APPARATUS AND METHOD FOR PRESSURIZING GAP-FILLING CEMENT TO A CONCAVELY RELIEVED SITE IN A BONE

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ABSTRACT
The securement of gap-filling cement to a concavely relieved site in bone is significantly improved, and the risk of mechanical failure correspondingly reduced when the cement is used to secure a prosthetic device in the site, by locating the cement to the site, and pressurizing the cement by forcibly applying an extrusion member to cement in one area within the site while sealing or covering the remaining area of the site to obviate or reduce outward escape of cement.

Apparatus for this purpose can comprise an extrusion member having a resilient annular sealing member fixed around one end of the former member, the seal preferably being inflatable by a piston-and-cylinder assembly operated like a syringe at the other end. Another form of apparatus comprises a tapered stem longitudinally movable in sealing relation through a separate U-shaped cover plate.

10 Claims, 3 Drawing Figures
APPROATUS AND METHOD FOR PRESSURIZING GAP-FILLING CEMENT TO A CONCAVELY RELIEVED SITE IN A BONE

This invention concerns cement fixation and more particularly a method and apparatus for improved fixation of prosthetic bone joint devices and other implantable devices which are to be fixed to natural bone by the use of acrylic or other suitable cements.

It is now well-known practice to secure prosthetic bone joint devices by way of stems, ribs and grooves, and other formations which are bonded in intramedullary canals, preformed bores or other suitably prepared sites in natural bone by the use of acrylic cement. The best known examples of this are probably found among total hip joint replacements in which a ball-headed stem is cemented into the medullary canal of an appropriately sectioned femur for cooperation with a hemispherical cup which is cemented into an appropriately reamed site in the acetabulum.

However, while the practice of cement fixation offers various advantages over other techniques, difficulty can sometimes arise as a result of mechanical failure in the fixation and it is an object of the present invention to reduce this difficulty.

The invention centres around an investigation of such failures to determine their cause. There is not, in fact, a single cause but several possible causes. A first possible cause arises from an insufficient extrusion of the cement into the bone and around the appropriate part of the device in the gap between that part and the adjacent bone. In this connection it is to be noted that the practice to date is to simply apply the cement to the fixation site with a syringe or some other tool, and then extrude the cement by pushing the device into the cement.

Another cause can arise from lamination formation within the cement and this can, in turn, result from a blood-cement interface.

It is now proposed, according to one aspect of the present invention, that these causes of potential difficulty in the application of gap-filling cement to a concavely relieved site in a bone be alleviated by locating the cement in the site and applying positive pressure to the cement located in an area within the site while sealing or covering substantially the whole of the remaining area of the site to obviate or reduce outward escape of cement from the site.

It will be appreciated that the proposed pressurisation of the cement serves to extrude the same into a more intimate contact with the bone of the site than is otherwise the case with existing techniques, and this is particularly true for a site including exposed cancellous bone into the pores of which the pressurised cement travels to a significantly deeper extent. Also, the pressurisation reduces the likelihood of lamination in the cement by forming the same to a more homogeneously dispersed body, while the pressurisation additionally "pushes" any blood present to the remote borders of the cement and thereby reduces the possibility of lamination-initiating blood-cement interfaces within the body of cement.

Also, it will be appreciated that the present invention is intended principally for use in the securement of a prosthetic device to bone and the invention will be discussed in this context hereinafter. However, the invention is not intended to be limited to such use since there are other circumstances in which the invention may be of benefit, such as when building-up a relieved bone site caused by a tumor.

In any event, in another aspect, the present invention provides apparatus for carrying out the above-proposed procedure which apparatus comprises an extrusion member for forcible longitudinal application to the cement in the area within the site, and an ancillary member for location around the extrusion member to seal or cover substantially the whole of the remaining area of the site.

The invention has been developed initially for use in association with an acetabular or similar site which is wholly bounded by a prepared bone surface and a single outermost access space. In this case, pressurisation of the cement is desired in all directions towards the site and it is accordingly appropriate for the ancillary member to be of annular form sealably connected around the extrusion member, and to be of resilient form to allow relative longitudinal movement of the extrusion member while tending to effect a seal at its periphery around the site. At present it is preferred that this ancillary member be of inflatable form.

However, there are other cases in which the form of the site does not equate with that just discussed, and the more common form of this second kind of site is that of a medullary canal which extends significantly further than the required cement penetration thereafter. Indeed, in this case an important requirement is for cement penetration in a lateral sense and it is appropriate to employ an elongate tapered extrusion member to effect a wedging action on the applied cement. The associated ancillary member is then suitably a rigid plate of U-shape to cover the remainder of the site while the extrusion member passes therethrough with the plate being moved to accommodate changes in the extrusion member by virtue of its taper. Preferably, the aperture of the plate is provided with a resilient seal connected therearound.

A fuller understanding of these aspects and forms of the invention can be gained from the following description of specific embodiments given by way of example and with reference to the accompanying drawings, in which:

FIG. 1 is a longitudinal sectional view of one embodiment;
FIG. 2 is a view of the embodiment of FIG. 1 from one end as indicated by an arrow; and
FIG. 3 schematically illustrates another embodiment.

The embodiment of FIGS. 1 and 2 has been developed for use in association with fixation of the acetabular component during total hip joint replacement by the so-called Southern approach, but it will be appreciated that the same general form, or similar forms of such apparatus can be used in other approaches and for similar prosthetic fixation requirements.

The more detailed construction of this embodiment includes an extrusion member comprising a nose piece 10 of generally mushroom form and a shaft 11 which is threadably engaged at one end with the free end of the stem of the nose piece 10 to extend co-axially therefrom. The shaft 11 terminates at its other end in a handle body 12 with which it is threadably engaged to form a generally T-shaped structure.

The embodiment also comprises an inflatable sealing arrangement including a resilient sealing member 13 in the form of the radially outer part of a torus. This seal-
ing member is located around the stem of the nose piece as shown with one side wall held against the undersurface of the nose piece head by an annular spacer 14, and the other side wall being held against the spacer by a washer 15 and nut 16, the spacer, washer and nut also being located around the stem of the nose piece, and the nut being threadably engaged therewith.

The sealing member 13 is inflatable by way of a piston-and-cylinder assembly in the handle body 12 which communicates with the interior of the sealing member by way of an axial bore 17 through the shaft 11, an axial bore 18 extending partway along the nose piece stem from its free end, a diametral bore 19 through such stem, an annular groove 20 around such stem, and a diametral bore 21 through the spacer 14. The piston-and-cylinder assembly in the handle body comprises two cylinders 22 formed in respectively opposite ends of the handle relative to the shaft, each aligned parallel to the shaft axis, and each opening towards the nose piece. Each cylinder receives a respective piston 23 mounted on one end of a strip 24 which is apertured at its centre to receive the shaft. Sealing between the pistons and cylinders is effected by the provision of O-rings 25 seated in circumferential grooves around the cylinders adjacent their open ends.

The cylinders communicate with the shaft bore 17 by way of a bore 26 therebetween, and an axial bore 27. The bore 26 is conveniently made from one end of the handle and then closed at that end by a plug 28, while the bore 27 passes through the handle and is threaded at one end to receive the shaft and at the other end to receive a filler cap 29.

Remaining components of the embodiment comprise bolts 30 which pass slidably through apertures in the strip 24 on respectively opposite sides of the shaft 11 to threaded engagement with the handle body 12. These bolts serve as stops to limit the outward movement of the pistons from their cylinders.

In use of the embodiment of FIGS. 1 and 2, the space within the sealing member, the cylinders and bores communicating the same is primed with a liquid, and then the handle gripped to forcibly apply the nose piece over cement in the relevant reamed acetabular cavity, while at the same time squeezing the strip towards the handle. This last action pushes the pistons into their cylinders, pressurises the liquid therein, and inflates and stiffens the sealing member to firmly engage the rim of the cavity. The nose piece can still move axially forwards relative to the inflated sealing member and this increases the sealing member/cavity rim engagement while extruding the cement into the adjacent cancellous bone.

It is preferred that the liquid used be of the same or medically equivalent form to that used for flushing the fixation site so that any leakage is not harmful.

Also, it is preferred that, with the cement in current usage, the apparatus be used to pressurise cement for a minute or two to effect a good extrusion of the cement into cancellous bone while still leaving the cement sufficiently plastic for the purposes of subsequent receipt of a prosthetic component therein.

Regarding materials: a prototype of the illustrated embodiment has been made substantially wholly of nylon, except the sealing member and O-rings, which were of a suitable rubber, and the shaft, which was of aluminium. However, this choice of materials is not critical and others can be used. It is useful though to bear in mind whether the materials of the nose piece and sealing member will release readily from cement extruded thereby. If there is any tendency to pull away some cement after extrusion, it is desirable to separate the apparatus and cement by a sheet of material which does readily release.

In the case of cement fixation of an intramedullary stem, such as in the femoral component of a total hip joint replacement, it is preferred that a different form of apparatus be used for the purposes of enhanced extrusion. FIG. 3 schematically illustrates one embodiment of such apparatus comprising a generally U-shaped cover member 40 formed by two like, superposed metal plates 41 having a rubber sheet 42 sandwiched therebetween. The sheet 42 is of similar U-shaping to the plates 41 but extends circumferentially around and radially inwardly from the inner periphery of this shaping to provide a U-shaped resilient rim 43.

The cover member is also provided with an elongate handle 44 extending therefrom as shown.

The associated extrusion member is in the form of an elongate tapered stem 45 similar to, or provided as, that of a femoral head or other stemmed prosthetic component.

In use of this embodiment, cement is applied into the medullary canal of a sectioned bone, and the cover plate is then held on the sectioned face of the bone with the space bounded by the rim 43 located over, but offset relative to, the exposed canal mouth. Then the associated extrusion member 45 is pushed into the canal while the cover member is progressively moved across the sectioned bone face to retain the resilient rim engaged with the stem. This operation will afford an enhanced extrusion of the cement into the surrounding bone and around the stem since the cover plate and its rim will reduce any tendency for the cement to escape directly from the canal.

We claim:
1. Apparatus for pressurizing gap-filling cement applied to a concavely relieved site in a bone, said apparatus comprising
   a. means for extruding said cement into said bone by longitudinal application thereof to said cement in one area of said site, said means comprising an elongate extrusion member having a solid end portion thereof for forcible application to said cement, and
   b. an inflatable resilient annular sealing member fixably and sealably connected around said extrusion member adjacent said solid end portion thereof to cover the remaining area of said site around said extrusion member for reducing the outward escape of cement therefrom when pressurized by application of said extrusion member.
2. Apparatus as recited in claim 1 further comprising a piston and cylinder assembly for inflating said sealing member, said assembly being located on the end of said extrusion member remote from said solid end portion and said assembly being in fluid communication with said sealing member by a passageway extending through said extrusion member, one of said said piston and cylinder components being fixably connected with said extrusion member, and the other of said components being coupled with said extrusion member for longitudinal movement relative thereto.
3. Apparatus as recited in claim 2 wherein said extrusion member and one of said components extends fur-
ther from said sealing member than said other component, the former being with a palm-engageable handle part, the latter being formed with a finger-engageable handle part, and said assembly being arranged to inflate said sealing member by mutual closing of said handle parts.

4. The method of applying gap-filling cement to a concavely relieved site with a single access opening in a bone, said method comprising the steps of
a. applying gap-filling cement to said site through said single access opening, and simultaneously
b. pressurizing said cement in said site to extrude cement into cancellous bone material in said site and
c. substantially covering the whole of said access opening to prevent outward escape of said cement.

5. The method recited in claim 4 wherein said step of pressurizing said cement in said site is accomplished by introducing a solid-ended instrument through said single access opening therein and applying a longitudinal force thereto to extrude said cement into said bone.

6. The method as recited in claim 4 wherein said step of substantially covering the whole of said access openings to prevent outward escape of said cement is accomplished by introducing an inflatable sealing element into said site through said single access opening and inflating said sealing element with a fluid.

7. A method of securing a prosthetic device to a bone comprising the steps of:
   a. preparing a concavely relieved site with a single access opening in the bone exposing thereby cancellous bone material in said site,
   b. applying gap-filling cement to said site through said single access opening,
   c. pressurizing said cement in said site to extrude cement into said cancellous bone material in said site,
   d. substantially covering the whole of said access opening to prevent outward escape of said cement, and
   e. applying a prosthetic device to said site.

8. Apparatus for pressurising gap-filling cement applied to a concavely relieved site in a bone, said apparatus comprising:
   a. an elongate extrusion member having a solid head part at one end thereof with a stem part extending therefrom to form a generally mushroom shaping, for extruding said cement into said bone by longitudinal application of said stem part to forcibly apply said head part to said cement in one area of said site, and
   b. a resilient annular sealing member in the form of the radially outer part of a torous fixably and sealably connected around said stem part behind said head part to cover the remaining area of said site and reduce the outward escape of cement therefrom when pressurised by application of said head part.

9. Apparatus for pressurising gap-filling cement applied to a concavely relieved site in a bone, said apparatus comprising:
   a. an elongate extrusion member longitudinally tapered towards a solid end portion for extruding said cement into said bone by longitudinal application of said member to forcibly apply said solid end portion to said cement in one area of said site, and
   b. means for covering the remaining area of said site around said extrusion member to reduce the outward escape of cement therefrom when pressurised by application of said solid end portion, such means including a U-shaped plate having a correspondingly shaped resilient rim extending in sealing connection circumferentially therearound and radially inwardly from the inner periphery of said plate to receive said extrusion member in wiping engagement therewith during longitudinal movement of said extrusion member through said plate.

10. Apparatus as recited in claim 9 wherein said extrusion member is an intramedullary stem forming part of a prosthetic device.

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