

CHAPTER 1

INTRODUCTION

This introduction contains a short description of the issues that initiated this D.Phil dissertation, including a background and historical outline of stents and stent grafts. The aim and scope of the research are outlined, followed by a layout of this dissertation.

1.1 Background of stents and stent grafts

A stent is a type of flexible tubular medical device which is capable of being folded into small dimensions for minimum invasive surgery, and then expanded to open up a blocked organ and also to protect a weakened wall in the human body. There are two types of stents: ordinary stents, made of a wire frame, and stent grafts in which a thin cover attaches to the stent. They are used, for example, in the treatment of such diseases as stenosis, aneurysm or cancer. Compared with traditional methods (e.g. open surgery, radiotherapy or chemotherapy) minimum invasive surgery using stents causes less pain and scarring and reduces recovery time for the patient, as well as providing lower health-care cost (Fischman, et al. 1994; Serruys, et al. 1994).

Figure 1.1 illustrates the stent treatment for a blocked coronary artery caused by arteriosclerosis. Arteriosclerosis is a disease caused by hardening of the arterial walls due to deposits of plaque including lipids, cholesterol crystals and calcium salts, which narrow and reduce the space available for blood flow. Coronary artery disease is the largest killer, responsible for more than one of every five deaths in 2003, according to the American Heart Association.

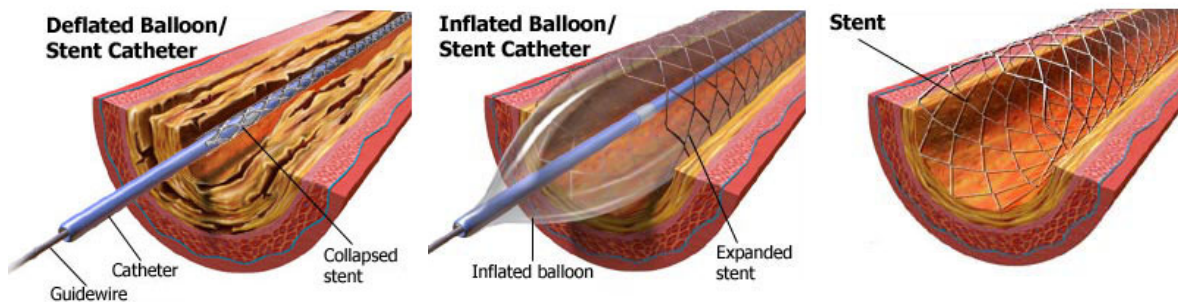


Figure 1.1 Illustration of a stent treatment of a narrowed artery
(source: Heart Center Online).

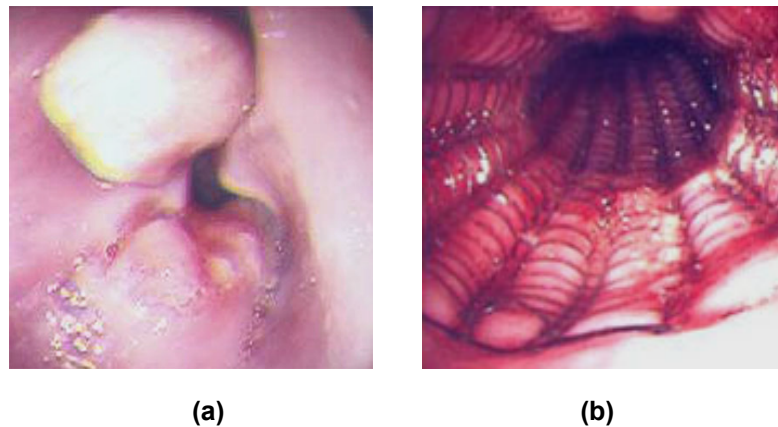


Figure 1.2 Telescopic views of (a) before and (b) after stent treatment of
an oesophagus cancer (source: Livingston).

As shown in Figure 1.1, a stent is made from wire mesh in a tubular profile. It is folded into a catheter so that it can be delivered from a femoral artery with very small incision in the groin to the diseased artery. A balloon initially placed inside the folded stent is then inflated to expand the stent. The balloon and catheter are subsequently removed, while the stent remains permanently in place. The stent is also used for the treatment of cancer (Chung and Qadir 1998; Cowling and Adam 1998; Roseveare, et al. 1998). Figure 1.2 shows photographs of a blocked oesophagus due to cancer before and

after the stent treatment (Livingstone). It can be seen that the passage is dramatically improved.

The term *stent* appeared in the late 19th century, derived from the splint used by British dentist Charles Stent to stabilise skin grafts. More than half a century later, in 1964, Dr. Charles Dotter first tried using polymer tubes in arteries to treat arterial shrinkage, which was followed by later attempts of using wire coils made from stainless steel (Kutryk and Serruys 1999). Before the stent became a routine clinical implantation, a balloon angioplasty was widely performed to open a blocked site in the body (Gruntzig, et al. 1979). However, re-occlusion occurred after removal of the balloon because of the elastic recoil of the artery wall. To overcome the limitation of the balloon, angioplasty stents were developed. The stent techniques have improved dramatically in the last twenty years and are now widely used in various locations throughout the body (Adam, et al. 1997). The success of stent technology is best illustrated by its rapidly expanding market, which approached a total of \$2 billion in 2003 and is expected to reach \$5 billion by 2005 (Smith 2002).

Compared to angioplasty treatment, the ratio of restenosis after insertion of the stent reduces to 15-20% from 33%-50% (Kurnik and Martens 2003). Unfortunately, restenosis is still a problem with the stent as the surrounding tissue grows through the netting and blocks the lumen (Edelman and Rogers 1996; Gottsauner-Wolf, et al. 1996). When this happens, it is not possible to remove the stent. Thus, it is quite normal that additional stents are placed inside the original stent to reopen the blocked lumens.

Stent grafts, consisting of a thin membrane/graft around a wire mesh stent, have been developed as an effective way for preventing restenosis (Hills, et al. 1998; Watson 1998). A typical example is shown in Figure 1.3(a). The stent graft is also used for supporting a weakened wall, such as that occurring during an aortic aneurysm, see Figure 1.3(b).

Figure 1.4 shows x-ray angiograms before and after the implantation of a stent graft (Kawaguchi and Ishimaru 2002). Figure 1.4(a) shows a thoracic aortic aneurysm. Considered high risk for open surgery, the patient was referred for endovascular repair with a stent graft. A complete exclusion of the aneurysm is shown in Figure 1.4(b).

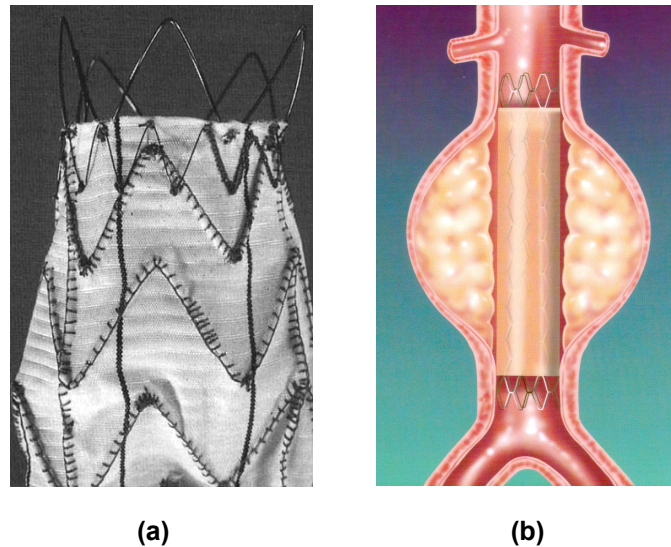


Figure 1.3 (a) A TALENT stent graft made by World Medical (source: Dolmatch, 2000).

(b) Illustration of the stent graft for supporting weakened aorta aneurysm

(source: Adam, 1997).

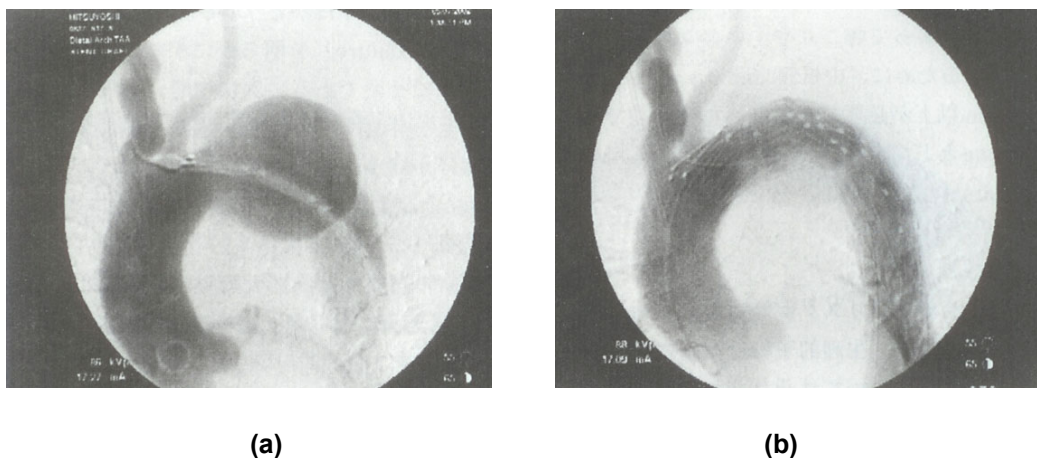


Figure 1.4 Angiograms of a thoracic aortic aneurysm

(a) before and (b) after implantation of stent graft (source: Kawaguchi, 2002).

The first endovascular stent graft repair to an abdominal aortic aneurysms (AAA) was performed by Parodi, Palmz and Barone in 1991 (Parodi, et al. 1991). In the following years the treatment of a thoracic aortic aneurysm (TAA) with the stent graft was first carried out by Dake and Mitchell (Dake, et al. 1994; Mitchell 1997). Approximately 205,000 new patients are diagnosed with aortic aneurysm each year. Presently approximately 100,000 procedures per year are performed worldwide. Compared with the conventional treatment for aortic aneurysm of open surgery which carries significant health risks for many older patients, the stent graft repair procedure is much superior, so that it is expected to expand from about 40% of the total patients treated in 2002 to 67% in 2007¹. To overcome the complications of the stent grafts and to achieve this expected market expansion, the stent graft designs, delivery and expansion devices, surgical monitoring devices, and stent graft procedures need to be improved. An important aspect is the improvement of the stent graft structural design, as described below.

As shown in Figure 1.3, the typical stent grafts currently in use consist of two pieces: an expandable wire mesh stent and a soft covering membrane. The membrane is either attached to the stent at proximal and distal ends only, or it is stitched more securely on the outside or inside of the wire stent at discrete points to avoid geometric incompatibility between the stent and its cover. Therefore, it is common that uneven distribution of stress or entanglement on the cover material occur due to both the deployment and to the plastic motions in the aorta after insertion. These stress on the cover result in stent graft fatigue (Chuter 2002; Drake 2003).

Figure 1.5 shows various forms of stent graft fatigue including metallic fractures, fabric ruptures and suture breakages. These failures cause endoleaks (persistent flow into the aneurysm through the stent graft), aneurysm ruptures and death (Jacobs, et al. 2003; Jacobs, et al. 2003).

¹ AAA Stent Grafts, Still Under Scrutiny, “*Medtech Insight*” Aug. 2003

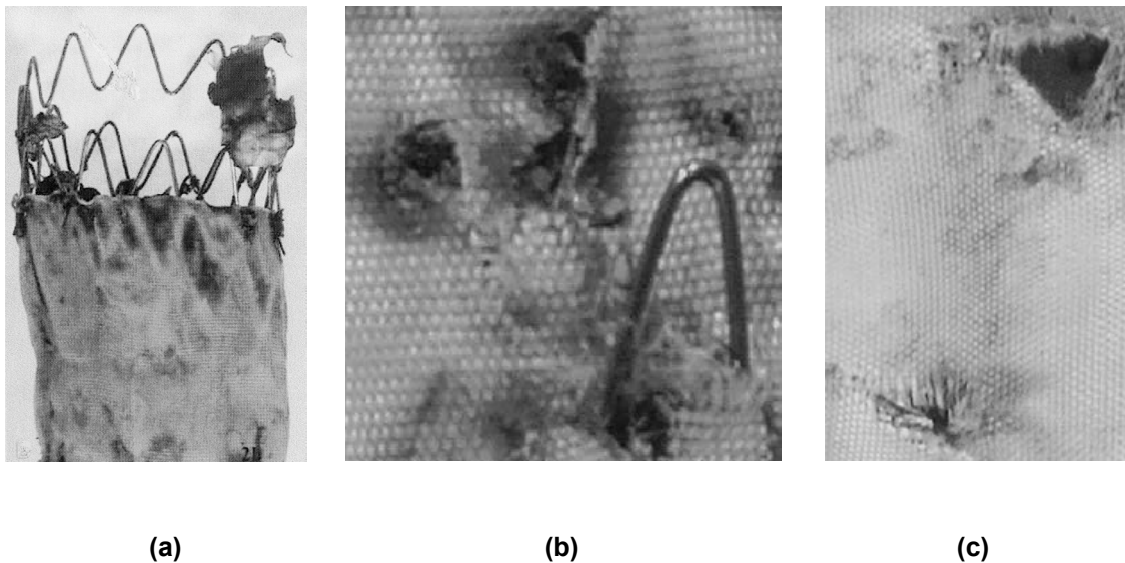


Figure 1.5 Clinical examples of fatigue in Boston Scientific Vanguard endovascular graft. (a) and (b) Structure disruption and (c) fabric fatigue and wear holes on prosthesis surface (source: Jacobs, 2003a,b).

Migration of the stent grafts due to inadequate fixation or as a result of material fatigue is also a problem of AAA and TAA stent grafts (Drake 2003). Furthermore, the complicated design of the stent grafts, such as the stitching of the membrane over the stent (Figure 1.3b), leads to high manufacture costs. Hence some doctors make stent grafts by themselves, which leads to an inconsistency in their quality and reliability (Matsumoto 1999).

1.2 Aim and scope

The aim of the work described in this dissertation is to improve the structural design of stent grafts by developing a new type of a single piece stent graft. The new stent graft has an integrated cover with much simpler geometry and no compatibility problem between wire stent and cover. The expanding mechanism of wire mesh and cover will

be considered together. In addition, it has a more reliable expanding performance and lower manufacture cost than the currently available two-piece stent grafts.

A current trend in stent and stent graft research is to develop a drug-eluting stent to prevent restenosis for cardiovascular stents, and to grow tissues so that biological anchors can be produced at the aortic wall (Hiatt, et al. 2001; Schwertz and Vaitkus 2003; Wey, et al. 2003). There have been very few investigations of the structural aspects of the stents or stent grafts. The research work presented in this dissertation will focus on the structural aspects of the improved stent graft.

The project includes the geometrical conceptual design of the stent graft, and the analysis and manufacture of a novel stent graft for oesophageal and aortal diseases. The stent grafts presented in this dissertation are named *origami stent grafts* due to the fact that paper folding patterns used in the Japanese art of origami are employed to produce the tubular stent grafts.

1.3 Layout of dissertation

This dissertation consists of two major topics: design and analysis of the origami stent graft, and its manufacture.

A brief overview of previous work is given in Chapter 2. Design characteristics of existing stents and stent grafts, stenting techniques, and the engineering aspects of stents are reviewed. The possibilities of applying principals of foldable structures and origami paper folding techniques are discussed. An overview of materials, such as stainless steel and shape memory alloy which are used in existing stents, is also given.

Chapters 3, 4 and 5 address the first theme of this dissertation: the design and analysis of the origami stent graft. In Chapter 3, families of folding patterns for a foldable cylindrical tube are presented. Key dimensions such as radius and length of the origami stent grafts are examined in detail. To understand the deployment process, the

fold-shortening during deployment is calculated, which is useful to determine the optimum design for the stent graft.

In Chapter 4, a foldable cylindrical tube with helical lines as part of the folding patterns in order to increase radial stiffness is introduced. The geometric properties of the tube such as helical angle, radius and deformation are defined and analysed. Moreover the buckling pattern of a folded thin-walled tube under torsion, which consists of a set of folds, is considered to optimise the locations of the folds for the origami stent graft with helical lines.

In Chapter 5, using numerical analysis of the finite element method (FEM), strain and deformation of the folds in the stent graft in its folded configuration is calculated. The deformed shape of a thin cylindrical tube without any folds is also identified and is compared with the pattern of folds for the origami stent graft.

The second theme of the dissertation is contained in Chapter 6: manufacture of the origami stent graft. The stent graft is manufactured using stainless steel sheets and two types of Titanium/Nickel (TiNi) shape memory alloy (SMA) sheets. The patterns of folds on stainless steel sheet are produced by photochemical etching. Processing techniques, such as photochemical etching and heat-treatment of SMA sheets are investigated. The self-expansion of the origami stent grafts with SMA by heat is also explored.

Chapter 7 contains conclusions and discusses future requirements.

CHAPTER 2

REVIEW OF PREVIOUS WORK

This chapter reviews three main topics. Firstly details of designs and characteristics of existing stents and stent grafts are presented and the engineering aspects of stent research are summarised. Secondly principles of foldable structures and mathematical aspects of origami paper folding are presented and the possibility of their applications to stent graft design are discussed. Thirdly an overview of stainless steel and shape memory alloy, which are used in the manufacture of existing stents and stent grafts, is given.

2.1 Design characteristics of stents and stent grafts

Stents and stent grafts are classified into three categories according to the anatomical location in which they are used: (i) coronary (blood vessels that supply the heart), (ii) peripheral (any other blood vessel), and (iii) non-vascular (parts of the digestive tract).

In structural terms, currently available stents can be classified as coil, mesh and slotted tubular stents (see Figure 2.1). Coil stents consist of zig-zag wires, mesh stents are made by netting metric wires, and slotted tubular stents are made of laser cut tubes. All of these are made mainly of two types of alloys: stainless steel and shape memory alloy (nickel and titanium alloy). The thickness of the struts is between 50 and 140 μm . A biodegradable poly-*l*-lactic acid (PLLA) stent has also been developed (Labinaz, et al. 1995; Tamai, et al. 2000). Unlike metallic stents which remain in the body permanently and may be obstacles to additional treatments (e.g., repeat angioplasty and bypass surgery), temporary biodegradable stents may be an ideal alternative to metallic stents in terms of compliance and tissue responses. Key features of these stents include high

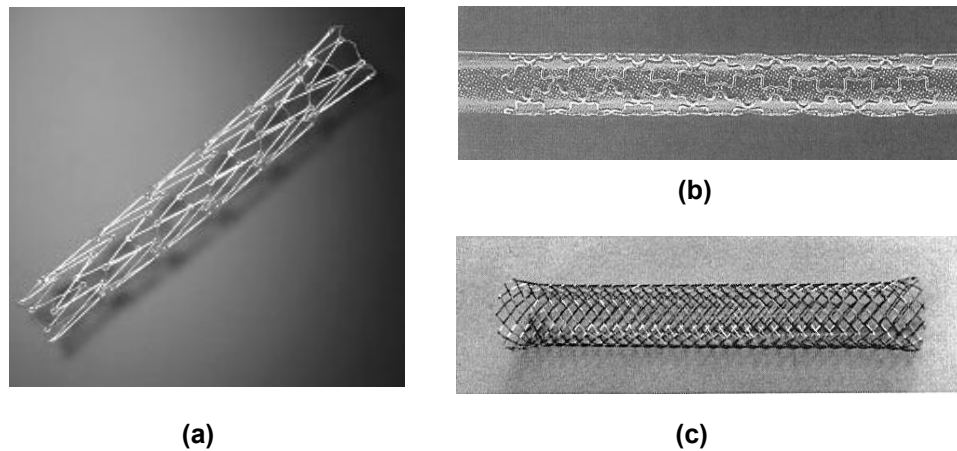


Figure 2.1 Existing stents. (a) Coil stent (Spiral Z, Cook); (b) slotted tubular stent (Palmaz-Schatz, Cardis/J&J) and (c) mesh stent (Wallstent, Boston Scientific).

expansion rate, high strength, good flexibility and good tractability (Flueckiger, et al. 1994; Phillips, et al. 1998; Kutryk and Serruys 1999; Dyet, et al. 2000).

A stent graft, also known as a covered stent, is composed of one of the above-mentioned stents with an attached synthetic material cover. Table 2.1 lists abdominal aortic aneurysm (AAA) stent grafts. Some of the stent grafts have a tubular shape, see Figure 2.2(a), while others are branched, see Figure 2.2(b).

The ideal material of the stent graft is flexible and thin, which provides for the capability of the stent being folded into small dimensions for minimum invasive surgery, and a high level of stiffness to avoid material damage. The most common covers for stent grafts include a thin knitted membrane of PTFE (poly-tetra-fluoro-ethylene) and woven polyester of Dacron, which have been widely used as artificial grafts in blood vessels. Their thickness is between 0.1 and 0.3 mm.

The most important parameters of the stents and stent grafts are the diameters and lengths in fully folded and expanded configurations. Normally, the stent or stent graft whose diameter is 10-20% larger than the vessel diameter is used so that they can anchor to the vessel wall when expanded. The dimensions of stents and stent grafts for cardiovascular use are around 4-6 mm in diameter and 10-40 mm in length in their fully expanded configuration. They are folded into a catheter of 2-3 mm (6-7 Fr.). The dimensions of stents and stent grafts for aorta or oesophagus are 10-40 mm in diameter and 30-60 mm in length when fully expanded. They are compressed into a catheter of 7-8 mm (18-24 Fr.) (Esato, et al. 1999). Examples of the expansion diameter of the AAA stent grafts and the size of the catheter are shown in Table 2.1.

There are two methods of expansion in use. The first involves a stent being gradually deformed under the influence of a cylindrical balloon inflated from the inside with a deployment pressure of 709-1216 kPa (7-12 atm). Figure 2.3(a) shows photographs taken during the expansion of a stent using this balloon technique. Once the stent is expanded, the balloon is deflated and withdrawn. The other method is self-expansion as shown in Figure 2.3(b). The self-expanding stents and stent grafts are normally made from shape memory alloys. The stent is packed like a compressed spring inside a sheath so that it can be passed through a narrow space. Once it reaches the intended site, the sheath is withdrawn gradually and the stent expands freely to resume its natural enlarged shape. The advantage of the self-expanding stent is that extra expanding tools (e.g., a balloon and air pump) are not required and also, accidents, such as the stent expanding more than the diameter of the lumen due to the high-pressure inflation of the balloon, can be avoided.

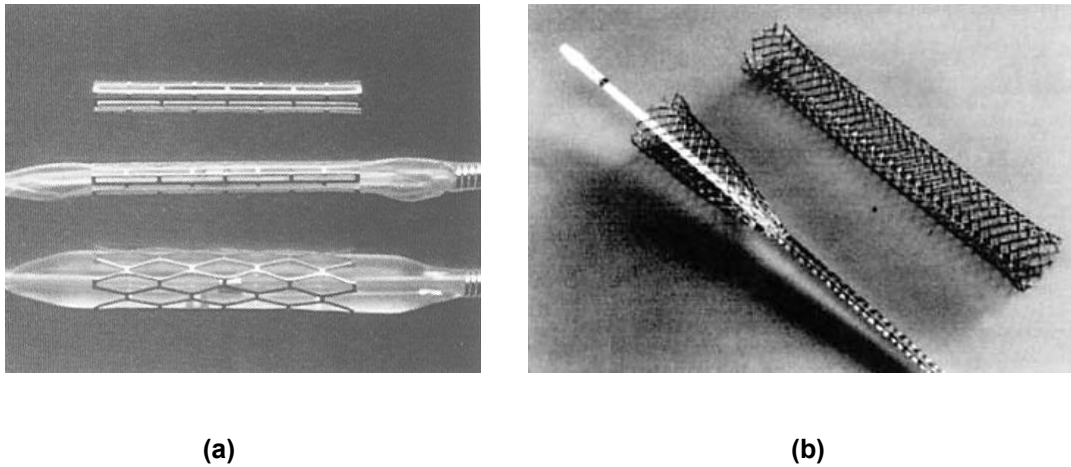


Figure 2.3 (a) Deployment sequence of a stent deployed by an inner balloon and (b) a self-expanding stent (source: Kurnik, 1999).

2.2 Engineering research of stents

Most articles published in engineering journals deal mainly with mechanical properties of stents. Experimental studies of the stent have been reported widely. The first study on the deformation characteristics of self-expanding metallic stents was given in 1988 (Fallone, et al. 1988). Agrawal also showed the deformation characteristics of polymeric stents fabricated from poly-*l*-lactic acid (Agrawal and Clark 1992). In these works, the effects of stent diameter and wire caliber were discussed. Schrader discovered that some stents show superior strength to others due to differences in strut diameter, design and metal properties (Schrader and Beyar 1998). Because an increase in the strut diameter not only provides higher stiffness but also reduces the longitudinal flexibility, he suggested that no more than an adequate mechanical support should be considered when designing or selecting stents. Mechanical tests also showed that slotted tubular stents have a greater radial strength to withstand higher external pressures than coil stents (Rieu, et al. 1999).

Mechanical properties of the stents have also been analysed numerically using finite element method (FEM) to understand stent expansion mechanisms, recoil and

structural failure of balloon-expandable stents (Dumoulin and Cochelin 2000; Etave, et al. 2001; Migliavacca, et al. 2002).

Mechanical action of the artery wall after implantation of the stent has also been investigated. A report by Rogers showed that restenosis was due to the damage of cells during the deployment of the stent because of forces imposed on the luminal surface (Rogers and Edelman 1995) The effect of the number of stent struts on tissue in-growth was studied by using mathematical models and clinical tests (Garasic, et al. 2000). 2D FE analysis of balloon-artery interactions during stent placement was presented by Rogers, et al. (1999). 3D FE analysis of the stent-artery interaction during stent deployment was examined by Auricchio, et al. (2000). Stress distribution and the degree of tissue prolapse (i.e. narrowing of the lumen as a result of elastic deformation of the vessel wall) within stented vessels were determined using FEM (Prendergast, et al. 2003).

In vitro tests before animal test are also important to verify stent designs. Expansion force, flexibility, compressibility and stability of stainless steel wire stents were measured by Maeda, et al. (1992). Experimental studies of oesophageal covered stents for preventing migration were carried out using clay to simulate stenosis (Makutani, et al. 2000). The effect of blood flow for the expansion of the stent graft was examined by Kawaguchi and Ishimaru (2002).

2.3 Foldable structures and their applications to stent graft design

Foldable structures are structures that can be folded compactly for delivery and be expanded when necessary. Well-known examples include tents and umbrellas. There are also foldable structures in nature, for instance, a leaf is folded as a bud and expanded when it grows (Kobayashi, et al. 1998). In recent years, there has been an explosion in foldable structure technologies, particularly in the aeronautical fields, where devices such as solar arrays and antennas must be packed into small bundles for

transport, and then expand to become useable. (Miura 1993; You and Pellegrino 1997). Depending on their mechanical behaviour, foldable structures can be classified into two types: mechanisms and deformable structures. Mechanisms do not induce any deformation in the structural components, e.g., a pair of scissors. Deformable structures, on the other hand, are those whose deployment involves deformation of the structure; e.g., balloons and springs.

Two foldable structures most relevant to the design of an expandable stent graft are shown in Figure 2.4. The structure in Figure 2.4(a) is a well-known spatial mechanism forming structure, the deployable hyperbola (Hilbert and Cohn-Vossen 1952). The diameter of this structure decreases when expanded in a longitudinal direction. The problem for applying the concept to stent graft design is that the struts are connected by universal joints, which may significantly increase the complexity of the deployment and cost of manufacture, particularly in small dimensions.

The structure in Figure 2.4(b) is a deformable structure based on the buckling pattern of a thin-walled tube. The buckling process can be reversed if the buckling folds in the collapsed tube are replaced by foldable hinge lines (Guest 1994a). This foldable structure can be folded by shortening the overall length as shown in Figure 2.5. However, the diameter of the structure does not alter very much during expansion, making it unsuitable for use as a stent graft because one of the crucial requirements for a stent graft is that its folding reduces its diameter. Nevertheless, this design indicates that it is possible to produce a collapsible and expandable cylinder using a simple folding pattern rather than a system of complex joints. Jointless structures such as these usually have the simplest structural forms, and are therefore extremely useful for small structures such as the stent grafts.

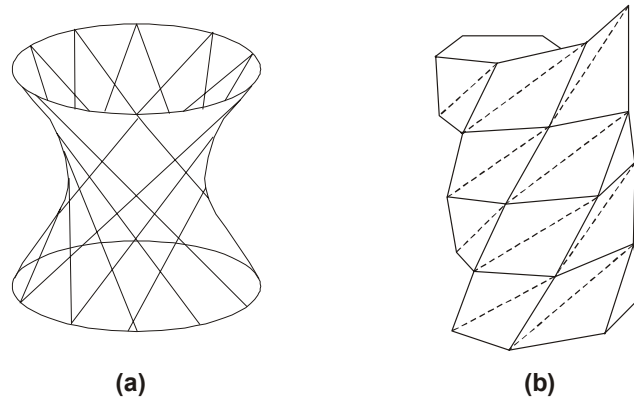


Figure 2.4 Two existing concepts for deployable cylinders: (a) a hyperbola made of straight struts and (b) a collapsible cylindrical tube.

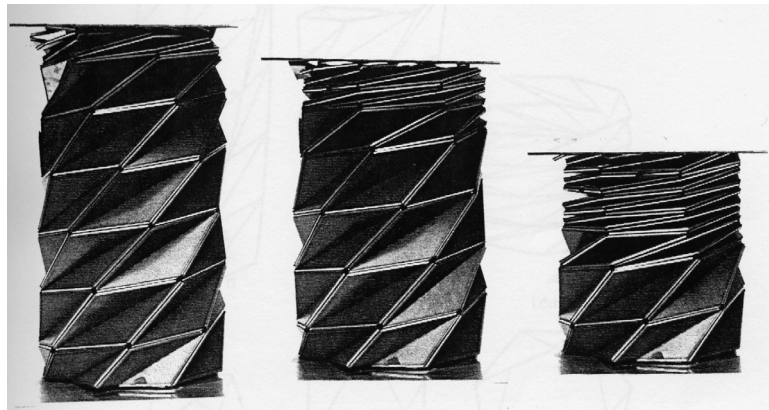


Figure 2.5 Folding sequence of the collapsible cylindrical tube (source: Guest, 1994a).

2.4 Principles of origami

The foldable tube reviewed in the previous section indicates that tubular structures can be folded simply by introducing folds. It is worthwhile to examine the basic mathematics behind origami paper folding methods, as stent grafts are also made from thin membranes.

Origami is an ancient Japanese art. It employs two types of straight folds: namely hill and valley. Most literature gives conditions to enable a sheet to be folded up completely, i.e., it is required that there should be no voids in the package (Fushimi 1980; Miura 1993; Kawasaki 1998; Nojima 1999). These conditions are illustrated in Figure 2.6, and are described in the following section.

In Figure 2.6, assuming n_v valley folds and n_h hill folds meet at node O, the total number of folds, n_t , is defined as:

$$n_t = n_h + n_v \quad (2.1)$$

When the sheet is partially folded, the sheet behaves as that shown in Figure 2.6(b). The shape of the folded sheet is a polygon as shown in its sectional view of the line between nodes A and B in Figure 2.6(c). The sum of interior angles of the polygon is $(n_t - 2) \times 180^\circ$. Each of the interior angles varies during folding, and when the sheet is folded completely the angles of valley and hill folds become either 360° or 0° , respectively. That is:

$$(n_t - 2) \times 180^\circ = n_v \times 360^\circ \quad (2.2)$$

Consequently, substituting Equation (2.1) to Equation (2.2) gives

$$|n_h - n_v| = 2 \quad (2.3)$$

Thus,

$$n_t = 2(1 + n_v) \quad (2.4)$$

Therefore, it is found that 2 is the minimum number of the folds required to fold a sheet, whenever different folds meet at a common point there should be at least 4 folds, and the total number of the folds is always an even number.

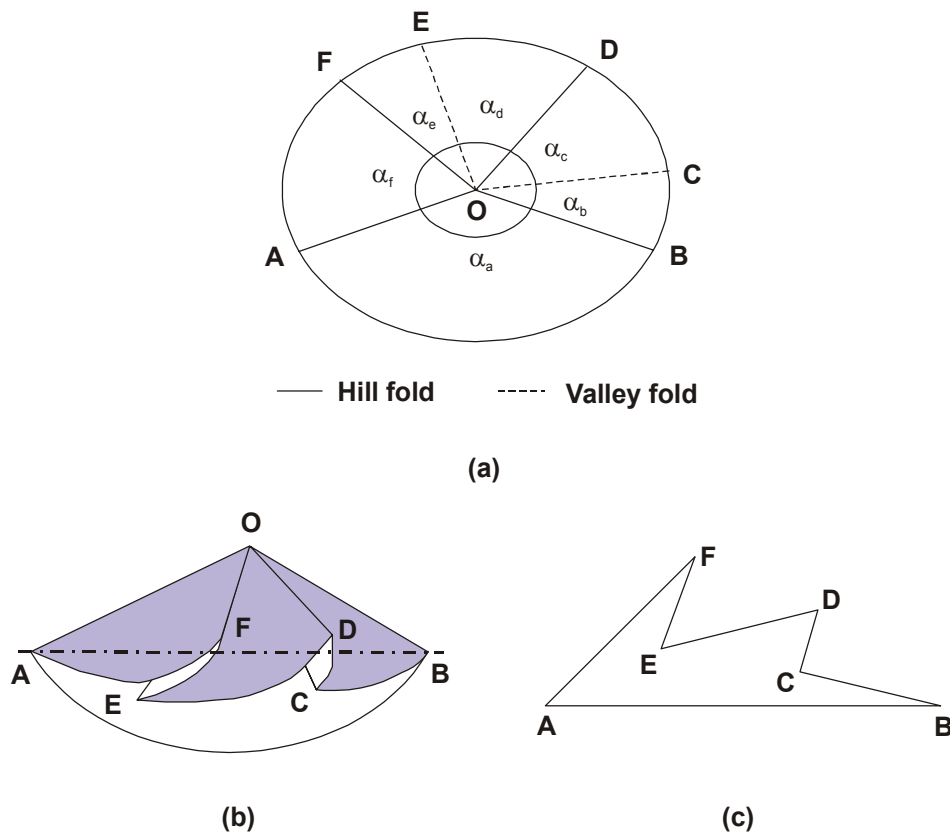


Figure 2.6 Sheet with folds when it is (a) completely open and (b) partially folded. (c) A schematic diagram of the section of folds.

For the folding pattern given in Figure 2.6(a) the sums of the alternating centre angles must be

$$\alpha_a + \alpha_c + \alpha_e = \alpha_b + \alpha_d + \alpha_f = 180^\circ \tag{2.5}$$

This can be proven easily by examining the completely folded configuration of the sheet. In origami, this condition is known as Fushimi's theorem.

Figure 2.7 shows an example of the foldable sheet with one node and four folds. The solid lines 1, 2 and 3 and the broken line 4 represent hill and valley folds, respectively. Due to Equation (2.5), we have:

$$180^\circ - \alpha + \gamma = 180^\circ - \beta + \beta - \gamma + \alpha \tag{2.6}$$

Consequently,

$$\alpha = \gamma \tag{2.7}$$

Similarly, in the case of the folding sheet with one node and six folds shown in Figure 2.8, there is

$$\beta - \alpha = \delta - \gamma + \theta \tag{2.8}$$

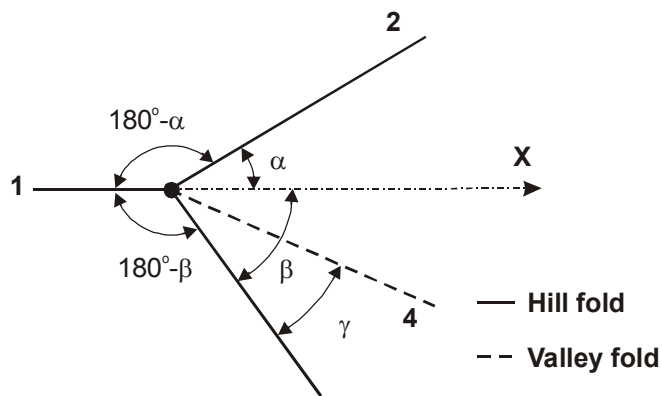


Figure 2.7 Angles among four folds meeting at one node.

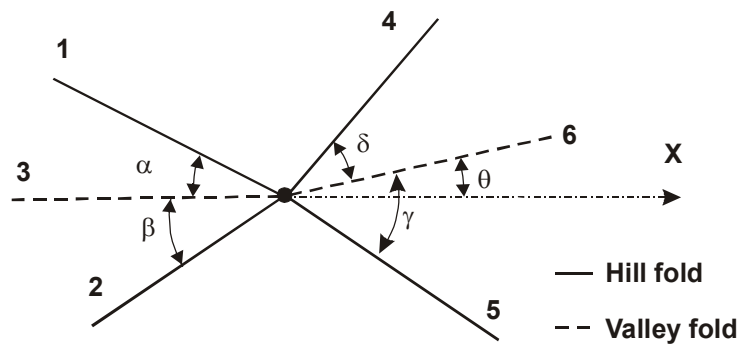


Figure 2.8 Angles among six folds meeting at one node.

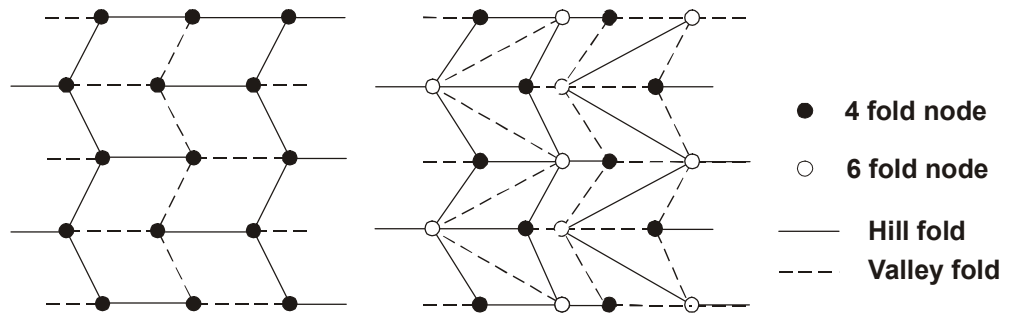


Figure 2.9 (a) The Miura-ori and (b) its more complex variation.

The fundamental relationships for folding a sheet can be applied to generate compact folding. A pattern, in Figures 2.9(a) known as the *Miura-ori*, has been applied to the design of foldable maps as well as solar antennas, which can be folded compactly and expanded easily and effectively (Miura, et al. 1980; Miura 1993). Figure 2.9(b) is a more complex variation of the *Miura-ori* with one node and four or six folds (Nojima 1999). A number of researchers have explored folding patterns for wrapping membranes in a similar manner (Guest and Pellegrino 1992; You 1994).

Using these fundamental conditions of origami, it is possible to design a foldable cylindrical tube. The angles of the folding pattern for the foldable cylinder were investigated by Nojima (1999). Figure 2.10(a) shows a strip/ribbon on which the angles between the folding line i ($i = 1, 2, 3 \dots$) with respect to the horizontal are defined as θ_i ($i = 1, 2, 3 \dots$) where $0 \leq \theta \leq 90^\circ$. The strip changes its direction through the folding process (Figure 2.10b). The directions of the strip with respect to the horizontal after the folding are defined as $X_1, X_2, X_3 \dots$. The angle of the direction X_1 after the first time folding is $\Theta_1 = 2\theta_1$, and the angles of the direction X_2 or X_3 after 2 or 3 times folding become $\Theta_2 = 2(\theta_1 - \theta_2)$ and $\Theta_3 = 2(\theta_1 - \theta_2 + \theta_3)$, respectively. The direction of the strip with respect to the horizontal after i times of folding is given by,

$$\Theta_i = 2 \sum_{j=1}^i (-1)^{j+1} \theta_j \quad (2.9)$$

where Θ_i is always an even number.

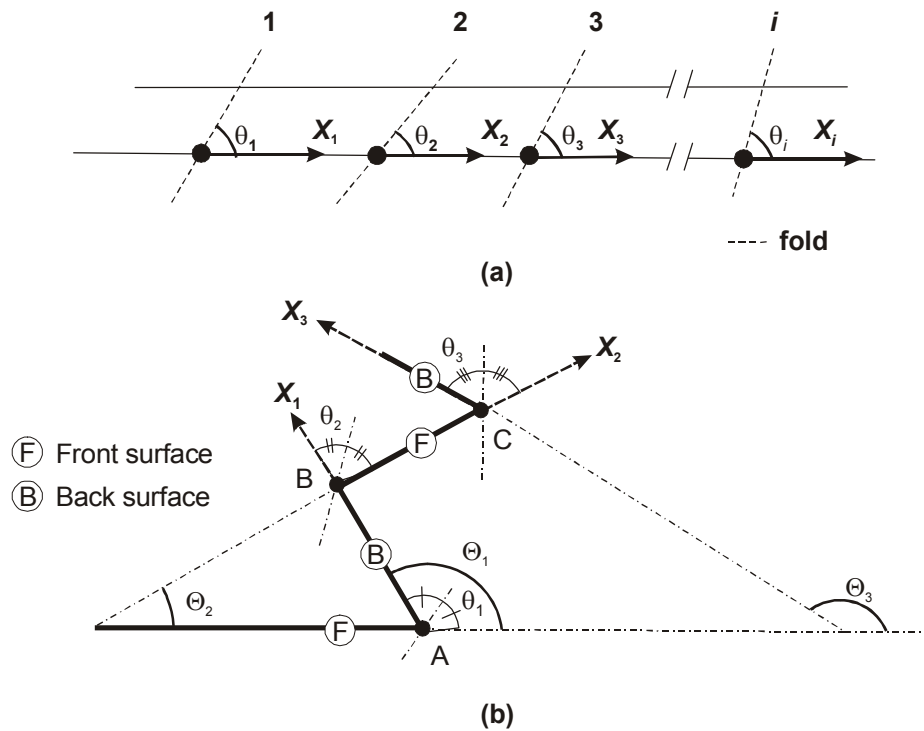


Figure 2.10 (a) Folds along a strip. (b) The change direction of the strip through the folding process.

Figure 2.11 shows an example of the deployment of a foldable cylinder when the angle α is assumed 30° and $i = 6$. From Equation (2.9), in order to joint both ends without mismatch and to make a cylindrical shape the angle Θ_i has to be 360° thus β is calculated as 150° . The opposite edges of the sheet, A-A are jointed together to form a cylindrical tube. A number of similar foldable cylindrical tubes have been explored (Guest and Pellegrino 1994b; Sogame 1998; Nojima 1999). A photograph of one of the examples has been shown already in Figure 2.5. As mentioned, the tube can be folded in a mainly longitudinal direction. However, a foldable cylindrical tube which can be folded radially to reduce the diameter during delivery to the human body, is of interest to a stent design, and is the main focus of this dissertation.

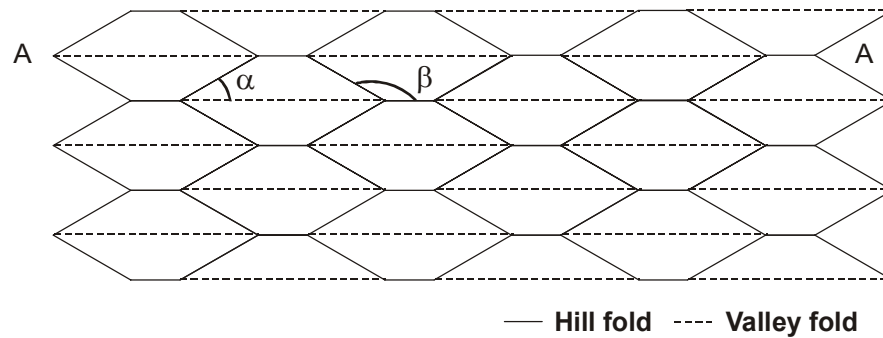


Figure 2.11 A diagram of a foldable cylindrical tube with 4 folding lines for each node in its unfolded state.

2.5 Materials

2.5.1 Stainless steel

Stainless steel has been used to make a stent as it is easy to fabricate and significantly cheaper than alternatives such as shape memory alloy. Among the hundreds of types of the stainless steels, 316L which consists of an austenitic steel, an alloy primarily of iron, chromium, and nickel with extra low carbon has better corrosion resistance compared with other types of stainless steel, and is thus ideal for medical application. It is most widely used for current stents and stent grafts.

2.5.2 Shape memory alloy (SMA)

SMA is also used in existing stents and stent grafts. SMA is a material which is able to remember shapes. This unique phenomenon was discovered in an alloy of copper and zinc in 1938 by A. B. Greninger and V. G. Mooradian. Later research revealed shape memory effects in other alloys as diverse as gold-cadmium, iron-platinum, iron-nickel and stainless steels. The phenomenon received worldwide attention in the 1960s when TiNi SMA, an alloy of titanium and nickel, was produced by W. J. Buehler (Buehler 1963).

In general, the shape memory effect (SME) of SMA can be triggered either thermally or mechanically. Figure 2.12 shows the stress-strain curve of one-way SMA, which is triggered by thermal action. The alloy is deformed with up to 8% of strain at an ambient temperature, which is more than 10 times larger than the yield strain of the conventional stainless steel as shown in Figure 2.12, and does not return to its original shape when the load is released. However, the alloy can completely recover its original shape when raised to a higher temperature.

Usually the SME involves two different crystal phases at the microstructural level; one stable phase at high temperature, the austenite phase (or the parent phase), and the other lower temperature phase, the martensite phase. The austenite phase usually has a cubic structure, represented by a square in Figure 2.13. The martensite structure is obtained by shearing deformation of the austenite. This is accomplished by the relative displacement of the atoms without breaking the bonding between them, and is called the martensitic transformation. Depending on the shear direction, martensite with two different orientations can form, referred to as variants or martensitic twins.

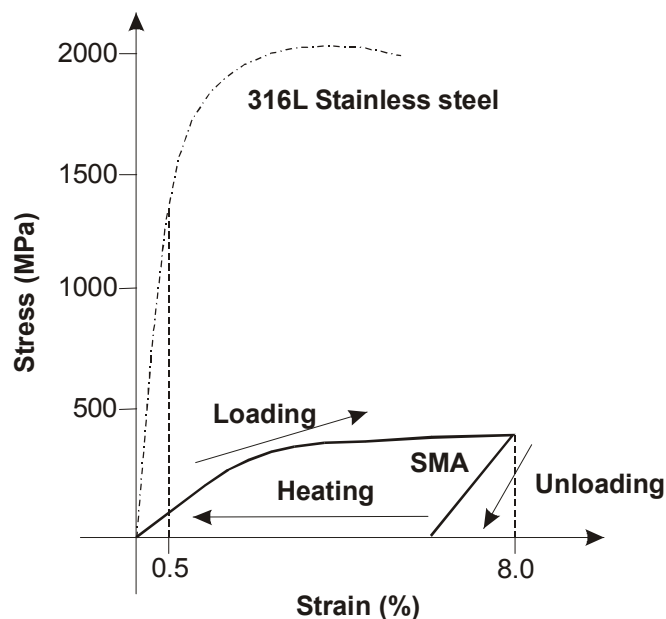


Figure 2.12 Illustration of stress-strain curves of SMA.

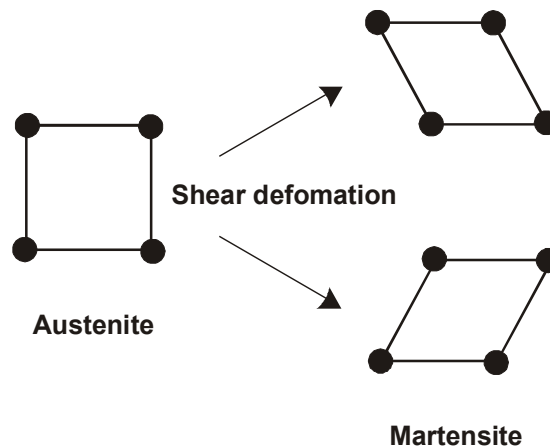


Figure 2.13 Illustrations of crystal phases of SMA.

Figure 2.14 shows the schematic diagrams of the crystal structures in the one-way SMA. It also shows the illustration of an example of a specimen with one-way SME. In this case, the specimen remembers the straight shape. When the austenite phase of the SMA is cooled to a lower temperature, a self-accommodating arrangement of the martensite variant forms (Figure 2.14a), which is composed of alternative layers of variants with opposite shear directions. The boundaries between these variants are highly mobile. Thus the material deforms easily under external forces, resulting in the specimen being bent and the martensite becomes non self-accommodating arrangement (Figure 2.14b). On reheating, the crystal structures start to change and the shape recovery begins (Figure 2.14c) and eventually become the single austenite phase (Figure 2.14d). At that time, the specimen is back to its original shape. Once the shape has recovered, there is no change in shape when the bar is cooled, though the material goes back to the self-accommodating martensite shown in Figure 2.14(a).

By repeating this one-way effect, the material can also be ‘trained’ to exhibit a ‘two-way’ memory. It remembers two configurations, for example, it may remember the straight and semi-circular shapes of the bar shown in Figures 2.14(a) and (c), and changes its shape between the two states on cooling and heating, respectively.

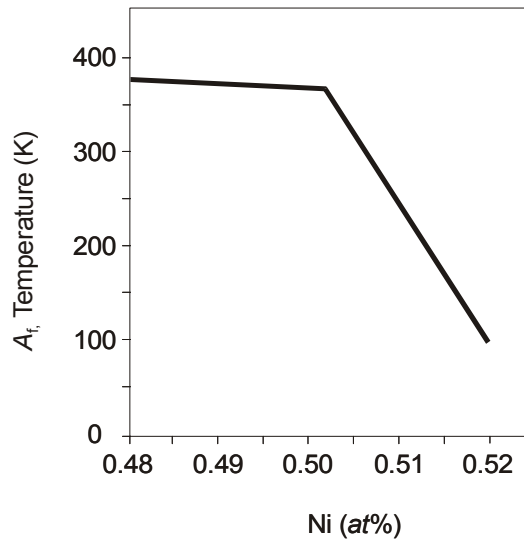


Figure 2.15 A_f vs. ratio of Ni in TiNi SMA.

It is also possible to trigger the SME of SMA mechanically due to the property of *superelasticity*. This occurs when SMA is used at a higher temperature than A_f . Figure 2.16 shows the stress-strain curve of the superelastic behavior in SMA. The deformation disappears and the alloy restores its original shape, not on the application of heat, but on a reduction of stress. As shown in Figure 2.17, during this process the austenite phase is changed to the martensite phase by the external force. Most self-expandable stents make use of superelasticity rather than temperature-induced shape alternation.

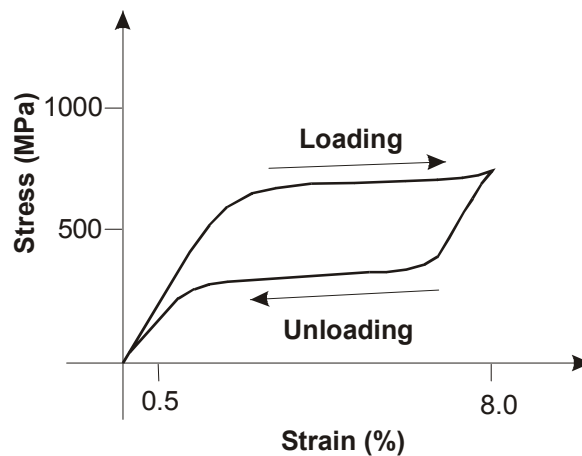


Figure 2.16 Illustrations of stress-strain curves of a superelastic behavior in SMA.

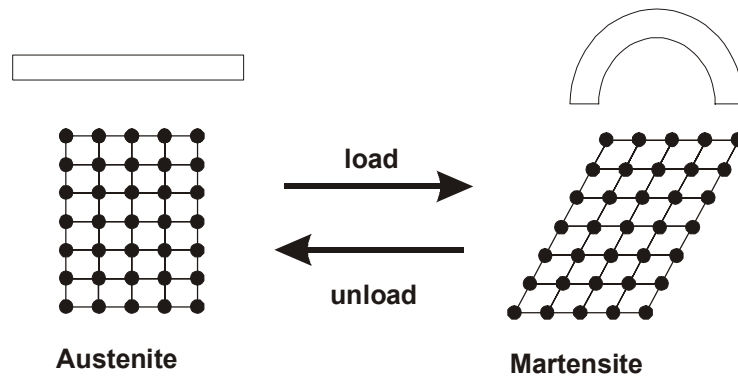


Figure 2.17 Schematic diagram of superelasticity.

At present, SMA materials are produced in wire, tubular and sheet forms. Many applications make use of the SMA wire and tubular configurations. In aerospace and aviation industries, for instance, tube and pipe connectors for pneumatic and hydraulic lines and flexible satellite antennas have been manufactured (Schetky 1979). SMA wire has been applied in medical industry for a broad range of devices used in orthopedics, neurology, cardiology and interventional radiology (Lipscomb and Nokes 1996). Self-expanding stents and stent grafts are among the most successful medical TiNi SMA applications (Domschke, et al. 1990; Cowling, et al. 1998b; Marks, et al. 1999; Cowling 2000).

Compared to the wire forms, usage of SMA sheets is very limited. The only notable use of the SMA sheets is for a small structure in Micro Electro Mechanical Systems (MEMS), such as those found in the microactuators of micropumps and those used as microelectrodes for neural recording (Obermeier and Thielicke; Kuribayashi 1989; Kahn, et al. 1998; Makino, et al. 2000; Takeuchi and Shimoyama 2000). Complex rolling and annealing methods are required to produce a large and thin sheet due to the low plastic workability and high work hardening rate of SMA. Therefore commercially available SMA sheets are still very expensive, resulting in the rarity of SMA sheets in industrial products. A new method has recently been developed to

produce the sheet using ultrafine laminates of pure Ti and Ni (Tomus, et al. 2003), which can reduce the cost. This improvement to the production of SMA sheets is expected to lead to a significant expansion in the number of applications of SMA.

In most applications involving SMA sheets, the material needs to be cut with sophisticated precision methods. The SMA sheet can be cut using either photochemical etching, which uses an etchant mixture of hydrofluoric acid (HF), nitric acid (HNO₃) and water, or using electrochemical etching, which uses an etchant of sulfuric acid (H₂SO₄) and anhydrous methanol (Makino, et al. 1998; Chen and Wu 1999; Mineta, et al. 2001). Other processing methods including laser cutting and electro-discharge machining (Kohl, et al. 1994) are thermal processes, which may influence the characteristics of the SME (Reynaerts, et al. 1996; Haferkamp, et al. 2001). Etching is less expensive and offers a finer control over the etching depth so that precise and complex designs may be produced. Moreover, as shown in Figure 2.18, the surface of an etched sample is smoother than the one cut by laser (Skrobanek, et al. 1998).

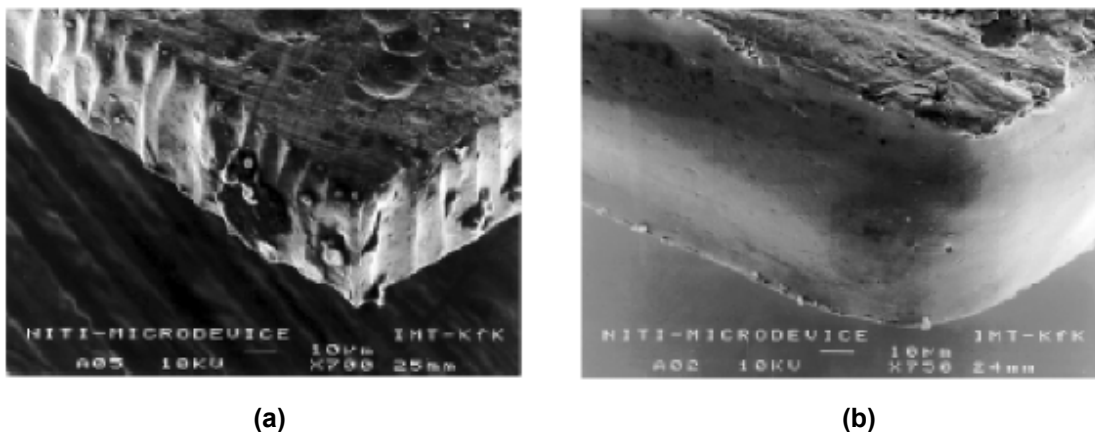


Figure 2.18 Surface of TiNi after (a) laser cutting and (b) electrochemical etching (source: Kohl 1994).

2.5.3 SMA for stents and stent grafts

The distinct characteristics of the SMA enable it to be used for medical devices. The ability of SMA to recover a designed shape allows the production of stents and stent grafts which are self-expanding at body temperature. The transformation temperature A_f can be adjusted to be less than the body temperature allowing it to be used for self-expanding stents and stent grafts. This eliminates the necessity for extra deployment devices, e.g., balloons, for an expansion.

As illustrated by the black line in Figure 2.19, a stent is compressed into the delivery system following the loading curve from point O to A. After the sheath is withdrawn, the stent starts to expand and is back to its original shape following the unloading path of the stress-strain curve from point A to B shown by the red dash line. At point B the stent reaches the diameter of the vessel lumen and is against the vessel

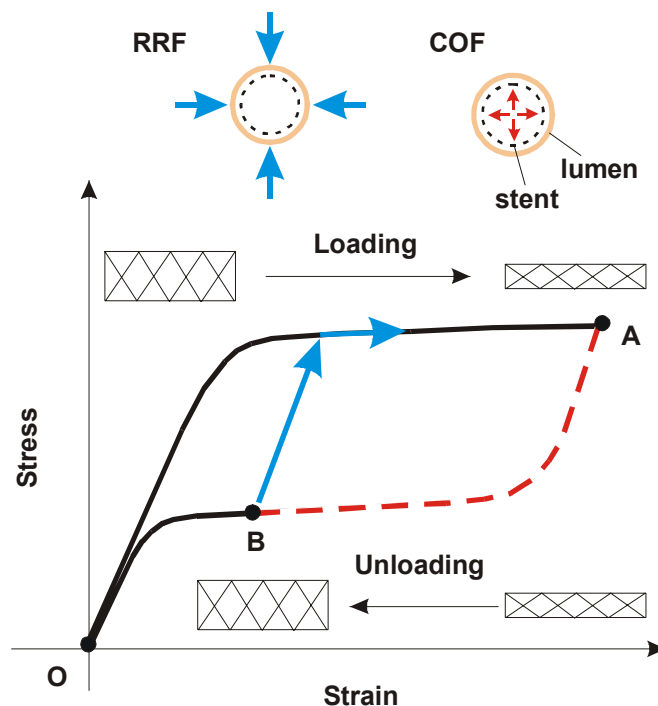


Figure 2.19 Illustration of high resistant deformation force

wall with small outward force (COF, chronic outward force). If the vessel contracts through spasms or is compressed from the outside, the stent resists deformation with a larger force (RRF, radial resistive force) which is indicated by the blue arrow. Therefore, SMA stents can withstand external pressure. (Friend and Morgan 1999; Stoeckel 2000).

Biocompatibility is the ability of material to be accepted by the body. It is related to the corrosion behavior of the material. TiNi SMA forms a passive titanium oxide layer that acts as a physical barrier to nickel oxidation and also offers chemical protection against corrosion (Moorleghem, et al. 1998; Ryhanen 1999). Tests show that there is no significant increase in the level of nickel in blood after the implant of a TiNi SMA. Such an increase would be expected if the SMA were not biocompatible (Duerig, et al. 1999). TiNi SMA also shows no cytotoxic (cell-damaging) effects.

Ferromagnetic materials that are often used in surgery typically have large magnetic susceptibilities, causing field distortion and Magnetic Resonance Imaging (MRI) artifacts around implanted metal objects. TiNi SMA is non-ferromagnetic with a lower magnetic susceptibility than some materials, such as stainless steel (Duerig, et al. 1999). Therefore, the TiNi SMA stent can be detected by MRI during an operation without the problem of artifacts (Holton, et al. 2002), which greatly aids doctors to insert and position the stents.