

Hemostatic efficacy of EVARRESTTM, fibrin sealant patch vs. TachoSil in a heparinized swine spleen incision model.

Authors: Matonick J.P., Hammond J.

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Abstract:

Background: First-generation single-component hemostats such as oxidized regenerated cellulose (ORC), fibrin, collagen, and gelatin have evolved into second and third generations of combination hemostats. **Objective:** This study compares two FDA approved products, EVARRESTTM, Fibrin Sealant Patch, a hemostat comprised of a matrix of nonwoven polyglactin 910 embedded in ORC coated with human fibrinogen and thrombin to TachoSil medicated sponge, an equine collagen pad coated with human fibrinogen and thrombin.

Materials and Methods: Swine were anticoagulated with heparin to 3X their baseline activated clotting time and a 15 mm long x 3 mm deep incision was made to create a consistent moderate bleeding pattern. Test material was then applied to the wound site and compressed manually for 3 min with just enough pressure to prevent continued bleeding. Hemostatic effectiveness was evaluated at 3 min and 10 min.

Results: At 3 min, the hemostasis success rate was 86% in the EVARRESTTM group and 0% in the TachoSil group, $p < .0001$. The overall success rate at 10 min was 100% with EVARRESTTM and 4% with TachoSil, $p < .0001$. Adhesive failure, in which the test material did not stick to the tissue, occurred in 96% of TachoSil sites. In contrast, 100% of the EVARRESTTM applications adhered to the test site.

Conclusions: EVARRESTTM, Fibrin Sealant Patch demonstrated greater wound adhesion and more effective hemostasis than TachoSil. Adhesive failure was the primary failure mode for TachoSil in this model.

