Figure 1
Declarations under Rule 4.17:

— as to applicant’s entitlement to apply for and be granted a patent (Rule 4.17(H))

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

Published:

— with international search report (Art. 21(3))
HYBRID ROD CONSTRUCTS FOR SPINAL APPLICATIONS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority from United States Provisional Application No. 61/264,623 filed on November 25, 2009.

BACKGROUND

1. Field.

[0002] The present invention provides support to a patient's spine by an implanted support system of rods, pedicle screws, and vertebrae, material and/or artificial, and more particularly, improved spinal rods.

2. Description of Related Art.

[0003] Stabilization of the spine is an important aspect of spinal surgery procedures and is a significant factor in the healing process for patients. One stabilization technique currently practiced is to drill screws into the bone of the patient spine and utilize one or more rods to hold the screws together to fashion a "frame" for holding the vertebrae still.

[0004] However, traditional screw and rod systems do not allow for movement of the patient's back. By limiting the patient's movement, substantial discomfort may arise, and in an effort to alleviate such discomfort, some patients may attempt to move their backs. Such movement may cause the screws and rods to loosen, leading to setbacks in the patient's recovery or worse, possibly leading to further damage to the patient's vertebrae.

[0005] Traditionally, steel and/or titanium have been used as the primary material for the rod. However, these relatively rigid materials bear the load when a force is applied to the screw and/or rod construct (e.g., when the patient moves his or her back). As a result, patients do not experience the optimal recovery and healing following surgery.

[0006] Accordingly, certain advancements have introduced dynamic rods that may have a slight flex to them to allow limited back movement. Over the last few years, polyetheretherketone (PEEK) has been introduced as an increasingly popular material. While PEEK increases
flexibility of the rods, it unfortunately has drawbacks of its own: purely PEEK constructed rods are also unable to redistribute load in such a way that optimizes patient recovery after surgery.

[0007]
Indeed, existing rods in the art are either much too stiff or much too flexible, with each end of the rigidity spectrum causing a different set of problems as discussed above. What is needed is a hybrid rod with a stiffness between an overly rigid metal and an overly flexible polymer in order to effectively avoid these pitfalls and improve the patient's recovery from spinal surgery.

[0008]
Moreover, a rod having increased versatility in its ability to be easily retrofitted into currently spinal constructs and future, undeveloped spinal constructs would be beneficial and cost effective, which cannot be overstated in today's economy and rising health care costs. In other words, such a hybrid rod would provide greater accessibility to more patients due to its versatility and its simple-but-innovative design.

SUMMARY

[0009]
The devices disclosed herein may be intended to be used for, but is not limited to, relieving stress from spinal levels adjacent to fusion by introducing more flexible connections therebetween. Alternatively, the devices may be used to correct kyphosis, scoliosis or other deformity ailments that a patient may be suffering from. That is by allowing certain parts of a patient's spinal construct to have a normal, intended, range of motion by allowing flexibility in these portions while fixing the rest of the patient's spinal column, the devices described herein may be able to provide correction to any of a number of deformity ailments. Generally, the hybrid rods and related constructs described herein may allow for additional flexibility levels previously unattained, thereby allowing physicians to more effectively treat patients that may benefit from such hybrid rods.

[0010]
The present application discloses in a first embodiment, a spinal rod, in which the rod comprises two or more elements, the rod comprising: an inner shaft; and an outer tube, wherein the material of the inner shaft and the material of the outer tube are of different rigidity, further wherein the material of the inner shaft and the material of the outer tube are medical grade for implantation purposes. The spinal rod may further include a characteristic of wherein the outer tube is made of a less rigid material. The spinal rod may further include the characteristic of wherein the inner shaft is quasi-fixed through an injection molding process to the outer tube. The
spinal rod may further include the characteristic of wherein the inner shaft provides stiffness to the spinal rod. The spinal rod may further include the characteristic of wherein the outer tube fully extends over the inner shaft. The spinal rod may further include the characteristic of wherein the inner shaft is curved to provide curvature to the spinal rod. The spinal rod may further include the characteristic of wherein the spinal rod is curved up to R150 mm bent. The spinal rod may further include the characteristic of wherein an outside diameter of the inner shaft is between 2 mm and 4 mm. The spinal rod may further include the characteristic of wherein an outside diameter of the outer tube is between 4 mm and 8 mm. The spinal rod may further include the characteristic of wherein the inner shaft is constructed out of material selected from a group consisting of titanium alloy, cobalt chromium and nitinol. The spinal rod may further include the characteristic of wherein the outer tube is constructed out of a material selected from a group consisting of: polyetheretherketone (PEEK), polycarbonate urethane (PCU) and polyethylene. The spinal rod may further include the characteristic of wherein the inner shaft includes a first and second end element, the first end element encapsulating a first end of the outer tube and the second end element encapsulating a second end of the outer tube.

[001]  
The present application may further disclose another embodiment wherein a spinal elongated fixation member comprises: an inner member; a first outer member; and a second outer member, wherein the inner member, the first outer member and the second outer member are constructed out of materials with different rigidity. The spinal elongated fixation member may further include the characteristic of wherein the inner member, first outer member and the second outer member are spaced apart to allow for specific length adjustment for a user and to allow the inner member to be curved. The spinal elongated fixation member may further include the characteristic of wherein the inner member, first outer member and the second outer member each include a mating element to allow for the inner member to be curved while the first and second outer members are in full contact. The spinal elongated fixation member may further include the characteristic of wherein the spinal rod or the spinal elongated fixation member are configured to be used in posterior applications by being mounted inside pedicle screw housings.

[0012]  
The present application may further disclose, in another embodiment, a method of manufacturing a straight or curved rod comprises one of a group consisting of: machining, extrusions, compression and injection molding, wherein a material used in the manufacturing of the straight or curved rod includes PEEK biomaterial preheated to a temperature of 680-750°F Fahrenheit (F). The method of manufacturing may further include the characteristic of wherein the method of manufacturing is injection molding and a temperature at an injection nozzle is set
between 690 - 743°F. The method of manufacturing may further include the characteristic of wherein a temperature of a mold used in injection molding is set between 350 - 500°F. The method of manufacturing may further include the characteristic of wherein pack pressure is set at 10000 - 20000 pounds per square inch (psi), peak pressure is set at 20000 psi, and hold pressure is set at 5800 - 1450 psi.

[0013]
In another embodiment, the spinal rod may be an elongated spinal fixation member (e.g., in the form of a rod that is to be tightened to devices) which may be fixably attached to spinal vertebra such as a pedicle screw. The rod member may be formed of multiple components that are made of materials with different stiffness. That is, the material for the inner shaft and outer tubes may be of different rigidities. For example, when the rod includes an inner shaft and one or more outer tube(s), the outer tube(s) may be made of a less rigid material than the material of the inner shaft.

[0014]
In one embodiment, an inner shaft may be quasi-fixed through an injection molding process to outer tube(s), where the purpose is to provide stiffness to the rod construct only. Here, the outer tube(s) may fully extend over the inner shaft.

[0015]
In a further embodiment, the spinal elongated fixation member is composed of an inner member and two or more outer members of different rigidity.

[0016]
In another embodiment, the spinal elongated fixation member is composed of an inner member and two or more outer members that are spaced apart to allow for specific length adjustment for the user and also to allow the inner shaft to be curved.

[0017]
In another embodiment, the spinal elongated fixation member is composed of an inner member and two or more outer members that have mating features to allow for the inner shaft to be curved, while the outer members are still in full contact with one another.

[0018]
In another embodiment, the spinal elongated fixation member is composed of an inner member that has features on the end to encapsulate outer member(s). In one aspect, one or more embodiments may include a device that may be used in posterior applications by being mounted inside pedicle screw housings and tightened down through a locking cap.

[0019]
In another embodiment, where a curved rod is desired, the inner core rod may be bent to
achieve a curved rod with a two-piece outer sleeve such that the inner core can be bent to achieve the desired angulation. An alternative method to achieve a curved or bent rod is through molding of a lower stiffness material (outer tube) over an inner core material to achieve a particular radius of curvature.

[0020]

In another embodiment, the inner shaft may be curved to provide curvature to a hybrid spinal construct. The interface between two portions might not vary over time and material selection or manufacturing process might not be limited to polyetheretherketone (PEEK) or other moldable materials. In other words, other materials and manufacturing processes may also be used.

[0021]

In another embodiment, the rod may be either straight or curved, where the degree of curvature is up to but not limited to, R150.0mm bent. The outside diameter of the rigid inner shaft may vary between 2mm - 4mm in diameter. The outside diameter of the outer tube may vary between 4mm - 8mm. The elongated membrane length may vary between 20mm - 600mm.

[0022]

The method of manufacturing of the straight or curved rods may include but are not limited to machining, extrusions, compression or injection molding. For embodiments where PEEK biomaterial is used during injection molding, material can be pre-heated to 680 - 750°F temperature. Temperature at injection nozzle and the mold can be 690 - 743°F and 350 - 500°F respectively. Pack pressure, peak pressure, and hold pressure recommended range are but not limited to 10000 - 20000 psi, 20000 psi, and 5800 - 1450 psi, respectively.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0023]

The objects and features of the present invention, which are believed to be novel, are set forth with particularity in the appended claims. The present invention, both as to its organization and manner of operation, together with further objects and advantages, may best be understood by reference to the following description, taken in connection with the accompanying drawings.

[0024]

FIG. 1 is a perspective view of a posterior pedicle mono screw and rod spinal construct, in accordance with one or more embodiments described herein;

[0025]

FIG. 2 is a perspective view of one embodiment of a side-loading polyscrew and rod spinal construct in accordance with one or more embodiments described herein;
FIG. 3 is a perspective view of another embodiment of a side-loading polyscrew and rod spinal construct in accordance with one or more embodiments described herein;

FIG. 4 is a perspective view of a spinal elongated fixation device in accordance with one or more embodiments described herein;

FIG. 5 is a perspective view of another embodiment of a spinal elongated fixation device having two or more outer members in accordance with one or more embodiments described herein;

FIG. 6 is a cross-sectional view of a spinal elongated fixation device having at least one inner and one outer member spaced apart to allow for length adjustment in accordance with one or more embodiments described herein;

FIG. 7 is a perspective view of another embodiment of a spinal elongated fixation device having inner and outer members that have mating features to allow for the inner member to be curved while the outer members are still in full contact in accordance with one or more embodiments described herein;

FIG. 8 is a cross-sectional view of the spinal elongated fixation device of FIG. 7 in accordance with one or more embodiments described herein;

FIG. 9 is a perspective view of another embodiment of a spinal elongated fixation device having an inner member that has a first and second cap portion for encapsulating both ends of an outer member in accordance with one or more embodiments described herein;

FIG. 10 is a perspective view of another embodiment of a spinal elongated fixation device having an inner member and layers of outer members in accordance with one or more embodiments described herein; and

FIG. 11 is a cross-sectional view of the spinal elongated fixation device of FIG. 10 in accordance with one or more embodiments described herein.
DETAILED DESCRIPTION

[0035] Persons skilled in the art will readily appreciate that various aspects of the disclosure may be realized by any number of methods and devices configured to perform the intended functions. Stated differently, other methods and devices may be incorporated herein to perform the intended functions. It should also be noted that the drawing FIGS, referred to herein are not all drawn to scale, but may be exaggerated to illustrate various aspects of the invention, and in that regard, the drawing FIGS, should not be construed as limiting. Further, although the present disclosure may be described in connection with various medical principles and beliefs, the present disclosure should not be bound by theory.

[0036] Referring now to FIG. 1, a flexible spinal fixation assembly 100 is shown. The spinal fixation assembly 100 may be a posterior pedicle mono screw that is fixably anchored to a functional spinal unit with bone screw 105 and connected to an adjacent spinal fixation assembly with rod 125. In one aspect, the adjacent spinal fixation assembly connected by rod 125 may be the same flexible spinal fixation assembly 100 or it may be a different fixation assembly. As shown in FIG. 1, the spinal fixation assembly 100 further includes a head component 150 comprising a screw attachment portion 110 and rod insertion portion 115. The head component 150 may further include a bolt 120 for holding the rod 125 in place. The head component 150 may also include a cap 130. In one aspect, some of the components such as the bolt, cap, screw, screw attachment portion and rod insertion portion may be constructed solely out of, or alternatively incorporate a material such as titanium, cobalt chromium, steel and nitinol.

[0037] Turning to FIG. 2, another embodiment of an assembly is shown. Here, a side-loading polyscrew assembly, namely assembly 200 is illustrated. Assembly 200 may include a screw 205, a top rod insertion portion 215, a bottom rod insertion portion 230, a bottom plate 210, and a cap 230. Other elements such as a screw seating, flexible membranes, and the like may further be included but are not shown for simplicity. The bottom rod insertion portion 230 and top rod insertion portion 215 may be a hinged arm construct and may be snapped or otherwise brought together and tightened to hold the rod 225 in place. Here, in this embodiment, the head component (e.g., the bottom rod insertion portion 230, and the bottom plate 210) may be angulated and rotated to proper position before being the side-loading polyscrew assembly 800 is tightened. For example, the screw 205 may be rotated inside membranes located within the head component (not shown) before being locked into location by a screw seating. The rod 225 may function to attach assembly 200 to other assemblies, such as another assembly 200 or assembly
Turning to FIG. 3, another embodiment of a side-loading polyscrew system is illustrated. As shown, assembly 300 includes a screw 305, bottom plate 310, rod insertion portion 315, and intermediate head portion 330. The assembly 300 may also include a rod 325 for attaching to other assemblies. For example, the rod 325 may attach to another assembly 300 or may attach to other assemblies such as assembly 100 of FIG. 1 or assembly 200 of FIG. 2, among other assemblies.

A more detailed explanation of the assembly 100 of FIG. 1, assembly 200 of FIG. 2, and assembly 300 of FIG. 3 may be found at PCT Application PCT/US10/57076 filed November 17, 2010, the contents of which are hereby fully incorporated by reference. In addition, other assemblies may also be connected by the rods (e.g., rod 125 of FIG. 1, rod 225 of FIG. 2 and rod 325 of FIG. 3) described herein. Turning to the rod, FIG. 4 illustrates one example of a hybrid rod 400 which may be used in connection with any of the spinal constructs described herein. In other words, rod 400 of FIG. 4 may constitute rod 125 of FIG. 1, rod 225 of FIG. 2 and rod 325 of FIG. 3. As shown, rod 400 may comprise two portions, namely an inner core 405 and an outer membrane 410. The rod 400 may be uniformly cylindrical in shape. The inner core 405 may be constructed as a solid, shaft-like object without any holes or hollow portions. The inner core 405 may also be a uniformly cylindrical object having a smaller diameter as compared to the entire rod 400. The outer membrane or tube 410 may be a separate element and may also be uniformly cylindrical in shape as well. However, the tube 410 may include a hollow diameter large enough to fit the inner core 405. Indeed, when the inner core 405 is inserted into the tube 410, the rod 400 is complete. In one aspect, the inner core 405 is constructed out of a first material and the tube 410 is constructed out of a second material. For example, the inner core 405 is made of a material with higher bending stiffness or higher rigidity, which has the advantage of providing strength for the rod 400 while the outer tube 410 may be made of a material with lower stiffness providing flexibility for the rod 400. When combined in the fashion as shown in FIG. 4, the comparative stiffness of the inner core 405 to the outer tube 410 provides a patient with the benefit of a sturdy rod with a flexible outer portion.

In one embodiment, the outer tube 410 is made of a material with lower stiffness such as PEEK, PCU, Polyethylene and its derivatives, and a more rigid inner core may be constructed out of material such as titanium alloy, cobalt chromium, or Nitinol.

FIG. 5 illustrates another example of a hybrid rod 500 which may be used in connection
with any of the spinal constructs described herein. In other words, rod 500 of FIG. 5 may constitute rod 125 of FIG. 1, rod 225 of FIG. 2 and rod 325 of FIG. 3. Here, rod 500 may include an inner shaft 505 and two adjacent outer cores, 510 and 515. As shown, the rod 500 has many similarities to rod 400. For example, the shape of the rods are similarly cylindrical. However, one main difference is that the hybrid rod 500 includes two adjacent outer cores 510 and 515. In one aspect, the outer cores may be constructed out of different materials. By using different materials to construct the two outer cores 510 and 515, the physician may advantageously adjust for different assemblies attached to the first core 510 and the second core 515. For example, a more flexible material may be used to construct first core 510 for usage with one type of assembly which is more effective with a more flexible outer core (e.g., mono/poly screw, side-loading, etc.) while a less flexible material may be used to construct a second core 515 with another type of assembly which is more effective with a less flexible outer core (e.g., a different one of mono/poly screw, side-loading, etc.)

[0041]

Alternatively, the outer cores 510 and 515 may be constructed out of the same material. Regardless, the outer cores 510 and 515 may be made of a material different than the inner shaft 505. As a further alternative, the hybrid rod 500 may include additional outer cores. For example, the two outer cores 510 and 515, may further be split into two separate outer cores. Moreover, while shown in FIG. 5 as substantially equally-sized, the adjacent outer cores 510 and 515 may have different lengths.

[0042]

FIG. 6 illustrates a cross section of the hybrid rod 500 of FIG. 5. Here, the gap 520 is illustrated to be minimal. That is, as shown, an edge of the first outer core 505 is contacting another edge of the second outer core 510. However, other embodiments are possible where the first outer core 505 does not contact the second outer core 510, but instead, the gap 520 between the first outer core 505 and the second outer core 510 is larger. These different configurations with different gap sizes may allow for length adjustment of the rod 500. While not shown, the inner core 505 may be curved or bent at a location of gap 520, while the first outer core 505 and second outer core 510 are substantially straight. In one aspect, the first outer core 505 and the second outer core 510 may contact each other at one portion of the respective contacting edges while not contacting each other at another portion of the same respective contacting edge. In another aspect, the first outer core 505 and the second outer core 510 might not contact each other along the respective edges where they are proximally the closest. Alternatively, the entire edge of the first outer core 505 and the entire edge of the second outer core 510 may contact each other thereby eliminating the gap.
FIG. 7 illustrates another example of a hybrid rod 700 which may be used in connection with any of the spinal constructs described herein. In other words, rod 700 of FIG. 7 may constitute rod 125 of FIG. 1, rod 225 of FIG. 2 and rod 325 of FIG. 3. Here, rod 700 may include an inner shaft 705 and two adjacent outer cores, 710 and 715. One advantage of the hybrid rod shown in FIG. 7 is that the inner shaft 705 and adjacent outer cores 710 and 715 have mating features which allow the inner shaft 705 to be curved while allowing the adjacent outer cores 710 and 715 to still be in full contact. For example, even if the outer cores 710 and 715 are made out of different materials the outer cores 710 and 715 may have a slight bend at the edge where they connect so that the outer cores 710 and 715 may be able to form a substantially continuous outer shield around the inner shaft 705. FIG. 8 shows a cross section of the hybrid rod 700 of FIG. 7 with the angled inner core 705 and the adjacent outer cores 710 and 715 having mating features which allow the inner shaft 705 to be curved while allowing the adjacent outer cores 710 and 715 to still be in full contact. The rod 700 may be curved up to R 150mm bent. In other words, the degree of bending in relationship to a straight rod is limited to 150mm at the point of bending. The limitation of 150 millimeters is an advantageous feature to ensure that any assembly screwed into the patient's spinal bones and connected by the rod would be able to be held in place by the rod. Especially at the outer ends of the rod, a displacement of greater than 150mm may require the attached assembly to be screwed into portions of the patient's body that might not provide the preferably stability (e.g., assemblies screwed into the edge of the patient's bones may be less stable and may break away from the patient's spinal bone). The hybrid rod 700 may further include the characteristic of wherein an outside diameter of the inner shaft is between 2mm and 4mm and wherein an outside diameter of the outer tube is between 4mm and 8mm. In one aspect, the ratio of the outside diameter of the inner shaft to the ratio of the outside diameter of the outer tube (which includes the outside diameter of the inner shaft) is 1:2. In other words, when measuring from an outside diameter, each layer is substantially the same length. However, other ratios are possible. More particularly, where a stiffer hybrid rod is desired, the inner shaft is thicker than the outer tube, and where a more flexible hybrid rod is desired, the outer tube may be thicker than the inner shaft.

FIG. 9 illustrates another embodiment of a hybrid rod 900 having an inner member 905 that has a first and second cap portion at the end of the hybrid rod 900 for encapsulating both ends of an outer member 910. As shown, the cap portions are rounded, however, any of a number of geometries may be utilized to cap the ends of the outer member 910. By having the cap portions be a part of the inner member 905, the outer member 910 may be reinforced in
place. While not shown, the hybrid rod 900 may be curved (e.g., similar to hybrid rod 700 of FIG. 7). In another aspect, the hybrid rod 900 may have multiple outer members (e.g., similar to the outer cores 710 and 715 of FIG. 7). This embodiment is further unique in that the outer member 910 complete wraps around the inner member 905 in a direction substantially along the axis of the inner member 905 while the inner member 905 completely wraps around the outer member 910 in a direction substantially perpendicular or orthogonal to the axis of the inner member 905. In other words, the outer member 910 wraps around the shaft portion of the inner member 905, and the protruding end portions of the inner member 905 wraps around the ends of the outer member 910. In this fashion, the outer member 910 and inner member 905 may be intertwined and fully locked in place with respect to one another. In another aspect, the inner member 905 and outer member 910 may be formed with different materials (e.g., inner member 905 may be constructed out of a more rigid material such as titanium alloy, cobalt chromium and/or nitinol while outer member 910 may be constructed out of a less rigid material such as PEEK, PCU, polyethylene and/or other derivatives thereof).

[0045]

In addition, the embodiments of the rods disclosed herein may be modified to include additional core layers which surrounds and contacts an immediately intermediate layer. For example, FIG. 10 illustrates a hybrid rod 1000 with an inner core 1005, an intermediate core layer 1010 and an outer core layer 1015. As shown, the intermediate core layer 1010 and the outer core layer 1010 may be subdivided into adjacent cores (e.g., outer core layer 1010 may include among other adjacent cores, cores 1025) separated by separation point or gaps 1030. In one aspect, the stiffness of each core layer may be different and may get increasingly more flexible starting from the inner core 1005 (stiff, e.g., by using a titanium alloy or nitinol) and moving towards the intermediate core 1010 (less stiff, e.g., by using PEEK with injected titanium alloys or nitinol) before the outer core layer 1015 (least stiff, e.g., by using a purely PEEK material). While not shown, the inner core layer 1005 may also be configured to include a bend and may further be configured to include the cap portions of FIG. 9 and encapsulate both the intermediate core 1010 and the outer core 1015. While FIG. 10 illustrates a hybrid rod 1000 with three core layers, additional layers may be included. For example, where three layers are utilized (an inner core, intermediate core and outer core, e.g., as described in connection with FIG. 10 and 11) a possible length ratio may be 2mm diameter for the inner core, 4mm diameter for the intermediate core (which may include the 2mm diameter for the inner core) and 6 mm diameter for the outer core (which may include the 4 mm diameter for the intermediate core). Moreover, while shown to be uniform in thickness, any thickness configuration may be possible. For example, for a stiffer construct, a thicker inner core 1005 may be used (since the inner core 1005
is generally the stiffer aspect of the hybrid rod 1000). And accordingly, for less stiff construct, a thinner inner core 1005 may be used (with respect to the entire diameter of the hybrid rod 1000). FIG. 11 illustrates a cross section of FIG. 10 with the inner core 105 surrounding on both the top and bottom side by the intermediate layer 1010, which is respectively surrounded by the outer core 1015.

[0046]

The method of manufacturing the straight or curved rods described herein may include, but are not limited to, machining, extrusions, compression or injection molding. For embodiments where PEEK biomaterial is used during injection molding, the biomaterial may be pre-heated to 680 - 750°F. Next, the temperature at injection nozzle may be set at 690 - 743°F. The mold may be set at a temperature substantially less than the biomaterial and injection nozzle, namely, 350 - 500°F, to begin cooling the biomaterial after injection. Pack pressure, peak pressure, and hold pressure range are recommended at but not limited to 10000 - 20000 psi, 20000 psi, and 5800 - 1450 psi respectively during the manufacturing process.

[0047]

The terms "a," "an," "the" and similar referents used in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. Recitation of ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated herein, each individual value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the specification should be construed as indicating any non-claimed element essential to the practice of the invention.

[0048]

Groupings of alternative elements or embodiments disclosed herein are not to be construed as limitations. Each group member may be referred to and claimed individually or in any combination with other members of the group or other elements found herein. It is anticipated that one or more members of a group may be included in, or deleted from, a group for reasons of convenience and/or patentability. When any such inclusion or deletion occurs, the specification is deemed to contain the group as modified thus fulfilling the written description of all Markush groups used in the appended claims.
Certain embodiments are described herein, including the best mode known to the inventors for carrying out the invention. Of course, variations on these described embodiments will become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventor expects skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

Furthermore, references may have been made to patents and printed publications in this specification. Each of the above-cited references and printed publications are individually incorporated herein by reference in their entirety.

Specific embodiments disclosed herein may be further limited in the claims using consisting of or and consisting essentially of language. When used in the claims, whether as filed or added per amendment, the transition term "consisting of" excludes any element, step, or ingredient not specified in the claims. The transition term "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s). Embodiments of the invention so claimed are inherently or expressly described and enabled herein.

In closing, it is to be understood that the embodiments of the invention disclosed herein are illustrative of the principles of the present invention. Other modifications that may be employed are within the scope of the invention. Thus, by way of example, but not of limitation, alternative configurations of the present invention may be utilized in accordance with the teachings herein. Accordingly, the present invention is not limited to that precisely as shown and described.
What is Claimed:

1. A spinal rod, in which the rod comprises two or more elements, the rod comprising:
   an inner shaft; and
   an outer tube,
   wherein the material of the inner shaft and the material of the outer tube are of different rigidity, further wherein the material of the inner shaft and the material of the outer tube are medical grade for implantation purposes.

2. The spinal rod of Claim 1, wherein the outer tube is made of a less rigid material.

3. The spinal rod of Claim 1, wherein the inner shaft is quasi-fixed through an injection molding process to the outer tube.

4. The spinal rod of Claim 1, wherein the inner shaft provides stiffness to the spinal rod.

5. The spinal rod of Claim 1, wherein the outer tube fully extends over the inner shaft.

6. The spinal rod of Claim 1, wherein the inner shaft is curved to provide curvature to the spinal rod.

7. The spinal rod of Claim 6, wherein the spinal rod is curved up to R150.mm bent.

8. The spinal rod of Claim 1, wherein an outside diameter of the inner shaft is between 2mm and 4mm.
9. The spinal rod of Claim 1, wherein an outside diameter of the outer tube is between 4mm and 8mm.

10. The spinal rod of Claim 8, wherein the inner shaft is constructed out of material selected from a group consisting of titanium alloy, cobalt chromium and nitinol.

11. The spinal rod of Claim 9, wherein the outer tube is constructed out of a material selected from a group consisting of: polyetheretherketone (PEEK), polycarbonate urethane (PCU) and polyethylene.

12. The spinal rod of Claim 1, wherein the inner shaft includes a first and second end element, the first end element encapsulating a first end of the outer tube and the second end element encapsulating a second end of the outer tube.

13. A spinal elongated fixation member comprising:

   an inner member;
   a first outer member; and
   a second outer member,

   wherein the inner member, the first outer member and the second outer member are constructed out of materials with different rigidity.

14. The spinal elongated fixation member of Claim 13, wherein the inner member, first outer member and the second outer member are spaced apart to allow for specific length adjustment for a user and to allow the inner member to be curved.
15. The spinal elongated fixation member of Claim 13, wherein the inner member, first outer member and the second outer member each include a mating element to allow for the inner member to be curved while the first and second outer members are in full contact.

16. The spinal rod of Claim 1 or the spinal elongated fixation member 13, wherein the spinal rod or the spinal elongated fixation member are configured to be used in posterior applications by being mounted inside pedicle screw housings.

17. A method of manufacturing a straight or curved rod comprises one of a group consisting of: machining, extrusions, compression and injection molding, wherein a material used in the manufacturing of the straight or curved rod includes PEEK biomaterial preheated to a temperature of 680-750°F.

18. The method of manufacturing of Claim 17, wherein the method of manufacturing is injection molding and a temperature at an injection nozzle is set between 690 - 743°F.

19. The method of manufacturing of Claim 18, wherein a temperature of a mold used in injection molding is set between 350 - 500°F.

20. The method of manufacturing of Claim 19, wherein pack pressure is set at 10000 - 20000 psi, peak pressure is set at 20000 psi, and hold pressure is set at 5800 - 1450 psi.
FIG. 10

FIG. 11
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(8) - A61 B 17/70  (2010.01)  
USPC - 606/254

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC(8): A61B 17/70 (2010.01)  
USPC: 606/254

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

IPC(8): A61B 17/56, 17/58, 17/68  (2010.01)  
USPC: 606/53, 60, 246, 255, 259, 261

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST (DB=PGB,USPT,USOC,EPAB,JPAB), Google Scholar: rod near5 spine3 and (shield or sleeve or jacket) and coaxial and rigid5 and inject5 near5 mold5 and curv5 and r150 near5 bent and diameter and (titanium or cobalt or nitinol) and (polyetheretherketone or peek or pcu or polyethylene) and (mate5 or mating) and pedicle

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US 2008/0306542 A1 (MITCHELL et al.) 11 December 2008  (11.12.2008) para [0107]-[0109], [0128]-[0141]; Fig. 1A-3A</td>
<td>1-2 and 8-16</td>
</tr>
<tr>
<td>X</td>
<td>US 2008/0177388 (PATTERSON et al.) 24 July 2008  (24.07.2008) para [0034]-[0061]; Fig. 5, 11b and 12</td>
<td>1-7</td>
</tr>
<tr>
<td>X</td>
<td>US 2008/0306540 A1 (MITCHELL et al.) 11 December 2008  (11.12.2008) para [0108]-[0111], [0128H0142]. Fig. 1A-3A</td>
<td>1-2, 4-6 and 8-16</td>
</tr>
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<td>X</td>
<td>US 2008/0306541 A1 (MITCHELL et al.) 11 December 2008  (11.12.2008) para [0108]-[0111], [0128]-[0142]; Fig. 1A-3A</td>
<td>1-2, 4-6 and 8-16</td>
</tr>
<tr>
<td>X</td>
<td>US 2009/0054932 A1 (BUTLER et al.) 26 February 2009  (26.02.2009) para [0033]-[0035]; Fig. 1-5, 4 and 8</td>
<td>1</td>
</tr>
<tr>
<td>X</td>
<td>US 2009/008782 A1 (MOUMENE et al.) 2 April 2009  (02.04.2009) para [0037]-[0051]; Fig. 2-4</td>
<td>1-2</td>
</tr>
<tr>
<td>X</td>
<td>US 2005/0149020 A1 (JAHNG) 7 July 2005  (07.07.2005) para [0091]-[0097]; Fig. 7-10</td>
<td>1</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C.

*: Special categories of cited documents:

**A** document defining the general state of the art which is not considered to be of particular relevance  
**E** earlier application or patent but published on or after the international filing date  
**L** document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  
**O** document referring to an oral disclosure, use, exhibition or other means  
**P** document published prior to the international filing date but later than the priority date claimed

**Y** later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  
**X** document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  
**Y** document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art  
**S** document member of the same patent family

Date of the actual completion of the international search 23 March 2011 (23.03.2011)  
Date of mailing of the international search report 06 APR 2011

Name and mailing address of the ISA/US  
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents  
P.O. Box 1450, Alexandria, Virginia 22313-1450  
Facsimile No. 571-272-3011

Authorized officer:  
Lee W. Young  
PCT FIG: 571-272-4300  
PCT GSP: 571-272-7774

Form PCT/ISA/2 10 (second sheet) (July 2009)
### Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **Claims Nos.:**
   - because they relate to subject matter not required to be searched by this Authority, namely:

2. **Claims Nos.:**
   - because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. **Claims Nos.:**
   - because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows.

**Group I** claims 1-16 directed to a spinal rod

**Group II** claims 17-20 directed to a method of manufacturing a rod

The groups of inventions above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- The special technical feature of the Group I claims is an inner and outer rod of different rigidity, which is not present in the claims of Group II.
- The special technical feature of the Group II claims is the machining, extrusion or molding of a PEEK rod, which is not present in the claims of Group I.

Groups I and II share the technical feature of a spinal rod. This generic feature does not avoid the prior art, as evinced by US 2008/0177388 A1 to Patterson which teaches an example of a spinal rod (Abstract).

1. **As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.**

2. **As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.**

3. **As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:**

4. **No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:**

   1-16

### Remark on Protest

- The additional search fees were accompanied by the applicant’s protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.