Development of gastroduodenal self-expandable metallic stents: 30 years of trial and error

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A B S T R A C T

In 1991, the author (H.Y.S.) reported the first case of self-expandable metallic stent (SEMS) placement in a patient with recurrent cancer after gastrojejunostomy. Since then SEMS placement has developed into a well-established method for the palliative treatment of malignant gastroduodenal obstruction. This year marks the 30th year the author has been implicated in the development of gastrointestinal SEMSs. Thus far, the author has developed successively a total of six generations of gastroduodenal SEMSs through trial and error over the years. In the present article, the author reviews his personal experience in developing gastroduodenal stents.

Introduction

In 1885, Symonds,1 a British surgeon, was the first to record the use of a short, rigid tube to internally stent a malignant esophageal stricture. The tube was six inches long and made from boxwood. Strings with one end attached to the tube and the other end strapped to the patient’s ear were used to maintain the tube’s position. Subsequently, a number of rigid tubes made from latex or silicone, without the need for external fixation, were developed, such as the Medoc-Celestin tube (Medoc, Tetbury, UK) and the Wilson-Cook tube (Wilson-Cook Medical, Winston-Salem, NC, USA).2,3 However, these fixed diameter tubes were technically difficult to place into the esophagus, let alone into the gastroduodenal tract, because of the large and rigid delivery system; the reported esophageal rupture rate was as high as 11%.4 The author (H.Y.S.) still vividly remembers how difficult it was to place these tubes with the 25 mm delivery system, and would toss and turn the night before the procedure, thinking about the possibility of failure and rupture.

In 1985, an article written by Wright et al5 about endovascular self-expandable Z-stents made a deep impression on the author. The author visited Drs. Wright and Wallace at the MD Anderson Cancer Center in Houston the following year and was graciously shown how to fashion the Z-stent. After his return, the author, due to a lack of funding, was restricted to constructing esophageal and gastroduodenal self-expandable Z-stents on a bench in the corner of his office. Subsequently, in 1991, the author reported the first case of gastroduodenal self-expandable metallic stent (SEMS) placement.6 Since then, SEMS placement has developed into a well-established method for the palliative treatment of malignant gastroduodenal obstruction.7,8 This year marks the 30th year the author has devoted to the development of gastrointestinal stents. Thus far, the author has developed successively a total of six generations of gastroduodenal SEMSs through trial and error over the years. The present review of the author’s own personal experience in the development of gastroduodenal stents is also a reflection of his own personal history as a physician-researcher.

First-Generation: Covered SEMS with Anchoring Barbs

In 1990, the author placed transorally a first-generation gastroduodenal SEMS in a 69-year-old man with recurrent gastric cancer after gastrectomy and gastrojejunostomy using a 12 mm delivery system.6 The first-generation stent was composed of several units with a diameter of 18 mm and a length of 2 cm constructed in-house of 0.5 mm stainless steel wire in a cylindrical zigzag configuration of six bends (Fig. 1). The entire stent was covered with nylon mesh and coated with silicone to prevent...
tumor ingrowth, and the second or third unit of the stent had two anchoring barbs to reduce stent migration. The procedure was technically and clinically successful, and no complications were experienced. However, there were several limitations to the first-generation stent that precluded further clinical applications. Firstly, transoral placement of the stent in patients without prior bypass surgery was not possible because the delivery system was too large and rigid. Secondly, it was cumbersome to advance the stent through the delivery system due to friction between the stent and the polyvinyl chloride introducer sheath. Thirdly, the poor flexibility of the stent and the anchoring barbs could result in severe pain and foreign body sensation after stent placement. Lastly, in the event of complications, it would be technically difficult to remove the stent because of the anchoring barbs.

Second-Generation: SEMS with Flared Ends

In 1991, the author placed a second-generation gastroduodenal SEMS (Song Stent; Myung Sung Medi-Tech, Seoul, Korea) in a 62-year-old man with unresectable gastric cancer through a surgical gastrostomy using a 13 mm delivery system. The second-generation stent was identical in design to the first-generation stent; however, instead of anchoring barbs, the proximal and distal units of the stent were flared up to 24 mm to reduce stent migration (Fig. 2). In addition, the introducing sheath was made from polyethylene rather than polyvinyl chloride to allow for easier passage of the stent through the delivery system. The patient tolerated the stent well and was able to eat a regular diet until his death 102 days after stent placement. However, our experience with the second-generation stent was limited to this patient only. The reason for this was that transoral stent placement in patients without prior bypass surgery was still not possible due to the large and rigid delivery system. In addition, the flexibility of the stent remained poor and could cause severe pain and foreign body sensation after stent placement.

Third- and Fourth-Generations: Nitinol SEMS

To reduce the size of the delivery system and improve the flexibility of the stent, the decision was made to develop stents from nitinol, which is a metal alloy of nickel and titanium known for its shape memory characteristics and super-elastic properties. Therefore, the author developed third- and fourth-generation gastroduodenal SEMSs (Fig. 3). These stents were constructed in-house from a single thread of 0.2 mm nitinol wire woven 16 times in a tubular configuration. The stents were 16 mm in diameter and 4 to 9 cm in length, and the ends of the stents were flared up to 26 mm to reduce stent migration. The third-generation stent had no covering membrane, whereas the fourth-generation stent was covered with polyurethane to prevent tumor growth. To avoid detachment of the polyurethane covering membrane from the stent wires, the ends of the stent were covered with nylon mesh and then coated with polyurethane.

In the late 90’s, the author performed transoral placement of fourth-generation gastroduodenal SEMSs in 19 patients without prior bypass surgery using a 6 mm delivery system. The procedure was technically successful in 95% of patients; however, merely 72% achieved clinical success because of stent migration, which occurred in 28% of patients 1 to 4 days after stent placement. This rate of stent migration was identical to the rate reported by Park et al in 24 patients with a covered SEMS, but was poor compared with the 3% reported by Adler and Baron in 36 patients with a bare SEMS, suggesting that a covered SEMS may result in a higher incidence of stent migration than a bare SEMS. This hypothesis was later confirmed in 2010 by a randomized control trial, which showed 26% and 3% stent migration rates for covered and bare SEMSs, respectively.

With the realization that covered SEMS might be more susceptible to stent migration than bare SEMS, the author placed...
transorally third-generation stents in the five patients who experienced stent migration with the fourth-generation stent. Technical and clinical success was achieved in all cases; however, recurrence due to tumor ingrowth occurred as anticipated in two (40%) patients 11 and 64 days after the procedure, respectively. In these two patients, an additional fourth-generation stent was placed coaxially inside the indwelling third-generation stent with good results; the patients resumed oral intake and experienced no stent migration or tumor ingrowth until their deaths.

**Coaxial SEMS Placement Technique**

After our experience with the third- and fourth-generation stents, the author decided to explore the possibility of using a coaxial SEMS placement technique to overcome the problems of stent migration with covered SEMSs and tumor ingrowth with bare SEMSs. The idea was that the outer bare stent would firmly grasp the inner covered stent and thereby reduce stent migration, while the covering membrane of the covered stent would prevent tumor ingrowth. Thus, the author developed two SEMSs for coaxial placement, a bare stent made from a single thread of 0.2 mm nitinol wire woven ten times in a tubular configuration, and a retrievable, covered SEMS made from a single thread of 0.2 mm nitinol wire woven 16 times in a tubular configuration (modified third- and fourth-generation stents, respectively) (Fig. 4). The bare stent was 18 mm in diameter and 4 to 10 cm in length, and the ends of the stent were flared up to 28 mm to reduce stent migration. The retrievable covered stent was 16 mm in diameter and 4 to 10 cm in length, and the ends of the stent were flared up to 26 mm to reduce stent migration. The entire stent was covered with polyurethane to prevent tumor growth, and the ends of the stent were covered with nylon mesh and then coated with polyurethane to avoid detachment of the polyurethane covering membrane from the stent wires. Two drawstrings made of nylon monofilament were attached to the upper inner margin of the stent so that it could be removed or repositioned using a hook if stent migration occurred (Fig. 5). The bare stent was placed first, and the retrievable covered stent was placed coaxially inside the outer bare stent using a 6 mm delivery system (Fig. 6).

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**Fig. 4.** Photograph shows a self-expandable metallic stent (SEMS) (constructed in-house) used for coaxial SEMS placement technique: outer bare stent (top), inner retrievable covered stent (middle), and assembled coaxial stent (bottom).

**Fig. 5.** Photograph of a retrievable covered stent (constructed in-house) shows the nylon draw strings (arrow).

**Fig. 6.** Placement of a coaxial self-expandable metallic stent (constructed in-house) in a patient with gastric cancer. (A) Endoscopic image shows the retrievable covered stent (arrow) placed coaxially inside the bare stent (arrowhead). (B) Radiograph shows good passage of contrast medium through the coaxial stent.
In 2002, we reported our experience with this technique in 39 patients. Technical and clinical success rates were 97% and 95%, respectively. The rate of stent patency was 32%, with a median stent patency of 157 days. Stent migration occurred in 8% of patients, which was much lower than the migration rate (28%) of third-generation stents. However, tumor ingrowth occurred unexpectedly in 8% of patients, and removal and examination of the inner covered stent in one case revealed disruption of the polyurethane covering membrane (Fig. 7), which was most likely caused by chemical degradation of polyurethane by acidic gastric juice or hydrolytic enzymes. Nevertheless, a subsequent study by another group comparing coaxial SEMSs with bare SEMSs showed that the former were superior to the latter in terms of the rate of tumor ingrowth (10% vs 60%) and patency duration (median, 150 vs 22 days).

Fifth-Generation: Dual-Design Partially-Covered SEMS

Although the results obtained with coaxial SEMS placement were encouraging, there were still some problems that needed to be addressed, including disruption of the polyurethane covering membrane and the large and rigid stent delivery system. Thus, the author developed the fifth-generation gastroduodenal SEMS (Hercules SP; S&G Biotech, Seoul, Korea), which consisted of two stents: an outer partially-covered stent and an inner bare stent (Fig. 8). The dual-stent design made possible the reduction of the delivery system to 3.8 mm. The outer partially-covered stent has three parts: a proximal and a distal bare stent (28 mm in diameter) to reduce stent migration, and a nylon mesh (18 mm in diameter) to prevent tumor ingrowth. The proximal and distal stents were constructed from a single thread of 0.22 mm nitinol wire in a tubular configuration in an interlocking diamond shaped pattern. The inner bare stent was 18 mm in diameter, and the ends were flared up to 28 mm to reduce stent migration. The inner bare stent was constructed from a single thread of 0.2 mm nitinol wire in a tubular configuration also in an interlocking diamond shaped pattern. The outer partially-covered stent was placed first, and the inner bare stent was placed coaxially inside the outer partially-covered stent (Fig. 9).

In 2004, the author reported his preliminary experience with the fifth-generation stent in 102 patients. Technical and clinical success rates were 99% and 84%, respectively. The stent migration rate was only 2%, and most importantly, there was no tumor ingrowth. These results were very encouraging; however, a prospective study with a larger sample size was clearly needed. Therefore, in 2007, the author reported his experience with this stent in a prospective cohort of 213 patients. Technical and clinical success were achieved in 98% and 94% of patients, respectively. The rate of stent malfunction was 17%, with a median stent patency of 270 days. Stent migration occurred in only 4% of patients, and again there was no tumor ingrowth (Fig. 10). These results compared favorably to those of third- and fourth-generation stents.

Fig. 7. Photograph of a retrievable covered stent (constructed in-house) removed 1 month after stent placement shows disruption of the polyurethane covering membrane. Reprinted from the book of Kozarek et al. (New York: Springer Science & Business Media; 2012) with permission.

Fig. 8. Photograph shows a fifth-generation gastroduodenal self-expandable metallic stent (Hercules SP; S&G Biotech): outer partially covered stent (top), inner bare stent (middle), and assembled fifth-generation stent (bottom).

Fig. 9. Placement of fifth-generation gastroduodenal self-expandable metallic stent (Hercules SP; S&G Biotech) in a patient with pancreatic cancer. (A) Radiograph shows a stricture (arrows) in the third duodenal segment. (B) Radiograph shows a partially covered stent (arrow) placed across the stricture. (C) Radiograph shows a bare stent (arrows) placed coaxially inside the partially covered stent. (D) Radiograph shows good passage of contrast medium through the stent.
However, the fifth-generation stent appeared to be more prone to stent collapse, an uncommon and often delayed cause of stent malfunction, albeit the rate is low at only 4% to 5% (Fig. 11A).\textsuperscript{19,20} The underlying mechanism leading to stent collapse is unknown; however, it has been postulated to be caused by centripetal growth of the tumor or fatigue fracture of the stent wires. Nonetheless, stent collapse can be easily managed by coaxial placement of an additional SEMS into the collapsed stent (Fig. 11B). In addition, the rate of stent malfunction of fifth-generation stents (17%) is near the lower end of the range of malfunction reported recently for other types of SEMSs (14%–26%).\textsuperscript{21–25} Another major disadvantage of the fifth-generation stent is that the stent placement is relatively complicated and time-consuming than a single stent insertion. However, this disadvantage seems to be outweighed by the advantages of decreased stent malfunction.

**Table 1** Summary of Outcomes of Third- to Fifth-Generation Gastroduodenal SEMSs

|                              | Third-generation SEMS (n = 5)\textsuperscript{10} | Fourth-generation SEMS (n = 19)\textsuperscript{16} | Coaxial SEMSs (n = 39)\textsuperscript{14} | Fifth-generation SEMS (n = 213)\textsuperscript{16} |
|------------------------------|--------------------------------------------------|-------------------------------------------------|------------------------------------------|-------------------------------------------------|
| Technical success            | 5 (100)                                          | 18 (95)                                         | 38 (97)                                  | 209 (98)                                        |
| Clinical success             | 5 (100)                                          | 13 (72)                                         | 36 (95)                                  | 196 (94)                                        |
| Stent malfunction            | 2 (40)                                           | 5 (28)                                          | 12 (32)                                  | 36 (17)                                         |
| Stent migration              | 0                                                | 5 (28)                                          | 3 (8)                                    | 8 (4)                                           |
| Tumor ingrowth              | 2 (40)                                           | 0                                               | 3 (8)                                    | 0                                               |
| Tumor overgrowth            | 0                                                | 0                                               | 6 (16)                                   | 14 (7)                                          |
| Food impaction              | 0                                                | 0                                               | 0                                        | 5 (2)                                           |
| Stent collapse               | 0                                                | 0                                               | 0                                        | 9 (4)                                           |
| Median stent patency (day)   | -                                                | -                                               | 157                                      | 270                                             |
| Median survival (day)        | -                                                | -                                               | 95                                       | 99                                              |

Values are presented as number (%) or number only.

SEMSs, self-expandable metallic stents.
Sixth-Generation: Retrievable SEMS with Double-Step Flared Ends

The fifth-generation stent was developed about 15 years ago but it still remains state-of-the-art. Notably, a number of recently introduced gastroduodenal SEMSs have also adopted the partially-covered design to reduce stent migration.\(^{26-28}\) However, it is uncommon for a stent device not to undergo evolutionary updates in over a decade. Furthermore, the fifth-generation stent is not without room for improvement (i.e., the radial force of the stent could be optimized to reduce stent collapse). Moreover, partially-covered stents are not retrievable, and therefore they cannot be repositioned or removed when complications occur (i.e., stent migration, mechanical occlusion of the ampulla of Vater leading to jaundice or pancreatitis), and they are relatively contraindicated in patients with benign gastroduodenal obstruction. Therefore, the author decided to develop a retrievable fully-covered SEMS with anti-migration features that can significantly reduce stent migration.

Recently, the author developed the sixth-generation gastroduodenal SEMS (EGIS; S&G Biotech) to address some of these shortfalls (Fig. 12). This stent was woven in a tubular configuration from two threads of nitinol wire with a diameter of 0.154 mm and 0.127 mm, respectively, and was 16 mm in diameter and 4 to 12 cm in length. There was a double-step flare at each end of the stent, which provides high mechanical resistance to migration; the larger flare was 24 mm in diameter and 15 mm in length, and the lesser flare was 20 mm in diameter and 10 mm in length. The main body of the stent was covered with an expanded polytetrafluoroethylene membrane to prevent tumor/tissue ingrowth. To make the stent retrievable, a drawstring made of nylon monofilament was attached to the upper inner margin of the stent. In addition, the double-step flare ends were coated in silicone so that the stent wires would not become embedded into the gastroduodenal wall. These design features (anti-migration, ingrowth-resistant, and retrievable) make the sixth-generation stent appropriate for both malignant and benign indications. However, future studies will be required to evaluate the efficacy and safety of this stent.

Conclusion

The introduction of the nitinol SEMS has greatly improved stent flexibility and reduced the size of the delivery system from stainless steel SEMSs. Covered SEMSs can prevent tumor ingrowth for as long as the covering membrane is in place, but they are associated with a higher incidence of stent migration than bare SEMSs. Coaxial placement of a bare and covered SEMS appears to prevent tumor ingrowth and reduce stent migration. The dual-design partially-covered SEMS has considerable advantages over the conventional bare and covered SEMS in terms of stent malfunction; however, this stent seems to be more prone to stent collapse. The retrievable covered SEMS with double-step flared ends is a promising new stent for both malignant and benign gastroduodenal obstruction. Future studies to evaluate the efficacy and safety of this stent are warranted.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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Fig. 12. Photograph shows a sixth-generation gastroduodenal self-expandable metallic stent (EGIS; S&G Biotech).
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