

Efficacy of topical hemostatic agents: a comparative evaluation of two gelatin/thrombin-based hemostatic matrices in a porcine kidney surgical model.

Slezak P, Heher P, Monforte X, Keibl C, Redl H, Spazierer D, Gulle H.

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OBJECTIVES

To compare the haemostatic efficacy of FloSeal gelatin-thrombin matrix (Baxter Healthcare) versus SURGIFLO™ gelatin-thrombin matrix (ETHICON)) in a porcine kidney bleeding model.

METHODS

Design

- This was a pre-clinical (animal) study.
- The study endpoint was blood loss before and 2, 5 and 10 minutes after treatment.

Subjects

- Four pigs were used in this study, each weighing approximately 35 kg.

Procedures

- Animals were anaesthetised and placed in dorsal recumbency, with lesions approximately 10 mm deep and 10 mm diameter created using biopsy punches. A total of eight lesions were created in each kidney.
- Each lesion was treated topically with either FloSeal or SURGIFLO™ Haemostatic Matrix Kit with Thrombin (MS0012, referenced as SURGIFLO™ in the following) in an alternating fashion.
- Blood loss was quantified by application of a pre-weighed dry gauze:
 - For 3 seconds prior to the use of any haemostatic agent.
 - For 30 seconds, and 2, 5 and 10 minutes after the use of haemostatic agent.
- The amount of blood taken up by the gauze was assessed by weight.
- The effect of initial bleeding rate on haemostatic performance was examined; a threshold of 29 mL/min was chosen to stratify lesions due to this being the median initial bleeding rate for lesions treated with SURGIFLO™.

RESULTS

- A total of 61 lesions (FloSeal, n=31; SURGIFLO™, n=30) were included in the analysis.
- Bleeding rate 2 minutes after haemostatic agent application was significantly lower for lesions treated with FloSeal than for those treated with SURGIFLO™ (p<0.0001; Table 1). However, at 5 and 10 minutes there was no statistical significance between the two products in terms of bleeding rates (Table 1).

TABLE 1: BLEEDING RATES WITH FLOSEAL VERSUS SURGIFLO HAEMOSTATIC AGENTS

Time point	FloSeal (n=31)	SURGIFLO™ (n=30)	P value*
Before application	27.6 (23.1–31.8)	29.1 (24.1–36.4)	NR
After application (mL/min), median (IQR)			
2 minutes	0.574 (0.390–0.924)	0.920 (0.518–1.786)	<0.0001
5 minutes	0.162 (0.132–0.230)	0.231 (0.181–0.317)	NS
10 minutes	0.104 (0.080–0.126)	0.155 (0.130–0.227)	NS

***Bold** style indicates statistically significant difference.

IQR: inter-quartile range; min: minute; NS: non-significant.

- For lesions with an initial bleeding rate of <29 mL/min, median bleeding rates were significantly lower for FloSeal (n=15) when compared with SURGIFLO™ (n=18) at 5 minutes (0.149 mL/min vs 0.242 mL/min; p<0.01) and 10 minutes (0.087 mL/min vs 0.154 mL/min; p<0.0001). Bleeding rate was not significantly different at 2 minutes.
- For lesions with an initial bleeding rate of ≥29 mL/min, median bleeding rate was significantly lower for FloSeal (n=12) when compared with SURGIFLO™ (n=13) at 2 minutes (0.567 mL/min vs 1.638 mL/min; p=0.040). Bleeding rate was not significantly different at 5 and 10 minutes.

CONCLUSION

- The authors concluded that FloSeal showed increased hemostatic efficacy in a severe, high-volume bleeding model of porcine kidneys when compared with SURGIFLO™. The authors suggest that these findings may be attributable to the differences in dry mass per unit volume and/or ultrastructural differences of the two adjunctive haemostats.

DECLARATION OF INTEREST

Two of the authors report conflicts of interest as they are full time employees of Baxter Medical Products GmbH. The study was funded by Baxter Healthcare Corporation. Meridian HealthComms Ltd provided writing assistance, which was paid for by Baxter Healthcare Corporation.