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Research Article

Real-World Experience with the Overstitch Endoscopic Suturing System: Insights from the Food and Drug Administration Manufacturer and User Facility Device Experience Database

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Abstract

Objective: The Overstitch Endoscopic Suturing System allows for the placement of full-thickness sutures endoscopically. Real-world data on the Overstitch system is sparse. We investigated the number and type of complications associated with the Overstitch device using a national database.

Methods: Postmarket surveillance data from the FDA Manufacturer and User Facility Device Experience database from October 2010 through July 2023 was analyzed for device failures and patient complications.

Results: During the study period, 142 cases with 93 patient-related adverse events, 40 device failures, and 8 combined device failures with patient complications were identified. The most recorded patient-related adverse events were hemorrhage (n=31; 41.8%), perforation (n=26; 35.1%), and mucosal laceration (n=21; 28.3%). The most common device failures included a failure of tissue helix release (n=13; 32.5%), suture cinch tip failure (n=9; 22.5%), end cap release from the endoscope (n=6; 15%), and failed anchor exchange in (n=5; 12.5%) patients.

Conclusion: Patient-related adverse events and device failures can occur while using the Overstitch Endoscopic Suturing System. An understanding of these outcomes by operators can help reduce the risk of injury and increase technical success when using this device.

Keywords: Endoscopy, suturing, therapeutic endoscopy

INTRODUCTION

The Overstitch Endoscopic Suturing System (Apollo Endosurgery, West Lake Hills, Tex, USA) is a device that allows for the endoscopic placement of full-thickness sutures within the lumen of the gastrointestinal tract. The first clinical use of the Overstitch device was for the closure of a chronic gastrocutaneous fistula.[1,2] Shortly thereafter, the Overstitch device was implemented in a variety of different clinical settings including: the fixation of endoscopic stents to reduce the risk of migration, the creation of an endoscopic sleeve gastroplasty, the closure of mucosal defects following endoscopic submucosal dissection, and endoscopic myotomy, as well as the closure of perforations and anastomotic leaks.[3-9]

The Overstitch system attaches to the working end of an upper endoscope and has 4 components: the needle driver/needle driver body, the anchor exchange channel, and a tissue helix channel. The needle driver is a semicircular, blunt needle-receiving apparatus that rotates on a hinge mechanism. When closed, the needle driver rotates in a vertical fashion from the needle driver body at the 12 o'clock position to the anchor exchange channel at the 6 o'clock position. The anchor exchange channel is a working channel that allows for the placement of a detachable needle-shaped anchor with an associated suture onto the needle driver. The tissue helix channel allows for the passage of a small corkscrew-shaped tool that, when advanced to the mucosa and rotated clockwise, will adhere tissue and allow the endoscopist to position the mucosa for proper suture placement. Operating the Overstitch system is a multistep process. First, the needle driver is closed, and an anchor is attached to the tip before the needle driver is again placed in the open position. The tissue helix can then be used to position the mucosa to allow for proper suture placement. Once the mucosa has been aligned, the needle drive is again closed, and the first stitch is placed. At last, the anchor is removed from the tip of the needle driver, and the needle driver is returned to the open position. This process is repeated for each individual suture placement. After the desired number of sutures have been placed, a cinch is attached to the distal end of the suture, and the tissue is approximated.

While many studies have reported on the use of the Overstitch system, there is a paucity of data on device failures and patient-related adverse events. Therefore, the aim of the current study is to examine reported device failures and patient-related adverse events.

METHODS

We analyzed postmarketing surveillance data for the Overstitch device from the FDA Manufacturer and User Facility Device Experience (MAUDE) database. The MAUDE database collects reports regarding major adverse events, including device-related deaths, patient injuries, and modes of device failure. Reporting is both mandatory (manufacturers, importers, and device–user facilities) and voluntary (health-care professionals, patients, and consumers).

The MAUDE database is freely and publicly accessible (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm). The database is federally maintained and updated monthly with reports containing device information, event date and type, users' and manufacturers' event narratives, and whether the device was returned to the manufacturer. Events are anonymous and categorized as either death, injury, device malfunction, or other. Events can be monitored, and if a device is determined to be defective, the FDA can issue safety alerts or recalls based on the reported information.

We collected all reported events from the MAUDE database on the Overstitch Endoscopic Suturing System from October 2010 through July 2023. Individual events were analyzed for event type (patient adverse event vs. device failure) and categories based on frequency of occurrence. A device failure was defined as any event that impaired the function of the device. Informed consent and ethics committee approval were not required, as the database is mandated for postmarketing surveillance and open access.

RESULTS

One hundred forty-two cases with 93 patient adverse events, 40 device failures, and 8 combined patient adverse events with device failure were identified. There were 10 reported major adverse events that lacked sufficient detail surrounding the event to be included for analysis. There were 21 instances in which the patient adverse event report identified multiple outcomes (ex. perforation and dysphagia). There were 9 instances in which the device failure report identified multiple modes of failure (e.g., bent needle driver and failed anchor exchange). There was a single instance of a duplicated report, which was removed from subsequent analysis. The number of reported major adverse events increased over the study period.

Patient-Related Adverse Events

The most recorded patient-related adverse events were hemorrhage in 31 (41.8%), perforation in 26 (35.1%), and mucosal laceration in 21 (28.3%) patients. Other less frequently reported patient adverse events included infection in 5 (6.7%), dysphagia in 1 (1.3%), odynophagia in 1 (1.3%), stenosis in 4 (5.4%), persistent pain in 14 (18.9%), nausea/vomiting in 4 (5.4%), fever in 6 (8.1%), persistent leak/failed perforation repair in 4 (5.4%), and pulmonary embolism in 3 (4.0%) patients. Two hospitalizations were reported (Table 1).

Device Failures

Device failures included a failure of tissue helix release in 13 (32.5%), suture cinch tip failure in 9 (22.5%), end cap release from the endoscope in 6 (15%), and failed anchor exchange in 5 (12.5%) patients. Other less frequently reported device failures included: needle driver jam in 3 (7.5%), kinked catheter in 1 (2.5%), bent working channel in 2 (5.0%), failed tissue helix rotation in 2 (5.0%), bent needle driver in 5 (12.5%), and needle driver jam within the anchor exchange body in 4 (10%) patients (Table 2).

Combined Patient Adverse Events with Device Failure

With regard to combined patient adverse events with device failures, there were 8 combined events reported. There were 4 (50%) reports of perforation that were related to a failed tissue helix release, 1 (12.5%) report of a persistent leak/failed perforation repair related to a suture cinch tip failure, and 3 (37.5%) reports of mucosal lacerations related to two instances of the end cap being released from the endoscope and 1 instance of a bent needle driver.

DISCUSSION

To date, this is the only known analysis of safety and common device failures related to the Overstitch Endoscopic Suturing System as reported to the MAUDE database. Herein, we demonstrate that the number of reported device failures and safety events has increased over the study period. We postulate that the increase in reported safety events and device failures is likely related to the greater availability and use of the device in clinical practice. The Overstitch device was commercially released in October of 2010 and was replaced by a second-generation system in December of 2011. Both the first- and second-generation devices were only compatible with Olympus endoscopes.

MAIN POINTS

- The Overstitch Endoscopic Suturing System is the only endoscopic device that provides a mechanism for full-thickness suture placement.
- Postmarketing surveillance data suggests an increase in device-related failures and patient-related adverse events associated with the Overstitch device since its appearance on the market.
- The most common device failure is the embedment of the tissue helix into the mucosal tissue, leading to impaired release and potential perforation.
- The most common patient-related adverse event was hemorrhage, followed by perforation and mucosal laceration.
- The Overstitch device has allowed for the expansion of endoscopic interventions; however, its use can result in significant patient-related adverse events and device failures.

Table 1. Patient-Related Adverse Events

Patient-Related Adverse Events	n
Hemorrhage	31
Perforation	26
Mucosal laceration	21
Pain	14
Fever	6
Infection	5
Nausea/Vomiting	4
Persistent leak/failed perforation repair	4
Pulmonary embolism	3
Stenosis	4
Odynophagia	1
Dysphagia	1

Table 2. Device Failures

Device Failure	n
Tissue helix failed release	13
Suture cinch tip failure or breakage	9
End cap released from scope	6
Failed anchor exchange	5
Bent needle driver	5
Needle driver body jam inside anchor exchange	4
Needle driver jam	3
Bent working channel	2
Failed helix rotation	2
Kink in catheter	1

However, in November of 2018, Apollo Endosurgery developed and released the Overstitch Sx system within the United States, which is compatible with a wider variety of single-channel flexible endoscopes (Olympus, Pentax, and Fuji) thereby increasing the availability of this technology.[10]

In this study, there were 40 reported primary device failures. The most reported event was a failure of the tissue helix to release from the adhered tissue, which occurred in 13 (32.5%) patients. This can be a particularly dangerous mode of failure, as it is often not discovered until after the first suture has been placed, thereby also making it difficult to remove the Overstitch system from the patient. One device failure report described a scenario in which the tissue helix failure resulted in the end cap of the Overstitch system being sutured into the mucosal wall, which in turn required a needle-knife procedure to remove. Furthermore, 4 (50%) of the reported combined patient adverse events and device failures resulted from perforations related to failed tissue helix release.

With regard to patient-related adverse events, there were 93 reported injuries. The most commonly reported injuries were hemorrhage (n=31, 41.8%), perforation (n=26, 35.1%), and mucosal laceration (n=21, 28.3%). The context of such injuries was not extensively described within the MAUDE database; however, several events arose from failure to close the needle drive handle while manipulating the device within the gastrointestinal lumen. Operating the Overstitch Endoscopic Suturing System requires a complex sequence of events to occur in a particular order prior to placing the first suture. A misstep in the sequence of events can increase the risk of device failure and place the patient at risk of injury related to the device. A single patient death was identified within the study period, but the surrounding circumstances were not elucidated.

The MAUDE database provides important insight into the most often encountered patient-related adverse events and mechanisms of device failure. We certainly acknowledge the limitations of the MAUDE database, most notably the inability to calculate true rates for patient-related adverse events and device failures, given the inability to know the denominator of cases and devices used in those cases. Still, there are over 500 MAUDE studies in PubMed at the time of this writing, and despite this limitation, MAUDE studies have been established as a means to provide end users with valuable information that is simply not available anywhere else.

While the MAUDE database cannot be used to establish definitive event rates, it does provide an effective mechanism for postmarket surveillance, and these facts are true for all published MAUDE database analyses. There are some limitations to the current study that must be considered when interpreting the MAUDE data. These limitations include the following: (1) MAUDE database reporting is completely voluntary and complications can be underreported; (2) details regarding specific procedures are limited, and thus it can be difficult to determine the exact cause of reported events (i.e., operator error, device defect, or an interaction between devices).

The Overstitch Endoscopic Suturing System provides a mechanism for endoscopic full-thickness suture placement. The most commonly encountered device failure is related to the tissue helix becoming embedded within the mucosa, with some reports of this subsequently causing perforation. This risk can, at least in part, be mitigated by ensuring that the tissue helix is not overtightened, thereby reducing its depth within the mucosa. Alternatively, the Overstitch system can be used without the tissue helix entirely; however, this is dependent upon endoscopic positioning and access to adequate tissue for suture placement. Additional common device failures include failure of the suture cinch system, end cap release from the endoscope, and failed anchor exchange. With regard to patient-related adverse events, hemorrhage was most frequently encountered, followed by perforation and mucosal laceration.

While the Overstitch device has allowed for the expansion of endoscopic interventions, its use can result in significant patient-related adverse events and device failures. An understanding of these outcomes by operators can help reduce the risk of injury and increase technical and clinical success when using this device.

Ethics Committee Approval: Ethics committee is not required as this is an analysis of a public database. No confidential information is included. This is a no-risk, no-harm, no-patient contact study.

Informed Consent: Informed consent is not required as this is an analysis of a public database. No confidential information is included. This is a no-risk, no-harm, no-patient contact study.

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REFERENCES

1. Kantsevoy SV, Thuluvath PJ. Successful closure of a chronic refractory gastrocutaneous fistula with a new endoscopic suturing device (with video). *Gastrointest Endosc*. 2012;75(3):688-690. [CrossRef]
2. Armengol-Miro JR, Dot J, Abu-Suboh Abadia M, Masachs M, Salord JC, Armengol Bertroli J, Benages A, Kantsevoy SV. New endoscopic suturing device for closure of chronic gastrocutaneous fistula in an immunocompromised patient. *Endoscopy*. 2011;43(Suppl 2):E403-E404. [CrossRef]
3. Kantsevoy SV, Bitner M. Esophageal stent fixation with endoscopic suturing device (with video). *Gastrointest Endosc*. 2012;76(6):1251-1255. [CrossRef]
4. Rieder E, Dunst CM, Martinec DV, Cassera MA, Swanstrom LL. Endoscopic suture fixation of gastrointestinal stents: proof of biomechanical principles and early clinical experience. *Endoscopy*. 2012;44(12):1121-1126. [CrossRef]
5. Sharaiha RZ, Kumta NA, DeFilippis EM, et al. A large multicenter experience with endoscopic suturing for management of gastrointestinal defects

and stent anchorage in 122 patients: a retrospective review. *J Clin Gastroenterol*. 2016;50(5):388-392. [CrossRef]
6. Kantsevoy SV, Bitner M, Mitrakov AA, Thuluvath PJ. Endoscopic suturing closure of large mucosal defects after endoscopic submucosal dissection is technically feasible, fast, and eliminates the need for hospitalization (with videos). *Gastrointest Endosc*. 2014;79(3):503-507. [CrossRef]
7. Kantsevoy SV, Bitner M, Davis JM, Hajiyeva G, Thuluvath PJ, Gushchin V. Endoscopic suturing closure of large iatrogenic colonic perforation. *Gastrointest Endosc*. 2015;82(4):754-755. [CrossRef]
8. Kumar N, Thompson CC. A novel method for endoscopic perforation management by using abdominal exploration and full-thickness sutured closure. *Gastrointest Endosc*. 2014;80(1):156-161. [CrossRef]
9. Henderson JB, Sorser SA, Atia AN, Catalano MF. Repair of esophageal perforations using a novel endoscopic suturing system. *Gastrointest Endosc*. 2014;80(3):535-537. [CrossRef]
10. Kantsevoy SV. The development of the overstitch system and its potentials. *Gastrointest Endosc Clin N Am*. 2020;30(1):107-114. [CrossRef]