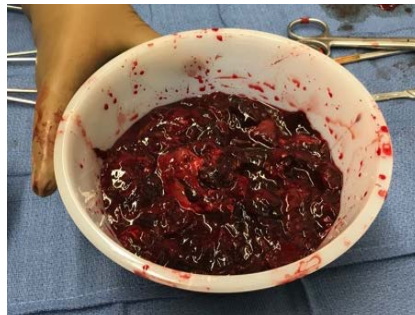


Second look operation, complete control of hemorrhage, dry and clean

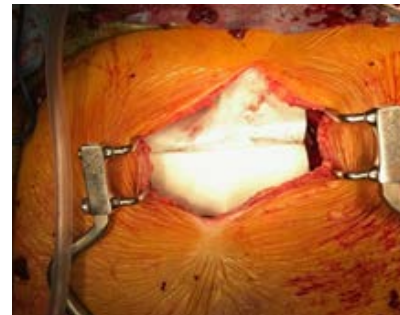
Hematoma Removal



Large abdominal clot

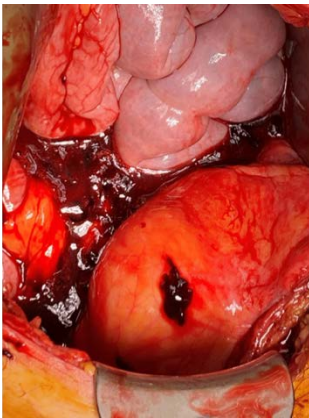


Removed clot

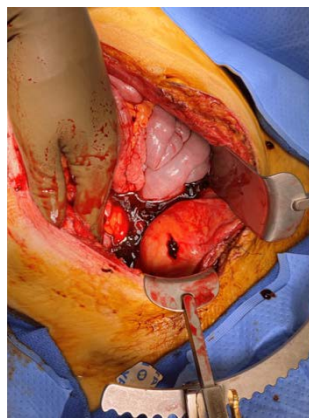


BloodSTOP iX placed at the base of the clot

Gunshot Wound to Pelvis



Abdomen/bladder on post-op day 1



No active hemorrhage identified



Removed clot from pelvis

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