

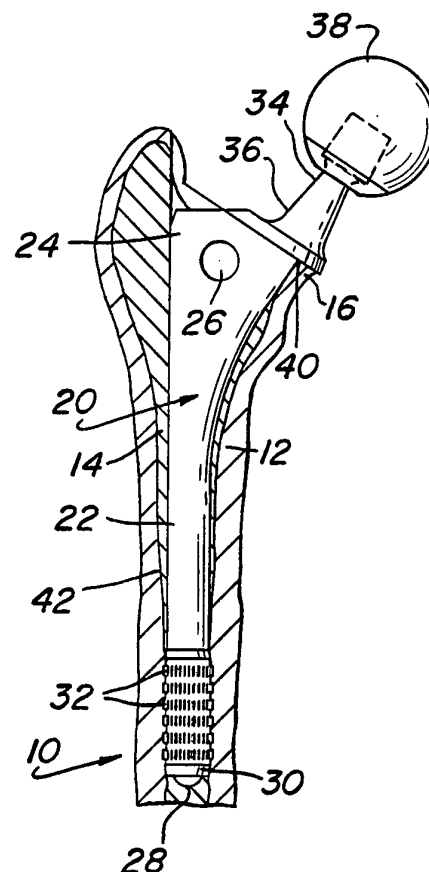


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US93/09323 (22) International Filing Date: 30 September 1993 (30.09.93) (30) Priority data: 07/955,079 1 October 1992 (01.10.92) US (71)(72) Applicant and Inventor: TRONZO, Raymond, G. [US/ US]; 1114 North Olive Avenue, West Palm Beach, FL 33401 (US). (74) Agent: BERNSTEIN, Alan, H.; Caesar, Rivise, Bernstein, Cohen &amp; Pokotilow, Ltd., 12th Floor, Seven Penn Center, 1635 Market Street, Philadelphia, PA 19103-2212 (US).</p>		<p>(81) Designated States: AU, BB, BG, BR, BY, CA, CZ, FI, HU, JP, KP, KR, KZ, LK, MG, MN, MW, NO, NZ, PL, RO, RU, SD, SK, UA, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: BEARING MECHANISM BUILT INTO THE FEMORAL COMPONENT</p>		

## (57) Abstract

A femoral stem prosthesis (20) to be implanted in the proximal end of the femoral canal. The prosthesis (20) comprises an elongated shaft (22) comprising a shank proximal portion (24) having an outer surface comprising an affixation surface adjacent the shank proximal portion (24). The distal portion (28) of the shaft (22) is located longitudinally from the shank proximal portion (24), and is of a diameter to permit it to fit within the femoral canal. A bearing (30) permits the prosthesis (20) to move in response to forces exerted on the prosthesis (20) when it is implanted. In one embodiment, the bearing (30) is located about the distal portion (28) of the elongated shaft (22) and additionally comprises a securing shoulder (44) to secure the bearing (30) within the femoral canal while permitting the distal portion (28) to rotate about the bearing (30). A retaining member retains the bearing at the distal portion of the elongated shaft. In another embodiment (55), the bearing comprises a rod (59) which can rotate within an interior channel (56) in the shaft with the sleeve (30) secured to the distal portion (28) of the rod (59), the bearing (30) being located either at its middle (prosthetic) section or at its upper or proximal portion (24).



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## BEARING MECHANISM BUILT INTO THE FEMORAL COMPONENT

FIELD OF INVENTION

The present invention generally relates to a hip replacement prosthesis and more particularly to improving the function of the femoral component as part of a hip replacement system by creating a bearing mechanism for transferring torque stresses to and/or from bone of which the following is the specification.

BACKGROUND OF INVENTION

A wide variety of hip replacement prosthesis are available which comprise generally of a ball attached to a stem which is secured inside of the femoral canal. The ball articulates with an acetabulum, or as a socket fixed inside of the acetabulum, either of which make up what is know as either a hemiarthroplasty for the former and total hip arthroplasty for the latter design.

From prior art there are generally two methods of fixing the components to bone: 1) Bone cement ("Cemented Prosthesis"), or 2) Bone Ongrowth, porous coated, or bone Ingrowth, relatively smooth sides and fitted into place by friction ("Cementless Prosthesis"). In either case, the components can become loose for reasons known and for reasons unknown. Many improvements have been made to the design of these implants, most of which have been made to the femoral component. In spite of these improvements in either system, the fixation can break down causing pain and destruction of surrounding bone.

There are several known biological and biomechanical stresses, or forces, that play against the femoral component which can possibly cause failure of fixation. One such stress is torque. Appreciating that bone as a dynamic, vitalized organ, its plastic nature allows for a certain amount of twisting between the two ends of the femur from its upper end, through its mid shaft, on to its far end. Such torque is applied to the femur much like the twisting of a wash cloth as one wrings out fluid from its substance.

It is the inventor's belief that torque is a major cause of failure of the femoral component when fixed either by bone cement, or by biological means (Bone Encasement).

Current methods are crafted to more firmly fix the components by improved cement techniques with improved cemented stem designs and by better porous coatings with like improvements in such stem designs. It is believed that the more solid the fixation, the better will be resistance to the destructive forces of torque.

Heretofore, however, to this inventor's knowledge, there has not been an implant system which reduces, or alleviates the torsional stresses between the hip prosthesis and its surrounding bone.

The present invention overcomes torsional stresses by the use of a bearing mechanism built into the femoral component which may extend the life of the arthroplasty and diminish, or eliminate thigh pain. The internal bearing mechanism can take one of three forms described as follows, Design I being the most preferred embodiment:

Femoral Stem Design I (Figs. 1-4)

The overall femoral stem is of a form with a porous coating on its upper surfaces with two exceptions: 1) The upper end is fenestrated as a round window which is porous coated within its interior. The fenestration with its specially coated inner surface is meant to more firmly secure the upper end of the prosthesis as an adjunct to the porous coating of its outer surface; 2) The distal end is shaped as a cylinder over which a bearing of various sizes fits. The cylindrical end is polished to a mirror finish. The bearing has its inner surface like a mirror finish with its outer surface roughened or coated with a porous finish. The net result of this design combination is:

While both ends of the prosthesis is fixed inside of the femoral shaft, the bearing mechanism allows the torque generated to be dissipated, or transferred through the main axis of the prosthesis, thereby preserving its stability in bone.

Femoral Stem Design II (Fig. 5 and 5A)

The basic prosthetic configuration is the same as in Design I with the exception of the location of the bearing mechanism. It is so located that the stem rotates within the longitudinal channel or opening.

Femoral Stem Design III (Fig. 6)

The basic prosthetic configuration is the same as in Design I with the exception of the location of the bearing mechanism. It is located within the upper end of the implant, where an upper portion of the stem rotates within an upper opening in the proximal shank portion.

Fenestration in the Upper End of the Prosthesis

The present invention utilizes an optional fenestration at the upper end of the prosthesis for additional fixation, which is preferred (there may be one or more such openings), however its presence is not essential to the function of the bearing mechanism. The fenestration feature, while uniquely different from previous art in that its inner walls are porous coated in some manner, is an option to the basic bearing design on the implant.

Location of the Bearing

The bearing can be located at various positions within the prosthesis depending on the circumstances of use.

When the femoral component of the present invention is implanted, the distal end of the femoral stem is located within the rotational bearing of the device. The bearing is secured within the femoral canal by a frictional fit which may be further enhanced by the eventual growth of bone about its textured outer surface for its secure position inside the femoral canal. The shaft of the femoral component rotates about the secured bearing in concert with the stresses induced, rather than antagonistic to them and thereby alleviates the torsional stresses placed on the prosthesis.

DISCUSSION OF PRIOR ART

While some prior art hip prosthetic devices have utilized a sleeve or collar in conjunction with the generally elongated femoral shaft component, they generally do so to permit

the proper sizing of a prosthesis to the individual by screwing or swedging the chosen collar length to the end of the device, thus the sleeve becomes a solid part of the prosthesis. None of these prior devices have utilized a device such as a bearing to reduce or eliminate torsional stresses placed on the prosthesis in accordance with the various embodiments of the present invention.

For example, in United States Patent No. 4,770,660, it is disclosed that a device which places an optional collar on a femoral stem which is removable so that the stem can be used with or without a collar as decided by the surgeon during surgery. This collar is also removable at surgery for a more precise fit of the stem at the time of its surgical insertion. The device of this invention fits at the upper end of the femoral stem. It is one attempt to firmly fix the prosthesis to the outer structure of bone.

In United States Patent No. 4,888,023, it is disclosed that the same type of femoral stem as disclosed in the previous patent, attached a "bullet" at the distal tip of the prosthesis for a more precise fit of the prosthesis in the distal, or far end of the femoral canal. The sleeve of that invention comes in various sizes whose final fit is chosen by the treating surgeon. In addition, the outer surface of this bullet is highly polished with a "fixation-resistant finish" to prevent fixation of the bullet by bone, in contrast to the roughened surface of the distal bearing of the present invention. The bullet of the 4,888,023 patent also claims to provide a micro-motion of its smooth outer surface against the bony walls of the femoral canal. The bullet of the 4,888,023 patent is firmly swedged onto the stem of the prosthesis by a solid blow of a mallet as it is held in a specialized instrument, in contrast to the bearing of the present invention which is free to run only the shaft of the femoral component. Another patent related to the two foregoing patents includes United States Patent No. 4,919,679 which discloses a tool for insertion of the prosthesis disclosed in United States Patent No. 4,888,023.

Some or all of these devices disclosed in the three foregoing patents are believed to be sold by the assignee of those inventions; Osteonics Corporation of Allendale, NJ, under trademarks including OMNIFLEX and/or OSTEONIC. For example, one such device is believed to be sold under the trademark OMNIFLEX and is advertised to minimize the potential of postoperative thigh pain and stress abrasion. The prosthesis is advertised to comprise a modular, cylindrical, polished cobalt chromium alloy femoral distal tip available in 1mm. increments from 8mm. to 25mm. The distal tip in this device is claimed to be well fitted inside the femoral canal and is further claimed to enhance both proximal and distal stem stability against torsional and toggling forces.

Other types of size-adjusting distal tips which are presently on the market include those sold by Intermedics Orthopedics, Inc., 1300 East Anderson Lane, Austin, Texas which advertises a distal fitting sleeve having a highly polished exterior and whose length can be chosen for each patient to provide a more congruent fit and which may be sold under the term, APR II HIP SYSTEM. The distal sleeve is claimed to permit the surgeon to have the ability to increase the effective prosthetic stem diameter without going to a larger implant having a comprised bone structure. The sleeves merely function to increase surface area contact of the prosthesis and are solidly fixed to its distal end.

Another type of device which utilizes a distal sleeve is that sold by Howmedica of Rutherford, NJ under the trademark, HOWMEDICA'S PRECISION OSTEOLOCK. That device comprises a femoral component design which is advertised to have achieved a cementless fixation in the proximal femur by making contact with the proximal femoral canal in strategic locations. Horizontal integration grooves, strategically located in the four corners of the proximal stem, are claimed by the manufacturer to enhance stability and reduce stem/bone micro-motion. The distal sleeves are stated to enable the independent filling of the canal distally and are solidly fixed to the prosthesis.

Other prior art femoral prosthesis have been invented which also attempt to stabilize the proximal component of the femoral prosthesis. For example, see the smooth quadrilateral openings used by Austin-Moore in the hip stem disclosed in an article in the Journal of Bone Surgery, entitled "The Self-Locking Metal Hip Prosthesis", 39A: 811 (1957).

Other references which relate generally to hip replacements include the following United States Patents: 4,784,663, 4,919,673, 4,921,501, 4,938,772, 4,944,761 and 5,041,114, including the inventor's own United States Patent Nos. 4,743,262 and 4,681,589, all of the disclosures of which are incorporated by reference herein.

Accordingly, a need exists for a femoral component with an internal mechanism which alleviates torsional stresses to be used in a wide variety of applications.

#### OBJECTS OF THE INVENTION

Accordingly, it is a general object of this invention to provide a femoral component of a hip prosthesis which overcomes the disadvantages of the prior art.

It is a further object of this invention to provide a femoral component which has a torque transfer effect built within the prosthesis itself.

It is another object of this invention to provide a femoral component which extends the durability and lifetime of the hip prosthesis by alleviating the stresses associated with torque thereon.

It is yet another object of this invention to provide a femoral component which has enhanced securement capabilities.

It is still yet another object of this invention to provide a hip prosthesis which eliminates thigh pain while resisting component failures.

#### SUMMARY OF THE INVENTION

These and other objects of this intervention are achieved by providing a femoral stem prosthesis to be implanted in the proximal end of the femoral canal.

The femoral stem prosthesis of the present invention is a device having an elongated shaft comprising a shank proximal



portion with one or more openings therethrough. The outer surface of the shaft comprises an affixation surface adjacent to the shank proximal portion. The distal portion of the shaft is located longitudinally from the shank of the proximal portion, and is of a diameter to permit it to fit within the femoral canal.

A bearing permits the prosthesis to have potential internal micro-motion in response to stresses exerted on the prosthesis when it is implanted. The bearing is located about the distal portion of the elongated shaft and additionally comprises a securing shoulder to secure the bearing within the femoral canal while permitting the distal portion to rotate only about the inner bearing.

In one embodiment, the bearing is fixed within the femoral canal about which the distal portion of the shaft may rotate.

#### DESCRIPTION OF THE DRAWINGS

Other objects and many attendant features of this invention will become readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

Fig. 1 is a side view of one embodiment of a device constructed in accordance with this invention shown implanted in the femoral canal; (Femoral Stem Design I).

Fig. 2 is an enlarged side view, partially in section of the device of Fig. 1.

Fig. 3 is an enlarged cross-section of a device constructed in accordance with this invention taken along line 3-3 of Fig. 2;

Fig. 4 is an enlarged, three dimensional view of the embodiment of a device constructed in accordance with the present invention as depicted in Fig. 1;

Fig. 5 is a partial view of the upper portion of the second embodiment of a device constructed in accordance with the present invention (Femoral Stem Design II);

Fig. 5A is a side view, partially in section, of the cooperating element used in conjunction with the other cooperating element shown in Fig. 5 (Femoral Stem Design II); and

Fig. 6 is an enlarged, partially in section, side view of the third embodiment of a device constructed in accordance with the present invention (Femoral Stem Design III).

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to various figures of the drawings where like reference numerals refer to like parts, there is shown at in Fig. 1, the proximal end of a femur 10 which has been resected for the implant of a femoral prosthesis. The femur 10 comprises an outer shell of cortical bone 12, inner cancellous bone 14 and calcar 16. A femoral prosthesis constructed in accordance with one embodiment of the present invention is shown at 20 as implanted at the prepared proximal end of the femur 10.

The femoral prosthesis 20 has an elongated shaft 22 having a proximal shank portion 24 with opening 26 therethrough and a distal portion 28 which may be rounded at its extreme end and is generally narrower in diameter than the proximal shank portion 24. The distal portion 28, is inserted into the proximal portion of the femur 10 so that the distal portion 28 can move within the bearing 30 (Fig. 2) which is fixedly secured within the femoral canal by its outer affixation surface 32 as described in further detail below. The motion of stem portion within the bearing 30 is a special type best described as "micro-motion".

The prosthesis 20 is designed so that the prosthetic portion 34 which is unitary with the elongated shaft 22 at the proximal shaft 22 at the proximal shank portion 24 will provide a neck 36 upon which is fitted a generally spherical head 38 to engage an acetabular prosthesis for articulation in a hip replacement (not shown).

The femur 10 is prepared to receive the prosthesis 20 by cutting tools to establish a neck resection level at 40 and then creating a passage 42 to receive first the bearing 30 followed by the insertion of the elongated shaft 22.

The distal portion 28 of the device 20 is seated within the bearing 30 which is fixedly secured within the passage 42.

For example, the bearing 30 may be manually pounded into place at the desired site. The outer affixation surface 32 of the bearing is designed to aid in retaining the bearing in place and may include a roughened or textured surface which may be achieved by conventional methods including, but not limited to, applying a conventional porous coating by sintering or plasma spraying, and/or by mechanical tooling methods such as knurling or sandblasting.

As shown in Figs. 1 and 2, the distal portion 28 of the elongated shaft 22 extends downward into the passage 42 and is of a generally cylindrical external peripheral surface, but not confined to a cylinder, and may be of an alternative configuration having a predetermined external diameter which is selected to be slightly less than the internal diameter of bearing 30. As shown in Fig. 3, the distal portion 28 is cylindrical and is located within bearing 30. The distal portion 28 is still permitted to freely rotate about its own longitudinal axis within the bearing 30 with minimized space between the two components. In order to facilitate this free movement, the inner surface 30A of bearing 30 and the exterior surface 28A of distal portion 28 may be highly polished in accordance with conventional methods.

In order to aid in retaining the bearing 30 in the desired location at the distal portion 28 and to prevent the migration of the bearing towards the proximal shank portion 24, (as shown in Fig. 2) a bearing retaining shoulder 44 is located on the elongated shaft 22 near the distal portion 28. When the bearing 30 buttresses the bearing retaining shoulder 44, the bearing is prevented from migrating towards the proximal shank portion of the prosthesis.

Therefore, when the device of the present invention is in place during use, the rotational capabilities of the distal portion 28 within bearing 30 will enable the prosthesis to dissipate the damaging effects associated with torque exerted during normal movement patterns, a "stress transfer" function.

As shown in Fig. 1, the device 20 may also optionally include an opening 26 through the proximal shank portion 24. The

opening 26 permits the ingrowth of bone therethrough to aid in retaining the prosthesis in place at the proximal portion. Although shown circular in Fig. 1, the opening may be of almost any shape, i.e., rectangular, polygonal, etc., and the present invention is not limited thereby. It is distinct in some way as to encourage or promote intimate layers of bone growth. In addition, alternatively a conventional bolt may also pass through the opening to permit bone growth thereabout to further secure the device.

To enhance the attachment of the prosthesis 20 to the femur 10, the exterior surface of the shank portion 24, the elongated shaft 22 (excluding the distal portion) and/or the interior surfaces of the opening 26, may include a roughened or textured affixation surface (not shown), to enhance bone attachment to the prosthesis 20. This affixation surface may be achieved by applying a porous coating such as by sintering or plasma spraying, and/or by mechanical tooling methods such as knurling or sandblasting.

If necessary, (as shown in Fig. 4) the prosthesis 20 may be removed after some period of time which is facilitated by the fact that the distal portion 28 will be easily removed from the bearing 30 since the cooperating surfaces of these two components may be highly polished.

All of the components of the present invention may be comprised of biocompatible materials. The proximal shank portion 24 for example, may be comprised of titanium steel while the distal portion 28 and bearing 30 may be comprised of cobalt chromium which does not abrade like titanium steel. The entire prosthesis may also be made from one material such as cobalt chromium. It should be readily apparent to those skilled in the art that the present invention should not be limited to these particular types of materials, but may be comprised of any suitable materials presently known or developed in the future which are suitable for the manufacture of hip replacement components.

The present invention also includes a second embodiment 50 (as shown in Fig. 5, Femoral Design II). The second

embodiment 50 is similar to the first embodiment 20 of Figs. 1-4 and to that end, the same reference characters for similar parts will be used in describing the second embodiment 50.

As shown in Fig. 5, the second embodiment of the femoral prosthesis 50 has an elongated shaft 22 having a proximal shank portion 24 with opening 26 therethrough. As shown in Fig. 5A, the distal portion 28 of this prosthesis 50 is in reality, a portion of an elongated rod 52 which fits and may rotate within elongated passage 54 and which extends outwardly from the distal portion thereof.

The elongated rod replaces part 30 as the bearing mechanism. Part 30 in Design I becomes a solid extension of rod 52.

By fixedly securing the bearing 52 with its solid distal portion 30 to the femur, as described above, the elongated rod 52 acts as a pivot member about which the elongated shaft 22 of the prosthesis may move in response to the torsional forces exerted on the prosthesis during use.

The second embodiment 50, (as shown in Figs. 5 and 5A) is also designed so that the prosthetic portion (not shown) which is unitary with the elongated shaft 22 at the proximal shank portion 24 will provide a neck 36 upon which is fitted a generally spherical head (not shown) to engage either the natural acetabulum, or an acetabular prosthesis for articulation in a hip replacement (not shown).

The distal portion of the device 50 may be solidly secured to the bearing 30, (as shown in Fig. 5A). The bearing 30 is fixedly secured within the passage 42 (as shown in Fig. 1). The outer affixation surface 32 of the bearing is designed to aid in retaining the bearing in place and may include a roughened or textured surface which may be achieved by conventional methods.

As shown in Fig. 5A, the elongated rod 52 is of a generally cylindrical external peripheral surface having a predetermined external diameter which is selected to be slightly less than the internal diameter of elongated passage 54 of Fig. 5. The exterior surface of elongated rod 52 and the internal

surface of elongated passage 54 are brightly polished to permit their micro-motion within each other.

In order to aid in retaining the elongated rod 52 in the desired location, (as shown in Fig. 1 of Design I) a retaining shoulder 44 is located on the elongated shaft 22 near the distal portion 22. When the upper portion of the bearing 52 buttresses the bearing retaining shoulder 44, the bearing portion and elongated rod 52 are prevented from migrating towards the proximal shank portion of the prosthesis. If desired, other forms of a bearing and rod retainer may be incorporated into the present invention, such as by conventional means such as a screw or protrusion (not shown), extending generally perpendicular to the elongated shaft.

As shown in Fig. 6, the third embodiment 55 of the present invention moves the rotational portion of the bearing mechanism up into the upper end of the prosthesis 24. The prosthesis contains a cylindrical opening or channel 56 through which a cooperating bearing 58 passes. Cooperating bearing 58 has a highly polished surface to match that of cylinder path 56. Cooperating bearing 58 is a unitary part of stem 59 whose outer surface is roughened by the same means as described for alternate surface 32. Cooperating bearing 58 has the potential of movement within the cylindrical channel 56 as described with respect to the other embodiments.

In this third embodiment 55, the bearing 30 is integral with stem 59 and the bearing 30 will be fixedly secured in the bone structure as previously set forth. It should be readily apparent to those skilled in the art that the actual longitudinal length of the bearing 30 may vary depending upon the circumstances of use, as may the degree of the outer surfacing thereof.

Therefore, when the device of the present invention is in place during use, the rotational capabilities of the bearing 58 and elongated rod 52 will enable the prosthesis to dissipate the damaging effects often associated with torque exerted during normal movement patterns.

To enhance the attachment of the prosthesis to the femur 10, the exterior surface of the shank portion 24 and/or the interior surfaces of the opening 26, may include a roughened or textured affixation surface (not shown) to enhance bone attachment to the prosthesis. The same is true of part 30 and parts 59. This affixation surface may be attained by any suitable method and includes, but is not limited to, the application of a porous coating such as by sintering or plasma spraying, and/or by mechanical tooling methods such as knurling or sandblasting.

Without further elaboration, the foregoing will so fully illustrate my invention that others may, by applying current or future knowledge, adapt the same for use under various conditions or service.

CLAIMS

What is claimed as the invention is:

1. A femoral stem prosthesis (20) to be implanted in the proximal end of a femur (10) having a femoral canal (42), the prosthesis (20) comprising:

(a) an elongated shaft (22) including:

(i) a proximal portion (24) having an outer surface comprising an affixation surface (not shown) adjacent the shank proximal portion (24); and

(ii) a distal portion (28) located longitudinally from the proximal portion (24), wherein the distal portion (28) is of a diameter to permit it to fit within the femoral canal (42);

(b) a bearing means (30) positioned on said distal portion (28) to permit the prosthesis (20) to move in response to forces exerted on the prosthesis (20) when it is implanted in the femoral canal (42), the bearing means (30) comprising securing means to rotatably secure the bearing means with reference to the distal portion (28) while permitting the distal portion (28) to rotate about the bearing means (30); and

(c) retaining means (44) to retain the bearing means (30) adjacent the distal portion (28) of the elongated shaft (22).

2. The prosthesis (20) of claim 1 wherein the affixation means comprises a roughened surface achieved by sintering, plasma spraying or mechanical tooling.

3. The prosthesis (20) of claim 1 wherein the proximal portion (24) of the elongated shaft (22) additionally comprises at least one opening (26) therethrough.

4. The prosthesis (20) of claim 1 wherein the bearing means (30) is located adjacent the distal end (28) of the elongated shaft (22).



5. The prosthesis (20) of claim 3 wherein the opening (26) is of a shape selected from the group consisting of round, rectangular, oval and polygonal.

6. The prosthesis (20) of claim 3 wherein the opening (26) through the proximal portion (24) of the prosthesis (20) additionally comprises the affixation surface comprising a roughened surface achieved by mechanical tooling, sintering or plasma spraying.

7. The prosthesis (20) of claim 1 wherein the bearing means (30) comprises a bearing (30) having an inner (30A) and outer surface (32) and an inner and outer diameter.

8. The prosthesis (20) of claim 7 wherein the inner surface (30A) of the bearing (30) is generally smooth and the outer surface (32) of the bearing (30) is generally roughened.

9. The prosthesis (20) of claim 8 wherein the securing means to secure the bearing means within the femoral canal comprises a roughened outer surface (32).

10. The prosthesis (20) of claim 9 wherein the roughened outer surface (32) is accomplished by mechanical tooling or by a porous surfacing process selected from the group consisting of sintering and plasma spraying.

11. The prosthesis (20) of claim 9 wherein the roughened surface of the proximal portion is accomplished by mechanical tooling.

12. The prosthesis (50) of claim 7 wherein the elongated shaft (22) additionally comprises an interior elongated passage (54) open to the distal portion (28) of the elongated shaft (22) and the bearing means (30) additionally comprises a generally elongated rod (52) having a proximal portion and a distal portion and a diameter sufficient to fit and rotate within the interior elongated passage and being of a length sufficient to permit the distal portion of the rod to extend beyond the elongated shaft (22) and into the bearing (30), wherein the bearing (30) is fixedly secured to the distal portion of the generally elongated rod (52).

13. The prosthesis (50) of claim 7 wherein the retaining means comprises a shoulder (44) located between the proximal portion (24) and the distal portion (28) of the elongated shaft (22) to prevent the bearing (30) from moving beyond a predetermined distance towards the proximal portion (24), wherein the shoulder (44) is formed by increasing the diameter of the elongated shaft (22) to a diameter larger than the interior diameter of the bearing (30).

14. The prosthesis (50) of claim 12 wherein the retaining means comprises a shoulder (44) located between the proximal portion (24) and the distal portion (28) of the elongated shaft (22) to prevent the bearing (30) and elongated rod (52) from moving beyond a predetermined distance towards the proximal portion (24), wherein the shoulder (44) is formed by increasing the diameter of the elongated shaft (22) to a diameter larger than the interior diameter of the bearing.

15. The prosthesis (50) of claim 12 wherein the bearing (30) and elongated rod (52) are fixedly secured to one another by being integrally formed.

16. The prosthesis (20) of claim 3 additionally comprising a bolt passing through the opening (26) to permit bone growth about the bolt to secure the prosthesis (20).

17. A femoral stem prosthesis (50) to be implanted in the proximal end of a femur having a femoral canal, the prosthesis comprising:

- (a) an elongated shaft (22) including:
  - (i) a proximal portion (24) having an outer surface comprising an affixation surface adjacent the shank proximal portion (24); and
  - (ii) a distal portion (28) located longitudinally from the proximal portion (24), wherein the distal portion (28) is of a diameter to permit it to fit within the femoral canal;
- (b) a bearing means to permit the prosthesis to move in response to forces exerted on the prosthesis

when it is implanted in the femoral canal, the bearing means (30) being located adjacent the elongated shaft (22) and comprising securing means to secure the bearing means within the femoral canal while permitting the bearing means to permit the prosthesis (50) to move in response to forces exerted on the prosthesis (50); and

(c) retaining means to retain the bearing means (30) adjacent the elongated shaft (22).

18. The prosthesis (50) of claim 17 wherein the proximal portion (24) additionally comprises at least one opening (26) therethrough.

19. The prosthesis (50) of claim 17 wherein the bearing means (30) is located adjacent the proximal portion (24).

20. The prosthesis (55) of claim 17 wherein the proximal portion (24) additionally comprises an elongated channel (56) and the bearing means (30) comprises an elongated rod (58) to be located adjacent the elongated channel (56).

21. The prosthesis of claim 20 wherein the elongated rod (58) when implanted in a body of a living being is placed within the elongated channel (56) to permit the elongated rod to rotate within the elongated channel (56).

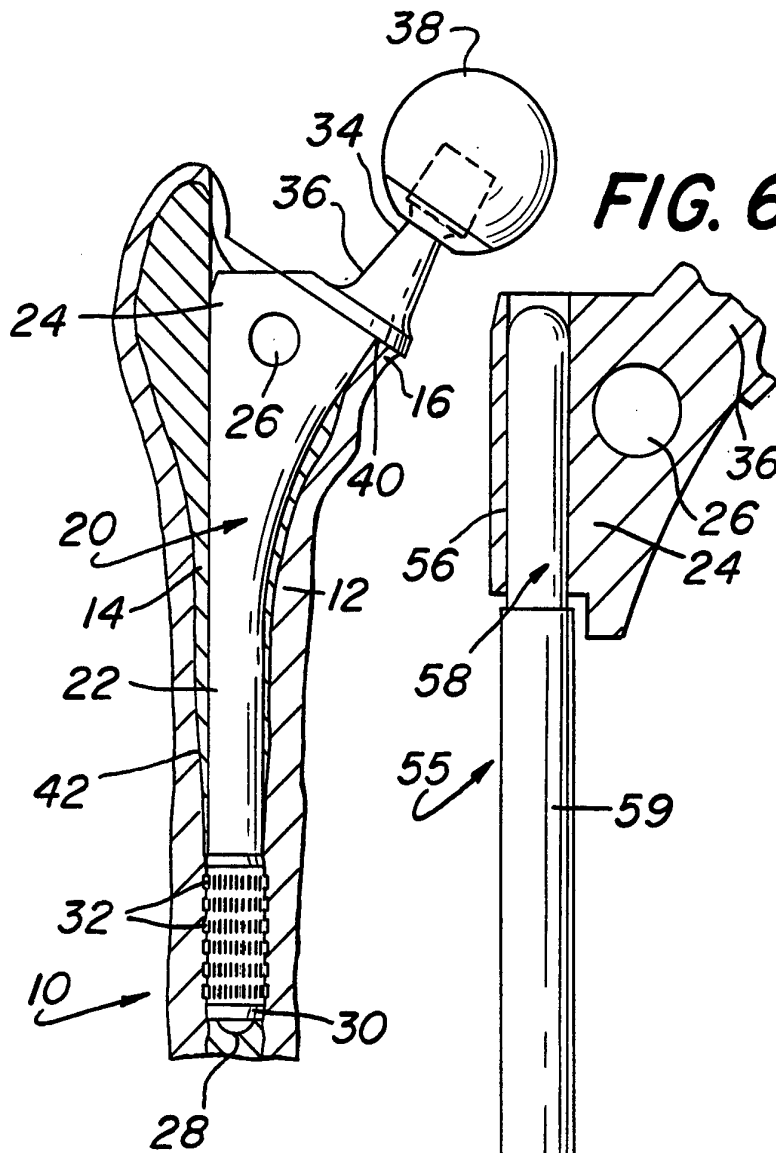
22. The prosthesis (50) of claim 17 wherein the bearing means (30) is located at the distal portion (28), the proximal portion (24) or at a position intermediate the distal (28) and proximal portions (24).

23. A femoral stem prosthesis (20) to be implanted in the proximal end of a femur having a femoral canal, the prosthesis (20) comprising:

an elongated shaft (22) including:

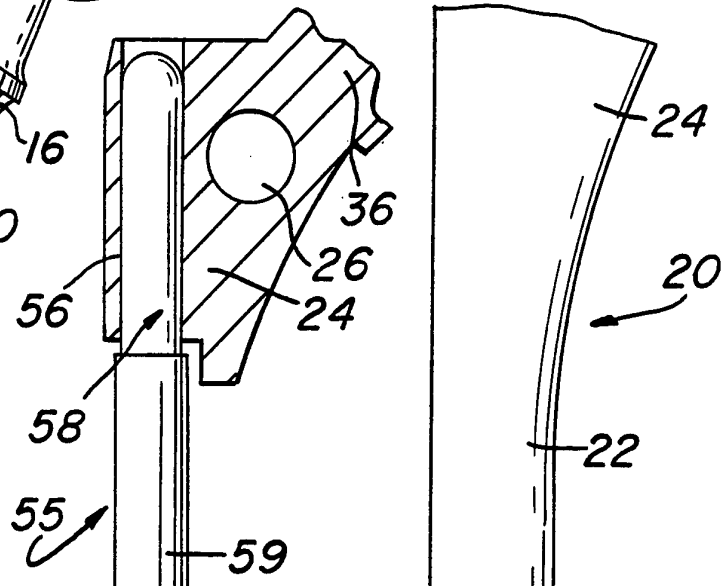
- (i) a proximal portion (24) having a fenestration therethrough, the fenestration comprising an affixation surface, and
- (ii) a distal portion (28) located longitudinally from the proximal portion (24), wherein the distal portion (28) is of a diameter to permit it to fit within the femoral canal.

**FIG. 1**

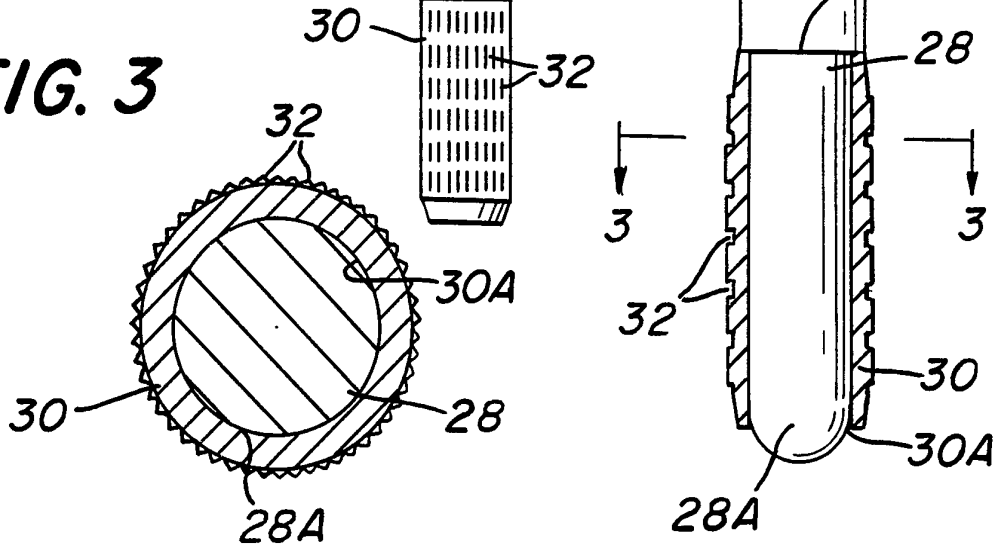


**FIG. 6**

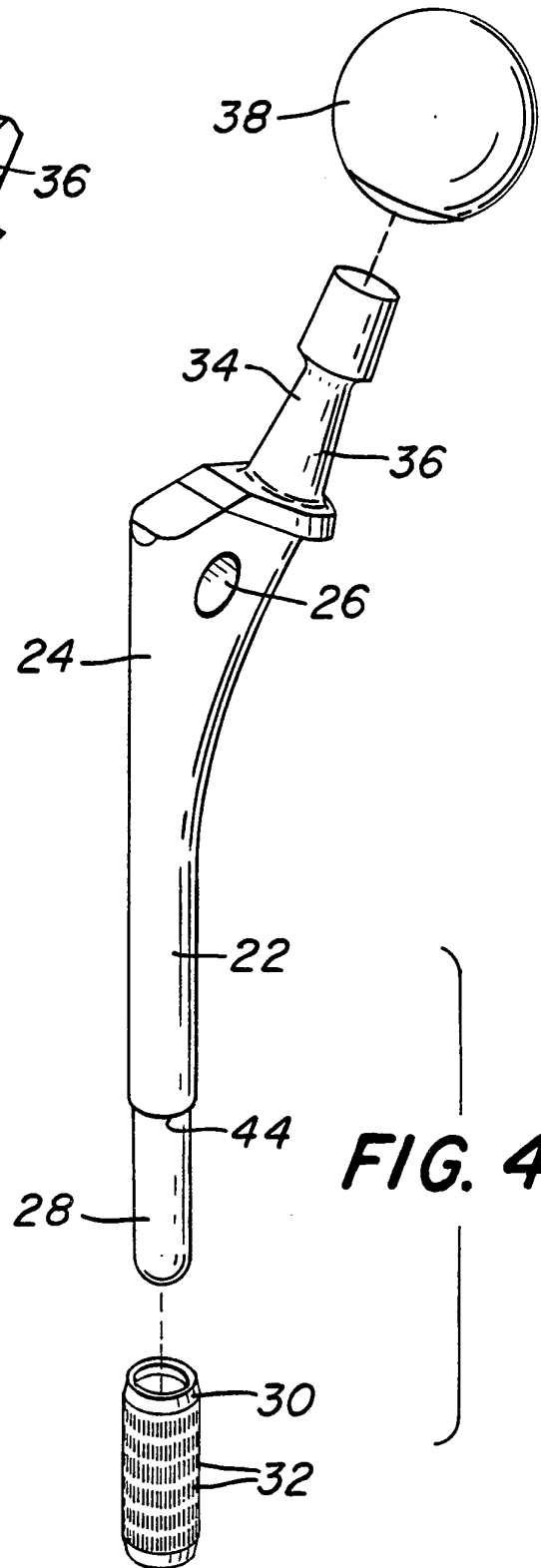
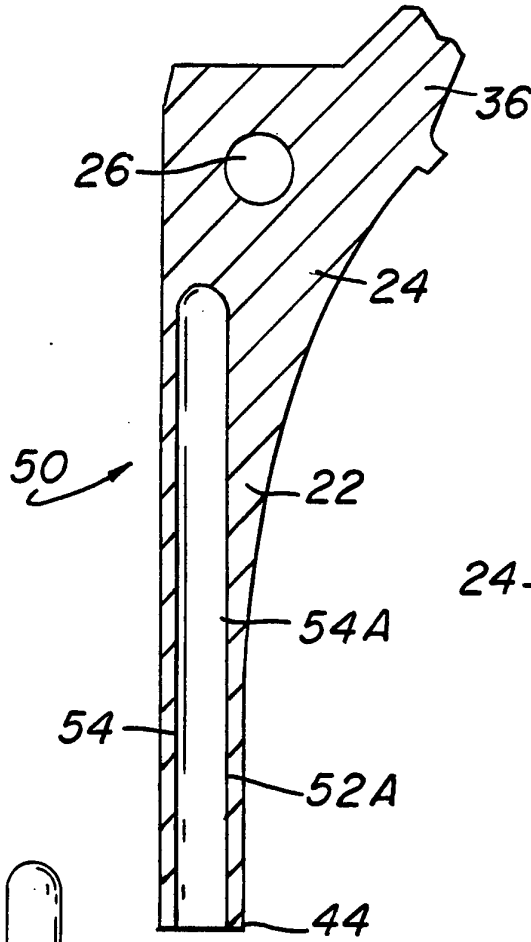
**FIG. 2**



**FIG. 3**

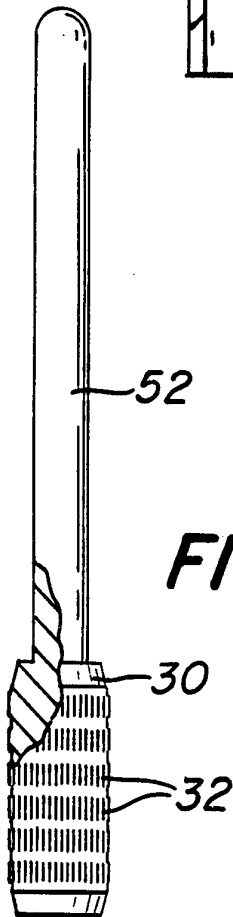


2 / 2  
**FIG. 5**



**FIG. 4**

**FIG. 5A**



INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US93/09323

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC(5) :A61F 2/34, 2/36  
 US CL :623/23  
 According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**  
 Minimum documentation searched (classification system followed by classification symbols)  
 U.S. : 623/22, 23

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
 NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
 NONE

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- A	WO, A, 91/03992 (Walker) 04 April 1991. See page 12 line 14 - page 13 line 8, and Fig. 11.	1, 4, 7, 13, 17, 22 ----- 12, 14, 15, 19, 20, 21
Y, P	US, A, 5,197,989 (Hinckfuss et al.) 30 March 1993. See column 5 lines 5-16/ column 17 lines 1-7 and 51-58; Figs. 3A-3C; column 11 lines 39-51; and Fig. 5A, Fig. 4A.	2, 3, 5, 8-11, 16, 18
Y	GB, A, 1 442 990 (English) 21 July 1976. See page 2, lines 13-55.	6, 23

Further documents are listed in the continuation of Box C.  See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 20 December 1993	Date of mailing of the international search report 02 FEB 1994
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