

Safety and Hemostatic Effectiveness of the Fibrin Pad for Severe Soft-Tissue Bleeding During Abdominal, Retroperitoneal, Pelvic, and Thoracic (Non-cardiac) Surgery: A Randomized, Controlled, Superiority Trial.[Erratum appears in World J Surg. 2015 Oct;39(10):2610; PMID: 26216641]

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Abstract:

BACKGROUND: In surgery, rapid hemostasis can be required in various settings and bleeding intensities to minimize complications related to blood loss. While effective hemostats are available for mild-to-moderate surgical bleeding, few are effective against challenging severe hemorrhage. We report the effectiveness and safety of the fibrin pad (FP), a novel combination hemostat (device/human biologic), in controlling severe soft-tissue bleeding as compared to the standard of care (SoC).

METHODS: This randomized, controlled, superiority study enrolled subjects ≥ 18 years, requiring elective abdominal, retroperitoneal, pelvic, or thoracic (non-cardiac) surgery. A severe target bleeding site (TBS) was identified intra-operatively following which, subjects were randomized to the FP or the SoC group. Hemostatic status was observed at 4 min (primary endpoint) and 10 min post-randomization. Safety variables included TBS-related bleeding and thrombotic events.

RESULTS: At 4 min post-randomization, 50/59 (84.7 %) subjects in the FP group and 10/32 (31.3%) [Corrected] subjects in the SoC group achieved hemostasis without needing re-treatment ($P <$

0.0001). Compared to the SoC group, the FP group showed better hemostasis at 10 min post-randomization [58/59 (98.3 %) vs. 28/32 (87.5 %); $P = 0.01$], lower mean time to hemostasis (6.1 +/- 13.5 vs. 17.8 +/- 32.0 min), and a less frequent need for re-treatment (5.1 vs. 53.1 %). The triangular test for binary response demonstrated the FP to be superior to SoC (95 % CI 1.474-3.290; $P < 0.0001$). Safety profiles in both groups were similar to those typically observed after long-duration surgery.

CONCLUSION: The FP is safe and superior to SoC for controlling challenging severe soft-tissue bleeding encountered during intra-abdominal and thoracic surgical procedures.