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(54) Title: HINGED FIXATION DEVICES FOR COMBINED UPPER JAW CORRECTION

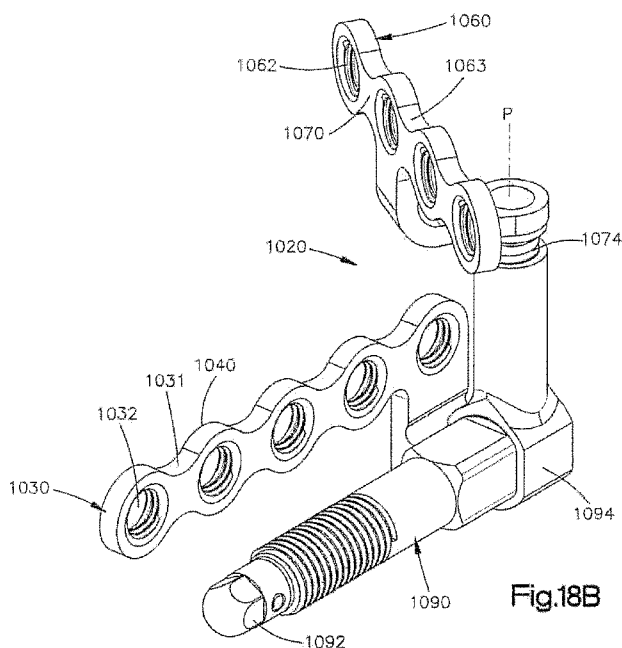


Fig.18B

(57) Abstract: Instrumentation and methods are provided for upper jaw correction surgery. The application discloses an orthopedic system that can be used to perform both a first distraction (for example a maxillary distraction) and a second distraction (for example a maxillary expansion) within the same surgical procedure. The instrumentation for separating first and second bone segments can include a first footplate; a second footplate; an actuator arranged to vary a distance between the first and second footplates; and a hinge that rotatably attaches the first and second footplates such that the first and second footplates can be angularly adjusted relative to each other about a pivot axis. Additionally, instrumentation is provided for a hinged fixation device capable of securing and adjusting both the linear separation and angular orientation of bone structures.



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1. A fixation device comprising:
a first footplate including a first footplate body configured to be attached to a first bone portion;
a second footplate including a second footplate body configured to be attached to a second bone portion; and
a joining element coupled between the first and second footplate bodies, the joining element including a hinge that defines a pivot axis about which the first footplate body is passively rotatable with respect to the second footplate body in response to a force applied to the second footplate body.
2. The fixation device of claim 1, wherein the first and second footplates each further comprise an attachment portion that defines a bore and the joining element is configured to fit within each of the bores to connect the first and second footplates.
3. The fixation device of claim 1, wherein the joining element defines a threaded outer surface, and the attachment portion defines a threaded inner surface that at least partially defines the bore, such that when the first and second footplates pivot with respect to one another the corresponding threads of the joining element and the bore mate and cause the first and second footplates to also translate with respect to one another along the first direction.
- 4-8. (Canceled).
9. The fixation device of claim 1, wherein the first and second footplate bodies each comprise a securing portion that is configured to receive at least one fastener to secure the first and second footplate bodies to the first and second bone portions respectively, each of the securing portions is configured to be a plate member comprising an upper surface configured to receive a fastener, a lower surface configured to conform to the first or second bone portion, and a side wall extending from the upper surface to the lower surface along an outer circumference of the plate member, and each of the plate members comprising at least one recess that is configured to receive a fastener to secure the plate member to the underlying bone structure.

10-14. (Canceled).

15. The fixation device of claim 1, wherein the joining element is coupled between the first and second footplate bodies along a first direction, and the joining element defines a variable spacer, such that at least one or both of the first and second footplate bodies can be actuated to move along the variable spacer from a first position spaced from the other of the first and second footplate bodies a first distance along the first direction to a second position spaced from the other of the first and second footplate bodies a second distance along the first direction, such that the second distance is different from the first distance.

16. The fixation device of claim 1, wherein the device is configured to be attached to a maxilla and a remaining portion of a skull after the maxilla has been separated from the remaining portion of the skull; and wherein:

the first footplate body is configured to be attached to the remaining portion of the skull;
the second footplate body is configured to be attached to the separated maxilla; and

wherein the hinge defines a pivot axis about which the at least one of the first and second footplate bodies are rotatable with respect the other of the first and second footplate bodies, such that when a sagittal split separates the maxilla into first and second segments, at least one of the first and second segments is angularly adjustable with respect to the other of the first and second segments about the pivot axis after the first and second footplate bodies have been attached to the remaining portion of the skull and the maxilla, respectively.

17. The fixation device of claim 16, wherein the joining element is coupled between the first and second footplate bodies along a first direction, and the fixation device further comprises an actuator configured to vary a distance between the first and second footplates along the first direction so as to advance the separated maxilla with respect to the remaining portion of the skull after the first and second footplate bodies have been attached to the remaining portion of the skull and the maxilla, respectively.

18. The fixation device of claim 17, wherein joining element includes a variable spacer, such that at least one or both of the first and second footplate bodies can be actuated to move along the variable spacer from a first position spaced from the other of the first and second footplate bodies a first distance along the first direction to a second position spaced from the other of the

first and second footplate bodies a second distance along the first direction, such that the second distance is different from the first distance.

19. The fixation device of claim 17, wherein the actuator comprises:
a sleeve having a body with an outer surface, the body defining a bore extending through the body; and
a screw connected to and disposed at least partially within the bore of the sleeve such that the screw can rotate relative to the sleeve but cannot translate relative to the sleeve;
wherein rotation of the screw causes the first and second footplates to translate with respect to the each other along a second direction that is substantially perpendicular to the first direction.
20. The fixation device of claim 19, wherein the first footplate further comprises:
a first actuator attachment portion defining an inner bore that is configured to be threadedly secured to the screw.
- 21-25. (Canceled).
26. The fixation device of claim 17, wherein the angularly adjusting of at least one of the first and second segments with respect to the other of the first and second segments causes at least one of the first and second footplates to translate along the pivot axis relative to the other of the first and second footplates.
27. (Canceled).
28. The fixation device of claim 17, wherein the hinge comprises a threaded post coupled to one of the first and second footplates, and the hinge further comprises a threaded receiving sleeve coupled to the other of the first and second footplates, wherein the receiving sleeve is rotatably and threadedly attached to the post.
29. (Canceled).
30. The fixation device of claim 17, wherein the hinge is movable between a first position and a second position about the pivot axis so as to angularly adjust the first and second footplates from a corresponding first relative angular position to a second corresponding angular position

and wherein the hinge is configured to maintain the first and second footplates in the second angular position during fixation of the fixation device to an underlying bone.

31. (Canceled).

32. The fixation device of claim 17, wherein the hinge comprises a hinge body that connects the first and second footplates, the hinge body defining one or more gaps positioned and dimensioned within the body so as to define a pair of spaced legs, at least one of the legs being deformable so as to adjust the angular orientation of the first and second bone attachment portions.

33. The fixation device of claim 17, wherein the pivot axis is substantially parallel to the first direction.

34. The fixation device of claim 19, wherein the actuator is arranged to vary a linear distance between the first and second footplates along both the first direction and the second direction, and the pivot axis is offset from the first direction.

35-43. (Canceled).

44. The fixation device of claim 17, wherein the first and second bone-facing surfaces substantially define first and second respective planes, and the actuator is arranged to translate at least one of the first and second footplates relative to the other along the respective first and second plane.

45. The fixation device of claim 44, wherein the first and second bone-facing surfaces substantially lie in initial first and second planes, and the hinge moves at least one of the first and second bone-facing surfaces out of the corresponding initial plane.

46. The fixation device of claim 17, wherein the hinge further comprises a first hinge member configured to be secured to the actuator, and a second hinge member configured to be secured to the first footplate body and rotationally attached to the first hinge member such that the first and second hinge members can rotate about the pivot axis relative to one another.

47. The fixation device of claim 46, wherein the hinge further comprises an axial locking mechanism that is configured to axially secure the first and second hinge members relative to each other such that relative translation of the first and second hinge members is prevented.

48. (Canceled).

49. The fixation device of claim 46, wherein the hinge further comprises a rotational locking mechanism configured to rotationally secure the first and second hinge members relative to each other such that the first and second hinge members cannot rotate relative to one another about the pivot axis.

50. (Canceled).

51. The fixation device of claim 46, wherein the first and second hinge members comprise a ball and socket joint that enables the first and second hinge members to rotate relative to each other about the pivot axis, as well as limited universal adjustability about other axes offset from the pivot axis.

52. The fixation device of claim 51, wherein the hinge further comprises an axial locking mechanism that is configured to axially secure the first and second hinge members relative to each other such that relative translation of the first and second hinge members is prevented.

53. The fixation device of claim 51, wherein the hinge further comprises a rotational locking mechanism configured to rotationally secure the first and second hinge members relative to each other such that the first and second hinge members cannot rotate relative to one another about the pivot axis.

54-56. (Canceled).

57. The fixation device of claim 17, wherein the hinge comprises:

a hinge spacer member having an actuator attachment portion configured to secure the hinge spacer member to the actuator and a first footplate attachment portion configured to be received within an inner bore of the first footplate, the first footplate attachment portion including a collet member that defines an inner bore; and

a pin configured to be inserted into the inner bore of the collet member;

wherein when the collet member is positioned within the inner bore of the first footplate the pin can be inserted into the inner bore of the collet member such that the collet member expands from an unlocked configuration wherein the collet member and the first footplate can translate relative to one another, to a locked configuration wherein the collet member and the first footplate are prevented from translating relative to one another.

58-60. (Canceled).

61. The fixation device of claim 57, further comprising a second hinge that defines a second pivot axis such that the second footplate body is angularly adjustable with respect to the first footplate body about the second pivot axis.

62. The fixation device of claim 61, wherein the second hinge comprises:

a second hinge spacer member having an actuator attachment portion configured to secure the second hinge spacer member to the actuator and a second footplate attachment portion configured to be received within an inner bore of the second footplate, the second footplate attachment portion including a second collet member that defines an inner bore; and

a second pin configured to be inserted into the inner bore of the second collet member;

wherein when the second collet member is positioned within the inner bore of the second footplate the second pin can be inserted into the inner bore of the second collet member such that the second collet member expands from an unlocked configuration wherein the second collet member and the second footplate can translate relative to one another, to a locked configuration wherein the second collet member and the second footplate are prevented from translating relative to one another.

63. (Canceled).

64. The fixation device of claim 17, wherein the hinge comprises:

a hinge body having an actuator attachment portion configured to secure the hinge body to the actuator and a first footplate attachment portion configured secure the hinge body to the first footplate, the first footplate and the first footplate attachment portion each including a pin hole; and

a pin configured to be inserted into the pin hole of the first footplate and the first footplate attachment portion;

wherein when the pin hole of the first footplate and the first footplate attachment portion are aligned, the pin can be inserted through the pin hole of the first footplate and the first footplate attachment portion such that the first footplate can rotate with respect to the hinge body about the pin and about the pivot axis.

65. The fixation device of claim 64, further comprising a second hinge, wherein the second hinge includes:

a second hinge body having an actuator attachment portion configured to secure the second hinge body to the actuator and a second footplate attachment portion configured secure the second hinge body to the second footplate, the second footplate and the second footplate attachment portion each including a pin hole; and

a second pin configured to be inserted into the pin hole of the second footplate and the second footplate attachment portion;

wherein when the pin hole of the second footplate and the second footplate attachment portion are aligned, the pin can be inserted through the pin hole of the second footplate and the second footplate attachment portion such that the second footplate can rotate with respect to the hinge body about the second pin and about a second pivot axis.

66. (Canceled).

67. The fixation device of claim 66, wherein the retention mechanism includes a one way ratchet system, the one way ratchet system including:

a gear rotationally coupled to the first footplate, the gear having a plurality of teeth that each define a front side and a back side; and

a pawl that is configured to engage the gear, the pawl including an arm that is attached to the distractor and a tip having a front surface, an opposed back surface, and a bottom surface the extends from the front surface to the back surface that is configured to engage the gear;

wherein the gear can rotate about the pivot axis in a first direction but rotation of the gear in a second direction is blocked by interference between the front surface of the tip of the pawl and the back side of one of the teeth of the gear.

68-93. (Canceled).