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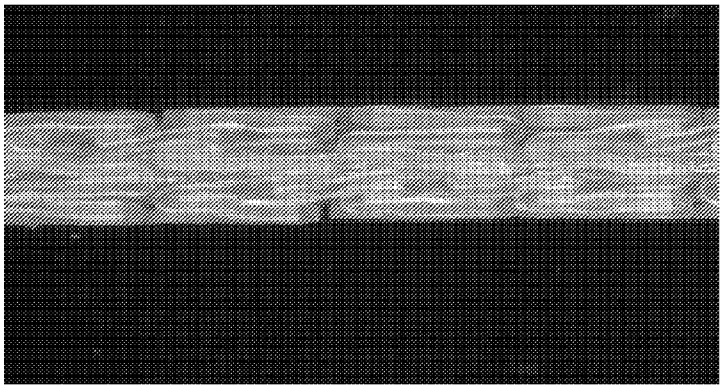

Figure 28

(57) Abstract: The present invention relates to an improved bioresorbable polymeric vascular stent device or patterns having least recoil and flexible enough to allow crimping and expansion for supporting and maintaining the patency of a body lumen. In particu - lar, the invention relates to stent pattern of bioresorbable and biocompatible polymer which fits within the body lumen namely blood vessels and is useful in treating various cardiovascular disorders like atherosclerosis, restenosis or cannanlicular obstructions. It also relates to delivering the drug via stent scaffold to adjacent vessel wall through a unique technology which leads to uniform distribu - tion of drug particles within the polymeric stent scaffold.

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"AN IMPROVED BIORESORBABLE POLYMERIC VASCULAR STENT DEVICE"

FIELD OF INVENTION

The present invention relates to an improved bioresorbable polymeric vascular stent device or patterns having least recoil and flexible enough to allow crimping and expansion for supporting and maintaining the patency of a body lumen. In particular, the invention relates to stent pattern of bioresorbable and biocompatible polymer which fits within the body lumen namely blood vessels and is useful in treating various cardiovascular disorders like atherosclerosis, restenosis or cannanlicular obstructions. It also relates to delivering the drug via stent scaffold to adjacent vessel wall through a unique technology which leads to uniform distribution of drug particles within the polymeric stent scaffold.

BACKGROUND AND PRIOR ART OF INVENTION

It is known that a stent is a medical device which serves as internal scaffold to increase or maintain the lumen of a body conduit. Stents have been widely used for coronary diseases, tracheobronchial obstruction; in oesophagus and gastrointestinal tract and in urology.

Metallic coronary stents are widely used for treatment of arterial dissection, elastic recoil, and intimal hyperplasia following percutaneous transluminal coronary angioplasty. Metal based stents permanently remain in the patient's body. They can induce endothelial dysfunction and inflammation which may further precipitate medical complications such as Late Stent Thrombosis (LST) and need for prolonged anti-platelet therapy. Currently metallic drug eluting stents are used for treating coronary artery disease. These stents are permanent implants and restrict natural healing process and vasomotion resulting in long term (more than 5 years post implantation) complications such as Very Late Stent Thrombosis. The risk of stent thrombosis due to metallic stents has not been overcome by even drug eluting stents. Rather, vascular lumen remodelling and expansion is prevented by use of such stents.

Restenosis is mainly caused by early constrictive remodelling (vessel shrinkage) and to some extent by hyper plastic healing response. Preventing constrictive remodelling can therefore, limit stent associated restenosis.

Bioresorbable stents overcome this limitation. They support a body conduit only during its healing process- usually 2 -3 years, leaving behind a normal, healthy artery free of any foreign body. With time, the mechanical load is transferred to the surrounding vessels and stent mass and strength decreases. During this process, it gradually loses its radial strength and ability to resist constrictive remodelling forces long before it is fully absorbed. Moreover, they allow longer term drug delivery to the vessel wall from an internal reservoir, which in turn eliminates the need for a second surgery to remove the device.

Nonetheless, technological challenges are associated with developing a stent from a bioresorbable polymer. It should have sufficient radial strength, also known as hoop or circumferential strength and rigidity to withstand radial compressive forces. The stent should prevent negative vessel remodelling and avoid stent deformity/strut fractures. It should have minimum recoil and should be sufficiently flexible to allow crimping and expansion. However, thickness of struts and long term creep are drawbacks associated with polymeric based stents.

A number of polymeric stents have been designed with varying geometries, linear or curved strut shapes (like diamond shaped cells, W-shaped cells, hour-glass shaped cells, parallelogram or quadrilateral shaped regions, bow-tie shaped cells, opposing M-shaped elements), and varying shapes of inter-linking bars like S, H, I, O, V. (e.g. *US Patent publication no.: US 2008/0234831 Al, US 2008/0046068 Al, US 2008/0132995 Al, 2007/0134289 Al, US 7,476245 B2, US 7,833,260 B2 , US 2010/0298926 Al, US 8,070, 793 B2, US 8002817 B2 , US 2011/0224778 Al, US 20130238078,)* to overcome the disadvantages associated with metallic stents. *US 7686843 B2* discloses a stent design which provides better radial rigidity, vessel coverage by allowing side branch access, reduced fore shortening, more flexibility. It provides better scaffolding per unit area of vessel wall to be supported.

US patent 7,988,721 B2 describes an axially-radially nested stent that maintains expanded size and resist recoil due to the slide and lock design. Such a locking mechanism has also been disclosed in US patent 7833260 B2, whereby the

locking mechanism secures the stent in crimped state onto a carrier module so that it stays immobilized for deployment. Another locking stent having multiple locking points has been disclosed in US patent publication number US 2004/0249442 Al wherein the inter-connecting elements of the stents are interlocked in one or the other position.

The inventors have identified following challenges and problems for developing Bioresorbable polymeric stent patterns.

Firstly, the stent pattern should be able to meet mechanical strength and should be capable of withstanding the structural loads, namely radial compressive forces, imposed on the stent as it supports the walls of a vessel. Therefore, a polymer stent must possess adequate radial strength. Radial strength, which is the ability of a stent to resist radial compressive forces, is due to strength and rigidity around a circumferential direction of the stent. Radial strength and rigidity, therefore, may also be described as, hoop or circumferential strength and rigidity.

Secondly, during deployment / expansion, the stent pattern must adequately maintain its size and shape throughout its service life despite the presence of various forces that may come to bear on it, including the cyclic loading induced by the beating heart. For example, a radially directed force may tend to cause a stent to recoil inward. Generally, it is desirable to minimize recoil of geometry after the forces are removed.

In addition, the stent pattern must possess sufficient flexibility to allow for crimping, expansion, and cyclic loading. Longitudinal flexibility is important to allow the stent pattern to be achieved through a circuitous vascular path and to enable it to conform to a deployment site that may not be linear or may be subject to flexure. Finally, the stent must be biocompatible so as not to trigger any adverse vascular responses.

Also, the structure of a stent pattern is typically composed of scaffolding that includes a pattern or network of interconnecting structural elements often referred to in the art as struts or bar arms. The scaffolding can be formed from polymeric tubes of cylindrical shape. The scaffolding is designed so that the stent pattern can be radially compressed (to allow crimping) and radially expanded (to allow deployment). A conventional stent is allowed to expand and contract through movement of individual

structural elements of a pattern with respect to each other. Thus, a stent pattern may be designed to meet the mechanical requirements of a stent described above which include radial strength, minimal recoil, plaque support, and flexibility.

In general, there are several important aspects in the mechanical behaviour of polymers that affect stent design. Polymers tend to have lower strength than metals on a per unit mass basis. Therefore, polymeric stents typically have less circumferential strength and radial rigidity than metallic stents of the same or similar dimensions. Inadequate radial strength potentially contributes to a relatively high incidence of recoil of polymeric stents after implantation into vessels.

Another problem with Bioresorbable polymeric stent patterns is that their ring struts or link arms can crack during crimping and expansion, especially for brittle polymers. The localized portions of the stent pattern subjected to substantial deformation tend to be the most vulnerable to failure. Furthermore, in order to have adequate mechanical strength, polymeric stents may require significantly thicker struts than a metallic stent, which results in an undesirably larger profile.

In addition, the bioresorbable polymeric stent patterns have long term creep. Long term creep is typically not an issue with metallic stents. Long term creep refers to the gradual deformation that occurs in a polymeric material subjected to an applied load. Long term creep occurs even when the applied load is constant. Long term creep in a polymeric stent reduces the effectiveness of a stent in maintaining a desired vascular patency. In particular, long term creep allows inward radial forces to permanently deform a stent radially inward.

Currently manufactured polymeric stents do not adequately provide sufficient tailoring of the properties of the material forming the stent to the desired mechanical behaviour of the device under clinically relevant in-vivo loading conditions. Moreover, the size of the stent scaffold for preventing restenosis depends on the vessel to be treated. There is a need to design and manufacture a vascular stent of various sizes (i.e. lengths and diameters) that can meet both clinical and mechanical requirements of the stent. Therefore, it would be desirable to have polymeric stents with stent patterns that provide adequate radial strength, minimal recoil, plaque support, and flexibility.

OBJECTIVES OF THE INVENTION

It is an object of the present invention to provide an improved bioresorbable polymeric vascular stent device or patterns with desired flexibility and strength which supports the vessel wall with a uniform force.

It is further an object of the present invention to provide a stent pattern which is made up of bioresorbable polymer whereby the geometry features and the material crystal orientation allows more radial rigidity.

It is yet another object of the present invention to provide a biodegradable polymer stent pattern with a crossing profile of less than 1.00 mm, preferably within 0.9-1 .00 mm diameter after crimping onto a balloon catheter.

It is yet another objective of the present invention preferable to have a circular or semi-circular cross section of the stent pattern to improve blood flow as well as reduce stress concentration in order to help in faster endothelisation within a diameter range of 100 - 150 microns.

SUMMARY OF THE INVENTION

The present invention relates to a radially expandable intravascular bioresorbable polymeric stent patterns for implanting in a bodily lumen, comprising a first radially expandable cylindrical ring of wavy ring struts in inverted double V-shape, a second radially expandable cylindrical ring adjacent to the first radially expandable ring, the first and second radially expandable cylindrical ring comprising wavy ring struts in inverted double V-shape, a plurality of link elements connecting adjacent cylindrical rings in such a manner that a plurality of interconnected cells are being created, each cell is formed by two flexible link elements, wherein the first proximal end of each link is connected to one location of the inverted double V-shape ring strut of first expandable cylindrical ring and distal end of each link is connected to the another location of the inverted V-shape ring strut of second expandable cylindrical ring. The said stent pattern as a scaffold has a cross over profile of 1.0 mm or less after crimping on a balloon catheter without failure of any ring struts or links.

Also, it is an aspect of the present invention that a bioresorbable expandable stent pattern having applications for supporting and maintaining the patency of a body lumen. In particular, the invention bioresorbable polymeric stent pattern hybrid design

is having ring strut and linking element / connector made of strut, corners and links. The link elements are seen as a tool to adding flexibility and connecting the ring struts; however, they can also be used as a counter for foreshortening if assembled and placed properly.

Another aspect of the present bioresorbable expandable stent pattern is that the said pattern enhances radial rigidity. Also, the stent design in the present invention minimizes cell area which in turn minimizes Maximum Circular Unsupported Surface Area (MCUSA).

The present design stent pattern struts are curved to add to radial strength and links are manipulated to achieve different design goals such as reduced foreshortening, minimum crossing profile, MCUSA etc.

Yet another aspect of present bioresorbable expandable stent pattern is that the different cell area is achieved by placing strut and links of radially expandable cylindrical ring. A converging/diverging area in the interconnected cells may be adapted for bifurcation. The present bioresorbable expandable stent pattern provides minimize cell area which minimizes MCUSA.

BRIEF DESCRIPTION OF FIGURES

Further aspects and advantages of the present invention will be readily understood from the following detailed description with reference to the accompanying drawings. Reference numerals have been used to refer to identical or similar functionally similar elements. The figures together with a detailed description below, are incorporated in and form part of the specification, and serve to further illustrate the aspects and explain various principles and advantages, in accordance with the present invention wherein:

FIG. **1** depicts a partial perspective view of an exemplary stent i.e. an inverted V shape ring strut of stent pattern according to the present invention.

FIG. la, lb, lc, Id: show the finite element simulation for crimped (la) and expanded (lc) profile of the stent and the movement of the struts and links during the same and

(lb) represent the recoil of the stent during crimping and 1 (d) represent recoil of stent during expansion respectively.

FIG 1e &FIG. 2 depicts various parts and angles of inverted V shape ring strut of stent pattern according to the present invention.

FIG. 3 depicts plurality of link elements connecting adjacent cylindrical ring struts in stent pattern according to the present invention.

FIG. 4 depicts plurality of link elements connecting adjacent cylindrical rings in one aspect of the stent pattern according to the present invention.

FIG. 5 depicts plurality of link elements connecting adjacent cylindrical rings in such a manner that pluralities of interconnected cell (as shown in enlarged view) are being created in stent pattern according to the present invention.

FIG. 6 depicts plurality of link elements connecting adjacent cylindrical rings in another aspect in such a manner that pluralities of interconnected cells are being created in stent pattern according to the present invention.

FIG. 7 depicts plurality of link elements connecting adjacent cylindrical rings in yet another aspect in such a manner that pluralities of interconnected cells (as sown in enlarged view are being created which are parallel to each other in stent pattern according to the present invention.

FIG. 8 depicts plurality of link elements connecting adjacent cylindrical rings in yet another aspect in such a manner that pluralities of interconnected cells are being created and interconnected cells are having converging or diverging cell areas in stent pattern according to the present invention.

FIG. 9 shows link element of stent pattern and ring strut of cylindrical ring of stent pattern wherein the thickness variation of each link element and ring strut according to one aspect of the present invention.

Fig. 10 & 11& 11a shows various aspect of the present invention of stent according to the present invention.

Fig. 12a shows a three-dimensional geometrical model of a stent pattern which consists usually two parts: links and rings.

Figure 12b shows a part of the stent which has been used for simulation and analysis.

Figure 12c shows the parameters of stent pattern such as Axial ring amplitude (f), Strut radius of curvature at the crown junctions (p), Strut width (e), and Thickness (t) which are studied and analysed.

Figure 12d shows Design-2 of present invention exhibit radial rigidity and radial strength compared to stent having conventional sinusoidal ring.

Figure 13 depicts a stent pattern in crimped condition during computer simulation illustration of the stent pattern according to the present invention as Case study 1

Figure 14 depicts a stent pattern in expanded condition during computer simulation illustration of the stent pattern according to the present invention as Case study 1

Figure 15 a) shows the Von-Misses after expansion b) Von-Misses after recoil c) diameter reduction after applying pressure and d) PEEQ on the stent pattern according to the present invention as Case study 1

Figure 16 shows a meshing and geometry of a commercial available stent pattern- 1 (AB) for the purpose of investigation and comparing with the stent pattern of the present invention as Case study 2

Figure 16a shows an expansion state of a meshing and geometry of a commercial available stent pattern- 1(AB) for the purpose of investigation and comparing with the stent pattern of the present invention as Case study 2

Figure 16b shows a recoil state of a commercial available stent pattern (AB) for the purpose of investigation and comparing with the stent pattern of the present invention as Case study 2

Figure 16c shows recoil and applying pressure condition of a commercial available stent pattern- 1 (AB) for the purpose of investigation and comparing with the stent pattern of the present invention as Case study 2

Figure 16d shows a graphical interpretation of the commercial available stent pattern- 1(AB).

Figure 16e shows stent pattern (l)-AB, (5)-AR, (6)-IG and (7)-MED as published in literature.

Figure 17 shows a commercial available stent pattern-3 (BO) for the purpose of investigation and comparing with the stent pattern of the present invention. Crimping is ignored in this simulation studies as Case study 3

Figure 17a shows a graphical interpretation of the commercial available stent pattern-3(BO).

Figure 18 shows a commercial available stent pattern-4 (OR) for the purpose of investigation and comparing with the stent pattern of the present invention. Crimping is ignored in this simulation studies as Case study 4

Figure 18a shows a graphical interpretation of the commercial available stent pattern-4 (OR).

Figure 19 depicts an inverted double V shape ring strut of stent pattern according to the present invention (DESIGN 2).

Figure 19a shows a graphical interpretation of the stent pattern DESIGN 2 according to the present invention.

Figure 20 shows a comparative graphical interpretation of the stent pattern DESIGN 2 according to the present invention and commercial available stent pattern Case study 2 (AB), Case study 3 (BO) and Case study 4 (OR).

Figure 21 & 21a shows the study on the flexibility of the stent pattern- 1(AB) that are commercial available or published in literature.

Figure 22 shows a graphical interpretation of flexibility study of the stent pattern-1(AB) of commercial available or published in literature.

Figure 23 a, b, c shows the study of the prior stent pattern and artery interaction during meshing stage and expansion stage.

Figure 23d shows the stresses on artery.

Figure 23e shows the recoil of stent due to artery pressure.

Figure 24 shows the prior art stent pattern (1) (AB) published in literature and studies on its geometry parameters.

Figure 25 shows the prior art stent pattern (5) (AR) published in literature and studies on its geometry parameters.

Figure 26 shows the prior art stent pattern (6) (IG) published in literature and studies on its geometry parameters.

Figure 27shows the prior art stent pattern (7) (MED) published in literature and studies on its geometry parameters.

Figure 28 shows the stent pattern (design 2) in crimped stage according to the present invention.

Skilled artisans will appreciate that elements in the drawings are illustrated for simplicity and have not necessarily been drawn to scale. For example, the dimensions of some of the elements in the drawings may be exaggerated relative to other elements to help to improve understanding of aspects of the present invention.

BRIEF DESCRIPTIONS OF THE TABLE

Table **1** shows the effect of thickness, width and amplitude on radial strength, recoil, foreshortening and PEEQ (equivalent plastic strain) on the stent pattern according to the present invention.

DETAIL DESCRIPTION OF INVENTION

While the invention is susceptible to various modifications and alternative forms, specific aspect thereof has been shown by way of example in the drawings and will be described in detail below. It should be understood, however that it is not intended to limit the invention to the particular forms disclosed, but on the contrary, the invention is to cover all modifications, equivalents, and alternative falling within the spirit and the scope of the invention as defined by the appended claims.

The Applicants would like to mention that the drawings are drawn to show only those specific details that are pertinent to understanding the aspects of the present invention so as not to obscure the disclosure with details that will be readily apparent to those of ordinary skill in the art having benefit of the description herein.

The terms "comprises", "comprising", or any other variations thereof, are intended to cover a non-exclusive inclusion, such that a system, device that comprises a list of components does not include only those components but may include other components not expressly listed or inherent to such system or device. In other words, one or more elements in a system or device proceeded by "comprises. .. a" does not, without more constraints, preclude the existence of other elements or additional elements in the system or device.

In the following description of the aspects of the invention, reference is made to the accompanying drawings that form part hereof and in which are shown by way of illustration specific aspects in which the invention may be practiced. The aspects are described in sufficient details to enable those skilled in the art to practice the invention, and it is to be understood that other aspects may be utilized and that changes may be made without departing from the scope of the present invention. The following description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined only by the appended claims.

Accordingly, the present invention relates to a radially expandable intravascular bioresorbable polymeric stent patterns for implanting in a bodily lumen, comprising: a first radially expandable cylindrical ring of wavy ring struts in inverted double V-shape, a second radially expandable cylindrical ring adjacent to the first radially expandable ring, the second radially expandable cylindrical ring comprising wavy ring struts in inverted double V-shape, a plurality of link elements connecting adjacent cylindrical rings in such a manner that a plurality of interconnected cells are being created, each cell is formed by two flexible link elements, wherein the first proximal end of each link is connected to one location of the inverted double V-shape ring strut of first expandable cylindrical ring and distal end of each link is connected to the another location of the inverted V-shape ring strut of second expandable cylindrical ring, the said stent pattern as a scaffold has a cross over profile of **1.0** mm or less after crimping on a balloon catheter without failure of any struts or links.

In a first aspect of the present invention, wherein a plurality of pairs of first and second radially expandable undulating cylindrical rings are longitudinally aligned and are connected at a plurality of intersections to form a plurality of irregular shaped cells.

In a second aspect of the present invention, wherein the first radially expandable cylindrical ring and second radially expandable cylindrical ring are either placed parallel or offset to each other.

In another aspect of the present invention, wherein inverted double V-shape ring struts having two diagonal arms and each arm is mirror shape of another arm and one is ascending arm and another is descending arm, that are joined at a point and forming an apex of double V-shape ring strut.

In yet another aspect of the present invention, wherein the inverted double V-shape ring strut of first and second radially expanded cylindrical ring having interior angle between 0 to 5 degree in crimped stage and 15 to 30 degrees in expanded condition.

In yet another aspect of the present invention, wherein the first and second radially expanded cylindrical rings are in non-deformed orientation, each ring is oriented at an angle less than 30 degrees relative to the direction in which stent pattern being expanded.

Still another aspect of the present invention, wherein each arm of inverted double V-shape ring strut is having three parts such as upper part, middle part and lower part, where the angle of inclinations of upper part and lower part are same.

Still another aspect of the present invention, wherein each arm of inverted double V-shape ring strut is having angle between 15 to 30 degrees in upper part, between 40 to 60 degrees in middle part and between 15 to 30 degrees in the lower part.

In yet another aspect of the present invention, wherein the link elements are flexible and straight connecting bar having proximal and distal ends in arc shape.

In yet another aspect of the present invention, wherein the proximal end of each link element is connected to the ring strut of first radially expanded cylindrical ring in the middle part or lower part or in between the middle part to lower part.

In yet another aspect of the present invention, wherein the distal end of each link element is connected to the ring strut of second radially expanded cylindrical ring in the upper part or middle part or in between the upper part to middle part.

Still another aspect of the present invention, wherein the first proximal end of each link element is connected to the descending arm of the inverted double V-shape ring strut of first expandable cylindrical ring and distal end of each link is connected to the descending arm of the inverted double V-shape ring strut of second expandable cylindrical ring.

A further aspect of the present invention, wherein the link element is positioned at various angles in the range of 0 to 5 degrees in crimped condition and in the range of 15 to 25 degrees in expanded condition.

A still further aspect of the present invention, wherein the link element having proximal end and distal end of higher thickness then the middle part of link element, the thickness proportion of ends/middle part is in the range of 150 to 200 microns.

In yet another aspect of the present invention, wherein the link elements are provided in the radially expanded cylindrical rings either alternate to each ring strut or adjacent to ring strut.

In yet another aspect of the present invention, wherein the link elements are provided in the radially expanded cylindrical rings in such a manner that converging or diverging interconnected cells are created in the stent pattern.

In yet another aspect of the present invention, wherein the interconnected cells in the stent pattern are irregular in shape and having cell area in the range of 2 to 3 mm^2.

Still another aspect of the present invention, wherein at least one sinusoidal cycle of first and second radially expanded cylindrical ring exist between the first and second link element.

A further aspect of the present invention, wherein comprising a medicinal agent included in or applied to the surface of the radially expandable undulating rings and the link elements.

In yet another aspect of the present invention, wherein the radially expandable undulating rings and link members are constructed of a material wherein an expansion of said stent to a deployment diameter involves marginal plastic deformation.

In yet another aspect of the present invention, wherein the radially expandable undulating rings and the link members are constructed of a material wherein an expansion of said stent to a deployment diameter involves substantially retained elastic deformation.

Still another aspect of the present invention, wherein the first radially expandable undulating ring, the second radially expandable undulating ring and the link element comprises a shape memory effect by design.

In yet another aspect of the present invention, wherein the first and second radially expandable undulating rings and the mirrored pair of first and second flexible members comprise a bioresorbable material.

In yet another aspect of the present invention, wherein said bioresorbable material is poly-L-lactic acid, PLLA, PLDA, PCL-PLA blends and alloys or any bioresorbable polymer or with suitable material properties for radial strength retention and degradation.

A still further aspect of the present invention, wherein the stent pattern has a cross over profile of 1mm or less in a crimped stage on to a balloon for easy insertion in a bodily lumen

Exemplary Devices

The various aspects of the present invention relate to polymeric stents pattern and methods of fabricating polymeric stents with favourable mechanical properties. The present invention can be applied to devices including, but is not limited to, self-expandable stents, balloon-expandable stents, stent-grafts, and grafts (e.g., aortic grafts).

FIG. 1 depicts a partial perspective view of an exemplary stent 100 that includes a pattern of a plurality of interconnecting structural elements or ring struts. Stent 100 has a cylindrical shape with an axis (X-X) and includes a pattern with a number of interconnecting structural elements or ring struts (lOOr). Axis (X-X) extends through the centre of the cylindrical shape. In general, a stent pattern is designed so that the stent can be radially compressed (as shown in figure (la) to allow for percutaneous delivery through an anatomical lumen, and then deployed (as shown in figure Id) for implantation at the desired segment of the anatomical lumen. As used herein, deployment of the stent refers to radial expansion (as shown in figure (lc) of the stent to implant (as shown in figure Id) the stent in the patient. The stresses involved during compression and deployment are generally distributed throughout various structural elements of the stent pattern.

The pattern of stent 100 in FIG. 1 allows for radial expansion (as shown in figure lc) and compression (as shown in figure la) and longitudinal flexure. The stent patterns may include bending elements i.e. arms of ring struts. Bending elements bend inward

when a stent is crimped to allow radial compression of the stent in preparation for delivery through an anatomical lumen. Bending elements also bend outward when a stent is deployed to allow for radial expansion of the stent within the anatomical lumen. After deployment, stent 100 is subjected to static and cyclic compressive loads from the vessel walls. Thus, bending elements may deform during use.

As indicated above, a stent must have certain mechanical requirements due to the magnitude and directions of stresses imposed on a stent during use, it is important for the mechanical stability of the stent to have suitable mechanical properties, such as strength and modulus, in the axial and circumferential directions. Therefore, it can be advantageous to modify the mechanical properties of a polymeric tube or sheet substrate, to be used in the fabrication of a stent pattern, by induced orientation from applied stress in the axial direction, radial or circumferential direction, or both simultaneously. Since highly oriented crystalline regions in polymers tend to be associated with higher strength and modulus, it may be desirable to incorporate processes that induce alignment of polymer chains along one or more preferred axes or directions into fabrication of stents.

A stent must have sufficient radial strength to withstand structural loads, namely radial compressive forces, imposed on the stent as it supports the walls of a vessel or other anatomical lumen. In addition, the stent must possess sufficient flexibility to allow for crimping, deployment, and cyclic loading. Also, a sufficiently low profile, that includes diameter and size of struts, is important. As the profile of a stent decreases, the easier is its delivery, and the smaller the disruption of blood flow during deployment.

As shown in figure (le), each ring strut having wavy ring strut double V-shape wherein each diagonal arm 103, 104, 106, 107 of inverted double V-shape ring struts are having three parts such as upper part 103U, middle part 103M and lower part 103L. The angle θ_2 is preferably in the upper part between 15 to 30 degrees, in middle part angle θ_3 between 40 to 60 degrees and angle θ_4 in the lower part between 15 to 30

degrees. However, it is preferred that the angle of inclinations of upper part and lower part remain same.

Further, as depicted in figure 2, each cylindrical ring 101 having wavy ring strut in inverted double V-shape 102 and having two diagonal arms 103, 104 and each arm is mirror shape of another arm and one is ascending arm 103 and another is descending arm 104, that are joined at a point and forming an apex 105 of double V-shape ring strut. Each inverted double V-shape ring strut of first and second radially expanded cylindrical ring having interior angle θι, between 0 to 5 degree in crimped stage and 15 to 30 degrees in expanded condition. When stent 100 is crimped, two diagonal arms 103, 104 moves inward and angles θι decrease, allowing the stent to be radially compressed. With respect to diagonal arms 103, 104, 106, 107 and so on, ring struts on either side of the diagonal arm elements bend toward each other.

Figure 3/4 depicts an exemplary stent pattern 100 cut from a polymeric substrate. Stent pattern 100 is shown in a flattened condition so that the pattern can be clearly viewed. When the stent pattern 100 is in a cylindrical form, it forms a radially expandable stent. Stent pattern 100 includes a plurality of cylindrical rings 101, 101A …etc. Embodiments of stent pattern 100 may have any number of rings 101 depending on a desired length of a stent. For reference, line X-X extends in a longitudinal or axial direction.

As shown in figure 3 and 4, the link elements 999 or 999(1), 999(2) etc are provided in the radially expanded cylindrical rings either alternate to each ring strut or adjacent to ring strut. As shown in figures 3 , each link elements 999 are provided after a gap of one inverted double V shape ring struts. In other words, two link elements 999(1) and 999(2) connecting adjacent cylindrical rings in such a manner that one cell area (900) is being created. Each cell area 900 consist two and half inverted V-shaped ring strut of both first 101 and second cylindrical ring 101A. The proximal ends (999(1)P, 999(2)P) of link element 999(1) and 999(2) are being connected to the first cylindrical ring (101) in the region between middle part (101M) and lower part (101L) of the diagonal arm (RA1, RA2) and distal ends (999(1)**D,** 999(2)**D)** are being connected to the second cylindrical ring in the region between

middle part (101AM) and upper part (101 AU) of the diagonal arm (RA3, RA4). The cell are in the stent pattern is in irregular shape and include at least one sinusoidal cycle of first and second radially expanded cylindrical ring that exists between the first and second link element. However, it is within the preview of modification in such a way that cell may consist any number of sinusoidal cycles in a cell area. The link element in figure 3 is having inclined placement as compared to figure 4 where the link element is substantially straight.

As shown in figure 5, one another aspect of the present invention is illustrated wherein stent pattern 100 includes linking elements 999, 999a, 999b that connect adjacent cylindrical rings. The link elements are flexible and straight connecting bar having proximal and distal ends in arc shapes. Linking elements 999 remain at an angle or inclined and connect adjacent cylindrical rings. For example Each link elements 999 is flexible and the first proximal end 999P of each linking element is connected to one location of the inverted double V-shape ring strut 102 of first expandable cylindrical ring 100 and distal end 999D of same link is connected to the another location of the inverted V-shape ring strut 102A of second expandable cylindrical ring.

As shown in figure 5, in a preferred aspect of the present invention the proximal end 999P of link element is connected to the ring strut 102 of first radially expanded cylindrical ring 101 in the middle part 102M or lower part 102L or in between the middle part 102M to lower part 102L. The distal end 999D of link element is connected to the ring strut 102A of second radially expanded cylindrical ring 101 A in the upper part 102AU or middle part 102AM or in between the upper part 102AU to middle part 102AM.

As illustrated in figure 5 the cell area between the adjacent cylindrical rings can be varied according the placement of the link elements between the adjacent cylindrical rings. The link elements 501, 502, 503, 504 may be provided in between each cylindrical ring in such a manner that two link elements 501 & 503 and 502 & 504 in axial direction being separated by one cell area as shown in figure 5. The cell area created by such link pattern shall be uniform throughout the cylindrical shape of

the stent as shown in figure 5. In the said illustration the cell area consist of 6 full arm of ring strut and 4, half arm of ring strut.

In yet another illustration of the present invention whereby the link elements 601, 602, 603, 604 may be provided in between each cylindrical ring in such a manner that two link elements 601 & 603 and 602 and 604 in axial direction next to each other as shown in figure 6. The expression next to each other means, the distal end of link 601D and proximal end of link element 603P is connected at one point and distal end of link 602D and proximal end of link element 604P is connected to the same point. The cell areas created by such link pattern are uniform throughout the cylindrical shape of the stent as shown in figure 6 and 7. In such illustration, each cell consists of 6 full arms of ring strut, and 4 half arms of ring strut.

In yet another aspect of the present invention the link elements 801, 802, 803, 804, 805, 806 may be provided in between each cylindrical ring in such a manner that two link elements 801 & 803 and 802 and 804 in axial direction next to each other as shown in figure 8 and further a gap of one cell area is provided. In other words, the link element 805 and 806 are provided in the adjacent cylindrical ring after first and second cylindrical ring and offset from the two link elements 801, 803 and 802, 804. The link elements 805, 806 is provided in between the third and fourth cylindrical ring in such a manner that each element is just next to each other as shown in figure 8. By providing link elements 801, 802, 803, 804, 805, 806 a converging cross section cell area can be achieved in between the cylindrical rings; and cell area created by such link elements obtained uniformly throughout the cylindrical shape of the stent pattern. The converging cell area is depicted by imaginary line B-B. A desired ratio of cell area CI: C2: C3 can be obtained by varying the position of link elements. However it is preferred to have this ratio in the range of 1:0.6: 0.2 to 1:0.9: 0.5. More preferably it should be 1:0.8:0.6. In such cases each cell area may consist varying number of arms, in between the cylindrical rings. Like cell area CI and C2, consist 8 full arms of ring strut & 4 half arm of ring strut and area C3 consist 4 half arm of ring strut.

Still another aspect of the present invention, wherein the thickness of link element 901 either may be uniform or may vary on the proximal ends 90IP and distal ends 90ID

as shown in figure 9. It is higher chances of failure of stent pattern at the proximal ends and distal ends of the link elements as these are curved portions and having bending area which experience substantial stress and strain when a stent is crimped and deployed. Therefore high strength and toughness are very important in these regions. Hence, it is within the purview of the present invention that the thickness of the link element at proximal end and distal end having higher thickness then the middle part of link element, the thickness proportion of ends/middle part is in the range of 120 to 200 microns.

Other aspect of the present invention

Figure 10 depicts another aspect of the present invention of exemplary stent pattern 100 for use with embodiment of a polymeric tube. The stent pattern 100 is shown in a flattened condition in order to have a clear view. A radially expandable stent is formed when this flattened portion of the stent pattern 100 is moulded in a cylindrical form.

As depicted in Figure 10, stent pattern 100 includes a plurality of cylindrical rings 302 with each ring including a plurality of amoebic (irregular) shaped cells 304. Any number of rings 302 can be included in the stent pattern 100 depending upon the length of the stent pattern which is desired. For reference, line Ac-Ac represents the longitudinal axis of a stent using the pattern depicted in Figure 10.

Amoebic shaped cells 304 are formed of two struts 305 and 306 lying opposite to other two struts 307 and 308. Struts 305 and 308 are S-shaped while struts 306 and 307 are N-shaped. The arrangement of the struts is such that struts with same shape lie diagonally opposite to each other. S-shaped strut comprises two diagonal linear bar arms 309 and 310, and three short linear bar arms 311, 312 and 313. N-shaped struts comprises two diagonal linear arms 314 and 315, and one short linear bar arm 316 which connects the two diagonal linear arms 314 and 315 via curved bar elements 317 and 318.

The stent pattern 100 further includes linking element i.e. interlinking arm 319 that is perpendicular to the line Ac-Ac. They connect the intersection of bar arms 305 and 306, and 307 and 308. Moreover, they connect cylindrical ring 304 with adjacent

cylindrical ring 304. The inter-linking elements are two question-marks being joined at their linear ends 320.

Another aspect of the present invention, wherein the stent pattern 100 can also be described as comprised of interconnected W-shaped elements 321. Embodiments of the stent depicted in the FIG. 11 above can include any number of circumferentially aligned W-shaped elements. Each W-shaped element is formed of one S-shaped strut 305 and one N-shaped strut 306. It comprises of three peaks 322,323, 324 and two depressions 325 and 326. The point of junction of these two ring struts links one W-shaped element with opposing W-shaped element by interlinking arm 319. This point of junction corresponds to one of the depressions 325 of W-shaped element 321. A valley 327 is formed when the inter-linking arm 319 connects two opposing W-shaped elements 321 at the junction point 325.

Yet another aspect of the present invention states that interlinking arm 319connects two opposing Y-shaped elements 328. As shown in figure 11a, Y-shaped elements have one long diagonal arm, two short straight arms one of which is connecting the interlinking arm 319. In this links are connected at end bar arm rather than at middle.

Accordingly, the invention relates to an improved stent design pattern comprising a plurality of irregular W-shape segments having three peaks and two depressions that is repeated circumferentially to form a ring and thereafter the ring is repeated along the length up to predetermined distance, and subsequently manipulated helically; link shown in Fig 10 & 11 & 11a., the said stent pattern consisting of 2 Y-shaped turning point and one fixed point and the link 319;. element described as 319 rotates about the fixed point in opposite direction in crimping and expansion to serve as a lock to reduce recoil; rotating link used for longitudinal stretching; two struts opening opposite at the peaks of Y-shaped element 328; helical aligned W-shaped elements 321; Element 319 for flexibility.

Manufacturing

Stent pattern 100 may be fabricated from a polymeric tube or a polymeric sheet that has been rolled and bonded to form a tube. A stent pattern may be formed on the polymeric tube or sheet by laser cutting away portions of the tube or sheet, leaving only struts and other members that function as scaffolding to support the walls of an anatomical lumen. Representative examples of lasers that may be used include, but are not limited to, excimer, carbon dioxide, and YAG. In other embodiments, chemical etching may be used to form a pattern on a tube.

Material Characteristics

The stents pattern of the present invention may be prepared from pure polymers, blends, and composites and may be used to prepare drug-loaded stents. The precursor material may be a tube or a film that is prepared by any suitable process, followed by laser cutting or any other suitable machining process. The precursor material may be used as prepared or can be modified by quenching, annealing, orienting or relaxing them under different conditions. Alternately, the laser cut stent may be used as prepared or may be modified by quenching, annealing, orienting or relaxing them under different conditions.

Mechanical Orientation

The effect of polymer orientation in a stent pattern may improve the stent performance including radial strength, recoil, and flexibility. Orientation may also vary the degradation time of the stent, so as desired, different sections of the stents may be oriented differently. Orientation may be along the axial and circumferential or radial directions as well as any other direction in the unit cell and flex connectors to enhance the performance of the stent in those respective directions. The orientation may be confined to only one direction (uniaxial), may be in two directions (biaxial) and/or multiple directions (multiaxial). The orientation may be introduced in a given material in different sequences, such as first applying axial orientation followed by radial orientation and vice versa. Alternately, the material may be oriented in both directions at the same time. Axial orientation may be applied by stretching along an axial or longitudinal direction in a given material such as tubes or films at

temperatures usually above the glass transition temperature of the polymer. Radial or circumferential orientation may be applied by several different methods such as blowing the material by heated gas for example, nitrogen, or by using a balloon inside a mold. Alternately, a composite or sandwich structure may be formed by stacking layers of oriented material in different directions to provide anisotropic properties. Blow molding may also be used to induce biaxial and/or multiaxial orientation.

Orientation may be imparted to tubes, films or other geometries that are loaded with drugs. For example, drug coated PLGA tubes prepared by any suitable process may be oriented at about 50° C to different amounts (for example, 30% to 200%) at different draw rates (for example, 95 mm/min to 900 mm/min). The conditions to draw the material is important to prevent excessive fibrillation and void formation that may occur due to the presence of drug. If the draw temperature is increased to a higher value (for example, 90 degrees C), then the orientation may not be retained as the temperature of orientation is much higher than the glass transition temperature of PLGA (about 60 degrees C.) and would cause relaxation of the polymer chains upon cooling.

Other methods of orienting the materials may include multi-stage drawing processes in which the material or device may be drawn at different draw rates at different temperatures before or after intermediate controlled annealing and relaxation steps. This method allows increasing the total draw ratio for a given material that is not otherwise possible in one-step drawing due to limitations of the material to withstand high draw ratio. These steps of orientation, annealing and relaxation will improve the overall strength and toughness of the material.

Polymeric material

Polymer tubes used for fabricating stents may be formed by various methods. These include, but are not limited to, extrusion and injection moulding. A tube used for fabricating a stent may be cylindrical or substantially cylindrical in shape. Conventionally extruded tubes tend to possess no or substantially no radial orientation or, equivalently, polymer chain alignment in the circumferential direction. In some embodiments, the diameter of the polymer tube prior to fabrication of a stent pattern

may be between about 1.5 mm and about 5.0 mm, or more narrowly between about 1.8 mm and about 3.5 mm.

Representative bio-absorbable material is poly-L-lactic acid, PLLA, PLDA, PCL-PLA blends and alloys or any bioresorbable polymer or any material with suitable material properties for radial strength retention and degradation. The polymeric material that may be used to fabricate embodiments of stent pattern disclosed herein include, but are not limited to, poly(N-acetylglucosamine) (Chitin), Chitosan, poly(3-hydroxyvalerate), poly(lactide-co-glycolide), poly(3-hydroxybutyrate),poly(4-hydroxybutyrate), poly(3-hydroxybutyrate-co-3 -hydroxyvalerate), polyorthoester, polyanhydride, poly(glycolic acid), poly(glycolide), poly(L-lactic acid), poly(L-lactide), poly(D,L-lactic acid), poly(D,L-lactide), poly(L-lactide-co-D,L-lactide), poly(caprolactone), poly(L-lactide-co-caprolactone), poly(D,L-lactide-co-caprolactone), poly(glycolide-co-caprolactone), poly(trimethylene carbonate), polyester amide, poly(glycolic acid-co-trimethylene carbonate), co-poly(ether-esters) (e.g. PEO/PLA), polyphosphazenes, biomolecules (such as fibrin, fibrinogen, cellulose, starch, collagen and hyaluronic acid), polyurethanes, silicones, polyesters, polyolefins, polyisobutylene and ethylene-alphaolefin copolymers, acrylic polymers and copolymers other than polyacrylates, vinyl halide polymers and copolymers (such as polyvinyl chloride), polyvinyl ethers (such as polyvinyl methyl ether), polyvinylidene halides (such as polyvinylidene chloride), polyacrylonitrile, polyvinyl ketones, polyvinyl aromatics (such as polystyrene), polyvinyl esters (such as polyvinyl acetate), acrylonitrile-styrene copolymers, ABS resins, polyamides (such as Nylon 66 and polycaprolactam), polycarbonates, polyoxymethylenes, polyimides, polyethers, polyurethanes, rayon, rayon-triacetate, cellulose, cellulose acetate, cellulose butyrate, cellulose acetate butyrate, cellophane, cellulose nitrate, cellulose propionate, cellulose ethers, and carboxymethyl cellulose. Additional representative examples of polymers that may be especially well suited for use in fabricating embodiments of stent pattern disclosed herein include ethylene vinyl alcohol copolymer (commonly known by the generic name EVOH or by the trade name EVAL), poly(butyl methacrylate), poly(vinylidene fluoride-co-hexafluoropropene) (e.g., SOLEF 21508, available from Solvay Solexis PVDF, Thorofare, NJ),

polyvinylidene fluoride (otherwise known as KYNAR, available from ATOFINA Chemicals, Philadelphia, Pa.), ethylene-vinyl acetate copolymers, poly(vinyl acetate), styrene-isobutylene-styrene triblock copolymers, and polyethylene glycol.

Drug Coatings / Threaupatic Agent

The bio absorbable polymer materials comprising the drug delivery stent according to the invention may include radiopaque additives added directly there to during processing of the matrix of the bioabsorbable polymer materials to enhance the radiopacity of the stent.

The radiopaque additives may include inorganic fillers, such as barium sulfate, bismuth subcarbonate, bismuth oxides and/or iodine compounds. The radiopaque additives may instead include metal powders such as tantalum, tungsten or gold, or metal alloys having gold, platinum, iridium, palladium, rhodium, a combination thereof, or other materials known in the art. The particle size of the radiopaque materials may range from nanometers to microns, preferably from less than or equal to 1 micron to about 5 microns, and the amount of radiopaque materials may range from 0-0.99 % by weight.

Because the density of the radiopaque additives is typically very high where the radiopaque materials are distributed throughout the matrix of bioresorbable absorbable materials, dispersion techniques are preferably employed to distribute the radiopaque additives throughout the bioresorbable materials as desired. Such techniques include high shear mixing, surfactant and lubricant additions, viscosity control, surface modification of the additive, and other particle size, shape and distribution techniques. In this regard, it is noted that the radiopaque materials may be either uniformly distributed throughout the bioresorbable materials of the stent, or may be concentrated in sections of the stent so as to appear as markers similar to as described above.

The local delivery of therapeutic agent/therapeutic agent combinations may be utilized to treat a wide variety of conditions utilizing any number of medical stent devices, or to enhance the function and/or life of the device.

For example, intraocular lenses, placed to restore vision after cataract surgery is often compromised by the formation of a secondary cataract. The latter is often a

result of cellular overgrowth on the lens surface and can be potentially minimized by combining a drug or drugs with the device. Other medical devices which often fail due to tissue in-growth or accumulation of proteinaceous material in, on and around the device, such as shunts for hydrocephalus, dialysis grafts, colostomy bag attachment devices, ear drainage tubes, leads for pace makers and implantable defibrillators can also benefit from the device-drug combination approach.

Devices which serve to improve the structure and function of tissue or organ may also show benefits when combined with the appropriate agent or agents. For example, improved osteointegration of orthopedic devices to enhance stabilization of the implanted device could potentially be achieved by combining it with agents such as bone-morphogenic protein.

Similarly other surgical devices, sutures, staples, anastomosis devices, vertebral disks, bone pins, suture anchors, hemostatic barriers, clamps, screws, plates, clips, vascular implants, tissue adhesives and sealants, tissue scaffolds, various types of dressings, bone substitutes, intraluminal devices, including stents, stent-grafts and other devices for repairing aneurysms, and vascular supports could also provide enhanced patient benefit using this drug-device combination approach. Perivascular wraps may be particularly advantageous, alone or in combination with other medical devices. The perivascular wraps may supply additional drugs to a treatment site. Essentially, any other type of medical device may be coated in some fashion with a drug or drug combination, which enhances treatment over use of the singular use of the device or pharmaceutical agent.

In addition to various medical devices, the coatings on these devices may be used to deliver therapeutic and pharmaceutic agents including: anti-proliferative/antimitotic agents including natural products such as vinca alkaloids (i.e. vinblastine, vincristine, and vinorelbine), paclitaxel, epidipodophyllotoxins (i.e. etoposide, teniposide), antibiotics (dactinomycin (actinomycin D) daunorubicin, doxorubicin and idarubicin), anthracyclines, mitoxantrone, bleomycins, plicamycin (mithramycin) and mitomycin, enzymes (L-asparaginase which systemically metabolizes L-asparagine and deprives cells which do not have the capacity to synthesize their own asparagines); antiplatelet agents such as G(GP) II_b/III_a inhibitors and vitronectin receptor antagonists; anti-proliferative/antimitotic alkylating agents such as nitrogen mustards

(mechlorethamine, cyclophosphamide and analogs, melphalan, chlorambucil), ethylenimines and methylmelamines (hexamethylmelamine and thiotepa), alkyl sulfonates-busulfan, nirtosoureas (carmustine (BCNU) and analogs, streptozoicin), trazenes — dacarbazinine (DTIC); anti-proliferative/antimitotic antimetabolites such as folic acid analogs (methotrexate), pyrimidine analogs (fluorouracil, floxuridine and cytarabine) purine analogs and related inhibitors (mercaptopurine, thioguanine, pentostatin and 2-chlorodeoxyadenosine {cladribine}); platinum coordination complexes (cisplatin, carboplatin), procarbazine, hydroxyurea, mitotane, aminoglutethimide; hormones (i.e. estrogen); anti-coagulants (heparin, synthetic heparin salts and other inhibitors of thrombin); fibrinolytic agents (such as tissue plasminogen activator, streptokinase and urokinase), aspirin, dipyridamole, ticlopidine, clopidogrel, abciximab; antimigratory; antisecretory (breveldin); anti-inflammatory; such as adrenocortical steroids (Cortisol, cortisone, fludrocortisone, prednisone, prednisolone, 6a-methylprednisolone, triamcinolone, betamethasone, and dexamethasone), non-steroidal agents (salicylic acid derivatives i.e. aspirin; para-aminophenol derivatives i.e. acetaminophen; indole and indene acetic acids (indomethacin, sulindac, and etodalec), heteroaryl acetic acids (tolmetin, diclofenac, and ketorolac), arylpropionic acids (ibuprofen and derivatives), anthranilic acids (mefenamic acid, and meclofenamic acid), enolic acids (piroxicam, tenoxicam, phenylbutazone, and oxyphenthatrazone), nabumetone, gold compounds (auranofin, aurothioglucose, gold sodium thiomalate); immunosuppressives: (cyclosporine, tacrolimus (FK-506), sirolimus (rapamycin), azathioprine, mycophenolatemofetil); angiogenic agents: vascular endothelial growth factor (VEGF), fibroblast growth factor (FGF); angiotensin receptor blockers; nitric oxide donors, antisense oligionucleotides and combinations thereof; cell cycle inhibitors, mTOR inhibitors, and growth factor receptor signal transduction kinase inhibitors; retenoids; cyclin/CDK inhibitors; HMG co-enzyme reductase inhibitors (statins); and protease inhibitors.

As described herein various drugs or agents may be incorporated into the stent by a number of mechanisms, including blending it with the polymeric materials or affixing it to the surface of the device. Different drugs may be utilized as therapeutic agents,

including sirolimus, or rapamycin, heparin, everolimus, tacrolimus, paclitaxel, cladribine as well as classes of drugs such as statins. These drugs and/or agents may be hydrophilic, hydrophobic, lipophilic and/or lipophobic.

As shown in figure 28, to improve visibility of the stent pattern when it is implanted in the patient is important to the medical practitioner for locating the stent, radiopaque materials may be added to the device.

The radiopaque materials may be added directly to the matrix of bioresorbable materials. Alternately, the radiopaque materials may be added to the stent in the form of a layer, a coating, a band , a metallic marker or powder at designated portions of the stent depending on the geometry of the stent and the process used to form the device.

Coatings may be applied to the stent in a variety of processes known in the art such as, for example, chemical vapor deposition (CVD), physical vapor deposition (PVD), electroplating, high-vacuum deposition process, microfusion, spray coating, dip coating, electrostatic coating, or other surface coating or modification techniques. Such coatings sometimes have less negative impact on the physical characteristics (e.g., size, weight, stiffness, flexibility) and performance of the stent than do other techniques.

Preferably, the radiopaque material does not add significant stiffness to the device so that the stent may readily traverse the anatomy within which it is deployed. The radiopaque material should be biocompatible with the tissue within which the device is deployed. Such biocompatibility minimizes the likelihood of undesirable tissue reactions with the device. Inert noble metals such as gold, platinum, iridium, palladium, and rhodium are well-recognized biocompatible radiopaque materials.

Other radiopaque materials include barium sulfate ($BaS0_4$), bismuth subcarbonate [$(BiO)_2C0_3$] and bismuth oxide. Preferably, the radiopaque materials adhere well to the stent such that peeling or delamination of the radiopaque material from the stent is minimized, or ideally does not occur. Where the radiopaque materials are added to the device as metal bands, the metal bands may be crimped at designated sections of the device. Alternately, designated sections of the device may be coated with a radiopaque metal powder, whereas other portions of the device are free from the metal powder.

Before describing working examples or case studies, following expressions are explained for the purpose of the present invention.

1. Plastic deformation

When sufficient load is applied to a structural member such that stresses go beyond the yield stress point, then the deformation is called plastic deformation. The deformation produced after yield stress is permanent.

2. Elastic strain

This is a form of strain in which the distorted body returns to its original shape and size when the deforming force is removed., it is within the proportional limit of the material behavior.

3. Radial recoil

Percentage by which the diameter of a stent decreases from its expanded diameter (when the balloon is inflated at the nominal pressure) to its relaxed diameter (when the balloon is retrieved from the stent).

4. Radial strength

Radial strength describes the external pressure that a stent is able to withstand without incurring significant permanent reduction in the vessel lumen.

5. Radial Stiffness

Stiffness is defined as how much the diameter of a stent is reduced by the application of external pressure. This correlates the rigidity of the tubular contraption and is linked with its collapsibility.

6. Foreshortening

Percentage by which the length of a stent decreases from its crimped state to its deployed state (when the balloon is retrieved from the stent).

7. Stress concentration

Stress concentrations are one of the factors contributing to catastrophic failure or reduce the fatigue life. Stress concentration occurs at the curved or sharp geometrical portions in all the simulations for a stent.

WORKING EXAMPLES / CASE STUDIES

Case Study-1

a) The purpose of this investigation is to employ the finite element method to evaluate the impact of varying specific stent design parameters on the radial force of stent.

b) Also, to discuss the difference in methodology for the development of metal and polymer stent.

c) To develop the methodology to compare different stent pattern designs.

Fig. 12a shows a three-dimensional geometrical model of a stent which consist usually two parts: links and rings. Figure 12b shows a part of the stent which has been used for simulation and analysis. Figure 12c shows the parameters of stent pattern such as Axial ring amplitude (f), Strut radius of curvature at the crown junctions (p), Strut width (e), and Thickness (t) which are studied and analysed. All stent (simplified to a ring) designs had the same original outer diameter of 1.2 mm which was served for the coronary arteries having an inner diameter of 3 mm.

Finite Element Models

A stent pattern model consisting of one sixth of a ring (Fig. 12(b)) is sufficient for prediction of more complex stent behaviour. The ABAQUS 6.10 finite element package is used to calculate the radial force and recoil of the stent. To develop the finite element model, the ring is first modelled on SolidWorks-2010 and then exported to ABAQUS. The stent is assumed to be made of PLLA. The Von Misses yield creation and bi-linear isotropic hardening rule are adopted here. The general mechanical properties of this material are as follows:

Density: 1260 Kg/m3 Young's modulus = 3.4 GPa

Poisson's ratio= 0.33 Yield strength=60 MPa.

Simulation methods

Figure 13 depicts a stent pattern in crimped condition during computer simulation illustration of the stent pattern according to the present invention and Figure 14 depicts a stent pattern in expanded condition during computer simulation illustration

of the stent pattern. In this study a three-step process is modelled (see Fig. 13). The first step was to expand the stent to nominal diameter (3.5) from its crimped diameter of (1.2) mm. The second step is to remove the constraint to simulate the deflation of balloon, restoring elastic deformation and retaining plastic deformation. The third step is to compress the stent by external pressure of 1.5 bar on the outer surface of the stent until it collapsed.

The balloon is modelled as cylinder of 30 micron thickness, and is placed at the centre of the ring. All the nodes of the balloon are given outward radial displacement, so that all the struts of the stent get deformed to the deployed shape. The stent underwent plastic deformation during deployment. Later the balloon is deflated by bringing the nodes of the balloon to its original coordinates. While doing so the stent slightly sprang back due to elastic strain. This phenomenon is called as radial recoil.

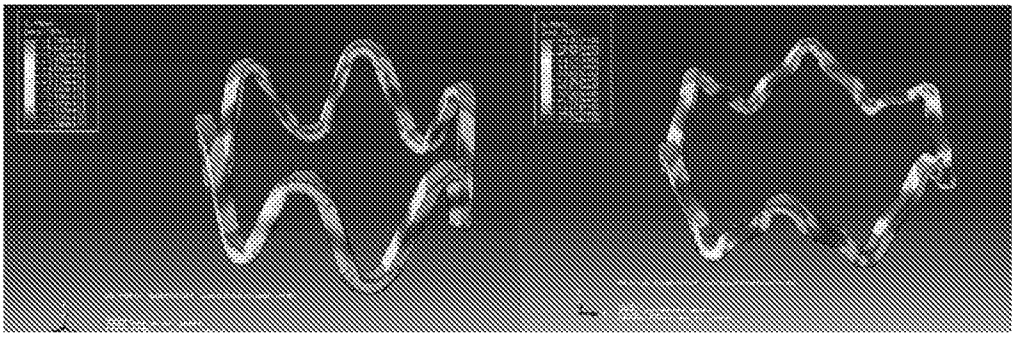
Radial strength describes the external pressure that a stent is able to withstand without incurring significant permanent reduction in the vessel lumen. In this study important stent parameters such as radial recoil, radial strength, foreshortening, stress concentration are studied using non-linear Finite Element Analysis with varying number of crowns, width, thickness and strut length. Crimp diameter is fixed to 1.2 mm. Effect on total amplitude and crown radius is also observed. Crimping is ignored in this simulation. This simple understanding can be used to optimize various design parameters in stent design. The dimensions of the ring used in this analysis are as listed below:

As crimp diameter:	1.2 mm (fixed)
Strut Length:	variable (0.6, 0.8,1 mm)
Number of coils:	variable (6, 7)
Width of the strut:	variable (0.12, 0.15, 0.18 mm)
Thickness of the strut:	variable (0.12, 0.15, 0.18 mm)

Simulation results

Table 1 shows the effect of thickness, width and amplitude on radial strength, recoil, foreshortening and PEEQ on the stent pattern according to the present invention.

The same modelling procedures which are used to study parameter variation Vs mechanical performance for case study- 1 is used to study the radial rigidity of Design-2.



Conventional Sinusoidal ring strut strut-modification (design-2)

Pressure Vs change in diameter graph is shown below.

As from the figure 12d Design-2 has better radial rigidity and radial strength compared to simple sinusoidal ring.

Discussion:

a) Effect of Thickness

As expected, the radial force increases linearly with an increasing strut thickness. It can be shown that with increase in thickness flexibility decreases. So it is necessary to optimize the stent thickness to provide the best balance between the radial force and the flexibility of the stent. Von Misses stress distribution in the simulation is found to be above the yield stress of the PLLA (60 Mpa). Figure 15 a) shows the Von-Misses stress analysis after expansion b) Von-Mises stress analysis after recoil c) diameter reduction after applying pressure and PEEQ (equivalent plastic strain) on the stent pattern according to the present invention.

b) Effect of width

With increase in width radial force also increase for same number of crown, thickness and amplitude. With increase in width foreshortening doesn't change much as expected, while PEEQ increases significantly. A little change in amplitude is observed. Recoil decreases.

c) Effect of strut length:

With increase in strut length recoil increase and radial strength decrease, Foreshortening and PEEQ also decrease. But amplitude increases.

d) Effect of Deployed Diameter

It can be shown that radial force required in expanding the stent increases as the deployment diameter increases. The percentage foreshortening increases and the percentage radial recoil decreases as expected with an increase in deployment diameter.

Effects of Accumulated Plastic Strain on Radial Strength, Recoil and Foreshortening

Radial strength of the stent increases with an increase in the accumulated plastic strain. This means that the stent can hold more pressure from the arterial walls i.e. the stent is stronger. Radial recoil and the foreshortening is reduced due to accumulated plastic strains.

CONCLUSION

The results show that amplitude was the dominant parameter in this study. Increasing either strut width or thickness generally improved radial force of stent. However, increasing amplitude generally weakened it.

The amount of radial force or crush resistance provided by each stent depends mainly on the stent material properties and design.

It is found that the thickness of the strut has a major effect on the radial strength of the stent. The radial strength increases with an increase in the strut thickness of the stents, this corresponds to a decrease in the flexibility of the stent. Since the stent is used in very complex areas it is important to have a balance between the radial strength and flexibility of the stent. The stent strut thickness has an important effect on the radial strength of the stent. The radial strength increases with an increase in the strut thickness while the max stress in the stent also increases. The analysis of the effects of accumulated plastic strain shows that the radial strength of the stent increases when there is an increase in the accumulated plastic strain also there is less radial recoil. This demonstrates that if the stent can be fabricated at a greater diameter and then crimped to its minimum diameter then the radial strength of the stent can be further increased.

Based on inventor's findings, a stent should have large strut thickness, large strut width, small amplitude, and small radius of curvature to possess excellent radial

force. However, there are practical limitations in the range of values of these parameters. For example, some stents show superior strength to others, largely due to an increased strut thickness but also due to differences in design and material properties. However, increasing the strut thickness not only provides higher mechanical strength and stiffness but also may reduce the longitudinal flexibility and increase the profile. Therefore, no more than an adequate mechanical support should be considered when designing stent patterns. Additional structural concerns include the need to tack up intimal flaps and fatigue behaviour. Finally, the impact on the flow field must also be considered, as fluid dynamics could influence many biologic responses.

Therefore, the methodology carried out is reliable and proposed as a pre-clinical testing tool, which could be used to compare and contrast exiting stent designs and to develop novel and improved stent pattern /designs. Based on above trials, it has been observed that an ideal stent 1) Should be easy to implant, 2) Have minimum crossing profile, 3) Have markers at different locations for accurate positioning, 4) Good radial strength to keep the arteries open, 5) Be available in different lengths, 6) Have good resistance to thrombosis and 7) Must have excellent bio and blood compatibility.

Case Study-2

The purpose of this investigation is to compare some commercially available stent designs. Similar steps as in Case study- 1 are adopted here. Crimping is ignored in this simulation too.

The stiffness has units of stress and is provided in classical units of N/mm^2. In contrast, stent strength is provide in atm (1 atm = 105 N/m^2) for the sake of coherence with the common physiological and clinical measurement units. A smooth step pressure of 1.5 bar=0.15 MPa was applied on outer surface of stent after the stress relaxation. Pressure and diameter was recorded. Following simulation cases are discussed: Procedure is illustrated by figures in following order

1. Design Solid Model (crimped)
2. Meshing (FEM)
3. Expansion (Von-Mises Stress)

4. Stress relaxation (Von Mises Stress)
5. Diameter and Von-Mises for 0.15 MPa

Pattern 1 (AB design)

It is an open cell polymer scaffold. It is an in phase sinusoidal rings joined by three longitudinally in line, straight bridges.

Figure 16 shows a FE mesh and geometry of commercial available stent pattern (AB) for the purpose of investigation and comparing with the stent pattern of the present invention. Crimping is ignored in this simulation studies. (Case study 2). As indicated in this figure the length of stent is 4.92 mm and outer diameter (crimped state) is 1.2 mm.

Figure 16a shows a commercial available stent pattern 1(AB) wherein the length of stent get reduced to 2.92 mm from original length of 4.62 mm when expanded to 3.68 mm diameter.

Figure 16b shows a recoil state of a commercial available stent pattern 1 (AB). Outer diameter of the stent recoils to 3.3 1 mm from 3.68 mm due to elastic recoil.

Figure 16c shows further recoil by applying pressure condition of a commercial available stent pattern 1(AB) .A pressure of 0.15 Mpa or 1.5 bar is applied on outer surface after elastic recoil to simulate load transfer from artery to stent. Diameter of stent is further reduced to 3.04 mm due to artery pressure.

Hence, from the said simulation results above recoil is calculated as:
Elastic recoil= (3.68-3.3 1)/3.68 =10.05%
Foreshortening = (4.92-4.62)/4.92 = 6.1 %

Figure 16d, A graph between change in diameter (mm) Vs applied pressure for stent pattern 1 (AB) is drawn to study radial strength. A 0.33 mm change in diameter was observed for 0.15 Mpa pressure.

Case Study-3 (BO)

Figure 17 shows a commercial available stent pattern 3 (BO) for the purpose of investigation and comparing with the stent pattern of the present invention. Crimping is ignored in this simulation studies. Geometry, meshing, expansion, elastic recoil and pressure recoil results are shown respectively.

(Case study 3)

It is an open cell scaffold with simplest manifestation in terms of geometry of ring-link topology. In this two inclined bridges join adjacent rings.

Figure 17 a. A graph between changes in diameter (mm) Vs applied pressure for stent pattern 3 (BO) is drawn to study radial strength. A 0.272 mm change in diameter was observed for 0.15 Mpa pressure.

Case Study-4 (OR)

Figure 18 shows a commercial available stent pattern 4 (OR) for the purpose of investigation and comparing with the stent pattern of the present invention. Crimping is ignored in this simulation studies. Geometry, meshing, expansion, elastic recoil and pressure recoil results are shown respectively.

(Case study 4)

This is a hybrid cell topology where adjacent rings are joined by inclined bridges.

Figure 18a. A graph between change in diameter (mm) Vs applied pressure for stent pattern 4 (OR) is drawn to study radial strength. A 0.556mm change in diameter was observed for 0.15 MPa pressure.

Case Study-5 (SMT-Present invention) (DESIGN 2)

Figure 19 depicts an inverted double V shape ring strut of stent according to the present invention (DESIGN 2) wherein a first radially expandable cylindrical ring of wavy ring struts in inverted double V-shape, a second radially expandable cylindrical ring adjacent to the first radially expandable ring, the second radially expandable cylindrical ring comprising wavy ring struts in inverted double V-shape, a plurality of link elements connecting adjacent cylindrical rings in such a manner that a plurality of interconnected cells are being created, each cell is formed by two flexible link

elements, wherein the first proximal end of each link is connected to one location of the inverted double V-shape ring strut of first expandable cylindrical ring and distal end of each link is connected to the another location of the inverted V-shape ring strut of second expandable cylindrical ring. The stent as a scaffold has a cross over profile of 1mm or less after crimping on a balloon catheter without failure of any struts or links.

.Figure 19 a shows a graphical interpretation of the stent pattern DESIGN 2 according to the present invention. A graph of diameter change Vs applied pressure is drawn for Design-2 stent pattern. From figure it can be seen that initially diameter decreases rapidly then becomes constant to 0.0215 mm. at 0.15 mpa.

Figure 20 shows a comparative graphical interpretation of the stent pattern DESIGN 2 according to the present invention and commercial available stent pattern Case study 2 (AB), Case study 3 (BO) and Case study 4 (OR). A comparison is shown in this figure. From figure it can be seen that the radial strength of Design-2 is greater than others.

The various aspect of the present invention is illustrated by the following set forth examples. All parameters and data are not to be construed to unduly limit the scope of the embodiments of the invention

Figures 16e, Geometry of some commercially available stent designs in published literature (AB-stent pattern- 1, AR-stent pattern-5, IG-stent pattern-6, MED-stent pattern-7) are shown for comparing the cell area, MCUSA and artery coverage.

A comparison of geometric properties is done in following table.

Assumption which has been considered:

1. All material properties, dimensions of tube diameter and wall thickness were kept equal in all the case studies.

2.The design values are calculated for 3 mm outer diameter PLA based manufactured stent as per individual design features for comparative assessment

S. no.		Cell Area	Average Crimp Profile	Artery Coverage	MCUSA
1.	Design 2 (Present invention)	2.52	1.2	0.24	0.636
2	Design- 1 (Present invention)	3.17	0.95	0.169	0.853
3	AB-pattern 1	3.05	1.5	0.239	0.79
4	AR-pattern 5	1.63	1.5	0.213	1.3
5	IG-pattern 6	4.46	1.5	0.203	0.85
6	MED-pattern 7	6.43	1.5	0.199	1.1 1

Figure 21 shows the study on the flexibility of the stent that are available in literature and stent according to the present invention. (Case study 4). Figure shows the deformed configuration in bending.

Figure 22 shows a graphical interpretation of flexibility study of the stent pattern DESIGN 2 according to the present invention and commercial available stent pattern. (Case study 4)

Graph of curvature index Vs Bending moment is shown to study the flexibility for the purpose of pushability and trackability in tortuous pathways of the artery.

Figure 23 a, b, c, d shows the study of the stent pattern and artery interaction of the present invention, in meshing stage, expansion stage and recoiling stage. In 23(a) solid model assembly of balloon plaque and artery is shown, which is imported in to ABAQUS for FEM analysis. Plaque is modelled as Hicks-Henne Bump function to simulate the general restenosis shape.

Figure 23(b) shows the mesh in ABAQUS.

In 23(c) the result after expansion through a rigid cylinder is shown. Stent is expanded to 3.5 mm diameter to serve an artery of 3 mm inner diameter. Then the cylinder is deflated inwards to allow the load transfer from artery to stent.

In 23(d) the contact pressure on artery due to interaction between stent and plaque is shown. Stresses on artery are used to study the injury during stent expansion, which is a measure of restenosis.

In figure 23(e), recoil due to artery pressure is shown.

Figure 24 shows the prior art stent pattern (1) (AB) and studies of Cell area, MCUSA and artery coverage.

Figure 25 shows the prior art stent pattern (5) (AR) and studies of Cell area, MCUSA and artery coverage.

Figure 26shows the prior art stent pattern (6) (IG) and studies Cell area, MCUSA and artery coverage.

Figure 27shows the prior art stent pattern (7) (MED) and studies Cell area, MCUSA and artery coverage.

Figure 28 shows the stent pattern of the present invention (Design 1) and studies of crimping, expansion and artery interaction.

ADVANTAGES OF THE INVENTION

1. The first advantage of the present invention is to provide an improved stent design with desired flexibility and strength which supports the vessel wall with a uniform force.
2. Another advantage of the present invention is to provide a stent which is made up of bioresorbable polymer whereby the crystal orientation allows more radial rigidity.
3. Yet another advantage of the present invention to provide a stent which remains radio-opaque for a fixed life of the bioresorbable stent and gradually elutes a drug into the vessel wall.

The inventors have developed the invention, so that advantage can be achieved in an economical, practical, and facile manner. While preferred aspects and example configurations have been shown and described, it is to be understood that various further modifications and additional configurations will be apparent to those skilled in the art. It is intended that the specific embodiments and configurations here in disclosed are illustrative of the preferred nature of the invention, and should not be interpreted as limitations on the scope of the invention.

THE CLAIM

1. An improved bioresorbable polymeric vascular stent device or patterns for implanting in a bodily lumen, comprising:
    a. a first radially expandable cylindrical ring of wavy ring struts in inverted double V-shape,
    b. a second radially expandable cylindrical ring adjacent to the first radially expandable ring, the second radially expandable cylindrical ring comprising wavy ring struts in inverted double V-shape,
    c. a plurality of link elements connecting adjacent cylindrical rings in such a manner that a plurality of interconnected cells are being created, each cell is formed by two flexible link elements, wherein the first proximal end of each link is connected to one location of the inverted double V-shape ring strut of first expandable cylindrical ring and distal end of each link is connected to the another location of the inverted V-shape ring strut of second expandable cylindrical ring,
    d. the said stent pattern as a scaffold has a cross over profile of 1.0 mm or less after crimping on a balloon catheter without failure of any struts or links.
2. The stent pattern as claimed in claim 1, wherein a plurality of pairs of first and second radially expandable undulating cylindrical rings are longitudinally aligned and are connected at a plurality of intersections to form a plurality of irregular shaped cells.
3. The stent pattern as claimed in claim 1, wherein the first radially expandable cylindrical ring and second radially expandable cylindrical ring are either placed parallel or offset to each other.
4. The stent pattern as claimed in claim 1, wherein inverted double V-shape ring struts having two diagonal arms and each arm is mirror shape of another arm and one is ascending arm and another is descending arm, that are joined at a point and forming an apex of double V-shape ring strut.
5. The stent pattern as claimed in claim 1, wherein the inverted double V-shape ring strut of first and second radially expanded cylindrical ring having interior

angle between 0 to 5 degree in crimped stage and 15 to 30 degrees in expanded condition.

6. The stent pattern as claimed in claim 1, wherein the first and second radially expanded cylindrical rings are in non-deformed orientation, each ring is oriented at an angle less than 30 degrees relative to the direction in which stent pattern being expanded.

7. The stent pattern as claimed in claim 1, wherein each arm of inverted double V-shape ring strut is having three parts such as upper part, middle part and lower part, where the angle of inclinations of upper part and lower part are same.

8. The stent pattern as claimed in claim 1, wherein each arm of inverted double V-shape ring strut is having angle between 15 to 30 degrees in upper part, between 40 to 60 degrees in middle part and between 15 to 30 degrees in the lower part.

9. The stent pattern as claimed in claim 1, wherein the link elements are flexible and straight connecting bar having proximal and distal ends in arc shape.

10. The stent pattern as claimed in claim 1, wherein the proximal end of each link element is connected to the ring strut of first radially expanded cylindrical ring in the middle part or lower part or in between the middle part to lower part.

11. The stent pattern as claimed in claim 1, wherein the distal end of each link element is connected to the ring strut of second radially expanded cylindrical ring in the upper part or middle part or in between the upper part to middle part.

12. The stent pattern as claimed in claim 1, wherein the first proximal end of each link element is connected to the descending arm of the inverted double V-shape ring strut of first expandable cylindrical ring and distal end of each link is connected to the descending arm of the inverted double V-shape ring strut of second expandable cylindrical ring.

13. The stent pattern as claimed in claim 1, wherein the link element is positioned at various angles in the range of Oto 5 degrees in crimped condition and in the range of 15 to 25 degrees in expanded condition.

14. The stent pattern as claimed in claim 1, wherein the link element having proximal end and distal end of higher thickness then the middle part of link element, the thickness proportion of ends/middle part is in the range of 150 to200 microns.

15. The stent pattern as claimed in claim 1, wherein the link elements are provided in the radially expanded cylindrical rings either alternate to each ring strut or adjacent to ring strut.

16. The stent pattern as claimed in claim 1, wherein the link elements are provided in the radially expanded cylindrical rings in such a manner that converging or diverging interconnected cells are created in the stent pattern.

17. The stent pattern as claimed in claim 1, wherein the interconnected cells in the stent pattern are irregular in shape and having cell area in the range of 2 to 3 mm^2.

18. The stent pattern as claimed in claim 1, wherein at least one sinusoidal cycle of first and second radially expanded cylindrical ring exist between the first and second link element.

19. The stent pattern as claimed in claim 1, further comprising a medicinal agent included in or applied to the surface of the radially expandable undulating rings and the link elements.

20. The stent pattern claimed in claim 1, wherein the radially expandable undulating rings and link members are constructed of a material wherein an expansion of said stent to a deployment diameter involves marginal plastic deformation.

21. The stent pattern as claimed in claim 1, wherein the radially expandable undulating rings and the link members are constructed of a material wherein an expansion of said stent to a deployment diameter involves substantially retained elastic deformation.

22. The stent pattern as claimed in claim 1, wherein the first radially expandable undulating ring, the second radially expandable undulating ring and the link element comprises a shape memory effect by design.

23. The stent pattern as claimed in claim 1, wherein the first and second radially expandable undulating rings and the mirrored pair of first and second flexible members comprise a bio-absorbable material.

24. The stent pattern as claimed in claim 1, wherein said bio-absorbable material is poly-L-lactic acid, PLLA, PLDA, PCL-PLA blends and alloys or any bioresorbable polymer or with suitable material properties for radial strength retention and degradation.

25. The stent pattern as claimed in claim 1 has a cross over profile of 1mm or less in a crimped stage on to a balloon for easy insertion in a bodily lumen

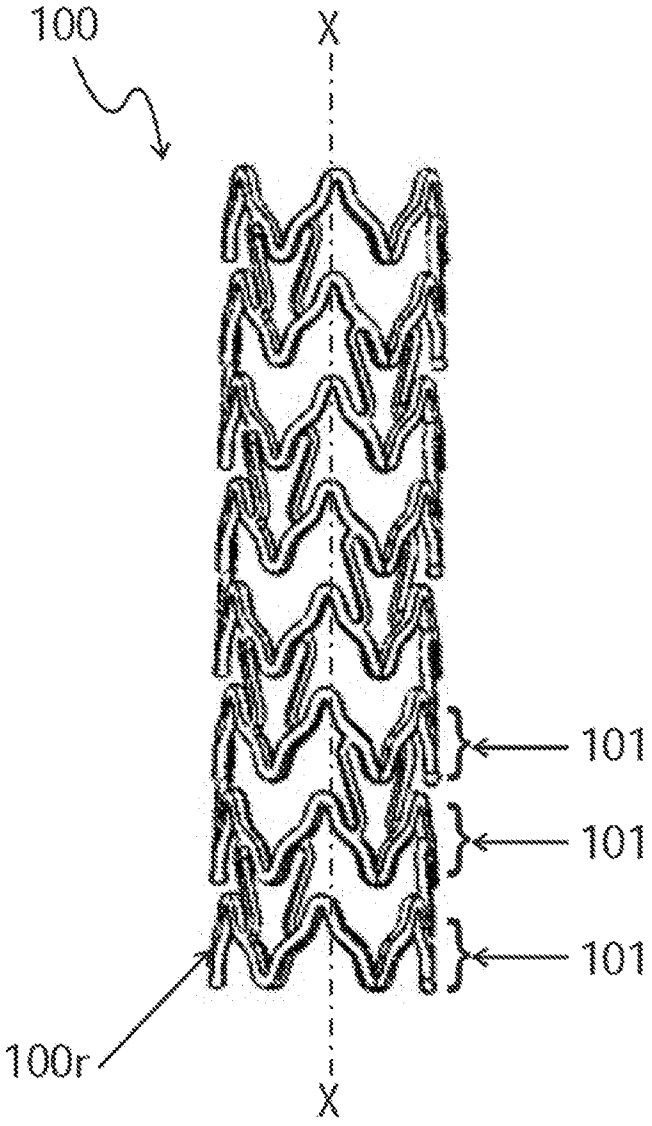


Figure 1

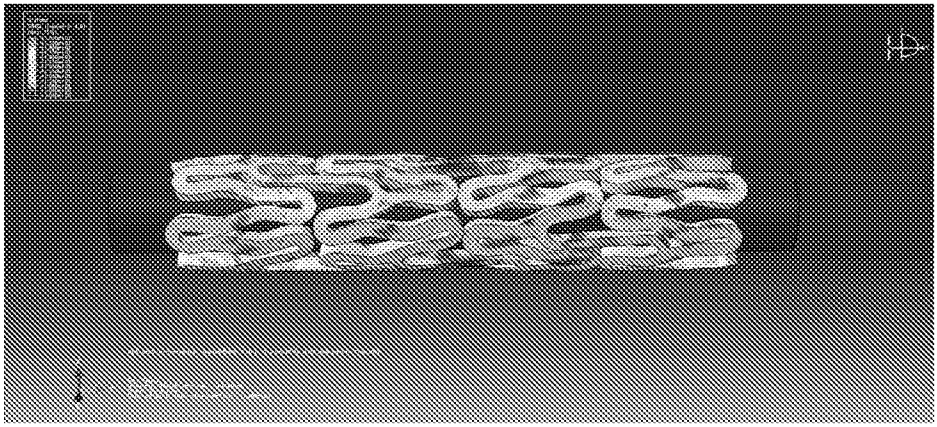


Figure 1(a)

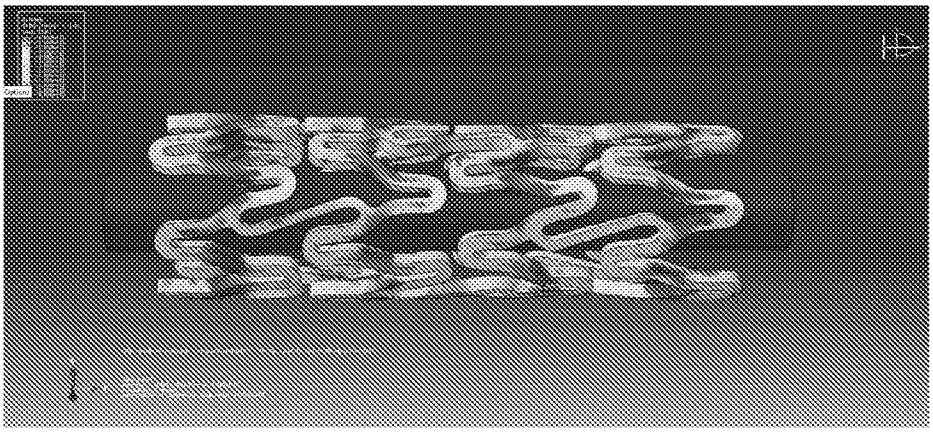


Figure 1(b)

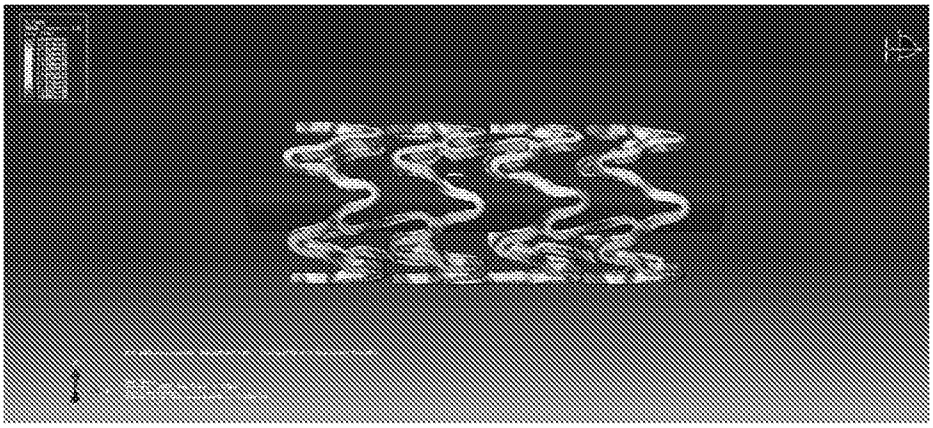


Figure 1(c)

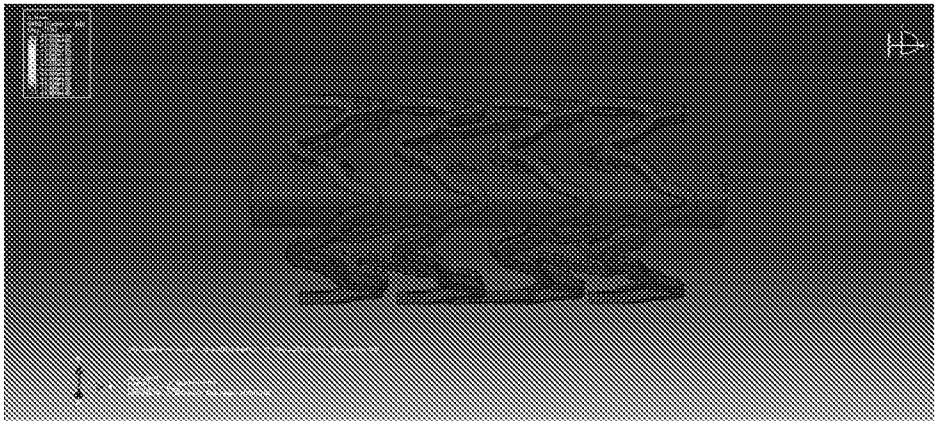


Figure 1(d)

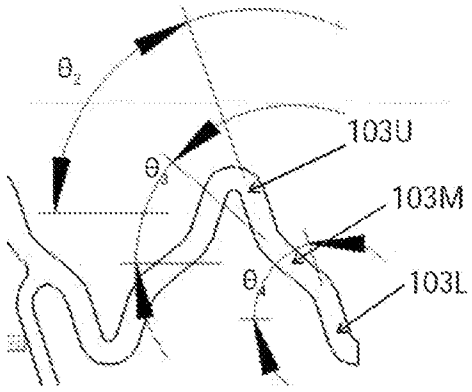


Figure 1(e)

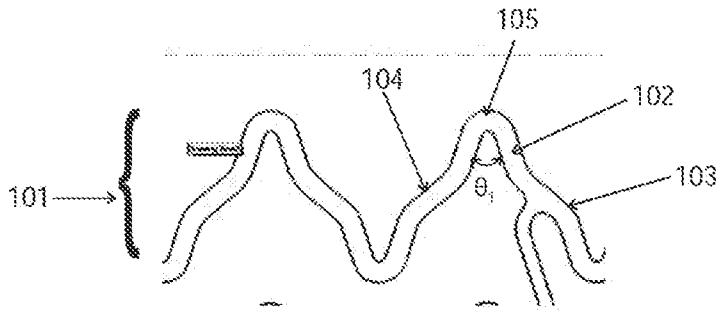


Figure 2

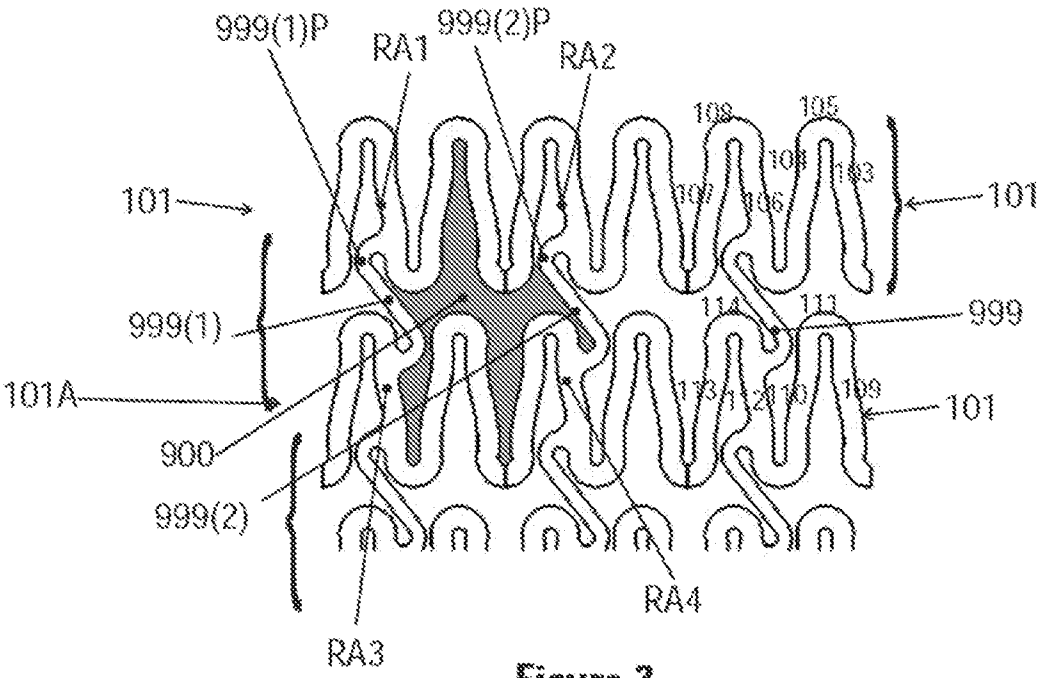


Figure 3

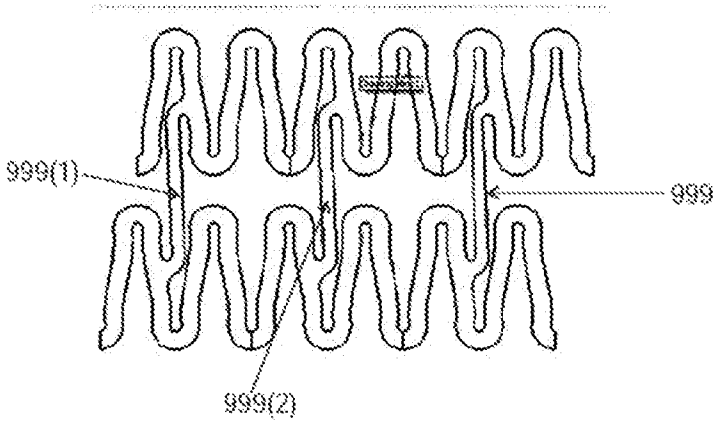


Figure 4

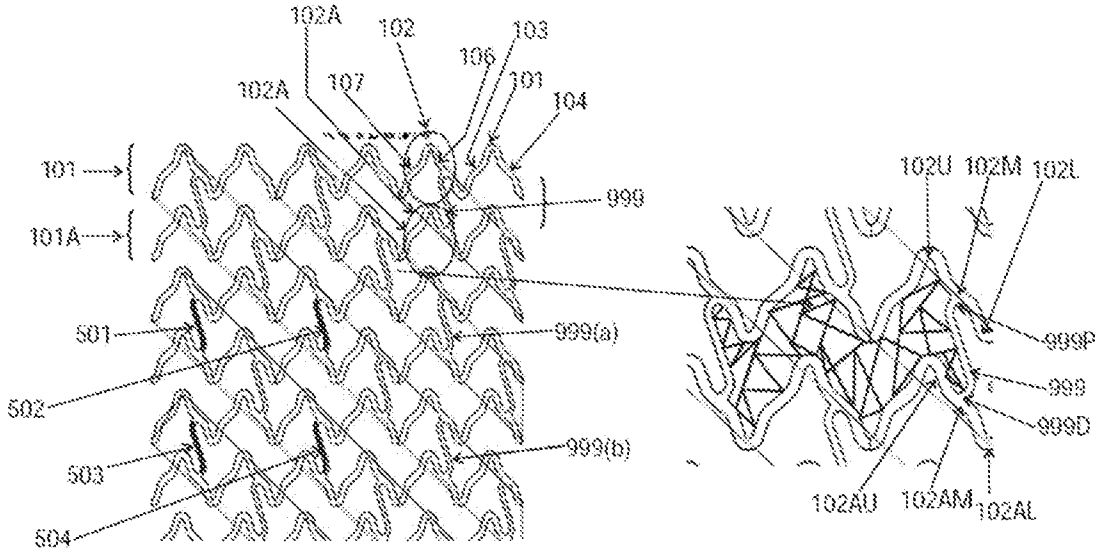


Figure 5

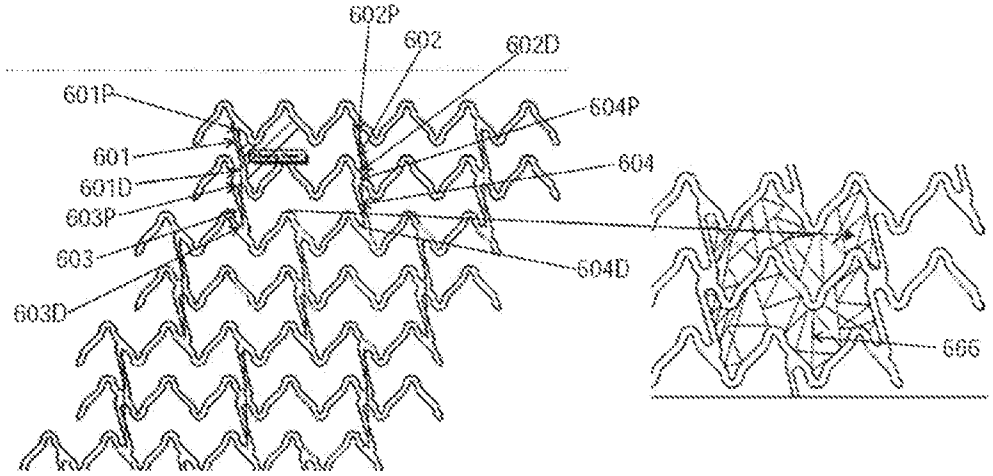


Figure 6

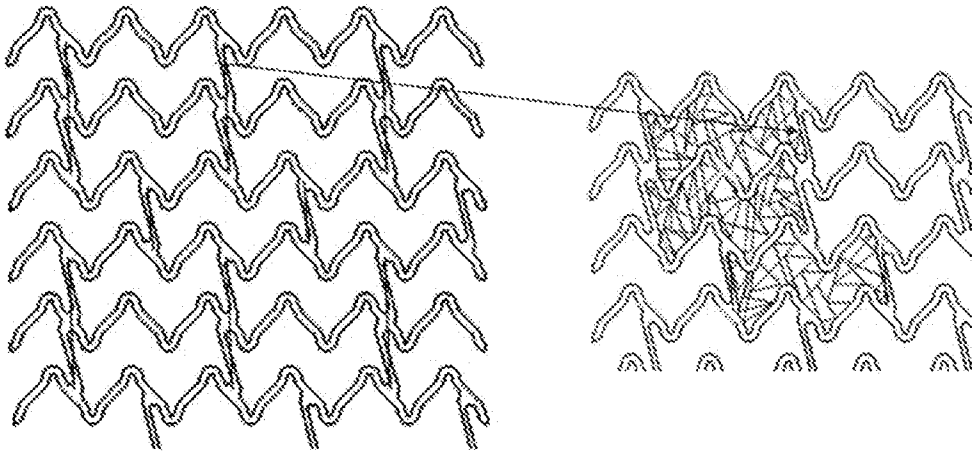


Figure 7

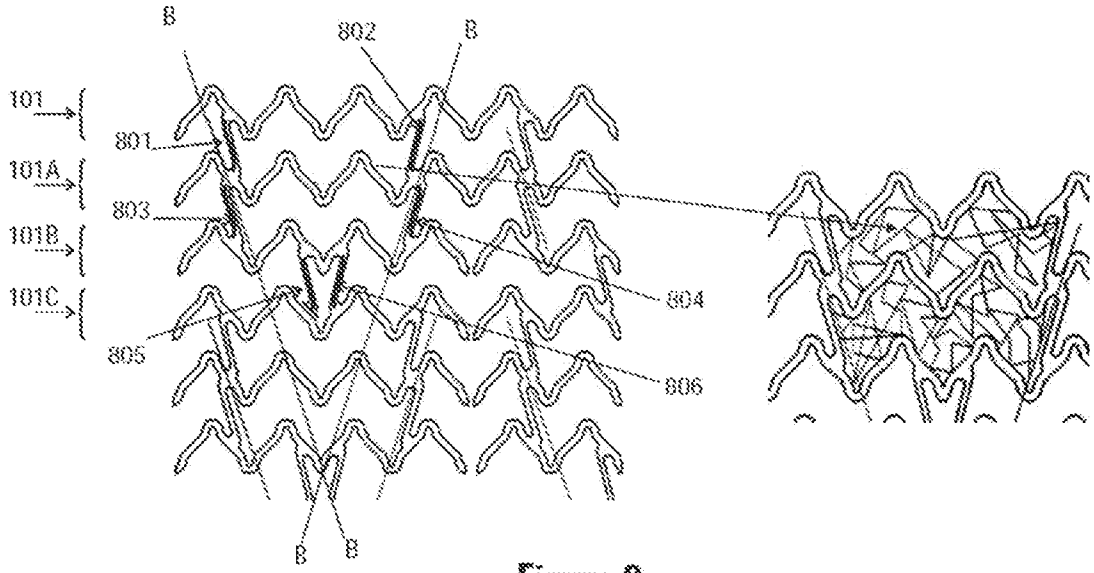


Figure 8

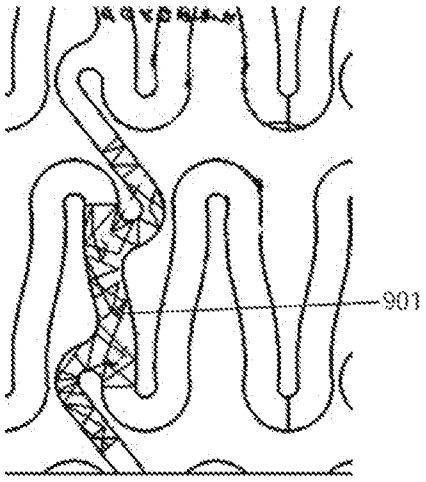


Figure 9

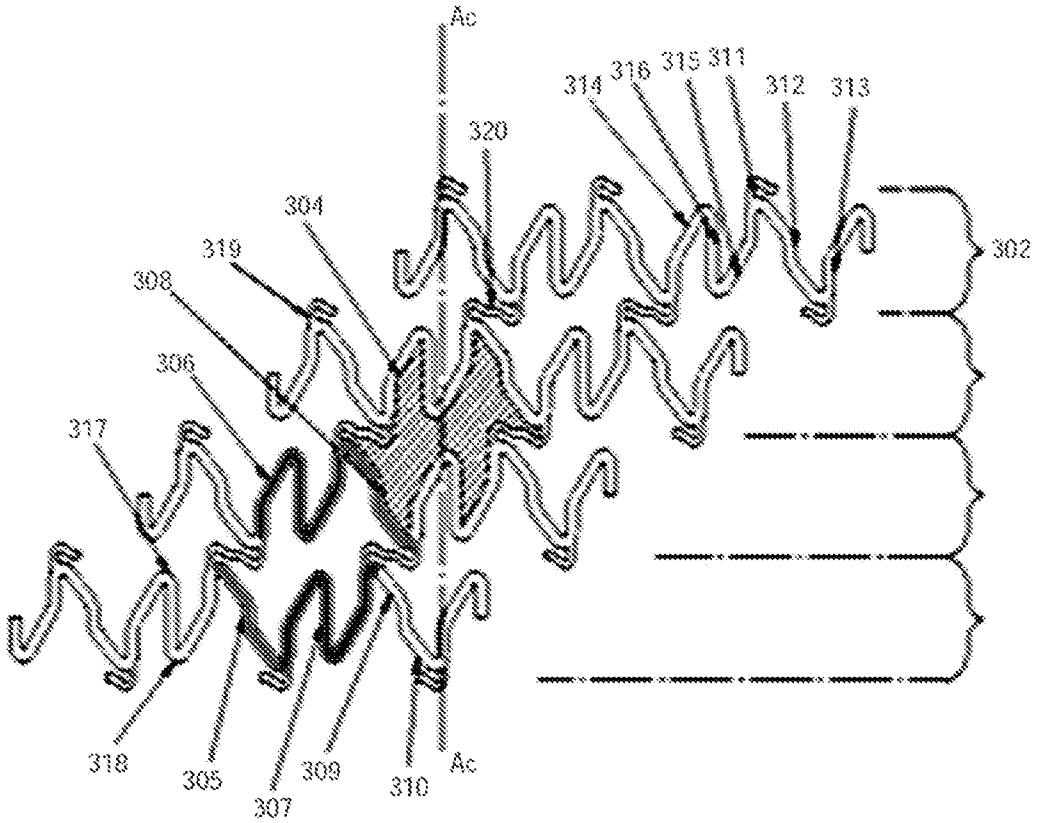


Figure 10

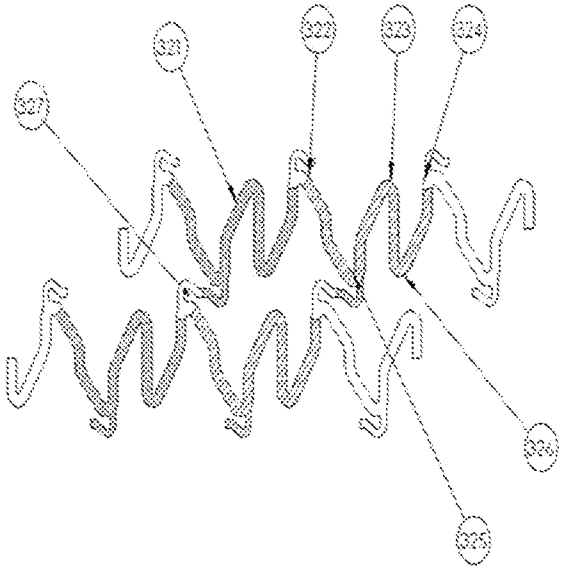


Figure 11

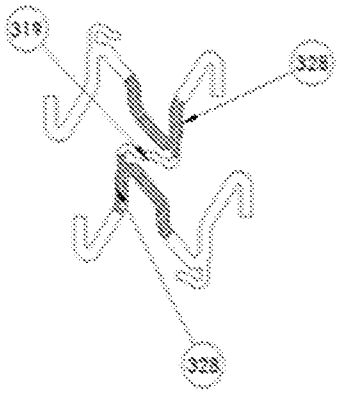


Figure 11(a)

Case Study-1

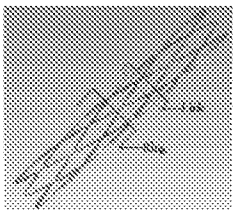


Figure 12(a)

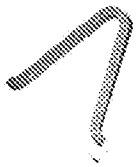


Figure 12(b)

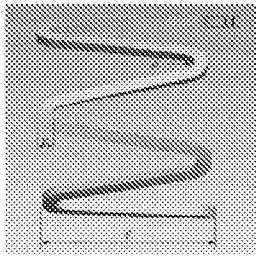


Figure 12 (c)

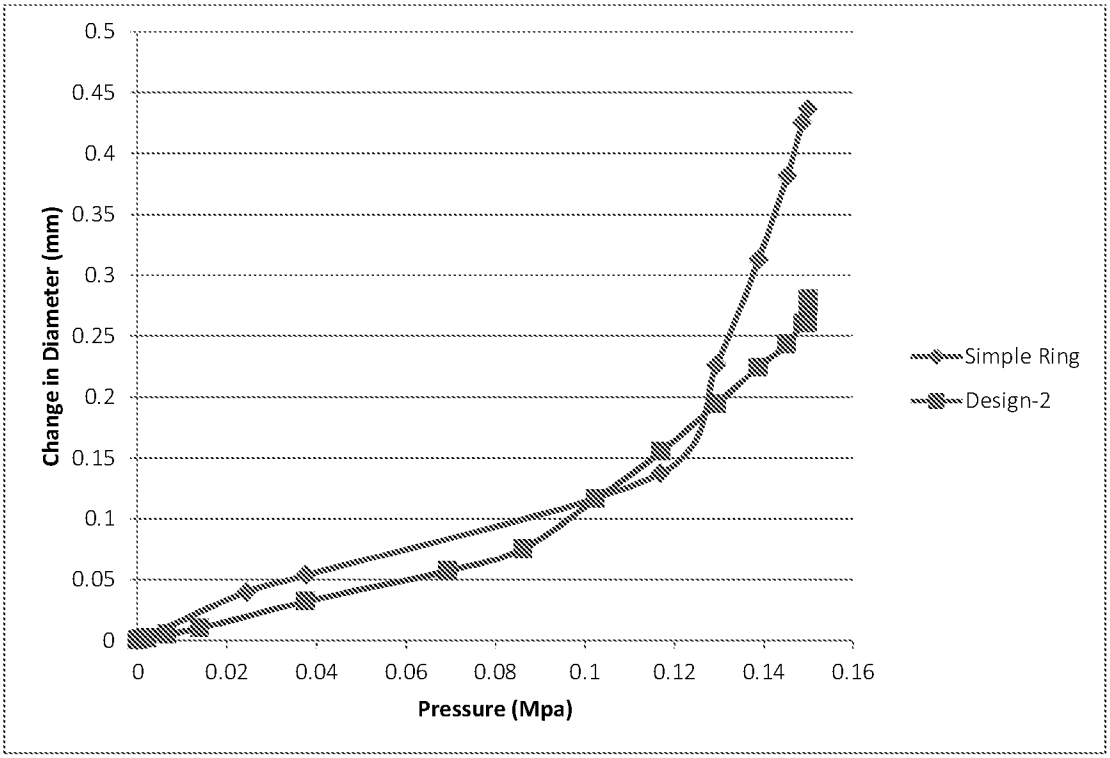


Figure 12 (d)

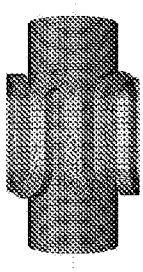


Figure 13

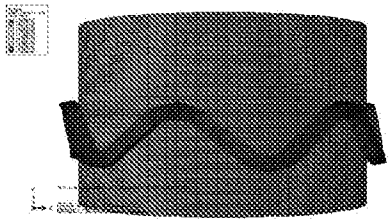


Figure 14

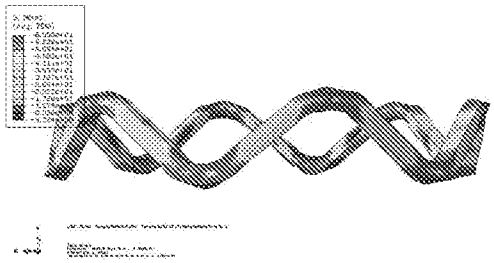


Figure 15(a)

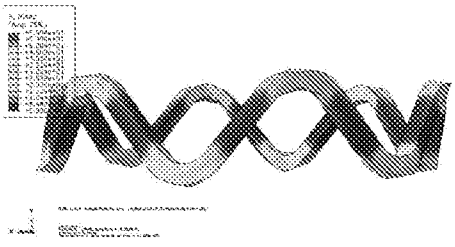


Figure 15(b)

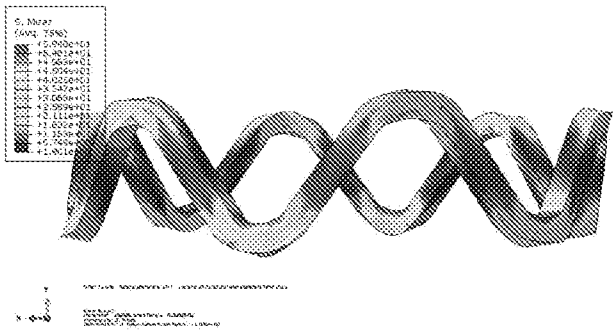


Figure 15(c)

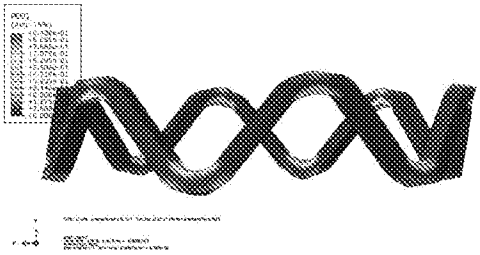


Figure 15(d)

Case Study -2

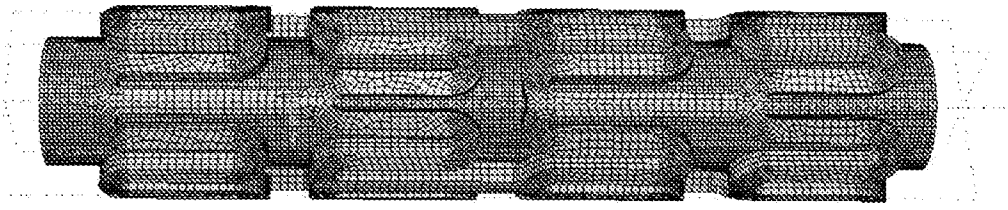


Figure 16

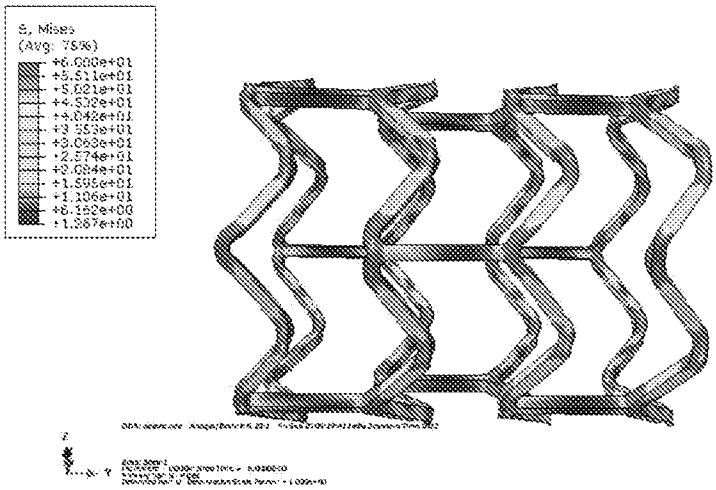


Figure 16(a)

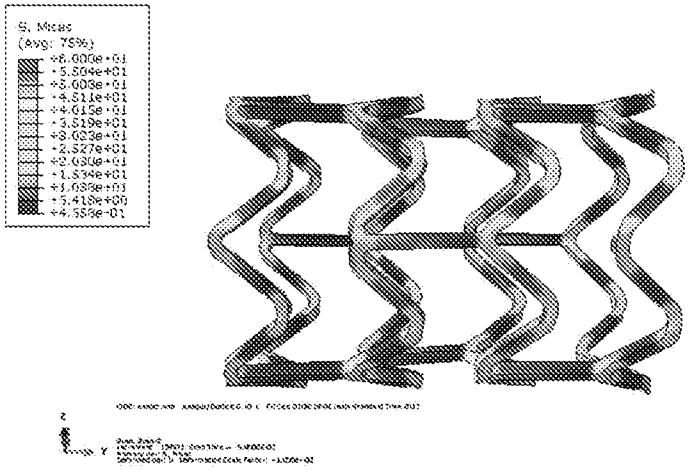


Figure 16(b)

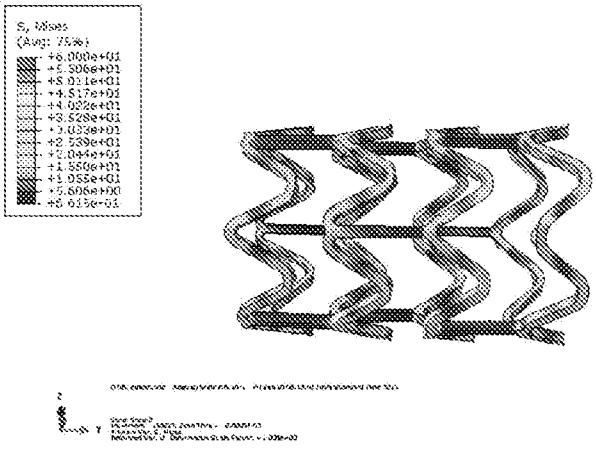


Figure 16(c)

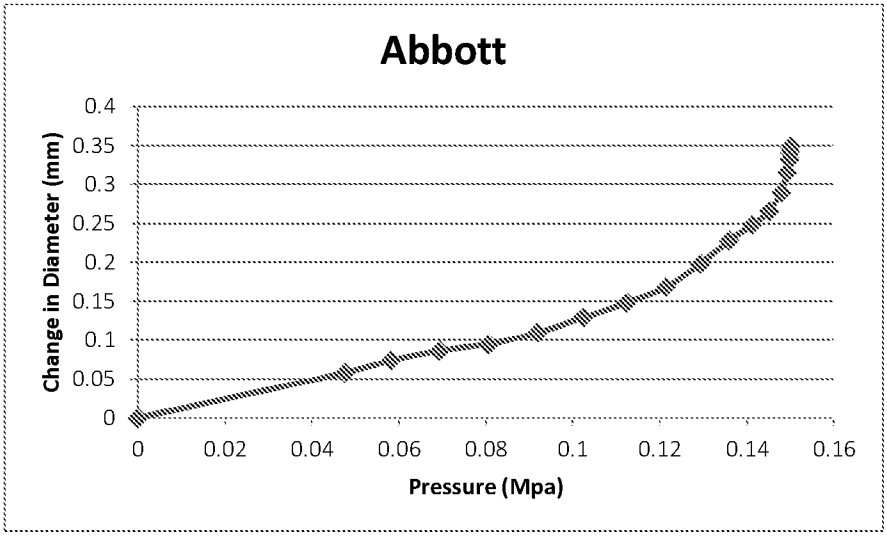
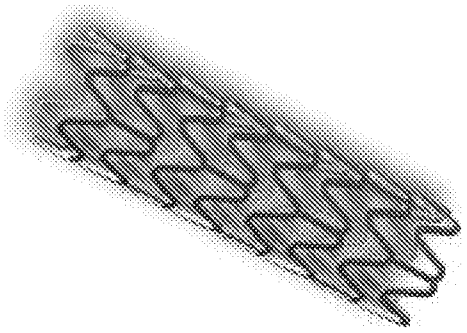
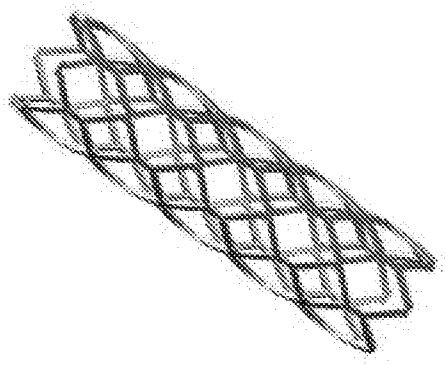


Figure 16(d)

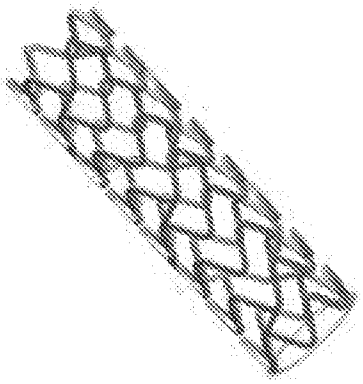
Stent Patterns as Published in literature:



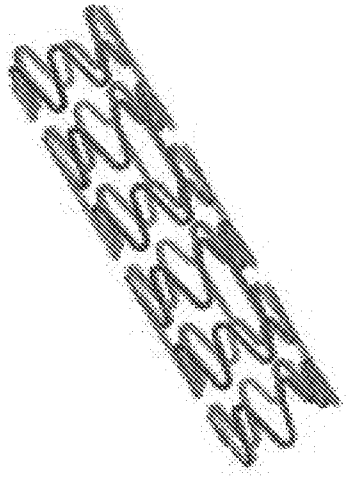
(1)-AB



(5)-AR



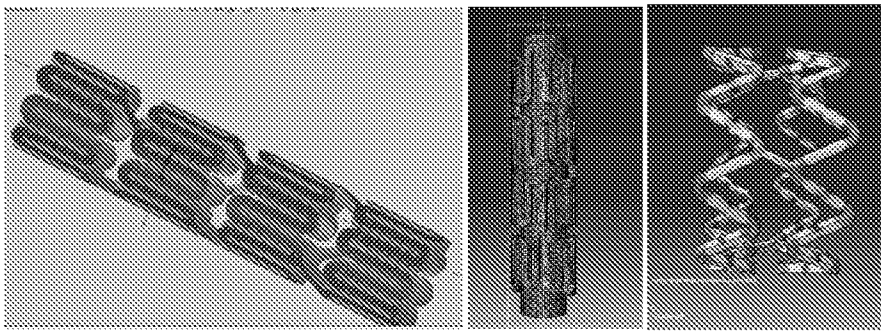
(6)-IG



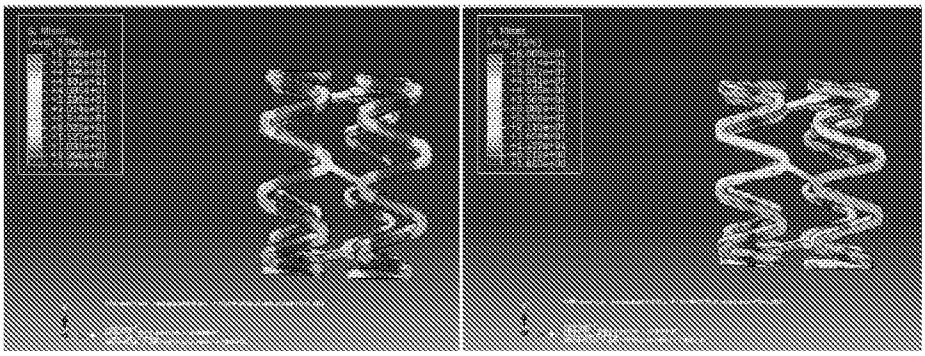
(7)-MED

Figure 16(e)

Stent Pattern-3 (BO)



Geometry Mesh Expansion



Elastic Recoil After Pressure

Figure 17

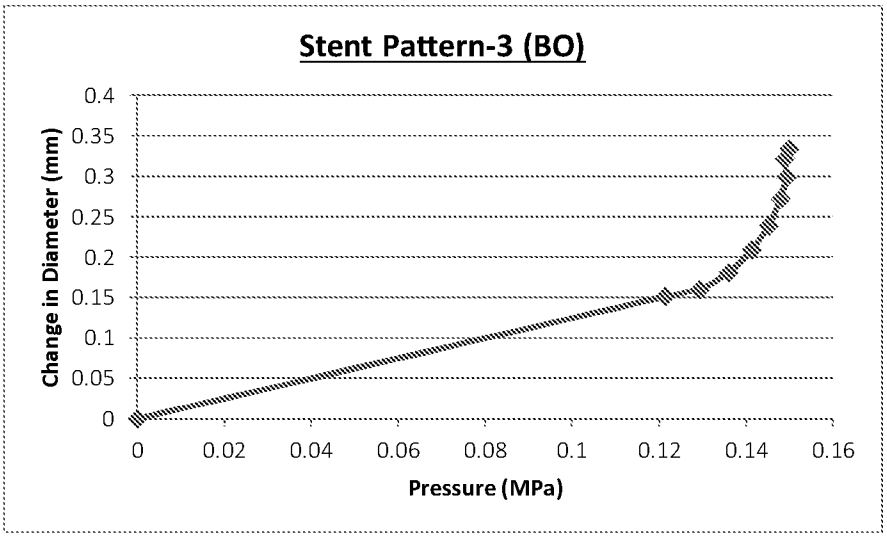


Figure 17(a)

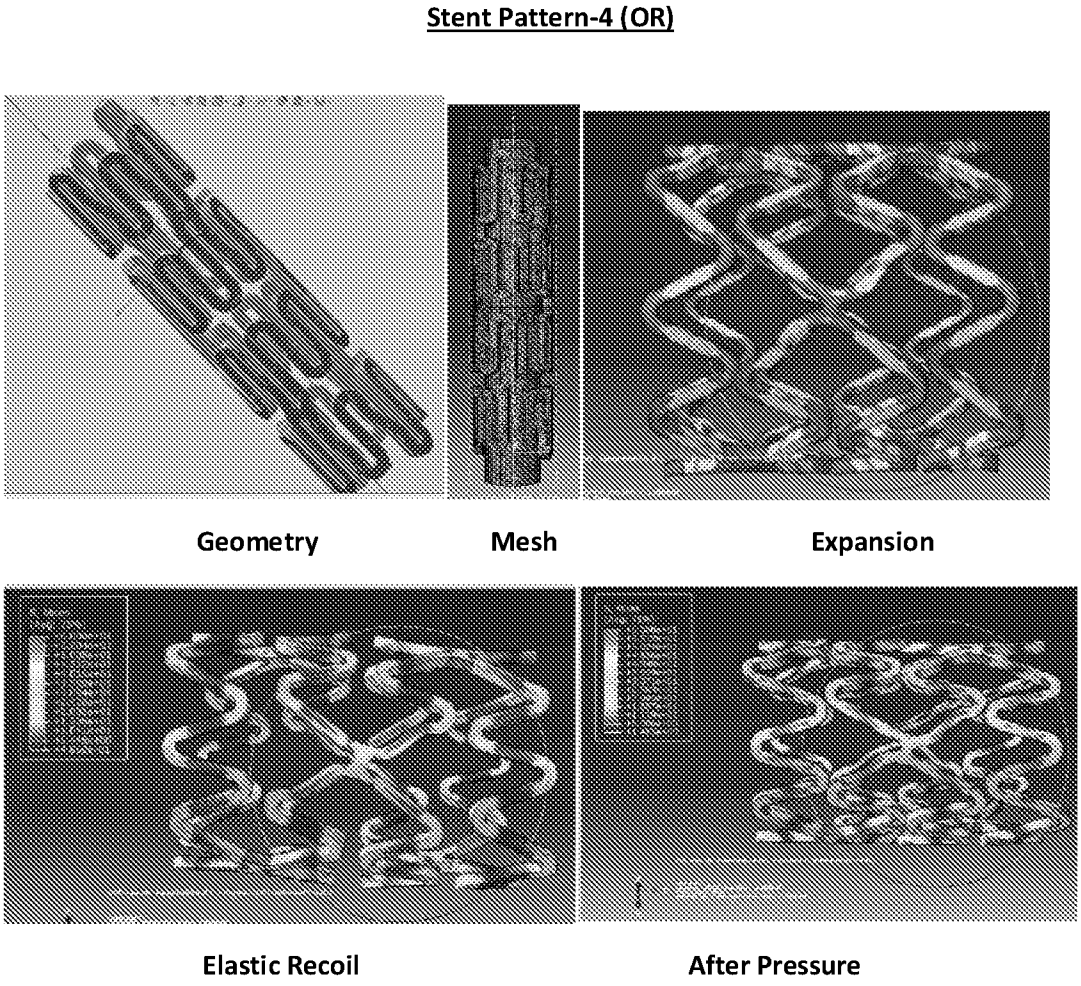


Figure 18

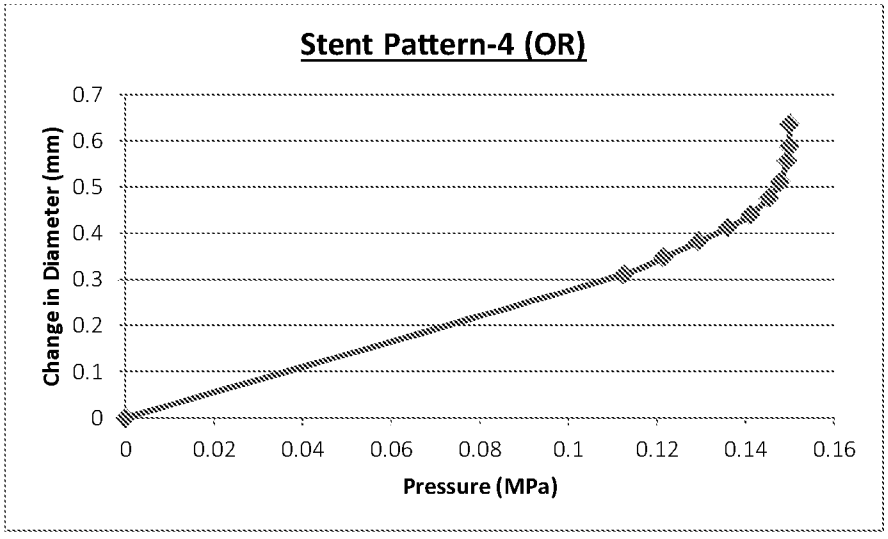


Figure 18(a)

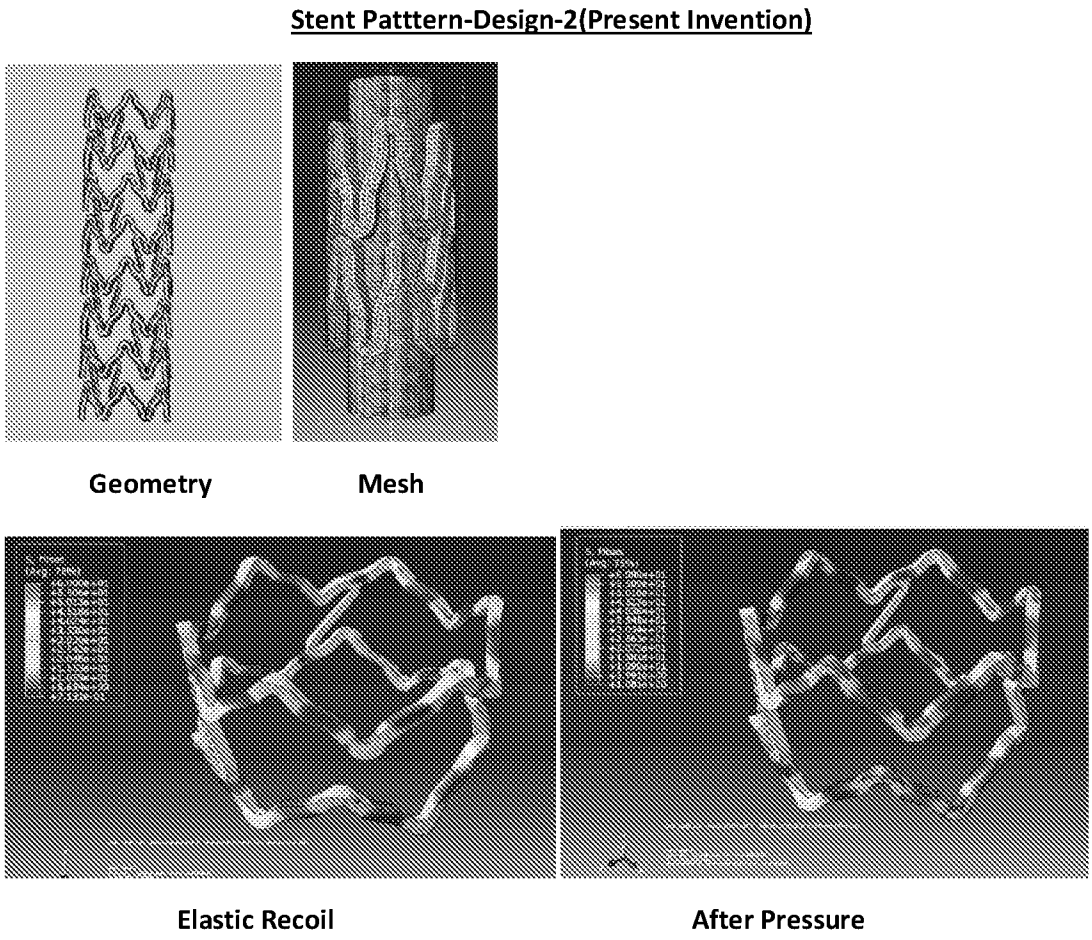


Figure 19

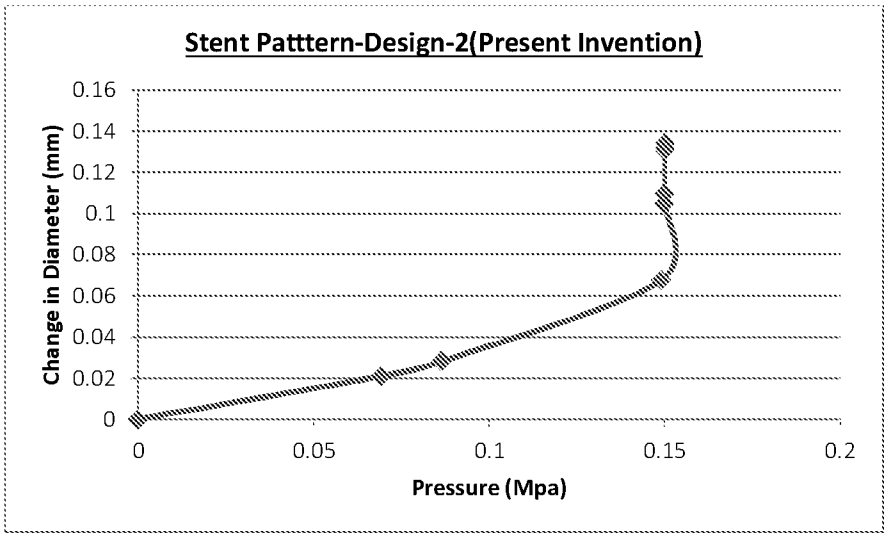


Figure 19(a)

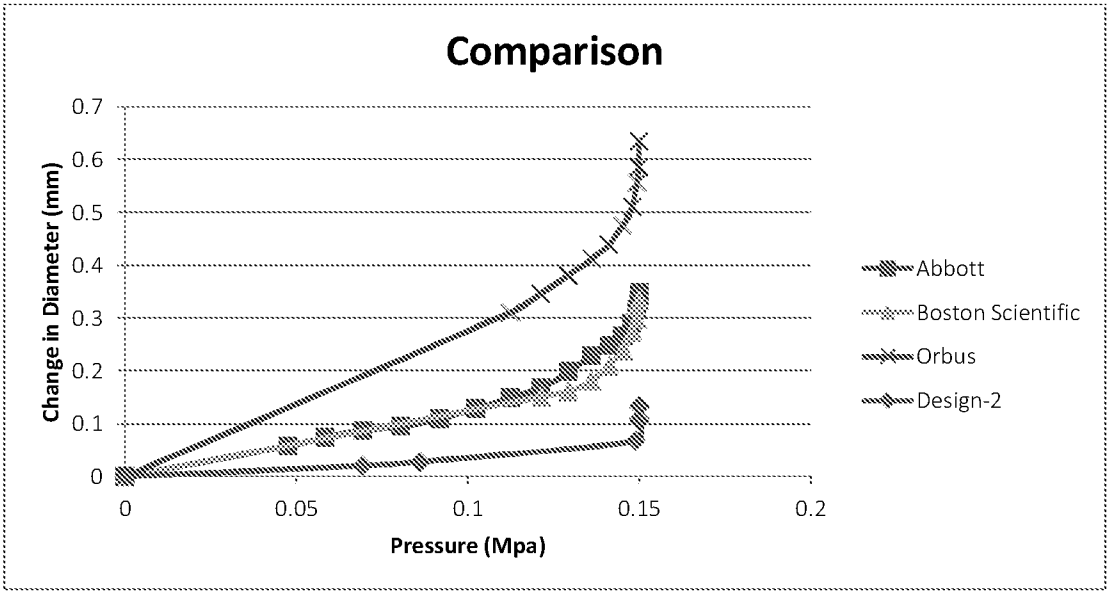


Figure 20

Case study-4

Flexibility

Abbott:

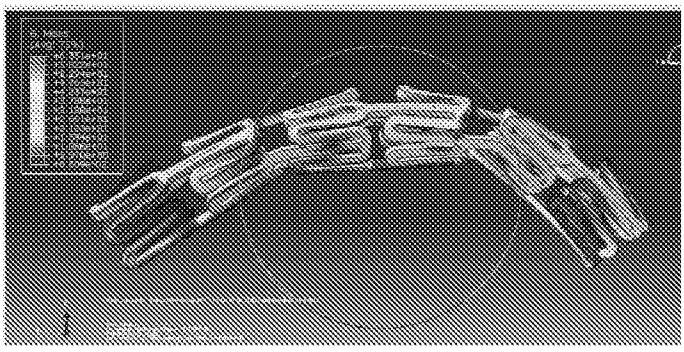


Figure 21

Curvature Index=

$$\chi = \Delta\varphi / L$$

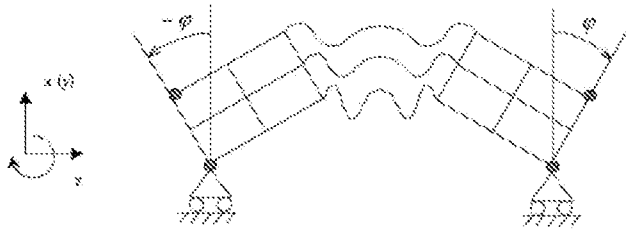


Figure 21(a)

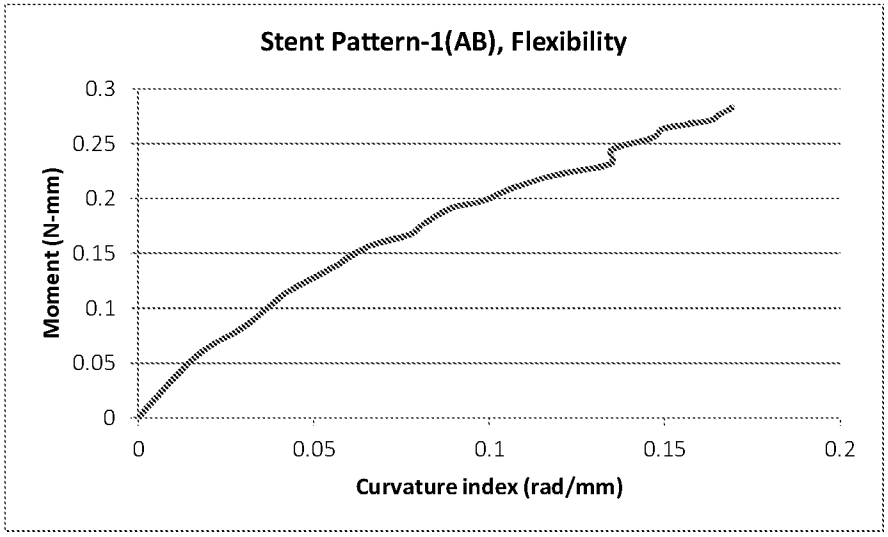


Figure 22

Artery Interaction

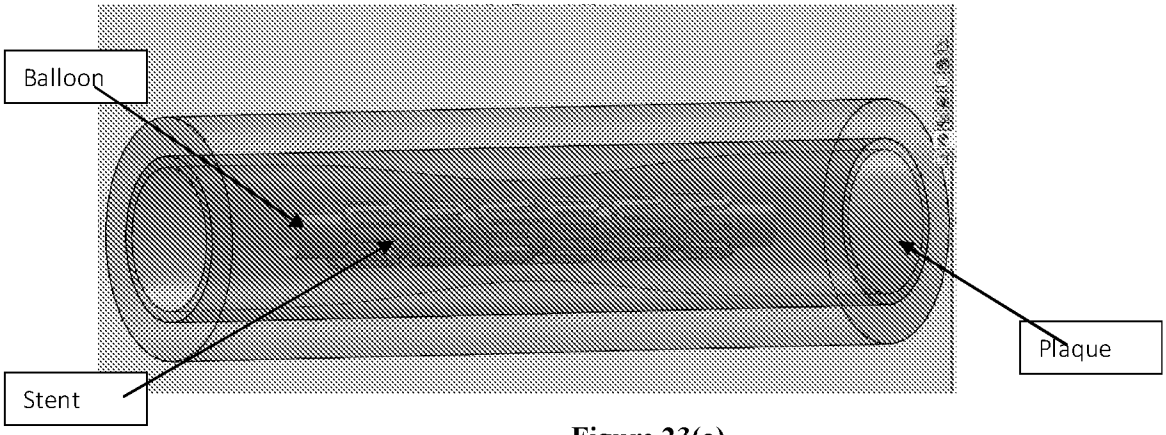


Figure 23(a)

Meshing

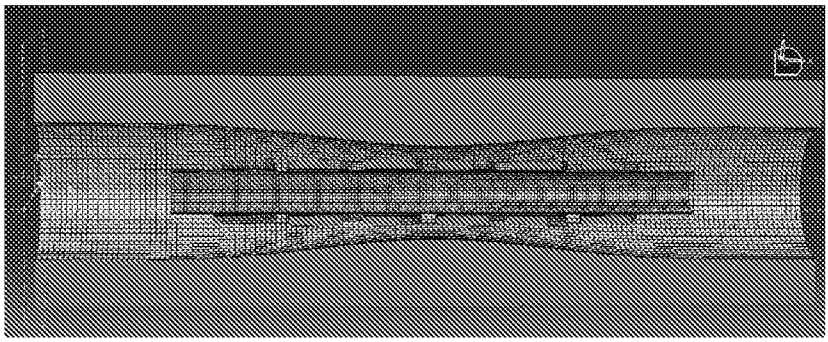


Figure 23(b)

Expansion step:

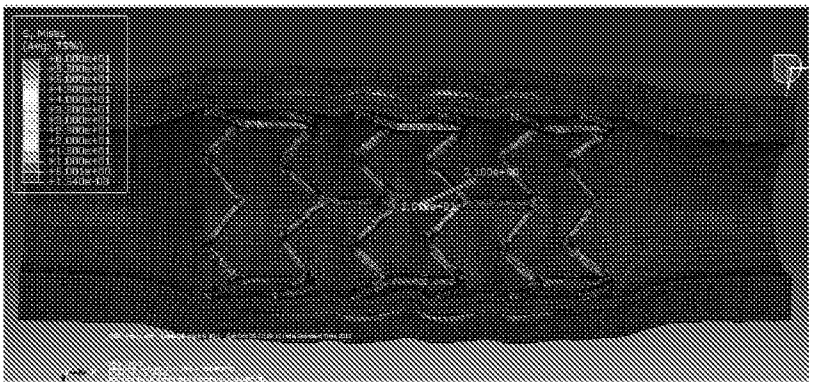


Figure 23(c)

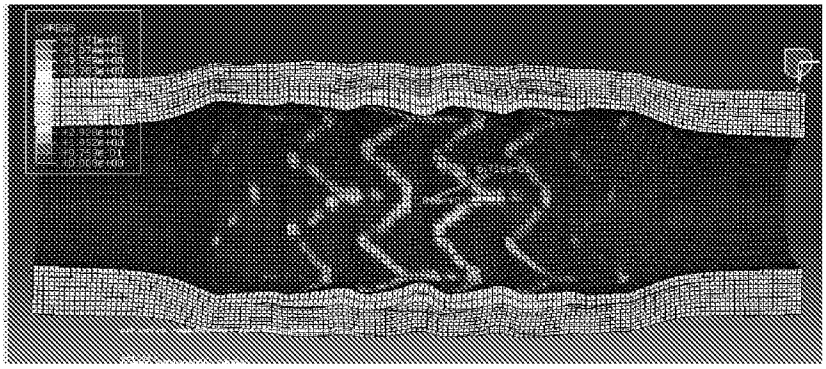


Figure 23(d)

Relaxation (Recoil):

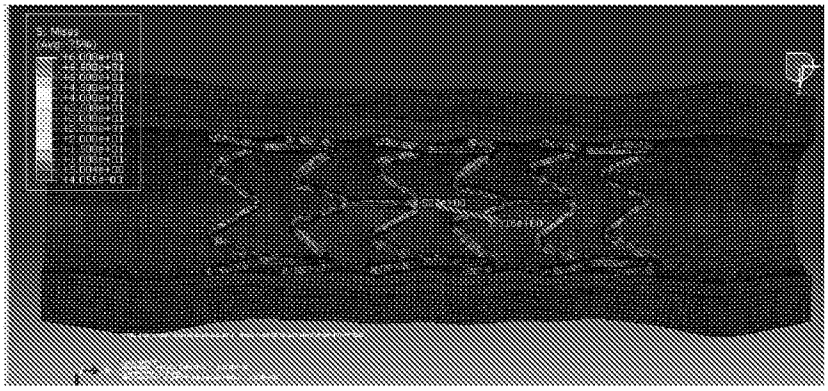


Figure 23(e)

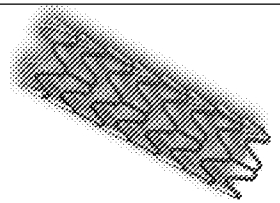
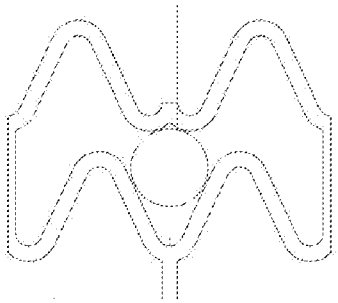
	Stent	Cell Area & MCUSA	
STENT PATTERN (1) (AB)			Length: 10 Open Cell Area: 3.05 MCUSA: 0.79 Artery Coverage: 0.239

Figure 24

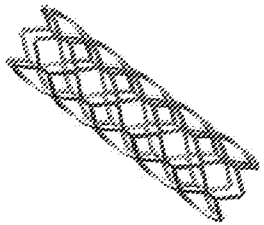
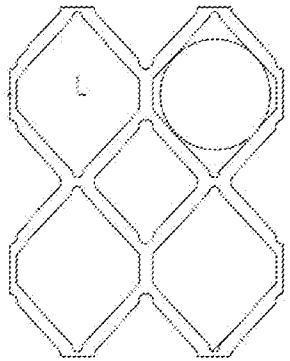
STENT PATTERN (5) (AR)			Length: 10.5 mm Open Cell Area: 1.63 mm2 MCUSA: 1.3 mm Artery Coverage: 0.213

Figure 25

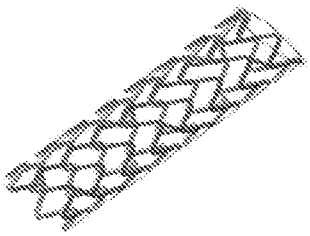
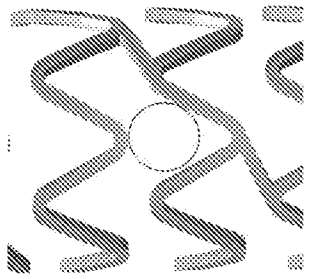
STENT PATTERN (6) (IG)	 	Length: 10.3 Open Cell Area: 4.46 MCUSA: 0.85 Artery Coverage:0.203

Figure 26

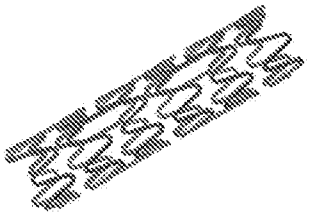
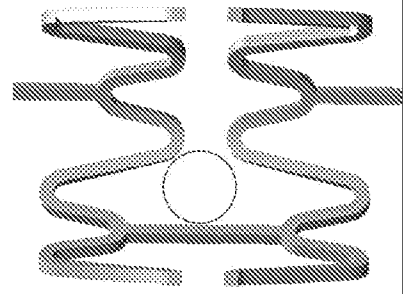
STENT PATTERN (7) (MED)	 	Length: 11.55 Open Cell Area: 6.43 MCUSA: 1.11 Artery Coverage:0.199

Figure 27

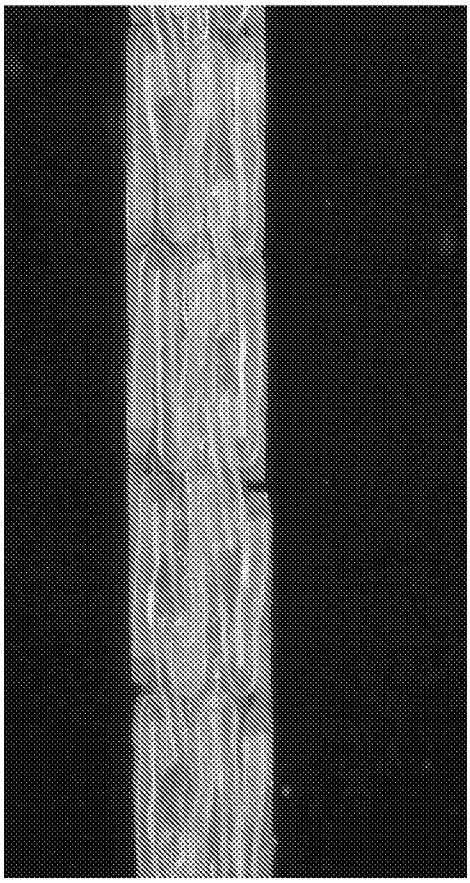


Figure 28

TABLE 1

	Varied Parameters					Result				
S No.	**No of crown**	**Width**	**Thickness**	**Strut length**	**Radius**	**Recoil %**	**Radial Strength(Mpa)**	**Foreshortening%**	**PEEQ**	**Amplitude**
1				0.6		12.39	0.147	42.25	0.5839	1.033
2			0.12	0.8		20.28	0.08	26.55	0.3374	1.233
3				1		25.12	0.014	18.7	0.22	1.433
4				0.6		9.83	>0.15	44.33	0.543	1.033
5		0.12	0.15	0.8		17.49	0.080	27.16	0.33	1.233
6				1		23.77	0.014	19.2	0.202	1.433
7				0.6		7.88	>0.15	46.07	0.543	1.033
8			0.18	0.8		14.76	0.080	28.06	0.326	1.233
9				1		21.40	0.014	19.39	0.2205	1.433
10				0.6		9.23	>0.15	43.83	0.974	1.063
11			0.12	0.8		16.05	0.12	27.94	0.566	1.263
12				1		21.83	0.028	19.05	0.368	1.464
13				0.6		6.57	>0.15	44.45	0.908	1.064

14	6	0.13	0.13	1.8		13.60	0.141	27.87	0.5939	1.263		
15				1		20.56	0.091	19.53	0.321	1.464		
16				0.6		5.91	>0.15	45.24	0.857	1.063		
17			0.18	1.2		11.97	>0.15	29.35	0.573	1.264		
18				1		18.02	0.091	20.01	0.359	1.464		
19				0.6		8.45	>0.15	42.77	1.258	1.094		
20			0.12	0.7		13.23	0.141	27.89	0.789	1.294		
21				1		18.98	0.08	19.34	0.538	1.494		
22				0.6		5.97	>0.15	43.87	1.20	1.094		
23		0.18	0.15	1.8		12.25	>0.15	27.35	0.76	1.294		
24				1		17.18	0.08	19	0.461	1.494		
25				0.6		4.46	>0.15	44.3	1.17	1.094		
26			0.18	1.8		10.19	>0.15	28.77	0.796	1.294		
27				1		16.05	0.13	19.81	0.461	1.494		