United States Patent [19]

Nicholson et al.

[11] **3,901,221**

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[54] **PRESSURE CYCLE FOR STIMULATING BLOOD CIRCULATION IN THE LIMBS**

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[73] Assignee: **Clinical Technology International, Inc.,** Canton, Mass.

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[52] **U.S. Cl.** ..... **128/24 R**

[51] **Int. Cl.²** **A61H 1/00**

[58] **Field of Search** ..... 128/24 R, 60, 297–299, 128/44

[56] **References Cited**

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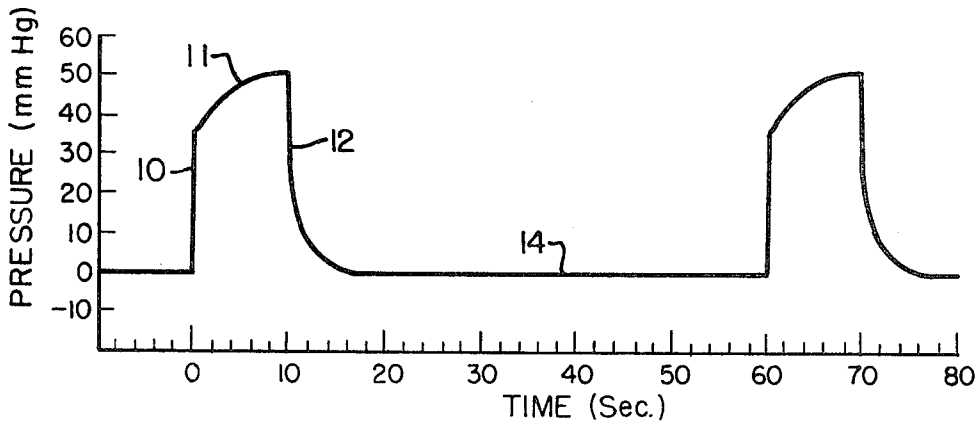
[57] **ABSTRACT**

A method of cycling pressure applied externally to a mammalian limb to obtain high amplitude surges of blood. A fast rise time followed by a holding period and a relatively long relaxation interval is utilized.

6 Claims, 4 Drawing Figures



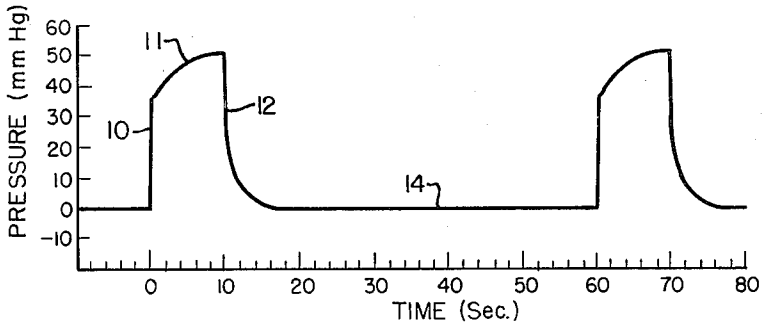


FIG. 1

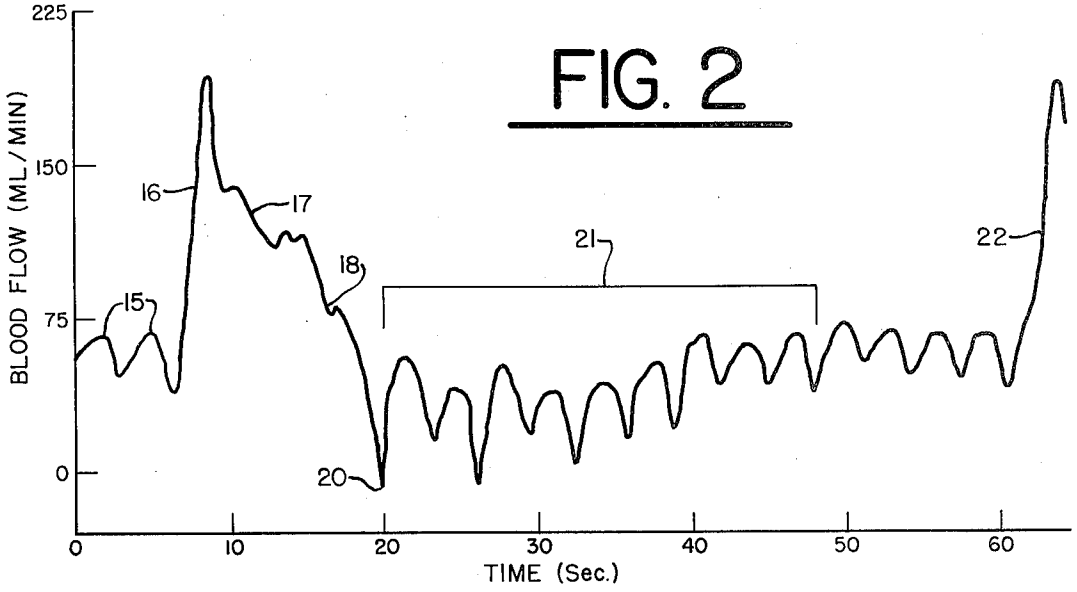


FIG. 2

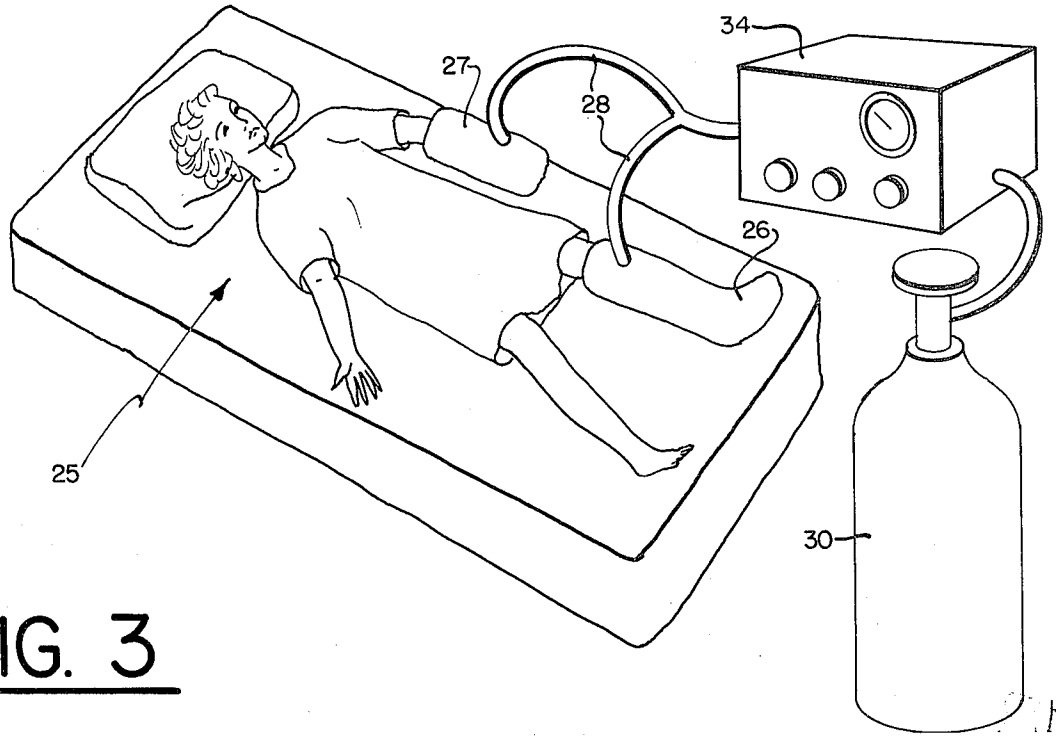


FIG. 3

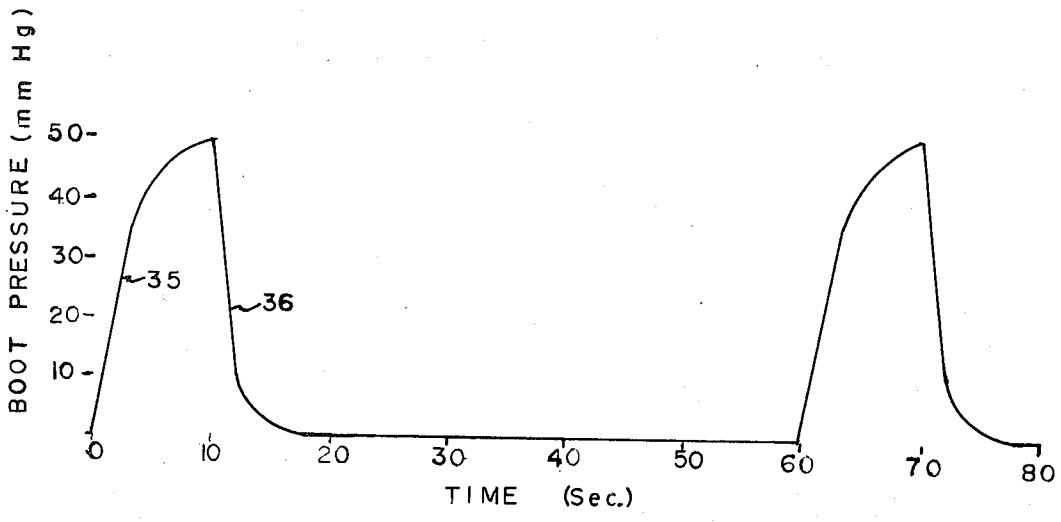

BOOT PRESSURE (mm Hg)
50
40
30
20
10
35
36
0
10
20
30
40
50
60
70
80
TIME (Sec.)

FIG. 4

PRESSURE CYCLE FOR STIMULATING BLOOD CIRCULATION IN THE LIMBS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to pressure garments used to apply cyclical pressure to mammalian extremities for the purpose of overcoming circulatory defficiency and particularly to a pressure cycling method.

2. Relation to the Prior Art

Roberts et al ("The Effect of Intermittently Applied External Pressure on the Haemodynamics of the Lower Limb in Man", British Journal of Surgery, 1972, Vol. 59, No. 3 March) disclosed that when pressure was applied to the legs with an inflatable plastic splint, increase in peak venous flow was directly proportional to the rate of pressure application. He purported to demonstrate that the peak increase in blood flow was maximal at an inflation rate of 10 mm. Hg. per second and the maximums in pulsatility and peak flow required an approximate interval of one minute between applications of pressure.

The primary interest in such dynamic stimulation of blood today is to combat the high rate of postoperative deep-vein thrombosis. The formation of dangerous thrombi is promoted by pockets of blood stasis. Blood stasis in the limbs is normally prevented by physical activity. Since surgery both prevents normal activity and exposes the system to coagulant stimulating effects, a high rate of thrombosis results. Increasing peak flow and pulsatility tends to overcome pockets of stasis.

While Roberts et al. disclose conditions of peak increased flow and maximum increase in pulsatility with respect to repetition intervals, they neglect the amplitude of flow during each pressure application concerning themselves only with peak increase.

SUMMARY OF THE INVENTION

In accordance with the present invention, it has been found that blood stasis pockets in the veins of mammalian extremities occur particularly behind the cusps which form the directional valves of the veins. It has been found that optimum disturbance of stasis behind these cusps is obtained when pulses of increased flow level have a maximum amplitude; that is, when as large a quantity of blood as is comfortable passes these cusps during a given pulse. It has been found that this result can be obtained by applying pressure through a pressure garment with a rise time of at least 10 mm of mercury per second and a holding time at the level of at least 30 mm of mercury for at least **8** seconds. A cycle period of one minute is near optimum.

Thus, it is an object of the present invention to provide a novel pressure cycling method for cycling pressure garments so as to overcome blood stasis in mammalian extremities.

It is a further object of the present invention to provide a method of pressure cycling for application to the external mammalian limb to maximize the amplitude of increased flow pulses by a pressure holding time of at least 8 seconds.

Further objects and features of the invention will become apparent upon reading the following description together with the drawing.

BRIEF DESCRIPTION OF THE DRAWING

FIG. **1** is a graph of a controller pressure cycle according to the invention.

FIG. **2** is a graph of femoral vein flow resulting from the pressure cycle of FIG. **1.**

FIG. **3** is a diagrammatical illustration depicting operation of the invention.

FIG. **4** is a graph of exemplary internal boot pressure resulting from the controller cycle of FIG. **1.**

DESCRIPTION OF THE PREFERRED EMBODIMENT:

FIG. **1** is a graph of pressure at the cyclic controller output in accordance with the preferred pressure cycle. When the pressure line is connected to the boot by operation of a valve at time zero, curve portion **10** indicates a rapid rise in less than 4 seconds to greater than 30 mm of mercury. The pressure then climbs gradually above 40 mm of mercury as indicated by curve **11** until 10 seconds is reached at which point the pressurizing valve is closed and the exhaust valve opening to the atmosphere is opened so that at 12 seconds the pressure has dropped below 10 mm as depicted by curve **12.** For the following 48 second time period, depicted by curve **14,** no pressure is applied allowing the blood veins to refill. The cycle repeats at 60 second intervals.

FIG. **2** depicts flow in the superficial femoral vein during the pressure cycle of FIG. **1.** Pulses **15** are normal blood pulsation provided by the heart. The normal flow level, in the particular instance depicted, averaged slightly over 50 milliliters per minute. Upon application of pressure from the pressure boot, the flow increased over an interval of approximately 2 seconds to approximately 195 milliliters per minute, as indicated by curve **16.** Curve **17** depicts the slow dropping off virtually immediately after reaching its peak. The pressure is released approximately at point **18** in the curve whereupon the flow drops to baseline level and flows for a short interval at a rate less than baseline level as indicated by inverted peak **20.** The blood flow characteristics remain below average normal blood flow for the following 28 seconds as indicated by portion **21** of the graph. The blood then returns to the normal flow characteristics prior to the next pressure pulse depicted by curve **22.**

The operation of the present invention is best understood by description of its utilization with a human being. Referring to FIG. **3,** a patient **25,** depicted as lying down, wears a boot **26** enclosing his foot and lower leg to the vicinity of the knee and also a mitten **27** enclosing his hand and forearm. Both boot and mitten are made of outer and inner layer with an inflatable space therebetween. The outer layer in each case has limited expandability so that, upon inflation, pressure is directed inward against the enclosed limb. Boot **26** and mitten **27** are inflated through hoses **28** from a pressure tank **30.** Pressure tank **30** may be connected to a pump for continuous duty use. Between pressure tank **30** and hoses **28** is a cyclic controller **34** for applying and releasing pressure in accordance with the graph in FIG. **1.**

FIG. **3** depicts operation of one boot and one mitten. The pressure cycling of the invention can be applied to any one or more of the four limbs.

FIG. **4** shows pressure measured inside a boot during a controller pressure cycle according to FIG. **1.** The

rise time inside the boot is 40 mm Hg. in approximately 4 seconds as shown in curve **35.** The fall time shown by curve **36** is likewise a little slower falling to 10 mm Hg. in about 2 seconds and then curving exponentially to 0 over the next 8 seconds.

While the invention has been described in accordance with a preferred embodiment, some latitude in the operation of the cycle is desirable depending on specific patients and conditions. A rapid boot pressure rise to at least 30 mm of mercury produces near optimum results when extended over 3 seconds. With particularly sensitive patients, this rise may be extended out to 5 seconds to reduce discomfort. Similarly, the maximum pressure attained is desirably between 40 and 50 mm of mercury, but a peak of 30 mm of mercury is sufficient for most cases. A range of 9 to 15 seconds is acceptable for the time interval between the beginning of pressure application and the onset of pressure release. For maximum effect it is desirable to delay the next application of pressure until the venous flow has returned to its normal equilibrium point, however, this differs with the individual patient and may vary within a fairly wide range with a total period between the cyclical commencement of pressure application being anywhere from about 40 to 80 seconds. A period of 60 seconds is suitable for most cases.

Using the pressure cycle depicted in FIG. **1,** it has been found that in an average case the total increase in blood flow over the 12 second interval beginning with the first application of pressure is approximately 30% more than if the pressure is released immediately after the peak pressure is attained. Thus the holding period after attaining the peak pressure has a significant effect.

Having described a preferred example of the invention along with an indication of the ranges of variation within its scope, the following claims set forth the scope to be covered.

We claim:

1. A method of overcoming circulatory stasis in mammalian limbs comprising:

a. Applying to a limb portion fluid pressure of at least 30 mm of mercury over a time interval of between 9 and 15 seconds with a rise time reaching 30 mm of mercury within 3 seconds;

b. keeping the applied pressure below 1 mm of mercury over a time interval of 30 to 60 seconds; and

c. cyclically repeating the above steps.

2. A method according to claim **1** wherein said pressure is applied for substantially 12 seconds and removed for substantially 48 seconds in repeating cyclical fashion.

3. A method according to claim **1** wherein said fluid pressure is in the range of 40 to 50 mm of mercury and has an inflation rate reaching at least 10 mm of mercury per second for at least 3 seconds.

4. A method according to claim **3** wherein said fluid is a gas.

5. A method according to claim **4** in which said fluid is applied by means of a plastic garment enclosing a limb extremity.

6. A method according to claim **4** wherein at the end of the said time interval over which the fluid pressure in the range of 40 to 50 mm of mercury is applied, the pressure is released falling to 10 mm of mercury in about 2 seconds and then more slowly to 0 mm of mercury.

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