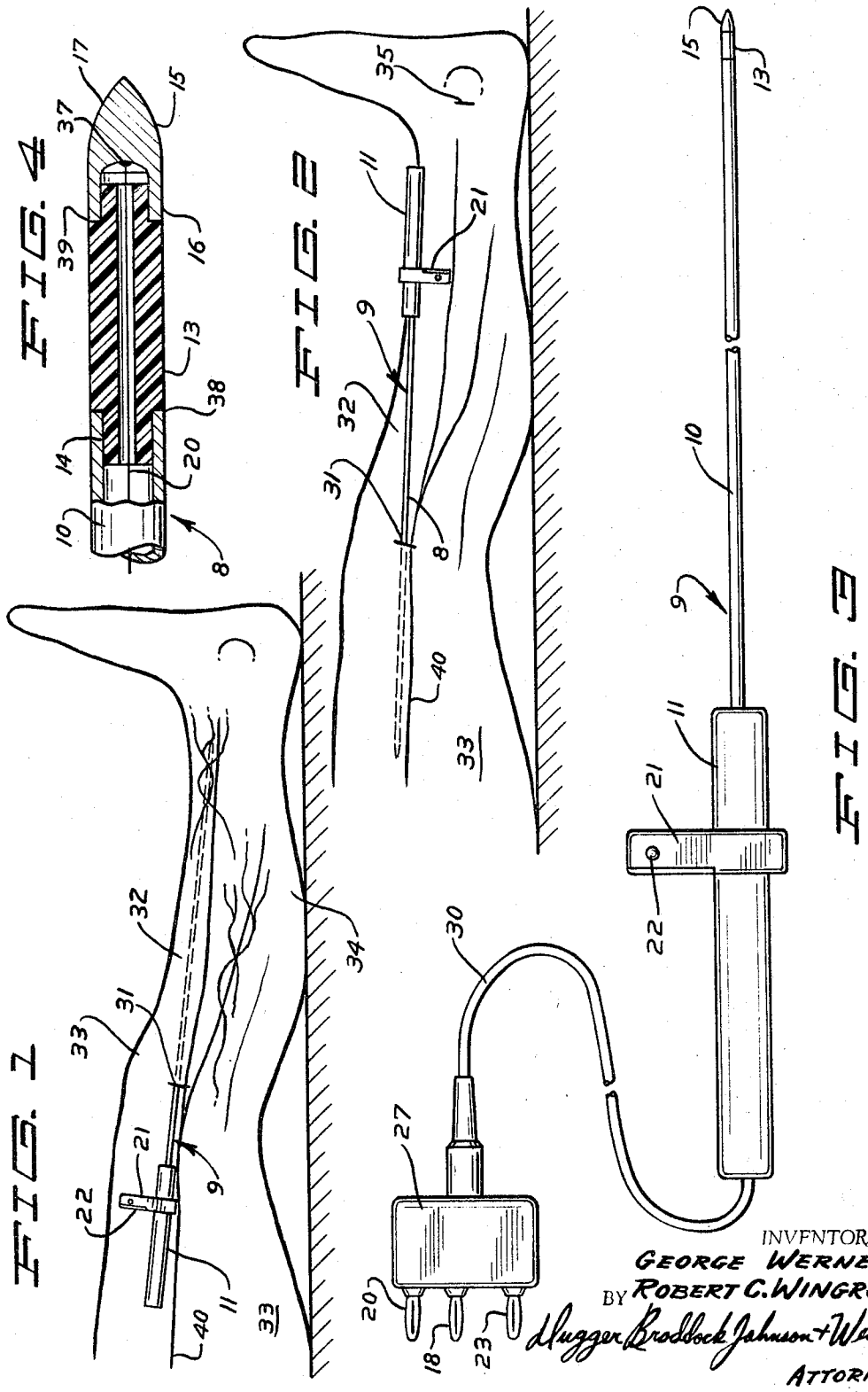
Jan. 31, 1967 G. WERNER ET AL 3,301,258

METHOD AND APPARATUS FOR TREATING VARICOSE VEINS

Filed Oct. 3, 1963 2 Sheets-Sheet 1



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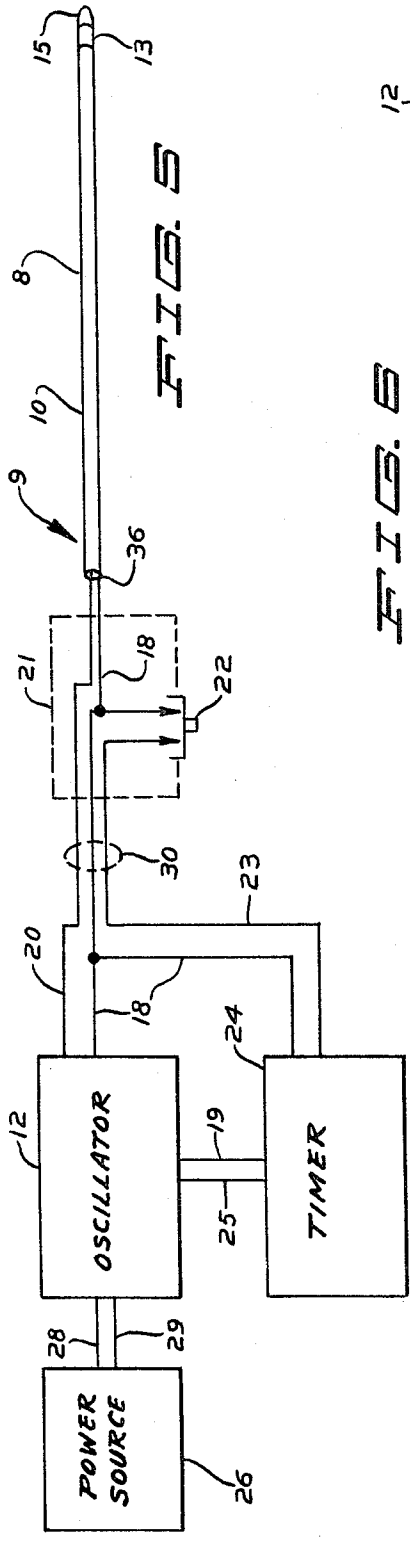

FIG. 5

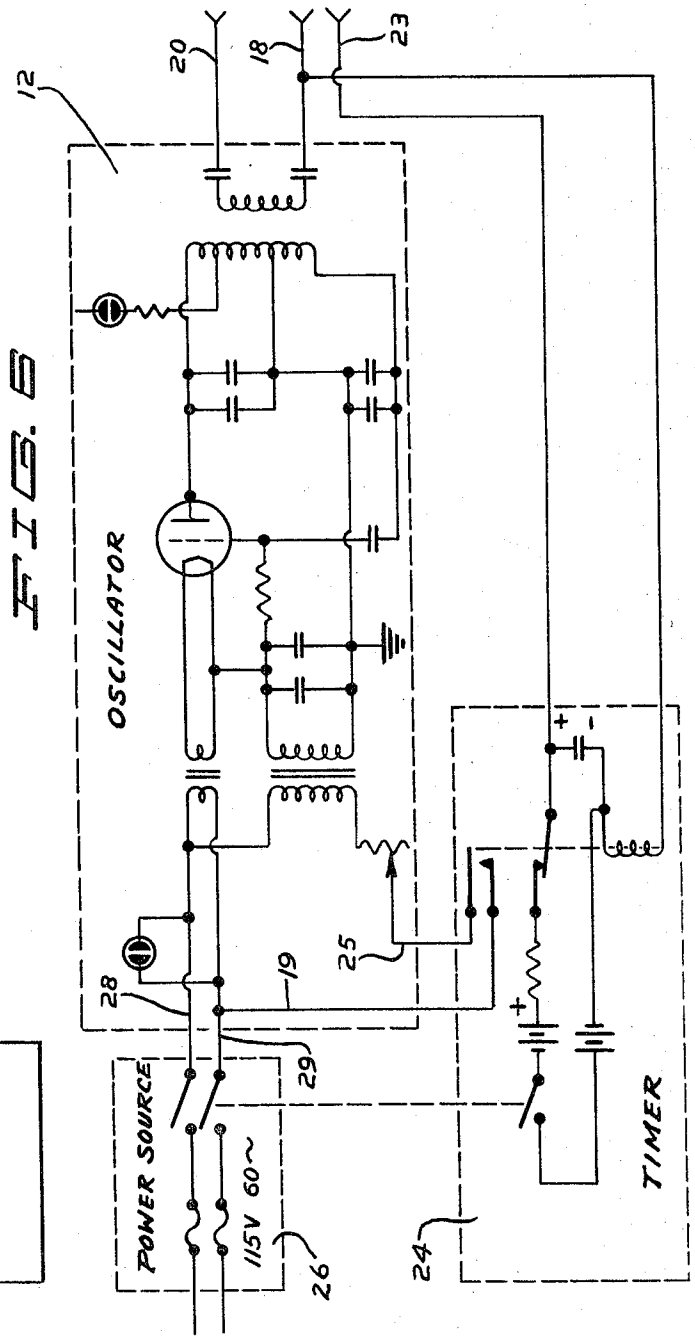

FIG. 6

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METHOD AND APPARATUS FOR TREATING VARICOSE VEINS

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This invention has relation to a method for treating varicose veins and to apparatus for performing that method.

In the method of the invention the veins are destroyed rather than removed. The destroyed veins are then consumed and absorbed by normal body process. This vein destruction is accomplished by application of intense localized heat applied through the instrumentality of a probe forced through the fatty subcutaneous tissue between the fascia and the skin. Two electrodes forming an outer end of the probe are spaced from and insulated from each other and an electric current is passed between them while they are in adjacent relationship to a portion of a vein to be destroyed. The duration of such current flow is brief and the amount of heat energy released by passage of such current is closely controlled.

This precisely located intense localized precisely controlled amount of heat energy destroys the vein but does not do permanent damage to the adjacent muscle or its covering fascia, does not permanently harm adjacent nerves and does not burn through to the skin. Instead the function of the nearby superficial sensory nerves is *temporarily* impaired and consequently no pain sensations from them are experienced by the patient during the healing process and some numbness is sometimes experienced by the patient during the postoperative healing process. However, as the tissue which has been heated heals, so do these nerves. As these nerves heal, they renew their function, so that full sensation is restored as healing is completed.

Varicose veins are enlarged twisted veins and are most commonly found on the lower leg and thigh. They sometimes occur following pregnancy, in persons whose occupations require standing positions, in the obese, and in persons having cogenitally defective venous valves.

The recognized proper treatment for this condition before the present invention has been to strip the dilated veins from the patient. The greater and short saphenous veins are usually straight tubes and can be easily removed using intraluminal strippers. However, the tortuous veins, the large venous plexuses, the veins in the anterior, lateral, and posterior thigh and calf do not permit the passage of strippers. Under procedures prevailing before the invention, these veins were removed by dissection through multiple incisions. This was and is tedious surgery and is often omitted or done inadequately. If such surgery is done thoroughly, the patient may be left with many incisional scars. If all these varicose veins are not removed, the patient has a persistence of the varicose vein condition.

While this stripping and excision procedure is the most successful operation to the date of this invention, and was the prevailing method of treating varicose veins, both doctors and patients have not been completely satisfied with it. The cosmetic damage occasioned by multiple disfiguring scars, and the persistence and recurrence of varicose veins where the surgery is not done thoroughly, and the intense and lingering pain associated with the operation and particularly with the recovery period have been factors contributing to the dissatisfaction of patients with the operation. For the surgeon, the operation can be long, arduous and tedious, and can sometimes actually tax or exceed the physical stamina of the surgeon.

It is an object of the method of the present invention and of the apparatus for performing that method to largely overcome these difficulties.

In the drawings, FIG. 1 is a side elevational view of a surgical instrument made according to the present invention showing its relationship to a patient's leg when used to destroy varicose veins in the lower leg;

FIG. 2 is a side elevational view of said instrument shown in position to destroy varicose veins in the thigh of a patient;

FIG. 3 is an enlarged side elevational view of the instrument;

FIG. 4 is a greatly enlarged transverse sectional view of an outer end of a probe of the instrument of the invention;

FIG. 5 is a block diagram of electrical components of apparatus of the invention; and

FIG. 6 is one useful form of circuit diagram of the components illustrated in FIG. 5.

Referring to the drawings and the numerals of reference thereon, an elongated probe **8** forms part of a surgical instrument referred to herein as probe assembly **9**. The probe **8**, as shown, includes a hollow cylindrical metallic tube **10** which forms a first electrode of the probe assembly. This first electrode **10** extends outwardly from an insulating handle **11** of the probe assembly, and an outer end of this first electrode fixedly receives a hollow tubular insulator **13** as at **14**. This insulator **13** fixedly receives, as at **16**, a metallic, hollow tip **15** which forms a second electrode of the probe assembly **9**. An outer, generally conical, portion of the second electrode **15** is designated **17**.

In addition to the probe assembly **9**, the electrical components of the apparatus of the invention includes an oscillator **12**, a timer **24** and an electrical power source **26**. The power source is connected to the oscillator through the instrumentality of wires **28** and **29**. The timer **24** is connected to the oscillator through the instrumentality of wires **19** and **25**. The output from the oscillator **12** is fed along a common wire **18** to an electrical contact with the first electrode **10** as at **36**. The output from the oscillator is also fed through a wire **20** which extends throughout the length of the electrode **10** in spaced, insulated relationship therefrom and is electrically connected to the second electrode **15** as at **37** (see FIG. 4).

Common wire **18** also extends to the timer **24** and to one terminal of a switch **22** which is included in a switch case **21** mounted on handle **11** to form part of the probe assembly **9**. The second terminal of the switch **22** is connected through a wire **23** to the timer **24**. As best seen in FIG. 3, these wires **18**, **20** and **23** leave the handle **11** of the probe assembly **9** as part of the cable **30** which terminates in a plug **27**. These wires extend outwardly from the plug in the form of banana-type connections. Obviously the oscillator **12** and the timer **24** can be mounted in a single case and the power supply to that case and the power supply to that case can come from any desired location such as a commercial power outlet. It is to be noted that the probe assembly **9**, including the switch **22** and the switch case **21** as well as the probe **8** and its insulator **13** and electrodes **10** and **15**, is a surgical instrument and as such is constructed so that it can be sterilized in an autoclave or by other known procedures. This, of course, is an imporatnt feature inasmuch as the instrument is used in surgery and, therefore, must be sterile.

The particular circuitry to be effective in performing the method of the invention can take any one of several forms; but a circuit which is particularly useful in performing the method of the invention is illustrated in FIG. 6.

In order to obtain the intense, highly localized, precisely controlled amount of heat energy at the precisely located point to effectively destroy adjacent varicose veins, it has been found satisfactory to utilize an oscillator which generates alternating current at the rate of 500 kilocycles per second. The circuitry is such that closing of the switch **22** by the surgeon will trigger the timer to introduce the output of the oscillator at about 200 volts between the first electrode **10** and the second electrode **15** for one-half of a second. While these values have been found to be the most satisfactory to date, it is to be understood that certain variations can be made within the spirit of the invention and the scope of the claims which follow. For example, in the anterior tibial area and behind the knee, the extreme thinness of the fatty subcutaneous layer increases the chance of burns through to the skin. In these areas, the frequency of the oscillator can be increased and the amplitude or duration of the impulse can be decreased. This can result in the release of the same amount of heat energy between the electrodes but the penetration of this heat will be restricted to even closer proximity to the surface of the insulator **13**, thus reducing the possibility of burning through the skin but still effectively destroying the adjacent veins.

Technique

The following technique has been found to be satisfactory for the performance of the method of the invention. Variation in this technique and even changes of technique will be possible within the spirit of the invention and the scope of the claims.

The patient is admitted to the hospital one day prior to surgery. On this day, every varicose vein on the patient's legs is carefully mapped out with indelible ink. In order to accomplish this careful marking, the patient stands on a stool in good light, and all varicose veins including small early varicose veins and large venous plexuses are carefully outlined. Perforators are identified and marked.

At surgery, a saphenous ligitation is done in a usual manner. The long saphenous vein, which is indicated as partially outlined on the patient's leg **32** at **40** in FIGS. 1 and 2, is picked up on the ankle or foot through a small incision **35** (see FIG. 2), and stripped to an inguinal incision (not shown). This can usually be done with one stripper. In cases where an additional incision is necessary, an incision **31** on the inner leg at the knee is utilized.

Whether or not this incision is necessary to strip the long or greater saphenous vein **40**, this incision **31** is utilized throughout the remainder of the operation as the site of the entrance of the probe **8** of the probe assembly **9**. This incision is a small stab incision made with a number 11 Bard-Parker blade. The probe **8** of the probe assembly **9** is forced through the subcutaneous layer under the skin to position under the indelible marking on the skin which represent the positioning of the varicose veins to be destroyed. Using these skin markings, the electrodes **10** and **15** at the outer end of the probe **8** are placed as close as possible to the vein. In doing this, the surgeon takes into consideration the fact that the current flow and hence the heat generated will be along the periphery of the insulator **13** between the electrodes **10** and **15**. The current will flow to and from the electrode **10** approximately at the circular line **38** around the probe. The current will flow to and from the electrode **15** approximately at the circular line **39**. Thus the area of generated heat will be cylindrical in shape and will extend between the lines **38** and **39**. The positioning of the probe may be under, over, alongside or through the vein. However, no effort is made to pass the probe down the lumen of the vein.

When the probe is properly positioned with respect to a portion of a vein to be destroyed, the switch **22** on handle **11** is touched by the surgeon, and a current flow to and from electrodes **10** and **15**. This flow causes an intense heat to be generated in the tissue through which it passes. Any vein adjacent the insulator **13** and in the area of this current flow will be effectively destroyed. The probe is then advanced or withdrawn a distance approximately equal to the length of the insulator **13** or to other position where it will be in immediate adjacent relationship to the next length of vein to be destroyed. When so positioned, the switch is again activated to heat the adjacent tissue and vein. The process is continued until all areas of tortuous veins are destroyed. As shown, the probe is approximately fifteen inches long and it can be passed long distances under the skin to destroy the veins.

In FIG. 1, the probe is shown as entering the leg **32** through the incision **31** to extend into the lower leg **34** and to destroy veins therein. Should it be necessary or desirable to destroy varicose veins in the thigh **33**, the probe **8** will be inserted through the incision **31** as shown in FIG. 2. The probe can be inserted either up or down the leg as many times as necessary to reach all veins to be destroyed.

Veins which have perforated through the fascia are known as perforators and are destroyed by pointing the probe down near the fascia in adjacent relationship to the afflicted vein. An increase in the length of the electrical impulse will often be advantageous in destroying such veins.

Throughout this fulguration period, the patient is kept in slight Trendelenburg position. This tends to empty the varicose veins of blood.

If the patient has incompetent, short, saphenous veins, these are stripped, as was the greater saphenous vein, in the conventional manner.

Upon completion of surgery, the legs are wrapped tightly with elastoplast. The foot of the bed is elevated, and the patients are encouraged to walk the evening of the day of surgery.

Postoperatively the only pain is in the inguinal incisions. As previously pointed out, lack of other pain is due to the anesthesia growing out of temporary impairment of the function of the sensory nerves adjacent the site of the electrodes of the probe. Part of the reason for the lack of pain during healing of the incisions **31** and **35** is the temporary impairment of the function of the nerves normally serving those areas due to application of heat to these nerves at other positions along the leg.

The inguinal incisions are made in the usual manner, and are closed in the usual manner. Thus the usual pain which accompanies healing of any such incision is to be expected. However, the incision **31** through which the probe is inserted is small enough so that no stitches are required. Typically the length of the incision will be about $\frac{3}{16}$ inch. The incision is closed with an adhesive bandage such as a Band-Aid. When this incision has healed, it will be, to all intents and purposes, invisible. The same can be said about the incision **35** and near the foot or ankle.

Because of the virtual invisibility of these lower incisions, the cosmetic aspects of the method of the invention are perfect. Consequently, models and other persons who cannot or will not have scar tissue on their legs are now candidates for this surgery, and such surgery has been performed on such patients with completely successful results from the cosmetic standpoint as well as other standpoints. Not only are there no scars as a result of the operation, but, after the destroyed veins have been absorbed and consumed by the normal processes of the body, the disappearance of the unsightly veins themselves enhances the appearance of the patient's legs.

Because the present operation consists only of passing the probe a number of times through the incision **31** to the site of the veins to be destroyed and of then passing current between the electrodes in the probe, the operation takes a much shorter time than formerly. Also, the operation by the method of the present invention is much more thoroughly performed as even the smallest of veins can be quickly destroyed without the necessity of separate incisions at the site of each such small vein.

What is claimed is:

1. The method of treating varicose veins including the steps of: making an incision through the cutaneous layer, inserting a probe into the incision and along the tissue of the subcutaneous layer to the site of a section of varicose vein to be treated, and passing an electric current through said tissue adjacent said section of vein between two electrodes of said probe, said current being such as to generate sufficient heat in said vein section to destroy said section.

2. The method as specified in claim 1 and the additional steps of: successively moving said probe to other sites of sections of varicose veins to be treated and passing an electric current through tissue adjacent each such site to destroy said vein sections.

3. The method of treating varicose veins in the legs of a patient including the steps of:

(a) causing the patient to stand;

(b) restricting the circulation in the legs of the patient to cause the veins to protrude;

(c) then indelibly tracing the pattern of the varicose veins in the patient's legs;

(d) preparing the patient for operative procedures;

(e) stripping varicose saphenous veins from the legs;

(f) placing the patient in a slight Trendelenburg position;

(g) making an incision through the cutaneous layer on the inside of the knee;

(h) inserting a probe into the incision and along the tissue of the subcutaneous layer to the site of a section of varicose vein to be treated;

(i) passing a high frequency electric current through said tissue adjacent said section of vein between two electrodes of said probe, said current being such as to generate sufficient heat in said vein section to destroy said section; and

(j) successively moving said probe to other sites of sections of varicose veins to be destroyed and passing a high frequency electric current through tissue adjacent each such site to destroy said vein sections.

4. Apparatus for treating varicose veins in an animate body including a slender cylindrical probe of a diameter to pass through an incision in the skin and along the subcutaneous layer of an animate body between the fascia and the skin, said probe having a first hollow cylindrical electrode, a cylindrical insulator concentric with, of the same diameter as, and extending forwardly from said first electrode, a second cylindrical electrode concentric with, of the same diameter as, and extending forwardly from said insulator; a first electrical connection extending the length of said probe through said first electrode in insulated relation thereto, through said insulator and into electrical contact with said second electrode; means for generating high frequency electrical energy; and circuit means for connecting the output of said generating means between said first electrode and said first electrical connection.

5. The combination as specified in claim 4, switch means for activating said generator means, and a timer operative upon actuation of said switch means for deactivating said generator means after a predetermined time interval.

6. The combination as specified in claim 4, switch means operative to activate said generator means, and metering means for effectively interrupting connection between said generating means and said electrodes when a predetermined amount of heat energy has been released between said electrodes.

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