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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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Additional inventors are being named on the 1 separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

MATERIALS, DEVICES AND METHODS FOR TREATING BONE.

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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ENCLOSED APPLICATION PARTS (check all that apply)

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[Page 1 of 2]

Respectfully submitted,

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Additional Page

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MATERIALS, DEVICES AND METHODS FOR TREATING BONES

RELATED APPLICATIONS

This application is related to PCT Applications Nos. PCT/IL00/00471, filed August 3, 2000, published as WO 01/54598 A1, PCT/IL00/00056, filed January 27, 2000, published as WO 00/44321, PCT/IL00/00058, filed January 27, 2000, published as WO 00/44319, and PCT/IL2004/000527, filed on June 17, 2004, the disclosures of which are incorporated herein by reference. This application is also related to US Provisional Applications for Patent Nos. 60/554,558, filed on March 18, 2003, the disclosure of which are incorporated herein by reference.

FIELD OF INVENTION

The present invention relates to materials, devices and a minimally invasive methods of use for treating bones.

BACKGROUND OF THE INVENTION

Treatment of fractured bones, osteoporotic bones, deformed bones and/or pathological bones occasionally includes the use of various types of bone fillers, in order to reinforce and stabilize the bone, restore its original configuration and alleviate pain.

Vertebral fractures, for example, may be treated using the vertebroplasty technique, during which liquid bone cement (PMMA) is injected into the vertebral body and hardens within it. Although the procedure reinforces the vertebra structure and helps in alleviating pain, there are complications associated with cement injection, as the high pressure required for cement injection may result in cement leakage, inducing clinical complication.

Another procedure for treating fractured vertebrae comprises the use of an expandable device prior to cement injection (PCT/IL2004/000527). The device is inserted into the vertebral body, and its expansion may result in fracture reduction and creation of bone void, into which the curable material is injected, in a relatively lower pressure compared to vertebroplasty. Although cement is injected in a more controlled manner, the risk of cement extravasation still exists.

The use of other curable bone void fillers, besides bone cement, is well known. These bone void fillers include, for example, calcium phosphate and its derivatives, calcium sulfate and its derivatives and calcified triglyceride cement.

Lately it has been suggested, that the use of bone cement, *i.e.*, material that sets within the vertebra to a hardened condition and thus provide for a rigid reinforcement, may provoke additional fractures at the adjacent vertebrae (Berlemann U. *et al.*, Adjacent vertebral failure

after vertebroplasty, *JBJS*, 84-B (5), or may incorporates at least one radiopaque marker, 2002, 748-752).

The treated bone may be also filled with bone grafts, of different origin and forms, *e.g.*, autograft, allograt or synthetic bone substitute, shaped in paste form, granules or other forms. In tibial plateau fractures, the use of bone graft is the surgeons preferred option.

Another option is to implant a device together with the cement/bone void filler. The B-Twin metal implant (PCT application PCT/IL00/00471, published as WO 01/54598 A1), for example, is percutaneously inserted into the vertebral body in its reduced diameter, and expanded within the vertebral body, causing displacement of the vertebral endplates. Following implant expansion, bone cement is injected through the implant, using a special mechanism, to fill the void created around the implant.

US Patent 20020068974A1 describes an expandable fabric bag, inserted into a cavity which was previously formed in a vertebra, and filled with material that promote bone growth through said bag.

SUMMARY OF THE INVENTION

An aspect of some embodiments of the invention relates to a material used for treating fractured/osteoporotic/deformed/pathological bone.

In one embodiment of the invention, the material is inserted into the interior of the bone in a relatively high viscosity, putty-like condition. Such condition is advantageous as it allows for a safer insertion of the material, with a reduced risk for material leakage. In an exemplary embodiment of the invention, the material may be injected into the interior of the bone using a designated injector, capable of delivering the viscous material while moderate manual force is applied. In alternative exemplary embodiment of the invention, the material is delivered into the interior of the bone using a high-pressure pump.

In another embodiment of the invention, said material does not set into a harden condition following its introduction into the bone, but rather remains in its quite flexible, putty-like state. Optionally, the material slightly hardens relative to its initial, insertion state, but still preserves its non-rigid condition. One of the benefits of such non-setting feature is a potential reduction in fractures of adjacent vertebrae. In an exemplary embodiment of the invention, the material having a non-setting behavior is, for example, hydroxyapatite with defined concentration of sodium alginate (Ishikawa *et al.*, Non-decay fast-setting calcium phosphate cement: Hydroxyapatite putty containing an increased amount of sodium alginate, *J Biomed Mater Res* 36, 1997, 393 - 399). Such material may also present osteoconductive properties.

In yet another embodiment of the present invention, said material has mechanical properties that enables its use in, but not limited to, load bearing bones, such as the spine. In an exemplary embodiment of the invention, the material is viscous enough to withstand, for example, vertebra compression forces, and thus to resist vertebral body collapse.

In another embodiment of the invention, said material is biocompatible and implant grade material.

In alternative embodiment of the invention, a material/device having a reduced configuration is inserted into the bone and expands following its deploying within the bone. In an exemplary embodiment of the invention, a spongy-like material is used, for example, Teflon incorporated material (*e.g.*, by W. L. Gore & Associated Inc.), or spongy polyurethane.

Another aspect of some embodiments of the invention relates to a method of use for treating fractured/osteoporotic/deformed/pathological bone, comprising:

a minimally invasive access into interior of the bone;

a minimally invasive delivery of said material (or device) into bone.

In one embodiment, prior to said material insertion, an expandable device is inserted and expanded within the bone, to reduce the fracture and create a void in the bone, which is later filled with said material. Following expansion, the expandable device is contracted and removed from the bone in its original, reduced configuration.

In addition embodiment of the invention, said method provides reinforcement and stability to the treated bone, for example, vertebra, as well as alleviates pain.

In another embodiment of the invention, material is inserted inside the bone percutaneously. In an exemplary embodiment of the invention, material is inserted into a fractured lumbar vertebral body in a trans-pedicular approach, and into a fractured thoracic vertebral body in an extra-pedicular approach. In another exemplary embodiment of the invention, bilateral insertion into the vertebra is performed.

In one embodiment of the invention, a delivery system is used to convey the material into the bone, optionally, through a cannula. Said delivery system may be, for example, an injector (*e.g.*, by Cardinal Health). Alternatively and/or additionally, a high-pressure pump, capable of producing and withstanding a pressure of 20 – 400 Atm, is used to convey the viscous material inside bone (US Patents No. 6,025,537, 6,127,597). Alternatively and/or additionally, material may be delivered by other means, such as impactor.

In yet another embodiment of the invention, said procedure is monitored by CT scanning and/or fluoroscopy. In one embodiment of the invention, material is constructed from

radiopaque material, or may incorporates at least one radiopaque marker, to enable its tracking during and after surgery.

In another embodiment of the invention, additional substance is added to the bone together with said material. Such substance may be, for example, growth stimulating factor and/or drug and/or antibiotics.

In an exemplary embodiment of the invention, an instrumentation set is provided, intended to assist minimal invasive surgery of inventive device.

Another aspect of some embodiments of the invention relates to a device, intended to treat fractured/osteoporotic/deformed/pathological bone, comprising:

an implant;

a delivery system.

In one embodiment of the invention, prior to its implantation, implant is inserted and strained inside delivery system tube having a smaller diameter than that of the implant, in order to enable implant insertion into the interior of the bone through a small insertion port. In an exemplary embodiment of the invention, delivery system tube is oval. Alternatively, tube is round. In another exemplary embodiment of the invention, said insertion into the tube deforms the implant, so that its diameter is reduced while its length is elongated (*i.e.*, implant volume does not change).

In an exemplary embodiment of the invention, loading of the implant into delivery system small diameter tube is performed via a loading device, having a tapered inner diameter into which the implant is positioned before deployment on the delivery system tube. In an exemplary embodiment of the invention, implant is loaded and strained into the smaller diameter tube of delivery system by hydraulic means. Alternatively, implant is strained using mechanical means. In another exemplary embodiment of the invention, loading of the implant inside delivery system tube is performed during surgery, by the surgeon. Alternatively, polymer implant is provided strained inside delivery system tube.

In another embodiment of the invention, following positioning of the delivery system tube (which is loaded with the implant) in the implantation site, implant is released from delivery system and un-strained to gain its original dimensions. In an exemplary embodiment of the invention, implant is released from delivery system tube by pushing it forward (distally), using mechanical means. Alternatively, hydraulic means are used for implant release. In an alternative exemplary embodiment of the invention, implant is released due to backward (proximally) movement, *i.e.* pulling, of delivery system tube. Optionally, prior to implant insertion, an expandable device is inserted into the bone and expanded within it, to reduce the

fracture and create a void, into which said implant is later inserted. Following expansion, the expandable device is contracted and removed from the bone in its original, reduced diameter.

In another embodiment of the invention, straining of the implant is enabled due to deformation of solid material. In an exemplary embodiment of the invention, elastic deformation occurs during implant deformation, and thus implant returns to its original configuration and dimensions upon its release. Alternatively, elastic-plastic deformation occurs during implant straining.

In another embodiment of the invention, implant is constructed from biocpmpatible, implant grade material. In an exemplary embodiment of the invention, implant is made of, for example, polyurethane, polycarbonate urethane, silicone or combination thereof. In another exemplary embodiment of the invention, implant is made of a water absorbing material, for instance, hydrogel.

In yet another embodiment of the present invention, said implant has mechanical properties that enables its use in, but not limited to, load bearing bones, such as the spine. In an exemplary embodiment of the invention, the implant is capable of withstanding, for example, vertebra compression forces, and thus resists vertebral body collapse.

In another embodiment of the invention, implant is designed to have a cubic configuration. Alternatively, implant has a trapezoid configuration. Additional configurations, symmetric or non-symmetric, may be constructed for the implant.

Another aspect of some embodiments of the invention relates to a method of use for treating fractured/osteoporotic/deformed/pathological bone, comprising:

minimally invasive access into interior of the bone;

minimally invasive delivery/insertion of said implant into bone;

implant release inside the interior of bone.

In one embodiment, an expandable device is inserted and expands within the bone, prior to implant insertion. Following expansion, the expandable device is contracted and removed from the bone in its original, reduced configuration.

In additional embodiment of the invention, said method provides reinforcement and stability to the treated bone, for example, vertebra, as well as alleviates pain.

In another embodiment of the invention, implant is inserted inside the bone percutaneously. In an exemplary embodiment of the invention, implant is inserted into a fractured lumbar vertebral body in a trans-pedicular approach, into a fractured thoracic vertebral body in an extra-pedicular approach.

In another embodiment of the invention, two implants are inserted inside a bone, for example, a vertebra.

In yet another embodiment of the invention, said procedure is monitored by CT scanning and/or fluoroscopy. In one embodiment of the invention, implant is constructed from radiopaque material, or may incorporates at least one radiopaque marker, to enable its tracking during and after surgery.

In an exemplary embodiment of the invention, an instrumentation set is provided, intended to assist minimal invasive surgery of inventive device.

structure.

CLAIMS

1. A material for treating fractured and/or osteoporotic and/or deformed and/or pathological bone, inserted into the interior of said bone in a relatively high viscosity, without its hardening within the bone.

2. A material as claimed in claim 1, wherein said material slightly sets/hardens relative to its initial, insertion state, but still preserves its non-rigid condition.

3. A material as claimed in claim 1, wherein said material is capable of withstanding the forces acting in load bearing bones.

4. A material as claimed in claim 3, wherein load-bearing bone is a vertebra.

5. A material as claimed in claim 1, wherein material compound contains hydroxyapatite and sodium alginate.

6. A method of use for treating fractured/osteoporotic/deformed/pathological bone, comprising:

a minimally invasive access into interior of the bone;

a minimally invasive delivery of a viscous material having a non-setting behavior, into bone.

7. A method of use as claimed in claim 6, wherein prior to material insertion, an expandable device is inserted and expanded within the interior of the bone, to create a void in the bone to be filled with said material, and contracted and removed from the bone in its original, reduced configuration.

8. A method of use as claimed in claim 6, wherein material is conveyed to the interior of the bone using a high-pressure injector.

9. A method of use as claimed in claim 6, wherein material is conveyed to the interior of the bone using a high-pressure pump, capable of producing and withstanding a pressure of up to 400 Atm.

10. A method of use as claimed in claim 6, wherein material is conveyed to the interior of the bone using an impactor.

11. A method of use as claimed in claim 6, wherein material is radiopaque.

12. A method of use as claimed in claim 6, wherein material includes at least one rediopaque marker.

13. An implant for treating fractured and/or osteoporotic and/or deformed and/or pathological bone, inserted into the interior of said bone in a relatively reduced configuration, and expands within the bone.

14. An implant as claimed in claim 13, wherein implant has a spongy-like form.

15. An implant as claimed in claim 13, wherein implant is capable of withstanding the forces acting in load bearing bones.

16. An implant as claimed in claim 15, wherein load-bearing bone is a vertebra.

17. An implant as claimed in claim 13, wherein device transforms to a more softened condition within the bone, relatively to its insertion state.

18. An implant as claimed in claim 13, wherein implant is made of a Teflon-incorporated material.

19. An implant as claimed in claim 13, wherein implant is a made of polyurethane.

20. A device for treating fractured and/or osteoporotic and/or deformed and/or pathological bone, comprising an implant and a delivery system, the delivery system including a tube having a smaller diameter than implant diameter, and implant is inserted into said smaller diameter delivery system tube prior to it introduction into bone.

21. A device as claimed in claim 20, wherein said insertion into delivery system tube deforms the implant.

22. A device as claimed in claim 20, wherein insertion of the implant into delivery system small diameter tube is performed via a loading device, having a tapered inner diameter.

23. A device as claimed in claim 20, wherein insertion of the implant into delivery system small diameter tube is achieved by hydraulic means.

24. A device as claimed in claim 20, wherein insertion of the implant into delivery system small diameter tube is achieved by mechanical means.

25. A device as claimed in claim 20, wherein the implant is introduced into the interior of the bone enclosed within the small diameter delivery system tube, and gains its original dimensions and configuration following its released inside the bone.

26. A device as claimed in claim 25, wherein implant is released inside bone using mechanical means.

27. A device as claimed in claim 25, wherein implant is released inside bone using hydraulic means.

28. A device as claimed in claim 20, wherein implant is capable of withstanding the forces acting in load bearing bones.

29. An implant as claimed in claim 28, wherein load-bearing bone is a vertebra.

30. A device as claimed in claim 20, wherein implant is made of urethane derivative.

31. A method for treating fractured/osteoporotic/deformed/pathological bone, comprising:
a minimally invasive access into interior of the bone;
a minimally invasive introduction of at least one implant into bone;
implant is released inside the interior of bone and gains an expanded configuration.

32. A method of use as claimed in claim 31, wherein prior to implant insertion, an expandable device is inserted and expanded within the interior of the bone, to create a void in the bone, and contracted and removed from the bone in its original, reduced configuration.

33. A method of use as claimed in claim 31, wherein following implant release within the interior of the bone, implant re-gains its original dimensions and configuration.

34. A method of use as claimed in claim 31, wherein following implant release within the interior of the bone, implant expands within the bone.

35. A method of use as claimed in claim 34, wherein implant expansion within the bone is due to its liquid absorption.

36. A method of use as claimed in claim 31, wherein implant is radiopaque.

37. A method of use as claimed in claim 31, wherein material includes at least one rediopaque marker.

38. A pump capable of producing and withstanding a pressure range of 20 - 400 Atm, for injection of high viscosity material, the material having a non-setting behavior.

39. A pump capable of producing and withstanding a pressure range of 20 - 400 Atm, for injection of high viscosity material, the material having a setting behavior.