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United States Patent [19]

Murray

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[45] **Date of Patent: Dec. 9, 1986**

[54] **BONE CEMENT SYSTEM AND METHOD**

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[21] Appl. No.: **730,379**

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[51] **Int. Cl.**[4] **A61B 17/00**

[52] **U.S. Cl.** ..... **128/303 R**; 128/305; 128/92 VQ; 128/92 VP; 623/16

[58] **Field of Search** ..... 128/303 R, 305, 92 E, 128/92 C, 92 CA, 345, 325, 92 XP, 92 XO; 604/104, 106, 107, 8–10, 278, 213, 96; 623/16; 141/367, 312, 189

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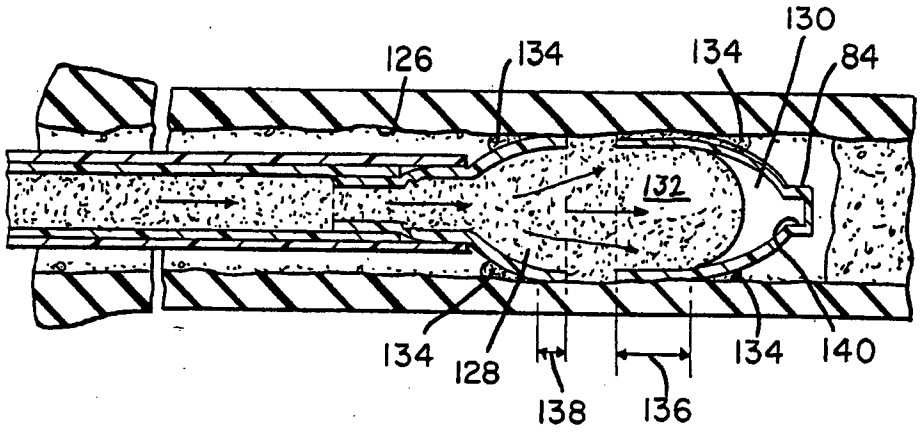
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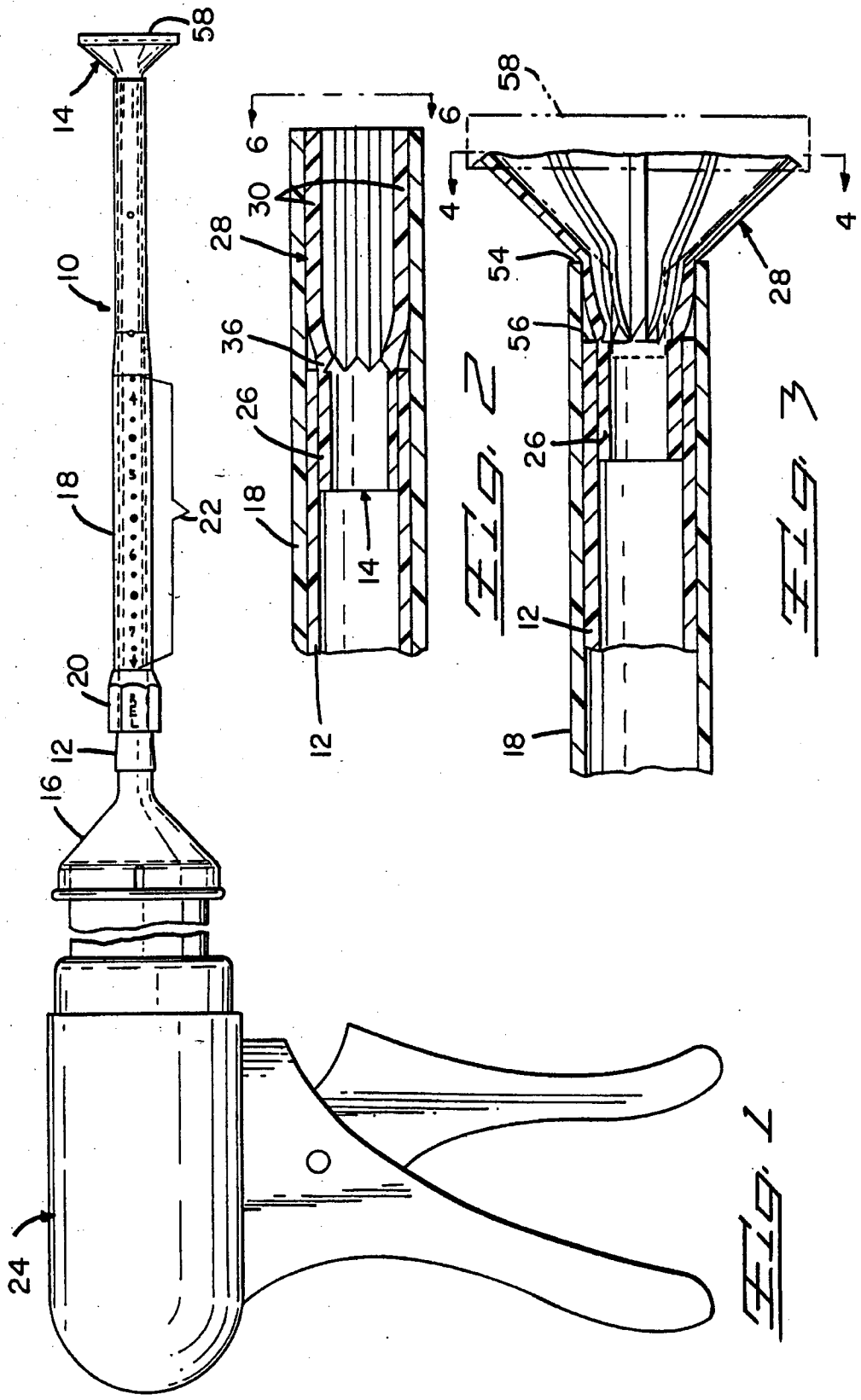
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[57] **ABSTRACT**

A bone cement system and related methods useful in flowing liquid bone cement into a prepared long bone medullary canal prior to implanting a prothesis stem in the canal.

18 Claims, 12 Drawing Figures




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FIG. 2
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FIG. 3
FIG. 1

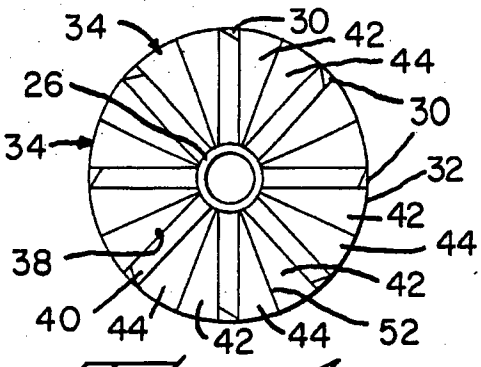


Fig. 4

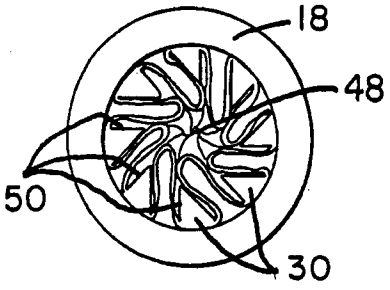


Fig. 6

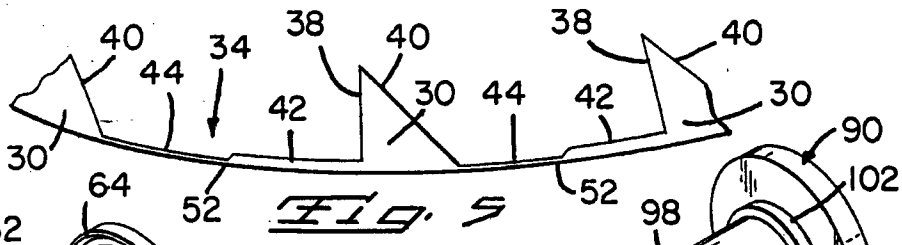


Fig. 5

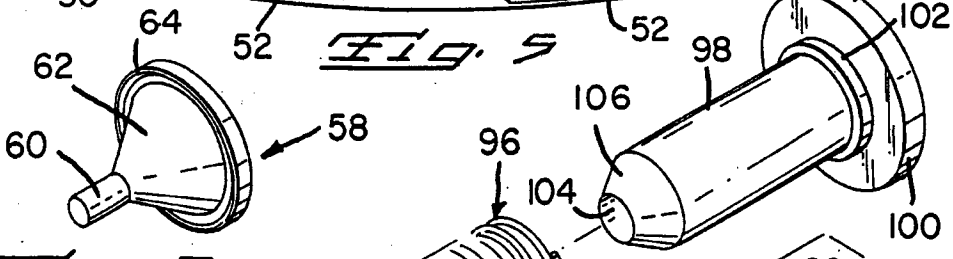


Fig. 7

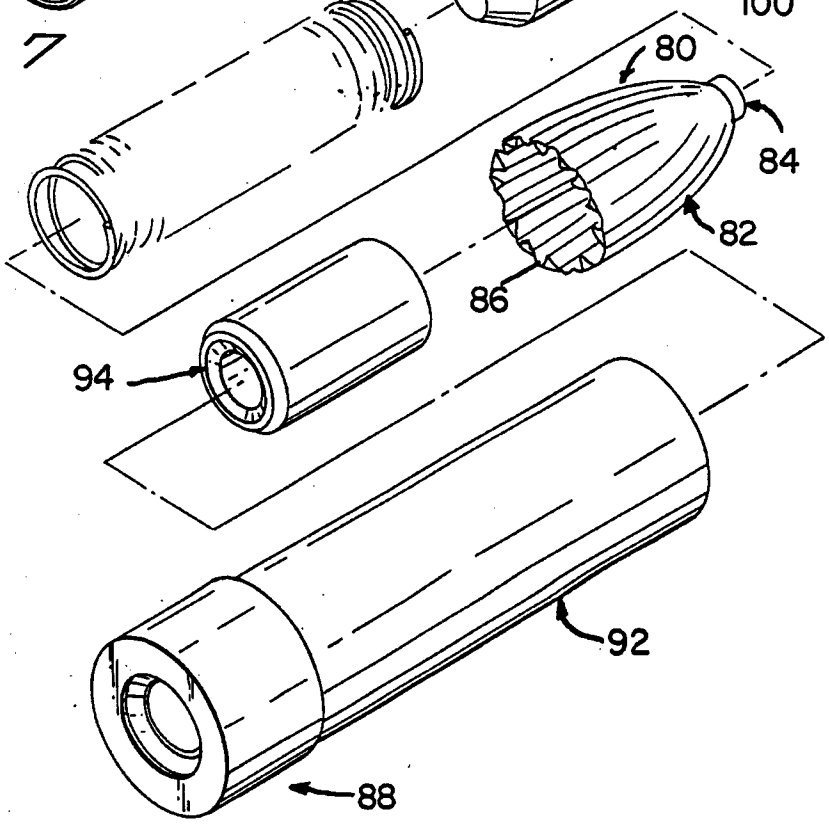
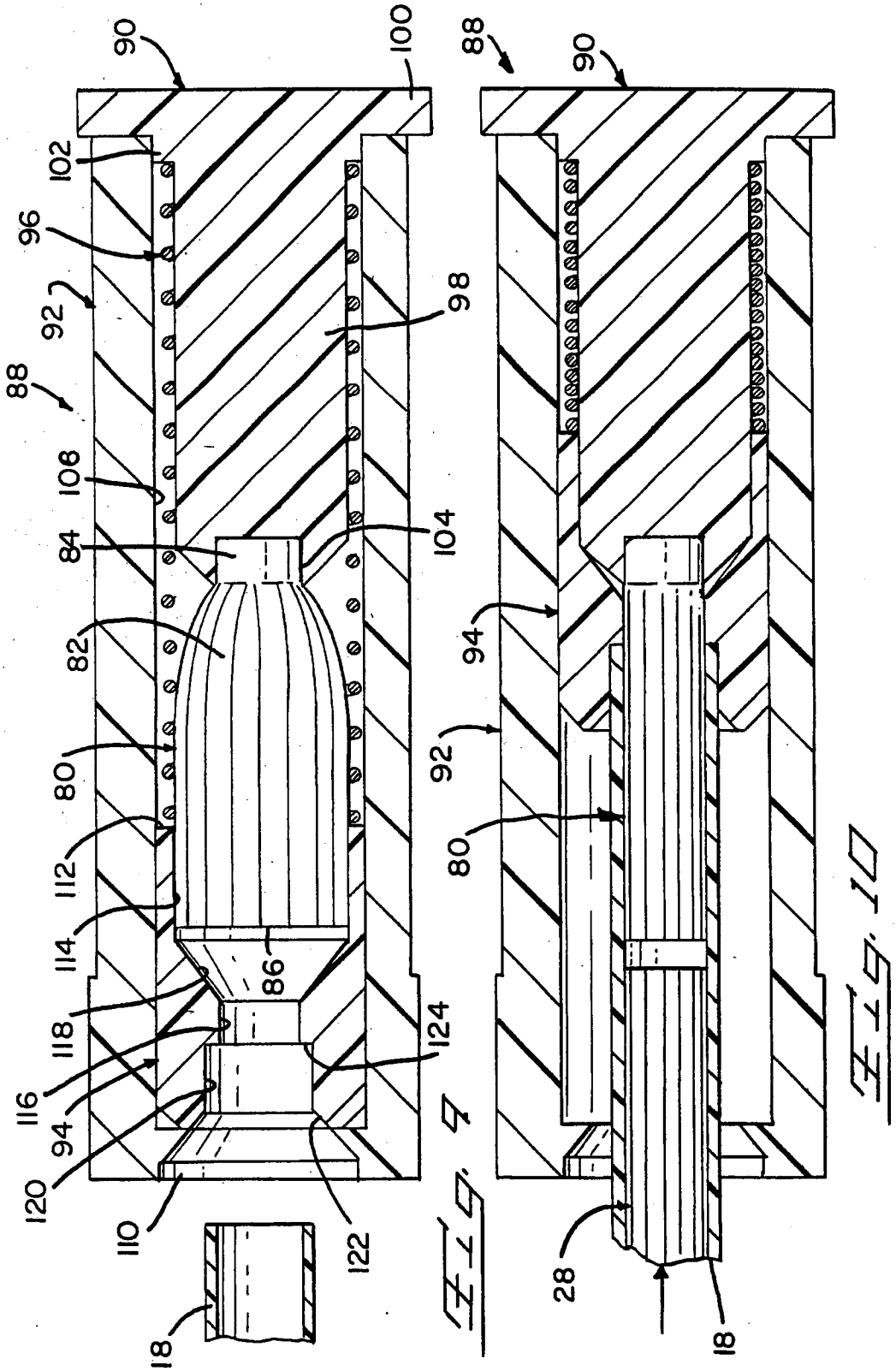


Fig. 8


90
100
102
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92
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108
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114
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116
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122
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FIG. 9
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FIG. 10

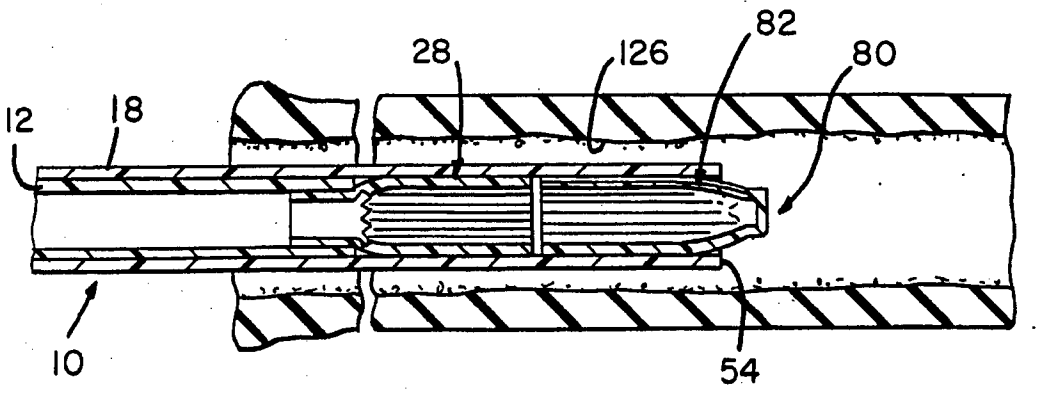

82
28
126
80
12
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Fig. 11

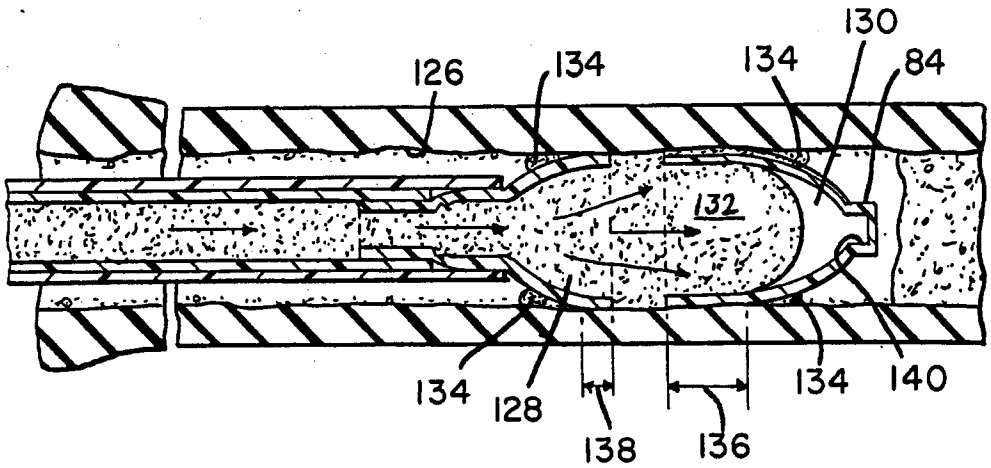

130
126
134
134
84
132
134
128
138
136
134
140

Fig. 12

BONE CEMENT SYSTEM AND METHOD

The invention relates to the components of a bone cement system for delivering liquid bone cement into a prepared long bone medullary canal and for sealing the distal end of the canal and to related methods. The components and methods are useful during implantation of a prothesis stem in the canal. The components include an improved umbrella-type delivery device, an improved pressure sealing intramedullary plug for closing the distal end of the canal and a holding and loading device for the plug.

Murray U.S. Pat. No. 4,466,435 discloses an umbrella-type delivery device for flowing liquid acrylic bone cement into a prepared long bone medullary canal before the stem is implanted in the canal. The charcteristics of liquid bone cement, techniques for using the delivery device and the advantages of the umbrella-type device are discussed in the patent.

Conventionally, the distal end of the prepared medullary canal is plugged prior to filling the canal with liquid bone cement. The purpose of the plug is to limit the extent of the canal which is filled with cement. The cement is pressurized as it is flowed into the canal and also during insertion of the prothesis stem into the filled canal. The plug must effectively seal the canal to maintain the pressure of the liquid cement and prevent the cement from flowing distally past the plug.

Three kinds of plugs are presently used to seal the distal end of the femoral canal: an acrylic cement plug, a molded plastic insert plug and a plug fashioned from the live bone.

The acrylic cement plug is a mass of liquid acrylic cement introduced into the distal end of the prepared canal and maintained in place until it hardens. The plastic, typically molded from polyethylene, is press-fitted in place. The bone plug is fashioned from a portion of compatible bone, preferably oversized with regard to the canal end, and is then moved through the canal into the desired location.

A number of problems are associated with the conventional plugs. The cement required for the acrylic plug must be mixed and then introduced while liquid into the distal end of the canal. The canal may not subsequently be filled with liquid bone cement until sufficient time has passed for the plug cement to harden in place and close the end of the canal. A bone plug must be sized and then fitted in place. Both these of procedures take considerable operating room time. Also, it is difficult to assure that the desired close fit between a bone plug and the surrounding bone is achieved. Pressure blow-out or dislodgement of acrylic and bone plugs does occur.

Use of the acrylic plug runs the real risk that withdraw of the cement delivery nozzle following filling of the canal with liquid cement can draw the cement and plug proximally with the nozzle, thereby breaking the plug-canal seal and reducing the length of the filled canal available for placement of the prothesis stem.

Conventional molded plastic plugs are weakly anchored to the surrounding bone and may be dislodged when the liquid cement in the canal is pressurized during delivery, withdrawal of the nozzle or insertion of the prothesis stem.

Plastic and bone plugs cannot be used for closing the end of a medullary canal located distally of a narrow point having a cross section smaller than the cross section at the plug site. Additionally one molded plastic plug will not close all size medullary canals commonly experienced in performing a given procedure, thus requiring that an inventory of different sized molded plugs be maintained in order to assure that an appropriate size plug is available as required.

The umbrella-type delivery device of the invention is an improvement over the device disclosed in U.S. Pat. No. 4,466,435 and includes a shield with ribs and webbing for improved collapse of the shield before insertion of the device into the canal and subsequent expansion of the shield within the canal for improved pressure engagement with the canal walls. The pressure of the liquid cement flowed through the device and into the canal overcomes the frictional engagement between the shield and the canal so that the device is automatically expelled as pressurized liquid bone cement fills the canal. A specialized keeper is provided to stress the ribs for spring engagement against the walls of the canal.

The invention also includes an improved pressure-type intramedullary plug for sealing the distal end of the canal. The plug includes an expandable umbrella-type shield similar to the shield of the improved delivery device which, when collapsed, may be carried in the lead end of the delivery device for movement through the canal to the sealed distal end. The plug is released from the delivery device to permit the plug shield to expand and form a large area contact with the canal wall and thereby close the canal end. The shield of the delivery device is also released at the same time and likewise expands to engage the walls of the canal proximally of the expanded plug.

Liquid bone cement flowed through the delivery device and into the canal between the shields pressurizes the interior of the expanded plug shield and biases the exterior of the plug shield against the wall of the canal. The axial length of the contact between the plug shield and the canal wall is sufficient to prevent pressure movement of the plug distally, despite expected variations in the diameter of the canal. In this way, only a single plug will fit canals having a wide range of diameters.

The pressure of the liquid cement confined between expanded shields of the plug and delivery device retains the plug in place while automatically expelling the device proximally along the canal. The proximal surface of the device shield cleans the wall of the canal to promote the desired intimate and large area contact between the pressurized liquid cement and surrounding bone, as explained more fully in U.S. Pat. No. 4,466,435.

The medullary canal plug is preferably stored in a plug holder which confines the plug shield ribs in an expanded position greater in diameter than the anticipated maximum diameter of the canal at the distal end. Prior to plugging and filling the canal with cement the end of the delivery device collar is inserted into the holder which automatically collapses and inserts the plug into the collar for movement, while collapsed, through the canal to the distal end. The collapsed plug is easily moved past narrow points in the canal which would obstruct conventional large molded plastic or live bone plugs.

Other objects and features of the invention will become apparent as the description proceeds, especially when taken in conjunction with the accompanying drawings illustrating the invention, of which there are 4 sheets.

IN THE DRAWINGS

FIG. 1 is a side view illustrating a bone cement dispenser with an umbrella-type delivery device according to the invention;

FIGS. 2 and 3 are sectional views of the free end of the delivery device showing the shield in different positions;

FIG. 4 is a view taken along line 4—4 of FIG. 3;

FIG. 5 is an enlarged view of the lip of the shield of FIG. 4;

FIG. 6 is a view taken along line 6—6 of FIG. 2;

FIG. 7 is a perspective view of a keeper shown in dotted lines in FIG. 3;

FIG. 8 is an exploded view of a holder for a intramedullary plug;

FIGS. 9 and 10 are cross sectional views of the plug holder illustrating normal retention of the intramedullary plug and insertion of the plug into the end of the delivery device; and

FIGS. 11 and 12 illustrate use of the plug and dispensing device in flowing liquid bone cement into a medullary canal.

Improved umbrella-type delivery device or interfacer **10** includes a number of elements like those of the similar delivery device of U.S. Pat. No. 4,466,435. The description of the present device uses terminology which in some respects differs from the terminology used in describing the prior device. In the present description, old terminology will be set forth in parentheses for puroses of clarification.

The delivery device (nozzle) **10** includes a liquid cement delivery nozzle (tube) **12**, with an expandable tip **14** on the free or distal end thereof and an enlarged cap **16** on the other or proximal end thereof as shown in FIG. 1. Cylindrical collar **18** surrounds the nozzle **12** and is slightly shorter in length than the nozzle. The collar has a sliding fit on the nozzle so that it may be moved distally and proximally on to the nozzle by gripping expanded hexagonal handle **20**. Indicia **22** are spaced along the length of the collar adjacent the handle to permit the surgeon to judge the depth of insertion of the delivery device within the medullary canal.

The device cap **16** includes means for attachment to a reservoir of liquid bone cement carried by bone cement dispenser **24** which, when actuated, flows pressurized liquid bone cement from the reservoir through the cap and nozzle and outwardly of the device through tip **14**.

Delivery device tip **14** is preferably molded from a plastic material and includes a cylindrical tip tube **26** and an expandable bone cement shield **28** extending from one end of the tip tube **26**. The shield includes a plurality of circumferentially spaced ribs **30** extending from the end of the tip tube to the shield lip **32**. Flexible plastic sheeting **34** extends between adjacent ribs **30** from the end of the tip tube to the lip so that when the shield is freely expanded the straight ribs **30** project outwardly of the tube and the sheeting is taut between the ribs. The inner ends of the ribs are joined to the tip tube by reduced cross section hinge connections **36**.

As illustrated in FIGS. **4** and **5**, the ribs **30** are triangular in transverse cross section and each includes a side **38** on the interior of the shield lying approximately in a radial plane with all of the ribs sides **38** facing in the same circumferential direction. Each rib **30** also includes an interior side **40** facing to the opposite circumferential direction and intersecting the adjacent side **38** at an acute angle. Each sheeting portion **34** between two ribs is generally triangular in shape as illustrated in FIG. **4** and extends between the surfaces **38** and **40** of the ribs **30**. The sheeting of portions **34** includes a triangular relatively thick portion **42** extending from adjacent rib surface **38** and a relatively thin sheeting portion **44** extending from the edge of portion **42** to the adjacent rib surface **40**. Each of the sheeting portions **40** and **42** extends along the ribs from lip **32** to the junction between the shield and the tip tube **26** and are joined mid-way between the ribs at boundary **52**.

The tip **14** is secured to the distal end of nozzle **12** by inserting the tip tube **26** within the end of the nozzle and forming a suitable permanent bond between the tip tube and nozzle.

The fully expanded molded tip **14** may be passed through a suitable collapsing die which includes surfaces for forcing the ribs and triangular sections of flexible sheeting **34** inwardly to collapse the shield and fold portions **42** and **44** onto themselves and form U-shaped folded pleats **48** as shown in FIG. **6** between the collapsed and generally parallel axially extending ribs **30**. When the ribs are collapsed to this position the surfaces **38** and **40** of adjacent ribs generally parallel to each other and define a series of pleat-confining slots **50** between the ribs, all of which extend in the same nonradial direction from the outer circumference of the collapsed shield. The boundary **52** between sheeting portions **42** and **44** is about equal distant between the adjacent ribs **30** so that when the sheeting **34** between the ribs is collapsed to form the pleats sheeting portions **42** form one side of the pleats adjacent surfaces **38**, portions **44** form the other side of the pleats adjacent rib surfaces **40** and the portions are folded over each other within the thinner or more flexible sheeting portions near the boundaries **52**. The boundaries are at the crests of the pleats. The angled slots **50** permit efficient use of the limited available storage space such that the pleats may have a collapsed length at the shield lip greater than the interior radius of the collar. Orderly collapse of the sheeting permits a shield having a relatively large diameter when expanded to be collapsed into a relatively small diameter configuration. The collapse of each sheeting portion **34** into a like pleat **48** assures that each of the sheeting portions opens properly when the shield is expanded to form a proper pressure seal between the shield and the surrounding wall of the medullary canal.

As shown in FIG. **2**, when the tip **14** is secured to the end of nozzle **12** the bone cement shield **28** may be collapsed within the extended free end of the surrounding collar **18**. In practice it has been found advantageous to maintain the shield in the position of FIG. **3** during the interval prior to use for delivery of cement into a medullary canal. In FIG. **3** the collar **18** has been withdrawn from the position of FIG. **2** proximally sufficiently to position the free collar end **54** about one-third of the length of the ribs distally of the hinge connections **36** joining the ribs and the tip tube. The hinge connections are located at or beyond the free end **56** of nozzle **12**. With the collar in this position a keeper **58**, shown in FIG. **7**, is inserted into the interior of the shield to expand the shield and bend ribs **30** outwardly about the collar end **54**. See FIG. **3**.

Keeper **58** is generally funnel-shaped and includes a cylindrical pilot **60**, a conical shaping member **62** and a circumferential lip **64** at the surrounding the major end of the shaping member.

As illustrated in FIG. 3, when the keeper 58 is inserted into the interior of the bone cement shield 28 the pilot 60 extends into the tip tube and the conical shaping member 60 engages the portions of the ribs outwardly of collar end 54 and flexes them outwardly against the end, which forms a fulcrum. The pleating between the outwardly bent portions of the ribs, is at least partially unfolded. When fully inserted, the keeper lip 54 meets the ends of the ribs and protects the shield lip prior to use.

Following manufacture of the delivery device 10 a keeper 58 is inserted into the nozzle as shown in FIG. 3 so that during the storage interval prior to use ribs 30 are confined in a shallow V-shape as shown in FIG. 3. While held in this position the plastic ribs experience cold flow and tend to assume the V-shape in which they are confined. Before the delivery device is used the keeper is removed and the bone cement shield is collapsed by distal extension of the collar as in FIG. 2 and the rib ends are biased outwardly against the collar so that they will snap open after the collar is withdrawn. This assures that the shield will properly open within the canal. Further, the expanded ribs will be forced outwardly against the wall of the canal thereby improving the shield-wall seal. This feature improves the ability of the shield 28 to make an effective seal with different diameter medullary canals so that a single delivery device may be reliably used to deliver bone cement into medullary canals of different diameters encountered in performing a given procedure.

Initial collapse of the bone cement shield 28 is achieved by moving the shield through the collapsing die as described. Subsequent collapse of the shield by the collar is achieved by pushing the ribs radially inwardly. As the collar is moved distally the end 54 pushes the ribs inwardly and the relatively thin sheeting portions 44 are first folded inwardly towards the adjacent rib surface 40 while the relatively thick sheeting portions 42 resist being bent with respect to its adjacent rib 30. Further rib collapse then folds the thick sheeting portions 42 inwardly with respect to the adjacent ribs 30, thereby completing the pleats as shown in FIG. 5 and assuring that each pleat is U-shaped as described with the webbing portions 42 and 44 forming the pleat sides.

FIG. 6 illustates that the relatively thick sheeting portions 42 resist being bent relative to their adjacent rib surfaces 40 and hold the relatively thin sheeting portions 44 closely against surfaces 40 of their adjacent ribs 40.

The bone cement shield of discharge device 10 is provided with eight ribs 30. It is contemplated that the shield may be provided with a greater number of equally spaced ribs. Such a shield would have the advantage of reducing the circumferential length of each portion of flexible sheeting between ribs. By reducing the length of the portions at the circumference of the shield the maximum length of the pleats is reduced, making storge of the pleats easier within the interior of the surrounding collar. For instance, increasing the number of ribs from 8 to 12 would markedly reduce the maximum circumferential length of each sheeting portion making it easier to fold and store the pleats within the limited interior of the collar.

The tip 14 may be molded from a polyurethane plastic possessing sufficient strength and elastomeric properties to permit the shield to be collapsed and expanded and to form the desired pressure seal with the medullary canal as described.

The delivery device 10 disclosed herein is particularly useful in flowing liquid bone cement into the interior of prepared femoral medullary canals prior to mounting a femoral prothesis within the canal. The normal diameter expected in an adult femoral medullary canal has a range of from 10 to 18 millimeters or about 0.39 to 0.71 inch. A single delivery device 10 may be used for reliably flowing cement into canals within this range.

In the device 10 the outside diameter of the tip tube is about 0.33 inch. The straight length of rib 30 is about 0.5 inch. When the shield is fully expanded the ribs diverge from the shield axis at 30 degrees and the maximum diameter of the shield at lip 32 is 1.33 inch. The relatively thin sheeting portion 44 has a thickness of about 0.006 inch and the relatively thick sheeting portion 44 has a thickness of about 0.015 inch, 2½ times the thickness of the thin sheeting. Rib surfaces 38 and 40 intersect at an angle of about 45 degrees. The fully collapsed shield shown in FIG. 2 is confined within the interior of collar 18 has an interior diameter of about 0.38 inch. The outside diameter of the distal end of the delivery device 10 is about 0.44 inch.

The keeper conical shaping member 62 has sides which diverge from its axis at an angle of 45 degrees so that when the keeper is inserted into the partially confined shield as shown at FIG. 3 the free portions of the ribs 30 are bent away from the shield axis 45 degrees in order to bend the ribs into the shallow V-shape previously described.

FIG. 8 includes a prospective view of an intramedullary canal plug 80 useful in pressure-sealing the distal end of a medullary canal to maintain the pressure of liquid acrylic bone cement within the canal and prevent the cement from flowing distally past the plug. Plug 80 includes a bone cement shield 82 and a solid base 84 at one end of the shield. The shield 82 is similar to the delivery device shield 28 previously described and includes 12 elongate ribs extending from the base to the shield lip 86, hinge connections between the ribs and the base and differential thickness webbing portions between the ribs as in shield 28. The diameter of the base is slightly smaller than the interior diameter of the collar 18. The ribs are 0.75 inch long, 1½ times the length of ribs 30. When the plug is fully expanded the maximum diameter at the shield at lip 86 is 1.83 inch. When fully expanded, the ribs extend outwardly of the plug axis at an angle of 30 degrees. The fully expanded plug has a maximum diameter at lip 86 of 1.83 inch. The ribs of shield 82 are triangularly shaped like ribs 30 and cooperate with the differential thickness flexible sheeting between the ribs for controlled collapse of the shield with the formation of U-shaped pleats between adjacent ribs when collapsed. When fully expanded, shield 82 assumes a conical shape with the straight ribs extending 30 degrees from the plug axis. The ribs of shield 82 are longer than the ribs of shield 28 in order to assure that the plug is immovably pressure sealed to the medullary canal wall during flowing of bone cement into the canal.

The intramedullary plug base 84 is cylindrical in transverse cross section, but unlike the tip tube is solid, without a central opening. In this way, the expanded plug effectively closes off the distal end of the medullary canal.

Plug 80 may also be molded from a strong, flexible plastic material such as polyurethane. The plug is molded in an expanded, generally conical shape and then moved through a collapsing die to fold the sheeting inwardly between the ribs in the same manner as described in connection with the shield 28. The plug is then positioned within the plug holder 88 shown in FIGS. 8 and 9.

Plug holder 88 includes base 90, an elongate cover 92, collapser element 94 and spring 96. Plug holder base 90 includes a cylindrical post 98, a circular flange 100 at one end of the post with a step 102 at the junction between the flange and the cylindrical post. A shallow bore 104 is provided on the other end of post 98 for receiving and holding plug base 84. Bevel surface 106 extends from the side of post 98 inwardly to the end of bore 104.

Cylindrical cover 92 includes a cylindrical interior recess 108' opening at one end such that the cover may be fitted over the base with the open end fitted snugly around step 102 to assure the cover is maintained coaxial with the base. A beveled lead-in opening 110 is provided in the other end of the cover away from the base and has a minimum diameter less than the diameter of recess 108'.

Collapser member 94 has a close sliding fit within bore 108' and is biased toward the opening 110 by spring 96. The spring is fitted over post 98 and is confined between the step 102 and the outer circumferential end 112 of the collapser member. The collapser member includes a first circular recess 114 having a diameter approximately equal to the interior diameter of the spring 96, a minimum diameter recess 116 spaced from recess 114 and having a diameter slightly less than the interior diameter of the delivery device collar 18, a beveled shield collapse recess 118 joining recesses 114 and 116 for collapsing the shield 82 and an end recess 120 located between recess 116 and the end of the collapser member 94 away from base 90. The diameter of recess 120 is slightly greater than the exterior diameter of collar 18. The outer end of recess 120 is provided with a lead-in champer 122 which forms a continuation of bevel surface 110 when the collapser member is held against the end of the cover as shown in FIG. 9.

The intramedullary plug 80 is confined within the plug holder 88 as shown in FIG. 9 with the plug base 84 fitted within bore 104 and the bone cement shield confined in a partially expanded position by the coils of spring 96 and bore 114. The ribs are molded straight so that when the plug is collapsed and confined as shown the ribs are stressed and resiliently hold the shield against the spring and bore thereby assuring that after the plug is collapsed and seated within the delivery device collar and released in the distal end of the canal the shield will snap open and the ribs will hold the shield against the canal wall for forming an immovable pressure seal. During storage of the plug within the holder the ribs tend to cold flow and assume the confined position thereby assuring that the released plug will snap open. In the case of a intramedullary plug used to close the proximal end of a femoral canal, the interior diameter of the spring and of recess 114 may be about 0.75 inch which is greater than the maximum expected diameter of the canal.

The expanded intramedullary plug 80 confined in holder 88 is collapsed and loaded into the lead or distal end of delivery device collar 18 immediately after the device bone cement shield 28 has been collapsed and loaded into the collar as shown in FIG. 2. The collar is extended distally from the position of FIG. 2 so that end 54 is beyond the collapsed device bone cement shield 28 a distance sufficient to receive the collapsed plug 80. The distal end of the collar is then positioned as shown in FIG. 9 and pushed into the plug holder through lead-ins 110 and 122 until it seats on step 124 at the end of end recess 120. The diameter of adjacent recess 116 is slightly less than the interior diameter of collar 18. With the base 90 supported against movement the collar is then forced toward the base as indicated in FIG. 10 so that the collapser member 94 is moved to the right and spring 96 is compressed. With plug base 84 bottomed in bore 104 the plug is held against movement so that the lip 86 of the partially collapsed plug shield 82 is brought into contact with the shield collapse recess surface 118 and moved radially inwardly and ultimately extended into the minimum diameter recess 116. During collapse of the plug shield the relatively thick and relatively thin sheeting portions between adjacent ribs are folded together as described in connection with the collapse of the device shield 28 to form U-shaped pleats which are confined within angled recesses between adjacent ribs upon full collapse.

As the collapser member 94 moves to the right the collapsed shield is loaded within the interior of the collar adjacent the previously loaded device shield 28 as indicated in FIG. 10. Loading is completed when the collapser member 94 bottoms on the end of post 98. The loaded device 10 may then be freely withdrawn from the plug holder 88. The base and part of the collapsed plug shield may extend beyond collar end 54.

After loading of plug 80 into the distal end of the extended collar 18 the surgeon moves the distal end of device 10 into the medullary canal, using indicia 22 to determine when the device is inserted to a proper depth. The surgeon then grips handle 20 and fully pulls back the collar while holding the dispenser 24 fixed so that collar 18 is withdrawn to the position of FIG. 12. Withdrawal of the collar substantially simulataneously releases both of the plug and device bone cement shields 82 and 28 for expansion in the distal end of the canal as illustrated in FIG. 12.

The ribs of the released bone cement shields are biased outwardly against the interior wall of the canal as illustrated. Liquid acrylic bone cement 128 is then flowed from dispenser 28 through the interior of nozzle 12 and outwardly through the tip 14 into the space 132 between the expanded bone cement shields. The pressurized cement biases the expanded shields against the canal wall 126 and may capture an air pocket 130 at the distal or base end of the plug. During initial flowing of the pressurized cement into the space 132 a limited amount of cement 134 may flow past the shields at small apertures between the ribs. These apertures are immediately plugged by the cement so that the pressure builds up in space 132 and forces the ribs and sheeting out against the wall 126, thereby maintaining a full pressure differential betwen the shields and the wall.

The bone cement shield 82 of plug 80 contacts the circumference of wall 126 for an axial distance indicated by 136 in FIG. 12. The bone cement shield 28 of delivery device 10 has circumferential contact with wall 126 for an axial distance indicated by 138, less than distance 136.

The pressure of the cement 128 within space 132 biases the shields against the wall 126 along a circumfer-

ential area determined by the diameter of the canal and the axial distance the shield contacts the canal.

Pressurization of the interior of a bone cement shield by liquid bone cement will exert an axial force on the shield tending to move the shield along the canal and will also force the shield against the wall of the canal and generate a frictional force resisting movement along the canal.

The axial force applied to the shield is:

$$F_{axial}=(P_c)\ (pi)\ (D_c/2)^2;$$

where P_c is the pressure of the bone cement, D_c is the diameter of the canal at the shield and pi as used in this and subsequent formulas, is the ratio of the circumference of a circle to its diameter.

The maximum frictional force resisting movement of the shield is:

$$F_{friction}=(L_a)\ (pi)\ (D_c)\ (P_c)\ (mu);$$

where L_a is the axial length of contact between the shield and the canal wall, D_c is the diameter of the canal at the shield, P_c is the pressure of the cement in the shield and mu is the co-efficient friction between the shield and the wall.

The pressurized cement will not move the shield along the canal when the axial force F_{axial} is less than or equal to the maximum friction force resisting movement, $F_{friction}$, or:

$$(P_c)\ (pi)\ (D_c/2)^2 \leqq (L_a)\ (pi)\ (D_c)\ (P_c)\ (mu);\ \text{or}$$

$$D_c/L_a \leqq 4\ mu$$

Conversely, in order to assure that a bone cement shield is moved along the canal by the pressure of the liquid cement flowed into the canal the axial pressure exerted on the shield, F_{axial}, must be greater than the maximum frictional force resisting movement between the shield and the canal wall or:

$$D_c/L_a > 4\ mu$$

It will thus be seen that for a given diameter canal a shield on the tip of a delivery device must have a short L_{axial} in order for the pressurized cement to expel the device from the canal while a intramedullary plug must have a relatively long L_{axial} to assure against pressure dislodgement. Expulsion or pressure retention of the bone cement shield is not dependent on the pressure of the cement.

The long ribs and sheeting between the ribs of intramedullary plug **80** assure that the end of the plug bone cement shield **82** has an annular area of pressure contact **136** with the canal wall sufficiently long to assure enough friction that the *axial* force exerted on the plug by the pressurized bone cement is incapable of dislodging the plug distally, independent of the pressure of the liquid bone cement. The pressurized liquid cement maintains the plug in place to seal the distal end of the canal.

The axial length of the engagement between the bone cement shield **28** of device **10** is considerably shorter than that of the intramedullary plug **80** so that, applying the formulas above, the axial force exerted on the shield **28** and the bone cement reservoir exceeds the frictional force restraining movement of the field in the canal so that the pressurized cement will force the shield, device and dispenser **24** axially proximally of the canal as pressurized liquid bone cement is flowed into the space **132** between the shields.

During the filling of the canal the surgeon actuates the dispenser **24** to maintain the pressure of the bone cement. Higher pressure may be achieved by actuating the device and manually resisting expulsion of device **10** from the canal. Movement of the bone cement shield **28** along the canal surface **126** as the canal is filled with pressurized bone cement cleans and scrapes the canal surface so that the liquid cement on the high pressure side of the shield flows into the interstatices of the clean surface, as explained more fully in U.S. Pat. No. 4,466,435. After the canal is filled with cement and device **10** has been expelled a prothesis stem is implanted in the canal in a conventional manner.

An intramedullary plug **80** may be positioned in the end of a conventional bone cement nozzle without a bone cement shield using a plug holder **88**. The empty end of the conventional nozzle is pushed into the holder to collapse the plug and seat it within the nozzle tip. After the nozzle is extended into the canal to position the plug at the distal end, cement is flowed through the nozzle to force the plug out into the canal, where it expands and seals the end as described.

Alternatively, an expanded plug **80** may be pushed through the canal to the distal end using an elongate insertion rod, the lead end of which is seated in recess **140** formed in the pressure side of the shield base **84**. See FIG. **12**. Presurized bone cement subsequently flowed into the canal assures that the plug immovably seals the distal end of the canal.

An additional advantage of this plug is that at time of prothesis insertion into the canal the plug can be pushed further distally by the prothesis tip if it was inadvertantly placed at too shallow a depth in the femoral canal. In contrast, other commonly used plugs cannot be moved more distally without the strong possibility of dislodging them so that they no longer are anchored in the canal or without having to exert excessive and dangerous pressure to move them, or both of these problems.

While I have illustrated and described a preferrred embodiment of my invention, it is understood that this is capable of modification, and I therefore do not wish to be limited to the precise details set forth, but desire to avail myself of such changes and alterations as fall within the purview of the following claims.

What I claim my invention is:

1. An intramedullary canal plug including a base imperforate to bone cement and an umbrella-type cement shield extending from the base, the shield comprising a plurality of ribs joined at one end to the base, circumferentially spaced around the base and extending outwardly of the base to a shield lip and a plurality of flexible sheeting portions each extending between adjacent ribs from the base to the shield lip, each sheeting portion including a first relatively more flexible part near one adjacent rib and a second relatively less flexible part near the other adjacent rib whereby upon collapse of the shield the first sheeting parts fold inwardly before the second sheeting parts fold inwardly.

2. A plug as in claim 1 wherein all said first parts are on the same circumferential side of the sheeting portions so that such portions collapse in a like manner.

3. A plug as in claim 2 wherein the thickness of the first sheeting part is less than the thickness of the second flexible sheeting part.

4. A plug as in claim 3 wherein each flexible sheeting portion is generally triangular in shape with long sides joining the adjacent ribs and a short side forming a portion of the shield lip when the shield is expanded and the parts are generally triangular in shape, join each other at a boundary approximately midway between the adjacent ribs and extend from the distal end of the nozzle to the shield lip.

5. A plug as in claim 4 wherein each rib includes a first side on the interior of the shield lying approximately in a radial plane and facing in a first circumferential direction and a second side on the interior of the shield extending toward the first side at an acute angle and facing in the opposite circumferential direction whereby upon collapse of the shield with the ribs extending in a parallel direction from the base the sides of adjacent ribs parallel each other and define like non-radial sheeting confining slots, said sheeting being folded in pleats in said slots.

6. A plug as in claim 5 wherein said ribs are generally triangular in cross section and the sides extend toward each other at angles of about 45 degrees.

7. An intramedullary canal plug including a base imperforate to bone cement and an umbrella-type cement shield extending from the base, the shield comprising a plurality of ribs joined at one end to the base, circumferentially spaced around the base, and extending outwardly of the base to a shield lip and flexible sheeting portions extending between adjacent ribs, each rib including a first side on the interior of the shield lying approximately in a radial plane and facing in a first circumferential direction and a second side on the interior of the shield extending toward the first side at an acute angle and facing in the opposite circumferential direction whereby upon collapse of the shield with the ribs parallel and extending from the base the sides of adjacent ribs parallel each other and define like non-radial sheeting confining slots, said sheeting being folded in pleats within said slots.

8. A plug as in claim 8 wherein the interior sides of said ribs extend toward each other at angles of about 45 degrees.

9. A device for plugging and flowing bone cement into a long bone medullary canal including a tubular nozzle, an umbrella-type bone cement shield at the distal end of the nozzle, means at the proximal end of the nozzle for attaching the device to a source of bone cement so that cement may be flowed from the source through the device and into the canal, a collar surrounding the nozzle and having a distal end located a distance beyond the distal end of the nozzle shield to define an interior space at the end of the collar, the nozzle shield being collapsed and confined within the collar proximally of said space, and an intramedullary canal plug including a base and an umbrella-type bone cement shield extending away from the base, said plug being fitted within the space at the distal end of the collar with the collapsed nozzle and plug shields adjacent each other whereby upon positioning the nozzle within a prepared medullary canal and moving the collar proximally relative to the nozzle both shields are released substantially simultaneously within the canal.

10. The device of claim 9 wherein the plug base is located outwardly of the distal end of the collar.

11. A holder for an intramedullary canal plug of the type having a base, an expandable umbrella-type cement shield and a shield lip, the holder comprising a holder base with first means for holding the plug base; a collapser member normally spaced from the first means and including (a) a relatively large shield-holding recess facing the first means, (b) a shield collapsing recess having a large area end adjacent the shield-holding recess and a reduced area end remote from the shield-holding recess, (c) an end recess larger than the reduced area end of the shield collapsing recess, and d) a step joining the end recess and the reduced area end of the shield-collapsing recess; and second means supporting the collapser member spaced from the holder base and permitting movement of the collapser member toward the holder base whereby an expanded intramedullary canal plug positioned within the holder with the plug base in said first means and the lip of the expanded shield in the shield-holding recess may be collapsed and loaded in the end of a collar by seating the collar within the end recess and moving the collar toward the holder base to force the collapser member toward the holder base as the shield is collapsed by the shield collapsing recess and loaded into the end of the collar.

12. A holder as in claim 11 wherein said second means includes a sliding connection joining the base and collapser member; and a spring biasing the base and collapser member apart.

13. A holder as in claim 12 wherein said recesses are symmetrical about a central axis.

14. The method of filling the medullary canal of a live bone with bone cement comprising the steps of:

a. Freely introducing an intramedullary canal bone plug with a collapsed bone cement shield into the distal end of the canal;

b. Freely introducing a bone cement delivery device with a collapsed bone cement shield into the canal with the delivery device shield position adjacent the plug shield;

c. Substantially simultaneously expanding both shields within the canal so that the plug shield contacts the canal wall at the distal end of the canal and closes the canal and the delivery device shield contacts the canal wall proximally of the plug shield to define a space within the canal between the expanded shields;

d. Flowing pressurized bone cement distally through the bone cement delivery device shield and into the space between the shields so that the cement biases the shields into pressure contact with the canal wall;

e. Maintaining the plug in place at the distal end of the canal during flowing of pressurized liquid cement into the space;

f. Moving the delivery device shield proximally along the canal as cement is flowed into the space while biasing the shield against the canal wall to prepare the wall to receive bone cement; and

g. Flowing pressurized bone cement in the space into the interstices of the prepared wall.

15. The method of claim 14 wherein the introducing steps comprise simultaneously moving the intramedullary bone canal bone plug with collapsed shield and the bone cement delivery device with collapsed shield into the canal.

16. The method of claim 15 including the steps of:

h. Maintaining the following relation at the plug shield:

$$D_e/L_a \leqq 4 \text{ (mu)},$$

where D_c is the diameter of the canal at the plug shield, L_a is the axial length of the circumferential pressure contact between the plug shield and the wall of the canal and (mu) is the coefficient of friction between the shield and the wall of the medullary canal; and

i. Maintaining the following relation at the nozzle shield:

$$D_c/L_a > 4 \text{ (mu)},$$

where D_c is the diameter of the canal at the nozzle shield, L_a is the axial length of the circumferential pressure contact between the nozzle shield and the wall of the canal and (mu) is the coefficient of friction between the nozzle shield and the canal wall.

17. The method of claim 15 including the step of maintaining the axial length of circumferential pressure contact between the plug shield and the wall of the canal greater than the axial length of the circumferential

pressure contact between the nozzle shield and the wall of the canal.

18. An intramedullary canal plug having an imperforate central base, and an umbrella-type shield, the shield having a lip away from the base, a number of ribs extending from the base to the lip and flexible sheeting extending between adjacent ribs, the portion of the shield adjacent the lip having a generally cylindrical shape with a diameter Dc and an axial length of La, and

$$Dc/La \leqq 4(mu)$$

where (mu) is the coefficient friction between the shield and the interior wall of a prepared medullary canal so that upon positioning of the shield within such a canal and placing a body of pressurized liquid bone cement in the shield the cement biases the cylindrical portion of the shield against the canal wall and the plug is stable in the canal.

* * * * *

8

REDACTED DOCUMENT

9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE
---o0o---

KYPHON, INC.,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No.
	)	04-0204-JJF
DISC-O-TECH MEDICAL TECHNOLOGIES, LTD., and DISC ORTHOPAEDIC TECHNOLOGIES, INC.,	)	
	)	
Defendant.	)	
	)	

---o0o---

WEDNESDAY, NOVEMBER 3, 2004

VIDEOTAPE DEPOSITION OF MARK REILEY, M.D.
---o0o---

REPORTED BY: BALINDA DUNLAP, CSR 10710, RPR, CRR, RMR

BARKLEY COURT REPORTERS (415) 433-5777

Q. Okay. Other than -- when I refer to the patents in suit, I'm referring to the four -- well, actually, the six patents that Kyphon has asserted against Disc-O-Tech. Are you familiar with those six patents?

A. No.

Q. Okay. Of the -- and I'm sorry. Forgive me if I misheard you. Of the 50 or so patents that you are an inventor on, how many of them involve the use of an inflatable balloon to reduce a fracture?

A. I don't know.

Q. Okay. More than two?

A. Oh, I would say so.

Q. Okay. Let's mark this as Exhibit 2. Just for explanatory sake, Karen, the court reporter didn't have deposition exhibits. So she just asked me to mark that. So that's why. Forgive the numbering system here.

(Reporter marked Exhibit No. 2 for identification.)

Q. BY MR. NAMROW: Dr. Reiley, what we have had here marked as Exhibit 2 is the 404 patent I referred to. Just for clarity sake, it is U.S. patent No. 5,108,404. Just take a minute to look through it briefly. I am not asking you to reread through the entire patent.

Dr. Reiley, while you're looking through it, I'll just ask you, I just want to get a sense of what you consider

to be the invention that's described in the 404 patent?

MS. BOYD: I'll object to that to the extent it calls for a legal conclusion.

THE WITNESS: Would you repeat the question?

Q. BY MR. NAMROW: Sure. I would like to know what you consider to be the invention described in the 404 patent?

A. My understanding is that an invention is essentially what's in the claims.

Q. Okay. But you're an inventor. I am not asking for a legal conclusion. As the inventor of what became the 404 patent, I would just like to know what you consider the invention to be?

A. The invention is a means of percutaneously accessing -- check that. Entering a vertebral body or any cancellous bone that's deformed and crushing the inside bone and elevating the lids or the joint surface of whatever bone you're working with and making the cavity and deflating the balloon, pulling it out and filling it with cement.

Q. Just want to -- that's fine. When you said it is entering a vertebral body that's deformed and crushing the inside of the bone, I assume -- and then deflating the balloon, I assume that the means for doing that is by blowing up a balloon?

A. Yes.

Q. And that's what's described in the patent?

MS. BOYD: This is fine.

(Reporter marked Exhibit No. 3 for identification.)

Q. BY MR. NAMROW: Okay. Dr. Reiley, I am showing you what's been marked -- sorry. You are still looking at the patent?

A. Yes, I believe a more complete description, if you are going to use the body to describe the invention, is found in column seven.

Q. Show me where in column seven you are referring to? You see the numbers down the middle of the page? Those are line numbers. If you can direct me approximately to the line number.

A. The second and third paragraph, yeah.

Q. It starts, "The progress of the balloon"?

A. Yes.

Q. Okay. I understand. And I understand -- I didn't mean to miss out on any of the steps described in the patent. What I was just getting at, simply, was that what's used and what's at base in the invention to do all these processes is a balloon, is an inflatable device; is that accurate?

MS. BOYD: Objection. Calls for a legal conclusion, and the document speaks for itself.

THE WITNESS: I'd have to say the document speaks for itself. Because we spent a long time with the wording to

10



Attorney Docket No. 14824-4

PATENT APPLICATION

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

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Attorney Docket: 14824-4

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

This invention relates to improvements in the surgical treatment of bone conditions of the human and other animal bone systems and, more particularly, to an inflatable balloon-like device for use in treating such bone conditions. Osteoporosis, avascular necrosis and bone cancer are diseases of bone that predispose the bone to fracture or collapse. There are 2 million fractures each year in the United States, of which about 1.3 million are caused by osteoporosis. Avascular necrosis and bone cancers are more rare but can cause bone problems that are currently poorly addressed.

BACKGROUND OF THE INVENTION

In U.S. Patents 4,969,888 and 5,108,404, an apparatus and method are disclosed for the fixation of fractures or other conditions of human and other animal bone systems, both osteoporotic and non-osteoporotic. The apparatus and method are especially suitable for use in the fixation of, but not limited to, vertebral body compression fractures, Colles fractures and fractures of the proximal humerus.

The method disclosed in these two patents includes a series of steps which a surgeon or health care provider can perform to form a cavity in pathological bone (including but not limited to osteoporotic bone, osteoporotic fractured metaphyseal and epiphyseal bone, osteoporotic vertebral bodies, fractured osteoporotic vertebral bodies, fractures of vertebral bodies due to tumors especially round cell tumors, avascular necrosis

of the epiphyses of long bones, especially avascular necrosis of the proximal femur, distal femur and proximal humerus and defects arising from endocrine conditions).

The method further includes an incision in the skin (usually one incision, but a second small incision may also be required if a suction egress is used) followed by the placement of a guide pin which is passed through the soft tissue down to and into the bone.

The method further includes drilling the bone to be treated to form a cavity or passage in the bone, following which an inflatable balloon-like device is inserted into the cavity or passage and inflated. The inflation of the inflatable device causes a compacting of the cancellous bone and bone marrow against the inner surface of the cortical wall of the bone to further enlarge the cavity or passage. The inflatable device is then deflated and then is completely removed from the bone. A smaller inflatable device (a starter balloon) can be used initially, if needed, to initiate the compacting of the bone marrow and to commence the formation of the cavity or passage in the cancellous bone and marrow. After this has occurred, a larger, inflatable device is inserted into the cavity or passage to further compact the bone marrow in all directions.

A flowable biocompatible filling material, such as methylmethacrylate cement or a synthetic bone substitute, is then directed into the cavity or passage and allowed to set to a hardened condition to provide structural support for the bone. Following this latter step, the insertion instruments are removed from the body and the incision in the skin is covered with a bandage.

While the apparatus and method of the above patents provide an adequate protocol for the fixation of bone, it has been found that the compacting of the bone marrow and/or the trabecular bone and/or cancellous bone

against the inner surface of the cortical wall of the bone to be treated can be significantly improved with the use of inflatable devices that incorporate additional engineering features not heretofore described and not properly controlled with prior inflatable devices in such patents. A need has therefore arisen for improvements in the shape, construction and size of inflatable devices for use with the foregoing apparatus and method, and the present invention satisfies such need.

Prior Techniques for the Manufacture of Balloons for In-Patient Use

A review of the prior art relating to the manufacture of balloons shows that a fair amount of background information has been amassed in the formation of guiding catheters which are introduced into cardiovascular systems of patients through the brachial or femoral arteries. However, there is a scarcity of disclosures relating to inflatable devices used in bone, and none for compacting bone marrow in vertebral bodies and long bones.

In a dilatation catheter, the catheter is advanced into a patient until a balloon is properly positioned across a lesion to be treated. The balloon is inflated with a radiopaque liquid at pressures above four atmospheres to compress the plaque of the lesion to thereby dilate the lumen of the artery. The balloon can then be deflated, then removed from the artery so that the blood flow can be restored through the dilated artery.

A discussion of such catheter usage technique is found and clearly disclosed in U.S. Patent 5,163,989. Other details of angioplasty catheter procedures, and details of balloons used in such procedures can be found in U.S. Patents 4,323,071, 4,332,254, 4,439,185,

4,168,224, 4,516,672, 4,538,622, 4,554,929, and 4,616,652.

Extrusions have also been made to form prism shaped balloons using molds which require very accurate machining of the interior surface thereof to form acceptable balloons for angioplastic catheters. However, this technique of extrusion forms parting lines in the balloon product which parting lines are limiting in the sense of providing a weak wall for the balloon itself.

Patent 5,163,989 discloses a mold and technique for molding dilatation catheters in which the balloon of the catheter is free of parting lines. The technique involves inflating a plastic member of tubular shape so as to press it against the inner molding surface which is heated. Inflatable devices are molded into the desired size and shape, then cooled and deflated to remove it from the mold. The patent states that, while the balloon of the present invention is especially suitable for forming prism-like balloons, it can also be used for forming balloons of a wide variety of sizes and shapes.

A particular improvement in the catheter art with respect to this patent, namely U.S. Patent 4,706,670, is the use of a coaxial catheter with inner and outer tubing formed and reinforced by continuous helical filaments. Such filaments cross each other causing the shaft of the balloon to become shorter in length while the moving portion of the shank becomes longer in length. By suitably balancing the lengths and the angle of the weave of the balloon and moving portions of the filaments, changes in length can be made to offset each other. Thus, the position of the inner and outer tubing can be adjusted as needed to keep the balloon in a desired position in the blood vessel.

Other disclosures relating to the insertion of inflatable devices for treating the skeleton of patients include the following:

U.S. Patent 4,313,434 relates to the fixation of a long bone by inserting a deflated flexible bladder into a medullary cavity, inflating the balloon bladder, sealing the interior of the long bone until healing has occurred, then removing the bladder and filling the opening through which the bladder emerges from the long bone.

U.S. Patent 5,102,413 discloses the way in which an inflatable bladder is used to anchor a metal rod for the fixation of a fractured long bone.

Other references which disclose the use of balloons and cement for anchoring of a prosthesis include U.S. Patents 5,147,366, 4,892,550, 4,697,584, 4,562,598, and 4,399,814.

A Dutch patent, NL 901858, discloses a means for fracture repair with a cement-impregnated bag which is inflated into a preformed cavity and allowed to harden.

It can be concluded from the foregoing review of the prior art that there is little or no substantive information on inflatable devices used to create cavities in bone. It does not teach the shape of the balloon which creates a cavity that best supports the bone when appropriately filled. It does not teach how to prevent balloons from being spherical when inflated, when this is desired. Current medical balloons can compress bone but are too small and generally have the wrong configuration and are generally not strong enough to accomplish adequate cavity formation in either the vertebral bodies or long bones of the body.

U.S. Patents 4,969,888 and 5,108,404 disclose a checker-shaped balloon for compressing cancellous bone,

but does not provide information on how this balloon remains in its shape when inflated.

Thus, the need continues for an improved inflatable device for use with pathological bones and the treatment thereof.

SUMMARY OF THE INVENTION

The present invention is directed to a balloon-like inflatable device or balloon for use in carrying out the apparatus and method of the above-mentioned patents 4,969,888 and 5,108,404. Such inflatable devices, hereinafter sometimes referred to as balloons, have shapes for 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.

In particular, the present invention is directed to a balloon for use in treating a bone predisposed to fracture or to collapse. The balloon comprises an inflatable, non-expandable balloon body for insertion into said bone. The body has a predetermined shape and size when substantially inflated sufficient to compress at least a portion of the inner cancellous bone to create a cavity in the cancellous bone and to restore the original position of the outer cortical bone, if fractured or collapsed. The balloon body is restrained to create said predetermined shape and size so that the fully inflated balloon body is prevented from applying substantial pressure to the inner surface of the outer cortical bone if said bone is unfractured or uncollapsed.

In addition to the shape of the inflatable device itself, another aspect of importance is the construction of the wall or walls of the balloon such that proper inflation the balloon body is achieved to provide for optimum compression of all the bone marrow.

The material of the balloon is also desirably chosen so as to be able to fold the balloon so that it can be inserted quickly and easily into a bone using a guide pin and a cannula, yet can also withstand high pressures when inflated. The balloon can also include optional ridges or indentations which are left in the cavity after the balloon has been removed, to enhance the stability of the filler. Also, the inflatable device can be made to have an optional, built-in suction catheter. This is used to remove any fat or fluid extruded from the bone during balloon inflation in the bone. Also, the balloon body can be protected from puncture by the cortical bone or canula by being covered while inside the canula with an optional protective sleeve of suitable material, such as Kevlar or PET or other polymer or substance that can protect the balloon. The main purpose of the inflatable device, therefore, is the forming or enlarging of a cavity or passage in a bone, especially in, but not limited to, vertebral bodies.

The primary object of the present invention is to provide an improved balloon-like inflatable device for use in carrying out a surgical protocol of cavity formation in bones to enhance the efficiency of the protocol, to minimize the time prior to performing the surgery for which the protocol is designed and to improve the clinical outcome. These balloons approximate the inner shape of the bone they are inside of in order to maximally compress cancellous bone. They have additional design elements to achieve specific clinical goals. Preferably, they are made of inelastic material and kept in their defined configurations when inflated, by various restraints, including (but not limited to) use of inelastic materials in the balloon body, seams in the balloon body created by bonding or fusing separate pieces of material together, or by fusing or bonding together

opposing sides of the balloon body, woven material bonded inside or outside the balloon body, strings or bands placed at selected points in the balloon body, and stacking balloons of similar or different sizes or shapes on top of each other by gluing or by heat fusing them together. Optional ridges or indentations created by the foregoing structures, or added on by bonding additional material, increases stability of the filler. Optional suction devices, preferably placed so that if at least one hole is in the lowest point of the cavity being formed, will allow the cavity to be cleaned before filling.

Among the various embodiments of the present invention are the following:

1. A doughnut (or torus) shaped balloon with an optional built-in suction catheter to remove fat and other products extruded during balloon expansion.

2. A balloon with a spherical outer shape surrounded by a ring-shaped balloon segment for body cavity formation.

3. A balloon which is kidney bean shaped in configuration. Such a balloon can be constructed in a single layer, or several layers stacked on top of each other.

4. A spherically shaped balloon approximating the size of the head of the femur (i.e. the proximal femoral epiphysis). Such a balloon can also be a hemisphere.

5. A balloon in the shape of a humpbacked banana or a modified pyramid shape approximating the configuration of the distal end of the radius (i.e. the distal radial epiphysis and metaphysis).

6. A balloon in the shape of a cylindrical ellipse to approximate the configuration of either the

medial half or the lateral half of the proximal tibial epiphysis. Such a balloon can also be constructed to approximate the configuration of both halves of the proximal tibial epiphysis.

7. A balloon in the shape of sphere on a base to approximate the shape of the proximal humeral epiphysis and metaphysis with a plug to compress cancellous bone into the diaphysis, sealing it off.

8. A balloon device with optional suction device.

9. Protective sheaths to act as puncture guard members optionally covering each balloon inside its catheter.

The present invention, therefore, provides improved, inflatable devices for creating or enlarging a cavity or passage in a bone wherein the devices are inserted into the bone. The configuration of each device is defined by the surrounding cortical bone and adjacent internal structures, and is designed to occupy about 70-90% of the volume of the inside of the bone, although balloons that are as small as about 40% and as large as about 99% are workable for fractures. In certain cases, usually avascular necrosis, the balloon size may be as small as 10% of the cancellous bone volume of the area of bone being treated, due to the localized nature of the fracture or collapse. The fully expanded size and shape of the balloon is limited by additional material in selected portions of the balloon body whose extra thickness creates a restraint as well as by either internal or external restraints formed in the device including, but not limited to, mesh work, a winding or spooling of material laminated to portions of the balloon body, continuous or non-continuous strings across the inside held in place at specific locations by glue inside or by threading them through to the outside and seams in

the balloon body created by bonding two pieces of body together or by bonding opposing sides of a body through glue or heat. Spherical portions of balloons may be restrained by using inelastic materials in the construction of the balloon body, or may be additionally restrained as just described. The material of the balloon is preferably a non-elastic material, such as polyethylene tetraphthalate (PET), Kevlar or other patented medical balloon materials. It can also be made of semi-elastic materials, such as silicone or elastic material such as latex, if appropriate restraints are incorporated. The restraints can be made of a flexible, inelastic high tensile strength material including, but not limited, to those described in U.S. Patent 4,706,670. The thickness of the balloon wall is typically in the range of 2/1000ths to 25/1000ths of an inch, or other thicknesses that can withstand pressures of up to 250-400 psi.

A primary goal of percutaneous vertebral body augmentation of the present invention is to provide a balloon which can create a cavity inside the vertebral body whose configuration is optimal for supporting the bone. Another important goal is to move the top of the vertebral body back into place to retain height where possible, however, both of these objectives must be achieved without fracturing the cortical wall of the vertebral body. This feature could push vertebral bone toward the spinal cord, a condition which is not to be desired.

The present invention satisfies these goals through the design of inflatable devices to be described. Inflating such a device compresses the calcium-containing soft cancellous bone into a thin shell that lines the inside of the hard cortical bone creating a large cavity.

At the same time, the biological components (red blood cells, bone progenitor cells) within the soft bone are pressed out and removed by rinsing during the procedure. The body recreates the shape of the inside of an unfractured vertebral body, but optimally stops at approximately 70 to 90% of the inner volume. The balloons of the present invention are inelastic, so maximally inflating them can only recreate the predetermined shape and size. However, conventional balloons become spherical when inflated. Spherical shapes will not allow the hardened bone cement to support the spine adequately, because they make single points of contact on each vertebral body surface (the equivalent of a circle inside a square, or a sphere inside a cylinder). The balloons of the present invention recreate the flat surfaces of the vertebral body by including restraints that keep the balloon in the desired shape. This maximizes the contacts between the vertebral body surfaces and the bone cement, which strengthens the spine. In addition, the volume of bone cement that fills these cavities creates a thick mantle of cement (4 mm or greater), which is required for appropriate compressive strength. Another useful feature, although not required, are ridges in the balloons which leave their imprint in the lining of compressed cancellous bone. The resulting bone cement "fingers" provide enhanced stability.

The balloons which optimally compress cancellous bone in vertebral bodies are the balloons listed as balloon types 1, 2 and 3 above. These balloons are configured to approximate the shape of the vertebral body. Since the balloon is chosen to occupy 70 to 90% of the inner volume, it will not exert undue pressure on the sides of the vertebral body, thus the vertebral body will not expand beyond its normal size (fractured or unfractured). However, since the balloon has the height

of an unfractured vertebral body, it can move the top, which has collapsed, back to its original position.

A primary goal of percutaneous proximal humeral augmentation is to create a cavity inside the proximal humerus whose configuration is optimal for supporting the proximal humerus. Another important goal is to help realign the humeral head with the shaft of the humerus when they are separated by a fracture. Both of these goals must be achieved by exerting pressure primarily on the cancellous bone, and not the cortical bone. Undue pressure against the cortical bone could conceivably cause a worsening of a shoulder fracture by causing cortical bone fractures.

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 epiphysis and metaphysis of the proximal humerus thereby creating a cavity. In some cases, depending on the fracture location, the balloon or inflatable device may be used to extend the cavity into the proximal part of the humeral diaphysis.

Due to the design of the "sphere on a stand" balloon (described as number 7 above), the cavity made by this balloon recreates or approximates the shape of the inside cortical wall of the proximal humerus. The approximate volume of the cavity made by the "spherical on a stand balloon" is 70 to 90% that of the proximal humeral epiphysis and metaphysis, primarily, but not necessarily exclusive of, part of the diaphysis. The shape approximates the shape of the humeral head. The "base" is designed to compress the trabecular bone into a "plug" of bone in the distal metaphysis or proximal diaphysis. This plug of bone will prevent the flow of injectable material into the shaft of the humerus,