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Device for metering surgical hardenable mass
Vorrichtung zum Dosieren von chirurgischen, härten Massen
Dispositif de dosage d'une masse durcissable chirurgicale

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Description

[0001] The present invention relates to a device for metering hardenable mass for application in vertebroplasty and other similar bone treatments, achieving significant improvements with respect to the prior art in this field.

[0002] As is known, in different pathological states of diverse origin which affect the bone structures (trauma, osteoporosis, bone tumours, bone metastases, ostearthritic implants, etc.), one of the forms of treating, stabilizing and consolidating said structures consists in the injection into their interior of biomaterials having cementing properties which may incorporate drugs having a curative effect.

[0003] Access to the interior of the bone structure may be provided by puncture of the bone once exposed in the surgical sphere by means of conventional surgical techniques, or by means of percutaneous puncture, a technique which does not require a surgical incision and in which, instead of this, minimally invasive access through the skin is effected.

[0004] Access to the interior of the bone structure may be effected with the operator viewing directly the bone being treated, if the latter has been exposed by means of open surgery. In the case of percutaneous access, the guiding of the puncture needle or needles and their accessories (stylets, fastenings, metallic guides) requires the use of complementary techniques used in medical diagnostics for imaging (fluoroscopy, Computerized Axial Tomography, Magnetic Resonance, etc.) which facilitate the viewing of the path followed by said puncture equipment until it reaches the target in the bone.

[0005] The injection of cementing biomaterials is customarily carried out conventionally with standard syringes in which the plunger moves longitudinally along the body of said syringe without there being any type of mechanical connection between the two components. The longitudinal force exerted by the operator is what permits the injection of the biomaterial, although if this is highly dense or is in a rapid hardening phase, the force to be applied to the plunger needs to be considerable. Owing to the density of the biomaterial to be injected, the conventional syringe is customarily connected directly to the puncture needle, already introduced into the interior of the bone structure. In this way, the distance travelled by the biomaterial between the syringe and its target is shortened, thus reducing as far as possible the force to be generated on the plunger in order for the injection to be effective. The puncture needles customarily used are of large diameter (size or gauge 8, 9 or 10) facilitating the passage of the dense biomaterial through them. If the biomaterial to be injected is rapid hardening, the procedure for the preparation, loading in the syringe and injection of said material needs to be carried out in a short time (a few minutes). In the contrary case, the hardening of the cement pre-vents its injection in spite of exerting considerable force on the plunger of the syringe, connecting the syringe directly to the puncture needle, and using large diameter needles.

[0007] WO-A-9501809 discloses a bone cement delivery gun with a main body including a piston, a distal end connector for connection to a delivery nozzle and a side opening for filling. The side opening is located near the distal end.

[0008] The aim of the present invention is to improve the methods for injecting hardenable masses in vertebroplasty by facilitating the loading of the biomaterial into the interior of an injector device having special features, making it possible to work with greater injection pressure and to obtain a greater capacity of adjustment thereof, so that the time for which injection of the material is possible is extended.

[0009] A further aim of the present invention consists in facilitating access by puncture in the interior of the bone structure by the use of a combination of stylets and needles having special features.

[0010] A further aim of the present invention consists in avoiding direct connection between the injection device and the puncture needle in order to avoid excessive exposure of the surgeon to X-rays.

[0011] In order to fulfill these aims, the present invention is based on an assembly of two stylets which have the same diameter adapted to the interior of the puncture needle.

[0012] The length ratio between the stylets may be variable, as a non-limiting example, from 1:1.5 to 1:3. The long stylet acts as a guide for the needle, which can move along said stylet. The length of the long stylet is such that, once its distal end reaches the outer surface of the bone being treated, the longitudinal portion which remains outside the body of the patient is greater than that introduced into said body.

[0013] The short stylet, once introduced completely into the needle, extends beyond the distal end of the latter for a distance of between 1 and 10 mm. That is to say, the length of the needle is slightly less than that of the short stylet.

[0014] The present invention also provides for the use of a tube of high pressure flexible plastics material, with connections at both ends adapted to the connections provided on the needle and the device for injecting the biomaterials. The device for injecting biomaterials according to the present invention has a plunger with screw-threaded shaft for exerting high injection pressures, and the body of the device incorporates a lateral entry connection adapted to the connection of conventional syringes, permitting the loading of the biomaterial from a conventional syringe into the body of the injection device.

[0015] The device of the present invention, is used in a method of introduction of the hardenable mass comprising the following steps:
1. Percutaneous puncture and access:

[0016] Using some diagnostic imaging technology (fluoroscopy, Computerized Axial Tomography, Magnetic Resonance, etc.) for guiding the introduction of the needle within the body of the patient and before initiating the percutaneous puncture, the operator introduces the long stylet completely through the needle.

[0017] By manual puncture, the distal end of the stylet is now introduced into the body of the patient. The stylet is advanced while controlling its path with the imaging system selected for the procedure, until the outer surface of the bone being treated is reached. The puncture needle and the proximal portion of the long stylet still remain outside the body of the patient.

[0018] The target having been reached with the distal end of the stylet, the puncture needle advances over the latter and is introduced into the inside of the body of the patient until its distal end reaches the distal end of the stylet. The long stylet has been used as described as a guiding element for the needle.

[0019] At that moment, the long stylet is substituted by the short stylet, so that the distal end of the latter will project a few millimetres beyond the end of the needle. By means of manual pressure, rotation or percussion, the needle/short stylet assembly is introduced into the interior of the bone to be treated. To inject the biomaterial, the short stylet must be withdrawn.

2. Injection of the biomaterial:

[0020] The body of the injection device must be loaded with the biomaterial as described previously. The high pressure flexible tube will be connected to the body of the device and the rotatable plunger will be advanced until the biomaterial completely occupies the interior of the pressure tube, thus displacing the air which it contained previously.

[0021] At that moment the distal end of the pressure tube will be attached to the connection of the needle.

[0022] By rotating the plunger of the device in a clockwise direction, the biomaterial will be introduced into the interior of the bone. The system of rotation of the plunger permits controlled, accurate injection, while at the same time allowing the use of different biomaterials even though the latter may be in an advanced state of hardening.

[0023] By means of the application of the present invention it is possible to obtain the following advantages compared with the processes known at present.

A. Puncture and access:

   The method proposed is less aggressive or traumatic for the patient. By initially introducing only the stylet, the diameter of the puncture path created is less than that which would be produced if the needle were to be introduced directly. Moreover, in many cases various punctures have to be carried out to reach the target conveniently. With the method proposed, the reorientation of the puncture path is carried out only with the portion of the long stylet introduced into the patient.

   The use of the long stylet also makes it possible to keep the operator’s hands away from the area subjected to ionizing rays (X-rays), if this technology is used during the procedure. In these circumstances, the irradiation which the hands may receive during the manipulation of the puncture equipment is reduced.

B. Use of the high pressure flexible tube:

   This makes it possible to keep the operator’s hands away from the irradiated area. Moreover, the movements of the operator’s hands are not transmitted to the needle, so that accidental displacements of the latter are avoided.

   C. The lateral entry of the device of the invention facilitates the loading of biomaterials into its interior. Using a conventional syringe, it is possible to transfer the biomaterial to the device of the invention in a few seconds.

   D. The rotatable plunger, with screw-threaded shaft, allows the operator to carry out the injection of the biomaterial with total accuracy. Even if the biomaterial is in an advanced state of hardening, the injection is possible. Once the desired quantity of biomaterial is injected, the injection is stopped easily by applying anticlockwise rotation to the plunger (negative pressure).
screw-thread 4 on its outer surface which combines with a complementary screw-thread of the entry region 5 of the body 1 so that the knob or control 6 coupled to the rod 3 can be rotated manually in one direction or the other, advancing or withdrawing the plunger 2, increasing or reducing the free volume of the body 1, so that the freeing of the interior volume of said body is obtained for the purpose of loading the latter, or the gradual compression of the hardenable mass which is inside it, in order to cause it to emerge through the terminal end 7 of said body, to which is coupled a tubular member or extension 8 provided with quick-fit terminals 9 and 10, to permit the subsequent placing of the stylets and the needle as will be explained.

[0036] A manual handle 11 is coupled in an articulated manner, by means of the articulation 12 and a retaining device in the form of a small ring 13, to the body 1 to facilitate its manipulation.

[0037] For the filling of the metering body, the present invention provides a lateral filling pump 14 constituted by a cylinder with lower coupling of the quick-fit type 15 which can be coupled to a lateral mouthpiece 16 of the body 1 and which has internally an assembly of plunger 17 and rod 18, integral with the outer handle 19. Said pump may be constituted by a conventional syringe.

[0038] The mouthpiece 16 is located in a position close to the end 5 of the main body so that when the plunger 2 is in the position of maximum internal free volume, the mouthpiece 16 communicates with the internal volume so that, once the hardenable mass is transferred to the body 1, the movement of the plunger by clockwise rotation of the assembly 3-4 closes the direct communication between the mouthpiece 16 and the internal volume, now full, of the body 1, thus preventing reflux of the hardenable material towards the pump 14, and further permitting the disconnection of the latter immediately for the purpose of manoeuvrability.

[0039] This arrangement of components allows the regular and uniform filling of the body 1 on proceeding with the prior filling of the manual pump 14 and then coupling it to the mouthpiece 16 so that, by actuating the terminal 19, the charge of hardenable mass is transferred towards the inside of the main body 1 and subsequently, on rotating the knob 6, the plunger 2 will bring about the gradual displacement of the mass, causing it to emerge through the terminal 7 and tubular member 8 capable of receiving high pressures.

[0040] The assembly of stylets and needle which form part of the present device have been shown in Figures 6, 7, and 8.

[0041] The stylets of different length 20, 21, have the same diameter and ratio of length of 1:1.5 to 1:3. The long stylet has the purpose of effecting the first puncture so that its end remains located in proximity to the site at which it is desired to carry out vertebroplasty, for which the assistance of X-ray screens or the like of customary type in this art will be employed. After the first operation indicated, for which the hollow needle 22 will have previously been introduced, on the stylet 21, forming the assembly shown in Figure 9, the entry of the needle 22 may be brought about until it is introduced into the site where vertebroplasty is to be carried out, in which position the long stylet 21 will be extracted and will be substituted by the short stylet 20, which will make it possible to carry out more intense penetration towards the site where the hardenable mass is to be injected. In these circumstances, the short stylet will be extracted and the needle will be connected to the metering body of the device for injecting hardenable mass in order to effect the progressive entry of the hardenable mass at the site provided for vertebroplasty.

[0042] By means of the device of the present invention it is possible to improve significantly all the functions necessary for carrying out vertebroplasty or similar bone treatments, from the loading of the metering body of the pressure propulsion cylinder, expulsion of the mass, even in a certain phase of hardening, the possibility that the tubular member coupled to the metering body can resist high pressures, and great facility in the process of puncture and subsequent introduction of the hardenable mass. The mass to be injected may vary, being of the cement or paste-like substance or other type.

[0043] Moreover, owing to the arrangement of the tubular member capable of functioning at high pressure, the surgeon’s hands can remain substantially separated from the direct site of the intervention, thus avoiding excessive exposure to the radiation of the X-ray apparatus used for locating the site of the operation.

Claims

1. System for metering a hardenable mass for vertebroplasty and other similar bone treatments, said system comprising:

   a main metering body (1) with a screw-threaded propulsion shaft (3) coupled to a propulsion plunger (2);
   a side connector (16) arranged on the side wall of and near the proximal end of said main metering body for connection to a manual pump (14) for filling said main metering body with hardenable mass for vertebroplasty;
   a high pressure flexible tubular member (8);
   a distal end connector (7) arranged at the distal end of said main metering body and connectable to the proximal end of the flexible tubular member (8);
   a needle (22) for injection of said hardenable mass at the vertebroplasty site, said needle being connectable to the distal end of said flexible tubular member (8);
   a long stylet (21) suitable for an initial puncture operation and a short stylet (20) suitable for a second and final puncture operation at the ver-
tebroplasty site, each adapted to be insertable through said needle (22) when the needle is detached from the tubular member (8), the stylets having the same diameter and the ratio of their lengths being between 1.5:1 and 3:1.

Patentansprüche

1. Vorrichtung zum Dosieren einer aushärtbaren Masse für die Vertebroplastie und ähnliche Knochenbehandlungen, umfassend:

   einen Hauptdosierkörpener (1) mit einer Schraubgewinde-Vorschubwelle, die an einem Vorschubkolben (2) gekoppelt ist;

   einen Seitenanschluß (16), angeordnet an der Seitenwand und in der Nähe des proximalen Endes des Hauptdosierkörpers für den Anschluß einer Handpumpe (14) zum Einfüllen von aushärtbarer Masse für die Vertebroplastie in den Hauptdosierkörper;

   ein flexibles Hochdruck-Schlauchelement (8);

   einen Distalende-Anschluß (7), der an dem distalen Ende des Hauptdosierkörpers angeordnet und an das proximale Ende des flexiblen Schlauchelements (8) anschließbar ist;

   eine Nadel (22) zum Einspritzen der aushärtbaren Masse an den Vertebroplastie-Ort, wobei die Nadel an das distale Ende des flexiblen Schlauchelements anschließbar ist;

   eine lange Senknadel (21), geeignet für einen Anfangs-Punturvorgang, und eine kurze Senknadel (20), geeignet für einen zweiten und abschließenden Punturvorgang an dem Vertebroplastie-Ort, jeweils ausgebildet für das Einführen durch die Nadel (22), wenn die Nadel von dem Schlauchelement (8) gelöst ist, wobei die Senknadeln den gleichen Durchmesser besitzen und ihr Längenverhältnis zwischen 1,5:1 und 3:1 liegt.

Revendications

1. Système pour doser une masse durcissable pour la vertébroplastie et autres traitements osseux similaires, ledit système comprenant :

   un corps de dosage principal (1) avec un arbre de propulsion fileté (3) accouplé à un piston de propulsion (2) ;

   un raccord latéral (16) disposé sur la paroi la-