(12) UK Patent Application (19) GB (11) 2 344 053 (13) A

(43) Date of A Publication 31.05.2000

(21) Application No 9826254.6

(22) Date of Filing 30.11.1998

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(51) INT CL[7]
A61F 2/06 , A61B 5/0215 8/06

(52) UK CL (Edition R)
A5R RAR

(56) Documents Cited

GB 2333044 A	**EP 0891752 A1**	**EP 0788802 A2**
EP 0706783 A	**WO 98/29030 A**	**WO 98/20810 A1**
WO 83/03348 A	**US 5879370 A**	**US 5807258 A**
US 5749919 A	**US 5674277 A**	**US 5411551 A**
US 5041126 A	**US 4760849 A**	

(58) Field of Search
UK CL (Edition Q) **A5R RAR**
INT CL[7] **A61B 5/0215 8/06 , A61F 2/06**
ONLINE:WPI,EPODOC,JAPIO

(54) Abstract Title
Stents for blood vessels

(57) A stent for supporting part of a blood vessel and adapted to flex three-dimensionally which stent includes a supporting portion around which or within which part of an intact blood vessel other than a graft can be placed so that the stent internally or externally supports that part and the supporting portion of the stent is of a shape and/or orientation whereby flow within the vessel is caused to follow a non-planar curve.

By maintaining non-planar curvature in the vessel itself, favourable blood flow velocity patterns can be achieved through generation therein of 'swirl' flow. Failures in such vessels through diseases such as thrombosis, atherosclerosis, intimal hyperplasia or through blockage, kinking or collapse, can be significantly reduced. The stent may have a sensor to monitor the vessel's condition.

Fig. 1(b)

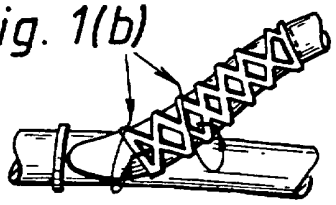
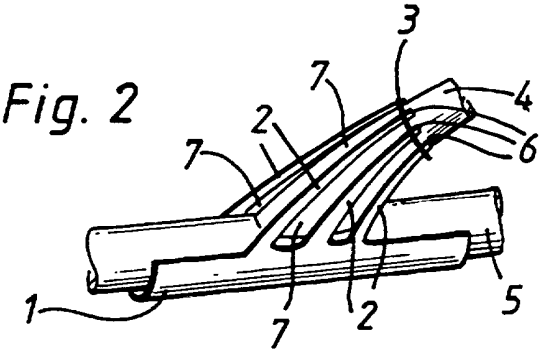


Fig. 2



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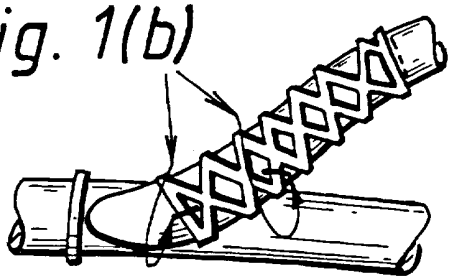
At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

Fig. 1(a)

Fig. 1(b)



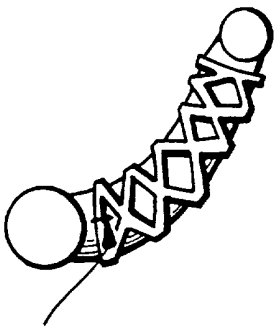
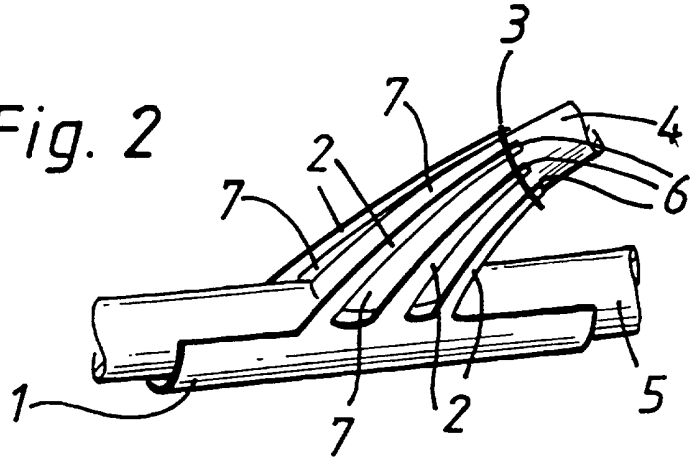


Fig. 1(c)

Fig. 2



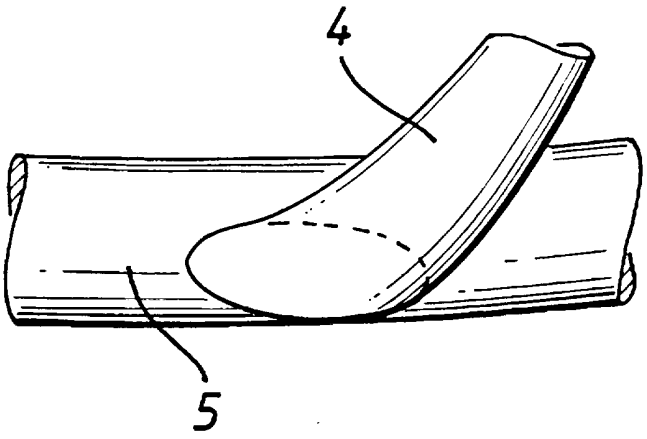
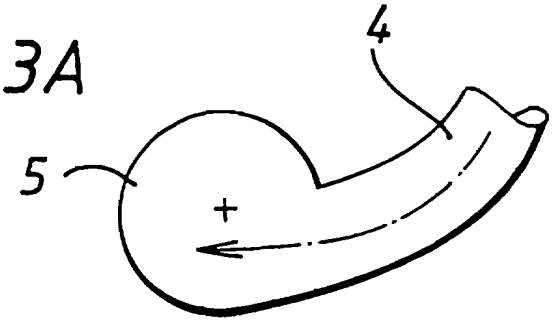


Fig. 3

Fig. 3A



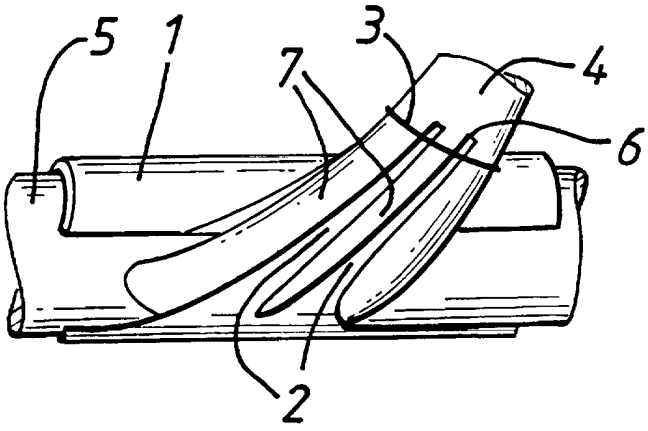


Fig. 4

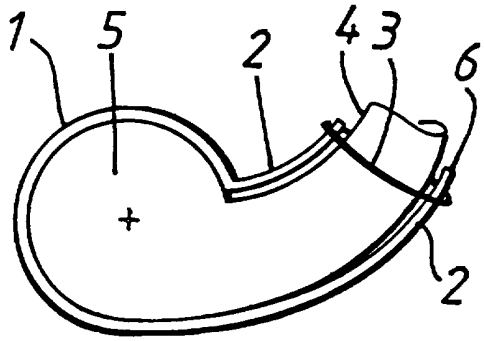


Fig. 4A

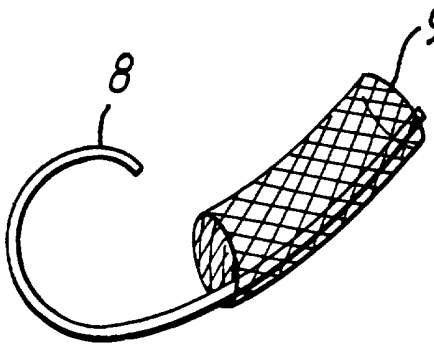
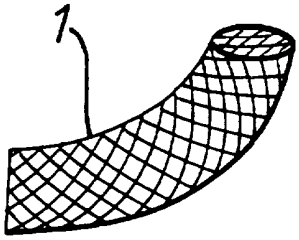


Fig. 5

Fig. 6A



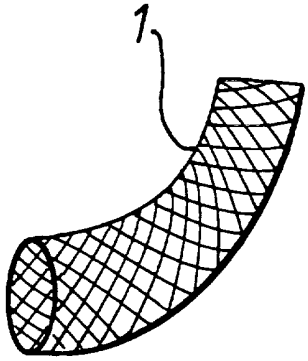
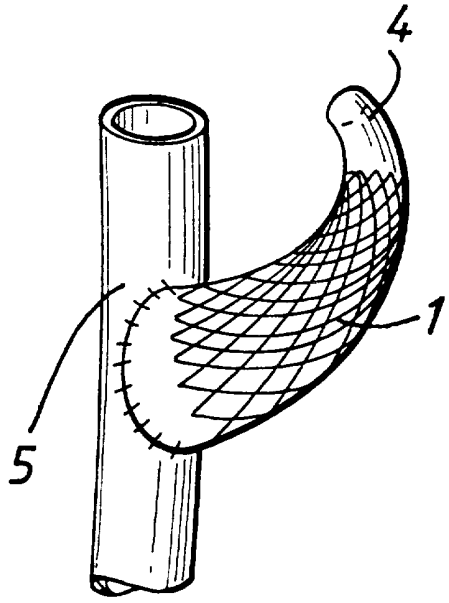


Fig. 6B

Fig. 6C



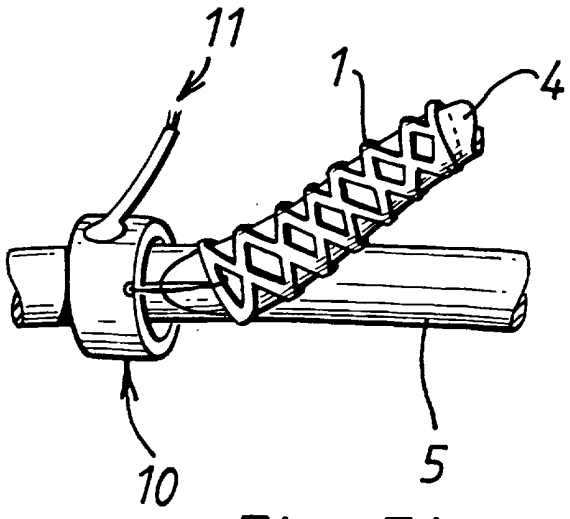


Fig. 7A

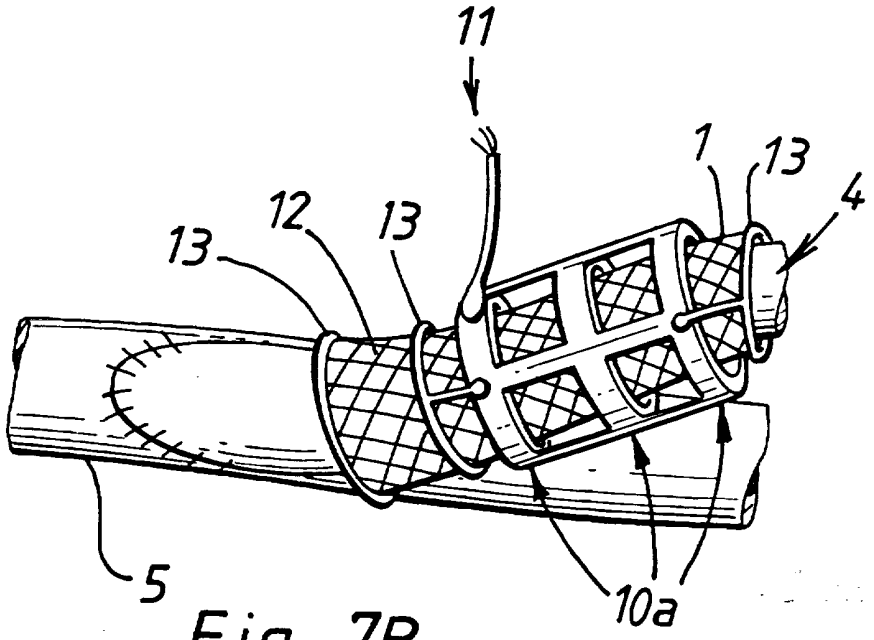


Fig. 7B

Fig. 8

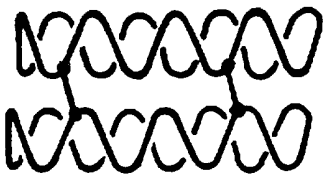


Fig. 9

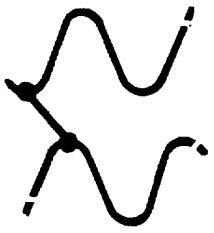


Fig. 10

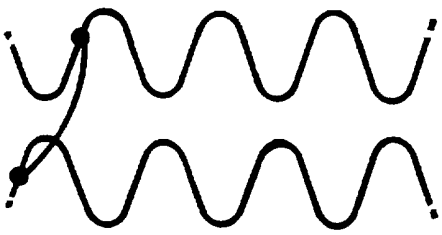


Fig. 11

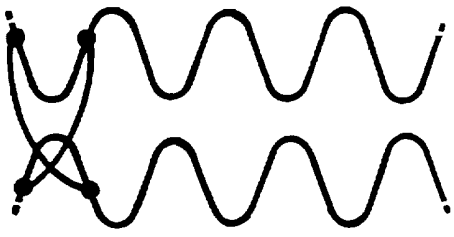
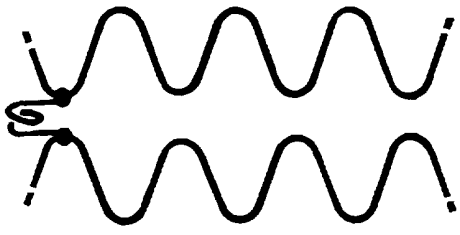


Fig. 12



STENTS FOR BLOOD VESSELS

This invention is concerned with stents for supporting parts of blood vessels. More particularly it is concerned with stents as in-situ supporting devices for arteries and veins within the vascular system. The term 'artery' and 'vein' in the singular or plural, refers to the vein or artery or a part thereof but excludes any parts thereof which is a graft or which has been removed to serve as a graft.

Stents are known devices used in surgery especially in vascular surgery for providing physical support to blood vessels i.e. they can be used to help prevent kinking/occlusion of blood vessels such as veins or arteries and to prevent their collapse after dilatation or other treatment to maintain their patency.

It has been proposed that the flow pattern in arteries including the swirling pattern induced by their non-planar curvature operates to inhibit the development of vascular diseases such as thrombosis, atherosclerosis and intimal hyperplasia.

We have now devised an apparatus and technique for establishing and/or maintaining physiological curvature, including non-planar curvature within blocked, constricted or otherwise flow-restricted blood vessels such as arteries or veins as defined above.

By maintaining physiological curvature, which may

include non-planar curvature in the blood vessels, favourable blood flow velocity patterns can be achieved often through generation therein of 'swirl' flow.

Failures in such vessels through thrombosis, atherosclerosis, intimal hyperplasia or other diseases leading to blockage or due to kinking or collapse, can be significantly reduced.

According to this invention there is provided a stent for supporting part of a blood vessel, such as part of an intact vein or artery within the vasculature, which stent includes a supporting portion around which or within which part of that blood vessel can be placed so that the stent internally or externally supports that part and the supporting portion of the stent is of a shape and/or orientation whereby flow within the vessel is caused to follow a physiologically appropriate curve which may be non-planar.

The supporting portion of the stent may be fabricated to incorporate means to increase the ability of the stent to sustain displacement due to bending and torsion so that it may more readily accommodate

(i) a non-planar curved form; and/or

(ii) it may be pre-formed to provide an appropriate geometry to sustain a more favourable flow in the selected vessel after insertion, and/or

(iii) a geometric arrangement of the junction between the stent and branching vessel e.g. artery whereby

the tangent vector from the centreline of the stent intersects the centreline of the host vessel by consequence of a symmetric disposition of the stent with respect to the host vessel.

The stent may be of generally hollow tubular shape with three dimensional curvature. The stent is particularly preferred for use as an in-situ support internally within or externally around arteries and veins.

The stent may take the form of a series of linked members forming a tubular frame e.g. an open lattice generally tubular framework with discrete openings at each end thereof. Alternatively it may take the form of series of curved rings joined together.

A stent may be passed through the interior section of a blood vessel, which stent then provides support for that part of the blood vessel through which it passes and preferably imparts thereby to the vessel a geometry which includes non-planar curvature i.e. the vessel part supported by the stent can assume and maintain curvature which is non-linear. Part of the supported vessel in such embodiments thereby acquires a geometry which can be regarded as a part-helical or helicoidal curve even if the physical extent of the supported vessel is less than one complete turn of a helix e.g. less than ½ or less than ¼ of such a turn.

A practical embodiment of a non-planar internal stent of type (ii) is one fabricated to adopt an appropriately helicoidal, helical, part helicoidal, or part-

helical form, to provide the required support for the blood vessel after its insertion.

In order that the invention may be illustrated, more easily understood and readily carried into effect by one skilled in this art, reference will now be made to the accompanying drawings of preferred embodiments by way of non-limiting example only, and in which:

Figures 1a to c depict an embodiment of a stent shaped to conform the blood vessel in non-planar curvature at a site where it is deployed,

Figure 2 shows an alternative embodiment of a stent,

Figure 3 shows a configuration of an artery with a stent deployed therein,

Figure 3a is a side view of the Figure 3 arrangement,

Figure 4 shows one suitably shaped stent adapted to establish and maintain non-planar curvature in an arterial part (i.e. part of a whole artery) as shown in Figures 3 and 3a,

Figure 4a is a side view of the Figure 4 stent - supported artery,

Figure 5 is an alternative embodiment of an internal stent based on a clip of e.g. shape memory alloy,

Figures 6a and 6b show a part-helical internal stent,

Figure 6c shows the stent of Figures 6a/6b internally supporting an arterial part,

Figure 7a shows an externally located stent for an artery and a sensor for transmitting flow or other data, and

Figure 7b shows a similar arrangement to figure 7a but wherein the sensor is located within the supported arterial part.

Referring to figures 1a to c of the drawings, the device shown may be fabricated from a thermosettable material, in the form of a hollow tube, the walls of which contain numerous openings so that the interior of the artery is not fully shielded.

In particular, figure 1(a) shows the stent before thermosetting, whereas figure 1(b) and (c) indicate possible configurations whereby prior thermosetting has rendered this stent to adopt the shape of a partially coiled, non-planar curve.

The stent is then inserted within the artery to ensure the geometrical configuration of the artery to a predetermined form in the locality of the stent.

The stent may be of constant diameter, or tapered, as in figure 1(a) to accommodate the common practice of deploying a stent in the vicinity of the junction of the artery with a parent or daughter artery. The stent may be fixed to the artery by sutures (shown arrowed) or to avoid trauma to the vessel, may be attached to a clip ring placed about the vessel.

The restraining action of the stent may be graduated, by mechanically "tapering" the rigidity of the

material: for example, at either end, material may be removed or the rigidity reduced by cuttings. An internally locatable stent is also provided which corresponds to the external stent just described, however such a stent is inserted into the interior of the vessel part rather than being placed exterior to the vessel.

Although intended for the cardiovascular system, embodiments of such stents could be incorporated elsewhere - e.g. in the gastrointestinal system, bile duct, genitourinary system for the "active "stent, this might for example be deployed with treatment of incontinence.

Referring to figure 2 the non-planarity of the vessel 4 is attained by supporting it with an external stent 1, 2 which comprises a longitudinal part section 1 of a cylinder, fabricated of a suitable porous biocompatible material, which may be of straight or curved section, to support that part of the artery 5 in the region of the stent, and integral with part section 1, or attached securely thereto are a plurality of elongate external support members 2, which are fabricated to define an internal region 7 of appropriate non-planar geometry.

The ends 6 of the support members 2 may be secured in situ by surgical thread (not shown) or by a fastening ring 3. The stented vessel 4 is located within that internal region 7.

Figures 3 and 3a depict a non-planar configuration of stent and artery wherein a stent (artery 5, stent 4)

having a non-planar curve is surgically attached offset to the central portion of the artery 5 in that it is at least partly tangential to the artery, see the direction of flow arrow in figure 3a.

The external stent (1,2) of Figure 2 can be modified to support and maintain the non-planar curvature of the artery in the Figure 3/3a arrangements, by for example the structure as depicted in Figures 4/4a. Figures 4 and 4a have reference numerals which correspond with those used in figure 2 described above.

As shown in Figure 5 an internal stent for establishing and/or maintaining non-planar curvature of a vessel part comprises a clip 8 which is part coiled or at least part helical of shape memory alloy, affixed to a cylindrical wire mesh 9. This is an embodiment of a torsionally flexible stent.

Figures 6A and 6B show an alternative embodiment of an internal stent, in which the stent 1 is fabricated from a linked wire mesh of part helical form. The material used is preferably a shape memory alloy to facilitate insertion of the stent. Figure 6C shows the stent located in the vessel post insertion. The stent 4 surgically attached to artery 5 has been shown 'transparent' for purposes of illustration, to show the internally located, part helical wire mesh stent in-situ.

Referring to Figures 7A and 7B, either internal or external stents may incorporate devices which assist in

monitoring the condition of either the graft or the host vessel or both.

In one possible embodiment shown in figure 7A, an external stent 1 incorporates a sensor portion 10 for monitoring the condition of the host artery. The sensor portion is a ring placed over the host artery 5, attached to the tubular stent 1 placed over the graft. The sensor and stent may be secured together by means of clips or threads during the operation to insert the graft. The sensor 10 may incorporate one or several ultrasound probes, or it may comprise a coil for use with magnetic resonance imaging. The sensor portion may be electrically connected by leads 11, only partly shown, to a remote module or modules (not shown) which incorporate the required power supply, signal detection and recording devices for data capture and transmission. Some or all of the modules to which the sensor is connected may be implanted within the body of the person receiving the graft, and incorporate appropriate means such as telemetry for transcutaneous data monitoring.

In a still further embodiment, shown in figure 7B, an external stent 1 comprises a fabric or porous structure 12 attached to several outer supporting members having the external appearance of linked rings or discs 13. For a portion of the stent, these outer members incorporate a sensor device 10a or series of sensors such as miniature radio frequency and/or gradient coils for magnetic resonance imaging, or ultrasound transducers. The power supply for

the sensors, excitation and data monitoring may be as in the figure 7A embodiment. Electrical wires 11 connect the sensor device 10a to the appropriate remote module or modules (not shown).

In another embodiment of an internal or external stent the sensor may incorporate a means to detect certain chemical markers which are indicative of the condition of the flow and/or arteries. It may also contain a means whereby a supply of pharmacological agent may be administered in situ, for example by being connected to an implanted supply of drugs which are caused to be delivered by appropriate implanted machinery.

In other embodiments of an internal or external stent, the sensory action of the stent may derive from the construction of some or all of the supporting members which form the stent. In one such embodiment, the sensory action derives from a coil or coils of an electrically conducting material wound around the perimeter of the stent or interspersed at intervals along the stent which coil or coils may be excited by extracorporeal magnetic and/or electromagnetic fields, and the signal from the stent detected by magnetic coupling with an external detecting coil.

STENT GEOMETRY AND FLOW

SUMMARY

Loss of patency of stents remains a serious problem. The principal pathology at later times is intimal hyperplasia and important sites of its occurrence are apparently immediately upstream and downstream of stents. Most attention appears to have focused on compliance mismatch (arterial distensibility greatly exceeds stent distensibility) as underlying this distribution. However, because stents are effectively straight cylinders and arteries curve three dimensionally, compliance mismatch is also likely to be associated with local distortion of arterial geometry and hence distortion of the flowfield, with implications for vessel biology and pathology.

We propose initially in the investigation of this problem ex vivo studies of stent-induced distortion of the geometry and flowfield in arteries. Stents will be deployed at a few selected sites of non-planar curvature in physiologically pressurised animal arteries and epoxy resin casts will be made of the stented vessels. Geometric data obtained by MRI from the casts, together with a range of assumed physiological flows, will enable detailed determination of the local flowfield including the distribution of wall shear stress by computational (CFD) simulations. In some instances moulds of the epoxy resin casts will be perfused and the flowfield, measured by MRI, will provide a check on the CFD simulations.

As a step towards remedying the problem of stent-induced distortion of the geometry and flowfield in arteries, we propose the deployment of appropriately pre-shaped stents, obtained by exploiting the shape-memory properties of nitinol. After their deployment the local geometry and flowfield will be studied using the same methods as adopted for control stents. The generation of swirling flows and a reduction of the geometric and flowfield distortion would encourage further work on the deployment of pre-shaped shape-memory stents and/or on the engineering of stents less liable to distort the local geometry and flowfield.

1.0 AIMS OF THE PROJECT

The principal questions addressed in the proposed research are:

(1) How is the geometry of an artery which is naturally curved in three dimensions altered by the insertion of a stent, which restricts the ability of the artery to maintain its curvature?

(2) What are the consequences of this modification in the local geometry for the flowfield within the stent and immediately adjacent to it?

(3) What geometric form should a stented portion of artery adopt in order to obtain as uniform a distribution of wall shear stress within the stent and immediately adjacent to the stent as possible?

2.0 BACKGROUND

2.1 INFLUENCE OF FLOW FIELD ON VESSEL BIOLOGY AND PATHOLOGY

The local flow pattern in blood vessels (including wall shear) markedly influences their biology (Davies, 1995; McIntire, 1997; Murase et al, 1998) and, it appears, the development of vascular disease.

For example, atherosclerosis appears to develop preferentially at locations in arteries where the wall shear is on average low and/or there are large oscillations of wall shear (Yoshida et al, 1988; Jaffrin and Caro, 1995). Furthermore, the preferred region for the occurrence of intimal hyperplasia at end-to-side arterial bypass grafts appears to be where wall shear is low, there is flow separation, and/or there are large oscillations of wall shear during the cardiac cycle (Rittgers and Bhambani, 1993; Berguer et al, 1980; Dobrin et al, 1989; Sottiurai et al, 1989; Bassiouny et al, 1992; Giddens, 1995; Okadome et al, 1991; Ojha, 1994). Increase of blood flow (assumed to imply increase of wall shear) decreases the severity of intimal hyperplasia (or causes the regression of pre-existing disease) (Dobrin et al, 1989; Kohler et al, 1991; Mattsson et al, 1997). However, a very large increase of wall shear in small diameter grafts is associated with low patency rates, seemingly because of thrombosis (Binns et al, 1989). Several studies suggest that the principal factor determining the flow field is vessel geometry (Moore et al, 1993; Friedman, 1993), but vessel elasticity (Hofer et al, 1996) and the non-Newtonian nature of blood (Liepsch et al, 1990) can affect the details of the flow.

There is an appreciable risk of loss of patency of stents at later times, principally due to intimal hyperplasia. Stenting is associated with acute mechanical injury to the intima/media (Sigwart, 1996). There would not appear to have been detailed work on the role of fluid dynamics in the occurrence of intimal hyperplasia at sites of stenting, or on the preferred sites of occurrence of the process (Davies and Hagen, 1994). However, histopathological cross-sections of stented vessels (Sigwart, 1996) show in some instances a non-axisymmetric distribution of intimal hyperplasia, consistent with a role of the local flowfield in its development. Sigwart (recent personal communication) has suggested that important sites for the occurrence of intimal hyperplasia are immediately upstream and downstream of stents.

These are sites where compliance mis-match (artery distensibility greatly exceeds stent distensibility) has been considered to favour the development of intimal hyperplasia. However, they are for the same reason (and because arteries curve naturally in three dimensions and stents are effectively straight cylinders) also sites where distortion is expected of the vascular geometry and, in consequence, of the flowfield.

2.2 Arterial Geometry and Flow

The Reynolds number for flow in large and medium-sized human arteries is typically much greater than unity, implying that inertial forces dominate over viscous forces. As a result and as implied above, the flowfield is substantially determined by the local geometry. We have recently proposed that the curvature and branching of arteries is commonly non-planar. We have proposed furthermore that the flow is commonly swirling in nature and, unlike that associated with planar curvature and branching, characterised by a relatively uniform distribution of wall shear (Caro et al, 1996; Doorly et al, 1997).

In the light of these proposals and that intimal hyperplasia at end-to-side arterial bypass grafts affects preferentially regions which experience low wall shear, we have studied the velocity field in model planar and non-planar end-to side grafts, using steady laminar flow and methods including flow visualisation, MRI and computational fluid dynamics (Sherwin and Kamiadakis, 1996). The outstanding findings were much improved mixing within the non-planar model at the 'heel', 'floor' and 'toe,' the preferred sites for intimal hyperplasia, (Sherwin et al, 1997). In addition, we found with the non-planar model a marked reduction of peak wall shear stress at the 'floor' of the anastomosis and a greatly increased flux of velocity into the occluded region proximal to the anastomosis. Consequently, wall shear stress in the occluded region was higher with the non-planar model than the planar model (Sherwin et al, 1998).

In recent model studies, we have used a physiological non-steady flow and obtained generally similar results (Doorly et al, 1998). Moreover, in other recent studies with a model incorporating a sharp bend, we have found non-planar geometry apparently to affect the location and extent of flow separation and markedly to reduce the unsteadiness of the flow (Caro et al, 1998).

3.0 Research Proposals

In view of the foregoing, we propose a programme of research on the effects of stenting arteries on the local geometry and flowfield.

The long-term objective is to assess the effects of arterial stenting on the local geometry and flowfield in vivo in animals. As the first phase of the programme, we propose ex vivo studies, using excised animal arteries.

Since assessment of stent-induced distortion of the geometry and flowfield by MRI will constitute an important part of the programme, we have carried out some preliminary MRI work. This was done in our small-bore scanner with nitinol stents supplied by the Company. As shown by the attached note, we have obtained encouraging results both with respect to the geometry and the flow.

3.1 Ex Vivo Studies

3.1.1 MRI Studies

Our MRI studies will greatly benefit from the presence with us for a year on a visiting professorship of Dr. C.L. Dumoulin, a senior scientist from the GE R&D Center, Schenectady, NY.

Our small-bore MR scanner was upgraded last year with a new set of gradient amplifiers and control electronics. The upgrade provided the scanner with a maximum gradient strength of 5.8 G/cm, but there was limitation to a relatively slow rise time by software. Recent changes (again carried out through the generosity of GE) now permit the scanner to attain the full gradient strength with a rise time of 300 μsec. This capability, when combined with the customized pulse sequence software written by Dr. Dumoulin, makes our small-bore scanner particularly well suited for the investigation of flow phenomena in vessels and vessel phantoms. Fields-of-view as small as 2 cm are possible (in a typical whole-body magnet the field-of-view is limited to 4-8 cm). The largest matrix size is 512x512. Excitation of slices thinner than 1 mm is also possible (a typical whole-body magnet can excite slices 3 mm or thicker). The scanner has the capability to perform the full complement of clinical MR imaging protocols in addition to research pulse sequences.

MR Imaging of Stents In Vitro

We propose extension of the preliminary in vitro MRI studies, in order to establish the accuracy of imaging the geometry and flowfield in a small series of nitinol stents of different diameter, in the range 8 mm -3 mm.

The flows will be laminar and either steady or non-steady in the physiological range; we have access to a pump capable of generating physiological flow waveforms. The tubes in which the stents will be deployed will curve in one or more planes. The latter curvature will test the ability to measure stent geometry and the flowfield under nearly physiological conditions.

Although nitinol stents are metallic, their magnetic susceptibility is sufficiently close to that of human tissue to permit high quality MR imaging. One focus of the proposed work will be to investigate imaging strategies which minimise artifacts. These strategies are likely to include ultra-short echo times and modified spin-echo methods. Changes to the construction of the stent will also be investigated with the goal of creating a stent which has both improved flow characteristics and MR imaging characteristics.

MR Imaging of Stents in Excised Arteries

We propose to deploy nitinol stents supplied by the Company in freshly excised pig arteries. Vasomotor activity may be lost in the preparations, but it is unlikely that their distensibility will be grossly abnormal; similar preparations are widely used in vascular distensibility studies (Nichols and O'Rourke, 1990).

The stents will be deployed at a few selected sites where non-planar geometry can be expected - probably the origins of the coeliac, renal and common iliac arteries. To ensure near-physiological anatomy and mechanics, the stents will be deployed in vessels still tethered by surrounding tissues and still supported by major structures such as the lumbar spine.

We have expertise in preparing vascular casts and in studying the geometry and flowfield by MRI. Vessel geometry will be determined by preparing epoxy resin casts at physiological transmural pressure; in a few instances casts in different pig preparations will be made at systolic and diastolic pressure, to determine static strain over the pulse pressure. After setting, the cast will be dissected from tissue and imaged in our small-bore MR scanner.

For some studies, a latex mould will be made of the epoxy resin cast including inflow and outflow connections. The cast will subsequently be extracted and a range of assumed physiological flows will be applied to the mould replica of the cast, the geometry and flows being measured by MRI.

3.1.2 Computational Modelling

We propose to perform computational investigations on stented arterial geometries previously imaged by MRI. The geometric data will be derived from MR imaging of the epoxy resin casts (Caro et al, 1996). Information on strain over the pulse pressure range will be available from casts prepared as described above. For the present research we do not propose to investigate wall mechanical effects, such as compliance mismatch between the stented and adjoining unstented regions. This should be addressed as a separate issue.

In the first instance, the focus will be on investigating the flow at particular sites of arterial stenting (see above - origins of coeliac, renal and common iliac arteries) to ensure ease of imaging and geometric definition. (Subsequently, we propose to consider studies of the coronary.) For geometries appropriate to stenting at these locations, physiological inflow and outflow conditions will be prescribed. Stents are commonly deployed close to sites of branching, where the flow is considerably distorted. Furthermore, the flow within the stented region may partially or fully reverse during the cardiac cycle. It is proposed therefore that a range of flow conditions appropriate to the location of the stent be simulated, to assess the sensitivity of the flow within and adjacent to the stent to inflow conditions. The flow data derived from MR imaging will provide a check on the CFD. (Doorly et al, 1997;1998; Sherwin et al, 1998).

The computations will examine the effects of alterations in arterial geometry due to the presence of the stent, particularly with regard to wall shear stress distribution. Computational procedures which we have developed will also permit the tracking of blood particles such as platelets, so that the effects of transport and residence times of activated platelets may be modelled for varying stented geometries.

3.1.3 Modification of Stents to Lessen Distortion and Improve Flow

Contingent on local distortion of the geometry and flowfield being found, corrective procedures will be attempted. As a first step, use will be made of the shape-memory properties of nitinol stents. Stents will be pre-shaped to assume on deployment an appropriate geometry and procedures described above will be used to assess geometric and flowfield distortion.

In subsequent work, consideration may be given to the engineering of stents less likely to distort 2D and 3D vascular geometries.

Current designs of stents are shown in Figure 8. A series of rings are provided in which the material has the form of a vase as the ring is harnessed in the azimuthal direction, with occasional link members (see figure 9) which join one ring to the next or simple spot welds.

To incorporate torsional and bending flexibility these link members are replaced by elements with a considerably greater flexibility;

The flexibility may be achieved by increasing the length of the link member whilst changing their point of attachment as in Fig 10.

Alternatively the link members may be made of an appropriate spring like shape.

In the embodiments of figures 10 and 11, the link member is welded at some distance away from closest point, and is more flexible by virtue of increased length.

In the embodiment of figure 12, the link member is a wavy or spring coil form (at least in part) so that it has greater flexibility.

CLAIMS

1. A stent for supporting part of a blood vessel which stent includes a supporting portion around which or within which part of an intact blood vessel other than a graft can be placed so that the stent internally or externally supports that part and the supporting portion of the stent is of a shape and/or orientation which corresponds to the geometry of the vessel whereby flow within the stent-supported such vessel can follow a non-planar curve if present in the vessel at the site of the stent.

2. A stent for an intact blood vessel other than a graft which is adapted to flex three dimensionally but which maintains sufficient torsional flexibility to accommodate and maintain in use non-planar curvature present in arteries or veins.

3. A stent as claimed in claim 1 or 2 wherein the supporting portion of the stent is fabricated to incorporate a non-planar curved form.

4. A stent as claimed in any preceding claim wherein the supporting portion is fabricated to incorporate a geometric arrangement of the vessel whereby the tangent vector from the centreline of the stent intersects the centreline of the vessel by consequence of a symmetric

disposition of the stent with respect to the vessel at the junction with the stent.

5. A stent as claimed in any preceding claim which is of generally hollow tubular shape with three-dimensional curvature.

6. A stent as claimed in any one of claims 1 to 4 in the form of an open lattice generally tubular framework with discrete openings at each end thereof.

7. A stent as claimed in any preceding claim comprising a first supporting structure adapted to support or otherwise contact part of the vessel, with a secondary supporting structure extending away from the first supporting structure, but simultaneously capable of supporting the vessel part, said secondary structure capable of maintaining a vessel part when located therein in non-planar curvature.

8. A stent as claimed in claim 7 wherein the secondary supporting structure comprises a plurality of elongate members linked in the region of their ends remote from the first supporting structure.

9. A stent as claimed in claim 7 or 8 wherein said elongate members define a curved section whose curvature is non-planar.

10. A stent as claimed in any preceding claim fabricated from a material capable of torsional flexibility, such as from shape memory alloy.

11. A stent as claimed in any preceding claim which is for use in supporting a vessel part internally, fabricated from a linked mesh or series of linked wire members which is coiled or partly coiled or helical or partly helical.

12. A stent as claimed in any preceding claim in combination with a device which assists in monitoring the condition of the vessel.

13. A stent as claimed in claim 12 wherein the device is a sensor adapted to transmit a signal responsive to one or more internal flow conditions.

14. A stent as claimed in claim 13 in which the sensor is ring-shaped and is electrically connected to a remote module incorporating power supply, signal detection and recording means.

15. A stent as claimed in claim 13 or 14 wherein the sensor is adapted to transmit signals which can be monitored by ultrasound and/or magnetic resonance imaging and/or electron spin resonance imaging techniques.

16. A stent as claimed in any one of claims 13 to 15 wherein the sensor portion forms an integral part of the stent and the means of excitation and signal detection are entirely extracorporeal.

17. A stent for supporting part of an intact blood vessel other than a graft which stent includes a supporting portion around which or within which part of that blood vessel can be placed so that the stent internally or externally supports that part, in combination with at least one sensor device adapted to assist monitoring the condition of the vessel.

18. A stent as claimed in claim 17 wherein the sensory device is adapted to transmit a signal responsive to one or more internal flow conditions within the vessel part.

19. A stent as claimed in claim 17 or 18 wherein the sensory device is ring-shaped and is electrically connected to a remote module incorporating power supply, signal detection and recording means.

20. A stent as claimed in any one of claims 17 to 19 wherein the sensory device is adapted to transmit signals which can be monitored by ultrasound and/or magnetic resonance imaging and/or electron spin resonance techniques.

21. A stent as claimed in any one of claims 17 to 20 wherein the sensory device forms an integral part of the stent and the means of excitation and signal detection are entirely extracorporeal.

22. A vascular stent capable of insertion into or attachment externally to an intact blood vessel other than a graft which is adapted to impose non-planar flow therein or adopt its configuration in use to the geometry of the blood vessel so as to maintain therein any blood flow therein which is non-planar.

23. A stent as claimed in claim 22 in combination with a sensor device as defined in any of claims 13 to 21.

Application No: GB 9826254.6 **Examiner:** Anwar Gilani
Claims searched: 1-16, 22 and, in part, 23 **Date of search:** 23 November 1999

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.Q): A5R (RAR)

Int Cl (Ed.6): A61F 2/06

Other: Online: WPI, EPODOC, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
E,X	EP0891752 A1	(SCHNEIDER) col.2 l.35-40, col.4 l.47-col.5 l.34	1,2 and 22 at least
X	EP0788802 A2	(SCHNEIDER) p.2 l.51-p.3 l.9	1,2 and 22 at least
X	WO98/20810 A1	(MEDTRONIC) whole document	1,2 and 22 at least
X	US5879370	(FISCHELL ET AL) whole document	1,2 and 22 at least
X	US5749919	(BLANC) whole document, particularly col.1 l.58-col.2 l.10	1,2 and 22 at least
X	US5674277	(FREITAG) whole document	1,2 and 22 at least
X	US5041126	(GIANTURCO) col.2 l.5-20, col.3 l.64-col.4 l.14	1,2 and 22 at least
X	US4760849	(KROPF) col.3 l.60-col.4 l.8	1,2 and 22 at least

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