Prevention of Intestinal Stomal Prolapse Using a Silicone Device

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Background

More than **500,000 Americans have an intestinal stoma**, with 120,000 new stomas created annually. Prolapse is a common complication, with an estimated **100,000 incidents per year**. Stomal prolapse can be painful, and is associated with obstruction, bleeding, and bowel ischemia. Prolapse is acutely managed with bedside manual reduction, however, recurrence rates are high. Definitive treatment of stomal prolapse involves an operation for stoma revision.

A non-operative medical device to prevent stomal prolapse would decrease emergency room visits, inpatient hospitalizations, and healthcare costs, while improving patient quality of life.

Design

We present the NoLapse device: a barbell-shaped semi-flexible silicone device that is placed at the stomal site to prevent prolapse. The device is composed of two rings connected by a rod (Figure 1). The inner ring is placed in the bowel lumen to dampen the propagation of intestinal peristaltic waves and prevent bowel intussusception (Figure 2). The outer ring rests on the abdominal surface to keep the inner ring in place. A thin connecting rod allows for the passage of stool. The device is made of medical-grade biocompatible silicone with semi-rigid and foldable properties, making it **easy to insert or remove bedside without general or local anesthesia**.

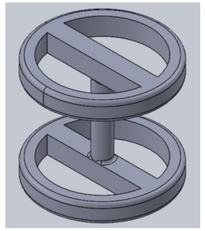


Figure 1. The NoLapse design features two rings connected by a thin rod.

Insertion

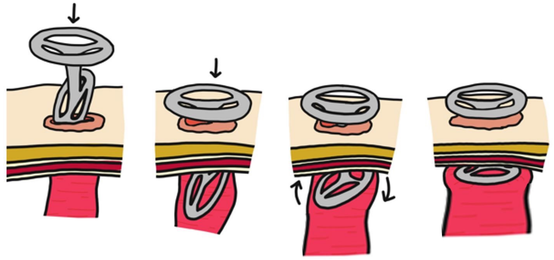


Figure 2. The NoLapse is foldable, allowing for easy bedside placement. The inner ring stents the bowel open, and the outer ring prevents the device from migrating.

Porcine Studies

Preliminary animal studies have demonstrated feasibility and efficacy. Using a cadaveric pig a prolapsed ileostomy was created, which could be reduced easily. Once the device was inserted, the ileostomy was unable to prolapse, despite direct manual pressure. The minimum pulling force required to dislodge the device was approximately 12 N. Although considerable force was required for inadvertent dislodgement of the device, the device was easily removed when folded intentionally. Additionally, we confirmed that the device does not obstruct the output of stool, and is compatible with the use of ostomy appliances and accessories.

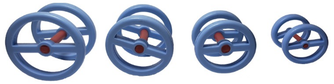


Figure 3. Prototypes of different sized devices

Clinical Experience

The device was used successfully in an emergency-use case for a 2-month-old in the pediatric intensive care unit who developed recurrent prolapse of her loop colostomy. The prolapse was reduced bedside and the NoLapse was inserted, to prevent recurrence until planned stoma reversal months later. The NoLapse was maintained for 4 months without any prolapse recurrence, obstruction, bleeding, injury to surrounding tissue, or other adverse effects.

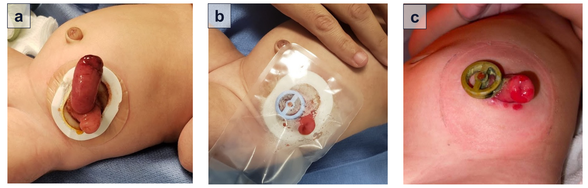


Figure 4. a) The patient's prolapsed stoma; b) After manual reduction and insertion of the device; c) 4 months after insertion

Conclusions

The NoLapse is the first non-operative device for preventing stomal prolapse and has demonstrated promising outcomes in pre-clinical studies and in-human experience.

Future directions include finalizing design specifications with different sizes, and developing an accompanying sizing kit to facilitate appropriate size selection. Lastly, additional preclinical studies will be done to understand long-term outcomes.

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