

Description**FIELD OF THE INVENTION**

- 5 The present invention relates to orthopedic implants, and more particularly to load bearing prosthetic devices that exhibit along the length modulus variations, and methods of preparation thereof.

BACKGROUND OF THE INVENTION

- 10 Orthopedic implants include a wide variety of devices, each suited to fulfill particular medical needs. Examples of such devices are hip joint replacement devices, knee joint replacement devices, and pins, braces and plates used to set fractured bones. Particular emphasis has been recently placed on hip joint prosthetic equipment.

- Contemporary orthopedic implants, including hip and knee components, use high performance metals
15 such as cobalt-chrome and titanium alloy to achieve high strength. These materials are readily fabricated into the complex shapes typical of these devices using mature metal working techniques including casting and machining. Yet, these metals are characterized by high, fixed moduli of elasticities which makes it difficult to achieve optimal device stiffness within a given anatomical geometric envelope. In particular, in regions in which metal implants share load with surrounding bone, e.g., the medullary canal of the femur,
20 the stress in the bone is substantially reduced versus the normal physiological level. This "stress-shielding" effect often leads to bone remodeling and may be implicated in clinical problems such as aseptic loosening and pain. Stress shielding is particularly acute in large metal implant systems. Further, large metal implants require more bone cement and are more susceptible to loosening than smaller implants.

- Since metals are characterized by a single, high modulus of elasticity (16 million psi -1.103×10^8 kPa,
25 for titanium alloy and 31 million psi $(2.137 \times 10^8$ kPa) for cobalt-chrome alloy) it is apparent that optimal design of metallic devices must focus on the geometric part of the rigidity without regard to the material parameter. Geometric design has several constraints. For example, it is generally agreed that good bone apposition is necessary for bone ingrowth into proximal porous coatings and that close distal stem fit is necessary for rotatory stability.

- Composite materials offer the potential to achieve high strength in orthopedic devices while permitting
30 the control of stiffness for enhanced load transfer to bone. In particular, the implant designer can control modulus by varying reinforcement type, orientation and amount. Such a device is revealed in PCT patent application WO/85/04323. The device is formed from a composite material of continuous filament carbon fibers embedded within a polymer matrix. The carbon fibers in the composite material are at specific
35 orientations relative to a specific dimension of the orthopedic device. The angularity of the carbon fibers modifies the modulus of the device. To effect fiber orientation, uniplanar sheets of carbon fibers are formed and cut into coupons. The coupons are then stacked into blocks or rolled into cylinders, to be fashioned into the final device. The manner in which the sheets or coupons are oriented will affect final mechanical properties. However, this device is limited in that the orientation of the carbon fibers cannot be systemati-
40 cally varied along the formed elongated body.

- European Patent Publication 0277 727 discloses an orthopedic device of a biocompatible polymer with oriented fibre reinforcement. Prostheses of this reference are formed from plies of continuous filament fibres that are curvilinearly disposed within a body. The plies may have a balanced orientation; that is, for each sheet having fibres offset at a positive angle there is essentially a sheet having fibres offset at about the
45 same negative angle. However, the prosthetic device of this variety is limited in that the orientation of the carbon fibres cannot be varied along the formed elongate body.

- U.S. Patent 4,750,905 (equivalent to WO 87/04916) reveals a prosthesis construction including an elongate, tapered polymer core containing continuous-filament fibres oriented substantially along the length of the core. The core includes a neck, an elongate distal stem and a tapered section which mates the neck
50 to the stem. A braided sheath encases the stem and tapered section of the core. The filaments in the braid encircle the core in a helical pattern extending along the stem and tapered section providing resistance to torsional stresses on the stem. However, devices according to this reference cannot be formed in a flexible laydown pattern as in the present invention.

- It is an object of the present invention to provide an orthopaedic implant with variable modulus wherein
55 the stresses in the surrounding bone are more nearly equal to their normal physiological level than achieved in a system without modulus variations. It is a feature of the present invention to provide a variety of composite materials to design an orthopaedic implant with particular properties. It is an advantage of the present invention that the subject orthopaedic implants have a variable modulus along their lengths due to

the use of filament winding and braiding techniques.

These and other objects, features and advantages of the present invention will become more readily apparent with reference to the following description of the invention.

6 SUMMARY OF THE INVENTION

The present invention provides an orthopedic device for human implantation comprising an extraosseous portion, a first intraosseous portion attached thereto and a second intraosseous portion attached to said first intraosseous portion. The orthopedic device is made of composite material, with the extraosseous
10 portion having a modulus greater than the modulus of the second intraosseous portion.

In another embodiment according to the invention, the modulus of the first intraosseous portion is greater than the second intraosseous portion and less than the modulus of the extraosseous portion. In general, the modulus of the orthopedic device may vary along the length thereof. This includes continuous variation; different regions having particular moduli, and combinations thereof.

15 The modulus variation may be accomplished according to another embodiment of the invention, wherein the orthopedic device is made of composite material comprising a plurality of filaments disposed within a polymer matrix. The filaments may be linearly or nonlinearly disposed about the longitudinal axes of the extraosseous portion and the first and second intraosseous portions. The filaments may also be disposed in either a helical or a braided pattern, and further other filaments may be incorporated therein
20 oriented axially along the longitudinal axes of the extraosseous portion and the first intraosseous portion.

The orthopedic device of the invention may be prepared according to a process of the invention. The process comprises shaping a mandrel in the configuration of the device, and winding or braiding filaments around the mandrel and applying a polymer matrix to form a layer. Additional layers may be disposed independently about the various portions thereof. The mandrel may be removed.

25 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of a typical hip implant.

Figure 2 is a side view of mandrel components useful to form an orthopedic implant according to the
30 invention.

Figure 3 is a mechanical idealization of a composite hip implant.

Figure 4 is a mechanical idealization of a press fit metal hip implant.

Figure 5 is a mechanical idealization of a polymethylmethacrylate grouted hip implant.

Figure 6 is another mechanical idealization of a composite hip implant.

35 Figure 7 is another mechanical idealization of a press fit metal hip implant.

Figure 8 is another mechanical idealization of a polymethylmethacrylate grouted hip implant.

Figures 9A and B depict a mandrel being wound or braided and a possible fiber orientation for an
40 implant according to the invention; and

Figure 10 depicts an implant according to the invention including axially oriented fibers.

45 DETAILED DESCRIPTION OF THE INVENTION

The orthopedic devices of this invention are considered to have a wide range of applicability throughout the human body. Thus, the extraosseous and intraosseous portions relate generally to any portion of the
45 body where they may be implanted into bone and further where prosthetics are desirable. For example, the devices may be implanted to support rotational movement at the shoulder, knee, hip, and the like. Much attention is focused herein on the relation of the orthopedic device to a hip implant. For this use, the extraosseous portion is considered a neck, the first intraosseous portion is considered a proximal body and the second intraosseous portion is a distal stem. While many of the features of the invention are discussed
50 in the context of a hip implant system, it is intended that the many components of the invention be given the wider applicability to implants throughout the body.

Having reference to Figure 1, a basic design of a hip implant is illustrated at 10. A neck 11 is secured to proximal body 12 which in turn is attached to a distal stem 14. The neck 11 engages a ball 16, which is rotatably engaged within an artificial cup attached to the pelvis. The proximal body 12 and distal stem 14
55 are positioned within an orifice in the femoral canal.

Note that the neck 11 of the femoral component is not surrounded by bone - the natural femoral neck is removed in conventional hip surgery along with the natural head. As such, the prosthetic neck 11 must bear the resultant loads and moments transmitted to the femur from the joint and surrounding muscles without

load sharing. So, the neck 11 must be adequately strong to avoid structural failure and adequately stiff to avoid excessive deflections which would compromise joint kinematics. There are constraints on the diameter of the neck region imposed by the need to maintain adequate range of motion of the joint.

The proximal body 12 of the femoral component provides the primary interface of the prosthesis with the femur in the trochanteric region. The proximal body 12 is designed for a tight interference fit (or, 'press fit') to the proximal femur. Such a fitting is assisted by the ingrowth of bioactive surfaces. Ideally, the proximal body 12 is given an anatomical shape to follow the contours of the intramedullary canal of the natural femur, thus, minimizing the removal of natural bone and maximizing the structural capacity of the compound bone-implant system. Alternatively, the proximal body 12 is undersized to permit grouting with polymethylmethacrylate (PMMA) bone cement.

The distal stem 14 serves to provide a secondary interface of the device to bone and, in particular, resist rotatory or 'toggling' motions which might compromise proximal fixation and long term biological fixation. The distal stem 14 may be press fit (attempting to follow the natural anatomy) or undersized and grouted with PMMA.

For each functional zone of the device (neck, proximal body and distal stem) one can define a set of rigidities and strengths which characterize the mechanical response of that region. Generally, the rigidities comprise the product of two quantities: a geometric parameter and a material parameter. In particular, we can define three rigidities as follows:

$$\begin{aligned} \text{Axial Rigidity} &= \text{Area} \times \text{Modulus} \\ \text{Flexural Rigidity} &= \text{Moment-of-Inertia} \times \text{Modulus} \\ \text{Torsional Rigidity} &= \text{Polar Moment-of-Inertia} \times \text{Shear Modulus} \end{aligned}$$

It is these rigidities which determine the response of the system to imposed loads and, in particular, control the extent to which the device shares load with any surrounding bone. Generally, load transfer will increase as device rigidity is reduced. Devices which maximize the amount of load transfer to surrounding bone are to be preferred since they will result in reduced bone remodeling consequent to "stress shielding".

However, regional rigidities must be high enough to achieve the functional requirements of the device. As noted above, the neck 11 must be stiff enough to minimize deflections which would otherwise destroy the proper kinematics of the joint. The distal stem 14 must have adequate flexural rigidity to resist 'rocking' or 'toggling' instability. In the present invention the distal stem is designed to optimize rigidity to meet the competing requirements of load transfer and rotatory stability. In addition, regional properties must be adequate to avoid structural failure of the device. Material strength usually correlates with material modulus which, thus, also sets constraints on the degree to which rigidity can be reduced to enhance load transfer.

Orthopedic implants of composite materials including fibers embedded within a polymer matrix offer the ability to control modulus of the implant by selectively orienting the fiber patterns with respect to the longitudinal or load axis of the device. In one composite system wherein a hip implant as in Figure 1 was constructed of AS4 graphite fibers within a polyether-ether-ketone matrix, the modulus of the implant was computed as the angle of the fibers formed relative of the load axis was allowed to vary. A tenfold variation in modulus is observed by varying the fiber orientation from 0° to 75° from the load axis. In particular, the use of axially oriented fibers (considered 0-5° offset from the load axis) markedly increases modulus of the implant. Note further that for this system a fiber orientation of from 0 to 75° corresponds to a modulus range of about 6.895×10^6 to 1.31×10^8 kPa (1 million to about 19 million psi). The modulus of cortical bone (2.5 million psi (1.723×10^7 kPa)) as well as the modulus of titanium/aluminum/vanadium alloy (16 million psi ($+1.103 \times 10^8$ kPa)) are included within this range. In composite systems offering more than a single orientation of fiber, it is apparent that increasing the amounts of axially oriented fibers will increase the modulus. Variations in modulus can also be effected by changing fiber type (e.g., aramid v. graphite) and fiber concentration.

In selecting the percentages of fibers of particular orientations for a given composite system, one skilled in the art also examines the strength response of the system as a function of fiber orientation. Thus, in the system developed previously with graphite fibers in polyether-ether-ketone polymer matrix, a system with 100% axial fiber orientation exhibited a compressive strength of 1.103×10^6 kPa (160 ksi). A similar system containing 60% axial fiber orientation and 40% fiber orientation varied from 5 to 75° exhibited a varied compressive strength from about 4.827×10^5 kPa (150 to about 70 ksi). It is important to note that compressive strength generally (but not necessarily) decreases as the percentage of axial fiber orientation decreases or as the load angle of the nonaxial fiber increases. For a desired composite system composite strength must be measured by the designer relative to fiber orientation. However, it is clear that for regions

of a device where high strength is prerequisite (e.g., the neck of a typical hip implant) low angle constructions are required relative to the directions of principal stress.

The present invention is directed to orthopedic implants, made from advanced composite materials and having an intentional variation in modulus along the length of the device. In particular, a femoral component for a hip implant is defined which has high modulus in the proximal region (the neck and its vicinity) and a lower modulus in the distal stem region. Specifically, the neck region has a modulus equal to or higher than typical metal alloys used in current orthopedic devices. This insures that the neck region does not undergo excessive deflections which would compromise functionality of the joint. The distal stem region comprises a modulus which optimizes load transfer to surrounding bone and rotatory stability of the structure. In particular, a preferred range for the modulus in the distal stem is 6.895×10^6 to 5.516×10^7 kPa (1 million to 8 million psi). The most preferred modulus will vary with the geometry of the system (e.g., the stem diameter).

Detailed design of the second intraosseous portion can be based on an analysis of the mechanical loading conditions in this portion and the surrounding bone. It is an objective of the present invention to enhance load transfer to the surrounding bone by using a composite vs. a metal distal stem. In particular, the present invention achieves a stress level in the bone closer to the normal physiological level than achieved with conventional all-metal implants.

Figure 3 shows a mechanical idealization of a hip implant according to the invention in which distal composite stem 14 and proximal body 12 are modeled as cylindrical entities fixed within a hollow cylinder of bone 40 representative of the shaft of the femur. Note that regions 12 and 14 need not have the same modulus of elasticity. For comparison, Figure 4 shows an analogous idealization for an all-metal system 50 press fit into bone 40 and Figure 5 is of an analogous idealization for an all-metal system 50 grouted into bone 40 using polymethylmethacrylate bone cement 60. In all three figures the idealized structure is subjected to bending moment M; bending being the principle mode of loading of hip implant systems.

The following nomenclature is used throughout this discussion:

D_o :	outer diameter of bone 40
D_i :	inner diameter of bone 40, and, outer diameter of distal portion of stem 14, and, outer diameter of stem 50
D_i'' :	outer diameter of PMMA grouted stem 50
I_b :	moment of inertia of bone cross section 40
I_c :	moment of inertia of distal portion of composite stem 14
I_{c2} :	moment of inertia of proximal portion of composite stem 12
I_m' :	moment of inertia of press fit stem 50
I_m'' :	moment of inertia of PMMA grouted stem 50
I_p :	moment of inertia of PMMA cross section
E_b :	modulus of elasticity of bone 40
E_c :	modulus of elasticity of distal portion of composite stem 14
E_{c2} :	modulus of elasticity of proximal portion of composite stem 12
E_m :	modulus of elasticity of metal
E_p :	modulus of elasticity of PMMA
L_1, L_2, L_3, L_4 :	lengths in figures

The maximum bending stress in bone 40 at section 1-1 for the system shown in Figure 3 is found using mechanics of materials analysis to be

$$\sigma_b = \frac{ME_b D_o / 2}{E_b I_b + E_c I_c}$$

This can be compared to the maximum bending stress in the bone without the implant in place

$$\sigma_{bo} = \frac{M D_o / 2}{I_b}$$

It is an objective of the current invention to maximize the ratio σ_b/σ_{b0} by modification of the modulus of elasticity of the composite, E_c .

For comparison, the maximum bending stress in bone 40 at section 1'-1' for the press fit metal system of Figure 4 is

$$\sigma_b' = \frac{ME_b D_o / 2}{E_b I_b + E_m I_m'}$$

and the maximum bending stress in bone 40 at section 1''-1'' for the PMMA grouted system of Figure 5 is

$$\sigma_b'' = \frac{ME_b D_o / 2}{E_b I_b + E_m I_m'' + E_p I_p}$$

By forming the ratios σ_b/σ_b' and σ_b/σ_b'' one can quantify the improvement in load transfer with a composite stem vs. the press fit metal stem and PMMA grouted metal stem. In particular, it is an objective of the current invention that the modulus of the distal composite stem be selected such that these ratios are both greater than 1 signifying that the stress in the bone is greater than that achieved for either the press fit metal stem or the PMMA grouted metal stem. To better define this criteria we consider the following typical values for the parameters defining the mechanical idealizations:

D_o = 25 to 35 (mm) Bone outer diameter

D_i = 12 to 22 (mm) Bone inner diameter and Composite stem and Press fit Metal stem diameter

D_i'' = ($D_i - 4$) (mm) Grouted metal stem diameter

E_b = 1.723×10^7 kPa (2.5 million psi)

E_m = 1.103×10^8 kPa (16 million psi) for Ti-6Al-4V alloy

E_p = 2.275×10^6 kPa (.33 million psi)

The ratio σ_b/σ_b' was computed as a function of composite modulus up to 1.103×10^8 kPa (16 million psi) for each of two bone outer diameters. For all values of E_c less than the modulus of the metal stem, the ratio σ_b/σ_b' is greater than 1; i.e., the bone stress is always higher in the composite implant system than in the press fit metal system if $E_c < E_m$. Thus, the modulus of a low modulus metal, titanium alloy, is one upper limit for the composite modulus of the invention.

The ratio σ_b/σ_b'' was computed as a function of composite modulus up to a value of 1.103×10^8 kPa (16 million psi). It is apparent that for each stem diameter there is a modulus E_1 lower than the modulus of the metal at which the ratio σ_b/σ_b'' becomes equal to one. At values of composite modulus lower than E_1 the ratio σ_b/σ_b'' is greater than 1. This value of modulus, thus, becomes a more preferred upper limit for the modulus of the composite stem. We state this criteria is

$$E_c \leq E_1 \text{ where } \sigma_b/\sigma_b'' = 1 \text{ when } E_c = E_1.$$

Those skilled in the art will recognize that there are other constraints on a hip implant system which may limit the maximum value of σ_b/σ_{b0} which can be attained in practice. The stem must, for example, be stiff enough to resist rotatory motion if proximal bone support is lost as modeled in Figure 6. The distal stem 14 remains well fixed to bone 40 but the proximal region 12 no longer makes intimate contact with bone. Physiologically, this lack of proximal bone support may typify the immediate post operative period prior to tissue ingrowth into proximal porous fixation means or be representative of the state of the implant years after implantation where bone remodeling has caused loss of bone support. In either case the distal stem 14 must have sufficient rigidity to resist rotatory motion caused by moment M. The rotatory stiffness of the structure in Figure 6 is given by:

$$S = \frac{1}{\left[\frac{L_1}{E_b I_b} + \frac{L_2}{E_b I_b + E_c I_c} + \frac{L_3}{E_c I_c} + \frac{L_4}{E_{c2} I_{c2}} \right]}$$

Again, for comparison Figures 7 and 8 present idealized mechanical models for rotatory stiffness for a press-fit all metal system and a PMMA grouted system respectively. The rotatory stiffness for these structures are given respectively as:

$$S' = \frac{1}{\left[\frac{L_1}{E_b I_b} + \frac{L_2}{E_b I_b + E_m I_m'} + \frac{L_3 + L_4}{E_m I_m'} \right]}$$

$$S'' = \frac{1}{\left[\frac{L_1}{E_b I_b} + \frac{L_2}{E_b I_b + E_m I_m'' + E_p I_p} + \frac{L_3 + L_4}{E_m I_m'' + E_p I_p} \right]}$$

It is apparent that the ratio S/S' will always be less than 1 when $E_c < E_m$. However, it is known that grouted metal stems provide adequate rotatory stability; thus, it is another objective of the present invention to have the ratio S/S'' as high as possible and preferably greater than 1; i.e., the rotatory stiffness of the metal-composite system should be preferably at least as stiff as the all-metal system which is grouted in place with PMMA. To better define this criteria we consider the following typical values for the parameters defining the mechanical idealizations:

$D_o = 25$ to 35 (mm) Bone outer diameter

$D_i = 12$ to 22 (mm) Bone inner diameter and Composite stem and Press fit Metal stem diameter

$D_1 = (D_i - 4)$ (mm) Grouted metal stem diameter

$L_1 = 25$ mm

$L_2 = 60$ mm

$L_3 = 50$ mm

$L_4 = 75$ mm

$E_b = 1.723 \times 10^7$ kPa (2.5 million psi)

$E_m = 1.103 \times 10^8$ kPa (16 million psi) for Ti-6Al-4V alloy

$E_p = 2.275 \times 10^8$ kPa (.33 million psi)

The ratio S/S'' was computed as a function of composite modulus up to 1.103×10^8 kPa (16 million psi), the modulus of Ti alloy, for a 25 mm and 35 mm bone outer diameter respectively. For each stem diameter there is a modulus E_2 such that the ratio S/S'' is greater than 1 if E_c is greater than E_2 . We specify this criteria for the preferred lower limit on the modulus E_c as:

$$E_c \geq E_2 \text{ where } S/S'' = 1 \text{ when } E_c = E_2$$

The computed values of E_1 and E_2 were plotted as a function of stem diameter. The most preferred embodiments of the current invention have composite moduli which fall between these two curves at the given stem diameter. It is apparent that all the values in this most preferred range fall in the range 6.895×10^6 to 5.516×10^7 kPa (1 to 8 million psi) so this forms a preferred range for the invention.

It will be apparent to those skilled in the art that more exact mechanical idealizations, e.g., those using three dimensional finite element analysis, can be used to define the most preferred range for composite modulus even more exactly than in the approximate analysis disclosed above.

Ultimately, the fatigue strength of the composite distal stem will further constrain the exact details of the composite construction. Often, strength correlates positively with modulus; strength considerations may impose higher values for the composite modulus than specified in the preferred or most preferred range.

The region between the neck and distal stem, the proximal body, represents the most desirable region for load transfer to bone. Local modulus in this region could be optimized to direct load at the medial (inner) calcar region of the femur to avoid the stress protection and bone remodeling often seen there. In the simplest embodiment of the invention the modulus is made to vary continuously from that prescribed in the neck region to that prescribed in the distal stem region so as to avoid stress concentrations which might otherwise compromise device durability.

An orthopedic implant is disclosed, which is fabricated from composite materials such that the extraosseous portion has an equivalent flexural modulus greater than 5.516×10^7 kPa (8 million psi) and

preferably greater than 16 million psi and the second intraosseous portion has an equivalent flexural modulus of up to 1.103×10^6 kPa (16 million psi), more preferably in the range of 6.895×10^5 to 5.516×10^7 kPa (1 million to 8 million psi). The first intraosseous portion of the component has an equivalent flexural modulus intermediate between them and which preferably varies continuously.

The present orthopedic device may be fabricated by filament winding or braiding in which the modulus variation is accomplished by a continuous variation in the winding or braiding angle. A winding or braiding process which results in a constant angle along the axis is known as a linear winding or braiding process. A process which results in a changing angle along the axis is known as a nonlinear process.

Devices according to this invention may be made by first fabricating a mandrel 20 such as in Figure 2 or as in Figure 9A bent to give an angle beta equal to the stem-neck angle desired in the finished part. This mandrel is fed into a braiding machine (such as manufactured by Mosberg Corporation) which applies bundles of reinforcing filaments at a prescribed orientation by controlling the rate of movement of the mandrel relative to the motion of the bobbins 30 feeding the filament bundles. The mandrel 20 is shown being fed into the braiding machine distal end first. As the mandrel advances such that the filament bundles are applied to the proximal region of the mandrel, the relative motion of the mandrel and bobbins is adjusted to reduce the angle which the filaments make with the mandrel axis, thus producing a higher modulus in this region. The resulting fiber orientation pattern after a single pass through the braiding machine is shown schematically in Figure 9B. The part may pass through the braiding machine several times to apply a number of layers of filaments so as to produce a final part of the correct thickness. Fiber angles in each layer may be different from those in other layers. Furthermore, all layers need not run the full length of the mandrel. This allows variations in part thickness along the length.

The local modulus of the device may be further varied by introducing axially oriented fibers along all or a portion of the length of the device. These axially oriented fibers may comprise a reinforcing fiber which is the same as or different from the angled fibers. A braiding machine is configured to introduce axially oriented filaments among the angled braiding filaments fed from bobbins 30. Figure 10 shows schematically a layer of axial fibers 31 applied by this process in which axially oriented fibers are incorporated in the proximal body 12 of the device, thus, increasing the modulus in only that region.

Filament bundles of varying orientation may also be applied using a filament winding machine instead of a braiding machine. Orientation of the filament bundles typically fed from a package is controlled in this process by the motion of a payout eye, through which filaments pass, relative to the rotation of a chuck which holds the mandrel. By increasing the speed of the payout eye relative to the chuck rotation, the fiber orientation angle is reduced as the proximal body of the mandrel is covered, thus, increasing its modulus relative to that in the distal stem. Note that curvature of a mandrel may be accommodated by moving the payout eye along a second axis normal to the first axis of motion so as to maintain close proximity of the payout eye and mandrel. The complex motion of the payout eye is best controlled by use of a computer. The motion of the filament bundle from a starting point on the mandrel to the end of travel along the mandrel and back to the starting point is called a circuit. One or more circuits is needed to complete a single layer of filaments. Furthermore, multiple layers of filaments may be needed to cover the entire surface of the part. The filament orientation within a layer and the extent of a layer along the mandrel length may vary from layer to layer.

The orthopedic device may hence be made of a plurality of layers composite material comprising filaments within a polymer matrix. These layers are independently arranged about the extraosseous portion and the first and second intraosseous portions. By "independent arrangement" it is meant that each layer may contain any filament type, laid down in any fashion (linear, nonlinear, wound, braided, containing axial windings or angular windings, and the like) and at any density, irrespective of other layers. It is further meant that the various portions of the device may contain different numbers of layers.

It is appreciated that there is an endless set of combinations of numbers of layers of composite with selected orientations of fibers. Without intending to limit the generality of the foregoing, a preferred device is a hip implant wherein the neck and proximal body contain layers of composite material with the filaments of each layer independently disposed at 5-45° from the longitudinal axes of these regions, while the distal stem contains layers of composite material with the filaments of each layer independently disposed at 30-90° from its longitudinal axis. By "independently disposed" it is meant that between layers and within each layer the fibers are laid down in any fashion and are of any type irrespective of other fibers. The neck and proximal body may contain an additional plurality of layers, with the filaments independently disposed at 0-55° from their longitudinal axes.

Alternatively the filament bundles may be applied to the mandrel 20 by use of a robot. In particular, a robotic winding system such as that disclosed in U.S. Patent 4,750,960 incorporated by reference herein is ideal for this application. In this system the mandrel remains stationary and the various degrees of freedom

of the robot allow application of the filament bundles to the mandrel at any orientation. It is apparent that fiber orientation may be easily achieved with this technique. Furthermore, use of a robot facilitates large changes in orientation angle within a given winding circuit. In particular, orientation can be changed such that individual circuits have a typical helical geometry in the distal region of the structure and become axial in the proximal region.

Braiding or winding onto a curved mandrel makes removal of the entire mandrel difficult. It may be desirable to remove all or part of the mandrel to achieve specific mechanical or biocompatibility objectives. A multi part structure may be used to facilitate removal of one section of the mandrel, e.g., the distal section, while another section, e.g., the proximal section is captured in the finished part. For this purpose the mandrel is any number of parts joined so that all or some components can be removed.

In an alternative system filament bundles are wound about the distal stem in the normal helical manner. However, rather than winding around the proximal body of the mandrel they are laid upon a tool or plate configured to support the windings in the exterior shape of the proximal body. After winding the appropriate number of circuits to build up the desired part thickness, the mandrel part together with the plate may be removed leaving the all composite part. The robotic winding system disclosed in U.S. Patent 4,750,960 is especially well suited for creating this type of structure. This structure may itself serve as a captive mandrel for further winding or braiding forming a sheath-core structure. This particular approach is especially useful for forming hip implants with complex outer geometry designed to match the normal anatomy of the intramedullary canal of the femur. In this case the core of the implant can be designed primarily to achieve the structural requirements of the device, including the intended variation in composite modulus along the length, while the sheath can be designed primarily to achieve the complex anatomical shape.

The sheath therefore forms an interior portion shaped substantially as the exterior surface of the core (which can be the distal stem and the proximal body, for example) and an exterior portion shaped substantially as the interior surface of the aperture into which it is inserted.

Those skilled in the art will recognize that the matrix of the composite may be introduced prior to braiding or winding by precoating the reinforcing filaments, during braiding or winding, or after braiding or winding by processes such as resin transfer molding. It is also noted that voids within the part and imperfections in the surface of the part may be corrected by finishing operations such as molding or autoclaving.

In an alternative embodiment according to the invention, a sheath/core structure is formed such that the core of the structure largely achieves the mechanical objectives of the device including the modulus variation and the sheath largely achieves the desired shape of the device.

The composite material may comprise wound filaments embedded in a polymer matrix. The filaments are selected from any of a wide variety of candidates, the criteria of selection being ease of manipulation, and compatibility with the polymer matrix. Preferred filaments include carbon, graphite, glass and aramid fiber. The organic matrix is selected according to its compatibility with both the wound filaments and the tissue and other materials with which it comes into contact. The matrix is preferably selected from polysulfone, polyether-ether-ketone, polyether-ketone-ketone, polyimide, epoxy and polycyanate.

The nature of the variable modulus and methods of making the orthopedic devices of the invention, will be readily understood by having reference to the examples that follow herein.

EXAMPLES

EXAMPLE 1

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A multilayer, circular braid of Kevlar 49® (a registered trademark of E. I. du Pont de Nemours and Company) tow was fabricated on a wire mandrel which was bent to give the curvature typical of the stem-neck angle of a hip implant. Three plies were first applied with a braid angle of 50 to 60° at all points along the length of the device. Four plies of braid with the same angle were then applied to the proximal region to build thickness. Finally, an additional four plies were braided along the entire length of the device such that the distal region of the stem had a braid angle of 50 to 60° while the proximal region had a braid angle of 35°. An epoxy resin was applied to each ply after braiding. The entire part was cured as a unit after all layers were braided.

EXAMPLE 2

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The braid was formed on a wire mandrel bent to the shape typical of the neck-stem geometry of a femoral hip component. Three plies of Kevlar 49® tow were braided along the entire length of the structure

at a 50 to 60° angle with respect to the axis of the structure. Four additional plies of Kevlar 49® were braided in the proximal region of the structure to build up thickness. Two additional full length plies of Kevlar 49® were then applied. Finally, two plies were braided to generate the along-the-length modulus gradient. Specifically, 16 axially oriented graphite yarns ("pass through" yarns) were introduced amongst the 32 braiding yarns forming a triaxial braid in the proximal region of the device. The axial graphite yarns were cut as the braider moved into the distal region of the device, yielding a gradient stiffness structure. The polymer matrix was applied to each ply after braiding. The entire structure was cured after all plies were braided.

10 EXAMPLE 3

A graphite/epoxy prepreg tow (graphite fibers pretreated with epoxy resin) was wound onto a shaped mandrel using a robot and computer controls. Wind angle was varied such that the distal region of the stem had a wind angle from 45 to 55° while the proximal region of the stem had a wind angle of 25 to 35°, thus, introducing a gradient in modulus such that the proximal region was stiffer than the distal region. The parts were cured in an oven at 350°F (177°C) after winding.

EXAMPLE 4

Using a robotic winding system and a winding circuit including primarily nonlinear windings for the distal stem and primarily axial windings for the proximal body, a tow of graphite fiber precoated with a thermoplastic resin was wound into the shape of a hip implant. The thermoplastic coated tow was consolidated during winding by the application of elevated temperature and pressure created by tensioning the tow and by use of a heated shoe which presses the tow against the mandrel of previously wound fibers. Several layers of material were applied in this fashion to achieve the desired part thickness. Layers which included the helical/axial circuit were used as well as layers which were purely helical in geometry but with lower angle in the proximal region of the structure.

EXAMPLE 5

Using a robotic winding system and tooling and winding circuits, the core of sheath/core hip implant structure was wound from graphite tow precoated with a thermoplastic matrix resin. The thermoplastic coated tow was consolidated during winding by the application of elevated temperature and pressure created by tensioning the tow and by use of a heated shoe which presses the tow against the mandrel or previously wound fibers.

After producing the core structure, additional helical windings were applied using the same robotic winding system in a manner which produced an outer shape of complex shape aimed at closely matching the anatomy of the medullary canal of the femur.

40 Claims

1. An orthopaedic device for human implantation comprising:
an extraosseous portion (11);
a first intraosseous portion (12) attached thereto; and
a second intraosseous portion (14) attached to said first intraosseous portion;
the orthopaedic device being made of composite material, wherein the extraosseous portion has a modulus of elasticity greater than the modulus of elasticity of the second intraosseous portion and wherein the modulus of the first intraosseous portion (12) is greater than the modulus of the second intraosseous portion (14) and less than the modulus of the extraosseous portion (11).
2. The orthopaedic device of claim 1 wherein the modulus varies along the length thereof.
3. The orthopaedic device of claim 1 wherein the equivalent flexural modulus of the extraosseous portion (11) is greater than 5.516×10^7 kPa (8 million psi).
4. The orthopaedic device of claim 1 wherein the equivalent flexural modulus of the extraosseous portion (11) is greater than 1.103×10^8 kPa (16 million psi).



at a 50 to 60° angle with respect to the axis of the structure. Four additional plies of Kevlar 49® were braided in the proximal region of the structure to build up thickness. Two additional full length plies of Kevlar 49® were then applied. Finally, two plies were braided to generate the along-the-length modulus gradient. Specifically, 16 axially oriented graphite yarns ("pass through" yarns) were introduced amongst the 32 braiding yarns forming a triaxial braid in the proximal region of the device. The axial graphite yarns were cut as the braider moved into the distal region of the device, yielding a gradient stiffness structure. The polymer matrix was applied to each ply after braiding. The entire structure was cured after all plies were braided.

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Using a robotic winding system and tooling and winding circuits, the core of sheath/core hip implant structure was wound from graphite tow precoated with a thermoplastic matrix resin. The thermoplastic coated tow was consolidated during winding by the application of elevated temperature and pressure created by tensioning the tow and by use of a heated shoe which presses the tow against the mandrel or previously wound fibers.

After producing the core structure, additional helical windings were applied using the same robotic winding system in a manner which produced an outer shape of complex shape aimed at closely matching the anatomy of the medullary canal of the femur.

40 Claims

1. An orthopaedic device for human implantation comprising:
 - an extraosseous portion (11);
 - a first intraosseous portion (12) attached thereto; and
 - a second intraosseous portion (14) attached to said first intraosseous portion;the orthopaedic device being made of composite material, wherein the extraosseous portion has a modulus of elasticity greater than the modulus of elasticity of the second intraosseous portion and wherein the modulus of the first intraosseous portion (12) is greater than the modulus of the second intraosseous portion (14) and less than the modulus of the extraosseous portion (11).
2. The orthopaedic device of claim 1 wherein the modulus varies along the length thereof.
3. The orthopaedic device of claim 1 wherein the equivalent flexural modulus of the extraosseous portion (11) is greater than 5.516×10^7 kPa (8 million psi).
4. The orthopaedic device of claim 1 wherein the equivalent flexural modulus of the extraosseous portion (11) is greater than 1.103×10^8 kPa (16 million psi).



5. The orthopaedic device of claim 1 wherein the equivalent flexural modulus of the second intraosseous (14) portion is up to 1.103×10^8 kPa (16 million psi).
6. The orthopaedic device of claim 1 wherein the equivalent flexural modulus of the second intraosseous portion (14) is 6.895×10^6 to 5.516×10^7 kPa (1 million to 8 million psi).
7. The orthopaedic device of claim 1 which is load bearing wherein:
the orthopaedic device made of composite material comprises a plurality of filaments disposed within a polymer matrix.
8. The orthopaedic device of claim 7 wherein said filaments are nonlinearly disposed about the longitudinal axes of the extraosseous portion (11) and first and second intraosseous portions (12, 14).
9. The orthopaedic device of claim 8 wherein said filaments are disposed in a helical pattern.
10. The orthopaedic device of claim 8 wherein said filaments are disposed in a braided pattern.
11. The orthopaedic device of claim 9 or 10 wherein filaments are further oriented axially along the longitudinal axes of the extraosseous portion (11) and the first intraosseous portion (12).
12. The orthopaedic device of claim 1 which is made of a plurality of layers of composite material, said composite material comprising a plurality of filaments disposed with a polymer matrix and said layers being independently arranged about the extraosseous portion (11) and the first and second intraosseous portions (12, 14).
13. The orthopaedic device of claim 12 wherein said filaments of each layer are independently nonlinearly disposed about the longitudinal axes of the extraosseous portion (11) and the first and second intraosseous portions (12, 14).
14. The orthopaedic device of claim 13 wherein said filaments are disposed within the polymer matrix in a helical pattern or in a braided pattern.
15. The orthopaedic device of claim 13 wherein said filaments further include tows oriented axially about the longitudinal axes of the extraosseous portion (11) and the first intraosseous portion (12).
16. The orthopaedic device of claim 12 useful as a human hip implant wherein said extraosseous portion is a neck (11) adapted to engage a ball (16) which rotatably engages a cup attached to the pelvis, said first intraosseous portion is a proximal body (12), and said second intraosseous portion is a distal stem (14), the proximal body and the distal stem being received within the femoral canal.
17. The orthopaedic device of claim 16 wherein the neck (11) and proximal body (12) are comprised of a plurality of layers of said composite material wherein said filaments of each layer are independently disposed at an angle of $5-45^\circ$ from the longitudinal axes thereof, and the distal stem (14) is comprised of a plurality of layers of said composite material wherein said filaments of each layer are independently disposed at an angle of $30-90^\circ$ from the longitudinal axis thereof.
18. The orthopaedic device of claim 17 wherein the neck (11) and proximal body (12) additionally comprise a plurality of layers of said composite material wherein said filaments of each layer are independently disposed at an angle of $0-5^\circ$ from the longitudinal axes thereof.
19. The orthopaedic device of claim 17 wherein the distal stem (14), the proximal body (12) or both comprise a core and a sheath, said core comprising the device according to claim 17, said sheath comprising a plurality of filaments disposed to form an interior portion shaped substantially as the exterior surface of the core and an exterior portion shaped substantially as the interior surface of the aperture within the femoral canal formed to accommodate the device.
20. The orthopaedic device of claim 1 wherein the orthopaedic device made of composite material comprises a plurality of filaments disposed within a polymer matrix, and said second intraosseous



portion (14) having an equivalent flexural modulus, E, selected according to the criteria

$$E_c \leq E_1 \text{ where } \sigma_b/\sigma_b'' = 1 \text{ when } E_c = E_1,$$

5 and

$$E_c \geq E_2 \text{ where } S/S'' = 1 \text{ when } E_c = E_2,$$

10 wherein E_c is the modulus of elasticity of the second intraosseous portion; σ_b is the maximum bending stress in the bone adjacent to the implanted device at the second intraosseous portion; σ_b'' is the maximum bending stress in the bone adjacent to an implanted orthopaedic device fabricated entirely from metal and affixed in place by polymethylmethacrylate bone cement; S is the rotatory stiffness of the implanted device made of said composite material; S'' is the rotatory stiffness of an implanted metal device affixed with bone cement; E_1 is a modulus lower than the modulus of the metal at which the ratio σ_b/σ_b'' becomes equal to one and E_2 is a modulus such that the ratio S/S'' is greater than 1 if E_c is greater than E_2 .

21. The orthopaedic device of any one of the preceding claims wherein the filaments are selected from carbon, graphite, glass and aramid fibre.

22. The orthopaedic device of any one of the preceding claims wherein the polymer matrix is selected from polysulphone, polyether-ether-ketone, polyether-ketone-ketone, polyimide, epoxy and polycyanate.

23. A process for the preparation of an orthopaedic device according to claim 1, comprising:

25 shaping a mandrel (20) in the configuration of a device comprising an extraosseous portion (11), a first intraosseous portion (12) attached thereto, and a second intraosseous portion (14) attached to said first intraosseous portion, the modulus of elasticity of the first intraosseous portion being greater than that of the second intraosseous portion and less than that of the extraosseous portion;

30 winding or braiding filaments around the mandrel and applying a polymer matrix thereto to form a layer thereon;

optionally disposing additional layers independently about the extraosseous portion and the first and second intraosseous portions (12, 14); and optionally removing said mandrel (20).

24. The process of claim 23 wherein the mandrel (20) comprises a plurality of parts joined together such that the mandrel or a portion thereof may be removed.

25. The process of claim 23 wherein the polymer matrix is applied to the filaments (31) as a precoating before winding or braiding said filaments around the mandrel (20).

40 26. The process of claim 23 wherein the polymer matrix is applied to the filaments (31) after winding or braiding said filaments around the mandrel (20).

Patentansprüche

45 1. Orthopädische Vorrichtung zur Implantation in den Menschen, umfassend:
einen extraossalen Teil (11);

einen ersten, daran befestigten intraossalen Teil (12) und einen zweiten intraossalen Teil (14), der am ersten intraossalen Teil befestigt ist;

50 wobei die orthopädische Vorrichtung aus Verbundmaterial hergestellt ist, worin der extraossale Teil einen Elastizitätsmodul aufweist, der größer als der Elastizitätsmodul des zweiten intraossalen Teils ist, und worin der Modul des ersten intraossalen Teils (12) größer als der Modul des zweiten intraossalen Teils (14) und kleiner als der Modul des extraossalen Teils (11) ist.

2. Orthopädische Vorrichtung nach Anspruch 1, worin der Modul sich mit seiner Länge verändert.

55 3. Orthopädische Vorrichtung nach Anspruch 1, worin der Äquivalenz-Elastizitätsmodul des extraossalen Teils (11) größer als $5,516 \times 10^7$ kPa (8 Millionen psi) ist.



4. Orthopädische Vorrichtung nach Anspruch 1, worin der Äquivalenz-Elastizitätsmodul des extraossalen Teils (11) größer als $1,103 \times 10^8$ kPa (16 Millionen psi) ist.
- 5 5. Orthopädische Vorrichtung nach Anspruch 1, worin der Äquivalenz-Elastizitätsmodul des zweiten intraossalen Teils (14) größer als $1,103 \times 10^8$ kPa (16 Millionen psi) ist.
6. Orthopädische Vorrichtung nach Anspruch 1, worin der Äquivalenz-Elastizitätsmodul des zweiten intraossalen Teils (14) $6,895 \times 10^6$ bis $5,516 \times 10^7$ kPa (1 Million bis 8 Millionen psi) beträgt.
- 10 7. Orthopädische Vorrichtung nach Anspruch 1, die tragend ist, worin:
die aus Verbundmaterial hergestellte orthopädische Vorrichtung eine Vielzahl von Filamenten umfaßt, die in einer Polymermatrix angeordnet sind.
- 15 8. Orthopädische Vorrichtung nach Anspruch 7, worin die Filamente nichtlinear entlang der Längsachsen des extraossalen Teils (11) und des ersten und des zweiten intraossalen Teils (12, 14) ausgerichtet sind.
- 20 9. Orthopädische Vorrichtung nach Anspruch 8, worin die Filamente in einem spiralförmigen Muster angeordnet sind.
- 25 10. Orthopädische Vorrichtung nach Anspruch 8, worin die Filamente in einem Flechtmuster angeordnet sind.
- 30 11. Orthopädische Vorrichtung nach Anspruch 9 oder 10, worin Filamente weiterhin axial entlang der Längsachsen des extraossalen Teils (11) und des ersten intraossalen Teils (12) orientiert sind.
- 35 12. Orthopädische Vorrichtung nach Anspruch 1, die aus einer Vielzahl von Schichten aus Verbundmaterial hergestellt ist, wobei das Verbundmaterial eine Vielzahl von Filamenten umfaßt, die in einer Polymermatrix angeordnet sind und wobei die Schichten unabhängig im extraossalen Teil (11) und im ersten und zweiten intraossalen Teil (12, 14) angeordnet sind.
- 40 13. Orthopädische Vorrichtung nach Anspruch 12, worin die Filamente jeder Schicht unabhängig nichtlinear entlang der Längsachsen des extraossalen Teils (11) und des ersten und zweiten intraossalen Teils (12, 14) ausgerichtet sind.
- 45 14. Orthopädische Vorrichtung nach Anspruch 13, worin die Filamente in der Polymermatrix in einem Spiralmuster oder in einem Flechtmuster angeordnet sind.
- 50 15. Orthopädische Vorrichtung nach Anspruch 13, worin die Filamente weiterhin Spinnkabel umfassen, die axial entlang der Längsachsen des extraossalen Teils (11) und des ersten intraossalen Teils (12) orientiert sind.
- 55 16. Orthopädische Vorrichtung nach Anspruch 12, die als ein Hüftimplantat bei Menschen nützlich ist, worin der extraossale Teil ein Hals (11) ist, der zum Einsetzen einer Kugel (16) angepaßt ist, die drehbar in einer am Becken befestigte Schale einrastet, wobei der erste intraossale Teil ein proximaler Körper (12) ist, und wobei der zweite intraossale Teil ein distaler Stiel (14) ist, wobei der proximale Körper und der distale Stiel im Femoralkanal aufgenommen werden.
17. Orthopädische Vorrichtung nach Anspruch 16, worin der Hals (11) und der proximale Körper (12) eine Vielzahl von Schichten aus dem Verbundmaterial umfassen, worin die Filamente aus jeder Schicht unabhängig mit einem Winkel von 5 bis 45° von deren Längsachse angeordnet sind, und wobei der distale Stiel (14) eine Vielzahl von Schichten aus dem Verbundmaterial umfaßt, worin die Filamente jeder Schicht unabhängig mit einem Winkel von 30 bis 90° von deren Längsachse angeordnet sind.
18. Orthopädische Vorrichtung nach Anspruch 17, worin der Hals (11) und der proximale Körper (12) zusätzlich eine Vielzahl von Schichten aus dem Verbundmaterial umfassen, worin die Filamente jeder Schicht unabhängig mit einem Winkel von 0 bis 5° von deren Längsachse angeordnet sind.



19. Orthopädische Vorrichtung nach Anspruch 17, worin der distale Stiel (14), der proximale Körper (12) oder beide einen Kern und eine Hülle umfassen, wobei der Kern die Vorrichtung nach Anspruch 17 umfaßt, die Hülle eine Vielzahl von Filamenten umfaßt, die so angeordnet sind, daß sie einen Innenteil bilden, der im wesentlichen als die Außenoberfläche des Kerns ausgebildet ist, und einen Außenteil, der im wesentlichen als die Innenoberfläche der Öffnung im Femoralkanal ausgebildet ist, die zum Aufnehmen der Vorrichtung ausgebildet ist.
20. Orthopädische Vorrichtung nach Anspruch 1, worin die aus Verbundmaterial hergestellte orthopädische Vorrichtung eine Vielzahl von Filamenten umfaßt, die in der Polymermatrix angeordnet sind, und wobei der zweite intraossale Teil (14) einen Äquivalenz-Elastizitätsmodul E aufweist, der nach den Kriterien

$$E_c \leq E_1, \text{ wobei } \sigma_b/\sigma_b'' = 1, \text{ wenn } E_c = E_1,$$

und

$$E_c \geq E_2, \text{ wobei } S/S'' = 1, \text{ wenn } E_c = E_2,$$

wobei E_c der Elastizitätsmodul des zweiten intraossalen Teils ist; σ_b die maximale Biegebeanspruchung im neben der implantierten Vorrichtung am zweiten intraossalen Teil liegenden Knochen ist; σ_b'' die maximale Biegebeanspruchung im Knochen ist, der sich neben einer vollständig aus Metall hergestellten und durch Polymethylmethacrylat-Knochenzement an Ort und Stelle befestigten implantierten orthopädischen Vorrichtung befindet; S die Drehbiegesteifheit der aus dem Verbundmaterial hergestellten implantierten Vorrichtung ist; S'' die Drehbiegesteifheit einer mit Knochenzement befestigten implantierten Metallvorrichtung ist; E_1 ein Modul ist, der geringer als der Modul des Metalls ist, bei dem das Verhältnis σ_b/σ_b'' gleich eins wird und E_2 ein Modul ist, so daß das Verhältnis S/S'' größer als 1 ist, falls E_c größer als E_2 ist.

21. Orthopädische Vorrichtung nach einem der vorhergehenden Ansprüche, worin die Filamente aus Kohlenstoff, Graphit, Glas und Aramid-Faser ausgewählt sind.
22. Orthopädische Vorrichtung nach einem der vorhergehenden Ansprüche, wobei die Polymermatrix aus Polysulfon, Polyether-Ether-Keton, Polyether-Keton-Keton, Polyimid, Epoxy und Polycyanat ausgewählt ist.
23. Verfahren zur Herstellung einer orthopädischen Vorrichtung nach Anspruch 1, umfassend: das Formen eines Formkerns (20) in der Konfiguration einer Vorrichtung, umfassend einen extraossalen Teil (11), einen daran befestigten ersten intraossalen Teil (12) und einen am ersten intraossalen Teil befestigten zweiten intraossalen Teil (14), wobei der Elastizitätsmodul des ersten intraossalen Teils größer als der des zweiten intraossalen Teils ist und kleiner als der des extraossalen Teils ist; das Wickeln oder Flechten von Filamenten um den Formkern und das Auftragen einer Polymermatrix darauf, so daß eine Schicht darauf gebildet wird; gegebenenfalls das unabhängige Abscheiden zusätzlicher Schichten um den extraossalen Teil und um den ersten und zweiten intraossalen Teil (12, 14); und gegebenenfalls das Entfernen des Formkerns (20).
24. Verfahren nach Anspruch 23, worin der Formkern (20) eine Vielzahl von miteinander verbundenen Teilen umfaßt, so daß der Formkern oder ein Teil davon entfernt werden können.
25. Verfahren nach Anspruch 23, worin die Polymermatrix als eine Vorbeschichtung vor dem Wickeln oder Flechten der Filamente um den Formkern (20) auf die Filamente (31) aufgetragen wird.
26. Verfahren nach Anspruch 23, worin die Polymermatrix nach dem Wickeln oder Flechten der Filamente um den Formkern (20) auf die Filamente (31) aufgetragen wird.

55 Revendications

1. Un dispositif orthopédique pour implantation humaine comprenant :
une partie extraosseuse (11) ;



une première partie intraosseuse (12) qui en est solidaire; et
une deuxième partie intraosseuse (14) solidaire de ladite première partie intraosseuse ;
le dispositif orthopédique étant constitué d'un matériau composite, la partie extraosseuse ayant un
module d'élasticité supérieur au module d'élasticité de la deuxième partie intraosseuse et le module de
la première partie intraosseuse (12) étant supérieur au module de la deuxième partie intraosseuse (14)
et inférieur au module de la partie extraosseuse (11).

2. Le dispositif orthopédique de la revendication 1 dans lequel le module varie le long du dispositif.
- 10 3. Le dispositif orthopédique de la revendication 1 dans lequel le module de flexion équivalent de la partie extraosseuse (11) est supérieur à $5,516 \times 10^7$ kPa.
4. Le dispositif orthopédique de la revendication 1 dans lequel le module de flexion équivalent de la partie extraosseuse (11) est supérieur à $1,103 \times 10^8$ kPa.
- 15 5. Le dispositif orthopédique de la revendication 1 dans lequel le module de flexion équivalent de la deuxième partie intraosseuse (14) peut aller jusqu'à $1,103 \times 10^8$ kPa.
- 20 6. Le dispositif orthopédique de la revendication 1 dans lequel le module de flexion équivalent de la deuxième partie intraosseuse (14) est de $6,895 \times 10^6$ à $5,516 \times 10^7$ kPa.
7. Le dispositif orthopédique de la revendication 1 qui supporte une charge, dans lequel :
le dispositif orthopédique en matériau composite comprend une pluralité de filaments disposés au sein d'une matrice de polymère.
- 25 8. Le dispositif orthopédique de la revendication 7 dans lequel lesdits filaments sont disposés non linéairement autour des axes longitudinaux de la partie extraosseuse (11) et des première et deuxième parties intraosseuses (12, 14).
- 30 9. Le dispositif orthopédique de la revendication 8 dans lequel lesdits filaments sont disposés selon une configuration en hélice.
10. Le dispositif orthopédique de la revendication 8 dans lequel lesdits filaments sont disposés selon une configuration en tresse.
- 35 11. Le dispositif orthopédique de la revendication 9 ou 10 dans lequel les filaments sont en outre orientés axialement le long des axes longitudinaux de la partie extraosseuse (11) et de la première partie intraosseuse (12).
- 40 12. Le dispositif orthopédique de la revendication 1 qui est constitué d'une pluralité de couches de matériau composite, ledit matériau composite comprenant une pluralité de filaments disposés au sein d'une matrice de polymère et lesdites couches étant disposées de manière indépendante dans la partie extraosseuse (11) et les première et deuxième parties intraosseuses (12, 14).
- 45 13. Le dispositif orthopédique de la revendication 12 dans lequel lesdits filaments de chaque couche sont indépendamment disposés de manière non linéaire autour des axes longitudinaux de la partie extraosseuse (11) et des première et deuxième parties intraosseuses (12, 14).
- 50 14. Le dispositif orthopédique de la revendication 13 dans lequel lesdits filaments sont disposés au sein de la matrice de polymère selon une configuration en hélice ou selon une configuration en tresse.
15. Le dispositif orthopédique de la revendication 13 dans lequel lesdits filaments incluent en outre des câbles orientés axialement autour des axes longitudinaux de la partie extraosseuse (11) et de la première partie intraosseuse (12).
- 55 16. Le dispositif orthopédique de la revendication 12 utile comme implant de hanche humaine dans lequel ladite partie extraosseuse est un col (11) adapté à coopérer avec une boule (16) qui est reçue à rotation dans une cuvette solidarifiée au bassin, ladite première partie intraosseuse est un corps



proximal (12) et ladite deuxième partie intraosseuse est une tige distale (14), le corps proximal et la tige distale étant reçus dans le canal fémoral.

- 5 17. Le dispositif orthopédique de la revendication 16 dans lequel le col (11) et le corps proximal (12) sont constitués d'une pluralité de couches dudit matériau composite où lesdits filaments de chaque couche sont indépendamment inclinés d'un angle de 5 à 45 degrés par rapport à leurs axes longitudinaux, et la tige distale (14) est constituée d'une pluralité de couches dudit matériau composite où lesdits filaments de chaque couche sont indépendamment inclinés d'un angle de 30 à 90 degrés par rapport à son axe longitudinal.
- 10 18. Le dispositif orthopédique de la revendication 17 dans lequel le col (11) et le corps proximal (12) comprennent en outre une pluralité de couches dudit matériau composite où lesdits filaments de chaque couche sont indépendamment inclinés d'un angle de 0 à 5 degrés par rapport à leurs axes longitudinaux.
- 15 19. Le dispositif orthopédique de la revendication 17 dans lequel la tige distale (14) et/ou le corps proximal (12) comprennent une âme et une gaine, ladite âme comprenant le dispositif de la revendication 17, ladite gaine comprenant une pluralité de filaments disposés de manière à former une partie intérieure de forme sensiblement identique à la surface extérieure de l'âme et une partie extérieure de forme sensiblement identique à la surface intérieure de l'ouverture formée dans le canal fémoral pour recevoir le dispositif.
- 20 20. Le dispositif orthopédique de la revendication 1 dans lequel le dispositif orthopédique en matériau composite comprend une pluralité de filaments disposés au sein d'une matrice de polymère, et ladite deuxième partie intraosseuse (14) présente un module de flexion équivalent E choisi selon les critères
- 25

$$E_c \leq E_1 \text{ pour } \sigma_b/\sigma_b'' = 1 \text{ quand } E_c = E_1,$$

et

$$E_c \geq E_2 \text{ pour } S/S'' = 1 \text{ quand } E_c = E_2,$$

où E_c est le module d'élasticité de la deuxième partie intraosseuse ; σ_b est la contrainte de flexion maximum dans l'os adjacent au dispositif implanté, au niveau de la deuxième partie intraosseuse ; σ_b'' est la contrainte de flexion maximum dans l'os adjacent à un dispositif de prothèse implanté entièrement constitué de métal et fixé en place par un ciment pour os de poly(méthacrylate de méthyle) ; S est la rigidité de rotation du dispositif implanté constitué dudit matériau composite ; S'' est la rigidité de rotation d'un dispositif implanté en métal attaché avec du ciment pour os ; E_1 est un module inférieur au module du métal pour lequel le rapport σ_b/σ_b'' devient égal à 1 et E_2 est un module tel que le rapport S/S'' soit supérieur à 1 si E_c est supérieur à E_2 .

35 40

21. Le dispositif orthopédique de l'une quelconque des revendications précédentes dans lequel les filaments sont choisis parmi les fibres de carbone, de graphite de verre et d'aramide.
- 45 22. Le dispositif orthopédique de l'une quelconque des revendications précédentes dans lequel la matrice de polymère est choisie parmi les polysulfones, les poly(éther-éther-cétones), les poly(éther-cétone-cétones), les polyimides, les époxy et les polycyanates.
- 50 23. Un procédé pour la réalisation d'un dispositif orthopédique selon la revendication 1, comprenant les opérations consistant :
- 55 à façonner un mandrin (20) à la configuration d'un dispositif comprenant une partie extraosseuse (11), une première partie intraosseuse (12) solidaire de la précédente et une deuxième partie intraosseuse (14) solidaire de ladite première partie intraosseuse, le module d'élasticité de la première partie intraosseuse étant supérieur à celui de la deuxième partie intraosseuse et inférieur à celui de la partie extraosseuse ;
- à enrouler ou à tresser des filaments autour du mandrin et à y appliquer une matrice de polymère pour former une couche dessus ;
- facultativement, à disposer des couches additionnelles indépendamment autour de la partie



extraosseuse et des première et deuxième parties intraosseuses (12, 14) ; et, facultativement, à enlever ledit mandrin (20).

- 5 24. Le procédé de la revendication 23 dans lequel le mandrin (20) comprend une pluralité de pièces réunies entre elles de manière à permettre de retirer le mandrin ou une partie de celui-ci.
- 10 25. Le procédé de la revendication 23 dans lequel la matrice de polymère est appliquée aux filaments (31) sous la forme d'un prérevêtement avant enroulement ou tressage desdits filaments autour du mandrin (20).
26. Le procédé de la revendication 23 dans lequel la matrice de polymère est appliquée aux filaments (31) après enroulement ou tressage desdits filaments autour du mandrin (20).

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