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Medical Device and Method to Correct Deformity

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ABSTRACT

A system (100) for correcting a spinal deformity includes an implant (104) fixed to one side of a vertebra and a rod (102) extending along an axis of the spine on a second side of the vertebra. An adjustment member (106), which may include a reel, is coupled to the rod (102). A force directing member (108), such as a cable, extends between the rod (102) and the adjustment member (106). The force directing member (106) is retractable toward and extendible from the adjustment member (106). A method of correcting spinal deformity includes providing an implant, a rod, an adjustment member coupled to the rod, and a force directing member extending between the rod and the adjustment member. The adjustment member is retractable toward and extendible from the adjustment member.

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TITLE

"Medical Device and Method to Correct Deformity"

TECHNICAL FIELD

[0001] This application generally relates to devices and methods for adjusting anatomical structures. More particularly, this application related to devices and methods for correcting skeletal deformities, such as spinal deformities.

BACKGROUND ART

[0002] Certain spine conditions, defects, deformities (e.g., scoliosis) as well as injuries may lead to structural instabilities, nerve or spinal cord damage, pain or other manifestations. Back pain (e.g., pain associated with the spinal column or mechanical back pain) may be caused by structural defects, by injuries or over the course of time from the aging process. For example, back pain is frequently caused by repetitive and/or high stress loads on or increased motion around certain boney or soft tissue structures. The natural course of aging leads to degeneration of the disc, loss of disc height, and instability of the spine among other structural manifestations at or around the spine. With disc degeneration, the posterior elements of the spine bear increased loads with disc height loss, and subsequently attempt to compensate with the formation of osteophytes and thickening of various stabilizing spinal ligaments. The facet joints may develop pain due to arthritic changes caused by increased loads. Furthermore, osteophytes in the neural foramina and thickening of spinal ligaments can lead to spinal stenosis, or impingement of nerve roots in the spinal canal or neural foramina. Scoliosis may also create disproportionate loading on various elements of the spine and may require correction, stabilization or fusion.

[0003] Pain caused by abnormal motion of the spine has long been treated by fixation of the motion segment. Spinal fusion is one way of stabilizing the spine to reduce pain. In general, it is believed that anterior interbody or posterior fusion prevents movement between one or more joints where pain is occurring from irritating motion. Fusion typically involves removal of the native disc, packing bone graft material into the resulting intervertebral space, and anterior stabilization, e.g., with intervertebral fusion cages or posterior stabilization, e.g., supporting the spinal column with internal fixation devices such as rods and screws. Internal fixation is typically an adjunct to attain intervertebral fusion. Many types of spine implants are available for performing spinal fixation, including the Harrington hook and rod, pedicle screws and rods, interbody fusion cages, and sublaminar wires.

[0004] Spinal stenosis pain or from impingement of nerve roots in the neural foramina has been treated by laminectomy and foraminotomy. Thereafter, the posterior spine is sometimes reinforced with rod and screw fixation. More recently, surgeons have attempted to relieve spinal stenosis by distracting adjacent spinous processes with a wedge implant. Pain due to instability of the spine has also been treated with dynamic stabilization of the posterior spine, using elastic bands that connect pedicles of adjacent vertebrae.

[0005] A number of spinal deformities exist where the spine is abnormally twisted and or curved. Scoliosis is typically considered an abnormal lateral curvature of the vertebral column.

[0006] Correction of scoliosis has been attempted a number of ways. Typically correction is followed by fusion. For example, a Harrington rod has been used where a compressing or distracting rod is attached above and below a curved arch of the deformity. The spine is stretched longitudinally to straighten the spine as the rod is lengthened. The spine is then fused. The correction force in this device and in similar devices is a distraction force that may have several drawbacks including possible spinal cord damage, as well as the high loading on the upper and lower attachment sites. Nowadays, segmental hook and screw fixation exists for providing distraction and derotating corrective forces.

[0007] A Luque device has been used where the spine is wired to a rod at multiple fixation points along the rod and pulls the spine to the rod. The spine is pulled to the rod with a wire and the spine is then fused. Anterior procedures also exist in the form of fusion via rod and screw fixation systems and newer technology involving staples across the disc space that purport to correct the deformity without requiring fusion. The corrective force is derotation with or without compression.

SUMMARY OF THE INVENTION

[0008] In accordance with one aspect of the present invention, there is provided a system for correcting an abnormal curvature of the spine, the system comprising:

a proximal attachment anchor configured for fixation to a proximal vertebra, wherein the proximal vertebra is located at a cephalad end of a spinal curvature to be corrected;

a distal attachment anchor configured for fixation to a distal vertebra, wherein the distal vertebra is located at a caudal end of the spinal curvature to be corrected;

a rod adapted to extend between, and be coupled to, the proximal and distal attachment anchors;

an implant configured for fixation to a vertebra, wherein the vertebra is positioned along a spinal column between the proximal vertebra and the distal vertebra;

an adjustment member coupled to the rod and comprising a driving element; and

a flexible force directing member;

wherein the flexible force directing member comprises a first end coupled to the adjustment member, a second end at least indirectly coupled to the implant, and a length extending between the implant and the adjustment member,

wherein the flexible force directing member is configured to exert a force on the vertebra when the length is shortened, and

wherein the adjustment member is configured to adjust the length.

[0009] The implant may be configured for fixation to a plurality of vertebrae. The adjustment member may be configured to adjust the length over time. A location of coupling the proximal attachment anchor to the rod and a location of coupling the distal attachment anchor to the rod may be adjustable over time. The adjustment member may be configured to adjust the length of the flexible force directing member noninvasively. The adjustment member may further comprise a gear and a reel; and the first end of the flexible force directing member may be coupled to the reel; the driving element may be configured to actuate the gear; the gear may be configured to spin the reel; and the reel may be configured to adjust the length of the flexible force directing member. The driving element may comprise a motor and the adjustment member may further comprise an implantable power supply configured to power the motor. The motor may be configured to adjust the length of the flexible force directing member at a programmed rate. The motor may comprise a stepper motor configured to adjust the length of the flexible force directing member in incremental amounts over time. The adjustment member may further comprise a sensor, and the motor may be configured to maintain a programmed tension in the flexible force directing member. The driving element may comprise an electric motor configured for remote actuation by an external energy source. The external energy source may be selected from the group consisting of: an HF transmission coil, an RF energy transmitter, and a magnetic energy transmitter. The driving element may comprise a spring configured to exert gradual forces on the flexible force directing member. The system may comprise a plurality of the said implants, a plurality of the said adjustment members, and a plurality of the said flexible force directing members. The rod may be adjustable in length.

[0010] In accordance with another aspect of the present invention, there is provided a method of correcting an abnormal curvature of the spine, the method comprising:

affixing a proximal attachment anchor to a proximal vertebra, wherein the proximal vertebra is located at a cephalad end of a spinal curvature to be corrected;

affixing a distal attachment anchor to a distal vertebra, wherein the distal vertebra is located at a caudal end of the spinal curvature to be corrected;

positioning a rod so that it extends between the proximal and distal attachment anchors;

coupling the rod to the proximal and distal attachment anchors;

affixing an implant to a vertebra, wherein the vertebra is positioned along a spinal column between the proximal vertebra and the distal vertebra;

securing an adjustment member to a position along the rod;

positioning a flexible force directing member such that a portion of the flexible force directing member extends from the adjustment member to the implant, wherein the portion extending from the adjustment member to the implant defines a length; and

adjusting the length, using a driving element, to exert a force on the vertebra.

[0011] Adjusting the length may repeated over time. The length may be adjusted noninvasively. The step of adjusting the length may comprise spinning a reel, around which at least an end of the flexible force directing member is positioned, by actuating a gear using a driving element. The driving element may comprise a motor which is powered by an implanted power supply. The length may be adjusted to a programmed tension in the flexible force directing member. The driving element may comprise an electric motor which is remotely actuated by an external energy source. The driving element may comprise a spring. The driving element may comprise a manually adjustable element. The method of correcting an abnormal curvature of the spine, as herein before described, may further comprise adjusting a position of the adjustment member along the rod after a period of time to accommodate positional changes of the vertebra relative to the rod. The method of correcting an abnormal curvature of the spine, as herein before described, may further comprise adjusting a vertical length of the rod after a period of time to adapt the rod to a straightening and lengthening of the spine. The method of correcting an abnormal curvature of the spine, herein before described, may further comprise adjusting a location of coupling the proximal attachment anchor to the rod and a location of coupling the distal attachment anchor to the rod after a period of time to adapt the rod to a straightening and lengthening of the spine.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The above-mentioned and other features of the invention will now be described with reference to the drawings of various embodiments which are intended to illustrate but not to limit the invention. The drawings contain the following figures:

[0013] FIGURE 1 is a schematic view of a spine deformity correction system in accordance with an embodiment.

[0014] FIGURE 2 is an enlarged view of a portion of FIGURE 1 showing a fixation device in accordance with the illustrated embodiment.

[0015] FIGURE 3 is a perspective view of a fixation device according to an embodiment.

[0016] FIGURE 4 is an exploded view of the fixation device shown in FIGURE 3.

[0017] FIGURE 5 is a perspective view of the transverse member of the fixation device shown in FIGURE 3.

[0018] FIGURE 6 is a top plan view of a fixation device according to an embodiment, shown implanted in a vertebra.

[0019] FIGURES 7A through 7C show plan views of various load-spreading members that can be used with embodiments of the invention.

[0020] FIGURE 8 is an enlarged view of a portion of FIGURE 1 showing an adjustment mechanism in accordance with the illustrated embodiment.

[0021] FIGURES 9 through 13 show schematic views of adjustment mechanisms according to various embodiments.

[0022] FIGURE 14 is a schematic view of a spine deformity correction system in accordance with a further embodiment.

[0023] FIGURE 15 is an enlarged view of a portion of FIGURE 14 showing an adjustment mechanism in accordance with the illustrated embodiment.

[0024] FIGURE 16 is a process diagram illustrating a method of correcting a spinal deformity, according to a further embodiment.

DESCRIPTION OF EMBODIMENTS

[0025] The following description and the accompanying figures, which describe and show certain preferred embodiments, are intended to demonstrate several possible configurations that systems for adjusting anatomical structures can take to include various aspects and features of the invention. The illustrated embodiments are shown correcting a scoliotic curvature of a spine. The illustration of embodiments in this context is not intended to limit the disclosed aspects and features of the invention to the specified embodiments or to usage only in correcting scoliosis. Those of skill in the art will recognize that the disclosed aspects and features of the invention are not limited to any specifically disclosed embodiment, and systems which include one or more of the inventive aspects and features herein described can be designed for use in a variety of applications.

[0026] As used herein, the term "vertical" refers to a direction generally in line with, or generally parallel to, a sagittal plane of the body (e.g., generally parallel to the axis of a straightened spine in a standing patient). The terms "transverse" and "horizontal" refer to a direction generally in line with, or generally parallel to, a transverse plane of the body (or a transverse plane of a vertebral body), and normal to a sagittal plane of the body (e.g., running from side to side across the spine of a standing patient).

[0027] The preferred embodiments of the present invention advantageously provide improved systems and methods for adjusting or correcting an anatomical structure, such as an abnormally curved spine, in a patient. According to one embodiment, the system includes a rod which can be disposed along a vertical axis to one side of a patient's spine. The system also includes one or more fixation devices or implants that can be disposed on the other side of the patient's spine, each of which can be inserted into, or otherwise attached to, one or more vertebrae. A connector extends between each implant and the rod. Coupled to the rod is at least one adjustment mechanism which is coupled to the connector. Activation of the adjustment mechanism adjusts the length of the connector, allowing adjustment of the forces applied to an individual vertebra through the connector and its associated implant. Some embodiments of the invention thus allow for reversibly adjustable forces to be applied to individual structures, such as individual vertebrae, allowing tensioning and loosening as appropriate. Embodiments of the system can be implanted surgically and then tightened (or loosened) over an extended period of time if desired, with minimally invasive or noninvasive procedures to provide gradual adjustment. Embodiments also provide a system for correcting a deformity of the spine which can be used with or without fusion.

[0028] With reference now to FIGURE 1, a system 100 generally includes a stabilizing rod 102, one or more implants 104, one or more adjustment mechanisms 106, and one or more connectors 108. The rod 102 extends generally vertically and is secured to individual vertebrae at locations above and below the curvature to be corrected. The illustrated rod 102 is attached, according to known methods, to transverse processes on the left side of the spine. Among other functions, the rod serves to establish a desired orientation of the spine. The rod 102 can have an adjustable length, such that its length can adapt to the changing length of the spine as its curvature is straightened. The rod can be a telescoping rod, or the rod can comprise rotatable threaded portions that may be actuated to change overall length of the rod. In addition or in the alternative, the rod 102 can be movable with respect to either or both of the attachment points above and below the curvature of the spine, so as to allow the system 100 to adapt to the lengthening of the spine as the affected vertebrae are translated toward the rod 102. Such a configuration can advantageously prevent buckling in the rod 102 and/or the spinal column as the curvature of the spine is corrected.

[0029] The implants 104 are shown fixed to individual vertebrae within the curved portion of the spine, on the opposite side of the spine from the rod 102. The implants 104 include transverse portions 110 which extend across the spine, toward the rod 102. As better illustrated in FIGURE 2, the transverse portions 110 can pass through the spinous processes of individual vertebrae. Each of the transverse portions 110 is coupled to one of the connectors 108. The connectors 108 extend transversely from the transverse portions 110 of the implants 104 toward the rod 102, and are coupled to the rod 102 via the adjustment mechanisms 106. The connectors 108 are preferably flexible so that they can be used with adjustment mechanisms 106 of a spooling or winding type. Suitable flexible connectors 108 include monofilament polymer materials, multifilament polymer materials (such as or similar to string or rope), multifilament carbon or ceramic fibers, wire, and multi-stranded cable. Stainless steel or titanium wire or rope are some examples of suitable materials. Of course, a wide variety of materials can be used to make the connectors 108. In an embodiment, those materials are preferably biocompatible; indeed, the entire system is preferably made of biocompatible materials.

[0030] FIGURES 3 and 4 illustrate in detail an implant 200 configured in accordance with an embodiment. The implant 200 includes a fixation portion 202 which is configured to be fixed to a portion of a vertebra, such as a pedicle. The fixation portion 202 can comprise any suitable structure capable of engaging a portion of a vertebra, such as, for example, the illustrated pedicle screw. The implant 200 also includes a transverse portion 204 coupled to the top end 206 of the fixation portion 202. The transverse portion 204 is disposed generally perpendicularly to the fixation portion 202. The fixation portion 202 includes at its top end 206 a slot 208 configured to receive a first end 210 of the transverse portion 204. The slot 208 is sized to receive a set screw 212 which, when engaged in the slot 208 on top of the first end 210 of the transverse portion 204, serves to secure the position of the transverse portion 204 relative to the fixation portion 202. In addition to or instead of the set screw 212, an external nut 218 can be used to provide additional securement of the transverse portion 204 relative to the fixation portion 202. Of course, as will be understood by one of skill in the art, any suitable coupling can be used to join the fixation portion 202 and the transverse portion 204. Further, depending on the particular application, the implant can also have a unitary construction.

[0031] A connector 214 extends from a second end 216 of the transverse portion 204 by an amount sufficient to connect to an adjustment mechanism coupled to a rod, as described herein. The connector 214 can be attached to the first end 210 of the transverse portion 204, extending along the length of and past the second end 216 of the transverse portion 204. Alternatively, the connector 214 can be attached at any other location along the length of the transverse portion 204. The connector 214 may advantageously comprise, for example, a cable or wire, or another material as set forth above, and can be fixed to the transverse portion 204 in any suitable manner, such as by welding or screw fixation. FIGURE 5 illustrates the transverse portion 204 in further detail. As shown in the figure, the transverse portion 204 can have a wider, roughly disk-shaped first end 210 so as to engage the receiving slot 208 in the fixation portion 202. Of course, the first end 210 of the transverse portion 204 and the top end 206 of the fixation portion 202 can have any other suitable cooperating configuration so as to guide and engage one another in an appropriate orientation. The transverse portion 204 can also have a hollow construction through which the connector 214 can extend.

[0032] With reference now to FIGURE 6, an implant 300 in accordance with an embodiment is shown fixed to a single vertebra. The implant 300 includes a pedicle screw 302 which is fixed to one side of the illustrated vertebra. A transverse member 304 is advantageously coupled to the head of the pedicle screw 302 and extends through the spinous process of the illustrated vertebra. A load-spreading member 306 can be provided which encircles, or partially encircles the transverse member 304 at the point of contact between the spinous process and the transverse member 304, contralateral to the adjustment mechanism and rod (not shown in FIGURE 6).

[0033] FIGURES 7A through 7C illustrate various configurations of load-spreading elements according to various embodiments. Element 402 has an annular configuration configured to spread loads evenly about the point of contact with the spinous process. Element 404 includes two wings extending from a ring configured to encircle the transverse member. Element 406 includes tentacles extending from a ring. Configurations such as these can also be used to distribute loads to the lamina, in addition to spreading loads across a larger surface area of the spinous process. Of course, a load-spreading element can have any other configuration suitable for reducing the concentration of force applied to the spinous process by a transverse member extending therethrough, distributing the forces to other portions of the vertebra (for example, to the lamina), and/or for anchoring the transverse member to the spinous process. In addition, the side of the load-spreading elements that contact bone can include such features as barbs, fins, pins, or other similar structure to achieve secure attachment of the extensions to the vertebral bone.

[0034] Although the illustrated embodiments generally include implants having transverse members which extend through the spinous process of a vertebra, and thus show examples of implants which are fixed at multiple locations on an individual vertebra, embodiments of the invention also include implants which are fixed to only a single location on an individual vertebra. For example, an implant according to an embodiment can include a transverse member configured to extend between spinous processes of adjacent vertebra. In such an embodiment, the transverse member can optionally be anchored to one or both of the adjacent spinous processes via a cable, tether, clasp, clamp, screw, hinge, or other suitable means. In addition, although the illustrated embodiments generally show each implant fixed to a single vertebra, embodiments can also include one or more implants configured to be fixed to multiple vertebrae. Additional examples of implants, as well as rods, which may be used with embodiments of the invention are set forth in copending U.S. Application Serial No. 11/196,952, the disclosure of which is hereby incorporated in its entirety. One advantage of multiple-point fixation is the ability to provide not only translational force to the vertebra through the implant, but also rotational force. The amount of rotational force will depend in part on the distance between the axis of the vertebra and the point of attachment of the connector 108 to the implant 104. This disclosure contemplates selecting or moving that point of attachment to achieve any desired rotational force, as well as a desired translational force.

[0035] With reference now to FIGURE 8 a particular adjustment mechanism 106 shown in FIGURE 1 is illustrated in further detail. The adjustment mechanism 106 may advantageously include a reel 502, a circumferential gear 504 surrounding the reel 502, and a vertical gear 506 in contact with the circumferential gear 504. The connector 108 is preferably attached to or engaged by the reel 502. Actuation of the vertical gear 506 via screw head 508 turns the circumferential gear 504, which turns the reel 502, thus winding (or unwinding, depending on the direction in which the reel 502 is turned) the connector 108 about the reel 502. Tightening of the reel 502 draws the connector 108 in toward the adjustment mechanism 106, thus pulling the associated implant 104 (not shown in FIGURE 8) toward the adjustment mechanism. The reel 502 and the gears 504, 506 are housed in a clamp 510. The adjustment mechanism 106 can be immovably fixed to the rod 102 or can be movable with respect to the rod 102. A movable adjustment mechanism 106 provides advantages, for example, as the spine straightens and thus lengthens, so that the adjustment mechanisms 106 can be moved to accommodate the relative movement of the spine in comparison to the rod 102. A movable adjustment mechanism 106 also tends to move to the point directly across from the implant 104, which is the position creating the least amount of tension in the connector 108 and which is also the ideal position for correction.

[0036] An adjustment mechanism can be configured in any manner suitable for retracting and letting out a connector. FIGURES 9 through 13 show examples of adjustment mechanisms according to further embodiments. FIGURE 9 shows an adjustment mechanism 520 comprising only a single reel or gear 522, around which a connector 524 is wound. The gear 522 is disposed along on an axis normal to the axis of the rod 526. The gear 522 can be directly actuated to tension or loosen the connector 524. FIGURE 10 shows an adjustment mechanism 530 according to a further embodiment. The mechanism 530 includes a spring 532 configured to actuate a vertical gear 534. The vertical gear 534 contacts a circumferential gear 535 on a reel 536 around which a connector 538 is wound. In such an embodiment, the spring 532 can exert gradual forces on the connector 538 (and thus, on an implant to which the connector 538 is attached) without the need for puncturing the patient's skin. FIGURE 11 shows an adjustment mechanism 540 according to another embodiment. The mechanism 540 includes an implantable power supply 542 configured to actuate a motor 544. The motor 544 drives a gear 545 on a reel 546 around which a connector 548 is wound. In such an embodiment, the motor 544 can be configured to exert gradual forces on the connector 548 (and thus, on an implant to which the connector 548 is attached) without the need for puncturing the patient's skin after the initial implantation of the system. For example, the motor 544 can be configured to draw in the connector 548 at a predetermined rate (e.g., 3 mm per day). In some embodiments, the motor 544 can be a stepper motor configured to draw in the connector 548 in incremental amounts over time. In other embodiments, the motor 544 can be configured to exert a predetermined amount of tension on the connector 548. Such embodiments can include one or more sensors, controllers, and related circuitry configured to measure the amount of tension on the connector 548 and adjust the tension applied by the motor 544 accordingly. Such embodiments can be configured to time-average the amount of tension on the connector 548 to allow for variation in tension caused by movement of the patient. In addition, such embodiments can be configured to maintain varying levels of tension on the connector 548 at different periods throughout the day, for example maintaining a lower level of tension during waking hours and a higher level of tension during sleeping hours. Further, in embodiments comprising multiple adjustment mechanisms configured to apply tension to multiple different vertebrae through multiple connectors, each adjustment mechanism can be configured to maintain a different level of tension on its associated connector, depending on the needs of the particular application. FIGURE 12 shows an adjustment mechanism 550 according to a still further embodiment. The mechanism 550 is coupled to a rod 551, and includes a first gear 552 configured to turn a second gear 554. The second gear 554 contacts a reel 556, to which a connector 558 is attached. Turning of the second gear 554 causes the reel 556 to rotate, thereby pulling in (or letting out) the connector 558 toward (or from) the rod 551. The first gear 552 is driven by an electric motor 559, which is configured for remote actuation by an external HF transmission coil 560. Such a configuration allows for post-implantation adjustment of the connector 558 without puncturing the patient's skin. Any suitable external energy source can be used in an embodiment configured for remote actuation, such as, for example, RF energy, HF energy, or magnetic energy. FIGURE 13 illustrates an adjustment mechanism 570, according to a still further embodiment, coupled to a rod 571. The mechanism 570 includes a reel 572 which is actuated by first and second gears 574, 576. The reel 572 is attached to a first connector 578, which extends generally transversely to an implant on the other side of the spine. Also connected to the reel 572 is a second connector 580, which extends generally parallel to the rod 571. The second connector 580 is connected to a second adjustment mechanism (not shown) and configured so that tightening of the mechanism 570 results in tightening of the second adjustment mechanism as well. Of course, additional adjustment mechanisms can be coupled to such a system so that a multiple-implant system can be adjusted using a single adjustment point.

[0037] In the various illustrated embodiments, the adjustment mechanism 106 is shown to be situated along the rod so that the connector 108 extends generally orthogonal to the rod toward the vertebra on which the implant 104 is located. Although this is a preferred embodiment, it is also contemplated that the adjustment mechanism 106 can be located along the rod 102 so that the angle between the axis of the rod 102 and the connector 108 is other than 90 degrees, e.g., 45 degrees, 60 degrees, 75 degrees, or other non-right-angles. Alternatively, instead of locating the adjustment mechanism(s) 106 along the rod 102 adjacent to (or opposite) the vertebra to be moved, they could be located more remotely, e.g., at an end of the rod 102. In that configuration, the connector could still extend from the implant 104 to the rod 102 at a desired angle, e.g., generally orthogonal to the rod 102, but could then change direction (e.g., by passing over a pulley or through a hole in the rod, not shown) and then extend parallel to or coaxial with the rod, alongside the rod or inside the rod, to the adjustment mechanism(s) 106.

[0038] With reference now to FIGURE 14, a system 600 according to another embodiment is illustrated. The system 600 includes a stabilizing rod 602, one or more implants 604, one or more adjustment mechanisms 606, and one or more connectors 608. The implants 604 are shown attached to alternate vertebrae. Depending on the particular needs of the application, implants 604 can be fixed to all the vertebrae in a curved portion of a spine, or only certain selected vertebrae. FIGURE 15 shows an enlarged view of one of the adjustment mechanisms 606. The adjustment mechanism 606 includes a housing 610 which surrounds a gear/reel mechanism (not visible in FIGURE 15) as described herein. The housing 610 includes an opening 612 configured to expose a screw head 614 configured to actuate the gear/reel mechanism. Such a configuration allows for actuation of the gear/reel mechanism 606 while separating the gear/reel mechanism and surrounding body tissues.

[0039] Embodiments also include methods of correcting a spinal deformity. Note that the following method description relates to some of the contemplated surgical methods, but it should not be inferred that all of the recited method steps are mandatory or that they must be performed in the identical manner specified. Instead, this disclosure is exemplary in nature. In some embodiments, individual vertebrae are targeted based on a pre-operative plan for correcting an abnormal curvature a patient's spine (such as a scoliotic curvature of a patient's spine). Pre-operative planning can involve review of x-rays or CT scans, as well as physical examination of the patient. Once the targeted vertebrae are identified, implants are surgically fixed to each of the targeted vertebrae. Fixing each implant can involve fixing a first portion of the implant into a pedicle of a vertebra on one side of the patient's spine, inserting a second portion of the implant through a spinous process of the same or different vertebra, and coupling the first and second portions together. A vertically extending rod is surgically fixed to the other side of the patient's spine so as to establish a desired orientation of the targeted vertebrae. Adjustment mechanisms of the same number as the implants (that is, the same number as the targeted vertebrae) are movably or immovably fixed to the rod. Connectors are positioned between each adjustment member and its corresponding implant. The adjustment mechanisms are then actuated to pull the connectors (and thus the targeted vertebrae) toward the rod. The adjustment mechanisms allow for both tightening and loosening of the connectors and, thus, the application of force is reversible. The adjustment mechanisms can be tightened or loosened as deemed appropriate by the practitioner and then locked with a locking mechanism such as a set screw. In embodiments having implants coupled to multiple points on each vertebra, applying tension to the connectors also exerts rotational forces on the targeted vertebrae, thus derotating the spine as the vertebrae are pulled toward the rod.

[0040] Once the initial adjustments are made to the adjustment mechanisms, the surgical site is closed using standard surgical procedures. The patient is then examined periodically (for example, every 3 to 6 months) and additional adjustments are made when appropriate. Depending on the configuration of the adjustment mechanisms, post-implantation adjustment can be made via a percutaneous puncture allowing the passing of a driver to actuate each adjustment mechanism. In embodiments including adjustment mechanisms configured for remote actuation, adjustments can be made without the need for puncturing the patient's skin. Adjustments can be different at each level or adjustment mechanism, depending on the particular anatomy to be adjusted, and different forces or force vectors can be applied to different vertebrae or sections of the spine. Both the curvature and the mal-rotation of the scoliotic spine can thus be corrected over multiple serial adjustments of the adjustment mechanisms. If desired, the system may be explanted after the deformity of the spine is eliminated or reduced to a clinically acceptable position.

[0041] A method of correcting a spinal deformity is illustrated in FIGURE 16. At step 702, an implant is affixed to a first side of a vertebra. At step 704, a rod is positioned on a second side of the vertebra so that the rod extends between the adjustment member and the implant. At step 706, an adjustment member is provided which is coupled to the rod. At step 708, a force directing member is positioned so that it extends between the adjustment member and the implant. At step 710, a force is applied to the force directing member with the adjustment member, thereby moving the vertebra toward the rod.

[0042] Embodiments of the invention can be used with or without fusion of vertebrae. For example, according to embodiments, some vertebrae of the spine may be fused according to known procedures using screws, hooks and/or rod systems following initial or subsequent adjustments or after explantation. Alternatively, some or all vertebrae may be left non-fused.

[0043] Although this invention has been disclosed in the context of certain preferred embodiments and examples, it will be understood by those skilled in the art that the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and modifications and equivalents thereof that would be readily apparent to the person skilled in the art. In particular, while the present system has been described in the context of particularly preferred embodiments, the skilled artisan will appreciate, in view of the present disclosure, that certain advantages, features and aspects of the system may be realized in a variety of other applications. For example, while particularly useful in the illustrated scoliosis-correcting application, the skilled artisan can readily adopt the principles and advantages described herein to a variety of other applications, including and without limitation, ameliorating or correcting other spinal conditions such as kyphosis, spondylolisthesis, laxity of spinal motion segments, and other disorders of alignment or loading of the spine.

[0044] In addition, as will be understood by one of skill in the art, one or more adjustment mechanisms according to embodiments can be used to adjust tension on anatomical structures other than spinal structures. For example, embodiments of the invention can be configured and used to adjust the tension, laxity, or distance between an anchor structure and an anatomical structure. Examples of such embodiments include providing an adjustable ligament between the femur and tibia of the leg, for example to correct a torn cruciate ligament; providing an adjustable sling between the pelvis or pubis and the bladder or urethra for the treatment of urinary incontinence; providing an adjustable attachment between a bone (such as the pelvis) and the uterus for the treatment of uterine prolapse; providing an adjustable attachment between the mandible or hyoid bone and the tongue or other upper airway structure for the treatment of snoring or obstructive sleep apnea; and providing an adjustable lifting mechanism between a cranial bone and soft tissue of the face to enable an adjustable face lift or eye lift.

[0045] Additionally, it is contemplated that various aspects and features of the invention described can be practiced separately, combined together, or substituted for one another, and that a variety of combination and subcombinations of the features and aspects can be made and still fall within the scope of the invention. Thus, it is intended that the scope of the present invention herein disclosed should not be limited by the particular disclosed embodiments described above.

[0046] Throughout this specification, unless the context requires otherwise, the word “comprise” and variations such as “comprises”, “comprising” and “comprised” are to be understood to imply the presence of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

[0047] Throughout this specification, unless the context requires otherwise, the word “include” and variations such as “includes”, “including” and “included” are to be understood to imply the presence of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

[0048] Any discussion of background art, any reference to a document and any reference to information that is known, which is contained in this specification, is provided only for the purpose of facilitating an understanding of the background art to the present invention, and is not an acknowledgement or admission that any of that material forms part of the common general knowledge in Australia or any other country as at the priority date of the application in relation to which this specification has been filed.

The claims defining the invention are as follows:

1. A system for correcting an abnormal curvature of the spine, the system comprising:

a proximal attachment anchor configured for fixation to a proximal vertebra, wherein the proximal vertebra is located at a cephalad end of a spinal curvature to be corrected;

a distal attachment anchor configured for fixation to a distal vertebra, wherein the distal vertebra is located at a caudal end of the spinal curvature to be corrected;

a rod adapted to extend between, and be coupled to, the proximal and distal attachment anchors;

an implant configured for fixation to a vertebra, wherein the vertebra is positioned along a spinal column between the proximal vertebra and the distal vertebra;

an adjustment member coupled to the rod and comprising a driving element; and

a flexible force directing member;

wherein the flexible force directing member comprises a first end coupled to the adjustment member, a second end at least indirectly coupled to the implant, and a length extending between the implant and the adjustment member,

wherein the flexible force directing member is configured to exert a force on the vertebra when the length is shortened, and

wherein the adjustment member is configured to adjust the length.

2. The system of claim 1, wherein the implant is configured for fixation to a plurality of vertebrae.

3. The system of claim 1 or 2, wherein the adjustment member is configured to adjust the length over time.

4. The system of any one of the preceding claims, wherein a location of coupling the proximal attachment anchor to the rod and a location of coupling the distal attachment anchor to the rod are adjustable over time.

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5. The system of any one of the preceding claims, wherein the adjustment member is configured to adjust the length of the flexible force directing member noninvasively.

6. The system of claim 5, wherein the adjustment member further comprises a gear and a reel; and wherein

the first end of the flexible force directing member is coupled to the reel;

the driving element is configured to actuate the gear;

the gear is configured to spin the reel; and

the reel is configured to adjust the length of the flexible force directing member.

7. The system of claim 5 or 6, wherein the driving element comprises a motor and the adjustment member further comprises an implantable power supply configured to power the motor.

8. The system of claim 7, wherein the motor is configured to adjust the length of the flexible force directing member at a programmed rate.

9. The system of claim 7 or 8, wherein the motor comprises a stepper motor configured to adjust the length of the flexible force directing member in incremental amounts over time.

10. The system of any one of claims 7, 8 or 9, wherein the adjustment member further comprises a sensor, and the motor is configured to maintain a programmed tension in the flexible force directing member.

11. The system of any one of claims 5 to 10, wherein the driving element comprises an electric motor configured for remote actuation by an external energy source.

12. The system of claim 11, wherein the external energy source is selected from the group consisting of: an HF transmission coil, an RF energy transmitter, and a magnetic energy transmitter.

13. The system of any one of claims 5 to 12, wherein the driving element comprises a spring configured to exert gradual forces on the flexible force directing member.

14. The system of any one of the preceding claims, wherein the system comprises a plurality of said implants, a plurality of said adjustment members, and a plurality of said flexible force directing members.

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15. The system of any one of the preceding claims, wherein the rod is adjustable in length.

16. A method of correcting an abnormal curvature of the spine, the method comprising:

affixing a proximal attachment anchor to a proximal vertebra, wherein the proximal vertebra is located at a cephalad end of a spinal curvature to be corrected;

affixing a distal attachment anchor to a distal vertebra, wherein the distal vertebra is located at a caudal end of the spinal curvature to be corrected;

positioning a rod so that it extends between the proximal and distal attachment anchors;

coupling the rod to the proximal and distal attachment anchors;

affixing an implant to a vertebra, wherein the vertebra is positioned along a spinal column between the proximal vertebra and the distal vertebra;

securing an adjustment member to a position along the rod;

positioning a flexible force directing member such that a portion of the flexible force directing member extends from the adjustment member to the implant, wherein the portion extending from the adjustment member to the implant defines a length; and

adjusting the length, using a driving element, to exert a force on the vertebra.

17. The method of claim 16, wherein adjusting the length is repeated over time.

18. The method of claim 16 or 17, wherein the length is adjusted noninvasively.

19. The method of any one of claims 16 to 18, wherein the step of adjusting the length comprises spinning a reel, around which at least an end of the flexible force directing member is positioned, by actuating a gear using a driving element.

20. The method of any one of claims 16 to 19, wherein the driving element comprises a motor which is powered by an implanted power supply.

21. The method of any one of claims 16 to 20, wherein the length is adjusted to a programmed tension in the flexible force directing member.

22. The method of any one of claims 16 to 21, wherein the driving element comprises an electric motor which is remotely actuated by an external energy source.

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23. The method of any one of claims 16 to 22, wherein the driving element comprises a spring.

24. The method of any one of claims 16 to 23, wherein the driving element comprises a manually adjustable element.

25. The method of any one of claims 16 to 24, further comprising adjusting a position of the adjustment member along the rod after a period of time to accommodate positional changes of the vertebra relative to the rod.

26. The method of any one of claims 16 to 25, further comprising adjusting a vertical length of the rod after a period of time to adapt the rod to a straightening and lengthening of the spine.

27. The method of any one of claims 16 to 26, further comprising adjusting a location of coupling the proximal attachment anchor to the rod and a location of coupling the distal attachment anchor to the rod after a period of time to adapt the rod to a straightening and lengthening of the spine.

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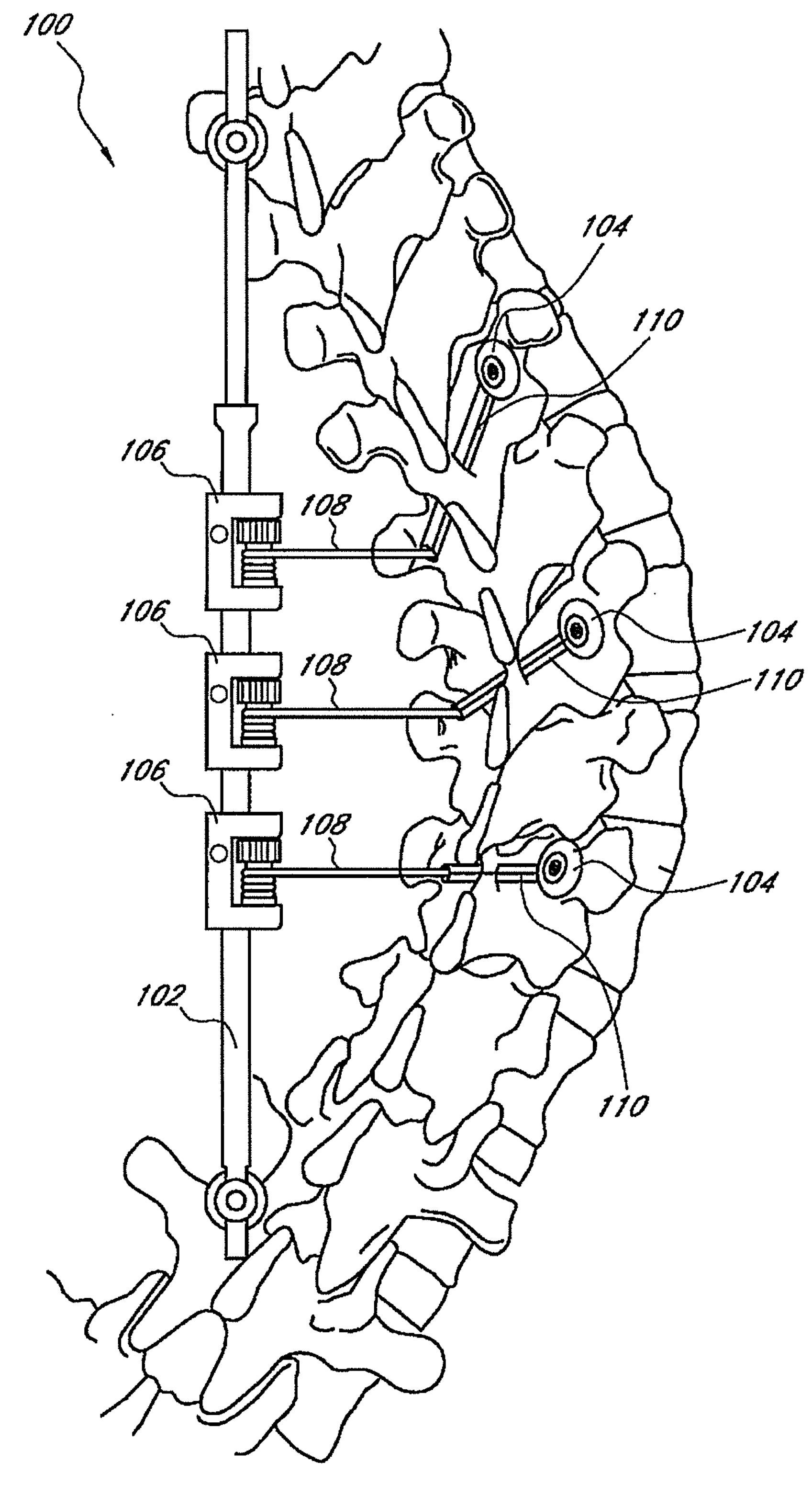

FIG. 1

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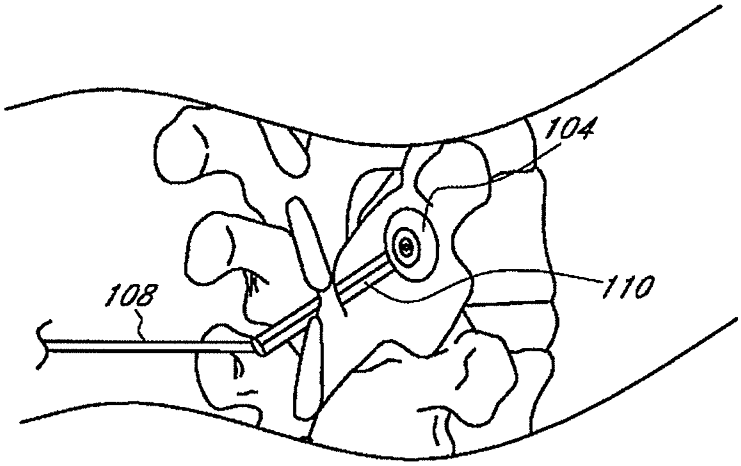

FIG. 2

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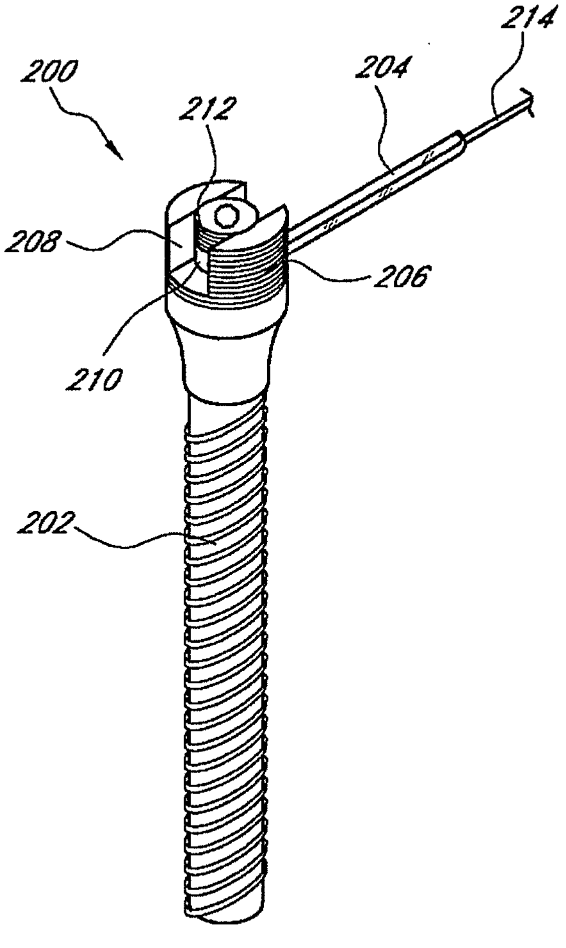

FIG. 3

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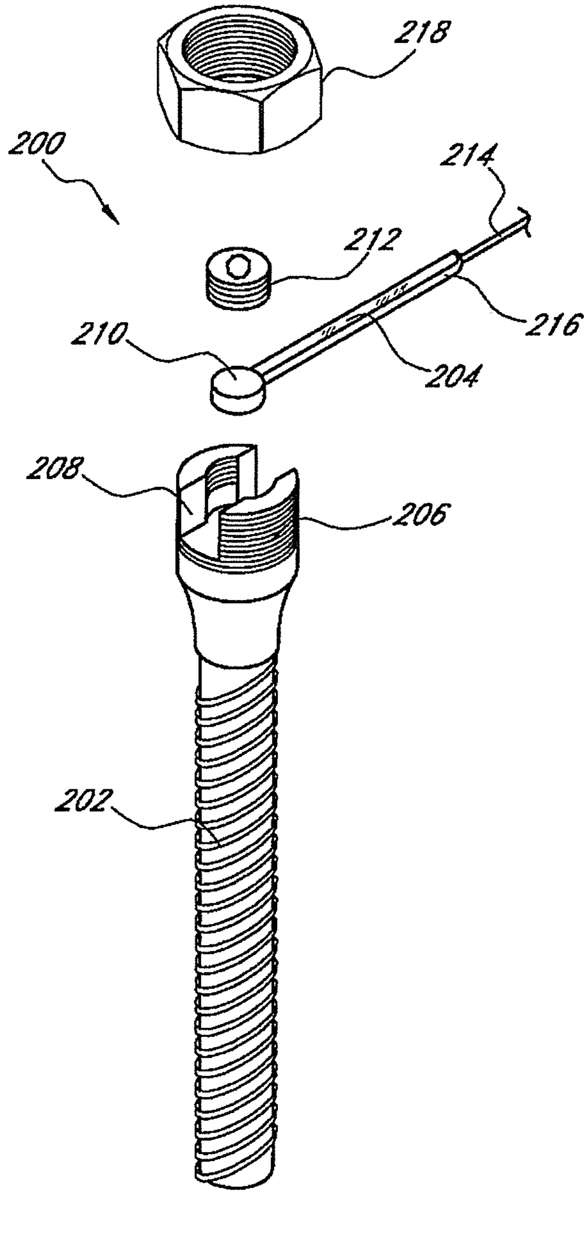

FIG. 4

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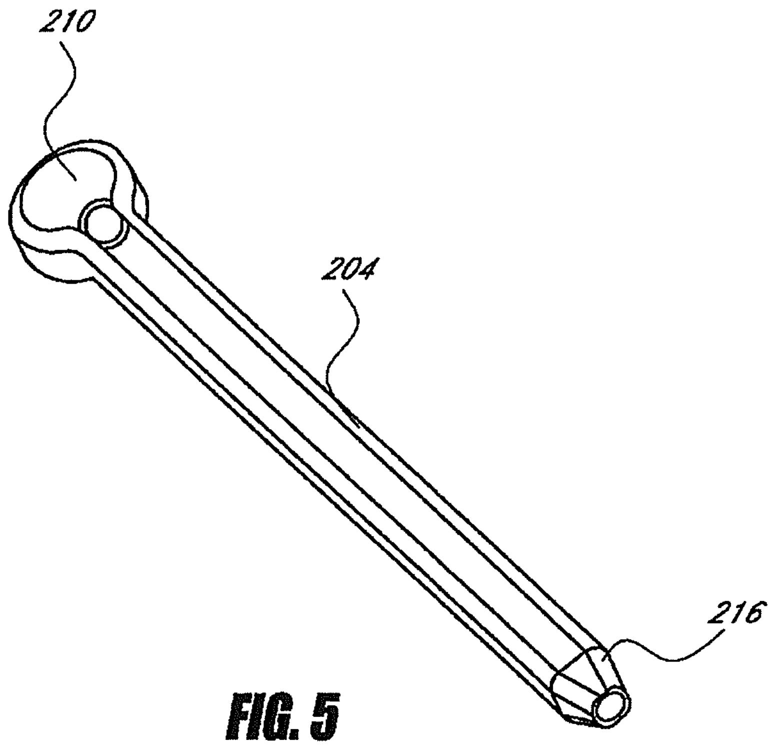

FIG. 5

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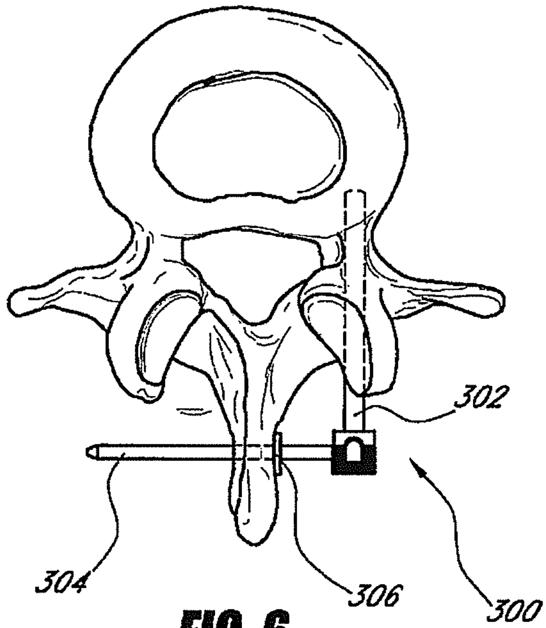


FIG. 6

FIG. 7A

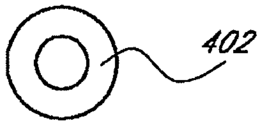
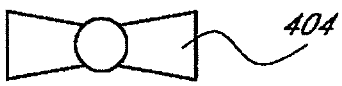


FIG. 7B



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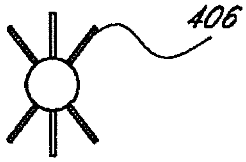

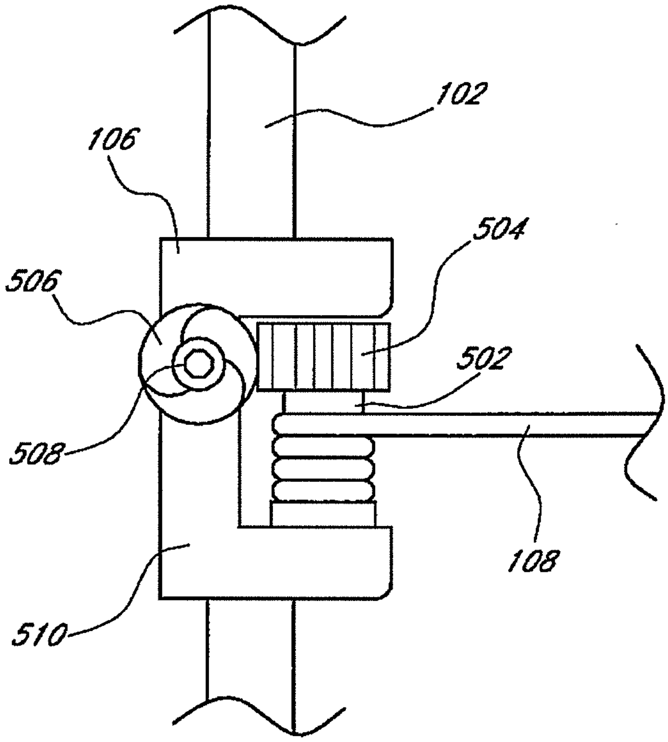

FIG. 8

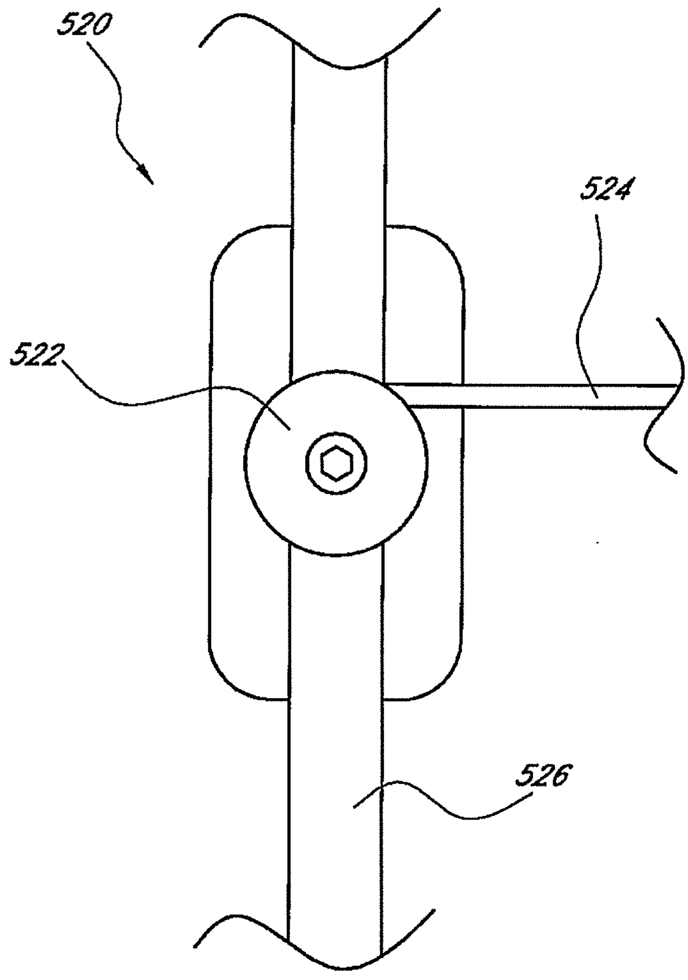

FIG. 9

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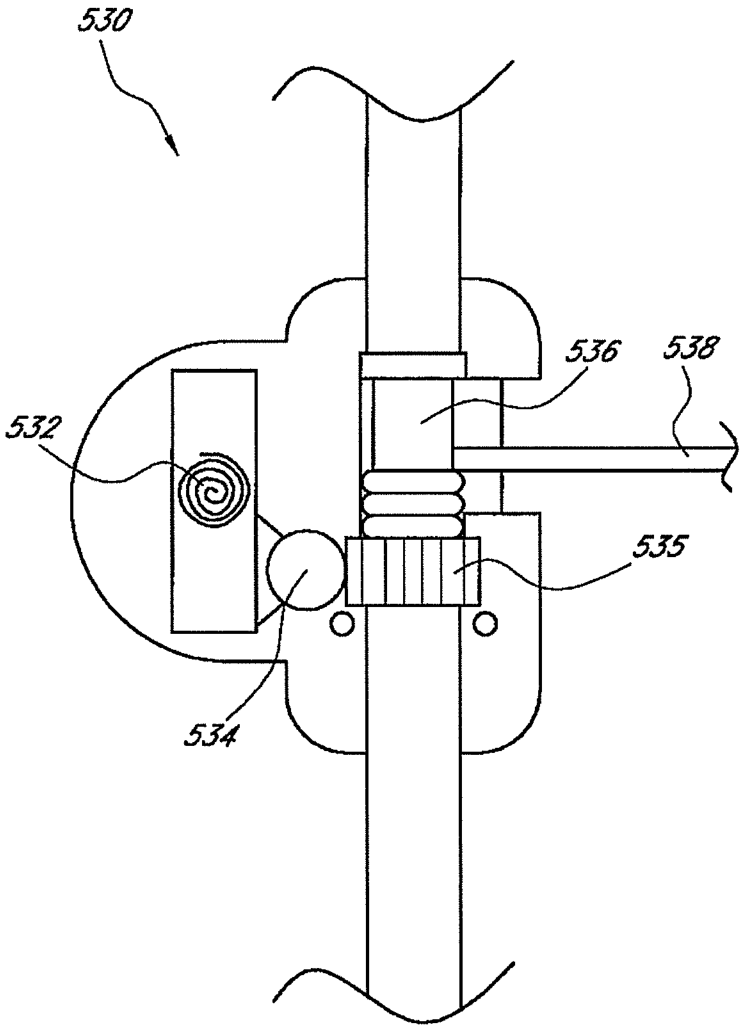

FIG. 10

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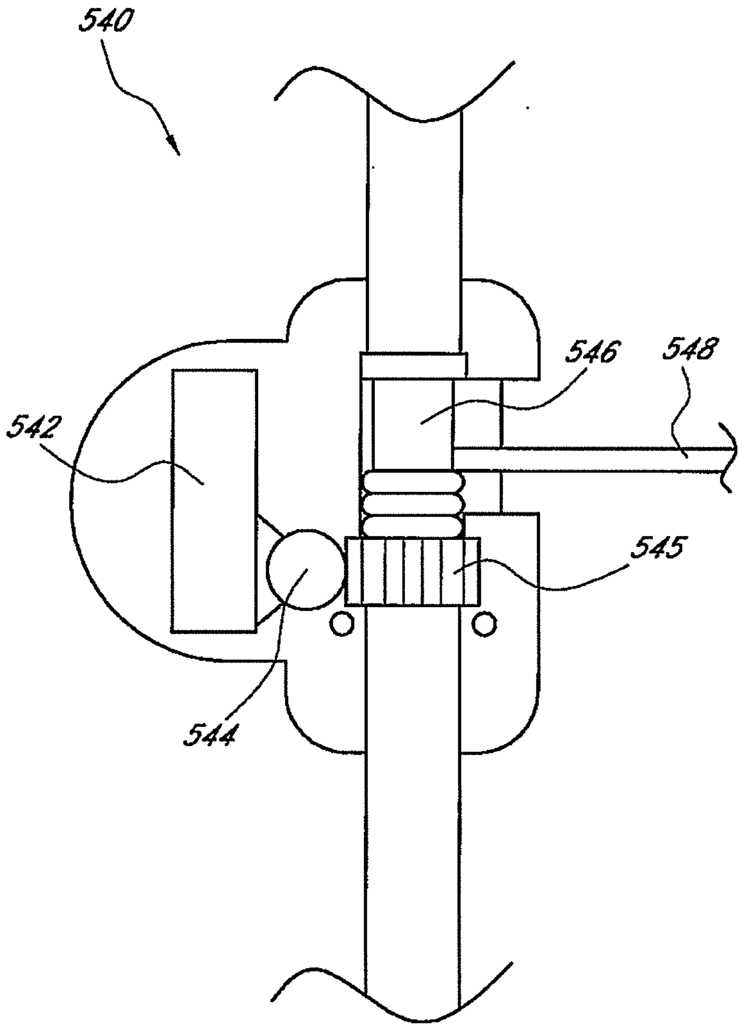

FIG. 11

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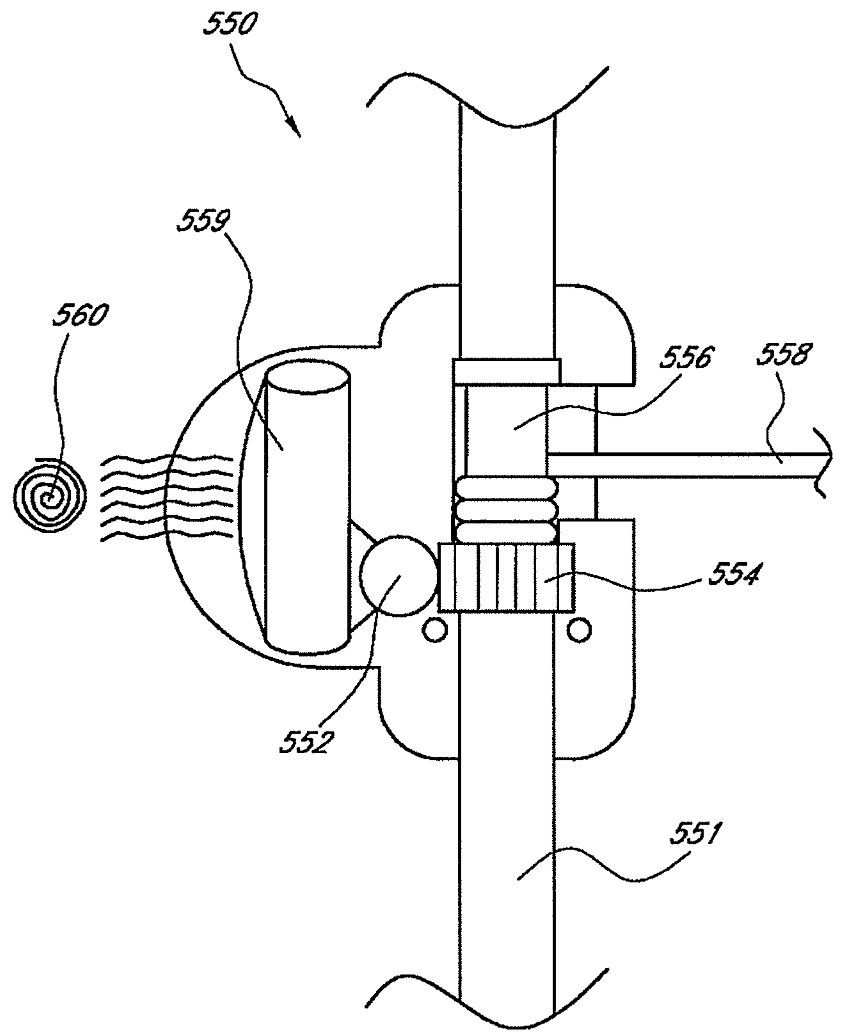

FIG. 12

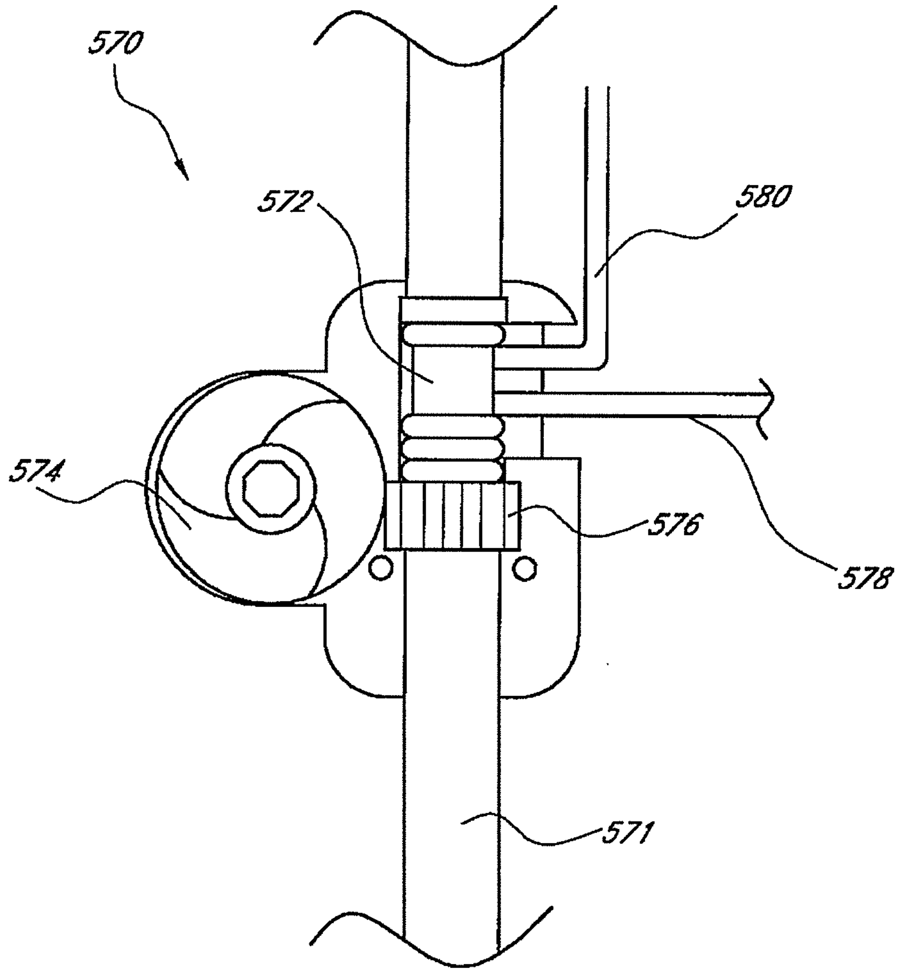

FIG. 13

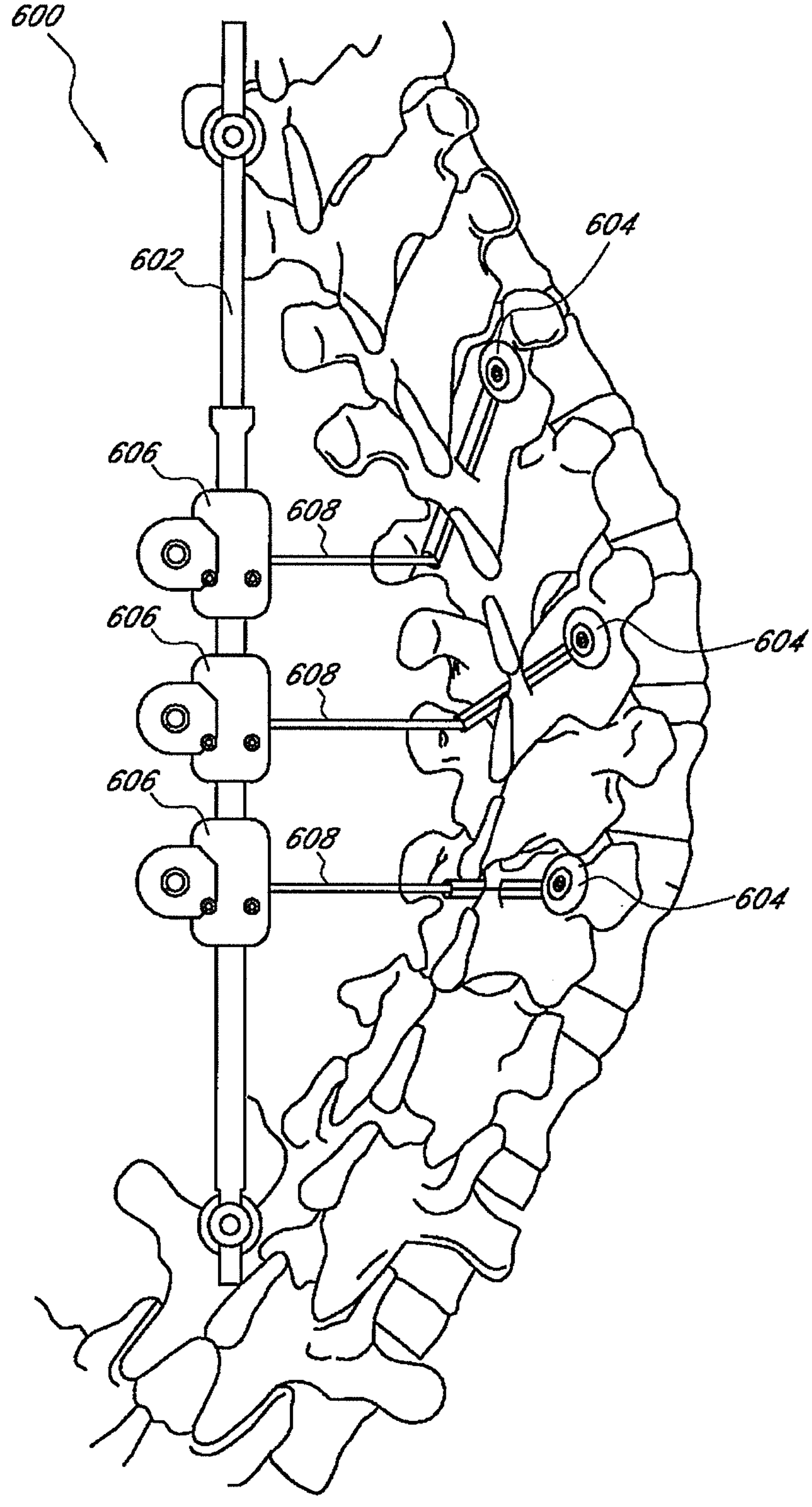

FIG. 14

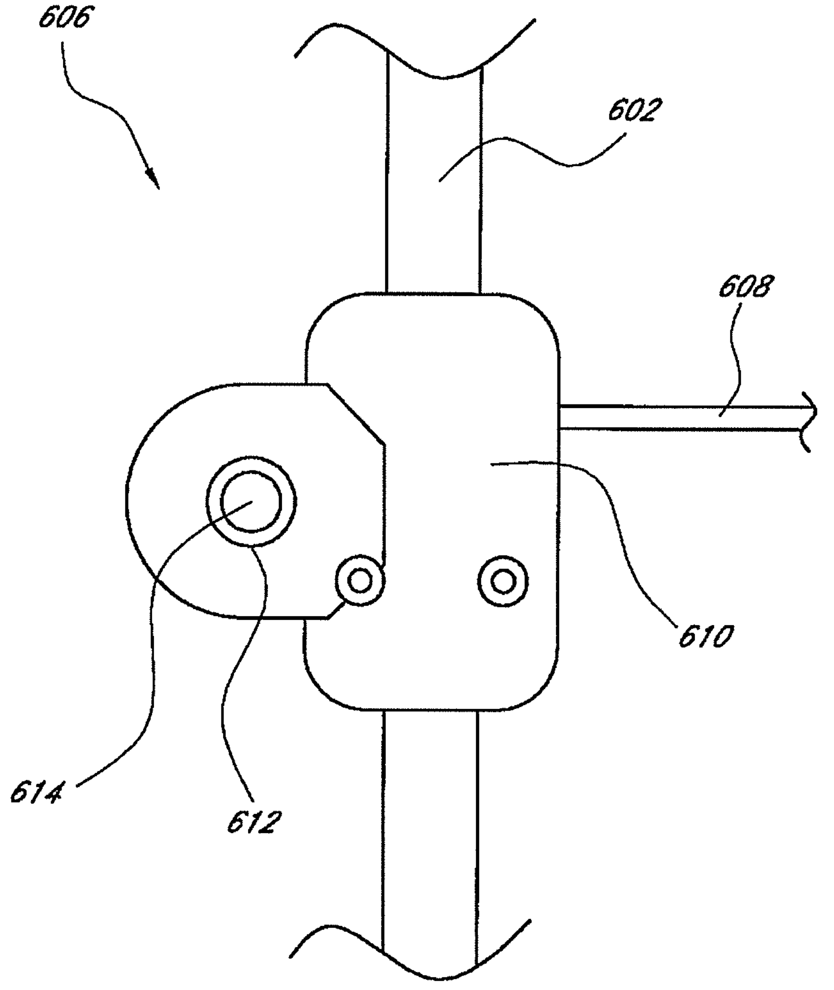

FIG. 15

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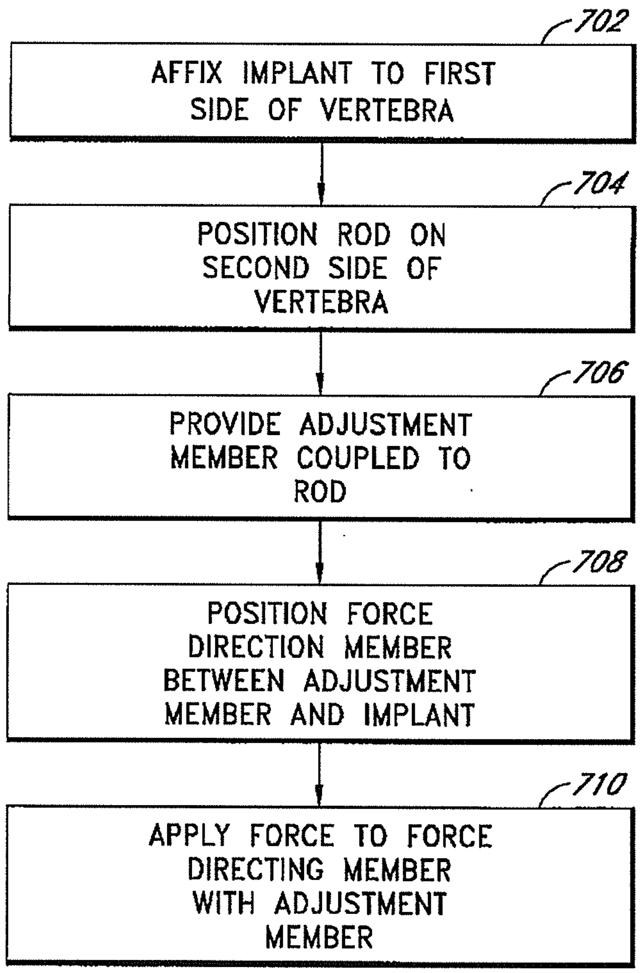

FIG. 16