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(54) **Title:** ENDOPROSTHESIS WITH SELECT CERAMIC MORPHOLOGY

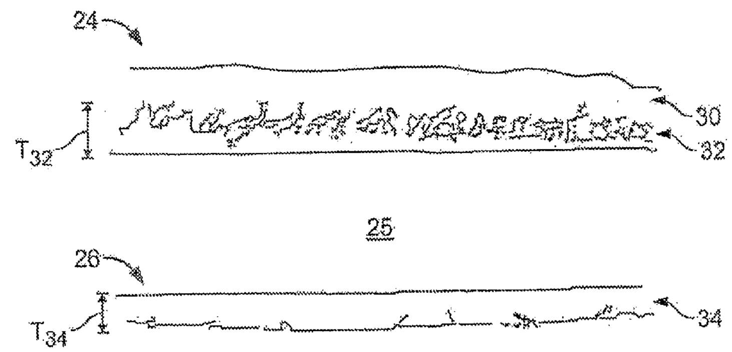

FIG. 3

(57) **Abstract:** An endoprosthesis, such as a stent, includes a ceramic, such as IROX, having a select morphology and composition.

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Endoprosthesis with Select Ceramic Morphology

TECHNICAL FIELD

This disclosure relates to endoprostheses with select ceramic morphology.

BACKGROUND

The body includes various passageways such as arteries, other blood vessels, and other body lumens. These passageways sometimes become occluded or weakened. For example, the passageways can be occluded by a tumor, restricted by plaque, or weakened by an aneurysm. When this occurs, the passageway can be reopened or reinforced with a medical endoprosthesis. An endoprosthesis is typically a tubular member that is placed in a lumen in the body. Examples of endoprostheses include stents, covered stents, and stent-grafts.

Endoprostheses can be delivered inside the body by a catheter that supports the endoprosthesis in a compacted or reduced-size form as the endoprosthesis is transported to a desired site. Upon reaching the site, the endoprosthesis is expanded, e.g., so that it can contact the walls of the lumen. Stent delivery is further discussed in Heath, U.S. 6,290,721, the entire contents of which is hereby incorporated by reference herein.

The expansion mechanism may include forcing the endoprosthesis to expand radially. For example, the expansion mechanism can include the catheter carrying a balloon, which carries a balloon-expandable endoprosthesis. The balloon can be inflated to deform and to fix the expanded endoprosthesis at a predetermined position in contact with the lumen wall. The balloon can then be deflated, and the catheter withdrawn from the lumen.

SUMMARY

In an aspect, the invention features an endoprosthesis including ceramic having a morphology of defined grains with an aspect ratio of about 5:1 or more.

In another aspect, the invention features an endoprosthesis including ceramic having an Sdr of about 100 or greater.

In another aspect, the invention features an endoprosthesis including ceramic having a morphology of globular features having a height of about 20nm or less, a diameter of about 100nm or less, and a peak distance of about 200nm or less.

In another aspect, the invention features an endoprosthesis including a ceramic having an Sdr of about 10 or less and an Sdr uniformity of about +/- 10% on about 25% or more of an abluminal or adluminal surface.

In another aspect, the invention features an endoprosthesis including a ceramic having a morphology of defined grains, and a polymer coating over the ceramic.

In another aspect, the invention features an endoprosthesis including a ceramic coating having an Sdr of about 1 or more, and a polymer coating over the ceramic.

In another aspect, the invention features an endoprosthesis including a first ceramic having a morphology of defined grains on a first portion, and a second ceramic having a globular morphology.

In another aspect, the invention features an endoprosthesis including a first ceramic having an Sdr of about 10 or less, and a second ceramic having an Sdr of about 100 or more.

In another aspect, the invention features a method of forming a prosthesis including forming a ceramic by plasma sputtering, forming a polymer on the ceramic, and utilizing the polymer-coated ceramic in a stent.

In another aspect, the invention features a method of forming an endoprosthesis including forming a first ceramic having a first morphology on said endoprosthesis, and forming a second ceramic having a second morphology on said endoprosthesis.

Embodiments may also include one or more of the following features. The aspect ratio is about 10:1 to 20:1. The grains have a length from about 50nm-400nm. The grains have a width of about 5 to 15nm. The ceramic has a peak distance of about 200 nm or less. The ceramic has a peak height of about 400 nm or less. The Sdr is about 120 to 200. The ceramic has an Sq of about 20 or more. The endoprosthesis includes a coating over the ceramic. The coating is formed of polymer. The coating includes drug. The ceramic is IROX.

Embodiments may also include one or more of the following features. The Sdr is about 120 to 200. The Sdr is about 150 or greater. The Sdr is about 180 or greater. The

ceramic has an Sq of about 20 or more. The Sq is about 20 to 30. The Sdr a uniformity is about +/- 20% or less. The ceramic includes defined grains having an aspect ratio of about 5:1 or more. The aspect ratio is about 10:1 to 20:1. The grains have a length from about 50nm-200nm. The grains have a width of about 5 to 15nm.
The ceramic has a peak distance of about 400 nm or less. The ceramic has a peak height of about 400 nm or less.

Embodiments may also include one or more of the following features. The ceramic is a coating on a metal. The coating is on the abluminal side of a stent. The adluminal surface is substantially free of said coating. The ceramic has an Sq of about 10 or less. The ceramic has an Sq of about 10 or less. The coating is on the adluminal side of the endoprosthesis. The ceramic is exposed to tissue, free of an overcoat. The ceramic has an Sq of about 10 or less. The ceramic has a peak distance of about 200 nm or less. The ceramic has a peak height of about 200 nm or less. The ceramic has a peak distance of about 15 nm or less. The ceramic has a peak height of about 5 nm or less. The ceramic has a peak height of about 5 nm or less. The grains have an aspect ratio of about 5:1 or more. The Sdr is about 100 or greater. The Sdr is about 1 to 200.

Embodiments may also include one or more of the following features. The ceramic has a defined grain morphology. The ceramic has a globular morplology. The first ceramic is on the abluminal side and the second ceramic is on the adluminal side. The coating over the second ceramic. The coating is polymer. The first ceramic is on top of the second ceramic. The second ceramic is on top of the first ceramic. The first ceramic is on the abluminal side and the second ceramic is on the adluminal side. The endoprosthesis includes a coating over the second ceramic. The coating is polymer. The polymer includes a drug. The second ceramic has a defined grain morphology. The first ceramic has a globular morphology.

Embodiments may also include one or more of the following. The ceramic has a morphology of defined grains with an aspect ratio of about 5:1 or more. The ceramic has a morphology of globular features having a height of about 20nm or less, a diameter of about 100nm or less, and a peak distance of about 200nm or less. The ceramic has an Sdr of about 10 or less and an Sdr uniformity of about +/- 10% about 25% or more of an abluminal or adluminal surface. The ceramic has a morphology of defined grains, and a polymer coating over the ceramic. The ceramic coating has an Sdr of about 1 or more, and a polymer coating over the ceramic. The first ceramic has a morphology of defined grains on a first portion, and a second ceramic having a morphology or globular features on a second portion. The first ceramic has an Sdr of about 10 or less, and the second ceramic has an Sdr of about 100 or more.

Embodiments may include one or more of the following advantages. Stents can be formed with ceramic coatings that have morphologies and/or compositions that enhance therapeutic performance. In particular, the ceramics are tuned to enhance mechanical performance and physiologic effect. Enhanced mechanical performance provides particular advantages during the challenging operations encountered in stent use, which typically includes collapsing the stent to a small diameter for insertion into the body, delivery though a tortuous lumen, and then expansion at a treatment site. Enhancing mechanical properties of the ceramic reduces the likelihood of cracking or flaking of the ceramic, and enhanced adhesion of the ceramic to the stent body and to overcoatings, such as drug eluting materials. Improved physiologic effects include discouraging restenosis and encouraging endothelialization. The ceramics are tuned by controlling ceramic morphology and composition. For example, the ceramic can have a morphology that enhances endothelial growth, a morphology that enhances the adhesion of overcoatings such as polymers, e.g. drug eluting coatings, a morphology that reduces delamination, cracking or peeling, and/or a morphology that enhances catalytic activity to reduce inflammation, proliferation and restenosis. The coverings can be tuned along a continuum of their physical characteristics, chemistries, and roughness parameters to optimize function for a particular application. Different coating morphologies can be applied in different locations to enhance different functions at different locations. For example, a high roughness, low coverage, defined-grain morphology can be provided on abluminal surfaces to enhance adhesion of a drug-eluting polymer coating and a low roughness, high coverage, globular morphology can be provided on the adluminal surface to enhance endothelialization. The composition is tuned to control hydrophobicity to enhance adhesion to a stent body or a polymer and/or control catalytic effects. The morphologies and composition can be formed by physical vapor deposition using methodologies that allow fine tuning of the morphology characteristics and permit highly uniform, predictable coatings across a desired region of the stent.

Still further aspects, features, embodiments, and advantages follow.

DESCRIPTION OF DRAWINGS

FIGS. 1A-1C are longitudinal cross-sectional views illustrating delivery of a stent in a collapsed state, expansion of the stent, and deployment of the stent.

FIG. 2 is a perspective view of a stent.

FIG. 3 is a cross-sectional view of a stent wall.

FIGS. 4A – 4C are enlarged plan views of surface morphologies.

FIGS. 5A-5C are schematic views of ceramic morphologies.

FIG. 6 is a schematic of an inverted cylindrical magnetron deposition system.

FIGS. 7A-7H are plan views of morphologies.

FIG. 8 is a graph of surface compositions.

FIGS. 9A–9C are graphs of composition as a function of depth.

FIG. 10A is a plan view, FIG. 10B and 10C are cross-sectional views and FIG. 10C is a perspective view of a morphology.

FIGS. 11A-11E are schematics of methods of providing variable morphologies on stents.

FIGS. 12–15 are perspective views of stents.

FIG. 16 is a schematic for computing morphology feature parameters.

DETAILED DESCRIPTION

Referring to FIGS. 1A-1C, a stent 20 is placed over a balloon 12 carried near a distal end of a catheter 14, and is directed through the lumen 16 (FIG. 1A) until the portion carrying the balloon and stent reaches the region of an occlusion 18. The stent 20 is then radially expanded by inflating the balloon 12 and compressed against the vessel wall with the result that occlusion 18 is compressed, and the vessel wall surrounding it undergoes a radial expansion (FIG. 1B). The pressure is then released from the balloon and the catheter is withdrawn from the vessel (FIG. 1C).

Referring to FIG. 2, the stent 20 includes a plurality of fenestrations 22 between struts defined in a wall 23. Stent 20 includes several surface regions, including an outer, or abluminal, surface 24, an inner, adluminal, surface 26, and a plurality of cutface surfaces 28. The stent can be balloon expandable, as illustrated above, or self-expanding stent. Examples of stents are described in Heath '721, supra.

Referring to FIG. 3, an axial cross-sectional view, a stent wall 23 includes a stent body 25 formed, e.g. of a metal, and includes a first ceramic coating 32 on one side, e.g. the abluminal side, and a second ceramic coating 34 on the other side, e.g. the adluminal side. The abluminal side includes a second coating 36, such as a polymer that includes a drug. As illustrated, the coatings 32, 34 have different morphologies and roughnesses.

Referring as well to FIG. 4A, the coating 32 on the abluminal side includes a morphology characterized by defined grains and high roughness. The defined grain, high roughness morphology of the coating 32 provides a high surface area characterized by crevices between and around spaced grains into which the polymer coating 36 can be deposited and interlock to the surface, enhancing adhesion.

Referring as well to FIG. 4B, the coating 34 on the adluminal side has a morphology characterized by a higher coverage, globular surface of generally lower roughness. The smoother globular morphology provides a surface tuned to facilitate endothelial growth by selection of its chemical composition and/or morphological features.

The morphology and composition of the ceramic is selected for its mechanical characteristics, to enhance adhesion to the stent body and enhance adhesion of a polymer coating, for example, and/or to enhance therapeutic function such as reducing restenosis and enhancing endothelialization. Certain ceramics, e.g. oxides, can reduce restenosis through the catalytic reduction of hydrogen peroxide and other precursors to smooth muscle cell proliferation. The oxides can also encourage endothelial growth to enhance endothelialization of the stent. When a stent is introduced into a biological environment (e.g., in vivo), one of the initial responses of the human body to the implantation of a stent, particularly into the blood vessels, is the activation of leukocytes, white blood cells which are one of the constituent elements of the circulating blood system. This activation causes a release of reactive oxygen compound production. One of the species released in this process is hydrogen peroxide, H_2O_2, which is released by neutrophil granulocytes, which constitute one of the many types of leukocytes. The presence of H_2O_2 may increase proliferation of smooth muscle cells and compromise endothelial cell function, stimulating the expression of surface binding proteins which enhance the attachment of more inflammatory cells. A ceramic such as iridium oxide (IROX) can catalytically reduce H_2O_2. The morphology of the ceramic can enhance the catalytic effect and reduce growth of endothelial cells. Iridium oxide (IROX) is discussed further in Alt, U.S. Patent No. 5,980,566. Defined grain morphologies may also allow for greater freedom of motion and are less likely to fracture as the stent is flexed in use and thus the coating resists delamination of the ceramic from an underlying surface and reduces delamination af an overlaying polymer coating. The stresses caused by flexure of the stent, during expansion or contraction of the stent or as the stent is delivered through a tortuously curved body lumen increase as a function of the distance from the stent axis. As a result, in embodiments, a morphology with defined grains is particularly desirable on abluminal regions of the stent or at other high stress points, such as the regions adjacent fenestrations which undergo greater flexure during expansion or contraction.

The morphology of the surface of the ceramic is characterized by its visual appearance, the size and arrangement of particular morphological features such as local maxima, and/or its roughness. In embodiments, the surface is characterized by definable sub-micron sized grains. Referring particularly to FIG. 4A, for example, in embodiments, the grains have a length, L, of the of about 50 to 500nm, e.g. about 100-300nm, and a width, W, of about 5nm to 50nm, e.g. about 10-15nm. The grains have an aspect ratio (length to width) of about 5:1 or more, e.g. 10:1 to 20:1. The grains overlap in one or more layers. The separation between grains can be about 1-50 nm. In particular embodiments, the grains resemble rice grains.

Referring particularly to FIG. 4B, in embodiments, the surface is characterized by a more continuous surface having a series of shallow globular features. The globular features are closely adjacent with a narrow minima between features. In embodiments, the surface resembles an orange peel. The diameter of the globular features is about 100nm or less, and the depth of the minima, or the height of the maxima of the globular function is e.g. about 50nm or less, e.g. about 20nm or less.

Referring to FIG. 4C, in other embodiments, the surface has characteristics between high aspect ratio definable grains and the more continuous globular surface and/or has a combination of these characteristics. For example, as shown in FIG. 4C, the morphology can include a substantially globular base layer and a relatively low density of defined grains. In other embodiments, the surface can include low aspect ratio, thin planar flakes. The morphology type is visible in FESEM images at 50 KX.

Referring to FIGS. 5A-5C, morphologies are also characterized by the size and arrangement of morphological features such as the spacing, height and width of local morphological maxima. Referring particularly to FIG. 5A, a coating 40 on a substrate 42 is characterized by the center-to-center distance and/or height, and/or diameter and/or density of local maxima. In particular embodiments, the average height, distance and diameter are in the range of about 400 nm or less, e.g. about 20-200 nm. In particular, the average center-to-center distance is about 0.5 to 2x the diameter.

Referring to FIG. 5B, in particular embodiments, the morphology type is a globular morphology, the width of local maxima is in the range of about 100nm or less and the peak height is about 20 nm or less. In particular embodiments, the ceramic has a peak height of less than about 5 nm, e.g., about 1-5 nm, and /or a peak distance less than about 15 nm, e.g., about 10-15 nm. Referring to FIG. 5C, in embodiments, the morphology is defined as a grain type morphology. The width of local maxima is about 400 nm or less, e.g. about 100-400 nm, and the height of local maxima is about 400 nm or less, e.g. about 100-400 nm. As illustrated in FIGS. 5B and 5C, the select morphologies of the ceramic can be formed on a thin layer of substantially uniform, generally amorphous IROX, which is in turn formed on a layer of iridium metal, which is in turn deposited on a metal substrate, such as titanium or stainless steel. The spacing, height and width parameters can be calculated from AFM data. A suitable computational technique is provided below.

The roughness of the surface is characterized by the average roughness, Sa, the root mean square roughness, Sq, and/or the developed interfacial area ratio, Sdr. The Sa and Sq parameters represent an overall measure of the texture of the surface. Sa and Sq are relatively insensitive in differentiating peaks, valleys and the spacing of the various texture features. Surfaces with different visual morphologies can have similar Sa and Sq values. For a surface type, the Sa and Sq parameters indicate significant deviations in the texture characteristics. Sdr is expressed as the percentage of additional surface area contributed by the texture as compared to an ideal plane the size of the measurement region. Sdr further differentiates surfaces of similar amplitudes and average roughness. Typically Sdr will increase with the spatial intricacy of the texture whether or not Sa changes.

In embodiments, the ceramic has a defined grain type morphology. The Sdr is about 100 or more, e.g. about 120 to 200. In addition or in the alternative, the morphology has an Sq of about 20 or more, e.g. about 20 to 30. In particular embodiments, the ceraminc has an Sdr of 150 or more, e.g., 180-300. In other embodiments, the ceramic has a globular type surface morphology. The Sdr is about 10 or less, e.g. about 1 to 8. The Sq is about 10 or less, e.g. about less than 3 or 1 to 5. In still other embodiments, the ceramic has a morphology between the defined grain and the globular surface, and Sdr and Sq values between the ranges above, e.g. an Sdr of about 1 to 200 and/or an Sq of about 1 to 30. The Sa, Sq, and Sdr can be calculated from AFM data. A suitable computation scheme is provided below.

The morphology of the ceramic coating can exhibit high uniformity. The uniformity provides predictable, tuned therapeutic and mechanical performance of the ceramic. The uniformity of the morphology as characterized by Sa, Sq or Sdr and/or average peak spacing parameters can be within about +/- 20% or less, e.g. +/- 10% or less within a 1μm square. In a given stent region, the uniformity is within about +/- 10%, e.g. about +/- 1%. For example, in embodiments, the ceramic exhibits high uniformity over an entire surface region of stent, such as the entire abluminal or adluminal surface, or a portion of a surface region, such as the center 25% or 50% of the surface region. The uniformity is expressed as standard deviation. Uniformity in a region of a stent can be determined by determining the average in five randomly chosen 1μm square regions and calculating the standard deviation. Uniformity of visual morphology type in a region is determined by inspection of FESEM data at 50 KX.

The ceramics are also characterized by surface composition, composition as a function of depth, and crystallinity. In particular, the amounts of oxygen or nitride in the ceramic is selected for a desired catalytic effect on, e.g., the reduction of H_2O_2 in biological processes. The composition of metal oxide or nitride ceramics can be determined as a ratio of the oxide or nitride to the base metal. In particular embodiments, the ratio is about 2 to 1 or greater, e.g. about 3 to 1 or greater, indicating high oxygen content of the surface. In other embodiments, the ratio is about 1 to 1 or less, e.g. about 1 to 2 or less, indicating a relatively low oxygen composition. In particular embodiments, low oxygen content globular morphologies are formed to enhance endothelialization. In other embodiments, high oxygen content defined grain morphologies are formed, e.g., to enhance adhesion and catalytic reduction. Composition can be determined by x-ray photoelectron spectroscopy (XPS). Depth studies are conducted by XPS after argon sputtering. The crystalline nature of the ceramic can be characterized by crystal shapes as viewed in FESEM images, or Miller indices as determined by x-ray diffraction. In embodiments, defined grain morphologies have a Miller index of <101>. Globular materials have blended amorphous and crystalline phases that vary with oxygen content. Higher oxygen content typically indicates greater crystallinity.

Referring to FIG. 6, the coatings can be formed using an inverted cylindrical physical vapor deposition arrangement 50 including a cathode 52 within which resides a target material 54, such as a ceramic (e.g. IROX) or a ceramic precursor metal (e.g. Ir). A stent 56 (or precursor component of a stent) is disposed within the cylinder. The cylinder also includes a gas, such as argon and oxygen. A plasma formed in the cylinder accelerates charged species toward the target. Target material is sputtered from the target and is deposited onto the stent (arrow 58).

The operating parameters of the deposition system are selected to tune the morphology and/or composition of the ceramic. In particular, the power, total pressure, oxygen/argon ratio and sputter time are controlled. By increasing the power and/or total pressure the morphology becomes more defined grain, rougher and crystalline. By decreasing these parameters the coating becomes more globular and less rough. In embodiments, the power is within about 340 to 700 watts, e.g. about 400 to 600 watts and the total pressure is about 10 to 30mTorr. In other embodiments the power is about 100 to 350 watts, e.g. about 150 to 300 watts, and the total pressure is about 1 to 10mTorr, e.g. about 2 to 6mTorr. The oxygen partial pressure is in the range of about 10 to 90%. Particular ranges are about 80-90%, e.g. for defined grain morphologies, and 10 to 40%, e.g. for globular morphologies. The deposition time controls the thickness of the ceramic and the stacking of morphological features. In embodiments, the deposition time is about 0.5 to 10 minutes, e.g. about 1 to 3 minutes. The overall thickness of the ceramic is about 50-500nm, e.g. about 100 to 300nm. The oxygen content is increased at higher power, higher total pressure and high oxygen to oxygen ratios.

Inverted cylindrical physical vapor deposition is described further in Siegfried et al., Society of Vacuum Coaters, 39th Annual Technical Conference Proceedings (1996), p. 97; Glocker et al., Society of Vacuum Coaters, 43rd Annual Technical Conference Proceedings-Denver, April 15-20, 2000, p. 81; and SVC: Society of Vacuum Coatings: C-103, An Introduction to Physical Vapor Deposition (PVD) Processes and C-248 – Sputter Deposition in Manufacturing, available from SVC 71 Pinion Hill, NE, Albequeque, NM 87122-6726. A suitable cathode system is the Model 514, available from Isoflux, Inc., Rochester, NY. Other sputtering techniques include closed loop cathode magnetron sputtering. Pulsed laser deposition is described in co-pending application USSN _____, filed concurrently [Attorney Docket No. 10527-801001]. Formation of IROX is also described in Cho et al., *Jpn. J. Appl. Phys.* 36(I)3B: 1722-1727 (1997), and Wessling et al., *J. Micromech. Microeng.* 16:5142-5148 (2006).

EXAMPLE

A series of IROX layers are formed as described in the following Table.

Table

Material	Deposition System	Parameters	Type	Sq nm	S_{dr} %	Uniformity (FESEM)	Peak Height (nm)	Peak Distance (nm)
A	magnetron sputtering	------	mixed	33	25	lower	~44	~20
B	magnetron sputtering	------	mixed	12	-	lower		
C	magnetron sputtering	------	mixed	7	3	lower	~10	~22
D	wet chemical	------	mixed	70	44	lower		
E	cylindrical vertical magnetron sputtering	------	globular	1	1	high	4-5	17-22
F	closed field balanced magnetron sputtering	------	defined grain	27	142	high	------	------
G	inverted cylindrical magnetron sputtering	P = 400-600W Pres = 18-24 mTorr 0_2/A = 80-90% T = 1-3 min	defined grain	30	180	high	------	------
H	inverted cylindrical magnetron sputtering	P = 150-300W Pres = 2-6 mTorr 0_2/A = 10-40% T = 1-3 min	globular	6	7	high	$1\text{-}5^{+}/\text{-}$ 1-5	10-15

Referring to FIG. 7, FESEM images at 50KX are provided for the ceramic materials A-H, along with morphlogy type, Sq and Sdr values, visual uniformity, and peak height and distance data. Materials A-C are formed by magnetron sputtering processes. The ceramics have surfaces that exhibit an intermediate morphology characterized by lobes or rock-like features integrated with or on top of smoother but still granulated surfaces. The uniformity is relatively low, with regions of lower and higher roughness and the presence of non-uniform features such as isolated regions of rock-like features. Material D is on a commercial pacemaker electrode formed by wet chemical techniques. The material exhibits a smoother but still granulated surface.

Material E is a globular material formed by cylindrical vertical magnetron sputtering. The material exhibits a relatively smooth surface, an Sq of about 1, and an Sdr of about 1. The peak height is about 4-5 nm and the peak distance is about 17-22 nm.

Material F is a defined grain material formed by closed field balanced magnetron sputtering. This material exhibits a complex, relatively rough textured surface of intersecting grains. This material has an Sq of about 27 and an Sdr of about 142. These materials exhibit high morphology uniformity.

Materials G and H are defined grain and globular materials, respectively, both of which are formed by inverted cylindrical magnetron sputtering but under varying operating conditions. The defined grain material (Material G) is formed as relatively high power of 400-600W, high pressure of 18-24 mTorr, and high oxygen to Argon ratio of 80-90. The globular material (Material H) is formed at lower power of 150-300W, lower pressure of 2-6 mTorr and lower oxygen to Argon ratio of about 10-40. Material G has an Sq of about 30 and a high Sdr of about 180. Material H has an Sq of about 6 and an Sdr of about 7. Material G also has a low peak height of about 1 to 5 and a peak distance of about 10-15.

Referring to FIG. 8, the surface chemistry of various materials are illustrated. Materials I-VI are formed by inverted cylindrical magnetron sputtering. Materials I-III are defined grain morphologies. Materials IV-VI are globular morphologies. Materials I-IV exhibit a greater oxygen content than Materials V and VI. Oxygen content can be increased by inverted cylindrical magnetron sputtering operating at generally higher power, high pressure and/or higher oxygen partial pressure.

Material VII, which corresponds to Material F in FIG. 8, is a relatively high oxygen content defined grain morphology formed by magnetron sputtering. Material VII, which corresponds to Material E in FIG. 8, is a relatively low oxygen content globular material. Material IX, which corresponds to the material in C in FIG. 8, is an intermediate material with intermediate surface oxygen.

Referring to FIGS. 9A-9C, the chemistry as a function of ceramic depth is illustrated. Referring to FIG. 9A, the oxygen and iridium depth provide for intermediate material XI in FIG. 8 is substantially constant. Referring particularly to FIGS. 9B and 9C, depth profiles are illustrated for globular materials IV and VI, respectively. Surface chemistry and depth profiles can be determined by x-ray photoelectron spectroscopy.

Referring to FIG. 10, ceramic material can also be characterized by its chrystalline structure. Referring particularly to FIG. 10A, a plan FESM view of a defined grain material is provided. Referring particularly to FIGS. 10B and 10C, cross-sectional FESM views at different magnification of the same material are provided. The cross-section illustrates a structure of crystals extending from a higher density IROX layer, which in turn extends from an interlayer of Iridium. Referring to FIG. 10D, a perspective view illustrates the shape of the crystals as a function of depth.

In embodiments, ceramic is adhered only on the abluminal surface of the stent. This construction may be accomplished by, e.g. coating the stent before forming the fenestrations. In other embodiments, ceramic is adhered only on abluminal and cutface surfaces of the stent. This construction may be accomplished by, e.g., coating a stent containing a mandrel, which shields the luminal surfaces. Masks can be used to shield portions of the stent. In embodiments, the stent metal can be stainless steel, chrome, nickel, cobalt, tantalum, superelastic alloys such as nitiniol, cobalt chromium, MP35N, and other metals. Suitable stent materials and stent designs are described in Heath '721, *supra*. In embodiments, the morphology and composition of the ceramic are selected to enhance adhesion to a particular metal. For example, in embodiments, the ceramic is deposited directly onto the metal surface of a stent body, e.g. a stainless steel, without the use of an intermediate metal layer. In other embodiments, a layer of metal common to the ceramic is deposited onto the stent body before deposition to the ceramic. For example, a layer of iridium may be deposited onto the stent body, followed by deposition of IROX onto the iridium layer. Other suitable ceramics include metal oxides and nitrides, such as of iridium, zirconium, titanium, hafnium, niobium, tantalum, ruthenium, platinum and aluminum. The ceramic can be crystalline, partly crystalline or amorphous. The ceramic can be formed entirely of inorganic materials or a blend of inorganic and organic material (e.g. a polymer). In other embodiments, the morphologies described herein can be formed of metal. In embodiments, the thickness T of the coatings is in the range of about 50 nm to about 2 um, e.g. 100 nm to 500 nm.

Referring to FIGS. 11A-11E, processes for providing different morphologies on different surfaces are illustrated. Referring to FIG. 11A, in an embodiment, in a first step 72, a stent is coated on all surfaces with a globular morphology. In a second step 74, a mandrel is inserted into the stent to mask the abluminal surface. In a third step 76, a defined grain morphology is coated on the abluminal and cutface surfaces over the previously deposited globular morphology.

Referring to FIG. 11B, in an embodiment, in a first step 82, a stent is coated on all surfaces with a globular morphology. In a second step 84, a mandrel is inserted into the stent and the stent is subject to plasma etching to remove the covering from he abluminal surface. In a third step 86, a defined grain morphology is deposited on the abluminal surface and over the globular morphology or cutface surfaces.

Referring to FIG. 11C, in an embodiment, in a first step 83, a mandrel is inserted in a stent. In a second step 85, a defined grain morphology is deposited onto the adluminal surface of the stent. In a third step 87, the mandrel is removed and a globular morphology is deposited on all surfaces of the stent. The thickness of the globular morphology is less than the depth of the grains of the defined grain morphology so that on the abluminal surfaces, the morphology retains a defined grain character.

Referring to FIG. 11D, in an embodiment, in a first step 88, a wire is provided inside a stent to partially shield the stent during deposition in a second step 89. The wire also inhibits deformed grain formulations and the conditions are varied during the deposition to provide a thin coating of a globular morphology on the adluminal surface and a thicker defined grain morphology on the abluminal surface.

Referring to FIG. 11E, in an embodiment, in a first step 73, a stent is inserted into a surface with a globular morphology. In a second step 75, the stent is compressed to a smaller diameter. In a third step 77, a defined grain coating is deposited. The compression of the stent to a smaller diameter inhibits growth of defined grain morphology on the adluminal surfaces. The resulting stent includes a defined grain morphology on abluminal surfaces and a globular morphology on adluminal surfaces.

Referring to FIGS. 12-15, other deposition patterns are illustrated. Referring to FIG. 12, a stent 90 including fenestrations 91 has first and second ceramic materials 92, 94. The ceramic material 92 covers substantially a surface of a stent except high stress regions such as adjacent to the species of the fenestrations, where material 94 is provided. Material 94 is, for example, a defined grain material that resists cracking or delamination in high stress locations and material 92 is a globular material.

Referring particularly to FIG. 13, a stent 100 includes a body 101 ceramic material 102, 104 over its end regions which correspond to the location of untreated tissue. Ceramic materials 102, 104 may be, e.g. of the same or different morphology and/or chemistry. For example, the ceramics 102, 104 can be selected to enhance endothelialization. Referring to FIG. 14, a stent 110 has a series of different ceramic materials 112, 114 arranged along its length. Referring to FIG. 15, a stent 120 has different ceramic materials 122, 124, 126 arranged radially about the stent axis. In embodiments, a polymer is provided only on the abluminal surface, as illustrated. In other embodiments, polymer layers are provided as well or only on the luminal surface and/or cut-face surfaces.

The ceramic material can also be selected for compatibility with a particular polymer coating to, e.g. enhance adhesion. For example, for a hydrophobic polymer, the surface chemistry of the ceramic is made more hydrophobic by e.g., increasing the oxygen content, which increases polar oxygen moieties, such as OH groups. Suitable drug eluting polymers may be hydrophilic or hydrophobic. Suitable polymers include, for example, polycarboxylic acids, cellulosic polymers, including cellulose acetate and cellulose nitrate, gelatin, polyvinylpyrrolidone, cross-linked polyvinylpyrrolidone, polyanhydrides including maleic anhydride polymers, polyamides, polyvinyl alcohols, copolymers of vinyl monomers such as EVA, polyvinyl ethers, polyvinyl aromatics such as polystyrene and copolymers thereof with other vinyl monomers such as isobutylene, isoprene and butadiene, for example, styrene-isobutylene-styrene (SIBS), styrene-isoprene-styrene (SIS) copolymers, styrene-butadiene-styrene (SBS) copolymers, polyethylene oxides, glycosaminoglycans, polysaccharides, polyesters including polyethylene terephthalate, polyacrylamides, polyethers, polyether sulfone, polycarbonate, polyalkylenes including polypropylene, polyethylene and high molecular weight polyethylene, halogenerated polyalkylenes including polytetrafluoroethylene, natural and synthetic rubbers including polyisoprene, polybutadiene, polyisobutylene and copolymers thereof with other vinyl monomers such as styrene, polyurethanes, polyorthoesters, proteins, polypeptides, silicones, siloxane polymers, polylactic acid, polyglycolic acid, polycaprolactone, polyhydroxybutyrate valerate and blends and copolymers thereof as well as other biodegradable, bioabsorbable and biostable polymers and copolymers. Coatings from polymer dispersions such as polyurethane dispersions (BAYHDROL.RTM., etc.) and acrylic latex dispersions are also within the scope of the present invention. The polymer may be a protein polymer, fibrin, collagen and derivatives thereof, polysaccharides such as celluloses, starches, dextrans, alginates and derivatives of these polysaccharides, an extracellular matrix component, hyaluronic acid, or another biologic agent or a suitable mixture of any of these, for example. In one embodiment, the preferred polymer is polyacrylic acid, available as HYDROPLUS.RTM. (Boston Scientific Corporation, Natick, Mass.), and described in U.S. Pat. No. 5,091,205, the disclosure of which is hereby incorporated herein by reference. U.S. Pat. 5,091,205 describes medical devices coated with one or more polyiocyanates such that the devices become instantly lubricious when exposed to body fluids. In another preferred embodiment of the invention, the polymer is a copolymer of polylactic acid and polycaprolactone. Suitable polymers are discussed in U.S. Publication No. 2006/0038027.

In embodiments, the polymer is capable of absorbing a substantial amount of drug solution. When applied as a coating on a medical device in accordance with the present invention, the dry polymer is typically on the order of from about 1 to about 50 microns thick. Very thin polymer coatings, e.g., of about 0.2-0.3 microns and much thicker coatings, e.g., more than 10 microns, are also possible. Multiple layers of polymer coating can be provided. Such multiple layers are of the same or different polymer materials.

The terms "therapeutic agent", "pharmaceutically active agent", "pharmaceutically active material", "pharmaceutically active ingredient", "drug" and other related terms may be used interchangeably herein and include, but are not limited to, small organic molecules, peptides, oligopeptides, proteins, nucleic acids, oligonucleotides, genetic therapeutic agents, non-genetic therapeutic agents, vectors for delivery of genetic therapeutic agents, cells, and therapeutic agents identified as candidates for vascular treatment regimens, for example, as agents that reduce or inhibit restenosis. By small organic molecule is meant an organic molecule having 50 or fewer carbon atoms, and fewer than 100 non-hydrogen atoms in total.

Exemplary therapeutic agents include, e.g., anti-thrombogenic agents (e.g., heparin); anti-proliferative/anti-mitotic agents (e.g., paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, inhibitors of smooth muscle cell proliferation (e.g., monoclonal antibodies), and thymidine kinase inhibitors); antioxidants; anti-inflammatory agents (e.g., dexamethasone, prednisolone, corticosterone); anesthetic agents (e.g., lidocaine, bupivacaine and ropivacaine); anti-coagulants; antibiotics (e.g., erythromycin, triclosan, cephalosporins, and aminoglycosides); agents that stimulate endothelial cell growth and/or attachment. Therapeutic agents can be nonionic, or they can be anionic and/or cationic in nature. Therapeutic agents can be used singularly, or in combination. Preferred therapeutic agents include inhibitors of restenosis (e.g., paclitaxel), anti-proliferative agents (e.g., cisplatin), and antibiotics (e.g., erythromycin). Additional examples of therapeutic agents are described in U.S. Published Patent Application No. 2005/0216074. Polymers for drug elution coatings are also disclosed in U.S. Published Patent Application No. 2005/019265A. A functional molecule, e.g. an organic, drug, polymer, protein, DNA, and similar material can be incorporated into groves, pits, void spaces, and other features of the ceramic.

The stents described herein can be configured for vascular, e.g. coronary and peripheral vasculature or non-vascular lumens. For example, they can be configured for use in the esophagus or the prostate. Other lumens include biliary lumens, hepatic lumens, pancreatic lumens, uretheral lumens and ureteral lumens.

Any stent described herein can be dyed or rendered radiopaque by addition of, e.g., radiopaque materials such as barium sulfate, platinum or gold, or by coating with a radiopaque material. The stent can include (e.g., be manufactured from) metallic materials, such as stainless steel (e.g., 316L, BioDur® 108 (UNS S29108), and 304L stainless steel, and an alloy including stainless steel and 5-60% by weight of one or more radiopaque elements (e.g., Pt, Ir, Au, W) (PERSS®) as described in US-2003-0018380-A1, US-2002-0144757-A1, and US-2003-0077200-A1), Nitinol (a nickel-titanium alloy), cobalt alloys such as Elgiloy, L605 alloys, MP35N, titanium, titanium alloys (e.g., Ti-6Al-4V, Ti-50Ta, Ti-10Ir), platinum, platinum alloys, niobium, niobium alloys (e.g., Nb-1Zr) Co-28Cr-6Mo, tantalum, and tantalum alloys. Other examples of materials are described in commonly assigned U.S. Application No. 10/672,891, filed September 26, 2003; and U.S. Application No. 11/035,316, filed January 3, 2005. Other materials include elastic biocompatible metal such as a superelastic or pseudo-elastic metal alloy, as described, for example, in Schetsky, L. McDonald, "Shape Memory Alloys", Encyclopedia of Chemical Technology (3rd ed.), John Wiley & Sons, 1982, vol. 20. pp. 726-736; and commonly assigned U.S. Application No. 10/346,487, filed January 17, 2003.

The stent can be of a desired shape and size (e.g., coronary stents, aortic stents, peripheral vascular stents, gastrointestinal stents, urology stents, tracheal/bronchial stents, and neurology stents). Depending on the application, the stent can have a diameter of between, e.g., about 1 mm to about 46 mm. In certain embodiments, a coronary stent can have an expanded diameter of from about 2 mm to about 6 mm. In some embodiments, a peripheral stent can have an expanded diameter of from about 4 mm to about 24 mm. In certain embodiments, a gastrointestinal and/or urology stent can have an expanded diameter of from about 6 mm to about 30 mm. In some embodiments, a neurology stent can have an expanded diameter of from about 1 mm to about 12 mm. An abdominal aortic aneurysm (AAA) stent and a thoracic aortic aneurysm (TAA) stent can have a diameter from about 20 mm to about 46 mm. The stent can be balloon-expandable, self-expandable, or a combination of both (e.g., U.S. Patent No. 6,290,721). The ceramics can be used with other endoprostheses or medical devices, such as catheters, guide wires, and filters.

Computation

The roughness and feature parameters are calculated from AFM data. A height map is imported from the AFM as a matrix of height values. An image of a 1 um square region is represented by a 512 x 512 pixel matrix for a resolution of about 2-3 nm. For morphologies that exhibit substantial defined grains, the roughness parameters, Sa, Sq, and Sdr, as well as feature parameters such as peak height, peak diameter and peak distance can be calculated directly from the pixel matrix. For globular type morphologies, in which the differential between minima and maxima are less pronounced, a watershed function can be used, which is illustrated in Fig. 16. The grey scale height map is inverted and a watershed function is used to generate local maxima and minima. The roughness parameter and the feature parameter are calculated from the watershed processed data. The watershed process is used to more efficiently find local maxima and minima in the generally smoother globular morphologies. Suitable software for calculating height map is the Scanning Probe Image Processor (SPIP) from Imagnet in Lyngby, Denmark. Software for determining feature parameters is developed using IDL Software from RSI, Inc., ITT Visual Information Solutions, Boulder, Colorado. Code for computing the image feature parameters is provided below.

```
;
; Routine for IDL Version 6.2 WIN 32 (x86)
; Analyzes local peaks on height maps
;
; xxxxxxxxxxxxxxxxxx
; INPUT variables:
; height_map: Matrix containing height in nm per matrix element (pixel)
; pixsize: Vector containing size of one pixel in x and y direction in nm
; xxxxxxxxxxxxxxxxxx
;
; IDL is a product of ITT Visual Information Solutions www.ittvis.com
; Corporate Headquarters
; 4990 Pearl East Circle
; Boulder, CO 80301


PRO analyze_peaks, height_map, pixsize

; Calculates amount of pixels in x and y direction
pix = {x:0,y:0}
pix.x = (size(height_map))[1]
pix.y = (size(height_map))[2]

; image size x-axis in nanometers
imagesizex = pixsize.x*pix.x/1000.0

; image size y-axis in nanometers
imagesizey = pixsize.y*pix.y/1000.0

res = height_map

;shift image to positive values
a = res - min(res)

;Invert the image
b = MAX(a) - a
c = b

;Create watershed image = identifies local maximum
d = WATERSHED(c,connectivity=8)

; initialize matrices
fa = make_array(pix.x,pix.y,/float)
fa_leveled = make_array(pix.x,pix.y,/float)
level_max = make_array(max(d)+1,/float)
level_min = level_max
level_dif = level_max
level_grad = level_max
level_loc = level_max
max_ix = level_max
max_iy = level_max
struct = make_array(2,2,/byte, value=1)

; repeat calculations for each local maxima i
for i=1, max(d) do begin
; erases boundaries from identified local maximum cell
 fc = a * dilate((d eq i),struct)
 fc_min = (a-max(a)) * dilate((d eq i),struct)
 tmpa = max(fc, location_max)
 ; calculate height of local maxima for each local maxima i
 level_max(i) = tmpa
 ; calculate height of next minima for each local maxima i
 level_min(i) = min(fc_min, location_min)+max(a)
 ; calculate difference between local maxima and next minima for each maxima i
 ; = local peak height
 level_dif(i) = tmpa - level_min(i)
 fa_leveled = fa_leveled + fc - tmpa* (fc ne 0)
 ; find pixels where maxima and minima on image located
 IX_max = location_max MOD pix.x
 IY_max = location_max/pix.y
 IX_min = location_min MOD pix.x
 IY_min = location_min/pix.y
```

```
  fa[ix_max,iy_max] = 1.0
  fa[ix_min,iy_min] = -1.0
  ; calculate lateral distance between local maxima and next minima for each local maxima i
  ; = local peak radius
  level_loc[i] = sqrt(((IX_max-IX_min)*pixsize.x)^2+((IY_max-IY_min)*pixsize.y)^2)
  ; calculate local maxima position
  max_ix[i] = IX_max*pixsize.x
  max_iy[i] = IY_max*pixsize.y
  ; calculate gradient between local maxima and next minima for each local maxima i
  level_grad[i] = (level_max[i]-level_min[i])/level_loc[i]
endfor

;calculate nearest distance to next local maximum
k = 0
k = long(k)
maxd = long(max(d))
max_dist1 = make_array(maxd*maxd,/float)
; repeat for each permutation
for i=1, maxd do begin
 maxdist_old =1000000.0
 for j=1, maxd do begin
   maxdist1 = sqrt((max_ix[i]-max_ix[j])^2+(max_iy[i]-max_iy[j])^2)
   if (maxdist1 gt 0.0) then begin
    if maxdist1 lt maxdist_old then begin
     maxdist_old = maxdist1
    endif
   endif
 endfor
 max_dist1[i] =  maxdist_old
endfor

; matrix containing distances to nearest/ next local maximum = peak distances distribution
max_dist = max_dist1[0:maxd-1]


; xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
; results
; xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

; amount of local maxima
print, max(d)

; peak density in 1/µm^2
print, float(maxd)/imagesizex/ imagesizey * 1E6

; average and standard deviation of nearest peak distance in nm
print, mean(max_dist)
print, stddev(max_dist)

; average and standard deviation of local peak height in nm
print, mean(level_diff)
print, stddev(level_diff)

; average and standard deviation of local peak diameter in nm
print, mean(2.0*level_loc)
print, stddev(2.0*level_loc)

; average and standard deviation of local peak gradient in 1
print, mean(level_grad)
print, stddev(level_grad)

End

; xxxxxxxxxxxxxxxxxxxxxxxxxxx
; End of routine analyze_peaks
; xxxxxxxxxxxxxxxxxxxxxxxxxxx
```

All publications, patent applications, patents, and other references mentioned herein including the appendix, are incorporated by reference herein in their entirety.

Still other embodiments are in the claims.

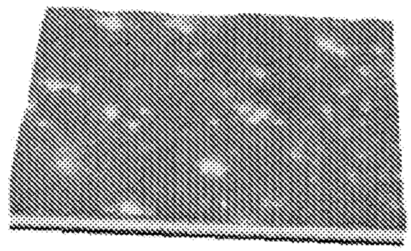
Appendix I

Sa and Sq

As illustrated in Figs. A and B, **Sa and Sq** are the average roughness and root mean square (rms) roughness evaluated over the complete 3D surface respectively. Mathematically, the Sa and Sq are evaluated as follows:

$$S_a = \iint_{\Omega} \left| Z(x, y) \right| dxdy$$

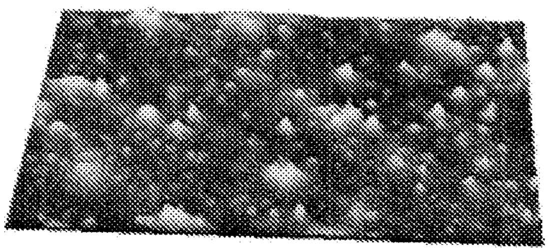
Fig. A



Plateau-like surface -Sa = 16.03nm Sq= 25.4nm

$$Sq = \sqrt{\iint_{\Omega} \left(Z(x, y) \right)^2 dxdy}$$

Fig. B



Surface with Peaks -Sa = 16.03nm Sq= 25.4nm

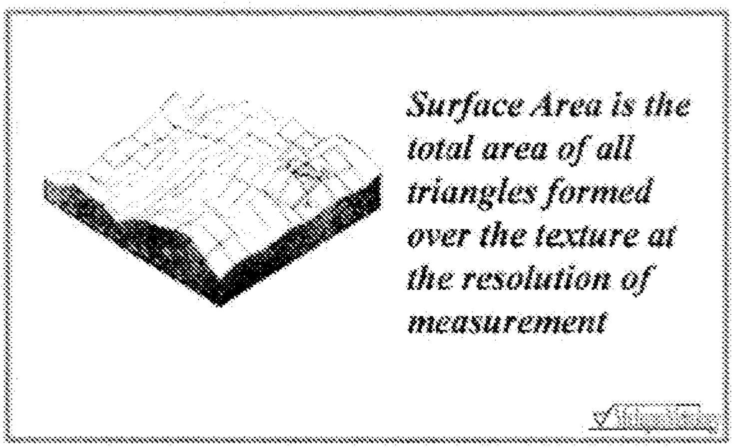
The Sa and Sq parameters represent an overall measure of the texture comprising the surface. Sa and Sq are insensitive in differentiating peaks, valleys and the spacing of the various texture features. The figure above demonstrates two very different surfaces with identical Sa and Sq values, indicating the insensitivity of the Sa and Sq parameters. Once a surface type has been established, the Sa and Sq parameters may be used to indicate significant deviations in the texture characteristics.

Sdr

As illustrated in Figs C and D, **Sdr**, the Developed Interfacial Area Ratio is expressed as the percentage of additional surface area contributed by the texture as compared to an ideal plane the size of the measurement region.

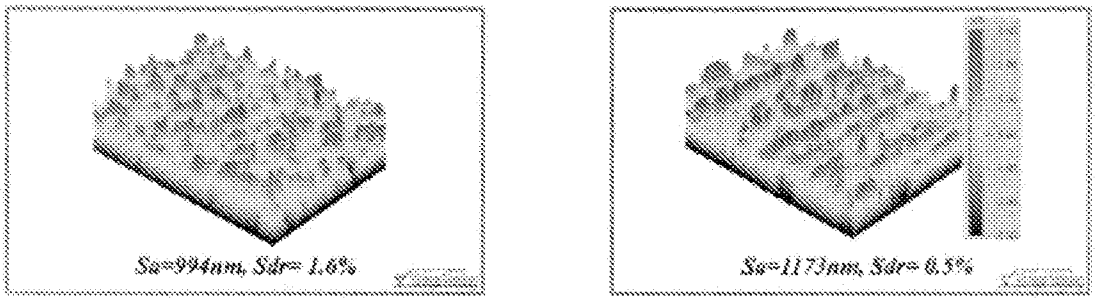
$$Sdr = \frac{(Texture\_Surface\_Area) - (Cross\_Sectional\_Area)}{Cross - Sectional - Area}$$

Fig. C



Christopher A. Brown, William A. Johnsen, Kevin M. Hult, Scale-sensitivity, Fractal Analysis and Simulations, Int. J. Mach. Tools Manufact. Vol 38, Nos 5-6, pp. 633-637, 1998

Fig. D



Sdr may further differentiate surfaces of similar amplitudes and average roughness. Typically Sdr will increase with the spatial intricacy of the texture whether or not Sa changes. Further information is available from Michigan Metrology, Inc., Livonia, MI.

WHAT IS CLAIMED IS:

1. An endoprosthesis, comprising

ceramic having a morphology of defined grains with an aspect ratio of about 5:1 or more.

2. The endoprosthesis of claim 1 wherein the aspect ratio is about 10:1 to 20:1.

3. The endoprosthesis of claim 1 wherein the grains have a length from about 50nm-400nm.

4. The endoprosthesis of claim 1 wherein the grains have a width of about 5 to 15nm.

5. The endoprosthesis of claim 1 wherein the ceramic has a peak distance of about 200 nm or less.

6. The endoprosthesis of claim 1 wherein the ceramic has a peak height of about 400 nm or less.

7. The endoprosthesis of claim 1 wherein the Sdr is about 120 to 200.

8. The endoprosthesis of claim 1 wherein said ceramic has an Sq of about 20 or more.

9. The endoprosthesis of claim 1 further including a coating over the ceramic.

10. The endoprosthesis of claim 9 wherein the coating is formed of polymer.

11. The endoprosthesis of claim 9 wherein the coating includes drug.

12. The endoprosthesis of claim 1 wherein the ceramic is IROX.

13. An endoprosthesis comprising
ceramic having an Sdr of about 100 or greater.

14. The endoprosthesis of claim 13 wherein said Sdr is about 120 to 200.

15. The endoprosthesis of claim 13 wherein said Sdr is about 150 or greater.

16. The endoprosthesis of claim 13 wherein said Sdr is about 180 or greater.

17. The endoprosthesis of claim 13 wherein said ceramic has an Sq of about 20 or more.

18. The endoprosthesis of claim 17 wherein said Sq is about 20 to 30.

19. The endoprosthesis of claim 13 wherein the Sdr a uniformity is about +/- 20% or less.

20. The endoprosthesis of claim 13 wherein the ceramic includes defined grains having an aspect ratio of about 5:1 or more.

21. The endoprosthesis of claim 20 wherein the aspect ratio is about 10:1 to 20:1.

22. The endoprosthesis of claim 20 wherein the grains have a length from about 50nm-200nm.

23. The endoprosthesis of claim 20 wherein the grains have a width of about 5 to 15nm.

24. The endoprosthesis of claim 13 wherein the ceramic has a peak distance of about 400 nm or less.

25. The endoprosthesis of claim 13 wherein the ceramic has a peak height of about 400 nm or less.

26. The endoprosthesis of claim 13 further including a coating over the ceramic.

27. The endoprosthesis of claim 26 wherein the coating is formed of polymer.

28. The endoprosthesis of claim 26 wherein the coating includes drug.

29. The endoprosthesis of claim 13 wherein the ceramic is a coating on a metal.

30. The endoprosthesis of claim 29 wherein the coating is on the abluminal side of a stent.

31. The endoprosthesis of claim 30 wherein the adluminal surface is substantially free of said coating.

32. The endoprosthesis of claim 13 wherein the ceramic is IROX.

33. An endoprosthesis, comprising

ceramic having a morphology of globular features having a height of about 20nm or less, a diameter of about 100nm or less, and a peak distance of about 200nm or less.

34. The endoprosthesis of claim 33 wherein the ceramic has an Sq of about 10 or less.

35. The endoprosthesis of claim 33 wherein the ceramic has an Sq of about 10 or less.

36. The endoprosthesis of claim 33 wherein the coating is on the adluminal side of the endoprosthesis.

37. The endoprosthesis of claim 33 wherein the ceramic is exposed to tissue, free of an overcoat.

38. An endoprosthesis, comprising

a ceramic having an Sdr of about 10 or less and an Sdr uniformity of about +/- 10% about 25% or more of an abluminal or adluminal surface.

39. An endoprosthesis, comprising

a ceramic having a morphology of defined grains, and

a polymer coating over the ceramic.

40. An endoprosthesis, comprising:

a ceramic coating having an Sdr of about 1 or more, and

a polymer coating over the ceramic.

41. An endoprosthesis, comprising

a first ceramic having a morphology of defined grains on a first portion, and

a second ceramic having a morphology or globular features on a second portion.

42. An endoprosthesis, comprising:

a first ceramic having an Sdr of about 10 or less, and

a second ceramic having an Sdr of about 100 or more.

43. A method of forming a prosthesis, comprising:

forming a ceramic by plasma sputtering,

forming a polymer on the ceramic, and

utilizing the polymer-coated ceramic in a stent.

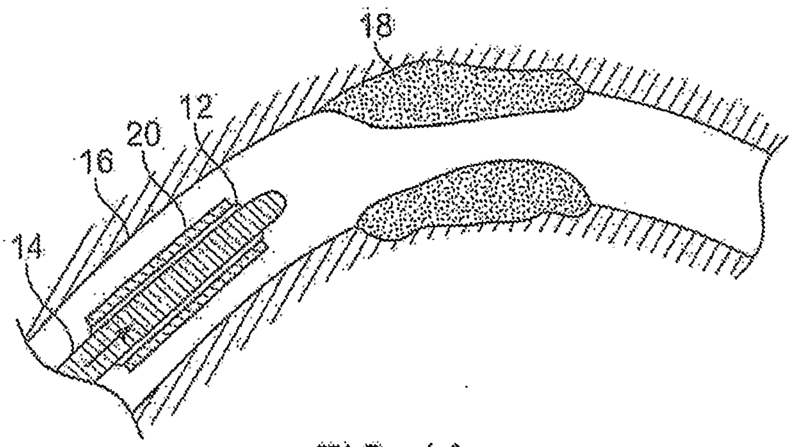


FIG. 1A

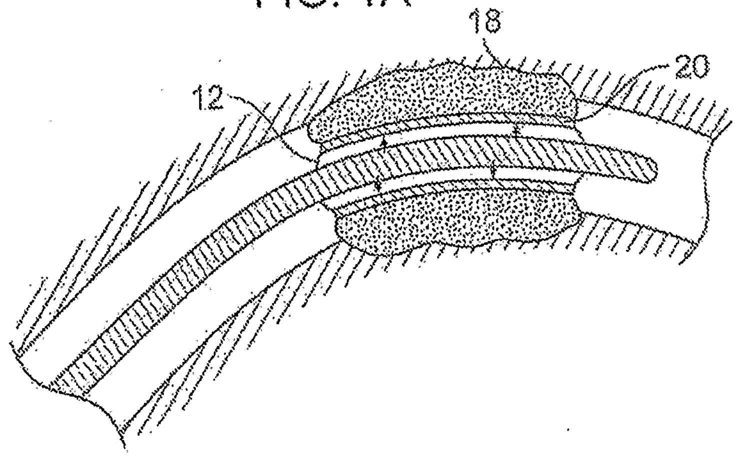


FIG. 1B

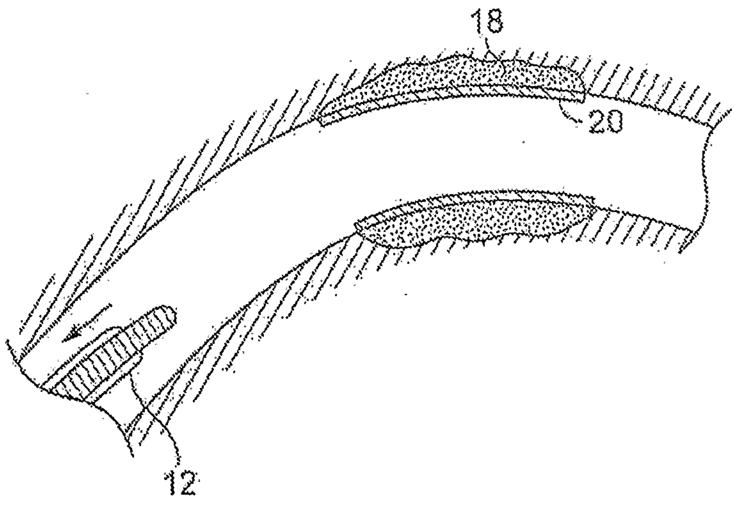


FIG. 1C

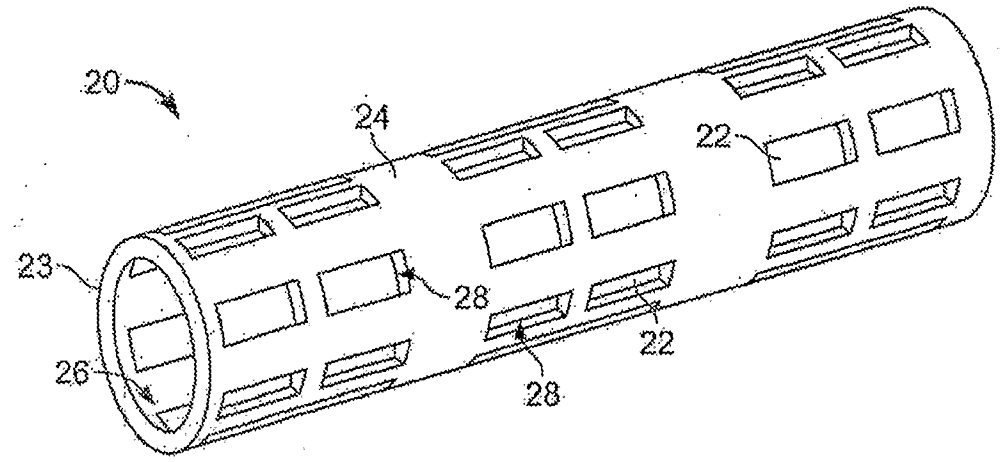


FIG. 2

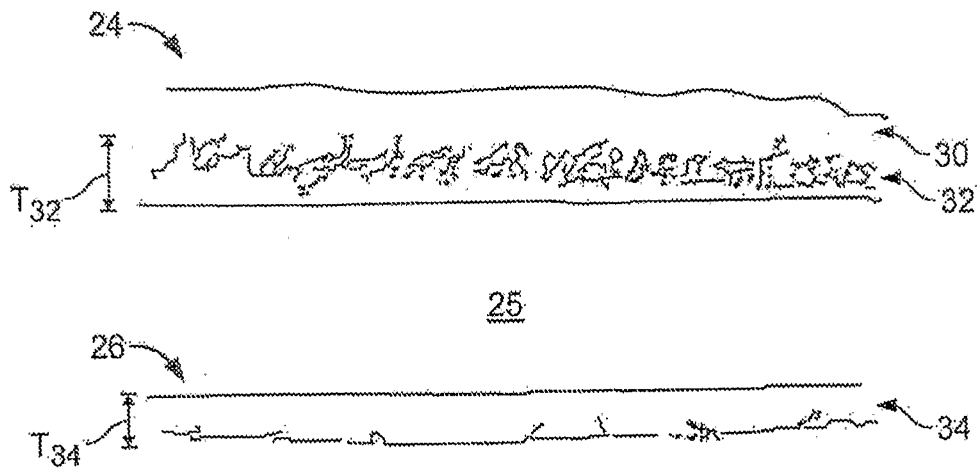


FIG. 3

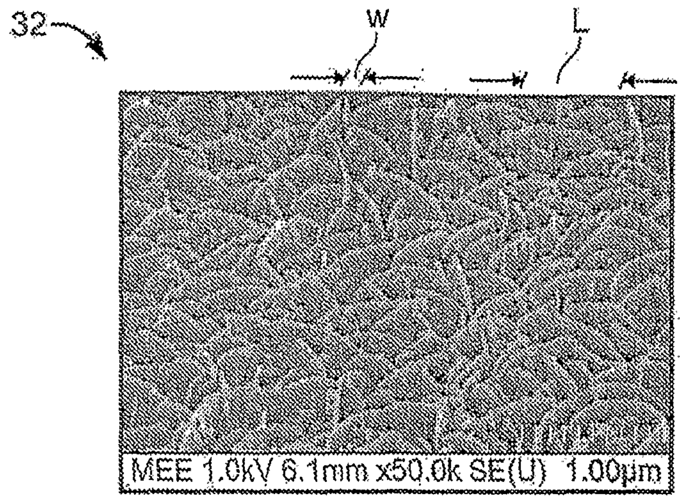


FIG. 4A

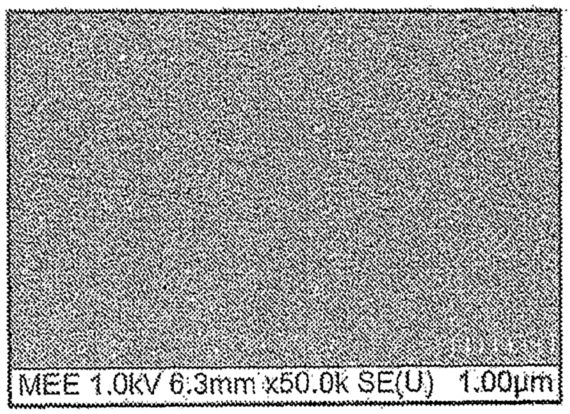


FIG. 4B

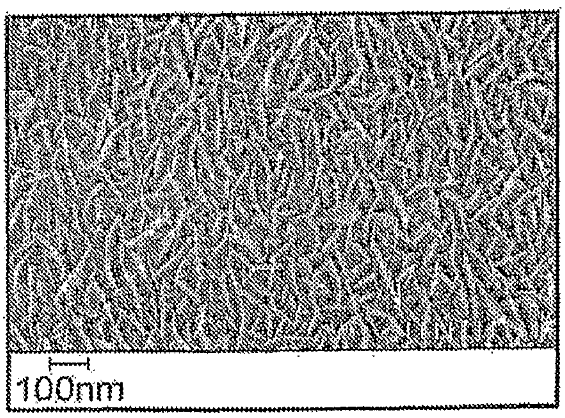


FIG. 4C

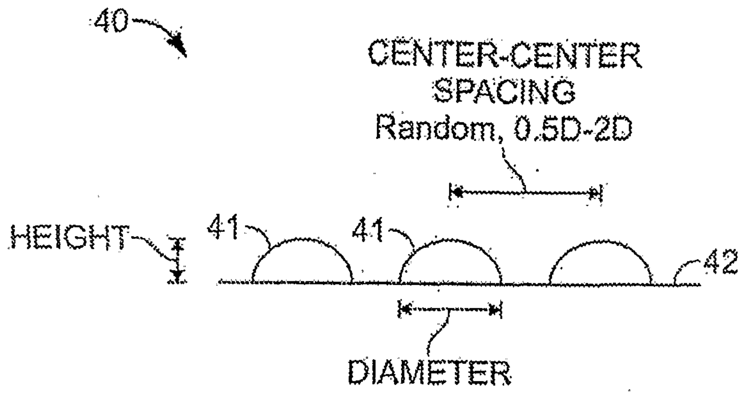


FIG. 5A

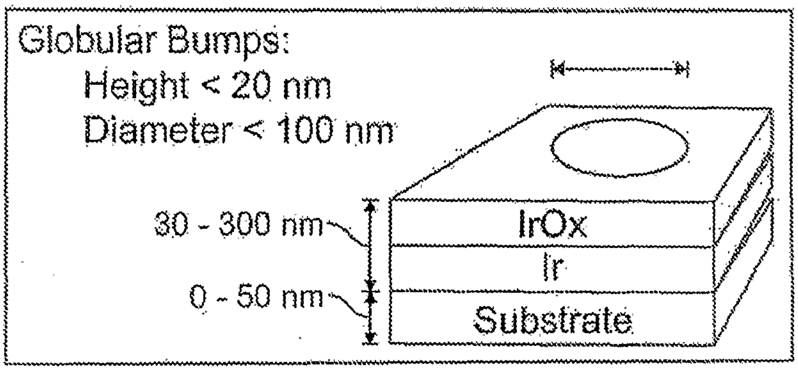


FIG. 5B

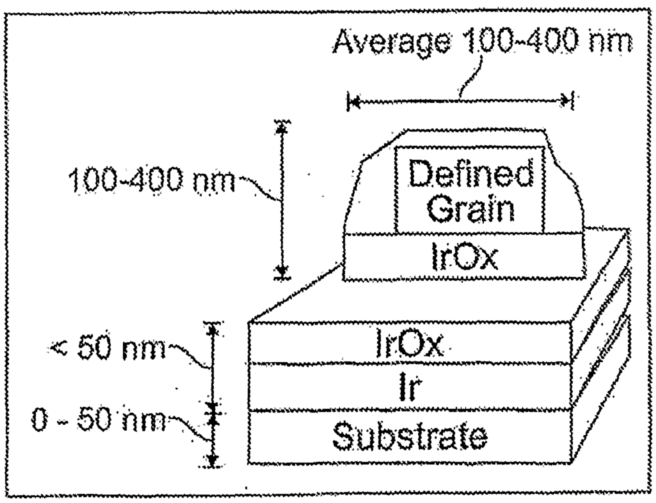


FIG. 5C

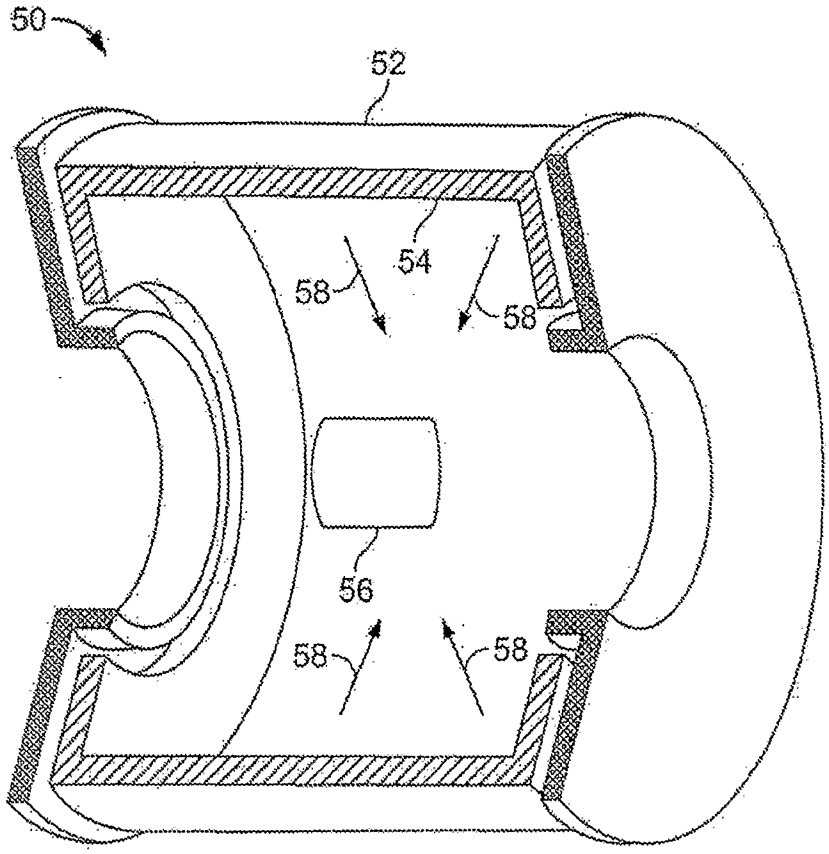

50
52
54
58
58
56
58
58

FIG. 6

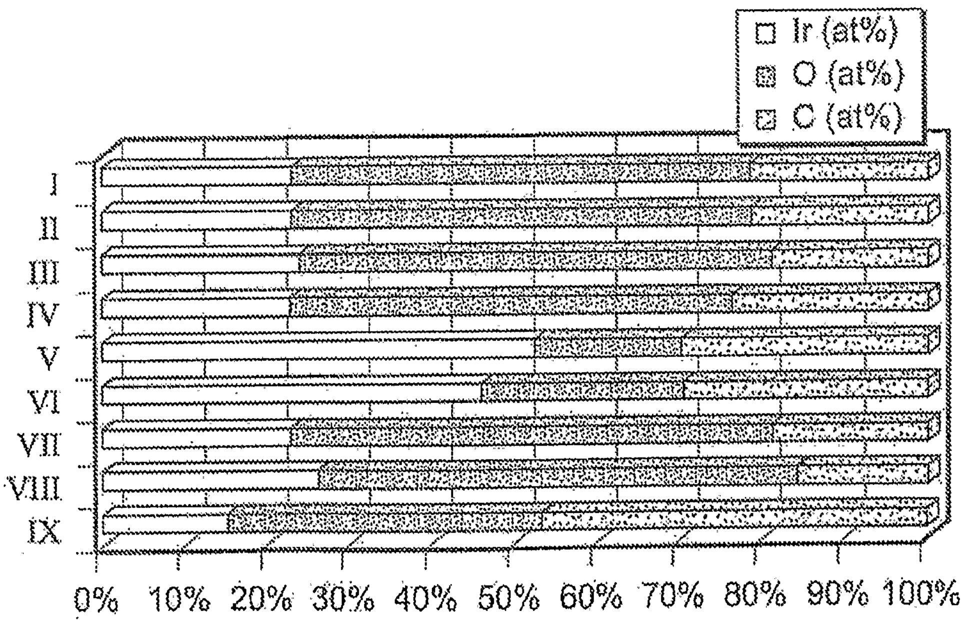

Ir (at%)
O (at%)
C (at%)
I
II
III
IV
V
VI
VII
VIII
IX
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

FIG. 8

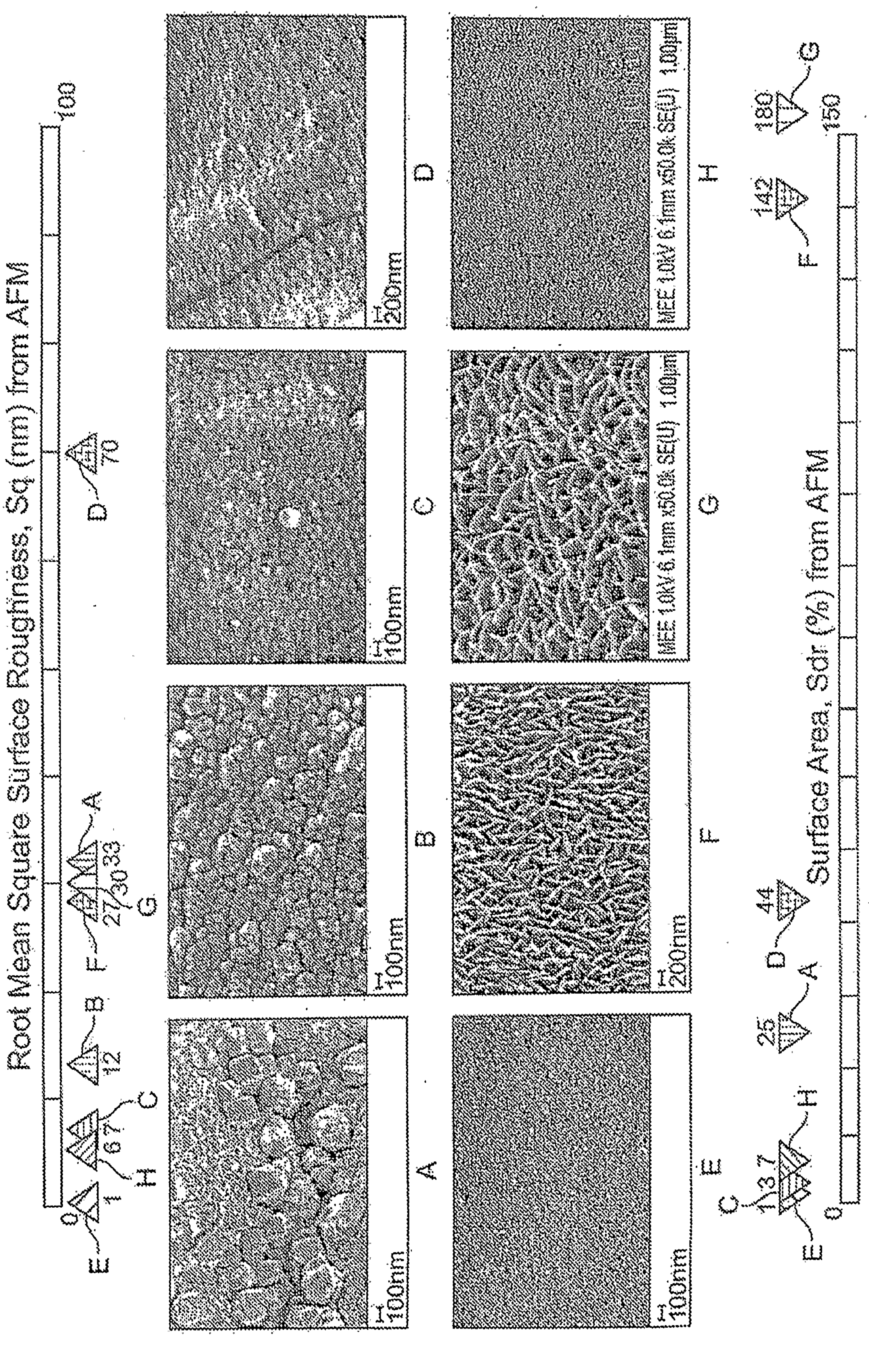

Root Mean Square Surface Roughness, Sq (nm) from AFM
0
100
E
1
H
6 7
C
12
B
F
27
30
33
G
A
D
70
A
B
C
D
E
F
G
H
100nm
200nm
MEE 1.0kV 6.1mm x50.0k SE(U) 1.00µm
Surface Area, Sdr (%) from AFM
0
150
1
3.7
25
44
142
180

FIG. 7

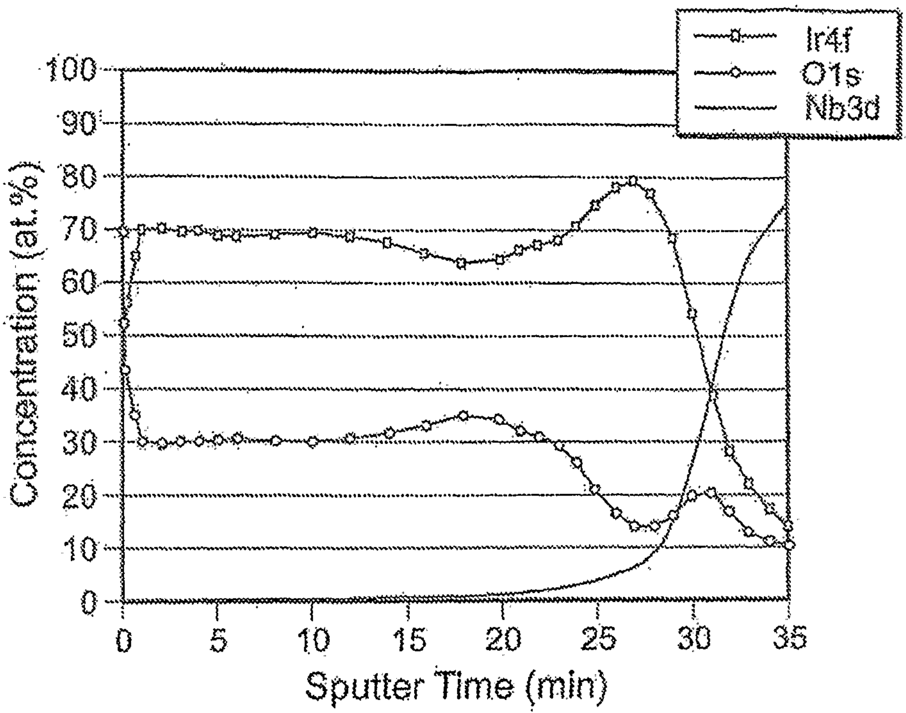

Ir4f
O1s
Nb3d
Concentration (at.%)
0
10
20
30
40
50
60
70
80
90
100
0
5
10
15
20
25
30
35
Sputter Time (min)

FIG. 9A

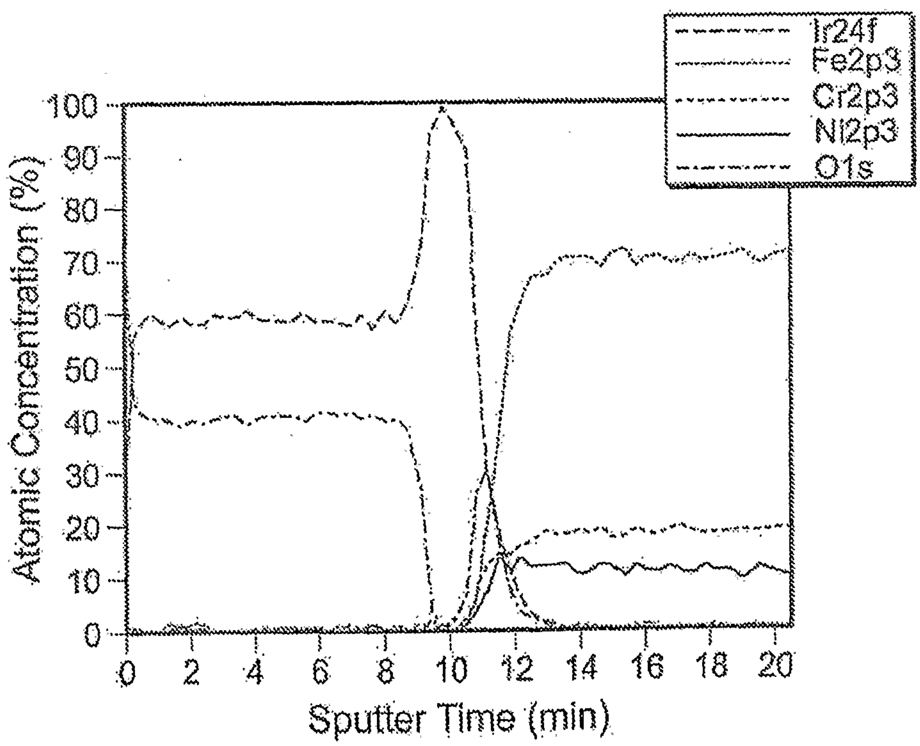

Ir24f
Fe2p3
Cr2p3
Ni2p3
O1s
Atomic Concentration (%)
0
10
20
30
40
50
60
70
80
90
100
0
2
4
6
8
10
12
14
16
18
20
Sputter Time (min)

FIG. 9B

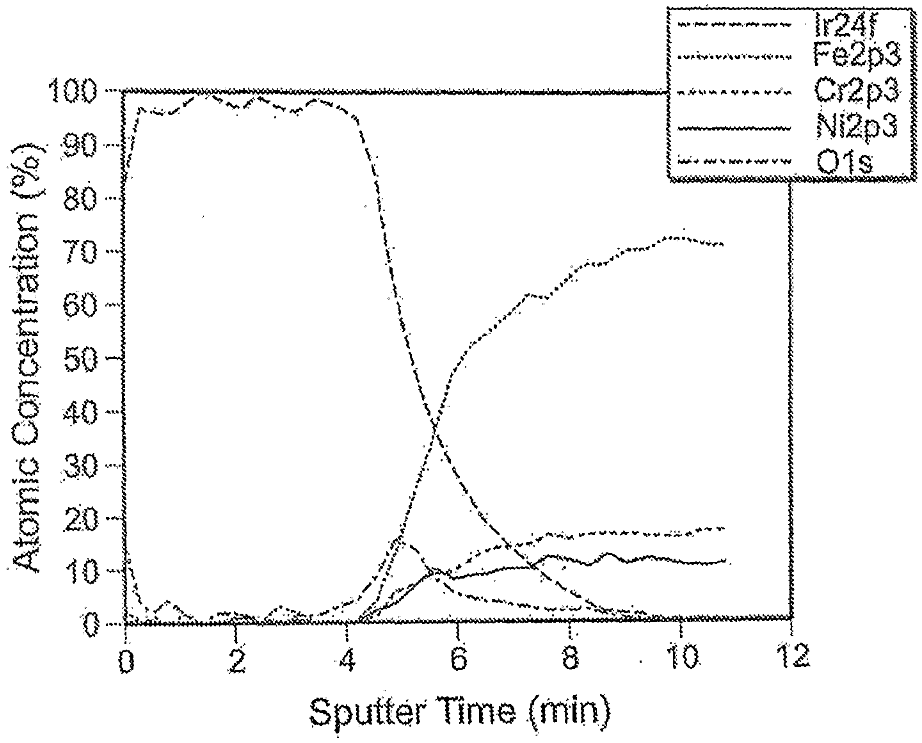

Ir24f
Fe2p3
Cr2p3
Ni2p3
O1s
Atomic Concentration (%)
100
90
80
70
60
50
40
30
20
10
0
0
2
4
6
8
10
12
Sputter Time (min)

FIG. 9C

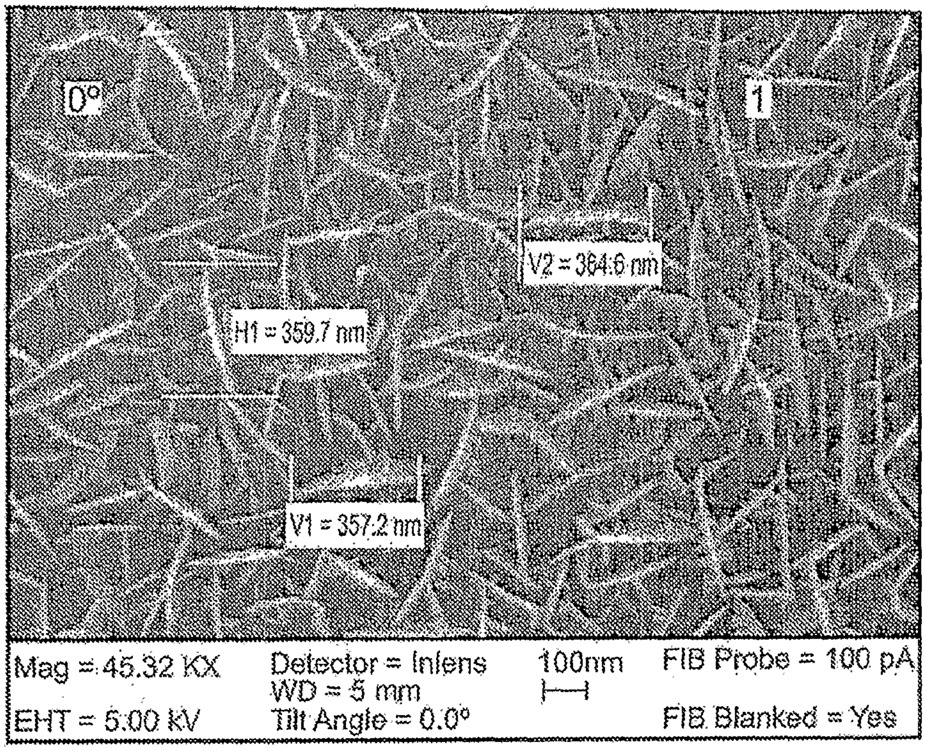


FIG. 10A

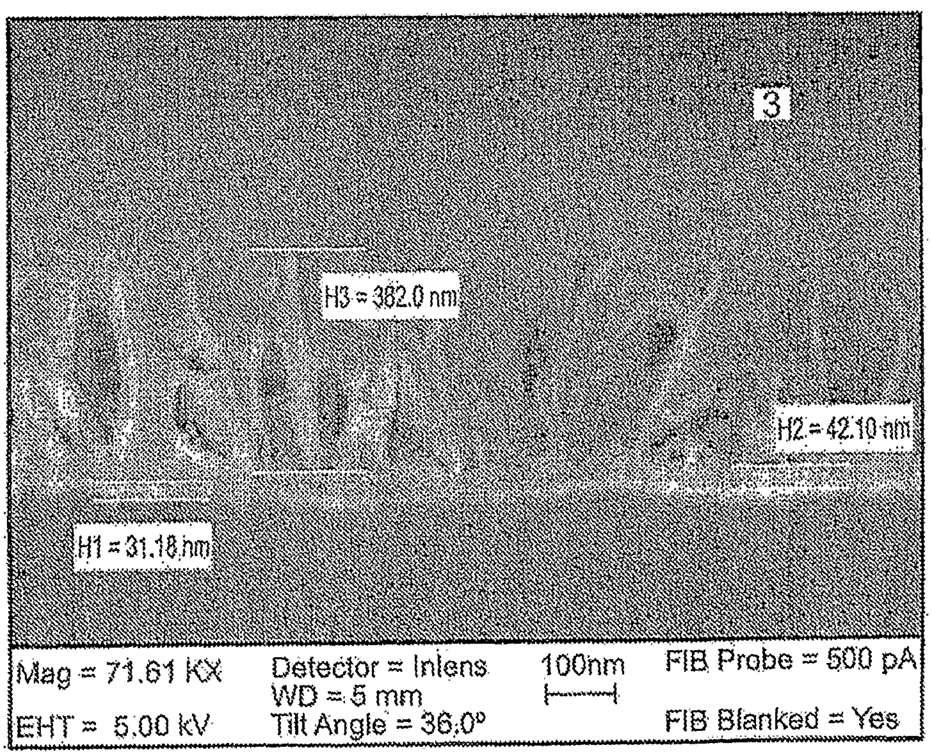


FIG. 10B

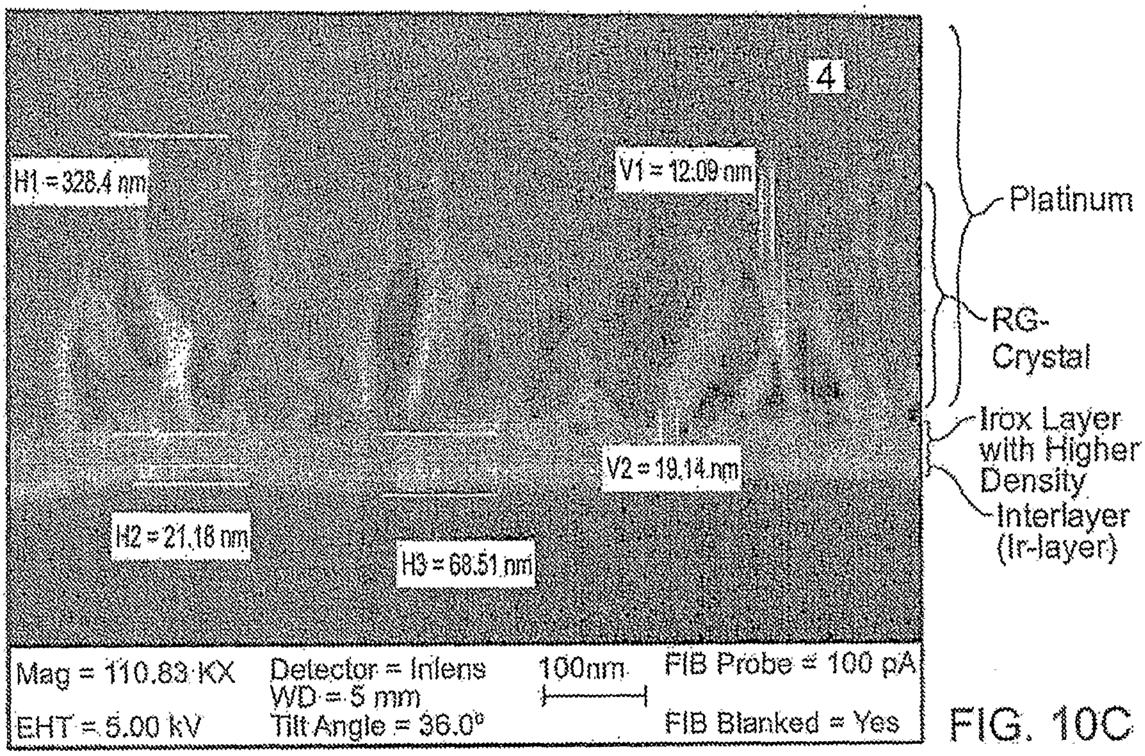


FIG. 10C

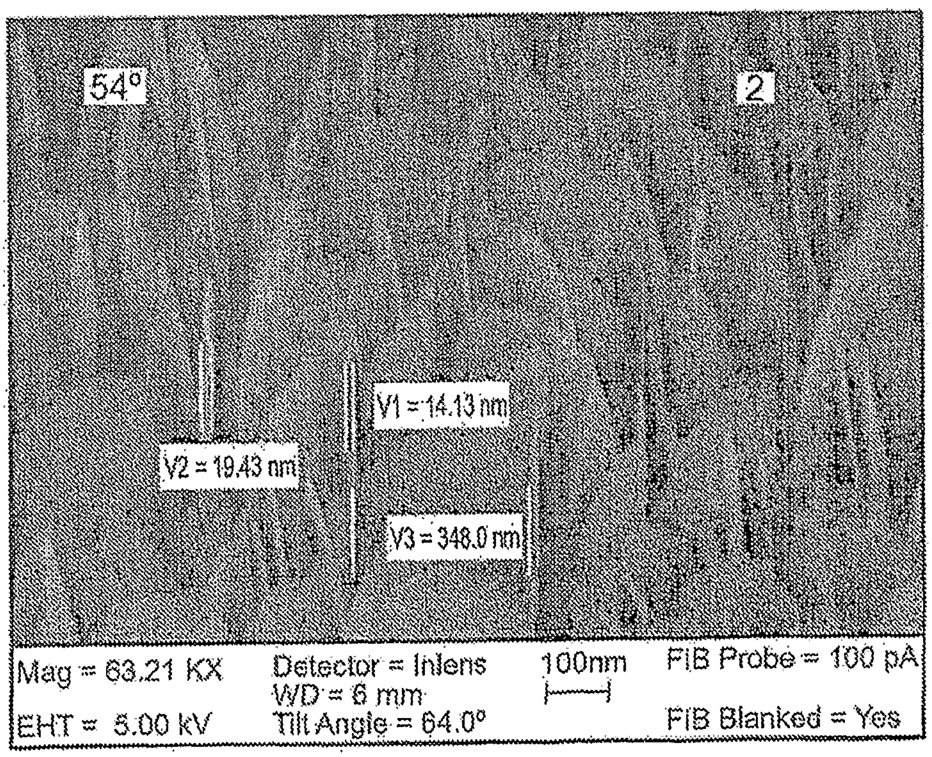


FIG. 10D

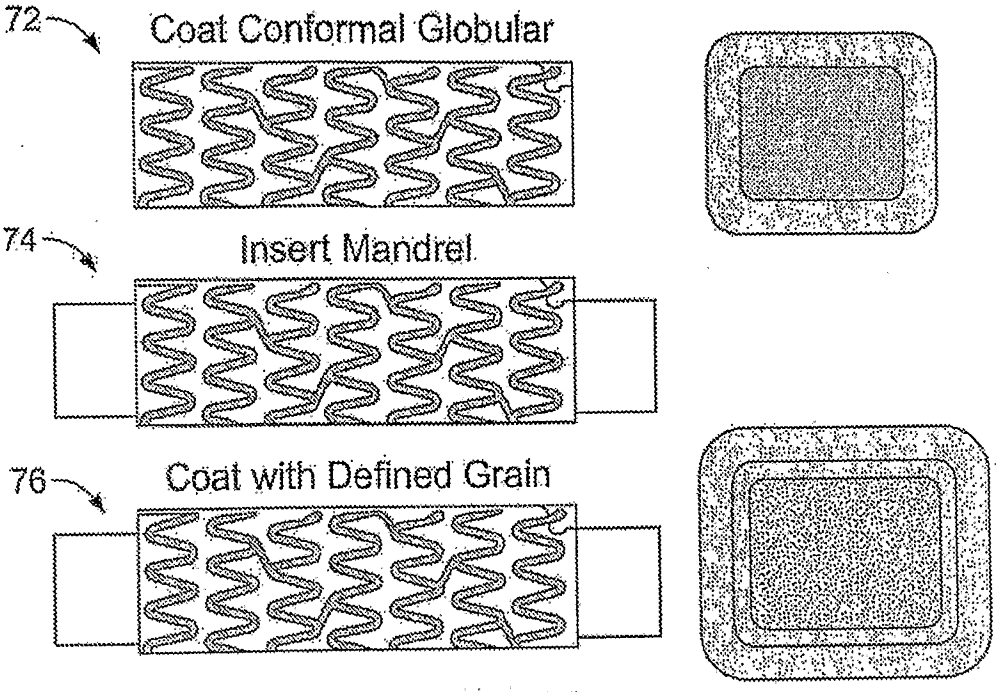


FIG. 11A

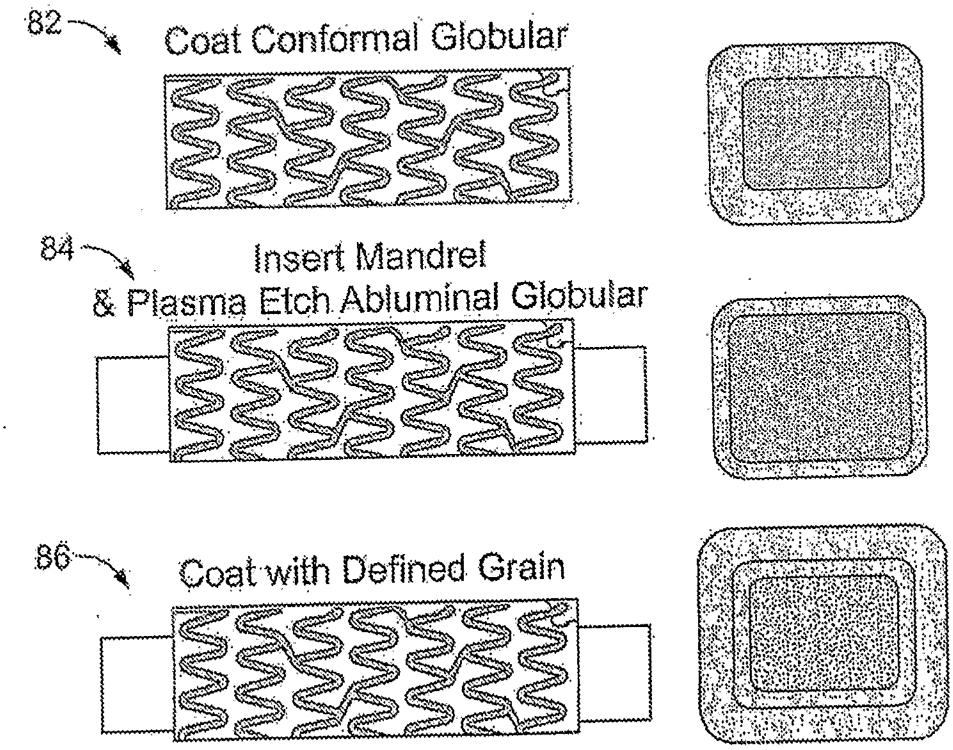


FIG. 11B

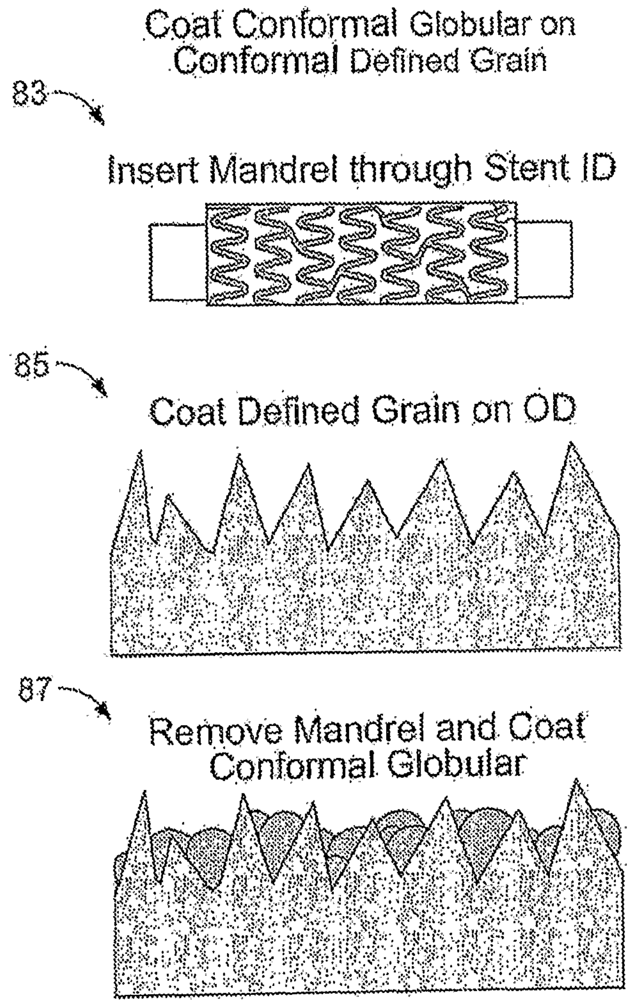

Coat Conformal Globular on
Conformal Defined Grain
83
Insert Mandrel through Stent ID
85
Coat Defined Grain on OD
87
Remove Mandrel and Coat
Conformal Globular

FIG. 11C

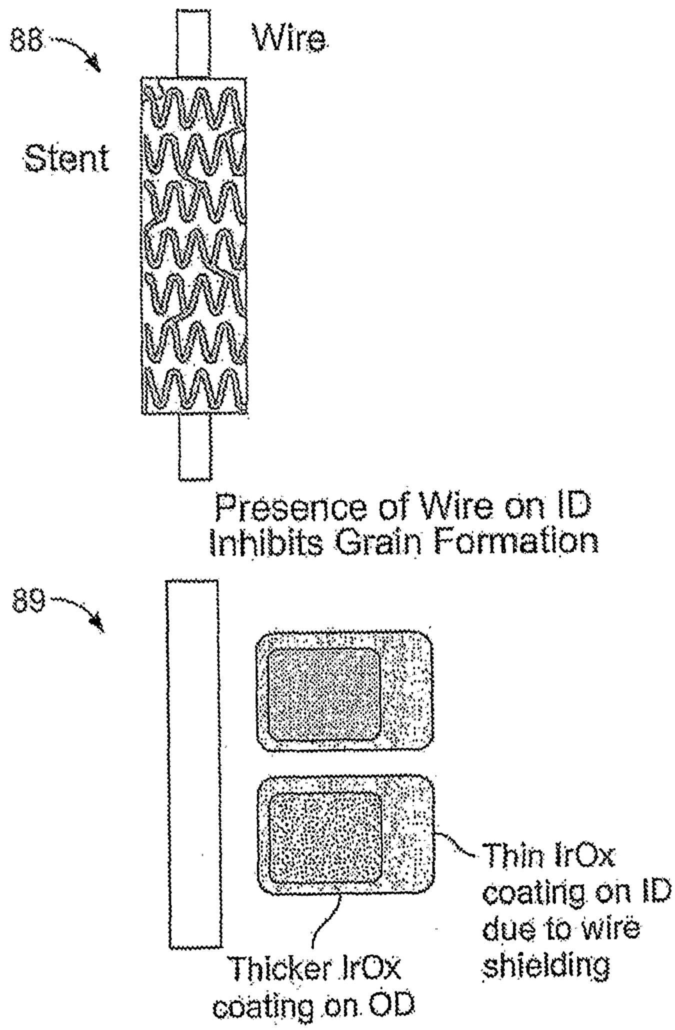

88
Wire
Stent
Presence of Wire on ID
Inhibits Grain Formation
89
Thin IrOx
coating on ID
due to wire
shielding
Thicker IrOx
coating on OD

FIG. 11D

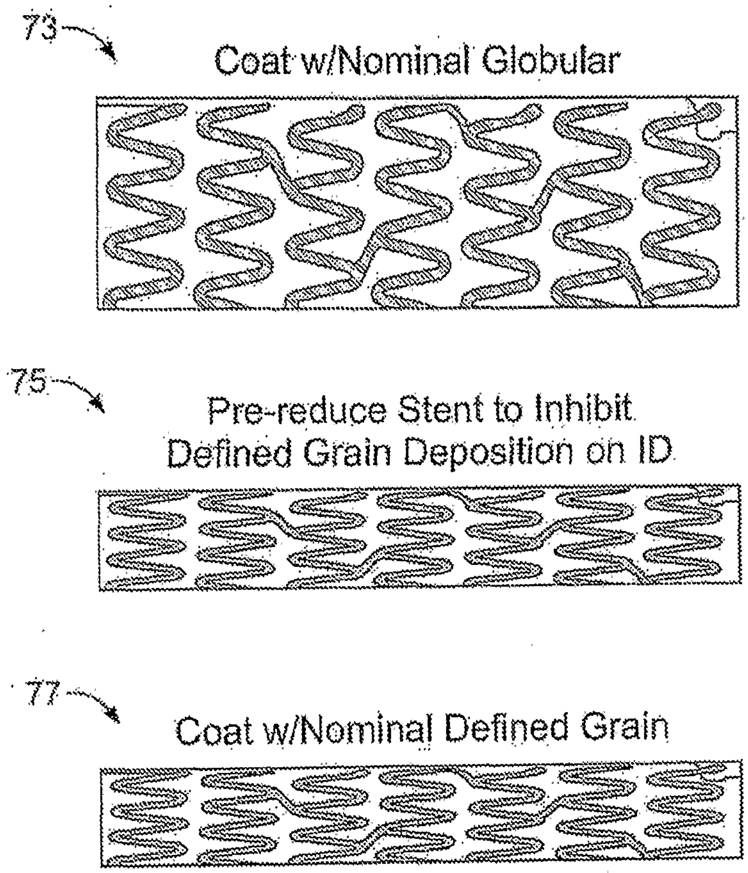

73
Coat w/Nominal Globular
75
Pre-reduce Stent to Inhibit
Defined Grain Deposition on ID
77
Coat w/Nominal Defined Grain

FIG. 11E

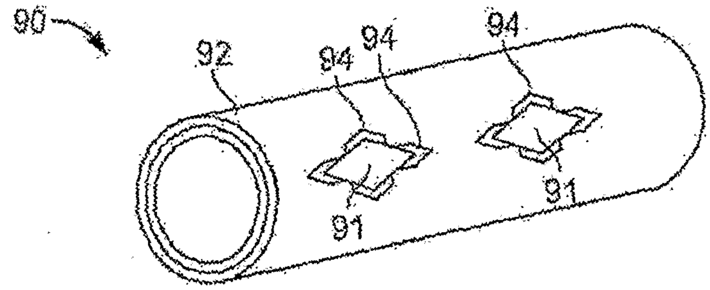


FIG. 12

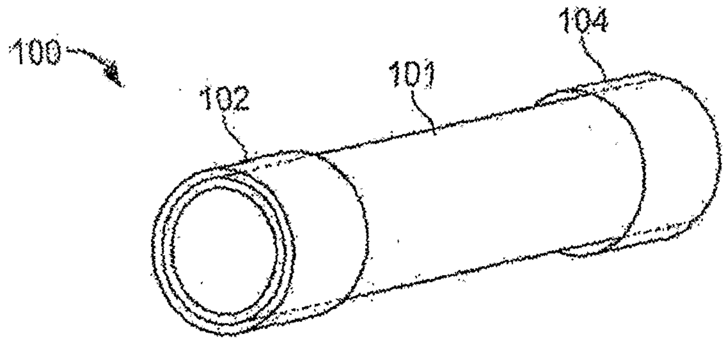


FIG. 13

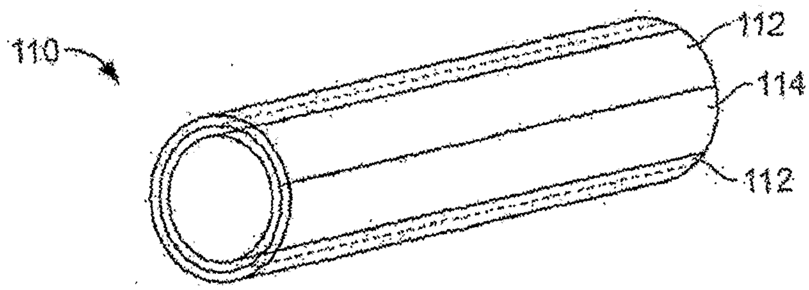


FIG. 14

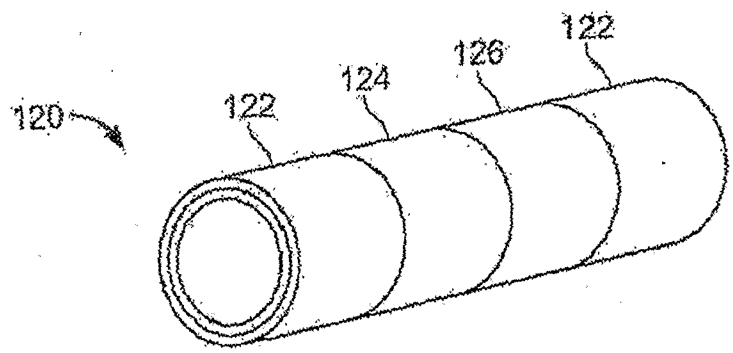


FIG. 15

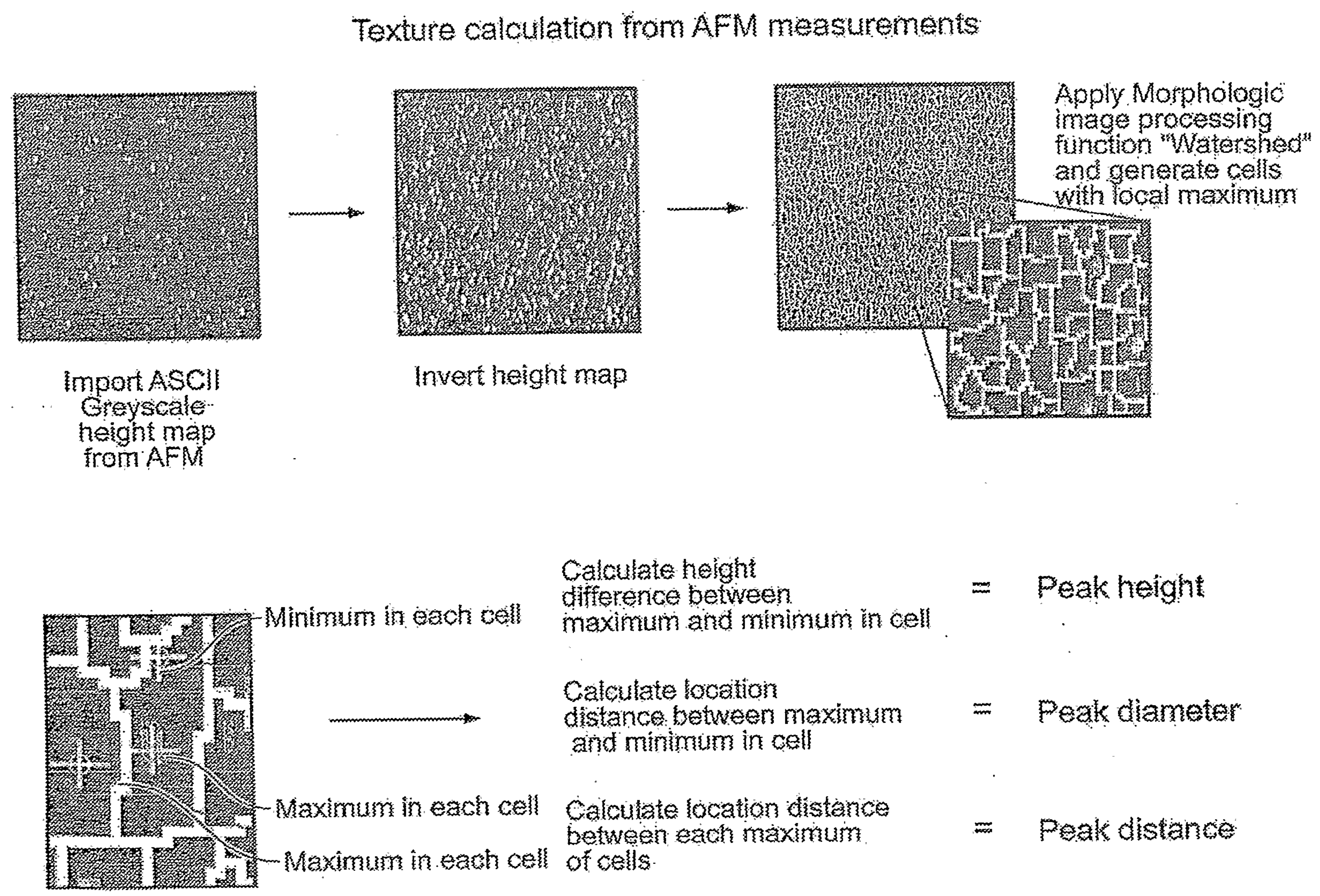

Texture calculation from AFM measurements
Import ASCII Greyscale height map from AFM
Invert height map
Apply Morphologic image processing function "Watershed" and generate cells with local maximum
Minimum in each cell
Maximum in each cell
Maximum in each cell
Calculate height difference between maximum and minimum in cell
=
Peak height
Calculate location distance between maximum and minimum in cell
=
Peak diameter
Calculate location distance between each maximum of cells
=
Peak distance

FIG. 16