Fibrocaps for surgical hemostasis: two randomized, controlled phase II trials.

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Abstract:

BACKGROUND: Fibrocaps, a ready-to-use, dry-powder fibrin sealant containing human plasma-derived thrombin and fibrinogen, is being developed as an adjunct for surgical hemostasis.

MATERIALS AND METHODS: Safety and efficacy of Fibrocaps applied directly or by spray device, in combination with gelatin sponge, was compared with that of gelatin sponge-alone in two randomized, single-blind controlled trials: FC-002 US (United States) and FC-002 NL (the Netherlands). A total of 126 adult patients were randomized (Fibrocaps: n = 47 [FC-002 US], n = 39 [FC-002 NL]; gelatin sponge alone: n = 23 [FC-002 US], n = 17 [FC-002 NL). One bleeding site was treated during a surgical procedure (n = 125). Time to hemostasis (primary end point) was measured, with a 28-d safety follow-up. Four surgical indications included hepatic resection (n = 58), spinal procedures (n = 37), peripheral vascular procedures (n = 30), and soft tissue dissection (n = 1).

RESULTS: Mean (standard deviation) time to hemostasis was significantly shorter after Fibrocaps treatment than after gelatin sponge alone (FC-002 US: 1.9 [1.3] versus 4.8 min [3.1], P < 0.001; FC-002 NL: 2.2 [1.3] versus 4.4 min [3.1], P = 0.004). The incidence of hemostasis was greater after Fibrocaps compared with that of gelatin sponge alone within 3 min (FC-002 US: 83% versus 35%, P < 0.001; FC-002 NL: 77% versus 53%, P = 0.11), 5 min (94% versus 61%, P = 0.001; 95% versus

71%, P = 0.022), and 10 min (100% versus 78%, P = 0.003; 100% versus 82%, P = 0.025). Adverse events were consistent with surgical procedures performed and patients' underlying diseases and generally similar between treatment arms; most were mild or moderate in severity. Non-neutralizing antithrombin antibodies were detected in 5% of Fibrocaps-treated patients on day 29.

CONCLUSIONS: Fibrocaps had good safety and efficacy profiles, supporting continuing clinical development as a novel fibrin sealant.