US 20070299511A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2007/0299511 A1

Gale (43) Pub. Date: Dec. 27, 2007

(54) THIN STENT COATING

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(21) Appl. No.: **11/476,240**

(22) Filed: **Jun. 27, 2006**

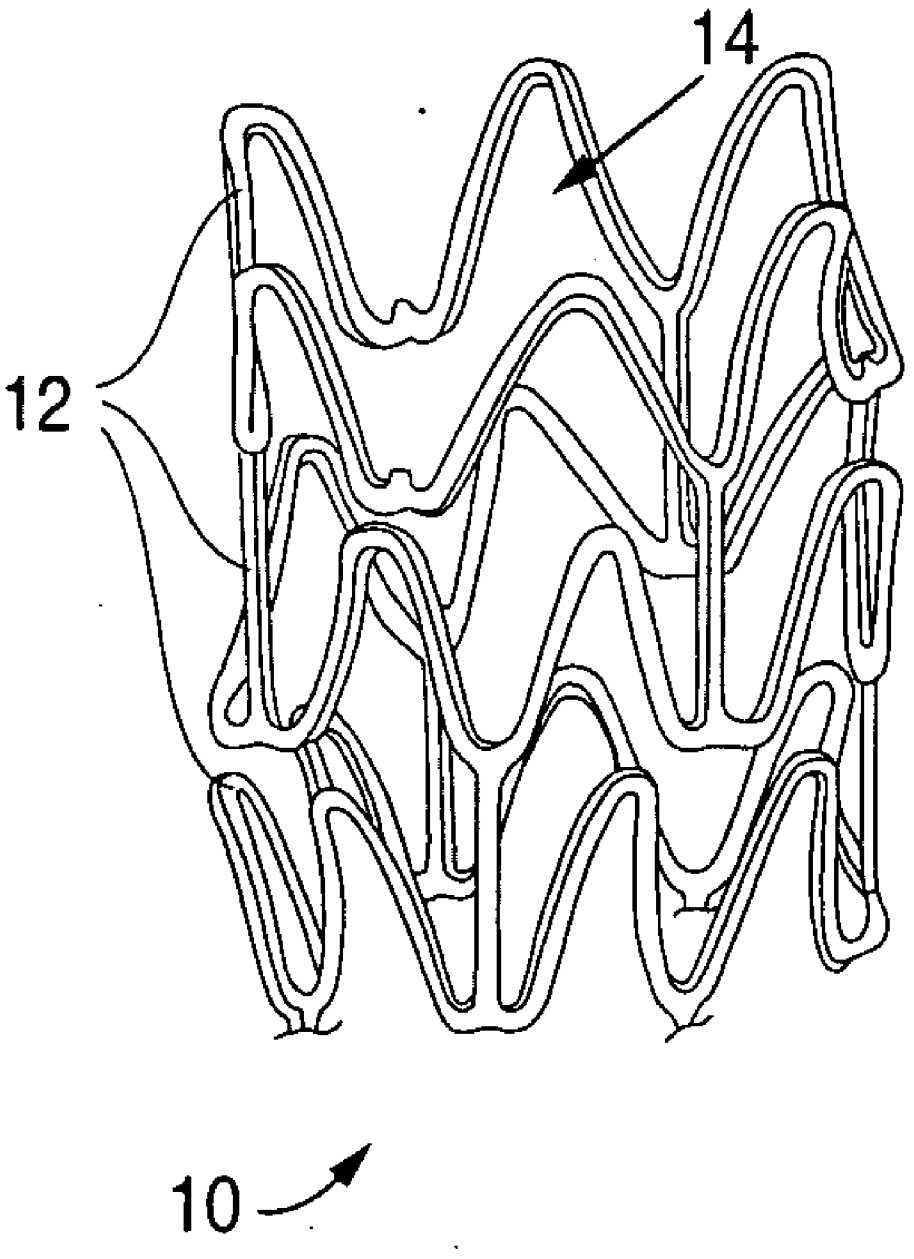
Publication Classification

(51) **Int. Cl.**
A61F 2/06 (2006.01)

(52) **U.S. Cl.** **623/1.46**

(57) **ABSTRACT**

A stent is disclosed comprising a radially expandable body and a coating, wherein the coating has a thickness of less than 3 microns. The thickness can be from 1 to 2 microns. The stent can be a polymeric, biodegradable stent. The coating can be a polymeric and biodegradable and can include a drug or therapeutic substance.



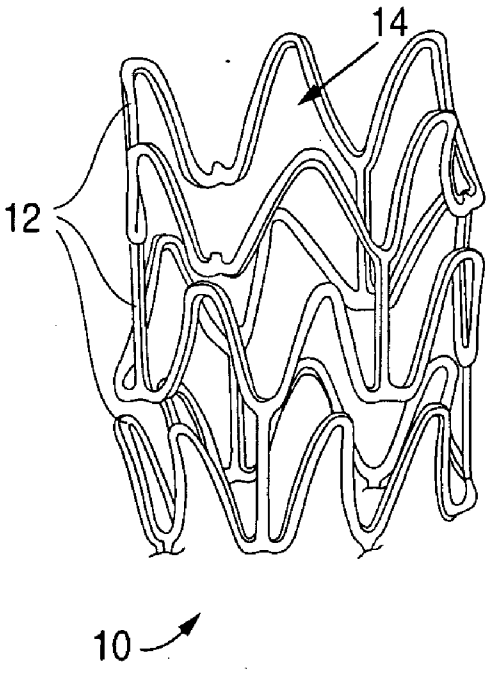


FIG. 1

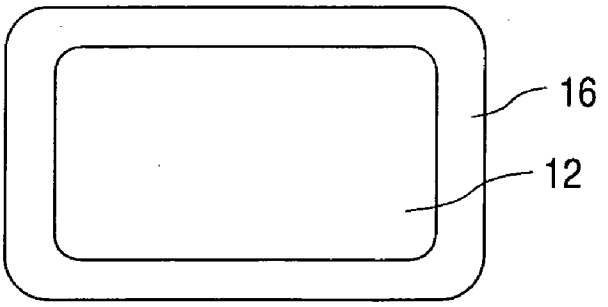


FIG. 2

THIN STENT COATING

TECHNICAL FIELD

[0001] This invention is directed to implantable medical devices having coatings, such as a drug delivery coating. More specifically, the invention is directed to a coating for a drug delivery stent.

BACKGROUND

[0002] Percutaneous transluminal coronary angioplasty (PTCA) is a procedure for treating heart disease. A catheter assembly having a balloon portion is introduced percutaneously into the cardiovascular system of a patient via the brachial or femoral artery. The catheter assembly is advanced through the coronary vasculature until the balloon portion is positioned across the occlusive lesion. Once in position across the lesion, the balloon is inflated to a predetermined size to radially press against the atherosclerotic plaque of the lesion for remodeling of the vessel wall. The balloon is then deflated to a smaller profile to allow the catheter to be withdrawn from the patient's vasculature.

[0003] A problem associated with the above procedure includes formation of intimal flaps or torn arterial linings, which can collapse and occlude the conduit after the balloon is deflated. Vasospasms and recoil of the vessel wall also threaten vessel closure. Moreover, thrombosis and restenosis of the artery may develop over several months after the procedure, which may necessitate another angioplasty procedure or a surgical by-pass operation. To reduce the partial or total occlusion of the artery by the collapse of arterial lining and to reduce the chance of the development of thrombosis and restenosis, an expandable, intraluminal prosthesis, one example of which is a stent, is implanted in the lumen to maintain the vascular patency.

[0004] Stents act as scaffoldings, functioning to physically hold open and, if desired, to expand the wall of the passageway. Typically stents are capable of being compressed, so that they can be inserted through small cavities via catheters, and then expanded to a larger diameter once they are at the desired location. Examples in the patent literature disclosing stents that have been applied in PTCA procedures include U.S. Pat. No. 4,733,665 issued to Palmaz, U.S. Pat. No. 4,800,882 issued to Gianturco, and U.S. Pat. No. 4,886,062 issued to Wiktor. Mechanical intervention via stents has reduced the rate of restenosis as compared to balloon angioplasty. Yet, restenosis is still a significant clinical problem with rates ranging from 20-40%. When restenosis does occur in the stented segment, its treatment can be challenging, as clinical options are more limited as compared to lesions that were treated solely with a balloon.

[0005] Stents are used not only for mechanical intervention but also as vehicles for providing biological therapy. Biological therapy can be achieved by medicating the stents. Medicated stents provide for the local administration of a therapeutic substance at the diseased site. In order to provide an efficacious concentration to the treated site, systemic administration of such medication often produces adverse or even toxic side effects for the patient. Local delivery is a preferred method of treatment in that smaller total levels of medication are administered in comparison to systemic dosages, but are concentrated at a specific site. Local delivery thus produces fewer side effects and achieves more favorable results.

[0006] This invention provides for a novel and improved stent coating capable of local delivery of therapeutic substances.

SUMMARY

[0007] A stent is disclosed comprising a radially expandable body and a coating, wherein the coating has a thickness of less than 3 microns. In some embodiments, the coating thickness is less than 2 microns. In some embodiments, the coating thickness is less than 1 micron. In some embodiments, the coating thickness is between 1 and 2 microns. In some embodiments, the stent is a non-metallic stent. In some embodiments, the stent is a polymeric, biodegradable stent. The coating can include a blend of a polymer and a drug and/or the polymer and the drug can be conjugated. The coating can comprise a biodegradable polymer as well. A method is also disclosed for manufacturing a drug delivery stent and coating a stent.

DESCRIPTION OF FIGURES

[0008] FIG. **1** illustrates a convention stent; and

[0009] FIG. **2** is a partial cross-section of a strut of a stent having a thin coating in accordance to one embodiment of the invention.

DESCRIPTION

[0010] The invention is directed to thin coatings for medical devices, more specifically an implantable medical device. In accordance to one embodiment, the invention is specifically directed to a coating for a stent. The stent can be a self-expandable stent or a radially expandable stent. As illustrated by FIG. **1**, the stent can include a tubular body **10** having structural elements or struts **12** separated by gaps **14**. In others embodiments, the stent can have a coil configuration or be made from a wire or fiber-type body. The stent body can be made from a metallic material, polymeric material, or a combination of metallic or polymeric material. The combination can be in a layered, disbursed, blended or conjugated form. In some embodiments, the metal or polymer can be biodegradable such that the stent is intended to remain at the implantation site for a temporary duration of time. Biodegradable, bioerodable, bioabsorbable, etc. are terms which are used interchangeably unless otherwise specifically intended. In one embodiment, a stent having a metallic body is specifically excluded from this invention. In other words, in this embodiment, the stent is limited to having a polymer body made from one or a combination of polymers. In some embodiments, the stent is from about 5 mm in length to about 40 mm in length. In some embodiments, the stent is at least 40 mm in length.

[0011] A thin coating **16**, as best illustrated by FIG. **2** is disposed on the surface of the structural element or strut **12**. The coating can be deposited on the outer surface, inner surface and the side walls of the strut **12**, as illustrated by FIG. **2**. In some embodiments, the coating is exclusively on the outer surface, and not the inner surface or the side walls. In some embodiments, the coating can be on the outer surface and at least a portion of the sidewalls of the strut. In one preferred embodiment, the thickness of the coating consists of 1 to 2 microns. In one embodiment, the thickness of the coating can be at any range between 1 and 2 microns. The coating can be at any range between any of the following thicknesses: 1.0, 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7,

1.8, 1.9 and 2.0 microns. For example, the coating can be from 1.0 to 1.5 microns. As another example, the coating can be between 1.3 to 2.0 microns thick. In one embodiment, the thickness of the coating should be less than 3 microns, such as between 0.1 to 3 microns. In one embodiment, the coating thickness should be less than 2 microns, such as between 0.1 to 2 microns. In some embodiments, the thickness is less than 1 micron. In some embodiments, the thickness should be not more than 3.0, 2.9, 2.8, 2.7, 2.6, 2.5, 2.4, 2.3, 2.2, 2.1, and 2.0 microns and at a minimum at 0.1 micron. Preferably, the minimum is 1.0 micron.

[0012] In some embodiments, the coating is a pure drug or therapeutic substance layer. In some embodiments, the coating is a combination of more than one drug or therapeutic substance without any polymers. In some embodiments the coating can be a combination of at least on polymer and at least one drug or therapeutic substance. Combination is defined as blending, mixing, dispersing, conjugating, and/or bonding of the drug/therapeutic substance to the polymer. The coating polymer can be the same as or different than a polymer from which the stent is made. At least one of the polymers for the coating can be the same or different than at least one of the polymers of the stent structure.

[0013] In some embodiments, the coating can include a primer layer and/or a topcoat layers or sub-layers. The primer layer will be beneath the drug/therapeutic substance layer and the topcoat layer above it. Both the primer layer and the topcoat layer can be without any drugs/therapeutic substances. In some embodiments, some drug may incidentally migrate into the primer layer or region. The topcoat layer reduces the rate of release of the drug and/or provides for biobeneficial properties.

[0014] The thin coating can be deposited by spray application, electrostatic application, "ink-jet"-type application, plasma deposition and the like. These processes are known in the art. A coating composition including polymer(s), solvent(s), and optionally drug(s)/therapeutic substance(s) can be used, for example. In some embodiments, the amount of solvent included in the composition can be low so as to allow for formation of the thin coating. In some embodiments, the method of coating may include modifying at least one process parameter of the spraying so that a weight percent of solvent in coating material applied on the polymeric surface is less than about 30 wt %, 20 wt %, 15 wt %, or more narrowly, 10 wt %.

[0015] 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, polyanrhydride, poly(glycolic acid), poly(glycQlide), 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.

[0016] 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, N.J.), polyvinylidene fluoride (otherwise known as KYNAR, available from ATOFINA Chemicals, Philadelphia, Pa.), ethylene-vinyl acetate copolymers, and polyethylene glycol.

[0017] The stent can also be made from the following metallic materials or alloys: cobalt chromium alloy (ELGILOY), stainless steel (316L), "MP35N," "MP20N," ELASTINITE (Nitinol), tantalum, nickel-titanium alloy, platinum-iridium alloy, gold, magnesium, or combinations thereof. "MP35N" and "MP20N" are trade names for alloys of cobalt, nickel, chromium and molybdenum available from standard Press Steel Co., Jenkintown, Pa. "MP35N" consists of 35% cobalt, 35% nickel, 20% chromium, and 10% molybdenum. "MP20N" consists of 50% cobalt, 20% nickel, 20% chromium, and 10% molybdenum.

[0018] The coating can be made from the following materials: poly(ester amide), polyhydroxyalkanoates (PHA), poly(3-hydroxyalkanoates) such as poly(3-hydroxypropanoate), poly(3-hydroxybutyrate), poly(3-hydroxyvalerate), poly(3-hydroxyhexanoate), poly(3-hydroxyheptanoate) and poly(3-hydroxyoctanoate), poly(4-hydroxyalkanaote) such as poly(4-hydroxybutyrate), poly(4-hydroxyvalerate), poly(4-hydroxyhexanote), poly(4-hydroxyheptanoate), poly (4-hydroxyoctanoate) and copolymers including any of the 3-hydroxyalkanoate or 4-hydroxyalkanoate monomers described herein or blends thereof, poly(D,L-lactide), poly (L-lactide), polyglycolide, poly(D,L-lactide-co-glycolide), poly(L-lactide-co-glycolide), polycaprolactone, poly(lactide-co-caprolactone), poly(glycolide-co-caprolactone), poly(dioxanone), poly(ortho esters), poly(anhydrides), poly (tyrosine carbonates) and derivatives thereof, poly(tyrosine ester) and derivatives thereof, poly(imino carbonates), poly (glycolic acid-co-trimethylene carbonate), polyphosphoester, polyphosphoester urethane, poly(amino acids), polycyanoacrylates, poly(trimethylene carbonate), poly (iminocarbonate), polyurethanes, polyphosphazenes, silicones, polyesters, polyolefins, polyisobutylene and ethylene-alphaolefin copolymers, acrylic polymers and copolymers, 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, copolymers of vinyl monomers with each other and olefins, such as ethylene-methyl methacrylate copolymers,

acrylonitrile-styrene copolymers, ABS resins, and ethylene-vinyl acetate copolymers, polyamides, such as Nylon 66 and polycaprolactam, alkyd resins, polycarbonates, polyoxymethylenes, polyimides, polyethers, poly(glyceryl sebacate), poly(propylene fumarate), poly(n-butyl methacrylate), poly (sec-butyl methacrylate), poly(isobutyl methacrylate), poly (tert-butyl methacrylate), poly(n-propyl methacrylate), poly (isopropyl methacrylate), pcly(ethyl methacrylate), poly (methyl methacrylate), epoxy resins, polyurethanes, rayon, rayon-triacetate, cellulose acetate, cellulose butyrate, cellulose acetate butyrate, cellophane, cellulose nitrate, cellulose propionate, cellulose ethers, carboxymethyl cellulose, polyethers such as poly(ethylene glycol) (PEG), copoly(ether-esters) (e.g. PEO/PLA), polyalkylene oxides such as poly (ethylene oxide), poly(propylene oxide), poly(ether ester), polyalkylene oxalates, polyphosphazenes, phosphoryl choline, choline, poly(aspirin), polymers and co-polymers of hydroxyl bearing monomers such as HEMA, hydroxypropyl methacrylate (HPMA), hydroxypropylmethacrylamide, PEG acrylate (PEGA), PEG methacrylate, 2-methacryloyloxyethylphosphorylcholine (MPC) and n-vinyl pyrrolidone (VP), carboxylic acid bearing monomers such as methacrylic acid (MA), acrylic acid (AA), alkoxymethacrylate, alkoxyacrylate, and 3-trimethylsilylpropyl methacrylate (TMSPMA), poly(styrene-isoprene-styrene)-PEG (SIS-PEG), polystyrene-PEG, polyisobutylene-PEG, polycaprolactone-PEG (PCL-PEG), PLA-PEG, poly(methyl methacrylate)-PEG (PMMA-PEG), polydimethylsiloxane-co-PEG (PDMS-PEG), poly(vinylidene fluoride)-PEG (PVDF-PEG), PLURONIC™ surfactants (polypropylene oxide-co-polyethylene glycol), poly(tetramethylene glycol), hydroxy functional poly(vinyl pyrrolidone), biomolecules such as collagen, chitosan, alginate, fibrin, fibrinogen, cellulose, starch, collagen, dextran, dextrin, fragments and derivatives of hyaluronic acid, heparin, fragments and derivatives of heparin, glycosamino glycan (GAG), GAG derivatives, polysaccharide, elastin, chitosan, alginate, or combinations thereof. In some embodiments, the substrate coating described herein can exclude any one of the aforementioned polymers.

[0019] As used herein, the terms poly(D,L-lactide), poly (L-lactide), poly(D,L-lactide-co-glycolide), and poly(L-lactide-co-glycolide) can be used interchangeably with the terms poly(D,L-lactic acid), poly(L-lactic acid), poly(D,L-lactic acid-co-glycolic acid), or poly(L-lactic acid-co-glycolic acid), respectively.

[0020] In some embodiments, the coating preferably includes a fluoropolymer such as a Solef™ polymer (e.g., PVDF-HFP).

[0021] In some embodiments, the coating can be made from or further include a biobeneficial material. The biobeneficial material can be polymeric or non-polymeric. The biobeneficial material is preferably substantially non-toxic, non-antigenic and non-immunogenic. A biobeneficial material is one that enhances the biocompatibility of a device by being non-fouling, hemocompatible, actively non-thrombogenic, or anti-inflammatory, all without depending on the release of a pharmaceutically active agent.

[0022] Representative biobeneficial materials include, but are not limited to, polyethers such as poly(ethylene glycol), copoly(ether-esters) (e.g. PEO/PLA), polyalkylene oxides such as poly(ethylene oxide), poly(propylene oxide), poly (ether ester), polyalkylene oxalates, polyphosphazenes, phosphoryl choline, choline, poly(aspirin), polymers and co-polymers of hydroxyl bearing monomers such as hydroxyethyl methacrylate (HEMA), hydroxypropyl methacrylate (HPMA), hydroxypropylmethacrylamide, poly (ethylene glycol) acrylate (PEGA), PEG methacrylate, 2-methacryloyloxyethylphosphorylcholine (MPC) and n-vinyl pyrrolidone (VP), carboxylic acid bearing monomers such as methacrylic acid (MA), acrylic acid (AA), alkoxymethacrylate, alkoxyacrylate, and 3-trimethylsilylpropyl methacrylate (TMSPMA), poly(styrene-isoprene-styrene)-PEG (SIS-PEG), polystyrene-PEG, polyisobutylene-PEG, polycaprolactone-PEG (PCL-PEG), PLA-PEG, poly(methyl methacrylate)-PEG (PMMA-PEG), polydimethylsiloxane-co-PEG (PDMS-PEG), poly(vinylidene fluoride)-PEG (PVDF-PEG), PLURONIC™ surfactants (polypropylene oxide-co-polyethylene glycol), poly(tetramethylene glycol), hydroxy functional poly(vinyl pyrrolidone), biomolecules such as fibrin, fibrinogen, cellulose, starch, collagen, dextran, dextrin, hyaluronic acid, fragments and derivatives of hyaluronic acid, heparin, fragments and derivatives of heparin, glycosamino glycan (GAG), GAG derivatives, polysaccharide, elastin, chitosan, alginate, silicones, PolyActive™, and combinations thereof.

[0023] The term PolyActive™ refers to a block copolymer having flexible poly(ethylene glycol) and poly(butylene terephthalate) blocks (PEGT/PBT). PolyActive™ is intended to include AB, ABA, BAB copolymers having such segments of PEG and PBT (e.g., poly(ethylene glycol)-block-poly(butyleneterephthalate)-block poly(ethylene glycol) (PEG-PBT-PEG).

[0024] In a preferred embodiment, the biobeneficial material can be a polyether such as poly (ethylene glycol) (PEG) or polyalkylene oxide.

[0025] In some embodiments, the substrate coating can exclude any one of the aforementioned polymers.

[0026] The drug or therapeutic agent can be any agent which is a therapeutic, prophylactic, or diagnostic agent. These agents can have anti-proliferative or anti-inflammmatory properties or can have other properties such as antineoplastic, antiplatelet, anti-coagulant, anti-fibrin, antithrombonic, antimitotic, antibiotic, antiallergic, or antioxidant properties. These agents can be cystostatic agents, agents that promote the healing of the endothelium (other than by releasing or generating NO), or agents that promote the attachment, migration and proliferation of endothelial cells while quenching smooth muscle cell proliferation. Examples of suitable therapeutic and prophylactic agents include synthetic inorganic and organic compounds, proteins and peptides, polysaccharides and other sugars, lipids, and DNA and RNA nucleic acid sequences having therapeutic, prophylactic or diagnostic activities. Nucleic acid sequences include genes, antisense molecules, which bind to complementary DNA to inhibit transcription, and ribozymes. Some other examples of bioactive agents include antibodies, receptor ligands, enzymes, adhesion peptides, blood clotting factors, inhibitors or clot dissolving agents, such as streptokinase and tissue plasminogen activator, antigens for immunization, hormones and growth factors, oligonucleotides such as antisense oligonucleotides and ribozymes and retroviral vectors for use in gene therapy. Examples of anti-proliferative agents include rapamycin and its functional or structural derivatives, 40-O-(2-hydroxy)ethyl-rapamycin (everolimus), and its functional or structural derivatives, paclitaxel and its functional and structural derivatives. Examples of rapamycin derivatives include ABT-578, 40-O-(3-hydroxy)

propyl-rapamycin, 40-O-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, and 40-O-tetrazole-rapamycin. Examples of paclitaxel derivatives include docetaxel. Examples of antineoplastics and/or antimitotics include methotrexate, azathioprine, vincristine, vinblastine, fluorouracil, doxorubicin hydrochloride (e.g. Adriamycin® from Pharmacia & Upjohn, Peapack N.J.), and mitomycin (e.g. Mutamycin® from Bristol-Myers Squibb Co., Stamford, Conn.). Examples of such antiplatelets, anticoagulants, antifibrin, and antithrombins include sodium heparin, low molecular weight heparins, heparinoids, hirudin, argatroban, forskolin, vapiprost, prostacyclin and prostacyclin analogues, dextran, D-phe-pro-arg-chloromethylketone (synthetic antithrombin), dipyridamole, glycoprotein IIb/IIIa platelet membrane receptor antagonist antibody, recombinant hirudin, thrombin inhibitors such as Angiomax (Biogen, Inc., Cambridge, Mass.), calcium channel blockers (such as nifedipine), colchicine, fibroblast growth factor (FGF) antagonists, fish oil (omega 3-fatty acid), histamine antagonists, lovastatin (an inhibitor of HMG-CoA reductase, a cholesterol lowering drug, brand name Mevacor® from Merck & Co., Inc., Whitehouse Station, N.J.), monoclonal antibodies (such as those specific for Platelet-Derived Growth Factor (PDGF) receptors), nitroprusside, phosphodiesterase inhibitors, prostaglandin inhibitors, suramin, serotonin blockers, steroids, thioprotease inhibitors, triazolopyrimidine (a PDGF antagonist), super oxide dismutases, super oxide dismutase mimetic, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl(4-amino-TEMPO), estradiol, anticancer agents, dietary supplements such as various vitamins, and a combination thereof. Examples of anti-inflammatory agents including steroidal and non-steroidal anti-inflammatory agents include biolimus, tacrolimus, dexamethasone, clobetasol, corticosteroids.or combinations thereof. Examples of such cytostatic substance include angiopeptin, angiotensin converting enzyme inhibitors such as captopril (e.g. Capoten® and Capozide® from Bristol-Myers Squibb Co., Stamford, Conn.), cilazapril or lisinopril (e.g. Prinivil® and Prinzide® from Merck & Co., Inc., Whitehouse Station, N.J.). An example of an antiallergic agent is permirolast potassium. Other therapeutic substances or agents which may be appropriate include alpha-interferon, pimecrolimus, imatinib mesylate, midostaurin, and genetically engineered epithelial cells. The foregoing substances can also be used in the form of prodrugs or co-drugs thereof. The foregoing substances also include metabolites thereof and/or prodrugs of the metabolites. The foregoing substances are listed by way of example and are not meant to be limiting. Other active agents which are currently available or that may be developed in the future are equally applicable.

[0027] The dosage or concentration of the bioactive agent required to produce a favorable therapeutic effect should be less than the level at which the bioactive agent produces toxic effects and greater than the level at which non-therapeutic results are obtained. The dosage or concentration of the bioactive agent can depend upon factors such as the particular circumstances of the patient, the nature of the trauma, the nature of the therapy desired, the time over which the ingredient administered resides at the vascular site, and if other active agents are employed, the nature and type of the substance or combination of substances. Therapeutically effective dosages can be determined empirically, for example by infusing vessels from suitable animal model systems and using immunohistochemical, fluorescent or electron microscopy methods to detect the agent and its effects, or by conducting suitable in vitro studies. Standard pharmacological test procedures to determine dosages are understood by those of ordinary skill in the art.

[0028] While particular embodiments of the present invention have been shown and described, it will be obvious to those skilled in the art that changes and modifications can be made without departing from this invention in its broader aspects. Therefore, the appended claims are to encompass within their scope all such changes and modifications as fall within the true spirit and scope of this invention.

What is claimed is:

1. A stent comprising a radially expandable body and a coating, wherein the body is made from a polymeric material and the coating has a thickness between 1 to 2 microns.

2. The stent of claim **1**, wherein the polymeric material is biodegradable.

3. The stent of claim **1**, wherein the polymeric material comprises a combination of at least two polymers such that at least one of the polymers is biodegreadable.

4. The stent of claim **1**, wherein the body additionally comprises a metallic material in combination with the polymeric material.

5. The stent of claim **4**, wherein the polymeric material comprises a combination of at least two polymer such that at least one of the polymers is biodegradable and wherein the metallic material is biodegradable.

6. The stent of claim **1**, wherein the coating comprises at least one polymer and at least one therapeutic substance.

7. The stent of claim **1**, wherein the coating is made from at least on biodegradable polymer.

8. The stent of claim **1**, wherein the coating comprises a layer including a therapeutic substance and at least one or a combination of a primer layer and a topcoat layer.

9. A stent comprising a radially expandable body and a coating, wherein the coating has a thickness of less than 3 microns.

10. The stent of claim **9**, wherein the thickness is less than 2 microns.

11. The stent of claim **9**, wherein the thickness is less than 1 micron.

12. The stent of claim **9**, wherein the stent is a non-metallic stent.

13. The stent of claim **9**, wherein the stent is a polymeric, biodegradable stent.

14. The stent of claim **9**, wherein the coating includes a blend of a polymer and a drug.

15. The stent of claim **9**, wherein the coating includes a conjugation of a polymer and a drug.

16. The stent of claim **9**, wherein the body of the stent comprises a biodegradable polymer and the coating comprises a biodegradable polymer.

17. The stent of claim **16**, wherein the biodegradable polymer for the stent is the same as the biodegradable polymer for the coating.

18. The stent of claim **16**, wherein the biodegradable polymer for the stent is different than the biodegradable polymer for the coating.

19. A method of manufacturing a drug delivery stent, comprising depositing a coating on the stent having a thickness of not greater than 3 microns.

20. The method of claim **19**, wherein the thickness is not greater than 2 microns.

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