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PROCESSES FOR PRODUCING ORTHOPEDIC IMPLANTS HAVING A SUBSURFACE LEVEL SILICON NITRIDE LAYER APPLIED VIA BOMBARDMENT

Abstract

The process for producing an orthopedic implant having an integrated ceramic surface layer includes steps for positioning the orthopedic implant inside a vacuum chamber, emitting a relatively high energy beam into the at least two different vaporized metalloid or transition metal atoms in the vacuum chamber to cause a collision therein to form ceramic molecules, and driving the ceramic molecules with the ion beam into an outer surface of the orthopedic implant at a relatively high energy such that the ceramic molecules implant therein and form at least a part of the molecular structure of the outer surface of the orthopedic implant, thereby forming the integrated ceramic surface layer.

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Background/Summary

BACKGROUND OF THE INVENTION
[0001] The present invention generally relates to processes for producing orthopedic implants (e.g., hip, knee, shoulder replacements, etc.) having a subsurface level ceramic embedded layer applied via ion bombardment, and related implant products. More specifically, the present invention relates to using an ion beam to implant a relatively uniform layer of ceramic molecules into a subsurface of one or more target orthopedic implants.
[0002] Orthopedic implants (e.g., prosthetic joints to replace damaged hips, knees, shoulders, etc.) are commonly made of metal alloys such as cobalt chromium (CoCr) or titanium (Ti-6Al-4V). The mechanical properties of such metal alloys are particularly desirable for use in load-bearing applications, such as orthopedic implants. Although, when orthopedic implants are placed within the body, the physiological environment can cause the implant material to wear and corrode over time (especially articulatory surfaces), sometimes resulting in complications that require revision surgery. While hip and knee replacement surgery has been reported to be successful at reducing joint pain for 90-95% of patients, there are several complications that remain and the potential for revision surgery increases at a rate around 1% per year following a successful surgery. These complications can include infection and inflammatory tissue responses stemming from tribological debris particles from metal alloy implants, such as cobalt chromium, as a result of wear and corrosion over time.
[0003] To reduce the risk of complications from orthopedic implants, ceramic coatings have been applied to address the coefficient of friction of a wear couple, to specifically improve the surface roughness, and to reduce adhesion of a broad range of bacteria for purposes of reducing the rate of infection. For example, alumina (Al.sub.2O.sub.3) and zirconia (ZrO.sub.2) are ceramics that have been used to coat the surfaces of orthopedic implants. These ceramic materials provide high wear resistance, reduced surface roughness, and high biocompatibility. But, both materials are not optimal for the fatigue loading of non-spherical geometry of most orthopedic implants due to poor tensile strength and low toughness. Accordingly, the disadvantages of these ceramic coatings, while addressing issues related to high wear resistance and surface roughness, cannot address other failure modes such as tensile strength and impact stresses.
[0004] Conventionally, ceramic coatings such as silicon nitride have been applied to the implant surface by a chemical vapor deposition (CVD) process or a physical vapor deposition (PVD) process. In one example, a PVD process is used to coat an implant joint with an external layer of silicon nitride. More specifically, such a process includes placing the implant, a silicon-containing material, and nitrogen gas (N.sub.2) in a chamber that is heated to between 100-600 degrees Celsius. In response to the high temperatures, silicon atoms sputter from the silicon-containing

material and subsequently react with the nitrogen gas at the heated surface of the implant to deposit a silicon nitride over-coat. One problem with this process is that there is no diffusion of the deposited silicon nitride molecules into the substrate material. That is, the silicon nitride is simply applied as an over-surface coating having a distinct boundary line between the deposited over-coating and the underlying substrate of the orthopedic implant. The adverse result is that the silicon nitride still experiences relatively poor surface adhesion and, over time, this over-surface coating can wear off, especially when the surface is an articulating surface (e.g., a ball-and-socket joint).

[0005] While vapor deposition of silicon nitride has been shown to work as an over-surface coating to certain orthopedic materials, such application is typically more expensive and less efficient than alumina or zirconia ceramic coatings. Moreover, it is often difficult, if not impossible, to attain a uniform application of silicon nitride to all surfaces of the orthopedic implant using known vapor deposition processes, such as those mentioned above. As a result, some areas of the over-surface coating have an undesirably thin layer of silicon nitride, wherein such areas are even more prone to reduced protection and wear. Alternatively, silicon nitride has also been used as the bulk or base material for orthopedic implants, but the production of a silicon nitride-based orthopedic implant is limited in size and inefficient to produce.

[0006] Recently, newer coating processes have been developed to provide greater adhesion by promoting diffusion of the coating material at the interface of the substrate and coating layers. Ion beam enhanced deposition (IBED), also known as ion beam assisted deposition (IBAD), is a process by which accelerated ions drive a vapor phase coating material into the subsurface of a substrate. Coatings applied by IBED may have greater adhesion than similar coatings applied by a conventional PVD process. Coatings applied by IBED may also have less delamination under impact stresses. For example, U.S. Pat. No. 7,790,216 to Popoola, the contents of which are herein incorporated by reference in their entirety, discloses a method of bombarding a medical implant with zirconium ions and then heating the implant in an oxygenated environment to induce the formation of zirconia (ZrO.sub.2) at the surface. In this respect, the ion beam drives the zirconium ions to a certain depth within the surface of the implant known as the “intermix zone”. Heat treatment within the oxygenated environment results in an embedded zirconia surface layer of approximately 5 micrometer (μm) thickness. The zirconia surface layer effectively penetrates the substrate and thereby resists delamination. But, this production method can be inefficient due to the high energy requirement for the heat treatment step. Likewise, the mechanical properties of the zirconia surface layer formed are not as desirable as those of a ceramic surface layer, which is incompatible with a heat treatment step.

[0007] There exists, therefore, a need in the art for processes for producing orthopedic implants having a subsurface ceramic layer applied via ion bombardment that provides greater integration of ceramics into the implant, thereby providing greater resistance to the emission of tribological debris. Such processes may include placing an orthopedic implant in a vacuum chamber, vaporizing at least two different metalloid or transition metal elements within the chamber, and bombarding a surface of the orthopedic implant with an ion beam sufficient to drive ceramic molecules into the subsurface of the medical implant. The present invention fulfills these needs and provides further related advantages.

SUMMARY OF THE INVENTION

[0008] In one embodiment, a process for producing an orthopedic implant having an integrated ceramic surface layer as disclosed herein may include steps for positioning the orthopedic implant inside a vacuum chamber, vaporizing at least two different metalloid or transition metal atoms inside the vacuum chamber, emitting a relatively high energy beam into the at least two different vaporized metalloid or transition metal atoms inside the vacuum chamber to form ceramic molecules, and driving the ceramic molecules with the same beam into an outer surface of the orthopedic implant at a relatively high energy level such that the ceramic molecules implant therein and form at least a part of the molecular structure of the outer surface of the orthopedic implant,

thereby forming the integrated ceramic surface layer. An intermix layer may be formed underneath the integrated ceramic surface layer, depending on the energy intensity of the beam. Here, the intermix layer may include a mixture of the ceramic molecules and a base material of the orthopedic implant. The base material may be a metal alloy selected from the group consisting of cobalt, titanium, and zirconium, a ceramic material selected from the group consisting of alumina and zirconia, an organic polymer, or a composite organic polymer. Moreover, in some embodiments, the intermix layer may be integrated with the base material such that the integrated ceramic surface layer and the base material cooperate to sandwich the intermix layer in between.
[0009] In one aspect of these embodiments, the beam may include an ion beam that emits nitrogen ions selected from the group consisting of N+ ions and N.sub.2+ ions. Accordingly, the emitting step may include delivering the nitrogen ions at a rate of about 1-5 nitrogen ions for cach vaporized metalloid or transition metal atom. The metalloid atoms may include silicon (Si), and the transition metal atoms may include titanium (Ti), silver (Ag), gold (Au), niobium (Nb), chromium (Cr), or Molybdenum (Mo). In one embodiment, the integrated ceramic surface layer may be a non-oxide nitride ceramic including at least two of the aforementioned elements and nitrogen. The ceramic surface layer, e.g., may include molecules selected from the group consisting of SiNAg, SiAuN, SiNbN, SiCrN, SiMoN, TiSiN, TiNAg, TiNAu, TiNbN, TiCrN, TiMoN, AgAuN, NbNAg, CrNAg, MoNAg AuNbN, AuCrN, AuMoN, NbCrN, NbMoN, and CrMoN. Of course, any combination and number of the different elements may be used so long as a ceramic is formed. For example, if titanium, niobium, and silver are used, the ceramic surface layer may be TiNbNAg.
[0010] During the emitting step, the relatively high energy beam may have an energy level between 0.1-100 kiloelectron volts (KeV), yet the temperature of the outer surface of the orthopedic implant may simultaneously remain below 200 degrees Celsius. The beam may propagate relative to the orthopedic implant, and the positioning step may include mounting the orthopedic implant to a selectively movable platen for repositioning an orientation of the orthopedic implant relative to the beam.
[0011] In other aspects of these embodiments, the outer surface of the orthopedic implant may be cleaned prior to implantation by setting the beam to an energy level between about 1-1000 electron volts. Additionally, an evaporator positioned within the vacuum chamber may vaporize metalloid or transition metal atoms off a metalloid or transition metal ingot at a rate determined by the desired ratio of nitrogen molecules to metalloid and/or transition metal atoms inside the vacuum chamber at any given time during the process. Here, for example, the formation rate of the ceramic molecules may be regulated by adjusting the beam energy or beam density. Additionally, the quantity of vaporized metalloid and/or transition metal atoms may be further controlled by backfilling the vacuum chamber with the same. The resultant integrated ceramic surface layer may have a substantially uniform thickness where the ceramic molecules are driven into the orthopedic implant. In some embodiments, the driving step may include the step of applying the integrated ceramic surface layer to less than an entire outer surface area of the orthopedic implant. The integrated ceramic surface layer may substantially include the ceramic molecules.
[0012] In another embodiment, a process for producing an orthopedic implant having an integrated ceramic surface layer may include steps for positioning the orthopedic implant inside a vacuum chamber, vaporizing at least two different metalloid or transition metal atoms inside the vacuum chamber, emitting ions via a relatively high energy ion beam into the at least two different vaporized metalloid or transition metal atoms in the vacuum chamber to cause a collision between the ions and the at least two different vaporized metalloid or transition metal atoms to form ceramic molecules, and driving the ceramic molecules with the ion beam into an outer surface of the orthopedic implant at a relatively high energy such that the ceramic molecules implant therein and form at least a part of the molecular structure of the outer surface of the orthopedic implant simultaneously while maintaining the outer surface of the orthopedic implant at a temperature below 200 degrees Celsius, thereby forming the integrated ceramic surface layer (e.g., substantially

made from ceramic molecules). Here, an intermix layer may form underneath the integrated ceramic surface layer and include a mixture of subsurface level ceramic molecules and a base material of the orthopedic implant. In one embodiment, the intermix layer may be molecularly integrated with the base material, and the integrated ceramic surface layer and the base material may cooperate to sandwich the intermix layer in between.

[0013] In some embodiments, the vaporized metalloid atoms may be silicon, the transition metal atoms may be selected from the group consisting of titanium, silver, gold, niobium, chromium, or molybdenum, and the integrated ceramic surface layer may be a non-oxide nitride ceramic, including molecules selected from the group consisting of SiNAg, SiAuN, SiNbN, SiCrN, SiMoN, TiSiN, TiNAg, TiNAu, TiNbN, TiCrN, TiMoN, AgAuN, NbNAg, CrNAg, MoNAg AuNbN, AuCrN, AuMoN, NbCrN, NbMoN, and CrMoN. Additionally, the base material may be made from a metal alloy selected from the group consisting of cobalt, titanium, and zirconium, a ceramic material selected from the group consisting of alumina and zirconia, an organic polymer, or a composite organic polymer. The ion beam may include nitrogen ions selected from the group consisting of N+ ions or N2+ ions, and the emitting step may further include delivering the nitrogen ions at a rate of about 1-5 nitrogen ions for each vaporized metalloid or transition metal atom.

[0014] In other aspects of these embodiments, the process may include steps for cleaning the outer surface of the orthopedic implant with the ion beam at an energy level between about 1-1000 electron volts, regulating a formation rate of the ceramic molecules by adjusting an energy level or a beam density of the ion beam, propagating the ion beam, and/or backfilling the vacuum chamber with vaporized metalloid atoms or transition metal atoms. Additionally, the vaporizing step may further include evaporating the at least two different metalloid or transition metal atoms off at least two different metalloid or transition metal ingots. The positioning step may further include the step of mounting the orthopedic implant to a selectively movable platen for repositioning an orientation of the orthopedic implant relative to the ion beam, and the driving step may include applying the integrated ceramic surface layer to less than an entire outer surface area of the orthopedic implant on the selectively movable platen. To this end, the integrated ceramic surface layer may have a substantially uniform thickness where driven into the orthopedic implant.

[0015] In another process disclosed herein, producing an orthopedic implant having an integrated ceramic surface layer may include steps for positioning the orthopedic implant inside a vacuum chamber, vaporizing at least two different metalloid or transition metal atoms off at least two different metalloid or transition metal ingots with at least one evaporator, and emitting ions via a relatively high energy ion beam having an energy level between 0.1 and 20 kiloelectron volts (KeV) into the at least two different vaporized metalloid or transition metal atoms in the vacuum chamber to cause a collision between the ions and the at least two different vaporized metalloid or transition metal atoms, thereby forming ceramic molecules. The outer surface of the orthopedic implant may be cleaned with the ion beam by setting the initial energy level between about 1-1000 electron volts. Thereafter, the ceramic molecules may be driven with the same ion beam into the outer surface of the orthopedic implant albeit at the same or a relatively higher energy level such that the ceramic molecules implant therein and form at least a part of the molecular structure of the outer surface of the orthopedic implant simultaneously while maintaining the outer surface of the orthopedic implant at a temperature below 200 degrees Celsius. Such a process may form the integrated ceramic surface layer therein.

[0016] The orthopedic implant may be mounted to a selectively movable platen within the vacuum chamber for repositioning an orientation of the orthopedic implant relative to the ion beam. In this embodiment, the formation rate of the ceramic molecules may be regulated by adjusting an energy level or a density of the ion beam. The driving step may also include the step of applying the integrated ceramic surface layer to less than an entire outer surface area of the orthopedic implant. Additionally, backfilling the vacuum chamber with the vaporized metalloid and/or transition metal atoms may maintain the desired ratios, e.g., including in embodiments where the ion beam includes nitrogen ions selected from the group consisting of N+ ions or N.sub.2+ ions. Moreover, the emitting step may include the step of delivering the nitrogen ions at a rate of about 1-5 nitrogen ions for each vaporized metalloid atom, for cach transition metal atom, or for a combination of metalloid and transition metal atoms.

[0017] The vaporized metalloid atoms may include silicon (Si), and the vaporized transition metal atoms may include titanium (Ti), silver (Ag), gold (Au), niobium (Nb), chromium (Cr), or Molybdenum (Mo). In one embodiment, the ceramic surface layer may be a non-oxide nitride ceramic including at least two of the aforementioned elements and nitrogen. The ceramic surface layer, e.g., may be SiNAg, SiAuN, SiNbN, SiCrN, SiMoN, TiSiN, TiNAg, TiNAu, TiNbN, TiCrN, TiMoN, AgAuN, NbNAg, CrNAg, MoNAg, AuNbN, AuCrN, AuMoN, NbCrN, NbMoN, CrMoN, etc. Of course, more than two of any combination of the different clements may be used as long as a ceramic is formed. For example, if titanium, niobium, and silver are used, the ceramic surface layer may be TiNbNAg.

[0018] In another aspect of these embodiments, an intermix layer may be formed underneath the integrated ceramic surface layer and molecularly integrated with a base material. Here, the intermix layer may include a mixture of subsurface level ceramic molecules and the base material of the orthopedic implant. As such, in this embodiment, the integrated ceramic surface layer and the base material may cooperate to sandwich the intermix layer in between. The integrated ceramic surface layer may include a substantially uniform thickness where driven into the orthopedic implant, such as by a propagating the ion beam, and the integrated ceramic surface layer may substantially include the ceramic molecules. The base material, in particular, may be made of a metal alloy selected from the group consisting of cobalt, titanium, and zirconium, a ceramic material selected from the group consisting of alumina and zirconia, an organic polymer, or a composite organic polymer.

[0019] Other features and advantages of the present invention will become apparent from the following more detailed description, when taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] The accompanying drawings illustrate the invention. In such drawings:

[0021] FIG. **1** is a flowchart illustrating a process for producing orthopedic implants having a subsurface level ceramic bombardment layer, as disclosed herein;

[0022] FIG. **2** is a diagrammatic view of an ion beam enhanced deposition (IBED) chamber, in accordance with the embodiments disclosed herein;

[0023] FIG. **3***a* is a diagrammatic view illustrating interaction of an ion beam with vaporized metalloid and/or transition metal atoms;

[0024] FIG. **3***b* is a diagrammatic view illustrating the ion beam promoting reaction of the vaporized metalloid and/or transition metal atoms to form ceramic molecules;

[0025] FIG. **4***a* is a diagrammatic view illustrating the ion beam driving the ceramic molecules into the angling and/or rotating surface of the orthopedic implant, thereby forming a subsurface intermixed layer;

[0026] FIG. **4***b* is a diagrammatic view illustrating the ion beam further driving the ceramic molecules into the angling and/or rotating surface of the orthopedic implant, thereby forming a subsurface ceramic layer of relatively uniform thickness over the subsurface intermixed layer; and

[0027] FIG. **5** is a cross-sectional view of the orthopedic implant having the subsurface ceramic layer produced by the ion beam implantation or bombardment of the ceramic molecules therein.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0028] As shown in the exemplary drawings for purposes of illustration, the processes for producing orthopedic implants having a subsurface level ceramic bombardment layer is referred to by numeral (**100**) with respect to the flowchart in FIG. **1**, while FIGS. **2**-**4***b* more specifically illustrate the operation of said processes, and FIG. **5** illustrates an exemplary orthopedic implant with a subsurface level ceramic bombardment layer **10**. More specifically, the first step (**102**) in the process (**100**), as shown in FIG. **1**, is to mount an orthopedic implant workpiece **12** onto an angling and/or rotating part platen **14** inside a vacuum chamber **16** suitable for performing ion beam implantation (e.g., ion beam enhanced deposition (IBED)). The processes disclosed herein improves the integration of a ceramic into the orthopedic implant by kinetically driving ceramic molecules into a subsurface layer of the orthopedic implant. This improved integration of the ceramic reduces delamination and prevents future wear and corrosion. Furthermore, the processes disclosed herein can reduce energy costs by performing the IBED process at temperatures well below 200 degrees Celsius and without a heat treatment step. Accordingly, the processes disclosed herein also reduce energy costs associated with manufacturing the related implant products.

[0029] More specifically, FIG. **2** illustrates the orthopedic implant workpiece **12** mounted to the angling and/or rotating part platen **14** within the vacuum chamber **16**. The orthopedic implant workpiece **10** may be made from a variety of metal alloys known in the art, such as cobalt, titanium, zirconium alloy, etc. In other embodiments, the orthopedic implant workpiece **10** may be made from ceramic materials known in the art, such as alumina (Al.sub.2O.sub.3) or zirconia (ZrO.sub.2). In still other embodiments, the orthopedic implant workpiece **10** may be made from organic polymers or composites of organic polymers. Of course, persons of ordinary skill in the art may recognize that the processes disclosed herein may be used with other types of materials, and that the scope of the present disclosure should not be limited only to those materials mentioned above. The part platen **14** may be able to rotate about a center axis **18** and/or tilt about a vertical axis **20** to facilitate maximum exposure of the orthopedic implant workpiece **10** to an ion beam **22** during the ceramic implantation process. In one embodiment, the orthopedic implant workpiece **10** may couple to the part platen **14** via an attachment **24** that may include a grip, clamp, or other device having a high friction surface to retain (e.g., by compression fit) the orthopedic implant workpiece **10**. In this respect, any attachment known in the art capable of sufficiently securing the orthopedic implant workpiece **10** to the part platen **14**, as the part platen **14** rotates and/or tilts, will suffice. The vacuum chamber **16** maintains a high vacuum environment during the ceramic implantation process to promote the propagation of ions from the ion beam **22** toward the surfaces of the orthopedic implant workpiece **10**. The high vacuum environment additionally reduces the amount of contaminant gases present to prevent contamination of a ceramic layer **26** (shown best in FIG. **5**) subsequently bombarded or implanted into a surface **28** of the orthopedic implant workpiece **10**. In further embodiments, a plurality of the part platens **12** may be present within the vacuum chamber **16** during the ceramic implantation process. In this embodiment, a plurality of the orthopedic implant workpieces **10** may be mounted in an array on each of the part platens **12** to produce multiple ceramic-implanted orthopedic implants **10** during cach ceramic implantation process.

[0030] Once the orthopedic implant workpiece **10** has been mounted on the part platen **14**, the next step (**104**), as shown in FIG. **1**, is to energize an ion beam generator **30** to produce the ion beam **22** of energized nitrogen ions capable of penetrating into the surface **28** of the orthopedic implant workpiece **10** as it rotates about the center axis **18** and/or pivots about the vertical axis **20**. Here, FIG. **2** illustrates the ion beam generator **30** emitting the ion beam **22** directed at the surface **28** of the orthopedic implant workpiece **10**. In one example, the ion beam generator **30** can include a Kaufman ion source (e.g., a gridded broad beam ion source of permanent magnet design). The ion beam generator **30** can be capable of delivering nitrogen ions (e.g., N+ ions and/or N.sub.2+ ions) at beam energies up to 102 kiloelectron volts (KeV) at currents up to 6 mA. In one embodiment, the beam energy may be in the range of 0.1 to 100 KeV; and in another embodiment, the beam energy may be in the range of 0.1 to 20 KeV. The ion beam **22** initially bombards the surface **28** of the orthopedic implant workpiece **10** with energized nitrogen ions during an ion beam cleaning process, thereby cleaning and augmenting the surface **28** of the orthopedic implant workpiece **10**. Specifically, the initial bombardment of the orthopedic implant workpiece **10** during step (**104**) efficiently removes absorbed water vapor, hydrocarbons, and other substrate surface contaminants from the surface **28** of orthopedic implant workpiece **10**. Removal of the substrate surface contaminants results in better implantation when the ceramic layer **26** is subsequently added to the subsurface of the orthopedic implant workpiece **10**. Step (**104**) may also create defects in the surface **28** of orthopedic implant workpiece **10** which further promotes the subsequent implantation of the ceramic layer **26**. At step (**104**) of the ceramic implantation process, relatively low energy ions (e.g., at beam energies between 1-1000 eV) can be employed to minimize sputtering at the surface **28** of orthopedic implant workpiece **10**, while still being sufficiently energetic to produce the desired effects mentioned above.

[0031] Once the surface **28** of the orthopedic implant workpiece **10** has been cleaned and augmented by the ion beam **22**, the next step (**106**) in accordance with FIG. **1** is to diffuse a mixture **32** of at least two different vaporized metalloid or transition metal atoms into the vacuum chamber **16**. In one embodiment, the metalloid and/or transition metal atoms vaporized into the vacuum chamber **16** may be silicon (Si), titanium (Ti), silver (Ag), gold (Au), niobium (Nb), chromium (Cr), or Molybdenum (Mo), or any combination thereof. Although, of course, any metalloid and/or transition metal atoms may be compatible with the processes disclosed herein. In this respect, a silicon, titanium, silver, gold, niobium, chromium, and/or molybdenum ingot can be used as source materials to produce the mixture **32**. In this regard, as shown in FIG. **2**, a first evaporator **34** located within the vacuum chamber **16** may produce a quantity of a first vaporized metalloid or transition metal atom **36** by electron beam evaporation, and a second evaporator **34′** may produce a quantity of a second vaporized metalloid or transition metal atom **36′** by electron beam evaporation. Here, the evaporators **34**, **34′** may direct an electron beam (not shown) at a silicon, titanium, silver, gold, niobium, chromium, and/or molybdenum ingot workpiece (also not shown) to provide a direct flux of the vaporized metalloid or transition metal atoms **36**, **36′**, which disperse within the vacuum chamber **16** as shown. In alternative embodiments, a single evaporator **34** may be used to produce the at least two different vaporized metalloid or transition metal elements **36**, **36′**. The ion beam **22** may then energize the mixture **32** to form ceramic molecules **42**, as discussed in detail herein.

[0032] Once the mixture **32** has been introduced into the vacuum chamber **16**, the next step (**108**) as shown in FIG. **1** is to promote and control the reaction of the at least two different vaporized metalloid or transition metal atoms **36**, **36′** in the mixture **32** using the ion beam **22**, as shown in FIGS. **3***a*-**3***b*. First, the positively charged nitrogen ions of the ion beam **22** collide with and kinetically excite the at least two different vaporized metalloid or transition metal atoms **36**, **36′** to promote the reaction process generally shown in FIG. **3***a*. Once kinetically excited, the vaporized metalloid or transition metal atoms **36**, **36′** react to form the ceramic molecules **42** as shown in FIG. **3***b*. The ceramic molecules **42** may be non-oxide nitride ceramic molecules and, e.g., may include SiNAg, SiAuN, SiNbN, SiCrN, SiMoN, TiSiN, TiNAg, TiNAu, TiNbN, TiCrN, TiMoN, AgAuN, NbNAg, CrNAg, MoNAg, AuNbN, AuCrN, AuMoN, NbCrN, NbMoN, CrMoN, etc. Of course, any combination of the different elements may be used so long as the ceramic molecules **42** are formed. For example, if titanium, niobium, and silver are used, the ceramic molecules **42** may be TiNbNAg. The rate of formation of the ceramic molecules **42** can be controlled by varying the energy and/or the density of the ion beam **22**. For example, increasing the energy and/or density of the ion beam **22** increases the rate of formation of the ceramic molecules **42**, and vice versa. As the vaporized metalloid and/or transition metal atoms **36**, **36′** react during step (**108**) to form ceramic molecules **42**, a controlled backfill of vaporized metalloid and/or transition metal atoms **36**, **36′**

may be employed to maintain the desired concentration of reactant molecules in the vacuum chamber **16**.

[0033] In some embodiments of the processes disclosed herein, steps (**106**) and (**108**) may be performed without halting the cleaning process described in step (**104**). That is, the vaporized metalloid and/or transition metal atoms **36**, **36**′ may be introduced into the vacuum chamber **16** without halting the ion beam cleaning process of step (**104**). In this way, the ion beam **22** immediately begins promoting the reaction of the vaporized metalloid and/or transition metal atoms **36**, **36**′ once introduced into vacuum chamber **16**. This can be more efficient from a manufacturing standpoint by reducing the duration required to perform the ceramic implantation process disclosed herein. Additionally, introducing the vaporized metalloid and/or transition metal atoms **36**, **36**′ without halting the cleaning process can prevent subsequent contamination of the substrate surface **28**. This may further promote generation of the subsurface ceramic layer **26** in the surface **28** of the orthopedic implant workpiece **10**.

[0034] Once the ceramic molecules **42** are formed, the ion beam **22** subsequently drives the ceramic molecules **42** into the surface **28** of the rotating and/or pivoting orthopedic implant workpiece **10**, per step (**110**) in FIG. **1**. The high-energy nitrogen ions of the ion beam **22** collide with the ceramic molecules **42** to impart kinetic energy thereto. The energized ceramic molecules **42** subsequently collide with the surface **28** of the orthopedic implant workpiece **10** and bombard or implant therein, thereby initially forming a subsurface intermixed layer **44**, as shown in FIG. **4***a*. The ceramic molecules **42** bombarded or implanted therein integrate with the surface **28**, as opposed to simply being deposited on the surface **28** as an over surface coating, as is the current practice with known silicon nitride deposition procedures. The intermixed layer **44** is basically a transition region wherein the surface molecules **46** of the orthopedic implant workpiece **10** become intermixed with the ceramic molecules **42** as a result of the energized bombardment by way of the ion beam **22**. The accumulation of ceramic molecules **42** within the intermixed layer **44** results in alloyed ceramic molecules **42** and substrate molecules **46**. By varying the energy and/or density of the beam **22**, persons skilled in the art can vary the depth into which the ceramic molecules **42** are driven.

[0035] As the intermixed layer **44** develops, the ion beam **22** continues to drive the ceramic molecules **42** into the subsurface of the surface **28** of the orthopedic implant workpiece **10**. As shown in FIG. **4***b*, through time, the ceramic layer **26** subsequently begins to form above the intermixed layer **44**. The depth the ceramic layer **26** forms into the subsurface of the surface **28** varies according to various variables, including the energy and/or density of the ion beam **22** (i.e., higher energy or greater density results in a thicker or deeper ceramic layer **26**, and vice versa) and/or the duration of bombardment with the ion beam **22** (i.e., a longer bombardment in a particular area may result in a thicker or deeper ceramic layer **26**, and vice versa). Similarly, varying the rate of nitrogen ion arrival can affect the stoichiometry of the resulting ceramic layer **26**. For example, the nitrogen ion arrival rate may be in the range of about one (1) nitrogen ion to about five (5) nitrogen ions for each vaporized metalloid and/or transition metal atoms **36**, **36**′ in the mixture **32**. Persons of ordinary skill in the art may vary the nitrogen ion arrival rate to obtain a ceramic suitable for the desired application.

[0036] As a result of step (**110**), the ceramic layer **26** is molecularly integrated into the subsurface of the surface **28** (e.g., as shown in FIG. **5**) of the orthopedic implant workpiece **10** and exhibits superior retention relative to silicon nitride coatings simply deposited as an over coating on the surface **28** by traditional PVD processes. This is due, at least in part, to the high strength of the alloy bond formed at an atomic level by the ion bombardment, which creates the intermixed layer **44** between the ceramic layer **26** and the surface molecules **46** of the orthopedic implant workpiece **10**. As such, this ultimately changes the atomic foundation of the subsurface of the orthopedic implant workpiece **12**. As the bombardment continues, the outermost ceramic layer **26** builds up, and does so over the entire orthopedic implant workpiece **12** as it rotates and/or pivots with the part platen **14**. Although, of course, the processes disclosed herein may include application to only a part of the orthopedic implant workpiece **12**, e.g., the articulation surfaces, as opposed to the entire orthopedic implant workpiece **12**. The articulation surfaces may later be polished, along with adjacent surfaces or other fixation surfaces. The material properties of the orthopedic implant workpiece **12**, in combination with the energy intensity characteristics of the ion beam **22**, limit the penetration depth to attain a more consistently uniform ceramic layer **26**. In this regard, the ceramic layer **26** is less likely to delaminate from the orthopedic implant workpiece **10** when compared to conventional PVD coatings. As such, the processes and implants disclosed herein are able to attain the benefits of ceramics across different types of surface finishes and surface requirements of an orthopedic implant.

[0037] During step (**110**), the surface **28** of the orthopedic implant workpiece **10** increases in temperature as a result of bombardment by the ion beam **22**. As such, a cooler can be utilized to cool the ceramic layer **26**, the intermixed layer **44**, and/or orthopedic implant workpiece **10** in general to prevent adverse or unexpected changes in the material properties due to heating. In this respect, cooling may occur in and/or around the area of the orthopedic implant workpiece **10** being bombarded or implanted with the ceramic layer **26**, and including the part platen **14**. Water or air circulation-based coolers may be used with the processes disclosed herein to provide direct or indirect cooling of the orthopedic implant workpiece **10**.

[0038] FIG. **5** is a diagrammatic cross-sectional view illustrating the surface **28** of the orthopedic implant workpiece **10**, including the resultant intermixed layer **44** and the ceramic layer **26** formed into the subsurface thereof. The processes disclosed herein result in the intermixed layer **44** having a thickness **48** and the ceramic layer **26** having an implantation thickness **50**, as shown in FIG. **5**. The intermixed layer **44** is positioned generally between the unaffected surface molecules **46** and the ceramic layer **26**. Accordingly, the intermixed layer **44** may form a uniform layer immediately above the unaffected surface molecules **46**, such as designated by a boundary **52**, and the ceramic layer **26** may form a uniform layer immediately above the intermixed layer **44**, such as designated by a boundary **54**. The intermixed width **48** and the depth of the boundary **52** may vary depending on the energy and/or density of the ion beam **22**, to increase (i.e., higher energy and/or density) or decrease (i.e., lower energy and/or density) the integration or implantation of the ceramic molecules **42** into the subsurface of the surface **28** of the orthopedic implant workpiece **10**. Likewise, the implantation thickness **50** and the depth of the boundary **54** may vary depending on the energy and/or density of the ion beam **22**, to increase (i.e., higher energy and/or density) or decrease (i.e., lower energy and/or density) the integration or implantation of the ceramic molecules **42** into the subsurface of the surface **28** of the orthopedic implant workpiece **10**. In an exemplary embodiment, the intermixed width **48** may be between 0.1-100 nanometers, while the implantation thickness 50 may be between 1-10,000 nanometers.

[0039] The resulting ceramic layer **26** may exhibit excellent tribological properties, including long-term material stability and high biocompatibility, at least relative to alumina. Likewise, the ceramics may be semitransparent to X-rays and non-magnetic, thereby allowing MRI of soft tissues proximal to ceramic coated implants. Meanwhile, the ceramics may also have wear rates comparable to alumina. Furthermore, unlike zirconia, which is a good conductor of electricity, the ceramics may advantageously have high electrical resistivity, such as on the order of 10.sup.16 Ω.Math.cm. Ceramics, e.g., containing silver (Ag) may have anti-microbial and/or anti-colonial properties that inhibit or prevent the growth of bacteria on the implant.

[0040] Although several embodiments have been described in detail for purposes of illustration, various modifications may be made without departing from the scope and spirit of the invention. Accordingly, the invention is not to be limited, except as by the appended claims.

Claims

1-45. (canceled)

46. A process for producing an orthopedic implant having an integrated ceramic surface layer, comprising the steps of: positioning the orthopedic implant inside a vacuum chamber; vaporizing metalloid atoms inside the vacuum chamber; emitting ions via an ion beam into the vaporized metalloid atoms in the vacuum chamber to cause a collision between the ions and the vaporized metalloid atoms to form ceramic molecules; driving the ceramic molecules with the same ion beam into an outer surface of the orthopedic implant such that the ceramic molecules implant therein and form at least a part of the molecular structure of the outer surface of the orthopedic implant simultaneously while maintaining the outer surface of the orthopedic implant at a temperature below 200 degrees Celsius, thereby forming the integrated ceramic surface layer; and forming an intermix layer underneath the integrated ceramic surface layer, the intermix layer including a mixture of subsurface level ceramic molecules and a base material of the orthopedic implant, wherein the intermix layer is molecularly integrated with the base material, and wherein the integrated ceramic surface layer and the base material cooperate to sandwich the intermix layer in between.

47. The process of claim 46, wherein the ions comprise nitrogen ions selected from the group consisting of N+ ions or N2+ ions.

48. The process of claim 47, wherein the emitting step includes the step of delivering the nitrogen ions at a rate of about 1-5 nitrogen ions for each vaporized metalloid atom.

49. The process of claim 48, wherein, when the rate is about one nitrogen ion for each metalloid atom, the integrated ceramic surface layer includes Si3N4, and, when the rate is about five nitrogen ions for each metalloid atom, the integrated ceramic surface layer includes SiN3.

50. The process of claim 46, including the step of cleaning the outer surface of the orthopedic implant with the ion beam at an energy level between about 1-1000 electron volts.

51. The process of claim 46, wherein the positioning step includes the step of mounting the orthopedic implant to a selectively movable platen for repositioning an orientation of the orthopedic implant relative to the ion beam.

52. The process of claim 46, including the step of vaporizing metalloid atoms off a metalloid ingot with an evaporator.

53. The process of claim 46, including the step of propagating the ion beam.

54. The process of claim 46, including the step of regulating a formation rate of the ceramic molecules by adjusting the ion beam energy or beam density.

55. The process of claim 46, including the step of backfilling the vacuum chamber with the vaporized metalloid atoms.

56. The process of claim 46, wherein the integrated ceramic surface layer substantially comprises the ceramic molecules.

57. The process of claim 46, wherein the driving step includes the step of applying the integrated ceramic surface layer to less than an entire outer surface area of the orthopedic implant.

58. The process of claim 46, wherein the integrated ceramic surface layer comprises a substantially uniform thickness when driven into the orthopedic implant.

59. The process of claim 46, wherein the ceramic surface layer comprises a silicon nitride surface layer, the metalloid atoms comprise silicon atoms, and the ceramic molecules comprise silicon nitride molecules.

60. A process for producing an orthopedic implant having an integrated ceramic surface layer, comprising the steps of: positioning the orthopedic implant inside a vacuum chamber; vaporizing metalloid atoms off a metalloid ingot with an evaporator; emitting ions via an ion beam into the vaporized metalloid atoms in the vacuum chamber to cause a collision between the ions and the vaporized metalloid atoms to form reacted ceramic molecules; cleaning an outer surface of the orthopedic implant with the ion beam at an energy level between about 1-1000 electron volts;

driving the ceramic molecules with the same ion beam into the outer surface of the orthopedic implant such that the ceramic molecules implant therein and form at least a part of the molecular structure of the outer surface of the orthopedic implant simultaneously while maintaining the outer surface of the orthopedic implant at a temperature below 200 degrees Celsius, thereby forming the integrated ceramic surface layer; and forming an intermix layer underneath the integrated ceramic surface layer, the intermix layer including a mixture of subsurface level ceramic molecules and a base material of the orthopedic implant, wherein the intermix layer is molecularly integrated with the base material, and wherein the integrated ceramic surface layer and the base material cooperate to sandwich the intermix layer in between.
61. The process of claim 60, wherein the ions comprise nitrogen ions selected from the group consisting of N+ ions or N2+ ions and the emitting step includes the step of delivering the nitrogen ions at a rate of about 1-5 nitrogen ions for each vaporized metalloid atom.
62. The process of claim 61, wherein, when the rate is about one nitrogen ion for each metalloid atom, the integrated ceramic surface layer includes Si3N4, and, when the rate is about five nitrogen ions for each metalloid atom, the integrated ceramic surface layer includes SiN**3**.
63. The process of claim 60, wherein the positioning step includes the step of mounting the orthopedic implant to a selectively movable platen for repositioning an orientation of the orthopedic implant relative to the beam.
64. The process of claim 60, including the step of propagating the ion beam, wherein the integrated ceramic surface layer substantially comprises the ceramic molecules.
65. The process of claim 60, including the step of regulating a formation rate of the ceramic molecules by adjusting the ion beam energy or beam density, wherein the driving step includes the step of applying the integrated ceramic surface layer to less than an entire outer surface area of the orthopedic implant.
66. The process of claim 60, including the steps of backfilling the vacuum chamber with the vaporized metalloid atoms, wherein the integrated ceramic surface layer comprises a substantially uniform thickness where driven into the orthopedic implant.
67. The process of claim 60, wherein the ceramic surface layer comprises a silicon nitride surface layer, the metalloid atoms comprise silicon atoms, and the ceramic molecules comprise silicon nitride molecules.