



Use of PerClot[®], a Plant-Based Polysaccharide Hemostat, for Bleeding Control of the Sternum in High Risk Patients

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Introduction

Profuse bleeding or persistent oozing from the sternal bone after sternotomy is routinely controlled with bone wax. Unfortunately, bone wax has been shown to inhibit osseous fusion, promote infections, and elicit an inflammatory reaction.^{1,2,3} At our institution, there is an increasing number of patients at high risk for sternal instability and wound healing complications following cardiac surgery; improved methods for bleeding control of the sternum without the use of bone wax are required.^{4,5,6} We present an alternative technique to control bleeding from the sternal bone using PerClot[®] Polysaccharide Hemostatic System (hereinafter referred to as PerClot), a plant-based hemostat manufactured by Starch Medical Inc. (San Jose, California).

PerClot is a medical device composed of absorbable polysaccharide particles and delivery applicators. These particles are biocompatible, non-pyrogenic, do not contain any human or animal components, and are manufactured from a purified plant-based polysaccharide using proprietary modification process. The particles can be applied directly to a bleeding wound to help obtain hemostasis. The hemostatic effect of PerClot results from the rapid dehydration of blood and subsequent concentration of red blood cells, platelets, and serum proteins (thrombin, fibrinogen, etc.), which accelerates the clotting cascade and produces a gelled adhesive matrix. Normal platelet activation and fibrin deposition produce a clot that limits further bleeding.

Methods

Cohort Study

A prospective, single-arm study was conducted at the University Hospital Grosshadern, Ludwig-Maximilians-University in Munich, Germany. The principles set forth in the Declaration of Helsinki were followed in this study. Twenty-one patients undergoing coronary surgery requiring median sternotomy received a single application of PerClot to help control sternal bleeding.

Results

Cohort Study

Control of sternal bleeding was observed in 18 cases. In 2 patients, persistent bleeding was noted and additional applications of PerClot were needed. In one case, continuous mild bleeding was noted throughout the operation; however, additional treatment was not necessary. No adverse events (e.g., unstable sternum, deep wound infection, general infection, graft alteration, or any severe organ dysfunction) or allergic reactions were observed. There were no cases of in-hospital mortality or morbidity observed during the three month follow-up duration. No reoperations due to graft alteration, bleeding, or unstable sternum were necessary. No irritation of by-pass-grafts was noted. None of the patients required refixation for instable sternum. One patient experienced a superficial wound infection unrelated to PerClot, requiring an outpatient procedure in which the wound was cleaned and secondary wound closure was performed.

Case Report

A 77-year-old male with unstable angina was referred for surgical revascularization. The patient's medical history included insulin-dependent diabetes, chronic obstructive lung disease, and obesity (Body Mass Index = 36).

After median sternotomy, severe osteoporosis was visible and there was excessive bleeding from the sternal bone. To control bleeding from this fragile sternum, electrocautery to the periosteum was used sparingly and PerClot was applied on each side of the sternal spongiosa (Figure 1).



Figure 1

Towels were wrapped around the absorbable hemostat for atraumatic management of the tissue before the thorax was opened. The patient was fully heparinized (Activated Clotting Time >300 seconds) and underwent off-pump coronary bypass grafting of the left internal thoracic artery to left anterior descending artery, circumflex artery, and right coronary artery. After the procedure, protamine was administered to reverse the effects of heparin. No additional applications of PerClot were required and the sternum was closed with wires.

The patient had an uneventful intraoperative and postoperative course. The sternal spongiosa was intact and no sternal fracture was observed. No enhanced bleeding, infection, or sternal wound healing complications occurred. The patient was discharged 8 days after hospitalization and at 3 months, was in good physical conditions presenting with no cardiac symptoms, wound infections, or other adverse events.

Additional Applications

In addition to using PerClot to control sternal bleeding, PerClot has also been used at our institution to achieve hemostasis in the following cases:

- During a combined aortic valve and supraannular aortic replacement, PerClot was applied around a native tissue and aortic Dacron-prosthesis anastomosis.
- PerClot was applied to the suture line for excessive bleeding from beyond the right pulmonary vein after epicardial ablation of the left atrium and pulmonary veins.
- Excessive bleeding after the placement of a thoracic drain (pleural catheter) on the left side required the use of PerClot and towels with compression to control bleeding.

Discussion

Surgeons commonly recommend avoiding the use of bone wax for control of sternal bleeding, especially in patients at high-risk for infection or nonunion.⁷ At our institution, bone wax is often not effective in elderly patients and those with osteoporosis; additionally, the spongiosa scaffold of the sternum is

destroyed during the setting of bone wax, which may result in the marrow cavity absorbing large quantities of the product without the achievement of hemostasis.

Despite the negative effects associated with the use of bone wax, the product remains in widespread use, presumably due to the perceived lack of suitable alternatives. As shown in our cases, PerClot is a simple, safe, and effective method for bleeding control in high-risk patients. We had satisfactory intraoperative bleeding control in most cases. There were no in-hospital mortalities and no patients requiring reoperation because of bleeding or instable sternum. None of the patients developed a deep sternal wound infection.

Other hemostatic agents like fibrin sealant or microfibrillar collagen are also efficacious, but are relatively expensive. Additionally, in our department, we are currently not using fibrin glue due to a possible correlation with increased morbidity.^{8,9} We also do not recommend microfibrillar collagen because of the potential for the small diameter of its needle-shaped structure passing through the filters of blood salvage systems, thereby entering the patient's circulation and possibly resulting in organ damage.¹⁰ In 2003, we evaluated the first generation of these innovative polysaccharide hemostats. Based on our observations in this series, we believe PerClot exhibits a greater hemostatic efficacy (decreased time to hemostasis and increased clot strength) and represents a new and improved generation of polysaccharide hemostatic agents.

In conclusion, to avoid sternal bleeding complications and wound healing problems including mediastinitis, PerClot can be administered safely and effectively.

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