

Attempted removal and subsequent fragmentation of 3 self-expanding metal stents

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Perforation is a dreaded complication of esophageal stricture dilation. The surgical treatment of esophageal perforation is associated with significant morbidity and mortality.¹ Self-expanding metal covered stents (SEMS) have been used to treat esophageal perforation with a high rate of success. However, the ability to remove these stents remains questionable.

CASE REPORTS

Case 1

An 84-year-old woman presented with dysphagia after radiation treatment for metastatic breast cancer. At endoscopy, an esophageal stricture was dilated and complicated by a 2-cm mid esophageal perforation. An Alimaxx-E (Alveolus Inc, Charlotte, NC) stent was placed without difficulty (Fig. 1). The patient did well initially, but 12 months later presented with dysphagia and a 9.07-kg (20-lb) weight loss attributed to esophageal stenosis around the proximal end of the stent. The stenosis was dilated with a through-the-scope balloon to a diameter of 12 mm, and stent removal was attempted. The manufacturer's guidelines for removal were followed; the purse string was grasped and pulled but the proximal end fragmented and broke away. Attempts to grasp the stent with an alligator forceps resulted in fragmentation into multiple small pieces (Fig. 2). A rigid esophagoscope and forceps were used to separate and remove the stent in a piecemeal fashion over 4 hours. The esophageal perforation healed, but the prolonged stent-removal procedure was complicated by aspiration pneumonia.

Case 2

A 71-year-old man presented with dysphagia after radiation treatment for head and neck cancer. At endoscopy, an esophageal stricture was dilated and complicated by a 5-cm mid esophageal perforation. Two Alimaxx-E stents were placed to completely cover the perforation. After 3 months, stent removal was attempted. Under endoscopic visualization, a forceps was used to grasp the purse string; the proximal end of the first stent fragmented and broke away. This stent was eventually removed in a piecemeal fashion. The second stent was grasped by the purse string, and this time removal caused the stent to break into larger frag-

ments (Fig. 3). The most-proximal fragment was easily removed, but the distal fragments could not be pulled proximally. The esophagus was accessed through a preexisting gastrostomy, and the stent remnants were pulled into the stomach. The distal end was then grasped with a snare and removed through the mouth. After 5 hours, both stents were successfully removed. The esophageal perforation had healed, and the patient was discharged from the hospital after overnight observation.

DISCUSSION

The only stent that has been approved by the U.S. Food and Drug Administration (FDA) to treat benign esophageal disease is the Polyflex stent (Microvasive Endoscopy, Boston Scientific Corp, Natick, Mass), a removable self-expanding covered plastic stent. There are 5 case series that evaluated the Polyflex stent to treat esophageal perforation or leak.²⁻⁶ The stent was an effective treatment in 67% to 94% of cases, but stent placement was complicated by migration (18%-59%) and esophageal stenosis (0%-18%). The high rate of Polyflex-stent migration has prompted clinicians to use other removable stents off label to treat benign disease.

The Ultraflex stent (Microvasive) is a braided nitinol self-expanding, partially covered stent that has been evaluated in 3 prospective observational studies to treat esophageal perforation or leak.⁷⁻⁹ The Ultraflex stent was effective in 78% to 95% of cases, and stent placement was complicated by migration (6%-14%), esophageal stenosis (9%-13%), and mucosal tears (0%-12.5%). The mucosal tears were attributed to the uncovered ends of the stent. These ends are susceptible to tissue in-growth, which may make the stent less likely to migrate but more difficult to remove.

The Alimaxx-E stent is a newer, fully covered self-expanding nitinol stent. Because the stent is fully covered, it is theoretically less susceptible to tissue in-growth, more prone to migration, but more easily removed (assuming no fragmentation). Before the Alimaxx-E, nitinol-stent fragmentation was thought to be rare, as only 5 cases were reported in the literature.^{10,11} In contrast, from September 2007 to September 2008, there were 5 cases of Alimaxx-E stent fragmentation reported in MAUDE (the Manufacturer and User

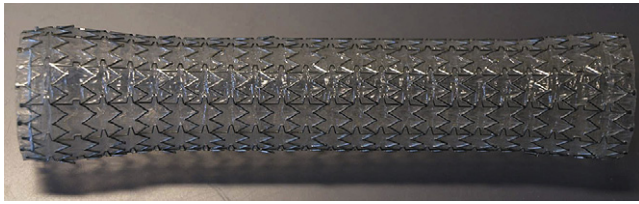


Figure 1. Normal Alimaxx-E stent.

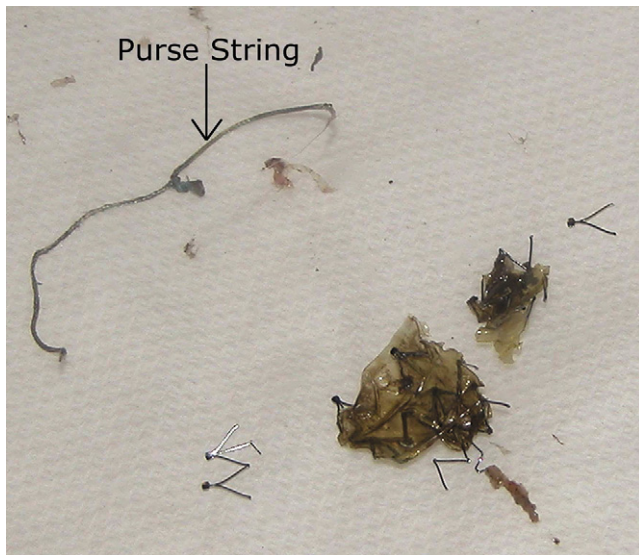


Figure 2. Case number 1 stent fragments.



Figure 3. Case number 2 stent fragments.

Facility Device Experience Database), a database maintained by the FDA to report adverse events related to medical devices.¹² In addition, there was 1 case of Alimaxx-E stent fragmentation recently reported in the GI literature.¹³ In our experience, 3 stents were placed to treat 2 patients with esophageal perforation. All of the stents were easily placed, and the perforations were effectively treated. However, all 3 stents fragmented on attempted removal.

Why did these stents fragment? Simply put, the force required to remove the stent was greater than its tensile strength (the stress at which a material breaks). The tensile strength is dependent on multiple factors, which include temperature, corrosion, and stent design. With respect to temperature, one of the properties of nitinol is temperature-dependant stiffness.¹⁴ Nitinol is soft and pliable at room temperature but stiffer at body temperature. This stiffness imparts increased radial forces that may make the stent less likely to migrate but more difficult to remove.

The tensile strength of metals is also affected by corrosion. However, nitinol implants used in orthodontic, orthopedic, and cardiovascular applications do not significantly corrode, even after 12 months.¹⁵ Our exception may be that the Alimaxx-E stents were placed in the esophagus and could have been exposed to gastric acid, which may have had a corrosive effect. The manufacturer recently made a change in the stent covering to address this possibility.

The inner covering is now silicone and the outer covering is urethane in an attempt to decrease acid damage. It is encouraging that the manufacturer has recognized the stent-fragmentation problem, but we are concerned that this change may not be sufficient. We do not have experience with the new stent, but there is evidence that corrosion due to gastric acid is an unlikely cause. Again, nitinol is generally resistant to corrosion. Both patients in the present case report were on high-dose proton pump inhibitor therapy (esomeprazole 40 mg twice daily), which should have resulted in negligible esophageal acid exposure. Also, after removal, the metal fragments did not appear to have corroded (ie, were unchanged compared to a newly opened stent).

Alternatively, the cause of fragmentation may be related to stent design, which is dependent on many variables (ie, preparation, composition of metal, the thickness of metal in the coils and at the joints, and spacing of joints). In case no. 1, the stent was dilated before removal, which could have weakened the stent. The proximal end of this stent fractured along a transverse axis (not shown). Interestingly, both stents used in case no. 2 also fragmented along a transverse axis (Fig. 3). This could be consistent with a failure of the longitudinal wires and/or connections. In comparison, the Ultraflex stent is also constructed from nitinol but is generally not susceptible to fragmentation (this despite being partially covered and theoretically more susceptible to corrosion from gastric acid). A major difference compared with the Alimaxx-E stent is that the longitudinal wires have a greater diameter and are more closely spaced.

There are limited data on the ideal time to leave stents in place. In the Ultraflex and Polyflex stents case series, stents were removed after a mean time of 44 to 135 days (range 1-438 days), and there were no reports of fragmentation.²⁻⁹ The Alimaxx-E stent may be more susceptible to fragmentation, and this may be, in part, due to weakness of the longitudinal wires and/or connections. Corrosion from gastric acid is another potential but less likely explanation. There is a need for large observational studies that evaluate the safety and technical difficulties associated with the removal of different SEMs when used for benign disease.

DISCLOSURE

All authors disclosed no financial relationships relevant to this publication.

Abbreviations: FDA, U.S. Food and Drug Administration; SEMS, self-expanding metal stent.

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EUS-guided diagnosis and successful endoscopic transpapillary management of an intrahepatic pancreatic pseudocyst masquerading as a metastatic pancreatic adenocarcinoma (with videos)

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Intrahepatic pancreatic pseudocyst extension is a rare complication of acute and chronic pancreatitis.¹⁻²⁵ It is estimated that up to 20% of pancreatic pseudocysts are extra-pancreatic in location.²⁶ Most of the published cases were managed by surgical or percutaneous means. There is only 1 case report of successful endoscopic treatment of intrahepatic pancreatic pseudocyst extension by using transpapillary drainage alone.¹⁵

CASE REPORT

A 62-year-old man with alcohol-induced chronic pancreatitis presented with a 3-month history of intermittent epi-

gastric pain. His physical examination was unremarkable. A laboratory evaluation revealed mildly elevated serum alkaline phosphatase (164 U/L [normal 20-140 U/L]) and alanine aminotransferase (60 U/L [0-40 U/L]) levels. Total serum bilirubin, aspartate aminotransferase, amylase, carbohydrate antigen 19-9, and alpha-feto protein levels were normal. Pancreas protocol CT of the abdomen revealed an 11-cm cystic mass that involved the head of the pancreas and extended into the right and left hepatic lobes (Fig. 1, Video 1, available online at www.giejournal.org). The cystic mass caused extrinsic compression of the inferior vena cava, which raised a concern for pancreatic adenocarcinoma with hepatic metastasis. An EUS examination revealed