A NOVEL MAGNETIC ANASTOMOSIS DEVICE FOR FULLY INTRACORPOREAL GASTROINTESTINAL ANASTOMOSIS

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Introduction

The majority of anastomoses are created using surgical staplers, typically performed outside the body. However, intracorporeal anastomoses are associated with reduced length of hospital stay, lower pain medication, and faster return to bowel function when compared to their extracorporeal counterpart [1]. Additionally, staples have demonstrated inferior tissue healing metrics compared with compression devices for anastomosis creation [2] [3], culminating in an overall sub-optimal therapy. Notably, traditional staplers often result in incomplete anastomoses, necessitating additional suturing. Furthermore, when performed laparoscopically, this process can be time-consuming and pose significant risks to patients. In response to these challenges, we present a novel gastrointestinal device designed to promote improved healing outcomes and streamline the process of intracorporeal anastomosis creation.

Methods

In ex-vivo porcine small bowel and colon, assessment of magnetic compression on the tissue over time was completed to assess magnet compression performance. A series of tensile tests were performed to define the optimal magnetic rating and positioning within the implant. Porcine cadaver studies assessing clinical usability and laparoscopic ready device deployment were performed in the Mater University Hospital, Dublin, in collaboration with the surgical innovation team. The assessment results and clinical feedback have informed the iterative development of both the device rings and delivery tool. Pre-clinical tests were performed in IHU Strasbourg, in chronic porcine models (40-55kg) to validate the Plio Surgical proof of concept. The magnetic rings were deployed in an open procedure, creating a small bowel end-to-end anastomosis (N=4), side-to-side ileocolic anastomosis (N=2) and side-to-side ileo-ileal anastomosis (N=1).

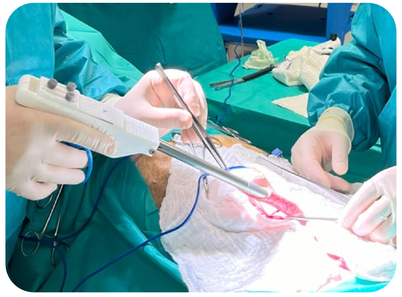


Fig 1: Plio Anastomosis Delivery Device IHU Strasbourg

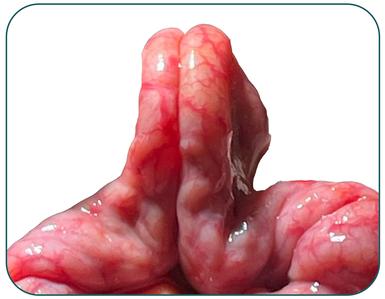


Fig 2: Anastomosis Creation

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Technology

The patented Plio Surgical device revolutionises the approach to anastomosis creation, providing an attractive alternative to traditional stapling techniques. The device consists of two soft rings with specially designed tissue anchors and magnetic components that reconnect the healthy tissue. The compression force results in superior anastomotic healing after which the rings detach and pass naturally.

- **Soft Elastomeric Material** allows the device to be compressed and deployed in a 12mm trocar compatible delivery device
- **Tissue Anchor** features anchor the rings inside the mucosal layer eliminating the need for sutures or staples at the anastomosis
- **Magnetic Elements** bring the rings together to form a compression anastomosis, resulting in superior tissue healing
- **Nothing Left Behind** once the healing strength is sufficient the coupled rings detach and pass naturally in less than 30 days

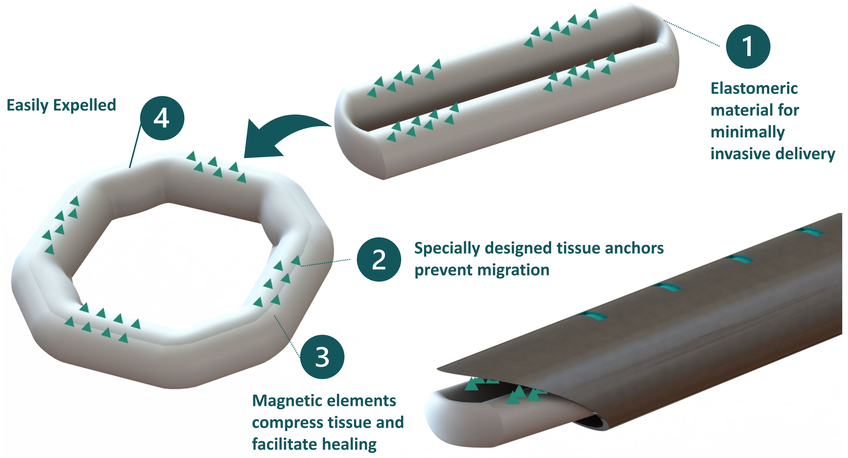


Fig 3: Deployment in a laparoscopic delivery tool from compressed configuration to deployed configuration

Results

Successful deployment of magnetic rings with specially designed laparoscopic compatible delivery device.

Histological assessment demonstrated well oriented and aligned intestinal wall layers, with adequate mucosal continuity.

Implant rings successfully created anastomosis. The pigs were survived for 29-days with the coupled rings passing within 10-days.

Anastomotic site necropsy and visual assessment was performed, garnering minimal scarring. Tissue healing notably softer when compared with stapled anastomosis.

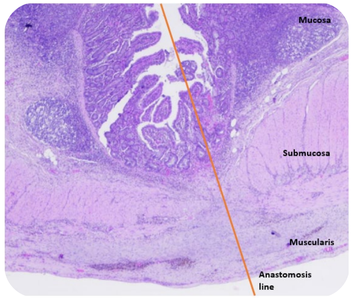


Fig 4: Histopathology Results - Day 29 post op



Fig 5: Anastomotic site mucosal healing Day 29

Conclusion

This work enables the advancement in gastrointestinal surgery, presenting a minimally invasive device for intracorporeal anastomotic creation. The technology was proven feasible in an animal model demonstrating promising results. The device is not currently commercially available, requiring further development and testing to ensure its safety and efficacy in humans.

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