Atraumatic Colonoscope for Treatment of C. diff

Overview
C. diff is a bacteria that infects the colon, particularly in hospital patients on antibiotics. While mild cases are easily treated with oral antibiotics, severe infections can be untreatable and deadly without direct access to the infection site. Traditional colonoscope use is not feasible due to a high risk of colon perforation due to the mechanical degradation of the colon wall by the infection, leaving high risk surgical procedures as the only treatment option.

Objectives
The primary project objective was to develop the system level design for a device that allows direct, atraumatic access to the colon through the rectum to treat C. diff.

Approach
• Customer needs were gathered through discussions with the sponsor and consulting physicians
• Review of patents and existing products for reducing colonoscope trauma gave additional insight into the challenges of the objective and potential solutions
• Several iterations of brainstorming ideas and receiving sponsor feedback were used for concept generation and selection that lasted 8 weeks
• Final design: an inflatable balloon attachment for a traditional colonoscope; medicated sodium alginate and calcium chloride deployed through colonoscope working channels to form hydrogel for drug delivery
• Balloon treated with Slippery Liquid Infused Porous Surface (SLIPS) technology to be frictionless
• SJTU students tested gel formation in porcine colon, determined that 0.3% sodium alginate solution and 10% calcium solution optimized gel adhesion, strength, and formation time
• PSU students fabricated alpha prototype of balloon attachment from high purity silicone film soaked in silicone oil to obtain SLIPS surface; film balloon was fixed to tygon tubing that supplied balloon with air and replicated the flexibility of traditional colonoscope
• Balloon attachment prototype was deployed in porcine colon; distension of colon wall and resistance to motion were qualitatively evaluated
• Prototype balloon cushioned the head of the scope against the colon wall; no conclusion could be made for overall atraumatic access potential of the balloon in clinical practice

Outcomes
• Design has potential to meet the requirements needed for atraumatic treatment of severe cases of C. diff infections.
• More robust and expensive prototype, improved test performed by a physician, and biological study of the hydrogel treatment of the infection are required for definitive proof of concept