

United States Patent [19]

[11] 3,862,630

Balamuth

[45] Jan. 28, 1975

- [54] **ULTRASONIC SURGICAL METHODS**
[75] Inventor: **Lewis Balamuth**, Southampton, N.Y.
[73] Assignee: **Ultrasonic Systems, Inc.**, Farmingdale, N.Y.
[22] Filed: **Dec. 10, 1973**
[21] Appl. No.: **423,061**

Related U.S. Application Data

- [62] Division of Ser. No. 179,459, Sept. 10, 1971, Pat. No. 3,794,040, which is a division of Ser. No. 678,649, Oct. 27, 1967, Pat. No. 3,636,943.
[52] U.S. Cl. **128/024 A, 128/334**
[51] Int. Cl. **A61h 1/00, A61b 17/12, A61n 3/00**
[58] Field of Search **128/024 A, 303.77, 325, 128/334, 399**

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3,794,040 2/1974 Balamuth 128/325 X

Primary Examiner—Channing L. Pace

[57] **ABSTRACT**

The method and apparatus of the invention use ultrasonic energy in the form of mechanical vibrations transmitted by a tool member to close off small severed blood vessels, such as in humans, by the formation of closures at the terminal portions thereof, and stop what is called "oozes", that requires constant mopping or cleaning techniques during an operation. This tool member may be in the form of a knife ultrasonically vibrated to simultaneously sever and close off respective terminal portions of the severed blood vessels while performing surgical procedures. The tool member, of a proper configuration, may also join together layers of tissue, including the walls of unsevered blood vessels, and with respect to the latter is foreseen as replacing the "tying off" of arteries and veins currently necessary in surgery.

3 Claims, 29 Drawing Figures

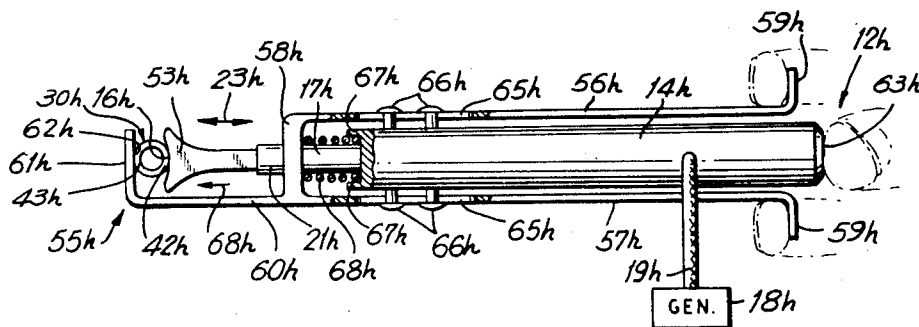
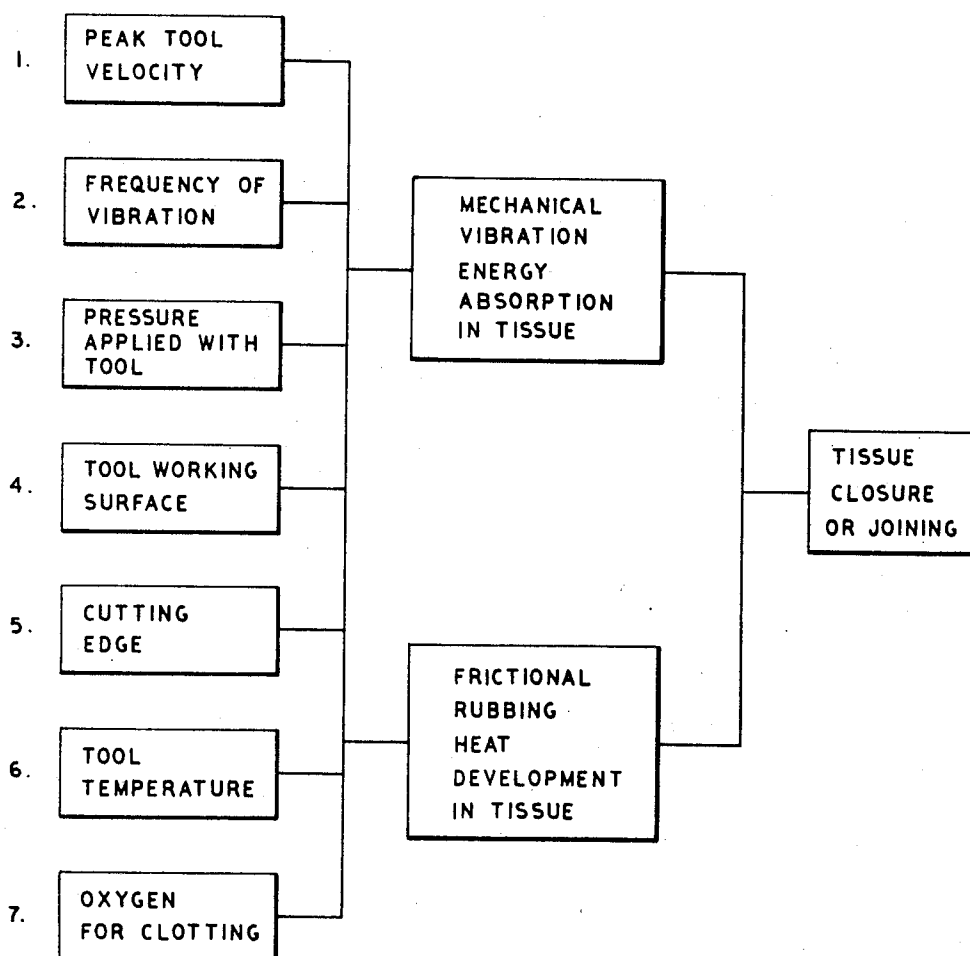


FIG. 1



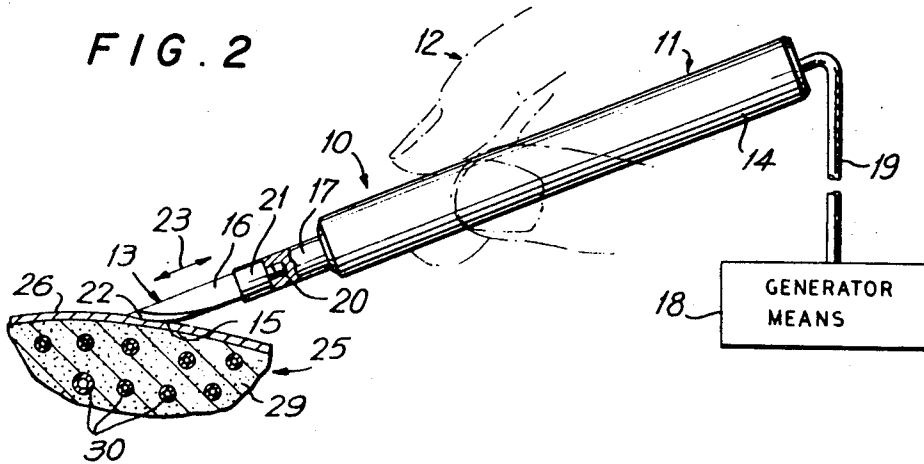


FIG. 4

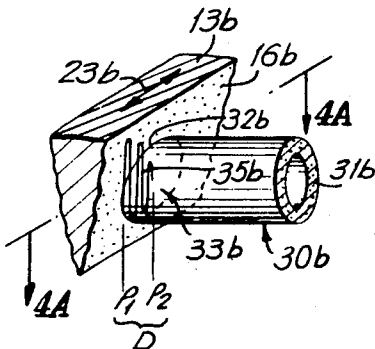


FIG. 4A

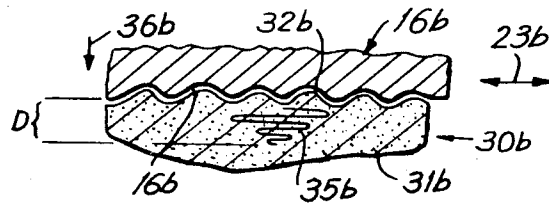


FIG. 4B

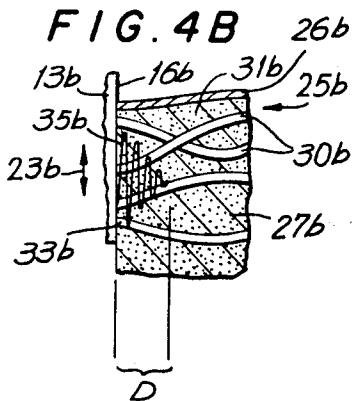


FIG. 4D

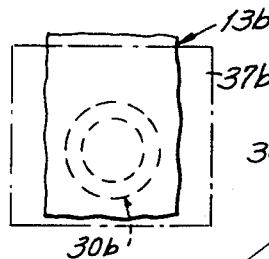


FIG. 4C

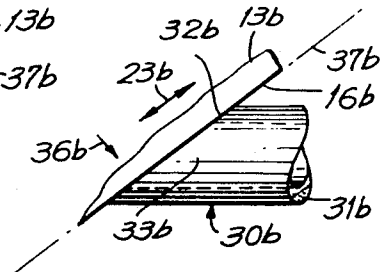


FIG. 3B

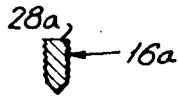


FIG. 3A

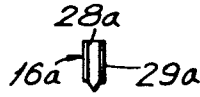


FIG. 3

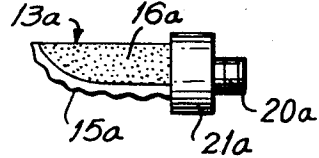


FIG. 5B

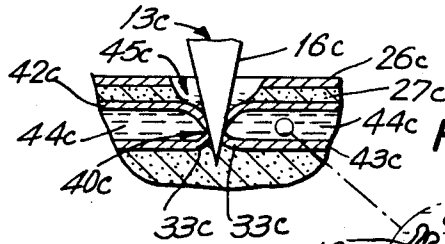


FIG. 5

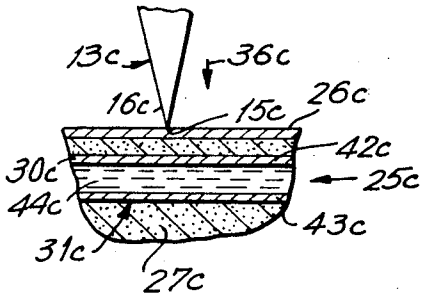


FIG. 5D

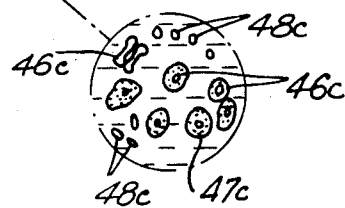


FIG. 5C

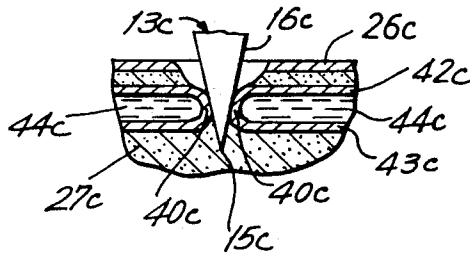


FIG. 5A

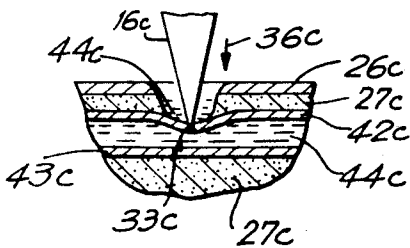


FIG. 6

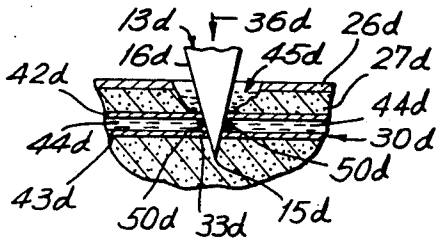


FIG. 7

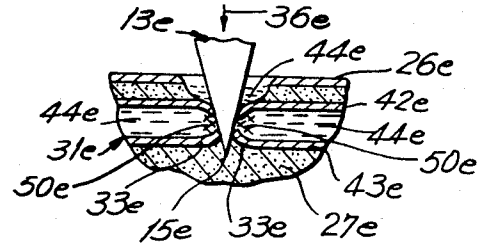


FIG. 6A

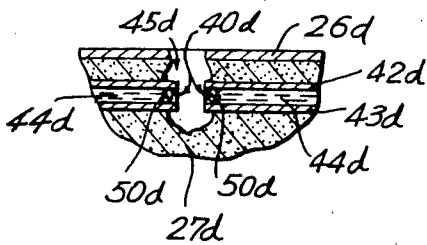


FIG. 7A

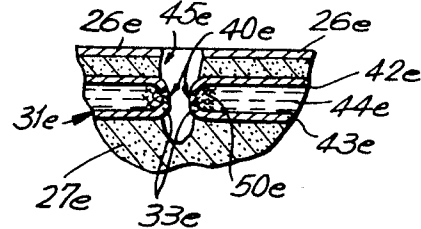


FIG. 8A

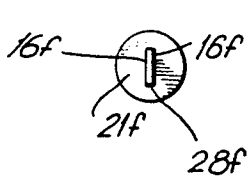


FIG. 8

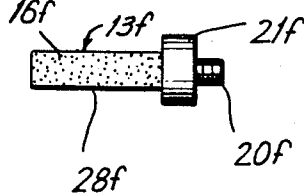


FIG. 9

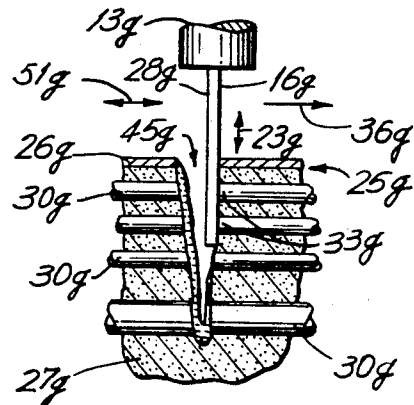


FIG. 11

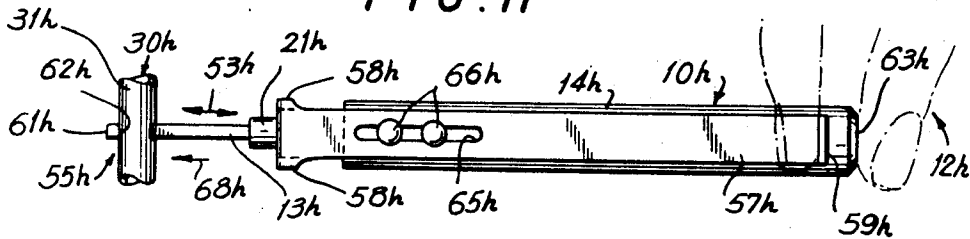


FIG. 10

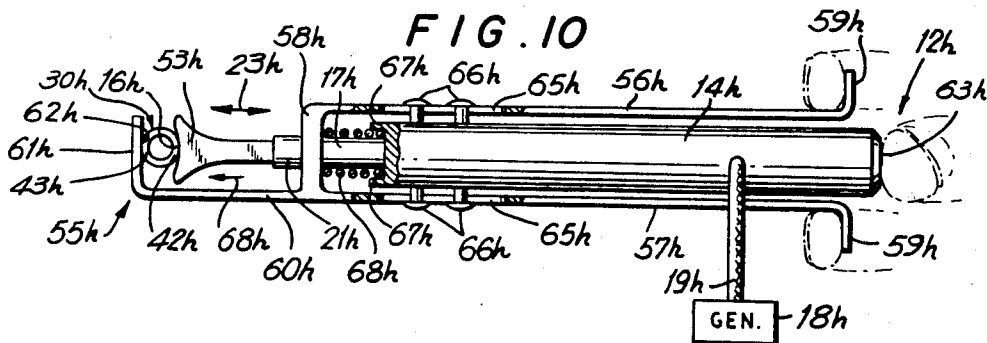


FIG. 12

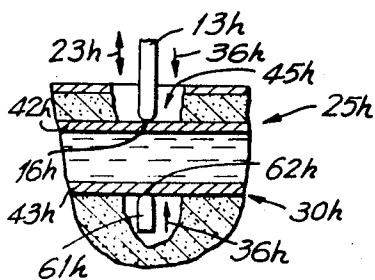


FIG. 12A

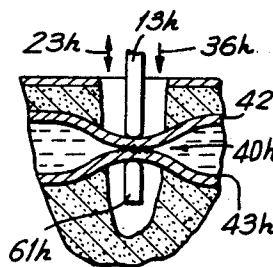


FIG. 12B

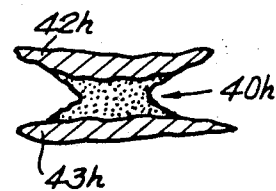


FIG. 12C

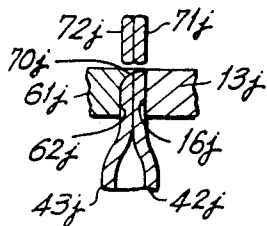
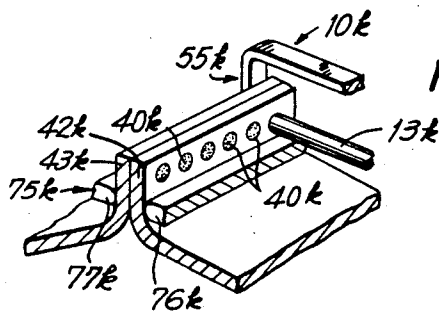


FIG. 12D



ULTRASONIC SURGICAL METHODS

CROSS-REFERENCE TO RELATED APPLICATION

This is a division of application Ser. No. 179,459, filed Sept. 10, 1971 now U.S. Pat. No. 3,794,040; which is a division of Ser. No. 678,649, Oct. 27, 1967 U.S. Pat. No. 3,636,943.

BACKGROUND AND SUMMARY OF THE INVENTION

The present invention relates generally to improvements in surgical procedures whereby ultrasonic energy is utilized and more particularly to methods and apparatus for closing off the terminal portions of severed blood vessels to stop or prevent the flow of blood therefrom during the surgical procedure and the joining of layers of tissue in biological organisms such as humans.

The outstanding and unexpected results obtained by the practice of the method and apparatus of the present invention, are attained by a series of features, steps and elements, working together in inter-related combination, and may be applied to biological organisms in general and particularly humans, and hence will be so illustrated and described with respect to humans.

Applicant has already participated in earlier developments which led to U.S. Pat. No. 3,086,288 covering the use of an ultrasonically vibrating scalpel or knife. The aim of that invention was to increase the ease with which a surgical knife could be used to cut organic tissues.

We are concerned in the present invention with new discoveries by applicant which allow dramatic improvements in the operation of high frequency vibrated knives, and also extend the use of the side area or working surface of a knife to perform a useful function, especially in relation to preventing or stopping bleeding.

Before proceeding to the details of the invention, let us first review briefly generally known facts of bleeding. The blood or circulatory system of the body (for warm blooded animals and humans) is comprised of two great and complex systems of arteries and veins. The arteries carry blood from the heart and these arteries divide in a complex network of smaller arteries or arterials, which in their turn connect to an extraordinarily complex network of very fine blood carrying tubes called capillaries. These capillaries are in communication with all the cells of the body and they provide the nutrients needed to feed these cells and they also supply the white blood cells needed to dispose of wastes and, in general, to police the cells and their environment in respect to unwanted substances and agents. After doing their job, the blood cells find their way back to the heart by means of a similar network of capillaries which join up to veinules or small veins, which in turn connect to veins which ultimately bring the blood back to the heart. There is also a lymph system which participates in this process, wherein again small tubes containing lymph (a kind of blood plasma with white corpuscles and waste products) convey this lymph through various strainers called lymph nodes and then, ultimately by means of the thoracic duct the purified lymph flow back into a large vein in the neck.

Now when the body is cut into at any location, in general a number of the tubes or vessels carrying blood are severed in this region. This severance will include many

capillaries, some small veins and arteries and in some cases even a regular artery or a vein or both. The capillaries comprise an area which is as much as 100,000 times the area of the arteries and veins, and thus it is seen that many more capillaries are involved per incision than any other vessels. The severing of capillaries produces an ooze of blood which must be mopped up or swabbed during an operation, while the larger blood vessels involved must be clamped or tied off to prevent bleeding during the surgery. The attending of these bleeding problems takes up about 67 percent of the time of most operations. It is a major aim of this invention to reduce this lost time considerably and at the same time to reduce the total loss of blood and to promote the healing of the wounds created. This is accomplished by the design of ultrasonic instruments so as to enhance those uses of ultrasonic energy needed to accelerate the desired objective, namely to stop bleeding.

Ordinarily, bleeding stops by virtue of the interaction between small bodies in the blood stream called platelets and the oxygen in the air, whereby the platelets disintegrate and form a network of fibers called fibrin which slow up and finally stop the blood flow by the formation of suitable clots. Heat may be used to accelerate this process, and in fact both electric cautery and hot wire cautery are used in controlling bleeding in some procedures. But these types of cautery produce, in addition to rapid clotting, an extensive destruction to all tissue, thereby requiring a long time in the healing. By means of ultrasonic energy it is possible to promote the clotting with far less damage, as will be disclosed herein, so that bleeding may be very quickly halted and at the same time, much quicker healing will take place.

Electric and hot-wire cautery as well as cryogenic techniques are not effective for the care of bleeding from veins and arteries and it is here that special tying-off methods or hemistatic clamping techniques are used. It is a further aim of this invention to teach how tying-off and clamping techniques may be replaced by utilizing ultrasonic energy in the proper way.

In all the ways whereby ultrasonic energy is used in this invention, the tool member supplying the energy executes vibrations of high frequency and small amplitude. Since the development of the ultrasonic knife, in part by present applicant, new alloys have become generally available which permit the maximum amplitude of vibration at a given frequency to be increased substantially. For example, in regular use a scalpel could be vibrated at 20 Kc/sec with a stroke of two to at most four thousandths of an inch. A larger stroke would cause a rapid fatigue failure of the ultrasonic motor driving the scalpel. With a new alloy of titanium (titanium with 6 Al - 4V is one such) it is possible to go to strokes as high as eight or ten thousandths of an inch. This means that the rubbing action of a single stroke may be greatly enhanced, because the peak velocity achieved during the stroke is more than double the peak velocities previously attainable on a practical basis.

This improvement led applicant into the development of procedures and tools whereby such large ultrasonic motions could be put to work to stop capillary bleeding while cutting the surrounding tissue. In order to understand this, let us consider the transfer of energy which occurs during cutting. Wherever the tissue comes into contact with the cutting tool or scalpel, the tool member is moving to and fro at high frequency

parallel to the surface of the tissue being severed. To the extent that there is good acoustic coupling between tissue and tool, there will be a transfer of shear waves into the tissue. But, tissue is of an acoustic nature as to be practically incapable of supporting high frequency shear waves. Therefore, the shear waves damp out very rapidly and dissipate their energy in the superficial tissue as heat. This promotes fibrin formation and clotting at the capillaries, while the damage to underlying tissue is minimal due to lack of penetration of this clotting energy. To the extent that the tool slips past the tissue during its to and fro motion, a rubbing action is set up, due to relative motion of tool and tissue and a frictional heat is generated at the tool tissue interface, again producing a heating and clotting action on the adjacent terminal portion of the opened capillaries and other blood vessels. Thus, entirely due to the ultrasonic to and fro motion of the tool, a cooperative dual effect is engendered whereby the "ooze" during an operation is effectively stopped while cutting.

Applicant has further found that the peak rubbing speed, which equals $\pi f x$ the peak to and fro stroke (f = frequency of tool) is relatively constant with respect to frequency. This is because the peak strain set up in the ultrasonic motor driving the cutting tool depends directly on the peak speed of the cutting tool and not on the peak frequency. Of course, this merely means that if one wishes to operate at a higher frequency, then one has to be content with a proportionately diminished to and fro stroke of the tool. In any case, due to the cooperative effect, above outlined, essentially all of the energy of the tool is used in local, superficial heating, except for that used to actually sever the tissue itself. This latter component of energy is only a small fraction of the total energy used.

In actual practice, applicant has discovered that, by texturing or roughening the side walls of the cutting tool, the transfer of superficial cauterizing energy is increased so as such for certain surgical procedures it is preferable to use scalpels whose working surfaces or side faces are roughened rather than very smooth. The same principle applies to spatulate tools wherein no cutting is contemplated, but the tool is designed primarily to cauterize an already opened bed of blood vessels such as capillaries in a wound. In the case of the spatulate tool the amount of energy transfer may be increased by pressing the spatula tool working surface, while vibrating, with increased pressure against the wound to apply a compressive force for the transmission of the shear waves or increasing the frictional rubbing. Applicant has also discovered, that although it is not essential, it is nevertheless desirable to supply the cutting edge of a knife or scalpel with a set of small serrations. This further aids in clotting, and permits faster cutting, while at the same time halting capillary bleeding.

Now, in addition to all of the above there are still additional aids arising from the use of ultrasonic energy during the cutting operation. This arises because the collagenous substances in the walls of the capillaries and also in those of veins and arteries, are capable of being joined or sealed together by the application of said high frequency energy. In fact, it is just this property which makes it possible to close off a vein or an artery by clamping it in a specially designed ultrasonic instrument, so that the walls of said blood vessel are briefly clamped while vibrating one or both of the tool

jaws. Since this same principle applies to other soft body tissue such as the skin, this same type of tool may be used in place of the conventional suturing which is used in closing incisions in surgical procedures.

Thus, it may be seen that we are dealing with a highly complicated set of phenomena in practicing applicant's method of bloodless surgery. At this time, it is not known quantitatively just how large a role is played by each factor, such as shear wave absorption, frictional heat production and tissue sealing. The point is that by employing ultrasonic motors capable of producing generally higher strokes than previously available, the combination of effects permits for the first time, true bloodless surgical procedure by ultrasonic means. Where extremely fast procedures are essential, one may also resort to auxiliary heating of the vibrating tool member, but only to sub-cautery temperatures. This temperature is preferably above room temperature but below a temperature that would normally burn the tissue. This may be accomplished conventionally, or in accordance with the method disclosed in U.S. Pat No. 3,321,558 in which applicant is a co-inventor.

OBJECTIVES OF THE INVENTION

25 An object of the present invention is to provide an improved method and apparatus for forming surgical procedures with ultrasonic energy.

Another object of the present invention is to provide 30 an improved method and apparatus for securing together layers of tissue in biological organisms, such as humans.

Yet another object of the present invention is to provide an improved method and apparatus for forming 35 closures at the severed terminal portions of blood vessels in vivo, which blood vessels are in the general neighborhood of what are called capillaries, so as to prevent "ooze," which requires contact mopping or cleansing during surgical operations.

40 A further object of the present invention is to provide improved method and apparatus for permanently or temporarily closing off blood vessels so as to replace the "tying off" of arteries and veins currently necessary in surgery.

45 Still another object of the present invention is to provide a method and apparatus of bloodless surgery which combines the surgical cutting of tissue and a closing off of the severed blood vessels to prevent the "ooze" normally associated with operations.

50 Yet still another object of the present invention is to provide a method and apparatus for simultaneously joining and trimming, as by cutting, a large blood vessel.

55 Yet still a further object of the present invention is to provide an improved method and apparatus for ultrasonically joining together layers of tissue.

60 Still a further object of the present invention is to provide an improved method and apparatus for increasing the flow of oxygen to the terminal portion of the severed blood vessel to expedite the clotting of the blood thereat.

Still yet a further object of the present invention is to provide an improved sealing apparatus for joining together layers of human tissue.

65 Still yet a further object of the present invention is to provide specially designed tools adapted to be ultrasonically vibrated and employed in surgical procedures.

Other objects and advantages of this invention will become apparent as the disclosure proceeds.

BRIEF DESCRIPTION OF THE DRAWINGS

Although the characteristic features of this invention will be particularly pointed out in the claims, the invention itself, and the manner in which it may be made and used, may be better understood by referring to the following description taken in connection with the accompanying drawings forming a part hereof, wherein like reference numerals refer to like parts throughout the several views and in which:

FIG. 1 is a chart indicating the relationship of the principal factors affecting the practicing of the present invention for surgical procedures;

FIG. 2 is an assembled somewhat schematic view of an ultrasonic motor generator system of the type in which the motor is capable of being hand held and manipulated, for driving a tool member adapted to engage the biological organism for performing a surgical procedure, and which in the present instance the tool member is illustrated as a knife for severing blood vessels, the latter shown on a greatly enlarged scale for discussion purposes;

FIG. 3 is a side view of an ultrasonic tool member having a textured working surface in accordance with the present invention;

FIGS. 3A and 3B are end views of the tool member in FIG. 3 and illustrates two preferred ways of obtaining the textured working surface;

FIG. 4 is a greatly enlarged schematic representation of a portion of a tool member with its working surface in engagement with the terminal portion of a blood vessel for forming a closure thereat to prevent the flow of blood from said terminal portion;

FIG. 4A is an enlarged section view taken along line 4A-4A of FIG. 4 to illustrate the interfacial contact between the tool working surface and blood vessel for the transmission of frictional energy and shear waves for localized heating of the terminal portion;

FIG. 4B is a greatly enlarged schematic representation illustrating an ultrasonically vibrating tool member engaging a severed portion of tissue for simultaneously forming a plurality of closures at the terminal portions thereof;

FIG. 4C is a greatly enlarged schematic representation illustrating the angular relationship between the tool member and blood vessel which defines a terminal plane that may define an extreme angle with the axis of the blood vessel and still obtain the desired results of the present invention;

FIG. 4D is an end view of the tool member and blood vessel of FIG. 4C;

FIGS. 5, 5A, 5B and 5C are enlarged schematic representations in cross-section of the method of forming a closure at the terminal portion of a blood vessel in which the side walls thereof are joined together;

FIG. 5D is an extremely enlarged view of a blood specimen to illustrate some of the important components thereof;

FIGS. 6 and 6A are enlarged schematic representations in cross-section of the method of forming a closure at the terminal portion of a blood vessel in which the closure is formed by partially converging the side walls thereof and forming a blood clot in the reduced opening;

FIGS. 7 and 7A are enlarged schematic representations in cross-section of the method of forming a closure at the terminal portion of a blood vessel in which the closure is formed by primarily forming a blood clot at the terminal portion thereof;

FIGS. 8 and 8A are side and elevational views respectively, of a spatula tool member having a textured working surface for ultrasonic cautery;

FIG. 9 is an enlarged sectional view illustrating the forming of a plurality of closures on respective terminal portions in an open wound by the use of a spatula shaped tool;

FIG. 10 is a top longitudinal view, of one preferred form of ultrasonic system, of the type capable of being hand held and manipulated, for joining together layers of tissue, such as in humans;

FIG. 11 is a side longitudinal view, partly in cross-section, of the ultrasonic system of FIG. 10;

FIG. 12 is an enlarged schematic view, in cross-section, illustrating the application of the ultrasonic instrument illustrated in FIGS. 10 and 11 for securing together the walls of a blood vessel;

FIG. 12A is an enlarged schematic view, in cross-section, similar to FIG. 12 illustrating the actual joining of the overlapping wall portions;

FIG. 12B is a further enlarged schematic view, in cross-section, showing the actual bond obtained between the wall portions of the blood vessel;

FIG. 12C illustrates the ultrasonic system as used for simultaneously joining and cutting layers of tissue; and

FIG. 12D illustrates the ultrasonic system clamping means for intermittently joining overlapped layers of tissue.

DETAILED DISCUSSION OF THE DRAWINGS

The high frequency transducer means may be either in the sonic or ultrasonic frequency range but for purposes of the present invention the word "ultrasonic" will be used to denote vibrations in the range of approximately 5,000 to 1,000,000 cycles per second. In addition the term "blood vessel" as used herein is intended to include any tubular member of the human body, but particularly capillaries, arterials, veinules, arteries and veins.

In performing the surgical procedures of the present invention there are several factors that have to be taken into consideration and analyzed in terms of a total or effective value to obtain the desired end results. The term "total value" may be defined as the proper combination of these factors to obtain the desired end result.

Referring now to the drawings, FIG. 1 is a chart illustrating the relationship of the seven principal factors which are involved in whole or in part for determining the total value associated with forming closures at the terminal portions of severed blood vessels, or joining together overlapping segments of layers of human tissue. The related factors are — peak tool velocity, frequency of vibration, pressure applied with tool, tool working surface, cutting edge, tool temperature and oxygen for clotting. These factors vary with respect to the procedure being performed.

In the embodiments of the invention discussed below the working surface of the tool member is placed in engagement with at least one of the layers of tissue at a surface thereof such that a small compressive force is applied in a plane substantially normal to the engaged surface. While this compressive force is maintained the

working surface of the tool member is vibrated at an ultrasonic rate to apply an additional energy producing force at the engaged surface. The compressive and energy producing forces are continued until the layers of tissue are secured together by the combined action of these forces.

When these layers of tissue form the walls of a blood vessel the forces are applied to the terminal surface thereof for producing localized heating in forming a closure to prevent the blood from escaping therefrom. The energy producing force may be divided into — mechanical vibration energy absorption in tissue — and — frictional rubbing heat development in tissue — both of which result in a localized heating of the walls of the blood vessel to obtain the — tissue closure. The performing of surgical procedures as related to this aspect of the invention is discussed with reference to FIGS. 2 through 9, inclusive.

In contrast to this we have the joining of layers of tissue in overlapping relation to each other and in which case the compressive and vibrational forces are applied to one of the overlapped surfaces in a plane substantially normal thereto and in which case we primarily rely on — mechanical vibration energy absorption in tissue — to obtain the — tissue joining. The performing of surgical procedures as related to this aspect of the invention is discussed with reference to FIGS. 10 through 12D, inclusive.

Referring again to the drawings, and with respect to FIG. 2, it will be seen that an apparatus 10 for ultrasonically performing surgical procedures on a biological organism, such as a human, may include an ultrasonic transducer or motor 11 for effecting the necessary high frequency vibrations of the tool member 13, such as a knife, having a sharp output edge or surface 15 with a working surface 16. The ultrasonic motor 11, as illustrated may be in the form of a driving member adapted for being hand held as by an operator 12, and generally comprising a tubular housing or casing 14 into which an insert unit 17 supporting the tool member 13 may be partially telescoped. The ultrasonic motor 11 is energized by an oscillation generator 18, with a power cable 19, connecting the two together. The generator is an oscillator adapted to produce electrical energy having an ultrasonic frequency.

The ultrasonic motor 11 may be one of a variety of electromechanical types, such as electrodynamic, piezoelectric and magnetostrictive. The ultrasonic motor for effecting surgical procedures through hand directed tools of suitable configuration, which are readily replaceable or inter-changeable with other work performing tools in acoustically vibrated material treating devices, may be of the type disclosed in U.S. Pat. Nos. Re 25,033, 3,075,288, 3,076,904 and 3,213,537, and wherein each work tool member is rigidly joined, in end-to-end relationship to a connecting body or acoustic impedance transformer and to a transducer which may form an insert unit or assembly which is removably supported in a housing containing a coil in surrounding relationship to the transducer and receiving alternating current for producing an alternating electromagnetic field.

The transducer in the ultrasonic motor 11 is longitudinally dimensioned so as to have lengths which are whole multiples of half-wavelengths of the compressional waves established therein at the frequency of the biased alternating current supplied so that longitudinal

loops of motion as indicated by arrow 23, occur both at the end of the insert unit 17 to which the tool member 13 is rigidly connected and the knife edge. Thus, the optimum amplitude of longitudinal vibration and hyper-accelerations of tool member 13 is achieved, and such amplitude is determined by the relationship of the masses of the tool member 13 and insert unit 17 which may be made effective to either magnify or reduce the amplitude of the vibrations received from the transducer.

The tool member 13 may be in the form of relatively flat metal spatula member, as shown in FIGS. 8 and 8A, hereinafter discussed in detail, to provide relatively wide surface areas for contact with the tissue to which the vibrations are to be applied for effecting the closure of severed blood vessels.

The tool member 13 may be permanently attached to the end of insert unit 17, for example, by brazing, solder or the like, or the tool may be provided with a threaded stud 20 adapted to be screwed into a tapped hole in the end of insert unit 17 for effecting the rigid connection of the tool to the stem. A base portion 21 is provided from which the stud 20 extends, from one end thereof, and from the other end a body 28 which is firmly secured thereto for the transmission of the ultrasonic vibrations. The body 28 may be brazed or welded to the base 21 of the tool member 13. A tapered surface 22 may be provided which connects the cutting edge 15 with the working surface 16.

As seen somewhat schematically in FIG. 2 the biological organism 25, such as a human, contains a layer of outer tissue or skin 26, an internal cellular structure 27 with a plurality of blood vessels 30 extending there-through shown in an enlarged scale, as well as in the skin (not shown).

FIGS. 3, 3A and 3B illustrate various types of replaceable surgical implements, such as knives, that may be employed in accordance with the present invention. The knife 13a of FIG. 3 is similar to that illustrated in FIG. 2 and includes a base portion 21a, capable of supporting ultrasonic vibrations and adapted to be set into vibration in a given direction by the driving member. A threaded stud 20a extends from one end of the base 21a for engagement with the insert unit. The body portion 28a, in the form of a cutting blade, extends from the opposite end of the base 21a and includes a textured working surface 16a for enhancing the coupling action between the tool member 13a and the terminal portion of the severed blood vessels to be engaged. The cutting edge 15a may be serrated and have an outwardly tapered portion 22a between the cutting edge 15a and the substantially flat working surface 16a. The textured surface 16a may begin in close proximity to or start at the working edge 15a so that when cutting and sealing small capillaries the rubbing action and transmission of shear waves begins immediately. The textured surface finish of 16a may vary from a micro finish in the range of 10 micro-inch to 10,000 micro-inch, but preferably in the range of 40 micro-inch to 200 micro-inch.

As illustrated in FIG. 3A the tool member 13a includes a body portion 28a having a coated textured layer of friction inducing material 29a which forms the working surface 16a and which may be of diamond or steel powder particles bonded to the body portion in any conventional manner well known in the art, to obtain the desired micro finish. The layer of coated mate-

rial may be applied to both surfaces of the tool member and each surface may be of the same or different micro finish to obtain a debriding and superficial cauterizing. The advantages are quicker healing as well as less damage to the tissue being treated.

FIG. 3B illustrates the obtainment of the working surface 16a by finishing the metallic body 28a in any conventional manner to obtain the desired surface roughness. By providing the textured surface it is possible to control the rate of frictional heating of the blood vessels. The surface roughness is generally selected in accordance with the ultrasonic rate of vibration and the compressive force to be applied. This will in many instances relate to the particular surgeon performing the operation.

THEORY OF PRESENT INVENTION

Whereas a scientific explanation of the theory based on the phenomena involved in disclosed below, it is to be clearly understood that the invention is by no means limited by any such scientific explanation.

Applicant has now discovered that mechanical vibrations properly applied may produce closures at the terminal ends of blood vessels to prevent the flow of blood therefrom and also join together layers of human tissue. With respect to forming the terminal closure it is possible to simultaneously cut through layers of tissue and seal off the terminal ends.

For purposes of illustration, we have in FIGS. 4 and 4A a single blood vessel 30b having a wall 31b with a terminal portion 33b terminating in an end surface 32b, the latter in engagement with the working surface 16b of the tool member 13b which is being ultrasonically vibrated in the direction 23b.

At the interface of the working surface 16b and terminal surface 32b we have a transmission of both rubbing forces and mechanical vibrational energy to the blood vessel 30b which results in a localized heating of the terminal portion 33b. FIG. 4A illustrates the contour of the surfaces in engagement with each other and the transmission of the shear waves over the distance D. The pressure applied with the tool member, partially determines the degree of shear waves and rubbing vibrations transmitted to the terminal portion 33b of the blood vessel for a given textured tool. At point P₁ shear vibration is developed in the tissue 31a, then at P₂ the shear vibration has dropped almost to zero whereby the shear vibration energy is converted into heat in the tissue of the blood vessel. The smallness or minimal depth of penetration of P₁, P₂ is what makes for quick healing and cauterizing action of the tool member.

The shear wave pattern 35b extends the distance D, which is the distance from P₁ to P₂, along the blood vessel 30b to obtain the localized heating of the terminal portion. The coupling action at the working surface 16b and blood vessel 30b is enhanced by the application of the small compressive force, as indicated by arrow 36b, in a plane substantially normal to the plane defined by said terminal end surface 32b. At P₁ in addition, to the extent that shear vibration is not induced in the tissue, there will be a slippage and a frictional rubbing action which will also produce heat practically instantaneously at P₁. It is a combination of these effects which create the closure at the terminal portion of the blood vessel.

It will be appreciated that the relative amounts of shear vibration and frictional rubbing action will be de-

termined or selected by the magnitude of the tool vibration and the tool surface in relation to the tissue surface. Many combinations are possible whereby either the frictional or the shear components may be emphasized.

The extent that the rise in temperature occurs at the terminal portion 33b of the blood vessel 30b is related to the rubbing vibrations applied and this is related to the peak speed which is:

$$V_{\text{peak}} = 2 \pi f A$$

A = peak amplitude

f = frequency

V = peak velocity

So that if f is raised, A is lowered and we can retain the same peak speed at all frequencies. This is why the more rubs per second the higher the frequency for the same output peak speed. Accordingly the working surface 16b of the tool member 13b may be surface finished for sufficient roughness to allow increased friction against the tissue. This is quite different from a standard knife or scalpel which has polished sides.

The thickness of the tool member should also be held to a minimum so as to permit a more rapid local temperature rise which is attributable to the shear production and absorption in the adjacent tissue and the temperature rise due to rubbing of tissue surface, which involves slippage between tool member and tissue surfaces. We can say that during the to and fro motion, neglecting the energy of cutting itself, when a knife is used we have:

Ultrasonic energy per stroke = Ultrasonic shear energy produced per stroke + Frictional rubbing energy per stroke.

Since, in both cases the energy absorbed goes into superficial heating of tissue and cutting tool, we can estimate the effects by considering all the energy to be frictional for ease of making approximate calculations.

Assuming an average force of friction, F, we have the power dissipated superficially at a tool tissue interface equal to:

S = stroke

F = average friction force

P = power

$P = f F S = F V_{\text{max}} / \pi$

Now V max. for a frequency of 20 Kc/sec and a stroke of 0.010 inch is approximately 50 FPS. Therefore P is approximately 15 watts, when F is between one half and one pound. Since this power is dissipated in a superficial region of the cutting, the heat capacity of the tissue and the tool are quite small. For example for a steel tool of dimension 1 inch × 0.125 inch × 0.010 inch the total heat capacity is only a few hundredths of a gram. In such a case it is possible to obtain local temperature rises of the order of hundreds of degrees centigrade under the condition outlined above. This is ample to stop "ooze."

Accordingly the frequency and amplitude of vibration of said tool member is selected at a level wherein the transmitted shear waves are substantially maintained at the terminal portion 33b with only superficial penetration and heating of the remainder of the blood vessel 30b.

Accordingly, the frequency and amplitude of vibration is preferably selected at a level to provide a peak velocity of at least 10 feet per second along the working

surface 16b of the tool member 13b and more generally the general range of approximately 40 feet per second to 100 feet per second.

FIG. 4B shows a portion of the biological organism 25b with an outer layer of skin 26b and a plurality of blood vessels 30b extending through the cellular structure 27b and terminating against the working surface 16b of the tool member 13b. The tool member 13b is being vibrated at an ultrasonic rate in the direction of arrow 23b, which is in a plane substantially parallel to the plane defined by the terminal end portions 33b, to induce shear waves 35b, which penetrate the blood vessels 30b and surrounding tissue structure 27b. The high frequency vibration and amplitude of the tool member is selected to obtain only a superficial penetration and resulting heating of the terminal portions 33b so that there is a minimum of damage to the underlying tissue area 31b and all of the blood vessels are simultaneously closed off.

As illustrated in FIGS. 4C and 4D the terminal portion 33b has an end surface 30b that defines a plane 37b that may vary in angular relationship to the axis of the blood vessel 30b. In practice the angular engagement between the working surface 16b of the tool member 13b and the end surface 32b may not always be controlled during a surgical procedure since the blood vessels such as capillaries, veinules, veins, arterials and arteries extend in various directions throughout the body. The important consideration is that the ultrasonic longitudinal mechanical vibrations, as indicated by arrow 23b, are applied having a major component of vibration parallel to the terminal plane 37b and a component of compressive force, as indicated by arrow 36b, in a plane substantially perpendicular to the terminal plane 37b.

FIGS. 5, 5A, 5B, 5C, 6, 6A, 7 and 7A illustrate the actual surgical procedure in vivo of obtaining a closure at the terminal portion of a blood vessel using the ultrasonic instrument illustrated in FIG. 2, or a tool member illustrated in FIGS. 4, 4A and 4B. As explained with respect to the theory of the present invention in FIGS. 3, 3A, 3B, 3C and 3D the degree of shear waves and frictional rubbing may be controlled so that a predominant reliance on one or the other is produced.

In FIGS. 5, 5A, 5B and 5C the terminal closure 40c is formed primarily by producing a plastic flow of the wall of the blood vessel and continuing the flow for a period of time sufficient to obtain a joining of the severed ends together. Initially the cutting edge 15c of the tool member 13c is placed in engagement with the skin 26c of the body 25c and the tool member 13c is ultrasonically vibrated and a small compressive force in the direction of arrow 36c is applied to obtain a cutting of the skin 26c and progressively sever the tissue by a continued movement of the cutting edge 15c through the cellular material 27c until the wall 31c of the blood vessel 30c is engaged. The wall 31c for purposes of discussion is considered as layers of tissue 42c and 43c, respectively.

As seen in FIG. 5A after the cutting edge 15c severs the tissue layer 42c a certain amount of blood 44c flows from within the blood vessel 30c into the opening 45c that has been formed. As the movement of the ultrasonic instrument is continued downwardly we have the engagement of the working surface 16c with the terminal end portion 33c of the blood vessel to apply a compressive force to the end surface to obtain a localized

heating of the terminal portion by the application of the ultrasonic mechanical vibration. The relative movement is continued so that the application of the mechanical vibrations are transmitted for a period of time sufficient for the localized heating to form the closure 40c at the terminal portion 33c. In this manner the terminal portion 33c is closed off by the formation of the closure 45c and the blood contained therein is prevented from escaping through the closure. The closure 45c is produced at least in part by the production of said shear waves and their conversion into heat coupled with the localized heating obtained by inducing frictional rubbing at the terminal portion 33c. The extent of each factor will vary with the texture of the working surface 16c and the degree of the compressive force applied by the working surface against the terminal portion.

FIG. 5D is an enlarged microscopic examination of the blood 44c and as illustrated the blood contains red corpuscles 46c, white corpuscles 47c and platelets 48c, the latter play an important role in the natural clotting of blood by producing fibrin when exposed to air. This natural clotting ability of blood is relied upon at least in part with respect to the formation of the closures illustrated in FIGS. 6, 6A, 7 and 7A.

FIGS. 6 and 6A illustrate the formation of the closure which is substantially formed by clotting of the blood at the terminal position. The working surface 16d is placed in engagement with the layers of wall 42d and 43d of the blood vessel 30d, which is of a size in the capillary range, with the blood 44d contained therein. The tool member 13d preferably has a textured surface to permit air and most importantly oxygen to be delivered past the layer of skin 26d to the terminal portion 33d of the blood vessel to obtain a clotting action. The tool member 16d acts as an ultrasonic pump and stimulates the flow of air to the work site. As the air reaches the work site we have the additional action of the conversion of the ultrasonic mechanical vibrations to obtain a localized heating by the conversion of the frictional motion into heat and the localized heating expedites the formation of the blood clot 50d which forms the closure 40d. Since the blood vessel is relatively small in diameter we have the formation of the closure 40d that is substantially formed by a clotting of the blood 44d therein. As seen in FIG. 6A the tool member is then removed leaving the opening of wound 45d and closures 40d formed on each respective end of the severed blood vessels.

FIGS. 7 and 7A illustrate the formation of a closure 40e by partially closing the layers 42e and 43e of the wall 31e of the blood vessel 30e at the terminal portions 33e by the localized heating and the remainder by forming a blood clot 50e of the blood 44e contained in the reduced area of the blood vessel. The ultrasonic tool member 13e transmits the mechanical vibration which produces a plastic flow of the wall 31e of said blood vessel which flow is continued for a period of time to obtain a reduced cross sectional area and during which same period of time the localized heating assists in the formation of the blood clot 50e which together with the reduced area forms the closure 40e to prevent the blood from escaping therefrom. The tool member is then removed past the skin 26e leaving the opening 45e.

It is appreciated that the process although illustrated for a single blood vessel can be occurring simulta-

neously on a plurality of blood vessels. To increase the rate at which the closure is formed and reduce healing time the working surface of the tool member may be heated to a temperature level which is above room temperature, but below a temperature that would normally sear the terminal portion of the blood vessel. The temperature of the tool may be heated in any conventional manner, as for example, in accordance with U.S. Pat. No. 3,321,558.

There are instances in surgical procedures where it is desirable to be able to stop bleeding independently of having previously cut the tissue of the body. As for example, in gunshot wounds and other accidents it is often desirable to stop bleeding and accordingly spatula like tools in accordance with the present invention may be utilized.

FIGS. 8 and 8A illustrate one form of readily replaceable implement, in the form of a spatula like tool member 13f, having a body portion 28f with substantially flat parallel working surfaces 16f that have been textured to a preselected micro finish to provide means for coupling the ultrasonic vibrations to the terminal portions of the blood vessels. The surface finish is selected for the transmission of rubbing vibrations and shear waves to obtain the localized heating. One end of the spatula body portion 28f is fixedly secured to the base portion 21f, and the latter has a threaded stud 20f for securement to the ultrasonic driving member. The base portion 21f is preferably of a metallic material capable of supporting ultrasonic vibrations and adapted to be set into vibration in a given direction at ultrasonic frequencies. The body portion 28f may be in the order of 0.010 to 0.160 inches thick and be concave in configuration for strength reasons. It may also be designed to vibrate elliptically to permit intermittent separation of the tool member and terminal portions to promote the flow of air to the terminal portions for clotting.

As illustrated in FIG. 9 the spatula like tool member is illustrated for surgical procedures in which it is desired to form closures at terminal ends of blood vessels 30g separately from when the actual cutting is performed. Accordingly the spatula like tool 13g is inserted within the opening 45g of the body 25g such that the working surface 16g of the tool member 13g applies a compressive force against the terminal portions 33g of the severed blood vessels. The compressive force is applied in the direction of arrow 36g. The tool 13g is simultaneously vibrated, in a direction as indicated by arrow 23g, and at an ultrasonic rate to transmit mechanical vibrations to the terminal portion 33g of the blood vessels to obtain a localized heating of at least some of the terminal portion. The application of said compressive force and mechanical vibrations are continued until a closure at the terminal portion is formed and the blood contained therein is prevented from escaping through the formed closure. The thickness of the spatula tool member 13g may be narrower, as illustrated in FIG. 9, than the opening 45g in the body, such that only one surface 16g engages the severed blood vessels. If desired the width of the spatula body 28g may be substantially equal to that of the body opening 45g so that both terminal ends 33g of a respective blood vessel 30g is closed during one insertion of the tool member within the wound.

The localized heating to obtain the closures may be induced by frictional rubbing at the terminal portion 33g of the blood vessel 30g so that the closure is pro-

duced at least in part by frictional heating. By providing a textured surface to the tool member 13g the rate of frictional heating may be controlled when combined with the other factors to produce the terminal closure. Depending upon the thickness of the spatula tool member either pure longitudinal vibration will be obtained or a flexural component of motion, as indicated by the arrow 51g, so as to obtain elliptical vibrational motion along the working surface 16g. This permits intermittent disengagement between the wall surface or terminal end of the blood vessel 33g and the working surface 16g so that air and in turn oxygen may be continuously supplied to the work site to assist in the clotting of the blood.

FIGS. 10 and 11 illustrate one form 10h of the ultrasonic system for joining together in vivo, overlapping layers of organic tissue. The system includes a hand held instrument including an ultrasonic motor 11h, which may be the type as discussed with reference to FIG. 2, and include a tool member 13h having an enlarged portion 53h terminating in a working surface 16h that extends in a plane substantially normal to the direction of mechanical vibrations illustrated by the arrow 23h. The base 21h of the tool member 13h is secured to the insert portion 17h. Support means 55h is provided to act as an anvil or clamp so that the overlapped layers of tissue 42h and 43h of the wall 31h of the blood vessel 30h may be compressed between the vibratory working surface and a support surface.

The support means 55h includes a pair of legs 56h and 57h respectively, secured together at their lower end by bands 58h and provided with gripping means in the form of individual lugs 59h that extend outwardly from the upper end of the legs for engagement by the fingers of the surgeon or operator 12h in a manner hereinafter described. The leg 57h has a lower extension 60h that terminates in a support arm 61h at substantially right angle to the extension 60h, and is provided with a support surface 62h in spaced relation to the working surface 16h of the tool member 13h.

The legs 56h and 57h are in spaced relation to each other and may be contoured to conform to the cylindrical configuration of the ultrasonic transducer housing 14h. The generator 18h is connected to the transducer 11h by means of cable 19h in a conventional manner. As seen in FIG. 10 the cable 19h may enter the ultrasonic motor 11h from the side so as to leave the rear end 63h free for engagement by the thumb or any other finger of the surgeon to permit manual control of the relative displacement between the overlapping working and support surfaces.

The support means 55h is mounted for relative movement, with respect to the ultrasonic motor 11h by providing a pair of slots 65h on each of the legs 56h and 57h, and which slots accept headed fasteners 66h which extend from the casing 14h through the slots 65h to permit free relative movement between the ultrasonic motor 11h and support means 55h. The lower end of the casing 14h is provided with an annular shoulder 67h which is adapted to receive spring means in the form of a spring 68h which is contained within the shoulder 67h at one end thereof and in engagement with the bands 58h at the opposite end thereof. The spring 68h applies a force in the direction of arrow 68h, so that the working surfaces of the support means and ultrasonic motor means are biased away from each other whereby the force applied by the surgeon is re-

quired to bring the overlapping working and support surfaces together. If desired the spring may be coupled to the support and ultrasonic motor means so as to force them together with predetermined static force which might be varied in a conventional manner not shown. In this manner once the static force is determined for the particular thickness of tissue the resultant permanent or temporary seal may be obtained. Accordingly the spring means may yieldably urge the support means 55h and transducer means 11h relative to each other to a position wherein the working and support surfaces 16h and 62h, respectively, are normally in engagement with each other under a predetermined static force, so that the support and transducer means are first separated for the placement of the layers of tissue 42h and 43h therebetween. In contrast to this the spring means may be adjusted such that the working and support surfaces are normally maintained in spatially fixed relation to each other, so that the layers 42h and 43h are positioned between the surfaces which are brought together by the operation of the hand held instrument.

As previously explained during surgical procedures it becomes necessary to tie-off veins and arteries so as to prevent the flow of blood therethrough. In accordance with the invention the joining of the walls may be of a permanent or semi-permanent nature, and this is accomplished by properly selecting the frequency and amplitude of ultrasonic mechanical vibrations to produce an optimum flow of the collagenous elements contained in the overlapping portions of tissue. This collagenous material is similar to that normally found in the formation of scar tissue. In practice the ultrasonic instrument 10h may be employed to join together, at a select area the wall of a blood vessel and as seen in FIG. 10 the wall 31h may be considered to include the overlapping layers of tissue 42h and 43h.

As seen in FIGS. 12, 12A and 12B we have the blood vessel 30h exposed within an opening 45h within the organic body 25h. To produce a joining of the overlapping layers of wall tissue 42h and 43h respectively, the arm 61h of the support means 55h is placed beneath the blood vessel 30h and the working surface 16h of the tool member 13h is brought into contact with the layer of tissue 42h. The working and support surfaces 16h and 62h are moved relative toward each other until the blood vessel 30h has the overlapping layers of tissue 42h and 43h in contact with each other as seen in FIG. 12A. Simultaneously therewith a small compressive force, in the direction of arrow 36h, is applied to the layers of tissue traversing the area of overlap.

The working surface of the tool member 13h is vibrated at an ultrasonic rate, as for example, in the frequency range of from 15 Kc/sec to 100 Kc/sec and preferably in the range of 20 Kc/sec to 40 Kc/sec, so as to apply an additional recurring force to the overlapped layers of tissue, and produce a superficial heating at the interface of the overlapped layers. The vibrational force has a substantial component of vibration normal to the overlapped surfaces, as indicated by the arrow 23h. The frequency of the ultrasonic rate of vibration is selected in the above frequency range so as to preferably also produce an optimum flow of the collagenous elements in the overlapped layers of tissue. The energy is then continually applied until a closure or bond 40h is formed between the collagenous elements in the overlapping layers of tissue, as seen in FIG. 12B, and

the blood is prevented from flowing past the closure. The closure 40h may be of a temporary nature or permanent one depending upon the proper control of the vibratory energy and static force to fuse together the superficially heated interface.

For certain applications it is desirable to join together the overlapping layers of tissue and at the same time cut off the excess material. As illustrated in FIG. 12C the support arm 61j is provided with a cutting edge 70j and as the overlapped layers of tissue 42j and 43j are compressed between the working surface 16j and support surface 26j and joined together by the energy transmitted through the tool member 13j and the excess tissue layers 71j and 72j are cut off. If desired the cutting edge may be placed on the working surface 16j of the tool member 13j.

For those applications in which it is desired to intermittently join together overlapping layers of tissue we have the apparatus illustrated in FIG. 12D. The overlapping layers of tissue 42k and 43k are first clamped together by clamping means 75k which includes clamping members 76k and 77k which may form part of the ultrasonic instrument or may be the forward portion of a pair specially designed clamping instrument. The clamping means 75k is applied in close proximity to the area of overlap of the layers of tissue 42k and 43k to be joined together. The ultrasonic instrument 10k includes the support means 55k for engaging one side of the overlapped layers of tissue and which opposite side is engaged by the tool member 13k which as illustrated is provided with a circular working surface. By intermittently moving the ultrasonic instrument along the area of overlap a number of closures or bonds 30k, such as stitches may be formed.

While the invention has been described in connection with particular ultrasonic motor and tool member constructions, various other devices and methods of practicing the invention will occur to those skilled in the art. Therefore, it is not desired that the invention be limited to the specific details illustrated and described and it is intended by the appended claims to cover all modifications which fall within the spirit and scope of the invention.

I claim:

1. A method of joining together overlapping portions of layers of tissue in vivo, comprising the steps of
 - A. applying ultrasonic mechanical vibrations to the overlapping portions of said layers of tissue in their area of overlap, said mechanical vibrations being applied in a direction substantially normal to said area of overlap,
 - B. simultaneously compressing said layers of tissue together in their area of overlap,
 - C. selecting the frequency and amplitude of said ultrasonic mechanical vibrations to produce a superficial heating at the interface of said overlapping layers of tissue, and
 - D. continuing the application of said mechanical vibrations and compressive force until said layers of tissue are fused together at said superficially heated interface.
2. A method of joining together layers of tissue in vivo, with a tool member having a working surface, comprising the steps of
 - A. overlapping the layers of tissue in contact with each other,

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- B. applying the working surface of said tool member against said overlapping portions at a surface thereof, such that said working surface applies a small compressive force to said tissue traversing the area of overlap,
- C. vibrating the working surface of said tool member at an ultrasonic rate to apply an additional recurring force to said layers of tissue, with said force having a substantial component of vibration normal to the overlapped surfaces of said layers of tissues,

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- D. selecting the frequency of said ultrasonic rate so as to produce an optimum flow of the collagenous elements in said layers of overlapping tissue, and
- E. continuing the application of said ultrasonic vibrations until a bond is formed between the collagenous elements, so as to join together said overlapping layers of tissue.

3. A method as claimed in claim 2, wherein said step of vibrating the working surface is in the range of approximately 20 Kc/sec. to 100Kc/sec.

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