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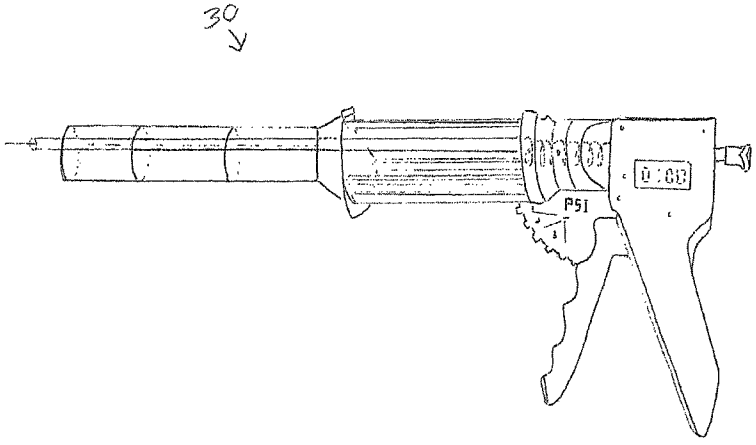

(57) Abstract: Instrumentation for the complete reduction, repair and tissue-engineering regeneration of bone defects or deformities caused by fractures, particularly fractures in relatively inaccessible areas of the human body or skeleton. The instrument is minimally invasive, creates a single access passage with a multitude of possible channels and a multitude of potential applications, including but not limited to debris removal, precise and controlled correction of translational, rotational and angular defects of bone, precise and controlled relocation or decompaction of bone fragments, structural reinforcement within the fracture site by delivery of a variety of micro-implants, and the delivery of a variety of tissue engineering materials and tissue engineering constructs to aid in the regeneration of living bone tissue at the fracture site. The instrument is capable of storing the various materials to be delivered, and controlling the location, quantity, shape, volume, alignment, orientation and internal pressure of said materials when they are delivered into the fracture site. Moreover, the instrument may be adapted for use with several existing techniques of visualization, computer assisted surgery and navigation.

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REPAIR OF BONE DEFECTS

FIELD OF THE INVENTION

The present invention relates generally to the field of surgical instrumentation and methods for the tissue-engineering treatment of skeletal fractures or deformities. More particularly, it relates to fractures or deformities in areas of the human body which are difficult to access, such as the spine, shoulder, elbow, wrist, hip, knee and ankle. The invention specifically describes instrumentation and methods for the precise reduction, relocation or removal of fractured bone parts, the structural reinforcement of fractured bone, and the delivery of tissue engineering materials to aid in repair and regeneration.

BACKGROUND OF THE INVENTION

Cortical bone makes up 80% of the skeleton, and is found in the outer shell of bone. It is composed of tightly-packed Haversian systems (osteons), comprising small, concentric, lamellar cylinders surrounding a central, vascular channel, connected by Haversian canals. Haversian canals contain capillaries, arterioles, venules and nerves. Between these osteons are interstitial lamellae.

Cancellous bone is less dense and more elastic than cortical bone, and also has a higher turnover rate than cortical bone. It is organised in trabecular struts, with lamellae running parallel to the trabeculae. It is located in the epiphyseal and metaphyseal regions of long bones and throughout the interior of short bones.

Immature or pathologic bone is woven and more random, with more osteocytes than lamellar bone. It is the product of rapid bone formation, resulting in an irregular, disorganised pattern of collagen orientation and osteocyte distribution. It occurs in response to bony injury and dramatic changes in mechanical stimulation, and provides a temporary mechanical adjunct to allow bone to maintain or return quickly to its role as a structural support.

All bone tissue is composed of a matrix that primarily consists of collagen protein, but is strengthened by deposits of calcium, hydroxyl and phosphate salts, referred to as hydroxyapatite. Inside and surrounding this matrix lie the cells of bone tissue, which include osteoblasts, osteocytes, osteoclasts and bone-lining cells. All four of these cell types are required for building and maintaining a healthy bone matrix, as well as remodelling of the bone under certain conditions.

Bone fractures are among the most common orthopaedic complaints, and can be caused by a number of factors including trauma, osteoporosis, disease (e.g. Paget's disease) and bone tumours.

For a fracture to heal quickly and correctly (i.e. without any deformity), the bones that are broken must sometimes be first put back into a substantially unfractured position in a process called reduction. Reduction involves putting the broken bone in a cast, after manipulation of the bone into proper alignment. The employment of casts for mending fractures is referred to as external fixation. For some breaks, immobilisation through the use of a cast may be enough to facilitate healing.

However, surgery is usually employed for more complicated breaks such as comminuted fractures (i.e. where the bone is splintered into many pieces). This is known as internal fixation. This can be done with plates and screws or with intramedullary devices such as intramedullary nails.

Alternative treatments for bone fractures include the use of inflatable devices (e.g. a balloon) that is delivered into a fracture zone via a catheter to separate segments of fractured bone, followed by the insertion of a bone cement into the fracture region, thus hardening the fractured zone. Such methods are described in US 6248110.

Bone fracture classifications as referred to in this specification include comminuted fractures, as well as greenstick fractures, compound fractures, spiral fractures, transverse fractures and compression fractures.

Compression fractures occur when two bones are forced against each other.

Vertebral compression fractures (VCFs) occur most frequently in patients suffering osteoporosis or cancer (up to 70% of patients with cancer and multiple myeloma have osteolytic involvement of the spine (Lieberman & Reinhardt, *Clin Orthop.* 2003 Oct;(415 Suppl):S176-86)) and are an extremely painful form of bone defect that can result in profound postural changes (e.g. pronounced stooping). Less frequent causes of VCFs include diseases such as osteogenesis imperfecta and ankylosing spondylitis, as well as trauma such as hyperextension-hyperflexion injury and stress fractures among athletes.

In bone injuries or deformities (i.e. bone fractures), there may occur three different movements of the bone: a parallel staggering of the longitudinal axis lines of a bone, which is known as translation, rotation (rotation in the longitudinal axis of the bone) and angulation.

Realignment of the fractured bone optimally requires a correction of all three of these deformities. For VCFs, as well as compression or other fractures of difficult-to-access bones, this has traditionally been difficult to achieve.

One technique that attempts to provide correction of these deformities of a vertebral body in a VCF is performed using pins inserted into the damaged vertebra and the adjacent vertebrae, or the placement of a piece of the patient's own bone (e.g. from the pelvis) in the space occupied by the intervertebral disc above and/or below the damaged vertebra. These procedures act to "fuse" the damaged vertebral disc. The fused vertebrae act as "one" solid bone, allowing virtually no movement between the fused vertebrae and reducing spinal flexibility to some extent. This reduces the

movement of the damaged vertebra and causes fracture healing, thus reducing the pain caused by movement.

Percutaneous vertebroplasty is a procedure used to treat painful vertebral body compression fractures, which involves injecting polymethylmethacrylate, a liquid cement, into the fractured vertebral body to restore the volume and strength of a vertebra (i.e. structural stabilisation). The cement thus stabilises the fracture. Vertebroplasty affects the nerves responsible for the pain felt after the fracture, hence the procedure is performed for pain control, to correct deformity and to prevent further deformity.

Balloon kyphoplasty offers an advantage over older surgical approaches through the insertion of a deflated balloon (bone tamp) into the bone defect, inflation of the balloon and thus the vertebra, and the use of polymethylmethacrylate to fill the space occupied by the balloon. The procedure thus restores height to the compressed vertebra, as well as vertebral stability. Accordingly, any kyphosis (curvature of the spine, and in particular, posterior convexity of the vertebrae) that is present can be corrected using the kyphoplasty technique. Devices used in this method, and the method itself, are described in US patent numbers 5972015 and 6066154. However, balloon kyphoplasty relies on (uncontrolled) global expansion to correct the deformity.

However, standard kyphoplasty and vertebroplasty are associated with several drawbacks, including an increased risk of vertebral fracture after a kyphoplasty procedure, consequential to the pressure placed on the spinal column from the cement used in the procedure (Fribourg *et al., Spine.* 2004 Oct 15;29(20):2270-6; Spivak *et al.*, supra), and an increased risk of rib fracture for kyphoplasty (Spivak et al., supra). Both kyphoplasty and vertebroplasty involve the risk of patient reactions to the use of the polymethylmethacrylate bone cement, (e.g. including hypotension and, in some cases, death, particularly when multiple vertebral levels are treated in a single procedure) and a suspected increased risk of spinal cord compression (Nussbaum *et al., J Vasc Interv Radiol.* 2004 Nov;15(11):1185-92). Additionally, both

vertebroplasty and kyphoplasty are associated with a risk of cement leakage, with vertebroplasty being linked with a higher risk of such leakage than kyphoplasty, as well as neurologic dysfunction through nerve damage, and a risk of pulmonary embolism from cement leakage into the vascular system (Spivak *et al., Jour Am Acad Orth Surg* 2005, 13(1):6-17).

Furthermore, current kyphoplasty methods, as well as balloon-expanding methods for treating fractures in non-vertebral bones, merely expand in an uncontrolled fashion or separate a compressed (fractured) vertebra or fractured non-vertebral bone, then cement it back to a position similar to its non-broken form. However, bone defects including VCFs commonly also involve a translational deformity of the bone (Gladback *et al., Orthopade.* 1999 Dec;28(12):1023-33). Appropriate adjustment of translation (i.e. staggering of the longitudinal axis of the bone), and indeed rotation as well as angulation, in bone fractures is not optimally achieved using existing balloon-expansion and cementing methods for treating bone fractures including VCFs.

A kit suitable for use in vertebroplasty is disclosed in US 2004/0092946. This kit may comprise a cannula, a stylet, a micro-reamer, a catheter and a syringe. All of these instruments may be used to enable the delivery of restorative or injectable compositions into an intraosseous space or surgical defect. An expandable micro-reamer is described in this application, for creating or enlarging a space to make it suitable for receipt of a composition. The reamer comprises expandable leaves in communication with an outer shaft and surrounding an inner shaft. The leaves are expanded by rotation of a knob to create uniform radial expansion. The leaves may be configured for cutting and/or compressing bone to create the desired cavity. Thus, the expandable leaves of this device are akin to the balloons traditionally used in kyphoplasty. As such, the uniform expansion of the reamer can only really help to separate bone and not enable translation and re-alignment.

Another kit is disclosed in US 2004/0167625. This particular kit comprises an expandable spacer and a quantity of a precursor to a biocompatible elastic material.

Thus, it provides an inter-vertebral spacer or implant that can be inserted using a narrow diameter needle. It does not teach translation and/or re-alignment of a bone fracture to its preferred anatomical position.

Accordingly, there is a need to improve existing bone-fracture repair technologies. Particularly for parts of the body which are difficult to access, such as spine, shoulder, elbow, wrist, hip, knee and ankle, there is a need to provide instruments and techniques which offer the surgeon precision and control in fracture reduction and the measured delivery of novel structural and tissue engineering implants. The present invention can be used to meet these needs and provide several other novel, beneficial clinical outcomes.

SUMMARY OF THE INVENTION

The present invention relates to a surgical instrument capable of the controlled synchronous correction of both anatomical and internal structural deficiencies of fractured or otherwise deformed bone. The said anatomical corrections comprise but are not limited to correction of translational, rotational and angular deformities as well as the reduction of fractures through the multi-axial, multi-planar divarication of compressed or compacted bone fragments; and the said internal structural corrections comprise but are not limited to the measured delivery and accurate placement of shaped scaffolds, discrete structural micro-implants, biomimetic constructs, or injectable fluids for the reinforcement and reconstruction of living bone tissue (hereafter, the said shaped scaffolds, discrete structural micro-implants, biomimetic constructs and injectable fluids are referred to as bone replacement materials).

In one embodiment of the present invention, the instrumentation is equipped with mechanical devices to translate, rotate or realign collapsed or compacted bone and bring it into a desirable anatomical position.

In a particular embodiment, the instrumentation comprises a precision-controlled tip assembly at the distal portion of an elongate catheter body. The tip assembly has an enlarging end portion, wherein the end portion comprises a plurality of spring-like flanges, capable of divaricating and translating compressed or compacted bone fragments. The spring-like flanges, (hereafter referred to as elevation arms) can each be controlled / actuated individually, may be rotated in any plane around the axis of the catheter, and have asymmetric shapes, thus allowing the operating surgeon to optimally address the area of defect that requires the most attention / correction.

In a preferred form, the spring-like flanges or elevation arms elevate and translate in an elliptical manner, relative to a long axis of the catheter body. In another preferred embodiment, the elevation arms come in a multitude of shapes and arc radii, allowing the operating surgeon to select the precise intraosseous relocation of bone fragments required by the patient.

In a preferred form, the elevation arms are controlled precisely and individually by a trigger on the body / handle of the instrument. In another preferred form, the elevation arms may be rotated around the axis of the catheter by means of a geared drive. In yet another preferred form, the elevation arms may be moved in and out of the bone or up and down along the axis of the bone to cause the necessary correction of rotational and angular defects. In still another preferred form, these motions may be caused by cam-wheels mounted close to the handle of the instrument, either transverse or parallel to the axis of the catheter.

In another preferred embodiment, the instrument comprises a suction drilling assembly insertable through the same or parallel catheter or cannula for the removal of tissue debris. In yet another preferred form, the suction drilling assembly is operable simultaneously with the tip assembly which divaricates and translates compressed or compacted bone.

Preferably, the elevation arms further include a scaffold fitted over or inside the arms, said scaffold for compressing fragments of the bone defect towards the outer surface of the scaffold.

In a preferred form, the scaffold is pre-shaped to the normal anatomical shape of the bone.

According to another preferred form, the scaffold is in a folded state upon insertion into the fracture, further wherein a trigger actuates the elevation arms causing expansion of the scaffold to an expanded or final state. The principles of negative Poissons ratio and / or Boundary Element Methods may or may not be used to manufacture such a scaffold.

In one preferred form, the instrumentation may disengage from the scaffold to allow it to remain within the intraosseous space. In another preferred form, the scaffold may be removed from the intraosseous space by the end of the surgical procedure. Preferably, the scaffold may be constructed of biocompatible metals, shape memory metals or alloys. Still more preferably, the scaffold may be made of biodegradable, resorbable polymers of any description.

Preferably, an access passage into the bone defect is formed by a trocar. Even more preferably, a cannulated system based on Seldinger technique is used to gain entry into the body of the bone. Alternatively, the guide wire is extruded from the expandable tip of the catheter body through the access passage.

According to another aspect of the invention, the surgical instrument is removed while the trocar is kept in place and a second gun like device is inserted, the second device having similar mechanical properties to the first except that it delivers the bone replacement material in a controlled and accountable (measurable) way. In this aspect of the invention, the second device may obtain materials stored in one or more chambers found on the body of said second device, and deliver these materials to the fracture site using various mechanical delivery methods. Preferably, such mechanical delivery methods are a screw conveyor, or ratcheted system, or discrete particles threaded on a guide wire etc. Still more preferably, the said second device incorporates

a pressure gauge to ascertain the pressure generated by filling the fracture gap with the bone replacement material.

In a further embodiment, the surgical instrument described above may itself provide for delivery of bone replacement material without the need for a second device. In this embodiment, the surgical instrument has all the features, instrumentation and assemblies of the said second device.

In another preferred embodiment, the instrument may allow for the addition of electronic features enabling it to be used for Computer Aided Surgery/ Navigation. Also, the instrument may allow for the deployment of an endoscope through the same access passage, allowing the operating surgeon to visualise the fracture region.

Thus, the invention relates to a surgical instrument for introducing bone replacement material into a bone defect through an access passage, comprising a precision-controlled tip assembly, said precision tip comprising an elongate catheter body with an enlarging end portion, wherein the end portion comprises a plurality of spring-like expandable flanges, which can be individually controlled, said tip for providing elevation and/or translation of a bone defect, said flanges further providing rotation and angulation, and said catheter further providing for delivery of a bone replacement material.

Preferably, said end portion is removed prior to delivery of said bone replacement material. Said bone material may be delivered to the surgical instrument through a second precision ratchet device that allows for control of amount of material, pressure and shape of the final delivered material.

Preferably, delivery of the bone replacement material to the bone defect is actuated by a trigger on the body of the device.

Preferably, the elevation arms further include a scaffold fitted over or inside the arms, said scaffold for compressing fragments of the bone defect towards the outer surface of the scaffold.

Desirably, the scaffold is removed along with the expandable arms prior to insertion of the bone replacement material.

In another preferred form, the scaffold is retained after insertion of the bone replacement material.

Preferably, the same trigger actuates expansion of the elevation arms and the delivery of the bone replacement material.

In another preferred form, different triggers actuate expansion of the elevation and translation arms and the delivery of the bone replacement material.

Preferably, the bone replacement material is bone cement.

In a particularly preferred form, the bone replacement material is a bone paste comprising hydroxyapatite crystals and at least one growth factor.
Preferably, the hydroxyapatite crystals are hexagonally shaped, thus allowing them to gain rapid initial stability in the bone / fracture defect due to their forming a honeycomb like self-reinforcing structure.

However, the material to fill the defect created by the fracture can be polymethylmethacrylate cement or some types of gel which harden after a certain time period or any type of biologic or non-biologic bone scaffold available.

Even more preferably, the bone paste further comprises osteoblast precursor cells.

Preferably, the osteoblast precursor cells are adult stem cells.

In another preferred form, the osteoblast precursor cells are embryonic stem cells.

In still another preferred form, the osteoblast precursor cells are haematopoietic stem cells.

In a further preferred form, the haematopoietic stem cells are derived from monocyte precursor cells.

Preferably, the at least one growth factor is selected from the group consisting of the bone morphogenetic protein (BMP) family members.

In a preferred form, the BMP is BMP-2.

In addition to the hydroxyapatite crystals the bone replacement material can be 'norian' or 'calcibon' crystals or 'geneX' (these are all trade names). These are made of calcium sulphate or calcium phosphate or a mixture of the two.

The present invention is particularly suitable for use when the bone defect is a vertebral compression fracture (VCF). Alternatively, the bone defect may be a non-vertebral fracture including tibial plateau fractures and other compression type fractures. In fact, the present invention may be useful for correcting all types of compression fractures.

In addition, a surgical instrument according to the present invention may incorporate endoscopic features and be fitted with electronics for Computer Aided Surgery. Thus it will be a Navigation Device as well.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a schematic representation showing a vertebral compression fracture from a lateral perspective.

Figure 2 is a schematic representation showing a guide wire being extruded from an expandable tip of a surgical instrument according to the present invention.

Figure 3 is a dorsolateral perspective of the device shown in Figure 2 showing advancement of the expandable tip into a collapsed vertebral body.

Figure 4 is an enlarged schematic representation of the device shown in Figure 2, showing placement of the expandable tip in the collapsed vertebral body.

Figure 5 is an enlarged schematic representation of the device shown in Figure 2, showing actuation of the expandable tip into an expanded state in the collapsed vertebral body.

Figure 6 is a schematic representation of the device shown in Figure 2, showing location of bone replacement material in the expandable device.

Figure 7 is an enlarged schematic representation of the device shown in Figure 5, showing delivery of bone replacement material to the expandable tip.

Figure 8 is a schematic representation of a surgical instrument according to the present invention being used for delivery of bone replacement material to a hip fracture.

Figure 9A is a schematic representation of a device or gun for the delivery of bone replacement material or cement, according to the present invention.

Figure 9B is an alternative device to that of Figure 9A.

Figure 10 is a schematic representation of the assembly of a particular surgical instrument according to the present invention.

Figure 11 is an enlarged view of a bush employed in the assembly of Figure 10. (The dimensions of such a bush may vary according to the type of fracture to be fixed.)

Figure 12 is an example of an inner shaft employed in the assembly of Figure 10.

Figure 13A is a longitudinal cross-sectional view of the end of a particular outer shaft that may be employed in the assembly of Figure 10.

Figure 13B is view from above of the end of the particular outer shaft shown in cross-section in Figure 13A.

Figure 14 is an example of a spring arm employed in the assembly of Figure 10. (The spring arm may be made of tempered steel like a watch spring or shape memory metal alloy for example titanium, the dimensions of which may vary depending on the fracture to be fixed.)

Figure 15 is an example of an outer shaft employed in the assembly of Figure 10.

Figure 16 is an example of a pusher tip which may be required when going through soft tissues or bony tissues.

Figure 17 is another example of an assembly of a particular surgical instrument according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is based on the development of a device for treating bone defects that provides not only elevation or separation of compressed bone defects, but also translation of the bone defect to its original load-bearing axis line.

Accordingly, the present invention can be used to reduce and correct a bone defect and deliver a bone replacement material or tissue engineering construct to a bone defect in a patient. This may be performed by

- forming an access passage to the bone defect; and
- introducing a device according to the present invention, comprising elevation arms with controllable multi-directional motion, into the defect through the access passage, wherein the arms are in a generally collapsed geometry, said arms being provided through or on an elongate catheter body having a controllable tip assembly, wherein the tip assembly comprises a plurality of arms; and
- causing the elevation arms to assume an expanded geometry within the bone defect to provide divarication and relocation of bone fragments, and translation of the bone defect to its normal anatomical position (rotation and angulation also being corrected if necessary); and
- removing by drilling or suction bone debris from the fracture site
- introducing the bone replacement material or tissue engineering construct into the bone defect using the same device or a second similar shaped gun like device, with a precision control mechanism which can control the pressure and amount of bone replacement material or tissue engineering construct being injected into the defect.

The term "patient" refers to patients of human or other mammal and includes any individual it is desired to examine or treat using the device of the present invention. However, it will be understood that "patient" does not imply that symptoms are present. Suitable mammals that may benefit from use of the device include, but are not restricted to, primates, livestock animals (e.g. sheep, cows, horses, donkeys, pigs), laboratory test animals (e.g. rabbits, mice, rats, guinea pigs, hamsters), companion animals (e.g. cats, dogs) and captive wild animals (e.g. foxes, deer).

The term "compression" when used in relation to a bone defect herein refers to a decrease in height of a bone, along the load-bearing axis line, which occurs when a bone is fractured or otherwise damaged. Bone fracture refers to a break in a bone that results in malalignment due to separation of fragments or collapse but could also be fracture without separation or collapse.

The term "translation" or "translational deformity" of a bone defect as used herein refers to a parallel staggering of the longitudinal axis line or depth of a bone that occurs when the bone is fractured.

The terms "bone defect" and "bone fracture" are used interchangeably herein, and refer to an abnormal aperture, breakage or other inadequacy in a normal anatomical shape of a bone, which may result from a bone growth disorder, disease, trauma or other condition.

The terms "elevation" and "separation" as used herein refer to the process of dividing surfaces of a bone defect in order to create an aperture in the defect. The processes of elevation and/or separation are employed, and translation, where required, to return a misshapen bone (caused by the bone defect or fracture) to the normal, anatomical shape of the bone, through correction of rotation, angulation and translation of the fracture or defect.

The access passage can be formed by any suitable means, such as via a trocar.

Preferably, the catheter body passes through the access passage created by the trocar by virtue of being passed along a guide wire that has firstly been inserted through the access passage into the bone defect. In a particularly preferred form, the guide wire is extruded from the tip of the elevation and translation arms into the bone aperture. Extrusion of the guide wire from the expandable structure may be actuated by any means suitable, such as by trigger action or by using a ratchet device which is controlled at the handle of the device.

In a particularly preferred embodiment, the device is suitable for use through open incisions, such as in minimal incision surgery (MIS) that reveal a bone having a defect, or it may be used endoscopically or in combination with a navigation system.

In one embodiment, the elevation arms of the structure are actuated via a trigger on the catheter body or a ratchet device on the handle.

The elevation arms of the expandable structure may expand in an elliptical or circular manner, relative to the longitudinal axis of the catheter body, to separate, elevate and/or translate the bone defect to its normal, anatomical shape. In this manner, bone fragments that are present in the bone defect are pushed towards the periphery of the defect prior to delivery of the bone replacement material.

In a particularly preferred form, the elevation arms of the structure are covered by an expandable scaffold, which is preferably anatomically pre-shaped to the normal anatomical structure of the bone, in an unfractured or non-defected state.

The term "normal anatomical structure of the bone", as used herein, refers to the non-fractured and non-translated position of the bone, such that the shape of the bone is substantially returned to its non broken state (i.e. separated or non-compressed) and non-staggered state along its load-bearing axis (i.e. non-translated).

Such a scaffold may be made from any suitable, expandable biocompatible material such as titanium mesh, stainless steel mesh, zirconium oxide mesh, ceramic tricalcium phosphate mesh, polymers, ceramics, tantalum, zirconium, polylactic acid, polyglycolic acid, bone substitutes, combinations of materials or the like.

The replacement bone tissue may comprise an artificial bone replacement material, such as a bone cement such as polymethylmethacrylate (PMMA) or commercially available bone substitutes like 'norian' or 'calcibon' or 'geneX'.

Accordingly, the present elevation and translation structure with its plurality of elevation arms achieves precision controlled divarication and relocation of bone fragments, creating pressures up to 350psi and a multi-planar correction of the loss of position of a bone defect.

This differs from a soft expansion method where there is uncontrolled global expansion (as used in balloon kyphoplasty), through an increased pressure in a closed space (i.e. within the fracture).

A hard divarication, relocation and translation such as that achieved by the devices of the present invention thus provides both increased pressure/force in a closed space and directed and controllable pressure and/or force on fracture fragments (translation). The devices of the present invention are thus more controllable and precise than those employed in balloon kyphoplasty. An additional difference is that the same device or a second device of similar shape can be inserted, which allows delivery of the bone replacement material or tissue engineering constructs in a controlled and measurable fashion by way of any of a combination of mechanical devices which maintain pressure while measuring the amount of payload added and the amount remaining in the storage chamber. This preloaded delivery device is also airtight thus preventing the possibility of air being introduced into the system and thus preventing the theoretical possibility of air embolism.

In a preferred embodiment, the expandable structure of the present invention also allows for use of a pre-shaped scaffold to expand (so allowing more accurate reduction of fracture fragments onto a pre-shaped structure that is shaped to the normal anatomical structure of the fractured bone).

Preferably, delivery of the bone replacement material is actuated by a trigger on the handle of the device.

More preferably, the bone replacement material may comprise a bone paste.

The term "bone paste" as used herein refers to a bone replacement material that promotes growth of replacement bone tissue within a bone defect.

Preferably, the bone paste comprises hydroxyapatite bone crystals and growth factors.

In a preferred form, the hydroxyapatite crystals of the bone paste are polyhedral in shape.

In a particularly preferred form, the bone paste comprises at least one osteoblast growth factor. Preferably, the at least one growth factor is a bone morphogenetic protein (BMP). The BMPs are a group of related proteins originally identified by their presence in bone-inductive extracts of demineralized bone. Molecular cloning has revealed at least six related members of this family, which have been designated BMP-2 through BMP-7. These molecules are part of the TGF-β superfamily.

The BMPs can be divided into subgroups with BMP-2 and BMP-4 being 92% identical, and BMP-5, BMP-6, and BMP-7 being an average of about 90% identical. Single BMP molecules, such as BMP-2, are capable of inducing the formation of new cartilage and bone (Li *et al., J Spinal Disord Tech.* 2004 Oct;17(5):423-8). Whether each of the BMPs possesses the same inductive activities in an animal is the subject of ongoing research. Studies of transgenic and knockout mice and from animals and humans with naturally occurring mutations in BMPs and related genes have shown that BMP signaling plays critical roles in heart, neural and cartilage development (Chen *et al., Growth Factors.* 2004 Dec;22(4):233-41).

In a preferred form, the BMP is BMP-7. In an even more preferably form, the BMP is BMP-2.

In a particularly preferred form, the bone paste further comprises osteoblast precursor cells, which may be adult stem cells, embryonic stem cells, haematopoietic stem cells or stem cells derived from monocyte precursor cells.

Preferably, an expandable scaffold is used that is expanded through the actions of the elevation arms of the device, and which is preferably shaped to the original anatomical shape of the bone defect. Preferably, anatomical modelling studies are performed for shaping the scaffold to optimise the scaffold shape to fit the site where replacement bone is required in the patient.

In order to shape the scaffold to fit the site where the replacement bone is required, anatomical modelling studies can be employed, such as computed tomography or magnetic resonance imaging. Preferably, the anatomical modelling studies may further include use of computer–aided design and computer controlled milling machines and / or selective laser melting machines. The scaffold can be nano, micro or macroparticle size.

When the scaffold is expanded, it acts to compact bone fragments within the bone defect to an exterior surface of the scaffold and thus the periphery of the bone defect. The scaffold may then optionally be removed, along with the elevation and translation arms of the device, prior to insertion of the bone replacement material..

Alternatively, the scaffold may be retained in situ within the bone defect, where it can act to retain the bone replacement material. In this embodiment, the scaffold may or may not comprise a bioabsorbable material. Such bioabsorbable materials are well known and include, but are not limited to, poly-L-lactic acid (PLLA), polyglycolic acid and polyglyconate.

The trigger used to actuate and control the elevation arms of the expandable structure may be the same or separate from the trigger that actuates delivery of the bone replacement material. The configuration of the catheter and trigger/s may thus take the

form of a "gun"-like instrument. In fact two different gun like devices may be used. The first to elevate and translate the compressed bone in a controlled manner and the second to deliver the bone substitute, cement or gel in a precise controlled and measurable fashion to a pre-set or measurable pressure for example 300 psi or 350 psi.

Navigation for the placement of the elevation and translation arms may be performed, using but not restricted to equipment such as Brainlab / Zimmer systems, Stryker systems, DePuy systems or Medtronic systems. Navigation will guide accurate placement of gun and accurate use to reduce fractures with minimal tissue dissection and an imaging system is preferably employed to ensure correct placement of the bone replacement material, bone paste and/or expandable scaffold. A number of suitable imaging systems exist in the field, and include, but are not limited to, radiolucent image intensifiers for biplanar fluoroscopy. Imaging systems also include computer assisted tomogram (CT) scanning systems or magnetic resonance image (MRI) systems. Also design will include option of instrumentation made of non-magnetic material for use under MRI (open or closed) navigation systems.

Preferably, the elevation arms are returned to their collapsed state prior to removal of the tip from the bone defect. The elevation arms of the tip structure may be returned to their collapsed state using any suitable mechanism. In the example where the tip comprises elevation arms actuated by a trigger or ratchet like handle, opposite movement of the trigger or ratchet can be employed to retract the arms prior to removal of the tip from the bone defect.

The devices of the invention may be used to reconstruct a vertebral body that has been damaged and/or fractured by cancer (metastases), particularly where the patient is experiencing pain.

The devices of the invention may also be employed for vertebral body damage that has occurred through trauma either due to osteoporotic compression fractures or accidents and falls causing acute compression fractures but not restricted to these indications

where non-union or progressive kyphosis has developed. The main indication for operation would be pain. Other indications include correction of deformity and restoration of structure to be as close as possible to normal anatomical structure.

Furthermore, the devices of the invention can be applied to most, if not all, fractures of the musculo-skeletal system, especially those with a crush or compression component.

The advantages of certain embodiments of the invention thus include the benefits of MIS Surgery (or percutaneous techniques), which are well known. The divarication, relocation, translation, rotation and angulation structures of the invention are capable of being used in MIS to provide divarication or relocation of bone fragments, and translation, rotation and angulation of the fracture. The devices of the invention seek to provide such repair of a bone defect with greater precision and control than any devices previously available because the elevation arms can be individually controlled in any direction.

Furthermore, where bone replacement material is delivered to the bone defect, an *in-vivo* tissue engineering capacity is employed, that can utilise the patient's own tissue (e.g. bone marrow stem cells). In this form of the invention, the problems of bone loss, rejection and complications of mechanical implant wear are avoided. This allows new bone tissue to grow *in situ* in the area where it is required. This embodiment of the invention thus avoids the use of fillers such as acrylic cement with their problems of high temperature setting, leakage (with possible neural and vascular damage), embolization, adjacent fracture precipitation and infection.

The present invention is thus provided. Various combinations and subcombinations and features may be practiced with or without reference to other combinations, subcombinations and/or features, alone or in combination, in the practice of the invention, and, moreover, numerous further adaptations and modifications can be effected within its spirit, the claim scope of which is pointed out in certain preferred embodiments described in the following non-limiting examples.

EXAMPLES

EXAMPLE 1

***In-vivo* tissue engineering using a minimally invasive surgical (MIS) technique for reconstruction of vertebral bodies damaged by acute fracture, osteoporotic fracture or metastasis from cancer.**

The following surgical method should not be used where:

- MIS techniques are contra-indicated, or
- there is a fracture or neoplasm(cancer) with spinal cord compression.

Accordingly, a patient having a vertebral compression fracture (Figure 1) undergoing surgery in the present example is firstly tested for the above-mentioned conditions.

Pre-operative Planning

The standard pre-operative planning (with radiographs, CT, MRI and Bone scan imaging) for bony and spinal surgery is applied. An evaluation is routinely made of the existing cancer (and metastases) and also of the presence of osteoporosis (and risk factors).

Patient Positioning

The patient is positioned prone on a radiolucent table. An Image Intensifier for biplanar (posterio-anterior and lateral) fluoroscopy is required. The patient is anaesthetised using general anaesthesia or regional / local anaesthesia.

The operative technique employed used the transpedicular approach. However, some surgeons may elect to use the extrapedicular approach.

STEP ONE: Placing guide wire in vertebral body

Standard access passage made using cannulated guide wire or Jamshedi needle and Seldinger technique (Figure 2).

Gun is then inserted (Figure 3).

STEP TWO: Use of triggered catheter

Translation / elevation arms are then inserted (Figure 4).

Proper placement with intravertebral venography is verified (confirmation according to the venous blush within the body).

Translation / elevation arms are elevated and used to elevate / translate the fracture (Figure 5).

Translation / elevation arms are removed.

The trigger actuates slow elevation of the arm tips until the fracture is elevated and translated (Figure 5). The second trigger is then actuated to inject the bone paste (Figures 6 & 7). Alternatively, a second injection gun is inserted into the first gun or into the trocar (working channel) - loaded and primed with payload (the bullet). This means that all air is extruded from the system during injection and thus there is no risk of air embolism.

The delivery or injection gun has 2 properties - it allows controlled volumes of payload to be injected and at controlled pressure direction and velocity thus allowing complete control, feedback and precision to the surgeons' hands. The delivery / injection gun is preferably a spring loaded ratchet type gun like the one used to inject cement in total hip arthroplasty.

STEP THREE: Closure of wound

The wound is closed using standard techniques.

The patient is mobilised as soon as pain allows.

Bracing is an option for some patients.

The elevation and translation structures of the invention may also be utilised for delivery of bone replacement material to non-vertebral body fractures, such as but not limited to hip fractures or tibial plateau fractures (Figure 8).

EXAMPLE 2

A particular embodiment of a device 10 according to the present invention is illustrated in Figures 10-17. This comprises an inner shaft 11 with a pusher 12 and a spacer 13 disposed at one end and expandable arms 14 disposed at the other end. An outer shaft 16, which is slightly shorter than the inner shaft 11, is disposed around the inner shaft 11 such that relative axial movement of the two shafts is permitted. One end of the outer shaft 16 includes apertures 20 to allow radial projection of the translation / elevation arms 14 from within. A cap 21 is provided adjacent the apertures 20 to retain the inner shaft 11 within the outer shaft 16. The outer shaft 16 is also fitted with a bush 17 and a handle 18, both disposed towards the end furthest away from the expandable arms 14 of the inner shaft 11. The bush 17 comprises a cylindrical receptacle 22 and a chamfered end 19.

Thus, as can be seen from Figure 10, the spacer 13 attached to the inner shaft 11, may slide axially within the receptacle 22, which is attached to outer shaft 16 via bush 17. Consequently, a user (i.e. surgeon) may grip the handle 18 with his/her fingers and apply pressure on the pusher 12 with the palm or heel of his/her hand. This will force the spacer 13 into receptacle 22 until it abuts end stop 15. In turn, the opposite end of the inner shaft 11, away from the spacer 13, will be forced towards the far end of the outer shaft 16. This will cause the free ends of the expandable arms 14 to abut cap 21. Further pushing of inner shaft 11 towards cap 21 will force the arms 14 to expand outwards of the shaft axis. Conversely, easing pressure on the pusher 12 will allow the arms 14 to relax and return to an unexpanded state.

Thus, in use, the end of the device 10, furthest from the pusher 12 may be inserted into a patient through an access passage formed using traditional surgical techniques.

Conveniently, the device 10 will be inserted with the arms 14 in a relaxed or unexpanded state. Thus, in position, the user may expand the arms 14 by forcing the pusher 12 towards the handle 18. Once the desired expansion is achieved, translation may be also be achieved by maintaining the relative positioning of the pusher 12 and handle 18, and moving the entire device 10 relative to the patient. Rotation and/or angulation may also be achieved in a similar manner.

Once the desired orientation is achieved, the inner shaft 11 and expandable arms 14 may be withdrawn, with the outer shaft 16 remaining in situ. Bone replacement material or cement may then be feed through the outer shaft 16 by use of a second gun 30, 40, such that the desired pressure and quantity can be delivered. After the required material has been delivered, both the gun 30, 40 and outer shaft 16 can be removed from the patient.

Alternatively, the entire device 10, including the inner 11 and outer 16 shafts may be removed prior to insertion of the bone replacement material or cement. In this case, a separate device 30, 40 may be inserted for delivery of the bone replacement material or cement. Thus, as illustrated in Figure 9A, gun 30 may be used to deliver the desired quantity of bone replacement material at a desired pressure setting. Alternatively, gun 40, illustrated in Figure 9B, may be employed whereby each complete rotation of pusher 41 within threaded barrel 42, delivers a fixed volume, say 0.5ml, of bone replacement material through shaft 43 when attached.

As can be seen from Figure 17, a single expandable arm 14 may be employed for elevation and translation of certain bone defects. Similarly, multiple arms 14 may be employed at a plurality of radial positions to suit particular circumstances.

The size and profile of the expandable arms 14 and the apertures 20 may also be varied as desired.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same should be considered as illustrative and not restrictive in character. It is understood that only the preferred embodiments have been presented and that all changes, modifications and further applications that come within the spirit of the invention are desired to be protected.

CLAIMS

What is claimed is:

1. Instrumentation for the treatment of fractures or bone defects, particularly those of relatively inaccessible bones in the body, namely those of the spine, shoulder, elbow, wrist, hip, knee and ankle, comprising

A main rigid cylindrical body

- which passes into the centre or any other part of the fracture, being hollow on the inside to accommodate a secondary body comprising flexible or semi flexible or rigid spring-like flanges which pass through the main body into the fracture site, and
- which is capable of guiding in or carrying additional hollow channels or barrels or catheters either within it or coaxial with it on the outside, and
- which carries around it or upon it a multiplicity of storage chambers for solids or liquids to be inserted or injected into the fracture site, and
- which has an ergonomically shaped 'pistol-grip' handle and conveniently located buttons, actuators, triggers or drivers for the operation and deployment of its multiplicity of features and capabilities

2. The instrumentation of Claim 1, whereby the bone defects are treated for anatomical or gross shape defects, such as compression or compaction, translation, rotation or angulation.

3. The instrumentation of Claim 2, whereby the anatomical defects such as translation, rotation or angulation are corrected by the deployment and

controlled multi-axial, multi-planar motion of spring-like flanges emerging from the distal tip of the instrument inserted into the fractured or defective bone.

4. The instrumentation of Claim 2, whereby the gross shape defects resulting from compression, compaction or comminution can be reduced by controlled divarication and/or relocation of bone fragments within the fracture site using spring-like flanges emerging from the distal tip of the instrument inserted into the fractured or defective bone.

5. The instrumentation of Claims 3 and 4, wherein the controls for the complex multi-directional motions and positioning of the spring-like flanges are located on the body or 'pistol-grip' handle of the instrumentation of Claim 1, and are operated mechanically or electronically, and either manually or powered electrically.

6. The instrumentation of Claim 1, whereby the bone defects are treated for internal deficiencies such as loss of structural integrity.

7. The instrumentation of Claim 6, being capable of restoring structural integrity immediately by the delivery of a shaped intraosseous scaffold into the fractured or defective bone, and wherein the instrumentation of Claim 6 is capable of delivering either a pre-shaped scaffold or one that is shaped by said instrumentation after insertion.

8. The instrumentation of Claim 6, being capable of restoring structural integrity immediately by the delivery of discrete micro-implants possessing hollow polyhedral shapes, and wherein the instrumentation of Claim 6 is capable of delivering the said micro-implants either pre-stacked or is capable of stacking said micro-implants one by one within the fracture site.

9. The instrumentation of Claims 6, 7 and 8, wherein the delivery of structural elements such as scaffolds or micro-implants is by any combination of a guide

wire, screw conveyor, drive piston, and ratchet assembly, and wherein such guide wire, screw conveyor, drive piston or ratchet assembly are operable by controls on the body or 'pistol-grip' handle of the instrumentation of Claim 1, either mechanically or electronically, and either manually or powered electrically.

10. The instrumentation of Claim 1, whereby one of the hollow channels accommodates a suction type device to remove fracture debris from the fracture site.

11. The instrumentation of Claim 1, whereby one of the hollow channels accommodates a drill type device to remove fracture debris from the fracture site.

12. The instrumentation of Claim 1, whereby once the bone defects are treated and the fracture site fully prepared (using the instrumentation of Claims 2 and 6), the delivery of hard, soft, gel or liquid tissue-engineering constructs is made possible by precise placement, insertion, packing, stacking or injection of said constructs.

13. The instrumentation of Claim 12, wherein the delivery of various tissue-engineering constructs is actuated and operable by controls on the body or 'pistol-grip' handle of the instrumentation of Claim 1, either mechanically or electronically, and either manually or powered electrically.

14. The instrumentation of Claim 1, wherein the internal pressure generated by the delivery of materials to the fracture site (as mentioned in Claims 6,7,8 and 12) is monitored by means of a distal pressure sensor inserted into the fracture site through a channel, which pressure sensor is connected to a proximal pressure gauge or electronic display on the body or handle of the instrument of Claim 1.

15. The instrumentation of Claim 1, wherein the main body has channels, ports, adaptors, receptacles and connectors for the addition of endoscopes or Computer Aided Surgery/ Navigation equipment.

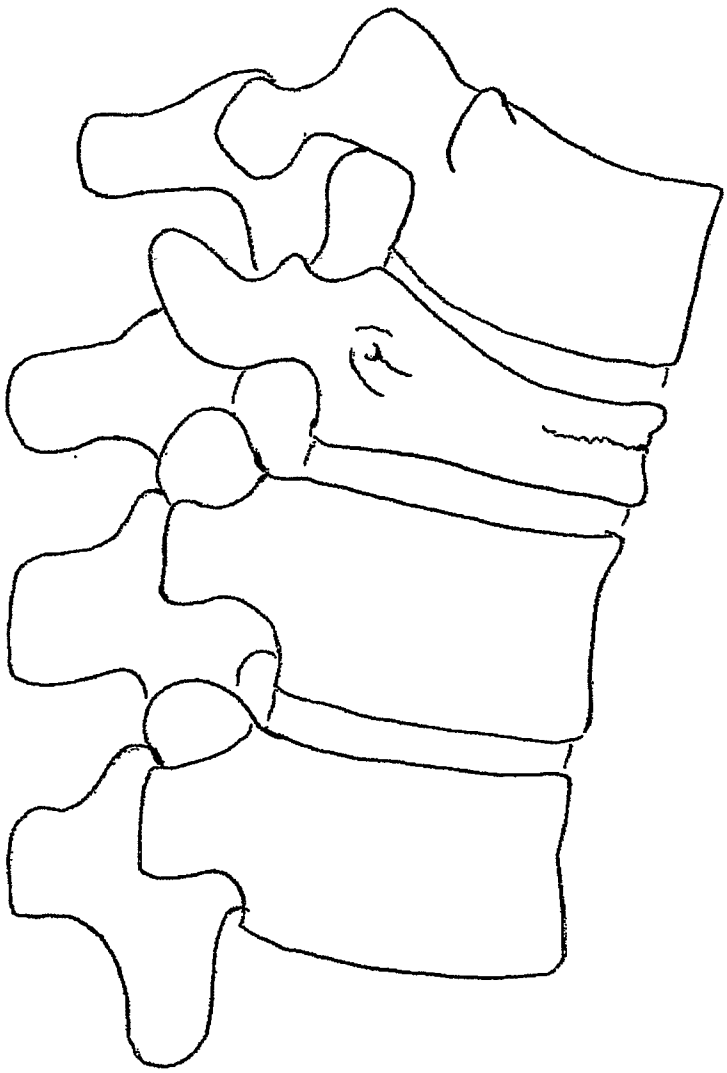

FIGURE 1

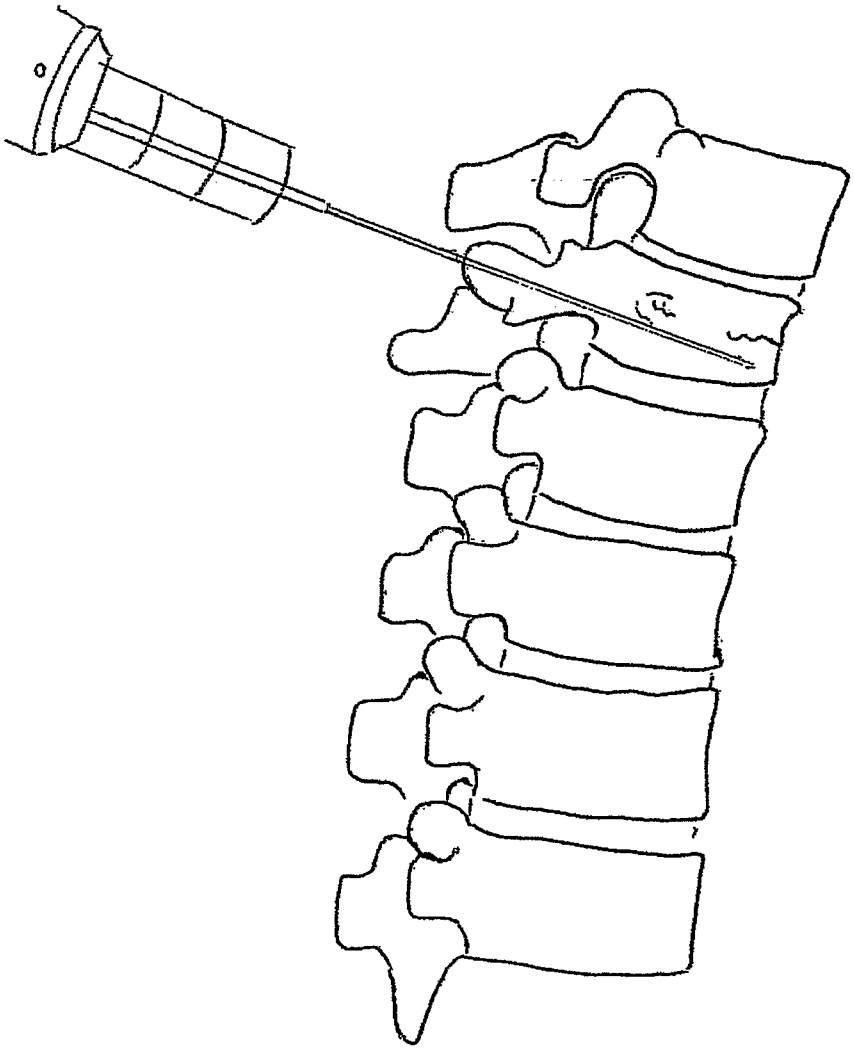

FIGURE 2

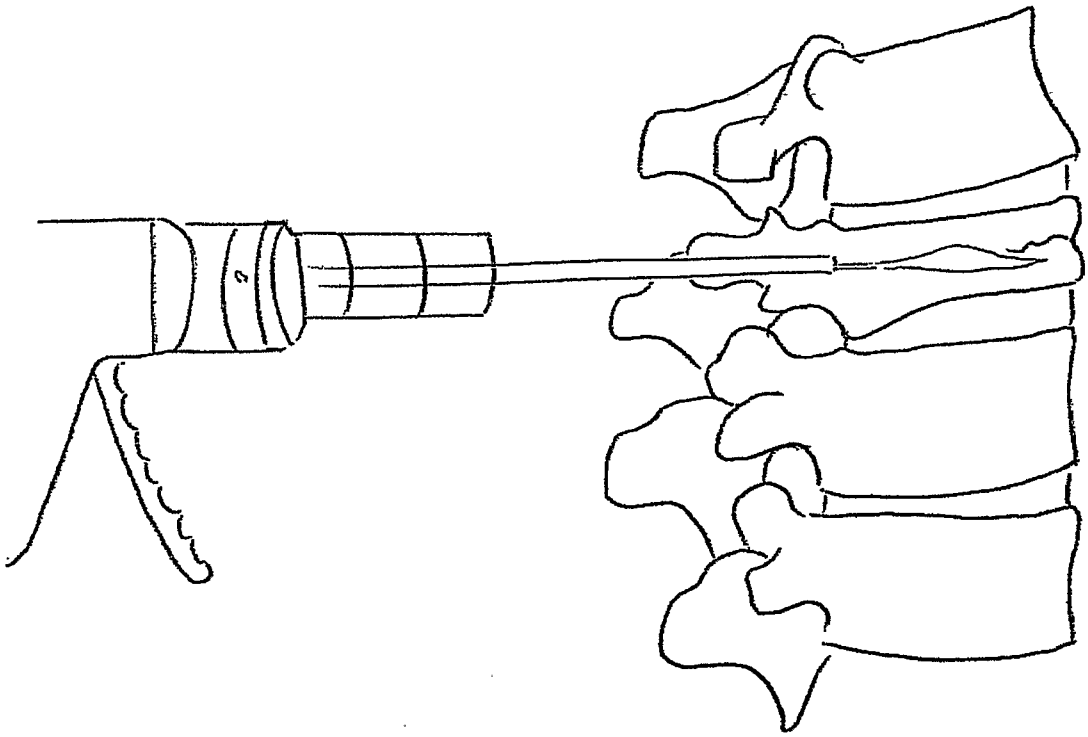

FIGURE 3

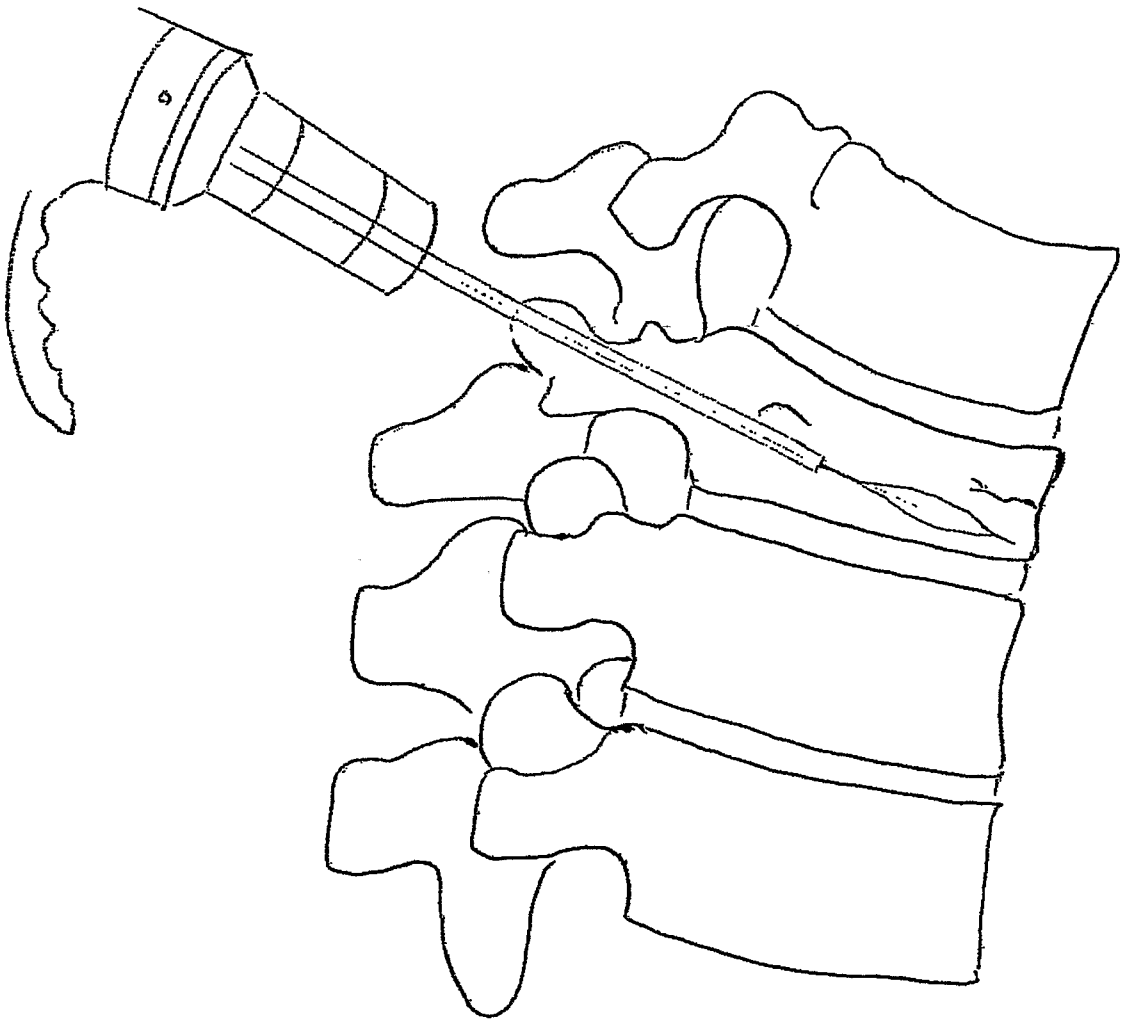

FIGURE 4

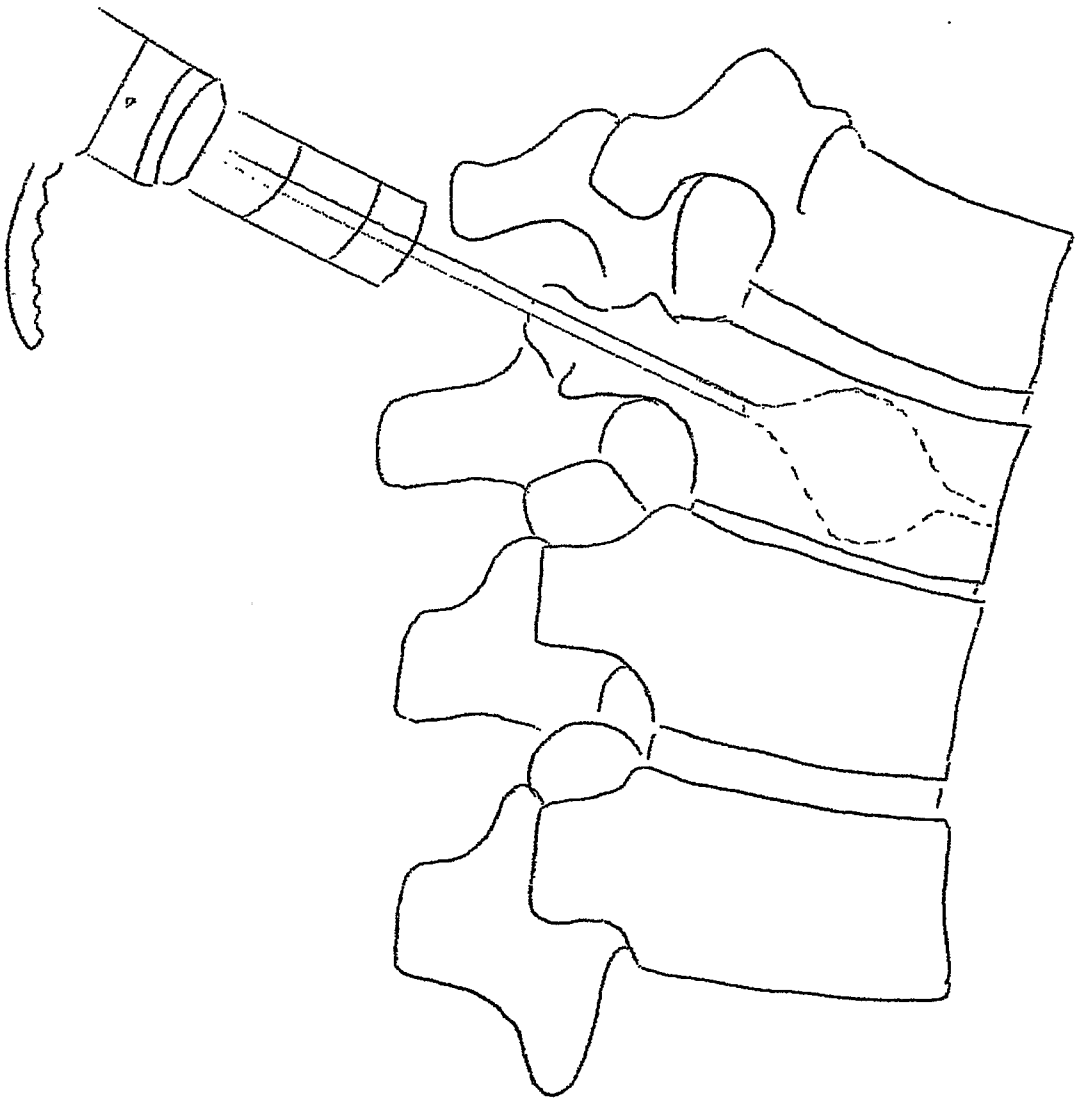

FIGURE 5

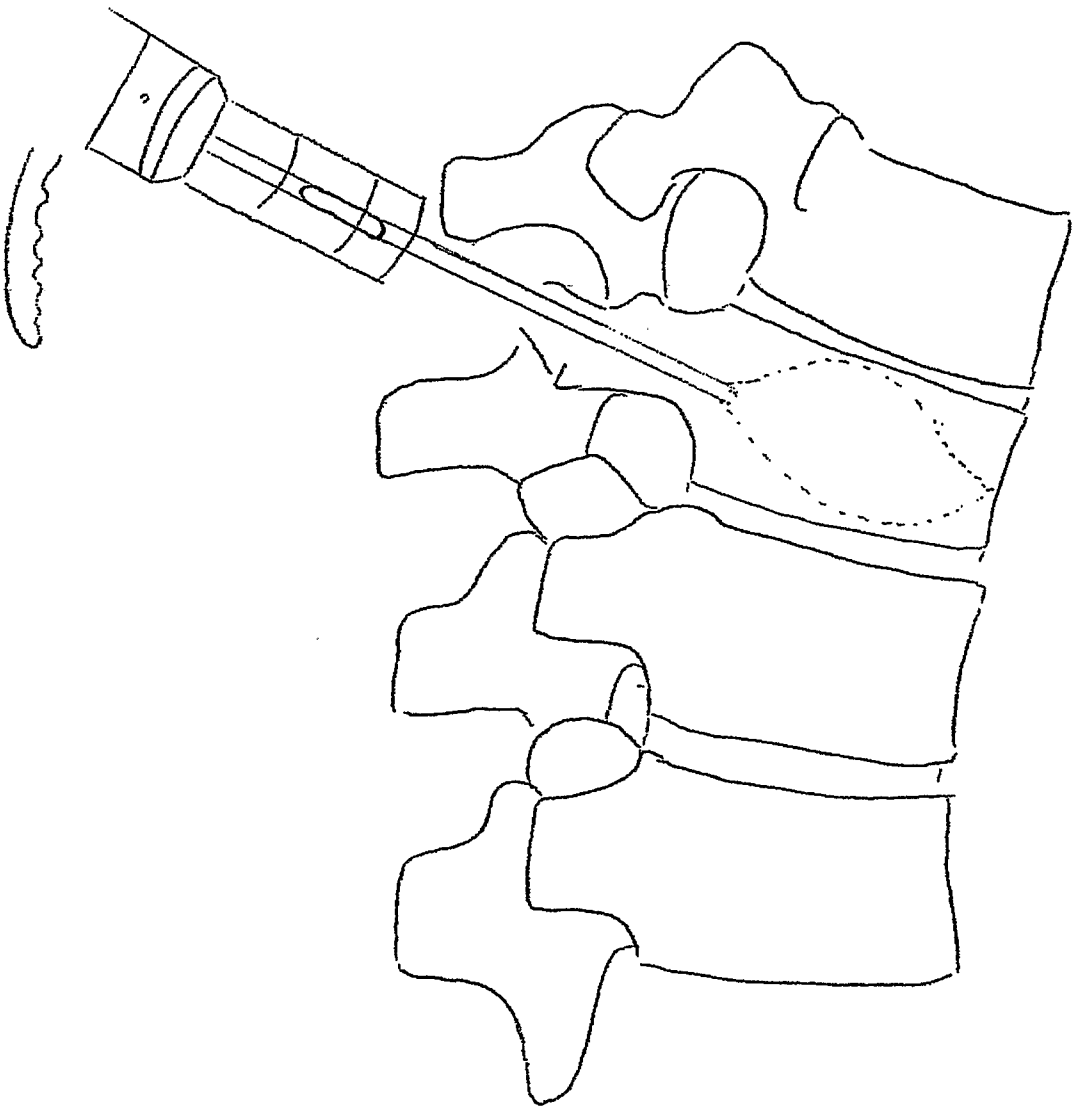

FIGURE 6

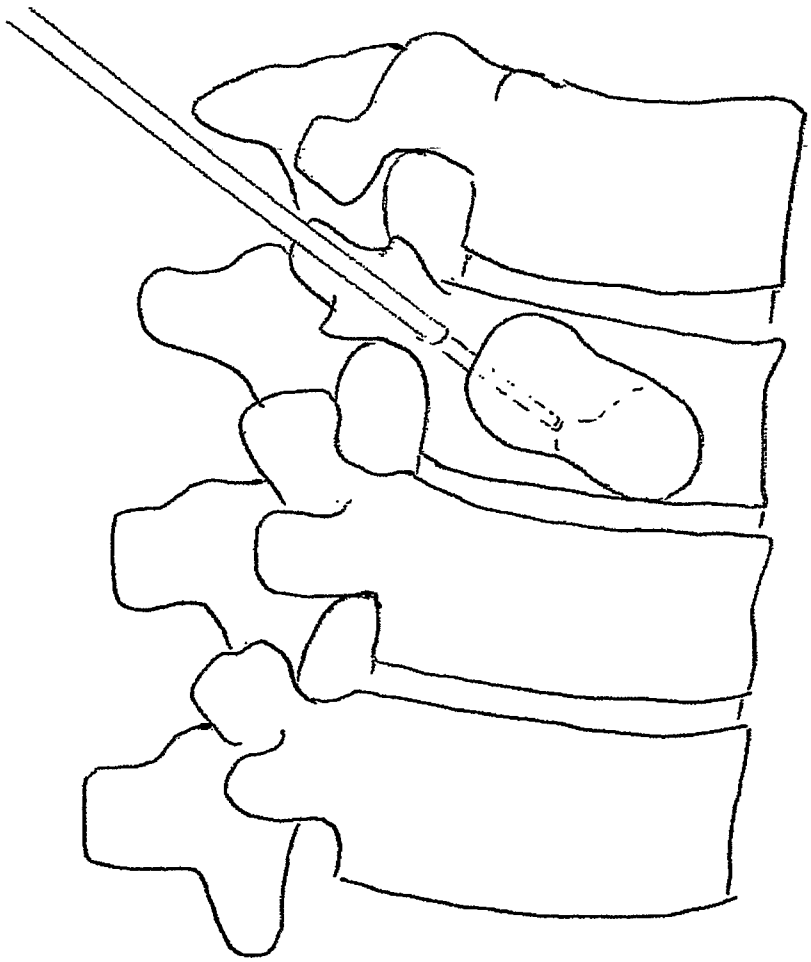

FIGURE 7

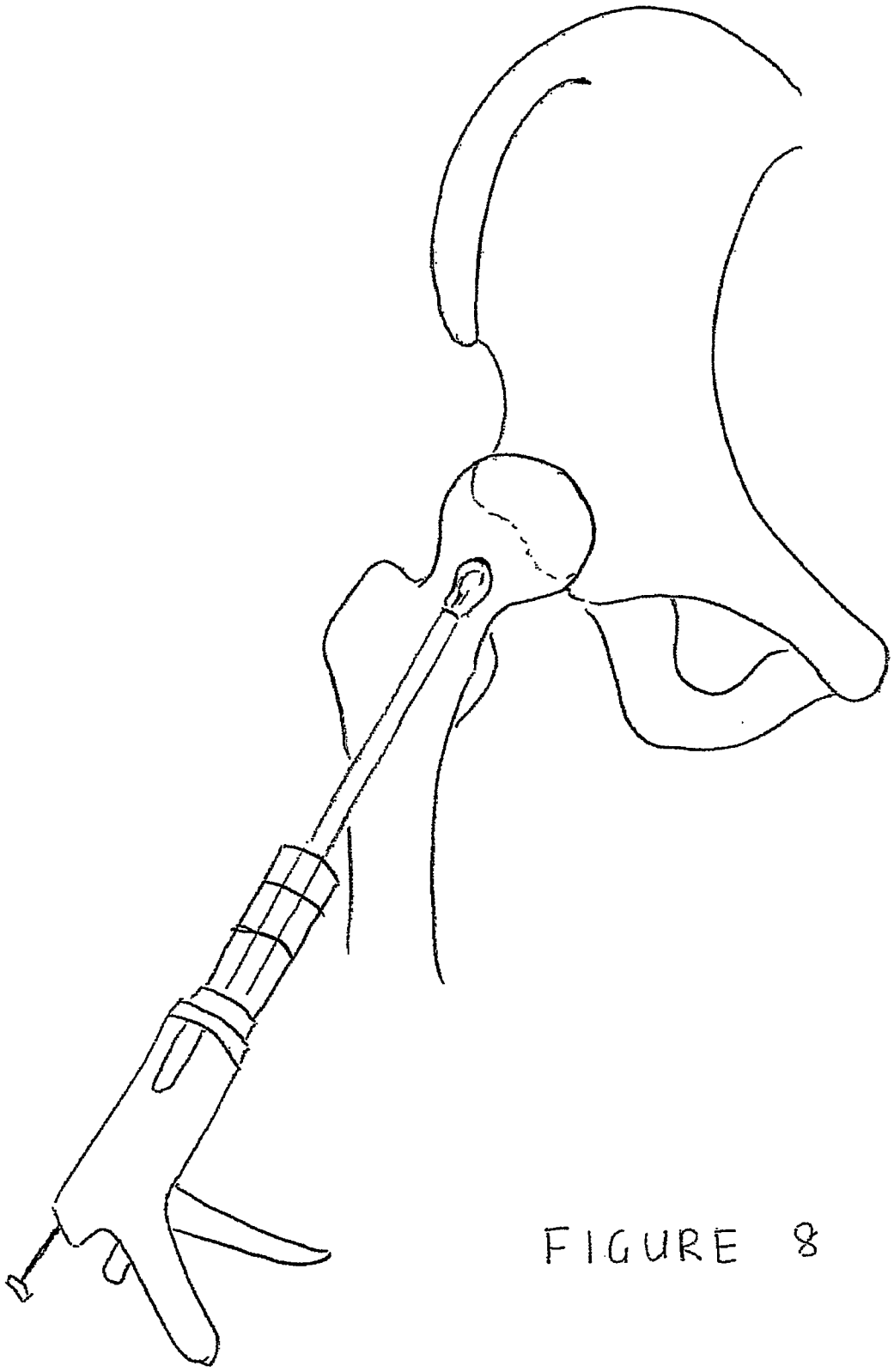

FIGURE 8

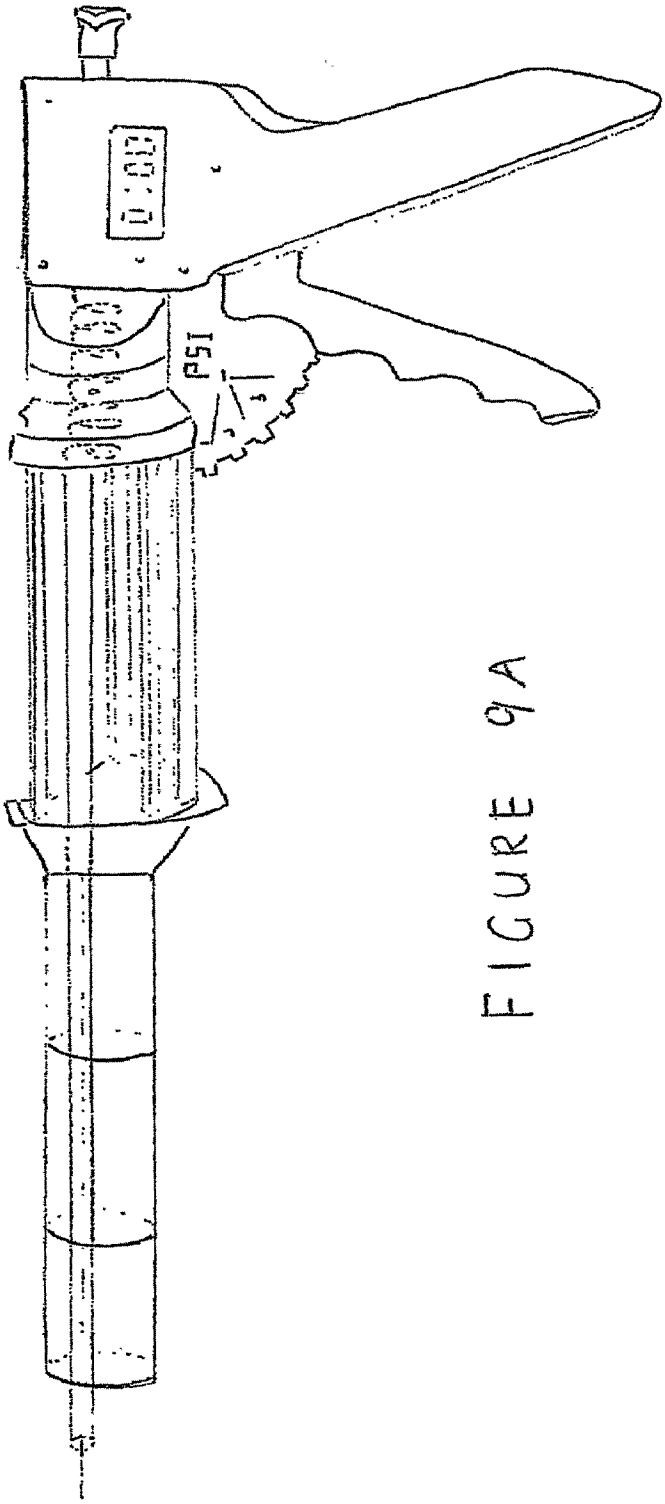

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FIGURE 9A

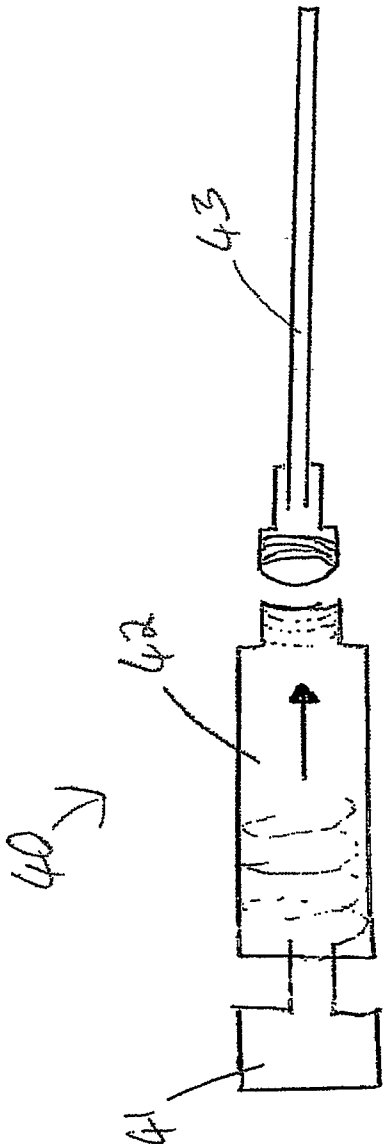

FIGURE 9B

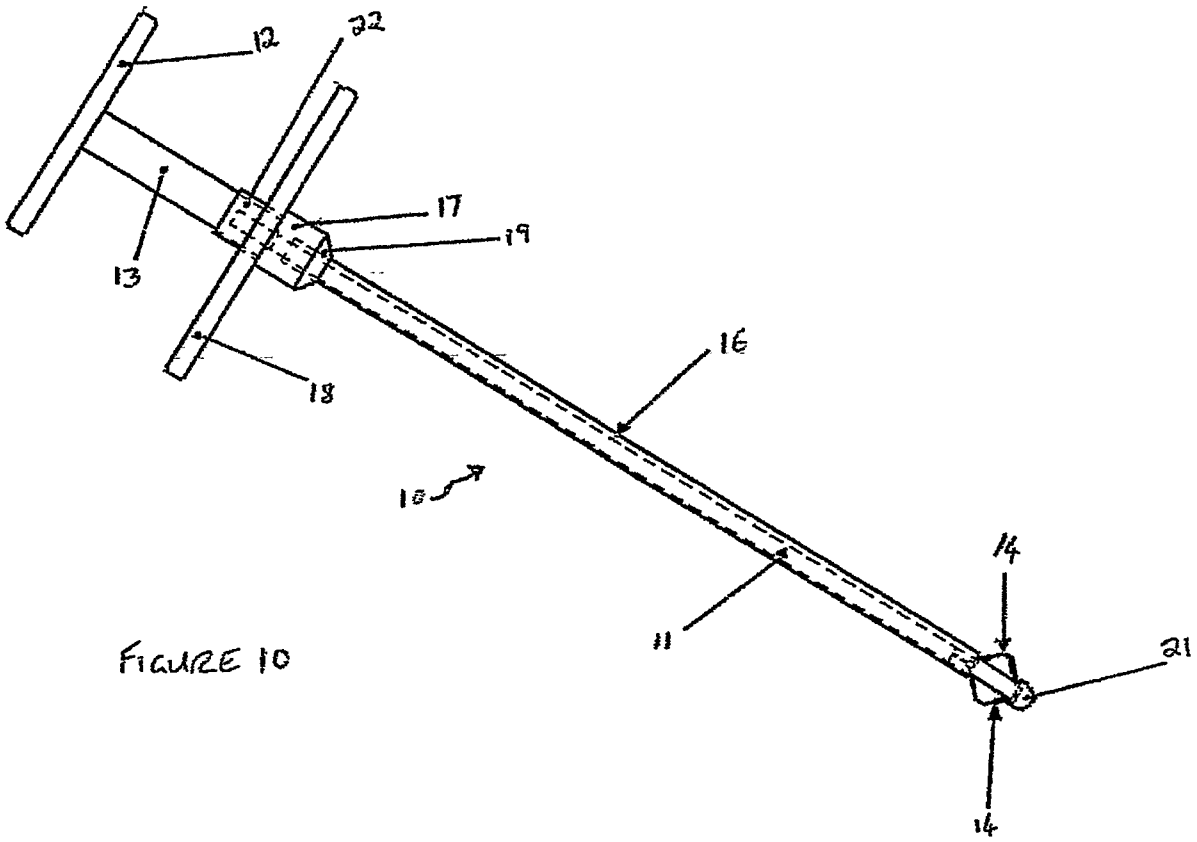

FIGURE 10

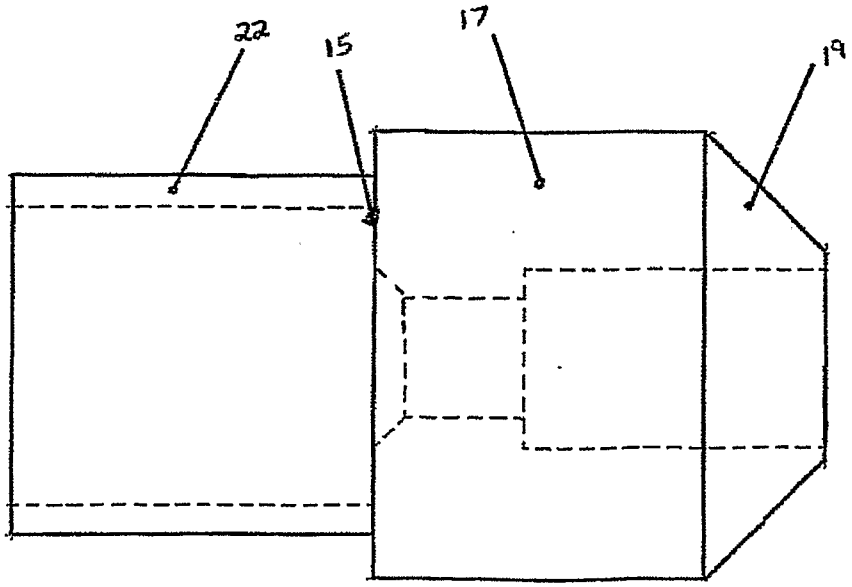

FIGURE 11

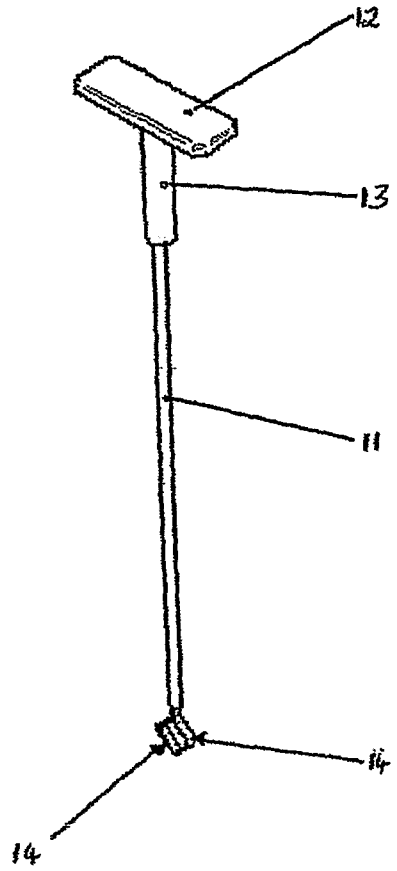

FIGURE 12

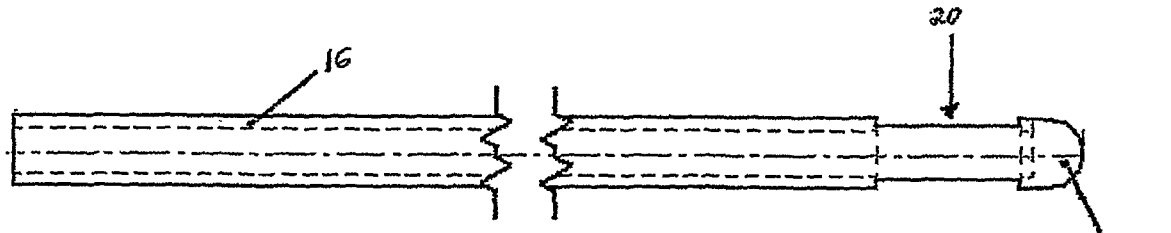

FIGURE 13A

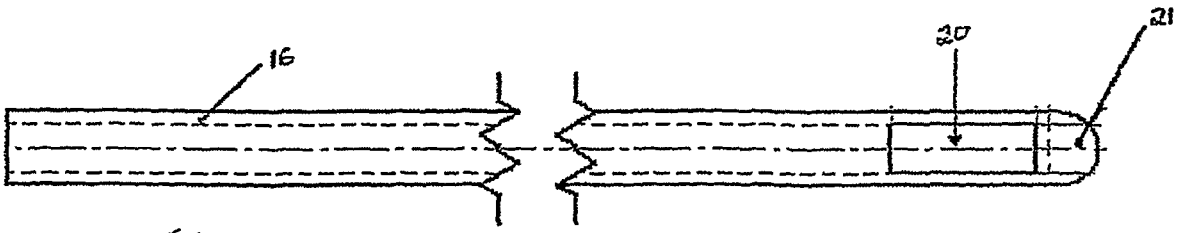

FIGURE 13B

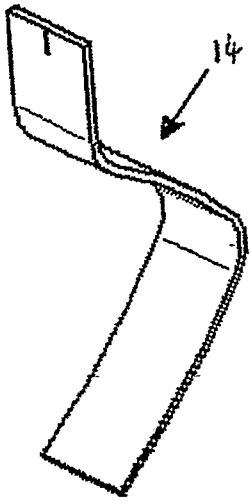

FIGURE 14

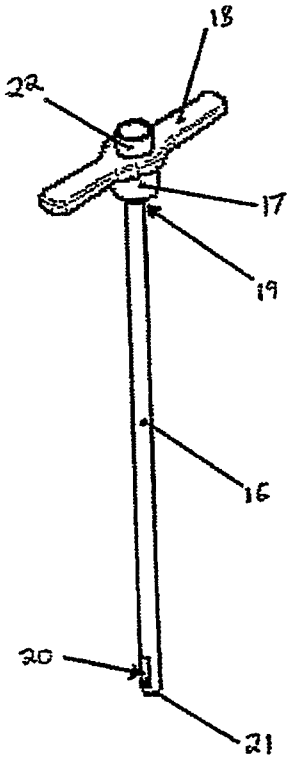

FIGURE 15

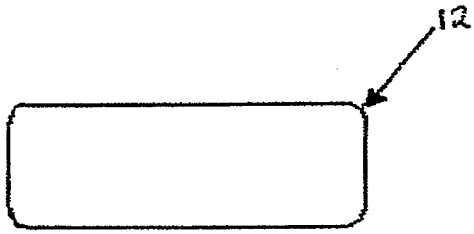

FIGURE 16

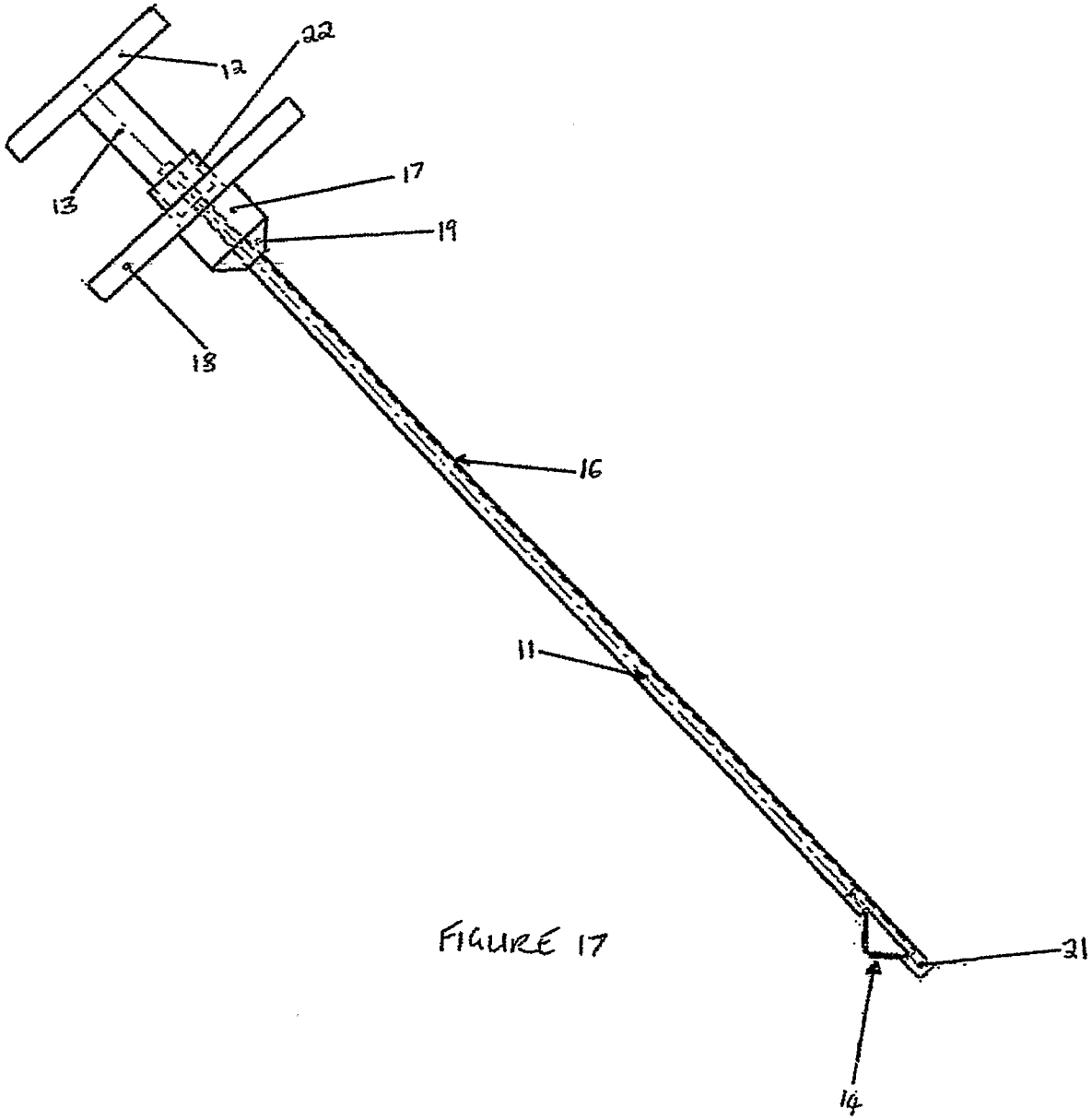

FIGURE 17