

Histological Evaluation of Synaero™ Hemostatic Gel

Pre-clinical Study Results in a Pig Model

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Introduction

A frequent complication of functional endoscopic sinus surgery (FESS) is the development of post-operative adhesions, which may block normal mucociliary drainage pathways of the sinuses. This blockage can cause a recurrence of sinusitis and require subsequent surgical procedures. To prevent post-operative bleeding and adhesion formation, nasal packing is often used. Alternatives to nasal packing include intranasal splints and gels, though the majority of these products employ the tamponade effect to achieve hemostasis, which can contribute to abnormal nasal breathing and significant patient discomfort. An optimal hemostat for endoscopic sinus surgery would effectively control bleeding and minimize adhesion formation, scar formation and inflammation of the mucosal tissue. The purpose of this pre-clinical study was to evaluate the post-operative performance of a novel hemostatic agent, Synaero™ Hemostatic Gel. Specifically, adhesion formation and healing of the mucosal injury were assessed in a pig model.

Materials and Methods

A porcine model published by Singer¹ was employed to mimic functional and morphological changes in mucosa following FESS. Mucosal stripping of the lateral nasal wall induced bleed rates characteristic of FESS in 10 Yorkshire pigs and Synaero Hemostatic Gel, an oxidized cellulose hemostat, was applied to control bleeding. Defect sites (n=10) were treated and allowed to heal for 2 weeks. At euthanasia, each site was qualitatively assessed for scarring, clot formation, nasal cavity patency and residual hemostatic material. Histological sections were taken from each defect site, stained with Hematoxylin and Eosin (H&E) and blindly evaluated by an independent pathologist to assess cell morphology, mucosal re-epithelialization and granulation tissue.

Results

All animals tolerated the surgeries well and returned to normal activity immediately. Intra-operative assessment showed that bleeding was effectively controlled at all defect sites in an average of 3.1 minutes following Synaero application. Endoscopic evaluation at necropsy indicated no evidence of adhesions, scarring or residual hemostatic material. No clots or signs of recent bleeding were observed and no gross inflammation or erythema was noted in any defect. Histological evaluation showed excellent re-epithelialization of all defect sites with no cellular abnormalities (Fig 1). No foreign material or granuloma formation was identified in any specimen. Quality of the underlying tissue was shown to be in a “healing” phase suggestive of a response to the mucosal stripping injury. A small amount of epithelial scarring was present in the normal range for this stage of healing, but no hypertrophic scarring was observed.

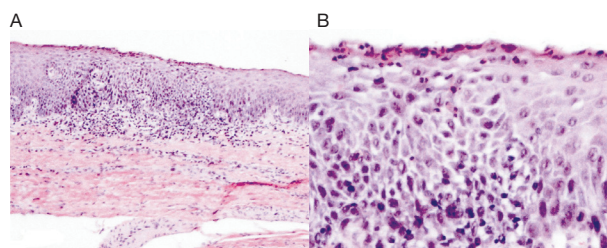


Figure 1. Representative histological appearance (H&E stain) at day 14 depicting re-epithelialization of defect with no granuloma formation (A - 10X, B - 40X).

Conclusion

The current pre-clinical investigation demonstrates that Synaero Hemostatic Gel can effectively control bleeding associated with FESS. Furthermore, the gel enables re-epithelialization of the mucosa and subsequent natural wound healing without adhesion or granuloma formation.

1 Singer AJ, McClain SA and Katz A. A porcine epistaxis model: hemostatic effects of octylcyanoarylate. *Otolaryngol Head Neck Surg*, 2004; 130(5): 553-557.