Title: EXPANDABLE SUPPORT DEVICE AND METHOD OF USE

Abstract: An expandable support device for tissue repair is disclosed. The device can be used to repair hard or soft tissue, such as bone or vertebral discs. A method of repairing tissue is also disclosed. The device and method can be used to treat compression fractures. The compression fractures can be in the spine.
TITLE OF THE INVENTION

EXPANDABLE SUPPORT DEVICE AND METHOD OF USE

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BACKGROUND OF THE INVENTION

[0001] This invention relates to devices for providing support for biological tissue, for example to repair spinal compression fractures, and methods of using the same.

[0002] Vertebroplasty is an image-guided, minimally invasive, nonsurgical therapy used to strengthen a broken vertebra that has been weakened by disease, such as osteoporosis or cancer. Vertebroplasty is often used to treat compression fractures, such as those caused by osteoporosis, cancer, or stress.

[0003] Vertebroplasty is often performed on patients too elderly or frail to tolerate open spinal surgery, or with bones too weak for surgical spinal repair. Patients with vertebral damage due to a malignant tumor may sometimes benefit from vertebroplasty. The procedure can also be used in younger patients whose osteoporosis is caused by long-term steroid treatment or a metabolic disorder.

[0004] Vertebroplasty can increase the patient’s functional abilities, allow a return to the previous level of activity, and prevent further vertebral collapse. Vertebroplasty attempts to also alleviate the pain caused by a compression fracture.

[0005] Vertebroplasty is often accomplished by injecting an orthopedic cement mixture through a needle into the fractured bone. The cement mixture can leak from the bone, potentially entering a dangerous location such as the spinal canal. The cement mixture, which is naturally viscous, is difficult to inject through small diameter needles, and thus
many practitioners choose to "thin out" the cement mixture to improve cement injection, which ultimately exacerbates the leakage problems. The flow of the cement liquid also naturally follows the path of least resistance once it enters the bone – naturally along the cracks formed during the compression fracture. This further exacerbates the leakage.

[0006] The mixture also fills or substantially fills the cavity of the compression fracture and is limited to certain chemical composition, thereby limiting the amount of otherwise beneficial compounds that can be added to the fracture zone to improve healing. Further, a balloon must first be inserted in the compression fracture and the vertebra must be expanded before the cement is injected into the newly formed space.

[0007] A vertebroplasty device and method that eliminates or reduces the risks and complexity of the existing art is desired. A vertebroplasty device and method that is not based on injecting a liquid directly into the compression fracture zone is desired.

BRIEF SUMMARY OF THE INVENTION

[0008] An expandable support device for performing completely implantable spinal repair is disclosed. The device has a first strut and a second strut attached to, and/or integral with, the first strut. The first strut is substantially deformable. The second strut can be substantially inflexible.

[0009] The device can be configured to expand in a single direction. The device can be configured to expand in two directions.

[0010] The device can have a buttress. The buttress can have, for example, a coil, a wedge, and/or a hoop.

[0011] The device can have a locking pin. The locking pin can be interference fit with the device, for example with the first strut, and/or with a longitudinal port of the device.
[0012] The device of Claim 1 can have a longitudinal axis, wherein the longitudinal axis has a radius of curvature.

[0013] A method for repairing a damaged section of a spine is also disclosed. The method includes expanding an expandable support device in the damaged section. The expandable support device is loaded on a balloon during the expanding. Expanding includes inflating a balloon. Inflating the balloon includes inflating the balloon equal to or greater than about 5,000 kPa of internal pressure, or equal to or greater than about 10,000 kPa of internal pressure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Figure 1 is a perspective view of an embodiment of the expandable support device.

[0015] Figure 2 is a side view of the embodiment of the expandable support device of Figure 1.

[0016] Figure 3 is a top view of the embodiment of the expandable support device of Figure 1.

[0017] Figure 4 is a front view of the embodiment of the expandable support device of Figure 1.

[0018] Figure 5 is a perspective view of an embodiment of the expandable support device.

[0019] Figure 6 is a side view of the embodiment of the expandable support device of Figure 5.

[0020] Figure 7 is a front view of the embodiment of the expandable support device of Figure 5.
[0021] Figure 8 is a perspective view of an embodiment of the expandable support device.

[0022] Figure 9 is a front view of the embodiment of the expandable support device of Figure 8.

[0023] Figure 10 illustrates a flattened pattern for an embodiment of the expandable support device.

[0024] Figure 11 is a perspective view of an embodiment of the expandable support device.

[0025] Figure 12 is a front view of the embodiment of the expandable support device of Figure 11.

[0026] Figure 13 is a perspective view of an embodiment of the expandable support device.

[0027] Figure 14 is a front view of the embodiment of the expandable support device of Figure 13.

[0028] Figure 15 is a perspective view of an embodiment of the expandable support device.

[0029] Figure 16 is top view of the embodiment of the expandable support device of Figure 15.

[0030] Figure 17 is a side view of the embodiment of the expandable support device of Figure 15.

[0031] Figure 18 is a front view of the embodiment of the expandable support device of Figure 15.

[0032] Figure 19 illustrates an embodiment of section A-A of the embodiment of the expandable support device of Figure 15.
[0033] Figure 20 illustrates an embodiment of section B-B of the embodiment of the expandable support device of Figure 15.

[0034] Figure 21 is a perspective view of an embodiment of the expandable support device.

[0035] Figure 22 is top view of the embodiment of the expandable support device of Figure 15.

[0036] Figure 23 is a front view of the embodiment of the expandable support device of Figure 15.

[0037] Figures 24 and 25 illustrate an embodiment of a method for using a delivery system for the expandable support element.

[0038] Figures 26 through 28 illustrate an embodiment of a method for accessing a damage site in the vertebra.

[0039] Figure 29 illustrates various embodiments of methods for deploying the expandable support device to the vertebral column.

[0040] Figures 30 through 32 illustrate an embodiment of a method for deploying the expandable support device into the damage site in the vertebra.

[0041] Figures 33 and 34 illustrate an embodiment of a method for deploying the expandable support device into the damage site in the vertebra.

[0042] Figures 35 and 36 illustrate an embodiment of a method for deploying one or more expandable support devices into one or more damage sites in the vertebra.

[0043] Figure 37 illustrates an embodiment of a method for deploying the expandable support device into the damage site in the vertebra.

[0044] Figures 38 illustrate an embodiment of a method for deploying the expandable support device into the damage site in the vertebra.
[0045] Figure 39 illustrates embodiments of methods for deploying the expandable
support device into the damage site in the vertebra.

[0046] Figures 40 and 41 illustrate an embodiment of a method for deploying the
expandable support device into the damage site in the vertebra.

[0047] Figures 42 and 43 illustrate an embodiment of a method for deploying a locking
pin into the expandable support device in the damage site in the vertebra.

[0048] Figures 44 through 49 illustrate an embodiment of a method for deploying a
locking pin into the expandable support device.

[0049] Figure 50 illustrates an embodiment of the buttress.

[0050] Figures 51 through 53 illustrate various embodiments of section C-C of the
buttress of Figure 50.

[0051] Figures 54 through 56 illustrate an embodiment of a method for deploying the
buttress.

[0052] Figure 57 illustrates an embodiment of a method for deploying the buttress.

[0053] Figures 58 through 60 illustrate an embodiment of a method for deploying the
buttress.

[0054] Figure 61 illustrates an embodiment of the buttress.

[0055] Figure 62 illustrates an embodiment of section D-D of the buttress of Figure 61.

[0056] Figure 63 illustrates an embodiment of a method for deploying the buttress.

[0057] Figures 64 through 67 illustrate a method for deploying the expandable support
device of Figures 1 through 4.

[0058] Figures 69 through 70 illustrate a method for deploying the expandable support
device of Figures 15 through 18.

[0059] Figure 71 illustrates the deployed expandable support device of Figures 15
through 18 in use.
[0060] Figures 72 and 73 illustrate a method for deploying the expandable support device of Figures 19 and 20.

[0061] Figure 74 illustrates a method of using the expandable support device of Figures 15 through 18 with the band.

[0062] Figure 75 through 77 illustrate various embodiments of the locking pin.

DETAILED DESCRIPTION

[0063] Figures 1 through 4 illustrate an biocompatible implant that can be used for tissue repair, for example for repair bone fractures such as spinal compression fractures, and/or repairing soft tissue damage, such as herniated vertebral discs. The implant can be an expandable support device 2, for example a stent. The expandable support device 2 can have a longitudinal axis 4. The expandable support device 2 can have an elongated wall 6 around the longitudinal axis 4. The expandable support device 2 can have a substantially and/or completely hollow longitudinal port 8 along the longitudinal axis 4.

[0064] The wall 6 can have one or more first struts 10. The first struts 10 can be configured to be deformable and/or expandable. The wall 6 can have can have one or more second struts 12. The second struts 12 can be substantially undeformable and substantially inflexible. The first struts 10 can be flexibly (e.g., deformably rotatably) attached to the second struts 12.

[0065] The wall 6 can be configured to expand radially away from the longitudinal axis 4, for example in two opposite radial directions. A first set of first struts 10 can be aligned parallel to each other with respect to the longitudinal axis 4. A second set of first struts 10 can be aligned parallel to each other with respect to the longitudinal axis 4. The second set of first struts 10 can be on the opposite side of the longitudinal axis 4 from the
first set of first struts 10. The second struts 12 can attached any or all sets of first struts
10 to other sets of first struts 10.

[0066] The second struts 12 can have one or more ingrowth ports 14. The ingrowth ports
14 can be configured to encourage biological tissue ingrowth therethrough during use.
The ingrowth ports 14 can be configured to releasably and/or fixedly attach to a
deployment tool or other tool. The ingrowth ports 14 can be configured to increase,
and/or decrease, and/or focus pressure against the surrounding biological tissue during
use. The ingrowth ports 14 can be configured to increase and/or decrease the stiffness of
the second struts 12. The ingrowth ports 14 can be configured to receive and/or attach to
a buttress.

[0067] The first struts 10 can be configured to have a "V" shape. The space between
adjacent first struts 10 can be configured to receive and/or attach to a locking pin during
use.

[0068] The wall 6 can have a wall thickness 16. The wall thickness 16 can be from about
0.25 mm (0.098 in.) to about 5 mm (0.2 in.), for example about 1 mm (0.04 in.). The wall
6 can have an inner diameter 18. The inner diameter 18 can be from about 1 mm (0.04
in.) to about 30 mm (1.2 in.), for example about 6 mm (0.2 in.). The wall thickness 16
and/or the inner diameter 18 can vary with respect to the length along the longitudinal
axis 4. The wall thickness 16 and/or the inner diameter 18 can vary with respect to the
angle formed with a plane parallel to the longitudinal axis 4.

[0069] Figures 5 through 7 illustrate an expandable support device 2 that can be
configured to expand away from the longitudinal axis 4 in more than two opposite
directions, for example in two sets of two opposite radial directions. The wall 6 can have
four sets of first struts 10. Each set of first struts 10 can be opposite to another set of first
struts 10, radially with respect to the longitudinal axis 4. Each of four sets of second
struts 12 can attach each set of first struts 10.

[0070] The first struts 10 on a first longitudinal half of the expandable support device 2
can be oriented (e.g., the direction of the pointed end of the “V” shape) in the opposite
direction as the first struts 10 on a second longitudinal half of the expandable support
device 2.

[0071] Figures 8 and 9 illustrate that the longitudinal port 8 can have one or more lock
grooves 20. The lock grooves 20 can be configured to receive and/or slidably and fixedly
or releasably attach to a locking pin.

[0072] Figure 10 illustrates a visually flattened pattern of the wall 6 for the expandable
support device 2. (The pattern of the wall 6 can be flattened for illustrative purposes
only, or the wall 6 can be flattened during the manufacturing process.) The pattern can
have multiple configurations for the first and/or second struts 10 and/or 12. For example,
first struts 10a can have a first configuration (e.g., a “V” shape) and first struts 10b can
have a second configuration (e.g., a “U” shape).

[0073] Figures 11 and 12 illustrate that the expandable support device 2 can have a
square, rectangular, circular (shown elsewhere), oval (not shown) configuration or
combinations thereof (e.g., longitudinal changes in shape).

[0074] Figures 13 and 14 illustrate that the expandable support device 2 can have
protruding tissue engagement elements, such as tissue hooks, and/or barbs, and/or cleats
22. The cleats 22 can be integral with and/or fixedly or removably attached to the first
and/or second struts 12. The cleats 22 can be on substantially opposite sides of the
expandable support device 2.

[0075] Figures 15 through 18 illustrate that the expandable support device 2 can have
panels attached to other panels at flexible joints. The expandable support device 2 can
have first panels 24 attached to and/or integral with second panels 26 at first joints 28.

The second panels 26 can be attached to and/or integral with third panels 30 at second joints 32. The expandable support device 2 can have one or more tool engagement ports 34, for example on the first panels 24. The expandable support device 2 can have one or more ingrowth ports 14, for example, on the third panels 30. The outside of the first panel 24 can be concave.

[0076] Figures 19 and 20 illustrate that the expandable support device 2 can have first and/or second struts 10 and/or 12 and panels. The first and/or second struts 10 and/or 12 can be internal to the panels. The first struts 10 can be attached to the third panels 30.

[0077] Figures 21 through 23 illustrate the expandable support device 2 that can have a radius of curvature 36 along the longitudinal axis 4. The radius of curvature 36 can be from about 1 mm (0.04 in.) to about 250 mm (10 in.), for example about 50 mm (2 in.). (The wall 6 is shown sans panels or struts for illustrative purposes.) The expandable support device 2 can have at least one flat side, for example two flat sides. The two flat sides can be on opposite sides of the expandable support device 2 from each other.

[0078] Any or all elements of the expandable support device 2 and/or other devices or apparatuses described herein can be made from, for example, a single or multiple stainless steel alloys, nickel titanium alloys (e.g., Nitinol), cobalt-chrome alloys (e.g., ELGILOY® from Elgin Specialty Metals, Elgin, IL; CONICHRÔME® from Carpenter Metals Corp., Wyomissing, PA), nickel-cobalt alloys (e.g., MP35N® from Magellan Industrial Trading Company, Inc., Westport, CT), molybdenum alloys (e.g., molybdenum TZM alloy, for example as disclosed in International Pub. No. WO 03/082363 A2, published 9 October 2003, which is herein incorporated by reference in its entirety), tungsten-rhenium alloys, for example, as disclosed in International Pub. No. WO 03/082363, polymers such as polyethylene terephthalate (PET)/polyester (e.g.,
DACRON® from E. I. Du Pont de Nemours and Company, Wilmington, DE),
polypropylene, (PET), polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE),
polyether ether ketone (PEEK), nylon, polyether-block co-polyamide polymers (e.g.,
PEBÁX® from ATOFINA, Paris, France), aliphatic polyether polyurethanes (e.g.,
TECOFLEX® from Thermedics Polymer Products, Wilmington, MA), polyvinyl chloride
(PVC), polyurethane, thermoplastic, fluorinated ethylene propylene (FEP), absorbable or
resorbable polymers such as polyglycolic acid (PGA), polylactic acid (PLA),
polycaprolactone (PCL), polyethyl acrylate (PEA), polydioxanone (PDS), and pseudo-
polyamino tyrosine-based acids, extruded collagen, silicone, zinc, echogenic, radioactive,
radiopaque materials, a biomaterial (e.g., cadaver tissue, collagen, allograft, autograft,
xenograft, bone cement, morselized bone, osteogenic powder, beads of bone) any of the
other materials listed herein or combinations thereof. Examples of radiopaque materials
are barium sulfate, zinc oxide, titanium, stainless steel, nickel-titanium alloys, tantalum
and gold.

[0079] Any or all elements of the expandable support device 2 and/or other devices or
apparatuses described herein, can be or have a matrix for cell ingrowth or used with a
fabric, for example a covering (not shown) that acts as a matrix for cell ingrowth. The
matrix and/or fabric can be, for example, polyester (e.g., DACRON® from E. I. Du Pont
de Nemours and Company, Wilmington, DE), polypropylene, PTFE, ePTFE, nylon,
extruded collagen, silicone or combinations thereof.

[0080] The elements of the expandable support device 2 and/or other devices or
apparatuses described herein and/or the fabric can be filled and/or coated with an agent
delivery matrix known to one having ordinary skill in the art and/or a therapeutic and/or
diagnostic agent. The agents within these matrices can include radioactive materials;
radiopaque materials; cytogenic agents; cytotoxic agents; cytostatic agents; thrombogenic
agents, for example polyurethane, cellulose acetate polymer mixed with bismuth trioxide,
and ethylene vinyl alcohol; lubricious, hydrophilic materials; phosphor choline; anti-
inflammatory agents, for example non-steroidal anti-inflammatories (NSAIDs) such as
cyclooxygenase-1 (COX-1) inhibitors (e.g., acetylsalicylic acid, for example ASPIRIN®
from Bayer AG, Leverkusen, Germany; ibuprofen, for example ADVIL® from Wyeth,
Collegeville, PA; indomethacin; mefenamic acid), COX-2 inhibitors (e.g., VIOXX® from
Merck & Co., Inc., Whitehouse Station, NJ; CELEBREX® from Pharmacia Corp.,
Peapack, NJ; COX-1 inhibitors); immunosuppressive agents, for example Sirolimus
(RAPAMUNE®, from Wyeth, Collegeville, PA), or matrix metalloproteinase (MMP)
inhibitors (e.g., tetracycline and tetracycline derivatives) that act early within the
pathways of an inflammatory response. Examples of other agents are provided in Walton
et al, Inhibition of Prostaglandin E₂ Synthesis in Abdominal Aortic Aneurysms,
Circulation, July 6, 1999, 48-54; Tambiah et al, Provocation of Experimental Aortic
Inflammation Mediators and Chlamydia Pneumoniae, Brit. J. Surgery 88 (7), 935-940;
Franklin et al, Uptake of Tetracycline by Aortic Aneurysm Wall and Its Effect on
Inflammation and Proteolysis, Brit. J. Surgery 86 (6), 771-775; Xu et al, Sp1 Increases
Expression of Cyclooxygenase-2 in Hypoxic Vascular Endothelium, J. Biological
Chemistry 275 (32) 24583-24589; and Pyo et al, Targeted Gene Disruption of Matrix
Metalloproteinase-9 (Gelatinase B) Suppresses Development of Experimental Abdominal
Aortic Aneurysms, J. Clinical Investigation 105 (11), 1641-1649 which are all
incorporated by reference in their entireties.

METHOD OF USE

[0081] Figure 24 illustrates that the expandable support device 2 can be loaded in a
collapsed (i.e., contracted) configuration onto a deployment tool 38. The deployment tool
38 can have an expandable balloon catheter as known to those having an ordinary level of
skill in the art. The deployment tool 38 can have a catheter 40. The catheter 40 can have
a fluid conduit 42. The fluid conduit 42 can be in fluid communication with a balloon 44.
The balloon 44 and the deployment tool 38 can be the balloon 44 and deployment tool 38
as described by U.S. Provisional Patent Application Titled "BALLOON AND
METHODS OF MAKING AND USING"; filed 21 September 2004, U.S. Patent
Application No. 60/611,972, which is herein incorporated by reference in its entirety.
The balloon 44 can be configured to receive a fluid pressure of at least about 5,000 kPa
(50 atm), more narrowly at least about 10,000 kPa (100 atm), for example at least about
14,000 kPa (140 atm).

[0082] The deployment tool 38 can be a pair of wedges, an expandable jack, other
expansion tools, or combinations thereof.

[0083] Figure 25 illustrates that the fluid pressure in the fluid conduit 42 and balloon can
increase, thereby inflating the balloon 44, as shown by arrows. The expandable support
device 2 can expand, for example, due to pressure from the balloon 44.

[0084] Figures 26 (side view) and 27 (top view) illustrates a vertebral column 46 that can
have one or more vertebra 48 separated from the other vertebra 48 by discs 50. The
vertebra 48 can have a damage site 52, for example a compression fracture.

[0085] An access tool 54 can be used to gain access to the damage site 52 and or increase
the size of the damage site 52 to allow deployment of the expandable support device 2.
The access tool 54 can be a rotating or vibrating drill 56 that can have a handle 58. The
drill 56 can be operating, as shown by arrows 60. The drill 56 can then be translated, as
shown by arrow 62, toward and into the vertebra 48 so as to pass into the damage site 52.

[0086] Figure 28 illustrates that the access tool 54 can be translated, as shown by arrow,
to remove tissue at the damage site 52. The access tool 54 can create an access port 64 at
the surface of the vertebra 48. The access port 64 can open to the damage site 52. The
access tool 54 can then be removed from the vertebra 48.

[0087] Figure 29 illustrates that a first deployment tool 38a can enter through the
subject’s back. The first deployment tool 38a can enter through a first incision 66a in
skin 68 on the posterior side of the subject near the vertebral column 46. The first
deployment tool 38a can be translated, as shown by arrow 70, to position a first
expandable support device 2a into a first damage site 52a. The first access port 64a can
be on the posterior side of the vertebra 48.

[0088] A second deployment tool 38b can enter through a second incision 66b (as shown)
in the skin 68 on the posterior or the first incision 66a. The second deployment tool 38b
can be translated through muscle (not shown), around nerves 72, and anterior of the
vertebral column 46. The second deployment tool 38b can be steerable. The second
deployment tool 38b can be steered, as shown by arrow 74, to align the distal tip of the
second expandable support device 2b with a second access port 64b on a second damage
site 52b. The second access port 64b can face anteriorly. The second deployment tool
38b can translate, as shown by arrow 76, to position the second expandable support
device 2 in the second damage site 52b.

[0089] The vertebra 48 can have multiple damage sites 52 and expandable support
devices 2 deployed therein. The expandable support devices 2 can be deployed from the
anterior, posterior, both lateral, superior, inferior, any angle, or combinations of the
directions thereof.

[0090] Figures 30 and 31 illustrate translating, as shown by arrow, the deployment tool
38 loaded with the expandable support device 2 through the access port 64. Figure 32
illustrates locating the expandable support device 2 on the deployment tool 38 in the
damage site 52.
[0091] Figures 33 and 34 illustrate that the deployment tool 38 can be deployed from the posterior side of the vertebral column 46. The deployment tool 38 can be deployed off-center, for example, when approaching the posterior side of the vertebral column 46.

[0092] Figures 35 and 36 illustrate that first and second deployment tools 38a and 38b can position and deploy first and second expandable support devices 2a and 2b simultaneously, and/or in the same vertebra 48 and into the same or different damage sites 52a and 52b.

[0093] Figure 37 illustrates that the fluid pressure in the fluid conduit 42 and the balloon 44 can increase, thereby inflating the balloon 44, as shown by arrows. The expandable support device 2 can expand, for example, due to pressure from the balloon 44. The balloon 44 can be expanded until the expandable support device 2 is substantially fixed to the vertebra 48. The balloon 44 and/or the expandable support device 2 can reshape the vertebral column 46 to a more natural configuration during expansion of the balloon 44.

[0094] Figure 38 illustrates that the access port 64 can be made close to the disc 50, for example when the damage site 52 is close to the disc 50. The deployment tool 38 can be inserted through the access port 64 and the expandable support device 2 can be deployed as described supra.

[0095] Figure 39, a front view of the vertebral column, illustrates that more than one expandable support device 2 can be deployed into a single vertebra 48. For example, a first expandable support device (not shown) can be inserted through a first access port 64a and deployed in a first damage site 52a, and a second expandable support device (not shown) can be inserted through a first access port 64a and deployed in a second damage site 52b.

[0096] The first access port 64a can be substantially centered with respect to the first damage site 52a. The first expandable support device (not shown) can expand, as shown
by arrows 78, substantially equidirectionally, aligned with the center of the first access
port 64a. The second access port 64b can be substantially not centered with respect to the
second damage site 52b. The second expandable support device (not shown) can
substantially anchor to a side of the damage site 52 and/or the surface of the disc 50, and
then expand, as shown by arrows 80, substantially directionally away from the disc 50.

[0097] Figure 40 illustrates that the fluid pressure can be released from the balloon 44,
and the balloon 44 can return to a pre-deployment configuration, leaving the expandable
support element substantially fixed to the vertebra 48 at the damage site 52.

[0098] The access port 64 can have an access port diameter 82. The access port diameter
82 can be from about 1.5 mm (0.060 in.) to about 40 mm (2 in.), for example about 8 mm
(0.3 in.). The access port diameter 82 can be a result of the size of the access tool 54.

After the expandable support device 2 is deployed, the damage site 52 can have a
deployed diameter 84. The deployed diameter 84 can be from about 1.5 mm (0.060 in.)
to about 120 mm (4.7 in.), for example about 20 mm (0.8 in.). The deployed diameter 84
can be greater than, equal to, or less than the access port diameter 82.

[0099] Figure 41 illustrates that the deployment tool 38 can be removed, as shown by
arrow, from the vertebra 48 after the expandable support device 2 is deployed.

[00100] Figures 42 and 43 illustrate that a locking pin 86 can be inserted, as shown
by arrow, into the deployed expandable support device 2, for example, after the
expandable support device 2 is deployed in the vertebra 48. The locking pin 86 can
prevent the expandable support device 2 from collapsing after the expandable support
device 2 is deployed in the vertebra 48. The locking pin 86 can form an interference fit
with the expandable support device 2.

[00101] The locking pin 86 can be parallel with the longitudinal axis 4, as shown in
Figure 42, for example when the locking pin 86 is slidabley received by and/or attached to
the lock grooves 20. The locking pin 86 can be perpendicular to the longitudinal axis 4, as shown in Figure 43, for example when the locking pin 86 is slidably received by and/or attached to ports formed between adjacent first struts 10 after the expandable support device 2 is expanded.

[00102] Figures 44 through 49 illustrate a method for deploying the locking pin 86 into the expandable support device 2. As shown in Figures 44 and 45, the locking pin 86 can be translated, as shown by arrow, into the expandable support device 2. As shown in Figure 46, a first end of the locking pin 86 can be translated, as shown by arrow, into a first port formed between adjacent first struts 10. As shown by Figure 47, a second end of the locking pin 86 can be rotated, as shown by arrow. As shown by Figure 48, the second end of the locking pin 86 can be translated, as shown by arrow, into a second port formed between adjacent first struts 10. Figure 49 shows the locking pin 86 deployed into, and forming an interference fit with, the expandable support device 2.

[00103] Figure 50 illustrates a buttress 88. The buttress 88 can have a longitudinal axis 4. The buttress 88 can have a tensioner 90. A first end of the tensioner 90 can be fixedly or removably attached a first end of the buttress 88. A second end of the tensioner 90 can be fixedly or removably attached a second end of the buttress 88. The tensioner 90 can be in a relaxed configuration when the buttress 88 is in a relaxed configuration. The tensioner 90 can create a tensile force between the first end of the buttress 88 and the second end of the buttress 88 when the buttress 88 is in a stressed configuration. The tensioner 90 can be, for example, a resilient wire, a coil spring, an elastic member, or combinations thereof.

[00104] The buttress 88 can have a coil 92. The coil 92 can have turns 94 of a wire, ribbon, or other coiled element. Figures 51 through 53 illustrate that the coil can be
made from a wire, ribbon, or other coiled element having a circular, square, or oval cross-section, respectively.

[00105] The buttress 88 can be a series of connected hoops.

[0100] Figure 54 illustrates that the buttress 88 can be loaded into a hollow deployment tool 38 in a smear (i.e., partially shear stressed) configuration. The buttress 88 in the smear configuration can have a relaxed first end 96, a stressed smear section 98, and a relaxed second end 100. The longitudinal axis 4 can be not straight (i.e., non-linear) through the smear section 98.

[0101] Figure 55 illustrates that part of the buttress 88 can be forced, as shown by arrow, out of the deployment tool 38. The second end 100 can exit the deployment tool 38 before the remainder of the buttress 88. The smear section 98 can then partially relax.

The second end 100 can be positioned to a final location before the remainder of the buttress 88 is deployed from the deployment tool 38.

[0102] Figure 56 illustrates that the remainder of the buttress 88 can be forced, as shown by arrow, out of the deployment tool 38. The smear section 98 can substantially relax.

The longitudinal axis 4 can return to a substantially relaxed and/or straight (i.e., linear) configuration.

[0103] Figure 57 illustrates that the buttress 88 can be deployed in the expandable support device 2, for example with the longitudinal axis 4 of the buttress 88 or the strongest orientation of the buttress 88 aligned substantially parallel with the primary load bearing direction (e.g., along the axis of the spine) of the expandable support device 2.

[0104] Figure 58 illustrates that the buttress 88 can be loaded into the hollow deployment tool 38 with the longitudinal axis 4 of the buttress 88 substantially parallel with the hollow length of the deployment tool 38. The entire length of the buttress 88 can be under shear stress.
[0105] Figure 59 illustrates that part of the buttress 88 can be forced, as shown by arrow, out of the deployment tool 38. The second end of the buttress 88 can exit the deployment tool 38 before the remainder of the buttress 88. The tensioner 90 can apply a tensile stress between the ends of the buttress 88, for example, forcing the deployed second end of the buttress 88 to “stand up straight”. The second end of the buttress 88 can be positioned to a final location before the remainder of the buttress 88 is deployed from the deployment tool 38.

[0106] Figure 60 illustrates that the remainder of the buttress 88 can be forced, as shown by arrow, out of the deployment tool 38. The buttress 88 can substantially relax.

[0107] Figure 61 illustrates that the buttress can have a first wedge 102 and a second wedge 104. The first wedge 102 can contact the second wedge 104 at a directionally locking interface 106. The directionally locking interface 106 can have directional teeth 108.

[0108] Figure 62 illustrates that the first wedge 102 can be slidably attached to the second wedge 104. The first wedge 102 can have a tongue 110. The second wedge 104 can have a groove 112. The tongue 110 can be slidably attached to the groove 112.

[0109] A gap 114 can be between the tongue 110 and the groove 112. The gap 114 can be wider than the height of the teeth 108. The gap 114 can be configured to allow the first wedge 102 to be sufficiently distanced from the second wedge 104 so the teeth 108 on the first wedge 102 can be disengaged from the teeth 108 on the second wedge 104.

[0110] The buttress 88 in a compact configuration can be placed inside of the longitudinal port 8 of the deployed expandable support device 2. Figure 63 illustrates that the first wedge 102 can then be translated, as shown by arrows, relative to the second wedge 104 along the directionally locking interface 106. The first wedge 102 can abut a first side of the inside of the deployed expandable support device 2. The second wedge
104 can abut a second side of the inside of the deployed expandable support device 2. The directionally interference fitting teeth 108 can prevent disengagement of the buttress 88. A stop 116 can limit the relative translation of the first wedge 102 and the second wedge 104.

[0111] Figures 64 through 67 illustrate the expandable support device 2 of Figures 1 through 4 that can be in a deployed configuration. The first struts 10 can be expanded, as shown by arrows 118. The expandable support device 2 can passively narrow, as shown by arrows 120. The expandable support device 2 can be deployed in a configuration where the second struts 12 can be placed against the load bearing surfaces of the deployment site.

[0112] The expandable support device 2 can have a minimum inner diameter 122 and a maximum inner diameter 124. The minimum inner diameter 122 can be less than the pre-deployed inner diameter. The minimum inner diameter 122 can be from about 0.2 mm (0.01 in.) to about 120 mm (4.7 in.), for example about 2 mm (0.08 in.) be from about 1.5 mm (0.060 in.) to about 40 mm (2 in.), for example about 8 mm (0.3 in.). The maximum inner diameter 124 can be more than the pre-deployed inner diameter. The maximum inner diameter 124 can be from about 1.5 mm (0.060 in.) to about 120 mm (4.7 in.), for example about 18 mm (0.71 in.).

[0113] Figures 68 through 70 illustrate the expandable support device 2 of Figures 15 through 18 that can be in a deployed configuration. A tool (not shown) can releasably attach to the tool engagement port 34. The tool can be used to position the expandable support device 2. The tool can be used to expand the expandable support device 2, for example, by forcing the first panels 24 toward each other.

[0114] The second joints 32 can form angles less than 90°. As shown in Figure 71, a compressive force, as shown by arrows 126, causes additional inward deflection, as
shown by arrows 128, of the first panels 24, and will not substantially compress the
expandable support device 2.

[0115] Figure 72 illustrates a deployed configuration of the expandable support device 2
of Figures 19 and 20. The first struts 10 can expand to the size of the expandable support
device 2. Figure 73 illustrates that the first struts 10 can touch each other, for example if
the expandable support device 2 is sufficiently expanded. In the case of extreme
compressive loads applied to the expandable support device 2, the first struts 10 can
buckle into each other, thereby providing additional resistance to compressive loads.

[0116] Figure 74 illustrates the expandable support device 2 that can have one or more
bands 130. The bands 130 can be attached to other bands 130 and/or attached to the
expandable support device 2 with band connectors 132. The bands 130 can be attached to
the expandable support device 2 before, during, or after deployment. The bands 130 can
increase the compressive strength of the expandable support device 2.

[0117] Figure 75 illustrates the locking pin 86 that can be configured to fit into the
longitudinal port 8, for example, of the expanded expandable support device 2 of Figures
64 through 67. Figure 76 illustrates the locking pin 86 that can be configured to fit into
the longitudinal port 8, for example, of the expanded expandable support device 2 of
Figures 68 through 71. Figure 77 illustrates the locking pin 86 that can be configured to
fit into the longitudinal port 8, for example, of the expanded expandable support device 2
of Figures 8 and 9 and/or Figures 11 and 12.

[0118] Once the expandable support device 2 is deployed, the longitudinal port 8 and the
remaining void volume in the damage site 52 can be filled with, for example,
biocompatible coils, bone cement, morselized bone, osteogenic powder, beads of bone,
polymerizing fluid, paste, a matrix (e.g., containing an osteogenic agent and/or an anti-
inflammatory agent, and/or any other agent disclosed supra), Orthofix, cyanoacrylate, or combinations thereof.

[0119] The expandable support device 2 can be implanted in the place of all or part of a vertebral disc 50. For example, if the disc 50 has herniated, the expandable support device 2 can be implanted into the hernia in the disc annulus, and/or the expandable support device 2 can be implanted into the disc nucleus.

[0120] It is apparent to one skilled in the art that various changes and modifications can be made to this disclosure, and equivalents employed, without departing from the spirit and scope of the invention. Elements shown with any embodiment are exemplary for the specific embodiment and can be used on other embodiments within this disclosure.


CLAIMS

We claim:

1. An expandable support device for performing completely implantable spinal repair, comprising:
   a first strut;
   a second strut attached to, and/or integral with, the first strut; and
   wherein the first strut is substantially deformable.

2. The device of Claim 1, wherein the second strut is substantially inflexible.

3. The device of Claim 1, wherein the device is configured to expand in a single direction.

4. The device of Claim 1, wherein the device is configured to expand in two directions.

5. The device of Claim 1, further comprising a buttress.

6. The device of Claim 5, wherein the buttress comprises a coil.

7. The device of Claim 5, wherein the buttress comprises a wedge.

8. The device of Claim 5, wherein the buttress comprises a hoop.

9. The device of Claim 1, further comprising a locking pin.
10. The device of Claim 9, wherein the locking pin is interference fit with the device.

11. The device of Claim 10, wherein the locking pin is interference fit with the first strut.

12. The device of Claim 10, wherein the device comprises a longitudinal port, and

wherein the locking pin is interference fit with the longitudinal port.

13. The device of Claim 1, further comprising a longitudinal axis, wherein the

longitudinal axis has a radius of curvature.

14. The device of Claim 13, wherein the radius of curvature is less than or equal to about

250 mm.

15. The device of Claim 13, wherein the radius of curvature is less than or equal to about

50 mm.

16. The device of Claim 1, further comprising protruding tissue engagement elements.

17. The device of Claim 1, wherein the device comprises an outer side, and wherein the

outer side has a flat section.

18. An expandable support device for performing completely implantable damaged bone

repair, comprising:

a first strut;

a second strut attached to the first strut; and
wherein the first strut is substantially deformable.

19. An expandable support device for completely implantable vertebral disc repair comprising:
   a first strut;
   a second strut attached to the first strut; and
   wherein the first strut is substantially deformable.

20. A method for repairing a damaged section of a spine, comprising:
   expanding an expandable support device in the damaged section, wherein the expandable support device is loaded on a balloon during the expanding; and
   wherein expanding comprises inflating a balloon.

21. The method of Claim 20, wherein expanding comprises inflating the balloon equal to or greater than about 5,000 kPa of internal pressure.

22. The method of Claim 20, wherein expanding comprises inflating the balloon equal to or greater than about 10,000 kPa of internal pressure.

23. A method for repairing a damaged section of a spine, comprising:
   deploying an expandable support device into the damaged section;
   expanding the expandable support device in the damaged section;
   supporting the damaged section with the expanded expandable support element;
   and
   leaving the expandable support element in the damaged section.
24. The method of Claim 23, wherein the damaged section is a vertebra.

25. The method of Claim 23, wherein the damaged section is a vertebral disc.

26. The method of Claim 25, wherein the damaged section is a vertebral disc annulus.

27. The method of Claim 25, wherein the damaged section is a vertebral disc nucleus.

28. The method of Claim 23, wherein expanding comprises inflating a balloon

29. The method of Claim 28, wherein the expandable support device is loaded on the balloon during the expanding, and wherein expanding comprises inflating the balloon equal to or greater than about 5,000 kPa of internal pressure.

30. The method of Claim 28, wherein expanding comprises inflating the balloon equal to or greater than about 10,000 kPa of internal pressure.
FIG. 60

FIG. 61

FIG. 62

FIG. 63

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