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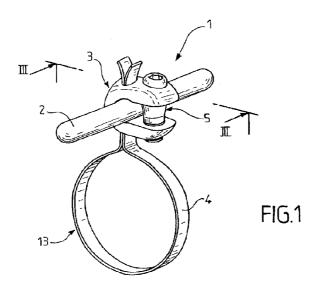
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(54) Titre: DISPOSITIF DE FIXATION VERTEBRALE



rachidienne

(57) Abstract: The invention relates to a vertebral attachment device (1), system and method for retaining a spinal vertebra (25) on a rod (2) by means of a device comprising a body (3) for attachment to the rod, a flexible strip (4) for linking said vertebra to the attachment body and a means (5) for adjustably locking the flexible strip on the attachment body. The attachment body (3) is made of a single part having a U-shaped cross-section, for passing the rod between the bottom wall (10) of the U and the adjustable locking means. The adjustable locking means (5) consists up of a linking part (18) connecting the opposite ends of the two arms (6, 7) of the U, arranged such as to compress the rod against the wall. The arms (6, 7) each include a recess (14) opposite thereof, located on the bottom side of the U, for passing the two ends of the strip between said bottom and the rod in order to form a loop for attachment to a vertebra.

(57) Abrégé : II s'agit d'un dispositif (1), d'un système et d'une méthode de fixation vertébrale pour maintien d'une vertèbre

[Suite sur la page suivante]



(25) sur une tige (2), par un dispositif comportant un corps (3) de fixation sur la tige, une bande souple (4) de liaison de ladite vertèbre avec le corps de fixation et des moyens (5) de blocage réglable de la bande souple sur le corps de fixation. Le corps (3) de fixation est formé d'une seule pièce de section transversale en forme de U, de passage de la tige entre la paroi (10) de fond du U et les moyens de blocage réglable. Les moyens (5) de blocage réglable sont formés par une pièce de liaison (18) reliant les extrémités en vis à vis des deux branches (6, 7) du U, agencée pour comprimer la tige contre la paroi. Les branches (6, 7) comprennent chacune un évidement (14) en vis à vis situé du coté du fond du U, de passage entre ledit fond et la tige des deux extrémités de la bande propre à former une boucle de fixation sur une vertèbre.

VERTEBRAL ATTACHMENT DEVICE

[0001] The present invention relates to a vertebral fixing device for securing a rachidian vertebra to a rod, comprising a fixing body on the rod, a flexible strip for linking said vertebra with the fixing body and adjustable means for blocking the flexible strip on the fixing body.

[0002] Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

[0003] It is particularly importantly applicable, although not exclusively applicable, in the field of the straightening of the spinal column of a patient having an abnormal curvature.

[0004] In this case, since the vertebrae are not correctly aligned relative to one another relative to the vertebral axis, they exhibit mutual inclinations.

[0005] In some places, the lateral edges of the vertebrae will therefore be, on one side, close to one another, and on the other side, distant from one another.

[0006] In order to straighten the assembly, it is known to reset to a substantially equivalent distance the lateral edges of the vertebrae on either side of the spinal column, by the use of rods linking together, either screws, that are inserted into the vertebrae themselves, or hooks, that are introduced along the rachidian channel.

[0007] Such devices do, however, present drawbacks.

[8000] The use of screws is first of all possible only if the vertebrae are in good condition and/or wide enough at the level of the fixing.

[0009] The use of hooks is very delicate since the operator must not touch the spinal cord for fear of paralyzing the patient.

[0010] To mitigate these drawbacks, there has been proposed (FR 02 09 317) a system that makes it possible to avoid the fixing screws or hooks.

- [0011] The system comprises a flexible link for fixing the vertebra to a link part which is in turn fixed to the straightening rod.
- [0012] Means for blocking the flexible link by reclosing the link part on the rod are provided. However, here again, this system does present drawbacks.
- [0013] In practice it requires, on the one hand, an articulation of the link part so as to allow for the lateral insertion of the rod and of the flexible link, and, on the other hand, a fixing of the link to the part to allow for such blocking after the part has been reclosed on the rod.
- [0014] Also known (EP 2 047 813) is a vertebral fixing device comprising a body for fixing a flexible strip on a rod, in the form of an articulated jaw. Each branch of the jaw is provided with an orifice for the passage of one of the two strands of a loop of the strip, designed to be blocked at the bottom of said jaw by the rod once the jaw is reclosed and screwed.
- [0015] The articulated device is fragile and does not allow for an easy adjustment of the flexible strip. The same document describes another system, this time formed by a cylindrical part provided with a bottom orifice for the passage of the loop, and two top slots through which the free strands exit allowing the two strands to be wedged against the inner face of the cylinder by the use of a semi-cylindrical element, of a height substantially equal to the length of the part, and a screw for compressing said element onto the strands of the loop.
- [0016] Such a system which clearly does not concern the securing of a vertebra on a cylindrical rod notably does not allow for easy placement, and notably requires a guiding tool.
- [0017] Also known (WO 2009/013397) is a vertebral fixing device for a system for correcting abnormal curvatures of the vertebral column using a clamping collar consisting of a notched flexible strip passing into a part folded in two for fixing between its two branches a rod with opening for attaching the collar by notching. Such a device is difficult to adjust, and once tightened does not allow for the tightening to be repeated.
- [0018] It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.
- [0019] According to a first aspect, the invention provides a vertebral fixing device for securing a rachidian vertebra to a cylindrical rod, comprising a fixing body on the rod, a flexible strip for linking said vertebra with the fixing body and adjustable means for blocking the flexible

strip on the fixing body, the fixing body being of U-shaped cross section, for passage of the rod between a bottom wall of the U and the adjustable blocking means, said adjustable blocking means being formed by a link part linking facing ends of two branches of the U, said branches each comprising a facing void situated on a side of the bottom of the U, namely a first void for passage of free ends of the flexible strip and a second void on the other side for passage of the strip specifically for forming a fixing loop on the vertebra,

wherein the body is formed of a single part, and the link part is formed by a clamping screw provided with a head for passage into a first branch of the U, said head including a tapered part arranged to engage and compress the rod as it is screwed, and thus compress two flexible strip portions against the wall of the U, said clamping screw further having an end for screwing onto a second branch of the U opposite the first.

[0020] Unless the context clearly requires otherwise, throughout the description and the claims, the words "comprise", "comprising", and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

[0021] Advantageously, at least in a preferred form the present invention aims to provide a vertebral fixing device that provides a better response than those previously known to the requirements of the practise, notably in that it will allow for a much wider flexibility, a better solidity by virtue of the absence of mechanical articulation which is always liable to blocking, and in that it offers much improved adjustment possibilities, and all for a lower cost.

[0022] The expression "single-piece body" should be understood to mean a rigid singlepiece part.

[0023] During the tightening for fixing, the fact that the loop has two initially noncompressed free strands, the rod being in position, namely two strands, one against the other, not-compressed, facing the rod, allows for a relative slippage of the link relative to the fixing body, and because of this a highly flexible adjustment that does not generate shear stresses on the vertebra and/or on the fixing body. The latter can also remain positioned facing the surgeon and the screw tightening tool.

[0024] Such an adaptive slip possibility, not allowed by the prior art either because of the fixing of the link to the fixing body, or because of an articulation whose jaws, to be fixed to one another, necessarily cause an initial compression on the rod itself, emerged as a factor of inaccuracy and of poor retention of the link on the rod.

[0025] With the invention and notably by virtue of the wedging effect obtained by the link part, that is no longer the case.

[0026] In advantageous embodiments there is also a recourse to one and/or other of the following arrangements:

-the bottom wall of the U is of semi-cylindrical form, complementing the shape of the rod, terminated on either side by longitudinal flanges allowing the rod to be clipped in the bottom of the U by virtue of a deformation of the branches.

[0027] It is then possible for the surgeon to prefix the rod with the body accurately, while also allowing possibilities for longitudinal slipping of the body along the rod. The clipping is in fact light and serves only a holding function, without exerting pressure on the bar and on the facing strands in the bottom of the U;

- the head of the clamping screw also includes a shoulder designed to cooperate with the outer face of the first branch of the U.

[0028] Such a shoulder, when it comes into abutment, thus indicates to the surgeon that he has obtained the appropriate tightening. It may also have a complementary tightening role.

Since the branches of the U are free, the part in fact has a certain flexibility during [0029] the tightening, the distance between the ends of the branches of the U then being slightly adjustable, with pinching effect;

- the fixing body, the rod and the link part are made of titanium;
- the fixing body is made of polymer material;
- the bottom of the U includes complementary blocking notches that work by friction;
- the notches are parallel to the longitudinal axis of the bottom of the U (or to the longitudinal plane of symmetry of the part), with flat top;
- the notches are non-return notches, parallel in the longitudinal plane of the U, and having edges forming angles opposite or perpendicular to the direction of slip towards the tightening of the loop;
 - the flexible strip is a braid made of polymer.

[0030] According to a second aspect, the invention provides a system for straightening a spinal column on a rod comprising at least two devices as described above, said system comprising said cylindrical rod on which are fixed said devices.

[0031] Advantageously it comprises two rods and at least four devices.

[0032] According to another aspect, the invention provides a vertebral fixing device comprising a fixing body and an adjustable member for blocking a flexible strip on the fixing body, the fixing body having a U- shape, allowing for passage of a rod between a bottom wall of the U and the adjustable blocking member, said adjustable blocking member being formed by a link part linking the ends of first and second branches of the U, said branches each comprising a void, namely a first void for the passage of free ends of the flexible strip and a second void on the other side for passage of the strip for forming a fixing loop,

wherein the body is a substantially rigid body, and

the link is provided with a head for passage into a first branch of the U, said head forming a proximal end of said link part and including a pressing part arranged distal of said proximal end to press against a said rod passed through said fixing device, as the link part is advanced, and thus also compress any two portions of the flexible strip present between the rod and wall, said link part further having distal end, distal of said pressing part, for advanceably engaging the opposite second branch of the U and wherein the pressing point is a tapered part.

[0033] The invention also relates to a method for fixing a rachidian vertebra to a rod implementing a device and/or system as described above.

[0034] The invention also proposes a method for fixing a rachidian vertebra to a rod, in which;

- -a flexible strip is passed around a part of the vertebra to form a loop clamping said part whose free ends exit on the side retained for fixing to the rod, and
- -said free ends are passed into two voids of a single-piece fixing body on the rod, of Ushaped cross section, each void being situated in a respective branch of the U and on the side of the bottom of the U, wherein;
- the rod is introduced by clipping via the opening of the U, so that the free ends are seized between the rod and the bottom of the U,
- -the tension of the loop on the vertebra part is adjusted by simultaneously pulling on the strands, and

-the rod is progressively compressed against the strands to block them in translation by adjustable blocking means, said adjustable blocking means being formed by a link part linking the facing ends of the two branches of the U.

[0035] Advantageously, the link part being formed by a clamping screw provided, on the one hand, with a head for passage into a first branch of the U, said head including a tapered part directed towards the other branch and, on the other hand, an end for screwing to the opposite branch of the U, said clamping screw is screwed so that the rod is compressed by the tapered part as it is screwed, and the two ends of the flexible strip are thus compressed against the wall of the bottom of the U.

[0036] Also advantageously, the screwing is stopped by blocking of a shoulder of the screw head on the outer face of the first branch of the U.

[0037] In an advantageous embodiment, at least two loops are formed by passing their respective ends into at least two fixing bodies as described above, then they are clipped and compressed by screwing on one and the same rod.

[0038] The invention will be better understood from reading the following description of embodiments given hereinbelow as nonlimiting examples.

[0039] The description refers to the accompanying drawings in which:

- Figure 1 is a perspective view of the device according to the invention.
- -Figure 2 shows an embodiment of the body, of the blocking means and of the joining rods separated from one another, according to the invention.
 - Figure 3 is a cross-sectional view through III III of the device of Figure 1.
 - Figure 4 is a plan view showing the device of Figure 1 fixed to a vertebra.

[0040] Hereinafter in the description, the same reference numbers will be used to designate the same elements.

Figure 1 shows a vertebral fixing device 1 for securing a rachidian vertebra (not [0041] represented) to a cylindrical rod 2.

[0042] The device comprises a fixing body 3 on the rod and a flexible strip 4 made of braided polymer, for example of polyester, 6 mm wide and thirty centimetres long.

[0043] It also comprises adjustable means 5 for blocking the flexible strip on the fixing body 3.

[0044] More specifically with reference to Figure 2, the body 3 is formed by a single-piece part forming a clamp having a U-shaped cross section, said U comprising two thick branches 6 and 7 of substantially semi-oval shaped cross section, symmetrical relative to a longitudinal plane 8, and linked together by a link part 9 in the form of a half torroidal ring forming, on one side, the semicylindrical bottom 10 of the U, and, on the other side, a rounded outer wall of the torroidal surface.

The bottom wall of the U is of a shape complementing that of the rod 2 or [0045] substantially complementing same, and comprises longitudinal lips or flanges 11 allowing the rod to be clipped into the bottom of the U once the braid 4 is passed in double thickness to form the loop 13 (see Figure I).

[0046] Each branch 6, 7 includes a void 14, for example in the form of a wide slot, for example 5 to 10 times wider than the thickness of the braid to facilitate its introduction during the operation.

The bottom 10 of the U also includes non-return blocking notches 15, parallel to the [0047] longitudinal plane 8 and having, in a manner known per se, edges forming angles opposite or perpendicular to the direction of slip, opposing the untightening of the loop once the tightening is done.

Each branch 6 and 7 includes a cylindrical orifice respectively 16 and 17 for passage [0048] of the blocking means 5, namely a bore 16 of the diameter D and a tapped cylindrical orifice 17 for screwing of diameter d < D.

[0049] The blocking means 5 are formed by a link part 18, or screw, provided on one side with a head 19 for passage into the bore 16 of the U, and on the other side an end 20 for screwing into the tapped orifice 17.

[0050] The head 19 of the part 18 comprises a top cylindrical part which cooperates with soft friction with the bore 16, said top part being securely connected with a tapered bottom part 21, narrowing towards the bottom and arranged to compress (bearing 22 in Figure 3) the rod 2 as the part is screwed.

- [0051] In the embodiment that is more particularly described here, the head of the screw also includes a shoulder 23, for example tapered, designed to cooperate with the outer face 24 of the first branch of the U and to serve as an abutment to stop the screwing.
- [0052] There now follows a description with reference to Figures 2, 3 and 4 of the fitting of the device 1 on the vertebra 25 (see Figure 4).
- [0053] The device 1 described above makes it possible to mechanically connect the flexible braid 4 to the rod providing the metal join 2 with the vertebra 25.
- [0054] This implant is particularly indicated in the context of scoliosis-type vertebral column surgery.
- [0055] The braid 4 is introduced beforehand into the body 3 while enclosing a part 26 of the rachidian anatomy (in this case, the transverse blade, posterior arc) in a loop.
- [0056] The same operation is performed on the vertebra or vertebrae on the side on which they are to be repositioned relative to one another, in this case to repair the scoliosis.
- [0057] Once the loops are made, the joining rod 2 is introduced by clipping by the side via the openings 27 of the Us of the bodies 3.
- [0058] Hereinafter, there follows only a description the fixing of a single body, the fixings of the others being performed in the same way once their respective positions are fixed along the rod.
- [0059] The screw 18 is inserted into the bore 16 then begins to be screwed into the bore 17.
- [0060] The screwing is done by the surgeon who has access to the screw heads each provided with a screwing orifice and/or void 28 that is known per se (see arrow 29 in Figure 4).
- [0061] Once everything is prepositioned and when there is still play on the braids, the latter are pulled so as to tighten the loops onto the blades of the respective vertebrae.
- [0062] The non-return edges 15 allow for tightening in one direction and prevent untightening in the other when the two ends of the flexible strip still have a little mobility.

[0063] Then the screwing of the screws 19 enables the tapered parts 21 to gradually bear on the joining rod 2 until the assembly is locked by blocking for each device by tightening the braid 4 between the bottom of the U and the joining rod.

[0064] As is clearly evident and as also results from the foregoing, the present invention is not limited to the embodiments that are more particularly described. On the contrary, it encompasses all the variants and notably those in which two or more rods are fixed in succession or on either side of the vertebral column.

CLAIMS

1. A vertebral fixing device for securing a rachidian vertebra to a cylindrical rod, comprising a fixing body on the rod, a flexible strip for linking said vertebra with the fixing body and adjustable means for blocking the flexible strip on the fixing body, the fixing body being of U-shaped cross section, for passage of the rod between a bottom wall of the U and the adjustable blocking means, said adjustable blocking means being formed by a link part linking facing ends of two branches of the U, said branches each comprising a facing void situated on a side of the bottom of the U, namely a first void for passage of free ends of the flexible strip and a second void on the other side for passage of the strip specifically for forming a fixing loop on the vertebra,

wherein the body is formed of a single part, and

the link part is formed by a clamping screw provided with a head for passage into a first branch of the U, said head including a tapered part arranged to engage and compress the rod as it is screwed, and thus compress two flexible strip portions against the wall of the U, said clamping screw further having an end for screwing onto a second branch of the U opposite the first.

- 2. The device according to claim 1, wherein the bottom wall of the U is of semicylindrical form, complementing the shape of the rod, terminated on either side by longitudinal flanges allowing the rod to be clipped in the bottom of the U by virtue of a deformation of the branches.
- 3. The device according to claim 1, wherein the head of the clamping screw also includes a shoulder designed to cooperate with the outer face of the first branch of the U.
- 4. The device according to claim 1, wherein the fixing body, the rod and the link part are made of titanium.
- 5. The device according to claim 1, wherein the fixing body is made of polymer material.
- 6. The device according to claim 1, wherein the bottom of the U includes complementary blocking notches that work by friction.
- 7. The device according to claim 6, wherein the notches are parallel to the longitudinal axis of the bottom of the U, with flat top.

- 8. The device according to claim 7, wherein the notches are non-return notches, parallel to the longitudinal axis of the bottom of the U, and having edges forming angles opposite or perpendicular to the direction of slip towards the tightening of the loop.
- 9. The device according to claim 1, wherein the flexible strip is a braid made of polymer.
- 10. A system for straightening a spinal column on a rod comprising at least two devices according to claim 1, said system comprising said cylindrical rod on which are fixed said devices.
- 11. The system according to claim 10, said system comprising two rods and at least four devices.
- 12. The device according to claim 1, wherein said link part extends substantially perpendicularly to the two branches of the U.
- 13. The device according to claim 1, wherein said head forms a proximal end of said claiming screw and said tapered part is arranged distal of said proximal end, and proximal of said end for screwing onto the second branch of the U.
- 14. A vertebral fixing device comprising a fixing body and an adjustable member for blocking a flexible strip on the fixing body, the fixing body having a U- shape, allowing for passage of a rod between a bottom wall of the U and the adjustable blocking member, said adjustable blocking member being formed by a link part linking the ends of first and second branches of the U, said branches each comprising a void, namely a first void for the passage of free ends of the flexible strip and a second void on the other side for passage of the strip for forming a fixing loop,

wherein the body is a substantially rigid body, and

the link is provided with a head for passage into a first branch of the U, said head forming a proximal end of said link part and including a tapered pressing part arranged distal of said proximal end to press against a said rod passed through said fixing device, as the link part is advanced, and thus also compress any two portions of the flexible strip present between the rod and wall, said link part further having distal end, distal of said pressing part, for advanceably engaging the opposite second branch of the U.

- 15. The device according to claim 14, wherein the link part comprises, at its distal end, a screw threadably engageable with the second branch of the U.
- 16. The device according to claim 14, wherein said body is formed of a single part.
- 17. The device according to claim 14, wherein the head of the link part includes a shoulder designed to cooperate with the outer face of the first branch of the U and serve as an abutment to stop further advancement of the link part.
- 18. The device according to claim 14, wherein said link part extends substantially perpendicularly to the two branches of the U.
- 19. A vertebral fixing device substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings and/or examples.
- 20. A system for straightening a spinal column on a rod, said system being substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings and/or examples.
- 21. A method for fixing a rachidian vertebra to a rod, said method being substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings and/or examples.

