A Novel Lumenal Apposition Device for Therapeutic Endoscopy

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Aim: We describe the design and features of a new Lumenal Apposition Device (LAD) and provide initial test results.

Introduction

Today, interventional endoscopy includes therapeutic translumenal procedures such as pseudocyst drainage and celiac plexus blockade. Future advances in therapeutic endoscopy will optimize and broaden the delivery of minimally invasive therapy to organs and tissues surrounding the GI lumen under endoscopic ultrasound (EUS) guidance. In the forefront will be translumenal bile duct and gallbladder drainage. These procedures require a new technology platform to enable robust lumenal apposition that: (1) is stable and well tolerated in GI tract, (2) holds the lumens in close apposition without leakage, (3) does not cause pressure necrosis and (4) causes fistula formation and tissue fusion.

Methods

The LAD is a collapsible braided structure delivered through a 10.5Fr catheter. The proximal and distal ends of the device self-expand to a diameter larger than the central

Figure 1: Lumenal Apposition Device

section, thereby forming a dual-flanged anchor capable of holding adjacent tissues in close apposition (Fig. 1). The central section forms a continuous 9mm lumen through which fluid can flow unobstructed from one lumen to the other. The proximal and distal flanges hold soft tissue in firm apposition without causing pressure necrosis. Bench-top measurements of the pressure exerted on tissue by the LAD flanges were obtained using an ex-vivo test fixture and porcine stomach tissue. Chronic porcine survival studies were also conducted in which a LAD was placed between the stomach and gall bladder of four survival animals (Fig. 2). Flange pressure, tissue reaction and bile drainage was measured or monitored.

Results

The force exerted by the LAD flanges was 0.15-0.20lbs based on a tissue thickness of 8mm. Survival animals were sacrificed at 2 and 6 weeks, with data pending on two animals, presently at 1 and 2 weeks. All animals were free of infection and showed no behavioral changes for the duration of the study. The LAD was well-tolerated by both the stomach and gall bladder tissue, as verified by gross necropsy inspection. Bile flow was visualized endoscopically throughout the study. EUS exams also confirmed the close apposition of the gall bladder to the stomach (Fig. 3).

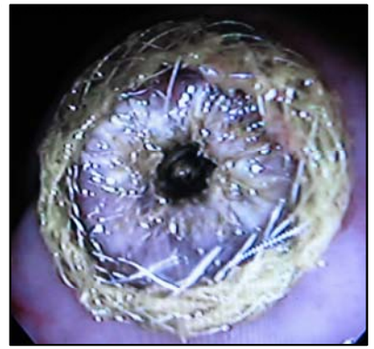

Figure 2: LAD after 2 weeks

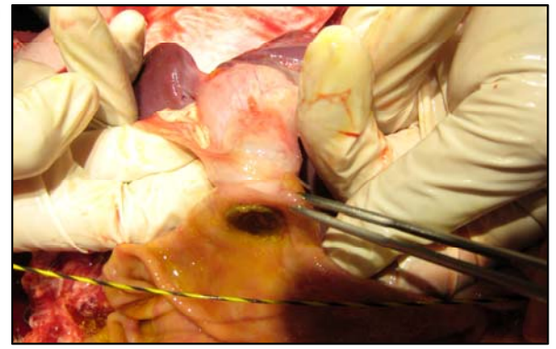

Figure 3: Tissue adhesions between the stomach & gallbladder

Conclusion

This novel lumenal apposition device represents an improvement that can extend the boundaries of therapeutic endoscopy by enabling a robust and reliable conduit between lumens in and around the GI tract.

Disclosures: *Drs. Binmoeller & Shah serve as Advisor to Xlumena.*


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