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Mizrachy et al.

[11] **3,853,121**

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[54] **METHODS FOR REDUCING THE RISK OF INCURRING VENOUS THROMBOSIS**

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[52] **U.S. Cl.** ..... **128/33,** 128/303 R

[51] **Int. Cl.** **A61h 1/00**

[58] **Field of Search** ..... 128/33, 25 R, 64, 24 R, 128/303

[56] **References Cited**

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Primary Examiner—Lawrence W. Trapp

[57] **ABSTRACT**

A method for reducing the risk of incurring venous thrombosis in operative and post-operative patients. Vibration and/or massage is imparted to the legs of a patient during and after surgery. The vibration and/or massage aids muscular activity in the legs, which in turn stimulates the blood vessels reducing the probability of formation of a blood clot therein.

12 Claims, 5 Drawing Figures

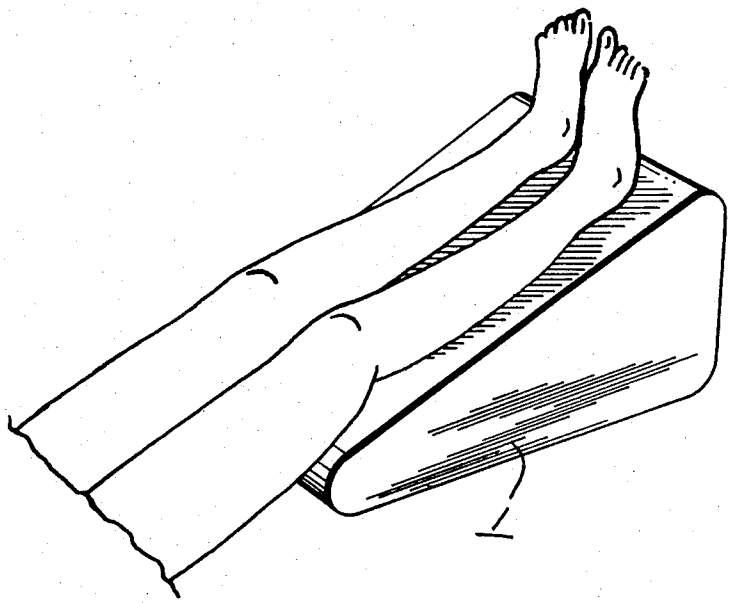


FIG. 1.

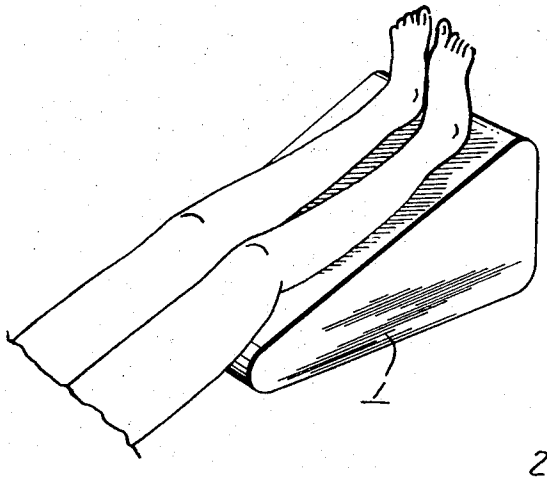


FIG. 2.

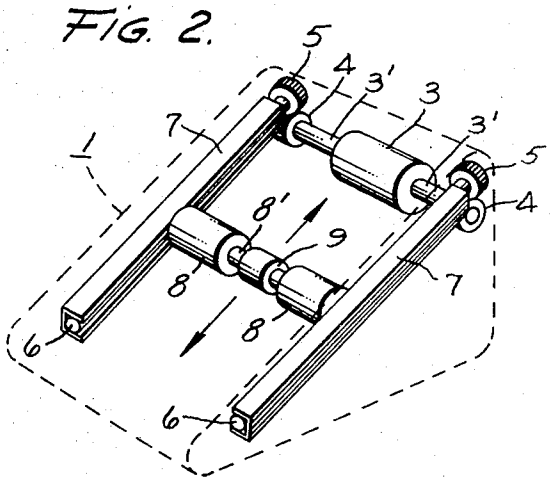


FIG. 3.

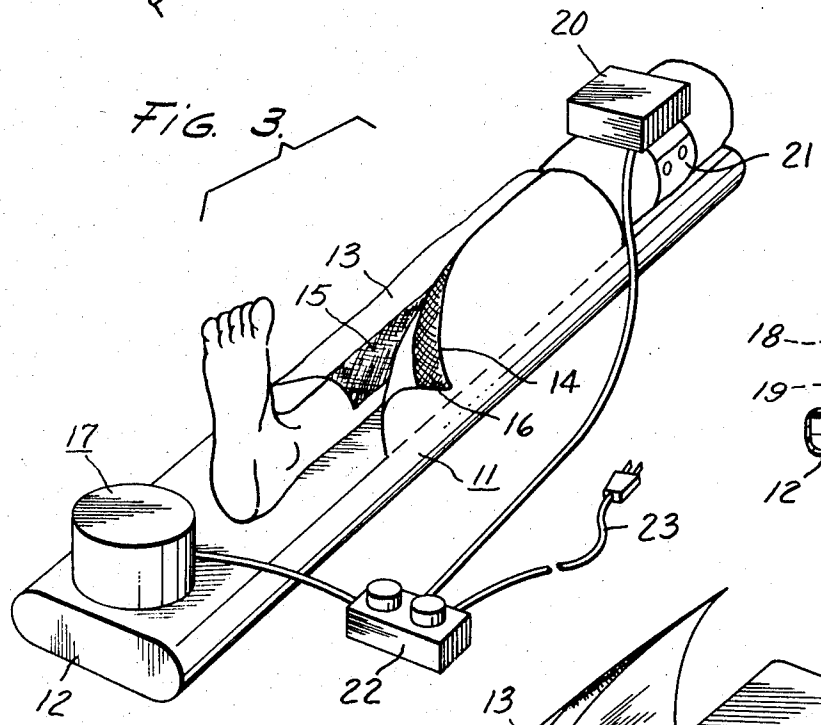


FIG. 5.

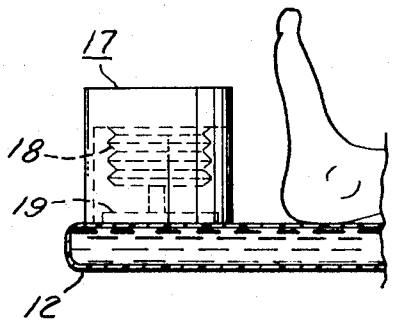
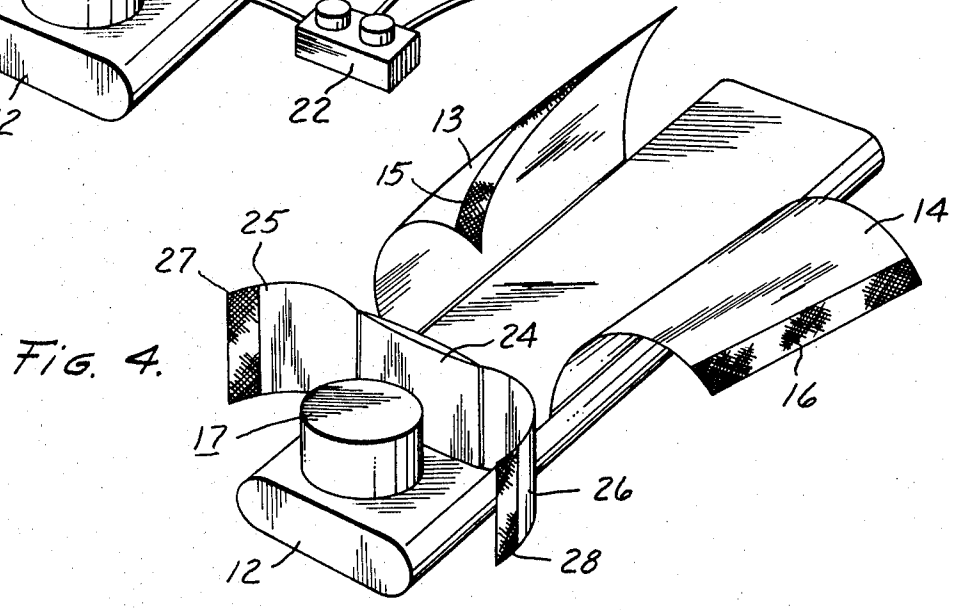


FIG. 4.



METHODS FOR REDUCING THE RISK OF INCURRING VENOUS THROMBOSIS

The invention pertains to a method for reducing the risk of incurring venous thrombosis and apparatus for applying the method. More particularly, the invention is for a method and apparatus for imparting vibration and/or massage to the legs of a patient during and after surgery.

It has been known for some time, that many patients surviving surgery would often develop venous thrombosis (blood clots) in their legs during post-operative recuperation. Usually this condition would present itself several days after surgery, and it was originally thought that the clotting was due to the inactivity of the bed-rested patient, whose legs were generally immobile while he lay in bed.

However, recent studies have shown that while the blood clot is usually recognized subsequent to the operation, it is actually during surgery that the beginnings, inception, or early formation of the blood clot occurs. In other words, the "seed" or nucleus of the clot is formed during surgery, when the patient's legs are completely flacid or inert of movement.

It has been shown that patients under "local" anesthesia, who are able to move their legs during surgery, are much less likely to suffer from venous thrombosis, than patients who are completely anesthetized, and whose legs exhibit no motion during this period.

Also, the lack of muscle tone in a patient's legs due to inadequate exercise or activity prior to surgery, seems to enhance the chances of his incurring a clotting condition.

What actually causes the formation of clots during surgery is unknown, but it is generally accepted that the thrombotic condition is related to muscular inactivity, although other factors may also play a role, such as (a) the effects of the anesthesia upon the blood and its ability to clot, and (b) changes in blood pressure, blood flow, or the general blood condition during surgery.

This invention is predicated upon the belief that the occurrence of venous thrombosis would be decidedly reduced, if the muscles of the patient's legs were stimulated during the operation, and to some extent thereafter. The stimulation of the muscles in turn stimulating the blood vessels.

The method of stimulation is accomplished by imparting vibration and/or massage to the patient's legs during surgery. As is presently known, vibration has never been used for this purpose, nor has massage been tried during surgery. It has been accepted practice in the past, for some sugeons who visit their post-operative patients, to stop awhile and manually massage their patients legs. Sometimes, this chore is delegated to the nurse attending the patient. More often, however, neither the surgeon or the attending nurse have ample time to provide the needed massage, because of the rigorousness of their daily schedules.

Therefore, there exists a need, not only during surgery, but also during post-operative care for a device or devices which will provide massage and/or vibration for the legs of the patient.

One means of providing vibration and/or massage comprises the use of a portable, fold-away, boot-like, leg-support which is filled with fluid. This device provides support to the legs of the patient similar in principle to the support provided by a "water-bed". The legs are made to rest upon a soft water cushion. The device

may be conveniently referred to as a "water-boot". The water (or other fluid) in the "water-boot" is induced to vibrate and/or pulsate, so as to cause the "water-boot" to flex and vibrate. The perturbations and displacements of the water are transmitted to the flexible plastic surface of the boot which supports the leg. The perturbations are in turn transmitted to the leg, thus providing the desired vibration and massage.

Another means of providing vibration and/or massage entails the use of an inclined leg-rest support containing movable massage inducing rollers and a vibration generator. The rollers and vibration generator are made to move back and forth under the legs of a patient resting thereon. As the rollers move, massage and vibration are imparted to the legs. The leg-rest is inclined as a means of aiding blood circulation and reducing clotting. This incline, however, makes it necessary to modify the operation table, where the need for antisepsis requires all personnel to remain at approximately the same height or level. Since the legs are raised by the incline, the personnel at that end of the operating table would naturally be working at a different height, thus requiring the aforementioned modification. This aspect of the use of the inclined leg-rest will not be discussed herein, since it is not considered as part of this invention.

Vibration is thought to be useful in two ways: (1) as a means to stimulate muscle activity, which in turn stimulates the blood vessels, and (2) as a direct means of stimulating circulation in the blood.

It is an object of this invention to provide stimulation to the legs of a patient during surgery so as to reduce the the risk of incurring venous thrombosis;

It is another object of this invention to aid muscular activity in the legs of a patient undergoing surgery;

It is yet another object of this invention to stimulate blood circulation in the legs of a patient during surgery;

It is still another object of this invention to provide improved and novel apparatuses for the care and treatment of patients during surgery and during post-operative or bed-ridden periods.

These and other objects of the invention will be better understood and will become more apparent with reference to the detailed description and the associated drawings, in which:

FIG. 1 is a perspective view of an inclined leg-rest support of this invention with a pair of legs resting thereon;

FIG. 2 is a phantom view of the leg-rest support of FIG. 1 showing a schematic view of the internal mechanism;

FIG. 3 is a perspective view of an alternate embodiment of FIG. 1 showing a so-called "water-boot" with a leg resting thereon;

FIG. 4 is a perspective view of the "water-boot" of FIG. 3 showing a modification thereto; and

FIG. 5 is a cut-away sectional side view of the "water-boot" of FIG. 3.

Generally speaking, the invention contemplates reducing the risk of incurring venous thrombosis in the legs of operative and post-operative patients by providing a support for the legs and applying stimulation to the legs to aid muscular activity.

The stimulation comprises vibration, massage, or a combination of the two. The stimulation is to be admin-

istered mainly during surgery, but may also have application in post-operative or bed-ridden situations.

Now referring to FIG. 1, an inclined leg-rest support member 1 is shown with a pair of legs resting thereon. The support comprises a wooden frame with a flexible plastic covering. Inside the leg-rest support (FIG. 2) are a pair of movable rollers 8, which are caused to move back and forth along the incline of the support 1 as shown by the arrows. The rollers positioned immediately below the plastic material, are biased spring-loaded) upwardly so as to be urged against the legs resting upon the support. As the rollers 8 move, they will impart massage to the legs of the patient. Positioned between rollers 8 is a vibration generator 9, which moves with the roller assembly so that a combination of massage and vibration may be administered. The roller assembly is mounted upon shaft 8', which is disposed between two guiding channels 7. The channels, respectively contain a traversing worm 6, which is driven by means of a motor 3 acting through two pairs of gears 4 and 5 as shown. The motor 3 drives shaft 3', which has gears 4 mounted at each end. The gears 4 in turn, drive two gears 5, each respectively attached to one of the traversing worms 6. The worms 6 are constructed similar to the traversing drives seen in fishing reels, wherein the fishing string is played back and forth as the reel rotates in the same direction. According to the same principle, the roller assembly of this invention is made to move back and forth within guide channels 7.

Another means of driving the assembly can be realized by having a regular worm, which reverses direction as the motor reverses in response to limit switches (not shown) situated at either end of the guide channels 7, and which are activated when the rollers reach the end positions in their travel.

FIG. 3 shows another means of supporting the legs of a patient in order to provide stimulation during surgery. A cushion 11 is shown supporting a leg. The size of the cushion is such that it can be designed for two legs as well as one without any difficulty. In practice, however, two supports may be used, one for each leg. The cushion 11 is made of flexible heat sealable plastic, which is fillable with fluid such as water in its hollow portion. The water-cushion 11 is not entirely filled with liquid, so that the water can be displaced therein, and the cushion can be made to flex without the danger of bursting. The water-cushion 11 works on a similar principle to that of the water-bed, in that flexible support is given to a body resting thereon. In this case, the leg is supported by cushion 11. The cushion is provided with two flaps 13 and 14, respectively. Flaps 13 and 14 wrap around the leg as shown, and are for the purpose of keeping the leg in snug engagement with the cushion member. The flaps are fastened to each other by means of Velcro stripping, shown by strips 15 and 16, respectively. Other fastening means can of course be employed instead, such as snaps, laces, zippers, etc. Velcro is useful in this application, because it is quickly and easily unfastened and fastened, and also allows for easy adjustment to different leg sizes.

At the far end of the cushion 11 is a non-supporting end 12 upon which a pulsation generating source 17 is mounted. This pulsation generator 17 is designed to push at the fluid in the cushion end 12 in a periodic manner, so that the fluid will be displaced from the end of the cushion. As a result, the cushion is caused to flex upon its upper leg supporting surface in an undulating manner. The perturbations created in the cushion are in turn imparted to the leg of the patient causing a massaging effect upon the legs. In other words, the displaced fluid will cause undulations to form in the flexible cushion surface, which travel the full length of the leg support.

FIG. 5 shows one possible way of displacing the fluid on the end of the cushion. A disc-shaped hammer 19 is forced downward against end 12, thus displacing the fluid in the end portion of the cushion. The hammer 19 is driven by a pneumatically controlled bellows 18, or by a concentric motor drive system. Pulsation unit 17 can be made integral with the cushion member, or separable thereto depending upon the pulsation system used.

Another means of displacing the fluid in periodic fashion is to have a bellows or diaphragm mounted within the fluid in the end 12 of the cushion. The bellows or diaphragm can be driven by motor, pneumatic, or hydraulic means depending upon the force and speed of operation required. If a motor drive is used, it can be electrically controlled by a control unit 22 shown in FIG. 3. The control unit 22 may be nothing more than a simple potentiometer, that apportions the electrical supply derived from an outlet through plug 23. The control unit 22 may be used to vary the intensity and/or the frequency of the pulsations.

Vibration can also be furnished in several different ways. One way is to mount one or more vibration generators 20 upon various portions of the leg, by means of straps 21. The control unit 22, may also have a separate control to vary the intensity and/or frequency of the vibration. Another means of imparting vibration is to rapidly pulse the fluid in the cushion, whereby vibration rather than displacement is the objective. The fluid will carry and transmit the vibration to the legs of the patient. Unit 17 may be constructed to have both a low speed and a high speed pulsation generator for the purpose of massage and/or vibration.

FIG. 4 shows another modification to the embodiment of FIG. 3 wherein an extra cushion 24 is provided for the foot of the patient. The cushion 24 is fluidically communicating with cushion 11. When cushion 11 pulsates or vibrates, cushion 24 will likewise pulsate or vibrate. Cushion 24 is designed to be in contact with the bottom of the foot, and is held in snug engagement therewith, by means of flaps 25 and 26, respectively. The flaps 25 and 26 wrap around the top of the foot in like fashion to flaps 13 and 14 about the leg. Flaps 25 and 26 are also fastened by means of Velcro strips 27 and 28, respectively. Other fastening means as aforementioned may also be employed.

The water-boot as this invention may be called, can be drained of its fluid, and conveniently folded away for quick storage. To this end, it is necessary that a valve be provided in the cushion for filling and draining purposes.

The cushion 11 may be contoured to conform to the underside of a leg to provide greater support, if so desired.

The cushion 11 may also be tapered so as to provide an incline for the purpose of increasing circulation of the blood.

Naturally, many modifications and changes as are described above will present themselves to the skilled practitioner in this art. The present invention is not

meant to be limited by any obvious modifications, and is deemed to embrace all these changes within the full scope and spirit of the invention, as presented by the appended claims.

What we claim is:

1. A method of reducing the risk of incurring venous thrombosis in the legs of operative, bedridden and post-operative patients, comprising the steps of:

A. supporting the legs of the patient so as to allow the legs to receive external stimuli during surgery;

B. anesthetizing the patient for the purpose of performing surgery; and

C. applying external stimulation to at least one leg of said patient while so anesthetized during surgery, so as to aid muscular activity in said leg, thereby reducing the risk of incurring venous thrombosis.

2. The method of claim **1,** wherein said external stimulation comprises applying vibration to said leg.

3. The method of claim **1,** wherein said external stimulation comprises applying massage to said leg.

4. The method of claim **1,** further comprising the step of:

C. elevating at least one leg of said patient during surgery.

5. The method of claim **1,** wherein said stimulation is additionally applied to the leg of said patient during post-operative care.

6. A method practiced during surgery which will reduce the risk of incurring venous thrombosis in the legs of operative patients, comprising the steps of:

A. supporting upon an operating table, at least one flexible leg supporting member containing a fluid;

B. supporting at least one leg of said operative patient upon said flexible leg supporting member;

C. during surgery of said patient, inducing perturbations in the fluid of said flexible leg supporting member;

D. during surgery of said patient, transmitting the perturbations from the fluid through said flexible leg supporting member, to the supported leg of said patient which is supported by said flexible leg supporting member; and

E. during surgery of said patient, stimulating the leg of the patient supported by said flexible leg supporting member by means of said perturbations in order to reduce the risk of incurring venous thrombosis.

7. The method of claim **6,** wherein said perturbations are vibratory perturbations.

8. The method of claim **6,** wherein both legs of said patient are supported and stimulated.

9. The method of claim **6,** wherein said stimulating perturbations provide massage to the leg being supported by said flexible leg supporting member during surgery.

10. A method practiced during surgery which will induce stimulation to the legs of operative patients, thereby reducing the risk of incurring venous thrombosis, said method comprising the steps of:

A. supporting upon an operating table, at least one flexible leg supporting member comprising stimulation generating means for generating vibratory stimulation, and stimulation generating means for generating massaging stimulation, the generated stimulation being imparted to at least one leg of an operative patient which is supported upon said flexible leg supporting member;

B. supporting at least one leg of said operative patient upon said flexible leg supporting member during surgery;

C. during surgery of said patient, activating at least one of said stimulation generating means in order to generate stimulation for the leg supported by said flexible leg supporting member; and

D. during surgery of said patient, imparting the generated stimulation to the leg supported by said flexible leg supporting member in order to reduce the risk of incurring venous thrombosis.

11. The method of claim **10,** wherein both of said stimulation generating means are activated during surgery of said patient.

12. The method of claim **10,** wherein both legs of the operative patient are supported and stimulated during surgery.

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