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(54) **ASSEMBLY FOR THE STABILISATION OF VERTEBRAL BODIES OF THE SPINE**

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(52) **U.S. Cl.** ..... **435/117**; 435/69.1; 435/193; 435/252.3; 435/471; 530/350; 536/23.2

(57) **ABSTRACT**

An assembly for the stabilisation of vertebral bodies (**12, 14**) of the spine is described. It comprises a pair of pedicle screws (**20**) each having a threaded shaft (**20***a*) with a tapering first end (**20***b*) for introduction into a vertebral body and a head portion (**20***c*) with a second end (**20***d*), and is characterised in that it further comprises a spring member (**18, 22, 24, 40, 42, 44**) of the following form. The spring member has first and second ends, substantially straight portions (**18***b*) adjacent each end and a substantially curvilinear central portion (**18***a*) therebetween, the straight portions and the substantially curvilinear central portion being substantially coplanar. The assembly also includes a pair of fixation mechanisms (**26**) for securing the first and second ends of the spring member to the pair of pedicle screws. Typically the assembly will be for stabilisation of two adjacent vertebral bodies of the spine, that is one motion segment.

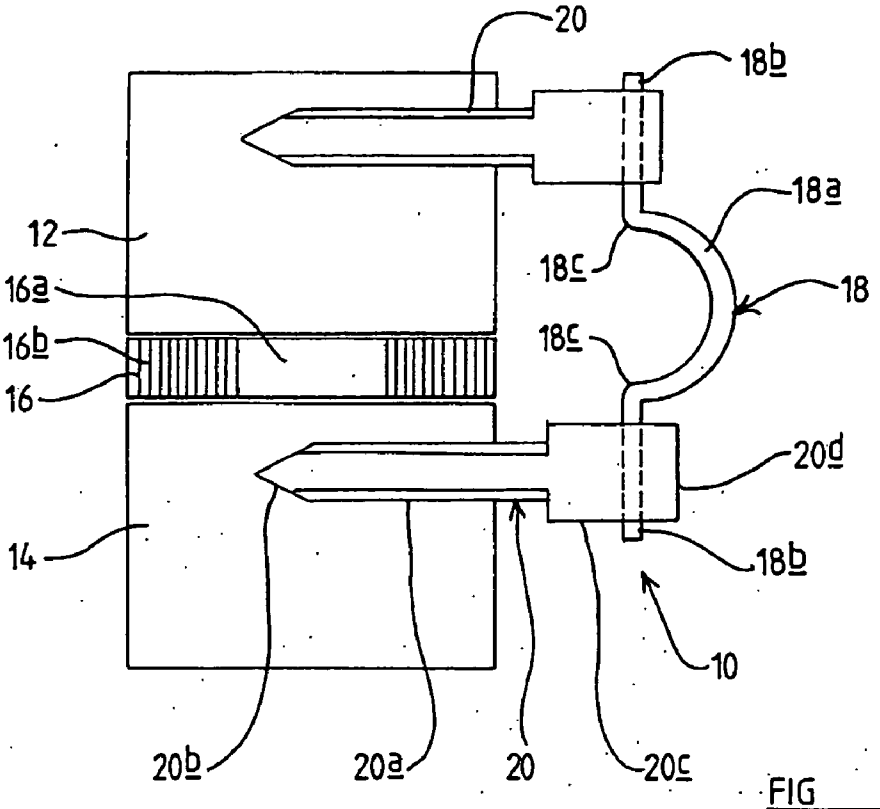



FIG 1

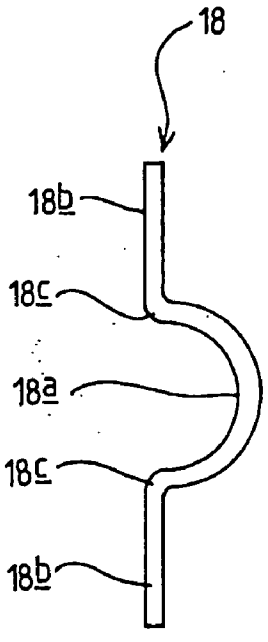



FIG 2a

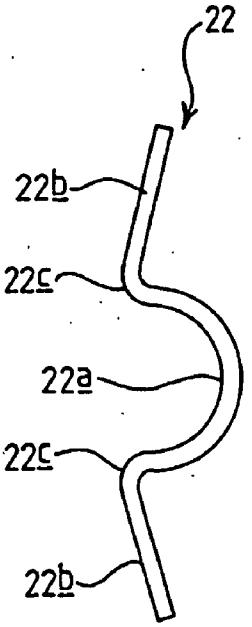



FIG 2b

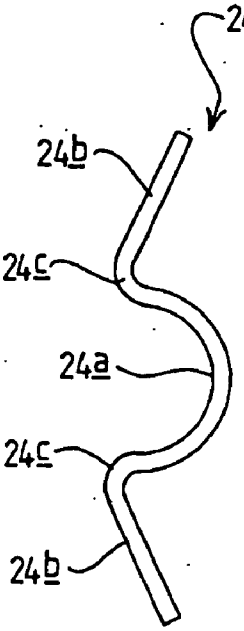



FIG 2c

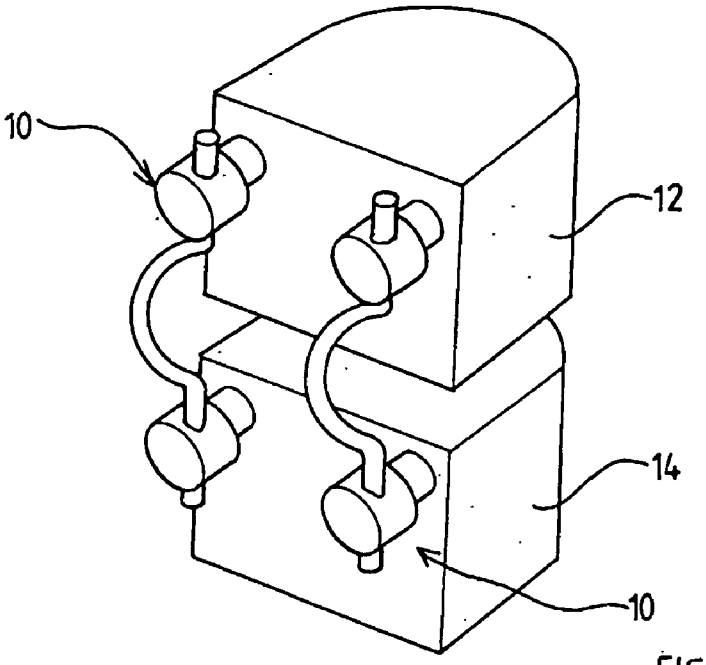



FIG 3

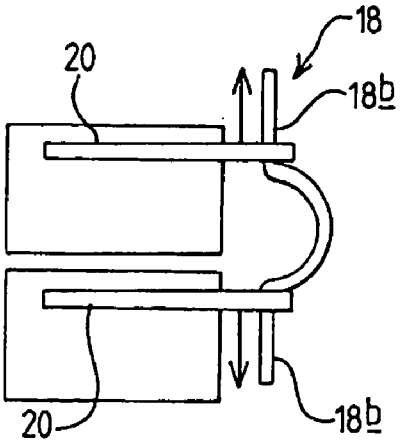



FIG 4a

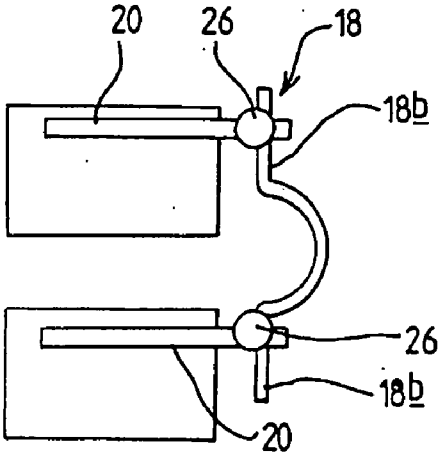



FIG 4b

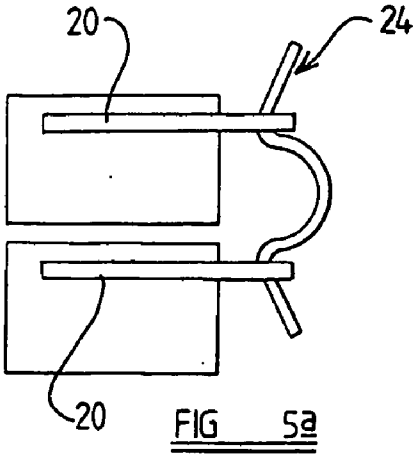



FIG 5a

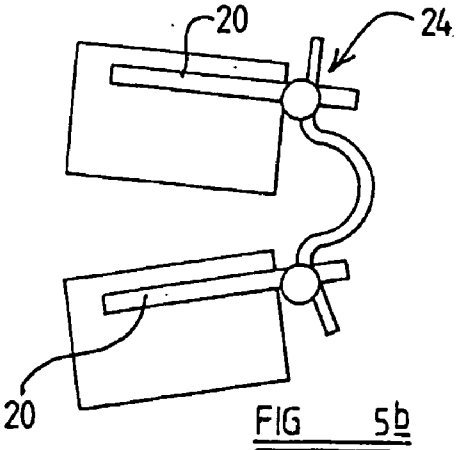



FIG 5b

FIG 6a

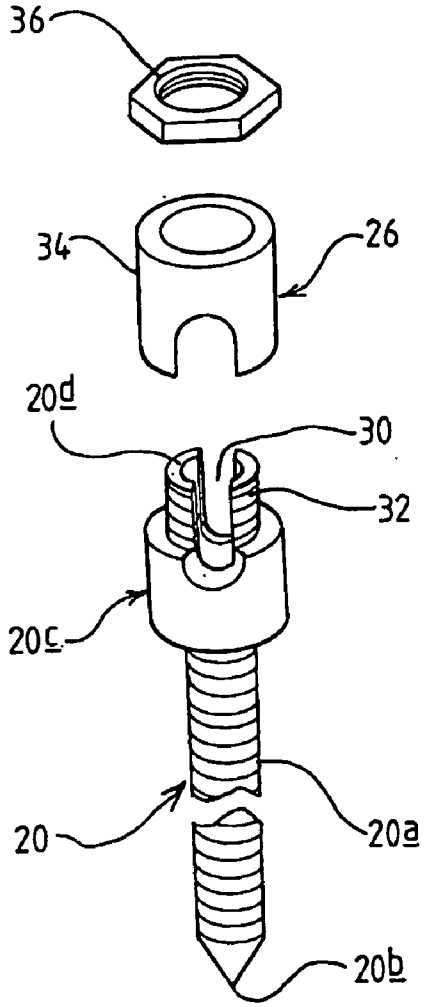
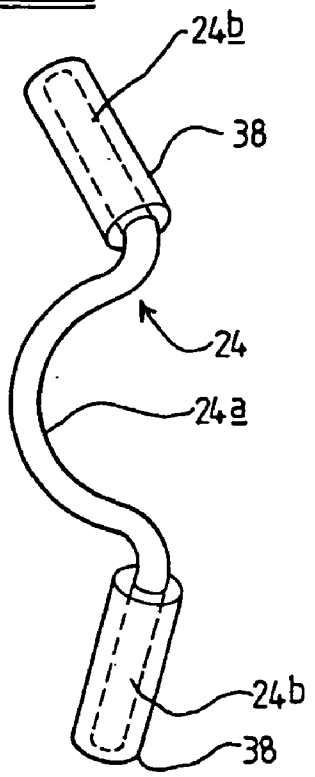



FIG 6b



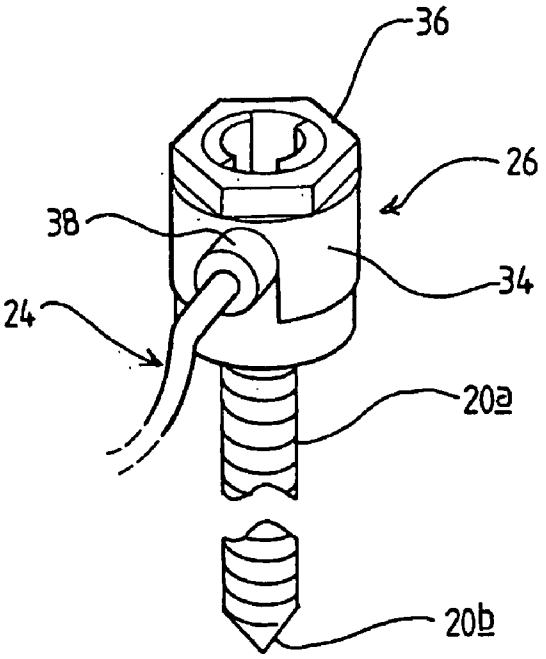




FIG 6c

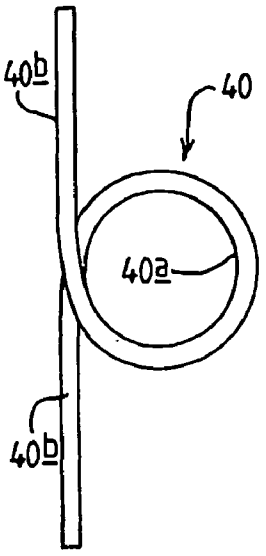



FIG 7a

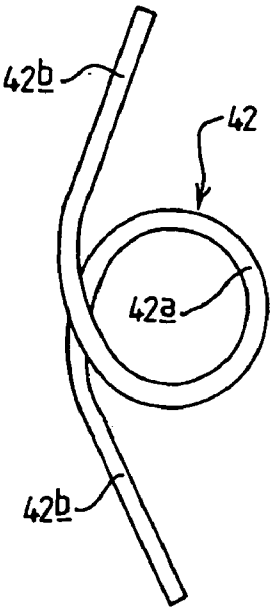



FIG 7b

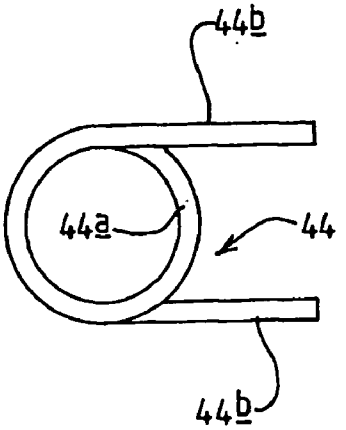



FIG 7c

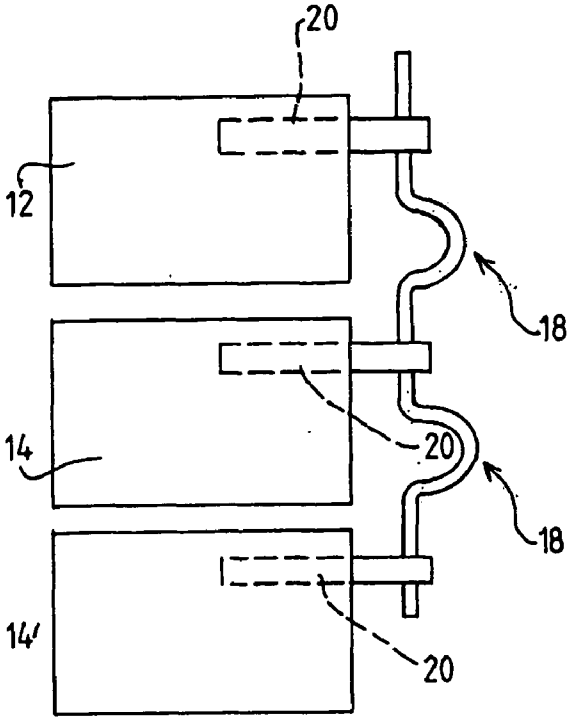



FIG 8

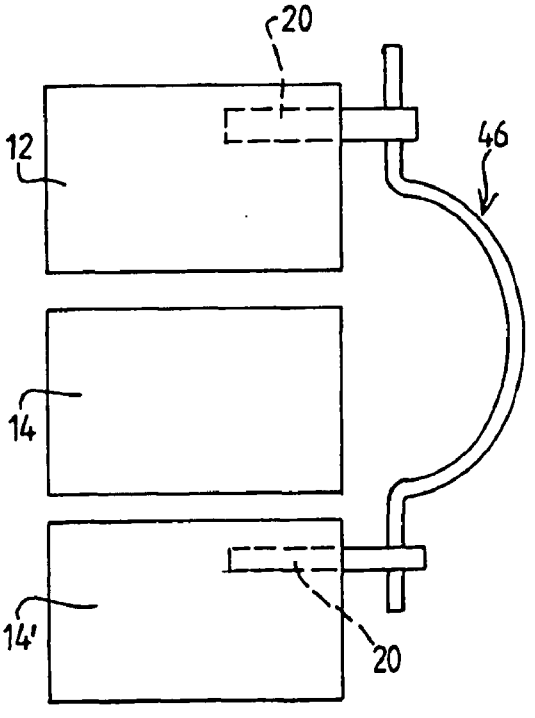



FIG 9

# ASSEMBLY FOR THE STABILISATION OF VERTEBRAL BODIES OF THE SPINE

[0001] The invention relates to an assembly for the stabilisation of vertebral bodies of the spine of the kind which is secured to the adjacent vertebral bodies by pedicle screws, and in particular although not exclusively to such an assembly for stabilisation of two adjacent vertebral bodies.

[0002] The lumbo-sacral region of the human spine consists of five lumbar vertebrae located above the large triangular bone called the sacrum. Between adjacent lumbar vertebrae are inter-vertebral discs (IVD) which have a complex structure, with a central jelly like nucleus pulposus and a peripheral rim of tough fibrous layers, the annulus fibrosus. Each lumbar vertebra is made up of a vertebral body, with upper and lower end plates, which contact the IVD's, and facet joints located posteriorlly. Movement in the lumbo-sacral spine occurs in the IVD's at the front and at the facet joints at the rear. Thus, the IVD's and the facet joints provide stability of the motion segment between adjacent vertebra. However, they also transfer load from one vertebra to the next, and it is estimated that the IVD bears approximately 80% of the load and the pair of facet joints at the rear bear approximately 20% of the load. A normal IVD can distribute the load uniformly across the surface of the end plate of the vertebral body. However, when the IVD and/or the facet joints are damaged or degenerate this can lead to instability of the motion segment between adjacent vertebra and commonly to low back pain. It is considered that the pain can be caused by abnormal movement, and/or by abnormal distribution of load across the end plates of the vertebrae.

[0003] Conventional treatment of low back pain is to limit movement between adjacent vertebrae, typically by fusing the adjacent vertebrae together. However, fusion has a high failure rate of pain relief.

[0004] More recently treatment with prosthetic IVD's has been tried in an attempt to preserve the normal movement and normal load bearing of the inter-vertebral joints. However, thus far the results are no better than in fusion of adjacent vertebrae.

[0005] An alternative approach is that of "soft stabilisation " which aims to prevent abnormal motion in painful motion segments of the lumbo-sacral spine, but to save as much as possible of the normal motion. Several methods of soft stabilisation have been described in the literature, but only two are currently in use.

[0006] The Graf ligament system consists of a fabric ligament secured across pedicle screws located in the adjacent vertebrae. Typically two such ligaments are located across each motion segment, one to each side on the rear of the spine. This system creates lordosis (curvature of the spine, convex forwards) and restricts the movement of the motion segment between the vertebrae concerned, but it also increases the load at the posterior part of the IVD. In one such system (Dynesys-Sulzer, as described in European patent application published under No. EP 0 669 109) excessive lordosis is prevented by a cylinder embracing the ligament between the pedicle screws. However, actual distraction of the disc space can only be achieved by producing flexion of the motion segment. This results in a kyphotic (convex backwards) segment, and kyphotic segments in the lumbo-sacral spine can produce back pain. Hence, there are significant problems with the use of such a system.

[0007] The other soft stabilisation system which is in the process of development is a fulcrum assisted soft stabilisation system (FASS) which is described in International patent application No. PCT/CH99/00612. In this system the compressing effect of the ligament found in the Graf ligament system is converted into a distraction effect by the use of a fulcrum bridging between the pedicle screws, and located between the ligament and the spine. This system can unload the IVD in forward flexion but not in extension. However, it is known from the literature that the IVD is loaded both in flexion and extension and the facet joints are specifically loaded in extension. Hence, this system also is expected to suffer from disadvantages.

[0008] None of the available soft stabilisation systems therefore addresses the important aim of addressing uniform IVD distraction to create a normal loading pattern across the end plates of the vertebrae, both in flexion and extension.

[0009] It is an aim of the present invention to provide a new soft stabilisation system which addresses that aim, and mitigates the problems described above.

[0010] According to the present invention there is provided an assembly for the stabilisation of vertebral bodies of the spine comprising a pair of pedicle screws each having a threaded shaft with a tapering first end for introduction into a vertebral body and a head portion with a second end, characterised in that it further comprises:

[0011] a spring member having first and second ends, substantially straight portions adjacent each end and a substantially curvilinear central portion therebetween, the straight portions and the substantially curvilinear central portion being substantially coplanar; and

[0012] a pair of fixation mechanisms for securing the first and second ends of the spring member to the pair of pedicle screws.

[0013] The substantially curvilinear central portion of the spring member may be C-shaped or a coil.

[0014] The substantially curvilinear central portion of the spring member typically has a radius of curvature in the range 3 to 17 mm or in the range 5 to 15 mm.

[0015] The substantially straight portions of the spring member may be at an angle to each other in the range 0 to 180 degrees, or 90 to 180 degrees. When the straight portions are at 180 degrees they are substantially coaxial. When the substantially straight portions of the spring member are at 0 degrees they are parallel, and this is most likely when the central curvilinear portion is a coil.

[0016] Preferably the spring member is formed from wire.

[0017] The spring member may have a diameter in the range 1 to 6 mm, or in the range 2 to 5 mm.

[0018] The spring member may have substantially straight portions of greater cross sectional area than that of the substantially curvilinear portion.

[0019] The assembly may have a pair of sleeves, one on each of the substantially straight portions, to effectively increase the external diameter of at least a part of each of the substantially straight portions.

[0020] Such sleeves may have external diameters in the range 5 mm to 8 mm.

[0021] The spring member may be round in cross section, or alternatively may be square or rectangular in cross section. The spring member is preferably formed from titanium or stainless steel.

[0022] The threaded shaft portions of the pedicle screws may have lengths in the range 30 to 60 mm, or in the range 35 to 55 mm. Preferably the pedicle screws are formed from titanium.

[0023] The assembly may be for stabilisation of two adjacent vertebral bodies of the spine, i.e. one motion segment. Typically for such embodiments the spring member has a length in the range 20 to 65 mm, but it may be in the range 25 to 60 mm.

[0024] The assembly may have a spring member which is specifically adapted for stabilisation of three vertebral bodies of the spine, that is two motion segments.

[0025] In such embodiments, the spring member typically has a length in the range 50-110 mm, but it may be in the range 60-100 mm.

[0026] Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

[0027] **FIG. 1** is a schematic illustration of an assembly according to the invention in use;

[0028] **FIG. 2** illustrates three alternative embodiments of a spring member. for incorporation in the assembly of **FIG. 1**;

[0029] **FIG. 3** schematically illustrates a pair of assemblies according to the invention in use, from perspective angle;

[0030] **FIG. 4** illustrates schematically how the assembly of **FIG. 1** can be used for distraction of the motion segment;

[0031] **FIG. 5** illustrates schematically how the assembly according to the invention can be used to cause backward angulation of the motion segment;

[0032] **FIG. 6** illustrates a fixation mechanism suitable for use in the assembly of **FIG. 1**;

[0033] **FIG. 7** illustrates three further alternative spring members;

[0034] **FIG. 8** illustrates schematically two assemblies according to the invention used across adjacent motion segments, and

[0035] **FIG. 9** illustrates schematically an alternative embodiment of an assembly according to the invention for use across two motion segments.

[0036] Referring first to **FIG. 1**, an assembly **10** for the stabilisation of two adjacent vertebral bodies **12**, **14** of the spine is illustrated schematically. The vertebral bodies **12**, **14** are separated by an inter-vertebral disc **16** which has a nucleus pulposus **16***a* and a fibrous outer-annulus, called the annulus fibrosus, **16***b*. For simplicity the facet joints have been omitted from the posterior of the vertebral bodies **12**, **14**. For clarity the assembly **10** is fixed to the posterior of the vertebral bodies **12**, **14**.

[0037] The assembly **10** comprises a spring member **18** which has a central substantially curvilinear portion **18**A, which in this embodiment is C-shaped, and substantially straight portions **18***b* extending outward therefrom. The straight portions **18***b* and curvilinear portion **18***a* are joined by reverse curvature portions **18***c*.

[0038] The assembly **10** further comprises a pair of pedicle screws **20** each of which comprises a threaded shaft portion **20***a* with a tapering first end **20***b* and a head portion **20***c* with a second end **20***d*.

[0039] The assembly **10** is illustrated in position secured to the posterior of a pair of adjacent vertebral bodies **12**, **14** with the threaded shaft portions **20***a* of the pedicle screws **20** inserted into the vertebral bodes **12**, **14**. The spring member **18** is secured to the heads **20***c* of each of the pedical screws **20** by a fixation mechanism as appropriate. An example of a fixation mechanism will be described later, although any appropriate mechanism may be used.

[0040] Referring now in particular to **FIG. 2**, three examples of spring members for incorporation into an assembly according to the invention are illustrated. **FIG. 2***a* shows the spring member **18** from **FIG. 1**. In the spring member **18** the substantially straight portions **18***b* are coaxial, i.e. at an angle of 180° to each other, and the substantially curvilinear portion **18***a* is C-shaped and approximately a semi-circle. The reverse curvature portions **18***c* are of small radius and approximate to right angles.

[0041] In **FIG. 2***b* a first alternative spring member **22** is illustrated in which the substantially straight portions **22***b* are at an angle to each other of approximately 150°, and the substantially curvilinear portion **22***a* is again C-shaped and approximately a semi-circle. The substantially straight portions **22***b* and the substantially curvilinear portion **22***a* are joined by reverse curvature portions **22***c* which in this spring member **22** are of relatively small radius, but not as small as in the embodiment above.

[0042] In **FIG. 2***c* a third embodiment of a spring member **24** is illustrated. The spring member **24** again comprises two substantially straight portions **24***b* with a substantially curvilinear portion **24***a* therebetween, these portions being joined by reverse curvature portions **24***c* which are of a larger radius of curvature than those **22***c* in the previous embodiment. The substantially straight portions **24***b* are again at an angle to each other, this time of approximately 140°.

[0043] The substantially curvilinear portions **18***a*, **22***a* and **24***a* are all shown as being smooth curves approximating to a semi-circle. However, they could take other forms, such as for examples being smaller arcs of a circle, or indeed not being strictly curvilinear but comprising a plurality of short straight portions.

[0044] The substantially straight portions **18***b*, **22***b* and **24***b* are all shown as being straight, but they could in alternative embodiments be very slightly curved. They will generally be at angles to each other in the range 90 to 180° for embodiments such as these with C-shaped curvilinear central portions **18***a*, **22***a* and **24***a*.

[0045] In each of the spring members **18**, **22** and **24** the substantially straight portions and the substantially curvilinear portion are coplanar.

[0046] The spring members **18**, **22** and **24** are made from titanium or stainless steel wire, each spring member being bent from a single piece. The wire will typically have a diameter in the range 1 to 6 mm, but preferably in a range of 2 to 5 mm. The wire may be round in cross-section or may be of other forms e.g. square, rectangular, or oval in cross section.

[0047] The spring members **18**, **22** and **24**, which are all designed to be used between adjacent vertebral bodies, have an overall length in the range 20 mm to 65 mm, but preferably in the range 25 mm to 60 mm.

[0048] Referring now in particular to **FIG. 3**, a pair of assemblies **10** according to this invention are shown secured to a pair of adjacent vertebral bodies **12**, **14**. This is the manner in which the assembly **10** will generally be used, with one assembly **10** applied to either side of the vertebral bodies on the posterior aspect of the spine.

[0049] Referring now to **FIGS. 4 and 5**, two effects of use of the assemblies **10** are seen illustrated. In **FIG. 4**, it can be seen that unloading of the inter-vertebral disc can be achieved by separation of the pedicle screws **20**, or distraction of them, along the substantially straight portions **18***b* of the spring member **18** before securing the spring member **18** to the pedicle screws **20** using the fixation mechanisms **26**. Thus the assembly **10** will hold the vertebral bodies **12**, **14** further apart, unloading the disc, yet still permit some movement which is relatively normal.

[0050] In **FIG. 5** the use of an alternative embodiment of spring member **24**, in which the substantially straight portions **24***b* are at an angle to each other, can be seen providing backward angulation (lordosis) of the motion segment between the adjacent vertebral bodies which in some conditions will be desirable.

[0051] Referring now to **FIG. 6** an example of a fixation mechanism **26** is illustrated, the mechanism being known in the prior art. The head **20***c* of the pedicle screw **20** is shown with a particular form. It comprises a slot **30** which provides the dual purpose of accepting the blade of a screw driver for insertion of the pedicle screw **20** into a vertebral body, and for receipt of the substantially straight portions **24***b* of the spring member **24**. The head **20***c* further comprises adjacent its second end **204**, and around the upper part of the slot **30**, a threaded portion **32**.

[0052] The fixation mechanism **26** further comprises a sleeve member **34** and threaded nut **36**, also sleeves **38** which are located on the substantially straight portions **24***b* of the spring member **24** before the assembly **10** is put together as shown in **FIG. 6***b*. The sleeves **38** effectively increase the outer diameter of the spring member **24** as necessary for use in the fixation mechanism **26**. For example, for a spring member **24** formed from wire with a diameter of 3 mm or 4 mm the sleeves **38** may typically increase the diameter to somewhere in the range 5 mm to 8 mm, as appropriate for the pedicle screw being used. As an alternative, the substantially straight portions **24***b* of the spring member **24** may be formed with a greater diameter than that of the substantially curvilinear portion **24***a*, and thus have a greater cross-sectional area than the substantially curvilinear portion **24***a*.

[0053] The fixation mechanism **26** is shown assembled in **FIG. 6***c*. Once the screw **20** has been inserted into the vertebral body one substantially straight portion **24***b* of the spring member **24**, with sleeve **38** in place, is located in the slot **30**. The sleeve member **34** is then placed over the head **20***c* of the pedicle screw **20**, and the nut **36** screwed down onto the threaded portion **32** to retain the spring member **24** in place. The fixation mechanism **26** may further include a check nut (not shown), as is known in the prior art, to further secure the mechanism together and to reduce the possibility of it loosening over time.

[0054] It should be appreciated that the fixation mechanism **26** is one example of many options which would be available, and any appropriate fixation mechanism may be used.

[0055] Referring now to **FIG. 7** three further embodiments of spring members according to the invention are illustrated. In the first, as shown in **FIG. 7***a*, a spring member **40** comprises a substantially curvilinear central portion **40***a* in the form of a coil, and two substantially straight portions **40***b* extending therefrom at substantially 180° to each other. The second, shown in **FIG. 7***b* is a spring member **42** comprising a substantially curvilinear portion **42***a* comprising a coil as for the previous embodiment, with two substantially straight portions **42***b* extending therefrom at an angle of approximately 120° to each other. The third embodiment, shown in **FIG. 7***c*, comprises a spring member **44** having a central substantially curvilinear portion **44***a* comprising a coil as previously, and two substantially straight portions **44***b* extending therefrom, but this time at approximately 0° to each other and substantially parallel. It will be appreciated that the spring members **40**, **42** and **44** are shown unloaded, rather than as they would be after implantation with the patient in a normal rest position, by which time they would be loaded.

[0056] In each of the embodiments of spring member **40**, **42** and **44** the substantially straight portions **40***b*, **42***b* and **44***b* are substantially coplanar, in that they are as close to coplanar as can be achieved when the substantially curvilinear portions **40***a*, **42***a* and **44***a* comprise coils.

[0057] The embodiments of assemblies according to the invention described and discussed thus far are for use between two adjacent vertebral bodies. Such embodiments can be used across adjacent motion segments, as illustrated in **FIG. 8**, if more than one motion segment requires stabilisation. In such cases the pedicle screw **20** located in the middle of the three vertebral bodies **14** has a modified fixation mechanism which can receive and secure the substantially straight portion of two spring members **18**.

[0058] It is also possible for embodiments of assemblies according to the invention to be appropriate for use across more than a single motion segment. One such example, for use across two motion segments, is illustrated in **FIG. 9** in which three vertebral bodies are shown referenced **12**, **14** and **14'**. A pedicle screw **20** is inserted into the upper most vertebral body **12**, and into the lower most vertebral body **14'**. A spring member **46**, substantially of the form of the spring member **18** but of larger dimension, is secured between the two pedicle screws **20**. Spring member **18** will be longer than embodiments previously described, and may be as long as 110 mm or 100 mm.

[0059] The exact design of spring members for use in a particular case will depend on a large number of factors.

These will include the sizes of the vertebral bodies, the number of motion segments requiring stabilisation, and the particular condition being treated.

[0060] In the present specification "comprises " means "includes or consists of" and "comprising " means "including or consisting of".

[0061] The features disclosed in the foregoing description, or the following claims, or the accompanying drawings, expressed in their specific forms or in terms of a means for performing the disclosed function, or a method or process for attaining the disclosed result, as appropriate, may, separately, or in any combination of such features, be utilised for realising the invention in diverse forms thereof.

1. An assembly for the stabilisation of vertebral bodies of the spine comprising:

a pair of pedicle screws each having a threaded shaft with a tapering first end for introduction into a vertebral body and a head portion with a second end,

a spring member having first and second ends, substantially straight portions adjacent each end and a substantially curvilinear central portion therebetween, the straight portions and the substantially curvilinear central portion being substantially coplanar; and

a pair of fixation mechanisms for securing the first and second ends of the spring member to the pair of pedicle screws, and

characterised in that the substantially curvilinear central portion of the spring member is a coil.

2. An assembly according to any one of the preceding claims characterised in that the substantially curvilinear central portion of the spring member has a radius of curvature in the range 3 to 17 mm.

3. An assembly according to claim 2 characterised in that the substantially curvilinear central portion of the spring member has a radius of curvature in the range 5 to 15 mm.

4. An assembly according to any one of the preceding claims characterised in that the substantially straight portions of the spring member are at angle to each other in the range 0 to 180° .

5. An assembly according to claim 4 characterised in the substantially straight portions of the spring member are at an angle to each other in the range 90 to 180 degrees.

6. An assembly according to any one of claims 1 to 3 characterised in that the substantially straight portions of the spring member are coaxial with each other.

7. An assembly according to any one of claims 1 to 3 characterised in that the substantially straight portions of the spring member are parallel to each other.

8. An assembly according to any one of the preceding claims characterised in that the spring member is formed from wire.

9. An assembly according to any one of the preceding claims characterised in that the spring member has a diameter in the range 1 to 6 mm.

10. An assembly according to claim 11 characterised in that the spring member has a diameter in the range 2 to 5 mm.

11. An assembly according to any one of the preceding claims characterised in that at least the parts of the substantially straight portions adjacent the ends of the spring member are of a greater cross-sectional area than that of the substantially central curvilinear portion.

12. An assembly according to any one of claims 1 to 10 characterised in that it further comprises a pair of sleeves, one on each of the substantially straight portions, to effectively increase the external diameter of at least a part of each of the substantially straight portions.

13. An assembly according to claim 12 characterised in that the sleeves have an external diameter in the range 5 mm to 8 mm.

14. An assembly according to any one of the preceding claims characterised in that the spring member is round in cross section.

15. An assembly according to any one of claims 1 to 13 characterised in that the spring member is square or rectangular in cross section.

16. An assembly according to any one of the preceding claims characterised in that the spring member is formed from titanium or stainless steel.

17. An assembly according to any one of the preceding claims characterised in that the threaded shaft portions of the pedicle screws have lengths in the range 30 to 60 mm.

18. An assembly according to claim 17 characterised in that the threaded shaft portions of the pedicle screws have lengths in the range 35 to 55 mm.

19. An assembly according to any one of the preceding claims characterised in that the pedicle screws are formed from titanium.

20. An assembly according to any one of the preceding claims characterised in that the spring member is specifically adapted for stabilisation of two adjacent vertebral bodies of the spine, that is one motion segment.

21. An assembly according to claim 20 characterised in that the spring member has a length in the range 20 to 65 mm.

22. An assembly according to claim 21 characterised in that the spring member has a length in the range 25 to 60 mm.

23. An assembly according to any one of claims 1 to 19 characterised in that the spring member is specifically adapted for stabilisation of three vertebral bodies of the spine, that is two motion segments.

24. An assembly according to claim 23 characterised in that the spring member has a length in the range 50-110 mm.

25. An assembly according to claim 24 characterised in that the spring member has a length in the range 60-100 mm.

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