VIBRATORY CATHETERIZATION APPARATUS AND METHOD OF USING

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3.4 Conduit 24 is connected to member 14 in passageway 23.

Catheter 10 is designed to operate at a given frequency, which is preferably a resonant frequency. Catheter 10 is preferably designed to have an overall physical length of 3,226, which is equivalent to an acoustic length of a whole number multiple of one-half wavelength in the material of which it is made at the said frequency (see FIGURE 1 wherein "n" indicates a whole number). For efficient operation, there is an antinode (loop) area of the vibration at the end 20.

Transducer 12 may be of the magnetostriuctive type as shown and of conventional construction comprising a half-wavelength long laminated core of nickel, nickel-iron alloy, or other magnetostriatic material, properly dimensioned to insure axial resonance with the frequency of alternating current applied thereto by coil 11 so as to cause it to increase or decrease in length according to its coefficient of magnetostriiction. The detailed construction of a suitable magnetostriuctive transducer is well known to those skilled in the art and does not form a part of the present invention and, accordingly, no description of its construction will be made herein. It will be appreciated by those skilled in the art that in place of the magnetostriuctive transducer 12 other known types of transducers may be substituted; for example, an electrostrictive or piezoelectric transducer made of barium titanate, quartz crystals, lead zirconate titanate, etc., may be utilized.

The power supply system, in a typical example, is capable of producing electrical signals in the range of between about 60 cycles per second and about 300,000 cycles per second. This frequency range is suitable for the present invention, including as it does frequencies in both the audible range (such as up to about 15,000 cycles per second) and the ultrasonic range (generally above about 15,000 cycles per second). A preferred frequency would be in the range of from about 3,000 to about 50,000 cycles per second. Normally, a frequency is chosen which will provide a suitable size of apparatus for a given application or set of applications, with the ultrasonic range having the further advantage of inaudibility for operator comfort.

Thus, catheter transducer-coupling system 10 may be constructed to operate at 28,000 cycles per second, for example. In an embodiment of FIGURE 1, a 100 watt power supply was used to drive a transducer 12 at said 28 kc. design frequency. As is well known to those skilled in the art, the electrical frequency of the alternating current power supply (such as 60 cycles per second) is changed to match the mechanical or elastic vibratory frequency of the transducer (28,000 cycles per second in this example, as aforesaid).

The member 18 is preferably semi-flexible and can be curved within certain limits established by the acoustical characteristics of the manipulation. Preferably, the curvature of the member 18 has a bend radius which is at least 4/7 wherein 4 is the wavelength of the material of member 18. The reason for this limitation on the bend radius is set forth more clearly in Patent 3,166,840.

A coolant fluid may be introduced through conduit 24 and passageway 22 to provide the member 18, to irrigate tissue in the vicinity of the tip 20, and flush away any micron sized particles resulting from decimation of plaques. A low molecular weight dextran solution at a temperature of from about ambient temperature to 40 degrees Celsius may be pumped through the system at low pressure. The solution exits through the tip 20. The micron sized particles of the plaques result from the physical effect of the vibrating catheter tip 20 upon calcified atheromata.

Sterilization of the catheter can be accomplished utilizing conventional sterilization equipment. If desired, the member 18 may be provided with removable tips which can be disposable. In order to facilitate sterilization or autoclaving, and simultaneously facilitate manipulation of the catheter with minimum power losses, a force-insensitive mount 15 is provided. One end of mount 15 is mechanically joined to the coupling member 14. The other end of mount 15 is free. The mount 15 is provided with a radially outwardly directed flange 17. Flange 17 is joined to a housing 25 with a waterproof joint. Housing 25 may constitute a handle and is preferably of sufficient length so as to encase the transducer 12 as shown. Suitable plug-in connections 27, 27' can be provided hermetically sealed to the housing 25 for electrically connecting to the coils 11 and 13, and to facilitate autoclaving the catheter.

A force-insensitive mount may comprise a sleeve such as the described in U.S. Patents 2,891,178; 2,891,179; and 2,891,180. The discussion of such sleeves is incorporated herein by reference. Such a mount facilitates the application of force necessary to insert the catheter into a cavity, artery, or the like. The sleeve is made from a metal such as steel or any other suitable resonant material and has a length equal to a single one-half wavelength. The sleeve surrounds the coupling 14 and is concentric therewith and spaced therefrom.

The flange 17 is spaced from the free end of mount 15 by an acoustical distance corresponding to one-quarter wavelength according to the properties of the mount and the desired frequency of operation. The mount 15 when so constructed will cause a true node of vibratory energy to be developed in the flange 17 so that no vibratory energy will be transmitted to the housing 25.

The operable usage of the ultrasonic endarterectomy catheter requires that a reliable source of vibratory energy be coupled to the working tip 20 having a diameter of the order of a millimeter. The members 16 and 18 may have a length of around 18 inches. To prevent temperature build-up and thereby minimize thermal damage to the tissue, a cooling system as described above is required.

The vibrational energy generated by the transducer can be coupled to the members 16 and 18 in one of several different ways. The first and simplest mode is that of longitudinal vibration, as shown, wherein the particle displacements occur in a direction parallel to the axis of members 16 and 18. A second mode of vibration is that of lateral or transverse vibration wherein particle displacements occur in a direction normal to the axis of members 16 and 18. This results in an excursion of the tip 20 parallel to the plane of the end face thereof. Other more complicated modes including torsional vibration wherein the system oscillates periodically in torsion about its own axis, or a radial vibration wherein the end tip 20 periodically expands and contracts radially may be utilized.

The exact mechanism by which the plaques of the calcified atheromata are destroyed is not well understood. The nature of the mechanism will depend in part on the physical characteristics of the vibrating tip. Several tip geometries may be employed depending on the characteristics of the tip. In FIGURE 1, the geometry of the removable tip 20 is a square edge. As shown more clearly in FIGURE 2, the tip 20 removably mounted on a coupling member 18 may have a chisel edge defined by an internal beveled surface. In FIGURE 2, the beveled surface 26 provides a sharp cutting edge at the periphery.

A second type of tip is illustrated in FIGURE 3. Tip 20' removably mounted on coupling member 18' is in
bulbous form. The bulb 28 may be either metal or plastic. The purpose of bulb 28 is to provide a more positive contact between the working surface of the catheter and the tissue being treated. The surface of bulb 28 may have an abrasive character. The tips of FIGURES 2 and 3 may be substituted for the tip 20 in FIGURE 1.

The method steps and conditions for practicing the present invention for treatment of disease or other conditions for therapeutic purposes is considered to be sufficiently known to those skilled in the art so as not to require a detailed explanation. Using the known principle of oxygen in solution, at 3 atmospheres positive pressure ischemia induced by introducing the catheter by way of the coronary ostia can be prevented. The flow of coolant, such as low molecular weight dextran, can replace oxygenated blood for long periods and prevent a means of oxygenation to the myocardium.

The present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof and, accordingly, reference should be made to the appended claims rather than to the foregoing specification as indicating the scope of the invention.

It is claimed:

1. A catheter comprising a transducer means for generating vibratory energy, a resonant coupling member having one end connected to said transducer and a tip at its other end, the end of said tip being at an anti-node on said member, said member having an acoustical length of a whole number multiple of one-half wavelength in the material of which it is made at the frequency of said transducer means, and said member being partially hollow with the hollow portion beginning at said tip, whereby a liquid for cooling said member may be pumped through said portion for discharge through said tip.

2. A catheter in accordance with claim 1 including a housing with said transducer means disposed within said housing.

3. A catheter in accordance with claim 1 wherein said transducer means is axially coupled to said member for vibrating said member in a direction corresponding to the longitudinal axis of said member.

4. A catheter in accordance with claim 1 wherein said tip has an end face which is substantially perpendicular to the longitudinal axis of said member.

5. A catheter in accordance with claim 1 wherein said tip is bulbous.

6. A catheter in accordance with claim 1 wherein said tip has an internal beveled face providing a sharp edge at the periphery of the tip.

7. A catheter in accordance with claim 1 wherein said coupling member has a length of approximately 18 inches and a diameter along a substantial length thereof beginning at the tip of approximately 1 millimeter.

8. A method comprising the steps of transmitting acoustical vibratory energy from a transducer means through a resonant coupling member at least a portion of which is hollow beginning from a tip end of said coupling member designed to have an anti-node at the end face of the tip, introducing a coolant through said portion for discharge through said tip, and transmitting the vibratory energy from the tip to a living animal by contacting the portion of the animal with said tip.

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U.S. Cl. X.R.

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