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(54) **EXPANDABLE ROD SYSTEM TO TREAT SCOLIOSIS AND METHOD OF USING THE SAME**

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A61B 17/70 (2006.01)

(52) **U.S. Cl.** **606/258**

(58) **Field of Classification Search** 606/61, 606/63, 68, 60, 258, 259, 260, 266; 623/17.11–17.16
See application file for complete search history.

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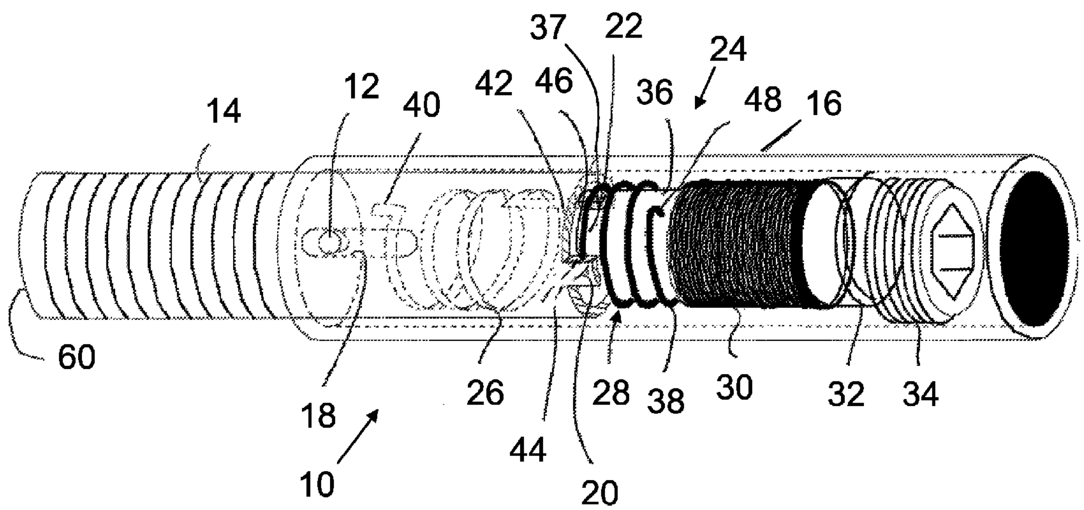
(57) **ABSTRACT**

Correction of a scoliotic curve in a spine comprises the steps of implanting an expanding rod isolated completely under the skin and attached to selected portions of the scoliotic curve of the spine at opposing ends of the rod; and producing a controlled force by means of expansion of the rod over at an extended time period under external control until a desire spinal curve is obtained. An incremental force is generated to stretch the scoliotic curve of the spine between the selected portions where attachment of the rod is defined. The controlled force is provided steadily for at least one month or alternatively 1-3 months. Multiple rods may be employed each associated with a different scoliotic curve of the spine or a different portion of the scoliotic curve.

16 Claims, 6 Drawing Sheets



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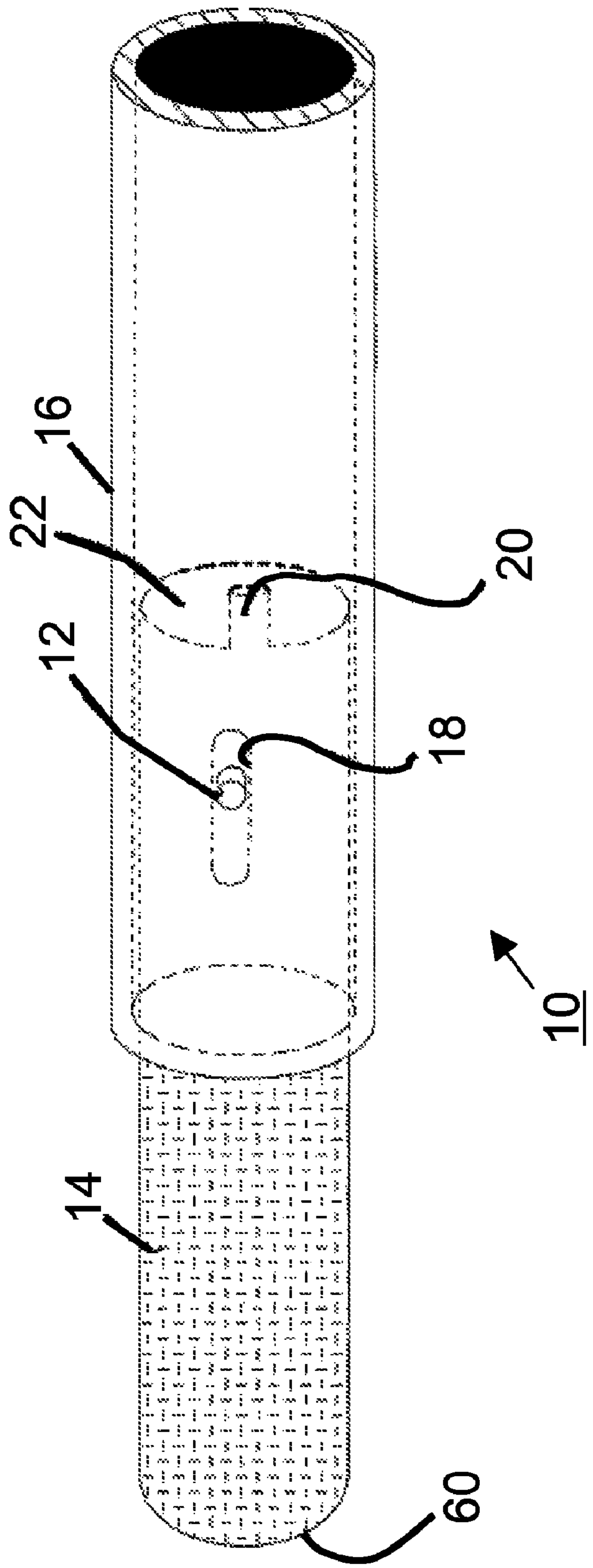

Fig. 1

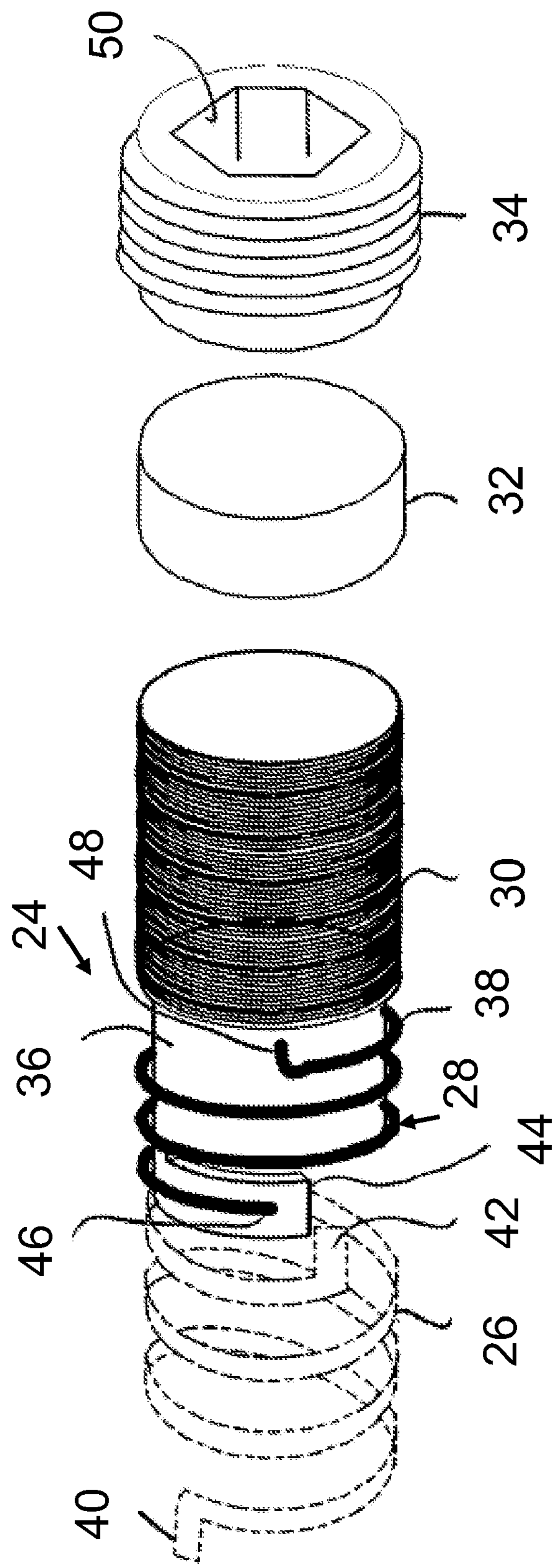

Fig. 2

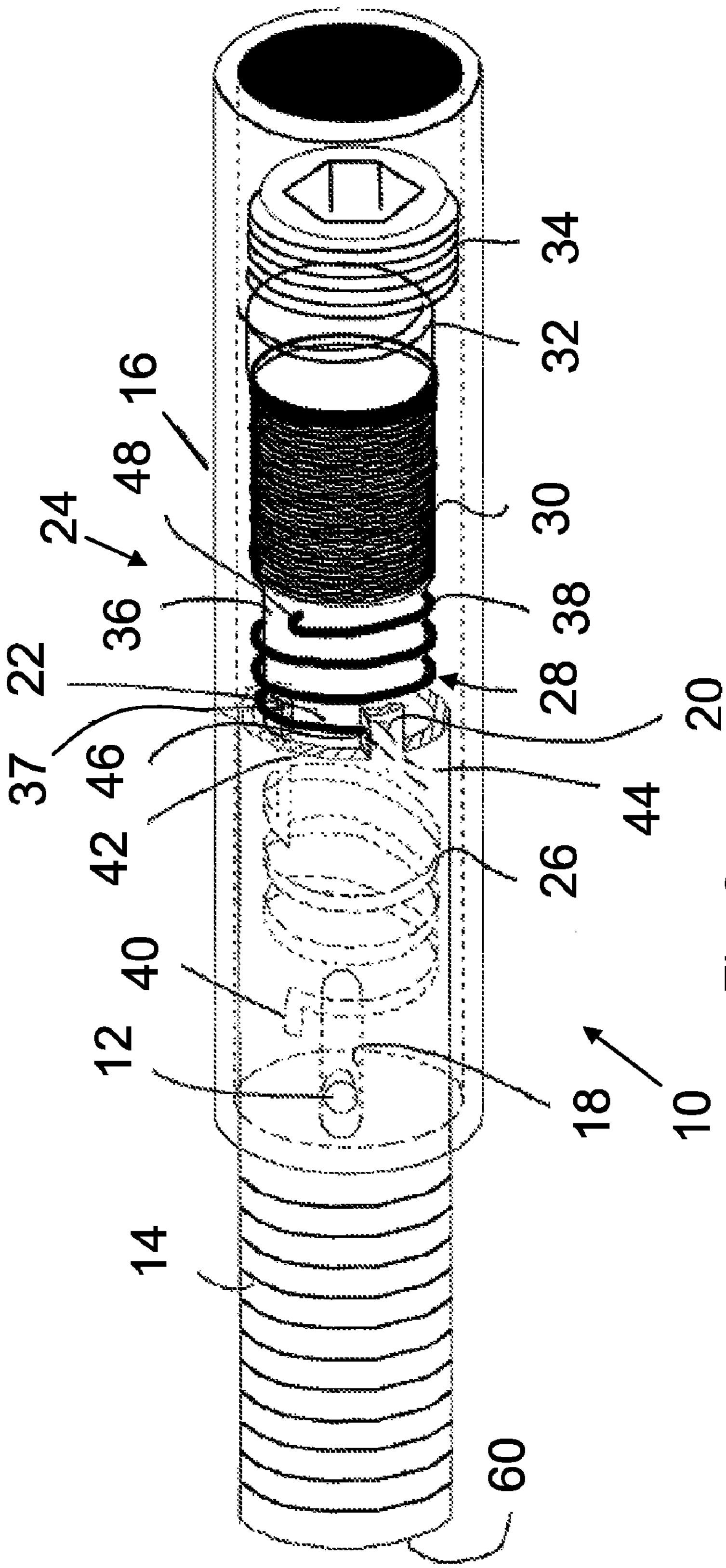

Fig. 2a

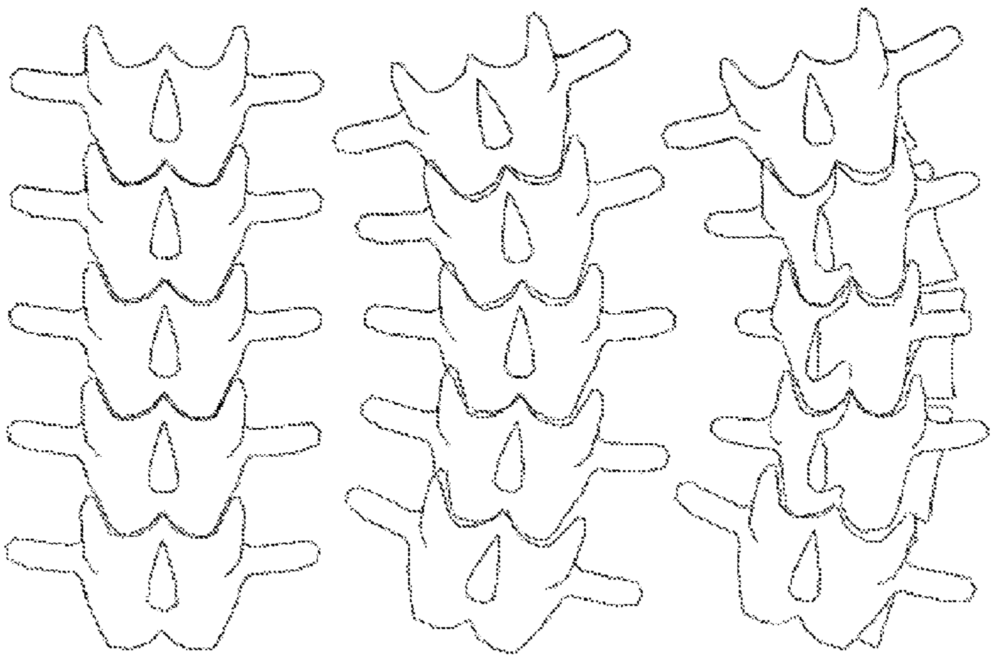

Fig. 3

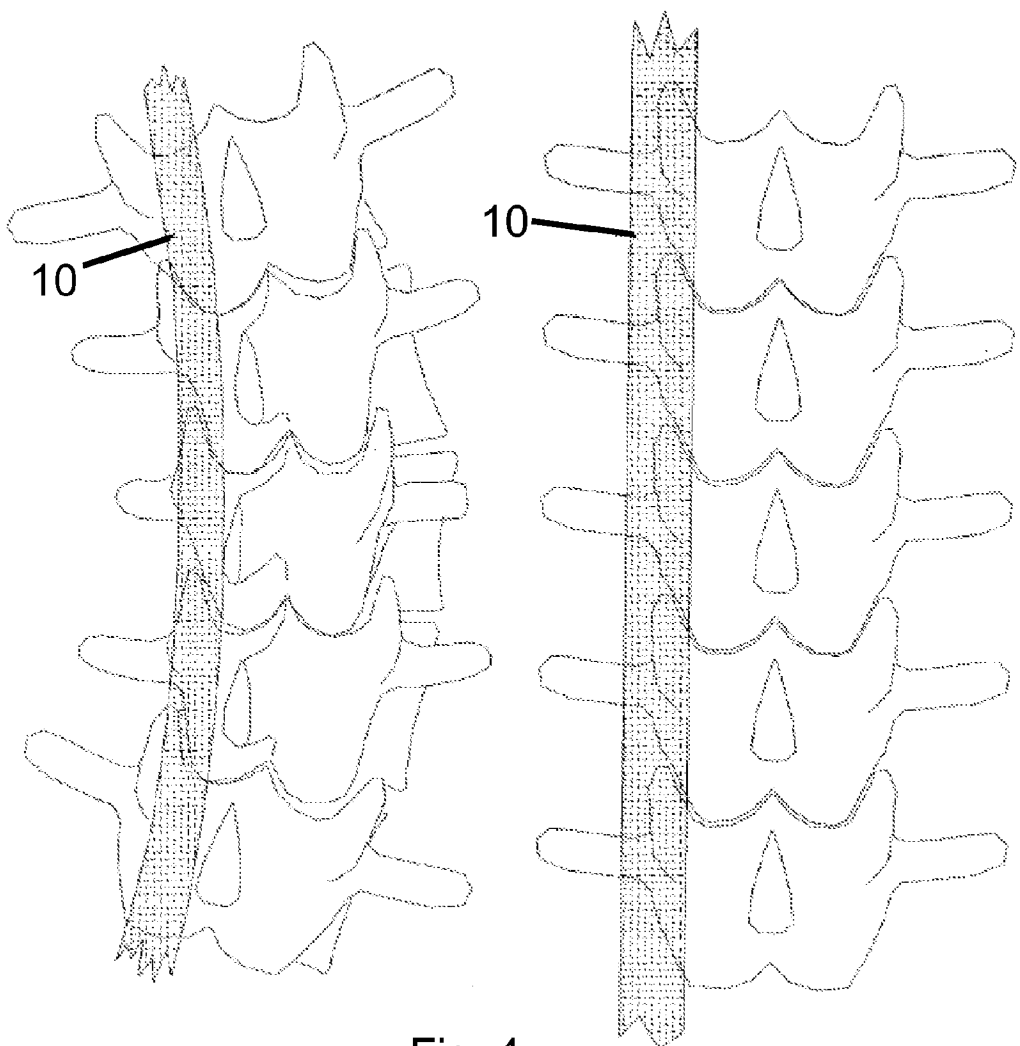

Fig. 4

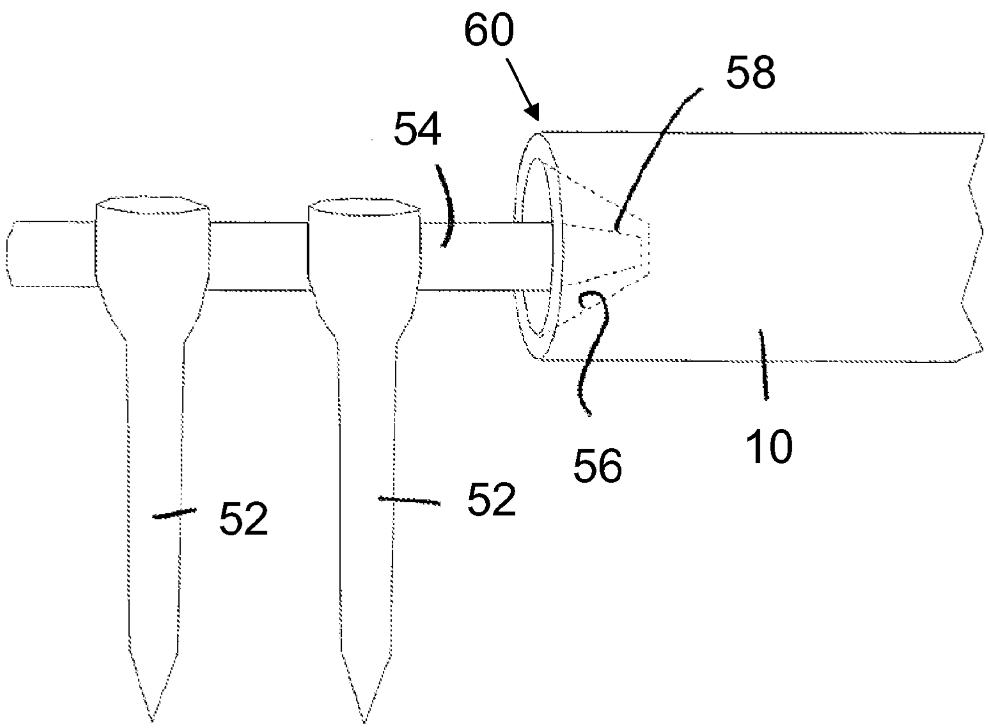

Fig. 5

EXPANDABLE ROD SYSTEM TO TREAT SCOLIOSIS AND METHOD OF USING THE SAME

RELATED APPLICATIONS

The present application is related to U.S. Provisional Patent Application, Ser. No. 60/584,961, filed on Jul. 2, 2004, which is incorporated herein by reference and to which priority is claimed pursuant to 35 USC 119.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to the field of medical devices for treating scoliosis and methods of treatment using such medical devices, or methods of using such devices.

2. Description of the Prior Art

Adolescent (also called idiopathic) scoliosis is believed to be the direct result of a tight ligamentum flavum during rapid growth. The ligamentum flavum is a strong discontinuous (or segmental) ligament full of elastic fibers (which gives it its yellow color) that runs along the posterior aspect of the spinal canal. The posterior aspect of the dura, at any given spinal level, touches lamina for one third of its length, and ligamentum for the other two thirds. In the lumbar spine it acts as the center of rotation (and maybe the center of rotation for the thoracic as well, which would help explain the limited rotation available in the thoracic spine).

If indeed scoliosis is the result of a tight ligamentum flavum, then correction of scoliosis should be achievable by mechanical stretching. Rapid correction of a scoliotic curve is now possible because great force through multiple points of solid fixation are now available. These methods still, however, are described as steps toward inserting instrumentation for a fusion of vertebrae. A slower and steady stretch over time, would be much less violent, and would allow the use of much less force and fewer points of fixation.

What is needed is some kind of device and mechanics to perform the needed mechanical stretching.

BRIEF SUMMARY OF THE INVENTION

The illustrated embodiment of the invention includes a method for correction of a scoliotic curve in a spine comprising the steps of implanting an expanding rod isolated completely under the skin and attached to selected portions of the scoliotic curve of the spine at opposing ends of the rod; and producing a controlled force by means of expansion of the rod over at an extended time period under external control until a desire spinal curve is obtained.

The step of producing a controlled force comprises the step of generating an incremental force to stretch the scoliotic curve of the spine between the selected portions where attachment of the rod is defined. The step of generating an incremental force to stretch the scoliotic curve of the spine comprises the step of generating a force using a curved rod in a direction tending to align with the spine at the selected portions where attachment of the rod is defined.

The step of implanting the expanding rod comprises implanting the expanding rod posteriorly to the spine.

The step of producing a controlled force by means of expansion of the rod over at an extended time period comprises the step of producing the controlled force at a predetermined level over time without any combination with fusion of vertebrae.

The step of producing the controlled force by means of expansion of the rod over at an extended time period comprises producing the controlled force steadily for at least one month or alternatively 1-3 months.

The step of producing the controlled force by means of expansion of the rod over at an extended time period comprises the step of producing the controlled force steadily for such period of time as is sufficient to stretch the ligamentum flavum of the spine enough to allow the spine to straighten.

The invention further contemplates repeating the steps of implanting an expanding rod with multiple rods, where each rod is associated with a different scoliotic curve of the spine or a different portion of the scoliotic curve of the spine, and separately producing a controlled force by means of expansion of each corresponding rod over at a corresponding extended time period.

The step of producing the controlled force by means of expansion of the rod comprises the step of producing the controlled force by means of a ratcheted longitudinal extension of the rod powered by an energy sources biologically isolated from the rod by a skin barrier.

The invention also comprises an apparatus used for performing each of the above embodiments of the illustrated method. The invention thus includes among other embodiments a kit of a plurality of expanding rods with multiple rods, each rod being associated with a different scoliotic curve of the spine or a different portion of the scoliotic curve of the spine and separately producing a controlled force by means of expansion of each corresponding rod over at a corresponding extended time period.

The means for producing the controlled force by means of expansion of the rod comprises means for producing the controlled force by a ratcheted longitudinal extension of the rod powered by an energy sources biologically isolated from the rod by a skin barrier.

Stated in an alternative form, the invention includes embodiments where the invention is an apparatus for correction of a scoliotic curve in a spine comprising an expanding rod isolated completely under the skin; attachment screws to couple the rod to the spine at opposing ends of the rod; and a source of controlled force coupled to the rod to longitudinal extend the rod over an extended defined period of time under external control until a desire spinal curve is obtained.

The rod comprises a pair of telescopically coupled sleeves; and means to prevent relative rotation of the sleeves. The apparatus is combined with an external source of power, and in one embodiment the source of the controlled force comprises a torsion spring coupled to a second one of the pair of sleeves, a torsion motor coupled to the spring for torsioning the torsion spring, a power pick up electrically coupled to the torsion motor for powering the motor from the external source of power, a ratchet and a screw drive coupled to the ratchet at one end and to a first one of the pair of sleeves at an opposing end, so that a force applied to the screw drive from the torsion motor to the first one of the pair of sleeves over time longitudinally expands the collective length of the pair of sleeves. In the illustrated embodiment the torsion motor comprises a muscle wire.

More generally, where the invention is characterized as a combination of an expanding rod, attachment screws, a source of controlled force, and a ratchet, where the source of controlled force produces a force over a defined period of time, which force is continually maintained to some degree by the ratchet after initial generation by the source until the spine to which the force is steadily applied straightens at least to a partial degree.

While the apparatus and method has or will be described for the sake of grammatical fluidity with functional explanations, it is to be expressly understood that the claims, unless expressly formulated under 35 USC 112, are not to be construed as necessarily limited in any way by the construction of "means" or "steps" limitations, but are to be accorded the full scope of the meaning and equivalents of the definition provided by the claims under the judicial doctrine of equivalents, and in the case where the claims are expressly formulated under 35 USC 112 are to be accorded full statutory equivalents under 35 USC 112. The invention can be better visualized by turning now to the following drawings wherein like elements are referenced by like numerals.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side perspective view of a telescoping rod of the invention showing the telescopic sleeves.

FIG. **2** is a side perspective view of a drive unit of the illustrated embodiment of the invention included in the rod of FIG. **1**.

FIG. **2***a* is a side perspective transparent view of the invention as depicted in FIGS. **1** and **2** shown in assembled form.

FIG. **3** is a posterior view, moving from the left to the right of the drawing, of a straight, lateral bending and sciolotic spine respectively.

FIG. **4** is a posterior view of the rod of the invention as implanted next to a bent sciolotic spine in the left most depiction and next to a straightened spine in the right most depiction of the drawing.

FIG. **5** is a side perspective view of a pair of pedicle screws showing a rotational coupling to the end of the rod of the invention.

The invention and its various embodiments can now be better understood by turning to the following detailed description of the preferred embodiments which are presented as illustrated examples of the invention defined in the claims. It is expressly understood that the invention as defined by the claims may be broader than the illustrated embodiments described below.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention comprises a rod, generally denoted by reference numeral **10**, for the treatment of scoliosis by slow stretching of selected biological tissues, for example, a selected portion of the spine, which is implantable into the body and is under external control. The invention allows for surgical treatment of the spine without fusion of any of the vertebrae, and can be used not only for scoliosis, but also in pediatric orthopedics such as for leg or limb lengthening.

For the purposes of the illustrated disclosure, it is assumed that adolescent (also called idiopathic) scoliosis is the direct result of a tight ligamentum flavum during rapid growth. The evidence for this assumption is impressive and overwhelming. The second assumption made in the illustrated disclosure for the sake of simplicity is that we are treating a simple, single curve, although the indications and complexities of extending the use of the invention to more complex curves is explicitly within the scope of the invention. Where multiple rods **10** are implanted each rod **10** may be fixed across a different scoliotic curve where multiple scoliotic curves exist, or may be fixed across different portions of a single scoliotic curve. In such a case, each one of the multiple rods can be separately controlled to produce the needed straightening force or expansion.

The proposed device comprises an expanding or telescopic rod **10** as shown in side perspective view in FIG. **1**. As described below, the opposing ends of rod **10** will be fixed to selected positions on the spine using conventional surgical screws. The rod **10** must produce a controlled force, slowly over time, under precise external control, and be isolated or implanted completely under the skin and protected by the natural barrier, which the skin provides. Rod **10** also needs to be small, powerful, simple enough to be readily manufactured, immune to accidental activation, and biologically inert. Rod **10** of the illustrated embodiment meets each and all of these criteria.

The rod **10** can be as small as ½" (1.27 cm) in diameter and typically can be made much smaller, subject only material limitations arising from the strength of the rod **10** itself. Rod **10** can be made from any bioengineered or biological inert material desired, and in the illustrated embodiment is fabricated from metal, such as surgical quality stainless steel. Rod **10** is comprised of an inner hollow cylindrical sleeve **14** telescopically disposed in outer, hollow cylindrical sleeve **16**. The outer diameter of cylindrical sleeve **14** is chosen to telescopically slide without binding in the inner diameter of cylindrical sleeve **16** along their common longitudinal axes. A pin **12** is fixed to cylindrical sleeve **14** and extends radially therefrom through a longitudinal slot **18** defined through the wall of cylindrical sleeve **16** to stop rotation of cylindrical sleeve **14** relative to cylindrical sleeve **16** while allowing free relative longitudinal movement of cylindrical sleeve **14** relative to cylindrical sleeve **16** at least to the extent of the length of slot **18**. Sleeves **14** and **16** are shown as circular cylinders in the illustrated embodiment, but pin **12** may be removed and elliptically or other prismatic shapes may be used in place of a cylindrical shape, which would equivalently stop or limit their relative rotation to each other. Therefore, when in the specification the term, "sleeve" is used without modification, it should be understood to have a general prismatic shape.

The larger cylindrical sleeve **16** is internally threaded. The small longitudinally extending post **20** on the right end **22** of the smaller cylindrical sleeve **14** as seen in FIG. **1** is where the drive unit, generally denoted by reference numeral **24**, attaches as described below. Drive unit **24** as shown in the side perspective view of FIG. **2** is housed or disposed inside the cylindrical sleeve **16** with the left end **40** of a torsion spring **26** disposed within and affixed to sleeve **14** as shown in FIG. **2***a*. The opposing end **42** of torsion spring **26** is coupled to or bears against a segment end **44** of shell **36**. Shell **36** is disposed in sleeve **16** as shown in FIG. **2***a* and rotates within the end of sleeve **14**, but is held by a stop(s) **37** from telescopically sliding into sleeve **14**. Shell **36** is thus longitudinally fixed relative to sleeve **14**, but is free to rotate relative to sleeve **14** at least through a defined angular range. Thus, as shell **36** is rotated as described below, torsion spring **26** which has on end connected to sleeve **14** and the other end to shell **36** will wind up or down depending on the sense of rotation of shell **36**.

FIG. **2** shows the drive unit in exploded view which is comprised of spring **26**, motor **28**, pickup coil **30**, ratchet **32** and screw drive **34**. These elements represent the simplest configuration for the drive unit **24**, although it must be understood that any drive unit now known or later devised capable of providing the same or similar force as the illustrated drive unit **24** can be equivalently substituted without departing from the illustrated embodiment of the invention. Because of energy transfer considerations relating to coil **30** and wire **38**, additional electronic or electrical components may be required as discussed below.

The motor **28** comprises a muscle wire **38** wound onto a cylindrical shell **36**. Muscle wire **38** is well known to the art and is also called nitinol wire. When current is passed through the wire **38**, it heats and contracts. Wire **38** is electrically connected to or in circuit with coil **30** in which a current is inductively generated. One end **48** of wire **38** is coupled or connected to shell **36**. The opposing end **46** of wire **38** is coupled or connected to sleeve **14** at post **20** as shown in FIG. **2***a*. The contraction of wire **38** causes the entire remaining portion of drive unit **24** to rotate against the spring **26**. In other words, as wire **38** ohmicly heats due to the current supplied to it from coil **30** and its length contracts, wire **38** will cause shell **36** to rotate. Shell **36** is rotationally coupled or connected to ratchet **32**, which rotates with shell **36** in both senses of rotation. Ratchet **32** is coupled to screw drive **34** through a conventional ratcheting mechanism (not shown) thereby causing screw drive **34** to rotate in one sense of rotation, but slipping with respect to screw drive **34** in the opposite sense of direction. Thus, the screw drive **34** is rotated within sleeve **16** and driven forward or to the left in FIG. **1** causing sleeve **14** to telescope out of sleeve **16**. The combined length of sleeves **14** and **16** thus increases. When the wire **38** cools there is no further torque applied to shell **36** by wire **38**, and torsion spring **26** will rotate shell **36** back to its original angular position within drive unit **24**. Grooves are cut into the screw threads to resist rotation of screw drive **34** in the opposite direction thereby insuring that ratchet **32** slips against the screw drive **34** when shell **3** is returned to its original angular orientation. Screw drive **34** remains in a new advanced longitudinal position within sleeve **16**. In this manner rod **10** can be repeatedly incrementally lengthened by repeated heat cycling of motor **28**. Rod **10** can only lengthen and the ratcheting action of ratchet **32** prevents it from shortening. The ratchet **32** is designed to release or disengage from screw drive **34** when a screw-driver or Allen wrench is placed into through-hex socket **50** of screw drive **34** during surgical placement and adjustment. Torsion spring **26** also provides some longitudinal compressive force which tends to urge ratchet **32** against screw drive **34**, but placement of a tool through socket **50** allows ratchet **32** to be backed off and to disengage from screw **32**. Withdrawal of the tool then allows spring **26** to urge ratchet **32** back into engagement with screw drive **34**. The initial length of rod **10** can thus be manually adjusted up or down at the time of its initial surgical implantation.

The pick-up coil **30** receives energy from an external hand-held source of energy (not shown), such as a low frequency generator of electromagnetic radiation, which is brought into proximity with coil **30**. Rod **10** is implanted beneath the skin barrier, while the source of energy is exterior to the body. The external inductive power source may be driven at conventional line frequency. In the event that the coil **30** is be able to efficiently drive the muscle wire **38**, then either a storage capacitor with a control diode can be added in circuit with coil **30**, or with more complexity, a battery with a diode voltage multiplier, and control diode could be used. Any means of impedance matching between coil **30** and wire **38** on one hand and between coil **30** and the inductive power source on the other may be employed. The use of external power sources and inductively powered implanted coils is well known to the art and are routinely used, for example, in charging implanted pacemaker devices.

For a first alternative, energy would be fed into the pick-up coil until enough was stored in the capacitor to drive the motor **28**. Upon the firing of the motor **28** the hand-held device would sense the discharge, and shut-off for the prescribed lock-out period.

The second alternative is the same, except that an on-board battery assists in charging the capacitor, and thus requires significantly more control electronics.

Consider now the surgical implantation of rod **10** and its operation within the body. Two pedicle screws **52** as shown in FIG. **5** are placed at the top and two pedicle screws **52** at the bottom of the curve in a spine which being treated. Fixed head screws (not shown) are used. The expandable rod **10** is run above the fascia and beneath the skin between the two constructs. The rod **10** is then expanded daily typically for 2-3 months. The duration of treatment is variable and is determined according to medical considerations, which are not directly relevant here. After the desired curve in the spine is attained, the screws **52** and rod **10** are removed.

FIG. **3** shows moving from left to right in the drawing a posterior view of a normal straight, normal in lateral bending, and a scoliotic spine. Note that with normal lateral bending as shown in the center there is no significant rotation. Indeed, in scoliosis as shown in the right most depiction as in lateral bending there is no significant increase in rotation. This is because scoliosis is caused by a tight ligamentum flavum. Because of this scoliosis patients have loss of kyphosis or are even lordotic, even in the thoracic spine. These facts can make a slight curve in the expanding rod **10** very useful as shown in the left most depiction in FIG. **4**. As the spine straightens, rod **10** is also flexible enough to slowly straighten with the spine as shown in the right most depiction in FIG. **4**.

FIG. **4** shows the initial rod placement in the left most drawing. As the rod **10** expands, the spine has nowhere to go except to have the pedicle screws **52** cut out or for the spine to straighten. Because the expansion is slow, the pedicle screws **52** don't cut out. As the spine straightens, and also because the rod **10** is posterior to the ligamentum flavum and is in a poor position to stretch the anterior longitudinal ligament, the spine will be pushed from a horizontal into a vertical position, thus restoring normal kyphosis.

In order to allow both rotation, and some play for the re-establishment of kyphosis, the rod-to-pedicle screw articulation is provided as shown in FIG. **5**. Rod **10** is coupled to pedicle screws **52** by means of a pin **54** fixed to screws **52**. The extend end **58** of pin **54** is tapered and is disposed into a conical socket **56** defined into the adjacent end **60** of rod **10**. This allows rod **10** to swivel around the pivot provided between the socket-to-pin connection to rod **10** by fixed pin **54** and pedicle screws **52**.

Scoliosis can be treated without difficult, conspicuous, (and ineffective) bracing; and without fusion. The key is to stretch out the ligamentum flavum. The proposed device discussed should be effective in stretching the spine out of scoliosis. This device would also have several applications other than the spine.

Many alterations and modifications may be made by those having ordinary skill in the art without departing from the spirit and scope of the invention. Therefore, it must be understood that the illustrated embodiment has been set forth only for the purposes of example and that it should not be taken as limiting the invention as defined by the following invention and its various embodiments.

For example, while a cycling rotational motor **28** with a rotary ratchet has been described, it is entirely within the scope of the invention that a cycled linear motor in combination with a linear ratcheting mechanism could be substituted to replace the illustrated embodiment.

Further, while an ohmicly heated motor is the preferred embodiment, it is also possible to conceive of use of a thermally or otherwise powered piston motor where the driving fluid may be heated by RF diathermy or ultrasound energy.

Still further the motor may be a rotary motor or linear motor with the propelling element of the motor is magnetically coupled to a moving magnetic field source and is combined through appropriate gearing to a ratcheting mechanism which telescopes rod **10**.

Any means by which energy from an external source can be coupled into a motor which will mechanically telescope rod **10** is included within the spirit and scope of the invention.

Therefore, it must be understood that the illustrated embodiment has been set forth only for the purposes of example and that it should not be taken as limiting the invention as defined by the following claims. For example, notwithstanding the fact that the elements of a claim are set forth below in a certain combination, it must be expressly understood that the invention includes other combinations of fewer, more or different elements, which are disclosed in above even when not initially claimed in such combinations. A teaching that two elements are combined in a claimed combination is further to be understood as also allowing for a claimed combination in which the two elements are not combined with each other, but may be used alone or combined in other combinations. The excision of any disclosed element of the invention is explicitly contemplated as within the scope of the invention.

The words used in this specification to describe the invention and its various embodiments are to be understood not only in the sense of their commonly defined meanings, but to include by special definition in this specification structure, material or acts beyond the scope of the commonly defined meanings. Thus if an element can be understood in the context of this specification as including more than one meaning, then its use in a claim must be understood as being generic to all possible meanings supported by the specification and by the word itself.

The definitions of the words or elements of the following claims are, therefore, defined in this specification to include not only the combination of elements which are literally set forth, but all equivalent structure, material or acts for performing substantially the same function in substantially the same way to obtain substantially the same result. In this sense it is therefore contemplated that an equivalent substitution of two or more elements may be made for any one of the elements in the claims below or that a single element may be substituted for two or more elements in a claim. Although elements may be described above as acting in certain combinations and even initially claimed as such, it is to be expressly understood that one or more elements from a claimed combination can in some cases be excised from the combination and that the claimed combination may be directed to a subcombination or variation of a subcombination.

Insubstantial changes from the claimed subject matter as viewed by a person with ordinary skill in the art, now known or later devised, are expressly contemplated as being equivalently within the scope of the claims. Therefore, obvious substitutions now or later known to one with ordinary skill in the art are defined to be within the scope of the defined elements.

The claims are thus to be understood to include what is specifically illustrated and described above, what is conceptionally equivalent, what can be obviously substituted and also what essentially incorporates the essential idea of the invention.

I claim:

1. An apparatus for treatment of a scoliotic curve in a spine of a subject comprising:
- an expanding rod having first and second ends, configured for subcutaneous placement along a length of the spine including at least two non-adjacent vertebrae, the expanding rod comprising an outer sleeve and an inner sleeve telescopically disposed in the outer sleeve;
- a drive unit disposed in the outer sleeve and operatively coupled to the inner sleeve, wherein actuation of the drive unit extends the inner sleeve longitudinally relative to the outer sleeve; and
- a rotational swivel disposed on at least one of the first and second ends of the expanding rod, the rotational swivel comprising a socket configured to swivel freely about a pin that is urged into the socket under axial compression and separates from the socket under tension to convert lateral scoliotic curving of the spine into kyphotic forward spinal flexion as the expanding rod expands.

2. The apparatus of claim **1**, wherein the pin is stationary.

3. The apparatus of claim **2**, wherein the pin has a tapered end and the socket is conical-shaped.

4. The apparatus of claim **1**, wherein the drive unit comprises a rotational motor.

5. The apparatus of claim **1**, wherein the drive unit comprises a linear motor.

6. The apparatus of claim **1**, wherein the drive unit comprises a propelling element magnetically coupled to a moving magnetic field source.

7. The apparatus of claim **1**, further comprising a screw operatively coupled to the drive unit.

8. The apparatus of claim **1**, wherein the expanding rod is curved.

9. The apparatus of claim **1**, wherein the drive unit generates an incremental force on the spine when actuated.

10. The apparatus of claim **9**, wherein the drive unit is configured for actuation periodically over a period of months.

11. The apparatus of claim **1**, wherein the inner sleeve comprises a hollow sleeve.

12. The apparatus of claim **1**, wherein the socket is disposed in a terminus of at least one of the first and second ends of the expanding rod.

13. The apparatus of claim **1**, wherein the rotational swivel moves with at least one degree of freedom.

14. An apparatus for treatment of a scoliotic curve in a spine of a subject comprising:
- an expanding rod having first and second ends, configured for subcutaneous placement along a length of the spine including at least two non-adjacent vertebrae, the expanding rod comprising an outer sleeve and an inner sleeve telescopically disposed in the outer sleeve;
- a drive unit disposed in the outer sleeve and operatively coupled to the inner sleeve, wherein actuation of the drive unit extends the inner sleeve longitudinally relative to the outer sleeve;
- at least one securing member configured to hold the expanding rod along the length of the spine; and
- an articulation disposed between the at least one securing member and at least one of the first and second ends of the expanding rod, the articulation comprising a socket configured to swivel about a pin that is urged into the socket under axial compression and separates from the socket under tension to convert lateral scoliotic curving of the spine into kyphotic forward spinal flexion as the expanding rod expands.

15. The apparatus of claim **14**, wherein the socket is disposed in a terminus of at least one of the first and second ends of the expanding rod.

16. The apparatus of claim **14**, wherein the articulation pivots in multiple degrees of freedom.

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