Polyflex self-expanding, removable plastic stents: assessment of treatment efficacy and safety in a variety of benign and malignant conditions of the esophagus

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Abstract

Background Historically, esophageal fistulas, perforations, and benign and malignant strictures have been managed surgically or with the placement of permanent endoprostheses or metallic stents. Recently, a removable, self-expanding, plastic stent has become available. The authors investigated the use of this new stent at their institution.

Methods The study reviewed all the patients who received a Polyflex stent for an esophageal indication at the authors' institution between January 2004 and October 2006. Duration of placement, complications, and treatment efficacy were recorded.

Results A total of 37 stents were placed in 30 patients (14 women and 16 men) with a mean age of 68 years (range, 28–92 years). Stent placement included 7 for fistulas, 3 for perforations, 1 for an anastomotic leak, 7 for malignant strictures, and 19 for benign strictures (8 anastomotic, 1 caustic, 5 reflux, 2 radiation, and 2 autoimmune esophagitis strictures, and 1 post-Nissen gas bloat stricture). The mean follow-up period was 6 months. Stent deployment was successful for all the patients, and no complications resulted from stent placement or removal. Nine stents migrated spontaneously. Three of three perforations and three of five fistulas sealed. Only one stent was removed because of patient discomfort. One patient with a radiation stricture experienced tracheoesophageal fistulas secondary to pressure necrosis. Of 20 patients with stricture, 18 experienced improvement in their dysphagia.

Conclusion Self-expanding, removable plastic stents are easily and safely placed and removed from the esophagus. This has facilitated their use in the authors' institution for an increasing number of esophageal conditions. Further studies to help define their ultimate role in benign and malignant esophageal pathology are warranted.

Keywords Endoprosthesis · Obstructive esophageal pathology · Polyflex stent · Removable plastic stents

The management of benign and malignant esophageal strictures has undergone continuous evolution over the past 60 years. Although dilation continues to be the most common treatment and surgery remains a last resort for various obstructive pathologies of the esophagus, esophageal stenting, particularly for malignant strictures, has seen an increased application as the technology has advanced.

Esophageal stenting for malignant strictures in the modern era initially used rigid plastic tubes such as Celestin (Medoc Ltd., Atlanta, Georgia) or Atkinson tubes (KeyMed Ltd., Southend-on-Sea, UK) [1]. These prostheses were placed fully deployed within, in the case of the Atkinson tube, specially designed introducers, which also allowed repositioning and removal in selected cases. These stents provided good palliation in many cases of malignant stricture, but have been replaced largely by a variety of self-expanding metallic stents (SEMS). These SEMS can be introduced in a collapsed form and expanded in place, minimizing the requirement for dilation and decreasing the incidence of trauma and perforation at the time of insertion. Ease of insertion has led to a significant increase in the

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application of these stents, especially for malignant disease [2, 3].

The current generation of SEMS was developed to restore esophageal luminal patency while minimizing the chance of migration. Their success in the treatment of malignant strictures and fistulas is well documented [4–8]. The fact that these stents were designed for permanent insertion has made them most appropriate for patients who are not surgical candidates or have limited life expectancy. This conversely has limited their application for patients with benign pathology [9–11].

Removal of the SEMS has been described [12]. However, the difficulty and potential danger associated with their removal has significantly limited their application for benign patients apart from sporadic reports of their use in highly selected patients with esophageal perforation [13].

More recently, the development of self-expanding plastic stents (SEPS) has added a new treatment option for patients with malignant and benign conditions. The potential advantages offered by this new generation of expandable plastic stents include decreased rate of tissue ingrowth, new stricture formation and increased levels of radial expansion that potentially decrease the need for dilation at the time of insertion, and the possibility of elective removal [14–20]. Experience with these stents in benign conditions is limited. This review assesses the efficacy of Polyflex stents (Boston Scientific, Inc., Boston, MA, USA) at one tertiary referral center in managing a variety of both benign and malignant esophageal conditions.

Patients and methods

All patients who had insertion of a Polyflex stent for esophageal pathology between January 2004 and October 2006 were included in this study. All the patients were retrospectively reviewed. A total of 16 men and 14 women with a mean age of 68 years (range, 28–92 years) underwent placement of at least one stent. Data were collected and recorded in an institutional review board–approved database. A total of 37 Polyflex stents were placed in 30 patients.

The indications for stent placement are documented in Table 1. All the patients had either malignant or benign obstructive pathology, esophageal perforation, fistula, or anastomotic leak. At the time of stent placement, 20 patients (66%) had benign conditions, whereas 10 (33%) had malignant disease. The majority of the patients were reviewed at presentation by both interventional gastroenterology and surgery.

Polyflex stents are composed of a polyester infrastructure with a complete silicone covering. They come in various luminal diameters with a proximal flare (Fig. 1). Specifically, luminal diameters of 16, 18, and 21 mm are available with proximal flare diameters of 20, 23, and 25 mm, respectively. In each of these sizes, lengths of 9, 12, and 15 cm are available. Stent size was selected on an individual case basis secondary to radiographic and endoscopic assessment.

At the time of insertion, each stent was individually loaded into the introducer sheath. Introducer systems ranged in size from 12 to 14 mm, depending on which diameter of stent was chosen. Radiopaque markers are located at the proximal end, midpoint, and distal end of the stent to aid in positioning at the time of deployment.

All stents were placed under fluoroscopic guidance. Strictures were first visualized using standard endoscopic techniques. Dilation was performed before introduction of the delivery system if indicated. Localization of esophageal pathology was highlighted with the intramural injection of contrast. The delivery system then was introduced over a wire and deployed. Stents could be repositioned with a "rat tooth" forceps if required. All but one patient had stent insertion using conscious sedation. One patient required general anesthesia for placement.

Stent removal was accomplished by one of two methods. The majority were removed with "shark's tooth" forceps. With this method, the edge of the proximal flange is grasped, which then becomes elliptical with traction. With additional gentle traction, the stent separates from the esophageal wall, allowing removal with the expectation of the greatest resistance being encountered at the upper esophageal sphincter. The other method involves pulling the stent over a dilator placed into the proximal esophagus with a "shark's tooth" forceps and simultaneously removing both.

Follow-up evaluation was completed for all but three patients. The mean follow-up period was 6 months (range, 1 week to 2 years).

Results

Technically, successful stent placement was accomplished in all cases. The etiology of stent placement and the number of stents placed and removed, as well as the complications, are shown in Table 1. Altogether, 37 stents were placed in 30 patients, and 26 stents were removed. The mean duration of stent placement was 45 days (range, 1–270 days). The mean duration of stent placement in patients with benign strictures was 52 days (range, 2–38 weeks). Patients with malignant strictures were the least likely to have their stents removed.

Clinical success, as manifested by the incidence of improved dysphagia or successful occlusion of fistula, acute perforation, or leak, as well as by requirements for additional treatments is shown in Table 2. Relief or improvement of dysphagia occurred for 90% of the

Table 1 Stents: application and complications

Pathologic condition	Patients (n)	Stents placed (n)	Stents removed (n)	Mean duration (weeks) n (range)	Complications
Malignant fistula	3	5	4	7 (3–10)	2 failures to occlude requiring surgery
Benign fistula	2	2	1	1	1 migration, 1 mucosal herniation
Perforation	3	3	1	7	1 migration
Radiation stricture	2	2	2	3 (3–4)	1 TE fistula
Anastomotic stricture	5	8	8	10 (2–38)	4 migrations
Caustic stricture	1	1	0	Never removed	N/A
Refractory reflux stricture	4	5	4	5 (2–6)	1 migration, 1 pain requiring removal
Anastomotic leak	1	1	1	7	N/A
Autoimmune esophagitis	1	2	1	6	N/A
Post-Nissen gas bloat	1	1	1	0	1 migration
Malignant stricture	7	7	3	3 (2–4)	1 migration, 1 tumor overgrowth

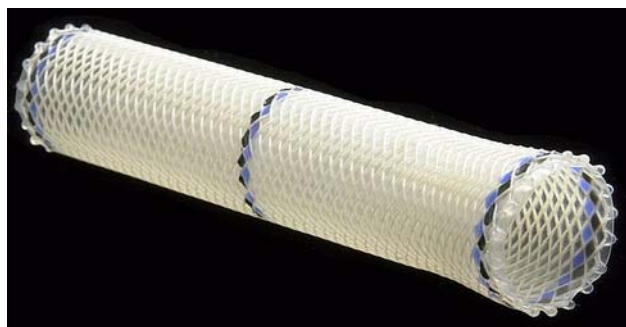TE tracheoesophageal fistula; N/A not applicable

Fig. 1 Self-expanding Polyflex stents come in three luminal diameters of 16, 18, and 21 mm with proximal flanges of 20, 23, and 25 mm, respectively. Lengths of 9, 12, and 15 cm are available

patients, and occlusion of fistulas, leak, or perforations was accomplished for 75% of patients, although two of three patients with malignant fistula could not be controlled with stent placement alone.

Five patients presented with chronic fistulas. Three of these patients had malignant fistulas, and two required surgical resection or bypass because stent placement failed to occlude the fistula. One of these two patients was a 53-year-old woman with an esophageal left bronchial fistula resulting from metastatic breast cancer to the mediastinum treated with definitive chemoradiotherapy. The other patient was a 49-year-old woman with a tracheoesophageal fistula who had undergone a complete laryngectomy with jejunal interposition followed by radiation therapy for laryngeal cancer. The two benign fistulas both involved barogenic perforations and fistula formation in patients with previous antireflux procedures. Stent placement required revision in both patients, one for migration and

Table 2 Stents: treatment success and need for additional therapy

Pathologic condition	Patients (n)	Dysphagia improved (n)	Leak/fistula sealed (n)	Additional therapy
Malignant fistula	3		1	2 surgery required
Benign fistula	2		2	
Perforation	3		3	
Radiation stricture	2	2		1 additional stent for TE fistula, 1 additional dilation
Anastomotic stricture	5	5		2 additional stents, 1 additional dilation
Caustic stricture	1	1		
Refractory reflux stricture	4	3		1 additional dilation
Anastomotic leak	1		1	
Autoimmune esophagitis	1	1		1 restenting with Polyflex required
Post-Nissen gas bloat	1			1 revision of Nissen
Malignant stricture	7	6		2 of 3 patients with stents removed requiring additional stents

one for mucosal herniation, but both perforations ultimately healed completely without the need for surgical intervention.

Three patients had acute esophageal perforations. Two occurred during endoscopic retrograde cholangiopancreatography (ERCP) for pancreatic cancer and gallstone pancreatitis. The third was a barogenic perforation in a patient with an incarcerated paraesophageal hernia. Migration occurred in the patient with the paraesophageal hernia, but not until healing had occurred. The migrated stent was discovered in the stomach at the time of its scheduled removal.

The patient with gallstone pancreatitis still has her Polyflex stent in place, but her most recent studies have shown complete occlusion of the fistula. The patient with pancreatic cancer was referred to hospice care after successful stent placement, and sealing of the perforation was confirmed with an esophogram.

Two patients with radiation strictures had insertion of a Polyflex stent for refractory dysphagia. Both had undergone unsuccessful dilations before stent placement. In one, a tracheoesophageal fistula developed associated with the proximal edge of the stent. This eventually required treatment with the insertion of an Ultraflex stent (Boston Scientific, Natick, MA), which was successful. This is the only incidence of fistualization or acute perforation related to a Polyflex stent in this series. The other patient went on to have periodic dilations after stent removal.

Five patients had refractory anastomotic strictures. Two of these patients were successfully treated long term with Polyflex placement and its subsequent removal (Fig. 2). One patient required two additional dilations, and two others with esophageal and locoregional cancer recurrences were ultimately managed with the placement of an Ultraflex stent.

One patient with a caustic stricture was sent to our institution with a Polyflex stent already in place, but with proximal restricturing. This patient was treated using an additional Polyflex stent, with the anticipation that the patient would return for removal of both stents. Despite multiple contact attempts, the patient has not returned for stent removal.

Four patients with refractory reflux strictures were treated with Polyflex stents to avert esophageal resection. These patients all had undergone at least five dilations before stent placement, with only transient relief. One patient required stent replacement secondary to migration and proximal stricturing. The remaining three patients did not require any further therapy after stent removal other than high-dose proton pump inhibitors.

Fig. 2 **A** Dense anastomotic stricture in a patient who had undergone six dilations with rapid restricturing. **B** Polyflex stent (length, 9 cm; diameter, 18 mm) in place. **C** Area of anastomotic stricture immediately after Polyflex stent removal at 35 days
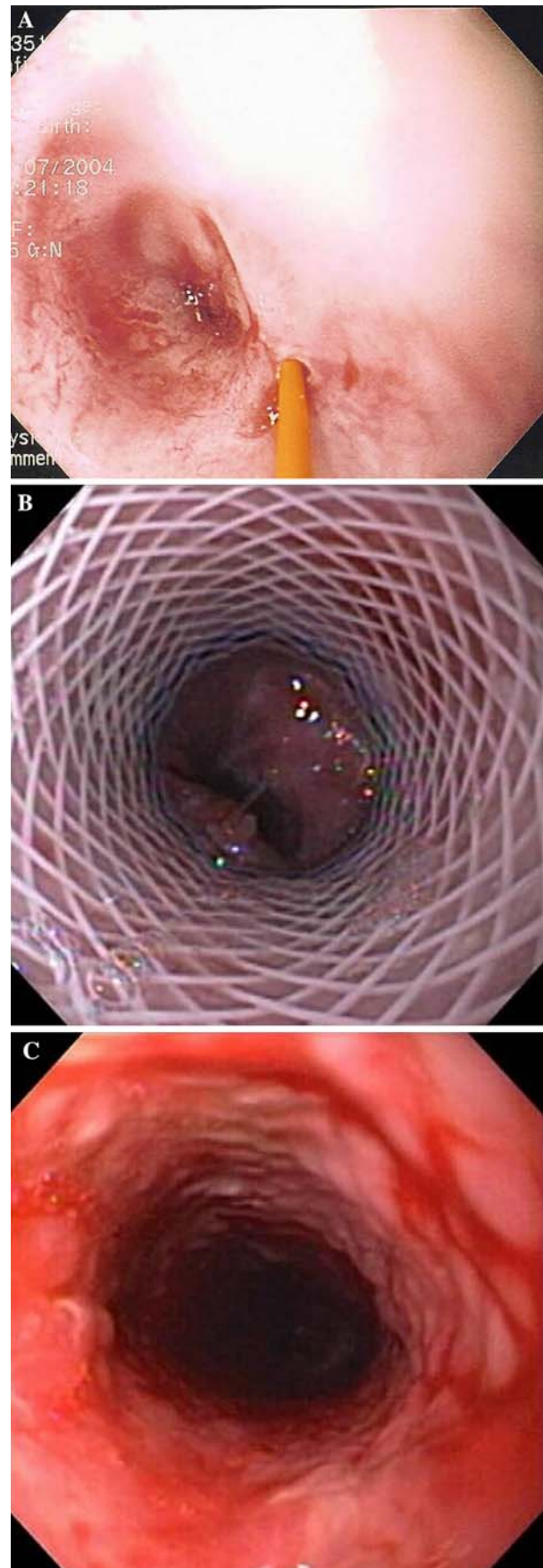
One patient required stent removal for unremitting pain. Pain was encountered as a transient issue by 11 (33%) of the 30 patients. However, it was successfully treated with medications alone for 91% of these patients.

One patient with an acute anastomotic leak was successfully treated with a single Polyflex stent (Fig. 3). Another patient with autoimmune esophagitis had excellent initial relief with stent insertion and removal, but required restenting 6 weeks later.

Seven patients with malignant strictures (6 primary cancers and 1 anastomotic recurrence) were treated. Only three of these patients had stent removal, and two ultimately required restenting.

Migration was the second most common complication encountered. Of the 30 patients, 9 experienced migration (8 distal and 1 proximal) at a mean of 21 days (range, 1–49 days). Table 3 shows the incidence of migration according to location of the stent, with the incidence being greatest for those placed at the esophagogastric junction. Migration was most commonly noted in patients with anastomotic strictures (Table 1).

As previously stated, all stents were placed successfully. However, one patient who had stent placement for post-Nissen gas bloat experienced distal migration within 24 h. Of particular note is the fact that 26 of the 37 stents were ultimately removed without any major difficulty or complication directly associated with removal. These included all the stents found *in situ* and those stents that had migrated.

Discussion

The role of expandable metal stents in the palliation of esophageal cancer is well established. These SEMS can provide significant improvement in dysphagia [4–7]. They
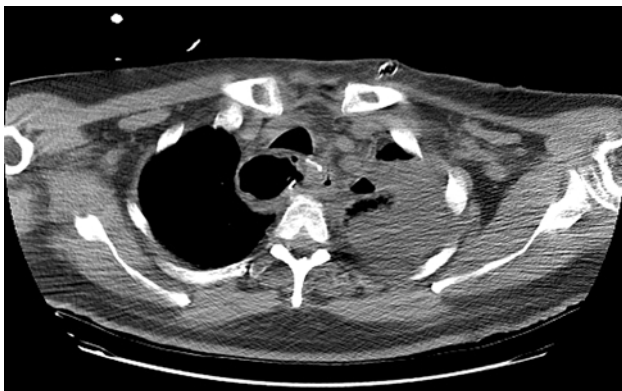

Fig. 3 Computed tomography (CT) scan of a 74-year-old man who underwent a left thoracoabdominal esophagectomy after neoadjuvant chemoradiotherapy for a T3N1 adenocarcinoma. The CT scan demonstrated air and fluid in the apex of the left chest associated with an anastomotic leak. The patient had insertion of an apical chest drain and a Polyflex stent with an uneventful recovery

Table 3 Stents: location and stent migration

Location of stent placement	Stents placed (n)	Stents removed (n)	Stents migrated n (%)
Proximal esophagus	12	10	3 (25)
Midesophagus	9	5	1 (11)
Distal esophagus	9	5	1 (11)
EG junction	7	6	4 (57)

EG, esophagogastric

are designed in a fashion that allows the stent to become incorporated into the wall of the esophagus, making migration less likely. These same factors that make SEMS successful for malignant disease have limited their application for benign obstructive conditions of the esophagus because they have not been designed for removal. Leaving stents in place long term in patients whose life expectancy is not limited is considered to be inappropriate and potentially dangerous [9]. We have previously published a report documenting the feasibility of safe SEMS removal [12]. It is clear, however, that this process can be associated with significant risk. Most surgeons and gastroenterologists are unwilling to consider the routine removal of metallic, expandable stents. This factor, above all others, limits their application in benign conditions.

Most benign esophageal strictures secondary to reflux disease, caustic injury, or postsurgical stricture can be treated successfully with standard dilation. For certain refractory strictures, other options such as steroid injections after dilation, needleknife incision, or self-dilation can be successful [21]. However, there is a subgroup of patients whose strictures are transmural and will not respond to current techniques. These patients previously would have selectively required surgical management [21–23]. The development of the Polyflex stent has provided an additional treatment alternative for patients with benign strictures who might otherwise require surgical therapy, including resection.

Strictures associated with transmural damage will normally recur with standard therapy. Theoretically, stenting after adequate dilation avoids early restricturing and allows nonobstructive remodeling of the scar tissue [24]. In the current series, 30% of the patient population required dilation at the time of stent placement. Because of the increased radial force applied by the Polyflex stent, the remainder were placed without predilation.

Previous studies have demonstrated that Polyflex stents can improve dysphagia in 75% to 85% of benign stricture cases [14, 15]. Our series demonstrated improvement of dysphagia for 90% of patients with a variety of benign strictures, and for 86% of patients with malignant dysphagia (Table 2).

Although a significant proportion of patients with benign disease did require additional interventions after stent removal, either restenting or additional dilations, 6 (46%) of the 13 patients with benign strictures did not require additional treatment after temporary placement of a Polyflex stent. Overall, our reintervention rate was 47%. However, this included all the patients who required multiple Polyflex stent placements, additional dilations, and metallic stent placement or surgical intervention as ultimate therapy. It also included those who required stent repositioning, of which there were only two patients. Both of these patients had acute perforations. Although our reintervention rate was higher than that of other series, which describe rates of 21% to 35% [25–27], the majority of the patients in these other series had malignant indications for stent placement, whereas the majority of our patients had benign indications.

It is possible that treatment success is related to the length of time the stent is left in place. The mean duration of stent placement in patients with benign stricture in the current series was 52 days (range, 2–38 weeks). Song et al. [11, 27] showed that long-term relief of dysphagia was 100% for patients whose stents remained in place at least 2 months. However, the optimum time frame still is to be determined.

One patient with radiation stricture experienced the development of a tracheoesophageal fistula that required additional treatment with an expandable metal stent. This patient had a history of laryngeal cancer treated with chemoradiotherapy. The fistula was noted at the time of stent removal after 21 days and considered the likely result of pressure necrosis. Esophagorespiratory fistulas associated with stenting of radiation strictures have been reported previously [28, 29], reinforcing the caution that must be exercised with any instrumentation of the definitively irradiated esophagus.

Migration remains the second most common overall complication, occurring for 9 (30%) of the 30 patients in the current series. Evrard et al. [15] documented a 100% migration rate with Polyflex stents used for refractory anastomotic strictures. We similarly found migration most common in anastomotic strictures (Table 1). In addition, we found that the esophagogastric junction was the most common site associated with migration (Table 3).

Methods used to reduce the incidence of migration include the design of the stent itself (with a proximal flare) and potential stent stabilization with endoclips at the time of deployment. Currently, there is no technique agreed upon to reduce stent migration. However, precise placement and full initial deployment are important. The use of clips may be indicated when stents are placed in areas with an increased probability of movement, such as the esophagogastric junction and anastomotic strictures. In our series, about half of the stents were clipped in place. We found no difference in migration rates between the stents that were clipped and those that were not. Ultimately, the role of clipping is unclear, but with increasing advances in endoscopic technology, other options may soon be used, one of which will be sewing of stents in place.

Migration does not preclude clinical success with stent placement, depending on the timing of migration. No problems were encountered with stent removal, which was accomplished in all cases of migration. In contrast to other series, we had no incidence of acute life-threatening complications such as tracheal compression or bleeding [8, 15, 30].

Stents have been used previously in patients with anastomotic leaks and acute perforations. In the current series, we were successful in treating three complex esophageal perforations and one anastomotic leak with a Polyflex stent. Success rates of 80% to 92% have been documented previously with SEPS used for anastomotic leaks [16, 20, 31], whereas Gelbmann has shown that 75% of selected patients with acute esophageal perforations can be treated nonsurgically, with SEPS as a component of their initial management [20]. However, similar to the findings in surgical series of treatment for esophageal perforations, Fischer et al. [13] in a series using SEMS showed that treatment success deteriorates with increasing delay between perforation and initial management. The use of SEPS for the management of leaks and perforations may allow for nonoperative treatment of patients who historically would have required surgical intervention. We regard this application as one of the most promising uses of Polyflex stents.

Only one of three patients with malignant fistulas was successfully treated with Polyflex stent placement. One of these failures involved a large (>1 cm) esophagorespiratory fistula, and the other involved multiple smaller fistulas. Both occurred in previously irradiated patients (Fig. 4). In retrospect, we now recommend careful assessment, with patients undergoing initial surgical repair or bypass, which was ultimately done successfully for both of our treatment failures.

Multiple reports have documented the successful treatment of malignant dysphagia with SEMS. However, the application of metallic stents in patients with obstructing esophageal cancer who are considered candidates for definitive or neoadjuvant chemoradiotherapy has been limited because of concerns regarding esophagorespiratory or esophagovascular fistualization.

A small number of patients in this series had SEPS placed for malignant stricture. We believe there is a subset of patients with esophageal malignancy who will undergo either neoadjuvant or definitive chemoradiotherapy for whom SEPS can be used to bridge early treatment

Fig. 4 Large esophago left main bronchus fistula in a 53-year-old woman with metastatic breast cancer to the mediastinum treated with radiation and chemotherapy. A 9-cm by 21-mm Polyflex stent was unable to occlude the fistula, and the patient ultimately underwent successful retrosternal bypass

dysphagia. The SEPS can be removed subsequently, thereby reducing the potential for fistula formation in these patients when chemotherapy or chemoradiotherapy has produced initial tumor shrinkage [32].

The current series demonstrated improvement of dysphagia for 86% of patients with malignant strictures, a success rate that has been documented in previous reports [25, 26, 33]. The use of SEPS under these circumstances may allow for the avoidance of more invasive procedures such as the placement of gastrostomy and jejunostomy tubes in patients with severe dysphagia.

Costamagna et al. [18] have suggested that Polyflex stents are less expensive than expandable metal stents. Data on charges from our institution, however, indicate that current charges for all sizes of Polyflex stents are $2,775, compared with the Ultraflex metallic stent, which varies in cost from $1,825 to $2,183.

The current series has demonstrated an encouraging degree of clinical success with a variety of benign and malignant strictures and for selected patients with esophageal perforation or fistulas. Most importantly, the entire group of 30 patients had 37 Polyflex stents placed and 26 removed without any identified complications associated with insertion or removal. This high level of safety and efficiency with respect to insertion and removal has been demonstrated in previous studies [14, 15]. A significant portion of our study group demonstrated persistent improvement in dysphagia or averted major surgical interventions for acute perforations or fistulas. The opportunity for safe and easy removal of these stents is a significant

advantage over previous types of expandable metal stents. Although follow-up evaluation for the current series was limited, the results do support ongoing assessment of optimal stent size, length of stent placement, optimal indications, and assessment of long-term benefit of Polyflex stents, especially for benign conditions of the esophagus.

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