Biodegradable 3D-printed Gastrointestinal Stents for Use in Small Bowel

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Introduction

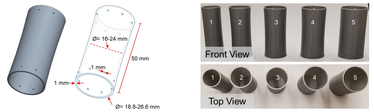
- Small bowel anastomotic breakdown sequelae include leaks, abdominal sepsis, re-operation, ileostomy creation or development of EC fistula
- These consequences can be devastating to the patient, particularly ileostomies or EC fistula
- Stents for use in esophagus and colon are available and can help heal a leak or protect an anastomosis
- These stents require endoscopy to place and to retrieve, which is difficult within the small bowel
- There are no tools currently to protect a small bowel anastomosis or help it heal without breakdown
- Poly(lactic acid) (PLA) is an FDA approved biodegradable polymer and can be used with 3D printers to create devices of any required size

Methods

- Biodegradable stents were created and placed within the lumen of small bowel anastomoses in pig models
- 1cm gaps were left open at the small bowel enterotomies used to place the small bowel
- Pigs were monitored for 2 weeks, and then necropsy was performed
- CT was performed at 1 week to evaluate for stent migration
- SEM/histology were used to evaluate stent after removal

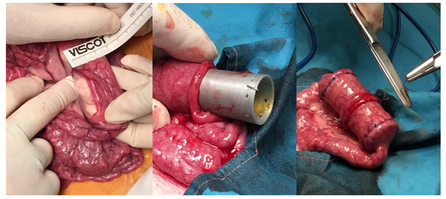
Stent Creation

- Stents were 3D printed out of PLA in multiple sizes



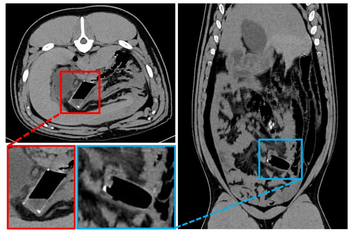
Stent Placement

- 4 pigs were used for this study
- Mini laparotomy was used to access the abdomen
- Small bowel was identified and enterotomy created over more than 50% of the circumference
- Stent of appropriate diameter was placed within the lumen and sutured in place via the holes at both ends
- Vascular clips were used to tag the stent as well as suture outside the bowel
- Enterotomy was closed, leaving 1cm gap with visible stent

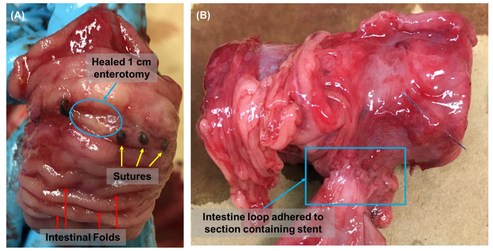


Results

- Pigs were kept on liquid diet for 2 weeks and monitored closely
- CT scans were performed at 1 week, which showed the stents in good position with no migration



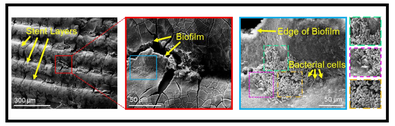
- Necropsy was performed at 2 weeks
- There were no signs of sepsis or intra-abdominal infection or abscess
- Enterotomies had healed well, although there were some adhesions around the enterotomy site
- One stent was 5cm distal to placement site



(A) Evaluation of the 1 cm enterotomy site through turning the inside of the intestine outward. The 1 cm enterotomy has healed without fistula. Sutures and intestinal folds can be observed on the inner surface of the intestines. (B) Adhesion of an intestinal loop to the intestinal segment containing the stent.

Results

- SEM/histology was used to evaluate the stent post explantation
- No mechanical failures were noted in the stents
- Biofilm was noted on the stents



Conclusions

- No pigs developed sepsis despite leaving 1cm enterotomy
- No pigs were found to have signs of intra-abdominal infection or abscesses on necropsy
- Small bowel enterotomies healed without fistula
- Small bowel stents can be used to help protect and heal tenuous anastomoses

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