Title: METHOD AND INSTRUMENT FOR DISTRACTING INTERVERTEBRAL SPACE

Abstract: A surgical instrument for use in distraction of vertebral discs is provided that has a handle end and a tip end, and a pair of elongated members each having grips at the handle end and jaws at the tip end. The members are pivotally connected together. The instrument has a biasing mechanism that serves to urge the jaws toward each other and also includes a ratcheting mechanism that allows the jaws to be held apart at predetermined distances. Preferably, the handle end of the instrument is offset from the tip end and the jaws may be offset from the tip end.
METHOD AND INSTRUMENT FOR DISTRACTING INTERVERTEBRAL SPACE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a method and instrument for aiding in the process of inserting an implant between adjacent bone structures. More particularly, the present invention relates to a method and instrument for distracting the intervertebral space between two adjacent vertebrae.

2. Description of the Prior Art

Intervertebral spinal fusion, a fast growing surgical specialty, is the process of using a bone graft or similar structure to cause two opposing vertebrae to grow or fuse together. This procedure is commonly used to alleviate back pain resulting from age, excessive use, injury, disease and degenerative disorders. The various techniques for this type of procedure are well known and include both anterior and posterior methods. Typically, the procedure involves the steps of removing an injured disc, distracting the adjacent vertebrae to the appropriate anatomical height via
mechanical force, and inserting a natural or artificial vertebral implant into
the intervertebral space previously occupied by the removed disc.

The step of distracting the adjacent vertebrae to the appropriate
anatomical height is typically accomplished by a distractor mechanism.
The distractor allows a surgeon not only the ability to insert the implant,
but also the ability to position and/or manipulate the inserted implant using
additional instruments.

There are several limitations to the intervertebral spinal fusion
procedure. The careful and non-traumatic separation of adjacent
vertebrae can be extremely difficult. In addition, it is difficult to maintain
adequate and accurate spacing during the implant insertion process.
Further, the intervertebral spinal fusion process requires the difficult
concurrent manipulation of several instruments.

The present invention provides for a method and instrument that
addresses the above-identified limitations. The present invention
facilitates the introduction of an implant structure by first, deftly restoring
the intervertebral space, second, providing a surgeon with more operating
space during the surgical procedure, third, providing a surgeon with
greater visibility of the treatment site by providing distractor handles angled out of the plane of the instrument, fourth, providing a calibration system for matching the distractor height to a predetermined height of an intervertebral space, fifth, providing a locking mechanism for maintaining the intervertebral space once the proper anatomical height has been achieved, and sixth, providing an ergonomic instrument that allows for the quick release of the locking device with the same hand that holds the distractor handles.

10 SUMMARY OF THE INVENTION

It is an object of the present invention to provide a method and instrument for efficiently and effectively restoring the intervertebral space between adjacent vertebrae.

15 It is yet another object of the present invention to provide an instrument that is configured to be relatively lightweight and easily handled.

It is still another object of the present invention to provide such a method and instrument that separates vertebrae to a predetermined distance.
It is a yet another object of the present invention to provide such a method and instrument that maintains the proper distance, referred to as the proper anatomical height, once it has been achieved.

It is a further object of the present invention to provide such a method and instrument that allows for a quick release such that the separated vertebrae may attempt to return to their original position.

It is still a further object of the present invention to provide a method and instrument that makes available additional operating space for performing the different procedures associated with intervertebral spinal fusion.

It is yet a further object of the present invention to provide a ratcheting distractor instrument in which the jaws of the distractor are angled out of the plane of the distractor mechanism, thereby preventing obstruction of the view of the intervertebral space treatment site while further operating steps are being undertaken.
These and other objects and advantages of the present invention are achieved by a surgical instrument for use in distraction of vertebral discs. The instrument has a pair of elongated members each having a grip at a first end and a jaw at the opposite end. The members are pivotally connected together. The instrument also has a biasing mechanism that serves to urge the jaws toward each other and a ratcheting mechanism that allows the jaws to be held apart at predetermined distances. The handle end of the instrument is offset from the tip end and the jaws may be offset at the tip end.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of a surgical instrument in accordance with a preferred embodiment of the present invention;

Figure 2 shows a cross sectional view of instrument 5 at section AA in Figure 1;

Figure 3 is a top view of the instrument of Figure 1; and

Figure 4 is an enlarged top view of the instrument of Figure 1, showing an offset between a tip end and a jaw of the instrument.
DETAILED DESCRIPTION OF THE INVENTION

Referring to the figures and, in particular, Fig. 1, there is shown a surgical instrument generally represented by reference numeral 5.

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Instrument 5 has a pair of elongated members 20, 25 that extend from a first or handle end 10, to a second opposite or tip end 15. Instrument 5 also has a biasing mechanism 100 and a ratcheting mechanism 105.

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Each member 20, 25 has a grip 30, 35, respectively, at handle end 10 and a jaw 40, 45, respectively, at tip end 15 of instrument 5. Members 20, 25 are pivotally connected together between their grips 30, 35 and jaws 40, 45 at pivot point 47. Pivot point 47 is preferably positioned toward tip end 15 so that a minor movement of grips 30, 35 toward each other results in a much larger movement of jaws 40, 45 apart from each other. That is, as a user squeezes grips 30, 35, jaws 40, 45 separate proportionately.
Referring to Figure 2, an example of pivot point 47 is illustrated showing members 20 and 25 pivotally connected.

Returning to Figure 1, members 20, 25 are preferably curved so that they converge toward each other in the vicinity of pivot point 47.

Grips 30, 35 may have a pad portion 50, 55 respectively, to assist a user in grasping and applying a squeezing force to handle end 10 of instrument 5. Each pad portion 50, 55, preferably has a textured surface 60, 65 that preferably is one or more grooved or waved surfaces, respectively, to assist in grasping. Grips 30, 35 may be contoured to also facilitate grasping.

Each jaw 40, 45 preferably has a smooth, rounded front edge 80, 85, respectively, to ease insertion of jaws 40, 45 between vertebrae. Each jaw 40, 45 preferably also has wide flat outer surfaces 70, 75, respectively, to properly distribute force across the vertebrae surfaces during separation.
Biasing mechanism 100 of instrument 5 urges jaws 40, 45 toward each other. Biasing mechanism 100 may be a coil spring, elastomeric member, leaf spring, or any other mechanism suitable for biasing jaws 40, 45 in a direction toward each other. Preferably, biasing mechanism 100 is a leaf spring having two spring members 145, 150. Spring member 145 is fastened at a first end to an inner surface of member 20, while spring member 150 is fastened at a first end to an inner surface of member 25. The second ends of spring members contact each other, causing the first end to apply force the inner surfaces of members 20 and 25, pushing them apart at handle end 10. This results in jaws 40, 45 being urged together at tip end 15 of instrument 5.

Ratcheting mechanism 105 allows jaws 40, 45 to be held apart at predetermined distances. Once jaws 40, 45 have been set apart at a predetermined distance, they can be held stationary without requiring continuous application of force. Ratcheting mechanism 105 is preferably located on handle end 10 of instrument 5. Ratcheting mechanism 105 has an interlocking plate 110 attached to the end of grip 30 and a corresponding grooved plate 115 fixed in one position at the end of grip 35. Interlocking plate 110 and grooved plate 115 are slidably retained against each other, and each includes an opposed set of grooves such that the grooves on the interlocking plate interlock with those on the grooved plate. As force is applied to grips 30, 35 and they move toward
each other, interlocking plate 110 and grooved plate 115 slide with respect to each other. As the sliding action progresses the opposed sets of grooves interlock at predetermined intervals, holding the grips together at predetermined distances. This results in the jaws 40, 45 being held apart at predetermined distances.

Interlocking plate 110 is pivotally mounted to the end of grip 30 so that it can be deflected away and disengaged from grooved plate 115. Interlocking plate 110 may have a tab 120 positioned along one side so that a user may apply pressure to the tab, causing interlocking plate 110 to swing away from grooved plate 115. This in turn may cause the opposing sets of grooves on interlocking plate 110 and grooved plate 115 to disengage. As a result, biasing mechanism 100 urges grips 30, 35 apart and jaws 40, 45 toward each other.

Ratcheting mechanism 105 may have a calibration system to determine the amount of distraction of the intervertebral space. The calibration system preferably is a scale 125 that allows a user to determine the distance between jaws 40, 45. Scale 125 is preferably calibrated to stop at distances one millimeter (mm) longer than standard bone sizes. For example, if scale 125 indicates a distance of 11 mm, the space between the vertebrae is prepared for a 10 mm bone or an implant
having a 10 mm bone size. Thus, once set, ratcheting mechanism 105 can maintain the proper intervertebral spacing, also referred to as the anatomical height, between vertebrae.

The instrument 5 is preferably formed from a surgical grade material. Such materials include steel, titanium, polymer, a composite material, or any other material suitable for the fabrication of surgical instruments. The instrument 5 is preferably lightweight and easily handled, but rigid enough to apply the proper forces for distraction. The instrument 5 may be sterilizable, and used multiple times, or may be disposable.

Referring to Figure 3, handle end 10 of instrument 5 is offset from tip end 15 to facilitate other operations that may be performed in conjunction with distraction. In a preferred embodiment, handle end 10 of instrument 5 lies in a first reference plane 130 and tip end 15 lies in a second plane 135 that is angularly displaced at angle A with respect to the reference plane. This offset allows tip end 15 of instrument 5 to be inserted at an angle to handle end 10, thus allowing for additional operating space and better visualization of the treatment area. For example, when performing various different procedures associated with intervertebral spinal fusion, instrument 5 may be angled away from the
operating field, allowing additional space for cleaning, deburring, implant insertion, etc.

As an additional aid in providing operating space and better visualization of the treatment area, jaws 40, 45 may be offset from the second plane 135 of tip end 15 of instrument 5. In the embodiment shown in Figure 4, it can be seen that the centerline of jaws 40, 45 lies in a third plane 140 that is offset a distance D from second plane 135 of tip end 15.

In operation, grips 30, 35 of instrument 5 are moved apart so that jaws 40, 45 are closed together. Jaws 40, 45 are placed between adjacent vertebrae that are to be distracted or separated. Grips 30, 35 are squeezed together until the vertebrae are separated a specific distance. The distance may be determined by observation of the vertebrae visually, by using fluoroscopy, x-ray, endoscopic techniques, etc., or by observing scale 125 on ratcheting mechanism 55. Once the vertebrae are distracted to the desired distance, other operations may be performed on the vertebrae such as implant insertion, and associated operations of cleaning, scraping, debulking, etc.
The present invention having been thus described with particular reference to the preferred forms thereof, it will be obvious that various changes and modifications may be made therein without departing from the spirit of the present invention as defined in the appended claims.
WHAT IS CLAIMED IS:

1. A distractor apparatus for distracting two adjacent vertebrae, comprising:

   a first member having a first handle portion and a first distractor portion, said first distractor portion having a first jaw adapted to engage a first vertebrae;

   a second member having a second handle portion and a second distractor portion, said second distractor portion having a second jaw adapted to engage a second vertebrae, said first member and said second member being pivotally connected between said first and second handle portions and said first and second distractor portions, whereby inward movement of said first and second handle portions causes outward movement of said first and second distractor portions; and

   a resilient member being operably connected to said first and second members, wherein said first and second handle portions lie in a first plane and said first and second distractor portions lie in a second plane that intersects said first plane.

2. The distractor apparatus of claim 1, wherein said first and second distractor portions have a distractor center-line, wherein said first
and second jaws have a jaw center-line, said distractor center-line and said jaw center-line being parallel and offset.

3. The distractor apparatus of claim 1, wherein said first and second jaws further comprise a smooth and rounded front edge.

4. The distractor apparatus of claim 1, wherein said first and second jaws further comprise a flat outer surface.

5. The distractor apparatus of claim 1, wherein said resilient member biases said first distractor portion toward said second distractor portion.

6. The distractor apparatus of claim 1, wherein said resilient member comprises a leaf spring.

7. A distractor apparatus for distracting two adjacent vertebrae, comprising:
a first member having a first handle portion and a first distractor portion, said first distractor portion having a first jaw adapted to engage with a first vertebrae;

a second member having a second handle portion and a second distractor portion, said second distractor portion having a second jaw adapted to engage with a second vertebrae, said first member and said second member being pivotally connected between said first and second handle portions and said first and second distractor portions, whereby inward movement of said first and second handle portions causes outward movement of said first and second distractor portions;

a resilient member being operably connected to said first and second members; and

a locking mechanism for selectively locking said first and second handle portions at predetermined distances.

8. The distractor apparatus of claim 7, wherein said locking mechanism comprises a ratchet assembly.

9. The distractor apparatus of claim 7, further comprising a calibration assembly for indicating movement between said first and second jaws.
10. The distractor apparatus of claim 9, further comprising a calibration assembly for indicating movement between said first and second jaws calculated from the movement between said first and second handles.

11. The distractor apparatus of claim 8, wherein said locking mechanism further comprises:

   a first plate being secured to said first handle and having a first set of grooves;

   a second plate being secured to said second handle and having a second set of grooves, said first set of grooves interlocking with said second set of grooves; and

   a release member being operably connected to said first and second plate, wherein actuation of said release member disengages said first and second sets of grooves.

12. The distractor apparatus of claim 8, wherein said first and second handle portions lie in a first plane and said first and second distractor portions lie in a second plane that intersects said first plane.
13. The distractor apparatus of claim 8, wherein said first and second distractor portions have a distractor center-line and said first and second jaws have a jaw center-line, said distractor center-line and said jaw center-line being parallel and offset.

14. The distractor apparatus of claim 8, wherein said first and second jaws further comprise a smooth and rounded front edge.

15. The distractor apparatus of claim 8, wherein said first and second jaws further comprise a flat outer surface.

16. The distractor apparatus of claim 8, wherein said resilient member biases said first distractor portion toward said second distractor portion.

17. The distractor apparatus of claim 8, wherein said resilient member comprises a leaf spring.
18. A method for distracting two adjacent vertebrae using the
distractor apparatus of claim 9, comprising the steps of:

placing said first and second jaws between said first and second
vertebrae;

moving said first handle toward said second handle causing said
first and second jaws to distract said first and second vertebrae; and

stopping the movement of said first and second handles when said
calibration assembly indicates that the desired movement between said
first and second jaws has been achieved.