A61B 17/56 (2006.01)

PCT/IB20 13/054826

13 June 2013 (13.06.2013)

English

600694

18 June 2012 (18.06.2012)

NZ

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Fig. 4b

METHOD AND APPARATUS FOR THE TREATMENT OF SCOLIOSIS

Spinal adjustment system including at least three implant modules, at least one of the implant modules being a first implant module including: means for engaging the first implant module with a first vertebra; and first force application means; characterised in that: the first force application means is adapted to engage with a second implant module engaged with a second vertebra superior to the first vertebra; the first force application means is adapted to also engage with a third implant module engaged with a third vertebra inferior to the first vertebra; and the first implant module includes means of adjusting the force applied to the first vertebra by the first force application means.
METHOD AND APPARATUS FOR THE TREATMENT OF SCOLIOSIS

Field of the Invention
The present invention is a method of treatment of scoliosis and an apparatus for applying this new method.

Background
Any discussion of the prior art throughout the specification is not an admission that such prior art is widely known or forms part of the common general knowledge in the field.

Scoliosis is a medical condition in which a person's spine has a deformity which causes the spine to be primarily curved from side to side; it may also be rotated along its axis. On an x-ray, when taken from the front or back of the spine of an individual with a typical scoliosis, the spine may take the form of an "S" or a "C" rather than a straight line. It is typically classified as congenital (caused by vertebral anomalies present at birth), idiopathic (sub-classified as infantile, juvenile, adolescent, or adult according to when onset occurred) or as having developed as a secondary symptom of another condition, such as cerebral palsy, spinal muscular atrophy or due to physical trauma.

Scoliotic curves greater than 10° affect 2-3% of the population of the United States. According to the US National Scoliosis Foundation, scoliotic curves greater than 20° affect about one in 2500 people. Curves convex to the right are more common than those to the left, and single or "C" curves are slightly more common than double or "S" curve patterns. Males are more likely to have infantile or juvenile scoliosis, but there is a high female predominance of adolescent scoliosis.

The prognosis of scoliosis depends on the likelihood of progression. The general rules of progression are that larger curves carry a higher risk of progression than smaller curves, and that thoracic and double primary curves carry a higher risk of progression than single lumbar or thoracolumbar curves. In addition, patients who have not yet reached skeletal maturity have a higher likelihood of progression.

Pain is often common in adulthood, especially if the scoliosis is left untreated. Spinal surgery may be performed to stabilize curvature and prevent worsening, therefore
improving the patient's quality of life. It should be noted that the surgery does not necessarily result in pain loss.

The underlying cause of scoliosis is not well understood. However, one theory is that the left to right curvature can develop as the growing body attempts to compensate for an abnormal front to back curvature. A "normal" mature spine is curved and includes a top area of lordosis (an arc pulling the head back and up), a mid area of kyphosis (a hunching curve forwards) and a lower area of lordosis. The net result of these curved areas is to position the head above the pelvis, for stability. These areas of curvature are caused by the wedge shapes of adjacent vertebrae in the spinal column, which locally tilt the spine in a forward or backward direction. However, where at least one vertebra is not sufficiently wedge-shaped, but too rectangular, the spine does not curve normally at that point. This most frequently results in insufficient kyphosis in the central part of the spine. According to one theory, scoliosis can develop when the body, attempting to add kyphosis, introduces a curvature in the perpendicular plane.

As noted above, scoliosis typically is diagnosed in children or adolescents, usually before full progression of the condition. Since the disease does not progress to a dangerous extent in 95% of sufferers, conventional treatment (which is outlined below) may be delayed until it is certain it will be needed.

The conventional treatment options for scoliosis are:
1. Observation
2. Bracing
3. Surgery

Observation is simply monitoring of the patient over time to determine if their condition is declining or stabilising. However, of late new genetic tests for adolescent idiopathic scoliosis have been introduced, for example by Axial Biotech. This test indicates the likelihood of progression to a severe curve for children diagnosed with adolescent idiopathic scoliosis. Such tests will help provide an insight into which young patients are likely to need surgical intervention and which are not. This opens up new possible early intervention techniques and options that would otherwise not be pursued if the likelihood of progression was unknown.
Bracing is only done when the patient has bone growth remaining, and is generally implemented in order to hold the curve and prevent it from progressing to the point where surgery is necessary. Bracing involves fitting the patient with a device that covers the torso and in some cases it extends to the neck. The effectiveness of bracing differs depending on the compliance of the patient, the type of brace used and on the individual scoliosis.

Surgery is usually indicated for curves that have a high likelihood of progression, curves that cause a significant amount of pain with some regularity, curves that would be cosmetically unacceptable as an adult, curves in patients with spina bifida and cerebral palsy that interfere with sitting and care, and curves that affect physiological functions such as breathing.

Known systems incorporating tethers or telescoping rods correct spinal deformity in one plane only, that of the restricting action provided by the construct or imparted by a corrective force applied, and do not fully correct a three-dimensional deformity. These systems may not allow the patient to retain a full range of motion.

Spinal fusion is the most widely performed surgery for the treatment of scoliosis and it is an irreversible procedure. In this procedure, spinal instrumentation (screws, hooks and rods) and bone grafts are utilized to link the vertebrae so that as the spine heals the vertebral bodies will become one solid bone mass and the vertebral column becomes rigid. This prevents worsening of the curve, but at the expense of spinal movement.

The purpose of the spinal instrumentation (screws, hooks and rods) is twofold. First, it enables the surgeon to adjust and reduce the curvature to some degree. The second purpose the instrumentation fulfils is to hold the spine still so that the grafted bone and vertebrae fuse into a solid bone mass, which can take up to a year or more to occur for adults. Once the fusion is solid, the instrumentation has done its job and may be removed, although it is usually left in place. If a solid fusion is not achieved, the instrumentation will eventually fatigue and fail and the patient will most likely experience pain at the spinal levels which have failed to fuse.

Spinal fusion is typically only carried out when the patient has reached, or is close to, skeletal maturity, as a fused spine cannot grow in length. The procedure involves an
operation typically taking about 8 hours, with a number of associated risks. The result of this treatment enables the patient to survive, but with a severely limited range of movement, since they cannot flex their spine to bend over or to the side.

**Summary of the Invention**

It is an object of the present invention to provide an alternative method for treatment of scoliosis and an apparatus for enabling the method. The invention may also provide a treatment and apparatus suitable for use in patients who may have not achieved skeletal maturity, and/or whose condition has not yet progressed but are identified as disposed to a dangerous progression.

The present invention provides a spinal adjustment system including at least three implant modules, at least one of the implant modules being a first implant module including:

- means for engaging the first implant module with a first vertebra; and
- first force application means;

characterised in that:

- the first force application means is adapted to engage with a second implant module engaged with a second vertebra superior to the first vertebra;
- the first force application means is adapted to also engage with a third implant module engaged with a third vertebra inferior to the first vertebra; and
- the first implant module includes means of adjusting the force applied to the first vertebra by the first force application means.

Preferably the first implant module further includes:

- means of engaging a second force application means associated with the second implant module; and
- means of engaging a third force application means associated with the third implant module.

In preferred embodiments, the means of engaging the second force application means and/or the means of engaging the third force application means is selected from the list consisting of: loops, brackets, shelves and recesses.

Preferably the first force application means is a spring, more preferably a leaf spring.
In preferred embodiments, the means of adjusting the force applied to the first vertebra by the leaf spring may be:

- the combination of a spring cap and a spring tensioner; or
- a lock nut.

Preferably the means for engaging the first implant module with the first vertebra is selected from the list consisting of: spinal screws and pedicle hooks, more preferably a spinal screw.

The present invention further provides an implant module for use in a spinal adjustment system as described above.

The present invention further provides for the use of the spinal adjustment system described above for the treatment of a condition selected from the list consisting of: scoliosis, spondylolisthetic vertebra and Scheuermann's Kyphosis.

The present invention further provides a method of adjusting the alignment of a spine, including the steps of:

- engaging a first implant module with a first vertebra, said first implant including:
  - means for engaging the first implant module with the first vertebra;
  - first force application means; and
  - means of adjusting the force applied to the first vertebra by the first force application means;
- engaging a second implant module with a second vertebra superior to the first vertebra;
- engaging a third implant module with a third vertebra inferior to the first vertebra; and
- engaging the first force application means of the first implant module with both the second implant module and the third implant module.

Preferably the method further includes the steps of:

- engaging a second force application means associated with the second implant module with the first implant module; and
- engaging a third force application means associated with the third implant module with the first implant module.
In a preferred embodiment, the method further includes the step of adjusting the force applied to the first vertebra by the first force application means.

The proposed system is based on the concept that rather than using traditional spinal instrumentation to attempt to forcibly correct the deformity during one procedure and then fusing the spine in the position achieved, the proposed instrumentation system would instead correct the deformity over a period of time through the application of small forces while still allowing motion of the spine.

All of the embodiments described will allow the patient some degree of spinal motion.

This is a similar concept to that used in modern orthodontics where braces apply small forces to the teeth in order to cause realignment of the teeth, as opposed to older brace systems which apply a large load to the teeth at the time of treatment causing an initial correction to occur with no significant correction thereafter, until the next adjustment of the bias occurs.

The intent of this system is that only a 'gentle' corrective force would be applied to the vertebral bodies rather than the application of large forces as is currently required in order to realign the spine during a spinal fusion procedure. Thus, in a similar way to which braces work in orthodontics, these gentle forces would over time cause 'realignment' of the vertebral bodies.

As the vertebral bodies start to become 'realigned', the springs will return to their unloaded rest state, thus reducing the spring force applied to the vertebral bodies and helping to prevent over correction of the scoliosis deformity.

The implant modules work by each applying force to a vertebra relative to the adjacent superior and inferior vertebrae. This force causes translation and rotation of the vertebra relative to its superior and inferior neighbours. By continued coupling of the implant modules, this pattern is repeated along the length of the system of implant modules (which preferably extends along the extent of the spinal deformity), with the end implant modules becoming the fixed reference points, and all the intermediate vertebrae being translated and rotated relative to these end points, and their engaged neighbours. This allows for correction of the deformity over time, while maintaining full natural motion at all spinal levels and allowing for growth of the patient.
The implant modules would preferably be implanted during one procedure and require no further surgical intervention, but further surgical procedures to adjust, add to, or reduce the implant construct could be accommodated, if required.

Once correction has occurred, the surgeon may chose to leave the implant system in place for some time, allowing for remodelling of the bone and soft tissues to accommodate the new spinal state. Removal too early may result in further progression of the scoliosis. In orthodontics correction occurs within three months, but braces are left in place a further nine months, to allow for stabilisation. The decision will be made by medical advisors on a case-by-case basis.

A number of advantages are anticipated for this system including:

1. The patient's spine would not be fused in order to correct the scoliotic deformity. Instead the patient would retain full motion (flexion, extension, lateral bending, twisting and growth) at each spinal level while the correction of the scoliotic curve was achieved slowly over time. As such, the patient will potentially not have any of the issues associated with spinal fusion.

2. It may be possible to achieve a better correction of the scoliosis deformity, as all of the spinal anatomy (musculature, ligaments, etc) would have time to adapt to the correction. In much as the same way this anatomy remodels to a deformed state as the patient's scoliosis progresses, these same structures will have time to remodel to a less deformed state as the deformity is corrected. This may provide an advantage over spinal fusion surgery.

3. As the spine has retained full motion and the spinal anatomy would have time to remodel using the proposed system, the result may be a full functional spine with the scoliosis deformity corrected. Therefore once the patient has reached skeletal maturity and the likelihood of the scoliosis deformity re-occurring and/or progressing had decreased sufficiently, it may be possible to remove the whole implant.

4. A limiting factor for spinal fusion is that it is preferable to wait until the patient has reached or is close to reaching skeletal maturity otherwise the spinal fusion
will cause restriction in their growth. (Clearly this has to be balanced against the progression of the scoliosis and associated problems.) However with the proposed system not resulting in the spine being fused, and given there is no intended fixing of adjacent vertebral bodies, growth of the spine could still occur. This would potentially allow for early treatment of scoliotic spines for patients whose condition is known to progress with less aggressive hardware and corrective forces - thus arresting any scoliosis progression and potentially correcting any deformity already present, at a younger age. This presents a significant advantage particularly where the patient's condition has been indicated as being likely to progress through genetic testing or similar.

5. This treatment method may also be used for the reduction of a spondylolisthetic vertebra, or for creating a lordosing force for the correction of kyphotic deformities, for example Scheuermann's Kyphosis, or for other conditions, not solely scoliosis.

**Brief Description of Drawings**

By way of example only, preferred embodiments of the present invention are described in detail below with reference to the accompanying drawings, in which:

Figure 1 is an exploded perspective view of a first preferred embodiment of an implant module of the present invention;

Figure 2 is a perspective view of the implant module shown in Figure 1 when assembled;

Figure 3a is a side view of the implant module shown in Figure 2;

Figure 3b is a cross-section of the implant module shown in Figure 3a along the line A-A;

Figure 3c is a cross-section of the implant module shown in Figure 3b along the line B-B;

Figure 4a is a side view of a series of implant modules according to the first preferred embodiment of the present invention;

Figure 4b is a perspective view of the series of implant modules shown in Figure 4a;

Figure 5 is an exploded perspective view of a second embodiment of an implant module of the present invention;

Figure 6 is a perspective view of the implant module shown in Figure 5 when assembled;
Figure 7 is an exploded perspective view of a third embodiment of an implant module of the present invention;  
Figure 8 is a perspective view of the implant module shown in Figure 7 when assembled;  
Figure 9 is a perspective view of a third embodiment of a series of implant modules according to the present invention; and  
Figure 10 is a bottom view of the implant modules shown in Figure 9.

Best Methods of Carrying Out the Invention

First Preferred Embodiment

Figures 1, 2 and 3 show a first preferred embodiment of an implant module 101 which is part of the apparatus of the present invention.

The implant module 101 includes a cage 102, a pedicle screw 103, a spring socket 104, spring 105, spring cap 106 and tensioner 107. Each part of the implant module is made of biologically inert, sterilisable materials suitable for implantation in a live host.

Pedicle screw 103 is similar to a well-known type including a screw threaded column 130 adapted to engage with a pedicle of a vertebra. At a first end of column 130, a rounded screw head 160 is provided with tool engagement means, preferably in the form of a screw tool cavity 132 adapted to receive a tool, e.g. an Allen key. Engagement of an appropriate known type of tool with these tool engagement means will allow rotation of the screw 103, and therefore engagement of column 130 with a pedicle.

Screw 103 may be similar to any of the many different commercially available spinal screws. In alternative embodiments, the pedicle screws 103 may be replaced with "pedicle hooks" or other known apparatus for engagement with vertebrae the spine.

Cage 102 has an essentially cylindrical cage body 161. A first end of cage body 161 includes a first cage aperture 162 dimensioned to allow screw threaded column 130 of pedicle screw 103 to pass therethrough, but not to allow screw head 160 to pass therethrough. An second cage aperture 163 at a second end of cage body 161 distal to the first end is dimensioned to allow screw head 160 to pass therethrough and extends into the cage body 161 to a depth greater than the height of screw head 160.
The first end of cage body 161 may be tapered between the width of second cage aperture 163 and the first cage aperture 162. The sidewall of cage body 161 includes two cage spring slots 164 opposite each other, each cage spring slot 164 extending from the second end of cage body 161 through a significant depth of the cage body sidewall. Extending outwards from opposite sides of cage body 161 are a pair of spring shelves 165. Preferably each of the spring shelves 165 is equidistant from the two cage spring slots 164 around the circumference of the cage body 161. Each spring shelf 165 includes a spring shelf upstand 166 extending approximately parallel to the longitudinal axis of cage body 161. A cage interior wall 167 of cage body 161 includes cap engagement means, preferably a screw-thread.

Spring socket 104 consists of an essentially cylindrical socket body 168. A socket aperture 169 passing through the entire length of socket body 168 is dimensioned to allow access to screw tool cavity 132 in screw head 160, but not to allow screw head 160 to pass therethrough. The sidewall of socket body 168 includes two socket spring slots 170 opposite each other, each socket spring slot 170 extending through a significant depth of the socket body sidewall.

Spring 105 include a first arm 138 and a second arm 139 extending in opposite directions in a spring plane from an engagement section 178 located partway along the length of spring 105. Engagement section 178 includes a pair of small opposing protrusions 171 dimensioned to complement the interior of socket aperture 169. Although spring 105 is shown as a leaf spring, other forms could be used, such as flexible rods or bars, or contoured and profiled forms, and the springs 105 of different implant modules 101 used in the apparatus may be of varying thickness and cross-section.

Spring cap 106 includes a cap lid 172 which is wider than a cap shaft 173, with a cap aperture 174 extending through both cap lid 172 and cap shaft 173. Cap shaft 173 is dimensioned to fit inside cage body 161, and includes cage engagement means, adapted to engage the cap engagement means of cage body 161, preferably in the form of an external screw thread dimensioned to engage the screw threaded cage interior wall 167 of cage body 161. Cap lid 172 is wider than cap shaft 173, and although it is shown in this embodiment as being circular, is may be narrower in one dimension, for example being elliptical or hexagonal in shape. Cap lid 172 includes tool engagement means, which may include external flats and/or a cap tool cavity.
adapted to receive a tool, e.g. an Allen key. Engagement of an appropriate known
type of tool with either of these tool engagement means will allow the engagement of
cap shaft 173 with cage 102, for example by rotation of the spring cap 106. In this
preferred embodiment, cap lid aperture 174a (being the section of cap aperture 174
enclosed by cap lid 172) is in the form of a cap tool cavity. The cap shaft
aperture 174b (being the section of cap aperture 174 enclosed by cap shaft 173) includes tensioner engagement means, preferably in the form of an internal screw	hread.

Tensioner 107 includes a tensioner crown 175 coaxially aligned with a tensioner
shaft 176. Tensioner shaft 176 is at least as long as cap shaft aperture 174b, and is dimensioned and adapted to engage with the tensioner engagement means contained therein, preferably in the form of an external screw thread. Tensioner crown 175 is dimensioned to fit within cap lid aperture 174a, and includes tool engagement means, preferably in the form of a tensioner tool cavity 177 adapted to receive a tool, e.g. an Allen key.

It will be recognised by one skilled in the art that the implant modules must be made of appropriate surgical materials, having the necessary characteristics of ability to be sterilized, biological inertness, strength and flexibility. In particular, different materials and spring geometries used for springs 105 will apply different strengths of spring force, as may be required in a particular case.

Implant modules 101 are used in the method of treatment of the present invention.

Cage 102, pedicle screw 103 and spring socket 104 may be preassembled by passing
the column 130 through the second cage aperture 163 and the first cage aperture 161 of cage 102, then inserting spring socket 104 into the second cage aperture 163 of the cage 102.

Screws 103 are screwed into the pedicles of vertebrae along the affected length of the spine, by passing a tool through socket aperture 169 and second cage aperture 163 to engage the screw tool cavity 132 in the screw head 160.

Screws 103 may be engaged with every vertebra, or some may be skipped, depending of the extent of the scoliosis and the desired end result. Screws 103 will usually be
engaged with the pedicles on only one side of the spine, but it is envisaged that in particular clinical cases it may be desirable to install implants on both sides of the spine.

5 The cage 102 on each screw 103 can rotate about the rounded screw head 160 until they are aligned, as shown for example in Figure 4. Once each screw 103 is in place, the springs 105 are sequentially installed. The engagement section 178 of spring 105 is placed inside the socket aperture 169 so that each of the first arm 138 and the second arm 139 extends from the engagement section 178 through a socket spring slot 170 and a cage spring slot 164. Protrusions 171 are inside the socket aperture 169, limiting the ability for lengthwise translation of the spring 105. Springs 105 having different characteristics may be provided in different implant modules engaged with different vertebrae, allowing the force applied to each vertebra to be deliberately selected to achieve the desired clinical outcome.

10 The first arm 138 of the spring 105 of a first implant module 101 is oriented to rest on a spring shelf 165 of a first adjacent implant module 101. The second arm 139 of the spring 105 of the first implant module 101 is oriented to rest on a spring shelf 165 of a second adjacent implant module 101, as shown in Figure 4. Thus, each implant module 101 (other than at the two ends), is engaged with two adjacent implant modules 101, one on a superior vertebra, and one on an interior vertebra.

15 As can be seen in Figures 4a and 4b, in respect of vertebrae at the extremal ends of the affected length of spine, a special "one-sided" spring is provided, so that the extremal implant modules are each only engaged with one adjacent first implant module 101. The end implant modules may be otherwise identical to the intermediate first implant modules.

20 The cap shaft 173 of a spring cap 106 is then engaged with cage body 161. A tool is engaged with the cap lid aperture 174a to screw the cap shaft 173 into the screw threaded cage interior wall 167 of cage body 161. Spring cap 106 presses spring socket 104 on to the screw head 160, locking the angle of cage 102 relative to the screw threaded column 130 of screw 103. Spring cap 106 also holds spring 105 of that implant module 101 in its position inside spring socket 104. When spring cap 106 is thus engaged with the cage 102, the cap lid 172 extends over each of the spring shelves 165 of that implant module 101. If the cap lid 172 is asymmetrical, the
narrower dimension is oriented in the inferior-superior direction. Thus, the second arm 139 of the spring 105 of the first adjacent implant module 101 is enclosed by a spring shelf 165 and spring shelf upstand 166, cap lid 172 and the wall of cage body 161 on one side of the implant module, and the first arm 138 of the spring 105 of the second adjacent implant module 101 is enclosed by a spring shelf 165 and spring shelf upstand 166, cap lid 172 and the wall of cage body 161 on the other side of the implant module 101.

A desired amount of pre-loading can now be separately applied to each vertebra by the use of tensioners 107. Each tensioner 107 is inserted into cap aperture 174, and the tensioner shaft 176 engages with the tensioner engagement means in the cap shaft aperture 174b. By engaging a tool with tensioner tool cavity 177, tensioner 107 is manipulated into the correct position, in which tensioner crown 175 is surrounded by cap lid aperture 174a. In an active implant module (such as is as shown in Figure 3), the end of tensioner shaft 176 abuts the centre of spring 105 inside spring socket 104. This causes tension to be applied to the implant module 101 relative to the first adjacent implant module and the second adjacent implant module via the spring 105, providing for a translation of the first vertebra relative to the first adjacent vertebra and the second adjacent vertebra. As will be appreciated by one skilled in the art, the amount of tension applied depends on the characteristics of spring 105, and also on the length of tensioner shaft 176, as the amount of force applied to the centre of spring 105 will depend on how far tensioner shaft 176 extends beyond cap shaft aperture 174b. In some cases, the desired tension may be achieved by having a tensioner shaft 176 of a length that does not extend beyond cap shaft aperture 174b at all.

The tension of each individual implant module can be adjusted until the correct desired amount of pre-loading is applied to each separate vertebra, according to the clinical needs of that patient to achieve the desired correction and freedom of movement.

Implant modules 101 of the type shown will exert an "outwards" force, pulling the pedicle screw away from the spine. However, it will be appreciated that with minor amendment, springs can be configured to exert an "inwards" force, and intermediate units switch between outwards and inwards force implant modules, to allow tailoring of the forces along a length of spine to meet the requirements of that patient.
After all the implant modules 101 have been installed and adjusted, the implant modules 101 are covered by tissue and skin.

The intent of this system is that only a ‘gentle’ straightening force would be applied to the vertebral bodies rather than the application of large forces as is currently required in order to realign the spine with standard spinal implants. Thus, in a similar way to which braces work in orthodontics, these gentle forces would over time cause ‘realignment’ of the vertebral bodies.

The implant modules 101 continue to apply forces to each vertebra based on the pre-load of its associated spring 105 over time following surgery. Rather than an immediate total correction, there is a gradual improvement in spinal alignment over time. As the spine nears the desired alignment, the springs 105 approach their rest state and the forces exerted by the implant modules 101 decreases, limiting the risk of over-correction. Although in some cases it may be desirable to readjust some of the implant modules after surgery, it is hoped that in most cases this will not be necessary. It may eventually be possible to remove the units from the spine, which has adjusted to its new position.

Second Preferred Embodiment

Figure 5 and Figure 6 show two different views of a second embodiment of an implant module 201 which is a part of the apparatus of the present invention.

The implant module 201 includes a pedicle screw 203, similar to a well known type including a screw threaded column 230 adapted to engage with a pedicle of a vertebra. The column 230 is co-axial with a screw-threaded shaft 233. To allow for screwing the screw 203 into a pedicle, tool engagement means may be provided on or adjacent the shaft 233. These tool engagement means may include external flats 231 and/or a screw tool cavity 232 adapted to receive a tool, e.g. an Allen key.

Engagement of an appropriate known type of tool with either of these tool engagement means will allow rotation of the screw 203, and therefore engagement of column 230 with a pedicle.

Screw 203 may be similar to any of the many different commercially available spinal screws. In alternative embodiments, the pedicle screws 203 may be replaced with "pedicle hooks" or other known apparatus for engagement with vertebrae the spine.
Instead of the fixed angle screw illustrated, a multi-axial screw may be used, to help facilitate alignment.

Implant module 201 further includes a spring 236, which includes a first arm 238 and a second arm 239 aligned in a spring plane. Near the centre of spring 236 a spring hole 234 is dimensioned to allow the shaft 233 of screw 203 to pass therethrough. On either side of spring hole 234 is formed a spring wing 235 which includes an upstand 237 extending approximately perpendicular to the spring plane. Each spring wing 235 further includes a shelf 240 which is approximately parallel to the spring plane, but displaced therefrom. Each shelf 240 extends towards, but does not block, the spring hole 234. Although springs 236 are shown as leaf springs, other forms could be used, such as flexible rods or bars, or contoured and profiled forms, and may be of varying thickness and cross-section.

A spring cap 241 is an essentially annular spacer having an internal screw threaded spring cap hole 242 adapted to engage with the shaft 233 of the screw 203. Spring cap 241 may also include tool engagement means such as internal/external cap tool cavities 243.

A spring retainer 244 includes a retainer hole 245 of similar dimension to spring cap hole 234 and two retainer wings 246. Each retainer wing 246 is slightly longer than a corresponding spring wing 235, and includes a notch 247 dimensioned to receive an end 248 of an upstand 237. In the embodiment shown, each retaining wing 246 is offset from the other, to match the corresponding offset of each upstand 237.

A lock nut 249 is an essentially annular nut having an internal screw threaded nut hole 250 adapted to engage with the shaft 233 of the screw 203. Lock nut 249 may also include tool engagement means such as nut tool cavities 251.

It will be recognised by one skilled in the art that the implant modules must be made of appropriate surgical materials, having the necessary characteristics of ability to be sterilized, biological inertness, strength and flexibility. In particular, different materials and spring geometries used for springs 236 will apply different strengths of spring force, as may be required in a particular case.
Implant modules 201 are used in the method of treatment of the present invention. Using known tools and techniques, screws 203 are screwed into the pedicles of vertebrae along the affected length of the spine. Screws 203 may be engaged with every vertebra, or some may be skipped, depending on the extent of the scoliosis, patient condition, and the desired end result.

Once the screws 203 are in place, the springs 236 are sequentially installed. A spring 236 is lowered over pedicle screw 203 so that shaft 233 passes through spring hole 234. An end 252 of first arm 239 of spring 236 rests on a shelf 240 of an adjacent spring 236. On the other shelf 240 of said adjacent spring rests an end 253 of the second arm 238 of a further spring 236, so that (other than for the two end implant modules), for each implant module 201 the end 252 of first arm 239 and the end 253 of second arm 238 of the spring 236 rest on the shelves 240 of different adjacent springs 236. This engagement of the arms 238, 239 and their ends 252, 253 with the shelves 240 may occur as each spring 236 is added, or after all the springs are in place.

It will be appreciated that implant modules 201 may be supplemented by similar end implant modules (not shown) wherein the spring has only one arm to engage with a spring of a single adjacent implant module. When implant modules 201 are not to be installed in every adjacent vertebra, springs 236 may have arms of different lengths, to reach the shelves 240 of the next adjacent springs.

The spring cap hole 242 of a spring cap 241 is aligned with shaft 233 and screwed into place for each implant module 201. The amount of pre-load on each spring 236 is determined by the spacing between the underside of spring cap 241 and column 230 of the pedicle screw 203. As the centre of spring 236 is displaced with respect to its neighbouring springs 236, the arms 238, 239 of the spring 236 flex, resulting in a force being exerted along the axis of the pedicle screw 203, and subsequently on a connected vertebra of the spine.

At this stage, the amount of pre-loading on each spring 236 is adjusted according to the desired end result, by appropriate tightening of the spring caps 241 during surgery. The amount of freedom of movement to be allowed the patient can also be selected by variations in the tightness of spring caps 241, or by use of spring caps of various heights. A coarser adjustment may also be effected by screwing screw 203 further
into its vertebra than in adjacent units, which will induce further bending forces to be exerted by the spring 236.

Implant modules 201 of the type shown will exert an "outwards" force, pulling the pedicle screw away from the spine. However, it will be appreciated that with minor amendment, springs can be configured to exert an "inwards" force, and intermediate units could be utilised to switch between providing an outwards or inwards force, to allow tailoring of the forces along a length of spine to meet the requirements of that patient.

Once the spring cap 241 has been appropriately adjusted, spring retainer 244 is fitted by passing shaft 233 through the retainer hole 245 and aligning the notch 247 in each retainer wing 246 with a corresponding upstand 237 of that spring 236. Lock nut 249 is then screwed into place on the top of shaft 233 to hold spring retainer 244 in place. Once spring retainer 244 is in place, an end 253, 252 of each arm 238, 239 of adjacent springs 136 is contained within a "cage" bounded by a shelf 240 on the bottom, spring cap 241 to one side and upstand 237 on the other, and on the top by a retainer wing 246 of spring retainer 244. This limits the risk of a spring disengaging from its neighbour as the patient moves, which would result in a change in the spring force applied by that spring.

After all the implant modules 201 have been installed and adjusted, the implant modules 201 are covered by tissue and skin.

As someone skilled in the art may note, the assembly sequence of each component may vary depending on surgical technique, surgeon preference, patient condition, etc., but with the same effect achieved.

The intent of this system is that only a 'gentle' straightening force would be applied to the vertebral bodies rather than the application of large forces as is currently required in order to realign the spine with standard spinal fusion implants. Thus, in a similar way to which braces work in orthodontics, these gentle forces would over time cause 'realignment' of the vertebral bodies.

It is envisaged that the implants would only be applied to one side (left or right) of the spine. This will result in the springs providing either inward or outward corrective
forces, as determined by spring configuration, but also given the absence of a spring on the alternate (left/right) side, there will be a rotational force applied to the spine which may correct any rotational deformity of the spine. Alternatively, it may be elected to position implants on both the left and right sides of the spine to provide corrective force of greater magnitude. In such a dual-spring configuration it may be required that one side exert inward forces and the other outward forces to supply the rotational corrective forces, if this is so desired.

The implant modules 201 continue to apply forces to each vertebra based on the pre-load of its associated spring 236 over time following surgery. Rather than an immediate total correction, there is a gradual improvement in spinal alignment over time. As the spine nears the desired alignment the springs 236 approach their rest alignment and the forces exerted by the implant modules 201 decrease, limiting the risk of over-correction. Although in some cases it may be desirable to readjust some of the implant modules after surgery, it is hoped that in most cases this will not be necessary. It may eventually be possible to remove the units from the spine, which has adjusted to its new position.

Third Embodiment

Figure 7 and Figure 8 show two different views of a third embodiment of an implant module 301 which is a part of the apparatus of the present invention.

The implant module 301 includes a cage 302, a pedicle screw 303, a spring socket 304, spring 305, and connection means 307. Pedicle screw 303 includes a screw threaded column 330 adapted to engage with a pedicle of a vertebra. At a first end of column 330, a rounded screw head 360 is provided with tool engagement means, preferably in the form of a screw tool cavity 332 adapted to receive a tool, e.g. an Allen key.

Cage 302 has an essentially cylindrical cage body 361, with a central bore 362 dimensioned such that screw threaded column 330 of pedicle screw 303 passes therethrough and the screw threaded column 330 extends from a first end of the cage body 361, but the rounded screw head 360 is retained within the bore 362 of the cylindrical cage body 361.
The sidewall of the cage body 361 includes two cage spring slots 364 opposite each other, each cage spring slot 364 extending from a second end of cage body 361 through a significant depth of the cage body side wall. Extending outwards from opposite sides of cage body 361 are a pair of spring engagement means 365, each of which is equidistant from the two cage spring slots 364. In this embodiment the spring engagement means 365 are closed loops, each configured to retain one arm 338, 339 of a leaf spring 305 of an adjacent implant module.

Leaf spring 305 is placed in the cage body 361, crossing the central bore 362, and is retained via adjustable connection means 307. A first arm 338 and a second arm 339 of the leaf spring 305 each extend through a cage spring slot 364. A pair of small opposing protrusions 371, located partway along the leaf spring 305, engage with an interior wall of the bore 362, limiting lengthwise translation of the leaf spring 305. The adjustable connection means 307 may be at least one screw threaded block engaged with a screw threaded section of the central bore 362 of the cage body 361. The connection means 307 also include tool engagement means to allow the engagement of the connection means with the central bore 362.

Where scoliosis affects a section of n vertebrae in a spine, the apparatus consists of at least n intermediate units 301 and two end units 380, as shown in Figures 9 and 10. Each end unit 380 is identical to an intermediate unit 301, except that an end spring 310 is a little over 50% of the length of a leaf spring 305, and is connected to cage 302 at a first end.

The apparatus is implanted in a scoliosis affected spine by attaching one intermediate unit 301 to a pedicle of each affected vertebra, along one side of the affected length of spine, and an end unit 380 to a pedicle of each of one vertebra above the affected length of spine and one vertebra below the affected length of spine.

Screws 303 may be engaged with every vertebra, or some may be skipped, depending on the extent of the scoliosis, patient condition, and the desired result. To implant a unit, screw 303 is inserted through cage 302 and screwed into a pedicle of the desired vertebra. In practice, screw 303 may be assembled with cage 302 and spring socket 304 installed in the central bore 362 above the screw head 360 before surgery commences, that is, these parts may be supplied as a pre-assembled unit. Once cage 302 has been attached to the vertebra by screw 303, leaf spring 305 (or end
spring 310 in the case of an end unit 380) is inserted into cage 302 so that the first and second arms 338, 339 of the spring 305 extend through the cage spring slots 364. Connection means 307 are inserted into place in the central bore 362 to retain the leaf spring 305 in place.

Once the units have been implanted, an end spring 310 of an end unit 380 engages a spring engagement means 365 of an adjacent intermediate unit 301. First arm 338 of leaf spring 305 of said intermediate unit 301 engages a spring engagement means 365 of said end unit 380. Second arm 339 engages a spring engagement means 365 of a subsequent intermediate unit 301. This progression repeats along all the units, as shown in the drawings, so that each leaf spring 305 of an intermediate unit 301 engages spring engagement means of two adjacent units, and each end spring 310 engages the spring engagement means of one adjacent intermediate unit 301. As shown, spring engagement means 365 are loops, to securely engage the spring ends. However, spring engagement means 365 could be in any appropriate form, including (but not limited to) L-shaped brackets, straight or shaped protrusions, grooves or recesses.

To create curvature, and thus tension, in the springs 305, 310, connection means 307 are adjusted. In this embodiment, screwing the block into the unit, towards screw 303, curves the centre of leaf spring 305 relative to its ends. Adjusting the connection means 307 of an intermediate unit 301 so that leaf spring 305 forms an spinewards arc between the spring engagement means 365 of the adjacent units imposes a force on cage 302 of the intermediate unit 301, which is transferred to screw 303, and thus to that vertebra. A coarser adjustment may also be effected by screwing screw 303 further into its vertebra than in adjacent units, which will induce further tension in the spring.

Thus, the adjustment of connection means 307 can be used to tune the force to be applied to each vertebra, depending on its location in the scoliosis-affected spine. Different strengths and types of spring can be used, depending on the desired force to be applied. The adjustment of connection means 307 allows fine tuning of the applied force, by affecting the amount of curvature in each spring.

As the vertebral bodies start to become 'realigned' the springs will straighten reducing the spring force applied to the vertebral bodies thus helping to prevent over correction
of the scoliosis deformity. It may further be possible to vary the tension applied by the
adjustment means 307 in subsequent operations, to apply appropriate force to each
vertebra as the spine adjusts. It may eventually be possible to remove the units from
the spine, which has adjusted to its new position.

Although springs 305, 310 are shown as leaf springs, other forms could be used, such
as flexible rods or bars, or contoured and profiled forms and may be of varying
thickness and cross-section.
Claims:

1. A spinal adjustment system including at least three implant modules, at least one of the implant modules being a first implant module including:

   means for engaging the first implant module with a first vertebra; and

   first force application means;

characterised in that:

   the first force application means is adapted to engage with a second implant module engaged with a second vertebra superior to the first vertebra;

   the first force application means is adapted to also engage with a third implant module engaged with a third vertebra inferior to the first vertebra; and

   the first implant module includes means of adjusting the force applied to the first vertebra by the first force application means.

2. The spinal adjustment system according to claim 1, wherein the first implant module further includes:

   means of engaging a second force application means associated with the second implant module; and

   means of engaging a third force application means associated with the third implant module.

3. The spinal adjustment system according to claim 2, wherein the means of engaging the second force application means and/or the means of engaging the third force application means is selected from the list consisting of: loops, brackets, shelves and recesses.

4. The spinal adjustment system according to any one of the preceding claims, wherein the first force application means is a spring.

5. The spinal adjustment system according to claim 4, wherein the spring is a leaf spring.

6. The spinal adjustment system according to claim 5, wherein the means of adjusting the force applied to the first vertebra by the leaf spring is the combination of a spring cap and a spring tensioner.
7. The spinal adjustment system according to claim 5, wherein the means of adjusting the force applied to the first vertebra by the leaf spring is a lock nut.

8. The spinal adjustment system according to any one of the preceding claims, wherein the means for engaging the first implant module with the first vertebra is selected from the list consisting of: spinal screws and pedicle hooks.

9. The spinal adjustment system according to claim 8, wherein the means for engaging the first implant module with the first vertebra is a spinal screw.

10. An implant module for use in a spinal adjustment system, said implant module including:

    means for engaging the implant module with a first vertebra; and

    first force applying means;

characterised in that:

    the first force applying means is adapted to engage with a second implant module on one vertebra superior to the first vertebra;

    the first force applying means is adapted to also engage with a third implant module on one vertebra inferior to the first vertebra; and

    the implant module includes means of adjusting the force applied to the first vertebra by the first force applying means.

11. The implant module according to claim 10, wherein the implant module further includes:

    means of engaging a second force application means associated with the second implant; and

    means of engaging a third force application means associated with the third implant.

12. The implant module according to claim 11, wherein the means of engaging the second force application means and/or the means of engaging the third force application means is selected from the list consisting of: loops, brackets, shelves and recesses.

13. The implant module according to any one of claims 10 to 12, wherein the first force applying means is a spring.
14. The implant module according to claim 13, wherein the spring is a leaf spring.

15. The implant module according to any one of claims 10 to 14, wherein the means for engaging the implant module with the first vertebra is selected from the list consisting of: spinal screws and pedicle hooks.

16. The implant module according to claim 15, wherein the means for engaging the implant module with the first vertebra is a spinal screw.

17. A method of adjusting the alignment of a spine, including the steps of:
   engaging a first implant module with a first vertebra, said first implant including:
   means for engaging the first implant module with the first vertebra;
   first force application means; and
   means of adjusting the force applied to the first vertebra by the first force application means;
   engaging a second implant module with a second vertebra superior to the first vertebra;
   engaging a third implant module with a third vertebra inferior to the first vertebra; and
   engaging the first force application means of the first implant module with both the second implant module and the third implant module.

18. The method according to claim 17, further including the steps of:
   engaging a second force application means associated with the second implant module with the first implant; and
   engaging a third force application means associated with the third implant module with the first implant module.

19. The method according to either one of claims 17 or 18, further including the step of adjusting the force applied to the first vertebra by the first force application means.
20. The use of the spinal adjustment system according to any one of claims 1 to 9 for the treatment of a condition selected from the list consisting of: scoliosis, spondylolisthetic vertebra and Scheuermann’s Kyphosis.
Fig. 5
Fig. 7
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/56 (2006.01)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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

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

EPODOC, WPI: A61 F2/00, A61B17/00, A61F5/00 & Keywords (Spine, Scoliosis, Screw, Align, Implant, Tension) and like terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<td>X</td>
<td>Further documents are listed in the continuation of Box C</td>
<td>X See patent family annex</td>
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- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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Date of the actual completion of the international search
30 October 2013

Date of mailing of the international search report
30 October 2013

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<td>US 2006/0189983 A1 (FALLIN et al) 24 August 2006 Figure 1-2, Abstract, Para 32-33, 39</td>
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