Title: TEMPORARY SPINE FIXATION DEVICE AND METHOD

Abstract: A temporary spine fixation device for application to the spine of a patient comprising an alignment plate (2) having top and bottom surfaces for temporary attachment to a pair of adjacent vertebrae (v) on a body, a pair of surgical screws (5), a fixation plate (3), and a pair of nuts (4). The alignment plate (2) has a means for preventing the plate (2) from moving transversely with respect to the longitudinal axis of the plate and the spine. It also has a pair of openings (7) spaced from each other a distance such that the openings (7) open onto adjacent vertebrae (v). In addition, the alignment plate (2) has a predetermined angle formed therein so as to position adjacent vertebrae (v) at said predetermined angle. The pair of surgical screws (5) are adapted to pass through the pair of openings (7) in the alignment plate (2) and to screw into the adjacent vertebrae (v) of the patient, over the openings (7) in the alignment plate (2).
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TEMPORARY SPINE FIXATION DEVICE AND METHOD

TECHNICAL FIELD

This invention relates to the field of surgical devices and methods to temporarily fix adjacent vertebrae in the spine.

More specifically, the present invention is a device and method which fixes adjacent vertebrae together to prevent movement of vertebrae with respect to each other during surgical operations involving the insertion of spinal implants or plugs to fuse the adjacent vertebrae together.

BACKGROUND OF ART

The history and art surrounding surgical articles and methods to aid in the fusion of adjacent vertebrae is aptly chronicled in United States Patent No. 5,797,909 to Michelson. Although a recap of that history is not necessary here, an understanding of the Michelson apparatus and method is necessary to appreciate the present invention.

The Michelson apparatus and method are believed to represent the current state of the art in temporary fixation of adjacent vertebrae during surgical procedures. As such, the Michelson invention appears to be widely used for spinal fusion operations. Essentially, the primary embodiment of the Michelson apparatus is a hollow sleeve with teeth at one end. When used in surgeries from the anterior aspect of the patient, the sleeve is driven into adjacent vertebrae over the anterior aspect of the intervertebral space between the vertebrae which are to be fused. The teeth, when driven into the adjacent vertebrae, work to help stabilize the anterior portions of the two vertebrae and, therefore, the intervertebral space during the various drilling and other surgical operations taking place through the hollow sleeve and within the intervertebral space.

In use, however, the teeth may allow some unwanted relative movement of the vertebrae because they do not stabilize both the anterior
and posterior aspects of the vertebrae. This is especially a concern during drilling operations where creating holes with parallel sides in the intervertebral space and the adjacent vertebral end plates is crucial. For example, when the known apparatus is attached to the anterior aspect of the adjacent vertebrae and drilling is commenced in the intervertebral space from the anterior aspect towards the posterior aspect, the force of the drill may cause the vertebral end plates of the adjacent vertebrae to separate at the posterior aspects of the vertebrae. Because of this movement, the sides of the hole drilled in the vertebral end plates will taper and will not be parallel when the drill is removed from the hole.

It is believed that this tapering of the walls of the drilled hole can be significant and detrimental. It is believed that this degree of inaccuracy may lead to misalignment of the fused vertebrae as well as the exertion of excessive pressures on parts of the plug inserted into the hole to fuse the vertebrae. This later consequence is of particular concern where a relatively fragile bone cage plug is used because the irregular pressures can damage the plugs. By temporarily fixing the adjacent vertebrae in all relevant planes, even during drilling and other surgical procedures, the present invention provides for the complete relative stabilization of the adjacent vertebrae, thus ensuring the accuracy and precision of surgical procedures performed on the vertebrae.

DISCLOSURE OF INVENTION

The apparatus aspect of the invention is a temporary spine fixation device for application to the spine of a patient. It includes an alignment plate having top and bottom surfaces for temporary attachment to a pair of adjacent vertebrae on a body, a pair of surgical screws, a fixation plate, and a pair of nuts. The alignment plate interacts fixation pins which prevent the plate from moving transversely with respect to the longitudinal axis of the plate and the spine. It also has a pair of openings spaced from each other a distance such that the openings open onto adjacent vertebrae. In addition,
the alignment plate has a predetermined angle formed therein so as to position the adjacent vertebrae at said predetermined angle.

The pair of surgical screws are adapted to pass through the pair of openings in the alignment plate and to screw their proximal ends into the adjacent vertebrae of the patient. The fixation plate has a pair of openings disposable over the openings in the alignment plate, which allow the distal ends of the surgical screws to pass therethrough. The fixation plate also has a predetermined angle formed therein substantially corresponding to the angle in said alignment plate.

Finally, the pair of nuts is disposed on the distal ends of the surgical screws to hold the fixation plate securely in place over the alignment plate. The adjacent vertebrae are thus fixedly secured at the predetermined angle by the apparatus.

In the method aspect, the invention consists of a procedure to temporarily fix the spine, comprising multiple steps. First, the physician temporarily attaches an alignment plate to a pair of adjacent vertebrae in a body and fixes the alignment plate from moving transversely with respect to the longitudinal axis of the plate through the use of fixation pins. Next, a pair of surgical screws are installed through the alignment plate into adjacent vertebrae so as to position the adjacent vertebrae at a predetermined angle with respect to each other. Then a fixation plate is fastened over the alignment plate to hold the fixation plate securely in place over the alignment plate. Thus, the adjacent vertebrae are fixedly secured at the predetermined angle by the alignment plate and the fixation plate.

Other objects and features will be in part apparent and in part pointed out hereinafter.

BRIEF DESCRIPTION OF DRAWINGS

Figure 1 is a side view of the inventive apparatus installed on the anterior aspects of adjacent vertebrae;

Figure 2 is a top view of the alignment plate;
Figure 3 is a perspective view of the alignment plate;
Figure 4 is a top view of the fixation plate;
Figure 5 is an exploded view of the sleeves, temporary spacer and sleeve cap;
Figure 6 is a perspective view of the apparatus; and
Figure 7 is another perspective view of the apparatus showing a cut-away view of the sleeve.
Similar reference characters indicate similar parts throughout the several views of the drawing.

MODE[S] FOR CARRYING OUT THE INVENTION

Turning to Figure 1, we see a cross section of the inventive apparatus, generally 1, disposed on adjacent vertebrae V over an intervertebral space I. The apparatus comprises an alignment plate 2, a fixation plate 3, two surgical screws 5, and two surgical nuts 4. As shown in Figures 2 and 3, the alignment plate 2 has top 12 and bottom 15 surfaces as well as a predetermined angle 16 formed between the ends of the plate 2. The alignment plate 2 also contains a pair of openings 7. The openings 7 are spaced from each other such that when the alignment plate 2 is affixed to the adjacent vertebrae V, the openings 7 each open onto a different vertebrae V.

The alignment plate 2 also interacts with a movement prevention means, which includes, as shown in Figure 1, the fixation pins 9. The fixation pins 9 prevent transverse movement of the plate 2 when initially mounted to the vertebrae V and could comprise small screws, nails or other suitable elements. In the preferred embodiment, one pin 9 is driven into each of the vertebrae V through holes 10 in the alignment plate 2. The holes 10 are sized such that their width, as measured perpendicular to the longitudinal axis of the plate 2, is only slightly larger than the corresponding width of the pins 9. This interference fit prevents movement of the plate 2 in a transverse direction perpendicular to its longitudinal axis. As shown in Figures 2 and 3, however, the longitudinal dimension of the holes 10 may, if desired, exceed the corresponding dimension of the pins 9. In this way the
apparatus allows for longitudinal movement of the plate 2 when initially mounted on the vertebrae V by the pins 9.

The movement prevention means also serves to aid in the convenient mounting of the plate 2 with the screws 5. By allowing the surgeon to transversely fix and align the plate 2 to the vertebrae V before attempting to install the screws 5, the surgeon’s workload is reduced and more accurate alignment of the plate 2 is possible.

As shown in Figures 1 and 3, the angle 16 in the alignment plate 2 ensures proper alignment of the vertebrae V once the apparatus 1 is mounted to them. Similarly, the self-centering spacer 11, shown in Figure 3, extends into the intervertebral space I and ensures that the proper spacing between the vertebrae V is achieved and maintained as the apparatus 1 is mounted. The self-centering nature of the spacer 11 ensures that the alignment plate 2 is properly centered over the intervertebral space I. Given the natural variances in spinal geometry due to differently sized patients and other factors, the spacer 11 may come in varying sizes and shapes.

To ensure effective use of the apparatus 1, a surgical kit for use of the invention may contain alignment plates 2 of various sizes, varying angles 16, and with various sizes of spacers 11. To lower the number of parts in such a kit, the spacers 11 may be removable and interchangeable among various sizes of alignment plates 2.

The openings 7 of the plate 2 are sized to receive the surgical screws 5. As shown in Figure 1, although the shanks of the screws 5 are of a slightly smaller diameter than that of the opening 7, the screw contains a flange 6, the diameter of which is larger than the opening 7. As a result, when the proximal end of the screw 5 is passed through the opening 7 when the screw 5 is inserted into the vertebrae V, progress of the screw 5 through the plate 2 is stopped by the contact of the flange 6 with the top surface 12 of the alignment plate 2. Thus, the screw 5 securely holds the alignment plate 2 to the vertebrae V.
The fixation plate 3, shown in Figures 1, 4 and 6, is secured to the apparatus 1 by placing it onto the alignment plate 2 with the distal ends of the screws 5 passing through openings 13 in each end of the fixation plate 2 and by tightening two nuts 4 onto the screws 5 and fixation plate 3. The openings 13 may, if desired, be sized such that their longitudinal dimension is greater than the diameter of the screws 5. In this way, the fixation plate 3 may be moved longitudinally with respect to the alignment plate 2. Like the alignment plate 2, the fixation plate 3 also has a predetermined angle formed therein, which substantially corresponds to the angle in the alignment plate 2 and the angle between the now-fixed adjacent vertebrae V.

The apparatus 1 may also contain a guide or guide rod 8 to aid in the alignment of other surgical instruments. As shown in Figures 1 and 3, this guide 8 may be a rod extending upwards from the top surface 12 of the alignment plate 2 through a hole 14 in the fixation plate 3. Alternatively, the guide 8 may extend upwards from the top surface of the fixation plate 3.

Unlike when it is part of the alignment plate 2, when the guide 8 is mounted to the fixation plate 3, the longitudinally extended openings 13 in the fixation plate 3 allow for some longitudinal movement of the guide 3 with respect to the vertebrae V. A surgeon may use this increased mobility to ensure accurate alignment of surgical instruments to the intervertebral space I. Also, the surgical instruments may be secured to the guide 8 on either side of the apparatus 1. In this way, a surgical instrument mounted to the guide 8 may, if desired, be swung from one longitudinal side of the apparatus 1 to the other for work on either side of vertebrae V, as shown in Figure 6. Thus, precise spacing and angular alignment of the vertebrae V is guaranteed during the drilling, tapping and inserting of the fixation implant (bone cage, plug, etc.).

As shown in Figures 5, 6 and 7, the apparatus 1 may also include one or more temporary spacers 17 for use during the procedure as well as one or more hollow sleeves 18. This temporary spacer 17 is self-centering in the longitudinal direction of the spine and sized to fit within the intervertebral
space V on one lateral side of the apparatus 1. The temporary spacer 17 may have a stem 19 permanently or removably secured to the head 22 of the temporary spacer 17. The stem 19 may be used to manipulate and manually align the temporary spacer 17 within the space V as well as to insert and remove the temporary spacer 17 itself.

Alignment of the temporary spacer 17 with the attached stem 19 also may be maintained through the use of a cap 20 on the sleeve 18. As shown in Figure 7, the stem 19 may be of sufficient length that it will extend though a hole 21 in the center of the cap 20 when the temporary spacer 17 is placed in the sleeve 18 and the sleeve cap 20 is placed on the end of the sleeve 18.

In the method aspect, the invention consists of a procedure to temporarily fix the spine, comprising multiple steps. First, the physician attaches an alignment plate 2 to a pair of adjacent vertebrae V on a body and simultaneously fixes the alignment plate 2 from moving transversely with respect to the longitudinal axis of the plate 2 and the spine using pins 9. Next, a pair of surgical screws 5 are installed through the alignment plate 2 into adjacent vertebrae V so as to position the adjacent vertebrae V at a predetermined angle 16 with respect to each other. Then a fixation plate 3 is fastened over the alignment plate 2 to hold the fixation plate 3 securely in place over the alignment plate 2, whereby the adjacent vertebrae V are fixedly secured at the predetermined angle 16 by the alignment plate 2 and the fixation plate 3.

Surgical fixation of the spine may then proceed with the use, if desired, of a hollow sleeve 18. As shown in Figure 6 by the dashed element 18a, the sleeve 18 is removably connected to the guide 8 and is repositionable on either lateral side of the apparatus 1 over the intervertebral space I. When operatively connected to the guide 8, the sleeve 18 may be used to help guide and align surgical instruments such as a drill or a temporary spacer 17. In addition, the sleeve 18 may have teeth 23 on one
end which may be driven into the vertebrae V over the space I to help stabilize the sleeve 18 during the fixation operation.

In view of the above, it will be seen that the several objects of the invention are achieved and other advantages are attained. As various changes could be made in the above construction without departing from the scope of the invention, it is intended that all matter contained in the above description shall be interpreted as illustrative and not limiting.
CLAIMS

1. A temporary spine fixation device comprising:
   an alignment plate, having top and bottom surfaces, for temporary
   attachment to a pair of adjacent vertebrae on a human body;
   said alignment plate having means for preventing said plate
   from moving transversely with respect to the longitudinal axis of the
   plate,
   said alignment plate further having a pair of openings spaced
   from each other a distance such that the openings open onto adjacent
   vertebrae,
   said alignment plate having a predetermined angle formed
   therein so as to position adjacent vertebrae at said predetermined
   angle;
   a pair of surgical screws adapted to pass through the pair of openings
   in the alignment plate and to screw into the adjacent vertebrae;
   a fixation plate having a pair of openings disposable over the openings
   in the alignment plate and allowing the distal ends of the surgical screws to
   pass therethrough;
   said fixation plate having a predetermined angle formed
   therein substantially corresponding to the angle in said alignment
   plate; and
   a pair of nuts disposable on the distal ends of the surgical screws to
   hold the fixation plate securely in place over the alignment plate, whereby
   the adjacent vertebrae are fixedly secured at the predetermined angle by the
   alignment plate and the fixation plate.

2. The temporary spine fixation device as set forth in Claim 1
   wherein the screws have a flange with a diameter larger than at least one
   dimension of the openings in said alignment plate such that when said
   screws are screwed into the adjacent vertebrae through the openings in said
   alignment plate, the flange rests on the top surface of said alignment plate
   and firmly secures the alignment plate to the vertebrae.
3. The temporary spine fixation device as set forth in Claim 1 wherein the alignment plate has an alignment spacer on its bottom surface; said alignment spacer having a predetermined length as measured along the longitudinal axis of the plate wherein the predetermined length is equal to the desired spacing between the adjacent vertebrae; and said alignment spacer is oriented on the bottom surface of the alignment plate such that when the alignment plate is installed on the adjacent vertebrae, said alignment spacer is between the adjacent vertebrae in the intervertebral space.

4. The temporary spine fixation device as set forth in Claim 3 wherein the alignment spacer is removable from the alignment plate.

5. The temporary spine fixation device as set forth in Claim 1 wherein the means for preventing the alignment plate from moving transversely comprises pins installed into the adjacent vertebrae and corresponding holes in the alignment plate shaped to prevent transverse movement of said alignment plate when the alignment plate is mounted to the adjacent vertebrae with said pins extending into said corresponding holes.

6. The temporary spine fixation device as set forth in Claim 5 wherein said corresponding holes are shaped so as to allow movement of the alignment plate along its longitudinal axis when the alignment plate is mounted to the adjacent vertebrae with said pins extending into said corresponding holes.

7. The temporary spine fixation device as set forth in Claim 1 wherein the openings in the fixation plate are shaped to allow the fixation plate to move along its longitudinal axis with respect to the alignment plate and the surgical screws.

8. The temporary spine fixation device as set forth in Claim 1 further comprising a guide for facilitating the accurate alignment of surgical procedures with respect to the adjacent vertebrae.
9. The temporary spine fixation device as set forth in Claim 8 wherein the guide comprises a post extending upward from the top surface of the alignment plate and through a hole in the fixation plate for operative connection with a drill or other surgical instrument requiring alignment with respect to the adjacent vertebrae.

10. The temporary spine fixation device as set forth in Claim 8 wherein the guide comprises a post extending upward from the top surface of the fixation plate for operative connection with a drill or other surgical instrument requiring alignment with respect to the adjacent vertebrae.

11. The temporary spine fixation device as set forth in Claim 8 wherein the guide is positioned such that the drill or other surgical instrument may be rotated around the guide from one side of the longitudinal axis of the plates to the other to guide drilling or other work into the vertebrae on both sides of the longitudinal axis.

12. The temporary spine fixation device of Claim 8 further comprising:
   
a hollow sleeve removably connected to said guide;
   
a temporary spacer having a stem, said temporary spacer sized to fit through said hollow sleeve and into an intervertebral space; and
   
a cap sized to fit over the end of said hollow sleeve, said cap having a hole through which the stem of the temporary spacer may extend.

13. The temporary spine fixation device of Claim 12 wherein said sleeve has teeth on one end for insertion into adjacent vertebrae over the intervertebral space.

14. A method of temporarily fixing the spine, comprising the steps of:
   
temporarily attaching an alignment plate to a pair of adjacent vertebrae on a body and fixing the alignment plate from moving transversely with respect to the longitudinal axis of the alignment plate;
placing a pair of surgical screws through the alignment plate into adjacent vertebrae so as to position adjacent vertebrae at a predetermined angle with respect to each other;

fastening a fixation plate over the alignment plate to hold the fixation plate securely in place over the alignment plate, whereby the adjacent vertebrae are fixedly secured at the predetermined angle by the alignment plate and the fixation plate.

15. The method of Claim 14 further comprising the step of drilling at least one hole into or between the adjacent vertebrae on each side of the alignment plate, said alignment plate and fixation plate holding the adjacent vertebrae at the predetermined angle while the holes are being drilled.

16. The method of Claim 15 further including the step of placing a hollow sleeve in operative contact with a guide and using the sleeve to guide the drilling.

17. The method of Claim 16 further including the step of placing a temporary spacer through the hollow sleeve and into the intervertebral space.

18. The method of Claim 17 further including the step of maintaining the alignment of the temporary spacer by placing a cap over the posterior end of the hollow sleeve with the stem of the temporary spacer passing through a hole in the cap sized to prevent lateral movement of the stem.
**INTERNATIONAL SEARCH REPORT**

**International application No.**

PCT/US00/24464

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/44
US CL. : 606/69

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U. S. : 606/1, 66-70

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

none

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US 5,766,254 A (GELBARD) 16 June 1998, see entire document.</td>
<td>1, 2, 7 and 14</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C.

See patent family annex.

Date of the actual completion of the international search

20 OCTOBER 2000

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05 JANUARY 2001

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks

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