

# The use of metallic endoprostheses in interventional radiology

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## Introduction

The use of metallic endoprostheses has advanced rapidly since 1969 when Charles Dotter first described the implantation of a spiral stent via a percutaneous route to maintain a patent lumen.<sup>1</sup> Initial problems arose from early occlusion but rapid advances and the use of various materials and configurations have increased the indications and use of metal stents throughout the body. Initial use was in the vascular system with later extension to the gastrointestinal, biliary, and respiratory systems. Metallic endoprostheses in current use are manufactured from a variety of alloys and are either self expanding or balloon expandable.

## Balloon expandable endoprostheses

### The Palmaz stent

This is a balloon expandable tubular meshwork of annealed steel. This is deployed by inflation of a coaxial balloon system which has been mounted using a special crimping tool and does not expand further when the balloon has been deflated. It has been widely used since 1987 in the vascular system<sup>2</sup> (both arterial and venous)

and also for Transjugular Intrahepatic Portosystemic Shunting (TIPS)<sup>3</sup>. The stent is manufactured from stainless steel and has an electropolished surface which reduces thrombogenicity. When expanded a diamond lattice shape forms (Figure 1a-d), the struts of which embed in the vessel wall and endothelialisation can occur. The stent is

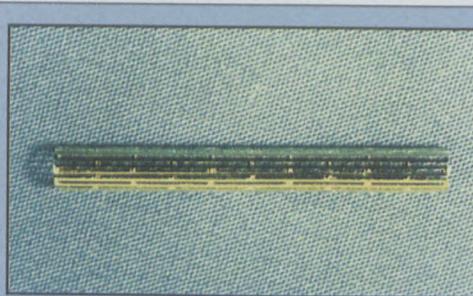


Figure 1(a): The unexpanded Palmaz stent. (Reproduced with permission from Isis Medical Press, Oxford)



Figure 1(b): The stent has been mounted coaxially onto a balloon system. A special crimping tool ensures this is secure and will not dislodge on introduction. (Reproduced with permission from Isis Medical Press, Oxford)

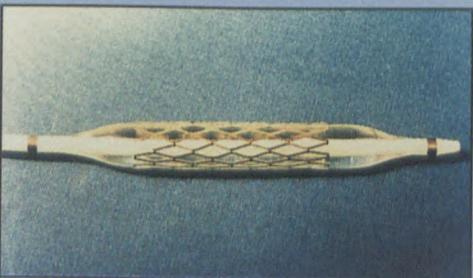


Figure 1(c): On balloon inflation the stent expands to the balloon diameter. (Reproduced with permission from Isis Medical Press, Oxford)

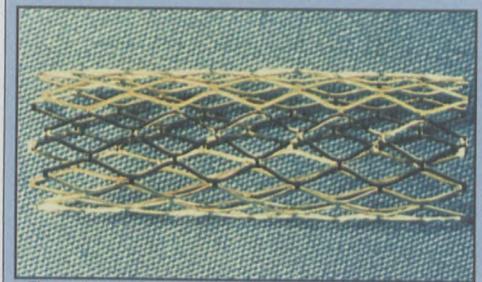


Figure 1(d): The fully expanded stent after balloon deflation and withdrawal. (Reproduced with permission from Isis Medical Press, Oxford)

limited by little longitudinal flexibility but accurate placement is aided by only a small amount of shortening. Recent development of this stent includes a heparin coating, which has potential use in low flow vessels, and articulated stents to increase flexibility.

### Strecker stent

The original Strecker stents were a balloon expandable endoprostheses made of tantalum which have been in use since 1987.<sup>4</sup> (Figure 2) More recently a nitinol

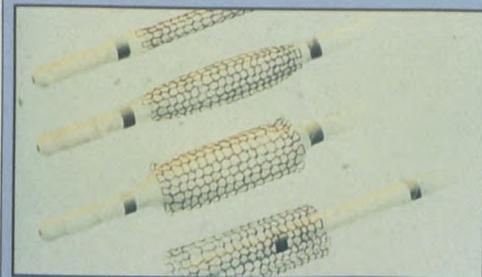


Figure 2: The original balloon expandable Strecker tantalum stent. An important feature is that both ends of the stent remain contained by thin walled sialastic sleeves until full balloon inflation. This prevents dislodgement on introduction and positioning. (Reproduced with permission from Isis Medical Press, Oxford)

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Strecker stent has been developed. The design for both materials is fundamentally the same. The stent is made from a metallic monofilament knitted into a tubular mesh of loosely connecting loops. The main advantage of this stent is its increased flexibility and compressibility, both radial and longitudinal and in the expanded and non-expanded state which makes its use possible in tortuous vessels. Although originally use was in the vascular system, Strecker stents have been deployed in the genitourinary, gastrointestinal and biliary systems.

Tantalum is less thrombogenic than copper or stainless steel and this is enhanced by surface electropolishing.<sup>5</sup> The stent is well seen fluoroscopically as it is relatively radiodense and due to its magnetic properties it is also MRI compatible.

## Self expanding endoprostheses

### Nitinol stents

Nitinol is an alloy of nickel and titanium which expands and contracts under the influence of changes in temperature.<sup>6</sup> Heat treatment during manufacture enables a shape memory to be gained so that it can be used to make thermoreactive self-expanding stents which include the Strecker Elastalloy Ultraflex™ (Figure 3). Other self

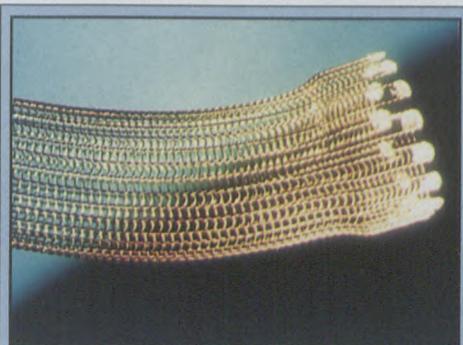
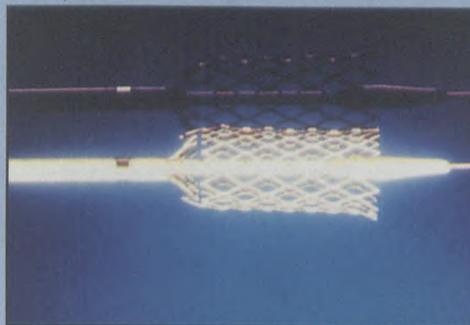


Figure 3: The Strecker Elastalloy Ultraflex self-expanding nitinol oesophageal endoprosthesis.

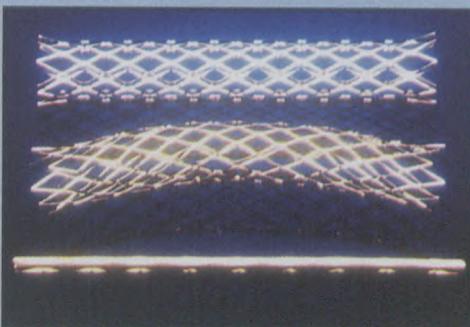
expanding nitinol stents are the Memotherm (Figure 4a-b), and the Cragg stent (Figure 5a).

The Memotherm stent has been available since 1993 and is made from a single

Figure 4: The self-expanding nitinol Memotherm endoprosthesis

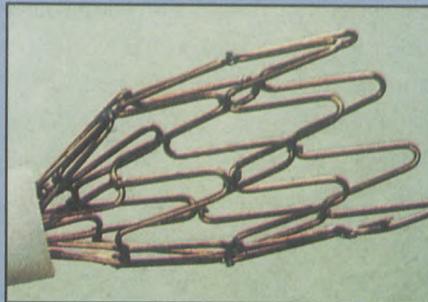


(a) Partial release of the stent after withdrawal of the outer sheath.

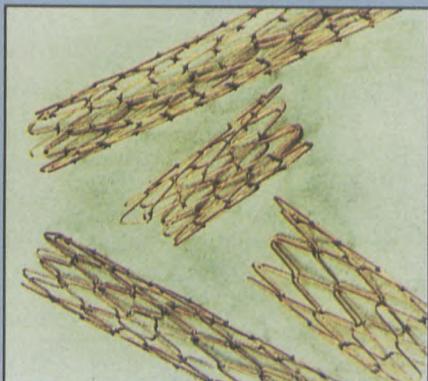


(b) The fully deployed stent. Note flaring of both ends. (Reproduced with permission from Isis Medical Press, Oxford)

Figure 5: The self-expanding nitinol Cragg endoprosthesis.



(a) The partially deployed stent emerging from the introduction sheath.



(b) The fully deployed stent. Note the sutures which hold together the nitinol filaments. (Reproduced with permission from Isis Medical Press, Oxford)

tube of nitinol with slightly flared ends to reduce the risk of migration. It is highly radio-opaque and undergoes minimal shortening. It can be repositioned during deployment as long as no more than 30% of the total length has been deployed, which aids accurate placement.<sup>7,8</sup>

The Cragg stent is constructed of a spiral of back and forth bends of a single nitinol filament held by a suture (Figure 5b). Infusion of cold saline during introduction through the introducer sheath keeps the wire maintained in the soft constrained state and aids placement. A covered stent (the Cragg Endopro) with ultrathin dacron sutured to the nitinol is also available (Figure 6).



Figure 6: The covered Cragg Endopro stent. The self-expanding stent is covered with ultrathin dacron sutured to the nitinol. (Reproduced with permission from Isis Medical Press, Oxford)

### Gianturco Z metallic endoprosthesis

An uncovered Gianturco Z stent is available for biliary, venous and tracheobronchial applications and a polyethylene covered stent is available for oesophageal use. An uncovered endoprosthesis is also available for use in the coronary arteries. The stent is made of stainless steel which is bent into a zigzag and joined at the ends forming a cylinder<sup>9</sup> (Figure 7). This is then compressed and loaded into a catheter. Deployment is by pushing the stent out of the lumen of the catheter into the vessel where re-expansion will occur. The final size and expansibility depend on the diameter of the

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wire and the angle and number of bends in the wire. The initial stents were short and rigid and various developments -

however the final choice is often dependent on personal preference and familiarity with the delivery systems.

## Use of metallic endoprostheses in the vascular system

### The lower limb

Most experience has been gained within the vascular system of insertion of metallic stents in the iliac arteries. Balloon expandable and self expanding stents have long term patency rates of 64-95%.<sup>2,15,16,17</sup> A study including 239 patients showed a 54 month patency rate of 81.5% with a significant difference in patency rates at 4 years between stented stenoses (82.9%) and stented occlusions (76.3%).<sup>18</sup> Both short stenoses and long occlusions have been successfully treated and several studies have shown long term patency rates to be better than percutaneous transluminal angioplasty (PTA) alone. PTA patency rates for aortoiliac lesions at 2 years are approximately 80% and at 5 years 72%.<sup>19</sup> A randomised trial of PTA vs iliac stenting with the Palmaz stent has shown stenting to be superior giving a better morphological response and lower trans-stenotic pressure gradient with fewer technical failures and fewer complications.<sup>20</sup> Stenting has this advantage because of the high resistance of the stent to the collapse of the vessel wall.

In addition the wall of the stent holds any dissection or plaque fracture away from the vessel lumen. Longer occlusions for which PTA is frequently unsuccessful, because of the collapse of thrombogenic material into the opened lumen and subsequent

thrombosis, can be stented with a long term success in approximately 76% of patients<sup>18</sup> (Figure 9a-b). This technique can be ex-

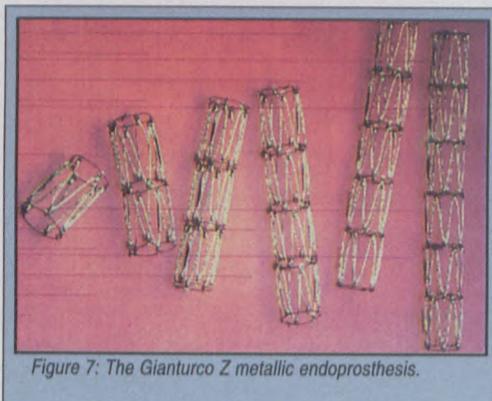


Figure 7: The Gianturco Z metallic endoprosthesis.

double stents for increased flexibility and siliconised stents for reduction of tumour ingrowth - have been made.

### Wallstent self expanding endoprosthesis

This is a self expanding stent with a cylindrical braided structure with variations in design depending on the application. The stent is able to conform to the shape of the vessel, the flexibility being attributed to its design which does not include any cross points (Figure 8). The stent is elongated for delivery on a narrow system and shortens during deployment dependent on the final diameter. This can make accurate placement difficult but it is possible to reposition the stent while it is only partially deployed. There has been rapid development of the Wallstent since 1989 and systems are currently available for vascular,<sup>10</sup> biliary,<sup>11</sup> oesophageal,<sup>12</sup> tracheobronchial<sup>13</sup> and TIPS<sup>14</sup> use, each with differing properties and delivery systems.

The use of these various stents in differing applications will be discussed -



Figure 8: The self expanding stainless steel Wallstent endoprosthesis.



Figure 9: (a) Digital subtraction angiogram performed from the right femoral approach demonstrates occlusion of the left common iliac artery.

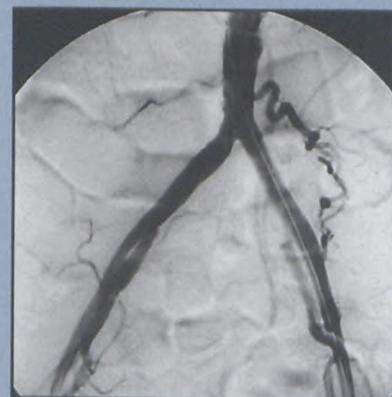


Figure 9 (b): Digital subtraction angiography after placement of a 10mm Wallstent endoprosthesis via a left femoral approach shows excellent flow through the recanalised vessel.

tended to reconstruct the aortic bifurcation in cases of Leriche syndrome (Figure 10a-b). Early occlusion rates are higher in occlusions (5-6%) than in short stenoses (1-2%) and careful anticoagulation post stenting is particularly important here. Local complications of inguinal haematoma and pseudoaneurysm at the puncture site are reported to have an increased incidence when metallic stents are used compared to PTA alone due to the larger size introducer systems. These can be minimised with the

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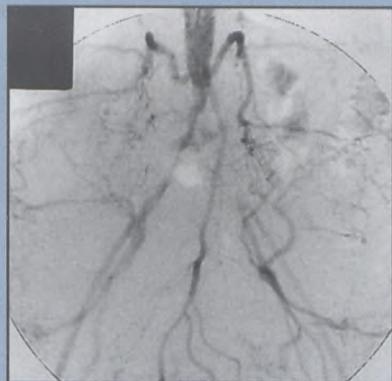


Figure 10 (a): Digital subtraction angiogram via a left brachial approach demonstrates distal aortic and bilateral common iliac occlusions.

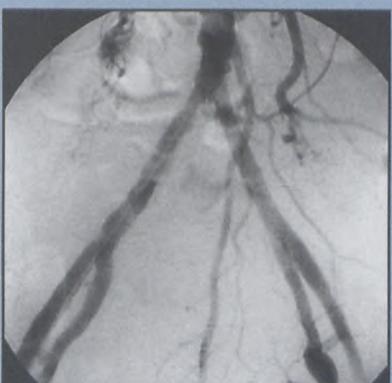


Figure 10 (b): Digital subtraction angiography after insertion of bilateral endoprotheses and reconstruction of the aortic bifurcation via bilateral retrograde common femoral artery punctures.

Wallstent which has a smaller diameter delivery system (7-9F) than the Palmaz stent (8-10F).<sup>2</sup> The FDA trial of the Wallstent included 130 iliac and 91 proximal femoral stents and showed a 96.4% primary angiographic success and a primary success rate of 88-96% with no significant difference between stenoses and occlusions. The 6 month patency rate was 77% with a complication rate of 16%, although the majority were minor complications with only 2.7% requiring surgery.

There is no one specific clinical indication for stenting in the iliac vessels. The clinical situation, technical aspects e.g. site and configuration of the lesion, and the post angioplasty results need to be considered. In our institution we have evolved our own guidelines for stent placement within the iliac vessels (Table I), which includes aneurysmal disease (Figure 11).

Placement of stents in the distal vessels of the leg is generally less successful because of the smaller size of the vessels and the increased turbulence, particularly in the adductor canal. Restenosis rates are 30-40% in trials using the Strecker stent, which is thought to be a consequence of intense endothelial hyperproliferation.<sup>21</sup> We do not routinely use stents below the inguinal

**Table I: Indications for the insertion of metallic stents in the iliac vessels**

Primary stent placement	Secondary stent placement
Occlusions	Initial PTA failure
Dissection/presence of a flap	Initial poor angiographic result
Aneurysm	Late PTA failure at the same site

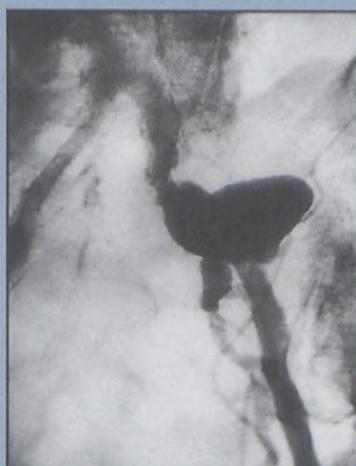


Figure 11 (a): Angiogram via the left common femoral artery demonstrates a left distal common iliac aneurysm.

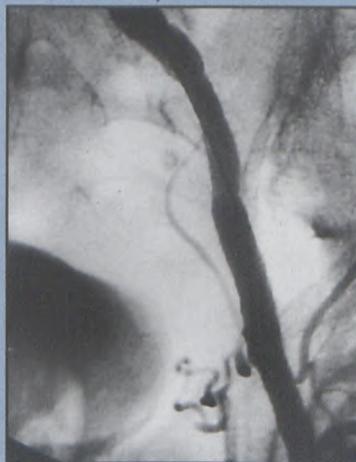


Figure 11 (b): Angiography via a left common femoral approach after placement of a 10mm covered Cragg stent demonstrating excellent distal flow.

ligament except in selected cases. Suggested indications are acute dissection producing occlusion that cannot be controlled by repeated PTA, reocclusion of a vascular segment which has been opened by PTA due to vascular wall deficiency, and exceptionally in cases of persistent restenosis after PTA with expected imminent restenosis.

## Renal arteries

In the renal vessels stents may be used in limited circumstances as restenosis occurs angiographically in 20-39%<sup>22,23</sup> of patients and further surgical management is difficult. Most experience has been with the Palmaz stent although other systems have been used including the Wallstent and the Memotherm stent. Suggested current indications are failure of initial angioplasty with residual stenosis >20%, renal artery dissection post PTA, restenosis after PTA, distal based flaplike plaque, or in patients who are unsuitable for surgical revascularisation. The accurate positioning of the stent is imperative as the stent must not extend into the aortic lumen.

## Coeliac and superior mesenteric arteries

The mortality of acute arterial occlusion in the abdominal visceral arteries (coeliac, superior and inferior mesenteric) is between 70 and 90%<sup>24</sup> and the postoperative mortality 3-20%.<sup>25</sup> PTA of mesenteric vessels has a primary success rate of 90% with redilation required in 50% of cases.<sup>26</sup> Stenting of mesenteric vessels requires a highly flexible stent because of the numerous curves between the puncture site and the site of deployment. Because of this the brachial approach may be easier to negotiate. We have used the Palmaz stent with good radiological and clinical results (Figure 12a-b). In our opinion the only indication for stent placement is failed PTA in a patient who is inoperable or a poor operative risk. This agrees with the limited amount of information in the literature.<sup>27,28</sup>

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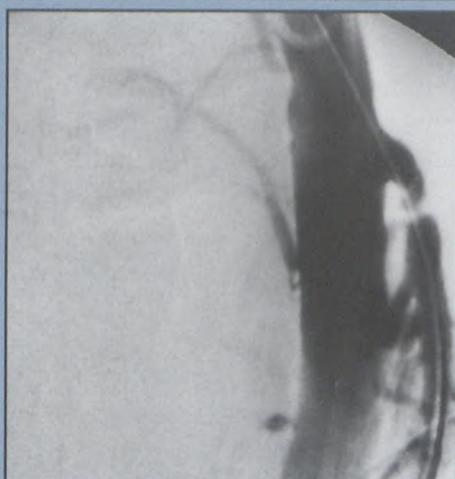


Figure 12 (a): Angiogram via a left brachial approach demonstrates tight occlusion at the origin of the superior mesenteric artery.

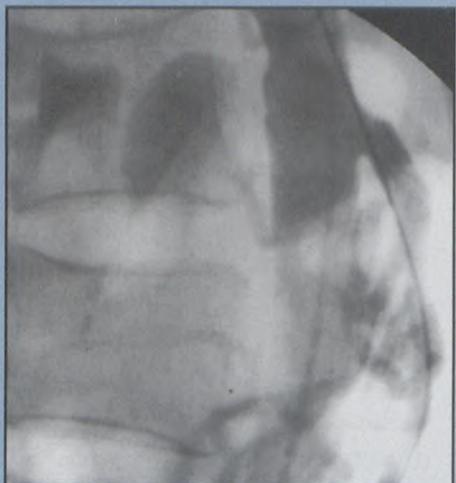


Figure 12 (b): Angiogram after placement of a 9mm Palmaz stent with a good radiological result.

## Supra-aortic arteries

The Wallstent has been successfully used in the supra-aortic vessels both as primary procedure and in restenosis after PTA. PTA is a high risk procedure in these vessels because of the risk of embolisation, particularly for the recanalisation of occluded vessels. In a series of 42 carotid stents<sup>29</sup> 2 patients had transient ischaemic attacks and there were no long term neurological deficits. The rate of recurrent stenoses in these vessels is low, this is probably because of the large vessel size and high flow. The Wallstent is used preferentially in this region because it is flexible and self

expanding so the artery is not occluded at any time during deployment. No migration of the Wallstent is reported; it is thought that the Strecker stent may potentially migrate if the ends are not sufficiently overdilated for anchorage.<sup>30</sup>

## Aorta

The first report of endoluminal stent placement for aortic aneurysm repair was in 1991.<sup>30</sup> Since then stents have been placed successfully in both the thoracic and abdominal descending aorta.<sup>31</sup> Early experience with the tube stent-graft combinations required the aneurysm to be in the descending aorta with well defined necks at both ends, not tortuous, with no sharp angles and with no side branch involvement. However more recently bifurcated stent-graft combinations have become available increasing the number of cases suitable for endoluminal grafting. Both balloon expandable and covered stents have been used, these have been custom made to fit the individual characteristics of each aneurysm. Careful preprocedure imaging in each patient is a prerequisite so that the stent-graft combination conforms to the aneurysm exactly. Leakage at the upper or lower end can prevent sealing of the aneurysm and enable continued expansion. Reported complications include difficulty of delivery of the large introducer system (up to 24 french), stent migration during deployment which can be partially overcome by lowering the systolic blood pressure during release, and relatively minor complications of pleuritic chest pain and pleural effusion.<sup>32</sup> Transient weakness of the lower limbs has also been described.<sup>32</sup>

## Venous stents

PTA for the treatment of venous stenoses has been used with limited success and high rates of restenosis.<sup>33</sup> However venous stenting has proved valuable in malignant disease,<sup>34,35</sup> stenting in benign

disease should only be performed after detailed discussion with clinical colleagues. It is important to distinguish between benign 'benign' disease and benign 'malignant' disease, where life expectancy is short although no strictly malignant disease is present. Self expanding stents (Wallstent, Gianturco) are most commonly used in tumour related stenoses and predilatation is recommended. Relief from obstructive symptoms, for example in superior vena cava obstruction, after stenting occurs within hours. Brachiocephalic stenosis complicating haemodialysis has a high restenosis rate following PTA.<sup>36</sup> Stenting here may give more permanent relief although restenosis in adjacent areas often occurs.<sup>37,38</sup>

## Metal stents in the oesophagus

The use of metal stents in the oesophagus is largely confined to the palliation of malignant disease. Balloon dilatation is generally successful in the treatment of benign strictures in the majority of cases and self expanding metallic stents should only be used with caution and after detailed discussion with clinical colleagues.<sup>39</sup> Self expanding metal stents can be used as first line treatment for inoperable malignant strictures and have distinct advantages over other palliative methods. Radiotherapy may relieve symptoms but may take 8 weeks to be effective.<sup>40,41</sup> Plastic endoprotheses are cheap but require general anaesthesia for placement and usually only allow a liquid diet.<sup>42</sup> Endoscopic laser therapy is safe and effective but needs repeating every 4-8 weeks.<sup>43</sup> The metallic stents commonly used in the oesophagus are the Ultraflex, Gianturco, and Wallstent (Figure 13). All are self expanding, with different expansile radial forces. Balloon dilatation up to 12 mm is advised prior to stent placement and if this is performed the Gianturco and Wallstent usually maintain

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patency of the oesophageal lumen without further intervention. However post placement dilatation is often required with the Ultraflex as its radial expansile force is less. Various diameters and lengths of stent are available to match the pre procedure contrast assessment of the stricture. The release

confined to lesions where the lower end of the stent lies above the cardia. Covered stents are the stent of choice where there is perforation or fistulation (Figure 14a-b). Laser can be used to treat tumour ingrowth which cannot be relieved by passage of an endoscope. A second stent can be placed where tumour overgrows the end of the stent. Manufacturers are currently improving designs to minimise the problems of migration and tumour ingrowth.

Using similar principles stents can be placed to relieve obstruction in the duodenum and proximal small bowel.

## Tracheo-bronchial stenting

Stenting for major airway obstruction in malignant disease in the trachea and bronchi has only become possible recently with the advancement of the development of metallic stents. Clinical assessment prior

mechanisms for the different devices are similar but have a number of important differences. The Ultraflex is compressed by a gelatine coating which dissolves on contact with secretions within the lumen of the oesophagus. The Telestop delivery system of the Wallstent has 3 coaxial shafts the outer of which can be readvanced over the partially released stent to allow repositioning during the procedure. The Gianturco device has a cord which needs to be severed once the stent is in the required position. Technical success using these stents is near 100% and improvement in dysphagia 90-100%.<sup>44,45</sup> Stent related mortality is 0-6%. Oesophageal perforation secondary to the procedure is rare, mortality is more commonly a result of GI haemorrhage or aspiration. Morbidity includes stent migration, tumour ingrowth and overgrowth, and food impaction. Gastro-oesophageal reflux is common especially where the end of the stent lies in the fundus of the stomach. Tumour ingrowth can be minimised by the use of covered stents but the migration rate of these is higher and their use is best

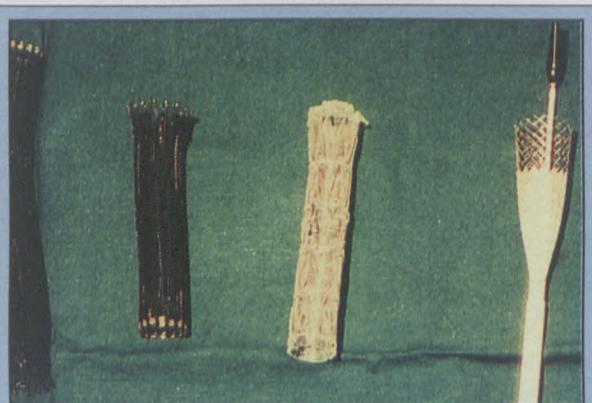


Figure 13: The self expanding metal stents commonly used in the oesophagus include the nitinol Elastalloy stent (left), the polyethylene covered Gianturco stent (centre), and the polyurethane covered Wallstent (right).

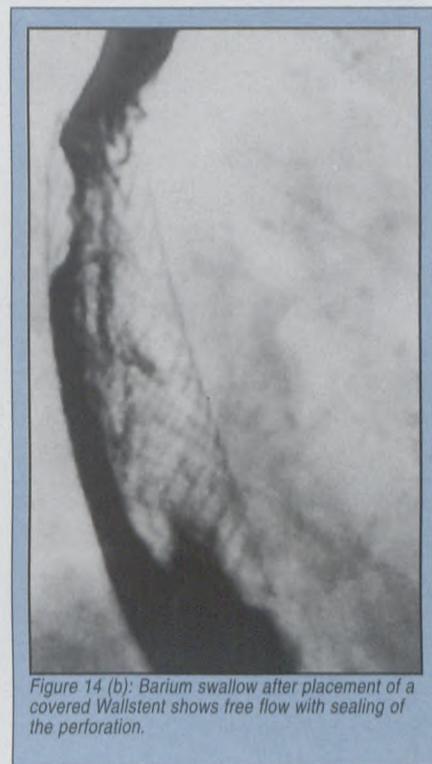


Figure 14 (b): Barium swallow after placement of a covered Wallstent shows free flow with sealing of the perforation.



Figure 14 (a): Barium swallow demonstrating a malignant stricture of the lower one third of the oesophagus which has spontaneously perforated. (Reproduced with permission from Watkinson A and Adam A (eds) (1996) *Interventional Radiology: a practical guide*. Radcliffe Medical Press, Oxford.)

to stenting is vital as recanalisation of the airway may not produce significant improvement in respiratory symptoms if there is distal disease. Silicone stents had been used previously but they can only be deployed in the major airways, tend to migrate and occlude due to mucus impaction.<sup>46</sup> Of the metallic stents available the Gianturco has been used most widely but is not without problems.<sup>47</sup> Distal migration may occur as the stent is pushed out of the sheath and tumour ingrowth may occur in uncovered stents while covered stents cannot not be used across airway bifurcations. Complication rates of up to 30% are recognised and a case of tracheal perforation has been reported.<sup>48</sup> The Wallstent has advantages over the Gianturco in that it is easier to reposition during deployment, migrates less frequently and has less tumour ingrowth while allowing aeration where side branches are crossed.<sup>49</sup> The nitinol stents eg. nitinol Memotherm are also achieving good results presumably because of their great rigidity whilst maintaining flexibility.<sup>50</sup>

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## Metal stents in the biliary system

Percutaneous transhepatic biliary drainage is well established in benign and malignant biliary obstruction<sup>51</sup> and is currently the procedure of choice if endoscopic methods fail. Historically plastic stents have usually been placed. These have the disadvantage of a high migration rate (3-6%) and need frequent replacement.<sup>52,53</sup> These problems may be overcome by the larger diameter of metal stents and the epithelialisation over the mesh preventing migration. Plastic stents occlude in most instances due to bile encrustation<sup>53</sup> whilst occlusion in metallic endoprostheses is secondary to tumour ingrowth or overgrowth. This was significant in early studies,<sup>11</sup> however more recent series, where longer stents have been placed to minimise the problem of overgrowth, have shown much lower occlusion rates (12%).<sup>54,55</sup> The only randomised trial of plastic versus metal stents<sup>53</sup> demonstrated a lower reintervention rate using metal stents (12% vs 43%). Other advantages of metal stents mainly centre around the smaller size of the introducer sheath (7Fr-8Fr vs 12Fr for plastic stents) reducing local complication rates and enabling a one stage procedure to be performed. In our institution we routinely use metallic stents for clinical benefit to the patient in the short term (smaller introducer system, one stage procedure) and the long term (longer patency rates therefore reduced reintervention). In addition the randomised trial<sup>53</sup> demonstrated a financial advantage due to reduced reintervention rate in the long term. A disadvantage of metal stents is that they cannot be removed after epithelialisation has occurred, and their use is therefore restricted to permanent stenting predominantly for the relief of malignant strictures. The role in benign strictures is limited to

strictures that are resistant to repeated balloon dilatation and in whom surgery is inadvisable or unwanted.<sup>56</sup> Most of the current literature refers to the Wallstent, however the nitinol Memotherm stent is being increasingly used (Figure 15a-d).

### TIPS (Transjugular Intrahepatic Portosystemic Shunt)

The development of metal stents has enabled TIPS to become established in the treatment of variceal haemorrhage and portal hypertension (Figure 16).<sup>57,58,59</sup> Contraindications to this procedure



Figure 15 (a): Percutaneous transhepatic cholangiogram demonstrating dilatation of the intrahepatic biliary tree.

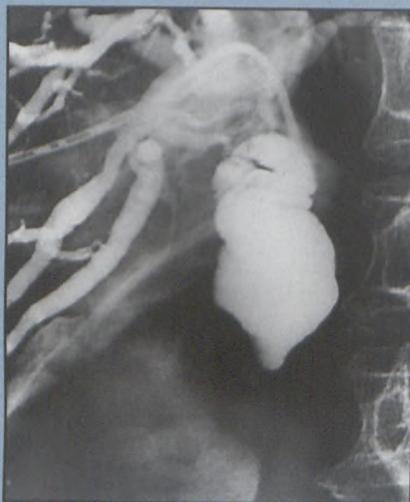


Figure 15 (b): This was confirmed to be due to carcinoma of the head of the pancreas with obstruction at the level of the lower common hepatic duct.



Figure 15 (c): A 10mm Memotherm stent has been introduced percutaneously with a safety catheter left in for 24 hours.

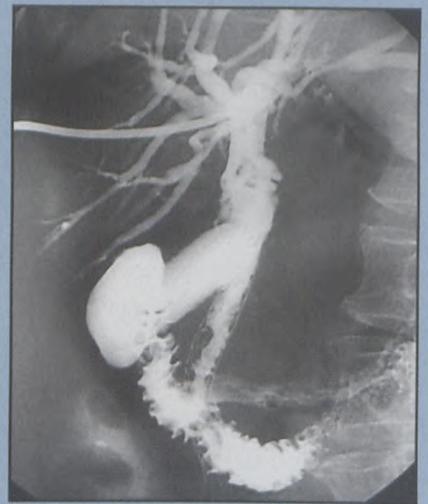


Figure 15 (d): A cholangiogram at 24 hours demonstrates free flow of contrast into the duodenum, through a fully expanded stent. The safety catheter can now be withdrawn.

include raised right heart pressure, sepsis, acute liver failure or extensive malignancy in the proposed transhepatic path. The technique involves dilatation of the intrahepatic tract between the hepatic and portal veins and the placement of an expandable metallic stent. This reduces the pressure gradient between the portal vein and hepatic vein to 10-15 mm Hg which is sufficient to reduce bleeding but not induce encephalopathy. A 10-12mm Wallstent or Memotherm endoprosthesis is the stent of choice. Technical success is 95-100%.<sup>60,61,62</sup> Procedural mortality is 1-10%, usually from capsular rupture.<sup>60,61,62</sup> Shunt malfunction may occur as a late

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Figure 16: TIPS (Transjugular Intrahepatic Portosystemic Shunt) Digital subtraction venography via a catheter introduced from the right internal jugular vein and positioned transhepatically in the portal vein. A 10mm Wallstent endoprosthesis has been positioned to create a shunt between the left portal vein and the right hepatic vein. There is excellent flow through this shunt into the right atrium. Embolisation coils are noted (arrows) following embolisation of the coronary vein. (Reproduced with permission from Watkinson A and Adam A (eds) (1996) *Interventional Radiology: a practical guide*. Radcliffe Medical Press, Oxford.)

complication in 25-40% and is usually due to intimal hyperplasia with reintervention rates rising to 68% at 2 years.<sup>60</sup> Regular surveillance with Doppler and direct catheterisation is necessary.<sup>63</sup> Shunt malfunction can be treated with balloon dilatation or placement of a second stent with good long term results. TIPS is particularly valuable for patients awaiting liver transplant and does not increase the operative difficulty in the short term (3-6 months.)

## Conclusion

Metal stents are now being used for a wide number of clinical applications in many areas. This incorporates restoration of patency in many vessels in the vascular system with good long term patency and palliation of numerous malignant conditions in which a compromised 'lumen' results in poor quality of life in many instances and a shortened life span in others. This is largely due to the advances in stent research and design over the past decades and the availability of a range of different stents for these applications. This has produced an improvement in patency rates

with, in many instances, reduced mortality and morbidity. The future is focussed on further improved stent design. Recent research work has centered on reducing intimal hyperplasia, particularly in the vascular system, using coated stents<sup>64</sup>, exploiting metallic properties to reduce cell growth locally<sup>65</sup> and even the use of local irradiation.<sup>66</sup> We look forward to the continued application of these devices as they become available.

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