

by red arrows. (C) *En face* OCTA image shows increased microvasculature over the regions corresponding to the enlarged lumen (as indicated by red arrows), suggestive of inflammation.

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Use of a Novel Synthetic, Topical Gel to Enhance Healing Post Endoscopic Mucosal Resection: A Randomised, Blinded Preclinical Study



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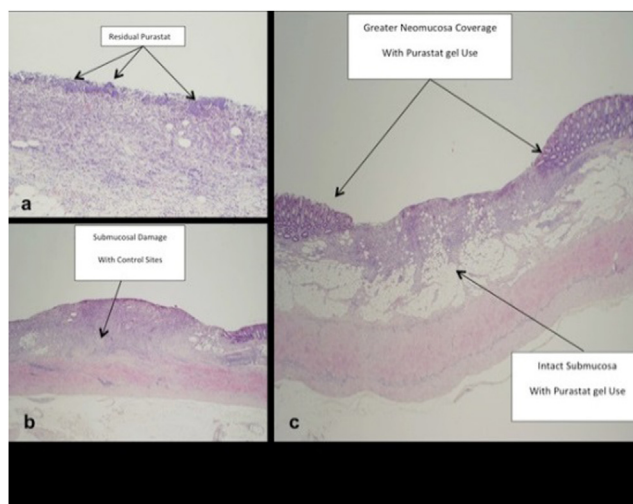
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Introduction: Submucosal Injection of biological agents immediately before mucosal polyp resection has been vaguely described but limited evidence regarding tissue repair after polyp excision. **Aims and Methods:** The purpose of this GLP (Good Laboratory Practise, registration study number: 3DM 281/16) randomised blinded animal study was to evaluate the performance of Purastat[®] Gel (a fully synthetic, non-biogenic, biocompatible, resorbable peptide hydrogel matrix scaffold, 3D Matrix, Japan) after mucosal resection in a porcine recovery model. We assessed the rate of primary healing on resection sites including the defect size and the cellular components of the wound healing process. In each animal, two resection sites were randomised to the treated (excision site covered with Purastat[®] Gel) and control (not covered with Purastat[®] Gel) groups. On days 0/3/6, all resection sites were measured using an open biopsy forceps. After a recovery period of 6 days, a full cellular histology analysis of all post-mortem sites/lymph nodes was reported blindly by an expert pathologist. Statistical analysis was performed using multilevel regression methods. **Results:** Four mucosal resection defect sites (day 0, control:20.9mm/SD+/-1, treated:21mm/SD +/-1.7) per four female pigs were created endoscopically using a 14mm Histolock snare (Diagmed, UK). No macroscopic immediate or delayed adverse events (bleeding/perforation) were reported. Defect sites were measured under the light microscope (day 6, control group 10.6mm/SD+/- 3.1, treated group 9.3mm/SD+/- 4.0) (Table). A trend was noted towards a greater reduction in size in the Purastat[®] Gel group, particularly on the day 6 measurements, suggesting that the defect size in the treated sites was 9% (p=0.16) smaller than in the control sites.

No observed microscopic perforations were observed in any of these defect sites. Geometry and integrity of the component tissues was retained in all sites after resection. Visible Purastat[®] Gel particles were seen in 42% of the treated sites, keeping a normal reparative cellular presence (Image a). Local lymph nodes resected showed normal architecture. The full thickness histological analysis revealed a greater neomucosa coverage (control:7.2mm/SD+/-0.9, treated:10mm/SD+/-5.3, p=0.05) within the Purastat[®] Gel sites (higher coverage of 3%) (Image c). Furthermore, a lesser submucosal damage (control:75%, treated:25%, p=0.08) was noted in the sites treated by Purastat[®] Gel (Image b/c). **Conclusion:** Purastat[®] Gel appears safe and remains visible on many excision sites 6 days after endoscopic resection. Histological assessment demonstrated a cellular boost to the primary healing process by enhancing the neomucosa coverage and restricting of submucosal damage. A marginal decrease of defect size was observed when Purastat[®] Gel was applied. A long-term survival animal study is warranted.

Outcomes of randomised preclinical study

Measurement	Control Mean SD	Purastat Gel Mean SD	Odds Ratio Mean (95% CI)	P-value
Defect size (mm)	-7.3 (3.4)	-8.8 (3.1)	-1.5 (-3.7, 0.6)	0.16
Day 0 to Day 6				
Neomucosa coverage (%)	7.2 (0.9)	10.0 (5.3)	3.2 (-0.1, 6.5)	0.05
Submucosal damage (%)	6 (75%)	2 (25%)	0.13 (0.01, 1.24)	0.08



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The Usefulness of EndoClot[™] Polysaccharide Hemostatic System in Non-Variceal Upper Gastrointestinal Bleeding



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Introduction: Despite advances and increased expertise in managing upper gastrointestinal bleeding (UGIB), the associated mortality and adverse events have been a burden for endoscopists. EndoClot[™] Polysaccharide Hemostatic System (PHS) is a starch-derived compound that consists of biocompatible absorbable hemostatic polysaccharides. The aims of our study were to assess the efficacy of the EndoClot[™] PHS in patients with non-variceal UGIB. **Methods:** We retrospectively analyzed consecutive 22 patients with UGIB treated with EndoClot[™] PHS between April 2016 and October 2016. The data were obtained from a prospectively established database. EndoClot[™] PHS was applied through a plastic catheter which was pushed through the working channel of any diagnostic or therapeutic endoscope. In contact with blood, it rapidly absorbed water, causing a high concentration of platelets, red blood cells and coagulation proteins at the bleeding site. After the procedure, patients were treated with high-dose proton pump inhibitors (PPIs) intravenously for 3 days thereafter standard dose of PPIs orally for at least 2 weeks. We analyzed the successful rate of hemostasis and re-bleeding rate. **Results:** Twenty-two patients who were treated with EndoClot[™] PHS were included. Peptic ulcer was the major cause of bleeding (15 patients). Six patients showed post-procedure bleeding (3 cases due to unroofing biopsy for superepithelial tumor and 3 cases due to endoscopic submucosal dissection). The remaining one patient showed radiation gastritis. Among the peptic ulcer and post-procedure bleeding, 1 case (4.5%) was classified to Forrest Ia, 17 cases (77.3%) were classified to Forrest Ib and 4 cases (18.2%) were classified to Forrest IIa. Of total 22 patients, 6 were treated with EndoClot[™] PHS alone (2 peptic ulcers, 1 unroofing biopsy, 2 post-ESD bleeding, and 1 radiation gastritis) and hemostasis was achieved without any adverse events. Sixteen patients were initially treated with conventional hemostatic method including epinephrine injection, electrical coagulation, hemoclips or argon plasma coagulation. Then they were further treated with EndoClot[™] PHS. Immediate hemostasis was achieved in all patients. Re-bleeding was observed in only 1 patient (4.5%), who was treated with EndoClot[™] PHS alone. The re-bleeding was occurred after 1 day from the hemostasis. **Conclusions:** EndoClot[™] PHS seemed to be a feasible modality for endoscopic treatment of UGIB due to the ease to use and the safety and also, it could reduce the re-bleeding rates when it combined with other hemostatic modalities. Therefore, EndoClot[™] PHS would be one of a new promising hemostatic method for non-variceal UGIB, although, more large group and comparative studies would be needed to confirm this.