

# Self-expanding metallic stents and self-expanding plastic stents in the palliation of malignant oesophageal dysphagia

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**Abstract:** Endoluminal stenting has revolutionised the practice of gastrointestinal endoscopy for many years. What started as rigid, inflexible, plastic stents have now evolved into flexible, easy-to-deploy self-expanding stents with a myriad of choices, including covered, partially covered and uncovered types. Many of these also come along with special features including anti-reflux, anti-migration and lasso for stent adjustment and retrieval. Numerous papers with meta-analyses and systemic reviews have without doubt confirmed the efficacy, safety and cost effectiveness of endoluminal stenting in the palliation of malignant obstruction of the oesophagus, stomach, duodenum, colon and the biliary tree. This paper will focus on the use of self-expanding plastic stents (SEPS) as well as self-expanding metallic stents (SEMS) in the palliation of malignant oesophageal obstruction.

**Keywords:** Stents; self-expanding; malignant dysphagia; oesophageal cancer; palliation

Submitted Mar 24, 2014. Accepted for publication Mar 24, 2014.

doi: 10.3978/j.issn.2224-5820.2014.03.03

View this article at: <http://www.amepc.org/apm/article/view/3677/4552>

Charles stent (1) would have been very proud to know that his last name has been immortalised and still frequently used in the fields of gastrointestinal endoscopy, cardiology, urology and gynaecology. What started as a dental mould then evolved into today's sophisticated self-expanding stents.

Self-expanding metallic wallstent was first used in 1990 for relieving malignant oesophageal obstruction (2). This was then essentially a compressed woven wire mesh, made of surgical grade stainless steel alloy filaments. However, subsequent reports of tumour ingrowth (3) with such stents led to the production of a silicon membrane covered stent to overcome this problem. The following years saw many more improved modifications to the self-expanding metallic stent (SEMS), in the attempt to achieve an ideal stent. Each one of these stents has its own unique features (see *Table 1*) to cater to the individual need.

## Self-expanding metallic stent (SEMS) (oesophageal)

In the palliation of malignant dysphagia, SEMS has

proven to be superior to the rigid plastic stents with less complications (3% *vs.* 43%), lower mortality (14% *vs.* 29%), and better relief of dysphagia (80% *vs.* 62-69%) (4,5). Except for self-expanding plastic stent (SEPS), SEMS have replaced the rigid plastic stents in the endoscopic management of malignant dysphagia. Endoscopic stenting of oesophageal and upper gastrointestinal malignancies have been proven to be safe, efficacious and cost effective (6,7).

SEMS are available commercially from several companies, each with their own special unique features, to cater to the individual need. The main common features of a SEMS include a woven metallic wire mesh cylinder, compressed within a small diameter delivery system, with/without a silicon/plastic membrane covering the mesh interstices. Most of the oesophageal SEMS are deployed over a guidewire outside the scope, though Taewoong Medical has commercialised an oesophageal SEMS that could be deployed through the scope (similar to that of a duodenal or colonic SEMS). Most SEMS are deployed by manually unsheathing the outer tube containing the inner compressed stent. The Evolution controlled release

**Table 1** Summary of table of various stents and their associated important features

	SEMS			SEPS	Biodegradable stent
	Fully covered	Fully uncovered	Partially covered		
Migration chance	High	Low	Moderate	High to very high	Low
Tumour ingrowth	Low	High	Low	Low	High
Tumour overgrowth	Low	High	Moderate	Low	High
Removable	Yes	No	Difficult	Yes	No need to
Closure of fistula or leakage	Yes	No	Yes	Yes	No
Assembly difficulty	Minimal	Minimal	Minimal	Difficult	Minimal

SEMS, self-expanding metallic stent; SEPS, self-expanding plastic stent.

SEMS (Cook Medical Endoscopy Inc, USA) are released by pulling the trigger of a gun handle; every trigger pull unsheathing a fixed 6 mm length of the stent. However, it remains to be seen whether such design can result in higher technical success rate of oesophageal stenting, as compared to conventional release method.

Verschuur *et al.* compared three different types of stents, partially covered Ultraflex stent (Boston Scientific, USA), polyflex stent (Boston Scientific, USA) as well as the fully covered Niti-S stents (Taewoong Medical, Seoul, Korea) for the palliation of malignant dysphagia (8). Technical success rate was 100%, 83% and 95% respectively. Dysphagia improved in all patients with no differences in complications. However, recurrent dysphagia (from tissue ingrowth/overgrowth or migration or food obstruction) was 52% *vs.* 37% *vs.* 31%. Stent migration was highest in those with polyflex stents whereas tissue ingrowth/overgrowth occurred more in Ultraflex stents and less in Niti-S stents. The conclusion was that polyflex stents are technically more difficult to deploy and with the highest chance of stent migration. We could also conclude that a covered stent is probably associated with less risk of tumour ingrowth/overgrowth.

### Uncovered SEMS

This SEMS has no silicon or plastic membrane covering the wire mesh interstices. The underlying oesophageal tissues will, with time, become embedded within the stent mesh. As the result, the migration chance is minimal. The main problem of such stent is the risk of tumour ingrowth due to the exposed wire interstices and it cannot be safely removed after deployment. Subsequent endoscopic intervention, including laser boring of tumour within the stent, or redeployment of a 2nd stent within the original stent, has to

be carried out for tumour ingrowth/overgrowth.

### Covered SEMS

Due to the presence of silicon membrane covering the wire mesh interstices, this SEMS is associated with a low chance of tumour ingrowth. Vakil *et al.* reported similar technical success and dysphagia relief but tumour ingrowth of 3% *vs.* 30% in covered Ultraflex *vs.* uncovered Ultraflex SEMS (9). Removal of this covered stent was also very easy though CE and FDA approval for benign oesophageal stricture varies with different stents (see *Table 2*). It is this easy removability that makes this covered SEMS suitable in trachea-oesophageal fistula or leakage. Neoadjuvant radiotherapy planning with CT scan and even oesophagectomy can be hindered with the presence of a stent and hence this removable stent is also suitable for such temporary deployment. However, this feature also results in the high chance of stent migration (7% to 25%) (10,11), with recurrence of dysphagia symptom and the need to retrieve the migrated stent.

### Partially covered SEMS

This SEMS attempts to reduce the migration risk of deployed stent, and yet reduce the chance of tumour ingrowth (8). The covered portion is usually in the centre, with the uncovered portion at the proximal and distal ends. However, the risk of migration, compared to uncovered stent, and the risk of tumour ingrowth/overgrowth, compared to covered stent are still relatively higher.

### Self-expanding plastic stent (SEPS)

This is a device with an encapsulated monofilament braid

**Table 2** List of oesophageal stents with FDA and CE approval (accurate as of time of writing)

	Manufacturer	Benign oesophageal stricture		Malignant oesophageal stricture	
		FDA approved	CE approved	FDA approved	CE approved
Wallflex fully covered	Boston Scientific	No	Yes	Yes	Yes
Wallflex uncovered	Boston Scientific	No	No	Yes	Yes
Wallflex partially covered	Boston Scientific	No	No	Yes	Yes
Niti-S stent fully covered	Taewoong Medical	No	Yes	Yes	Yes
Hanarostent Choostent	M.I.Tech	No	Information not available	Yes	Yes
Evolution fully covered controlled release stent	Cook Medical	No	Yes	Yes	Yes
Polyflex stent	Boston Scientific	Yes	Yes	Yes	Yes

made of polyester. The meshes are completely covered by a silicone layer with a smooth inner surface and a more structured outer surface. This stent has to be loaded with a large 13 mm diameter introducer sheath before deployment and the assembly is rather cumbersome. The obvious main advantage of this stent is the easy removal and hence it is, like the covered SEMS, suitable in tracheo-oesophageal fistula and in cases where temporary relief of obstruction is indicated. In fact, it has been approved for refractory benign oesophageal stricture with initial good encouraging outcome (12-14) of 90% clinical relief and migration chance of 6.7% to 52.4%. However, a recent retrospective study of 83 deployments in 30 patients with benign stricture/fistula revealed a 62.1% stent migration with 81.9% patients reporting recurrence or persistence of symptoms during long term follow-up (15). It is this high migration risk and cumbersome assembly with a large introducer that makes the SEPS less favoured over covered SEMS in relieving oesophageal obstruction. It is both FDA and CE approved for the treatment of both malignant and benign oesophageal stricture (see *Table 2*).

A few unique features of certain SEMS deserve to be mentioned here.

#### *Anti-reflux features*

Up to one third of patients with distal oesophageal stenting across the GE junction experiences significant acid reflux symptoms (16). The polyurethane coating of some SEMS is extended beyond the distal end to form a windsock valve. The Dua antireflux stent (Cook Medical Endoscopy Inc, USA) in canine model, has been shown to reduce oesophageal acid reflux from 49% to 1% (17). However, a randomised controlled trial comparing this stent with

other stents without anti reflux features did not show any significant improvement in reflux symptoms (18-20). These anti-reflux features are also available in Niti-S stent (Taewoong Medical Co, Seoul, Korea) and Hanarostent (M.I.Tech, Seoul, Korea).

#### *Anti-migration features*

The double layered Niti-S oesophageal stent (Taewoong Medical, Seoul, Korea) comprises of a silicon membrane covered inner layer and a wire mesh external layer. The wire mesh will gradually embed within the underlying tissues and hence reduce the chance of migration while the covered inner layer reduces tumour ingrowth and facilitates smooth passage of food through the stent.

M.I.Tech oesophageal SEMS (Choostent and Hanarostent) comprised of segmented stent structure with larger bands than others. This unique feature is supposedly useful to reduce migration chance. Davide Bona *et al.* (21) compared Choostent *vs.* covered Ultraflex oesophageal stents and reported a 4.6% migration rate in Choostent. Though there were two Ultraflex migration compared to one Choostent, these were not statistically significant. The Choostents were also reported to be easily removed up to eight week post deployment under sedation.

#### **Use in upper oesophageal obstruction**

Stenting of the upper oesophagus continues to be shunned by many endoscopists who are concerned about intolerable throat pain, stridor, aspiration pneumonia and stent migration into the hypopharynx. Small studies have shown that 28% of patients experienced intolerable throat pain when the standard SEMS was placed 1.5 cm from the upper

oesophageal sphincter (UES), as compared to none when the proximal limit is 2 cm (22,23). A large retrospective study of 104 patients with oesophageal stenting near the UES reported 33% complications including aspiration pneumonia and 15% intolerable throat pain (24).

Most SEMS are released from the distal end to the proximal end. For stenting of the upper oesophagus, accurate placement is crucial due to the small margin of error allowed as stent encroachment onto the upper oesophageal sphincter may lead to stridor or significant throat pain. Boston Scientific has an Ultraflex stent that can be released proximally so that satisfactory position can be determined with confidence before the irreversible full deployment.

A special cervical stent is available (Taewoong Medical and M.I.Tech) comprising a much smaller 7 mm proximal funnel in an obtuse angle. These features appear to relieve the throat discomfort frequently experienced after cervical oesophageal stenting using a conventional stent. From my personal experience, no significant discomfort will be felt as long as the proximal end of the stent is deployed not nearer than 1.5 cm from the upper oesophageal sphincter (25).

### Biodegradable stents

Biodegradable oesophageal stents have been recently developed in the aim to obviate the need to remove the stent after deployment for temporary relief of obstruction. The first case series published on the use of biodegradable stents made of poly-L-lactic acid monofilaments (for oesophageal cancers after surgery or endoscopic submucosal dissection) reported stent migration of 77% (10 out of 13) within 10-21 days of deployment (26). However, all the migrated stents were passed out in the stools and no symptoms of re-stenosis were observed in any patients two years later.

The SX-Ella Esophageal Stent Degradable BD (Ella-CS, Czech Republic) is a stent completely made of polydioxanone, a crystalline biodegradable polymer. This material is partly absorbable and partly excreted through the gastrointestinal tract lumen and the stent is supposed to start degrading after 4-5 weeks. Van Boeckel *et al.* compared this BD stent to Polyflex SEPS and reported similar rates of long term relief of dysphagia but the BD stent was associated with few re-intervention as it need not be removed (27). Repici *et al.* reported a 9.5% stent migration with all stents completely dissolved after six months deployment (28). However, a few serious complications including tracheo-oesophageal fistula and collapse of stent

mesh have been reported (29,30).

Overall, BD stents appear to be a viable alternative to SEPS and SEMS for cases where temporary relief is needed. We await more studies to establish its efficacy and safety.

### Conclusions

Self-expanding metallic and plastic stents are now used worldwide and are essential tools in the endoscopy armamentarium. So what is the ideal stent? Perhaps the ideal oesophageal stent for palliation of malignant dysphagia should have the following features:

- (I) No assembly required before deployment;
- (II) Strong radial expansile force for tight stricture;
- (III) Minimal foreshortening;
- (IV) Durable material with low risk of stent fracture after deployment;
- (V) Easy to deploy with easily identifiable markers endoscopically or fluoroscopically;
- (VI) Able to re-sheath or re-adjust during or immediately after deployment;
- (VII) Small diameter of delivery system so that it could be deployed through the standard accessory channel;
- (VIII) Low risk of stent migration;
- (IX) Low risk of tumour ingrowth and overgrowth;
- (X) Low risk of acid reflux if stenting has to traverse the GE junction;
- (XI) Ability to close up fistula, leakage effectively;
- (XII) Biodegradable negating the need for re-intervention to remove the stent. Better still, able to initiate easy self-degradation with a simple ingestion of a tablet or simple endoscopic flushing with a safe dissolution reagent;
- (XIII) Low cost to patients.

Many of the current SEMS have many of these ideal properties. I am confident that we may soon see the ideal SEMS available for the management of both benign and malignant oesophageal dysphagia.

### Acknowledgements

*Disclosure:* The author declares no conflict of interest.

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**Cite this article as:** Yim HB. Self-expanding metallic stents and self-expanding plastic stents in the palliation of malignant oesophageal dysphagia. *Ann Palliat Med* 2014;3(2):41-46. doi: 10.3978/j.issn.2224-5820.2014.03.03