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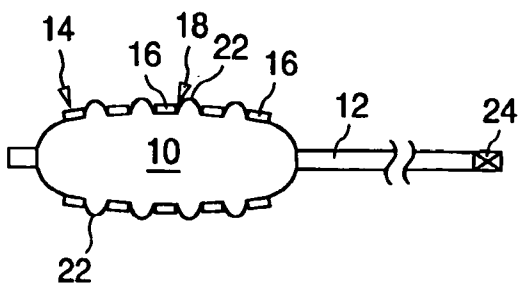
(54) Title: METHODS FOR IMPROVING STENT RETENTION ON A BALLOON CATHETER



(57) Abstract: A method of crimping a stent on a balloon of a catheter assembly is provided. A polymeric stent is disposed over a balloon in an inflated configuration. The stent is crimped over the inflated balloon to a reduced crimped configuration so that the stent is secured onto the balloon. The balloon wall membrane is wedged or pinched between the strut elements of the stent for increasing the retention of the stent on the balloon.

Methods for Improving Stent Retention on a Balloon Catheter

Technical Field

This invention relates to methods of crimping or mounting a stent on a balloon of a catheter assembly.

Background

A stent, as illustrated in Figure 1, is an intravascular prosthesis that is delivered and implanted within a patient's vasculature or other bodily cavities and lumens by a balloon catheter. For example, stents can be used in percutaneous transluminal coronary angioplasty (PTCA) or percutaneous transluminal angioplasty (PTA). Conventional stents and catheters are disclosed by U.S. Patent Nos. 4,733,665, 4,800,882, 4,886,062, 5,514,154, 5,569,295, and 5,507,768. In advancing a stent through a body vessel to a deployment site, the stent must be able to securely maintain its axial as well as rotational position on the delivery catheter without translocating proximally or distally, and especially without becoming separated from the catheter. Stents that are not properly secured or retained to the catheter may slip and either be lost or be deployed in the wrong location. The stent must be "crimped" in such a way as to minimize or prevent distortion of the stent and to thereby prevent abrasion and/or reduce trauma to the vessel walls.

Generally, stent crimping is the act of affixing the stent to the delivery catheter or delivery balloon so that it remains affixed to the catheter or balloon until the physician desires to deliver the stent at the treatment site. Current stent crimping technology is sophisticated. Examples of such technology which are known by one of ordinary skill in the art include a roll crimper; a collet crimper; and an iris or sliding-wedge crimper. To use a roll crimper, first the stent is slid loosely onto the balloon portion of the catheter.

This assembly is placed between the plates of the roll crimper. With an automated roll crimper, the plates come together and apply a specified amount of force. They then move back and forth a set distance in a direction that is perpendicular to the catheter. The catheter rolls back and forth under this motion, and the diameter of the stent is reduced. The process can be broken down into more than one step, each with its own level of force, translational distance, and number of cycles. This process imparts a great deal of shear to the stent in a direction perpendicular to the catheter or catheter wall. Furthermore, as the stent is crimped, there is additional relative motion between the stent surface and the crimping plates.

The collet crimper is equally conceptually simple. A standard drill-chuck collet is equipped with several pie-piece-shaped jaws. These jaws move in a radial direction as an outer ring is turned. To use this crimper, a stent is loosely placed onto the balloon portion of a catheter and inserted in the center space between the jaws. Turning the outer ring causes the jaws to move inward. An issue with this device is determining or designing the crimping endpoint. One scheme is to engineer the jaws so that when they completely close, they touch and a center hole of a known diameter remains. Using this approach, turning the collet onto the collet stops crimps the stent to the known outer diameter. While this seems ideal, it can lead to problems. Stent struts have a tolerance on their thickness. Additionally, the process of folding non-compliant balloons is not exactly reproducible. Consequently, the collet crimper exerts a different amount of force on each stent in order to achieve the same final dimension. Unless this force, and the final crimped diameter, is carefully chosen, the variability of the stent and balloon dimensions can yield stent or balloon damage.

In the sliding wedge or iris crimper, adjacent pie-piece-shaped sections move inward and twist, much like the leaves in a camera aperture. This crimper can be

engineered to have two different types of endpoints. It can stop at a final diameter, or it can apply a fixed force and allow the final diameter to float. From the discussion on the collet crimper, there are advantages in applying a fixed level of force as variability in strut and balloon dimension will not change the crimping force. The sliding wedges impart primarily normal forces. As the wedges slide over each other, they impart some tangential force. Lastly, the sliding wedge crimper presents a nearly cylindrical inner surface to the stent, even as it crimps. This means the crimping loads are distributed over the entire outer surface of the stent.

All current stent crimping methods were developed for all-metal stents. Stent metals, such as stainless steel, are durable and can take abuse. When crimping is too severe, it usually damages the underlying balloon, not the metal stent. But polymeric stents present different challenges. A polymer stent requires relatively wider struts than metal stents so as to provide suitable mechanical properties, such as radial strength. At the crimping stage, less space is provided between the struts which can result in worse stent retention than a metallic stent. Moreover, the use of high processing temperature during the crimping process to enhance stent retention may not be possible as a polymeric stent may have a glass transition temperature generally equivalent to the glass transition temperature of the balloon. Higher processing temperatures may cause the stent to lose some of its preferred mechanical properties.

The present invention provides a novel method of crimping a stent, more specifically a polymeric stent on an expandable member or a balloon.

Summary

In accordance with one embodiment, a method of crimping a stent on a balloon of a catheter assembly is provided, comprising: providing a polymeric stent disposed over a balloon in an inflated configuration; and crimping the stent over the inflated balloon to a

reduced crimped configuration so that the stent is secured onto the balloon. In some embodiments, the act of providing comprises inserting a balloon in a collapsed configuration into a stent; and expanding the balloon to the inflated configuration, wherein the inflated configuration is equal to or less than the intended expansion configuration of the balloon. In some embodiments, the inflated configuration is a configuration which provides for a membrane or wall of the balloon to protrude into gaps between structural elements of the stent. As a result, subsequent to crimping the stent on the balloon, a membrane or wall of the balloon is pinched or wedged between the structural elements of the stent. During the crimping process, the pressure in the balloon can be controllably released by a valve. In some embodiments, the stent is not a metallic stent. In some embodiments, the stent is a biodegradable polymeric stent. In some embodiments, the stent is a biodegradable polymeric stent with or without a biodegradable metallic component.

In accordance with another embodiment, a method of crimping a stent on a balloon, is provided comprising the following acts in the order as listed:(a) providing a stent disposed over a balloon in an inflated configuration; (b) crimping the stent to a first reduced diameter; (c) at least partially deflating the balloon; (d) inflating the balloon to at least an inner diameter of the stent; and (e) crimping the stent to a second reduced diameter. The second reduced diameter can be the final crimped diameter.

Description of Figures

The figures have not been drawn to scale and portions thereof have been under or over emphasized for illustrative purposes.

Figure 1 illustrates an example of a stent;

Figures 2A, 2B1, 2B2, 2C, 2D, and 2E (collectively referred to as Figure 2) illustrate methods for crimping a stent on a balloon of a catheter;

Figure 3 illustrates an embodiment of the end result of a stent/catheter assembly produced in accordance with a method of the invention;

Figures 4A and 4B are photographs of a stent crimped on a balloon in accordance with an embodiment of the invention; and

Figure 5 is a graph illustrating the result of the Example.

Description

The stent crimping methods are suitable to adequately and uniformly crimp a balloon expandable stent onto a balloon or expandable member of a catheter assembly. The embodiments of the invention are also applicable to self-expandable stents and stent-grafts. In one embodiment, the method of the present invention is particularly directed to crimping of a biodegradable, polymeric stent on a balloon of a catheter assembly. A biodegradable polymer stent has many advantages over metal stents, including the ability to be placed in the body only for the duration of time until the intended function of the stent has been performed. However, retention of a polymer stent has been proven to be more challenging than that of a metallic stent. Polymer stents can require wider struts than metal stents so as to provide suitable mechanical properties, such as radial strength, for the stent. At the crimping stage, less space is provided between the struts which can result in worse stent retention than a metallic stent. Moreover, the use of high processing temperature during the crimping process to enhance stent retention may not be possible as a polymeric stent may have a glass transition temperature generally equivalent to, or lower than the glass transition temperature of the balloon. Higher processing temperatures may cause the polymeric stent to lose some of its preferred mechanical properties.

Figure 2A illustrates an expandable member, such as a balloon 10, integrated at a distal end of a catheter assembly 12. In some embodiments, the balloon 10 is intended to include any type of enclosed member such as an elastic type member that is selectively inflatable to dilate from a collapsed configuration to a desired and controlled expanded configuration. The balloon 10 should also be capable of being deflated to a reduced profile or back to its original collapsed configuration. The balloon 10 can be made from any suitable type of material and can be of any thickness so long as the ability to crimp the stent onto the balloon and optimum performance capabilities of the balloon are not adversely compromised. Performance properties include, for example, high burst strength, good flexibility, high resistance to fatigue, an ability to fold, and ability to cross and re-cross a desired region of treatment or an occluded region in a bodily lumen, and a low susceptibility to defects caused by handling and crimping, among other possibilities.

The balloon is illustrated in Figure 2A in a collapsed configuration. The collapsed configuration can be the configuration that is conventionally used during the process of crimping of a stent on a balloon. The balloon 10 includes no liquid or gas in the internal chamber of the balloon 10 and includes regions where the balloon material is folded over giving the balloon a crease-like appearance. Such collapsed configuration can be the configuration of introduction and navigation of the balloon 10 in the vascular system of a patient.

As illustrated in Figure 2B1, a stent 14 is positioned over the balloon 10. The stent 14 is illustrated to have struts 16 separated by gaps 18 (as can also be seen in Figure 1). In some embodiments, the diameter of the stent 14 as positioned over the collapsed balloon 10 is much larger than the collapsed diameter of the balloon 10. In some embodiments, as illustrated in Figure 2B2, the diameter of the stent 14 is large enough so that an operator is capable of slipping the stent 14 over the balloon 10 with minimal gap or space between the

balloon 10 and the stent 14. The balloon 10 can be inflated to a crimp inflation state before being placed into a crimping device 20 (Figure 2C) or after being placed into the crimping device 20. The crimp inflation state is a state greater than the collapsed configuration and is a state equal to or less than the intended expansion configuration or use state. The intended expansion configuration is defined as inflation of a balloon to a diameter or size within the range of its intended use or design. The intended expanded configuration is provided by the manufacturer of the balloon or can be determined by one having ordinary skill in the art and is intended to include the range of diameter of use or the range of pressure to be applied for the planned performance of the balloon. In some embodiments, the balloon's intended use state is up to the threshold inflated configuration where the balloon becomes damaged or disapproved for use if the balloon was inflated more.

The balloon 10 can be inflated by application of a fluid or a gas. The temperature of the fluid or gas can be adjusted to other than ambient or room temperature. In one embodiment, a heated fluid or gas is used. In some embodiments, heated can be defined as above 25 deg. C. In some embodiments, the temperature can be below 200 deg. C, or alternatively below 150 deg. C, or alternatively below 100 deg. C, or alternatively below 75 deg. C. In some embodiments, the temperature can be between 25 deg. C and 100 deg. C. In some embodiments, the temperature is equal to or above the glass transition temperature (Tg) of a polymer of the stent body or a polymer of the stent coating (if applicable). In some embodiments, the temperature is equal to or above Tg but less than melting temperature of the of a polymer of the stent body or a polymer of the coating. In some embodiments, a cooled or chilled fluid or gas can be used to inflate the balloon. Cooled can mean below 25 deg. C. Chilled can mean below 0 deg. C.

In some embodiments, the crimped inflation state can include hyper-inflation of the balloon. Over or hyper-inflation is defined as any diameter or size above the intended expanded configuration but less than a diameter or size which the balloon will be damaged or no longer suitable or its intended use. Balloon diameter tolerances depend on the type of balloon and the material from which the balloon is made, among other factors. The manufacturer of the balloon can provide such information to a user, for example.

As illustrated in Figure 2C, when the balloon 10 is inflated, it is preferred for the balloon wall or membrane to protrude out, as shown by reference number 22, from the gaps 18 between the stent struts 16. In one embodiment, the protrusion 22 should not extend beyond the outer surface of the struts 16. Alternatively, the protrusion 22 can extend beyond the outer surface of the struts 16. This ensures that the balloon wall or membrane becomes adequately wedged, lodged, squeezed, or pinched between the struts 16 when the crimping process is completed.

Next, as illustrated in Figure 2D, the balloon 10 and the stent 14 are placed in the crimping device 20. Again, the balloon 10 can be inflated after being placed in the crimping device. The stent 14 can be positioned in the device 20 and held in place by application of pressure from the crimping device 20. The balloon 10 is then inserted within the stent 14. The balloon 10 is then inflated. The balloon 10 can be inflated to the inner diameter of the stent 14 or the diameter of the crimping device 20. In some embodiments, the balloon 10 can radially expand the stent 14 to a certain degree. The crimp device 20 then applies inward radial pressure to the stent 14 on the balloon 10.

The crimping device 20 can be any device used in the art. The stent 14 positioned over the balloon 10 is crimped to a reduced balloon and stent configuration (reduced crimped configuration), as illustrated in Figure 2E. The reduced crimped configuration can be the final, desired configuration (i.e., the configuration used to introduce the device into

the patient). Alternatively, reduced crimped configuration can be an intermediate configuration such that further crimping is needed. In one embodiment, the stent 14 is reduced in diameter, the balloon 10 is deflated (such as by application of a vacuum) and then re-inflated to the inner diameter of the stent 14 or diameter of the crimper. This is followed by further application of pressure by the crimping device 20. The process of application of pressure by the crimper, deflation of the balloon, re-inflation of the balloon, and application of pressure can be performed any number of times until the final, desired crimped state is achieved.

Crimping can be defined as the process of mounting, fastening or securing a stent on a balloon. The stent can be fixedly carried by the balloon but can be deployed by inflation and subsequent withdrawal of the balloon in order to be implanted at a target site, such as a region of stenosis. The crimp process can include selectively, radially compressing or applying pressure for positioning a stent on a balloon of a catheter assembly or an expandable delivery member of a catheter assembly. The compression or radial pressure during crimping can be segmented or uniform across the length and/or circumference of the stent. The application of pressure by the crimping device 20 can be continuous or applied in an intermittent or step-wise fashion. In an intermittent embodiment, the balloon can be deflated and re-inflated until final crimp configuration has been achieved. In some embodiments, the crimping device can hold the pressure at the reduced crimped configuration for duration of time prior to release of pressure. The process of crimping can also include, unless otherwise specifically indicated, modification made to the stent and/or balloon prior, during or subsequent to the application of crimping pressure that are directed to retention of the stent on the balloon. For example, the balloon can be coated before crimping to improve the retention of the stent on the balloon. In some embodiments, the balloon can be dipped into a fluid or solvent such as acetone

before sliding the stent on the balloon in order to soften the balloon material. This makes it easy for the balloon material to squeeze into the space between the struts or structural elements. The solvents, such as acetone, may also partially dissolve the surface of the stent or coating on the stent allowing for better adhesion between the stent and the balloon. In some embodiments, a softening fluid can be used that is a non-solvent for the stent or the coating on the sent. By way of another example, a grip process can be conducted after crimping to further increase stent retention. An outer sleeve restrains the crimped stent. Simultaneously, pressure and heat are applied to the stent-balloon section. Under this action, the balloon material deforms slightly, moving in between the struts.

Reduced balloon configuration (i.e., reduced crimp configuration) is a size or diameter greater than the size or diameter of the balloon 10 in its collapsed configuration. In some embodiments, the measured reduced size or diameter can be equivalent or generally equivalent to that of the collapsed configuration. Since the balloon 10 is pressurized by a fluid or gas, a pressure release valve 24 is provided to allow release of pressure from the balloon 10 during the crimping process. During the crimping process, the pressure release valve 24 will open to release pressure when the compression pressure caused by the crimping is higher than a set value of the valve 24. The release of the pressure is controlled so as to allow the crimper 20 to apply adequate pressure on the stent 14 for fastening the stent 14 on the balloon 10. If too much pressure is released from the balloon 10 during crimping, the stent 14 may not be adequately crimped on the balloon 10. The set pressure value of the valve depends on a variety of factors including the type of crimping device, stent, and balloon used. The calculation of the amount of applied pressure and preset valve pressure intake can be readily determined by one having skilled in the art.

As illustrated in Figure 3, the balloon 10, in a reduced configuration, has the stent 14 tightly crimped thereon. Balloon folds 22 have been tightly lodged, squeezed, wedged or pinched between the struts 16 of the stent 14. As the stent 14 is crimped, the struts 16 are shifted or brought closer together, causing the balloon wall or membrane 22 to be pinched between the struts 16. As for the end ring(s) of the stent 14, the balloon wall membrane 22 can be disposed between the structural elements of the stent as well. Figures 4A and 4B are two photographs which illustrate this crimping configuration in accordance to some embodiment of the present invention. As illustrated by the photographs, balloon wall or membrane is wedged between the structural elements of the stent.

In some embodiments, the stent 14 is arranged on the balloon 10 so that an outside surface of the balloon 10 and an inside surface of the stent 14 contact each other to form a combination of the balloon and stent. In some embodiments, the outer surface of the balloon or the inner surface of a stent can include a coating such as an adhesive coating, a drug delivery coating, a protective coating, a polymeric coating, a blocking agent or the like. The blocking agent is intended to reduce adhesion and/or friction between the stent 14 or a coating on the stent 14 and the balloon 10.

The stent body itself is preferably made from a polymeric material such as one or a combination of polymers. In some embodiments, such body can be made from a combination of polymeric and metallic material(s). In some embodiments, the stent is biodegradable. Both polymers and metallic materials can be biodegradable. In one preferred embodiment, the stent is completely or exclusively made from a polymeric material or combination of polymeric materials, more specifically biodegradable polymer(s). A polymeric stent can include some metallic components for allowing the stent to be viewed during the procedure; however, the amount of material is insignificant,

does not impart any structural function to the stent, or for viewing means only such that the stent is in essence made from a polymeric material or combination of polymers as is understood by one having ordinary skill in the art. In some embodiments, metallic stents are completely excluded from any of the embodiments of this invention. Metallic stents have a stent body (i.e., struts or structural elements) made mostly or completely from a metallic material such as an alloy. It should be noted that biodegradable is intended to include bioabsorbable, bioerodable, etc. unless otherwise specifically indicated.

In some embodiments, the stent can include a drug coating. The coating can be a pure drug or combination of drugs. The coating can include a polymeric carrier of a single or multiple polymers. The coating can be layered as is understood by one of ordinary skilled in the art.

The stent or the coating can be made from a material including, but are not limited to, poly(N-acetylglucosamine) (Chitin), Chitosan, poly(hydroxyvalerate), poly(lactide-co-glycolide), poly(hydroxybutyrate), poly(hydroxybutyrate-co-valerate), polyorthoester, polyanhydride, poly(glycolic acid), poly(glycolide), poly(L-lactic acid), poly(L-lactide), poly(D,L-lactic acid), poly(D,L-lactide), poly(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. Another type of polymer based on poly(lactic acid) that can be used includes graft copolymers, and block copolymers, such as AB block-copolymers ("diblock-copolymers") or ABA block-copolymers ("triblock-copolymers"), or mixtures thereof.

Additional representative examples of polymers that may be especially well suited for use in fabricating or coating the stent 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-hexafluororpropene) (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, and polyethylene glycol.

Example 1.

A first polymer stent was crimped by in-house process. A second polymer stent was placed on a balloon and then inserted into the crimper. The crimper head was reduced to the stent's outer diameter. Then the balloon was inflated to stent's outer diameter or the crimper's inner diameter at the pressure of 30 psi. The stent was crimped down further under pressure or release pressure at a slow rate and then held at target crimping diameter for certain time without balloon pressure present.

Both groups were measured by Instron Tester. Bottom grip on the Instron held the balloons below the stent and the upper grip held a stent section on the balloons. The device was used to pull the stents away from the balloons by moving the upper grip in an upwards direction. The force was measured when the stents moved at least of 1 mm from the original location. Figure 5 illustrates the result.

Example 2.

A stent can be mounted on a balloon, followed by inflating the balloon to an inner diameter of the stent. Crimp to intermediate diameter, between original diameter of the stent and final, desired diameter of the stent. The balloon can then be deflated by pulling vacuum on balloon, for example. Next, the balloon can be inflated to an intermediate diameter (diameter is controlled by position of crimping head). Crimp to final, desired diameter. This method can provide support to the stent during the initial crimping process and reduces crimping defects during the manufacturing process.

While particular embodiments of the present invention have been described, it will be obvious to those skilled in the art that changes and modifications can be made without departing from the spirit and scope of the teachings and embodiments of this invention. Therefore, the appended claims are to encompass within their scope all such changes and modifications as fall within the true spirit of this invention.

Claims

What is claimed is:

1. A method of crimping a stent on a balloon of a catheter assembly, comprising:

providing a polymeric stent disposed over a balloon in an inflated configuration; and

crimping the stent over the inflated balloon to a reduced crimped configuration for securing the stent on the balloon.

2. The method of claim 1, wherein the providing comprises:

inserting a balloon in a collapsed configuration into a stent; and

expanding the balloon to the inflated configuration, wherein there inflated configuration is equal to or less than the intended expansion configuration of the balloon.

3. The method of claim 1, wherein the inflated configuration is a configuration which provides for a membrane or wall of the balloon to protrude into gaps between structural elements of the stent.

4. The method of claim 1, wherein subsequent to crimping the stent on the balloon, a membrane or wall of the balloon is pinched or wedged between structural elements of the stent.

5. The method of claim 1, wherein during the crimping process, the pressure in the balloon is controllably released by a valve.

6. The method of claim 1, wherein the providing comprising inserting a balloon in a collapsed configuration into the stent and expanding the balloon, and wherein the reduced crimped configuration comprises a larger diameter or size than the collapsed configuration.

7. A stent-balloon catheter assembly made in accordance with the method of claim 1.

8. The method of claim 1, wherein the stent is not a metallic stent.

9. The method of claim 1, wherein the stent is a biodegradable polymeric stent.

10. The method of claim 1, wherein the stent is a biodegradable polymeric stent with or without a biodegradable metallic component.

11. The method of claim 1, additionally including applying a solvent to the balloon prior to the placement of the stent over the balloon.

12. The method of claim 11, wherein the solvent is acetone.

13. The method of claim 1, wherein the polymeric stent includes a drug coating.

14. The method of claim 1, additionally including applying a balloon softening fluid to the balloon prior to the placement of the stent over the balloon.

15. The method of claim 1, wherein the balloon is inflated by a heated fluid or gas.

16. The method of claim 1, wherein the balloon is inflated by a heated fluid or gas having a temperature not greater than 200 deg. C.

17. The method of claim 1, wherein the balloon is inflated by a heated fluid or gas having a temperature not greater than 150 deg. C.

18. The method of claim 1, wherein the balloon is inflated by a heated fluid or gas having a temperature not greater than 100 deg. C.

19. The method of claim 1, wherein the balloon is inflated by a heated fluid or gas having a temperature not greater than 75 deg. C.

20. A method of crimping a stent on a balloon, comprising the following acts in the order as listed:

(a) providing a stent disposed over a balloon in an inflated configuration;

(b) crimping the stent to a first reduced diameter;

(c) at least partially deflating the balloon;

(d) inflating the balloon to at least an inner diameter of the stent; and

(e) crimping the stent to a second reduced diameter.

21. The method of claim 21, wherein the second reduced diameter is the final crimped diameter.

22. The method of claim 21, additionally comprising, following act (e):

(f) at least partially deflated the balloon; followed by

(g) inflating the balloon to at least an inner diameter of the stent; followed by

(e) crimping the stent to a third reduced diameter.

23. The method of claim 22, wherein the third reduced diameter is the final crimped diameter.

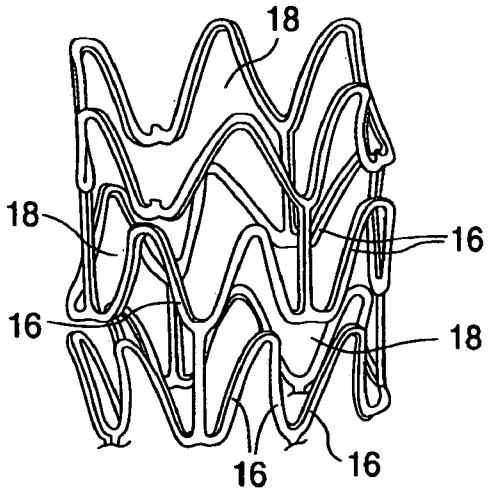


FIG. 1

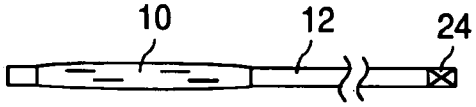


FIG. 2A

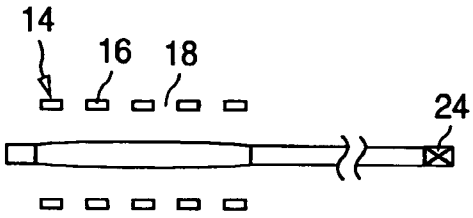


FIG. 2B1

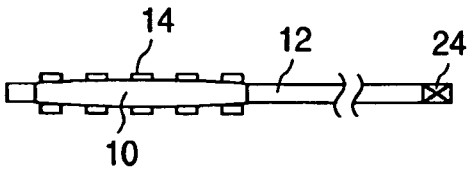


FIG. 2B2

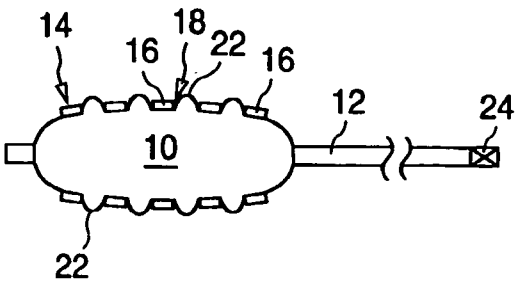


FIG. 2C

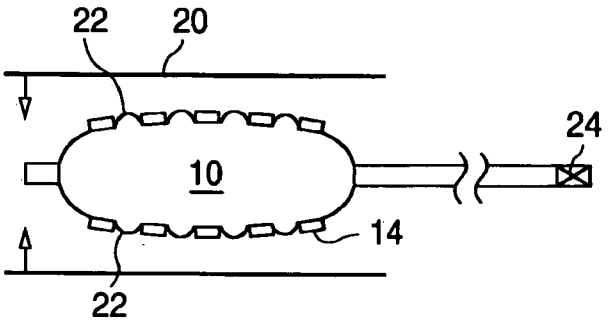


FIG. 2D

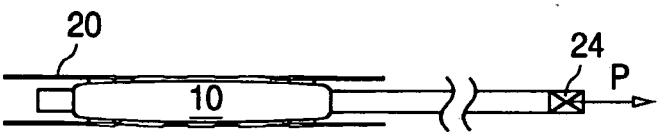


FIG. 2E

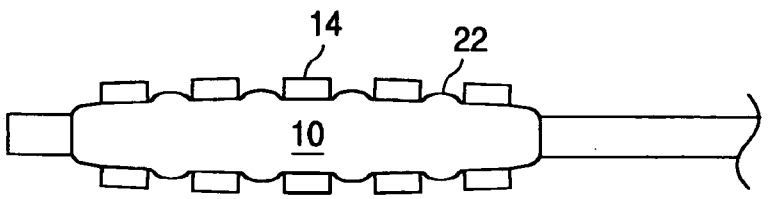


FIG. 3

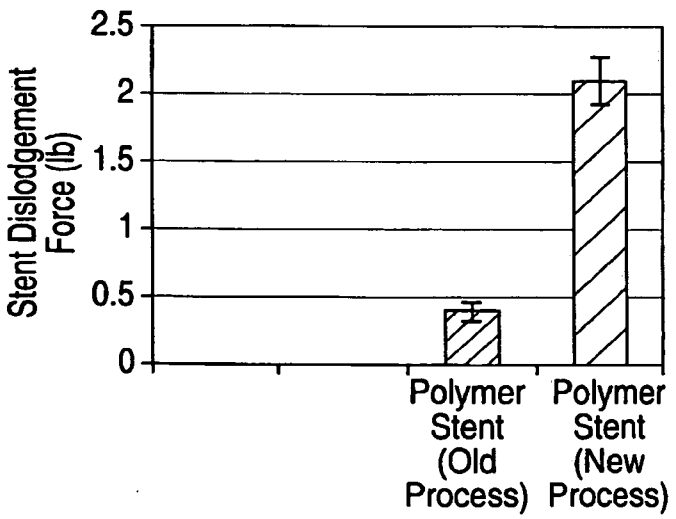


FIG. 5

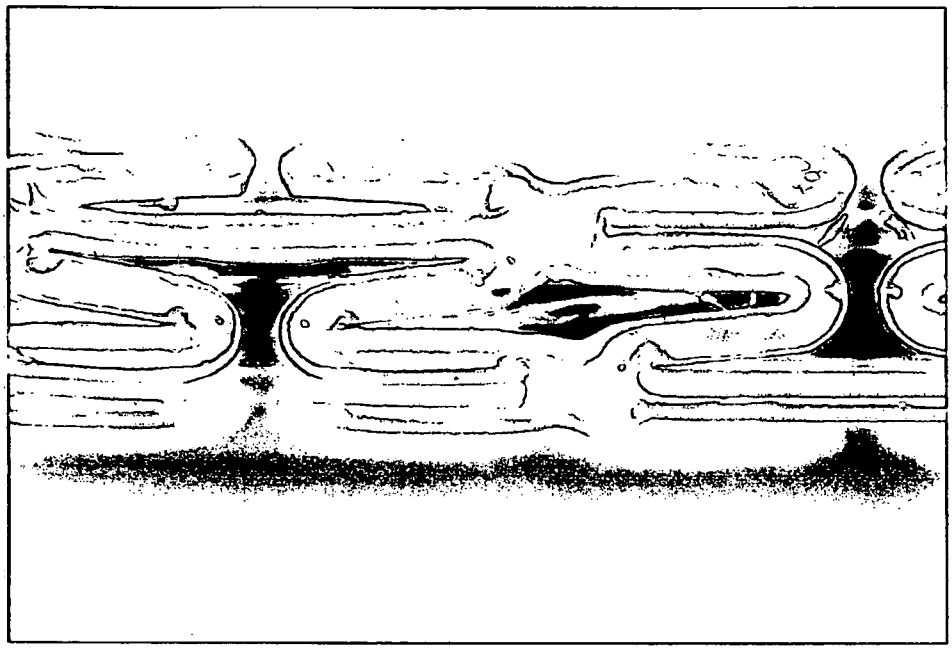


FIG. 4A

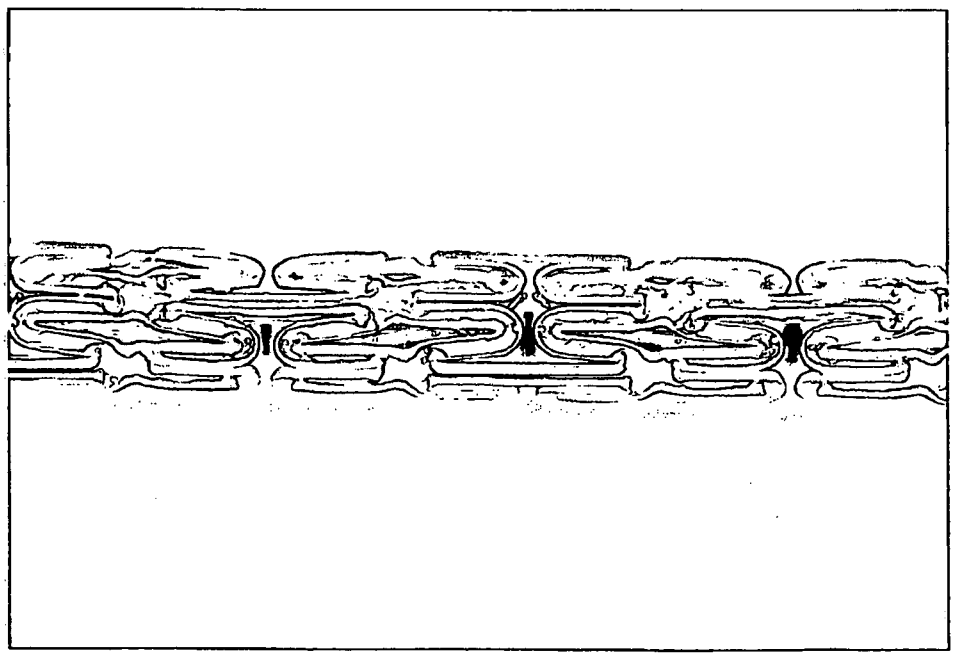


FIG. 4B