Real-World Experience with the Overstitch Endoscopic Suturing System: Insights from the FDA Manufacturer and User Facility Device Experience (MAUDE) Database

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ABSTRACT

Background
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 public-access governmental database.

Research Design and Methods
Post-market surveillance data from the FDA Manufacturer and User Facility Device Experience (MAUDE) database from October 2010 through Dec 2021 was analyzed for device failures and patient complications.

Results
During the study period, 102 cases were reported with 64 patient complications, 31 device failures, and 7 combined device failures with patient complications were identified. The most recorded patient related adverse events were mucosal laceration in 18 (24.3%), perforation in 17 (22.9%), and hemorrhage in 16 (21.6%) patients. The most common device failures included a failure of tissue helix release in 10 (25%), suture cinch tip failure in 7 (17.5%), end cap release from the endoscope in 5 (12.5%), and failed anchor exchange in 5 (12.5%) patients.

Conclusion
Use of the Overstitch system 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 success when using this device.

INTRODUCTION

The Overstitch Endoscopic Suturing System allows for the placement of full thickness sutures endoscopically.

The Overstitch system attaches to the working end of an upper endoscope and has four components: the needle driver/needle driver body, the anchor exchange channel, and a tissue helix channel. The needle driver is a semi-circular blunt needle receiving apparatus that rotates on a hinge mechanism. 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 mucosa for proper suture placement.

While many studies have reported on the many uses 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 was to examine reported device failures and patient-related adverse events as reported to the Food and Drug Administration (FDA) in the USA.

METHODS AND MATERIALS

We analyzed post-marketing 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 (healthcare professionals, patients, and consumers). 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.

We collected all reported events from the MAUDE database on the Overstitch Endoscopic Suturing System from October 2010 through December 2021. 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.

RESULTS

One hundred and two cases with 64 patient adverse events, 31 device failures, and 7 combined patient adverse events with device failure were identified.

The most recorded patient related adverse events were mucosal laceration in 18 (24.3%), perforation in 17 (22.9%), and hemorrhage in 16 (21.6%) patients. Other less frequently reported patient adverse events included: Infection in 4 (5.4%), dysphagia in 1 (1.3%), odynophagia in 1 (1.3%), stenosis in 1 (1.3%), persistent pain in 5 (6.7%), nausea/vomiting in 2 (2.7%), fever in 5 (6.7%), persistent leak/failed perforation repair in 2 (2.7%), and pulmonary embolism in 2 (2.7%) patients.

Table 1. Patient-related adverse events.

Patient-Related Adverse Events	n
Mucosal laceration	18
Perforation	17
Hemorrhage	16
Pain	5
Fever	5
Infection	4
Nausea / Vomiting	2
Persistent leak/failed perforation repair	2
Pulmonary embolism	2
Dysphagia	1
Odynophagia	1
Stenosis	1

Table 2. Device Failures.

Device Failure	n
Tissue helix failed release	10
Suture cinch tip failure or breakage	7
Failed anchor exchange.	5
End cap released from scope	5
bent needle driver	3
Needle driver body jam inside anchor exchange	3
Needle driver jam	2
Bent working channel	2
Failed helix rotation	2
Kink in catheter	1

Device failures included a failure of tissue helix release in 10 (25%), suture cinch tip failure in 7 (17.5%), end cap release from the endoscope in 5 (12.5%), and failed anchor exchange in 5 (12.5%) patients. Other less frequently reported device failures included: Needle driver jam in 2 (5.0%), 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 3 (7.5%), and needle driver jam within anchor exchange body in 3 (7.5%) patients.

With regards to combined patient adverse events with device failures, there were 7 combined events reported. There were 3 (42.8%) reports of perforation that were related to a failed tissue helix release, 1 (14.2%) report of a persistent leak/failed perforation repair related to a suture cinch tip failure, and 3 (42.8%) 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 the safety of and common device failures related to the Overstitch Endoscopic Suturing System as reported to the MAUDE database. The most commonly reported device failure was a failure of the tissue helix to release from the adhered tissue which occurred in 10 (25%) patients. The most commonly reported patient injury was mucosal laceration in 18 (24.3%), perforation in 17 (22.9%), and hemorrhage in 16 (21.6%) patients. The MAUDE database provides important insight into the most often encountered patient-related adverse events and mechanisms of device failure.

Figure 1. The Overstitch Working Tip.

Figure 2. The Overstitch controls.

CONCLUSIONS

The Overstitch Endoscopic Suturing System provides a mechanism for endoscopic full-thickness suture placement. 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 in unexperienced hands. An understanding of these outcomes by operators can help reduce the risk of injury and increase technical success when using this device.

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