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(54) **SEMI-RIGID SPINAL FIXATION APPARATUS**

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(57) **ABSTRACT**

A semi-rigid spinal apparatus has a first pedicle screw array and a second pedicle screw array substantially parallel to the first pedicle screw array. A first rod array is associated with the first pedicle screw array and a second rod array is associated with the second pedicle screw array. Each of the first and second pedicle screw arrays include a plurality of pedicle screws for joining to vertebrae of a spine. Each pedicle screw includes a head portion having a plurality of receptacles and a leg portion having a male thread for implanting into a vertebra. Each of the first and second rod arrays include a plurality of rod segments and each rod segment includes a first end coupled to a first receptacle on a first pedicle screw and a second end coupled to a second receptacle on a second pedicle screw adjacent to the first pedicle screw.

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Continuation-in-part of application No. PCT/KR04/03301, filed on Dec. 15, 2004.

(30) **Foreign Application Priority Data**

Sep. 22, 2004 (KR) 10-2004-0076105

Sep. 22, 2004 (KR) 10-2004-0076106

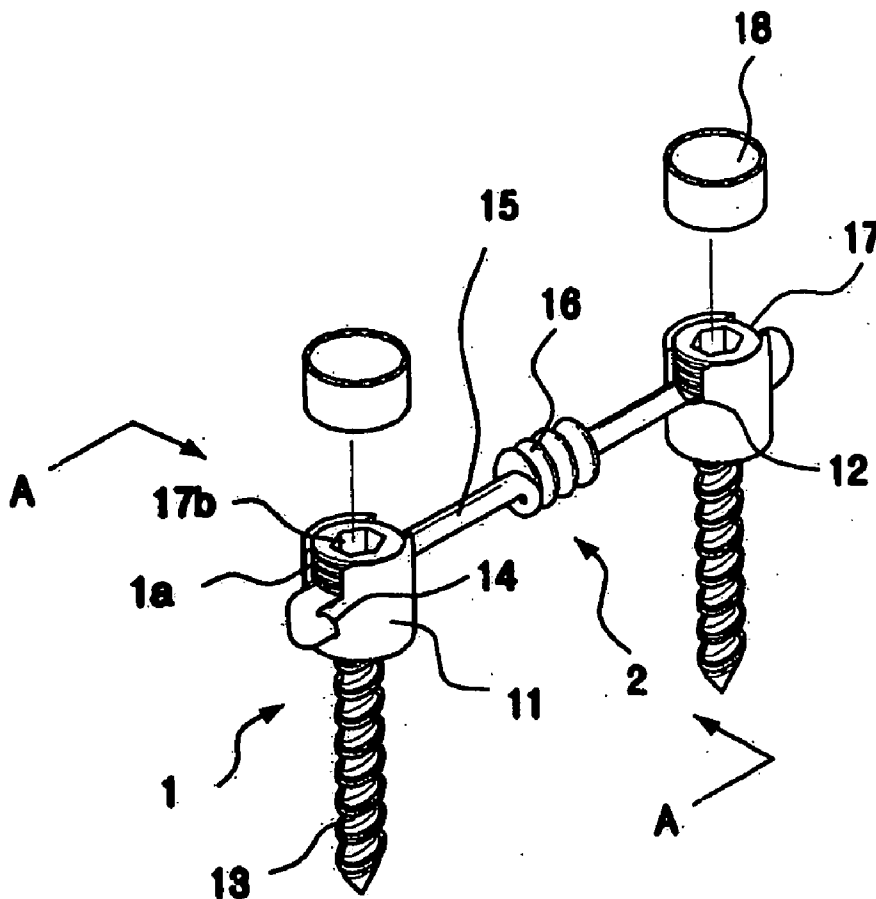


Fig. 1

(Prior Art)

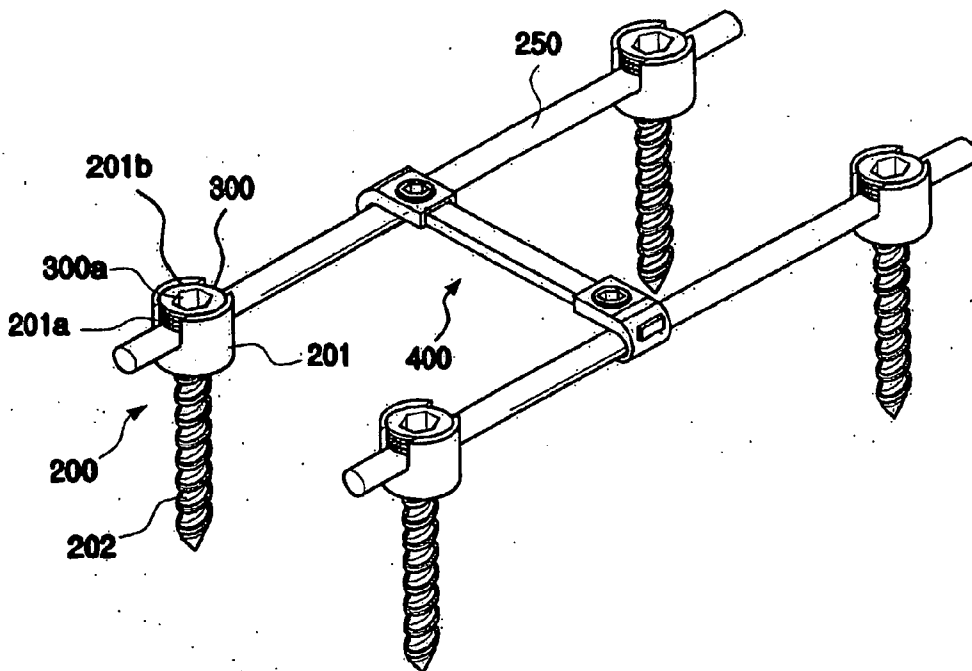


Fig. 2

(Prior Art)

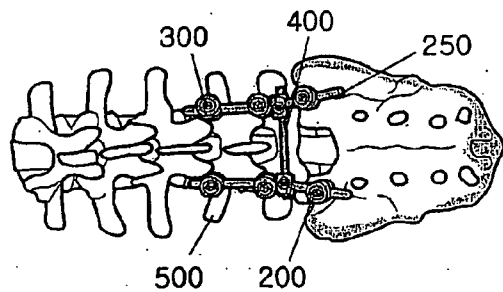


Fig. 3

(Prior Art)

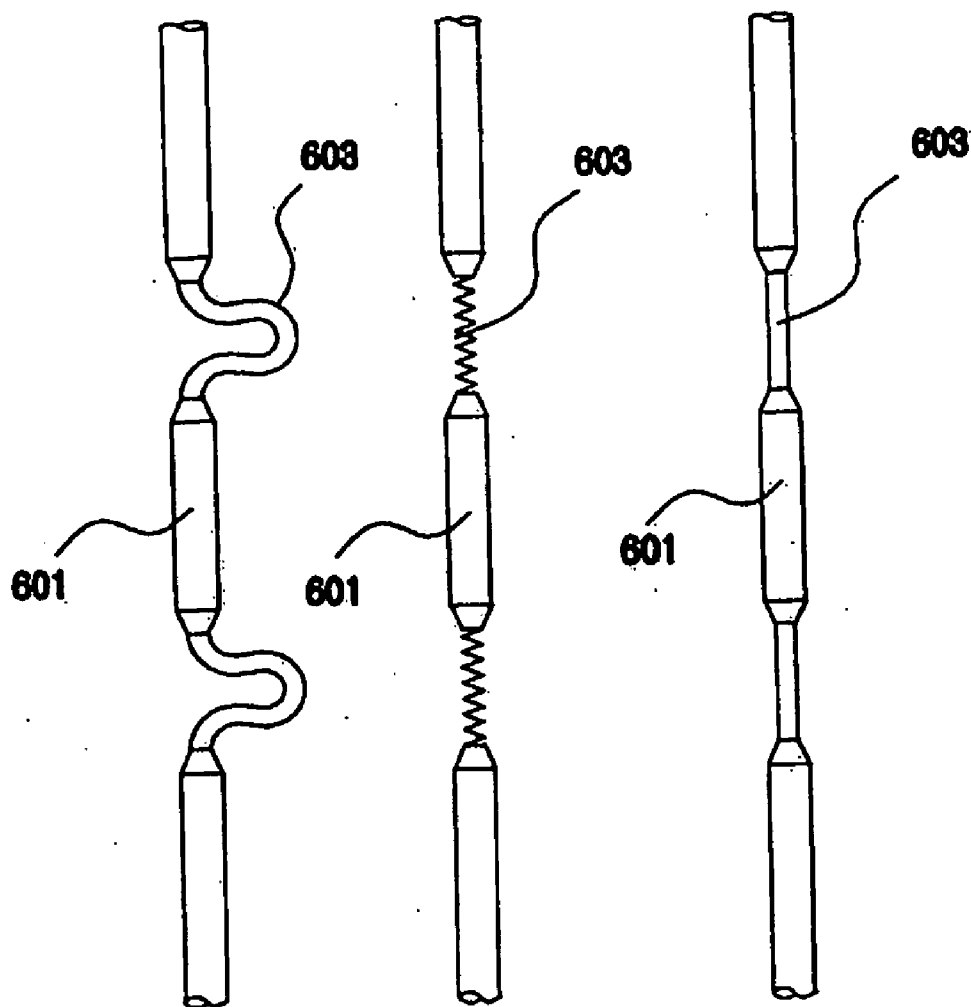


Fig. 4

(Prior Art)

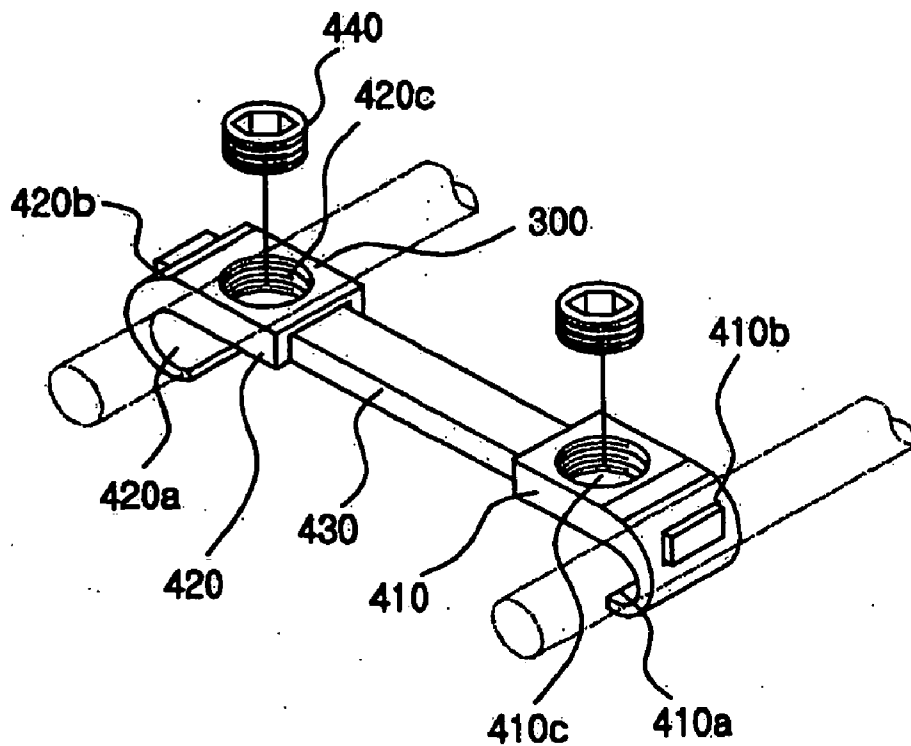


Fig. 5

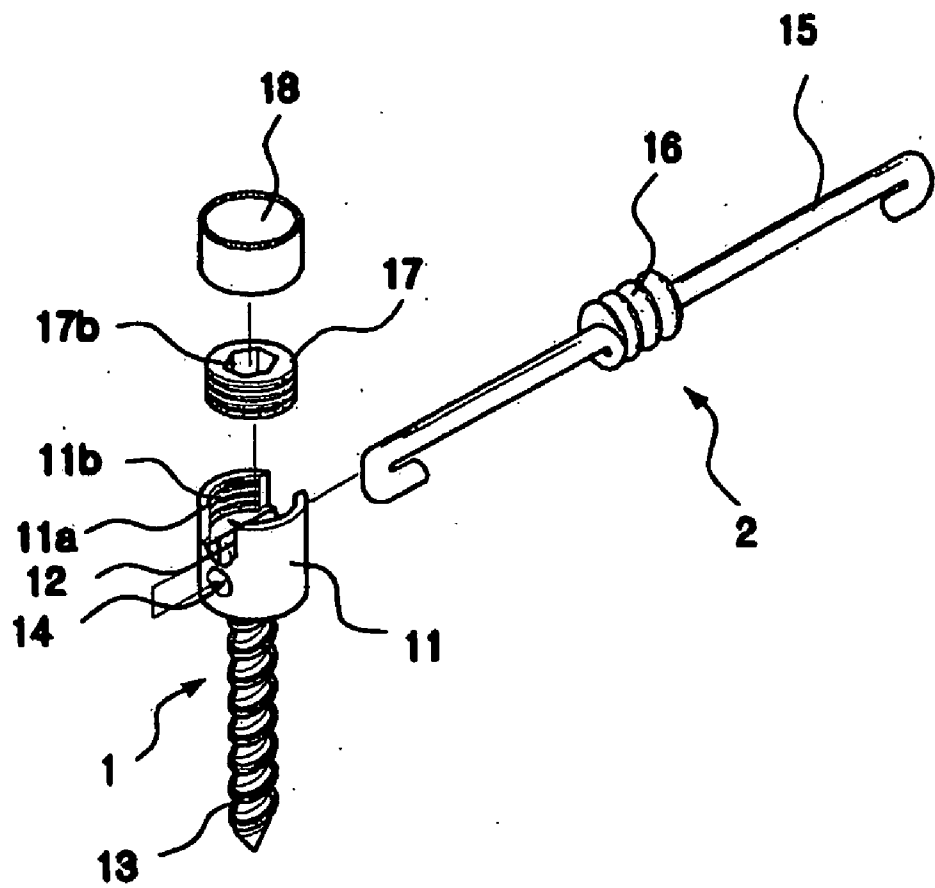


Fig. 6

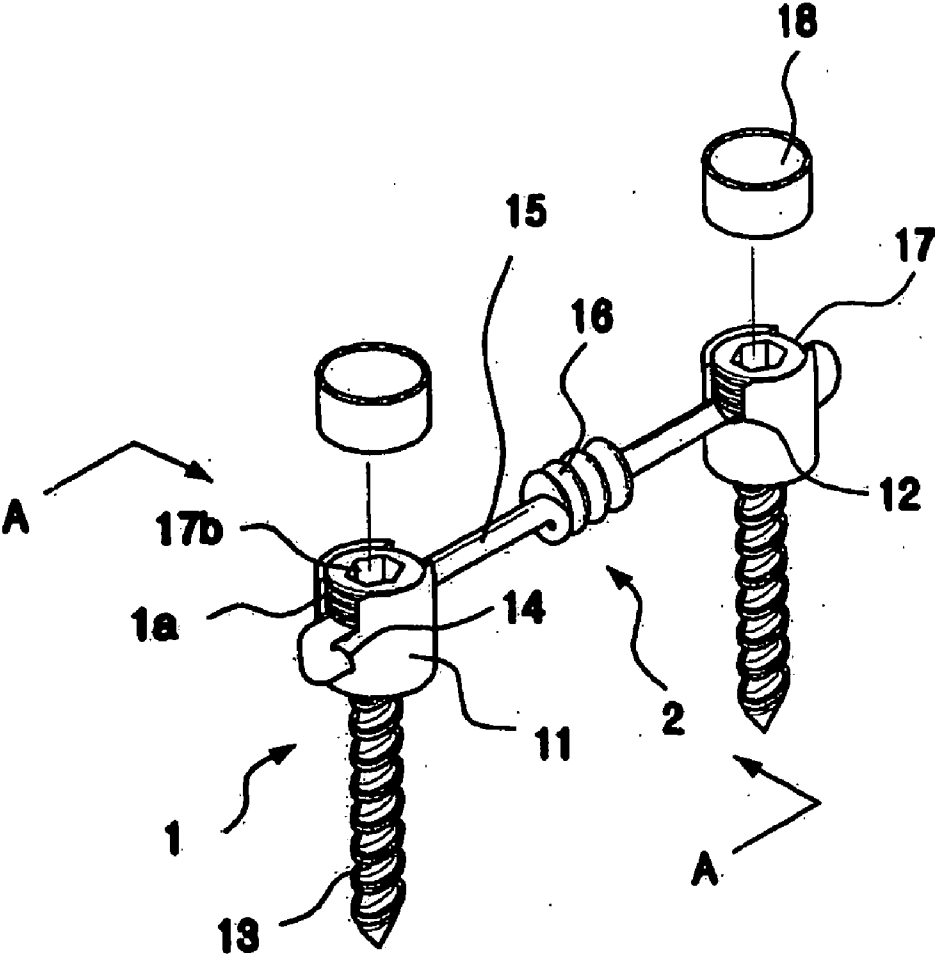


Fig. 7

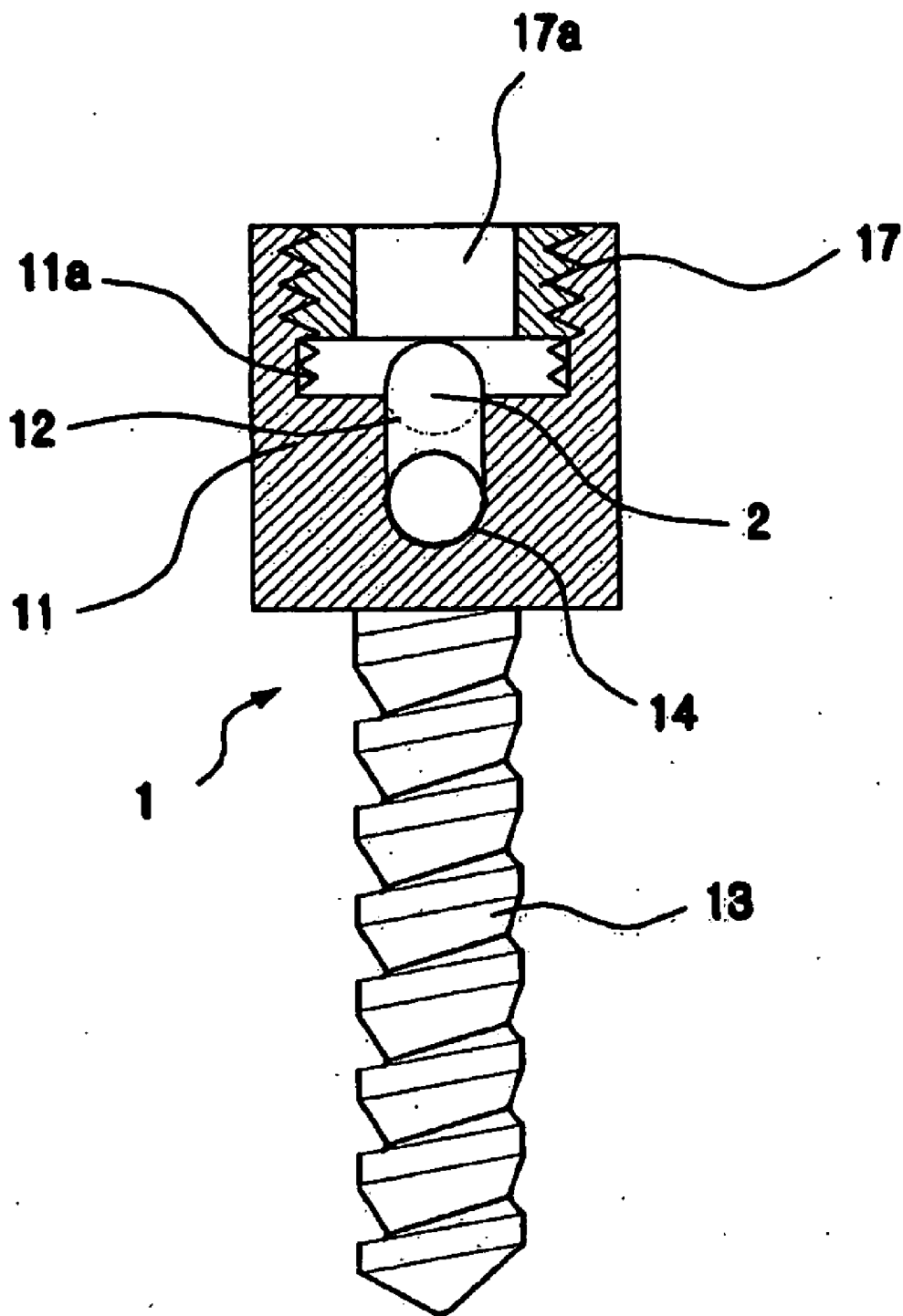


Fig. 8

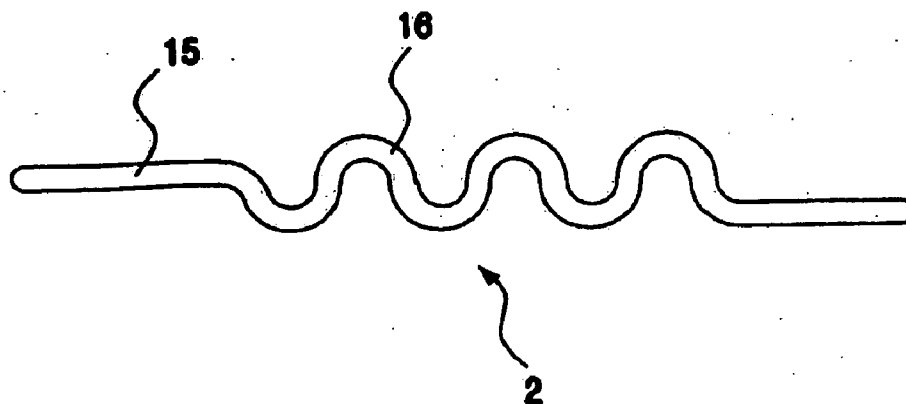


Fig. 9

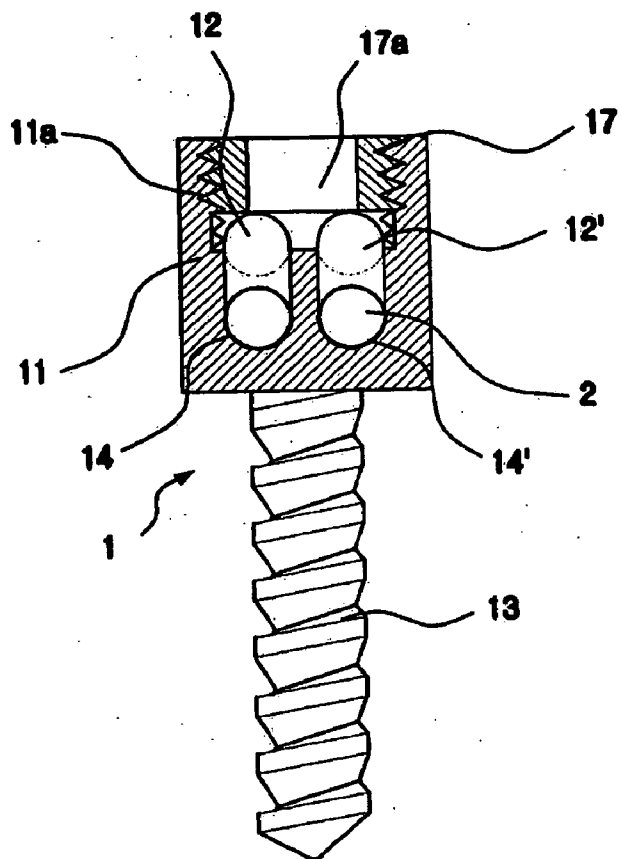


Fig. 10

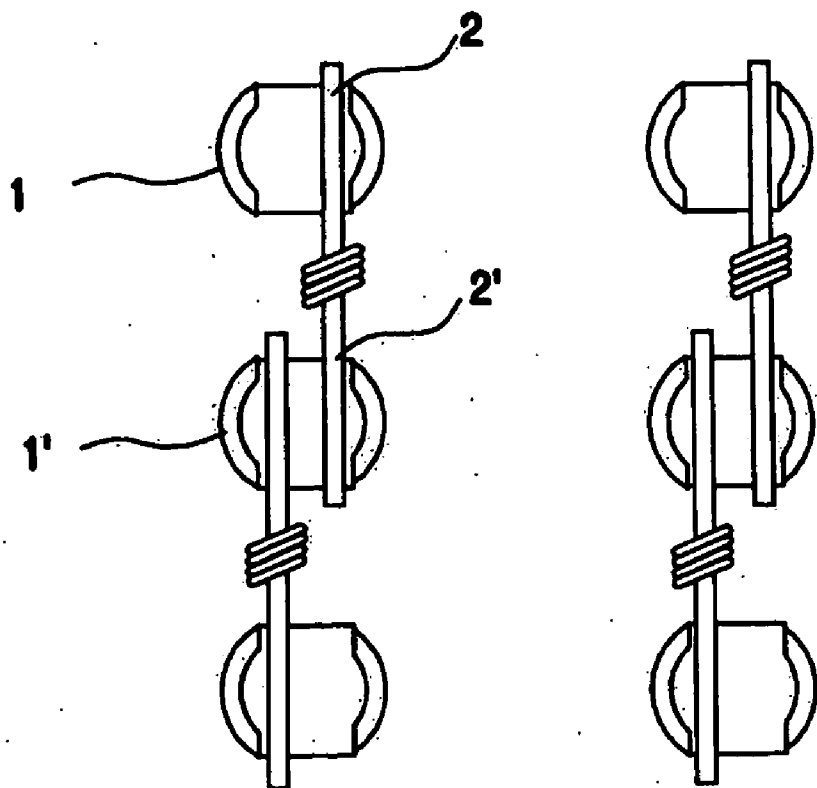


Fig. 11

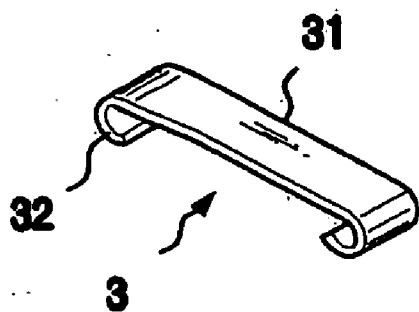


Fig. 12

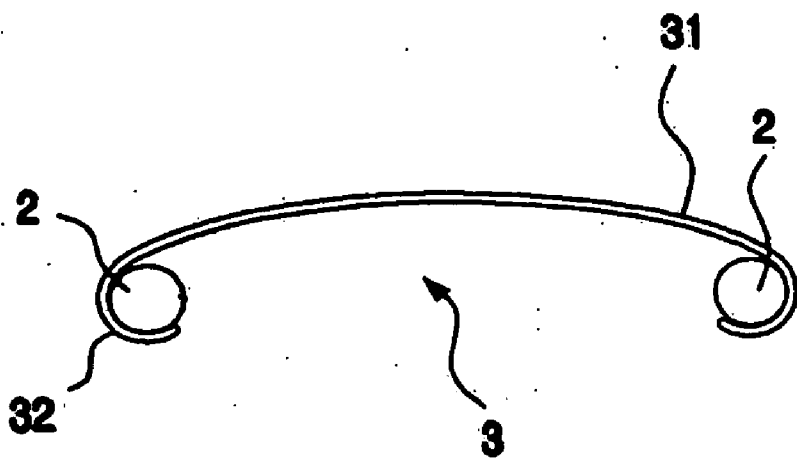


Fig. 13a

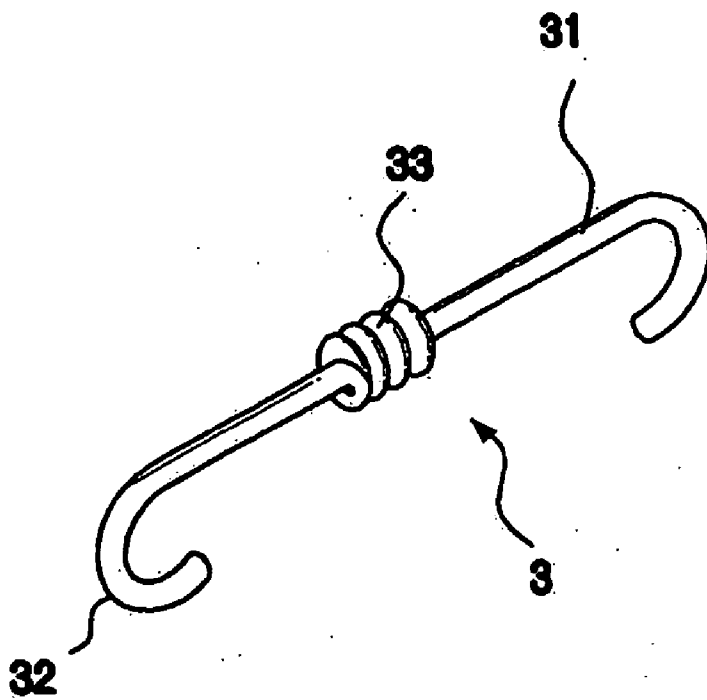


Fig. 13b

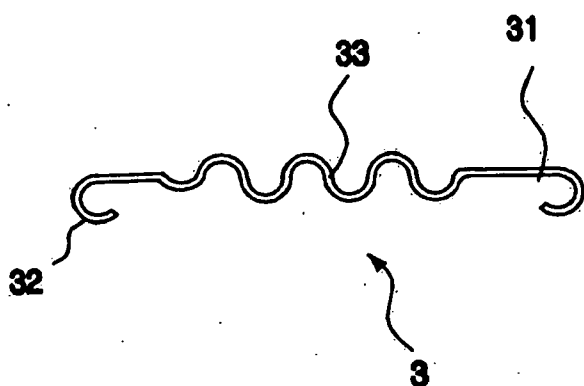


Fig. 14

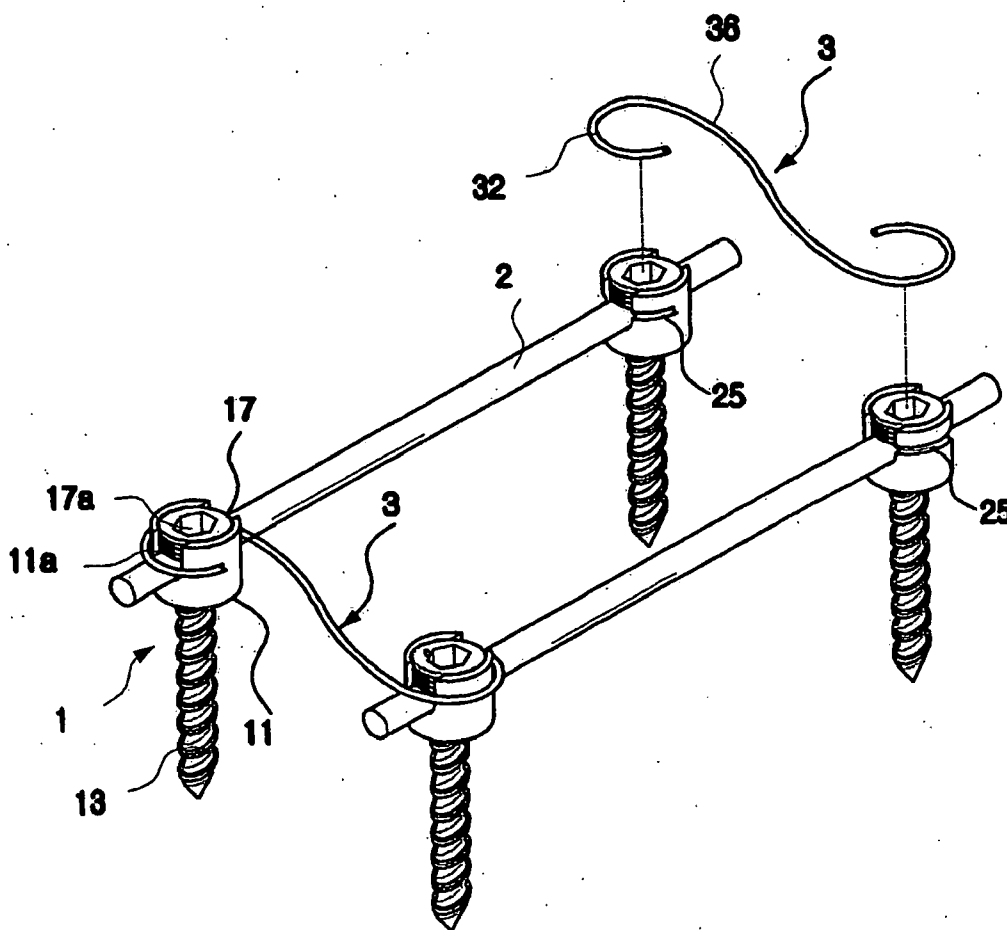


Fig. 15

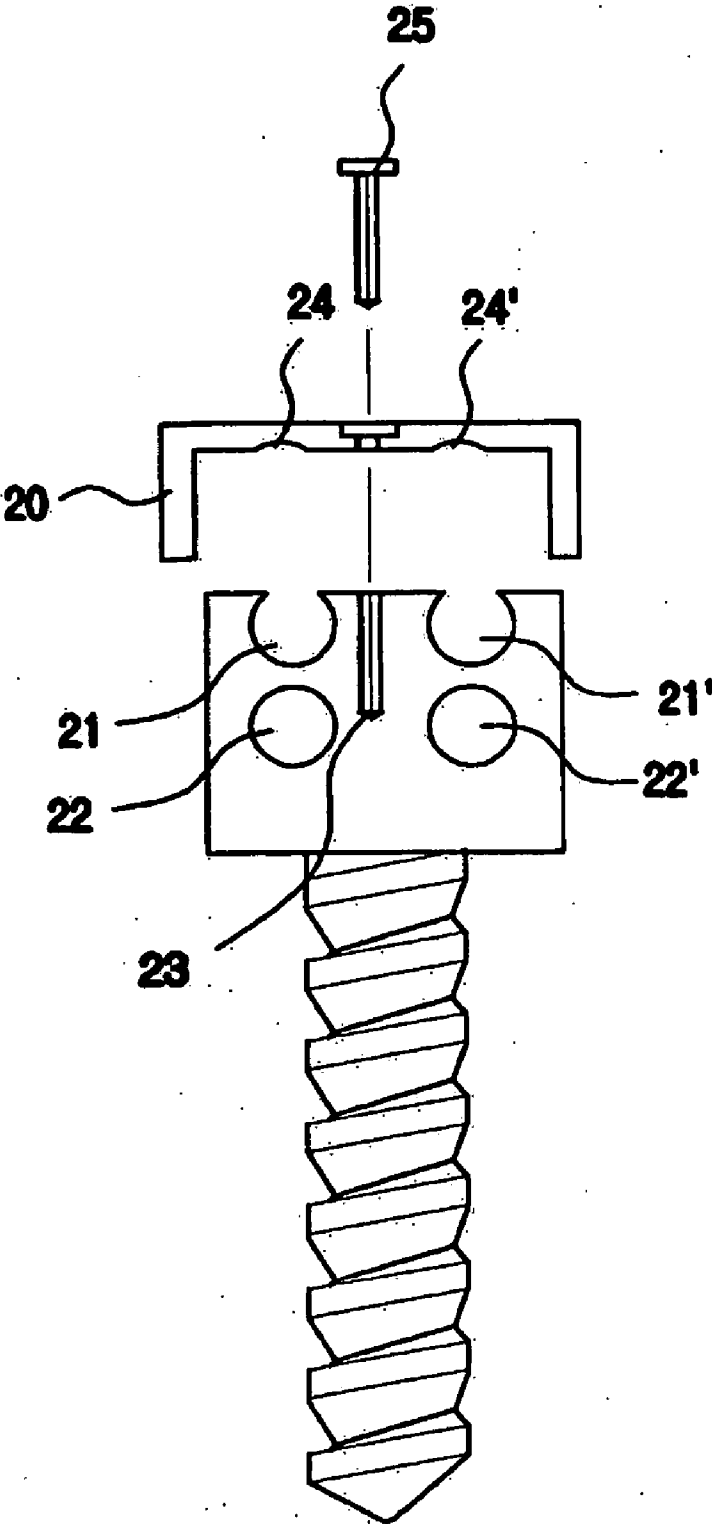


Fig. 16

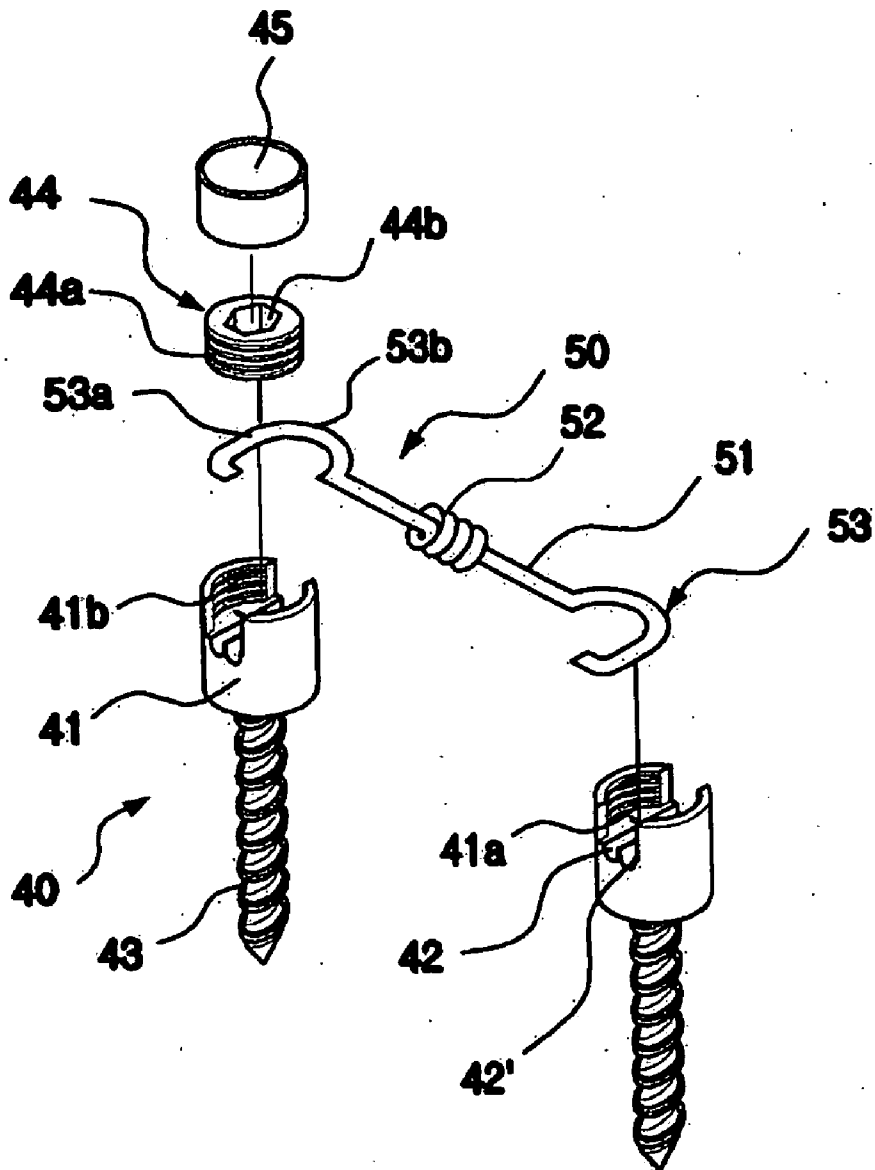


Fig. 17

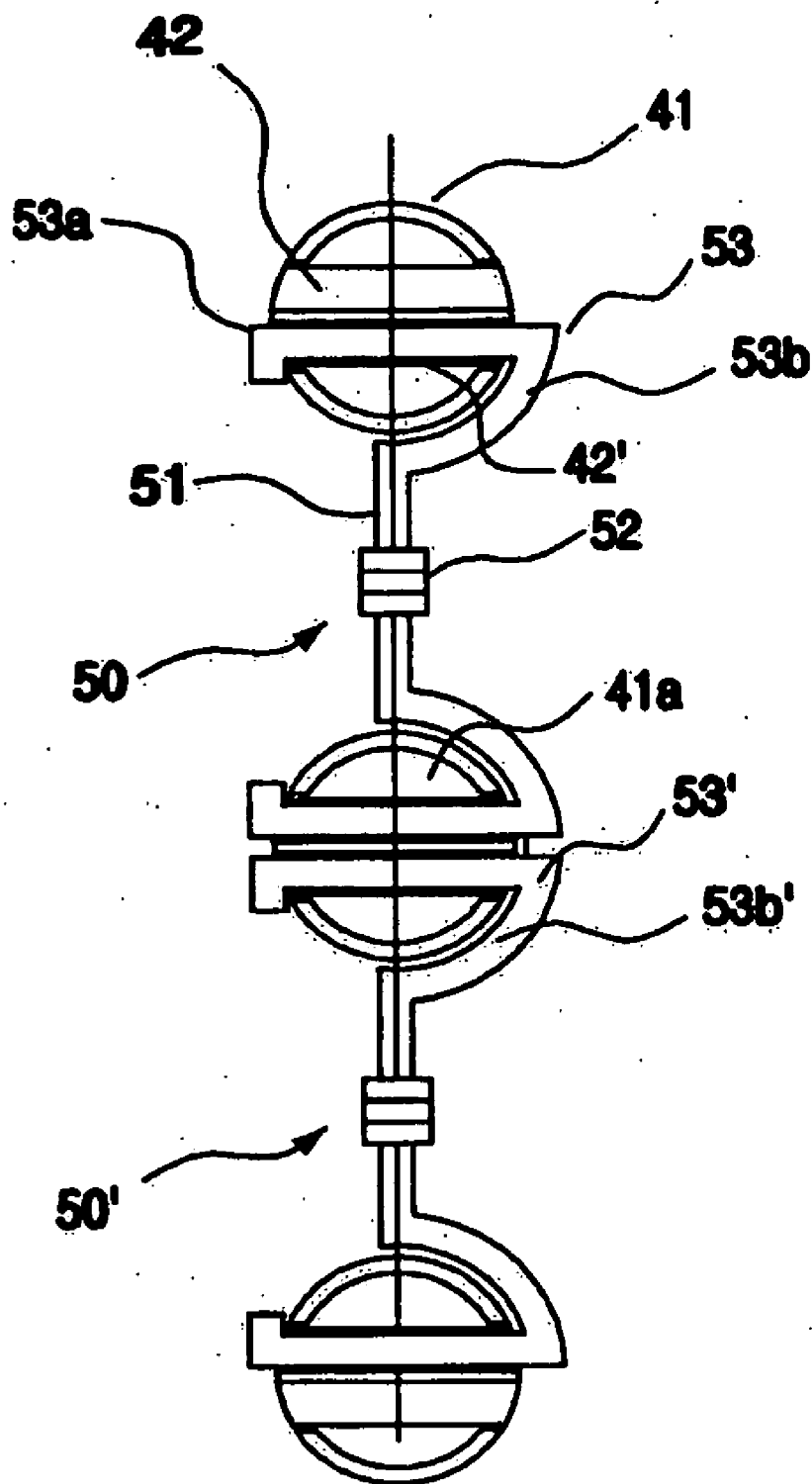


Fig. 18

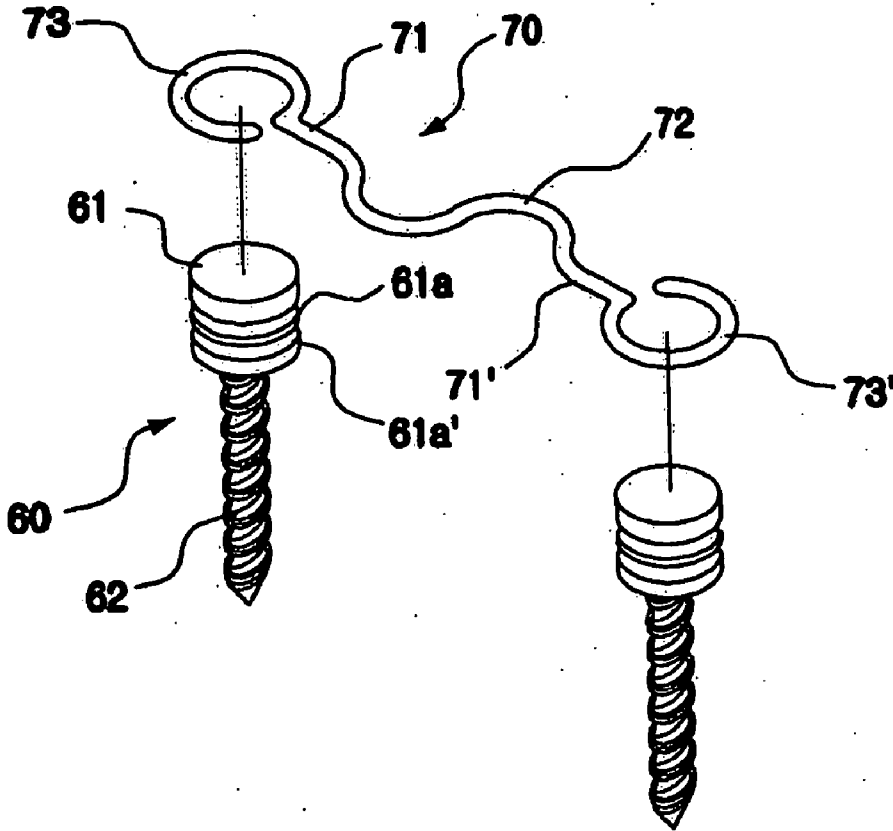


Fig. 19

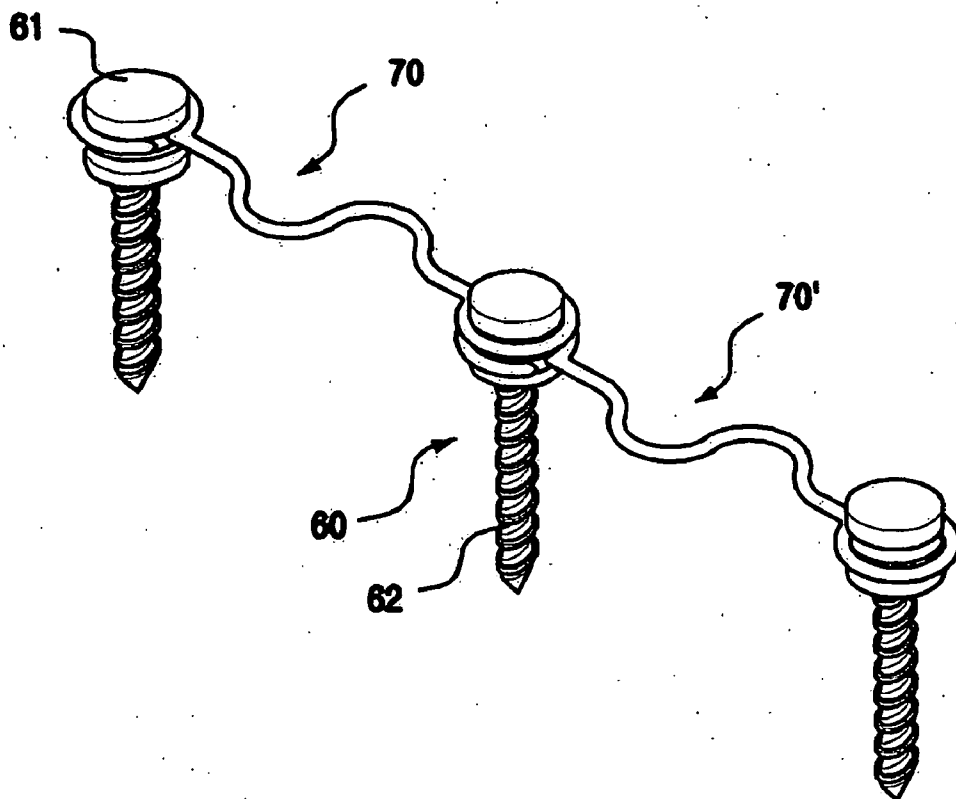


Fig. 20

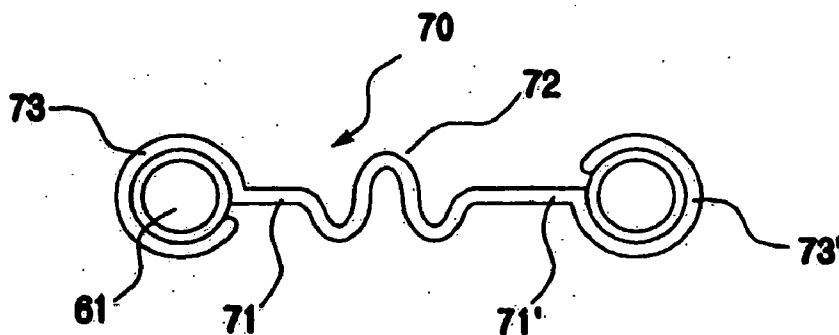


Fig. 21

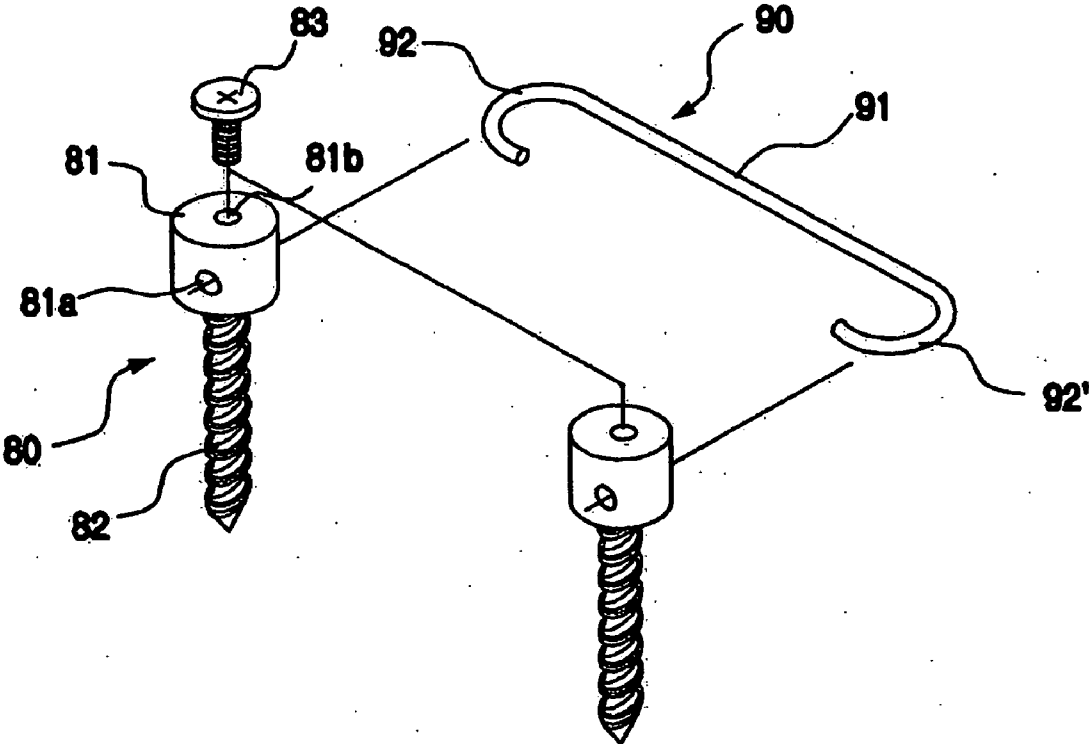


Fig. 22a

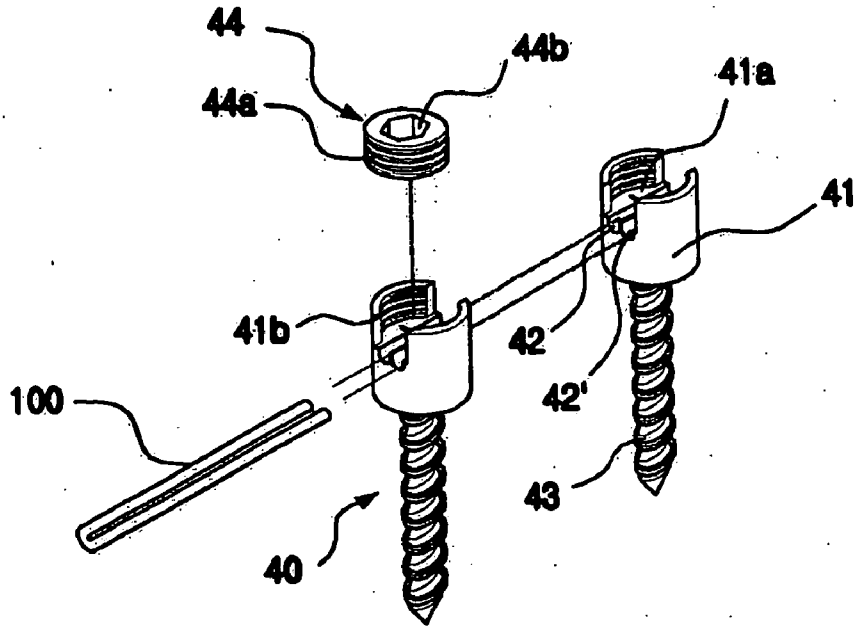


Fig. 22b

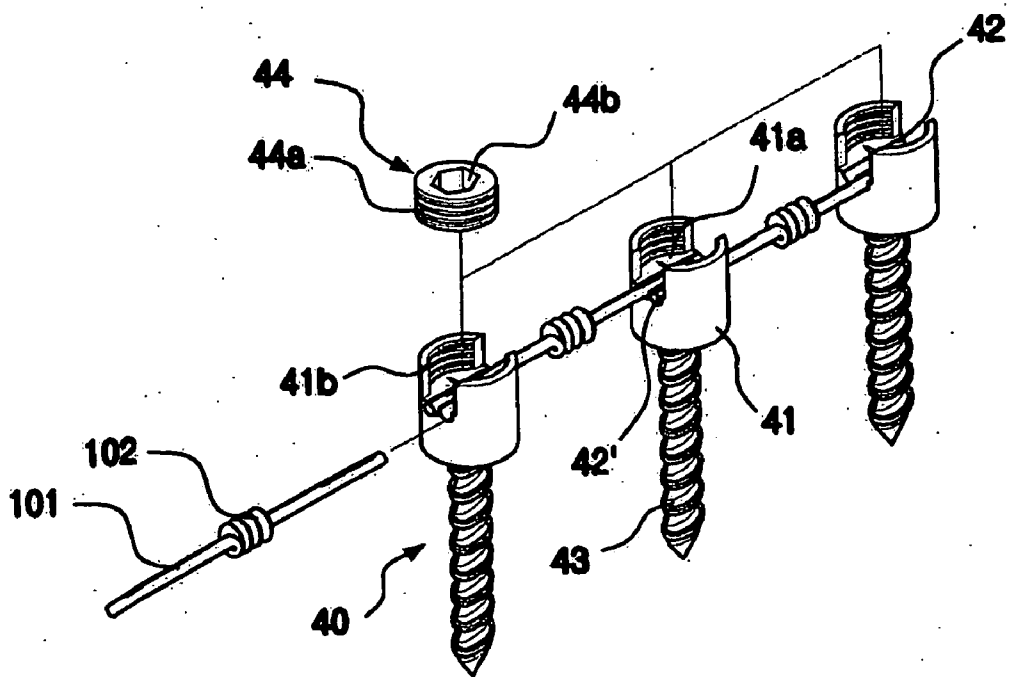


Fig. 23

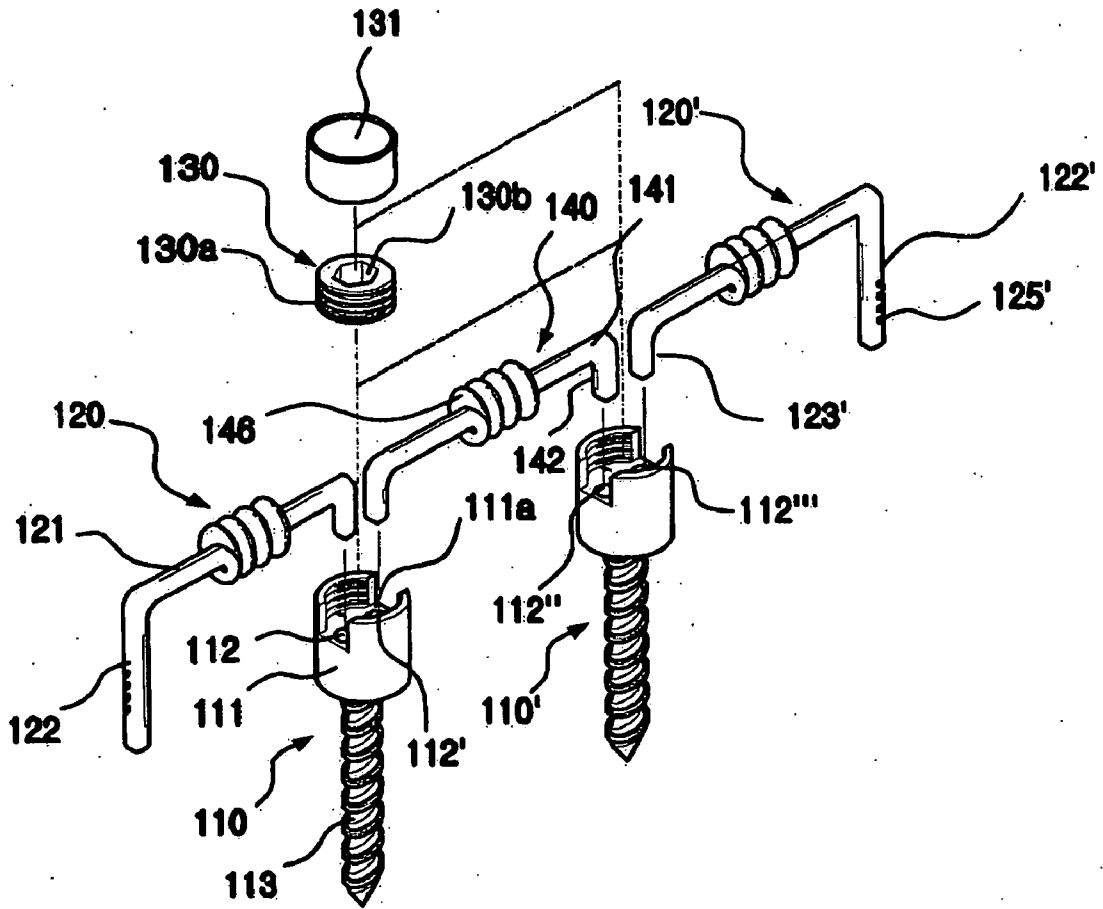


Fig. 24

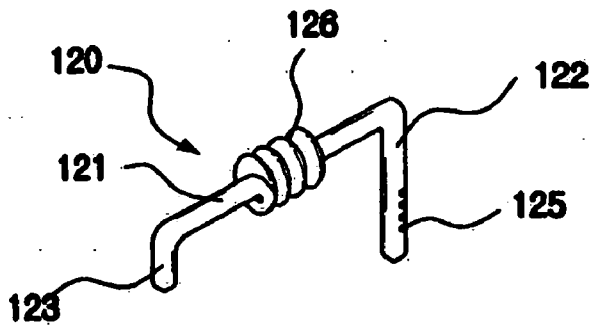


Fig. 25

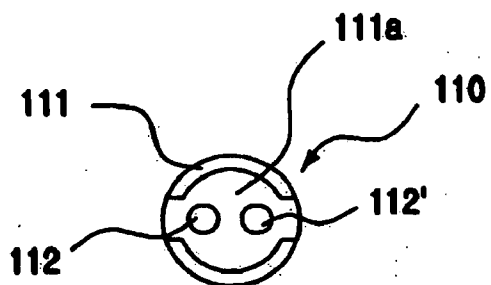


Fig. 26

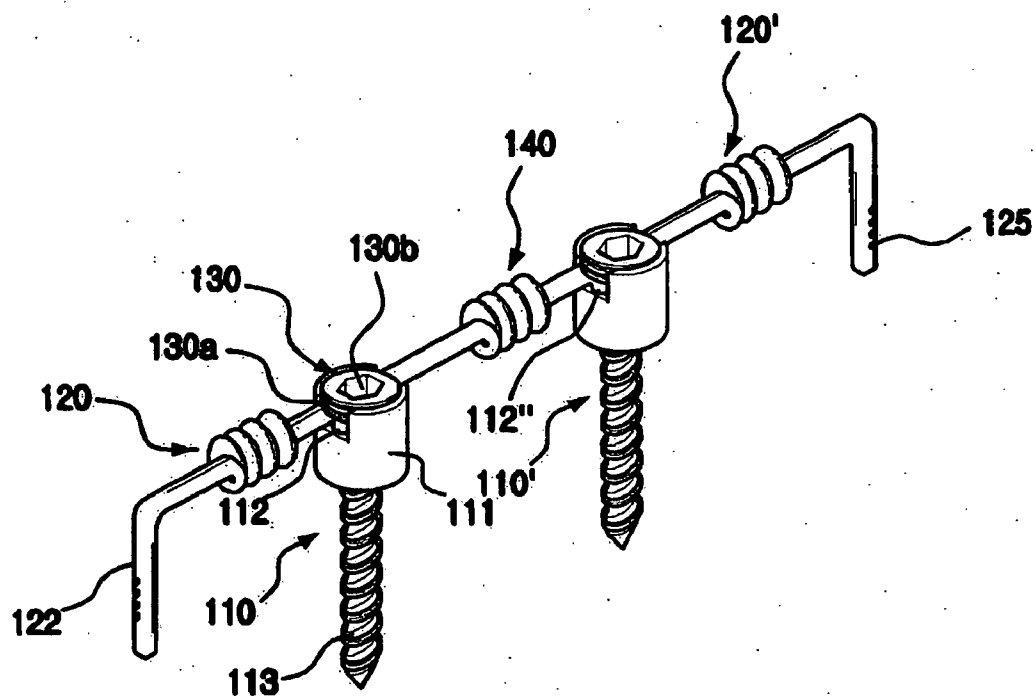


Fig. 27

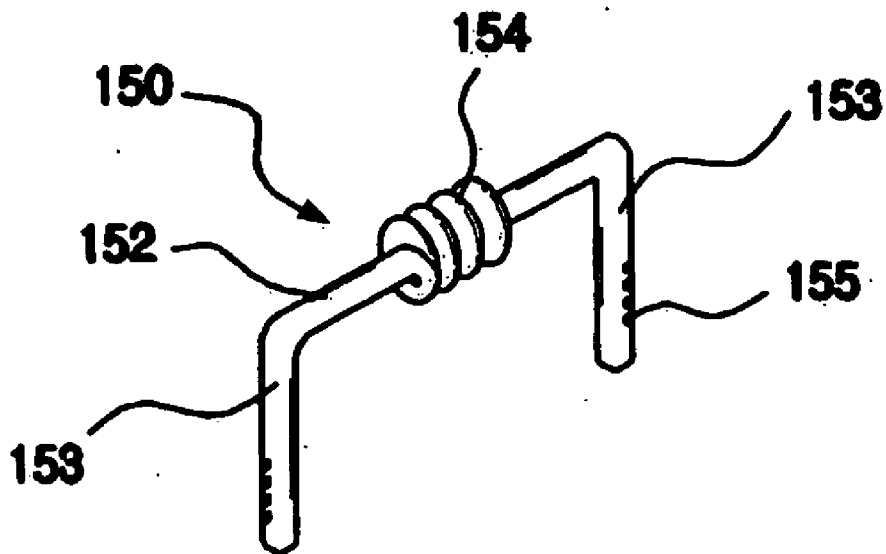
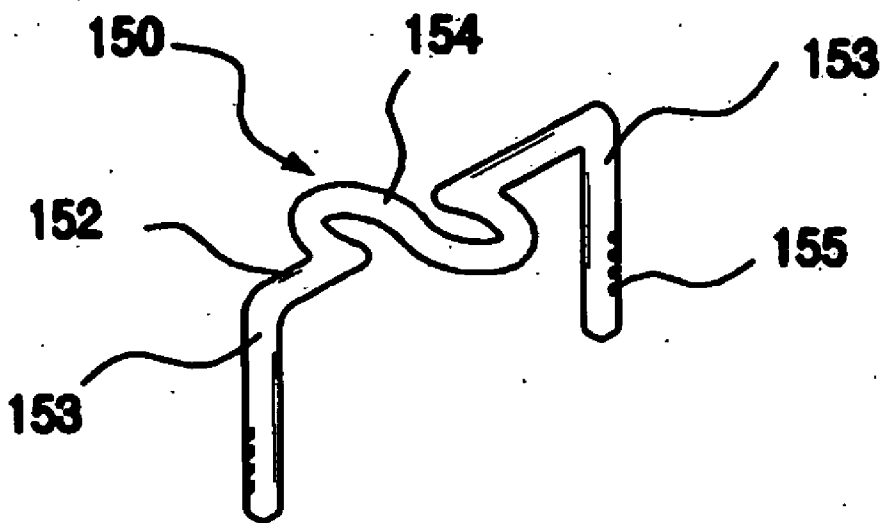


Fig. 28



SEMI-RIGID SPINAL FIXATION APPARATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in part of U.S. application Ser. No. 11/044,268 filed on Jan. 28, 2005, which claims priority under 35 USC § 119 of Korean Application No. 10-2004-0076105 filed on Sep. 22, 2004; Korean Application No. 10-2004-0076106 filed on Sep. 22, 2004; Korean Application No. 10-2004-0097833 filed on Nov. 26, 2004 and Korean Application No. 10-2004-0097834 filed on Nov. 26, 2004.

[0002] This application is also a continuation-in part of International Application NO. PCT/KR2004/003301 filed on Dec. 15, 2004 which claims priority from Korean Application No. 10-2004-0076105 filed on Sep. 22, 2004; Korean Application No. 10-2004-0076106 filed on Sep. 22, 2004; Korean Application No. 10-2004-0097833 filed on Nov. 26, 2004 and Korean Application No. 10-2004-0097834 filed on Nov. 26, 2004.

BACKGROUND OF THE INVENTION

[0003] 1. Field of the Invention

[0004] The invention relates to a spinal fixation apparatus which can correct and immobilize an injured or deformed human spine. More particularly, the invention relates to a spinal fixation apparatus for easily carrying out an operation on the spine, by using segment flexible rods.

[0005] 2. The Prior Art

[0006] Typically, the vertebra includes 24 bones (except for sacral vertebra) connected to each other through joint segments. Discs are disposed between the joint segments. This structure allows the vertebra to maintain posture and absorb shock. The vertebra is also essential for exercise and protects all internal organs from external shocks. However, the vertebra of the spine can be injured or wrenched by external environments, prolonged abnormal posture, anaplastia and other influences, which may induce serious back pain by pressing on the nerve system passing through the spine.

[0007] Patients sustaining injuries to the spine may be unable to participate in many activities of daily life, because the injured part of the spine is compressed by other adjacent parts of the spine. This spinal disorder requires surgical intervention to treat the pain which is induced in nerve roots by the compression and instability of the intervertebral joints.

[0008] As shown in FIG. 1, a conventional rigid spinal fixation apparatus includes a plurality of pedicle screws **200** which are respectively inserted through the pedicle into the injured or deformed vertebra. Each of the pedicle screws **200** may have a head **201** formed at a top portion thereof. The head **201** has a U-shaped rod passage **201a** and a female thread **201b** is formed on an inner surface thereof. A thread **202** is formed below the head **201** in order that the pedicle screws **200** can be implanted into the vertebra. A pair of longitudinal rods **250** are located in both laterals of the spine and coupled to the pedicle screws **200** for preventing a movement of the vertebra. A number of set screws **300**, each of which has a male thread and a wrench hole **300a** on an

upper surface thereof are inserted into the rod passage **201a** of the head **201** of the pedicle screw **200** for preventing a movement of the rod. A transverse link **400** is provided for holding the longitudinal rods **250**.

[0009] In the conventional rigid spinal fixation apparatus, the rods and the pedicle screws are described below with reference to the accompanying drawing.

[0010] As shown in FIG. 2, the thread **202** of the pedicle screws **200** is implanted into the vertebral body **500**. The rod **250** is then inserted into the rod passage **201a**. In this situation, the set screw **300** is joined to the female thread **201b** of the rod passage **201a**.

[0011] The set screw **300** is also joined to the rod passage **201a** by inserting it into a groove **300a** and turning it with a wrench on the top thereof. As a result, the bottom side of the set screw **300** compresses the top of the rod **250** within the rod passage **201a** of the pedicle screws **200**.

[0012] According to this assembly, the rod **250** is tightened up on the pedicle screw **200** to correct the diseased or injured vertebral body **500**. Each end of the transverse link **400** is coupled to a respective one of the pair of rods **250** and the transverse link **400** is laid across the rods **250** which are connected to the pedicle screws **200**. When a patient does a wrenched action toward his left or right side, the transverse link **400** prevents rotation and migration of the rod **250**.

[0013] In the conventional rigid spinal fixation apparatus, the rod **250** functions as a basic element to correct the vertebra. Therefore, the material and properties of the rod, such as elasticity, have a large effect on human body, as the rod is inseparably fused together with the vertebra. The conventional rod **250** may be made from a titanium alloy for medicine and is not elastic. It is very difficult to keep the line of his lumber normal since the vertebra segment is fused together with the rod to correct the vertebra bodies.

[0014] Various post operation problems may arise when using the conventional rigid spinal fixation apparatus. For example, after the vertebra is integrally fused together with the rod, the weight is concentrated upon the upper segment or the lower segment so that it will cause another vertebra stegnotic or instability of a lumbar vertebra within a few years after the vertebra fusion. Additionally, the rod of the conventional rigid spinal fixation apparatus can be broken and buried in the vertebra when a shock is inflicted upon the lumbar vertebra. Other complications attributable to the conventional rigid spinal fixation apparatus include pseudoarthrosis, adjacent segmental disease, abnormal load transmission and abnormal sagittal balance.

[0015] In the conventional rigid spinal fixation apparatus, the rod is made to have a normal spinal curvature shape without being related to a specific spinal shape of individual. This causes the difficulty of standardizing each single product and making various shapes, thereby increasing the cost of the product. Also, the conventional rod structure induces a series of bottlenecks in connecting the pedicle screw to the rod because the rod has a straight shape wherein individual spinal shapes differ from patient to patient. Therefore, if the pedicle screws are not fixed uniformly between the segments, it was very difficult to install the conventional straight rod on the pedicle screws. This is caused by the physical properties of the rod.

[0016] In the case of the conventional rigid spinal fixation apparatus, an operator must adjust a distance and direction of the pedicle screw based on the location of the rod by making the pedicle screw slanted. Also, the operator has to adjust an angle of the pedicle screw's head, using a polyaxial type screw, which can freely rotate a head around the screw in a range of predetermined angles and set the rod up thereon. The procedure using the conventional rigid spinal fixation apparatus requires great accuracy, because the operator must correctly grasp the location to install the pedicle screw and then make a hole in vertebra, placing a burden on the surgeon. Additionally, making the rod based on a curved shape of patient's vertebra and setting the location of pedicle screw require a substantial period of time.

[0017] To solve the problems of the conventional rigid spinal fixation apparatus, various types of the rods has been provided with elasticity.

[0018] An example of an elastic rod for connecting the pedicle screws is illustrated in Korean utility model No. 0,338,006. This rod comprises a rod body 601 and an elastic connection portion 603 formed in the middle of the rod body 601. As shown in FIG. 3, the elastic rod may be provided in various types, such as a semicircular ring, a coil spring, a bar type smaller than the diameter of the rod body, and the like.

[0019] The known elastic rods shown in FIG. 3 provide an elastic connection portion for the rod in order that the rod body can be bent. This structure is capable of giving fluidity to the rod in a predetermined range between the pedicle segments. However, the known rod structure results in a loss of the basic function of the spine correction since the elastic connection portion causes large movement. That is, the rod has to support and connect the spinal segments. In the above-mentioned structure, the pieces of the rod body are detachable so that they are freely movable in a given elastic range. Therefore, a secure connection between the spinal segments is not achieved.

[0020] A further disadvantage of the known rod structure is that when the pedicle screws are not aligned in a straight line, it is difficult to connect the rod to the pedicle screw.

[0021] FIG. 4 shows a perspective view of a conventional transverse link 400 for preventing the pedicle from a minute movement.

[0022] The conventional transverse link 400 comprises a fixed type housing 410 and a movable type housing 420 which are respectively hooked on both ends of the rod 250; a space bar 430 supported on the rod 250; and a set screw 440 connected with the fixed type housing 410 and the movable type housing 420 so that the space bar 430 is fixed to the rod 250.

[0023] The conventional fixed type housing 410 and movable type housing 420 shown in FIG. 4 respectively include half circle hooks 410a and 420a for connection on the rod 250; support holes 410b and 420b inserted into the both ends of the rod 250; and screw holes 410c and 420c into which set screws 440 are inserted.

[0024] The hook 410a of the conventional fixed type housing 410 is hooked on the rod 250 and then one end of the space bar 430 is inserted into the support hole 410b. The hook 420a of the conventional movable type housing 420 is

hooked on the rod 250 and then another end of the space bar 430 is inserted into the support hole 420b. The set screws 440 are joined to the screw holes 410c and 420c respectively, for securely tightening the rod 250 under the space bar 430.

[0025] In the conventional transverse link 400 structure, the inner diameter of the hook 410a is almost equal to that of the rod 250. Therefore, if one of the rods 250 is tilted or adjacent rods are not in parallel, the transverse link 400 cannot comply with such a declination or unbalance of the rods 250. In the case of declination or unbalance of the rods 250, the support holes 410a and 420a of the conventional fixed type housing 410 and conventional movable type housing 420 are also unbalanced and thus the space bar 430 cannot be inserted into the support holes 410b and 420b. If stress is put on the space bar 430 for fixation on the support holes 410b and 420b, the position of the conventional movable type housing 420 may be wrenched and distorted so that the rod 250 may be separated from the hook 420a of the conventional movable type housing 420. In this case, even if the set screw 440 is joined to the screw hole 430, it is impossible to securely support the space bar 430 upon the rod 250. This problem in the conventional transverse link 400 increases the time required for surgery. The conventional transverse link 400 may be omitted in cases where it is difficult to assemble, however, this omission may cause a defect in the surgery.

[0026] The known rigid spinal fixation systems provide fixation which allows little or no motion whatsoever. In operation of the known rigid spinal fixation systems, a single rod is used to adjust each section. This causes complications in that the pedicle screws inserted into each section are not always aligned, thus leaving no option except bending the rod.

[0027] Accordingly, a need exists for a semi-rigid spinal fixation apparatus which can provide dynamic fixation allowing for movement or motion. A need further exists for a semi-rigid spinal fixation apparatus employing a segmental connection method which allows for the connecting of individual rod segments to each section of the apparatus, thereby eliminating the need to bend the rod in the event that the pedicle screws are not aligned.

SUMMARY OF THE INVENTION

[0028] To solve the problems of the known spinal fixation devices, a primary object of an embodiment of the present invention is to provide a spinal fixation apparatus which can easily and simply achieve a connection between pedicle screws and a rod during surgery, even if the pedicle screws are slightly out of alignment.

[0029] Another object of an embodiment of the present invention is to provide a semi-rigid spinal fixation apparatus which has enough strength to correct the spine during restoration from an elastic force so that the spinal fixation apparatus gives flexible behavior to correct vertebral segments.

[0030] A further object of an embodiment of the invention is to provide a semi-rigid spinal fixation apparatus which provides for segmented connection of pedicle screws and eliminates the need for bending of a rod.

[0031] Further, another object of an embodiment of the present invention is to provide a staple type rod which is

made from a shape memory alloy. The staple type rod of the present invention can easily and simply perform a vertebra correction operation and reduce the number of parts being implanted directly into selected vertebra without a pedicle screw.

[0032] In one aspect, a semi-rigid spinal apparatus according to an embodiment of the invention includes a first pedicle screw array and a second pedicle screw array disposed substantially parallel to the first pedicle screw array. A first rod array is associated with the first pedicle screw array and a second rod array is associated with the second pedicle screw array.

[0033] Each of the first pedicle screw array and the second pedicle screw array include a plurality of pedicle screws for joining to vertebrae of a spine. Each pedicle screw includes a head portion having a plurality of receptacles and a leg portion having a male thread for implanting into a vertebra.

[0034] Each of the first rod array and second rod array include a plurality of rod segments and each rod segment includes a first end coupled to a first receptacle on a first pedicle screw and a second end coupled to a second receptacle on a second pedicle screw adjacent to the first pedicle screw.

[0035] In another aspect, a semi-rigid spinal apparatus according to an embodiment of the invention includes a first pedicle screw, a second pedicle screw and a third pedicle screw. Each of the first, second and third pedicle screws include a head portion having a plurality of receptacles and a leg portion having a male thread for implanting into a vertebra.

[0036] A first rod segment includes a first end coupled to a first receptacle associated with the first pedicle screw and a second end coupled to a first receptacle associated with the second pedicle screw. A second rod segment includes a first end coupled to a second receptacle associated with the second pedicle screw and a second end coupled to a first receptacle associated with the third pedicle screw.

[0037] In accordance with another aspect of an embodiment of the present invention, a spinal fixation apparatus is provided comprising: a plurality of pedicle screws, each of which has a head formed at a top portion thereof and a thread formed below the head to be implanted into a pedicle of a vertebra. The head has a reception cavity and at least one rod groove on a bottom surface of the reception cavity. A pair of rods is connected to the pedicle screws for preventing a movement of the vertebra. The rods have an elasticity section therein and are mounted on the rod groove in the reception cavity. At least one transverse link having an elasticity section in a straight member and hooks extending from both ends of the straight member is provided for rigidly holding the pair of rods. A plurality of set screws, each of which is rigidly inserted into the reception cavity of the head, prevent movement of the rods. The rods and/or the transverse link may be made from a shape memory alloy which can be deformed at a predetermined temperature.

[0038] In accordance with another aspect of an embodiment of the present invention, a spinal fixation apparatus is provided comprising a plurality of pedicle screws, each of which has a head formed at a top portion thereof and a thread formed below the head to be implanted into a pedicle of a vertebra. The head has a first rod groove formed in a bottom

surface of the head. A plurality of head caps is provided for covering the head of the pedicle screw. The head caps have a second rod groove formed on an inner surface thereof. A pair of rods surrounded by the first rod groove of the head and the second rod groove of the head cap prevent movement of the vertebra. The rods have an elasticity section therein. At least one transverse link which has an elasticity section in a straight member and hooks extended from both ends of the straight member is provided for rigidly holding the pair of rods. A plurality of fixing means, each of which tightens the head cap to the head of the pedicle screw, are inserted into the reception cavity of the head of the pedicle screws for preventing movement of the rod. The rods and/or the transverse links may be made from a shape memory alloy which can be deformed at a predetermined temperature.

[0039] In accordance with another aspect of an embodiment of the present invention, a spinal fixation apparatus is provided comprising a plurality of pedicle screws, each of which has a head formed at a top portion thereof and a thread formed below the head to be implanted into a pedicle of a vertebra. The head has a reception cavity and two parallel rod grooves in a bottom surface of the reception cavity. A pair of rods is connected to the pedicle screws for preventing movement of the vertebra. The rods may be made of shape memory alloy which can be transformed at a designated temperature. The rods include a straight bar placed in line with a center of the heads, an elastic section formed in the straight bar, support bars having bending portions extending from both ends of the straight bar and bent along an outer surface of the head, and line portions extended from both ends of the bending portions and put in the rod grooves. A plurality of set members, each of which is inserted into the reception cavity of the head of the pedicle screws, prevent movement of the rods.

[0040] In accordance with still another aspect of an embodiment of the present invention, a spinal fixation apparatus is provided comprising a plurality of pedicle screws, each of which has a head formed at a top portion thereof, and a thread formed below the head to be implanted into a pedicle of a vertebra. The head has at least one circular groove on an outer surface thereof. A pair of rods is connected to the pedicle screws for preventing movement of the vertebra. Each of the rods has a straight bar placed in line with a center line of the heads, an elastic section formed in the straight bar, and support rings wound on the circular grooves of the heads. The rods may be made from a shape memory alloy which can be deformed at a predetermined temperature.

[0041] In accordance with still another aspect of an embodiment of the present invention, a spinal fixation apparatus is provided comprising a plurality of pedicle screws, each of which has a head formed at a top portion thereof, and a thread formed below the head to be implanted into a pedicle of a vertebra. The head has a horizontal opening passing through a head body and a perpendicular thread hole to receive a fixing means. A pair of rods is connected to the pedicle screws for preventing movement of the vertebra. The rods have a straight bar and hooks extending from both ends of the straight bar which are bent to be inserted into the horizontal openings. The rods may be made from a shape memory alloy which can be deformed at a predetermined temperature. A plurality of fixing means are

coupled to the perpendicular thread hole of the head for preventing movement of the rod.

[0042] In accordance with still another aspect of an embodiment of the present invention, a spinal fixation apparatus is provided comprising a plurality of pedicle screws, each of which has a head formed at a top portion thereof and a thread formed below the head to be implanted into a pedicle of a vertebra. The head has a reception cavity and two parallel rod grooves in a bottom surface of the reception cavity. A pair of rods is connected to the pedicle screws for preventing movement of the vertebra. Each of the rods has a "U" shape. The rods may be made from a shape memory alloy which can be deformed at a predetermined temperature. A plurality of set members, each of which is inserted into the reception cavity of the head of the pedicle screws, prevent a movement of the rod.

[0043] In accordance with still another aspect of an embodiment of the present invention, a spinal fixation apparatus is provided comprising at least one pedicle screw which has a head at a top portion thereof and a thread formed below the head to be implanted into a pedicle of a vertebra. The head has a reception cavity and two parallel sockets formed in a bottom of the reception cavity. A pair of staple rods is connected to the pedicle screws for preventing movement of the vertebra. One side of each of the rods is directly implanted into a pedicle of the vertebra and the other side is inserted into one of the sockets. At least one set member is inserted into the reception cavity of the head of the pedicle screws for preventing movement of the rod.

[0044] In accordance with still another aspect of an embodiment of the present invention, a spinal fixation apparatus is provided comprising at least one staple rod having a bridge member for providing a space between a selected vertebra and an adjacent vertebra. An elastic section and a spike member to be implanted into the pedicle of a vertebra are formed in the bridge member. The spike member extends downwardly from both ends of the bridge member. The rod may be made from a shape memory alloy which can be deformed at a predetermined temperature.

[0045] In accordance with still another aspect of an embodiment of the present invention, a spinal fixation apparatus is provided comprising a plurality of pedicle screws having a head part and a pair of rods for connecting the pedicle screws. The rods are in a first structure at a first temperature range and are in a second structure at a second temperature range, wherein the second structure is a memorized shape of a shape memory alloy. The rods provide a handling margin in the first structure so that the rods of the memorized shape are tighter than those of the first structure. The head part has a fixating means for securely fixing the rod. The end parts of the rod are joined to the fixating means.

[0046] In accordance with still another aspect of an embodiment of the present invention, a spinal fixation apparatus is provided comprising first and second pedicle screw arrays perpendicularly arranged, substantially being in parallel to each other. Each of the first and second pedicle screw arrays includes a plurality of pedicle screws joined to vertebrae of human spine. Each pedicle screw includes a head having a plurality of reception means and a male thread formed on a leg part to be implanted into the vertebrae. First and second rod arrays are provided, respectively connected to the first and second pedicle screw arrays. Each of the first

and second rod arrays includes a plurality of segment rods. An end of each of the segment rods is safely secured to one of the plurality of reception means. The segment rods may be a shape memory alloy.

[0047] An advantage of a semi-rigid spinal fixation apparatus according to an embodiment of the invention is that a dynamic apparatus is provided which allows motion. Such motion results from a configuration of the rod which may include an elastic section having a spiral or spring shape.

[0048] Another advantage of a semi-rigid spinal fixation apparatus according to an embodiment of the invention is that the apparatus may employ a segmental connection method wherein individual rod segments are coupled to each pair of adjacent pedicle screws. Such a segmental connection method eliminates the need for bending of the rod. Additionally, an arrangement according to an embodiment of the invention also has the advantage of simplifying a subsequent operation on damaged adjacent spinal segments as it is unnecessary to tamper with or disturb prior segments that have been operated on and only the damaged adjacent segments are the subject of the subsequent operation.

[0049] A further advantage of a semi-rigid spinal fixation apparatus according to an embodiment of the invention is that the apparatus is particularly advantageous for operations requiring fusion.

[0050] A further advantage of a semi-rigid spinal fixation apparatus according to an embodiment of the invention is that the apparatus may be adapted in terms of stiffness or flexibility to achieve the goals of different types of spinal operations by choosing a suitable material, rod diameter and rod elastic section configuration.

BRIEF DESCRIPTION OF THE DRAWINGS

[0051] Other objects and benefits of the present invention will become apparent upon consideration of the following written description taken in conjunction with the following figures:

[0052] FIG. 1 is a perspective view illustrating a conventional spinal fixation apparatus;

[0053] FIG. 2 is a perspective view illustrating a conventional spinal fixation apparatus applied to the lumbar spine;

[0054] FIG. 3 is a plan view illustrating various forms of conventional rods;

[0055] FIG. 4 is a perspective view illustrating a conventional transverse link applied to the rods;

[0056] FIG. 5 is a perspective view illustrating a spinal fixation apparatus according to an embodiment of the present invention;

[0057] FIG. 6 is a perspective view illustrating an assembly of the spinal fixation apparatus shown in FIG. 5;

[0058] FIG. 7 is a cross-section view taken along A-A line shown in FIG. 6;

[0059] FIG. 8 is a plan view illustrating another form of a rod according to an embodiment of the present invention;

[0060] FIG. 9 is a sectional view illustrating a pedicle screw according to an embodiment of the present invention;

[0061] FIG. 10 is a plan view illustrating a serial connection of the rods and the pedicle screws shown in FIG. 9;

[0062] FIG. 11 is a perspective view illustrating a transverse link applied to the rods according to an embodiment of the present invention;

[0063] FIG. 12 is a front view illustrating a connection between the transverse link and rods;

[0064] FIG. 13*a* is a perspective view illustrating another form of a rod;

[0065] FIG. 13*b* is a plan view illustrating another form of a rod;

[0066] FIG. 14 is a perspective view illustrating a connection between the transverse links and a head of the pedicle screw;

[0067] FIG. 15 is a front view illustrating a spinal fixation apparatus according to another embodiment of the present invention;

[0068] FIG. 16 is a perspective view illustrating a spinal fixation apparatus according to another embodiment of the present invention;

[0069] FIG. 17 is a plan view illustrating a serial connection of the rods to a head of a pedicle screw shown in FIG. 16;

[0070] FIG. 18 is a perspective view illustrating a spinal fixation apparatus according to another embodiment of the present invention;

[0071] FIG. 19 is a perspective view illustrating a serial connection of the rods to a head of a pedicle screw shown in FIG. 18;

[0072] FIG. 20 is a plan view illustrating an assembly of spinal fixation apparatus shown in FIG. 18;

[0073] FIG. 21 is a perspective view illustrating a spinal fixation apparatus according to another embodiment of the present invention;

[0074] FIGS. 22*a* and 22*b* are perspective views illustrating a spinal fixation apparatus according to another embodiment of the present invention;

[0075] FIG. 23 is a perspective view illustrating a spinal fixation apparatus according to another embodiment of the present invention;

[0076] FIG. 24 is a perspective view illustrating a staple rod according to an embodiment of the present invention;

[0077] FIG. 25 is plan view illustrating a pedicle screw in the seventh embodiment of the present invention;

[0078] FIG. 26 is a perspective view illustrating a serial connection of the stapling rods to a head of the pedicle screw shown in FIG. 23;

[0079] FIG. 27 is a perspective view illustrating a spinal fixation apparatus according to another embodiment of the present invention; and

[0080] FIG. 28 is a perspective view illustrating another form of the staple rod.

DETAILED DESCRIPTION OF THE DRAWINGS

[0081] Hereinafter, the present invention will be described in detail referring to the accompanying drawings. A spinal fixation apparatus according to embodiments of the present invention can easily correct injured spines by using rods and/or transverse links. The rods may be made from a titanium alloy, a shape memory alloy or any other suitable material. The transverse links are preferably made from Nitinol alloy (Ni—Ti alloy) which has superelastic characteristics.

[0082] Various embodiments of the invention will be described in detail referring to FIGS. 5 to 14.

[0083] According to one embodiment of present invention, a spinal fixation apparatus includes a plurality of pedicle screws 1 implanted into the patient's vertebra; a pair of rods 2 located in both laterals of the spine and connected to the pedicle screws for preventing a movement of the vertebra; and a number of transverse links 3 for providing space between the rods.

[0084] Referring now to FIGS. 5 to 7, the pedicle screw 1 comprises a head 11 formed at a top portion thereof and a thread 13 formed below the head to be implanted into the vertebra. The head 1 has a reception cavity 11*a* to receive the rod 2 and at least one rod groove 12 at the bottom of the reception cavity 11*a*. A diameter of the rod groove 12 corresponds to that of the rod 2.

[0085] The rod 2 has a rod body 15 which is bent and then has a hook shape at both ends thereof and the rod 2 has an elasticity or elastic section 16 formed in the middle of the rod body 15 to generate an elastic force corresponding to a shock which is inflicted on the patient's vertebra.

[0086] The elastic section 16 may be made of a coil spring. The coil spring may be equal to the rod body 15 in diameter. Another form of the elastic section 16 is shown in a wave shape as shown in FIG. 8. The flexibility and stiffness of a rod according to an embodiment of the invention may be adjusted by adjusting the diameter of the rod and/or adjusting the configuration of the elastic section 16 of a rod. For example, the distance between coils of a coil shaped elastic section may be increase or reduced to adjust the flexibility/stiffness of the rod 2.

[0087] The diameter of the rod is approximately in a range of 2 to 7 mm and it can be adjusted on a basis of unit diameter of 0.5 mm. When the stiffness of a 6 mm titanium rigid straight rod is said to be 100, a 4 mm titanium rigid straight rod would have a stiffness of 60. At this level, the 4 mm rod would be characterized as semi-rigid. Due to an elastic section included in rod segments according to embodiments of the invention, rod segments according to embodiments of the invention have even less stiffness than straight rods and may be characterized as flexible.

[0088] There is an inverse relationship between flexibility and stiffness, as one increase the other decreases. In the case of known rigid spinal fixation systems having 6 mm titanium rods, the system has only stiffness making motion of the effected spinal segments impossible. In the case of a spinal fixation system according to an embodiment of the invention, secured fixation, suitable body motion and durability can be achieved by varying the degree of flexibility. In particular, the desired characteristics can be met by selecting

the proper material, rod diameter and elastic section configuration. For example, a study indicated that when a rod diameter was increased by 0.25 mm, the rod stiffness rose by 14.5-17.17% and when a direction of the rod spring or elastic section moved from back to front, the stiffness rose 17.34%.

[0089] The elastic section **16** serves as a buffer between spinal segments when the pedicle screw **1** is fused together with the spine. That is, when a patient bends or wrenches his waist or a shock is inflicted on his waist, the elasticity section **16** can alleviate stimuli which are caused by patients' activities or the external shock.

[0090] A set screw **17** is inserted into the reception cavity **11a** of the head **11** of the pedicle screws **1** for preventing a movement of the rod **2**. The set screw **17** has an outer thread **17a** for securely tightening the rod **2** and a recess **17b** having a hexagonal cross-section view on the upper portion thereof so that the set screw **17** is inserted into the reception cavity **11a** of the head **11**. The length of the set screw **17** should be short enough not to protrude from the upper surface of the reception cavity **11a** of the head **11**.

[0091] The reception cavity **11a** of the head **11** also has an inner thread **11b** to be joined to the outer thread **17a** of the set screw **17**.

[0092] The head **11** of the pedicle screw **1** has a rod fixing recess **14** for tightening an end of the rod **2**. The rod **2** is inserted into the reception cavity **11a** and is put into the rod groove **12** as the end of the rod is tightly inserted into the rod fixing recess **14**.

[0093] The rod fixing recess **14** and the rod **2** may have the same diameter or the diameter of the rod fixing recess **14** may be slightly larger than that of the rod **2**.

[0094] A head cap **18** can be adopted on the upper portion of the head **11** to eliminate the change from a misaligned fixation of the set screw **17**. Since the head cap **18** provides an additional support to improve the rod holding power, this can be used as an additional rod such as a fastening element. The head cap **18** is additionally set as needed, and may not be essential.

[0095] The head **11** of the pedicle screw **1** may include two rod grooves **12** and **12'** and two rod fixing recess **14**, **14'**, as shown in FIG. 9. According to this structure, it is able to serially set the rods **2** without using an additional connector by inserting the rods **2** and **2'** into the rod grooves **12** and **12'** alternately, as shown in FIG. 10.

[0096] The pedicle screws **1** of a semi-rigid spinal fixation apparatus according to an embodiment of the invention may be arranged in a first pedicle screw array and a second pedicle screw array disposed substantially parallel to the first pedicle screw array. The rods may be arranged in a first rod array associated with the first pedicle screw array and a second rod array associated with the second pedicle screw array.

[0097] Each of the first and second pedicle screw array includes a plurality of pedicle screws **1** for joining to vertebrae of a spine. Each pedicle screw **1** has a head portion **11** having a plurality of receptacles and a leg portion **13** having a male thread for implanting into a vertebra.

[0098] As shown for example in FIGS. 10, 19 and 22b, each of the first rod array and second rod array comprise a

plurality of rod segments, each rod segment of said plurality of rod segments comprising a first end coupled to a first receptacle of said plurality of receptacles on a first pedicle screw of said plurality of pedicle screws and a second end coupled to a second receptacle of said plurality of receptacles on a second pedicle screw of said plurality of pedicle screws, said first pedicle screw being adjacent to said second pedicle screw.

[0099] The plurality of receptacles in the head of a pedicle screw according to various embodiments of the invention may be in the form of rod grooves **12**, **12'** (FIG. 9), parallel rod grooves **42**, **42'** (FIG. 16), circular grooves **61a**, **61a'** (FIG. 18) or any other structure suitable for coupling to an end of a rod segment.

[0100] The pedicle screws in a semi-rigid spinal fixation apparatus according to an embodiment of the invention may include a first pedicle screw, a second pedicle screw and a third pedicle screw, as shown, for example in FIGS. 10, 17, 19 and 22b. Each pedicle screw included a head portion having a plurality of receptacles and a leg portion having a male thread for implanting into a vertebra.

[0101] As shown, for example in FIGS. 10, 17, 19 and 22b a first rod segment has a first end coupled to a first receptacle of associated with the first pedicle screw and a second end coupled to a first receptacle associated with the second (middle) pedicle screw. A second rod segment has a first end coupled to a second receptacle associated with the second pedicle screw and a second end coupled to a first receptacle associated with the third pedicle screw.

[0102] The rod or rod segments according to various embodiment of the invention can be formed in a straight bar shape or a right angle bar shape which is perpendicular to both ends of the rod body. In such a modified rod, the structure of the pedicle screw **1** may be formed with a single rod groove without a rod fixing recess **14**. Additionally, it may be employed in different structures of the pedicle screw corresponding to the modified rod. Furthermore, the modified rod **2** is securely fixed by the set screw **17** within the reception cavity **11a** of the head **11**.

[0103] A transverse link **3** will be described in detail referring to FIGS. 11 and 12. The transverse link may extend between a first rod segment associated with the first rod array and a second rod segment associated with the second rod array.

[0104] The transverse link **3** may include one straight member **31** and two hooks **32** which are respectively extended and bent from both ends of the straight member **31**. The transverse link **3** may be formed as a rectangular plate. The length of the transverse link **3** is approximately in a range of 20 to 80 mm and it can be adjusted on a basis of unit length of 2 mm. As shown in FIG. 12, the transverse link **3** keeps a space between the rods **2** and **2'** by grasping the rods **2** and **2'** through the hooks **32**. Here, the transverse link **3** of a plate shape has strength to maintain the space between the rods **2** and **2'** even if an external force is applied to the rods **2** and **2'** and the rods **2** and **2'** are then wrenched.

[0105] FIG. 13a and FIG. 13b are views illustrating transverse links which are different from that of FIG. 11. That is, an elastic or elasticity section **33** is formed in the middle of a straight member **31**. The elasticity section **33** has a coil spring as shown in FIG. 13a or a wave shape as shown in

FIG. 13*b*. The elasticity section 33 of the transverse link 3 absorbs a load which is applied to the rod 2.

[0106] FIG. 14 illustrates an S-shaped transverse link 3 which is different from that of FIG. 11. The S-shaped transverse link 3 includes one bending member 36 and two hooks 32 which are horizontally extended and bent from both ends of the bending member 36 for holding the head 11 of the pedicle screw 1. A slit 25 is provided on the circumference of the head 11 of the pedicle screw 1 in order to insert the hooks 32 of the S-shaped transverse link 3 into the head 11.

[0107] The rods 2 and 2' may be made from a titanium material, from a shape memory alloy causing deformation at a specific temperature, or from any suitable material. The transverse links are preferably, but not necessarily, made from a shape memory alloy. For example the rods 2 and 2' and/or the transverse links 3 may have a temperature characteristic that they are in a martensite phase at a temperature of +10 degree C. and below and in an austenite phase at a temperature of more than +35 degree C. to return back to a memorized original shape. In particular, the deformed shape is kept unchanged up to +26 degree C. and the memorized shape is gradually restored by a heat treatment up to +35 degree C.

[0108] In an embodiment of the invention, the rods 2 and 2' and/or the transverse link 3 are obtained by performing a heat treatment at a temperature of 650 degree C. to 750 degree C. for one hour or so, after forming the hooks and elastic section at both ends and the middle section of the shape memory material, respectively. Thus, the rods 2 and 2' and the transverse link 3 can have a deforming characteristic at a specific temperature.

[0109] An installation procedures for an embodiment of the present invention is described in detail as follows:

[0110] The pedicle screws 1 are implanted into a selected pedicle of the vertebrae in a predetermined angle and depth. At this time, that is not considered configuration of screws that are not well aligned in general. The elastic section 16 of the rod 2 is lengthened by deforming the rod 2 at a temperature of +10 degree C. and below so that the rod 2 is easily set into the reception cavity 11*a* of the head 11 of the pedicle screw 1, before the rod 2 is inserted into the reception cavity 11*a* of head 11 for coupling the rod 2 to the plurality of the screws 1. Then, the end of the rod 2 having a hook shape is inserted into the rod fixing recess 14, while a deformed straight member (the rod body 15) of the rod 2 is inserted to the rod groove 12 which is formed in the bottom of the reception cavity 11*a* of head 11. The outer thread 17*a* of the set screw 17 is downwardly joined to the reception cavity 11*a* of the head 11 so that the set screw 17 is tightly fixed to the inner thread 11*b* of the reception cavity 11*a* using a wrench tool. The rod 2 is pressed by the set screw 17 and the rod 2 is securely and rigidly fixed to the pedicle screw 1.

[0111] After the installation of the rods 2, a heat treatment is applied to the rod 2 at a temperature of more than +35 degree C. using a surgical heating source. Thus, the lengthened elastic section 16 of the rod 2 is shrunk and returns back to the memorized original shape in the transforming austenite phase. At this time, the end of the hook-shaped rod is rigidly fixed to the rod fixing recess 14 of the head 11

while the rod 2 is returning back to the memorized original shape. Thus, both ends of the rod 2 are fixed to the rod fixing recess 14 of the head 11 without any separation.

[0112] According to the embodiment described above, although the pedicle screws are not well aligned with others, the rods can be easily and simply connected to the pedicle screw 1 because the rod 2 can be freely bent toward the pedicle screw 1. In addition, the rod 2 provides for movement of the spinal segments through the superelastic action of the elastic section 16 when the patients bends or wrenches his back, after the spinal fusion.

[0113] In the installation procedure for the rods 2, when the rods 2 and 2' are respectively coupled to the rod grooves 12, the pedicle screw 1 having two rod grooves 12 and 12' may be used. That is, the rods 2 and 2' are respectively and alternately set to the rod grooves 12 and 12' positioned in the reception cavity 11*a*, as shown in FIG. 10. When a pedicle screw 1 having two rod grooves 12 and 12' is used, it is not necessary to use an additional connector for a serial connection.

[0114] Next, an installation procedure of the transverse link 3 according to an embodiment of the invention will be described in detail.

[0115] After coupling the rods 2 and 2' to the pedicle screws 1, the transverse link 3 is hung on a pair of the rods 2 to provide a space between the two rods 2. The installing work of the transverse link 3 is taken in the same manner as it done in the above-mentioned rod installation procedure. That is, it lengthens a body 31 or widens a space of the hooks 32 thereof, by deforming the transverse link 3 at a temperature of +10 degree C. and below. The deformed hook 32 of the transverse link 3 is inserted into the outer surface of the rod 2. In the case of an S-shaped transverse link, it is inserted into a slit 25 of the head 11. After the installation of the transverse link 3, it returns back to the memorized original shape, being transformed to the austenite phase through the heat treatment at a temperature of more than +35 degree C. so that the transverse link 3 is rigidly fixed on the rod and, in the case of an S-shaped transverse link 3, it is fixed on the slit 25 of the pedicle screw 1.

[0116] Thus, in the case of the above-mentioned structure of the transverse link 3, it easily holds the rod 2 even if a space between the rods 2 and 2' is not in parallel.

[0117] Another embodiment of the present invention will be described in detail referring to FIG. 15, wherein the same reference numerals denote the same elements as illustrated in the previously described embodiments of the present invention.

[0118] In this embodiment, the head 11 of the pedicle screw 1 is formed with receptacles comprising a pair of first rod grooves 21 and 21' to locate the rod 2 on an upper portion thereof. Also, a pair of rod inserting recesses 22 and 22' are respectively formed below the rod grooves 21 and 21' and the rod inserting recesses 22 and 22' are positioned in the same axis of the rod grooves 21 and 21', respectively. A female thread 23 is formed on an inner surface of the head 11 at a predetermined depth.

[0119] A head cap 20 is provided on the upper portion of the head 11 and the head cap 20 has a pair of second rod grooves 24 and 24' corresponding the first rod grooves 21

and 21'. A fixing screw 25 is joined to the female thread 23 passing through the head cap 20 so that the head 11 is strongly fixed to the head cap 20.

[0120] A diameter of the first rod grooves 21 and 21' and the second rod grooves 24 and 24' may correspond to that of the rods 2 and 2'. The rod inserting grooves 22, 22' may have the same or slightly large diameter than that of the rod 2.

[0121] If only one of the first rod grooves 21 and 21' is provided, two female threads may be positioned at both sides of the first rod groove. If two rod grooves are provided, one female thread may be positioned in the middle of the first rod grooves 21 and 21'. In this drawing, a pair of the first rod grooves 21 and 21' is shown. These two grooves are required to serially and alternately set the two rods 2 and 2' on the first rod grooves 21 and 21'.

[0122] Additional embodiments of the present invention will be described in detail referring to FIGS. 16 to 28.

[0123] The rod segments shown in these embodiments may be formed from a titanium material or any suitable material. Alternatively, a rod, a staple rod and a middle connection rod in these embodiments may comprise a shape memory alloy which is in a martensite phase at a temperature of +10 degree C. and below and in an austenite phase at a temperature of more than +35 degree C. to return back to the memorized original shape. The shape memory alloy undergoes a preliminary deformation at a temperature of +10 degree C. and below. A deformed shape is kept unchanged up to temperature +26 degree C. A shape restoration is occurs under the heating up to +35 degree C.

[0124] An embodiment of the present invention will be described in detail referring to FIGS. 16 and 17.

[0125] A plurality of pedicle screws 40 according to this embodiment may include a head formed at a top portion thereof, wherein the head has a reception cavity 41a and two parallel rod grooves 42 and 42' in bottom surface of the reception cavity 41a; and a thread 43 formed below the head to be implanted into a pedicle of the vertebra.

[0126] Two parallel rod grooves 42 and 42' in the reception cavity 41a contribute to a connection of the rod segments 50 and the pedicle screws 40 without an additional connector. Here, the rod grooves 42, 42' may have a diameter equivalent to the rod segment 50.

[0127] A set screw 44 is inserted into the reception cavity 41a of the head 41 of the pedicle screws 40 for preventing a movement of the rod segment 50. In order to securely tighten the rod segment 50, the set screw 44 has an outer thread 44a and a recess 44b which has a hexagonal cross-section view in the reception cavity 41a of the head 41. The length of the set screw 44 should be short enough not to protrude from the upper surface of the reception cavity 41a of the head 41. The reception cavity 41a of the head 41 has an inner thread 41b to be joined to the outer thread 44a of the set screw 44.

[0128] A head cap 45 can be coupled to the upper portion of the head 41 to eliminate the change from a misaligned fixation of the set screw 44. The head cap 45 may serve as an additional supporter to improve the rod holding power using an additional rod-fastening element.

[0129] A pair of rods or rod segments 50 according to this embodiment may comprise a straight bar 51 placed at the

center line of the heads; an elastic section 52 formed in the middle of the straight bar 51 to generate an elastic force for absorbing a shock which is inflicted on the patient's vertebra; and a support bar 53 extended from both ends of the straight bar 51 to be put in one of the rod grooves 42 and 42'.

[0130] The diameter of the rod may be approximately in a range of 2 to 7 mm and can be adjusted on a basis of unit diameter of 0.5 mm.

[0131] The elastic section 52 is similar to a coil spring. The coil spring may be equal to the straight bar 51 in diameter. The elastic section 52 can also have a wave shape as another form.

[0132] The support bar 53 may have a line portion 53a, which can be coupled to one of the rod grooves 42a and 42', and a bending portion 53b which extends from both ends of the straight bar 51 and curves along the outer surface of the head 41.

[0133] The straight bar 51 of the rod segment 50 is positioned on the central axis of the head 41 by the shape of the support bar 53.

[0134] One of the two support bars 53 is opposite to the other in the same head 41; however, the two support bars 53 can also be in a reverse phase to each other (not shown). That is, rod segment 50 can be serially and alternately connected to the pedicle screw 40 with the support bar 53 of which the bending portions 53b are reversibly positioned and are curved along the outer surface of the heads 41.

[0135] Referring to FIG. 17, the support bars 53 at both sides of the rod segment 50 are respectively put into the rod grooves 42 and 42'. Also, the set screws 44 are coupled to the inner threaded 41b of the reception cavity 41a of the head 41, being rigidly fixed to the rod 50 segment.

[0136] Another embodiment of the present invention will be described in detail referring to FIGS. 18 to 20. Referring now to FIG. 18, a plurality of pedicle screws 60 and a rod 70 are shown.

[0137] The pedicle screws 60 include a head 61 formed at the top portion thereof and a thread 62 formed below the head 61. The head 61a plurality of receptacle in the form of first and second circular grooves 61a and 61a' formed in an outer surface thereof.

[0138] Rod segment 70 includes two straight bars 71 and 71' placed at the center line of the head 61 of the pedicle screw 60, an elastic section 72 formed in a type of wave between the two straight bars 71 and 71', and support rings 73 and 73' respectively extended from both ends of the straight bars 71 and 71' to be inserted into one of the first and second circular grooves 61a, 61a'.

[0139] The support rings 73 and 73' of the rod segment 70 are may be in reverse phase to each other; however, they may be opposite to each other in the same head 61, even if it is not shown in the drawings.

[0140] Referring now to FIGS. 19 and 20, the rod segments 70 are serially and alternately connected to the plurality of circular grooves 61a and 61a' of the heads 61 of the pedicle screws 60, using the above support rings 73 and 73'.

[0141] A further embodiment of the present invention will be described in detail referring to FIG. 21.

[0142] Referring now to FIG. 21, this embodiment comprises a plurality of pedicle screws 80 having a head 81, which is formed at the top portion thereof and has a cylindrical type block, and a thread 82 formed below the head 81. The head 81 has an opening 81a horizontally passing through the cylindrical type block to receive both ends of a rod 90 and a thread hole 81b which is upwardly formed and is perpendicular to the opening 81a. The thread hole 81b of the head 81 is joined to a bolt 83 in order to tighten the rod 90.

[0143] The rod 90 has a straight bar 91 and hooks 92 and 92' which are roundly extended from both ends of the straight bar 91 to be inserted to the opening 81a. The straight bar 91 can be provided with an elastic section in the middle of the rod 90.

[0144] Hereinafter, the installation procedure of the rod 90 will be described in detail.

[0145] In this embodiment, when the rod 90 is coupled to the pedicle screw 80, the roundly curved hooks 92 of the rod 90 are deformed to a straight bar shape at a temperature +10 degree C. and below. On the other hand, the straight bar shaped hooks 92 of the rod 90 are inserted to the opening 81a. Thereafter, a heat treatment is applied to the rod 90 at a temperature of more than +35 degree C. and the deformed hooks 92 of the rod 90 are returned back to the memorized original shape and are rigidly fixed to the head 81. After the rod 90 is inserted into the pedicle screw 80, the bolt 83 is joined to the thread hole 81b of the head 81 for tightening the rod 90 to the pedicle screw 80.

[0146] A further embodiment of the present invention will be described in detail referring to FIG. 22.

[0147] This embodiment makes the connecting work simple, by simply coupling the rod to the pedicle screw after a plurality of the pedicle screws are installed in the pedicles of the vertebrae.

[0148] Referring now to FIG. 22a, the detailed description of the pedicle screw will be omitted because the structure of the pedicle screw 40 is the same as that in an above-mentioned embodiment. The same reference numerals denote the same elements as illustrated in the prior embodiment.

[0149] A rod segment 100 of this embodiment is formed in a "U" shape. The U-shaped rod segment 100 is put into the rod grooves 42 and 42' of the head 41, after the pedicle screws 40 is inserted into a pedicle of the vertebrae. The connection of the rod segment 100 is achieved by tightening the set screw 44 to the reception cavity 41a of the head 41 in order to fix the rod segment 100 to the pedicle screw 40. If the pedicle screws 40 are not well aligned, the U-shaped rod segment 100 may be deformed to comply with the misaligned pedicle screw 40. Accordingly, the deformed rod segment 100 is easily positioned in the rod grooves 42 and 42' of the reception cavity 41a of the head 41. The deformed rod segment 100 may be returned back to the original shape according to a memorized shape of the rod segment 100, thereby correcting a position of the misaligned pedicle screw 40.

[0150] The U-shaped rod segment 100 can be replaced with straight bar type rod segments 101 and 101' as shown in FIG. 22b. An elastic section 102 may be provided in the middle of the straight rods segment 101 and 101'. The straight rod segments 101 and 101' are respectively and alternately set to the rod grooves 42 and 42' which are positioned in the reception cavity 41a. Therefore, in the case wherein the straight rod segments 101 and 101' having elastic section 102 are used, it is not necessary to have an additional connector for such a serial connection.

[0151] Another embodiment of the present invention will be described in detail referring to FIGS. 23 to 26.

[0152] Referring now to FIGS. 23 to 25, this embodiment comprises at least one pedicle screw 110, a pair of stapling rods 120, and a middle connecting rod 140.

[0153] Referring now to FIG. 25, the pedicle screw 110 has a head 111 at the top portion thereof and a thread 113 formed below the head 111 to be implanted into the pedicle of the vertebra, wherein the head 111 has a reception cavity 111a and first and second sockets 112 and 112' formed in the bottom surface of a reception cavity 111a.

[0154] The rod 120 is formed in a staple structure for preventing a movement of the vertebra.

[0155] One side of the staple rod 120 is directly implanted into the pedicle of the vertebra and other side thereof is inserted into one of the sockets 112 and 112'.

[0156] The middle connecting rod 140 is employed for serially connecting the staple rod 120 to the pedicle screw 110 by inserting both ends thereof to the sockets 112 and 112' of the head 111, respectively.

[0157] Referring to FIG. 24, the staple rod 120 has a first bridge 121 for providing a space between selected vertebra and adjacent vertebra, an elastic section 126 formed in the middle of the first bridge 121, a spike 122 downwardly extended from one end of the first bridge 121 to be implanted directly into the pedicle of the vertebra, and a first connecting pole 123 downwardly extended from the other end of the first bridge 121 to be fixed to the pedicle screws 110. The length of the first connecting pole 123 is shorter than the depth of the reception cavity 111a of the head 111 so that the first connecting pole 123 is inserted into the socket 112 of the pedicle screw 110. The spike 122 has a plurality of scarred regions 125 for preventing the spike 122 from being detached from the pedicle of the vertebra. The scarred regions 125 may be formed by an electro discharge machine. The diameter of the staple rod 120 is approximately in a range of 2 to 7 mm and it can be adjusted on a basis of unit diameter of 0.5 mm.

[0158] Once a spinal fusion has been finished, the staple rod 120 is not separated from the vertebra because the scarred regions 125 are buried in the vertebra.

[0159] According to an embodiment of the present invention, it is possible to make a connection among three adjacent vertebrae, using two staple rods 120 and one pedicle screw 110.

[0160] The middle connecting rod 140 has a second bridge 141 for providing a space between the pedicle screws 110, an elastic section 146 formed in the middle of the second bridge 141, and second connecting poles 142 downwardly

extended from both ends of the second bridge **141**, wherein the length of the second connecting poles **142** is shorter than the depth of the reception cavity **111a** of the head **111**. The reason for this is that a volume should be prepared for the insertion of a fixing member such as a set screw.

[0161] The first connecting pole **123** of the staple rod **120** and the second connecting poles **142** are substantially equal to each other. In the serial connection, one of the second connecting poles **142** extended at both ends of the middle connecting rod **140** is inserted into the socket **112** of head **111** of the pedicle screw **110** and the other is inserted into the socket **112'** of head **111'** of the adjacent pedicle screw **110'**.

[0162] The elastic sections **126** and **146** can be made up of a coil spring or a wave shape element. The diameter of each elastic section **126** and **146** is substantially the same as that of first and second bridge **121** and **141**.

[0163] In this embodiment, at least one set screw **130** is joined to the reception cavity **111a** of the head **111** of the pedicle screws **110** for preventing a movement of the staple rod **120**.

[0164] Likewise, in this embodiment, at least one head cap **131** is adopted to the upper surface of the head **111**. The head cap **131** is provided to improve holding power of the staple rod **120** without an additional rod such as a fastening element.

[0165] Hereinafter, an installation procedure of the staple rod **120** among the first to fourth vertebrae will be described in detail.

[0166] Referring to FIGS. **23** and **26**, the first and second pedicle screws **110** and **110'** are implanted into second and third middle vertebrae, respectively. The first connecting pole **123** of the first staple rod **120** is inserted into one of the sockets **112** and **112'** of the first pedicle screw **110** and another connecting bar (**123'**) of the second staple rod **120'** is inserted into the socket **112''** of the second pedicle screw **110'**.

[0167] The spikes **122** and **122'** of the first and second staple rods **120** and **120'** are implanted into the first vertebra and fourth vertebra, respectively. The two second connecting poles **142** at both sides of the middle connecting rod **140** are inserted into the sockets **112'** and **112''** of the first and second pedicle screws **110** and **110'**, respectively.

[0168] After the installation of the staple rods **120** and **120'** and the middle connecting rod **140**, the outer thread **130a** of the set screw **130** is joined to the reception cavity **110a** of the head **110** and the set screw **130** is then joined to the inner thread **10b** of the reception cavity **110a** by a wrench tool. Accordingly, the staple rod **120** and the middle connecting rod **140** are simultaneously pressed by the set screw **130** so that the staple rod **120** and the middle connecting rod **140** are securely and rigidly fixed in the pedicle screw **110**. Although the pedicle screws **110** and **110'** are not well aligned, the staple rods **120** are easily and simply connected to the pedicle screw **110**. This can be further achieved by the deformation of the staple rods **120** and the middle connecting rod **140**.

[0169] Before the first connecting poles **123** and **123'** of the first and second staple rods **120**, **120'** are inserted into the sockets **112**, **112'** of the head **111**, the staple rod **120** can be deformed at a phase transformation point (+10 degree C. and

below) on condition that one end of the first staple rod **120** is optimally connected to the socket **112** of the head **111**. Further, the spikes **122** and **122'** of the deformed first and second staple rods **120** and **120'** are implanted into bores of the vertebrae. Also, the first connecting poles **123** and **123'** of the first and second deformed staple rods **120** and **120'** are joined to the sockets **112** and **112'** of the head **111**. Finally, the rod connection is completed among the pedicle screws **110** and **110'**, the staple rods **120** and **120'** and the middle connecting rod **140**.

[0170] Next, a heat treatment may be applied to the staple rods **120** and the middle connecting rod **140** at a restoration point (+35 degrees C. and over), using a surgical tool having a heating source. The lengthened elastic sections **126** and **146** are returned back to the memorized original shape and are transformed to an austenite phase.

[0171] At this time, the first and second connecting poles **123** and **142**, the staple rod **120** and the middle connecting rod **140** are rigidly fixed to the sockets **112** and **112'** of the head **110**, during the restoration to the memorized original shape.

[0172] According to this embodiment, a movement between spinal segments is given by the superelastic action of the elastic section **126** and **146**, which are respectively formed in the staple rod **120** and the middle connecting rod **140**, when the patient bends or wrenches his back after the spinal fusion.

[0173] According to the structure of the above-mentioned embodiment, the first and second staple rods **120** and **120'** are formed in a symmetric structure. Thus, it is necessary to have four pedicle screws even though all of them are needed in the conventional spinal fixation system; however, it is necessary to have only two pedicle screws in this embodiment. Therefore, according to this embodiment, the number of pedicle screw is reduced. In particular, in case of the correction of two vertebrae, it may be possible to perform the correcting work of the vertebrae by using only one single staple rod **120** without an additional pedicle screw. In case of correction of three vertebrae, it is necessary to have only one pedicle screw.

[0174] Another embodiment of the present invention will be described in detail referring to FIGS. **27** and **28**.

[0175] In this embodiment, the staple rod **150** is directly implanted into the pedicle of the vertebra without any pedicle screw.

[0176] Referring now to FIGS. **27** and **28**, at least one staple rod **150** is located at both laterals of the spine.

[0177] The staple rod **150** has a bridge **152** for providing a space between a selected vertebra and an adjacent vertebra, a spike **153** extending downwardly from both ends of the bridge **152** for implantation into the pedicle of the vertebra, and an elastic section **154** formed in the bridge **152**.

[0178] The elastic section **154** can be made of a coil spring (see FIG. **27**) or a wave shape element or a S-shaped element (see FIG. **28**). Also, The spike **153** has a plurality of scarred regions **155** which prevents the spike **153** from being detached from the pedicle of the vertebra.

[0179] The scarred regions **125** may be formed by an electro discharge machine.

[0180] Although the preferred embodiments of the invention have been disclosed for illustrative purposes, those skilled in the art will appreciate that various modifications, additions and substitutions are possible, without departing from the scope and spirit of the invention as disclosed in the accompanying claims.

[0181] According to the various embodiments of the present invention, the rod segments may be made from any suitable material, including surgical grade titanium alloys. The transverse links may be made of a shape memory alloy, such as for example Nitinol alloy (Ni—Ti alloy) which has superelastic characteristics. Although the pedicle screws are out of alignment during the surgery, embodiment of the present invention can easily and simply make a structural connection between the rods and the pedicle screws without excessive force on the spine and/or implants.

[0182] In addition, in the present invention, the rod sections and/or transverse links may have an elastic section in an optional range thereof. The elastic portion of the rod allows a delicate movement after the spinal segments fuse. Thus, it disperses a load, which is put on the spinal segments which have been fused, through the rods and the transverse links having flexibility. As a result, a burden on lumbar vertebra may be reduced. Also, the use of a spinal fixation apparatus according to an embodiment of the present invention may have the effect of decreasing complications that can arise between an upper segment and a lower segment.

What is claimed:

1. A semi-rigid spinal fixation apparatus comprising:

- a) a first pedicle screw array;
- b) a second pedicle screw array disposed substantially parallel to said first pedicle screw array;
- c) a first rod array associated with said first pedicle screw array; and
- d) a second rod array associated with said second pedicle screw array;

wherein each of said first pedicle screw array and said second pedicle screw array comprise a plurality of pedicle screws for joining to vertebrae of a spine, each pedicle screw of said plurality of pedicle screws comprising a head portion having a plurality of receptacles and a leg portion having a male thread for implanting into a vertebra; and

wherein each of said first rod array and said second rod array comprise a plurality of rod segments, each rod segment of said plurality of rod segments comprising a first end coupled to a first receptacle of said plurality of receptacles on a first pedicle screw of said plurality of pedicle screws and a second end coupled to a second receptacle of said plurality of receptacles on a second pedicle screw of said plurality of pedicle screws, said first pedicle screw being adjacent to said second pedicle screw.

2. The semi-rigid spinal fixation apparatus according to claim 1 further comprising a transverse link extending between a first rod segment associated with said first rod array and a second rod segment associated with said second rod array.

3. The semi-rigid spinal fixation apparatus according to claim 1, wherein each rod segment of said plurality of rod segments comprises an elastic section.

4. The semi-rigid spinal fixation apparatus according to claim 3, wherein said elastic section comprises a coil spring shape.

5. The semi-rigid spinal fixation apparatus according to claim 3, wherein said elastic section comprises a wave shape.

6. The semi-rigid spinal fixation apparatus according to claim 1, wherein said head portion of said pedicle screw comprises a reception cavity and wherein said plurality of receptacles comprises a plurality of rod grooves disposed on a bottom surface of said reception cavity.

7. The semi-rigid spinal fixation apparatus according to claim 6, further comprising

- a) a head cap coupled to said head portion of said pedicle screw, said head cap comprising a second plurality of rod grooves; and
- b) a fastener for securing said head cap to said head of said pedicle screw;

wherein said rod segment is secured between a rod groove of said plurality of rod grooves in said reception cavity and a respective rod groove of said second plurality of rod grooves in said head cap.

8. The semi-rigid spinal fixation apparatus according to claim 6, wherein said rod segment further comprises a hook shaped portion at each end and said head portion of said pedicle screw comprises a fixing recess positioned under a rod groove of said plurality of rod grooves, wherein said hook shaped portion is fixed in said fixing recess.

9. The semi-rigid spinal fixation apparatus according to claim 1, further comprising a head cap coupled to said head portion of said pedicle screw.

10. The semi-rigid spinal fixation apparatus according to claim 1, wherein said head portion of said pedicle screw further comprises a reception portion having a female threaded portion on an inner surface of said reception portion, said apparatus further comprising a set screw having a male threaded portion for engaging said female threaded portion, wherein said set screw secures said rod segment to said pedicle screw.

11. The semi-rigid spinal fixation apparatus according to claim 1, wherein said head portion of said pedicle screw comprises a reception cavity and wherein said plurality of receptacles comprises two parallel rod grooves disposed on a bottom surface of said reception cavity and wherein said rod segment comprises a straight bar placed in line with said head portions of said first and second pedicle screws, an elastic section, a support bar having a bending portion extending from an end of the straight bar and bending around an outer surface of said head portion, and a line portion extending from said bending portion, said line portion coupled to a groove of said two parallel rod grooves.

12. The semi-rigid spinal fixation device according to claim 11, further comprising a set screw inserted into said reception cavity for securing said rod segment to said pedicle screw.

13. The semi-rigid spinal fixation apparatus according to claim 1, wherein said plurality of receptacles comprise a plurality of circular grooves disposed on an outer surface of said head portion of said pedicle screw and wherein said rod segment comprises a straight bar placed in line with said

head portions of said first and second pedicle screws, an elastic section and a support ring, said support ring coupled to a circular groove of said plurality of circular grooves.

14. The semi-rigid spinal fixation apparatus according to claim 1, wherein said rod segment has a substantially u-shaped cross section.

15. A semi-rigid spinal fixation apparatus comprising:

- a) a first pedicle screw, a second pedicle screw and a third pedicle screw, each comprising a head portion having a plurality of receptacles and a leg portion having a male thread for implanting into a vertebra;
- b) a first rod segment comprising a first end coupled to a first receptacle of said plurality of receptacles associated with said first pedicle screw and a second end coupled to a first receptacle of said plurality of receptacles associated with said second pedicle screw; and
- c) a second rod segment comprising a first end coupled to a second receptacle of said plurality of receptacles associated with said second pedicle screw and a second end coupled to a first receptacle of said plurality of receptacles associated with said third pedicle screw.

16. The semi-rigid spinal fixation apparatus according to claim 15 further comprising a transverse link for coupling said first rod segment to a rod segment extending between two additional pedicle screws.

17. The semi-rigid spinal fixation apparatus according to claim 15, wherein said first rod segment and said second rod segment each comprise a respective elastic section.

18. The semi-rigid spinal fixation apparatus according to claim 17, wherein said elastic section comprises a coil spring shape.

19. The semi-rigid spinal fixation apparatus according to claim 17, wherein said elastic section comprises a wave shape.

20. The semi-rigid spinal fixation apparatus according to claim 15, wherein said head portion of each of said first, second and third pedicle screw comprises a respective reception cavity and wherein said plurality of receptacles comprises a plurality of rod grooves disposed on a bottom surface of said reception cavity.

21. The semi-rigid spinal fixation apparatus according to claim 20, further comprising

- a) a head cap coupled to said head portion of a respective pedicle screw of said first, second and third pedicle screw, said head cap comprising a second plurality of rod grooves; and
- b) a fastener for securing said head cap to said head of said pedicle screw;

wherein a respective rod segment of said first and second rod segment is secured between a rod groove of said plurality of rod grooves in said reception cavity and a respective rod groove of said second plurality of rod grooves in said head cap.

22. The semi-rigid spinal fixation apparatus according to claim 20, wherein a rod segment of said first and second rod segment further comprises a hook shaped portion at each end and said head portion of a respective pedicle screw of said first, second and third pedicle screw comprises a fixing recess positioned under a rod groove of said plurality of rod grooves, wherein said hook shaped portion is fixed in said fixing recess.

23. The semi-rigid spinal fixation apparatus according to claim 15, further comprising a head cap coupled to said head portion of a respective pedicle screw of said first, second and third pedicle screw.

24. The semi-rigid spinal fixation apparatus according to claim 15, wherein said head portion of a respective pedicle screw of said first, second and third pedicle screw further comprises a reception portion having a female threaded portion on an inner surface of said reception portion, said apparatus further comprising a set screw having a male threaded portion for engaging said female threaded portion, wherein said set screw secures a rod segment of said first and second rod segment to said respective pedicle screw.

25. The semi-rigid spinal fixation apparatus according to claim 15, wherein said head portion of a respective pedicle screw of said first, second and third pedicle screw comprises a reception cavity and wherein said plurality of receptacles comprises two parallel rod grooves disposed on a bottom surface of said reception cavity and wherein a rod segment of said first and second rod segment comprises a straight bar placed in line with said head portions of said first, second and third pedicle screws, an elastic section, a support bar having a bending portion extending from an end of the straight bar and bending around an outer surface of said head portion, and a line portion extending from said bending portion, said line portion coupled to a groove of said two parallel rod grooves.

26. The semi-rigid spinal fixation device according to claim 11, further comprising a set screw inserted into said reception cavity for securing said rod segment to said pedicle screw.

27. The semi-rigid spinal fixation apparatus according to claim 15, wherein said plurality of receptacles comprise a plurality of circular grooves disposed on an outer surface of said head portion of a respective pedicle screw of said first, second and third pedicle screw and wherein said a rod segment of said first and second rod segment comprises a straight bar placed in line with said head portions of said first, second and third pedicle screws, an elastic section and a support ring, said support ring coupled to a circular groove of said plurality of circular grooves.

28. The semi-rigid spinal fixation apparatus according to claim 1, wherein said first and second rod segment have a substantially u-shaped cross section.

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