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(54) Title: DEVICE AND METHOD FOR VERTEBRAL COLUMN DISTRACTION AND OSCILLATION

(57) Abstract: The present invention is generally directed to a device for manipulating the spinal vertebrae of a subject. Said device comprises at least one activator having a moveable element which is capable of being displaced in response to externally induced energizing signals, wherein said activator is affixed to at least one vertebra, and coupled to at least one other vertebra, such that said activator is capable of moving the vertebra(e) to which it is coupled in an axial direction, wherein said movement can be unidirectional, resulting in either distraction or compression of the vertebrae, or bidirectional, resulting in an oscillatory movement of the vertebrae.

Device and method for vertebral column distraction and oscillation

Field of the Invention

The present invention relates to methods and devices for manipulating spinal vertebrae. More particularly, the invention relates to methods and devices for distracting, compressing, and/or oscillating, spinal vertebrae.

Background of the Invention

Some orthopedic treatments, in particular treatments of spinal deformities, involve the straightening and/or lengthening of the spinal cord, and/or enhancing spinal fusion. Patients suffering from spinal deformities such as scoliosis are prone to loss of height following spinal fixation. The expected lost height for each vertebra is 0.07 cm per year of growth remaining until skeletal maturity. These patients would potentially benefit from the controlled distraction of their vertebral column, as a means of regaining lost height.

Patients suffering with pain resulting from spinal instability (for example, following surgical procedures such as dissectomy and laminectomy) often find relief following spinal fusion of the affected region. In many of these procedures spinal fusion is performed by using pedicular screws and rods in addition to bone graft in the form of bone chips between the corresponding transverse processes of the vertebrae. However, in many cases - particularly where the local blood supply to the vertebrae is less than ideal - the prior art procedures that utilize the implantation of bone chips along with rigid spinal fixation are unsuccessful due to lack of fusion of said chips resulting in a failure rate of the above said fusion of 10-30%, especially when more than one segment is fused and in case the patient is a smoker. There thus exists a need for an improved method for obtaining spinal fusion.

In addition, in cases of spinal stenosis, one of the main etiologies is loss of disc height which starts a vicious circle of spinal instability and production of bony spurs (osteophytes) leading to the spinal canal stenosis and to stenosis of the spinal foramina. It would be advantageous to perform controlled elongation of the stenotic spinal segments in order to restore the height of the spinal segment and thus decrease the pressure both in the spinal canal and at the spinal foramina.

Moreover, the technique of bone grafting is a cornerstone of many spinal fusion operations, including but not limited to scoliosis. In that situation, patients need to wear cumbersome braces for long periods of up to one year in order to allow the fusion process to take place without risking hardware failure of the instrumentation. These patients would be highly satisfied if this period could be considerably shortened.

U.S. Patent application serial No. 2005/261682 (to Bret A. Ferree) describes a vertebral shock absorber constructed from telescopic members. In this shock absorber a compressible resilient component, such as a spring, elastomeric material, liquid, gel, or hydrogel, is disposed in the cavity of the telescopic members. The ends of the shock absorber are fastened to an upper vertebra and a lower vertebra by pedicle screws or by way of ball-and-socket joints for enhanced range of motion.

Heretofore known prior art devices for treating the spinal cord have not provided suitable means for applying controlled retraction, compression and/or oscillation of adjacent vertebrae, and of stimulating bone union in the spinal cord.

The primary aim of the present invention is to provide a device that may be implanted in close relation to the desired region of the vertebral column and which may be used for either controlled vertebral distraction or for stimulating bone union by means of causing mechanical oscillation, compression, and/or tension.

Another aim of the present invention is to provide a surgical procedure for causing controlled distraction that may be followed, if required, by mechanical vibrations (oscillations), of the spinal column, said procedure being suitable for use in the management of spinal deformities such as scoliosis and stenosis.

A further aim of the present invention is to provide a surgical method for causing stimulating bone union in clinical situations by compression and/or vibration (oscillation) in which it is desirable to initiate and/or enhance spinal fusion.

It is a further object of the present invention to provide a device capable of applying distraction, compression, oscillation (vibration), and/or tension, between spinal vertebrae for stimulating bone union.

Summary of the Invention

The present invention describes a device for manipulating spinal vertebrae of a subject, wherein said device may be implanted by means of screws onto at least two vertebrae of said subject. The device generally comprises at least one activator comprising a moveable element which is capable of being displaced in response to externally induced energizing signals, wherein said activator is affixed to at least one vertebra, and coupled to at least one other vertebra, such that said activator is capable of moving the vertebra(e) to which it is coupled in an axial direction, wherein said movement can be unidirectional, resulting in either distraction or compression of the vertebrae, or bidirectional, resulting in an oscillatory movement of the vertebrae.

The phrase "manipulating spinal vertebrae" and phrases related thereto refer to manipulations whereby the vertebrae are caused to move axially, in any desired direction (i.e. distractive, compressive and/or oscillatory movements).

The phrase "energizing signals" in the context of the present disclosure refers to signals (e.g. a magnetic field) capable of remotely and wirelessly actuating mechanical displacement means attached to the spinal column, which react in the presence of said signal. These "energizing signals" may be applied according to a predetermined pattern of signals, or they may be determined according to a feedback signal received from the device that monitors the obtained movements.

The device preferably comprises one or more elongated platforms, each of which is horizontally affixed to one of the vertebrae of said subject, wherein said elongated platforms are used for affixing said at least one activator, and/or for attaching coupling means, to the respective vertebra. The device may further comprise linear guidance means slidably attached to the sides of said two or more vertebrae. Alternatively or additionally, the device may comprise stabilizing and synchronizing arms rotatably attached to the sides of some of said at least two vertebrae and/or to elongated platforms horizontally affixed thereto. The coupling means may be implemented by lever arms and/or ramp surfaces attached to one or more of said elongated platforms.

The activator may be configured to be energized by an externally induced magnetic field. In one specific embodiment of the invention the activator comprises at least one pair of ferromagnetic/magnetic elements, wherein each pair of ferromagnetic/magnetic elements comprises a stationary ferromagnetic/magnetic element affixed to the internal wall of said activator and a movable ferromagnetic/magnetic element affixed in proximity to said stationary ferromagnetic/magnetic element to a shaft coaxially and slidably supported therein, such that magnetic attraction forces are evolved between said ferromagnetic/magnetic elements in the presence of a magnetic field, and wherein said magnetic attraction forces may affect axial movements of said shaft. The activator may further comprise a gear unit coupled to said shaft by means of a clutch and motion conversion units. The activator may further comprise a feedback monitoring assembly for indicating obtained movements and outputting the same to the user, to an external device, or to a controlled feedback system.

In one specific embodiment of the invention the device comprises at least one parallel pair of activators affixed to the lateral sides of at least one vertebra and coupled to another vertebra. The at least one pair of activators, and/or coupling means coupled thereto, may be affixed to at least one vertebra by means of elongated platforms horizontally affixed to said vertebra.

In another aspect, the present invention is directed to a method for regaining lost height in a subject having already undergone a spinal fixation procedure comprising the steps of:

a) Removing one of the fixation rods previously implanted for the purpose of reducing a spinal deformity;

b) Connecting a first device of the present invention as disclosed hereinabove to the same side of the spinal column from which the previously implanted fixation rod was removed in step (a);

c) Removing the second fixation rod;

d) Connecting a second device of the present invention as disclosed hereinabove to the same side of the spinal column from which the second fixation rod was removed in step (c);

e) Optionally interconnecting the two devices by means of one or more interconnecting elements (as described hereinabove);

f) Applying a magnetic field induced by an externally placed coil to the region of the spinal column in which the devices were implanted, such that the activators of said devices respond by applying distracting forces to the vertebrae to which they are coupled in order to increase the distance between the said vertebrae and the vertebrae to which the other ends of said activators are affixed;

g) Optionally applying, at the end of the distraction phase, a magnetic field induced by an externally placed coil to the region of the spinal column in which the devices were implanted, such that the activators of said devices respond by oscillating the vertebrae to which they are coupled in order to increase the healing process and reduce the healing time.

In one preferred embodiment of the above-disclosed method, the subject is a patient being treated for scoliosis.

In one preferred embodiment of the method, the magnetic field is applied at least once per day between 1 second to 30 minutes for a total period of between 1 and 30 days, preferably for a period of one week.

The magnetic field may be applied in several sessions per day where in each session the obtained distraction length may range between few micro-millimeters and up to few tenths of a millimeter. The magnetic field may be applied within time intervals of 0.5 to 30 seconds, where in each of said time intervals the magnetic field is applied for a period of time ranging between 0.1 to 1.5 sec.

Optionally, the magnetic field may be applied in pulses, wherein, the width of said magnetic pulse is in the range of 0.001 second to 10 seconds and the frequency of said pulses is in the range of 0.01 Hz to 500 Hz.

The present invention also provides a method for causing spinal fusion comprising the steps of:

a) connecting a first device of the present invention as disclosed hereinabove to one side of the spinal column and a second said device to the other side of the spinal column;
b) optionally interconnecting the two devices by means of one or more interconnecting elements (as described hereinabove);
c) applying a magnetic field induced by an externally placed coil to the region of the spinal column in which the devices were implanted, such that the activators of said devices respond by applying compressive forces to the vertebrae to which they are coupled in order to reduce the distance between the said vertebrae and the vertebrae to which the other ends of said activators are affixed.

In a preferred embodiment of this method, the compressive force is applied between once and fifty times per day, each time for a period of between 1 milisecond and 120 minutes. Preferably, the compressive force is applied once per day for a period of 20 minutes.

The present invention also provides a method for causing spinal fusion comprising the steps of:

a) connecting a first device of the present invention as disclosed hereinabove to one side of the spinal column and a second said device to the other side of the spinal column;

b) optionally interconnecting the two devices by means of one or more interconnecting elements (as described hereinabove);

c) applying a magnetic field induced by an externally placed coil to the region of the spinal column in which the devices were implanted, such that the activators of said devices respond by applying axially-directed oscillatory forces to the vertebrae to which they are coupled thereby causing axial oscillation of said vertebrae.

In one preferred embodiment of this method, the frequency of the axial oscillation is between 0.01 and 50 Hz, preferably 0.5 Hz. This oscillatory motion may be induced between 1 and 8 times per day, preferably once a day for a period of 20 minutes.

In the above-defined methods of treatment, the first and second devices are preferably connected to the vertebral column using pedicular screws.

Brief Description of the Drawings

The present invention is illustrated by way of example in the accompanying drawings, in which similar references consistently indicate similar elements and in which:

- Fig. 1A is a block diagram generally demonstrating an axial activator of the invention;

- Fig. 1B schematically illustrates a preferred embodiment of an axial activator of the invention based on a magnetic driving source;
- Fig. 1C schematically illustrates another implementation of the magnetic activator of the invention wherein the driving force is delivered to the activator by an arm-lever transferring means;
- Fig. 1D is a block diagram generally demonstrating a rotary output activator of the invention;
- Fig. 1E schematically illustrates a preferred embodiment of a rotary output activator of the invention based on a magnetic driving source;
- Fig. 1F schematically illustrates a preferred embodiment of an axial magnetic activator of the invention in which the axis of rotations is perpendicular to the activator;
- Fig. 1G schematically illustrates a preferred embodiment of a rotary output magnetic activator of the invention based on a linear ratchet mechanism;
- Fig. 2A schematically illustrates a magnetic activation scheme wherein the windings of an electromagnet enclose an axial/rotary magnetic activator;
- Fig. 2B schematically illustrates a magnetic activation scheme wherein the windings of an electromagnet are positioned in the proximity of an axial/rotary magnetic activator;
- Fig. 3A schematically illustrates a device of the invention operating with a pair of parallel axial activators;
- Fig. 3B schematically illustrates a device of the invention operating with a single axial activator and linear guidance means;
- Fig. 3C schematically illustrates a device of the invention operating with a single axial activator and with stabilizing and synchronizing arms;

- Fig. 3D is a variation of the device illustrated in Fig. 3C, wherein the activator is not centered;
- Fig. 3E schematically illustrates a device of the invention operating with a single axial activator and with two pairs of stabilizing and synchronizing arms;
- Fig. 3F schematically illustrates a device of the invention operating with a single axial activator and a lever arm;
- Fig. 3G schematically illustrates a device of the invention operating with a pair of axial activators and respective lever arms linked thereto;
- Fig. 3H schematically illustrates a device of the invention operating with a pair of horizontally disposed axial activators and respective ramp surfaces;
- Fig. 4A schematically illustrates a device of the invention operating with a single rotary activator and ramped surfaces;
- Fig. 4B schematically illustrates a device of the invention operating with a single horizontally disposed rotary activator and an eccenter;
- Fig. 4C is a variation of the device illustrated in Fig. 4B, operating with linear guidance means;
- Fig. 4D is a variation of the device illustrated in Fig. 4B, operating with stabilizing and synchronizing arms;
- Fig. 4E is a variation of the device illustrated in Fig. 4B, operating with two pairs of stabilizing and synchronizing arms;
- Fig. 5A illustrates a portion of a typical vertebral column;
- Fig. 5B shows a top view of a typical spinal vertebra;
- Fig. 6A schematically illustrates a device of the invention comprising a pair of rotary activators and

designed to concurrently operate on a number of vertebrae;

- Fig. 6B schematically illustrates a device of the invention comprising a pair of axial activators and designed to concurrently operate on a number of vertebrae;
- Fig. 6C schematically illustrates a device of the invention comprising a pair of axial activators and designed to concurrently push a number of vertebrae throughout a pin to pin coupling;
- Fig. 6D schematically illustrates a device of the invention comprising a number of rotary activator and designed to concurrently operate on a number of vertebrae with linear guidance means; and
- Fig. 6E schematically illustrates a device of the invention comprising a number of axial activators and designed to concurrently operate on a number of vertebrae with linear guidance means.

Detailed Description of Preferred Embodiments

The present invention aims to provide devices and methods for treating spinal deformities. More particularly, the present invention aims to provide devices and methods for straightening and/or lengthening the spinal cord, and/or enhancing spinal fusion.

Fig. 5A schematically illustrates a portion of a typical vertebral column comprising series of vertebrae **50a**, **50b**, and **50c**. As seen in the top view shown in Fig. 5B, each vertebrae **50** is composed of a disk (anterior body) **100** and a (posterior) neural arch **107**. The neural arch **107** comprises two transverse processes **101** protruding transversely, a spinous process **104** protruding posteriorly, and superior articular facets **103** protruding upwardly.

The device of the present invention comprises an activator configured to generate axial or rotary motion which may be used to cause increased or decreased separation between pairs of adjacent vertebrae. A typical axial activator is composed of at least one pair of mutually-contacting elongate members which are arranged such that the overall end-to-end length thereof may be altered by causing each member of the at least one pair to move axially in relation to each other. The cross section of said members can be circular, elliptic, rectangular, square or any other shape. The members may be solid, hollow or a combination of the two, and are manufactured by the use of the standard machining processes that are well known in the art. Said members may be constructed from any suitable biocompatible material including (but not limited to) titanium alloys and a biocompatible stainless steel alloy such as 316LVM. The overall end-to-end length of a device activator of the invention (i.e. comprising one or more pairs of elongate members) is usually in the range of 2 cm to 40 cm. The precise length will, of course, be determined by the length of the vertebral column that requires to be treated. Each elongate member will typically have, but not be limited to, an external diameter of between 1 and 25 mm.

Connected to each of said members is at least one connecting element, the purpose of which is to connect said member with a pedicular screw inserted into a vertebra **50**. The pedicular screws will generally have a diameter of between 1 mm and 16 mm, preferably 3.5 mm, and can be fully or half threaded, the screws may be uncoated or coated either with hydroxyapatite or with other materials improving their lasting purchase of bone.

The pedicular screws are typically screwed into the transverse processes **101** and/or the into disk **100** section of the vertebra.

Preferably, each activator is linked with two connecting elements. However, any suitable larger number of connecting elements (in accordance with the overall length of the elongate member in question) may be used, as required, without exceeding the bounds of the present invention.

Optionally, one or more of said members may also have connected thereto a longer interconnecting element, the purpose of which is to provide a connection with the corresponding member of a similar device located on the contralateral side of the vertebral column.

Standard connectors for use in spinal surgery (such as the De Puy and Aesculap connectors, both of which are well-known in the art) may be used to construct both the aforementioned connecting elements and the aforementioned optional interconnecting elements.

The mutual contact and interaction of each pair of members may be arranged in one of the two following ways:

1) Each pair of members (i.e., activator) may consist of two mutually-telescoping members, such that the overall change in end-to-end length of said member pair is caused by the axial telescopic movement of one member within the other member. One of the pair of members is hollow, that is, it comprises an internal cavity in which the second member may engage in its axial movement.

2) Each pair of members (i.e., activator) may consist of two members arranged so that they may be caused to slide axially in relation to each other, such that the overall change in end-to-end length of said member pair is caused by the axial sliding of one member over the other member.

In both cases (i.e. the case of a pair of sliding members and the case of telescopic pair), one or both of said members may comprise guide means (e.g., linear guidance) for ensuring the accurate, controlled axial movement of the other member along its length. The guide means may consist of a guide-track having lateral lips that prevent sideways slipping of the second member or guiding pin(s) (e.g., guided pin comprising rollers to minimize friction) that is inserted therein, without impeding the desired axial movement. In another embodiment, the guide means comprises a semi-circular channel into which the second member (having a circular or semi-circular cross-section) is able to move in an axial (but not lateral or rotary) direction. In a further embodiment, the guide means may be provided in the form of a "tongue-and-groove" structure, whereby an axially-directed tongue (or ridge) located on one member may move freely in an axial direction within a complementarily-shaped groove or slot in the second member. Clearly, many other types of guide means are possible, all of which fall within the scope of the present invention.

Both members of the activator are constructed of a non-magnetic material. However, one of said members comprises a ferromagnetic and/or magnetic material (present either in the form of one unit or in the form of several discrete units) that are capable of being actuated by an external magnetic field, such that the member with the ferromagnetic/magnetic unit(s) and/or the member without the ferromagnetic/magnetic parts move axially in relation to each other. By way of example, the aforementioned magnetic material may be provided in the form of a series of pairs of cylindrical (or other shape, such as square) ferromagnets (and/or magnets), each ferromagnet (or magnet) having, for example, a diameter of 3-12 mm and a length of up to 2-40mm (or any other suitable length according to the device dimensions), with a spacing of up to 6 mm between each pair to minimize attraction forces between moveable Ferromagnets and stationary Ferromagnets of adjacent pairs. The gap between the moving and the stationary Ferromagnets/magnets in each pair is preferably up to 1.5mm.

Typically, this arrangement would consist of a series of up to 8 pairs of ferromagnets. It should be emphasized that this configuration is given by way of example only, and is not intended to be limiting in any way.

The axial movement in one direction is caused by the magnetic forces induced by the external magnetic field acting on the member comprising the ferromagnetic/magnetic material, as described hereinabove. In cases where it is required that said moving member will be capable of moving in a second, reverse direction, this axial returning movement in the other direction is caused either by said magnetic forces or by means of a spring and/or other return mechanism, for example a ratchet together with appropriate screws or bolts and nuts (e.g., lead screw). In the case that the activator is formed as a telescoping pair, said spring and/or other return mechanism is located in the internal space of the hollow section. A similar arrangement will also be present when a pair of sliding members is employed.

The above-described axial movements of the elongate members may be used to cause the two sections of the activator to distract from each other in one embodiment (thereby increasing the total end-to-end length of the device), or cause compression in a second embodiment (thereby reducing the total end-to-end length of the device), or to oscillate in a third embodiment.

Progressive spinal distraction (which is most typically used in cases in which height restoration is required) can be achieved by uni-directional magnetically-induced distraction (as described hereinabove) combined with a ratchet or/and unidirectional clutch mechanism or a transmission mechanism pushing an internal and/or external screw or a slider in order to prevent backward motion.

In one embodiment, the device of the present invention may comprise a single pair of mutually-contacting elongate members, as described hereinabove. In other embodiments, however, the device may comprise a plurality of pairs of elongate members, such that upon application of the external magnetic field, the members comprising the magnetic/ferromagnetic material will move in an axial or rotational direction, thereby altering the end-to-end length of the entire device. Various possibilities exist for the forms which the plurality of pairs may take. In one embodiment, for example, each member is a hollow member, capable of accommodating the telescope-like axial movement of another hollow member within its internal cavity. In this embodiment, the device will comprise an assembly of three or more hollow members, each of said members having a larger outer diameter than its neighbor (on one side), in order to accommodate said neighbor within its internal cavity. In a further embodiment, the device of the invention comprises an assembly of three or more members, arranged such that a hollow member alternates with a piston-like member that is capable of moving axially within the internal space of said hollow member. In this case, the middle (i.e. non-terminal) hollow members have either an internal space running through their entire length or two separate internal spaces extending inwards from each end of the member, in order to allow telescopic interaction of piston-like members on both sides of said hollow member. In this embodiment (unlike in the previously described embodiment) the outer diameter of each of the hollow members will be the same. In a further embodiment, the device comprises a plurality of pairs of members, each having the same diameter, said members being connected in series, the end-to-end distance of each pair being elongated by the magnetic field

The spinal vertebra manipulator of the invention may utilize a multi vertebral linear guiding mechanism such as bushings and guide rods or linkage mechanism. As will be described and exemplified herein below, in such implementations a single activator may be effectively used to manipulate a relevant spinal section.

Fig. 1A is a block diagram generally demonstrating an axial activator **18** of the invention. In this example the activator **18** comprises a driving source **1** that is preferably adapted for generating axial movements to a movement transformation unit **2** capable of transforming said axial movements into angular movements, i.e., rotary motion. Said angular movements are received by a gear and unidirectional clutch unit **4** via a ratchet mechanism **3**, wherein said gear is configured to allow the actuation of the vertebra manipulation device of the invention with reduced moments. The rotary movements outputted by gear device **4** are then transformed into axial movements by the transformation unit **5**.

Fig. 1B schematically illustrates an implementation of an axial activator **18a**, constructed according to the scheme described above with reference to Fig. 1A, and in which the driving source (**1**) is based on magnetic force actuation. Axial activator **18a** comprises an elongated hollow body 9 used for housing the units and devices (**1**, **2**, **3**, **4** and **5**) utilized in axial activator **18a**. In a preferred embodiment of the invention the driving source (**1**) is implemented by one or more pairs of stationary magnetic (or ferromagnetic) elements **11** and movable magnetic elements **10**, wherein magnetic elements **11a**, **11b**,..., **11n**, are affixed to the inner wall of body **9**, and movable magnetic elements **10a**, **10b**,..., **10n**, are affixed to shaft **122** slidably centered thereinside.

Stationary magnetic elements **11** are configured to provide a concentric passage suitable to slidably comprise shaft **122**. Each stationary magnetic element **11** preferably occupies a circumferential cross-sectional area of hollow body **9** while providing a passage thereinside, where the passage of the adjacent stationary magnetic elements **11** are centered about the longitudinal axis of elongated body **9**.

Stationary magnetic elements **11** are preferably distributed over a longitudinal section of body **9** in equal distances therebetween, and movable magnetic elements **10** are preferably distributed along shaft **122** in corresponding distances therebetween, such that corresponding pairs of stationary and movable magnetic elements ({**10a**, **11a**}, {**10b**, **11b**},...) are obtained. In this way shaft **122** may be moved horizontally, as exemplified by arrow **7**, by applying a magnetic field along the longitudinal axis of elongated body **9**, which in turn cause attraction forces to develop between each pair of stationary and movable magnetic elements **11** and **10**.

Elongated body **9** is preferably a hollow cylindrical body manufactured from a non-magnetic material such as S.S316LVM or Titanium alloy. Its length is generally in range of 30 mm to 400 mm, preferably about 100 mm. The outer diameter of body **9** is generally in the range of 6 mm to 12 mm, preferably about 10 mm, and its inner diameter in the range of 4 mm to 8 mm, preferably about 7 mm. Stationary magnetic elements **11** are preferably toroid shape elements manufactured form ferromagnetic or magnetic material, such as carbon steel or industial Ferromagnetic alloy, preferably from VACCOFLUX 50, SAE1010, SAE1018, or SAE1020, Carbon steel. The diameter of stationary magnetic elements **11** is determined to allow fitting thereof in the hollow interior of elongated body **9**. Stationary magnetic elements **11** preferably comprise a hollow bore, aligned with the longitudinal axis of elongated body **9**, wherein said bore is configured to allow shaft **122** to move therethrough, for example, said bore may be in the range of 1.5 mm to 3.5 mm, preferably about 2.4 mm.

Shaft **122** may be manufactured from Stainless steel or Titanium alloy, preferably from S.S316LVM. The length of shaft **122** is generally in range of 20 mm to 80 mm, preferably about 30 mm, and its diameter is generally in range of 1 mm to 3 mm, preferably about 2 mm. The distance between pairs of magnetic elements (e.g., the distance between magnetic element **10a** and **10b**) along the longitudinal axis of elongated hollow body **9** is generally in range of 6 mm to 20 mm, preferably about 11 mm. The gap between a stationary magnetic elements **11** and a movable magnetic elements **10** is generally in range of 0.4 mm to 2 mm, preferably about 1.2 mm, and the magnetic force applied during operation of the activator may bring said elements to come into contact.

As exemplified in Fig. 1B, one end tip of shaft **122** contacts the base **12a** of plunger **12**. Plunger **12** is slidably centered in elongated body **9** by means of collar **17** and bearing (or roller) **14** which are affixed to the inner wall of elongated body **9**. Collar **17** is engaged with the body section **12c** of plunger **12**, wherein said body section **12c** comprises a returning spring **13** disposed thereover and between said collar **17** and said base **12a**. Bearing **14** engaged in a horizontal groove **12b** provided on the outer surface of base **12a**, prevents rotational movements thereof and utilized provide linear guidance thereto. This assembly of plunger **12** and spring **13** is efficiently used in the motion transformer (2) to transfer the axial movements of shaft **122**, and to return shaft **12** backwards to its initial position when the applied magnetic force is reduced or zeroed, thereby restoring the gap between the stationary and movable magnetic elements **10** and **11**.

One end of body section **12c** is attached to base **12a** of plunger **12** while its other end is slidably engaged in the hollow interior of base section **18a** of motion converter **18**. One or more rollers **16** provided on body section **12c** are engaged in corresponding helical grooves **18d** provided on the inside wall of the hollow interior of base section **18a**. Alternatively, grooves **18d** may be implemented as helical slits passing from the outer surface of base section **18a** into its hollow interior.

Hollow interior of base section **18a** of motion converter **18** should be respectively configured to allow body section **12c** of plunger **12** perform the entire axial movements forwarded thereto by shaft **122**. An annular groove **18b** is provided over the outer surface of motion converter **18** for rotatably centering it in the internal space of elongated hollow body **9** by means of bearings (or rollers) **8** affixed to the inner side wall of elongated hollow body **9**. This linkage between plunger **12** and converter **18** by means of said rollers **16** and helical groove **18d** translates the axial motion of plunger **12** into an angular motion of converter **18**.

Alternatively, bearing **8** may be implemented without a corresponding groove **18b**, but with one or more concentric ball bearings arranged in tandem, wherein the axes of said bearings coincides with the axis of converter **18**.

Plunger **12** may be manufactured by lathing or mold casting in a cylindrical shape from a stainless steel or Titanium alloy, preferably from S.S316LVM. The diameter of the base **12a** of plunger **12** is generally in the range of 4 mm to 8 mm, preferably about 7.5 mm, and the diameter of its body section **12c** is generally in the range of 2.5 mm to 6.5 mm, preferably about 6 mm.

Converter **18** is coupled to gear and unidirectional clutch unit (**4**) via ratchet mechanism (**3**) implemented by the coupling of a driving ratchet element **18c**, attached to (or formed on) a cross-sectional surface of motion converter **18**, and a driven ratchet element **19a** attached to (or formed on) the base of ratchet **19**. For example, said ratchet elements, **18c** and **19a**, may be implemented by a circular saw tooth arrangement (not shown) provided on opposing faces of said elements, and configured such that rotations of converter **18** resulting from movements forwarded by shaft **122** establish coupling therebetween, while the rotations in the opposite direction, caused by the return of plunger **12** due to spring **20**, breaks said coupling due to the sliding of the saw tooth ramps. Said sliding of the saw tooth ramps results in axial motions of ratchet **19**, the body section **19b** of which is received in a coupling element **20**.

Motion converter **18** may be manufactured by lathing, milling, EDM (Electro Erosion), or mold casting, in a cylindrical shape, from stainless steel or Titanium alloy, preferably from S.S316LVM. The length of motion converter **18** is generally in the range of 6 mm to 8mm, preferably about 7 mm, its diameter is generally in the range of 6 mm to 8 mm, preferably about 7.5 mm, and the angular motions it performs are generally in the range of 4° to 12° , preferably about 6.4°.

As illustrated in Fig. 1B, the cross section of body section **19b** of ratchet **19** is smaller than the cross section area of the driven ratchet element **19a,** which defines an annular recess between driven ratchet element **19a** and coupling element **20,** wherein returning spring **27** resides. The hollow base **20a** of coupling element **20** is configured to receive an end portion of body section **19b** of ratchet **19** thereinto and any axial movements thereof during the sliding of the saw tooth ramps. Returning spring **27** retract portion of said body section **19b** from the interior of hollow base of coupling element **20,** thereby restoring the coupling between ratchet elements, **18c** and **19a**.

Backwards angular motion of ratchet **19** is prevented by means of friction like O-ring seal , the shape of the interacted teeth's profile angle (moderate) and the unidirectional clutch. A sliding pin **19c,** provided on body section **19b** of ratchet **19,** transfers the angular displacements of driven ratchet element **19a** to coupling element **20**. The hollow interior of coupling element **20** receives body section **19b** of ratchet **19** and sliding pin **19c** provided thereon is received in horizontal groove **20b,** thus allowing ratchet **19** to move back and forth, linearly guided, while the ratchet teeth of ratchet elements, **18c** and **19a**, are being engaged/disengaged during their rotation.

Ratchet **19** may be manufactured by lathing, milling, EDM (Electro Erosion), or mold casting, in a cylindrical shape from stainless steel or Titanium alloy, preferably from S.S316LVM. The diameter of driven ratchet element **19a** of ratchet **19** is generally in the range of 6 mm to 8 mm, preferably about 7.5 mm, and its length is preferably about 2 mm. The diameter of body section **19b** of ratchet **19** is generally in the range of 4.5 mm to 6.5 mm, preferably about 5.5 mm, and its length if preferably about 5 mm.

Linear guidance means **20** may be manufactured by lathing or mold casing in a cylindrical shape from stainless steel or Titanium alloy, preferably from S.S316LVM. The outer diameter of hollow base **20a** is generally in the range of 6 mm to 8 mm, preferably about 7.5 mm, and its length is preferably about 6 mm. The inner diameter of hollow base **20a** is generally in the range of 5 mm to 7 mm, preferably about 6 mm, and its length is preferably about 6 mm. The diameter of coupling portion **20c** of linear guidance means **20** is generally in the range of 2 mm to 8 mm, preferably about 5 to 7.5 mm, and its length is preferably about 7 mm.

The rotations transferred by linear guidance means **20** are received via coupling portion **20c** thereof in gear **21**. The chassis **21a** of gear and unidirectional clutch **21** is affixed to inner wall of elongated hollow body **9**, and a stationary part **22a** of thrust bearing element **22** is affixed on its cross section surface. The rotating part **22b** of said thrust bearing element **22** is affixed to the base **23a** of rotating shaft **23**. Thrust bearing element is designed to absorb external shocks and payload axial force which may be delivered via rotating shaft **23**. A cross sectional portion area of said base **23a** is coupled to the output shaft **21b** of gear **21**, where said output shaft **21b** outputs rotational movements received via coupling portion **20c** and which are transformed by transmission elements (not shown) of gear **21**. An annular groove may be formed on the circumference of said base **23a** in which O-ring **23b** may be mounted for sealing elongated hollow body **9**. O-ring **23a** may be implemented by a single, or a pair of, silicone O-rings mounted in grooves provided in base **23a** of rotating shaft **23**.

Gear and unidirectional clutch **21** may be a type of planetary gear head (e.g., 16/1 of Faulhaber group), its diameter is generally in the range of 6 mm to 8 mm, preferably about 7.5 mm, and its length is preferably about 6 mm. The unidirectional clutch is preferably an "of the shelve" unidirectional clutch, such as manufactured by INA integrated in a gear and unidirectional clutch **21**. Thrust bearing element **22** may be implemented by F3-8M manufactured by SAPPORO PRECISION INC.

Rotating pivot **23** comprises a threaded section **23c** for translating the rotational motions received via gear **21** into linear movements outputted via moving arm **24** slidably centered inside elongated hollow body **9**. Some portion of moving arm **24** is made hollow and its internal space can be accessed via an opening provided by the bore of nut **24a** mounted at the base of moving arm **24**. Moving arm **24** may further comprise horizontal grooves for receiving linear guiding means such as rollers, keys, pins, and the like. Affixed to respective locations on the inner wall of elongated hollow body **9**.

Rotating pivot **23** may be manufactured from stainless steel or Ti alloy, preferably from S.S316LVM, its diameter is generally in the range of 5 mm to 7.5 mm, preferably about 7 mm, and its length is preferably about 50 mm. Moving arm **24** may be manufactured by lathing and milling from stainless steel or Titanium alloy, preferably from S.S316LVM, its diameter is generally in the range of 8 mm to 7 mm, preferably about 7.5 mm, and its length is preferably about 90 mm. The diameter of the hollow interior of moving arm **24** is generally in the range of 2.4 mm to 4.4 mm, preferably about 3.4 mm, and its length is preferably about 50 mm.

The axial motion output of magnetic activator **18a** is provided by axial movements of moving arm **24** which protrudes outwardly via opening **28** of elongated hollow body **9**. Said axial motion is obtained from the angular motion outputted by gear **21** which is translated by the threaded section **23c** of rotating pivot **23** and the nut **24a** affixed to the opening to the hollow interior of moving arm **24** into corresponding axial movements.

The magnetic actuation scheme described hereinabove may be used to implement a reciprocating motion device (e.g., for oscillation purposes) operating with lower force magnitudes (e.g., up to 10Kg pushing/pulling force). Such reciprocating motion device may be implemented using pairs of Ferromagnets and/or magnetic elements ({**10a**, **11a**}, {**10b**, **11b**}... {**10n**, **11n**}) and a shaft (**122**) and returning spring (**13**), as described above. The motion converters, ratchet mechanism and gear and clutch devices are not needed in such implementation. Furthermore, the magnetic actuation may be implemented in various Ferromagnetic and/or magnetic elements arrangement using 3 such element in tandem, for instance 2 moving ferromagnetic/magnetic elements and one stationary. Such reciprocating motion implementation may be useful in cases wherein pushing two bone's fracture to each other stimulates and improves fusion at the fracture zone.

The activator may also comprise a monitoring feedback device for measuring directly or indirectly the axial/rotary movements of the activator and output corresponding indications. For example, the monitoring feedback device may be implemented by one of the following options:

1. RF Transmission - A standard miniature RF transmitter may be located inside the activator. Said RF transmitter may be energized via a small battery and transmit system displacement (rotary or linear) to an external monitor. A RF antenna can be located external to the activator.

The rotary or linear displacement measuring may be carried out using a rotary chopper disc (disc with many slots) passing through an opto-coupler device (Infra red solid state diode illuminating a receiver) capable of counting the received pulses. Similarly, a capacitance proximitter, a Hall Effect proximitter,a mechanical switch, or a rotary or linear encoder, may be used in such implementation to provide a readout of the measured movements.

2. An internal Buzzer alert may be used to provide indication relating to the measured movements. The buzzer may be located inside the activator, such that whenever it is indicated that the required elongation was accomplished the buzzer is energized and generates an audible signal that may be sensed by an external microphone located outside the body of the treated subject.

3. A mechanical internal feedback scheme may utilized to lock the Ferromagnets/magnets actuation system whenever a complete elongation cycle (e.g., 0.25mm) is accomplished. In this way, an external microphone may be used to sense that no internal impact noise is created and stop the elongation. An additional electro-magnetic field or internal mechanism may be used to actuate the locking index into a disable position in which it is ready for the next elongation treatment.

Fig. 1C schematically illustrates another possible embodiment of a magnetically-actuated linear activator **18b** of the invention wherein the driving force is delivered from a driving source (**1**) by an arm-lever transferring means **33**. In this example the driving source (**1**) is produced by a driving unit comprising a single pair (or several pairs) of ferromagnetic/magnetic elements, movable ferromagnetic/magnetic element **31** attached to shaft **122b** which passes through stationary ferromagnetic/magnetic element **32** affixed to the inner wall of the driving unit. The axial movements produced by this driving unit in the presence of an alternating magnetic field are transferred by an arm-lever transferring means **33** to a parallel unit comprising axial to rotary motion transformation means (**2**), ratchet mechanism (**3**), gear and unidirectional clutch unit (**4**), and rotary to axial motion transformation means (**5**), similar to those which were previously described hereinabove. As demonstrated in Fig. 1C, such implementation can effectively provide a magnetic activator having a shorter longitudinal length. The arm-lever means **33** may be encapsulated inside the activator hollow body, for example where the plunger (**12** in Fig. 1B) and return spring (**13** in Fig. 1B) to prevent backlash. The rotary arm of arm-lever means **33** may be implemented by a pivoted rod rotatably supported at the center of its length to assure pure rotational displacement.

Fig. 1D is a block diagram demonstrating construction of an activator **30** of the invention which outputs rotary movements. Activator **30** is substantially similar to activator **18**, which was described hereinabove with reference to Fig. 1A. Activator **30** comprises driving source **1**, axial to rotary motion transformer **2**, a ratchet mechanism **3**, and a gear and unidirectional clutch device **4**. As demonstrated in Fig. 1E, a rotary motion magnetic activator **30a** may be constructed with similar components as in the axial magnetic activator which was described hereinabove with reference to Fig. 1B. In this implementation rotary magnetic activator **30a** outputs rotary motion directly via rotating pivot **23**, the end tip of which may protrude outwardly via opening **28a** of elongated hollow body **9a**.

Fig. 1F schematically illustrates a magnetic rotary activator **30b** of the invention in which the axis **36** of the outputted rotary motions is perpendicular to the axis of the elongated hollow body of the activator **30b**. Activator **30b** may comprise a driving source (**1**), axial to rotary motion transformer (**2**), ratchet mechanism (**3**), and gear and unidirectional device (**4**), similar to those described herein above with reference to Fig. 1B. In this implementation the rotary motions outputted by gear device **21** are transferred to rotating shaft **35** via bevel gear **34** comprised of conical transmission wheels **34a** and **34b**. In this case elongated hollow body **9b** is preferably formed in a "L" shape having an opening **28b** perpendicular to the axis of elongated hollow housing **30b**. The base of transmission wheel **34a** is coupled to output shaft **21b** of gear **21**, and its tapered end is coupled to the tapering end of transmission wheel **34b**. Rotating shaft is concentrically affixed in transmission wheel **34b** and is rotatably affixed to the inner wall of elongated hollow body **9b** via supports **26a** and **26b**.

Bevel gear **34** may be a type of straight, spiral or hypoid shape gear, manufactured by milling from stainless steel or Titanium alloy, preferably from S.S316LVM. Of course, the rotary motion may be transferred perpendicularly using other gear means, such as a worm gear.

Fig. 1G schematically illustrates a rotary magnetic activator **30c** of the invention based on a standard linear ratchet mechanism. In this example, elongated hollow body **9c** comprises a pair of actuating magnetic elements, movable magnetic element **41** attached to shaft **122c** which passes through stationary magnetic element **42** affixed to the inner wall of elongated hollow body **9c** via supports **43**. The axial movements produced by this driving unit in the presence of an alternating magnetic field are transferred via shaft **122c** to a linear ratchet **45** coupled to driven rotary ratchet **47**. Return spring **44**, which returns shaft **122c** to its initial position, after each magnetic activation, is mounted between inner end wall of elongated hollow body **9c** and linear ratchet **45**. Pawl mechanism **46** may used to prevent angular backward motion of driven rotary ratchet **47** during the return cycles of shaft **122c**. Gear head **48**, outputting angular motions via output shaft affixed thereto, may be concentrically affixed to driven rotary ratchet **47**.

Linear ratchet **45** is guided linearly via rolling or friction means to maintain consistent coupling with the rotary driven ratchet **47**. Linear ratchet **45** may be manufactured by milling or mold casting from stainless steel or titanium alloy, preferably from S.S316LVM. Driven rotary ratchet **47** is designed to output a desired angular motion, it may be manufactured by milling, EDM, or mold casting from a stainless steel or Titanium alloy, preferably from S.S316LVM. Gear head **48** is preferably a type of planetary gear head, manufactured by milling or mold casting from a stainless steel or Ti alloy, preferably from S.S316LVM.

Figs. 2A and 2B demonstrates magnetic activation schemes which may be possibly used in actuating the spinal column manipulator of the invention. As exemplified in Fig. 2A the windings of electromagnet **112** may enclose the magnetic activator **18/30** (**18** - axial activator; **30** - rotary activator) of the invention. In this way the magnetic activator can be actuated by magnetic flux **111** emanating from electromagnet **112** and passing therethrough, when connected to an electrical current source **113**. Alternatively, as exemplified in Fig. 2B electromagnet **112** may be located adjacent to activator **18/30** such that magnetic flux 111 surrounding it can actuate it. Of course, other magnetic field sources may be similarly used, such as a permanent magnet.

The magnetic field induced by the electromagnet **112** is in the range of 0.01 Tesla to 2 Tesla. The magnetic forces induced by electromagnet **112** are generally in the range of 0.1Kg to 20Kg. Electromagnet **112** may be helmholtz type such as manufactured by TESLA. The electrical currents driven by current source **113** are sinusoidal alternating currents or DC currents, generally in the range of 1 to 500 Amper, preferably about 50 Amper, and their frequency is generally in the range of 0.01 to 50 Hz, preferably about 1 Hz.

Electromagnet **112** may comprise 1 or 2 serially connected coils, wherein said coils are encapsulated, or partially encapsulated, in a suitable Ferromagnetic shielding such as carbon steel to minimize environmental electro magnetic field interferences, and to concentrate the electro magnetic flux within an active area.

Although it is possible to utilize a device of the present invention on only one side of the vertebral column in order to achieve the desired results, in a particularly preferred embodiment, one device is situated on each side of the vertebral column. In this case, the two devices are of equal end-to-end length. Coordination of the end-to-end length changes between the two devices is achieved, in part, by the use of the interconnecting elements described hereinabove.

The following examples describes with reference to Figs. 3A to 3H and Figs. 4A to 4E, a particular solution of the invention which may be utilized in cases wherein manipulation of two neighboring vertebrae is required (e.g., spinal stenosis).

In general, the devices used in these examples are comprised of the following elements:

A. Platform (**53**) - hooked up to the spinal column (vertebrae **50**) by two tightening screws (**51**), which may be used to support linear guidance means (**85** and **86**, Fig. 3B), activators **18/30**, and additional means, if needed.

B. Tightening screws (**51**) - the screw heads may be circular or rectangular or any other suitable shape. Using rectangular shapes heads accompanied by two respective open slots at the platform front side enables easy insertion of the platform onto the two rectangular screw heads and then clamping or securing the platform to the screws.

C. The magnetic activator (**18/30**) may activate a linearly bushing guided telescopic arm (Figs. 3B, 3G, 4C), or a mechanical cantilever leverage mechanism (Figs. 3F, 3G) or a rotational axial cam shaft (Fig. 4A) (Figs. 4B-4E), or a cam shaft mechanism (Figs. 4B, 4C, 4D, 4E) or arms kinematics mechanism with 3-10 arms etc (Fig. 3C, 3D, 3E, 4D,4E).

Fig. 3A schematically illustrates a device of the invention operating with a pair of parallel axial activators **18**. Two platforms, **53a** and **53b**, are attached to the manipulated vertebrae **50a** (lower) and **50b** (upper), respectively, by means of screws **51a** and **51b**, respectively. The screws **51** may be threaded into the disc (**100**, Figs. 5A and 5B), and/or the transverse processes (**101**, Figs. 5A and 5B) bony portions of the vertebrae **50**. The body part of axial activators **18** may be affixed (e.g., by screws **51a**) to the lower platform **53a**, and the moving arm thereof may be similarly affixed to the upper platform **53b**, or the other way around.

Platforms **53a** and **53b** may be manufactured form a S.S316LVM or Ti alloy type of material, preferably from S.S316LVM, and their geometrical dimensions should be determined according to the dimensions of the manipulated vertebrae. For example, the horizontal length of the platforms may be in general in range of 30 mm to 60 mm, preferably about 40 mm, their width in range of 10 mm to 30 mm, preferably about 15 mm, and their thickness in the range of 4 mm to 10 mm. Screws **51a** and **51b** may be any type of suitable screws, such as pedicular screws.

Fig. 3B schematically illustrates a device of the invention operating with a single axial activator **18** and with linear guidance means, **85** and **86**. Axial activator is preferably attached to the centers of platforms **53a** and **53b** by means of clamping or tightening screws on one side where in the other floating/rigid coupling such as surface to surface contact, ball and socket mechanism, clevis mechanism, round edge against conical shape slot or cavity. Linear guidance means may be constructed from shafts **85b** and **86b**, affixed (e.g., by screws **51a**) to the lower platform **53a** and telescopically engaged in respective bushings and **85b**, which are affixed (e.g., by screws **51b**) to the upper platform **53b**.

Shafts **85b** and **86b** may be manufactured by lathing from a stainless steel or Titanium alloy type of material, preferably from S.S316LVM, their diameter is generally in range of 2 mm to 6 mm, preferably about 3 mm. Bushings **85a** and **86a** may be manufactured by lathing from stainless steel or Titanium alloy, preferably from S.S316LVM, their outer diameter is generally in range of 5 mm to 10 mm, their inner diameter is generally in range of 3 mm to 8. The length of said shafts and bushings should be determined in each specific case according the distance between the vertebrae.

It should be noted that a bio-compatible low friction polymeric bushing may be implemented into the metallic bushing inner diameter spacing to be in-contact with the shaft in order to reduce friction.

Fig. 3C schematically illustrates a device of the invention operating with a single axial activator and with stabilizing and synchronizing arms **56a** and **56b**. As in the device described above with reference to Fig. 3B, activator **18** is affixed to the centers of platforms **53a** and **53b**. Arms **56a** and **56b** are rotatably attached to respective supporting means, **55b** and **55a**, which are welded or machined at one lateral side to the lower side of platform **53b** and to the upper side of platform **53a**, respectively. Mutual rotational axis **59** attached the centers of arms **56a** and **56b**, and their other end is rotatably attached to wheels **52a** and **52b**, respectively. Wheels **52a** and **52b** are slidably enclosed in compartments **58a** and **58b**, respectively, wherein said wheels are free to horizontally slide in said compartments thereby permitting the vertical manipulation of vertebrae **53a** and **53b** by the device.

Arms **56a** and **56b** are preferably made from stainless steel or Titanium alloy, preferably from S.S316LVM, their width may be in the range of 3 mm to 8 mm, their thickness in the range 0.5 mm to 4 mm, and their length should be determined in each specific case according to the distance between the vertebrae. Compartments **58a** and **58b** are attached to the upper side of the lower platform **53a** and to the lower side of the upper platform **53b**, at the lateral side opposing supports **55a** and **55b**.

Compartments **58a** and **58b** may be manufactured from the same material of platforms **53b** and **53a**, and their geometrical dimensions are determined according to the wheels **52a** and **52b** which are used. Wheels **52a** and **52b** may be manufactured from a stainless steel, Titanium alloy or Bio-compatible polymer, preferably from S.S316LVM, and their diameter is generally in the range of 3 mm to 8 mm.

In this embodiment arms **56a** and **56b** enhance the stability of the device and maintains parallelism and synchronization of the applied manipulations. Fig. 3D is a variation of the device illustrated in Fig. 3C, wherein axial activator **18** mounted near one of the lateral sides of the device (off center positioning). In this example axial activator **18** is mounted at the same side with compartments **58a** and **58b**, and its moving arm **24** is attached to the lower part of compartment **58b** (or to arm 56b).

Fig. 3E schematically illustrates a device of the invention operating with a single axial activator **18** and with two pairs of stabilizing and synchronizing arms **63** and **64**. Two lateral supports with rotational axes **55c** and **55d** are welded or machined with to the upper side of the lower platform **53a**. First arms, **63c** and **63d**, are rotatably attached at one end thereof to respective supports **55c** and **55d**, and second arms **64c** and **64d**, are rotatably attached at one end thereof to the other end of said first arms. Gear wheels **62c** and **62d** are rotatably attached to the other end of said second arms **64c** and **64d**, where said gear wheels are slidably enclosed in respective compartments **58c** and **58d**, which are attached to the lower side of upper platform **53b**.

A rack and pinion mechanism may be provided to couple wheels **62c** and **62d** to respective racks **65c** and **65d** attached to the lower side of upper platform **53b**. Said rack and pinion mechanism synchronizes the movements applied to platforms 53a and 53b by activator **18**. Arms **63a**, **63b**, **64a**, and **64b** are preferably made from a stainless steel or Ti alloy, preferably from S.S316LVM, their width may be in the range of 3 mm to 8 mm, their thickness is in the range 0.5 mm to 4 mm, and their length should be determined in each specific case according to the distance between the vertebrae.

Fig. 3F schematically illustrates a device of the invention operating with a single axial **18** activator and a lever arm **68**. Lever arm **68** may be rotatably attached to supporting means **66** affixed to the upper side of lower platform **53a**. In this example the body of activator **18** is affixed to the upper platform **53b** and its moving arm is linked to the actuated part **68b** of arm **68**. Wheel **67** may be rotatably attached to the manipulating part **68a** of arm **68**, where said wheel **67** is slidably engaged with the lower side of platform **53b**, such that it may slide horizontally thereon according to the movements of arm **68**. The ratio between the lengths of the manipulating part **68a** and the actuated part **68b** of arm **68** may be utilized to amplify the applied movements or applied pushing force.

Arm **68** is preferably made from stainless steel or Titanium alloy, preferably from S.S316LVM, its width may be in the range of 3 mm to 8 mm, and its thickness in the range 0.5 mm to 6 mm. Fig. 3G schematically illustrates a device of the invention operating with a pair of axial activators **18** and respective lever arms **68** and **70** linked thereto.

Fig. 3H schematically illustrates a device of the invention operating with a pair of horizontally disposed axial activators **18** and respective ramp surfaces **74a** and **74b**. Axial activators **18** are horizontally affixed to support members **72a** and **72b**, attached to the upper side of platform **53a** and to the lower side of platform **53b**, respectively. Wheels **73a** and **73b** are rotatably attached to the moving arms of said activators **18**, wherein each of said wheels is sandwiched between a respective ramp surface, **74a** and **74b**, and the horizontal surface a support member, **72b** and **72a**, respectively. The elevation force applied in this embodiment is proportional to $1/tg\alpha$, where α is the angle of the ramps. For example, if the angle of ramps **74a** and **74b** is $\alpha=20°$ the output force applied would be 2.7 times higher.

Ramps **74a** and **74b** are preferably made from a stainless steel or Titanium alloy, preferably from S.S316LVM, their horizontal widths may be in the range of 4 mm to 15 mm, their thickness in the range 1 mm to 6 mm, and their ramp angle may be in the range of 15° to 45°. Support members **72a** and **72b** are preferably made from a stainless steel or Ti alloy, preferably from S.S316LVM, their horizontal widths may be in the range of 5 mm to 15 mm, their thickness in the range 1 mm to 7 mm.

Fig. 4A schematically illustrates a device of the invention operating with a single rotary activator **30** and ramped surfaces **76** and **77**, or additional ramp surfaces used to improve stability. In this example rotary activator **30** is centrically affixed to lower platform **53a** and its rotating shaft is attached to the bottom side of the ramp surfaces **76** and **77**. Said ramp surfaces are rotatably attached to the upper side of platform **53a** via bearings (or rollers, or low friction bio-compatible polymeric material) **66**. The upper side of ramp surfaces **76** and **77** is coupled with the lower side of upper platform **53b** via wheels **75** rotatably attached thereto.

Ramps **76** and **77** are preferably made from stainless steel or Titanium alloy, preferably from S.S316LVM, their horizontal widths may be in the range of 5 mm to 30 mm, their thickness in the range 1 mm to 6 mm, and their ramp angle may be in the range of 15° to 45°.

Fig. 4B schematically illustrates a device of the invention operating with a single horizontally disposed rotary activator **30** and an eccenter **79** mounted on its rotating shaft. Activator **30** is horizontally affixed to support means **78** that is attached to the upper side of lower platform **53a**. Eccenter **79** is mounted on the rotating arm of rotary activator **30**, and it is coupled with cam follower **80** that is rotatably mounted on the lower side of upper platform **53b** via a clevids affixed thereto. Eccenter **79** is preferably made from stainless steel or Titanium alloy, preferably from S.S316LVM, its thickness may be in the range of 1 mm to 5 mm, and its diameter in the range 6 mm to 25 mm. Cam follower **80** is preferably made from the same material exxenter 79i made from, its thickness may be in the range of 1 mm to 5 mm, and its diameter in the range 3 mm to 10 mm.

Figs. 4C, 4D and 4E, exemplifies implementations of the device described above wherein vertical manipulations are affected by a horizontally disposed rotary activator **30** having an eccenter **79** mounted on its rotating shaft, which eccenter is coupled with a cam follower **80**, and wherein the devices utilizes linear guidance means **85** and **86**, stabilizing and synchronizing arms **56a** and **56b**, and two pairs of stabilizing and synchronizing arms **63c**, **64c**, **63d**, and **64d**. The use of linear guidance means and stabilizing and synchronizing arms exemplified in Figs. 4C, 4D and 4E, is substantially as was described hereinabove with reference to figs. 3B, 3C-3D, and

3E, and for the sake of brevity will not be further discussed in detail.

Obviously, the rotary activator **30** used in the device demonstrated in Figs. 4A to 4E may be a type of rotary activator in which the axis of rotation is aligned with axis of the elongated hollow housing (e.g., **30a** in Fig. 1E), or a type of rotary activator in which the axis of rotation is perpendicular to the axis of the elongated hollow housing (e.g., **30b** and **30c** in Figs. 1F and 1G), *mutatis mutandis*.

The following examples relate to the case where several vertebrae are evolved (e.g., in scoliosis). In this case various versions of the above described concepts may be used. For example, said concepts may be implemented as follows:
A. One activator is actuating all of the selected vertebra, each of which is equipped with two bushings (or other linear guidance measures) which allows them to slide linearly during distraction on mutual or/and separate linear guidance rods.
B. Each two neighbor vertebrae are equipped with guiding measures and single activator.
C. Mutual activator for all participating vertebrae while using rack and pinion mechanism capable of rotating several eccentric cams located in tandem, or any other mechanism as mentioned before, where each of said mechanisms is elevating a single vertebra. It is important to mention that in case of tandem arrangement adequate synchronized distraction among vertebrae may be used.

Fig. 6A schematically illustrates a device of the invention comprising several pairs of rotary output shafts **130a, 130b** and **130c**, and designed to concurrently manipulate a number of vertebrae. In this example said pairs of rotary output shafts activators **130a, 130b** and **130c**, have a rotating pivot which axis is perpendicular to the axis of the body of the activators, wherein a respective eccenter **79a, 79b** and **79c** is mounted on the rotating pivot of each manipulator. This vertebrae manipulating device comprises two elongated members **131** which may comprise, or alternatively function as, the hollow elongated body of rotary output shafts **130a, 130b** and **130c**. When such device is implemented with several activators, in order to manipulate each vertebra independently, the eccentiricity of the eccentric cam should be gradually increased from lower to upper manipulated vertebra respectively.

The elongated members of this vertebrae manipulating device are affixed (e.g., by screws) to the lowermost and upper most platforms, **531** and **53u**. The eccenters **79a, 79b** and **79c** are coupled to intermediate platforms **53a, 53b** and **53c,** via respective cam followers **80a, 80b** and **80c,** rotatably attached to lower side of said intermediate platforms. This device allows manipulating the respective vertebrae to which said intermediate platforms (**53a, 53b** and **53c**) are attached relative to the vertebrae to which said uppermost and lowermost platforms (**53u** and **531**) are attached.

Fig. 6B schematically illustrates a device of the invention comprising a tandem of axial (linear) activators **18** and designed to concurrently manipulate a number of vertebrae. Axial activators **18** are affixed (e.g., via screws or clamping) to the lower platform **53a,** wherein the moving arms of said activators are attached to the lower side of the consecutive platform **53b** via support members **136b.** The consecutive platforms **53c** and **53d** are attached to platforms **53b** and **53c,** respectively, via rods, **135c** and **135d,** and support members, **136c** and **136d,** assemblies, wherein rods **135c** and **135d** are affixed to platforms **53b** and **53c,** respectively. In this way the vertebrae located above the vertebra to which platform **53a** is attached may be manipulated by the device.

Fig. 6C schematically illustrates a device of the invention comprising a tandem of axial (linear) activators **18** and designed to concurrently operate on a number of vertebrae with linear guidance means. In this example axial activators **18** are affixed to lower platform **53l**. Said activators **18** comprise elongated moving arms **131** which slidably pass through the upper platform **53u** and thus provide linear guidance. The vertebrae located between said upper and lower platforms (**53u** and **53l**), **50a-50c**, have respective pairs of rods **132a-132c** attached at their lateral sides. Respective pairs of support members **133a-133c** are distributed along elongated moving arms of activators **18**, and are engaged with said rods **132a-132c**, such that the axial movements applied by activators 18 are transferred to vertebrae **50a-50c**.

Fig. 6D schematically illustrates a device of the invention comprising a number of rotary activators **30b**, **30c**, **30d**, mounted in-between each pair of vertebrae and designed to concurrently manipulate a number of vertebrae with linear guidance means. In these examples supporting shaft **138** connects the lower and the upper vertebrae platforms **53a** and **53e**, wherein bushings **137b**, **137c** and **137d**, are linearly guided onto mutual linear shaft **138** on both sides. In this case each moving vertebra is being guided on the same mutual shafts **138** which are attached to the lowermost and uppermost vertebrae **53a** and **53e**, and thereby provide linear guidance. Each vertebra platform is being attached to the linear guiding bushing via clamping, welding or screwing.

In the example shown in Fig. 6D, the rotary activator **30b** is affixed to the lowermost platform **53a** and eccenter **79** mounted on its rotating pivot is coupled to cam follower **80** rotatably attached to the lower side of platform **53b**. Alternatively, each pair of vertebrae may be driven by separate activator.

Fig. 6E schematically illustrates a device of the invention comprising a number of axial activators **18b**, **18c**, **18d**, and designed to concurrently manipulate a number of vertebrae with linear guidance means. These examples are substantially similar to the device described with reference to Fig. 6D, respectively. As demonstrated in these figures The moving arm of activator **18** may be attached to the respective platforms via clevis means **140b**, **140c**, and **140d**, respectively.

All of the abovementioned parameters are given by way of example only, and may be changed in accordance with the differing requirements of the various embodiments of the present invention. Thus, the abovementioned parameters should not be construed as limiting the scope of the present invention in any way. In addition, it is to be appreciated that the different shafts, rods, pivots, and other members, described hereinabove may be constructed in different shapes (e.g. having oval, square etc. form in plan view) and sizes differing from those exemplified in the preceding description.

It should be noted that the activator used in the device of the invention may be driven using other wirelessly energizable means, such as linear or rotary piezoelectric motors (e.g., Nanomotion linear piezo electric), motors that may actuated by an external applied alternating magnetic or electromagnetic filed (e.g., rotary synchronized magnetic or electromagnetic field which could drive invasive permanent core).

2. Operative procedures:

2.1 *Scoliosis distraction procedure:*

Prior to the surgical procedure requiring the use of the device of the present invention, the patient will have already undergone a spinal fixation procedure. During this earlier procedure, pedicular screws will have been inserted into certain, relevant vertebrae, and a helically-twisted rod inserted and wound (in accordance with the Cotrel-Dubouset maneuver) in order to achieve unwinding of the abnormally curved vertebral column. Bone chips (usually obtained by autografting from other anatomical sites) are placed between the transverse processes on both sides of adjacent vertebrae in the treated region. With time, growth of the bone chips will result in the formation of a single, unified bone bar on each side of the vertebral column, thereby resulting in spinal fixation.

Turning now to the surgical procedure of the present invention, for causing vertebral distraction (i.e. regaining lost height following spinal fixation), said procedure comprises the following steps:

1. Removal of one the rods that was necessary for reduction of the spinal deformity.
2. Replacement of that rod by a device of the present invention, by connecting it to the pedicular screws that are already placed or adding new pedicular screws, or replacing the old pedicular screws by new ones, as clinically necessary. The connection will be performed by connectors that will enable straight alignment of the rod.
3. Removal of the second rod and its replacement by a second device of the present invention, in a similar fashion.
4. The replacement by the fixation rods by devices of the present invention can be performed either at the end of

the first operation, or later on, when elongation is decided upon.

5. The two devices may be interconnected by one or more interconnecting elements (as described hereinabove), in order to co-ordinate the distraction of one side of the vertebral column with the other, contralateral side.
6. If performed primarily, and elongation is required acutely, the distraction will start between 3 to 28 days post operatively, preferably after 7 days.
7. If elongation will be performed after bony union of the immobilized column has been achieved, the any bone bridges between to vertebrae, should be severed and soft tissues should be released to allow elongation to take place. The distraction will start between 3 to 28 days post operatively, after the bone bar and soft tissue release, preferably after 7 days.

Following completion of the foregoing surgical procedure, progressive distraction of the vertebral column in the region where the device of the present invention is implanted is accomplished by means of application of an external magnetic field -induced by an external coil or open magnet. Whilst any suitable electromagnet coil or coils may be used, the following two alternative embodiments are particularly preferred:

1) A single electromagnetic coil placed over the trunk region of the patient being treated, such that it overlays the length of the vertebral column that is being treated with the device of the present invention. In this way, a homogenous magnetic field is created, such that an attractive magnetic force is applied to the magnetic or ferromagnetic elements situated within the telescopic or sliding member pair(s).

2) A pair of electromagnetic coils is placed in contact with the body surface overlaying the region of the vertebral column that is being treated with the device of the present invention, such that the current flowing through one coil runs in the opposite direction to the current flowing through the other coil. The design of the two coils and the precise position of placement thereof are such that the area of the magnetic field generated by one coil is connected to the magnetic field area generated by the second coil by way of the magnetic/ferromagnetic material located in the telescopic or sliding member pair(s) of the present invention. In this way, an attractive force is exerted on one or more of the members of each pair.

The two alternative configurations described above are given by way of non-limiting example only: many other suitable magnetic field generators may also be used in connection with the device and methods of the present invention, without deviating from the scope thereof.

By way of further example, a suitable magnetic coil would be one generating a magnetic field at total current in about 500 amps, the power consumption at that field being about 25 KW. Such a coil, when used together with the exemplary 8-pair ferromagnet configuration described hereinabove, has been found to exert a 2 Kg force on the telescopic or sliding member pair.

It is to be reiterated that the magnetic coil parameters and ferromagnet details provided hereinabove relate only to one particular coil that is suitable for use in conjunction with the device of the present invention. Said list is therefore not intended to be limiting in any way.

The application of the magnetic field is performed at least once per day for a period of between 1 and 150 days, preferably for a period of one month. This regime will normally result in elongation of the treated vertebral column by 0.05 mm to 2 mm per day, preferably 1mm per day.

2.2 *Spinal fusion procedure:*

As discussed hereinabove, spinal fixation procedures, when performed according to the prior art are not uniformly successful. Rather, on many occasions (especially when local blood supply is compromised), complete fusion of the bone bars does not always occur.

In the procedure according to the present invention, any pre-existing rods are removed and replaced by the presently-disclosed devices, essentially as described in steps 1 to 5 of section 2.1, hereinabove. However, in the case of the spinal fusion procedure, either compression, that is reduction of the total -end-to-end length of the elongate member pair(s), or axial oscillation of said elongate member pairs (rather than distraction) is performed by application of an external magnetic field, as described above. It should be noted that, in addition to the use of the instantly-described procedure in the cases of unsuccessful fusion, said procedure may also be used as a primary treatment, i.e. as a method of first choice for obtaining spinal fusion

In the oscillation mode, the reverse-direction movement is driven by means of spring or other return mechanism as described hereinabove. The amplitude of the oscillatory motion is controlled by standard means such as slot and fin mechanisms that are well known in the art. The frequency of the oscillatory motion is generally between 0.01 and 50 Hz, preferably 0.5 Hz. This oscillatory motion may be induced between 1 and 50 times per day, preferably once a day for a period of 20 minutes.

When used to cause compression, a total end-to-end distance reduction in the range of 0.1 to 3 mm is desirable. The compressive force is applied for a period of between 1 milisecond and 120 minutes, between once per day and fifty times per day, preferably once per day for 20 minutes. A constant compressive force can also be changed to other level by applying an appropriate magnetic field produced by the coil system that decrease the length of the device thus inducing compression force

Without wishing to be bound to any particular theory, in both of the above-described modes (axial oscillation and compression), the mechanical movements of the elongate members cause stimulation of the bone growth and healing processes, thereby assisting in causing the closure of the bone chips, thus creating the continuous bone bars.

It should be noted that both the oscillation and compression procedures may be used also to expedite fusion of bone chips at the end of a primary scoliosis surgery.

The above examples and description have of course been provided only for the purpose of illustration, and are not intended to limit the invention in any way. As will be appreciated by the skilled person, the invention can be carried out in a great variety of ways, employing more than one technique from those described above, all without exceeding the scope of the invention.

CLAIMS

1. A device for manipulating the spinal vertebrae of a subject, comprising at least one activator having a moveable element which is capable of being displaced in response to externally induced energizing signals, wherein said activator is affixed to at least one vertebra, and coupled to at least one other vertebra, such that said activator is capable of moving the vertebra(e) to which it is coupled in an axial direction, wherein said movement can be unidirectional, resulting in either distraction or compression of the vertebrae, or bidirectional, resulting in an oscillatory movement of the vertebrae.

2. The device according to claim 1, further comprising one or more elongated platforms, each of which is horizontally affixed to one of the vertebrae of said subject, wherein said elongated platforms are used for affixing said at least one activator, and/or for attaching coupling means, to the respective vertebra.

3. The device according to claim 1, further comprising linear guidance means slidably attached to the sides of the two or more vertebrae.

4. The device according to claim 1 or 2, further comprising stabilizing and synchronizing arms rotatably attached to the sides of some of the at least two vertebrae and/or to elongated platforms horizontally affixed thereto.

5. The device according to claim 1, wherein coupling means are used to transfer the displacements of the movable element of the activator to at least one vertebra.

6. The device according to claim 5, wherein the coupling means are implemented by lever arms.

7. The device according to claim 5, wherein the coupling means are implemented by ramp surfaces.

8. The device according to claim 5, wherein the energizing signals are implemented by an externally induced magnetic field.

9. The device according to claim 1, wherein the activator comprises at least one pair of ferromagnetic/magnetic elements, wherein each of said pairs comprises a stationary ferromagnetic/magnetic element affixed to the internal wall of said activator and a movable ferromagnetic/magnetic element affixed in proximity to said stationary ferromagnetic/magnetic element to a shaft coaxially and slidably supported therein.

10. The device according to claim 9, wherein magnetic attraction forces are evolved between the magnetic elements in the presence of a magnetic field, and wherein said magnetic attraction forces may affect axial movements of said shaft.

11. The device according to claim 9, wherein the activator further comprises a gear unit coupled to the shaft by means of a clutch and motion conversion units.

12. A device for manipulating the spinal vertebrae of a subject, comprising at least one parallel pair of activators affixed to the lateral sides of at least one vertebra and coupled to another vertebra.

13. The device according to claim 12, further comprising at least one elongated platform horizontally affixed to at least

one vertebra, wherein the at least one pair of activators, and/or coupling means coupled thereto, are affixed to the lateral sides of at least one vertebra by means of said at least one elongated platform.

14. An activator for manipulating displaceable elements by means of externally induced energizing signals, comprising at least one pair of ferromagnetic/magnetic elements, wherein each of said pairs of ferromagnetic/magnetic elements comprises a stationary ferromagnetic/magnetic element affixed to the internal wall of said activator and a movable ferromagnetic/magnetic element affixed in proximity to said stationary ferromagnetic/magnetic element to a shaft coaxially and slidably supported therein, wherein said shaft is coupled to a moveable element which is capable of being displaced in response to movements of said shaft.

15. The activator of claim 14, wherein the coupling between the shaft and the movable element is achieved directly and/or by means of a gear and clutch devices.

16. The activator of claim 14, wherein the energizing signals are implemented by an externally induced magnetic field.

17. A method for regaining lost height in a subject having already undergone a spinal fixation procedure comprising the steps of:

a) removing one of the fixation rods previously implanted for the purpose of reducing a spinal deformity;

b) connecting a first device of the present invention as defined in any one of claims 1 to 13, to the same side of the spinal column from which the previously implanted fixation rod was removed in step (a);

c) removing the second fixation rod;

d) connecting a second device of the present invention as defined in any one of claims 1 to 13, to the same side of the spinal column from which the second fixation rod was removed in step (c);

e) optionally interconnecting the two devices by means of one or more interconnecting elements (as described hereinabove);

f) applying a magnetic field induced by an externally placed coil to the region of the spinal column in which the devices were implanted, such that the activators of said devices respond by applying distracting forces to the vertebrae to which they are coupled in order to increase the distance between the said vertebrae and the vertebrae to which the other ends of said activators are affixed; and

g) Optionally applying, at the end of the distraction phase, a magnetic field induced by an externally placed coil to the region of the spinal column in which the devices were implanted, such that the activators of said devices respond by oscillating the vertebrae to which they are coupled in order to increase the healing process and reduce the healing time.

18. The method according to claim 17, wherein the subject is a patient being treated for scoliosis.

19. The method according to claim 17, wherein the magnetic field is applied at least once per day between 1 second to 30 minutes for a total period of between 1 and 30 days.

20. The method according to claim 17, wherein the magnetic field is applied in pulses, wherein, the width of said magnetic pulses is in the range of 0.001 second to 10 seconds and the frequency of said pulses is in the range of 0.01 Hz to 500 Hz.

21. A method for causing spinal fusion comprising the steps of:

a) connecting a first device of the present invention as defined in any one of claims 1 to 13, to one side of the spinal column and a second said device to the other side of the spinal column;

b) optionally interconnecting the two devices by means of one or more interconnecting elements (as described hereinabove);

c) applying a magnetic field induced by an externally placed coil to the region of the spinal column in which the devices were implanted, such that the activators of said devices respond by applying compressive forces to the vertebrae to which they are coupled in order to reduce the distance between the said vertebrae and the vertebrae to which the other ends of said activators are affixed.

22. The method of claim 21, wherein the compressive force is applied between once and fifty times per day, each time for a period of between 1 second and 120 minutes.

23. The method according to claim 22, wherein the compressive force is applied once per day for a period of 20 minutes.

24. A method for causing spinal fusion comprising the steps of:

a) connecting a first device of the present invention as defined in any one of claims 1 to 13, to one side of the spinal column and a second said device to the other side of the spinal column;

b) optionally interconnecting the two devices by means of one or more interconnecting elements (as described hereinabove);

c) applying a magnetic field induced by an externally placed coil to the region of the spinal column in which the devices were implanted, such that the activators of said devices respond by applying axially-directed oscillatory forces to the vertebrae to which they are coupled thereby causing axial oscillation of said vertebrae.

25. The method according to claim 24, wherein the frequency of the axial oscillation is between 0.01 and 50 Hz.

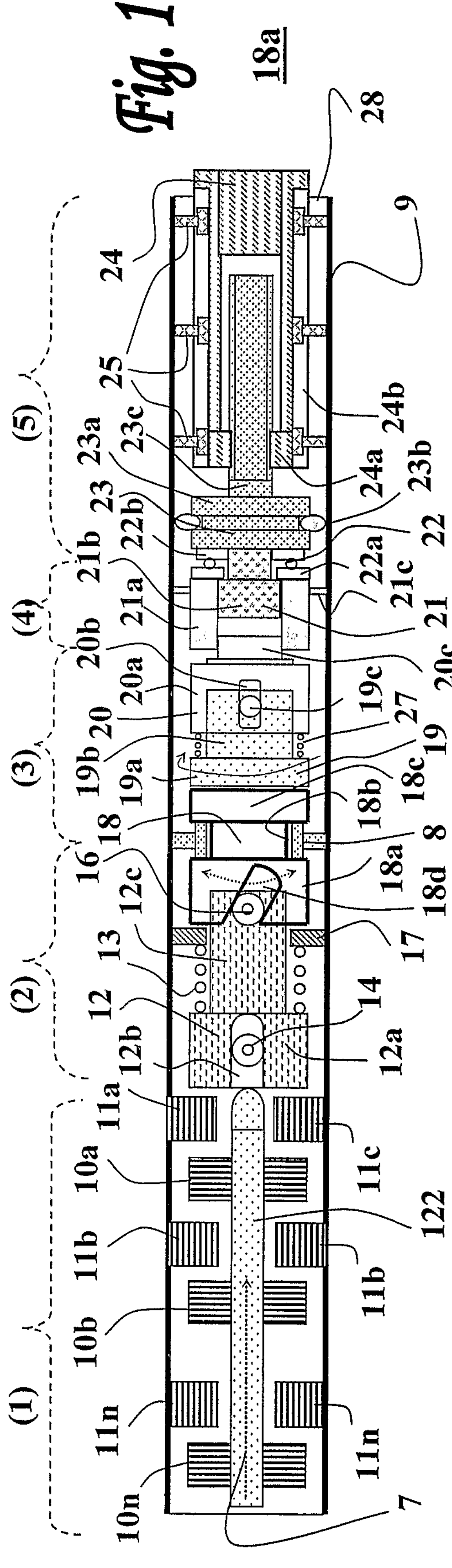
26. The method according to claim 25, wherein the frequency of the axial oscillation is preferably 0.5 Hz.

27. The method according to claim 25 or claim 26, wherein the oscillatory motion is induced between 1 and 8 times per day.

28. The method according to claim 27, wherein the oscillatory motion is induced once a day for a period of 20 minutes.

29. The method according to any one of claims 17 to 28, wherein the first and second devices are preferably connected to the vertebral column using pedicular screws.

Fig. 1B



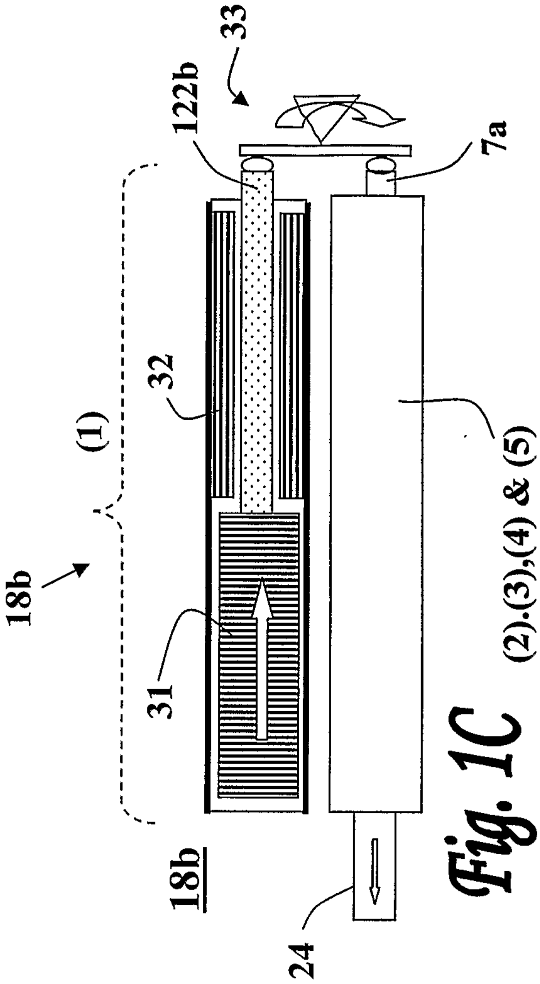


Fig. 1C

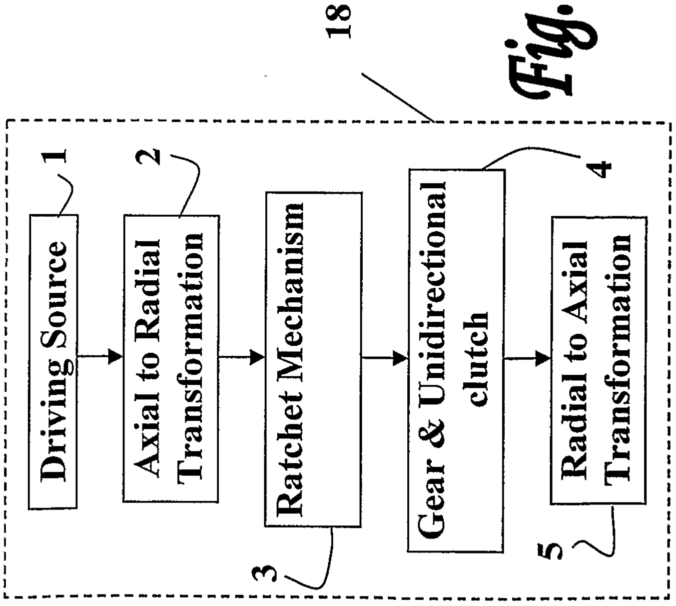


Fig. 1A

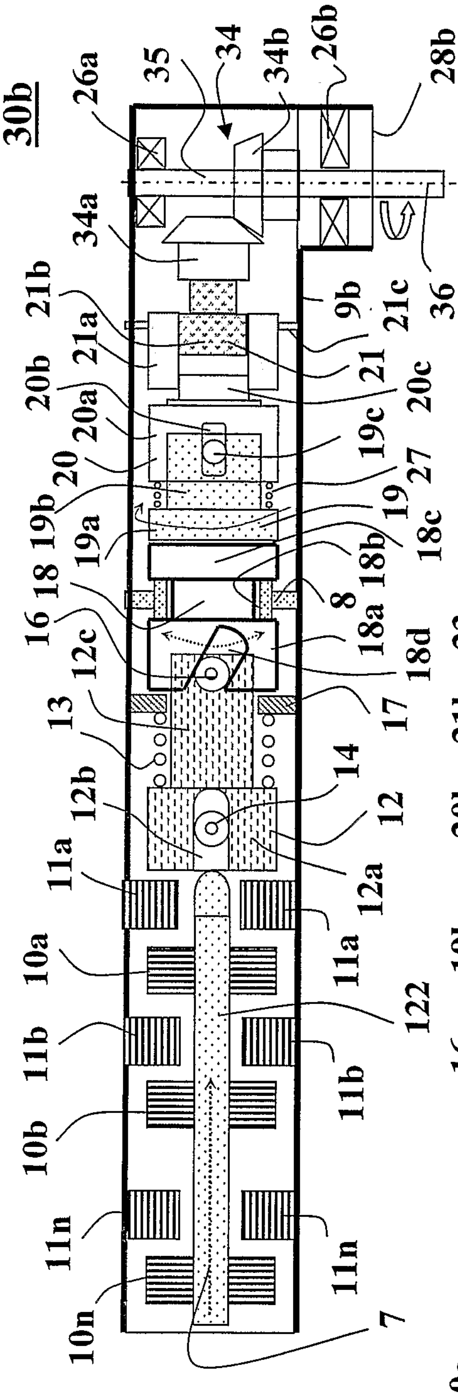


Fig. 1F

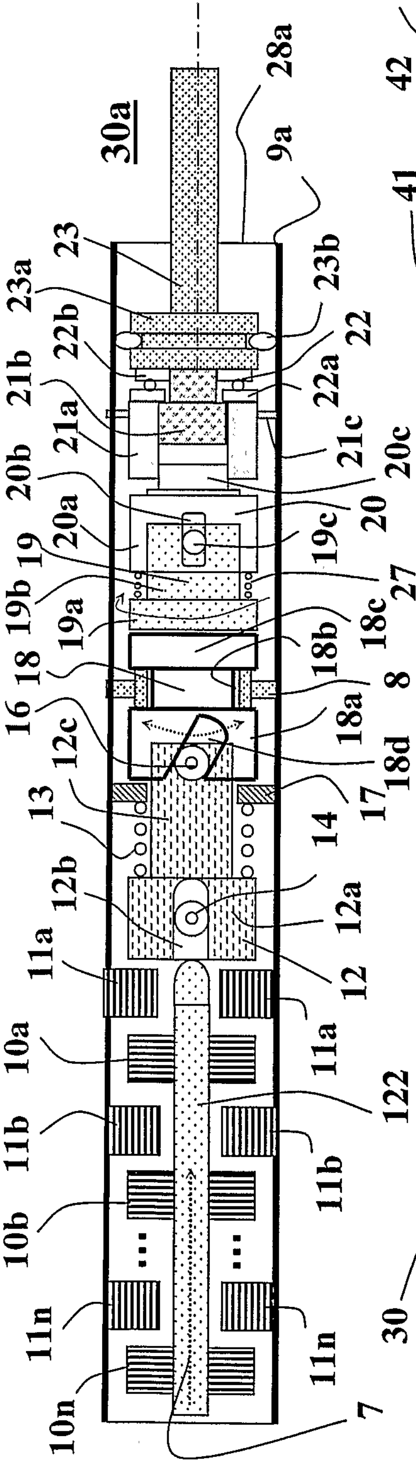


Fig. 1E

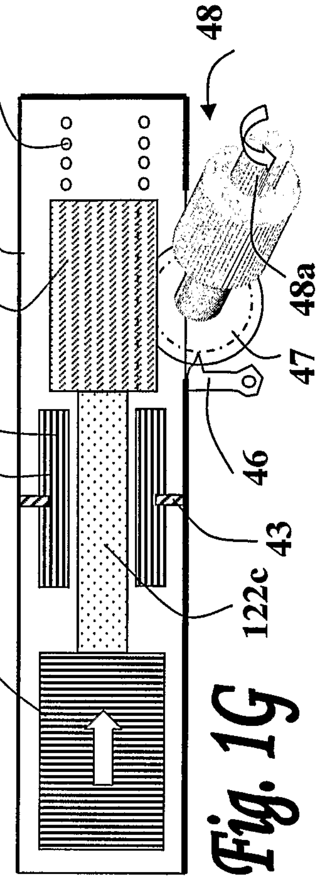


Fig. 1G

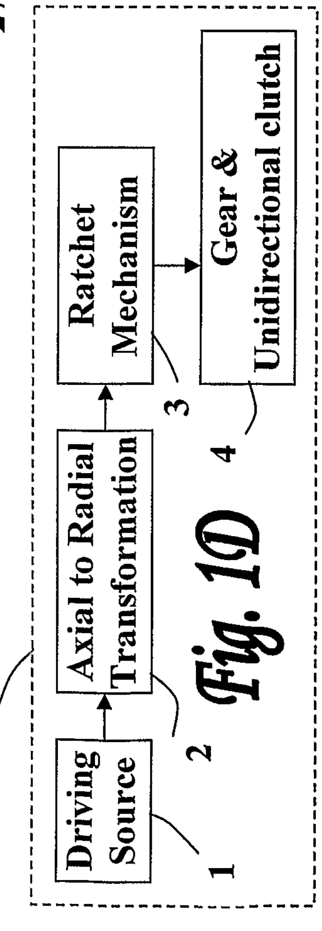


Fig. 1D

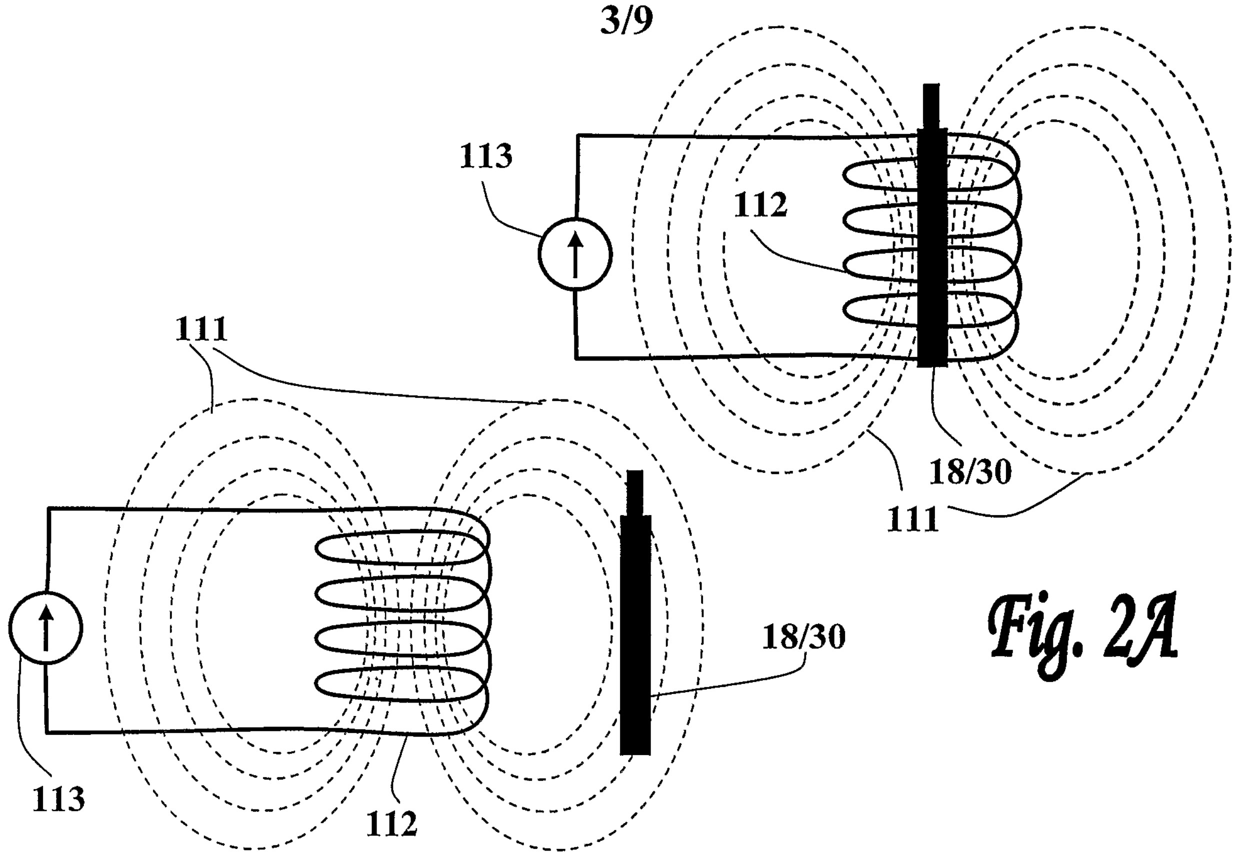


Fig. 2A

Fig. 2B

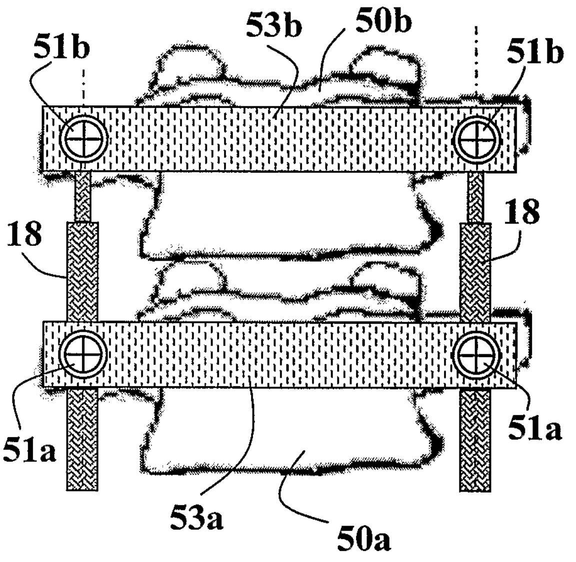


Fig. 3A

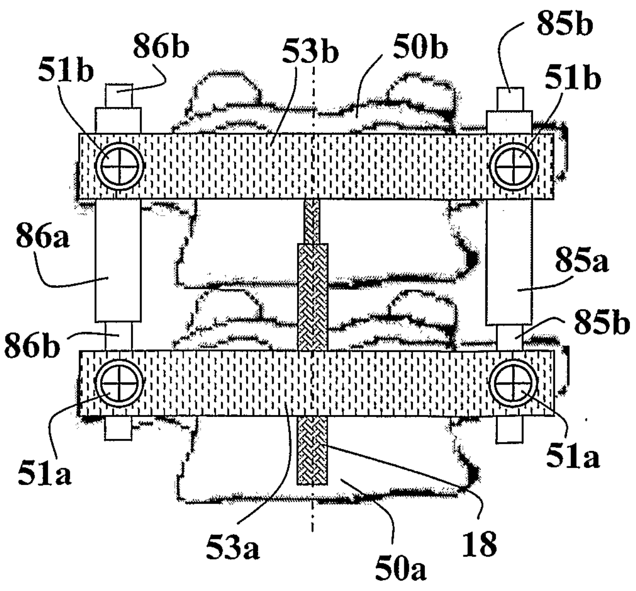
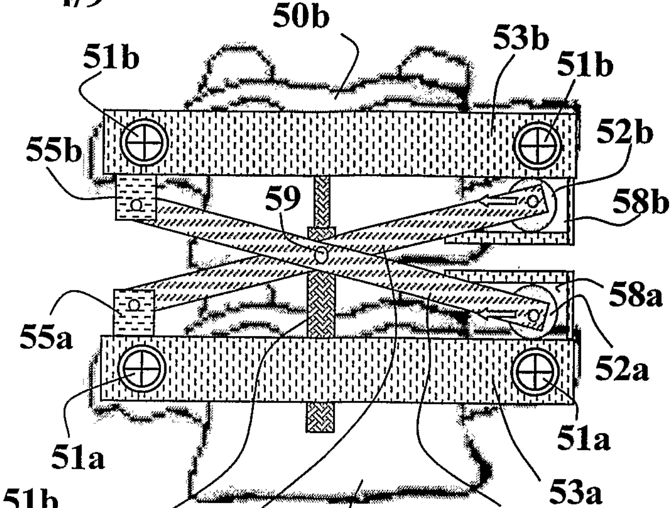


Fig. 3B

Fig. 3C



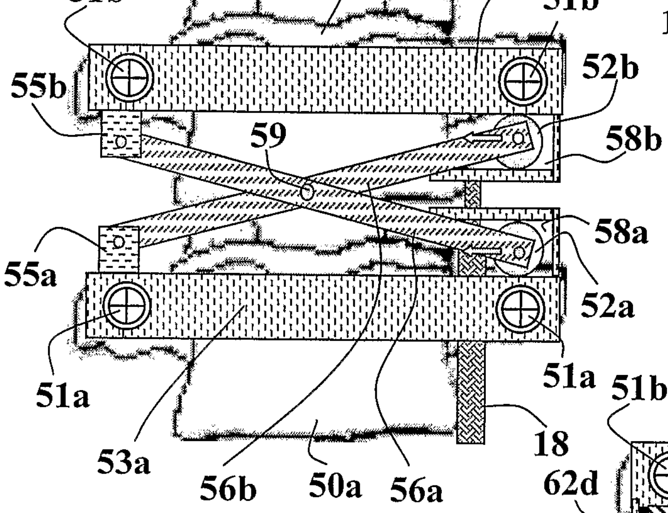
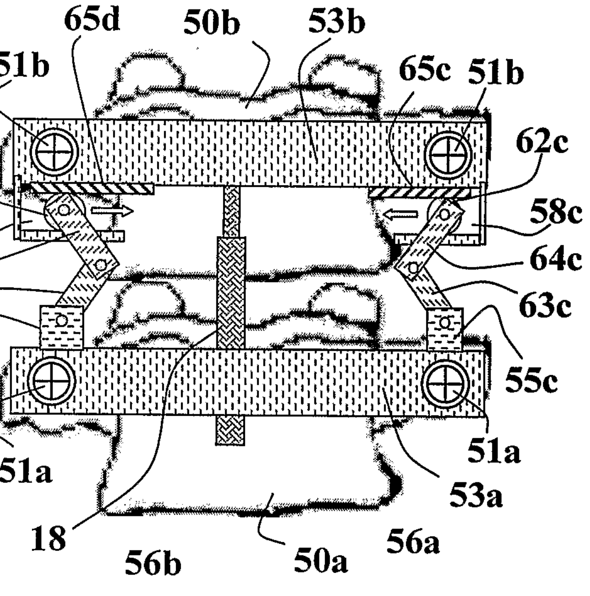


Fig. 3D

Fig. 3E



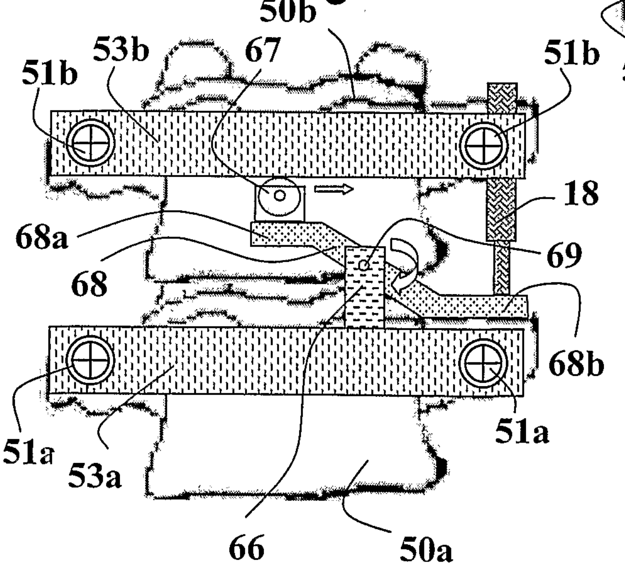


Fig. 3F

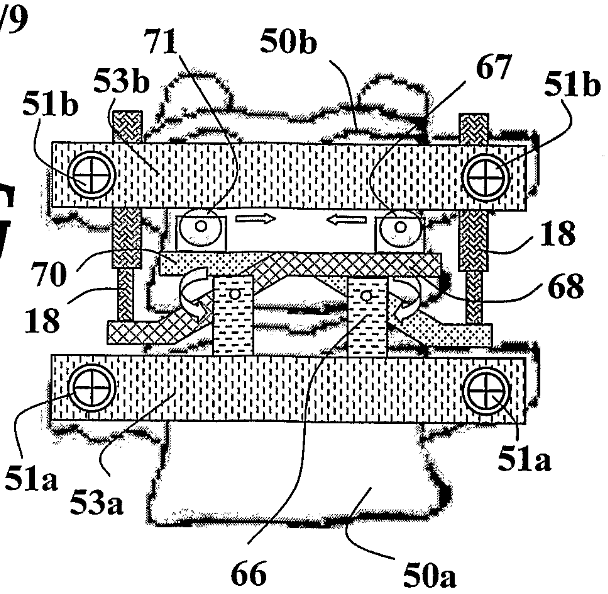


Fig. 3G

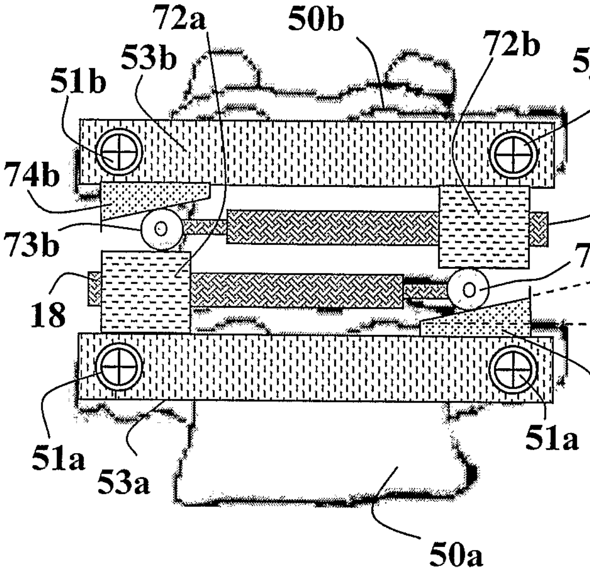


Fig. 3H

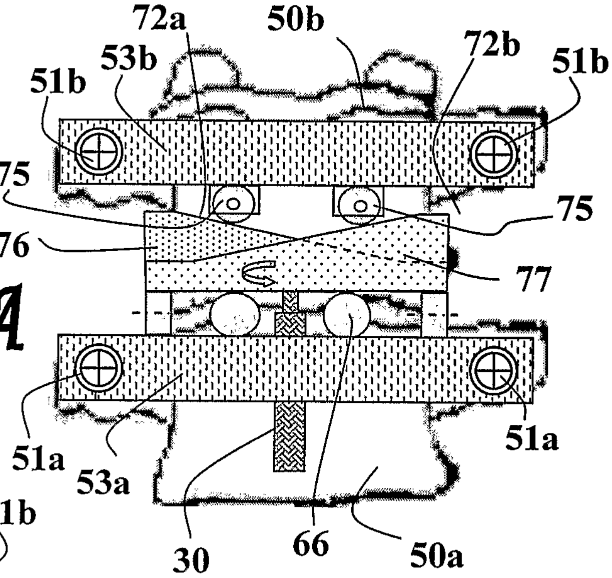


Fig. 4A

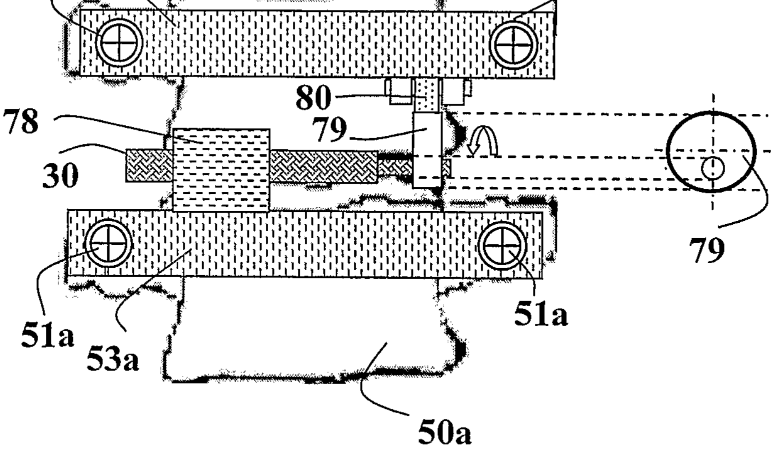
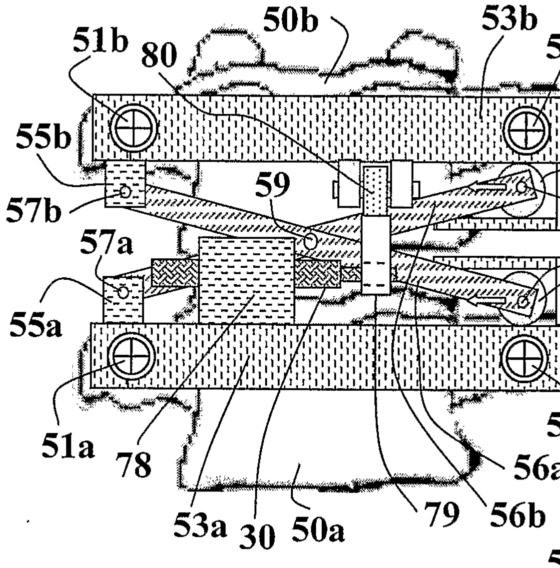


Fig. 4B

Fig. 4C



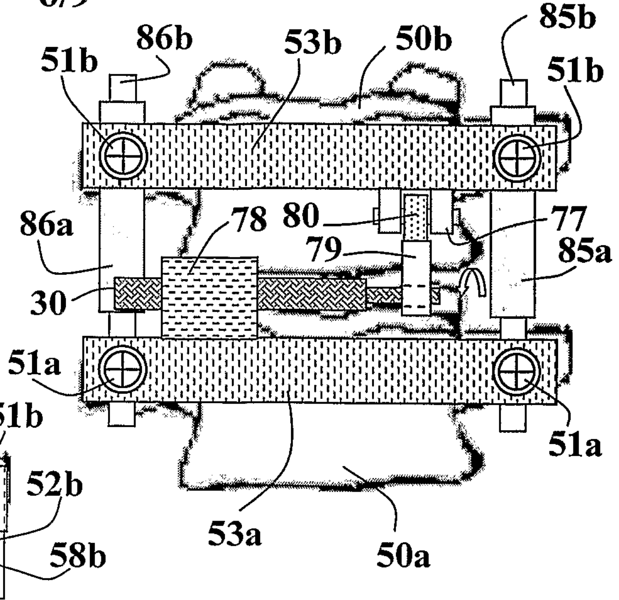


Fig. 4D

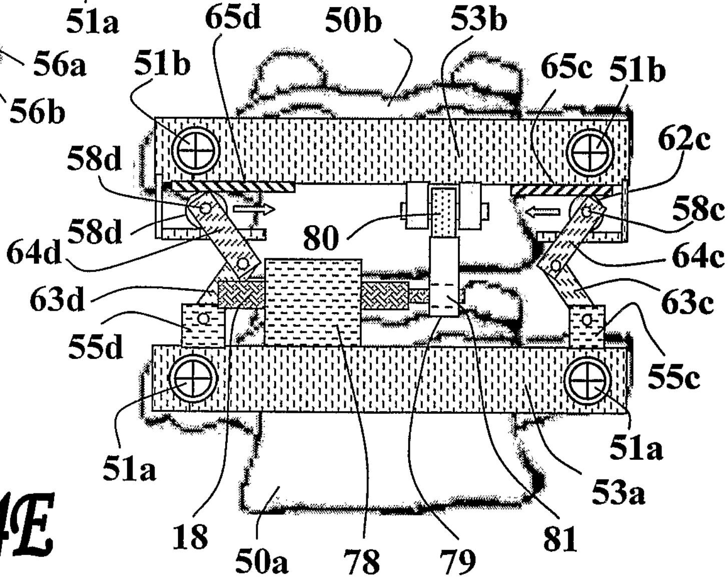
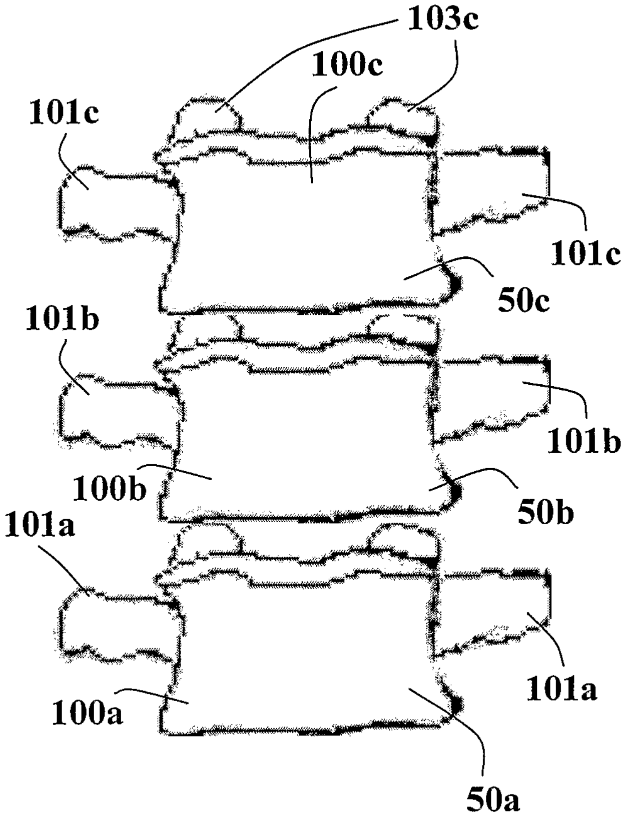


Fig. 4E

Fig. 5B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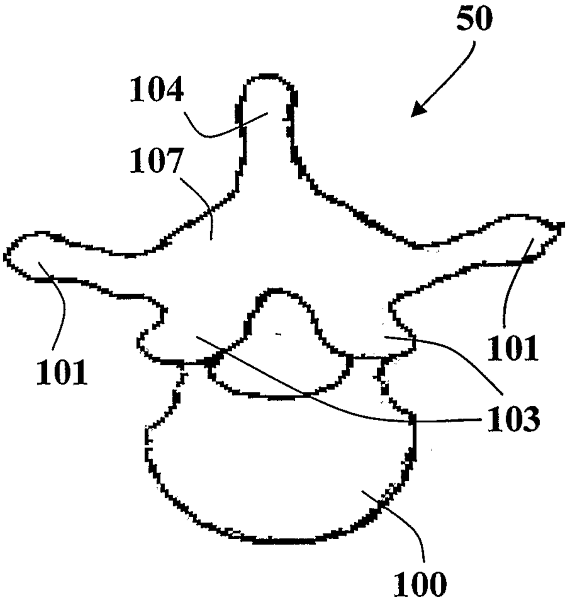
101c
101c
50c
101b
101b
100b
50b
101a
101a
100a
50a

Fig. 5A


50
104
107
101
101
103
100

53l

Fig. 6B

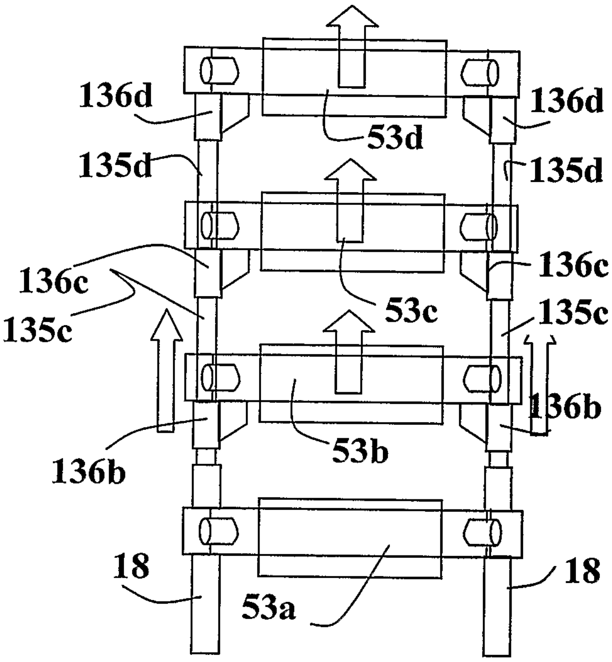
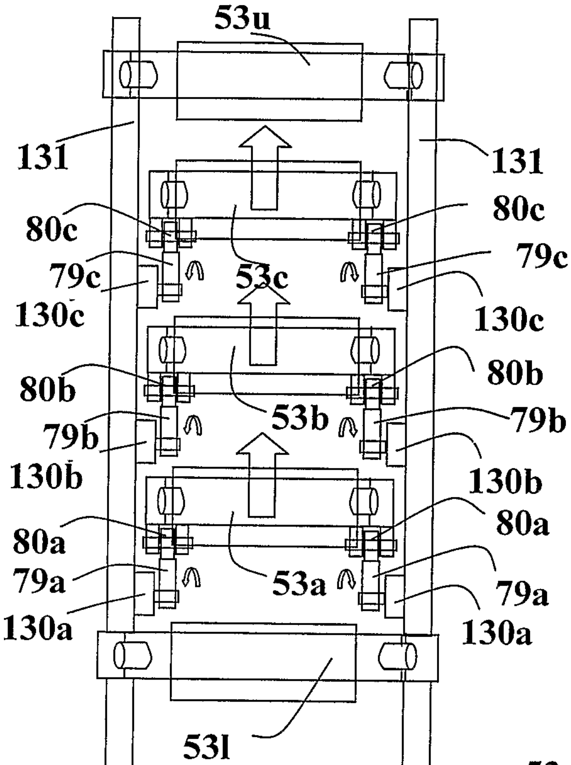


Fig. 6A



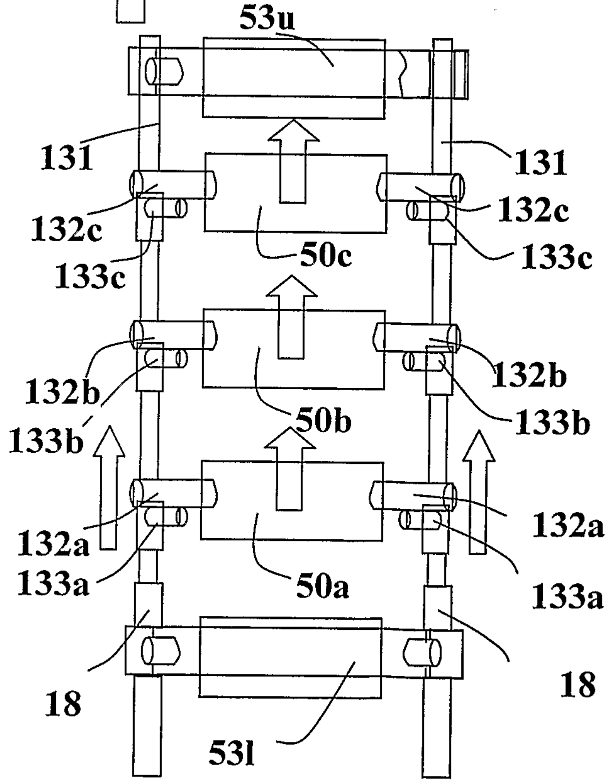
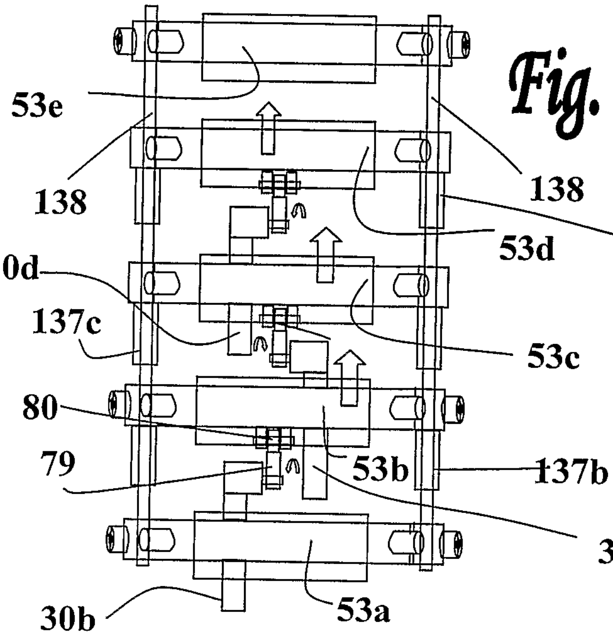


Fig. 6C


53e
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53d
137
30d
137c
53c
80
79
53b
137b
30c
30b
53a

Fig. 6D

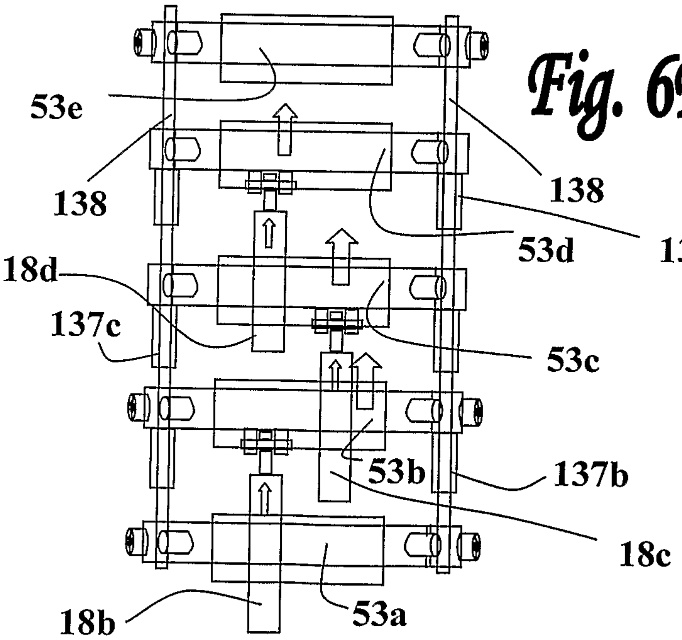
53e
138
138
53d
137
18d
137c
53c
53b
137b
18c
18b
53a

Fig. 6E