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(54) **FLEXIBLE LINKING PIECE FOR STABILISING THE SPINE**

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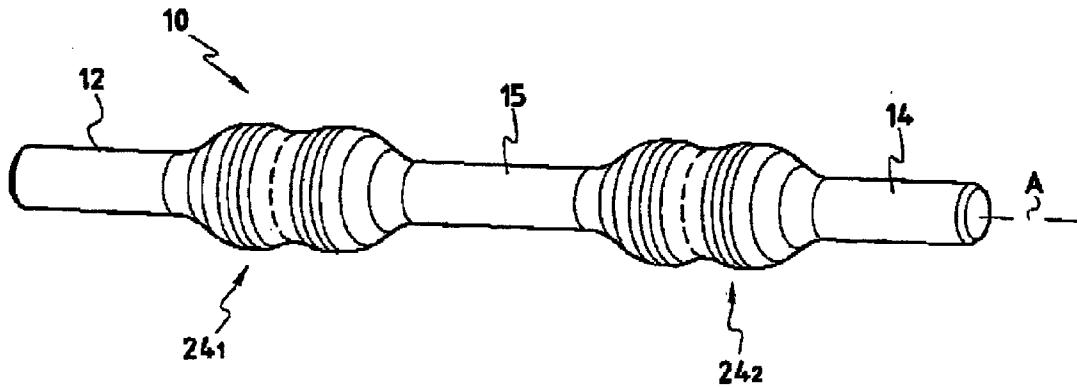
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(57) **ABSTRACT**

Embodiments described herein relate to a connecting member for maintaining the spacing between at least two anchor members screwed into vertebrae and methods for stabilizing the spine using a connecting member. One embodiment of a connecting member can include a first rigid portion, a second rigid portion and a connecting body disposed between the first rigid body and the second rigid body that is more flexible than the first rigid body and the second rigid body. The connecting member can be provided as a preassembled connecting member.



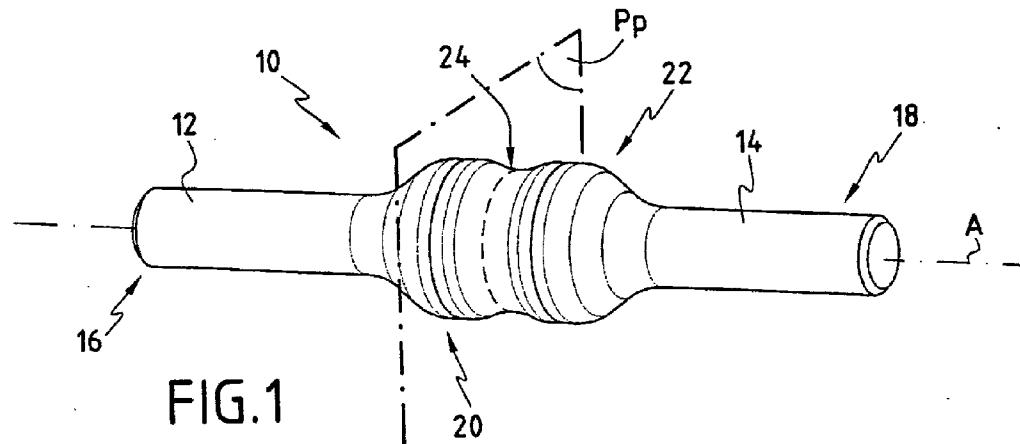


FIG. 1

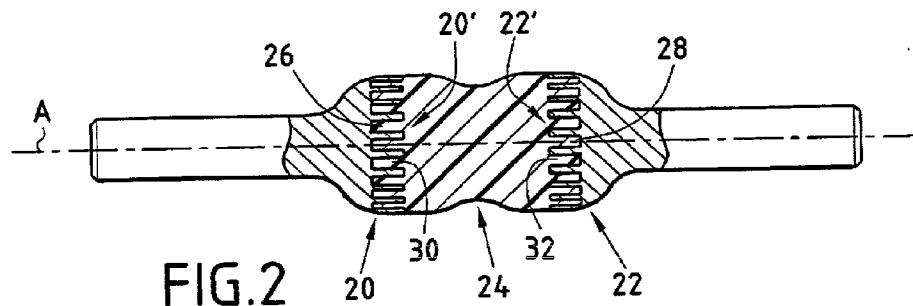


FIG. 2

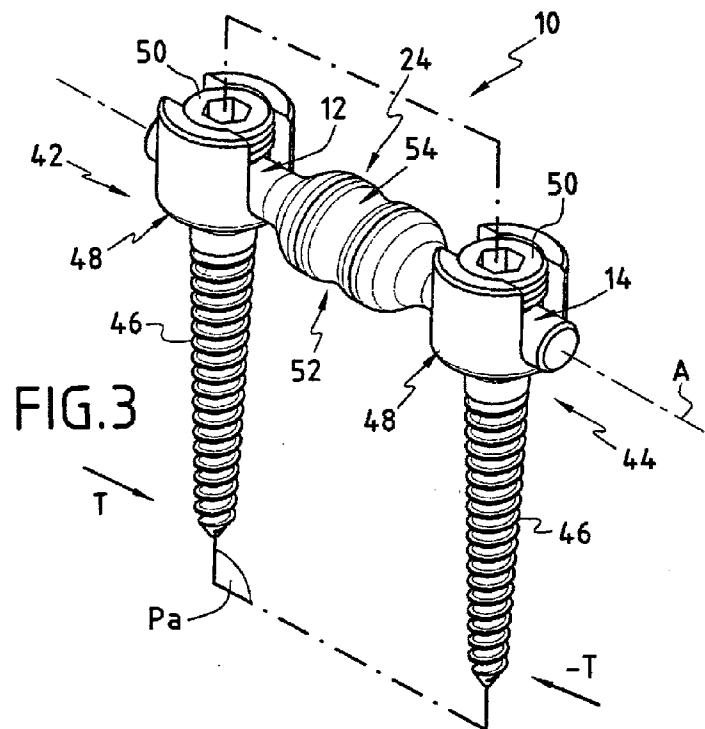


FIG. 3

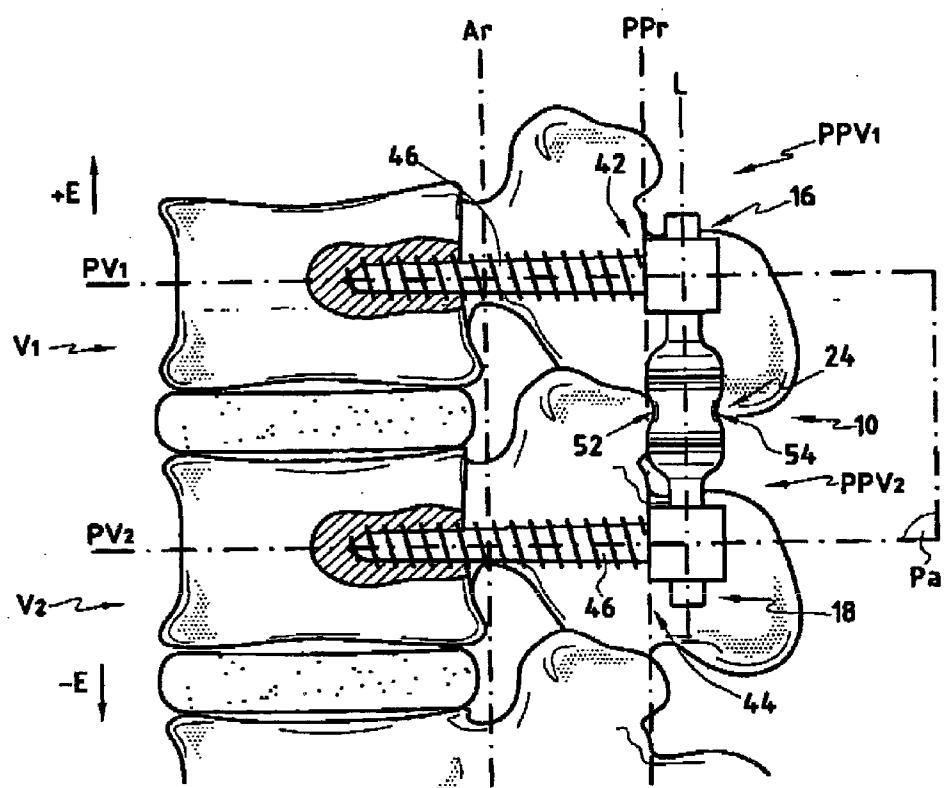


FIG. 4

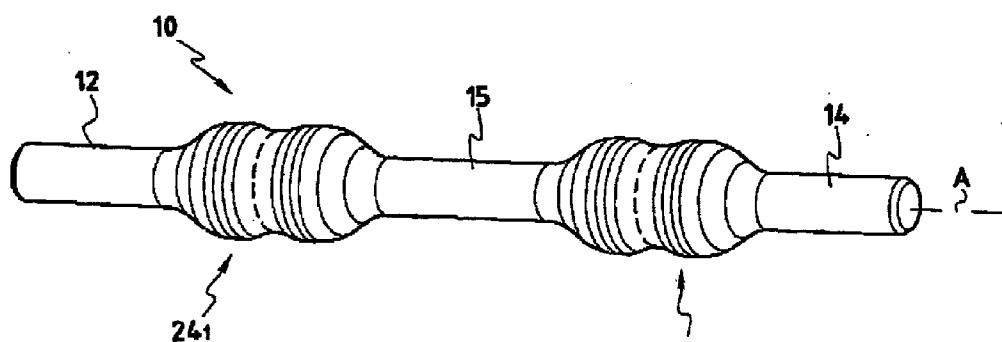


FIG. 5

FLEXIBLE LINKING PIECE FOR STABILISING THE SPINE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of and claims priority under 37 CFR 1.53(b) to U.S. patent application Ser. No. 10/333,881, filed Jan. 24, 2003, entitled "Flexible Linking Piece for Stabilising the Spine" by inventors Regis LeCouedic and Denis Pasquet, which claims priority under 35 U.S.C. 371 to International Application No. PCT/FR01/02426, filed Jul. 25, 2001, entitled "Flexible Linking Piece for Stabilising the Spine" by inventors Regis LeCouedic and Denis Pasquet, which claims benefit of priority to French Application No. 00/09706 entitled "Flexible Linking Piece for Stabilising the Spine" by inventors Regis LeCouedic and Denis Pasquet, filed Jul. 25, 2000, all of which are incorporated herein by reference.

TECHNICAL FIELD

[0002] This disclosure relates to a connecting member for maintaining the spacing between at least two anchor members which are interconnected by said connecting member.

BACKGROUND

[0003] Systems for stabilizing the vertebral column by bracing at least two consecutive vertebrae by means of anchor members fixed into said vertebrae and connected by rigid connecting rods are well known in the art. Systems of this kind are generally coupled systems such that two consecutive vertebrae are interconnected by two substantially parallel rods fixed one on each side of the spinous processes. The anchor members are screwed into the posterior portions of the vertebrae and pass through the pedicles and a substantial portion of the vertebral bodies and therefore provide a fixed and durable connection.

[0004] The above stabilizing systems are routinely used to consolidate several consecutive vertebrae. Thus the vertebrae are interconnected by rigid rods over a substantial length of the vertebral column. Such assemblies hold the vertebrae correctly relative to each other; however, they considerably stiffen the spine in terms of bending. It has been shown that a more flexible stabilizing system, which confers greater relative mobility on the vertebrae, is beneficial in some pathologies.

BRIEF SUMMARY

[0005] A first object of embodiments described herein is to provide a connecting member for maintaining the spacing of existing anchor members while at the same time allowing relative mobility of said anchor members.

[0006] To achieve the above object, a connecting member in accordance with one embodiment, adapted to maintain the spacing between at least two anchor members screwed into vertebrae, comprises at least two rigid rod-forming parts made of a first material and each having a fixing, first portion adapted to be fixed into an anchor member and a fastening, second portion, said rods being aligned with each other and said fastening portions facing each other, and a connecting body that is made entirely from a second material that is more elastically deformable than said first material and interconnects the facing fastening portions of said rigid parts so that said connecting body is able to deform elastically, whereby

the vertebrae, which are held spaced from each other, are movable relative to each other.

[0007] Thus a feature of the connecting member lies in the way the two rigid parts are fastened together by means of an elastically deformable connecting body which imparts relative mobility to the rigid parts when under stress, with the reaction force to the stress being proportional, within certain limits, to the deformation of the connecting body. As a result, the connecting member can be bent by stresses in directions that are not parallel to the axis of the connecting member; it can also be stretched or contracted by opposing forces acting parallel to the axis of the connecting member.

[0008] Consequently, the two anchor members, when at rest, are interconnected by the connecting member with its fixing portions fastened to the anchor members, and can be moved relative to each other by forces proportional to the movement.

[0009] Said rigid parts are preferably mechanically connected together by a single connecting body providing the whole of said mechanical connection. In this way a single member provides the connection between the rigid parts at the same time as controlling relative movement of the rigid parts. Also, in a particular embodiment, said connecting body consists entirely of a single second material to simplify assembly and to impart homogeneous mechanical properties to it.

[0010] The connecting member of an embodiment has n rigid parts with n-1 connecting bodies disposed between them along the longitudinal axis of said member, each rigid part situated between two connecting bodies having one fixing, first portion and two fastening, second portions, there being one fastening, second portion at each end of said fixing, first portion, and said fastening, second portions being connected respectively to said two connecting bodies, and the rigid parts at the two ends of said member advantageously have respective single fastening, second portions connected to the connecting bodies, whereby said connecting member is adapted to interconnect n anchor members.

[0011] Thus, by virtue of this feature, the connecting member maintains the spacing between all the anchor members that it interconnects, each of which can be fixed to a respective vertebra, to align them. Each rigid part is fixed to an anchor member and, between successive anchor members, there is a connecting body that interconnects the two fastening portions. Thus a single connecting member stabilizes several vertebrae, which reduces the time to assemble the stabilizing system as a whole and consequently the operating time. Also, by virtue of this feature, the connecting member stabilizes several consecutive vertebrae by connecting them together, while at the same time making them highly flexible and conferring on them a high degree of relative compressibility in the longitudinal direction.

[0012] In a preferred embodiment, each of said fastening portions of said rigid parts that said connecting body interconnects has a fastening wall to which said connecting body is adapted to adhere. Thus no additional fixing member is needed and the adhesive properties of the second material to the fastening wall are sufficient to connect them.

[0013] In one particular embodiment, said fastening wall has openings adapted to cooperate with asperities on said connecting body to increase the surface area of contact between said wall and said body.

[0014] Obviously, providing openings in a wall increases the surface area of that wall, which increases the contact area between the two materials if one of the materials can be

molded onto the wall of the other material. The increase in contact area increases the connecting forces between said connecting body and said fastening portions. Also, the static friction forces of the material of the connecting member on said two members are increased in a corresponding manner and these forces are added to the connecting forces.

[0015] Said second material of which said connecting body is made is advantageously obtained by polymerization. In this way, the connecting body can easily be hot molded onto the fastening walls if the material is polymerized beforehand, or it can be formed *in situ* if the rate of polymerization of the monomers constituting said second material is sufficiently low to provide the time necessary for completing the assembly.

[0016] In a preferred embodiment, said first material of which said rigid parts are made is a titanium alloy. It is therefore easy to form openings in said fastening wall to which said connecting body is able to adhere.

[0017] In another preferred embodiment, the section of said rigid rod-forming parts is circular, which facilitates the manufacture of the member. Also, if prior art circular section connecting rods are to be replaced by connecting rods described herein without making it necessary to replace the anchor members, it is necessary for said rigid parts to have sections identical to the sections of the prior art connecting rods.

[0018] The present disclosure also provides a vertebral stabilization system for fastening together at least two vertebrae each having a median plane substantially perpendicular to the axis of the spine of which they form a part and a posterior wall defining a posterior median plane of said spine, said system comprising at least two anchor members each adapted to be fixed into the posterior wall of a respective vertebra so that a line which intersects said two anchor members is substantially parallel to said axis of the spine, which system further comprises at least one connecting member whose two rigid parts are adapted to interconnect said two anchor members so that the axis of said connecting member is substantially parallel to said axis of the spine, whereby said vertebrae, which are interconnected via their posterior portions, present relative mobility along said axis of said spine.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] Other features and advantages of various embodiments will emerge on reading the following description of particular embodiments, which is given by way of non-limiting example and with reference to the accompanying drawings, in which:

[0020] FIG. 1 is a diagrammatic perspective view of a connecting member in accordance with an embodiment,

[0021] FIG. 2 is a diagrammatic view in axial section of the connecting member in accordance with an embodiment,

[0022] FIG. 3 is a perspective view showing anchor members connected by the connecting member,

[0023] FIG. 4 is a side elevation view of a vertebral column showing two consecutive vertebrae into which there are screwed anchor members interconnected by a connecting member in accordance with an embodiment, and

[0024] FIG. 5 is a perspective view showing a connecting member having two connecting bodies and three rigid parts.

DETAILED DESCRIPTION

[0025] The various portions of a connecting member are described initially with reference to FIG. 1.

[0026] The connecting member 10 has two cylindrical rigid parts 12 and 14. Each rigid part 12, 14 has a fixing, first portion 16, 18 and a fastening, second portion 20, 22 forming an enlargement. The facing fastening portions 20 and 22 are connected together by a connecting body 24 so that the rigid parts 12 and 14 are in axial alignment. The connecting member 10 is therefore circularly symmetrical about the axis A.

[0027] How the two rigid parts 12 and 14 are fastened together is described below with reference to FIG. 2.

[0028] The connecting body 24 is a plastics material body obtained by polymerization. The material of the body is chosen from materials which are more elastically deformable than the material of said rigid parts 12, 14 and, most importantly, whose elastic properties are of the same order of magnitude as those of the posterior ligaments that hold the spine together.

[0029] Organic silicon compounds constitute polymers whose mechanical properties can be determined by the choice of their basic components, in particular by their degree of substitution, the nature of the substituents, and their molecular weight, and whose elastic behavior predominates over its plastic behavior. They therefore constitute a family of materials suitable for interconnecting the two rigid parts 12 and 14. Also, these polymers can adhere strongly to materials of inorganic composition. Thus the connecting body 24 provides good means for fastening together the rigid parts 12, 14, which are generally made of titanium alloy.

[0030] Nevertheless, the polymer materials that can be used are not limited to organic silicon compounds, and any other material having comparable properties could be suitable.

[0031] The material of the connecting body 24 is adapted to adhere to the fastening walls 20' and 22' of said fastening second portions 20, 22. However, to increase the adhesion, openings 30, 32 are formed in the fastening walls 20, 22 of the fastening, second portions and are adapted to cooperate with asperities 26, 28 on the connecting body 24 which are inserted into the openings 30, 32.

[0032] This feature increases the contact area between the two materials and thereby increases the connecting force between them in a direction normal to said surface of contact and creates static friction forces which are additional to the adhesion force.

[0033] A connection of the above kind is obtained either by injecting the polymer while hot between the two rigid parts 12 and 14 held facing each other in a mold, or by cold molding the mixture of monomers between the two rigid parts 12 and 14, if the speed of the reaction is sufficiently low. The asperities 26, 28 are therefore formed *in situ*, when the polymer liquid or paste inserted into the openings 26, 28 solidifies after cooling or after a chemical reaction. Obviously, the connecting body 24 consists of the polymer disposed between the rigid parts 12 and 14, more specifically between the fastening walls 20' and 22', and, in order to retain the polymer between the facing portions while it is in the liquid state, the walls of the mold must necessarily surround the space between and in line with the two rigid parts 12, 14.

[0034] In a particular embodiment (not shown) the openings 30, 32 formed in the fastening walls 20' and 22' open onto the outside wall of the rigid parts 12 and 14 so that the liquid polymer penetrates entirely into the openings 30, 32 without it being possible for air to be trapped therein. This reinforces the fastening of the connecting body 24 to the rigid parts 12, 14.

[0035] Also, the openings **30**, **32**, which are shown as parallel to the longitudinal axis of the connecting member in FIG. 2, can be oblique to that longitudinal axis and/or not rectilinear. These configurations increase the static friction forces of the polymer on the rigid parts, which fastens them together more strongly.

[0036] Now that the manner in which the two rigid parts are fastened together has been described, movement of the rigid parts relative to each other is described with reference to FIG. 1.

[0037] Given the circular symmetry of the rigid parts **12** and **14** and the connecting body **24**, and the nature of the material of the connecting body **24**, the connecting member **10** is able to bend in all directions in a plane **Pp** perpendicular to the axis **A** of the connecting member when the two first portions are immobilized. Bending of the connecting member **10** compresses one edge of the connecting body **24** and stretches the diametrically opposite edge, whereas the rigid parts **12** and **14** retain their shape. Because the material of the connecting body **24** is elastically deformable, when the stresses causing the bending are removed, the connecting member **10** returns to its original state in which the rigid parts **12** and **14** are in axial alignment.

[0038] Also, the rigid parts **12** and **14** can move relative to each other in opposite directions along the longitudinal axis **A** to compress or stretch the connecting body **24**.

[0039] The relative movement of the two rigid parts **12** and **14** can occur in directions other than the directions described above, but the connecting member is principally loaded in bending, tension and compression, as described in more detail below.

[0040] Deformation of the connecting member connected with relative movement of the anchor members **42** and **44** is described next with reference to FIG. 3.

[0041] FIG. 3 shows the connecting member **10** whose two rigid parts **12** and **14** interconnect the two anchor members **42** and **44**. The two anchor members **42** and **44** are parallel to each other in a common axial plane **Pa**.

[0042] Each anchor member **42**, **44** has a threaded shank **46** with a U-shaped head **48** at the top whose inside wall is threaded so that a screw-forming member **50** can be screwed into it. Thus the first portions **16** and **18** of the rigid parts **12** and **14** are accommodated in the heads **48** of the respective anchor members **42** and **44** and are locked to them by tightening the screw-forming members **50**.

[0043] As a result, when the threaded shanks **46** of the anchor members move towards each other due to the effect of opposite forces **T** and **-T** in the plane **Pa** and substantially parallel to the axis **A** the anchor members **42** and **44** deform the connecting member, which bends.

[0044] The bending of the connecting member **10** compresses the lower edge **52** of the connecting body **24** and stretches the diametrically opposite upper edge **54**, while the rigid parts **12** and **14** retain their shape. Because the material of the connecting body **24** is elastically deformable, when the stress is removed the connecting member reverts to its original rectilinear shape and the threaded shanks of the anchor members **46** return to their former relative position.

[0045] The mechanism of elastic bending of the connecting member **10** and the anchor members **42**, **44** described above is the same if the threaded shanks **46** of the anchor members **42** and **44** move away from each other, the connecting member bending with the opposite curvature.

[0046] Also, the anchor members **42** and **44** are movable in translation relative to each other along the axis **A**, their relative movement stretching or compressing the connecting body **24**.

[0047] The use of the connecting member **10** in a vertebral stabilization system for fastening together at least two vertebrae **V1** and **V2** is described below with reference to FIG. 4.

[0048] The vertebrae **V1**, **V2** each have respective median planes **PV1**, **PV2** substantially perpendicular to the axis **Ar** of the spine of which they form part, and respective posterior walls **PPV1**, **PPV2** defining a posterior median plane **PPr** of said spine.

[0049] The stabilizing system includes at least two anchor members **42** and **44** respectively screwed into the posterior walls **PPV1**, **PPV2** of the vertebrae **V1**, **V2**, so that a line **L** that intersects the two anchor members **42** and **44** is substantially parallel to said axis **Ar** of the spine. The two first portions **16** and **18** of the connecting member **10** interconnect the two anchor members **42** and **44**. As a result, the vertebrae **V1** and **V2**, which are interconnected in their posterior portions, possess relative mobility along the axis **Ar** of the spine.

[0050] Thus when the spine is stretched, the vertebrae **V1** and **V2** move away from each other in opposite directions **E** and **-E**, which causes the threaded shanks **46** to move away from each other, deforming the connecting member **10**, and in particular its connecting body **24**. This is because the connecting body is compressed both longitudinally and at the upper edge **54**. The deformed connecting member has its concave side facing away from the spine.

[0051] When the spine is bent, the inverse effect occurs and the vertebrae **V1** and **V2** move towards each other, which induces deformation of the connecting member with its concave side facing toward the spine.

[0052] The connecting body is then subjected to longitudinal extension of its upper edge **54** and possibly to compression of its lower edge **52**.

[0053] It will be understood that the connecting member **10** achieves greater relative mobility of the vertebrae compared to the prior art connecting rods, which cannot be compressed longitudinally.

[0054] In a particular embodiment as shown in FIG. 5, the connecting member has three rigid rod-forming parts **12**, **14**, **15** and two connecting bodies **24₁**, **24₂** interconnecting the three rigid parts **12**, **14**, **15**. To this end, the central rigid part **15** includes a fixing, first portion and two fastening, second portions, with one fastening, second portion on each side of said fixing, first portion. The fastening, second portions are connected to the two connecting bodies **24₁**, **24₂**. The other two rigid parts **12**, **14**, situated at the two ends of the connecting member, have a single fastening, second portion connected to the connecting bodies.

[0055] The connecting member therefore maintains the spacing between three anchor members that it interconnects, which are fixed to three substantially equidistant vertebrae, to align them. Each rigid part of the connecting member is fixed to an anchor member so that there are respective elastically deformable connecting bodies between the pairs of vertebrae. In this way, a single connecting member stabilizes three vertebrae, which reduces the time needed to assemble the stabilizing system as a whole and consequently the operating time. Also, because the three vertebrae are interconnected by a single connecting member, their mobility relative to each other is better controlled.

[0056] It goes without saying that providing connecting members having more than three rigid parts connected together by elastically deformable connecting bodies would not depart from the scope of the invention.

1. A method of stabilizing a spinal segment of a body comprising:

providing a connecting member comprising a first rigid portion, a second rigid portion and connecting body disposed between the first rigid portion and the second rigid portion to form a preassembled connecting member, wherein the connecting body is more flexible than the first rigid portion and the second rigid portion; securing a first anchor to a first vertebra, the first anchor including a head portion and a bone attachment portion; securing a second anchor to a second vertebra, the second anchor including a head portion and a bone attachment portion; inserting the preassembled connecting member into the body to the spinal segment; positioning the connecting body between the head portion of the first anchor and the head portion of the second anchor; and positioning the first rigid portion within the head portion of the first anchor and the second rigid portion in the head portion of the second anchor.

2. The method of claim 1, wherein assembling further comprises securing the connecting body between the first rigid portion and the second rigid portion.

3. The method of claim 1, further comprising:

securing the first rigid portion to the head portion of the first anchor by engaging a locking member to the head portion of the first anchor; and securing the second rigid portion to the head portion of the second anchor by engaging a second locking member to the head portion of the second anchor.

4. The method of claim 1, wherein the head portion of each of the first and second anchors includes a slot adapted to receive the first rigid portion and second rigid portion respectively.

5. The method of claim 1, wherein:

the first rigid portion comprises:

a first rod portion adapted to be secured in the head of the first anchor; a first wall;

the second rigid portion comprises:

a second rod portion adapted to be secured in the head of the second anchor; a second wall;

wherein the connecting member abuts the first wall and the second wall and is secured between the first wall and the second wall.

6. The method of claim 5, wherein the connecting body has a greater cross-sectional area than the first rod portion and the second rod portion.

7. The method of claim 5, wherein the first rigid portion and second rigid portion partially overlap said connecting body.

8. The method of claim 5, wherein the first rod portion and second rod portions are formed of a biocompatible metal and the connecting body comprises a polymer.

9. The method of claim 5, wherein the first rigid portion defines an opening passing from the first wall through the first rigid portion and open to an end of the first rod portion and the second rigid portion defines an opening passing from the

second wall through the second rigid rod portion and open to and of the second rod portion.

10. The method of claim 5, wherein the first wall and second wall each comprise at least one protrusion that abuts the connecting body.

11. The method of claim 1, wherein the connecting member is formed by injecting the connecting body between the first rigid portion and the second rigid portion.

12. A connecting member comprising:
a first rigid portion formed of a first material comprising;
a first portion adapted to secure in a head portion of a first anchor; and
a first wall;
a second rigid portion formed of the first material comprising;
a second portion adapted to secure in a head portion of a second anchor; and
a second wall; and
a connecting body secured between the first wall and the second wall, wherein the connecting body comprises a second material that is more elastically deformable than the first material;
wherein the connecting member is adapted to be inserted into the body as a preassembled connecting member.

13. The connecting member of claim 12, wherein the first material is a biocompatible metal and the second material is a polymer.

14. The connecting member of claim 12, wherein the connecting body is substantially symmetrical about a longitudinal axis.

15. The connecting member of claim 14, wherein the first rigid portion and the second rigid portion are cylindrical.

16. The connecting member of claim 14, wherein the connecting body has a greater radius than the first portion and the second portion.

17. The connecting member of claim 12, wherein the first rigid portion and second rigid portion partially overlap the connecting body.

18. The connecting member of claim 12, wherein the first rigid portion defines an opening passing from the first wall through the first rigid portion and open to an end of the first portion and the second rigid portion defines an opening passing from the second wall through the second rigid portion and open to and of the second rod portion.

19. The connecting member of claim 12, wherein the first wall and second wall each comprise at least one protrusion that abuts the connecting body.

20. A method of stabilizing a spinal segment of a body comprising:

forming, outside of the body, a connecting member comprising:
a first rigid portion formed of a first material comprising;
a first portion adapted to secure in a head portion of a first anchor; and
a first wall;
a second rigid portion formed of the first material comprising;
a second portion adapted to secure in a head portion of a second anchor; and
a second wall; and
a connecting body secured between the first wall and the second wall, wherein the connecting body comprises a second material that is more elastically deformable than the first material;
inserting the connecting member into the body;
positioning the connecting body between a head portion of a first anchor and a head portion of a second anchor; and

positioning the first portion within the head portion of the first anchor from the top of the first anchor and the second portion in the head portion of the second anchor from the top of the second portion.

21. The method of claim **20**, wherein the first rigid portion and second rigid portion partially overlap said connecting body.

22. The method of claim **20**, wherein the first rigid portion defines an opening passing from the first wall through the first rigid portion and open to an end of the first portion and the second rigid portion defines an opening passing from the second wall through the second rigid portion and open to and of the second portion.

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