**Title:** BONE CEMENT INJECTION DEVICE, PARTICULARLY FOR VERTEBROPLASTY

**Abstract:** The invention relates to a bone cement (5) injection device (1), comprising a body (2) for clamping said device (1); a reservoir (4), fixed to said body (2), for containing bone cement (5) to be injected in bone tissue, said reservoir (4) having a hole (6) for exit of said bone cement (5); and a piston (7), slidable within said reservoir (4), suitable to push said bone cement (5) outside said reservoir (4) through said hole (6); characterised in that it comprises a chamber (13), said chamber (13) being in thermal exchange with said reservoir (4), said chamber (13) not communicating with said reservoir (4) and being suitable to contain a refrigerating substance for refrigerating the same bone cement (5) contained within said reservoir (4).
The present invention relates to a bone cement injection device for bone plasty.

More specifically, the invention concerns a device studied and realised for permitting bone cement injections during vertebroplasty interventions with a high precision and versatility.

As it is well known, at present, vertebroplasty technique concerns injection of bone cement (a polymethylacrylate) within one or more vertebral bodies of backbone of a patient.

Vertebroplasty is particularly used for treatment of fractures, osteoporosis and tumours, and can be applied to every subject, independently from age and sex.

Bone cement injection mainly occurs by suitable devices. They are substantially provided with a piston sliding within a reservoir filled with bone cement. Advancement of the piston is obtained by different systems. One of these is the one coupling piston with reservoir by screwing. Rotation of the piston permits a controlled injection of the cement within the bone tissue.

Known devices can further provide a cannula, that can be coupled with an end of the outlet hole of said reservoir, and provide a needle on the other end.

Said needle, that can have different sizes, is introduced from rear and percutaneously until the vertebral body to be subjected to treatment.

Thus, cement is injected through the needle, said cement being pushed by pressure exerted on the piston by the surgeon (radiologist, neurosurgeon, orthopaedic).

All the above procedure is carried out by radiological help, so as to guide introduction of the needle within the vertebral body, controlling the position of the cement introduced and the filling of the vertebral body.

Said technique was introduced about fifteen years ago, and it strongly developed in the western countries during the last five years. At present, it is strongly diffusing all over the world, as it is demonstrated by the fact that different devices exist on the market for carrying out vertebroplasty by injection of bone cement. Said known devices are
essentially divided into two categories: syringe devices and injection gun devices.

First kind of devices is very similar to a standard syringe for injection of liquids. Second kind generally comprises an ergonomic gun handle and an advancement system controlled by piston inside the bone cement reservoir.

After careful studies in this specific technical field, it has been determined that it is important during introduction of cement that:

- it is possible introducing bone cement against the resistance of the same cement, which is a material with a high viscosity, and of bone tissue of vertebral body;
- it is possible preventing return of cement within the chamber caused by high pressure exerted on bone tissue;
- it is possible gradually introducing cement, so that possible raising of pressure of the same cement is not excessive and such to create injuries to the vertebral body, causing damages to the surrounding organs;
- it is possible clasp the device and pushing cement by a single hand, so that the doctor can use the other hand for continuously manoeuvring the needle when carrying out complex procedures;
  - it is possible measuring pressure exerted by cement;
  - it is possible maintaining cement at a low temperature, so as to delay as more as possible priming of polymerisation of the same cement and its hardening.

Devices having all the above requisites are not presently available on the market. For example, device described in WO 9416951 A1 of BIOMET, INC., concerns an injection device wherein components of bone cement are placed within two chambers, insulated each other by a gasket, contained within a reservoir. Gasket, once removed, e.g. by heat, permits mixing the two components for realising bone cement.

Device has the shape of a gun and provides both bone cement reservoir, and the needle, communicating with the above chambers.

The above-mentioned device has the advantage of permitting high use versatility to the surgeon thanks to its ergonomic shape. Further, thanks to the system for mixing the components of bone cement, it is possible limiting preparation errors of the same cement.
However, said device does not permit controlling temperature and pressure of injected bone cement. Operator must realise, on the basis of his/her sensibility and experience, that cement is warming and thus polymerising, and that pressure exerted is too high, thus risking causing further pathological damages to the patient.

In view of the above, it is object of the present invention that of suggesting a device permitting controlling temperature and pressure of bone cement on the vertebral body during the injection.

A further object of the present invention is that device has an ergonomic handle with such dimensions to permit firm clasping by the hand fingers and a calibrated and gradual pushing of piston by palm.

It is therefore specific object of the present invention a bone cement injection device, comprising a body for clasping said device; a reservoir, fixed to said body, for containing bone cement to be injected in bone tissue, said reservoir having a hole for exit of said bone cement; and a piston, slidable within said reservoir, suitable to push said bone cement outside said reservoir through said hole; characterised in that it comprises a chamber, said chamber being in thermal exchange with said reservoir, said chamber not communicating with said reservoir and being suitable to contain a refrigerating substance for refrigerating the same bone cement contained within said reservoir.

Always according to the invention, said reservoir can have a cylindrical shape.

Still according to the invention, said chamber can have a toroidal shape, placed about said reservoir.

Further according to the invention, said refrigerating substance can be water.

Advantageously, according to the invention, said body can be comprised of two parts, on which the fingers can be placed making resistance, so as to place said reservoir between two fingers and actuating piston by the palm.

Always according to the invention, said device can comprise means for measuring pressure of said bone cement when it is within said reservoir.

Still according to the invention, said pressure measurement means are placed within said piston and can comprise a rod, one end of which is suitable to contact said bone cement, and elastic means with one
end coupled with said rod and the other one with said piston; due to the pressure of said bone cement, said elastic means vary the position of said rod with respect to the piston, overcoming resistance of said elastic means, displacement being indicated by a graduated scale.

Preferably, according to the invention, said elastic means can be a spring, coaxial with respect to said rod.

Furthermore, according to the invention, said pressure measurement means can comprise a rod, one end of which is suitable to contact said bone cement; a piezoelectric element, in correspondence of one end of said rod suitable to contact said bone cement, and signalling means, electrically connected with said piezoelectric element, suitable to indicate pressure reached by said bone cement contained within said reservoir; said piezoelectric element supplying said signalling means due to pressure exerted by said bone cement on said rod and on said piezoelectric element.

Advantageously according to the invention, said signalling means can comprise one or more LED diodes, eventually with different colours, to identify different pressure thresholds of said bone cement contained within said reservoir, or a warning horn.

Always according to the invention, said device can comprise piston blocking means, suitable to prevent moving back of piston due to the pressure exerted on said piston by said bone cement contained within said reservoir while injecting said bone cement.

Still according to the invention, said blocking means can comprise a hook coupled with said body by a pin and a button by further elastic means, said hook being kept engaged by saw teeth on said piston by said further elastic means; said hook permitting said piston entering within said reservoir, preventing its moving back following pressure of said bone cement contained within said reservoir, and said button, once actuated, releasing said hook from said saw teeth.

Furthermore, according to the invention, said further elastic means can be a spring.

Advantageously, according to the invention, said piston can comprise a surface for resting palm, in correspondence of the end not introduced within said reservoir.

Still according to the invention, a needle or cannula can be applied in said hole.
The present invention will be now described, for illustrative but not limitative purposes, according to its preferred embodiments, with particular reference to the figures of the enclosed drawings, wherein:

- figure 1 is a transparent perspective view of bone cement injection device for vertebroplasty;
- figure 2 is a longitudinal section of a particular of device of figure 1;
- figure 3 is a longitudinal section of a particular of device of figure 1;
- figure 4 shows a first embodiment of a pressure measurement device for bone cement contained within reservoir of device according to the invention; and
- figure 5 shows a second embodiment of a pressure measurement device for bone cement contained within reservoir of device according to the invention.

Making reference to figure 1, it is possible observing bone cement injection device 1 for vertebroplasty.

Device 1 provides a body 2 comprised of two parts 3, 3' realising an ergonomic handle, so as to be clasped with a hand by the operator.

Device also comprises a reservoir 4 containing bone cement 5. Said reservoir 4 has, in the present embodiment, a substantially cylindrical shape and a hole on one end.

A piston 7 can slide within reservoir 4, said piston having on its stem saw teeth 8.

Piston 7 provides at its rear end a surface 9 for resting palm. User puts reservoir 4, that is substantially perpendicular with respect to said handle realised between parts 3 ad 3' of body 2, among hand fingers, placing the fingers on the handle, and pushes piston 7 by palm acting on said surface 9.

A button 10 is provided on handling. It also has function of controlling moving back of piston 7.

In fact, a hook 11 is associated with said button 10, engaged with said teeth of said piston 7, so that said piston 7 can be pushed according to direction A, thus operator can inject bone cement 5 contained within the reservoir 4, but said piston 7 cannot go back.
Said hook 11 is fixed to said body 2 by a pin 12 about which it can rotate. Said hook 11 is coupled with said button 10, so as to rotate with respect to said pin 12 due to the action of the same button 10.

During the injection of bone cement 5, being it elastically compressible and due to the resistance exerted by bone tissue, it goes back into the reservoir 4. It causes that piston 7, during the injection step, tends going back. Therefore, it is necessary providing a system limiting this effect.

During advancement of piston 7 along direction A, hook 11 is engaged and kept engaged with saw teeth 8, e.g. by a spring, not shown in the figures, thus preventing reflux of bone cement 5 within reservoir 4.

Pushing button 10, hook 11 releases from saw teeth 8 against spring action, freeing piston 7 and permitting its sliding according to the opposite direction. It permits loading again reservoir 4 with new bone cement 5.

Thanks to the above handle, device 1 has the advantage of being usable by one hand only and permitting exploitation of natural force exerted when closing the fist. Applying said force, it is possible obtaining a gradual advancement. Operator can notice not return snapping of hook 11 preventing return of bone cement 5 just introduced.

Device 1 is provided with a toroidal chamber 13 about said reservoir 4 and not communicating with the same (see also figure 2). A refrigerating liquid can be introduced within said chamber 13. It permits slowing down or interrupting polymerisation of bone cement 5, thus preventing its hardening.

Usually, refrigerating liquid is water.

Device 1 also comprises a system for measuring pressure of bone cement 5 during injection. Said system is placed within end T of piston 7 inside said reservoir 4, as it can be observed from figure 3.

A first mechanical embodiment of the system for measuring pressure is shown in figure 4, wherein it is observed measurement device 14 to be inserted within piston 7. Said device 14 is provided with a spring 15 coaxial with respect to a rod 16. Said spring 15 has one end fixed to said piston 7 and the other one with said rod 16, the latter being slidable within said piston 7.

Pressure of the bone cement 5 varies position of rod 16 with respect to piston 7, overcoming resistance of spring 15. An indicator or
graduated scale 16' is provided in correspondence of one end of said rod 16, said graduated scale moving from a rest position indicating the value of pressure exerted by bone cement 5.

A second embodiment of device 14 is shown in figure 5, always provided in piston 7, said device in correspondence of its end 16a contacting with bone cement 5, said device 14 comprising a piezoelectric element 17. Further, LED (Light Emitting Diode) diodes 18 are placed on rod 16, said diodes having different colourations, and eventually also a sound emission device (not shown in the figures).

Piezoelectric elements 17, under pressure P of bone cement 5, supplies LED diodes 18 and sound emission device. Colour of LED 18 switching on and/or frequency of sound emitted by sound emission device indicate level of bone cement 5 pressure.

On the basis of the above specification, it can be noted that a basic feature of the present invention is that it includes a bone cement refrigeration system contained within the reservoir, thus preventing its polymerisation.

An advantage of the present invention is that device has reduced dimensions, similar to those of a big syringe, i.e. a 5 - 10 cc syringe.

Another advantage of the present invention is that the device permits making very different operations.

The present invention has been described for illustrative but not limitative purposes, according to its preferred embodiments, but it is to be understood that modifications and/or changes can be introduced by those skilled in the art without departing from the relevant scope as defined in the enclosed claims.
CLAIMS

1. Bone cement (5) injection device (1), comprising a body (2) for clasping said device (1); a reservoir (4), fixed to said body (2), for containing bone cement (5) to be injected in bone tissue, said reservoir (4) having a hole (6) for exit of said bone cement (5); and a piston (7), slidable within said reservoir (4), suitable to push said bone cement (5) outside said reservoir (4) through said hole (6); characterised in that it comprises a chamber (13), said chamber (13) being in thermal exchange with said reservoir (4), said chamber (13) not communicating with said reservoir (4) and being suitable to contain a refrigerating substance for refrigerating the same bone cement (5) contained within said reservoir (4).

2. Device (1) according to claim 1, characterised in that said reservoir has a cylindrical shape.

3. Device (1) according to one of the preceding claims, characterised in that said chamber (3) has a toroidal shape, placed about said reservoir (4).

4. Device (1) according to one of the preceding claims, characterised in that said refrigerating substance is water.

5. Device (1) according to one of the preceding claims, characterised in that said body (2) is comprised of two parts (3, 3'), on which the fingers can be placed making resistance, so as to place said reservoir (4) between two fingers and actuating piston (7) by the palm.

6. Device (1) according to one of the preceding claims, characterised in that said device (1) comprises means (14) for measuring pressure of said bone cement (5) when it is within said reservoir (4).

7. Device (1) according to one of the preceding claims, characterised in that said pressure measurement means (14) are placed within said piston and comprises a rod (16), one end of which is suitable to contact said bone cement (5), and elastic means (15) with one end coupled with said rod (16) and the other one with said piston (7); due to the pressure of said bone cement (5), said elastic means (15) vary the position of said rod (16) with respect to the piston (7), overcoming resistance of said elastic means (15), displacement being indicated by a graduated scale (16°).

8. Device (1) according to one of the preceding claims, characterised in that said elastic means are a spring (15).
10. Device (1) according to claim 9, characterised in that said spring (15) is coaxial with respect to said rod (16).

11. Device (1) according to one of the preceding claims, characterised in that said pressure measurement means (14) comprise a rod (16), one end of which is suitable to contact said bone cement (5); a piezoelectric element (17), in correspondence of one end (16a) of said rod (16) suitable to contact said bone cement (5), and signalling means (18), electrically connected with said piezoelectric element (17), suitable to indicate pressure reached by said bone cement (5) contained within said reservoir (4); said piezoelectric element (17) supplying said signalling means (18) due to pressure exerted by said bone cement (5) on said rod (16) and on said piezoelectric element (17).

12. Device (1) according to one of the preceding claims, characterised in that said signalling means comprise one or more LED diodes (18), eventually with different colours, to identify different pressure (P) thresholds of said bone cement (5) contained within said reservoir (4).

13. Device (1) according to one of the preceding claims 11 or 12, characterised in that said signalling means comprise an warning horn.

14. Device (1) according to one of the preceding claims, characterised in that said device (1) comprises piston (7) blocking means (8, 10, 11), suitable to prevent moving back of piston (7) due to the pressure (P) exerted on said piston (7) by said bone cement (5) contained within said reservoir (4) while injecting said bone cement (5).

15. Device (1) according to one of the preceding claims, characterised in that said blocking means can comprise a hook (11) coupled with said body (2) by a pin (12) and a button (10) by further elastic means, said hook (11) being kept engaged by saw teeth (8) on said piston (7) by said further elastic means; said hook (11) permitting said piston (7) entering within said reservoir (4), preventing its moving back following pressure of said bone cement (5) contained within said reservoir (4), and said button (10), once actuated, releasing said hook (11) from said saw teeth (8).

16. Device (1) according to claim 15, characterised in that said further elastic means are a spring.

17. Device (1) according to one of the preceding claims, characterised in that said piston (7) comprises a surface (9) for resting
palm, in correspondence of the end not introduced within said reservoir (4).

18. Device (1) according to one of the preceding claims, characterised in that a needle is applied in said hole (6).

19. Device (1) according to one of the preceding claims. 1 - 17, characterised in that a cannula is applied in said hole (6).

20. Device (1) according to each one of the preceding claims, substantially as illustrated and described.