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(54) **A bone implant**

(57) A bone implant includes a non-metallic core (24) and a metallic porous surface (30, 31) secured to the non-metallic core. The non-metallic core is designed to closely approximate the modulus of elasticity for bone and the metallic porous surface is intimately engaged with bone to enhance bone growth into the metallic porous surface. In one embodiment the core (24) comprises a plurality of longitudinally extending fibres, an intermediate layer (26) consisting of a braided sheath of fibres, and a polymer skin (28). The porous metallic surface may be provided by fibre metal pads (31, 32) partially embedded in the polymer skin of the core.

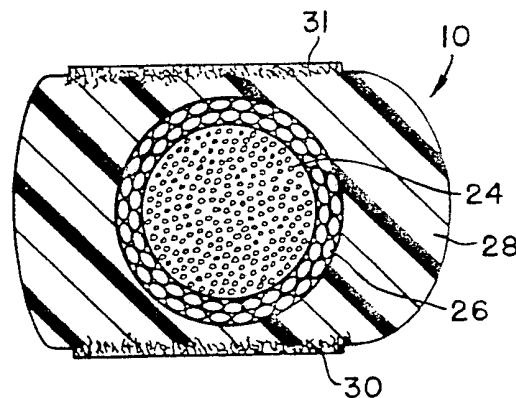
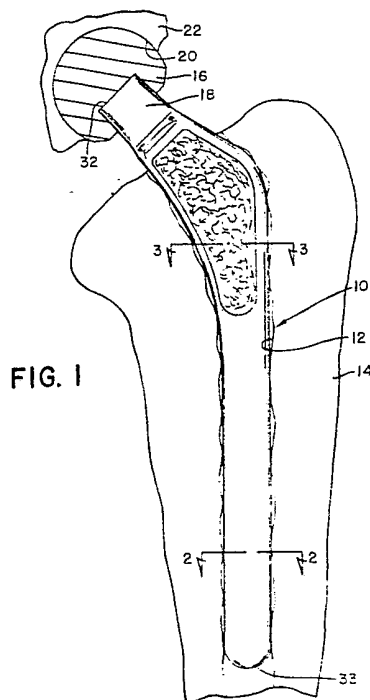


FIG. 3

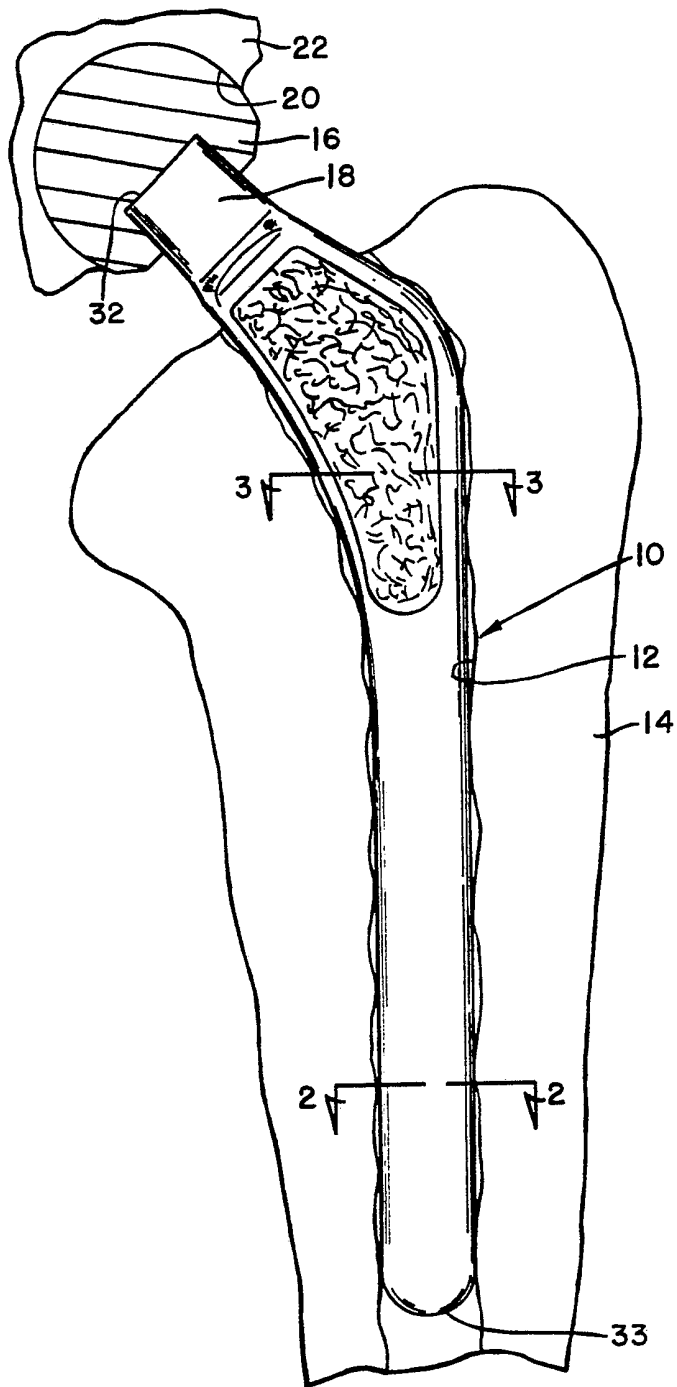


FIG. 1

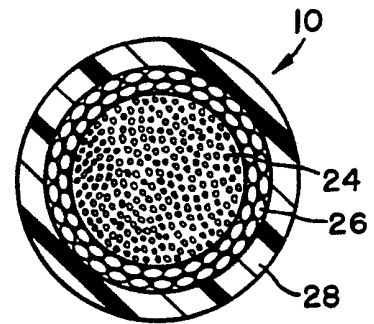


FIG. 2

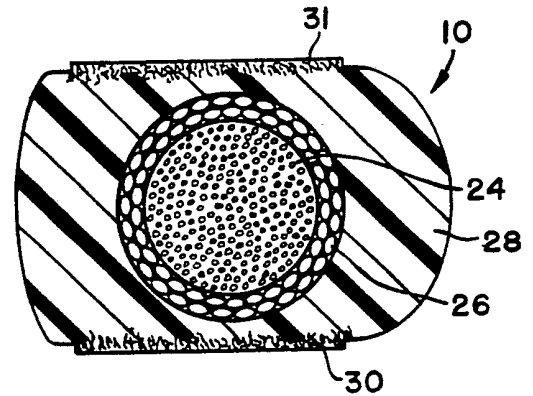


FIG. 3



FIG. 4



FIG. 5

The present invention relates to a bone implant which is used in a surgical proceeding to repair or reconstruct skeletal deformities. These bone implants have been utilized by orthopaedic surgeons in hip and knee arthroplasty to reconstruct articulating joints, as well as in trauma situations to secure fractured bones together.

Various metals have been proposed to manufacture bone implants. Titanium and cobalt chrome, for example, are in widespread use because of their biocompatibility with bone tissue and their strength characteristics for carrying loads imparted to the skeletal structure following implantation. With a metal bone implant, US patents 3 605 123 and 3 900 550 further provide a porous metallic surface to enhance fixation of the implant with a resected bone at the intramedullary canal. These metals are stronger than bone; however, bone is somewhat flexible, and the stiff metals do not exactly match the flexibility of bone. As a result, numerous recent articles and patents are proposing the use of composites or non-metals for the construction of bone implants in order to provide the implant with a modulus substantially the same as bone.

In US patent 4 662 887 a polyetheretherketone commonly referred to as PEEK is disclosed for use as an orthopaedic device. The PEEK polymer is biocompatible and sufficiently flexible in final form to approximate the anatomic elasticity of bone. In Hochman US patent 3 893 196, a composite hip implant is provided with a graphite fiber core, an outer layer of graphite fiber circumscribing the core and a plastic skin enclosing all of the fiber and providing a porous plastic surface to enable the bone to knit thereto. In further support of Hochman is

patent 4 164 794, wherein a porous composite material is provided on the surface of a hip prosthesis to enhance fixation to bone.

Comparing the metal implant with the composite implant, advantages and disadvantages are apparent. With the metal implant, the strength characteristics of metals results in a stiff implant which may stress shield portions of the bone. To date, no composite implant has established the intimate bone association believed to be necessary for adherence to bone for long term fixation in spite of the numerous attempts to provide a porous composite surface for the composite implant. Further it is believed that polymer surfaces may be insufficiently durable to transfer load and possess inadequate abrasion resistance for long term fixation.

It is an object of this invention to provide an improved bone implant and method for constructing the implant.

In accordance with one aspect, this invention consists in a bone implant comprising a non metallic core and a porous metallic component fixedly secured to the non metallic core.

Preferably, the core is a composite core which closely approximates the flexibility of the bone.

In one embodiment, the core includes polyetheretherketone and the porous metallic component includes a fiber metal pad.

Suitably, the metallic porous surface component includes a substantially non-porous barrier embedded therein and the non metallic core extends into the metallic porous surface component up to but not past the non-porous barrier.

In one form of the invention, the non-metallic core comprises a first set of fibers oriented in a longitudinal direction from one end to an opposite end for the bone implant, a second set of fibers forming a braided sheath covering the first set of fibers, and a polymer layer surrounding the first and second sets of fibers.

In accordance with another aspect, the invention includes a bone implant for a hip prosthesis comprising a first set of composite fibers extending longitudinally from one end to an opposite end for the implant, a second set of composite fibers forming a braided sheath over the first set of fibers, a polymer skin enclosing the first and second sets of fibers, and a porous metallic pad fixedly secured to the polymer skin and adapted for intimate contact with the hip bone.

Preferably, the first set of fibers, the second set of fibers and the polymer skin include polyetheretherketone as a material component of each.

The first set of fibers and the second set of fibers are preferably designed to sustain a substantial portion of the load transmitted to the bone implant, with the polymer skin designed to transmit loads from the bone to the first and second set of fibers, and the porous metallic pad designed to encourage bone ingrowth therein to fixedly secure the bone implant to the hip bone.

The first set of fibers may comprise a plurality of long fibers made from carbon impregnated with polyetheretherketone, the second set of fibers comprising a plurality of long fibers made from carbon impregnated with polyetheretherketone, and the polymer skin being made from polyetheretherketone for ready assimilation with the first and

second sets of fibers.

Preferably, the porous metallic pad penetrates into an outer portion of the polymer skin such that an inner portion of the polymer skin separates the porous metallic pad from the second set of composite fibers.

In accordance with yet another aspect, the invention consists in a bone implant for a hip prosthesis comprising a non-metallic core forming a predetermined shape adapted to fit into a femoral canal of the hip and a metallic porous surface fixedly secured to the non-metallic core for intimate contact with the femoral canal.

Preferably, the porous metallic surface is formed from a fiber metal pad.

Suitably, the fiber metal pad defines an inner portion embedded into the non-metallic core and an outer portion with open pores for bone ingrowth.

The non-metallic core may include a plurality of fibers some of which extend in a longitudinal direction and a skin enclosing the plurality of fibers, with the metallic porous surface fixedly secured to the skin.

Suitably, the metallic porous surface comprises a discrete metallic porous element with a first portion of the element embedded in the skin and a second portion of the element forming open pores.

The non-metallic core may comprise polyetherketoneketone.

The present invention thus teaches, in one aspect, an orthopaedic implant which incorporates the advantages of metal and composite materials. Rather than relying upon a total composite or a total metal

implant, the invention provides a composite core which closely approximates the flexibility of bone and a porous metallic surface secured to the composite core so that bone growth and/or cement will readily penetrate and adhere to the porous metallic surface for long term fixation of the orthopaedic implant.

It is an advantage of the preferred form of the present invention that the composite/metal implant approximates the flexibility of bone and provides a porous metallic surface which is readily compatible with bone to provide unrestricted ingrowth of bone into the porous surface and such porous metallic surface is sufficiently strong and durable to provide for long term fixation. Moreover, the porous metallic surface is provided by a metallic fiber metal pad which resists abrasion and remains integrally secured to the composite core during implantation as well as after implantation.

In accordance with a further aspect of the invention, there is provided a method for constructing a bone implant, comprising the steps of:

- (a) providing a non-metallic composite core of predetermined configuration for orientation adjacent the bone;
- (b) providing a metallic porous pad;
- (c) heating the metallic porous pad to a temperature sufficient to permit penetration of the core into the metallic porous pad;
- (d) advancing the heated metallic porous pad into engagement with the non-metallic composite core to melt a portion of the latter and

permit penetration of a portion of both the core and pad into each other; and

- (e) cooling the heated metallic porous pad to the same temperature as the non-metallic composite core such that the penetrated portion of the metallic porous pad fixedly secures the latter to the non metallic composite core.

Preferably, the heating and advancing steps take place in the absence of oxygen.

The invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a side view of a femoral component following implantation,

Figure 2 is a cross sectional view taken along line 2-2 of Figure 1,

Figure 3 is a cross sectional view taken along line 3-3 of Figure 1,

Figure 4 is a cross sectional view of the porous fiber metal pad separate from the composite stem, and

Figure 5 is a view similar to Figure 3 showing an alternative embodiment of the invention.

The femoral component 10 is surgically implanted into the intramedullary canal 12 of the femur 14. The intramedullary canal 12 is exposed by resection of the anatomic femoral head (not shown). A head 16 is coupled to a neck 18 of the femoral component. The head 16 is

spherical in shape to provide for articulation within a socket 20 of an acetabulum 22.

The femoral component 10 includes a core 24 comprising a plurality of longitudinally extending fibers, an intermediate layer 26 comprising a braided sheath of fibers, a skin 28 enclosing the core 24 and intermediate layer 26, and a pair of porous fiber metal pads 30 and 31 secured to the skin 28. In the drawings the intermediate layer 26 is shown as a larger fiber cross section than the core 24 for illustration purposes only. The core 24 and intermediate layer 26 are constructed from the same fibers.

The core 24, intermediate layer 26 and skin 28 extend from a distal end 33 to a proximal end 32 forming the neck 18. The porous fiber metal pads 30 and 31 are preferably disposed adjacent the neck 18 and on both sides, anteriorly and posteriorly, of the femoral component.

The plurality of fibers forming the core 24 and the braided sheath of fibers forming the intermediate layer 26 are made of APC-2 as sold by FIBERITE (registered trade mark), an Imperial Chemical Industry affiliate, see FIBERITE data sheet 3a propriety data of aromatic polymer composite, APC-2/Hercules Magnamite (registered trade mark) AS4 Carbon Fibre. This material includes continuous carbon fibre with PEEK impregnated into the continuous carbon fibre.

The skin 28 is made of polyetheretherketone or PEEK as taught by US patent 4 662 887. This material is available from Imperial Chemical Industries per the specification for Victrex (registered trade mark) 450G polyetheretherketone (PEEK) natural color granular molding resin.

The fiber metal pads 30 and 31 are disclosed in US patent 3 906 550 as short titanium wires which are kinked in a sinusoidal pattern with a specific amplitude to period ratio of .24. Numerous short wires are sintered together to form a unitary porous pad for fixation to the skin 28.

In order to manufacture the femoral component 10, the longitudinal fibers for the core 24 are bundled together and pulled through braiders for braiding a sheath or layer 26 over the core 24. With the sheath or layer covering the core 24, a suitable length is cut and disposed in a mold so that the skin 28 can be injection molded over the sheath 26 and core 24. The PEEK material for the skin 28 is heated in the injection molding step and readily attaches to the impregnated PEEK in the carbon fibers of the sheath 26 and the core 24. After the skin is cooled, a fiber metal pad as shown in Figure 4 is heated to a temperature sufficient to permit the skin to penetrate the heated pad. It is believed that a temperature of about 600°F (315°C) suffices for penetration. A heated fiber metal pad is then forced into each side of the stem to penetrate via melting into the skin 28 a predetermined distance. Preferably, one-half of the thickness of the fiber metal pad is penetrated into the skin as seen in comparing Figures 3 and 4. When the fiber metal pad cools, the penetrated portion of the fiber metal pad is trapped within or secured to the skin 28 while an outer portion of the fiber metal pad remains porous or open for intimate contact with bone and the resulting bony ingrowth that follows in view of the affinity for bone to associate with titanium wire.

In the alternative embodiment of Figure 5, a metal barrier 40 separates the fiber metal pads 30 into an inner fiber metal portion 42 and an outer fiber metal portion 44. The barrier 40 separates that portion of the pad intended for impregnation into the skin from that portion of the fiber metal pad intended for bony ingrowth.

Although the foregoing description proceeds with reference to PEEK and titanium fiber metal pad, it is contemplated that other composite cores with or without fiber reinforcement can be utilized with other types of metallic porous surfaces, e.g. beads, to generate a hybrid composite/metal bone implant that includes a modulus substantially the equivalent of bone and a porous metallic surface to encourage bone ingrowth. Prosthetic knee components can also be made by the composite/metal bone implant of the present invention. In addition, the composite bone implant with the porous metallic surface of the present invention, is also readily adapted for use in a cemented hip arthroplasty where PMMA bone cement is used to secure the implant to bone.

The material for the skin 28 is referred to hereinabove as polyetheretherketone or PEEK; however, such material is also referred to as polyaryletherketone. As an alternative material, it is believed that polyetherketone (PEK) or polyetherketoneketone (PEKK) is suitable for forming the skin and as a matrix for the carbon fibers of the core and braid. The polyetherketone (PEK) is available from Imperial Chemical Industries and the polyetherketoneketone is available from DuPont as PEKK polymer. As such this material is also included in the invention claimed.

CLAIMS

1. A bone implant comprising a non-metallic core and a porous metallic component fixedly secured to the non-metallic core.
2. A bone implant as claimed in Claim 1, in which the non-metallic core includes polyetheretherketone and the porous metallic component includes a fiber metal pad.
3. A bone implant as claimed in Claim 1 or Claim 2, in which the metallic porous surface component includes a substantially non-porous barrier embedded therein and the non-metallic core extends into the metallic porous surface component up to but not past the non-porous barrier.
4. A bone implant as claimed in any one claims 1 to 3, in which the non-metallic core comprises a first set of fibers oriented in a longitudinal direction from one end to an opposite end for the bone implant, a second set of fibers forming a braided sheath covering the first set of fibers, and a polymer layer surrounding the first and second sets of fibers.
5. A bone implant for a hip prosthesis comprising a first set of composite fibers extending longitudinally from one end to an opposite end for the implant, a second set of composite fibers forming a braided sheath over the first set of fibers, a polymer skin enclosing the first and second sets of fibers, and a porous metallic pad fixedly secured to the polymer skin and adapted for intimate contact with the hip bone.

6. A bone implant as claimed in Claim 5, in which the first set of fibers, the second set of fibers and the polymer skin include polyetheretherketone as a material component of each.

7. A bone implant as claimed in Claim 5 or Claim 6, in which the first set of fibers and the second set of fibers are designed to sustain a substantial portion of the load transmitted to the bone implant, and the polymer skin is designed to transmit loads from the bone to the first and second set of fibers, and the porous metallic pad is designed to encourage bone ingrowth therein to fixedly secure the bone implant to the hip bone.

8. A bone implant as claimed in Claim 6, in which the first set of fibers comprises a plurality of long fibers made from carbon impregnated with polyetheretherketone, the second set of fibers comprises a plurality of long fibers made from carbon impregnated with polyetheretherketone, and the polymer skin is made from polyetheretherketone for ready assimilation with the first and second sets of fibers.

9. A bone implant as claimed in any one of claims 5 to 8, in which the porous metallic pad penetrates into an outer portion of the polymer skin such that an inner portion of the polymer skin separates the porous metallic pad from the second set of composite fibers.

10. A method for constructing a bone implant comprising the steps of:

- (a) providing a non-metallic composite core of predetermined configuration for orientation adjacent the bone;
- (b) providing a metallic porous pad;
- (c) heating the metallic porous pad to a temperature sufficient to permit penetration of the core into the metallic porous pad;
- (d) advancing the heated metallic porous pad into engagement with the non-metallic composite core to melt a portion of the latter and permit penetration of a portion of both the core and pad into each other; and
- (e) cooling the heated metallic porous pad to the same temperature as the non-metallic composite core such that the penetrated portion of the metallic porous pad fixedly secures the latter to the non metallic composite core.

11. The method of Claim 10, in which the heating and advancing steps take place in the absence of oxygen.

12. A bone implant for a hip prosthesis comprising a non-metallic core forming a predetermined shape adapted to fit into a femoral canal of the hip and a metallic porous surface fixedly secured to the non-metallic core for intimate contact with the femoral canal.

13. A bone implant as claimed in Claim 12 in which the porous metallic surface is formed from a fiber metal pad.

14. A bone implant as claimed in Claim 13, in which the fiber metal pad defines an inner portion embedded into the non-metallic core and an outer portion with open pores for bone ingrowth.

15. A bone implant as claimed in any one of claims 12 to 14, in which the non-metallic core includes a plurality of fibers some of which extend in a longitudinal direction and a skin encloses the plurality of fibers, and the metallic porous surface is fixedly secured to the skin.

16. A bone implant as claimed in Claim 15, in which the metallic porous surface comprises a discrete metallic porous element with a first portion of the element embedded in the skin and a second portion of the element forming open pores.

17. A bone implant as claimed in any one of claims 12 to 16, in which the non-metallic core comprises polyetherketoneketone.

18. A bone implant substantially as described with reference to, and as shown in, the accompanying drawings.

19. A method for constructing a bone implant, substantially as described.