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(54) **Title:** METHOD FOR THE CORRECTION OF SPINAL DEFORMITIES USING ROD-PLATES ANTERIOR SYSTEM

(57) **Abstract:** An anterior instrumentation method of treating spinal deformities involves a combination of a spinal rod anterior system and one or two spinal plates fixed on the cephalad and caudal end vertebrae of the instrumented segment. Deformities are treated by the anterior rod system through compression, distraction and derotation. Two spinal plates are fixed to the cephalad and caudal end vertebrae respectively to prevent the end vertebrae from rotating into kyphosis. A number of cancellous screws are inserted into the cephalad and caudal end vertebrae and their adjacent vertebrae through the spinal plate to provide several points of fixation on the end vertebrae to prevent implant failure and loss of correction.

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METHOD FOR THE CORRECTION OF SPINAL DEFORMITIES USING ROD-PLATES ANTERIOR SYSTEM

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FIELD OF THE INVENTION

The present invention concerns an anterior spinal instrumentation system (Rod-Plate Anterior System) which allows two spinal plates at the cephalad and caudal end vertebrae to be combined with a rod type anterior system. The rod-plate anterior system will be used for the surgical management of thoracolumbar and lumbar scoliosis and other situations requiring spinal stabilization.

BACKGROUND OF THE INVENTION

Dwyer first introduced spinal Instrumentation for anterior spinal fusion in 1969. The Dwyer system used screws and a flexible cable; this system merely provided limited stability by the compressive effect of the one vertebral body against the other. The flexible cable resisted only the tension forces, and the inability of the Dwyer system to provide a rigid connection between vertebrae often led to cable or screw failure with subsequent pseudarthrosis. In 1976 Zielke modified the Dwyer system by substituting a small diameter threaded rod and nuts for the cable and introduced a derotator designed to correct rotation and to prevent kyphosis. Over time, the Zielke instrumentation procedure for management of thoracolumbar and lumbar scoliosis was recognized to have significant advantages over the Dwyer system in terms of effective correctability of the coronal curvature, the ability to correct deformity by instrumenting shorter segments of the spine and also its derotation capability. However, the Zielke has been reported to have high incidence of the implant breakage, loss of correction, progression of the kyphosis, and pseudarthrosis caused primarily by lack of segmental stiffness in the relatively small-diameter rod.

With the introduction of a larger diameter solid rod system by TSRH in 1989, creation of lordosis in the instrumented segment was possible by the appropriate contouring and rotation of a larger-diameter rod. The 300% to 400% increased stiffness of the 6.4 mm rod over that of the Dwyer or Zielke longitudinal members was expected to provide stiffness sufficient to increase fusion rates while maintaining correction without external immobilization. However, after review of cases performed with the instrumentation, the incidence of loss of correction in both frontal and sagittal planes remained unacceptable, though improved compared to Dwyer and Zielke.

Some authors documented significantly high strains at the bone-screw interface of the cephalad and caudal end vertebral screws. Loss of correction and kyphosis in the single rod instrumented segment probably resulted from insufficient construct stiffness in the early postoperative period as a consequence of bone-screw interface loosening, especially at the cephalad and caudal interspaces. The single rigid rod may provide sufficient stability for the correction of the deformed spine during the early postoperative period. However, it may not prevent the vertebral rotation about each screw axis at the bone–screw interface during everyday activity. The possible reason is that the single solid rod system lacks two fixation points on each vertebra, particularly in the most cephalad and caudal end vertebrae of the instrumented segment.

In 1996, Kaneda introduced a two-rod anterior system (KASS) with two fixation points on each vertebra for management thoracolumbar and lumbar scoliosis. It seems to answer this problem, preventing the end vertebrae from rotating into kyphosis. This technique has been performed with good results in the early follow-up period. However, this system has some limitations to use since it has a high prominent profile and is difficult to apply to the severely deformed spine.

To combine the relative ease of implanting a single rigid rod structure with two fixation points on each end vertebra, we have developed a rod-plate anterior system that will improve the single solid rod anterior system (TSRH), yet allow spinal plate fixation at the cephalad and caudal end vertebrae of the instrumentation segment.

SUMMARY OF THE INVENTION

The present disclosure provides a rod-plate spinal anterior instrumented system having improved the single rigid rod anterior system to allow spinal plate fixation at the cephalad and caudal end vertebrae in the instrumented segment. This disclosure combines the relative advantages of a rod based anterior instrumentation with plates to increase bone implant strength and stability.

DESCRIPTION OF THE DRAWINGS

FIG. 1a is a representation of the thoracolumbar spine with a rod-plate anterior system.

FIG. 1b is a representation of the thoracolumbar spine with the rod-plate anterior system.

FIG. 2a is a top view of an L-shaped spinal plate in accordance with one embodiment of the invention as depicted in FIG 1b.

FIG. 2b is a bottom view of an L-shape spinal plate.

FIG. 2c is a front view of an L-shape spinal plate.

FIG. 2d is a lateral view of an L-shape spinal plate.

FIG. 2e is a side cross-section view of an L-shape spinal plate in FIG. 2a taken along line 1—1 as viewed in the direction of the arrows.

FIG. 2f is a side cross-section view of an L-shape spinal plate in FIG. 2a taken along line 2—2 as viewed in the direction of the arrows.

FIG. 3a is a side view of an embodiment of a cancellous bone screw for use with present invention.

FIG. 3b is a cross-sectional view of a bone screw in FIG. 3a with spinal plate connection.

FIG. 4 is a side cross-sectional view of the end vertebra fixation in FIG. 1b, showing a stable triangular construct of the end vertebra between the two screws and the transverse portion of the spinal plate.

FIG. 5 is a representation of the thoracolumbar spine with another embodiment of the rod-plate anterior system.

FIG. 6a is a top view of a rectangular-shaped spinal plate in accordance with one embodiment of the invention as depicted in FIG 5.

FIG. 6b is a bottom view of a rectangular-shape spinal plate.

FIG. 6c is a frontal view of a rectangular-shape spinal plate.

FIG. 7a is a top view of a pair of vertebral staples in accordance with one embodiment of the invention as depicted in FIG 5.

FIG. 7b is a bottom view of vertebral staple.

FIG. 7c is a top view of a pair of vertebral staples with less profile than those in FIG. 7a.

FIG. 7d is a bottom view of a vertebral staple.

FIG. 8a is a side view of an embodiment of a bone screw with serration-wall junction in accordance with one embodiment of the invention as depicted in FIG 5

FIG. 8b is a side view of an embodiment of a bone screw with plain-wall junction in accordance with one embodiment of the invention as depicted in FIG 5.

FIG. 9a is a top view of a serration-washer in accordance with one embodiment of the invention as depicted in FIG 5.

FIG. 9b is a bottom view of a serration-washer in accordance with one embodiment of the invention as depicted in FIG 5.

FIG. 9c is a front view of a serration-washer in accordance with one embodiment of the invention as depicted in FIG 5.

FIG. 10 is a representation of spinal plate, bone screws, washer and nuts in accordance with one embodiment of the invention as depicted in FIG 5, showing that the spinal plate can mount to a bone screw in varying angular orientations and with variable positions to match the adjacent bone screw.

FIG. 11 is a representation of the thoracolumbar spine with another rod-plate anterior system that is similar with FIG 5.

FIG. 12 is a representation of the thoracolumbar spine with another embodiment of a rod-plate anterior system that has a lower profile than the embodiment shown in FIG. 5.

FIG. 13a is a top view of a rectangular spinal plate.

FIG. 13b is a bottom view of a rectangular spinal plate.

FIG. 13c is a front view of a rectangular spinal plate.

FIG 13d is a cross-sectional view of a bone screw with the spinal plate connection as shown in FIG. 12.

DETAILED DESCRIPTION

The present invention provides numerous advantages over the Dual-Rod system, including fewer parts and lower profile, accommodation of spinal deformity, ease in applying implants to severely deformed spine, ease in adjusting the end vertebrae to avoid wedging and/or degeneration of disc caudal of the last screw, usable from thoracic spine to lumbar spine, reduced operation times and simplification of the operational steps.

In preferred embodiments, the invention includes an anterior spinal instrumented method of treating spinal deformities, the spine having a convex side and a concave side, the method comprising the steps of:

on the convex side of the deformity, attaching two spinal plates to cephalad and caudal end vertebrae respectively; and

fixing a rod anterior system on the posterior portion of the convex side. Two spinal plates are attached on the most cephalad and caudal end vertebrae through the vertebral screws of the single-rod anterior system; and the deformity of the spine is corrected through compression, distraction and derotation of the rod anterior system. The method may further include inserting several cancellous screws into the cephalad and caudal end vertebrae and their adjacent vertebrae at the anterior portion of the convex side through the spinal plate which is connected to the rod spinal instrumentation.

This preferred method may also include a spinal plate that is an "L" shape that connects at least two vertebrae, which comprises: a first end and a second end: where the first end has a longitudinal portion and a length sufficient to span between two vertebrae. The longitudinal portion has an elongated slot which has a series of openings for receiving screws such that the plate can be attached to the vertebrae. The openings allow the force transmitting members to be positioned on the vertebra where desired and enables the spinal plate to be used with different sized vertebrae.

The second end has a transverse portion that is vertical with the longitudinal portion. The transverse portion fits together with the lateral side of the vertebra in anterior-posterior direction. In the superior-inferior direction the plate's thickness is narrowed to avoid endplate prominence and so that the plate fits closely to the bone. The transverse portion has a first aperture in the anterior region and a second aperture in the posterior region. The second aperture is located in the middle point of the superior-inferior direction, which indicates the spinal screw safely in the middle position. The first aperture is angled towards the center allowing the screw to be inserted in the posterior direction to avoid damaging the aorta and disrupting the front edge of the vertebral body. The two-hole design provides a stable triangular screw construct in the vertebrae between the two screws and the transverse portion of the spinal plate. Different angles are designed from 80° to 100° between the longitudinal portion and the transverse portion of the spinal plate so that the spinal plate can accommodate different spinal deformities. Different lengths are designed for the longitudinal portion of the spinal plate, so the spinal plate can span at least two vertebrae.

On the bottom side surface and top side surface, the spinal plate has a bottom side surface for facing the vertebrae. In the longitudinal portion, pluralities of serrations are formed along the slot. The serrations prevent sliding of the spinal plate relative to the vertebrae. In the transverse direction, the spinal plate is slightly concave in shape so that it matches the vertebral anatomy for optimum anatomic fit and to minimize the construct profile in the anterior-posterior direction. On the top surface, in the longitudinal portion, the slot is provided with a beveled upper or outer edge portion, which slopes at the same angle as the lower rounded surface of the head portion of cancellous screw. A plurality of recesses is provided in the beveled edge portions to engage the lower rounded surface of the cancellous screw. The recesses hold the screw against sidewise movement relative to the spinal plate. The recesses are defined by surfaces, which form a portion of a cone having the same included angle as the lower round surface of the screw head. In the transverse portion, an anterior hole is provided with a beveled upper edge portion, which slopes at the same angle as the lower rounded surface of the screw head. The topside surface of the transverse portion is slightly convex in anterior-posterior direction so that it matches the vertebral anatomy.

The cancellous screw may also include a bone engaging portion having cancellous threads thereon, and a head portion. The head portion includes a lower rounded surface and an upper rounded surface. A generally cylindrical portion separates the lower rounded surface and the upper rounded surface. The screw head also includes a tool-engaging recess. The tool-engaging recess may be of any suitable configuration, including hexagonal, hexalobed, or any other appropriate configuration. The rod anterior system may be any suitable single-rod anterior system including TSRH, CDH, Miami, or any others.

In practice of the preferred method, the spinal plate also may be of rectangle-shape that connects at least two vertebrae through a pair of similar upper and lower vertebral-staples, which comprise a first end and a second end: The first end has a first hole and second end has an elongated u-shaped slot. The plate also includes a bottom side surface (screw-facing side) and top side surface (washer-facing side): On the bottom side surface, the first hole defines a plurality of serrations extending radially about the hole so that the spinal plate can mount to a cancellous screw in varying angular orientations. On the top side surface, the elongated u-shaped slot defines a plurality of parallel serrations so that the spinal plate may be placed in a variable position to match the adjacent bone screw through a rectangle-serrated washer. Using this plate, a pair of similar upper and lower vertebral staples may be attached to both end vertebrae of the instrumentation segment. The vertebral staples have a posterior hole and an anterior hole. The posterior hole receives the screws of the anterior rod system, and the anterior hole receives a cancellous screw for the spinal plate fixation. The vertebral-staple is wedge-shaped and capable of securing a pair of metal tensioning cables to a vertebra via spinal screws. The staple preferably comprises: three prongs: a pair of substantially parallel, perpendicularly offset laminar posterior legs which are inserted into the vertebral endplates, the parallel distance between said posterior legs being such as to fit snugly over either side of a vertebra. The third prong is located in central position of the staple to avoid damaging the aorta and thoracic-abdominal organs. The staple may further include a pair of spinal screw receiving apertures: the posterior hole is located in the middle portion between the two posterior staple prongs, which positions the spinal screw safely in the middle position. The anterior hole is inclined towards the center of the anterior portion of the staple. The anterior hole geometrically allows the anterior screw to be directed posterior to avoid damaging the aorta and disrupting the front edge of the vertebral body for good purchase. The posterior hole allows the posterior vertebral screw to be directed anterior to avoid the injury spinal cord. The two-hole design provides a stable triangular screw construct in the vertebra between the two screws and the staple. The staple further comprises an integral substantially solid and wedge-shape laminal bridge portion which is slightly convex in shape so that it matches the vertebral anatomy for optimum anatomic fit to minimize the construct profile of the anterior-posterior direction. The portion of the superior-inferior direction is narrower than the two posterior prongs to avoid endplate prominences and so that the plate fit closely to the bone.

As a template to start a hole for the screw insertion, the vertebral staple increases the screw pullout force and has been shown to be very effective in preventing screw migration and screw pullout. Different sizes and shapes accommodate a variety of anatomical shapes of vertebra so as to allow the lateral plates to be fixed to either lumbar or thoracic vertebrae.

In the preferred method, the cancellous screw may receive the rectangle-shaped spinal plate via the anterior hole of the staple, which comprises a first end and a second end. The first end has an insertion tip with cancellous thread extending from the insertion-tip along a substantial portion of the first end. The second end defined as a protruding shaft extending outwardly from said first end with at least a portion of said protruding shaft threaded. The protruding shaft has the same diameter as the first end. The second end also includes a tool-engaging recess. The tool-engaging recess may be of any suitable configuration, including hexagonal, hexalobed, or any other suitable configuration. A wall junction is formed between the first end and second end. There are radial serrations on the top surface of the wall junction in the most end cancellous screw, but a plain top surface of the wall junction in the adjacent most end cancellous screw. The radial serrations allow the spinal plate to match the adjacent vertebral screw.

The preferred method may also include embodiments in which the rectangle-serrated washer is a rectangle-shaped washer, which comprises: a bottom side surface defined by a plurality of parallel serrations so that the washer can mount to the lateral plate to lock the anterior screw. The topside surface may be plain to receive the nut tightening, and the washer may further include an aperture in the central position of the washer. The rectangle-shape spinal plate also may have a sufficient length to cover more vertebrae, even from cephalad to caudal vertebrae of the instrumented segment.

CLAIMS

1. An anterior spinal instrumented method of treating spinal deformities, the spine having a convex side and a concave side, the method comprising the steps of:

on the convex side of the deformity, attaching two spinal plates to cephalad and caudal end vertebrae respectively;

fixing a rod anterior system on the posterior portion of the convex side, wherein a first spinal plate is attached on the most cephalad end vertebrae and a second spinal plate is attached on the most caudal end vertebrae through the vertebral screws of the single-rod anterior system;

correcting the deformity of the spine through compression, distraction, and/or derotation of the rod anterior system; and

inserting a plurality of cancellous screws into the cephalad and caudal end vertebrae and their adjacent vertebrae at the anterior portion of the convex side through the spinal plate which is connected to the rod spinal instrumentation.

2. The method of claim 1, wherein the spinal plate is an "L" shape that connects at least two vertebrae, wherein the spinal plate comprises:

a first end and a second end, a bottom surface for facing the vertebra and a top surface;

the first end comprising a longitudinal portion and a length sufficient to span between two vertebrae, wherein the longitudinal portion includes an elongated slot providing a series of openings for receiving screws such that the plate can be attached to the vertebrae, wherein the openings are configured to allow the screws to be positioned on the vertebra where desired and to accommodate different sized vertebrae, a plurality of serrations formed along the bottom portion of the slot, configured to prevent sliding of the spinal plate relative to the vertebrae, a beveled upper or outer edge portion of the slot, which conforms to the lower rounded surface of the head portion of a cancellous screw, and wherein a plurality of recesses is provided in the beveled edge portions to engage the lower rounded surface of the cancellous screw, effective to hold the screw against sidewise movement relative to the spinal plate, and wherein the recesses are defined by surfaces, which form a portion of a cone having the same included angle as the lower round surface of the screw head;

the second end comprising a transverse portion that is configured to fit together with the lateral side of the vertebra in anterior-posterior direction during use, wherein in the superior-inferior direction the plate's thickness is narrowed to avoid endplate prominence and so that the plate fits closely to the bone,

the transverse portion comprises a first aperture in the anterior region and a second aperture in the posterior region, wherein the second aperture is located in the middle point of the superior-inferior direction, and the first aperture is angled towards the center allowing a screw to be inserted in the posterior direction to avoid damaging the aorta and disrupting the front edge of the vertebral body during use, and providing a stable triangular screw construct in the vertebrae between the two screws and the transverse portion of the spinal plate;

wherein the bottom surface is slightly concave in shape so that it matches the vertebral anatomy for optimum anatomic fit and minimizes the construct profile in the anterior-posterior direction

wherein the top surface transverse portion forms an anterior hole configured with a beveled upper edge portion, which conforms to the lower rounded surface of a screw head and wherein the topside surface of the transverse portion is slightly convex in anterior-posterior direction so that it matches the vertebral anatomy.

3. The method of claim 2, wherein the angle between the longitudinal portion and the transverse portion is from 80° to 100°.

4. The method or claim 2, wherein the length of the longitudinal portion is sufficient to span more than two vertebrae.

5. The method of claim 1, wherein the cancellous screw includes a bone engaging portion having cancellous threads thereon, and a head portion;

the head portion comprising a lower rounded surface and an upper rounded surface, and wherein a generally cylindrical portion separates the lower rounded surface and the upper rounded surface and comprising a tool-engaging recess.

6. The method of claim 5, wherein the tool-engaging recess is hexagonal or hexalobed.

7. The method of claim 1, wherein the spinal plate is configured in a rectangle-shape that connects at least two vertebrae through a pair of similar upper and lower vertebral-staples, the plate comprising:

a first end and second end, the first end forming a hole and the second end forming an elongated u-shaped slot;

a bottom side surface configured to face the screw, and a top side surface configured to face a washer, wherein the perimeter of the hole on the bottom surface comprises a plurality of serrations extending radially about the hole so that the spinal plate can mount to a cancellous screw in varying angular orientations during use, and wherein the top side surface in the vicinity of the elongated u-shaped slot provides a plurality of parallel serrations effective to place the spinal plate in a variety of positions to match the adjacent bone screw through a rectangular, serrated washer.

8. The method of claim 7, wherein a pair of similar upper and lower vertebral staples are attached to both end vertebrae of the instrumentation segment, wherein the vertebral staples form a posterior hole and an anterior hole;

wherein the posterior hole is configured to receive a screw of the anterior rod system, and the anterior hole is configured to receive a cancellous screw for the spinal plate fixation;

and wherein a vertebral-staple is wedge-shaped and capable of securing a pair of metal tensioning cables to a vertebra via spinal screws, which comprises:

wherein the vertebral staples comprise two laterally extending members, one extending from each side of the staple in parallel relation to each other, wherein the distance between the first and second members is configured to fit snugly over either side of a vertebra during use;

wherein the vertebral staple comprises a third member perpendicular to the first and second members and located in the central position of the staple to avoid damaging the aorta and thoracic-abdominal organs during use;

wherein the vertebral staple forms an anterior aperture and a posterior aperture configured to receive spinal screw, wherein the posterior aperture is formed in the central portion of the staple between the first and second members and inclined toward the center of the anterior portion of the staple, the aperture forming portion being configured to allow an anterior screw to be directed in a posterior direction to avoid damaging the aorta and disrupting the front edge of the vertebral body for good purchase during use; the posterior aperture forming portion being configured to allow a posterior vertebral screw to be directed in an anterior direction to avoid the injury to a spinal cord during use; wherein the anterior and posterior apertures are configured to provide a stable triangular screw construct in the vertebra between the two screws and the staple during use;

wherein the vertebral staple comprises an integral substantially solid and wedge-shape laminal bridge portion which is slightly convex in shape, configured to match the vertebral anatomy for optimum anatomic fit and to minimize the construct profile of the anterior-posterior direction, wherein the superior-inferior portion is narrower than the portion adjoining the first and second members to avoid endplate prominences and to fit the plate fit closely to the bone during use.

9. The method of claim 8, wherein the vertebral staple is configured to be fixed to a lumbar vertebra.

10. The method of claim 8, wherein the vertebral staple is configured to be fixed to a thoracic vertebra.

11. The method of claim 7, comprising inserting a cancellous screw through the anterior hole of the staple, the cancellous screw comprising:

a first end and a second end, the first end comprising an insertion tip with cancellous thread extending from the insertion-tip along a substantial portion of the first end, the second comprising a shaft extending from the first end in the direction opposite the insertion tip, wherein at least a portion of the shaft is threaded and wherein the end of the shaft provides a tool engaging recess; and

a wall junction formed between the first end and second end.

12. The method of claim 11, wherein the wall junction comprises radial serrations on the top surface thereof.

13. The method of claim 11, wherein the tool engaging recess is hexagonal or hexalobed.

14. The method of claim 7, wherein the rectangular-serrated washer comprises:

a bottom side surface comprising a plurality of parallel serrations configured to mount to the lateral plate to lock the anterior screw;

a topside surface configured to receive a nut.

15. The method of claim 7, comprising a rectangular spinal plate configured to connect at least two vertebrae without use of upper and lower vertebral-staples, the plate comprising:

a first end portion providing an aperture and a second end forming a series of openings for receiving bone screws; wherein a plurality of serrations are formed along the bottom of the plate, and wherein the top edges of the openings are beveled to conform to the lower rounded surface of the head portion of a cancellous screw.

16. The method of claim 8, wherein the first and second members each terminate in an offset laminar posterior leg, configured to be inserted into vertebral endplates during use.

17. The method of claim 8, wherein the posterior aperture receives a screw of the anterior rod system, and the anterior aperture receives a cancellous screw for spinal plate fixation, wherein the vertebral-staple is wedge-shaped and capable of securing a pair of metal tensioning cables to a vertebra via spinal screws;

wherein the first and second members are located in a central position of the staple to avoid damaging the aorta and thoracic-abdominal organs during use;

wherein the posterior aperture is located in the corner portion of the posterior aspect of the staple plate and the anterior aperture is inclined towards the posterior portion and located in the anterior aspect of the staple plate, wherein the anterior aperture geometrically allows the anterior screw to be directed in a posterior direction to avoid damaging the aorta and disrupting the front edge of the vertebral body for good purchase, wherein the posterior aperture allows the posterior vertebral screw to be directed in an anterior direction to avoid injury to the spinal cord during use, and wherein the two-hole design provides a stable triangular screw construct in the vertebra between the two screws and the staple during use; and

an integral substantially solid and wedge-shape laminal bridge portion which is slightly convex in shape so that it matches the vertebral anatomy for optimum anatomic fit to minimize the construct profile of the anterior-posterior direction.

18. the method of claim 17, wherein the staple is sized to be fixed to a lumbar vertebra.

19. The method of claim 17, wherein the staple is sized to be fixed to a thoracic vertebra.

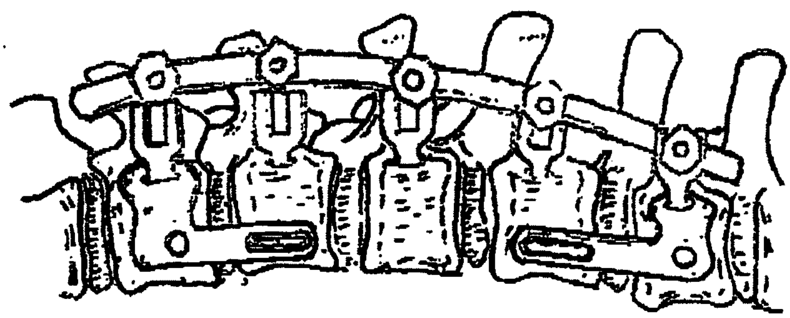

Fig. 1a

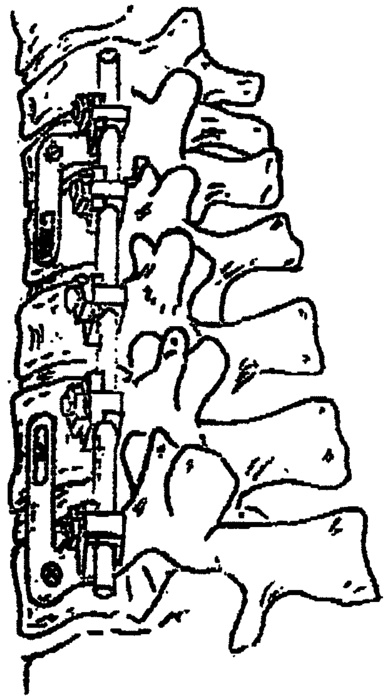

Fig. 1b

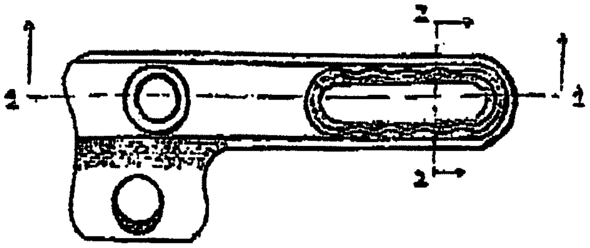

Fig. 2a

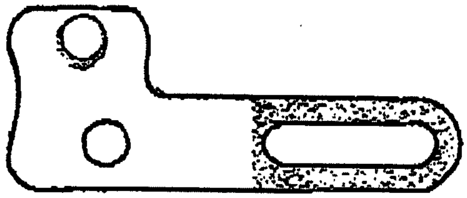

Fig. 2b

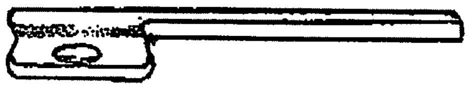

Fig. 2c

Fig. 2d

Fig. 2e

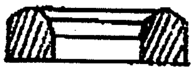

Fig. 2f

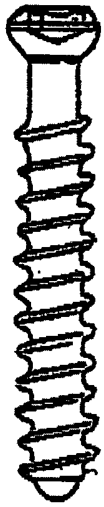

Fig. 3a

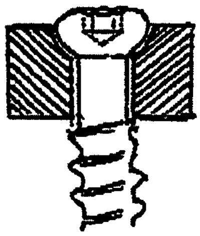

Fig. 3b

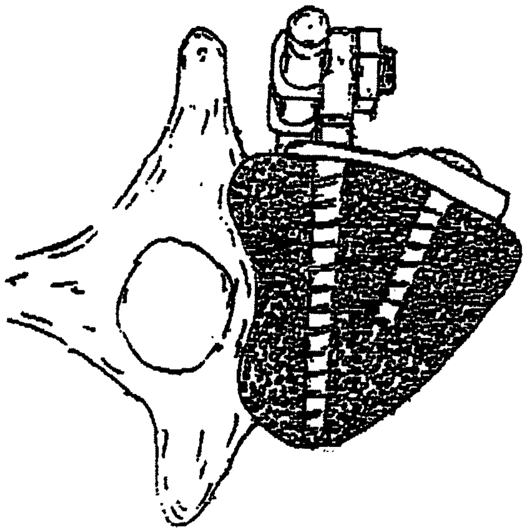

Fig. 4

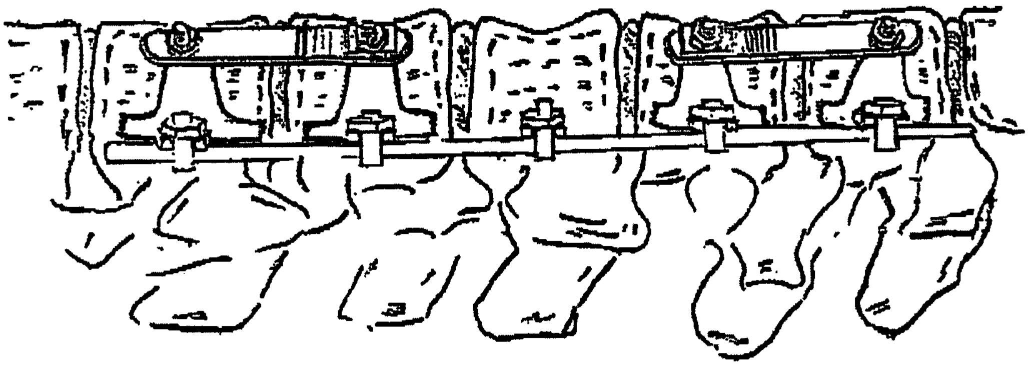

Fig. 5

Fig. 6a

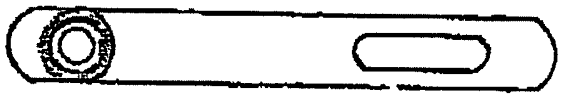

Fig. 6b

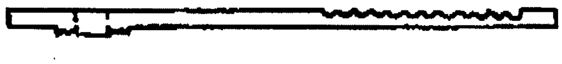

Fig. 6c

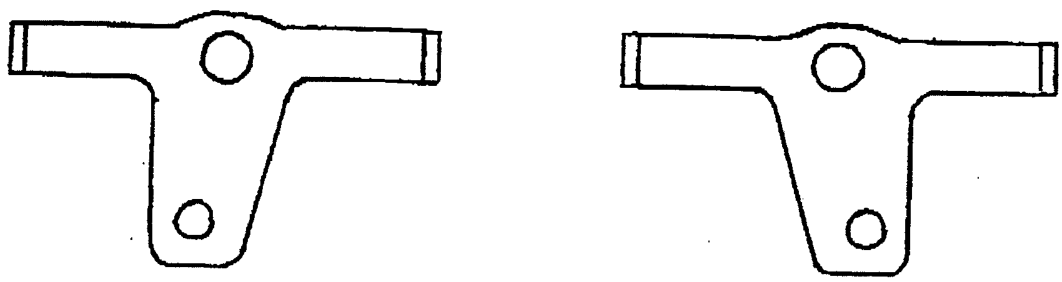

Fig. 7a

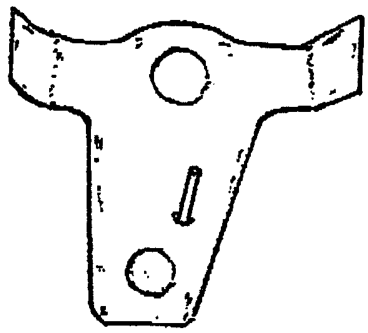

Fig. 7b

Fig. 7c

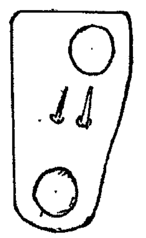

Fig. 7d

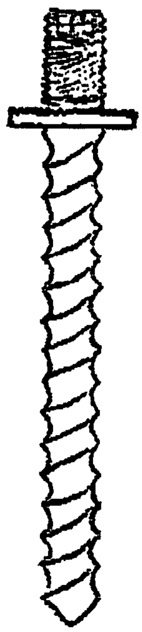

Fig. 8a

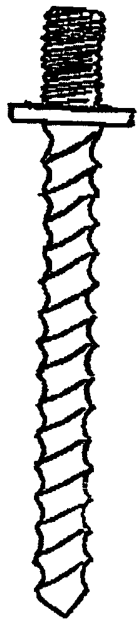

Fig. 8b

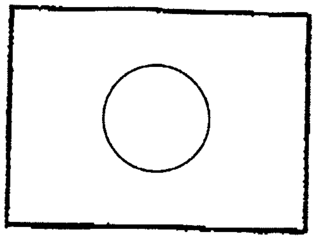

Fig. 9a

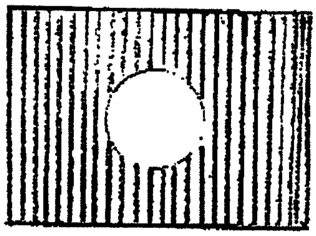

Fig. 9b

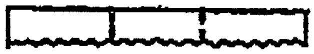

Fig. 9c

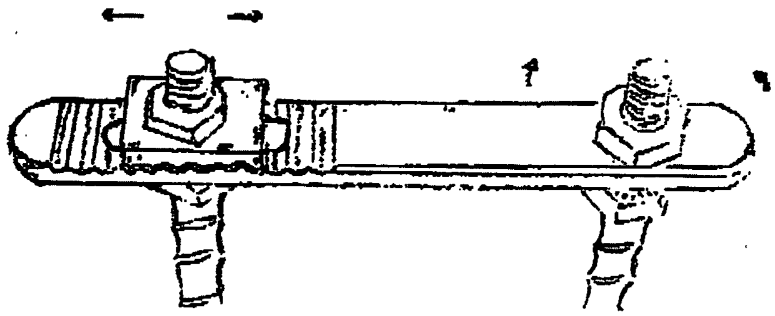

Fig. 10

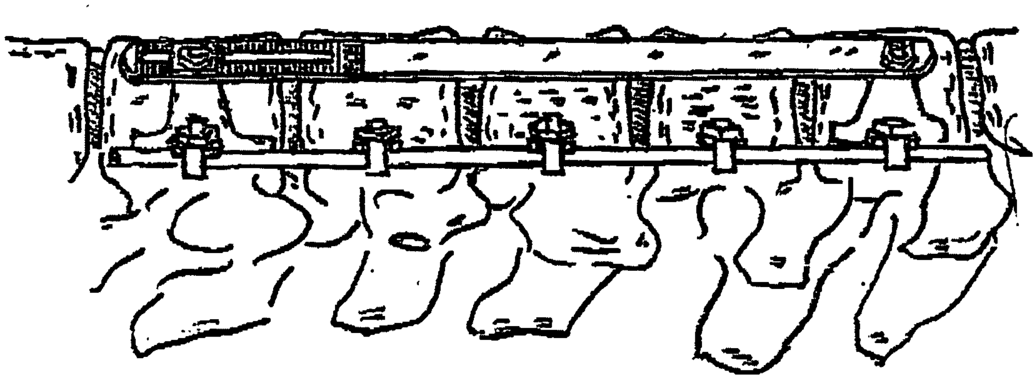

Fig. 11

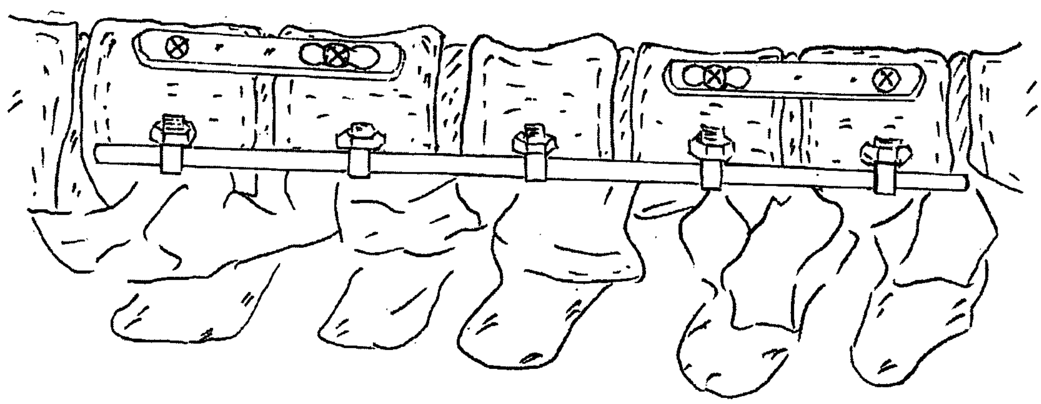

Fig. 12

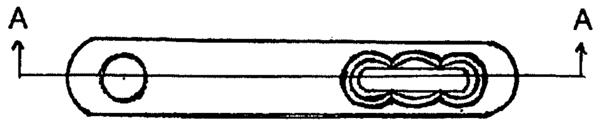

Fig. 13a

Fig. 13b

Fig. 13c

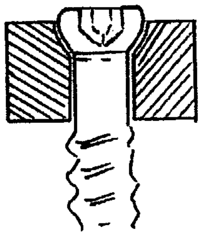

Fig. 13d