

The Cost-Effectiveness of DiLumen™ for Endoscopic Intervention of Complex Colonic Polyps

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Therapeutic interventions in most specialties have progressed to less invasive approaches due to patient preference, lower complication rates, and shorter hospital stays typically associated with these healthcare advancements. The preferred treatment for benign, pre-cancerous colonic adenomas is polypectomy via Endoscopic Mucosal Resection (EMR) or Endoscopic Submucosal Dissection (ESD).

Unfortunately, lesions greater than 2cm or those on a flexure or fold (complex polyps) make an endoscopic approach more technically challenging and time consuming. As a result, surgical colectomy is often the alternative to a more minimally invasive procedure. Despite no change in the incidence of screening colonoscopies between 2000 and 2014, the incidence of surgery for benign colon polyps has risen during the same period^{1,2}.

Several studies have demonstrated the cost-effectiveness of an endoscopic approach versus a surgical one (laparoscopic colectomy) for complex colon polyps^{3,4,5}. Superior cost-effectiveness outcomes with an endoscopic intervention were demonstrated with statistical significance in reference to procedural costs, hospital stays, quality adjusted life-years, and morbidity and mortality. Devices that could help make endoscopic therapy less technically challenging and less time consuming would increase physician adoption, improve patient outcomes, and provide cost savings/additional revenue potential for hospital institutions. Some of the current technical challenges include a lack of scope stability (especially beyond the splenic flexure), the absence of good tissue traction during ESD, and the inability to efficiently handle any complications (i.e., perforations) endoscopically.

DiLumen (Lumendi, LLC, Westport, CT) is an endoscopic accessory sheath, compatible with all colonoscopes and gastroscopes, that is advanced over the scope through DiLumen's device handle prior to insertion [Figure 1]. The device consists of two balloons that can be manually inflated (up to 6cm diameter) and deflated as needed during the procedure. The balloons can facilitate navigation by shortening and straightening the colon similar to double balloon enteroscopy, providing easier access around flexures and to the right side of colon. The Fore Balloon (FB) can be advanced or retracted

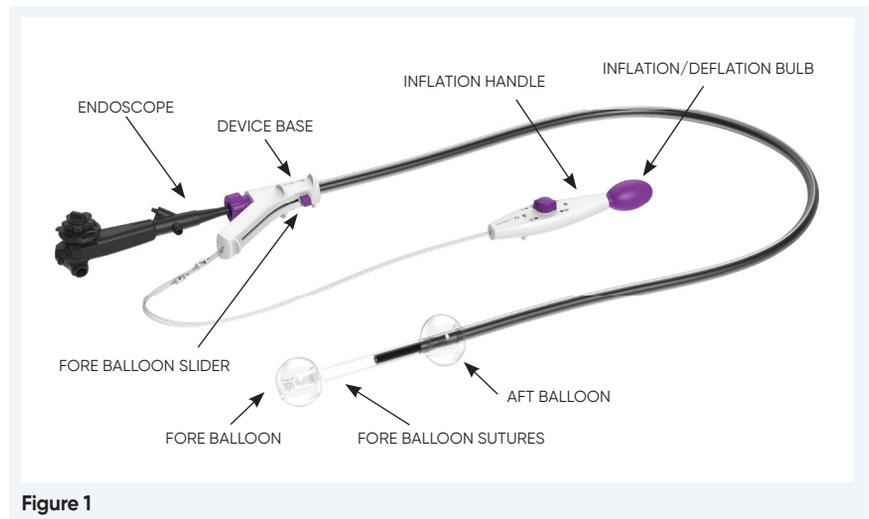


Figure 1

from the scope tip to create a Therapeutic Zone (TZ) with use of the FB slider at the device base.

The FB has two incorporated sutures of different lengths that can lift lesions after attachment to the specimen margin by use of an endoscopic clip to create "dynamic retraction" of the polyp with the use of the FB slider. This provides traction or retraction as needed, to facilitate better visualization of tissue planes, thereby leading to more efficient dissection during ESD [Figure 2].

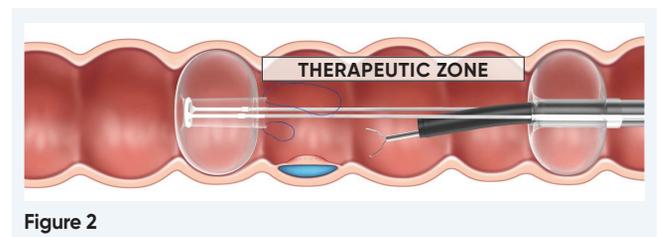


Figure 2

The scope can be removed and re-inserted independent of the device during the procedure allowing the DiLumen to maintain its position in the colon to clean the scope lens, change scopes, or remove multiple specimens during piecemeal EMR. Finally, and most importantly, the AB provides stability to more precisely and safely perform endosurgical procedures.

There have been more than 1,300 DiLumen cases performed worldwide since Spring of 2017. Sharaiha et al. (2019)

demonstrated DiLumen's ability to navigate to the cecum and successfully set up a therapeutic zone (TZ) in both the sigmoid and ascending colon⁶. Othman and Kantsevoy demonstrated the value of dynamic retraction for facilitating ESD⁷. Stavropoulos demonstrated statistically significant time savings achieved by using DiLumen as a conduit to navigate a gastroscope to the right colon for sutured closure of the lesion defect post-resection⁹. This enabled him to discharge patients post-procedure versus the usual two-day stay, saving institutional resources.

As a result of observational time savings due to stabilization, traction, improved visualization, and use of the device as a conduit, some users chose to evaluate retrospective case-match analyses of ESD cases performed with DiLumen versus those without the device. Stavropoulos case-matched 19 cases in each group based on lesion size, lesion location, and whether the lesion was fibrotic due to previous manipulation. He demonstrated a 52% increase in dissection speed utilizing DiLumen as well as a 20-minute time savings with use of the device ($p=0.098$)⁹. Kantsevoy also performed a similar analysis looking at large complex colonic polyps¹⁰. Using propensity case-matched criteria, he analyzed 53 DiLumen ESDs to 33 non-DiLumen cases with lesion size and lesion location as variables. Analysis showed a reduction in total procedure time with DiLumen of 31 minutes ($p = .032$).

Finally, an IRB-approved prospective randomized trial comparing DiLumen ESD to non-DiLumen ESD began in February 2019¹¹ investigating time savings and cost effectiveness. Based on the hypothesis of a 20-minute time savings favoring DiLumen, the study was statistically powered to 200 patients (1:1 randomization) with a primary endpoint of difference in total procedure time. An interim analysis was performed after 140 patients were enrolled (per protocol) to see if the primary endpoint was met and the study recruitment could be ended early. The primary statistical endpoint was met at this interim analysis, meaning that significant time was saved with the device; thus no further recruitment was necessary. Publication of this randomized prospective study is pending, and detailed data will be forthcoming. The anticipated time savings and cost effectiveness would be expected to positively influence the site of service, the possible length of stay, and

other resources associated with more invasive procedures. This initial analysis has far ranging implications.

Bourke et al¹² published a comprehensive study evaluating the cost effectiveness of colorectal ESD versus EMR for the treatment of laterally spreading colorectal lesions (LSLs) >20mm. The conclusion was that ESD was indeed more cost-effective versus EMR (avoiding colectomy) when there was a high suspicion of submucosal invasion. In contrast, cost-effectiveness was not shown for all LSLs. However, the study revealed that the endoscopic prediction rate of submucosal invasion was only 34.9%. Furthermore, Bourke made his cost-effectiveness argument against universal ESD based on an assumption of a two-day hospital stay with ESD. With the DiLumen device as a conduit, the ability to suture the defect closed (versus clips) in the colon and cecum is technically easier and can allow a quicker hospital discharge (even same day), as there is less concern of delayed bleeding or perforation^{8,9,13}.

Shorter time per procedure with DiLumen can result in an institution's potential ability to increase the number of cases scheduled per day, decrease staff overtime, and/or save money/increase revenue per case. Discussions with hospital endoscopy administrators provided information that the cost of providing care in an interventional ESD endoscopy suite (including anesthesia, personnel, etc.) costs between \$40-80 USD/minute, depending on the institution¹⁴. Assuming a mean of \$60 dollars/minute and a 30-minute time savings with DiLumen, it can result in procedural savings of up to \$1,800.00 dollars during complex polypectomy. This more than covers the cost of the device and allows time for additional sources of revenue (or less personnel time). On top of this, the ability to facilitate a same day discharge for ESD with sutured defect closure provides supplemental benefit. Treatment for complex colon polyps with DiLumen assistance can have very favorable implications for managed care decisions.

DiLumen-assisted endosurgical procedures provide value-based options for favorable cost shifting that includes savings compared to current options. Simultaneously, it allows payment for new devices and physician fees commensurate with the expertise needed for these procedures, while still yielding savings to both payers and patients.

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