Richard Kozarek · Todd Baron
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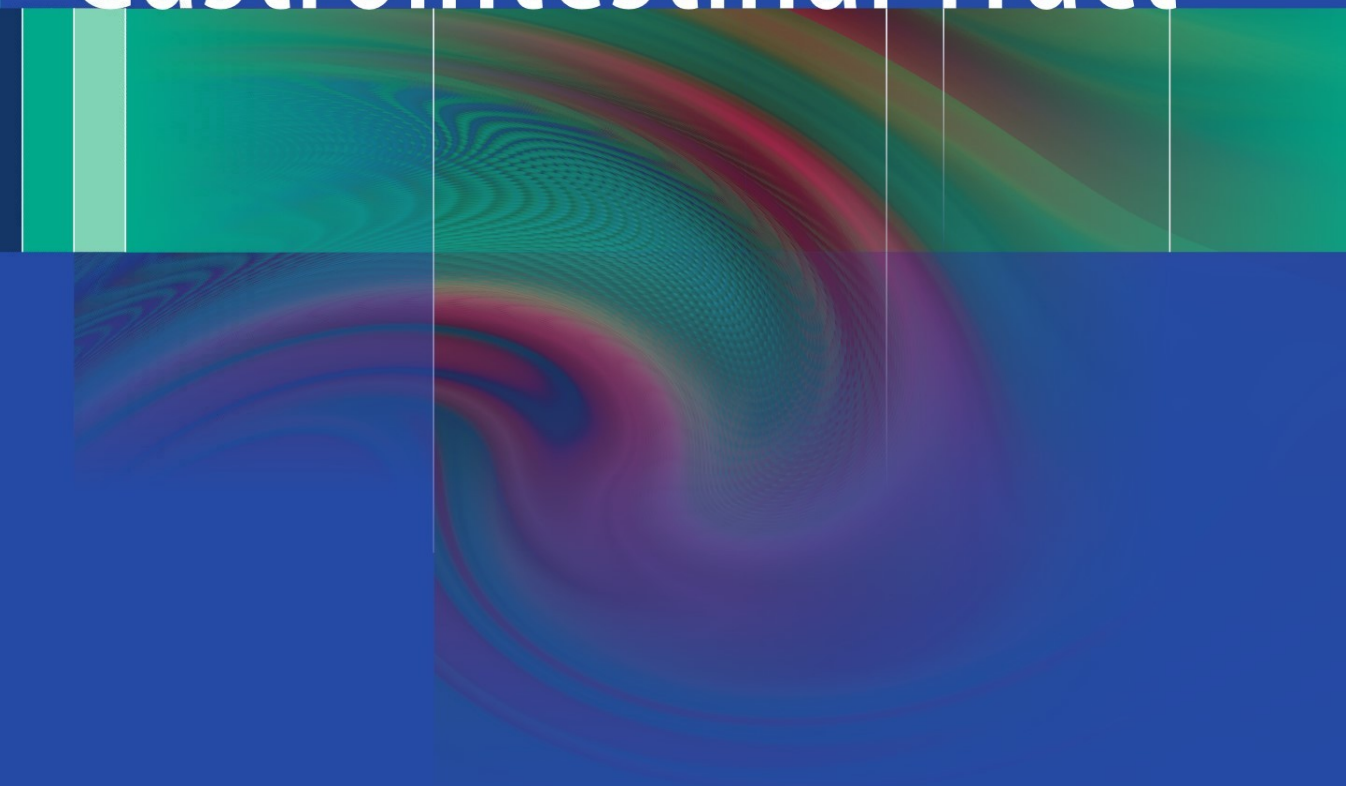
Self-Expandable Stents in the Gastrointestinal Tract



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Editors
Richard Kozarek
Digestive Disease Institute
Virginia Mason Medical Center
and University of Washington
Seattle, WA 98111, USA

Todd Baron
Division of Gastroenterology
and Hepatology
Mayo Clinic College of Medicine
Rochester, MN 55905, USA

Ho-Young Song
Department of Radiology
Asan Medical Center
388-1 Pungnap-2 Dong
Songpa-Gu, Seoul 138-736
Korea, Republic of (South Korea)

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Preface

Historically, nonsurgical reconstitution of the gut lumen was limited to the placement of rigid tubes in unresectable esophageal cancer. Initially fashioned out of boxwood or ivory, they were fixed into place by suture tied to a handlebar mustache or looped around the ears. Later they were fashioned out of a compound used by British dentist, Charles T. Stent (1807–1885), who initially developed it to create dental impressions. These conduits ultimately were called *stents,* a term that first appeared in the medical literature in 1952.

Rigid biliary prostheses (stents) were first placed surgically in the mid-1950s, and the first percutaneous placement was described by Molnar and Stockum approximately two decades later. A mere 5 years later, in 1979, Reynders-Fredrix and Soehendra described the first endoscopic placement of a 7 Fr plastic stent in the biliary tree, although it took almost another decade to routinely place small diameter prostheses into the pancreas and to produce endoscopes with a channel size large enough to place 10–11.5 Fr stents.

Self-expandable metal stents (SEMS), placed through a small diameter delivery system and which conform to the body's angulations, have allowed additional anatomical areas to be bypassed, decreased risks associated with placement of relatively large diameter plastic tubes through natural orifices, and have expanded our ability to palliate and effectively treat a wide variety of GI disorders, benign as well as malignant. Their development and application has been nothing short of revolutionary in the treatment of malignant, and to a lesser extent, noncancerous stenoses and acute and chronic GI tract leaks and perforations.

This is the context of our text, *Self-Expandable Stents in the Gastrointestinal Tract*. It brings together the world's experts in stent design and placement, including polyethylene (plastic) prostheses, and a variety of expandable stents (metal, silicone, and absorbable/polylactide). It also brings together the disciplines with the greatest experience in their use in the GI tract: therapeutic endoscopists and interventional radiologists.

This book covered the state of the art in a rapidly changing technology. Despite this evolution, however, and the fact that the FDA and its equivalent in other countries, defines ultimate product availability, basic physics and the design of expandable prostheses are crucial in defining current and future devices and their applications. Although defined historically and anatomically throughout the text, this distinction is artificial and is limited by anatomic access, either percutaneously or by the current use of natural orifices (mouth and anus). The

ability to deliver these prostheses by endoscopic ultrasound to straddle the inner and outer wall of the GI tract has revolutionized our ability to drain extraluminal fluid collections and perform anastomoses to include gastrojejunostomy, cholecystoduodenostomy, and other anastomoses from the stomach or duodenum into the intra- or extrahepatic biliary tree. Add the application of these stents through laparoscopic portals or transgastric or transcolonic neolumens in the setting of NOTES and one can begin to see the yet unrealized potential of this technology.

It is with enthusiasm and the humility of knowing, that by the time of this text's publication, that there will be continued evolution in SEMS technology and placement techniques, that the editors proffer *Self-Expandable Stents in the Gastrointestinal Tract.*

Seattle, WA, USA — Richard A. Kozarek, M.D
Rochester, MN, USA — Todd Baron, M.D
Seoul, Republic of Korea — Ho-Young Song, M.D

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Contents

Contributors

Todd Baron Department of Medicine, Mayo Clinic, Rochester, MN, USA

Maarten W. van den Berg Department of Gastroenterology and Hepatology, Academic Medical Center, University of Amsterdam, Amsterdam, AZ, The Netherlands

Kenneth F. Binmoeller Paul May and Frank Stein Interventional Endoscopy Center, California Pacific Medical Center, San Francisco, CA, USA

Antonella De Ceglie Department of Gastroenterology and Digestive Endoscopy, Cancer Institute Giovanni Paolo II, Bari, Italy

Il Ju Choi Center for Gastric Cancer, National Cancer Center, Goyang, Republic of Korea

Massimo Conio Department of Gastroenterology and Digestive Endoscopy, General Hospital Sanremo, Sanremo (IM), Italy

John T. Cunningham Department of Internal Medicine, Section of Gastroenterology and Hepatology, University of Arizona, Tucson, AZ, USA

Daniel de Paula Pessoa Ferreira Instituto Clinico Humanitas, Rozzano, Milan, Lombardia, Italy

Martin L. Freeman Division of Gastroenterology, Hepatology and Nutrition, University of Minnesota, Minneapolis, MN, USA

Jesús García-Cano Department of Digestive Diseases, Hospital Virgen de la Luz, Cuenca, Spain

Jeanin E. van Hooft Department of Gastroenterology and Hepatology, Academic Medical Center, University of Amsterdam, Amsterdam, AZ, The Netherlands

Shayan Irani Departments of Gastroenterology and Hepatology, and Colorectal Cancer, Digestive Disease Institute, Virginia Mason Medical Center, Seattle, WA, USA

Chan Gyoo Kim Center for Gastric Cancer, National Cancer Center, Goyang, Republic of Korea

Jin Hyoung Kim Radiology Department, Asan Medical Center, Seoul, Republic of Korea

Tae Il Kim Division of Gastroenterology, Department of Internal Medicine, Institute of Gastroenterology, Severance Hospital, Yonsei University College of Medicine, Seodaemun-gu, Seoul, Republic of Korea

Richard A. Kozarek Digestive Disease Institute, Virginia Mason Medical Center and University of Washington, Seattle, WA, USA

Hans-Ulrich Laasch Department of Radiology, The Christie NHS Foundation Trust, Manchester, UK

Dong Ki Lee Department of Internal Medicine, Gangnam Severance Hospital, Yonsei University, Gangnam-gu, Seoul, Republic of Korea

Joseph W. Leung Department of Gastroenterology, VA Northern California Health Care System, Davis School of Medicine, Sacramento VA Medical Center, University of California, Mather, CA, USA

Wesley Leung Center for Endoscopic Research and Therapeutics, Section of Gastroenterology, Department of Medicine, The University of Chicago Medical Center, Chicago, IL, USA

Mohan Ramchandani Gastroenterology Department, Asian Institute of Gastroenterology, Hyderabad, AP, India

D. Nageshwar Reddy Gastroenterology Department, Asian Institute of Gastroenterology, Hyderabad, AP, India

Alessandro Repici Digestive Endoscopy Unit, IRCCS Istituto Clinico Humanitas, Rozzano (Milano), Italy

Andrew S. Ross Digestive Disease Institute, Virginia Mason Medical Center and University of Washington, Seattle, WA, USA

Mariano Gonzalez-Haba Ruiz Center for Endoscopic Research and Therapeutics, Section of Gastroenterology, Department of Medicine, The University of Chicago Medical Center, Chicago, IL, USA

Peter D. Siersema Department of Gastroenterology and Hepatology, University Medical Center Utrecht, Utrecht, The Netherlands

Ho-Young Song Department of Radiology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Republic of Korea

Mustafa A. Tiewala Division of Gastroenterology, Hennepin County Medical Center, Minneapolis, MN, USA

Irving Waxman Center for Endoscopic Research and Therapeutics, Section of Gastroenterology, Department of Medicine, The University of Chicago Medical Center, Chicago, IL, USA

Chang Jin Yoon Department of Radiology, Seoul National University Bundang Hospital, Seongnam, Republic of Korea

Part 1

History of GI Tract Stenting

History of GI Stenting: Rigid Prostheses in the Esophagus

1

Shayan Irani and Richard A. Kozarek

The major function of the esophagus is to serve as a conduit to the passage of a food bolus from the mouth to the stomach. Mechanical obstruction of the esophagus usually produces symptoms late in the disease process, usually when the luminal diameter is less than 13 mm or at least 50% narrowed [1]. The majority of esophageal cancer patients have unresectable disease at presentation. Even after curative therapy, about 20% of patients develop dysphagia from recurrent strictures. Therefore, palliative therapy has been, and will continue to remain, an important part of the management of esophageal malignancy [2].

There have been several modalities used to palliate esophageal obstruction. Surgery carried a high morbidity and mortality and quickly fell to the wayside once less invasive options became available. Dilation of malignant esophageal strictures was associated with the lack of durability, required multiple procedures, and carried a significant perforation rate. Gastrostomy tube placement provided the ability for nutritional support but did nothing to improve quality of life or ability to eat or to swallow one's secretions. Radiation and chemotherapy are effective in relief of dysphagia, but with a delay in improvement ranging from weeks to months, are not universally tolerated, and have complications [3]. Neolumen creation with Nd-YAG laser is effective in patients with short, exophytic lesions but requires frequent interventions and is not suitable for treatment of long tortuous strictures and does not allow closure of fistulas. Photodynamic therapy was shown to be as effective as Nd-YAG laser in relieving malignant dysphagia due to esophageal cancer with a lower perforation rate than Nd-YAG laser [4]. These modalities were used as an alternative to esophageal stents which continued to evolve and are now the palliative modality of choice due to their ability to provide instant, long-lasting relief from dysphagia with minimal morbidity and negligible mortality [2, 5].

Era Prior to the First Successful Esophageal Stent

Prior to the first successful placement of an esophageal stent across a malignant stricture, surgery was the only option for patients with esophageal cancer. The four types of surgeries performed up until 1884 were outlined in an article by Dr. Samuel Gross, surgeon at Jefferson College, Philadelphia: (1) Esophagectomy with a curative intent was initially considered only for lesions in the upper esophagus. (2) Internal

S. Irani, M.B.B.S., M.D. (✉)
Departments of Gastroenterology and Hepatology, and Colorectal Cancer, Digestive Disease Institute, Virginia Mason Medical Center, 1100 9th Ave., MS: C3-GAS, Seattle, WA 98101, USA
e-mail: shayan.irani@vmmc.org

R.A. Kozarek, M.D.
Digestive Disease Institute, Virginia Mason Medical Center and University of Washington, 1100 9th Ave., C3-GAS, Seattle, WA 98111, USA

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esophagotomy (internal division of the carcinomatous stricture). This was performed in one patient and required repeated dilation to maintain patency. (3) Esophagostomy (establishment of a permanent fistula in the neck for the introduction of food). The mortality within the first 17 days was unacceptably high at 81% and with no advantage over gastrostomy. It was quickly abandoned along with internal esophagostomy. (4) Surgical gastrostomy carried a 29% associated mortality [6].

Endoesophageal intubation now known as nasogastric or orogastric (external-internal) tube placement was initially used in the mid-1800s for the palliation of esophageal cancer. Drs. Krishaber (four cases), Croft (two cases), and Durham (one case) recommended the use of a long esophageal tube, made of gum-elastic or black caoutchouc (natural rubber) passed through the nose or mouth, to be used as a feeding tube. These tubes had a prolonged patency and had no immediate or procedure-related mortality. However, they did not provide relief of dysphagia and the control of one's secretions and were uncomfortable [7, 8].

As early as 1845, James Leroy d'Etoilles (1798–1860), a French surgeon, was the first to toy with the idea of making a short internal esophageal tube, which was made from decalcified ivory to tunnel through a malignant growth. His attempts as well as similar attempts by a British surgeon, Sir Morrell Mackenzie, to use such tubes failed [7].

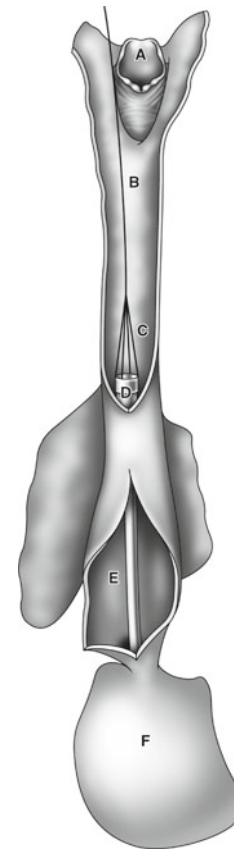

Fig. 1.1 Sir Charters Symonds' esophageal tube in situ. (**a**) Larynx. (**b**) Esophagus laid open. (**c**) Silk thread by which tube is held in position. (**d**) Wide upper end of the tube above the stricture. (**e**) Narrow lower part of the tube below the stricture. (**f**) Gastric cardia

The First Successful Esophageal Stent

In 1885, Sir Charters James Symonds (1852–1932), a Canadian-born surgeon working at Guy's Hospital in London, was the first to record the successful use of a short, rigid, esophageal tube to internally stent a malignant stricture. The tube was 6 in. long made of No. 10 esophageal tubing that was fixed to a boxwood funnel by German silver wire. Later he used a funnel made of silver and ivory instead of boxwood but finally settled on a tube and funnel made from the same gum-elastic material (Fig. 1.1). After stricture dilation, the 6-in. tube was passed over a conical bougie or by a special introducer made of copper wire. To overcome the problem of migration, a proximal funnel was used in addition to the attachment of a silk suture to the proximal end of the tube, which was brought out of the mouth and attached to the patient's ear. With the tube in place, patients were allowed to ingest liquids. Every 10 days or so, the tube would be removed for cleaning, and the patient was permitted to eat solid food for a short period of time until the tube was replaced, occasionally with a larger diameter tube. This tube not only provided adequate nutrition and palliation but also improved quality of life [8].

The Post-Symonds Era

Until this point, tubes had been inserted blindly. In 1914, M. Guisez, a French surgeon suggested esophageal stenting over an introducer. A De Pezzer-like catheter was used which was 6 cm long and ended blindly. Side holes were in place to allow passage of fluid. It was stretched thin over an introducer, making it easier to navigate through the stricture. Once in position, the introducer was withdrawn and the catheter was gripped by the stricture. Guisez made full use of the esophagoscope and bougies and reported low complication rates [9].

In 1924, Sir Henry Souttar continued the trend for direct endoscopic visualization prior to tube/stent placement [10]. Souttar had a background in engineering from Oxford before taking up medicine at London Hospital. He designed a stent made of a tightly coiled metal spring from a 1-mm wire with 25 turns per inch. This coiled metallic stent, originally made of German silver and later stainless steel, was placed using a special introducer (Fig. 1.2). The stent was rigid enough to be pushed through the esophagus without collapsing, yet had the flexibility to bend and elongate through a tortuous stricture. A proximal lip, 2 mm wider than the body of the prosthesis, was present and sometimes reinforced with an even wider funnel made of rubber [10, 11]. Results were satisfactory in the 100 personal cases he reported. However, two problems remained: false passage and spontaneous migration. To reduce the risk of a false passage/perforation, J. H. Resamo (Argentina) modified Souttar's technique using a guide to direct the stents, and in his hands, the mortality rate from intubation was 0.5% [5].

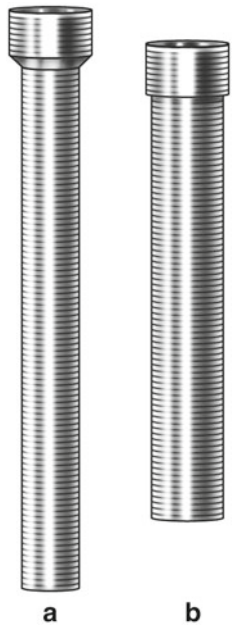

Fig. 1.2 (**a**, **b**) The Souttar tube. The original type made of German silver and the subsequent model made of stainless steel

After World War II, there was a resurgence in esophageal surgery and at the same time a rise in the use of stents to palliate esophageal cancer. In 1949, A. L. Brown, an American physician, recommended the use of a tube made of silver with a distal flange. He inserted the tube surgically through a slit opened below the esophageal obstructing lesion. Under direct visualization, the stent was advanced proximally (retrograde). A suture was then placed around the esophagus below the distal flange to prevent migration into the stomach, while the flange prevented proximal migration [12]. The use of silver was abandoned for more flexible synthetic materials after a review showed plastic to be superior to metal and rubber [13].

In 1952, M. Ravitch and T. Bahnson inserted a plastic prosthesis (variant of the Souttar tube) over an obturator intraoperatively when an unresectable esophageal cancer was encountered [14]. Similarly, in 1954, S. Mackler and R. Mayer introduced an indwelling tube through a longitudinal incision in the esophagus 2 in. above the lesion at the time of thoracic exploration when resection was not possible. Mortality using this approach was around 32% [15]. In the same year, Coyas in Greece in collaboration with Triboulet-Piton in France introduced a plastic tube to palliate esophageal cancer under direct endoscopic visualization. The stent lacked a funnel but had parallel rings to grip the tumor and metal rings at the end to make it radiopaque [16]. In the same year, Kropff described a funnel-shaped polyethylene tube introduced through a cervical esophagotomy [17].

There was even an alternative approach in which the combination of resection and stent placement was attempted. In 1952, Berman reported his experience of replacing the midesophagus of 20 dogs with plastic tubes through a thoracoabdominal approach, which translated to resection of the lesion with reattachment of the defect with the stent. In 1956, this was followed by a thorough review of esophageal cancer and rationale to abandon this combined approach. This was due to the poor prognosis of esophageal cancer, the high morbidity and mortality of any esophageal surgery, and the inability for complete resection of malignancy [18, 19].

One of the more ingenious prostheses produced during this time was a tube designed by Sachs in 1958 [20]. The prosthesis was designed in the form of a hollow screw machined from a nylon rod for per oral insertion without the need for preinsertion dilation. The thread of the screw had a horizontal shoulder perpendicular to the axis of the tube, which prevented proximal migration. The inner diameter of the screw was 8 mm and was inserted by screwing it through the lesion using a driver that fit snugly in knurls at the proximal end of the prosthesis. The stent was placed successfully in four patients (Fig. 1.3) [21].

The Push and Pull Technique of Placing Esophageal Stents

The aforementioned esophageal prostheses were placed by the *push* technique alone, initially blindly, and then under endoscopic visualization. In 1956, Mousseau and Barbin, two French surgeons, reported a new method of permanent intubation/stenting of the esophagus using the *push and pull* technique. Their stent consisted of a circular, neoplex tube with a catheter-like portion at the distal end and a funnel at the proximal end. After passing the catheter transorally blindly into the proximal stomach, a high gastrostomy was performed and the lower end of the catheter portion was grasped and pulled distally until the proximal stent funnel engaged the stricture. The excess lower end of the catheter was then cut in the stomach and the prosthesis remained in place. The authors claimed that this method had a lower false passage and perforation rate, given the guidance provided by the pull from the stomach ensuring its luminal placement (Fig. 1.4) [22].

The Celestin Tube

In 1959, Celestin reported an improvement/modification of the Mousseau-Barbin tube. This new tube was made from natural polythene, was oval in its various diameters (as opposed to circular), and carried a thin barrel-shaped funnel (as opposed to the more conventional V-shaped funnel). The author claimed that the oval lumen of the tube would be more desirable in view of the natural shape of the lumen of the esophagus in situ. The barrel shape to the proximal end was also supposed to provide a more secure fitting as well as potentially reduce the risk of obstruction by a ring of proximal edematous hypertrophic tissue. The prosthesis consisted of two parts, a solid pilot bougie attached by a suture to the endoesophageal tube/stent (25 cm long, 10 mm diameter, and 1 mm thick) (Fig. 1.4). The bougie was introduced under direct visualization, often preceded by dilation of the stricture. Through a high gastrostomy, the lower end of the bougie was grasped and the stent pulled securely into place. In the event that the stent was not well gripped by the stricture, the lower end of the stent was sutured in place in the stomach. This allowed patients to tolerate a solid diet with careful mastication and frequent sips of water or carbonated beverages [7]. Celestin later modified his tube to be made of latex rubber and enmeshed a nylon spiral into it with a radiopaque strip (Fig. 1.5).

Era of Plastic and Latex Endoprosthesis

After the introduction of the Celestin tube, plastic (polyvinyl/Tygon) became the predominant material of which esophageal stents were manufactured, and direct endoscopic insertion became the standard insertion technique. In 1976, Tytgat et al. of the Amsterdam group standardized the

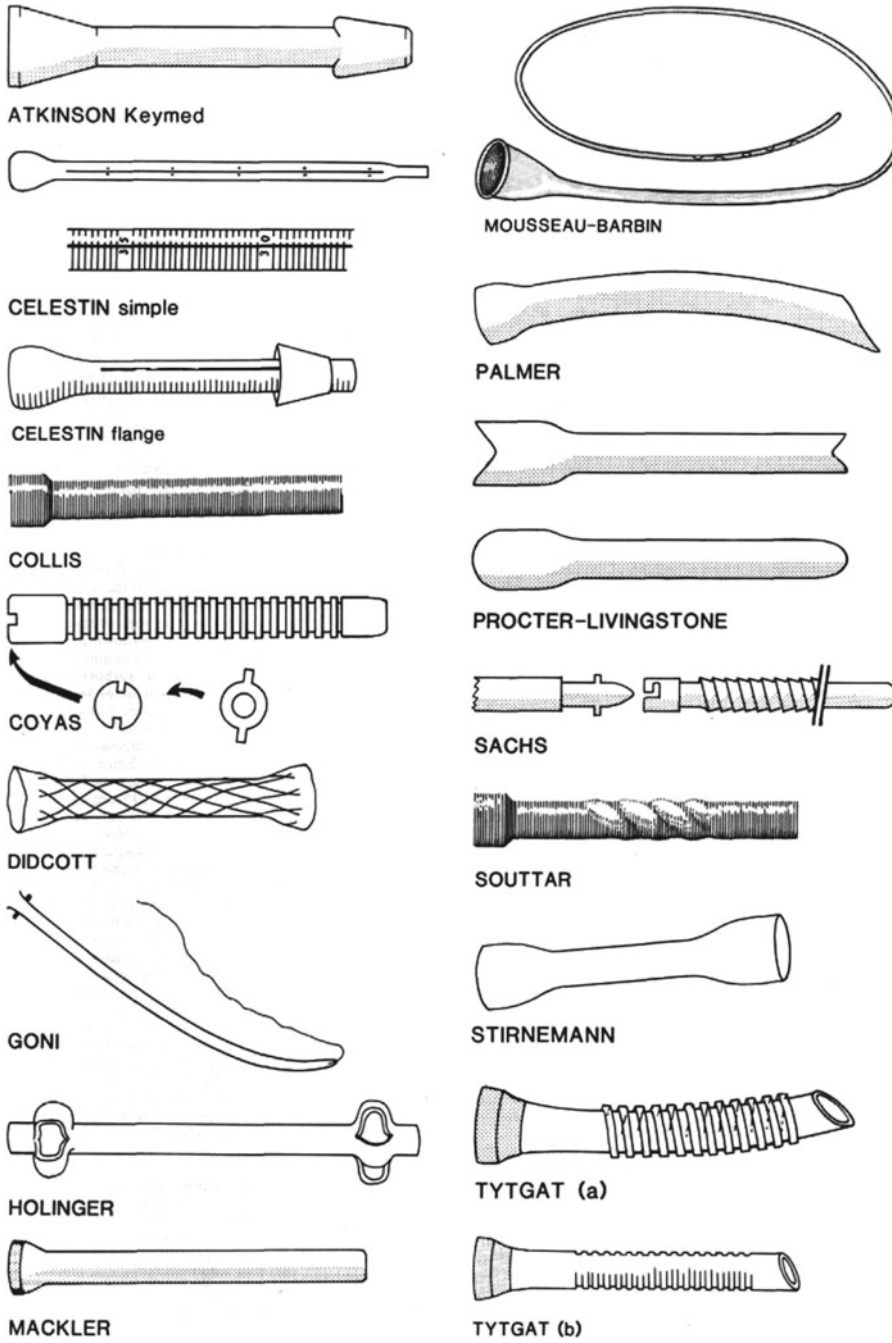

Fig. 1.3 A schematic of a variety of rigid esophageal prosthesis (From [67] Printed in Great Britain, with permission)

endoscopic insertion of plastic endoprosthesis. Measurement of the exact length of the stricture and use of external radiopaque markers for fluoroscopic guidance were felt to be imperative prior to stent placement [23]. The stricture was dilated to a diameter that was a few millimeters larger than the external diameter of the stent (usually 16–20 mm). An over the wire dilator was

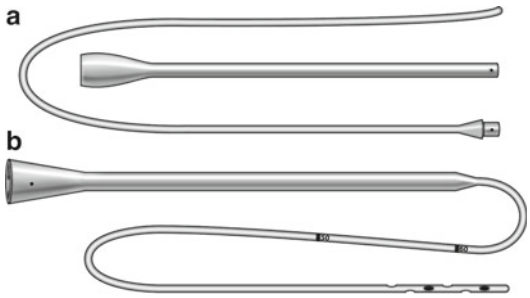

Fig. 1.4 (**a**) The original Celestin tube. (**b**) Mousseau-Barbin tube

Fig. 1.5 The commercially manufactured Medoc-Celestin tube (Medoc, Tetbury, UK), with and without a distal flange

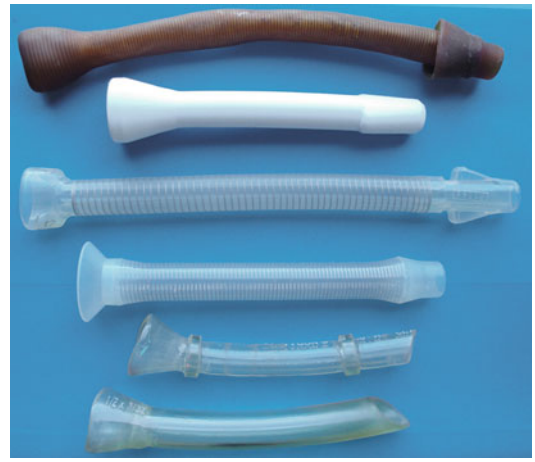

Fig. 1.6 The common commercially available prostheses: from *top to bottom*: Celestin tube (distal flange), Atkinson's tube, Eska-Buess prosthesis, Wilson-Cook prosthesis (low profile), homemade Tygon stent with and without ridges

used which was originally Eder-Peustow and later Savary. Stents were passed over an insertion device which was usually a Savary dilator (30–33 Fr), although an Atkinson introducer (Olympus America) or an endoscope shaft could also be used. The stent was advanced into place using a pusher tube such as a Dumon introducer (Wilson-Cook, Inc., Winston Salem, NC) under fluoroscopic guidance [24]. A barium esophagram was usually obtained to ensure adequate positioning.

The most common plastic endoprosthesis used was homemade from polyvinyl (Tygon) tubing. The tubing was cut to sufficient length to exceed the length of the tumor by about 6–7 cm. This allowed for a 2–3 cm proximal flange and about a 2–4 cm extension beyond the distal end of the tumor to prevent later occlusion by tumor overgrowth. The proximal flange was created by heating the Tygon tubing in hot mineral oil and then pressing it on an inverted laboratory glass funnel or an anoscope obturator. The distal end was beveled to facilitate passage through the tumor. Both ends of the stent were smoothed with a file to reduce mucosal damage. A second tube (pusher tube) was cut to sufficient length so as to extend from the orad tumor margin to about 8–10 cm beyond the incisor teeth. Both the pusher tube and the prosthesis were then placed over a dilator (Savary or Hurst) and inserted under fluoroscopic guidance [25].

The common commercially available prostheses were the Medoc-Celestin tube (Medoc, Tetbury, UK), Proctor-Livingstone tube (Latex Products, Johannesburg), Wilson-Cook prosthesis (Wilson Cook), Key-Med Atkinson stent (Olympus America, USA), and Eska-Buess stent (Eska, Germany) (Fig. 1.6). The Medoc-Celestin tube was made of latex reinforced with a nylon spiral, available in lengths of 12.5, 15, and 21 cm, with an outer diameter of 15 mm and inner diameter of 12 mm. The Proctor-Livingstone tube was also an armored latex tube with an internal diameter of 12 mm and outer diameter of 18 mm and a proximal 3 cm long flare of 25 mm diameter. It was available in lengths of 10, 15, and 19 cm [26]. The Wilson-Cook prosthesis was made of silicone with a stainless steel spiral spine, an outer diameter of 16 mm, inner diameter of 12 mm, and lengths ranging from 4.4 to 16.4 cm. The Key-Med Atkinson prosthesis was made of silicone with a central nylon spiral, ranging in length from 14 to 19 cm, an outer diameter of 16 mm, and inner diameter of 14 mm. The Eska-Buess prosthesis was made of silicone with a stainless steel spiral, with hooks in the proximal flange to allow grasping the stent for repositioning or retrieval, if needed [2].

Table 1.1 Plastic/rubber esophageal prosthesis: review of selected series

Author/year (Ref #)	Prosthesis	Number of patients	Technical success (%)[a]	Complications (%)[b]	Deaths (%)[c]
O'Connor/1963 [25]	Tygon	388	97	17	0.6
Hegarty/1977 [26]	Proctor-Livingstone	181	98	NR	17
Angorn/1979 [27]	Proctor-Livingstone	652	97	9	8
den Hartog/1979 [28]	Tygon	200	97	57	7
Tytgat/1980 [29]	Tygon	297	97	47	1
Ogilvie/1982 [30]	Celestin and silicone	121	98	50	7
Buset/1987 [32]	Tygon	116	95	32	4
Gasparri/1987 [32]	Medoc, Atkinson, Celestin, Harring	248	100	21	7
Cotton/1988 [33]	Proctor-Livingstone	250	76	NR	27

NR not reported
[a]Technical success was defined as the successful placement of the prosthesis
[b]Complications included short- and long-term, fatal and nonfatal complications
[c]Deaths included both procedure-related and delayed deaths as a direct complication of the stent

The larger case series using plastic and latex prostheses to palliate malignant esophageal strictures are listed in Table 1.1 [25–33]. In addition to the nine series reported, multiple other smaller series using one or a combination of prostheses resulted in similar outcomes [34–43]. The cumulative experience of palliation of malignant dysphagia in 2,951 patients with a plastic or latex prosthesis was associated with mean technical success rates of 94% (range 75–100%) and complication rates of 23% (3–60%). The differences in complication rates were attributed to the retrospective nature of most studies. Some authors included immediate complications and others only included perforations as complications. Studies that included long-term complications had mean complication rates of 45–50%. Perforation rates ranged from 2% to 12%. Mean procedure-related mortality was 8% (0.5–27%). With such high perforation and complication rates and associated mortality due to the need for aggressive dilation of strictures prior to placement of rigid stents, there was a search for a less cumbersome and safer stent to palliate malignant dysphagia.

Era of Self-Expandable Metal Stents

Frimberger appears to be the first to have developed the concept of placing a self-expandable metal stent (SEMS) in the gastrointestinal tract. Although the Souttar tube was a metal stent made of a coiled spring, it required the stricture to be dilated to 1–2 mm larger than the size of the prosthesis that needed to be placed (10 mm). The Frimberger stent was a metal spiral coil with an initial diameter of 13–15 mm (Fig. 1.7). With a special fixation tube and a thread, the spiral was wound tightly around a pediatric gastroscope. The prosthesis was advanced into the stricture and then released by the fixation tube. It was held in place

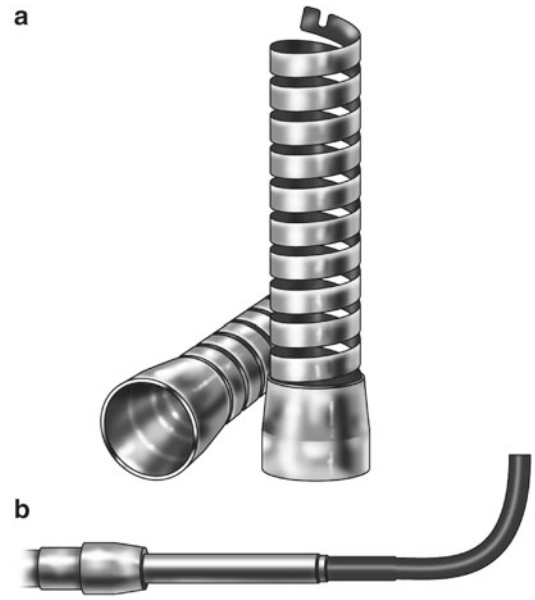

Fig. 1.7 (**a**) The Frimberger expanding spiral stent. (**b**) The spiral stent wound around a pediatric gastroscope

by the radial expansion of the stent as well as by tumor pressing into the spaces between the windings. Frimberger reported his experience in 10 patients in whom stents were successfully placed [44]. There were no deaths, but three distal migrations occurred. It took nearly a decade before modern manufacturing methods and new stent designs allowed the development of clinically applicable SEMS. The basic principle of the Frimberger stent was embodied in the EsophaCoil stent.

In the early 1990s, there were many retrospective and prospective case series on self-expandable metal stents but it was the seminal randomized controlled trial by Knyrim et al. in 1993 that provided evidence that led to the replacement of rigid prostheses with SEMS for the palliation of malignant dysphagia. In this study, the uncovered Wallstent was the SEMS used. Complications, particularly stent-insertion-related complications, were significantly higher in the rigid prosthesis group. Although initial costs were higher in the SEMS group, lower hospitalization rates and mortality resulted in overall cost-effectiveness [45]. Later in 1996, DePalma et al. published the second randomized controlled study comparing a rigid plastic prosthesis (Wilson-Cook prosthesis) to an uncovered SEMS (Ultraflex, Boston Scientific). In this small study of 39 patients, technical success rates and improvement in dysphagia scores were similar, but early complications (21% vs. 0%) and mortality (16% vs. 0%) were significantly higher in the plastic prosthesis group [46].

The first commercially produced self-expandable metal stent was the Wallstent, made of stainless steel and manufactured originally by Schneider Inc. (Switzerland). The stent and delivery systems were essentially the same as endovascular Wallstents, already in production in the late 1980s. In addition, SEMS had already been shown to have better patency rates in the biliary tree compared to plastic stents [47–49]. The first SEMS to be inserted in the esophagus was by Domschke in Germany. He inserted two 20 mm endovascular Wallstents in patients with inoperable esophageal cancer with relief of dysphagia for 4 months [50]. Some of the disadvantages or the endovascular stents were also seen including the relatively short lengths, absence of a proximal flare, and the exposed wire filaments at the ends, which caused mucosal injury and endoscope damage [51, 52]. The main limiting factor however was tumor ingrowth through the stent interstices with subsequent obstruction. This led to termination of a multicenter European study. Attempts to fully cover this stent with a synthetic material were also unsuccessful. Due to the above problems, an American model of the Wallstent with a partial silicone covering and a tulip-shaped proximal end was designed. This prototype stent had a bulky insertion delivery system (13 mm diameter), making delivery difficult [53]. A partially covered version of this stent was later produced and found to be effective [54, 55].

The second type of esophageal SEMS to be manufactured was the Gianturco Z-stent. This was also a stainless steel metal stent designed in the United States by interventional radiologists, Gianturco and Rösh. This stent had interconnected consecutive Z-shaped segments, was not braided, and thus did not foreshorten during deployment. A polyurethane covering was applied to prevent tumor ingrowth. The European version of this stent had two rows of external, lateral projecting barbs to reduce migration. The Song stent was essentially a Z-stent without antimigration barbs [56–58].

The third SEMS to be developed was the Ultraflex stent, developed by Boston Scientific (Natick, MA, USA). It was the first stent to be made of nitinol, a shape-retaining nickel and titanium alloy. The first-generation Ultraflex stent was completely uncovered and encountered the same problem of tumor ingrowth, as other uncovered SEMS [59–61]. In addition to the advantages of nitinol as a material, the stent being more flexible, the delivery system was also small enough to allow easy deployment. Subsequently, a partially covered Ultraflex stent was developed and is still being used in many parts of the world. A disadvantage of this stent is the high degree of foreshortening (25–40%) that occurs during deployment, which makes precise stent placement difficult. There were also reports of poor stent expansion, requiring dilation in up to a third of patients [51].

Fig. 1.8 Self-expandable metal stents (SEMS) no longer routinely manufactured or marketed in the United States. From *left to right*: EsophaCoil (Medtronic/Instent), uncovered Ultraflex (Boston Scientific), partially covered Wallstent (Boston Scientific), partially covered Flamingo Wallstent (Boston Scientific), fully covered Z-stent (Cook Inc.)

The EsophaCoil stent was the second SEMS to be made from nitinol, with a similar design to the spiral coil stent of Frimberger. Developed in Israel in 1994, by Goldin and colleagues, they reported successful deployment in four patients [62]. This stent was designed to overcome the disadvantages of previously designed uncovered stents, i.e., tumor ingrowth and tissue injury due to sharp exposed stent ends. This flat wire coil spring stent was wrapped tightly on an introducing catheter 9 mm in diameter and deployed by pulling a wire holding the distal and proximal ends. Once released, the stent foreshortened by 50% from the ends toward the center. This stent not only foreshortened more than any other stent, it also had the strongest and most rapid radial expansile force (Fig. 1.8).

With the large-scale production of the above-mentioned stents, and where upfront costs were not an issue, SEMS quickly replaced plastic prosthesis as the method of choice to palliate esophageal cancer. Thus, the SEMS revolution began, an era that has not ended. Of the previously mentioned SEMS, all but the uncovered Ultraflex have been discontinued in most markets for different reasons, mostly due to improvement in stent designs. In a nonrandomized, uncontrolled study in 82 patients, Schmassmann et al. compared the uncovered Wallstent with the Ultraflex stent (Boston Scientific Inc.). The Wallstent was associated with higher stent-related mortality (16% vs. 0%), higher rate of early complications (32% vs. 8%), and severe persistent chest pain (23% vs. 0%) compared to the Ultraflex stent [63]. At least some of these differences were attributed to the sharp uncovered stainless steel ends of the Wallstent. Given these differences, the Wallstent is no longer manufactured. Another version of the esophageal Wallstent was the Flamingo Wallstent marketed in Europe for use in distal esophageal malignant strictures. It had a tapered design to theoretically reduce migration with a proximal flare (30 or 24 mm) and a gradual distal taper (20 or 16 mm). In two separate, prospective, randomized controlled trials comparing it to the Gianturco Z-stent (Cook Inc.) and Ultraflex stent (Boston Scientific Inc.), there were no differences in outcomes for palliation of dysphagia, migration rates, or complication rates [64, 65]. Due to the higher cost of the Flamingo Wallstent and reports of higher rates of chest pain (given the proximal flare of 30 mm), this stent was never marketed in the United States. The EsophaCoil stent was the first to be withdrawn from the market. In addition to the 50% foreshortening, making accurate placement difficult, the very high expansile force led to sudden full expansion of the stent at deployment, often resulting in severe chest pain [3, 66]. The most recent stent to be withdrawn from the US market was the esophageal Z-stent (Cook Medical Endoscopy) and was replaced by the Evolution stent by the same company.

Summary

Esophageal stents have come a long way since their origin in the late nineteenth century, from decalcified ivory, to boxwood and German silver, to rigid plastic and latex, to stainless steel, and now to the most commonly used stent material, nitinol. There been an explosion in stent design with many manufacturers joining the SEMS revolution. Indications for esophageal stents have recently come to include benign conditions. Lately, self-expandable plastic stents and biodegradable stents have been manufactured,

studied, and are finding a niche in the treatment of benign esophageal conditions. Drug-eluting stents are on the horizon. The future looks bright for the continued role of esophageal stents in the management of various esophageal disorders, especially in the palliation of malignant dysphagia.

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History of Bile Duct Stenting: Rigid Prostheses

2

Joseph W. Leung

Biliary Obstruction: The Need for Drainage

Malignant obstructive jaundice caused by tumor obstruction at the head of pancreas, peri-ampullary area, bile duct or gall bladder, and hilar lymphadenopathy carries considerable morbidity and mortality (Fig. 2.1a, b). Biliary obstruction can lead to severe itching, and prolonged obstruction leads to impaired immune (both humoral and cellular) defense mechanisms predisposing the patient to increased risk of infection, endotoxemia, coagulopathy, impaired vascular response with acute renal failure, bleeding, wound sepsis, and impaired wound healing [1–13].

Various imaging modalities have evolved over time to define the exact level and nature of bile duct obstruction. In addition, the advent of needle aspiration and biopsy allows nonoperative tissue sampling to help discern the underlying cause of malignant biliary obstruction. Surgery is the only hope of cure for many of these patients, but for those with unresectable lesions, direct cholangiography via ERCP [14] and percutaneous transhepatic access [15] provides imaging as well as access to the biliary system for decompression and palliative drainage.

Over the past several decades, we have seen the evolution and development of different biliary stent technologies with improved plastic stents and stent deployment systems as well as the introduction of self-expandable metal stents (SEMS). This chapter will discuss the development of plastic biliary stents for the management of bile duct obstruction. As noted above, stents were originally developed for the palliative treatment of malignant obstructive jaundice. Currently, indications for the use of plastic biliary stents have widened to include the treatment of patients with numerous benign biliary processes, such as large bile duct stones and benign bile duct strictures.

The Evolution of Techniques for Bile Duct Drainage

Surgical Drainage for Malignant Obstructive Jaundice

Until the late 1970s, surgical bypass including cholecystojejunostomy and choledocho- and hepaticojejunostomy was the mainstay for bile duct decompression in patients with unresectable head of pancreas cancers or cholangiocarcinomas. Patients treated with surgical bypass tended to have a longer survival compared to those with only exploratory laparotomy [16, 17]. For patients with duodenal involvement, a gastric bypass operation was also performed to prevent gastric

J.W. Leung, M.D., F.R.C.P., F.A.C.P., M.A.C.G., F.A.S.G.E. (✉)
Department of Gastroenterology, VA Northern California Health Care System, Davis School of Medicine, Sacramento VA Medical Center, University of California, 10535 Hospital Way, Mather, CA 95655, USA
e-mail: jwleung@ucdavis.edu

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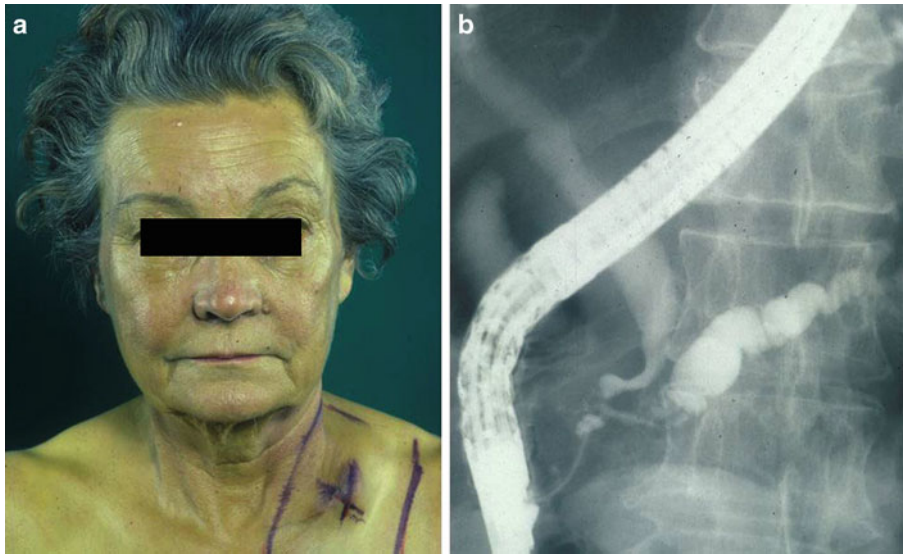

Fig. 2.1 (**a**) A patient with malignant obstructive jaundice and lymph node metastasis. (**b**) Cholangiogram showing double duct stricture sign with obstruction of the pancreatic duct and distal bile duct from head of pancreas cancer

outlet obstruction (a double bypass procedure). However, even surgical palliation carried a significantly high morbidity and mortality in the presence of obstructive jaundice [18, 19], and alternative drainage methods were sought to improve clinical outcomes.

Percutaneous Transhepatic Biliary Drainage

Percutaneous transhepatic cholangiography (PTC) became popular with the introduction of the thin flexible 22-gauge needle (Chiba needle) by Okuda in 1974 [20]. The percutaneous approach to the intrahepatic biliary system improved the safety and efficiency of fluoroscopic visualization of dilated bile ducts with success rates of 90%. Further modification of the PTC technique with catheter placement changed this from a diagnostic to a therapeutic procedure by allowing the insertion of a simple external drainage catheter [21, 22]. However, prolonged external drainage led to significant bile loss and electrolyte imbalance. Hoevels [23] and Nakayama [24] successfully negotiated a guidewire and catheter across a bile duct stricture (now

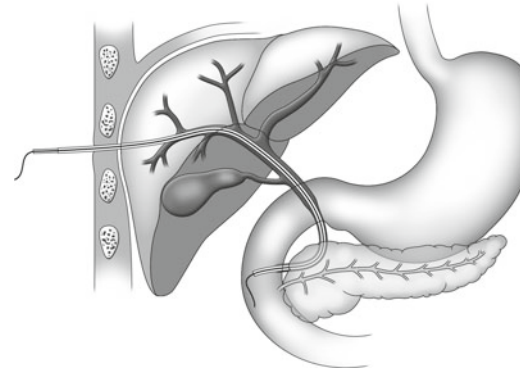

Fig. 2.2 Schematic diagram for percutaneous transhepatic biliary drainage (PTBD)

called percutaneous transhepatic biliary drainage or PTBD) to provide combined external and internal drainage of bile into the duodenum (Fig. 2.2). Ring [25] and Ferrucci [26] further improved this technique and reported a success rate of 95% [27]. The main advantage of PTBD was to minimize the external loss of bile; flushing the catheter via an external connector helped prevent blockage of the drainage catheter. Exchange of the blocked catheter could also be performed over a guidewire. Long-term complications related to bacterial contamination included sepsis,

and intrahepatic abscesses formation, and local skin irritation by the catheter and bile seepage [28, 29]. Despite the initial success, subsequent use of PTBD for preoperative biliary drainage did not show improvement in postsurgical outcome compared to surgery alone [30, 31].

Pereira [32] and Burcharth [33] described a percutaneous internal drainage method by the insertion of a prosthesis through a tumor obstruction, thus allowing antegrade flow of bile into the duodenum. These 6–7-Fr tubes blocked soon after placement leading to cholangitis and recurrent jaundice. Larger diameter stents were subsequently placed to prevent early stent occlusion [23]. However, bleeding, hematoma formation, and tumor seeding at the puncture site [34, 35] as well as the inability to remove a blocked prosthesis have limited the application of this drainage method. Soon after reports of percutaneous transhepatic biliary drainage (PTBD), endoscopic retrograde biliary drainage (ERBD) with placement of biliary endoprostheses using a side-viewing duodenoscope using endoscopic retrograde cholangiopancreatography (ERCP) was reported and offered a better alternative for nonoperative palliation of malignant obstructive jaundice [36].

Endoscopic Retrograde Biliary Drainage

Although first described in 1969, ERCP only became popular after introduction of side-viewing duodenoscopes in 1970 [37]. It is now an established treatment for patients with many pancreaticobiliary diseases. The advent of duodenoscopy and biopsy allows for direct examination of the papilla to rule out ampullary lesions, endoscopic (tumor) papillotomy, and improved drainage and allows for access to bile duct obstruction and strictures for therapeutic intervention.

Early Teflon-coated steel guidewires were stiff, kinked easily, and made manipulation difficult. The ability to traverse biliary obstruction was further improved with the use of flexible tip guidewires to negotiate strictures. Even with flexible guidewires, manipulation through angulated or hilar biliary strictures remains challenging. Prior to the advent of internal endoscopically placed stents, nasobiliary drainage tubes offered a reasonable alternative to percutaneous biliary tubes. Nasobiliary catheters can be inserted over a guidewire above an obstruction to provide biliary decompression and subsequent noninvasive cholangiographic access. Placement of these devices involves pushing the nasobiliary tube over the wire, removing the duodenoscope, and rerouting the tube through the nose. The tube may be connected to a drainage bag to provide decompression of the obstructed biliary system if so desired [38, 39]. Like percutaneous catheters, nasobiliary drains cause external loss of bile and may be dislodged accidentally.

Soehendra and Reynders-Frederix [36] working in Hamburg, Germany, described the first case of endoscopic insertion of a biliary endoprosthesis for drainage of malignant obstructive jaundice. They fashioned a single-pigtail endoprosthesis using the cut end of an angiography catheter. The procedure was technically successful, but ultimately, the stent migrated upstream. Cotton [40], working in London, reported the use of an endoprosthesis made with a double-pigtail design to prevent upward migration. Huibregtse and Tytgat [41] from Amsterdam described the creation of side flaps in the wall of a straight endoprosthesis instead of pigtails to prevent migration. Cremer from Brussels introduced a different endoprosthesis design with a snake-shaped proximal tip and a distal C-loop in the duodenum to prevent migration (Fig. 2.3).

Because the working channel diameters of the first duodenoscopes were small, early biliary endoprostheses were only 8-Fr tubes. Cholangitis and stent occlusion occurred at high rates [42]. With the introduction of larger (3.2 mm) channel duodenoscopes, placement of larger (10 Fr) endoprosthesis was possible [43, 44]. One plastic stent – the Tannenbaum stent [45] (Fig. 2.4) – maintained an intact inner surface with anchoring side flaps cut out from the wall of the stent without damaging the lumen to insure a smooth bile flow. It was initially reported to reduce the risk of bacterial attachment as compared with the conventional stents and to minimize the risk of stent occlusion.

Over time, other concepts have been tried to reduce stent occlusion. Endoprostheses with

Fig. 2.3 A display of different types of plastic stents available in the mid-1980s with single-pigtail, double-pigtail, straight with flaps, and curved stents

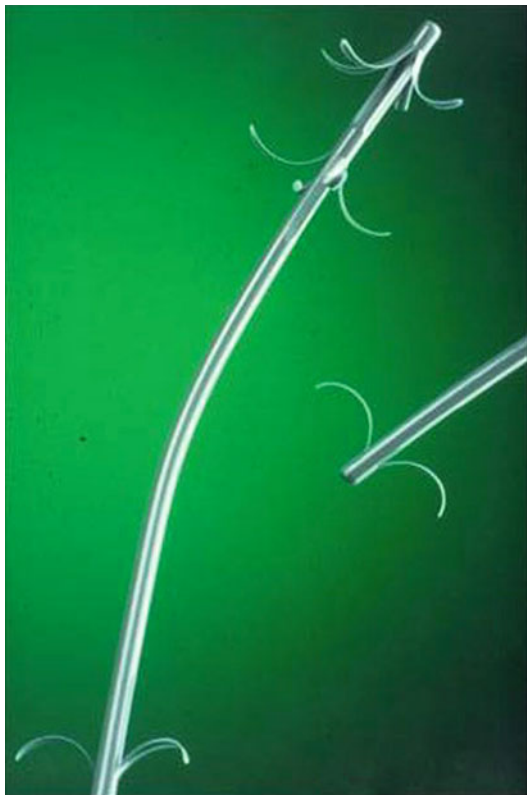

Fig. 2.4 Tannenbaum stent with multiple side flaps for anchorage

different designs have been investigated. Pigtail stents with small side holes placed over the pigtail portion of the prosthesis, straight endoprosthesis with side flaps and small side holes along the shaft, endoprosthesis with multiple side flaps and curves created to resist migration, and in addition, different plastic materials were incorporated including Teflon, polyethylene (PTFE), polyurethane, and other plastic polymers. These materials varied considerably in their physical properties including wall thickness, rigidity, and the *melting* temperature which affected their ability to be molded into different shapes or curves. There was no consensus or standard in endoprostheses design at the time of early development which made comparison of study results difficult [46]. This clinical hodgepodge prompted a retrospective review of endoscopic biliary drainage at the Middlesex Hospital. The lack of clarity of that study led to subsequent laboratory work in search of an *ideal* biliary endoprosthesis [47, 48].

Design of the Cotton-Leung Stent

Early pigtail designs had very small side holes at either end of the stent that limited bile drainage; this concept was abandoned early in the design process and replaced with a straight tube. Similarly, the small end hole at the tapered tip of a Cremer endoprosthesis, which also restricted bile flow, was removed. Despite pigtail ends and anchoring flaps, the single-pigtail endoprosthesis

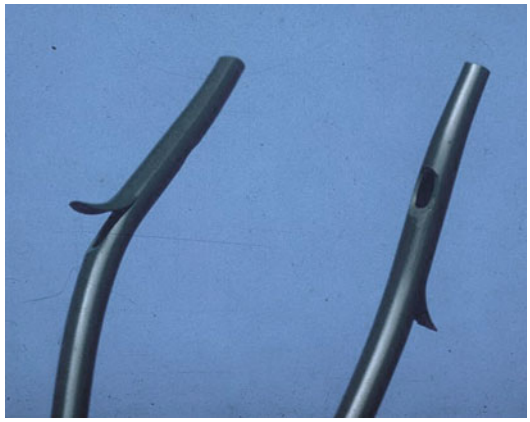

Fig. 2.5 Original design of Cotton-Leung stent showing proximal tapered tip, side flap, and side hole for drainage

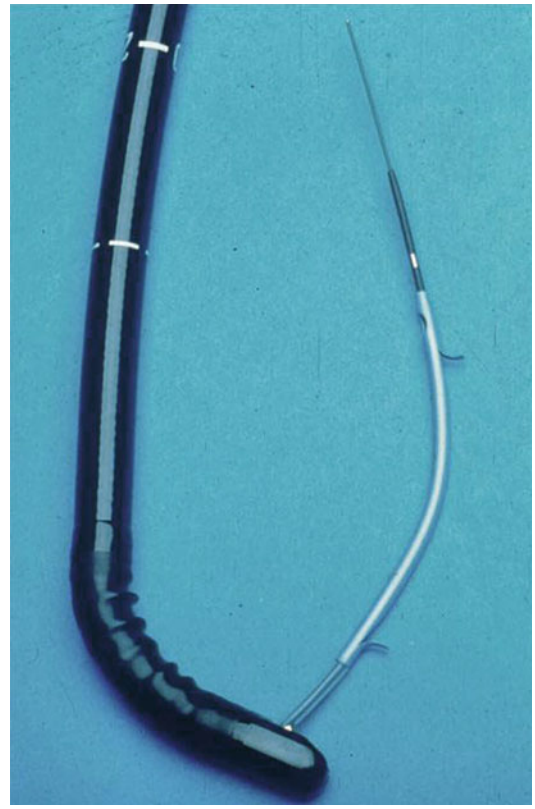

Fig. 2.6 Setup of stenting system with large channel duodenoscope and stenting unit consisting of a 0.035 guidewire, a 6-Fr guiding catheter and a 10-Fr (PTFE) CL stent, and a 10-Fr Teflon pusher

and the early Amsterdam endoprosthesis were prone to migration because of the straight shaft. The proximal tip of the Amsterdam endoprosthesis tended to get stuck at the lower level of a tight or angulated bile duct stricture because of the gap between the guidewire and the stent lumen (a shoulder effect), which created resistance to passage of the endoprosthesis. The curved ends of a double-pigtail endoprosthesis also made it difficult to push over a guidewire or through a tight stricture because of the bending effect on the guidewire.

The unique feature of the Cotton-Leung stent (Cook Endoscopy, Winston-Salem, NC) is the proximal coaxial tapered tip design, which minimizes the potential gap between the guidewire and the inner guide catheter and the proximal tapered tip of the stent, thus offering a good fit to facilitate passage of the stent through tight or angulated bile duct strictures [48] (Figs. 2.5 and 2.6). In vitro flow studies demonstrated that drainage through a tube (inserted through a stricture) depended on the diameter of the end hole (Table 2.1) (Fig. 2.7). A tapered proximal tip reduced the flow through the stent [48, 49]. To overcome this problem, we created a 5-mm side hole at the proximal end of the tube to optimize flow through the stent. Without completely cutting and removing the plastic, we created a side flap design very similar to that of the Amsterdam endoprosthesis. This side flap offered resistance to the downward migration of the stent but could be collapsed if it were being pushed against the bile duct wall or a tumor, which closed off the opening and reduced flow. To avoid this potential problem, we created another 5-mm side hole (without flap) on the reverse side of the proximal shaft between the end hole and the side flap to

Table 2.1 The effect of changing configuration of tube on flow rates (ml/min)

French size	8	10
Internal diameter (mm)	1.75	2.2
Control straight tube	115	288
Proximal flap and large side hole	111	277
Sharp proximal tapered tip	103	239
Less proximal tapered tip + side hole	110	263
Proximal tapered tip + side hole + flap	110	261
Complete Cotton-Leung stent	110	258