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Nitinol - A Material with unusual Properties

Stoeckel

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Nitinol - A material with unusual properties

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Nitinol (nickel-titanium) alloys exhibit a combination of properties which make them particularly suitable for the manufacture of self-expanding stents. Some of these properties are not possessed by other materials currently used to manufacture stents. This paper describes the fundamental nitinol properties of shape memory and superelasticity. Material properties and device characteristics such as elastic deployment, thermal deployment, kink resistance, constancy of stress, dynamic interference, biased stiffness, magnetic resonance imaging (MRI) compatibility, radiopacity and biocompatibility are discussed.

Introduction

Nitinol alloys are rapidly becoming the materials of choice for use in self-expanding stents, graft support systems, filters, baskets and various other devices for interventional procedures. Companies such as Bard-Angiomed (Memotherm), Boston Scientific (Symphony a.o.), Medtronic-AneuRx, Nitinol Medical Technologies, World Medical Technologies and Cordis offer nitinol products, the performance of which is based on the highly unusual properties of nitinol alloys.

The best-known properties of nitinol alloys are their superelasticity and thermal shape memory. While the term 'shape memory' describes the phenomenon of restoring a predetermined shape by means of heating, having 'plastically' deformed that shape, the term superelasticity refers to the enormous elasticity of these alloys, which can be 10 times greater than the best stainless steels used in medicine today. Although both effects are clearly spectacular, they are not the only important properties of the material. In this paper, features such as biomechanical compatibility, constancy of stress, dynamic interference and 'biased stiffness' will be described. In combination with strength, fatigue resistance, biocompatibility and MRI compatibility, these nitinol-specific properties allow interesting solutions for the design of superior medical devices [1].

Superelasticity and shape memory of nitinol

Conventional metallic materials such as stainless steel, titanium and Elgilloy a.o., which are used in stents, filters and other interventional devices, exhibit a distinctly different elastic deformation behaviour from that of the structural materials of the human body. The elastic deformation of these metals and alloys is limited to ≈1% strain and elongation typically increases and decreases linearly (proportionally) with the applied force. In contrast, natural materials such as hair, tendon and bone can be elastically deformed, in some cases, up to 10% strain in a non-linear way [2]. When the deforming stress is released, the strain is recovered at lower stresses. As shown in Fig. 1, the loading/unloading cycle is characterized by a pronounced hysteresis.

A similar behaviour is found with nitinol alloys, which are equiatomic or near-equiatomic intermetallic compounds of titanium and nickel. Figure 2 shows a characteristic load/deflection (stress/strain) curve for a nitinol alloy wire at body temperature (T in Fig. 2; as will be shown later, the properties of nitinol alloys are strongly temperature-dependent). As with natural materials, the loading and unloading curves show plateaus, along which large deflections (strains) can be accumulated on loading, or recovered on unloading, without a significant increase or decrease respectively in load (stress). Because a deformation of more than 10% strain can be elastically recovered, this behaviour is called 'superelasticity' or sometimes more scientifically 'pseudoelasticity'. It is the basis for most applications of nitinol in medical devices.

If the temperature is raised by, for example, 10°C, the complete hysteresis loop, i.e. the loading and unloading curves, shifts to a higher level (denoted $T+\Delta T$ in Fig. 2).

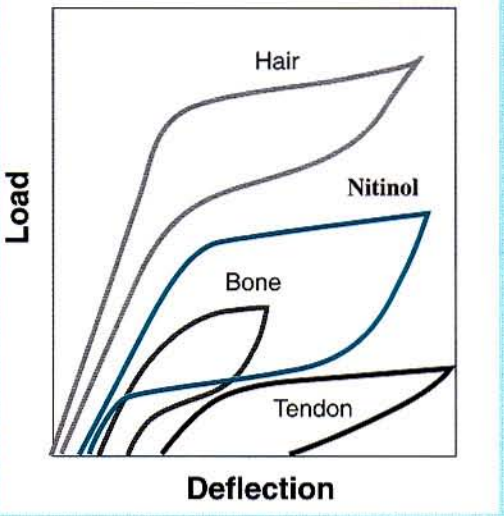


Figure 1. Deformation characteristics of natural materials and nitinol [2].

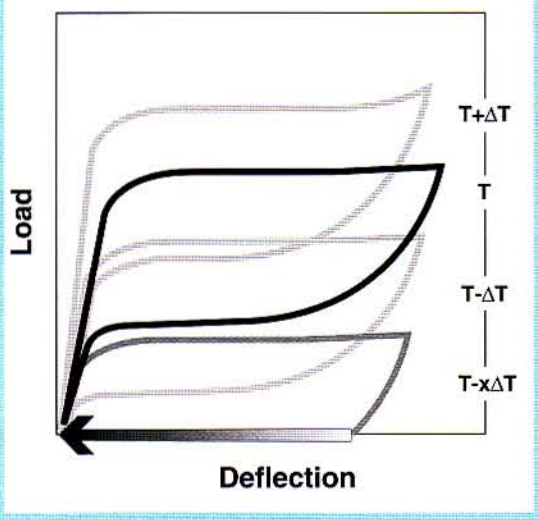


Figure 2. Influence of temperature on the deformation characteristics of nitinol.

However, the qualitative appearance of the curves is maintained. Lowering the temperature by 10°C, however, will shift the hysteresis loop to a lower level (T–ΔT). Lowering the temperature even further will cause the load to reach zero before the deflection is recovered, i.e. the sample will stay deformed at this temperature (T–xΔT). If the temperature is increased to ≥25°C after unloading, the deformation will be recovered thermally. This effect is called thermal shape memory, or simply shape memory.

The temperature at which the material can no longer recover the elastic strain depends upon the alloy composition and processing and can be adjusted to between ≈ –20°C and ≈+100°C. This transition temperature is an important characteristic of nitinol components used in medical applications. Nitinol alloys are superelastic over a temperature range of ≈50°C above the transition temperature.

At higher temperatures, nitinol alloys gradually lose their ability to recover the deforming strain until, at a certain maximum temperature (typically >100°C), they behave like a 'normal' material. An alloy with a transition temperature of 25°C will recover all but ≈0.5% of the deforming strain after being deformed by 8% in the temperature range 25–75°C. The same alloy can be deformed 'plastically' up to 8% (under ideal circumstances) below 25°C and its shape restored by heating to above 25°C. (Note: this description is simplistic. The transition temperature is not a distinct temperature but a temperature range.)

The mechanism responsible for both superelasticity and shape memory is a solid-state phase transformation, known as the 'thermoelastic martensitic transformation'. Detailed explanations can be found in Ref. 3. In the following sections some important device characteristics will be discussed, all of which can be attributed to specific nitinol properties and used advantageously in the manufacture of self-expanding stents and other medical devices.

Elastic deployment

The enormous elasticity of nitinol allows such alloy devices to be introduced into the body through catheters or other delivery systems with a small profile. Once inside the body, the devices can be released from their constraints and unfolded or expanded to a much larger size. Figure 3A shows the elastic deployment of a stent of 20 mm diameter from a 3 mm i.d. cartridge. In order to fully expand at body temperature (37°C) the transition temperature of the alloy should be ≤30°C. If full deployment is required at room temperature (20°C) the transition temperature of the alloy should be ≤15°C. Typical expansion ratios for self-expanding nitinol stents range between 1:2–1:5.

As with stents, filters and occlusion devices (atrial septal defect occlusion, Botalli duct occlusion) can be deployed superelastically through small-sized catheters. Nitinol is also used in retrieval baskets and snares.

Thermal deployment

A stent with a transition temperature of 30°C can be compressed at ≤20°C. It will stay compressed until the temperature is increased to >30°C. It will then expand to its pre-set shape. If this stent could be kept cold during introduction into the body it would not expand. When positioned at the desired location it would warm up by means of body heat and expand. However, this is difficult to accomplish. All self-expanding stents are therefore constrained in the delivery system to prevent premature deployment. Stents could theoretically be built with a transition temperature of 40°C. These stents would have to be heated after delivery to the site to make them expand.

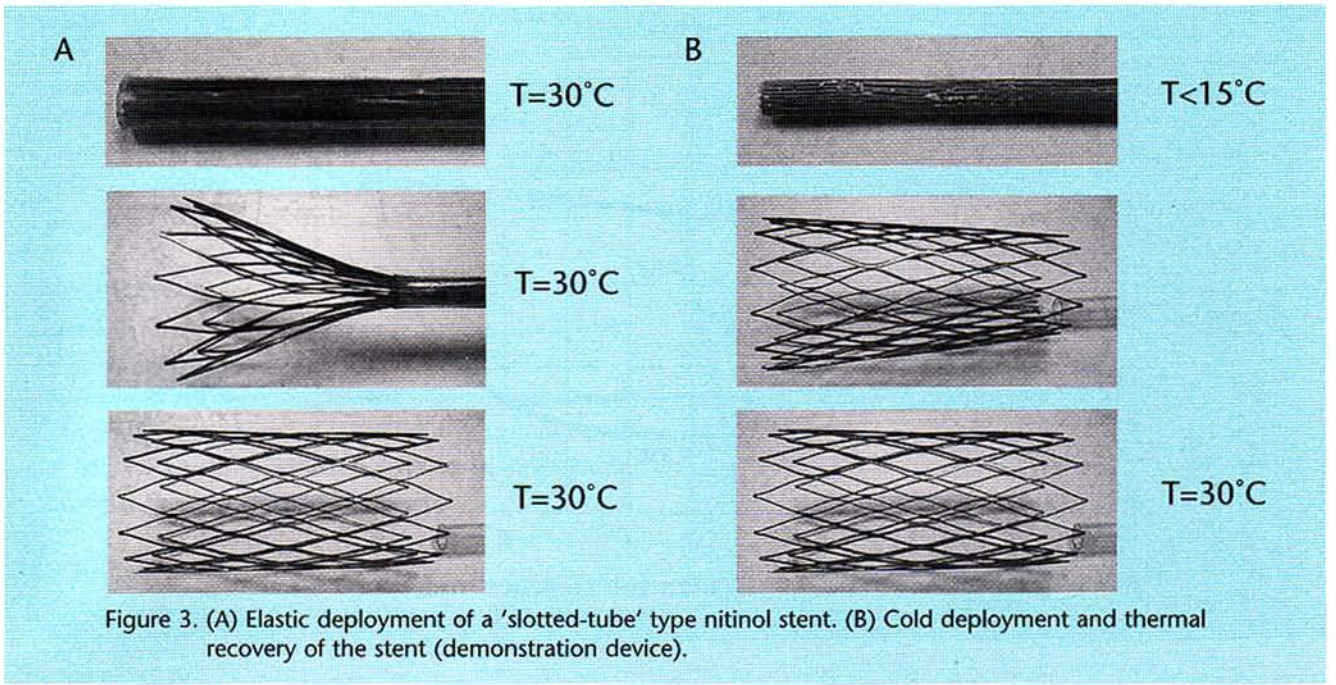


Figure 3. (A) Elastic deployment of a 'slotted-tube' type nitinol stent. (B) Cold deployment and thermal recovery of the stent (demonstration device).

Figure 3B shows the stent in Fig. 3A being released from a cooled delivery cartridge. The stent stays compressed until its temperature exceeds the transition temperature of 30°C.

The Simon Vena Cava Filter (Nitinol Medical Technologies) was the first shape memory vascular implant to use the property of thermal deployment. The device is preloaded into a catheter in its low-temperature state. Flushing chilled saline solution through the catheter keeps the device in this state while positioning to the deployment site. Upon release from the catheter the device is warmed by body heat and recovers its 'pre-programmed' shape.

Constant force (stress)

As shown in Fig. 2, an important feature of superelastic nitinol alloys is that their unloading curves are flat over a wide deflection (strain) range. This allows the design of devices that apply a constant force or load (stress) over a wide range of shapes. Stents deployed in vessels therefore exert an almost constant force independent of the amount of unresolved recovery. (Note: it is typically recommended that stents with diameters 1–2 mm greater than the vessel diameter are used.) The orthodontic archwire was the first product to use this property. Stainless-steel and other conventional wires are regularly tightened by the orthodontist. As treatment continues, the teeth move and the force applied by stainless-steel wires quickly relaxes according to Hooke's law. This causes treatment to slow, retarding tooth movement. In contrast nitinol wires are able to 'move with the teeth', applying a constant force over a very broad range of treatment times and tooth positions.

Dynamic interference

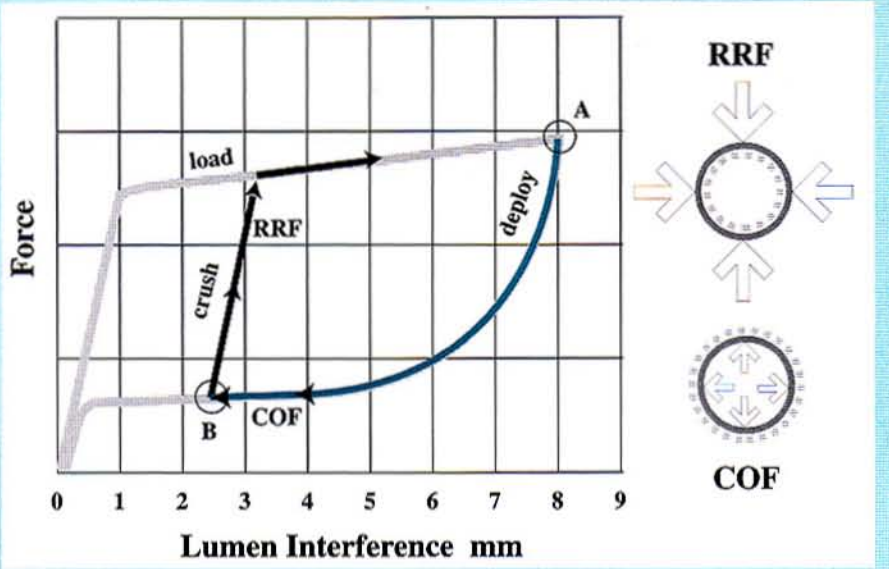
Self-expanding nitinol stents will always expand to their pre-set diameters with no recoil, while balloon-expandable stents have to be over-expanded to achieve a certain diameter (due to elastic spring-back after deflation). The nitinol stent will continue to gently push outwards against the vessel wall after deployment. Typically, the pre-set diameter of a nitinol stent is ≈1–2 mm greater than the target vessel diameter. It will therefore try to reach this diameter. Should the vessel increase in diameter the nitinol stent will also expand until it reaches its final diameter.

Biased stiffness (force hysteresis)

The most unusual feature of nitinol alloys is force or load hysteresis. While in most engineering materials load (or stress, if normalized) increases linearly with deflection (strain) upon loading and decreases along the same path upon unloading, nitinol exhibits distinctly different behaviour. After an initial linear increase in load with deflection, large deflections can be obtained with only a small further load increase. This is called the loading plateau. The end of this plateau is reached at ≈8% strain. Unloading from the end of the plateau region causes the load to decrease rapidly until a lower plateau (the 'unloading plateau') is reached. Deflection is recovered in this region with only a small decrease in load. The last portion of the deforming strain is finally recovered in a linear fashion. The unloading stress can be as low as 25% of the loading stress.

The 'biased stiffness' of a stent made from superelastic nitinol is illustrated in Fig. 4. A stent is compressed into the delivery system following the loading curve to point A. Upon release from the delivery system inside the vessel it expands, following the unloading path of the stress/strain curve. At point B it reaches the diameter of the vessel lumen, positioning itself against the vessel wall with a low outward force (chronic outward force; COF). As can be seen from Fig. 4, this force remains nearly constant, even if

Figure 4. 'Biased stiffness' of a stent as a result of the stress hysteresis of nitinol.



the vessel increases in diameter (dynamic interference). If the vessel contracts, through spasms for instance, or is compressed from the outside, the stent resists deformation with a greater force (radial resistive force; RRF). In such a way the stress hysteresis of nitinol allows the design of self-expanding stents with biased stiffness, meaning that the stents exert only small outward force but resist deformation with a much greater force.

Kink resistance

Nitinol wires, by virtue of their kink resistance and torquability, have been used to make guidewires since the early 1980s. These wires can be bent 10 times more than stainless-steel wire without permanent deformation. For example, a 0.035 in. diameter nitinol wire can be wrapped around a 0.5 in. diameter mandrel without being permanently deformed, whilst a stainless-steel wire of the same diameter can only be bent around a 5 in. diameter mandrel without being plastically deformed.

Kink resistance is an important feature of nitinol for stents in superficial vessels that could be deformed by external forces. The carotid artery is a prime example. There is a perceived risk that balloon-expandable stents deployed in carotid arteries can be permanently deformed by external pressure, resulting in a partially or completely blocked vessel once the buckling strength of the stent has been exceeded. Although nitinol stents typically do not have the buckling strength of stainless-steel stents, they cannot be permanently deformed by external forces. Nitinol stents can be completely compressed (crushed) flat and will return to their original diameter when the deforming force is removed.

MRI compatibility

Nitinol is non-ferromagnetic with a lower magnetic susceptibility than stainless steel. MRI compatibility is directly related to the susceptibility properties of a material relative to human tissue. Therefore, nitinol produces fewer artefacts than stainless steel, and is similar to pure titanium in this regard. Figure 5 shows an MRI image of a partially deployed nitinol stent (spin echo sequence, 0.2 T scanner) [4]. Most features of the stent are clearly visible. It has to be noted, however, that processing of the material can significantly influence the quality of the MRI image.

Biocompatibility

Nitinol alloys contain a higher proportion of nickel than stainless steel. This causes understandable concern because nickel is considered to be toxic. However, as nitinol is an intermetallic compound and not an alloy in the metallurgical sense, the bonding force of nickel to titanium is much stronger than that of nickel to the alloy components in stainless steel. Moreover, as nitinol oxidizes after proper surface treatment it forms a TiO_2 layer with no nickel present at the surface [5]. Polarization testing in Hank's solution has repeatedly shown that nitinol is chemically more stable and less corrosive than stainless steel [6]. In Europe and Asia, nitinol components have been implanted in humans since the early 1980s, with vascular and non-vascular stents being implanted since the early 1990s. A few years ago, the Simon Vena Cava Filter and the Mitek Suture Anchor System, which are both permanent nitinol implants, were approved by the Food and Drug Administration (FDA) in the US. Recently, the FDA has approved the Nitinol Radius Coronary Stent (Scimed).

Radiopacity

Nitinol produces a fluoroscopic image comparable to that of stainless steel if the mass and dimensions of the

parts examined are similar. Although this degree of radiopacity is sufficient in many cases, an improvement would be beneficial. While stainless steel can be gold-plated, for example, with sufficient thickness to enhance radiopacity, layers of gold and other radiopaque materials might negatively influence the superelastic performance of nitinol.

Conclusions

Nitinol offers an intriguing array of properties, not found in other engineering materials, which are useful for the manufacture of self-expanding stents. The medical device industry has recognized the potential of this material and uses it in a wide range of vascular and non-vascular stents, as well as for other devices and accessories.

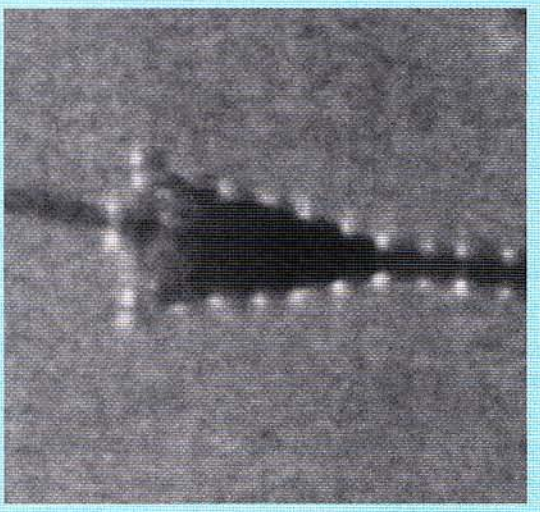


Figure 5. MRI image of a partially deployed nitinol stent [4].

References

1. Duerig TW, Pelton AR, Stöckel D. The utility of superelasticity in medicine. *Biomed Mater Eng* 1996;**6**:255-66.
2. Shabalovskaya SA. On the nature of the biocompatibility and on medical applications of NiTi shape memory and superelastic alloys. *Biomed Mater Eng* 1996;**6**:267-89.
3. Duerig TW, Melton KN, Stöckel D et al., editors. *Engineering aspects of shape memory alloys*. Butterworth Heinemann, 1990.
4. Picture provided by A Melzer, Mühlheimer Radiolgie Institut.
5. Chan CM, Trigwell S, Duerig TW. Oxidation of an NiTi alloy. *Surf Interface Anal* 1990;**15**:349-54.
6. Speck KM, Fraker AC. Anodic polarization behaviour of Ti-Ni and Ti-6Al-4V in simulated physiological solutions. *J Dent Res* 1980;**59**:1590-5.

Study update – The PRECISE and CRISP studies of PERFLEX™ and SMART™ endovascular stents

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Two clinical studies, PRECISE (Percutaneous Revascularization, a Clinical Investigation for Stents in Endovascular Management) and CRISP (Crush Resistant Iliac Stent Project), are being conducted to evaluate two new stent designs, the PERFLEX™, a balloon expandable endovascular stent, and the SMART™ stent, a self-expandable nitinol stent. Both studies are examining the performance and the safety of the new stents in comparison with currently available stents. The primary objective of both studies is to determine initial clinical success of the stents by means of the clinical primary patency rate in patients with symptomatic claudication and rest pain, scheduled to undergo percutaneous transluminal angioplasty (PTA) of a stenotic, restenotic or occluded lesion in a common or external iliac artery. The studies are multicentre, prospective, non-randomized, non-concurrent historical-controlled studies. A total of 128 patients have been recruited in the PRECISE study and follow-up data are being collected. Enrolment in CRISP is ongoing with 60 patients included thus far.

The preliminary results of these studies indicate that both stents are safe and that the performance is promising. The final results will be presented when all the data are available.

Introduction

PTA has become a well-established and accepted intervention for the treatment of atherosclerotic peripheral artery disease [1–6]. There are a number of inherent limitations to current PTA procedures, the most common of which are [1,2,4–8]:

- suboptimal PTA from vessel recoil and/or dissection;
- failed PTA due to acute closure of the vessel;
- restenosis, which occurs in up to 20% of patients who have had a prior PTA procedure.

One of the newer treatment modalities used to address the limitations of PTA is peripheral artery stenting. Stents are expandable metallic or polymeric mesh, coil or tube-shaped structures that exert an outward force from within the vessel and are intended to assist in keeping a diseased artery open. They are either self-expanding or are deployed using a balloon dilatation catheter. Stents act like a scaffold to prevent the vessel from either closing abruptly or, in the case of an arterial dissection (which can be a precursor to acute closure), to treat arterial flaps that might reduce or obstruct arterial blood flow. Stents also prevent elastic recoil by maintaining outward radial pressure on the inner vessel wall [3,9].

Recent data [1,3,4,7,8,10–12] indicate that intravascular stents improve the immediate results after angioplasty. Immediate post-procedural improvement in clinical status has been observed in 88-99% of all patients [1,4,6,7,9–11]. Stents may play an important role in reducing restenosis in some patients [4,6,11]; patency rates of >95% have been found at 1 year follow-up [1,5,6,11]. Restenosis is caused by intimal hyperplasia and, in part, by elastic recoil of the vessel [3]. Stents resist the constrictive forces of smooth muscle elastic recoil [7]. They do not prevent neointima hyperplasia but reduce restenosis by increasing the post-dilatation inner luminal diameter of the diseased arterial segment. This creates a larger cross-sectional diameter for regrowth of neointima and smooth muscle cells in the diseased section.

Problems associated with initial stent designs included difficulties with arterial access due to bulkiness, unpredictable expansion, poor radiopacity, migration, abrupt thrombosis and intimal hyperplasia leading to restenosis. Improvements to the early design have led to the development of stents that have been successfully implanted in humans by a number of investigators.

Two clinical studies are being conducted, evaluating two new stent designs. These two new examples of stents may demonstrate the improvements discussed above. Both studies will examine the performance and safety of the new stents in comparison with currently available stents. The stents' design and studies are described below and preliminary results are presented.

PRECISE (Percutaneous Revascularization, a Clinical Investigation for Stents in Endovascular Management) study

Investigators

Principal Investigator: JA Reekers.
Participating Investigators: D Vorwerk, Aachen, Germany; P Gaines, Sheffield, UK; H Rousseau, Toulouse, France; M Sapoval, Paris, France; L Stockx, Leuven, Belgium; G Voshage, Hannover, Germany; C Delcour, Charleroi, Belgium; G Biamino, Berlin, Germany; and J Busquet, Bordeaux, France.

Device

The Cordis Peripheral Stainless-Steel Stent is manufactured from a single 0.0075 in. diameter stainless-steel wire, formed into a single-plane sinusoidal wave pattern and wrapped in a tubular helical fashion (Fig. 1). This tube is maintained by a series of welded joints. The number of consecutive welded joints varies with the length of the stent. These consecutive joints form a backbone. There may be multiple backbones located along the axial direction of the stent which are

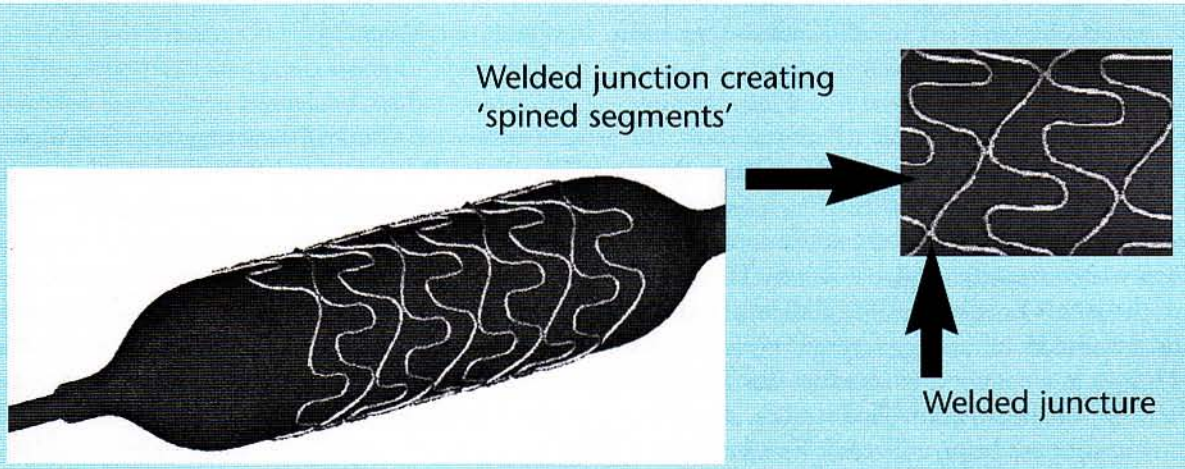

Figure 1. The PERFLEX™ stent.

opposed to one another radially and equidistantly around the circumference of the stent (in the three-backbone stent the backbones are 120° apart; in the four-backbone stent they are 90° apart). The sinusoidal waveform terminates in an end-weld at both ends of the stent.

The family of Peripheral Stainless-Steel Stents is comprised of two groups as described below. Each group of stents exhibits a variable range of expanded diameters, uniform flexibilities, lengths, number of spines and welds.

Group 1: Three-spine design, semi-rigid with an expansion range of 4–7 mm diameter. These stents are deployed to sizes of 7.0 mm diameter (15, 35, 55 and 75 mm minimum length). These stents are offered pre-mounted on a Cordis PowerFlex™ PTA Balloon Catheter.

Group 2: Four-spine design, semi-rigid with an expansion range of 8.0–10.0 mm diameter. These stents are offered pre-mounted on a Cordis OPTA5™ PTA Balloon Catheter.

Study outline

The primary objective of the PRECISE study is to determine the initial clinical success of the Perflex™ stent by means of the clinical primary patency rate in patients with symptomatic claudication and rest pain, scheduled to undergo PTA of a stenotic, restenotic or occluded lesion in a common or external iliac artery.

The PRECISE study is a multicentre, prospective, non-randomized, non-concurrent, history-controlled study. One hundred and twenty-five patients with iliac occlusive disease have been recruited. Patients are followed for a period of 12 months for evaluation of continued vessel patency and the incidence of complications. Follow-up evaluations are conducted at discharge and at 1, 6 and 12 months post-procedure.

The main admission criteria of the study were:

- lifestyle-limiting claudication or rest pain;
- lesions in the common or external iliac artery with an angiographically documented unsatisfactory angioplasty result which potentially includes:
- de-novo stenotic lesions with a mean pressure gradient after predilatation of ≥10 mmHg following vasodilator challenge (100 µg intra-arterial nitroglycerine);
- restenotic lesions with a mean pressure gradient after predilatation of ≥10 mmHg following vasodilator challenge (100 µg intra-arterial nitroglycerine);
- occluded lesions to be treated with primary stent placement.

The primary endpoint of the study is clinical primary patency defined as the absence of, within the first 6 months after stent implantation, any procedure following implantation (either endovascular or surgical) that might preserve or extend patency of the treated lesion or the margins to the segment treated initially and/or a >0.15 deterioration from the maximum early ankle brachial pressure index and/or downward change in the Rutherford scale.

The PRECISE study has been developed in such a way that the results can be compared with an historical control. The DIST (Dutch Iliac Stent Trial) study [12] will serve as the control group for the PRECISE study, which is ongoing. The last patient was recruited in December 1997 and therefore the last 12 month follow-up is planned for December 1998. The Perflex stent is currently commercially available. It is anticipated that the results of the PRECISE study will be available in early 1999.

Results and conclusion

Between February 5 and December 12, 1997, 128 patients were enrolled. The technical and procedural success rates (100% and 93% respectively) are comparable to those in the DIST study, in which the Palmaz stent was deployed, and in other studies [1–3,8]. This also applies to the rates of primary patency (92%) and clinical success (improvement of at least one clinical category) to 6 months (89%), and to complication rates (8% procedural, of which 4% were major).

The preliminary results of this study suggest that the Perflex stainless-steel stent is an effective device for the treatment of iliac artery occlusive disease. Moreover, it appears to be comparable to the Palmaz stent in terms of clinical outcomes and patency rates. The main advantages of the Perflex stent over the Palmaz stent are its enhanced flexibility and modular configuration, which render it more (manually) adjustable to local morphology.

The 6 month follow-up data are on file and are being analysed. They will be presented by the Principal Investigator in the near future. The 12 month follow-up data are currently being collected.

CRISP
(Crush Resistant Iliac Stent Project) study

Investigators

Principal Investigator: D Vorwerk.
Participating Investigators: JA Reekers, Amsterdam, Netherlands; P Gaines, Sheffield, UK; H Rousseau, Toulouse, France; M Sapoval, Paris, France; L Stockx, Leuven, Belgium; G Voshage, Hannover, Germany; C Delcour, Charleroi, Belgium; D Vroegindeweij, Alkmaar, Netherlands; K Schürmann, Aachen, Germany.

Device

The most recent development in endovascular stents is the nitinol self-expandable stent. The Cordis Self-Expandable Nitinol Stent (Fig 2.) is a tubular prosthesis comprised of a nickel-titanium alloy designed to maintain vessel patency post-deployment in the peripheral vasculature. The stent is

Figure 2. The Cordis self-expandable nitinol stent (SMART™ stent).

made of a laser-cut hypo tube and is constrained in a 7 F, 0.035 in.-compatible delivery system.

Study outline

The primary objective of the CRISP study is to determine the initial clinical success of the SMART™ stent by means of the clinical primary patency rate in patients with symptomatic claudication and rest pain, scheduled to undergo PTA of a stenotic, restenotic or occluded lesion in a common or external iliac artery.

The CRISP study protocol is similar to that of PRECISE. It is a multicentre, prospective, non-randomized, non-concurrent, history-controlled study. One hundred and ten patients with iliac occlusive disease have been recruited. Patients will be followed-up at 1, 6 and 12 months, for evaluation of continued vessel patency and complications.

The main admission criteria of the study are:

- patients with lifestyle-limiting claudication or rest pain;
- lesions in the common or external iliac artery with an angiographically documented unsatisfactory angioplasty result which potentially includes:
- de-novo stenotic lesions with a translesion peak systolic gradient of ≥10 mmHg. If a gradient of 10 mmHg is not measured the measurement should be performed again following vasodilator challenge (100 µg intra-arterial nitroglycerine);
- restenotic lesions within 90 days of a previous angioplasty or other endovascular procedure;
- chronically occluded (≥3 months) lesions to be treated with primary stent placement.

The primary endpoint is identical to that of PRECISE. The results of the CRISP study will be compared with those of the DIST study [12]. It is likely that the patient populations of CRISP and PRECISE will be similar.

Results and conclusion

The study started on 23 March 1998. Sixty patients have been included and enrolment is ongoing. The initial results indicate that the device performs according to the instructions of use. The stent can be placed accurately and it deploys well. The acute results for the initial cases indicate that the device is safe. Furthermore, no device-related sub-acute events have been observed to date.

References

1. Bonn J, Gardiner GA, Shapiro MJ et al. Palmaz vascular stent: initial clinical experience. *Radiology* 1990;**174**:741-5.
2. Fontaine AB, Dake MD, Tschang T-P et al. Stainless steel balloon-expandable stent: in vivo swine studies. *J Vasc Intervent Radiol* 1993;**4**:749-52.
3. Günther RW, Vorwerk D, Bohndorf K et al. Iliac and femoral artery stenoses and occlusions: treatment with intravascular stents. *Radiology* 1989;**172**:725-30.
4. Palmaz JC, Garcia OJ, Schatz RA et al. Placement of balloon-expandable intraluminal stents in iliac arteries: first 171 procedures. *Radiology* 1990;**174**:969-75.
5. Vorwerk D, Günther RW. Stent placement in iliac arterial lesions: three years of clinical experience with the Wallstent. *Cardiovasc Intervent Radiol* 1992;**15**:285-90.
6. Zollikofer CL, Antonucci F, Pfyffer M et al. Arterial stent placement with use of the Wallstent: midterm results of clinical experience. *Radiology* 1991;**179**:449-56.
7. Becker GJ, Palmaz JC, Rees CR et al. Angioplasty-induced dissections in human iliac arteries: management with Palmaz balloon-expandable intraluminal stents. *Radiology* 1990;**176**:31-8.
8. Bosch JL, Hunnink MGM. Meta-analysis of the results of percutaneous transluminal angioplasty and stent placement for aortoiliac occlusive disease. *Radiology* 1997;**204**:87-96.
9. Rees CR, Palmaz JC, Garcia O et al. Angioplasty and stenting of completely occluded iliac arteries. *Radiology* 1989;**172**:953-9.
10. Martin E, Katzen B, Benenat J et al. Multicenter trial of the Wallstent in the iliac and femoral arteries. *J Vasc Intervent Radiol* 1995;**6**:843-9.
11. Palmaz JC, Laborde JC, Rivera FJ et al. Stenting of the iliac arteries with the Palmaz stent: experience from a multicenter trial. *Cardiovasc Intervent Radiol* 1992;**15**:291-7.
12. Tetteroo E, van der Graaf Y, Bosh JK et al. Randomized comparison of primary stent placement versus angioplasty with selective stent placement in patients with iliac artery obstructive disease. The Dutch Iliac Stent Trial – results from a randomized multicenter study [thesis]. University Hospital, Utrecht, Netherlands, 1997.