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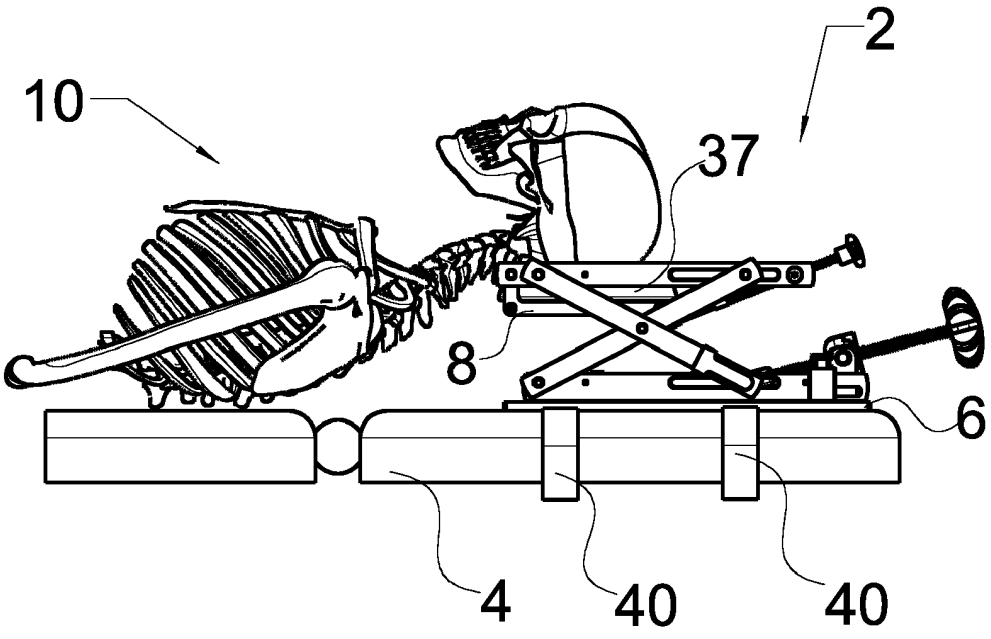
(54) **SURGICAL HEAD POSITIONING DEVICE FOR USE WITH A BODY SUPPORT**

(57) The present invention relates to a surgical head positioning device for use with a body support, comprising: a head rest configured to support a head of an essentially reclined patient's body resting on the body support; a base; a height adjustment means configured to adjust the height of the head rest relative to the base, while essentially maintaining the angular orientation of the head rest relative to the base; a shifting means configured to shift the head rest relative to the base along a shifting axis, the head positioning device being configured to be arranged with the shifting axis parallel to a longitudinal body axis of the patient.

Fig. 1



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Description

[0001] The present invention relates to a surgical head positioning device for use with a body support. The invention is specifically useful in surgeries related to the head and cervical spine, particularly anterior cervical decompression and fusion (ACDF) and posterior cervical decompression and fusion. However, the surgical head positioning device may also be used in other surgical procedures including the supine and prone positioning, e.g. for thoracic and lumbar spine surgeries.

[0002] A human patient who suffers from one or more herniated or damaged spinal discs and/or a spinal stenosis as a result of degenerative, traumatic, congenital, neoplastic or infectious disease of the neck may undergo an anterior cervical decompression and fusion (ACDF) surgery or a posterior cervical decompression and fusion surgery. The goals of these surgeries are a decompression of the stenosis, a spinal fusion of the unstable vertebras segment(s) and a reconstruction of the physiologic alignment, i.e. lordosis, of the vertebrae using spinal instrumentation. ACDF is one of the most often performed surgical procedures of the spine with reliable clinical outcomes. During an ACDF procedure, the reconstruction of a patient's natural cervical alignment in lordosis is one of the objectives. In clinical practice, this can be technically difficult.

[0003] An ACDF procedure comprises 4 main aspects:

1. Patient position and positioning of the relevant body parts before surgery and repositioning during surgery;
2. Release of rigid spinal structures (e.g. the disc, the uncovertebral joints, the ligaments) to increase segmental spinal flexibility;
3. Use of cages or intervertebral grafts with lordotic and hyperlordotic shape;
4. Anterior plating techniques.

[0004] In ACDF, reconstruction of a close to normal cervical lordosis becomes increasingly recognized to be one of the relevant treatment goals. Currently known devices and methods for positioning of the relevant body parts do not allow a reliable installment of cervical lordosis during surgery. Devices or positioning techniques yielding for repositioning during surgery are limited. The simplest option is to have the patients head resting on a donut shaped head rest, the head rest being supported by a stack of individually removable plates or surgical towels with the trunk being elevated by sheets of surgical towels or similar devices. The position of the head may be changed by adding or removing one or more plates to/from the stack. The drawbacks of this technique are its inaccuracy in positioning and the poor stabilization of the head during removal of one or more plates, which may result in an unintended movement of the head.

[0005] Another option are so-called horse-shoe type head rests as disclosed, e.g., in US 2013/019877 A1. Although the horse-shoe type head rests often provide a better stabilization and accuracy in positioning the head, their installation, i.e. coupling to an operating table, as well as the head positioning procedures are usually time consuming and complicated. A step less change of the position of the headrest is not possible.

[0006] A further option is a head rest with a pin fixation of the patient's head with a classical Mayfield-clamp, or different variants of the Mayfield-clamp principle (for further information see, e.g., The Mayfield Skull Clamp: A Literature Review of Its Complications and Technical Nuances for Application; World Neurosurgery, Volume 151, July 2021, Pages 102-109). Although it provides adequate fine adjustment of the head position and orientation when its hinges and connections to the operation table are manually released, its installation as well as the head positioning procedures are even more complex and time consuming than with the horse-shoe type head rests. Use of skull tongs and head calipers indicate an invasive positioning technique and, using these devices, the position of the head cannot be easily changed during surgery.

[0007] It is therefore an object of the present invention to provide an easy-to-use head positioning device for use with a body support, e.g. an operation table, the head positioning device providing adequate degrees of freedom for positioning and adequate positioning accuracy for the surgical techniques mentioned herein. This and other objects are achieved with the claimed invention as recited.

[0008] The present invention relates to a surgical head positioning device for use with a body support, comprising a head rest configured to support a head of an essentially reclined patient's body resting on the body support, a base, a height adjustment mechanism or means configured to adjust the height of the head rest relative to the base, while essentially maintaining the angular orientation of the head rest relative to the base, and a shifting mechanism or means configured to shift the head rest relative to the base along a shifting axis. Herein, shifting or moving "along an axis" includes shifting or moving parallel to the axis. The head positioning device is configured to be arranged with the shifting axis at least substantially parallel to, preferably coincident with, a longitudinal body axis of the patient.

[0009] The body support may be an operation table or the like. The surgical head positioning device may be configured to tilt the head rest relative to the base about a tilt axis extending in a transverse direction.

[0010] The longitudinal body axis may be defined as extending from the head to the feet, when the body and the head are in a generally straight position. The transverse direction may be defined as being transverse to the shifting axis.

[0011] Particularly, the shifting axis may be orthogonal to the direction of the height adjustment. The tilt axis may be orthogonal to the direction of the height adjustment and/or orthogonal to the shifting axis. However, the shifting axis may be non-orthogonal to the direction of the

height adjustment. The tilt axis may be non-orthogonal to the direction of the height adjustment and/or non-orthogonal to the shifting axis. Any combination of orthogonality and non-orthogonality among the tilt axis, the shifting axis and the direction of the height adjustment is contemplated. The direction of the height adjustment may correspond to a height adjustment axis, i.e., a straight movement. The direction of the height adjustment may define a height adjustment plane, i.e., the height adjustment direction may correspond to a non-straight movement such as a two-dimensional movement. The direction of height adjustment is understood to be bidirectional, i.e. to include back and forth.

[0012] Directional statements are used as appropriate for the head positioning device in the intended orientation during use. If not stated otherwise, they are not to be understood in a limiting manner but are understood to be adapted for other orientations of the head positioning device.

[0013] The surgical head positioning device may be configured to maintain the angular orientation of the head rest relative to the base when shifting the head rest relative to the base along the shifting axis. Particularly, the surgical head positioning device may be configured to maintain a tilting position of the head rest relative to the base when shifting the head rest relative to the base along the shifting axis.

[0014] The adjustment of the height of the head rest relative to the base, shifting the head rest relative to the base along the shifting axis, and tilting the head rest relative to the base about the tilt axis extending in the transverse direction may be decoupled from each other. When two movements are decoupled, this may mean that performing one of these movements does not cause the other movement of the headrest and, stating it the other way around, coupling of two movements may mean that performing one of two movements does cause the other movement of the headrest. Such decoupling may refer to the head positioning device itself, without a head resting on the head rest.

[0015] The surgical head positioning device may be configured for the following operations with the head resting on the head rest:

a. height adjustment of the head by height adjustment of the head rest relative to the base with the height adjustment means, preferably stepless;
b. optionally tilting the head by tilting the head rest relative to the base about the axis extending in the transverse direction; and
c. allowing a shifting of the head along the shifting axis and preferably along the longitudinal body axis by shifting the head rest relative to the base along the shifting axis with the shifting means.

[0016] Each of the operations a, b and c may cause a collateral strain of the head. For example, a height adjustment of the head rest may not only cause the head to move up or down but may, due to the head being connected to the body, also result in a tilt and/or shift of the head or a corresponding strain of the head. Such collateral strains may be used intentionally for head positioning or compensated by performing the corresponding other operation(s) of operations a, b and c.

[0017] The base of the surgical head positioning device may be configured for being mounted to the body support, preferably by placing the base onto a portion of a resting surface of the body support. The resting surface is the surface of the body support on which a body of a patient will rest, when the patient lies on the body support. This is advantageous because the body support can be used in its standard configuration, i.e. with its standard head rest, and the head positioning device is simply to be placed freely onto the body support without any time-consuming demounting and reassembling of the body support. The base may be configured to contact the body support, when the head positioning device is set onto the body support. The base may be made from one piece, e.g. be a plate, or a post. Alternatively, the base may be composed of two or more pieces, e.g. two or more pieces selected from plates, posts, and a frame like construction. The base may preferably comprise two or more fixation means, preferably two or more openings, configured for attachment of one or more straps. The strap(s) may be attached to the base and wrapped around or otherwise fixed to the body support in order to comply with safety requirements and to ensure proper fixation of the head positioning device to the body support.

[0018] The base may comprise and preferably be made of one or a combination of materials selected from a metal, an alloy, stainless steel, carbon fibers, hard plastic and any other material suitable for use in an operation room and mechanically stable enough for the desired purpose. This also applies for all other components of the head positioning device.

[0019] Preferably, the height adjustment means is configured for stepless height adjustment. This increases accuracy and improves handling of the device. Stepless adjustment mechanisms are well known in the art, for example a spindle drive or screw, a hydraulic mechanism, etc.

[0020] Preferably, the height adjustment means is configured for a height adjustment range of at least 15 cm to 30 cm, for example a height adjustment range of at least 18 cm or at least 20 cm. Additionally or alternatively, the surgical head positioning device may provide a shifting range along the shifting axis for the head rest of 5-10 cm. Additionally or alternatively, the surgical head positioning device may provide a tilting range of plus/minus 15 degrees.

[0021] Preferably, the head positioning device is configured such that a resting surface of the head rest has a height of 35 mm above a bottom side of the base when the head rest is in the lowest position. Additionally or alternatively, the head positioning device is preferably configured such that a resting surface of the head rest

has a height of 215 mm above a bottom side of the base when the head rest is in the highest position.

[0022] The height adjustment means may comprise a mechanical and/or a hydraulic height adjustment mechanism, preferably a scissor mechanism, a parallelogram mechanism, an inclined plane mechanism, a lifting curve mechanism and/or a post mechanism. Such mechanisms are well known in the art.

[0023] The height adjustment means may comprise a screw type operating means, preferably configured for manual and/or motorized operation and/or automated operation. Additionally or alternatively, the surgical head positioning device may comprise a screw type operating means, preferably configured for manual and/or motorized and/or automated operation, for tilting the head rest relative to the base.

[0024] The shifting means may comprise a guiding mechanism configured for ensuring a shift along the shifting axis. For example, the shifting means may comprise a guide groove and a corresponding guide pin, the guide groove being configured for guiding the guide pin along the shifting axis, and/or a guide rail and one or more corresponding wheels, the guide rail being configured for guiding the one or more wheels along the shifting axis, and/or a guide rail and one or more corresponding guide claws, the guide rail being configured for gliding within one or more guide claws along the shifting axis.

[0025] The surgical head positioning device may comprise a head support base (not to be confused with the base already mentioned above) configured for supporting the head rest. The head rest may be a padded head rest and/or may comprise an exchangeable pad configured for contacting the head. For example, the exchangeable pad may be removably attachable to the head support base, e.g. by means of a hook and loop fastener, a snap fit connection, corresponding groove and pin, and the like. The head support base, on the other hand, may be configured to remain permanently attached to the head positioning device. Different types of exchangeable pads may be provided. For example, the exchangeable pad may be configured for a special type of patient, e.g. for a head size below average, as average or above average. Moreover, the exchangeable pad may be more easily cleaned in a removed state or even be exchanged for every patient or surgical procedure. The exchangeable pad may be provided as a sterile, single-use product.

[0026] The allocation of the individual parts of the guiding mechanism may be implemented in any suitable way. For example, the guiding mechanism may be associated with the base. The base may comprise the guide groove and the height adjustment means may comprise the guide pin. Alternatively or additionally, the base may comprise the guide pin and the height adjustment means may comprise the guide groove. Alternatively or additionally, the base may comprise the guide rail and the height adjustment means may comprise the one or more wheels. Alternatively or additionally, the base may comprise the one or more wheels and the height adjustment means comprises the guide rail. Alternatively or additionally, the base may comprise the guide rail and the height adjustment means may comprise the one or more guide claws. Alternatively or additionally, the base may comprise the one or more guide claws and the height adjustment means may comprise the guide rail.

[0027] As an alternative or in addition, the guiding mechanism may be associated with the head rest. For example, the head support base may comprise the guide groove and the headrest may comprise the guide pin. Alternatively or additionally, the head support base may comprise the guide pin and the headrest may comprise the guide groove. Again, instead of a groove-pin-pair the device may comprise a correspondingly located guide rail-wheel(s)-combination or guide rail-guide claw(s)-combination.

[0028] The guiding mechanism may comprise more than one guide groove and/or more than one guide rail. The guiding mechanism may comprise a combination of one or more guide grooves and one or more guide rails with corresponding guide pins and guide wheels/claws, respectively. The allocation of the one or more guide grooves and/or guide rails among the base and the height adjustment means may be implemented in any suitable combination.

[0029] The head rest may be tiltably, preferably pivotably, mounted to the height adjustment means, preferably via a/the head support base. For example, the head support base may be mounted to the height adjustment means via one or two pins or a shaft.

[0030] The head positioning device may be configured for surgical procedures. It may be necessary for an operator, such as a surgeon or other medical personnel, to take radiographs of the relevant body structures, e.g. the neck and spine. Inter alia for this purpose, an irradiation path and an imaging path for radiography may be radiolucent and/or free of obstacles for X-rays, preferably free of any component of the surgical head positioning device. For example, the irradiation path and the imaging path for radiography may comprise carbon fibers, PEEK, or any hard plastic material suitable for the constructive requirements, which are radiolucent, i.e. X-rays may pass in an amount sufficient for taking X-ray pictures. Additionally or alternatively, the head positioning device may comprise holes at the respective locations, e.g. in the base and/or the head rest.

[0031] The surgical head positioning device may comprise a force measuring means configured to measure a force exerted onto the head rest by the head. An output of the force measuring means may be directly forwarded to the operator, e.g. by means of a mechanical, analog and/or digital output. The output may be presented to the operator in any suitable form e.g. be displayed and/or be an acoustic signal. The operator may then react accordingly. For example, if the force measuring means indicates that the head positioning device no longer supports the head, or at least not sufficiently, the user may readjust the position of the head rest to ensure proper support of

the head of the patient. Additionaly or alternatively, the output of the force measuring means may be transferred to an electronic device, e.g. a controller and/or computer, that further processes the output of the force measuring means.

[0032] The surgical head positioning device may be configured for supporting the head in the prone and/or supine position. Although ACDF with the body resting in the supine position is the most important surgical procedure for correcting a spinal stenosis in the cervical spine, a surgical procedure with the patient's body in the prone position may be necessary and/or more promising in certain cases. The head positioning device may be accordingly configured. For example, the head rest and particularly the head rest pad may be configured, e.g. be shaped, accordingly.

[0033] The surgical head positioning device may comprise supervision means for supervision of the eyes of the head when mounted in the prone position, preferably a camera, more preferably one or more mirrors, the one or more mirrors being preferably adjustable. In this way, a user may at any time during a surgery check for the eyes lying free without pressure or contact from components of the positioning device during anesthesia. Mirror(s) may be directly observed by a user. If a camera is used, the imaging data may be transferred to a controller, computer or the like and displayed to the user on a screen.

[0034] The surgical head positioning device may be configured such that an operator may perform a height adjustment / operation a single-handed. Additionally or alternatively, the surgical head positioning device may be configured such that an operator may perform a tilting / operation b single-handed. Single-handed operation of the device is a great advantage during surgery because it may save time and/or additional personnel and/or improve coordination of certain actions that may then be performed by a single person instead of two persons.

[0035] The surgical head positioning device may be configured such that shifting of the head rest relative to the base / operation c occurs automatically in accordance with a movement of the head along the shifting axis upon a height adjustment / operation a. Additionally or alternatively, the surgical head positioning device may be configured such that shifting of the head rest relative to the base / operation c occurs automatically in accordance with a movement of the head along the shifting axis upon a tilting operation. As a result, the head is in an unconstrained condition as regards the direction of the shifting axis, and to the extent of their parallelism and/or coincidence, the longitudinal direction.

[0036] However, a strained condition of the head in the direction of the shifting axis may also be intentionally brought about by a user in order to correctly position the spinal components for reconstruction of the biological lordosis. Accordingly, the surgical head positioning device may comprise a blocking mechanism for the shifting along the shifting axis. For example, the device may comprise a screw configured to inhibit shifting along the shifting axis when in a tightened state and to allow for shifting when in an open state. The blocked state corresponds to an uncoupling of the height adjustment and the tilting from the shifting, as described above.

[0037] The surgical head positioning device may comprise a locking means configured to lock the shifting means, preferably reversibly. Such a locking means may be and/or comprise a screw, a magnetic, an electro-magnetic mechanism or any other suitable means. The locking means may be configured for manual and/or motorized operation.

[0038] The present invention is also directed to a kit comprising the surgical head positioning device and one or a combination of the following:

- one or more flexible fixation straps, wherein the one or more flexible fixation straps are configured for fixing the surgical head positioning device to the body support, preferably via attachment of the one or more flexible fixation straps to i) the base, preferably the fixation means, and/or ii) the body support;
- one or more pads configured for supporting the head in an elevated position relative to the head rest, wherein the one or more pads are optionally configured for supporting the head in the supine position or in the prone position;
- one or more covers configured for protecting the head positioning device from contamination and enabling easy cleaning after use.

[0039] All parts of the present invention are preferably configured to be easily cleaned and/or sterilized. Additionally or alternatively, some parts of the device may be configured for single use, such as the exchangeable head rest pad. The specific mechanical implementation of the present invention is preferably simple and self-explanatory in use in order to keep the costs low and training times short.

[0040] The following aspects are preferred embodiments of the invention:

1. A surgical head positioning device for use with a body support, comprising:

   a head rest configured to support a head of an essentially reclined patient's body resting on the body support;
   a base;
   a height adjustment means configured to adjust the height of the head rest relative to the base, while essentially maintaining the angular orientation of the head rest relative to the base;
   a shifting means configured to shift the head rest relative to the base along a shifting axis, the head positioning device being configured to be arranged with the shifting axis parallel to a longitudinal body axis of the patient.

2. The surgical head positioning device of aspect 1, configured to tilt the head rest relative to the base about a tilt axis extending in a transverse direction.

3. The surgical head positioning device of any one of the preceding aspects, configured to maintain the angular orientation of the head rest relative to the base when shifting the head rest relative to the base along the shifting axis, particularly maintaining a tilting position.

4. The surgical head positioning device of any one of the preceding aspects, wherein adjustment of the height of the head rest relative to the base, shifting the head rest relative to the base along the shifting axis, and tilting the head rest relative to the base about the tilt axis extending in the transverse direction are decoupled from each other.

5. The surgical head positioning device of any one of the preceding aspects, wherein the base is configured for being mounted to the body support, preferably by placing the base onto a portion of a resting surface of the body support, the base preferably comprising two or more fixation means, preferably two or more openings, configured for attachment of one or more straps.

6. The surgical head positioning device of any one of the preceding aspects, wherein the height adjustment means is configured for stepless height adjustment.

7. The surgical head positioning device of any one of the preceding aspects, the height adjustment means is configured for a height adjustment range of at least 15 cm to 30 cm, for example a height adjustment range of at least 18 cm or at least 20cm, and/or wherein the surgical head positioning device provides a shifting range along the shifting axis for the head rest of 5-10 cm, and/or optionally wherein the surgical head positioning device provides a tilting range of plus/minus 15 degrees.

8. The surgical head positioning device of any one of the preceding aspects, the height adjustment means comprising a mechanical and/or a hydraulic height adjustment mechanism, preferably a scissor mechanism, a parallelogram mechanism, an inclined plane mechanism, a lifting curve mechanism and/or a post mechanism.

9. The surgical head positioning device of any one of the preceding aspects, wherein the height adjustment means comprises a screw type operating means, preferably configured for manual and/or automated operation; and/or
optionally wherein the surgical head positioning device comprises a screw type operating means, preferably configured for manual and/or automated operation, for tilting the head rest relative to the base.

10. The surgical head positioning device of any one of the preceding aspects, wherein the shifting means comprises:

- a guide rail and one or more corresponding guide claws, the guide rail being configured for guiding the one or more guide claws along the shifting axis and/or the one or more guide claws being configured for guiding the guide rails along the shifting axis;
- a guide groove and a corresponding guide pin, the guide groove being configured for guiding the guide pin along the shifting axis; and/or
- a guide rail and one or more corresponding wheels, the guide rail being configured for guiding the one or more wheels along the shifting axis

11. The surgical head positioning device of any one of the preceding aspects, further comprising a head support base configured for supporting the head rest.

12. The surgical head positioning device of aspects 10-11, wherein the base comprises the guide groove and the height adjustment means comprises the guide pin; or wherein the base comprises the guide pin and the height adjustment means comprises the guide groove; or wherein the base comprises the guide rail and the height adjustment means comprises the one or more wheels; or wherein the base comprises the one or more wheels and the height adjustment means comprises the guide rail; or wherein the base comprises the guide rail and the height adjustment means comprises the one or more guide claws; or wherein the base comprises the one or more guide claws and the height adjustment means comprises the guide rail.

13. The surgical head positioning device of any one of aspects 2-12, wherein the head rest is tiltably, preferably pivotably, mounted to the height adjustment means, preferably via a/the head support base.

14. The surgical head positioning device of any one of the preceding aspects, wherein the head rest is a padded head rest and/or comprises an exchangeable pad configured for contacting the head.

15. The surgical head positioning device of any one of the preceding aspects, wherein an irradiation path and an imaging path for radiography are radiolucent and/or free of obstacles for X-rays, preferably free of any component of the surgical head positioning device.

16. The surgical head positioning device of any one of the preceding aspects, comprising a force measuring means configured to measure a force exerted onto the head rest by the head.

17. The surgical head positioning device of any one of the preceding aspects, configured for supporting the head in the prone and/or supine position.

18. The surgical head positioning device of aspect 17, comprising supervision means for supervision of the eyes of the head when mounted in the prone position, preferably a camera, more preferably one or more mirrors, the one or more mirrors being preferably adjustable.

19. The surgical head positioning device of any one of aspects 1-18, further configured such that an operator may perform a height adjustment single-handed and/or perform a tilting single-handed.

20. The surgical head positioning device of any one of aspects 1-19, further configured such that shifting of the head rest relative to the base occurs automatically in accordance with a movement of the head along the shifting axis upon a height adjustment and/or upon a tilting operation .

21. The surgical head positioning device of any one of the preceding aspects, comprising a locking means configured to lock the shifting means, preferably reversibly.

22. A kit comprising the surgical head positioning device of any one of the preceding aspects and one or a combination of the following:

- one or more fixation straps, wherein the one or more fixation straps are configured for fixing the surgical head positioning device to the body support, preferably via attachment of the one or more fixation straps to i) the base, preferably the fixation means, and/or ii) the body support;
- one or more pads configured for supporting the head in an elevated position relative to the head rest, wherein the one or more pads are optionally configured for supporting the head in the supine position or in the prone position;
- one or more covers configured for protecting the head positioning device from contamination and enabling easy cleaning after use.

[0041] Embodiments of the invention will be further described with reference to the Figures. The invention is not restricted to the embodiments shown in the Figures.

Fig. 1 schematically shows a head positioning device according to the invention in use with a body support and a patient's body;

Fig. 2A shows an embodiment of the head positioning device in a three-dimensional view;

Fig. 2B shows the embodiment of the head positioning device of Fig. 2A in a second three-dimensional view;

Figs. 3A-3C show the head positioning device of Figs. 2A and 2B in three different tilting states and three different views;

Fig. 4A shows a head positioning device in a configuration for supine use

Fig. 4B shows a head positioning device in a configuration for prone use

Fig. 5A shows a head positioning device, in a top view including an imaging path for radiography;

Fig. 5B shows a head positioning device, in prone configuration including supervision means for supervision of the eyes;

[0042] Figure 1 shows a schematic overview of a head positioning device 2 in use. The head positioning device 2 according to the present invention is suitable for use with a body support 4. The head positioning device 2 comprises a base 6 and a head rest 8. The head rest 8 is configured to support a head of an essentially reclined patient's body 10 (represented in the drawing by bones only) resting on the body support 4.

[0043] As shown in Figure 2A, the head positioning device 2 comprises a height adjustment means 12 configured to adjust the height of the head rest 8 relative to the base 6, while essentially maintaining the angular orientation of the head rest 8 relative to the base 6. The height adjustment may occur along a height adjustment axis H (indicated by the arrow). Preferably, the height adjustment means 12 is configured for a height adjustment range of at least 15 cm to 30 cm, for example a height adjustment range of at least 18 cm or at least 20 cm. For example, with a height adjustment range of 20 cm the highest position of the head rest 8 is at least 20 cm above the lowest position of the head rest 8 as measured along the height adjustment axis H.

[0044] The head positioning device 2 also comprises a shifting means 14 configured to shift the head rest 8 relative to the base 6 along a shifting axis L (indicated by the arrow). The surgical head positioning device may provide a shifting range for the head rest of 5-10 cm along the shifting axis L.

[0045] As shown, the height adjustment means 12 may comprise a scissor mechanism 16, which may be operated by means of a screw type mechanism such as a threaded rod 18. The threaded rod 18 may be mounted in a correspondingly threaded mount 19. The scissor mechanism 16 is implemented as generally known in the art. It comprises two linked supports 20 that are configured to fold in a criss-cross 'X'-pattern with hinges at the crossings and the return points. The figures show the

special case where only 1 crossing and no return point is present, but the invention is not so limited. Each support 20 has a lower end 20a and an upper end 20b. A lower guide 22a for the lower ends and an upper guide 22b for the upper ends 20b is provided. The upper and lower ends 20b, 20a may be mounted to the upper and lower guides 22b, 22a, respectively, with the necessary degrees of freedom. For example, the ends 20a, 20b may be mounted to the guides 22 by means of respective pins or shafts 23, which allow for pivoting of the ends 20a, 20b relative to the respective guide 22a, 22b. At least one of the lower ends 20a and at least one of the upper ends 20b may be slidably or otherwise movably mounted to the respective guide 22a, 22b, and thus movable relative to the other lower end 20a and upper end 20b, respectively. For example, this may be the case for the ends 20a, 20b, which are closer to the threaded rod 18. The threaded rod 18 and the lower ends 20a are mounted and coupled such that actuation, i.e. rotation, of the threaded rod 18 causes a movement of the lower ends 20a relative to each other. As shown, the rod 18 may be coupled to one of the lower ends 20a of the scissor mechanism 16, e.g. the lower end 20a that is located closer to the rod 18 and movable relative to the lower guide 22a, while the other one of the lower ends 20a is fixed relative to the lower guide 22a. Operation of the rod 18 causes a movement of the coupled lower end 20a relative to the lower guide 22a and thus to the other lower end 20a. When the two lower ends 20a approach each other, this movement occurs analogously in all other points of the supports 20, except for the connection points of the supports 20, i.e. the hinges at the crossings of the criss-cross 'X'-pattern. As a consequence, the two upper ends 20b move away from the lower ends 20a, i.e. the height of the head rest 8 relative to the base 6 increases. When the two lower ends 20a move away from each other, the two upper ends 20b approach the lower ends 20a, i.e. the height of the head rest 8 relative to the base 6 decreases. As shown in Fig. 2A, the lower guide 22a may be attached to or be part of a guide rail 28, which may also be a component of the shifting means 14, as explained below. The mount 19 for the rod 18 may be attached to or be part of the rail 28 and/or the lower guide(s) 22a, as shown in the figures. However, any other suitable location may be chosen.

[0046] As shown Figure 2A, the plane defined by the moving supports 20 of the scissor mechanism 16 may be parallel to the shifting axis L. However, other orientations are contemplated. The height adjustment means 12 preferably comprises two scissor mechanisms 16 in order to increase the stability and reliability of the device 2, as shown in the figures. The two scissor mechanisms may be configured to have the head resting between them during surgery. The two scissor mechanisms may be symmetric and/or comprise identical parts. Any other number of scissor mechanisms 16 is contemplated. With two or more scissor mechanisms, the height adjustment means 12 preferably comprises a stabilizing element, which may contribute to coupling and/or homogenizing the movement of the scissor mechanisms 16 as well as providing additional stability to the system. The stabilizing element may be a common shaft of two scissor mechanisms or be a separate component. All scissor mechanisms may be coupled to the rod 18, such that actuation of the rod 18 actuates all scissor mechanisms simultaneously. Instead of the shown scissor mechanism 16, other mechanisms that are well known in the art may be used. For example, a post mechanism or a parallelogram mechanism may be used. In any case, the height adjustment means 12 may preferably be configured for stepless height adjustment.

[0047] As shown in Fig. 2A, the threaded rod 18 may be configured for manual operation and/or for single-handed operation via knob or screw head 24. However, alternatively or additionally, the threaded rod 18 may also be coupled to a motor. The motor may be configured to be controlled by a user, i.e. manually, and preferably single-handed, and/or for automated operation, e.g. via a computer, controller or the like. The movement of the threaded rod 18 may be transferred to any suitable number of scissor mechanisms 16 or equivalent mechanisms, e.g. by means of a shaft 25 or the like. As shown in Fig. 3B, this shaft 25 may be or be integrated with hinges of the scissor mechanism(s), e.g. the hinges of the lower ends 20a that are closer to the threaded rod 18.

[0048] As opposed to Figure 2A, as an alternative to threaded rod 18 any other suitable mechanism for providing a movement of lower ends 20a relative to each other is contemplated, e.g. a hydraulic or pneumatic mechanism.

[0049] The shifting means 14 may be implemented in any suitable way. As shown in figure 2B, the shifting means 14 may comprise one or more guide elements 26 and one or more corresponding guide rails 28. As shown, the base 6 may comprise the one or more guide elements 26 for the guide rail 28. The guide rail(s) 28 may move relative to the guide element(s) 26. Thus, the guide element(s) 26 may restrict the movement of the guide rail(s) 28 to a movement along the shifting axis L. In the figures, the guide rails 28 comprise the lower guides 22a of the scissor mechanisms 16, however, the invention is not so limited. As shown in Figure 2B, the shifting means 14 may comprise one or more guide claws 26 as the guide elements 26, which partially enclose guide rail 28. One or more of the guide elements 26 maycomprise a fixation means 29 configured for reversibly inhibiting shifting. The guide elements 26 may be blocks of sufficiently stable material that inhibit a movement of the associated guide rail 28 in a direction transverse to the shifting axis L. The head positioning device 2 may comprise different types of guide elements 26. For example, one or more of the guide elements 26 may be guide claws 26 and one or more of the guide elements 26 may be blocks.

[0050] As an alternative to guide elements 26 and guide rail 28, the shifting means 14 may comprise a guide groove and a corresponding guide pin. The base 6 may

comprise the guide groove and the rail 28 may comprise a corresponding pin. Of course, this may be arranged vice versa and/or the pin may be located at another portion of the device. As an additional alternative guide wheels (not shown) running on a corresponding guide rail are contemplated.

[0051] The head rest 8 may be tiltably, preferably pivotably, mounted in the head positioning device 2. As shown in Figures 3A, 3B and 3C, the surgical head positioning device may be configured to tilt the head rest 8 relative to the base 6 and/or the height adjustment means 12 and ultimately relative to the body support 4, when installed on the latter, about a tilt axis T extending in a transverse direction. The transverse direction is "transverse" as compared to the shifting direction. Figure 3B shows the head rest 8 in a horizontal state. This horizontal state may correspond to the head rest 8 being parallel to the base 6 and/or parallel to the body support 4. Figure 3A shows a declined state of the head rest 8 and Fig. 4c shows an inclined state of the head rest 8 as compared to the horizontal state. The surgical head positioning device may provide a tilting range of plus/minus 15 degrees relative to the horizontal state. A user/operator may use the tilting mechanism to tilt a patient's head that is resting on the head positioning device 2 relative to the body. With the additional degree of freedom of tilting the head rest 8, the head positioning device 2 provides for increased adjustability of the position and orientation of a patient's head relative to the body. This may result in better outcomes of the reconstruction of the physiological lordosis. This said, with the synergistic geometry of the device features to enable translation and tiling while the height of the head rest is changed, the head movement during change of position follows a motion curve. This may ease the reconstruction of a cervical lordosis e.g. correction between two vertebrae is not achieved only by intervertebral angulation, but by allowing an intersegmental shortening and posterior translation of one vertebra over the adjacent-caudad vertebra.

[0052] The head positioning device 2 may comprise any suitable operating mechanism for tilting the head rest 8. As shown in Figs. 2A, 2B and 3A-3C, the head positioning device 2 may comprise a threaded tilting rod 30 configured to change the tilting state of the head rest 8 upon operation, i.e. rotation. For manual operation, the tilting rod 30 may comprise a knob or screw head 31 on its operating end, which may be grabbed by an operator's hand. Any suitable alternative to the knob 31 can be used, e.g. a cross bar or the like. Any mechanism of translating the rotation of the tilting rod 30 into a change of the tilting state is contemplated. As shown in Figs. 2A, 2B and 3A-3C, the tilting rod 30 may be mounted with a counterpart 32 including a counter threading on the head positioning device 2, which transforms a rotation of the tilting rod 30 into a translation of the tilting rod 30 relative to the counterpart 32 and thus the head rest 8 of the head positioning device 2. Any suitable transformation mechanism for transforming the translational movement of the tilting rod 30 to a tilting of the head rest 8 is contemplated. The head positioning device 2 may, e.g., comprise a connector 34, which is pivotably connected to the tilting rod 30 at one end and pivotably attached to the head rest 8 on the other, opposed end. The point of connection to the head rest 8 may be chosen as appropriate. In the figures, the connector 34 is attached to the head rest 8 at the end of the head rest 8 opposite the tilting axis T. The head rest 8 may be attached to the shaft 36, the shaft 36 serving as an axis for tilting for the head rest 8. The point of connection of the connector 34 to the head rest 8 may as well be chosen at the shaft 36. By means of the connector 34 the translational movement of the tilting rod 30 may be transformed to a rotation of the shaft 36 and thus a tilting of the head rest 8. The length of the connector 34 defines the transformation ratio and may be chosen according to the specific requirements of the device. Any other suitable transformation mechanism for transforming the movement of the tilting rod 30 to a tilting of the head rest 8 is contemplated.

[0053] As shown in Fig. 2, the head rest 8 may be mounted to the height adjustment means 12, and particularly to the upper guide(s) 22b. Unlike in the Figures, the tilting axis may be integrated with the upper end 20b of one of the supports 20 of the one, some of or all of the scissor mechanisms 16. Particularly, the pins or shaft 36 of the tilting mechanism may be integrated with or be the pins or shaft 25 of the height adjustment means (not shown).

[0054] The orientations of the shifting axis L, the transverse axis T and the axis of height adjustment relative to each other may be orthogonal. However, they may also be non-orthogonal, and any combination of orthogonal and non-orthogonal may be chosen.

[0055] As shown in Fig. 4A, the head rest 8 may be a padded head rest 8, i.e. comprise one or more pads 37, e.g., one or more exchangeable pads 37, configured for contacting the head of the patient. The head positioning device 2 may further comprise a head support base 38, which may be configured to support the one or more pads 37. The head support base 38 may be attached to other parts of the head positioning device in such a way as to provide for the necessary degrees of freedom.

[0056] The head rest 8 may, for example, be tiltably, preferably pivotably, mounted to the height adjustment means 12 via the head support base 38. For example, the head support base 38 may be mounted to the height adjustment 12 means via one or two pins or a shaft. Particularly, the head support base 38 may be mounted via the shaft 36.

[0057] The surgical head positioning device 2 may be configured for supporting the head in the supine (Figure 4A) and/or prone position (Figure 4B). The ranges of tilting, height adjustment and shifting may be adapted accordingly. Particularly, the shape of the pads 37may be adapted to the shape of the respective portion of the head, i.e. the back of the head for the supine position (Figure 4A) and the front of the head for the prone position

(Figure 4B).

[0058] As shown in Fig. 4B, the base 6 may comprise two or more fixation means, preferably two or more openings 39, configured for attachment of one or more straps 40 (Figure 1). The strap(s) 40 may be attached to the base 6 and wrapped around or otherwise fixed to the body support 4 in order to comply with safety requirements and to ensure proper fixation of the head positioning device 2 to the body support 4. Attachment of the strap(s) 40 may include knotting the strap(s) 40 to the openings 39 and/or the structures of the base 6 defining the openings 39. Attachment of the strap(s) 40 may include threading the strap(s) 40 through the openings 39.

[0059] In order to provide for the possibility of taking radiographs of relevant anatomical structures, an irradiation path and an imaging path for radiography may be radiolucent, i.e. X-rays may pass in a sufficient amount for radiography, and/or free of obstacles for X-rays, preferably free of any component of the surgical head positioning device 2, as in the embodiments shown in Figs. 2A-5B. As shown, the head positioning device 2 may comprise an opening at the respective locations, e.g. in the base 6 and/or the head rest 8. Such opening is marked with hatching in Fig. 5A.

[0060] As shown in Fig. 5B, the surgical head positioning device 2 may comprise supervision means 42 for supervision of the eyes of the head when the head is mounted in the prone position. Such supervision means 42 may be a camera (not shown), more preferably one or more mirrors 42. The one or more mirrors 42 are preferably adjustable. For example, the mirror(s) 42 may be mounted on one or more corresponding flexible posts such that the mirror(s) 42 may be arranged in any suitable orientation. An operator or surgeon may adjust the position and orientation of the mirror(s) 42 to the position of his/her own eyes. If more than one person needs to survey the eyes of the patient, a corresponding number of mirrors 42 may be mounted such that each person may adjust at least one mirror 42 to his/her position. In this way, the operator(s) may at any time during a surgery, check for optimum position of the patient's face and eyes, respectively.

[0061] As in the embodiments shown in the figures, the surgical head positioning device 2 may be configured such that an operator may perform operation a single-handed and/or operation b single-handed. In the embodiments shown in the figures this is achieved by the respective operation mechanisms (i.e. tilting rod 30 and rod 18) being a screw-type mechanism, which may be operated via a knob or screw head (i.e. knob or screw head 24 and knob or screw head 31) with one hand only. However, any other suitable implementation is contemplated.

[0062] The surgical head positioning device 2 may be configured such that shifting of the head rest relative to the base 6 (corresponding to operation c) occurs automatically in accordance with a movement of the head along the shifting axis upon height adjustment of the head rest 8 (and along with that operation a) and/or upon tilting of the head rest 8 (and along with that operation b). As a result, the head is always able to take and/or to remain in an unconstrained condition as regards the shifting axis. As shown in the figures, this may be achieved by implementing the shifting means 14 in such a way that the head rest 8 may shift freely along the shifting axis (within the constraints of the size of the device) without the need for an operator to perform the shifting. For example, guide element 26 and guide rail 28 provide for such a free shifting.

[0063] However, as already mentioned, a strained condition of the head in the shifting direction L may also be intended and may be intentionally brought about by an operator in order to correctly position the spinal components for reconstruction of the physiological lordosis. Inter alia for this purpose, the head positioning device 2 may comprise a locking means for the shifting of the head rest 8 along the shifting axis L, i.e. the locking means is configured for locking the shifting means 14, preferably reversibly. For example, the locking means may comprise a locking screw 29 configured to reversibly inhibit the shifting means 14. The locking screw 29 may be configured to press down the guide element 26 onto the rail 28 in the tightened state, thereby inhibiting the shifting means 14. The locking screw 29 may be configured to inhibit the shifting of the head rest 8 along the shifting axis L when in a tightened state and to allow for shifting when in an open state.

[0064] The Locking means 41 is an option to additionally secure the scissor mechanism of the head positioning device 2. In the locked position, it inhibits movement of the scissor mechanism in the guides for the lower ends 20a what results in improved stiffness of the system in the high adjustment direction H especially in the lower position of the headrest 8. It is also a safety feature, as in the locked position turning the nob 24 for high adjustment is not possible.

[0065] The surgical head positioning device 2 may comprise a force measuring means (not shown) configured to measure a force exerted onto the head rest 8 by the head. The force measuring means may be located for example in the base 6 or integrated in the head rest 8 or at any position in the head positioning device 2 that is suitable for the intended purpose. For example, if the purpose is to indicate whether there is a force exerted onto the head rest without the need of an absolute value, almost any position in the device is suitable. An output of the force measuring means may be handled as mentioned above, i.e. directly forwarded to the user and e.g. be displayed and/or be an acoustic signal (not shown). Additionally or alternatively, the output of the force measuring means may be transferred to an electronic device (not shown) for further processing.

[0066] The present invention is also directed to a kit comprising the surgical head positioning device 2 and one or a combination of the following:

- one or more fixation straps 40, wherein the one or more fixation straps 40 are configured for fixing the surgical head positioning device 2 to the body support 4, preferably via attachment of the one or more fixation straps 40 to i) the base 6, preferably the fixation means, and/or ii) the body support 4;
- one or more pads 37 configured for supporting the head in an elevated position relative to the head rest 8, wherein the one or more pads 37 are optionally configured for supporting the head in the supine position or in the prone position;
- one or more covers (not shown) configured for protecting the head positioning device 2 from contamination and enabling easy cleaning after use.

[0067] Covers configured for protecting the head positioning device may be made from plastic material and/or any other suitable material known in the art. The cover(s) may be single use products and/or suitable for being sterilized. The head positioning device may be covered with the cover(s) prior to surgery, thus protecting the device during surgery, and be removed/exchanged after surgery.

List of reference signs

[0068]

2 head positioning device;
4 body support;
6 base;
8 head rest;
10 patient's body;
12 height adjustment means;
14 shifting means;
L shifting axis;
16 scissor mechanism;
18 threaded rod;
19 mount for rod 18;
20 support of scissor mechanism;
20a lower end of support 20;
20b upper end of support 20;
22a guide for lower ends 20a;
22b guide for upper ends 20b;
23 pin or shaft;
24 knob or screw head of rod 18;
25 shaft
26 guide element;
28 guide rail;
29 locking screw
T tilt axis;
30 threaded tilting rod;
31 knob or screw head of tilting rod 30;
32 counterpart of tilting rod;
34 connector;
36 shaft;
37 pad;
38 head support base ;
39 openings for fixation;
40 strap;
41 Locking means for scissor mechanism
42 supervision means / mirror;

Claims

1. A surgical head positioning device for use with a body support, comprising:

a head rest configured to support a head of an essentially reclined patient's body resting on the body support;
a base;
a height adjustment means configured to adjust the height of the head rest relative to the base, while essentially maintaining the angular orientation of the head rest relative to the base;
a shifting means configured to shift the head rest relative to the base along a shifting axis, the head positioning device being configured to be arranged with the shifting axis parallel to a longitudinal body axis of the patient.

2. The surgical head positioning device of claim 1, configured to tilt the head rest relative to the base about a tilt axis extending in a transverse direction.

3. The surgical head positioning device of any one of the preceding claims, configured to maintain the angular orientation of the head rest relative to the base when shifting the head rest relative to the base along the shifting axis, particularly maintaining a tilting position.

4. The surgical head positioning device of any one of the preceding claims, wherein adjustment of the height of the head rest relative to the base, shifting the head rest relative to the base along the shifting axis, and tilting the head rest relative to the base about the tilt axis extending in the transverse direction are decoupled from each other.

5. The surgical head positioning device of any one of the preceding claims, wherein the base is configured for being mounted to the body support, preferably by placing the base onto a portion of a resting surface of the body support, the base preferably comprising two or more fixation means, preferably two or more openings, configured for attachment of one or more straps.

6. The surgical head positioning device of any one of the preceding claims, wherein the height adjustment means is configured for stepless height adjustment.

7. The surgical head positioning device of any one of

the preceding claims, the height adjustment means is configured for a height adjustment range of at least 15 cm to 30 cm, for example a height adjustment range of at least 18 cm or at least 20cm, and/or wherein the surgical head positioning device provides a shifting range along the shifting axis for the head rest of 5-10 cm, and/or optionally wherein the surgical head positioning device provides a tilting range of plus/minus 15 degrees.

8. The surgical head positioning device of any one of the preceding claims, the height adjustment means comprising a mechanical and/or a hydraulic height adjustment mechanism, preferably a scissor mechanism, a parallelogram mechanism, an inclined plane mechanism, a lifting curve mechanism and/or a post mechanism.

9. The surgical head positioning device of any one of the preceding claims, wherein the height adjustment means comprises a screw type operating means, preferably configured for manual and/or automated operation,
wherein optionally the surgical head positioning device comprises a screw type operating means, preferably configured for manual and/or automated operation, for tilting the head rest relative to the base.

10. The surgical head positioning device of any one of the preceding claims, wherein the shifting means comprises:

- a guide rail and one or more corresponding guide claws, the guide rail being configured for guiding the one or more guide claws along the shifting axis and/or the one or more guide claws being configured for guiding the guide rails along the shifting axis; optionally wherein the base comprises the guide rail and the height adjustment means comprises the one or more guide claws; or optionally wherein the base comprises the one or more guide claws and the height adjustment means comprises the guide rail; and/or
- a guide groove and a corresponding guide pin, the guide groove being configured for guiding the guide pin along the shifting axis; optionally wherein the base comprises the guide groove and the height adjustment means comprises the guide pin; or optionally wherein the base comprises the guide pin and the height adjustment means comprises the guide groove; and/or
- a guide rail and one or more corresponding wheels, the guide rail being configured for guiding the one or more wheels along the shifting axis; optionally wherein the base comprises the guide rail and the height adjustment means comprises the one or more wheels; or optionally wherein the base comprises the one or more wheels and the height adjustment means comprises the guide rail.

11. The surgical head positioning device of any one of claims 2-10, wherein the head rest is tiltably, preferably pivotably, mounted to the height adjustment means.

12. The surgical head positioning device of any one of the preceding claims, wherein

- the head rest is a padded head rest and/or comprises an exchangeable pad configured for contacting the head, and/or
- an irradiation path and an imaging path for radiography are radiolucent and/or free of obstacles for X-rays, preferably free of any component of the surgical head positioning device, and/or
- the surgical head positioning device comprises a force measuring means configured to measure a force exerted onto the head rest by the head, and/or
- the surgical head positioning device is configured for supporting the head in the prone and/or supine position, and/or
- the surgical head positioning device comprises supervision means for supervision of the eyes of the head when mounted in the prone position, preferably a camera, more preferably one or more mirrors, the one or more mirrors being preferably adjustable, and/or
- the surgical head positioning device is configured such that an operator may perform a height adjustment single-handed and/or perform a tilting single-handed.

13. The surgical head positioning device of any one of claims 1-12, further configured such that shifting of the head rest relative to the base occurs automatically in accordance with a movement of the head along the shifting axis upon a height adjustment and/or upon a tilting operation .

14. The surgical head positioning device of any one of the preceding claims, comprising a locking means configured to lock the shifting means, preferably reversibly.

15. A kit comprising the surgical head positioning device of any one of the preceding claims and one or a combination of the following:

- one or more fixation straps, wherein the one or more fixation straps are configured for fixing the surgical head positioning device to the body support, preferably via attachment of the one or more fixation straps to i) the base, preferably the fixation means, and/or ii) the body support;

- one or more pads configured for supporting the head in an elevated position relative to the head rest, wherein the one or more pads are optionally configured for supporting the head in the supine position or in the prone position;
- one or more covers configured for protecting the head positioning device from contamination and enabling easy cleaning after use.

Fig. 1

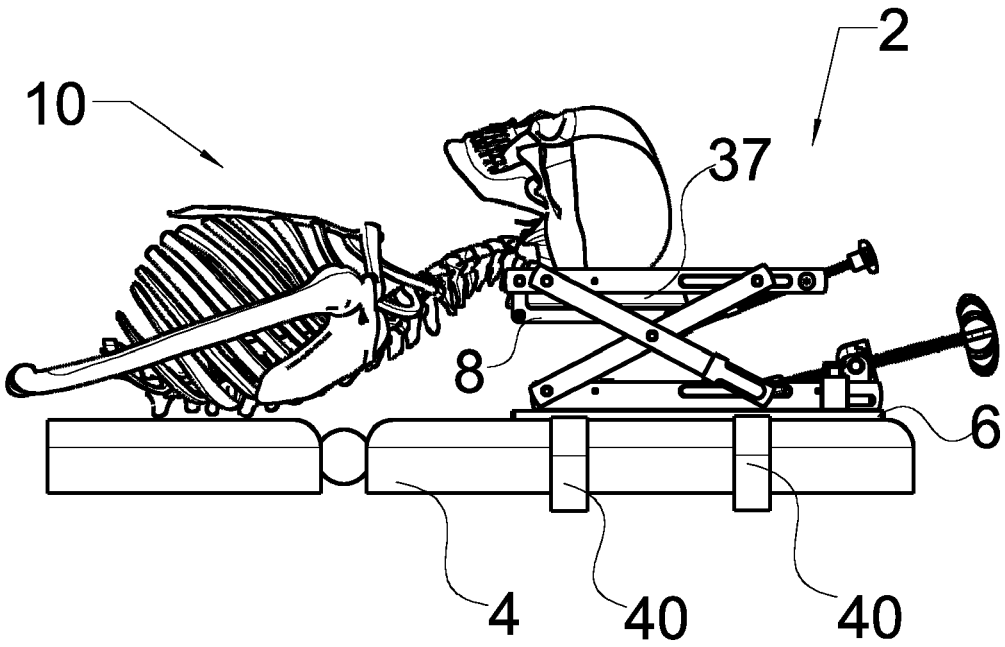
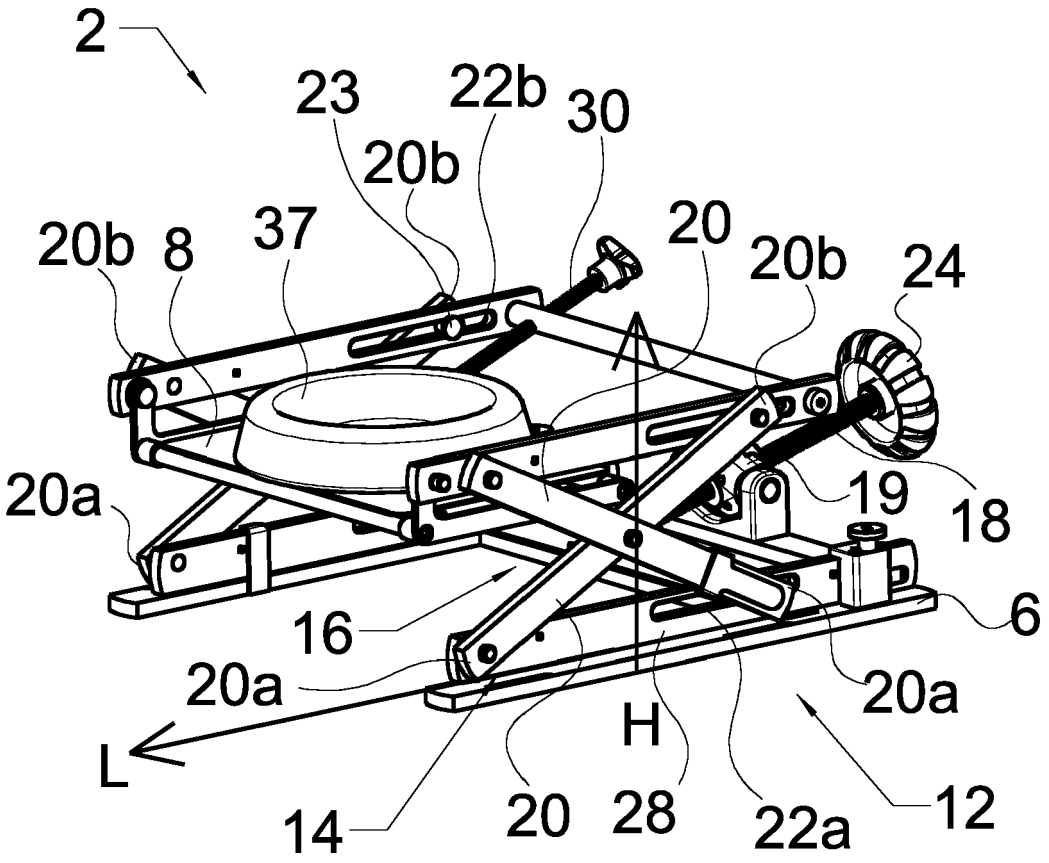


Fig. 2A


2
23
22b
30
20b
20b
8
37
20
20b
24
20a
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18
16
6
20a
20a
H
L
14
20
28
22a
12

Fig. 2B

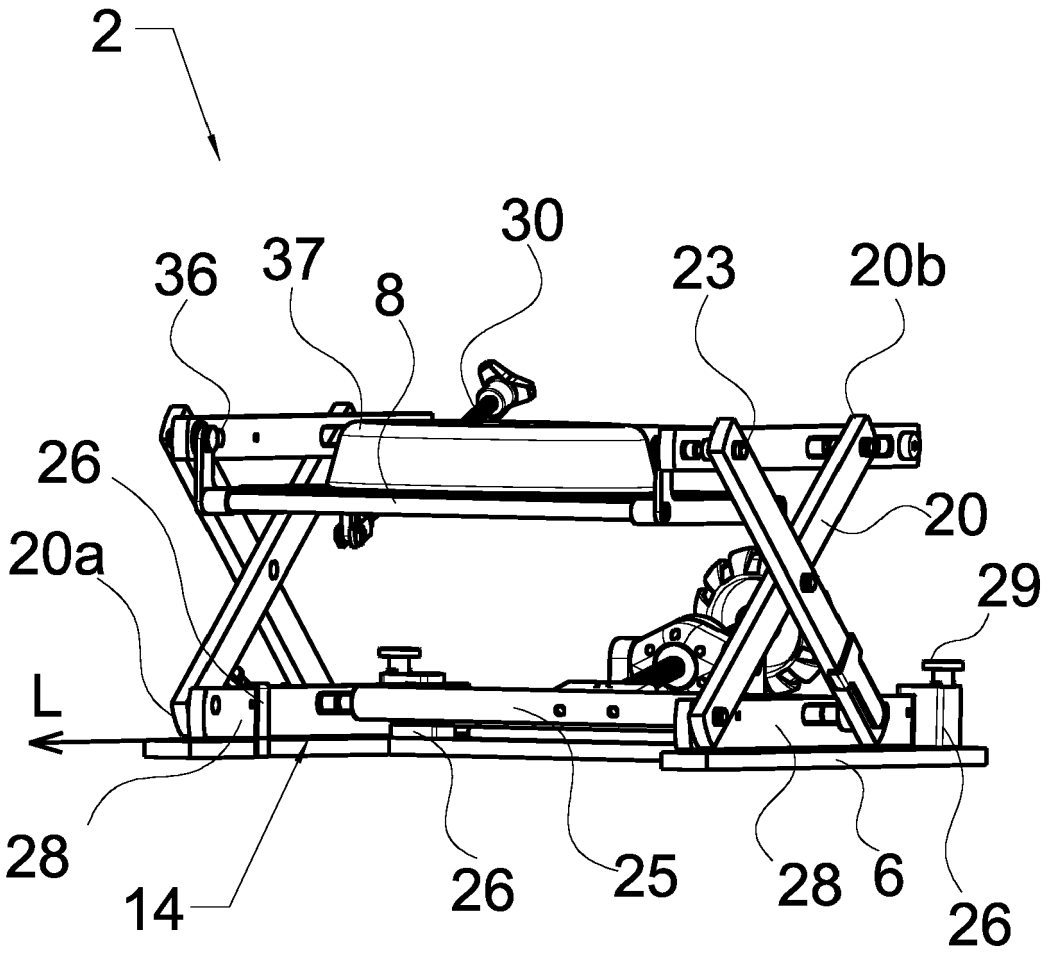


Fig. 3A

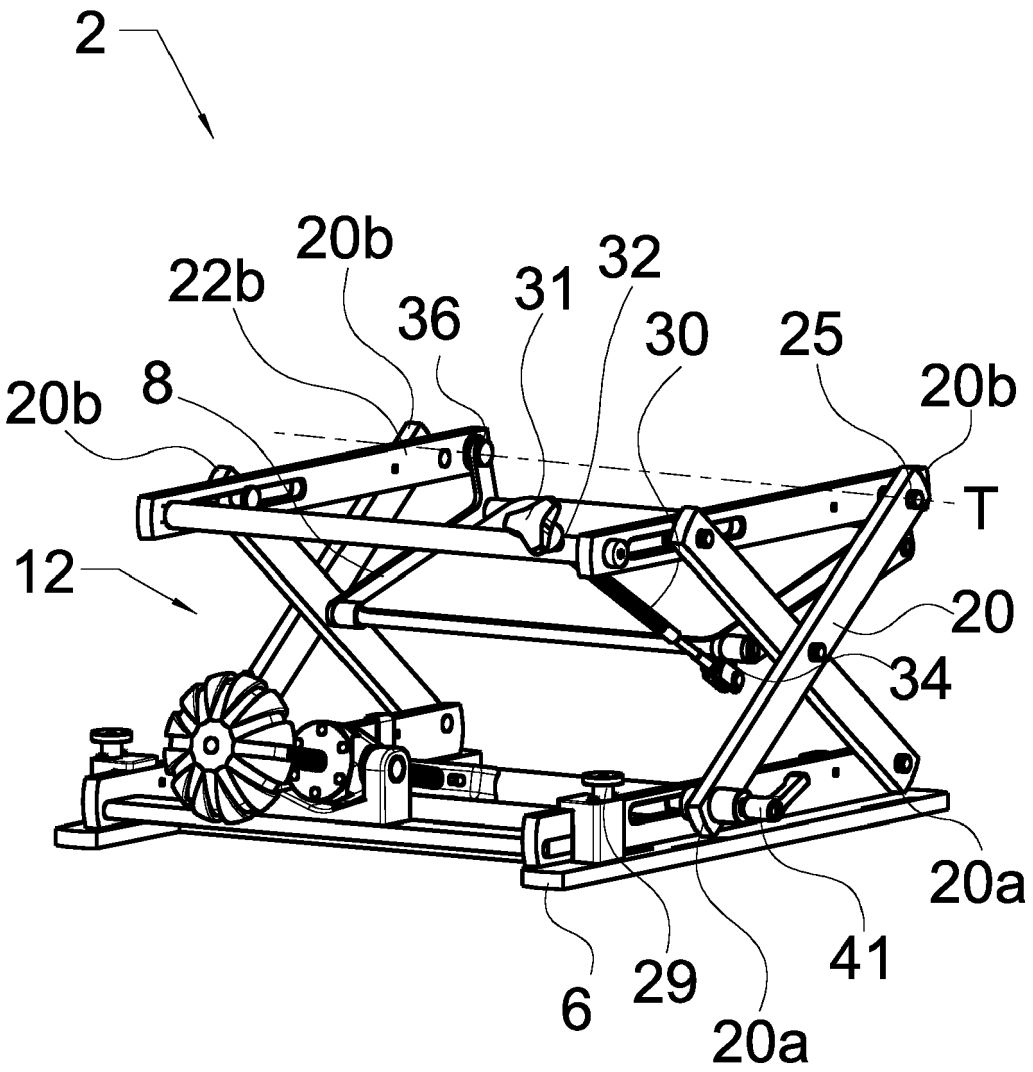


Fig. 3B

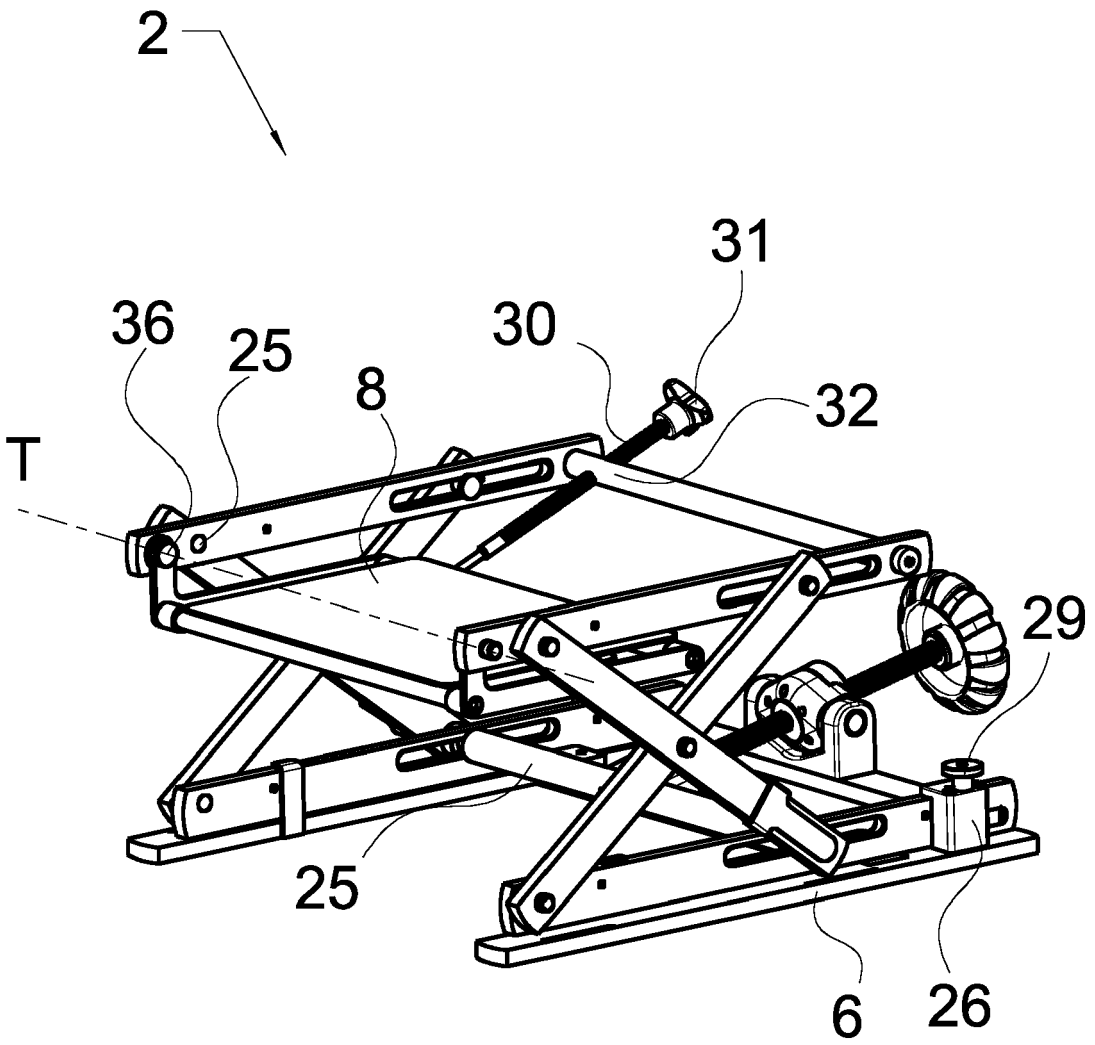


Fig. 3C

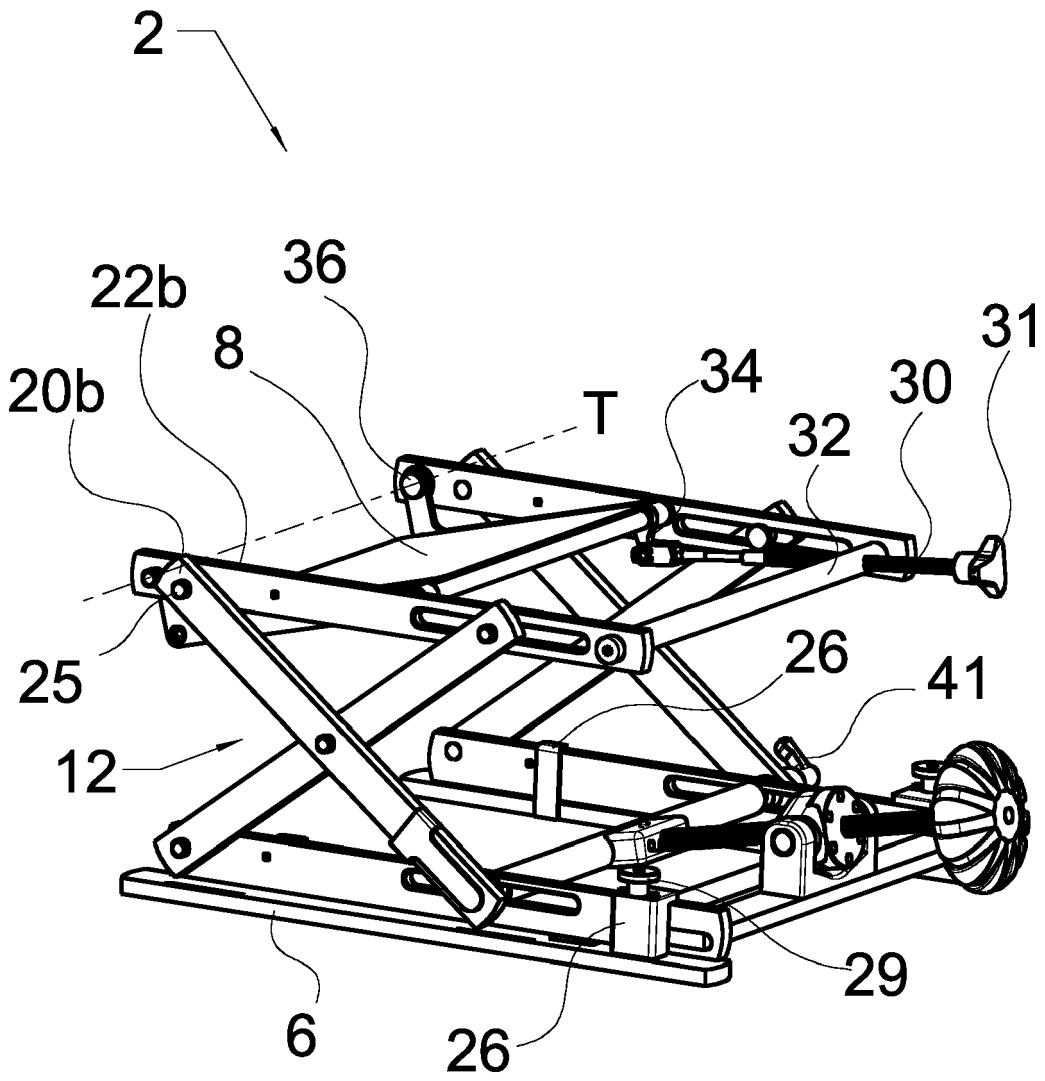


Fig. 4A

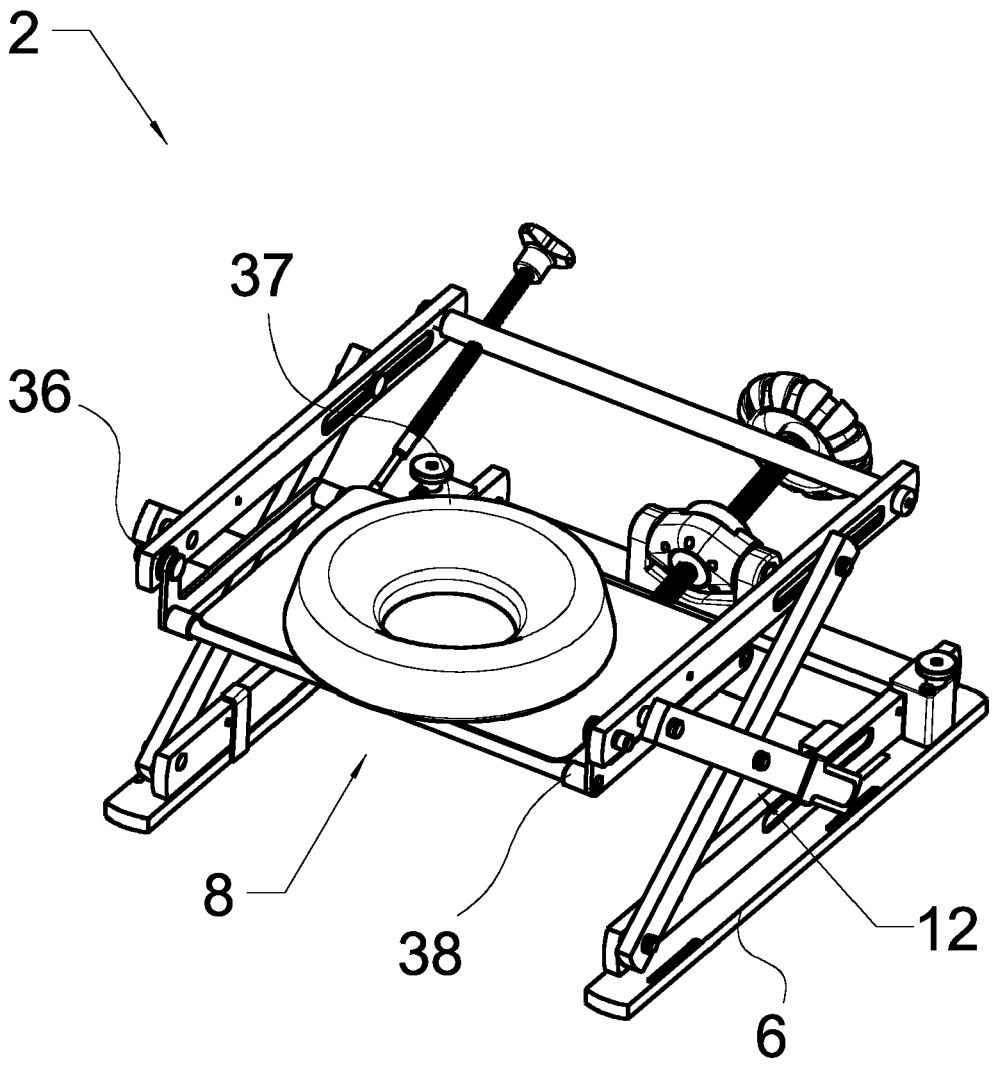


Fig. 4B

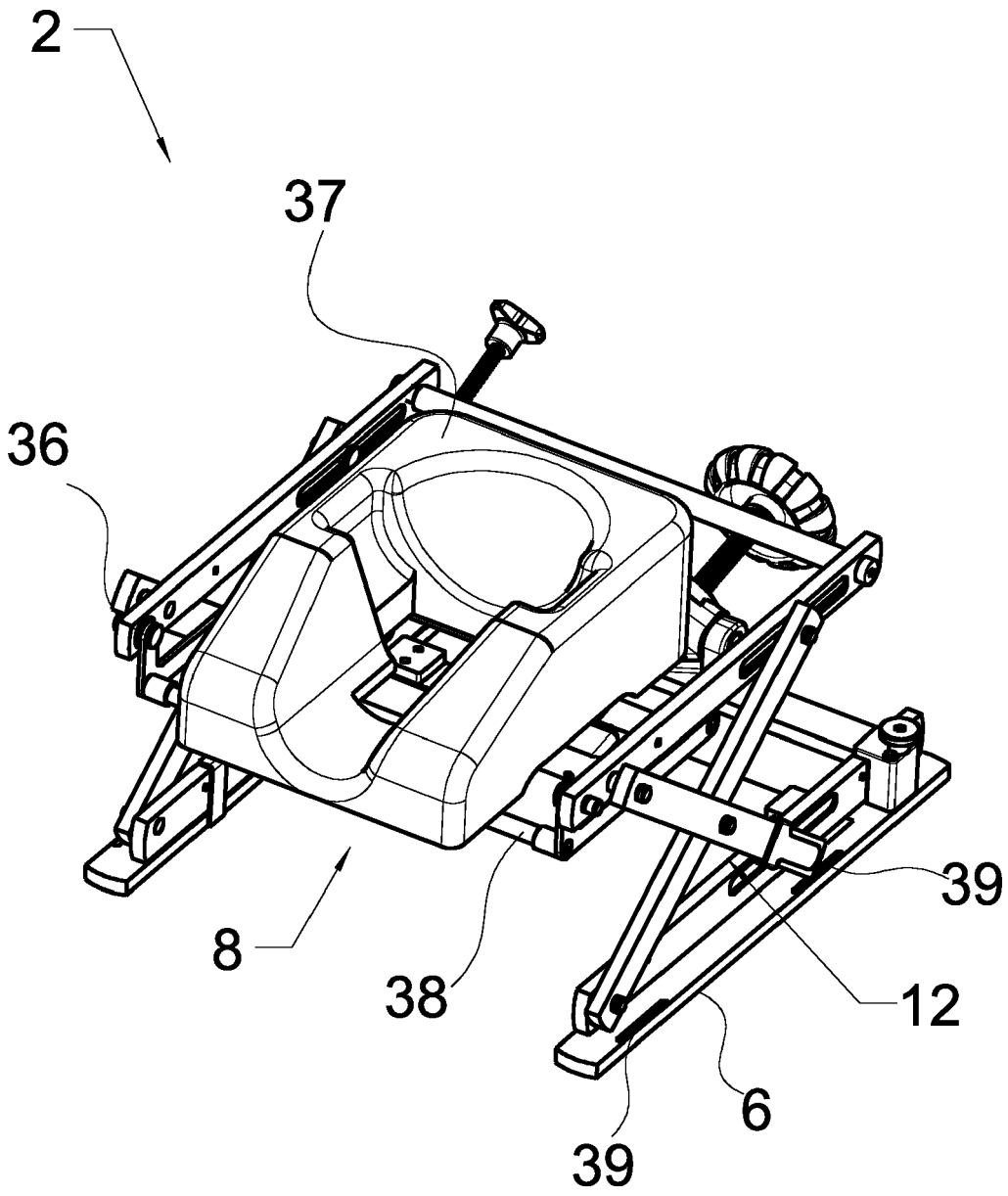


Fig. 5A

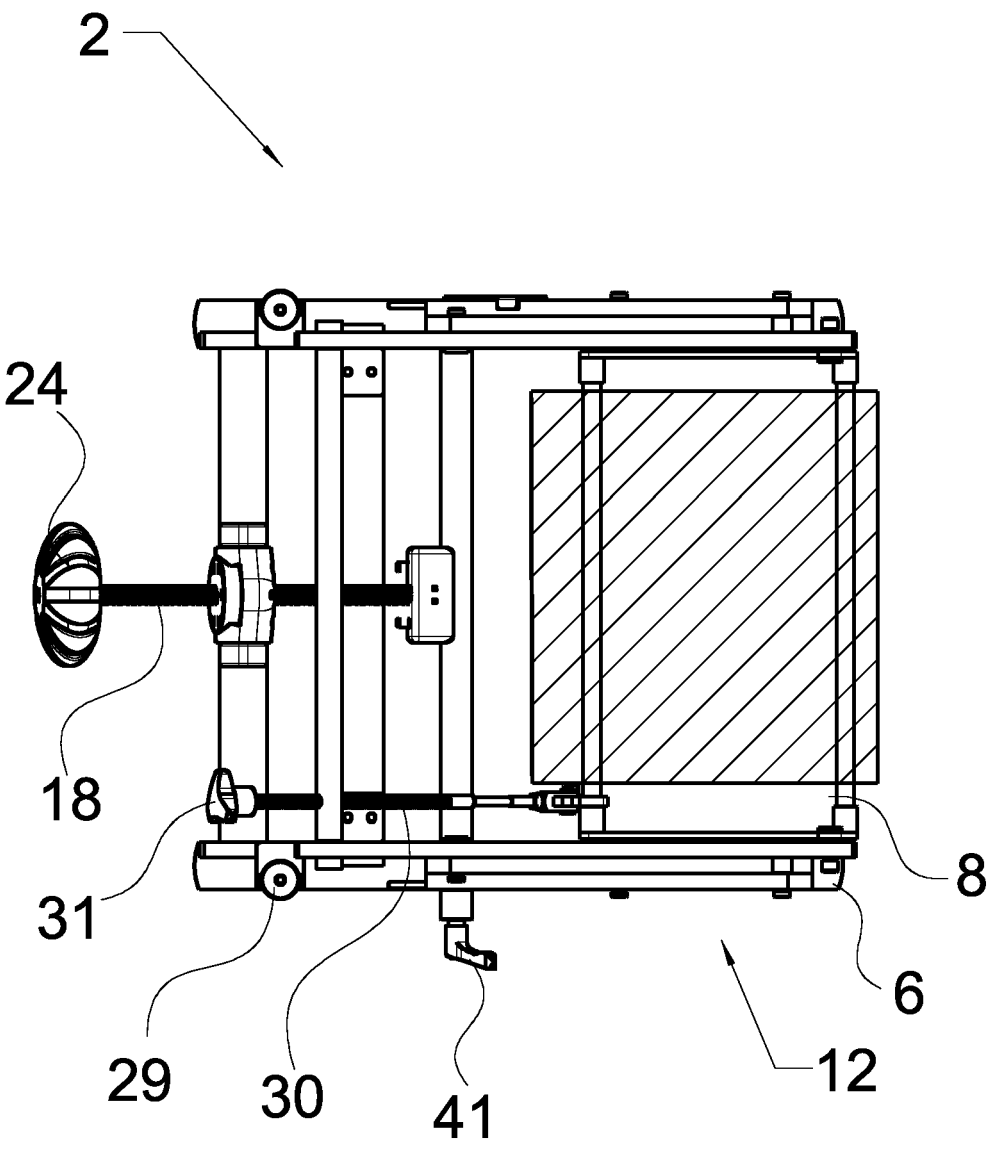
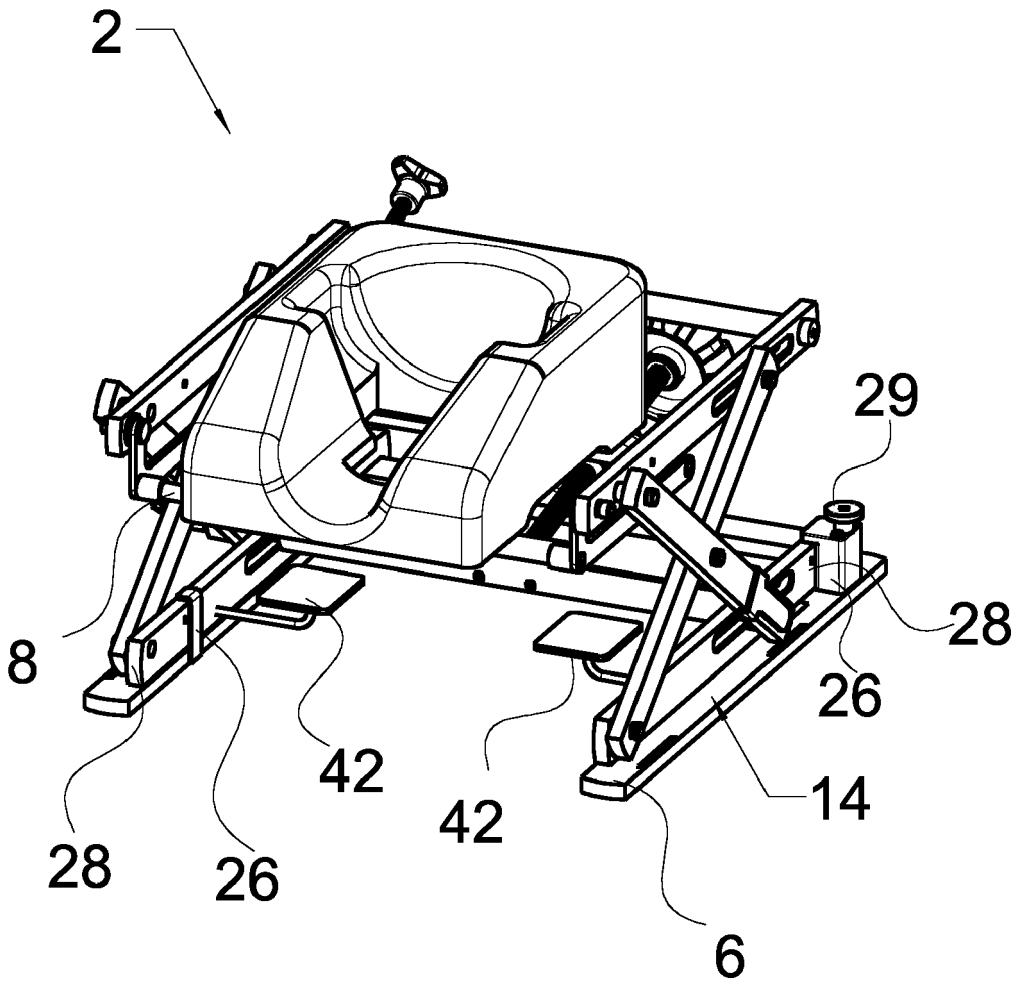


Fig. 5B



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EUROPEAN SEARCH REPORT

Application Number
EP 22 17 4478

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2005/160532 A1 (FROELICH MICHAEL [US]) 28 July 2005 (2005-07-28) * paragraphs [0038] - [0043]; figures *	1-15	INV. A61G13/12
X	US 2016/151222 A1 (PEDRO MICHAEL J [US] ET AL) 2 June 2016 (2016-06-02) * the whole document *	1-15	
A	US 8 336 142 B1 (SEE JEFFREY J [US] ET AL) 25 December 2012 (2012-12-25) * the whole document *	1-12	
A	CN 107 928 961 A (LIANG YUCHANG) 20 April 2018 (2018-04-20) * the whole document *	1-12	

TECHNICAL FIELDS SEARCHED (IPC)

A61G

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	30 September 2022	Kousouretas, Ioannis

CATEGORY OF CITED DOCUMENTS

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EPO FORM 1503 03.82 (P04C01)

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30-09-2022

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