improving the clinical outcome. The sphere can also be used without a base.

A primary goal of percutaneous distal radius augmentation is to create a cavity inside the distal radius whose configuration is optimal for supporting the distal radius. Another important goal is to help fine tune fracture realignment after the fracture has been partially realigned by finger traps. Both of these goals must be achieved by exerting pressure primarily on the cancellous bone and not on the cortical bone. Excessive pressure against the cortical bone could conceivably cause cortical bone fractures, thus worsening the condition.

The present invention satisfies these goals through the design of inflatable devices either already described or to be described.

The design of the "humpbacked banana", or modified pyramid design (as described as number 5 above), approximates the shape of the distal radius and therefore, the cavity made by this balloon approximates the shape of the distal radius as well. The approximate volume of the cavity to be made by this humpbacked banana shaped balloon is 70 to 90% that of the distal radial epiphysis and metaphysis primarily of, but not necessarily exclusive of, some part of the distal radial diaphysis. Inflating such a device compresses the cancellous bone against the cortical walls of the epiphysis and metaphysis of the distal radius in order to create a cavity. In some cases, depending on the fracture location, the osseous balloon or inflatable device may be used to extend the cavity into the distal part of the radial diaphysis.

A primary goal of percutaneous femoral head (or humeral head) augmentation is to create a cavity inside the femoral head (or humeral head) whose configuration is

optimal for supporting the femoral head. Another important goal is to help compress avascular (or aseptic) necrotic bone or support avascular necrotic bone is the femoral head. This goal may include the realignment of avascular bone back into the position it previously occupied in the femoral head in order to improve the spherical shape of the femoral head. These goals must be achieved by exerting pressure primarily on the cancellous bone inside the femoral head.

The present invention satisfied these goals through the design of inflatable devices either already described or to be described.

The design of the spherical osseous balloon (described as balloon type 4 above) approximates the shape of the femoral head and therefore creates a cavity which approximates the shape of the femoral head as well. (It should be noted that the spherical shape of this inflatable device also approximates the shape of the humeral head and would, in fact, be appropriate for cavity formation in this osseous location as well.) Inflating such a device compresses the cancellous bone of the femoral head against its inner cortical walls in order to create a cavity. In some cases, depending upon the extent of the avascular necrosis, a smaller or larger cavity inside the femoral head will be formed. In some cases, if the area of avascular necrosis is small, a small balloon will be utilized which might create a cavity only 10 to 15% of the total volume of the femoral head. If larger areas of the femoral head are involved with the avascular necrosis, then a larger balloon would be utilized which might create a much larger cavity, approaching 80 to 90% of the volume of the femoral head.

The hemispherical balloon approximates the shape of the top half of the femoral (and humeral) head, and provides a means for compacting cancellous bone in an

area of avascular necrosis or small fracture without disturbing the rest of the head. This makes it easier to do a future total joint replacement if required.

A primary goal of percutaneous proximal tibial augmentation is to create a cavity inside the proximal tibia whose configuration is optimal for supporting either the medial or lateral tibial plateaus. Another important goal is to help realign the fracture fragments of tibial plateau fractures, particularly those features with fragments depressed below (or inferior to) their usual location. Both of these objectives must be achieved by exerting pressure on primarily the cancellous bone and not the cortical bone. Pressure on the cortical bone could conceivably cause worsening of the tibial plateau fracture.

The present invention satisfies these goals through the design of the inflatable devices to be described. Inflating such a device compresses the cancellous bone against the cortical walls of the medial or lateral tibial plateau in order to create a cavity.

Due to the design of the "elliptical cylinder" balloon (described as balloon type 6 above) the cavity made by this balloon recreates or approximates the shape of the cortical walls of either the medial or lateral tibial plateaus. The approximate volume of the cavity to be made by the appropriate elliptical cylindrical balloon is 50 to 90% of the proximal epiphyseal bone of either the medial half or the lateral half of the tibial.

Other objects of the present invention will become apparent as the following specification progresses, reference being had to the accompanying drawings for an illustration of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a first embodiment of the balloon of the present invention, the embodiment being in the shape of a stacked doughnut assembly;

Fig. 2 is a vertical section through the balloon of Fig. 1 showing the way in which the doughnut portions of the balloon of Fig. 1, fit into a cavity of a vertebral body;

Fig. 3 is a schematic view of another embodiment of the balloon of the present invention showing three stacked balloons and string-like restraints for limiting the expansion of the balloon in directions of inflation;

Fig. 4 is a top plan view of a spherical balloon having a cylindrical ring surrounding the balloon;

Fig. 5 is a vertical section through the spherical balloon and ring of Fig. 4;

Fig. 6 shows an oblong-shaped balloon with a catheter extending into the central portion of the balloon;

Fig. 6A is a perspective view of the way in which a catheter is arranged relative to the inner tubes for inflating the balloon of Fig. 6;

Fig. 7 is a suction tube and a contrast injection tube for carrying out the inflation of the balloon and removal of debris caused by expansion from the balloon itself;

Fig. 8 is a vertical section through a balloon after it has been deflated and as it is being inserted into the vertebral body of a human;

Figs. 9 and 9A are side elevational views of a cannula showing how the protective sleeve or guard member expands when leaving the cannula;

Fig. 9B is a vertical section through a vertebral bone into which an access hole has been drilled;

Fig. 10 is a perspective view of another embodiment of the balloon of the present invention formed in the shape of a kidney bean;

Fig. 11 is a perspective view of the vertebral bone showing the kidney shaped balloon of Fig. 10 inserted in the bone and expanded;

Fig. 12 is a top view of a kidney shaped balloon formed of several compartments by a heating element or branding tool;

Fig. 13 is a cross-sectional view taken along line 13-13 of Fig. 12 but with two kidney shaped balloons that have been stacked.

Fig. 14 is a view similar to Fig. 11 but showing the stacked kidney shaped balloon of Fig. 13 in the vertebral bone;

Fig. 15 is a top view of a kidney balloon showing outer tufts holding inner strings in place interconnecting the top and bottom walls of the balloon;

Fig. 16 is a cross sectional view taken along lines 16-16 of Fig. 15;

Fig. 17A is a dorsal view of a humpback banana balloon in a right distal radius;

Figs. 17B is a cross sectional view of Fig. 17A taken along line 17B-17B of Fig. 17A;

Fig. 18 is a spherical balloon with a base in a proximal humerus viewed from the front (anterior) of the left proximal humerus;

Fig. 19A is the front (anterior) view of the proximal tibia with the elliptical cylinder balloon introduced beneath the medial tibial plateau;

Fig. 19B is a three quarter view of the balloon of Fig. 19A;

Fig. 19C is a side elevational view of the balloon of Fig. 19A;

Fig. 19D is a top plan view of the balloon of Fig. 19A;

Fig. 20 is a spherically shaped balloon for treating avascular necrosis of the head of the femur (or humerus) as seen from the front (anterior) of the left hip; and

Fig. 20A is a side view of a hemispherically shaped balloon for treating avascular necrosis of the head of the femur (or humerus).

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

BALLOONS FOR VERTEBRAL BODIES

A first embodiment of the balloon (Fig. 1) of the present invention is broadly denoted by the numeral 10 and includes a balloon body 11 having a pair of hollow, inflatable, non-expandable parts 12 and 14 of flexible material, such as PET or Kevlar. Parts 12 and 14 have a suction tube 16 therebetween for drawing fats and other debris by suction into tube 16 for transfer to a remote disposal location. Catheter 16 has one or more suction holes so that suction may be applied to the open end of tube 16 from a suction source (not shown).

The parts 12 and 14 are connected together by an adhesive which can be of any suitable type. Parts 12 and 14 are doughnut-shaped as shown in Fig. 1 and have tubes 18 and 20 which communicate with and extend away from the parts 12 and 14, respectively, to a source of inflating liquid under pressure (not shown). The liquid can be any sterile biocompatible solution. The liquid inflates the balloon 10, particularly parts 12 and 14 thereof after the balloon has been inserted in a collapsed condition (Fig. 8) into a bone to be treated,

such as a vertebral bone 22 in Fig. 2. The above-mentioned patents 4,969,888 and 5,108,404 disclose the use of a guide pin and cannula for inserting the balloon into bone to be treated when the balloon is deflated and has been inserted into a tube and driven by the catheter into the cortical bone where the balloon is inflated.

Fig. 8 shows a deflated balloon 10 being inserted through a cannula 26 into bone. The balloon in cannula 26 is deflated and is forced through the cannula by exerting manual force on the catheter 21 which extends into a passage 28 extending into the interior of the bone. The catheter is slightly flexible but is sufficiently rigid to allow the balloon to be forced into the interior of the bone where the balloon is then inflated by directing fluid into tube 88 whose outlet ends are coupled to respective parts 12 and 14.

In use, balloon 10 is initially deflated and, after the bone to be filled with the balloon has been prepared to receive the balloon with drilling, the deflated balloon is forced into the bone in a collapsed condition through cannula 26. The bone is shown in Fig. 2. The balloon is oriented preferably in the bone such that it allows minimum pressure to be exerted on the bone marrow and/or cancellous bone if there is no fracture or collapse of the bone. Such pressure will compress the bone marrow and/or cancellous bone against the inner wall of the cortical bone, thereby compacting the bone marrow of the bone to be treated and to further enlarge the cavity in which the bone marrow is to be replaced by a biocompatible, flowable bone material.

The balloon is then inflated to compact the bone marrow and/or cancellous bone in the cavity and, after compaction of the bone marrow and/or cancellous bone, the balloon is deflated and removed from the cavity. While inflation of the balloon and compaction

occurs, fats and other debris are sucked out of the space between and around parts 12 and 14 by applying a suction force to catheter tube 16. Following this, and following the compaction of the bone marrow, the balloon is deflated and pulled out of the cavity by applying a manual pulling force to the catheter tube 21.

The second embodiment of the inflatable device of the present invention is broadly denoted by the numeral 60 and is shown in Figs. 4 and 5. Balloon 60 includes a central spherical part 62 which is hollow and which receives an inflating liquid under pressure through a tube 64. The spherical part is provided with a spherical outer surface 66 and has an outer periphery which is surrounded substantially by a ring shaped part 68 having tube segments 70 for inflation of part 68. A pair of passages 69 interconnect parts 62 and 68. A suction tube segment 72 draws liquid and debris from the bone cavity being formed by the balloon 60.

Provision can be made for a balloon sleeve 71 for balloon 60 and for all balloons disclosed herein. A balloon sleeve 71 (Fig. 9) is shiftably mounted in an outer tube 71a and can be used to insert the balloon 60 when deflated into a cortical bone. The sleeve 71 has resilient fingers 71b which bear against the interior of the entrance opening 71c of the vertebral bone 22 (Fig. 9A) to prevent tearing of the balloon. Upon removal of the balloon sleeve, liquid under pressure will be directed into tube 64 which will inflate parts 62 and 68 so as to compact the bone marrow within the cortical bone. Following this, balloon 60 is deflated and removed from the bone cavity.

Figs. 6 and 6A show several views of a modified doughnut shape balloon 80 of the type shown in Figs. 1 and 2, except the doughnut shapes of balloon 80 are not stitched onto one another. In Fig. 6, balloon 80 has a

pear-shaped outer convex surface 82 which is made up of a first hollow part 84 and a second hollow part 85. A tube 88 is provided for directing liquid into the two parts along branches 90 and 92 to inflate the parts after the parts have been inserted into the medullary cavity of a bone. A catheter tube 16 is inserted into the space 96 between two parts of the balloon 80. An adhesive bonds the two parts 84 and 85 together at the interface thereof.

Fig. 6A shows the way in which the catheter tube 16 is inserted into the space or opening 96 between the two parts of the balloon 80.

Fig. 7 shows tube 88 of which, after directing inflating liquid into the balloon 80, can inject contrast material into the balloon 80 so that x-rays can be taken of the balloon with the inflating material therewithin to determine the proper placement of the balloon. Tube 16 is also shown in Fig. 6, it being attached in some suitable manner to the outer side wall surface of tube 88.

Still another embodiment of the invention is shown in Fig. 3 which is similar to Fig. 1 except that it is round and not a doughnut and includes an inflatable device 109 having three balloon units 110, 112 and 114 which are inflatable and which have string-like restraints 117 which limit the expansion of the balloon units in a direction transverse to the longitudinal axes of the balloon units. The restraints are made of the same or similar material as that of the balloon so that they have some resilience but substantially no expansion capability.

A tube system 115 is provided to direct liquid under pressure into balloon units 110, 112 and 114 so that liquid can be used to inflate the balloon units when placed inside the bone in a deflated state. Following

the proper inflation and compaction of the bone marrow, the balloon can be removed by deflating it and pulling it outwardly of the bone being treated. The restraints keep the opposed sides 77 and 79 substantially flat and parallel with each other.

In Fig. 10, another embodiment of the inflatable balloon is shown. The device is a kidney shaped balloon body 130 having a pair of opposed kidney shaped side walls 132 which are adapted to be collapsed and to cooperate with a continuous end wall 134 so that the balloon 130 can be forced into a bone 136 shown in Fig. 11. A tube 138 is used to direct inflating liquid into the balloon to inflate the balloon and cause it to assume the dimensions and location shown vertebral body 136 in Fig. 11. Device 130 will compress the cancellous bone if there is no fracture or collapse of the cancellous bone. The restraints for this action are due to the side and end walls of the balloon.

Fig. 12 shows a balloon 140 which is also kidney shaped and has a tube 142 for directing an inflatable liquid into the tube for inflating the balloon. The balloon is initially a single chamber bladder but the bladder can be branded along curved lines or strips 141 to form attachment lines 144 which take the shape of side-by-side compartments 146 which are kidney shaped as shown in Fig. 13. The branding causes a welding of the two sides of the bladder to occur since the material is standard medical balloon material, which is similar to plastic and can be formed by heat.

Fig. 14 is a perspective view of a vertebral body 147 containing the balloon of Fig. 12, showing a double stacked balloon 140 when it is inserted in vertebral bone 147.

Fig. 15 is a view similar to Fig. 10 except that tufts 155, which are string-like restraints, extend

between and are connected to the side walls 152 of inflatable device 150 and limit the expansion of the side walls with respect to each other, thus rendering the side walls generally parallel with each other. Tube 88 is used to fill the kidney shaped balloon with an inflating liquid in the manner described above.

The dimensions for the vertebral body balloon will vary across a broad range. The heights (H, Fig. 11) of the vertebral body balloon for both lumbar and thoracic vertebral bodies typically range from 0.5 cm to 3.5 cm. The anterior to posterior (A, Fig. 11) vertebral body balloon dimensions for both lumbar and thoracic vertebral bodies range from 0.5 cm to 3.5 cm. The side to side (L, Fig. 11) vertebral body dimensions for thoracic vertebral bodies will range from 0.5 cm to 3.5 cm. The side to side vertebral body dimensions for lumbar vertebral bodies will range from 0.5 cm to 5.0 cm.

The eventual selection of the appropriate balloon for, for instance, a given vertebral body is based upon several factors. The anterior-posterior (A-P) balloon dimension for a given vertebral body is selected from the CT scan or plain film x-ray views of the vertebral body. The A-P dimension is measured from the internal cortical wall of the anterior cortex to the internal cortical wall of the posterior cortex of the vertebral body. In general, the appropriate A-P balloon dimension is 5 to 7 millimeters less than this measurement.

The appropriate side to side balloon dimensions for a given vertebral body is selected from the CT scan or from a plain film x-ray view of the vertebral body to be treated. The side to side distance is measured from the internal cortical walls of the side of the vertebral bone. In general, the appropriate side to side balloon dimension is 5 to 7 millimeters less than this

measurement by the addition of the lumbar vertebral body tends to be much wider than side to side dimension then their A-P dimension. In thoracic vertebral bodies, the side to side dimension and their A-P dimensions are almost equal.

The height dimensions of the appropriate vertebral body balloon for a given vertebral body is chosen by the CT scan or x-ray views of the vertebral bodies above and below the vertebral body to be treated. The height of the vertebral bodies above and below the vertebral body to be treated are measured and averaged. This average is used to determine the appropriate height dimension of the chosen vertebral body balloon.

BALLOONS FOR LONG BONES

Long bones which can be treated with the use of balloons of the present invention include distal radius (larger arm bone at the wrist), proximal tibial plateau (leg bone just below the knee), proximal humerus (upper end of the arm at the shoulder), and proximal femoral head (leg bone in the hip).

Distal Radius Balloon

For the distal radius, a balloon 160 is shown in the distal radius 152 and the balloon has a shape which approximates a pyramid but more closely can be considered the shape of a humpbacked banana in that it substantially fills the interior of the space of the distal radius to force cancellous bone 154 lightly against the inner surface 156 of cortical bone 158.

The balloon 160 has a lower, conical portion 159 which extends downwardly into the hollow space of the distal radius 152, and this conical portion 159 increases in cross section as a central distal portion 161 is approached. The cross section of the balloon 160 is

shown at a central location (Fig. 17B) and this location is near the widest location of the balloon. The upper end of the balloon, denoted by the numeral 162, converges to the catheter 88 for directing a liquid into the balloon for inflating the same to force the cancellous bone against the inner surface of the cortical bone. The shape of the balloon 160 is determined and restrained by tufts formed by string restraints 165. These restraints are optional and provide additional strength to the balloon body 160, but are not required to achieve the desired configuration. The balloon is placed into and taken out of the distal radius in the same manner as that described above with respect to the vertebral bone.

The dimensions of the distal radius balloon vary as follows:

The proximal end of the balloon (i.e. the part nearest the elbow) is cylindrical in shape and will vary from 0.5 x 0.5 cm to 1.8 x 1.8 cm.

The length of the distal radius balloon will vary from 1.0 cm to 12.0 cm.

The widest medial to lateral dimension of the distal radius balloon, which occurs at or near the distal radio-ulnar joint, will measure from 1.0 cm to 2.5 cm.

The distal anterior-posterior dimension of the distal radius balloon will vary from 0.5 to 3.0 cm.

Proximal Humerus Fracture Balloon

The selection of the appropriate balloon size to treat a given fracture of the distal radius will depend on the radiological size of the distal radius and the location of the fracture.

In the case of the proximal humerus 169, a balloon 166 shown in Fig. 18 is spherical and has a base design. It compacts the cancellous bone 168 in a proximal humerus 169. A mesh 170, embedded or laminated

and/or winding, may be used to form a neck 172 on the balloon 166, and second mesh 170a may be used to conform the bottom of the base 172a to the shape of the inner cortical wall at the start of the shaft. These restraints provide additional strength to the balloon body, but the configuration can be achieved through molding of the balloon body. This is so that the cancellous bone will be as shown in the compacted region surrounding the balloon 166 as shown in Fig. 18. The cortical bone 173 is relatively wide at the base 174 and is thin-walled at the upper end 175. The balloon 166 has a feed tube 177 into which liquid under pressure is forced into the balloon to inflate it to lightly compact the cancellous bone in the proximal humerus. The balloon is inserted into and taken out of the proximal humerus in the same manner as that described above with respect to the vertebral bone.

The dimensions of the proximal humerus fracture balloon vary as follows:

The spherical end of the balloon will vary from 1.0 x 1.0 cm to 3.0 x 3.0 cm.

The neck of the proximal humeral fracture balloon will vary from 0.8 x 0.8 cm to 3.0 x 3.0 cm.

The width of the base portion or distal portion of the proximal numeral fracture balloon will vary from 0.5 x 0.5 cm to 2.5 x 2.5 cm.

The length of the balloon will vary from 4.0 cm to 14.0 cm.

The selection of the appropriate balloon to treat a given proximal humeral fracture depends on the radiologic size of the proximal humerus and the location of the fracture.

Proximal Tibial Plateau Fracture Balloon

The tibial fracture is shown in Fig. 19A in which a balloon 180 is placed in one side 182 of a tibia 183. The balloon, when inflated, compacts the cancellous bone in the layer 184 surrounding the balloon 180. A cross section of the balloon is shown in Fig. 19C wherein the balloon has a pair of opposed sides 185 and 187 which are interconnected by restraints 188 which can be in the form of strings or flexible members of any suitable construction. The main purpose of the restraints is to make the sides 185 and 187 substantially parallel with each other and non-spherical. A tube 190 is coupled to the balloon 180 to direct liquid into and out of the balloon. The ends of the restraints are shown in Figs. 19B and 19D and denoted by the numeral 191. The balloon is inserted into and taken out of the tibia in the same manner as that described above with respect to the vertebral bone. Fig. 19B shows a substantially circular configuration for the balloon; whereas, Fig. 19D shows a substantially elliptical version of the balloon.

The dimensions of the proximal tibial plateau fracture balloon vary as follows:

The thickness or height of the balloon will vary from 0.5 cm to 5.0 cm.

The anterior/posterior (front to back) dimension will vary from 1.0 cm to 6.0 cm.

The side to side (medial to lateral) dimension will vary from 1.0 cm to 6.0 cm.

The selection of the appropriate balloon to treat a given tibial plateau fracture will depend on the radiological size of the proximal tibial and the location of the fracture.

Femoral Head Balloon

In the case of the femoral head, a balloon 200 is shown as having been inserted inside the cortical bone

202 of the femoral head which is thin at the outer end 204 of the femur and which can increase in thickness at the lower end 206 of the femur. The cortical bone surrounds the cancellous bone 207 and this bone is compacted by the inflation of balloon 200. The tube for directing liquid for inflation purposes into the balloon is denoted by the numeral 209. It extends along the femoral neck and is directed into the femoral head which is generally spherical in configuration. Fig. 20A shows that the balloon, denoted by the numeral 200a, can be hemispherical as well as spherical, as shown in Fig. 20. The balloon 200 is inserted into and taken out of the femoral head in the same manner as that described with respect to the vertebral bone. The hemispherical shape is maintained in this example by bonding overlapping portions of the bottom, creating pleats 200b as shown in Fig. 20A.

The dimensions of the femoral head balloon vary as follows:

The diameter of the femoral head balloon will vary from 1.0 cm to up to 4.5 cm. The appropriate size of the femoral head balloon to be chosen depends on the radiological or CT scan size of the head of the femur and the location and size of the avascular necrotic bone. The dimensions of the hemispherical balloon are the same as the those of the spherical balloon, except that approximately one half is provided.

IN THE CLAIMS:

1. A balloon for use in treating a bone predisposed to fracture or to collapse, or that is fractured or collapsed, comprising:

an inflatable, non-expandable balloon body for insertion into said bone, said body having a predetermined shape and size, when substantially fully inflated, sufficient to compress at least a portion of the inner cancellous bone to create a cavity in said cancellous bone, said balloon body being restrained to create said predetermined shape and size so that the fully inflated balloon is prevented from applying excessive pressure to the inner surface of the outer cortical bone if said bone is unfractured or uncollapsed.

2. A balloon as set forth in Claim 1, wherein said balloon body has restraining means to limit the size of said body.

3. A balloon as set forth in Claim 1, wherein said balloon body has restraining means to limit the shape of said body.

4. A balloon as set forth in Claim ~~1~~, wherein said body has a number of corners, said corners defining a restraint to restrain said balloon body.

5. A balloon as set forth in Claim 1, wherein said body includes a pair of stacked body parts having means for coupling the body parts together, the coupling means of said body parts defining a restraint to restrain the balloon body.

6. A balloon as set forth in Claim 1, wherein is included a seam in the body, said seam defining a restraint to restrain the balloon body.

7. A balloon as set forth in Claim 1, wherein is included a number of strings extending between the sides of the body, said strings defining at least part of a restraint to restrain the balloon body.

8. A balloon as set forth in Claim 1, wherein is included internal meshwork, said meshwork defining at least part of a restraint to restrain the balloon body.

9. A balloon as set forth in Claim 1, wherein is included external meshwork, said meshwork defining at least part of a restraint to restrain the balloon body.

10. A balloon as set forth in Claim 1, wherein said body is of a material capable of withstanding fluid pressures free of damage within the cortical bone of 50 to 400 psi.

11. A balloon as set forth in Claim 1, wherein said body has an outer surface adapted to assume the normal configuration of the inner surface of the cortical bone for compressing cancellous bone in a human lumbar vertebral body.

12. A balloon as set forth in Claim 11, wherein said body has a height in the range of 0.5 centimeter to 3.5 centimeters, there being an anterior-to-posterior dimension in the range of 0.5 centimeters to 3.5 centimeters, the side-to-side dimension of the body being in the range of 0.5 centimeters to 5.0 centimeters.

13. A balloon as set forth in Claim 1, wherein the body has an outer surface adapted to assume the normal configuration of the inner surface of the cortical bone for compressing cancellous bone in the human thoracic vertebral body.

14. A balloon as set forth in Claim 13, wherein said body has a height in the range of 0.5 to 3.5 centimeters, and having an anterior-to-posterior dimension in the range of 0.5 to 3.5 centimeters, and having a side-to-side dimension in the range of 0.5 to 3.5 centimeters.

15. A balloon as set forth in Claim 1, wherein said body has an outer surface adapted to assume the normal configuration of the inner surface of the cortical bone for compressing cancellous bone for compressing cancellous bone in the human distal radius.

16. A balloon as set forth in Claim 15, wherein said body has a proximal end whose dimensions range from 0.5 x 0.5 to 1.8 x 1.8 cm, whose length ranges from 1.0 to 12.0 cm, whose widest medial lateral dimension ranges from 1.0 to 2.5 cm and whose distal anterior-posterior dimension ranges from 0.5 to 3.0 cm.

17. A balloon as set forth in Claim 1, wherein the body has an outer surface adapted to assume the normal configuration of the inner surface of the cortical bone for compressing cancellous bone in a human tibial plateau.

18. A balloon as set forth in Claim 17, wherein said body has a height ranging from 0.5 to 5.0 cm, the anterior-posterior dimension ranging from 1.0 to 6.0 cm, and the medial and lateral dimension ranging from 1.0 to 6.0 cm.

19. A balloon as set forth in Claim 11, wherein said body has an outer surface adapted to assume the normal configuration of the inner surface of the cortical bone for compressing cancellous bone in the proximal humerus.

20. A balloon as set forth in Claim 12, wherein said body has a spherical portion whose dimensions vary from 1.0 x 1.0 cm to 3.0 x 3.0 cm, whose neck will range from 0.8 x 0.8 cm to 3.0 x 3.0 cm, the width of the base portion ranging from 0.5 x 0.5 cm to 2.5 by 2.5 cm, and whose length ranges from 4.0 to 14.0 cm.

21. A balloon as set forth in Claim 11, wherein said body has an outer surface adapted to assume the normal configuration of the inner surface of the cortical bone for compressing cancellous bone in the femoral head.

22. A balloon as set forth in Claim 12, wherein said body has a diameter ranging from 1.0 to 4.5 cm.

23. A balloon as set forth in Claim 1, wherein the material of the body is taken from the group consisting of Kevlar and polyethylene tetraphthalate (PET).

24. A balloon as set forth in Claim 1, wherein said balloon is doughnut shaped.

25. A balloon as set forth in Claim 1, wherein said balloon body includes a central part having a substantially spherical outer surface and a ring-shaped part surrounding the spherical part.

26. A balloon as set forth in Claim 25, wherein the part is spherical.

27. A balloon as set forth in Claim 25, wherein the part is hemispherical.

28. A balloon as set forth in Claim 1, including a number of elongated balloon units defining said balloon body, and restraint means coupling the balloon units together to restrict the expansion thereof in the direction transverse to the longitudinal axes of the units.

29. A balloon as set forth in Claim 1, wherein the balloon is formed of a pair of hollow, stacked inflatable parts, each part having a pair of opposed faces, and means bonding the adjacent faces of the parts together.

30. A balloon as set forth in Claim 29, wherein the balloon parts have a substantially circular outer periphery.

31. A balloon as set forth in Claim 29, wherein the balloon parts are doughnut shaped.

32. A balloon as set forth in Claim 29, wherein is included a catheter tube between said balloon parts for removing fats and debris.

33. A balloon as set forth in Claim 1, wherein the balloon is kidney bean shaped.

34. A balloon as set forth in Claim 1, wherein the balloon has a number of restraints interconnecting the end walls to limit expansion.

35. A balloon as set forth in Claim 1, wherein the end walls of said balloon has a number of interconnected

parts defining transversely circular, generally cylindrical compartments.

27 36. A balloon as set forth in Claim ~~1~~, wherein the balloon is kidney bean shaped and has a number of spaced strings extending between the opposed sides of the balloon, said strings defining restraints.

28 37. A balloon as set forth in Claim ~~1~~, wherein said balloon body includes a pair of stacked doughnut shaped members, each member having a pair of opposed sides, a string extending between each pair of sides, respectively, to present a restraint for the balloon body.

29 38. A balloon as set forth in Claim ~~1~~, wherein the balloon body is spherical.

30 39. A balloon as set forth in Claim ~~1~~, wherein the balloon body approximates a hemisphere.

31 40. A balloon as set forth in Claim ~~1~~, wherein the balloon body approximates a pyramid.

41. A balloon as set forth in Claim 1, wherein a portion of the body is modified to further compress cancellous bone.

42. A balloon as set forth in Claim 41, wherein the modification is designed to compress cancellous bone into the shaft of a long bone.

43. A balloon as set forth in Claim 42, wherein the balloon body has a base.

44. A balloon as set forth in Claim 43, wherein the balloon body is a sphere on a base.

45. A balloon as set forth in Claim 40, wherein the balloon body approximates the shape of a banana.

46. A balloon as set forth in Claim 45, wherein the balloon body approximates the shape of a humpback banana.

47. A balloon as set forth in Claim 1, wherein a suction device is attached to remove debris.

48. A balloon as set forth in Claim 1, wherein the balloon body is protected from puncture during inflation by a guard member that covers the cortical bone and extends into the cancellous bone without preventing the balloon from inflating.

49. A non-expandable balloon device suitable for compressing cancellous bone comprising:

a hollow, flexible, inflatable, non-expandable balloon body having a shape approximating a configuration taken from the group including a square, a rectangle, an oblong member and a cylinder, said body having a shape, when substantially fully expanded, to form a pair of sides, said body having restraints operable to cause the sides to be substantially parallel with each other when inflated.

50. A device as set forth in Claim 49 wherein said body has a number of corners, said corners defining at least one of the restraints.

51. A device as set forth in Claim 49 wherein said body includes a number of stacked body parts having means for coupling the body parts together, the coupling means of said body parts defining the restraint.

52. A device as set forth in Claim 49 wherein is included walls with additional thickness in the body, said thickness defining the restraints.

53. A device as set forth in Claim 49 wherein is included a number of strings extending between the sides of the balloon body, said strings defining said restraints.

54. A device as set forth in Claim 49, wherein is included a winding, said winding creating a restraint.

55. A device as set forth in Claim 49, wherein is included a meshwork, said meshworking created by a restraint.

56. A device as set forth in Claim 49, wherein is included bonding of portions of the body, said bonding creating a restraint.

57. A device as set forth in Claim 49 wherein the material of the body is taken from the group consisting of polyethylene tetraphthalate (PET) or Kevlar.

58. A balloon as set forth in Claim 49, wherein a suction device is attached.

59. A balloon as set forth in Claim 49, wherein the balloon body is covered by a guard member.

60. An inflatable device for insertion into a cortical bone to be treated for cavity formation and for compacting the bone marrow and trabecular bone thereof comprising:

a balloon body having flexible non-expandable wall means for conforming to the shape of the inner cortical

surface of the bone to be treated, said wall means including a generally continuous side wall and a pair of opposed end walls integral with the side wall, said balloon having a fluid duct for directing an inflating liquid into the balloon, whereby the balloon can be inflated, said walls extending outwardly and into engagement with the inner surface of the bone to be treated and into compacting relationship to the cancellous bone.

61. An inflatable device as set forth in Claim 60, wherein is included restraints, the end walls of the balloon being held by said restraints when the balloon body is inflated.

62. An inflatable device as set forth in Claim 60, wherein the side wall of the balloon body is held together by restraints.

63. An inflatable device as set forth in Claim 60, wherein said balloon is doughnut shaped.

64. An inflatable device as set forth in Claim 60, wherein said balloon body includes a central, substantially spherical part and a ring-shaped part surrounding the spherical part.

65. An inflatable device as set forth in Claim 60, is included a number of elongated balloon units defining said balloon, and restraint means coupling the balloon units together to restrict the expansion thereof in the direction transverse to the longitudinal axes of the units.

66. An inflatable device as set forth in Claim 60, wherein the balloon body is formed of a pair of

hollow, stacked inflatable parts, each part having a pair of opposed sides and means bonding the adjacent sides of the parts together as a unit.

67. An inflatable device as set forth in Claim 44, wherein the balloon parts have a circular outer periphery.

68. An inflatable device as set forth in Claim 60, wherein the balloon parts are doughnut shaped.

69. An inflatable device as set forth in Claim 60, wherein is included a catheter tube between said balloon parts for removing fats and debris from a location between said parts.

70. An inflatable device as set forth in Claim 60, wherein the balloon is kidney shaped.

71. An inflatable device as set forth in Claim 60, wherein the balloon has a number of restraints interconnecting the end walls to limit expansion.

72. An inflatable device as set forth in Claim 60, wherein the end walls of said balloon has a number of interconnected parts defining transversely circular, cylindrical compartments.

73. An inflatable device as set forth in Claim 60, wherein the balloon is kidney shaped and has a number of spaced strings extending between the opposed sides of the balloon, said strings defining restraints.

74. An inflatable device as set forth in Claim 60, wherein said balloon includes a pair of stacked

doughnut shaped members, each member having a pair of opposed sides, a string extending between each pair of sides, respectively, to present restraints for the balloon.

75. An inflatable device as set forth in Claim 60, wherein the balloon body is pyramid-shaped.

76. A method for treating a bone predisposed to fracture or to collapse, or fractured or collapsed, comprising:

providing a hollow, collapsible, inflatable, non-expandable cavity former;

inserting the cavity former while collapsed into said bone with said cavity former having a predetermined shape and size, when substantially fully inflated;

inflating the cavity former to a sufficient fluid pressure to compress at least a portion of the inner cancellous bone;

forming a cavity in the cancellous bone as a function of the inflating step wherein said cavity will have the predetermined shape and size appropriate for the bone to be treated; and

restraining the cavity former to create said predetermined shape and size, preventing the cavity former from applying excessive pressure to the inner surface of the cortical bone if said bone is unfractured or uncollapsed.

77. A method as set forth in Claim 76, wherein said restraining step includes forming substantially parallel sides for said cavity former when the space has been inserted in the cortical bone.

78. A method as set forth in Claim 76, wherein said cavity former is capable of withstanding internal fluid pressures within the cortical bone of 50 to 400 psi.

79. A method as set forth in Claim 76, wherein said inserting step includes placing the cavity former in the distal radius to adapt the cavity for use in treating a radius fracture.

80. A method as set forth in Claim 76, wherein said inserting step includes placing the cavity former in the proximal tibia to adapt the cavity for use in treating a tibial fracture.

81. A method as set forth in Claim 76, wherein the inserting step includes placing the cavity former in the proximal humerus to adapt the cavity for use in treating a proximal humerus fracture.

82. A method as set forth in Claim 76, wherein the inserting step includes placing the cavity former in the femoral head to adapt the cavity for use in treating necrosis of the femoral head.

83. A method as set forth in Claim 76, wherein the inserting step includes placing the cavity former in the vertebral body for treating a vertebral body fracture.

84. A method as set forth in Claim 76, wherein the restraining step includes providing a winding bonded to the cavity former to reinforce critical areas of the circumference of the cavity former.

ADD D10

ADD E3



IMPROVED INFLATABLE DEVICE FOR USE IN SURGICAL PROTOCOL RELATING TO FIXATION OF BONE

ABSTRACT OF THE INVENTION

A balloon for use in compressing cancellous bone and marrow (also known as medullary bone or trabecular bone) against the inner cortex of bones whether the bones are fractured or not. The balloon comprises an inflatable, non-expandable balloon body for insertion into said bone. The body has a shape and size to compress at least a portion of the cancellous bone to form a cavity in the cancellous bone and to restore the original position of the outer cortical bone, if fractured or collapsed. The balloon is prevented from applying excessive pressure to the outer cortical bone. The wall or walls of the balloon are such that proper inflation the balloon body is achieved to provide for optimum compression of all the bone marrow. The balloon is able to be folded so that it can be inserted quickly into a bone. The balloon can be made to have a suction catheter. The main purpose of the balloon is the forming or enlarging of a cavity or passage in a bone, especially in, but not limited to, vertebral bodies.

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Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of	:	Reiley et al.	Examiner: D. Shai
Serial No.	:	08/788,786	Group Art Unit: 3731
Filed	:	January 23, 1997	
For	:	Improved Inflatable Device for Use in Surgical Protocol Relating to Fixation of Bone	

RESPONSE TO RESTRICTION REQUIREMENT
AMENDMENT A

Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

Applicant responds to the restriction requirement mailed April 30, 1999, with a shortened one month period to respond.

Applicant respectfully requests an automatic five month extension of time to respond, up to and including October 30, 1999.

The Examiner's time and attention at an interview conducted July 1, 1999 is appreciated. As discussed with the Examiner during the interview, in lieu of a species election, please amend the application as follows:

IN THE CLAIMS:

Please cancel claims 4 to 22, 24, 25, 28 to 40, 45, 46, and 76 to 113, which were presented in the First Preliminary Amendment, filed at the time this continuation application was filed.

Please also cancel claims 114 to 143, which were submitted in the Second Preliminary Amendment, filed by fax on March 20, 1999 (and which were not acknowledged as having been entered in the April 30, 1999 restriction requirement).

Please consider the following new claims 144 to 172:

144 (New). A device for compacting cancellous bone comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, characterized in that the body includes material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone, and further includes changes in thickness

of the body to constrain the expansion in cancellous bone.

145 (New). A device for compacting cancellous bone comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, characterized in that the body includes material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone, and further includes an internal restraint coupled to the body to constrain the expansion in cancellous bone.

146 (New). A ~~device~~ method according to claim 145 wherein the internal restraint includes mesh material.

147 (New). A ~~device~~ method according to claim 145 wherein the internal restraint includes string material.

148 (New). A ~~device~~ method according to claim 145 wherein the internal restraint includes a woven material.

149 (New). A ~~device~~ method according to claim 145 wherein the internal restraint includes a seam.

150 (New). A ~~device~~ method according to claim 145 wherein the internal restraint includes an essentially non-elastic material.

151 (New). A device for compacting cancellous bone comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, characterized in that the body includes material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone, and further includes an external restraint coupled to the body to constrain the expansion in cancellous bone.

152 (New). A ~~device~~ method according to claim 151 wherein the external restraint includes mesh material.

153 (New). A ~~device~~ method according to claim 151 wherein the external restraint includes string material.

154 (New). A ~~device~~ method according to claim 151 wherein the external restraint includes a woven material.

155 (New). A ~~device~~ method according to claim 151 wherein the external restraint includes a seam.

156 (New). A ~~device~~ method according to claim 151 wherein the external restraint includes an essentially non-elastic material.

157 (New). A ~~device~~ method according to claim 144 ~~or 145 or 151~~ wherein the material includes an essentially non-elastic material.

158 (New). A ~~device~~ method according to claim 144 or 145 or 151 wherein the material includes an essentially semi-elastic material.

159 (New). A ~~device~~ method according to claim 144 or 145 or 151 wherein the material includes an essentially elastic material.

160 (New). A device for compacting cancellous bone comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, characterized in that the body includes at least two materials that, during the expansion in cancellous bone, apply a force capable of moving fractured cortical bone and constrain the expansion in cancellous bone.

161 (New). A device according to claim 160 wherein the at least two materials possess essentially similar elastic properties.

162 (New). A device according to claim 160 wherein the at least two materials possess essentially different elastic properties.

163 (New). A method for treating bone comprising the steps of inserting a device as defined in claims 144 or 145 or 151 or 160 inside bone, causing constrained expansion of the body in cancellous bone, and compacting cancellous bone by the constrained expansion.

164 (New). A method according to claim ~~163~~ 144 or 145 or 151 or 160 wherein the constrained expansion lifts vertebral end plates.

165 (New). A method according to claim ~~163~~ 144 or 145 or 151 or 160 wherein the constrained expansion lifts tibial plateau depressions.

166 (New). A method according to claim ~~163~~ 144 or 145 or 151 or 160 wherein the constrained expansion lifts proximal humerus depressions.

167 (New). A method according to claim ~~163~~ 144 or 145 or 151 or 160 wherein the constrained expansion lifts cortical bone.

168 (New). A method according to claim ~~163~~ 144 or 145 or 151 or 160 wherein the step of compacting forms a cavity.

169 (New). A method according to claim ~~168~~ 24 further including the step of filling the cavity with a material.

170 (New). A method according to claim ~~169~~ 25 wherein the material comprises bone cement.

171 (New). A method according to claim ~~169~~ 25 wherein the material comprises synthetic bone substitute.

~~172~~ 35 (New). A method according to claim ~~169~~ wherein the material comprises a flowable material that sets to a hardened condition.

REMARKS

As discussed during the interview in July 1, 1999, in an effort to simplify prosecution, applicant has canceled the pending claims and substituted a new claim format, which is directed to a generic definition of one aspect of the invention. Applicant respectfully requests that the election of species requirement be withdrawn in view of the submission of the new claim format.

Claims 144 to 172 remain in the application. Of these, claims 144, 145, 151, and 160 are independent device claims, and claim 163 is a multiple dependent method claim.

New claims 144 to 162 are directed to a device comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone. As defined in the claims, the body is characterized in that it includes material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone. The body is further characterized in that its expansion in cancellous bone is constrained.

As was discussed during the interview, there is a need to constrain expansion of an expandable body within cancellous bone, in order to provide proper compaction and/or *en masse* reduction of fractured cortical bone and restore pre-fracture anatomy. The discovery of this need was surprising and unexpected. It was not known or appreciated at the time the invention arose, that variations in density in cancellous bone were sufficient to cause significantly non-uniform and unpredictable volume expansion of an expandable body inside bone, unless expansion of the body is constrained. Unless constrained, an expandable body follows paths of least density resistance through cancellous bone, assuming non-uniform and unpredictable geometries inside bone that are not oriented for proper compaction and/or *en masse* reduction of fractured cortical bone. Without constrained expansion in cancellous bone, the proper compaction of cancellous bone and /or restoration of pre-fracture anatomy using an expandable body becomes problematic.

As discussed during the interview, constrained expansion of the body can be achieved in various ways. As defined in independent claim 144, the body includes changes in thickness to constrain the expansion in cancellous bone. As defined in independent claim 145, an internal restraint is coupled to the body to constrain the expansion in cancellous bone. As defined in independent claim 151, an external restraint is coupled to the body to constrain the expansion in cancellous bone. As defined in independent claim 160, the body includes at least two materials that constrain the expansion in cancellous bone. Support for the subject matter defined in these claims is found, e.g., on Specification page 9, line 14, to page 10, line 18.

New multiple dependent claim 163 defines a method for treating bone by inserting a device as defined in claims 144 or 145 or 151 or 160 inside bone, causing constrained expansion of the body in cancellous bone, and compacting cancellous bone by the constrained expansion.

The Examiner's attention is directed to the prior submission of three Information Disclosure Statements in this application, on June 20, 1997 and July 1, 1997, and March 16, 1998.

Allowance of new claims 144 to 172 is respectfully requested.

Respectfully submitted,

By _____
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