

A Comprehensive Review of Esophageal Stents

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Abstract: Esophageal stents are important tools for palliative treatment of inoperable esophageal malignancies. With the development of multiple self-expandable stents, there are now several therapeutic options for managing benign and malignant esophageal diseases. This paper discusses the various types of esophageal stents currently available, indications for their placement, challenges and complications that gastroenterologists face when placing these stents, and some of the innovations that will become available in the near future.

Historically, esophageal stents have been used to palliate patients with dysphagia or obstruction caused by a malignancy.¹ However, these rigid plastic prostheses have been associated with high complication and morbidity rates.² Currently, esophageal stents are made from metal alloy compounds and durable polymers, and these stents are used for the treatment of a variety of benign and malignant esophageal conditions. Benign conditions include refractory strictures (such as those induced by peptic ulcers, anastomoses, and radiation), tracheoesophageal fistulae, iatrogenic perforations, and leaks; malignant conditions that can be treated with stents include inoperable esophageal cancer, gastroesophageal junction cancer, and gastric cardia cancer.^{3,4}

With the recent development of self-expanding plastic stents (SEPS) and self-expanding metal stents (SEMS), stent placement for esophageal pathologies can be safe and cost-effective.

Types of Esophageal Stents

A variety of SEPS and SEMS are currently available in the United States, including those manufactured by Boston Scientific, Cook Medical, EndoChoice, Merit Medical Endotek, and Taewoong Medical Co (Table 1 and Figures 1–3). Additional stents manufactured by ELLA-CS are available in Europe

Table 1. Esophageal Stents Currently Available in the United States

Manufacturer and product name	Material and design	Outer diameter (mm)	Length (cm)	Introducer diameter (mm)
Boston Scientific				
Polyflex Esophageal Stent*	Polyester/silicone	16 (proximal flare, 20) 18 (proximal flare, 23) 21 (proximal flare, 25)	9, 12, 15	12, 14
Ultraflex Esophageal NG Stent System (covered)**	Nitinol (polyurethane)	18 (proximal flare, 23) 23 (proximal flare, 28)	10 (covered portion, 7) 12 (covered portion, 9) 15 (covered portion, 12)	6
Ultraflex Esophageal NG Stent System (noncovered)**	Nitinol	18 (proximal flare, 23)	7, 10, 12, 15	6
WallFlex Partially Covered Esophageal Stent†	Nitinol (silicone-coated, wire-braided, removal suture)	18 (proximal flare, 23) 23 (proximal flare, 28)	10 (covered portion, 7) 12 (covered portion, 9) 15 (covered portion, 12)	6
WallFlex Fully Covered Esophageal Stent	Nitinol (silicone-coated, wire-braided, removal suture)	18 (proximal flare, 25) 23 (proximal flare, 28)	10, 12, 15	6
Cook Medical				
Esophageal Z-Stent with Dua Anti-Reflux Valve‡	Stainless steel (polyurethane coating)	18 (proximal flare, 25)	8, 10, 12, 14	10
Evolution Esophageal Fully Covered Controlled-Release Stent§	Nitinol (internal and external silicone coating)	18 (flange, 23) 20 (flange, 25)	8, 10, 12	8
Evolution Esophageal Partially Covered Controlled-Release Stent§	Nitinol (internal and external silicone coating)	20 (flange, 25)	8, 10, 12.5, 15	8
EndoChoice				
Bonastent Esophageal Stent	Nitinol (silicone coating)	18	6, 8, 10, 12, 14, 16	6
Merit Medical Endotek				
Alimaxx-ES Fully Covered Esophageal Stent	Nitinol (covered with polyurethane)	12, 14, 16, 18, 22	7, 10, 12	5.3
Taewoong Medical Co				
Niti-S Esophageal Double Stent	Inner, covered layer: polyurethane; outer, uncovered layer: nitinol wire	16 (ends, 24) 18 (ends, 26) 20 (ends, 28)	Inner layer, 6; outer layer, 1.5 Inner layer, 8; outer layer, 2.5 Inner layer, 10; outer layer, 3.5 Inner layer, 12; outer layer, 4.5 Inner layer, 15; outer layer, 7	5.8, 6.5
Niti-S Esophageal Covered Stent (fully covered)§	Nitinol (completely covered with polyurethane)	16 (ends, 24) 18 (ends, 26) 20 (ends, 28)	6, 8, 10, 12, 15	5.8, 6.5
Niti-S Esophageal Covered Stent (antireflux)	Nitinol (covered with polyurethane) and a polytetrafluoroethylene antireflux skirt¶	16 (ends, 24) 18 (ends, 26) 20 (ends, 28)	6, 8, 10, 12, 15	5.8, 6.5

*Indicated for the management of refractory benign strictures. **Available as a proximal-release stent. †Reconstrainable for up to 75% of deployment. ‡The antireflux valve has a 1-way windsock design. §Can be recaptured to position. §Available as proximal- and distal-release stents; reconstrainable for up to 50% of deployment. ¶The skirt has a length of 4 cm and a diameter of 1.6 cm or 2.6 cm.



Figure 1. From left to right, Boston Scientific's Polyflex Esophageal Stent, Ultraflex Esophageal NG Stent System, WallFlex Fully Covered Esophageal Stent, and WallFlex Partially Covered Esophageal Stent.



Figure 2. A sample of partially and fully covered esophageal stents.



Figure 3. The Alimaxx-ES Fully Covered Esophageal Stent (Merit Medical Endotek).

(Table 2). Each company has created stents with several advantages, including radial forces that maintain stent patency and positioning, no or minimal foreshortening on stent deployment, a silicone or polymer stent coating that decreases tissue ingrowth, and improved fluoroscopic visibility for accurate placement.

Stents are available in 3 types: uncovered, fully covered, and partially covered. The original esophageal SEMS were uncovered, with no synthetic material covering the metal mesh. However, a variety of covering materials (most commonly polytetrafluoroethylene) have been developed due to complications of tumor and granulation tissue ingrowth. Fully covered stents do not have any exposed bare metal, but they are more prone to stent migration. Partially covered SEMS have a small portion of exposed bare metal at the proximal and distal ends to allow embedding into the esophageal wall, which helps to prevent migration.⁵

Complications Associated with Esophageal Stents

Complications associated with esophageal stents are generally classified as either early or delayed.⁶ Early complications occur immediately or within 2–4 weeks postprocedure and include chest pain, fever, bleeding, gastroesophageal reflux disease, globus sensation, perforation, and stent migration.⁷ In 1 study, early complications were reported in up to 32% of patients, with stent migration being the most common complaint.⁸ Prolonged chest pain has been reported in 12–14% of cases, while rates of direct perforation have been lower. A small amount of bleeding is relatively common after stent placement; more severe bleeding is rare, occurring in 1% of cases in 1 study.⁹ Among both early and delayed complications, stent migration is the most common complication, occurring at a frequency of 7–75%.³

Table 2. Esophageal Stents Currently Available in Europe

Manufacturer and product name	Material and design	Outer diameter (mm)	Length (cm)	Introducer diameter (mm)
ELLA-CS				
FerX-Ella Esophageal Stent Boubella*	Stainless steel (fully covered with polyethylene)	20 (proximal flare, 36)	9, 10.5, 12, 13.5, 15, 16.5, 18, 19.5, 21	5.9
FerX-Ella Esophageal Stent Boubella E**	Stainless steel (partially covered with polyethylene)	20 (proximal flare, 36)	9, 10.5, 12, 13.5, 15, 16.5	5.9
SX-Ella Esophageal Stent Flexella Plus†	Nitinol (fully covered with silicone)	20 (proximal flare, 25)	8.5, 11, 13.5, 15	4.7, 5.9
SX-Ella Esophageal Stent HV—HV Stent Plus‡	Nitinol (fully covered with silicone)	20 (proximal flare, 25)	8.5, 11, 13.5, 15	5.9
SX-Ella Esophageal Stent Degradable BD§	Polydioxanone absorbable surgical suture	18 (ends, 23) 20 (ends, 25) 23 (ends, 28) 25 (ends, 31)	6, 8, 10, 13.5	5.9

*Antimigration segment between the proximal end and the body of the stent; optional antireflux valve. **No antimigration segment; partially uncovered proximal end; optional antireflux valve. †Atraumatic stent ends; optional antireflux valve.

‡Antimigration collar; optional antireflux valve. §Disintegration of the biodegradable stent occurs after 11–12 weeks.

Delayed complications are more common than early ones and are defined as complications that occur at least 2–4 weeks after placement of a stent; however, delayed complications can often present months after the procedure. These complications include tumor ingrowth, stent migration, stent occlusion, development of esophageal fistulae, and recurrence of strictures.⁷ Delayed complications have been reported in 53–65% of patients, with a reintervention rate of up to 50%.^{6,10} In a study of 133 patients who underwent placement of SEMS for treatment of malignant strictures, Homann and colleagues reported an overall delayed complication rate of 53.4% (71/133 patients).¹¹ Recurrent dysphagia was caused by tumor ingrowth (22%), bolus obstruction (21%), stent migration (9%), or esophageal fistulae (9%). In another study, approximately 0.5–2% of patients died as a direct result of esophageal stents.¹²

Challenges in Esophageal Stent Placement

Placement of esophageal stents may be associated with several challenges depending on the location of strictures or tumors in the esophagus. Because a stent must be long enough to bridge a stricture and extend 2–4 cm beyond each end, a stricture located proximally or distally can be difficult to stent properly. Strictures that

have narrow or tortuous lumens present another challenge because the luminal diameter must allow passage of the endoscope.⁶

High-Grade Strictures

If a stricture is very tight or difficult to traverse with a standard endoscope, there are currently several ways to bypass the stricture.¹³ One option is to use a dilator. There are 3 types of dilators currently available. Mercury or tungsten-weighted bougies, such as a Maloney (Medovations) bougie, of increasing diameters can be inserted blindly. Polyvinyl dilators (Savary-Gilliard, Cook Medical) can be inserted over a 0.035-inch guidewire passed through a biliary or balloon catheter to cross the stricture. Through-the-scope (TTS) balloon dilators (CRE, Boston Scientific) can be used with or without a guidewire. These dilators are used to dilate the esophagus by imparting only radial forces, whereas mercury and polyvinyl dilators impart both radial and longitudinal shear forces. Savary-Gilliard dilators and TTS balloon dilators are currently the most commonly used dilators.¹³

Another method of bypassing high-grade strictures involves using a stent with a smaller diameter. The Alimaxx-ES Fully Covered Esophageal Stent (Merit Medical Endotek) is available in small diameters (12 mm, 14 mm, and 16 mm) and can be deployed using

an introducer with a small diameter (5.3 mm). Pediatric endoscopes, which are usually small in diameter (5–8 mm), can also be used.¹¹

Upper Esophageal and Cervical Esophageal Strictures

Traditionally, strictures close to the upper esophageal sphincter (UES) have been considered more difficult to manage. In the past, the use of stents has been limited by patient complaints of chest pain and globus sensation, as well as complications such as perforation, proximal migration, and aspiration pneumonia.^{14,15} However, studies have recently demonstrated the effectiveness and safety of stent placement for the palliation of dysphagia and sealing of fistulae in patients with strictures close to the UES.¹⁶ Verschuur and associates examined 104 patients with malignant strictures within 8 cm of the UES; the researchers achieved technical success in 96% of patients, an average improvement in dysphagia score from 3 to 1, and a fistula sealing rate of 79%.¹⁶ Complications included pain (15%), globus sensation (8%), aspiration pneumonia (8%), perforation (2%), and migration (3%), all of which were unrelated to the stricture's distance from the UES. Multivariate analysis showed that there were no differences in complication rates based on the stricture's distance from the UES.

Distal Esophageal Strictures, Gastroesophageal Cancers, and Cardia Cancers

Distal esophageal strictures still present a significant challenge because stent placement across the gastroesophageal junction can lead to gastroesophageal reflux disease and aspiration. In an attempt to remedy these problems, stents with antireflux mechanisms have been developed. Dua and coworkers demonstrated the efficacy of a windsock valve—currently used in Cook Medical's Esophageal Z-Stent with Dua Anti-Reflux Valve—for preventing gastroesophageal reflux disease; the study also demonstrated dysphagia relief comparable to that associated with standard stents.¹⁷ A randomized controlled trial (RCT) by Laasch and colleagues confirmed these findings, as reflux was seen in only 12% of patients (3/25) who received an antireflux Esophageal Z-Stent, compared to 96% of patients (24/25) who received a standard open stent ($P < .001$).¹⁸

However, recent RCTs have not reproduced these findings.^{19–21} Blomberg and associates studied 65 patients who received an antireflux Esophageal Z-Stent or a standard stent (Ultraflex Esophageal NG Stent System, Boston Scientific or WallFlex Esophageal Stent, Boston Scientific).¹⁹ No differences were found in health-related quality of life due to reflux.¹⁹ Sabharwal and coworkers conducted an RCT of 49 patients with dysphagia due to distal esophageal cancer who

received either an antireflux FerX-Ella Esophageal Stent (windsock valve; ELLA-CS) or combination treatment with a standard Ultraflex stent and the proton pump inhibitor (PPI) omeprazole.²¹ The researchers found no demonstrable difference between the antireflux stent and the standard stent plus PPI treatment. Given these equivocal data, larger studies and/or improved study designs are necessary to determine whether antireflux valves are effective.

Management of Benign Esophageal Conditions

The use of self-expandable esophageal stents for the management of benign conditions has grown immensely over the past decade. Temporary placement of self-expandable stents is now used in a variety of benign conditions, including postoperative anastomotic leaks, refractory strictures due to peptic ulcers or radiation, and tracheoesophageal fistulae.²²

Use of Self-Expanding Plastic Stents for Treatment of Benign Esophageal Conditions

SEPS are increasingly being used for the treatment of benign esophageal conditions. These stents are thought to have several advantages over standard SEMS—including low cost, ease of placement and retrieval, and limited local tissue reaction—and still provide symptomatic relief of dysphagia.²³

Several studies have shown SEPS to be very effective for treating benign esophageal conditions.^{24–26} Langer and colleagues described the effective use of SEPS for the treatment of postoperative esophageal anastomotic leaks.²⁴ Nearly 90% of treated patients had successful initial closure with SEPS, enabling early oral feeding. Late stent dislocation requiring intervention occurred in 37.5% of patients. Repici and associates examined 15 patients with recurrent strictures after unsuccessful repetitive endoscopic dilation.²⁵ The researchers reported long-term resolution of strictures (mean follow-up, 22 months) in 80% of patients (12/15) and a significant reduction in the dysphagia score (from 3 to 1), as well as 1 case of migration.

However, recent studies suggest that SEPS may not be as useful for managing benign esophageal conditions as was initially thought.^{23,27} Holm and coworkers retrospectively studied 30 patients who underwent a total of 83 placements of SEPS for treatment of esophageal leaks or strictures.²³ The researchers reported a high overall rate of stent migration (62.1%), with 81.8% of stents migrating when placed for treatment of strictures. A high percentage of patients (81.9%; 68/83) experienced recurrence or persistence of symptoms during long-term follow-up. In a prospective study of 40 patients with refractory benign esophageal strictures, Dua and

colleagues reported that 40% of patients (16/40) were dysphagia-free at 53 weeks, with 22% of patients (8/40) experiencing stent migration.²⁷

According to published studies, SEPS appear to be safe for use with minimal tissue trauma.²⁸ These stents can be useful for alleviating dysphagia caused by benign strictures, as well as for treating esophageal leaks, fistulae, and perforations. However, the use of these stents is limited by migration and poor long-term outcomes for treatment of benign diseases.

Use of Self-Expanding Metal Stents for Treatment of Benign Esophageal Conditions

Although SEMS are very effective for the palliation of malignant strictures, several limitations have precluded routine use of these stents. Tissue embedment after stent placement renders removal of the stents very difficult and often traumatic.³ Also, multiple studies of conventional uncovered SEMS have reported significant complications, such as bleeding, fistulae, recurrent or new strictures, embedment, and erosion.²⁹⁻³¹

However, recent studies have shown that fully covered SEMS (FCSEMS) may be able to overcome the problems of partially or completely uncovered SEMS. Eloubeidi and associates recently published a study in which 35 patients underwent stent placement with nitinol FCSEMS (Alimaxx-ES) for treatment of benign diseases (perforations, leaks, fistulae, or strictures).³² Dysphagia scores improved 1 month after stent placement. In addition, 31% of patients had successful long-term outcomes without the need for reinterventions; this figure included 21% of patients with refractory strictures and 44% of patients with fistulae or leaks. Stent migration was observed in 12 patients (34%), but all of the stents were successfully retrieved, with no complications of bleeding, fistulae, or erosions.

In another study, Buscaglia and coworkers examined 31 patients who underwent placement of FCSEMS for treatment of esophageal fistulae, leaks, or strictures.³³ In total, 28 of 31 patients (90.3%) experienced improvement of their dysphagia or resolution of their fistulae, and 41 of 43 stents (95.3%) were removed without any complications. The researchers reported 13 complications (11 migrations and 2 cases of chest pain/globus sensation) that occurred due to the 43 stent placements, for a complication rate of 30.2%.

Many of the problems associated with uncovered or partially covered SEMS may be solved by the use of FCSEMS, and given the complications and poor long-term outcomes associated with SEPS, FCSEMS may represent an attractive alternative for treatment of benign esophageal conditions. However, further research is necessary, due to the lack of RCTs in this area.

Management of Malignant Esophageal Diseases

Despite advances in the diagnosis, staging, neoadjuvant care, and perioperative care of patients with esophageal cancer, the 5-year survival rate of these patients remains less than 15%, and chemotherapy has shown limited survival benefit.^{34,35} Therefore, patients with incurable esophageal and other nonluminal malignancies of the head and neck often require palliation for dysphagia and/or tracheoesophageal fistulae.

Use of Self-Expanding Metal Stents for Treatment of Esophageal Malignancies

Since the introduction of SEMS 20 years ago, these stents have been shown to be safer and more cost-effective than the plastic esophageal prostheses used previously.³⁶ In a retrospective study of 153 patients, Eickhoff and colleagues found comparable rates of survival, recurrent dysphagia, and improvement in dysphagia scores between SEMS and SEPS; however, SEMS had a much lower complication rate than SEPS (9% vs 22%, respectively).³⁷ Currently, SEMS, along with SEPS, have become the mainstay of treatment for malignant esophageal strictures and fistulae.

As previously discussed, SEMS are currently available in several types: covered, partially covered, and uncovered. Covered stents resist tumor ingrowth because they do not have an uncovered region that embeds into tissue; however, covered stents are also more susceptible to stent migration. In a retrospective study of 152 patients who received either a covered or uncovered stent, Saranovic and associates found that covered stents were associated with more migration (10% vs 0%) but less tumor ingrowth (53% vs 100%) and less restenosis with recurrent dysphagia (8% vs 37%) than uncovered stents.³⁸ Fully covered stents also offer the advantage of being completely removable.

Although the use of SEMS to treat lower esophageal cancer is widely accepted, their use for treating cancer closer to the UES is controversial because of the perceived increased risk of complications such as perforation, migration, pain, and patient intolerance. A recent case-control, matched study by Parker and coworkers showed that the mean dysphagia score decreased by the same amount in both patients with upper esophageal cancer and patients with lower esophageal cancer who were treated with the same types of SEMS.³⁹ In addition, there were no statistically significant differences in early or late complications or median survival rates, showing that SEMS effectively treated both proximal and distal cancers of the esophagus.

Use of Self-Expanding Plastic Stents for Treatment of Esophageal Malignancies

In the early 2000s, SEPS emerged as an alternative to SEMS. Costamagna and colleagues described the use of

plastic Polyflex Esophageal Stents (Boston Scientific) for the management of 16 patients (15 men) with inoperable esophageal strictures.⁴⁰ After stent placement, patients experienced significant improvement in dysphagia; complications included stent migration (in 2 patients) and repeat interventions (in 4 patients). Szegedi and associates conducted a large study in which SEPS were placed for palliation of malignant dysphagia in 66 patients; the researchers reported dysphagia score improvement, a migration rate of 4.5%, and no tumor ingrowth during a mean follow-up period of 129 days.⁴¹

Although SEPS have been shown to be effective, recent studies have shown that they may not be preferred over SEMs. A recent prospective trial by Conio and colleagues randomized 101 patients with unresectable carcinoma to SEPS (Polyflex) or partially covered SEMs (Ultraflex).⁴² There was comparable dysphagia relief between the 2 groups, but there was a significantly higher complication rate (hemorrhage, tumor overgrowth, and migration) with SEPS (odds ratio, 2.3; 95% confidence interval, 1.2–4.4). An RCT by Verschuur and associates examined Ultraflex SEMs, Polyflex SEPS, and Niti-S Esophageal Covered Stents (Taewoong Medical Co) and showed that all 3 stents improved dysphagia scores by the same amount.⁴³ Recurrent dysphagia occurred more frequently with Ultraflex SEMs than Polyflex SEPS or Niti-S stents (52%, 37%, and 31%, respectively); however, stent migration occurred more frequently with Polyflex SEPS.

The Future of Esophageal Stents: Biodegradable Stents

Biodegradable stents have recently been developed in the hopes of avoiding the complications of tissue ingrowth and migration and decreasing the need for reinterventions for stent removal. In a case series by Saito and coworkers, 13 patients with benign esophageal stenosis were treated with a custom-made stent composed of biodegradable poly-L-lactic acid monofilaments.⁴⁴ Stent migration was seen in 10 stents (77%) within 10–21 days of stent placement, while the other 3 stents (23%) remained in position at 21 days postplacement. However, no symptoms of restenosis were observed in any patients 2 years later, and no further therapy was required by any patients. These researchers also reported encouraging results in 2 patients with benign esophageal strictures after endoscopic submucosal dissection of esophageal cancer and 1 patient who also underwent chemoradiation.^{45,46}

The SX-Ella Esophageal Stent Degradable BD (ELLA-CS) is a biodegradable stent composed of polydioxanone absorbable surgical suture. In a study comparing SX-Ella stents (n=18) and Polyflex SEPS

(n=20), Van Boeckel and colleagues found similar rates of long-term dysphagia relief (33% and 30%, respectively), with fewer reinterventions indicated with SX-Ella stents.⁴⁷ Černá and associates treated 5 patients with esophageal leaks or anastomotic perforations with SX-Ella stents; long-term leak sealing was achieved in 80% of patients (4/5).⁴⁸ Repici and colleagues conducted a prospective study of 21 patients who received SX-Ella stents at 2 European centers.⁴⁹ The mean stricture length was 3±1 cm, and stents were mainly placed from the mid-esophagus to the distal esophagus. After 7 weeks, stent migration occurred in 2 patients (9.5%). The median dysphagia score decreased by 2 points over a median follow-up period of 53 weeks. By 6 weeks postplacement, the stents were completely dissolved in all of the patients. Nine of 20 patients (45%) no longer experienced dysphagia at the end of the follow-up period. However, the remaining 11 patients (55%) suffered symptom recurrence (10 patients with stricture recurrence and 1 patient with obstruction from tissue ingrowth). Three patients experienced severe pain after stent placement, and 1 patient experienced minor bleeding.

The use of biodegradable stents remains problematic due to complications of migration, stricture recurrence, and tissue ingrowth; 1 case study even reported development of a tracheoesophageal fistula.⁵⁰ These stents also present new challenges: In 1 case report, the biodegradable stent mesh collapsed inside the esophageal lumen, preventing the passage of a standard endoscope.⁵¹

Although biodegradable stents are still associated with the complications of migration, stricture recurrence, and tissue ingrowth, preliminary data show that these stents may provide a valuable alternative to plastic and metal stents and may eliminate the need for repeat esophageal dilations. However, biodegradable stents may also present new challenges, and further studies are necessary.

Conclusion

Esophageal stents remain important tools for the palliative treatment of inoperable esophageal and gastric cardia cancers. With the development of multiple SEPS and SEMs, there are now several therapeutic options for managing benign and malignant esophageal diseases. The minimally invasive approach of esophageal stenting has improved the quality of life of these patients, who would otherwise face a possibly morbid surgical procedure or who may have limited treatment options because of multiple comorbidities. In the future, new innovations such as biodegradable stents may improve stent patency, mitigate stent-related complications, and decrease the need for reinterventions.

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