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# History of Bile Duct Stenting: Rigid Prostheses

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## 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.

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## The Evolution of Techniques for Bile Duct Drainage

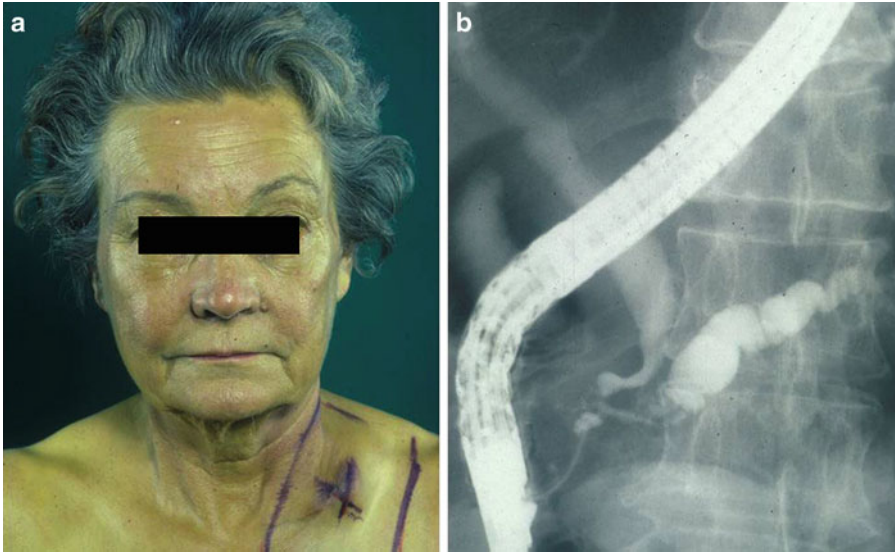
### Surgical Drainage for Malignant Obstructive Jaundice

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

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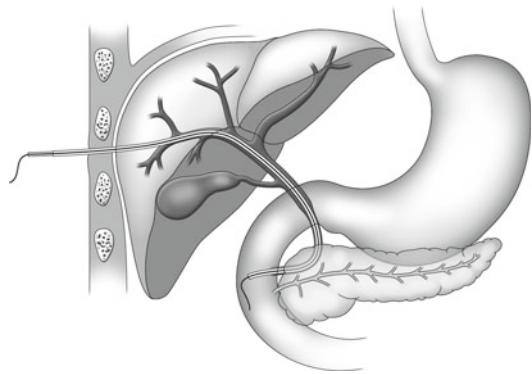


**Fig. 2.1** (a) A patient with malignant obstructive jaundice and lymph node metastasis. (b) Cholangiogram showing double duct stricture sign with obstruction of the pancreatic duct and distal bile duct from head of pancreas cancer

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 endoprotheses 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.

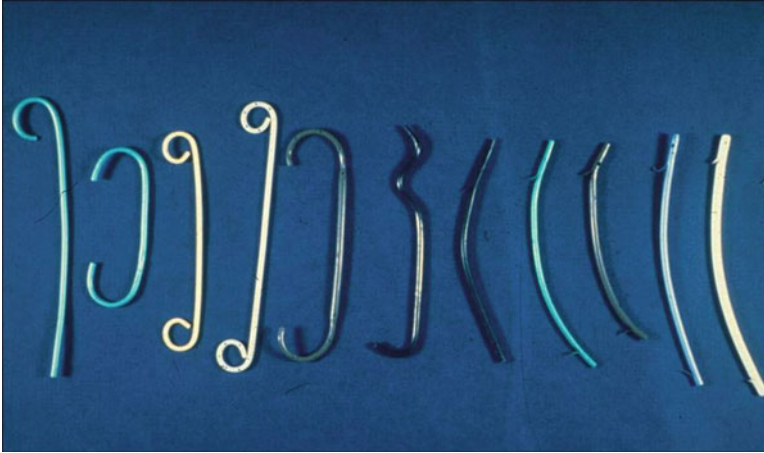
Early Teflon-coated steel guidewires were stiff, kinked easily, and made manipulation difficult. The ability to traverse biliary obstruction was further improved with the use of flexible tip guidewires to negotiate strictures. Even with flexible guidewires, manipulation through angulated or hilar biliary 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 endoprotheses 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. Endoprotheses 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

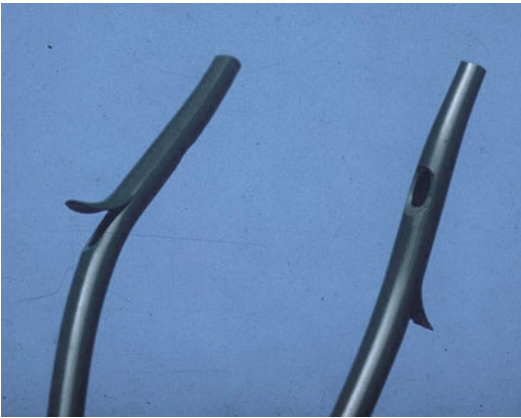
different designs have been investigated. Pigtail stents with small side holes placed over the pigtail portion of the prosthesis, straight endoprosthesis

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

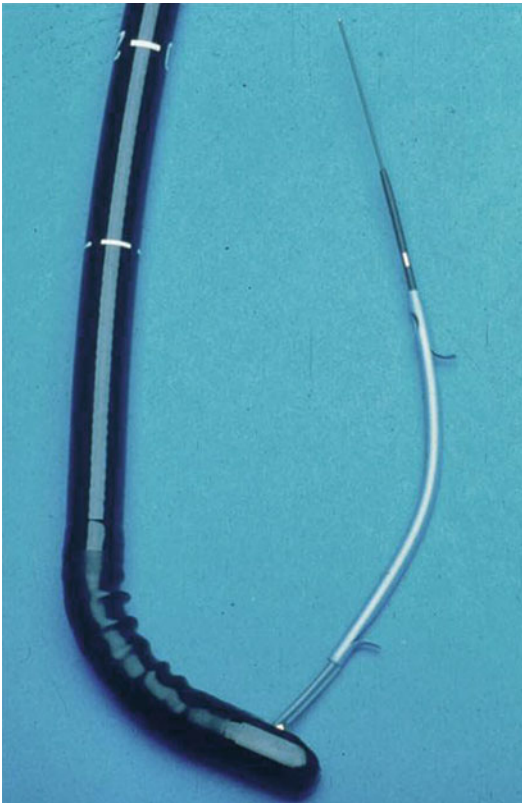




**Fig. 2.5** Original design of Cotton-Leung stent showing proximal tapered tip, side flap, and side hole for drainage

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

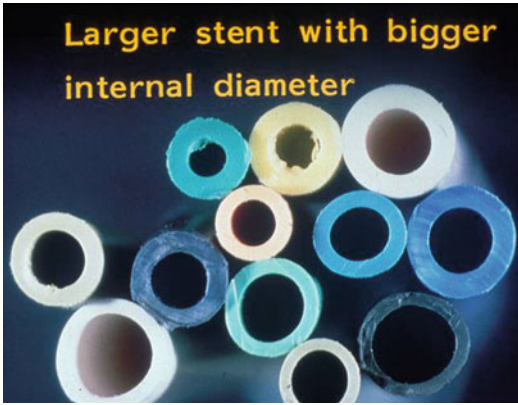


**Fig. 2.6** Setup of stenting system with large channel duodenoscope and stenting unit consisting of a 0.035 guidewire, a 6-Fr guiding catheter and a 10-Fr (PTFE) CL stent, and a 10-Fr Teflon pusher

**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

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



**Fig. 2.7** Picture showing cross section of plastic tubes with different diameter and wall thickness; drainage is dependent on the inner diameter

ensure optimal drainage of an obstructed system. In addition, the proximal tip of the stent extended for about 1.5 cm above the proximal side flap to allow the side hole on the reverse side to be made without weakening the stent and to prevent buckling of the stent in the deployed position. In order to prevent upward stent migration, we created another 5-mm side flap on the same side over the distal end of the stent about 1 cm from the distal tip of the stent. This side flap, which opened up almost at a right angle to the shaft to provide maximum resistance to prevent upward stent migration, was meant to be positioned at the level of the papilla in the final deployed position (Fig. 2.5). The side hole at the distal flap also allowed continuous drainage from the stent in the event of downward stent migration should the distal end hole become blocked by the opposite duodenal wall (a problem that could affect straight stents without a distal side hole). Assuming a perfect stent deployment and no subsequent stent migration, the distal side (flap) hole would be placed close to the pancreatic orifice, thus avoiding any local pressure effect on the pancreatic opening. (NB: We have not observed a significant increase in poststenting pancreatitis when a single 10-Fr stent was used without performing a biliary sphincterotomy). It is worth noting that a partially collapsed distal side flap might not be

**Table 2.2** Comparison of mean flow rates (ml/min) through stents of different caliber and configurations

French size	8	10
Internal diameter (mm)	1.75	2.2
Control tube	121	305
Single-pigtail stent	95	188
Double-pigtail stent	89	133 (sharp taper) 187 (less taper)
Straight Cotton-Leung stent	110	246

effective in preventing upward migration in the presence of a large papillotomy.

There is a small risk of duodenal irritation, ulcer formation, and rarely even perforation if downward stent migration occurs and the distal end of the stent impacts against the opposite duodenal wall [43]. In order to avoid this complication, we placed the distal tip of the stent just 1 cm beyond the distal flap. We also created a C-curve at the midshaft of the stent to conform to the shape of the bile duct. The idea was that in the deployed position, the curvature of the stent followed the contour of the bile duct, thus also providing a springlike action holding the stent in place, further reducing the risk of stent migration. We purposely did not place side holes in the shaft of the stent (which traversed the tumor) between the side flaps to avoid the theoretical risk of tumor ingrowth. In subsequent laboratory flow studies, the final Cotton-Leung stent design provided more effective drainage than double-pigtail endoprotheses (Table 2.2).

There was a less commonly used design specifically catered to provide drainage of the left hepatic system in patients with hilar obstruction where bilateral stent placement was desirable. This design was never manufactured as a regular item, but the goal was to avoid kinking of the stent at the proximal flap when the usual design was deployed in the left hepatic duct. A modification of the design (left hepatic duct or LHD stent) was created by removing the proximal side flap and shaping a 15-cm-long stent into an S-shape configuration instead of the usual C-shape. This allowed the proximal limb to be placed inside the left hepatic system and the angulations of the stent served to prevent stent migration (Fig. 2.8).



**Fig. 2.8** Cholangiogram showing common hepatic duct stricture (*left*) and bilateral *right* and *left* hepatic duct stents (*right*)

### Why Cotton-Leung Stents Are Made of Polyethylene

In the early 1980s, homemade stents were popular and were often tailor-made for the individual patient. Therefore, it was crucial to find a material that could be easily shaped, manipulated, or cut by hand. After experimenting with different plastic materials, polyethylene was chosen over Teflon or polyurethane. Polyethylene (PTFE) was chosen because of its lower *melting* temperature (87°C) – a temperature at which the material became soft and malleable, compared to the much higher temperature required to soften Teflon (Product guide, Wilson-Cook, Winston-Salem, NC). A polyethylene stent could be shaped and molded easily using boiling water or steam and subsequently set by holding it and immersing it in cold (sterile) water. PTFE was also softer than Teflon, making the creation of side holes and cutting side flaps much easier. To date, manufacturers have developed more complex plastic materials that are softer and have memory to retain their shape. Although a softer material is less traumatic to tissue, there is a higher tendency

for the stent to kink. In addition, soft material does not transmit the pushing force well and therefore may buckle when being pushed against resistance such as a tight stricture, making deployment more difficult without prior dilation of the stricture. On the other hand, stiffer materials are less malleable, and the stents are more prone to migration.

### Selection of Stent Length

By definition, the length of a straight stent was defined as the distance between the proximal and distal anchoring flaps. In order to accommodate obstruction at different levels, stents were made available in different lengths between 5 cm for distal CBD obstruction to 15 cm for hilar obstructions. Ideally, the proximal flap of a deployed stent should extend about 1 cm above the upper level of the stricture or tumor obstruction (to accommodate tumor growth), while the distal flap should remain at the level of the papilla. In the event of a downward stent migration, only 2 cm of the stent could protrude from the papilla

into the duodenum in theory. However, this was true only if a significantly tight stricture was holding the stent in position and might not apply when the stent was placed for stones or when the stricture had been dilated. In general, an 8-cm stent would be suitable for obstruction at the level of the common bile duct, either caused by a stricture or large CBD stones. Stents were also available in various diameters: 7, 8.5, 10, and 11.5 Fr. The larger stents provided a higher flow, and there was a difference observed in the reported stent patency rates between the 10- and 12-Fr stents [50]. There was also a difference in wall thickness resulting in comparable internal diameters between the 10- and 11.5-Fr stents. Since larger 11.5-Fr stents were more difficult to remove through the 4.2-mm therapeutic endoscope channel because of the thicker wall, we preferred to use 10-Fr stents because they could be easily removed. Some would argue that a 7- or 8.5-Fr stent would provide sufficient drainage to empty the biliary system and they could be more easily placed, but my concern is that the smaller lumen was too prone to blockage by sludge and biofilm formation.

### **Position of the Stent: Why Leave the Distal Tip in the Duodenum?**

Over the years, there have been many discussions as to the best/proper position for the distal end of the stent, i.e., should the distal end be placed within the bile duct to avoid ascending infections and stent blockage, or should the tip protrude into the duodenum to maximize the ease of removal when exchange was necessary. Our experience suggested that ease of removal was more important; therefore, the original design of the Cotton-Leung stent provided for placement of the distal tip in the duodenum with the distal flap preventing upward migration. The 1-cm distal tip allowed the stent to be captured easily with a snare and removed through the endoscope channel. Although total internal placement might minimize ascending reflux and infection, placement of the stent above the papilla was equivalent to upward migration and it was well-recognized that

retrieval of an upwardly migrated stent could be very challenging, and the risks outweighed any potential benefits in our minds.

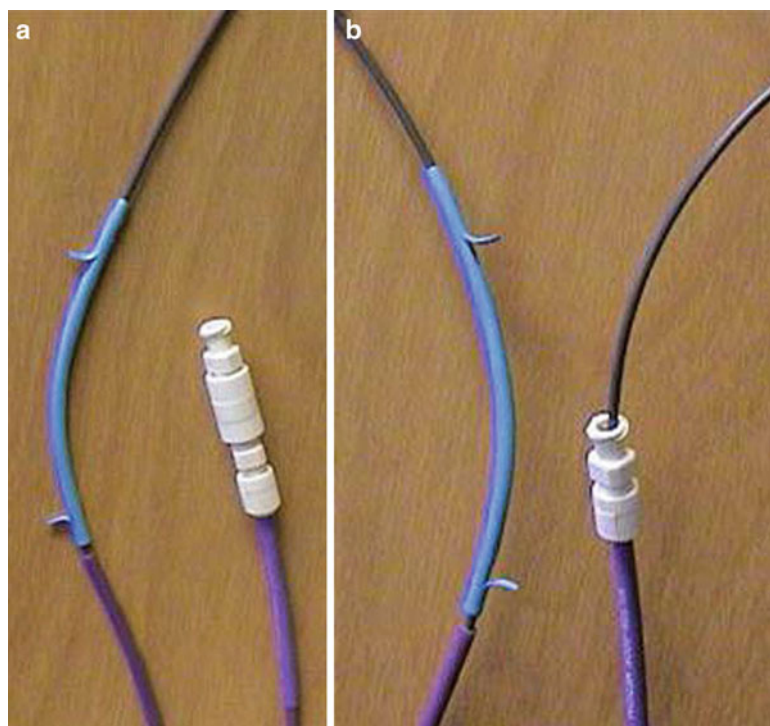
### **The Stent Introducer System**

The early stent introducer system for the Cotton-Leung stent (Wilson-Cook, Winston-Salem, NC) consisted of a three-layer coaxial system – a regular Teflon-coated 0.035" guidewire, a 6-Fr Teflon guiding catheter with radiopaque markers (placed 7 cm apart), and a 10-Fr Teflon pusher. Stent placement was performed in a systematic manner with initial manipulation of the guidewire across the stricture followed by inserting the guiding catheter over the guidewire. The markers on the guiding catheter helped in the selection of a stent of suitable length which was then loaded onto the guiding catheter. The stent was advanced over the guiding catheter and positioned across the stricture using the pusher. When the stent was deemed to be in the proper position, the pusher was used to hold the stent in position and the guidewire and guiding catheter were removed to deploy the stent. This method of stent deployment required multiple coordinated exchanges with risk of losing control from a lack of coordination between assistant and operator resulting in placement failure. This design was later improved to a double-layer system using a Luer lock mechanism to combine the guiding catheter and the pusher into the simplified “One Action Stent Introducer System” (OASIS, Cook Medical, Winston-Salem, NC), which was launched in the early 1990s (Fig. 2.9a, b). To date, all of the plastic stent deployment systems (from different manufacturers) utilize a similar concept of interlocking the inner guiding catheter and the pusher using with a Luer lock mechanism to minimize the number of exchanges and to facilitate stent deployment.

### **Stent Length Measurement**

As discussed before, the length of the stent is defined as the separation between the anchoring





**Fig. 2.9** (a) OASIS stenting system combined the guide catheter and pusher into one unit using a Luer lock mechanism. (b) Stent deployment is effected by separating the Luer lock and pulling back on the inner catheter to release the stent

flaps for straight stents and the separation between the pigtailed ends for the double-pigtail stents. Obviously, the vertical separation could be less if the stent was bent to conform to the shape of the bile duct. Using the old stent system, the length of the stent could be estimated by referencing the radiopaque markers on the inner guiding catheter (which are 7 cm apart). Alternatively, the length of the stent could be measured by using the scope diameter as a guide (1.3 cm for the therapeutic endoscope). If the measurement was obtained directly from a radiograph, a correction for the magnification (usually 30%) was necessary. Another method was to measure the distance traveled by the guidewire outside the endoscope at the accessory port when the tip of the guidewire was pulled back (within the catheter/accessory) from the upper level of the obstruction to the level of the papilla (as seen endoscopically through the catheter).

With a combined guiding catheter and pusher system such as the OASIS, a suitable length stent

had to be chosen and loaded onto the deployment system before advancing the delivery system over the guidewire (as described above). The radiopaque marker(s) on the inner catheter (e.g., set 5 cm apart in the OASIS system) could be used to aid positioning of the guiding catheter for proper stent deployment. The stent was then advanced over the guiding catheter and deployed by unlocking the guiding catheter from the pusher. For patients in whom the stent was placed to provide drainage but without an obvious stricture, e.g., large obstructing CBD stones, a bile leak, or to insure drainage from a small papillotomy complicated by postpapillotomy bleeding, an 8-cm long stent could suffice.

### Guidewire Selection for Stent Placement

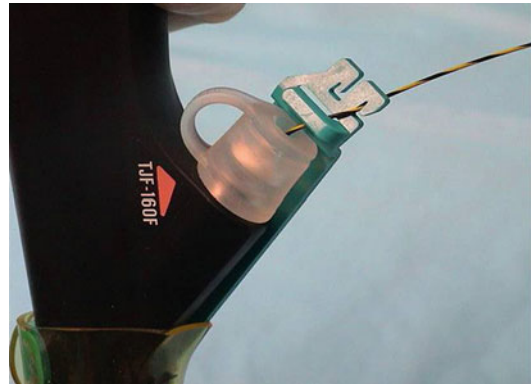
Early stent systems included a Teflon-coated steel wire which was stiff and kinked easily, thus

increasing the resistance to the passage of the guiding catheter and other accessories (dilating or brushing devices). For the past 15 years, Teflon-coated memory (nitinol) guidewires with a flexible hydrophilic tip have been available to facilitate negotiation of strictures and deployment of stents. Guidewires come in different diameters ranging from 0.018" to 0.021" to 0.025" and 0.035". The thicker guidewires were stiffer and allowed better application of the pushing force, whereas smaller, e.g., 0.025", guidewires were more flexible and could be shaped (i.e., creating curves at the tip of the guidewire) to allow bending and loop formation to help negotiate tight or angulated strictures. For stenting of the left hepatic system, a stiffer or stronger guidewire was necessary because of the angulations and to provide a more stable system while pushing the stent. If a soft guidewire was used to negotiate the stricture, then exchange to a stiffer guidewire might be needed to facilitate subsequent stent placement.

It is important to note that proper positioning of the guidewire is necessary for successful stent placement. A steady or secure position of the guidewire requires coordination between the endoscopist and the assistant during the exchange process. The introduction of guidewires with different colored stripes or even numbers helps with endoscopic observation and monitoring of the position of the guidewire during the exchange process. In order to secure the position of the guidewire, other novel ideas have been tried including the *Peel-Away* catheter, which allows the catheter to be split in half around the guidewire without having to move the guidewire once it is inserted in position. Insertion of a single biliary stent across a common bile duct stricture is feasible with any type of guidewire.

### Short-Wire Technology for Stent Placement: Rapid Exchange, Fusion, and V-Scope

Concerns over control of the guidewire during the exchange process and a desire to give the endoscopist better control over the guidewire and



**Fig. 2.10** Wire locking device for the RX system



**Fig. 2.11** Wire locking device for the Fusion system

deployment of accessories have led to the introduction of different short-wire technology platforms, notably the Rapid Exchange system (RX, Boston Scientific, Natick, MA) and the Fusion system (Cook Endoscopy, Winston-Salem, NC). The use of a wire locking device strapped to the endoscope (RX) (Fig. 2.10) or as a modified biopsy valve with a set of plastic *teeth* (Fusion) serves to anchor the guidewire (Fig. 2.11) during exchange and to minimize the risk of losing guidewire position.

Only a short segment of the accessory passes over the guidewire, making manipulation of accessories and exchange much easier and more controlled. On the other hand, the V-system (Olympus Tokyo, Japan) incorporates a modified elevator that provides additional elevation and a V-notch that serves to grip and hold a much shorter guidewire during insertion and removal



**Fig. 2.12** The V-scope system with a small notch created on the elevator mechanism

of the accessory over the guidewire (Fig. 2.12). This allows short wires to be used with traditional long-wire (nonmonorail) accessories. With the V-scope, the only time the elevator loses its grip on the guidewire is when the accessory is passing over the elevator mechanism. This can easily be compensated for with proper endoscope positioning. Locking the guidewire to the endoscope with whichever mechanism serves to stabilize the guidewire during exchanges, but it also means that the endoscope position has to be stable; otherwise, the guidewire can easily be dislodged from the bile duct with excessive endoscope movement or manipulation.

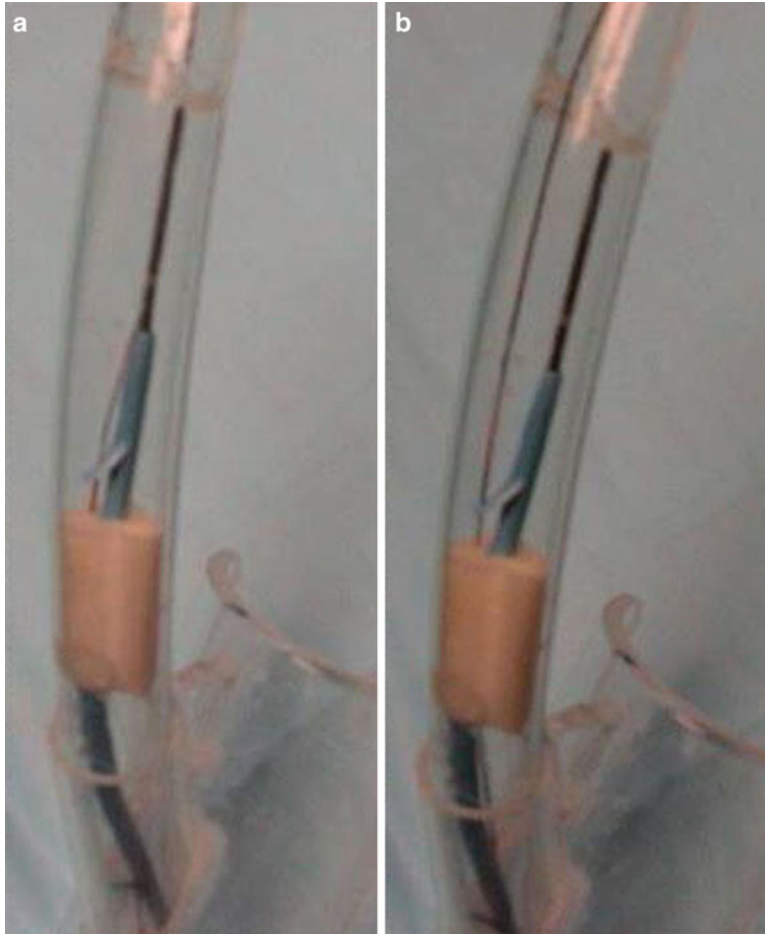
One advantage of the new Fusion OASIS design (Cook Endoscopy, Winston-Salem, NC) is the incorporation of a side port close to the tip (2.5 cm) of the guiding catheter which allows the guidewire to be freed above the stricture or obstruction in the bile duct (Fig. 2.13a, b). This concept of intraductal release (or exchange, IDR, or IDE) of the guidewire has proven to be useful in facilitating the placement of multiple stents

across a bile duct stricture especially for the management of benign strictures, without having to reattempt cannulation or negotiation of the guidewire across the stricture (Fig. 2.14a–c). With this setup, prior to final stent deployment, the guidewire must be separated from the guiding catheter using the intraductal release feature before the guiding catheter is pulled back to deploy the stent. The guidewire is left inside the bile duct across the stricture, and a second stent can be delivered over the same guidewire, thereby decreasing procedure time.

## Complications of Biliary Stenting

Complications and risks of biliary stenting are those inherent to the ERCP procedure and papillotomy which include postpapillotomy bleeding and perforation and post-ERCP pancreatitis. The most common complication of biliary stenting is occlusion from bacterial contamination with subsequent biofilm and biliary sludge formation [51–53] (Fig. 2.15a, b). Observational studies have shown that even though the bile is considered to be sterile, transient bacteriobilia from enteric bacteria that migrate from the portal circulation into the bile duct radicals is relatively common [54]. The Kupffer cells that line the hepatic sinusoids generally limit the migration of these organisms. Any residual bacteria which reach the biliary system are then attacked by immunoglobulin A (IgA) secreted by the bile duct epithelium and trapping by the mucus secreted in bile and the downward flow of bile into the small bowel. However, the presence of a foreign body such as a stone or an indwelling device (stent or NB tube) will provide a surface for the attachment of the bacteria leading to infected biofilm [54, 55]. In addition, an indwelling stent with the tip in the duodenum will lead to ascending infection and contamination of the biliary system and sludge formation. Clinical manifestations of a blocked stent include recurrent jaundice, with or without cholangitis.

A series of laboratory studies have examined ways to prevent bacterial attachment and sludge



**Fig. 2.13** (a) Stent introduced through an artificial bile duct with a simulated stricture using the Fusion OASIS system. The stent is caught between the guidewire and the guiding catheter. (b) Intraductal release of the guidewire

above the simulated stricture allows the stent to be deployed while maintaining the guidewire above the stricture to minimize the need for repeat cannulation if a second stent is to be deployed

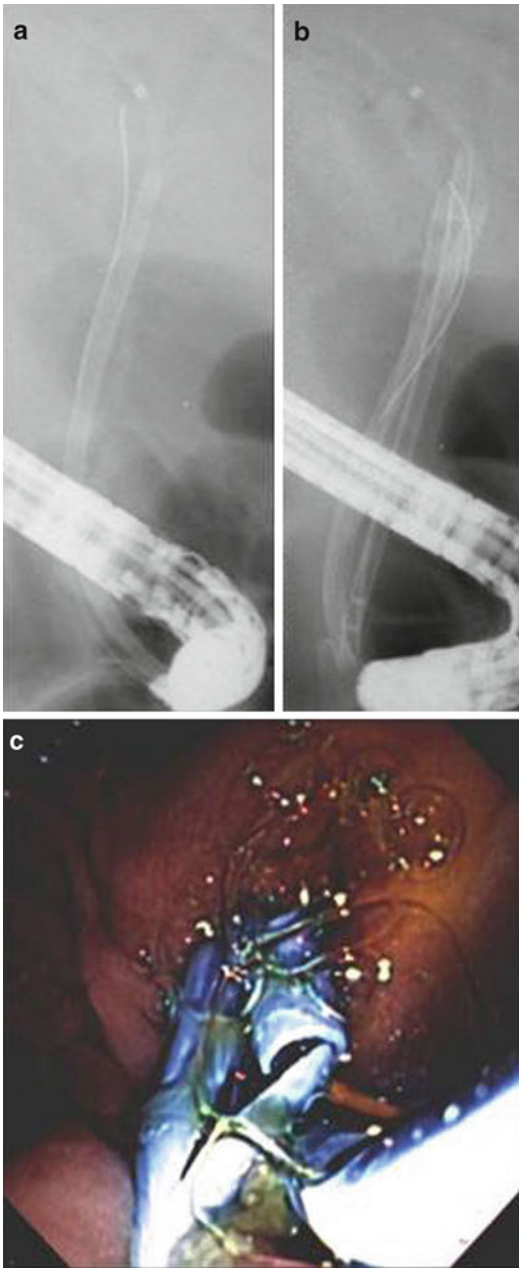
formation, but the overall results have not been impressive [56–58].

The use of different plastic polymers, changing stent design by eliminating the side holes and creating side flaps that do not cut through the lumen to maintain a laminar flow [45] and anchorage, the use of hydrophilic materials which are more slippery and may even be useful for antibiotic loading to provide antibacterial effects [59], as well as surface modification using different polymers have been used to overcome this problem. A more recent design change involves the

use of plastic stent with an antireflux valve to minimize ascending infection [60].

Although temporary reduction of bacterial attachment has been reported, prolonged exposure of the stent to bile still leads to bacterial biofilm formation. Biodegradable expandable nonmetallic *plastic* stents may hold promise in the future [61], and future exploratory research may involve the use of nanotechnology to modify the stent surface as well as the possibility of using external stimulation or energy to alter the surface properties of the stent material to prevent





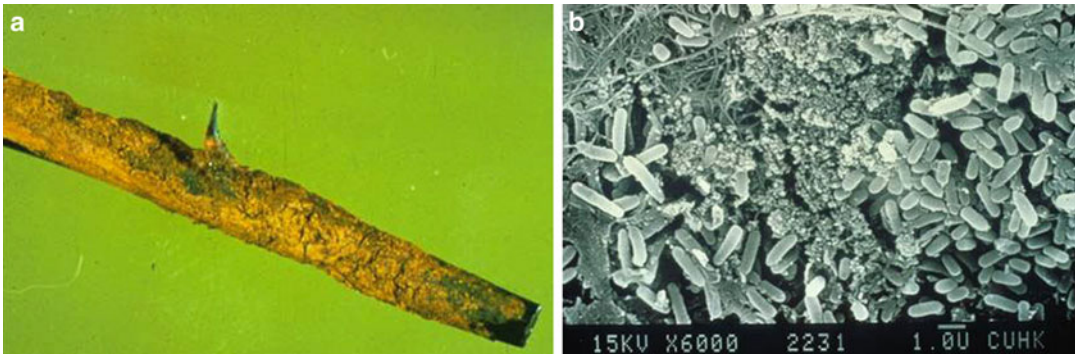
**Fig. 2.14** (a) Radiography showing guidewire is released from the guiding catheter to facilitate stent deployment. (b) Multiple plastic stents have been deployed using the Fusion OASIS system, and the radiograph showed three stents side by side with the guidewire alongside the stents. (c) Endoscopic view of multiple biliary stenting (c, Reprinted with permission from SLACK, Incorporated: Leung J, Lo S. Curbside Consultation in Endoscopy: 49 Clinical Questions. Thorofare, NJ, Slack Incorporated; 2009)

or minimize bacterial attachment. However, currently, the most effective method to prevent stent blockage is still elective stent exchange on a regular basis as well as antibiotic therapy if the patient develops symptoms of cholangitis (Fig. 2.16). The observation that bacterial adherence can occur on different plastic surfaces raises the concern that this phenomenon can also occur on the plastic membrane of the covered self-expandable metal stent (SEMS). However, with the much larger lumen, the effect of bacterial attachment and blockage may be less obvious for covered SEMS.

### Stent Retrieval Systems

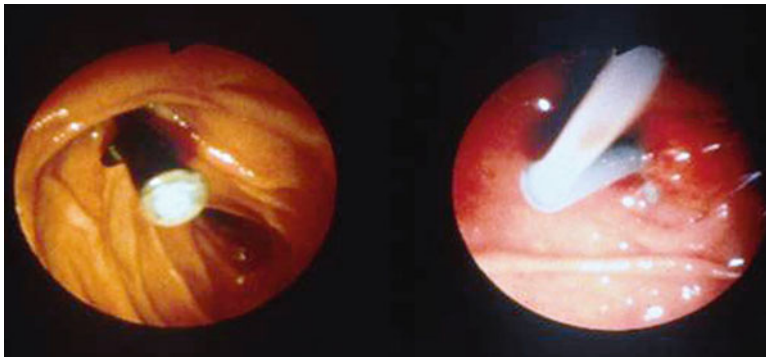
Stent blockage by biliary sludge necessitates the removal of the blocked stent and replacement with a new one to insure drainage of the obstructed bile duct. With the distal tip of the stent in the duodenum, it can be grasped with a polypectomy snare and pulled out of the bile duct. It is important to avoid grasping too much of the distal tip of the stent to avoid unnecessary resistance when the stent is buckled when pulled into the scope channel. Grasping the stent at the level of the flap can potentially break the stent, as this is the weakest part of the stent. To avoid the risk of losing access through the bile duct stricture when the stent is pulled, different methods have been tried [62] including initially inserting a guidewire through the blocked stent and engaging the distal end of the stent using the Soehendra stent retriever (Cook Endoscopy, Winston-Salem, NC) which has a screw tip that is used to hold on to the stent and then exchanging the stent retriever over the guidewire. There is a risk of pushing the stent into or further proximally in the bile duct while engaging the distal end of the stent. Another method is to use a mini-snare over the guidewire to engage the distal end of the stent and subsequently exchanging it over the guidewire. However, in the majority of cases, access through the stricture is possible immediately after non-wire-guided stent removal without using special devices using either a catheter or a wire-guided papillotome.





**Fig. 2.15** (a) A blocked biliary stent covered with thick yellowish sludge on the outside of the stent. (b) Scanning electron micrograph of a blocked biliary stent showing

the microcolonies of rod-shaped bacteria on the surface of the stent – typical appearance of a bacterial biofilm



**Fig. 2.16** Cholangitis secondary to blocked biliary stent (left) and exchanged stent-draining pus (right) (Reprinted with permission from SLACK, Incorporated; Leung J, Lo

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## Removal of a Migrated Stent

Downward or distal stent migration is possible if the stent does not conform to the shape of the bile duct. Rarely, perforation of the duodenum caused by the distal end of the stent can occur. Removal of a migrated stent can be achieved by advancing the scope further into the second/third part of the duodenum to engage the stent with a snare. Alternatively, it may be necessary to grasp the stent with rat-tooth forceps and deliver the stent back into the bile duct in order to engage the distal end of the stent. Upward migration of the stent can also occur, especially in patients with a prior papillotomy where the distal flap failed to hold the stent in position. Attempts can be made to engage the stent with a snare, basket, or grasping forceps inside the bile

duct and pulling the stent back into the duodenum and removing it with a snare as described. If the engaged stent is difficult to be pulled into the endoscope, the engaged stent and endoscope can be removed as a whole. A stone extraction balloon can be inflated alongside the migrated stent and pulled back to create sufficient friction against the stent in the hope of dragging the stent into the duodenum. A papillotomy is usually necessary to facilitate retraction of an upwardly migrated stent. If grasping the stent inside the bile duct proves to be difficult, a guidewire can be inserted initially through the stent and advancing a small stone extraction balloon or a wire-guided papillotome into the distal end of the stent. The stent can then be removed by insufflating the balloon or tightening the papillotome cutting wire within the distal end of the stent [63].

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## Shaping the Stent

Because of the varying shape of the bile ducts (and as a personal preference), it may be necessary to alter the C-curve on the stent to conform to the curvature of the bile duct. Also, the side flaps may sometimes be collapsed when the stent is removed from the sterile package. It is easy to use hot water from a kettle (contained in a plastic kidney tray) to open the flaps and shape the stent and then set it in sterile cold water.

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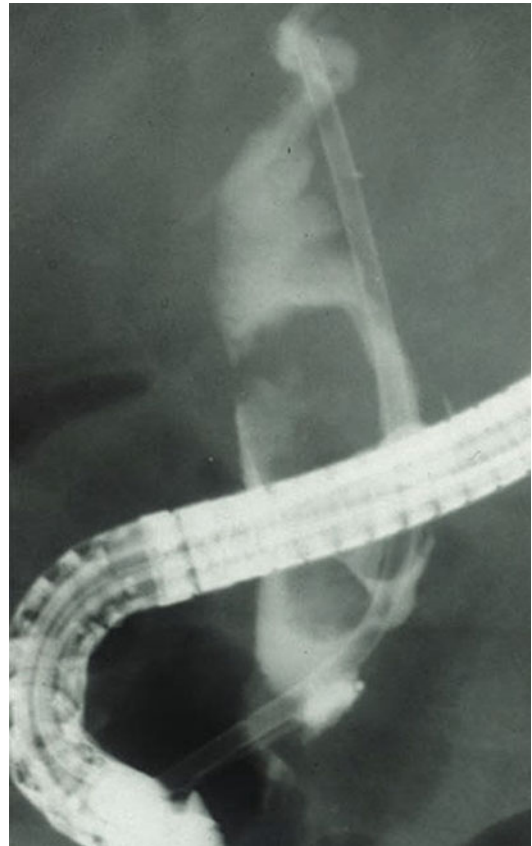
## Application of Plastic Stents in Biliary Diseases

Plastic stents were first introduced for palliative drainage of malignant biliary obstruction. Successful application of endoscopic stent placement in patients with benign bile duct strictures has since been reported. This drainage method has also been applied to the management of patients with acute suppurative cholangitis secondary to bile duct stones [64]. Pilot data as well as subsequent RCT demonstrated a significant benefit with urgent endoscopic biliary drainage when papillotomy and stent placement (or nasobiliary catheter) are used compared with emergency surgery for acute cholangitis as well as a significant reduction in morbidity and mortality [64, 65] (Figs. 2.17 and 2.18). Spontaneous disintegration of the bile duct stones has been observed with stent placement (in combination with oral stone dissolution agents) [66] and with stent placement alone in patients with large bile duct stones [67].

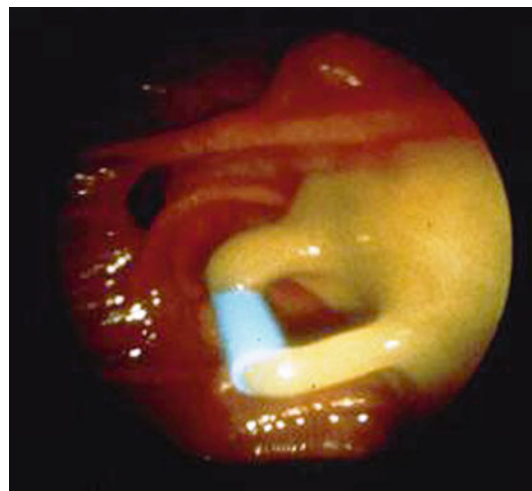
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## Conclusion

Over the past three decades since the introduction of the Cotton-Leung stent, many new stent designs and materials have been developed and tested. Expandable metal stents have played an important role in patients with unresectable malignancies. Despite these changes, the original Cotton-Leung stent has remained one of the most popular endoscopic biliary stents throughout the world.



**Fig. 2.17** Cholangiogram showing stenting for large obstructing bile duct stone



**Fig. 2.18** Stent-draining pus in acute suppurative cholangitis (Reprinted with permission from SLACK, Incorporated: Leung J, Lo S. *Curbside Consultation in Endoscopy: 49 Clinical Questions*. Thorofare, NJ, Slack Incorporated; 2009)

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