Fibrin sealant patch for temporary intraoperative hemostatic control of large vessel wounds: Feasibility study.

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Abstract:

Objective: Injuries resulting in large blood vessel defects create a vexing surgical challenge. Optimal surgical management demands immediate control of bleeding from the defect to facilitate stabilization of the patient and execution of the surgical plan for vascular control and definitive repair of the defects. Fibrin sealant patch (FSP) device technology has hemostatic capability that may fulfill the needs for temporary hemostatic control of large blood vessel injuries. The feasibility of two different FSP technologies for this purpose was evaluated in a porcine aortic injury model. Methods: The efficacies of two different FSP devices (FSP-1, FSP-2) were evaluated in an acute heparinized porcine aortic injury and repair model. Evaluations included: 1) achievement of hemostasis at a 4.4 mm aortic biopsy punch wound, 2) maintenance of hemostasis for a 3-hour period with a mean arterial pressure of >= 60 mmHg; 3) ability to be removed after 3 hours of hemostasis; and 4) allowance for subsequent repair of the vascular defect by suturing. Treatment sites were also examined histologically. Results: FSP-1 achieved hemostasis in 3 out of 4 aortic injuries, and failed to achieve hemostasis at 1 test site due to adhesion failure. FSP-1 maintained hemostasis for the 3-hour period (3/3 injuries) and was successfully removed after 3 hours (3/3 injuries), allowing for repair of the aortic punch injuries by suturing (3/3 injuries). FSP-2 failed to achieve hemostasis after two sequential applications in 4 of 4 aortic injury test sites, with both cohesive and adhesive failures observed at each test site. No biologically significant adverse macroscopic or microscopic level findings (such as evidence of thrombus) were observed for either FSP-1 or FSP-2 treated sites. Conclusions: In this preclinical model, FSP demonstrated immediate hemostatic capability in

treatment of a punch defect in the aorta as well as acute maintenance of hemostasis, and could be removed to permit definitive surgical repair of the defect. Differences in FSP technologies may impact capability for this application, and require further investigation. FSP may be a new tool in the surgical management of large blood vessel defects to facilitate acute injury management and definitive repair.