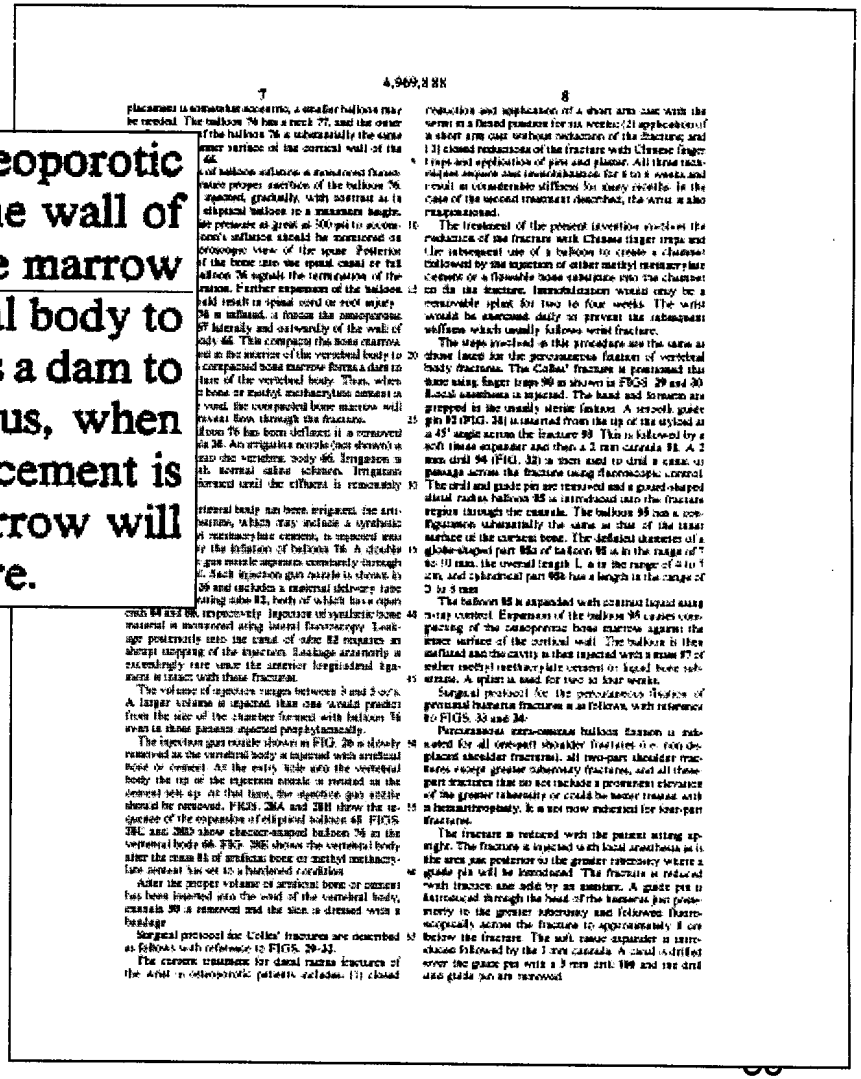
The Claims of the '404 and '888 Patents Require a Balloon

Specification:

As balloon **76** is inflated, it forces the osteoporotic bone marrow **67** laterally and outwardly of the wall of the vertebral body **66**. This compacts the bone marrow and leaves a void in the interior of the vertebral body to be treated. The compacted bone marrow forms a dam to block any fracture of the vertebral body. Thus, when liquid synthetic bone or methyl methacrylate cement is forced into the void, the compacted bone marrow will substantially prevent flow through the fracture.



placement is somewhat eccentric, a smaller balloon may be needed. The balloon 76 has a neck 77, and the outer ... of the balloon 76 is substantially the same ... inner surface of the cortical wall of the ... 66.

... of balloon inflation a transducer (transducer proper insertion of the balloon 76 ... inserted, gradually, with contrast as it ... elliptical balloon to a maximum height ... pressure as great as 300 psi to accommodate inflation should be monitored on ... fluoroscopic view of the spine. Posterior ... of the bone into the spinal canal or the balloon 76 signals the termination of the ... motion. Further expansion of the balloon ... could result in spinal cord or root injury.

... 76 is inflated, it forces the osteoporotic ... 67 laterally and outwardly of the wall of ... body 66. This compacts the bone marrow ... at the interior of the vertebral body to ... compacted bone marrow forms a dam to ... flow of the vertebral body. Then, when ... bone or methyl methacrylate cement is ... void, the compacted bone marrow will ... prevent flow through the fracture.

... balloon 76 has been deflated it is removed ... 36. An irrigation nozzle (not shown) is ... into the vertebral body 66. Irrigation is ... with normal saline solution. Irrigation ... continued until the effluent is reasonably ... clear.

... cortical bone has been irrigated, the anti-... substance, which may include a synthetic ... methacrylate cement, is injected into ... by the inflation of balloon 76. A double-... gun nozzle apparatus constantly through ... Such injection gun nozzle is shown in ... 39 and includes a material delivery tube ... mixing tube 82, both of which have open ... ends 84 and 86, respectively. Injection of synthetic bone material is monitored using lateral fluoroscopy. Leakage posteriorly into the canal of tube 82 requires an abrupt stopping of the injection. Leakage anteriorly is exceedingly rare since the anterior longitudinal ligaments is intact with these fractures.

The volume of injection ranges between 3 and 5 cc's. A larger volume is injected than one would predict from the size of the chamber formed with balloon 76 even in these patients injected prophylactically.

The injection gun nozzle shown in FIG. 26 is slowly removed as the vertebral body is injected with artificial bone or cement. As the early tide into the vertebral body the tip of the injection nozzle is rotated as the desired jets up. At that time, the injection gun nozzle should be removed. FIGS. 28A and 28B show the appearance of the expansion of elliptical balloon 68. FIGS. 28C and 28D show cheese-shaped balloon 76 in the vertebral body 66. FIG. 29E shows the vertebral body after the mass 88 of artificial bone or methyl methacrylate cement has set to a hardened condition.

After the proper volume of artificial bone or cement has been inserted into the void of the vertebral body, cannula 90 is removed and the skin is dressed with a bandage.

Surgical protocol for Colles' fractures are described as follows with reference to FIGS. 29-33.

The current treatment for distal radius fractures of the wrist in osteoporotic patients includes: (1) closed reduction and application of a short arm cast with the wrist in a flexed position for six weeks; (2) application of a short arm cast without reduction of the fracturing and (3) closed reduction of the fracture with Chinese finger traps and application of pins and plaster. All three techniques require long immobilization for 6 to 8 weeks and result in considerable stiffness for many months. In the case of the second treatment described, the wrist is also malpositioned.

The treatment of the present invention involves the reduction of the fracture with Chinese finger traps and the subsequent use of a balloon to create a channel followed by the injection of either methyl methacrylate cement or a flowable bone substitute into the channel to fix the fracture. Immobilization would only be a removable splint for two to four weeks. The wrist would be exercised daily to prevent the subsequent stiffness which usually follows wrist fracture.

The steps involved in this procedure are the same as those used for the percutaneous fixation of vertebral body fractures. The Colles' fracture is positioned that same using finger traps 90 as shown in FIGS. 29 and 30. Local anesthesia is injected. The hand and forearm are grasped in the usually sterile fashion. A smooth guide pin 92 (FIG. 31) is inserted from the tip of the styloid at a 45° angle across the fracture 93. This is followed by a soft tissue expander and then a 2 mm cannula 94. A 2 mm drill 96 (FIG. 32) is then used to drill a canal or passage across the fracture using fluoroscopic control. The drill and guide pin are removed and a guard-shaped distal radius balloon 98 is introduced into the fracture region through the cannula. The balloon 98 has a configuration substantially the same as that of the distal surface of the corrected bone. The deflated diameter of a globe-shaped part 98a of balloon 98 is in the range of 7 to 10 mm, the overall length L is in the range of 3 to 5 cm, and cylindrical part 98b has a length in the range of 2 to 3 mm.

The balloon 98 is expanded with contrast liquid using ... control. Expansion of the balloon 98 causes compacting of the cancellous bone marrow against the inner surface of the cortical wall. The balloon is then inflated and the cavity is then injected with a mass 97 of ... methyl methacrylate cement or liquid bone substitute. A splint is used for two to four weeks.

Surgical protocol for the percutaneous fixation of ... fractures is as follows, with reference to FIGS. 33 and 34:

Percutaneous extra-osseous balloon fixation is indicated for all one-part shoulder fractures (i.e. non-displaced shoulder fractures), all two-part shoulder fractures except greater tuberosity fractures, and all three-part fractures that do not include a prominent elevation of the greater tuberosity or could be better treated with a hemiarthroplasty. It is not now indicated for four-part fractures.

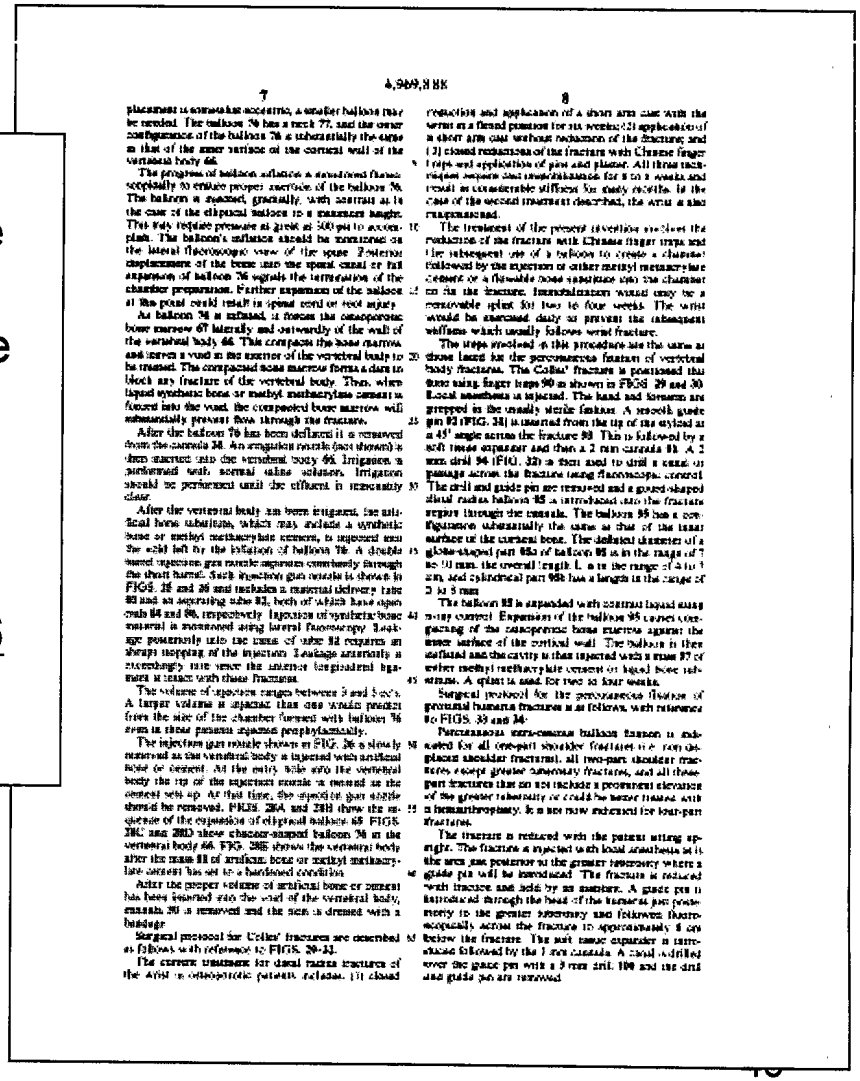
The fracture is reduced with the patient sitting upright. The fracture is injected with local anesthesia in the area just posterior to the greater tuberosity where a guide pin will be introduced. The fracture is reduced with traction and aided by an assistant. A guide pin is introduced through the head of the humerus just posteriorly to the greater tuberosity and followed fluoroscopically across the fracture to approximately 1 cm below the fracture. The soft tissue expander is introduced followed by the 3 mm cannula. A canal is drilled over the guide pin with a 3 mm drill. The drill and the guide pin are removed.

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The Claims of the '404 and '888 Patents Require a Balloon

Specification:

After the balloon 76 has been deflated it is removed from the cannula 30. . . . After the vertebral body has been irrigated, the artificial bone substitute, which may include a synthetic bone or methyl methacrylate cement, is injected into the void left by the inflation of balloon 76. . . . A larger volume is injected than one would predict from the size of the chamber formed with balloon 76 even in those patients injected prophylactically.



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placement is somewhat eccentric, a smaller balloon may be needed. The balloon 76 has a neck 77, and the outer configurance of the balloon 76 is substantially the same as that of the inner surface of the cortical wall of the vertebral body 66.

The progress of balloon inflation is monitored fluoroscopically to ensure proper insertion of the balloon 76. The balloon is inserted, generally, with contrast as in the case of the elliptical balloon to a maximum height. This may require pressure as great as 300 psi to accomplish. The balloon's inflation should be monitored on the lateral fluoroscopic view of the spine. Posterior displacement of the bone into the spinal canal or full expansion of balloon 76 signals the termination of the chamber preparation. Further expansion of the balloon at this point could result in spinal cord or root injury.

As balloon 76 is inflated, it forces the cancellous bone marrow 67 laterally and outwardly of the wall of the vertebral body 66. This compacts the bone marrow and leaves a void in the interior of the vertebral body to be treated. The compacted bone marrow forms a dam to block any fracture of the vertebral body. Then, when liquid synthetic bone or methyl methacrylate cement is forced into the void, the compacted bone marrow will substantially prevent flow through the fracture.

After the balloon 76 has been deflated it is removed from the cannula 30. An irrigation nozzle (not shown) is then inserted into the vertebral body 66. Irrigation is performed with normal saline solution. Irrigation should be performed until the effluent is reasonably clear.

After the vertebral body has been irrigated, the artificial bone substitute, which may include a synthetic bone or methyl methacrylate cement, is injected into the void left by the inflation of balloon 76. A double barrel injection gun nozzle apparatus constructed through the chest barrel. Such injection gun nozzle is shown in FIGS. 35 and 36 and includes a material delivery tube 93 and an aspirating tube 93, both of which have open ends 94 and 96, respectively. Injection of synthetic bone material is monitored using lateral fluoroscopy. Leakage posteriorly into the canal of tube 92 requires an abrupt stopping of the injection. Leakage anteriorly is exceedingly rare since the anterior longitudinal ligament is intact with these fractures.

The volume of injection ranges between 3 and 6 cc's. A larger volume is injected than one would predict from the size of the chamber formed with balloon 76 even in those patients injected prophylactically.

The injection gun nozzle shown in FIG. 36 is slowly removed as the vertebral body is injected with artificial bone or cement. As the nozzle tube exits the vertebral body the tip of the injection nozzle is encased as the cement sets up. At that time, the injection gun nozzle should be removed. FIGS. 28A and 28B show the sequence of the expansion of elliptical balloon 65. FIGS. 28C and 28D show chamber-shaped balloon 76 in the vertebral body 66. FIG. 28E shows the vertebral body after the mass 88 of urethane, bone or methyl methacrylate cement has set to a hardened condition.

After the proper volume of artificial bone or cement has been injected into the void of the vertebral body, cannula 30 is removed and the area is dressed with a bandage.

Surgical protocol for Colles' fractures are described as follows with reference to FIGS. 29-33.

The current treatment for distal radius fractures of the adult in osteoporotic patients includes: (1) closed reduction and application of a short arm cast with the wrist in a flexed position for six weeks; (2) application of a short arm cast without reduction of the fracture; and (3) closed reduction of the fracture with Chinese finger traps and application of pins and plaster. All three techniques require long convalescence for 6 to 8 weeks and result in considerable stiffness for many months. In the case of the second treatment described, the wrist is also compromised.

The treatment of the present invention includes the reduction of the fracture with Chinese finger traps and the subsequent use of a balloon to create a chamber followed by the injection of either methyl methacrylate cement or a flowable bone substitute into the chamber to fix the fracture. Immobilization would only be a removable splint for two to four weeks. The wrist would be exercised daily to prevent the subsequent stiffness which usually follows wrist fracture.

The steps involved in this procedure are the same as those used for the percutaneous fixation of vertebral body fractures. The Colles' fracture is positioned through finger traps 90 as shown in FIGS. 29 and 30. Local anesthesia is injected. The hand and forearm are grasped in the usually sterile fashion. A smooth guide pin 92 (FIG. 31) is inserted from the tip of the styloid at a 45° angle across the fracture 98. This is followed by a soft tissue expander and then a 2 mm cannula 91. A 2 mm drill 94 (FIG. 32) is then used to drill a canal or passage across the fracture using fluoroscopic control. The drill and guide pin are removed and a gourd-shaped distal radius balloon 95 is introduced into the fracture region through the cannula. The balloon 95 has a configurance substantially the same as that of the inner surface of the cortical bone. The deflated diameter of a globe-shaped part 95a of balloon 95 is in the range of 7 to 10 mm, the overall length L is in the range of 3 to 5 cm, and cylindrical part 95b has a length in the range of 2 to 3 mm.

The balloon 95 is expanded with contrast liquid using x-ray control. Expansion of the balloon 95 causes cortical gaping of the cancellous bone fracture against the inner surface of the cortical wall. The balloon is then deflated and the cavity is then injected with a mass 97 of either methyl methacrylate cement or liquid bone substitute. A splint is used for two to four weeks.

Surgical protocol for the percutaneous fixation of proximal humerus fractures is as follows, with reference to FIGS. 33 and 34:

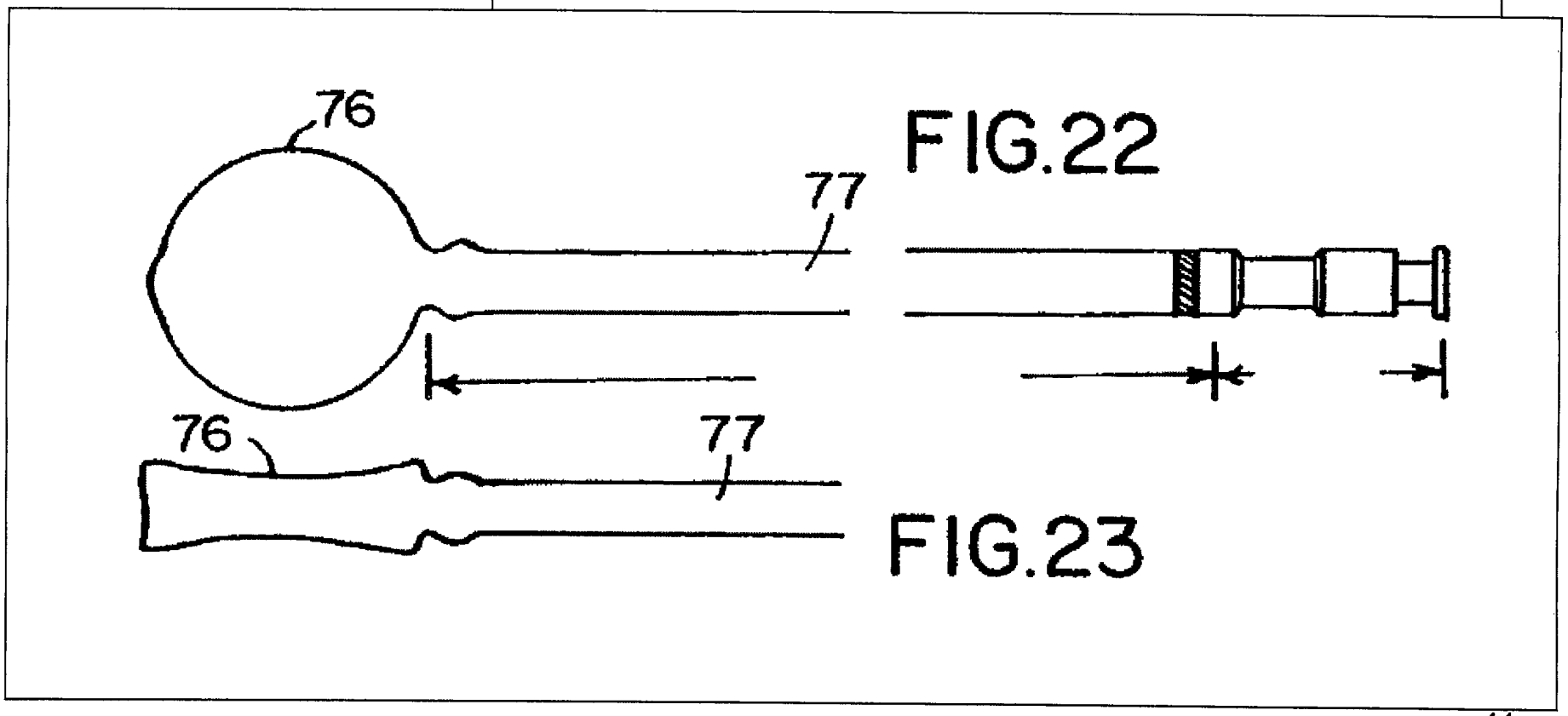
Percutaneous extra-cortical balloon fixation is indicated for all one-part shoulder fractures (i.e. non displaced shoulder fractures), all two-part shoulder fractures except greater tuberosity fractures, and all three-part fractures that do not include a prominent elevation of the greater tuberosity or could be better treated with a hemiarthroplasty. It is also now indicated for four-part fractures.

The fracture is reduced with the patient sitting upright. The fracture is injected with local anesthesia in the area just posterior to the greater tuberosity where a guide pin will be inserted. The fracture is reduced with traction and held by an assistant. A guide pin is introduced through the head of the humerus just posteriorly to the greater tuberosity and followed fluoroscopically across the fracture to approximately 5 cm below the fracture. The soft tissue expander is introduced followed by the 7 mm cannula. A canal is drilled over the guide pin with a 9 mm drill. The drill and guide pin are removed.

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The Claims of the '404 and '888 Patents Require a Balloon

Figures:



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The Claims of the '404 and '888 Patents Require a Balloon

- Only the use of a balloon is described
- The word "balloon" is used 42 times in the Specification
- The words "Inflatable," "Inflation," "Inflated," "Inflating" collectively are used 46 times in each of the patents
- **NO OTHER STRUCTURE, DEVICE OR METHOD IS DISCLOSED OR DESCRIBED**

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The Claims of the '404 and '888 Patents Require a Balloon

Prosecution History:

- Explicit Statements that "compacting" step requires an inflatable device

- Original Application as filed included 16 apparatus claims, all of which explicitly required an inflatable device

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