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(54) Title: A SYSTEM TO GUIDE THE GROWTH OF THE SPINAL COLUMN

(57) Abstract: The invention relates to a system to guide the growth of the spinal column, the system comprising at least one elongated support member and at least one connector comprising a guiding portion having a bearing surface for the elongated support member, a bone connecting portion designed to secure the connector to a vertebra, and between the bone connecting portion and the guiding portion at least one transverse opening extending transversely to the longitudinal center line of the connector.

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Title: A system to guide the growth of the spinal column

Description

This disclosure relates to a system to guide the growth of the spinal column.

The disclosure further relates to a connector.

The system can be used to treat for example scoliosis which is a three-dimensional deformity of the spine that can occur due to neuromuscular or syndromic pathology, spinal degeneration, congenital disorders, but most commonly in an idiopathic manner. Scoliosis can occur at various ages, but when scoliosis arises at young age such as for example below the age of 10, it is referred to as early onset scoliosis. The treatment of this spinal deformity is normally non-surgical by exercises and bracing of the spine. However, when the curve progresses and thereby hinders organ function, such as the lung capacity, surgical correction of the spine is necessary.

It is imperative to maintain spinal growth in these patients in order to accompany lung development. This can be achieved by passive growth guidance systems. Such a passive growth guidance system is known from EP 2 337 512 B1. A drawback of this known system is that its components, in particular due to the configuration of the disclosed connectors, require a relatively high invasive procedure, i.e. insertion of the system requires relatively large incisions in the patient.

It is an object of the present disclosure to provide an improved system to guide the growth of the spinal column. In addition, it may also be an object of the present disclosure to provide a more user friendly system and/or a system allowing a reduction of surgical invasiveness.

At least one of these objects is achieved by the system as defined in claim 1.

The system is configured to guide the growth of the spinal column, wherein the system comprises:

- at least one elongated support member;

- at least one connector comprising a guiding portion having a bearing surface for receiving the elongated support member, a bone connecting portion designed to secure the connector to a vertebra, and between the bone connecting portion and the guiding portion at least one transverse opening extending transversely to the longitudinal center line of the connector; and

- at least one cable configured to extend around an outer surface of the elongated support member and through the transverse opening for securing the elongated support member to the guiding portion of the connector such that relative sliding movement of the elongated support member, such as in its elongated direction, over the bearing surface is permitted with respect to the connector, wherein

the at least one transverse opening is designed to hold the cable extending through the transverse opening at a distance with respect to the longitudinal center line of the connector.

This system provides an improved growth-guidance construct which may be particularly advantageous for treating early onset scoliosis in a relatively user-friendly manner or as an additional semi-rigid fixation for the treatment of degenerative scoliosis. This system is user-friendly from a surgeon's perspective as the securing step of the elongated support member to the connector is relatively easy and/or fast by using a cable. The system may also provide improvements from a patient's perspective as an incision in the patient required for the system is relatively small. The system may therefore allow percutaneous surgery and reduce surgical invasiveness. The system may also reduce associated risks of neurological damage and epidural bleeding. In addition, the system may also allow sliding of the elongated support member over the bearing surface, while maintaining the desired orientation of the elongated support member with respect to the (growing) spine. The system is configured such that the elongated support member is slidable against the bearing surface in its elongated direction and may be substantially constrained from movement in other directions by the bearing surface and/or the at least one cable.

The system may also be applied as a semi-rigid fixation in an addition to a standard spinal fusion construct for treating degenerative scoliosis in patients. For example, one or two levels of bilateral fixation of the system may be added to at least one of the outer sections of the standard spinal fusion construct seen in the longitudinal direction of the standard spinal fusion construct, preferably cranially. An elongated support member of the standard spinal fusion construct may be used to provide the system as defined in this disclosure.

It is a further object of the present disclosure to provide an improved connector. In addition, it may also be an object of the present disclosure to provide a user-friendly connector which allows a reduction of surgical invasiveness.

At least one of these objects is achieved by the connector as defined in claim 2.

The connector of this disclosure comprises a guiding portion having a bearing surface for receiving an elongated support member, a bone connecting portion designed to secure the connector to a vertebra, and between the bone connecting portion and the guiding portion at least one transverse opening extending transversely to the longitudinal center line of the connector; wherein the at least one transverse opening is designed to hold a cable extending through the transverse opening at a distance with respect to the longitudinal center line of the connector.

Such a design of transverse opening of the connector is beneficial to reduce surgical invasiveness. In an user-friendly embodiment, the cable used to secure the elongated support member to the connector secured to a vertebra may be knotted using a sliding knot for securing the elongated support member to the connector. The sliding knot may have two strands, wherein these two strands are guided for fixation through the transverse opening. Without any means to separate the strands in the transverse opening the risk of entwinement is relatively high. Entwinement of the strands reduces the likelihood of a successful connection of the elongated support member to the connector, e.g. the desired semi-rigid connection of the elongated support member to the connector permitting sliding in the desired direction for guiding growth of the spinal column. In an embodiment, the transverse opening is configured to prevent that a cable extending through the transverse opening and securing the elongated support member to the connector is able to coincide with or to cross the longitudinal center line of the connector. Hence, in an embodiment, the at least one transverse opening of the connector is designed to hold a first strand of a cable extending through the transverse opening at a distance with respect to the longitudinal center line of the connector for example on a first side of the transverse opening, whereas the second strand is also held at a distance with respect to the longitudinal center line of the connector for example on a second side of the transverse opening opposite to the first side. The connector may be configured to provide a desired and predetermined connection of the elongated support member thereto, i.e. a semi-rigid fixation between the connector and the elongated support member. The connector itself may require a relatively small incision in a patient for insertion in a percutaneous surgical procedure with minimal surgical invasiveness. This connector can also be used to provide an additional semi-rigid fixation for the treatment of

degenerative scoliosis in combination with a standard spinal fusion construct, wherein seen in the longitudinal direction of the standard spinal fusion construct at least one end section of its elongated support member is connected to at least one connector as disclosed in this disclosure.

5 In one aspect, the connector may comprise a central bore coinciding with the longitudinal center line of the connector. Such a central bore through the connector allows, by using a tool extending through the central bore, an accurate positioning of the connector with respect to the vertebra, for example its pedicle, and the tool may also facilitate a user-friendly fixation of the bone connecting portion of the connector
10 into the vertebra with minimal surgical invasiveness. As a result of the at least one transverse opening of the connector being designed to hold the cable extending through the transverse opening at a distance with respect to the longitudinal center line of the connector, there is further no risk that the tool is hindered by the cable or that the cable is hindered by the tool during insertion of the connector in the vertebra.
15 Hence, the configuration of the connector facilitates a relatively fast, accurate and user-friendly percutaneous surgical procedure. The bone connecting portion may be designed as a bone connecting portion of a pedicle screw to provide a reliable and strong fixation of the connector in the vertebra, i.e. the pedicle.

 In a further aspect, the transverse opening comprises two partially
20 connected opening portions wherein the opening portions are connected in a communicating manner by an open bridging portion which crosses the longitudinal center line of the connector, preferably the transverse opening has a cross section resembling the outline of a capital B. The open bridging portion has a reduced height seen in the direction of the longitudinal center line of the connector compared to the
25 height of the opening portions. The two opening portions provide a clear indicator for a user how to arrange the strands of a cable in the transverse opening, i.e. one strand in the first opening portion and the other strand in the second opening portion. In other words, the transverse opening of the connector is adapted for using a sliding knot connection as discussed above. The two opening portions may be two symmetrical
30 opening portions.

 The bearing surface of the guiding portion may be a flat surface or a substantially flat surface. Such a flat surface facilitates a less rigid fixation which facilitates preventing the occurrence of auto-fusion, in particular when used with a sliding knot. In an alternative embodiment, the bearing surface may be shaped as a

groove, wherein the groove-like bearing surface is adapted to receive a portion of the elongated support member. The groove may have complementary shape to the elongated support member. The groove has for example the shape of a partial circle or a partial ellipse in its cross-section. The groove may provide that the elongated support member is slidable against the bearing surface in its elongated direction and that the elongated support member is substantially constrained from movement in other directions when secured to the connector by the at least one cable.

The bone connecting portion of the connector preferably may be designed as one of the group of pins, tacks, stakes, nails, and screws. The guiding portion is a top portion of the connector which is located above vertebra if the connector is secured to the vertebra by the bone connection portion of the connector. The top end surface of the guiding portion (and of the connector) is the bearing surface.

The system and the connector will be explained in more detail below with reference to the appended figures showing exemplary embodiments, in which:

Figure 1 shows diagrammatic view of an embodiment of a system to guide the growth of the spinal column;

Figures 2A-C show various diagrammatic views of the steps of securing an elongated support member to a connector to obtain the system as shown in figure 1;

Figure 3 shows two views of a detachably connectable guiding portion of the connector also shown in figures 1-2c;

Figure 4 shows two views of a different embodiment of a detachably connectable guiding portion of the connector.

In the following description identical or corresponding parts have identical or corresponding reference numerals. Each feature disclosed with reference to a specific figure can also be combined with another feature disclosed in this disclosure, unless it is evident for a person skilled in the art that these features are incompatible.

In Fig. 1 a system 100 to guide the growth of the spinal column is shown. The system 100 comprises an elongated support member 3 extending mainly in a elongated direction indicated by arrow P1, and two identical spaced apart connectors 1 for supporting the elongated support member 3. The elongated support member 3 is also known as a spinal rod. Each connector 1 comprises a guiding portion 5 having a bearing surface 7 for receiving the elongated support member 3. The connector 1

further comprises a bone connecting portion 9 designed to secure the connector to a vertebra (not shown). As can be seen in figure 1 the bone connecting portion 9 is only partially shown. The bone connecting portion 9 is designed as a bone connecting portion of a pedicle screw. The connector 1 further comprises between the bone connecting portion 9 and the guiding portion 5 at least one transverse opening 25 extending transversely to the longitudinal center line (indicated with dotted lines in Figs. 1, 2a, 2b) of the connector 1. The system 100 also comprises two cables 21, wherein each cable 21 is configured to extend around a portion of an outer surface of the elongated support member 3 and through the transverse opening 25 of one of the connectors 1 for securing the elongated support member 3 to the guiding portion 5 of the connector 1 such that relative sliding movement in the direction indicated by the arrow P1 of the elongated support member in its elongated direction over the bearing surface 7 is permitted with respect to the stationary connectors 1. Each of the connectors is stationary secured to a vertebra. In the system 100 each connector extends substantially in a direction transverse to the elongated support member, i.e. the longitudinal center line of the elongated support member extending in a direction indicated by arrow P1, extends substantially transversely to the longitudinal center line of the connector 1 indicated by the dotted lines. Each transverse opening 25 in the connector 1 is designed to hold the cable 21 extending through the transverse opening 23 at a distance with respect to the longitudinal center line of the connector 1. Each transverse opening 25 extends transversely to the longitudinal center line of the connector 1 and extends substantially transversely to the elongated direction (P1) of the elongated support member 3.

Figs. 2a-c show how to obtain the system 100 shown in Fig. 1. Figs. 2a-c shows how the configuration of the connector 1 facilitates to provide a desired semi-rigid connection of the elongated support member 3 to the (stationary) connector 1 permitting sliding in the desired direction P1 for guiding growth of the spinal column (not shown) and allowing percutaneous surgery with minimal surgical invasiveness. The connector 1 comprises the guiding portion 5 having the bearing surface 7 for receiving the elongated support member 3, the bone connecting portion 9 (partially shown in Fig. 2a-c) designed to secure the connector 1 to a vertebra (not shown), and between the bone connecting portion 9 and the guiding portion 5 the transverse opening 25 extending transversely to the longitudinal center line of the connector 1. The transverse opening 25 is designed to hold the cable 21 extending through the

transverse opening 25 at a distance with respect to the longitudinal center line of the connector 1 (see Fig. 2b). The connector 1 further comprises a central bore 31 (Fig. 2a) coinciding with the longitudinal center line of the connector 1, i.e. the longitudinal center line of the central bore 31 corresponds with the longitudinal center line of the connector. The central bore 31 extends through the connector 1 completely. The central bore 31 allows by using an external tool 200 inserted in the central bore 31 and extending through the central bore 31 an accurate positioning of the connector 1 with respect to the vertebra. The transverse opening 25 comprises two partially connected opening portions 25a, 25b (Fig. 2b) wherein the opening portions 25a, 25b are connected in a communicating manner by an open bridging portion 25c which crosses the longitudinal center line of the connector 1. As shown in Fig. 2b the transverse opening 25 has a cross section resembling the shape of a capital B. The open bridging portion 25c has a reduced height seen in the direction of the longitudinal center line of the connector 1 compared to the height of the opening portions 25a,b. The two opening portions 25a,b provide a clear indicator for a user how to arrange the strands 21a, 21b of the cable 21 in the transverse opening 25, i.e. one strand 21a in the first opening portion 25a and the other strand 21b in the second opening portion 25b. In other words, the transverse opening 25 of the connector 1 is adapted for using a cable 21 with a sliding knot 21c as shown in Figs. 1, 2B, 2C for securing the elongated support member 3 to the connector 1. The two opening portions 25a,b are two symmetrical opening portions. The transverse opening 25 has a cable guiding section 25d above the open bridging portion 25c between opening portions 25a, 25b. This guiding section 25d has a design such that a cable 21, or one of its strands 21a, 21b, is guided automatically to one of the two opening portions 25a, 25b. This design prevents that a cable 21 can be arranged for securing the elongated support member 3 in the open bridging portion 25c, i.e. provides automatic guidance for a user for positioning the cable 21 or its strands 21a, 21b in a correct manner in the opening portions 25a, 25b. In addition, edges of the connector defining the transverse opening, see for example edge 26 indicated in fig. 2a, are designed to prevent that the cable is abraded during use, for example these edges 26 are rounded. The cable 21 is a round braided cable made from ultra-high molecular weight polyethylene.

Figure 3 shows details of the guiding portion 5. The guiding portion 5 has a bearing surface 7 being a flat surface or a substantially flat surface. Such a flat

surface facilitates a less rigid fixation of the elongated support member 3 to the stationary connector 1.

The guiding portion 5 is connectable to the connector 1. The connector 1 has a first fastening portion 35, in fig. 2A an upper cavity 35 on its top end surface 37, and the guiding portion 5 has a second fastening portion 39, in Fig. 2A a projection 39 mating with the cavity for connecting the guiding portion 5 to the connector 1. The guiding portion 5 may be detachably connected to the connector 1. Before insertion of the connector 1 in a patient or after securing the connector 1 in the vertebra the guiding portion 5 is connected to the connector 1.

The guiding portion 5 or at least the bearing surface 7 is substantially made from a first material facilitating sliding of the at least one elongated support member, such as for example a biocompatible polymer such as polyethylene which provides an excellent sliding surface with minimal wear and minimal wear particle generation. The connector 1 and/or the elongated support member 3 is substantially made from a second material which is different from the first material, such as for example a biocompatible metal. The connector 1 without the guiding portion 5 is an integral one-piece connector, preferably the connector 1 is substantially made of one material. The guiding portion 5 also has a central bore 41 for the tool 200, wherein the central bore extends completely through the guiding portion 5 and coincides with the center line of the guiding portion 5. After connecting the guiding portion 5 to the connector 1, the longitudinal center line of the connector 1 and the center line of the guiding portion 5 coincide. The center line of the guiding portion 5 is the center line of the central bore 41. In the connector 1, the central bore 31 extends between the guiding portion 5 and the opposite end of the connector seen in its longitudinal direction, i.e. the direction of the longitudinal center line of the connector.

In figure 4 two views are shown of an alternative embodiment of a guiding portion 5', wherein the main difference with the guiding portion 5 shown in figure 3 is that the upper surface comprises a groove 43 as a bearing surface. The groove 43 is of complementary shape to the elongated support member 3, such that the groove 43 is adapted to receive a portion of the elongated support member 3 therein for providing more support to the elongated support member 3 without affecting its sliding capacity in a direction indicated by the arrow P1, i.e. its elongated direction. The groove 43 also contributes to hold the elongated support member 3 in a desired orientation with respect to the guiding portion 5' and the connector 1. In the figures the

elongated support member 3 has a cylindrical shape, such that the groove 43 has the shape of a partial circle in its cross-section (as can be seen in the lower drawing of figure 4) to provide maximum sliding capacity for the elongated support member 3 in the direction indicated by the arrow P1, while the elongated support member 3 is restricted in moving in a direction extending traverse to the direction indicated by the arrow P1 and traverse to the center line of the guiding portion 5'. The guiding portion 5' also has a central bore 41' for the tool 200, i.e. a central bore 41' as the central bore 41 of the guiding portion 5 shown in figure 3.

In an embodiment not shown, the transverse opening may comprises two closed transverse openings which are separated from each other, wherein in the section of the connector separating the two closed transverse openings from each other the longitudinal center line of the connector extends. The two space apart closed transverse openings may extend parallel with respect to each other.

A method for guiding the growth of the spinal column, the method comprises the following steps:

- attaching a cable in a transverse opening of a connector, wherein the transverse opening extends transversely to the longitudinal center line of the connector;

- securing the connector to the vertebra by using a bone connecting portion of the connector;

- positioning an elongated support member on a guiding portion of the connector, wherein the elongated direction of the elongated support member extends substantially traverse to the longitudinal center line of the connector;

- attaching the elongated support member positioned on the guide member to the connector by the cable which extends around an outer surface of the elongated support member and through the transverse opening in manner that relative sliding movement of the elongated support member in its elongated direction is permitted with respect to the connector, wherein the transverse opening is designed to hold the cable extending through the transverse opening at a distance with respect to the longitudinal center line of the connector.

The method may use a knotted cable using a sliding knot for securing the elongated support member to the connector to reduce surgical invasiveness. In the system and method of this disclosure, the elongated support member is secured to each connector by a single double looped knotted cable. The sliding knot has two

strands, wherein these two strands are guided for fixation through the transverse opening in a separated way, wherein each strand is located in the transverse opening at a distance from the longitudinal center line of the connector. These two distances may be substantially identical such that a first strand may be located or positioned on a first side of the transverse opening and the second strand may located or positioned on a second side of the transverse opening opposite to the first side. In addition, the connector may comprise a central bore coinciding with the longitudinal center line of the connector. Such a central bore through the connector allows by using a tool extending through the central bore an accurate positioning of the connector with respect to the vertebra, for example its pedicle, and the tool may facilitate a user-friendly fixation of the bone connecting portion of the connector into the vertebra with minimal surgical invasiveness.

CLAIMS

1. A system to guide the growth of the spinal column, the system comprising:

5 at least one elongated support member;

at least one connector comprising a guiding portion having a bearing surface for receiving the elongated support member, a bone connecting portion designed to secure the connector to a vertebra, and between the bone connecting portion and the guiding portion at least one transverse opening extending transversely to the longitudinal center line of the connector; and

10 at least one cable configured to extend around an outer surface of the elongated support member and through the transverse opening for securing the elongated support member to the guiding portion of the connector such that relative sliding movement of the elongated support member, such as in its elongated direction, over the bearing surface is permitted with respect to the connector, wherein

15 the at least one transverse opening is designed to hold the cable extending through the transverse opening at a distance with respect to the longitudinal center line of the connector.

2. A connector for a system as defined in claim 1, wherein the connector comprises a guiding portion having a bearing surface for receiving an elongated support member, a bone connecting portion designed to secure the connector to a vertebra, and between the bone connecting portion and the guiding portion at least one transverse opening extending transversely to the longitudinal center line of the connector, wherein the at least one transverse opening is designed to hold a cable extending through the transverse opening at a distance with respect to the longitudinal center line of the connector.

3. The system or the connector according to claim 1 or 2, wherein the bone connecting portion is a bone connecting portion of a pedicle screw.

4. The system or the connector according to claim 1 or 2, wherein the connector comprises a central bore coinciding with the longitudinal center line of the connector.

5. The system or the connector according to claim 4, wherein the central bore extends between the guiding portion and the opposite end of the connector seen in its longitudinal direction.

6. The system or the connector according to claim 1 or 2, wherein the guiding portion is detachably connectable to the connector.

7. The system or the connector according to claim 6, wherein the connector comprises at least one first fastening portion, for example an upper cavity on its top end surface, and the guiding portion comprises at least one second fastening portion, for example a projection, wherein the guiding portion is connected to the connector by fastening the first fastening portion to the second fastening portion.

8. The system or the connector according to claim 6 or 7, wherein the connector is an integral one-piece connector.

9. The system or the connector according to claim 1 or 2, wherein the transverse opening comprises two closed transverse openings which are separated from each other.

10. The system or the connector according to claim 1 or 2, wherein the transverse opening comprises two partially connected opening portions wherein the opening portions are connected in a communicating manner by an open bridging portion which crosses the longitudinal center line of the connector, preferably the transverse opening has a cross section resembling the outline of a capital B.

11. The system or the connector according to claim 1 or 2, wherein the bearing surface is a flat surface or a substantially flat surface.

12. The system or the connector according to claim 1 or 2, wherein the guiding portion has a central bore extending completely through the guiding portion, wherein the central bore of the guiding portion coincides with the center line of the guiding portion.

13. The system or the connector according to claim 1 or 2, wherein the guiding portion or at least the bearing surface is substantially made from a first material facilitating sliding of the at least one elongated support member, such as for example a biocompatible polymer, wherein the connector and/or the at least one elongated support member is substantially made from a second material which is different from the first material, such as for example a biocompatible metal.

14. The system or the connector according to claim 1 or 2, wherein the bearing surface is shaped as a groove, wherein the groove-like bearing surface is adapted to receive a portion of the elongated support member, preferably the groove has complementary shape to the elongated support member, for example the groove has the shape of a partial circle or a partial ellipse in its cross-section. .

15. The system according to claim 1, wherein the cable is a round braided cable, preferably made from ultra-high molecular weight polyethylene, and/or the cable is knotted using a sliding knot for securing the elongated support member to the connector.

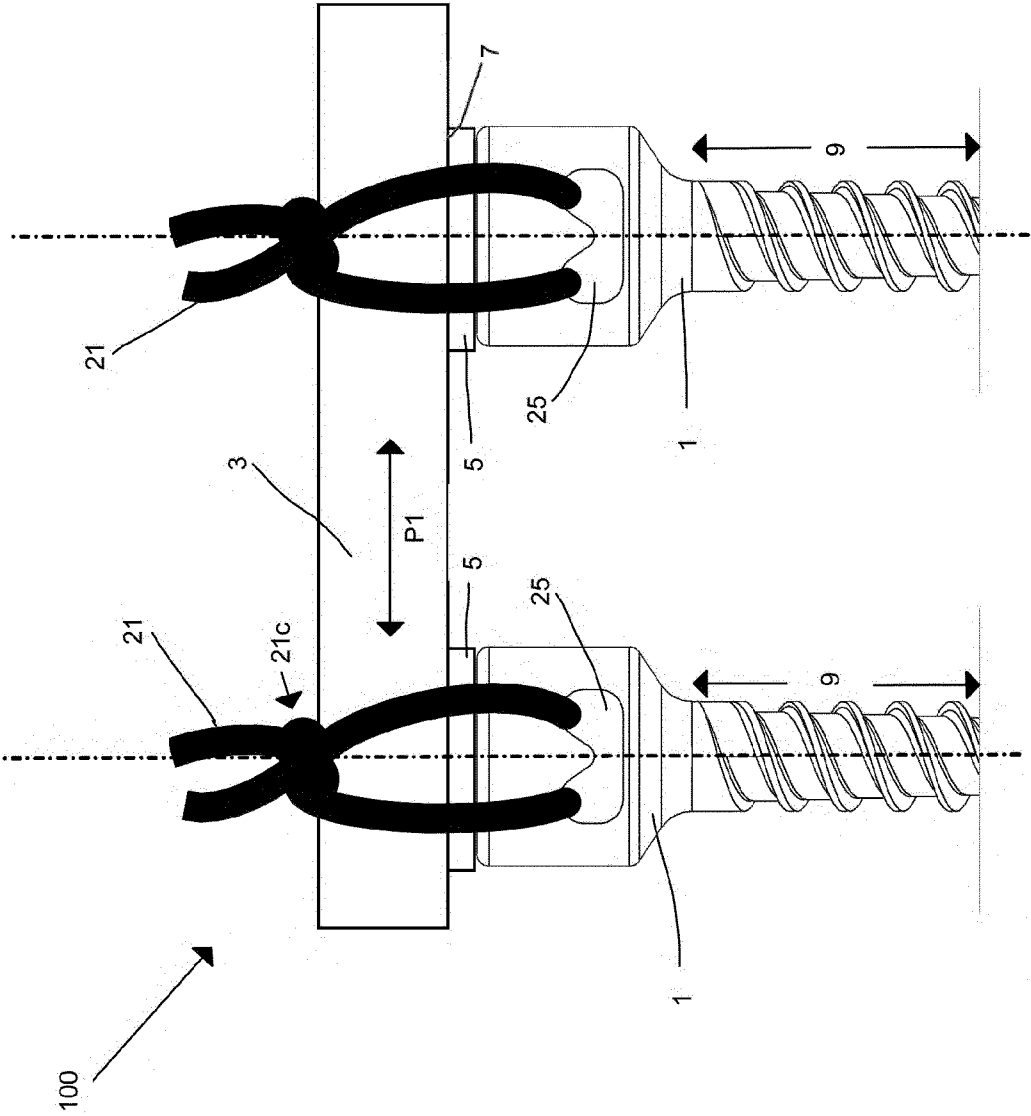


Fig. 1

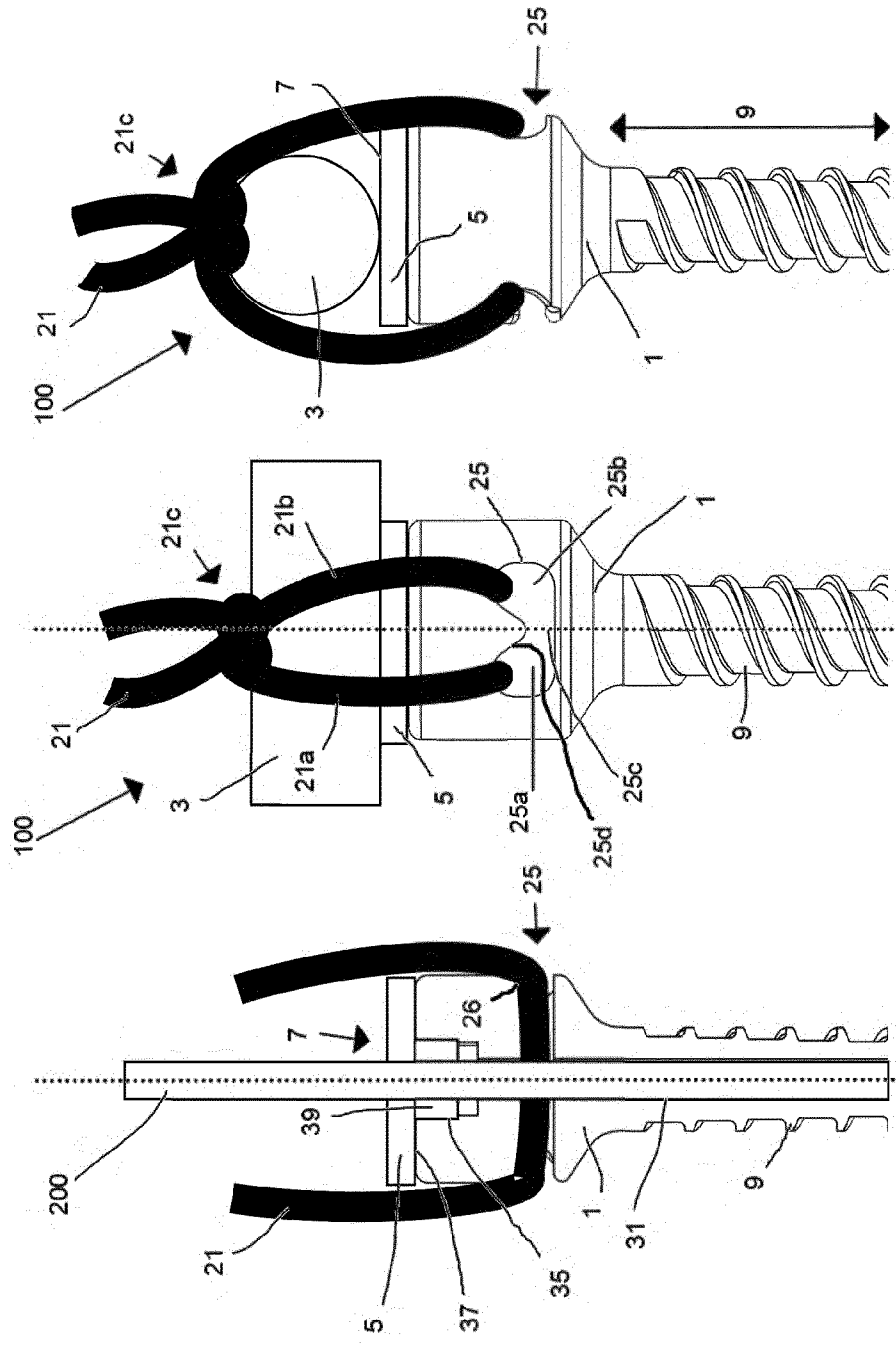


Fig. 2c

Fig. 2b

Fig. 2a

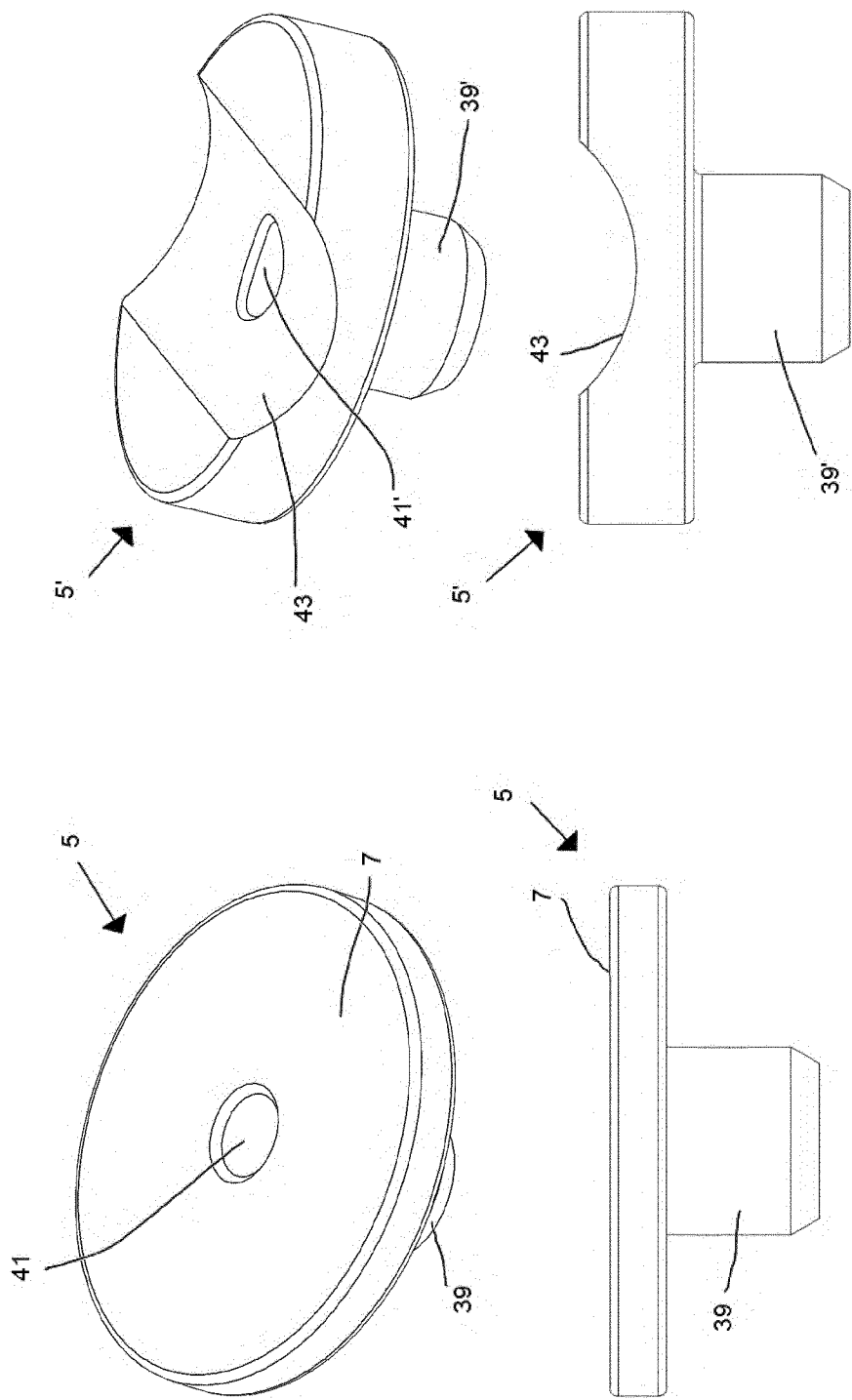


Fig. 4

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2022/057691

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/70
ADD.

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)

A61B

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)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 805 602 A (PUNO ROLANDO M [US] ET AL) 21 February 1989 (1989-02-21)	1-9, 11, 14, 15
Y	column 3, line 24 - column 4, line 36; figures 7, 8 column 6, lines 6-31 -----	12
X	US 2001/034522 A1 (FRIGG ROBERT [CH]) 25 October 2001 (2001-10-25) the whole document -----	1-5, 8, 9, 11, 13-15
X	US 5 242 446 A (STEFFEE ARTHUR D [US] ET AL) 7 September 1993 (1993-09-07) the whole document -----	1-3, 10, 11
Y	FR 2 937 531 A1 (MILADI LOTFI [FR]) 30 April 2010 (2010-04-30) page 5, lines 1-7 -----	12

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"P" document published prior to the international filing date but later than the priority date claimed

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Date of the actual completion of the international search

22 June 2022

Date of mailing of the international search report

01/07/2022

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2022/057691

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