

[54] **CEMENT RESTRICTOR FOR TOTAL HIP OPERATIONS**

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[58] **Field of Search**.... **3/1; 128/92 C, 92 CA, 92 R, 128/83**

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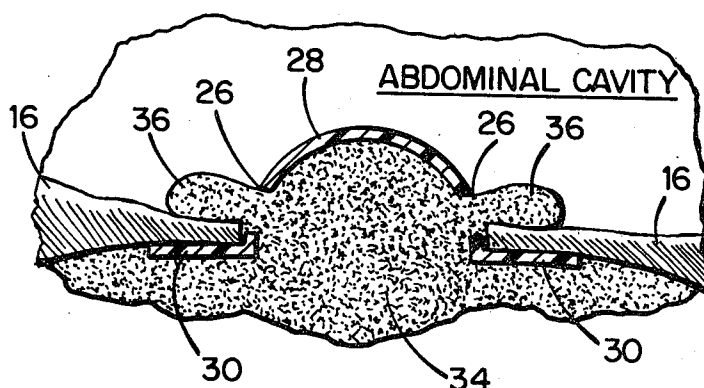
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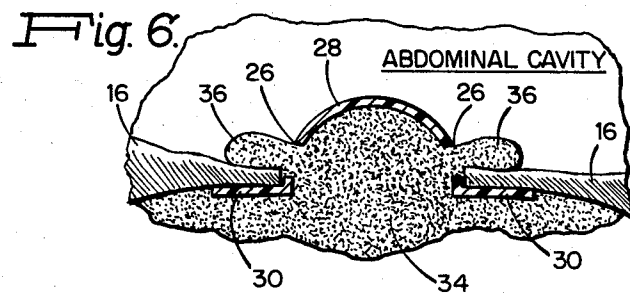
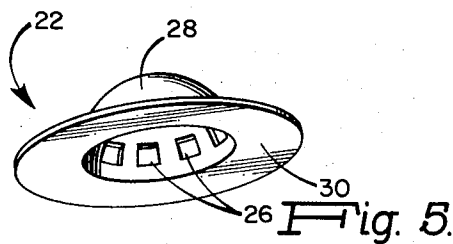
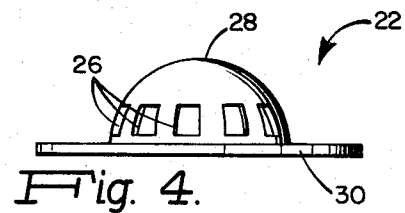
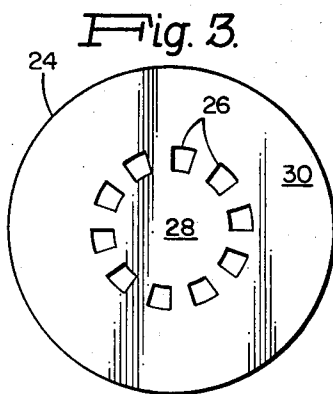
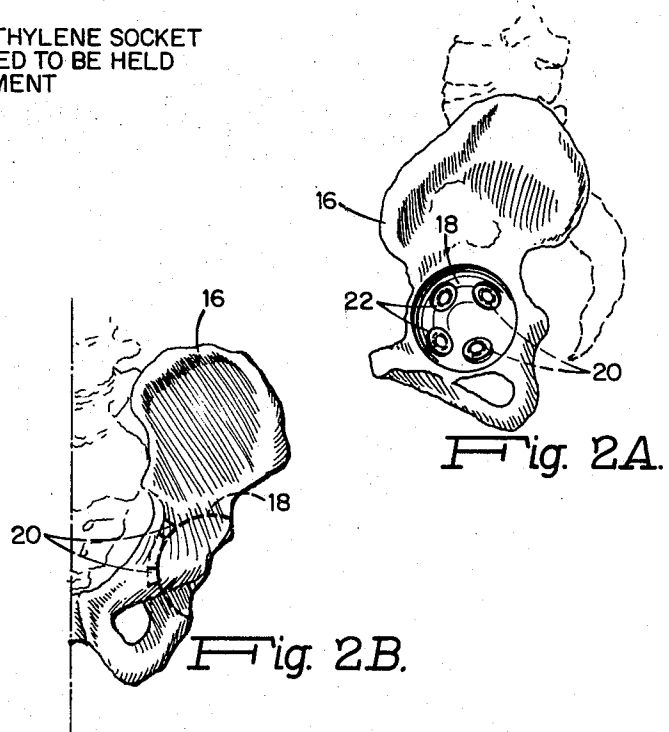
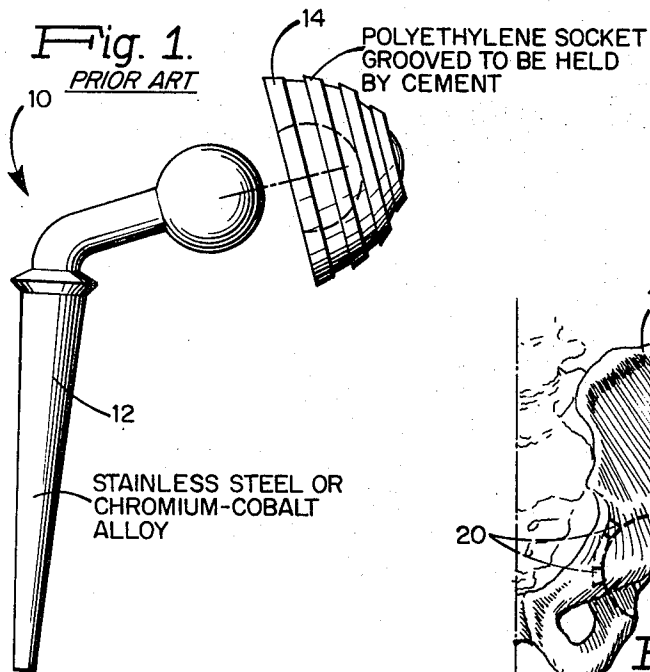
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[57] **ABSTRACT**

A cement restrictor device adapted for use in a hip replacement operation, which device comprises: a raised cap-like upper element defining a cavity therein, the upper element having a continuous solid upper surface, the lower edge of the element adjoined to a peripheral lid element extending outwardly from the lower edge thereof, the lower crown portion of the cap-like element generally adjacent to the adjoinment to the lid element characterized by a plurality of peripheral passages therein to permit the passage of a cement material therethrough, whereby the upper element may be inserted into a hole in a bone of about the size of the upper element and cement applied to the interior cavity and forced through the passageway so as to lock the device between the lid element and the cement into the hole in the bone.

12 Claims, 7 Drawing Figures





CEMENT RESTRICTOR FOR TOTAL HIP OPERATIONS

BACKGROUND OF THE INVENTION

The employment of prosthetic devices in a total hip operation for the replacement of diseased or damaged hips is becoming a rather common operation. A number of prosthetic devices used in such hip operations are available. One such device referred to as a Charnley device comprises a metal femoral (ball or shank) component which articulates in an acetabular polymer socket component. In use, the surgeon reams a hemispherical shaped cavity into the pelvic bone and then drills typically three or four holes into the bone at the bottom of the cavity to aid in anchoring the socket therein. A device known as a Charnley cement restrictor is then inserted into each of the drilled holes. The Charnley cement restrictor comprises a fine wire mesh screen in the general shape of a top hat, with the wire formed of stainless steel or a cobalt-chromium alloy known as Vitallium (a trademark of Howmedica, Inc.) A dough-like polymeric cement material is then spread onto the inner surface of the reamed pelvic hole. The purpose of the Charnley cement restrictor is to prevent the cement from entering the abdominal cavity of the patient, and to aid in mechanically locking the socket in the pelvic cavity with the hardened cement. Typically, the cement penetrates the screen of the Charnley cement restrictor and forms small beads thereon. The polymeric socket is then inserted into the cement-lined cavity and the cement hardened to hold the socket therein.

Recent work (Corrosion Behavior of a Metallic Implant: A Scanning Electron Microscope Study, by J. W. Pugh, W. Jaffe, F. J. Kummer and J. C. Runkle, 2nd Annual Bioengineering Conference of New England Proceedings, April 1974) indicates that such implanted metallic components corrode with crevice corrosion particularly rapidly, which corrosion may necessitate a major operation to remove the corroded metallic components.

Further, a disadvantage of the Charnley cement restrictor employed in such total hip operations is the penetration of the cement into and through the fine wire screen and the formation of small hard cement beads on the abdominal side of the screen. Such beads are subject to breaking off in use and migrating into the abdominal cavity and effecting a loosening of the prosthesis socket component in the cavity.

SUMMARY OF THE INVENTION

My invention concerns an improved cement restrictor, the method of manufacturing and the method of employing such restrictor. In particular, my invention relates to an all-polymeric cement restrictor and the method of employing such restrictor in place of the Charnley cement restrictor in total hip operations.

My cement restrictor comprises a polymeric device formed into a general top-hat or derby-hat-like shape having dome and lid sections, with a plurality of holes about the periphery of the crown where the dome section joins the flat lid section. My cement restrictor device provides an effective and efficient means through the position of the holes to distribute the cement material to insure excellent locking and mechanical stability of the device within the pelvic holes. Further, the holes employed in my device distribute and direct the cement

in a manner to lock the prosthesis into the holes within the pelvic cavity. The employment of a solid dome section and holes about the crown prevents small beads of cement from forming on the abdominal side of the dome section, while permitting the larger beads of cement forced through the crown holes to hold the device in place.

My device is formed of a medically acceptable polymer and preferably of the same or similar type of polymer as the type of socket component used, such as, but not limited to, olefinic resins like polyethylene and polypropylene, polyamides like nylon, and other polymeric materials capable of being employed within the human body. My polymeric cement restrictor is nonreactive with the cement material, noncorrosive, and particularly avoids crevice corrosion problems of the prior art, is noncarcinogenic in nature and exhibits sufficient strength and stiffness to prevent the cement from pushing the restrictor out of place. My cement restrictor has many distinct and important advantages over the presently employed Charnley or other cement restrictor devices.

My cement restrictor may be manufactured by forming the polymeric material into the desired shape, such as by forming a thermoplastic polymer as a sheet material under heat and pressure on a mandrel or in a mold or by other techniques of forming such polymers, such as by casting, extruding, blow-molding and the like, either as one component or in separate components, and then formed or assembled into the desired form.

My cement restrictor is characterized by a continuous solid, raised, central component, such as a dome or other shape. The number, type, arrangement, size and shape of the holes about the periphery of the crown or the area just above the lid section may vary, depending on the particular needs and use of the device. It is essential that the holes be positioned in the crown area near the lid and about the periphery in a single or multiple lines. It is preferred also that the holes be sufficient in size to permit the cement to be forced therethrough to form a large bead, such as a mushroom shape when arcuate-like slits are used to hold the restriction in the holes and to prevent the formation of very small beads which might break off; e.g., average hole sizes or diameters of 1/16 to 1/4 inch, with from about 5 to 15 holes equally spaced. Holes of such size in the form of circles, slots, stars, crosses, etc. may be usefully employed.

Holes should not be placed in the upper dome section, since the cement forced therethrough does not contribute to the locking action and may break off if small beads are formed. Thus, it is essential that the upper top section be a solid section. With a continuous solid dome section, the cement is forced by the hemispherical dome shape back toward the holes in the crown section, and is used more effectively.

Any cement material medically acceptable for use in the operation may be employed; however and typically, a polymeric cement which is noncarcinogenic, nonreactive with the polymer used for the socket component, and in a dough-like form or a composition of similar consistency is employed. A common cement material is a curable acrylic polymer, such as polymethylmethacrylate known as Simplex (a Trademark of Howmedical, Inc.).

My invention will be described for the purposes of illustration only in reference to a cement restrictor device in a total hip operation with a Charnley prosthetic

device; however, my device may be usefully employed in other prosthetic operations and with other prosthetic devices as a cement restrictor.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic illustration of a Charnley prosthetic device.

FIGS. 2A and 2B are representative illustrations of the side and front views respectively of a pelvic bone section showing my cement restrictor used therein.

FIG. 3 is an illustrative view of a polymeric sheet prior to being formed into my device.

FIG. 4 is a side view of my cement restrictor device.

FIG. 5 is a perspective view of my cement restrictor device.

FIG. 6 is a representative enlarged cross-sectional view of my cement restrictor device in use along lines 6—6 of FIG. 2.

DESCRIPTION OF THE EMBODIMENTS

FIG. 1 shows a Charnley prosthetic device 10 used in total hip operations comprising a femoral ball and shank element 12 of stainless steel or Vitallium, and a high-density polyethylene socket element 14, with the external surface to be placed into the reamed pelvic cavity grooved or otherwise formed or treated to be held by the hardened cement. The polyethylene socket 14 has a diameter of about 3 inches and a depth of slightly less than 1 ½ inches.

FIGS. 2A and 2B show views of a pelvic bone section 16 with a hemispherical cavity 18 therein reamed out by the surgeon during the hip operation and typically to a diameter of about 4 inches and a depth of 1 and ½ inches. Four holes 20 are drilled into the bone element 16 and inserted in each hole is my cement restrictor 22. The holes 20 are usually about ½ inch in diameter.

FIG. 3 shows a generally circular polymeric sheet material 24 composed of high-density polyethylene preferably of the same or similar type as used in the socket 14, the sheet about 40 to 60 mils. in thickness to provide sufficient strength to the restrictor 22 to prevent it from being forced out of the holes 20 on the application of the cement by the surgeon. The sheet 24 has a plurality of arcuate-shaped holes or slots 26 distributed in a circular ring about the center of the sheet, with the area in the middle to form the dome element 28 and the area outside the slots 26 to form the lid element 30. The sheet 24 is then hat-formed, such as, for example, over a mandrel or in a vacuum mold, to form the cement restrictor as shown in FIGS. 4 and 5.

FIGS. 4 and 5 show one embodiment of the cement restrictor 22 of my invention comprising a rounded, continuous solid, dome-like top element 28, a plurality of slots 26 equally spaced and formed about the lower crown area of the top element 28 just above the lid element 30. The restrictor 22 has a hemispherical internal cavity therein. It is essential to position the slots 26 only in the crown area and not in the middle or top of the dome area 28, since, otherwise, cement may be permitted to enter the abdominal cavity. The slots 26 illustrated are about ⅜ of an inch in depth, and the ten slots are equally spaced about the crown periphery. The restrictor is about 1 inch in overall diameter, with the cavity diameter of about ½ inch to fit into the holes 20, and a depth of about ½ inch. Arcuate-type slots of from 7 to 10 in number are preferred for the holes, since

such slots provide for a large mushroom-like bead of cement adjacent the pelvic bone which insures a good locking action.

FIG. 6 is an enlarged cross-sectional view along lines 6—6 of FIG. 2 showing the restrictor device 22 in use, with a hardened cement material 34 forming mushroom-like beads 36 by being forced through slots 26 to secure the device 22 to the bone wall 16, while the lid 30 is on the other side of the bone wall. The cement material is polymethylmethacrylate or other acceptable hardenable cement.

In use, the surgeon smears and packs the dough-like cement material 34 into the internal walls of the cavity 18 to a depth of about ¼ to ½ an inch, and then inserts the socket 14 into the cavity.

My cement restrictor may be formed of a metal or metal alloy where corrosion is not a problem. My device may be used in any application where it is desired to provide a cement-locking means with restricted cement on the opposite side of the device.

What is claimed is:

1. A cement restrictor device adapted for use in a hip replacement operation, which device comprises:

25 a raised cap-like upper element defining a cavity therein, the upper element having a continuous solid upper surface, the lower edge of the element adjoined to a peripheral lid element extending outwardly from the lower edge thereof, the lower crown portion of the cap-like element generally adjacent to the adjoinment to the lid element characterized by a plurality of peripheral passages therein to permit the passage of a cement material therethrough, whereby the upper element may be inserted into a hole in a bone of about the size of the upper element and cement applied to the interior cavity and forced through the passageway so as to lock the device between the lid element and the cement into the hole in the bone.

30 2. The device of claim 1 wherein the upper cap-like element is a hemispherical dome-like element.

3. The device of claim 1 wherein the device comprises a polymeric material of olefinic resin or nylon.

45 4. The device of claim 1 wherein the passageways are generally equally spaced about the periphery and the number of passageways ranges from about 5 to 15.

5. The device of claim 1 wherein the diameter of the cavity is about one-half the diameter of the lid element.

50 6. The device of claim 1 wherein the passageways comprise a plurality of slots about the periphery.

7. A cement restrictor device adapted for use in an operation to lock the device into a hole in a bone, which device comprises:

55 a hemispherical dome-like raised upper element defining a cavity therein, the upper element having a continuous solid upper surface, the lower edge of the upper element adjoined to a peripheral flat lid element extending outwardly from the lower edge thereof, the lower crown portion of the upper element generally adjacent to the lid element characterized by a plurality of equally spaced slot passageways therein to permit the passage of cement therethrough, the device composed entirely of a medically acceptable polymeric material, whereby the dome-like element may be inserted into a hole in a pelvic bone, cement applied to the cavity and forced through the slot passageways and hardened

to lock the device into the hole between the hardened beads of cement and the lid element.

8. In a method of replacing a diseased or damaged hip which comprises:

- a. reaming a cavity into the pelvic bone of a patient;
- b. drilling a plurality of holes into the bone to provide a means to anchor a socket element therein by the use of a hardenable cement;
- c. inserting in the holes a cement restrictor device which comprises a raised cap-like upper element defining a cavity therein, the upper element having a continuous solid upper surface, the lower edge of the element adjoined to a peripheral lid element extending outwardly from the lower edge thereof, the lower crown portion of the cap-like element generally adjacent to the adjoinment to the lid element characterized by a plurality of peripheral passages therein to permit the passage of a cement material therethrough;
- d. applying a cement material to the interior of the reamed cavity and forcing some of the cement through the passageways of the cement restrictor

device;

e. inserting a prosthetic socket element into the cement-coated cavity; and

f. hardening the cement to secure the cement restrictor to the holes and the socket element within the cavity.

9. The method of claim 8 wherein the cement restrictor device and the socket element are composed of the same or similar polymeric material.

10. The method of claim 8 wherein the cement restrictor device is composed of high-density polyethylene.

11. The method of claim 8 wherein the cement material is a dough-like composition of polymethylmethacrylate.

12. The method of claim 8 wherein the passageways in the cement restrictor device are slot passageways equally distributed about the periphery, the device is composed of a polymeric material, and the upper element comprises a hemispherical dome-like element.

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