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(54) **DUAL FUNCTION PROSTHETIC BONE IMPLANT AND METHOD FOR PREPARING THE SAME**

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Publication Classification

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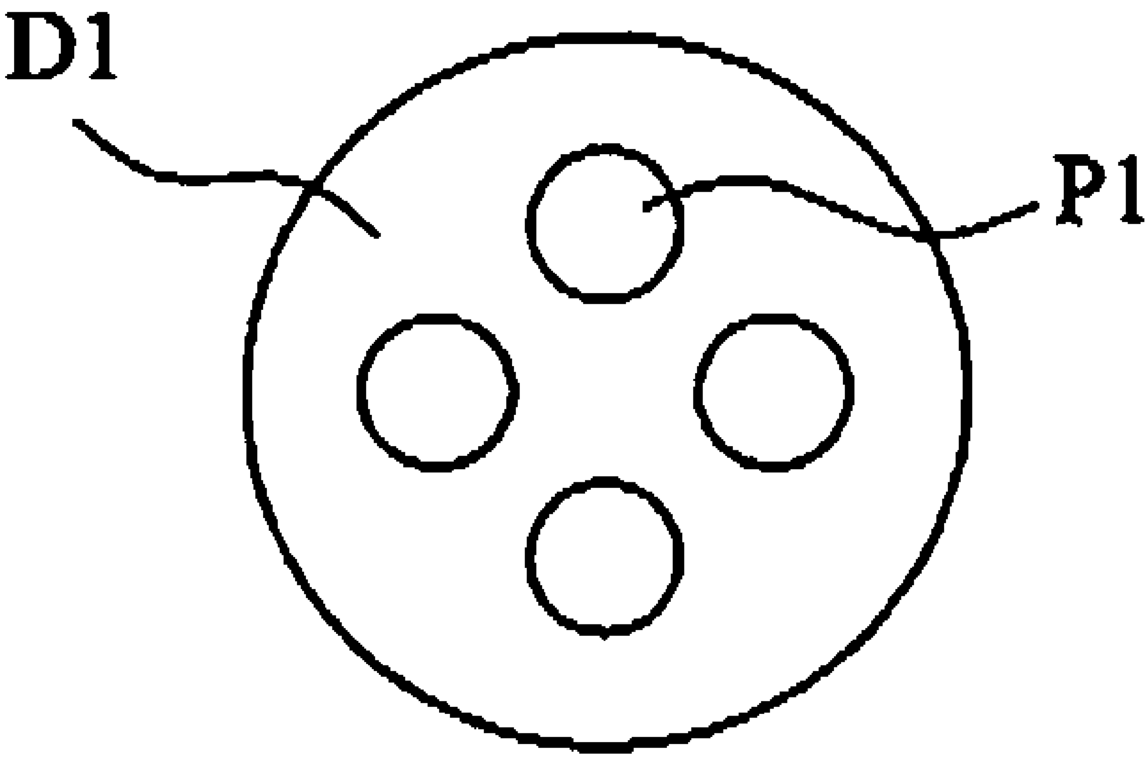
(52) **U.S. Cl.** **623/23.5**; 623/23.56

(57) **ABSTRACT**

The present invention discloses a prosthetic bone implant made of a hardened calcium phosphate cement having an apatitic phase as a major phase, which includes a dense cortical portion bearing the majority of load and a porous cancellous portion allowing a rapid blood/body fluid penetration and tissue ingrowth.



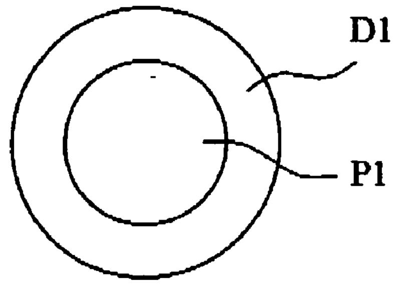


FIG. 1a

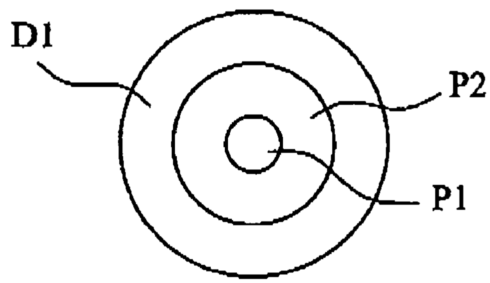


FIG. 1b

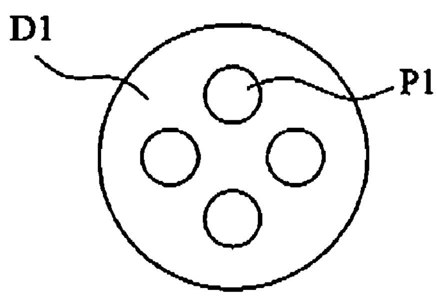


FIG. 1c

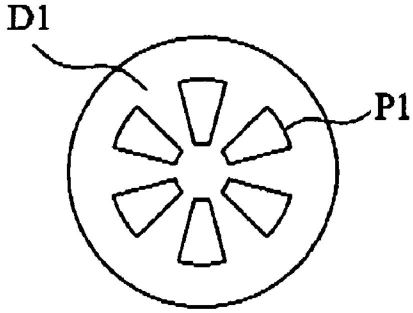


FIG. 1d

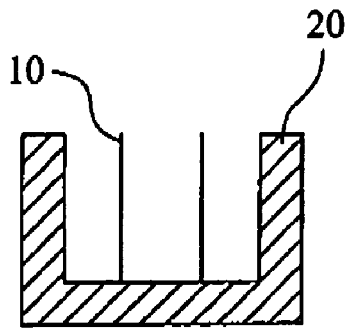


FIG. 2a

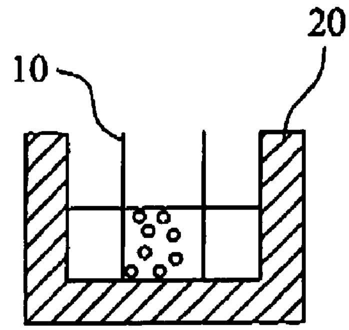


FIG. 2b

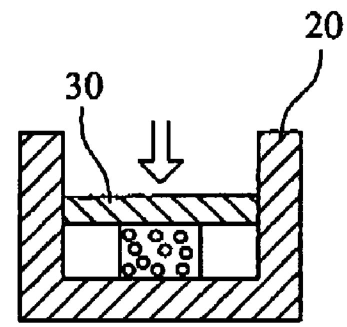


FIG. 2c

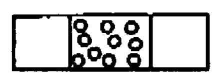


FIG. 2d

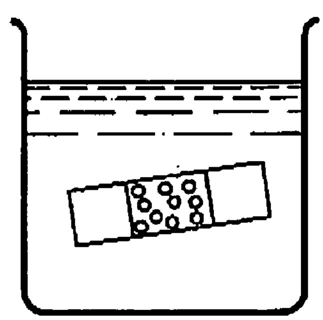


FIG. 2e

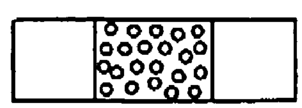


FIG. 2f

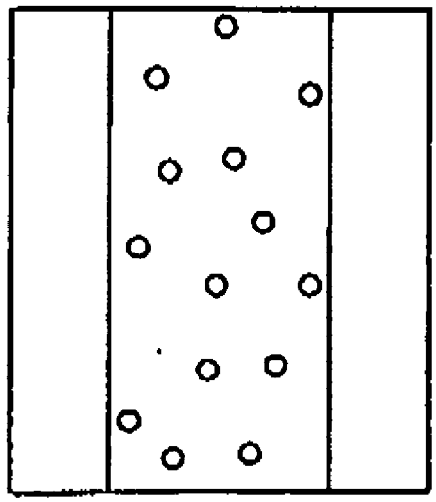


FIG. 3a

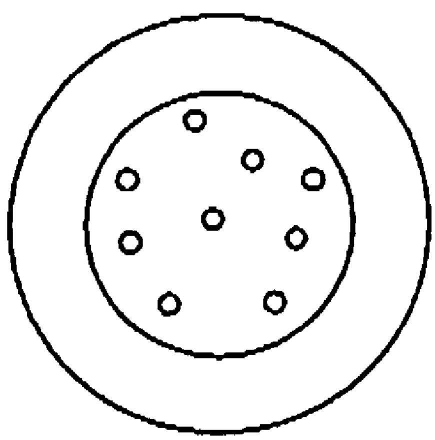


FIG. 3b

DUAL FUNCTION PROSTHETIC BONE IMPLANT AND METHOD FOR PREPARING THE SAME

PRIORITY CLAIM

[0001] This application claims priority to Non-Provisional patent application Ser. No. 10/852,167 entitled "DUAL FUNCTION PROSTHETIC BONE IMPLANT AND METHOD FOR PREPARING THE SAME" filed on May 25, 2004.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention is related to a prosthetic bone implant made of a hardened calcium phosphate cement having an apatitic phase as a major phase, and in particular to a prosthetic bone implant comprising a dense cortical portion bearing the majority of load and a porous cancellous portion allowing a rapid blood/body fluid penetration and tissue ingrowth.

[0004] 2. Description of the Related Art

[0005] It is advantageous if a prosthetic bone implant is bioresorbable and is supportive at the same time. Accordingly, an article made of calcium phosphate will be preferable than that made of a metal, if the former has strength which is comparable to a human cortical bone. One way of making such a bone implant is by sintering a calcium phosphate powder, particularly a hydroxyapatite (HA) powder, into a block material at a temperature generally greater than 1000° C. Despite the fact that the high temperature-sintered HA block material has an enhanced strength, the bioresorbability of the material is largely sacrificed, if not totally destroyed, due to the elimination of the micro- and nano-sized porosity during the sintering process.

[0006] The conventional spinal fusing device is composed of a metallic cage and a bioresorbable material disposed in the metal cage, for example the one disclosed in U.S. Pat. No. 5,645,598. An inevitable disadvantage of this fusion device is the sinking of the metallic cage sitting between two vertebrae to replace or repair a defect spinal disk, because the hardness and the relatively small size of the cage wear out or break the bone tissue, and in particular the endplate of the vertebra.

SUMMARY OF THE INVENTION

[0007] A primary objective of the invention is to provide a prosthetic bone implant free of the drawbacks of the prior art.

[0008] The prosthetic bone implant constructed according to the present invention is made of a hardened calcium phosphate cement having an apatitic phase as a major phase, which comprises a dense cortical portion bearing the majority of load and a porous cancellous portion allowing a rapid blood/body fluid penetration and tissue ingrowth.

[0009] The prosthetic bone implant of the present invention is made by a novel technique, which involves immersing an article molded from two different pastes of calcium phosphate cement (CPC), one of them having an additional pore-forming powder, in a liquid for a period of time, so that the compressive strength of the molded CPC article is significantly improved after removing from the liquid while the pore-forming powder is dissolved in the liquid, creating pores in a desired zone or zones of the molded article.

[0010] Features and advantages of the present invention are as follows:

[0011] 1. Easy process for different shape and size of the prosthetic bone implant of the present invention, so that the outer circumferential dense portion thereof can sit over the circumferential cortical portion of a bone and the porous portion thereof can contact the cancellous portion of the bone adjacent to a bone receiving treatment.

[0012] 2. The dense cortical portion of the prosthetic bone implant made according to the present invention exhibits a high strength comparable to that of human cortical bone (about 110-170 MPa). The strength is adjustable by adjusting process parameters.

[0013] 3. The dense cortical portion of the prosthetic bone implant made according to the present invention contains significant amount of micro- and nano-sized porosity, that improves bioresorbability thereof. Conventional high temperature-sintered HA block, on the other hand, does not possess sufficient micro/nano-sized porosity and is not bioresorbable.

[0014] 4. The porous cancellous portion of the prosthetic bone implant made according to the present invention possesses a porosity greater than 40% in volume, prepferably 40-90%, allowing rapid blood/body fluid penetration and tissue ingrowth, thereby anchoring the prosthetic bone implant.

[0015] 5. A wide range of medical application includes bone dowel, spacer, cavity filler, artificial disc and fixation devices for spine and other locations, to name a few.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] **FIGS. 1***a* to **1***d* show schematic cross sectional views of four different designs of prosthetic bone implants constructed according to the present invention.

[0017] **FIGS. 2***a* to **2***f* are schematic cross sectional views showing steps of a method for preparing a prosthetic bone implant according to one embodiment of the present invention.

[0018] **FIGS. 3***a* and **3***b* are schematic vertical and horizontal cross sectional views of a prosthetic bone implant prepared according to another embodiment of the present invention, respectively.

DETAILED DESCRIPTION OF THE INVENTION

[0019] Preferred embodiments of the present invention includes (but not limited to) the following:

[0020] 1. A prosthetic bone implant comprising a cortical portion having two opposite sides, and a cancellous portion integrally disposed in said cortical portion and being exposed through said two opposite sides, wherein said cortical portion comprises a hardened calcium phosphate cement has a porosity of less than 40% in volume, and said cancellous portion comprises a porous hardened calcium phosphate cement having a porosity greater than 20% in volume, and greater than that of said cortical portion.

[0021] 2. The implant according to Item 1, wherein the cortical portion is in the form of a hollow disk, and the cancellous portion is in the form of a column surrounded by the hollow disk.

[0022] 3. The implant according to Item 2 further comprising a transitional portion between said column and said hollow disk surrounding said central cylinder, which has properties range from those of said cancellous portion to said cortical portion.

[0023] 4. The implant according to Item 1, wherein the cortical portion is in the form of a disk having one or more longitudinal through holes, and the cancellous portion is in the form of one or more columns surrounded by said one or more longitudinal through holes.

[0024] 5. The implant according to Item 1, wherein said hardened calcium phosphate cement of said cortical portion comprises an apatitic phase as a major phase giving rise to broadened characteristic X-ray diffraction peaks in comparison with a high-temperature sintered apatitic phase.

[0025] 6. The implant according to Item 5, wherein said broadened characteristic the X-ray diffraction peaks are at 2-Theta values of 25-27° and 30-35°.

[0026] 7. The implant according to Item 1, wherein said hardened calcium phosphate cement of said cortical portion is prepared without a high temperature sintering.

[0027] 8. The implant according to Item 1, wherein said hardened calcium phosphate cement of said cortical portion comprises an apatitic phase as a major phase having a Ca/P molar ratio of 1.5-2.0.

[0028] 9. The implant according to Item 1, wherein said hardened calcium phosphate cement of said cancellous portion comprises an apatitic phase as a major phase giving rise to broadened characteristic X-ray diffraction peaks in comparison with a high-temperature sintered apatitic phase.

[0029] 10. The implant according to Item 9, wherein said broadened characteristic the X-ray diffraction peaks are at 2-Theta values of 25-27° and 30-35°.

[0030] 11. The implant according to Item 1, wherein said hardened calcium phosphate cement of said cancellous portion is prepared without a high temperature sintering.

[0031] 12. The implant according to Item 1, wherein said hardened calcium phosphate cement of said cancellous portion comprises an apatitic phase as a major phase having a Ca/P molar ratio of 1.5-2.0.

[0032] 13. The implant according to Item 1, wherein said cortical portion comprises 10-90% in volume of said implant.

[0033] 14. The implant according to Item 1, wherein said cortical portion has a porosity of less than 30% in volume.

[0034] 15. The implant according to Item 1, wherein said cancellous portion has a porosity greater than 40-90% in volume.

[0035] 16. A method for preparing a prosthetic bone implant comprising a cortical portion having two opposite sides, and a cancellous portion integrally disposed in said cortical portion and being exposed through said two opposite sides, said method comprises the following steps:

[0036] a) preparing a first paste comprising a first calcium phosphate cement and a first setting liquid;

[0037] b) preparing a second paste comprising a second calcium phosphate cement, a pore-forming powder and a second setting liquid;

[0038] c) i) preparing a shaped article in a mold having two or more cells separated by one more partition walls comprising introducing said first paste and said second paste into said two or more cells separately, and removing said one or more partition walls from said mold, so that said second paste in the form of a single column or two or more isolated columns is integrally disposed in the first paste in said mold; or ii) preparing a shaped article comprising introducing one of said first paste and said second paste into a first mold to form an intermediate in said first mold, placing said intermediate into a second mold after a hardening reaction thereof undergoes at least partially, and introducing another one of said first paste ad said second paste into said second mold, so that said second paste as a single column or as two or more isolated columns is integrally disposed in the first paste in said second mold;

[0039] d) immersing the resulting shaped article from step c) in an immersing liquid for a first period of time so that said pore-forming powder is dissolved in the immersing liquid, creating pores in said single column or said two or more isolated columns; and

[0040] e) removing the immersed shaped article from said immersing liquid.

[0041] 17. The method according to Item 16 further comprising

[0042] f) drying the immersed shaped article.

[0043] 18. The method according to Item 16, wherein said pore-forming powder is selected from the group consisting of LiCl, KCl, NaCl, $MgCl_2$, $CaCl_2$, $NaIO_3$, KI, Na_3PO_4, K_3PO_4, Na_2CO_3, amino acid-sodium salt, amino acid-potassium salt, glucose, polysaccharide, fatty acid-sodium salt, fatty acid-potassium salt, potassium bitartrate ($KHC_4H_4O_6$), potassium carbonate, potassium gluconate ($KC_6H_{11}O_7$), potassium-sodium tartrate ($KNaC_4H_4O_6.4H_2O$), potassium sulfate (K_2SO_4), sodium sulfate, and sodium lactate.

[0044] 19. The method according to Item 16, wherein said first calcium phosphate cement comprises at least one Ca source and at least one P source, or at least one calcium phosphate source; and said second calcium phosphate cement comprises at least one Ca source and at least one P source, or at least one calcium phosphate source.

[0045] 20. The method according to Item 19, wherein said first calcium phosphate cement comprises at least one calcium phosphate source, and said second calcium phosphate cement comprises at least one calcium phosphate source.

[0046] 21. The method according to Item 20, wherein said calcium phosphate source is selected from the group consisting of alpha-tricalcium phosphate (α-TCP), beta-tricalcium phosphate (β-TCP), tetracalcium phosphate (TTCP), monocalcium phosphate monohydrate (MCPM), monocalcium phosphate anhydrous (MCPA), dicalcium phosphate dihydrate (DCPD), dicalcium phosphate anhydrous (DCPA), octacalcium phosphate (OCP), calcium dihydrogen phosphate, calcium dihydrogen phosphate hydrate, acid calcium pyrophosphate, anhydrous calcium hydrogen phosphate, calcium hydrogen phosphate hydrate, calcium pyrophosphate, calcium triphosphate, calcium phosphate tribasic, calcium polyphosphate, calcium metaphosphate, anhydrous tricalcium phosphate, tricalcium phosphate hydrate, and amorphous calcium phosphate.

[0047] 22. The method according to Item 21, wherein said first calcium phosphate cement and said second calcium phosphate cement are identical.

[0048] 23. The method according to Item 22, wherein said first calcium phosphate cement and said second calcium phosphate cement are tetracalcium phosphate.

[0049] 24. The method according to Item 16, wherein the first setting liquid and the second setting liquid independently are an acidic solution, a basic solution, or a substantially pure water.

[0050] 25. The method according to Item 24, wherein said acidic solution is selected from the group consisting of nitric acid (HNO_3), hydrochloric acid (HCl), phosphoric acid (H_3PO_4), carbonic acid (H_2CO_3), sodium dihydrogen phosphate (NaH_2PO_4), sodium dihydrogen phosphate monohydrate ($NaH_2PO_4.H_2O$), sodium dihydrogen phosphate dihydrate, sodium dihydrogen phosphate dehydrate, potassium dihydrogen phosphate (KH_2PO_4), ammonium dihydrogen.phosphate ($NH_4H_2PO_4$), malic acid, acetic acid, lactic acid, citric acid, malonic acid, succinic acid, glutaric acid, tartaric acid, oxalic acid and their mixture.

[0051] 26. The method according to Item 22, wherein said basic solution is selected from the group consisting of ammonia, ammonium hydroxide, alkali metal hydroxide, alkali earth hydroxide, disodium hydrogen phosphate (Na_2HPO_4), disodium hydrogen phosphate dodecahydrate, disodium hydrogen phosphate heptahydrate, sodium phosphate dodecahydrate ($Na_3PO_4.12H_2O$), dipotassium hydrogen phosphate (K_2HPO_4), potassium hydrogen phosphate trihydrate ($K_2HPO_4.3H_2O$), potassium phosphate tribasic (K_3PO_4), diammonium hydrogen phosphate ($(NH_4)_2HPO_4$), ammonium phosphate trihydrate ($(NH_4)_3PO_4.3H_2O$), sodium hydrogen carbonate ($NaHCO_3$), sodium carbonate Na_2CO_3, and their mixture.

[0052] 27. The method according to Item 16, wherein step c-i) further comprises allowing said first paste and said second paste undergoing a hardening reaction in said mold.

[0053] 28. The method according to Item 16, wherein step c-i) further comprises pressurizing said first paste and said second paste in said mold after removing said one or more partition walls from said mold to remove a portion of liquid from said first paste and said second paste, so that a liquid/powder ratio of said first paste and of said second paste decreases; and allowing said first paste and second paste undergoing a hardening reaction in said mold.

[0054] 29. The method according to Item 16, wherein step c-ii) further comprises allowing said intermediate undergoing a hardening reaction in said first mold, and allowing said another one of said first paste and said second paste undergoing a hardening reaction in said second mold.

[0055] 30. The method according to Item 16, wherein step c-ii) further comprises pressurizing said one of said first paste and said second paste in said first mold to remove a portion of liquid therefrom before the hardening reaction of said intermediate is completed; allowing said intermediate undergoing a hardening reaction in said first mold; pressuring said another one of said first paste and said second paste in said second mold, so that a liquid/powder ratio of said another one of said first paste and of said second paste decreases; and allowing said another one of said first paste and second paste undergoing a hardening reaction in said second mold.

[0056] 31. The method according to Item 28, wherein said pressuring is about 1 to 500 MPa.

[0057] 32. The method according to Item 30, wherein said pressuring is about 1 to 500 MPa.

[0058] 33. The method according to Item 16, wherein the immersing liquid is an acidic aqueous solution, a basic aqueous solution, a physiological solution, an organic solvent, or a substantially pure water.

[0059] 34. The method according to Item 33, wherein the immersing liquid comprises at least one of Ca and P sources.

[0060] 35. The method according to Item 33, wherein the immersing liquid is a Hanks' solution, a HCl aqueous solution or an aqueous solution of $(NH_4)_2HPO_4$.

[0061] 36. The method according to Item 16, wherein the immersing in step d) is carried out for a period longer than 10 minutes.

[0062] 37. The method according to Item 16, wherein the immersing in step d) is carried out for a period longer than 1 day.

[0063] 38. The method according to Item 16, wherein the immersing in step d) is carried out at a temperature of about 10 and 90° C.

[0064] 39. The method according to Item 38, wherein the immersing in step d) is carried out at room temperature.

[0065] 40. The method according Item 17 further comprising cleaning said immersed shaped article before said drying; and heating the resulting dried shaped article at a temperature between 50 and 500° C.

[0066] Four different designs of prosthetic bone implants constructed according to the present invention are shown in **FIGS. 1***a* to **1***d*. In **FIG. 1***a*, the prosthetic bone implant of the present invention has a dense cortical portion **D1** in the tubular form and a porous cancellous portion **P1** formed in the central through hole of the tubular cortical portion **D1**. Both the dense cortical portion **D1** and the porous cancellous portion **P1** are made of a hardened calcium phosphate cement having an apatitic phase as a major phase. In **FIG. 1***b*, the prosthetic bone implant of the present invention has a dense cortical portion **D1** in the tubular form; a cylindrical porous cancellous portion **P1** in the center of the tubular cortical portion **D1**; and an annular transitional portion **P2** connecting the tubular cortical portion **D1** and the cylindrical cancellous portion **P1**. The transitional portion **P2** is made of a hardened calcium phosphate cement having an apatitic phase as a major phase, and a porosity gradient increasing from the lower porosity of the cylindrical cancellous portion **P1** to the higher porosity of the tubular cortical portion **D1**, which may be formed in-situ during molding of two different two different CPC pastes, one of them having an additional pore-forming powder for forming the cylindrical cancellous portion **P1**, and another one being a regular CPC powder for forming the dense cortical portion **D1**. The porous cancellous portion **P1** may be in the forms of isolated columns surrounded by the dense cortical portion **D1** as shown in **FIGS. 1***c* and **1***d*. Other designs are also possible in addition to those shown in **FIGS. 1***a* to **1***d*.

[0067] A suitable method for preparing the prosthetic bone implant of the present invention includes placing a tubular partition wall **10** in a hollow cylindrical mold **20**, as shown in **FIG. 2***a*; pouring a first paste comprising a calcium phosphate cement and a setting liquid in the annular cell and a second paste comprising the calcium phosphate cement, a pore-forming powder and the setting liquid in the central cell, as shown in **FIG. 2***b*; removing the partition wall and pressing the CPC pastes before hardening, as shown in **FIG. 2***c*, wherein a portion of the setting liquid is removed from the gap between the mold **20** and the press **30** and/or holes (not shown in the drawing) provided on the press **30**. The CPC paste will undergo a hardening reaction to convert into apatitic phase. The hardened disk is removed from the mold and is subjected to surface finishing to expose the central portion hardened from the second paste, as shown in **FIG. 2***d*, followed by immersing in a bath of an immersing liquid as shown in **FIG. 2***e*, where the pore-forming powder is dissolved in the immersing liquid while the hardened CPC thereof gaining compressive strength. The immersing may last from 10 minutes to several days. The composite disk so formed is washed with water after being removed from the bath, and dried and heated in an oven to obtain the prosthetic bone implant as shown in **FIG. 2***f*. The heating is conducted at a temperature between 50 and 500° C. for a period of several hours to several days, which enhance the compressive strength of the cortical portion of the prosthetic bone implant.

[0068] An alternative method for preparing the prosthetic bone implant of the present invention from the same raw materials includes pouring the second paste in a first mold, pressing the second paste to remove a portion of the setting liquid from the second paste before the hardening reaction is completed, so that the liquid/powder ratio in the second paste decreases, and allowing the hardening reaction undergo in the mold for a period of time, e.g. 15 minutes starting from the mixing of the CPC powder, the pore-forming powder and the setting liquid, to obtain a cylindrical block having a diameter of 7 mm. Then, the cylindrical block is removed from the first mold, and placed in the center of a second mold having a diameter of 10 mm. The first paste is poured into the annular space in the second mold, and a press having a dimension corresponding to the annular shape is used to pressure the first paste to remove a portion of the setting liquid from the first paste before the hardening reaction is completed, so that the liquid/powder ratio in the first paste decreases. Again, the first paste will undergo a hardening reaction to convert into apatitic phase. The hardened cylinder having a diameter of 10 mm is removed from the second mold, followed by immersing in an immersing liquid, where the pore-forming powder contained in the second paste is dissolved in the immersing liquid while the hardened CPC thereof gaining compressive strength, to obtain the prosthetic bone implant of the present invention, as shown in **FIGS. 3***a* and **3***b*. It is apparently to people skilled in the art that the prosthetic bone implant shown in **FIGS. 3***a* and **3***b* can also be prepared by changing the sequence of the molding of the first paste and the second paste with modifications to the second mold used in this alternative method.

[0069] The following examples are intended to demonstrate the invention more fully without acting as a limitation upon its scope, since numerous modifications and variations will be apparent to those skilled in this art.

PREPARATIVE EXAMPLE 1

Preparation of TTCP Powder

[0070] A $Ca_4(PO_4)_2O$ (TTCP) powder was prepared by mixing $Ca_2P_2O_7$ powder with $CaCO_3$ powder uniformly in ethanol for 24 hours followed by heating to dry. The mixing ratio of $Ca_2P_2O_7$ powder to $CaCO_3$ powder was 1:1.27 (weight ratio) and the powder mixture was heated to 1400° C. to allow two powders to react to form TTCP.

PREPARATIVE EXAMPLE 2

Preparation of Conventional TTCP/DCPA-Based CPC Powder (Abbreviated as C-CPC)

[0071] The resulting TTCP powder from PREPARATIVE EXAMPLE 1 was sieved and blended with dried $CaHPO_4$ (DCPA) powder in a ball mill for 12 hours. The blending ratio of the TTCP powder to the DCPA powder was 1:1 (molar ratio) to obtain the conventional CPC powder. Particles of this C-CPC powder have no whisker on the surfaces thereof.

PREPARATIVE EXAMPLE 3

Preparation of Non-Dispersive TTCP/DCPA-Based CPC Powder (Abbreviated as ND-CPC)

[0072] The TTCP powder prepared according to the method of PREPARATIVE EXAMPLE 1 was sieved and blended with dried $CaHPO_4$ (DCPA) powder in a ball mill for 12 hours. The blending ratio of the TTCP powder to the DCPA powder was 1:1 (molar ratio). The resultant powder mixture was added to a 25 mM diluted solution of phosphate to obtain a powder/solution mixture having a concentration of 3 g powder mixture per 1 ml solution while stirring. The resulting powder/solution mixture was formed into pellets, and the pellets were heated in an oven at 50° C. for 10 minutes. The pellets were then uniformly ground in a mechanical mill for 20 minutes to obtain the non-dispersive TTCP/DCPA-based CPC powder (ND-CPC). The particles of this ND-CPC powder have whisker on the surfaces thereof.

[0073] Dense Blocks

EXAMPLE 1

Effect of Immersion Time on Compressive Strength of CPC Block

[0074] To a setting solution of 1M phosphoric acid solution (pH=5.89) the ND-CPC powder from PREPARATIVE EXAMPLE 3 was added in a liquid/powder ratio (L/P ratio) of 0.4, i.e. 4 ml liquid/10 g powder, while stirring. The resulting paste was filled into a cylindrical steel mold having a length of 12 mm and a diameter of 6 mm, and was compressed with a gradually increased pressure until a maximum pressure was reached. The maximum pressure was maintained for one minute, and then the compressed CPC block was removed from the mold. At the 15th minute following the mixing of the liquid and powder, the compressed CPC block was immersed in a Hanks' solution for 1 day, 4 days, and 16 days. Each test group of the three different periods of immersion time has five specimens, the compressive strength of which was measured by using a AGS-500D mechanical tester (Shimadzu Co., Ltd., Kyoto, Japan) immediately following the removal thereof from the Hanks' solution without drying. The CPC paste in the mold was compressed with a maximum pressure of 166.6 MPa, and in the course of the compression the compression speeds were about 5 mm/min during 0~104.1 MPa; 3 mm/min during 104.1~138.8 MPa; 1 mm/min during 138.8~159.6 MPa: and 0.5 mm/min during 159.6~166.6 MPa. The measured wet specimen compressive strength is listed Table 1.

TABLE 1

Immersion time (Day)	Compressive strength (MPa)	Standard deviation (MPa)
No immersion	37.3*	0.6
1 day	149.2	12.9
4 days	122.7	6.7
16 days	116.4	7.7

*This value was measured before the compressed CPC blocks were immersed in the Hanks' solution, and it was substantially the same for the compressed CPC blocks not immersed in the Hanks' solution measured a few days after the preparation.

[0075] It can seen from Table 1 that the compressive strength of the compressed CPC blocks is increased remarkably after one-day immersion in comparison with the non-immersed block, and declines a little for a longer immersion time.

EXAMPLE 2

Effect of Whiskers on Compressive Strength of TTCP/DCPA-Based CPC Block

[0076] The procedures of EXAMPLE 1 were repeated by using the C-CPC powder prepared in PREPARATIVE EXAMPLE 2 and the ND-CPC powder prepared in PREPARATIVE EXAMPLE 3. The maximum pressure used to compress the CPC paste in the mold in this example was 156.2 MPa. The results for one-day immersion time are listed in Table 2.

TABLE 2

CPC powder	Compressive strength (MPa)	Standard deviation (MPa)
C-CPC (no whisker)	62.3	5.0
ND-CPC (with whisker)	138.0	8.2

[0077] It can be seen from Table 2 that the compressive strength, 62.3 MPa, of the immersed compressed CPC block prepared from the conventional CPC powder (no whisker) is about 1.7 times of that (37.3 MPa) of the non-immersed compressed CPC block in Table 1, and the compressive strength, 138.0 MPa, of the immersed compressed CPC block prepared from the non-dispersive CPC powder (with whisker) is about 3.7 times of that of the non-immersed compressed CPC block in Table 1

EXAMPLE 3

Effect of Whiskers on Compressive Strength of TTCP-Based CPC Block

[0078] $Ca_4(PO_4)_2O$ (TTCP) powder as synthesized in PREPARATIVE EXAMPLE 1 was sieved with a #325 mesh. The sieved powder has an average particle size of about 10 μm. To the TTCP powder HCl aqueous solution (pH=0.8) was added according to the ratio of 1 g TTCP/13 ml solution. The TTCP poweder was immersed in the HCl aqueous solution for 12 hours, filtered rapidly and washed with deionized water, and filtered rapidly with a vacuum pump again. The resulting powder cake was dried in an oven at 50° C. The dried powder was divided into halves, ground for 20 minutes and 120 minutes separately, and combined to obtain the non-dispersive TTCP-based CPC powder, the particles of which have whisker on the surfaces thereof. A setting solution of diammonium hydrogen phosphate was prepared by dissolving 20 g of diammonium hydrogen phosphate, $(NH_4)_2HPO_4$, in 40 ml deionized water. The procedures in EXAMPLE 1 were used to obtain the wet specimen compressive strength for one-day immersion time, wherein the maximum pressure to compress the CPC paste in the mold was 156.2 MPa. The results are shown in Table 3.

TABLE 3

CPC powder	Compressive strength (MPa)	Standard deviation (MPa)
TTCP (no whisker)	79.6	8.8
TTCP (with whisker)	100	4.2

[0079] The trend same as the TTCP/DCPA-based CPC powder in Table 2 of EXAMPLE 2 can be observed in Table 3.

EXAMPLE 4

Effect of Molding Pressure on Compressive Strength of ND-CPC Block (in Low Pressure Regime: 0.09~3.5 MPa)

[0080] The procedures of EXAMPLE 1 were repeated except that the maximum pressure used to compress the CPC paste in the mold was changed from 166.6 MPa to the values listed in Table 4. The period of immersion was one day. The results are listed in Table 4.

TABLE 4

Pressure for compressing the CPC paste in mold (MPa)	Compressive strength (MPa)	Standard deviation (MPa)
0.09	12.3	2.0
0.35	16.0	2.3
0.7	20.7	2.5
1.4	26.4	1.4
3.5	35.2	3.7

[0081] The data in Table 4 indicate that the compressive strength of the CPC block increases as the pressure used to compress the CPC paste in the mold increases.

EXAMPLE 5

Effect of Reducing Liquid/Powder Ratio During Compression of the CPC Paste in the Mold on Compressive Strength of ND-CPC Block

[0082] The procedures of EXAMPLE 1 were repeated except that the maximum pressure used to compress the CPC paste in the mold was changed from 166.6 MPa to the values listed in Table 5. The liquid leaked from the mold during compression was measured, and the liquid/powder ratio was re-calculated as shown in Table 5. The period of immersion was one day. The results are listed in Table 5.

TABLE 5

Pressure for compressing the CPC paste in mold (MPa)	L/P ratio (after a portion of liquid removed)	Compressive strength (MPa)	Standard deviation (MPa)
1.4	0.25	26.4	1.4
34.7	0.185	75.3	3.9
69.4	0.172	100.4	6.8
156.2	0.161	138.0	8.2
166.6	0.141	149.2	12.9

[0083] The data in Table 5 show that the compressive strength of the CPC block increases as the liquid/powder ratio decreases during molding.

EXAMPLE 6

Effect of Post-Heat Treatment on Compressive Strength of CPC Block

[0084] The procedures of EXAMPLE 1 were repeated. The period of immersion was one day. The CPC blocks after removing from the Hanks' solution were subjected to post-heat treatments: 1) 50° C. for one day; and 2) 400° C. for two hours with a heating rate of 10° C. per minute. The results are listed in Table 6.

TABLE 6

	Compressive strength (MPa)	Standard deviation (Mpa)
No post-heat treatment	149.2	12.9
50° C., one day	219.4	16.0
400° C., two hours	256.7	16.2

[0085] It can be seen from Table 6 that the post-heat treatment enhances the compressive strength of the CPC block.

[0086] Porous Blocks

EXAMPLE 7

Effect of KCl Content and Immersion Time on Compressive Strength of Porous CPC Block

[0087] To a setting solution of 1M phosphoric acid solution (pH=5.89) the ND-CPC powder from PREPARATIVE EXAMPLE 3 was added in a liquid/powder ratio (L/P ratio) of 0.4, i.e. 4 ml liquid/10 g powder, while stirring. KCl powder in a predetermined amount was mixed to the resulting mixture by stirring intensively. The resulting paste was filled into a cylindrical steel mold having a length of 12 mm and a diameter of 6 mm, and was compressed with a gradually increased pressure until a maximum pressure of 3.5 MPa was reached. The maximum pressure was maintained for one minute, and then the compressed CPC block was removed from the mold. At the 15th minute following the mixing of the liquid and powders, the compressed CPC block was immersed in a deionized water at 37° C. for 4 days, 8 days, and 16 days. The compressive strength of the specimens of the three different periods of immersion time was measured by using a AGS-500D mechanical tester (Shimadzu Co., Ltd., Kyoto, Japan) after the specimens were dry. The measured dry specimen compressive strength is listed Table 7.

TABLE 7

	Dry compressive strength (MPa) Immersion time (Day)		
KCl/CPC ratio by weight	4 days	8 days	16 days
1	7.0	5.4	6.6
1.5	3.9	2.7	4.3
2	1.3	2.3	2.6

[0088] It can seen from Table 7 that the dry compressive strength of the porous CPC blocks decreases as the KCl/CPC ratio by weight increases.

EXAMPLE 8

Porosity and Compressive Strength of Porous CPC Blocks Prepared from Different Pore-Forming Powders

[0089] The procedures of EXAMPLE 7 were repeated by using sugar, KI, $C_{17}H_{33}COONa$ and $C_{13}H_{27}COOH$ instead of KCl. The immersion time was 14 days in deionized water. In the cases where the $C_{17}H_{33}COONa$ and $C_{13}H_{27}COOH$ were used, the CPC blocks were further immersed in ethanol for additional four days. The conditions and the results are listed in Table 8.

TABLE 8

Pore-forming powder	S[a)]	C.S. (MPa)[b)]	Porosity (vol %)[c)]
Sugar	1	4.1	58.4
KI	2	4.3	62.2
KI	3	1.7	75.5
C17H33COONa	1	8.0	56.0
C13H27COOH	2	5.9	60.1

a)S = Pore-forming powder/CPC by volume.
b)C.S. = dry compressive strength (hereinafter abbreviated as C.S.).
c)Porosity: Porosity (vol %) was measured by Archimedes' method, and calculated as in ASTM C830.

[0090] It can be seen from Table 8 that various powders which are soluble in water can be used in the preparation of a porous CPC block according to the method of the present invention.

[0091] Dual-Functional Block

EXAMPLE 9

[0092] To a setting solution of 1M phosphoric acid solution (pH=5.89) the ND-CPC powder from PREPARATIVE EXAMPLE 3 was added in a liquid/powder ratio (L/P ratio) of 0.4, i.e. 4 ml liquid/10 g powder, while stirring. KCl powder in a ratio of KCl powder/CPC by volume of 2 was mixed to the resulting mixture by stirring intensively. The resulting paste was filled into a cylindrical steel mold having a length of 12 mm and a diameter of 7 mm, and was compressed with a gradually increased pressure until a maximum pressure of 3.5 MPa was reached. The maximum pressure was maintained for one minute, and then the compressed CPC block was removed from the mold at the 15th minute following the mixing of the liquid and powders.

[0093] The resulting cylinder having a diameter of 7 mm was placed in another cylindrical steel mold having a diameter of 10 mm. To a setting solution of 1M phosphoric acid solution (pH=5.89) the ND-CPC powder from PREPARATIVE EXAMPLE 3 was added in a liquid/powder ratio (L/P ratio) of 0.4, i.e. 4 ml liquid/10 g powder, while stirring. The resulting paste was filled into the gap between said cylinder and said another mold, and was compressed with a gradually increased pressure until a maximum pressure of 50 MPa was reached. The maximum pressure was maintained for one minute. At the 15th minute following the mixing of the liquid and ND-CPC powder, the CPC/KCl composite block was immersed in a deionized water at 37° C. for 4 days. KCl powder was dissolved in the deionized water, and a dual-functional CPC block having a porous CPC cylinder surround by a dense CPC annular block was obtained.

[0094] The compressive strength of the specimen was measured by using a AGS-500D mechanical tester (Shimadzu Co., Ltd., Kyoto, Japan) after the specimens were dry. The measured dry specimen compressive strength is 68.8 MPa.

[0095] The porosities of the porous CPC cylinder and the dense CPC annular block were measured by Archimedes' method, and calculated as in ASTM C830, after the dual-functional CPC block was broken intentionally, and the results are 74% and 30%, respectively.

[0096] X-ray diffraction pattern of the powder obtained by grinding the dual-functional CPC block shows broadened characteristic X-ray diffraction peaks of apatite at 2θ=25-27° and 2θ=20-35° with a scanning range of 2θ of 20-40° and a scanning rate of 1°/min. The results indicate that the powder is a mixture of apatite and TTCP with apatite as a major portion.

1-40. (canceled)

41. A prosthetic bone implant comprising:

a load bearing component; and

at least one porous component coupled to the load-bearing component;

wherein the load bearing component and the porous component comprise a hardened calcium phosphate cement, wherein the calcium phosphate cement is prepared from a calcium phosphate compound, and wherein at least a portion of particles of the calcium phosphate compound comprise whiskers on the surface of the calcium phosphate particles.

42. The prosthetic bone implant of claim 41, wherein the porosity of the porous component is greater than the porosity of the load bearing component.

43. The prosthetic bone implant of claim 41, wherein the porosity of the porous component is from about 20% by volume to about 90% by volume.

44. The prosthetic bone implant of claim 41, wherein the porosity of the load bearing component is less than about 30% by volume.

45. The prosthetic bone implant of claim 41, wherein the load-bearing component is adapted to withstand compressive force of greater than about 35 MPa.

46. The prosthetic bone implant of claim 41, wherein the load bearing component is adapted to withstand a compressive force of from about 35 MPa to about 250 MPa.

47. The prosthetic bone implant of claim 41, wherein the load bearing component is adapted to withstand a compressive force of from about 110 MPa to about 170 MPa.

48. The prosthetic bone implant of claim 41, wherein the hardened calcium phosphate cement of the load bearing component and the hardened calcium phosphate cement of the porous component is made from at least one calcium phosphate source.

49. The prosthetic bone implant of claim 48, wherein the calcium phosphate source comprises alpha-tricalcium phosphate (α-TCP), beta-tricalcium phosphate (β-TCP), tetracalcium phosphate (TTCP), monocalcium phosphate monohydrate (MCPN), monocalcium phosphate anhydrous (MCPA), dicalcium phosphate dihydrate (DCPD), dicalcium phosphate anhydrous (DCPA), octacalcium phosphate (OCP), calcium dihydrogen phosphate, calcium dihydrogen phosphate hydrate, acid calcium pyrophosphate, anhydrous calcium hydrogen phosphate, calcium hydrogen phosphate hydrate, calcium pyrophosphate, calcium triphosphate, calcium phosphate tribasic, calcium polyphosphate, calcium metaphosphate, anhydrous tricalcium phosphate, tricalcium phosphate hydrate, amorphous calcium phosphate, or mixtures thereof.

50. The prosthetic bone implant of claim 41, wherein at least a portion of the hardened calcium phosphate cement of the load bearing component and at least a portion of the hardened calcium phosphate cement of the porous component is made from tetracalcium phosphate.

51. The prosthetic bone implant of claim 41, wherein at least a portion of the hardened calcium phosphate cement of the load bearing component and at least a portion of the hardened calcium phosphate cement of the porous component is made from tetracalcium phosphate and dicalcium phosphate anhydrous.

52. The prosthetic bone implant of claim 41, wherein at least a portion of the hardened calcium phosphate cement of the load bearing component and at least a portion of the hardened calcium phosphate cement of the porous component comprises apatite.

53. The prosthetic bone implant of claim 52, wherein the molar ratio of calcium/phosphate of the apatite is about 1.5-2.0.

54. The prosthetic bone implant of claim 41, further comprising a transitional component coupling one or more porous components to the load bearing component, the transitional component comprising a hardened calcium phosphate cement.

55. The prosthetic bone implant of claim 54, wherein the transitional component comprises a porosity gradient increasing from the porosity of the porous component to the porosity of the load bearing component.

56. The prosthetic bone implant of claim 41, wherein the implant is adapted to allow body fluid and/or tissues to penetrate the implant when the implant is implanted into a patient.

57. The prosthetic bone implant of claim 41, wherein the porous components are substantially surrounded by the load bearing component.

58. The prosthetic bone implant of claim 41, wherein at least a portion of load bearing component and/or the porous components are exposed to the surface of the implant.

59. The prosthetic bone implant of claim 41, wherein the configuration of the porous components relative to the load bearing component is such that, when the prosthetic bone implant is implanted into bone, at least a portion of the load bearing component is coupled to cortical bone, and at least a portion a porous component is coupled to cancellous bone.

60. The prosthetic bone implant of claim 41, wherein at least a portion of the hardened calcium phosphate cement comprising the load bearing component and the porous component is made from tetracalcium phosphate, wherein at least a portion of tetracalcium phosphate particles comprises whiskers on the surface of the tetracalcium phosphate particles.

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