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(54) **COMPOSITES AND METHODS FOR TREATING BONE**

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(57) **ABSTRACT**

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A system and method for treating bone abnormalities including vertebral compression fractures and the like. In one vertebroplasty method, a fill material is injected under high pressures into cancellous bone wherein the fill material includes a flowable bone cement component and an elastomeric polymer component that is carried therein. The elastomer component can further carry microscale or mesoscale reticulated elements. Under suitable injection pressures, the elastomeric component ultimately migrates within the flowable material to alter the apparent viscosity across the plume of fill material to accomplish multiple functions. For example, the differential in apparent viscosity across the fill material creates a broad load-distributing layer within cancellous bone for applying retraction forces to cortical bone endplates. The differential in apparent viscosity also transitions into a flow impermeable layer at the interface of cancellous bone and the flowable material to prevent extravasation of the flowable bone cement component.

(21) Appl. No.: **11/148,973**

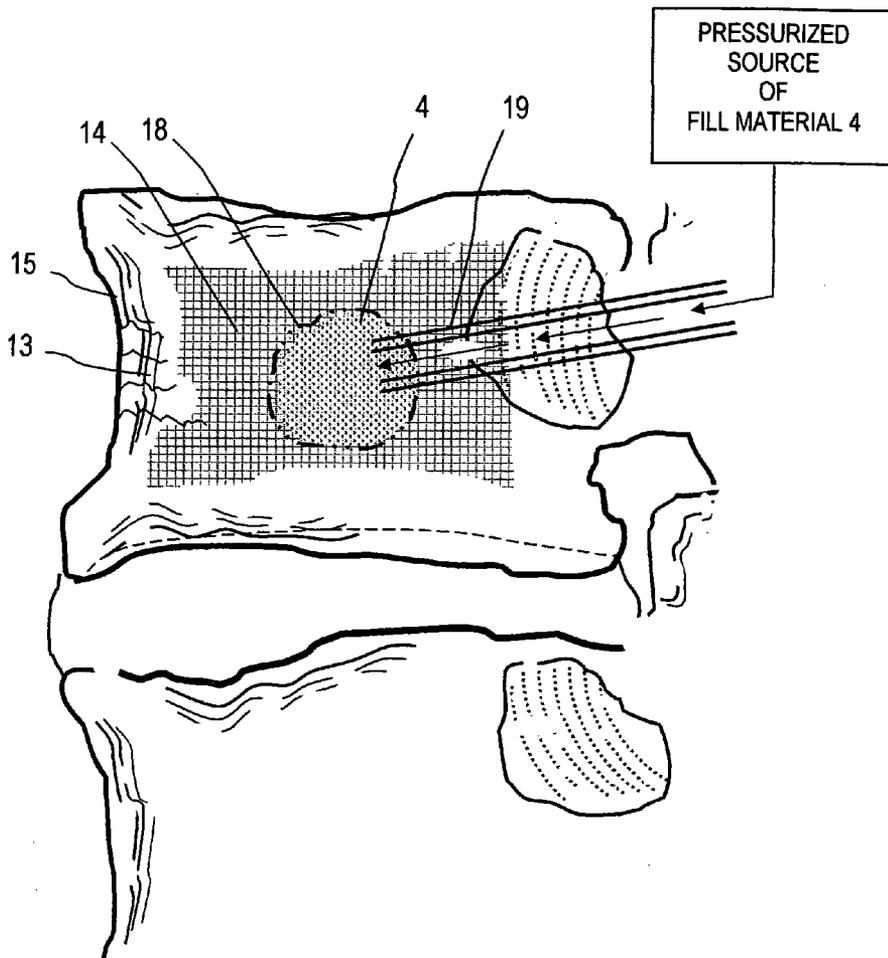
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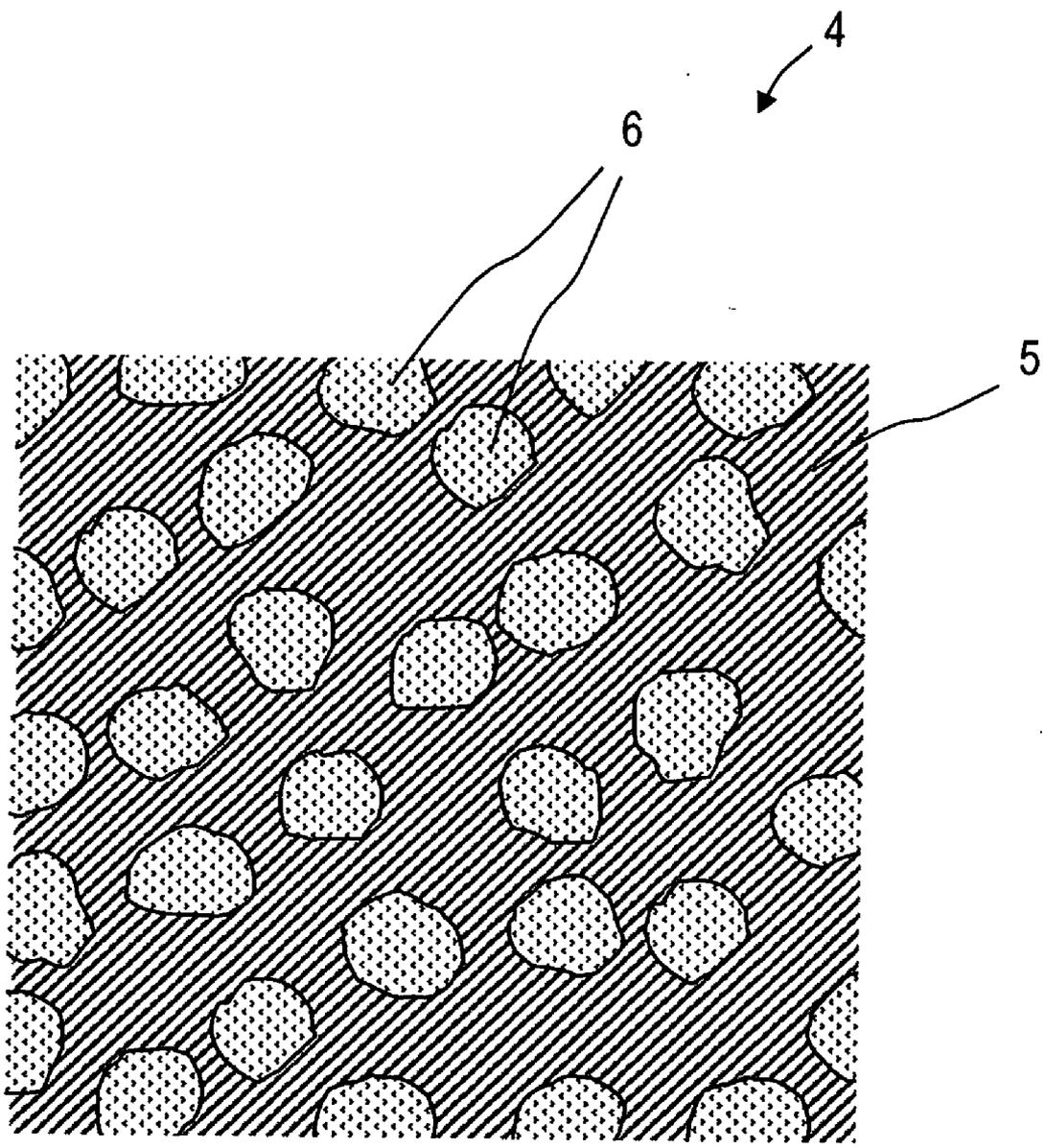
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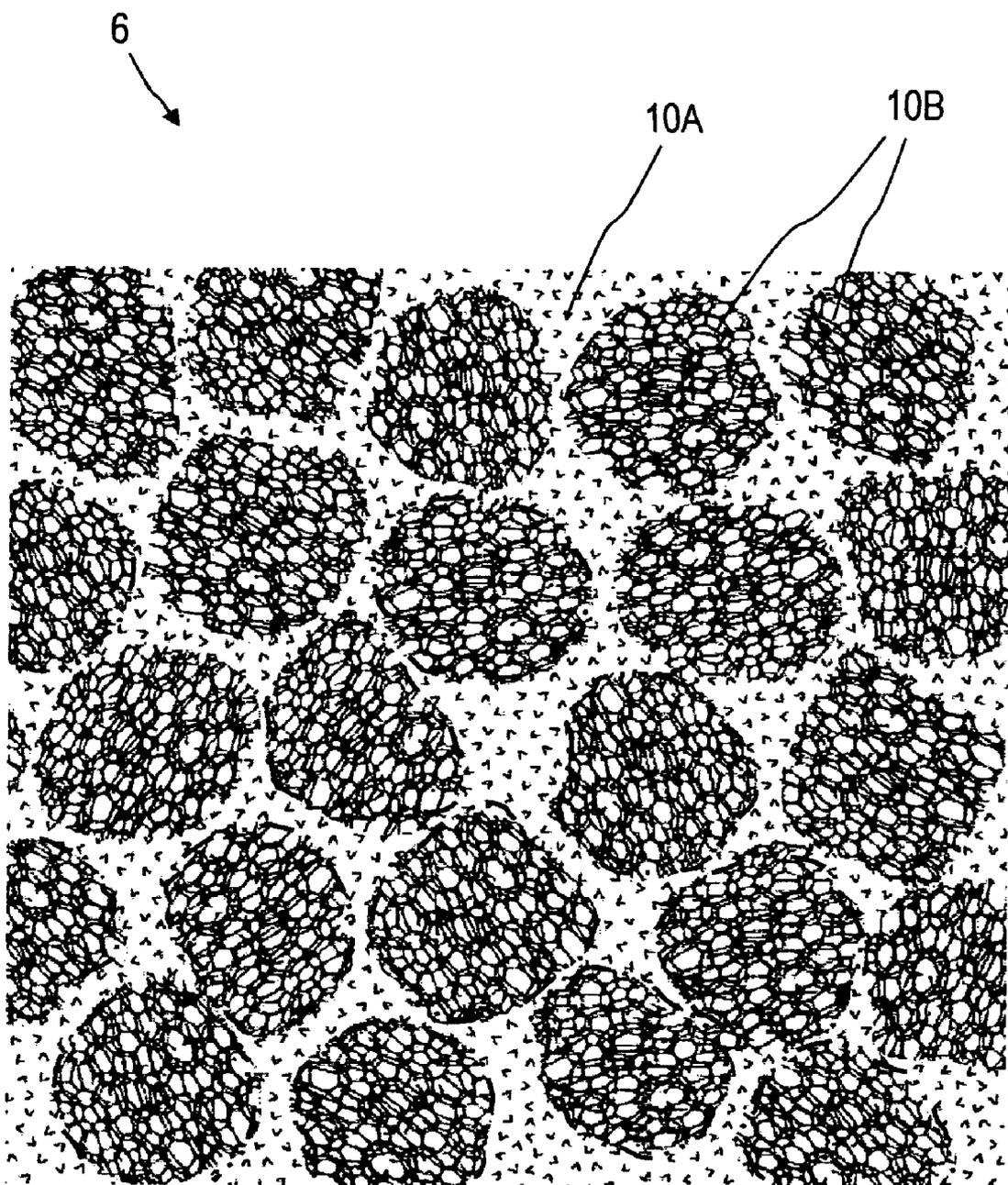
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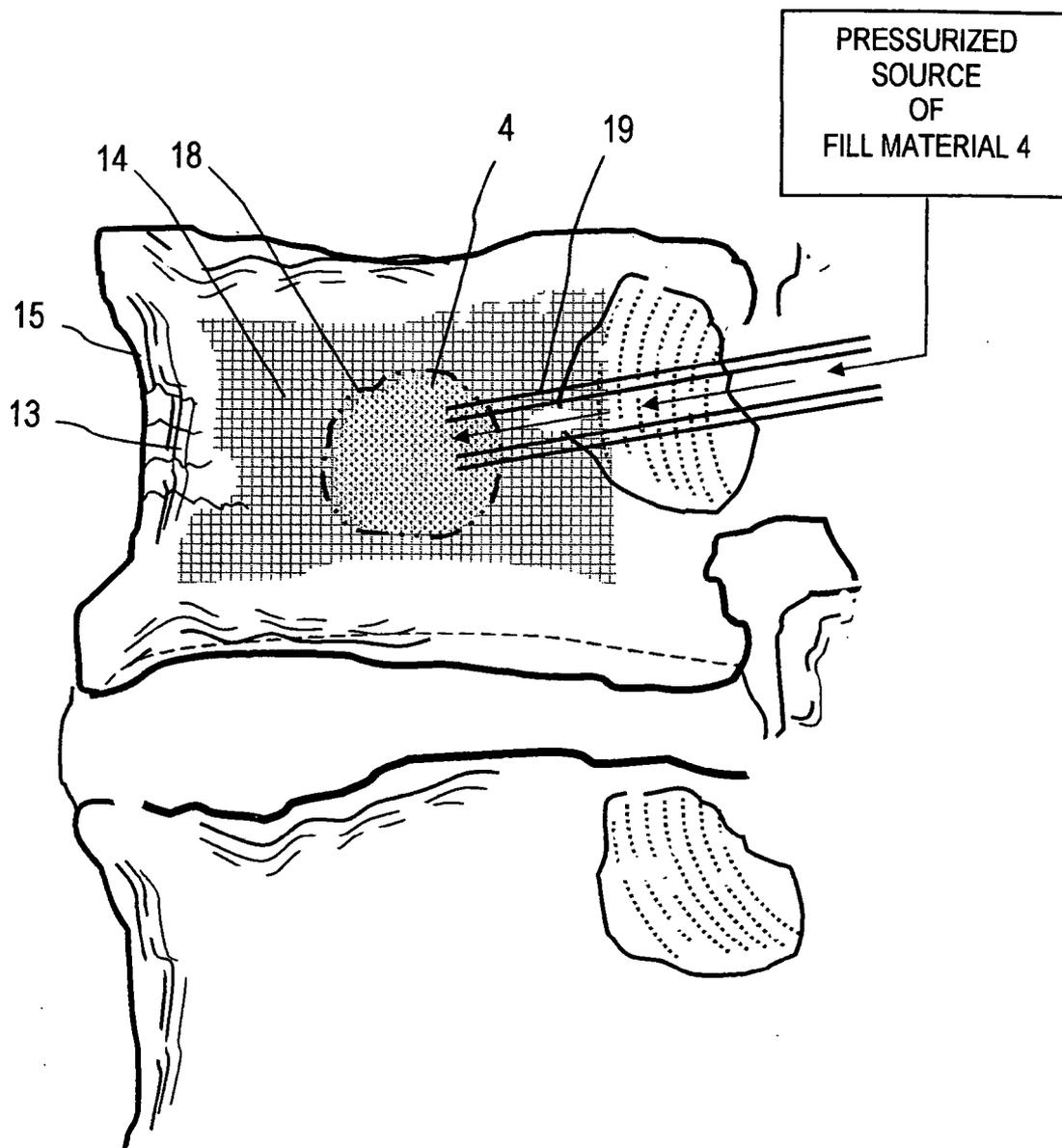




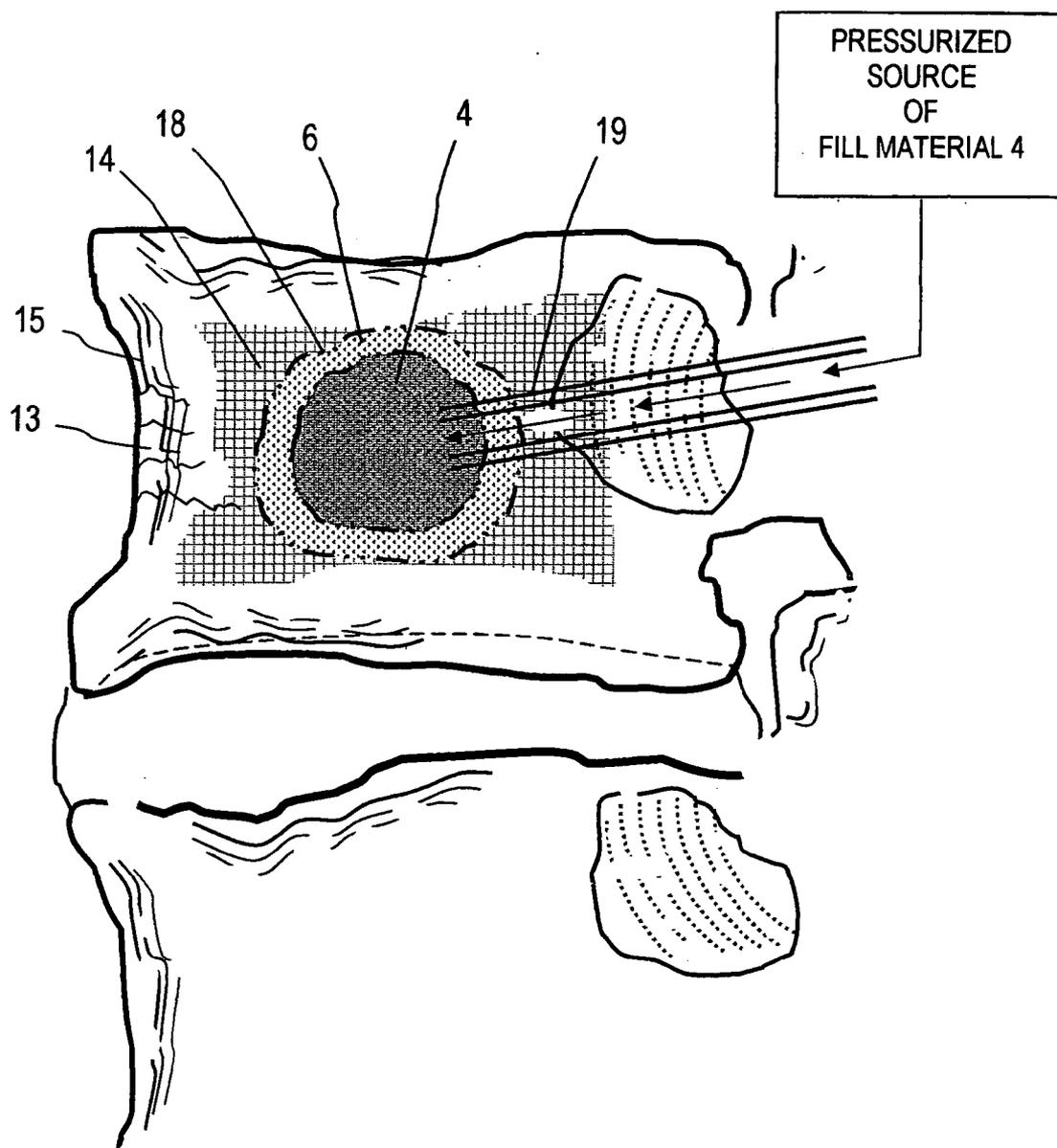
**FIG. 1A**



**FIG. 1B**



**FIG. 2A**



**FIG. 2B**

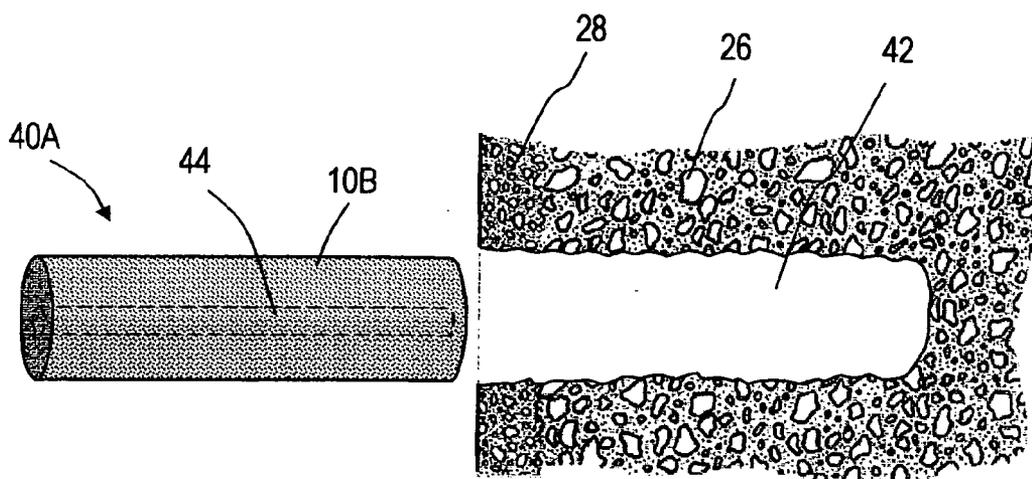


FIG. 3A

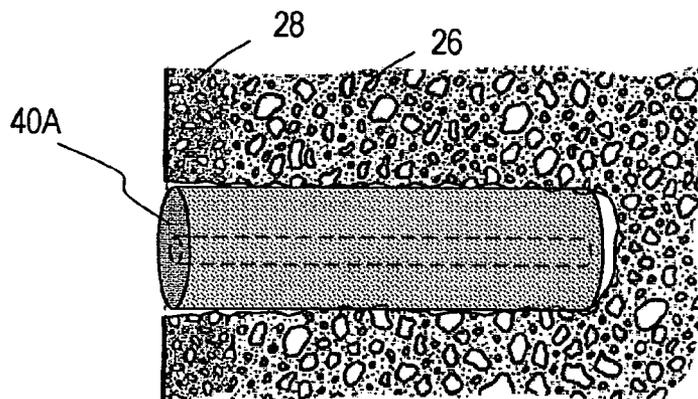


FIG. 3B

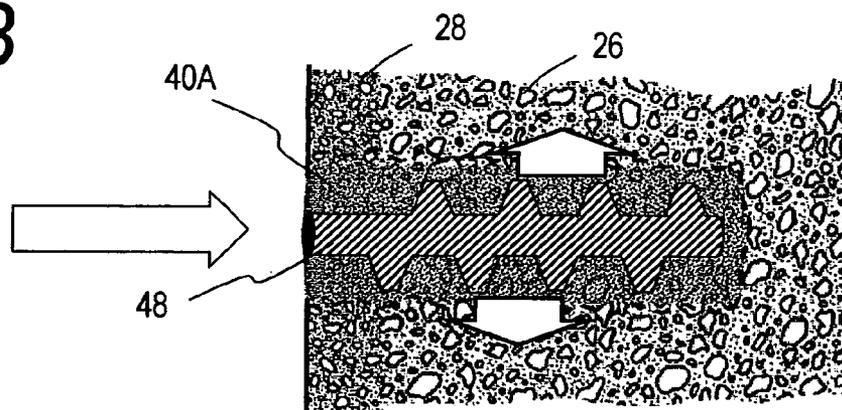
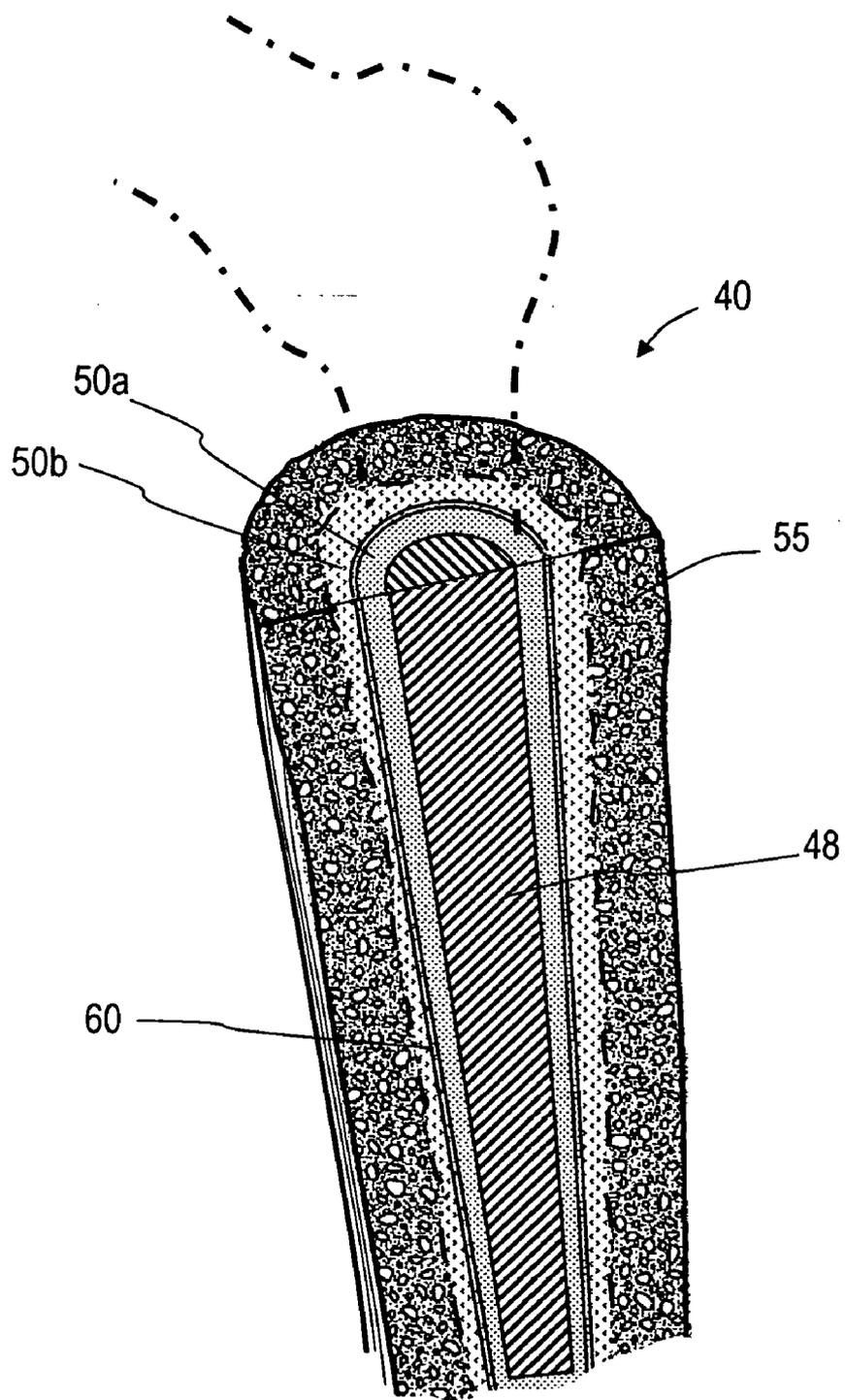
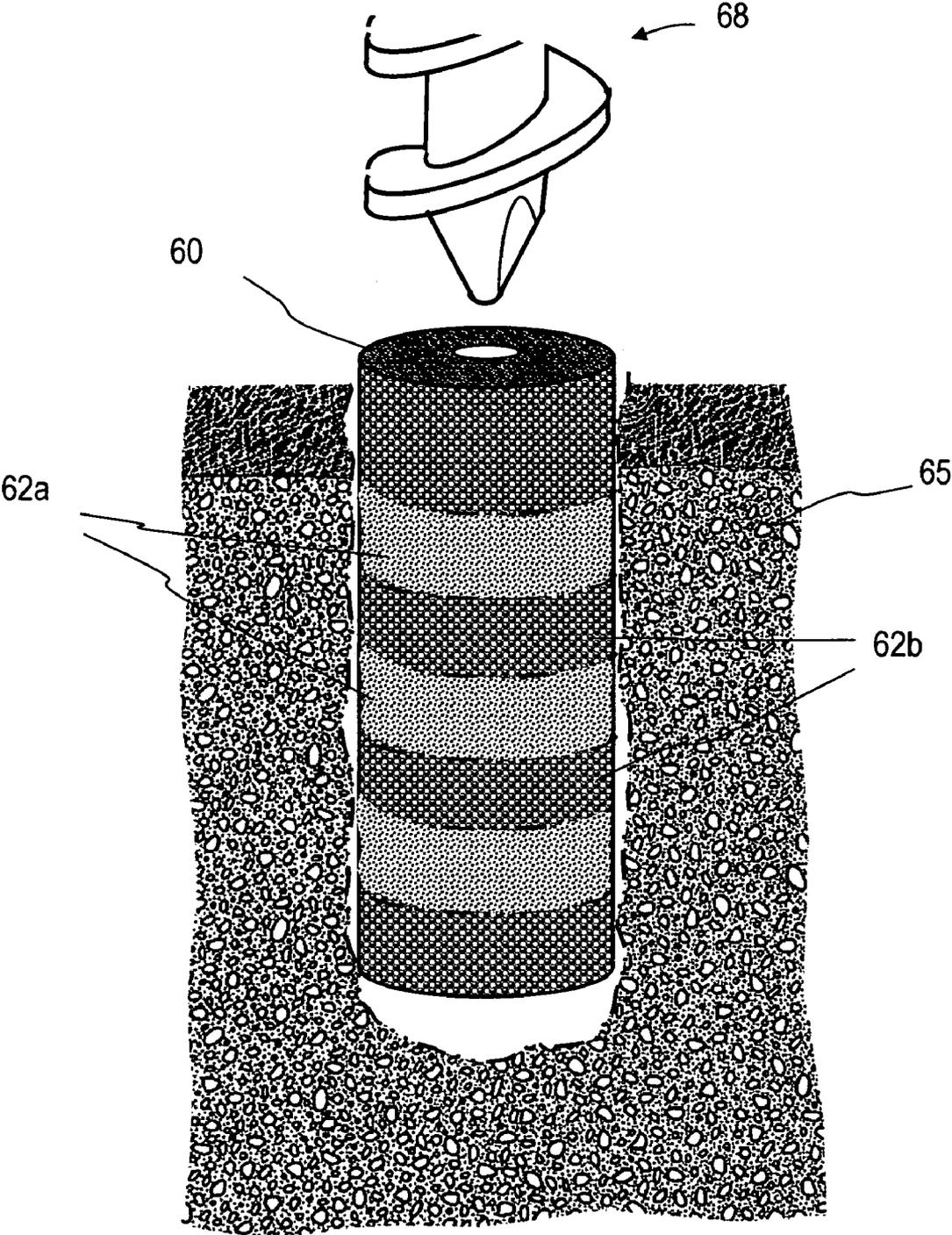


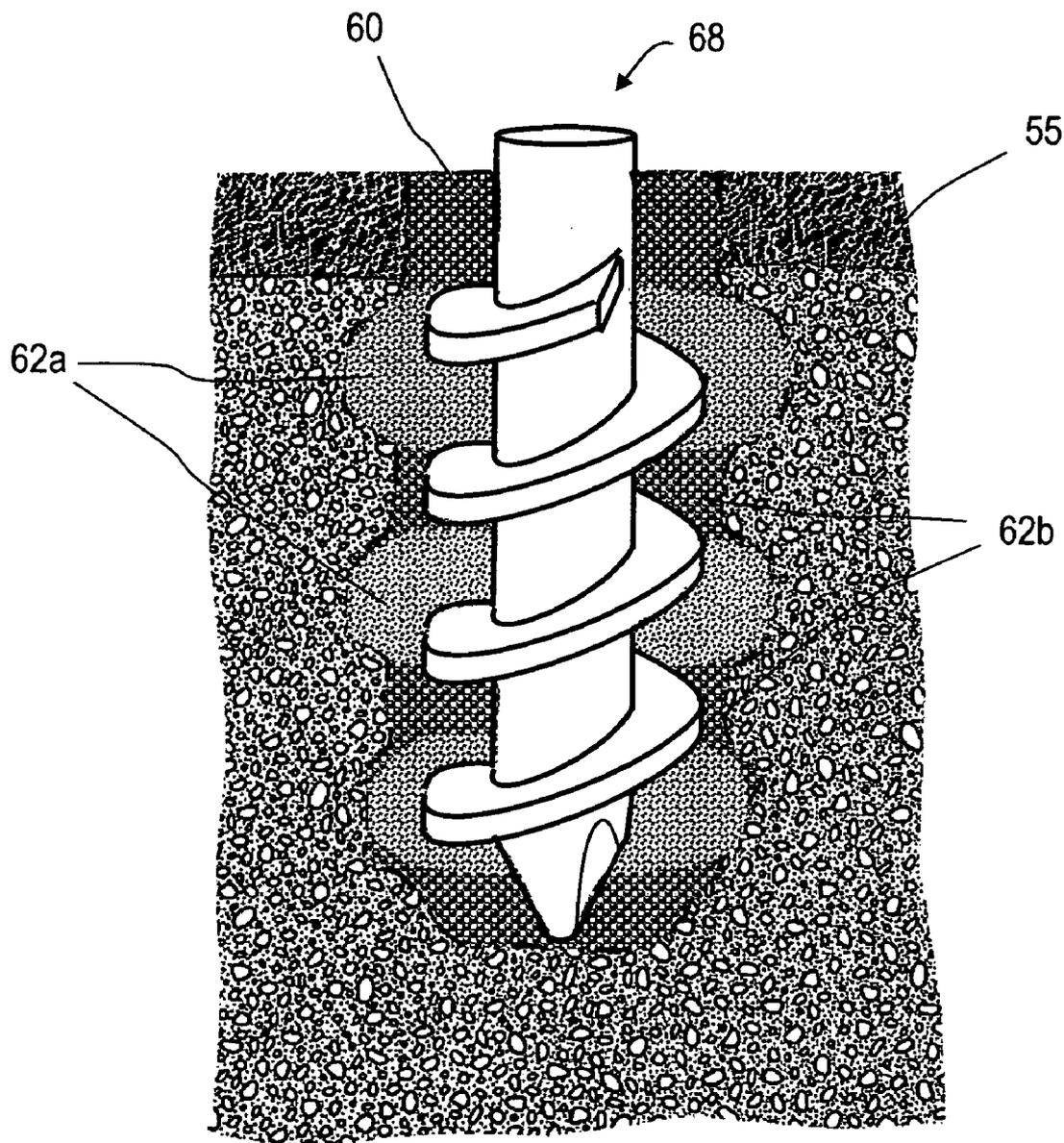
FIG. 3C



**FIG. 4**



**FIG. 5A**



**FIG. 5B**

**COMPOSITES AND METHODS FOR TREATING BONE**

**CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] This application claims benefit of Provisional U.S. Patent Application Ser. No. 60/578,182 filed Jun. 9, 2004 (Docket No. S-7700-030) titled Scaffold Composites and Methods for Treating Abnormalities in Bone, the entire contents of which are hereby incorporated by reference in their entirety and should be considered a part of this specification.

**BACKGROUND OF THE INVENTION**

[0002] 1. Field of the Invention

[0003] This invention relates to bone implant materials and methods and more particularly to composite materials including an elastomer component for treating abnormalities in bones such as compression fractures of vertebra, necrosis of femurs, joint implants and the like. An exemplary method includes introducing a flowable composite material into the interior of a bone wherein increasing pressures result in the elastomer component causing a differential apparent viscosity within selected regions across the flowable material to thereby allow controlled application of forces to the bone for reducing a fracture.

[0004] 2. Description of the Related Art

[0005] Osteoporotic fractures are prevalent in the elderly, with an annual estimate of 1.5 million fractures in the United States alone. These include 750,000 vertebral compression fractures (VCFs) and 250,000 hip fractures. The annual cost of osteoporotic fractures in the United States has been estimated at \$13.8 billion. The prevalence of VCFs in women age 50 and older has been estimated at 26%. The prevalence increases with age, reaching 40% among 80-year-old women. Medical advances aimed at slowing or arresting bone loss from aging have not provided solutions to this problem. Further, the affected population will grow steadily as life expectancy increases. Osteoporosis affects the entire skeleton but most commonly causes fractures in the spine and hip. Spinal or vertebral fractures also have serious consequences, with patients suffering from loss of height, deformity and persistent pain which can significantly impair mobility and quality of life. Fracture pain usually lasts 4 to 6 weeks, with intense pain at the fracture site. Chronic pain often occurs when one level is greatly collapsed or multiple levels are collapsed.

[0006] Postmenopausal women are predisposed to fractures, such as in the vertebrae, due to a decrease in bone mineral density that accompanies postmenopausal osteoporosis. Osteoporosis is a pathologic state that literally means "porous bones". Skeletal bones are made up of a thick cortical shell and a strong inner meshwork, or cancellous bone, of collagen, calcium salts and other minerals. Cancellous bone is similar to a honeycomb, with blood vessels and bone marrow in the spaces. Osteoporosis describes a condition of decreased bone mass that leads to fragile bones which are at an increased risk for fractures. In an osteoporotic bone, the sponge-like cancellous bone has pores or voids that increase in dimension, making the bone very fragile. In young, healthy bone tissue, bone breakdown

occurs continually as the result of osteoclast activity, but the breakdown is balanced by new bone formation by osteoblasts. In an elderly patient, bone resorption can surpass bone formation thus resulting in deterioration of bone density. Osteoporosis occurs largely without symptoms until a fracture occurs.

[0007] Vertebroplasty and kyphoplasty are recently developed techniques for treating vertebral compression fractures. Percutaneous vertebroplasty was first reported by a French group in 1987 for the treatment of painful hemangiomas. In the 1990's, percutaneous vertebroplasty was extended to indications including osteoporotic vertebral compression fractures, traumatic compression fractures, and painful vertebral metastasis. In one percutaneous vertebroplasty technique, bone cement such as PMMA (polymethylmethacrylate) is percutaneously injected into a fractured vertebral body via a trocar and cannula system. The targeted vertebrae are identified under fluoroscopy. A needle is introduced into the vertebral body under fluoroscopic control to allow direct visualization. A transpedicular (through the pedicle of the vertebrae) approach is typically bilateral but can be done unilaterally. The bilateral transpedicular approach is typically used because inadequate PMMA infill is achieved with a unilateral approach.

[0008] In a bilateral approach, approximately 1 to 4 ml of PMMA are injected on each side of the vertebra. Since the PMMA needs to be forced into cancellous bone, the technique requires high pressures and fairly low viscosity cement. Since the cortical bone of the targeted vertebra may have a recent fracture, there is the potential of PMMA leakage. The PMMA cement contains radiopaque materials so that when injected under live fluoroscopy, cement localization and leakage can be observed. The visualization of PMMA injection and extravasion are critical to the technique and the physician terminates PMMA injection when leakage is evident. The cement is injected using small syringe-like injectors to allow the physician to manually control the injection pressures.

[0009] Kyphoplasty is a modification of percutaneous vertebroplasty. Kyphoplasty involves a preliminary step that comprises the percutaneous placement of an inflatable balloon tamp in the vertebral body. Inflation of the balloon creates a cavity in the bone prior to cement injection. Further, the proponents of percutaneous kyphoplasty have suggested that high pressure balloon-tamp inflation can at least partially restore vertebral body height. In kyphoplasty, it has been proposed that PMMA can be injected at lower pressures into the collapsed vertebra since a cavity exists to receive the cement—which is not the case in conventional vertebroplasty.

[0010] The principal indications for any form of vertebroplasty are osteoporotic vertebral collapse with debilitating pain. Radiography and computed tomography must be performed in the days preceding treatment to determine the extent of vertebral collapse, the presence of epidural or foraminal stenosis caused by bone fragment retropulsion, the presence of cortical destruction or fracture and the visibility and degree of involvement of the pedicles. Leakage of PMMA during vertebroplasty can result in very serious complications including compression of adjacent structures that necessitate emergency decompressive surgery.

[0011] Leakage or extravasation of PMMA is a critical issue and can be divided into paravertebral leakage, venous infiltration, epidural leakage and intradiscal leakage. The exothermic reaction of PMMA carries potential catastrophic consequences if thermal damage were to extend to the dural sac, cord, and nerve roots. Surgical evacuation of leaked cement in the spinal canal has been reported. It has been found that leakage of PMMA is related to various clinical factors such as the vertebral compression pattern, and the extent of the cortical fracture, bone mineral density, the interval from injury to operation, the amount of PMMA injected and the location of the injector tip. In one recent study, close to 50% of vertebroplasty cases resulted in leakage of PMMA from the vertebral bodies. See Hyun-Woo Do et al., "The Analysis of Polymethylmethacrylate Leakage after Vertebroplasty for Vertebral Body Compression Fractures", *Jour. of Korean Neurosurg. Soc.* Vol. 35, No. 5 (May 2004) pp. 478-82, (<http://www.jkns.or.kr/htm/abstract.asp?no=0042004086>).

[0012] Another recent study was directed to the incidence of new VCFs adjacent to the vertebral bodies that were initially treated. Vertebroplasty patients often return with new pain caused by a new vertebral body fracture. Leakage of cement into an adjacent disc space during vertebroplasty increases the risk of a new fracture of adjacent vertebral bodies. See *Am. J. Neuroradiol.* 2004 February; 25(2):175-80. The study found that 58% of vertebral bodies adjacent to a disc with cement leakage fractured during the follow-up period compared with 12% of vertebral bodies adjacent to a disc without cement leakage.

[0013] Another life-threatening complication of vertebroplasty is pulmonary embolism. See Bernhard, J. et al., "Asymptomatic diffuse pulmonary embolism caused by acrylic cement: an unusual complication of percutaneous vertebroplasty", *Ann. Rheum. Dis.* 2003; 62:85-86. The vapors from PMMA preparation and injection are also cause for concern. See Kirby, B., et al., "Acute bronchospasm due to exposure to polymethylmethacrylate vapors during percutaneous vertebroplasty", *Am. J. Roentgenol.* 2003; 180:543-544.

[0014] Another disadvantage of PMMA is its inability to undergo remodeling—and the inability to use the PMMA to deliver osteoinductive agents, growth factors, chemotherapeutic agents and the like. Yet another disadvantage of PMMA is the need to add radiopaque agents which lower its viscosity with unclear consequences on its long-term endurance.

[0015] In both higher pressure cement injection (vertebroplasty) and balloon-tamped cementing procedures (kyphoplasty), the methods do not provide for well controlled augmentation of vertebral body height. The direct injection of bone cement simply follows the path of least resistance within the fractured bone. The expansion of a balloon also applies compacting forces along lines of least resistance in the collapsed cancellous bone. Thus, the reduction of a vertebral compression fracture is not optimized or controlled in high pressure balloons as forces of balloon expansion occur in multiple directions.

[0016] In a kyphoplasty procedure, the physician often uses very high pressures (e.g., up to 200 or 300 psi) to inflate the balloon which first crushes and compacts cancellous bone. Expansion of the balloon under high pressures close to

cortical bone can fracture the cortical bone, or cause regional damage to the cortical bone that can result in cortical bone necrosis. Such cortical bone damage is highly undesirable and results in weakened cortical endplates.

[0017] Kyphoplasty also does not provide a distraction mechanism capable of 100% vertebral height restoration. Further, the kyphoplasty balloons under very high pressure typically apply forces to vertebral endplates within a central region of the cortical bone that may be weak, rather than distributing forces over the endplate.

[0018] There is a general need to provide systems and methods for use in treatment of vertebral compression fractures that provide a greater degree of control over introduction of bone support material, and that provide better outcomes. Embodiments of the present invention meet one or more of the above needs, or other needs, and provide several other advantages in a novel and non-obvious manner.

#### SUMMARY OF THE INVENTION

[0019] The invention provides systems and method of treating bone abnormalities including vertebral compression fractures, bone tumors and cysts, avascular necrosis of the femoral head and the like. In one embodiment, the invention comprises a bone infill system or implant system with a fill material that includes a flowable component and an elastomeric polymer component that is deformable in-situ (**FIG. 1A**). In one embodiment, the elastomer component comprises a matrix of base elastomer and a filler of microscale or mesoscale reticulated elements (**FIG. 1B**). The elastomeric component corresponding to the invention performs multiple functions, for example, (i) forming a load-distributing structure between a bone fill material or structure and the elastomer component; (ii) mechanically creating a seal at the interface of cancellous bone and bone fill material or structure to prevent extravasation of a flowable material, (iii) creating a substantially porous layer around the surface of non-porous bone fill material or structures and/or (vi) creating an insulative layer around the surface of an exothermic bone fill material. The elastomer component can be used in bone support treatments or in treatments to move apart cortical bone surfaces as in treating vertebral compression fractures.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0020] In the following detailed description, similar reference numerals are used to depict like elements in the various figures.

[0021] **FIG. 1A** is a greatly enlarged sectional view of a flowable composite bone infill material such as PMMA with a volume of elastomeric elements or particles carried therein.

[0022] **FIG. 1B** is a greatly enlarged sectional view of an elastomeric element of **FIG. 1A** with reticulated elements dispersed within the elastomer.

[0023] **FIG. 2A** is a schematic view of a spine segment with a vertebra having a compression fracture showing a method of the invention wherein a volume of the flowable media of **FIG. 1A** is injected under pressure into cancellous bone in a targeted treatment site.

[0024] FIG. 2B is a schematic view of the spine segment of FIG. 2A showing the pressurized injection of additional flowable wherein the apparent viscosity of the media is altered at surface regions of the plume by outward migration of the elastomeric element to thereby create flow-impermeable surface regions.

[0025] FIGS. 3A-3B are schematic sectional views of a monolith implant structure fabricated of the composite elastomeric material of FIG. 1B; with FIG. 3A illustrating the implant structure introduced into a bore in a bone.

[0026] FIG. 3B illustrate the elastomeric material of FIG. 3A being inserted in the bore in the bone.

[0027] FIG. 3C illustrates an interference fit bone screw driven into the elastomeric material of FIGS. 3A-3B which distributes loads about the bore in cancellous bone.

[0028] FIG. 4 is a sectional cut-away view of one an implant segment with multiple layers having different moduli.

#### DETAILED DESCRIPTION OF THE INVENTION

[0029] FIG. 1A illustrates a cross-sectional view of fill material 4 that comprises flowable component 5 with elastomeric polymer component 6 dispersed therein. The flowable component or material 5 is an in-situ hardenable bone cement (e.g., PMMA) that is intermixed with elastomeric component 6 that comprises a plurality of small elastomeric elements, such as silicone particles or elements of another biocompatible polymer. The flowable material 5 and elastomeric elements 6 can be intermixed prior to introduction into bone or contemporaneous with introduction into bone from separate channels in an introducer. The elastomeric elements 6 are typically dimensioned to be small enough to allow their passage within the openings of cancellous bone in a targeted treatment site. In one embodiment as depicted in FIG. 1B, the elastomeric elements 6 themselves comprise a composite of base elastomer 10A and reticulated, open-cell scaffold structures indicated at 10B. Such reticulated open-cell structures can allow for later bone ingrowth into the surface of the volume of fill material. The term "reticulated" as used herein describes open-cell structures 10B and means having the appearance of, or functioning as, a wire-like network or a substantially rigid net-like structure. The terms reticulated and trabecular are used interchangeably herein to describe structures having ligaments that bound open cells or closed cells in the interior of the structure.

[0030] FIG. 2A-2B illustrate a method corresponding to the invention for use in the treatment of a vertebral compression fracture indicated at 13. In FIG. 2A, an initial volume of fill material 4 comprising a flowable bone cement component 5 and intermixed elastomeric elements 6 is injected under substantial pressure into cancellous bone 14 of the vertebra 15 resulting in plume 18. The fill material 4 is introduced in a unilateral or bilateral transpedicular approach through cannula 19 as is well known in the art of vertebroplasty. The fill material 4 propagates within the openings in cancellous bone and may also follow pre-existing fracture lines in cancellous bone, for example as may exist following a compression fracture. FIG. 2B illustrates the same step of injecting fill material 4 but after a greater volume of material has been introduced resulting in

plume 18 of fill material being larger and engaging the cortical bone endplates. In the high pressure injection of a such a composite fill material, the elastomeric elements 6 migrate toward surface region 20 of plume 18 and create a differential in the apparent viscosity of the flowable material across the volume or plume. The term "apparent viscosity" is used herein to describe the flow characteristics of the combination of flowable component 5 and intermixed elastomeric elements 6. As the injection pressures and the resistance to inflows of fill material increase, the accumulation of elastomeric elements 6 about surface region 20 also increases. The elastomeric elements 6 can additionally deform and ultimately the pressures cause elastomeric elements 6 to form in-situ a substantially flow-impermeable surface region 20. As the surface region becomes substantially impermeable to flows or extravasion therethrough of flowable component 5, continued injection of fill material will elastically expand the surface regions and apply expansion forces to the bone. In a vertebral body as in FIG. 2B, the expansion pressures can expand cancellous bone 14 in which the flowable material 4 has flowed and apply retraction forces to the cortical bone endplates to at least partly reduce a vertebral fracture.

[0031] In general, an exemplary method corresponding to the invention for treating mammalian bone comprises the following: (a) flowing an initial volume of flowable media into the interior of a bone wherein the media includes a volume of elastomeric elements, and (b) flowing under pressure increasing volumes of the flowable media wherein injection pressures causes a differential apparent viscosity within selected regions across the flowable media. The method further includes causing surface regions 20 of the plume 18 of flowable media to be substantially impermeable to flows therethrough (FIG. 2B). The method includes allowing an in-situ polymerizable component of the flowable media to harden to thereby support expanded cancellous bone and to maintain retracted cortical bone in an altered position.

[0032] In another embodiment, the fill material 4 described above includes an elastomer filler composite 6 that carries microscale or mesoscale reticulated elements 10B (FIG. 1B). As the elastomer elements 6 aggregate about surface region 20 of the plume 18, the reticulated material is proximate to bone and can thus allow for subsequent bone ingrowth. In addition, elastomer elements 6 and surface region 20 create an insulative layer that prevents or moderates heating of the bone external to surface region 20 from an exothermic reaction of a typical bone cement used as flowable component 5 that is interior of surface region 20.

[0033] In any embodiment, elastomer composite elements 6 can carry radiosensitive and magnetic-sensitive fillers for cooperating with an RF source or an inductive heating source for elevating the polymer to a targeted temperature. Alternatively, the polymeric composition can be substantially transparent or substantially translucent and carry chromophores for cooperating with a light source introduced with the material for heating to material to a selected temperature for increasing the modulus of the material. Thus, such methods of heating surface regions 20 (FIG. 2B) in which the elastomer composite elements 6 have aggregated will cause accelerated heating of adjacent interior regions of flowable component 5. This system can be used to selectively polymerize regions of flowable media 5 adja-

cent the surface region 20. By this means, the peripheral portions of plume 18 interior of, and within, the aggregated elastomeric elements, can be formed into a flow-impermeable layer.

[0034] The reticulated structures 10B as in FIG. 1B define a mean cross section which can be expressed in microns. In preferred embodiments, the cells are bounded by polyhedral faces, typically pentagonal or hexagonal, that are formed with five or six ligaments 15. The cell dimension is selected for enhancing tissue ingrowth, and mean cell cross-sections can range between 10 microns and 200 microns; and more preferably ranges between 20 microns and 100 microns. Such reticulated materials and structures are available from ERG Materials and Aerospace Corp., 900 Stanford Avenue, Oakland Calif. 94608 and Porvair Advanced Materials, Inc., 700 Shepherd Street, Hendersonville N.C. 28792, and are more fully described in co-pending U.S. patent application Ser. No. 11/\_\_\_\_\_, filed Jun. 7, 2005 (Docket No. S-7700-020A) titled Implants and Methods for Treating Bone, the contents of which are incorporated herein by this reference in their entirety and should be considered a part of this specification.

[0035] Referring back to FIGS. 1A and 1B, the elastomeric composition comprises any biocompatible polymer having an elastic modulus ranging between about 10 MPa and 1 KPa. The polymer can be a foam, or a shape memory polymer (SMP) that releases stored energy after heating and moving from a compacted temporary shape to an expanded memory shape. A description of suitable shape memory polymers is described in U.S. patent application Ser. No. 10/837, 858 titled Orthopedic Implants, Methods of Use and Methods of Fabrication filed May 3, 2004, the contents of which are incorporated herein by this reference in their entirety and should be considered a part of this specification. In a preferred embodiment, the elastomer elements 5 are at least one of bioerodible, bioabsorbable or bioexcretable.

[0036] FIGS. 3A-3C illustrate an alternative embodiment of the invention wherein the composite of an elastomer 10A and reticulated elements 10B (FIG. 1B) is formed into exemplary implant body 40A. In FIGS. 3A and 3B, implant 40A is fabricated by molding in a suitable dimension for introduction into bore 25 in a bone, indicated as cancellous bone 26 and a cortical bone surface 28. FIG. 3C illustrates that implant 40A can have an optional channel or opening 44 for receiving or guiding the positioning of fill material 48 comprising a threaded implant. In FIG. 3C, it can be seen that a threaded implant 48 can be screwed into the implant wherein the elastomeric implant 40A and reticulated elements 10B dispersed therein are compressed to form an interference fit between the bone and implant member 40A. Of particular interest, the insertion of the threaded implant 48 causes self-adjustment of the distribution, location and orientation of the reticulated elements 10B within the elastomer matrix, thus optimally self-distributing loads between the implant 48 and the bone. In the prior art, a threaded implant would engage the bone highest engagement pressures generally about the apex of the threads. In the system as in FIG. 3C, the engagement forces would be distributed about all surfaces of threaded implant 48—which also preferably has a surface region that is reticulated, roughened or porous.

[0037] FIG. 4 illustrates another exemplary implant 40B that is fabricated of an elastomer composite. In this embodi-

ment, the composite body has at least two layers 50a and 50b that are polymer matrices that carry reticulated elements having different parameters (density, cell dimensions etc.) to provide different elastic moduli. The scope of the invention thus encompasses an implant structure 40B that has a gradient modulus for transitioning from an interface with cortical bone 55 to the interface with a rigid member 48 which is needed in various implants and reconstructions, such as in hip implants.

[0038] In another embodiment depicted in FIGS. 5A and 5B, the elastomeric composite implant 60 can be configured with a plurality of composite regions 62a and 62b that provide variations or gradients in material properties for enhancing implant fixation in bone 64. In FIG. 5B, it can be seen that regions 62a of the composite are deformable but more rigid than the adjacent regions 62b. Thus, the higher modulus regions will be forced outward more into the bone than other regions 62b upon insertion of bone screw 68. The scope of the invention encompasses varying all the obvious properties of different regions of the composite to achieve the desired regional variations or gradients, and include adjusting the: (i) density of ligaments of the reticulated elements dispersed in the matrix; (ii) the overall shape, dimensions and orientations of the reticulated elements; (iii) the pore size of the reticulated elements; (iv) the modulus, deformability and material of the reticulated elements; (v) the percentage volume of reticulated elements in the matrix, (vi) the properties media carried in the pores of the reticulated elements, and (vii) the modulus and other properties of the polymer base material 10A (FIG. 1B).

[0039] The above-described embodiments describe elastomer composites that cooperate with fill materials to control properties of the interface between fill material and bone. The scope of the invention extends to elastomer composites as in FIGS. 2A-2B, 3A-3C and 4 that are introduced into bone wherein a base polymer can be elevated to a transition temperature so that the composite then adjusts its orientation. Upon cooling, the elastomer composite can then freeze in a particular form. In such embodiments, it is preferred that reticulated elements in the composite have varied shapes for non-slip engagement between such elements to thereby increase the modulus of the material. In an exemplary embodiment, the polymeric composition has a transition temperature in the range of 40° C. to 120° C.; and preferably in the range of 40° C. to 80° C. The transition temperature is a glass transition temperature or a melt temperature. Again, the polymeric matrix can carry radiosensitive or magnetic-sensitive fillers for cooperating with an RF source or an inductive heating source for elevating the polymer to a targeted temperature. Alternatively, the polymeric composition can be substantially transparent or substantially translucent and carry chromophores for cooperating with a light source for heating to material to a selected temperature for elevating the composition to a transition temperature.

[0040] In any embodiment, the fill materials or implants can further carry a radiopaque or radiovisible composition if the material of the reticulated elements is not radiovisible.

[0041] In any embodiment, the fill materials or implants can carry any pharmacological agent or any of the following: antibiotics, cortical bone material, synthetic cortical replacement material, demineralized bone material, autograft and allograft materials. The implant body also can

include drugs and agents for inducing bone growth, such as bone morphogenic protein (BMP). The implants can carry the pharmacological agents for immediate or timed release.

[0042] The above description of the invention intended to be illustrative and not exhaustive. A number of variations and alternatives will be apparent to one having ordinary skills in the art. Such alternatives and variations are intended to be included within the scope of the claims. Particular features that are presented in dependent claims can be combined and fall within the scope of the invention. The invention also encompasses embodiments as if dependent claims were alternatively written in a multiple dependent claim format with reference to other independent claims.

1-31. (canceled)

32. A method of treating mammalian bone, comprising introducing a flowable media under pressure into cancellous bone, the media including a volume of elastomeric elements wherein the elastomeric elements cause differential apparent viscosity within regions of the flowable media.

33. The method of claim 32 wherein the elastomeric elements cause surface regions of the flowable media to have substantially higher apparent viscosity than interior regions thereof.

34. The method of claim 32 wherein the elastomeric elements cause surface regions of the flowable media to be substantially less permeable to flows therethrough.

35. The method of claim 32 wherein introducing the flowable media applies expansion forces to the bone substantially without extravasation.

36. The method of claim 32 wherein introducing the flowable media expands the cancellous bone.

37. The method of claim 32 wherein introducing the flowable media includes introducing a hardenable cement.

38. The method of claim 37 including permitting the cement to harden thereby providing support to the cortical bone about the cancellous bone.

39. The method of claim 32 wherein introducing the flowable media reduces a fracture.

40. The method of claim 32 wherein introducing the flowable media moves cortical bone.

41. The method of claim 32 wherein introducing the flowable media increases height of a fractured vertebra.

42. The method of claim 32 further including the step of applying energy to the elastomeric elements to heat the flowable media.

43. The method of claim 42 wherein applying energy is carried out by at least one of a radiofrequency energy source and a light energy source.

44. A method of treating mammalian bone, comprising flowing a volume of flowable composite media into cancellous bone and transforming the surface regions of the flowable composite media to a substantially flow impermeable form while introducing additional flowable media into the interior of volume.

45. The method of claim 44 wherein transforming the surface regions to a substantially flow impermeable form includes causing the aggregation of elastomeric elements in said surface regions.

46. The method of claim 44 wherein transforming the surface regions to a substantially flow impermeable form includes causing the expansion of shape memory polymer elements.

47. The method of claim 44 wherein transforming the surface regions to a substantially flow impermeable form includes delivering energy to said surface regions from a remote energy source.

48. The method of claim 44 wherein flowing the volume of composite media expands cancellous bone.

49. The method of claim 44 wherein flowing the volume of composite media moves cortical bone.

50. A method of treating mammalian bone, comprising:  
introducing a volume of elastomeric elements into the interior of a bone; and

introducing a flowable media within the volume of elastomeric elements, wherein the elastomeric elements aggregate in outward regions of a plume of the flowable media to cause said outward regions to be substantially flow-impermeable.

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