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(54) **Synthetic threaded vertebral implant**

(57) This invention provides a synthetic threaded vertebral implant (10, 80, 100) for treatment of spinal deformities. The implant can be formed of variety of materials including synthetic organic materials, composites, and ceramics. The threaded implant can restore and maintain a desired disc space height. In one embodiment, the threaded implant (10, 80, 100) has an elongate cylindrical body (12) with an external thread (26). Implant (10) terminates in a proximal end (16) and an opposite distal end (18). One or both of ends (16, 18) can include chamfer surfaces (20 and 22).

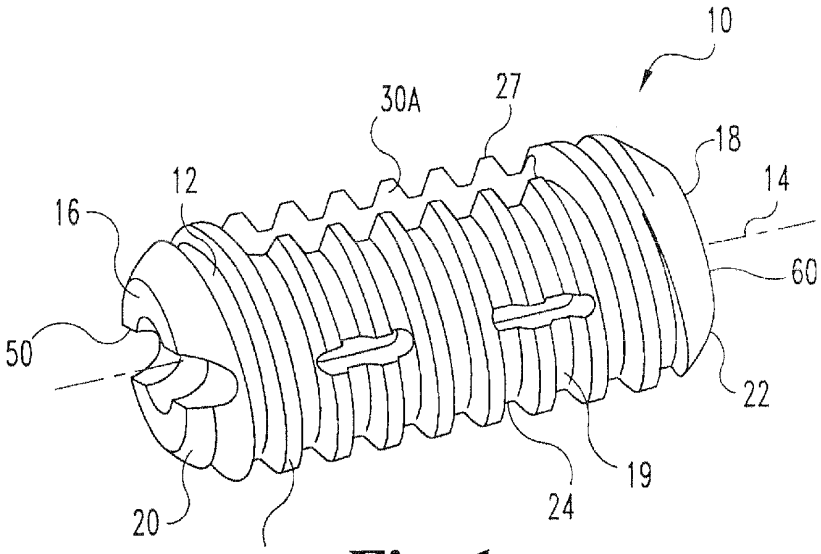

Fig. 1

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Description

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application claims the benefit of German Utility Model Application No. 200 04 692.6 filed on March 14, 2000, which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] In general this invention relates to a synthetic vertebral implant and methods of manufacturing and using the implant. More specifically but not exclusively, this invention is directed to a synthetic, threaded vertebral implant suitable for restoring and or maintaining desired disc space height.

BACKGROUND OF THE INVENTION

[0003] For degenerated, diseased or otherwise damaged spinal columns and vertebrae, it is known to treat these defects by removal of all or a portion of the vertebral disk and inserting an implant such as a spinal spacer into the disc space to restore normal disk height and spine orientation, and repair the spinal defects. When desired, osteogenic material also can be implanted into the intervertebral space to promote arthrodesis, or spinal fusion between the two vertebrae adjacent to the intervertebral space. Selected spacers are formed to provide a cavity for receipt of the osteogenic material.

[0004] The spinal column can exert tremendous force on the individual vertebrae, and consequently also on any implant implanted in between the vertebrae. Spinal implants typically are formed of a metal such as titanium or surgical steel. While the selection of the implant configuration and composition can depend upon a variety of considerations, for arthrodesis it is often desirable to select a material that does not stress shield the bone ingrowth. Titanium and surgical steel provide the requisite strength to maintain correct disk space height and orientation; however, these materials have been shown to stress shield the bone. Bone and bone derived material can provide an acceptable material having the similar strength and compressibility as living bone tissue. However, suitable donor bone is scarce. Further, extensive screening and sterilization must be strictly observed to minimize the risk of transmission of infections, either real or perceived, from the donor to the recipient.

[0005] The following patents are representative of the current state of the art for the relevant technology.

[0006] In United States patent 5,669,909 issued to Zdeblick et al. disclosed an interbody fusion device for threaded insertion into the intervertebral space. The device has a generally elongate, conical body defining a series of interrupted external threads The elongate body has two truncated or flattened sidewalls diametrically opposed to each other. The truncated sidewalls are touted to facilitate insertion of the implant into the intervertebral space. The body encloses a cavity for receipt of bony material. The device is inserted into the disk space so the opposing truncated sidewalls bear against the endplate of adjacent vertebrae. Once inserted, the device is turned 90° to engage the interrupted threads with the bone tissue of the endplates.

[0007] Brosnahan in U.S. Patent 5,766,253 discloses a solid spinal fusion device having a threaded exterior. The device includes two indentions on its outer surface for bone attachment material. This reference mentions that the fusion device can be formed of a biocompatable osteoconductive material such as bioactive hydroxyapatite-polymer composites, preferably a hydroxyapatite reinforced polyethylene composite.

[0008] Bagby in U.S. Patent No. 6,010,502 discloses a metallic cylindrical base body having a helically configured spline or thread configured on its outer surface. The body can have a hollow interior. Large and small circular fenestrations extend from the surface into the hollow interior. The metallic body can be fitted with a plastic cap to protect the spinal cord from abrading against the end of the metallic body.

[0009] There remains a continuing need for advancements in the relevant field, including treatment of damaged or diseased spinal columns, improved implants, selection of suitable materials from which the implants are formed and methods of enhancing the bone fusion between adjacent vertebrae. The present invention is such an advancement and provides a wide variety of benefits and advantages.

DISCLOSURE OF INVENTION

[0010] The present invention relates to spinal implants, the manufacture and use thereof to treat degenerated, diseased or otherwise damaged spinal columns. Various aspects of the invention are novel, nonobvious, and provide various advantages. While the actual nature of the invention covered herein can only be determined with reference to the claims appended hereto, certain forms and features, which are characteristic of the preferred embodiments disclosed herein, are described briefly as follows.

[0011] The invention provides a vertebral implant capable of being threaded into an intervertebral space and which is stable with respect to the expected biomechanical forces. In one embodiment, the implant or intervertebral spacer can be integrated into the bony tissue. In alternative embodiments the implant or spacer is biodegradable. The implants according to this invention can be manufactured at low cost.

[0012] The vertebral implant to be screwed into an intervertebral space according to one aspect of this invention and comprises a hollow cylindrical base body arranged to receive bone material and provided with an external thread so that the base body can be threadedly implanted by engaging the two vertebrae defining the

intervertebral space or disc space. The vertebral implant further comprises two holes preferably located diametrically opposing each other and extending across several thread ribs in the longitudinal direction of the base body so as to interrupt the course of the thread ribs. The holes are preferably elongated. Although it will be understood, that the holes can be provided in a wide variety of configurations. The holes allow a bone bridge to form between the two vertebrae and through the implanted base body. The two circumferential wall portions of the base body disposed between the holes are each provided with at least one longitudinal through-slit extending in the longitudinal direction of the base body and interrupting, at least partially, the course of the thread ribs. Each longitudinal slit is narrower and shorter than the elongated holes, and is designed to enable tissue lateral of the implanted base body to grow sideways into the interior of the base body. The vertebral implant is preferably made of a synthetic material, for example, a polymeric material, a composite, a ceramic or a reinforced material.

[0013] To insert the vertebral implant into an intervertebral space according one embodiment of this invention, the implant is screwed or threaded into the intervertebral space. Thus, unlike an implant that has to be pushed, driven or impacted, the risk of the implant being suddenly displaced to an unintended position is minimized. Rather the implant can be gradually rotated and screwed axially forward into the intervertebral space and, thus, positioned accurately in the intervertebral space without any hazard. To this end, the thread of the vertebral implant preferably has a small lead angle, advantageously less than about 10°, more preferably between about 2° and about 8°. Owing to its simple integral design, the implant has a smooth, tapering--albeit threaded profile, i.e. lacking any projections, so there is hardly any risk of hurting surrounding tissue when the implant is being screwed into the intervertebral space. This integral, compact and still sufficiently stable construction of the implant further allows it to be made of a synthetic material, for example, a reinforced material, a polymeric materiel, a composite or a ceramic. These materials are preferred for a variety of advantageous benefits including low cost, long durability, strength and good biocompatability.

[0014] In its implanted state, the implant is positioned in the intervertebral space such that the two elongated holes face the respective vertebrae so that a bone bridge can build up between these vertebrae through the elongated holes and the vertebral implant, i.e., spinal fusion of the adjacent vertebrae.

[0015] Lateral portions of the circumferential wall are reinforced by thread ribs. The vertebral implant constitutes a sufficiently stable support to receive the biomechanical forces occurring between the two vertebrae until the complete bone bridge has formed. As the elongated holes and slits are formed directly in (or through) the thread, the circumference for the base body is provided with thread ribs over a maximum surface of its outer periphery, thus strengthening the circumferential walls of the implant.

[0016] This design increases the stability of the implant. At the same time, this design enables the vertebral implant to be fixed in a reliable manner because the growing bone tissue intimately engages the thread ribs, which are interrupted completely by the elongated holes and at least partially by the longitudinal slits. Moreover, the number of manufacturing steps is also reduced. The slits arranged in the two circumferential wall portions between the elongated holes form a sufficiently large passage for vascular tissue lateral of the implanted implant to grow into the implant, thus improving the nutritional supply of the bone material accommodated in the implant. At the same time, however, the slits are sufficiently small not to jeopardize the stability of the implant. In addition, this enabled lateral nutritional supply stimulates the bone tissue in the implant to also grow from inside into the lateral slits thus further improving the fit of the implant.

[0017] The reinforced implant can include a wide variety of reinforcing materials included fibers, platelets, and/or particulate elements. The fiber-reinforced implant material may be embodied by glass fibers, ceramic fibers or carbon fibers. Preferably, the implant material comprises long carbon fibers, in particular endless carbon fibers, allowing a predetermined high strength to be achieved at low manufacturing cost.

[0018] The implant can also be formed of a polymeric material, for example, polyanhydrides; polyamides, poly (amino acids), polycaprolactones, polylactate, poly(lactide-co-glycolide); polyorthoesters; acrylics; polycarbonates; polyesters; polyethers, poly(ether ketone); poly (ether, ether ketone) (PEEK); poly(aryl ether ketones) (PAEK; poly(ether ether ketone ether ketone) (PEEKEK); poly(ethylene terephthalate) (PET), poly(acrylate) poly (methyl (meth)acrylate), polyolefins, polysulfones, polyurethane; poly(vinyl chloride), epoxy resins, carbon reinforced composites, glass reinforced composite, ceramic reinforced composites, and mixtures thereof. Alternatively the implant can be formed of a ceramic, for example, a material selected from the group of: hydroxylapatite; alumina, zirconia and mixtures thereof.

[0019] Each longitudinal through-slit preferably extends across at least one rib of the thread. The bone material can grow sideways through the longitudinal through-slit and through a complete gap of the course of the thread rib of the implant. This inhibits axial rotation of the implant. The inhibition of axial rotation of the implant is even enhanced with respect to a situation where bone material can primarily grow sideways around the outside parameter of the implant between two adjacent thread ribs.

[0020] The base body may be circular or slightly conical or may have at least one conical end portion. Preferably, the overall shape of the base body is cylindrical; this can allow it to be manufactured even more easily and at lower costs. A separating force (or distraction) can be exerted on the vertebrae; this can be achieved by distraction during surgery using distractors. Additionally

the implant itself can provide distraction by selecting a base body having a diameter greater than the existing disc space height between the adjacent vertebrae. The selected implant can be threaded into the disc space. The threads of the implant engage in the opposing surfaces of the vertebrae, and pulling the implant into the disc space and consequently distracting the disc space as the implant becomes fully seated or positioned at a desired position within the disc space.

[0021] In other embodiments the base body can define a lordotic profile. In this configuration the circumferential wall portions are shaped to provide a spacer that conforms to the desired lordosis or natural curvature of the spine. In one form the circumferencetial wall portions are formed as conical wall portions while still retaining an exterior thread.

[0022] The longitudinal openings or slits can be arranged at any place in the circumferential wall portions, it is preferred that the longitudinal openings or slits oppose each other diametrically. It will be understood that one, two, three or more pairs of longitudinal openings can be provided in the circumferential wall portions of the implant. This arrangement allows the vascular tissue lateral of the implanted implant to communicate with the osteogenic material deposited in the implant so that the nutritional supply of the bone material is greater and more homogeneous. The blood supply, and thus, the supply of nutrition to the bone tissue growing through the implant are further improved enabling the implant to be integrally incorporated in the growing bone tissue.

[0023] It is further preferred that at least one longitudinal slit is disposed in the circumferential wall at an angular distance of about 90° from the respective elongated hole, as seen in the circumferential direction of the base body. This design allows the vascular tissue a more direct path into the implant. An additional advantage resides in that the bone tissue can grow orthogonally through the implant resulting in a particularly stable crosswise anchoring of the implant or pair of implants.

[0024] A preferred embodiment provides two longitudinal slits in each circumferential wall portion between the elongated holes of the base body. The two longitudinal slits are disposed at a distance from each other in the longitudinal direction of the base body. Owing to this design, a circumferential web remains between the two longitudinal slits in the axial direction of the implant and ensures sufficient stability of the implant with respect to the compressive forces to be received. The circumferential web between the two longitudinal slits is preferably wide enough to carry at least one uninterrupted thread rib, preferably two or more interrupted thread ribs, thereon. It is further preferred for the slits to be arranged symmetric with respect to the longitudinal center of the base body. This can facilitate the osteogenic material or bone material within the implant to contact vascular tissue from the lateral side of the implant as far as possible over the entire length of the implant without jeopardizing the inherent stability of the implant.

[0025] The thread may be embodied by any type of thread, such as a sharp, triangular, or rounded-over thread. It is preferred, however, that the external thread be formed as a trapezoidal thread. The natural thickness of the ribs of a trapezoidal thread inhibits the implant from sinking or subsiding into the vertebrae, particularly into degenerative vertebrae. Further, the wide thread ribs also increase the reinforcement of the circumferential wall. According in a preferred embodiment of the invention the average thickness of the thread ribs is in the range of between about 1/25 to 1/15 of the overall length of the implant, more preferably about 1/20 of the overall length of the implant.

[0026] In order to facilitate the screwing of the implant into a prepared threaded bore between the vertebrae and also to facilitate the threading operation on the implant during manufacture thereof, the two axial ends of the base body are preferably provided with beveled edges. The beveled edges may be tapered or round chamfers, for example. According to a preferred embodiment, the axial front end portion of the base body is provided with an insertion end tapering axially from the larger first, outer diameter of the implant to a smaller second, outer diameter proximate the front end. The insertion end can be arranged to be set onto the vertebrae when the implant is threaded into the intervertebral space. This particularly applies to cases where the vertebrae are to be spread apart by means of the implant to a larger extent, i.e., using the implant itself to distract the adjacent vertebrae. In an alternative form, the insertion end does not include an external thread. To this end, initially the implant can be easily driven or impacted into the intervertebral space to initially spread the vertebrae apart and to enter the intervertebral space until the thread on the circumferential wall portion engages the opposing end plates or surfaces of the adjacent vertebrae. In still other alternative embodiments, the insertion end includes a threaded portion. In this embodiment, the implant can be threadedly implanted into the disc space without the necessity of impaction. Regardless, after initial placement the implant can be positioned accurately in the intervertebral space by screwing the implant in the axial direction, with reduced risk of the implant damaging or penetrating adjacent tissue or structures, for example, the spinal cord. The implant can include a set-head, which is preferably at least 1/10 of the base body in the axial direction thereof.

[0027] While the implant may be gripped manually or with a tong-type tool and threaded into the intervertebral space in any manner, the axial rear end of the base body advantageously comprises a receiving means or tool engaging portion for receiving a manipulation tool in order to exert a torque on the base body. This receiving means enables a more accurate implantation process, and minimizes damage to the implant during surgery, which finally better ensures a durable functionality of the implant in the implanted state thereof.

[0028] In one embodiment the receiving means can be embodied by two or more holes, for example, arranged

in the front wall of the base body. The holes are provided for mating engagement with matching pins of the manipulation tool. A torsional moment torque can be exerted on the implant by rotating the engaged manipulation tool. In other embodiments, the receiving means preferably comprises two grooves opposite each other with respect to the cavity of the base body, and a mating blade or a matching counterpart on the manipulation tool can engage these grooves from outside. The manipulation tool can be prevented from slipping inadvertently off and away from the end of the implant by providing an engagement groove or other engagement means with an undercut portion or a dove tail, for example, that can be detachable locked or engaged with a matching counterpart overcut portion of the manipulation tool.

[0029] Preferably, the receiving means also comprises a threaded central bore into which a corresponding threaded counterpart of the manipulation tool, for example, a threaded pin can be screwed in such a manner that the manipulation tool is firmly engaged to the implant. This provides the advantage that the implant is coupled integrally to the manipulation tool and can be manipulated accurately together with the manipulation tool by the surgeon.

[0030] The above-described implants can be prepared of a wide variety of materials including synthetic organic materials, composites, and ceramics. Preferably the implants are formed of a synthetic, non-metallic material. The implants of the present invention can be either essentially permanent implants, which do not readily biodegrade. These implants can remain in the intervertebral space and often are incorporated into the bony tissue. Alternatively, the implant can biodegrade or erode over time and are substantially replaced by bone tissue.

[0031] Examples of nondegradable polymeric or oligomeric materials include the, polyacrylates, polyethers, polyketones, polyurethanes, epoxides and copolymers, alloys and blends thereof. Use of the term co-polymers is intended to include within the scope of the invention polymers formed of two or more unique monomeric repeating units. Such co-polymers can include random copolymers, graft copolymers, block copolymers, radial block, diblock, triblock copolymers, alternating co-polymers, and periodic co-polymers. Specific examples of nondegradable polymeric materials include: poly(vinyl chloride) (PVC); polyacrylates, poly(methyl (meth)acrylate); acrylics; polyamides; polycarbonates; polyesters; polyethylene terephthalate; polysulfones; polyolefins, i.e. polyethylene, polypropylene, and UHMWPE (ultra high molecular weight polyethylene); polyurethane; polyethers, i.e., epoxides; poly(ether ketones) (PEK), poly (ether, ether ketones) (PEEK), poly(aryl ether ketones) (PAEK), and poly(ether ether ketone ether ketone) (PEEKEK). A wide variety of suitable poly(ether-co-ketone) containing materials are commercially available.

[0032] Alternatively, implants of this invention can be made of a material that either biodegrades or is bioabsorbed. Typically, biodegradable material is a polymeric material or oligomeric material and often the monomers are joined via an amide linkage such as is observed in poly(amino acids). When the implant is formed of material that biodegrades, it is desirable to provide a biodegradable material that degrades at a rate comparable to the bony ingrowth characteristic of bone fusion often referred to as creeping substitution. It is still more preferred to select the biodegradable material to remain *in situ* and capable of providing sufficient biomechanical support for the spine even after a bone bridge has grown and formed through the through-holes of the implant. The biodegradation rate of the implant can be varied by selecting an appropriate synthetic material. The degradation rate of the selected material can be further modified; for example, the degradation rate can be decreased by increasing the amount of crosslinking between the polymer chains and/or the increasing the degree of polymerization. Further, it is not intended to limit the preferred materials to substances that are partly or totally reabsorbed within the body. Rather substances that can be broken down degraded and eventually flushed from the body are also intended to come within the scope of this invention.

[0033] Examples of biodegradable polymers for use with this invention include poly(amino acids), polyanhydrides, polycaprolactones, polyorthoesters, polylactic acid, poly(lactide-co-glycolide), i.e., copolymers of lactic acid and glycolic acid, including either D, L and D/L isomers of these components. One example of a preferred biodegradable polymer for use with this invention is a copolymer of 70:30 poly(L, DL) lactate commercially available from Boehringer Ingelheim.

[0034] A particularly advantageous benefit provided by this invention is the ease of manufacturing suitable synthetic implants. Implants formed of polymeric, oligomeric and composite material can be manufactured using known fabricating techniques, including various extrusion, injection molding and blow molding processes. In addition, selected polymeric materials are provided by suppliers in a form that can readily formed, and/or molded, usually at an elevated temperature. A copolymer of D/L lactate is one specific example. This material can be obtained in a wide variety of forms including pellets or granules, sheets, ingots. The material can be molded at a temperature of about 55°C or greater to provide a desired shaped and sized implant. The material can be repeatedly heated and contoured without any significant change in its material or chemical properties. In addition, material is readily cut using a cautery to readily conform the implant to the bone. The lower cautery temperature even permits cutting the material during the operation.

[0035] Specific examples of ceramic materials for use with this invention include glass, calcium phosphate, hydroxyapatite, alumina, zirconia, and mixtures of these materials.

[0036] Composites are also useful with this invention. Composites can combine two or more of the desired materials to form an implant body for implantation. Examples of composites include combinations of ceramics, glass

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