ABSTRACT OF THE DISCLOSURE

A system for injecting fluids, such as local anesthetic liquids, into the soft tissues, particularly the gums, of a living body comprising a hand piece having a probe terminating in a jet orifice from which a high-velocity jet of liquid may be ejected from an ampule within the hand piece by movement of a piston within the hand piece and actuated by a liquid column in a flexible tube connected to a remote pneumatic motor. In the preferred form, the pneumatic motor includes a major piston and an auxiliary piston spring urged away from said major piston but movable, under the influence of pressure blow, to strike a hammer blow against said major piston in the direction of liquid-ejecting motion of said major piston, to start said major piston in such motion.

The present invention relates to a system for injecting fluids into the soft tissues of a living body without the use of a solid instrument for puncturing the skin. The principle of this type of injection has been in use for several years and its effectiveness for the hypodermic placement of anesthetics, medicaments and the like is recognized. However, apparatus for accomplishment such injection, which is usually referred to as “jet injection” has hitherto been heavy, cumbersome, difficult to apply and the restricted regions, expensive to produce and not well adapted to maintenance in reasonably sterile condition.

Because of the awkwardness of previously known apparatus, and because of other characteristics thereof, the principles of jet injection have not been applied to dental anesthesia, so far as I know, except in one series of experiments conducted under the auspices of the United States Armed Forces and reported in the United States Armed Forces Medical Journal, volume IX, No. 5, dated May 1958. In that series of experiments, the basic principles of previously-known apparatus for jet injection were used, the only significant modification being the provision of an elongated and bent probe attached to the main housing of such known apparatus. So far as I am advised, all of those experiments were reasonably successful, they have not since been extended and the principle of jet injection has not been adopted at all by the dental profession.

Among the disadvantages of previously-known apparatus for jet injection is the fact that such apparatus has universally depended upon heavy springs, pre-stressed by suitable “winding” means and trigger-released, to drive piston means for applying pressure and motive force to eject a fluid, through a restricted orifice, to accomplish the injection. Inevitably, when the spring-driven piston reaches the end of its stroke in such apparatus, at least a slight mechanical blow is delivered to the body of the apparatus; and since the apparatus is necessarily in contact with the patient, the patient will feel some physical shock. If the site of the injection is a patient’s jaw, even a slight mechanical shock is highly objectionable. The fall of the piston also necessarily produces some noise; and, again, if the apparatus is in contact with the patient’s jaw, that noise will be exaggerated in the patient’s hearing.

Among the objects of the present invention is the provision of jet injection apparatus in which motive force is applied to the fluid for injection through fluid motor means, in which the probe, the medicament-containing ampule and the piston directly associated with the ampule may be assembled in a small, light, readily-manipulable housing and that housing may be physically remote from the prime mover through which power is applied to the said piston. In its optimum form, the above mentioned assembly will be operatively connected to the prime mover through a flexible tube in which is contained a liquid column through which motion of the prime mover is transmitted to the piston element of the said assembly.

A further object of the invention is to provide apparatus of the character described in which all of the apparatus except the small, above mentioned assembly may be screened from the vision of the patient. A still further object of the invention is to provide such apparatus in which the prime mover will not deliver a physical shock to the hand-held assembly, in which the noise resulting from operation of the prime mover will not be transmitted to the hand-held unit and in which the patient will not be subjected either to physical shock or to exaggerated noise transmitted to his cranial bone structure through the probe.

Another object of the invention is to provide jet injection apparatus which is devoid of springs, which is simple and inexpensive in construction and in which the portions which must be brought into close contiguity to the patient may be readily dismounted for easy sterilization.

Still another object of the invention is to provide a novel ampule for containing the fluid to be injected, the particular construction of said ampule adapting it for highly advantageous use in the apparatus herein disclosed.

Still further objects of the invention will appear as the description proceeds.

To the accomplishment of the above and related objects, my invention may be embodied in the forms illustrated in the accompanying drawings, attention being called to the fact, however, that the drawings are illustrative only, and that change may be made in the specific constructions illustrated and described, so long as the scope of the appended claims is not violated.

FIG. 1 is a more or less diagrammatic illustration of a system embodying the present invention;

FIG. 2 is an enlarged, longitudinal section through a portion of the hand-held assembly forming a feature of the invention, and illustrating a novel ampule in place for use in the system;

FIG. 3 is a further-enlarged, fragmentary section illustrating details of construction of the distal end portion of a probe constituting an element of the invention, shown in use position and illustrating the mode of cooperation of the probe end with the soft tissues of the patient, in a somewhat idealized form;

FIG. 4 is an enlarged, axial section through the fluid motor constituting the prime mover of the system of the present invention; and

FIG. 5 is a section of the distal end portion of a modified form of probe.

Referring more particularly to the drawings, it will be seen that I have illustrated a tubular body 10, open at both ends and formed at one end with a reduced, externally threaded extension 11. A tubular probe is indicated generally by the reference numeral 12 and comprises a shank or distal portion 13 and an enlarged base 14 formed at its proximal end with a socket 15 having an internally threaded extension 16 for cooperative engagement with the extension 11 of the body 10. The probe is formed with an axial bore 17 in which is received, with an easy push fit, a hollow tube 18.

Advantageously, the hollow tube 18 may be essentially a conventional hypodermic needle whose bore 19 is of
the desired diameter, but whose unsharpened end has been spin down or tapered as at 20 to define a minute orifice 21. Such a needle is conventionally provided with a fixed bead 22 and the socket 15 is desirably formed with a seat 23 so that the shell 24 of the tube toward the distal end of the probe Shank 13. It will be perceived that, when the bead is so seated, the sharpened end 24 of the needle 18 is disposed within the socket 15 at a predetermined axial position and for a reason which will appear.

An ampule for use in the assembly is indicated generally by the reference numeral 25. It comprises a body 26 proportioned and designed for snug reception in the tubular body 10, and a neck 27 of reduced diameter adapted to extend beyond the open end of the reduced extension 11. The neck 27 is closed by a penetrable diaphragm 28, such as a rubberoid stopper, held in place by a preferably metal collar 29 externally gripping the neck of the ampule and centrally formed with a perforation 30. It will be readily perceived that, when the ampule is positioned in the body 10 and when the probe base 14 is moved by the coaction of the threads 11 and 16 to bring the socket 15 into communicating registry with the open end of the body 10, the sharpened end 24 of the needle 18 will penetrate the diaphragm 28 to enter the interior of the ampule and the base of the socket 15 will bear upon the collar 29 to hold the ampule positively against movement viewed in FIG. 2.

The opposite end of the ampule is closed by a stopper 31 which is designed and intended to act as a piston within the ampule, movable toward the left to eject the contents of the ampule through the needle 18. The piston 31 is formed of material which is resiliently transaxially compressible, and its equilibrium diameter somewhat exceeds the internal diameter of the ampule body 26. Preferably, the forward or distal end of the piston 31 is formed with a reduced extension 34 whose diameter is slightly less than the internal diameter of the ampule neck 27, and that extension is circumscribed by an annular groove 35 defining a forwardly-tapered annular lip 36. The piston 31 is inserted in the rear end of the ampule by peripherally contracting the lip 36, entering the lip in the ampule end, and then forcing the piston toward the left, as viewed in FIG. 2, until the major portion of the length of the piston is enclosed within the ampule body, but a minor portion 32 of the piston's length remains outside the ampule body. As the piston is so entered in the ampule body, of course it will be transaxially compressed, while the portion 32 will retain its equilibrium diameter. As a consequence, when the piston reaches its illustrated po-

suitable coupling means 50 connects the upper end of the chamber 45 with the bottom head 51 of a pneumatic motor indicated generally by the reference numeral 52. An end of the liner 53 has its distal end closed by an upper head 54 to define a chamber 55 which is entered by the stem 56 of the piston 49; and within said chamber 55, said stem carries a fourth piston 57 which is penetrating by one or more axially extending ports 58 and which is reciprocally moved within an effective diameter than the pistons 49 and 37. A head guide pin 59 is fixed to said fourth piston 57 and limits the path of travel, relative to the piston 57, of a fifth piston 60, a coiled spring 61 being confined between the pistons 57 and 60 to urge the piston 60 away from the piston 57. The head 51 is formed with a port 62 to which is connected a branch pipe 63, and the head 54 is formed with a port 64 to which is connected a branch pipe 65 for purposes which will appear.

In FIG. 4, the assembly comprising the pistons 49, 57 and 60, the stem 56 and the pin 59, is shown in normal, retracted position, with the pistons 50, 57 and 60 fully separated. The cylinder 53 is formed with a port 66 at a level which, when the said assembly is so retracted, registers with the space between the pistons 57 and 60. The reduced neck 67 of a valve housing 68 is threadedly received in the port 66. Said housing is formed to provide an internal seat 69 with which cooperates a valve member 70 yieldably held in closed contact with said seat by a coiled spring 71 confined between said valve member and an adjustable screw 72 threadedly received in that end of the housing 68 remote from the neck 67. It will be apparent that adjustment of the screw 72 will vary the effective force with which the spring 71 urges the valve member against the seat 69. A jam nut 73 may be provided to retain the screw 72 in any selected position of adjustment. An exhaust port 74 opens from the interior of the housing 68 to atmosphere.

A conduit 75 leads from a source (not shown) of air under pressure to a T-fitting 76 with which is connected an accumulator chamber 77, a pressure gauge 77' being in communication with said chamber. A pipe 78 leads from the fitting 76 to the inlet port 79 of a conventional four-way valve 80 having one delivery port 81 by which is connected the branch pipe 63 and a second delivery port 82 to which is connected the branch pipe 65. To the ex-

From the T-fitting 43 extends a pipe 87 with which communicates a pressure gauge 88, and said pipe leads, through a check valve 89, to a manually- operable pump 90 connected to a liquid reservoir 91. The pump 90 is operable to establish a continuous column of liquid within the tube 42, the tubular body 10 and the elongated chamber 45, providing an affirmative motion-transmitting link between the piston 49 and the piston 37; and it will be seen that said pump is further operable to establish a predetermined degree of pressure within said column.

In FIG. 3, I have illustrated what 1 presently consider to be an optimum form for the distal end face 92 of the probe 13. As shown, said end face 92 is formed with a central, outwardly flaring cavity 93 within which is disposed the tip of the needle 18 defining the jet orifice 21, said tip being substantially flush with the transaxial surface 92. The cavity 93 is circumscribed by an annular groove 94. Thus, when the probe face 92 is pressed against a region 95 of the soft tissue of a living body, it tends to establish a mound 96 protruding into the cavity 93 and centrally depressed by the tip 20 of the needle; and it tends to establish, as well, an annular mound 97 surrounding the mound 96. Thus, substantial normality of the axis of the tip region of the needle 18 relative to the surface of the tissue engaged by the needle tip is assured; and this is important because it has been discov-

ered that unless such normality is maintained, the issuu
ing jet of liquid is likely to lacerate the tissues instead of establishing the desired rectilinear channel within the tissues.

In FIG. 5, I have illustrated a fragment of a modified form of probe 12 in which the Shank 13 is bent to facilitate the location of its tip 92 in a restricted region near the body. Needles described above are quite flexible, and I have found that a needle 18 can be inserted in the bore 17” of such a probe without difficulty.

It is known that, for optimum practice of jet injection, the initial portion of the jet stream, which is to accomplish the "drilling," tissue-penetration of opening of a channel to a desired depth beneath the skin must be moving at extremely high velocity, and therefore under maximum pressure. This penetrating stream should be followed by an abrupt pressure decay to a much lower velocity whereby the following liquid may flow into the channel so defined and may disperse radially through the tissue layers, primarily near the bottom of the channel which has thus been prepared by the initial pressure stream.

As the injection nears completion, the pressure and velocity of the stream should again drop sharply to zero. While quantitative pressure and velocity values cannot be specifically prescribed, it can be stated that the pressure program which starts at zero p.s.i. should climb almost instantaneously to a maximum of, for instance, 8000 p.s.i. for drilling, should then fall off steeply to perhaps 3000 p.s.i. for injection and dispersal of the main charge and then should fall off steeply to zero p.s.i. at the end of the injection cycle.

In apparatus of the character here under consideration, pressure and velocity through a given orifice bear a direct relationship to each other and therefore it can be seen that regulation of the pressure which is brought to bear on the injection fluid (upstream from the orifice) will determine the velocity of injection and thus the depth of the channel and the amount of dispersal of the following liquid charge. The apparatus herein disclosed inherently will operate to accomplish the pressure program above described as optimum.

**Operation**

The apparatus is designed primarily for use with forty pound air pressure which is available in most dental offices and in the offices of many physicians; but of course it will be understood that, by adaptations which will be obvious to the skilled in the art, the fluid motor or pump 52 could be supplied from pressure cylinders or in any other way. When the apparatus is to be used, the probe 12 will be removed from the tubular body 10 and an ampule 25 containing the proper volume of the fluid to be injected will be inserted through the thus-opened end of the tubular body 10. The ampule is so proportioned and designed that, when its piston 31 is pressed against the distal end of the retracted piston stem 38, the ampule neck will project beyond the open end of the body 10. Now, the probe 12 is mounted on the body 10 by threading the extensions 16 and 11 together, and as the extension 16 approaches its seat, the sharpened end 24 of the needle 18 will pass through the port 30 in the collar 29 and will penetrate the diaphragm 28, thus opening the interior of the needle 18 to the contents of the ampule 25.

The column of liquid between the pistons 49 and 37, once established, will normally be maintained at all times. Just before the apparatus is to be used, the plunger of the pump 90 will be depressed a few times in order to pre-pressurize that column or hydraulic link to approximately 1 to 2 p.s.i. as indicated on the gauge 88 in order to be certain that the hydraulic link is "solid" throughout the system so that the movement of the piston 37 shall certainly be directly proportional to the movement of the piston 57. The lip 33 of the piston 31 provides sufficient resistance to leftward movement of the piston to retain said piston against such pre-pressurization of the hydraulic link.

The "normal" or rest condition of the valve 57 is such as to retain the piston assembly 57-60 in its illustrated position. The operator now places the distal face 92 of the probe 12 or 12' in proper position against the tissue to be injected, and trips a trigger (not shown) which actuates the control 84 to allow compressed air from the accumulator tank 77 through the branch pipe 65 into the upper end of the cylinder 53. Instantly, the fifth piston 60 is forced downward with an accelerating velocity, against the tendency of the spring 61, toward the upper face of the fourth piston 57. Air entrapped between the pistons 60 and 57, of course, freely moves upon the piston 57 and thence through the branch pipe 63 to be discharged through the exhaust pipe 85. By the time the piston 60 comes into contact with the piston 57, the piston 60 is moving at high velocity and its mass transmits a heavy initial hammer blow to the piston 57. If desired, the contacting surfaces of the pistons 60 and 57 may be cushioned with a nylon or Teflon pad to reduce the noise of contact. The hammer blow, of course, moves the piston 49 instantaneously, but through a very short distance, at extremely high velocity; and movement of the piston 49, of course, is transmitted through the hydraulic link to the piston 31 so that the jet of the fluid contained in the ampule 25 will be emitted at extremely high velocity through the minute orifice 21 to drill the desired channel in the tissues 95.

If, for instance, the effective area of the pistons 60 and 57 has a two inch diameter while the pistons 49 and 38 have one-quarter inch diameters, a pressure of 40 p.s.i. on the pistons 60 and 57 will be multiplied to approximately 8000 p.s.i. delivered to the piston 31; and of course the initial starting pressure exerted on the piston 31 will be considerably higher than that because of the inertial effect of the impetus of the pistons 60 upon the piston 57.

After the piston 60 has thus delivered its hammer blow to the piston 57, the two pistons will continue to move downwardly to force following portions of the contents of the ampule 25 to enter the channel defined in the soft tissues. Momentarily thereafter, the upper end of the piston 60 will clear the port 66 whereby a metered escape of a portion of the incoming air past the valve 70 will be established to aid in reducing the velocity of travel of the piston assembly, thus controlling the rate of decay of the velocity of discharge of the contents of the ampule.

During travel of the piston 31, of course, the lip 36 is forcibly pressed against the internal wall of the ampule to inhibit escape of the fluid past the piston. The provision of the reduced extension 34, which will enter the ampule neck 27 at the end of the piston stroke, provides for maximum use of the contents of the ampule. It is not intended, however, that the extension 34 shall have a fluid tight fit in the ampule neck; and the lip 36 will engage the shoulder of the ampule at the base of the neck to stop piston movement before the extension 34 can come into contact with the sharpened end 24 of the needle 18.

Preferably, the control 84 for the valve 80 will be of such character that, upon completion of the stroke of the piston 31, the valve 80 will be actuated to connect the pressure supply to the branch pipe 63 and connect the branch pipe 65 to exhaust, whereby the pistons 57 and 60 will be lifted. Such movement, of course, will be accompanied by retraction of the piston 37, whereupon the probe 12 may be disconnected from the exhaust pipe 85. The exhausted ampule may be removed and a new ampule may be inserted if the mechanism is to be promptly used again.

I claim as my invention:

1. A system for injecting fluids into the soft tissues of a living body, said system comprising a tubular body provided at one end with a probe formed with an axial orifice, an ampule containing a fluid to be injected, said ampule being received in said body in communication with said orifice, a first piston closing that end of said ampule remote from said orifice and movable toward said orifice to eject such fluid through said orifice, a second piston
reciprocally received in said body and bearing axially on said first piston, a flexible tube having one end connected to the other end of said body, an elongated chamber connected to the other end of said tube, a third piston reciprocably mounted in said chamber, a column of liquid in said flexible tube providing a driving connection between said third piston and said second piston, and a pneumatic motor operatively connected to drive said third piston toward said tubular body, said pneumatic motor comprising a cylinder, a fourth piston reciprocably mounted in said cylinder, operatively connected to said third piston and having an effective diameter significantly exceeding that of said first piston, a fifth piston reciprocably mounted in said cylinder and yieldably separated from said fourth piston in a direction remote from said third piston, said motor being formed to provide open communication between opposite sides of said fourth piston except when said fifth piston substantially engages said fourth piston, and said cylinder being provided with an inlet port at a point more remote from said third piston than is said fifth piston and with an outlet port at a point between said fourth piston and said third piston.

2. The system of claim 1 in which said fourth piston is axially ported to provide such open communication.

3. The system of claim 1 including a source of pneumatic fluid under pressure, conduit means connecting said source with said inlet port, and valve means disposed in said conduit means and controlling communication between said source and said inlet port.

4. The system of claim 1 in which said cylinder is provided with a bleed port normally located between said fourth piston and said fifth piston, said bleed port providing communication between the atmosphere and the interior of said cylinder only when said fourth and fifth pistons have been advanced.

5. The system of claim 4 including adjustable valve means associated with said bleed port to control the effective flow capacity of said bleed port.

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