An improved bone graft is provided for human implantation, particularly such as a spinal fusion cage for implantation into the inter-vertebral space between two adjacent vertebrae. The improved spinal fusion cage includes a substrate block of high strength biocompatible material having a selected size and shape to fit the anatomical space, and a controlled porosity analogous to natural bone. The substrate block may be coated with a bio-active surface coating material such as hydroxyapatite or a calcium phosphate to promote bone ingrowth and enhanced bone fusion. Upon implantation, the fusion cage provides a spacer element having a desired combination of mechanical strength together with osteoconductivity and osteoinductivity to promote bone ingrowth and fusion, as well as radiolucency for facilitated post-operative monitoring. The fusion cage may additionally carry one or more natural or synthetic therapeutic agents for further promoting bone ingrowth and fusion.
This is a continuation-in-part of U.S. Ser. No. 10/137,108, filed Apr. 30, 2002, which in turn claims the benefit of U.S. Provisional Application No. 60/287,824, filed May 1, 2001.

This invention relates generally to improvements in bone grafts such as spinal fusion cages of the type designed for human implantation between adjacent spinal vertebrae, to maintain the vertebrae in substantially fixed spaced relation while promoting interbody bone ingrowth and fusion therebetween. More particularly, this invention relates to an implantable bone graft such as a spinal fusion cage having an improved combination of enhanced mechanical strength together with osteoinductive and osteoconductive properties, in a device that additionally and beneficially provides visualization of bone growth for facilitated post-operative monitoring.

Implantable interbody bone grafts such as spinal fusion devices are known in the art and are routinely used by spine surgeons to keep adjacent vertebrae in a desired spaced-apart relation while interbody bone ingrowth and fusion takes place. Such spinal fusion devices are also used to provide weight bearing support between adjacent vertebral bodies and thus correct clinical problems. Such spinal fusion devices are indicated for medical treatment of degenerative disc disease, discogenic low back pain and spondylolisthesis. These conditions have been treated by using constructs, typically made from metals such as titanium or cobalt chrome alloys such as used in orthopedic implants, and allograft (donor) or autograft (patient) bone to promote bone ingrowth and fusion.

Typical interbody spinal fusion devices, such as plugs for example, have hollow or open spaces that are usually filled with bone graft material, either autogenous bone material provided by the patient or allogeneous bone material provided by a third party donor. These devices also have lateral slots or openings which are primarily used to promote ingrowth of blood supply and grow active and live bone. These implants may also have a patterned exterior surface such as a ribbed or serrated surface or a screw thread to achieve enhanced mechanical interlock between adjacent vertebrae, with minimal risk of implant dislodgement from the site. See, for example, U.S. Pat. Nos. 5,785,710; and 5,702,453. Typical materials of construction for such interbody spinal fusion devices include bio-compatible carbon fiber reinforced polymers, cobalt chrome alloys, and stainless steels or titanium alloys. See, for example, U.S. Pat. No. 5,425,772.

Most state-of-the-art spinal fusion implants are made from titanium alloy and allograft (donor) bone, and have enjoyed clinical success as well as rapid and widespread use due to improved patient outcomes. However, traditional titanium-based implant devices exhibit poor radiolucency characteristics, presenting difficulties in post-operative monitoring and evaluation of the fusion process due to the radioshadow produced by the non-lucent metal. There is also clinical evidence of bone subsidence and collapse which is believed to be attributable to mechanical incompatibility between natural bone and the metal implant material. Moreover, traditional titanium-based implant devices are primarily load bearing but are not osteoconductive, i.e., not conducive to direct and strong mechanical attachment to patient bone tissue, leading to potential graft necrosis, poor fusion and stability. By contrast, allograft bone implants exhibit good osteoconductive properties, but can subside over time as they assimilate into natural bone. Further, they suffer from poor pull out strength resulting in poor stability, primarily due to the limited options in machining the contact surfaces. Allograft bone implants also have variable materials properties and, perhaps most important of all, are in very limited supply. A small but finite risk of disease transmission with allograft bone is a factor as well. In response to these problems some developers are attempting to use porous tantalum-based metal constructs, but these have met with limited success owing to the poor elastic moduli of porous metals.

A typical titanium alloy spinal fusion device is constructed from a hollow cylindrical and externally threaded metal cage-like construct with fenestrations that allow communication of the cancellous host tissue with the hollow core, which is packed with morselized bone graft material. This design, constrained by the materials properties of titanium alloys, relies on bony ingrowth into the fenestrations induced by the bone graft material. However, the titanium-based structure can form a thin fibrous layer at the bone/metal interface, which degrades bone attachment to the metal. In addition, the hollow core into which the graft material is packed may have sub-optimal stress transmission and vascularization, thus eventually leading to failure to incorporate the graft. Mechanical stability, transmission of fluid stress, and the presence of osteoinductive agents are required to stimulate the ingrowth of vascular buds and proliferate mesenchymal cells from the cancellous host tissue into the graft material. However, most titanium-based spinal fusion devices in use today have end caps or lateral solid walls to prevent egress of the graft outwardly from the core and ingress of remnant disc tissue and fibroblasts into the core.

Autologous (patient) bone fusion has been used in the past and has a theoretically ideal mix of osteoconductive and osteoinductive properties. However, supply of autologous bone material is limited and significant complications are known to occur from bone harvesting. Moreover, the costs associated with harvesting autograft bone material are high, requiring two separate incisions, with the patient having to undergo more pain and recuperation due to the harvesting and implantation processes. Additionally, autogenic cancellous bone material has inadequate mechanical strength to support intervertebral forces by itself, whereby the bone material is normally incorporated with a metal-based construct.

Ceramic materials provide potential alternative structures for use in spinal fusion implant devices. In this regard, monolithic ceramic constructs have been proposed, formed from conventional materials such as hydroxyapatite (HAP) and/or tricalcium phosphate (TCP). See, for example, U.S. Pat. No. 6,037,519. However, while these ceramic materials may provide satisfactory osteoconductive and osteoinductive properties, they have not provided the mechanical strength necessary for the implant.

Thus, a significant need exists for further improvements in and to the design of bone grafts such as spinal fusion implant devices, particularly to provide a high strength implant having high bone ingrowth and fusion characteristics, together with substantial radiolucency for effective and facilitated post-operative monitoring.

Hence, it is an object of the present invention to provide an improved bone graft such as an interbody spinal fusion implant or cage made from a bio-compatible open pore structure; which has a radiolucency similar to that of the
surrounding bone. It is also an object of the present invention to provide a substrate of high bio-mechanical strength for carrying biological agents which promote intervertebral bone ingrowth, healing and fusion. It is a further objective of the present invention to provide an interbody fusion device which has mechanical properties that substantially match that of natural bone.

SUMMARY OF THE INVENTION

[0011] In accordance with the invention, an improved bone graft such as a spinal fusion cage is provided for human implantation into the space between a pair of adjacent vertebrae, following removal of disc material between endplates of the adjacent vertebrae, to maintain the adjacent vertebrae in a predetermined and substantially fixed spaced relation while promoting interbody bone ingrowth and fusion. In this regard, the improved spinal fusion cage of the present invention is designed for use in addressing clinical problems indicated by medical treatment of degenerative disc disease, discogenic lower back pain, and spondylolisthesis.

[0012] The improved bone graft, as embodied in the form of the improved spinal fusion cage, comprises a substrate block formed from a bio-compatible material composition having a relatively high bio-mechanical strength and load bearing capacity. This substrate may be porous, open-celled, or dense solid. A preferred composition of the high strength substrate block comprises a silicon nitride ceramic material. The substrate block may be porous, having a porosity of about 10% to about 80% by volume with open pores distributed throughout and a pore size range of from about 5 to about 500 microns. When the substrate is porous, the porosity of the substrate block is gradated from a first relatively low porosity region emulating or mimicking the porosity of cortical bone to a second relatively higher porosity region emulating or mimicking the porosity of cancellous bone. In a second embodiment, the substrate block is a dense solid comprised of a ceramic, metal or polymer material. This dense solid substrate would then be attached to a second highly porous region emulating or mimicking the porosity of cancellous bone. Preferably, the porous region would be formed around the substrate.

[0013] In the method where a dense, solid material is used as the substrate block, the block will be externally coated with a bio-active surface coating material selected for relatively high osteoconductive and osteoinductive properties, such as a hydroxyapatite or a calcium phosphate material. The porous portion is internally and externally coated with a bio-active surface coating material selected for relatively high osteoconductive and osteoinductive properties, such as a hydroxyapatite or a calcium phosphate material. The porous region, however, may be in and of itself a bio-active material selected for relatively high osteoconductive and osteoinductive properties, such as a hydroxyapatite or a calcium phosphate material.

[0014] The thus-formed bone graft can be made in a variety of shapes and sizes to suit different specific implantation requirements. Preferred shapes include a generally rectangular block with a tapered or lordotic cross section to suit the required curvature of the inter-vertebral space, in the case of a spinal fusion device. The exterior superior and inferior surfaces of the rectangular body may include ridges or teeth for facilitated engagement with the adjacent vertebrae. Alternative preferred shapes include a generally oblong, rectangular block which may also include serrations or the like on one or more exterior faces thereof, and/or may have a tapered or lordotic cross section for improved fit into the inter-vertebral space. A further preferred shape may include a crescent shape block which may also include serrations or the like on one or more exterior faces thereof, and/or may have a tapered or lordotic cross section for improved fit into the inter-vertebral space. The bone graft may desirably include notches for releasable engagement with a suitable insertion tool. In addition, the bone graft may also include one or more laterally open recesses or holes for receiving and supporting osteoconductive bone graft material, such as allograft (donor) or autograft (patient) material.

[0015] Further alternative bone graft configurations may include a dense substrate region substantially emulating cortical bone, to define a high strength loading bearing zone or strut for absorbing impaction and insertion load, in combination with one or more relatively high porosity second regions substantially emulating cancellous bone for contacting adjacent patient bone for enhanced bone ingrowth and fusion.

[0016] The resultant bone graft exhibits relatively high mechanical strength for load bearing support, for example, between adjacent vertebrae in the case of a spinal fusion cage, while additionally and desirably providing high osteoconductive and osteoinductive properties to achieve enhanced bone ingrowth and interbody fusion. Importantly, these desirable characteristics are achieved in a structure which is substantially radiolucent so that the implant does not interfere with post-operative radiographic monitoring of the fusion process.

[0017] In accordance with a further aspect of the invention, the bone graft may additionally carry one or more therapeutic agents for achieving further enhanced bone fusion and ingrowth. Such therapeutic agents may include natural or synthetic therapeutic agents such as bone morphogenic proteins (BMPs), growth factors, bone marrow aspirate, stem cells, progenitor cells, antibiotics, or other osteoconductive, osteoinductive, osteogenic, or any other fusion enhancing material or beneficial therapeutic agent.

[0018] Other features and advantages of the invention will become more apparent from the following detailed description, taken in conjunction with the accompanying drawings which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The accompanying drawings illustrate the invention. In such drawings:

[0020] FIG. 1 is a perspective view depicting the spinal fusion cage in the inter-vertebral space;

[0021] FIG. 2 is a perspective view showing one preferred embodiment of the spinal fusion cage;

[0022] FIG. 3 is a perspective view showing the load bearing portion of the device of FIG. 2 with anterior and posterior load bearing walls connected by a strut, relieved in the superior and inferior aspects;

[0023] FIG. 4 is a perspective view depicting one alternative preferred and generally rectangular bone graft such as a spinal fusion cage;

[0024] FIG. 5 is a perspective view depicting the load bearing portion of the device of FIG. 4 with anterior and posterior load bearing walls connected by a strut, relieved in the superior and inferior aspects;
FIG. 6 is a perspective view showing still another alternative preferred form of the invention, comprising a generally oblong, rectangular bone graft such as a spinal fusion cage;

FIG. 7 is a perspective view depicting the load bearing portion of the device of FIG. 6 with anterior and posterior load bearing walls connected by a strut, relieved in the superior and inferior aspects;

FIG. 8 is an axial view of still another alternative form of the invention, taken generally on the load bearing axis of the spine, comprising a generally crescent shaped device conforming to the natural vertebral body shape;

FIG. 9 is a perspective view of the device of FIG. 8, showing a porous posterior margin;

FIG. 10 is a perspective view of the load bearing portion of the device of FIG. 8, showing an anterior and lateral load bearing walls connected by a central strut, relieved in the superior and inferior aspects;

FIG. 11 is an axial view of a further preferred alternative embodiment of the invention, comprising of a generally rectangular shape with macro-pores;

FIG. 12 is a perspective view of the device of FIG. 11 showing the interconnection of the macro-pores; and

FIG. 13 is a sectional view of the device of FIG. 11 taken generally along the mid transverse plane 6-6 of FIG. 11 of the device.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the exemplary drawings, a radiolucent bone graft such as a spinal fusion cage referred to generally in FIGS. 1-3 by the reference numeral 10 is provided for seated implantation between a pair of adjacent patient bones such as spinal vertebrae 12 (FIG. 1) to maintain the vertebral bodies spaced relation while promoting interbody bone ingrowth and fusion. In general, the improved bone graft 10 comprises a bio-compatible substrate having a porous construction to define an open lattice conducive to interbody bone ingrowth and fusion, while providing a strong mechanical load bearing structure analogous to the load bearing properties of cortical and cancellous bone. This open-celled substrate is coated internally and externally with a bio-active surface coating selected for relatively strong osteoconductive and osteoinductive properties, whereby the coated substrate provides a scaffold conducive to cell attachment and proliferation to promote interbody bone ingrowth and fusion attachment. The substrate may also carry one or more selected therapeutic agents suitable for bone repair, augmentation and other orthopedic uses.

FIGS. 1-3 illustrate the improved bone graft in the form of an improved spinal fusion cage 10 in accordance with one preferred embodiment, in the shape of a generally rectangular body having ridges formed on the exposed top and bottom ends or faces 14. The lateral, anterior, and posterior walls of the body having notches 18 for the reusable engagement with an insertion tool.

The preferred substrate composition comprises a relatively high strength block 16 (FIG. 3). In accordance with one preferred form of the invention, this substrate block comprises a relatively dense 16 silicon nitride composition having a controlled porosity and having a suitable size and shape for seated implantation, such as into the inter-vertebral space in the case of the spinal fusion cage 10. In a preferred form, the remainder of the substrate is comprised of a relatively porous silicon nitride 20 (FIG. 2) having an open-celled controlled porosity. One preferred silicon nitride ceramic material, comprises a doped silicon nitride of the type disclosed in copending U.S. Ser. No. 10/171,376, which is incorporated by reference herein.

Moreover, in the preferred form, the pores are arranged with a variable porosity gradient to define a first region of relatively low or reduced porosity (less than about 5%) substantially mimicking cortical bone structure and a second region of relatively large or increased porosity (ranging from about 30% to about 80%) substantially mimicking cancellous bone structure. In one preferred configuration, the outer or external surfaces of the reticulated substrate block comprise the first or low porosity region for improved load bearing capacity, while the interior surfaces of the substrate block comprises the second or high porosity region mimicking cancellous bone for enhance bone ingrowth and fusion.

This high strength substrate block is surface-coated internally and externally with a bio-active organic or inorganic surface coating material selected for relatively strong osteoconductive and osteoinductive properties to provide a nutrient rich environment for cellular activity to promote interbody bone ingrowth and fusion attachment. Preferred surface coating materials comprise a-resorbable material such as hydroxyapatite or a calcium phosphate ceramic. Alternative glassy (amorphous) materials having a relatively rich calcium and phosphate composition may also be used, particularly wherein such materials incorporate calcium and phosphate in a ratio similar to natural bone or hydroxyapatite. Such glassy compositions may comprise a partially or fully amorphous osteoinductive material comprising a composite of a glass and osteoconductive calcium compound, with a composition varying from about 100% glass to 100% osteoinductive calcium compound. The surface coating may also comprise autologous bone marrow aspirates.

The resultant bone graft 10 thus comprises the substrate block formed from the high strength material having bio-mineral properties and which is nonresorbable, or slowly or infinitely slowly resorbable when implanted into the patient, in combination with the bio-active surface coating which is comparatively rapidly resorbable to promote rapid and vigorous bone ingrowth activity.

The substrate block may also advantageously be coated or impregnated with one or more selected therapeutic agents, for example, such as autologous, synthetic or stem cell derived growth factors or proteins and growth factors such as bone morphogenetic protein (BMP) or a precursor thereto, which further promotes healing, fusion and growth. Alternative therapeutic agents may also include an antibiotic, or natural therapeutic agents such as bone marrow aspirates, and growth factors or progenitor cells such as mesenchymal stem cells, hematopoietic cells, or embryonic stem cells, either alone or as a combination of different beneficial agents.

The result illustrative spinal fusion cage 10 exhibits relatively high bio-mechanical strength similar to the load bearing characteristics of natural bone. In addition, the spinal fusion cage 10 exhibits relatively strong osteoconductive and osteoinductive characteristics attributable primarily to the surface coating, again similar to natural bone. Importantly, the fusion cage 10 is also substantially radiolucent, so that the fusion cage does not interfere with post-operative radiological analysis of interbody bone ingrowth and fusion.

The relatively dense, high strength portion 16 is preferably formed in a manner and With exposed faces or
ends 14 with which to withstand the axial loading of the spine. In the preferred embodiment as shown, the anterior and posterior walls of the device are formed as part of this high strength portion, each with exposed upper and lower ends or faces 14. This is done to allow the high strength region to interface with the cortical ring of the adjacent vertebral body 12. Additionally, a strut 22 of the high strength material extends between the anterior and posterior walls, which beneficially provides a load bearing structure capable of withstanding impaction and insertion loading in the anterior-posterior direction. Consequently, the relatively porous portion is formed in-between the dense anterior-posterior walls and around the central strut. The porous portion thereby forms the remainder of the device, including a large region of the superior, inferior, and lateral aspects. The porous portion, being less dense in nature than the high strength regions of the device, is Increasingly radiolucent, thus allowing for assessment of bone growth and bony attachment to the adjacent vertebral body.

[0042] FIGS. 4-10 illustrate alternative configurations for improved bone grafts such as spinal fusion cages constructed in accordance with the present invention, it being recognized and understood that the bone graft can be constructed in a wide range of different geometric sizes and shapes. FIG. 4 shows a spinal fusion cage 110 having a generally rectangular shape similar to the fusion cage 10 shown and described in FIGS. 1-3, but the form is elongated, as for use in replacing an entire vertebral body. As shown, the spinal fusion cage 110 (FIG. 5) has a relatively dense structure defined by a high strength substrate block 112 (as previously described) coated with the bio-active surface coating material, but wherein the relatively dense interior structure is defined multiple struts 116 with high strength for withstanding impaction and insertion loading in an anterior-posterior direction between anterior and posterior walls with exposed upper and lower ends or faces. The multiple struts 116 additionally create interior openings which provide for lateral fluid transmission and optimize bone growth laterally through the center of the implant. FIG. 5 shows multiple dense struts, thereby demonstrating that the porous region is able to make contact with the adjacent superior and inferior vertebral. The porous region 114 is more radiolucent than the surrounding dense portion and therefore provides enhanced visualization for analysis of bone growth and subsequent fusion with the adjacent vertebrae. Each of the embodiments depicted in FIGS. 1-13 has a height dimension and may be tapered or lordotic in shape for enhanced anatomical fit, for example, into the inter-vertebral space or the like.

[0043] FIGS. 6-7 depict still another alternative preferred embodiment of a generally oblong, rectangular geometry 410 having both a high strength, dense region 40, as well as a relatively porous region 44 for bone in-growth. This geometry would be useful for surgical approaches in which it is necessary to place two implants next to each other in the intervertebral space. More particularly, FIGS. 6-7 show a generally oblong, rectangular bone graft such as a spinal fusion cage 410 having a tapered height dimension in the anterior-posterior direction. The substrate block is formed with the first region 40 of relatively low porosity substantially mimicking cortical bone to extend across the anterior and posterior faces and further to include at least one interconnecting load bearing strut 42 shown in the illustrative drawings to extend centrally in an anterior-posterior direction within the body of the substrate block. The remainder of the substrate block comprises the second portion 44 of relatively high porosity substantially mimicking cancellous bone. The harder first region 40 including the central strut 42 beneficially provides a hard and strong load bearing structure analogous to that shown and described with respect to FIGS. 1-5, and capable of withstanding impaction and insertion forces in the anterior-posterior direction without damage to the implant, while the softer second region 44 presents an exposed and large surface area for substantially optimized interknitting ingrowth and fusion with adjacent patient bone. In a spinal fusion cage application, the medial-lateral faces of the implant are advantageously defined by the softer second region 44, wherein these regions are thus exposed to traditional medial-lateral X-ray imaging for post-operative radiological analysis of the implant/bone interface. Persons skilled in the art will recognize and appreciate that alternative configurations for the load bearing strut or struts 42 may be used, such as an X-shaped strut configuration extending in a cranial-caudal direction, in combination with or in lieu of the exterior faces 40 and/or the anterior-posterior central strut as shown.

[0044] FIGS. 8-10 depict a further alternative preferred form of the invention, with a generally crescent shaped geometry 510. The substrate block is formed of a relatively dense, high strength region 50 substantially mimicking cortical bone extending along the anterior and lateral walls and including exposed upper and lower ends or faces. The dense portion 50 once again beneficially provides a strong load bearing structure capable of withstanding axial loads in the spine. Also, the high-strength region 50 is located along the anterior of the substrate, thereby interfacing with the load bearing cortical bone of the adjacent vertebral body. An integral dense strut 52 extends between the dense lateral walls providing a load bearing structure for impaction and insertion forces exhibited in a lateral approach. The superior, inferior, and posterior portions of the substrate are formed with a relatively porous material 54. This provides for bone growth and increased radiolucency.

[0045] FIGS. 11-14 depict a still further alternative preferred embodiment which is formed entirely of a relatively low porosity, high-strength substrate 610. The subsequent porous structure 60 is created by drilling or boring a plurality of macro-pores 62 into the superior, inferior, and lateral faces of the device. This method allows the anterior and posterior walls to remain intact and thus be able to withstand the loading of the spinal column. The macro-pores are oriented in both the axial direction of the spine, as well as between the lateral walls of the device, thereby allowing bone to grow in the direction of the spinal loading and laterally through the substrate. The macropores are positioned in such a manner as to allow for continuous interconnection 70, thereby creating a meshwork of pores for bony ingrowth into the device. The macropores extend either from one face of the device to the opposite face 64, or towards the center of the device, extended to a certain depth, and terminated therein 66. The blind macropores 66 in-turn create a portion in the center of the device which remains solid and is therefore a load bearing strut 68 extending from the anterior wall to the posterior wall and capable of withstanding impaction and insertion loads in the anterior-posterior direction. This micropore method can also be utilized with geometries similar to those depicted in FIGS. 6-10, such as the oblong rectangular 410 and the crescent 510.
In all of the embodiments of FIGS. 1-13, the substrate block comprises a high strength porous ceramic as previously described, and is coated with the bio-active surface coating material, again as previously described, to enhance bone ingrowth and fusion. The substrate block may also include one or more therapeutic agents. Persons skilled in the art will recognize and appreciate that the relatively low and high porosity regions 16 and 20 shown in FIGS. 2-3 will be integrally joined by a suitable albeit relatively narrow gradient region wherein the porosity transitions therebetween.

The improved bone graft such as the illustrative spinal fusion cage of the present invention thus comprises an open-celled substrate block structure which is coated with a bio-active surface coating, and has the strength required for the weight bearing capacity required of a fusion device. The capability of being infused with the appropriate biologic coating agent imparts desirable osteoconductive and osteoinductive properties to the device for enhanced interbody bone ingrowth and fusion, without detracting from essential load bearing characteristics. The radiolucent characteristics of the improved device beneficiably accommodate post-operative radiological examination to monitor the bone ingrowth and fusion progress, substantially without undesirable radioshadowing attributable to the fusion cage. The external serratations or threads formed on the fusion cage may have a variable depth to enable the base of the device to contact the cortical bone for optimal weight bearing capacity. In addition to these benefits, the present invention is easy to manufacture in a cost competitive manner. The invention thus provides a substantial improvement in addressing clinical problems indicated for medical treatment of degenerative disc disease, discogenic low back pain and spondylolisthesis.

The bone graft of the present invention provides at least the following benefits over the prior art:

[a] a porous osteoconductive scaffold for enhanced fusion rates;
[b] a bio-mimetic load bearing superstructure providing appropriate stress transmission without fatigue; 
[c] a pore structure and size suitable for ingrowth and vascularization,
[d] the ability to absorb and retain an osteoinductive agent such as autologous bone marrow aspirate or BMPs;
[e] bio-inert and bio-compatible with adjacent tissue and selected for ease of resorption;
[f] fabricatable and machinable into various shapes;
[g] sterilizable; and
[h] low manufacturing cost.

A variety of further modifications and improvements in and to the spinal fusion cage of the present invention will be apparent to those persons skilled in the art. In this regard, it will be recognized and understood that the bone graft implant can be formed in the size and shape of a small pellet for suitable packing of multiple implants into a bone regeneration/ingrowth site. Accordingly, no limitation on the invention is intended by way of the foregoing description and accompanying drawings, except as set forth in the appended claims.

What is claimed is:

1. A spinal fusion cage for implantation between and fusion with adjacent vertebrae, comprising:
   a substrate block having a first region of relatively high strength corresponding substantially with natural cortical bone and a second region of porous form corresponding substantially with natural cancellous bone.
   2. The spinal fusion cage of claim 1 wherein said substrate block where either the first or second portion comprises a ceramic structure formed from silicon nitride, alumina, zirconia, zirconia toughened alumina, hydroxyapatite, calcium phosphate, or composition thereof.
   3. The spinal fusion cage of claim 1 wherein said substrate block where either the first or second portion comprises a metallic structure formed from titanium, tantalum, stainless steel, cobalt chrome alloy, or composition thereof.
   4. The spinal fusion cage of claim 1 wherein said substrate block where either the first or second portion comprises a polymeric structure formed from peek, carbon fiber reinforced polymer, PMMA, PLA (or other bioreabsorbable polymer), or composition thereof.
   5. The spinal fusion cage of claim 1 wherein said substrate block where either the first or second portion comprises a flexible material formed from silicone, polyurethane silicone, hydrogels, elastomers, or composition thereof.
   6. A spinal fusion cage of claim 1 wherein a bio-active and resorbable surface coating applied to said substrate block, said surface coating having osteoconductive and osteoinductive properties to promote interbody bone ingrowth and fusion attachment with the adjacent vertebrae.
   7. The spinal fusion cage of claim 1 wherein said substrate block where the second portion is comprised of a bio-active and resorbable material having relatively high osteoconductive and osteoinductive properties, such as a hydroxyapatite or a calcium phosphate material.
   8. The spinal fusion cage of claim 1 wherein said substrate block where the first portion being relatively non-resorbable or resorbable at a rate substantially less than the second portion.
   9. The spinal fusion cage of claim 1 wherein the first region and the second region of the said substrate block has a porosity ranging from about 0% to about 80% by volume, and further wherein the pore size ranges from about 1 micron to about 1,500 microns.
   10. The spinal fusion cage of claim 9 wherein the said first region of the said substrate block has porosity ranges from about 0% to about 50% by volume, and wherein the pore sizes range from about 1 micron to about 500 microns.
   11. The spinal fusion cage of claim 9 wherein the said second region of the said substrate block has porosity ranges from about 30% to about 80% by volume, and wherein the pore sizes range from about 100 microns to about 1000 microns.
   12. The spinal fusion cage of claim 9 wherein the said substrate block has a variable porosity gradient substantially mimicking natural cortical and cancellous bone.
   13. The spinal fusion cage of claim 9 wherein said substrate block has a first region of relatively low porosity substantially mimicking natural cortical bone, and a second region of relatively high porosity substantially mimicking cancellous patient bone.
   14. The spinal fusion cage of claim 9 wherein said first region has a porosity of less than about 5%, and wherein said second region has a porosity ranging from about 30% to about 80%.
   15. The spinal fusion cage of claim 9 wherein said first region is generally disposed on the exterior of said substrate block, and said second region is generally disposed on the interior surfaces of said substrate block.
16. The spinal fusion cage of claim 9 wherein said second region is generally disposed on the exterior of said substrate block, and said first region is generally disposed on the interior surfaces of said substrate block.

17. The spinal fusion cage of claim 13 wherein said first region is generally disposed on anterior and posterior surfaces of said substrate block and further defines at least one structural load bearing strut extending through said substrate block between said anterior and posterior surfaces, said second region including an extended exposed surface area for contacting the adjacent vertebrae.

18. The spinal fusion cage of claim 17 wherein said second region is substantially exposed on medial and lateral surfaces of said substrate block.

19. The spinal fusion cage of claim 13 wherein said first region circumferentially surrounds and supports said second region, said second region including an extended exposed surface area for contacting the adjacent vertebrae.

20. The spinal fusion cage of claim 13 wherein said second region circumferentially surrounds said first region, said second region including an extended exposed surface area for contacting the adjacent vertebrae.

21. The spinal fusion cage of claim 13 wherein said first region comprises at least one structural load bearing strut extending through said substrate block, wherein said second region including an extended exposed surface area for contacting the adjacent vertebrae.

22. The spinal fusion cage of claim 1 wherein said substrate block further includes means for facilitated grasping and manipulation with a surgical instrument for implantation.

23. The spinal fusion cage of claim 6 wherein said bioactive surface coating is internally and externally applied to said substrate block.

24. The spinal fusion cage of claim 6 wherein said bioactive surface coating is selected from the group consisting of hydroxyapatite and calcium compounds.

25. The spinal fusion cage of claim 6 wherein said bioactive surface coating comprises a partially or fully amorphous osteoinductive material including a glass and osteoinductive calcium compound.

26. The spinal fusion cage of claim 6 wherein said bioactive surface coating comprises an organic coating material.

27. The spinal fusion cage of claim 26 wherein said organic coating material is selected from the group consisting of autologous bone marrow aspirates, bone morphogenic proteins, growth factors and progenitor cells, and mixtures thereof.

28. The spinal fusion cage of claim 27 wherein said progenitor cells include mesenchymal stem cells, hematopoietic cells, and embryonic stem cells.

29. The spinal fusion cage of claim 1 wherein the first region of the said substrate block is substantially radiolucent.

30. The spinal fusion cage of claim 1 wherein the second region of the said substrate block is substantially radiolucent.

31. The spinal fusion cage of claim 1 further including a therapeutic agent carried by said substrate block.

32. The spinal fusion cage of claim 31 wherein said therapeutic agent comprises a natural or synthetic osteoinductive or osteoinductive agent.

33. The spinal fusion cage of claim 1 wherein said substrate block has a rough exterior surface.

34. The spinal fusion cage of claim 1 wherein said substrate block has a ribbed exterior surface.

35. The spinal fusion cage of claim 1 wherein said substrate block has a laterally open bore formed therein, and further including an osteoconductive material supported within said bore.

36. The spinal fusion cage of claim 35 wherein said osteoconductive material comprises morcellized bone graft material.

37. The spinal fusion cage of claim 1 wherein the pores formed within the second region of the said substrate block are in substantially open fluid communication sufficient to transmit fluid pressure therebetween.

38. The spinal fusion cage of claim 1 wherein the pores formed within the first region of the said substrate block may be in substantially open fluid communication sufficient to transmit fluid pressure therebetween.

39. A spinal fusion cage for implantation between and fusion with adjacent vertebrae, comprising:
   a substrate block having a relatively high strength corresponding substantially with natural cortical and cancellous bone; and
   a bio-active and relatively rapidly resorbable surface coating applied to said substrate block, said surface coating having osteoconductive and osteoinductive properties to promote interbody bone ingrowth and fusion attachment with the adjacent vertebrae;
   said substrate block being relatively nonresorbable or resorbable at a rate substantially less than said surface coating.

40. A spinal fusion cage for implantation between and fusion with adjacent vertebrae, comprising:
   a substrate block including at least one load bearing strut having high strength structural characteristics; and
   a bio-active and resorbable surface coating carried by said at least one strut, said surface coating having osteoconductive and osteoinductive properties to promote interbody bone ingrowth and fusion attachment with adjacent patient bone.

41. The spinal fusion cage of claim 40 wherein said at least one strut substantially mimics the structural characteristics of natural bone.

42. The bone graft of claim 40 wherein said at least one strut is formed from a porous material.

43. A spinal fusion cage for implantation between and fusion with adjacent vertebrae, comprising:
   a first region formed by load bearing anterior and posterior wall connected by at least one load bearing strut; and
   a relatively porous second region comprising the superior, inferior, and lateral aspects.

44. The spinal fusion cage of claim 43 wherein said substrate block where either the first or second portion comprises a ceramic structure formed from silicon nitride, alumina, zirconia, zirconia toughened alumina, hydroxyapatite, calcium phosphate, or composition thereof.

45. The spinal fusion cage of claim 43 wherein said substrate block where either the first or second portion comprises a metallic structure formed from titanium, tantalum, stainless steel, cobalt chrome alloy, or composition thereof.

46. The spinal fusion cage of claim 43 wherein said substrate block where either the first or second portion comprises a polymeric structure formed from peek, carbon fiber reinforced polymer, PMMA, PLA (or other bioreversible polymer), or composition thereof.

47. The spinal fusion cage of claim 43 wherein said substrate block where either the first or second portion comprises...
a flexible material formed from silicone: polyurethane silicone, hydrogels, elastomers, or composition thereof.

48. The spinal fusion cage of claim 43 wherein a bio-active and resorbable surface coating applied to said substrate block, said surface coating having osteoconductive and osteoinductive properties to promote interbody bone ingrowth and fusion attachment with the adjacent vertebrae.

49. The spinal fusion cage of claim 43 wherein said substrate block where the second portion is comprised of a bio-active and resorbable material having relatively high osteoconductive and osteoinductive properties, such as hydroxyapatite or a calcium phosphate material.

50. The spinal fusion cage of claim 43 wherein said substrate block where the first portion being relatively non-resorbable or resorbable at a rate substantially less than the second portion.

51. The spinal fusion cage of claim 43 wherein the first region and the second region of the said substrate block has a porosity ranging from about 0% to about 80% by volume, and further wherein the pore size ranges from about 1 micron to about 1,500 microns.

52. The spinal fusion cage of claim 51 wherein the first region of the said substrate block has porosity ranging from about 0% to about 50% by volume, and wherein the pore sizes range from about 1 micron to about 500 microns.

53. The spinal fusion cage of claim 51 wherein the said second region of the said substrate block has porosity ranges from about 50% to about 80% by volume, and wherein the pore sizes range from about 100 microns to about 1000 microns.

54. The spinal fusion cage of claim 51 wherein the said substrate block has a variable porosity gradient substantially mimicking natural cortical and cancellous bone.

55. The spinal fusion cage of claim 51 wherein said substrate block has a first region of relatively low porosity substantially mimicking natural cortical bone, and a second region of relatively high porosity substantially mimicking cancellous patient bone.

56. The spinal fusion cage of claim 51 wherein said first region has a porosity of less than about 5%, and wherein said second region has a porosity ranging from about 30% to about 80%.

57. The spinal fusion cage of claim 51 wherein said first region is generally disposed on the exterior of said substrate block, and said second region is generally disposed on the interior surfaces of said substrate block.

58. The spinal fusion cage of claim 51 wherein said second region is generally disposed on the exterior of said substrate block, and said first region is generally disposed on the interior surfaces of said substrate block.

59. The spinal fusion cage of claim 55 wherein said first region is generally disposed on anterior and posterior surfaces of said substrate block and further defines at least one structural load bearing strut extending through said substrate block between said anterior and posterior surfaces, said second region including an extended exposed surface area for contacting the adjacent vertebrae.

60. The spinal fusion cage of claim 59 wherein said second region is substantially exposed on medial and lateral surfaces of said substrate block.

61. The spinal fusion cage of claim 55 wherein said first region circumferentially surrounds and supports said second region, said second region including an extended exposed surface area for contacting the adjacent vertebrae.

62. The spinal fusion cage of claim 55 wherein said second region circumferentially surrounds said first region, said second region including an extended exposed surface area for contacting the adjacent vertebrae.

63. The spinal fusion cage of claim 55 wherein said first region comprises at least one structural load bearing strut extending through said substrate block, wherein said second region including an extended exposed surface area for contacting the adjacent vertebrae.

64. The spinal fusion cage of claim 43 wherein said substrate block further includes means for facilitated grasping and manipulation with a surgical instrument for implantation.

65. The spinal fusion cage of claim 48 wherein said bio-active surface coating is internally and externally applied to said substrate block.

66. The spinal fusion cage of claim 48 wherein said bio-active surface coating is selected from the group consisting of hydroxyapatite and calcium compounds.

67. The spinal fusion cage of claim 48 wherein said bio-active surface coating comprises a partially or fully amorphous osteoinductive material including a glass and osteoinductive calcium compound.

68. The spinal fusion cage of claim 48 wherein said bio-active surface coating comprises an organic coating material.

69. The spinal fusion cage of claim 68 wherein said organic coating material is selected from the group consisting of autologous bone marrow aspirates, bone morphogenetic proteins, growth factors and progenitor cells, and mixtures thereof.

70. The spinal fusion cage of claim 69 wherein said progenitor cells include mesenchymal stem cells, hematopoietic cells, and embryonic stem cells.

71. The spinal fusion cage of claim 43 wherein the first region of the said substrate block is substantially radiolucent.

72. The spinal fusion cage of claim 43 wherein the second region of the said substrate block is substantially radiolucent.

73. The spinal fusion cage of claim 43 further including a therapeutic agent carried by said substrate block.

74. The spinal fusion cage of claim 73 wherein said therapeutic agent comprises a natural or synthetic osteoconductive or osteoinductive agent.

75. The spinal fusion cage of claim 43 wherein said substrate block has a rough exterior surface.

76. The spinal fusion cage of claim 43 wherein said substrate block has a ribbed exterior surface.

77. The spinal fusion cage of claim 43 wherein said substrate block has a laterally open bore formed therein, and further including an osteoconductive material supported within said bore.

78. The spinal fusion cage of claim 77 wherein said osteoconductive material comprises morselized bone graft material.

79. The spinal fusion cage of claim 43 wherein the pores formed within the second region of the said substrate block are in substantially open fluid communication sufficient to transmit fluid pressure therebetween.

80. The spinal fusion cage of claim 43 wherein the pores formed within the first region of the said substrate block may be in substantially open fluid communication sufficient to transmit fluid pressure therebetween.

81. A spinal fusion cage for implantation between and fusion with adjacent vertebrae, comprising:
a substrate block having a relatively high strength corresponding substantially with natural cortical and cancellous bone; and

a bio-active and relatively rapidly resorbable surface coating applied to said substrate block, said surface coating having osteoconductive and osteoinductive properties to promote interbody bone ingrowth and fusion attachment with the adjacent vertebrae;

said substrate block being relatively nonresorbable or resorbable at a rate substantially less than said surface coating.

82. A spinal fusion cage for implantation between and fusion with adjacent vertebrae, comprising:

a substrate block including at least one load bearing strut having high strength structural characteristics; and

a bio-active and resorbable surface coating carried by said at least one strut, said surface coating having osteoconductive and osteoinductive properties to promote interbody bone ingrowth and fusion attachment with adjacent patient bone.

83. The spinal fusion cage of claim 82 wherein said at least one strut substantially mimics the structural characteristics of natural bone.

84. The bone graft of claim 82 wherein said at least one strut is formed from a porous material.